

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

**EQUITY AND FAIR PROCESS
IN SCALING UP ANTIRETROVIRAL
TREATMENT: POTENTIALS AND
CHALLENGES IN THE UNITED
REPUBLIC OF TANZANIA**

CASE STUDY



**World Health
Organization**

gtz

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ACRONYMS

AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal care
ARV	Antiretroviral (medication)
ART	Antiretroviral treatment
C&T	Care and treatment
CDC	Centers for Disease Control and Prevention
CIDA	Canadian International Development Agency
CSSC	Christian Social Services Commission
CTU	Care and treatment unit
FBO	Faith-based organization
GDP	Gross domestic product
GFATM	Global Fund to Fight AIDS, TB, and Malaria
GFCCP	Global Fund Country Coordinated Proposal
GF-CCM	Global Fund Country Coordinating Mechanism
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit GmbH (German Technical Cooperation)
HAART	Highly active antiretroviral therapy
HDI	Human development index
HHS-HIV	Health Sector Strategy on HIV/AIDS
HIV	Human immunodeficiency virus
HSSP	Health sector strategic plan
MAP	Multi-Country HIV/AIDS Program for Africa
MSD	Medical Stores Department
MoH	Ministry of Health
NACP	National AIDS Control Programme
NCTP	National Care and Treatment Plan
NGO	Nongovernmental organization
NMSF	National Multisectoral Strategic Framework
NTLP	National TB and Leprosy Programme
OP	Operational Plan
PEP	Post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	Prevention of mother-to-child transmission
PLWHA	People living with HIV/AIDS
QSP	Quick Start Plan
SIDA	Swedish International Development Agency
STI	Sexually transmitted infection
TACAIDS	Tanzania Commission for AIDS
TB	Tuberculosis
T-MAP	Tanzania Multisectoral AIDS Programme
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary counselling and testing
WB	World Bank
WHO	World Health Organization

1. INTRODUCTION

On World AIDS Day 2003, the World Health Organization (WHO) and UNAIDS established an ambitious goal: by the end of 2005, 3 million people living with HIV/AIDS in developing and transitional countries would be receiving anti-retroviral (ARV) therapy. Since then, the 3 by 5 target has galvanized governments and communities around the world to multiply their efforts to counteract the epidemic's devastating toll, with the ultimate goal of providing comprehensive HIV/AIDS treatment to all in need.

Despite all the progress made, the approximately 1 million people who were in ARV treatment as of June 2005 only represent about 15% of the estimated 6.5 million adults who currently need ARV therapy in developing and transitional countries. By mid-2005, 14 countries reached their 3 by 5 target of 50% coverage. For all countries, scaling up comprehensive HIV/AIDS treatment remains an enormous challenge.

Resources are falling short of what is needed. No matter how fast countries succeed in expanding access to ARV therapy, not everyone in need can gain access to antiretroviral treatment (ART) immediately, and this means that some will be saved while others will die. This situation requires difficult choices in priority-settings that involve serious ethical issues. It obligates governments to scale up programmes in ways that are ethically sound and as fair, beneficial, and sustainable as possible. These approaches to scaling up must respond to local needs, be locally legitimate and in accord with human rights norms.

Countries are challenged to scale up activities in several areas simultaneously. Some stakeholders caution not to overburden the health sector by aiming for quick wins in rapid scale-up of HIV/AIDS treatment that could jeopardize gains achieved in building the broader health-sector capacity over decades. Yet, so far, experience shows that the scale-up of ARV therapy, if managed wisely, can lead to the strengthening of broader health systems and prevention programmes.

This case study analyses the decision-making processes in scaling up services for HIV/AIDS in the United Republic of Tanzania, where WHO and GTZ are collaborating partners in supporting the Ministry of Health (MoH). The first part of this document provides a short description of the Tanzanian framework for scaling up services for HIV/AIDS, followed by an overview of key concepts used in this study. The subsequent chapters emphasize equity and fair process in decision-making and present key issues in the scale-up, such as the

scale-up targets, the localization of treatment centres, social eligibility criteria and pricing of ARTs. The case study underlines the potential and challenges of the country-specific situation in the United Republic of Tanzania and presents lessons learned and recommendations.

2. FRAMEWORK FOR SCALING UP SERVICES FOR HIV/AIDS IN THE UNITED REPUBLIC OF TANZANIA

A population-based survey carried out in 2003–2004 showed an overall HIV prevalence rate in the United Republic of Tanzania of 7.0%. An estimated 2 million people over the age of 15 are infected out of a total population of 34.4 million. With a per capita GDP of US\$ 478 (in 2000), the United Republic of Tanzania is a severely resource-restricted country. The Government spends US\$ 6 per capita on health annually and US\$ 15 on basic education. Life expectancy at birth is 55 and the literacy rate is 67%. Before the end of 2004, about 3000 people living with HIV/AIDS were reportedly receiving ART. At the same time, there were up to 440 000 people in need.

In recent years, multiple efforts have been made to increase access to ART, and the Government launched its public sector ART programme in October 2004. In this regard, the United Republic of Tanzania has attracted significant international resources for HIV/AIDS through the Global Fund for AIDS, TB and Malaria (GFATM), the World Bank-supported Multi-country AIDS Programme (MAP), the William J Clinton Foundation, the United States President's Emergency Plan for AIDS Relief and various multi- and bilateral development partners. Altogether these amount to over US\$ 370 million over the next five years.

According to the principles of the "three ones", the national response to HIV/AIDS is officially guided and coordinated by one common national strategy, one multisectoral coordinating body and one common monitoring and evaluation framework.

Multiple policies, strategies, plans and funding proposals related to ART scale-up

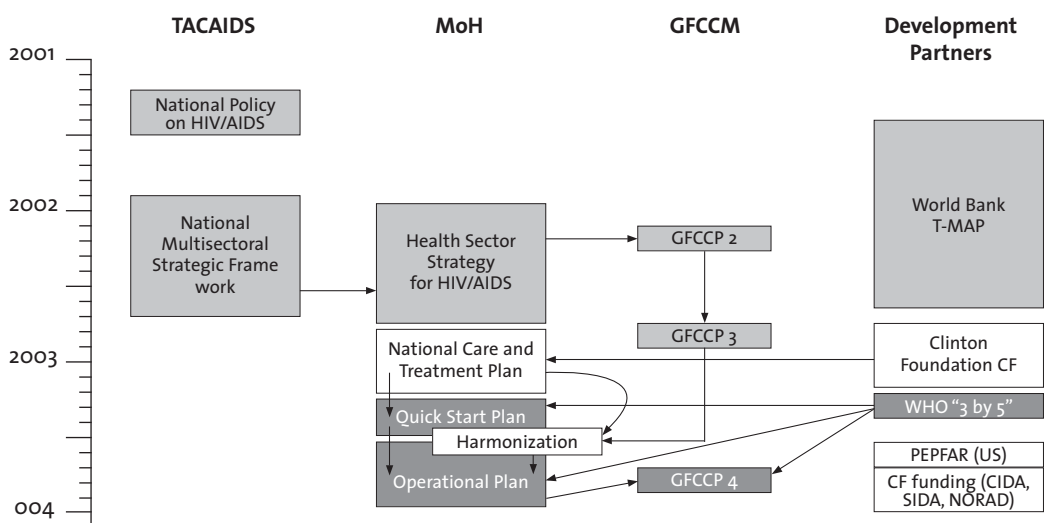
In reality, efforts to harmonize coordinating mechanisms and strategies must occur within the context of a plethora of strategies, operational plans and funding proposals that were developed by various actors with a stake in ART scale-up (Diagram 1).

With the launch of the National HIV/AIDS Policy by President Benjamin W Mkaia in November 2001, compre-

hensive health care (including ART) was recognized for the first time as a right for people living with HIV/AIDS. The national policy had been developed by the Tanzania Commission for AIDS (TACAIDS), which was designated as the overriding coordinating body for the Tanzanian HIV/AIDS response.

TACAIDS also became responsible for organizing broad stakeholder contributions to the development of the National Multisectoral Strategic Framework (NMSF) as a guiding document for coordinating various aspects of the HIV/AIDS response for 2003–2008.

Diagram 1. HIV/AIDS Policy and Strategy, C&T Plans and Funding Proposals



These two frameworks were complemented by a number of operational plans and funding proposals focusing on health-sector leadership in scaling up HIV/AIDS treatment services:

► The Health Sector Strategy on HIV/AIDS (HSS-HIV).

This strategy was developed by the National AIDS Control Programme (NACP) of the MoH in February 2003. Based on a comprehensive situation analysis, field visits, the formation of thematic working groups and broad stakeholder contributions, this plan proposed a cautious, step-by-step and integrated scale-up of ART from tertiary centres to include up to 15 000 people in ART by the end of 2006.

► The National Care and Treatment Plan (NCTP).

Developed jointly by Tanzanian experts and an international team sponsored by the William J Clinton Foundation, this plan expands the Health Sector Strategy's goal of providing ART to all eligible people living with HIV/AIDS by the end of 2008. The plan was discussed in two large stakeholder meetings and adopted as the Government's HIV/AIDS care and treatment (C&T) plan in October 2003.

► **Quick Start Plan (QSP).** Initiated in November 2003, this plan aimed to prepare 19 selected health facilities for ART introduction within a three-month time period. The plan was based on the NCTP and later merged with its first-year operational plan.

► **Operational Plan for Care and Treatment for HIV/AIDS (OP).** In an attempt to integrate the various plans and frameworks, this plan was developed by a broad team, including the MoH, the National AIDS Control Programme (NACP), the William J Clinton Foundation, WHO, nongovernmental organizations (NGOs) and the private sector. It covered a 1-year period starting in July 2004 and projected the involvement of 91 health facilities.

Since the scale-up of HIV/AIDS programmes in the United Republic of Tanzania was a joint venture of national and external funding, a number of parallel efforts were initiated to attract more international investments:

► **Global Fund for AIDS, Tuberculosis and Malaria (GFATM).** Endorsed by the Country Coordinating Committee (CCM), the United Republic of Tanzania submitted proposals to rounds two, three and four. The second round proposal, which suggested the scale-up of testing and counselling and other entry point services to 90 districts, was not approved. It was followed by the third round proposal, which was scaled down to 45 districts. The proposal was submitted in May 2003 and signed in August 2004. While the third round budgeted for providing ART services to 12 500 people living with HIV/AIDS (PLWHA), the fourth round proposal envisages a massive treatment scale-up to provide them to 220 000 PLWHA by the end of 2005. The plan was approved and signed on 13 May 2005.

► **Tanzania Multisectoral AIDS Programme (T-MAP).** The process began in 2001 under the leadership of TACAIDS and the support of a World Bank consultant team, and was signed in 2003. Although ART is not explicitly enumerated in the plan, the World Bank agreed that some of the funds can be allocated to C&T activities.

► **United States President's Emergency Plan for AIDS Relief (PEPFAR).** Developed by United States-based institutions and in collaboration with 19 health facilities that were identified for ART scale-up, this plan proposes to provide ART to 11 000 people with HIV/AIDS in 1 year. Grants were awarded by the Governments of the United States of America and the United Republic of Tanzania, and development partners were informed of the decisions in April 2004.

The development of every single strategy, operational plan and budget proposal involved complex consultation processes. These processes varied significantly in the degree to which they built on and complemented previous discussions related to choosing the location for ART sites, eligibility criteria for patient selection, drug protocols and procurement decisions

and allocation of human and financial resources. Recognizing that the result of strategy development may differ widely, the following analysis investigates the process by which results were achieved from a fair process perspective. It focuses on how decisions on each of these key parameters for scale-up were made.

3. KEY CONCEPTS: EQUITY AND FAIR PROCESS

Equity is a multi-faceted concept. From an ethical perspective, equity requires adherence to both substantive and procedural principles. The formal principle of equity is often stated as “treat like cases alike and different cases differently”. Egalitarian theories call for distributing resources equally among different persons or groups, which could mean that everyone should receive the same access to health services. The “maximin” principle calls for giving preference to those who are worst off, for example the poorest, the most vulnerable or the sickest. The principle of reciprocity or compensation calls for providing something in return for contributions that people have made, for example individuals who have participated in AIDS treatment trials, or compensation for a harm by the system, such as having been the recipient of unsafe blood transfusions. Finally, utilitarian theories require that overall societal benefits be maximized. A commonly used definition of inequities in health is given in Box 1.

Box 1. Definition of inequities in health

Inequities are differences in health that are unnecessary, avoidable, and are considered unfair and unjust. (Whitehead, 1990).

Fair process

Many decisions may appear simply technical at first, but a closer look reveals significant ethical underpinnings. In the process of scaling up ART, many crucial decisions on controversial issues must be made, including:

- (1) The target numbers for PLWHAs to receive treatment within a certain time frame
- (2) ART centre locations
- (3) The eligibility criteria for starting a PLWHA on ART and priority-granting to certain groups
- (4) The drug protocols and whether generic or branded products will be bought
- (5) Allocation of human resources to the expansion of ART
- (6) Whether ART will be free of charge or whether cost-sharing will be required

As this study will demonstrate, competing principles exist in decision-making and priority-setting in implementing the scale-up of ART. For instance, in order to set the targets, principles like feasibility, urgency, sustainability or benefit maximization will be put forward by different stakeholders. But no uniquely correct way exists to balance these concerns. When there is no general consensus on how to apply and weigh competing principles of distribution, then “fair process”, a form of procedural justice, should be followed to arrive at an agreement and achieve legitimacy for ethically controversial decisions. It is a procedure that can be applied in decision-making about resource allocation in situations of scarcity where not everyone in need can benefit. By employing fair process in implementing scale-up of ART, disagreements can be resolved, moral legitimacy achieved and decisions accepted that are ethically controversial. Fair process, then, helps health systems to be generally accountable for the legitimacy and fairness of decisions about resource allocation and priority-setting.

Daniels and Sabin (1997) propose the following key elements in a fair process for setting priorities:

- ▶ **Publicity.** The process, including the rationales for setting priorities, must be made public and transparent; consultations and public hearings should be held. Publicity and involvement of key stakeholders are particularly important in contexts where policy and programmatic decisions occur in a multi-actor environment and affect large parts of the population.

- ▶ **Relevance.** The affected stakeholders must view as relevant the reasons, principles and evidence that form the basis of rationales for fair decision-making on priorities.

- ▶ **Revisability and appeals mechanisms.** In the case of new evidence and arguments, the process must allow for reconsidering and revising decisions. It must allow for an appeals process that protects those who have legitimate reasons for being an exception to the adopted policies. This criterion is particularly important in the scale-up’s implementation phase.

- ▶ **Enforcement or regulation.** There must be a mechanism in place that ensures that the previous three conditions are met.

In the following analysis, we apply the criteria of fair process in examining the decision-making processes during the scale-up of HIV/AIDS services in the United Republic of Tanzania. Competing principles in reaching various decisions and decision-making levels are also discussed. The enforcement criterion is not considered separately in every individual section as the fair process concept was only applied retroactively as a framework for analysis and hence no enforcement specific to the fair process concept was built into the national system.

4. ANALYSIS OF DECISION-MAKING IN THE SCALE-UP OF ART, USING THE CONCEPT OF FAIR PROCESS

A number of key issues for ART scale-up have attracted debate and controversy in the United Republic of Tanzania, and the proposed targets and strategies evolved significantly over time. Recognizing that for many issues there is no “one right approach”, the following analysis will focus on how the discourse was led and to what extent it corresponded to features of fair processes.

4.1 Targets for ART scaling-up

Numerical targets for scaling up have been formulated in various planning documents and funding proposals and have been the source of considerable disagreements between stakeholders. Table 1 gives an overview of the targets that have been proposed at the various stages of planning and of funding proposal development.

Table 1. Cumulative targets in planning documents and proposals for funding

Source	2004	2005	2006	2007	2008
HSS-HIV ^a			7500 – 15 000		
NCTP ^a	16 000	65 000	151 000	274 000	423 000
3 by 5 Mission ^a		220 000			
OP ^b	44 000				
GFCCP3 ^c	1400	5500	8500	12 500	
PEPFAR ^d	11 000				
GFCCP4 ^e		220 000			

^a By the end of the respective year

^b By end of June 2005

^c By end of August of the respective year

^d By end of March 2005

^e Provisionally by March 2007 (two years from signing of the agreement)

Competing principles. Sustainability and urgency are competing principles in decision-making about targets. Those who consider sustainability the main concern propose a slow and careful scaling up. This would take into account the limited capacity of the health-care system to cope with the ART programme and the danger that an already weak health system could be further overburdened and resources diverted from other health priorities towards ART. Sustainability proponents also advocate for setting targets according to committed or expected long-term funding, ensuring that those who are started on ART will receive it lifelong. Those who consider urgency the main concern

propose providing ART access to as many eligible PLWHAs as possible in the shortest amount of time to save a maximum number of lives. To this end, urgency proponents advocate that even putting a PLWHA on ART for a few years would be beneficial to the individual and his or her family, and would provide the prospect for extending treatment as more resources become available.

Publicity and level of decision-making. The decisions about targets have largely been made at the national level (MoH, experts, cabinet) with advice provided by experts at the international level who incorporated experiences from other

countries and recommendations from the global level. Stakeholders were broadly involved in discussions on the targets of the Health Sector Strategy on HIV/AIDS (HHS-HIV), NCTP and Global Fund proposals, but were less involved in discussions on the targets and list of facilities of the OP and PEPFAR sites.

Relevant arguments, rationales and agreement among stakeholders. National treatment targets evolved with changing conditions over time. The HHS-HIV target of supplying up to 15 000 patients with ART by the end of 2006 was developed in response to the scarcity of resources (infrastructure and human resources) and the drugs' high cost. The plan suggests a very cautious scale-up, starting with PMTCT plus, hospital-based ART and post-exposure prophylaxis (PEP) for health workers. The plan allocates 58% of the five-year Health Sector HIV/AIDS budget to care and support and, of this, 38% to ART scale-up. It suggests analysing opportunities for scaling up carefully and realistically, without jeopardizing an already weak health system. When the plan was presented in the stakeholder meeting, there were no objections raised to the proposed scaling-up targets.

The NCTP development started with a systematic appraisal of options for overcoming resource limitations that had led to setting the modest HSS-HIV target, and the plan suggested a massive upgrading of existing facilities with human resources and infrastructure. Based on this rational approach to scaling up, the plan's target is to reach all 400 000 eligible Tanzanian residents by the end of 2008, starting with 16 000 patients by the end of 2004 and reaching 65 000 by the end of 2005. Stakeholders agreed on the feasibility of the proposed scale-up strategy based on the assumption of sufficiently available financial resources. There were reservations that prevailing fear, denial and stigma might prevent people from coming forward in large numbers to be tested.

Both, the HHS-HIV target and the NCTP target had been developed prior to the declaration of lack of access to ART as an emergency in the context of the WHO/UNAIDS 3 by 5 Initiative. During a mission to review existing treatment targets following this declaration, targets were once again increased to reach 220 000 patients on ART by the end of 2005, to take into account the fact that lack of access to ART for those in need had been declared an emergency.

The mission stated that there was "...a need to [revisit] the targets of the NCTP and be even more aggressive and ambitious, particularly considering the new WHO '3 by 5' simplified guidelines on how to scale up care and treatment". The mission therefore worked with the country's Government to revise the target upwards from 65 000 to 220 000 by the

end of 2005, i.e. a more than 3-fold increase. The mission team included representatives from WHO, NACP, the William J Clinton Foundation, the Centers for Disease Control and Prevention (CDC) and the United Republic of Tanzania.

Following the publication of the revised target, its feasibility was challenged by some development partners, who urged that the previously agreed NCTP targets be respected. However, taking into account the need for an emergency response vis à vis lack of access to ART, the Global Fund CCM followed the more ambitious treatment targets and proposed treatment scale-up to 220 000 people living with HIV/AIDS by the end of 2005. In accordance with the global 3 by 5 target, this figure represents half of those estimated number of people in urgent need of ART.

Finally, the OP for the financial year July 2004–June 2005 translated these proposals, based on available and expected funding, into a revised list of 91 sites with the final target of 44 000 patients on ART by the end of the first year. This target was based on the funding expected to be available from Government and partners for procuring ARVs in the first year. The lists of sites and number of patients to be covered by the ART programme were decided by the National Task Force on Care and Treatment. A phased scaling-up plan was developed, showing how all the sites will be upgraded and certified in one year.

Revisability and implementation. As discussed, ART treatment targets have been revised several times. International advocacy for accelerated treatment scale-up, reduced prices of ARVs and increased international funding for ART translated into more ambitious targets and plans. These changes were accompanied by considerable discussion among some development partners, in particular when targets were changed without extensive consultation with development partners, as was done following the 3 by 5 mission.

At the implementation level, the actual number of patients on treatment will be largely determined by the availability of drugs. The Government has procured first-line regimen, generic drugs, sufficient to cover a year of treatment of about 4200 patients. These drugs arrived in the country in October 2004 and were distributed to the 32 sites with trained treatment teams. The calculations for the second consignment of drugs have been finalized and the tender has been issued. This consignment arrived in April 2005 and would allow for treatment of an additional 20 000 PLWHAs for a year.

4.2 Site selection of ART centres

In the process of developing various documents, there has been agreement on scale-up in phases, but the type and number of facilities included in many plans have varied. While different proposals have been advanced regarding the type of

facilities to be scaled up next and how quickly, there is general agreement to start with referral hospitals. The proposed site selection in the documents is summarized in Table 2.

Table 2. Site selection of new ART centres in planning documents and funding proposals

Source	Referral hospitals	Regional hospitals	District hospitals	FBO hospitals and NGOs	Private and other hospitals	Total in Year 1
HSS-HIV	Y1: 4	Y1: 1 Y2:11 Y3: 17	Y3: some urban	Y3: some	Y3: some	5
NCTP	Y1: 4 + military	Y1: 9 Y2:17	Y1: 5 Y2: 49	According to accreditation	According to accreditation	19+
QSP	4 + military	2	0	3	9	19
OP list for year 1	4 + military	21	34	22	9	91
GFCCP-3	Y1: 4 Y2: military	Y1: 4 Y2: 2	Y1: 4 Y2: 8	Y1: 1 Y2: 1	Y1:2	15
PEPFAR	4+military	4	3 (all in Dar es Salaam)	6 (2 urban, 4 rural)	1	19

Y=year

Competing principles. Efficiency and equity are competing principles in deciding on site selection of ART centres.

Those who consider *efficiency* the main concern argue that scaling up should start in urban tertiary facilities, where infrastructure, equipment and trained personnel already exist and where larger numbers of eligible patients can be reached quickly. Those concerned primarily with *equity* argue that the rural and traditionally underserved populations should have access from the programme's outset, and that the existing inequities should be remedied rather than exacerbated by the scale-up.

Publicity and level of decision-making. Decisions on the ART centre site selections have been made largely at the national level by the technical teams involved in developing plans and proposals. The sites proposed in the QSP were suggested based on lessons learned during a trip to Mozambique by government and development partner representatives. The

Global Fund Country Coordinated Proposal (GFCCP) sites were proposed by a consortium of Government, NGO, faith-based organizations (FBO) and private-sector representatives, who jointly formulated the proposal. The OP list of 91 facilities and the decision on which facilities to include in each phase of the scale-up were made by the Care and Treatment Unit (CTU) of the MoH on the advice of the National Care and Treatment Task Force.

Relevant arguments, rationale and agreement among stakeholders. HSS-HIV proposes to start with four referral hospitals and one regional hospital in year one, to act as training centres for roll-out to regional and eventually district level hospitals. The nodal facilities would develop, test and adapt guidelines and standards for C&T and would assist in scaling up ART in regions and districts. The plan lists minimal criteria that facilities will have to fulfil before they can be accredited to start ART.

The NCTP proposes to start with at least 19 facilities in the first year: four referral, one military, nine regional and five district hospitals, while accrediting facilities in the voluntary and private sector according to requests. Five regional hospitals were added to ensure equitable geographical coverage of the country. Although not mentioned explicitly, the inclusion of some district hospitals will enhance the chances for rural populations to benefit and thus increase equity in access to ART in the first year.

A joint visit by government and development partners to Mozambique showed that starting with facilities that are already providing voluntary counselling and testing (VCT) and treatment, including FBO and private hospitals, would offer a possibility to scale up faster. The lessons learned from the visit contributed to the decision to include these facilities in the QSP, which lists 19 institutions that are presumably ready to expand quickly. These institutions could serve as training centres for other sites (referral hospitals, private hospitals in urban areas, where patients/employers are paying, hospitals run by faith-based organizations (FBOs), services provided by NGOs and company clinics).

The OP states that the criteria for selecting facilities would be: readiness to start; potential to serve as a learning centre; and geographical distribution. Facilities that fulfil the first two criteria are predominantly located in urban areas and will therefore favour access for the urban populations in the early stages of the scaling up.

The list of proposed facilities has been amended several times. It initially included all regional hospitals in order to ensure equitable geographical coverage. However, most regional centres are still viewed as serving mainly urban or semi-urban areas. In the list of 91 facilities, 31 district hospitals have been included as well as 17 FBO hospitals, most of which serve predominantly rural populations. This reflects the Government's concern about closing the urban–rural gap and improving equity in access to ART.

The GFCCP-3 proposes a list of 45 districts that will be included in the five-year scaling-up plan. The districts have been selected according to where the implementing partners have ongoing activities. In years one and two, half of the districts proposed to be included are urban, while mainly rural districts will be incorporated in the following three years.

Revisability and implementation. Decisions on the site selection of ART centres have been revised several times in the process. Initially the main criteria were readiness to start and potential to function as a learning centre. These criteria take into account efficiency in reaching a large number of patients

quickly as well as future rapid scaling up through training of staff from other facilities. Geographical coverage has become a concern in the later revisions of the list of sites for ART centres, which includes all regional hospitals. This does not address the concern that rural and already-underserved populations will initially miss out on the programme's benefits. The extended list of 91 facilities, of which about half are rural hospitals, will allow a better balance of access for urban and rural populations.

4.3 Eligibility criteria for patient selection and priority for special groups

Competing principles. Best expected outcomes and fair chance to benefit are the competing principles in decision-making on medical eligibility criteria. In the decision-making on priority for certain groups, some of the competing principles are equal worth of every individual and social value (e.g. when HIV-positive health workers are kept alive, ART programmes can be scaled up). The principles underlying special provision for children are fair access for vulnerable groups versus equal worth of each individual.

Publicity and levels of decision-making. The decisions about medical eligibility criteria have largely been suggested at the global level (WHO) and adopted at the national level by the MoH and technical advisers, who were involved in drafting the guidelines for clinical management of HIV/AIDS. There have not been discussions on altering the eligibility criteria and the possibility of modifying them at district or facility level. Granting priority for special groups has been discussed but has not been made explicit in the guidelines.

Relevant arguments, rationales and agreement among stakeholders. The NCTP uses the WHO-recommended medical eligibility criteria for low-resource countries to start patients on ART (CD4 count below 200 or presenting with an AIDS defining condition). These criteria have been adopted by the technicians without any significant challenges from stakeholders or PLWHAs. The benefits of starting treatment using these criteria have been well demonstrated and applying these criteria ensures that treatment is reserved for patients who are most critically ill and most likely to die soon without treatment. All patients are assessed for adherence when determining their eligibility.

The OP mentions that an “economic indicator” should be added to the criteria to start ART. The plan includes an activity to define social criteria for rationing ART, with the MoH Policy and Planning Unit as the key actor. Other MoH

departments, associations of PLWHAs and collaborating partners would participate in this activity. So far, policy debate has not been initiated on these issues.

In the OP list of 91 facilities there is a provision to have children comprise 20% of the programme's enrolment. According to the CTU, this proportion was based on the experiences from the national referral hospital (Muhimbili). During the quantification for the second consignment of drugs, the proportion of paediatric drugs was reduced to 10%, without a clear rationale being available.

Priority-granting to specific groups, such as health workers, has been proposed during stakeholder discussions. The rationale behind this proposal is that health workers will be more motivated if they have priority access to treatment and that keeping them alive and healthy will enable them to provide services to others. It has also been argued that health workers on ART would be the best counsellors and motivators of fellow PLWHAs. Although this priority treatment of health workers has not been explicitly articulated, the HSS-HIV and NCTP both recommend that the MoH should encourage early enrolment in C&T for HIV-positive health workers. The MoH was also encouraged to develop workplace programmes, including access to post-exposure prophylaxis (PEP). It is likely that health workers will be among the first to know about the ART availability and this will give them an advantage in accessing treatment if they satisfy the eligibility criteria.

Gender balance in access has not been explicitly considered or discussed so far. Since eligible PLWHAs will largely be identified initially among hospitalized patients, TB and STI patients and antenatal clients, it is likely that both genders will have equal chances to be identified as eligible. This assumption needs to be verified when services are in place.

During the signing of the GF-CCP3 agreement in August 2004, President Benjamin Mkapa of the United Republic of Tanzania elaborated upon the three pillars of the national HIV/AIDS strategy: C&T, prevention and impact mitigation. He remarked, "The first [pillar of the national strategy against HIV/AIDS] is to ensure that those infected with HIV and those with AIDS, live as long as possible so as to raise their own children and reduce the number of orphans. They must live as long as possible to use their education, skills and experience in national development and provide for their families."

At the implementation level, access to ART in the accredited centres might occur largely on a first-come-first-serve basis. Some ART centres have already compiled lists of eligible patients awaiting the arrival of the next consignment of drugs.

Revisability. In the revised version of the "Guidelines for Clinical Management of HIV/AIDS" of 2004, the eligibility criteria have been expanded to include WHO clinical stage III patients with a CD4 count below 350. Criteria are likely to be modified further as evidence becomes available to suggest that the current ones are not optimal. The proportion of children has also been revised down from 20% for the first drug order to 10% for the second order.

4.4 Drug protocols and procurement decisions

Competing principles. Likelihood of adherence and lower cost and a wider spectrum of choice among more expensive and more complex regimens are competing principles in protocol decision-making. WHO's simplified guidelines recommend fixed-dose combinations and generic products, where possible, to improve adherence and to reduce cost in order to reach as many people in need as possible with given resources. Manufacturers of branded ARVs and some clinicians argue that therapeutic choice between more drugs and regimens allows for better adaptation to the individual patient's needs and justifies higher prices and more complex regimens.

Publicity and level of decision-making. The decision on actual quantities of drugs to be procured was made at the national level by a committee of experts from the MoH, the Pharmacy Board, the Medical Stores Department (MSD) and with involvement of international consultants. International WHO guidelines are followed for the drug protocols, giving preference to fixed-dose combinations and to generic products, which are approved by WHO. Government tendering procedures have been followed for identification of suppliers.

Relevant arguments, rationale and agreement among stakeholders. It was decided that first-line, adult drugs will be bought as generic, fixed-dose combinations whenever possible. This is based on the international experience with these regimens, on the increased likelihood of adherence and on the lower costs. For the first-year drug supply, most of the second-line drugs, paediatric preparations and drugs used in the case of contra-indications to first-line, fixed-dose combinations will need to be procured as branded products, since generics are not yet available. Since PEPFAR has funds available for drugs, but can only procure drugs approved by the Food and Drug Administration (FDA), the Government has proposed that PEPFAR buy drugs other than the first-line, fixed-dose combinations as branded products. Although there is no evidence of widespread emergence of resistance among patients who have previously initiated treatment, the quantities of second-line drugs are estimated at

5% to 10% of the total in the initial phase. This relatively high proportion is due to the fact that, among the patients who were previously on ARVs through private arrangements, a considerable number are on drugs other than first-line regimens or have already developed resistance to first-line drugs. Once mainly new patients are enrolled, the required proportion of second-line drugs is expected to decrease.

Revisability and implementation. Treatment protocols have been revised in line with scientific evidence and global recommendations. Flexibility was needed to accommodate donors' requirements and ensure that all available funds could be utilized for the benefit of the ART programme.

The de-listing of some generic ARVs in 2004 has caused considerable delays in procurement since alternative producers had to be identified. The initial consignment of first-line combination drugs was received in October 2004 and was distributed to the 32 health facilities that had their C&T teams trained in September 2004. Since the drug formulations for initiating treatment (starter kits) were not available at the same time, the facilities decided to use either the drugs for patients who had previously been procuring their own drugs (or were sponsored by their employers) or for patients already enrolled in pilot and research projects. Some facilities might have started new patients on combination treatment without challenging them with starter kit drugs first. Others might have procured their own starter kits or might have waited to start new patients on ART until January 2005, when the starter kits were distributed.

Another unforeseen problem occurred when it was observed that the majority of patients are below 60 kg. Yet, two thirds of the procured quantities were higher-dose combination tablets (containing 40 mg d4T) for patients of 60 kg and above, and only one third contained 30 mg of d4T for patients below 60 kg. These two factors (late arrival of starter kits and more high- than low-dose combination drugs) might have an impact on selection of beneficiaries of this first consignment and possibly favour the inclusion of those who were able to already initiate treatment privately and/or have a higher body weight.

4.5 Allocation of human resources for ART

Competing principles. Integration of ART into existing services and creation of new, designated C&T teams and/or services are competing principles in human resource allocation to the scale-up. Those who are in favour of *integration* argue that existing health workers can be trained to provide ART services and the additional workload can be absorbed by the system, which needs to be strengthened as a whole. Those who defend *verticalism* argue that establishment of designated ART teams is necessary because the tasks involved in managing patients on ART are so complex that they can only be performed properly by teams of specialists, preferably operating from specialized AIDS clinics.

Table 3. Allocation of human resources to ART in planning documents

Source	Additional staff at national level	Additional staff in treatment centres	Existing staff in treatment centres
HSS-HIV	1	No	Yes
NCTP	44 (23 CTU and 21 other units in NACP/ MoH)	Designated team of up to 18 staff per centre. 10 000 additional health workers to be hired over a 5-year period	
OP	20	No	Identify and train 91 treatment teams of 4 to 6 persons each

Publicity and level of decision-making. The decisions on human resources allocation have mainly been made at national level by the MoH officials and experts involved in developing the plans.

Relevant arguments, rationale and agreement among stakeholders. The HSS-HIV proposed that existing health workers in the identified facilities be trained in ART, starting with referral hospitals, and that all ART tasks be executed without employing additional health workers. This decision was based on a phased, cautious approach to scale-up over a three-year period.

The NCTP, with its much bolder target, proposed the creation of a national CTU in the NACP, with 23 professional staff. At the health facility level, designated C&T teams, would be established in each treatment centre, consisting of 7 to 18 professional staff, plus support staff. The treatment teams would be hired from among unemployed and retired staff available in the country. Estimates of required additional staff are based on meticulous calculations of health worker time spent per patient on all the various tasks according to the recommended frequency of patient visits. The additional staff would initially be financed by donor funding and would gradually be absorbed into the government payroll over a three-year period. The main rationales for establishing dedicated C&T teams are the complexity and life-long continuation of treatment and avoiding the diversion of health workers from other priority tasks.

The OP only mentions new recruitment for the CTU (20 staff) and one C&T coordinator for every region and district (total 142 staff). The C&T teams will be identified from among existing health workers, at least in the first year. It is unclear how the C&T teams will combine their previous responsibilities with the additional workload. An assumption could be that the workload of caring for AIDS patients will diminish once they are on ART. These shifts and changes in workload, caused by the scaling up of ART, will need to be closely monitored during implementation.

Revisability and implementation. Decisions on human resource allocation to the scaling up of ART have been revised throughout the process. A human resources audit has been planned to clarify the situation of health-worker availability in the country and to allow for better evidence-based planning. The total government health sector workforce is estimated at 43 000 and about 40% of established posts are currently vacant. In the context of an overall shortage of health workers in the country actual staff-up will be likely limited by the absolute shortage of health workers.

The Government has recently announced that 2000 health workers will be recruited to fill vacant posts in the districts with the lowest health worker per population ratio. The additional health staff is not supposed to be specifically allocated to the ART programme but would more generally strengthen a number of neglected and under-served areas.

C&T teams were trained in three phases between September 2004 and February 2005. Each training session lasted one week and was organized in the four zonal training hospitals simultaneously. To date, 95 teams of 4 to 6 health workers (totalling over 500 health workers) have been trained in care and treatment of HIV/AIDS. The training manual and curriculum were developed and revised after each session.

4.6. Cost-sharing or free access to ART

Competing principles. Consistency and benefit maximization and equity are competing principles in decision-making on free access to ART. Those who consider consistency and benefit maximization most important will argue that the system already charges user fees for other medical services and that ART should not be exempt. The income from cost-sharing will allegedly allow more patients to benefit from ART as resources will stretch further. Those who consider equity to be most important will reason that even small financial contributions might be a deterrent for poor families to access ART.

Publicity and level of decision-making. Decisions on this central issue have been made at the national level by the MoH.

Relevant arguments, rationales and agreement among stakeholders. The national HIV/AIDS policy of Tanzania states that, "PLWHAs have the right to comprehensive health care and other social services, including legal protection against all forms of discrimination and human rights abuse. However, PLWHAs may be required to meet some of the cost of the Highly Active Anti Retroviral Therapy (HAART)". The NMSF does not address the issue of who will pay for ART. There is an implicit recognition that people will have to pay for ART in the warning that, "...Families and individuals have to be protected from ruining their financial abilities [so they can] provide treatment for infected members." The HSS-HIV expects that the Government will develop a clear policy on financing of HAART in the United Republic of Tanzania. The NCTP proposes that HIV testing be provided free of charge and that it become a routine part of health care for all individuals. It also makes a clear statement that ARV drugs will be without charge and includes all the costs for drugs in the budget so that patients will not have to contribute. In stake-

holder meetings, the MoH clarified that the current health sector cost-sharing policy exempts patients with chronic illnesses from cost-sharing. This existing clause also applies to PLWHAs since HIV/AIDS is considered a chronic illness.

The issue of lack of consistency in granting exemption from payment to patients with chronic illnesses was raised by stakeholders. In practice, most other chronic patients are requested to pay in the health facilities, while exemptions are routinely applied to children under the age of five and pregnant women only.

The 3 by 5 mission report specifically recommended that the Government clarify its ART policy by enumerating whether or not ART services are free. The report also suggests that the Government clearly define the social criteria for rationing ART.

The OP is silent on the issue of cost-sharing versus free drugs. Again, the inclusion of all the cost for drugs in the budget implies that there will be no need for patients to share costs.

Revisability and implementation. During the signature of the GF-CCP3 agreement in August 2004, the President stated clearly that the life-prolonging drugs will be freely provided. In concluding his speech he again confirmed this, when he said, “It is our goal to ensure that care and treatment is freely accessible to as many people living with HIV/AIDS as possible.” He also emphasized the importance of a comprehensive approach in addressing HIV/AIDS, which is integrated into a wider and sustainable national health delivery system. He further states, “We are not creating a new parallel system for HIV/AIDS; we are strengthening the entire health-care delivery system.”

It is not clear whether private sector employers, who have already taken the initiative to make ARV available for their eligible workers, will be expected to continue paying for ARVs or will be entitled to benefit from free ARVs. The establishment of a fund that will use employers’ contributions to provide generic drugs procured by the Government at cost for employees, has been forwarded as an option to safeguard the contribution of the private sector towards ART.

5. CONCLUSION

The analysis looked at the evolution of key parameters for ART treatment scale-up in the United Republic of Tanzania from the fair process perspective, with a focus on the key dimensions of “publicity”, “relevance” and “revisability”. It was demonstrated that in all three domains, policy and technical decisions have an immediate ethical and equity impact.

The “publicity” of decision-making, i.e. the transparency of decision-making processes and the involvement of key stakeholders, was particularly relevant within the context of multiple actors from within and outside the United Republic of Tanzania who sought to support the scale-up process.

The various development processes made clear that treatment targets and scale-up strategies had the broadest constituency when broad consultative arrangements were built in. The involvement of people living with HIV/AIDS was of particular importance and especially relevant where they did not merely participate but were also empowered to ensure that they could consult with their constituency adequately and inform them of important decisions made.

The drafting of the National Health Sector Strategy and the NCTP demonstrated the relevance of broad consultation processes: both enjoyed broad support at the time of their inception, despite significant differences in their treatment targets. Conversely, discontent among some development partners appeared when treatment targets were changed based on consultations that were less broadly based. However, these examples also testify to the fact that broad consultation processes do take significant time and might be unsuitable for responding quickly to new developments and declared emergency situations. With the round 4 Global Fund proposal in the United Republic of Tanzania, an interplay of both expanded and restricted publicity finally resulted in the broad acceptance of a strategy that combines elements of the initially agreed upon strategies with more ambitious, externally informed treatment targets.

The “relevant reasons” criterion of a fair process, i.e. that decisions for certain strategies and approaches rest on rational arguments and evidence, were crucial in the evolution of ART scale-up policies, strategies and plans in the United Republic of Tanzania.

An example of how clear, evidence-based guidelines have informed decisions and policies is the seamless integration of WHO guidelines into strategy development, in particular clinical recommendations. Some difficulties occurred where guidance was less clear, as illustrated in debates on the applicability of global 3 by 5 targets to national contexts, but the target helped to trigger key actions for responding to the emergency situation. The analysis also illustrated that seemingly minor technical decisions might have a major impact on the reality of access to ART treatment in the scale-up phase, such as the non-availability of starter kits in the introductory phase or overestimating patients' body weight and the resulting lack of appropriate medication for patients who weighed less. Of equal concern is the absence of a discussion on relevant arguments on patient selection beyond medical eligibility criteria, which might favour ad hoc decisions by treatment providers about agreed upon and validated selection strategies.

The existence of an agreed upon National Multisectoral Strategic Framework, Health Sector HIV/AIDS Strategy and National Care and Treatment Plan is crucial to ensuring that all partners involved in the scaling up of ART have a shared understanding of relevant reasons for policy, strategic and operational decisions.

Finally, the "revisability" of decisions made, i.e. the degree to which agreed policies and strategies could be adapted to changing realities and knowledge, proved to be a critical issue throughout the evolution of the Tanzanian HIV/AIDS response.

Existing approaches were revised on various occasions and in response to numerous interventions from within and outside the United Republic of Tanzania. This flexibility is often needed to accommodate, on an ad-hoc basis, changing magnitude and time horizons of financial support to treatment scale-up. Moreover, there is a need to respond to international developments relevant to scale-up, such as decreases in drug prices or changes in the choice of pre-qualified products. In addition to this reactive type of "revisability", there is now growing recognition of the importance of instituting pro-active efforts. These should include monitoring the implementation of plans based on agreed-upon indicators (e.g. coverage of rural population), discussing progress and problems in the appropriate coordination bodies and initiating necessary revisions.

As countries confronted with these complex processes must make difficult decisions, they may ask for external support. WHO and GTZ are agencies that provide technical support in a complementary manner. The partnership between the two builds on the comparative advantages of each organiza-

tion by linking multi- and bilateral development cooperation. It has shown great synergy in producing this case study.

WHO focuses on global policy, strategy and technical direction with tools, guidelines and standards at the international level for scaling up ART. It does so by mobilizing leadership and commitment at different levels, building consensus that facilitates international policy dialogue and developing and implementing global initiatives like 3 by 5. In an effort to help ensure the ethical distribution of HIV/AIDS treatment and care, WHO and UNAIDS convened the international Consultation on Equitable Access to Treatment and Care for HIV/AIDS (Geneva, 26-27 January 2004). Based on the outcome of the meeting and further consultations, the WHO/UNAIDS publication *Guidance on ethics and equitable access to HIV treatment and care* was produced. This publication seeks to raise awareness about the ethical issues involved in scaling up ART and other HIV-related treatment and care programmes in an equitable manner and to help with their planning and implementation. UNAIDS and WHO provide a set of recommendations for countries to utilize in the scaling-up process. These include:

- Creating opportunities for public dialogue to allow a wide range of stakeholders to offer their views and expertise and to be involved in making plans and setting priorities;
- Developing special policies and outreach programmes to prioritize the potentially underserved, vulnerable and marginalized groups so as to overcome barriers to their access to care;
- Defining a set of measurable indicators to monitor the fairness of HIV treatment scale-up.

GTZ has many years of experience in providing technical support to partner countries for political, economic, ecological and social development and has a large infrastructure at the implementation level. These significant experiences comprise developing health-sector systems; hands-on expertise in clinical/public health and HIV/AIDS programming. GTZ supports comprehensive approaches for prevention, care, treatment and mitigation. It has experience in linking HIV/AIDS with broader issues of development cooperation such as poverty reduction and mainstreaming HIV/AIDS in all others sectors. In the United Republic of Tanzania, GTZ has been offering technical assistance for over 20 years. Its comprehensive HIV/AIDS programmes at the local and district level and prevention of mother-to-child transmission (PMTCT) programmes show strong results.

More research is needed on how to monitor the extent to which the scale-up of health services in general, and of ART in particular, adheres to the criteria of fair process. Studies should examine the effects of applying fair process on outcomes, including the perceived legitimacy and acceptability of decisions made. For example, they should address the question of whether there is less resistance to recommendations when the process is perceived to be legitimate and fair, or whether there is an increased perception of fairness in the system when central elements of fair process are used and made visible. The present study has concentrated on the analysis of the fairness of decision-making on a national level. Methodological research should address the question of how to concretely implement the principles of fair process at regional and local levels.

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ANNEX – LIST OF PEOPLE INTERVIEWED

Name	Title	Organization
Joseph Temba	Director, Policy and planning	Tanzania Commission for AIDS (TACAIDS)
Rowland Swai	Manager, National AIDS Control Programme (NACP)	MoH, the United Republic of Tanzania
Bwijo Bwijo	Coordinator, Care and Treatment Unit (CTU), National AIDS Control Programme (NACP)	MoH, the United Republic of Tanzania
Brigitte Jordan-Harder	Team leader, Multisectoral AIDS Control Component, Tanzanian German Programme to Support Health	GTZ, the United Republic of Tanzania
Klint Nyamuryekung'e	National Professional Officer- HIV/AIDS	WHO, the United Republic of Tanzania
Edward Maganu	Representative	WHO, the United Republic of Tanzania
Bergis Schmidt-Ehry	Programme leader, Tanzanian German Programme to Support Health	GTZ, the United Republic of Tanzania
Carmen Perez-Samaniego	Project Manager, AIDS Control in Developing Countries	GTZ, Germany
Bernadette Olowo-Freers	Country Coordinator	UNAIDS, the United Republic of Tanzania
Elly Ndyetabura	HIV/AIDS Programme Officer	UNDP, the United Republic of Tanzania
Elly Nangawe	National Professional Officer-Human Resources for Health	WHO, the United Republic of Tanzania
Emmanuel Malangalila	Senior Health Adviser	World bank, the United Republic of Tanzania
Edwin Macharia	Country Coordinator	Clinton Foundation, the United Republic of Tanzania
Julius Kaaya	Chairperson	Tanzania Network of Organizations of People with HIV and AIDS (TANOPHA), the United Republic of Tanzania
Kenneth Lema	Deputy Executive Director	Axios, the United Republic of Tanzania
Geert Haverkamp	Team Leader	PharmAccess, the United Republic of Tanzania
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Elske Straatsma	Project Manager	PharmAccess, the United Republic of Tanzania
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PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

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Eunice Mmari	Programme Officer	CDC, the United Republic of Tanzania
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Rene Berger	HIV/AIDS Officer	USAID, the United Republic of Tanzania
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Pius Wanzala	HIV/AIDS Officer	NORAD, the United Republic of Tanzania
Judith Sullivan		CIDA, the United Republic of Tanzania
Catherine Severo	Health Adviser	Management Sciences for Health, the United Republic of Tanzania
Adolph Kivimba	Journalist	Association of Journalist against AIDS, the United Republic of Tanzania (AJAAT)
Joseph Kato	Chairman	SHEDEPHA+
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