

Implementation Research Toolkit

Workbook



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ABBREVIATIONS

ACT	artemisinin-combination therapies
ANC	antenatal care
ART	antiretroviral therapy
BCC	behavior change communication
BMI	body mass index
CAS	complex adaptive system
CHW	community health worker
CMS	Cooperative Medical Scheme
COS	Community of Science
DOT	directly-observed therapy
ERC	ethics review committee
FGD	focus group discussion
HDI	Human Development Index
HIV	human immunodeficiency virus
HRP	Special Programme of Research, Development and Research Training in Human Reproduction
IC	informed consent
ICF	intensified case finding
IDRC	International Development Research Centre
IEC	information, education and communication
IKT	integrated knowledge translation
IR	implementation research
IRB	institutional review board
IRP	Implementation Research Platform
KT	knowledge translation
KZN	KwaZulu-Natal
LLIN	long-lasting insecticide-treated net
LOI	letter of intent
LSHTM	London School of Hygiene and Tropical Medicine
LTFU	loss to follow-up

M&E	monitoring and evaluation
MDR-TB	multidrug-resistant tuberculosis
NGO	nongovernmental organization
NSF	National Science Foundation
NTBCP	national TB control programme
OER	Office of Extramural Research
PI	principal investigator
PLHIV	person/people living with the human immunodeficiency virus
PMTCT	prevention of mother-to-child transmission
QDA	qualitative data analysis
RFP	request for proposals
SAGE	Strategic Advisory Group of Experts
SARS	severe acute respiratory syndrome
SMART	specific, measurable, achievable, realistic and timebound
SOP	standard operating procedure
SWOT	strengths, weaknesses, opportunities and threats
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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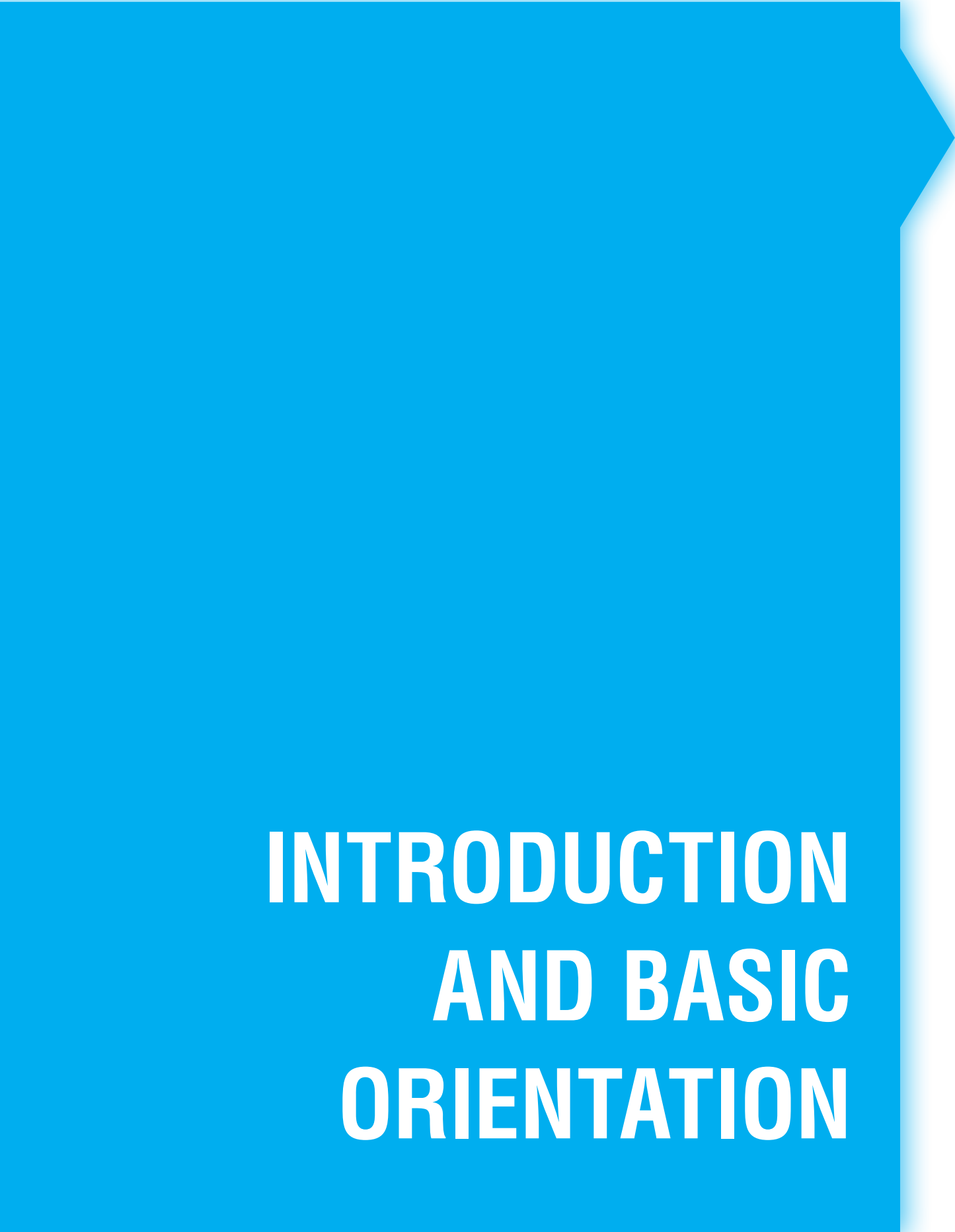
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INTRODUCTION AND BASIC ORIENTATION

LEARNING OBJECTIVES

This introductory module serves as a baseline introduction and a quick reference guide. You will receive an introduction to basic terms and principles, along with an orientation to subsequent toolkit modules and their rationale. By the end of the introduction, you will have a good overall understanding of the following key concepts and their application:

1. What is implementation research (IR)?
2. Key characteristics of IR and the IR cycle.

The module is typically combined with an introduction/formal opening ceremony and comprises a half-day workshop/tutorial, slides and materials for further reading. It also includes a self-assessment questionnaire gauging your current IR-related knowledge and understanding.

KEY CONCEPTS

What is implementation research?

The importance of research in identifying solutions and options for overcoming implementation obstacles in health systems and programmes is widely recognized. *This form of research addresses implementation bottlenecks, identifies optimal approaches for a particular setting, and promotes the uptake of research findings:* ultimately, it leads to improved health care and its delivery.

While IR has been defined in various ways by different institutions, common interpretations focus on the systematic approach to understanding and addressing barriers to effective and quality implementation of health interventions, strategies and policies. IR is demand-driven and the research questions are framed based on needs identified together with relevant stakeholders/implementers in the health system. Key characteristics of IR are summarized in Table 1.

The need to address implementation bottlenecks is often greatest in settings where health systems are the weakest or non-existent. Unfortunately, local institutions often have limited knowledge of IR and lack essential capacities to frame relevant research questions, and conduct, manage and interpret research results for programme planning and policy implementation. Academic public health curricula tend not to focus on such research. As a result, most training does not adequately prepare researchers, practitioners, providers or decision-makers for essential partnership and interdisciplinary approaches.

This current toolkit comprises seven modules, each providing a participant manual, workshop session slides, and links to relevant further reading and references. The purpose of the toolkit is to help strengthen participant skills in six areas:

- Contextualizing implementation research issues.
- Developing an implementation research proposal.
- Planning to execute implementation research.
- Analysing implementation research data.
- Communicating the findings and feeding them back into the health system.
- Monitoring and evaluating the project.

Table 1: Key characteristics of implementation research

Characteristic	Summary/description
Systematic	The systematic study of how evidence-based public health interventions are integrated and provided in specific settings, and how resulting health outcomes vary across communities. Balances relevance to real life situations with rigor, strictly adhering to norms of scientific inquiry.
Multidisciplinary	Analysis of biological, social, economic, political, system and environmental factors that impact implementation of specific health interventions. Interdisciplinary collaborations between behavioural and social scientists, clinicians, epidemiologists, statisticians, engineers, business analysts, policy makers, and key stakeholders.
Contextual	Demand driven. Framing of research questions is based on needs identified by implementers in the health system. Research is relevant to local specifics and needs, and aims to improve health care delivery in a given context. Generates generalizable knowledge and insights that can be applied across various settings. Mindful of cultural and community-based influences.
Complex	Dynamic and adaptive. Multi-scale: occurs at multiple levels of health systems and communities. Analyses multi-component programmes and policies. Non-linear, iterative, evolving process.

This set of skills is an important element of IR capacity in both individuals and institutions, particularly in low- and middle-income countries, where the greatest need for expanding IR capacity exists. Throughout the capacity-building process there are feedback loops for monitoring, adaptation and improvements, as well as suggestions for ensuring integrated knowledge translation and uptake of results.

Implementation research is not a single activity, but a stepwise, cyclical process (Figure 1). The initial step is a clear identification of the intervention problem(s), working with key stakeholders to generate relevant research questions. In this manner, an interdisciplinary team can bring together the relevant skills and backgrounds to develop a detailed proposal, plan, mobilize resources and execute the study. Ultimately it can present the findings in an appropriate format for uptake and use by planners and decision-makers within the health system.

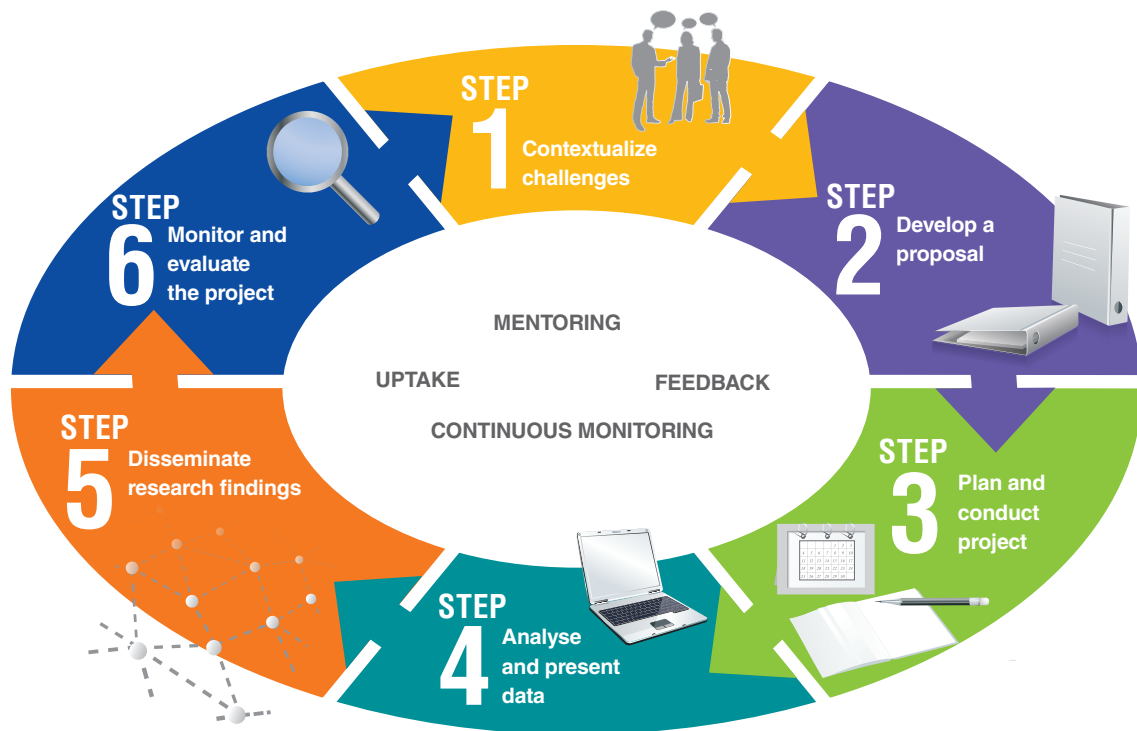


Figure 1: The six steps of the implementation research cycle

While conducting IR, there must be active and continuous monitoring of activities and regular feedback for necessary changes and amendments. Dissemination of findings in IR should occur continually throughout the cycle as well as after the completion of the research project. The findings must be presented appropriately for each partner and stakeholder, so that the most relevant results are available in a timely manner to influence practice.

Interacting IR domains

It is instructive to think of IR in terms of the five main interacting ‘domains’ that it encompasses (Figure 2). You will encounter more detailed descriptions of these domains throughout subsequent modules, in addition to the general descriptions outlined here.

The intervention. The characteristics of the intervention determine whether it will be adopted or ‘fit’ for the local health system. Here the term ‘intervention’ includes the core components and those elements that may be adapted to suit local needs and/or conditions. The characteristics of core components, such as complexity, cost and evidence strength, play a crucial role.

Outer setting. This includes the economic, political and social contexts in which an intervention is carried out and that are external to the implementing organization/institution. It is influenced by external policies and incentives – such as global funding streams – as well as by interactions and peer pressure among organizations.

Inner setting. This refers to the context within the implementing organization/institution. It includes the structure of the organization, its culture (internal climate) and networks, as well as readiness for change.

Individuals involved. These are people who have a direct role in the implementation process. This includes health care providers, managers in various parts of the organization/institution, policy-makers and many other stakeholders and beneficiaries. In addition to the usual concerns regarding the capacity to implement, their perceptions and attitudes towards the intervention have an important influence on their commitment to its success and impact.

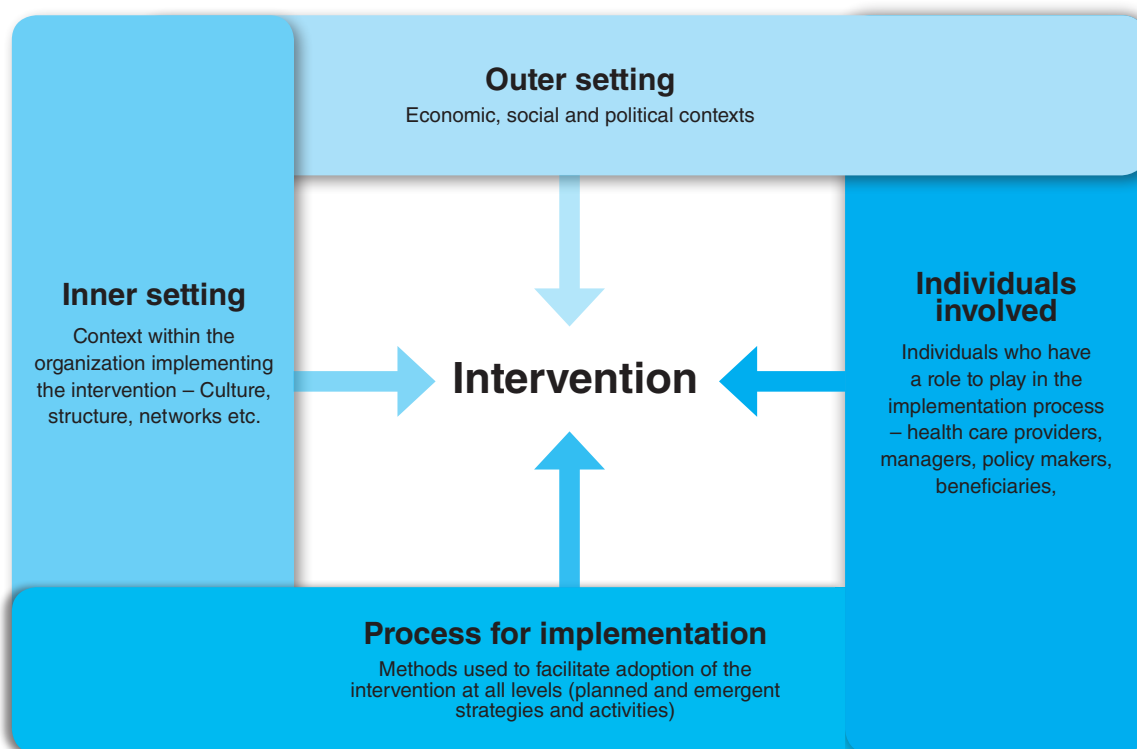


Figure 2. Interacting domains in implementation research

Process for implementation. This incorporates all of the methods and approaches used in facilitating adoption of the intervention at all levels of the organization, including the planning of strategies and activities. Processes include both those explicitly planned and unforeseen ones that emerge during implementation.

Self-assessment exercise

The team you bring together to tackle a specific IR challenge should be multidisciplinary: members of the team have varied roles, work in diverse sectors, and likely have very different backgrounds. Members may also have diverging ideas about how the elements of IR fit together and what they mean and varying degrees of competence in each area. An IR-focused self-assessment within each team allows you to identify some of those differences in opinion, individual strengths and the distribution of competences within the team. It also allows you to walk at your own pace through the content and focus on the six skill sets the toolkit helps to strengthen, setting your team's broad learning targets.

Using the matrix shown in Figure 3, select your team's current level of:

- awareness
- understanding
- knowledge
- skills
- competence

in each of the steps in the IR cycle. You can also refer to the more detailed matrix provided in Appendix 1 if there are individual steps you/your team are not clear about at this stage.

Each team member should keep a copy of the completed self-assessment matrix, and refer to it during the remainder of the workshop.

Skill sets		1 Some awareness	2 Understanding	3 Knowledge	4 Skills	5 Competence
Contextualizing IR issues						
Developing an IR proposal						
Planning IR						
Analysing IR data	Qualitative					
	Quantitative					
Communicating IR findings and feeding them back into the health system						
Monitoring and evaluating the project						

Figure 3: Self-assessment framework for IR cycle steps

Summary of toolkit modules

A brief summary of individual modules and their rationales is presented below.

Module 1: Defining and contextualizing implementation research

Implementation research is conducted within routine systems and real life settings, removed from the controlled settings associated with other types of scientific research. The prevailing physical, socioeconomic, cultural, health systems, stakeholder and institutional culture are all key aspects of the environment where the research is conducted. Together they contribute to and affect the planning, implementation, monitoring and outcomes of interventions. This module facilitates consideration of the context and engagement of stakeholders in order to help identify bottlenecks and formulate appropriate research questions. The overall objectives of the module are to:

- Facilitate engagement between researchers and implementers.
- Identify implementation bottlenecks or inefficiencies.
- Frame appropriate research questions to address the issues identified.
- Highlight the different methodological approaches to generating information.
- Consider ethical issues in context.
- Facilitate mentorship to ensure sustained IR capacity at all levels.

Over the past decade an half, many efficacious disease control tools, (e.g. bednets and artemisinin-based combination therapy for malaria, praziquantel for schistosomiasis, ivermectin for lymphatic filariasis and onchocerciasis) became available.

Studies have demonstrated that these tools can be delivered at the community level. Nevertheless, many have had only limited impact because of inadequate implementation. Once integrated into the in the health system and/or community, an intervention can lose effectiveness or impact due to several factors including, for example, poor uptake of clinical guidelines into practice despite supporting evidence or financial costs to the target population limiting access.

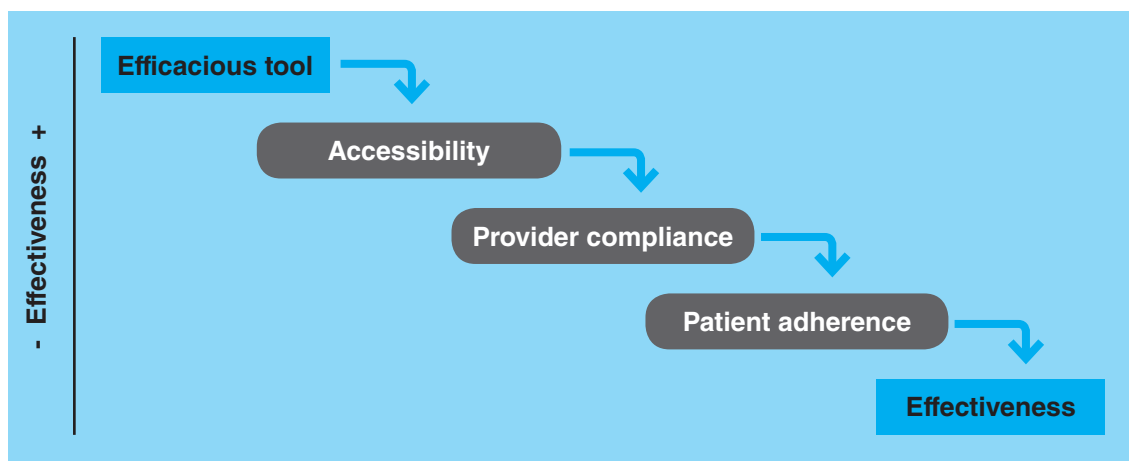


Figure 4: Influence of health system factors on intervention effectiveness and impact

Figure 4 highlights that in order for a proven and efficacious tool to be effective, it must be accessible to the target group, health care providers must comply with the relevant policies and patients must adhere to the information on use of the tool. However, there are several challenges including inequities that affect the ability of various stakeholders to use the tool as expected eventually rendering the tool ineffective.

In order for IR to be successful, the researcher must have an active link with and rapidly respond to the needs of disease control. There must be partnerships and links with other health related ministries or departments and agencies so that relevant findings during the entire process can be taken up and utilized for action as and when it becomes necessary.

Because implementation research takes place in real, non-experimental settings and within complex dynamic systems (1), understanding the specific context of the implementation is important. The physical, socioeconomic, cultural and health system, stakeholders, as well as the institutional contexts within which the intervention is taking place affect the planning, design and conduct of the research. Therefore for IR to be relevant, researchers with appropriate stakeholders should interrogate these contexts through situation and institutional analyses. This entails face-to-face interactions, discussions and sharing of documents to ensure that the appropriate questions are asked, addressed in context and have the commitment of all concerned to facilitate uptake of results during and at the end of the research.

Module 2: Developing an implementation research proposal

This module assumes the participants understand the contextual nature of IR, have engaged the right stakeholders, have articulated the problem/barrier to be addressed and have assembled an appropriate and multi-disciplinary team. The underlying principles are presented in the introductory module and module 1. It takes you step-by-step through the process of formulating appropriate research question(s), choosing the appropriate study design to answer the question(s) and preparing an outline of the project activity plan. It covers the following key concepts with examples:

- Identifying barriers to implementation and formulating the research question.
- Making your case for funding (introduction, rationale and objectives).
- Study design and appropriate methodologies.
- Planning the project (budget, personnel, timelines, monitoring and evaluation).

Regardless of the subject area or study approach, research proposals generally follow a similar outline (Box 1).

Box 1

Typical outline of a proposal for implementation research

1. Title

This should be a brief statement explaining what the proposal is about.

2. Executive Summary

A brief summary of the entire proposal (usually no more than 1 page).

3. Introduction and background

An explanation of the issue(s) being examined.

4. Literature review

A description of what is already known in the subject area articulating why the background studies are not sufficient.

5. Rationale

An explanation of why it is necessary and relevant to conduct the study.

6. Objectives

Statement of what will be achieved through the study and when it will be achieved.

7. Methodology/study design

A description of how the study would be conducted, what procedures and standards will be followed, the type of data to be collected and the responsible team member.

8. Ethical issues

Issues about the autonomy, protection and confidentiality of the subjects and how these will be addressed.

9. Budget/resources

An outline of the financial costs involved in implementing the proposed study and any other essential resources.

10. References

Acknowledgment of the literature (e.g. research articles, policy papers and documents) used as references for the information provided in the proposal.

The difference between an IR proposal and other types of research proposals is the process of identifying the research problem and the involvement of the end users in the research process (2). An IR research project (be it an intervention or analysis of routine data) should achieve the following.

- Better inform health care delivery.
- Facilitate the uptake of research results.
- The process through which the results were achieved should be generalizable so they can be applied across settings and contexts.
- Involve and engage partners across multiple disciplines to address the identified problem.
- Lead to the development of policy recommendations for practical solutions (3).

Module 3: Planning to conduct the research

This section of the toolkit addresses the steps that you will take once resources to support an IR proposal have been secured. It provides information to facilitate planning to conduct the research project, including preparation of the study protocol for an ethical review process. Module 3 covers the following key concepts with examples.

- Preparing for ethical review.
- Project implementation process.
- Good practices in IR.

For the successful execution of any project the importance of a good project plan cannot be over-emphasized. The project needs a team where each member has a specific role that is clearly defined and linked to specific outputs. The aims are to: (a) ensure the project has a common goal and (b) provide a clear vision of the project including what needs to be done and at what quality standards, who will do it, when it is to be done, cost of the project, source of funding, milestones and reporting timelines.

Planning for IR involves:

- defining the scope (consulting stakeholders, agreeing on roles and responsibilities, defining deliverables);
- articulating an implementation plan (methods and inputs required);
- timelines (Gantt chart);
- reporting activities;
- estimating resources needs (human and other).

Module 4: Data analysis and presentation

This module has been designed to help the research team (implementers and researchers):

- understand appropriate data analysis procedures for qualitative and quantitative data;
- use of statistics in quantitative research;
- and describe and document the data analysis processes in a qualitative study.

It also employs examples to illustrate the applications of the underlying concepts.

In IR, data management and analysis is an ongoing process throughout the project. At all stages (the situation analysis stage prior to, during and following the intervention) data must be collected, managed, analysed and presented in a way that will be useful to end users. The type of research problem identified and question asked will determine the type of analysis to be conducted. Examples of analysis include:

- Stakeholder analysis (the process of identifying individuals or groups that are likely to affect or be affected by a proposed action, and sorting them according to their impact on the action and the impact the action will have on them).

- SWOT analysis (framework for organizing and using data and information gained from the study of organizations and in monitoring and evaluation of organizations and activities). Institutional analysis (systematic study of the behaviour of organizations).
- Other types of analysis include the continuous monitoring and evaluation of the main intervention.

At each stage of the process, data collected is either qualitative or quantitative and the standard procedures for analysing such data must be employed (4). It is critical that the researchers do not do this in isolation, but involve all stakeholders in the data management and analysis process to provide the relevant stakeholders the opportunity to use the results as they are generated (5).

Module 5: Dissemination of research findings

This module has been designed to assist the research team to:

- appreciate the concept of knowledge transfer in the uptake and use of research results;
- describe the barriers and facilitators of knowledge transfer in relation to a research project;
- understand the value of disseminating information throughout the project cycle;
- appreciate the value of developing of a comprehensive dissemination strategy in a research project;
- appreciate the importance of tailored dissemination tools for the different target audiences.

It illustrates the key concepts of knowledge translation with examples and provides structured guidance on preparation of research reports, peer reviewed papers, press releases, conference presentations and policy briefs.

Dissemination in IR is not a one-step process. Implementers, working with researchers, take up and use research results as they are generated. The key issue as it relates to IR is that dissemination cannot be deferred until the research is 'completed'. Dissemination of research findings must be packaged appropriately for each category of stakeholders and key decision-makers.

Policy-makers often highlight the failure of researchers to make research results available, while researchers often express frustration that policy-makers do not use research results provided. Brownson et al (6) have used the phrase "travellers in parallel universes" to describe researchers and policy-makers. This disconnect can be avoided by adopting a more comprehensive approach to dissemination. Too often, researchers become aware of the following questions only after the study is completed:

- Which stakeholders will benefit from the information to be generated?
- What particular questions are these stakeholders seeking to answer?
- How do we involve stakeholders in defining and asking the 'right' questions?
- Who should be targeted in order to get the intervention or finding into action?
- How do stakeholders actually absorb research evidence?
- Who will be directly or indirectly affected by the outcome of this research?
- Is there is a plan for operationalizing the findings, who will support or oppose it? How might we respond to any opposition? Or take advantage of support?
- How can we best leverage critical stakeholder insights or allay their objections?

These questions should be an integral part of the project planning. If IR is conducted appropriately researchers, implementers and policy-makers should communicate and collaborate throughout the entire journey of the IR cycle. Conventional publication of research findings in peer reviewed

journals, written policy briefs and research reports are also essential aspects of dissemination in IR and have their roles.

Module 6: Monitoring and evaluation

The final module has been designed to help you and the research team track progress in accordance with set plans, check compliance with established standards, identify trends and patterns, adapt strategies and inform decisions for project management. It also helps build skills to determine the relevance and fulfilment of objectives, developmental efficiency, effectiveness, impact and sustainability. On completion of this module, your team will be able to appreciate the process involved in the development of a monitoring as well as evaluation plan and describe the overall implementation process of an IR project.

The audience

IR involves teamwork. It requires people with different and complementary skills, experiences and backgrounds to come together in order to address an implementation problem and answer questions posed by health care providers, programme managers, implementers and/or other service providers in the execution of their duties. An IR project can therefore include researchers and other stakeholders such as health care providers, programme managers, policy-makers, students, civil society organizations, nongovernmental organizations and any other groups or individuals interested in the IR process and results.

Although it is important for everyone involved in an IR project to have an understanding of the entire IR cycle and their role in the project, the modules in this toolkit specifically target health care providers, researchers, policy-makers/managers and administrators.

Figure 5 suggests the engagement requirements for the various participants in an IR team. The levels may vary, however, depending on the context and the nature of the project. The IR toolkit is meant for all categories of people listed and other interested parties.

Audience	Health service providers programme staff	Researchers	Decision- makers	Finance and administration	Media	Ethics committees
Introduction to IR	++	++	++	++	++	+
1. Contextualizing IR	++	++	++	?	+	-
2. Proposal development	++	++	+	-	-	-
3. Planning and executing the research	++	++	-	++	-	-
4. Data analysis and presentation	++	++	++	-	?	-
5. Dissemination and research findings	++	++	++	?	++	-
6. Monitoring and evaluation	++	++	-	-	-	-
Mentoring and continuous engagement						
Mandatory ++ Optional ? Desirable + Not required -						

Figure 5: Suggested participants/audiences and respective critical engagement needs in the various stages of the IR process

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Additional reading

- Peters, David, Nhan Tran, Taghreed Adam, and World Health Organization. "Implementation research in health: a practical guide/edited by David Peters...[et al]." (2013).

Appendix 1: Self-assessment framework for IR cycle steps

Skill sets	1 Some awareness	2 Understanding	3 Knowledge	4 Skills	5 Competence
Defining and contextualizing IR issues	We rely on our subjective views of context	We are aware of the distinctive context of IR and its range/scope	We share a partial view of the real IR context and are filling gaps in what we know about the fuller context	We have a full factual understanding of context and are developing adaptation skills	We integrate contextual factors into all steps in the IR process/cycle to identify solutions and adapt IR approaches
Developing an IR proposal	We are familiar with research proposal components	We can distinguish specific requirements of IR proposals and projects	We have completed our IR proposal and have identified funding	We are learning more about proposal development as we implement our project and ongoing M&E	We are able to guide other project teams to use good practices in proposal development
Planning to execute IR	We have never planned IR research, so learning as we go	We understand the required planning principles, but yet to apply them directly to our project	Able to apply planning principles to our own project	We are conducting our research according to good planning principles and practices	We are working with considerable planning and are able to mentor others
Analysing IR data	We are new to research and/or data management	We are aware of different data collection methods and distinguish quantitative and qualitative approaches	We apply appropriate research and data methods in our work	We possess specific data analysis skills	We are able to readily translate IR data into action and policy recommendations
Communicating IR findings and feeding them back into the health system	We regularly publish research results in specialized journals	We are familiar with and competent in end-of-project results dissemination	We consider dissemination and communication issues in the first meetings with key stakeholders	We integrate our dissemination and communications strategies throughout the IR cycle	We harness multiple opportunities for dissemination synergy and cooperation among project stakeholders and team
Monitoring and evaluating the project	We are new to M&E of IR	We are aware of the benefits and requirements of effective M&E	We understand what needs to be monitored and evaluated at the different stages of our project	We use M&E data from the project to conduct periodic reviews	We build M&E into all stages of proposal development, project execution and adaptation

MODULE

1

CONTEXTUALIZING IMPLEMENTATION RESEARCH ISSUES

LEARNING OBJECTIVES

This module is designed to emphasize the importance of contextual factors surrounding implementation research (IR) projects. The module increases understanding of the relationships between the research environment, specific intervention strategies and related ethical considerations. At the end of this module, your research team will be able to:

1. Analyse the environment in which IR projects are conducted.
2. Understand and appreciate the context relevant to your proposed/planned intervention.
3. Describe the ethical principles related to IR.

KEY CONCEPTS

Understanding the IR context

The physical, socioeconomic and cultural environments, health systems, stakeholder and institutional culture are key aspects of the research context. Together they contribute to and affect the planning, implementation, monitoring and outcomes of any intervention. During the pre-implementation phase of an IR project, the factors presented in Figure 1 should be analysed. It should be noted that these factors vary considerably from one location to another, and from one project to the next.

The physical, socioeconomic and cultural context

Various aspects of the physical, socioeconomic and cultural context may be relevant depending on the specific intervention. Careful planning must be conducted in order to effectively focus resources on the factors that are most likely to be critical.

Physical and demographic factors

Attention should be paid to the relevant geographical features: rural/urban location, distance, physical barriers to access (e.g. mountains, rivers), relevant infrastructure such as transport systems, electricity and water supply; demographics (e.g. population size, distribution by location, gender and age). As appropriate, the burden of disease, trends in morbidity and mortality by location and/or population group should be analysed in detail.

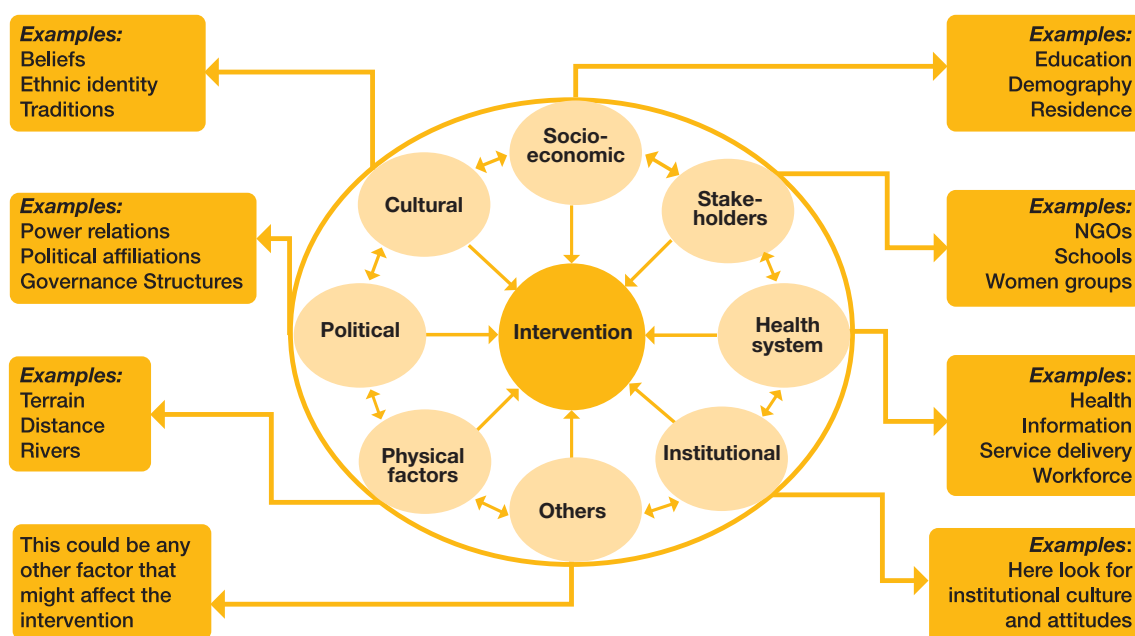


Figure 1: Contextual factors for implementation research

Socioeconomic status

Analysis of the general standard of living; the level of inequality, identification of vulnerable groups, socioeconomic status based on income levels, assets, educational status and occupation should be undertaken. In addition, the main types of dwellings (e.g. communal huts, apartments or gated communities), by location, food consumption, nutrition, access to clean water and sanitation e.t.c. should also be analysed.

Cultural and political factors

Analysis of the cultural beliefs related to health, gender equality, literacy rates, ethnicity/tribal segregation; policy environment and political factors, including level of support for social services and health care services; government capacity to provide services and any other ongoing or recent health interventions should be conducted.

The health system

Every health system is made up of multiple sub-systems (1) with the primary focus being the promotion, restoration or maintenance of health. The World Health Organization (WHO) has identified six key groups or 'building blocks' (2) that make up health systems: leadership/governance; health care financing; health workforce; medical products, technologies; and information and research. These blocks address access to and coverage of health services, as well as quality and safety of services (Figure 2).

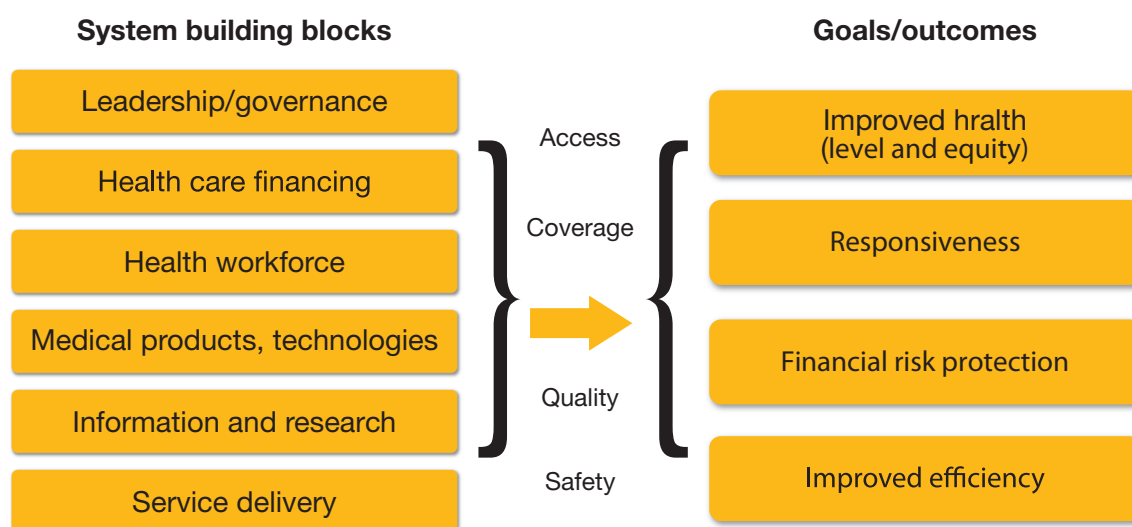


Figure 2: Building blocks of a health system

Other factors, such as self and community care, also contribute to health systems. For each component relevant to an IR project, it is helpful to undertake a systematic descriptive analysis to help identify the relevant decision-making agents and the (formal and informal) institutions that govern its operation.

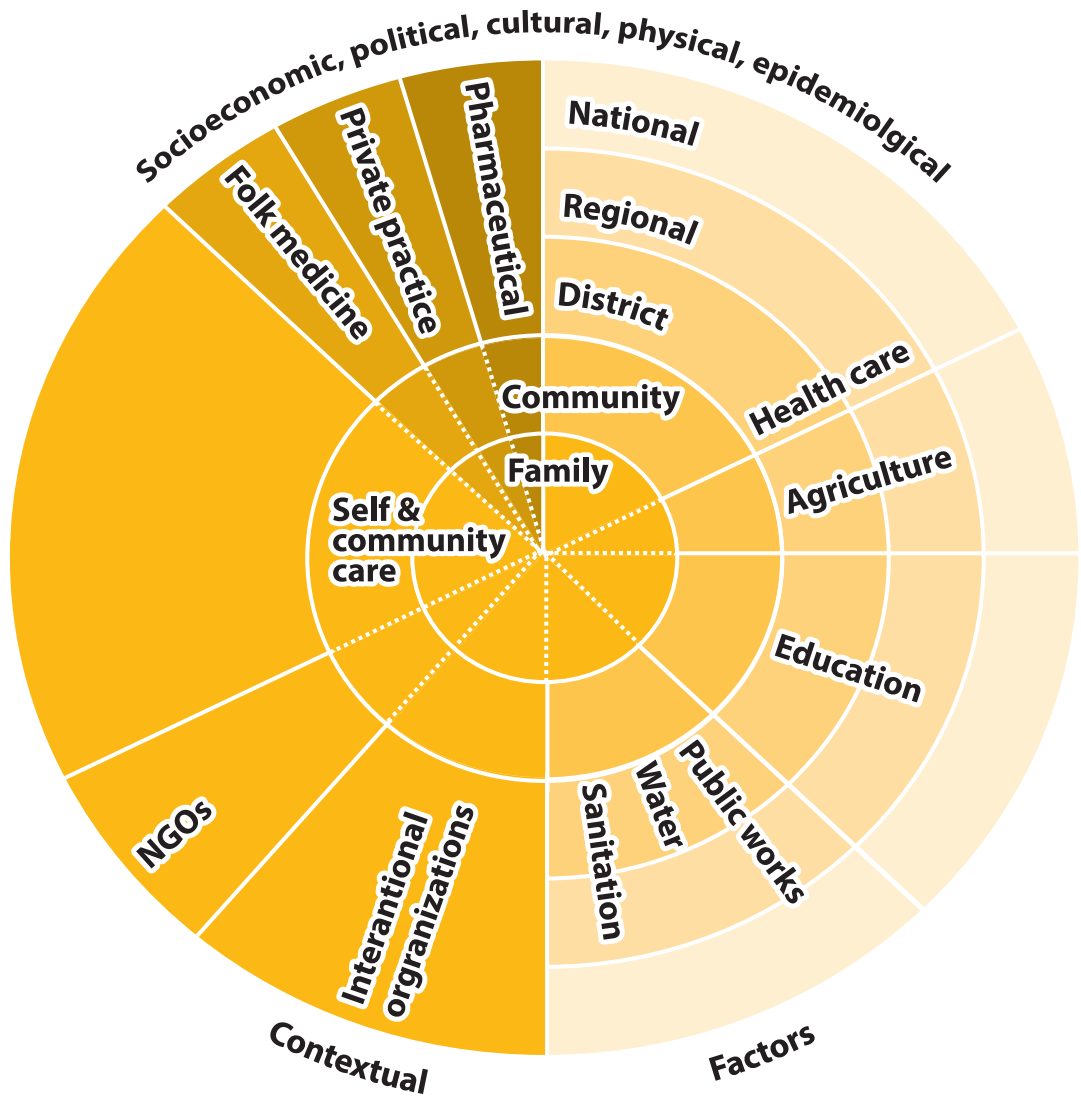


Figure 3: Elements of a typical health system

In the example summarized below (Box 1), researchers accumulated information about the physical, socioeconomic and cultural factors, as well as health system considerations regarding a study undertaken in KwaZulu-Natal (South Africa). The study involved a review of relevant documents and interaction with the local population. The information comprised baseline data/indicators for planning and monitoring the research programme in addition to contributing to development of appropriate communication strategies.

Box 1

Example: TB/HIV collaboration in Sisonke District

In a study to assess engagement of nongovernmental organizations and community care workers in collaborative tuberculosis (TB)/human immunodeficiency virus (HIV) activities in KwaZulu-Natal (KZN), researchers reviewed the South African health review report with specific emphasis on health and health-related indicators. They established that KwaZulu-Natal is the epicentre of TB and HIV epidemics with a TB-HIV co-infection rate of 75–80% in some settings. They also established that Sisonke District – one of KZN's 11 districts – was mostly rural with poor roads, an area of 11 128 km², a population of ~500 000, 79% of whom were unemployed, and poverty levels among the population was 71%. The people of Sisonke District had relatively poor access to basic health services when compared to residents of similar, inland rural districts. Only 33% of Sisonke residents had access to piped water (on or off site), 57% relied on candles for lighting, 74% were reliant on either paraffin or wood for cooking and only 22% had access to good sanitation (i.e. flush or chemical toilets). The most common spoken language was IsiZulu while majority of the district population (53.62%) were females. The antenatal HIV prevalence, which was estimated at 35% compared to 39.5 province-wide in 2008–2009, was determined through review of the National Antenatal Sentinel HIV and Syphilis Prevalence Survey in South Africa, 2010. New TB cases numbered 1079 per 100 000 population, with an HIV co-infection rate of 81% (compared to 52% overall in South Africa in 2009).

At the time of the study (August 2008 to Sept 2009) the health system in the district comprised a total of 32 nongovernmental organizations managing home-based care services, 26 of which were funded by the Department of Health. These 26 nongovernmental organizations employed a total of 414 community health workers (CHW). Another large independent organization managed 402 CHWs.

Source: (3)

One of the main purposes of analysing the health system is to predict how specific considerations might potentially affect the viability and impact of a given intervention. As a result of a variety of context-specific factors, interventions that may be effective in one setting can have a diluted impact in other contexts (Figure 4).

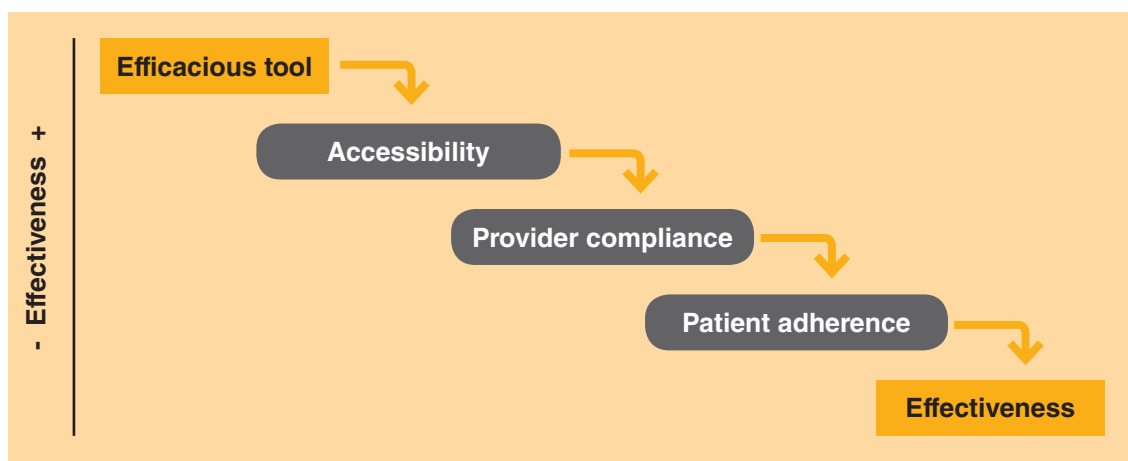


Figure 4. Influence of health system factors on intervention effectiveness and impact

Stakeholder analysis

In practice, IR involves various stakeholders who should be identified in the developmental stages of the research project. Stakeholder analysis is one of the most important activities undertaken by researchers in terms of understanding the context of the intervention, and should be done in a systematic and comprehensive way (4–6). Stakeholder analysis aims at identifying all relevant stakeholders, assessing how they are likely to be affected by the research, and how they might respond to the research outcome. Stakeholder identification requires careful judgment, must be neither non-inclusive (limiting breadth of perspectives) nor over-inclusive (diluting essential focus).

The process of conducting stakeholder analysis involves: (i) Defining the purpose of the analysis; (ii) Generating the list of stakeholders (an initial list can be constructed by brainstorming relevant issues and further additions to the list can utilize a snowball technique, during which stakeholders identify additional stakeholders); (iii) collecting necessary data (using interview guides semi-structured questionnaires) – it is advisable to book appointments ahead of time, where necessary seek consent and record the interview; (iv) analysing and presenting data in matrices (i.e. type of stakeholder, levels of interest and influence, and the roles they will be or are playing in the implementation of the proposed intervention).

Table 3 shows the various stakeholders in an example health project, and the roles they played.

Table 3: Examples of typical project stakeholders and respective roles

Stakeholder	Role
ProNet	Key nongovernmental organization in policy implementation
UNICEF	Influential, United Nations agency and represents other nongovernmental organizations at many conferences
Ministry of Environment	National-level policy formulating and implementing agency
Christian Council	Represents faith-based groups for policy development

Box 2 highlights how stakeholder analysis was used to assess the perceptions, aspirations and expectations of a range of stakeholders in order to assess the policy environment prior to the introduction of a series of health service innovations.

Box 2

Example: Qualitative assessment of stakeholders in Santiago de Chile

A study in the Santiago Metropolitan region of Chile used stakeholder analysis to assess the policy environment prior to the introduction of a series of innovations of ambulatory care for acute lower respiratory disease in children (pneumonia and obstructive bronchitis), as well as prevention of stroke.

Priority stakeholders were defined according to the knowledge of the researcher about the Chilean health sector. They included policy-makers, doctors, nurses, managers and professions allied to health care.

The study mainly involved the collection of qualitative data about the perceptions, aspirations and expectations of a range of stakeholders. It also gathered material on perception of power and authority, as this was seen as likely to affect implementation processes.

While this methodology did not permit statistical inference, it was seen as providing understanding of the context and probable responses of stakeholders to the planned innovations. The research was intended to provide data on the negotiation and construction of meanings within social interaction. It considered domains such as experience, knowledge and action.

Source: (7).

Institutional analysis

Institutional/organizational analysis (a systematic study of the behaviour of organizations) is another important dimension to consider in planning for IR. This can be achieved through an analysis of strengths, weaknesses, opportunities and threats (or 'SWOT') to establish the factors with potential impact on the success or failure of an intervention.

The example summarized in Box 3 used a SWOT analysis to provide information on various issues affecting the efficiency and sustainability of mosquito control operations in various study settings for a mosquito control programme.

Box 3

Example: Analysis of mosquito control efforts in seven sites

Mosquito control programmes at seven urban sites in Costa Rica, Egypt, Israel, Kenya and Trinidad were described and compared. Site-specific urban and disease characteristics, organizational diagrams, and strengths, weaknesses, opportunities and threats (SWOT) analysis tools were used to provide a descriptive assessment of each mosquito control program, and provide a comparison of the factors affecting a reduction in mosquito population.

The information for the SWOT analysis was collected from surveys, focus group discussions, and personal communications. The SWOT analysis identified various issues affecting the efficiency and sustainability of mosquito control operations. The main output of the study was the description and comparison of mosquito control operations within the context of each study site's biological, social, political, management and economic conditions.

The issues identified in the study ranged from lack of inter-sectoral collaboration to operational issues of mosquito control efforts. A lack of sustainable funding for mosquito control was a common problem for most sites. Many unique problems were also identified, which included lack of mosquito surveillance, lack of law enforcement, and negative consequences of human behaviour.

Identifying common merits and shortcomings of mosquito control operations was seen as very useful in identifying best practices for mosquito control operations, thus leading to better control of mosquito biting and mosquito-borne disease transmission.

Source: (8).

Reflection activity



We have discussed the importance of understanding the environment within which an IR project is planned and implemented. Reflect on your own IR projects and identify the environmental factors that you should take into account before and during implementation. At a very broad level, consider the cultural beliefs and practices, the political structure, the way the health system is organized and the wide range of stakeholders in the environment. Then address the following questions:

1. What are the sociocultural and political systems in your project area?
2. How is the health system structured (public and private)?
3. How might the health system impact your project?
4. Who are the stakeholders?
5. What specific knowledge and (or) skills will each stakeholder bring to the research project?
6. How will the consideration of these factors impact the planning of your project?

Understanding the intervention

Interventions (policy changes, projects, programmes) attempt to scale up health innovations that have demonstrated efficacy in the laboratory, clinical trials or small-scale pilot studies in order to benefit larger populations. Those involved in the development of such innovations promote authentic implementation and often warn that veering from the intended plan may reduce efficacy. They focus on 'fidelity' (9, 10). On the other hand, health providers are often more concerned with the effectiveness of the intervention, which they see as being enhanced by appropriate adaptation to the local context.

The dilemma facing IR is that the more rigidly the implementation is controlled to ensure fidelity of a proven intervention, the more likely it is that local factors (e.g. resource constraints, cultural factors, infrastructure, etc.) will reduce its effectiveness. The better adapted the interventions are to local conditions, the more difficult it will be to argue that findings can be generalized to other localities or populations.

An additional problem in using evidence-based interventions is that there may be considerable uncertainty in the extent to which the intended intervention has been modified in application. The implication is therefore that the claimed fidelity may be substantially lower than actually expected.

Furthermore, IR typically involves complex social interventions that result in dependency on the context, which may in turn result in low fidelity. Consequently, the outcomes depend on detailed processes and pathways that may not be well understood.

Therefore, to conduct meaningful IR, there is a need for an in-depth understanding of: (i) the intended intervention (for example identifying those elements seen as essential and those that could be modified without undermining the intervention objectives); and, (ii) the planned implementation process, with particular attention to modifications driven by a perceived need for adaption to a specific local context.

A monitoring system to track changes in the implementation process and check for deviations from the original plan is essential. Such a system can be a useful starting point to construct (or review if one already exists) a 'logical model' for the intervention (11, 12). Such models are commonly required by international donors as a simplified explanation of how a specific intervention is intended to address and achieve its objectives.

Intervention Logic

This model of the intervention adopts an 'if-then' approach (see Figure 4):

- If activities are undertaken then outputs should be produced.
- If outputs are produced then outcomes that serve the purpose should result.
- If outcomes result then they should contribute towards achieving the goal.

Those managing the intervention are considered responsible for producing a defined and quantified set of outputs. The output → outcomes step is frequently founded on assumptions about existing evidence and on a thorough contextual understanding.

For each step in the logic model to function effectively, relevant assumptions relating to the external context must be accurate. More certainty regarding the robustness of individual steps generates more likelihood that the implementation of the intervention will be successful.

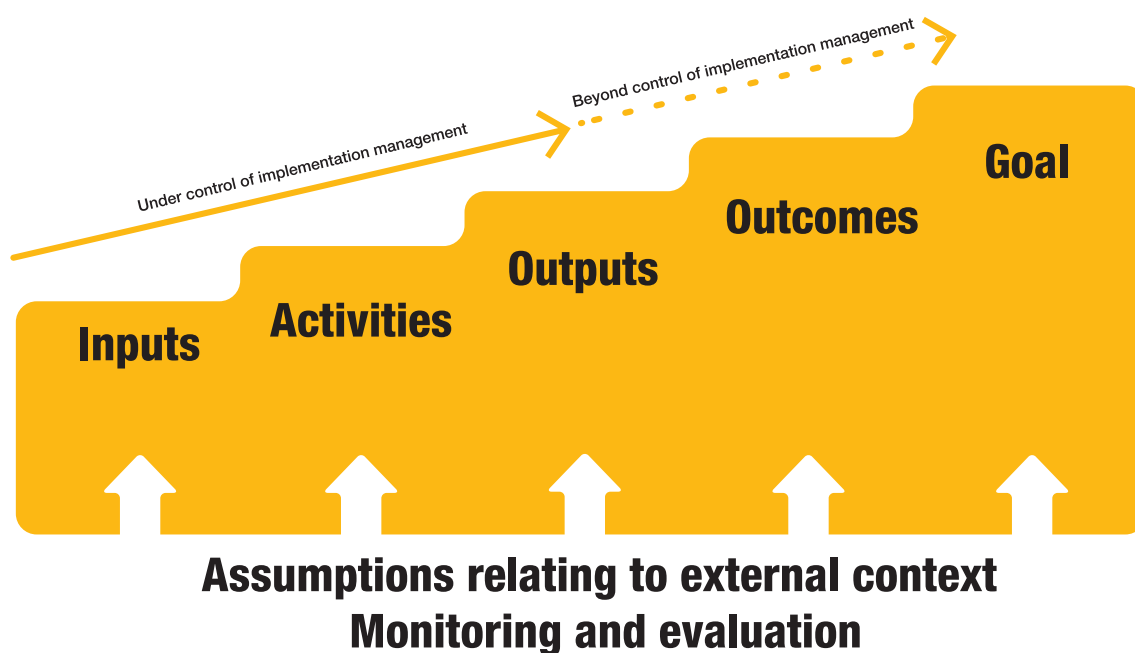


Figure 4: The logic model of an intervention (13)

The Logic model matrix

The logic model can be displayed in a simple matrix format.

	Objectively verifiable indicators	Means of verification	Assumptions
Goal			
Outcomes			
Outputs			
Activities	Inputs		

The 'logic' of the matrix

Definitions:

Goal: The higher-level objective towards which the intervention is expected to contribute (e.g. reduced infant mortality rate).

Outcomes: The ultimate effects or changes anticipated as a consequence of the intervention outputs (e.g. increased child immunization rates).

Outputs: Results that can be directly influenced, and for which the implementation management team are responsible (e.g. improved access to immunization).

Activities: The activities that will be undertaken in order to produce the intended outputs (e.g. reform of provider incentives).

Objectively verifiable indicators

One primary purpose of the logic model is to explore and identify how the key implementation activities, outputs and outcomes can be effectively monitored in order to assess the extent to which implementation of a given intervention is progressing as intended. In particular, this process involves generating information and documentation of the expected outputs and outcomes,

although the logical model requires the identification of a set of objectively verifiable indicators at each level:

- **Goal:** Measures to verify the extent to which goal(s) is/are accomplished.
- **Outcomes:** Measures to verify the extent to which outcome targets are achieved.
- **Outputs:** Measures to verify which output targets are achieved.
- **Activities:** Measures of the inputs (i.e. resources) required to undertake the activities.

Assumptions

The logic model also requires identification of important conditions or events outside the control of the implementation management team that are seen as necessary:

- to contribute to the goal;
- for the achievement of specific outcomes;
- for the production of intended outputs;
- for the implementation to begin and continue in a sustained manner.

Assumptions are of particular interest for IR because they are of particular relevance in assessment of the possibilities for replicating, scaling up or relocating the intervention. Some key questions to be addressed are:

Are the stated assumptions plausible in the existing context?

How specific are the assumptions to the research context?

- Are there important implicit (unidentified) assumptions?
- What consequences might result from incorrect assumptions?
- Have any assumptions proved to be incorrect?

Possible uses of the logic model in IR

- To summarize and test the underlying logic of a given intervention. This should include an initial assessment of plausibility, feasibility and context dependency.
- To promote common expectations of the intervention.
- To define indicators of success/failure and provide a basis for the design of the monitoring and evaluation framework.
- To identify sources of data that can be used to verify implementation failures and accomplishments.
- To specify all assumptions that, if incorrect, would have serious adverse consequences for the intervention.
- To track significant revisions of the implementation plan over time, and facilitate modification of the logical framework accordingly.

Table 4. Example of a completed logic model matrix

	Objectively verifiable indicators	Means of verification	Assumptions
Goal Eradication of malaria	National malaria prevalence	National malaria prevalence surveys	Other interventions contribute to stated goal
Outcome Increased proportion of children under 5 years of age sleeping under a long-lasting insecticide-treated net (LLIN)	Number of children sleeping under LLIN	Project records Community discussions Mini surveys	Communities can be persuaded of benefits of LLINs
Output 1 Under-5 children have the means to protect themselves from malaria	Mass distribution of LLINs to families with children under 5	Household assessment forms Focus group discussions	Adequate funding for the project Families use LLINs for children under-five
Output 2 IEC/BCC activities to encourage appropriate LLIN use; early health-seeking behaviour	Increase in timely consultations for malaria and use of LLINs by under-five children	Health centre records Focus group discussions, Pocket charts	Assumes accessibility of health facilities and availability of skilled health workers
Activity 1 Identify public health counterparts and training for managers and providers	Number of staff identified, training completed	Project records Training evaluation	Support from local officials, providers and communities
Activity 2 Baseline survey of malaria knowledge, LLIN use and health-seeking behaviour	Number of focus groups and research sessions held with different groups Data quality/quantity	Project records and reports	Assumes ability to communicate with target population
Activity 3 Identify and train community volunteers to promote LLINs	Number of volunteers identified and trained	Project records Training evaluations Community action plans	Assumes willingness of community to volunteer for these activities
Activity 4 Mass distribution of LLINs	Number of LLINs distributed	Project records	Assumes prompt purchase and delivery of nets
Activity 5 Production of IEC/BCC materials	Number of leaflets and posters produced	Project records	Availability of IEC* experts and printing facilities
Activity 6 Development of reliable information systems	Data quality/quantity	Project records	Community remains committed Health services accessible

* (IEC/BCC: Information, education and communication/behaviour change communication)

Complex adaptive systems

It has been suggested that many health initiatives give rise to what can be described as 'complex adaptive systems' (CAS) (14–17), a theory based on relationships, emergence, patterns and iterations. The premise is that myriad complex systems (weather systems, immune systems, social systems etc.), may interact with and consequently trigger adaptations to the immediate environment.

A CAS involves a large number of interacting agents, which have adaptive capabilities. They adapt in response to a changing environment, the context and to changes induced by a given intervention. One common adaptation, for example, is the formation of new organizational alliances.

The ultimate implication of the CAS notion is that there is no easy way to 'control' agent behaviour. CAS are intrinsically unpredictable and unintended responses to interventions often occur. Therefore understanding CAS phenomena is important for better planning, implementation, monitoring and evaluation approaches to scaling up health services.

What is the evidence that many health interventions result in CAS?

- Due to contextual differences, such as levels of health system development, ecological factors, social and cultural variation, interventions that were successful on a small scale in a controlled research setting, or in one country or region, have often failed when replicated elsewhere or on a larger scale.
- In many instances the implementation process rarely proceeds according to plan and often has to be rapidly adapted to suit an alternative and/or changing context.
- The ability of implementation managers to exercise control over the behaviour of providers, communities and even their own staff, is in practice often highly constrained by the organizational environment.
- Even apparently simple technical interventions can exhibit CAS behaviours when multiple stakeholder groups interact.
- Major interventions can sometimes result in very limited outcomes and relatively small inputs can have major positive/negative consequences.

CAS behaviour

CASs can display unexpected behaviours. Three such behaviour patterns of relevance to health interventions are: feedback loops, path dependence and emergent behaviour. Feedback loops are described in more detail below.

Feedback loops occur when the output of a process within the system is fed back as an input into the same system. For example, positive feedback increases the rate of change of a factor in a given direction (i.e. it is self-reinforcing), whereas negative feedback modulates the direction of change (i.e. is balancing).

Reflection activity

.....

In the last section we reflected upon the complex interactions of cultural beliefs, practices and political structure on health services. Use family planning services as an example of an intervention currently taking place in your project area.

What are the environmental and contextual issues that are currently affecting (positively and negatively) the implementation of these services?



Box 4

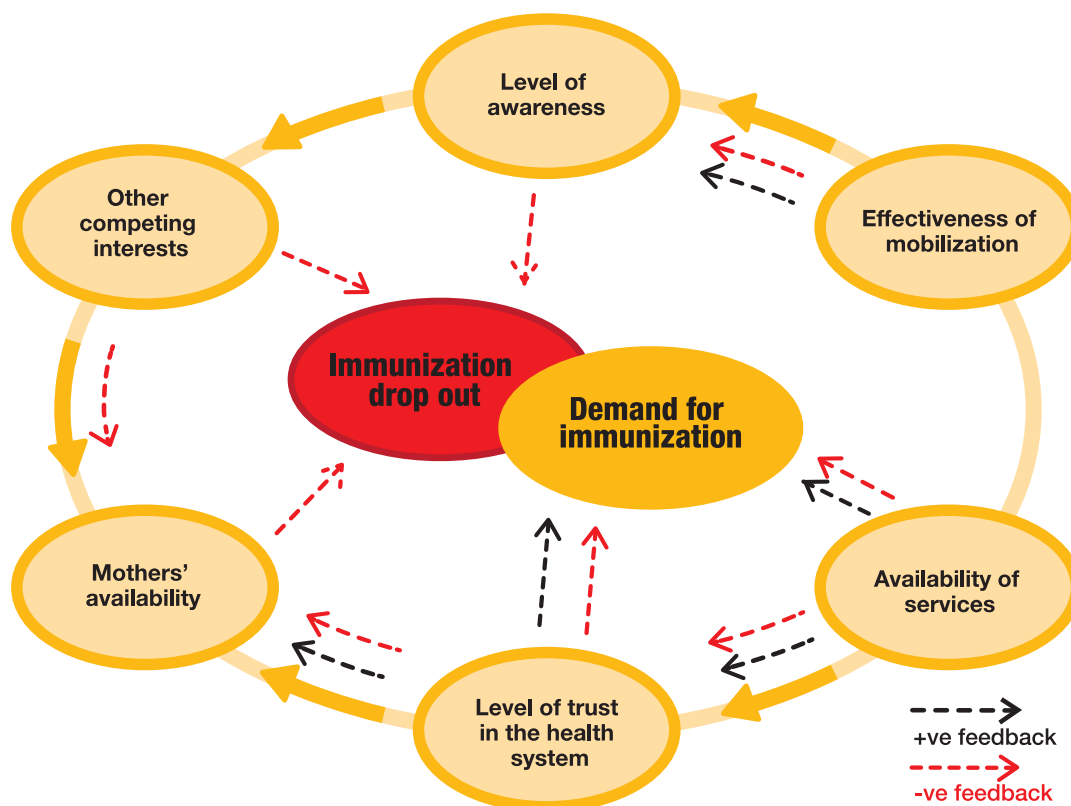
Example: Feedback loops positively and/or negatively influence demand for immunization services

Demand for immunization services is positively influenced (enhanced) by high levels of community awareness about immunization, which is in turn also enhanced by effective community mobilization, high literacy levels of mothers, media campaigns and the extent of health education activities. On the contrary, misconceptions about immunization reduce levels of community awareness about immunization, which will subsequently reduce demand for immunization services.

Whereas mothers' availability increases demand for immunization, family responsibility and low socioeconomic status of the mothers can negatively affect their availability.

The quality and availability of health services can affect the demand for immunization services either positively or negatively. Availability of immunization services increases the number of children immunized thereby increasing the herd immunity in the community – which reduces the risk of outbreaks of vaccine preventable diseases. The reduction in morbidities due to vaccine-preventable diseases contributes to an increase in confidence of the community in the immunization programmes and subsequently increases the demand for immunization services.

Poor quality health services, for example lack of the vaccines, long waiting hours, children developing abscesses after vaccinations etc. discourage mothers from bringing their children for immunization. This contributes to high dropout rates and unimmunized children in the community, which leads to low immunity and increased risk of outbreaks of vaccine-preventable diseases. The result is lost confidence in the health system, which contributes further to the reduction in demand for the immunization services.



Source: Adapted from (14).

Ethical issues in research

The rigour in reviewing research proposals/protocols has steadily increased in the past two decades. A number of initiatives have been implemented to strengthen ethics review capacities and increase awareness among those involved in research. It is difficult, and often inappropriate, to lay down ethical rules that apply to all studies in all places. In terms of ethics, it is important that each study be judged in relation to the context in which it will be conducted. Most ethical issues arise from conflicts between 'competing' values. This also suggests that a study that might be deemed ethically unacceptable in one setting may be considered acceptable in another, and both of these might be correct, appropriate judgments.

Several guidelines and international standard documents are available with regard to ethical guidelines for human research. Although these will not be discussed in this module, it is worth noting that individual guidelines vary with regard to the scope and level of detail or information to be provided, especially in relation to the consent process, obligations to provide universal standards of care to control groups, the use of placebos and the extent to which research participants have access to health products after the research is completed (18). From a public health perspective, research ethics should be guided by giving due consideration to the relative risks and benefits to society in addition to the individual research participants. Situations of poverty and limited health care – conditions in which research is frequently conducted in many low and middle income countries often present certain conflicts. Those conducting field trials of interventions against diseases associated with poverty are likely, therefore, to be faced with unique and difficult ethical dilemmas. Some of the IR-related ethical issues may be unpredictable and only emerge once the study has begun, and so may not have been addressed in the research protocol presented for ethical review. Ethical issues identified prior to the study and those that emerge in the process of conducting an IR project, should be addressed promptly by the research team.

Ethical principles of research involving human subjects

Research involving human subjects should abide by the basic ethical principles to safeguard individuals, communities and society at large against unnecessary risks.

These principles have been widely discussed as they express different ethical, economic and political theories. In practice, the principles may assume different weights according to the context, but there is universal consensus as far as their validity and the need for use in guiding proposals for research studies go.

In large-scale health intervention studies, especially those developed with international partners, moral and ethical issues may transcend national and political interests (19). Low- and middle-income countries have a broad range of health issues and may have limited local capacity to find solutions. In most cases there are limited scientific, managerial, political as well as economic capacities to adequately deliver essential health care. Conducting research under such conditions is both challenging and critical.

Three established ethical principles apply to public health research, including IR:

1. **Autonomy/respect** for persons is based on the ethical conviction that all individuals have a moral value and autonomy and as such should not be used as a means for the benefit of others. Individuals should be treated equally as far as access to the truth, loyalty, privacy and confidentiality are concerned. The two major ethical assumptions derived from this principle are: (i) respect for autonomy of those who are capable of deliberating about their personal choices and for self-determination; and, (ii) protection of persons with diminished autonomy,

which requires that those who are dependent or vulnerable be afforded security against harm or abuse (20).

2. **Beneficence** is concerned with promoting the welfare of individuals as the primary goal of health research by maximising its benefits. **Non-maleficence** is the bioethics principle of avoiding harm, acting with malice towards individuals or providing ineffective interventions. Causing harm to individuals is not justifiable in any case, even if this may bring benefit to the population – research is only justifiable if there is an appropriate balance between risks and benefits. It is the responsibility of the researcher as well as that of their organization to ensure beneficence. Broader society also shares responsibility for understanding the risks and benefits of any proposed research.
3. **Justice** refers to the moral obligation of treating people with respect and giving equal opportunity to the participants in both high-risk and beneficial research. Vulnerable populations should be protected and no exclusion of selective groups for reasons unrelated to the research should be applied. Provision of health care to the participants should also be equitable, and local research/health service capacities should be strengthened.

Ethical dilemmas in implementation research

The ethical and scientific integrity of the researchers is critical for ethical acceptability in IR projects. In the context of IR, specific ethical dilemmas may occur since studies are usually carried out in high-burden and vulnerable populations with limited access to health care. The autonomy and understanding of volunteers in such situations are likely to be limited. Undue expectations of research results and social/authority pressure may lead to forms of forced consent/coercion. In social science research, individual observations or personal interviews are likely to generate psychological distress when sensitive issues are discussed or recorded, or if there is any breach of confidentiality (21).

The ethical issues associated with IR can generate controversies. This may involve both quantitative and qualitative research approaches and a range of disciplines and perspectives such as epidemiology, statistics, anthropology, sociology, health economics, health promotion and education, political science etc. Although research protocols are applied in real-life settings and the risks are often minor compared with those encountered in clinical trials, for example, participants in implementation studies may be burdened by loss of privacy, time spent in interviews and examinations, and by possible adverse psychological effects. Such risks can be minimized by careful attention to study procedures, limiting the length of questionnaires or additional clinical examination and samplings, and considerate timing of observations. Implementation research also poses specific ethical challenges, given that it requires the collection of information from a large number of subjects in diverse situations involving a broad range of stakeholders. Ethics review committees should therefore be well informed about such proposals or protocols and ensure that all perspectives are protected (22).

Tables 5 and 6 summarize some of the ethical dilemmas and their consequences, as well as highlighting the relevant ethical principle(s) that may be flawed.

Table 5: Ethical principles flawed by characteristics of the participants/setting

Variable	Consequences	Ethical principles flawed
Language barrier	Misunderstanding of informed consent	Autonomy
Family and individual's role in the community	Presence of power relationships and dependence, hindering the individual decision-making process Respect for traditional figures of wisdom and authority including leaders of the community	Autonomy Beneficence Justice
Traditions and beliefs of healthcare and disease	Difference in the respect for traditional healers, doctors/researchers	Autonomy
Unfamiliar with research	Sensitivity to research procedures	Autonomy
Poverty and low education	Difficulty in understanding the information provided by researchers Possibility of exploitation and coercion, inducements, financial benefits Increased burden on research participants	Autonomy Justice
Low access to health services and goods	Possibility of exploitation and coercion, inducements, financial benefits	Autonomy Justice
Belonging to vulnerable groups	Possibility of exploitation and coercion	Autonomy Justice
Research being carried out from a health facility	Interference with public health system	Justice

Table 6: Ethical principles flawed by the characteristics of the researcher

Variable	Consequences	Ethical principles flawed
Language barrier	Failure to get informed consent	Autonomy
Double role: medical assistant and researcher	Confusion between research and health care Considering it more important to participate in the research than go without health care	Beneficence Justice
Conflict of interest	Influence the capacity of impartial judgement	Autonomy Justice
Unjustified intrusion	Breach of privacy/confidentiality	Autonomy
Unclear procedures for participant selection	Inequitable selection of participants	Justice
Failure to explain the benefits of research	Raising participants expectations	Autonomy

Variable	Consequences	Ethical principles flawed
Poor dialogue with legitimate community representatives	Failure to communicate with potential participants (due to poor or no skills in local language) Failure to obtain informed consent Failure to determine appropriate/reasonable incentives Failure to use an appropriate dissemination strategy	Autonomy

Reflection activity

Using the information presented in this section and Tables 5 and 6, what are some of the ethical considerations specific to your project?



APPLICATION OF KEY CONCEPTS

The examples below describe how the key concepts of understanding the environment, the intervention and the ethical issues can be applied to IR.

Box 5

Example: A case of voluntary male circumcision

Background: Although many studies strongly suggest that male circumcision could be important in tackling the continued rise of new HIV infections in Sub-Saharan Africa, in many settings it has proved difficult to translate this research into policy and practice. This has mainly been due to economic, social and ethical considerations. Specific factors should be considered when planning to implement/ scale up voluntary male circumcision as a public health intervention. Below you may find some contextual issues and ethical dilemmas for consideration when planning for male circumcision as an HIV prevention intervention.

Key concept 1: Understanding the context

The socioeconomic and cultural situations, as well as the health systems where the intervention is to be implemented, should be analysed. For example, the level to which the country is able to afford the costs associated with providing safe circumcision services. Furthermore, the cultural values associated with male circumcision, as well as the organization of available health services should be examined. The organization of the health services has a bearing on decisions regarding the feasibility of either integrating neonatal male circumcision into postnatal services or as a stand-alone service. The existing country's policies on male circumcision also have an important bearing on the implementation process. For example, is there an age when a child should not be circumcised, are there specialized circumcision surgeons, or places where circumcision takes place? In the analysis of the health services, capacity of existing human resources to provide safe circumcision and other HIV services should also be analysed. Lastly, stakeholders (i.e. policy-makers, ministry of health, health workers, the community and the prospective beneficiaries including spouses) and their respective roles should be assessed.

Key concept 2: Understanding the intervention

The following contextual issues in relation to the intervention itself should be analysed. This is important because of the different factors that will either facilitate or hinder implementation. Factors involved include the following as cultural acceptability of different male circumcision approaches (i.e. neonatal, preadolescent, adult); the feasibility of integrating the intervention into existing health services; the resources required to provide the intervention; how it could be provided equitably across all the intended beneficiaries; and the social and psychological dimensions of traditional circumcision.

Key concept 3: Ethical dilemmas

Autonomy – Voluntary male circumcision implies several ethical dilemmas. For one, obtaining consent for a neonatal circumcision operation in the case of minors under the age of consent. What should be done in cases where the child refuses to assent but the parents want the circumcision to take place, or conversely where the child wants circumcision but the parents refuse to provide consent? Furthermore, the very notion of obtaining consent for circumcision may be culturally absent.

Justice – The question of who qualifies for the intervention should be closely considered. For example, should populations at risk of HIV acquisition/transmission be targeted for circumcision (e.g. truck drivers, soldiers, migrant workers)? This may lead to subsequent stigmatization if specific populations become associated with HIV and related services.

Beneficence – The principle of beneficence is also an important ethical issue that should be considered. For example, deciding the best age at which to implement the intervention; whether male circumcision should be offered only to men who test negative for HIV or should it also be extended to men living with HIV?

Source: (23).

Box 6**Example: Improving the coverage of the PMTCT programme in South Africa**

This intervention comprised a data-driven participatory quality improvement approach implemented in a high HIV prevalence district in South Africa. The design comprised three phases: (i) a participatory assessment phase to build capacity of the local programme managers; (ii) a feedback and planning phase, during which weaknesses in the system were identified and a corresponding intervention was developed; (iii) a 12-month implementation and monitoring phase, during which the intervention to reduce prevention of mother-to-child (PMTCT) HIV transmission took place, and related output indicators were monitored.

Data was collected using structured interviews from the managers and counsellors, observation of the health facilities, review of documents and routinely collected PMTCT data. The data showed large improvements in all key PMTCT output indicators.

Key concept 1: Understanding the context

The population in the study area, the components of the PMTCT programme, the current PMTCT policy, South Africa's district health system, the referral system and the core activities of the health care providers were described in the background information. The documents reviewed included country health review reports, protocols on PMTCT care, PMTCT programme implementation policy guidelines, and HIV seroprevalence survey reports. The baseline PMTCT indicators were extracted from routine district PMTCT data. The stakeholders included the middle-level managers in the health system (e.g. facility managers, the primary health care supervisors and district programme coordinators) and the community. Their different roles were described accordingly.

Key concept 2: Understanding the intervention

The conceptual framework used in developing the intervention was based on an expanded health systems approach. (The framework was based on the critical conditions the managers needed to consider to ensure that a programme moves from efficacy to effectiveness). The researchers further acknowledged that the weaknesses identified during the assessment were due to the complex interaction of the clients with the health system factors. The client factors included lack of information and fear of disclosing HIV status, and the health systems factors included lack of ownership of the PMTCT programme among nurses, unclear roles and responsibilities, lack of knowledge of the protocol, as well as poor recording systems and continuity of care.

Key concept 3: Ethical dilemmas

- This research involved human subjects (the health care providers, children, and caretakers).
- Should being part of the routine health care and system qualify the intervention for expedited ethical review?
- How to minimize interference with routine health care?
- How and at what level of interaction do you draw a line between routine care services and/or research?

Source: (24).

Further examples of contextual issues impacting IR planning

Box 7

Example: Health worker protection or patient stigma?

In Somali communities, the use of medical face masks presents a challenge for both patients and doctors. The doctor wearing a mask during consultation with a patient creates the perception that the patient has a highly contagious disease such as tuberculosis (TB), for example. As a result, and given the stigma associated with TB, the patient may feel humiliated, disrespected and perceives the doctor as arrogant. This often affects the patient–doctor relationship and erodes trust, which may impact willingness to return for follow-up consultations or visits. Additionally, it also presents a safety dilemma for the health worker/doctor.

Source: (25).

Box 8

Example: Reproductive health research in Sudan

Implementation research on reproductive health issues conducted in Sudan faced ethical and cultural issues because of the mutually different sociocultural contexts of South and East Sudan. The research team had to adapt their approach and team composition to for each context.

Ethics: Obtaining appropriate consent for the study

South Sudan

- Community consent: Given by the chief and religious leaders of the tribe;
- Informed consent: Obtained from the participants individually;

East Sudan

- Community consent: Given by the chief and religious leaders at the village level but some villages will not participate until they have observed the morning sessions from afar. Only after that do the allow members of the tribe to attend sessions and participate in the project.

Culture: Optimizing research team composition to ensure acceptance, sustainability and high response rate of the project

South Sudan

- Project team had equal numbers of men and women. The composition of the team structure was culturally acceptable to the community.

East Sudan

- The project team composition was changed in response to the cultural context of the community (i.e. closed, complex communities). The team comprised mostly women researchers and this facilitated access to the female participants. The limited number of men in the team interacted with the leaders of the tribe (who are men and are culturally not receptive to directions from women).

Research topic and related sensitivities

This was seriously considered from project conception and planning to avoid unintentional consequences such as any misconceptions, negative perceptions or misunderstandings that could compromise the success of the project.

South Sudan

- Community open to discussing intimate reproductive issues and rights.

East Sudan

- Community closed and certain reproductive issues were considered taboos and as socially unacceptable for discussion. Therefore, designing the research (i.e. the objectives of the research as well as methodology) differed from South Sudan.

Source: (26).

CONCLUSION

Congratulations on completing Module 1 – *Contextualizing Implementation Research Issues*. This module was designed to increase your understanding of and knowledge of the environmental issues of IR. The module should also have increased your understanding of intervention strategies and ethical considerations when implementing IR projects.

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MODULE

2

**DEVELOPING AN
IMPLEMENTATION
RESEARCH PROPOSAL**

INTRODUCTION

The purpose of this module is to support you and your team to develop a high quality implementation research (IR) proposal so that you can be competitive in securing research funding.

If you are setting out on developing an IR proposal and are not sure where to start, you are not alone! Even defining the research question can at first seem overwhelming. This module has been designed to help team members understand and conduct the basic processes involved in writing an IR proposal.

After completing this module, participating research teams will be able to complete their IR proposals.

The content and activities in this module are organized into five sessions, with each addressing a specific section of an IR proposal in a stepwise way. Each session consists of the following elements:

- *Learning objectives*: identifying what you will accomplish by the end of each session.
- *Content presentation*: providing you with the information necessary to understand the specific aspects of proposal writing.
- *Activities*: exercises facilitating the understanding of the content and putting theory into practice.
- *Group work*: discussions providing an opportunity to ask questions, and consider specific issues in relation to your specific project.
- *Write-shops*: provides an opportunity to work together each evening in drafting elements of your research proposal, as covered each day.

The workshop will be facilitated by researchers experienced in IR, who will guide and support you during the process of developing your team's IR proposal.

The module also provides harmonized guidelines for proposal development to train researchers from different backgrounds.

Pre-workshop preparation

This module is organized into three stages: before, during and after the workshop (Figure 1).

Before the workshop, you should have completed an online component that introduces key terminology, core concepts, research frameworks, programme components and appropriate questions. The online course takes approximately three hours to complete and its specific objectives are:

- Identifying characteristics of IR.
- Describing implementation/scale up and relating IR to these processes.
- Classifying research questions and associated research that falls under the umbrella of IR.
- Summarizing framework characteristics and identifying strategies for applying them to IR.
- Recognizing how IR is applied to different implementation problems.
- Classifying IR priorities for grant applications.
- Reviewing the roles of various stakeholders and identifying appropriate means for integrating stakeholders in planning and in communicating and disseminating results.

The online component is available online at <https://training.measureevaluation.org/certificate-courses/ir>. You should also have completed an initial stakeholders consultation (module 1) as well as literature review to enable you to put your IR problem into a broader context.



Figure 1. Three stages of the current module

Introduce your team and research challenge

From earlier modules, you may already have a good understanding of what IR is and how this IR approach can help meet your research objectives. You have also likely identified some of the members of your IR team, established each member's roles and responsibilities, and identified a research problem for which you would like to develop a proposal.

To get started, one member of your team will be asked to briefly describe the research problem/ challenge your team is developing a research project to address.

Then invite each member of your team to introduce themselves and explain their ongoing work, as well as roles and responsibilities in your planned project.

Group activity: Refresher on IR fundamentals

Organize into small groups. Ideally, members of each team should split into different groups. Each group is assigned one of seven topics (see slide). In individual groups, prepare a two-minute presentation summarizing your assigned topic, drawing on content from the pre-workshop online component/ previous modules.

Choose a spokesperson to present your key points in plenary (in two minutes).

Funding an IR project

There are essentially three types of funding agencies that are potential sources of support for research projects:

- Multilateral organizations

- e.g. WHO, World Bank, United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), European Commission, and special programmes such as TDR, the Alliance for Health Policy and Systems Research and the Special Programme of Research, Development and Research Training in Human Reproduction (HRP).

The Alliance, TDR and HRP, as designated research programmes, periodically issue calls for health research proposals, including those focused on IR. Most multilateral organizations have developed implementation programmes in low- and middle-income countries of which part of programme budget is allocated for monitoring and evaluation, as well as implementation research.

- Bilateral donors
 - e.g. Canada Government, United Kingdom Government (DFID), United States Government (USAID, National Institutes of Health, Fogarty International Center), Norway Government (Norad), Sweden Government (SIDA) Australia Government, and the International Development Research Centre (IDRC).

An increasing number of bilateral organizations, such as IDRC, NIH/FIC DFID, USAID, and NORAD have supported implementation research. Almost all the bilateral organizations have aid projects/programmes in low- and middle-income countries of which a certain percentage of the programme budget is allocated for monitoring and evaluation, as well as implementation research.

- Private foundations and trusts
 - e.g. Gates Foundation, Rockefeller Foundation, Ford Foundation, Wellcome Trust.

Private foundations and trusts have a tradition of supporting health research, among other issues. Implementation research is one of the areas where some private foundations and trusts have gotten interested in supporting. Note that this list of examples is not exhaustive. National governments in low and middle income countries also fund research to improve access and delivery of interventions within their health systems.

Find a match

To find a good match for your proposal, consider:

- your level of experience;
- the resources/funds you need;
- timing and deadlines;
- your location;
- who is interested in the topic.

Related resources

Government grants:

- NIH Office of Extramural Research (OER) Grants Guide (<http://grants.nih.gov/grants/guide/index.html>)
- National Science Foundation (NSF)
- Other individual government agencies
- Grants.gov (www.grants.gov) – portal collecting funding/application information from all United States government agencies
- Ministries of health
- National medical research councils

Private associations or foundations

- Foundation Center Directory (Free Library)
- PA Foundation Directory (Free Library)
- GrantsNet – from American Association for the Advancement of Science (AAAS)
- Bill and Melinda Gates Foundation
- Doris Duke Foundation

Subscription databases like the ones listed below provide information on sources of research funding. (government and non government)

- Community of Science (COS)
- InfoEd (Spin/Genius)
- Others (IRIS, Egrants)

Do your searching...

- Go to a library that has good internet access.
- Talk to your institution's Office of Research Administration, if you have one.
- Search comprehensive databases such as COS, eRACOMMONS and Spin.
- Set up alerts from your database searches.
- Search US government grant websites such as OER or Grants.gov, or individual agency websites.
- Search association and foundation websites.
- Find out what projects related to your area were already funded.

This is a very important aspect of your work. If you have some experience in searching databases, you can proceed, otherwise ask for help from a library in or outside of your institution. Whatever approach you take, there are basic steps that you have to follow and several things to consider when deciding where to submit your IR proposal for funding.

Find out which funding opportunities are offering research calls or requests for proposals (RFP)/ letters of intent (LOI). This is important as often they call for applications is once a year. Therefore, planning ahead and working back from the application deadline is important. If you miss the deadline it could be a year until another competition or opportunity arises. In implementation research, a 12 month delay is significant.

In addition to regular RFP/LOI invitations, some funding agencies may also be interested in supporting IR in accordance with their health research strategies. In other words, researchers from low- and middle-income countries could play a proactive role by sending short research proposals for their consideration. Some funding agencies are more interested to commission or solicit health research proposals, based on their mandates and strategies.

You need to ensure a good match between the funding agency and your research project, with regard to research topic, size of grant, geographic region, partners' eligibility, participating countries, required affiliations etc. Explore research that has already been done on the topic to ensure you are not duplicating existing work. Assess the types of projects the agency has funded in the past, so you can extend or compliment these activities. Demonstrate that you have done your homework and are aware of what exists on the topic, identify the gaps and justify what needs to be done and how the findings will benefit the community.

Preparing your application

- Read the instructions for submitting a proposal carefully

- Refer to pertinent literature
- State rationale of proposed investigation
- Include clearly presented tables and figures
- Present an organized, lucid write-up, including as much detail as possible
- Request pre-review from experienced researchers
- Use the style and elements required by the funder's specifications

When applying for a research grant, take advantage of the resources available to you. Most universities in Europe and North America have an Office of Research with trained staff to assist researcher with large grant applications. This may not be available in institutions and health agencies in low and middle income countries, however there may also be many resources available on the Internet that can be helpful. It is important to visit the website of the funding agency to which you plan to submit your proposal. They will usually have full instructions on what to do and when to submit your proposal.

For example: NIH Grant Writing Tips: http://grants.nih.gov/grants/grant_tips.htm. *Reviewers will be looking for projects that make a significant impact on the community or state of health care services offered.*

You can also explore the possibility of communicating with the project manager in the funding agency to obtain more clarity on the application process. Reviewers will look for clear, innovative and exciting ideas, clarity and brevity of writing and realistic objectives and timelines. They will expect a clean, well-written application that promises outcomes that are useful to the population.

What reviewers look for

- Significance and impact – this is very important in implementation research
- Exciting ideas
- Ideas they can understand – avoid assuming too much knowledge or familiarity
- Realistic aims and timelines – do not be overly ambitious
- Stay brief with widely known information
- Note the limitations of the study
- Prepare and submit a clean, well-written application with a justifiable budget

Depending on the funding agency, reviewers may be looking for varied things in different proposals. It is always useful to refer to the instructions in the call for applications before submitting the proposal.

In general, IR proposals are typically rated on the basis of scientific merit and policy relevance using a specific scale (e.g. a 1–5 scale, where 1 is high and 5 is low). Ratings for both categories may be averaged together for a final score, which may be one of the main determinants of the funding decision. Specific criteria that are frequently used in each of these categories are outlined below.

Scientific merit and policy relevance

- Scientific 'soundness'
- Synthesis of existing knowledge (which could include a literature review) – make it concise; pertinent; complete; appropriate
- Research questions – make them appropriate and feasible
- Analytical framework – apply as appropriate and make it sound
- Proposal should be in accordance with IR principles outlined in the call for proposals

- Proposal should address issues relevant in the country/community where the research would be conducted
- Proposal should fit the specific call for proposals

Methodology

- Is the design feasible and appropriate?
- Are data collection methods and tools appropriate for the design?
- What is the sampling method, and size?
- How is data management and analysis planned?
- Is the overall time plan realistic?

Other considerations

- Ethical considerations.
- Critical assumptions.
- Innovation and originality.
- Programmatic practicality.

Additional critical issues

- Is team expertise appropriate for the proposed study?
- Could the project findings be scaled up?
- How generalizable will the results be?
- Is a multidisciplinary approach proposed?
- Will the study foster collaboration and team work?
- Is the budget appropriate?
- Utilization and dissemination possibilities/potential impact on policy and programmes?
- Is there potential for research capacity building/strengthening? This could be important to some funders because it could enhance sustainability of an IR culture in the health system.

Common problems with applications

The following common problems/pitfalls with research proposals should be avoided.

- Lack of new or original ideas.
- Absence of an acceptable scientific/public health rationale.
- Lack of experience in the essential methodology. Lack of sufficient detail on the methodology.
- Lack of relevance to policies, programmes and projects.
- Diffuse, superficial or unfocused research plan.
- Lack of knowledge of relevant published work.
- Unrealistic amount of work required.
- Uncertainty concerning future directions.
- It is helpful to ask the question “So what?” – What difference will the results from the research make to the health system and population if applied.

Components of an IR proposal

In general, the proposal structure is similar for all research.

What is a research proposal?

- A document that describes:
 - the proposed research
 - why it is being conducted
 - the research design

- the expected impact
- A proposal is a requirement for most grant applications, which are typically judged by a committee. To be effective, you need to know:
 - what you are doing;
 - why you are doing it;
 - when you plan to do it;
 - how you plan to do it.

If you have ever written a thesis as part of your studies, you will remember that you were required to write a research proposal and have it 'approved' by a thesis committee and your supervisor prior to applying for ethical clearance (if using human subjects) and beginning your data collection.

When developing an academic proposal, the intent is to generate new knowledge and ideas. Conversely, when developing an IR proposal the intent is to generate research evidence to inform policy and improve programme implementation.

Most grant applications require you to write a research proposal that will be evaluated by a committee to determine if the proposal is worthy of funding.

Writing a research proposal is probably one of the most difficult stages of research. In order to write a proposal, you have to know what you are doing, why, when, and how. You need to develop research question(s), a rationale for why the study is necessary and important, and a conceptual framework. You need to conduct a review of existing literature. You need to design the research and specify what research methods you will be using to collect and analyse your data.

What is different about an IR proposal

IR proposals may differ from conventional research proposals in relation to the:

- origin of the research problem
- involvement of the end users in the research process

These differences arise from the need for IR interventions to help:

- better inform health care service quality improvement efforts
- facilitate uptake by end users
- generate 'generalizable' knowledge so it can be applied across settings and contexts
- engage multiple sectors, e.g. including epidemiology, social science, anthropology, communication science and health economics
- develop policy recommendations and practical solutions

Because it can take years for research findings, guidelines and best practices to be completely integrated into practice, researchers, decision-makers and practitioners constantly seek improved knowledge transfer processes.

To address this challenge, IR originates with a problem identified and prioritized by end users. Encouraging end-user uptake of research results requires end-user engagement in all steps of the research process, including proposal development.

To be effective, IR research findings need to be usable within the available health system framework and implemented appropriately so that end users are able to benefit. IR also aims to produce generalizable knowledge so it can be applied across various settings and contexts (although they may be intervention specific).

Characteristics of an IR proposal

- Each funding agency has its own proposal format and requirements.
- Requirements vary and not all agencies will require all components included in this session.
- Some agencies may require a letter of intent (LOI) as a preliminary screening to ensure your proposal will align with their needs.
- LOI include the same components as a research proposal but with less detail.

Additional characteristics may include the following:

- Clear distinction between routine disease control and systematic study and analysis of issues.
- Indicators to measure outcomes.
- A focus on a limited number of priority areas, rather than focusing on a large number of small isolated issues that are unlikely to have significant health impact.
- Possibility to extrapolate to other settings and diseases.
- Active link to disease control.
- Partnership and link up with other ministries, departments and agencies.
- Involvement of mentoring train the young and involve the experienced.
- Involvement of health professionals from the study setting.
- Active dissemination of results at all levels of implementation.

The components of a research proposal may vary slightly depending on the purpose outlined by the funding agency to which it is being submitted. Many funding agencies indicate specifically what should be addressed in the proposal.

As each funding agency has its own format and requirements, some of the elements covered in this module may not be required in every research proposal.

Components of an IR proposal

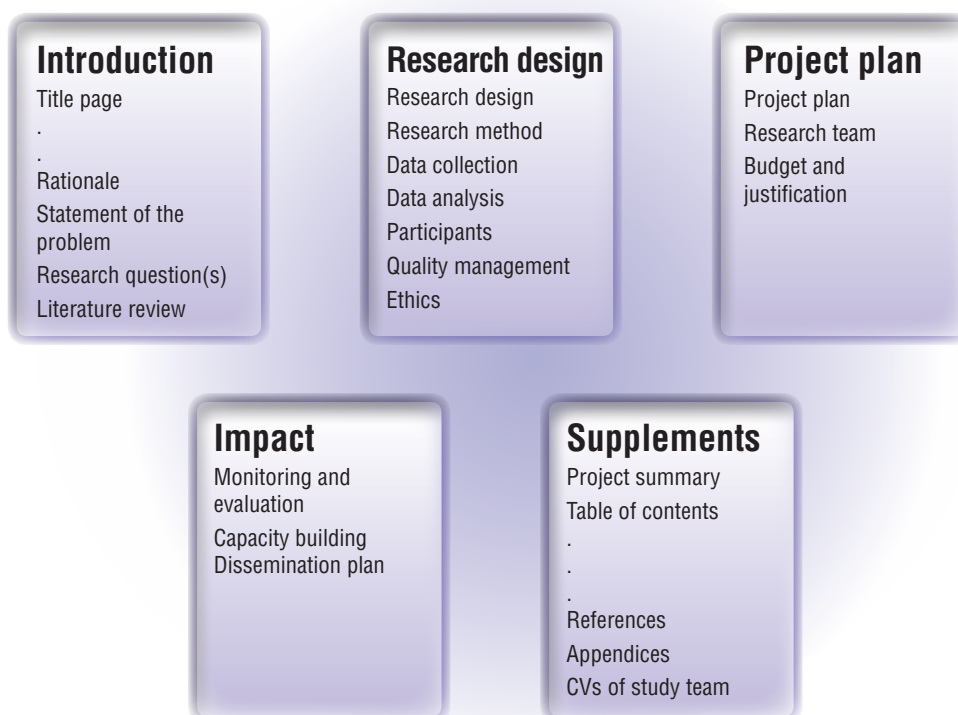


Figure 2. Components of an IR proposal

This session has been designed to be general enough so it can be adapted to fit the priorities of different users and funding agency calls for proposals. Below is a list of common components of IR proposals:

- **Introduction:** containing title page, rationale, statement of the problem, objectives and research question(s), and literature review (synthesis of existing knowledge) (Table 1).
- **Research design:** outlining participants, research methods, data collection, data analysis, quality management and ethics (Table 2).
- **Project plan:** containing project plan, research team and budget (Table 3).
- **Impact:** including monitoring and evaluation, capacity building plan and dissemination plan (Table 4).
- **Supplements:** including project summary, table of contents, references, appendices and CVs of investigators (Table 5).

Introduction

The introduction to your proposal includes the title page, project rationale/summary, table of contents, rationale, statement of the problem, objectives and research question(s), and a review of the literature (synthesis of existing knowledge).

Table 1. Sub-components of introduction section

Section	Description
Title page	• Four components of a good title: – Use action words. – Reflect implementation and intervention themes. – Include specific target populations (adolescents, children under 5 years of age etc.). – Include specific geographic location(s).
Rationale	• Outlines what is being studied and why. • Summarizes expected outcomes, including the anticipated impact(s). • Provides clear succinct rationale for why the project should be funded.
Statement of the problem	• Summarizes the purpose of the study. • Is a paragraph rather than a single statement. • Establishes the direction and captures the essence of the study. • Is clear and concise. • Incorporates your general objectives and uses action words to succinctly outline the purpose of the study. • Reflects the research design of the study. • Leads logically to the research question(s).
Objectives and research question(s)	• Should be of interest to the research community, researchers, policy-makers; decision-makers, funding agencies, and the health care providers the research will ultimately affect. • Should be answerable. • Are shaped by the problem, and in turn should logically influence the design of the research. • Are clear and specific. • Are feasible.

Section	Description
	• Provides information required to evaluate ongoing interventions or progress. • Analyses possible causes for missed targets in order to find solutions. • Answering the question will result in important information.
Literature review	• Demonstrates familiarity with the topic. • Summarizes what is not known about the topic. • Establishes credibility. • Places proposed research in a broader context. • Demonstrates relevance by making connections to a body of knowledge. • Integrates and summarizes what is already known about a topic.

Research design

The research design section includes: research design, research methods, data collection, data analysis, quality management, and participants and ethics.

Table 2. Sub-components of research design section

Section	Description
Research design	• Describes the nature or structure of the research. • Describes whether it is qualitative, quantitative or mixed methods; between- or within-subjects; experimental or correlational; individual or collective case study etc.
Research method	• Comprises the various methods you will use to obtain and analyse data. • Justifies what you will do when and how. • Provides a rationale for your research design. • Justifies how your methodology will enable you to produce results that are new or unique. • Comprises a number of sub-sections such as research design, participants, data methods, data collection, and data analysis.
Data collection	• Explains how you intend to gather the information that will be used to answer the research question(s). • May involve the use of quantitative (e.g. surveys, recording the number of times an incident occurs, laboratory experiments), qualitative (e.g. interviews, observations).
Data analysis	• Describes exactly how you plan to compile the data you collect and how you will organize and interpret the data to make sense of what you find. • Identifies themes, developing tables and charts, identifying relationships, and/or calculating frequencies.
Participants	• A full description of the subjects (sample) or participants involved in the research. • How participants will be selected. • Criteria for becoming a participant.

Section	Description
Quality management	• System to ensure the quality of the research project. • Helps provide confidence that the conduct of the study and data generated optimally fulfill applicable requirements. • NOT OPTIONAL – You must have a quality management plan.
Ethics	• You must apply to an ethics board/committee if you will collect information/data from human participants (directly or indirectly). • If you are collecting data in more than one site you may need to apply to more than one board. • Stipulate that you intend to apply for ethics approval. • Ethics approval may take several months to receive, so apply as soon as you submit your proposal for funding. • Most agencies will not release funds until ethics clearance has been received in writing.

Project plan

The project plan includes: Project plan, research team, and budget.

Table 3. Sub-components of project plan section

Section	Description
Project plan	• Presents a clear indication of the timeframe for the project and the times when each aspect of the project will be implemented. • Often a work plan or timeline is displayed most effectively in a graphic, table or Excel sheet. • Will help demonstrate the feasibility of the project in a very visible way. • Identifies tasks; when the activity will take place; and by whom.
Research team	• Describe the members of your team and the experience/assets they contribute to the project. • Team must be multidisciplinary and diverse (depending on the nature of the research, it may include members of the community as well as researchers, healthcare providers and decision makers). • Convince the reviewers you have enough expertise on your team to conduct the proposed research effectively. • Include the role(s) and responsibility of each individual listed on the project. • Indicate whether team members are involved in a full- or part-time basis.
Budget and justification	• Outlines the resources needed to effectively conduct the proposed research. • Outlines exactly what is realistically needed from the funding agency to carry out the project. • Should be realistic in the context of the research setting. • Outlines how much money is needed in each phase of the project. • Aligns with agency suggested/required budget categories. • The budget should align with the proposed activities in the research design.

Impact

The impact section contains the following: monitoring and evaluation, capacity building, and dissemination plan.

Table 4. Sub-components of impact section

Section	Description
Monitoring and evaluation	• Describes exactly how the team will decide whether or not the project meets its objectives. • Informs the prospective funding agency how they will be shown at the end of the project that their investment was a good one. • Facilitates the implementation of evidence-based practice and improved health outcomes. • Examines the difference between the implementation effectiveness and the efficacy of health intervention.
Capacity building	• How the project can help improve the research capacity of national and local institutions involved, via training, mentorship, etc. • How the project, can help increase capacity for using research evidence for policy or decision-making by key stakeholders, such as government officials, involved in the project.
Dissemination plan	• The dissemination plan should include intended publications, newsletters, workshops, radio broadcasts, presentations, printed hand-outs, slide shows, training programmes, etc. • Identify key stakeholders target audience and their needs. • Involve stakeholders throughout the process. • Tailor the message accordingly – stakeholder groups vary by their familiarity with research terminology and preferences for receiving information.

Supplements

Supplements include: Project summary, table of contents, references, appendices, and CVs of members of the project team.

Note that the project summary and table of contents are placed at the beginning of your proposal, but are only written *after* you have completed the other sections.

Table 5. Sub-components of supplementary sections

Section	Description
Project summary	• Briefly describes the entire proposal. • Although read first, written last. • Includes a description of the problem under investigation, a rationale (situated in the existing literature) for why the research is needed and/or important, the participants, the methodology, and the implications of conducting the research. • Is your 'first impression' with reviewers and may influence whether reviewers choose to fund your proposal. • Makes it very easy for reviewers to comprehend and evaluate your proposed project according to the review criteria.

Section	Description
Table of contents	• Organizes the proposal by outlining 'what' is in it and where each item can be found. • Presents a convenient list of the topics and sections in a logical sequence 'at a glance'. • Word processors automatically place the headings, sub-headings and page numbers for you in a professional manner.
References	• Lists all references cited in the text of your proposal (in a recognized referencing style). • If a reference is not cited in the text of your proposal, it should not be listed in your reference list.
Appendices	• Include those aspects of your project that are of secondary interest to the reader. • Assume the reader can obtain all the necessary information from the body of the proposal. • May include things such as investigators' CVs, research instruments, or letters of support. • Can provide a place to put additional information you would like the reviewers to have access to, but that the length restrictions prohibit.
CVs of members of the project team	• Can have an influence on the reviewer's assessment of your proposal. • Ensure that at least one member of your team has IR experience, a good track record and a strong publication record. • Complementary qualities such as credibility in the community can be equally important. • Agencies usually have a limit of 1–3 pages for an investigator's short CV. • Develop a template to highlight the most relevant aspects of team members' CVs to align with the scope of the funding agency.

In each of the following sessions, your team will develop and write one section of your research proposal.

1. WRITING THE INTRODUCTION SECTION

In this session, you will take the first steps in writing your IR proposal by drafting your introduction section. This involves writing an overview of your research problem and conducting a systematic review of existing materials and literature to provide a rationale for why this problem is important and should be addressed. You will also develop general and specific research objectives, a statement of the problem and your research question(s).

After completing this session, you will be able to:

- Write the introduction for your proposal.
- Develop the research question(s) for your proposal.

Writing the introduction

The introduction to your proposal:

- Outlines what is being studied and why (i.e., the rationale).
- Builds an argument for the current study.
- Includes the statement of the problem, general objectives, specific objectives and research question(s).
- Reviews existing literature.
- Summarizes expected outcomes, including the impact the results will have.
- Provides clear succinct rationale for why the project should be funded.

The introduction is essentially a focused review of the pertinent existing knowledge, including published studies, project reports, and other literature. It builds an argument for conducting the study, including general and specific research objectives, the statement of the problem, and research question(s). This argument or rationale might be based on a need identified by the community, policy-makers, and programme managers. In sum, the proposal introduction provides a clear, succinct description of what the research is and a rationale for why the project should be funded.

Introduction objectives

The introduction provides critical information for funding and community support by accomplishing the following three things:

- Provide a foundation for the further development of the proposal (overview of the problem).
- Facilitate background information on, and reports from, similar studies (systematic analysis and succinct review of literature).
- Systematically state why the proposed IR should be undertaken (rationale), what you hope to achieve (objectives) and expected results (outcomes).

Guidelines for writing the introduction

- Begin by conducting a systematic analysis about the problem you want to research and why it is important that this research is done.
- Once you have your initial ideas clarified, continually edit the introduction as you progress, discuss issues with your team and receive feedback from the larger workshop group and facilitator.

The rationale should indicate why the research should be undertaken including the scientific, public health and policy relevance of the problem to be investigated, as well as the magnitude, frequency, affected geographical areas, ethnic and gender considerations of the problem. The introduction should also list other available options to the research problem and make a case as to why the chosen approach should be researched. It should also indicate how the results will be used and why it is likely to affect health care and health systems/policies, and who will ultimately benefit if the project results are used appropriately.

What to write about

- Overview of the health system and setting (context).
- Description of the nature of the problem.
- Analysis of the different factors that may influence the problem.
- Description of solutions tried (background), and justification for further research.
- Information expected from the research and how this information will be used to solve the problem (outcomes).

To accomplish this, succinctly write about each of the items listed below. Just start writing, do not worry about how your ideas sound initially or perfecting what you write: you will continually change, elaborate, delete and edit the introduction as you progress with researching and discussing the topic provided.

- An overview of the health care system in the country/region/district as these are relevant to the problem. Include illustrative statistics (if and when appropriate and/or available) to describe the context in which the problem occurs.
- A description of the nature of the problem.
- An analysis of the various factors that may influence the problem – why some factors need to be investigated.
- A brief description of any solutions to the problem that have been tried in the past (background), how well they worked and why further research is needed (justification for the study).
- A description of the type of information expected to result from the IR study and how this information will be used to solve the problem (outcomes).

Developing the title

There are four components to a good title:

1. Use 'action' words
2. Reflect implementation and intervention themes
3. Include specific target populations (adolescence, children under five year of age, etc.)
4. Include specific geographic location

The title of a research proposal should describe the study, be concise and inform the reader what the research is about. It should include key words that would also help to identify appropriate reviewers. The title may not differ significantly from that of any other research proposal, but the topic it addresses will reflect a need identified in the community. It is possible that you may also have "Implementation research" in your proposal title if you are applying for a research grant that is specific to IR.

For example:

- Identifying gaps in HIV prevention among adolescents in Sub-Saharan Africa: An implementation research study.

- Using implementation research to explore the rise in under-five mortality rates in Cameroon, Central African Republic, Chad, Democratic Republic of the Congo, Kenya and Zambia.

Rationale

- The introduction must justify why the research problem you have identified is important and worthy of funding.
- To provide this justification, begin by providing evidence through a systematic analysis of existing information.

Information to support your literature review can be found from a variety of resources and locations including:

- local documentation – project progress reports, theses, dissertations, seminar proceedings
- programme progress or evaluation reports
- medical literature, including reviews that outline gaps in research
- scientific meetings and conferences
- new ideas/recommendations from previous research
- funding agencies' annual reports
- questions asked by programme staff and/or students

Example

A major challenge for onchocerciasis control is to deliver annual ivermectin treatment to all target communities and to sustain high treatment coverage over a very long period. To achieve this, the African Programme for Onchocerciasis Control (APOC) has adopted the strategy of community-directed treatment (ComDT) with ivermectin. This strategy has proven very effective. Ivermectin treatment is popular and communities have responded enthusiastically to the concept of a community-directed intervention, in which they are themselves in charge of planning and implementation. A recent external evaluation of APOC concluded that ComDT was a timely and innovative strategy. The communities themselves were deeply involved in their own health care on a significant scale. This strategy could be used as a model in developing countries for other community-based health programmes.

There is a growing interest at the national and international level to use the approach of ComDT for interventions against other diseases. The current momentum provides an important opportunity to integrate ivermectin treatment with other disease control activities, and to contribute to health care development for some of the poorest populations in Africa. But to ensure that this opportunity is properly exploited, there is an urgent need for good scientific evidence on the effectiveness of the ComDT process for interventions against other diseases, and for integrated disease control at the community level.

During its meeting in December 2002, the Joint Action Forum of APOC recommended that the Special Programme for Research and Training in Tropical Diseases (TDR) undertakes, in collaboration with APOC, a multi-country study on the use of ComDT for other diseases. TDR and APOC have responded positively to this request and the multi-country study has now been launched. The research protocol for the multi-country study was developed during a protocol development workshop held from 4–8 November 2002 in Limbe, Cameroon.

Because of the complexity of the issues involved, it was decided to prepare the study through a series of consultative meetings with key partners concerned with a multi-disease approach

to ComDT, in order to identify the principal research questions to be addressed in the study. An important finding of these consultations was that the attitudes towards ComDT vary widely, ranging from the very positive attitudes of those with experience of ComDT in onchocerciasis control, to doubts of experts in other disease areas who were not always convinced about the potential of the ComDT approach for the diseases they are concerned with. It became very clear that a scientific comparison of community-directed and alternative approaches for delivery of interventions against endemic diseases, including onchocerciasis, is very much needed to provide objective evidence on the advantages and disadvantages of community-directed interventions as compared to other approaches to the delivery of health interventions at the community level in Africa.

Statement of the problem

- Summarizes the purpose of the study.
- Is a paragraph rather than a single statement.
- Establishes the direction and captures the essence of the study.
- Is clear and concise.
- Incorporates general objectives and uses action words to succinctly outline the purpose of the study.
- Reflects the research design of the study.
- Leads to the research question(s).

The term “statement of the problem” may be misleading as it usually comprises a self-contained paragraph, rather than a single statement.

- Use words such as “purpose,” “intent” or “objective” to highlight the main idea of the research.
- Identify the key concepts being explored.
- Identify the research design (e.g. case study, ethnographic study, correlational, experimental).
- Identify the unit of analysis in the study (e.g. independent and dependent variables, population, classroom, organization, programme, event); data collection methodologies (e.g. surveys, interviews).

Example 1

In the 1990s, the Government of [x country] introduced an economic structural adjustment programme. This meant a reduction in financial allocations to social services and removal of subsidies and consequently a limit of the public health budget. Health sector spending over a percentage of total government spending declined from 5.3% in 1980 to 4.2% by the mid-1990s. The diminishing resource allocation to the Ministry of Health has seriously affected a variety of programmes, including malaria control. Malaria still ranks among the major health and development challenges in the country and remains one of the major five killer diseases. The 1998 statistics of the country's 57 districts, 16 showed an incidence rate higher than 100 per 1000 people (Source et al, 1998).

Despite the existence of the Medical Care Plan (MCP) in several districts in the country, districts such as y still record one of the highest incidences (885/1000) (Source, 1999). On the other hand, districts such as z located in the same agro-ecological region have managed to reduce the incidence of malaria over the past three years from 575/1000 in 1997 to 305/1000 in 1999. Out of the 57 districts in the country, both y and z are in the top eight poorest districts with a Human Development Index (HDI) of 0.47 (Source 2000). The proposed study will identify factors that have shaped success in malaria control in one district and not the other and draws lessons for

the development of effective strategies to optimise the use of limited resources in a country that is currently facing an economic crisis.

Example 2

Only 5–10% of the Chinese rural population, mostly in the richer eastern coastal areas, were still covered by Cooperative Medical Scheme (CMS) during the 1990s. In Vietnam, after the introduction of user charges in 1989, several provincial health insurance schemes were developed. In the schemes, industrial workers, constituting a minority in the population, were in principle insured on a compulsory basis, while other citizens, including farmers in the rural areas, could join on a voluntary basis. However, less than 2% of the rural target population was enrolled in the voluntary health insurance in 1999. The problem here is the low enrollment in the health insurance scheme and by extension, limited access to health care in the rural population.

How to know if the problem is worthy of research

To get an indication whether the problem identified would be an appropriate research project, ask the following questions:

- Is there a perceived difference or discrepancy between the situation that exists and the ideal or planned situation?
- Is there a clear reason for the difference or discrepancy to the problem?
- Is there more than one possible answer or solution to the problem?

Example

Review the following overview of a problem situation:

In District Y (population 145 000), sanitary conditions are poor (5% of households have toilets) and diseases connected with poor sanitation such as hepatitis, gastroenteritis and worms infestations are very common. The Department of Health has initiated a sanitary project that aims at increasing the percentage of households with toilets by 15% every year. The project provides materials and the population is expected to provide labour. Two years after the programme began less than half the target was reached.

Now review the following questions to understand how to conduct a systematic analysis of the situation and provide a rationale for the need to conduct research to arrive at answers to the problem:

- What is the discrepancy?
- What factors can explain this difference?
 - Service-related factors? Failure to inform and involve the community? Bottleneck in the supply of materials? Training and effectiveness of sanitary inspectors?
 - Population-related factors? Lack of understanding of relationship between disease and sanitation? Poverty?
 - Physical factors? Ecosystems? Hard soil? Area always flooded?

To ensure that you have identified a legitimate problem in need of research and worthy of funding, strategically situate your proposal so that it will:

1. enable researchers and stakeholders to critically evaluate existing knowledge, pool this knowledge and identify gaps that IR projects should fill;
2. clarify the problem and the possible factors that may be contributing to it;
3. facilitate decisions concerning the focus and scope of IR (relate significance to specific aims).

These three considerations will be emphasized in the introduction of your proposal and help formulate the rationale for why the research needs to be conducted. Reflecting upon these considerations is also important in helping you first think broadly in order to be able to then narrow your focus to identify research objectives within the broader context.

Narrowing the research problem

1. Clarify the viewpoints of all stakeholders.
2. Specify and describe the core problem.
3. Identify the factors that may have contributed to the problem and clarify the relationship of the problem.

By now, the research team should be able to develop an overview of the problem and – through a systematic analysis of existing resources and literature – provide a rationale for why conducting the proposed research would provide answers, solutions or alternative strategies to the identified problem. Now follow the steps below to help narrow focus and identify research objectives within the broader research problem:

1. Clarify the viewpoints of all stakeholders.
 - List all problems
 - Illustrate the discrepancy

Example: Increasing defaulter rate among TB patients

- *Poor health services management, as identified by policy-makers.*
- *Social stigma associated with TB, as identified by affected communities.*
- *Negative attitudes of health workers, as perceived by service users.*

2. Specify and describe the core problem.
 - Quantify the problem
 - Describe the problem in detail

Example: Increasing defaulter rate among TB patients

- *How widespread is the observation? Which regions are persistently affected? Are there certain areas that may be potential low compliant areas?*
- *Who is affected the most?*
- *How severe is the problem? What are the consequences? e.g. increasing morbidity, deaths, a waste of resources, development of multidrug resistance.*

3. Identify the factors that may have contributed to the problem and clarify the relationships of the problem.

Example: Increasing defaulter rate among TB patients

- *Staff who are poorly trained because there are inadequate materials on TB.*
- *Health educators who have little understanding of patient prescriptions and do not provide systematic advice and counselling to patients. This results in patients not understanding treatment requirements and a high default rate.*

Research objectives

Research objectives should be SMART (i.e. Specific, Measurable, Achievable, Realistic and Timebound). In addition, you need to consider whether the research is:

- relevant
- new or innovative
- urgent
- politically acceptable
- ethical

When writing the Research objectives, ensure that the team addresses the following questions:

Is the research realistic?

Describe the complexity of the proposed research. Are there adequate resources to do the research? Is it feasible to conduct and report the findings in 12 to 36 months?

Is the research timely?

Provide a rationale for why your research is timely, and convince readers of the urgency for research in this area in order to generate information/solutions to problems affecting a specific community.

How is the research relevant?

Describe how large or widespread the problem is, and also who is affected, who considers this a problem. Also refer to the potential for the disease/condition to spread/increase if not treated, the potential burden to the health system, and existing or potential economic impacts of the problem on the target population.

For example:

Both the Chinese and Vietnamese governments have recently recognized the problems of lack of access to health care for the rural population. New policy initiatives are being developed to address the issues. In China, the central government has taken a decision to allocate 10 yuan/year/person for all the rural population in the central and western parts of China, in order to subsidize the re-establishment of a new Cooperative Medical Scheme, while it has also asked the provincial government to provide the same amount of money to support the schemes. In Vietnam, the government has issued a decree to significantly expand coverage of voluntary health insurance schemes providing the near-poor with subsidized insurance cards. This implies that the governments of the two countries have considered direct financial support to service the demand side (particularly the poor and the near-poor) via health insurance mechanisms, although they continue to allocate certain amounts of money from the government health budget to support the formal health sector. Against this background, the proposed research is expected to support policy initiatives by the governments, by bringing together the resources of experienced researchers from China, Vietnam and three European countries to study, evaluate and draw policy lessons for the ongoing movement to strengthen access to effective healthcare by making health insurance schemes work for the most vulnerable rural population in the two countries.

Is the research new or innovative?

Point out how the research will add value by doing something new or extend/improve upon something already in existence. You need to convince readers that you are not duplicating something that has already been done.

For example:

The project will produce innovations in a number of areas through its approaches and activities as follows:

- Piloting and testing new rural health insurance arrangements including innovations in:
 - benefit packages, in particular the development of schemes including primary and outpatient health services in addition to catastrophic health care costs in China;
 - provider payment mechanisms, in particular options such as capitation for pay for outpatient services at the village and township level health services in China, and commune health stations in Vietnam;
 - organization and management, including measures to increase accountability and transparency;
 - government subsidies in both countries.
- A participatory approach to involving major stakeholders such as policy-makers and potential/ actual service users at all stages of the research in order to maximize the relevance and impact of the findings.

Is the research urgent?

Demonstrate how the research results are urgently needed by policy-makers, implementers and health care providers in order to provide evidence to create a change, implement an intervention or put a stop to current practices.

For example:

During the SARS (severe acute respiratory syndrome) outbreak of 2003–2004, implementation research regarding uptake of SARS protocols was urgent.

Is the research politically acceptable?

IR projects often address topics of high interest to local and national authorities. It is advisable to involve policy-makers in the project design to ensure political acceptability and facilitate implementation of study results.

For example:

Undertaking TB research among the prisons in some communist countries may be seen as politically unacceptable. Consulting with and involving the authorities could mitigate this.

How will the results and/or recommendations be applicable to the target community?

Explain the likelihood of adoption of recommendations resulting from the research and how the findings will be used to improve health and health care. Demonstrate that you have done your homework and are aware of resources available, as well as any additional resources needed to facilitate implementing the recommendations.

Is the research ethical?

Explain how the research will be beneficial to the members of the community being studied. How will the research findings be shared with the target group? Can informed consent be obtained from the research participants? How will you take into account the condition of the participants? Will the results be shared with those who are being studied?

For example:

In scaling-up use of GeneXpert TB diagnostic device, more multidrug-resistant tuberculosis (MDR-TB) would be detected. It would be seen as unethical if diagnosed MDR-TB cannot be treated in an appropriate way (e.g. because of lack of technical capacity).

Overall objectives

- List specific and overall objectives.
- Outline the purpose for conducting the research.
- Clearly state what the study is expected to achieve in general terms.
- Align with the broader social, economic and health concerns outlined in the overview of the introduction, and further focus the context of the research down to an essential purpose.

Different funding agencies use different terminology (objectives, goals, aims). Sometimes these terms are used interchangeably.

The term “general objectives” is sometimes used interchangeably with “purpose of the research” or “overall objectives.” The general objectives should not be unrealistic (reduce morbidity and mortality) but rather reasonable, such as provide programme managers with information useful for improving service delivery. The General objectives outline the purpose for conducting the research. The purpose section may organize the study into clearly defined phases and facilitate the development of the research methodology and data collection to gather information to address the identified problem.

The particular research project could contribute in part to the overall objectives, but cannot fully fulfil them, since they may be affected by other factors such as education, manufacturing, etc. On the other hand, the specific objectives must be completely achievable through this project. The specific objectives will be used to measure the success or failure of the project.

Example 1

To contribute towards poverty reduction and health improvement for people living in poor rural areas of developing countries; to increase equity in health by making evidence available for health policy-makers for an effective, sustainable and affordable rural healthcare financing system in China and Vietnam.

Example 2

To maximize the equity, effectiveness and efficiency of close-to-community services in rural areas and urban slums in six countries.

Specific objectives

- Specific objectives are a breakdown of general objective(s) into measurable action statements that outline what will be done, where and for what purpose.
- Use action verbs when defining specific objectives (e.g. *determine, compare, verify, calculate, describe, establish, evaluate*).

Avoid the use of vague, non-action verbs when writing your Specific objectives (e.g. *appreciate, understand or study*). Use verbs such as: *train, supervise, distribute* when describing project activities. Resist the temptation to put too many or over-ambitious specific objectives in your IR proposal that cannot be achieved. After formulating your specific objectives ask yourself the following questions: Are the specific objectives clear, defined in operational terms that can be measured, realistic, and do they demonstrate how the research results will be used to solve the research problem?

Good example

To determine progress and constraints of visceral leishmaniasis active case detection at the district level using findings from previous years as baseline.

Poor examples

- *To provide patient-focused training programmes to enhance both self-management and peer-management of diabetes as a means to develop leaders.*
- *To study the behaviours of health workers in Uganda.*
- *To develop an implementation strategy for elimination of TB for a national TB control programme in China.*

Research question(s)

- Should be of interest to the researchers, policy-makers; decision-makers, funding agencies, health care providers and the community the research will affect.
- Should be answerable.
- Are shaped by the problem and in turn shape the design of the research.
- Are clear and specific.
- Are feasible.
- Provide information required to evaluate ongoing interventions and/or progress.
- Analyse possible causes for missed targets (in order to find solutions).
- Answering the question will result in important information.

The research methodology should be designed in such a way that by conducting the research the research question(s) will be answered.

IR question(s)

- Primarily address the needs of policy-makers, programme managers and health care providers, not only.
- Describe the health situation and intervention (include those in place and potential interventions).
- Provide information required to evaluate ongoing interventions or progress needed for making adjustments in the intervention.
- Analyse possible causes for missed targets (in order to find solutions).

IR questions are identified through an analysis of the situation and evidence, not merely based on the instinct of the researcher, policy-makers, programme managers or health care providers.

An IR question does one or more of the following:

1. Describes the health situation and intervention (include both situations and interventions in place and potential interventions)
 - Magnitude of the problem
 - Distribution of health needs of the population
 - Risk factors for some problems
 - People's awareness of the problem
 - Utilization patterns of services
 - Cost-effectiveness of available and potential other interventions

2. Provides information required to evaluate ongoing interventions or progress needed for making adjustments in the intervention
 - Coverage of priority health needs
 - Coverage of target groups
 - Acceptability of the services
 - Quality of services
 - Cost-effectiveness of the intervention
 - Impact of the programme on health
3. Analyses possible causes for missed targets in order to find solutions
 - Availability
 - Acceptability
 - Affordability
 - Service delivery problems

This information is required to formulate adequate policies, adapt or plan an intervention, and assess progress and the need for adjustments.

As your team conducts its own implementation research, remember that *the question determines the methods, and the purpose determines the framework*. IR questions address the design, implementation and outcomes of programmes. IR also asks: “Are there unintended consequences?” and “Why is it happening as it is?” IR questions are driven by implementation problems and should be designed for action-oriented research in collaboration with stakeholders.

Formulating IR questions

When formulating an IR question, you should consider the following:

- How could it best be answered?
- How could it feasibly be answered?
- What data is available? What data is needed?
- What can be controlled?

Once the problem has been identified, the next step is to formulate a question addressing that problem. Your approach depends on context and availability of information. Remember that IR problems are programme embedded – *they begin and end in programmes*. So, engage programme stakeholders early to formulate IR questions. The way questions are formulated drives research methods. These are helpful sources for formulating IR questions:

- Programme progress, annual, or evaluation reports from monitoring and evaluation activities.
- Medical literature, meta-analyses, and literature reviews.
- Scientific meetings and conferences.
- New ideas from previous research or formative qualitative studies (e.g., interviews).
- Funding agencies’ annual reports.
- Questions asked by programme staff and students.
- Local documents – project progress reports, theses, dissertations, seminar proceedings.
- Annual review or dissemination meetings.
- Geographic information systems (GIS) data that identify geographic location and distribution of problems.

Prioritizing IR questions

In prioritizing research questions, pay attention to:

- relevance
- avoiding duplication
- urgency of need
- political acceptability
- feasibility
- applicability of results or recommendations
- ethical acceptability

A programme may generate multiple, simultaneous implementation problems and questions. This can be overwhelming, so it is important to prioritize IR questions, ensuring efficiency and responsible practice of IR. The following seven criteria should help with prioritizing IR questions (Table 6):

Table 6. Criteria for prioritizing IR questions

Criteria	Considerations
Relevance	• How large or widespread is the problem? • Who is affected by the problem? • How severe is the problem? • If the problem is not checked, is there potential for spread? • Who considers this a problem? • Is this problem a burden to the health system? How severe is the burden? • What is the economic impact of this problem on the population?
Avoidance of duplication	• Has this question or problem been researched before? • Are there any interventions that have effectively addressed this problem? • If yes, are there any major questions that deserve further research? • Is my context so different that I cannot use the results of previous intervention research?
Urgency of need	• How urgently do the policy-makers, implementers and health care providers need results? • Will timeliness impact changing course, taking on new interventions or stopping what they are doing?
Political acceptability	• It is advisable to do study implementation problems of high interest and those that are supported by local or national authorities. • Study results for salient issues with political support are more likely to be implemented. • Politically accepted implementation problems can likely rely on involvement of the policy makers in the study.
Feasibility	• How complex is the research? • Are there adequate resources to do the study? • Is it feasible to conduct and report the findings in 12 to 36 months?

Criteria	Considerations
Applicability of results or recommendations	• What is the likelihood that recommendations will be adopted? • How would the findings be used to improve health and health care? • Are there available resources for implementing the recommendations?
Ethical acceptability	• How acceptable is the research to those who will be studied? • Does the target group share the implementation problem? • Can informed consent be obtained from the research subjects? • Will the condition of the subjects be taken into account? • Will the results be shared with those who are being studied?

Review of literature (synthesis of existing knowledge)

- Involves library searches to find relevant and up-to-date resources, reading and synthesizing the existing information and literature into a succinct overview.
- Demonstrates relevance by establishing what is already known about the research problem and how it has been approached in the past.
- Provides a rationale for why it is crucial to conduct the research.
- Indicates what is not known about the topic.
- Helps you refine the statement of the problem.
- Provides the 'state of knowledge' on the topic and sets up the research question(s) being investigated.
- Establishes credibility.

The review of literature synthesizes the relevant and most up-to-date information on the proposed research topic and leads to setting up the research question(s) being investigated. A literature review should demonstrate that you have read the existing work in the field with insight, thereby providing the reader with a picture of the state of knowledge and of major questions in the subject area being investigated.

By providing an overview of the existing available information, you avoid duplicating existing research by finding out what research has already been done on the topic. Reviewing the existing information will help you refine your statement of the problem, analyse various approaches already used in related studies, and assist in forming convincing arguments related to your research. By reading your overview, readers should be convinced that you are familiar with the topic and you have done extensive background research in the field.

In session one 'Write-shop', you will strategically situate your research problem in the existing knowledge and literature, in order to establish a rationale for why it is important that your identified problem be researched. Writing your rationale is the first step in developing the synthesis of existing knowledge for your IR proposal.

Completing review of literature

- Reading and writing can be an iterative process and time consuming.
- You are unlikely to complete your synthesis of existing knowledge during the current training.

Our goals are to:

- ensure you understand what is involved

- ensure you are aware of tools available to assist you with this task
- provide you with examples of a brief review of literature from IR proposals

Conducting a literature review involves reviewing the existing knowledge and doing library searches to find relevant resources (i.e. research articles, research studies, reports, government documents, and white papers), reading, and then organizing and synthesizing the information into a succinct overview of the topic. You may find you need to read about the topic for several days or weeks before beginning to write. At some point, however, you need to begin to write. Often you will find that once you begin to write, the process can feel overwhelming and you need to go back and do some more reading. You need to look for major concepts, read with a purpose, be a critical reader and start to write while still reading. Reading and writing can be an iterative process. As such, developing a comprehensive synthesis of the existing information can be an extremely time-consuming and laborious task.

During this workshop you will not have time to produce your review of literature for your research topic to an extent sufficient to support your IR proposal. As indicated earlier in this workbook, it is important to at least read about the problem you have identified before attending the workshop.

We will, however, provide an overview of what synthesizing the existing information and literature means, make certain that you are aware of the tools available to assist you with this task and provide you with IR examples of syntheses of the existing knowledge and literature.

Once you are back in your communities, you can continue to collect and read articles and develop your review of literature. If you have the resources, you may even want to outsource this task to a consultant who has conducted reviews of literature before.

Characteristics of literature review

- Presents an argument based on existing information (e.g. published literature; reports, government documents etc.).
- Synthesizes information from many sources.
- Critiques research studies for methodological shortcomings (when and if appropriate).
- Synthesis should support your research question.

The review of literature is not merely an expression of the research team's opinion of an issue or topic, but instead presents an argument based on the existing information, including published literature. An effective synthesis doesn't depend on, or elaborate upon, one or two studies, but synthesizes the existing information from many sources. It should be well written with one paragraph logically flowing into the next. The review of literature does not just describe or summarize the content of an article but critiques research studies for methodological shortcomings, as appropriate.

In the past, it may have been acceptable not to provide a strong synthesis of the existing knowledge due to the research team's location and lack of access to libraries and resources. However, today anyone who has access to the Internet can find most of the existing literature. Several search engines such as Pubmed (<http://www.ncbi.nlm.nih.gov/pubmed>), Hinari (<http://www.who.int/hinari/en/>) and Google Scholar (<http://scholar.google.com>) will be helpful in this regard. You can also work with a librarian, or assign a specific member of the project team to help you find and access the information you need.

In summary, the synthesis of existing information:

- defines and limits the problem or research question(s);

- demonstrates familiarity with the topic;
- establishes credibility;
- places the research in context;
- demonstrates relevance by making connections to a body of knowledge;
- integrates and summarizes what is already known about an area;
- helps avoid duplication;
- identifies agreement and discrepancies between and among prior research;
- helps the researcher select methods and measures;
- stimulates new ideas.

Referencing

- The ideas included in the review of literature should be properly cited.
- Software programmes are available to help manage, store and use references effectively.
- Improper referencing can hamper your chances of success in your grant application.
- Not referencing or referencing improperly can result in plagiarism.
- All references cited in the proposal text should be included in the reference list.

The ideas included in the review of literature should be properly cited using the reference style required by the agency to which the proposal is being submitted (e.g., APA, MLA, Chicago, Harvard). There are various software programmes available to help manage, store and use references effectively (e.g. EndNote, Mendeley). If possible, install the 30-day trial EndNote software or the free Mendeley software onto your computer.

It is essential that you reference properly. Not adhering to the conventions of proper referencing is an indication of sloppy research and consequently will hamper your chances of being successful in your grant application. Moreover, if you do not reference properly, you run the risk of plagiarizing, which can have severe career and academic ramifications. There are programmes that can help you check against plagiarism during your write up. An example is Desktop Plagiarism Checker.

All the references cited within your proposal (and only the ones cited in your proposal) must be listed in the references section of your proposal document.

Example 1 (well referenced)

Following World War II, [Q country] had built an extensive tuberculosis control system that relied on active case-finding using mass-miniature radiography and prolonged inpatient treatment with effective anti-TB drugs (Ref., 1999). The collapse of that country left the burden of TB control on impoverished regional authorities and precipitated a disruption in case finding, diagnostic quality and clinical effectiveness. The emergence of multidrug-resistant TB (MDR-TB) in this region has followed the disruption of effective drug delivery to TB patients (Ref., 1998).

Because the international community had judged the Q country's system of TB control as being too costly, in 1994, the WHO assembled the heads of TB control programmes in this region to promote a standardized framework for TB control later known as 'DOTS' (Ref., 2001). In 1998, the Q country Government adopted the DOTS strategy and proceeded to strengthen TB services throughout the country. While a fall in the TB mortality rate has followed the availability of first-line TB drugs and smear microscopy facilities, TB control continues to suffer from at least two limitations: TB patients continue to abandon treatment at a rate of 8% or higher, and more than 5% of newly diagnosed patients have MDR-TB (Ref., 1999). Rates of TB infection have risen in z City and w district during the past decade, as in other parts of the country, and may be

associated with poverty and the deterioration of TB control and prevention systems due to a lack of resources. The incidence of other communicable diseases such as diphtheria and hepatitis has also increased (Ref., 1999).

The international literature on directly-observed therapy (DOT) suggests that successful community-based TB control programmes depends on some combination of incentives and enablers for patients and health care workers to promote treatment adherence (Ref. et al., 2000). In addition, the medical literature on MDR-TB treatment shows that short-course chemotherapy does not produce acceptable clinical outcomes for patients already resistant to isoniazid and rifampin (Ref., 2000). In settings with highly prevalent MDR-TB, effective TB control will likely require 18- to 24-month courses of individualized treatment regimens that include second-line anti-TB drugs (WHO, 2001). In response to the problems of treatment adherence and MDR-TB, the National Tuberculosis Control Programme and the State Medical University have initiated MDR-TB treatment with second-line drugs in several pilot regions, and have begun to develop an innovative programme of outpatient enhancers and enablers they have termed DOT-flexibility and follow-up (DOT-FF) (Ref., 2001).

Example 2 (poorly referenced)

Large segments of the world's rural population remain vulnerable to the full financial cost of illness. Over the past two decades a growing number of developing countries have organized community-based or rural health insurance schemes to improve access to health care for those working in the informal sector. The need to develop and organize health insurance for the rural population and informal sector workers, as well as their dependents, has been linked to two sets of failures in a number of countries:

- *Government failure to collect taxes and organize public finance, to provide social protection for vulnerable populations, and to exercise oversight of the health sector.*
- *Market failure to offer an effective exchange between supply and demand, partly due to the gap between needs, demand and ability to pay, and partly due to the prevalence of non-monetary transactions in the informal sector.*

The strengths of health insurance in mobilizing and managing health resources are seen as based on three factors: social capital (safety net formalized by family, friends and community for the low-income groups); pre-existence of some community institutions; and interconnectivity between local communities and external institutions committed to advance the general welfare of society. However, there are also many problems and challenges in developing sustainable health insurance schemes in low- and middle-income countries because of a variety of constraints, including human and financial resources.

Group activity: Statement of the problem

Now that your team has developed an overview of your research problem(s), a rationale for why the research is justified, and general and specific objectives, you are ready to draft your statement of the problem, which will logically lead you to your research questions.



In your teams, read the example statement of the problem and use it as a guide to discuss the statement of your own research problem.

Example [based on a proposal related to malaria control in two different districts in an African country]:

In the 1990s, the government of country x introduced an economic structural adjustment programme. This meant a reduction in financial allocations to social services and removal of subsidies and consequently a limit of the public health budget. Health sector spending over a percentage of total government spending declined from 5.3% in 1980 to 4.2% by the mid-1990s. The diminishing resource allocation to the ministry of health has seriously affected a variety of programmes, including malaria control. Malaria still ranks among the major health and development challenges in the country and remains one of the five major killer diseases. The 1998 statistics of the country's 57 districts showed an incidence rate higher than 100 per 1000 people in 16 districts (Source, 1998).

Despite the existence of the malaria control programme in several districts, some districts (such as y) still record one of the highest incidences (885/1000) (Source, 1999). On the other hand, districts such as z, located in the same agro-ecological region, have managed to reduce the incidence of malaria over the past three years from 575/1000 in 1997 to 305/1000 in 1999. Out of the 57 districts in the country, both y and z are in the top eight poorest districts with a Human Development Index (HDI) of 0.47 (Source, 2000). The proposed study will identify factors that have shaped success in malaria control in one district and not the other, and draws lessons for the development of effective strategies to optimize the use of limited resources in a country that is currently facing an economic crisis.

Write-shop

During the evening, work in your teams to develop the following for your team's project:

- Working title
- Statement of the problem for your IR proposal (1/2 page)
- Research question(s)
- Specific objectives for your project (4 to 6 objectives)

Be prepared to present your drafts on day 2.



Group discussion

Each group will give a 10-minute presentation to the group with their results from the previous evening's write-shop.



2. RESEARCH DESIGN

As part of this session, your research team will build capacities that allow you to determine the specific research design that will be most effective in meeting your research objectives and answer your research question(s):

- Develop a research design outlining the procedures that will be taken to collect and analyse the data.
- Identify the research method (qualitative, quantitative/or mixed) that will be most effective in attaining your research objectives and answering the research question(s).
- Describe the quality management plan that your team will put in place to ensure quality.
- Describe the participants.
- Explain the steps you will take to ensure all ethical protocols and procedures will be addressed.

The research design is a blueprint or plan delineating your research methods; the steps or procedures you will take to collect and analyse your data; research sample size and participants; and how you will address ethical considerations. The research design section of your proposal will generally include four sub-sections:

- Study participants
- Research methods
- Data collection
- Data analysis

There are also four main options of research design, with each one addressing a different fundamental need in the study setting (Table 7).

Table 7. Research design categories and the needs they address

Need	Design	Example
Adequacy	Before-after or time series	Introduction of health insurance in a resource-poor setting, and examination of the impact of health insurance on access to health care. Using before-after or time-series design to collect corresponding data for evaluation.
Plausibility	Comparison of intervention to control group (pre-post intervention) Cross-sectional studies	Introduction of a new approach to the improvement of maternal health care in selected districts. A number of districts with a similar socioeconomic development levels were selected as control sites. The impacts or effects of the new approach were assessed by a comparison of new approach/ intervention to control districts, using the method of 'differences in differences', for example.
Probability	Clusters RCT; pre-post intervention and control sites	Using mobile phones as a reminder to increase adherence to TB treatment. Each district is used as a cluster. Among ten districts, a cluster-randomized controlled trial is employed to test the impact of using mobile phones as a reminder in the five districts randomly selected. The other five districts served as control sites.

Need	Design	Example
Explanatory	Repeated measures on context and mechanisms	Using quantitative, qualitative or mixed methods to understand and examine change in use of health services by pensioners after retirement, and analyse main factors resulting in the changes.

Once the overall study design has been determined, it informs the choice of participants, research methods and data collection/analysis approaches that are used/adopted.

Study participants

The participants section should include a full description of the subjects (sample) or participants who will be involved in the research, along with how they will be selected (purposeful or random sampling) details of the sample size and participant criteria. This allows the reader to make conclusions regarding the generalizability of the study. Criteria for becoming a participant, which may include demographic information such as age and sex, should be specified, along with descriptions of characteristics that are relevant to the research (e.g. years of experience, when they were diagnosed with the disease being researched, level of education etc.).

Outline the strategies that will be taken to ensure participants feel free to express their opinions during interviews, focus group discussions and other data collection procedures. For example, are venues private? Are there power dynamics to consider so that participants do not feel intimidated or threatened to say exactly what they are feeling and thinking? For example, if interviewing a patient, they may not feel comfortable expressing their opinion in front of their physician. Or when interviewing health care staff they may not feel comfortable saying how they feel in front of their superiors or managers. Consider how your IR proposal can outline appropriate procedures to ensure that participants feel comfortable and confident to provide honest, reliable responses.

The exact structure of the study participant section of your proposal will also be influenced by the selected research methods.

Example of Participants section of an IR proposal

For the key informant interviews for a study on TB in the prison system of country X, a comprehensive list of officials to be interviewed will be developed based on the stakeholder analysis and on consultations with the national TB control programme (NTBCP) personnel. A preliminary list of officials has been compiled and includes the following:

- Minister of health (or his deputy)
- Deputy of the ministry of health responsible for epidemiology and infection control
- Director of the NTBCP
- Chair of the sanitation and epidemiological services committee
- Ministry of justice
- Deputy of the ministry of justice responsible for the prison system
- Chief medical doctor that oversees the prison system
- Ministry of internal affairs
- Deputy responsible for detention centres

- Chief TB medical doctor (detention centres)
- Ministry of social security (head administrator)
- Ministry of finance (head of budgeting department)
- Head of regional political authority
- Head of health department of that authority

Group activity: Study participants

In your research teams discuss who you think your research population will be. Will you have one site or multiple sites? Why will you choose the site(s) you choose? Discuss who you think your participants will be in the study. How many participants will you need? What will be the criteria for becoming a participant?

Will you need a variety of participants in order to get different perspectives on an issue (patients, physicians, family members, members of the community)? Will you have a control group of participants? Do you need to choose a representative population for certain aspects of data collection? For example if you are conducting individual interviews do you want your participants to vary in (age, gender, education, experience etc.) in order represent the sample population?

Draft an outline of your participant section. You will need a general section describing your participant population. You will also need to estimate how many participants you will want from this population for each data collection method (surveys, focus group discussion, interviews etc.).



Research methods

There are three general types of research methods qualitative, quantitative or a combination of both (mixed methods), depending on the purpose of the design. Quantitative methods are better for answering the question: What is happening? Qualitative methods are suited for answering the question: Why is it happening?

Qualitative methods

Qualitative research is generally used to explore values, attitudes, opinions, feelings and behaviours of individuals and understand how these affect the individuals in question. It may also be used to help explain the results of a previous quantitative study.

Qualitative researchers are concerned with individuals' perceptions of specific topics, issues, or situations and the meanings they assign to their lives. This kind of research is important for theory generation, policy development, improving educational practice, justifying change or a particular practice, and illuminating social issues. Qualitative research uses data collection methodologies such as interviewing, observation, and documents (e.g. diaries, historical documents). The results are descriptive or explanatory rather than predictive.

For qualitative approaches, your proposal will need to outline the following sections:

- Rationale
- Data collection
- Data analysis
- Trustworthiness
- Participants
- Rationale

If your research team decides to use qualitative methods in your study, your proposal should describe why qualitative approaches were chosen (explain how qualitative methods will provide information that will help you address your research objectives and research questions).

For example, qualitative research may be appropriate because in your research you want to explore values and behaviours of individuals, and to understand how these affect the phenomena in question. Qualitative methods may also be appropriate because it will help further understanding of the results of a previous quantitative study.

Qualitative methods may be used because the study aims to generate theory, develop policy, improve health care practice, justify change of a particular practice, or illuminate social issues. Other reasons for using qualitative methods could be to provide context, a deeper understanding of stakeholder's need, rich data and participants' perspectives.

Qualitative data collection

When collecting qualitative data it is preferable to gather data using more than one data collection method. Obtaining information on the same phenomena in a variety of ways allows the researcher to 'triangulate' (or cross-check/verify) the data, which adds rigor to the research. The data collection process in qualitative research is emergent. The design is flexible to allow the researcher to investigate themes (findings) in more detail as they emerge.

Qualitative methods use data collection methodologies such as interviewing, observation, discussions and review of documents (e.g. diaries, historical documents). The results of qualitative research are descriptive or explanatory rather than predictive, and are typically time-consuming to collect.

In your IR proposal, indicate which data collection methods you intend to use and why. The following table may be helpful to you in this process. It provides an overview of qualitative data collection strategies (Table 8).

Table 8. Qualitative data collection strategies

Strategy	Summary and examples
Participant observation	Researcher participates to some degree in the natural setting over an extended period of time: Systematic observation of verbal and non-verbal actual behaviour in which trained observers use a structured recording form. Data are collected by observing, interviewing, note taking and/or journaling. Researcher develops a relationship with the participants, which may affect the data collected. <i>Proposal example:</i> <i>Semi-structured direct observation will be carried out in selected facilities to assess and compare the behaviour of health staff towards patients who are/not members of the revised schemes in at least two facilities in each study county, such as one township or commune health centre and one county or district general hospital.</i>
Non-participant observation	The researcher does not participate in any activity in the natural setting. Data are collected by observing, note-taking and/or journaling. Researcher does not develop a relationship with the participants and therefore cannot explore further issues in relation to observations made unless this approach is complemented with a follow up.

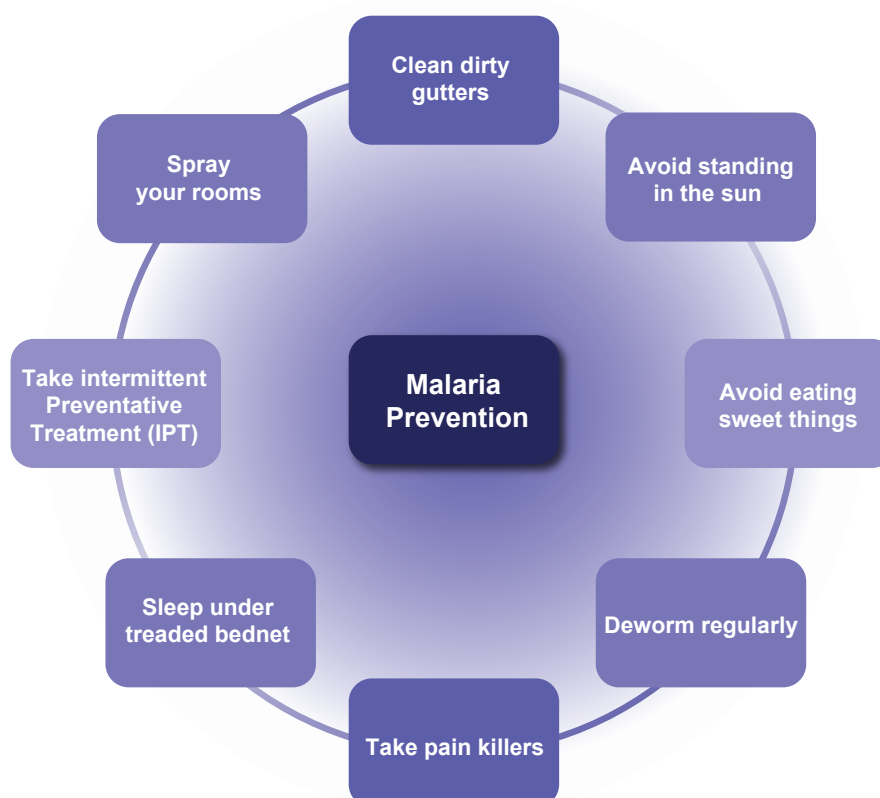
Strategy	Summary and examples
Field observation during a transect walk	Detailed descriptions of events, actions, behaviours, people and objects in a natural setting. Field observations are written in the form of field notes.
In-depth interviews	A purposeful conversation directed to the participant by the researcher. The researcher will typically develop an interview guide beforehand. The researcher encourages the participant to talk in-depth, prompting more detail whenever possible without leading the participant to specific answers. Interviews are often recorded and transcribed. The average length of an interview is one hour (or less). <i>Proposal example:</i> <i>It will include in-depth individual interviews with: people suffering from 'catastrophic illnesses'; including both members and non-members of revised schemes and those who have used and not used services; health policy-makers at national and local levels; and rural health insurance scheme managers.</i>
Review of documents and artefacts	Records of past events that are written or printed (e.g. letters, anecdotal notes, diaries). Material objects and symbols of a current or past event, groups, organization, or person that reveal social processes, meaning, and value (e.g. diplomas, awards, papers, logos etc.).
Video/film/ photographs	Media that capture the daily life of an individual, group or event under study. Can be viewed repeatedly to record behaviours.
Focus group discussion	A 1–2 hour discussion, guided by a trained moderator in which 6 to 10 similar respondents (age, gender, social status) focus on a list of defined topics. The discussion, designed to reveal beliefs, opinions and motives, should take place in an informal setting. Data collection may be enhanced by the interaction between and among participants. <i>Proposal example:</i> <i>This will comprise of focus group discussions using participatory techniques with: members and non-members of the revised schemes (including different age, gender and socioeconomic groups); and health service providers at county/ district levels and below, including general practitioners/ primary care providers, preventive service providers, and out-patient and in-patient providers</i>

Plan for qualitative data analysis

Qualitative data analysis consists of data management, data reduction and coding of data. In short, the goal is to identify patterns (themes) in the data and links between them. There is no set formula for analysing qualitative data, but the following steps are commonly used in many qualitative research studies and may be helpful to include in your IR proposal:

1. All interviews and discussions are recorded.
2. All recordings have to be transcribed verbatim (i.e. typed out in full, word-for-word).
3. All background information about the participants should be appended to each transcript.
4. In the initial step of the analysis, the researcher will read/re-read the first set of data and write notes, comments and observations in the margin, with regard to interesting data that is relevant to answering the research question(s).

5. While reading the data, the researchers begin developing a preliminary list of emergent categories into which they will group the notes and comments. These categories are guided by the purpose of the study, the researchers' knowledge and orientation, and the meanings made explicit by the participants (1). A list of these categories is compiled and attached to the data.
6. The next set of data collected is then carefully read and, with the previously constructed list of categories in mind, notes, comments and observations are once again recorded in the margin. This second data set are then grouped into categories and a list of the categories compiled. The two lists are then compared and merged to create a master list of categories. This list reflects the recurring regularities or patterns in the study.
7. These categories are then given names. Category names may emerge from the researcher, from the participants or from the literature. According to Merriam (1), these categories should be: exhaustive; mutually exclusive; sensitive to what is in the data; conceptually congruent; and, in effect, the answers to the research questions. Category names or codes in data analysis can also be derived from the questions asked in the data collection tools based on the objectives of the study.
8. Once the researchers are satisfied with the categories, the data is assigned to these categories. Taking a clean copy of the data, the researcher organizes the data into meaning units and assigns them to the relevant categories, writing the category code in the margin.
9. The researchers then create separate files for each category and cut and paste the meaning units into the relevant category, creating a file containing all the relevant data. Care should be taken to avoid context stripping by carefully cross-referencing all units and coding them with the participant's pseudonym, the date of data collection, and the page number (2).
10. The researchers then try to link the categories in a meaningful way. Diagrams can be used to facilitate this process. For example, in a study to determine causes of malaria:



11. Researchers can also use several different computer qualitative data analysis (QDA) software to help them manage their data. The term “QDA software” is slightly misleading because the software does not actually analyse the data, but organizes it to make it easier to find and identify themes. Software can also be expensive (up to around US\$900 per single user). For these reasons, some researchers prefer analysing data by hand. However, as the software improves, researchers are finding QDA increasingly useful in helping analyse data and save time. Here are some of the more common QDA software names:

- AtlasTi (<http://www.atlasti.com>)
- MAXQDA (<http://www.maxqda.com>)
- QSR NVivo (<http://www.qsrinternational.com>) previously called Nud*ist 6)
- EZ-TEXT 3.06C (<http://www.cdc.gov/hiv/topics/surveillance/resources/software/ez-text/index.htm>)

Examples: Qualitative data analysis descriptions

1. *Transcripts from key informant interviews and group interviews will be coded and analysed according to emerging themes using Ethnograph software for qualitative analysis. Data will be reported in the form of narratives or frequency tables in addition to standard thick ethnographic descriptions.*
2. *Coding of focus group interviews, ethnographic field notes and interviews with health workers using Atlas-Ti software will allow analysis of emerging themes and presentation of data in the form of narratives or frequency tables.*
3. *Transcripts from life histories will be coded and analysed according to emerging themes (Ethnograph or Atlas-Ti software). Data will be reported in the form of narratives or frequency tables. In addition, videotaped recordings of patients will be used for national and international advocacy with the permission of interview subjects. Semi-structured, open-ended interviews from patients and family members of patients will be coded and reported as narratives or frequencies of coded responses to better understand the impact of the persistence of MDR-TB in this setting.*

Trustworthiness

IR proposals should stipulate how the research team will ensure scientific rigour in qualitative methods. For example, will your study provide participants with a copy of their interview transcripts to provide them an opportunity to verify and clarify their points of view? Will you use software to help manage your data and increase rigour? Will you conduct member checks (have more than one researcher analyse sections of the data to compare and verify results)? Will you triangulate the data to increase the rigour? Will you report disconfirming evidence?

Participants

As mentioned above, ensure that numbers of participants, recruitment and selection criteria align with your qualitative methods. You may also have to consider some specific issues: Will you use purposeful sampling? What are the demographics relevant to the study, and characteristics related to the disease of interest.

Quantitative methods

The three most common designs associated with quantitative methods are: quasi-experimental, correlational, and monitoring evaluation.

Quasi-experimental research

Experimental research is the only type of research that can establish cause and effect. Furthermore, it is the only type of research where the researcher attempts to manipulate a particular variable. In experimental research, the researcher is interested in the effect of an independent variable (also known as the experimental or treatment variable) on one or more dependent variables (also known as the criterion or outcome variables). The researcher manipulates the independent variable and measures the dependent variable(s). There are usually two groups of subjects in experimental research: the experimental group, which receives a treatment of some sort (e.g. taught by a new teaching method, or receives a new drug) and the control group, which receives no treatment (e.g. continues to be taught by the old method, or receives a placebo). Sometimes, a comparison group will also be used as well as, or instead of, a control group. The comparison group receives a different treatment from the experimental group. The control and/or comparison groups are critical in experimental research as they allow the researcher to determine whether the treatment had an effect or whether one treatment was more effective than another. When possible, the subjects should be randomly assigned to the treatment and control groups.

Correlational research

In correlational research, researchers seek to determine relationships between two (or more) variables without trying to influence those variables. The degree to which the variables are related is described by a correlation coefficient, which can take any value from -1 to 1 . A positive correlation means that high scores on one variable relate to high scores on the other variable or low scores on one variable relate to low scores on the other variable (i.e. a positive correlation). Conversely, a negative correlation means that high scores on one variable relate to low scores on the other. A correlation coefficient of zero means that there is no relationship between the variables. Contrary to experimental research, correlational research does not establish cause and effect.

Not only do researchers use correlational research to describe relationships between variables, but also for prediction. If a strong enough relationship (positive or negative) exists between two variables it is possible to predict a subject's score on one variable (criterion variable) using their score on the other variable (predictor variable).

Monitoring and evaluation research

One main objective of monitoring and evaluation (M&E) research is to track implementation progress against the original design, identifying potential weaknesses, testing initial assumptions and adjusting the implementation process if those assumptions fail to hold true. Data collection activities should be carefully justified as addressing the research objective(s). Otherwise there is a risk of wasting scarce resources on data that will never be used.

One main source of data can come from the routine health information reporting systems, which often exist in low- and middle-income countries. Community health centres, district and regional hospitals, and other health facilities are usually required to submit their monthly or quarterly reports to local and national health authorities. The information often includes disease patterns, service use and expenditure, and other relevant information.

While the data from the routine health information reporting systems can be easily available and collected, the quality of the data may not be reliable, as there has been a tendency of underreporting health problems or service usages, etc. Therefore, special surveys or regular record monitoring arrangements may have to be carried out to collect data required to achieve this objective. These data collection methods include household health interview surveys, health facility surveys (e.g. hospitals, health centres, etc.), and patient surveys. When using these methods for data collection,

researchers need to develop instruments and tools, e.g. questionnaires, checklists, and organize visits to selected households and health facilities.

In your IR proposal, you should indicate who will be expected to undertake the data collection and whether training will be provided before carrying out the tasks. Appropriate supervision during the process of data collection is also required.

For quantitative approaches, your proposal will need to outline the following sections:

- A rationale
- Data collection
- Data analysis
- Reliability and validity
- Participants

Rationale

If your research team decides to use quantitative methods in your study, your proposal should describe why quantitative methods are being used (i.e. explain how quantitative methods will provide information that will help you address your research objectives and research questions).

For example, quantitative methods may be appropriate because in your research you want to illustrate the cause and effect of the issue or situation being investigated. You may also justify using quantitative methods in order to determine the relationship between variables in a population or explore differences between two groups (e.g. pre-post intervention; different populations).

Quantitative data collection

Quantitative methods involve the collection and analysis of objective data, often in numerical form. The research design is determined prior to the start of data collection and is not flexible. The research process, interventions and data collection tools (e.g. questionnaires) are standardized to minimize or control possible bias.

In your proposal, explain where the data will come from – health centre, district hospital, region (hierarchies for quarterly reports); how surveys will be delivered; who is facilitating delivery; how you will ensure anonymity; time required to complete survey; length of survey; number of questions on survey; sample size; how the survey will be designed; is the survey validated, etc.

The data collection tools used (e.g. questionnaire) may be one developed by the researcher or, more preferably, one that has been previously developed. Developing an appropriate and effective instrument takes a lot of time and effort and often requires special skills. If you are developing the tool, specify if you will conduct a pilot.

In your IR proposal, indicate what data collection methods you intend to use and why. The following table (Table 9) provides an overview of quantitative data collection strategies and may be helpful to this process.

Table 9. Overview of quantitative data collection strategies

Strategy	Summary
Structured observation	The researcher directly observes (watches and listens to) some phenomenon and then systematically records the resulting observations. The researcher pre-determines specific categories of behaviours that will be observed.
Questionnaire	In a questionnaire, the subjects are required to respond to questions in writing or, more commonly, by marking an answer sheet. In the latter type of questionnaire, response options are often closed lists of responses in the form of yes/no/maybe; strongly disagree/disagree/undecided/agree/strongly agree; Never/rarely/sometimes/often/frequently etc. <i>Proposal example:</i> <i>Quantitative data will be collected through the use of structured questionnaires. A standardized form will be developed at baseline and will include the following categories: 1) socio-demographic characteristics; 2) economic status; 3) medical and treatment history related to tuberculosis; 4) current health status, including but not limited to assessment of symptoms, smear, culture, weight and height (for calculation of BMI); 5) history of imprisonment or substance abuse; 6) psychosocial status; and 7) knowledge of TB.</i>
Performance-based instruments	Performance-based instruments are alternative forms of assessment used to demonstrate a skill or proficiency by having the participant create, produce or do something (e.g. write a paper, create a portfolio, do an athletic performance). Although popular in recent years, use of these approaches is fraught with technical difficulties. They are often time-consuming and require equipment or other resources that are not readily available.

Source: Adapted from McMillian & Schymacher (3) and Fraenkel & Wallen, (4)

Plan for quantitative data analysis

It is important to outline a plan for data management and analysis. The methods and models of data analysis should be in accordance with the proposed objectives and types of variables.

Quantitative data analysis will involve summarizing the results by calculating frequency and descriptive statistics such as means and standard deviations, and scale alphas for the participants' responses on the questionnaire items. You should explain how basic descriptive statistics such as means and standard deviations will be calculated from data collected.

The tests that you intend to conduct on the data should be explained (e.g. t-tests; hierarchical multiple regression). Specify if you intend to control variables. Indicate if any software will be used in your data analysis).

Outline as many of the following that relate to your study:

- Demonstrate appropriate analysis procedures.
- Provide a general plan for data analysis and justify its technical and theoretical soundness.
- Describe what information is needed to complete the analysis, the potential sources for this information and the instruments that will be used for its collection.
- Provide sufficient detail to demonstrate the technical soundness of all data collection instruments and procedures.
- Identify and justify procedures for analysis, reporting and utilization.

- Identify any anticipated constraints on the analysis.
- Discuss who will be responsible for analysis, and the roles of the consultants or external personnel.

Examples: Quantitative data analysis descriptions

Example 1. *Patients will be assigned a unique identifier that can be linked with outcome data collected on a quarterly basis. This standardized form will include information on: a) smear and culture conversion; b) current health status, including data on treatment outcome (e.g. cure, abandonment, failure, death); and c) psychosocial status. Some variables on socioeconomic status will also be included in the quarterly assessment form in order to assess changes over time.*

In addition to the quarterly assessment, drug susceptibility testing will be performed every six months. A separate form will be developed for these results and will be linked using the same unique identifier with information collected at baseline and on a quarterly basis.

Three databases will be constructed in Epi2000 for the intake, quarterly and laboratory forms. Prior to data entry, forms will be reviewed for random and systematic error and possible corrections will be made in consultation with the interviewers. Data entry clerks will be given a structured training that also enables them to identify problems with data quality prior to the entry of the forms into the database(s).

Subsequent to entry, the databases will be reviewed closely during the first few weeks of entry to ensure that the data are being entered and stored correctly. After this initial intensive phase, the data will be reviewed on a quarterly basis for systematic errors, blank fields, and other problems. Feedback will be provided to data entry clerks and to interviewers on a monthly basis to reduce the likelihood of systematic and random error.

Example 2. *Descriptive statistics will be generated from the structured questionnaires that will be administered with service providers. Frequencies, means and standard deviations will be calculated where appropriate for a number of health provider variables, including sociodemographic variables (such as gender, age, household size, etc.), socioeconomic status, job satisfaction, relationships with clients, and barriers to providing follow-up care.*

Example 3. *For the cohort study, descriptive statistics will be generated for baseline characteristics of the patients who are enrolled in both retrospective and prospective cohorts. Differences in sociodemographic characteristics will be noted for subsequent multivariate analyses. A description of clinical status and medical history, among other factors collected at baseline, will also be provided for both cohorts by generating frequencies, means, standard deviations and medians, where appropriate. In terms of examining time to smear and culture conversion for both cohorts, Kaplan-Meier survival curves will be constructed. In order to account for confounding variables in the analysis, Cox proportional hazards models will be employed. Linear regression will be used to examine DST outcomes based on number of drugs the patient is resistant to at follow up. Logistic regression will be used for the assessment of binary outcomes, such as treatment outcome (poor versus good), low body mass index, radiographic findings, and occupational status. Poor outcome will be defined as treatment failure, default or death. Interim outcome analysis will be done at the end of year 1 and the final analysis will be performed at the end of the 2-year follow-up period.*

Biosocial factors related to MDR-TB will also be presented descriptively. In order to examine the association of biosocial factors with MDR-TB emergence, linear regression will be employed

using the increase in the number of drugs that the patient is resistant to at follow up as the outcome. In terms of persistence of MDR-TB, biosocial factors will be associated with poor treatment outcomes using logistic regression. Confounding variables will be controlled by using multiple regression analysis.

Reliability and validity

When evaluating a data collection tool for use, it is important to consider its psychometric properties; that is, its reliability and validity. A tool is considered to be valid if it measures what it purports to measure. It is always valid for something specific (e.g. assessing attitude to care); a survey cannot be valid in general.

Ideally, any tool used to collect data should have demonstrated validity and reliability for the target population. However, researchers often need to tailor a standardized tool to make it applicable to their research. Adding questions, or amending existing ones, may negatively affect the psychometric properties of the instrument though and so is discouraged.

Your proposal should stipulate how your research team will ensure scientific rigour in your quantitative methods. It is important to explain the validity (i.e. how you will be able to draw meaningful inferences from a population) and reliability (i.e. control for stability of instrument scores over time) of the quantitative data.

For example, indicate whether the instruments you are using are standardized and whether they have been shown in previous studies and reports to have strong reliability and validity (with respect to content, criterion, and construct).

How have you indicated you will ensure scientific rigour (control group, placebo etc.)?

Participants

Include a section called 'Participants' and ensure that your sample size, recruitment and selection criteria align with your quantitative methods. Will you use a random sample? Indicate whether variables are dependent or independent. Describe the study population; selection criteria; provide demographics relative to the study (age, gender, ethnicity, income bracket, etc.) characteristics related to the disease of interest, etc.

Mixed methods

The majority of proposals use mixed methods in which qualitative and quantitative approaches are combined. Under many circumstances, a mixed methods approach can provide a better understanding of the problem than either a quantitative or qualitative research approach. Nevertheless, one of the main challenges may be to create the optimal combination (and sequence) of the two approaches.

The four most common types of mixed methods research design are: sequential explanatory; sequential exploratory; concurrent triangulation; and concurrent embedded (Table 10).

Table 10. Main mixed methods research approaches

Design type	Description
Sequential explanatory	Collection and analysis of quantitative data in the first phase is followed by the collection and analysis of qualitative data that builds on the results of the first phase. Weight is typically given to the quantitative data. Mixing of the data occurs when the initial quantitative results are used to inform the secondary qualitative data collection. It can be especially useful when unexpected results arise from a quantitative study. The straightforward nature of the design is its strength and so it is easy to implement. The main weakness of the design is the time required to implement since it falls into two phases.
Sequential exploratory	Collection and analysis of qualitative data in the first phase is followed by the collection and analysis of quantitative data that builds on the results of the first phase. Weight is typically given to the qualitative data. This design tends to be used when the primary purpose is to explore a phenomenon (e.g. testing elements of an emergent theory or determining the distribution of a phenomenon in a given population). It is easy to implement but requires substantial time for data collection.
Concurrent triangulation	Quantitative and qualitative data are collected simultaneously and then the two datasets are compared to see if there is convergence, differences, or some combination of the two. Ideally, the weight given to the quantitative and qualitative findings is equal but in reality more weight may be given to one methodology over another. Concurrent triangulation is one of the most popular types of mixed methods design. It can, however, be difficult to compare results, particularly if discrepancies arise. It also requires great effort and expertise on the part of the researcher to adequately study a phenomenon using two methods.
Concurrent embedded	Quantitative and qualitative data are collected simultaneously but there is a primary method that guides the approach. Either quantitative or qualitative data will be used to provide a supportive or supplementary role based on the primary data type. The researcher is able to collect two types of data during a single research phase. Often an embedded design is used to answer different research questions with a study.

Since mixed-methods use both qualitative and quantitative methods, mixed method proposals should include:

- Rationale (describing type of mixed methods being used)
- Data collection
- Data analysis
- Reliability and validity
- Trustworthiness
- Participants

Rationale

If your research team decides to use mixed methods in your study, your proposal should describe why (explain how using qualitative and quantitative methods will provide information that helps you to address your research objectives and research questions).

For example, using a mixed methods approach may be appropriate because you want to provide a better understanding of the problem than either a quantitative or qualitative research approach could achieve alone. Your explanation may state that you want to create a design that provides the

optimal combination and sequence of both approaches. Additional justifications for using a mixed methods approach may be because your project is interdisciplinary involving team members with diverse views or your project will be dealing with complex problems that will benefit from blending qualitative and quantitative data.

Mixed methods data collection and analysis

There are several elements related to mixed methods research that researchers need to consider for research design:

- *Timing*: Will quantitative and qualitative methods be used simultaneously (concurrent designs) or in two distinct phases (sequential designs)?
- *Weighting*: How much emphasis will be put on the quantitative or qualitative methods? Will they be weighted equally?
- *Mixing*: Data analysis needs to be matched to the design of the study. For example, in a concurrent design, one way of mixing the data is to provide a discussion about the emerging themes from the data and how they support or refute the statistical analysis. Another approach could be to combine the qualitative and quantitative data to arrive at new variables or new themes (5). In a sequential design, for example, a researcher might collect and analyse quantitative data in the first phase of the study and may then select some extreme cases to follow-up in a qualitative phase.
- *Visual diagrams*: An important mixed methods tool that incorporates a notation system and a flow chart of the research process.

In your proposal, indicate what data collection strategies and tools you intend to use and why. Use the information outlined in both the qualitative and quantitative sections (above) according to which data collection method you are explaining (for example, if using a focus group discussion, refer to the qualitative methods section – when explaining how you will use a questionnaire, refer to the quantitative methods section).

In your proposal it is important that you outline a plan of data management and analysis. The methods and models of data analysis should be in accordance with the proposed objectives and research questions.

Trustworthiness, validity and reliability

In a mixed methods IR proposal, showing how scientific rigour will be ensured throughout your study is critical. It is important to examine the validity (i.e. being able to draw meaningful inferences from a population) and reliability (i.e. stability of instrument scores over time) of the quantitative data.

To ensure qualitative validation, the researcher will use a number of strategies. First, opportunity will be provided for the participants to review the findings and then provide feedback as to whether the findings are an accurate reflection of their experience. Second, triangulation of the data will be used from various sources (transcripts and individual interviews) and from multiple participants. Finally, any ‘disconfirming’ evidence will be reported. This is to ensure that accounts provided by the participants are trustworthy.

Refer to the trustworthiness section of qualitative methods and the validity and reliability section of quantitative methods for more detailed information.

Group activity: Research design

In your research teams discuss which research design will work best for your project. Which methods will you use to collect your data? Use the examples below to help you create a table containing your research objective(s) and research question(s) and identify which data source(s) will be used to collect the data to meet the objectives of the research and answer your research questions.



Example

(1) *For the first objective, the study will analyse qualitative interviews, public discourse from newspapers and decrees, and objective measures of commitment to tuberculosis control in X city. Fifteen key informant interviews and several consensus panel discussions will be used to generate information on national and local policy processes and the translation of national and international guidelines to the behaviour of local health and social security systems in relation to MDR-TB control and ambulatory case-management. This stakeholder analysis will entail interviews with officials at four levels of government: national, region, district and city.*

(2) *For the second objective, the study will employ (a) focus group discussions with health care providers structured by occupation (e.g. nurse, physician); (b) ethnographic assessments carried out by researchers/clinicians trained in ethnographic methods; and (c) structured and open-ended interviews with health care providers responsible for TB control at the district and city levels.*

(3) *Methods for the third objective will include collection of qualitative and quantitative social data, as well as data on clinical and microbiological outcomes as part of a cohort study of patients and providers receiving a package of enablers and incentives termed DOT-FF.*

(4) *For the fourth objective, the study will compare bacteriological and clinical data with quantitative and qualitative social data collected from patients and family members in order to identify biosocial determinants and effects of MDR-TB emergence and persistence. The study will obtain the life histories of patients with MDR-TB and TB on video, if possible. Semi-structured, open-ended interviews will be conducted with patients and family members of patients to better understand the impact of the persistence of MDR-TB in this setting. In addition, the quantitative methods from M3 will help elucidate the biosocial factors potentially related to MDR-TB emergence and persistence (e.g. education, socioeconomic status, lack of social support, sideeffects from second-line anti-tuberculosis drugs as well as HIV and other co-morbidities, such as substance use.)*

Write-shop

During the evening, work in your teams to develop the following for your team's project:

- Research design
- Research methods including:
 - step-by-step procedures for your data collection
 - data analysis



- trustworthiness, validity, reliability
- participants

Be prepared to present your drafts on day 2.

Group discussion

Each group will give a 10-minute presentation to the group with their results from the previous evening's write-shop.



Quality management

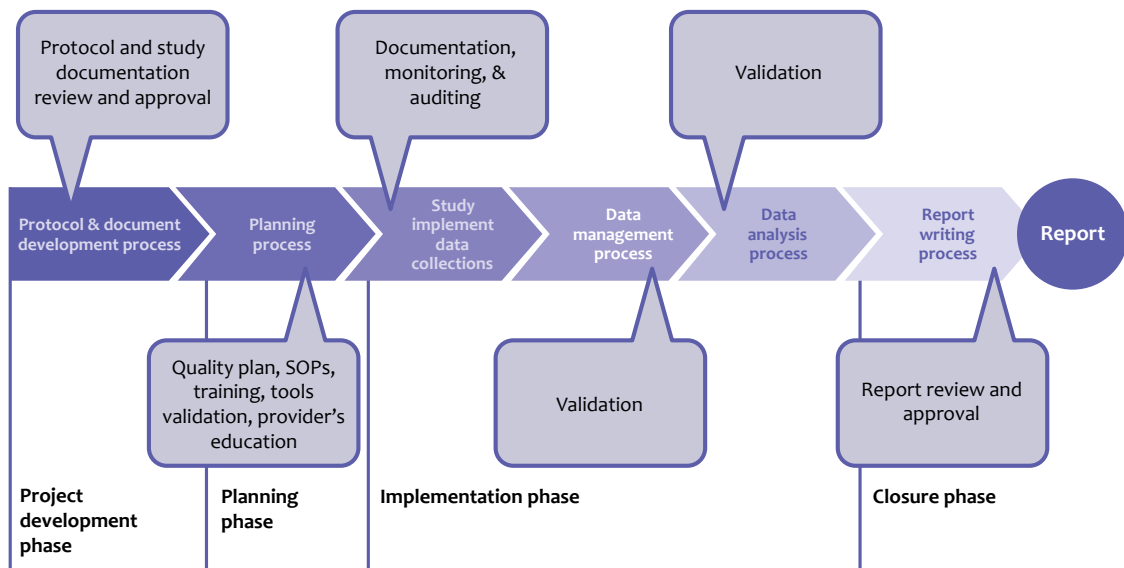
Embedding quality management into your proposal is not an optional step. Quality management is essential to ensuring that research meets or exceeds scientific, ethical and regulatory standards. Quality systems, control and assurance is integral to all research activities. Everyone engaged in the project carries the responsibility of ensuring quality. Quality management should be planned and adhered to in the research design.

In your proposal, outline exactly how you will demonstrate that your research team will take consistent, ongoing measures to monitor and evaluate quality and rigour of the research. Indicate how you will evaluate quality at various stages. How will you demonstrate that you will conduct due diligence at all data collection and data analysis steps?

If your project lasts more than one year, you may want to stipulate that you intend to have annual quality monitoring evaluations and reports. Discuss a communication plan with all stakeholders to inform them of quality standard procedures to facilitate rapid adjustments and corrections.

Quality management should also express a constant and consistent concern for research participants. How will you protect their privacy? What measures will you take to protect them from harm (e.g. train staff, adhere to ethical standards in the research ethics application etc.)?

Activities to address quality issues



The diagram provides a visual example of how you could plan and ensure continuous and consistent quality management strategies in an IR study.

Quality management activities

Some of the activities you can integrate into your IR proposal to help manage quality include:

- protocol review and approval
- standard operating procedures
- validation of research instruments
- project team training
- quality control and monitoring
- evaluation of services provided
- evaluation of the performance of service providers
- review of reports

There are many strategies that can be incorporated into your IR proposal to begin the quality standard monitoring process. Monitoring and evaluation strategies that can be implemented to facilitate the quality of your research project include:

- Information log: keep track of feedback from stakeholders, news stories published and articles written, and the number of times research has been cited in the academic literature.
- A survey: this can be conducted with stakeholders from the target audiences in order to generate feedback. For example, questionnaires can be sent via email six months and one year after a dissemination event or clients attending a family planning clinic can be asked to complete a survey regarding improvements in the quality of care.
- A series of key informant interviews with stakeholders at various levels of the health system can provide insight into whether, and how, research was used.

Use the table below (Table 11) to get additional ideas about how you can incorporate quality management into your research proposal.

Table 11. Descriptions of various quality management strategies

Strategy	Description
Protocol review and approval	Research rigour includes stipulating how you will protect the rights and welfare of research participants. Protocols may also be established to ensure consistency and diligence in data and collection procedures (standardized instruments, consistent interview protocols); checklists and established protocols to ensure consistency and rigour of data analysis across sites and among researchers.
Standard operating procedures	A project manager must establish protocol to establish rigour and consistency between and among researchers and research sites. This may include standardizing research collection procedures (establishing a protocol or checklist); creating standardized instruments and interview protocols to be used across sites and among all researchers; constant checks to ensure procedures are diligently adhered to; and holding training sessions with researchers and research assistants.
Validation of research instruments	Indicate whether research instruments are standardized and whether they have been shown in previous studies and reports to have strong reliability and validity (with respect to content, criteria and construction).
Project team training	Adequate training and appropriate infrastructure are essential to patient safety, protocol implementation, and quality assurance and improvement – especially in interventional clinical trials. Training of researchers and assistants in data collection procedures to ensure safety of the participants, as well as to ensure consistency and research rigour between and across sites, is essential.
Quality control and monitoring	Quality control is important to ensure reliable and consistent findings. What procedures will be incorporated into the research design to ensure consistent data collection methods are implemented between and among research sites and among different researchers? The proposed methodology should help investigators identify data quality problems that can be corrected while data are still being collected, and also to identify biases in data collection that might be adjusted for later.
Evaluation of services provided	Monitoring and evaluating service provision is essential for analysing and, if possible, improving the effectiveness of service regimes. Establish 'critical limits' to measure the effectiveness and quality of the services provided to participants/clients/patients. Establish appropriate record-keeping and documentation systems. Make regular site visits to monitor progress and assess impact. Establish corrective actions. Evaluate, with relevant health care workers, achievements made and lessons learnt, and apply any lessons learnt to existing and new arrangements.
Evaluation of the performance of service providers	Generating and using information on the performance of service providers can lead to substantial enhancement of transparency and accountability, which in turn fosters adherence to higher quality standards in service delivery. Assessment tools rely on external experts measuring quality and performance against a pre-determined set of indicators. Participatory monitoring and evaluation tools seek to engage service users beyond the provision of feedback, to also take an active role in the planning and implementation of the assessment. This helps to build the capacity of the local community to analyse, reflect and take action. Community scorecards envisage active involvement of the group and allow participants themselves to identify indicators of quality and performance.
Review of reports	Reports should be drafted and shared in sufficient time to provide an opportunity for all researchers and appropriate stakeholders to have the opportunity to read, react to, provide feedback on, edit, revise, and provide input into the report.

Research ethics

Any research study that collects data from or involving human subjects must undergo an ethics review. You must stipulate that you intend to apply for ethics approval if you have not done so already. You should have an ethics section in your proposal that describes the steps you will take to ensure the protection, dignity, rights and safety of potential research participants before, during and after the research takes place. In addition, your IR proposal should describe how you will ensure that universal ethical values and international scientific standards will be adhered to in terms of local community values and customs in planning, conducting and evaluating the research. If you are collecting data in more than one site you may have to apply to more than one ethics board. Agencies will not distribute funds until ethics clearance has been received in writing.

In the ethics section of your proposal, state explicitly how the research will address the following codes of ethics (it may however be worth going to the website of the review board to whom you are submitting your proposal, to make sure you have complied with all their specific requirements):

- Balance potential harm to participants against potential benefits. Possible harms fall into several categories such as physical injuries, loss of privileges, inconvenience (including wasted time, psychological injuries (e.g. embarrassment), economic loss, or legal risks).
- Maintain privacy, anonymity, and confidentiality:
 - when health care providers are research participants;
 - when reviewing medical records;
 - by maintaining the boundary between researchers and physicians.
- Construct the informed consent letter and form (include in proposal appendices).
- Where necessary, include a translation of the consent form in appropriate local language(s) as this may be required by some ethical review committees
- Obtain voluntary consent of all human subjects/participants. In the case of minors, parental/guardian consent must be obtained.
- Make research results freely available as a public good.
- Demonstrate that results cannot be obtained by other methods or means.
- Avoid all unnecessary physical and mental suffering and injury.
- Risks do not exceed the humanitarian importance of the problem the research will solve.
- Cultural diversity considered to ensure participants understand the purpose of the study.
- Adequate provisions taken to protect participants.
- Involve scientifically qualified, well trained and properly supervised individuals in the research team.
- Protocols will be submitted for approval to appropriate ethical and scientific review committees.
- Research procedures involving human subjects will be submitted for approval to an independent ethics committee *before* research begins.
- Research and related procedures will be conducted in adherence to the protocol that received scientific and ethical approval.
- Any alterations to the protocol will be re-submitted for ethics approval.
- Special attention will be paid if the research involves vulnerable subjects.
- Subjects will be informed their participation is voluntary and they are at liberty to withdraw from the research at any time without explanation and/or prejudice.
- Research will be terminated at any stage if there is any reason to believe harm is being caused to the subjects/participants.

- Participants will be provided with the option to receive the results of the study in which they are participating.
- The consent form has two parts: (a) a statement describing the study and the nature of the subject's involvement in it; and (b) a certificate of consent attesting to the subject's consent. Both parts should be written in sufficiently large letters and in simple language so that the subject can easily read and understand the contents. As far as possible, medical terminology should be avoided in writing up the consent form. (These should be included in the proposal appendices).
- It is not anticipated that any participant could suffer harm in this study.

Example

In conducting this study, we will follow the key principles of ethical conduct of research. In the current proposal, we propose to conduct an intervention that we are not certain will work at scale, nor are we certain of the impact (i.e. there is equipoise). Therefore, we have incorporated a control group into our research design. Another key ethical concern is beneficence and justice. The intervention is not invasive and no risks to patients are expected. This intervention may in fact benefit the most vulnerable populations, such as pregnant women and newborn babies. Within this group, it is mainly designed to ensure the poorest can access health care delivery, in case of danger signs, or in case of a sick baby. Efforts will be made to improve health units to support referral in both intervention and control areas.

A rigorous consent process will be put in place. Approval will be obtained from the district health teams and from the local communities including community groups, traditional birth attendants (TBAs), and community leaders following a detailed sensitization about the goal and objectives of the study, the implementation strategy and the evaluation processes. For the evaluation component, informed consent will be requested from study subjects and the local community, and confidentiality will be assured. No patient-specific data will be collected apart from aggregated figures (e.g. such as the number of women delivering at health facilities). This data will be collected from registers, which are routinely maintained by health facilities. In addition, such data will be restricted to the medical care staff and the investigators directly involved in the study, and the study team records no names. During the study period, anybody in the community found sick by the study team will be referred appropriately.

For the evaluation stage of the intervention, uptake and mortality surveillance consent will not be sought from the subjects. The subjects will be free to accept or refuse, and where necessary, women will be free to consult with their husbands and/or community members before consent. The Safe Deliveries study and the Uganda Newborn Estimated Survival Time (UNEST) already have ethical approval from Makerere University School of Public Health (MUSPH) Institutional Review Board (IRB) and from the Uganda National Council for Science and Technology (UNCST). The current protocol will again be submitted to the same bodies for amendment of ethical approvals. The study will continue using the existing Data Monitoring and Advisory Board, which has been serving both the Safe Deliveries study and UNEST. The DMSB members are local experts, all with PhDs in their respective fields of specialty, and have strong policy linkages. The DSMB will meet annually. The study will be registered as a trial both locally and internationally.

Protocols for social science research involving human participants are subject to review, and necessitate approval, of both a local/national institutional review board (IRB) and where the research is funded by WHO, WHO's Research Ethics Review Committee (ERC), which has

the responsibility for reviewing the ethical aspects of proposals for research involving human subjects that are funded or otherwise supported through WHO. ERC's website can be consulted at http://www.who.int/rpc/research_ethics/en/.

Example consent forms

Templates for consent forms can be found at the WHO research policy page (http://www.who.int/rpc/research_ethics/en/). These templates should be adapted to the local situation in which you elicit informed consent. Please make sure that you use the letterhead of your research institution, not that of WHO's Research Review Ethics Committee.

Ethics checklist

Checklists and other guidance documents for preparing proposals in the manner recommended by WHO's Research Ethics Committee (ERC) are available online at http://www.who.int/rpc/research_ethics/guidelines/en/. Remember to provide all necessary documentation and annexes. The protocol should provide the necessary information and details to comply with the questions proposed in the checklist. Also remember to attach any necessary explanations either in the proposal or relevant accompanying documents.

3. PROJECT PLAN

In this session you will work on your project plan, developing a timeline, describing the research team you need to effectively carry out the research project, and creating and justifying the project budget.

After completing this session, your team will be able to:

- Develop a project plan (work plan/timeline) to guide the implementation and monitoring of your project.
- Develop a work schedule (or GANTT chart) to effectively implement and monitor your project, including the tasks and activities to be performed, roles and responsibilities of team members, as well as main milestones/deadlines to be met.
- Describe the research team (including the knowledge and skills that each team member possesses and how they will contribute to the success of the project).
- Develop a realistic, itemized budget linked to specific objectives and activities.
- Provide information required for the justification of various budget items.

Planning the IR project

A project plan presents a clear indication of the time frame for the project and when each aspect of the project will be implemented. Often a work plan or timeline is displayed most effectively in a graphic, table or spreadsheet. If done well, your timeline will help demonstrate the feasibility of the project in a very visible way. The work plan will identify tasks (i.e. developing surveys, conducting a needs analysis; administering surveys; conducting interviews; developing curriculum; administering an evaluation); when the activity will take place (often over a time period); and by whom (responsibilities and accountability).

Rationale for project plan

There are several important reasons for project planning and its value cannot be overstated. A plan establishes a common goal for the project and a clear understanding of the research process. Effective planning:

- facilitates the development of a project focus;
- ensures consensus around a project development strategy and plan;
- ensures ownership of the project;
- ensures everyone understands who is doing what, when, and how each action impacts the project as a whole;
- enhances teamwork and transparency;
- facilitates project monitoring and identification of issues;
- facilitates project evaluation and reporting;
- provides management/donors with key information for project review.

A project plan identifies each task and activity that will be completed throughout the duration of the project. The plan establishes expectations of team members and standards that must be met. Individual team member's responsibilities are outlined as well as timelines for when each task or activity will be completed. The project plan establishes the magnitude of the project in order to be able to develop an appropriate budget to carry out the plan. It helps anticipate or identify potential barriers or constraints in adhering to the timetable, implementation and/or completion of the project and suggests possible solutions. This is a document that facilitates communication

between and among stakeholders, coordinates procedures, teamwork and collaboration. Your research design and procedures will be instrumental in identifying the tasks and activities that need to be completed in your project plan. In summary, the project plan facilitates systematic monitoring of your project.

Phases of an IR project plan

Project plans are generally presented in three major phases (see Table 12): the planning, implementation and follow-through phases.

Table 12. Main activities associated with project planning phases

Phase	Main activities
Planning	• Organize the research group and advisory committee • Determine issues or problems to study and frame the research question(s) around these • Develop a research proposal • Obtain ethical clearance • Identify funding sources and obtain support for IR • Establish budget and financial management procedures • Plan for capacity building and technical support
Implementation	• Monitor the project implementation and maintain quality • Pre-test all research procedures • Establish and maintain data management and quality control • Explore with stakeholders interpretations and recommendations arising from the research findings
Follow-through	• Develop a dissemination plan • Disseminate results and recommendations • Document any changes in policy and/or guidelines that resulted from the research • Monitor changes in the revised programme • Consider ways of improving the programme that can be tested through further research.

Project timelines

The project's total duration should realistically reflect the time needed to carry out each phase of the project plan. Be sure the plan takes into account the time required for staff recruitment and equipment purchases. The project plan should outline:

- work schedules;
- a description of the tasks to be performed;
- schedule and deadlines within tasks;
- people assigned to the tasks;
- The number of person-days required to complete each task.

The duration of a project has serious consequences in terms of meeting deadlines for deliverables and the final report. Project planning must follow rigorous project management standards. There are commercial software packages available to help prepare and monitor the implementation of a work plan.

Project plans can be presented in a variety of ways (Figures 3–5). Choose the most appropriate style for your particular project's needs, for example: bar chart/Gantt chart.

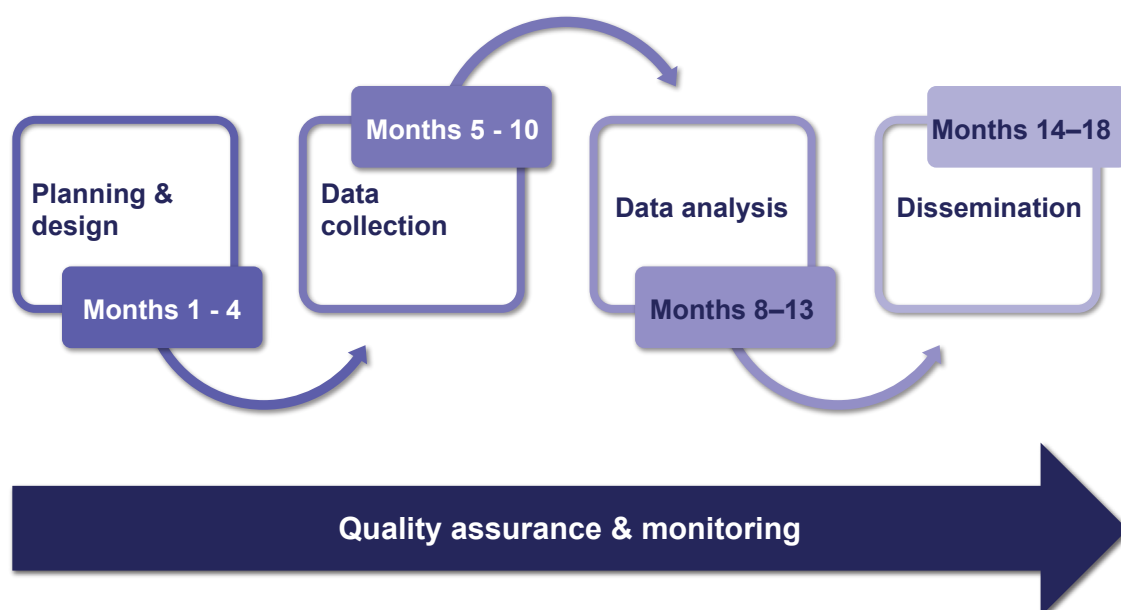


Figure 3. IR project timeline (example)

Year 1			Month							
Activities	Responsible	Supervision/ Support	1	2	3	4	5	6	7	12
1. Preparation										
1.1 Ethical Clearance	1									
1.2 Finalize TSA	1									
1.3 Recruit Researchers and Review Task Assignment	1									
1.4 Instrument Development	1									
1.5 Hiring Field Personnel	1									
1.6 Briefing Research Site Personnel And Authorities	1	/3								
1.7 Local Approval Meetings	1	/3								
1.8 Set Up Bank Account and Field Financial Procedures	1									
1.9 Training Field Personnel and Local Support	2,3	/7,8								
1.10 Pilot Study	2	3/7								
1.11 Final Refinement of Instruments	1	/2								
2. Data Collection, Entry and Analysis										
2.1 National and Regional Policy and Health Services Assessment										
2.1.1 Archival Record Research	3	1/								
2.1.2 Key-Interviews	3	1/								
2.2 Local Health Delivery Assessment										
2.2.1 Archival Record Research	3	1/								
2.2.2 Key Interviews	3	1/								
2.3 Environmental/Water Management Study	4,5	/8								

Figure 4. IR project GANTT chart (example)

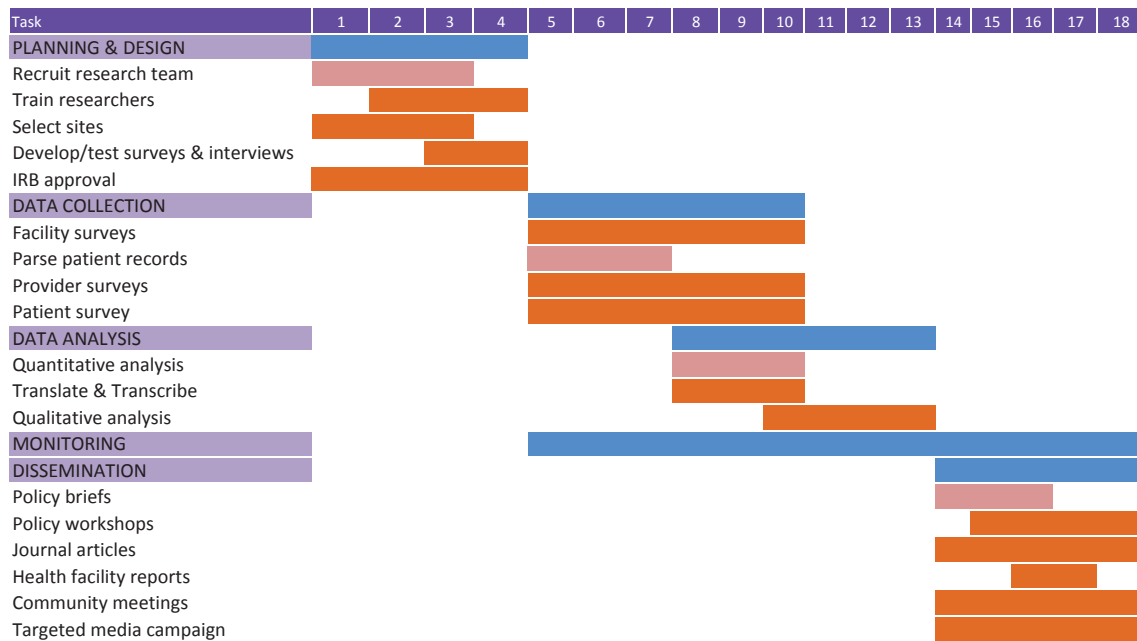


Figure 5. IR project GANTT chart (example)

Research team

The Research team section of your proposal should succinctly describe the members of your team and the assets they contribute to the project. This team will be multidisciplinary and diverse (researchers from academia, health care providers, program implementers, social scientists as well as members of the community). This section should convince the reviewers you have enough expertise on your team to conduct the proposed research effectively. In addition, the proposal needs to include the detailed roles and responsibilities for each of the key team members.

Starting with the principal investigator (PI), list the names of all individuals who will be involved in the study. Include all collaborating investigators, community research partners, research assistants, individuals on training, and support staff. The proposal also includes any “to-be-appointed” positions. Identify the experience and expertise of each team member and how their knowledge and/or skill are essential and add value to the effective completion of the project. Finally, include the role and responsibility of each individual listed on the project.

The members of the research team usually include:

- principle investigator
- project manager(s)
- multidisciplinary key researcher (public health specialist, statistician, social scientist, etc.)
- research assistants
- community members
- collaborators
- advisory committee

Proposals should also include outlines/summaries of the planned research team management structure (see Figure 6 for example) and descriptions of respective roles and responsibilities of team members (see below).

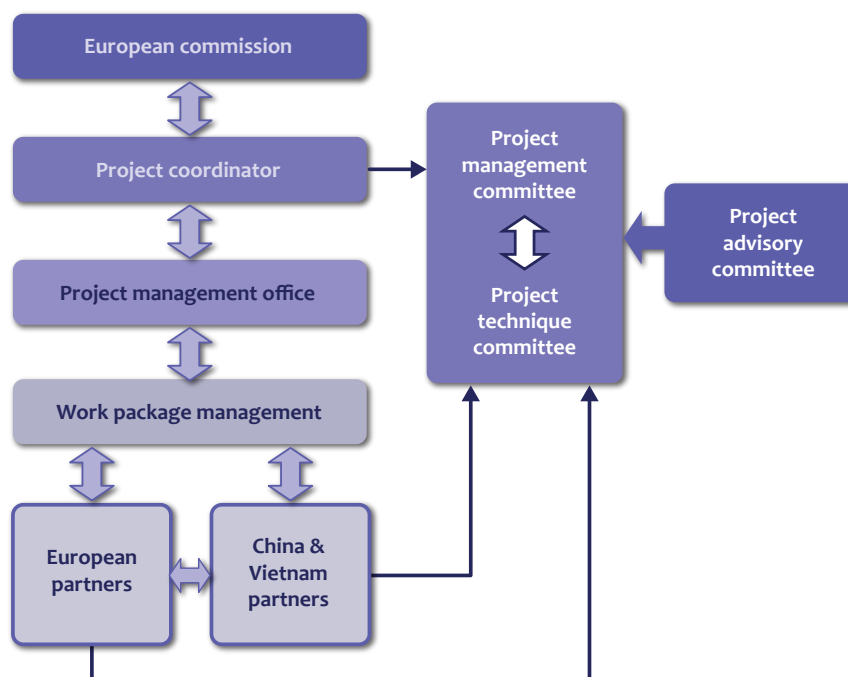


Figure 6. Research team management structure (example)

Example 1. Team roles and responsibilities

Principal investigators: United States (2)

- *Oversee research conceptualization, design and implementation*
- *Liaise between key collaborators, community leaders and research team*
- *Recruit researchers*
- *Supervise community meetings and policy dialogue workshops*

Researchers: United States (2)/Tanzania (2)

- *Analyse data*
- *Train research assistants*
- *Quality assurance*
- *Monitoring and evaluation*
- *Research assistants: Tanzania (10)*
- *Conduct interviews*
- *Collect data for surveys and audits*
- *Enter data into database*
- *In-country coordinators: Tanzania (2)*
- *Administrative assistants: Tanzania (2)*

Example 2. Team roles and responsibilities

ABC University School of Public Health is the applying institution and has the overall responsibility for the project including the day-to-day implementation and management. The school has a financial department that will be responsible for all financial management and reporting requirements in collaboration with the Department of Health Policy Planning and Management. In addition, ABC University School of Public Health, in collaboration with the Ministry of Health, will be responsible for organizing dissemination activities and meetings. The School of Public Health has a strong and long-term linkage with policy and the ministry of health and other key partners, such as WHO, UNICEF, USAID, districts, and the local communities, and is the leading public health academic and research institution in Uganda.

Research team composition

The team comprises a multidisciplinary selection of national and international specialists who will provide the skills that are necessary for the effective design, implementation, evaluation and dissemination of findings that will inform the scale up of maternal, newborn and HIV-related studies, as well as guide the implementation of ongoing programmes. The PI is an epidemiologist who has 10 years' experience working as a district medical officer/MoH and is currently a PI for the UNEST study and lecturer at the School of Public Health. He has also played a key role in several other health system projects. Other members include Dr Jane Doe, a medical officer for reproductive health in the MOH. She will be the main link to policy and, together with the district medical officers, she will provide technical advice that will be crucial for ensuring that the study is aligned with the country's priorities, policies and plans. In collaboration with several local NGOs, Dr Doe also plays a role linking the research team with the relevant policy-makers and providing expert advice on aligning the project with the country's newborn-related priorities.

Other team members from Uganda include Mrs Claire Smith, a health economist and maternal health specialist and Dr David Johnson, a health systems expert with over 30 years of experience. They will be jointly responsible for the costing aspect of the study, as well as the designing of the demand-side financing scheme. Dr John Smith, a consultant obstetrician at CDE University, will be responsible for the training and support supervision of health workers. Dr Jane Davis, a statistician, will be responsible for the design and implementation of the baseline and end line survey. Jane Johnson, a communication specialist, will be responsible for ensuring that study findings are communicated to policy-makers appropriately and in a timely way. The international research team members include John Doe (JHU, health systems expert) the director for the Future Health Systems Program Consortium, Jane Smith (JHU, newborn specialist), David Johnson (JHU, maternal health specialist) and Claire Davis (KI, health systems and policy specialists). They will all play the role of providing technical advice to the team during the design, implementation and evaluation of the study. All research team members will participate in the writing of manuscripts.

The project will recruit two field coordinators, with priority given to those in existing projects, experience already gained and an excellent rapport with the districts and local communities.

Group activity

In teams, use the examples from real IR proposals to reflect on the content presented during the past hour or so, and draft the following sections in relation to your own project:



- The three phases of IR planning.
- The work plan/time line of activities (you can use a simple flow chart or GANTT chart approach).
- The research team, including expertise and roles (a table is one way to display this information effectively).

Budget and Justification

The budget should outline the funds required to be able to effectively conduct the proposed research. You will need to carefully think through what you realistically need from the funding agency(ies) to carry out the project. If your budget is too low or inflated, it can negatively influence the judging of your proposal. One way to assess this is to ask if it is possible to reduce a budget without compromising the quality of the research.

Information such as required funding for each phase of your project is important to outline. Check to see if the funding agency has any restrictions before preparing the budget. Ensure that the budget is presented in the indicated currency, for example. Check with the agency to see if they have suggested/required budget categories that must be used.

If the potential funding agency doesn't have any suggested/required budget categories, organize your budget around a set of meaningful categories that work for your specific project. The types of resources you budget for should align with the proposed activities in the research design. The budget will need to supply the resources necessary to deliver all the proposed research and intervention outputs. Begin by using the project plan to identify the budget you will require for each activity or task. Once each resource is itemized, the unit cost and total cost for the resource can be indicated. Make sure to provide an itemized budget with a detailed breakdown of the funds requested. The budget information should be complete and unambiguous.

If the project plans to extend an intervention to a control population after the study, this also needs to be planned and budgeted for. It is important to also budget for dissemination and evaluation of related activities and outcomes. Find out whether there will be any inadmissible items such as overhead costs. Inflation and currency fluctuation in exchange rates and contingency might affect the budget and final available income. It is important to include mechanisms that will help take care of this.

Budget categories

Categories you may want to consider for itemizing your budget include:

- personnel (salary and benefits)
- researcher (time, salary and benefits)
- training
- consultants and/or resource person (salary)
- instruction
- equipment

- supplies (e.g. paper, toner, batteries, publication cost etc.)
- communication (telephone/postage/Internet/media)
- materials preparation (software, medical supplies, copying and printing)
- travel and subsistence
- community liaison
- rental of facilities
- evaluation
- indirect costs (costs that your organization requires you to include)
- other expenses (lunches for meetings, interviews etc.)

Budget justification

Justify each and every budget item, starting with how the budget items were derived in relation to the activities to be undertaken in your research design. Pay particular attention to major or unusual items (some funding agencies might require extra explanation for anything considered to have major cost). Provide details of additional sources of funding available to the organization or principal investigator. If the funds will go to different institutions, indicate allocation of funds by site.

Example: Budget justification information

Personnel (salary and benefits)

Regardless of the number of months being devoted to the project, indicate only the amount of time (usually in days) being requested for each individual listed for each budget period. Provide names (if known), position and salaries, including percentage for fringe benefits if such benefits represent actual costs to the employer. Fringe benefits should follow institutional guidelines and an understanding of what is/not allowable by the sponsor. Also, make sure to include those who are involved in the project but are not paid (or are not being paid out of the proposal budget). If you plan to involve consultants or other outside personnel, make sure to include all associated costs in the budget.

Provide the names and organizational affiliations of all consultants (include members of external monitoring or advisory committees). Describe the services to be performed under budget justification (number of days, rate of compensation, travel, per diem and other related costs).

Supplies

List the costs of the various categories of expendable supplies (e.g. paper, toner, tapes, film, batteries, printing costs, other field supplies). Itemize supplies in separate categories with amount requested. Justify each purchase.

Equipment

List each equipment item with the amount requested. Include equipment maintenance. Provide justification for each piece of equipment in relation to the work proposed. Identify any piece of equipment considered as major equipment (e.g. major equipment might be any equipment costing more than US\$ 1000) and provide additional information if required.

Patient (research subjects) costs

Explain the nature of the costs (e.g. transportation, drugs for field trials) and method of calculation. It is important to check on limitations linked to the funding organization.

Give details of the locations where patient care will be provided and the budget allocated to each site. Indicate, in detail, the basis for estimating costs, including the number of patients, days of treatment, cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site. Include patient travel, patient participation incentives, etc.

Travel

Itemize each travel item. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested. Include the costs of local transportation and field research expenses necessary for carrying out the proposed research. List separately the costs of transportation, subsistence allowance (indicate the scale paid by the institution) and any other costs (specify). Check on limitations linked to the funding organization. Also, some organizations might require separate international and national/local travels cost. Include lodging and subsistence expenses for field workers. Justify the number of trips per year and relate them to individual's tasks. If samples will need to be transported from the field to a lab, indicate how this will happen and the costs involved.

Field costs

Indicate whether there will be a need for renting or purchasing a vehicle and provide detailed justification for why a vehicle is needed. Also make sure to include associated fuel, insurance and maintenance costs. In case a vehicle will be purchased, indicate what will happen to it once the project ends.

Overhead

Find out whether the funding organization will cover overhead costs and include this in the budget accordingly.

Other expenditures

Itemize any other expenditure required for the proposed research to be carried out. This might include things such as insurances cost, outsourcing, publication costs, computer charges, rental and leases, service contracts and communication costs, especially if the work involves many countries/institutions. It is important to note that some organizations do not provide funding for things listed as miscellaneous or other. Make sure to clarify this with the funding organization before submitting the budget.

Group activity

In your IR teams, review the sample IR proposal budget provided by the facilitator(s). Using the information covered in Session 3 and the example budget as a guide, develop a budget for your team's IR proposal.



4. IMPACT

In this session, the sections of your IR proposal that address measures to ensure quality standards in your research project will be reviewed. Specifically, after completing this session you will develop:

- monitoring and evaluation plan for your IR project
- capacity-building plan
- dissemination plan

Considerable effort must be made to ensure that your proposal clearly demonstrates how your research findings will have an impact on the health and/or health care of the communities/populations concerned, policy-making, and on research communities. For example, how will your proposal demonstrate that your research team has:

- Acknowledged, monitored and planned for competing priorities, limited logistic capacity, a lack of political will, and/or inadequate infrastructure and resources – all of which could affect health care packages from being delivered to those who need them most?
- Planned for developing and maintaining capacity building in your IR project to facilitate the adoption of evidence-based health interventions in developing countries?
- Demonstrated that you will disseminate your research findings to ensure your project will generate research evidence to inform policy and programme implementation?

When developing a typical research/academic proposal, the intent is to generate new knowledge and ideas. Conversely, when developing an IR proposal, the intent is to generate research evidence to inform policy and programme implementation. Despite the growing knowledge base on evidence-based practices in health care, there is a large gap between what is known as a result of research and what is consistently implemented in practice. Why is there such a wide gap between what we know and what we do? The fact that it can take years or even decades for research findings, best practices and guidelines to be implemented into health care workers' daily practice is one of the stimuli behind the IR 'movement'.

Utilization of research results is the core purpose of IR. Translating evidence into health care practice requires a monitoring and evaluation process to ensure quality and improve health outcomes. Your proposal should demonstrate that your project will facilitate the adoption and integration of evidence-based health interventions and change practice patterns, particularly in developing countries. In order to be convincing, your proposal should demonstrate that you have considered the complexity of the situation and environments where the research will take place.

Monitoring and Evaluation

A monitoring and evaluation plan:

- Describes exactly how it will be assessed whether or not the project meets its objectives and delivers what has been promised in the proposal.
- Informs the prospective funding agency their investment is/was sound.
- Facilitates the use of research findings for implementation of evidence-based practice and thus improves health outcomes.
- Examines the difference between the implementation effectiveness and efficacy of health intervention.

Monitoring activities

Monitoring activities in your proposal include: steps you will take to assess the progress of the project (e.g. recruitment rate, the extent to which timelines are being adhered to, deadlines concerning required reports to donors etc.) so that any problems or issues can be detected early and any essential changes or interventions can be made as soon as possible.

Monitoring activities include identifying aspects of the project that need to be observed, who is responsible for the various activities and the organization of the monitoring activities. Such monitoring activities are usually associated with specific milestones or timeline events within your project. When identifying your project timeline, consider including your specific monitoring activities. For example, at milestone X you will report on Y.

A description of the monitoring component should include the following:

- Identifying the resources needed for the project, including staff, equipment, supplies, logistics support and funds, and the precautions you will take to ensure these resources will be appropriately used.
- Adherence to the research design procedures to ensure they are being followed correctly and in a timely manner. This includes how you intend to monitor the roles, responsibilities and activities of each team member in relation to the project as a whole in order to ensure the work plan will be carried out as envisaged. Measures that will be taken to identify delays or difficulties.
- Connections between the intervention and quality of data.
- Plans for how the research team intends to communicate and coordinate with the study population, other collaborating groups and/or funding authorities.

Evaluation plan

An evaluation plan should be included in your proposal, outlining exactly how you will demonstrate whether or not your project meets its objectives and was 'successful'. Many research proposal criteria stipulate that approximately 10% of total budget should be designated to evaluation. Often research teams hire a consultant to conduct their evaluation. In your IR proposal, indicate whether the evaluation will be conducted by an internal team member or an external consultant.

The evaluation plan demonstrates how the research objectives will be met and indicates how you intend to keep close track of changes in the project plan and problems encountered and solved (or not solved), so you can inform the stakeholders and include this information in the preliminary report. An evaluation plan should also consider the following:

- Identifies who will use the evaluation findings.
- Describes information needed, sources and evaluation methods/instruments.
- Examines how the project objectives will be met.
- Tracks the expected impact of the intervention.
- Demonstrates that the scope of the evaluation is appropriate.

The evaluation plan will indicate to the prospective funding agency how you will demonstrate that their investment in you will be a good one. If you plan to use a survey or questionnaire to help evaluate the success of your project, include a draft of your evaluation tools in the appendices.

Monitoring and evaluation assesses the success and impact at various stages of the project. Various approaches have been used to measure how well a treatment, programme, or service has been effectively implemented. Some evaluation strategies infer implementation success by measuring clinical outcomes at the client or patient level, while other studies measure the actual

targets of the implementation, quantifying for example the desired provider behaviours associated with delivering the newly implemented treatment. Proctor et al. (6) define implementation outcomes as the effects of deliberate and purposive actions to implement new treatments, practices and services. They propose incorporating the following eight conceptually distinct implementation outcomes into the evaluation plan: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration and sustainability.

Include both a concern for formative or process evaluation (evaluation while the project is being conducted) and summative evaluation or product evaluation (evaluation that is conducted during/ at the end of the project to demonstrate the project fulfilled what was originally proposed). If your project is more than one year long, you may want to stipulate that you intend to have annual evaluations and reports. Make direct reference to your research objectives in your evaluation plan, in order to highlight consistency within your proposal.

Your evaluation plan should include a sense of concern for what goes on following the conclusion of the funding period. How will the initiatives that have been started under your project be sustained in the future? How will other cooperating agencies assist in continuing the project after the conclusion of the funding period? To facilitate uptake of your research findings, your proposal should indicate how you intend to inform all stakeholders of your research findings at all stages of the research.

Monitoring and evaluation tools

Monitoring and evaluation strategies that can be implemented to facilitate the quality of your research project include:

- Information log: keeps track of feedback from stakeholders, related news stories reported and articles written, and the number of times research has been cited in the academic literature.
- A survey: conducted with stakeholders from the target audiences to provide feedback. For example, questionnaires can be sent via email six months and one year after a dissemination event, or clients attending a family planning clinic can be asked to complete a survey regarding improvements in the quality of care.
- A series of key informant interviews with stakeholders at various levels of the health system can provide insight into if and how research was used.

One way to display an evaluation plan is to use a table outlining the research objectives or research question(s) and evaluation strategies to evaluate if the objective has been met.

Research objective	How it will be measured
Objective 1	Focus group interview to ... Pre-post surveys
Objective 2	Individual interviews with key stakeholders

Example: Evaluation of intervention process and impact

Objectives

1. *To evaluate the extent to which the revised rural health insurance schemes in the study areas were implemented as planned.*
2. *To explain why or why not implementation occurred as planned.*
3. *To evaluate the impact of the revised health insurance schemes implemented on: improving equity in access to/use of health care; reduction of financial burdens due to expensive medical*

bills; equity and extent of scheme coverage; member satisfaction; and financial viability and sustainability of the schemes.

Description of work

This work package includes a number of work tasks (WT), which aim to undertake a comprehensive evaluation of the intervention impacts, according to the research objectives.

The evaluation will include both a process and an impact evaluation. Parts of the data collection and analysis for the process evaluation will begin simultaneously with the interventions. This is to ensure that effective monitoring of the process of intervention will enable the majority of problems encountered in implementation to be identified and addressed as quickly as possible. Data from a rapid household health survey, qualitative studies, and the management information system operated in the intervention counties and districts, will be used.

WT 1. The first work task is to refine the evaluation frameworks (Figures x and y), which will be used to guide the collection of data for the evaluation. Key researchers and the members of the project advisory committee will use one of the project meetings (to be held at the end of year 2) to discuss how to refine the evaluation framework and finalize it before the completion of the interventions.

WT 2. The research team will also repeat the household health survey using the same methods, the same study counties/districts, and the same population sample as in the situation analysis and baseline survey. The survey will be conducted after completing 18 months of intervention. The questionnaire may be modified to reflect changes made during the intervention period. However, the overall contents of the questionnaire will be the same, covering household general information (e.g. family size, income, insurance membership, etc.), perceived illness (including 1–2 tracer studies – TB suspects/chronic cough patients and diarrhoea patients) and service utilization and expenditure, and reasons for not using services needed, as well as patient satisfaction with services. After completing the survey, all the questionnaires will be entered for analysis based on the evaluation framework developed.

WT 3 Qualitative data will also be collected and analysed, including: focus group discussions using participatory techniques and in-depth individual interviews (with the same social groups in the target population as those consulted in the situation analysis); focus group discussions and in-depth interviews with health service providers at county/ district levels and below, health policy-makers at national and local levels, rural health insurance scheme managers and relevant non-health policy-makers at local levels; semi-structured direct observation will be carried out in selected facilities to assess and compare the behaviour of health staff towards patients who are members/non-members of the revised schemes

WT 4 The relevant data from the management information system operated in the designated health facilities and the insurance fund management organizations will be collected and analysed in line with the evaluation framework.

Deliverables

- *Evaluation framework finalized*
- *Report on impact evaluation of the interventions in the two countries*

Milestones

Finalising the evaluation framework by project month (PM) 20 and writing up the evaluation report by PM 46.

Expected results

More equitable and sustainable health insurance schemes tested in the study areas upon which policy recommendations can be made for the governments of two countries.

Capacity building

Restricted research capacity has been identified as one of the constraints to addressing health care priorities in low- and middle-income countries (7). Generating appropriate, trustworthy evidence depends on the existence of good research organizations. Capacity-strengthening strategies need to focus on the comprehensive needs of institutions, including overall skills and career development, development of leadership, governance and administrative systems, and strengthening networks among the research community, both nationally and internationally.

When writing your IR proposal, two specific considerations may help address capacity building:

- How the project can help improve the research capacity of national and local institutions involved, via training, mentorship, etc.
- How the project, via the process of the implementation, can help increase the capacity of using research evidence for policy- or decision-making by key stakeholders, such as government officials.

Example: Research capacity development

The development and strengthening of research capacity for both partners from China/Viet Nam and Europe will be a continuous process throughout the implementation of the project. The following are key activities aimed for research capacity development.

Each partner should analyse its current situation of research capacity and the gap between what research skills and capacity are required and what are available. A strategy for research capacity building for all the partners involved will then be developed and approved in the first meeting of the project management committee. In light of this strategy, a detailed plan for research capacity building will be developed in the first half of Year 1. The plan will include a system of mentoring and supervision for junior researchers from both developing countries and European countries, and exchange of visiting researchers between Chinese/Vietnamese partners and European partners. The issue of gender will be taken into account in developing such a plan.

A number of appropriate strategies will be used to build up research capacity, particularly for the two developing countries during the project implementation. Researchers from those countries will be invited to visit European partners during the period of the development of study design and research instruments, and data analysis and report/paper writing. While they are with the European partners, these junior researchers will attend a programme aimed at developing their skills in research techniques relevant to the project and analytical issues related to health system development in general and health insurance in particular. Wherever possible, junior researchers will be encouraged to register as Masters/PhD students in their own institutions, with joint supervision by senior researchers from China/Viet Nam and European partners. Junior researchers from European partners will also be encouraged to spend adequate time working in the study field to gain direct experience of undertaking research in developing countries. Junior

researchers from all the partners will also be encouraged to be involved in project management activities in order to enhance capacity of research project management. The strengthening of research capacity of EU partners will ensure a common understanding of key elements of the research, including gender-specific qualitative and quantitative methods and data analysis, health policy analysis, health economics models, etc.

Dissemination plan

An important aspect of your proposal will be the plan for disseminating information of/from the project. Most funding agencies are interested in seeing how their financial support of your project will extend to other audiences. Therefore, your proposal should include a section on Dissemination and will include the kind of dissemination you plan to carry out, and where you intend to disseminate your research findings.

Information dissemination strategy

- To ensure you communicate research information, plans and findings most effectively to stakeholders, answer the following questions:
- What are the objectives of the dissemination strategy?
- Who are the target audiences?
- What are appropriate channels of communication?
- How will you assess information uptake and use?
- What are the most useful tools or products? (e.g. policy briefings, research reports)

Dissemination activities typically include:

- 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.
- Policy advocacy briefs.
- Use of life history interviews of patients in advocacy work (with the permission of interview subjects).
- Annual reports.
- Media (e.g. radio broadcasts, press releases, newspaper articles etc.).

This section of the proposal should include:

- An estimate of the number of refereed and professional publications you intend to develop during each year of the project (including the names of journals you will submit to and professional journals, newsletters, printed hand-outs, policy reports and other publications intended);
- The number and names of the academic and professional conferences you intend to attend each year;
- Educational or informal community presentations you propose to make during each year of the project (including workshops or training programs; information sessions; policy briefings; press conferences; slide shows etc).

It is often better to 'under-promise and over-deliver' in this regard. Proposals that make elaborate claims (especially without similar track records to support such a publication or dissemination record) tend to lose credibility with reviewers.

Too often, research findings are published in relatively esoteric /highly specialised journals intended for or likely to be understood by only a small number of people with a specialized knowledge or interest and, that are largely only read by other researchers. Disseminating the research findings to all stakeholders in a format suitable for the target audience (key messages) is essential to ensure better use and uptake of research findings.

Group activity

Review the sample dissemination plan (below). What aspects of this dissemination plan may be helpful to consider for your IR proposal? What aspects would not be appropriate?



Example: Consulting with, and disseminating findings to, national policy-makers

The involvement of regional/provincial and national policy-makers throughout the research process is a crucial factor for the success of the project because attaining the expected strategic impact of the research depends critically on them taking up the research recommendations. The following methods will be used to identify key policy-makers, consult with them and communicate the final project conclusions and recommendations to them:

- A stakeholder analysis will be conducted at the beginning of the project and involve the following:
- A project workshop in Project Month 2.
- Key stakeholders identified will be invited to attend joint research planning workshops between both study countries, including the situation analysis and study baseline design workshop in Project Month 4 (see WP 2).
- A workshop to discuss the findings of the situation analysis and discuss possible revisions to existing schemes in Project Month 12 (see WP 3).
- A workshop to present and discuss the preliminary findings of the evaluation of the revised schemes in Project Month 42 (see WP 6).
- A workshop presenting the final study findings in Project Month 47.

Policy briefs will be developed, and aimed at policy-makers and managers at different levels, including regional and national policy-makers. Consultations with primary stakeholders will occur, and they will be provided with full project findings in due course. The primary project stakeholders are the target population, providers of health care and providers of health insurance in the study sites. These groups will be consulted and informed of the findings in the following ways:

- Representatives of primary stakeholder groups such as farmer's associations, and grassroots women's groups will be invited to join the initial project start-up workshop.
- Further consultation will be carried out with these groups prior to the redesign of health insurance schemes through qualitative data collection as part of the situation analysis.
- The preliminary findings of the evaluations of the pilot schemes will be disseminated to representatives of these stakeholder groups through a workshop in month x to enable them to comment on the findings and appropriate recommendations.
- The final study findings will be communicated to these stakeholders through the development and dissemination of appropriate materials such as radio broadcast slots and newsletters.

- Consulting with and disseminating the project findings to international policy-makers and researchers.
- In order to inform the design and implementation of more sustainable, equity-oriented health insurance schemes internationally, it will be important to ensure that the study methodology will produce information on the specific questions and indicators of concern to international policy-makers. The project will involve representatives of international policy makers and their advisers on the technical advisory committee, which will meet twice a year to discuss plans and review results.

The study results will be disseminated more widely through a number of mechanisms, including:

- Submission of academic papers for publication in national, regional and international high impact peer-reviewed journals.
- The production of policy briefings for international policy-makers.
- The presentation of papers at relevant regional and international conferences attended by the health research and policy making community.
- Submission of the final research report to the EU.
- Web-based dissemination of project findings through a project website and submission of the project findings to research dissemination websites such as ID21.
- Presentation to community members, academia, district and regional health teams and other relevant stakeholders.

Write-shop

During the evening, work in your teams to develop the following aspects of your team's IR proposal:

- Monitoring and evaluation plan
- Capacity building plan
- Dissemination plan
- Make any changes necessary to improve, update, or align all sections of your proposal



5. SUPPLEMENTS

In this session you will develop several of the final sections of your proposal. Specifically, information on the project summary, table of contents, appendices, and your researcher CVs will be covered. You will have a write shop to prepare these aspects, and review all the previous components and update and align your entire proposal. Finally, you will prepare a 20-minute presentation and present and receive feedback on your IR proposal.

By the end of the session, participants will be able to:

- Develop a proposal summary
- Develop a table of contents
- Identify which appendices need to be included
- Develop a template for your CVs
- Prepare a 20 minute presentation summarizing your IR proposal

Project summary

An IR project summary (sometimes called an abstract or an executive summary) briefly describes the entire proposal. Researchers often write their summary or abstract last, when they are best able to concisely describe their research proposal. The summary should include a description of the problem under investigation, a rationale for why the research is needed or important (situated in the literature), the participants, the methodology, the research activities to be undertaken and the expected outcomes or implications of conducting the research. Depending on the requirements of the funding agency, your summary/abstract may be limited to anywhere from 150–200 words (abstract) to a page (summary). Like a research report or journal article, your proposal summary or abstract might be the most important paragraph/page of your proposal because it will be the first thing most reviewers come into contact with when reviewing your proposal. The summary will create the ‘first impression’ with reviewers and may influence whether reviewers choose to fund your proposal or not.

Example: IR project summary

Proposal title: Bringing health care to the vulnerable – developing equitable and sustainable rural health insurance in China and Viet Nam

Proposal acronym: RHINCAV

Overall objective: The goal of the project is to contribute towards poverty reduction and health improvement for people living in poor rural areas of developing countries. The overall objective of the project is to promote equity in health by making evidence available for health policy-makers for an effective, sustainable and affordable rural health care financing system in China and Viet Nam.

Specific objectives

- 1. To carry out a situation analysis of perceived needs for rural health insurance and strengths and weaknesses of existing schemes.*
- 2. To develop and implement pilot rural health insurance schemes that are feasible and meet the perceived needs of their target populations.*

3. To monitor and evaluate the effects of the new schemes from the perspectives of equitable coverage, user satisfaction, efficient service utilization and provision, poverty reduction and sustainability.
4. To support the design and implementation of sustainable, equity-oriented rural health insurance schemes by effective dissemination of the research findings.

Abstract

A growing number of developing countries are developing health insurance schemes to protect people, particularly the poor, from financial catastrophe caused by expensive medical care. Among them are China and Viet Nam, which have experienced rapid economic development and dramatic social changes over the past two decades. All these changes have had profound implications for every aspect of people's lives. Health care financing reforms in the two countries have led health facilities to rely increasingly on user charges, which have resulted in greater financial difficulties in accessing health care, especially for the rural poor.

Although the central governments of both countries have promoted the development of rural health insurance for many years, the population coverage has been far from satisfactory, due to many political, socioeconomic and managerial factors. The proposed research will promote equitable health care financing mechanisms in the two countries by developing and disseminating an evidence base for the design and implementation of sustainable and acceptable rural health insurance schemes. The research project will adopt a case study approach in which a number of study counties and districts where rural health insurance schemes already exist will be selected for implementing revised schemes that are feasible and meet the perceived needs of their target population. It will monitor and evaluate the effects of the schemes from the perspectives of equitable coverage, user satisfaction, efficient service use and provision, poverty reduction and sustainability. It is expected that the final project results (good practice and lessons learnt) will be disseminated to a wide audience and used to inform relevant policies on rural health insurance in China, Viet Nam and other developing countries.

Project summary checklist

The summary should be informative to those working in the same or related fields. A good summary makes it very easy for reviewers to comprehend and evaluate your proposed project according to the review criteria. Although the criteria for a research proposal will vary depending on the funding agency, a summary typically will include a brief description of each of the following:

- The problem (what problem are you trying to solve?).
- A convincing rationale for why this problem is important (i.e. how the proposed research will advance knowledge, improve health care practice etc.).
- Where the research will take place and with whom (sites and participants).
- How the data will be collected and analysed.
- The extent to which the proposed research is innovative.
- The expected results or the impact of conducting the research.
- How the findings will be disseminated.
- The implications (change policy, improve health care practice etc. and who will benefit).

Table of contents

The table of contents organizes the proposal by outlining what is in the proposal and where each item can be found. It presents a convenient list of the topics and sections in a logical sequence 'at a glance'.

Word processing software such as Microsoft Word and Open Office, have the ability to automatically generate a table of contents. You can tag your headings with the appropriate heading style (e.g. Heading 1, Heading 2, Heading 3) and use the *Insert > Table of contents* features.

Appendices

Appendices include those aspects of your project that are of secondary interest to the reader. The reader should be able to obtain all the necessary information from the body of the proposal and will go to the appendices if they need or want additional information. Appendices may include things such as the CVs of members of the research team, research instruments, or letters of support. This is also a place to put additional information you would like the reviewers to have access to but the length restrictions prohibit space for them to be included in the body of the proposal.

CVs of investigators

The CVs of investigators have an influence on the reviewer's assessment of your proposal. You may want to ensure at least one member of your team has IR experience, a good track record and a strong publication record. Complementary qualities such as credibility in the community are equally important.

Usually agencies have a limit of 1–3 pages for an investigator's short curriculum vitae. So investigators will need to shorten their CVs to highlight the most relevant aspects of their professional/academic life to the project and to align with the scope of the funding agency. A template can help investigators to shorten their CVs and to keep them uniform.

Write-shop

In your teams develop the following aspects of your team's IR proposal:

- Project summary (one page).
- Title page.
- Appendices (make a list of all the appendices and add the ones that are ready).
- Researchers' CVs (create a template of the CV components so that all researchers have a similar look and format).
- Review all components of your proposal and update and align.



Group activity: Proposal presentation

Prepare a 20-minute presentation (slide or poster presentation) including the following aspects of your IR proposal

- Title
- Rationale
- Statement of the problem
- Research question(s)
- Research design
- Research method



- Data collection
- Data analysis
- Quality management
- Participants
- Ethics
- Project plan
- Research team
- Budget and justification
- Monitoring and evaluation plan
- Capacity building plan
- Dissemination plan

Group presentation

Present your team's proposal to the large group in 20 minutes. This will be followed by 20 minutes of comments, questions, suggestions and comments from the large group and facilitators.



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MODULE

3

**PLANNING AND
CONDUCTING AN
IMPLEMENTATION
RESEARCH PROJECT**

INTRODUCTION

This module addresses the immediate steps that take place once funding/resources for an IR proposal is secured. It provides information on planning for conduct of the research project, including preparation of the study protocol for ethical review. It covers the following key concepts with examples:

- Preparing and applying for ethical review.
- Planning for project implementation.
- Implementing good IR principles and practices.

LEARNING OBJECTIVES

The *Planning and conducting an implementation research project* module provides information on the essential steps of research execution, including: applying for ethical review, planning for programme implementation, and implementing good IR principles and practices. These processes will be illustrated using the example of an IR project.

By the end of this module your research team will be able to:

- Describe the ethical requirements and processes required to successfully submit a research project protocol for ethics review.
- Describe the related ethical processes in a project cycle.
- Systematically describe the steps needed to implement a research project.
- Appreciate the value of good practices in the full cycle of a research project.

KEY CONCEPTS

Seeking ethical clearance

Implementation research offers unique ethical perspectives in that it involves, in most cases multiple perspectives and interfaces with health services. As such, IR implementers may find it difficult to differentiate between routine health care and the research process. When the lines blur between routine health care and the research process, it may be difficult to identify the potential risks associated with the research, especially participatory research.

Research funding agencies require the approval of research proposals by the appropriate ethics review committee before project funds are released. Depending on the circumstances, ethical review may be required from more than one such committee. For example, ethics approval may be required from an institutional as well as a national ethics review committee, or by more than one research or health institution in case of collaborative projects. The ethics committee(s) will review the study proposal and require full details of the study plan and procedures. The committee(s) pay particular attention to how consent will be obtained from potential study participants, and carefully scrutinize all informed consent documents. Any changes in the study, such as adding new objectives, extending the study catchment area, adding or removing inclusion or exclusion criteria will require additional approval by the ethics committee(s). It is important to consider the ethical aspects of a research study right from the initial stage planning of the project. However, due to the fact that IR is conducted in real-life settings, sometimes certain unforeseen circumstances not considered before the project was presented for ethical review may arise.

Submission of the research protocol for ethical review

The ethics review process is essential to ensure that the research project will protect research subjects' dignity, rights, safety and well-being. Therefore, before initiating a study, a written approval of the protocol, written informed consent (preferably in the local language in which it will be administered) and defined recruitment procedures are required. The principal investigator is responsible for complying with the study protocol as agreed by the sponsor and regulatory authority (if appropriate), and approved by the scientific and ethical committees.

Table 1 outlines the documents generally required to be submitted to research ethics committees. The requirements may vary between committees so it is important to check the specific documentation and protocol requirements with the ethics committee(s) to whom you are applying.

Table 1. Documents to be submitted to the institutional review board (IRB) and/or the ethics review committee (ERC)

Cover letter briefly describing the research proposal and ethical issues involved, if any.
Full research protocol including rationale, research problem, review of literature, methodology, data collection tools, procedures and expected outcomes.
Analysis of potential risks and benefits, including protection of privacy and confidentiality.
Detailed subject recruitment process and target population.
Informed consent or assent for minors available in the local language.
Process of communicating the research findings to participants and communities.
Plan for addressing post-study obligations such as: • improvements in health care and facilities; • provision of new-proven interventions to participants; • long-term surveillance; • strengthening of local research expertise.
Curriculum vitae of the principal investigator and the research team members.
Proposed dissemination of the study results.

Ethical issues to be considered during project implementation

Ethical principles of autonomy, risk/beneficence and justice (as described in Module 1) should be adhered to during the implementation and post-implementation phases of IR projects. In this section, issues regarding informed consent, privacy and confidentiality will be discussed.

Seeking informed consent

Informed consent (IC) is recognized as a fundamental ethical requirement for conducting research involving human subjects (1). Informed consent ensures that individuals can freely make decisions to participate according to personal interest, values and priorities. The IC is more than a contractual obligation and should be understood as a process that begins with the initial contact (during the recruitment process), and carries through to the end of

participants' involvement in the project. The establishment of the process requires four basic elements: 1) accurate and appropriate information; 2) understanding the purpose of and procedures in the research process; 3) capacity to consent; 4) voluntary participation.

To have an effective consent, full information should be explained in the local language of the participants. Furthermore local/simplified words (i.e. rather than scientific and professional jargon) should be used. The consent form should also include information about the research and the procedure as well as the consent certificate (Table 2).

Table 2. Elements in an informed consent document

Part 1: Information sheet
Introduction of the investigator and his/her institution.
Purpose of the research.
Type of research intervention.
Participant selection.
Voluntary participation.
Procedures (interview, focus group discussions (FGD), where interview will take place, privacy and confidentiality issues).
Duration of the procedures/interview, the length of the intervention including follow-up.
Anticipated risks.
Benefits at different levels (individual, community or society).
Reimbursements (if necessary).
Confidentiality (note: FGDs provide particular challenge to confidentiality, because once something is said in the group, it becomes common knowledge).
Sharing of results (process that will be used to share the research results).
Right to refuse or withdraw.
Who to contact (e.g. for any additional information).
Part 2: Certificate of consent
This section must be written in the first person.
Should include a few brief statements about the research and be followed by a statement, indicating that the participant has read or the information has been read to him/her, they understand and are participating voluntarily.
If the participant is illiterate, but provides oral consent, a witness must sign.
The researcher or person going over the informed consent must sign each consent form.

Privacy, confidentiality, anonymity

Protecting the anonymity and confidentiality of research participants is another practical component of research ethics. Disclosure of personal information may, in some circumstances pose a risk of discrimination or prejudice. Protecting the privacy and confidentiality of participants is the investigator's duty (2). Protecting the anonymity and confidentiality of research participants involves adhering to ethical procedures during data collection, storage and analysis as well as during the publication process. During data collection, the participant should be accorded as much privacy as possible to ensure that the information being provided is not shared with other individuals. Unless the respondent gives permission, at no time should the identity of the respondent be disclosed to any third party during data collection, storage or analysis, or

during dissemination or publication. Identity of the respondents may be associated with Plan anonymous identifiers which cannot be linked to individuals.

Seeking ethical clearance during implementation of the project

When the ethical committee(s) issues an approval certificate it will inform the principal investigator (PI) of the need for regular reviews as described in the section below. In most study designs, the original research protocol is followed precisely. However in IR, the research team continuously monitors and reviews the intervention activities to ensure meaningful and practical outcomes for programme planning and implementation. During this process, unexpected circumstances may arise leading to changes in the original research plan (in the best interest of the project and/or the participants). In such situations, a number of amendments are likely to be made to the original proposal submitted for ethical review. The IR team must inform the ethical committee of any major changes to the original research protocol or procedures. For example when submitting a proposal for ethical review, the research team may indicate that patients be given daily injections by the nurse in charge of the facility. However during the research process, the planned injection process was not effective due to unanticipated problems. The ethics committee must be informed of any change(s) in procedure including those due to unanticipated problems. This can be done during periodic ethical reviews of the project.

Periodic reviews may be requested since most ethics committees require follow up to ensure compliance with procedure, to evaluate any protocol deviation, or to follow up with medical intercurrentence during a study. The committee proposes the frequency and procedures for follow-up and review of operations and data on a case-by-case basis.

Interim ethical review may be needed in special circumstances due to significant change in the study design or when information used for the original approval of the proposal has changed.

Final ethical review is a process whereby the project PI communicates to the ethical committee the conclusion of the project, through a progress report since last approval, a summary of study results and the future disseminations plans.

Reflection activity

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An anthropologist was conducting an ethnographic study on Buruli ulcer patients in a half-way home. The study was designed such a way that a health worker was to make a daily visit to the half-way home to administer injections. However due to the distance between the half-way home and the nearest health facility, the health worker was unable to make the necessary daily trips. Should the health worker train the researcher to give the daily injections?



Project implementation process

Implementing the project involves the process of conducting and monitoring the proposed activities, as well as updating and revising the research plan accordingly as conditions dictate. The activities include assembling the research team(s), applying for the logistical needs and allocation of activities and tasks. Furthermore, the research sites, the timeline for the research activities, and the procedures for the data collection must all be established. This phase also includes closure and evaluation of the project, as well as reporting and disseminating the processes and findings of the research. In the following section, the process involved in starting

the implementation process and ensuring quality data is described. Monitoring is a process that is interwoven throughout the implementation process of any IR project.

Starting the implementation process

When the project work plan is complete, agreed by all involved parties and approved by relevant management groups, the implementation of the project may begin. It can be very helpful to include the entire research team (including stakeholders, partners and frontline workers) in the launching of the project. The team members review the project goal, objectives, indicators and work plan. They address potential issues and set up a mechanism of communication to ensure teamwork during implementation. The team leader must ensure that the work begins on time and the agreed standards of performance are followed within the approved budget limits.

Good practices in implementation research

Implementation research must generate credible data. Good research practice can ensure credible data by reducing the risk of obtaining inconclusive results on account of uncertainty. Uncertainty arises when the intervention is ineffective or the implementation procedures are unclear (3).

Documentation of processes

Implementation research is a dynamic process that often requires adaptations, flexibility and latitude during the course of execution. Such changes/adaptations to the research process must be documented, coordinated and monitored to ensure credibility and fidelity.

The following questions should underpin the documentation:

- What is happening?
- Why is it happening in this way?
- Is this expected?

It is important to be objective when documenting processes and report both negative and positive experiences. This will facilitate learning and evidence to support previously anecdotal reports.

Documentation of the various processes, adaptations, revisions and experiences that occurred and impacted the research will ensure that programme planners and policy-makers do not only receive the results of the study but understand the process by which the results are obtained.

Training of the implementers

Plans do not always proceed as intended in IR projects. Therefore adaptations may be required as the implementation process proceeds and more information is obtained. The set procedures (e.g. sampling and data tools) should be reviewed regularly to compare what is happening in practice with the original planned procedure, so that any necessary adjustments can be made. Staff training is a critical part of this process in order to ensure that the procedures are understood and adhered to. Training for all essential procedures should be standardized and targeted to all the key staff. To ensure a continuous learning process, training should be followed by mentoring and/or supervision activities.

Researchers need to ensure that the set procedures are adhered to during training using the prescribed materials and the most up-to-date versions of the data collection tools and instruments. In IR, there is the possibility of adverse events or unintended consequences of the intervention. Adverse events can have a negative impact on the adoption and sustainability of the intervention,

particularly when these events occur during the initial stage of implementation. Resistance to change, inertia and investment in the status quo – coupled with the inherently difficult and complex new task – may affect the adoption of a new practice.

Pre-testing

In any research, a pre-test is usually conducted to check the validity and reliability of a data collection tool. Pre-testing allows the research team to check whether the research instructions and questions are clear, adequate time is provided to administer the questionnaire, etc. Since data management is critical to the success of the research, the data management team should be available during the discussion that follows the pre-test to incorporate changes into the final design of the tool and facilitate incorporation of appropriate checks into the data entry system. This stage includes designing the forms for recording measurements, developing programmes for data entry, management and analysis; and planning dummy tabulations to assure the appropriate variables are collected.

Note

All study instruments (qualitative and quantitative) should be tested.



Data management

Collection and storage/documentation of accurately recorded and retrievable results are essential for any research. Good data collection practices will ensure that data can be traced to their source and originality (i.e. the raw data that constitutes the first recording of the observation). To ensure these characteristics, raw data must be recorded:

- *Promptly*: After a specific task is completed. Delaying data recording will reduce data quality as memory may fail or be inaccurate.
- *Accurately*: Inaccurate data recording will reduce the reliability of the data collected, and is therefore a critical part of the integrity of the study.
- *Legibly*: Hand-written data should be clearly written, electronic records should not be difficult to decipher.
- *Indelibly*: Handwritten raw data should be recorded in permanent ink. Any changes to the raw data should not obscure the previous entry. The date, reason for the change and signature of the person responsible for the change should be added.

Clear and regularly checked data flow prevents data loss. As IR collects different types of data (i.e. patient, organizational and surveillance-related data) from various sources (i.e. human subjects, medical records, health services and laboratory registers, surveillance systems, and administrative systems) a detailed chart should be made describing the critical pathway(s) to be used for the data collection process in handling questionnaires, coding, data entry, data verification, cleaning and storage of hard copies and back-up of data files.

Storage or archiving of data means that recorded data are appropriately stored for future use. The *WHO Good Clinical Practice Guideline* recommends that data and essential documents should be for at least two years after the research project has ended. Data should be kept in secured storage areas or locked cabinets.

APPLICATION OF KEY CONCEPTS

Example project: Key findings from an evaluation of the Mothers2Mothers programme in KwaZulu-Natal, South Africa (4)

Background: Mothers2Mothers (M2M) is a peer support programme that aims to provide education and psychosocial support to HIV-positive pregnant women and new mothers, help women access existing health care services to prevent mother-to-child transmission (PMTCT) of HIV, and follow up with mothers and babies to ensure they receive appropriate medical care after delivery.

While there has been much interest in innovative psychosocial support programmes that complement PMTCT clinical services, only a few such programs exist, and there is very little data about their effectiveness. Although M2M is a well-known programme with anecdotal accounts of successfully supporting HIV-positive women, it has yet to undergo an external evaluation. The Horizons Program of the Population Council, in collaboration with Health Systems Trust, completed the first evaluation of M2M as part of its introduction in KwaZulu-Natal Province, in South Africa.

Study design and methods

The researchers used a pre–post, quasi-experimental study design to assess programme effectiveness. There were three evaluation sites in the Pietermaritzburg area of KwaZulu-Natal. These sites drew women from urban and peri-urban settings. The eligibility criteria for the study included being between the ages of 18 and 49, knowing one's HIV status, and either 6–9 months pregnant or 12 weeks or less postpartum. Two cross-sectional surveys were conducted. At baseline data collection in 2005, before M2M was introduced, 183 HIV-positive pregnant women and 178 HIV-positive postpartum women were interviewed using a structured questionnaire. At follow-up data collection in 2006, one year after M2M was introduced, 345 HIV-positive pregnant women and 350 HIV-positive postpartum women were interviewed using the same questionnaire but with additional questions about programme exposure and interaction.

Concept 1: Seeking ethical clearance

- The evaluation protocol was approved by the Population Council's IRB, USAID, and the University of Stellenbosch in South Africa. The Horizons Program obtained ethical approval in the United States, while Health Systems Trust obtained in-country approval.
- The questionnaire was translated into isiZulu and translated back into English.
- The study's interviewers were trained on the importance of following ethical guidelines, including maintaining confidentiality.
- Written informed consent was obtained from all women interviewed.
- Participants were compensated 40 Rand (approximately US\$6) in recognition of costs such as travel, child care, and other expenses associated with participation in the study.
- Interviews were conducted in a private space at the clinics.
- All of the interviewers were female as it was deemed culturally appropriate to have only women in the health facilities conducting the interviews.
- Participants were not asked to give their names except to sign the written informed consent form.
- These forms were stored in a locked office, and kept separately from the data, which were in an electronic format.

Concept 2: Project implementation process

The programme implementation period was 2005–2006 and the M2M project activities included:

- Health talks by the site coordinators and mentor mothers on days when there are appointments for antenatal clinics and/or maternal and child health services.
- Counselling and support groups by mentor mothers and site coordinators on a daily basis.
- Daily visits by the mentor mothers to the labour and delivery wards to speak with expectant mothers or newly delivered mothers awaiting discharge.
- Regular support group meetings within the clinic, providing nutritious lunches to the women who visit the site.
- Community outreach by mentor mothers and site coordinators.
- Pre–post, quasi-experimental study design to assess programme effectiveness.

Changes in programme implementation

Due to slight delays in obtaining the necessary approvals for conducting the research activities at the sites, and the need to start programme activities, there was some overlap of baseline data collection with intervention activities.

Concept 3: Good practices in implementation research

Protocol Development

The evaluation protocol and instruments were jointly developed by the principal investigators from the Horizons Program and Health Systems Trust, and were further reviewed by the staff from M2M.

During programme implementation

1. The m2m project employed experienced health care professionals as program managers to oversee local programs based in the individual health care facilities.
2. Mentor mothers participated in two weeks of training using a standard curriculum which covered basic medical knowledge about HIV infection and antiretroviral therapy (ART), behaviours that prevent mother-to-child transmission.
3. To ensure a continuous learning process, the site coordinator (a mentor mother who has participated in the programme) supervised the delivery of care provided by mentor mothers.

Good practices in data collection and data management

1. Staff from the Horizons Program and Health Systems Trust jointly conducted the training of interviewers.
2. Health Systems Trust recruited university graduates with previous work experience as interviewers.
3. The interviewers completed two weeks of training prior to each round of data collection.
4. The questionnaire was pre-tested to ensure that the study population understood the questions, and that culturally appropriate phrases were used.
5. Participants' responses were recorded electronically using Perseus Mobile Survey software operating on a Dell Azim x51 handheld computer (this programme allowed for all of the questionnaire's skip patterns and range checks to execute automatically during the interview).
6. On a daily basis, after the interviews were completed, the data manager uploaded the data to a desktop computer then converted the data to SPSS software for quality control, management, analysis and storage.
7. Backup files were encrypted and emailed offsite daily to the research team, who were the only ones who had access to the data.

CONCLUSIONS

Congratulations on completing Module 3 *Planning and conducting an implementation research project*. This module provided information on the various steps to plan for to conduct the research including: applying for ethical review, planning for programme implementation, and implementing good IR principles and practices. An example of these processes was demonstrated through the use of an authentic IR project.

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Additional reading

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MODULE

4

**DATA,
ANALYSIS AND
PRESENTATION**

INTRODUCTION

The purpose of this module is to outline the fundamentals of IR data analysis and interpretation, (step 4 in the IR cycle). It also describes design of data analysis, presentation and interpretation for the target audience, with the objective of enhancing the uptake and use of research findings.

Upon completion of this module, you will be able to:

- Describe appropriate data analysis planning processes for both quantitative and qualitative data.
- Understand the appropriate measures for statistical analysis in quantitative research.
- Describe the data analysis processes in a qualitative study.

The module is divided into two main sections: the first focuses on quantitative data management, analysis and presentation, and the second one qualitative data management, analysis and presentation.

Before we begin...

We assume you are already familiar with these two approaches and tools of data collection (from Module 2). As a brief reminder you will be asked by the facilitator to identify some of the main differences between them (Table 1).

Table 1. Comparing qualitative and quantitative approaches

	Qualitative	Quantitative
Social theory	Action	Structure
Methods	Observation, interview	Experiment, survey
Question	What is x? How? Why? (classification)	How many xs? (enumeration)
Reasoning	Inductive	Deductive
Sampling	Theoretical	Statistical
Strength	Validity	Reliability

KEY CONCEPTS

Data analysis plan

Most IR proposals use mixed methods in which qualitative and quantitative techniques are combined. Under the right circumstances, a mixed-methods approach can provide a better understanding of the problem than either approach alone.

To ensure that the analysis is undertaken in a systematic manner, an analysis plan should be created first. The analysis plan contains a description of the research question and the various steps that will be carried out in the process.

Designing analysis for use

Designing analysis for use in an IR project is based on the premise that the IR aims to: (i) understand the implementation processes, focusing on mechanisms that support or constrain those processes; and (ii) communicate that understanding of the implementation process to multiple stakeholders, who may consequently contribute to the integration of findings into current and/or future research.

Few of the stakeholders in the IR project team are likely have specialized knowledge of both quantitative or qualitative research methods. It is therefore essential that the analysis and most importantly, the presentation of findings, be carefully considered to avoid potential misinterpretations that could lead to inappropriate conclusions and/or responses.

Emphasis should be placed on simplicity and interpretability because stakeholders need to both understand the information provided and also be able to interpret it correctly (1). Data analysis should take place along with the data collection process. This continual data analysis process facilitates regular sharing and discussion of findings.

Emphasis on quantitative analysis should be on simple summary statistics, such as changes in:

- counts, means, medians, ranges, percentiles;
- rates, trends, ratios and (for some stakeholders) risks;
- frequency distributions, proportions and percentages.

Designing analysis by purpose

An important preliminary consideration when designing data analysis plan is to clearly define the primary objectives of the analysis by identifying the specific issues to be addressed. It is important to remember that data from IR is by nature intended not to simply describe the intervention but also to improve it.

For example, IR research may focus on:

- **Effectiveness:** Aims to modify implementation procedures in order to improve the generation of benefits.
- **Efficiency:** Attempts to assess the implications of possible modifications to the implementation process in order to increase the benefits in relation to resources.
- **Equity:** Focuses on distributional issues, i.e. how benefits and resource costs are distributed.
- **Sustainability:** Focuses on identifying essential inputs, potential constraints on their availability and other possible barriers to medium and long-term sustainability.

Quantitative data analysis

In IR, quantitative data analysis will include one or more of the following considerations:

- Frequency distribution and summary statistics.
- Relationships and confounding variables.
- Sub-group analysis.
- Statistical models.
- Generalizing from samples to populations.
- Trend analysis.

Variables in quantitative analysis are usually classified by their level of measurement, as indicated below.

- Rational – e.g. weight of child, number of vaccinations.
- Interval (*based on predetermined equal intervals*) – e.g. temperature, some disability measures.
- Ordinal (*ranks*) – e.g. facility levels, quality of life indices.
- Nominal (*categories*) – e.g. district names.

Distributions and summary measures

Quantitative research generates large volumes of data that require organization and summarizing. These operations facilitate a better understanding of how the data vary or relate to each other. The data reveals distributions of the values of study variables within a study population. For example:

- The number of children under five years in various households in a given population.
- Daily outpatient attendance in a health facility.
- The birth weights of children born in a particular health facility over a period of time.
- Educational levels of mothers of children born in a particular health facility.

Analysis of the type of data described above essentially involves the use of techniques to summarize these distributions and estimate the extent to which they relate to other variables. For example, in a sample of newborns we might summarize the distribution of birth weights by calculating the frequency of low, normal and high birth weights, classifying as normal those in some standard range. If we also calculated the frequency of different education levels for the mothers of those newborns, we could then estimate the strength of a possible relationship between these two variables.

The use of frequency distributions for this purpose has several advantages:

- useful for all types of variables.
- easy to explain and interpret for audiences without specialist knowledge.
- can be presented graphically and in different formats to aid interpretation (e.g. tables, bar charts, pie chart, graphs, etc.).

Defining intervals for frequency distributions

A key decision in constructing a frequency distribution relates to the choice of intervals. For example:

- Ordinal: Level of health facility (e.g. primary, secondary, tertiary).
- Interval: Body temperature (e.g. below normal, normal, above normal).
- Rational: Body mass index (BMI) (e.g. <25, 25–29, 30+).

There are two conflicting objectives when determining the number of intervals:

- Limiting the loss of information through the use of a relatively large number of intervals.
- Providing a simple, interpretable and useful summary through the use of a relatively small number of intervals.

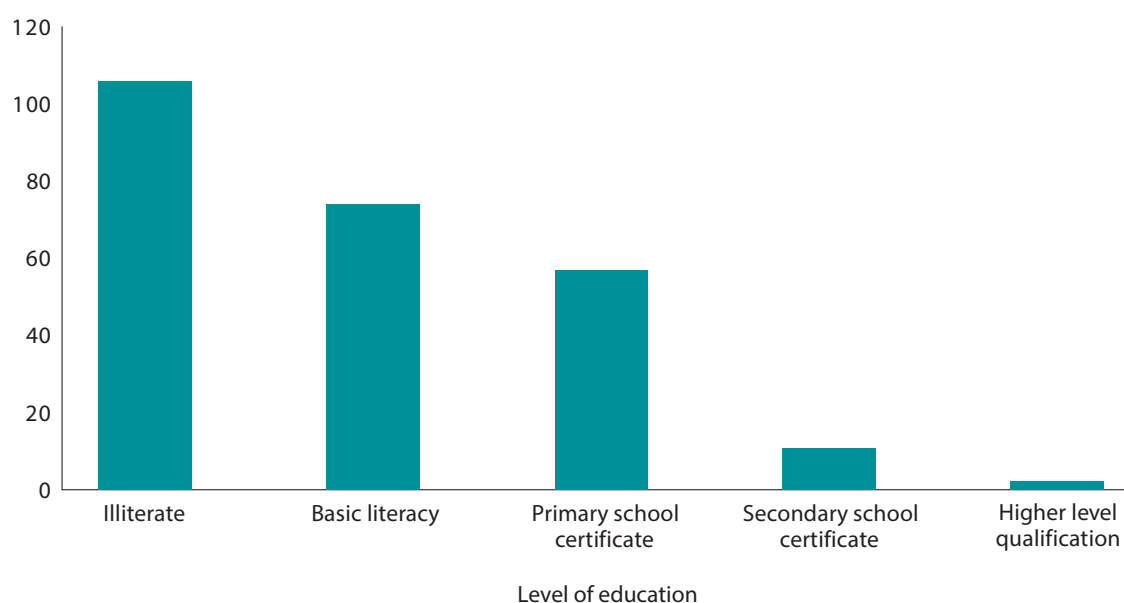
Distributions based on unequal intervals should be used with caution, as they can be easily misinterpreted, especially when distributions are presented graphically.

Data presentation formats

Data reporting should be presented in both textual and visual formats (such as diagrams, maps, graphs, tables). Organizing and displaying the data in visual formats is useful in identifying trends and forecasts. The example below presents the same data in a variety of formats (e.g. table of frequencies, table of proportions/percentages, bar chart, pie chart, etc.).

Table 2: Provider education expressed as frequency table (example)

Level of education of private providers	Frequency
Illiterate	106
Basic literacy	74
Primary school certificate	57
Secondary school certificate	11
Higher level qualification	2
Total	250

**Figure 1: Provider education expressed as a bar chart (example)****Table 3: Provider education presented as proportion, percentage and cumulative percentage (example)**

Level of education	Proportion	Percentage	Cumulative percentage
Illiterate	0.424	42.4	42.4
Basic literacy	0.296	29.6	72.0
Primary school certificate	0.228	22.8	94.8
Secondary school certificate	0.044	4.4	99.2
Higher level qualification	0.008	0.8	100.0
Total	1.000	100.0	

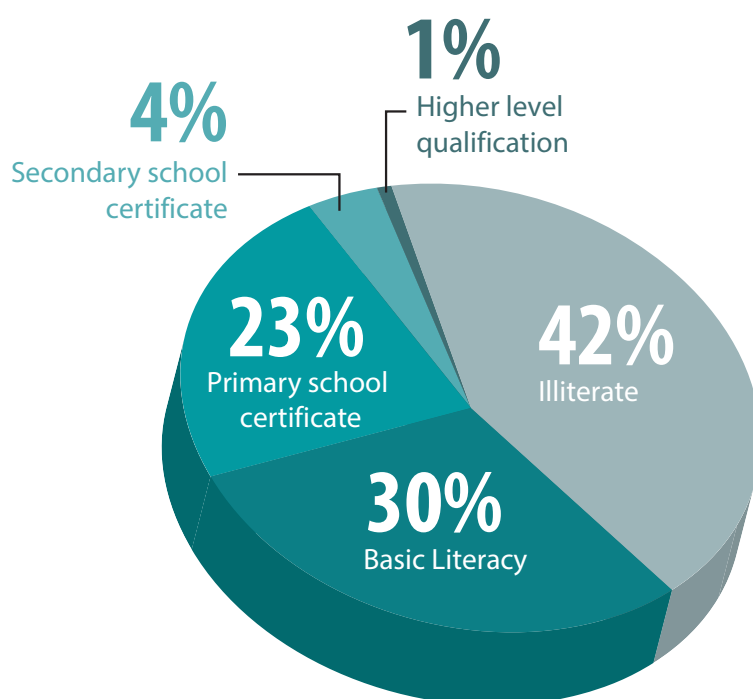


Figure 2: Provider education presented as a pie chart (example)

Table 4: Joint frequency distributions for two or more variables (example)

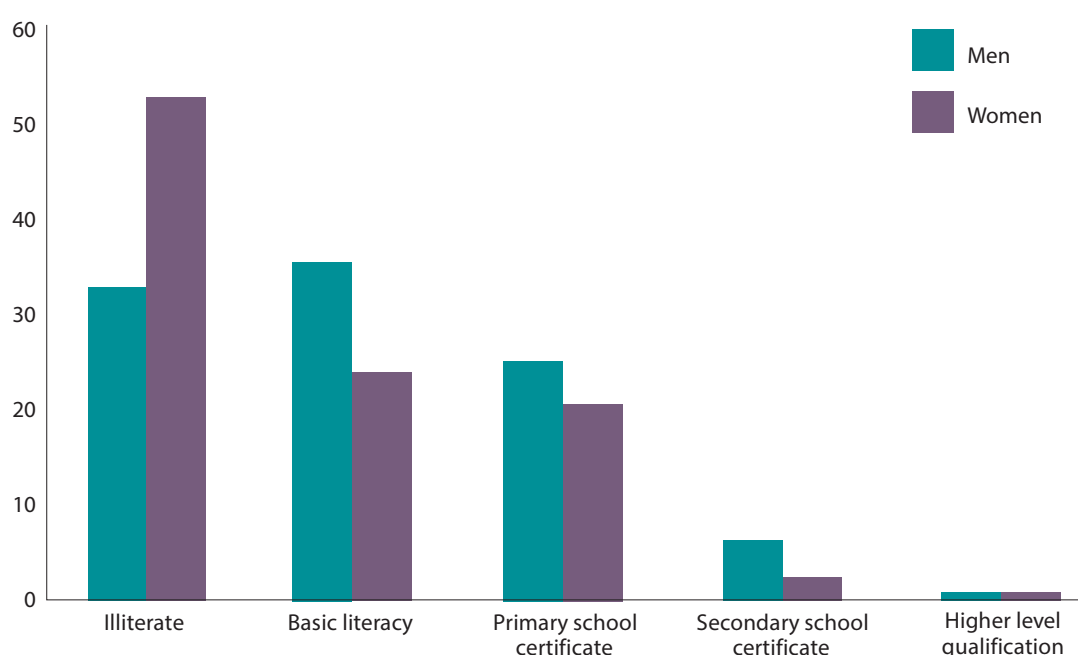
Highest level	Men	Women	All
Illiterate	42	64	106
Basic literacy	45	29	74
Primary school certificate	32	25	57
Secondary school certificate	8	3	11
Higher level qualification	1	1	2
Total	128	122	250

Table 5: Row percentages (example)

Highest level	Men	Women	All
Illiterate	39.6	60.4	100.00
Basic literacy	60.8	39.2	100.00
Primary school certificate	56.1	43.9	100.00
Secondary school certificate	72.7	27.3	100.00
Higher level qualification	50.0	50.0	100.00
Total	51.2	48.8	100.00

Table 6: Column percentages (example)

Highest level	Men	Women	All
Illiterate	32.8	52.5	42.4
Basic literacy	35.2	23.8	29.6
Primary school certificate	25.0	20.5	22.8
Secondary school certificate	6.3	2.5	4.4
Higher level qualification	0.8	0.8	0.8
Total	100.00	100.00	100.00

**Figure 3: Bar chart for two variables (example)**

Summary statistics and frequency distribution

Careful examination of the frequency distribution of a variable is a crucial step and can be an extremely powerful and robust form of analysis. There can be a tendency to move too quickly to the calculation of simpler summary statistics that are intended (but often fail) to capture the essential features of a distribution.

Summary statistics usually focus on deriving the measure indicating the overall location of a distribution (e.g. how sick, poor or educated a study population is, on average) OR to indicate the extent of variation within a population. However, the reasons for selecting a particular summary statistic should relate to the purpose for which it is intended.

Box 1

Example: Summary statistics and frequency distribution

To find out if a recently implemented intervention reduced the problem of malnutrition among five year-old children in a given village, a researcher may ask: “Which summary statistic is most appropriate?”

- Change in mean or median daily calorie intake of all five year-olds in village?
- Change in proportion of five year-olds in village falling below predetermined minimum calorie requirement?

The criteria for making such choices include:

1. Face validity (i.e. is the statistic relevant to the specific concern?).
2. Whether stakeholders understand how the data was derived.
3. Whether stakeholders are able to interpret the findings as intended.

Use of mean or median

The mean, or average, is the most commonly used summary measure of location. However, it is often inappropriately used as the standard measure of central location because the mean is simple to calculate and manipulate. For example, it is straightforward to combine the mean of sub-populations to calculate the overall population mean. The mean is also frequently misinterpreted as the typical value in a population. For example, the GDP of a certain middle-income country was calculated as 3200 US\$. Interpreting this as the income of an ‘average’ person in that country does not reflect reality (in fact, it was closer to 1200 US\$). The mean is often unrepresentative when the underlying distribution is skewed.

The median, defined as the middle value, is relatively easy to explain. The magnitudes of other values are irrelevant. For example, if the largest value in a given range increases or the smallest value decreases, the median remains unchanged.

When a data set is not skewed (or when data are distributed ‘normally’), the mean and the median will be the same (Figure 4).

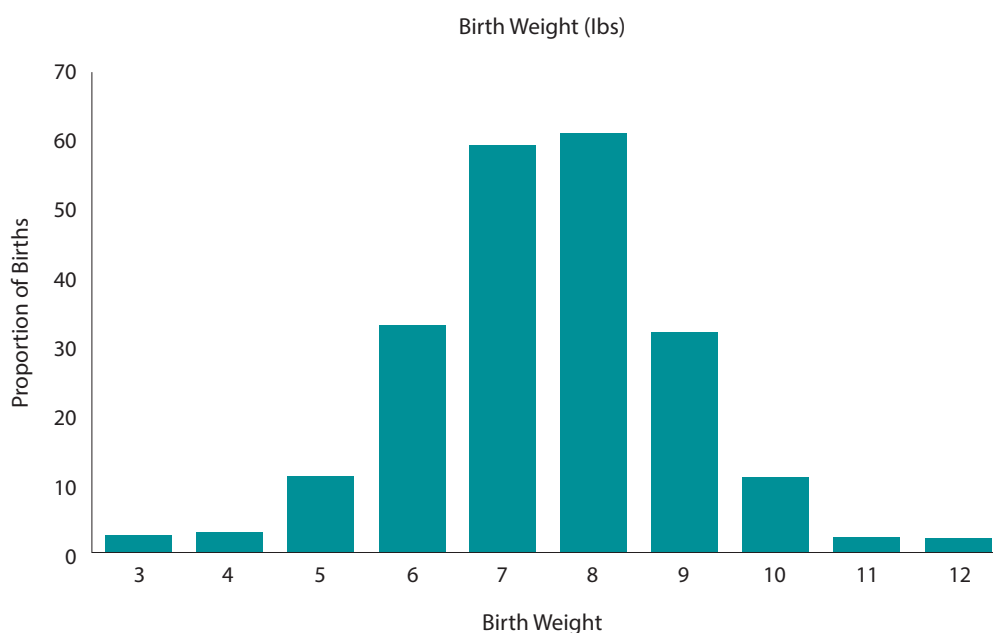


Figure 4: Normal distribution: The mean is the measure of central location



Figure 5: Skewed distribution

In a skewed distribution, the mean is more difficult to interpret.

Measures of risk

Although measures of risk are widely used in health research, they are not always well understood. For example, risk and odds are often used interchangeably however do not mean the same thing.

- Risk (P): number of people experiencing an event/population exposed to the event.
- Relative risk (PA/PB): risk in group A compared to risk in group B.
- Odds: number experiencing versus number not experiencing = $P / (1-P)$
- Odds ratio: $[PA/(1- PA)] / [PB/(1-PB)]$

Furthermore, reduction in risk is not equivalent to reduction in odds:

- PB (malaria before intervention) = 0.5
- PA (malaria after intervention) = 0.1
- Reduction in risk = $0.1/0.5 = 0.2$
- Reduction in odds = $(0.1 / 0.9) / (0.5 \times 0.5) = 0.11$

The 'denominator problem'

When calculating risk, it is essential to know the overall size of the population at risk. In implementation studies, it is often difficult to calculate or reliably estimate these summary statistics because the denominator is not reliably known. For example, we may only have an estimate of the number of children who should be immunized or should be sleeping under a mosquito net in a given district. Similarly, the catchment population of a facility or actual number of births over a period of time are often unknown. For these reasons, denominators are usually based on projected populations resulting in reported coverage of over 100% in some instances.

Because of this uncertainty, it is good practice to provide the estimates of both the numerator and denominator alongside any proportion, percentage or risk estimate and indicate the sources used in the calculation.

Measures of variation

How much variability occurs in a given population?

- Low variability: Measures of location can be seen as reasonably representative of the overall population; there is limited loss of information through aggregation.
- High variability: Representative measures of location are less useful; there is a substantial risk of losing information by aggregation unless the nature of the distribution is well understood.

Choice of measures

Variances, standard deviations and coefficients of variation are widely used in statistical analysis. As with the mean, this is not because they are always the best measures of variability (they can be easily interpreted for normally distributed variables but not for other distributions), but mainly because they can be readily calculated and manipulated.

For example, given the variances of two population sub-groups it is easy to combine them to calculate the overall population variance. However, while they may have technical advantages, these measures have serious limitations in terms of policy application.

Alternative measures

More readily interpreted measures include quartiles and percentiles.

Quartiles: divide data into four quarters (Q1 to Q4) – 25% in each:

1. Q2 is the median.
2. Q1 is the median of the data points below the median.
3. Q3 is the median of the data points above the median.
4. Q3-Q1 is the inter-quartile range, comprising the middle 50% of a population.

Percentiles divide the data into two parts:

- p percent have values less than the percentile.
- (100 – p) percent have greater values.
- 50th percentile = median; 25th percentile = first quartile.
- Other common percentiles:
 - 20th (which defines the first quintile group).
 - 10th (which defines the first decile group).

Sub-group analysis

The outcomes of an intervention may vary substantially between different sub-groups of the target population. Sub-group analysis can be complex if the sub-groups are not pre-defined. Investigating a relationship within a sub-group because it appears interesting could bias the findings.

Data mining (i.e. exploring data sets to discover apparent relationships) is useful in formulating new hypotheses but requires great caution in IR. The context within which this sub-analysis is undertaken should be considered carefully, because relationships between inputs and outcomes may be mediated by contextual variables. For example, we might assume that it would be useful to undertake an analysis of chronic illness by age group and sex, as shown in Table 7. For meaningful interpretation of the results, the type of chronic illness and the background of the patients experiencing them are important variables to consider.

Table 7. Background variables of patients with chronic illnesses

Age group	Chronic illness prevalence	
	Males	Females
15–24	0.55	0.80
25–44	1.79	4.01
45–64	4.91	12.28
65	12.86	20.00
All	1.77	4.25

Controlled and confounding variables

In the example of chronic illness (Table 7), we often describe such an analysis as one that assesses the relationship between inputs and outcomes by controlling for age group and sex. However, we know that in practice, a very large number of other factors may influence this relationship, for example occupation, level of education, socioeconomic status, household size, type of dwelling, rural/urban location, etc. Random allocation of subjects to intervention and control groups would allow us to argue that the potentially confounding effects of such variables average out. If that is not possible, we should find some way to control for these effects. Because IR takes place in real life and within complex adaptive systems, these effects may be difficult to control, however they must be considered.

Analysis of qualitative data

There are many traditions of qualitative research and it has been argued that “there cannot and should not be a uniform approach to qualitative methods (2). Similarly, there are few “agreed-on” canons for qualitative data analysis, in the sense of shared ground rules for drawing conclusions and verifying sturdiness (3). Many qualitative studies adopt an iterative strategy – collect some data, construct initial concepts and hypotheses, test against new data, revise concepts and hypotheses, etc. This approach implies that data collection and analysis are embedded in a single process and undertaken by the same individuals.

However, with the increasing use of qualitative research in epidemiology and health research, objectives are pre-defined prior to data collection. Qualitative data analysis can be done manually or with proprietary software like the examples listed below:

- *Atlas-ti* deals with large data sets, unstructured coding, mimic paper code and sort.
- *NVivo* handles relatively less data, caters for unstructured coding, find patterns/relationships in codes.
- *MaxQDA* provides powerful tools for analysing interviews, reports, tables, online surveys, videos, audio files, images and bibliographical data sets.

There is a considerable range of choice in software for analysing qualitative data. Researchers should feel free to use whatever analysis method (with or without software) they are comfortable with. Whatever approach is used, all qualitative analysis involves making sense of large amounts of data, identifying significant patterns and communicating the essence of what the data reveal.

The three core requirements of qualitative analysis are:

1. Detailed description of techniques and methods used to select samples and generate data.
2. Carefully specified analysis, with attention to issues of validity and reliability.
3. Triangulation with other data collection method.

Validity and reliability in qualitative research

Validity in qualitative studies focuses on internal validity, with researchers seeking an in-depth understanding that will allow them to counter alternative explanations for their findings. Qualitative studies often rely on purposive sampling, which tend to detract from claims for external validity (generalizability).

In quantitative studies, 'reliability' means repeatability and independence of findings from the specific researchers generating those findings. The term reliability is most often associated with quantitative research. However in qualitative research, reliability implies that given the data collected, the results are dependable and consistent (4). The strength of qualitative research lies in validity (closeness to the truth). Good qualitative research, using a selection of data collection methods, should touch the core of what is going on rather than just skimming the surface (4).

4. Analysis of textual material

The basic process for the analysis of text derived from qualitative interviews or discussions is relatively straightforward and includes:

1. Identification of similar phrases, themes and relationships between themes.
2. Identification of similarities and differences between population sub-groups (e.g. men/women, rural/urban, young/old, richer/poorer, etc.).
3. Initial attempts to generalize by identifying consistent patterns across or within sub-groups.
4. Critical review and revision of generalizations, paying particular attention to contradictory evidence and outliers.

Box 2

Example: Focus group discussions

As far as possible, outputs of focus group discussions (FGD) should be verbatim records. The notes taken by the recorder should be compared to a recording of the discussion. The recorder and moderator should agree on a final transcript. The transcripts (from multiple FGDs) should provide the material for systematic analysis.

FGD analysis will typically address a number of specific research topics and sub-topics, such as eliciting additional topics of local concern, which can be used to define the broad domains for analysis. These can be sub-divided further into themes, sub-themes, etc. and allocated systematic codes.

The initial descriptive analysis should also capture: (i) most common themes mentioned; (ii) less common themes; (iii) common associations between themes; and (iv) similarities and difference between sub-groups.

The critical review and revision should: (i) review original text to assess the extent to which it conforms to the above analysis; and (ii) pay particular attention to any contradictory evidence, minority viewpoints, etc.

Domain /theme analysis

One relatively simple approach is based on the identification of key topics, referred to as 'domains', and the relationships between them (2).

There are four stages in domain /theme analysis:

1. Identify main issues raised by the interviewees – the domains /themes.
2. Group more detailed topics within each of these domains to construct a taxonomy of sub-categories.
3. Specify what was actually said, the components within each sub-category.
4. Exploration of interrelationships between the various domains.

Domain /theme identification

- Index texts, identifying topics line-by-line.
- Collate these topics across all interviews to identify a preliminary list.
- Some will recur more frequently than others and some of the latter can be classified as sub-topics.
- Systematically combine related topics to develop a list of just a few fairly broad domains.

Example of an initial list of topics and sub-topics (6):

- Getting and being pregnant: Signs of pregnancy, danger signs, physical problems.
- Feelings during pregnancy: Anxiety, anger/fright, worries, embarrassment, inconvenience, impressions.
- Family planning: Methods.
- Advice/activities to promote health: Exercise, activities, smoking, self-care, advice sources, information sources.
- Birth and miscarriage: Previous experiences, place, signs, caesarean/normal, birth weight.
- Antenatal care: Staff, place, experiences, meetings, tests, distance/cost, logistics, waiting time.
- General background: Family, employment, geography.

Initial list of potential domains /themes

From the above example, the following broad domains were identified:

- Motivations for antenatal care.
- Medical process (experiences of antenatal care and evaluation of that care).
- Risks during pregnancy.
- Reproductive histories.
- Socioeconomic background.

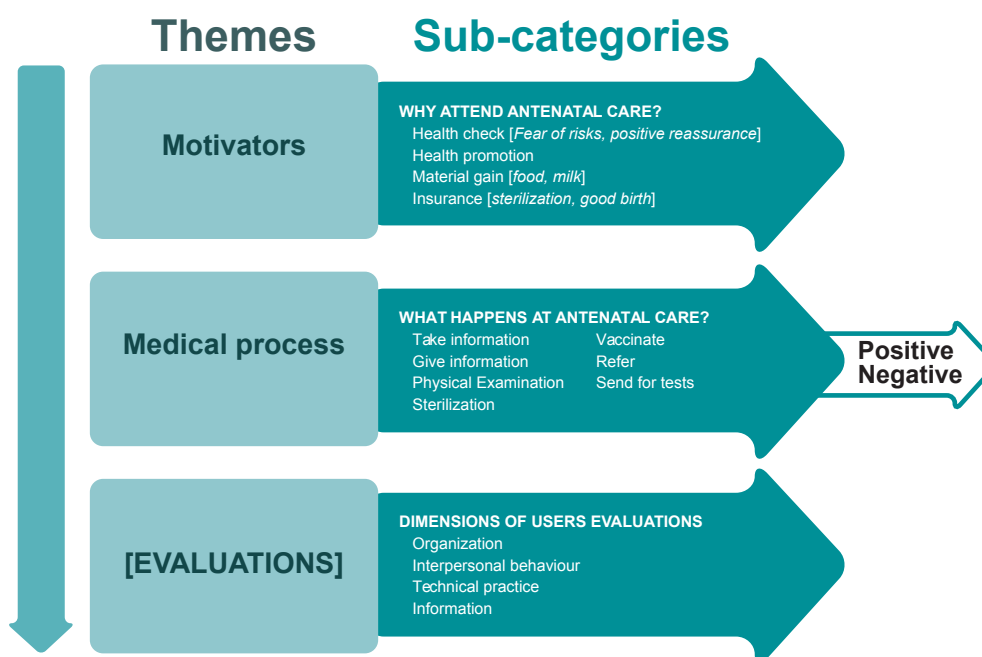


Figure 6. Taxonomy of sub-categories (from Atkinson and AbuEl Haj, 1996)

After listing the domains (Figure 6), it is useful to start arranging the actual segments of text into the primary domains. This process groups actual phrases together and allows the sub-categories to emerge directly from the interviewees' own words.

Relationships between domains /themes

This stage involves identifying relationships between the domains or topics to build up an overall picture. Within the collection of actual quotations from respondents, the researcher should identify statements that relate one topic to another. For example, in the study described above, researchers were able to establish associations between the domains that linked women's previous experiences, risk perceptions and socioeconomic situation to their evaluations of health services.

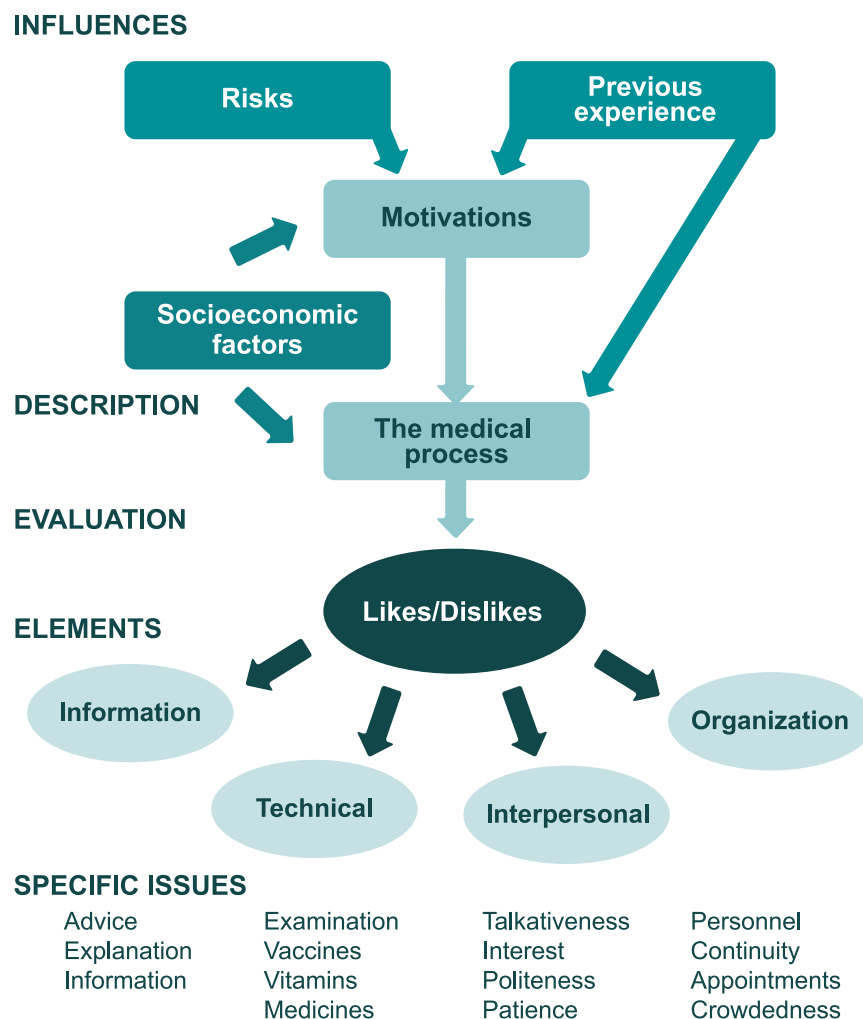


Figure 7. Relationship between domains (from Atkinson and AbuEl Haj, 1996)

Coding schemes

Following an initial analysis to gain an overall understanding of the main features of the data, many analysts apply a systematic coding procedure. The researchers determine the most appropriate way to conduct a systematic analysis, uncovering and documenting links between topics, themes and sub-themes (3). These codes are assigned to specific occurrences of words or phrases, highlighting patterns within the text while preserving their context, as in Table 8.

Table 8. Matrix of perceived cause and signs of malaria

	Focus group discussion			
	Village A women	Village A men	Village B women	Village B men
Malsign	Hot body	Bloody stool	Hot body	Hot body
	Yellow eyes	Hot body	White lips	Yellow eyes
	White lips	Yellow Eyes	Yellow eyes	White lips
			Bloody Stool	
Malcause	Mosquitoes	Mosquitoes	Mosquitoes	Eating fresh mangoes
	Fresh mangoes	Standing in the heat	Standing in the heat	Mosquitoes
		Fresh mangoes		

Reflection activity

We have discussed the need for an analysis plan including various methods of and tools for analysing and presenting the data.

- In your research team, discuss how you plan to analyse and present your data.
- How will you ensure validity and reliability of your data?
- What kind of analysis will you/your team undertake?
- Will you be using any software for your data analysis?
- Discuss the reasons for your decision to use (or not use) software for your analysis.
- How will you present your data?



APPLICATION OF KEY CONCEPTS

The example below describes thematic analysis, presentation and interpretation of FGD data.

Box 3

Example: Njeru et al. 2011 (7)

Practicing provider-initiated HIV testing in high prevalence settings: Consent concerns and missed preventive opportunities

Background: A population-based survey was conducted among adults in the three study districts (Malindi, Mbarali & Kapiri Mposhi) in Kenya. Two HIV counselling models were compared: Model 1: Client-initiated HIV counselling and testing is commonly referred to as voluntary counselling and testing (VCT) and Model 2: Provider-initiated testing, in contrast to the client-initiated testing, is recommended by a health provider to people attending a health facility.

In-depth interviews and focus group discussions were employed to explore informants' experiences and perceptions of the HIV testing services with an emphasis on experiences with the provider-initiated testing model. The groups consisted of: female outpatients, male outpatients, pregnant women attending antenatal clinics and youths aged 18 to 24 years.

Analysis was conducted through the use of a framework analysis. Data analysis for all data sets involved five main steps: familiarization, identification of a framework, indexing, charting and interpretation.

Below are some of the results presented as verbatim quotations from the respondents and the made by the researchers' interpretation.

Objective: to explore respondents' perceptions and experiences with counselling during HIV testing

Main theme: The value of counselling

Sub Theme: The Preventative Aspect

Opportunities for HIV prevention provided by counseling emerged as important issues in our interviews and discussions.

- *"The importance of counselling emerges when a person who has not been infected gets advice and follows it, because s/he will not get this disease." (Female 26 years old, urban Malindi). "Counselling is very important because if you are counselled you get the courage or the strength to prevent being infected as you are told the way forward." (Female youth, FGD, urban Malindi)*
- *"As for me I was tested at the VCT. There they really counselled me on HIV and on how I can protect my life." (Male adults, FGD, urban Malindi)*

Sub theme: The support dimension

The need for counselling as an important dimension in supporting those already infected with HIV was a point that was brought up in both the IDIs and the FGDs across the three districts. Both male and female informants from the three countries expressed the view that sufficient post-test counselling has the potential to reduce worry, fear and blame as illustrated in the quotations below:

- *"Because if you have been made aware through counselling, even if you tested positive, there will be no fear, that's why some people declare that they are HIV positive, they had seminars where they were counselled and that is why they have that courage. But if one discloses his status as positive here people will talk about him; some will even deny him drinking water because of fear." (Male adults, FGD, Mbarali)*

Sub theme: The time dimension

The need for sufficient time during counselling to clearly convey messages emerged as vital in the testing services. In order to fully conceptualise and understand the information presented more time was identified as needed before embarking on the testing. In this manner, so that one would be prepared to receive the test results whatever the outcome might be.

- *"When I say we need education, I mean we need counselling, we need counselling that is offered step by step until we are ready to test." (Male adults, FGD, Mbarali)*
- *"When you enter the facility and after the counselling you are immediately asked if you are ready for the test. No! That also can cause a lack of willingness to test. The counsellor should counsel me and tell me I have the right to go for testing. Therefore, if the time for counselling is increased, I see that as an improvement." (Female adult, FGD, rural Malindi)*

Major Theme: Challenges Experienced with the Implementation of the PITC Model in HIV Testing

Sub theme: Threat to counselling

- *“During the second pregnancy we were not given a choice. It was a must to get tested on HIV and then (after that) on the pregnancy. We were not asked; you enter in the room for HIV testing and then you go for other tests. To tell you the truth, some there got quite scared that day when we were suddenly tested. People panicked a lot. So people were not happy, but it was a must that they do it.”* (Female 35 years old, urban Malindi)
- *“It was said that according to the rules of the hospital if someone reaches the time of delivery and does not have HIV results she is not received.”* (Female 35 years old, urban Malindi)
- *“If you refuse to test they don’t examine your stomach. So when it is time for delivery they don’t accept you.”* (Female pregnant, FGD, Urban Malindi)

Sub theme: HIV testing as mandatory

In Malindi our informants reported that the HIV test within PMTCT was no longer voluntary. A common phrase that was used to describe the new testing model was “it is a must”, a point noted by both female and male respondents:

- *“I was not tested at a VCT centre, but at that place for women (ANC clinic). Because when you are pregnant, you are tested on many things, but first they must test you for AIDS.”* (Female pregnant 40 years old, urban Malindi)
- *“Here let’s say women and men go for (HIV) testing, but a majority of them are women because the woman must be tested when she goes to the clinic.”* (Male 34 years old, urban Malindi)

Sub theme: The expressed burden on women

- *These counsellors should be many to help us because we are wives, and when you ask your husband to go to test himself he stays quiet refusing to talk. He tells you ‘you get tested, if you are found to be ok, I am also ok.’ He does not go.”* (Female pregnant, FGD, urban Malindi)
- *“You know also there are many incidents which have come up because you find that when a woman is heavy (pregnant) it’s like the husband forces the wife to go for testing, you see? If anything bad arises (meaning if she is HIV positive) he starts questioning the wife, and asks ‘where did it come from?’”* (Female pregnant, FGD, rural Malindi)

CONCLUSION

Congratulations on completing Module 4 *Data Analysis and Presentation*. This module provided you with an outline of the basics of IR data analysis and interpretation. It also described the design of data analysis, and data presentation and interpretation for the target audience to enhance uptake of the findings. We hope that you have enjoyed this module and have increased your knowledge and understanding of data analysis and presentation. We encourage you to continue with Module 5 entitled, *Communicating the findings and feeding them back into the health system*.

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MODULE

5

DISSEMINATING THE RESEARCH FINDINGS

INTRODUCTION

The purpose of this module is to illustrate the key concepts of knowledge translation (KT) as relevant to implementation research (IR). It provides structured guidance on preparation of research reports, peer reviewed papers, press releases, conference presentations and policy briefs.

Upon completion of this module, you will be able to:

- Appreciate the value of continuous stakeholder engagement for dissemination and utilization of research results.
- Appreciate the value of developing of a comprehensive dissemination strategy as an integral part of a research project.
- Understand the importance of tailored dissemination tools for various target audiences.

KEY CONCEPTS

Knowledge translation

KT techniques can help researchers become more active, context-aware, and collaborative in disseminating the results of research. Application of these techniques help make research results more relevant to the target audience, and ultimately more useful.

KT activities

There are essentially two types of KT activities: end-of-grant and integrated knowledge translation (iKT). End-of-grant activities is often built into funding proposals (1). As the name suggests, such activities are typically conducted at the end of the knowledge creation process. They are focused on translating knowledge into effective communication tools and disseminating those to a particular audience. These include peer-reviewed papers, guidelines, conference presentations, press releases, radio spots, community dramas, and so on. These activities essentially present completed findings. Although end-of-grant KT activities can be conducted as part of IR, it is a limited (and relatively expensive) activity (2, 3). By its nature, it lags behind the research and findings may not be available in time to address the problem.

Integrated KT approaches allow more innovation and are effective in providing timely solutions to implementation problems. This approach is a mixture of art and science, and in many ways illustrates the core features of IR itself. For example, it is multi-stakeholder and multidisciplinary, as well as dynamic and interactive (4). The integrated approach requires researchers and key knowledge end-users to collaborate and jointly conduct many of the essential steps, identify research questions; determine methodologies; conduct the research; interpret findings; disseminate and apply the findings – together. Because the findings reflect the needs of knowledge users, they have a much higher likelihood of being acknowledged and used. iKT also includes activities such as priority setting, development of policy briefs, facilitation of dialogues, and the development of knowledge translation platforms/rapid response services. Integrated approaches do not treat knowledge as something that can be generated, disseminated and then applied (as it is sometimes simplistically envisioned in end-of-grant KT). Rather, iKT views research knowledge – from its creation through to its application – as a collective, co-productive undertaking (5). It respects a two-way dynamic, in which research evidence is created, shaped and ultimately used by many different stakeholders. In some ways, this approach reverses the usual ‘authority’ of researchers, who no longer possess exclusive control of research evidence. In order to make research evidence more relevant and

responsive, iKT approaches involve practitioners, planners and programme managers (among others) in the process of identifying, designing and conducting research. This uniquely positions research as a tailored, context-sensitive input responding to user needs and demands.

Box 1

Example: IR evidence uptake and use for policy-making

This project addressed scaling up of zinc for young children (SUZY) in Bangladesh. The integrated KT approaches aided policy-makers to integrate IR outcomes into making decisions on the treatment of childhood diarrhoea.

Various stakeholders were involved throughout the entire project cycle. Collaboration between policy-makers and researchers facilitated the sharing of tacit knowledge, policy positions and the setting of common priorities and goals. Whereas some stakeholders had not been considered during the conceptualization of the project, they were brought on board later to expedite the scale-up process. The other lesson from the collaborative approach was the adoption of best delivery methods. For example, the use of existing community health systems [i.e. community health workers whose primary focus was family planning] was initially contemplated as a channel to scale up the intervention. However, this was discontinued when they realized it would not be feasible (an additional task for the community health workers). Zinc products were available over-the-counter, and could be administered easily, physicians (especially paediatricians) were identified as key players in promoting and prescribing it. The outcome of these findings enabled the project to embark on training within medical colleges and of public health physicians at the district and sub-district levels. Some 8000 village doctors acted as trainers for more than 200 000 informal providers.

Research conclusions:

- In order to effectively implement evidence-informed policy, policy-makers and researchers should learn together and work in partnership to improve access and delivery.
- Steps should be taken to increase the demand for research use and KT through sustainable partnerships and mechanisms, including KT platforms (at the district, provincial and national levels), which promote the early involvement of policy-makers, managers, health care providers and patients, and serve as the basis for capacity-strengthening activities.

Source: (6)

Barriers and facilitators to uptake of research evidence

There are various barriers and facilitators to the uptake of research evidence. Many users of research evidence (e.g. programme managers and implementers) operate in an environment with unique pressures and imperatives. Their timelines for action can be very short, and their expertise in applying or balancing different inputs to solve problems may be limited.

Barriers to research evidence uptake

1. Perception of research evidence by practitioners: How do practitioners balance evidence with other competing influences? (7). This can include practitioners lacking a clear idea of where to access relevant, tailored information to suit their needs, how to distinguish quality of evidence sources, and how to ultimately use it (8). After all, “evidence speaks with many voices,” and any one piece of evidence might have multiple different (and even contradictory) implications (9). Findings may also be ambiguous and lack precise estimates of intended effects (10).
2. Organizational culture. How does an organization make decisions? How does information flow within an organization? What are its abilities to interact with research evidence? (11, 12). ‘Groupthink’ or ‘how we do things around here’ can also slow or distort the use of research evidence. The prevailing administrative context may also shield programme managers,

implementers or technical officers from a researchers' advocacy, and they may feel no accountability to the research community (8).

3. The low skills (especially research or evidence-appraisal skills) among practitioners, either to assess research evidence or to balance it against competing sources of influence (8).
4. The perceived cost and timelines of research. Given the short time horizons that many practitioners have to make decisions, research could be considered too expensive, too time-consuming or too much of a luxury to have real practical value (13).
5. Information overload. Practitioners, programme managers and implementers may become overwhelmed by the sheer number of information sources; or become persuaded by other influences (e.g. lobbyists or other interest groups who have financial resources, abilities, and/or insider knowledge on advancing a particular agenda) (10).

Facilitators of research evidence uptake

Facilitators leading to wider adoption of the research evidence may include:

1. Researchers reframing practice issues to align with the existing evidence base (8). Framing the problem is an essential step in many KT activities (e.g. a policy brief) and can bring together many different types of evidence to respond to a particular practice or implementation need.
2. Strengthening the capacity of practitioners to: demand research evidence that responds to and supports their needs; and to access, assess, adapt and apply research evidence in their daily work (14).
3. Researchers collaborating with practitioners to generate essential information, to encourage active sharing, and identify pressing priorities (8).
4. Creating targeted messaging (e.g. policy briefs, press releases) emphasizing the role that research evidence can play in contributing to better programmes or improved interventions (12, 15). Research evidence can be communicated more effectively by turning them into compelling stories. For example, by contrasting 'the costs of action versus those of inaction' the likelihood of evidence influencing decision-making may be much higher (10).
5. Researchers pursuing personal contact with practitioners and developing trust (16). Trust built from personal relationships can be a vital ingredient connecting the worlds of research and practice.

Box 2

Example: Research translation to inform national health policies. Learning from multiple perspectives in Uganda

Background: Research and evidence can have an impact on policy and practice, resulting in positive outcomes. However, research translation is a complex, dynamic and non-linear process. Although universities in Africa play a major role in generating research evidence, their strategic approaches to influence health policies and decision-making are generally weak. This study was conducted with the aim of understanding the process of translating research into policy in order to guide the strategic direction of Makerere University College of Health Sciences (MakCHS) and similar institutions in their quest to influence health outcomes nationally and globally.

Methods: A case study approach using 30 in-depth interviews with stakeholders involved in two HIV prevention research projects was purposively selected. The study sought to analyse the research-to-policy discourses for the prevention of mother-to-child transmission (PMTCT) of HIV. The analysis sought to identify entry points, strengths and challenges by interviewing three major groups of stakeholders in Uganda: researchers (8), policy-makers (12) and media practitioners (12).

Results: Among the factors that facilitated PMTCT policy uptake and continued implementation were: Shared platforms for learning and decision-making among stakeholders; implementation pilots to assess feasibility of the intervention; the emergence of agencies to undertake operations research; and the high visibility of policy benefits to child survival.

Implication: For effective uptake of IR findings, all stakeholders should be involved throughout the entire process of the research project in order to enhance the learning and decision-making processes among various stakeholders.

Source: (17).

Reflection activity

Taking a cue from the Uganda example above, reflect on a health programme you are familiar with in your country. Is there a policy underpinning this programme? What research evidence was used to formulate this policy?



Dissemination tools

Various dissemination tools are available to research teams pursuing the uptake of research findings. All these tools should be considered less as individual pieces and more as parts of a whole. The various tools should be used in concert within a larger plan that together produces a complete effective dissemination package. Each tool has different strengths and weaknesses in reaching audiences and therefore by using more than one, the tools complement one another to produce a strong dissemination plan. In many cases, the work that goes in the development of one tool can be replicated or modified into the development of another. Increasing the number of ways that research findings reach key audiences increases the chances of uptake and action. The dissemination tools considered in this module will include, research reports, peer review papers, press releases, and policy briefs.

Research reports

At the conclusion of any IR project, funders expect reports from the grantees. The content of the research report depends on the funder and their specific requirements. A review of the initial

grant agreement is therefore the obvious place to start when deciding on the structure and content of the report. If the funder has provided a report template with sections that need to be followed, then the exercise of writing a research report is relatively straightforward. The following sections are typical of many research reports, and peer-reviewed papers: title; list of authors and institutional affiliations; acknowledgement; abstract; executive summary; introduction; literature review; research design/methodology; results; discussion; conclusions; and references. However it is essential to follow guidelines from respective funders and/or journal publishers/editors.

Other uses of research reports



One key question to have in mind throughout the process of writing the report is: What other ways can we use or present this information? A research report can be the source of information and insights for various kinds of additional products. The tables and charts can become the major visuals of a conference presentation. The executive summary can contribute to a page of take-home messages, to a press release, or suggest the argument of a policy brief. And most of all, the research report can be a template for peer-reviewed papers, a way of ordering thought and simplifying very complex processes into phrases suited for digestion by the wider research community. Many parts of the report can be lifted, often with only moderate adjustments, straight into a peer-reviewed paper.

Peer-reviewed papers

For many researchers, publication in a peer-reviewed journal is a peak achievement. It signals acceptance of the work within the community, a visible contribution to the field and a reward for many years of work. Although publication is extremely important, it is by no means the end of the implementation research process. Instead, the publication should be considered as the beginning of a new cycle of achieving influence. The big limitations of peer-reviewed publications, is that key audiences (for instance, practitioners and programme implementers) tend not to read them extensively if at all.

Although the structure of a peer-reviewed paper can be very similar to a report, its audience differ. Every journal has specific requirements and formats for submitted articles, a preferred style (e.g. length of abstracts, reference style, etc.), and particular guidelines to be followed by all authors. Therefore, before writing a paper, the logical first step is to identify the intended journal. Browsing back issues (most make some content available online) to see the types of articles to published is a useful place to begin. Choose a journal that routinely publishes content related to your study and follow the instructions for authors closely. Journals that accept IR research include: *Health Policy and Planning*; *Tropical Medicine and International Health*; *Social Science and Medicine*; *Human Resources for Health*; *Global Public Health*; *Community Health Education*; and *The Bulletin of the World Health Organization*. Publication in an “Open Access” journal (i.e. a journal that permits unrestricted access and reuse of the published article) is encouraged by many funders of research. Upon selecting a journal, locate the submission guidelines on the journal web site.

Examples of abstracts for peer-reviewed papers

Example 1:

Intensified tuberculosis case finding among people living with the human immunodeficiency virus in a hospital clinic in Ethiopia. Assefa et al., *International Journal of Tuberculosis and Lung Disease*. 2011 Mar;15 (3):411–3.

Abstract

Intensified tuberculosis case finding (ICF) is used in people living with the human immunodeficiency virus (PLHIV) to reduce the burden of tuberculosis (TB). We conducted a retrospective study in 300 PLHIV attending an HIV care clinic in Ethiopia to assess ICF performance during a 12-month period. Between 80% and 95% of patients were screened for TB at enrolment and at each 3-month follow-up visit. Thirty-four (11%) patients were diagnosed with TB, of whom 27 (79%) were identified in the first 6 months. This study assessed serial ICF in routine settings, showing that TB screening had its largest diagnostic yield in the first 6 months.

Example 2:

Identification of losses to follow-up in a community-based antiretroviral therapy clinic in South Africa using a computerized pharmacy tracking system. Nglazi et al., BMC Infectious Diseases. 2010 Nov 15;10:329.

Abstract

Background: High rates of loss to follow-up (LTFU) are undermining rapidly expanding antiretroviral treatment (ART) services in sub-Saharan Africa. The intelligent dispensing of ART (iDART) is an open-source electronic pharmacy system that provides an efficient means of generating lists of patients who have failed to pick-up medication. We determined the duration of pharmacy delay that optimally identified true LTFU.

Methods: We conducted a retrospective cross-sectional study of a community-based ART cohort in Cape Town, South Africa. We used iDART to identify groups of patients known to be still enrolled in the cohort on the 1st of April 2008 that had failed to pick-up medication for periods of ≥ 6 , ≥ 12 , ≥ 18 and ≥ 24 weeks. We defined true LTFU as confirmed failure to pick up medication for three months (since last attendance). We then assessed short-term and long-term outcomes using a prospectively maintained database and patient records.

Results: On the date of the survey, 2548 patients were registered as receiving ART but of these 85 patients (3.3%) were found to be true LTFU. The numbers of individuals (proportion of the cohort) identified by iDART as having failed to collect medication for periods of ≥ 6 , ≥ 12 , ≥ 18 and ≥ 24 weeks were 560 (22%), 194 (8%), 117 (5%) and 80 (3%), respectively. The sensitivities of these pharmacy delays for detecting true LTFU were 100%, 100%, 62.4% and 47.1%, respectively. The corresponding specificities were 80.7%, 95.6%, 97.4% and 98.4%. Thus, the optimal delay was ≥ 12 weeks since last attendance at this clinic (equivalent to eight weeks since medication ran out). Pharmacy delays were also found to be significantly associated with LTFU and death one year later.

Conclusions: The iDART electronic pharmacy system can be used to detect patients potentially LTFU and who require recall. Using a short a cut-off period was too non-specific for LTFU and would require the tracing of very large numbers of patients. Conversely prolonged delays were too insensitive. Of the periods assessed, a ≥ 12 weeks delay appeared optimal. This system requires prospective evaluation to further refine its utility.

Press release

The media is a crucial audience for research findings because it is both a target for *and* disseminator of research evidence. The media can reach stakeholders that research teams cannot. They can popularize findings, press governments for change, and highlight inequities or programmes that are not working. However, researchers must be aware that the media can be sensational with bold headlines, while the actual reporting may lack important facts. For these reasons, one of the best

ways to reach media organizations is through a press release. This is similar in many regards to a sheet of take-home messages, but a press release has its own style and structure which should be followed.

In general, press releases are:

- No longer than one page. It may feature a photograph and/or logo of the research institution; other than this it comprise text.
- Topped by a strong and informative headline. Newspapers, depend upon a catchy 'hook' (the title) to convince people to read their articles, and a press release is no different. This is no simple task – to use ten words or less to capture the essence of a research project is very challenging. For a non-specialist audience you can focus on the most compelling/shocking and/or fascinating aspect of the project. Brainstorming on this might help to find the ten words that really capture what the project is about and why people should care about the results/conclusions.
- Summarized in several lines – justifying why the research findings deserve publication (dissemination /sharing). A small photograph or graphic may be helpful in reducing complexity to a simple but powerful image.

Have a two-paragraph body that answers the who, what, where, why and how questions for a lay audience. The media typically structures its articles to begin with the most important information and end with the least important. End with a section containing more information about the research institution or principal investigator. Also include contact information so that the newspaper or journalist can follow up if need be.

Box 3

Example: Yellow fever vaccination booster not needed

News release

17 May 2013 | Geneva – The yellow fever 'booster' vaccination given ten years after the initial vaccination is no longer necessary, according to WHO. An article published in WHO's Weekly Epidemiological Record (WER) reveals that the organization's Strategic Advisory Group of Experts (SAGE) on Immunization has reviewed the latest evidence and concluded that a single dose of vaccination is sufficient to confer life-long immunity against yellow fever disease. Since yellow fever vaccination began in the 1930s, only 12 known cases of yellow fever post-vaccination have been identified, after 600 million doses have been dispensed. Evidence showed that among this small number of 'vaccine failures', all cases developed the disease within five years of vaccination. This demonstrates that immunity does not decrease with time.

Important news for yellow fever endemic countries and travellers

"The conventional guidance has been that the yellow fever vaccination has had to be boosted after ten years," says Dr Helen Rees, chair of the SAGE. "Looking at really very good evidence, it was quite clear to SAGE that in fact a single dose of yellow fever vaccine is effective. This is extremely important for countries where yellow fever is endemic, because it will allow them to reconsider their vaccine scheduling. It is also important for travellers."

Yellow fever is an acute viral haemorrhagic disease transmitted by infected mosquitoes that is endemic to 44 countries in tropical areas of Africa and the Americas. Infection with the yellow fever virus causes varying degrees of disease, from mild symptoms to severe illness with bleeding, jaundice and fatal outcomes.

Estimated 200 000 new cases each year

There are an estimated 200 000 cases of yellow fever worldwide each year. About 15% of people infected with yellow fever progress to a severe form of the illness, and up to half of those will die, as there is no cure for yellow fever. Treatments are aimed simply at reducing patients' discomfort.

The vast majority of reported cases and deaths occur in sub-Saharan Africa. In endemic regions of Africa, yellow fever natural immunity is acquired with age, putting children at highest risk of infection. Over the past two decades, the number of yellow fever cases worldwide has increased due to declining population immunity to infection, deforestation, urbanization, population movement and climate change.

Vaccination is the most effective measure

Vaccination is considered to be the most important and effective measure against yellow fever. Protective immunity develops within 30 days for 99% of people receiving the vaccination. For routine immunization programmes in Africa, home to 31 of the 44 yellow fever-endemic countries, the vaccine costs about \$0.82 per dose.

SAGE is the principal advisory group to WHO for vaccines and immunization. It is charged with advising WHO on overall global policies and strategies, ranging from vaccines and technology, research and development, to delivery of immunization and its linkages with other health interventions. SAGE is concerned with all vaccine-preventable diseases including childhood vaccines and immunization.

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Policy brief

Policy briefs are short documents that present the findings and recommendations of a research project to a non-specialized audience. It is a stand-alone document, focused on a single topic and no more than 2–4 pages (~1500 words). Jones and Walsh (18) have observed that: "Policy briefs, if carefully designed, can be a powerful tool for communicating research findings to development policy audiences." Because policy-makers are constrained by time and overwhelmed by various sources of information, they are likely to make quick decision by selecting the 'evidence' most appropriate to their political leanings.

Furthermore, in practice, research evidence is considered through the lens of policy-makers' experience, expertise and judgment, contextual pragmatics, available resources and the policy context, as well as the habits, values and traditions of policy-makers, and the influence of lobbyists and pressure groups. Increasing the usage of evidence in policy-making therefore requires a communication approach that is informed by an understanding of and engagement with these competing influences.

Key ingredients of effective policy briefs (19)

To effectively serve its intended purpose a policy brief should be (19):

1. *Focused* on achieving the intended goal of convincing the target audience.
2. *Professional* (i.e. not academic). The typical audience for a policy brief is not interested in the research/analysis procedures conducted to generate the evidence, but rather the writer's perspective on the problem and potential solutions based on the new evidence.
3. *Evidence-based*. The policy brief is a communication tool. The audiences not only expect a rational argument but will only be convinced by arguments supported by evidence that the problem exists and the consequences of (or not) adopting a particular course of action.

4. *Limited* to a particular problem or specific aspect of a given problem.
5. *Concise*. Typical audiences often do not have the time or inclination to read an in-depth, 20-page argument on a policy problem. Therefore, it is expedient that policy briefs do not exceed a maximum of 6–8 pages.
6. *Understandable*. Use clear and simple language (i.e. not jargon and concepts of an academic discipline).
7. *Accessible* to the intended target audience.
8. *Promotional*. i.e. should catch the eye of the intended audience through use of colour, logos, photographs, slogans and illustrative quotes.
9. *Practical and feasible*. It must provide arguments based on what is actually happening in practice with a particular policy and propose recommendations that are realistic and feasible to the target audience.

Common structural elements of a policy brief

Policy briefs directly reflect the range of roles that policy analysts fill (from researcher to advocate). The IR projects that policy briefs typically focus on are from the more action-oriented, advocacy end of the continuum. Although there is much variation even at this end of the scale, the most common elements of policy briefs are: title of the document; executive summary; context and importance of the problem; critique of policy option(s); policy recommendations; appendices and sources consulted or recommended.

Box 4

Example: Policy brief on support for scaling up ACTs in treatment of simple *P. falciparum* malaria in Burkina Faso

Policy issues

The resistance of *P. falciparum* to conventional antimalarial drugs is well attested by a number of studies throughout the world, including in Burkina Faso. The efficacy of artemisinin-combination therapies (ACTs) has also been proven in various studies and the large-scale use of ACT is recommended by WHO. Like other countries, Burkina Faso opted to change its drugs strategy for treatment of simple malaria by substituting ACT for chloroquine treatment in February 2005. At the time of writing, this scaling up of ACTs has not been applied to all age groups.

Scale of the problem

Malaria is a major public health problem in Burkina Faso, with more than 2 million recorded cases and over 4000 deaths every year, especially among children under 5 years of age. The majority of medical consultations, hospital admissions and deaths are malaria-related. Proper management of malaria requires the use of *effective treatment*. However, the socioeconomic status of the population, limited public resources and poor health service infrastructure prohibit large parts of the population from accessing this life-saving treatment.

Policy options

Given this situation, there is an urgent need for policies to improve universal and equitable access to ACTs for treatment of non-complicated malaria. These policy options are:

- Urge private-sector stakeholders (pharmacies, clinics and surgeries) to comply with national directives on subsidized pricing of ACTs.
- Motivate community health workers responsible for home-based management of simple malaria.
- Withdraw the antimalarial drugs used in monotherapy to treat simple malaria.

Implementation considerations

To implement any of these three policy options, it is essential to:

- Provide information/raise awareness of the principal malaria control stakeholders.
- Ensure that ACTs adapted to each age group are available countrywide.
- Train the staff tasked with dispensing ACTs.
- Review certain regulatory arrangements relating to policy implementation.

Source: Personal communication, EVIPNet Team in Burkina Faso.

Using multiple dissemination platforms

IR involves researchers and multiple stakeholders with different capabilities and access to different dissemination platforms or channels. The nature and implications of your findings may suggest a particular channel. For example, if the major audience of a study is a group of patients in a rural clinic, then creating a community drama may be an effective channel, as might printing up a very simple brochure for patients awaiting care, or the use of colorful cartoon/animations for young children.

The Internet also offers various platforms to disseminate your team's work, such as social media platforms or blogs.

Dissemination strategy***Developing a dissemination strategy***

The dissemination process must be part of the IR project cycle. Involving stakeholders in the dissemination process early will enhance greater ownership of the research process and the ultimate uptake of the research findings.

Specific steps are recommended for research teams as they discuss and identify their dissemination strategies and related needs. This is intended as generic guidance that can be modified and customized for specific projects. The end result should be a context-sensitive strategy designed to disseminate particular research findings to specific audiences.

The overall approach

The research team could be tempted to focus on the creation of particular information products. For example, there have been instances where a research project has created videos featuring a visual component to the research and feature interviews with the researchers and other major stakeholders. However, single one-way products do not constitute a dissemination strategy.

Strong dissemination strategies feature: two-way dialogues (not just from the stakeholders/researchers to an audience, but also feedback and responses from the audience); precisely tailored and targeted messages suited to particular audiences; and mechanisms to evaluate relevant indicators, so that the strategy and its products can be revised and improved.

Steps in developing a dissemination strategy

The figure below highlights nine separate steps research teams should consider in developing a dissemination strategy.



Figure 1. Steps in developing a dissemination strategy

Step 1: Review past dissemination efforts

When developing a dissemination strategy, it is prudent to begin by looking at what was done in the past. How did the research team disseminate information in the past? What products were created? Which ones worked? How did particular audiences respond? This can be done as an internal brainstorming exercise, review of relevant documents, or as a survey (formal or informal) with stakeholders who received the team's communications in the past. Alternatively, a formal audit of previous dissemination efforts (often conducted by a third party) can assess performance and, more importantly, gauge perceptions that key stakeholders have of the team's research, and of the climate surrounding the research. This type of information can significantly influence the selection of future tools and dissemination channels.

Step 2: Devising dissemination objectives

The research team should brainstorm around what it hopes to achieve by disseminating IR results. Why does the team wish to communicate processes or findings to particular audiences? Is the purpose of the dissemination to increase awareness, understanding, action, or to support local involvement?

Below are examples of dissemination objectives for a youth HIV prevention campaign:

Box 5

Example: By the end of 2013, the project will provide the youth with information on:

- HIV prevention strategies
- The life skills to prevent/mitigate HIV infection

Step 3: Determining primary and secondary audiences

Determining the primary and secondary audiences for the information being disseminated is a critical aspect of the dissemination strategy. The research team must understand who the audience is, how they absorb research evidence, their timelines, needs, etc. This will greatly increase the likelihood that the dissemination approach will meet its objectives.

Every IR project has multiple audiences with unique abilities and needs. Messages must be appropriately tailored taking these into consideration.

One tested way to ensure your team addresses the needs of all stakeholders in the dissemination process is to classify them into primary and secondary audiences. Primary audiences are those who need to make a decision or a change. Secondary audiences are those in a position to influence the decisions or actions of the primary audience. The level of audience (primary or secondary) is determined by the dissemination objectives.

Box 6

Example:

In an intervention to perform safe male circumcisions for HIV prevention, where you are aiming to **persuade the men to come for circumcision**, the primary audiences are men who are at risk of HIV infection in relation to safe male circumcision (e.g. the uncircumcised men and sexually active circumcised men). Secondary audiences would include health workers, opinion leaders, caretakers of uncircumcised boys and female sexual partners. Each audience requires its own targeted communication strategy.

However, in the same intervention, if the objective of the dissemination is rather to seek support of the policy-makers to incorporate circumcision policies into existing national health policy, then the ministry of health officials and legislatures, plus other opinion leaders, would be the primary audience.

Step 4: Developing messages

Messages are at the heart of any dissemination product. Messages should be direct, simple, and explain the problem the research sets out to address. In addition, the solution the research may have generated, the particular implications of the research findings, and/or what might be expected of different audiences as a consequence of those findings should be captured in the message. IR projects often result in three to five key messages. While of course this does not represent the research in its totality, these messages can convey the essence of the research and its implications in a few concise words and phrases.

Messages should be written exclusively for one audience, bearing in mind the audience's needs and abilities with respect to the research evidence. A member of this audience should be able to read (or watch or listen to) those key messages in two minutes or less.

Step 5: Deciding on dissemination approaches

One way of choosing dissemination approaches is by initiating several stages of 'conversation' with a specific audience. The CHSRF's 'graded-entry' approach (14) offers one such idea. As an initial outcome of this approach, the research team develops a short document (i.e. 1 page or less) for a major audience. The document should focus exclusively on the most important findings for that audience and their major implications. Assuming the audience's positive reaction, a more detailed 3-page document could then follow, providing more detail about the research project itself, and positioning the implications against the context and other scientific evidence, etc. This could then be followed by a 25 page document (and/or a peer-reviewed paper) that explains technical matters such as the methodology.

Step 6: Determining dissemination channels

No matter how good the dissemination product, it will have very little impact if it is not disseminated via the most relevant channels. For example, a beautifully produced DVD with videos and photographs that capture the magnitude of a research project impact is useless if members of the intended audience do not have DVD players or even reliable electricity supply. Relying on the Internet as a channel for dissemination obviously assumes user connectivity, access to certain minimum bandwidth and sufficient skills to be able to find and use the research team's work.

The consideration of appropriate channels is an essential step as it helps to narrow down, in very realistic ways, the types of communications tools that are practical, reach the right audiences and within the available budgets. Above any other consideration, the choice of channel(s) dictates who receives (and therefore who might act upon) messages.

Step 7: Reviewing available resources

It is important to consider the resources available for the dissemination activities. What materials are available for this work? Who can do it and what kinds of skills do they have? How much funding is available to create and implement this strategy? Will any of these variables change as we implement the strategy?

One reason why research teams tend not to be adept at sharing their findings is because dissemination can be expensive to carry out. Some forms of dissemination require significant resources as well as a high level of capacity. Communication products can also carry hidden costs, such as translation of materials into multiple languages, or costs for specialized skills such as graphic design, etc. The more realistic and precise the team can be about all of these costs the more realistic the expectations for this work will be. This is best achieved by drawing up detailed budgets for each product from the outset.

Step 8: Considering timing and windows of opportunity

A timeline for developing and disseminating information/communication products may be obvious but worth reiterating. There may be, for instance, an upcoming conference or other event at which the research team can distribute several different communication products, deliver a plenary presentation, and/or arrange some face-to-face meetings.

Given some of these suggestions for a staged approach, the research team must pay attention to issues of timing. This involves being aware of shifts within an audience (suggesting greater receptivity to your team's work), windows of strategic opportunity that might suddenly open to which your team must respond quickly, and the activities of like-minded researchers and institutions, whose actions may help in advancing your team's agenda.

Step 9: Evaluating dissemination efforts

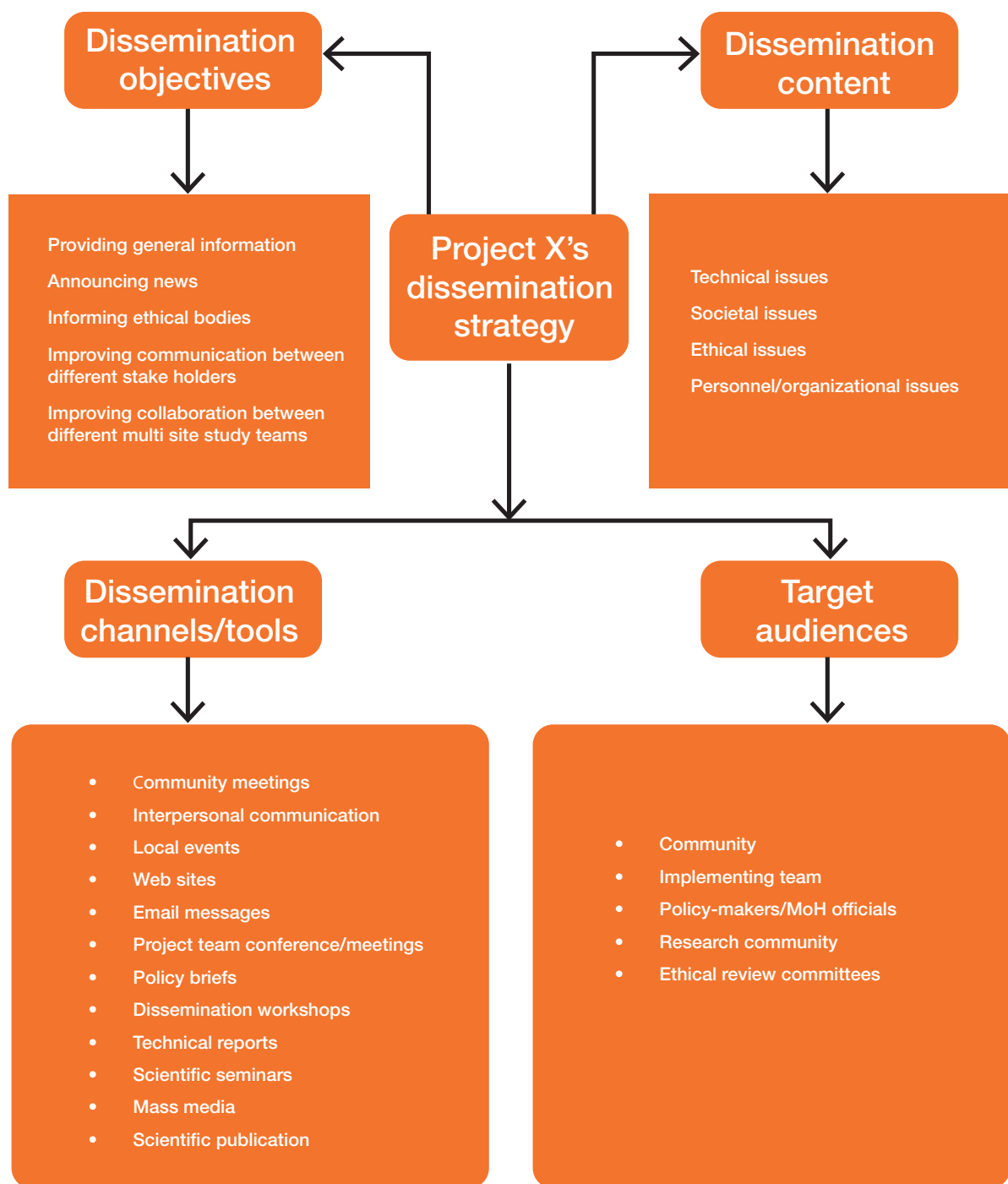
As with all aspects of the IR process, dissemination of results and implications also requires careful evaluation and feedback. Dissemination should be carefully planned so that the intended audience(s) are reached. During implementation, adjustments may be needed to ensure a maximum return on investment and attention. One question that can usefully guide the entire approach to dissemination is: *What will change if communications are completely successful?* You don't just want to get your findings into the public domain, you want specific audiences to receive them and *act* upon them. What kind of action then, among key audiences, equates with success?

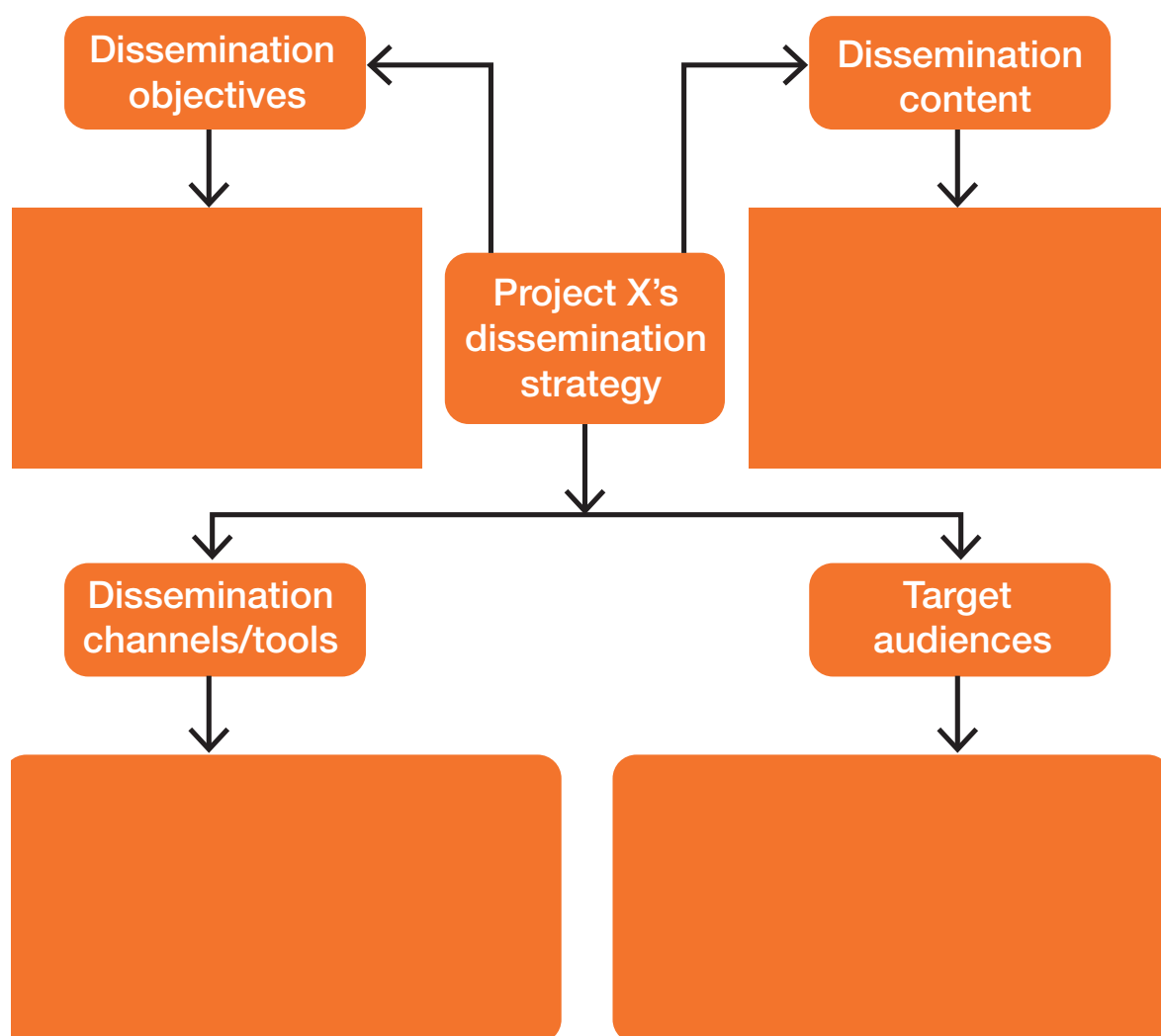
Assessing budgetary implications is also important. Recognizing the effort that goes into successful dissemination, you need to be clear that you have used the right tools, struck the right balance among available tools, and received sufficient user feedback. This can be collected via some formal surveying and key informant interviews, and be invaluable of planning future strategies. An 'impact log' (20) can be another way to accumulate feedback on your communications strategies. Usually done informally, an impact log documents stakeholder reactions, media references, peer review references, etc.; media references to the work; peer-review references, etc. The research team can then synthesize all of this information into a lessons learnt or best-practice document. In some cases, the feedback may immediately shift or alter some of the products to ensure they reach the right audiences with the right messages.

Reflection Activity

Below is an example of a dissemination strategy. Use this example and the template provided to guide your team in developing a first draft of your dissemination plan.







CONCLUSION

Congratulations on completing Module 5 *Dissemination of Research Findings*. This module illustrates the key concepts of knowledge translation that relate to IR. This module also described the value of continuous stakeholder engagement for discussion and utilization of research results, the value of developing of a comprehensive dissemination strategy in a research project, and the importance of tailored dissemination tools for the different target audiences. We hope that you found enjoyed this module helpful and have increased your knowledge and understanding of dissemination of results and research findings. We encourage you to continue with Module 6 entitled, *Monitoring and evaluation*.

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MODULE

6

**MONITORING AND
EVALUATING AN
IMPLEMENTATION
RESEARCH
PROJECT**

INTRODUCTION

This module has been designed to help your research team track progress against your set plans, check compliance to established standards, identify trends and patterns, adapt strategies and inform decisions for project management. The module is also designed to build skills to determine the relevance and fulfilment of objectives, developmental efficiency, effectiveness, impact and sustainability. It covers the following key concepts with examples:

- Monitoring and evaluation (M&E) plan
- Developing an M&E plan
- Implementing the M&E plan

LEARNING OBJECTIVES

Upon completion of this module, your research team will be able to:

1. Appreciate the process involved in the development of a monitoring and evaluation plan.
2. Describe the implementation process of a monitoring and evaluation plan.

KEY CONCEPTS

Monitoring and evaluation plan

A monitoring and evaluation (M&E) plan is a document that outlines how an implementation research project is monitored and evaluated, and that links strategic information obtained from various data collection systems to decisions about how to improve the project on an ongoing basis. The M&E plan serves several main purposes, including: (i) stating how achievements of the programme/project will be measured; (ii) documenting consensus, thereby encouraging transparency, accountability and responsibility; (iii) guiding implementation of M&E; and (iv) preserving institutional memory.

An M&E plan is built on the key parameters of a project, which include the:

- overall goal or desired change or effect;
- main beneficiaries or audience of the project;
- hypotheses or assumptions that link the project objectives to specific interventions or activities;
- project scope and size;
- extent of participation in and capacity for M&E;
- project duration; and
- overall project budget.

Each project has different M&E needs, depending on the operating context, implementing agency capacity, donor requirements, and other factors. In preparing an M&E plan, it is important to identify these needs and coordinate the methods, procedures and tools used to meet them; this conserves resources and streamlines M&E planning.

Standards for an M&E plan

An effective M&E plan should conform to the following standards:

Utility: It must be useful and serve the practical and strategic information needs of the intended users for decision-making purposes, these may range from assessing programme performance to allocating resources, etc.

Feasibility: Be realistic and practical. Given the scarcity of resources, the M&E plan should make the best use of existing data collection systems. However, if new data collection systems are involved, resources (cost and technical capacity) must carefully be considered.

Ethically sound: Abide by ethical principles with regard to those involved in and affected by the M&E activities.

Accuracy: Provide technically accurate and useful information for decision-making and programme improvement.

Key components of an M&E plan

There are four key components that form the foundation upon which the M&E plan should be built. Answering these four corresponding questions is critical to M&E planning:

What does the project want to change and how? (ii) What are the specific objectives that are designed to achieve this change? (iii) What are the indicators and how will they will be measured, and, (iv) How the M&E data will be collected and analysed?

Developing an M&E plan

Before you set up an M&E plan, the team should define the overall project goals and objectives, understand the context for the study and identify the key players/stakeholders (the details of understanding the intervention and identifying the stakeholders were described in detail in Modules 1 and 2). The most appropriate approach (e.g. M&E framework and data collection methods to conduct M&E) should also be selected. The frameworks (logic model, logical framework) and data collection methods were also explained in Modules 1 and 2 respectively.

Below are the key steps that should be taken when developing an M&E plan. It should be noted that these steps are not necessarily independent from each other, and may actually overlap quite substantially. Many of these steps may be developed or need to be considered in conjunction with others.

Key steps in developing an M&E plan

Stakeholder consultation and participation

Stakeholder consultations and participation should be regular occurrences throughout the entire process of developing and implementing your M&E plan. These consultations ensure dialogue, a clear understanding of the project goals and objectives, and how these will be assessed. They also ensure that various perspectives are understood and integrated, and that authentic needs are being met. Stakeholder participation in the design of the M&E plan facilitates the selection of appropriate and useful M&E indicators. Furthermore, taking extra measures to promote stakeholder participation creates a sense of ownership and responsibility among partners. Stakeholder involvement increases the probability that the information and results guided by the M&E plan will be consistent with their expectations.

Developing the M&E plan

One of the first tasks in developing your M&E plan is translating your project's research problem, goals and objectives into variables that can be objectively measured. Specific M&E plans highlight and refer to the conceptual foundation upon which the project as a whole is built. It is essential to understand the differences between project inputs, outputs, outcomes, and impact, since the indicators to be measured under the M&E plan will most likely reflect this hierarchy.

Consensus should be reached on key questions in the following areas: "What do we want to know at the end of the project?" and "What do we expect to change by the end of the project?" Again, answering the question of what you expect your project to change will guide decisions about what strategic information is needed for project management decisions as well as what elements should be monitored and evaluated in order to assess progress. The rigor and scope of your M&E plan will depend on what you commit to and what results or outcomes your project is accountable for.

Developing the M&E plan provides your team with a clear picture of the following:

- How project activities are linked to expected outputs, outcomes and population-level impacts.
- How different types of information will be collected and used by different levels of the health system.
- What elements need to be measured (e.g. resources, service statistics, coverage and quality, costs, and outcomes associated with the project).
- Appropriate indicators to be selected. To enable standardization and comparison with other similar projects, indicators should be consistent with international/national standards. They should also be feasible and realistic to collect. The data sources identified must provide the information needed to measure the indicators.

Determining the M&E methodology

Once your team has developed the M&E plan, defined the indicators, and identified the data sources necessary, the appropriate methods by which data can be collected and analysed should be determined. For example, your team should determine whether you will use existing data collection systems or if new systems need to be developed. Your team must also determine how information will be recorded, analysed and reported. Furthermore your team should also carefully consider the resources available in terms of technical competencies, costs, and time when determining the methods and tools to be used.

Assign responsibilities for implementation

After developing the M&E plan, the roles and responsibilities of the different stakeholders should be described clearly. This step will determine how the M&E plan will be specifically implemented and what reporting system will be adopted. The implementation of the plan should include the data collection plan (i.e. who is responsible for collection of specific data; ensuring quality control at each stage; how often the data will be collected; format of the data (e.g. raw, summary); what resources will be required at each stage; who will analyse the data) and the dissemination plan.

Setting targets

Target should be set in consultation with all stakeholders so that everyone understands what the project has committed to achieve. By setting targets, you will have a concrete measure by which to judge whether the project is progressing as expected. The process of target setting, must focus on answering the question: "What can realistically be achieved given the resources and the

environment in which the project is operating?” The factors to consider include: baseline levels; past trends; expert opinions; research findings; what has been achieved elsewhere; client expectations; and the capacity and logistics to achieve targets. When setting specific project targets, you must also decide the direction of any potential changes that may be indicated over time.

Defining reporting system, dissemination and utilization of results

Throughout the process of developing the M&E plan, the end users' information needs must be addressed to ensure utilization of the findings from the research project. In the M&E plan, your team should clearly articulate a plan for disseminating and utilizing M&E findings (see also Module 5). Preliminary findings should be prepared and presented during strategically timed user meetings and/or workshops. The information should be tailored to the specific stakeholders' interests and needs. Relevant information will solicit input and feedback that could affect decision-making and project improvement.

Below are some practical considerations in planning information reporting and utilization planning:

- Design the M&E dissemination plan around the information needs of the users. It is important to be mindful that the content and format of data reports will vary according to their intended use. For example, is the M&E required to monitor processes? To conduct strategic planning? To comply with requirements? Help identify problems? Justify a funding request? Or to conduct an impact evaluation?
- Identify the frequency of data reporting needs. For example, project managers may want to review M&E data frequently to assess project progress and make planning decisions, whereas donors may need data only once or twice a year to ensure accountability.
- Tailor the reporting formats to the intended audience. Since reporting may entail different levels of complexity and technical language, the report format and media should be tailored to specific audiences and different methods used to solicit feedback.
- Identify appropriate outlets and media channels for communicating M&E data. This should consider both internal reporting, such as regular project reports, to management and progress reports to donors, as well as external reporting, such as public forums, news releases, briefings, and websites.

Implementing the M&E plan

Implementation of the M&E plan occurs in three stages, namely: (i) checking and measuring progress; (ii) analysing the situation; and (iii) reacting to new events, opportunities and issues. These are described in detail below.

Checking and measuring progress

Ideally, monitoring focuses on the project's three main characteristics of quality, time and cost. The project manager coordinates the project team and should always be aware of the status of the project. When checking and measuring progress, the project manager should communicate with all team members to find out whether planned activities are implemented on time and within the agreed quality standards and budget. The achievement of milestones is measured and reflects the progress of the project.

Analysing the situation

The second stage of monitoring consists of analysing the situation. The status of project development is compared to the original plan, and causes and impact of potential deviation are identified. Actions are identified to address these causes and the impacts of any deviations.

Reacting to new events, opportunities and issues

It is important to anticipate and react quickly to new situations, events, opportunities and issues, and to identify the possible actions to be taken. If appropriate, various options are considered and discussed with the project team and a decision is taken regarding the most appropriate path to pursue.

Adjustments to/updating the M&E plan

The M&E plan should be seen as dynamic and should always reflect the reality of what is known and understood. Each time a deviation from the original M&E plan is identified, whether or not it requires any further action, the M&E plan should be revised and changes documented accordingly. The revised plan reflects the new situation and should demonstrate the impact of the deviation on the whole research project. This is crucial for effective implementation and good communication with the project team, donors and all stakeholders. Adapting the M&E plan also facilitates the management of the project budget and finances. Updating the M&E plan involves including the entire project team (key stakeholders/partners) in the decision-making process; revising the work plan (including costs) as and when necessary; and meticulously documenting all adjustments. Circulate the revised plan to all stakeholders including the relevant Ethical Review Board(s) and Institutional Review Board(s), highlighting the changes and their impact on the project. Your team must obtain approval for the plan amendments from all relevant parties as appropriate. Below are examples of questions that can be considered to help your team assess how well the M&E plan is working.

- Are M&E activities progressing as planned?
- Are the evaluation questions being answered sufficiently?
- Have new evaluation questions been raised and, if so, should they be incorporated into the M&E plan?
- Are there any methodological or evaluation design issues that need to be addressed?
- Are there any outside factors (political, environment) that are affecting the M&E plan?
- Are appropriate staff and funding still available to implement the M&E plan?
- Are M&E findings being disseminated and used by stakeholders for decision-making and programme improvement?

APPLICATION OF KEY CONCEPTS

The example below describes the six steps taken by the research team and the implementers to develop the M&E plan for the use of vouchers for scaling up insecticide-treated nets in the United Republic of Tanzania (2003–2007).

Example: Hanson et al (2008) (1).

Step 1: Stakeholder consultation and participation

The M&E strategies were developed during scheduled meetings of Tanzania National Voucher Scheme (TNVS) partners. The stakeholders included officers from the National Malaria Control

Programme, groups involved in implementing insecticide-treated net (ITN) distribution activities in Tanzania, and researchers from the Ifakara Health Research and Development Centre (IHRDC) and the London School of Hygiene and Tropical Medicine (LSHTM). Following broad-based consultation and participation, a comprehensive and multidisciplinary approach to monitoring and evaluation was agreed upon to cater for novelty and complexity of the intervention, involving multiple partners and depending on both the health system and the retail sector.

Step 2: Developing the M&E plan

The researchers and stakeholders developed an M&E plan. This was to investigate the programme effects over five main domains: (1) ITN coverage among target groups; (2) provision and use of reproductive and child health (RCH) services; (3) 'leakage' of vouchers (i.e. in terms of non-target groups receiving vouchers, and vouchers being used to purchase items other than ITNs); (4) the commercial ITN market; and (5) cost and overall cost-effectiveness of the scheme. They also developed the indicators to measure the progress. The indicators were agreed upon by the Global Fund to fight AIDS, TB and Malaria (GFATM), which funded the project. Table 1 below shows the evaluation domains, the core indicators, and the data sources for each.

Step 3: Determining the M&E methodology

The team used the principle of triangulation, in which data was collected from multiple sources. These included household, facility and exit surveys, focus group discussions (FGD) and in-depth interviews, a retail audit for data on ITN availability, retail prices at the shops, voucher tracking as well as cost analysis.

Reflection activity

Using the information from the table above as a reference, complete the template below (Table 2) and create an initial draft of your rproject M&E plan.



Step 4: Assign responsibilities for implementation

Independent researchers from IHRDC and LSHTM conducted the M&E activities. Activities involved collecting and analysing data, and reporting findings to the implementers who included the National Malaria Control Programme and groups involved in implementing ITN M&E activities in the country. Sometimes it may be appropriate to contract M&E activities out. However, if the research team is implementing the intervention, it would be appropriate for the entire team to be involved in monitoring of the activities.

Step 5: Setting targets

Targets for the effects of the voucher programme included:

- Measuring the effect of the voucher scheme on ITN use among pregnant women and children under five years of age.
- Use of RCH services including the voucher scheme.
- Effect of the scheme on RCH service provision.
- Pregnant mothers' use of RCH services, their voucher knowledge and use, ITN use and knowledge of malaria in pregnancy.

Table 1. Evaluation domains and data collection methods

Evaluation domain	Indicator(s)	Surveys			FDGs and in-depth interviews	Retail census	Voucher tracking	Cost analysis
		Household	Facility	Exit				
Coverage of target groups (ownership, use)	- Household ownership of at least one net/ITN; - Individual slept under a net/ITN on the night prior to the survey	X	X	X				
Provision and use of RCH services, including voucher scheme	- Currently/recently pregnant woman* attended ANC; - Mean weeks of gestation at time of first ANC visit; - Received a voucher; - Received 1 dose of SP as IPTp; - Received 2 doses of SP as IPTp	X	X	X	X		X	
Leakage of vouchers	% of voucher recipients who could be identified, interviewed, and confirmed they received a voucher				X		X	
Impact on ITN market	% of wards with at least one retail source of ITNs, insecticide	X				X		
Cost and cost-effectiveness	- Cost per voucher - Delivered; - Cost per ITN delivered	X						X

Indicators of voucher coverage were calculated for both currently pregnant women and for women who had a live birth in the 12 months preceding the survey.
 ITN = insecticide-treated net; RCH = reproductive and child health; ANC = antenatal care; SP = sulphadoxine-pyrimethamine; IPTp = intermittent preventive treatment in pregnancy

- Community and provider perspectives on the scheme.
- ITN availability and retail prices at selected shops.
- Degree of 'leakage' of vouchers.
- Economic and financial costs of the voucher scheme.

The scope of the M&E and the targets set were based on available resources. For example, whereas this was a national programme, activities were in a representative sample of 21 focal districts. The health impact of the programme (in terms of mortality and morbidity prevented) was not measured. More importantly, health impact of ITN use on morbidity, mortality and anaemia had been demonstrated under effectiveness conditions in an earlier study in the country and were therefore considered unnecessary in this intervention.

Table 2. Template for evaluation domains and data collection methods

Evaluation domain	Indicator (s)	Level of data collection*		Data collection technique	Data collection technique	Data collection technique	Data collection technique
		e.g. House-hold	e.g. Facility				

Indicate level(s) of data collection relevant to your project

Step 6: Define reporting system, utilization and dissemination of results

(a) Reporting system and dissemination of results

Results from the various segments of research were presented to TNVS partners at scheduled meetings in the first two years. Table 3 outlines result reporting dates for each of the main data collection methods.

Table 3. Schedule of reporting dates for specific, by data collection method

Data collection method	Time of reporting results
Household and facility surveys	November 2005
Retail audit	January 2006
Voucher tracking	April 2006
Key informant interviews and FGDs	August 2006
Household survey and costing	November 2006
Retail audit and voucher tracking	August 2007
Household and facility surveys	November 2007

(b) Utilization of the findings

Regular feedback regarding the research findings helped implementers identify problems early in the project. Identifying problems allowed the research team to revisit and modify their M&E strategies where necessary, as outlined in Table 4.

Table 4. Ongoing and emerging issues and corresponding responses

Issue identified	Evaluation response	Implementer response
Relatively low levels of voucher coverage	Qualitative investigation with facility staff to identify reasons for not distributing vouchers	Redevelop training messages for facility workers
Stock-outs of vouchers and antenatal cards required for issuing of voucher	In-depth facility level analysis	Work with the Medical Supplies Division and MEDA to improve supply chains
Relatively low levels of voucher coverage in most geographically isolated clusters	Survey instruments modified in subsequent rounds to include questions about use of outreach services for ANC, and the interventions received	Develop mechanisms for outreach providers to distribute vouchers
Relatively low levels of retreatment of ITNs	Qualitative investigation to identify what voucher recipients understand about retreatment kits	Amend insecticide treatment messages to respond to user knowledge and perceptions
Low knowledge of voucher value	Qualitative investigation into understanding of the value of the value	Develop IEC materials to address voucher value and top-up

CONCLUSION

Congratulations on completing Module 6 Monitoring and Evaluation. This final module provided you with an outline of how to help your research team track your progress against your set plans, check compliance to established standards, identify trends and patterns, adapt strategies and inform decisions for project management. This module also described the process involved in the development and implementation process of a monitoring and evaluation plan.

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