

Operational research in support of antiretroviral therapy scale-up

Lessons learnt workshop and
product development team meeting
7-9 July 2008



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Lessons learnt workshop
and product development
team meeting for
operational research projects
in support of antiretroviral
therapy scale-up

Geneva, Switzerland, 7–9 July 2008

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Abbreviations

AIDS	acquired immunodeficiency syndrome
CBO	community-based organization
aOR	adjusted odds ratio
ART	antiretroviral therapy
HIV	human immunodeficiency virus
IR	implementation research
NGO	non-governmental organization
OR	operations research
PDT	Product Development Team
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
WHO	World Health Organization

Executive summary

In 2004, the World Health Organization (WHO) and the Special Programme for Research and Training in Tropical Diseases (TDR) began to develop an operational research (OR) process in support of the scaling-up of antiretroviral therapy (ART). After an expert consultation in July 2004, involving participants from various countries and disciplinary backgrounds, three guiding principles of the research were established: a multidisciplinary approach, country ownership of the activities and links to implementation and policy.

At a workshop in December 2004, five selected country teams – from Burkina Faso, Malawi, Uganda, the United Republic of Tanzania and Zambia – began to develop research proposals aimed at examining ART scale-up among HIV patients and HIV-infected health-care workers.

Following data collection, analysis and documentation of the results, country reports were reviewed in early 2008. In July 2008, a three-day meeting was held in Geneva, Switzerland, bringing together members of the research teams, WHO and TDR staff, and members of the Product Development Team who had guided the country research.

This meeting report summarizes the findings from the country OR projects, reviews the lessons learnt in the research and reflects on how to take the OR agenda forward.

1. Introduction

In July 2008, a three-day meeting was convened to review the operational research (OR) process that was initiated in 2004 by the World Health Organization (WHO) HIV/AIDS department and the Special Programme for Research and Training in Tropical Diseases (TDR). The overall aim of the meeting was to reflect on the process and draw lessons for future implementation of OR projects. The meeting brought together members of the five country teams who had carried out the research, members of WHO and TDR who had been present at the initial meetings in 2004 and members of the Product Development Team (PDT) who had been tasked with, among other things, guiding the research in each country. In particular, the meeting objectives included:

- reviewing findings from the country OR projects
- providing suggestions on how to finalize the studies and relevant documents
- reviewing lessons learnt for dissemination to other countries, and
- discussing follow-up studies and plans for next steps.

2. Background to the OR process

The OR process was initiated in Geneva, Switzerland, in 2004 when a group of experts were brought together by WHO and TDR to brainstorm on key OR topics that would link to the “3 by 5” initiative. A follow-up meeting was held in Kampala, Uganda, at which five country teams were invited to start preparing OR proposals, guided by the experts. Proposals were prepared on the understanding that US\$ 100 000 seed money would be made available (from WHO/TDR and the Global Fund to Fight AIDS, Tuberculosis and Malaria) to each of the country teams.

The research proposals were framed by a set of three guiding principles:

- the research had to be multidisciplinary;
- country ownership was essential, with a range of stakeholders being involved from the outset;
- the research had to have clear links to implementation and policy, and would not be carried out in a vacuum.

The country teams then returned to their home countries and finalized the proposals. These proposals were reviewed by the PDT and, following approval by the WHO Ethics Review Board, data collection and analysis were carried out in the five countries. The timescale for carrying out the research varied in each country due to a variety of reasons and difficulties faced by some countries.

Following data collection, analysis and documentation of findings in the five countries, country reports were submitted to the PDT for review in early 2008. The July 2008 workshop was an opportunity not only to present the research findings to the other country team members but also to reflect on and respond to the PDT comments. The meeting was therefore an occasion to review the lessons learnt in the projects and reflect on how to take the OR agenda forward.

3. TDR's new vision, OR research Framework and from "3 by 5" to universal access

Since the original discussions in 2004, TDR has developed a broader focus on infectious diseases of poverty. TDR is also now decentralizing to regional offices and hubs – a process that was welcomed. Some people, however, had not been aware that TDR is a WHO-executed special programme co-sponsored by the United Nations Children's Fund, the United Nations Development Programme, the World Bank and WHO.

A framework for operations and implementation research in health and disease control programs (Global Fund, 2008) has been developed by a wide range of partners, led by TDR and the Global Fund, to serve as a primary reference for people who plan and carry out operational or implementation research (OR/IR) in order to improve the implementation and management of disease control and other health programmes. The overall approach is that of a framework that helps researchers and programme managers identify the steps needed to set a research question and then work through the steps of research design, implementation, management and reporting, ultimately leading to the use of the findings to improve health policies and programmes in order to attain the desired impact.

The scope of OR/IR is defined as:

Any research producing practically usable knowledge (evidence, findings, information, etc.) which can improve programme implementation (e.g. effectiveness, efficiency, quality, access, scale-up, sustainability), regardless of the type of research (design, methodology, approach), falls within the boundaries of operational research.

The document includes a wealth of information (e.g. a 16-step method and management flowchart, OR resource toolkit, funding sources) that will be updated and expanded in future editions.

Since starting the five-country OR projects, there has been a large increase in human immunodeficiency virus (HIV) treatment coverage (the "3 by 5" target of 3 million people on antiretroviral therapy (ART)¹ was reached in 2007), which brings its own challenges, including more people in need of second-line treatment and associated higher costs. Women have better access to treatment than men, and although children's access to treatment is increasing, obstacles still remain.

It is necessary to continue to recognize the importance of integrating research on prevention and treatment. But there is a change of emphasis now, from "treatment" to "response."

In terms of this five-country OR, there needs to be a focus on inter-country learning. Related to this, a publication strategy should be considered, which goes beyond the five individual country reports.

3.1 Issues emerging

The importance of looking at the integration of HIV with tuberculosis (TB) and malaria programmes was discussed; this has to be seen as a basic package. There is also a need to integrate HIV with other programmes.

The issue of disclosure of HIV status among discordant couples was raised; as more people go onto treatment and become well again, the numbers of discordant couples are likely to rise.

¹ The target was to provide 3 million people living with HIV in low- and middle-income countries with ART by the end of 2005.

Since 2004 new interventions have arrived on the scene, including male circumcision. The potential roles of such new interventions needs to be explored.

Task shifting is now being widely discussed, but concerns were raised by the meeting participants that there was too much focus on this issue and that it cannot answer all the questions as there is still a need for someone to whom to shift the tasks. It was pointed out that this is just one of many health systems issues to be addressed.

The issue of people presenting for testing and treatment too late was discussed and also that they wait too long before starting treatment. Stage 4 patients who start treatment late sometimes die from complications and many are lost to follow-up. There is a need to stabilize patients first, before starting them on ART.

3.2 Implementation of OR projects

The OR teams were unclear about what technical support would be provided to finalize the OR process. More broadly, clear guidelines relating to what kind of technical support would be provided in the projects are needed.

It was felt that there had not been enough interaction between countries, with little opportunity for countries to discuss the OR process on their own (without WHO). Intermediate meetings would have been useful as well as contributing to capacity building, such as workshops at country level.

The issue of the low level of funds was raised, given the fact that costs for OR projects are high.

Many national treatment programmes are too busy to carry out research and have difficulties in finding partners for their day-to-day work and research activities. It was noted that the Global Fund is a good source.

Research institutions have traditionally focused on hard-core science. Integration of communities into programmes has been lacking.

A lack of behavioural scientists in the studies was pointed out. Training should be skewed towards social science and social scientists need to be more influential in the projects. All countries had social scientists involved, but the levels of involvement varied. Some were brought in for specific projects; others were leading the qualitative work, but were not involved across the board.

It was difficult for other researchers to get access to information from the research teams; these challenges were not overcome. Clearance was needed from the programme managers. There is a need to get clearance so that those holding data can release them to other researchers.

Ownership of data is a complex issue. Whose data belong to whom? To be used for what purpose? When are data shareable?

4. Review of in-country OR processes²

Before the OR projects in each country were completed, a review of the processes was commissioned as a joint exercise by WHO and the Global Fund. The review had the following three objectives:

- assessing how the process functioned in each of the five countries;
- assessing how it connected to other stakeholders involved in OR and;
- drawing out lessons for future efforts to include OR in Global Fund proposals.

Managed by WHO, a team of local and international consultants were hired to undertake the five country visits, and to produce five country reports as well as an initial overview report.

The review focused on three overarching issues:

- quality of the research project, in terms of teams, research design and research capacity;
- relevance, in terms of country involvement and ownership and relevance to policies and priorities and;
- implementation, in terms of management, technical assistance from WHO/TDR and challenges.

Topic guidelines were developed around these three themes and in each country the same sets of issues were raised and the same questions asked. Using semi-structured interview formats, the country consultants interviewed: members of the OR teams; representatives of ministries of health; other researchers working on similar issues; members of the local WHO offices; members of the Global Fund country coordinating mechanisms; and respondents of the OR, e.g. health staff. Secondary material was also collected.

4.1 Quality of the OR projects

In terms of quality of the research projects, the review found:

- a range in size of teams (from 5 to 14 members);
- only in two countries (Malawi and Burkina Faso) did teams include a wide mix of organizations (governmental, non-governmental (NGO) and research institutes);
- while all teams consisted of highly qualified and appropriate representatives from the medical and social sciences, the medical sciences tended to dominate;
- all studies used cross-sectional design and all, except Zambia, which used quantitative and qualitative methods;
- there was wide variation in terms of sampling and breadth of research, ranging from rigorous sampling techniques to more purposive and convenient sampling; quality control, data management and quality of data also varied considerably, with some countries (e.g. Uganda) having rigorous systems and a specifically assigned person, while others were more random and haphazard;
- all countries (except Zambia) trained fieldworkers and carried out close supervision. Though researchers had knowledge of other similar research, links between them were rare (except in the United Republic of Tanzania).

² For further details, see Samuels et al. (2007) and Annex 3, section A3.1.3.

4.2 Relevance of the OR projects

The findings of the review showed, especially in Malawi and Burkina Faso, extensive involvement of different stakeholders at all stages, from development of the protocol to the design of instruments and discussions of findings. At the other extreme were cases where no stakeholders beyond the immediate research team were involved or knew about OR. Nevertheless, all countries reported high levels of national level ownership and all themes were key areas of national interest and concern.

4.3 Implementation of the research

The review found that in most of the countries the roles and responsibilities of different members of the OR teams were clear. The support from WHO/TDR was much appreciated, but the reporting and communication channels between in-country WHO offices and other stakeholders were found to be confusing.

Challenges faced by the teams included:

- delays in disbursement of funds;
- burdensome accounting and administrative procedures;
- delays in implementation which led to, among other things, longer-than-planned data collection periods, loss of staff/fieldworkers, increasing costs and a need to review the study objectives since the studies were overtaken by events.

The review concluded by suggesting which elements contribute to successful OR projects:

- Protocol development and topic selection should involve a range of different stakeholders at all stages in order to increase ownership, and to facilitate implementation of and feedback to programmes.
- A combination of methods – qualitative, quantitative and participatory – should be encouraged and rigorous data collection (including quality control), data entry and data analysis plans should be developed.
- Teams should be multidisciplinary; social scientists should be involved from the start and not only brought in to carry out certain tasks.
- Teams should consist of people from different organizations/sectors; members should be of relatively high status to ensure interest at national level.
- Detailed implementation plans should be developed to include piloting of instruments, training of fieldworkers, quality control and data management.
- Reporting requirements need to be rigorously specified and funds need to be disbursed quickly and efficiently.
- Technical support needs to be ongoing, timely and responsive to need with clear and open communication channels; and guidelines should be developed to identify what kinds of technical assistance are appropriate and available.

5. Key findings from country OR projects

5.1 Burkina Faso – Treatment and care practices among people living with HIV in Burkina Faso

5.1.1 Objectives

The overall aim of the project was to improve coordination between NGOs and public health care facilities providing care for HIV-positive people. The specific objectives were to:

- identify and test strategies regarding definition of the “package” of acquired immunodeficiency syndrome (AIDS) care and treatment;
- improve the performance of the programme in order to ensure treatment scale-up, by identifying applicable consensual strategies and;
- improve collaboration between public, private, faith-based, NGO and community-based organization (CBO) health providers.

5.1.2 Methodology

A highly participative methodology was used at all stages of the OR process. The project had three phases:

1. reviewing literature on access to ART in the country;
2. analyzing and evaluating the key questions in relation to ART (access, adherence, quality of life, coordination) and;
3. developing strategies on how to conduct the study.

Quantitative and qualitative methods were used. EpiData and SPSS 11 were used for processing quantitative data; qualitative data were analysed manually.

5.1.3 Key findings

The study was carried out in 26 facilities and included 740 patients. The majority of the patients sampled were female (79%); 35% were widows. Most patients (80%) received ART free of charge. Medical visits were free of charge in all the health facilities, but the costs of laboratory tests depended on the type of facility (they were free of charge in faith-based facilities; in other facilities, costs could be up to US\$ 6 per examination).

Treatment practices and follow-up

For patients undergoing ART, an initial assessment was made, comprising complete clinical examination and biological test (CD4 count). The periodicity of follow-up visits varied. As physicians did not respect appointments, patients frequently went to the facility for antiretroviral drugs, but were unable to be seen by the physician for physical examination.

For patients not undergoing ART, the frequency of their visits to the facilities depended on their symptoms or the clinicians' availability.

Adherence

Based on self-reporting, the level of adherence was 91% during the three days before the survey. Some 8% suspended ART for at least two days since starting treatment; 9% stopped their treatment

in the week preceding the study. A total of 17% modified the time of treatment (i.e. they did not take the antiretroviral drugs on time).

Community support

Some 29% of patients received a home visit – the majority did not want a visit, because of the risk of disclosure of their HIV status. A total of 79% had participated in support groups; 43% had received nutritional support; only 7% had income-generating activities. There was no legal support for patients.

Conclusions

- High levels of adherence were considered to be as a result of the contribution of NGOs and CBOs.
- In terms of universal access to ART, most patients live in poverty and access to laboratory tests is a large problem.
- Some clinicians are involved in facilities in more than one sector during a day; the limited number of clinicians is an obstacle to scaling-up ART.
- The study did not involve private facilities, but these facilities are important in scaling-up ART.
- Patients had to be mobile, in order to look for services.
- For patients not undergoing ART, follow-up is not standardized.
- It was difficult to manage the many investigators, programme managers and people living with HIV who were involved in the project.
- Public health managers require rapid results, but OR takes time.
- The research requires more money if a meeting for investigators and for all stakeholders is to be held.

5.1.4 Capacity building, dissemination plans and next steps

Capacity building

Senior and junior investigators worked together, thus building the capacity of the latter. Institutional capacity also occurred: research has become institutionalized, with an increase in the ability of institutions to carry out research and to use OR for policy development. As a result, the research institute in the country has gained through conducting the research and conveying the results to policy-makers.

Dissemination plans and next steps

Three regional meetings were organized (November–December 2007), a national meeting was held in June 2008, and a symposium that included neighbouring countries was also held in June 2008, with funds from Canada.

Discussions were held with the national AIDS programme concerning AIDS policies, especially access to ART, and the involvement of private facilities. The results of the study were used by the national programme to improve collaboration with the private sector.

Results of the study have been presented at the following meetings:

- French AIDS meeting, Paris, France, March 2007 (two posters on patients' mobility and access to ART);
- AIDS Impact, Marseille, France, July 2007 (two posters on adherence and access to ART);
- International Conference on AIDS and STIs in Africa, Dakar, Senegal, December 2008.

One article has been submitted to *AIDS*; three other articles are in preparation.

The research has already improved the response to AIDS in the country. The researchers found that 80% of patients received treatment free of charge, while 20% paid. They also learned about what happens in the private sector. The findings also raised new research questions, e.g. how to improve care in the private sector.

5.1.5 Discussion among meeting participants

Role of the private sector

The private sector works outside national programmes in Burkina Faso. This sector is important, with many patients choosing to attend private health facilities for reasons of confidentiality. In the public sector, there are specific facilities for certain diseases; if a person attends an HIV facility, they are seen to be HIV-positive. In contrast, in the private sector it is not known why a person is attending, as they are not seen to be visiting for a specific disease.

It is important to monitor the private sector, as problems with adherence and development of drug resistance can arise if they are not involved.

User fees

A health user-fee policy is in place in the country. Stakeholders in the Ministry of Health have listened to others, including the current OR team, on the issue of free access and it has already been discussed at policy level.

Possible future work could explore the effect of user fees. The public/private mix could also be examined further, as well as other financing strategies.

Implementing OR

As OR is a process, unlike some other types of research, there is no imperative to wait until the end of the research to use the data. The goal is not the research itself, but improving the quality of services.

The idea of twinning research institutions with ministries of health was raised; this could be something that TDR could kick-start.

It is important that countries decide on the topic they want to research. It was suggested that regional hubs be created, with the ministries of health acting as sensors to see what countries need and work with them to meet the needs.

OR looks outside programmes – e.g. young postgraduates could be involved. This builds capacity and improves performance.

Funding is never enough. The increased price of oil has greatly increased other costs. TDR makes adjustments where possible, but this is dependent on donors.

Multidisciplinarity

Many disciplines were represented in the research (health economics, medical epidemiology, sociology, anthropology and public health), as well as people living with HIV. However, this was not easy to manage. Priorities differ and there was disagreement, e.g. about sample size and type of approach (qualitative versus quantitative), making it generally difficult to reach a consensus.

Multidisciplinarity is a continuum, not a binary event. It is not simply a matter of having more than one discipline in a team; there is a need to integrate diverse experts more fully in the research.

Roles of different kinds of stakeholders

NGOs are strong in Burkina Faso and links were set up through this project between the Ministry of Health, the research institute and NGOs. There is a need to consider the comparative advantages of different kinds of stakeholders. If there are many NGOs, it is impossible to include them all. Only the most appropriate ones should be involved. The roles of different NGOs need to be defined and decided on collectively before the community is involved. Coordination meetings should be held, to decide on how to proceed.

5.1.6 Future OR projects

Three proposals were suggested:

- looking at the link between prevention of mother-to-child transmission programmes and treatment programmes, for the treatment of mother and child and the wider family. It was noted that there could be potential problems with this: e.g. would women inform their partners of their HIV status?
- decentralization of ART in health centres. This would need to be considered in the light of any ART scale-up plan;
- factors affecting children's adherence to ART.

5.2 Zambia – Uptake of ART among TB patients and prevention of mother-to-child transmission of HIV clients

5.2.1 Objectives

The overall objective of the OR in Zambia was to increase uptake of ART among TB patients and prevention of mother-to-child transmission clients. Specific objectives were to:

- determine the current rate of uptake of ART among TB and prevention of mother-to-child transmission clients;
- identify the constraints to accessing ART among both types of clients;
- identify and evaluate existing strategies for scaling-up of ART among both types of clients;
- formulate, implement and evaluate appropriate strategies for scaling-up ART among both types of clients.

5.2.2 Study sites and methodology

The study was carried out in Lusaka (because of its high prevalence of TB) and in Mumbwa, 100 km west of Lusaka (in order to obtain a comparative semi-rural perspective). In Lusaka, the study sites were six urban clinics: Kalingalinga, Chelstone, Chainda, Chipata, Kamwala and Chilenge. Selection of these clinics was purposive, taking into account their well-established TB clinics, ART clinics and prevention of mother-to-child transmission programmes. In Mumbwa, data were collected from the two health institutions that provide services to the entire population in the district and surrounding communities.

The study used a qualitative approach, consisting of in-depth interviews and focus group discussions. Respondents were adult men and women who were on anti-TB treatment at the time of the study and pregnant women attending antenatal clinics. Lay community health workers and nurses working with these clients were also interviewed as key informants. Purposive sampling was used to select all

participants. Data were collected over a period of four months from July 2006 to October 2006. Further information was obtained from an audit of the TB and prevention of mother-to-child transmission register in order to triangulate with the data from the interviews.

5.2.3 Key findings

Uptake of ART among TB patients

Perceptions of TB health care workers

Statistics on TB patients testing HIV-positive and accessing ART were not available, despite a recently introduced form designed to capture this information.

Relatives of TB patients often collect drugs on behalf of patients; thus direct contact between health care workers and TB patients is usually lost.

The number of nurses trained in TB management is inadequate. The workload of the TB nurses was overwhelming, resulting in the recommended guidelines for TB management not being strictly followed and possible candidates for ART not being captured.

Health workers at the TB corner view counselling for HIV as separate from their job or from what they were expected to do; this results in an extra task that was not paid for.

In Mumbwa, both the patients and the health personnel seemed to lack information on TB and its relationship with HIV/AIDS; health workers expressed concern that little information on HIV/AIDS and TB reaches them.

Patients' perceptions

Patient interviews identified stigma as the main problem they face in the community: TB patients were openly told that they were soon to die of AIDS. It was for this reason that many people were hesitant to visit the health care centre once they started showing TB symptoms.

The respondents believed that denial was worse in men than in women. Men suffering from TB preferred sending their partners or other dependants to get drugs for them and would never be seen at the TB corner after being tested positive for TB. This attitude was blamed on the perceived association of TB with HIV and the stigma associated with these. For the women, their major concern was lack of support from their partners if they are diagnosed with TB.

Fear of being found to be positive inhibited most people from being tested for HIV. The only reason that would force patients to take an HIV test was when they were not responding to anti-TB treatment or they had a TB relapse. The patients who were open about their HIV status were those who knew that they were positive before contracting TB.

Informal discussions were conducted with personnel in ART clinics to determine how patients who are on both ART and anti-TB treatment cope with the treatments. They reported that the main complaint they receive from patients is that they have to take too many drugs.

Observations by the facilitator

TB corners are designed to be in an open space in order to avoid cross-infection. However, there was no privacy or confidentiality, since everyone can see and hear what is happening.

The shortage of TB staff resulted in some patients staying in the clinic for many hours waiting to be seen by health staff.

Some TB patients were turned away because their area of residence was not included in the catchment area of the facility.

Conclusion and recommendations – TB

1. TB corners should provide a degree of privacy to patients; by ensuring an adequate airflow, this can be done without placing health workers at risk of contracting TB. Infrastructural changes may be required to ensure the safety of health care workers and privacy for clients.
2. More health personnel should be trained in TB management so that there is no lapse in services when the TB nurse is not available.
3. Record keeping needs to be improved urgently. The newly introduced TB cards have not been adequately used to capture the HIV status of patients. Collaboration between the TB clinic and the ART clinic is also important in order to establish the total number of patients attending both clinics.
4. Attitudes of health personnel towards patients should improve; stigma towards TB patients was observed in some health care providers.
5. For patients to be adequately monitored by health personnel, they should be encouraged to go to the health centre, as opposed to sending another individual to collect drugs on their behalf.
6. HIV counsellors should be attached to the TB corner so that patients are given adequate counselling. The importance of being tested for HIV must be properly explained to them.
7. There is need for more sensitization in the communities.

Uptake of ART among prevention of mother-to-child transmission of HIV clients

Perceptions of prevention of mother-to-child transmission of HIV by clients

Focus group discussions revealed that women were being forced to take an HIV test without being adequately prepared. According to them, they went to the health centre to seek antenatal services, not HIV testing. Some pregnant women were reported to have never attended antenatal clinics for fear of being requested to have an HIV test.

The fear of being denied antenatal services was the main reason the women tested for HIV; hostility of health care providers was reported among clients who declined to take the test.

Breaking the news of an HIV-positive result was ranked high among the problems that the women faced. Most partners were said to be hostile to the subject of HIV, often rejecting and abandoning their HIV-positive partners.

Reluctance to be tested was also a result of economic vulnerability: pregnant women who knew about the need to use infant formula if they were found to be HIV-positive did not see the benefit of starting prevention of mother-to-child transmission since they knew that they would not be able to sustain the infant feeding regime due to their economic situation.

As for TB, mothers in the semi-rural town of Mumbwa had little knowledge of prevention of mother-to-child transmission.

Observations by the facilitator

Group counselling is employed in the prevention of mother-to-child transmission clinics in Lusaka: women attending antenatal clinics are given pre-test counselling in large groups of 50 or more. After this they submit their blood for HIV testing and are given post-test counselling as a whole group. The results are given in privacy but in an extremely hurried manner.

Women who are found to be HIV-positive are referred to the ART clinic; depending on the stage of the illness, they are either placed on ART or they are monitored. However, scrutiny of records showed major disparities between numbers being sent to the ART clinic and those who are actually attended to. The explanation from the ART clinic was that a good number of women who are referred do not proceed to the clinic. The other reason given was that those who are not yet eligible for ART are not recorded as having attended the clinic.

The main observation in prevention of mother-to-child transmission clinics in Mumbwa was a critical shortage of personnel.

Conclusion and recommendations – prevention of mother-to-child transmission

1. Counselling of couples should be encouraged; it is hoped that this will protect pregnant women from abandonment by and blame from their partners.
2. Group counselling should be done in smaller groups.
3. Lay counsellors should be employed to assist health care workers, as the clinics are usually understaffed.
4. Staff retention should be an option considered in future plans. Most of the shortcomings in provision of prevention of mother-to-child transmission services are blamed on inadequate staffing levels.
5. Strategies more suitable to the Zambian environment should be formulated. Interventions that have worked in other settings may not be applicable to the Zambian setting.
6. Women in vulnerable economic situations are unable to make independent decisions without compromising their means of livelihood.

5.2.4 *Capacity building, dissemination plans and next steps*

The OR team identified the need to increase the number of social scientists working on such projects in Zambia.

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The Zambian team has been closely working with the Malawi team. A joint meeting was held and technical assistance was provided by the Malawi team.

In terms of further capacity building, it was suggested that more training of MSc and PhD students was necessary, as was more training of nurses (also in relation to task shifting). Similarly, institutional capacity building is needed: sites need to be upgraded and the capacities of HIV programme laboratories needs to be further increased.

The Ministry of Health intends to disseminate the results; once this has happened, the results can then be published.

5.2.5 Discussion among meeting participants

Country ownership and uptake of results

The OR team pointed out that the Ministry of Health was pleased with the research and accepted the findings as they were from internal researchers. As a result of the study, the Ministry developed a white paper on research.

The issue of hostile treatment of patients by health workers has been taken up by the Ministry; which has included such issues in their human resources plan. This is not just related to HIV, but to a larger holistic approach. Staff have been retrained, but there is a need to assess the outcome of the training.

Children

Data on children were not collected, as this was not part of the research proposal.

Data management

Data management is a problem, not just in Zambia; but in Africa generally. Poor record-keeping did not allow the OR team to meet its objectives. There is a need for an information management system with correct and complete recording – this would be important for future research. The team mentioned that a course on data management for line managers (trainers of trainers) has been carried out, though an evaluation of this training has not yet been undertaken.

Privacy and confidentiality

TB corners exist because of the need to control TB infection, but the lack of privacy is a problem.

Lack of confidentiality can result in women avoiding antenatal clinics altogether. Thus there is need to consider what recommendations can be made to encourage privacy and confidentiality; similarly, health systems need to be able to address these issues.

Donor and political interest

In rural areas of Zambia where donors and politicians are involved in HIV care and management, knowledge of HIV is good. In other areas, it is not. In Mumbwa, the Health Minister is the Member of Parliament for that area. As a result, attitudes have changed. But it is difficult to generalize as the findings are relevant only to the specific sites. High-burden areas were chosen, as it was not possible to undertake a nationwide survey.

Intra- and inter-country learning

It was suggested that further learning, sharing and exchange between countries should have happened and can happen in the future.

There has historically been fragmentation of research in general in Zambia, with researchers not knowing what others were doing. Now there is a national research conference organized by the Ministry of Health. All studies should be registered and the results disseminated.

At the 2004 Kampala meeting, it was suggested that a review of research be carried out at that time. It could be useful to know what research is going on now.

Coordination

It was pointed out that clearly defined reporting channels are necessary to ensure the smooth running of OR projects.

5.2.6 Future OR projects

The fourth objective of the current study (to formulate, implement and evaluate appropriate strategies for scaling up ART among both types of clients) could not be realized in the timeframe.

Short-term training could be provided to:

- improve data management;
- improve the patient referral system;
- train lay counsellors and
- evaluate interventions, to determine their impact.

Quantitative data on the training (e.g. number of people trained, number of patients treated before and after the training) could be collected. It was noted that relevant tools are available (e.g. from Horizons, Population Council).

The Ministry of Health was keen to improve the TB/HIV network.

The involvement by communities participating in the studies could be looked at further, to assess their influence in reducing stigma.

5.3 United Republic of Tanzania – Evaluation of an ART adherence measurement tool in the context of the Tanzanian health care system

5.3.1 Objectives

The broad objective of the study was to establish and document factors that influence adherence to ART in the United Republic of Tanzania. Specifically, the study documented the actual and perceived socio-demographic and clinical factors enabling or limiting adherence to ART.

5.3.2 Study sites and methodology

This study was conducted in eight health facilities selected from the 91 facilities accredited by National AIDS Control Programme to initiate antiretroviral care and treatment in the country. These were: Bugando Referral Hospital, Kahama District Hospital, Oysterbay Hospital, TMJ Hospital, Morogoro Regional Hospital, Masasi District Hospital, Igogwe Mission Hospital and Muheza Mission Hospital.

Qualitative methods were used to collect data and included focus group discussions, in-depth interviews and structured observations. Respondents included people on ART, health workers providing HIV/AIDS-related services and treatment supporters. The focus group discussions and in-depth interviews were tape recorded and research assistants wrote a summary of each session on the same day. In total, 208 individuals (80 males and 128 females) participated in this study.

5.3.3 Key findings

Factors that enable or limit patients' adherence to ART are categorized in the following subgroups: individuals, health systems and the community.

Individuals

The majority of participants in this study mentioned that patients who have effective treatment supporters are more likely to adhere to the treatment. The treatment supporter reminds patients to take the antiretroviral drugs at the right time and consistently; prepares food for them; provides support when they fall sick; and discourages them from engaging in behaviours that could jeopardize their health (drinking alcohol, having unprotected sex, working too hard or becoming pregnant).

The relationship between patients and the treatment supporters varied greatly. Treatment supporters could be spouses, friends, relatives, village home-based health care providers, spiritual leaders or a fellow patient on ART. However, most respondents did not have treatment supporters.

Poverty was another factor mentioned by the majority of study participants as affecting adherence to treatment. Specifically, they spoke about not having enough food with which to take their antiretroviral drugs and related to that, being unemployed. Lack of money to pay for transport to hospital was also linked to inability to adhere to ART.

Misconceptions still persist: some people on ART did not see themselves being “cured” and thus stopped taking the treatment saying, “These drugs are so strong ... You need to be rich to adhere to the directives they [the health care providers] give us ... I am afraid, the drugs will kill us ... not HIV or AIDS ... Sometimes, I give myself a break [not taking the drugs] ... When I find it necessary I take them [antiretroviral drugs] for some time” (interview, Mbeya, February, 2007).

Disclosure of HIV status was positively associated with adherence; patients who had disclosed their status to a member of their family or community, or were members of associations of people living with HIV, reported having no problem in taking the drugs even if there were people present whom they did not know.

Several patients, treatment supporters and health care providers reported that some patients skip doses when they experience side-effects such as stomach ache, diarrhoea, dizziness and loss of appetite or when they are using medications for treating opportunistic infections and other health problems.

Stigma is still evident among family members, in the community, and among health care providers, though findings on the health personnel were mixed, with the majority of informants observing that health care providers were friendly and supportive. Stigma inhibits people from seeking voluntary counselling and testing, it results in failure to disclose an HIV-positive status and it interferes with the coping process and hence limits adherence to ART.

The patient’s ability to track the trend of his or her CD4 count was identified as one of the factors that influences adherence to ART. The majority of respondents knew their CD4 changes, a factor which encouraged them to take the drugs as recommended by the health care providers.

Health systems-related factors

While public health facilities provide HIV/AIDS-related services only two days per week, clients who experienced problems were free to see the doctor on any day.

Time spent at a health facility ranged from 10 minutes to several hours. People who had recently started ART spent longer in the clinic than those who had been undergoing treatment for a longer time. It was observed that spending a long the time at the clinic had a negative impact on patients’ adherence to ART.

Shortages of antiretroviral drugs, drugs to treat opportunistic infections and other supplies (e.g. laboratory reagents) were reported to be common in the public facilities. Clients served by private facilities reported that there had been no such shortages.

Assurance of privacy (physical, visual and audio) and confidentiality increases good adherence to ART. The majority of people on ART and their treatment supporters were comfortable with the privacy and level of confidentiality provided. However, they were suspicious that some health workers leak patients' information. Observations by the team found that files for patients on ART were a different colour (yellow) from those of other outpatients' files. Health care providers observed that the rooms allocated for their activities were not soundproof. In addition, the level of interruptions (including telephone calls) during counselling or consultation sessions was high. All these factors are likely to compromise privacy and confidentiality.

Many of the health facilities studied did not have machines for CD4 counts; those that did often had low capacity, had technical problems or had broken down. In such situations, the health workers have to send blood samples to the nearest facility, resulting in delays in registering qualifying patients on ART.

All health workers, the counsellors in particular, complained of the heavy workload, associated with working in the HIV/AIDS clinic often being another task added to the already overburdened health workers.

All the health workers interviewed had undergone training that was conducted and funded by the Ministry of Health and Social Work through the National AIDS Control Programme. All found the training very useful, enabling them to work confidently.

The majority of health workers reported that they take precautions and operate very carefully and as such do not perceive themselves to be at risk. Whenever they have doubt, they use preventive creams or prophylaxis or take post-exposure prophylaxis.

Community level

The majority of respondents observed that stigma, which is still rampant among community members, is the major factor limiting people living with HIV from adhering to ART. Fear of stigma can be understood at three levels: the individual, family and community levels.

Both members of the community as well as family members perceive and label people living with HIV as "deviants" from the traditional and religious sexual norms, resulting in isolation, rejection or segregation of people living with HIV. This kind of labeling inhibits individuals from seeking voluntary counselling and testing services. Those who have tested positive may also feel compelled to keep their status a secret, including from spouses and partners, and avoid seeking social or adherence support or follow-up by the health system.

Deeply rooted religious beliefs among some communities were reported to limit patients' adherence to ART. Some religious groups perceived HIV and AIDS to be a punishment from God due to wrong behaviours. In their view, God is the only solution to every problem, including HIV and AIDS. Hence, turning to God for cure is mandatory. They consider that individuals with HIV should be "born again" and must fast and repent as a curative process.

RECOMMENDATIONS

The following recommendations emerged from the study.

1. Further research is needed on some issues emerging from this study. Information to be generated could facilitate Phase III (Intervention) of this project by including topics such as:
 - The increasing stigma towards people living with HIV by health care providers and its impact on adherence to ART.
 - Strategies to reduce waiting time at the clinic, i.e. how can client flow be increased at the antiretroviral drug outlets? Negotiating with the clients on ART an appropriate time for refill or for next appointments could be one of the approaches.
 - What strategies could be used to keep health workers providing HIV/AIDS-related services motivated as a means of reducing the level of burnout observed among them and movement from the rural and hard-to-reach areas of this country?
 - Determining the types and levels of stigma towards people living with HIV among the community and health workers;
 - Establishing strategies for appropriate and effective ways of coordinating HIV/AIDS activities at all levels to reduce confusion and workload currently shouldered by HIV and AIDS health care providers.
2. There should be an evaluation of the messages and models used in training health care workers and in counselling people living with HIV on the nutritious foods to be taken by patients on ART.
3. Effort should be made to make antiretroviral drugs available to patients in the rural and hard-to-reach areas of the country.
4. Frequent supportive supervision visits should be implemented at all levels.
5. The National AIDS Control Programme should plan and conduct training programmes (initial and refresher) for health workers providing HIV/AIDS-related services.

5.3.4 Capacity building, dissemination plans and next steps

An adherence forum has been initiated involving a range of stakeholders; one meeting has been held and another is due soon. Among others tasks, the forum is reviewing the adherence component of their training manual.

The research team has plans to carry out a study on viral load. There was considerable discussion at the workshop on the value of measuring viral load given the costs.

The team is also moving into Phase III of the study. The intervention pilot has been started; it explores how to strengthen the system for patient appointments and tracking. The protocol has been developed and sent for ethics clearance. The study will involve control sites, baseline measurements and follow-up for seven months.

Funds from the Global Fund have been received by the Tanzanian team to pursue this OR project further.

5.3.5 Discussion among meeting participants

Viral load

There was some contention regarding the potential utility of viral load measurement and other adherence tools in determining the level of adherence at HIV care and treatment centres. The consideration was to evaluate the utility of other adherence measures (e.g. pill counting, etc.) against quantitative determinants

such as viral load. It is anticipated that the expense of carrying out viral load measures would be absorbed by the existing care and treatment centres.

An alternative view suggests that other factors could be used to evaluate and measure adherence. These would include socio-economic factors, e.g. barriers to access, stigma and cultural and religious issues. However, it would be important to relate these approaches to quantitative evaluations of adherence by provided clinical and laboratory screening methods.

It was agreed that there was no strong basis to suspect that different social factors would be associated with adherence in different settings. The consensus of the meeting was to focus on one manageable area within the identified care and treatment sites.

Role of traditional healers

It was suggested that traditional healers could be involved in Phase III; in Zambia, for example, traditional healers have been successfully involved and were acting as referral points. In the Tanzanian pilot study, traditional healers were currently not involved, but the idea was considered to be a good one.

Others suggested caution in involving traditional healers in this way, as they may have other motives and may be in competition with the programme. Using people living with HIV and community health workers would be more appropriate. The issue of possible toxicity between traditional medicines and ART was also mentioned.

Stigma

Although stigma was not analysed quantitatively in the study, it was still viewed to be a problem. Nevertheless, things are slowly changing, especially following a national campaign on HIV testing that was launched by the President in which both he and his wife were tested. This campaign has helped to reduce stigma, but it is not yet known if this will last or if this is a temporary effect. Generally, political leadership is important in such aspects.

Confidentiality and privacy

It appears that a bill was passed in Parliament last year in which health workers who release data on HIV status are to be penalized; the bill has yet to become operational.

Food security

The issues of food security and links to nutritional programmes were raised. According to the team, the Government has taken the policy that there would be no food handouts. Giving food to HIV patients and their families would result in impossible numbers. But the Government does provide counselling on which foods will improve their nutritional status.

More generally, it was pointed out that the World Food Programme is working with national programmes to give people on ART access to food. It was found in Zambia, for instance, that adherence to anti-TB therapy was affected by lack of food. Studies are under way that look at the benefits of food versus cash transfers: if the person is very sick, provision of food is preferable, but if the person is able to work perhaps the cash transfers are better. An individual can then choose what to do with the money, e.g. whether to buy the kind of food they prefer, whether to exchange it for something else or even to invest it.

It was also pointed out that the collection of food from programmes providing supplements can be a source of stigma, as often people associate food handouts with people who are sick and/or who are

HIV-positive. It may be better to empower citizens; providing cash transfer means that they are given responsibility, which may be more empowering than the provision of food.

Children

The issue of ART adherence in children was raised. HIV-positive children are often orphaned, looked after by stepparents or grandparents who may not care as much for them as their parents would have. More studies are needed in this area.

5.3.6 Future OR projects

The researchers are ready to bring in a larger team to carry out future OR activities:

- The Phase I trial should be finalized.
- Phase II should be continued, with follow-up of patients.
- The findings from the Phase I trial could be used to look at health systems factors that affect adherence (e.g. the frequency of clinic days, length of waiting time, privacy issues, workload and task-shifting). Clinical outcomes such as weight gains would be used.
- The effect of missing appointments could be assessed.

It was noted by the participants that the time for ethics clearance in the countries and in WHO should be factored into the projects. It would also be important to learn from other countries' experiences. Involving traditional healers has worked in other places and the reasons for this could be examined.

5.4 Malawi – A study to determine the challenges for accessing HIV and AIDS prevention, treatment, care and support services among health care workers in Malawi

5.4.1 Objectives

The study set out to investigate factors that lead to use and underuse of HIV counselling and testing, post-exposure prophylaxis and ART services by health workers in Malawi. The study set out to achieve the following specific objectives:

1. Exploring health workers' knowledge, attitudes and perceptions about HIV counselling and testing, post-exposure prophylaxis and ART in Malawi;
2. Investigating factors associated with use and underuse of these services by health workers in the country;
3. Determining the extent to which health workers practice universal precaution guidelines and to investigating factors influencing their actions and
4. Recommending to the Ministry of Health and its partners interventions that can lead to more health workers using the above-mentioned services.

5.4.2 Methodology

The study used both qualitative and quantitative research methods. The qualitative study was carried out in two districts and a total of 45 in-depth interviews were conducted with health workers and key district-level informants. Interviews were taped, transcribed and analyzed using a framework analysis approach. The quantitative study used a cross-sectional research design and a three-stage sampling methodology. A total of 906 respondents in eight districts were interviewed. Findings from the qualitative

study were used in the development of a questionnaire. Quantitative data were double-entered and analyzed using Epi Info v.6.04b.

5.4.3 Key findings

In the quantitative study, 58.6% of respondents were female and the majority (47.9%) were nurses; in the qualitative study, the largest group of respondents (20/45) were health surveillance assistants, of whom 13 were female.

Most health workers (96.8%) felt they were at risk of contracting HIV through occupational exposure. Nurses, clinical officers and patient attendants were perceived to be most at risk. Some 39.8% of health workers reported experiencing an occupational injury.

In the qualitative study, most respondents observed that occupational exposure to HIV brings anxiety and stress and is like facing a death sentence. Due to fear of occupational exposure to HIV, health workers reported that they fear offering care to people living with HIV.

While some respondents felt that post-exposure prophylaxis could effectively prevent transmission of the virus after occupational exposure, most respondents were sceptical, either due to lack of knowledge about post-exposure prophylaxis or saying that there was no concrete evidence to demonstrate its effectiveness. Results from the survey showed that out of those who had experienced an occupational injury in the past 12 months ($N = 349$), only 12.3% accessed post-exposure prophylaxis.

Regarding HIV testing, the qualitative study indicated that few health care workers had ever gone for counselling and testing. However, from the quantitative results, most health workers, 76.1%, reported having had an HIV test. The commonly reported factors motivating health workers to take an HIV test included: just to know their HIV status, occupational exposure and for marriage purposes. Most respondents felt that it is more difficult for a health care worker to access HIV counselling and testing than it is for other people. Some 69.3% of respondents ($N = 879$) indicated that health workers face challenges when they want to access such services, while 30.7% stated that health workers do not face any challenges when they want to access these services. Lack of confidentiality and fear of stigma were the most cited barriers health workers faced in accessing HIV counselling and testing.

Among the health workers who had not had an HIV test, the major reasons for failing to access HIV counselling and testing were not being ready for a test and fear of stigma after testing positive.

In the course of the study, 41 health workers voluntarily disclosed their HIV-positive status. Out of these, 30 (73.2%) were on ART while 11 (26.8%) had not started treatment as they were not yet eligible. Lack of confidentiality was a frequently mentioned challenge for health workers' access to ART services. In the qualitative research, several challenges faced by health workers in accessing ART included unavailability of special ART services for health workers (health workers are required to queue with other general patients), fear of stigma and lack of nutritional support.

Study participants were asked some questions to elicit information on stigma. The analysis showed that 17.2% ($N = 895$) had observed fellow health workers giving less care or attention to patients with HIV or suspected of having AIDS, and 27% reported testing a client without seeking his or her consent.

The study showed that most health workers were knowledgeable about HIV/AIDS, HIV counselling and testing and ART. However, most respondents displayed poor knowledge about post-exposure prophylaxis, especially those of the lower cadres. It was clear from the results that post-exposure prophylaxis was a

relatively new issue among most health workers in Malawi. A relatively small proportion had accessed this service.

While the qualitative research showed that most health workers had not had an HIV test, the survey revealed that most health workers had gone for counselling and testing. Most health workers who indicated that they had not yet undergone counselling and testing pointed out that they had not done so due to lack of confidentiality and fear of stigma. It is clear that stigma is prevalent among health workers. A considerable percentage of health workers showed stigmatizing attitudes towards people living with HIV. The results also show a considerable percentage of health workers observing other health workers displaying stigmatizing attitudes towards people living with HIV.

Although it could be said that most health workers are in a better position to use ART than members of the general public, caution might be needed, as it is recognized that health workers are not a homogenous group and that the study has shown that health workers face challenges in accessing HIV/AIDS services. Therefore health workers still need to be targets of interventions, especially as data on HIV prevalence among health workers are not available.

RECOMMENDATIONS

- There is a need to work towards creating an environment where health workers can be open about their HIV status without fear.
- Efforts being carried out by the Nurses Association of Malawi, encouraging health workers to support each other in the face of HIV/AIDS, should be encouraged.
- Efforts aimed at supporting health workers currently on ART as well as those not yet eligible for treatment should be enhanced. Most health workers on treatment expressed concern that their salaries are not enough for them to maintain a healthy diet and meet other day-to-day needs.
- There is a need to enhance training and discussion and encourage the use of protective equipment among health workers, emphasizing the need not to be selective in practising universal precaution guidelines by assuming that some patients are HIV-free.
- More health workers of higher cadres need to be trained to provide HIV counselling and testing services to health workers who are uncomfortable accessing such services when they are provided by health surveillance assistants.
- The possibility of establishing special HIV/AIDS services for health care workers should be explored. Such efforts could be modelled on the wellness centres in Swaziland, where health workers have separate HIV/AIDS services. The implementation of this would partly depend on health workers' openness among each other, as it will be the same group of health workers providing the HIV/AIDS services.
- There should be different counsellors for different categories of health care workers to ensure that senior health staff access HIV counselling and testing.
- There is a need to explore the possibility of enhancing self-testing; creative thinking is needed about how self-testing could be implemented to ensure that the counselling aspect is not ignored.

5.4.4 Capacity building, dissemination plans and next steps

In terms of capacity building, the research has led to two team members pursuing their master's degree at a local university. More broadly, institutional capacity has been enhanced as has been the capacity for possible future implementation of OR projects.

The study findings were presented in May 2007 at the national HIV and AIDS research dissemination conference. Presentations were also made at the implementers conference in Marseille in 2007, and

at the International AIDS Conference in August 2008. The team also presented its findings to the REACH Trust annual dissemination meeting in September 2007 and submitted abstracts to the 2008 International Conference on AIDS and STIs in Africa. Additionally, the team has plans for publications and has identified three possible papers on HIV testing and counselling, stigma among health workers and post-exposure prophylaxis.

5.4.5 Discussion among meeting participants

Difference between qualitative and quantitative results

Findings on some issues appear to differ considerably between the quantitative and qualitative data, e.g. uptake of HIV counselling and testing. It would be useful to pull out the differences, further exploring, for instance, variations according to gender, age, and clinic. This could be the next phase of research. Currently, there are no obvious gender differences, but further exploration might reveal some.

Workplace and post-exposure prophylaxis policies

A workplace policy for the care of carers is currently being developed, but most health care workers do not know about the content and its implementation has been slow, being left mostly to NGOs to implement. The Government has made no effort to make the policy known.

There is a policy on post-exposure prophylaxis; workshops are held on this, but are not working well. Health care workers providing ART understand the issues better. Lack of post-exposure prophylaxis facilities in peripheral facilities is a problem. This service is currently being decentralized but further decentralization is needed.

Even if there is a workplace policy, health care workers fear losing their jobs if they are found to be HIV-positive. Health care authorities have no policies in place to protect their health personnel. HIV-positive health care workers can be openly exposed to patients with TB. A strategy is needed for HIV-positive health care staff; they need to be stratified, for instance, by facility and exposure to risk. While task shifting has promise in this regard, it does not solve everything.

Needs of health workers

Special health care services could be developed for health care workers, where they could get their treatment (for whatever their condition may be) and then go back to work. This would reduce the need to travel for treatment. The Ministry of Health provides a monthly allowance to HIV-infected health care workers for nutritional support.

In terms of self-testing for HIV, although it is not allowed, it was recognized that some health care workers self-test anyway. If the self-test is positive, however, the person cannot have post-test counselling. This is a challenge, but OR should be able to help to deal with this issue.

Importance of HIV counselling

Counselling has benefits as it prepares a person to receive the results. If a person is found to be HIV-positive, there are referral services. Counselling is carried out to encourage new behaviours, for treatment for opportunistic infections and for ART support services. If there are insufficient numbers of counsellors, it puts stress on the counsellors.

But how much HIV counselling do health care workers need? Abridged counselling could be considered in some settings. A shortened version of counselling would need to be pilot tested.

In the United Republic of Tanzania, many people came forward for testing; they did not want to have counselling. Millions were tested and no one committed suicide; emphasis was placed on post-test counselling. Counselling is a process; it may not have an effect on behaviour.

Specific counselling for HIV can actually increase stigma. But root causes of stigma need also to be addressed.

Use of mobile telephones

The possibility of using landline and mobile telephones to improve treatment adherence was discussed since the telephones could also be beneficial in terms of confidentiality. Although mobile telephones have been shown to help with adherence, it was questioned whether they are an upcoming tool. In the United Republic of Tanzania, telephones are currently used only to track patients if they do not attend an appointment. It should be remembered that having a telephone line will not necessarily help reduce stigma.

Importance of recommendations

There is a need to turn what has been found into ideas that decision-makers can move forward. It is also important to examine whether the data support any recommendations. For example, it is easy to state that health care workers need training if they are not doing what they should, but is there any evidence that the training has an effect?

Dissemination and use of findings

Meetings have been held with multiple stakeholders (e.g. civil societies, NGOs and the Ministry of Health), which will have direct implications. There was some resentment at the start of the research, as the issue of health care workers was not seen as a major concern, but as the research progressed interest grew. There was also interest from the media. There is still keen interest among stakeholders, e.g. GTZ. There has not yet been a meeting to discuss the issue of health care workers with policy-makers, due to limited funds. It was pointed out that in Burkina Faso, the Phase III presentation within the country was part of the project and had been budgeted for; but for the regional meeting, funds had to be obtained from Canada.

It was noted that funding often stops after data collection, and there are insufficient funds for analysis and dissemination.

The possibility of pulling together a special issue of the *Bulletin of the World Health Organization* on OR was discussed. The TDR communications team will look into the communications strategy within WHO and also at country level.

5.4.6 Future OR projects

Future OR projects would be part of an ongoing process.

- *Adherence*
 - Issues that affect adherence would be examined. Some 4000–5000 patients would be recruited to obtain basic data on health-seeking behaviour.
 - The role of traditional healers and religious groups would be examined.
 - People who drop out of treatment would be identified and the reasons for the drop-out examined.

- *Health care workers*
 - The challenges should be defined and discussed with policy-makers (e.g. lack of basic materials for carrying out universal precautions).
 - For the training of health care workers, the researchers should work with the country's nurses' associations.

It was noted that many different issues were raised. All were important, but they would need to be prioritized. Outcome measures should also be clearly defined.

5.5 Uganda – Adherence to ART and integration of HIV prevention into AIDS care: a situation analysis of different ART programmes in Uganda

5.5.1 Objectives

The objectives of the study were to:

- Determine the levels of ART adherence among ART patients across multiple ART programmes;
- Determine the levels of integration of HIV prevention into AIDS care programmes and HIV prevention behaviour of ART patients across programmes;
- Identify modifiable factors associated with suboptimal ART adherence and risk-taking sexual behaviour by ART clients and;
- Identify the adherence support mechanisms and HIV prevention strategies that exist in various ART programmes in the country.

5.5.2 Site selection and methodology

A cross-sectional research design was used in which 2285 exit interviews were carried out with ART clients and 389 service providers in 86 facilities. Some clinical data were also abstracted from clients' medical records. Semi-structured questionnaires were used, adapted from the WHO generic tools project (see WHO, 2006). Facilities were sampled from the central, western and eastern regions, excluding the North and West Nile regions. Data were entered in an Epi Info database and exported to Stata version 9.0 for analysis.

5.5.3 Key findings

Two thirds of respondents were women and the median age was 38 years (37 years among women, 40 years among men). About 80% of clients were on free ART, i.e. they were not paying for their antiretroviral drugs or associated laboratory tests.

Adherence to ART based on a composite score of the 3-day self-recall and the 30-day visual analogue was 89% (95% confidence interval: 87.7–90.2). The pattern of ART adherence varied little across subgroups of respondents based on ART service delivery modes and other covariates. Older respondents – adjusted odds ratio (aOR) 2.0 (1.12–3.53) – and those not working for a salary – aOR 1.8 (1.31–2.57) – were more likely to adhere.

Clients subscribing to non-Christian/non-Muslim religions or to no religious group had suboptimal adherence, aOR 0.6 (0.41–0.86), just like those who had not disclosed their HIV status to partners, aOR 0.6 (0.35–0.98).

Females were not only over-represented in ART programmes but adhered better, aOR 1.4 (0.98–1.85).

Sub-optimal adherence to ART was associated with complex regimens, > 4 pills per day, aOR 0.7 (0.46–0.95) and triple single-dose combinations, aOR 0.6 (0.43–0.88).

Adherence was better in programmes that offer free ART services, aOR 1.4 (1.00–1.87) and those run by non-religious NGOs, aOR 1.6 (1.01–2.56); those run by institutions such as the military and prisons had suboptimal adherence, aOR 0.5 (0.27–0.99).

No previous treatment interruption due to shortage of money, aOR 1.8 (1.15–2.84), and no treatment interruption ever, aOR 4.2 (3.12–5.62), were associated with better adherence.

Side-effects, especially those affecting physical appearance, sexual activity and mental state, were also associated with suboptimal adherence.

Individuals who had never disclosed their HIV status to their partners were far more unlikely to adhere to their treatment than the few who had ever disclosed it, aOR 0.6 (0.35–0.98).

Most programmes provide HIV prevention education; however, provision of HIV prevention services such as provision of condoms, referral for partner HIV testing, prevention of mother-to-child transmission, etc., was suboptimal.

While most clients were sexually active, with more than 62% having recently had sex, about one third last had sex with a non-spousal partner, and about 19% had a history of multiple partners.

Although condom use was reportedly high, with 81% having used a condom at last sex, only half of the clients used one consistently.

About 82% had disclosed their HIV status to their most recent sexual partner. About one fifth of respondents indicated that their partners were serodiscordant, i.e. HIV-negative. However, only 37% indicated consistent use of condoms with their serodiscordant (negative) partners.

Conclusions and recommendations

1. Most programmes in Uganda had high ART adherence and integrated HIV prevention; however, most programmes were still recent and should be monitored closely for sustained high levels especially as chronicity of treatment sets in.
2. Subgroups of clients with suboptimal adherence, such as younger clients, those in employment, and non-Christians/non-Muslims, should not be excluded from ART; instead they should constitute the focus of adherence support measures.
3. ART-related factors associated with suboptimal adherence, e.g. complicated regimens, should be considered during ART roll-out and selection of ART regimens.
4. Programmes should pay special attention to the frequent interruption of treatment, which was mostly due to failure of the ART supply chain management system.
5. Religious and traditional misconceptions about ART, such as “miracle cures,” witchcraft and herbal cures, should be addressed in the ART information, education and communication strategy.
6. The under-representation of men and their relatively low levels of ART adherence remains unexplained and should be explored in future studies.

7. Roll-out of ART should continue across all modes of ART service delivery and all levels of facilities. However, institutional and private, for-profit clinics need additional support, e.g. linkages with social support groups.
8. Integration of HIV prevention into AIDS care should involve actual provision of prevention services and should address the HIV transmission behaviours of ART clients, particularly non-condom use among HIV-discordant couples, multiple and casual partnerships and non-disclosure of HIV status to partners.
9. The suboptimal adherence among clients who had not disclosed their HIV status to partners can be attributed to lack of family-centred support for this complex and life-long treatment.
10. Women predominated in practice of HIV transmission risk-taking behaviour. More than one third of sexually active women had recently had sex with boyfriends or cohabiting or casual partners. More than half indicated that they do not consistently use condoms. Nearly half of women with HIV-discordant partners indicated that they sometimes engage in sex without condoms. This finding needs further exploration.

5.5.4 Capacity building, dissemination plans and next steps

Further analysis of the qualitative data is under way. The research has been presented at the national AIDS conference and at the national preventive committee.

There is no publication plan yet, but there is a need to consider the writing-up of the study findings.

5.5.5 Discussion among meeting participants

ART versus prevention

This research has shown that as ART increases, preventive measures decrease, e.g. condom use. Other studies have shown the opposite (for example, Eisele et al., 2008), in which people on antiretroviral drugs become model citizens.

A reason for the decrease in preventive measures could be that when people start on ART, their health is quite poor; women may be widowed or abandoned by their partners. As their health improves, they get new partners or their old partners return. They often then decide that they want a child. Despite intensive counselling, they think that they cannot infect others any more.

Additionally, as ART increases, complacency also increases, leading to increased numbers of infections.

Understanding the adherence rate used

There was discussion of the interpretation of adherence rate. The use of composite scores is a rather strict measure of adherence: a person has to pass on all scores to be adherent. It is thought by some not to be ideal, as it is not clear who is adhering to what.

Possible reasons for lack of adherence

- Lack of one-to-one counselling (on antiretroviral drugs, lifestyle and other necessary information) may lead to lack of adherence. In institutions (e.g. prisons, the military and the police), there is no counselling.
- In church-based or private settings, a mixture of healings, prayer and treatment does not lead to optimal adherence.

- The social support provided may be insufficient to ensure adherence.
- Alcohol use might affect adherence.

Difference between men's and women's condom use

Women in new relationships may have less power than men to negotiate. They have little control over male condom use. This issue needs to be looked at further.

The reproductive health options for HIV-positive people must be considered. Their right to have children should not be forgotten.

Conclusions

Caution is needed regarding conclusions related to treatment guidelines and ART adherence and treatment interruption. WHO is reluctant to modify the current 2006 guidelines on treatment, which maintain certain first-line drugs and certain second-line drugs. If ART is started early, this can lead to immune reconstitution inflammatory syndrome and unregulated levels of liver enzymes (resulting clinically in inability to swallow tablets). There are currently five clinical trials under way looking at modification of the guidelines.

There is a need to consider the policy implications regarding ART adherence and treatment interruption. Some drugs require less adherence than others. There is a need to rationalize the capacities of the health system; treatment interruption has been used with success.

There are two considerations:

1. There is a need to be conservative in how many patients are treated.
2. If the entry point (CD4 cell count) is increased, there will not be enough drugs or a sufficient infrastructure to manage the massive numbers of patients this would lead to.

HIV discordance

Uganda has the highest levels of HIV discordance in sub-Saharan Africa, but no one has looked at the reasons for this. There is a need to look at the link between ART adherence and sexual activity and the implications of successful treatment, when viral levels are very low. Discordance over time should be looked at: will the HIV-positive person infect their partner? If so, could this have been prevented if their status had been known earlier?

Interview environment

How is the interview environment in such research projects controlled? Each in-depth interview can be considered to be unique, but the environment can potentially have an effect on the interview.

In the Ugandan study, the environment depended on the context, with interviews being held under trees, in churches, in classrooms and in health facilities (if a room was available). In Malawi, when health care workers were interviewed, the research team had access to private rooms. Interviewing patients was a big challenge. In the United Republic of Tanzania, the research team was able to use secure rooms. In Zambia, interviews were held in a corner of a large hall, though this was not always suitable, and in Burkina Faso, a wide range of places were used.

Intercountry learning

The Uganda OR team has regular meetings through the Great Lakes Initiative. There has, however, been no opportunity yet to reach other countries.

5.5.6 Future OR projects

There is a need to focus on adherence and social support, in partnership with other organizations.

Other issues raised that could be examined were:

- sexual education programmes
- the need to motivate male clients: can programmes improve the adherence of male clients?
- high-risk behaviour of women
- HIV-discordant couples
- children's adherence to treatment

It was noted that there is a need to find out what other research is being carried out in the country. This applies to the other countries too.

A number of small projects (3–5) were thought preferable to one large project.

More needs to be known about the particular epidemiology of HIV in Uganda – e.g. there is a need to determine the number of discordant couples. Such data could be linked to, for example, condom use.

6. Common themes between the countries

Several common themes emerged from the studies:

- Most of the respondents have common problems.
- Women on ART often become pregnant. This is sometimes a demonstration of wellness rather than wish for a child. It is important for the women to be seen to be well, to be seen not to be HIV-positive.
- Stigma is still an important issue.
- It is unusual for a person to declare his or her HIV status.
- A question asked was: which should be tackled first: stigma or privacy/confidentiality?
- HIV-positive people should not be refused their right to have children. If prevention of mother-to-child transmission is carried out well, less than 5% of HIV-positive women will infect their babies. Although the chance of passing on the infection is small (with effective prevention of mother-to-child transmission), there is an increased risk of miscarriage and the pregnancy can put a strain on the woman's health. This should be included in counselling.
- Counselling should be ongoing. There is a need to look at the needs of the patients, not the needs of the health care system.

In summary:

- the studies revealed a wide range of complex issues;
- the problems are huge and have to be considered in the light of, for example;
 - religious developments
 - women's empowerment
 - nutritional policy
 - food prices, etc.

7. Lessons learnt and way forward

Two closed sessions were held to discuss lessons learnt and way forward: one consisted of the OR teams, the other of the PDT members.

7.1 Report from the OR teams

Generally the OR teams were happy with how the process evolved. In particular, they pointed out the user-friendly way in which the protocols were developed. A major challenge was that funding was inadequate and funds were not disbursed on time. This led to delays, with some countries' studies being overtaken by events. As a result of some of these challenges, some projects had to be shortened to fit into the predefined timeframe.

They stressed the importance of having a timeframe for project start-up that included follow-up meetings. Similarly, they noted that more regular meetings would have been useful.

As studies progressed, funding was obtained elsewhere. This resulted sometimes in ownership of the projects becoming unclear.

Despite the relatively high level of involvement of countries, it was still felt there was a need to involve countries more at the start.

In terms of technical support, the teams felt it was somewhat haphazard and it was not clear when it would come and why. Linked to this, they pointed out the importance of recognizing the existence of technical expertise within countries that could be drawn upon.

Related to the above, they felt that there was a communication breakdown between WHO and TDR and that different messages were received. There is therefore a need to streamline networks of communication.

Finally, it was noted that it was important to consider how and where things go from here.

7.2 Report from the PDT

The Chair pointed out that these OR projects had been a learning experience also for TDR, and that TDR is trying to effect improvements.

TDR recognized that it was almost impossible to disburse funds in time because of bureaucratic procedures. Since 1 July 2008, a new disbursement system has been introduced, which should improve disbursement and efficiency.

TDR also recognized that there was a problem with management of the projects: originally the PDT and other experts were supporting the OR projects, but they did not have sufficient funds to manage this effectively. A consultant was brought in, but resigned soon after, resulting in loss of momentum in the projects.

The research is country-owned; if collateral funds are obtained, ownership is an issue to be resolved between the funders and the countries.

There was agreement on the need to recognize and use technical expertise within countries. Similarly, regular dialogue and sharing of expertise between countries is important.

TDR has earmarked funds to take the research to the next phase. This phase would be opened up to a further five countries and all 10 countries would have a chance to bid for the funds. Funds would also be put aside for providing technical support, clear lines of communication and reporting would be developed and an attempt would be made to remedy the shortcomings identified from this first round of OR.

In conclusion, the Director of TDR drew attention to the need to streamline communication and the importance of better matching of expertise for technical assistance. He acknowledged that there had been managerial limitations in TDR, and that TDR had been aware of this at the time; there had also been a human resource issue. Authority has now been delegated down to the managers.

In terms of the issue of needing more funds, he pointed out that there is an element of responsibility on both sides. At the preparatory stage, the teams knew how much they were going to be given so this needed to be taken into account when developing the projects.

In terms of delays, he pointed out that these started in 2004 as essentially 12-month projects. Four years later, there is a need to review where the delays occurred and the reasons for them (e.g. whether they were due to management issues, related to the time needed for ethics review, and/or the time needed for implementation on the ground).

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Annex 1. Meeting agenda

Day 1		
Time	Item	Name
09:00–09:15	Welcome and introductory remarks	R Ridley
09:15–09:45	Objectives and proposed outcomes of the meeting	P Onyebujoh M Vahedi
09:45–10:00	From “3 by 5” to universal ART scale-up; lessons learnt and way forward	Y Souteyrand
10:00–11:20	Coffee break	
10:20–10:45	Operational research for treatment and prevention: A review of the WHO HIV/AIDS and TDR 5-country project	F Samuels
10:45–11:10	Highlights of framework for operations and implementation research in health and disease control programmes (TDR and GFATM joint document)	J Kengeya
11:10–11:35	Overview of the OR projects: review process and way forward	B McPake
11:35–12:00	Discussion	
12:00–13:30	Lunch break	
13:30–14:00	Country presentation: Burkina Faso Findings, challenges and next step	PI Burkina Faso
14:00–15:00	Discussion	
15:00–15:20	Coffee break	
15:20–15:50	Country presentation: Zambia Findings, challenges and next step	PI Zambia
15:50–16:50	Discussion	
16:50–17:00	Chairperson summation of day’s events	
	Closure day 1	

Day 2		
Time	Item	Name
09:00–09:15	Proposed objectives for the day’s proceedings	Chairperson
09:15–09:45	Country presentation: United Republic of Tanzania Findings, challenges and next step	PI United Republic of Tanzania
09:45–10:05	Coffee break	
10:05–11:05	Discussion	
11:05–11:35	Country presentation: Malawi Findings, challenges and next step	PI Malawi
11:35–13:30	Lunch break	
13:30–14:30	Discussion	
14:30–15:00	Country presentation: Uganda Findings, challenges and next step	PI Uganda
15:00–15:20	Coffee break	
15:20–16:20	Discussion	
16:20–16:40	Chairperson summation of day’s events	
	Closure day 2	

Day 3		
Time	Item	Name
09:00–09:15	Proposed objectives for the day’s proceedings	PDT Chair
09:15–10:30	PDT review and discussions about future OR priorities for TB/HIV, procedures for selection and support to investigators (closed session)	
10:30–10:50	Coffee break	
10:50–11:05	Report back to plenary by PDT chair and members	PDT
11:05–12:30	Presentation by PIs on future OR projects	
12:30–14:00	Lunch break	
14:00–15:00	Continuation and wrap-up	PDT Chair
	Closure day 3	

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