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SELECTING PATIENTS FOR ANTI-RETROVIRAL CARE AT A RURAL CLINIC IN LESOTHO: RESULTS FROM A CASE STUDY ANALYSIS

RESEARCH REPORT
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ABSTRACT

The number of people in immediate need of anti-retroviral treatment (ART) in the southern African region continues to significantly exceed the capacity of health systems to provide it. Approaches to this complex rationing dilemma have evolved in different directions. The ethical concepts of fairness and equity have been suggested as a basis guiding rationing or patient selection processes for ART. The purpose of the study was to examine whether or not such concepts had relevance or operative value for a treatment team providing ART in rural Lesotho. Using an exploratory, single case study design the study found that while concepts of fairness and equity were relevant to the work of the treatment team, patient selection practices did not necessarily reflect what these concepts entail. The idea of fairness as a structured, formalized selection process did not figure in the approach to ART provision at St. Charles. A less formal, 'first-come-first-served' approach was adopted. While there was knowledge amongst some team members that social, economic or geographic conditions inhibit individuals and groups from gaining access to ART and that this was inequitable, it was felt that there was little they could do to try to mediate the impact of these conditions. The study findings pose importance questions about the approach to ART programming in resource constrained settings. The findings also question the relevance of trying to achieve fairness and equity when the gap between need for care and capacity to provide it remains so large.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Treatment
ARV	Anti Retroviral drugs
CD4	T-helper cell, a component of the immune system that is infected and destroyed by HIV
GoL	Government of Lesotho
GTZ	Gesellschaft für technische Zusammenarbeit (the German overseas development agency)
HAART	Highly-active anti-retroviral therapy
HIV	Human Immunodeficiency Virus
IMAI	Integrated Management of Adult and Adolescent Illness
MOHSW	Ministry of Health and Social Welfare
OPD	Outpatient department
TB	Tuberculosis
XDR-TB	Extreme Drug Resistant Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organisation

SELECTING PATIENTS FOR ANTI-RETROVIRAL CARE AT A RURAL CLINIC IN LESOTHO: RESULTS FROM A CASE STUDY ANALYSIS

Introduction

It is now more than three years since anti-retroviral treatment (ART) for people living with HIV/AIDS was made widely available in the public sector across the southern African region. The number of people in need of immediate treatment continues to exceed by a significant margin the capacity of health systems to provide it. In South Africa, for example, it was estimated that in 2006, 520,000 individuals were in need of immediate access to ART while only 124,000 were receiving it (Stewart, Padarath, Milford 2006: 287). By mid-2006, the number of those receiving treatment had increased to 200,000 while those in immediate need stood at 711,000 (Dorrington et al, 2007: 27, 29). Similarly in Lesotho, where an estimated 23.2% of the population is HIV-positive (UNAIDS 2006), it was estimated in 2007 that 81,270 individuals were in need of treatment and only 31,808 were receiving it (GoL 2007a: 52, 53). In these assessments, those considered in need of treatment already experience advance symptoms of HIV disease. Most of these individuals have only limited time before their condition becomes unresponsive to the range of anti-retroviral therapies (ARVs) available in the region.

While it was known at the beginning of the regional effort to provide ART that not all those in need of treatment would receive it, effective ways of selecting those HIV-positive individuals who should go first and those who should continue to wait have not developed as was originally anticipated. Despite the creation of model eligibility criteria and selection processes by teams of experts associated with the World Health Organization (WHO 2004a), the advice of prominent legal and ethical scholars (Macklin 2004; Daniels 2004), and consensus statements by globally

representative multi-stakeholder groups (WHO 2004b), approaches to this complex rationing dilemma have evolved in different directions. This study examines the patient selection process at an ART program operating in a rural area of Lesotho. The experience of the treatment team is enlightening. It challenges the practical value of the theoretical approaches to patient selection originally articulated by the World Health Organization and others. It suggests the need for much deeper ethical reflection and ongoing questioning of the dominant approach to ART provision in Lesotho and elsewhere. Finally, it raises anew the far greater challenge of global health inequity and whether current efforts to treat HIV in resource-limited settings can effectively address and resolve it.

Background

In 2004, the World Health Organization (WHO 2004b) proposed some clinical and social criteria to assist in selecting patients for ART in settings were need was greater than capacity. In general, the criteria targeted individuals who were already experiencing advanced symptoms of HIV-disease. The criteria also targeted those individuals who were most likely to be able to take ART regularly and correctly over their lifetime in order to maximize the health benefits of treatment. In settings like South Africa or Lesotho, however, these have proved insufficient as effective rationing criteria (Rosen et al. 2005: 354). The number of individuals who meet the eligibility criteria continues to exceed spaces available for treatment in many settings. There is a step between those who are eligible and those who actually gain access to treatment which is a much more explicit process of patient selection that was not part of the WHO model. Very few programs, if any, have attempted this step. Stewart et al. (2006: 298), noting the large gap

between need and availability throughout South Africa, lamented the absence of more explicit patient selection strategies and the resulting form of indirect or implicit rationing that is occurring there:

> "Currently this rationing is indirect and implicitly favours those who are informed, can afford it, are in proximity to facilities, and/or have time to wait in queues. In some instances, clinicians are forced to make choices as to who can or cannot receive treatment, decisions they are ill-equipped to handle. Implicit rationing is likely to increase the inequity in provision of, and access to services, while undercutting the potential societal benefits of the programme."

In the absence of explicit guidelines, the rationing dilemma falls at the feet of the health care providers in treatment programs. The conclusions of Bennett and Chanfreau (2005: no page), reviewing rationing strategies for ARV treatment programmes in Mexico, Senegal, Thailand and Uganda, were that:

> "…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."

These studies affirmed that patient selection strategies in addition to those proposed by WHO would be required to address the gap between need and availability of ART. Such strategies needed to be in the form of guidelines or other directives above the level of the treatment team or

the individual health care provider. Otherwise, ad-hoc approaches would evolve that were not sufficient to achieve an effective distribution of the benefits of ART. Ad-hoc approaches could even compromise the ability of treatment programs more generally to effectively mitigate the larger, more devastating social and economic impacts of HIV/AIDS in settings like southern Africa.

What form should selection strategies take? Within the specific context of providing ART in resource-limited settings, Ruth Macklin (2004) and Norman Daniels (2004) have provided detailed advice. David McCoy (2003) and Kalanda et al. (2004), through Equinet,[1] also contributed to the debate. The legal and ethical concepts of equity and fairness link the different perspectives. Macklin (2004: 4-6), addressing equity, described the need to chose between different principles of equity and to develop corresponding approaches to patient selection. Signalling that a 'first-come-first-served' approach to equity might not be the best choice, she put forward three other approaches to equity for consideration:

- *utilitarian* or provide treatment to the greatest number of those who will derive the greatest benefit;
- *egalitarian* or aim for equitable distribution of resources or benefits (including providing more to some groups in order to reduce disparities in health status); and,
- *maximin* or *prioritarian* which is to give preference to those who are worse off in some material respect (the sickest, for example, or the poorest or the most marginalized) while

[1] Equinet is the Regional Network on Equity in Health in Southern Africa, a network of professionals, civil society members, policy makers, state officials and others within the region who act as an equity catalyst to promote and

others who are comparatively more advantage continue to wait.

'First-come-first-served' approaches may be effective in contexts where those who need a benefit share comparative or relative equity but not where the gap between the amount of benefit available and the amount of need for it is as stark as it is in southern Africa settings in relation to ART. Consider the case of a ship that founders with only limited space on life-boats. Some additional selection criteria are usually applied with a view to trying to preserve some essential aspects of the group or community that is at risk. In addition, it is considered unfair and inequitable that those who get seats in boats are those who are closest, who can run faster or who have knowledge of where the boats are. It is for these reasons that other approaches to equitable selection should be considered.

Macklin (2004: 3), in her argument, stepped back, however, from recommending which approach should be followed in relation to ART programs. She noted only that the decision would be complex and difficult and that the ethical debate on rationing problems offers no clear guidance on which principles or values should predominate. Macklin made her views known at the outset of large scale implementation of ART programs in countries like Lesotho where HIV-prevalence was extremely high, the epidemic was generalized throughout the population, and the need for ART was acute and overwhelming. She acknowledged the possibility that governments and others in these settings might not chose an explicit approach to equity and, moreover, would not directly commit themselves to offering ART to some groups in the population and not others. Rather, they might chose an indirect approach to selection by simply offering what limited ART

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realise shared values of equity and social justice in health. See http://www.equinetafrica.org

that was available to whoever gained access to the treatment programs first. As a result, the substantive equity she desired for the scaling-up of ART in southern Africa and elsewhere would not be achieved (*ibid*.: 2).

In order to avoid such an outcome, Macklin (2004: 12) concluded her advice with an emphasis on the need for formal, inclusive, deliberative processes at all levels of ART delivery to decide which of the available approaches to equity should guide patient selection. In this respect, she relied on Norman Daniels' approach to rationing problems. In earlier work, Daniels (Daniels, Sabin 2002) argued for a reliance on principles of procedural justice when faced with the dilemma of not knowing which values or other criteria should guide rationing decisions. Where there was not enough ART for all who needed it, according to Daniels, there could be no substantively fair outcome. Some would get treatment and others would not. All that could be aspired to in this setting would be a fair process of choosing between those in need. This led him to propose his "accountability for reasonableness" model as a tool to assist in the development of patient selection processes and rationing strategies (Daniels 2004: ii-iv). According to the model, provided the selection process was procedurally fair, and was viewed as such by all involved, even those who did not benefit from the outcome would still accept the selecting decision. As Daniels (Daniels, Sabin 2002: 4) stated:

> "In the absence of broadly accepted consensus on principles of fair distribution, the problem of fair allocation becomes one of procedural justice. The basic idea behind this appeal to procedural justice is quite familiar. When we lack consensus on principles that tell us what is fair, or even when we have general principles but are burdened by

> reasonable disagreements about how they apply, we may nevertheless find a process or procedure that most can accept as fair to those who are affected by such decisions. That fair process then determines for us what counts as a fair outcome."

This approach was created in the context of rationing dilemmas in developed countries where the issues at stake were predominately access to advanced technological interventions or those still in the experimental stage. When Daniels recommended this approach in the context of rationing access to ART, it had not, as yet, been tested in a settings like Lesotho where the rationing dilemma affects a substantial portion of the population, where the impact of HIV-related morbidity and mortality on the social and economic viability of the country is significant in the absence of treatment programs, and where such an evolved conception of distributive justice in terms of health care resources has not necessarily taken hold within the national approach to providing ART.

Researchers at Equinet were more direct in their response to the challenge of patient selection for ART. McCoy (2003), for example, argued for a particular type of equity as the only effective outcome of patient selection processes. Formally, equity was the absence of discrimination in an ART program on the basis of arbitrary or non-relevant criteria. Substantively, it was the alleviation of unfair or avoidable health inequalities or disparities in the distribution of ART through a 'fair share' rather than an 'equal share' approach. As he stated (McCoy 2003: 11), "Equity implies an approach that gives more to those who have little, and thus less to those who have much." Practically this meant using concentrated efforts to break through the barriers of health inequities by, in effect, prioritizing the provision of ART towards those least able to

access health care services or to benefit from health care resources. It also meant limiting or refusing access to those with comparative social or economic advantages who were able to obtain ART from alternative sources. McCoy (2003: 11) warned that unless proactive attempts were made to ensure equity, the distribution of ART was likely to follow the path of existing inequities and not to benefit those in greatest need. Loewenson and McCoy (2004: 242; McCoy 2003: 42) went further to suggest that, in the extreme, corruption and abuse within treatment programs could also occur in the absence of explicit efforts to promote equity and to protect access to treatment for those who were least advantaged. For the Equinet group, the provision of ART on a large scale was a major opportunity to strengthen weak and dysfunctional health systems. It was also a chance to try to address and resolve entrenched inequities in many southern African settings in terms of which individuals and groups, based on social and economic condition, had ready access to health care services and which had little or none. The expectations of ART programs were large indeed in terms of addressing much broader, systemic health challenges.

When taken together, all of the commentators suggested that (procedural) fairness and (substantive) equity should be the measures of success in providing ART in resource-limited settings. They further suggested that the following characteristics of the patient selection process (over and above issues of eligibility), where they were apparent, had the greatest potential to achieve these outcomes:

- The existence of formal, explicit eligibility criteria developed through a structured, inclusive and transparent process of deliberation; and,

- The existence of a structured, inclusive, transparent and publicly accessible process for applying the criteria and for deliberating on exceptions.

How have health care teams who work at the front-line of ART program delivery fared in terms of this advice? Have the proposed relationships between patient selection processes, fairness and equity been absorbed and implemented in these settings? The limited evidence that is emerging in the literature regarding the experience of health care teams suggests that it has not.

Recently, an example of this was provided in a published case study of a *Médecins-sans-frontières*-sponsored treatment project in Khayelitsha, South Africa (Fox & Goemaere 2006). The study, when published, was accompanied by ethical reflections written by Macklin (2006) and Solomon Benatar (2006). The two authors were sensitive to the struggles of the treatment teams to develop and maintain patient selection processes that achieved fair distribution of their service to a maximum number of individuals in need. The Khayelitsha team adopted a 'first-come-first-served' approach using clinical and social criteria to evaluate patients' eligibility for ART. Committees were established at each treatment site to determine patients' eligibility; however, few if any patients were deemed not eligible, they were simply given more time and assistance to meet the eligibility criteria: "We never definitively give a 'no'…We just say, 'not ready.'" (Fox & Goemaere 2006: 306). There was extreme reluctance on the part of the team to enter into more direct forms of selection and more explicit approaches to rationing. It was felt that doing this struck at the core of important values and beliefs about the provision of ART and the appropriate role of the treatment team (Benatar 2006: 326).

Aside from the Khayelitsha study, there have been few other published accounts of how ART programs have addressed patient selection and the need to ration. The literature is predominantly normative or speculative, with little reference to how rationing or targeting has been carried out (see, for example, McGough et al., 2005; Wilson, Blower, 2005; Capron, Reis, 2005). There are many common features to the advice that has been given, including the need to establish clear goals in distribution strategies, the need for them to reflect sound legal and ethical approaches, the advantages and challenges of prioritizing certain groups, the need to achieve equitable and fair distribution outcomes and, finally, the need to use broadly inclusive, deliberative processes in the development of rationing strategies.

In one of the few articles to document actual experience, Muula (2004) described ethical and programmatic challenges in Malawi where, although 150,000 individuals were estimated to need antiretroviral therapy in 2004, only between 25,000 and 50,000 were to receive it over a five-year roll-out period. While the National AIDS Commission did organize a broad, deliberative process to discuss eligibility criteria and priority groups, ultimately a first-come-first-served approach was chosen mainly because no consensus could be reached on which groups should be treated first. A GTZ-sponsored case study in Tanzania (WHO 2006c) documented the decision-making process in the development of that country's national ART program. Although determining priority groups for access to treatment was discussed in the process, no prioritization decisions were made. Clinical and social eligibility criteria were created that would be applied to all individuals who gained access to the program. Finally, Rennie et al. (2006) gathered preliminary data on attitudes to the selection of patients for ART in a small community in the

Democratic Republic of Congo. Their work showed the potential for discrimination and exclusion where attempts to prioritize groups or individuals are made in the absence of an informed, deliberative process to develop selection criteria. In this situation, socially marginalized or 'different' groups and those considered to have 'caused' their HIV infection were identified as those to be denied preferential access to ART.

Study Purpose

Overall, it would appear that there are variations in how ART programs have evolved and how they have confronted the challenge of who should be treated now and who should continue to wait. In many respects, this very direct issue has been addressed only indirectly. The approach favoured in the few programs where experience has been documented is to treat all those who gain access to ART programs and who meet eligibility criteria. There is no process of explicit or active patient selection and there is an extreme reluctance at the different levels of program development and implementation to engage in this. Why does the first-come-first-served approach predominate and does this mean that ART programs are unfair or inequitable? The purpose of the study was to examine this question using the experience of a health care team working at an ART site in rural Lesotho. It was further to assess whether or not the concepts of fairness and equity had relevance or operative value for the treatment team. Finally, the study had a practical aim which was to provide a reflective learning opportunity. Study results were shared with the treatment team and their observations are included in the study findings. These in turn led to action-oriented recommendations to help guide process improvement and further reflection on the ethical challenges raised by patient selection.

Method

The study followed an exploratory case study design (Yin 1994: 38-44). It occurred at St. Charles Mission Hospital, Seboche, Lesotho. The hospital serves a rural population of approximately 40,000. It provides ART through its outpatient department as part of a collaborative project with the Government of Lesotho and as Swiss-based international development organization called SolidarMed. The site was chosen largely because it is representative of the setting where most local ART programs operate in Lesotho (i.e. outside of urban settings where the population is impoverished and geographically disbursed across extremely difficult terrain). The period of analysis was from program inception in 2005 to the most recent, available data in 2007.

There were two components to the method structure: a qualitative component to document and assess the selection process and to examine the relevance of concepts of fairness and equity within the treatment team; and, a quantitative component to measure substantive equity. Data for the study was collected through semi-structure interviews of key informants, document reviews, direct observation, and the abstraction of aggregate, anonymized data on patient characteristics from monthly progress reports and treatment registers. Fifteen key informants were interviewed during two field visits (4 doctors, 1 nurse clinician, 2 nurses, 3 HIV counsellors, 1 peer educator, 2 pharmacy technicians and 2 administrators). All those approached for interview agreed to participate. Two individuals originally identified as informants were not available either during the first or the follow up visits.

The qualitative data analysis process followed procedures suggested by Yin (1994: 110) and Miles and Huberman (1994: 85) for building explanations of phenomena based on interviews and document reviews. This involved isolating and coding data segments, arranging them into thematic groups and then using an iterative process of combining and distilling the segments to come up with concise, robust explanations of what was observed. Equity was examined using a quantitative approach.[2] A χ^2 analysis of key characteristics (data was only available on age and sex) of the population receiving treatment against those in need of treatment was performed, including a comparison involved comparison these groups against the general population living around St. Charles. This statistical test for independence would show, for example, if certain groups were overrepresented in either the general population or the HIV-positive population and under-represented in the treatment population without a justification.

This study was approved by the Health Research Ethics Committee of the Faculty of Health Sciences, University of the Witwatersrand. It was also approved by the Research Ethics Committee of the Ministry of Health and Social Welfare, Government of Lesotho. Finally, the study was approved by the Medical Superintendent of St. Charles Mission Hospital on behalf of the board and the administration of the facility (see Appendix B for clearance certificates).

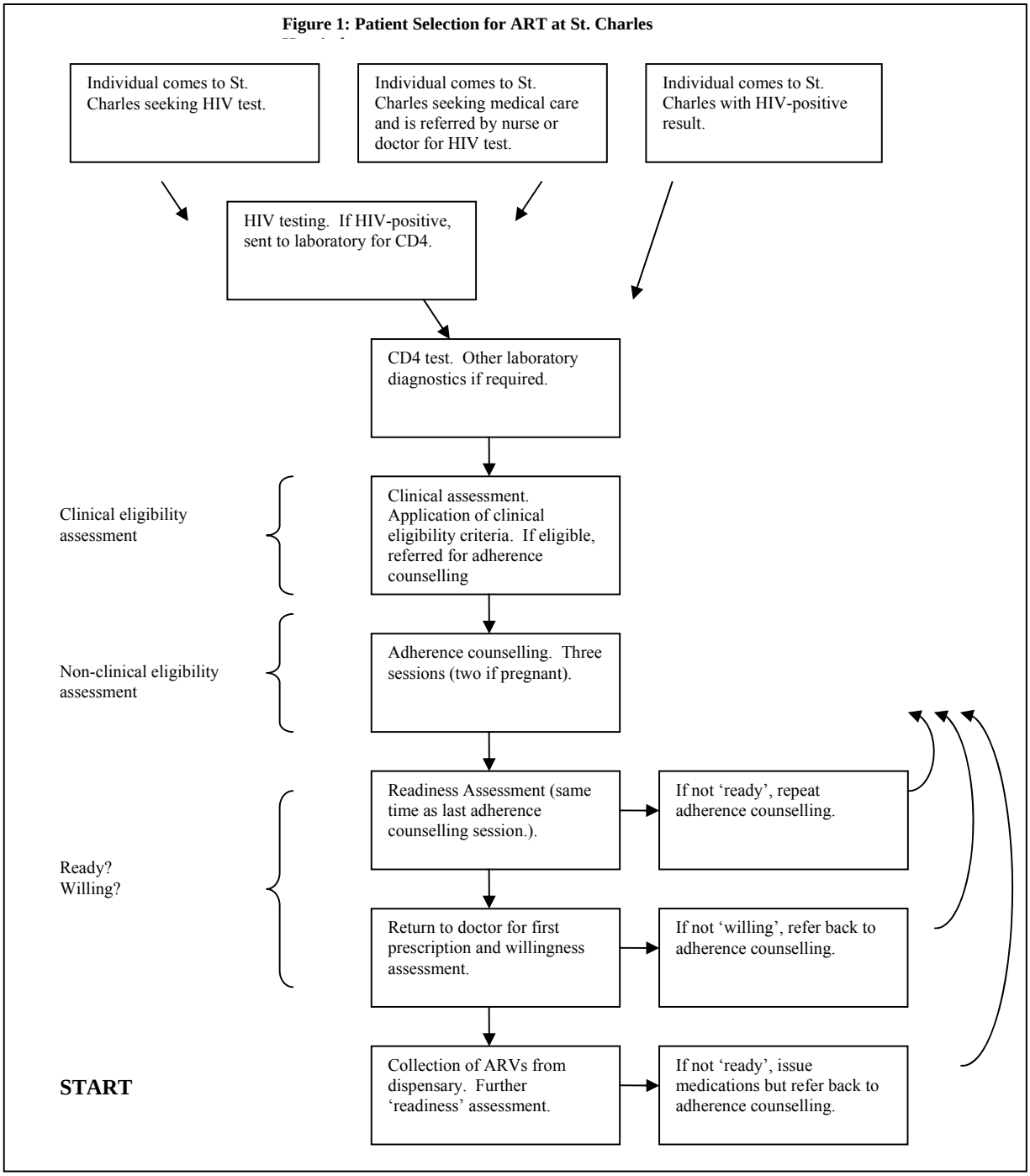
[2] This aspect of the study followed an approach suggested by Kalanda et al. (2004: 18-19) at Equinet.

Findings

a) Setting the Stage: Patient Selection for ART at St. Charles Hospital

To situate the analysis of fairness and equity in relation to patient selection at St. Charles Hospital, it is first necessary to briefly describe the selection process itself. Currently, ART is provided at St. Charles in the Outpatient Department (OPD) along with other health care services. Figure 1 below shows the main stages an individual passes through in gaining access to ART:

Figure 1: Patient Selection for ART at St. Charles



Individuals enter the ART program at St. Charles in a variety of ways. A clinical finding of HIV-disease, in the form of a documented HIV-positive test result, is the first step. Once an individual is determined to be HIV-positive, an eligibility assessment is performed on both

clinical and social grounds. The eligibility criteria originate from different sources, including guidelines published by WHO in 2004 and revised in 2006 (WHO 2006); national ART treatment guidelines for Lesotho (GoL 2004); practices based on the WHO's Integrated Management of Adult and Adolescent Illness (IMAI) program (WHO 2004b; WHO 2006b); and practices based on what the team at St. Charles understands the national approach to be even when the source of such understanding cannot be fully substantiated (sometimes it is simply a verbal direction given during a supervisory visit by the national consultant in charge of monitoring the ART program). There is not one, overall document either at St. Charles or nationally that sets out all of the eligibility criteria.

The clinical eligibility criteria for ART are as follows:

Table 1: Clinical eligibility criteria

Criteria	**Sources**
Adults	
▪ clinical finding that the patient is HIV+ documented in the bukana	National ART guidelines (GoL 2004) WHO guidelines (WHO 2006a) IMAI Chronic Care Module (WHO 2006b)
▪ WHO stage IV, any CD4 ▪ WHO stage III, consider treatment if CD4 < 350 ▪ CD4 < 200, any WHO stage ▪ **do not start ART if:** WHO stage I and II **and** CD > 200 ▪ not active TB (ART initiation is delayed for two weeks if the patient is CD4 <200)	
Pregnant women	
▪ if CD4<350, initiate ARV treatment as soon as possible	Revised national PMTCT guidelines (GoL 2007c)
For Children <15 years	

<table>
<tr>
<td>When to start ART (according to revised WHO guidelines 2005):

▪ depending on:
CD4 % and/or CD 4 count

< 11 months: < 25 % < 1500
12-35 months < 20 % < 750
36–59 months < 15 % < 350
>= 5 years < 15 % < 200

▪ and/or clinical stage IV;
▪ in clinical stage III: doctors decision considering stage, CD4% and clinical appearance</td>
<td>National ART guidelines (GoL 2004)
WHO guidelines (WHO 2006a)
IMAI Chronic Care Module (WHO 2006b)</td>
</tr>
</table>

These are based on the WHO approach to prioritizing access to ART. The requirement in adults for a CD4 count of <200, for example, selects only the sickest of those who might otherwise be able to benefit from ART. Individuals with CD4 counts between 200 and 350 might benefit from treatment but offering it to them would overwhelm the national ART program according to the national guidelines (GoL 2004: 18).[3] For pregnant women, initiation of ART on an urgent basis prevents against transmission of HIV to newly born children during labour and delivery by suppressing viral load. For children, the decision to initiate ART is more complex depending on the age of the child, the stage of immune system breakdown as a result of HIV-infection and where or not other symptoms of advancing HIV-disease are present.

If the patient meets the clinical eligibility criteria for ART, the patient is referred to the ART

[3]New national treatment guidelines for Lesotho, which are still in draft form, raise the CD4 eligibility requirement to 350 copies/ml2 (GoL 2007b: 34). While this allows more individuals the potential to access ART, there has been no corresponding adjustment to the capacity of treatment programs or, more controversially, no guidance in terms of whether very sick individuals with little chance of sustained benefit of ART should no longer gain access to treatment programs. Admittedly, such a determination is an extremely difficult one to make.

Nurse or the HIV/AIDS Coordinator for an assessment against non-clinical eligibility criteria. These relate primarily to the question of adherence, specifically prospective adherence. They are meant, ostensibly, to both prepare and select those patients most likely to adhere to treatment regimens. Adherence primarily means taking ARV treatment at specific times daily for the rest of the patient's life even though it may cause significant side effects. Adherence also means attending ART clinics or health centres on a regular basis for routine clinical monitoring and for refills of medications. At St. Charles, the non-clinical eligibility criteria are as follows:

Table 2: Non-clinical eligibility criteria

Criteria	Source(s)
▪ the patient has disclosed his/her status	National guidelines (GoL 2004) IMAI Chronic Care Module (WHO 2006b) IMAI Participant Manual (WHO 2004b)
▪ the patient has identified a treatment supporter (treatment supporter to come to 2nd and 3rd sessions)	National guidelines IMAI Chronic Care Module IMAI Participant Manual
▪ the patient has attended 3 adherence counselling sessions (first two at Seboche or at nearest health centre; last session at Seboche with either ART nurse or ART coordinator)	IMAI Participant Manual IMAI Chronic Care Module Site-specific practice (particularly last session with ART Nurse or HIV/AIDS Coordinator)
▪ the patient is READY to start ART (understands the content of the adherence counselling sessions, i.e. patient can answer most of nine 'Adherence Check List' questions correctly; cleared by ART nurse or ART coordinator)	National guidelines IMAI Chronic Care Module IMAI Participant Manual
▪ the patient is WILLING to start ART (patient gives informed consent)	National guidelines
▪ patient has capacity (there is no substitute decision-making practice except in the case of minors)	Standard clinical practice (not documented)

Patients must attend a minimum of three adherence preparation sessions where they learn in detail what ART is and what commencing such treatment involves. During the last adherence session, the patient's readiness, or his or her knowledge of ART and the implications of starting

treatment, is assessed by either the ART Nurse or the HIV/AIDS Coordinator. If the patient successfully completes the readiness assessment, he or she then returns to the doctor to be given the first ART script. If the patient is not successful, more adherence preparation sessions are scheduled. During the consultation with the doctor, the doctor may also do a readiness assessment and will determine 'willingness' or the degree to which the patient actively consents to start ART (rather than simply deferring to the recommendation of the doctor, as one key informant explained). If the patient is not ready according to the doctor, then he or she will be referred for more adherence preparation sessions.

There are inconsistencies between what is stated in the source documents for some of the non-clinical eligibility criteria and what is practiced at St. Charles. The requirement that a patient attend three adherence preparation sessions is one such example. The national guidelines and the IMAI training tools suggest that multiple sessions may be required but do not stipulate a specific number (GoL 2004: 9; WHO 2004b: 71; WHO 2006b: H44). Similarly, with regard to requiring disclosure and identifying a treatment supporter, these are recommendations for improving adherence in the national guidelines and the WHO materials (GoL 2004: 9; WHO 2004b: 29; WHO 2006a: 70-71). They are not requirements. There is one other condition that an individual must meet to be selected for ART. He or she must be mentally competent. Patients who are too weak or mentally confused (as a result of complications of advanced HIV disease, for example) may not be counselled or tested. In addition, if they are HIV-positive, adherence counselling may not be done and the patient not started on ART.

Some selection criteria have exceptions; others do not. In a selection process, the purpose of

exceptions is to recognize special circumstances and enable access to treatment in these cases where individuals might otherwise be ineligible for ART. The exceptions to eligibility criteria are detailed below:

Table 3: Exceptions to eligibility criteria

Criteria	Exception
HIV+ test result	There are no exceptions.
WHO Stage/CD4	There are no exceptions.
Disclosure	Patients can be started on ART if they are reluctant to disclose but meet other criteria, in particular having attended adherence counselling and being assessed as ready and willing to start ART.
Treatment supporter	Not having identified a treatment supporter is related to reluctance to disclose. If patient meets other criteria then he/she can start treatment.
Adherence Counselling	Pregnant women can be initiated after two sessions if they meet the ready and willing criteria.
Ready to start ART	Pregnant women can be 'ready' after only two sessions.
Willing to start ART	No exceptions.
Capacity	Parents or guardians can request testing and consent to treatment for minors. Must be authorized by an MD. Otherwise, no exceptions.

A finding of being HIV-positive is required before ART can be prescribed. However, if a patient is unable to give consent to be tested and to participate in pre-test counselling, this particular aspect of the diagnosis cannot be made. Doctors may or may not have the ability to test in the absence of consent in order to initiate treatment in life-threatening circumstance (an official change to Lesotho's HIV testing policy has not yet been formally communicated). New treatment guidelines for Lesotho propose a substitute decision-making mechanism that allows hospital authorities to give provisional consent for the initiation of treatment. Such provisional consent lasts until the patient regains capacity to make his or her own decision whether or not to

continue treatment.[4] On the requirement for disclosure and for a treatment supporter, discretionary room is limited. Some individuals are able to begin ART without having disclosed their status or identifying a treatment supporter. It was not clear from the key informants on what basis such an exception was granted other than the persuasiveness of the particular patients to argue that either disclosing or identifying a treatment supporter was impossible to do. What is clear is that exceptions to eligibility criteria are limited. None appear to have emerged from a lengthy deliberative process. Most have been adopted by the ART team as a result of either training curricula or specific statements in national or international guidelines. There is no formal process of deliberation on exceptions. Individual team members confer with each other. There are no group discussions of specific patient issues.

b) Issues Arising from the Patient Selection Process

At the moment at St. Charles, patient selection for ART follows eligibility criteria that are largely externally imposed through the national ART program. There has been no inclusive, deliberative process at the site to adopt these criteria. Nor is there a formal process of patient selection. Some individuals or groups gain access to ART without meeting all of the eligibility criteria. Not all eligibility criteria have an empirical basis and some may be unduly onerous for some patients. What does this mean for patient selection in terms of fairness and equity? A selection process will be fair or equitable to the extent that it relies on a principle or goal that can be justified in relation to those who are affected by the rationing problem. The goal must be explicit in terms of who is to be given priority in the selection process and why these individuals or groups should be preferred over others.

[4]Personal communication, Dr. Roland Dürig.

According to Lesotho's national treatment guidelines and the WHO-developed training program that supports them, the goal of the ART provision at St. Charles and elsewhere is to put as many of the 'right' or eligible people on treatment as possible (WHO 2006b: H26):

> "Remember: ARV therapy for the individual is rarely an emergency! The public health emergency is to get large numbers of the right patients on treatment with good adherence and good overall HIV chronic care. For the individual patient, management of life-threatening opportunistic infections can be an emergency."

Here the principle is explicitly utilitarian in that it aims to provide treatment to the greatest number of those who will derive the most benefit. This means selecting those whose clinical condition allows for maximum clinical improvement (not too sick, not too well) and those whose social circumstances are conducive to adherence (taking the treatment correctly for as long a period of time as possible).

If there are 'right' people for treatment, then there are those who are ineligible for treatment. In this latter group are, presumably, those whose clinical condition does not yet warrant ART (to the extent that they would experience significant greater benefit over those who are less well) or whose social condition or personal motivation are not conducive to successful adherence. This group may also include the very sick whose clinical condition has deteriorated to such an extent that ART will provide little if any sustained benefit. The goal is very indirect in this respect. As patient selection was observed at St. Charles, an incompletely realized approached to the utilitarian goal emerged. While there was alignment with the need to put as many individuals on

treatment as possible there was reluctance to explicitly deny anyone treatment and the team made extended efforts to assist some individuals to meet all of the eligibility criteria (or to grant exceptions). It raised the question of whether more individuals could have been initiated on treatment if less time and effort was expended with some patients to assist them to meet the eligibility criteria. Was fairness emphasized at the expense of equity, perhaps, or vice versa? Can this utilitarian approach effectively guide treatment teams in the absence of greater clarity and direction on who should be denied treatment and what ART programs in these settings should strive to achieve?

c) Fairness

Daniels (2004: i) has proposed that in situations where benefits are limited and need is greater than supply, fairness can only occur in the form of fair process. Fairness as an outcome cannot be achieved when some are denied benefits for the sake of others. The situation in Lesotho, where need for ART exceeds the capacity to provide it, is fundamentally unfair. Certain individuals receive treatment while others do not. Fairness was explored in the interviews using a simple open-ended question: "Do you think the [ART patient selection] process is fair?" Informants viewed fairness as both an absence of (moral) judgement and the consistent application of the national guidelines as they are understood by the treatment team. According to one informant:

> "I didn't judge that person. I treated that person like every other client. I didn't do any favour. I didn't impinge upon his or her right. I just did what was agreed upon....We are

not only making our decisions. We are following the guidelines."

In the words of another: "I try to treat everyone the same. I just sit in my office. I just see the people I see." Fairness also means that no patients are refused: "We don't refuse anybody...Anyone who needs help from us, they get it. We don't pick and choose." When a patient does not proceed through the steps towards gaining access to ART, it is not because they were not selected for treatment. It is because the eligibility criteria were not met, a situation that is the responsibility of the patient. To the extent that there is patient selection, it is implicit. Where selection occurs, it is viewed by the team as self-selection, meaning that patients self-select not to continue with the process of meeting eligibility criteria for reasons that are beyond the team's control.

While the treatment team perceives that it impartially administers a set of well-defined eligibility criteria, between perception and practice, there are some challenges at St. Charles in terms of fairness. Procedural fairness requires decision criteria that have a definable relationship to an overall goal and, upon analysis, not all criteria used at St. Charles are clearly connected to providing ART to the greatest number of patients who will derive the most benefit. The requirement that an individual disclose his or her HIV status to someone else and provide proof of disclosure is a very significant one, particularly within a rural context where stigma against HIV-disease predominates. Similarly, the requirement that individuals also seek out a treatment supporter may be equally burdensome. As Macklin (2006: 316-317) has noted, requiring disclosure infringes on individual privacy and insisting on a treatment supporter limits autonomy. Limiting privacy and autonomy requires careful justification in terms of the

effectiveness of such limits on improving the benefit of ART. Despite statements in WHO training materials and in Lesotho's national guidelines assuring health care providers that such things lead to better adherence, there exists little empirical evidence to support these criteria as improving the efficacy of treatment.[5] Given repeated counselling sessions and other tactics that are used with patients in order to persuade them to disclose their status or to locate a treatment supporter, and given the fact that some who do not disclose or cannot locate a treatment supporter are not started on ART, the rationale for the application of these criteria becomes questionable. One must ask what is the value of these efforts if, in the end, the effect on patient adherence is not measurable.

Within the patient selection process, those who lack capacity, including those who are very sick or have other mental capacity challenges, are more likely than others not to receive ART. For the very sick, some team members would like to initiate ART immediately as this would improve a patient's condition to the point where the capacity issue would resolve. Others, either explicitly or implicitly, feel that the very sick will die anyway and that the efforts of the team should be directed at those who are likely to have better, longer term improvement from ART. There is evidence to show that starting the very sick immediately on treatment does not lead to better outcomes. The number that improves and survives is very small in comparison to the number that die within a short period following initiation of treatment.[6] Unfortunately, for the

[5] In the study by Mills et al. (2006: 2055) there was evidence in developed world settings that disclosure within a supportive social network improved adherence. No such evidence was found in developing world settings largely because the issue had never been explored. In the ARV treatment guidelines of 2006, the WHO comes to a similar conclusion (WHO 2006a: 70).

[6] See, for example, the study by Rosen et al. (2007). Across the many cohorts examined in this systematic review,

treatment team at St. Charles, there is little guidance for them in terms of how to resolve this dilemma. The Lesotho treatment guidelines and the WHO standards are silent on when treatment should no longer be considered. As one informant noted:

> "The guidelines help me to do the decision. But what I think is difficult is that we cannot start patients without all these counselling sessions...The patients in bad condition, we lose them."

The absence of more explicit decision rules regarding the very sick causes challenges for the treatment team at St. Charles. While the effect of the eligibility criteria is to deny ART to this group, it achieves this indirectly.

The idea of fairness as a structured, formalized selection process which includes the ability to make carefully justified exceptions does not figure in the approach to ART provision at St. Charles. The differing views on whether or not it is fair to not initiate ART for the very sick highlights the reluctance of the team as a whole to face patient selection more directly. For them, fairness is non-discrimination in any direct sense and the equal opportunity patients have, once they enter the ART program at St. Charles, to meet eligibility requirements. Selection occurs as a result of externalities not as a result of deliberate decisions by the team to choose one individual or group of patients over another.

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late entry into treatment programs (i.e. low CD4 counts) was consistently associated with early death.

d) Equity

Fairness as correct procedure requires a counter weight to ensure that individuals or groups are not denied access to treatment for avoidable or irrelevant reasons that may arise not only from the decision rules themselves but from the larger context in which the selection process operates (McCoy 2003: 11). Equity in rationing problems links (procedural) fairness to outcomes. At St. Charles, for example, individuals may not be able to receive ART not because they are not eligible but because they cannot travel to the hospital to enter the program. Equity is a measure of what efforts are made to overcome such barriers or exclusions. It was explored in two ways in the study: through the key informant interviews and through an analysis of operational data. In the interviews, the researcher explained equity as all individuals having equal chances to receive treatment suggesting that where there were barriers or challenges, efforts were made to address these inequities. For some informants, the opportunity to access treatment was the same for all. What hindered access to treatment were individual barriers that could not be resolved by the treatment team: "We don't hinder anyone. The clients hinder themselves."

Other members of the treatment team had different views. Issues of poverty and distance prevent some from accessing treatment. According to one informant, "Some people don't get treatment because they are too far." She suspects that the sick, neglected, or very poor, do not return to the clinic once they are seen initially. "I can imagine they won't come back. They are badly dressed or the translator says they won't come back." However, this happens for all services provided by St. Charles, not just ART. In the words of another informant:

> "The more you know, the closer you are, you are more likely to come for service. I'm not sure. But it's not only for ARVs, it is for everything."

According to still another, there are insurmountable challenges in the way of achieving equity, including geography, infrastructure and lack of staff: "We are not marginalizing. We are forced by circumstances." One informant felt that individuals should not all have the same chances and that there should be priorities: "I don't think everyone should have the same chance. I am more reluctant to put older people on treatment unless they are care takers." For this informant, younger people, children and mothers are priorities. "We have to do a triage....I don't tell them [older patients] I won't put you on treatment. I just don't insist."

Accordingly, there is a range of interpretations of equity within the treatment team. There is knowledge amongst some that social, economic or geographic conditions inhibit individuals and groups from gaining access to ART and that this is inequitable. The ART program at St. Charles does make efforts to address these. It provides reimbursement for transport costs for those patients with this difficulty. The hospital works with patients who have no funds to make arrangements for payment (this can include bartering food, livestock or some other possession of value in exchange for exemption from cash payment). A limited amount of food aid is provided through the primary health outreach program. The outreach team conducts regular visits across the region and integrates HIV testing and counselling and patient follow-up within these more general efforts. The hospital is in the process of implementing decentralization of ART, meaning that it is attempting to make it available at local health centres across the region rather than exclusively through the hospital's OPD. At the moment, adherence preparation sessions take

place at health centres; HIV testing and counselling is available at all health centres, and one health centre is beginning to provide ART.

As for the many other individual and environmental factors that inhibit access to treatment (and health care generally), there is less ability on the part of the team to address them. Stigma in a range of forms is deeply entrenched in the communities around St. Charles. Traditional beliefs, coupled with poverty and literacy challenges, also impede the extent to which the treatment team can provide services across the area. These constraints raise much larger issues beyond one health service area and one treatment program. They occur all across the southern African region. They raise much more complex issues of equity and fairness.

There is no doubt that the treatment team does its best to address stigma, fear and general reluctance on the part of patients to either test for HIV or to start ART. Messages are repeated, individuals are re-counselled, some are found in their villages and homes for more persuasion to seek help. Attachments to traditional beliefs are part of world views that orient individuals to their surroundings and help to sustain them in times of adversity and change. Accepting the decisions that result from these is part of respecting patient autonomy as crushing as it may be for health care providers to see individuals deny themselves the benefit of ART. ART is inaccessible to the very sick and the very poor who cannot overcome the barriers of inadequate food, no transportation other than walking, and roads and footpaths that may be inaccessible due to weather conditions. The efforts of the treatment team to reach all in need are blocked by broader health system challenges in Lesotho. There is little at their level that they can do to try to mediate this broad network of constraints that create inequity.

What does the operational data suggest in terms of the efforts to address inequities and to improve access to ART across the Seboche region? Table 4 shows estimated and actual values for the population surrounding St. Charles Hospital and those seeking HIV counselling, testing and initiation on ART. There are some variances between what is recorded by the St. Charles team and both the age and sex distribution for the population area, and the estimated differences in HIV prevalence amongst these groups. The proportions of those seeking HIV testing in the Seboche area are 75% women, 19% men and 5% children (vs 30%, 29.6% and 40.4% according to the estimated age/sex distribution). Those seeking testing are overwhelmingly adult women. Of the males in the population who seek out HIV testing, a much larger proportion are HIV-positive (36% vs 18.7%) than what is estimated nationally in Lesotho. Of those who present for testing and are found to be HIV-positive, they are also overwhelmingly women. 67% of HIV-positive individuals are women as compared to 29% men and 4% children.

Table 4: HIV testing and ART provision for 2006/2007

	A	B	C	D	E	F	G	H	I	J	K
	Population by Age and Sex	**%of Total**	**%HIV+ (Estimate)**	**Estimated HIV+ (A*C)**	**Seeking HIV testing[e]**	**% of Total**	**HIV+[e]**	**%HIV+**	**% of Total**	**Started on ART[f]**	**% of Total**
Adult Males	11264[a]	29.6%	18.7%[c]	2106	554	19%	199	36%	29%	119	26%
Adult Females	11492[a]	30%	24.3%[c]	2793	2166	75%	464	21%	67%	301	65%
Children (<15 yrs)	15426[a]	40.4%	6%[d]	919	158	5%	29	18%	4%	42	9%
TOTAL	38182[b]	100%	NA	5873	2878	100%	692	24%	100%	462	100%

[a]Of the total population in Lesotho, it is estimated that 40.4% are under the age of 15 (UNDP 2007) [.404*38,183=15,426]. For the adult population, 49.5% are male (GoL 2007b) [.495*(38,182-15,426)=11,264].
[b]Estimated population for the Seboche area, combining the constituencies of Mechachane and Hololo (GoL 2007b).
[c]GoL 2005: 37.
[d]GoL 2008: 5
[e]Data from operational reports covering January to December, 2007
[f]Data from operational reports covering May 2005 to December 2007

There are other findings of note when comparisons are made using other indicators of HIV-disease burden and need for ART. Table 5 shows estimated need for ART in the Seboche area compared to those currently receiving treatment.

Table 5: Estimated need for ART and actual coverage

	A	B (.15*A)	C (.15*A)	D	E [(D/B)*100]	F [(D/C)*100]
	Estimated HIV+	**Estimated Need for ART Low (15%)[a]**	**Estimated Need for ART High (19%)[a]**	**On ART at Dec 2007[b]**	**%Coverage Low**	**% Coverage High**
Males	2106	316	400	119	38%	30%
Females	2793	419	531	301	72%	57%
Children (<15 yrs)	919	138	175	42	30%	24%
TOTAL	5873	873	1105	462	53%	42%%

[a]The WHO estimates that, at any one time, 15% to 19% of the HIV-positive population is in immediate need of ART (WHO 2005).[7]
[b]Data from operational reports covering May 2005 to December 2007

Comparing the estimated need of ART with the number of those initiated on ART at St. Charles, one could conclude that the program has reached between 41% and 53% of the overall immediate need for treatment. For men the range is 30% to 38%; for children the range is 24% to 30%.[8] These estimates are broad and speculative. To the extent that they reflect the nature of need for treatment and the efforts of the treatment team at St. Charles to address it, they suggest much greater equity challenges in that for these groups, the majority of those in need do not yet obtain ART.

To test the independence of these variances, a χ^2 analysis was performed using the observed and

[7]This model uses CD4 lymphocyte count of <200 cells/ml2 as one of the criteria to estimate need. Under new eligibility criteria (CD4 count of <350 cells/ml2) the number of individuals in need of treatment would be greater.

[8] Estimates of HIV prevalence, need for ART and coverage of ART for children <15yrs have been difficult to obtain

expected values set out in Table 6 below. The results were significant [rejection region: $\chi^2 \geq$ 14.8602 df=4 p=.005; χ^2=3130.882]. The analysis confirms what was noted above, that adult males and children of both sexes are significantly under-represent amongst those seeking HIV testing and those estimated to be in need of ART in the geographic region service by St. Charles Hospital. None of these patterns are unique to St. Charles; they reflect what has been observed across the southern African region. They are the result of the complex interplay of social, economic and cultural factors. In the rural areas of Lesotho, men must travel far to seek work while women remain in their villages to care for families. Culturally, illness generally, and HIV disease in particular, are stigmatized among males, particularly in rural environments where the traditional attitudes and beliefs about men's roles still predominate. Lesotho, overall, has very poor child health indicators with very high rates of mortality, even in comparison to other countries at similar stages of development (UNDP 2007). It is not surprising, then, to see this reflected in the absence of children amongst those seeking HIV testing and treatment.

for Lesotho. Recently, it was estimated that the ART coverage was 26% nationally for this group (GoL 2007a: 53).

Table 6: Observed and expected values for uptake of HIV testing and ART

A	B	C	D	E	F	G	H	I	J	K	L
Sex/Age	**Population**	**%Total**	**Observed Seeking Testing**	**Expected Seeking Testing**	**Estimated HIV+%**	**Observed HIV+**	**Expected HIV+ (E*F)**	**Estimated Need for ART (at 15%)**	**%Total**	**Observed ART**	**Expected ART (at 15%)**
Male	11,264	30%	554	863	18.7%	199	104	316	36%	119	167
Female	11,492	30%	2166	863	23.4%	464	537	419	48%	301	222
Child (<15yrs)	15,426	40%	158	1151	6%	29	9	138	16%	42	73
Total	38,182	100%	2878	2878		692	692	873	100%	462	462

Discussion

a) The Ethics of Patient Selection

What light can fairness and equity shed, then, on the ethics of patient selection at St. Charles? As for fairness, the treatment team applies eligibility criteria that are national and internationally determined on a first-come-first-served basis in what it perceives to be an open and non-discriminatory fashion. As for equity, there are some efforts to address barriers of poverty or distance, for example, for some groups. For others, such as the absence of men from the treatment program, the team feels somewhat powerless. There is no overall strategy to target or prioritize segments of the community around the treatment site. There is no evidence of any discussion in terms of which groups in the community should gain immediate access to treatment and which groups should continue to wait, beyond what the eligibility criteria determine in terms of minimum CD4 lymphocyte counts. The advice of Macklin and Daniels, quoted earlier, appears to have gone unheeded and, in fact, there is some reluctance to consider such questions. The team believes its role to be to administer externally determined eligibility criteria and not to engage in any more direct process of rationing or prioritization. For the team, a first-come-first served approached is the only morally acceptable one to the situation it finds itself in. It believes that it is doing the best it can in terms of the overall national goal of offering ART to as many eligible individuals as possible. What prevents more adults and children for coming forward for treatment are largely things beyond what the treatment team can influence.

Why is there this reluctance to consider the larger questions of fairness and equity? It may be that staying within such an externally imposed structure, even when it may appear to have

inconsistencies, is a very pragmatic approach for a team faced with a difficult task. Too many exceptions or too much deliberation put a burden on the treatment team that may impede the efficiency of the program or make it inoperable. A more explicit patient selection process may also be morally burdensome to such an extent that team members would refuse to participate. At the moment, given the lack of adequate data, it is impossible to know the extent to which individuals may be denied access to treatment because of the selection process. As the ART program operates now, many have an opportunity to start ART, many take that opportunity and many succeed. What puts all of this in perspective, however, is the fact that most of those who need treatment do not yet receive it and this much greater challenge to fairness and equity goes far beyond the local efforts of the team at St. Charles.

It is clear that the architecture of criteria and selection processes aimed at achieving fairness and equity have not informed the St. Charles treatment program. Is it the absence of this that is contributing to the extraordinary gap between those on treatment and those in need or is it something else? Rather than highlight challenges and opportunities in the work at St. Charles, perhaps the ethical analysis should point to much larger limitations in the overall approach to ART provision in such circumstances. This is not a criticism of the team at St. Charles or its tremendous efforts. Rather, it is a challenge to the global effort to provide ART in resource-limited settings which, as McCoy et al. (2005: 20) warned, was fraught with pitfalls and would not result in an equitable distribution of ART. The pitfalls, however, may not be caused by the lack of more explicit approaches to equity or more formal, deliberative processes within treatment programs. They may be caused by something more fundamental. As Alvarez (2007: 432) has observed, for example, in similar settings of extreme resource scarcity:

> "Some resource scarcities are too severe and way below the amount that can sustain a decent level of health that they undermine any attempt to make allocation ethical…."

Perhaps, when the gap between need and capacity is so large, there can be no such thing as an ethical approach. What emerges are approaches that are pragmatic and expedient and that try to give a limited benefit to as many as possible without engaging intractable questions of which individuals to choose and which not. It may be that measuring equity and fairness in such situations is at best fruitless or, worse, irrelevant.

While selection criteria and selection processes help facilitate difficult work in rationing dilemmas by attempting to make the outcome of such choices as fair and equitable as possible, they also serve other ends. With respect to ART, they also balance risk. An ART program improperly implemented or controlled runs the risk of encouraging the development and spread of treatment-resistant strains of HIV. While this has not yet emerged in Lesotho (there is no technology in-country at the moment to examine this), the rise of XDR-TB in the region is a striking reminder that it could given how this very dangerous form of TB arises from poor adherence to TB treatment regimens and poorly administered first-line TB treatment programs. Using a process like the one at St. Charles sets a certain pace for how many people can move through the various stages of preparation and end up on treatment within the limits of a standard working day or a standard working week. The team is not, at the moment, inundated with individuals seeking ART (elsewhere in Lesotho there are treatment sites that are). If it wanted to significantly improve the coverage of the ART program, much bolder steps are required than

tinkering with eligibility criteria or the number of steps in the selection process. To reach significantly more people with ART perhaps only a minimum of steps are required and a new balancing of the risk equation. What would the outcome be of much wider access and much fewer eligibility steps? Some individuals would die from not taking their treatment properly. Some individuals would develop drug resistant virus and potentially transmit it to others. Would these risks be balanced, though, by a significantly greater number of people taking treatment and doing it correctly over the long term? As Rosen et al. (2007: 1695,1698) have noted, early experience with long term retention of patients in ART programs in sub-Saharan Africa is not encouraging, suggesting, perhaps, that the current approach to preparing patients for treatment is not having its intended effect. At the moment, the balance between individual entitlement to the means for health improvement and the need for an overall public health benefit through a well managed ART program is not being met.[9] As long as this is the case, the premises underlying ART program design should be revisited. This should be done with a view to examining whether the balance between the public health objective of a well-administered treatment program and individual entitlement to the means to preserve life and health with only the minimal necessary restrictions is correctly proportioned. Surely, given the consequences of not receiving ART in a timely way and given the great number of those not yet receiving ART, the analysis should lead us to skew this balance in favour of those individuals whose lives will be lost unless some radical changes are made.

Commenting on the performance of a treatment team that functions in the midst of such

[9]It was recently estimated in Free State, South Africa, a region adjacent to Lesotho and near Seboche, that 87% of those who qualified for treatment according to eligibility criteria similar to those use by St. Charles were not

quandaries is a delicate matter. The ART program at St. Charles operates within a larger health system that does not substantially address equity. On the question of ethical inconsistencies in the selection process, one must ask to what extent these are significant barriers when placed beside the constraints of stigma, literacy, cultural beliefs, poverty and geography. To what extent would bringing forward inconsistencies and conflicts disrupt relationships and damage the functioning of the team for an increase in access to treatment that may only be marginal in the face of more powerful forces keeping individuals away? Health care professionals are highly educated individuals who must balance a number of important aspects in their daily work of providing care and treatment. Rarely can a health care worker hide behind the screen of doing only what the national guidelines said or what the national program director demanded when, in the context of patient care, problems and inconsistencies arise that, in extreme cases, prevent access to care. The services they provide and the care they give must not only be competent and effective, they must also be ethical. At St. Charles, the team is not well equipped to deal with the ethical challenges it faces. There is pressure nationally to just keep moving, to keep putting individuals on treatment. While this may utilize the limited capacity of the team more or less effectively in the short term, there is no ability to measure what impact the program will have over the long term.

Which essential aspects of the communities around St. Charles will be preserved by the ART program, which will not? There is little support for the team for reflection and dialogue on this challenge. One of the issues to be explored at the outset of the study was whether the ethical concepts of fairness and equity had operative value or 'traction' in the daily work of the

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currently receiving it (SABC 2007).

treatment team. One must conclude from the study that they do and they do not. There is an awareness of these things across the team even is if there is not, necessarily, the means to fully implement in the treatment program what such concepts demand. On the other hand, circumstances surrounding the treatment program at St. Charles may be such that equity and fairness have little relevance and shed little light for them on how to better accomplish their difficult task.

b) Study Participant Feedback

As part of the study design, a summary of the findings, including the ethical reflection and the conclusions and recommendations, was presented to the treatment team in January, 2008. The aim of the session was to enable the research to confirm the conclusions of the study and to prompt the treatment team to engage in some additional reflection on their work. Not all of those originally interviewed attended the session. Overall, the session validated the findings of the research. The team has very little opportunity to reflect on what it does and rarely does so in relation to ethical concepts raised by the work that they do. There was general agreement that such reflection is very helpful at identifying challenges and guiding improvements. When the estimate of overall need for treatment and care was placed before the team, there was general silence. There is awareness that many of those who need care do not access it. There is perhaps a sense of sadness and defeat given the multiple challenges that surround the ART program. The team, nonetheless, believes in the benefit that it provides and is encouraged by the growing number of those on treatment and by the efforts they make for many individuals who experience problems.

c) Study Limitations

A single case study has limitations. Broad generalizations are made on the basis of only a single instance of a phenomenon. For that reason, certain findings may be overstated or overemphasized. Much of the data for this enquiry came from key informant interviews. There was little opportunity for external validation of some of the information obtained in the interviews. Sufficient data to assess equity was not available. Any statements and conclusions in this respect are therefore tentative. Some key informants and some important documentation were not available during either the site visit or the follow up visits. For this reason, some aspects of the work at St. Charles may not be fully represented in the study. The study is only a partial look at a much larger question. It could be that other places where ART programs are offered have resolved some of the key challenges and dilemmas brought forward in this analysis. In a single case study design there is no test for general significance of a finding and the likelihood that it reflects a common phenomenon. That type of finding will have to await a much larger, more comprehensive assessment of patient selection processes.

Conclusion

The purpose of this study was to bring forward the experience of a health care team providing ART at a rural hospital in Lesotho. That experience was examined in the light of two ethical concepts related to rationing dilemmas in situations of scarcity: equity and fairness. Model or 'right' approaches had been proposed by prominent ethical and legal scholars at the outset of the

global effort to provide ART in places where it was never available before. However, the approached used by the treatment team in Lesotho appears to have gone in a different direction and reflected other front-line experiences of those confronted with the challenged of too much need for ART at the community level and not enough capacity to provide it. There is another instance here of the use of a first-come-first-served approach, one that seems to predominate over other more complex responses to such rationing problems. Was this approach fair and equitable? To the treatment team who work in a rural community devastated by HIV disease, the answer is yes, as fair and as equitable as it can be given the tremendous social, economic, cultural, and geographic challenges of their region. One must also add here the lack of direction from the national level to do anything other than administer a defined set of criteria to as many individuals as possible. From a larger, analytical perspective, however, the results are much less conclusive.

Rationing dilemmas generally, and the specific dilemma of need for ART versus capacity in the southern African region, raise fundamental moral challenges that neither law nor ethics can yet fully address. There are a number of normative frameworks that have been put forward but the gap remains between these and the real experience of health care teams. As for ART provision, while the global gap is so large between those in need and those who receive treatment, we are firmly entrenched in something that is inequitable and unfair, a distance that it is impossible for a treatment team and, arguably, the national leadership of a impoverished country to even attempt to cross. While this is the case, as this exploratory case study has attempted to show, there may be few reasons to go searching for fair and equitable approaches at the program delivery level. Instead, more pragmatic tools are required to enable health care teams to more fully understand

the ethical dimensions of what they do in ways that enlighten and empower them to develop creative, context-specific approaches to the difficult task they face. There may indeed by ethical problems at this level, and the experience of the treatment team at St. Charles has shown this, but these will not be fully resolved until much larger questions of fairness and equity are addressed regionally and globally.

Recommendations

Despite the larger challenges and questions raised by the study, there may be some ways to improve patient selection at St. Charles and for similar programs in similar settings:

- The health care team should receive some basic orientation to the ethical principles involved in selecting patients for ART. Skills in ethical reflection are an important tool for a health care team doing work like the one at St. Charles. While they may not be able to fully resolve their dilemmas, reflection can provide a way of easing tension and pointing towards improvements.

- The health care team could strengthen some of the formality and objectivity that should be a part of patient selection process. Criteria could be documented for example in one 'official' source for the team. In some cases, it was observed that some individuals were given exceptions to eligibility criteria while others were not. Such decisions should be more explicit and formalized to prevent inconsistency.

- Some of the eligibility requirements should be reviewed in light of the fact that they differ from some of the source documents and may not be justifiable given existing evidence. This involves in particular the requirement to disclose HIV status, to identify a treatment supporter, and to attend a minimum of three adherence preparation sessions. While there is still some urgency to increase the number of individuals on treatment, the goal of reflection and review should always be in the direction of simplifying selection criteria and processes and potentially reducing the number of eligibility steps.

- Data collection should be improved. The health care team should define ART coverage indicators that are easy to capture and then assess them on a regular basis.

This inquiry raises items for further research and action:

- Selection criteria and selection process should continue to be challenged. Limitations on privacy and liberty, even for the most disadvantaged, require adequate justification. Some aspects of patient selection have little or no empirical evidence to justify them.

- Data to assess equity must become more of a priority. It may be that some original aspirations around equity were utopian. However, there is a large gap at the moment preventing even tentative conclusions from being drawn.

- The model for ART delivery should be continually challenged. The WHO IMAI model predominates in Lesotho and elsewhere which emphasizes utilitarian, public health objectives.

The adherence preparation process it recommends can be burdensome to some with the result that they do not access treatment. Does this approach achieve the right balance with the rights and entitlements of individuals to access what will give them health and preserve their life?

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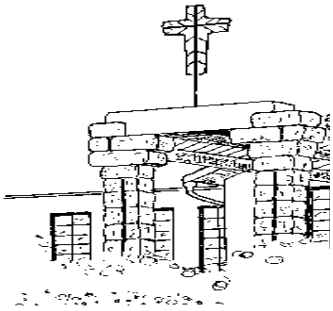
APPENDIX A: ETHICS REVIEW CLEARANCES

NOTE: The original title for the research study was, "Achieving Equity and Fairness in Rationing of Access to Anti-Retroviral Care at a Rural Clinic in Lesotho: A Case Study Analysis." At the request of the internal assessors review committee, the title was changed to its current form. A new clearance certificate was issued with the amended title. This was the only aspect of the original protocol that was changed. The research did not, therefore, requested amended clearances from the Ministry of Health and Social Welfare, Lesotho, or the St. Charles Mission Hospital.



SEBOCHE MISSION HOSPITAL

ST. CHARLES MISSION P.O. BOX 304
BOTHA-BOTHE 400
TEL.: 00266 27 00 58 22

IN PRAYER AND CONTEMPLATION WE RECEIVE THE VITALITY NECESSARY FOR OUR APOSTOLIC ACTIVITY

Dr. med. R. Duerig
Med. Sup.
Seboche Hospital
P.O. Box 304
Butha Buthe 400
Lesotho

Mr. R. Armstrong
108 de la Harpe
Rosendal 9720
RSA

Dear Mr. Armstrong

I am writing in reply to your request of participation in your research project titled: Achieving Fairness and Equity in Rationing of Access to Anti-retroviral Care at a Rural Clinic in Lesotho: A case study.

We are certainly aware of the discrepancy between the number of patients in need of treatment and the capacity of our institution. To provide Equity and Fairness in the selection process should be one of the leading aspects of antiretroviral treatment and is one of the hardest aims to reach.

We would therefore appreciate if you select our hospital as base of your case study and we will support you in all the aspects mentioned in your letter dated June the 29th 2007 and the attached research proposal.

Best Regards

Dr. med. R. Duerig
Med. Sup. Seboche Hospital

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Armstrong

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M070736**
PROJECT	Achieving Fairmess and Equity in Rationing of Access to Anti-Retrociral Cae at a Rural Clinic in Lesotho: A Case Study Analysis
INVESTIGATORS	Dr R Armstrong
DEPARTMENT	Steve Biko Centre
DATE CONSIDERED	07.07.27
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07.08.01 **CHAIRPERSON** .....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof A Dhai

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Ministry of Health and Social Welfare
Director General of Health Services
P.O. Box 514
Maseru 100

Sept 25, 2007

Mr. Russell Armstrong
3 Orphen Road
Maseru, 100
Lesotho

Dear Mr. Armstrong

Re: Achieving fairness and equity in rationing of access to Anti-Retroviral care at a rural clinic in Lesotho: A case study analysis

Reference is made to your letter requesting ethical approval of the above mentioned study.

The Ministry of Health and Social Welfare Research and Ethics Committee having reviewed your protocol hereby authorizes you to conduct this study among the specified population. The study is authorized with the understanding that the protocol will be followed as stated. Departure from the stipulated protocol will constitute a breach of the permission.

Regards,

(Signature)

Dr. M. Moteetee
Director General
Health Services

M0
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14 49 Armstrong

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M070736**
PROJECT	Selecting Patients for Antiretroviral Care at a Rural Clinic in Lesotho: A Case Study Analysis
INVESTIGATORS	Dr R Armstrong
DEPARTMENT	Steve Biko Centre
DATE CONSIDERED	07.07.27
DECISION OF THE COMMITTEE*	APPROVED UNCONDITIONALLY

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07.08.24 **CHAIRPERSON** .....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof A Dhai (Co Supervisor Prof Dhai Bayard)

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B:

PARTICIPANT INFORMATION SHEET AND CONSENT FOR INTERVIEW

SELECTING PATIENTS FOR ANTI-RETROVIRAL CARE AT A RURAL CLINIC IN LESOTHO: A CASE STUDY ANALYSIS

PARTICIPANT INFORMATION SHEET

Lumela!

My name is Russell Armstrong and I am a post-graduate student at the Steve Biko Centre for Bioethics, University of Witwatersrand in Johannesburg, South Africa. I am studying for a Masters of Science in Medicine in Bioethics and Health Law. I would like to conduct a research project at your ARV clinic as part of the requirements for my degree. Below is information about my project. I would like you to consider participating in the project with me.

Background

As a doctor or a nurse or a counsellor involved in the delivery of anti-retroviral (ARV) care for people living with HIV/AIDS, you may already be aware that not everyone who needs this treatment is able to receive it. In Lesotho, some criteria have been developed to help select which patients should receive ARV treatment (CD4 count <200, for example). These criteria do not always help, though, as sometimes more people meet the criteria than there are spaces available for ARV treatment. Sometimes, you and your colleagues have to make choices and decide who should get treatment now and who should continue to wait.

Purpose

The purpose of this project is to investigate how a team of people working at an ARV centre makes choices and decides who can receive ARV treatment. Prominent ethicists and legal scholars around the world have suggested that in making choices, we should be trying to achieve equity and fairness. Equity means that the selection process should not be easier for some and harder for others (those who live close to your clinic, for example, versus those who live far away). Fairness means that the process used to select patients is based on clear criteria and that the selection process follows the same steps each time. This project will investigate whether this is useful advice and whether it helps you to make the selection of patients easier.

Research Method

The research method to be used for this project is called case study. It is a very in-depth way of looking at something and produces a very detailed, multi-dimensional picture. To do the study, I will be spending up to five days at the clinic interviewing you and others, reviewing documents and watching how you select your patients for treatment. If I want to interview you, and you agree, I will ask you to sign a consent form. The consent form says that any information I get from you in an interview is strictly confidential. It also says that if I want to use a quotation from you later in my research report, I need your permission first. If you decide to participate, the interview will last between 45 and 60 minutes in a private place at a time that is convenient to you.

Participant Feedback

Following my time at the clinic, I will take all of my notes and observations and analyse them to see how patient selection at your clinic relates to the legal and ethical concepts of equity and fairness described above. Once the analysis is complete, I will return to the clinic to present my findings and to ask you what you think of them. I will also ask you to help me come up with some recommendations both for your clinic and for other clinics in Lesotho that have the same challenges. After the session, I will write a final version of the report and a short summary of my findings. I will share the summary with you and will give you a copy of the full report if you request one.

…/2

Ethics Review and Supervision
My project has been approved by the Post-Graduate Research Committee and Health Research Ethics Committee at Faculty of Health Sciences, University of Witwatersrand. It has also been approved by the management of St. Charles Hospital and supported by the STI/HIV&AIDS Directorate.

My project is supervised by Prof. Ames Dhai and Prof. Donna Knapp van Bogaert at the Steve Biko Centre for Bioethics. If, for any reason, you wish to contact them, they can be reached at +27 11 717 2635, or at Amaboo.Dhai@wits.ac.za or Donna.VanBogaert@wits.ac.za

Benefits and Risks
If you agree to participate, I hope that my project will help you learn more about the concepts of equity and fairness and that this will help to improve the way you select patients for treatment when you simply cannot treat everyone who needs it. I also hope that by allowing me to document and share your experience, together we can help other treatment sites improve their selection process as well.

Some people may think that I am trying to judge the way you make difficult choices or to look for mistakes in the treatment program. I want to assure you that I am there to observe and not to judge. The quality of a case study is the way that it documents what is happening and tries to learn from the experience. I have also managed an ARV treatment program in Lesotho. I know how difficult it is and, through my research, want to try to make things easier.

There may be some risks to you if you participate. I will make every attempt to keep everything you say to me confidential. **However, since the treatment site is quite small, even if I don't identify you as the source of some of my information, someone else may guess that it was you who told me.** If this concerns you, you can choose not to share sensitive things with me in the interview. You can choose to withdraw your participation at anytime, even during or after the interview. You can choose not to participate at all.

Questions or Concerns

If you have any questions about my project, you can contact me, Russell Armstrong, at +266 58020749 or russellarms@gmail.com. You may also contact my research supervisors, Prof. Dhai or Prof. van Bogaert at the coordinates listed above.

If you have any concerns about your rights as a research participant you can contact Anisa Keshav, Wits Research Office, at +27 11 717 1234 or anisa.keshav@wits.ac.za. She will put you in contact with Prof. Peter Cleaton-Jones (Chair), Health Research Ethics Committee.

July, 2007

SELECTING PATIENTS FOR ANTI-RETROVIRAL CARE AT A RURAL CLINIC IN LESOTHO: A CASE STUDY ANALYSIS

Consent for Interview

I, _____, have been asked to participate in this research study. I have received a copy of the Participant Information Sheet from Russell Armstrong. I have read the sheet and understand the purpose of this research project.

I understand that everything I say to Russell during the interview will be kept strictly confidential meaning that he cannot share what I say with anyone unless I give my express permission.

Russell may use quotations that do not identify me in anyway. Before the research report is finalized, Russell will show me where he has used quotations so that I can know that I am not identified as the source of the quote unless I specifically agree.

Russell has explained to me that there may be some risks to me if I participate. ***The treatment team is small at Seboche and even if Russell does everything he can to protect my confidentiality, someone may guess that I have given certain information to him.*** *I understand this risk.*

I understand that my participation in the interview is voluntary. I can choose not to answer any questions Russell asks me. I can end the interview at any time that I wish. I can also ask that Russell destroy his notes and not use any material from the interview if I am dissatisfied in any way.

If I have any questions or concerns about Russell's conduct, I can raise them with the Medical Superintendent, Dr. Dürig. I can also contact Russell's supervisors directly at the University or I can contact the Chair of the Health Research Ethics Committee. The contact details for these individuals are contained in the participant information sheet.

Having read this consent form, having read the participant information sheet, and having heard Russell's explanation of the study and the consent process, I agree to be interviewed for the study.

_____ Date:
Signature of participant

_____ Date:
Signature of researcher (Russell Armstrong)

Please sign TWO copies. One is for you, the participant. The other is for the researcher.

APPENDIX C:

KEY INFORMANT INTERVIEW FRAMEWORK

After obtaining informed consent and reviewing the purpose of the study with the key informant, proceed as follows:

Thank you for agreeing to be interviewed. I have a few questions to get us started. Basically, I am trying to understand how decisions are made by you and your colleagues about who gets to receive anti-retroviral therapy. Please stop me at any time if there is something you don't understand and would like me to clarify. If a question makes you feel uncomfortable, you are free not to answer it. You are free to stop me at any time and end the interview if you wish. Are you ready?

1. What role do you play in the clinic with respect to giving out anti-retroviral treatment?

2. How do you determine whether someone will receive anti-retroviral therapy? Tell me about each step in the process….

3. Are there specific criteria that you use? Can you tell me about them? Where did they come from? Are there any additional rules that the clinic uses?

4. Do you ever make exceptions to these criteria? Can you give me an example?

5. Have you ever not given someone anti-retroviral therapy? Can you tell me why?

6. Have you ever been challenged by a patient who did not get anti-retroviral therapy? If yes, what happened?

7. Do you think that the way the anti-retroviral therapy is given out is fair? Can you tell me what 'fair' means to you and how it relates to the decisions you make about who gets treatment?

8. If one defines equity as no one having more of a chance than others to get anti-retroviral therapy (providing everyone qualifies as defined by the Lesotho guidelines), would you say that the way patients receive treatment is equitable? Are their groups, in your opinion that, are favoured over others?

9. Would you put more people on treatment if you could? If yes, what is preventing you from doing this? If no, why not?

10. Is there anything else you would like to add?

Thank key informant. Repeat assurances around confidentiality. Ask for permission to re-interview if necessary. Remind informant of how to contact you if they have anything they wish to raise later.