Implementing Operational Research in Global Fund-supported disease control programmes: Strategic and managerial guide for applicants

Introduction

Operational research (OR) is key to the improvement of programs aimed at disease prevention, treatment and care, and applicants are encouraged to use a percentage of the resources they obtain from GFATM on relevant studies to improve program implementation and the quality of services provided.

However Operational Research is defined, its goal is to establish what is working and how to improve programs—it is sometimes referred to as the "science of better". An evidence-based approach will strengthen policies, enhance programmatic impact, and make better use of resources.

This document provides advice to potential applicants on how to formulate and implement a high quality OR project that will produce evidence relevant to national disease control priorities. It focuses on preparations for an OR project, building the research team, and making plans for implementation. The document complements the technical guide on Operational Research in Global Fund-supported proposals [provide reference/link here] which covers the substantive and methodological aspects of OR projects, a dimension that is not dealt with in this document. Here, we consider 3 dimensions:

1. **Relevance**: How to formulate the research project so that it provides evidence that can help improve disease control programs
2. **Quality**: How to ensure that the planned project will yield solid evidence
3. **Implementation**: How to set up the project so that it is well managed and efficiently implemented

We discuss the different steps that are involved in formulating and implementing an OR project from the identification of the research topic, to the release of funds, to the collection and analysis of data, to the reporting, monitoring and sharing of findings. The advice is organized according to four phases of the work, as summarized in the diagram below:

1. Selecting the research topics and formulating the protocol
2. Putting together and supporting the research team
3. Looking ahead to a smooth implementation process
4. Dissemination [links to country reports when available].

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1 This document was produced by the World Health Organization and the Global Fund to facilitate the inclusion of Operational Research as part of Global Fund-supported programs. It is based on a review of Operational Research projects about Scaling-up antiretroviral treatment for HIV, conducted in 5 African countries between 2005 and 2007. Contributors to this report and the review on which it is based are: Carla Makhlouf Obermeyer (HIV Department, WHO Geneva), Fiona Samuels (Overseas Development Assistance, UK), Winny Koster and John Kinsman (University of Amsterdam), Odette Ky-Zerbo (Programme d'Appui au Monde Associatif et Communautaire, Burkina Faso), and Joseph Simbaya (Independent Consultant, Zambia).
Steps in conducting a successful OR project

1. Topic Formulation
   - Situation analysis/review of sources
   - Multi-stakeholder consultation
   - Priority-setting

2. Team building
   - Multi-sectoral, multi-disciplinary
   - Senior+junior members
   - Clear responsibilities
   - Advisory group

3. Implementation
   - Methodology and training
   - Fieldwork, data management, analysis
   - Involve stakeholders

4. Dissemination
   - Regular reporting
   - Tailor to different audiences
   - Translate findings into concrete recommendations

The advice given in this document is based on the experience gained as part of implementing OR projects on HIV in Burkina Faso, Malawi, Tanzania, Uganda, and Zambia, with support from WHO and TDR between 2005 and 2007. Lessons learned and good practices identified during an interim review of these research projects are summarized here, with a view to their applicability to OR in the context of Global Fund proposals.

1. Priority research topics, relevant to programs

Multiple stakeholders should participate in the formulation of OR projects in order to ensure a broad ownership base, maximise anticipated interest in the findings, and increase the chances that the evidence will be used to inform programs and policies. A multi-stakeholder group should be set up and remain involved throughout the life of the OR project.

The specific composition of the stakeholder group will vary according to particular settings, but several key constituencies need to be represented:

- Policy makers or individuals who are connected to national policy making; usually this includes representatives from the Ministry of Health (MoH).
- Researchers from the medical and social sciences; they may be based in national research institutes and/or in organizations outside the country who have experience with research on the selected topics.
- People involved in implementation on the ground, as local level actors often have crucial insights that can help identify the problems to be investigated.
- Civil society groups, NGOs, and associations of people living with HIV, TB, or malaria.
- Depending on the context, other members may be included to represent international donors, and technical agencies.

In several of the research projects, the 'multiple stakeholder approach' brought about a high level of national ownership. As a member of the Uganda team said: because of the involvement of local actors, the OR project would 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."

Within the framework of problems of implementation and scale-up, it is important that the specific topics selected for OR be researchable and relevant. This can be enhanced by the following:

1. As part of preparations for priority-setting, a situation analysis should be conducted. It can be based on a review of the available literature and a rapid inventory of existing research in the country. This would help ensure that the project builds on previous work, avoids duplication, and identifies gaps in the
knowledge base. It also provides a good basis for discussions among stakeholders during the priority-setting exercise.

2. The question: ‘what do policy makers and practitioners need to know in order to improve programs?’ should be kept in mind as topics are considered.

3. Where national priorities for HIV, TB and malaria control have been formulated, priority research questions can be informed by reviewing existing documents.

4. Priorities should, to the extent possible, be identified over the longer term: which issues are likely to be of importance in one, two, or five years time? What evidence may be needed in anticipation of resolving future problems?

The five-country review suggested that the themes selected for the OR projects were highly relevant to national priorities. Once completed, the selected projects had the potential to, for instance, assist in the development of the new ART policy in Uganda, provide input into policies concerning health providers in Malawi, provide a set of indicators of adherence which could be used in national ART programmes in Tanzania, and help to revise the guidelines for care and support for people living with HIV and AIDS in Burkina Faso.

After the situation analysis is completed, a list of policy-relevant topics can be drawn up and a meeting organized to discuss priorities. The objective of the meeting is to select one (or more) priority areas on which a protocol can subsequently be developed. The meeting should follow a clearly delineated procedure for prioritizing and selecting the topic/s. The first step should involve a presentation of the findings from the situation analysis, which will provide a basis for discussion. If the number of participants is high, small groups can be convened to discuss and rank the various issues that have been identified. The core problems to be investigated can be agreed upon in plenary.

It is clear that priority-setting cannot be a completely "objective" process, that there are many obstacles to program implementation that call for OR, and that individuals usually feel strongly about their own areas of work. The priority-setting exercise can clarify the trade-offs of selecting particular topics, and help develop an agenda of topics that may be taken up at different times. An experienced chair will be required to run the meeting in order to foster a collaborative rather than competitive approach to the selection of topics; half a working day or, better still, a full working day should be put aside in order to work through all the issues. It may be helpful to request support from technical partners such as the WHO country office, both to involve them in the process, and to facilitate links with people who can offer technical assistance.

The titles of the projects initiated in 2005 exemplify the different results of the priority-setting process in the 5 countries:

- **Burkina Faso**: Treatment and care practices for people living with HIV/AIDS.
- **Malawi**: Are health care workers accessing counselling and testing and ART?
- **Tanzania**: Evaluation of an ART adherence measurement tool
- **Uganda**: Patient adherence to ART and integration of HIV prevention into AIDS care
- **Zambia**: Uptake of ART in TB and PMTCT clinics

It is important that issues are not framed from a single perspective, be it medical, managerial, or behavioral, but rather that a multi-disciplinary approach be adopted, since most of the problems that are identified will have multiple dimensions. Data collection should be from several sources, so as to obtain as broad a view of the problem at hand as possible; where surveys are planned, different types of
respondents should be included: the project should solicit information from people living with the disease(s), from individuals in the community, as well as from health care providers and managers. This also enables triangulation and makes it possible to verify data from multiple sources.

2. A strong research team

Ideally the research team should have close connections with the program and policy fields and with the public, private and NGO sectors where appropriate. It is generally recommended to include representatives of local authorities, in particular the Ministry of Health (MoH). In four of the five OR country-teams, the inclusion of a representative from the MoH facilitated implementation and increased the likelihood that research recommendations would be taken up into national policy and programming.

The team should include both members of relatively high status to ensure credibility and national level interest, as well as junior members who can commit sufficient time to the project. Senior researchers are often scarce and over-committed, and an OR project can represent a valuable capacity building exercise for promising junior researchers.

In Malawi, junior researchers conducted the day-to-day work under close supervision by a senior researcher from the same organisation. In Tanzania the project took some time to get off ground because the Principal Investigator and the Manager, while both well professionally positioned, were too senior and too committed elsewhere. The project eventually took off when a part-time Assistant Project Coordinator was employed.

Since implementation of HIV, TB and malaria programs involves medical as well as socio-cultural aspects, the team will require both quantitative and qualitative researchers. To promote a truly multi-disciplinary approach, team members trained in both medical and social sciences should be recruited right from the start. This is preferable to the alternative of splitting up the research and the team into separate quantitative and qualitative sections, and will contribute to fostering a collaboration within the team.

In Zambia there were problems with sampling due to the absence of quantitative researchers in the team. In Malawi the team hired a statistician to help with sampling for the quantitative phase. In Burkina Faso, researchers from different backgrounds were recruited from the start, and this helped integrate qualitative and quantitative components.

How the team is managed is especially important when the team includes people from different organisations and backgrounds. The hierarchy has to be delineated and roles and responsibilities clarified at the outset. The optimal size for the team depends on the nature of the research; in the projects reviewed, the research teams ranged from 5 members in Zambia to 14 in Burkina Faso. Regardless of size, each research team should have the following core members:

- A Principal Investigator (PI). The PI is a researcher who takes responsibility for the implementation of the study; s/he closely follows progress and convenes and chairs technical meetings. While full-time commitment is not usually
necessary or possible, expectations about the commitment and responsibilities of the PI must be made explicit.

- A Project Coordinator, preferably full time, to assist the PI with the management of the project. S/he participates in all key activities, including training, data collection, cleaning and entry, and contributes to the analysis. S/he sees to the smooth running of the project and reports on the progress and meetings to the PI and stakeholders.
- Technical experts familiar with developing data collection instruments, qualitative and quantitative methods and field research, including interviewing, observation, data management, and analysis.
- An administrative/financial manager, usually part-time, who reports to the PI.
- In addition to these members who need to contribute to the project from inception to conclusion, others can be hired for specific phases of the work, for example interviewers during the fieldwork phase, or data entrists, or statisticians.

In Uganda, in the words of one of the team members, “the chain of command has worked beautifully”. This was partly because the hierarchy was clearly delineated from the start, and people understood their respective roles. The full-time manager of the Uganda team appears to have been very effective in managing the day-to-day details of the project, which has been essential for ensuring continuity and quality fieldwork.

Advisory Group

Stakeholders from government, international organizations, universities, civil society, and NGOs should be kept involved throughout the project to provide scientific, technical and ethical guidance, and to facilitate implementation. Where appropriate, key stakeholders should be invited to participate in a project advisory group. The group can be a formal committee or a working group. It should meet regularly, be appraised of progress, and provide advice at key points in the project. Individual committee members can also facilitate clearance and authorization for the work.

The team should also create strategic linkages with local and international technical organizations. For example, the WHO country office can be helpful with linkages to sources of information, as well as to key players. In the projects reviewed here, the inclusion of the WHO HIV officer in the advisory group greatly facilitated implementation. Furthermore, consultants could be brought in to assist with specific tasks and participate in strategic discussions.

By establishing partnerships with researchers working within and/or outside the country, teams can receive valuable technical assistance. In Burkina Faso, for example, the local WHO office was involved in the project from the outset, acting on both the steering and management committees. In Burkina Faso, Malawi, and Uganda WHO Geneva provided input in study design and data collection instruments.
3. Looking ahead to smooth implementation

To maximize efficiency and maintain momentum, clear plans must be made regarding funding mechanisms, ethical clearance, training of staff, as well as infrastructure.

All research will need ethical clearance and the team should obtain information on national criteria, procedures, application forms, and the meetings of review committees. This helps avoid delays in obtaining authorization.

Whereas OR seeks to rapidly respond to questions emerging during implementation, when planning research in the context of a Global Fund-supported program, a considerable time-lapse may occur between submission of the original grant proposal and receipt of funding. Such time lags should be taken into account when planning activities and hiring team members. The group that prepares the proposal should also be clear about when and how funds are disbursed, what funds can be used for, and the financial reporting that will be required; they will want to make sure they have some administrative assistance to do so, and put in place mechanisms for keeping track of incoming and outgoing funds. It is often necessary, once funds are received, to update the proposed research in consultation with stakeholders, in order to take into account new developments in the disease control programmes, findings of other studies, changing costs, or new technologies. This may require that the methodology or sampling be revisited, and that budgets and timelines be updated.

Delay in clearance and funding can create problems for research teams, as happened in some of the projects reviewed. By the time funding was received, some team members had moved on to other projects, which caused further delays in starting the research. The Malawi and Tanzanian teams had to revise their sampling because new research projects had in the meantime been initiated.

It is important to maintain communication with stakeholders throughout the preparatory, implementation, and dissemination phases of the work. The advisory group is key, and it should meet regularly, in turn providing updates to the broader group of stakeholders about the work. Formal and informal contacts will facilitate authorization and funding, help obtain critical advice, and ensure feedback to programmes.

In Burkina Faso, stakeholders from different fields and disciplinary backgrounds met at key phases in the work. The advisory committee provided input into the study design and content, and met regularly afterwards, often in connection with meetings to review progress with WHO technical advisors. Workshops continue to be organised at national and local levels to discuss findings and determine strategies to overcome emerging challenges. The Malawi team involved the stakeholder team at critical stages of selecting the topic, and re-directing the study after funding had been received.

A combination of qualitative and quantitative methods is often optimal for OR projects, and it is possible to sequence the use of different approaches to fit with different phases of the work. For example, several of the five ART research projects started with an exploratory qualitative phase, followed by a quantitative
survey phase. It may also be useful to conduct qualitative research after preliminary results of the survey are available, in order to help interpret survey results. A participatory 'evaluation' phase can also be planned to feed back results to those who provided information, and to engage research participants in discussing how to translate research findings into recommendations to improve service delivery.

While national representativeness is often a goal of survey research, this is not a necessary requirement for OR, and smaller-scale projects within specific control services may yield more rapid and useful results.

The development of data collection tools is key to a quality project, and resources need to be allocated to careful piloting, preferably with the involvement of the fieldworkers who are going to collect the data. Pre-testing is best done during the training of fieldworkers; this is time efficient and enhances involvement, familiarity with the tools, and ownership.

### Training

The duration of training for those who will collect the data depends on their experience with the research topic and on the complexity of data collection methods. In the five reviewed projects the training lasted between 3 and 10 days. Training may need to be not only technical and methodological, but also include ethics and how to respond to the suffering of study participants. Guidelines can be developed which specify the competences required for interviewers and these could be included in a training module for fieldworkers.

In Uganda and Burkina Faso, interviewers identified a need for counselling and psychosocial training, as the research projects touched on emotional and sensitive issues that are not usually covered during training.

### Fieldwork and data entry

It is important to inform the participating communities and health institutions about the forthcoming visit of the fieldworkers. The PI should send official letters to this end, and follow up with phone calls shortly before the visit. Advance communication with the planned research locations helps avoid inconvenience for respondents and facilitates preparation on the part of responsible persons.

Senior researchers' engagement in fieldwork allows them to gain a clearer picture of the research issue, which will improve the richness of their writing and dissemination activities. It is especially important where data have to be collected from senior health staff or community members.

Experiences from Uganda and Malawi showed that in health facility surveys, senior health staff members can be usually reluctant to be interviewed by junior interviewers.

The quality of the collected data needs to be checked regularly during the fieldwork phase. Ideally, this is done on a daily basis by fieldworkers and their supervisors. The study coordinator overseeing the data collection should maintain regular contact with the research teams in the field.

In Uganda, where teams were spread all over the west, centre and east of the country on any given day, the study coordinator used her mobile phone to contact each team at least twice daily in order to stay informed about developments.
4. Dissemination

The needed reporting should be specified at the outset, and include potential timelines for narrative and financial reports. A detailed dissemination plan should also be made at the start of the work, including discussing findings with policy makers, program managers, and other stakeholders, presenting results at national and international conferences, and publishing in scientific journals and other media.

Time and funds must be set aside to cover the analysis phase, which is often time consuming if rich data are obtained. Resources also have to be budgeted for appropriate dissemination, both to connect with researchers in the same country and to bridge the gap between research and policy through regular meetings that bring together researchers and policy makers.

If the advisory group functions well and stakeholders are being kept involved in the project, the results will have a greater likelihood of being taken into account in subsequent decisions regarding programs and policies. A research project should not be considered concluded with the writing of reports or academic papers, although these are important. Additional efforts should be made to organize meetings to share the results with those who contributed information, those who may use the results in their own work, and those who provide input for the formulation of policies and programs. These different audiences require different formats and approaches, and the work needed to disseminate results in this manner has to be considered part of the research project, and budgeted accordingly in terms of human and financial resources.

In Burkina Faso, the research project included a participatory "restitution" phase to share results with groups of providers, clients, policy makers, and community associations. This essential step in the research project helped define concrete recommendations to improve the care provided to people living with HIV.

Because the evidence derived from Operational Research—or indeed from any research—does not inevitably bring about policy change, it is not enough simply to produce the evidence and expect policy makers to take action. Researchers need to think ahead about the significance of their findings for policies and programs, and present them as unambiguously and simply as possible to the different audiences that may make use of them.

5. Summary

OR can be an instrument to improve programmes, if a quality project is conducted on a relevant topic, by a competent team, with sufficient resources and support. The lessons and advice drawn from 5 projects conducted on HIV treatment in Africa have relevance for OR projects on other diseases. The fundamentals for successful preparation and implementation are similar, and require a solid process of priority setting to formulate a relevant topic, support for building a strong research team, thorough planning of the different administrative, budgetary, and managerial aspects needed for smooth implementation, and careful dissemination of results.