Operational Research for HIV Treatment and Prevention
A Review of the WHO/TDR 5-Country Project

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List of Acronyms

ACP   AIDS Control Programme
APC   Assistant Project Coordinator
ART   Anti-Retroviral Therapy
CCM   Country Co-ordinating Committee
CDC   Centre for Disease Control
CHAM  Christian Health Association of Malawi.
CHAZ  Churches Health Association of Zambia
COMREC  College of Medicine Research and Ethics Committee
CMLS  Comité ministériel de lutte contre le VIH/SIDA
CTP   Care and Treatment of PLWHA Programme (Tanzania)
FBOs  Faith Based Organisations
FGD   Focus Group Discussions
FHI   Family Health International
GFATM Global Fund for AIDS, TB and Malaria
HSA   Health Surveillance Assistant
HCT   HIV Counselling and Testing
ICOHRTA  International Clinical Operations and Health Services Research
IDIs  In-Depth-Interviews
IDRC  International Development Research Centre, (Canada)
IRSS  Institut de Recherche en Sciences de la Santé
DFID  Department for International development
KCN   Kamuzu College of Nursing
MNH   Muhimbili National Hospital
MoH   Ministry of Health
MUCHS  Muhimbili University College of Health Sciences
NAC   National AIDS Commission (Malawi)
NAC   National AIDS Council (Zambia)
NACP  National AIDS Control Programme
NANM  National Association of Nurses in Malawi
NHSRC National Health Sciences Research Committee
NIMR  National Institute for Medical Research
OR   Operations Research
PDT   Product Development Team
PI    Principal Investigator
PLWHA People Living with HIV and AIDS
PMTCT Prevention of Mother-To-Child-Transmission
RAs   Research Assistants
REACH Research for Equity and Community Health
SWAP  Sector Wide Approach
TACAIDS Tanzania Commission for AIDS
TDR   Tropical Disease Research Centre
TNCM  Tanzanian National Control Mechanism
TSh   Tanzania Shilling
UNC   University of North Carolina
UTH   University Teaching Hospital
WHO   World Health Organisation
ZNAN  Zambia National AIDS Network
1.0 Introduction

In July 2004, an expert consultation was convened by WHO/TDR in Geneva in order to define a framework for operational research in the light of ART scale-up. The term ‘Operational Research’ (OR) here refers to “the use of analytical techniques to define optimal processes of delivery, achieve better outcomes through evidence-based approaches, and provide more cost-effective care” (WHO, 2006). The overall OR strategy, therefore, seeks to address the longstanding challenge of linking research to policy in the emergency context of the HIV epidemic, and to provide rapid evidence to scale-up and improve programs.

The July meeting brought together about 30 participants from different countries and disciplinary backgrounds. It discussed a framework to define priorities for operational research and “endorsed a multidisciplinary approach, in recognition of the multiple factors that influence scale-up, and in light of evidence showing that many of the important questions are at the intersection of disciplinary areas” (WHO, 2006). The meeting explored the various dimensions of scale-up including: individual, community and social factors; economic questions; health systems concerns; and clinical regimens. Keeping in mind these various dimensions, the meeting concluded with the identification of the priority questions to be addressed and the research methodologies to be employed; it initiated the process of developing plans for implementing OR, through active involvement of partners and country health staff and scientists; and discussed ways to disseminate the results.

Alongside the importance of multidisciplinarity, a further guiding principle for this process was country ownership of OR activities. “The process of priority setting should be informed by inputs from multiple players, including national programmes, national research institutes, international donors, technical agencies, academic institutions, and NGOs, including PLWHA associations” (WHO 2006). The second phase of the OR project was marked by a workshop in Kampala in December 2004 which brought together teams from Burkina Faso, Malawi, Tanzania, Uganda, and Zambia. Participants included representatives of national programs and non-governmental organizations in the selected countries; experts who would act as facilitators; and partners who would be interested in supporting operational research. The process of selection of these countries took into account a number of factors, including the estimated prevalence of HIV, the presence of an HIV officer in the WHO country office, geographic and linguistic diversity in Africa, and local capacities to undertake OR. After discussions at WHO and TDR, a list of five countries was drawn up, with the idea that these represented a first wave of countries, and an opportunity to define and revise the overall approach, to be later expanded to other countries. The objectives of the workshop were to set priorities and to start the development of OR proposals.

During the workshop, the five country teams began work on their respective proposals; this process continued after the meeting, culminating in proposals being submitted to a Product Development Team (PDT) which was formed to provide ongoing proposal development support, to review the final proposals and to advise on the disbursement of funds for the projects. The PDT consisted of researchers, funders, and program implementers (see Annex 3 for list of members). Thus between December 2004 and April 2005, the 5 country teams worked to develop full proposals. By the end of 2005, all proposals were revised and funds were disbursed to: Uganda in March 2006, Malawi in April 2006, Tanzania in June 2006, Burkina Faso in September 2006 and to Zambia in February 2006. Funding for the OR projects was provided by WHO, from contributions made to the HIV Department by the Canadian Government.

As the countries’ OR projects are progressing and some are now nearing completion, a review of the process has been commissioned as a joint exercise between WHO and the Global Fund. The overall aim of the review is to take stock of what has been done thus far to facilitate the conduct of OR to help improve HIV treatment and prevention programs; to assess how the process has functioned and how it has connected to other stakeholders involved in OR; and to draw lessons for future efforts to include OR in Global Fund proposals. This report summarises key findings from the review.
Following this introduction, the next section provides a summary of the situation regarding ART in the 5 countries. This is followed by a short section reviewing the methodology of the review. Section 4 contains the findings from the country reviews, and section 5 has some suggestions for areas in which the Global Fund could support in relation to OR. The final section summarises key findings, provides some general recommendations and identifies key elements which lead to the successful implementation of OR projects.
2.0 The state of ART scale-up in the 5 countries

The following provides a brief background of each of the 5 countries in terms of ART scale-up.

2.1 Burkina Faso

As of 2005, there were an estimated 150,000 adults and children living with HIV (estimated number of children age 0-14, 17,000), with approximately 12,000 adults and children dying of AIDS in 2005. The estimated national adult prevalence rate is 2% (15-49 year olds); amongst 15-24 year olds, the prevalence rate for women is almost 3 times more than that of men, i.e. 1.4% compared to 0.5%.

In 2005, an estimated 25,000 adults needed ART, with 10,644 receiving ART by June 2006 (WHO, 2007). This represents a substantial increase from 1000 people who were receiving ART in 2003. The target declared by the country was getting 30,000 onto ART by the end of 2006 (WHO, 2005).

At the end of 2003, three facilities were providing ART; by December 2005, there were 44 ART delivery sites: 21 in the public sector, 11 operated by NGOs, 2 by FBOs and 1 in the private sector. Treatment is provided with support from various initiatives, including the World Bank Multi-Country HIV/AIDS Program for Africa and Treatment Acceleration Project, the French project ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau), the Italian Cooperation, the French Cooperation, the Global Fund, the Red Cross/Red Crescent and Médecins Sans Frontières. TAN-ALIZ, a private company, is providing treatment to more than 500 people and Médecins Sans Frontières to more than 1000 people (WHO, 2005).

2.2 Malawi

In 2005, an estimated 940,000 adults and children were living with HIV, with approximately 78,000 adults and children dying of AIDS in 2005. The estimated national adult prevalence rate is 14.1% (15-49 year olds); amongst the 15-24 year olds, prevalence rates for women is, like Burkina Faso, almost 3 times more than that of men, i.e. 9.7% compared to 3.4% (WHO, 2006).

In 2005, an estimated 160,000 adults needed ART, with 33,000 receiving ART by the end of 2005, i.e. 21% of those in need. This represents a substantial increase from 3000 people who were receiving ART in 2003, i.e. 3% of those in need (WHO, 2006). The target declared by the country was getting 80,000 onto ART by the end of 2006 (WHO, 2005). By the end of March 2006, there were 46,500 people on ART and by the end of September 2006, 69,295 (WHO, 2007).

The number of facilities providing ART in the public sector increased from 9 at the end of 2003 to 23 at the end of 2004 and 60 by the end of 2005, covering all districts in the country. By the end of September 2006, there were 102 facilities in Malawi in the public sector delivering ART free of charge; at the time of the review (January 2007) there were a total of 130 sites providing ARVs (Malawi consultant report).

2.3 Tanzania

In 2005, an estimated 1,400,000 adults and children were living with HIV, with approximately 140,000 adults and children dying of AIDS in 2005. The estimated national adult prevalence rate is 6.5% (15-49 year olds); amongst the 15-24 year olds, the prevalence rate for women is 3.8%, whilst for men it is 2.8%. Notably there is much less difference between young men and women in Tanzania than in Malawi and Burkina Faso (WHO, 2006).

In 2005, an estimated 240,000 adults needed ART, with 22,000 receiving ART by the end of 2005, i.e. 9% of those in need. This represents a substantial increase from 2000 people who were receiving ART in 2003, i.e. 1% of those in need, but has not reached the target declared to be getting 44,000 onto ART by the end of 2005 (WHO, 2005). At the time of the review, the NACP
reported that 50,000 people were on ART (out of 400,000 eligible HIV-positives) (Tanzania consultant report).

In 2004, the government integrated all existing initiatives into one comprehensive National Operational Plan for Care and Treatment for HIV/AIDS with the involvement of 96 health facilities. The government also announced a commitment to provide antiretroviral drugs free of charge in the public sector. The number of centres providing antiretroviral therapy increased from 32 at the end of 2004 to 96 as of September 2005, covering 64 of 121 districts in the country. Of these, 61 were in the public sector (WHO, 2005; 2006b). At the time of the review, the NACP reported that there were 212 sites providing ARVs (Tanzania consultant report).

2.4 Uganda

In 2005, 1,000,000 Ugandans were living with HIV (UNAIDS, 2006). The national adult prevalence rate is estimated to be just over 6% (MoH, 2006).

In 2004, Uganda committed to providing access to antiretroviral therapy free of user charges in the public sector and declared a national target of 60,000 people receiving treatment by the end of 2005. In June 2004, an estimated 20,000 people living with HIV/AIDS had access to ART in Uganda. By September 2006, 89,193 people were receiving ART (WHO, 2007) in 175 accredited health facilities. Treatment also continues to be provided through community- and faith-based organizations and research programmes (WHO, 2006b).

2.5 Zambia

In 2005, an estimated 1,100,000 adults and children were living with HIV, with approximately 98,000 adults and children dying of AIDS in 2005. The estimated national adult prevalence rate is 17% (15-49 year olds); amongst the 15-24 year olds, prevalence rates for women is more than 4 times that of men, i.e. 12.7% compared to 3.8% (WHO, 2006).

Recognizing the urgent need for ART, the Government allocated funds in 2002 to purchase drugs to treat 10,000 people. Within one year, the government raised its national target to provide ART to 100,000 people by the end of 2005. By September 2005, close to 110 sites were providing ART across the country. The number of people receiving antiretroviral therapy increased from 8500 in June 2004 to more than 43,000 in November 2005 through the public sector and an additional 2000 people through private facilities. As of September 2006, a total of 71,529 people were on ART (WHO, 2007); unofficial figures (to be confirmed by MoH) show that there were 300 health facilities providing ARVs by March 31, 2007 and about 120,000 people were actively receiving ART (Zambia consultant report). The government’s decision in 2005 to provide antiretroviral therapy free of charge in the public sector is likely to have contributed to this rapid increase (WHO, 2006b).

The above brief country summaries show the different situations of the 5 countries. Prevalence rates, for instance, vary ranging from 2% in Burkina Faso to 17% in Zambia; in some countries, young women are 3 or more times more likely to be infected than men, whilst in other countries the rates are more similar. In some countries, we can talk about a mature, stable epidemic with, prevalence levels lower than in recent years, e.g. Uganda, whilst in other countries, e.g. Burkina Faso the epidemic is relatively recent and less spread. Similarly, country responses differ, with some countries pronouncing free access to ART through the government system (Zambia, Malawi and Tanzania), whilst in other countries a multitude of providers are involved in the delivery of ART (e.g. Burkina Faso). Finally, only Uganda reached and even exceeded the 3by5 target, the other countries moving towards them, some, e.g. Malawi, faster than others. Nevertheless, all countries are putting more people on ART, the number of facilities providing ART is rapidly increasing and in general it can be said that scale-up is happening.
3.0 Methodology of review

Following discussions between WHO and the Global Fund on the objectives and requirements for such a review, a group of consultants were identified to undertake individual country reviews. One consultant reviewed the OR process in Malawi and Tanzania, and a further three (two of which were local consultants), reviewed the processes in the other countries. A further consultant was hired to assist with the Zambia review and to pull together the 5 country reports into one document; this consultant had also been involved in the OR process since the first meeting in July 2004.

Prior to the country visits, the team met in Geneva with the WHO responsible officers. The outputs of this meeting included: a list of areas of enquiry formatted into an interview guide (see Annex 1); a list of different stakeholders to interview; draft outlines of country reports and the combined report; and a rough time-line including when fieldwork would take place and when country and combined reports would be due. Global Fund interested stakeholders were also present for part of the discussions, providing updated information of the status of Global Fund mechanisms and interventions in the 5 countries and their particular areas of interest for the current review.

Following the meeting, the country consultants carried out their reviews. All consultants interviewed members of the OR teams; additionally they spoke to people representing the Ministries of Health (often they were involved in some capacity in the OR, e.g. in the core team or in the steering committee), other researchers working on similar issues, members of the local WHO offices and people involved in the Global Fund in-country. The consultants also made trips to some of the project sites, speaking to, for instance, health staff who had either been interviewed or had facilitated the interview process. Secondary material was also collected in-country by the consultants and referred to in their country reports. Some of the consultants faced challenges including: difficult access to some members of the OR teams; some key members of the team were travelling during the review process and hence were unavailable for interview; and because of lack of time and planning, in some countries setting up interviews with key informants was delayed.

The country reports can be found in Annex 2, the current report summaries and combines key areas of interest and discussion from the individual country reports.

Before exploring findings of the review, it is important to briefly comment on the selection of topics that took place during the Kampala meeting. What was already apparent during the meeting was the diversity of topics. This selection was seen to reflect the particular concerns of national programs. The individuals who were present during the Kampala meeting also clearly had a role in influencing the focus of the OR projects. In Box 1 the title of the OR and the overall aim is displayed.
As can be seen, the different aims reflect different country needs and imperatives. Thus, in both Burkina and Uganda there is a multiplicity of providers of ARVs, with the resulting potential for fragmentation and uneven quality of care. The focus in the OR projects was, therefore, to explore these different models, identifying their strengths and weaknesses and possible ways to streamline and harmonize. The overburdened health system, the shortage of health workers and the problem of silence around HIV in Malawi is an issue which need to be addressed in order for effective scale-up to occur. In Zambia there is a large potential to increase uptake of ART by using PMTCT and TB sites as entry points, so this OR explores how this could happen and what may be the barriers to this. Some themes were also shared by the proposals: the adaptation of clinical regimens to various populations and in the context of overburdened health systems; the need to measure adherence and support it; improving access and the quality of testing and care as a basis for scaling-up; making better use of various entry points and coordinating the different services that can contribute to scale-up; and obtaining a clear view of how the system as a whole functions around HIV treatment. Also common across country proposals is the effort to consider medical and socio-economic factors in an integrated way, and the preference for phased approaches to implementation, starting from situational analyses, and later focusing on specific themes (WHO, 2006).

This section will be structured in the following way: firstly the quality of the research that was undertaken in each country will be reviewed. This will be followed by an exploration of the relevance of the research at country level. The final section will focus on the implementation of the project in terms of, for instance, management and technical assistance. Throughout these sections success stories as well as learnings and challenges will be brought out. Clearly there is much overlap between sections; nevertheless, for purposes of presentation the findings will be separated.

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**Box 1**

**Title and Aim of the 5 Projects**

**Burkina Faso:**
Title: Treatment and care practices amongst people living with HIV/AIDS in Burkina Faso.
Aim: To improve coordination between NGOs and public healthcare facilities providing care for HIV positive persons.

**Malawi:**
Title: Are health care workers accessing counselling and testing and ART services in Malawi?
Aim: To develop an intervention that results in increased uptake of counselling and testing and ART amongst health workers.

**Tanzania:**
Title: Evaluation of ART adherence measurement tool in the context of the Tanzania health care system.
Aim: To develop a national tool to routinely evaluate adherence and determinants.

**Uganda:**
Title: Patient adherence to ART and integration of HIV Prevention into AIDS Care: A situation analysis of different ART programmes in Uganda.
Aim: To provide a situation analysis of different models of care provision, with the aim to identify and generalize good practices.

**Zambia:**
Title: Operational research for ART scale-up: ART in TB and PMTCT clinics in Zambia.
Aim: To determine the uptake of ART among HIV-infected TB patients and amongst PMTCT clients as potential entry-points for facilitating and improving ART uptake.
4.0 The quality of the research

The issues that this section explores include; how the research teams were put together and what implications this has for the questions and approaches to OR; the research design, including the methods used and the sites that were selected; and the research capacity and ability of the teams to link with other researchers in similar field.

4.1 The Teams

Many of the people from the 5 countries who attended the Kampala meeting continued to be involved in the research. In Zambia 2 of the 3 people, one as the PI, the other in the steering committee were still involved; the third member attending the meeting had passed away and was replaced. In Malawi two of the three remained, one person from CDC had since left the country. In Tanzania only one of the 3 people who had gone to Kampala was still involved at the time of the review. There was also much coming and going in general in the Tanzanian team. Two of the key people from ACP in Uganda stayed with the project – the others who attended the Kampala meeting all stopped their involvement, but these were all less central than the two who stayed. The 3 representatives from Burkina Faso at the Kampala meeting continued to be involved in the study, one of whom become the scientific coordinator, with the other 2 becoming members of the steering committee.

In keeping with one of the key principles of this OR process, all core research teams consisted of people from both the medical and social sciences. Nevertheless, other than in Malawi and Burkina Faso, there is a sense that the medical sciences dominated, with the PIs or the research managers/coordinators being usually from the medical fields. Invariably social scientists were involved; however, they were often drawn on to assist with the qualitative components and often did not see through the whole process from start to end. In Zambia, whilst the social scientists were key members of the implementing team, they felt that social scientists had not been involved enough (if at all) when the protocol was being developed and that there should have been some prominent social scientists in the steering committee or guiding the research, as a qualitative methodology was used throughout.

Team members in Malawi and Burkina Faso represented a mix of government, Associations, NGOs and research institutes. In Burkina Faso there are 2 research institutes involved. Reactions from respondents during the review were mixed regarding the involvement of 2 research institutes some said: « L'équipe de recherche était très lourde, d'où des difficultés de coordination. Il aurait fallu confier la RO à une seule structure qui constitue son équipe de recherche et qui la gère » others said « Il était pertinent de mettre les compétences des deux instituts ensemble pour cette recherche opérationnelle » (see also section 4.3).

At the other extreme is Zambia, where the team essentially came from one organisation, the University Teaching Hospital (UTH), with the MoH being heavily represented on the steering committee. There was also a sense in Zambia that people involved in the study were there as individuals rather than representing government or and the MoH. Members from the NACP dominated the study in Tanzania, providing both the PI and study coordinator, though the MUCHS, the University of Dar es Salaam and the local WHO office were also involved. In Uganda, the team was made up of people from the government, MoH, and academic institutes, including Makerere University, the Institute of Public Health and the Uganda Virus Research Institute.

There was considerable variation across countries in terms of the size of the teams, clearly also relating to the size and nature of the research and the percentage time individuals spent on the project. In Zambia, for instance, the team essentially consisted of 5 people – the PI, 2 social scientists, 1 research assistant and the data manager/administrator. The consultant was told that the bulk of the work was carried out by the 2 social scientists (developing the instruments, collecting and analysing data and writing up findings), but in reality it seems that only 1 of them was really involved. At the other extreme the team in Burkina Faso consisted of 14 researchers – a
PI, a coordinator, a co-PI, 7 co-PIs, and 5 associated researchers; an additional 2 research assistants and 8 interviewers were also recruited.

In Uganda, 6 people made up the core team, but an additional 24 fieldworkers were hired to collect both the qualitative and quantitative data; these 24 were assembled into 8 teams of three fieldworkers each. In Malawi, although the team in the protocol numbered 12, as of January 2007, 7 active members made up the core team – 3 expatriates had left the country and one person had gone for studies; an additional 6 research assistants (RAs), all graduates, were also hired to collect the data. Eleven people are currently in the Tanzanian team, this includes the three members of the WHO office in Dar es Salaam who have been involved in the research since the onset (see also next section stakeholder involvement). In addition to these key team members, 8 RAs were hired to be involved in data collection; the RAs are students at MUCHS.

It appears that in Malawi and Burkina Faso, there are more full-time members of the OR team than in Zambia and Uganda. Thus in Malawi there are 2 full time people working on the project and another 40% of the time, the rest all being 10%. In Burkina Faso 2 full-time research assistants were recruited to coordinate the surveys and prepare and facilitate the workshops. The scientific and social science coordinators were allocated 40% and 30% respectively of their time to the OR, the community representative and the PI were 20% on the project. The other researchers were allocated either 15% (6 people),10% (2 people) or 5% (1 person) time on the project. In Uganda, there is only one full-time person; data entry staff have worked full time since data collection got underway and field workers have worked full time in two intensive four-week periods. In Zambia, given the size of the project, in response to whether people are full time, the answer was invariably, when necessary. With the 2 social scientists being at the University Teaching Hospital, we were told that they are given time to do research, “but when she was needed to be full time she used her leave of which 90 days had accumulated”. In Tanzania, one person, the assistant coordinator is full-time on the project, the others appear to have very busy schedules: “It seemed difficult to start the research, partly related to busy schedules of the PI and study coordinator, who are both from NACP. Other team members are senior lecturers who are busy as well, with teaching and exams”.

In all countries, alongside the project teams there were steering committees or other kinds of support structures providing scientific and technical guidance. In Tanzania there is a consultative group of researchers working on similar research topics. In Malawi, members of the steering committee come from the National AIDS commission, HIV Unit MOH, Health Education Unit of the MOH, the Lighthouse (service provider and OR centre) and Universities. In Zambia the committee is made up of 6 people, 4 from the MoH based in Lusaka and 2 from the University. In Burkina Faso, the president of the steering committee is the Coordinator of the CMLS/Santé (Ministerial committee on the fight against HIV/AIDS, Department of Health) other members include members of the research team, NGOs, associations and financial and technical partners, e.g. the World Bank, UNAIDS and WHO. As is commensurate with the high level of national support and ownership of the project (see section 4.2.1), the Minister of Health officially instated this steering committee in June 2006. This committee meets every 6 months.

The role of these steering committees varies by country, in Zambia, for instance, this committee on the one hand was reported to have been quite key in providing advice and technical support. The following is an account from the Zambia country review:

People selected to be on the steering committee were chosen by the PI; the selection was based on people that he knew, they had to be senior, experienced and from different professional backgrounds. The steering committee meets quarterly, but can be called upon when there is a problem. They do not get any allowances apart from transport refunds to the amount of approximately K500,000. The meetings are held at UTH conference room, minutes are taken by the PI’s secretary. They have been very supportive. The PI acts as a bridge between the research team and the steering committee. They will be meeting soon to discuss how to move into Mumbwa.
A somewhat different picture emerged, however, when the consultant tried to interview a member of the steering committee: he was unresponsive and seemed to know little about the project so whether in fact the steering committee was essentially down in name rather than in reality needs further exploration. What emerged from further discussions was that whilst the steering committee was constituted, there were no regular meetings, according to an informant: “the committee was there, except all the members were too busy and did little if anything to add value to the study”.

4.2 The research designs

Post the Kampala meeting all country team started elaborating and developing further the protocols. Once the proposals were drafted, with different degrees of involvement of country-level stakeholders (see below), they were sent to the PDT for review. The quality of the draft proposals appeared to have varied considerably: some proposals, after modifications, were approved relatively quickly whilst for others there were detailed and lengthy exchanges between WHO and TDR, and between Geneva and the PDT. In particular, for Tanzania and Zambia the process was very drawn out. In addition, review of the proposals by the WHO Ethics Review Committee resulted in quick approval for some but not for others and, for one (Tanzania), approval was granted (because of the need for approval in one calendar year) on the condition that further, specified changes would be made.

All studies used a cross sectional design, none were longitudinal or followed a cohort, though in Tanzania the aim is to follow patients on ART for a period of one month so in a sense a cohort will be followed for a short period of time. Also common across country proposals is the preference for phased approaches to implementation, starting from situational analyses, and later focusing on specific themes. All countries, except for Zambia used or plan to use both quantitative and qualitative methods, with different phases often associated with different methodologies. In Tanzania a qualitative methodology was used in the first phase to generate variables on adherence and its interaction with socioeconomic, health care, clinical and personal factors. “The team will design the tools for the second phase with input from the preliminary findings of the first phase”. Similarly, in Malawi, quantitative data collection follows qualitative, with the questionnaires for the second quantitative phase being designed with findings from the first qualitative phase. In Burkina Faso, the quantitative data collection was done first with the same team then going on to do the qualitative data collection, thus already knowing many of the themes that they wanted to probe further.

In Uganda, more qualitative data collection was originally intended than had occurred: “The study includes both qualitative and quantitative aspects, but the initial plan included more qualitative work than was ultimately feasible. The reason was that the people skilled in this approach were unable to commit sufficient time, and the Ministry of Health itself does not have adequate qualitative research capacity. The team therefore held a ‘soul-searching session’ in which they discussed issues that they really wanted to include, and there remained few areas that were exclusively qualitative”. In the end semi-structured interviews took place collecting both quantifiable and textual data, with the idea that further in-depth work could be conducted after preliminary analyses. In Zambia, only qualitative methods were used, though tracking of uptake is currently being done and there are plans to do a follow-on qualitative and quantitative study in a rural site (Mumbwa, see below).

In terms of site selection, sampling and breadth of the research, there are considerable variations across countries, ranging from rigorous quantitative sampling techniques being used to less rigorous and more purposive and convenient sampling. Similarly, whilst some countries chose to cover almost the whole country (Uganda), others were much smaller in scope and scale.

At one extreme lies Uganda and Tanzania which attempted to sample from almost the whole country, the exception being the North in Uganda because of security concerns. The team in Uganda, went through a rigorous sampling process, consulting with a sampling expert and developing a sampling frame. “A sampling frame consisting of all facilities providing ART – including the number of clients enrolled as of the latest report – was generated and used in selecting the sample. Facilities were stratified into: i) level of service delivery (such as referral
hospitals, centres of excellence, district hospitals, health centres and private clinics); ii) type of service (public, private-for-profit, and private-not-for-profit). On this basis, a sample of 48 facilities was obtained from facilities in the East, Central and Western regions. (Northern Uganda was omitted from the study primarily for logistical reasons.) However, during pre-visiting the centres both in preparation for pilot testing and for the actual field work, it was realised that majority of these centres operate only once a week... This would have created serious logistical problems if research teams were to be deployed to one facility to work for just one day in the week... Consequently a design guided by the sampled facilities but not limited exclusively to them was used, whereby more ART centres in the neighbourhood of the sampled facilities were included. Hence the number of facilities included in the study is more than 48 facilities – the final tally will be an estimated 84 facilities”.

A total of 2,271 clients on ART were interviewed in Uganda, as well as 391 ART service providers and 76 Key Informants. Both key informants and service providers were selected purposively. Key informants were either coordinators or persons in charge of the ART programme selected to provide key information on the ART programme. Service providers were all clinicians, nurses and counsellors providing services to the clients on ART in the facilities. The exit client questionnaire was administered to clients over the age of 15 years who had been receiving ART for at least 3 months at the time of the interview. Research instruments for each of the three groups were semi-structured. The open ended questions collected qualitative information which is being analysed qualitatively and, as far as possible, also coded so that it can be analysed quantitatively.

In Tanzania, plans for the selection of facilities and study participants were rigorously drawn. Seventy-five facilities providing AIDS comprehensive care and treatment1 were stratified in 4 strata: i) secondary and tertiary hospitals, ii) primary level hospitals, iii) private facilities, and iv) faith based organizations hospitals. From each stratum, two facilities were randomly selected. For the qualitative study, 8 hospitals have been selected and include one referral hospital, one regional hospital, two district hospitals, two private hospitals, and two faith based hospitals. In each facility 20 IDIs were conducted with people on ART. In the second quantitative phase, which had not started at the time of the review, a total of 75 people on ART will be interviewed in each facility (n=600) and followed for a month – interviews will be conducted, pill counts made, and there will be taking of viral loads and CD4 counts twice during this period and the patients will be keeping diaries.

At the other extreme is Zambia, where the study was conducted in 6 urban clinics in Lusaka. The clinics were selected based on where TB and PMTCT activities were taking place and on ease of access. A total of 17 FGDs with patients and 30 IDIs with patients and staff were carried out in the 6 clinics; a sample size was not pre-selected, but interviewing continued until information was exhausted and saturation point was reached. In discussion with a TB/HIV researcher in Zambia not involved in the study it was felt that the outlying areas had been neglected in this study; all the sites were in Lusaka, all team members had Lusaka experience and all the steering committee members also had predominantly Lusaka experience. Thus the possibility to be more representative had been lost. Phase 2 is about to start up in which the team will move to a “rural” area, though how rural it really is remains to be seen as it is close to Lusaka and it is a district capital.

In Malawi an epidemiologist was engaged to assist with sampling for the quantitative study and eventually, following changes in design, “… the sample was increased to 8 (districts) and the sample size to 953. A three-stage random sampling methodology was used to select the eight districts (urban and rural), three health facilities per district (government hospital and health centre and CHAM hospital) and workers within the health facilities. In all the health institutions HCT and ART services are provided. Study populations are all levels of health staff, including HSAs”. The qualitative data collection had occurred prior to that in 2 districts (one in the Southern and Central Region), with a total of 48 health workers being interviewed.

1 At the time of the proposal 177 sites were providing AIDS services; excluded from the sampling frame were military facilities and facilities where other research on adherence was taking place or had taken place.
In Burkina Faso 30 health structures were selected representing different existing care models in the country and also representing a relatively wide range of sites and cities, i.e. 9 out of 13 regions of Burkina Faso were covered by the quantitative instruments (see below). The breadth of the Burkina Faso OR can also been seen in the number of different tools and different kinds of respondents they interviewed: 3 quantitative questionnaires were developed and administered to 512 people on ART, 247 pre-ART individuals and 116 health providers; 4 qualitative guides were also developed and were applied to 31 patients, 6 programme managers, 1 donor (WHO) and 7 directors of associations.

Regarding the quality of the data, in Malawi the following account was given “Reading through the transcripts of the interviews, the quality of the interviews was very good. It showed rapport between the interviewer and the respondent and good way of probing. I went to visit one of the health institutions where the team had done the study (3 months earlier) and the rapport between interviewer and respondents (I met with three of them) was obviously still there, judging from the way respondents and Grace (the interviewer) were familiar with one another”.

The rigorous way in which the questionnaire was developed and pre-tested and the quality control system that was set up both for data collection and data management suggests that much effort was made to ensure good quality data in Uganda:

“Round 1 of Data Collection: The first phase of data collection was conducted between 20th September and 20th October 2006. Regular communication and contact between the teams and the study coordinators was maintained throughout the period of data collection to provide guidance and support. At the end of each day’s work, field workers edited the filled questionnaires both individually and as a team. Officials from the Ministry of Health, Makerere University (Department of Sociology), the Institute of Public Health, as well as the Uganda Virus Research Institute supervised work in the field. Supervisors reviewed the data collected and provided support to the field workers. They also conducted key informant interviews with persons in charge of the ART Programmes, in addition to pre-visiting other ART sites in the area as necessary. The supervision visits were fundamental in identifying some of the areas of the study that may need further qualitative inquiry. They also helped detect areas of service delivery that may need to be strengthened or addressed. Supervisors met regularly to review the performance of the teams, to assess the progress of data collection, and to register the various challenges and successes met.

Data Management: A full time data manager and four data entry officers were hired for data entry, management and analysis. A data entry screen has been developed and tested, and data management is undertaken in the computer room of the ACP. Data entry clerks were trained by the data manager and have completed entering the responses to open ended questions from the first round of data collection to aid qualitative analysis. Qualitative data entered in word is currently being reviewed by the two qualitative research experts who are part of the core research team to come up with the main themes. Entry of quantitative data into the database has also commenced”.

In Zambia, on the other hand, the in-country consultant was unable to get hold of the transcripts, nor listen to tape recordings of the IDIs and FGDs; he did manage to see the guides but they were very brief and did not seem to be particularly comprehensive. When probing, it transpired that FGDs were comprised of 7-10 people and would last about 30 minutes; IDIs with health staff lasted a maximum of 20 minutes and with patients between 30-40 minutes. This does not bode well for qualitative research as IDIs and FGDs normally range from 60-90 minutes. The consultant also looked at the quantitative instruments which had both been referred to as a “questionnaire”, in fact it was essentially an instrument to obtain data at facility level, i.e. uptake of services. (Even the qualitative instruments (FGD and IDI guides) were also referred to as questionnaire). On a positive side, when visiting 3 of the study sites, the rapport between the member of the team and the health staff was good and strict adherence to ethical standards was reported by the health workers, who also spoke on behalf of patients/clients involved in the study.
In Tanzania at the time of the review the data had not yet been collected, though the plan for data collection appears to be rigorous.

The highly participative nature (see section 4.2.1) of the process in Burkina Faso whilst leading to a wide-ranging level of stakeholder involvement, nevertheless meant that in order to accommodate different perspectives and priorities, the instruments that were developed ended up being very long and somewhat unwieldy. This point was also raised by some study participants whom the consultant was able to meet. Nevertheless, the data collection and data entry is being rigorously supervised and managed: the interviewers are closely supervised by 2 research assistants, the PIs also making fieldtrips to support data collection; double entry is occurring for the quantitative data.

The preparation and revision of the instruments took place in parallel with a project also initiated by WHO, designed to produce data collection tools on key topics related to HIV treatment and prevention. Initiated in 2006, the Generic Tools project identified several topics on which reviews of evidence were conducted, and compiled the tools used by various organizations and groups, with the goal of producing a core set of instruments that would facilitate the conduct of OR in countries. As the OR project in countries and the Generic Tools project progressed, an effort was made to share with the OR teams the latest drafts of the Generic Tools instruments, and to incorporate the lessons learned in the field into the preparation of the instruments. The Generic Tools are expected to be available for the next round of OR projects.

4.3 Research capacity

In terms of capacity of the research teams, in all countries core members of the teams were highly qualified and very appropriate for carrying out the particular operations research, with overall, a wide range of disciplines represented in the teams. As mentioned above, there was a sense from the Zambian team that more social scientists should have been involved from the onset to provide guidance. Also in Zambia, as was pointed out to the consultant, an ART specialist should have been included in the core team as well as in the steering committee since this was a key area in the research. Whilst in Tanzania, the capacity of the team was high and wide-ranging in terms of disciplines, it seems that a severe constraint was their lack of time to commit to the OR (see also section 4.3.1). In Burkina Faso, there is a sense that the team is a permanent structure coming mainly from one research institute, often being called up by MoH and other national and international organisations to carry out research. Given this permanence, the team will continue to draw on the experiences and findings from the current OR in future OR/research.

In all countries except for Zambia, training was carried out for fieldworkers, and field-teams were closely supervised and supported. In Malawi the training lasted 10 days; in Tanzania the 8 RAs were trained for 3 days by 4 supervisors. In Uganda the fieldworkers also attended a refresher training prior to carrying out the second round of data collection. The teams were supervised and quality control was continuously carried out. In Burkina Faso, sociologists and members of HIV/AIDS associations hired to collect the data have all attended a 10-day training. Zambia, on the other hand, did not provide training for its field-team, this was partly because the fieldworkers (with social work and nursing backgrounds) were viewed as having social science skills. Nevertheless, this lack of training and capacity building was in fact pointed out as being one of the shortcomings of the process, as explained by one of the social scientists: “There is need for refresher courses, capacity building, packages for analysing qualitative data are out there but they don’t know them”

Whilst team members mostly had knowledge about other research being conducted in the country on similar issues, except for Tanzania, where a taskforce of research groups on adherence is formed, links with other researchers rarely occurred. This was also demonstrated by the fact that few researchers outside the immediate team members and members of the steering committee (though even in some cases they were not fully aware) were aware of the specific OR (see also section 4.2).

Generally, infrastructure to support the teams was deemed to be sufficient in all cases. Because core members of the Uganda team had been previously involved in the national sero-survey, the building and computing facilities that had been set aside for this work, were taken over for the
present OR study. Thus key infrastructure, expertise in conducting large surveys, and knowledge of the country’s many languages were already in place and available. In Zambia, the teams were able to use the facilities at UTH so they had 2 offices, 3 computers and bought a further laptop with the study funds. In Burkina Faso offices were made available to the team within the IRSS and 4 computers and other equipment were purchased on initial receipt of funds. The two full-time researchers in Malawi secured a laptop with the research funds; the REACH office, the implementing organization in Malawi, has PCs available. In Tanzania, a laptop was bought for the assistant study coordinator.

The research teams in Burkina Faso, Tanzania and Malawi have access to internet facilities in their offices, though the connections are slow. The Zambian team is renting internet access from another project within UTH at the cost of US$60 per month. This lack of or limited internet facilities clearly limits communication between team members as well as with outside technical support. Additionally, it is unlikely that many team members have institutional or online access to peer-reviewed journals, all of which will make comparisons and contextualization with other similar OR work being carried out more difficult.

**Summary**
The overall sense one gets from reading the review reports is that in Burkina Faso, Uganda and Malawi the team was committed to the research, a rigorous process was adopted from the start from developing and reviewing the protocol, to developing the research design and instruments to carrying out the data collection and data management. Overall one would expect high quality results from the studies, results which can be disseminated and published to a wide audience, and in fact, abstracts based on the first batch of analyses have been submitted by the three teams to upcoming conferences and have been accepted. In Tanzania, because of the late starting of the project, due to various factors including the fact that key members of the team, including the PI, were heavily committed elsewhere, it is too early to say whether the results will be of high quality, but early indications in term of plans for data collection and respondent types are positive. Although the topic is very appropriate (see also section 4.2), one gets the sense from Zambia that the study was conducted in a somewhat haphazard way, that the research design and instruments were not reviewed thoroughly enough, that perhaps sites beyond Lusaka could have been considered (now there is a move to this) and that the interviewers perhaps needed more skills in qualitative interviewing. Whilst the research teams themselves all had the relevant and necessary capacities, and in most countries rigorous training of field teams was carried out, links with other researchers working in similar areas, except for Tanzania, where a taskforce on adherence research was set up, were limited. Finally, all teams said that the support and infrastructure set up for the particular OR projects were sufficient, the only challenges being links to internet facilities.
5.0 The relevance of the project at country level

This section will explore the extent to which different stakeholders were involved in the OR process and whether teams and countries felt a sense of ownership of the OR. This will then be followed by a discussion on how and indeed if, the themes and areas investigated in the OR projects reflect in-country policy and programme concerns, including the links to ART scale-up and gaps in evidence. The concluding section will provide a brief discussion on how countries plan to disseminate results and findings.

5.1 Country stakeholder involvement and ownership

In Malawi there was extensive involvement by a range of different stakeholders in the OR process. This is seen by a number of factors: firstly, the team that went to Kampala represented both government (MOH) representatives and research institutes (CDC and REACH); upon their return the team presented the suggested topic to the HIV Unit of the MOH to get feedback, input and buy-in. Because of the delay between submitting a revised proposal and disbursement of funds, the Malawi team decided to call a stakeholder meeting to ensure that the study was still in line with current developments of rapid scale up of HCT and ART and to discuss whether the study was still relevant. The twenty participants in the meeting were from MOH (3), various hospitals (5), universities (2), and NGOs (3) and from REACH Trust (7). Five members of the research team were present. The current active team also represents a range of views including government, NGO implementing agencies and research institutes, both local (REACH) and international (CDC, based in Malawi).

Similar to Malawi, Burkina Faso adapted a highly participatory approach at all stages, from the development of the protocol to the design of the instruments. Members of the team who had gone to Kampala developed a first draft of the protocol, drawing on technical assistance from others who had been at the Kampala workshop. Following this, a national level workshop was organised with a range of different stakeholders including clinicians, policy makers, NGOs and researchers, to raise awareness of the proposed OR and to obtain input and feedback. At instrument design phase, another workshop was held with a range of stakeholders from different fields and different disciplinary backgrounds to input into the design and content. The participatory process will continue over the next few months with workshops being organised at national and local levels to discuss findings and results, to determine strategies and develop recommendations for overcoming emerging challenges and/or gaps. As a member of an association said: “J’ai l’impression que c’est la première fois qu’on fait de la recherche opérationnelle en associant les acteurs de bout en bout. D’habitude, notre implication (les associations) se limite juste à la phase restitution. C’est une recherche opérationnelle au sens des associations qui ont été impliquées et ont facilité les choses aux chercheurs sur le terrain »

At the other extreme, in Zambia one gets the sense that once the team returned from Kampala, no other stakeholders became involved in the research, it was not shared with other key bodies working on HIV/AIDS related issues, e.g. NAC, ZNAN and the local WHO office was not involved in any way until much later. One researcher in the TB/HIV field had heard of the study during a trip he made to WHO in Geneva, but had not heard further about it locally, nor did he know any details about it. The PI also sensed that probably no one else was aware of it saying that it was a small project compared to other studies going on in Zambia. The problem of sharing of information about research in-country is a challenge faced in most countries and will be discussed further in section 4.3.3.

Uganda lies somewhere in between Malawi and Zambia in terms of wider stakeholder involvement in country. Thirteen people working in Uganda attended the Kampala meeting, including Ministry of Health officials, senior academics from Makerere University, and expatriate experts. In contrast to Zambia, the ACP was involved from the start in the OR proposal development and in particular was supported by the STD/ACP programme manager. Also involved in the project from the start was the in-country WHO HIV team (the fact that the initial workshop was held in Kampala may have facilitated their involvement). Nevertheless, during the review other than people from the
ACP, the in-country WHO HIV team and those who were part of the project research team itself, no one else the consultant spoke to had much awareness of the OR. He was not, however, able to speak to people who assisted in refining the research tools and project objectives – including people from CDC, the Infectious Disease Institute, the Joint Clinical Research Centre and the Mulago-Mbarara Joint AIDS Programme. “Nonetheless, perhaps the lack of awareness of the study outside very particular circles at this stage is not so surprising, since the results have not yet been produced and disseminated. However, since one of the initial objectives of the study was to ensure a broad ownership base, in this sense the objective has not been met”.

The above points to a similar issue that was expressed in Zambia, i.e. the sense that other researchers do not know about other similar research happening in-country and that there is no platform or forum for sharing of research findings. Additionally, it could also be the case (perhaps more so in Uganda than in Zambia and other countries), that there is just so much research happening that it is difficult to keep track of it.

The team that went to Kampala from Tanzania consisted of the head of M&E at the NACP, a researcher from the Tanzanian CDC and someone from Muhimbili National Hospital; also present as part of the team was the local Tanzanian WHO HIV country officer. Upon returning, they asked other Tanzanian researchers to join the team, from the MUCHS, AIDS Relief Consortium and two other local WHO HIV officers. It is difficult to get a sense of the extent to which other country stakeholders were involved or knew about the project, as the OR essentially stalled shortly after that, only being picked up again around June 2006, when a full time assistant coordinator was recruited and started work in November 2006. Also in November 2006, NACP and WHO decided to call a two-day stakeholder meeting to re-plan and discuss the design of the quantitative and qualitative phase and progress in the NACP/WHO OR and to have other researchers (from CDC/FHI and MUCHS/Harvard) on ART adherence present their proposals/studies. Participants were the researchers of the three research teams, others from Tanzanian Universities, NACP, Harvard University and FHI and a member of the OR team in the HIV Department of WHO Geneva.

Resounding throughout the country reviews was a level of national ownership of the OR projects. According to the Malawi consultant: “The big strength of this project was that country teams could set their priorities and that the research topic and design was not externally driven, as so often research is, according to the complaints of local researchers”. Similarly, in Tanzania the team appreciated that the choice of the topic was not externally driven: “…that the research is conducted by local researchers, and data analysis is done in Tanzania. Researchers are very sensitive and complained that in a lot of externally driven research, ‘foreigners do the research and take the data away and analyse them overseas. Tanzanians have to request for the data if they want to use them. In this way Tanzanians are selling the country.’” The OR project in Uganda is also not seen to be seen a “WHO-driven, top-down project – there is genuine national-level ownership”. As a result of this national level ‘ownership’ of the project, one of the team members explained that the OR project will enable Uganda to “use our own data to set our policy, and not have it be defined by data from other resource-poor settings, or even from developed countries.”

In Zambia there was also a sense that the local team drove the design process and there was no external influence, or top down pressure, so the PI felt ownership, that it was “our thing”. The PI thought the process of developing the proposals, starting from the Kampala meeting was very effective giving “options and possibilities”.

5.2 Relevance of OR themes to country programmes, policies and priorities

Broadly it can be said that all the themes selected for the individual country OR represent key areas of national interest and concern. In Zambia, despite the current OR being relatively low-key and little known about, when talking to other researchers about the focus of the OR, it was evident that it is a key issue. Given the fact that “2/3 TB patients and 1/5 of pregnant women are HIV+” (interview with PI), these can be viewed as “immediate captive groups that would enable and speed-up scale-up”. People who come for TB and PMTCT need to be better linked up to ART services. The current OR explores why they are not linked up and why people are defaulting, all
issues that are of concern both for adherence to ARVs and to TB drugs. Generally, findings from such an OR could help in the scaling up of TB/HIV collaborative activities which are a key concern for government.

In Malawi the topic of the research is acknowledged to be highly relevant to the national AIDS programme, by researchers and MOH staff. Human resources are seen as the major bottleneck in scaling up of ART. Considering the ambitious plans for nation-wide scale up of ART, the availability of healthy and sufficient health workers is critical for the scaling up of ART provision and caring for patients with AIDS related diseases. However, there were severe staff shortages in the Ministry of Health - in 2003 it was estimated that 75% of the posts were unfilled. Health workers themselves were severely affected by the epidemic and anecdotal evidence suggests that there was (too) low uptake of AIDS services among health staff.

During the time the team was waiting for the funds, two other related initiatives had developed: The NANM ‘Care for the Carer Project’ and the MOH ‘National Care of the Carer, HIV and AIDS Workplace Policy’ document which is being operationalised in 2007. The heads of both initiatives are keen to cooperate with the OR team and research findings could be very useful for both the training of health workers project of NANM and the operationalisation of the MOH HIV and AIDS Workplace Policy.

Scaling up of the care and treatment for PLWHA programme (CTP) in Tanzania started in early 2004 and it is increasingly realized that adherence to treatment is of utmost importance to the success of the programme. Adherence to their treatment needs to be monitored as it will assist health workers to assess the implementation of their CTP. The aim of the OR project is to identify/develop a measurement of adherence tool that can/will be used for routine assessment of adherence throughout Tanzania. Thus the study is highly relevant to the NACP and HIV and AIDS service delivery institutions and is of increasing relevance with patients being longer on ART and therefore adherence getting more difficult. Identification of poor adherence and associated factors in the country will be followed by implementation of appropriate urgent measures to improve the level of adherence.

There are two other current studies that also have a measuring of ART adherence component. According to the PI, Dr Swai, who is also head of NACP, all three studies are highly relevant for the Tanzanian AIDS programme and they do complement one another, one being more qualitative, (MUCHS/Harvard study), another being more quantitative (FHI/CDC study), and the NACP/WHO OR study exploring adherence assessment tools and then, if sufficient funds can be mobilised, having an intervention phase. The three teams have created a taskforce on ART adherence and meet every six months, with ongoing consultation about the study sites to prevent overlap.

The OR project in Uganda “amply fulfils the goal of providing evidence that will be relevant for both programmes and policy”. A member of the in-country WHO HIV team explained how it is hoped, for example, that the project will inform a national consensus meeting due to be held on ART monitoring in March 2007. There is also recognition that Uganda’s ART policy – first published in 2003 – is now out of date, and moves are afoot to revise the document. By identifying best practice models, both with respect to adherence and HIV prevention, this study should inform that process as well. One factor that could help bridge the ever-challenging gap between evidence and policy development is the high level of awareness and ownership of the project amongst key individuals within the ACP and Ministry of Health. This should help bring the findings to the attention of key top policy makers.

In terms of other research in the country, the consultant met with a Belgian researcher planning a three-country ART study, including Uganda, who was interested in using and/or adapting the interview tools used in the OR project. A number of other large-scale OR projects are currently underway (through the MoH) nevertheless this will be the first to produce results and as such it could play an important role in linking evidence, policies and programmes. There are also a wide range of smaller ART-related OR projects being conducted by a number of academic research institutions in the country.
In Burkina Faso, the theme of the OR remains pertinent, as since 2004, there has been an increase in organisations and actors providing care services alongside the increasing numbers of people on ART, i.e. 24% at the end of 2006 compared to only 8.4% in 2004. Little is known about the extent to which there is harmonisation of different models of care. Similarly, there is still little known about the effectiveness and quality of these different models of care. Linked to this, whilst many studies have been carried out on prevention in Burkina Faso, official data are nonexistent on care for PLHA, especially in relation to ART. Thus this OR will provide evidence of the different kinds of models in existence and their relative strengths and weaknesses as well as to reliable data in relation to care or PLHA in a context of ART. According to a member of an association: « Le thème est très pertinent car les acteurs de prise en charge au Burkina sont différents et les pratiques varient également d’une structure à une autre, alors que les cibles sont les mêmes d’où la nécessité d’une telle étude qui va permettre d’harmoniser les pratiques et construire un meilleur partenariat entre les différents acteurs de prise en charge »

Although findings from the OR projects are not yet available and no dissemination activities have yet taken place (see section 4.2.3), in some countries the fieldwork and initial discussions have already had some effects. In Uganda, for instance, field work activities have contributed to improving ART service delivery: fieldworkers helped several clinics to obtain ARVs from other sources during the shortages in late 2005 and after identifying some medics with insufficient ART training, their facilities have been prioritised for training within the framework of the national ART scale-up training programme.

5.3 Dissemination plans
Dissemination of results is just beginning, with abstracts being sent to upcoming conferences by the teams who have conducted a first set of data analyses. Plans for detailed dissemination are limited, except in Burkina Faso, where a number of local and national level workshops will be held in which preliminary findings will be discussed with a range of stakeholders, and strategies and recommendations identified as a result of these discussions. Preliminary results from the Burkina Faso OR have been presented at the Francophone HIV/AIDS conference held in Paris in March 2007. In Uganda, plans to present findings to the National ART Committee and at special stakeholder workshops were mentioned. Additionally presentations will be given at regional and international conferences. In addition to the report that will be produced, there are plans to publish the findings in a local Ugandan journal as well as in some international peer-reviewed journals. There are no definite plans for dissemination in Zambia. The PI and rest of team indicated that there would be a dissemination, but had no timeline in mind. The PI also felt it would be good to bring all the five countries together to share experiences. In the Tanzanian and Malawi broad workplans, dissemination meetings are indicated, but no detailed activity plans exist.

Summary
From the 5 country review it emerged, therefore, that different degrees of wider stakeholder and country level involvement occurred. In Burkina Faso, for instance, a participatory approach was adopted and a large range of stakeholders were involved at every stage of the process; in Zambia, there was limited involvement of people beyond the immediate team that attended the Kampala workshop. On an extremely positive note, all countries expressed a high degree of ownership of their projects, feeling that they were in control of the development of the study themes, the research design and ultimately the use of findings. Similarly, there was a high degree of acceptance that the themes selected for the OR projects were very relevant to national priorities and would, for instance, assist in the development of the Uganda ART policy, input into policies around health providers in Malawi, provide a set of instruments and methods which could be used in national AIDS programmes (Tanzania), and help to revise the guidelines for care and support for PLHA in Burkina Faso. Dissemination plans are just starting and further thought and planning around such events needs to take place.
6.0 Implementation of the project

This section will explore the management of the project, the quality of technical support from WHO and TDR, the timeliness and delays in the project and other challenges the teams faced.

6.1 Management of the project

In all countries generally the different roles and responsibilities of team members was clear; this was facilitated by their relative expertise and institutional affiliations. The amount of time individuals have allocated to the OR (see above) also clearly has an effect on management. In Malawi, the team seems to have been effectively managed and run with the PI, also being head of SWAP MOH, calling for regular consultative meetings. The project coordinator, with 40% time allocated to this project, liaises closely with the 2 full-time social science researchers who are all in the same institute (REACH) and have regular meetings, dividing the work amongst themselves. A team member did feel, however, that REACH could have kept the rest of the team better updated, calling for more regular meetings, even if there is no progress to report. The research members of the REACH office (Malawi) send minutes of meetings and drafts of research instruments to the other team members and to the focal person in WHO Geneva for their inputs. Since all the team members reside in Lilongwe they also meet regularly in other fora and informally.

Whilst in Tanzania, roles of different members of the team are now clear, management at the onset was almost non-existent (see also above). There was lack of time for coordination of research activities, leading to severe delays in implementation of the project. This had to do with the constitution of the team, with both PI and coordinator being senior in NACP. The PI himself commented: ‘I do not understand why they wanted me to take this position of PI – I cannot be a functional PI, because I am too committed.’ As this country OR has just started up again, it still remains to be seen how management will be taken forward. The Tanzania team has since November 2006 started meeting more regularly and the assistant study coordinator reports on meetings and progress.

Uganda appears to represent a success story in terms of management. Due to the consultative way in which the study was developed, there have been many different people involved, which could have presented challenges for management. However, as one team member said, “the chain of command has worked beautifully”, partly because the hierarchy was clearly delineated from the start, and people have understood their respective roles. The full time manager appears to have been very effective, managing the day-to-day details of the project, which has been essential for ensuring continuity and quality field work. This is also reflected in the fact that all aspects of the project have been well documented on an ongoing basis and the team reported regularly to WHO.

The following aspects of the study have been documented:

- Meetings to review data collection methods and tools
- Scientific steering committee meeting, 24th May 2006
- Progress update, 31st August 2006
- Training of field workers
- Pre-visiting sites in preparation for pilot testing
- Pilot testing of data collection methods and tools
- Pre-visiting sites for study
- Phase 1 of data collection
- Data collection supervision
- Progress update, 11th Oct 2006
- Workshop to prepare field workers for the second phase of data collection

The Zambian implementing team is very small, with one person appearing to do the bulk of the work. It was clear that the PI had ultimate responsibility for the study, and he is approached regularly to review and comment on interview guides, on reports, etc. The social scientist sends monthly and quarterly reports to the PI, but the consultant was unable to see the reports. The social scientist did, however, say that everything worked well, she faced no constraints from the
In terms of outside communications, there were severe problems with the team in Geneva not receiving any reports or updates from Zambia, until a trip was made in November 2006.

The management of the project in Burkina Faso changed over time. Initially, the MoH was coordinating the research and financial management was undertaken by the local WHO office. Because of possible biases with the MoH coordinating, in March 2006, coordination responsibilities were handed over to a research institute, on the assurance that the MoH would be kept regularly updated. As well as the full team, a project management team has been set consisting of the PI, the scientific and social science coordinators, a community representative, a co-investigator and a WHO representative. The team meets once every 3 months essentially to review and coordinate research activities. At the time of the review the team had met twice.

Whilst at the start 2 research institutes were involved in the OR, one in Ouagadougou one in Bobo-Dioulasso, communication between the 2 institutes was limited. Difficulties of transportantion between Bobo and Ouagadougou, combined with busy schedules, made it hard for Bobo researchers to attend meetings, and generally limited their participation. “En effet ceux qui ont beaucoup contribué à l’élaboration du protocole et des outils disent n’avoir pas été associés par la suite à la mise en œuvre des activités du projet de RO, car non régulièrement tenus informés du déroulement des activités”.

Reporting to WHO by the Burkina Faso team was carried out through email exchanges; the exchanges consisted of updating WHO on progress of the project and requesting information and support from WHO to resolve challenges and difficulties. A field report was also made available to WHO. Internally, communication also took place through email exchange; this, however, was mostly at the start of activities, as the project progressed communication, according to those interviewed by the consultant, decreased.

6.2 Technical Assistance from WHO/TDR

The support and TA provided by WHO and TDR both from Geneva and from the local offices varied considerably by country. Early on, the WHO HIV Department and WHO/TDR agreed to divide the responsibilities of technical support, so that the WHO HIV Department would work with Burkina, Malawi, and Uganda, while WHO/TDR would work with Tanzania and Zambia.

In Uganda, the local WHO office was involved from the outset, partly because they hosted the conference in 2004, so perhaps they felt increased ownership. The local WHO office even promised a further sum of money in addition to the seed money provided by WHO/TDR. The relationship with the in-country WHO offices were described as “very cordial – we get along beautifully.” “They are facilitating us,” another team member said, “not telling us what to do – we have never had anything forced on us.” The funds for the project, for instance, went through the local WHO offices (though see below for delays), graduate-level interviewers recruited to conduct the field work, were hired through the local WHO office rather than via the MoH or the Public Service to facilitate bureaucratic procedures and the country office also organised the contracting of local vehicles for use by field workers and supervisors. The involvement of the in-country WHO team was also evident as they had a first hand knowledge of the OR and what potential programmatic and policy implications it may have; additionally, they were key informants in the consultant’s review.

In addition to the support from local WHO office, the WHO HIV Department has been providing important ongoing technical support, and when possible, team members from the countries were able to participate in meetings in Geneva, including one on Generic Tools where team members from Uganda and Burkina participated.

Following the Kampala meeting in 2004, the Tanzanian team organised a workshop in early 2005 to discuss and write-up further the research proposals. Two members of WHO/TDR from Geneva were present at the workshop. The WHO HIV country officer had been present at the Kampala workshop and continued to be involved in the OR, assisting with the development of the research proposal, the hiring of staff for the project and organising a 2 day workshop in November 2006 to
review the research proposal. Nevertheless, between early 2005, when technical assistance was provided from both the local WHO office and Geneva WHO/TDR, and the end of 2006, there seems to have been little input from both the in-country and Geneva WHO/TDR staff. Since November 2006, WHO Tanzania has provided additional funds to support the assistant project coordinator; a trip made by a member of the WHO HIV Department served to kick-start the study again, he also provided advice and guidance during the 2 day stakeholder meeting convened to re-plan and discuss the design of the OR. It is also envisaged that another two HIV officers of the WHO office in Dar es Salaam will provide technical assistance during implementation, analysis and dissemination.

In Zambia, there appears to have been little or no involvement from the local WHO office and the PI said that WHO/TDR in Geneva were assisting but only remotely. Generally, it seems there has been little support provided by WHO/TDR both within Zambia and from Geneva; if the team had problems, according to the PI, the steering committee provided them with advice and technical assistance. A trip made by a member of the WHO HIV Department in November 2006 was very much appreciated by the whole team, as he provided guidance and useful suggestions for the next phase. When speaking about WHO/TDR, the PI mentioned them as being “both useless and confused”; he stated that there was ‘confusion’ and it was not clear who the team would report to and who would provide technical assistance. He also said that recently the WHO local office has started asking questions and wanting updates of what they are doing, and they had not been involved before. This has resulted in confusion for the PI regarding to whom he should send reports; he suggests that there is need for WHO to streamline their reporting and communication system. The local WHO offices also mentioned the problems of communications between them and Geneva. Similarly, the local WHO office felt that they could have been more involved from the start.

Like in Uganda, to speed up the process, the WHO office in Malawi channelled the funds for the project and disbursed to REACH trust, the main implementer. The WHO Malawi HIV/AIDS 3 by 5 officer has been actively involved since the beginning by facilitating communications with WHO Geneva and giving technical input during meetings. The team appreciated that they received ongoing support from WHO Geneva: the person responsible was easy to reach, visited the team and gave good and timely input into proposals.

In Burkina Faso, the local WHO office was involved from the outset and continues to be: they are members of both the steering and management committees; they are always kept abreast of progress in the study; they have helped facilitate the research process and have organised missions from WHO Geneva. Initially, the research team had to go through various levels to get feedback from Geneva, thus causing delays; now the team goes directly to Geneva. The WHO team from Geneva, including external consultants have provided valuable technical support from the development of the project to its execution, including reviewing the data collection instruments. A total of 4 visits were made and ongoing support has also been made provided through telephone and internet.…. “ces personnes ressources sont restées présentes tout au long du processus de mise en œuvre du projet ».

In January/February 2007 a consultant (on assignment from the Department of Community Medicine, College of Medicine, University of Nigeria, Enugu Campus), was hired by TDR to provide administrative oversight to the projects on the part of TDR. The consultant made a visit to Zambia; the PI mentioned that he was not quite certain why he was there and what he was supposed to be doing. Later the country consultant for Zambia was told that he helped with the development of the uptake and referral tracking forms and left the team collecting the data. The consultant also made visits to Malawi and Uganda, but after the current OR review was carried out. Visit reports written by the consultant provide summaries updates of the process of OR implementation in the countries.
6.3 Challenges in implementation

**Delays in disbursement of funds**

Other than in Zambia, the main challenged faced by all countries was the delays in disbursing of funds. In Uganda, the disbursement of funds throughout this study has been, as one respondent put it “very unpredictable”, causing delays at several points in the implementation process. The problem started with the initial tranche of $89,000 from Geneva to WHO-Uganda which was delayed because Uganda moved faster than the other four countries in developing their proposal, and the funds could not be released until all five countries were ready and approved. The Malawi OR team witnessed similar problems with the revised proposal being submitted in July 2005 and funds disbursed only in April 2006.

In Tanzania disbursement occurred in June 2006, whilst the OR had been approved by NIMR in August 2005. This delay was largely due to the fact that the WHO Ethics Committee, after reviewing the proposal, found that it needed substantial revisions before granting ethical clearance, which resulted in additional rounds of revisions. This delay led to researchers “doubting whether their abilities are taken seriously”.

In Zambia, problems related to disbursement of funds were not an issue; the PI in fact stated that “WHO was smart as they were to send the money in 2 batches, as of now they have only sent the first disbursement which was enough to carry out the required activities and proved to be more than enough for the activities”. The money were meant to be allocated in two tranches: an initial tranche sufficient to conduct initial activities ($69,986) and a second tranche ($29,994) upon submission of satisfactory progress reports. Funds were not channelled through the local WHO office but went through UTH.

Burkina Faso also faced problems of delays in funding. In order to get round the problem, the research institute coordinating the study was able to advance funds from another budget. The local WHO office also assisted in covering some of the initial meeting costs before the funds arrived.

Part of the reason for the delay in disbursements were related to procedures in place at WHO/TDR where the financial management of the projects was based, the heavy travel schedules of the persons responsible, and the difficulty of expediting matters in their absence. Other reasons, related to local processes in country compounded the problem (see below)

**Burdensome accounting and administrative procedures – WHO and country government**

Two sorts of problems contributed to making the administrative and accounting processes burdensome. One was related to the requirement that money from WHO/TDR be channelled through the local WHO office and disbursed to the MOH; this was not necessarily the best way to go in all settings, especially when the work was implemented by a group that was not part of the MoH, or where the WHO office had some special constraints. The other was related to the fact that some of the implementing groups did not have the cash flow ability to advance money to the project while the administrative processes were underway, so as not to delay the work.

WHO disbursement and accounting procedures posed challenges in Malawi. Once the money was received by WHO Malawi, it had to be spent in the same year (i.e. 2006) – this was not possible since the agreement for performance of work was only signed in August 2006, the quantitative part of the study only got approval in November 2006 and data collection for the second phase will start in early 2007. Another challenge faced by REACH concerns requirements by WHO that they can only release the rest of the funds after the report is finished. However, REACH does not have the money to pre-finance research activities (paying research assistants and consultants, and salary of team members).

The Uganda team also faced complicated bureaucratic procedures, as money had to be first sent to the Ministry of Health from the WHO country office and then on to the research team. The project’s February 2007 progress report summarizes the problem thus: “The new systems are too
involving and not suitable for a research programme involving deployment of field teams where predictability of release of funds is a paramount requirement” (page 5).

Once the funds arrived in Burkina Faso they were initially managed by the local WHO office; the coordinating research institute then had to request for funds via the MoH who then approached WHO. In order to avoid these complicated administrative procedures, the funds were eventually transferred directly to the research institute.

**Delays in implementation caused by…**

**Longer than planned study periods:** Partly as a result of delays in disbursing of funds, the first round of data collection in Uganda was delayed by more than a month and the second round of data collection – initially projected to commence one week after the first round – was delayed by over three months. Similarly, in Malawi the field-work started later than planned causing a loss of momentum and also a need to re-visit the objectives of the research (see below)

**Loss of staff/fieldworkers:** In addition to an unwelcome lengthening of the study period, in Uganda some of the best field workers had found other jobs by the time the second of data collection commenced. Similarly, in Malawi, the delay led to some of the original team members being lost to the project – expatriates left the country, and Malawians went for training.

**Increasing costs** – because of delays, staff had to be updated and field-workers in Uganda had to undergo refresher training after months of inactivity thus increasing costs of the project.

**Reviewing study objectives** - Another result of the delay was that the research questions and design were overtaken by the rapid scale up of ART in Malawi. There were more institutions providing HIV and AIDS services and generally there had been more IEC on HIV and AIDS and promotion of the HCT and ART services. However, the team was flexible and with input from stakeholders they adjusted the proposal.

**Missing key policy events** – In Burkina Faso because of the delays, the findings could not be used by the government during the formulation of the 2006-2010 CSLS. According to one informant: “Il y a eu beaucoup de retard dans la mise en œuvre du programme, ce qui n’a pas permis de prendre les résultats en compte pour la formulation du CSLS 2006-2010. Les résultats auraient également pu orienter la mise en œuvre du TAP car au commencement du TAP il y avait un conflit entre les services de santé et les associations »

**Difficulties in recruiting respondents**

A problem faced by most countries was the reluctance of some respondents to participate. This is a usual challenge in much research. In Uganda, a number of health care providers, especially more senior cadres such as doctors were reluctant to participate in the study. Some were “suspicious”, while others wanted to be given some sort of compensation for their time. “They don’t give easy consent,” one field worker said, “and it takes a lot of time to get them to be interviewed.” A number of clients from private clinics also declined to participate; these include clients at two private clinics in Kampala, who refused “because they are wealthy and expect total privacy.” This was also the case in Burkina Faso, where patients from private clinics refused to participate.

As in Uganda, the research assistants in Malawi experienced some difficulties interviewing more senior staff who were reluctant to spend time being interviewed by a junior; to overcome these difficulties, the more senior members of the OR team conducted interviews with the senior health workers. The issue of incentives was also experienced in Malawi, with some health workers demanding incentives to participate in the study.

In Zambia, the health staff were given incentives to assist with recruitment of respondents, as well as to be respondents themselves. The main constraints the OR team found, however, was the difficulty in recruiting respondents: health staff had limited time, there were always clients waiting for them, thus reducing the time available for discussion. TB patients usually sent their relatives and friends to collect medicine for them; as a result they had few eligible respondents to talk to. It
was also difficult to mobilize TB patients for FGDs as this implied some clients waiting for others to be attended to first before they could join the discussions. The team ended up interviewing more people through IDIs than FGDs and they had to keep returning to the clinics to find respondents and to make repeat or other appointments as the respondents often did not show.

Because most of the facilities included in the study in Uganda operate their ART clinic just one day a week, in order for the teams to complete their interviews, they had to return various times to recruit respondents, thus also causing a time-delay and having cost implications, since field workers sometimes had to travel long distances to reach other clinics in order to avoid redundancy.

**Poor communication and sharing**

Inappropriate communication with participating facilities also sometimes prevented the smooth flowing of data collection. The consultant in Uganda observed a situation in one facility during the first day of a field team’s work there at which the Medical Superintendent had not received the formal introductory letter. Other senior staff had also not been informed of the project, and some were wondering “who these people were as they wandered about” the hospital. Communication in advance had not been adequate in this case, and neither had the formal introduction on the day that work started.

Communication was also an issue in Zambia between members of the OR project team and other researchers in the clinics. Part of the OR project in Zambia involved collecting uptake/referral data. Currently these data are collected by another OR project working in many of the clinics in Lusaka; there is a certain amount of protectiveess over this data. If communication had been better between the managers of the OR projects then this challenge may not have arisen.

**Incomplete coverage of OR projects**

In Uganda, because of the war in the Northern region and other related logistical difficulties, the OR project did not cover this area. Thus the particular difficulties in providing ART in such a situation would not be explored and similarly, evidence derived from this study will therefore not necessarily be applicable there. Because of the inaccessibility of certain sites during the survey period, the team in Burkina Faso were unable to access respondents there. They hope that the qualitative data and the upcoming national level discussion and feedback meetings will help deal with these shortcomings as well as get additional information from the 5 regions in which the OR project did not collect data.

**Summary**

Generally, management of the OR projects worked well, with clearly defined roles and responsibilities. There were some hiccups at the onset, but they were mostly smoothed out over time. Countries, however, did vary in terms of how much they kept WHO Geneva informed of progress as well a keeping wider in-country team members informed. Technical assistance provided by the local WHO offices and WHO/TDR in Geneva varied considerably, with some countries getting more ongoing support, e.g. Burkina Faso, Malawi, and Uganda, than others. Disbursement of funding was a major challenge faced by all teams, except for Zambia. Funding delays, along with unavailability of some key staff, led to delays in implementing the OR, loss of staff, increasing costs, the need to review study objectives and missing important occasions when OR findings could have potentially been very influential. Recruiting of respondents was also a challenge as was identifying appropriate communication channels. Most countries, however, developed strategies to overcome the challenges and continued with their OR projects.
7.0 The GFATM and promoting and funding of research

In the 5 countries, the GF process is different: in Tanzania and Uganda, for instance, the principal recipient is the Ministry of Finance, whilst in Malawi it is the NAC, in the office of the President and Cabinet. In Zambia there are 3 principal recipients: Zambia National AIDS Network for civil society (ZNAN), Churches Health Association of Zambia (CHAZ) for faith-based organisations and Ministry of Finance for line ministries. It appears that the MoH is also a recipient for the health sector. In all the OR countries, there is no formal collaboration between the OR teams and the Global Fund offices. Nevertheless, in some countries, e.g. Burkina Faso, some of the people involved in the OR also sit on various committees organised around the Global Fund.

Generally, it is felt that findings from the OR projects will be useful for the Global Fund. According to the Burkina Faso report:

« Nul doute que les résultats de la RO serviront au fonds mondial à plusieurs titres :

- le fonds mondial contribuant pour la prise en charge de la majorité des patients, une réorganisation/ harmonisation des pratiques de prise en charge améliorera la qualité des services offerts aux patients grâce aux ressources du fonds mondial
- l’expérience acquise dans la mise en œuvre de cette RO va contribuer à mieux formuler les RO entreprises dans le cadre du fonds mondial
- les résultats pourront servir de base pour la formulation des prochaines requêtes. Comme le disait un informateur, la formulation des requêtes nécessite une certaine cohérence et la présente RO va aider à cela
- certaines questions de recherche de la présente RO resteront sans réponse ou feront émerger d’autres questions de recherche qui peuvent être prises en compte au prochain round »

The country reviews also identified two broad areas in which the Global Fund could contribute to OR. The first concerned specific topics that people felt could usefully be studied through OR; the second was related to the broader structural issues that need to be addressed in order to facilitate quality OR work in the country.

7.1 Possible topics for OR

The OR projects have stimulated varying degrees of discussion of research priorities, and in some settings, specific topics were mentioned by different stakeholders in response to the consultant's query. In Uganda researchers identified the following kinds of areas they thought needed further research:

- **HIV Prevention** – With so much focus today on treating people with AIDS – who constitute approximately 1% of the Ugandan adult population – some people felt that the HIV prevention needs of the uninfected general population are being neglected. One respondent suggested conducting a long term general population HIV prevention intervention study, with messages specifically designed for the context of staying HIV-negative in the era of ARVs. The prevention component of the present OR project could inform such a study.

- **Evaluating faith-based work** – Monitoring and evaluation work is ongoing in many ART-providing facilities, but this tends to focus more on ‘how many and how much’ rather than ‘how well’. A medical superintendent, for instance, working within the faith-based sector wanted to know how he could use OR techniques to help understand how best the imams in his area can contribute to the improving ART uptake and adherence. “We are already working with them,” he explained, “but we don’t know well it works.”

- **Collecting data at local level** – Recognizing the problem of poor routine data collection in many clinics, a senior official in the Ministry complained that “we need to change the culture about documentation”. People need training and support in recording particular key indicators: adherence, patient retention, the numbers who have initiated treatment, early warning indicators for resistance, etc.
Standardizing and validating adherence measures – A clinician working on a research programme in Kampala spoke of how the current situation in ART provision and research resembles "a zoo because of the fragmentation of funding… this is the pathology of the donors". One of the outcomes of this fragmentation is that different groups measure adherence using different tools – 3 day recall, 7 day recall, pill counts etc – and as such comparability between sites and different modes of provision is virtually impossible. "If the Global Fund could help gain consensus on a method that is consistent, uniform and sustainable," the respondent said, "this would be helpful."

Similarly, in Zambia, a TB/HIV researcher identified the following kinds of OR he thought was needed, some of which resemble the Uganda suggestions:

- On the ground, there is a problem of data, there is little understanding of what's happening out there. There is need to find out why data is not being collected, what are the issues surrounding collection of data; even if they have the data they don't analysed it; it is related to capacity issues, workload and to synthesise is difficult. There is need for an electronic database which can generate reports.
- There is need for further research on why people are defaulting on ART and TB drugs, what are the characteristics of the defaulters
- There is need to understand better rural and urban differences
- There is need to understand how infrastructure effects uptake and defaulting
- With respect to resistance regarding ART, there is not done much research, especially now with scale-up happening, and as ART is now in its fourth year, resistance is likely to become an issue

In both Malawi and Tanzania, NAC and NACP have formulated research priorities; this was done by organizing national research priority setting workshops. NAC Malawi has published a booklet which contains the research priorities – “HIV/AIDS research strategy for Malawi”; for Tanzania the consultant collected a final draft document ‘Research priorities on HIV/AIDS/STDs of the HIV/AIDS health sector strategy’.

7.2 OR-related structural issues

Simplifying OR proposals to the Global Fund – A member of the former CCM in Uganda explained that application procedures to the Global Fund for OR require a complete protocol, including full details of the funding requirements and other details of the study. This, he said, goes counter to the whole principle of OR, which should be quick to respond to a problem. He therefore requested that the process be made more flexible, permitting decisions on expenditure of a lump sum to be made at national level without the need to engage in detailed discussion with Geneva about each proposed OR project. Otherwise, he said, "we have to navigate the Global Fund bureaucratic system, and then the Ministry of Health system", and this creates significant delays. He acknowledged the need for bureaucracy in order to ensure that money is spent properly, but suggested that there could still be ways to streamline the system. The national sero-survey of 2004/5, for example, hired an accounting firm for the dispersal of funds, thereby allowing quick responses to needs as they arose, but also ensuring complete transparency. A similar model could also be used for the rapid dispersal of Global Fund OR financing.

Establishing a locally-run fund for OR – This point is directly linked with the point above. A senior official in the Ministry of Health explained that much of the AIDS research conducted in Uganda is linked to external interests. There is an urgent need to ensure that Ugandans lead and conduct research that is relevant to Uganda. An official at the Uganda AIDS Commission argued similarly that there should be a fund to support local researchers to focus on priority issues, but that as things stand now, national policy makers cannot commission research because they have no money. There has been a critique in the past that the Global Fund has been financing the drugs – the ‘hardware’ – but has provided little in the way of supporting the system that delivers those drugs – the ‘software’. A locally run OR fund, such as that suggested here, could contribute significantly to improving ARV-related health systems ‘software’ in Uganda.
Money is available but due to lack of capacity is not being accessed, there is need to support the setting up of a AIDS research centre – In both Malawi and Tanzania there is money earmarked for OR as well as for basic research but it is not being accessed. This does not appear to be the case for Zambia, Uganda or Burkina Faso. In Malawi there is an HIV and AIDS research strategy which includes priorities for research, but the problem is lack of local research capacity and therefore lack of proposals being submitted for funding. A solution to the paucity of national AIDS research, as suggested by the NAC in Malawi, is the creation of a national HIV and AIDS research institute. They see such an institute attracting researchers and being an incentive for doctors and social scientists in training to specialise in research. In Tanzania, the NACP has identified priority areas for research and created a taskforce on research; the taskforce had not yet met at the time of the review.

Coordination and communication – A key concern that emerged in discussion with members of all the OR teams, researchers and people based in the Ministries, though to a lesser extent in Malawi, was that they felt they were not sufficiently aware of wider OR developments in the country. The problem exists at all stages of the research process, from study design to implementation to dissemination of findings. This inadequate communication and coordination results in: unnecessary duplication of work, including respondent fatigue; studies that are not focused on national research priorities; and policy-relevant findings that are unknown to policy makers. Whilst individual projects may be sharing findings amongst themselves, they are not sharing amongst the wider researcher community and there is a sense that currently researchers are competing rather than collaborating or complementing each other.

Whilst some countries do hold dissemination meetings of research findings, e.g. recently in Uganda there was a meeting to discuss recent findings on the impact of male circumcision on HIV incidence, these meetings tend to be ad hoc and irregular. In some of the countries, e.g. Uganda a number of bodies already exist that could act in a coordinating role for OR, as well as for AIDS research more broadly. These bodies include: Uganda AIDS Commission, Uganda National Council for Science and Technology and Uganda National Health Research Organization. In Malawi, the NAC does hold national HIV and AIDS research conferences in which researchers present their studies; these perhaps could be built on and made more regular, at specific intervals. In Zambia, a researcher suggested that the Public Health faculty at the University of Zambia could organise on a monthly basis meetings in which researchers present their findings. Another researcher mentioned that there was some talk about the MOH wanting to set up a national research bank in which all research happening in health in country would be listed/identified. When asked why the Zambian NAC could not do this, a researcher said that their role was as an adviser, and whilst they provide a forum for discussion and coordinating research he thought that they have capacity issues and that there were no "experts" there.

This issue of communication and coordination is not new, but the funds have not been consistently available to ensure proper organization. As one respondent in Uganda said, "these initiatives are currently limping because of a lack of funding." The strengthening of existing information-sharing channels is therefore an important gap that the Global Fund could fill. There is need to create awareness around the importance of OR and how it links to programming among GF recipients. In Zambia, ZNAN, which is one of the major recipients of GF indicated that they were not mandated to do research nor provide funds for such and thus did not see how they were relevant in anyway to the WHO OR and other researches taking place in the country.

Improving links between the research and policy spheres- Linked to the above point, and in spite of many countries’ rhetoric that AIDS policies are ‘evidence-based’ and there is a general willingness to use research findings to inform policy, there was a general consensus that links between AIDS researchers and policy makers remain inadequate, that in all the countries, other than perhaps in Malawi, research findings are not communicated to policy makers. A regular forum for discussion between these two groups would greatly benefit the process of evidence-based policy formulation. This could be one area in which the Global Fund could facilitate. Additionally, it is crucial that policy makers have active involvement in OR projects from the start and for the duration of the project.
8.0 Summary, recommendations and elements for successful OR projects

This section is comprised of three sub-sections: the first summarises key findings from the 5 country reports; the second makes some general recommendations; and the final section identifies elements and factors that have been found to produce high quality and relevant OR projects.

8.1 Summary

Quality of research

- All teams consisted of medical and social scientists, but in Zambia, Uganda and Tanzania, the medical scientists took the lead and it was felt that the social scientists were often an add on, being brought in only to advise on the qualitative components.

- A few teams were made up of a large variety of stakeholders, including government, research institutes and NGOs; the research proceeded less well and may have less of an impact in cases where only one institution was represented or in which the OR project remained in the hands of one individual or a few individuals.

- Most countries combined qualitative and quantitative methodologies - with one only using the qualitative; those combining used a phased approach with, for instance, the qualitative informing the development of the quantitative.

- The size and scope of the OR projects varied by country, with some being carried out in a few sites and others covering almost the whole country.

- The quality of the OR projects is varied, with some undergoing rigorous processes of sample selection, training of interviewers, whilst others being less rigorous and therefore results are likely to be of lesser quality.

Relevance and ownership

- The topics of the OR projects differ considerably across countries but are all representative of key areas of national concern and are closely linked to ART scale-up in the countries.

- Local ownership of the OR projects was keenly felt by all teams: they felt they had selected the areas for research, had designed the projects and had implemented them with support from outside but not being dominated by external influences.

- Outside the immediate OR team, there was generally little knowledge about the OR project; this represents a wider problem in which researchers are unaware of similar research being conducted, leading to unnecessary duplication and fragmentation.

- None of the teams have finished collecting the research, with the majority going into the final phase of data collection; as such, study findings are not yet available and dissemination activities have not yet taken place.

- The extent to which findings from the studies will be used to inform programmes and policies is still unclear as findings are not yet out, though there are some initial findings which have already had an affect on programmatic issues.
Implementation

- Overall, management of the OR projects worked well, with clearly defined roles and responsibilities.

- Technical assistance provided by the local WHO offices and WHO/TDR in Geneva varied considerably, with some countries getting more ongoing support, e.g. Burkina Faso, Uganda, and Malawi, than others.

- Disbursement of funding was a major challenge faced by all teams, except for Zambia; once funds were obtained complicated accounting and administrative procedures also caused challenges.

- Other challenges relate to overcommitted and too senior members of the OR team; the need to replace staff incurring increased costs, the need to review study objectives and missing important occasions when OR findings could have potentially been very influential.

- Recruiting of respondents was also a challenge as was identifying appropriate communication channels. Most countries, however, developed strategies to overcome the challenges and continued with their OR projects.

OR and the Global Fund

- Most countries reports identified research themes which could be explored further and could be areas in which the GF could potentially support.

- In addition to the substantive themes, a number of structural issues were identified which if addressed could facilitate OR in-country.

8.2 Recommendations

Below are some recommendations for carrying out OR projects. The recommendations apply to different types of people or institutions, in some cases more than one group can be involved. Also identified below, therefore, is the possible target for the recommendation.

Implementation of OR projects

- In order to simplify disbursement and speed up implementation, there is need for WHO (and in-country governments) and donors in general to re-think more efficient and timely ways of channelling funds.

- To reduce administrative burden and encourage research, there is need for WHO (and in-country governments) to streamline and develop user and OR friendly procedures.

- In order to standardize the type and quality of technical assistance, detailed TORs for those providing TA in relation to OR could be developed jointly by the OR teams in-country and by those providing the TA.

- Careful consideration needs to be taken when selecting an OR team, with some guidance provided from the donors: on the one hand ideally team members should come from the research, implementation (public, private and NGO sector where appropriate) and policy fields and they should be of relatively high status to ensure country ownership and commitment to use of findings; on the other hand, consideration of time and availability of senior actors is essential, and it will be necessary to include more junior members who are dedicated researchers, to ensure the OR process is carried out in an efficient and timely manner.
Capacity issues

- Research capacity has long been recognized as a limited factor in both the formulation and implementation of research. Even where resources are available, people are not applying for it; this is an area which the GF could support. Capacity building could have been included as a core component of the OR projects - most countries trained research assistants/data collectors, but perhaps it could have been more systematic with sharing of new knowledge, skills, etc.; this could be included as a core requirement when reviewing in-country research proposals.

- The dearth of experienced social scientists identified in Zambia is shared to various degrees in other countries; there is need, therefore, to identify and develop a cadre of social scientists who can be drawn on when needed; this is an area which the GF could support.

- In addition to supporting research per se, it is important to support exchanges within the countries, as well as among the countries involved in the OR; this could be through the organization of meetings, exchanges among institutions, visits to other countries/ institutions involved in OR. Such exchanges would facilitate the sharing ideas, methods and tools and contribute to building capacity; they could be included in the specific guidelines for doing OR and funds and/or a budget line be specifically allocated for that.

- In Uganda and Burkina Faso the need for counselling/psycho-social training for interviewers was mentioned, as they often touch on emotional and sensitive issues and yet feel they are not adequately trained to deal with it; guidelines could be developed which specify the attributes needed for interviewers and these could be included in an overall training module for fieldworkers and either funded from within the OR project budget or with outside support, e.g. the GF.

National level involvement and sharing

- National level stakeholder involvement and awareness of the OR projects varied greatly across the countries. The experience in some of the countries provides specific lessons regarding the convening of meetings as part of priority setting, the participation of specific groups of stakeholders in the research, policy and implementation fields, the strategic location of the project (in MoH, local research institute), as well as the selection of members of the OR teams (see also above recommendation).

- In most countries communications between researchers in-country is lacking at all stages of research; fora need to be organised in which findings are shared; additionally an organisation/body could also be charged with compiling ongoing research and ensuring that it is continuously updated; this is a key area in which the GF could lead and support.

- Communications between researchers and policy makers is also lacking in most countries; regular meetings/events need to be organised in which the two groups of people can be brought together; policy makers need to be included at all stages of a research project; similarly, as the above, this is a key area in which the GF could lead and support.

8.3 Elements that facilitate OR processes

Below are the elements and factors which were found to facilitate the execution of high quality and relevant OR projects and that can be used in the future development of OR.
Protocol development
- Protocols should be developed by in-country stakeholders to ensure ownership (all countries)
- In-country researchers, policy makers and implementers need to be involved from the start in the development of an OR project

Multidisciplinarity
- Teams should be multidisciplinary and consist of people from the medical and social sciences
- People from the medical and social sciences need to be involved from the start, i.e. in the development of the protocol to the dissemination of findings and should not only be brought in to carry out certain tasks

Teams
- Teams should consist of people from different organisations and sectors, including research, government, NGO/CBO/FBO implementers, organisation of positive people, etc.
- Sufficient time needs to be allocated to key individuals in the OR team in order to ensure the smooth running of the project; there needs to be at the very least 1 full time member on the team at the beginning of the project and throughout
- Other key members of the team need to have sufficient time allocated for their input and need to ensure that they can commit that time to the project
- Roles and responsibilities need to be clearly identified for all members of the team
- Sufficient training needs to be provided for all field teams

Methodology
- A combination of methods qualitative, quantitative and participatory should be encouraged
- Selection of sites needs to be carefully carried out in order to ensure representativeness and rigour

Implementation
- Momentum needs to be kept going, once a project starts it should not stall but progress through to the end
- Challenges need to be minimised, i.e. funds need to be disbursed quickly and efficiently, staff loss should be minimised, delays in fieldwork should be minimised
- Reporting requirements need to be rigorously specified, i.e. time-lines identified for narrative and financial reports, reporting structures, etc.

Technical Support
- Needs to be ongoing, timely and responsive to need
- Guidelines could be developed identifying what kind of TA is appropriate

Use of research findings
- In order to ensure evidence is taken up and used, the teams need to consist of, or be supported by people from different organisations, but also be supported by people who have an influence with policy makers
- Stakeholder involvement is also crucial at all stages to ensure evidence is used
To end it is worth stressing again that due to the very nature of OR with its central focus on informing programmes and policies as they are developed, implemented, monitored and evaluated, timing is of the essence, i.e. evidence based messages need to be passed on and shared with relevant stakeholders at timely occasions and in appropriate fora. This is especially the case in relation to OR on HIV/AIDS and in particular ART, which is a fast moving and continually changing field. In order for this to occur, OR projects need to benefit from efficient implementation from the identification of topics of research, to the release of funds, to the reporting, monitoring and sharing of findings.
References


Annex 1 Questions for Review of OR 5-Country Project

This document is designed to be used as a guide in collecting information about the implementation of Operational Research in the 5 countries that were included in the project. It lists the information to be collected about each country project, and provides questions and interview guides that are to be used when speaking with different groups of informants in each country. The document will need to be adapted to each setting, and it is not necessary to adhere strictly to the format and questions below, but it would be good to try and cover the same territory across all sites in order to facilitate comparisons.

There are 3 overarching questions to address for each country:

**Quality**: Do you think this is a good research project that will yield solid evidence?
**Relevance**: To what extent does the project fulfill the goal of linking evidence to programs?
**Implementation**: How was the project managed and implemented? What were the worst difficulties in implementation? What worked well?

These 3 questions can in fact be asked to key informants, at the conclusion of the interview.

An open question can also be added:
If there was one thing [if there were 3 things] you could do to improve the whole of this OR process – from proposal formulation to field work to subsequent policy development – what would it be?

There are two sets of items included, the first is largely factual information about each project, that needs to be gathered only once at the outset; the second are questions to be addressed to different groups of key informants. These are grouped into sections. Team members would be able to answer most of the questions, other groups of respondents can deal with subsets as indicated below.

**Largely Factual Information to gather about each project**

The most efficient way to do this is to obtain this information through a meeting with the research team itself. The information will be used as a reference and for comparisons across projects. It includes:

**Information about the team**
1. Tell me about the team:
   - number of members → enough people to implement?
   - backgrounds (CV) → adequate representation of skills (skills related to research, HIV, management, other)
   - research experience, experience in writing research protocols
   - division of responsibilities → clear division of tasks?
   - percent on project → is there enough time for the project
   - time on project, changes over time → continuity
   - financial and technical oversight

2. Do you have the tools to do the work?
   - computers
   - internet access
   - access to journals
   - access to information from similar projects, if needed
   - other needs?

3. Is the team linked with other groups of researchers? Knowledge of research and researchers in areas related to the project
**Information about the project** (obtain/ review documents, checklist of meetings, reports etc.)
- The protocol
- Reviewers' comments
- Ethical clearance
- Interim reports on the work, including financial and technical reports
- Sites, sampling, and logistics of data collection
- Research instruments
- Data collected
- Reports of stakeholder meetings

**Questions to Team Members**

These have to do with the team, the management of the project, the topics and methods selected, links to stakeholders, local ownership, and relevance. The questions can be addressed to team members individually or as a group. The questions can be adapted when speaking to new vs. old team members, and individuals who were associated with the project at first but did not continue to be involved.

Some of the sections can be used for gathering information from interviews with other types of respondents (see below)

1. **The team**
   - How were the teams selected and put together?
   - What influenced this process? What do you think of the result?
   - Do you think there is a good balance between research and programs? Between different sorts of research/disciplines?
   - Is the team right for the project? For other OR projects?

2. **Management of the project and technical assistance**
   - How do you think this project has been run?
   - Budgeting, reporting, payment of services, transportation etc
   - Delays, difficulties? What were they due to? How were they resolved?
   - Exchanges with WHO, with TDR over the life of the project thus far; quality of support/guidance received, and changes over time
   - How do you view WHO's role as a partner in this work (i.e. as an equal partner, or as a top-down authority, or…)?
   - What have been the key lessons learned during the day-to-day field research? What difficulties have been faced and how have they been tackled? What difficulties – if any – remain unresolved?

3. **The topic and methodologies selected**
   - How did the team come to select the topic? What influenced the selection?
   - How did the protocol get written? Did the team do it themselves or get assistance from elsewhere? What would have been the "ideal" method to write the protocol?
   - How were the different methods selected?
   - Do you think the project balances research and links to programmes? Why or why not?
   - Is this work actually connected to interventions? Are there discussions of this work between researchers and program people?

4. **Links to stakeholders and relevance to local situation**
   - Does project refer to current situation, keep up with developments? Does project take account of MOH concerns?
   - Has been the interest on the part of national level policy makers in the OR process to date? Are there regular contacts with MOH?
- To what extent were other country stakeholders (NACs, government staff, other researchers working on the issues), consulted in the development of the protocols? If so, how did they influence the protocols, if not why not?
- Is there any other ART OR ongoing in the country, or is any planned? Who is conducting it, who is funding it, what topics is it addressing? Are you connected to them?
- Have you been in touch with colleagues involved in Global Fund proposals? Do you know about the process? (When interviewing GFATM colleagues, the question can be phrased: Did you know about the OR project etc)
- How have the various stakeholders worked together? Has there been broad agreement on most issues? If not, what have been the contentious points, who has disagreed, why have they disagreed (other unrelated political and professional issues may be involved), and how has any resolution been brought about?
- Have there been any moves towards programmatic decisions as a result of any preliminary findings that have emerged from the OR projects? If so, what form have these moves/decisions taken, who has led the process, have they met with any resistance, and if so from whom and why?
- Plans to share results with local colleagues—interim, final, other? What kinds of dissemination events have happened/are planned?
- Do you hear about any success stories of OR in the country that can inspire this work?

Questions to Various Stakeholders, including MOH

All questions from sections 3-4 above.
Additional questions specific to MOH and stakeholders:
- Did relevant stakeholders at national level know about this process, i.e. those involved in the GF processes, those involved in 3x5 scale-up how known was this process, etc.
- How well do you think the selected topics reflect country priorities?

Questions to Researchers in the Country

Sections 1, 3, plus the first 3 questions from section 4
Additional question:
- Do you think this is a good project that will yield useful and solid evidence?
- Do you think this project will "make a difference?" Why and how? What will need to be done with the results?

Questions to Colleagues who have been involved in Global Fund Proposals

Questions from section 4, adapting the phrasing to refer to Global Fund stakeholders, and the extent to which there have been exchanges between the OR team and Global Fund.
Additional question:
- How can such a project feed into future work of the Global Fund?
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