Framework for Operations and Implementation Research in Health and Disease Control Programs

Acknowledgements

For questions and comments please contact:

TDR: Dr Jane Kengeya-Kayondo at: kengeyakayondo@who.int
The Global Fund: OR@theglobalfund.org

PREFACE

Operations research (OR) is critical in providing scientific evidence for health and disease control programs to improve their quality and "learning" as they scale up. In the context of aligning international health support, the need to develop a framework endorsed and recognized by a wider professional community as a commonly-used instrument for designing, planning, implementing and taking full advantage of effective OR has been well recognized.

The Framework for Operations and Implementation Research in Health and Disease Control Programs is a result of a collaborative effort between the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Special Program for Research and Training in Tropical Diseases (TDR) and an inter-agency technical working group. The culmination of this collaboration was a three-day meeting held in Geneva in April 2008 and attended by over fifty participants representing the Global Fund, TDR, the World Health Organization (WHO), the Joint United Nations Program on HIV/AIDS (UNAIDS), United States Agency for International Development (USAID), the World Bank, field-based programs, policy-makers and research communities from all over the world, which finalized and endorsed the framework.

The overall goal of the document is two-fold: to standardize the practice of OR across the international health community and to stimulate the integration of OR into health programs. In general, OR needs to be integrated as an essential part of monitoring and evaluation (M&E) efforts. Thus, the concept of *M'OR'E* could become a new paradigm enhancing the practice of integrating monitoring, research and evaluation dimensions as one common component into program management systems. It would not only strengthen program implementation, but would also facilitate more effective utilization of M&E resources (currently recommended at five to ten percent of overall Global Fund grant budgets).

The range of target audiences for this document is wide and varies from policy-makers to program managers, from researchers to program implementers, from donors to government agencies, from technical organizations to civil society and other stakeholders.

The document is divided into three main sections. Section A contains an overview of OR definitions, scope and uses. Section B is the OR process flowchart and offers a step-by-step 16-item checklist of major activities required in the planning, implementation and follow-through (dissemination and use) of OR at the country level. Section C provides case studies of OR activities from the field and an annotated reference list of available handbooks, guidelines and other tools for OR. Feedback from people who use this document will help make improvements in future editions.

We strongly suggest that programs and partners use this tool to incorporate OR in a systematic way, so that we can maximize the "learning" and quality of the scale-up of health services.

Daniel Low-Beer,
Director,
Performance Evaluation and Policy,
The Global Fund to Fight AIDS,
Tuberculosis and Malaria

Robert Ridley,
Director,
UNICEF/UNDP/ World Bank/WHO Special
Program for Research and Training in
Tropical Diseases

Technical working group members and consultation meeting participants

Name	Organization	Country of Work
Dr Abdullah S. Ali	The Ministry of Health and Social Welfare of the Revolutionary Government of Zanzibar	United Republic of Tanzania
Dr Hoda Youssef Atta	WHO EMRO	Egypt
Dr Hastings Banda	EQUI-TB Knowledge Program/ National TB Program	Malawi
Dr Richard Carr	RBM/WHO	Switzerland
Dr Keith Carter	AMRO/PAHO	USA
Dr Alexandra De Sousa	UNICEF	Kenya
Dr Charles Delacollette	WHO-Mekong Malaria Program	Thailand
Dr Alice Desclaux	Institut de Recherche pour le Développement (IRD)	Senegal
Dr Elizabeth Elhassan	Sight Savers International	Nigeria
Dr Bayo Segun Fatunmbi	WHO Representative Office	Nigeria
Dr Melba Gomes	MPR/TDR	Switzerland
Ms Andrea Godfrey	WHO TBS/STB	Switzerland
Professor John Gyapong	Health Research Unit, Ghana Health Service	Ghana
Dr Nguyen Binh Hoa	National Hospital of TB and Respiratory Disease	Viet Nam
Dr Scott Kellerman	Population Council	USA
Dr Wilford Kirungi	Ministry of Health Headquarters	Uganda
Dr George Alfred Ki-Zerbo	WHO AFRO	Congo
Professor Sinata Koulla-Shiro	Ministry of Public Health	Cameroon
Dr Ireen Makwiza	Equi-TB Knowledge Program	Malawi
Dr Kelly Mann	Division of Pediatric Infectious Disease	USA
Dr Kamini Nirmala Mendis	GMP/WHO	Switzerland
Dr Bernard Nahlen	President's Malaria Initiative, USAID	USA
Dr P.R. Narayanan	Tuberculosis Research Centre	India
Dr Jerome Ndaruhutse	Conseil National de Lutte Contre le SIDA	Burundi
Dr Pierre-Yves Norval	WHO TBS/STB	Switzerland
Mr John Novak	USAID/GH/HIV-AIDS	USA

Name	Organization	Country of Work
Dr Ayoade MJ Oduola	STE/TDR	Switzerland
Dr Philip Onyebujoh	TBR/TDR	Switzerland
Dr Miguel Orozco	Centero de Investigaciones y Estudios de la Salud (CIES)	Nicaragua
Dr Leonard I. Ortega	WHO Representative Office	Myanmar
Dr Jan H.F. Remme	NPR/TDR	Switzerland
Dr Rosalia Rodríguez-Garcia	The World Bank Global Aids Program	USA
Dr Deborah Rugg	UNAIDS	Switzerland
Dr Omar Sam	Health Services Department of State for Health and Social Welfare	The Gambia
Dr George Schmid	HIV/WHO	Switzerland
Dr Bernhard Schwartländer	UNAIDS	China
Dr Joseph Simbaya	Institute of Economic and Social Research	Zambia
Dr Yves Souteyrand	HIV/WHO	Switzerland
Professor Richard Speare	Anton Breinl Centre for Public Health and Tropical Medicine, James Cook University	Australia
Dr Sergio Spinaci	GMP/WHO	Switzerland
Dr Awash Teklehaimanot	Director Malaria Program, Columbia University	USA
Dr Zaida Yadón	AMRO/PAHO	Brazil
Dr Richard Zaleskis	WHO EURO	Denmark
Dr Christina Zarowsky	International Development Research Centre (IDRC)	Canada
Dr Matteo Zignol	WHO TBS/STB	Switzerland
Dr Susan Zimicki	Infectious Diseases Initiative, Academy for Educational Development	USA

LIST OF TERMS & ABBREVIATIONS USED

ACT	artemisinin-based combination therapy
ART	antiretroviral treatment
ARV	antiretroviral
BCC	behavior change communication
CBD	community-based distribution
CBO	community-based organization
CDI	community-directed interventions
FGD	focus group discussion
IBRD	International Bank for Reconstruction and Development (the World Bank)
IDRC	International Development Research Centre (Canada)
IEC	information/education/communication
IPTp	intermittent preventive treatment in pregnancy
IR	implementation research
IRB	institutional review board
ITN	insecticide-treated bed net
LLIN	long-lasting insecticide-treated nets
LOI	letter of intent
M&E	monitoring and evaluation
MCHN	maternal and child health and nutrition
MRC	Medical Research Center (The Gambia)
NGO	nongovernmental organization
NMCP	National Malaria Control Programme (The Gambia)
OI	opportunistic infections
OR	operations research
ORS	oral rehydration solution
PAHO	Pan American Health Organization
PEPFAR	President's Emergency Plan for AIDS Relief (U.S.)
PLWHA	people living with HIV/AIDS
PMTCT	prevention of mother-to-child transmission
PR	Principal Recipient
RAP	rapid assessment procedures
RDT	rapid diagnostic tests
SP	sulfadoxine-pyrimethamine
TB	tuberculosis
TDR	Special Program for Research and Training in Tropical Diseases
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
VCT	voluntary counseling and testing
WHO	World Health Organization

CONTENTS

SECTION A
CONCEPTS

Introduction to the Framework

1. This document is meant to serve as a primary reference for people who plan and carry out operations or implementation research (OR/IR)[1] in order to improve the implementation and management of disease control and other health programs. The overall approach is that of a framework that helps researchers and program 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 programs in order to attain the desired impact. The added value of this document is to produce the analysis of practical OR/IR experiences to create a one-stop document for program managers/staff and researchers who want to use OR/IR to improve their health and disease control program and policies.

2. The framework is organized in three major sections. Section A gives an overview of OR/IR including definitions, scope and use. Section B consists of a flowchart or series of steps in planning, implementing and disseminating OR/IR. Section C is a collection of resources including case studies, existing guidelines and tools and a reference list of materials and papers quoted in Sections A and B.

3. The framework will be a living document that can be updated periodically. This is not an extensive document, but more like a checklist to aid in planning. Section C provides more of an annotated description of guidelines and references for the actual conduct of operations and implementation research (IR) and use of research results. The actual guidelines and articles are not attached, but nearly all can be found on the internet and downloaded freely. In these instances a short synopsis of the material is given, followed by its web address.

4. The framework is intended to be for people and organizations involved in disease control efforts to plan and implement research that will answer questions they have about how to make these programs better. Users may include people involved in national control programs for HIV/AIDS, tuberculosis, malaria and other endemic diseases and health issues such as reproductive health, nutrition and child survival and development. Users may be based in the public, private, academic or nongovernmental organization (NGO) sectors. The framework is designed to be generic and broad enough to be used by any researcher or implementer who undertakes OR/IR.

5. This framework is not intended to be a capacity-building tool. It may certainly be used by those who organize training for researchers as reference material. Hopefully, this framework will enhance the practical application of research and bring research and practice closer to each other.

6. One stimulus for the production of this framework arose from observations by the Global Fund. Since its inception, the Global Fund has made it possible for countries to include in their proposals opportunities for operations and IR. This has traditionally and appropriately been placed under the section dealing with M&E. Research components in approved Global Fund grants rose from only 19 percent overall in the Round 1-5 activities to 52 percent in Round 6 alone (Korenromp et al., 2007). Now, after seven rounds of Global Fund support, people have realized that it is time to harness the knowledge derived from these OR/IR studies and those supported by many other donors in order to "standardize" the steps for conducting OR/IR within a practical framework that would enhance the research efforts and lead to better disease control programs and policy-making.

Scope and Categorization of Implementation and Operations Research (Conceptual Issues)

7. This is a framework on OR. The terminology for such research may vary by setting and sponsor, but the intent of OR and this framework is to learn about management, administrative, cultural, social, behavioral, economic and other factors that either exist as bottlenecks to effective implementation or could be tested to drive insights into new, more effective approaches to programming. By its very nature, this research is usually specific to the environment in which the program operates, although there are multi-country research projects that address a problem common to several countries in a region.

8. Several definitions are available concerning OR and IR. These are located in Annex A to stimulate the thinking of readers. Some of the key ideas in these definitions explain that OR/IR can accomplish the following:

- identify and solve program problems in a timely manner
- help policy-makers and program managers make evidence-based program decisions
- improve program quality and performance using scientifically valid methods

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[1] In this document Operations Research (OR) represents Implementation Research (IR) as well.

- help program managers and staff understand how their programs work

9. A discussion of OR would not be complete without reference to rapid assessment procedures (RAP). In Annex A, one can see a close affinity with OR in terms of emphasis and methods. The annex also refers to the area of formative research which can help in designing and monitoring interventions being tested through OR/IR.

10. Finally, during the working meeting on OR/IR held in Geneva as part of the development of this framework, participants agreed on the statement below as reflecting the scope of OR/IR.

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

Methodology for Developing the Framework

11. The Global Fund joined efforts with TDR to develop this framework. Three major processes were undertaken to design the framework. The first consisted of a review of available and existing tools and guidelines in order to extract common lessons and themes. Internet search was the primary tool for identifying these tools and guidelines for the simple reason that if one could access these tools on the internet for this review they would be likely be in the public domain and therefore also accessible to users of the framework. The framework draws on a number of multilateral and bilateral disease control programs that provide funds for research that addresses questions concerning how to make these programs function better.

12. The second step was based on country visits where known OR/IR had taken place as part of a disease control program. The goal was to be broadly representative. Initially, seven countries in different regions with a focus on different diseases (TB, HIV and malaria) were selected. Country visits consisted of in-depth interviews with program managers, managers of the actual research grants and the research team members themselves. An interview guide was developed for this purpose and senior professional staff from TDR and WHO undertook the visits with assistance from Global Fund Portfolio Managers and country-based program managers and researchers. The guide encouraged data collection in a way that tested the major steps in OR/IR as outlined in this framework. Due to logistical challenges it was only possible to visit five countries prior to the drafting of this framework.

13. The third process in framework development was a three-day "Joint WHO-TDR/TGF Consultative Technical Meeting on the Framework for Implementation/OR in Health and Disease Control Programs". Over 50 disease program managers and researchers, representatives of international agencies (USAID, World Bank, UNAIDS, the United Nations Children's Fund (UNICEF) and others) attended and reviewed the draft materials and made their own contributions to enliven the contents with more practical examples from the field.

Applications of OR/IR: Types of Issues/ Questions OR/IR Can Address

14. According to RBM/WHO (2003), planners of OR should ask, "What are the operational gaps (problems) which, if solved, could enhance malaria control activities in your country? List them under health system, preventive and control measures, and community issues" (WHO, 2003).

15. The issues and questions that OR/IR can address may fall in the following categories (generic, not disease-specific):

- Health System – service issues (drug availability, quality, safety, access, distribution, affordability, skills and capacity of health workers, etc); or policy issues (policy guidelines, regulations and their applicability);
- Preventive and control measures – availability and use of insecticide-treated bed nets (ITNs), insecticides, intermittent preventive treatment, environmental management, availability of effective drugs, cost of the drugs etc.
- Community issues – knowledge, attitudes, behaviors and practices, self-medication etc.

16. The Quality Assurance Project (2004) examined the role of the private sector in tuberculosis (TB) control and addressed the following issues:

- The nature and extent of TB services provided by private sector providers (private doctors, pharmacies, and drug sellers),
- The TB client's motivation in using the private sector, and
- The willingness of private providers to participate in TB service provision (screening, counseling, referrals, and treatment).

17. According to Walley et al. (2007) a major focus of OR/IR questions should be based on an understanding of the barriers to large-scale access. "Then trials and social and economic studies can be embedded within program sites, and provide knowledge on how to overcome these barriers and deliver effective interventions. Because these operational issues are commonly relevant to other high-burden countries, the publication of the results should have international as well as national influence."

18. A program might not be reaching its coverage goals. Maybe this is due to procurement and supply problems or maybe to low levels of compliance. If the problem focuses on procurement and supply, a set of research

EXAMPLE OF OR/IR POTENTIAL ISSUES: THE CHALLENGES OF OBTAINING AND DELIVERING COMMODITIES

The delivery system is not reaching sufficient numbers of the target group because of:

- ➤ Low coverage
- ➤ Failure to scale-up
- ➤ Equity issues such as not reaching the poor, those living in remote areas, the marginalized, women, children, adolescents
- ➤ Not reaching those who are stigmatized
- ➤ Insufficient staffing - may need to look at task shifting approaches, e.g., use of community workers.

The delivery system may be having quality issues

- ➤ Poor quality of services and target groups avoiding the service
- ➤ Poor diagnostic and dispensing services
- ➤ Other technical problems
- ➤ Poor information/education/communication (IEC) programs
- ➤ No job aids or poor use of them
- ➤ Poor referral systems

Managerial issues may be the main bottleneck

These may include:

- ➤ Poor adherence to policy recommendations
- ➤ Poor record-keeping and reporting, M&E
- ➤ Poor information dissemination
- ➤ Ethical issues
- ➤ Interaction or competition with other interventions for other diseases
- ➤ Marketing and advocacy

Issues may be at the community/societal and individual levels

- ➤ Levels of household income that influence affordability
- ➤ Stigma
- ➤ Other participation barriers
- ➤ Perceptions and misperceptions

questions might ask whether a program is having trouble getting the right quantity or amount of commodities and supplies (drugs, diagnostics, ITNs, condoms, etc.) or once procured, these are not reaching the target groups (see box). This may be the result of supply chain issues which can be overcome by better supply chain management, stocking, restocking practices, supplies forecasting etc. but it may also have to do with the 4As - accessibility, affordability, acceptability and availability, which are linked to demand and supply and also the system issues below.

19. The commodities may have poor quality or reduced potency because of packaging problems, expiry dates monitoring, storage problems, use and misuse, compliance and adherence, the extent to which use guidelines are adhered to, torn ITNs. Or adverse events which give the impression that the tool is not good or is unsafe may be interfering with appropriate use.

20. The commodities may be facing unexpected outcomes such as resistance to drugs, adverse reactions, faults in case detection etc. Most problems are linked to the system and examples are given in the box.

Role of OR/IR in Health and Disease Control Programs

21. Before looking at examples, it is important to examine the context of OR. Walley et al. (2007) observed that, "Discovering ways to increase access to and delivery of interventions is a major challenge. Typically research is divorced from implementation, which has led to a growing literature about how to get research into practice. However, OR is best prioritized, designed, implemented and replicated from within national programs."

22. According to TDR (UNICEF/UNDP/World Bank/ WHO, 2005) "There are many examples of potentially-effective disease control products that have had only limited impact on the burden of disease because of inadequate implementation, resulting in poor access." To address this problem, TDR suggests research that will "significantly improve access to efficacious interventions against tropical diseases by developing practical solutions to common, critical problems in the implementation of these interventions."

23. OR has been used by the International Food Policy Research Institute to monitor a child nutrition program in Haiti (Loechl et al., 2005). This is a good example of OR used to identify and overcome program bottlenecks. The report "describes the methods and results of OR undertaken to assess the effectiveness of World Vision's food-assisted maternal and child health and nutrition (MCHN) program in the Central Plateau region of Haiti. The research had three main objectives: (1) to assess the effectiveness of implementation and operations of the program relative to plans; (2) to assess the quality of delivery of the various services; and (3) to explore the perceptions of different stakeholders (i.e., beneficiaries and field implementers) regarding program operations and service delivery and the motivational factors that may affect staff's performance and job satisfaction. The overall goal was to identify constraints to effective operations; it was more important to identify and implement corrective actions that will ensure smooth implementation of the program and its various components. The report is directed to program managers, researchers, and development professionals who are interested in applying OR methods to evaluate and strengthen similar MCHN programs with a food aid component in developing countries."

24. CBD is a good example of OR that eventually led the way to a key service delivery mechanism in a variety of health programs. WHO (2003) reported that, "Early OR work (in reproductive health) with CBD of contraceptives led to significant programmatic changes through work conducted in Pakistan, Egypt, Ghana, and Kenya. OR showed that there is a demand for family planning services within communities, and that CBD programs can increase family planning use even in settings where the health-care infrastructure is inadequate. OR also identified issues that affect program effectiveness, such as variations in agents' productivity and the effects of different types of compensation on program productivity."

Examples from the Field

25. Examples of OR/IR implementation were gathered from field visits and contributors at the working group meeting in Geneva. These give some idea of the scope and steps involved. More detailed case studies are found in Section C as full examples and in the annotated reference section.

NICARAGUA: Examining the Effectiveness of Testing and Treatment Programs for Malaria

26. The increasing prevalence of malaria arising after national health system decentralization and frequent natural disasters provided the rationale for an OR study on the testing and treatment of malaria in the isolated North Atlantic region of Nicaragua. The Nicaraguan Ministry of Health, the Pan American Health Organization (PAHO), a national university and a local NGO collaborated to examine several OR questions, including the efficacy of chloroquine and sulfadoxine-pyrimethamine (SP) to treat uncomplicated malaria, the feasibility and validity of using a rapid diagnostic test, the use of biological agents in vector control and the identification of local knowledge, attitudes and practices in relation to malaria in the region. Several challenges arose during the implementation of the research. Managing the diverse procedures, administrative interactions and reporting needs of all the different implementing partners proved difficult.

27. Partners found that the need to build capacity to conduct OR was an important lesson that emerged, as well as the need to clearly establish the research work plan, a data quality and monitoring system, process and outcome indicators and general training and guidance in project management. Upon completion of the study, research findings were disseminated to national health programs and other national stakeholders. Because the research was planned and executed in the context of an existing program, research results were immediately translated into programmatic changes and utilized to inform subsequent operations research.

ZIMBABWE: Identifying Gaps in HIV Prevention among Orphans and Young People in Hwange District

28. OR/IR was built on a study that found that girls who have been orphaned because of HIV are at greater risk of acquiring HIV themselves. During a stakeholders meeting, Hwange District was chosen because of its high prevalence of HIV and a large number of orphans. Community informants listed venues where people - particularly young people - meet new partners, including bars, taverns, nightclubs, hotels, hostels, schools and borehole wells, and these became places where interviews could be done. A household survey was also carried out and it confirmed that young girls actually spend a lot of their time in ordinary homes, not just public places. The study documented that females aged 18-24 years seemed to have riskier sexual behavior than females of other ages, and that there was commonly mixing of older males and these younger females. The study concluded that because individuals in Zimbabwe are meeting new sexual partners in a variety of venues, it is important to incorporate HIV programs into everyday life.

29. Several program recommendations arose from this research. First, prevention programs need to target all youths, including those who socialize at the venues identified above. Some of these venues - like schools and borehole wells - would not have been identified without the research. Secondly, because of the wide variety of places where sexual contact can be initiated, community programming was recommended, not just activities in obvious public venues. Also, the findings implied that condoms need to be made available in a variety of venues in the community. (Source: Measure Evaluation, 2008).

THE GAMBIA: Testing Effectiveness of ACTs to Treat Malaria

30. The National Malaria Control Programme (NMCP) of The Gambia, in collaboration with the Medical Research Center (MRC), WHO and several NGOs, is conducting OR to examine the effectiveness of artemisinin-based combination therapy (ACTs) (Coartem©) at national public health facilities. With the use of mixed methods, this OR aims to examine community compliance and acceptability of Coartem to treat malaria in children aged six months to five years. Treatment is being provided by NMCP at health facilities and research data is being collected and managed by MRC. This research received full ethical approval of the study protocol from national and institutional ethics committees, which helped to vet and strengthen the research plan.

31. Although research is currently ongoing, several lessons have already emerged. A focus on creating a strong consensus and collaboration among study partners has enabled research activities to proceed on time and with the involvement and support of all stakeholders. The inclusion of a well-established and experienced research institution in the study has strengthened the quality and rigor of the research and has allowed other study partners to focus on other activities, such as project implementation and monitoring. A dissemination strategy has been created that plans to communicate study findings through a variety of mechanisms, including ongoing reports to implementing study partners and stakeholders, community members, and the presentation of findings to the wider public through conferences, press, and the publication of findings in scientific journals.

CAMBODIA: Treating Tuberculosis in the Private Sector

32. In 2003 little was known about the role of the private sector in treating TB in Cambodia. The first step was to undertake OR to learn the nature and extent of TB management in the private sector. Interviewers reached doctors, pharmacists, pharmacy staff, drug sellers and TB patients. Trained research staff posing as "Mystery Clients" also approached the private providers. Key findings included the following:

- Most people with a chronic cough visited pharmacies/ drug stores to seek initial remedy.
- TB case management knowledge was low.

- Practice of the TB DOTS strategy was low.
- TB drug dispensing practices were not in accordance with National TB Control Program guidelines.
- TB information provided to clients was limited.
- TB stigma was strong.

33. Policy recommendations arising from the study included training private providers in use of national guidelines and developing linkages and working relationships between public and private sector from national to community level in order to improve the quality of this important source of care. (Source: Quality Assurance Project, 2004).

MEKONG REGION: Improving Malaria Control Among Vulnerable Populations

34. Improving malaria control in vulnerable populations such as among hard-to-reach ethnic minorities remains a challenge. Barriers such as poverty, isolation, geographic and cultural barriers hamper access to and use of health services. In an attempt to increase control of malaria, WHO and the Asian Development Bank joined efforts to sponsor OR to inform the development of behavior change communications (BCC) programs for the vulnerable populations of the Mekong region. Program managers and data collectors across the region were trained to use a standardized research methodology which included household surveys and focus group discussions (FGDs). Implementation challenges were numerous, and consisted largely of a lack of capacity to conduct surveys in difficult settings where language barriers existed. A lack of database management and reporting and inadequate follow-up from central stakeholders were also problematic.

35. In spite of these difficulties, research results provided important information that was used to adjust programmatic interventions and increase access to malaria control efforts. Improvements to better monitor interventions were also instigated. BCC materials were adjusted based on OR findings and awareness about malaria control and health services was increased among vulnerable populations. OR also highlighted the urgent need to increase national expertise in social sciences and anthropology and to build national capacity to conduct research. (Source: Mekong Malaria Project).

Partners and Sources of Support in OR/IR

36. Several large international donor partners have been sponsoring OR/IR in the context of their support for national health and disease control programs. Below are some examples - including but not limited to - TDR, USAID, and the Global Fund. Other partners who focus more on research include the International Bank for Reconstruction and Development (IBRD, the World Bank), Rockefeller Foundation and CODESRIA (with more examples found in Annex B). TDR has for 30 years sponsored IR aimed at:

- Assessing the real-life, setting-specific, large-scale effectiveness of disease control tools, products and approaches in order to provide the evidence that policy-makers need to take decisions on options and to set realistic implementation targets.
- Identification of common critical implementation problems that are susceptible to research and their consumer-related determinants which, if addressed, could result in effective large-scale equitable access to interventions.
- Development of practical solutions to implementation problems and testing whether new implementation strategies based on these solutions are effective and can significantly improve access under real-life conditions of routine disease control.
- Determination of the best and most cost-effective way to introduce new implementation strategies into the public and private-health care systems and approaches to facilitate their full-scale implementation, evaluation and modification as required.

37. A strong example of TDR's IR is development, field testing and expanding the application of community-directed interventions (CDI), first in the control of onchocerciasis through community involvement and subsequently in testing the approach in interventions to control malaria, distribute Vitamin A and treat TB. The CDI approach was adopted by the African Programme for Onchocerciasis Control and used by national disease control programs throughout the African continent.

38. Since its inception, the Global Fund has made funds available for countries to conduct OR as part of a broader M&E effort. Countries have the option to include such research in their proposals or to add OR/IR studies as the need arises. Ideally, such OR/IR should produce results in a timely manner so that findings can be integrated into grant implementation to improve program performance. The fact that little is presently known about whether and how countries are using this research opportunity prompted staff at the Global Fund to engage TDR to take research experiences from the field and draw on the rich resources of published guidelines to develop a simple, user-friendly framework to enhance likelihood of OR/IR being planned, implemented and its results used, not only with Global Fund grants but with resources from a variety of donors including those within countries. [One can find OR guidance for Global Fund proposals currently at the following website http://www.theglobalfund.org/en/apply/call8/technical/]

39. USAID has developed research over the years to address child and reproductive health and HIV efforts, as for example the Applied Diarrheal Diseases Research, Horizons, and Applied Research for Child Health programs. These programs not only provide country-specific information and lessons learned but have also resulted in production of handbooks and guidelines to aid others in conducting similar research.

SECTION B
METHODS AND MANAGEMENT
FLOWCHART

The OR/IR Flowchart

1. Based on a review of experiences and existing documents, the core of this framework consists of a flowchart of 16 steps that will lead from conceptualization and the design of OR/IR through implementation into strategies to ensure dissemination and uptake of the findings to improve health and disease control programs. This flowchart of OR/IR activities is outlined below and forms the basis of Section B of this framework. As mentioned, a checklist developed from the flowchart was also used to help gather data from OR/IR projects in the field and was thus in part validated through these experiences. Note that this process in not always step-by-step, as several activities may be happening simultaneously.

A FLOWCHART OF THE OR/IR PROCESS

I. PLANNING

1. Organize the research group and advisory committee
2. Determine issues or problems to study and frame research questions around these
3. Develop a research proposal to answer OR/IR questions
4. Obtain ethical clearance
5. Identify funding sources and obtain support for OR/IR
6. Establish a budget and financial management procedures
7. Plan for capacity building and technical support

II. IMPLEMENTATION

8. Monitor project implementation and maintain quality
9. Pre-test all research procedures
10. Establish and maintain data management and quality control
11. Explore together with stakeholders interpretations and recommendations arising from the research findings

III. FOLLOW-THROUGH

12. Develop a dissemination plan
13. Disseminate results and recommendations
14. Document changes in policy and/or guidelines that resulted from the research
15. Monitor changes in the revised program
16. Consider ways of improving the program that can be tested through further research

I. PLANNING PHASE

STEP 1: Organize the research group

2. At the beginning of planning for OR/IR, the people involved in the particular health or disease control program need to think carefully about who will be involved in carrying out the actual research. Possibly the first few steps outlined below will be led by the program people themselves so that the OR/IR will be based in real program needs.

a) Selecting the researchers

3. Because of their major work responsibilities, program managers and staff will rarely conduct the OR themselves, but may contract with a university, research institute, NGO or even another unit within a health ministry (e.g., a planning/research unit) to carry out the day-to-day research activities. Program managers therefore need to identify and choose the researchers relatively quickly. Depending on national regulations, the choosing of a research group may need to be put up for competitive bid or it may simply be a matter of requesting a proposal from an experienced and trusted group.

4. An important criterion for choosing an appropriate research team will likely be the availability of members with multidisciplinary backgrounds. Since OR/IR deals with real-life program challenges, researchers may need a mix of backgrounds such as public health management, health behavior change, epidemiology, biostatistics, clinical services and laboratory investigation, to name a few. As people begin to consider the first step below, the nature of the OR/IR will become clearer and so will the specific research skills needed.

b) Form an advisory committee or working group

5. After researchers are chosen, the program managers and staff still have an important role to play in the OR/IR to ensure the results meet program needs. A working relationship between program managers/staff and the researchers must be built. Since OR should be a relatively short process, this relationship does not have to involve establishing a formal group. A simple advisory committee or working group that consists of five to six people including researchers, program managers and if possible, constituencies of people affected by the issue/problem could meet on a regular basis (e.g., monthly) to ensure that there is ownership of the results by all concerned parties and that the results are put to use in a timely fashion. An example of how researchers and program staff work together in Nigeria is found in Annex E.

6. While the actual research will most likely be conducted by a team from a well-known research organization, others will have a valuable perspective on the practical issues the research is addressing. Since the ultimate aim of the research is to benefit health policy and programming, and may in fact be tied to improving the performance of a specific health or disease control program, it is important for program managers/implementers and program beneficiaries/affected people to be kept informed about and involved in the progress of the research and offer their suggestions.

7. This is not to suggest that major stakeholders actually play a role in conducting the research. This may introduce some bias in the results since it may be the performance of the implementers that is under study. In research - even of the operational or applied kind - it is still important to maintain objectivity.

8. Advisory committee meetings can be used to update committee members and seek their advice about any implementation problems encountered. Toward the end of the research the advisory committee can play an active role in planning dissemination activities.
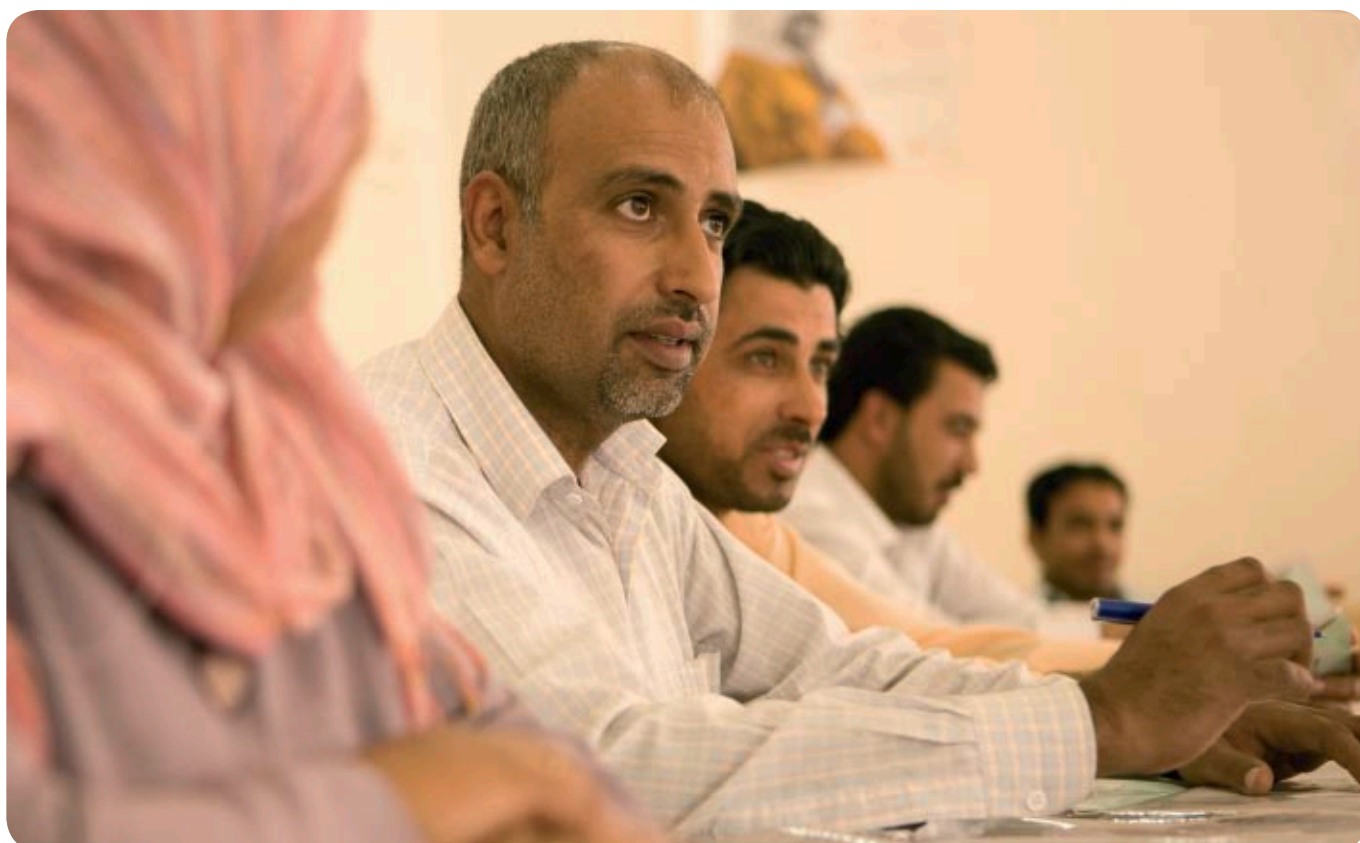
STEP 2: Determine issues or problems to study and frame research questions around these

9. The first step in undertaking OR is to identify an appropriate research question that will serve to improve the functioning of a health program. Questions addressed by OR should arise out of the actual implementation of a health or disease control program and should emerge from discussions with program managers, researchers and clients of the services. OR questions should relate to specific challenges faced in implementing and managing health programs such as service delivery or program uptake problems, and should thus serve to provide answers that will improve overall program performance. Additionally, it is important to distinguish between questions that are appropriate for OR and those that are not. For example, finding out the number of people served by a program is not a research issue, but rather should be a part of regular program monitoring.

10. OR/IR questions may be defined at three levels. The actual OR/IR may start at different levels depending on the extent of previous relevant research in the country on which one can build.

1. Identifying the health program implementation issue or problem,

2. Considering underlying reasons for the issue or problem that can be examined through OR, and

3. Proposing possible solutions that can be tested to address the issue or problem.

LEVEL 1: Identifying the Program Implementation Problem:

At the first level, project staff may know from basic M&E reports that there is a problem in program performance or service uptake. This information helps project staff identify what component of their program needs to be modified in order to improve service delivery.

LEVEL 2: Considering Underlying Reasons:

Once the problem has been identified, the next step is to understand why it is occurring. Once programmers understand what barriers exist to solving the problem identified in level one and why those barriers are occurring, solutions to overcome the problem can be proposed.

LEVEL 3: Testing Possible Solutions:

A key function of OR is to test and compare potential improvements to existing health services. From personal experience, collaboration with partners and a review of existing literature, staff and researchers can identify potential approaches that may be applied to address the problems identified in Levels 1 and 2. Two examples of these levels of developing research questions are found in the following chart.

11. Prior to framing research questions, it is important to take into account any research, project reports or assessments which may have previously been conducted that might provide insight into research questions. Conducting a literature review is essential in developing research questions pertaining to all three levels outlined above. In addition to learning what other OR has been conducted so that efforts are not unnecessarily duplicated, learning from others' experience can provide insight into OR design and provide a foundation on which to build. For example, a program needs assessment may have been conducted that documents the extent and reasons for drug stock-outs in clinics. Based on the report of the assessment, the problem (level 1) and its underlying causes (level 2) may already be known and OR designed for testing possible strategies for improved program delivery (level 3) can be done. Or, research emerging from other local groups or universities about ARV adherence may examine similar research questions, and these existing resources can be used as a starting point for suggesting possible problem-solving approaches that can be tested.

Two Examples of Developing the Operations/Intervention Research Questions		
LEVEL	HIV	MALARIA
1. Identifying the Problem	Reports at a health clinic may show that despite the presence of a program offering antiretrovirals (ARVs) to HIV-positive clients, the prevalence of opportunistic infections (OI) such as diarrhea and pneumonia among clients has risen. An OR question arising at this stage may be "Why are HIV-positive clients experiencing poorer health outcomes?" An OR study examining this question might discover that HIV-positive clients are not adhering to their treatment regimens and are therefore more susceptible to developing other illnesses.	Monitoring data from several districts in the state/province may show that less than 40 percent of pregnant women who register for prenatal care are getting the required two doses of intermittent preventive treatment in pregnancy (IPTp). This reflects only those who register. A look at recent data from a Demographic and Health Survey (DHS) indicates that, on average, only 70 percent of pregnant women attend prenatal care at least twice. This means that the country is far behind the RBM targets of 80 percent of IPTp by 2010. An OR study might want to find out why women are not getting this preventive medicine.
2. Considering the Reasons	An OR question at this level may be "Why are HIV-positive clients not adhering to their treatment regimens?" Research might discover that clients are not adhering to their regimens for several reasons, such as poor communication between clients and staff; low-income clients do not have enough money to afford transportation to the clinic to refill their prescriptions; clinic hours are too short and clients cannot afford to miss work to visit the clinic during the day; clients are reluctant to visit the clinic because of the perceived stigma associated with seeking services there; or clients are discouraged from returning to refill their prescriptions because of frequent drug shortages.	Two types of questions may be addressed at level two. First, the research team might ask, "Why are more pregnant women not attending prenatal care?" Secondly, "For those who attend, why are they not getting two doses of IPTp?" For the second question, the researchers may discover that women tend to register very late for their first prenatal care visit and not have time to complete two IPTp doses. There may also be local beliefs that a pregnant woman should not let people, including prenatal care staff, know she is pregnant until the pregnancy is really showing. Others may believe pregnancy is "normal" and so there is no rush to register. Finally even if they attend, there may be shortages of drugs for IPTp.
3. Testing the Solutions	For example, in regards to the barriers to drug adherence discussed above, one possible solution to address the problem of drug stock-outs may be to conduct an in-service training for clinic staff to improve drug forecasting. Another potential solution may be to develop clinic-based performance standards that inform the basis for problem solving among staff. Also, OR could be designed to examine and compare the effectiveness of both of these approaches.	At this level the research team in consultation with program staff may learn that the issue of "hiding" the pregnancy may be the major issue, especially for younger or low-parity women. The group may decide to test two approaches, one based in the clinic and the other in the community. The clinic approach may be to train the health staff with better interpersonal communication skills, especially stressing confidentiality and combine this with offering prenatal care registration any day of the week so no one will suspect a woman is coming because she is in the early stages of pregnancy. The second approach may to train older and trusted women in the community to administer the first does of IPTp in homes.

12. A good place to start a literature review is with local documentation such as project reports and university dissertations/theses/projects. To learn more about relevant research conducted elsewhere, one can check Medline or PubMed on the internet, both of which can be used to search for relevant reference materials. An example of how to conduct a search on

PubMed and the "gray" or informal literature (e.g., project documents and reports) is found in Annex C. Case studies of OR/IR experiences that can provide lessons and offer guidance about conducting the research are found in the toolkit.

STEP 3: Develop a research proposal to answer OR/IR questions

13. A research proposal is a document that outlines - in as much detail as possible - what the research is about, why it is important, how the researchers plan to carry it out and how the results may be used. Sometimes one sees requests for proposals that provide a specific preferred outline that one must follow. Sometimes a group develops its own proposal and looks for donors, foundations and other potential funders. This framework provides an overview of the proposal process. Various guidelines and handbooks listed in Section C provide more details and should be consulted along with guidelines published by specific donors and foundations.

14. These tools outline different types of studies that can be broadly grouped into observational and experimental. The former may include surveys while the latter may use an intervention and a control group. Observational studies may be helpful in identifying the factors that have created bottlenecks to current programs. Experimental studies are useful for teaching and comparing different approaches, strategies and technologies for disease control. The decision may partly rest on time and resources. If a program needs answers to challenges and to address bottlenecks in order to reapply for continued funding, one might not have time to conduct a full-scale comparative intervention.

15. Listed are some of the common elements found in a research proposal in the general order in which they might occur. Remember that each funding agency usually has its own format, so the following list is only a suggestion.

COMMON ELEMENTS FOUND IN A RESEARCH PROPOSAL

1. Title page
2. Abstract/summary
3. Statement of research questions and objectives
4. Statement of purpose, rationale and importance of the research
5. Background information from reports and published articles on what is known about the research problem and how it has been approached in the past (literature review)
6. Overview of the study area providing information that is relevant to the problem at hand, the communities involved and the nature of the health system
7. Description of the intended research team (membership and capacity) including involvement of actual program management staff
8. Ethical considerations and approval processes (see Step 3)
9. Research methods (Examples of methods are found in several of the resources listed in Section C)
   a. Type of study design (cross-sectional, intervention, quasi-experimental, case control, etc. and whether the approach is qualitative, quantitative or mixed)
   b. Study population (this could be individuals, clients, health staff, health facilities, etc.)
   c. Sampling procedures
   d. Key variables under study (related to study objectives)
   e. Specific data collection instruments linked with study variables
   f. Plan for data collection in the field
   g. Procedures for data management, entry and ensuring data quality
   h. Possible sources of bias, error and limitations and means to address these
   i. Data analysis plan including some empty/sample (dummy) tables
10. Plans for dissemination and use of findings
11. Budget for the proposed project (see Step 5)
12. Budget justification
13. List of references for literature cited

16. Often researchers are not required to submit a fully-developed proposal in the first instance. Some organizations issue calls for "letters of intent" (LOI) that summarize the research idea in relatively small number of pages (which are specified in the letter). The box at the right gives a recent example from a call for LOI by TDR. If the funding agency is impressed with the LOI, it may ask the researchers to submit a more detailed proposal.

17. Applying for OR/IR within a Global Fund grant follows a different process. In the basic country proposal for HIV, TB and/or malaria, CCMs are encouraged to include plans for OR/IR as part of the M&E component of the proposal. In general, countries provide a couple of paragraphs in the proposal that explain the potential needs for OR/IR and outline some of the ideas they have based on the challenges that are currently facing their programs. After the grant has been awarded to a country and a Principal Recipient (PR) has been chosen, more specific negotiations start in terms of planning the OR/IR and identifying the research team or institution. Ideally OR/IR within a Global Fund grant will help overcome implementation bottlenecks and test interventions that can improve program (and thereby grant) performance.

HOW TO APPLY/SUBMIT A "LETTER OF INTENT"

Interested groups are invited to submit a letter of intent of no more than four pages (size A4, font 12pt) outlining the following:

1. Project title
2. Background and statement of the research question
3. Overall and specific objectives
4. Methods
5. Estimated budget
6. Relationship with any ongoing program, research project, network, any previous research experience with CDI and network
7. Proposed principal investigator, research institution and study team.

Letters of intent can be submitted in English or French (submissions in French should include a summary in English). A CV of the principal investigator should be attached. Letters of Intent must be submitted no later than ...

STEP 4: Obtain ethical clearance

18. Any research that studies human beings - whether they are community members or health workers - may put those people at risk. Most OR/IR activities will involve human beings who are receiving various health and disease control services. Researchers may be simply asking people to answer questions on a questionnaire or during a focus group, or they may be asking participants to take different medicines or to provide blood or urine samples. The latter are said to be more "invasive" and have a greater potential for harm than the former. Even with "simple" interviews there are costs involved, such as time of the respondent and risks involved in sharing personal information with a stranger (the interviewer).

19. In all cases, researchers must be sure that the potential for risk and harm is known and minimal and that procedures are set in place to explain the potential risk in easily-understandable terms to the people included in the study so that they can voluntarily make an informed choice whether or not to participate. As part of the proposal, researchers need to spell out the details of how they will explain research procedures and risks to potential participants and obtain evidence (a signature, a mark) that participants agree to take part in the research. Most organizations that fund research require not only that the researchers spell out these procedures, but that researchers show evidence of having gotten approval for these procedures. Note that consent forms must be written in a language that research participants can understand.

20. Most research institutions in particular have an "institutional review board" (IRB) or a "committee on human subjects" that reviews and approves the ethical and safety issues surrounding a research proposal before it can be implemented. Many countries have a national IRB also, which can undertake review for government agencies and other organizations that do not have their own IRBs. Some funding agencies require this ethical approval prior to considering the proposal. One needs to contact an IRB and follow their procedures to ensure that the OR/IR procedures are approved. Examples of a consent forms and IRB checklists are found in Annex D.

STEP 5: Identify funding sources and obtain support for OR/IR

21. Funding for OR/IR may come from different sources. The Global Fund encourages countries to include ideas for OR/IR within their proposals to the Global Fund and has an OR checklist on its website under the technical resources for proposal writing. TDR advertises new grant announcements on its website. Pharmaceutical companies and others who produce disease control products often offer small grants for OR/IR in the countries where they work. Foundations ranging from the more established (Rockefeller) to the newer (Gates) list grant opportunities on their websites (see Annex B). It is usually the case that most research funders have an established agenda and often do not accept unsolicited proposals not falling within their agenda, which can change from year to year. Bilateral donors often set aside a small amount of funds for OR/IR related to the implementation of programs they are assisting in order to make these relevant to the countries concerned.

22. Specifically, if one is in the process of preparing for a large donor grant, one should check out the provision and requirements for OR/IR in that particular grant. Make sure that the actual instructions are read carefully and followed to ensure that the OR/IR request actually links with the goals of the broader grant and meets any criteria specified by the granting organization.

23. This does not stop a group or agency from developing an OR/IR proposal and checking with other potential funders who might be interested. One needs to do a thorough search of the types of foundations and donors who might fund the idea – e.g., find out who funds HIV/AIDS studies at the community level. This will require talking to various donor agencies in the country to learn about their interests and priorities. The first step is often sending a potential foundation, donor or funding agency a short letter of intent that briefly describes the intended project. If the funder is interested, they may ask for a more detailed proposal.

STEP 6: Establish a budget and financial management procedures

24. Funding agencies will expect that the researchers will have devised a comprehensive budget and can justify the need for each item. Since researchers are planning OR, researchers may have budget items that relate to the research itself as well as to any programming activities that are being tested. The chart below outlines some of these cost/budget items. Guides and

Illustrative Examples of Budget Items for Operations Research		
Research Costs	Implementation or Program Costs	Institutional Costs
• Personnel* including staff, field workers, research assistants, data managers, etc. as well as consultants who could provide short-term technical support • Supplies and materials including printing of study instruments (e.g., questionnaires), notepads, pens, etc. • Equipment such as computer, printer, tape recorder (for interviews) – some funding agencies may limit the type of equipment • Travel or transportation including hiring of vehicles, taxi fare, fueling of available vehicles, vehicle maintenance • Per diems or travel allowances for project staff are usually part of the travel budget • Dissemination costs including renting of halls for seminars, purchase of media time or space, production of briefing sheets	• Educational materials for clients and community members • Funds for mobilization • Job aids for health-care staff • Training programs for implementers • Commodities needed for intervention (bed nets, medicines, test kits, etc.) which are not already being provided by the existing program	Most research institutes and universities have what are known as overhead costs. These cover their basic operating costs ranging from electricity to support staff, but are difficult to itemize directly in a research budget. Most institutions have a standard overhead charge that is a certain percentage of the total costs of running the research (i.e., those items in the first two columns). Some donors do not pay for overhead costs. They see these as part of "local contribution" to the research effort. Be sure to check the donor requirements before including overhead costs.

*Some agencies that fund research will pay a reasonable percentage of the normal salary of the actual researchers, while others will pay researchers' travel costs and per diems but expect that their time (salary) be "donated" as part of the research institution's contribution to the project. Check budget guidelines for any funding agency very carefully before including any item listed above.

manuals in the Toolkit (Section C) provide more details and examples.

25. Any research project should include on its administrative staff a financial officer (accountant). This is usually a person already on the research institution's staff and a reasonable portion of this person's salary is included in the budget. The financial officer keeps track of expenditures and reports regularly to the team. The funding agency may also require an independent audit of project expenditures.

STEP 7: Plan for capacity building and technical support

26. Capacity building for OR means ensuring that all persons involved in carrying out the research have the skills and knowledge necessary to perform their roles. These people might range from staff at the institution responsible for the research to the interviewers, field workers and other assistants they hire or health workers in the facilities where new health and disease control interventions are being tested and community members who may take part in delivering and monitoring services at the grass-roots level.

27. One must balance the need for longer-term institutional capacity development with the immediate need to acquire the skills and capacity to conduct OR now. This is because OR tries to answer the near-term questions that will make a health or disease control program function better. For example, some programs receive annual or mid-term reviews on their performance. Results from OR may be needed to provide evidence that the program has gained knowledge to overcome the difficulties it faces in achieving results so that funding can be continued. Therefore capacity-building plans should not consider sending people off to another country for a five-year doctorate program but rather find ways to help those involved in the project right now do their jobs better.

28. Researchers can consider appropriate short-term capacity-building mechanisms such as mentoring by senior researchers, direct experience (on-the-job training) for researchers and staff through the actual implementation of the OR project or organizing short courses that might last no more than a month. These activities need to be planned in advance and may have costs that need to be included in the budget.

29. Technical assistance or support can be another way to build capacity. One can budget for experts/consultants in a particular aspect of OR to work with the research team for short periods of time. The consultants would be expected to pass on their skills to the research team so that the team can complete this project and be in a better position to undertake similar research in the future. For example, the team may not have much experience in managing and analyzing data (either quantitative or qualitative). There may be a person from another university or even NGO in the country or in a neighboring country who could come to work with the team during the data collection process to help them develop and implement the procedures for data management and teach team members to use both manual techniques and computer software to analyze their data.

II. IMPLEMENTATION PHASE

30. In implementation - as in planning - there is a need to continue to involve key program managers, staff and communities in the process (e.g., through the advisory committee) to ensure that the OR/IR remains based in and addresses the needs of the health or disease control program.

31. It is quite possible that during the process of developing and formulating the research questions the team found that in fact cultural issues were among the reasons that health and disease control programs were experiencing difficulties. Therefore, one needs to be sensitive to gender, social and cultural issues when implementing the research. For example, in some places women feel more comfortable talking to other women, and if the issue concerns something like pregnancy and reproductive health, women might be more comfortable talking with other women who have been pregnant before. This understanding could guide selection of research staff and determine how they interact with people in the field.

STEP 8: Monitor project implementation and maintain quality

32. A key issue of quality control in research is maintaining fidelity (faithfulness) to implementation of the research as planned. Once a proposal has been accepted for funding it is important for the team to develop a **research protocol** that spells out in detail the steps to be taken in implementing the project, ranging from sampling procedures to staff preparation, instrument development, data collection procedures, field work procedures, data management processes and reporting standards, to name a few. More information can be found in the reference guides and handbooks listed in the Toolkit (Section C). One role of the small advisory committee can be regularly checking that the protocol procedures are being followed correctly and in a timely manner.

33. The research team must have a plan of action or **work plan**. The plan can include the following components:

- A comprehensive listing of all activities to be implemented
- Indication of date of commencement for each activity

- Indication of expected date of completion of the activity
- Indication of responsible person/s for each activity
- Indication of important milestones for each activity

34. Regular progress meetings are needed among the research team members to ensure that the research plan is being implemented as intended. If problems arise, the team can make timely decisions to correct these. During implementation, the research team probably needs to meet on a weekly basis.

35. It is important to stress again that monitoring of the research should also be done as part of regular team meetings. Since OR is a relatively short-term activity, meetings to report on progress may need to be held weekly or at least monthly. The team will likely have weekly meetings and then report to the advisory committee on a monthly basis.

36. One aspect of monitoring is ensuring that the action or work plan is progressing according to the desired timetable and that expenditures are also adequate and timely. Other specific details that must be addressed at different stages of the research are outlined below. Ideally the team would want to report regularly to the funding or oversight group and the health/disease program implementers to ensure they are carried along. The items below can form a monitoring checklist.

During preparation ensure that:
- Adequate numbers of research instruments are printed/prepared in advance of field work
- Equipment and supplies are purchased
- Field staff are recruited, interviewed, selected and trained
- Data entry formats are designed and data entry staff are recruited and trained
- Logistical arrangements (e.g., transportation) for fieldwork are arranged
- Key persons in the field are notified and their concurrence obtained (health staff, community leaders)

During implementation ensure that:
- Community members, agency staff, and other respondents/informants are actually responding
- Field staff are punctual and enthusiastic about their work

- Funds are adequate and provided in a timely manner (keep an eye on the budget)
- Materials and instruments needed for each day's activities are adequate and provided in a timely manner
- Logistics are functioning to ensure that field staff can move around
- Data quality is maintained through daily review of instruments completed
- Data entry/transcription begins within 24 hours of data collection in order to provide timely feedback if data quality problems are observed

During wrap-up and analysis ensure that:
- A clear data-analysis plan is in place including mock/dummy tables, charts
- A report outline is ready and agreed upon by all
- There is agreement about analysis procedures, statistical tests and software
- Preliminary analysis is reviewed by the team before final analysis
- Findings are reviewed by researchers and stakeholders to come up with interpretations and suggestions for action

During dissemination ensure that:
- Key audiences have been identified
- Preferred methods and media for reaching each audience are ascertained
- Briefings, presentations are prepared and reviewed
- Briefings, presentations are scheduled and delivered
- Follow-up is done to ensure commitment to utilizing results to improve programs, policies
- Program managers and researchers monitor implementation of findings

STEP 9: Pre-test all research procedures

37. Research instruments, whether quantitative (questionnaires, observation checklists) or qualitative (FGDs, in-depth interviews) should be both valid and reliable. *Valid* instruments elicit the "truth" from respondents. *Reliable* instruments provide consistent information. If questions are vague and use complicated language or if checklists seek items that are difficult to observe, then they may not achieve the aims of validity and reliability. It is therefore necessary to test out the

instruments under the type of circumstances where they will be used in the field, possibly in a different community not within the study area with similar characteristics to the study community.

38. Instruments may be available from similar studies from the same country or from other countries in the region. It certainly saves time to adapt available research tools, but if these were developed in a different environment or focused on a different health issue, the adapted product still needs to be pre-tested in the relevant environment.

39. One aspect of the pre-testing is to ensure that the instruments are formatted in a language that the respondents can understand. Translation and back translation are needed to ensure that the concepts and variables as expressed in a local language match those that the researchers intended. The instruments should be written using translated questions and items so that each data collector is consistent in administering the instrument.

40. If there is a survey, one might pre-test 10 to 20 questionnaires with people with similar characteristics to those who will be included in the full study. One could try a few in-depth interviews and a couple of FGDs to see whether people respond appropriately. Ideally with qualitative interviews (FGDs, in-depth interviews, etc.) it is helpful to both tape-record and take handwritten notes. Remember to clear the use of tape recording as part of the ethical review process.

41. The pre-testing process should help identify questions that are misunderstood or difficult to comprehend. The pre-test may identify questions where everybody gives the same or similar answer with no variety. One might see that mothers respond affirmatively concerning use of health services but are unable to show their child's growth charts and immunization card. One might be trying to observe drugs kept at home for malaria but find that no one admits to keeping these. These are examples of problems that raise an alarm and indicate that certain questions or items should be dropped or changed. If major changes are made, a second pre-test may be needed.

42. Two groups of people can be involved in the pre-testing process to strengthen their skills and contributions to the research project. One group is

the actual interviewers and field assistants. As part of their training they can be involved in the pre-testing. The second group is the data management staff. They will gain insights into the nature and the quality of the data to help them develop the most appropriate data entry formats and analysis procedures.

STEP 10: Establish and maintain data management and quality control

43. Quality data management begins with the design of the research instruments. As noted above, these need to be pre-tested to ensure that they elicit reasonable and truthful responses. Review by colleagues and experts who compare the instruments against the research questions and objectives is needed to ensure that the data collected actually corresponds to with variables that should be studied. In short, one needs to ensure that the study variables are operationalized to reflect the objectives of the study.

44. The instruments must be easy for the data collectors to use. Ambiguities for both respondents and data collectors should be removed. Well-supervised training of data collectors in real-life field conditions is required to ensure that all use the instrument accurately and in the same way.

45. During field work, research supervisors should be trained to observe the data collectors regularly. Senior researchers must be in the field to ensure that the data collectors take the project seriously. The research supervisors need to review all study instruments at the end of each day (questionnaires, FGD transcripts, in-depth interview transcripts, observational checklists, etc.) for completeness and accuracy. Before field work begins the next day the supervisors - together with members of the research team - should organize a short feedback session with the data collectors to discuss general concerns about data quality. After this, individual data collectors can meet with supervisors for personal feedback.

46. The team should consider software needs for data entry. If one is going to be doing simple quantitative analysis that involves frequencies and tests of association, EpiInfo Version 6 may be adequate. If one plans to test multiple associations and develop a model to explain, for example, health service utilization behavior, more complex (and expensive) software may be required. The research institution may already have a license to use these software programs or the cost may need to be added to the budget.

47. Qualitative software helps code and sort information in typed transcripts. Qualitative software does not replace the need for the researchers to thoroughly read all available data. There is always the basic and reliable option of hand coding and analysis where no software packages or software competencies exist. Research teams must develop analysis plans showing clearly how the data will be analyzed and for example, develop "content analysis tables" that clearly show/compare views of all respondents by all relevant quotations on all the key study variables.

48. Data entry (computer entry of survey results, typing of interview transcripts) should begin while data collectors are still in the field. Data entry clerks should be trained on the job with actual completed instruments. In the process of entering data, the data clerks are likely to identify additional problems, and if data collection is still going on in the field, they can send these instruments back for clarification and correction before it is too late. As a reminder, ensure that all needed equipment and supplies for data management are included in the budget.

49. Some quantitative data entry programs like EpiInfo allow for double entry and/or a checkfile that limits entries to accepted values and compares entries. If double entry is not feasible, then it is possible to spot some problems when running simple frequencies where inappropriate values may become apparent. Concerning typed transcripts of qualitative interviews, one can have the interviewer/moderator review and compare these with the hand-written versions.

50. Missing values should be caught at all stages – daily review, data entry, and simple frequency analysis. One should be sure there are no missing values because one never knows whether a blank means that the question was not asked or that the person did not respond or that the interviewer forgot to fill in the response. Missing information may occur in both qualitative and quantitative instruments due to oversight. For example, FGD moderators may forget to ask a follow-up probe.

STEP 11: Explore together with stakeholders interpretations and recommendations arising from the research findings

51. The next phase, the "follow-through", involves the actual dissemination and use. Prior to dissemination it is important for the research team and the stakeholders (e.g., community leaders, program managers/staff, donors) who were members of the project advisory committee or working group to review the results and have a clear and shared understanding of the implications of these findings.

52. The first meeting about the findings should occur within a week after data entry is finished and a set of preliminary frequency tables or qualitative interview summaries can be produced. The group can pick out the highlights and make suggestions for further analysis. For example, the study may have documented that only 25 percent of women in the community got two doses of IPTp during their last pregnancy. FGD respondents explained that younger and older women are most likely to register late. The data management team could then compare age with IPTp coverage to present at the next meeting. If the project also addressed alternative delivery mechanisms and found that, in communities where local volunteers were used, it was the volunteers who got women started on IPTp, then, rather than programs to improve interpersonal communication and confidentiality at clinics, the group might ask the data team to provide more information from the in-depth interviews to explain why women preferred the community volunteer approach.

53. By the second meeting, the group should start listing the key findings and the related implications for improving the program. They can brainstorm about appropriate audiences with whom to share this information in a timely manner. Feedback to communities is essential, as seen in the Malawi case study on TB in Section C. The group can then agree on recommendations and final messages that are appropriate to each group. The group should some up with a road map that leads from findings to action, that is, a step-by-step plan of whom to contact and how to approach them.

54. An important consideration is reviewing the key stakeholders that can act on the information and recommendations. These may have changed in light of findings/conduct of study. The study may have found that there are respected women's associations in the community that were crucial in selecting and supporting the community volunteers. These now become stakeholders in the future success of IPTp program coverage. Another finding may have pointed to the role of something like a public service commission that is responsible for staff placement and promotion. It may be the actions of this group in frequently transferring staff that made it difficult for health workers to develop a trusting relationship with community members. Reaching out to these "new" stakeholders with the appropriate messages should be considered by the committee/group.

55. As a final step, the group should start assigning responsibilities for follow-up actions. The group can begin to outline the budget needs for packaging and sharing the findings.

III. FOLLOW-THROUGH PHASE

56. Those who provide financial and technical support for OR/IR, including national stakeholders, are concerned about the long-term effects of that research. They want to ensure that something happens as a result of the research that will have a lasting and beneficial effect on health programs. "Three decades' experience with OR projects [in reproductive health and in TDR] shows that OR can effect lasting changes in programs and in some cases findings also can result in policy changes. Collaboration with policy-makers, provisions for sustainability, and responsiveness to local needs are among the ways of ensuring sustainability of program changes that result from OR" (WHO, 2003). This section outlines steps to take the results from research to practice and policy and hopefully longer-term change in program quality.

STEP 12: Develop a dissemination plan

57. Dissemination activities must be matched to key audiences, including policy-makers, program managers, service providers, program beneficiaries and donors (Marin and Bertrand, 2003). In planning dissemination, researchers need to distinguish between "internal" and "external" audiences. Researchers can make the following distinctions when planning to disseminate the findings:

➤ **Using the results** focused on one set of people – an "internal" audience

- Approach those who can directly and immediately act on the knowledge and lessons generated
- Recognize that the main purpose is to use the information

➤ **Sharing the results** looking at a broader set of people – an "external" audience

- Approach those who might adapt the information
- Address those who may have general interest

58. TDR (2005) provides a good example of a simple dissemination plan for a TB OR project:

This research program seeks to have a significant impact on the future of TB control in several countries. In order to achieve this objective, the program includes a stakeholder and political analysis, and beyond publication in international peer-reviewed journals, dissemination efforts will target those individuals and institutions that will have the most impact on local and national TB policy.

Dissemination plans for external audiences may include:
- Annual presentation of research findings at national and international conferences
- Publication of research findings in national and international peer-reviewed journals
- Meetings with local and national stakeholders to discuss research findings
- Use of videotaped life histories of patients in advocacy work with the permission of interviewed subjects
- Regular reports to the funding agency (e.g., TDR requires annual reports)
- Press releases and briefings

59. The public media is often of equal importance to professional channels (peer-reviewed journals) because OR should result in programs that are more accessible and acceptable to the public.

60. Dobbins et al. (2007) examined the issue of knowledge dissemination from the viewpoint of agency and program managers who are potential users of OR. They found four dissemination approaches preferred by over 90 percent of their respondents (people from a variety of public and NGO agencies). These four were 1) conferences/workshops, 2) short summaries, 3) colleagues and 4) professional journals. Even though this study took place in Canada, the respondents were least interested in internet/web-based dissemination approaches.

61. Regardless of audience (internal, external) the team needs to think about the advocacy process. This entails determining who has the best "voice" to promote the results with the audience most likely to act on the findings. While the research team is in the best position to disseminate and explain their actual findings, they may not "have the ear" of important decision-makers. Sometimes program managers

and policy-makers are more likely to listen to citizen groups. Sometimes respected former national leaders are good advocates. There may be key journalists or media personalities who have good experiences in promoting certain health and related issues. Identifying and involving the most effective advocacy voice must be part of the dissemination plan.

STEP 13: Disseminate results and recommendations

62. Dissemination itself involves carrying out the suggested steps and activities as planned. The research team needs to involve the advisory committee as mentioned. An important role of the committee is serving as a reality check. Marin and Bertrand (2003) ask, "Were results of the OR study judged to be credible/valid in the local context?" This question, they say, "refers to the judgment of stakeholders (policy-makers, researchers, donors, program managers). It is assumed that utilization of results would be limited if stakeholders seriously questioned the validity of the results."

63. They also ask, "Was the research relevant for the national program?" The answer is "based on the perceptions of the same stakeholders listed above. Relevant research addresses a priority problem of the program, whether a national program of the Ministry of Health or a more local program of an NGO."

64. Issues like timing, venue and opportunity need to be considered. There are several elements to timing, including presenting the results after the research has been fully concluded. Early results may be misleading and create false expectations. The presentation of results also needs to be timed for when it is most likely to be used. If a country completes its budgeting process in June or a donor requires that renewal proposals for a grant are due in July, it does little good to present the results in August.

65. Dissemination must take into consideration the convenience of the audience/stakeholders. Staff from the Ministry of Health may be reluctant to attend a meeting at the university campus some miles away. Hold an event in the ministry auditorium.

66. The International Food Policy Research Institute (Loechl, 2005) describes a personalized process for disseminating the results of a child nutrition program in Haiti. Structured feedback was provided.

The results of this first round of OR were presented in Haiti and discussed with the program staff. A one-and-a-half-day meeting was held to identify and prioritize potential solutions to address the operational constraints identified and to develop a plan of action to implement corrective actions to strengthen program operations and improve the quality of service delivery. The tools used to guide this process and the action plans agreed upon by the … staff are presented in the final section of [the] report. A second round of OR will be conducted … to monitor the implementation of the corrective measures and to document improvements in program operations.

STEP 14: Document changes in policy and/or guidelines that resulted from the research

67. Marin and Bertrand (2003) encourage OR teams to ask, "Did the implementing/collaborating organization(s) "act on" the results (i.e., continue to implement the activities tested in the OR study after its completion if effective or not implement/discontinue this activity if ineffective)?"

68. They explain that " "acting on the results" consists of implementing the actual services of the intervention or the activities to support those services (e.g., training courses, development of service delivery guidelines, changes in allocation of personnel, production and testing of IEC materials, supervision, monitoring) if the intervention was effective, or not implementing or discontinuing these services and activities if the intervention proved not to be effective."

STEP 15: Monitor changes in the revised program

69. At this point, responsibilities for the research results pass back to the program managers and stakeholders, although the researchers may still have a role to play. It is incumbent on the program to use its existing M&E mechanisms (Health Management Information Systems) to report on key indicators that show whether the changes were effective on the larger scale, in particular if the OR/IR was carried out to address a program performance bottleneck, and the suggested changes in policy and procedures have been implemented.

70. For example, an OR field test may have found that in several communities, distribution of ITNs by community-chosen volunteers achieved greater coverage and use than campaigns based at the district health facilities. If the national malaria control program adopted and implemented this new approach, one would want to monitor whether in fact after scale-up the coverage increased uniformly across the country. The original OR team could still be involved in conducting coverage and use surveys around the country, even though this activity would be part of routine M&E activities.

STEP 16: Consider ways of improving the program that can be tested through further research

71. The above example about changing the ITN distribution strategy provides a good example also of how monitoring the results of implementing one set of research findings may lead to new research questions. The regular program monitoring surveys just mentioned may find that in most areas of the country ITN coverage and use did, in fact, increase and reach program targets. Unfortunately, the surveys might have found that in a riverine/coastal area or among a group of primarily nomad people the new strategy did not work any better than the previous campaign approach. This finding raises new OR/IR questions and can start the OR/IR process over again with a new focus. Program improvement is an ongoing process.

SECTION C
CASE STUDIES, TOOLKIT, RESOURCES AND REFERENCES

1. This section consists of three parts. The first part offers two additional case studies supplied by attendees of the consultative meeting/workshop on OR/IR that reviewed the first draft of this document. The second section offers links to a sample of existing handbooks, guidelines, and other reference materials that can help people plan OR/IR. Finally there is a brief list of references to materials quoted in Sections A and B.

Selected Case Studies of Operations Research

MALAWI: Linking Civil Society with Care for Tuberculosis

2. An OR study was conducted by the Research for Equity and Community Health (REACH) Trust to explore barriers experienced by the poor in one squatter area in the capital city of Malawi, Lilongwe. Although TB services are free at the point of delivery, it was found that the poor incur much higher transport and opportunity costs than the non-poor.

Feedback to the researched

3. Researchers are always concerned with data ownership but the question of ownership of the problem(s) identified through research is seldom thought about; REACH Trust went back to the community to make the findings known. Stakeholders at community level and local leaders were briefed about the research findings.

Problem ownership and source of solution

4. After the main research findings were communicated to the community in simple, understandable fashion, the local village chiefs understood the problem of TB in their community and asked, "So how are you going to help us?" This question was particularly pertinent because, despite a local population exceeding 32,000 people, there was no public health facility in the area. Furthermore, 24 percent of the population lived in extreme poverty.

5. In resource-poor settings such as a squatter community in Lilongwe, it can be difficult to provide novel solutions to effectively reach communities. Infrastructure is costly and human resource scarcity poses a critical problem. REACH Trust posed the question to the community in order to include their views and opinions about how to solve their problem. Such dialogue with the communities is critical if service delivery programs are to be improved and designed appropriately to meet the needs of each unique setting.

Intervention Developed

6. Based on the suggestions from the community, REACH Trust then developed the intervention, "Linking Civil Society with TB Care" to bring TB services closer to the people. A main objective of this program was to reduce transport and opportunity costs incurred by the poor in the area in order to improve use of TB services. The project was funded by the Norwegian Association of Heart and Lung Patients.

"Mtsiliza Model"

7. Community leaders suggested that a sputum collection center be created and village volunteers - four from each of the four villages - were identified. A TB Coordinating Committee for the area was put in place and each of the 12 community-based organizations (CBOs) chose TB care delivery component(s) to integrate into their programs. REACH Trust briefed local leaders and the coordinating committee on basic facts about TB and trained the volunteers on all aspects of recording and handling of sputa specimens from suspects. REACH also provided bicycles for transporting sputa specimens to and results from a diagnostic facility. Only then would identified TB cases travel to the TB registry to enroll for treatment.

8. Encouraging problem "ownership" and including the community in proposing and enacting solutions has been an integral component of ensuring the acceptability and sustainability of the intervention. The "Mtsiliza model" has been such a success that the Ministry of Health and the national TB program are now scaling it up to all regions of Malawi in order to intensify TB case detection and provide universal access to TB care. The capacity to identify problems and promote solutions has been increased in the community, and TB care is now well integrated into other health services delivered by CBOs.

SOURCE: EQUI-TB Knowledge Program/National TB Program, Lilongwe, Malawi www.reachtrust.org

BURKINA FASO: Examining Treatment and Care Practices for People Living with HIV/AIDS

9. In Burkina Faso, CBOs and NGOs were the first to set up HIV/AIDS prevention, testing and counseling and psychosocial support for people living with HIV. When antiretroviral treatment (ART) became available at the end of the 1990s, the same organizations opened medical facilities and started providing global care with the support of many foreign funding agencies and local donors. In 2005, various care practices co-existed within the context of the National Programme for ART. Thus, caregivers as well as program supervisors had little knowledge about the type of care provided in all facilities, the distribution of the people living with HIV between the public, private and CBO/NGO sectors, the profile of populations treated and the reasons for their choice of a health facility amongst various options. Moreover, caregiv-

ers witnessed a "therapeutic grazing" that led some patients from one sector to another according to the availability of support or aid. Caregivers were unsuccessful at understanding or controlling these multiple recourses.

10. In response to this issue, a research project entitled "Treatment and care practices for people living with HIV/AIDS in Burkina Faso" was proposed. Its aim was to get a precise knowledge of actual care practices in various settings, in order to understand patients' behaviors and needs and harmonize the provision of care. The main issues that were explored and treated included: circumstances of testing and provision of counseling in three sectors; access to various types of care and factors influencing selection; care practices; patients' follow-up; factors of adherence to ART; prevention; caregivers' attitudes towards professional risk; collaboration and coordination between health-care facilities.

The chosen approach was based on three phases:

- The first phase was devoted to a situation analysis and review of sources that allowed priority-setting through a multistakeholders consultation through an advisory committee.

- During the second phase, a multidisciplinary study was held by a team composed of two public health institutes and members of people living with HIV/AIDS (PLWHA) organizations as well as the national AIDS program. After fieldwork based on interviews with patients and caregivers, observation, collection of documents, followed by data analysis, the study produced quantitative and qualitative results on a range of issues which were discussed by the advisory committee.

- The third phase was participative. The most relevant results and a synthesis of objective and felt needs were selected. Three two-day workshops were held with stakeholders (caregivers from private, public and NGO sectors, PLWHA associations, policy-makers, program managers) in Ouagadougou and Bobo-Dioulasso. The results were presented, then groups were allocated priority topics on which a detailed discussion allowing experience-sharing provided concrete recommendations. A final report was produced by the research team.

11. The study approach was multidisciplinary, the aspects involved being socio-cultural as well as economical and related to the functionality of services and institutional organization. Through the ongoing involvement of the advisory committee that provided scientific and institutional guidance, this approach ensured a broad ownership of the research. The participation of more than 45 stakeholders during workshops and the opportunity they found to discuss their practices using the insight from the study results allowed the team to shorten the usually-long delay between the production of results and their reaching of target actors.

12. The difficulties encountered were mainly the large amount of information collected that required an important amount of work for analysis and publication and several delays due to administrative reasons that jeopardized the process. The results showed that care practices amongst public facilities and CBOs or NGOs were not as different as expected by health professionals, but were, rather, complementary to global care and used as such by patients. Practices in private health facilities, on the other hand, were very difficult to study due to patients' and caregivers' reluctance to participate in the study, and are still beyond the reach of collaboration efforts. An important result was the extent of difficulties in access to care for patients living in rural areas due to the lack of CBOs and NGOs. After the study, a national conference was planned to tackle the issue of free access to HIV global care for PLWHA in Burkina Faso.

13. The process of conducting this OR brought together various stakeholders and provided them with an opportunity to share individual and collective experiences, as well as to discuss practical or strategic issues. This ability to exchange experiences, increase collaboration and build capacity was as important for project outcomes as the results of the study.

SOURCE: Institut de Recherche en Sciences de la Santé, Ministry of Health, Burkina Faso

OPERATIONS RESEARCH RESOURCE TOOLKIT

Being a framework, this document has not gone into all the details involved in designing and conducting OR/IR. There are a variety of existing guidelines and handbooks that provide full guidance on selecting research methods and explain the different methods available. Some provide more explicit steps in planning a budget or writing a proposal. Several of these resources for conducting OR/IR are listed in the first sub-section below. Each item includes the title, an abstract of the major contents of the material and a web link to use for obtaining a full copy. The second sub-section outlines some more practical examples of OR/IR as well as reference articles that discuss OR/IR issues. There are links included so that readers can obtain their own copies of the materials. Again, this section is not exhaustive, but only illustrative. Even if a specific disease control or health program concerned is not mentioned, it is still possible to adapt these guidelines and examples to help plan OR/IR for the issues of greatest concern.

Operations Research Handbooks and Assorted Resources

de Savigny, D., H. Kasale, et al. (2004). *Fixing Health Systems* Ottawa, International Development Research Center.

In 1993, the World Development Report suggested that mortality rates could be significantly reduced if resources were directed more in line with local "burden of disease". The Tanzania Essential Health Interventions Project (TEHIP) was founded to test this idea. After a decade of research and experience, the verdict is in: the idea is solid, and has produced some remarkable results. This document presents the TEHIP story and holds important lessons that can be applied widely throughout the countries of the developing world and beyond.

Available at www.idrc.ca/openebooks/155-8/

Fisher, A. A., J. R. Foreit, et al. (2002). *Designing HIV/AIDS Intervention Studies; An Operations Research Handbook.* New York, Population Council.

This is a resource for HIV/AIDS researchers that can be used to inform research design and proposal development. Organized chapter by chapter like a proposal, it gives users the tools to develop and write a detailed OR proposal. By reviewing many key concepts and methods essential for conducting HIV/AIDS field research studies, the handbook also helps program administrators and health policy-makers understand how OR works and how to use research findings to improve HIV/AIDS service delivery.

Available at http://www.popcouncil.org/horizons/orhivaidshndbk.html

Fisher, A. A., J. E. Laing, et al. (1991). *Handbook for Family Planning Operations Research Design.* New York, Population Council.

This handbook is specifically designed to help health and family planning researchers develop and write a detailed OR proposal. It is also intended to help program administrators and managers understand the process of OR and the uses of research findings for service delivery and improvement. The handbook also provides a review of key concepts and important methods essential to conducting field OR studies.

Available at http://www.popcouncil.org/pdfs/frontiers/Capacity_Bldg/HbkFPOR.pdf

Marin, M. C. and J. T. Bertrand (2003). *Evaluation Manual: Evaluating Operations Research Utilization: Guidelines for Assessing Process and Impact.* Washington, DC, Population Council, FRONTIERS Program.

The purpose of this document is to describe an example of an evaluation methodology and give detailed instructions on its implementation. It is intended for use primarily by FRONTIERS project monitors, who will be conducting the evaluations. It covers information pertaining to the implementation of an evaluation plan, evaluation indicators and a final report.

Available at http://www.popcouncil.org/pdfs/frontiers/Evaluation_Manual.pdf

Neufeld, V. and N. Johnson, Eds. (2001). *Forging Links for Health Research: Perspectives from the Council on Health Research for Development.* Ottawa, IDRC Books.

As part of the lead up to the October 2000 International Conference on Health Research for Development in Bangkok, the Council on Health Research for Development (COHRED) called upon its associates around the world to reflect on achievements and setbacks in the 1990s. This book is the result of those reflections.

Available at www.idrc.ca/en/ev-9430-201-1-DO_TOPIC.html

Nichter, M., C. S. Acuin, et al. *Introducing Zinc in a Diarrheal Control Program: A Manual for Conducting Formative Research.*

This formative research manual summarizes a process for employing qualitative research when introducing a new drug, such as zinc, to communities in a clinical trial and evaluating its impact.

Available at www.popline.org/docs/317374

Piwoz, E. G. (2004). *What are the Options? Using Formative Research to Adapt Global Recommendations on HIV and Infant Feeding to the Local Context.* Geneva, Department of Child and Adolescent Health and Development, WHO.

Current recommendations on HIV and infant feeding suggest that feeding options for HIV-positive mothers should be identified locally through formative research. The purpose of this manual is to provide program managers, researchers, and policy-makers with basic guidance on how to conduct local assessments to establish the range of replacement feeding options and breast-milk feeding options that are appropriate, sustainable and safe in different contexts. Findings from local assessments may be used to develop national policies and guidelines for health workers, content for training of counselors and for BCC strategies to support safer infant feeding practices to prevent HIV infection in infants and young children. The manual contains general guidelines and describes a 12-step process to be carried out, recommends research methods, gives suggestions for analyzing findings and for disseminating the results. The annexes contain useful examples from actual field experience.

Available at www.who.int/child_adolescent_health/documents/9241591366/en/index.html

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Scrimshaw, N. S. and G. R. Gleason, Eds. (1992). *Rapid Assessment Procedures - Qualitative Methodologies for Planning and Evaluation of Health Related Programs.* Boston, International Nutrition Foundation for Developing Countries.

The 42 chapters on Rapid Assessment Procedures (RAP), Rapid Rural Appraisal (RRA) and related approaches deal with research tools that offer strong potential both in national and international public health and other areas. These approaches investigate household and individual health-related behaviors within their complex, rational matrix of personal, organizational, and social realities. They search for opinions and attitudes, behavior, and motivations of both the clients of development programs and also those who deliver services. These tools lead to the type of understanding of both groups that is essential both to planning and evaluating health, nutrition and other social development programs. A wide range of RAP and RRA applications is provided along with insight into the core concepts on which they rest and the methods that are used.

This publication can be found for sale through internet booksellers.

Varkevisser, C., I. Pathmanathan, et al. (2003). *Designing and Conducting Health Systems Research Projects: Volume 1 Proposal Development and Fieldwork.* Amsterdam, KIT/IDRC.

The resource contains 20 modules, of which the first 18 describe all the steps involved in developing a research proposal. The last two modules provide guidance for conducting fieldwork and preliminary data analysis. Each module contains detailed instructions for group work on the successive steps in the development of a proposal.

Available at www.idrc.ca/en/ev-33011-201-1-DO_TOPIC.html

Varkevisser, C., I. Pathmanathan, et al. (2003). *Designing and Conducting Health Systems Research Projects: Volume 2 Data Analyses and Report Writing.* Amsterdam, KIT/IDRC.

This publication is meant to be used in combination with Volume 1: *Proposal Development and Fieldwork.* Volume 2 consists of 13 training modules that cover data analysis, report writing and planning for implementation of recommendations.

Available at www.idrc.ca/en/ev-33013-201-1-DO_TOPIC.html

Werner, A. (2004). *1:* An Introduction to Implementation Research *A Guide to Implementation Research.* Urban Institute Press.

Evaluation research provides information that informs the effective and efficient use of community resources to promote social goals. This book explores how one type of evaluation research - implementation research - can assist those designing and operating social programs.

Available at www.urban.org/pubs/implementationresearch/chapter1.htm

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WHO (2001). *Expanding Capacity for Operations Research in Reproductive Health: Summary Report of a Consultative Meeting.* Geneva, WHO.

The strategic objective of this consultation was to promote capacity building in OR and to identify ways to increase resources in support of OR. Specifically, the consultation sought to create a shared understanding of the definition and benefits of OR, define the need for OR capacity building, identify effective strategies for capacity building, develop donor plans for mobilizing resources for OR capacity building and identify areas for collaboration.

Available at http://www.popcouncil.org/pdfs/frontiers/reports/WHO_expand_capacity.pdf

WHO/The Global Fund to Fight AIDS, Tuberculosis and Malaria *Guide to Operational Research Programs Supported by the Global Fund.* Geneva.

OR provides decision-makers with information to enable them to improve the performance of their programs. The Global Fund believes that OR has an important role to play in the success of the programs it funds, and strongly encourages proposals with an OR component. Global Fund-supported programs are recommended to spend five to ten percent of their grant budget on M&E, which can include spending on relevant OR.

Available at www.theglobalfund.org/publications

WHO/HTM/RBM (2003). *Operations Research for Malaria Control, Learner's Guide Part 1,* WHO.

This module is addressed to health personnel responsible for malaria control at national and sub-national levels of the health-care system. The content of the module is flexible enough to allow the emphasis to be placed according to specific training needs while informing professionals of the basics and methods of OR. The module is divided into two parts - the *Learner's Guide* covers basic concepts and information together with a series of problems and hints or partial solutions to them. The exercises in the *Learner's Guide* include both individual and group work.

Available at http://www.who.int/malaria/docs/operational_research_lg.pdf

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WHO/HTM/RBM (2003). *Operations Research for Malaria Control, Tutor's Guide Part 2*, WHO.

This module uses a training method based on learning by problem-solving to facilitate the understanding of OR in different epidemiological situations. The main objective of this module is to inform professionals of the basics and methods of OR. This will help health workers operating in different epidemiological and socioeconomic circumstances to understand the use and methods of OR for decision-making, M&E of malaria control activities. The module is divided into two parts - the *Learner's Guide* Part 1 and the *Tutor's Guide* Part 2. The *Tutor's Guide* is designed to stimulate active learning and has been conceived for group work.

Available at http://www.who.int/malaria/docs/operational_research_tg.pdf

WHO/TDR (2005). *Guidelines for Preparing a Grant Application to the TDR Steering Committee for Implementation Research.*

These guidelines are intended to assist social science and public health researchers to apply for collaborative research grants from the Steering Committee on IR of the Special Programme for Research and Training in Tropical Diseases (TDR). The TDR Programme, part of WHO's Programme on Communicable Diseases (CDS), is a lead international partnership/co-sponsorship in research, product development and training related to infectious diseases that disproportionately affect poor and marginalized populations.

Available at http://www.who.int/tdr/grants/workplans/ir_guidelines.htm

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Winch, P., J. Wagman, et al. (2000). *Qualitative Research for Improved Health Programs: A Guide to Manuals for Qualitative and Participatory Research on Child Health, Nutrition and Reproductive Health.* Washington DC, JHU/AED/USAID.

This guide is designed for program managers, researchers, funders of health programs and others who are considering using qualitative research methods to help them design more effective health programs and/or evaluate the strengths and weaknesses of existing programs. This guide describes some of the existing manuals for conducting qualitative research on health and provides information to help would-be users select the manuals that are most appropriate to their needs.

Available at http://sara.aed.org/publications/cross_cutting/qualitative/qualitative.pdf

Selected Examples of Publications on Operations Research, Translating Research Findings into Action and Research Dissemination

Canadian International Immunization Initiative Phase 2 Operation Research Grants: Project Profile.

The Canadian International Immunization Initiative was initiated in 1998 to increase and intensify routine immunization for all children of the world. This document provides a project profile for their Phase 2 OR grants.

Available at www.idrc.ca/uploads/user-S/11237718311CIII2.pdf

Africa_OR/TA_Project_2 (1999). *Strengthening Reproductive Health Services in Africa through Operations Research.* Nairobi, Population Council.

The Africa Operations Research and Technical Assistance (OR/TA) Project 2 was implemented by the Population Council. The program was supported by USAID to provide technical assistance to program managers and policy-makers to assist them in pilot-testing innovative and alternative strategies when restructuring their programs. This report discusses research studies achieved during the project that used social science and other research methods to provide decision-makers with empirically-based and scientifically-valid answers to service delivery problems.

Available at http://www.popcouncil.org/pdfs/frontiers/Capacity_Bldg/strengthen%20RH%20in%20Africa.pdf

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Barbour, V., P. Chinnock, et al. (2008). From theory to practice: translating research into health outcomes. *PLoS Med* **5**(1): e15.

An editorial discussion about what it takes to implement actual behavior and policy change resulting from research findings.

Available at http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050015

CEPROD (2003). *Using Data to Improve Service Delivery: A Self-Evaluation Approach.*

This guide will help frontline health workers use the data collected at health facilities to solve common problems in service delivery and improve their response to community needs. The overall aim of the guide is to promote greater use of existing service data to improve health services. It does not require the collection of additional data.

Available at http://sara.aed.org/publications/cross_cutting/self_evaluation/self-evaluation%20guide%20(English).pdf

Desclaux, A., Lanièce, I., Ndoye, I., Taverne, B. (eds), 2004. *The Senegalese Antiretroviral Drug Access Initiative - An Economic Social Behavioural and Biomedical Analysis.* Paris, ANRS, UNAIDS, WHO.

The book presents the results and analyses of the study outcomes and process of OR conducted during the National ART Programme in Senegal and helps to understand the pitfalls and successes in four main areas: access to treatment, adherence, treatment efficacy and impact and program's impact on the health system. A multidisciplinary research program was set up gathering epidemiologists, virologists, economists, anthropologists, clinicians, psychiatrists, and public health professionals in a team composed of scientists, program managers, health professionals and representatives of PLWHA associations. The outcomes of the research led to reorienting the program regarding economic access, among other topics. As a result, free access for patients was implemented in 2003, the Senegalese ARV Drug Access Initiative becoming then the first program of its kind to do so. Stakeholders' participation was an ongoing process, even on topics that were less easy to control for the national program, such as patients' perceptions of treatment or the circulation of ARV drugs in the informal drug market.

Available at www.ird.sn/activites/sida/Thesenegalese.pdf

Chinbuah, A. M., J. O. Gyapong, et al. (2006). Feasibility and acceptability of the use of artemether-lumefantrine in the home management of uncomplicated malaria in children 6-59 months old in Ghana. *Tropical Medicine & International Health* **11**(7): 1003-16.

In this descriptive study with a pre- and post-evaluation of an intervention, community perceptions of fever, health-seeking behavior and current treatment practices for children were ascertained through qualitative research and surveys in order to inform the feasibility and acceptability of and the willingness to use artemether-lumefantrine (Coartem) for treatment of malaria/fever in children aged 6-59 months at the community and household level in a rural malaria-endemic area in Ghana. Study results suggest that a Home Management of Malaria strategy with Coartem using trained community-based agents supervised monthly is feasible, acceptable, and can achieve high levels of compliance. However, if the intervention is to be sustainable, the agents need to be paid.

Available at www.ncbi.nlm.nih.gov/pubmed/16827701?dopt=Citation

Crawley, J., J. Hill, et al. (2007). From evidence to action? Challenges to policy change and program delivery for malaria in pregnancy. *The Lancet Infectious Diseases* **7**(2): 145-55.

This paper discusses the factors that influence whether strategies for preventing and treating malaria in pregnancy are successfully translated into national policy and program implementation, and identifies key OR issues. The provision of clear policy guidance on malaria in pregnancy and its translation into evidence-based guidelines that are made widely available at a country level are central to improving malaria control in this particularly vulnerable group.

Available at http://www.thelancet.com/journals/laninf/article/PIIS1473309907700269/abstract

Davis, D., M. Evans, et al. (2003). The case for knowledge translation: shortening the journey from evidence to effect. *The British Medical Journal* 327(7405): 33-5.

Attempts to reduce the gap between evidence and practice have been many and include educational strategies to alter practitioners' behavior and organizational and administrative interventions. This paper explores three constructs aimed at improving understanding of and reducing barriers to implementing evidence-based practice.

Available at www.ncbi.nlm.nih.gov/pubmed/12842955?dopt=Citation

Dobbins, M., P. Rosenbaum, et al. (2007). Information transfer: what do decision-makers want and need from researchers? *Implementation Science* **2**: 20.

The purpose of this study was to undertake a systematic assessment of the need for research-based information by decision-makers working in CBOs. It is part of a more comprehensive knowledge transfer and exchange strategy that seeks to understand both the content required and the format/methods by which such information should be presented. Preferred formats for receiving information were executive summaries, abstracts, and original articles. These findings support the importance of developing interactive, collaborative knowledge-transfer strategies, as well as the need to foster relationships with health-care decision-makers, practitioners and policy-makers.

Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=17608940

Durrheim, D. N., S. Frieremans, et al. (1999). Confidential inquiry into malaria deaths. *The Bulletin of the World Health Organization* **77**(3): 263-6.

The results of a confidential inquiry into mortality attributed to malaria in South Africa's Mpumalanga Province are being used to guide the design of strategies for improving the management of cases and reducing the probability of deaths from the disease.

Available at www.who.int/bulletin/volumes/en/

Durrheim, D. N., R. Speare, et al. (2002). Research that influences policy and practice - characteristics of operational research to improve malaria control in Mpumalanga Province, South Africa. *Malaria Journal* **1**: 9.

A series of OR studies were conducted to refine malaria diagnosis in Mpumalanga Province, South Africa between 1995 and 1999. The principal positive attributes of the OR studies were high local relevance, greater ability to convince local decision-makers, relatively short lag-time before implementation of findings, and the cost-effective nature of this form of research. Potential negative features elicited included opportunities forfeited by using scarce resources to conduct research and the need to adequately train local health staff in research methodology to ensure valid results and accurate interpretation of findings. OR effectively influenced disease control policy and practice in rural South Africa by providing relevant answers to local questions and engaging policy-makers.

Available at www.malariajournal.com/content/1/1/9

Ellis, A. A., P. Winch, et al. (2007). Home management of childhood diarrhoea in southern Mali-implications for the introduction of zinc treatment. *Social Science & Medicine* **64**(3): 701-12.

Formative research is being conducted in a number of countries to prepare for the large-scale promotion of this new treatment. In-depth and semi-structured interviews with parents, community health workers and traditional healers were conducted to examine the household management of diarrhea in Mali in preparation for the introduction of a short course of daily zinc for childhood diarrhea at the community level. The results that emerged from this study suggest that a joint therapy of zinc and oral rehydration solution (ORS) should be well accepted in the community. Mothers-in-law and fathers, who play a significant role in decisions to seek treatment for sick children, as well as traditional healers, should also be considered when designing new programs to promote zinc. Similarities with OR conducted for a previous generation of diarrhea control programs are discussed.

Available at www.ncbi.nlm.nih.gov/pubmed/17097788?dopt=Citation

FHI (2006). *Integrating Family Planning Services into Voluntary Counseling and Testing Centers in Kenya: Operations Research Results.* Research Triangle Park.

Advocates of family planning and HIV service integration require evidence of service delivery strategies that comprehensively and effectively respond to the contraceptive needs of HIV/AIDS clients without detracting from HIV/AIDS services. To help generate such evidence, FHI undertook an OR study of the costs and effectiveness of integrating contraceptive services into voluntary HIV counseling and testing (VCT) services. The study findings reinforce assumptions that integration of contraception into VCT has the potential to reduce HIV-positive births, in addition to extending the benefits

of contraception to all clients who want to prevent pregnancy. After strengthening the content and coverage of the intervention, more research is needed to be able to make a definitive statement about whether integration of family planning services into VCT can indeed result in contraceptive uptake.

Available at http://www.fhi.org/en/RH/Pubs/booksReports/Integration_Kenya_Lessons.htm

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Glasgow, R. E., E. Lichtenstein, et al. (2003). Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *American Journal of Public Health* **93**(8): 1261-7.

The gap between research and practice is well documented. One of the underlying reasons for this gap is addressed in this article: the assumption that effectiveness research naturally and logically follows from successful efficacy research. These two research traditions have evolved different methods and values; consequently, there are inherent differences between the characteristics of a successful efficacy intervention versus those of an effectiveness one. Moderating factors that limit robustness across settings, populations, and intervention staff need to be addressed in efficacy studies as well as in effectiveness trials. Greater attention needs to be paid to documenting intervention reach, adoption, implementation, and maintenance. Recommendations are offered to help close the gap between efficacy and effectiveness research and to guide evaluation and possible adoption of new programs.

Available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=12893608

Madon, T., K. Hofman, et al. (2007). Implementation Science. *Science* **318**: 1728-1729.

This paper discusses how researchers and funders need to use systems approaches that translate research not only to clinical practice but also to global health programs.

Available at www.sciencemag.org

OPS/DPC/CD (2005). *Operations Research on the Use of Rapid Diagnostic Tests for Malaria.* Guayaquil.

As one of the activities of the Amazon Network for Surveillance of Anti-malarial Drug Resistance, a meeting on OR on the use of rapid diagnostic tests (RDTs) for malaria was held in the city of Guayaquil in May 2005. In the context of introducing RDTs to diagnose malaria, research needs were defined and issues related to quality assurance, implementation, and evaluation of effectiveness and impact were discussed.

Available at http://www.paho.org/english/AD/DPC/CD/ravreda7-rdts-guayaquil.pdf

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Quality Assurance Project (2002). *Vendor-to-Vendor Education to Improve Malaria Treatment by Drug Outlets in Kenya. Operations Research Results.* Bethesda, Quality Assurance Project.

Private drug outlets have grown increasingly important as the main source of malaria treatment for residents of malaria-endemic areas, although the quality and quantity of information about this source of treatment is deficient. In Kenya, an OR study tested an innovative, low-cost approach for improving the prescribing practices of private drug outlets. The approach, called Vendor-to-Vendor Education, involved training and equipping wholesale counter attendants and mobile vendors with customized job aids for distribution to rural and peri-urban retailers.

Available at http://www.qaproject.org/pubs/PDFs/vendorkenya.pdf

The Quality Assurance Project (QAP) undertook a study in Niger to improve adherence to cotrimoxazole therapy, the antibiotic recommended there for treating childhood pneumonia. QAP designed and tested program job aids for health workers and caretakers aimed at improving drug adherence. The job aids were supplemented with training in counseling techniques for the health workers. A second program addressed the number of doses of cotrimoxazole given to caretakers at the first visit. The findings of the study have important implications for policy changes and program design.

Available at http://www.qaproject.org/pubs/PDFs/pneumnigerbookrev403.pdf

Quality Assurance Project (2004). *The Zambia HIV/AIDS Workforce Study: Preparing for Scale Up*. Bethesda.

This report presents the findings of a study conducted at 16 health-care sites in Zambia offering VCT, prevention of mother to-child transmission of HIV (PMTCT), and ARV therapy. The purpose of the study was to assist the government of Zambia in determining whether it will have sufficient staff to be able to scale up VCT, PMTCT and ARV treatment to reach its targeted numbers of clients. The report analyzes the time taken to carry out the prescribed tasks involved in each of the services, analyzes the extent to which the services are following the national service delivery standards, describes the present workforce involved in providing these services, and analyzes the human resource costs associated with the present workforce arrangements. It then uses these findings to project the staffing and related staffing costs of scaling up services.

Available at http://www.qaproject.org/pubs/PDFs/ORMZambiaWorkforcel.pdf

Sanders, D. and A. Haines (2006). Implementation research is needed to achieve international health goals. *PLoS Med* **3**(6): e186.

Health research needs to focus not just on the growing divide in health status between the world's rich and the poor but also on the unacceptable gap between our unprecedented knowledge of diseases (including their control) and the implementation of that knowledge, especially in poor countries. Directed and innovative research is needed to analyze the causes of this situation and to point toward solutions at the global and local levels, both within and outside the health sector. Unless mainstream research organizations actively promote OR, and policy-makers demand that the implementation of interventions and programs be rigorously evaluated, the substantial gap between knowledge and its implementation will persist in the health field.

Available at http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030186

Smith, C., M. B. Bingman, et al. (2006). Effective Research, Dissemination: Lesson from NCSALL. *Focus on Basics: Connecting Research & Practice* **8**(C).

Over the past ten years, NCSALL has tried a variety of approaches to disseminating research. This article reviews their experiences and shares some lessons learned about disseminating research findings.

Available at www.ncsall.net/?id=1157

Walley, J., M. A. Khan, et al. (2007). How to get research into practice: first get practice into research. *Bulletin of the World Health Organization* **85**(6): 424.

The problem of failing to get research into policy and practice is well known. The aim should not be to perfect techniques of feeding results to decision-makers, but to start from the perspective of the decision-makers even before devising the questions. This means "getting practice into research".

Available at www.who.int/bulletin/volumes/85/6/07-042531.pdf

WHO/HRP (2006). *Turning Research into Practice: Suggesting Actions from Case Studies of Sexual and Reproductive Health Research.* Geneva, WHO/HRP.

This document is the result of two expert meetings that reviewed case studies of utilization of sexual and reproductive health research in order to elicit lessons that researchers, program managers and others could apply to increase the use of findings emerging from OR. The document presents guidelines for optimizing the use of research findings as well as suggesting how to monitor the extent to which research-based evidence is used for policy change.

Available at www.who.org/reproductive-health/publications/trip/index.html

WHO/HTM/TB (2005). *TB/HIV Research Priorities in Resource-Limited Settings: Report of an Expert Consultation.* Geneva, Switzerland.

This expert consultative meeting convened to define TB/HIV research priorities and outline their research relevance in the context of program activities and to solicit and promote the building of TB/HIV research capacity at the country level. Five major areas for research prioritization emerged, although it was determined that evaluating the implementation of the current policy package should be given more emphasis than generating more research questions.

Available at http://www.who.int/tb/events/tbhiv_research_priorities_in_resourcelimited_settings_feb05/en/

WHO-EM/TDR (2003). *Operational Research in Tropical Diseases: Final Report Summaries 1992-2000*. Cairo.

This document summarizes the outcomes of 63 OR projects conducted between 1992 and 2000. With relatively limited funds, they have all generated results that point the way to practical and affordable local solutions to problems in communicable disease control. Disease control research programs included a focus on leishmaniasis, malaria, TB, schistosomiasis, onchocerciasis, and lymphatic filariasis.

Available at www.emro.who.int/

Winch, P. J., M. A. Alam, et al. (2005). Local understandings of vulnerability and protection during the neonatal period in Sylhet District, Bangladesh: a qualitative study. *The Lancet* **366**(9484): 478-85.

Understanding of local knowledge and practices relating to the newborn period, as locally defined, is needed in the development of interventions to reduce neonatal mortality. This study describe the organization of the neonatal period in Sylhet District, Bangladesh, the perceived threats to the well-being of neonates and the ways in which families seek to protect them. The implications for the design of interventions for neonatal care based on findings of how newborns are cared for and how newborn management is organized in the home are discussed.

Available at www.ncbi.nlm.nih.gov/pubmed/16084256?dopt=Citation

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The materials and articles listed below have been quoted or used in the main text. There are additional annotated reference materials and articles in the annotated Resource/Toolkit part of Section C. This is not an exhaustive list of items relevant to OR/IR.

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Department of Child and Adolescent Health and Development, WHO. *What are the options? Using formative research to adapt global recommendations on HIV and infant feeding to the local context.* Geneva, 2004

Dobbins, M., Rosenbaum, P. et al. Information Transfer: What do decision-makers want and need from researchers. *Implementation Science* 2007, 2:20.

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Fisher, A.A., Laing, J.E. et al. *Handbook for Family Planning Operations Research Design*, 2nd Edition, Population Council, New York, 1991.

Korenromp, E., Komatsu, R. et al. Operational research on HIV/AIDS, tuberculosis and malaria control in Global Fund-supported programs: Rounds 1-6 Grants. *Proceedings of the Fifth European Congress on Tropical Medicine and International Health*, May 2007, Bologna, Italy. Medimond, SRL, pp.251-255.

Loechl C, Marie T. Ruel, Gretel Pelto, and Purnima Menon. "The Use of Operations Research as a Tool for Monitoring and Managing Food-Assisted Maternal/Child Health and Nutrition (MCHN) Programs: An Example from Haiti". FCND Discussion Paper 187. Food Consumption and Nutrition Division, International Food Policy Research Institute, Washington, February 2005.

Marin MC and Jane T. Bertrand, Evaluation Manual Evaluating Operations Research Utilization: Guidelines for Assessing Process and Impact. Frontiers in Reproductive Health, Population Council, Family Health International and Tulane University, 2003 Measure Evaluation (2008) PLACE in Zimbabwe: Identifying Gaps in HIV Prevention among Orphans and Young People in Hwange District, 2006. Carolina Population Center, University of North Carolina, Chapel Hill.

Quality Assurance Project/University Research Corporation. Treating Tuberculosis in the Private Sector, Cambodia, Washington, D.C., December 2004. Sanders D and Andy Haines. IR Is Needed to Achieve International Health Goals. PLoS Medicine June 2006 | Volume 3 | Issue 6 | e186.

Scrimshaw NS and Gary R. Gleason, Editors. Rapid Assessment Procedures - Qualitative Methodologies for Planning and Evaluation of Health Related Programs, 1992 International Nutrition Foundation for Developing Countries (INFDC), Boston, MA. USA. www.unu.edu/unupress/food2/UIN08E/uin08e00.htm

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ANNEXES

ANNEX A - Definitions of Operations and Implementation Research

Operations Research

1. WHO (2003)[1] defines OR as "the use of systematic research techniques for program decision-making to achieve a specific outcome. OR provides policy-makers and managers with evidence that they can use to improve program operations. It is distinguished from other kinds of research by the following characteristics:

   - It addresses specific problems within specific programs, not general health issues;
   - It addresses those problems that are under control of managers, such as program systems, training, pricing and provision of information;
   - It utilizes systematic data collection procedures, both qualitative and quantitative, to accumulate evidence supporting decision-making;
   - It requires collaboration between managers and researchers in identification of the research problem, development of the study design, implementation of the study and analysis and interpretation of results; and
   - It succeeds only if the study results are used to make program decisions; publication alone is not a valid indicator of successful OR."

2. The Population Council (2000)[2] explains that, "Operations research helps policy-makers and program managers to review, redirect and restructure programs that have been in place for many years. OR uses social science and other research methods to provide decision-makers with empirically-based and scientifically-valid answers to service delivery problems." The Population Council identifies three types of OR studies.

   - Diagnostic studies are used to assess the nature and extent of a health or service delivery problem.
   - Evaluative studies are used to evaluate ongoing innovative health interventions.
   - Intervention studies are used to test, usually through a quasi-experimental research design, the effectiveness of service delivery interventions explicitly designed to address a specific service delivery problem.

3. Andrew Fisher et al. (1991)[3] offer the following scope for OR: "OR is a process, a way of identifying and solving program problems. As currently applied in health, family planning and other development programs, OR can be defined as a continuous process with five basic steps: 1) problem identification and diagnosis, 2) strategy selection, 3) strategy experimentation and evaluation, 4) information dissemination, and 5) information utilization. The process of OR is designed to increase the efficiency, effectiveness, and quality of services delivered by providers; and the availability, accessibility and acceptability of services desired by users."

4. The International Food Policy Research Institute (2005)[4] considered that, "OR aims at studying the processes by which programs are implemented and interventions are delivered to intended beneficiaries. The main purpose is to identify, as early as possible in the life of a program, any shortcomings in the process that may affect the effective delivery of the intervention, and as a result, its potential impact on the expected outcomes. Thus, the overall goal of OR is to generate the necessary information to program planners and implementers that will allow them to design and test potential solutions to improve program delivery and will lead to the timely implementation of corrective actions. OR methods have been used to evaluate the quality of implementation of a number of social programs. A major focus of OR as described is to assess the implementation and operational aspects of programs, with the overall goal of identifying areas that could be improved and to propose solutions for strengthening the program and maximizing its effectiveness."

5. Special Program of Research, Development and Research Training in Human Reproduction (HRP) (2006)[5] addressed the following question about OR: "**In relation to the research question, what level of interaction exists between the research group and the service delivery programs?** Close interaction between researchers and service delivery programs is particularly important in the case of OR."

Implementation Research

1. The overall objective of IR is to significantly improve access to efficacious interventions against tropical diseases by developing practical solutions to common, critical problems in the implementation of these interventions (TDR, 2005).[6] In order to achieve this objective, IR will:

   a. identify common implementation problems and their main determinants which prevent effective access to interventions and determine which of these problems are susceptible to research;

   b. develop practical solutions to these problems and test whether new implementation strategies based on these solutions can significantly improve access under conditions of routine disease control;

   c. determine - in collaboration with partners - the best way to introduce these new implementation strategies into the health system and facilitate their full scale implementation, evaluation and modification, as required.

   IR will focus on diseases for which a disease control tool (or package of tools) is available and proven to be efficacious and that has the potential to greatly reduce the burden of disease if the major implementation problems could be resolved and access be improved. Access is defined as the facility with which disease-affected populations can obtain relevant components of specific public health interventions. Access reflects both the supply of and the demand for the intervention.

2. Sanders and Haines (2006)[7] see IR as part of health systems research. IR is that subset of health services research (HSR) that focuses on how to promote the uptake and successful implementation of evidence-based interventions and policies that have, over the past decade, been identified through systematic reviews. IR is used as a general term for research that focuses on the question 'What is happening?' in the design, implementation, administration, operation, services, and outcomes of social programs; it also asks, 'Is it what is expected or desired?' and "Why is it happening as it is?" In the health field, IR often encompasses "impact research", which includes both research aimed at understanding what is happening during the processes of implementing changes in policy or practice and intervention studies that are designed to compare different approaches to implementing change. IR is often multidisciplinary, encompassing both quantitative and qualitative approaches that require expertise in epidemiology, statistics, anthropology, sociology, health economics, political science, policy analysis, ethics and other disciplines.

3. Alan Werner (2004)[8] talks about IR as "one type of evaluation research" and notes that "IR can assist those designing and operating social programs." He further explains that, "IR is used as a general term for research that focuses on the question 'What is happening?' in the design, implementation, administration, operation, services, and outcomes of social programs. Implementation studies can have multiple purposes, such as supporting the impact study by describing the precise nature of the program being tested and explaining the pattern of impact findings over time or across program sites."

Other Relevant Forms of Research

1. Scrimshaw and Gleason (1992)[9] edited a web resource book on **Rapid Assessment Procedures**. In that collection of materials they explain that, in the 1980s Rapid Assessment Procedures (RAP), Rapid Rural Appraisal (RRA) and related approaches were used to collect information that contributed to the planning and evaluation of public health and other social program areas. The origins of these approaches lie in the practical needs of program planners and decision- makers; they also focused on the needs and interests of clients that development programs should serve. These approaches investigated household and individual health-related behaviors within their complex, rational matrix of personal and social realities. They search for opinions and attitudes, behavior, and motivations of both the clients of development programs and also those who deliver services. Understanding both groups is essential both to planning and to evaluating health, nutrition and other social development programs. Trained investigators used RAP approaches to explore behavior, attitudes, practices and causal factors through careful observation, probing interviews and FGDs. Other methods included a variety of highly-participative activities whereby people score, diagram, map, sort cards, and use other simple but powerful tools to describe and often explain their current and past situations and environment. While not aiming at statistical generalizations to popula-

tions, these approaches provide a framework for data verification and analysis through an iterative process allowing correction and learning as the research progresses. With RRA/RAP control of some tools is given over to the client, reversing roles and generating a process of self-analysis by decision-makers and giving them new insights on client capabilities to plan, lead and manage development efforts.

2. The AIDS Partnership of California (2003)[10] has found **Formative Research** to be a useful approach in planning and evaluating programs. When planning a new intervention, agencies often do not have an idea what to do, but need to understand the best way to do it. And when a new intervention is designed for a relatively new population, they need to know if what they've been doing in other communities will work for them. That's where formative research fits in. Formative research looks at the community in which an agency is situated and helps agencies understand the interests, attributes and needs of the populations and persons in their community. Formative research is research that occurs before a program is designed and implemented, or while a program is being conducted. Formative research can help:

- Understand populations in need of services
- Create programs that are specific to the needs of these populations
- Ensure that programs are acceptable to clients and feasible before launching
- Improve the relationships between clients and agencies

Contact Information

[1] **Expanding Capacity for Operations Research in Reproductive Health:** Summary Report of a Consultative Meeting, WHO, Geneva, Switzerland, December 10–12, 2001, © **World Health Organization 2003**

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ANNEX B - Examples of Organizations that Fund/Support Operations Research

ORGANIZATION	WEB INFORMATION	LINKS
Bill & Melinda Gates Foundation	The foundation is now accepting grant proposals for the first round of Grand Challenges Explorations, a US $100 million initiative to encourage bold and unconventional global health solutions. Proposals will be accepted online through the Grand Challenges Explorations website through 30 May 2008.	www.gatesfoundation.org/default.htm Grand Challenges in Global Health www.gcgh.org/Explorations/Pages/Introduction.aspx
Council for the Development of Social Science Research in Africa	CODESRIA, the Council for the Development of Social Science Research in Africa is headquartered in Dakar, Senegal. It was established in 1973 as an independent pan-African research organization with a primary focus on the social sciences, broadly defined. It is recognized not only as the pioneer African social research organization but also as the apex nongovernmental center of social knowledge production on the continent.	www.codesria.org/ www.codesria.org/French/default.htm Research Mandate and Objectives www.codesria.org/Research.htm Training Grants and Fellowships www.codesria.org/training_grants.htm
Global Fund to Fight AIDS, Tuberculosis and Malaria	The Global Fund was created to finance a dramatic turnaround in the fight against AIDS, tuberculosis and malaria. These diseases kill over six million people each year, and the numbers are growing. Operations research proposals must be submitted as part of national disease control proposals.	www.theglobalfund.org/en/ Checklist on Round 8 Operations/Implementation Research www.theglobalfund.org/documents/rounds/8/R8OpRChecklist_en.doc links to Operations Research Information for Applicants planning on including Operations Research in their proposal: www.theglobalfund.org/en/apply/call8/technical/
International Development Research Center	IDRC is a Canadian Crown corporation that works in close collaboration with researchers from the developing world in their search for the means to build healthier, more equitable, and more prosperous societies.	www.idrc.org/en/ev-1-201-1-DO_TOPIC.html Funding Opportunities www.idrc.org/en/ev-54473-201-1-DO_TOPIC.html
John D. and Catherine T. MacArthur Foundation	Grant-making in population and reproductive health (2008) reflects a comprehensive approach to reproductive and sexual health and rights, one that places women's well-being at the center of population policy and emphasizes the rights of individuals to determine and plan family size. Through its offices in India, Mexico, and Nigeria, the foundation makes grants that support efforts to reduce maternal mortality and morbidity and to advance the sexual and reproductive health and rights of young people in these three countries.	www.macfound.org/site/c.lkLXJ8MQKrH/b.3599935/ Population and Reproductive Health www.macfound.org/site/c.lkLXJ8MQKrH/b.932747/k.B59A/International_Grantmaking__Population_and_Reproductive_Health.htm
PEPFAR (The US President's Emergency Plan for AIDS Relief)	Critical to ensuring that the PEPFAR has the desired impact is the collection of strategic information though the monitoring of core indicators, the surveillance of disease trends, and the implementation of special studies and OR. An example is OR in Rwanda to identify strategies for increasing nevirapine acceptance in prenatal clinics. Such plans need to be developed with PEPFAR implementing partners in countries.	www.pepfar.gov/ Activities supported by PEPFAR www.pepfar.gov/guidance/78260.htm

ORGANIZATION	WEB INFORMATION	LINKS
Rockefeller Foundation	The foundation seeks to promote the well-being of humanity by addressing the root causes of serious problems. It works to expand opportunities for poor or vulnerable people and to help ensure that globalization's benefits are more widely shared. It is one of the few institutions to conduct such work both within the United States and internationally.	www.rockfound.org/ See: Role of Private Sector in Health Systems www.rockfound.org/library/020108private_sector_health.pdf
Tropical Disease Research Program	The Special Program for Research and Training in Tropical Diseases (TDR) is an independent global program of scientific collaboration. Established in 1975 and cosponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and the WHO, it aims to help coordinate, support and influence global efforts to combat a portfolio of major diseases of the poor and disadvantaged. TDR focuses on neglected infectious diseases that disproportionately affect poor and marginalized populations.	www.who.int/tdr/index.html Research Lines www.who.int/tdr/research_lines/default.htm Strategic Emphases www.who.int/tdr/grants/strategic-emphases/default.htm Calls for Applications www.who.int/tdr/grants/grants/calls.htm
The French National Agency for Research on AIDS and Viral Hepatitis (ANRS)	The ANRS in France leads and funds research in all relevant fields (basic science, clinical research, social sciences, etc.) on AIDS and viral hepatitis. A quarter of its budget is devoted to research in developing countries and OR is one of the priorities of the Agency since 2005. The ANRS accepts grant proposals two times a year (September and March). Proposals in developing countries have to be submitted by a team of researchers from both North and South institutions in accordance with the ethic's charter of the agency.	http://anrs.fr
Wellcome Trust	The trust supports many different kinds of research and activities with the ultimate aim of protecting and improving human and animal health. This support is not restricted to UK researchers - it devotes significant funding to international research too - research support for those working in developing countries, with an emphasis on public health, tropical medicine and building research capacity.	www.wellcome.ac.uk/ Starting a grant www.wellcome.ac.uk/Managing-a-grant/Starting-a-grant/index.htm

ANNEX C - Literature Review Procedures and Relevant Journals

1. Formal or Published Literature

One of the most common places to start gathering examples of previous studies that can inform a new research effort is PubMed. This service is based on the internet and provides free abstracts of published articles and links to journals that contain the full article.

The two pictures here show the PubMed as one would find it on the web. The web address is in the first picture. The "for" line below the PubMed logo is used to enter search terms and as seen in the second picture, retrieve a list of articles. The more terms one adds, the fewer selections are provided. One needs to balance this process in order to get enough helpful articles without missing important information. The central part of this webpage gives more guidance on how to conduct a search.

Some of these journals also provide their articles free (for example, *Malaria Journal:* www.malariajournal.com/), while others require a subscription or payment for downloading a specific article. There are services where researchers working in developing countries can request free copies of articles. One place where people can access articles for free is: **Health InterNetwork Access to Research Initiative** www.who.int/hinari/en/

The HINARI program, set up by WHO together with major publishers, enables developing countries to gain access to one of the world's largest collections of biomedical and health literature. Over 3,750 journal titles are now available to health institutions in 113 countries, benefiting many thousands of health workers and researchers, and in turn, contributing to improved world health.

Free online journals can be found at:

BioMed Central (BMC)

www.biomedcentral.com/

The Public Library of Science (PLoS)

www.plos.org/oa/index.html

2. Gray literature

Gray Literature is a term used for studies and reports that are not formally published in a scientific journal or by a book publisher. These reports contain much useful information about health and disease control program efforts as well as good descriptions of the overall health system and disease characteristics in particular countries and locations. Some of the organizations listed in Annex B have such reports on their websites. Some websites have tabs for "publications" where these studies and reports can be found. Below are a few examples.

Tropical Disease Research Program Publications
www.who.int/tdr/publications/default.htm

UNICEF Publications
www.unicef.org/publications/index.html

BASICS (child survival) Publications
www.basics.org/publication.htm

International Development Research Center Publications
(English)   www.idrc.org/en/ev-8574-201-1-DO_TOPIC.html
(French)   www.idrc.org/fr/ev-8574-201-1-DO_TOPIC.html

Quality Assurance Project Publications
www.qaproject.org/products.html

Council for the Development of Social Science Research in Africa
(English) www.codesria.org/Publications.htm
(French) www.codesria.org/French/Publications_fr.htm

Gray literature can also include internal reports from the national ministry of health and unpublished dissertations and theses from local universities and institutes.

3. Journals that May Publish Operations Research

The following chart provides just a few examples. In doing literature reviews it is possible to see the types and names of journals that published studies of interest. The websites of these journals will enable researchers to review their scope and purpose as well as their instructions to authors.

www.heapol.oxfordjournals.org/

www.blackwellpublishing.com/
journal.asp?ref=1360-2276&site=1

www.elsevier.com/wps/find/journaldescri
ption.cws_home/315/description#description

www.human-resources-health.com/home/

www.informaworld.com/
smpp/title~content=t716100712

www.baywood.com/journals/
PreviewJournals.asp?Id=0272-684x

ANNEX D - Sample Consent Forms and IRB Checklists

1. Consent for Clinic Based Survey

2. Consent for Focus Group

3. Consent for Community Survey

4. Items to include in IRB

5. Checklist for IRB

IRB # 2002-257   Perception of VCT Among Women in _____

_____ INSTITUTE OF MEDICAL RESEARCH
_____ MINISTRY OF HEALTH

RESEARCH CONSENT FORM
(Clinic Survey

KNOWLEDGE AND PERCEPTION OF VOLUNTARY
ANTENATAL HIV COUNSELING AND TESTING AMONG
WOMEN IN _____: A CASE STUDY OF _____ LOCAL
GOVERNMENT AREA OF _____ STATE

Principal Investigator: _____, M.Sc

Co-Investigators: _____, PhD
                _____, MB;BS
                _____, PhD
                _____, MBBCh, PhD, FWACP

Why are we giving you this form?
We are giving you this form to tell you about this research study. You have the opportunity to participate in this study. Your husband or relations will not know if you participate. After you have learned more about the study, you can decide if you would like to participate.

Who is carrying out this study?
A team of researchers from the _____ Institute of Medical Research is carrying out the study. The main researchers are:
  I.   _____, M.Sc
  II.   _____ (PhD), _____ PU (PhD), _____ AA (MBBS),
        _____ (MBBCh, PhD, FWACP)
The staff from _____ University supports them.

The number identifying the study in _____ is IRB # 2002-257.

The title of the study is "Knowledge and Perception of Voluntary Antenatal HIV Counseling and Testing Among Women in _____: A Case Study of _____ North Local Government Area of _____ State."

Background Information
HIV infection is increasing common among pregnant women in _____. HIV is the virus that causes AIDS. Infection is possible through contact with infected blood and other body fluids, from mother-to-child during pregnancy, delivery and breastfeeding. Mother-to-child HIV infection is responsible for more than 90% of HIV infection in children. Weare trying to understand the acceptability and demand for confidential antenatal HIVcounseling and testing (VCT) by pregnant women and want to know what people in the community think about VCT. We hope that this information will encourage the government, health specialists, and businesses to take more action to prevent and control mother-to-child transmission of HIV and introduce nevirapine therapy in the country. You are registered here for antenatal care. We would therefore like you to participate in our study. Your participation is voluntary. No one else will know whether or not you participated. We expect up to 800 women to participate in the study over the next 6 weeks. Participation will take less than 45 minutes of your time.

What Happens in this Research Study
There are two steps to the study.
1. Clinic Survey:
   Questionnaire: We will ask you several questions about yourself, your knowledge of the modes of HIV transmission, signs and symptoms of HIV/AIDS, prevention of HIV infection. We will also want to know if you would be willing to seek VCT. The person asking the questions will be an employee of the study. He or she will not be from the community and will not be someone you know. This will take approximately 30-45 minutes to complete.

2. <u>Focus Group Discussion:</u> Men and women in the community will be invited to participate in discussion sessions to know individual and collective opinions and views about VCT. These discussions will be taped and last for about 30-45 minutes.

Possible Risks and Discomforts from Participating in this Study
The time it takes to answer the questions may be inconvenient.

Benefits from Participating in this Study
There may be no direct benefits to your participation in this study. Participation in this study may provide benefits to your community. By improving our understanding of women's knowledge of mother-to-child transmission of HIV and how they perceive VCT, your participation in the study may improve the prevention and management of mother-to-child HIV transmission during pregnancy, delivery and breastfeeding in the community.

Your Right to Participate, Not Participate, or Withdraw from this Study
Your participation in this research is voluntary. If you choose not to participate, that will not affect your right to health care or other services to which you are otherwise entitled. You will still receive the standard medical care that this clinic provides.

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice.

Confidentiality of the Information Used in the Study
Records and tapes relating to your participation in the study will remain confidential. Your information will be kept in a secured place. The questionnaires and audio tapes used for information collection will be destroyed hopefully after 2-3 years after the study results would have been published in peer-reviewed journal. Your name will not be used for this study. Representatives of the _____ Institute of Medical Research, _____ and the Center for _____ at _____ University, the _____ University _____ Institutional Review Board and if appropriate, the U.S. Food and Drug Administration may examine the study records, as part of their responsibility to oversee the research.

Questions and Medical Care for Injury
If you have questions about this study or should you be injured as a direct result of participating in this study, you should contact _____, Public Health Division, _____ Institute of Medical Research, _____, Phone: 123456. In case of injury, you will be provided with medical care, at no cost, for that injury. Note that you will not receive any injury compensation, only medical care. Any questions regarding your rights should be directed to the Office of the Institutional Review Board, Phone: 456789.

By signing below, you confirm that you have been informed about the study of the impact of tuberculosis on work performance and agree to participate. If there is any part of this explanation that you do not understand, you should ask the investigator before signing.

IRB # 2002-257   Perception of VCT Among Women in _____

You will receive a copy of this signed consent form.

SIGNATURE OF PARTICIPANT _____

PERMANENT ADDRESS OF PARTICIPANT   _____

                                                              _____

                                                              _____

                                                              _____

DATE _____

SIGNATURE OF PRINCIPAL
INVESTIGATOR _____

IRB # 2002-257   Perception of VCT Among Women in _____

_____ INSTITUTE OF MEDICAL RESEARCH
_____ MINISTRY OF HEALTH

RESEARCH CONSENT FORM
(Focus Group)

KNOWLEDGE AND PERCEPTION OF VOLUNTARY ANTENATAL HIV COUNSELING AND TESTING AMONG WOMEN IN _____: A CASE STUDY OF _____ LOCAL GOVERNMENT AREA OF _____ STATE

Principal Investigator: _____, M.Sc

Co-Investigators: _____, PhD
                     _____, MB;BS
                     _____, PhD
                     _____, MBBCh, PhD, FWACP

Why are we giving you this form?
We are giving you this form to tell you about this research study. You have the opportunity to participate in this study. Your husband or relations will not know if you participate. After you have learned more about the study, you can decide if you would like to participate.

Who is carrying out this study?
A team of researchers from the _____ Institute of Medical Research is carrying out the study. The main researchers are:
  I.   _____, M.Sc
  II.   _____ (PhD), _____ PU (PhD), _____ AA (MBBS),
        _____ (MBBCh, PhD, FWACP)
The staff from _____ University supports them.

The number identifying the study in _____ is IRB # 2002-257.

The title of the study is "Knowledge and Perception of Voluntary Antenatal HIV Counseling and Testing Among Women in _____: A Case Study of _____ North Local Government Area of _____ State."

Background Information
HIV infection is increasing common among pregnant women in _____. HIV is the virus that causes AIDS. Infection is possible through contact with infected blood and other body fluids, from mother-to-child during pregnancy, delivery and breastfeeding. Mother-to-child HIV infection is responsible for more than 90% of HIV infection in children. We are trying to understand the acceptability and demand for confidential antenatal HIV counseling and testing (VCT) by pregnant women and know what people in the community think about VCT. We hope that this information will encourage the government, health specialists, and businesses to take more action to prevent and control mother-to-child transmission of HIV and introduce nevirapine therapy in the country. You are a resident of this community; we would therefore like you to participate in our study. Your participation is voluntary. No one else will know whether or not you participated. We expect up to 800 women in a survey and other men and women in this community to participate in the group discussions of the study over the next 6 weeks. Participation will take less than 1 hour of your time.

What Happens in this Research Study
There are two steps to the study.
1. Clinic Survey:
   Questionnaire: We will ask you several questions about yourself, your knowledge of the modes of HIV transmission, signs and symptoms of HIV/AIDS, prevention of HIV infection. We will also want to know if you would be willing to seek VCT. The person asking the questions will be an employee of the study. He or she will not be from the community and will not be someone you know. This will take approximately 30-45 minutes to complete.

2. <u>Focus Group Discussion:</u> Men and women in the community will be invited to participate in discussion sessions to know individual and collective opinions and views about VCT. These discussions will be taped and last for about 30-45 minutes.

Possible Risks and Discomforts from Participating in this Study
The time it takes to answer the questions may be inconvenient.

Benefits from Participating in this Study
There may be no direct benefits to your participation in this study. Participation in this study may provide benefits to your community. By improving our understanding of women's knowledge of mother-to-child transmission of HIV and how they perceive VCT, your participation in the study may improve the prevention and management of mother-to-child HIV transmission during pregnancy, delivery and breastfeeding in the community.

Your Right to Participate, Not Participate, or Withdraw from this Study
Your participation in this research is voluntary. If you choose not to participate, that will not affect your right to health care or other services to which you are otherwise entitled. You will still receive the standard medical care that this clinic provides.

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice.

Confidentiality of the Information Used in the Study
Records and tapes relating to your participation in the study will remain confidential. Your information will be kept in a secured place. The questionnaires and audio tapes used for information collection will be destroyed hopefully after 2-3 years after the study results would have been published in peer-reviewed journal. Your name will not be used for this study. Representatives of the _____ Institute of Medical Research, _____ and the Center for _____ at _____ University, the _____ University _____ Institutional Review Board and if appropriate, the U.S. Food and Drug Administration may examine the study records, as part of their responsibility to oversee the research.

Questions and Medical Care for Injury
If you have questions about this study or should you be injured as a direct result of participating in this study, you should contact _____, Public Health Division, _____ Institute of Medical Research, _____, Phone: 123456. In case of injury, you will be provided with medical care, at no cost, for that injury. Note that you will not receive any injury compensation, only medical care. Any questions regarding your rights should be directed to the Office of the Institutional Review Board, Phone: 456789.

By signing below, you confirm that you have been informed about the study of the impact of tuberculosis on work performance and agree to participate. If there is anypart of this explanation that you do not understand, you should ask the investigator before signing.

IRB # 2002-257   Perception of VCT Among Women in _____

You will receive a copy of this signed consent form.

SIGNATURE OF PARTICIPANT _____

PERMANENT ADDRESS OF PARTICIPANT   _____

_____

_____

_____

DATE _____

SIGNATURE OF PRINCIPAL
INVESTIGATOR _____

The _____ University
School of _____
Committee on Human Research

CONSENT FORM: written at 8.2 grade level
TITLE: HIV and Violence in the Context of Women's Lives: Implications for HIV Counseling and Testing in _____
Principle Investigator: _____
CHR #:   123456789

PURPOSE: We (_____ University) are doing a study with women who come to here to be tested for HIV. We want to learn about things that influence women's decisions to talk with their partners about their HIV status. We also want to learn about how partner violence is related to women's decision to tell their partners about their HIV status. Because you have come here to have an HIV test, we would like to talk to you about your experience.

PROCEDURES: If you decide to join this study, we will set up a date to meet with you in three months' time. The survey that we would like you to take will last about one hour. You will be asked questions about yourself and your decision to come in for an HIV test, and how you involved your partner in your decision. Questions will ask things like; What were the main reasons that you came in for HIV testing? Did you talk about getting tested with your partner before you came? How did your partner react when you told him that you wanted to be tested? Have you ever had any partners who have physically hurt you? If you decide to participate in the study, you will be paid 1200 Tsh for your time and travel costs.

RISKS/DISCOMFORTS: Some of the topics that you will be asked about are personal and may make you feel sad or upset. Should you become upset, you can stop the interview at any time and talk to a counselor. There is also a risk that your partner may find out that you talked to us and may become unhappy. However, everything that you tell us during the interview will be kept secret within the research team. You will not receive any medical benefits from being in this study, and it will require about an hour of your time.

BENEFITS: You may find that there are some benefits to being in this study. You may enjoy talking with an interviewer about your personal experiences, and should you want to, counselors will be able to talk with you. Also, the things that you tell us will help us make a program that may help other women in similar situations, and improve the services available to people who want to get an HIV test.

CONFIDENTIALITY: If you take this survey, many things will be done to protect your privacy. We will not tell the MMC staff or anyone else anything about what you have told us. Even if someone asks us, we will not tell them anything. Your interview will take place at the HIV test site, and what you tell us will be marked with a number rather than your name. Anything that you tell us will be seen only by members of the research team, and will be kept in a locked cabinet for no longer than 3 years.

VOLUNTARINESS: Whether or not you decide to do this survey is your choice. If you decide not to do it, there is no bad effect and you will still receive the same care at the MMC. If you decide to talk to us, you can stop the interview at any time and can choose not to answer any questions that you do not want to.

Persons to Contact: If you have any questions about this study in the future, please contact the person in charge of this study, _____. You can call her phone number 123-456-7890 or come and talk to her at _____ location. If you feel you have been treated unfairly in this study, or have other questions, you may call the local Office for Research Subjects at 456-789-0123.

If this form has been read and explained to you and you agree to be in this study, please sign or make your mark below.

_____
Print name of subject

_____ _____
Signature or Mark of Subject   Date

_____ _____
Signature of Person Obtaining Consent   Date

_____ _____
Witness to Consent if Subject Unable to Read or Write Date
(Must be different than the person obtaining consent)

Signed copies of this consent form must be
1) kept on file by the principal investigator, 2) given to the subject

**NOT VALID WITHOUT THE CHR
STAMP OF APPROVAL**

CHR#: _____

VALID FROM_____ TO_____

Sample IRB Checklist

**COMMITTEES ON HUMAN RESEARCH
NEW APPLICATION
SUBMISSION CHECKLIST**

NOTE: All new applications must include this checklist. All items must be checked.
If not applicable, write (N/A).

1. **Application**
2. **Grant/Contract Proposal (including budget pages)**
3. **Complete Research Plan: (address each item under the following Headings)**
   a. **Research Question**(s)
   b. **Rationale** (Motivation, Summary of Importance of the Research)
   c. **Methods:**
      i. Study Design and Rationale
      ii. Population (sample size, inclusion/exclusion criteria, gender, age and locale)
      iii. Procedures (including the recruitment process)
      iv. Questionnaire/Interview Instrument
      v. Methods of Intervention
      vi. Methods for Dealing with Adverse Events
      vii. Methods for Dealing with Illegal Reportable Activities
   d. **Risks/Benefits:**
      i. Description of Risks
      ii. Description of Measures to Minimize Risks
      iii. Description of Level of Research Burden
      iv. Description of Benefits
   e. **Disclosure/Consent Processes - Description of the Process**
   f. **Confidentiality Assurances**
      i. Plans for record keeping and data security
      ii. Location of the data
      iii. Person responsible and telephone number
      iv. Who will have access to the data
      v. Plans for disposition of the data at end of the study
      vi. Certificate of Confidentiality (sensitive biomedical, behavioral or other type of study)
   g. **Collaborative Agreements** (name of the institution/person and a description of the collaboration)
   h. **Other IRB Approvals** (e.g. collaborating institutions)
4. **Study Instruments:**
   a. Recruitment Materials (flyers, newspaper ads, etc.)
   b. Consent Form(s)
   c. Assent Form(s)
   d. Disclosure Letter(s)
   e. Telephone Script(s)
   f. Interview Instrument(s) or Draft Questionnaire(s)

5. **Other Supporting Documents:**
      a. **Special Forms and Populations**
          i. Radiation Forms
          ii. Children's Checklist
          iii. Prisoner's Checklist
          iv. Letters of Support
          v. Letters of Collaboration
      b. **If study involves a drug or a biologic:**
          i. Investigator Drug Brochure
          ii. Sponsor's Protocol
          iii. Drug Data Sheet
      c. **If study involves a device:**
          i. FDA letter approving the Investigational Device Exemption (IDE) OR
          ii. 510(k) clearance OR
          iii. Letter from Sponsor stating significant or non-significant risk
      d. **If the device is cleared for marketing, but involves a new investigational use:**
          i. Pre-Market Approval (PMA) Letter OR
          ii. PMA Supplement Letter
          iii. PMA Amendment Letter
      6. Evidence of human subjects training for all investigators listed on the application. One copy.

NOTE: An Original + three (3) copies of the CHR Application, Research Plan, study instruments and all supporting documents must be submitted with two exceptions noted above.

Principal Investigator:

Project Title:

PI:_____

Study Title:_____

OPTIONAL
CHECKLIST FOR CONSENT DOCUMENT

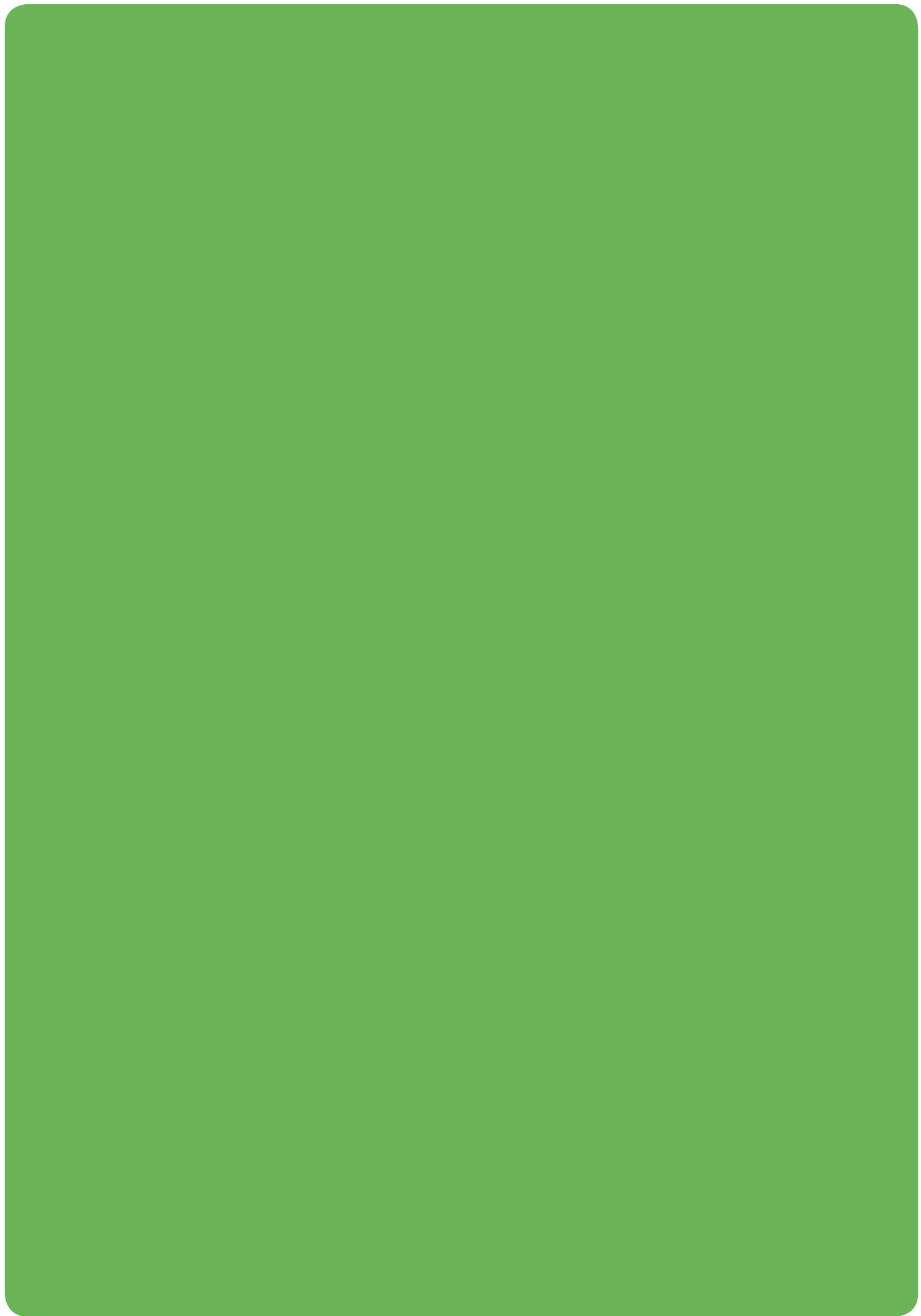|	Does this consent form contain each element, if appropriate:	Check all that apply			If you respond N or NA, please explain
		Y	N	NA	
1.	That the study involves research				
2.	An explanation of the purposes of the research				
3.	That the study is being conducted by Johns Hopkins and the [Name of the Principal Investigator]				
4.	An explanation of how selected for the study				
5.	An explanation of why selected for the study				
6.	The expected duration of the subject's participation				
7.	A description of the procedures to be followed				
8.	Identification of any procedures which are experimental				
9.	A description of any benefits to the subject or to others which may reasonably be expected from the research				
10.	A description of any reasonably foreseeable risks or discomforts to the subjects				
11.	A disclosure of appropriate alternative procedures or courses of treatment, if any				
12.	A statement that participation is voluntary				
13.	A statement that the subject can withdraw at any time and will not affect any benefits that they would normally receive or they will not be penalized for withdrawing from the study				
14.	The consequences of a subject's decision to withdraw from the study				
15.	A statement under which the subject's participation may be terminated by the investigator, where appropriate				
16.	A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained				
17.	An explanation of whom to contact for information about the research study itself [name and phone number for primary investigator]				
18.	An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights [name and phone number for CHR]				
19.	For research involving more than minimal risk, a statement that Johns Hopkins does not have a program to provide compensation any injuries or bad effects which may be incurred by the subject which are not the fault of the investigator				
20.	Language is understandable and written at the eighth-grade level and in no smaller than 12 point type. If not written at 8th grade level, please provide at what reading level the consent form was written				

Completed by _____

ANNEX E - Linkage between Researchers and Public Health

Building Capacity for IR/OR – Nigeria Experience in Linkage and Networking between National Malaria Control Program and Research Institutions

1. The TDR-WHO Studies:

a. **TDR-WHO Intersectoral Linkage Project: aimed at linking research (The Ibadan Malaria Research Group – IMRG) with policy (State Ministry of Health [SMOH], Ibadan, Oyo State) and Program (Adeoyo Maternity Hospital, Yemetu, Ibadan).** This was a successful project as information generated by the research team was adopted and approved by the State Ministry of Health through the Department of Planning, Research and Statistics; and was passed on to the State Hospitals Management Board, the implementing body supervising the Adeoyo Maternity Hospital, Yemetu, Ibadan.

b. **Scaling up of Community Management of Fever (Proposed) 2002 following successful implementation of the TDR-supported Community Management of Fever and Cough project in 3 communities in Igbo-Ora (Oyo State), Ugwogwo-Nike (Abia State) and Usokwato (Enugu State)**. The proposal, which was to be implemented in four states in four zones of Nigeria was developed in 2002 with the support of WHO. It has a researcher as the Principal Investigator (PI) and the NMCP Coordinator as the Co-PI. Unfortunately, it was not funded due to inadequacy of resources. The scope was then scaled down to a few communities in one Local Government Area (LGA) in Oyo State alone.

c. **Home Management of Malaria project in Ona-Ara LGA, Oyo State, Nigeria: Involvement of Federal Ministry of health (FMOH), SMOH, LGA and Communities in implementation, documentation of findings and results dissemination**. The research team is now providing technical assistance (TA) in the scaling-up process using evidence from research for control program in six LGAs of the Federal Capital Territory with a plan to scale to 18 States before 2008. One example of such TA is to conduct a baseline evaluation of the feasibility of scaled-up home-based management of malaria.

d. **TDR Community Directed Interventions (CDIs) in the treatment of Onchocerciasis, Diarrhoea, Malaria, etc in 5 Sites in Nigeria (Ibadan, Iseyin, Saki, Kaduna and Garba-Chede, near Jalingo, Taraba State, Nigeria**. Program officials visited some research laboratories and field sites severally and during documentation/dissemination workshops and also supplied all the sites with antimalaria commodities such as ACTs for malaria, long-lasting insecticide-treated nets (LLINs) and IPTp drugs as requested by the PI. The researchers have also provided TA to programs upon request.

e. **TDR Malaria in the Nomads Project in Yola, Adamawa State, Nigeria.**

2. Drug Efficacy Trials 2002 (Chloroquine) and 2004 (Arthemeter-Lumefanthrine and Atesunate-Amodiaqunine) to inform malaria treatment policy change towards Artemisinin-based Combination Therapy in Nigeria in 2005. All the PIs were Researchers who worked and are still working as Consultants to the National Malaria Control Program (NMCP) at all levels.

3. Antimalaria sentinel sites monitoring to keep track of anti-malarial tools' effectiveness. The community sites are being managed by researchers in collaboration with community members, program managers at LGA and State levels, with support from the national level.