



Implementation Research Toolkit

Second edition

Editors: Olumide Ogundahunsi and Edward Mberu Kamau



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The named editors alone are responsible for the views expressed in this publication.

Designed by Inis Communication

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The current revision and online version of the Implementation Research Toolkit was developed in the Special Programme for Research and Training in Tropical Diseases (TDR) as a self-learning tool to help researchers and programme implementers systematically identify barriers to effective implementation of health programmes, strategies and interventions and to support the planning and conduct of research aimed at understanding and addressing such bottlenecks. The toolkit evolved from a project initiated by Jane Kengeya-Kayondo and Soumya Swaminathan at TDR.

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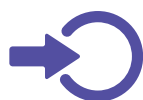
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- *Integrating implementation research into health systems*: Tim France, Alison Krentel, Margaret Gyapong and Edward Mberu Kamau.
- *Implementation research case studies*: Compiled by Ayat Abu Agla and Robinah Najjemba.
- *Developing IR project with an intersectional gender lens*: Mariam Otmani del Barrio, Chandani Kharel, Robinah Najjemba and Edward Mberu Kamau.

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Responsibility for the views expressed and for any errors of fact or judgment rests with Olumide Ogundahunsi, Edward Mberu Kamau, Alison Krentel, Phylis Dako-Gyeke, Tuoyo Okorosobo, Riris Andono Ahmad, Robinah Najjemba, Tim France, Ayat Abu Agla, Mariam Otmani del Barrio and Chandani Kharel, the editors and authors of the revised toolkit.



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IMPLEMENTATION RESEARCH TOOLKIT



Introduction to Implementation Research

Olumide Ogundahunsi and Margaret Gyapong




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INTRODUCTION TO IMPLEMENTATION RESEARCH

The close connection between health and human development is well recognized. Healthy lives influence and shape the overall course of sustainable development. Diseases, inadequate access to health technologies such as medicines, vaccines, diagnostics and devices, and poor implementation of health policies all hinder holistic progress. The 2030 Agenda for Sustainable Development acknowledges this fundamental relationship. Sustainable Development Goal 3 (SDG3)¹ captures the global ambition to end some of the major epidemics of poverty by 2030, including tuberculosis (TB), malaria and neglected tropical diseases (NTDs). In turn, underlying targets stress the need for universal health care coverage for all citizens, and for stronger health systems that enable access to essential health services and technologies. Dig even deeper and SDG3 calls for more research and development (R&D) on new medicines, diagnostics and vaccines: critical innovations that fill current gaps in health care and keep national programmes one step ahead of shifting epidemics.

The optimum introduction of new and/or proven health interventions and technologies – including ensuring access, delivery and usage – is critical to good health outcomes, and ultimately to the well-being of populations. All too often this is unfortunately not the case. For example, a new health technology or intervention that proves efficacious in strictly controlled clinical trial settings



may not be as effective when used within ‘real life’ health system contexts, particularly in fragile or resource-limited settings.

The optimum introduction of new and/or proven health interventions and technologies – including ensuring access, delivery and usage – is critical to good health outcomes, and ultimately to the well-being of populations.



During the development of an intervention, there is a strong focus on ‘authentic’ implementation: A strict adherence to a study protocol under carefully controlled and monitored conditions, including follow up of subjects (if applicable), to ascertain the efficacy and fidelity of the intervention. However, when the intervention is subsequently deployed in the health system, effectiveness becomes the overriding goal and this can sometimes be enhanced by adaptation to specific contexts.


The large-scale deployment of an intervention within a health system may therefore encounter previously unforeseen barriers to its uptake and penetration. These barriers are often related to deficiencies in the detailed identification and contextualization of regional, country or community-specific characteristics, as well as failures to prepare for or address them. Such context-specific barriers may be due to the physical environment, socioeconomic and cultural contexts, as well as health systems and user characteristics. Failure to identify and address these barriers before large-scale deployment of a new technology results in considerable losses to the health system, as well as loss of confidence in the technology among the target population and other stakeholders.²

Implementation research (IR) aims to first identify and then address such barriers.

What is implementation research?

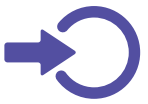
The importance of research in identifying solutions and options for overcoming implementation obstacles in health systems and programmes is widely recognized. This form of research addresses implementation bottlenecks, identifies optimal approaches for a particular setting, and promotes the uptake of 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 a systematic approach to understanding and addressing barriers to effective and quality implementation of health interventions, strategies and policies. IR is demand-driven and the underlying research questions are framed around and based on needs identified together with relevant stakeholders and implementers who are themselves embedded in the local context. Uniquely, programme implementers are an integral part of the research process itself.



IR is the systematic approach to recognizing, understanding and addressing health system and implementation bottlenecks, identifying optimal implementation options for a given setting, and promoting the uptake of research findings into policy and practice.

IR has been applied to increase the effectiveness of bed nets used to reduce malaria in Africa; address the rise in multidrug-resistant TB in eastern Europe; prevent mother-to-child transmission of HIV in South Africa; and ensure that the medicine ivermectin is distributed to 60 million Africans to control onchocerciasis (river blindness). It is a very powerful and essential form of research that identifies contextual implementation barriers, helps design and put in place strategies to address them, and ultimately leads to improved health outcomes.



The audience for this toolkit

First and foremost, IR is team work. It requires people with differing and complementary skills, experiences and backgrounds to come together in addressing an implementation problem together. An IR project team can include health care providers, programme managers, researchers, policy-makers, as well as other stakeholders such as civil society groups, nongovernmental organizations, the media and others interested in or impacted by the IR process and its results.

The modules of this toolkit specifically target health care providers, researchers, policy-makers, programme managers and administrators, and take into consideration their varying levels of involvement in a typical IR project.



Relevance of IR for improved access and delivery of interventions

Appropriately designed IR can help deliver and apply interventions more effectively and with greater impact. Emphasis on IR is increasingly important as the global health community faces the challenge of optimizing proven interventions in the real world (i.e. outside the controlled experimental environment associated with clinical trials or proof-of-concept studies). In many settings, this requires innovative approaches to reach populations and optimize delivery. Interventions that may be effective in one setting may have a reduced impact in other contexts due to a variety of context-specific factors. In other words, many proven and efficacious health technologies (medicines, vaccines, diagnostics and devices), lose traction within the health system for various reasons (see Box).

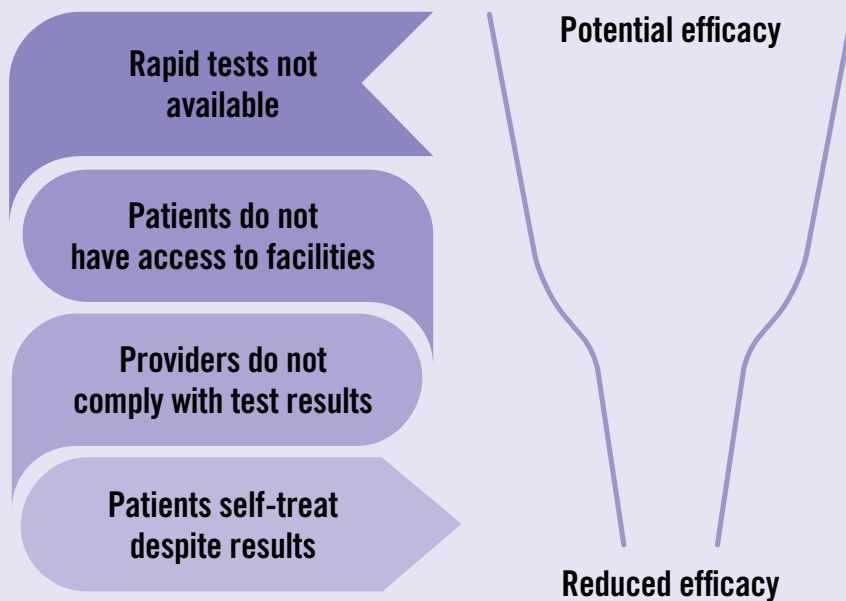
Summary of the malaria ‘Test, Treat, Track’ initiative

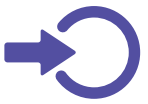
After several laboratory and clinical studies, the value of rapid diagnostic tests (RDTs) as efficacious tests for the timely identification of malaria infection was established. Malaria RDTs became an important component of malaria diagnostic testing in the clinical management of febrile illness.

In 2012, WHO launched the ‘T3’ (Test, Treat, Track) initiative, which anchors key policy messages of WHO recommendations – on diagnostic testing, treatment and surveillance of malaria – such that every suspected case of malaria should be tested; every confirmed case should be treated with a quality-assured antimalarial medicine; and all cases should be tracked through a timely and accurate surveillance system.³ Accordingly, RDTs should be deployed in the health system as a cornerstone of malaria case management.



In many settings, however, and due to several health system and patient-related factors, the use of RDT’s has not been as effective as anticipated. For example, the tests may not be available at the health facilities that need them. Even in facilities where they are available, some patients may not have access to the facilities, and hence to the test (because they cannot reach the facility). Providers may not always comply with RDT results and treat for suspected malaria solely on the basis of clinical symptoms. Patients may also decide to self-treat for malaria despite negative RDT results. Taken in combination, such factors can render an efficacious test ineffective, thereby increasing costs and undermining health outcomes in the complex, real-life context of the health system.





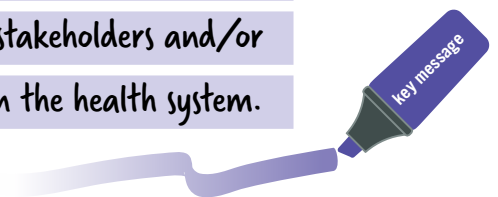
An intervention that has proven efficacious in a trial settings, may not perform as well as expected within a given health system due to wide-ranging potential contextual factors, such as issues of accessibility and/or acceptability, health care providers' adherence to policy recommendations and patient compliance. Managers in the health system have varied and unpredictable control over the behaviours of providers and patients, as well as other aspects such as managers' understanding of implementation processes. In this way, efficacious interventions typically become less effective when deployed in real-life settings.

Figure 1. Influence of health system factors on intervention effectiveness and impact⁴



IR is the systematic approach to recognizing, understanding and addressing such system and implementation bottlenecks, identifying optimal implementation options for a given setting, and promoting the uptake of research findings into policy and practice. IR is demand-driven and underlying research questions are framed according to needs identified by relevant stakeholders and/or implementers in the health system.

IR is demand-driven and underlying research questions are framed according to needs identified by relevant stakeholders and/or implementers in the health system.



Essential elements of conducting meaningful IR include:

- A good understanding of the intended intervention (for example identifying those elements seen as essential and those that could be modified without undermining the intervention objectives or performance).
- A robust grasp of how the intervention is to be delivered in a given health system (implementation process), with particular attention to modifications driven by a perceived need for adaptation to a specific local context.
- Identification and early and continuous engagement of crucial stakeholders including the community itself.
- A monitoring system that tracks any changes in the implementation process, checks for deviations from the original plan and accurately documents all key processes.

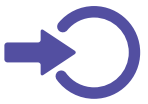
Case study 1

Identifying barriers to accessing integrated community case management services

Background: Integrated community case management (iCCM) is an equity-focused strategy adopted by WHO/UNICEF to improve access to essential treatment services for children. In 2010, the Government of Ethiopia used its health extension workers (HEWs) programme to scale up the iCCM of childhood illness strategy throughout the country. However, after two years, utilization of HEWs remained low despite the presence of a service delivery strategy that focused on minimizing several common access barriers related to cost, distance and quality of services. For instance, HEWs were trained and subsequently supported, volunteer community health workers were deployed to the villages and children below the age of five years received free healthcare. In addition, the HEW's community mobilization and education activities were part of existing national child health initiatives to promote community engagement and programme sustainability. Research was undertaken to elucidate perceptions and experiences of caregivers and to better understand the reportedly low utilization of iCCM services. The parameters used to define accessibility were availability of qualified health providers and health commodities at the health post; geographic accessibility; affordability of the services; and acceptability of the providers and services.

Rapid ethnographic assessments in eight rural health post catchment areas of Jimma and West Hararghe zone were conducted using focus group discussions (FGDs) and in-depth interviews (IDIs). FGDs focused on social norms of care-seeking and community perceptions regarding HEWs and iCCM services. IDIs focused on care-seeking experiences of caregivers over the course of the most recent illness of a child, including perceptions relating to barriers and facilitators to utilizing HEWs delivering iCCM services at the health post. The study participants were mothers, fathers, HEWs and community health workers.

Findings: HEWs were frequently absent. Although the services were free, many caregivers could not access services due to related social and transport costs. Long distances to the health posts, bad terrain coupled with inadequate transportation frequently rendered the health posts inaccessible. Lack of ownership of the health posts due to insensitive HEWs, lack of trust of the quality of care provided and lack of decision-making power of the primary caregiver regarding care choices for their child were also cited as prohibiting factors. However, caregivers also had limited awareness of child illness and the services provided at the health posts.

**Case study 1****Identifying barriers to accessing integrated community case management services**

Conclusions: In spite of the conducive and supportive health policies, the use of iCCM services was suboptimal due to challenges at the personal and systems level.

Lessons: Innovative approaches are needed to address challenges identified and in order to reduce barriers and promote utilization of iCCM services for all caregivers and children in need.

Source: Shaw B et al. Access to integrated community case management of childhood illnesses services in rural Ethiopia: A qualitative study of the perspectives and experiences of caregivers. *Health Policy and Planning*. 2015; Nov 24:czv115.

The purpose of this Toolkit

This Toolkit is a practical aid that supports IR. It is designed to guide those conducting IR and to help in the formation of multidisciplinary research teams.

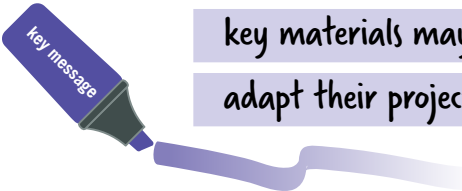
The Toolkit helps IR teams:

- apply a structured process to identifying bottlenecks and barriers to programme implementation (the ‘problem’) in the health system/community;
- contextualize the problem;
- identify and engage appropriate stakeholders;
- formulate appropriate research questions;
- determine an appropriate study design;
- articulate a proposal that explores and responds to the questions;
- implement and monitor the project in a credible manner;
- feed the solutions/adaptations back into the health system; and,
- communicate effectively throughout the process.⁵

Many of the concepts presented in the Toolkit are cross-cutting and interrelated throughout the different modules.

At its core, IR is collaborative: From the initial problem identification phase through to the research results dissemination, collaboration between the research team, relevant stakeholders and health personnel is key. Correct constitution and composition of the IR team helps encourage and facilitate collaboration by bringing together people who represent different disciplines, strengths and knowledge bases. IR’s multidisciplinary approach is essential from the early stages of identifying bottlenecks to the choice of study design and research method(s), conducting the research project and communicating the findings.

By its nature, IR means research teams must remain dynamic, organic (flexible) and adaptive in their outlook. Unlike other forms of research, IR is an ongoing process that requires continuous feedback of results back to the team, the study design and, ultimately, into the health system, allowing for each to adapt the intervention as required.



Because it occurs in real-life settings, IR must be adaptive. People may not come to work; the rains may impact service delivery or delivery of key materials may be delayed. IR teams must be willing and able to adapt their projects to address these real-life likelihoods.

The Toolkit is not a training course on IR and does not offer in-depth deliberations of definitions or the various theoretical frameworks used in implementation science.⁶ The overall goal is to facilitate practical research aimed at the optimization of interventions for improved health outcomes.

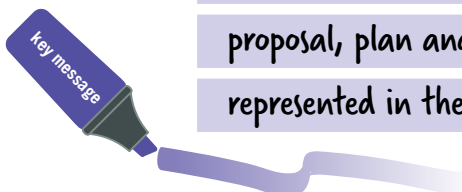
Research teams

The research team assembled to address a specific IR question or implementation challenge should reflect the full range of disciplines required to address related research question(s). Members of the team have varied roles, they may work in diverse sectors (for example health, finance, planning, academia etc.), and likely have very different backgrounds. The diversity of disciplines and roles is an asset in understanding an implementation problem and developing solution(s) to address it. Because conventional public health training does not typically prepare researchers, practitioners, providers or decision-makers for the types of partnership and interdisciplinary approaches essential for IR, this toolkit includes a dedicated section on team building. It addresses the attributes and core concepts for establishing a successful research team. In recognition of the fact that some members of the team may have limited knowledge of IR, capacity to frame relevant research questions, or design, conduct, manage and interpret research findings for feedback into the health system, the Toolkit provides some guidance on team dynamics and the drivers of effective sustainable teams.

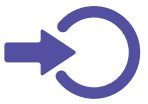


THE BUILDING
AN IR TEAM
MODULE

SEE



IR is team work. The ideal IR team is a multidisciplinary one, with relevant skills, backgrounds and experience to develop a research proposal, plan and mobilize essential resources and conduct the study represented in the composition of the team.



The Massive Open Online Course (MOOC) on Implementation Research is a prerequisite for all members of the team. If you have not taken part in that course yet, you should do so before using this Toolkit.

SEE

'MOOC ON IR'



Case study 2 Key characteristics of implementation research

Background: Implementation Research (IR) in comparison to other research domains, is demand-driven and research questions are based on the needs identified by the implementers in the health system. It is context-specific and is mindful of cultural and community-based influences. Furthermore, although IR is dynamic and adaptive, it takes place within real-life settings and there is no attempt to manipulate the setting within which the intervention is taking place. It engages with relevant stakeholders including the beneficiaries. Since IR is especially concerned with the users of the research and not purely the production of knowledge, it aims to promote the uptake of research findings into routine practice. The process of knowledge translation is promoted through the active involvement of the relevant actors in the identification, design and execution of research and should not be used only as a target for the dissemination of study findings.

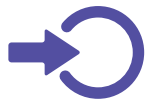
Example of an IR project: To inform a planned mass drug administration (MDA) for lymphatic filariasis (LF) in two districts of Indonesia, a micro-narrative survey tool was developed to capture community members' experiences with MDA and the social realms where drug delivery and compliance occur. The goal of the project was to enhance coverage and compliance in MDA for the elimination of LF in two 'endgame' districts. It was a three-phase study involving a baseline survey, implementation of the identified recommendations and an end-line survey. The systematic approach began with the multidisciplinary research team collaborating with the stakeholders and programme implementers to identify barriers related to the delivery of MDA. The relevant stakeholders were involved in the selection of the study sites, development of the survey tool, analysis of both the baseline and end-line surveys, discussion of research findings and resulting recommendations, dissemination of research findings and identification of feasible actions to improve delivery and access.

The barriers to effective coverage of MDA identified included: Men and 15–24 years old youths lacked appropriate information about the programme; misconceptions about drug safety were common; ineligibility criteria were not clear; and there were limited distribution points. The findings were discussed with the relevant stakeholders and feasible recommendations and interventions were executed using existing health system structures. The recommended interventions were implemented within the local sociodemographic context. For example, social media and texting were used for reaching young people, specific messaging was developed for 'systematic non-compliers', and flow charts were produced to guide drug distributors. The eligibility criteria was adapted to the local context. Specific messages addressing drug safety, drug-taking procedure, information on eligibility, benefits of compliance by all people and where to go for assistance, were carefully crafted on the packaging of the medicines. Both districts that were responsible for implementing the identified recommendations and the end-line survey showed an improvement in coverage of MDA.

Conclusion: The research conducted was demand-driven and the findings were used by the local health offices to improve delivery and access of MDA services. Furthermore, the research did not manipulate the routine health services. Active involvement enhanced stakeholders' ownership and enabled them to mobilize local resources and relevant networks to promote drug uptake, improving compliance.

Lessons: The research team profile should reflect the skill sets required to address an implementation challenge and the team should actively engage relevant stakeholders to fully understand the context where the intervention occurs.

Source: Krentel A et al. Improving Coverage and Compliance in Mass Drug Administration for the Elimination of LF in Two 'Endgame' Districts in Indonesia Using Micronarrative Surveys. *PLoS Neglected Tropical Diseases*. 2016; 10 (11): e0005027. doi:10.1371/journal.pntd.0005027.

**Case study 3****Sustaining PMTCT in real life settings: challenges in Mother Infant Retention for Health**

Background: Although services to prevent mother-to-child HIV transmission (PMTCT) have increased in sub-Saharan Africa throughout the past decade, with the improvement of HIV testing and anti-retroviral treatment (ART) improving, retention in PMTCT care remains a challenge. Kenya, one of the countries in the region facing this barrier, has committed to eliminating new paediatric HIV infections. In 2014, the country had a 5.6% national HIV prevalence, including an estimated 75 000 women living with HIV who become pregnant annually. Although the percentage of pregnant women tested for HIV is >90%, only 64% of HIV-exposed infants (HEI) received ART for PMTCT. To increase the proportion of infants protected from HIV exposure, the barriers preventing pregnant women and their infants from being identified, linked to and followed up/referred to care services need to be tackled.

The US National Institutes of Health (NIH), the President's Emergency Plan for AIDS Relief (PEPFAR) and the Implementation Science (IS) Alliance funded the current study (MIR4H). A combination intervention was designed to reduce loss-to-follow-up for women entering PMTCT services in ten health facilities in Kenya using an individual randomized trial approach. Their aim was to evaluate the effectiveness of standard of care (SOC) with active patient follow-up among pregnant women living with HIV and their infants at six months postpartum. The SOC included antenatal care (ANC) and HIV services, while the interventions delivered by lay counsellors included four additional components: individualized health education; retention and adherence support; SMS appointment reminders; and follow-up and tracking of missed clinic visits. Routine data and questionnaires were used to collect the data for the study. The study results highlighted that pregnancy complications, infant deaths, and transfer out of specific facilities increased loss-to-follow-up among women and infants in PMTCT care.

Conclusion: This study encountered many of the realities encountered on the ground when conducting implementation research. The MIR4H study faced real-life challenges – such as delays in funding, health-care worker strikes, shortage of rapid HIV test kits, slow uptake of new HIV guidelines – that together led to evident delays and resulted in an adaptation to the project implementation.

Lessons: Implementation research must be adaptive to any challenges.

Source: Fayorsey R. N. et al. Mother and infant retention for health (MIR4Health): Study design, adaptations, and challenges with PMTCT implementation science research. *Journal of Acquired Immune Deficiency Syndrome*. 2016; 72:Supplement2.

Self-assessment and reflection activities

An assessment of the current level of awareness and competence in skill sets relevant for IR is essential to effectively use this toolkit. Ideally, this assessment is completed jointly by the members of the research team, but can also be used by individual team members.

This self-assessment of core skills within the team will help the team select and focus on the skill sets that need to be strengthened. Complete the matrix below (Table 1). Using a simple YES/NO approach, indicate the team's current level of awareness and competence in each of the eight specified areas.

Repeat this assessment once again each time the team completes successive modules of the Toolkit. Compare team responses with previous assessments to help gauge the knowledge and confidence gained from each module.

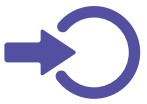
Table 1: Self-assessment framework for IR awareness and competence

Skill/expertise set	No	Some awareness	Competent awareness
Contextualizing IR issues			
Team building			
Applying IR concepts			
Developing an IR proposal			
Designing an IR project, collecting and analysing IR			
Qualitative methods			
Quantitative methods			
Planning an IR project			
Conducting and monitoring an IR project			
Communicating IR findings and feeding them back			



REFLECTION ACTIVITY

After jointly completing the initial self-assessment, identify and select specific modules in the Toolkit that members of the team need to concentrate on and the level of detail needed to achieve each competence.



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1. SDG 3: Ensure healthy lives and promote well-being for all at all ages. New York: United Nations; 2017 (<http://www.un.org/sustainabledevelopment/health/>, accessed 16 October 2017).
2. Status report 2017: Access and Delivery Partnership (ADP). New York: United Nations Development Programme; 2017. (http://adphealth.org/upload/resource/ADP_Status_Report_2017.pdf, accessed 16 October 2017).
3. Guidelines for the treatment of malaria. Third edition. Geneva: World Health Organization; 2015 (<http://www.who.int/malaria/publications/atoz/9789241549127/en/>, accessed 16 October 2017).
4. Adapted from de Savigny D. and Kuepfer I. (2015). Phase IV Studies. In: Field Trials of Health Interventions: A Toolbox. 3rd Edition. Eds. Smith P.G., Morrow R.H., Ross D.A. Chapter 22. Oxford: Oxford University Press; 2015.
5. In reality, some steps may occur simultaneously.
6. For further reading and in-depth discussion on IR see: Implementation research in health: a practical guide. Geneva: World Health Organization; 2013 (<http://www.who.int/alliance-hpsr/resources/implementationresearchguide/en/>, accessed 16 October 2017).

IMPLEMENTATION RESEARCH TOOLKIT



Understanding Implementation Research

Margaret Gyapong, Alison Krentel, Phylis Dako-Gyeke and Olumide Ogundahunsi



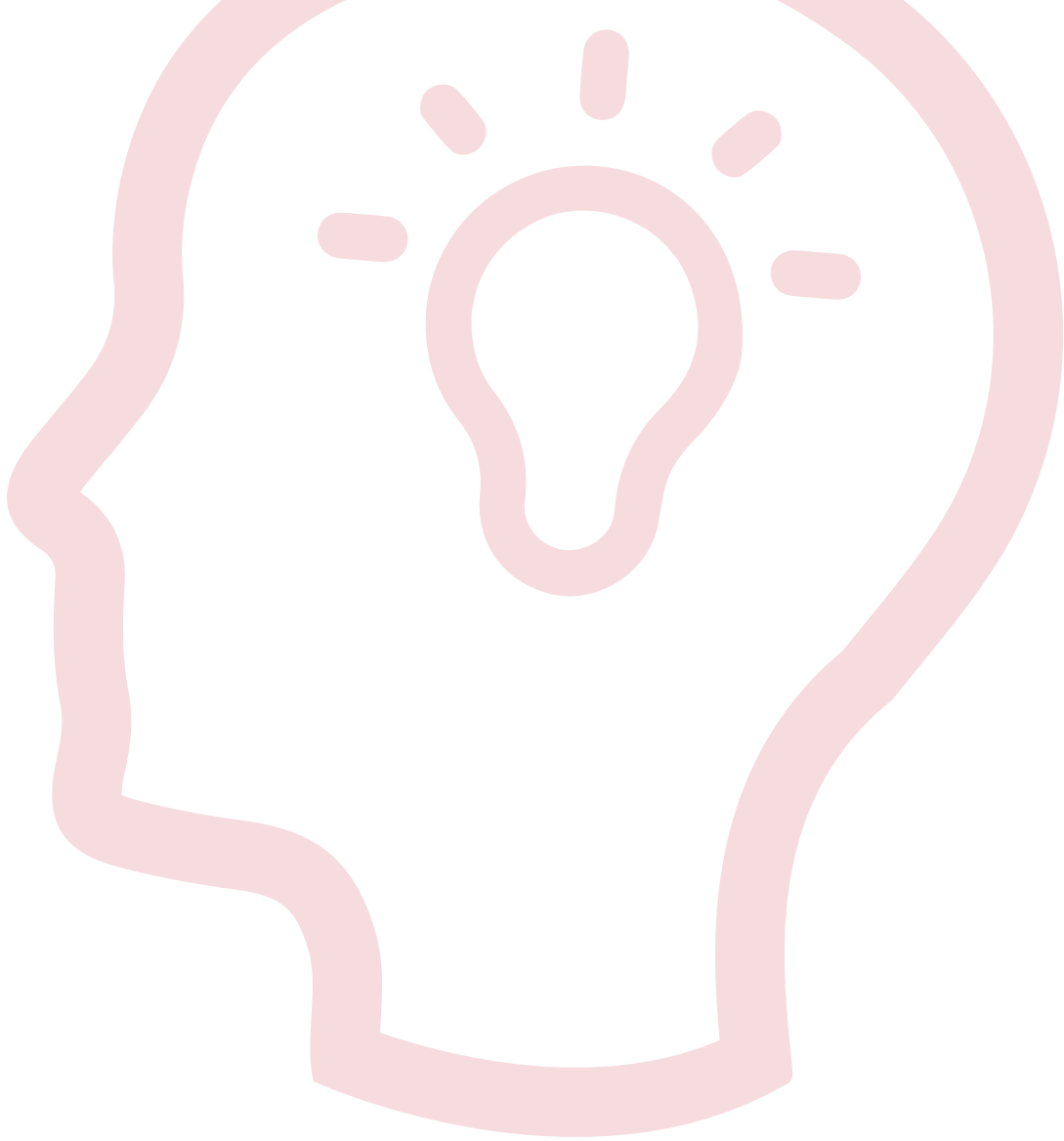
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IMPLEMENTATION RESEARCH TOOLKIT: UNDERSTANDING IMPLEMENTATION RESEARCH

This section is designed to help you understand the processes involved in implementation research (IR). Before starting, you should have already completed the TDR Massive Open Online Course (MOOC) on Implementation Research¹ and worked through the Introduction section of this Toolkit.

This module comprises six sections:

- 1. *The need for IR:*** Highlights the central importance of a real-life problem in framing the research questions, the composition of the research team and the range of stakeholders to engage.
- 2. *Implementation:*** Describes the three possible levels at which implementation outcomes can be measured, and stresses the underlying point that IR ultimately optimizes an intervention for better outcomes.
- 3. *Characteristics of IR:*** Outlines the defining characteristics of IR.



- 4. *How IR works:*** Maps out eight key activities in the IR process, considers the role of contextual factors and describes the crucial role of stakeholders in more detail.
- 5. *Community engagement:*** Focuses on the community as a key stakeholder in the IR process.
- 6. *Ethical challenges in IR:*** Employs case studies to illustrate some of the potential ethical issues surrounding IR.



The need for IR

The importance of research in identifying solutions and options for overcoming implementation barriers and bottlenecks (problems) in health systems and programmes is now widely recognized.² These problems are typically identified in the course of implementing a health programme and may be anchored in factors related to the local community, national, regional or health system contexts, for example. Identifying, understanding and characterizing the problem are the foundations of the research methodology and experimental design of IR.

IR is the systematic approach to understanding and addressing barriers to effective and quality delivery of health interventions, strategies and policies. Implementation barriers are best identified by health workers and programme managers, who have direct experiential knowledge of such problems and of the contexts in which they are encountered. The module “developing an implementation research proposal” of this Toolkit describes the process of identifying the problem and formulating corresponding research questions in greater detail.

DEVELOPING AN
IR PROPOSAL
MODULE **SEE**



IR is demand-driven and the research questions are framed based on problems identified through engagement with relevant implementers and stakeholders in the health system.

Problems are best identified by health workers and programme managers

Introducing innovation (technology, policy, programming)



Implementation barriers and bottlenecks are variable and can occur at any point

Access and delivery



Many efficacious disease control tools (e.g. bednets and artemisinin-based combination therapies for malaria; praziquantel for schistosomiasis; ivermectin for lymphatic filariasis and onchocerciasis; oral rehydration solution (ORS) for treating diarrhoea; vaccinations for human papilloma virus, polio, influenza, hepatitis B); or strategies (preventing the transmission of HIV from mother to child, testing, tracking and treating malaria) are available. Despite Phase I–III clinical trials that have shown the potential of such tools and strategies to be effective at the community level, impact on health outcomes frequently fall below expectation after scale up and system-wide implementation. In order for a ‘proven’ intervention to be effective, it must be accessible to the target group, health care providers/service providers must comply with the relevant national or local policies, and patients must adhere to the intervention. However, there are several challenges that affect these requirements, including issues related to inequity.

Non-compliance or poor adherence can ultimately render a proven intervention ineffective. There is evidence that after integration into health systems and/or communities, interventions lose impact due to various factors (see Introduction module for example of rapid diagnostic tests for malaria).

IR focuses on identifying the challenges and bottlenecks related to the roll-out of health interventions, as well as on developing and testing effective strategies designed to overcome them, and determining the best way to introduce innovations into the health system, or to promote their large-scale use and sustainability.³

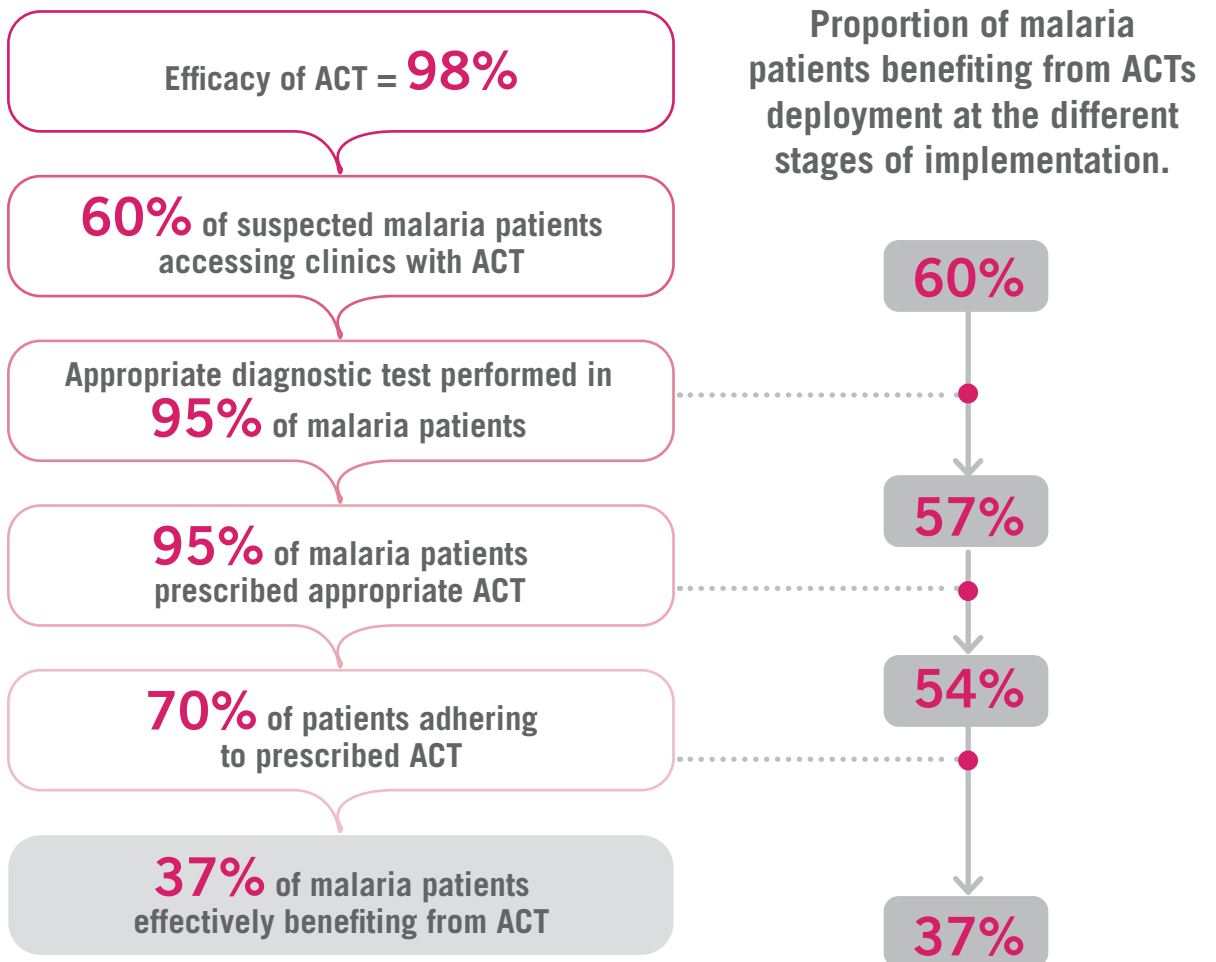
What does implementation research involve?

- Identifying implementation problems that hinder access to interventions, the delivery of services, as well as usability of effective, evidence-based interventions and their main determinants.
- Developing and testing practical solutions to address these problems, which are specific to particular health systems and environments or that address a problem common to a region.
- Identifying how evidence-based interventions, tools, and services should be modified or adapted to achieve sustained health impacts in real-world settings.
- Determining the best way to introduce practical solutions into health systems and facilitating their full-scale implementation, evaluation and modification.



The need to address implementation bottlenecks is often greatest in settings where health systems are weakest or non-existent, as illustrated by studies on health system effectiveness designed to understand reasons for the loss of the impact of a proven intervention. Loss of impact was associated with individual and systemic behaviour, including access to the intervention, diagnostic targeting, provider compliance and patient adherence (Figure 1).

Figure 1. Sequentially decreasing efficacy of artemisinin-based combination therapies (ACTs) when implemented at a local level





Studies on health system effectiveness

Figure 1 summarizes the outcome of studies conducted in Tanzania to determine why highly efficacious anti-malarial treatments low effectiveness when implemented at the community level.

Clinical trials show that artemisinin-based combination therapies (ACTs) have very high efficacy for the treatment of uncomplicated malaria: About 98% of patients who receive treatment within carefully conducted efficacy trials were cured of malaria. A community-based survey found that only 60% of suspected malaria patients accessed treatment at a clinic that had ACTs. Studies within the clinics showed that 95% of those who came to the clinics had an appropriate diagnostic test performed, and that 95% of those diagnosed with malaria were prescribed the correct treatment. Further studies showed that only 70% of patients who received the correct prescription of ACT adhered to the treatment as recommended.

Taken together, these series of studies showed that less than 40% of people with uncomplicated malaria in the community were effectively treated, despite the availability of ACTs, an intervention with an efficacy of 98%. Such studies not only document and measure the failings in the health system, but can also be used to investigate the reasons behind these problems and the potential actions that can be taken to address them.



REFLECTION ACTIVITY

In relation to your IR project, address the following questions:

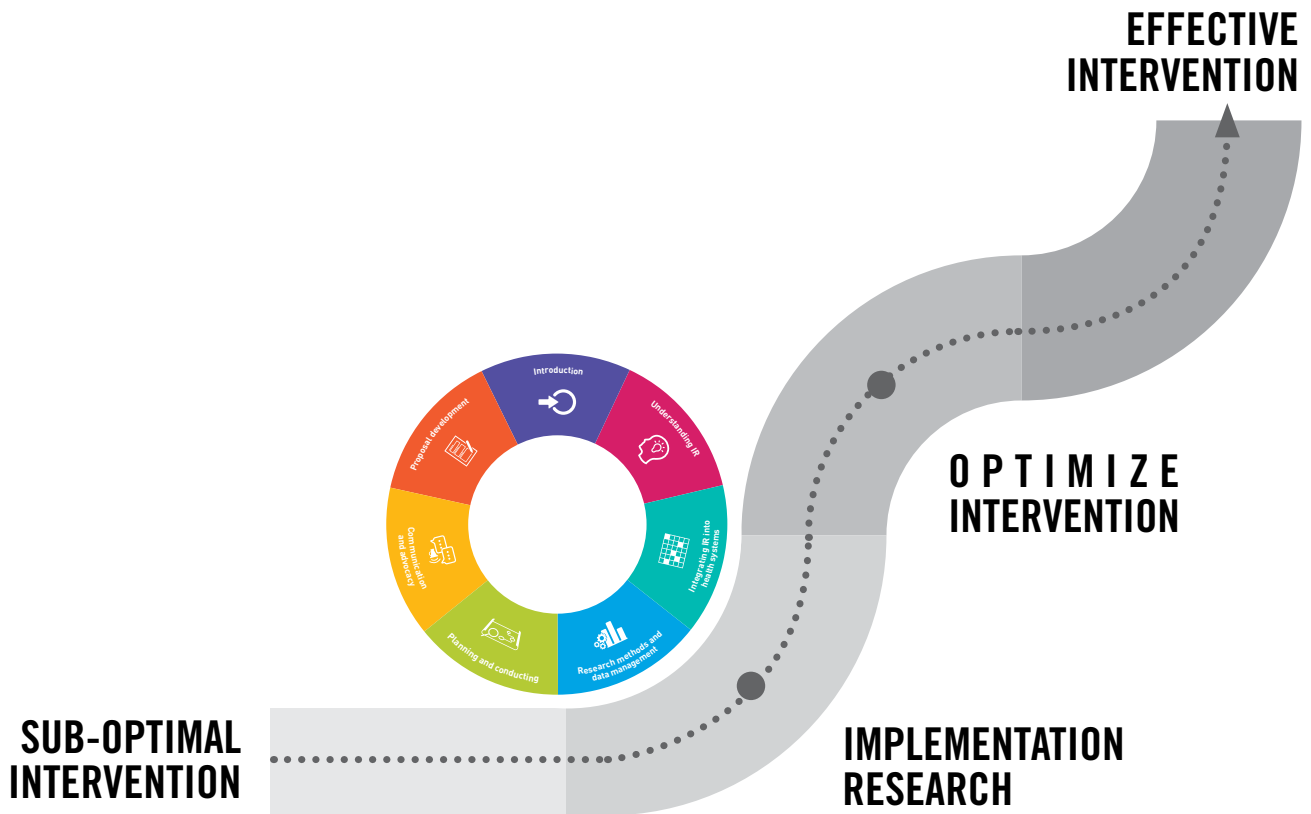
- **What is the real-life problem or intervention bottleneck to be addressed?**
- **How was the problem identified? Is it demand-driven?**



Outcomes of IR



Implementation research ultimately aims to optimize an intervention for better health outcomes.



IR uses scientific inquiry to guide the problem-solving process, with a view to providing evidence for policy and programmatic decisions. In this way, IR lends itself to change through continuous learning and, where necessary, adaptation. Such change can be best achieved when implementers or programme personnel:

- identify and describe an implementation problem clearly;
- are engaged in the process of formulating research question(s) to address the problem;
- work closely with researchers and specialist academics to conduct related IR.



The IR must have clear measurable outcomes.⁴ These can be conceptualized at three levels:⁵

1. **Client outcomes:** Individual level; can be measured from client satisfaction whilst accessing the services, improvement in performance of the service provider / personnel and/or symptoms experienced.
2. **Service outcomes:** Measured using the following quality dimensions: efficiency, safety, effectiveness, equity, patient-centeredness and timeliness.⁶
3. **Implementation outcomes:** Measured using indicators of acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability (See Table 1).

Table 1: Definition of implementation outcomes

Outcomes	Definition
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable, or satisfactory.
Adoption	The intention, initial decision or action to try/employ an innovation or evidence-based practice. Adoption also may be referred to as “uptake”.
Appropriateness	The perceived fit, relevance or compatibility of the innovation or evidence based practice for a given practice setting, provider or consumer; and/or perceived fit of the innovation to address a particular issue or problem. “Appropriateness” is conceptually similar to “acceptability”.
Cost	The cost impact of an implementation effort. Implementation costs vary according to the complexity of three components: the intervention, the implementation strategy, and the setting(s).
Feasibility	The extent to which a new treatment or an innovation, can be successfully used or carried out in a given agency or setting.
Fidelity	The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the programme developers.
Penetration	The integration of a practice within a service setting and its sub-systems. Penetration can be calculated in terms of the number of providers who deliver a given service or treatment, divided by the total number of providers trained in or expected to deliver the service.
Sustainability	The extent to which a newly implemented intervention is maintained or institutionalized within a service setting’s ongoing, stable operations. There are three stages that determine institutionalization: 1) passage (a single event such as transition from temporary to permanent funding); 2) cycle or routine (i.e. repetitive reinforcement of the importance of the evidence-based intervention through inclusion in organizational or community procedures and behaviours, such as the annual budget and evaluation criteria); and 3) niche saturation (the extent to which an evidence-based intervention is integrated into all sub-systems of an organization).

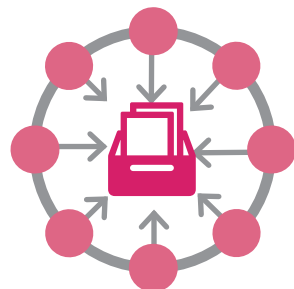
Adapted from Proctor et al (2011)

In the IR context, an ‘intervention’ is broadly defined as any health technology (medicine, vaccine or diagnostics), treatment and/or prevention practice and strategy, or efforts executed at the individual, community or institutional levels. Interventions include policy changes, strategies or scaling up health innovations that have demonstrated efficacy in the laboratory, clinical trials or small-scale pilot studies.⁷ Lack of compliance awareness or contextual issues related to culture, politics and geography can constitute barriers to the effective delivery of these interventions. It is critical to identify the intervention outcome indicators of key relevance to an IR project (see Table 2).

Table 2: Stages of an intervention and examples of main outcome indicators

Stage of intervention	Examples of main outcome indicators
New (introduction and scale up)	Acceptability, adoption, appropriateness, feasibility and sustainability
Well established intervention	Implementation as originally designed (fidelity), cost and coverage

For IR, it is important to describe the process of introducing an intervention (in the context of a specific environment), and the intervention itself in sufficient detail.



Describe the process of introducing the intervention in context and the intervention itself.



REFLECTION ACTIVITY

In relation to your IR project, address the following questions:

1. What is the proposed intervention in your IR project?
2. Describe the intervention as it is currently being implemented. How will the proposed IR improve the intervention?
3. List the main outcome indicators for the IR.




Characteristics of IR

An IR process can optimize interventions available to address health problems.⁸ Thus, while bed nets and artemisinin-based combination therapy are key examples of available, affordable and life-saving interventions for preventing and treating malaria, access to and proper use of these interventions remain suboptimal (See Figure 1).⁹

IR is characterized by the complex, iterative, systematic, multidisciplinary and contextual processes that take place at multiple levels in order to identify and address implementation problems (Table 3).

Table 3: Key characteristics of IR

Characteristic	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 the norms of scientific inquiry.
Multidisciplinary	Analysis of biological, social, economic, political, systemic and environmental factors that impact implementation of specific health interventions. Requires interdisciplinary collaborations between behavioural and social scientists, clinicians, epidemiologists, statisticians, engineers, business analysts, policy-makers, community leaders and key stakeholders.
Contextual	Demand-driven. Framing of research questions is based on needs identified by implementers and other stakeholders 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.
Real Life Situations	Takes place within real-life settings. There is no attempt to manipulate the setting within which the intervention is taking place. Engages with populations of interest including the actual implementers (e.g. health practitioners, policy-makers) and beneficiaries (communities, target population).

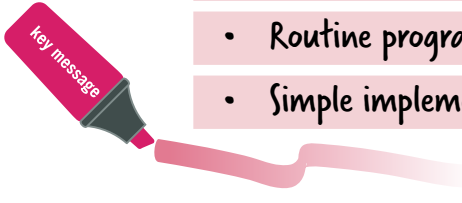


A simple paradox that IR acknowledges is that the more rigidly the implementation is controlled to ensure fidelity of a proven intervention, the more likely it is that local factors will reduce its effectiveness. Similarly, the more adapted an intervention is to local conditions the more effective it is likely will be.

As an intervention is tailored or adapted for a specific context, it becomes more difficult to argue that findings can be generalized to other localities or populations. It is important to apply scientific rigor to an IR project. The implication is that processes leading to outcomes must be well documented to be understood. As any other type of scientific investigation, IR must comply with good research practices, including:

- Access to data collection and analysis methods and clear presentation to allow replication.
- Concepts and propositions should be logically consistent, clearly defined, and, in general, lead to empirically verifiable hypotheses.
- Methods and concepts should be intentionally subjected to criticism and evaluation by subject area experts.

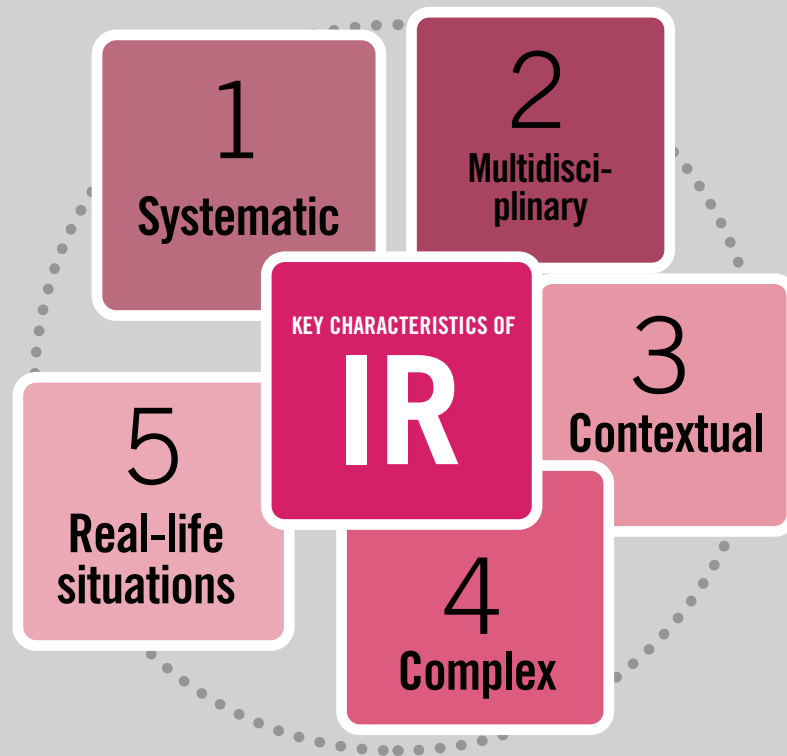
IR is NOT:

- 
- Basic biomedical research (e.g., discovery of a new gene pathway or aetiology research).
 - Initial or replication of intervention efficacy trials in a top-down controlled setting.
 - Routine programme progress reporting.
 - Simple implementation of health interventions.



REFLECTION ACTIVITY

Analyse your proposed IR project using the key characteristics of IR (see Table 3). Does the proposed approach align with the characteristics listed?





How IR works



Implementation research is not a single or a linear activity,
but a continuous process.

Each aspect of the IR process is crucial to project success, and the degree to which individual steps are interconnected in practice increases the dissemination and uptake of the IR findings (see Figure 2). For this reason, the composition of the IR team should be multidisciplinary, bringing together people with relevant skills, backgrounds and experiences.

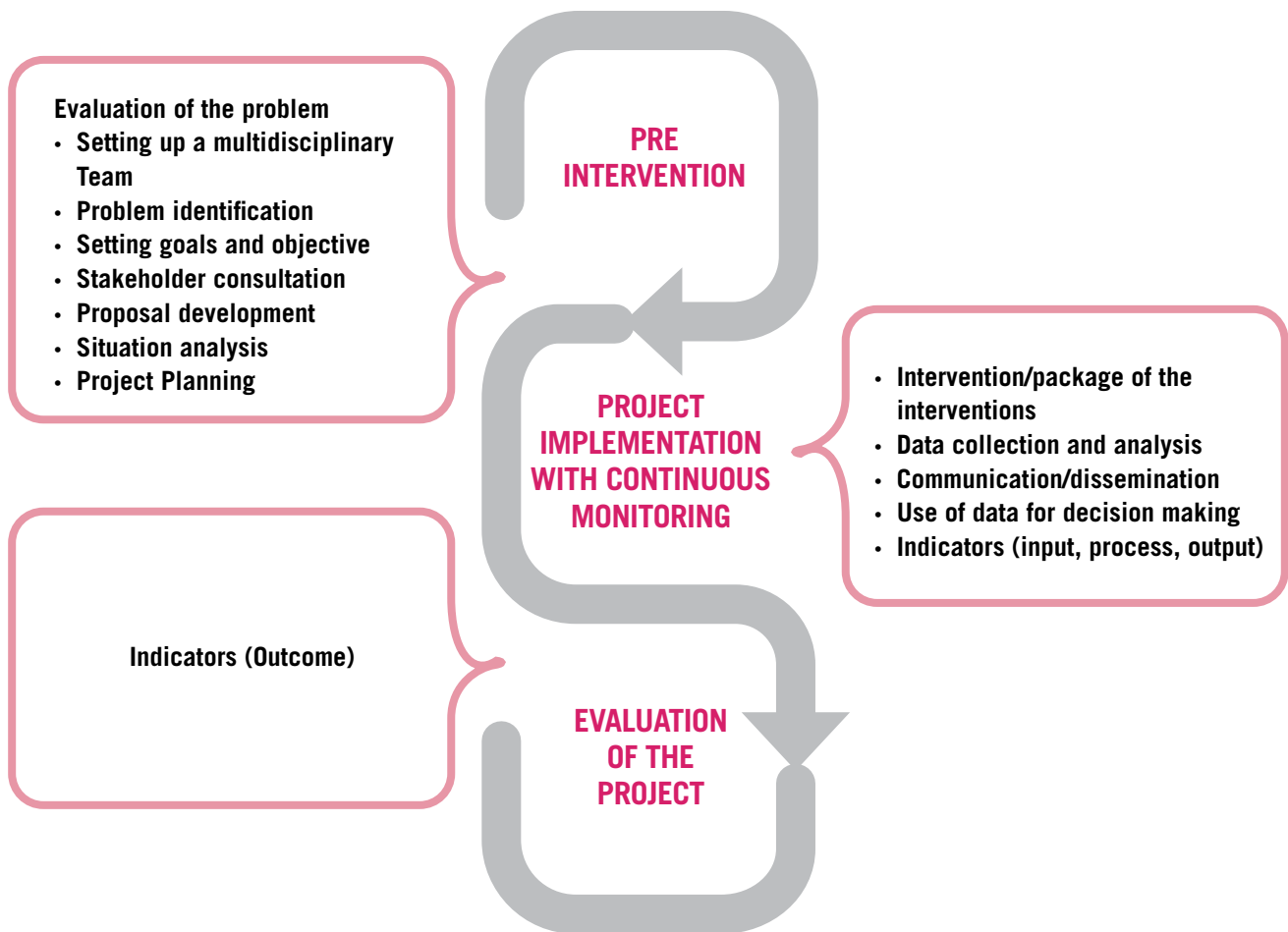
Key steps in the IR process

- Identify barriers/problem preventing optimization of a defined intervention.
- Form the research team. Should reflect the skill sets needed to address the implementation problem.
- Identify other key stakeholders. Engage relevant stakeholders (e.g. the community) to understand the context where the intervention occurs.
- Discuss the implementation problem(s) and generate pertinent research questions that provide important insights and identify feasible solutions.
- Identify an appropriate study design to address the research question.
- Develop a detailed proposal and research plan, mobilize resources and conduct the study aimed at addressing the question(s) using good management practices.
- Continuously monitor and document processes throughout the research and provide feedback to key stakeholders to maximize the value of the research.
- At the end of the research project, the team has an obligation to document and disseminate the knowledge generated through the appropriate media, including publication in indexed scientific literature.

Stakeholders can play a crucial role in disseminating the IR findings through their own networks, supporting any recommended changes in the delivery of the intervention and promoting uptake within their networks.

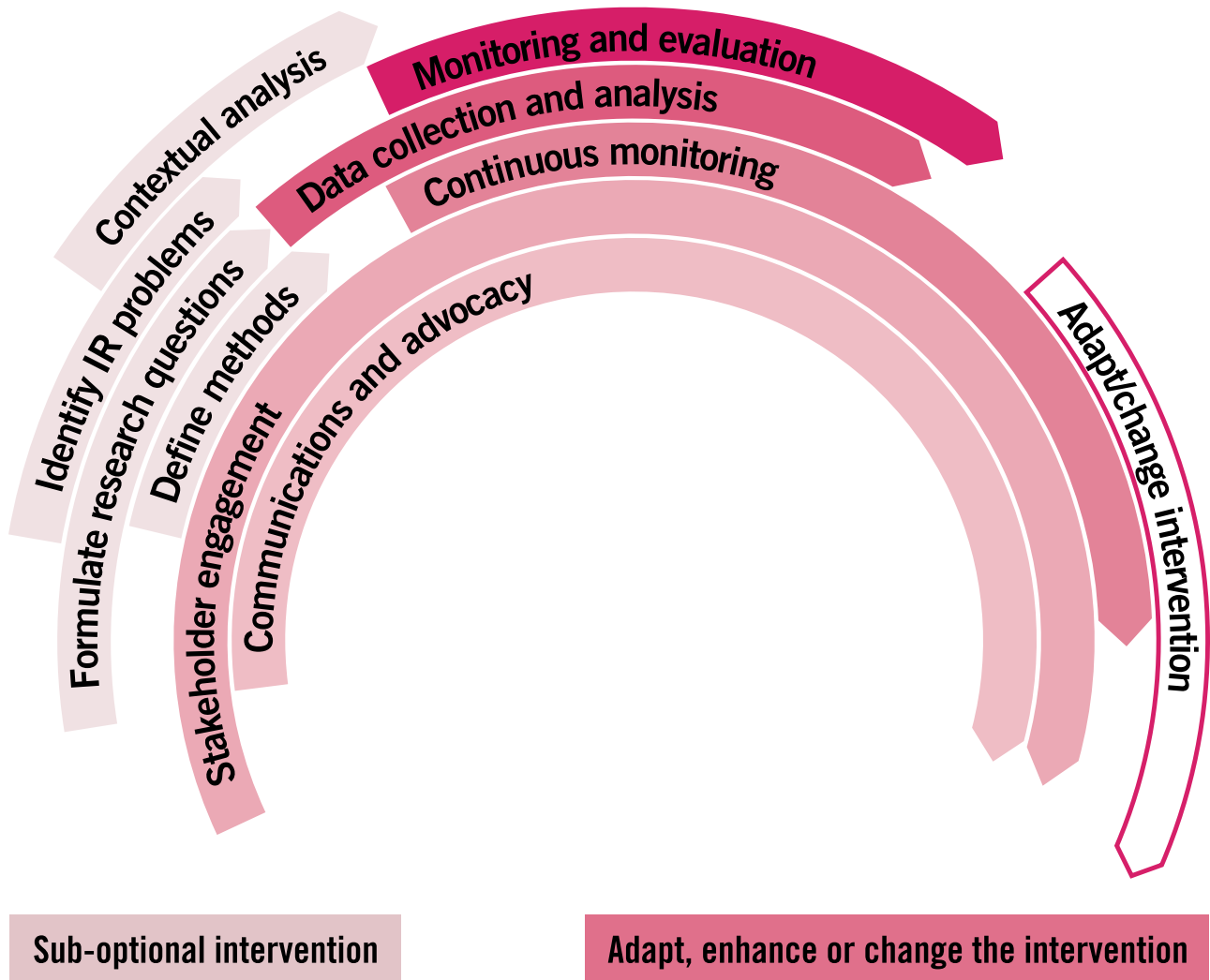


Figure 2. Key steps in the IR process



An IR project has many overlapping steps that do not necessarily occur in a linear manner. The roadmap in Figure 3 illustrates the timings and steps in the IR process. Remember that each context is different and has its own complexities, so this roadmap should be adapted to your situation. The timing for an IR project will depend on the intervention problem and research methods chosen. This sample roadmap indicates some of the key overlapping activities that occur throughout an IR project.

Figure 3. Road map of an IR project



IR uses contextual knowledge to study processes to improve practice, it applies research findings and methods to real-world contexts and settings.



Unlike other types of research – where the setting is controlled to create an ideal situation for success – IR is conducted in real life contexts and must necessarily address problems identified in the course of delivering an intervention in context. The research team does not manipulate the setting in any way and allows life to go on “as usual”. Factors such as political changes, health staff circumstances (e.g. staff changes or transfer), physical settings (e.g. natural disasters and geographic terrain), tradition (cultural, religious, institutional), stakeholder characteristics and public health related issues (e.g. disease outbreaks and epidemics) influence the real-life context in which an intervention takes place. These factors, which can be broadly classified as physical, socioeconomic and cultural environments, health systems, stakeholders and institutional cultures are key aspects of the research context in IR and require critical analysis to ensure that the research questions are framed in context. Together they contribute to and affect the planning, implementation, monitoring and outcomes of any intervention.

Political context and successful sustained policy implementation

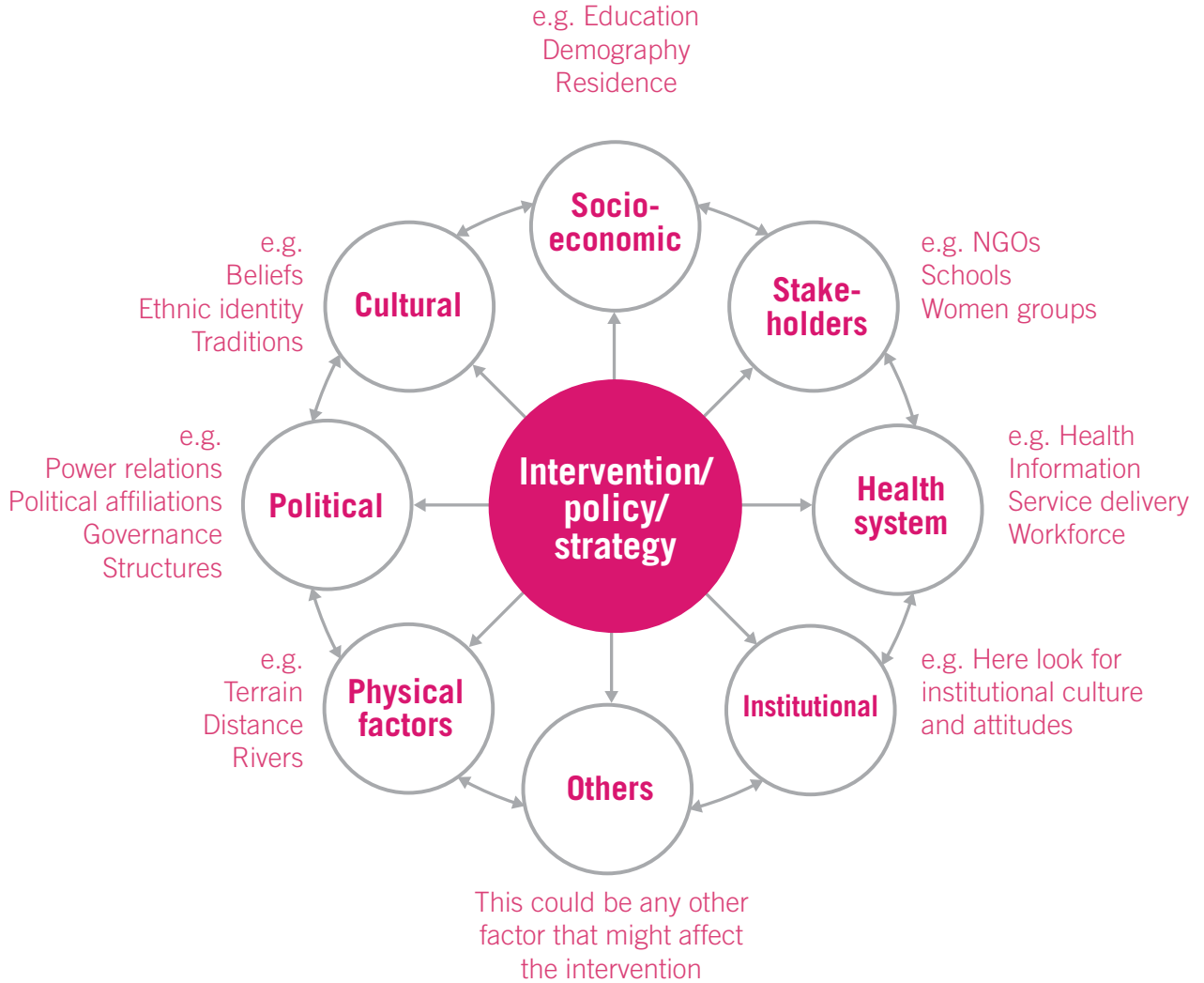
Thailand is one of the countries that succeeded in meeting several Millennium Development Goal (MDG) targets, i.e. poverty and hunger reduction, universal primary education, gender equality, fight against HIV/AIDS, access to clean drinking water and sanitation, improving the lives of people in slums and participation in global partnerships.¹⁰

Thailand achieved the health-related MDGs and introduced the concept of ‘MDG plus’. A review of the Thailand health system highlighted key factors underpinning the success. Although there were multiple changes in political context during that period, technocrats in the relevant government departments were stable and thus able to maintain focus on achieving the long-term plan of strengthening the health system. Health managers at provincial and district levels had the authority and flexibility to implement policies and regulations set at national level. This allowed them to respond to local context and needs, especially where financial and human resources were concerned. Financial managers were able to retain revenues generated from user fees to purchase medicines at the best possible price. Human resources were managed to enhance programme integration and avoid vertical duplication. For example, HIV prevention programme services were integrated with the antenatal care clinic delivered by nurses after training and piloting.¹¹

During an IR project, the key contextual factors should be analysed objectively (Figure 4). These factors vary considerably from one location to another and can be impacted by international, regional, national and local events.



Figure 4. Contextual Factors in IR¹²





Socioeconomic and cultural context

Cultural context plays an important role in treatment decisions and health seeking behaviour.



Various aspects of the socioeconomic and cultural context can impact the delivery of an intervention such that an intervention that was effective in one locale could well be ineffective due to constraints inherent to the culture or circumstances. These factors also change over time as societies transition.

Traditional beliefs influence treatment decisions and behaviour

This is especially so in transitional societies where traditional and modern medicine are employed with the choice of one or the other determined by changing belief systems. Geographic distance and associated costs also come into play. In some cultures, the traditional health belief system places responsibility and blame on women and imposes a system of social control over the adult female population. Changing health beliefs are less the result of the introduction of a new health philosophy than of the retreat of traditional beliefs under the impact of other societal factors embodied in the older health philosophy.¹³

Physical and demographic factors

Geography can have a profound effect on the delivery of an intervention especially when related to access to health services and health interventions. Location of a target population (rural/urban), distance from the central facility or capital, physical barriers (such as mountains, rivers), extreme weather conditions, infrastructure (transport systems, electricity and water) and demographics (population size, distribution by location, gender and age) must be analysed where relevant to put the problem in context.

Socioeconomic status

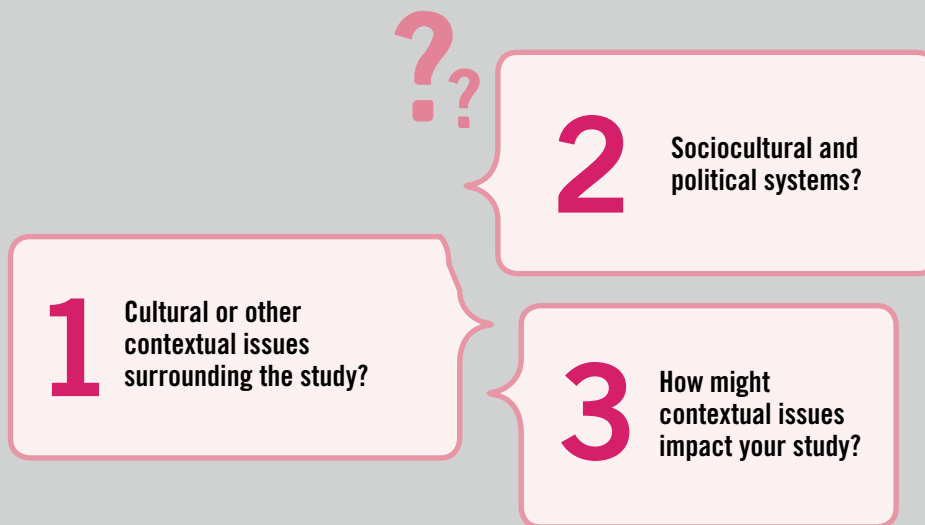
The general standard of living and level of inequality, as well as identification of vulnerable groups and socioeconomic status based on income levels, assets, educational status and occupation should be analysed. The main types of dwellings (e.g. communal huts, apartments or gated communities), by location,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



REFLECTION ACTIVITY

In relation to your IR project, address the following questions regarding context:

- What are the sociocultural and political systems in your project area?
- What are the contextual issues currently affecting (positively and negatively) the intervention of interest.
- How might these contextual issues impact aspects of your study?



Cultural and political factors

Analysis of cultural beliefs related to health, gender equality, literacy rates, ethnicity/tribal segregation related to the following should be conducted;

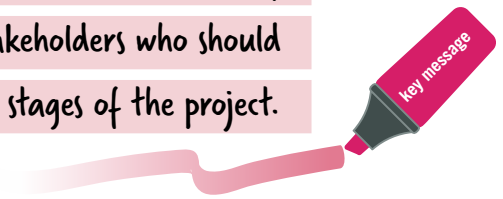
1. policy environment and political factors, including the level of support for social services and health care services;
2. government capacity to provide services
3. ongoing or recently introduced health interventions should be conducted.

Stakeholders

Engaging stakeholders in an IR project involves face-to-face consultations and discussions from the national to the community level – not just briefing the stakeholders and seeking their approval for the study, but actively involving them in the various discussions, decisions and negotiations.¹⁴



A stakeholder is anyone whose involvement is crucial to the success of an activity. In practice, IR involves multiple stakeholders who should be identified in the developmental stages of the project.



Involving stakeholders throughout IR projects

One of the distinguishing features of IR is the importance of involving implementers in all aspects of the research process. Researchers worked with the programme implementers of an insurance scheme in India, the Rajiv Aarogyasri Scheme (RAS), in the state of undivided Andhra Pradesh. One of the objectives of the collaboration was to identify research questions that could serve as a guide for an evaluation of the RAS. Meetings were held over a period of one year to identify appropriate research questions. The results of this collaboration were compared with those published in the literature on evaluations of insurance programmes in other low- and middle-income countries. The results showed great disparity in the types of questions that were generated through the collaboration and those that were published in literature. Whereas in the published literature, 60% of the research questions pertained to the output/outcome of the programme and the remaining 40% related to processes and inputs, in the RAS participatory research process, 81% of the questions generated looked at programme input/processes, and only 19% on outputs and outcomes. The study therefore concluded the implementation research approach of involving implementers can lead to a substantively different emphasis of research questions, which are more relevant to the research needs of policy-makers, and therefore contribute to greater translation of the research findings.¹⁵

Conducting a 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.^{16 17 18} The objective of the stakeholder analysis is to identify all relevant stakeholders, assess how they are likely to be affected by the research, and how they might respond to the research outcome. Stakeholder identification requires careful judgment, should not be exclusive (limiting the breadth of perspectives) or over-inclusive (diluting essential focus).

Steps in a stakeholder analysis process

1. Define the purpose of the analysis.
2. Generate a list of potential 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).
3. Collect necessary data (e.g. using interview guides and semi-structured questionnaires).
4. Analyse and present 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).

Depending on the IR issue of interest, stakeholders could include (but are by no means limited to):

- 1. Policy-makers and political leaders.** Representatives who will ensure that health workers and end-users of the study are properly informed of any shift in policy.
- 2. Health care providers at facility and community level.** Include health professionals in government and private medical facilities, traditional healers and drug sellers, managers of drug shops etc. who have been providing health care in a particular way for a long time. Since change does not come easily, it is critical to involve them in the design and implementation of any strategies that will enhance programme implementation.
- 3. Media specialists.** Consulting this group of stakeholders is critical since with their capacity to communicate, they can help to share the results of an IR project widely.
- 4. Community members.** It is at the community/village level that all health care interventions are implemented. In this light, community members can help ensure maximum support. Consultations at the community level should cut across all social, political and religious lines. Constant interaction is crucial for success and to ensure that the activity or proposed intervention is not discredited.

SECTION ON
BUILDING
AN IR TEAM
(INTEGRATING
IMPLEMENTATION
RESEARCH
INRO HEALTH
SYSTEMS)

SEE

Engaging stakeholders often requires a similar approach and set of skills as creating a successful IR team, and the two activities can be usefully seen as forming a continuum (see “Module on Building an IR Team”).

The box highlights how stakeholder analysis was used in one instance 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.



Case study 1 Importance of involving stakeholders throughout an IR project

Background: The distinguishing features of IR includes the importance given both to the context within which a programme operates, as well as the populations that are affected by the project. It seeks to involve implementers and populations affected by an intervention in all aspects of research right from the research design, the process of research, and as users of research outcomes. The emphasis on involving 'local' populations and groups in research to enable a 'bottom-up' approach ensures that local priorities are recognized and participants have a voice. This subsequently makes research and the actions that result from it more relevant and acceptable locally. Incorporating programme implementers' perspectives makes the research process sensitive to the complexity of the world that the programme implementers inhabit and are trying to change.

The IR approach was used to ascertain how the nature of emerging questions differed in focus when compared to those found in the literature on the evaluation of health insurance programmes in low- and middle-income countries (LMICs). The context was one of the longest serving government-funded insurance schemes in India, the Rajiv Aarogyasri Scheme (RAS) in the state of Andhra Pradesh. The RAS has been operating since 2007 and covers the cost of inpatient care for people below the poverty line. The programme has around 70 million beneficiaries. The IR approach was comprised of a series of meetings during 2012, involving various groups of stakeholders. Staff from the Aarogyasri Health Care Trust, the Public Health Foundation of India and the Indian Institute of Public Health, Hyderabad met to identify research questions that could serve as a guide for evaluation of the RAS. The derived research questions were compared with the ones identified by a literature review.

Findings: Around 60% of the research questions in the published literature pertained to programme outputs and outcomes while 40% were related to programme input/process. This was in contrast with the questions generated through IR, where 81% of questions were related to input/processes and only 19% focused on outputs and outcomes. Furthermore, the majority of the studies in published literature that sought to evaluate health insurance programmes were researcher-driven. They also had a stronger tendency to evaluate the insurance programme against a set of outcomes rather than to the process and input aspects of the programme.

Conclusions: The research questions identified through the collaborative approach established and offered a more comprehensive view of programme performance and were more closely aligned to with the implementers' needs. Furthermore, involving implementers/stakeholders gave an insight into the programme activities. If implementers are not involved, it becomes difficult for external researchers to incorporate the implementers' tacit knowledge (which are often more relevant into the needs of policy-makers) in formulating the research questions and the subsequent research process

Lessons: The set of research questions resulting from IR were much broader in scope and put more emphasis on processes and inputs. The collaborative process also enabled the researchers to appreciate the heterogeneous nature of implementers, a fundamental characteristic of IR.

Source: Rao, K.D. et al. An implementation research approach to evaluating health insurance programs: insights from India. *International Journal of Health Policy and Management*. 2016; 5.5: 295.



Institutional assessment

An institutional analysis (a systematic study of the behaviour of organizations) is another important dimension to consider in planning for an IR project. This can be achieved through an analysis of strengths, weaknesses, opportunities and threats (or 'SWOT') associated with institutions that could potentially interact with the IR team in the course of the project, and with the intervention under study. A SWOT analysis will help establish the institutional factors with a potential impact on the success or failure of a given intervention.

Qualitative assessment of stakeholders

A study in the Santiago Metropolitan region of Chile used stakeholder analysis to assess the related policy environment prior to the introduction of a series of ambulatory care innovations 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 the perception of local 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 an understanding of the context and probable responses of stakeholders to the planned innovations. The research was intended to provide data on the negotiation and understanding perceptions within social interaction. It considered domains such as experience, knowledge and action.¹⁹



REFLECTION ACTIVITY

In relation to your IR project, address the following questions:

1. Who are the relevant stakeholders, what institutions do they belong to and how will you engage them?
2. What skills and knowledge are required in your team in order to implement a successful IR project?
3. What specific knowledge and (or) skills will each stakeholder bring to the research project?



1

Relevant stakeholders, what institutions do they belong to? How will you engage them?

2

What skills and knowledge are required in your team in order to implement a successful IR project?

3

What specific knowledge and (or) skills will each stakeholder bring?

SWOT analysis to identify issues affecting a mosquito control programme²⁰

Mosquito control programmes in seven urban sites in Costa Rica, Egypt, Israel, Kenya and Trinidad were compared. Site-specific urban and disease characteristics, organizational diagrams, and SWOT analysis tools were used to provide a descriptive assessment of each mosquito control programme. They also provided a comparison of the factors affecting the resulting reductions in mosquito populations.

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 programmes. The main output of the study was the description and comparison of mosquito control programmes within the context of each study site's biological, social, political, management and economic conditions.

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

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

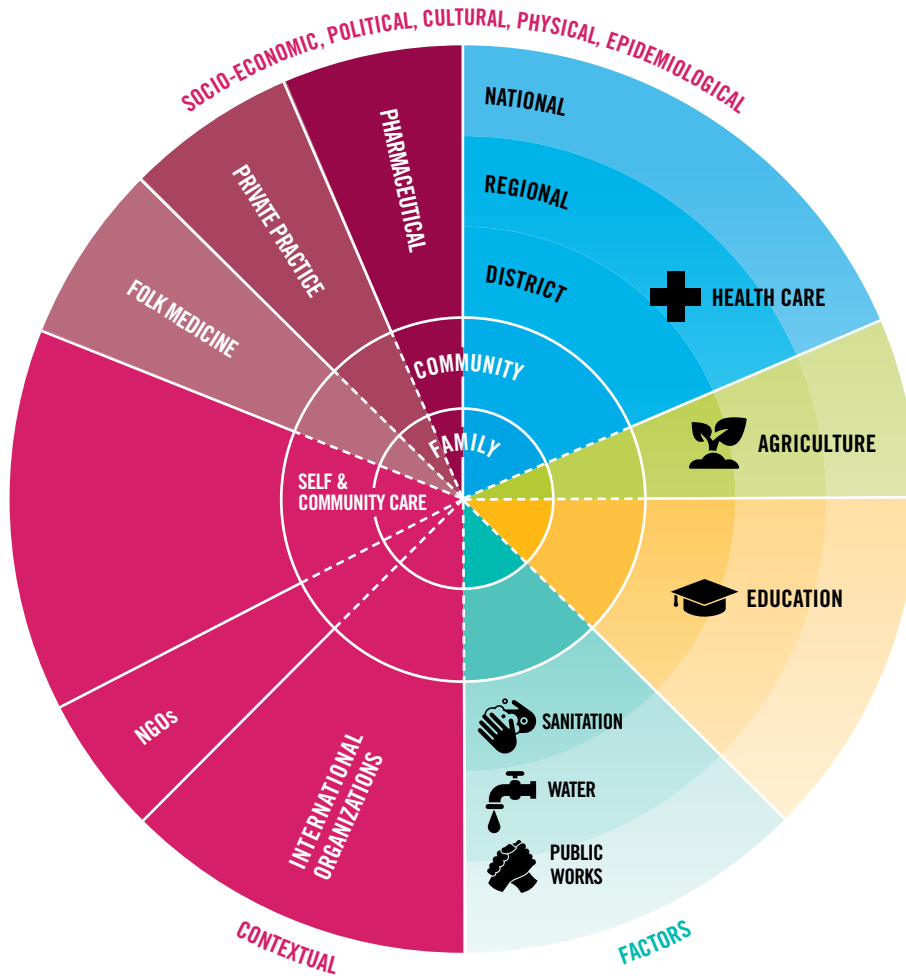
Health systems

Core research questions of IR projects are driven by implementation problems/issues and should be formulated in collaboration with stakeholders, including implementers, programmes or decision-makers in the health system, and should be designed to suit action-oriented research. As a result, IR is typically conducted within the health system, at least in part. One of the main purposes of analysing the health system is to predict how specific considerations might potentially affect the viability and impact of an intervention.

Figure 5 illustrates the many components of a health system beyond the health centres, clinics or hospitals that are found in the formal health sector.²¹ For example, community members may have a strong belief in the informal health sector and access it alongside the formal health system. From the community level, right up to the national level, there are various non-health ministries, departments and agencies whose work directly or indirectly impacts health care provision. The critical roles these stakeholders play must be fully considered in any IR study. For each component that is relevant to a specific IR project, it is helpful to undertake a systematic descriptive analysis to help identify the relevant decision-making agents and both the formal and informal institutions that govern its operation. All these complex, real-life interactions need to be considered when addressing IR. These complex interactions of individuals, groups, institutions, the family and society and the pluralistic health care systems that are available in many countries not only influence the health of people, they also affect the health services and health care provision in the formal and informal sectors.



Figure 5. Elements of a typical health system



REFLECTION ACTIVITY



Address the following questions in relation to your IR project:

1. How is the health system in your project area structured (public, private and other related sectors)?
2. How might the various components of the health system impact your project?



1 How is the applicable health system structured (public, private and other related sectors)?

2 How might the various components of the health system impact your project?



Complex adaptive systems

Many health initiatives give rise to what can be described as ‘complex adaptive systems’ (CAS), a theory based on relationships, emergence, patterns and iterations.²²^{23 24} The underlying idea being that a myriad of complex systems continuously interact and trigger subsequent adaptations in their 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. The implication of this notion is that it is difficult to ‘control’ agent behaviour in real life situations. CAS are intrinsically unpredictable and unintended responses to interventions often occur. Therefore, understanding the CAS phenomena is important for better awareness, planning, implementation, monitoring and evaluation of approaches to scaling up health services.

Health interventions and complex adaptive systems

Pilots/trials may not be effective on a larger scale because of contextual differences. e.g. levels of health system development, ecological factors, social and cultural differences.

HEALTH INTERVENTIONS AND COMPLEX ADAPTIVE SYSTEMS (CAS)

Inputs/impacts disproportionate in many cases

Implementation rarely proceeds according to plan and often has to be rapidly adapted to suit an alternative and/or changing context.

Behaviour of providers, communities and staff are often highly constrained.

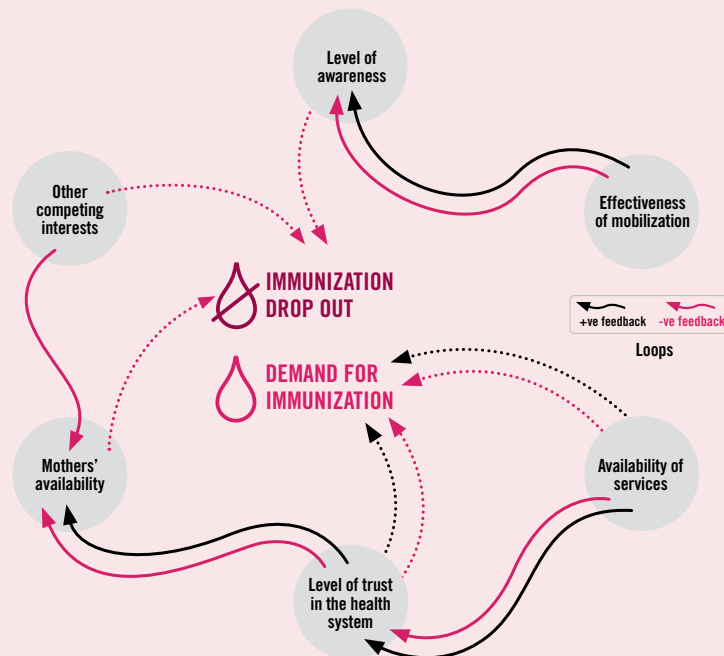
Multiple stakeholder groups and independent factors interact → CAS.

- Interventions that were shown to be successful on a small scale in a controlled research context may not be effective on a larger scale because of contextual differences, such as levels of health system development, ecological factors, social and cultural differences.
- The process of implementing an intervention 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.
- Apparently simple technical interventions can exhibit CAS behaviours when multiple stakeholder groups and independent factors interact.
- Substantial interventions can sometimes result in very limited outcomes and conversely, relatively small inputs can have major positive/negative consequences.



CAS can result in unexpected behaviours in the context of health interventions through, for example, feedback loops, path dependence and emergent behaviours.

Feedback loops positively/negatively influence demand for immunization services²⁵



Demand for immunization services is positively influenced (i.e. increased) 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, subsequently reducing demand for immunization services. In addition, whereas mothers' availability increases demand for immunization, maternal family responsibility and low socioeconomic status can negatively affect their availability.

Furthermore, the quality and availability of health services can affect the demand for immunization services either positively or negatively. For example, 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. This reduction in morbidities due to vaccine-preventable diseases contributes to an increase in confidence of the community in the immunization programmes, which subsequently increases the demand for immunization services. On the other hand, poor quality health services – for example lack of vaccines, long waiting hours, children developing abscesses after vaccinations etc., discourage mothers from bringing their children for immunization. This contributes to high drop-out rates and the proportion of unimmunized children in the community, leading to low immunity and an 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.



REFLECTION ACTIVITY

This section considered the complex interactions of culture, politics, stakeholders, organizational culture (for example) on health-related interventions. Taking all these into consideration, summarize the environmental and contextual factors that are currently affecting (positively or negatively) the implementation of your intervention of interest.

1. To what extent are the outcomes of the intervention affected?
2. How should this knowledge influence your IR question(s) and project approach?





Community engagement in IR

Delivery of interventions will not be effective if the community does not trust the health authorities.



Invariably, most if not all health care interventions are targeted at community members – engaging them throughout the IR process is critical. Engagement is a process that involves consultation, education, communication, participation, extension work and partnerships. For example, by:

- Informing the community of policy directions of the government.
- Consulting the community as part of a process to develop government policy, or build community awareness and understanding.
- Involving the community through a range of mechanisms to ensure that issues and concerns are understood and considered as part of the decision-making process.
- Collaborating with the community by developing partnerships to formulate options and provide recommendations.
- Empowering the community to make decisions and to implement and manage change.

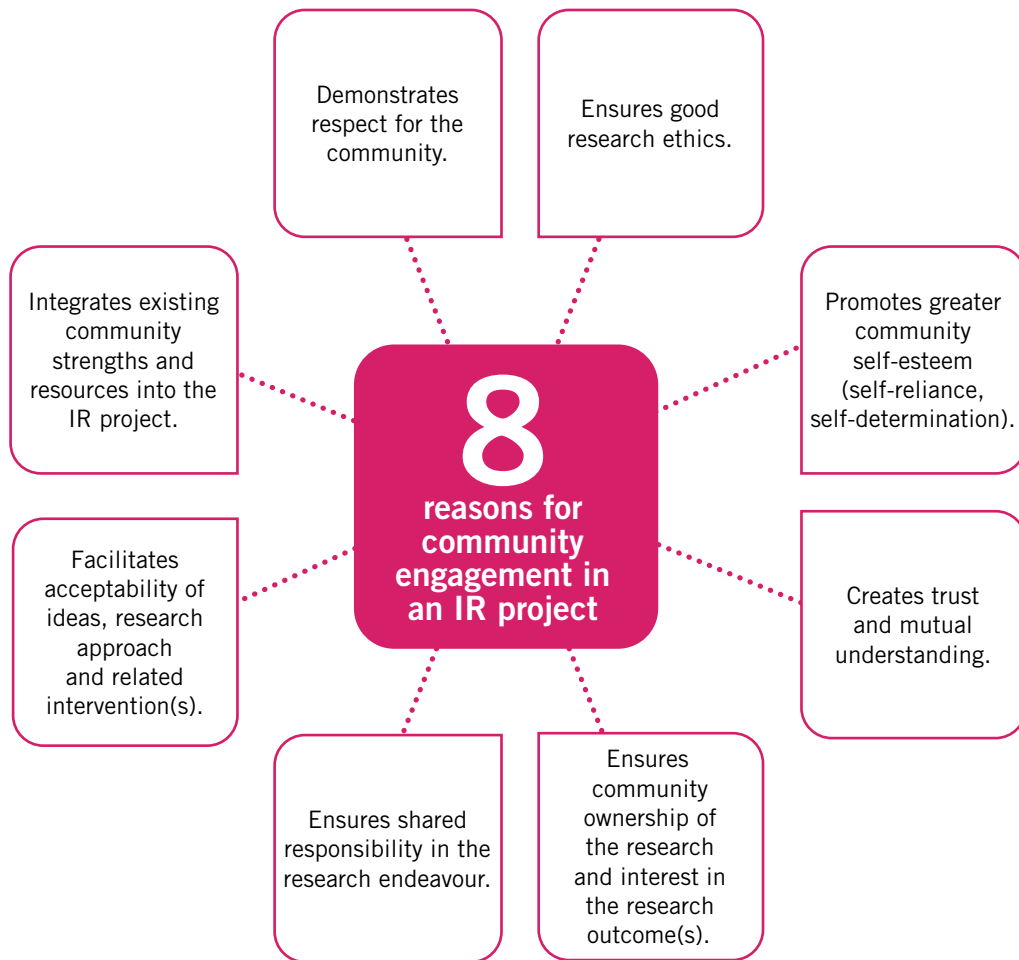
one of the critical outcomes of community engagement is literacy – a situation where individuals in the community are sufficiently informed to engage meaningfully in dialogue and discussions on the intervention.



Engagement allows the IR team to draw on the collective contextual knowledge of the community, as well as their understanding of existing strengths and resources within the intervention area. Community engagement should therefore be facilitated throughout the entire IR cycle – from pre-intervention, to intervention and continuous monitoring to the final evaluation – and not only during the IR design or conceptualization process (Figure 6).

Too often, unfortunately, researchers simply present an idea or approach to the community that they think will work and expect them to ‘buy in’. In engaging the community, it is best to first discuss the problem at hand, as well as strengths and resources existing within the community, and then seek their opinions on the optimal interventions and IR approaches that will address the problem.

Figure 6. Reasons for community engagement in an IR project



‘Gatekeepers’ in the communities where IR will be conducted are particularly important research stakeholders. They can be considered de facto experts in the field, and an invaluable source or conduit of local information and knowledge, as well as of innovative solutions.

Community engagement: A process of working collaboratively with and for groups of people affiliated by geographical proximity, special interest, or similar situations, to address issues affecting the well-being of those people.²⁶





A frequent barrier to effective community engagement is the use of complicated informed consent forms, typically employed in a bid to follow principles of good research ethics. Complicated material with a lot of research jargon and fragmented information leaves the community wondering if they are safe or not. All materials provided to community members should be presented simply, with the critical information designed to make the community comfortable and to reassure them of their safety. Complex technical language – and the confusion and mistrust it can potentially generate – are critical barriers that should not be overlooked.



REFLECTION ACTIVITY

Address the following questions in relation to your IR project:

1. Who are the community 'gatekeepers' in your project area?
2. How will you engage them?



2 How will you engage them?

1 Who are the community 'gatekeepers'?



Case study 2

Community engagement: *Majigi educational intervention for polio eradication in Northern Nigeria*

Background: Over two decades ago, the global polio eradication effort was launched. It sought to end the disease through an efficacious polio vaccine that is delivered through routine vaccinations and supplementary campaigns among susceptible populations. To date, however, Nigeria is yet to be declared polio free. This is mainly because of the low polio vaccine coverage in northern Nigeria despite the repeated polio campaigns in the region. The main bottleneck was low community acceptance due to misconceptions, distrust and myths around the cause of the disease, the safety of the vaccine, inadequate social mobilization, improper channels of communication, and lack of programme commitment and ownership at the local government level. Thus, to enhance the effectiveness of the intervention, there was a need to actively engage community gatekeepers with a special focus on political, traditional and religious leaders, traditional healers, birth attendants, town criers and traditional surgeons. A pilot trial using a mass media campaign was launched in 2008 in four northern communities within the same local council. This campaign, dubbed the 'Majigi' educational intervention, targeted the beliefs about the disease and the negative attitudes towards polio vaccination. Majigi involved a road side film show in communities using mobile vans. Community leaders encouraged attendance and participation in subsequent vaccination activities through their circles of influence. Regular polio supplemental vaccination activities were conducted and the outcomes monitored for six successive months.

Results: The campaign resulted in a 310% increase in polio vaccination uptake and net reduction of 29% of never-vaccinated children in the targeted region. 'Majigi's successful innovative contextually- sensitive approach enhanced community ownership and cleared misconceptions around the polio vaccine.

Conclusions: Targeting the community gatekeepers facilitated the implementation as well as the outcomes of the intervention. Furthermore, polio vaccination uptake was enhanced by a locally adapted programme that promoted effective communication with and within the community.

Lessons: To promote a given intervention, communities need to be empowered so that they are able to make informed decisions.

Source: Nasiru, S.-D. et al. Breaking community barriers to polio vaccination in Northern Nigeria: the impact of a grass roots mobilization campaign (Majigi). *Pathogens and Global Health*. (2013); 106(3):166–71



Ethical challenges in IR

As with all research, ethical and scientific integrity is an essential good practice in IR. In the context of IR, there may be specific ethical dilemmas because the studies are often conducted within the routine activities of the health system, and without the level of control associated with most clinical research studies especially clinical trials. The autonomy and understanding of volunteers are likely to be limited if the studies are conducted in high-burden and vulnerable populations with limited access to health care. In some IR projects, individual observations or personal interviews risk generating psychological distress when sensitive issues are discussed or recorded, or if there are any potential breaches of confidentiality.²⁷

Ethical issues associated with IR can generate controversy. This may affect both quantitative and qualitative research approaches, across a broad range of disciplines such as epidemiology, statistics, anthropology, sociology, health economics, health promotion and education, political science and others. Although research protocols are applied in real-life settings there are nevertheless inherent ethical pitfalls and risks.

For example, participants in IR may be burdened by the 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 sampling, and considerate timing of observations. IR also poses specific ethical challenges, given that it frequently requires collection of information from a large number of subjects in diverse situations, and involving a broad range of stakeholders.

Research ethics committees are often more familiar with the protocols developed for more mainstream clinical studies and trials. Study protocols developed by IR teams should inter alia take special note to address issues such as power relationships, illiteracy, disruption of routine health services, inequitable selection of participants, raising expectation of participants and over-burdening staff in the health system with research responsibilities, diverting their time and efforts from health care provision.



REFLECTION ACTIVITY

Critically reflect on the ethical challenges that might be associated with your IR project considering the principles of autonomy, beneficence and justice. How will you minimize the impact of these challenges?



Ethical challenges in obtaining informed consent in IR

In general, the ethical codes of biomedical research – such as those prescribed in the Declaration of Helsinki, the Nuremberg Code and as espoused by the Council for International Organizations of Medical Sciences – do not provide adequate insight to guide IR projects. Nevertheless, with a robust research protocol, appropriate study design, a competent and skilful research team and rigorous review by the relevant scientific and ethics committees, ethical interests of the participants and the community can be safeguarded.

Because IR is conducted in real-life situations, researchers face changing sociocultural, economic and political context. Hutton et al²⁸ argue that: “The level at which an intervention is delivered may determine whether patients can opt in or out;” and further state: “For interventions delivered at the level of the health care facility, it is unclear whether one could ever reasonably seek consent for randomization to intervention and control arms from individual patients who may be affected by the trial interventions”.

Example: Voluntary medical male circumcision as an HIV prevention strategy

In 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued recommendations on medical male circumcision as an HIV prevention strategy, based on strong and consistent scientific evidence. In many settings, however, it has proven difficult to translate this research into policy and practice due to economic, sociocultural and ethical challenges. Thus, specific factors ought to be considered when planning to implement/scale up voluntary male circumcision as a public health intervention.²⁹

Context: For an intervention to be successful, it is important that researchers understand the context in which the intervention will be implemented. Since IR is complex and involves multiple stakeholders, policy-makers, programme implementers, health workers, the community and the prospective beneficiaries should be identified and their respective roles assessed. Furthermore, voluntary male circumcision is a public health intervention impacting cultural dynamics and the health system. For example, in communities where circumcision part of a boy's right of passage into manhood, introducing neonatal circumcision may be difficult to implement. In addition, power relations in the community should be explored. The level of organization of the health services and capacity of existing human resources to provide safe circumcision will influence decisions to either integrate neonatal male circumcision into postnatal services or as a stand-alone service. At a policy level, the country's existing policies on male circumcision (such as the age at which a child should not be circumcised or if there are specialized circumcision surgeons, or designated places where circumcision takes place) should be analysed to guide the implementation process.

Ethical challenges: Ethical issues at both individual (neonates and minors under the age of consent) and community level that influence the intervention feasibility:

What should be done in cases where the child refuses to consent but the parents want the circumcision to take place, or where the child wants circumcision but the parents refuse to provide consent?

What if the very notion of obtaining consent for circumcision is culturally absent?



Ethical challenges in obtaining informed consent in IR (continued)

Should only populations at risk of HIV acquisition/transmission such as truck drivers, soldiers, migrant workers be targeted for circumcision? If yes, how can the subsequent stigmatization of this specific population be minimized?

What is the optimal age at which circumcision should be implemented?

Should it be offered only to men who test negative for HIV or be extended to men living with HIV?

To have an ethically sound implementation of voluntary male circumcision as a HIV- prevention strategy, elements of acceptability of different approaches among currently circumcising and non-circumcising groups should be comprehensively assessed.

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.³⁰ It was designed in three phases: i) a participatory assessment 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 prevent mother-to-child (PMTCT) HIV transmission was implemented, and related output indicators were monitored. Data were collected using structured interviews from the managers and counsellors, observation of the health facilities, review of documents and routine PMTCT data. The data showed large improvements in all key PMTCT output indicators.

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 IR proposal. 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 mid-level managers in the health system (e.g. facility managers, the primary health care supervisors and district programme coordinators) and the community. Their various roles were described accordingly.

Intervention: The conceptual framework used in developing the intervention was based on an expanded health systems approach. The researchers further acknowledged that the weaknesses identified during the assessment were due to the complex interaction between the clients' lack of information and fear of disclosing their HIV status, and the health system factors of 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.

Ethical challenges:

- Should being part of the routine health care 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?



Case study 3

Contextual factors leading to persistence of malaria in remote Central Viet Nam

Background: The persistence of malaria in Viet Nam is related to complexities within the health system, sociocultural, economic and environmental contexts. The establishment of the National Malaria Control Programme with a strategy to distribute bed nets, as well as diagnosing and treating confirmed cases free of charge, dramatically reduced the malaria incidence rate from 1.2 million clinical cases in 1991 to 185 529 in 2002. Despite these efforts, however, the central province of Quang Tri – with poor, low-educated and culturally diverse minority populations – had one of the highest malaria burdens in the country. A study aiming to strengthen malaria control sought to identify how the health system and community factors are linked to malaria persistence. A multidisciplinary team conducted the study from March 2004 to April 2005. A mixed-methods approach was used in two of the districts with the highest malaria burden. In the formative stage, qualitative approaches were used to inform the later quantitative part of the study. Semi-structured interviews and focus group discussions were conducted with purposively selected health care managers, village heads and villagers to explore beliefs, attitudes, awareness, health care-seeking behaviour and circumstances relevant to malaria exposure and control. A knowledge attitude and practices (KAP) survey was conducted in the assessment stage, face-to-face with the village health workers (VHWs) and community members. Checklists were used to assess the visibility and status of malaria treatment guidelines, quality of microscopy, as well as bed net quality (during KAP survey home visits). To determine actual bed net use, unannounced night visits to homes were also conducted.

Findings: The main deficiencies at a health facility level were understaffing, unqualified staff, lack of in-service training, inaccessible treatment guidelines and lack of equipment and supplies. At a community level, socioeconomic and cultural factors impeded access to and effective use of interventions. Although diagnosis and treatment of malaria were free, patients were unable to afford the associated costs and this led to early self-discharge and failure to attend follow up appointments. Furthermore, although bed nets were supplied free of charge, the target of 80% coverage (i.e. one net per two people) was not met due to cultural sleeping norms, as well as low education and poverty. Overnight socializing among male neighbours is typical and yet the majority of homes did not have spare nets for guests. Risks to exposure was also increased due to the high mobility, which is culturally and economically driven. Whereas the geographical access to health services was addressed by having community health workers (CHWs), many of whom had insufficient training and this greatly affected their capacity to cope with all expected tasks. In addition, due to delays in rolling out the new guidelines for some of the medicines included in VHW kits, some CHWs did not follow prescribed treatment guidelines. Language barriers and mistrust between the ethnic minorities in western Quang Tri and service providers was also reported, and this may have contributed to the community's lack of responsiveness to medical advice. Geographical inaccessibility due to poor roads, and shortage of telephones, were among the contextual barriers identified.

Conclusion: Deficiencies were established throughout the continuum of care from the health facility all through to the community level. These observations were used as a basis of the proposed intervention.

Lessons: A comprehensive analysis of context is critical for the effectiveness and ultimate success of any proposed intervention.

Source: Morrow M. et al. Pathways to malaria persistence in remote central Vietnam: a mixed-method study of health care and the community. *BMC Public Health*. 2009; 9:85.



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IMPLEMENTATION RESEARCH TOOLKIT



Developing an Implementation Research Proposal

Tuoyo Okorosobo and Olumide Ogundahunsi



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Developing an implementation research proposal

This module is designed as an aid to the development of a high quality implementation research (IR) proposal by a research team. It draws extensively and builds upon the content of the proposal development module in the first edition of this toolkit.¹

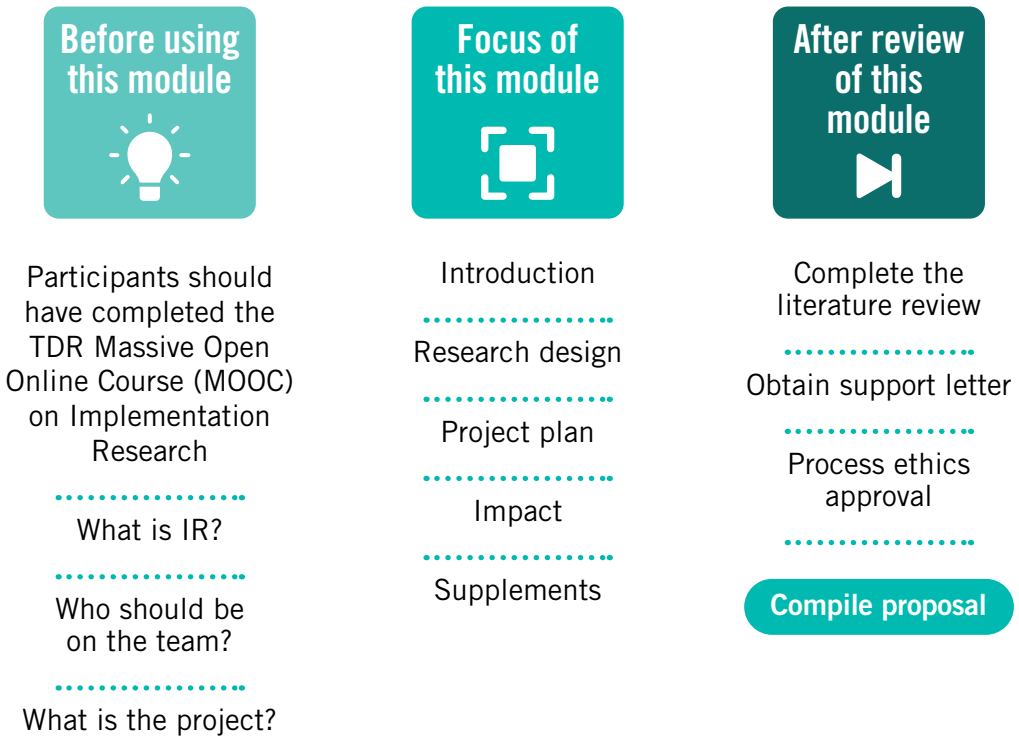
Although there are certain elements that are common to various types of research proposals, some aspects are emphasized in this module to guide the process of developing a proposal designed to address barriers to optimizing the effectiveness of a given health intervention, policy or strategy that form the basis of an IR ‘problem’.



The module takes a practical approach and assumes its use by IR teams is to shape the development of specific proposals. It is therefore not ideal for abstract or theoretical application. This module is structured as shown in Figure 1, which includes activities to be undertaken before starting the module, the focus of the module itself and actions to be taken after its completion.



Figure 1. Overall structure and approach for developing an IR proposal



If your team is embarking on the development of an IR proposal and are unsure where to begin, rest assured you are not alone! Even defining the research question can seem overwhelming at the outset. The purpose of this module is to help team members understand the process and take each of the individual steps involved in writing an IR proposal.

Before starting, team members should have already completed the *Massive Open Online Course (MOOC) on Implementation Research*,² and/or other relevant online resources,^{3,4,5} as well as working through the Introduction module of this Toolkit. These resources familiarize you with key terminology, core concepts, research frameworks, programme components and other fundamental issues related to IR. A review of literature on the subject of your research, including research articles and other resources mentioned in the references section, are also essential reading.





The content and activities in this module are organized into a series of sections, each addressing a specific element of an IR proposal in a step-wise process. Respective sections comprise the following elements:

- Identifying what you will accomplish by the end of each section.
- Essential information to help you understand the specific steps in proposal writing.
- Exercises to facilitate your understanding and put ideas into practice.
- Reflection opportunities for you to consider specific issues in relation to your project, and explore how successive ideas should be incorporated into your team's evolving proposal and thinking.

Overall, the module provides harmonized guidelines for proposal development, recognizing that an IR team includes members from diverse backgrounds. Many users are likely to be seasoned researchers or at least have some research experience.

The team and the research challenge

Having already taken the MOOC on IR and read the recommended materials, by now you should have a good understanding of what IR is and its significance in meeting your research objectives. At this stage, you should have identified your main stakeholders and constituted your initial research team. The roles and responsibilities of each member of the team should be established and appropriate for the research problem to be addressed by your proposal.



REFLECTION ACTIVITY

Refresher on IR fundamentals

- **Reflect on the research problem/challenge your research project will address.**
- **Review the composition of your team and assess their roles and responsibilities in your planned project.**
- **Refresh your understanding of the following:**
 - **What is IR and what are its key characteristics?**
 - **How did you identify the IR problem you are addressing in your proposal?**
 - **What are the steps involved in your IR project?**
 - **How could the scaling up of a programme or intervention benefit from an IR project?**
 - **How did you formulate your IR research question(s)?**
 - **Who are the main stakeholders, how do you identify and integrate them into your project?**

Structure of an IR proposal

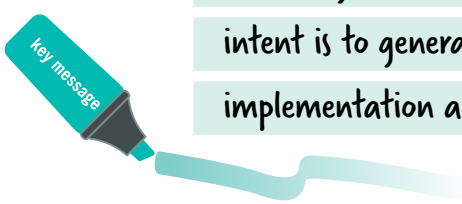
In general, the proposal structure is similar for all research. A research proposal is a document that describes:

- the proposed research;
- why it is being conducted;
- the research design;
- the expected impact.

A proposal is a requirement for most grant/funding applications, which are typically evaluated 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 written research proposals before, or a thesis as part of your previous studies, you will remember that you were required to write a proposal and have it approved by a research/thesis committee (and probably 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. However, when developing an IR proposal the intent is to generate research evidence to improve programme implementation and inform policy.

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 robust research proposal is probably one of the most challenging – and crucial – stages of research. You need to develop the 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.⁵



What is different about an IR proposal?

WHAT IS DIFFERENT ABOUT AN IR PROPOSAL?

What?

Information about the problem being addressed originates from the health system;

Involvement of the end users of the outcomes of the research all through the research process.

How?

Generate knowledge so it can be applied across multiple settings and contexts;

Engage multiple sectors, including epidemiology, social science, anthropology, communication science and health economics;

Contribute to the development of policy recommendations and practical solutions.

Why?

Better inform health care service quality improvement efforts;

Facilitate uptake of research results and outcomes by end users.

In particular, IR proposals differ from those used in other types of research in relation to the:

- origin of the research problem;
- involvement of the end users of the research outcomes all through the research process.

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

- better inform health care service quality improvement efforts;
- facilitate the uptake of research results and outcomes by end users.

In general, IR projects:

- generate knowledge so it can be applied across settings and contexts;
- engage multiple sectors, including epidemiology, social science, anthropology, communication science and health economics;
- contribute to development of 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 ways to improve related knowledge transfer. 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.⁶

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 knowledge that can be applied across various settings and contexts (although they may also be intervention specific).

Characteristics of an IR proposal

Characteristics of an IR proposal

- 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 a 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 and training for younger researchers and involvement of more experienced individuals.
- Involvement of health professionals from the study setting.
- Active dissemination of results at all levels of implementation.

Additional characteristics to consider:

- Each funding agency has its own proposal format and specific requirements.
- Not all agencies will require all components included in this module.
- Some agencies may require a letter of intent (LOI) or a concept note as a preliminary screening step, to ensure your proposal will align with their needs.
- LOIs include the same components as a research proposal, but with less detail.

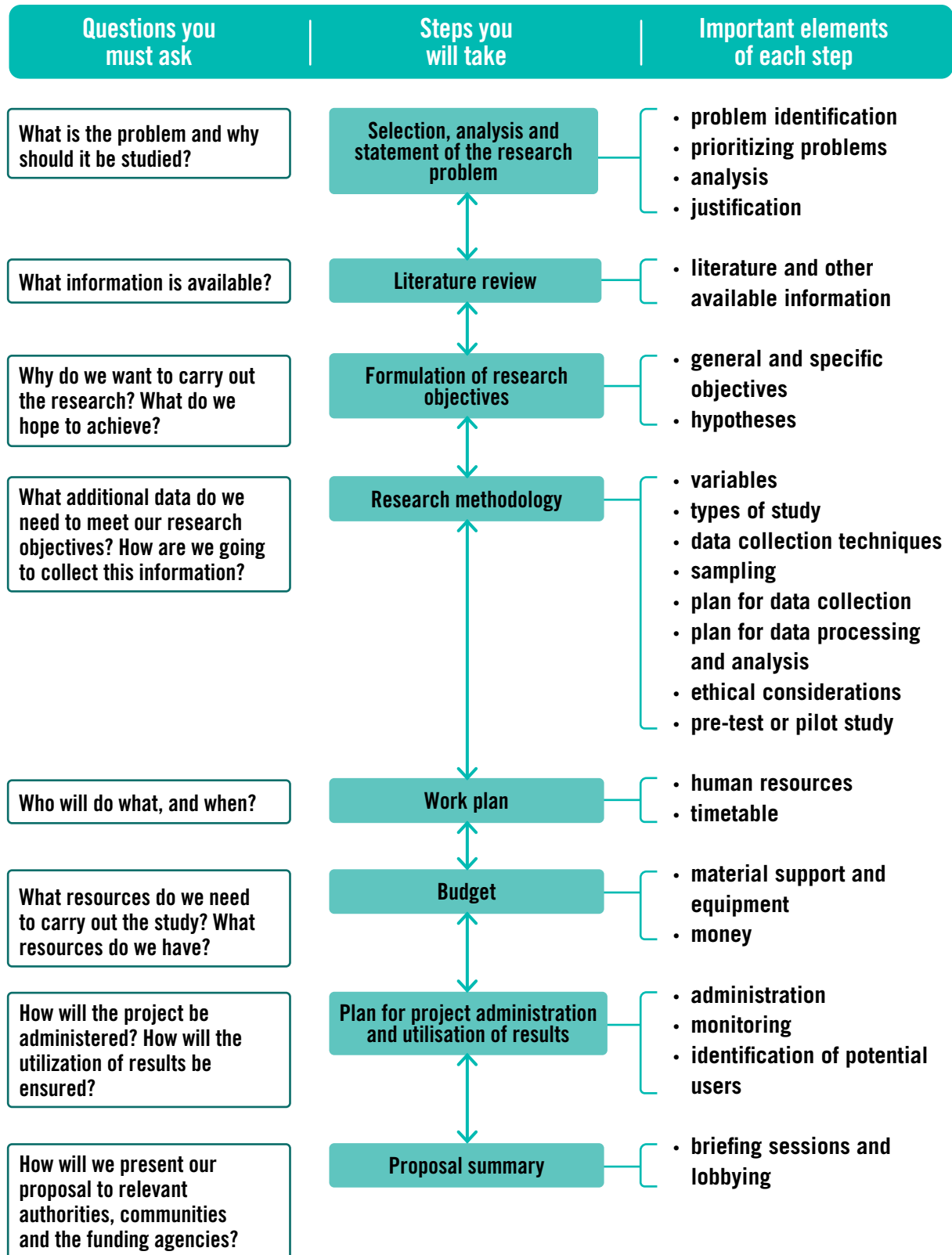
Components of an IR proposal

The components of an IR proposal may vary slightly depending on the type of research planned and/or requirements outlined by the funding agency to which it is being submitted. Many funding agencies indicate specifically what should be addressed in a proposal.

The following section has been designed to be general enough so it can be adapted to fit the priorities of different users and various calls for proposals, recognizing that not all sections will be used in every proposal submitted for funding consideration. It is helpful to see the components of the IR proposal as being structured to respond to a series of questions that the research process aims to answer, as outlined in Figure 2.7 The different steps are discussed briefly in this module and further elucidated in the other modules of the toolkit.



Figure 2. The IR framing process



Source: Varkevisser et al.

Typically, an IR proposal comprises the following components, as described in more detail in respective tables in this module:

Introduction: Including title page, rationale, statement of the problem, objectives and research question(s) and literature review (synthesis of existing knowledge) (Table 1).

Research design: Outlining the participants, intended research methods, data collection, data analysis, quality management and ethics (Table 4).

Project plan: Presenting a more detailed project plan, research team description and budget information (Table 6).

Impact: including monitoring and evaluation, capacity building plan and results/outcome dissemination plan (Table 7).

Supplements: Such as project summary, table of contents, references, appendices and CVs of investigators (Table 8).

Figure 3. Components of an IR proposal





In each of the following sections, these different parts of the research proposal are considered to help your team in writing your research proposal.

Introduction

The first step in writing and refining your IR proposal is drafting the introduction section. This involves drafting an overview of your research problem and conducting a systematic review of existing materials and literature. This provides a rationale for tackling the problem and highlights the significance of the problem. You will also develop general and specific research objectives, a statement of the problem and your research question(s).

After completing this section, you will be able to:

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

The introduction to your proposal should:

- Outline what is being studied and why (i.e. the rationale).
- Build an argument for the current study.
- Include a statement of the problem, general objectives, specific objectives and research question(s) based on a critical analysis of the core problem identified and factors that contribute to the problem.
- Review existing literature.
- Summarize expected outcomes, including the impact the results will have.
- Provide a clear, succinct rationale for why the project should be funded.

The introduction content is summarized in Table 1.

Table 1: Sub-components of introduction section

Section	Description
Title page	Four components of a good title: <ul style="list-style-type: none"> • Use action words. • Reflect implementation and intervention themes. • Include specific target populations (adolescents, children under 5 years of age etc.)
Rationale	<ul style="list-style-type: none"> • Outlines what is being studied and why. • Summarizes expected outcomes, including the intended impact(s). • Provides a clear succinct rationale for why the project should be funded
Statement of the problem	<ul style="list-style-type: none"> • Summarizes the purpose of the study. • It is a paragraph rather than a single statement. • Establishes the direction and captures the essence of the study. • Should be 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)	<ul style="list-style-type: none"> • Should be of interest to the research community, researchers, policy-makers; decision-makers, funding agencies, health care providers, and the communities the research will ultimately affect. • Should be answerable. • Are shaped by the problem, and in turn should logically influence the research design. • Are clear and specific. • Are feasible. • Provide information required to evaluate interventions or progress. • Analyse possible causes for missed targets in order to find solutions. • Answering the question will result in important information or in developing relevant interventions.
Literature Review	<ul style="list-style-type: none"> • 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.



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 rationale might be based on a need identified by the community, policy-makers and/or 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 carried out and be supported.

The introduction provides critical information for funding and community support by:

- Providing a foundation for the further development of the proposal (overview of the problem).*
- Facilitating access to background information on, and reports from, similar studies (systematic analysis and succinct review of literature).*
- Systematically stating 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 of the problem you intend 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 and discuss issues with your team.

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 address the research problem, and make a case as to why the chosen approach should be undertaken. It should also indicate how the results will be used, 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 the 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 and do not worry about how your ideas sound initially or about perfecting what you write. During the proposal development process, you will continually change, elaborate, delete and edit the introduction as you progress with researching and discussing the topic provided.

- Overview of the health care system in the country/region/district/community 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.
- Description of the nature of the problem.
- Analysis of the various factors that may influence the problem – why some factors need to be investigated.
- 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).
- 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:

- Use 'action' words rather than passive language.
- Reflect implementation and intervention themes.
- Include specific target populations (adolescents, children under five year of age, etc.).
- Refer to specific geographic location(s).



The title of a research proposal should describe the study, be concise and inform the reader what the research is about.



The title may not differ significantly from that of other research proposals, but the topic it addresses will reflect a need identified within the community. It is possible that you may also include “Implementation research” in your proposal title in order to highlight that you are applying for a research grant that is specific to IR.

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.
- Increasing access to care and appropriateness of treatment at private sector drug shops through integrated management of malaria, pneumonia and diarrhoea.

Rationale

Every IR proposal needs a robust rationale to present the case to policy-makers and/or funding agencies outlining the benefits of committing scarce resources to the proposed research project. The introduction section of the proposal must therefore strongly justify why the research problem you have identified is important and worthy of support. Justification should also be provided explaining how the selected research problem aligns with the national research agenda. To provide this justification, it is useful to 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 (e.g. related project progress reports, theses, dissertations, seminar proceedings);
- programme progress, annual or evaluation reports;
- medical and social science literature, including reviews that outline gaps in research and/or programmes;
- research results in journal articles and scientific publications;
- abstracts/presentations/papers from scientific meetings and conferences;
- new ideas/recommendations from previous research;
- funding agencies’ annual reports;
- questions asked by programme staff and/or students.

Not all problems that contribute to the sub-optimal delivery of an intervention can be addressed by IR. In some instances, for example, solutions may be quite obvious, and the result of management problems can be addressed without further research.



Statement of the problem

An IR project has its origin in the recognition of a problem that impedes the effective implementation of an intervention, strategy or policy, and that requires specific new understanding in order for the problem to be addressed.

If, for example, a malaria control programme has concerns over low levels of bed-net ownership in a given district – and yet its stores are filled with undistributed bed-nets – the programme may best be served by strengthening the distribution of the bed-nets rather than embarking on research to explore the problem.

The statement of the problem is an important part of the IR proposal because it:

- summarizes the purpose of the study;
- establishes the direction and captures the essence of the study;
- succinctly outlines the purpose and objectives of the study;
- reflects the research design;
- leads to the research question(s).

How to know if the problem is worthy of research?

To confirm that the problem identified constitutes an appropriate research project, you can 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 in relation to the problem?
- Is there more than one possible answer or solution to the problem?
- Do current programme implementers/policy-makers identify the problem as a priority?

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

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

These three considerations should be emphasized in the introduction of your proposal and help formulate the rationale for conducting the research. Reflecting upon these considerations is also important in helping you first think broadly, and to subsequently narrow your focus to identify research objectives within that broader context.



The term 'statement of the problem' may be misleading as it usually comprises of a self-contained paragraph, rather than a single statement. Here are some brief, additional suggestions to help ensure clarity:

- Use terms/ideas such as 'purpose', 'intent' and 'objectives' to highlight the main idea underlying the research.
- Identify the key concepts being explored.
- Describe the research design (e.g. case study, ethnographic study, descriptive, correlational, experimental).
- Highlight the unit of analysis in the study (e.g. independent and dependent variables, population, classroom, organization, programme, event) and data collection methodologies (e.g. surveys, interviews, observations).

Consider the following examples to guide you in the development of your statement.

Example 1:

In Vietnam, after the introduction of user charges in 1989, several provincial health insurance schemes were developed. In these schemes, industrial workers, constituting a minority of 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 was the low enrolment in the health insurance scheme and by extension, limited access to health care in the rural population.

Example 2:

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 worm infestations are very common. The Department of Health has initiated a sanitary project that aims to increase 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. (adapted from Varkevisser et. al. 1991)



Case study 1 Is your research problem justifiable?

Background: Any worthy research should be preceded by a knowledge gap. Accordingly, in implementation research, the knowledge should be used to overcome any identified bottlenecks to improve health service delivery. Therefore, any proposed research should address the discrepancy between the observed status and what is desired. Furthermore, a successful research project should be able to garner the support of the relevant stakeholders. Hence it must be acceptable, relevant, a priority, politically acceptable, timely, ethically sound, urgent and feasible. The table presents an analysis of the above variables for a study that set out to determine the barriers and motivators to voluntary medical male circumcision (VMMC) uptake among various age groups of men in Zimbabwe. The aim of the analysis is to establish if the research was justifiable.

Variable	Explanation
Was there a discrepancy between the situation that existed and the ideal?	Yes: The programme started in 2009, but as of September 2013, only 170 000 men were reached against a five-year target (2013–2015) of 1.9 million.
Was the research a priority ?	Yes: In 2009, Zimbabwe was one of the priority countries identified by WHO/UNAIDS to scale up VMMC. But after four years of implementation, a coverage of only 4.8% of the target population was achieved. Therefore, understanding the barriers and motivators to VMMC uptake can create a will an effective demand to address them as an urgent priority.
Was there a clear reason for the difference or discrepancy to the problem?	No.
What factors could explain this difference?	Negative attitudes towards circumcision; fear of pain; fear of complications; perceived threats to masculinity; costs.
Were the results urgently required by stakeholders e.g. policy-makers, implementers, health care providers	Yes: There was a need to establish why the programme was not achieving its set targets.
Was the research politically acceptable?	Yes: The project was run by the Ministry of Health (MoH) and Population Services International (PSI), and therefore had political support. The topic was of high interest to local and national authorities.
Was the research ethically sound?	Yes: Results were shared with the stakeholders, research group and were beneficial to the community. Furthermore, informed consent was obtained from the research participants?
Were the recommendations applicable to the target community?	Yes: The recommendations were used to craft context specific IEC (Information, Education and Communication) messages. Specific goodwill ambassadors were identified within the community. [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].
Was the research timely ?	Yes: Because despite the rapid scale up of service provision, uptake of VMMC had been slower than expected.
Was the research relevant ?	Yes: HIV is a public health problem affecting a significant proportion of the population, in terms of health as well as social and economic impacts.
Was the research new or innovative ?	Yes: The results identified other target populations such as women for the information, education and communication messages. Other modes of dissemination were also identified.
Was the research feasible ?	Yes: Human resources to collect the information and implement the recommendations were available and WHO and PSI were willing to support the research.



Case study 1 Is your research problem justifiable?

Conclusion: The study to determine barriers and motivators to VMMC uptake among different age groups of men in Zimbabwe was justifiable because there was a discrepancy between the status and the desired state, the information was needed urgently, the research was politically acceptable to the stakeholders, and it was ethically sound and feasible to conduct in terms of human resources, time and funding.

Source: Hatzold K. et al. Barriers and motivators to voluntary medical male circumcision uptake among different age groups of men in Zimbabwe: results from a mixed methods study. PLoS One. 2014; 9(5):e85051.

To help you narrow your focus on, clarify and describe the core research problem from a broad perspective, it helps to consider the viewpoints of different stakeholders and to begin identifying the factors that may have contributed to the problem.

The research team should now 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.

Follow the steps below to help narrow the focus and identify specific research objectives within the broader context of the research problem:

a. Clarify the viewpoints of all stakeholders.

- List all the problems.
- Illustrate existing discrepancies.

e.g. In relation to an increased 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.

b. Specify and describe the core problem.

- Quantify the problem.
- Describe the problem in detail.

e.g. In relation to an increased defaulter rate among TB patients:

- How widespread is the observation? Which regions/settings 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.

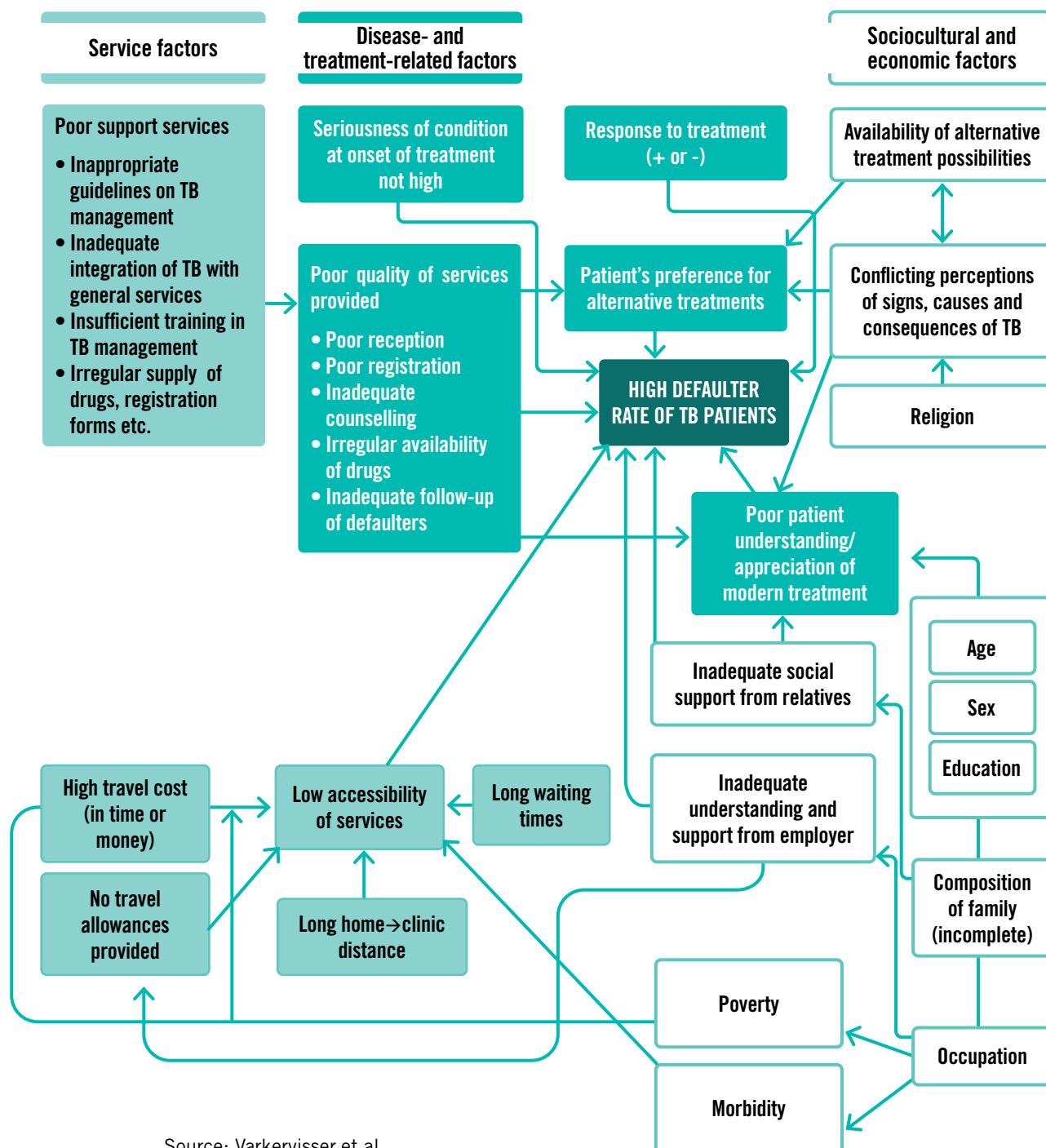
c. Identify the factors that may have contributed to the problem and clarify their relationship to the problem.

e.g. In relation to an increased 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.

Focusing on the core research problem may be best carried out by means of a problem analysis diagram depicted in Figure 4.

Figure 4. Problem analysis diagram to explore reasons for high TB default rate

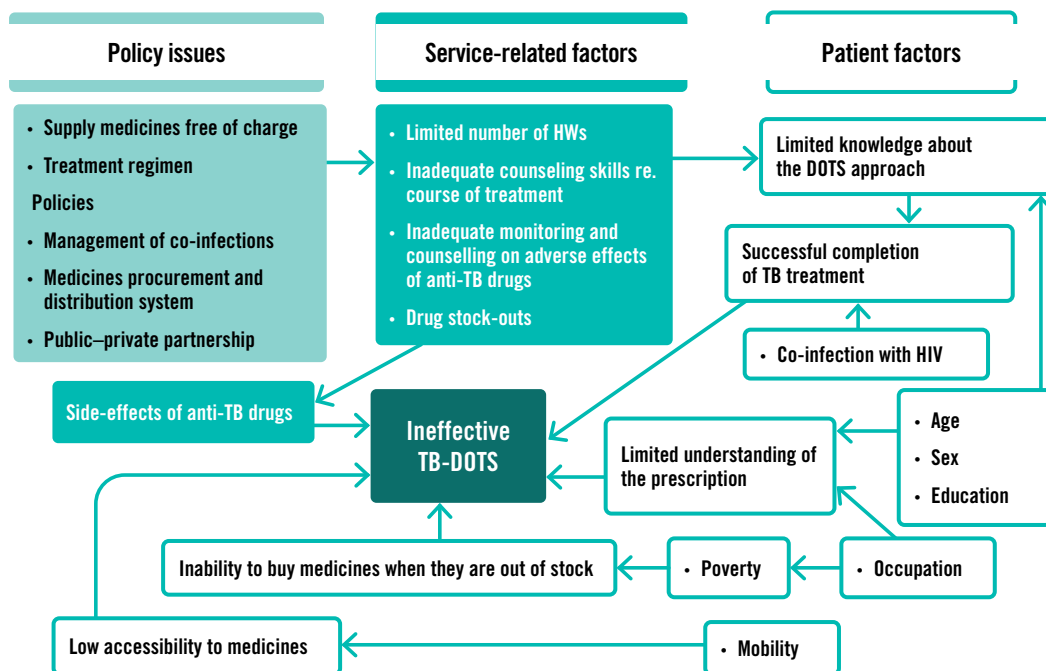


Source: Varkervisser et al.



Case study 2 Analysis of the research problem

Background: The directly-observed treatment strategy (DOTS) short-course approach has been adopted as an effective strategy for the management of tuberculosis (TB) and is reported to have significantly improved TB disease detection, treatment and control. In Nigeria, however, neither the set target for TB detection rate nor the cure rate has been achieved nationwide. This is due to several challenges at various levels of the health system (i.e. policy, health service delivery, community and individual levels). To unpack the research question and to also establish the relationship of the factors at the different levels within the health system, the problem was critically analysed. The process involved a brainstorming session on the different factors contributing to the core problem, descriptions of the cause-effect relationships between the different factors and grouping them under the relevant thematic areas (see diagram). The process also actively involved relevant stakeholders. A previous study by Bello et al, examined the challenges of the DOTS in the treatment of TB patients with the view to determining the obstacles to effective implementation. Associated patient-level factors included a lack of knowledge about DOT, poor adherence to medicines, co-infection with HIV, poverty and the sex of the patient. Poor counselling by the health personnel and medicines stock-outs as well as side-effects of medicines were identified at the health facility level. These observations were encountered despite the existence of national policies intended to improve the uptake of the DOTS programme.

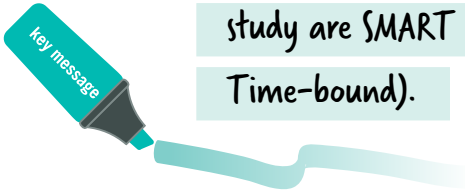


Lessons: A comprehensive analysis of the problem identified specific bottlenecks and their mutual relationships at the various levels of the health system. This was helpful in the development of research tools, as well as recommendations for targeted interventions.

Source: Bello SI. Challenges of DOTS implementation strategy in the treatment of tuberculosis in a tertiary health institution, Ilorin, Nigeria. African Journal of Pharmacy and Pharmacology. 2010;;4(4):158–64.

Research objectives

In IR studies, because the research problem is identified by and articulated by people who implement programmes, the tendency is to phrase the IR objectives in the typical way that programme objectives are stated, e.g. “to increase the Expanded Program on Immunization (EPI) coverage from 45% to 80%”, rather than as research objectives, i.e. “to explore factors contributing to the poor EPI Coverage.”



In all cases make sure that the research objectives stated for your study are SMART (Specific, Measurable, Achievable, Realistic and Time-bound).

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 carry out the research? Is it feasible to conduct and report the findings in 12 to 36 months?
- Is the research timely? You should 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, who it affects and, and who considers it 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.

**REFLECTION ACTIVITY**

Review the example below and assess if the research is *realistic, timely* and *relevant*.

Both the China and Viet Nam Governments have recently recognized the problem of lack of access to health care for the rural population. New policy initiatives are being developed to address the issue. In China, the central government has taken the decision to allocate 10 yuan/year/person for the rural population in the central and western parts of the country, in order to subsidize the re-establishment of a new cooperative medical scheme. It has also asked the provincial government to provide the same amount of money to support the scheme. In Viet Nam, 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 for 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 innovative policy initiatives, by bringing together the resources of experienced researchers from China, Viet Nam and three European countries. The goal is to study, evaluate and draw policy lessons for the ongoing movement to strengthen access to effective health care by making health insurance schemes work for the most vulnerable rural population in the two countries.

Possible responses:

From the available information, the proposed research could be said to be realistic. Although policy analyses are challenging and expensive, we are told that experienced researchers from the two countries as well as from Europe will conduct the study. The apparent strong political will could be expected to translate into sufficient resource commitments from the two governments, complemented by external resources from their European collaborators.

With respect to timeliness, it is possible to infer that the research is timely as a critical driver towards the attainment of universal health coverage goals is the rapid expansion of pre-paid mechanisms, particularly among the poor.

Finally, the research is potentially relevant as it addresses a problem that affects a significant proportion of the population. Failure to address the problem would leave the populations with limited access to health services, exposure to catastrophic expenditures, and possibly without recourse to coping mechanisms. This could leave them trapped in a vicious cycle of poverty and poor health.



Is the research *new or innovative*?

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

Example

The research will produce innovations in a number of areas, as follows:

- *Piloting and testing new rural health insurance arrangements including innovations in:*
 - *benefit packages, in particular the development of schemes such as primary and outpatient health services to reduce incidence of catastrophic health care expenditures in China and Viet Nam;*
 - *provider payment mechanisms – in particular options such as capitation payment for outpatient services at the village and township level health services in China, and commune health stations in Viet Nam;*
 - *organization and management, including measures to increase accountability and transparency;*
 - *government subsidies in both countries.*
- *A participatory approach 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*?

Consider 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.

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 should typically 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.

Example

Undertaking tuberculosis (TB) research among prison inmates may be seen as politically unacceptable in some countries. Consulting with and involving the authorities could mitigate such problems.



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

Explain the likelihood of the adoption of the 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.

Example

A study to identify the optimal mix of services/procedures that can be provided or performed by lower level health care cadres will be of interest to both policy-makers and community members, as a potentially wider range of services will become available while maintaining existing staffing levels.

Is the research *ethical*?

Explain how the research will be beneficial to 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?

Example

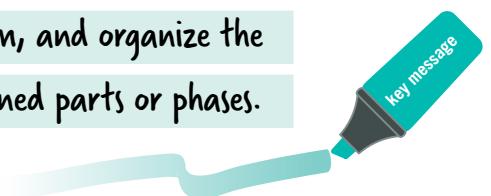
In scaling-up the use of the GeneXpert TB diagnostic device, more multidrug-resistant TB (MDR-TB) cases would be detected. It would be seen as unethical if MDR-TB diagnosed in this way cannot be treated appropriately (e.g. because of lack of medicines or technical capacity).

a. Overall objectives

The overall objectives of an IR project should outline the purpose for conducting the research. It should also:

- state clearly 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.

The statement of the overall objectives is important as it helps to focus the study, ensure the collection of only the data that is required for understanding and solving the identified problem, and organize the study into clearly defined parts or phases.



Different funding agencies use varying terminology to describe and characterize objectives, goals, aims etc. Sometimes these terms are used interchangeably.

b. 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. Here are some brief suggestions for framing specific objectives:


- Use action verbs when defining specific objectives (e.g. determine, compare, verify, calculate, describe, establish, evaluate).
- Avoid the use of vague, non-action verbs (e.g. appreciate, understand or study). Use verbs such as: train, supervise and 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.
- Ensure that the different aspects of the problem and its contributory factors are covered logically and in a coherent manner by the specific objectives.

After formulating your specific objectives ask yourself the following questions: Are the specific objectives clear, defined in operational terms that can be measured, realistic? Do they demonstrate what the research will do, where and for what purpose?, and, how will the research results will be used to solve the research problem?

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. In addition, research questions:

- are answerable;
- are shaped by the problem and in turn shape the design of the research;
- are clear and specific;
- provide important information required to evaluate ongoing interventions and/or progress;
- analyse possible causes for missed/failed targets (in order to find solutions).



IR questions are identified through an analysis of the known situation and evidence, and are not based simply on the instincts of researchers, policy makers, programme managers or health care providers.



An IR question aims to achieve one or more of the following:

a. Describe the health situation and intervention (include both situations and interventions in place, as well as potential/new interventions). For example:

- Magnitude of the problem.
- Distribution of the health needs of the population.
- Risk factors for specific problems.
- People's awareness of the problem.
- Utilization patterns of relevant services.
- Cost-effectiveness of available and potential/new interventions.

b. Provide information required to evaluate ongoing interventions or progress and needed for making adjustments in the intervention. For example:

- Coverage of priority health needs.
- Coverage among target groups.
- Acceptability of services.
- Quality of services.
- Cost-effectiveness of the intervention(s).
- Impact of the programme on health outcomes.

c. Analyses possible causes for missed targets in order to find solutions. i.e.:

- Availability.
- Acceptability.
- Affordability.
- Service delivery challenges/barriers.

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 research question determines the methods, and the purpose determines the design. IR questions address the design, implementation and outcomes of programmes. IR also explores the following questions: Are there any unintended consequences? 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.

In light of this, IR questions:

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

Table 2 provides examples of how various research and IR domains – such as epidemiological, clinical efficacy and programme effectiveness – respectively address a question of zinc deficiency and diarrhoea.

Table 2: Research domains and examples of research questions

Research domain	Research question
Epidemiological research	<p>What is the association of zinc deficiency with the severity of diarrhoea?</p> <ul style="list-style-type: none"> • Establishes an association between zinc and diarrhoea.
Clinical efficacy research	<p>What is the association of zinc deficiency with severity of diarrhoea? What is the effect of zinc as an adjunct for the treatment of diarrhoea?</p> <ul style="list-style-type: none"> • Examines how well zinc treatment works on the health outcome (diarrhoea).
Programme effectiveness research	<p>What is the effect of a programme of promoting zinc as an adjunct treatment of diarrhoea</p> <ul style="list-style-type: none"> • Examines how well a specific intervention or programme works in promoting the use of zinc treatment.
Implementation research	<p>Why is the zinc promotion programme not reaching all children with diarrhoea? How can the barriers to scaling up zinc promotion programmes be overcome so that they reach all children with diarrhoea?</p> <ul style="list-style-type: none"> • Uses findings from previous research in practical applications, examining implementation strategies to scale up the programme and treatment coverage.

Source: MEASURE Evaluation

Formulating IR questions

When formulating an IR question, the following are priority considerations:

- 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 the particular context and availability of information.



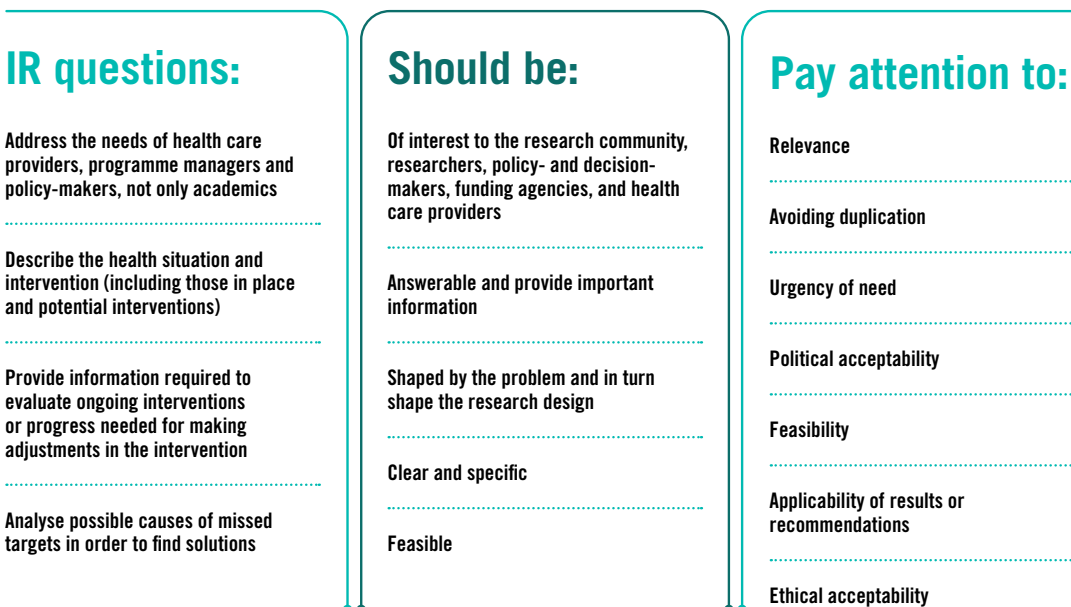
Remember that IR problems are programme embedded – they begin
and end in programmes.



Therefore, 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, health and social science 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.

Figure 3F. Defining and prioritizing IR questions



A programme may generate multiple implementation problems and questions, simultaneously. This can be overwhelming, so it is important to prioritize IR questions, to ensure efficiency and the responsible practice of IR. The criteria shown in Table 3 help with prioritizing IR questions.

Table 3: Criteria for prioritizing IR questions

Criteria	Considerations
Relevance	<ul style="list-style-type: none"> • How large or widespread is the problem? • Who is affected by the problem? • How severe is the problem? • If the problem is not addressed, is there a potential for it to 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	<ul style="list-style-type: none"> • Has this question or problem been researched before? • Are there any interventions that could effectively address this problem? • If yes, are there any major questions that deserve further research? • Is the context so different that I cannot use the results of previous intervention research?
Urgency of need	<ul style="list-style-type: none"> • How urgently do 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	<ul style="list-style-type: none"> • Is the implementation research problem of high interest and does it have the support of local or national authorities? • Would the study results generate sufficient political support that will more likely lead to their implementation? • Does the implementation problem have political acceptance that can engender the involvement of the policy-makers in the study?
Feasibility	<ul style="list-style-type: none"> • How complex is the research? • Are there adequate resources to carry out the study? • Is it possible to conduct and report the findings in 12 to 36 months?
Applicability of results or recommendations	<ul style="list-style-type: none"> • What is the likelihood that recommendations will be adopted? • How will the findings be used to improve health and health care? • Are there available resources for implementing the recommendations?
Ethical acceptability	<ul style="list-style-type: none"> • 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

The review of literature synthesizes the relevant and most up-to-date information on the proposed research topic and frames 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 current state of knowledge and of major questions in the subject area that are also being investigated.

A thorough literature review enables you to avoid duplicating existing research by discovering what research has already been conducted on a given topic. Reviewing the existing literature will help you refine your statement of the problem, analyse various approaches already used in related studies, and assist in forming a convincing rationale for your research. By reading your overview, readers should be convinced that you are familiar with the topic and that you have carried out extensive background research in the field.

A literature review:

- Involves comprehensive literature searches to identify relevant and up-to-date resources, reading and synthesizing the existing information and literature into a succinct overview.
- Demonstrates the relevance of proposed research 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.
- Highlights what is not known about the topic.
- Helps you refine the statement of the problem.
- Frames the 'state of knowledge' on the topic and sets up the research question(s) being investigated.
- Establishes credibility.

You should 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 should be researched. Writing this kind of rationale is the first step in developing the synthesis of existing knowledge for an IR proposal.

Conducting a literature review involves reviewing the existing knowledge and carrying out 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 that you need to read about the topic for several days or weeks before beginning to compile or collate available information. At some point, however, you do need to begin to draft the review content. 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 try to write while still reading and



reviewing. Writing, reading and re-writing is typically an iterative process. As such, developing a comprehensive synthesis of the existing information can be a protracted task.

Ultimately, a literature review should aim to:

- Present an argument based on existing information and publications.
- Synthesize information from many sources.
- Critique research studies for methodological shortcomings (when and if appropriate).
- Support your research question through analysis and synthesis.

The review of literature is not merely an expression of the research team's opinion of an issue or topic, but instead presents an objective argument based on 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 various sources. It should be well written with one paragraph logically flowing into the next. A literature review does not simply describe or summarize the content of cited articles/publications, but critiques research studies for methodological shortcomings, as appropriate.

It may have been acceptable previously for proposals 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. That is no longer the case now that anyone who has access to the Internet can explore 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.

Referencing

The ideas included in the review of literature should have a logical flow and should be properly cited using the reference style (e.g. Chicago, Harvard etc.) required by the agency to which the proposal is being submitted. 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 use and cite references properly and consistently, and in accordance with the applicable style guide. Not adhering to the conventions of proper referencing suggests sloppy organization and may hamper the chances of a proposal being successful. Moreover, if you do not reference properly, you run the risk of plagiarizing content and/or ideas, 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 (https://desktop_plagiarism_checker.en.softonic.com/).



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.



REFLECTION ACTIVITY

At the end of this section your team should be able 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)**

Research design

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

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

In this section of your research proposal, you will be required to:

- Develop and describe a research design outlining the procedures that will be taken to collect and analyse the study 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 research and data quality.
- Describe the study participants in detail.
- Explain the steps you will take to ensure all ethical protocols and procedures will be fully addressed.

The specific content of this section of the proposal is outlined in more detail in Table 4.

Full details of the requirements of research design for IR are also discussed in the Module on research methods and data management in this toolkit.

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Table 4: Sub-components of the research design section

Section	Description
Research design	<ul style="list-style-type: none"> • Describes the nature or structure of the planned research. • Describes whether it is an intervention or non-intervention study design.
Research methods	<ul style="list-style-type: none"> • Comprises the various methods you will use to obtain and analyse data – qualitative, quantitative or mixed. • 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 collection, and data analyses.
Data collection	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Describes exactly how you plan to compile the data you collect and how you will organize and interpret the data to make sense of your findings. • Identifies themes, developing tables and charts, identifying relationships, and/or calculating frequencies.
Participants	<ul style="list-style-type: none"> • Provides a full description of the subjects (sample) or participants involved in the research. • Describes the selection of participants. • Lists the criteria for becoming a participant.
Quality management	<ul style="list-style-type: none"> • Describes the system to ensure the quality of the research project. • Helps provide confidence that the conduct of the study and data generated optimally fulfil applicable requirements. <p>[NOT OPTIONAL – You must have a quality management plan].</p>
Ethics	<ul style="list-style-type: none"> • You must apply to an ethics board/committee if you intend to collect information/data from human participants (directly or indirectly). • If you are collecting data from 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.



There are four main research design options, with each addressing a different fundamental need in the study setting, as shown in Table 5.

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Table 5: Research design categories and the specific needs they each address

Status of knowledge regarding problem	Type of research question	Appropriate research study design
Knowing that a problem exists but knowing little about its characteristics or possible causes.	<ul style="list-style-type: none"> • What is the nature/ magnitude of the problem? • Who is affected? • How do the affected people behave? • What do they know, believe, think about the problem and its causes? 	<ul style="list-style-type: none"> • Descriptive studies: • Cross-sectional surveys
Suspecting that certain factors contribute to the problem (or are associated with it)	<ul style="list-style-type: none"> • Are certain factors indeed associated with the problem? (e.g. lack of pre-school education related to low school performance? Is low-fibre diet related to carcinoma of the large intestine?) 	<ul style="list-style-type: none"> • Analytical (Comparative) studies: • Cross-sectional comparative studies • Case control studies • Cohort studies
Having established that certain factors are associated with the problem: Establishing the extent to which a particular factor causes or contributes to the problem	<ul style="list-style-type: none"> • What is the cause of the problem? • Will the removal of a particular factor prevent or reduce the problem? (e.g. stopping smoking, providing safe water). 	<ul style="list-style-type: none"> • Cohort studies • Experimental or quasi-experimental studies
Having sufficient knowledge about cause(s) to develop and assess an intervention that would prevent, control or solve the problem	<ul style="list-style-type: none"> • What is the effect of a particular intervention/ strategy? (E.g. treating with a particular drug; being exposed to a certain type of health education) • Which of two alternate strategies gives better results? • Which strategy is most cost-effective? 	<ul style="list-style-type: none"> • Experimental or quasi-experimental studies



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. In your proposal, you will need a strong justification for your choice of research design for your study. Click on each of the headings below to explore each of the sections individually.

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 measures 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, while interviewing a patient, they may not feel comfortable expressing their opinion in front of their physician, or while 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.

REFLECTION ACTIVITY



Study participants

With members of your team 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 select? Discuss how many participants you will 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 (e.g. 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 to 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 include in your research from this population for each data collection method (surveys, focus group discussion, interviews etc.).



Example

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 their deputy).*
- *Deputy of the Minister 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 Minister of Justice responsible for the prison system.*
- *Chief medical doctor, who 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.*

Research methods

In your IR proposal, you should indicate which data collection methods you intend to use and why.

There are three general types of research methods: qualitative, quantitative or a combination of the two (mixed methods), depending on the purpose of the research. Quantitative methods are better for answering the question: What is happening? Qualitative methods are suited for answering the question: Why is it happening? These methods are presented and described in detail in the module on Research methods and data management in this toolkit. Several useful resource materials are included in the references.

Qualitative methods

In your IR proposal, you will need to justify why you have chosen to use a qualitative approach. If the focus of the research is generally used to explore values, attitudes, opinions, feelings and behaviour of individuals and understand how these affect the individuals in question, then this method is most appropriate.⁸ You will also choose qualitative methods, if your study is used to help explain the results of a previous quantitative study.

When it is preferable to collect data using more than one method –allowing the researcher to ‘triangulate’ (or cross-check/verify) the data – qualitative methods should be selected. If the research seeks to investigate themes (findings) in more

detail as they emerge, your proposal will select the qualitative methods, as the related data collection process is more emergent and flexible.

Qualitative research uses data collection methodologies such as interviewing, focus group discussions, observation and documents (e.g. diaries, historical documents).

Quantitative methods

Quantitative methods involve the collection and analysis of objective data, often in numerical form. They are used when it is necessary to establish cause and effect relationships, where the researcher can manipulate a particular variable (experimental research) or in instances where no attempt is made to influence the variables (correlational research). 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 (e.g. health centres, district hospitals, regions); how surveys will be delivered, who will facilitate delivery; how you will ensure anonymity; time required to complete survey; length of survey; number of questions in the survey; sample size; how the survey will be designed; is the survey validated, etc.

The data collection tools used (e.g. questionnaire) may be developed by the researcher or, preferably, may be one that has been previously developed and used. 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 to test it.

Mixed methods

With the majority of IR problems requiring answers to both the ‘what’ and the ‘why’ in relation to research questions, the majority of proposals use mixed methods that combine qualitative and quantitative approaches. Under many circumstances, a mixed methods approach can provide a better understanding of the problem than either approach alone.⁹ Nevertheless, one of the main challenges may be to create the optimal combination (and sequence) of the two approaches. The module on research methods and data management provides detailed guidance in this area.

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If your research team decides to use mixed methods in your study, you will need to describe why you chose this approach, explaining how the combination of 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 require 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 justification for using a mixed methods approach may be



because your project is interdisciplinary, involving team members with diverse views and expertise, or that your project will be dealing with complex problems that will benefit from blending qualitative and quantitative data.

Whatever the method that is selected, your proposal will need to explain how the selected methods will provide information that will help you address your research objectives and research questions. This section of the proposal should have the following sub-sections:

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

These are discussed in detail in the research methods and data management module of this toolkit.

Plan for data analysis

It is important to outline a plan for data management and analysis in the proposal. The methods and models of data analysis should be in accordance with the proposed objectives and types of anticipated variables. The plan for data analysis should be developed with the target audiences in mind, with a focus on simplicity and interpretability. The proposal should specify the data collection strategies and tools to be used and why. The tests that you intend to conduct on the data should be explained. Indicate if any software will be used in your data analysis.

You should outline/highlight the following as they 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 of 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 any consultants or external personnel.



REFLECTION ACTIVITY

Research design

In your research team, discuss which research design will work best for your project. Which methods will you use to collect your data? Use the example 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

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 city X. 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.

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

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.

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 gain a better understanding of the impact of the persistence of MDR-TB in this setting. In addition, the quantitative methods described in the module on Research Methods and Data Management will help elucidate the biosocial factors potentially related to MDR-TB emergence and persistence (e.g. education, socioeconomic status, lack of social support, side-effects from second-line anti-tuberculosis drugs as well as HIV and other co-morbidities, such as substance use.)

**REFLECTION ACTIVITY**

Your research team is now in a position to develop the following proposal components for your project proposal:

- **Research design.**
- **Research methods including:**
 - **step-by-step procedures for your data collection;**
 - **data analysis;**
 - **trustworthiness, validity, reliability;**
 - **participants.**

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 are integral to all research activities. Everyone engaged in the project carries the responsibility of ensuring quality. Quality management should be planned and strictly 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 the quality and rigor of the research. Indicate how you will evaluate quality at various stages. How will you demonstrate that you will conduct due diligence at all stages of the data collection and data analysis process?

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.)?

SEE**MODULE ON
RESEARCH
METHODS
AND DATA
MANAGEMENT
MODULE**

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.

MODULE ON
IR-PLANNING AND
CONDUCTING IR
MODULE

SEE

There are many strategies that can be incorporated into your IR proposal to begin the quality standard monitoring process; they are discussed in details in the Planning Module of this toolkit.

Case study 3 Quality management plan

Background: Embedding quality management into your IR proposal is not an optional step. Quality management is essential to ensuring research meets or exceeds scientific, ethical and regulatory standards. Since quality assurance is integral to all research activities, the quality management plan of the proposal should explicitly outline how the research team will ensure consistent quality of the research during the project life cycle. The table illustrates the quality control measures taken by a research team that assessed the knowledge and attitudes of key community members towards tuberculosis in Bangladesh. The measures adopted to selection of safeguard scientific integrity ensured appropriate study designs, sample size, sampling strategy and selection of study participants. To ensure that tools were standardized, specific elements were pre-tested and essential adjustments were made before actual data collection. Similarly, to minimize errors in the data collection processes, all data collectors and supervisors were briefed about the scope of the project and were trained in the use of the data collection tools. Furthermore, all data collectors were assigned supervisors who checked for consistency and completeness of the data collected. Focus group discussions (FGDs) and key informant interviews (KII) were recorded for reference. The ethical concerns of research participants were taken into consideration through the translation of the study tools into Bengali (the local language), seeking informed consent and observing confidentiality and privacy. Ethical clearance was sought from the relevant ethical review committee.



Case study 3 **Quality management plan**

Table. Data quality management measures

Study phase	Variable	Quality control measure	
Design	Study design	Mixed methods enabled the capture of both quantitative and qualitative aspects	
	Sample size	Scientifically derived (i.e. based on prevalence, power of study, degree of error, design effect)	
	Study area	Randomly selected	
	Sampling of participants	Participants were selected through purposive sampling and convenient sampling of key informants	
	Study tools		Structured questionnaires for quantitative methods
			FGD guide and KI guide for qualitative methods
			Data collection tools translated into Bengali
	Ethical concerns	Sought ethical approval from the Ethical Review Committee of James P. Grant School of Public Health	
		Pilot testing of the tools to ensure they were accurate and culturally sensitive	
Data collection	Data quality	Training of data collectors	
		Field protocol with all the instructions, including skipping and probing	
		Supervision of the data collectors	
		Notes were taken during FGDs and IDIs	
		Recording of interviews and discussions done to avoid information loss	
	Ethical concerns	Informed verbal consent, observation of confidentiality and privacy	
Data Management	Qualitative data	Data was cleansed	

Lessons: Quality processes should start right from the study design stage and continue throughout the project life cycle. These should be succinctly described and justified in every research proposal.

Source: Paul S. et al. Knowledge and attitude of key community members towards tuberculosis: mixed method study from BRAC TB control areas in Bangladesh. BMC public health. 2015; 15(1):1.

Research ethics

Any research study that collects data from or involves 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. You may also be required to apply for a research permit in addition to ethical clearance in certain countries or disciplines. In some cases, you may be required to submit your protocol to the funding agency for ethical review by the agency ethical clearance unit in addition to obtaining local ethical review/research permit.

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, including for example, evidence of having completed an online ethics course).

- 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;
 - when collecting data in field settings.
- Construct the informed consent letter and form (include in the proposal appendices). [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)].
- Where necessary, include a translation of the consent form in the appropriate local language(s) as this may be required by some ethical review committees.
- Obtain voluntary consent from all human subjects/participants. In the case of minors, parental/ guardian consent must be obtained, and in the cases where the information is to be obtained from a patient by a non-health worker, state the process to be followed.



- Subjects must be informed that their participation is voluntary and that 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.
- Adequate provisions must be taken to protect participants.
- 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 must be considered to ensure participants understand the purpose of the study.
- Special attention should be paid if the research involves vulnerable subjects.
- Teams should involve scientifically qualified, well trained and properly supervised individuals.
- Protocols should be submitted for approval to the appropriate ethical and scientific review committees.
- Research procedures involving human subjects should be submitted for approval to an independent ethics committee before research begins.
- Research and related procedures must be conducted in adherence to the protocol that received scientific and ethical approval.
- Any subsequent alterations to the protocol should be re-submitted for ethics approval.
- Research results should be made freely available as a public good.
- Participants should be provided with the option to receive the results of the study in which they are participating.

The specific ethical considerations of the different aspects of the IR study are provided as appropriate across all the modules of this toolkit. With most ethical review boards primarily composed of experts with limited IR experience, it is important that the common pitfalls detailed in the planning module of this toolkit are avoided in the preparation of the research protocols for ethical approval.





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). 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, and community leaders following a detailed sensitization about the goals 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 consenting. The Safe Deliveries study and the Uganda Newborn Estimated Survival Time (UNEST) already have ethical approval from the 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 IRB approval, of both a local and national institutional review board and where the research is funded by WHO, WHO's Research Ethics Review Committee (ERC) ERC's website can be consulted at <http://www.who.int/ethics/en/>.

Templates for consent forms can be found at the WHO research policy page http://www.who.int/ethics/review-committee/informed_consent/en/. These templates should be adapted to the local situation in which you elicit informed consent.



Ethics checklists

Checklists and other guidance documents for preparing proposals in the manner recommended by WHO's Research Ethics Review Committee (ERC) are available online at <http://www.who.int/ethics/review-committee/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.



REFLECTION ACTIVITY

In your research team, review the details of the ethical issues presented in this and other modules of the toolkit. Identify the specific ethical issues that will have to be considered in your project.

Project plan

In this section of your proposal, you will present the project plan, a timeline, describe the research team you need to effectively carry out the research project, and the project budget, including its justification. The content of this section is summarized in Table 6 and the issues are covered in detail in the Planning and Conducting an IR Project module of this toolkit.

Table 6: Sub-components of the project plan section

Section	Description
Project plan	<ul style="list-style-type: none"> • 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 (Gantt chart), table or Excel sheet. • Helps to demonstrate the feasibility of the project in a very visible way. • Identifies tasks; when the activity will take place; and by whom. • Highlights project milestones and deliverables. • Includes time for protocol review and approval.
Research team	<ul style="list-style-type: none"> • Describes 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 from different disciplines and institutions, healthcare providers and decision-makers). • Convinces the reviewers you have enough expertise on your team to conduct the proposed research effectively. • Includes the role(s) and responsibility of each individual listed on the project. • Indicates whether team members are involved on a full- or part-time basis.
Budget and justification	<ul style="list-style-type: none"> • Outlines and justifies the resources needed to effectively conduct the proposed research. • Summarizes 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 for each phase of the project. • Aligns with agency suggested/required budget categories. • The budget should align with the proposed activities in the research design.



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 should be multidisciplinary and diverse (researchers from academia, health care providers, programme implementers, social scientists, as well as communications specialists and members of the general community). This section should convince the reviewers that 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 assistant, individuals on training, and support staff. The proposal should also include 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 included in the research team.

The membership of a research team typically includes:

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

Proposals should also include outlines/summaries of the planned research team management structure and descriptions of respective roles and responsibilities of team members.



Example

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 strong and long-term links with 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.

Composition of the research team

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 a 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 will also play 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' 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 the 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 communications specialist, will be responsible for ensuring that study findings are communicated to policy-makers in an appropriate and timely manner. 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 specialist). They will all provide technical advice to the team during the design, implementation and evaluation phase 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, who have already gained experience and built an excellent rapport with the districts and local communities.

**REFLECTION ACTIVITY**

In your research team, review the content of the planning module of this toolkit 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 enable the effective delivery of 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 the team 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 agencies 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 controlled population after the study, this also needs to be planned and budgeted for. It is important to also budget for the dissemination and evaluation of related activities and outcomes. Find out whether there will be any inadmissible items such as overhead costs and salaries for research team members e.g. PI and co-PIs. 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.



In your proposal, 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 implications). Provide details of additional sources of funding available to the organization or PI. If the funds will go to different institutions, indicate allocation of funds by site.



REFLECTION ACTIVITY

Using the information covered in this section, and the illustration as a guide, develop a budget for your team's IR proposal.

Impact and measuring project results

This is the section of your IR proposal that addresses measures to ensure quality standards in your research project. Its content is summarized in Table 7. Specifically, your proposal must provide information on the:

- monitoring and evaluation plan for your IR project;
- capacity-building plan, including mentoring;
- dissemination plan.

Considerable effort must be made to ensure that your proposal clearly demonstrates the impact our research findings will have on the health and/or health care of the communities/populations concerned, the health system, policy-making, and 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 the most?
- Planned for developing and maintaining capacity building in your IR project to facilitate the adoption of evidence-based health interventions in the country and other similar settings/developing countries?
- Demonstrated that you will disseminate your research findings to ensure your project will generate research evidence to inform policy and programme implementation?



Table 7: Sub-components of the measuring project results section

Section	Description
Monitoring and evaluation	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

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.

The different aspects relating to monitoring and evaluation, capacity building and dissemination plans that will help you in completing this section of the proposal are covered in other modules in this toolkit.

An important aspect of your proposal will be the plan for disseminating information from the project. Most funding agencies are interested in seeing how their financial support of your project will apply to other audiences. Therefore, your proposal should include a section on dissemination and also the kind of dissemination you plan to carry out, and where and to what audience you intend to disseminate your research findings. You should as much as possible aim to communicate the results and findings of your research to all the stakeholders engaged in the research effort with the most appropriate and relevant means.

MODULE ON IR
RELATED COM-
MUNICATIONS
AND ADVOCACY

SEE

The dissemination section of the IR proposal should include:

- 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.).
- 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.

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.

REFLECTION ACTIVITY



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



Example

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 from 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 (i.e. regional and national). Consultations with primary stakeholders will occur, and they will be provided with the 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 with and informed of the findings in the following ways:

- Representatives of primary stakeholder groups such as farmers' 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 from 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 make 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.*



Example (continued)

- *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.*



REFLECTION ACTIVITY

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.**



Supplements

In this section, you will develop the final sections of your proposal. The content of this sections is summarized in Table 8. Specifically, information on the project summary, table of contents, appendices, and the CVs of your researchers will be covered. You will prepare these aspects, review all the previously completed components and update and align your entire proposal.

Table 8: Sub-components of the supplements section

Section	Description
Project summary	<ul style="list-style-type: none"> • Briefly describes the entire proposal. • Although this is read first, you should write it 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. • This section is your 'first impression' with reviewers and may influence whether reviewers choose to fund your proposal. • Makes it very easy for reviewers to understand and evaluate your proposed project according to the review criteria.
Table of contents	<ul style="list-style-type: none"> • Organizes the proposal by outlining where each item can be found. • Presents a convenient list of the topics and sections in a logical sequence 'at a glance.'
References	<ul style="list-style-type: none"> • 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 included in your reference list.
Appendices	<ul style="list-style-type: none"> • May include CVs of team members.

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

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

Overall objective: The goal of the project is to contribute towards poverty reduction and health improvement for people living in the 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

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



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 practices 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 (or similar).

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 require additional information. Appendices may include things such as the CVs of members of the research team, research instruments, or letters of support. This section is also appropriate for any additional information you would like the reviewers to have access to but which the length restrictions in the body of the proposal may prohibit.

The CVs of investigators will influence 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. Therefore, investigators will need to shorten their CVs and highlight the



most relevant aspects of their professional/academic life to the project to align with the scope of the funding agency. A template can help investigators shorten their CVs and to keep them uniform.



REFLECTION ACTIVITY

Develop the following aspects of your IR proposal with your team:

- **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' CVs have similar look and format).**
- **Review all components of your proposal and update and align.**

Having reached this stage of this module, your research team has completed all the different sections of the IR proposal. You should now prepare a 20-minute presentation (slide or poster presentation) including the following aspects of your IR proposal:

- **Title.**
- **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.**



Funding an IR project

All through the course of the IR project process, consideration must be given to how the funds to carry out the project will be obtained. There are several potential sources from which research teams can hope to obtain funding for their implementation research project. Click on each of the headings below to explore each of the sections individually.

In-country sources

Many low- and middle-income countries (LMICs) have developed national health research agendas, which, although not always fully resourced, provide a framework for obtaining domestic resources for IR projects. Specific institutions also exist in some countries for the funding of research efforts. Teams should include such institutions as they explore the possible sources of funding for their projects. Generally, the first place to look for funding for IR projects should be within the budgets of the programmes themselves. Disease programmes in several LMICs routinely earmark small amounts of funds directly for research efforts or for monitoring and evaluation aimed at improving access and delivery of interventions.

Multilateral organizations

For example, this might include the World Health Organization (WHO), World Bank, United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), Global Fund to Fight AIDS, Tuberculosis and Malaria, the European Commission (EC) and programmes such as the Special Programme for Research and Training in Tropical Diseases (TDR), the Alliance for Health Policy and Systems Research (AHPSR), the Special Programme of Research, Development and Research Training in Human Reproduction (HRP).

Most multilateral organizations, particularly the GF, have developed implementation programmes in LMICs of which part of the programme budget is allocated for monitoring and evaluation. Countries can include IR in their concept notes/proposals if such research will clearly improve the implementation of programmes.

Bilateral donors

For example, the Canadian 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, CDC and NORAD have supported IR. Almost all bilateral organizations have aid projects/programmes in LMICs with a certain part of the programme budget allocated to monitoring and evaluation. A case could be made for using such resources for IR if such research will significantly improve the delivery of their programmes.

Private foundations and trusts

For example, the Bill & Melinda 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 a potential area of interest for these entities.

To find a good donor 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.

Other related resources

- NIH Office of Extramural Research (OER) Grants Guide.
- National Science Foundation (NSF).
- Grants.gov (www.grants.gov): – A portal collecting funding applications information from all United States government agencies.
- Ministries of Health/National Research Councils.
- National Medical Research Councils.
- Foundation Center Directory (Free Library).
- PA Foundation Directory (Free Library).
- GrantsNet – from the American Association for the Advancement of Science (AAAS).
- The Doris Duke Foundation.

Subscription databases like the ones listed below provide information on sources of government and nongovernmental research funding:

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

Do your searching...

- Go to a library where good internet access is available.
- 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.
- Search specialized research websites such as AuthorAID (<http://www.authoraid.info/en/>).
- Find out what projects related to your subject 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 seek help from a library within or outside 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 matters.

Find out which funding opportunities are offering research calls or requests for proposals (RFP)/ letters of intent (LOI). This is important as often they only call for applications 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 IR, 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 LMICs could play a proactive role by sending short research proposals for their consideration. Some funding agencies are more interested in commissioning or soliciting 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 expand or complement 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 the rationale for the 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 researchers with large grant applications. This may not

be available in institutions and health agencies in LMICs, but there may also be resources available online 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.

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 clear, well-written application that promises outcomes that are useful to the population.

What reviewers look for

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, reviewers are looking for:

- Significance and impact – very important in IR.
- 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.

In general, research 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 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 will 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 the 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?

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- Offredy, M., & Vickers, P. (2013). *Developing a healthcare research proposal: An interactive student guide*. John Wiley & Sons.
- The NIH Office of Extramural Research free tutorial on Protecting Human Research Participants available at <https://phrp.nihtraining.com/users/login.php?l=3>

IMPLEMENTATION RESEARCH TOOLKIT



Research Methods and Data Management

Alison Krentel and Riris Andono Ahmad



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Research Methods and Data Management

The purpose of this module is to describe the fundamentals of implementation research (IR) methodologies including study design, data collection methods, data analysis, presentation and interpretation of IR findings with the objective of enhancing their uptake and use by target audiences.

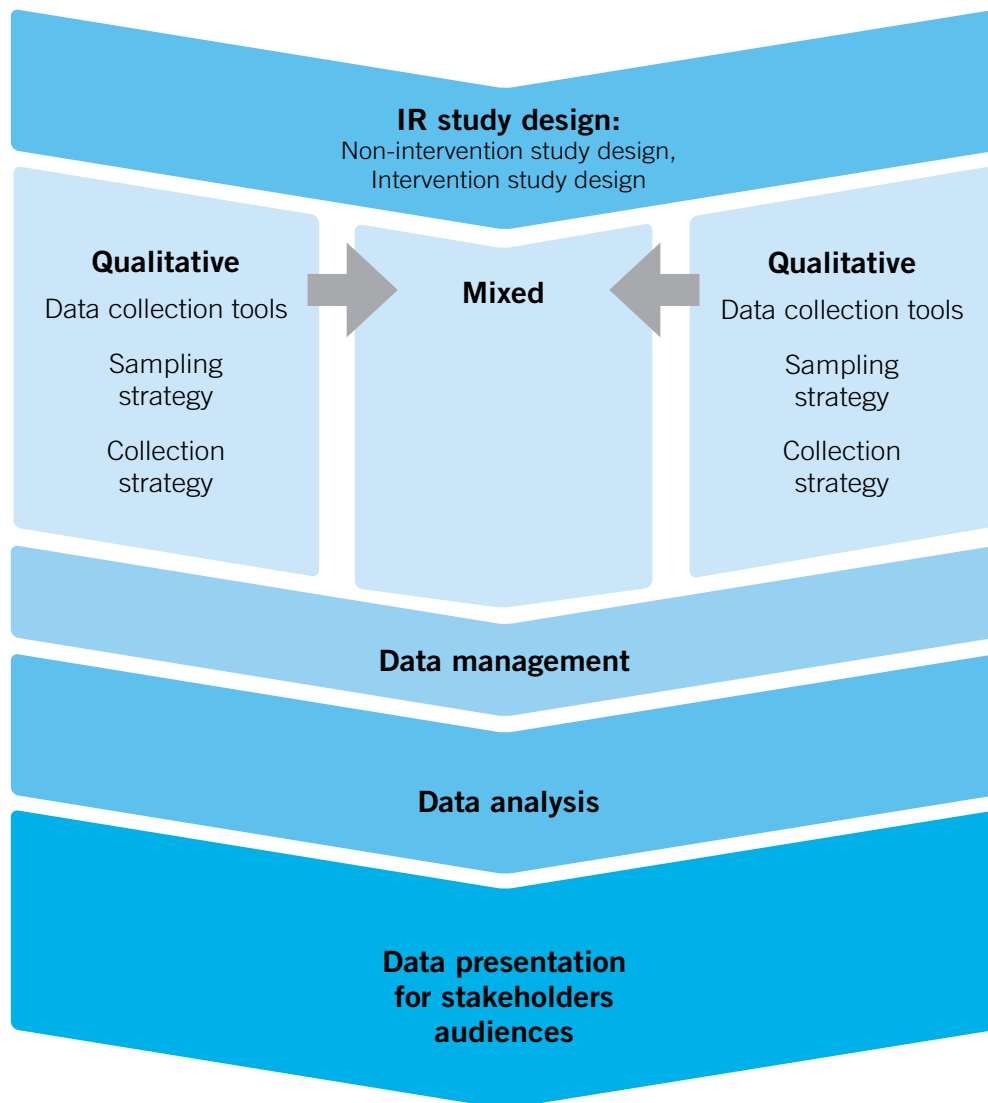
This module covers the concepts of: a. Research approach; b. Research designs c. Data collection methods; d. Data analysis; and, e. Data presentation. The overall pathway followed by the module is outlined in Figure 1. These concepts are illustrated through examples of completed IR projects. The module describes IR study design and research methodologies at a general level, and does not replace materials that specialize in research methodologies. For those interested in further information, many useful resources are available to supplement this module. Some of these key materials are signposted in the module.



After reviewing of this module, you should be able to:

- Describe the designs commonly used in IR projects.
- Identify the strengths of quantitative, qualitative and mixed methods approaches in IR data collection.
- Select the appropriate data collection approaches and tools for your IR project(s).
- Describe the sampling processes used for both quantitative and qualitative research tools.
- Highlight relevant ethical issues in data collection.
- Describe appropriate data analysis processes for both quantitative and qualitative data and for mixed methods approaches.
- Describe various formats of data presentation.

Figure 1. Outline of the research methods and data management module content



Study design for IR projects

Similar to other types of research, study designs used in IR can be interventional or observational. In an interventional research design, the researcher influences objects or situations and then measures the outcome of these manipulations. In an observational study design, the researcher observes and analyses researchable objects or situations without intervening. These non-intervention studies can be exploratory, descriptive and comparative (analytical) studies, while intervention studies can be experimental studies, quasi-experimental, before and after, cohort studies or randomized controlled trials. Below each of these study designs is briefly explained.



Non-intervention studies

Descriptive

Descriptive studies are used when you want to describe the implementation of health-related interventions and any problems or barriers within that context. Depending on your familiarity with the subject of the study, different study designs can be used to answer your research questions. If the subject is new and no prior knowledge exists, you can conduct an exploratory study using qualitative methods. The results from this qualitative study can then be used to develop subsequent research, using quantitative methods, to measure to what extent these problems occur. A descriptive study can also begin with quantitative methods (i.e. survey) to quantify the intervention barrier followed by qualitative methods to describe the context where the implementation problems exist. More details about methods are provided later in this module.

Most surveys used within descriptive studies use a cross-sectional design, a relatively simple and inexpensive design that is useful for investigating contexts with many variables to take into consideration. Data from repeated cross-sectional surveys provide useful indicators of trends, given that they have representative, independent and random samples as well as standardized definitions. Each survey should have a clear purpose. Valid surveys need well-designed questionnaires, an appropriate sample of sufficient size, a scientific sampling method and a good response rate.

Analytical

Analytical studies investigate and establish a causal relationship between the independent and dependent variables under study. Traditionally, cohort or case control study designs are used for non-intervention studies, in order to establish likely causal relationship. However, cohort study design is more commonly used for IR.

In a cohort study, the researcher recruits a group of people – who are free from disease, for example – and who are classified into sub-groups according to exposure status. Sub-groups are then followed up to see subsequent development of specific outcomes, such as specific health conditions. Cohort design can be used to measure typical IR-related outcomes over time (i.e. acceptability, adoption, appropriateness, feasibility, fidelity of interventions, implementation costs and cost-effectiveness, determinants of coverage and sustainability/maintenance). This design produces high quality, individual level data, enabling researchers to examine if better implementation outcomes are associated with exposures at the individual level, including the timing and direction of any effects.¹ A cohort design can also be used to assess the uptake and retention of patients in specific services, particularly for chronic illnesses such as the continuation of antiretroviral (ARV) therapy among people living with HIV or treatment adherence among people with multidrug-resistant TB (MDR-TB).



Analytical studies can have a cross-sectional study design. However, such study designs cannot establish causal relationships between independent and dependent variables, as the measurement of both variables is conducted simultaneously.

Intervention/Experimental studies

Experimental research is the only type of research that can establish cause and effect. The randomized controlled trial (RCT) study in particular, is known for establishing causal relationships due to its ability to control for confounders, and for ensuring that the only difference between different study arms is the intervention in question. In an experimental study, 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). In effect, the researcher changes the independent variable and measures the dependent variable(s). There are usually two groups of subjects in experimental research: The experimental group, which receives an intervention (e.g. taught by a new teaching method, receives a new drug), and the control group, which receives no intervention (e.g. continues to be taught by the old method, receives a placebo). Sometimes, a comparison group will also be used in addition, 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 intervention had an effect or whether one intervention was more effective than another.

The following are different types of experimental studies.

Randomized control trial (RCT)

This is the ‘gold standard’ for efficacy studies in clinical trials. IR, on the other hand, focuses more on generalizability of results to different settings rather than the efficacy of a given intervention. For this reason, RCT is not a commonly used study design in IR. In RCT, the subjects should be randomly assigned to the treatment and control groups to ensure that all groups are homogenous before an intervention is applied, and that the intervention is the only difference between the groups. Randomization is used to ensure internal validity.

Quasi-experimental

This study design is similar to RCT but lacks the key characteristic of random assignment. The design is frequently used when it is not logistically feasible or ethical to conduct an RCT. The assignment to the treatment group uses criteria other than randomization e.g. matching by individual or matching by group of sociodemographic factors. Quasi-experimental design is suitable for IR by virtue of the fact that the design allows for real-life factors – such as cost, feasibility and political concerns – to be integral factors in the study.

**Case study 1****Community-directed education intervention: Quasi-experimental study in the malaria endemic areas of Sarpang District, Bhutan**

Background: Malaria remains a public health problem in spite of the efficacious interventions such as long lasting insecticidal nets (LLINs) and artemisinin-based combination therapy. The Kingdom of Bhutan has achieved notable success in the prevention and control of malaria, and the country is moving towards the malaria elimination phase. For example, in 2011 only 194 malaria cases were registered compared to 5935 cases in 2000. To attain the elimination goal, current efforts need to be reinforced by community-directed interventions in order to empower the community to enhance their health-seeking and other preventive behaviours. Community-directed interventions have proved to be useful in the prevention and control of infectious diseases such as onchocerciasis. This study was conducted to elucidate the effectiveness of the community-directed educational intervention on malaria prevention and control in the malaria-endemic areas of Sarpang District, Bhutan. A quasi-experimental study design was adopted, using both qualitative and quantitative methods (Figure). The study district (Sarpang) was purposively selected from seven malaria endemic districts. The study basic health units (BHU) were Umling and Chuzerganga (intervention arm), and Jigmeling (control arm). These were purposively selected. These BHUs were similar in population size and other relevant contextual criteria. Baseline data was collected during the formative phase using in-depth interviews and focus group discussions (FGDs), household surveys and document/data review. The training tool was developed in collaboration with the BHU staff. Health workers and community action groups (CAGs) were trained on malaria transmission, care and in the use of LLINs, proper use of indoor residual spraying, control of mosquito breeding sites, and the importance of early diagnosis and treatment. The intervention package was implemented in addition to the regular programme activities in the intervention BHUs while in the control BHU, only regular programme activities were conducted. The effectiveness of the intervention was evaluated using household survey, FGDs, in-depth interviews and review meetings. Comparison of the pre- and post-intervention group, showed a significant improvement in knowledge, attitude and practice of the community intervention arm as compared to the control arm.

Conclusion: The quasi-experimental study design was able to elucidate the effectiveness of the community-directed educational intervention on malaria prevention and control in malaria-endemic areas.

Lessons: Quasi-experimental study design is an appropriate approach to establish the impact of a given intervention. However, to ensure reliable results, the intervention and control arms should be as similar as possible in terms of population characteristics and context. The only distinguishing variable should be the intervention in question.

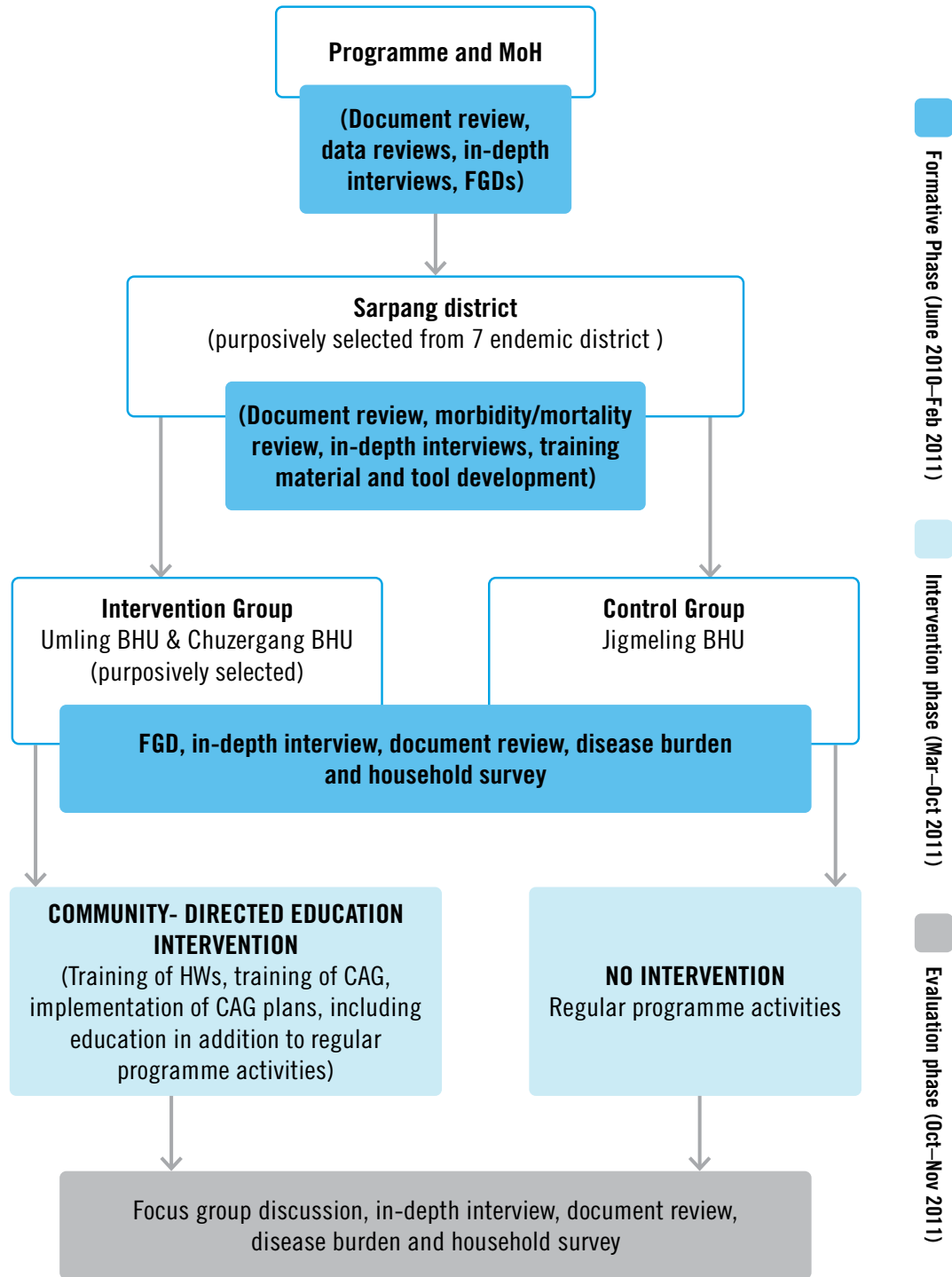
Source: Tobgay T. et al. Community-directed educational intervention for malaria elimination in Bhutan: quasi-experimental study in malaria endemic areas of Sarpang district. *Malaria Journal*. 2013; 12(1):1.



Case study 1

Community-directed education intervention: Quasi-experimental study in the malaria endemic areas of Sarpang District, Bhutan

Figure. Schematic diagram of research activities





Pragmatic trials

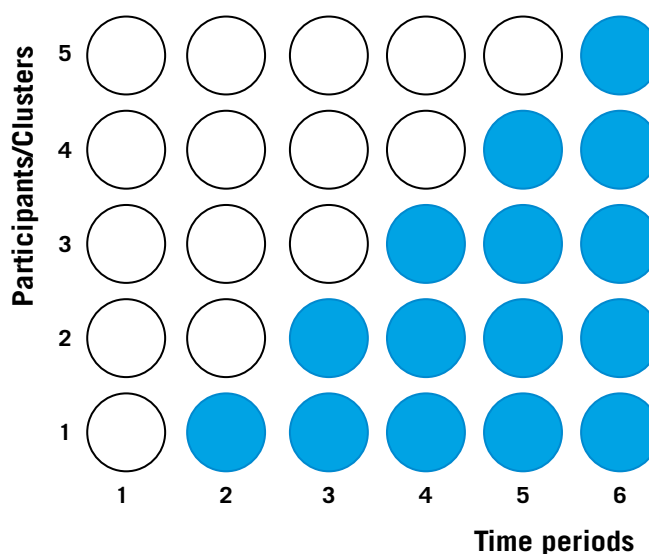
Pragmatic trials evaluate the effects of health service interventions under the human, financial and logistic constraints of typical, real-world situations. The aim of this study design is to measure effectiveness rather than efficacy.^{2,3} *Contrary to the efficacy study, where participants are recruited from a homogeneous sub population (e.g. gender, age, ethnicity etc.) and randomly assigned to arms of the study, the design of the pragmatic trial presents higher degrees of variation in study participants. Participants are selected from within a real clinical or population setting to be representative of the population. To improve validity of pragmatic trials, randomization is conducted at the facility level (cluster randomization) rather than at the individual level.*

As the effectiveness of a treatment is influenced by the extent to which an intervention is acceptable to patients, a pragmatic trial not only measures treatment outcome but also evaluates measures designed to increase effectiveness. For example, while patients in both control and interventions arms receive identical treatment, the intervention group receives additional interventions to increase treatment acceptance or adherence (e.g. counselling, home visit or mobile reminder).

Stepped-wedge cluster randomized trial

This is a variant of cluster randomized trial design in which the selected clusters are randomly allocated at the time point when they receive the intervention. In this design, all clusters are assigned in both intervention and control arms (Figure 2). The cluster can be geographical areas, clinics or other types of facilities.⁴ The advantage of this design is that each cluster can serve as a control for itself. The design also addresses any ethical issues where, for example, the randomization of patients to an intervention believed to be inferior or the withdrawal of an intervention believed to be superior, is considered unethical.

Figure 2. Diagrammatic illustration of stepped-wedge study design



Shaded cells represent intervention periods
Blank cells represent control periods
Each cell represents a data collection point

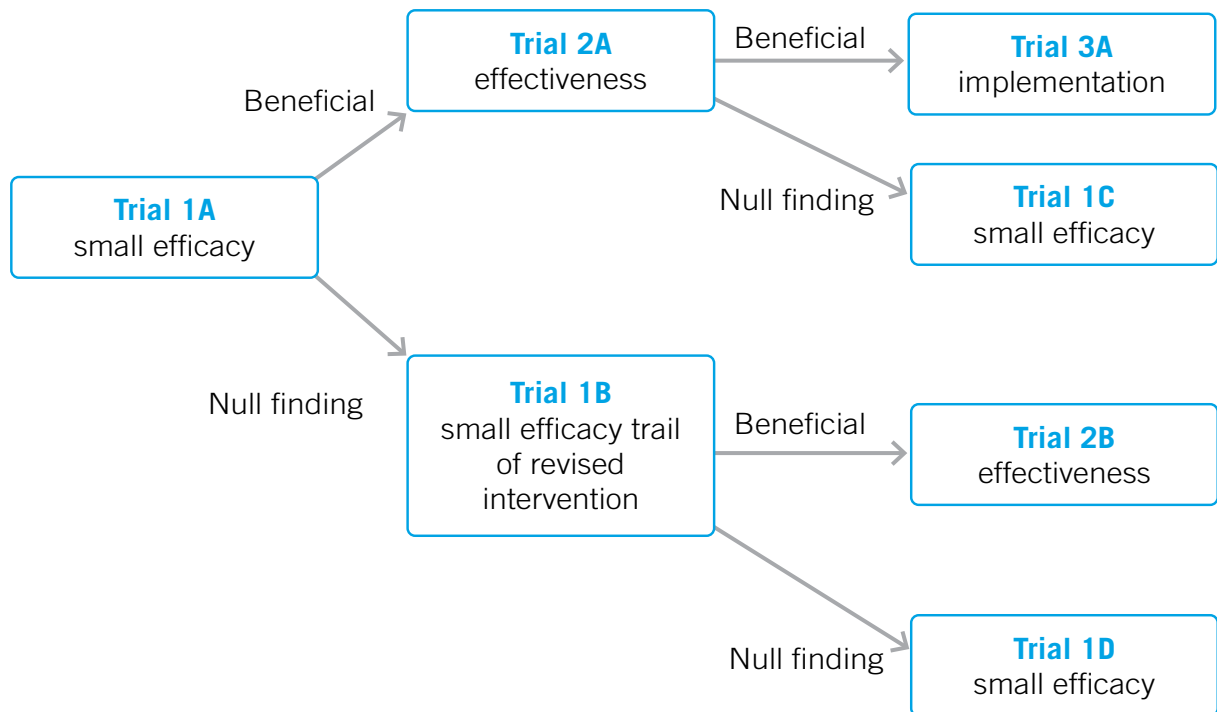
Adaptive design trial

This variant of experimental design anticipates intentional changes to the trial plan. It is characterized by the idea that collected data will be used to make decisions regarding the trial while it is ongoing. The objective of an adaptive design is to maintain the validity of the study while maintaining the flexibility to identify optimal treatment. Researchers can modify both trial and statistical procedures. Adaptation of statistical procedures can include the sample size, randomization, study design, data monitoring and the analysis plan. Typical trial procedures can include eligibility criteria, enrolment design, study dose, treatment duration including early stopping, follow-up design, study endpoints or laboratory/diagnostic procedures.^{5,6} Figure 3 provides a description of the adaptive sequencing of trials. The changes in the subsequent trials are conditional on the outcome of the previous trial and/or certain parameter values.

From an ethical standpoint, adaptive design is advantageous since the methods enable the researcher to detect outcome differences early and allow for changes to the intervention concurrently during the trial. However, this flexibility limits the measurement of treatment effect for each group.



Figure 3. A typical adaptive sequencing trial design⁵



The choice of the study design depends on:

- state of knowledge about the problem;
- nature of the problem and its environment;
- type of objectives;
- available resources;
- ingenuity and creativity of research team.



Table 1: Factors dictating the most appropriate choice of study design

State of knowledge of the problem	Type of research question	Appropriate study design
Knowing that a problem exists, but little understanding of its characteristics or possible causes.	<ul style="list-style-type: none"> • What is the nature/ magnitude of the problem? • Who is affected? • How do the affected people behave? • What do they know, believe and/or think about the problem and its causes? 	Descriptive studies: <ul style="list-style-type: none"> • Cross-sectional surveys.
Suspecting that certain factors contribute to the problem.	<ul style="list-style-type: none"> • Are certain factors indeed associated with the problem? (e.g. lack of pre-school education related to low school performance? Is a low fibre diet related to carcinoma of the large intestine?) 	Analytical (comparative) studies: <ul style="list-style-type: none"> • Cross-sectional comparative studies. • Cohort studies.
Having established that certain factors are associated with the problem: establishing the extent to which a particular factor causes or contributes to the problem.	<ul style="list-style-type: none"> • What is the cause of the problem? • Will the removal of a particular factor prevent or reduce the problem? (e.g. stopping smoking, providing safe water) 	<ul style="list-style-type: none"> • Cohort studies. • Experimental or quasi-experimental studies.
Having sufficient knowledge about cause(s) to develop and assess an intervention that would prevent, control or solve the problem.	<ul style="list-style-type: none"> • What is the effect of the particular intervention/ strategy? (e.g. treating with a particular drug; being exposed to a certain type of health education). • Which of two alternate strategies gives better results? Which strategy is most cost-effective? 	<ul style="list-style-type: none"> • Experimental/ or quasi-experimental studies.



Example

A mixed methods protocol to evaluate the effect and cost-effectiveness of an integrated electronic diagnosis approach (leDA) for the management of childhood illnesses at primary health facilities in Burkina Faso.⁷

Background: Burkina Faso introduced the Integrated Management of Childhood Illnesses (IMCI) strategy in 2003. However, an evaluation conducted in 2013 found that only 28% of children were assessed for three danger signs as recommended by IMCI, and only 15% of children were correctly classified. About 30% of children were correctly prescribed with an antibiotic for suspected pneumonia or oral rehydration salts (ORS) for diarrhoea, and 40% were correctly referred. Recent advances in information and communication technologies (ICT) and the use of electronic clinical protocols hold the potential to transform health care delivery in low-income countries. However, no evidence is available on the effect of ICT on adherence to IMCI. A mixed methods study that aims to measure the effect of the leDA innovation (an electronic IMCI protocol provided to nurses) is planned in two regions of Burkina Faso.

The study focuses on three key questions: (i) How does the effectiveness and the cost of the intervention vary by type of health worker and type of health centre? (ii) What is the impact of changes in the content, coverage and quality of the leDA intervention on adherence and cost-effectiveness? (iii) What mechanisms of change (including costs) might explain the relationship between the leDA intervention and adherence? In order to answer these questions, the study combines the following mixed methods: stepped-wedge trial, a realistic evaluation and an economic study in order to capture the effect of the innovation after its introduction on the level of adherence, cost and acceptability.

Table 2 provides a summary of study designs reviewed in this module, according to the stage of the intervention under study. This table has been adapted from Bowen et al (2009)³ to reflect IR questions.



REFLECTION ACTIVITY

Considering your team's IR question, which study design is most appropriate for your work?

Table 2: Sample study design: Phases of intervention development by area of focus (adapted from Bowen et al 2009)³

	Intervention development phase		
	Can it work?	Does it work	Will it work
Area of focus	Is there some evidence that intervention X might work?	Is there some evidence that X might be efficacious under actual conditions, compared to whatever other practices might already be in place instead?	Will it be effective in real life contexts, settings and cultures/ populations that might adopt the intervention as practice?
Acceptability	Focus groups with target population participants to understand how this intervention would fit in with their daily-life activities.	An RCT to compare the satisfaction of the intervention group to that of a control group that does not receive the intervention.	A population based survey before, during and after implementation of a policy intervention. A cohort study comparing the actual use of facilities with and without the intervention over time.
Demand	Survey to determine whether people in the target population would use the intervention to guide their behavioural choices.	Pre-post intervention survey design to compare frequency of use and patterns of use across different populations.	Post-only design with multiple surveys over time to test reactions to the intervention in a new population.
Implementation	Pre-post design to evaluate whether the intervention can be deployed in any clinical or community context, using focus groups as the method of evaluation.	Different types of trial designs (pragmatic, stepped-wedge, adaptive design) to test whether the intervention can be implemented in different clinical settings or community contexts: Using surveys and observations to compare practices and outcomes before and after interventions; using focus groups and in-depth interviews to further explain what works during the intervention processes.	



Intervention development phase			
	Can it work?	Does it work	Will it work
Practicality/cost	Small-scale demonstration study to examine the predicted cost, burden, and benefit because of appropriate and intensity, frequency, duration of the intervention, using key-informant interviews to gather data.	Cost-effectiveness analysis combined with in-depth interviews with community leaders or other stakeholders to determine how easily the intervention was used in the health system.	Cost analyses with in-depth interviews with providers to identify potential areas of concern during implementation.
Adaptation	FGD, key informant interviews to drive the adaption of the intervention. Quasi-experimental design using pre- and post-surveys to examine the effects of the adapted intervention in communities.	Experiment using adaptive design to examine whether an effective intervention continues to show evidence of efficacy once modified and implemented in a practice context.	Small-scale experiment testing appropriate intensity, frequency, and duration of the modified intervention, or intervention for the new target population.
Integration	Pre-post design to observe the extent to which people in the target setting are using the new intervention activities and with what costs and benefits to their other responsibilities.	Prospective longitudinal study to identify the sustainability of a recently tested package of intervention activities.	Annual monitoring of important systems to measure outcomes across years.
Expansion	Quasi-experimental, pre-post design using interviews with key informants to determine how well an expanded version of an intervention is perceived to work after implementation.	Uncontrolled pre-post study to test new, enhanced the version of a previously tested intervention.	Continued monitoring to identify any decay of intervention effects after implementation.

Selecting the research methods for your IR project

IR can use quantitative, qualitative research methods or a combination of the two. Quantitative and qualitative techniques can be said to offer a trade-off, between breadth and depth, and between generalizability and targeting to specific populations. Before you choose the most appropriate methods and design for your IR study, it is important to understand some of the principles behind both qualitative and quantitative research methods. Table 3 provides a summary of the characteristics of both methodologies.

Table 3: Summary characteristics of quantitative and qualitative research

	Quantitative	Qualitative
Purpose	Explanatory/causal.	Exploratory, descriptive.
Perspective regarding reality	Naturalist, positivist perspective common in natural science.	Interpretive perspective common in social science.
Research tradition	Naturalist, positivist perspective common in natural science.	Interpretive perspective common in social science.
Sample and sample size	Sample size is large using mostly probability sampling strategy.	Sample size is small using purposive sampling strategy.
Sample is representative of	Population being studied. Sample represents the existing variation in the population.	Phenomenon being studied. Sample with rich information regarding the phenomenon.
Methods	Structured/Semi-structured Surveys or observations.	In-depth interviews, focus groups, observations, etc.
Gathering Data	More efficient, tests specific hypotheses.	Time-consuming process; often real-world environments.
Administration	Researcher uses tools to gather data (requires less training).	Researcher is the instrument for gathering data (requires training).
Types of Questions	Closed, yes/no responses.	Probing, open-ended.
Forms of data	Numbers and statistics.	Words, stories and pictures.
Types of Analyses	Statistical, summarize results using numbers.	Interpretive, establishes themes or patterns.
Interpretation of study	Generalization of findings.	Context-specific findings.

The main difference between quantitative and qualitative approaches comes from the research traditions and the philosophy of how researchers in each research tradition see the nature of the world. Researchers from the natural science tradition developed quantitative research methods, where the philosophical



approach in creating knowledge is through positivism. Knowledge creation is characterized by empirical observation, the testing of theories and development of universal laws. Qualitative research methods on the other hand came from a social research tradition, where social phenomena (reality) are considered to be constructed through interaction among individuals in the community. A shared understanding or interpretation of its nature creates the meaning of the phenomena. These meanings are constructed within the context (for example cultural beliefs) where the phenomena exist. Therefore, the nature of reality is subjective and particular to the interpretation given to them. Click on each heading for details.

Strengths and limitations

Implementation research can employ both quantitative and qualitative methods. However, researchers need to be aware that each approach has its own strengths and limitations. Table 4 summarizes the strengths and limitations of quantitative and qualitative methods. In general, the strengths of one method can be seen as the weakness of the other. Therefore, combining both quantitative and qualitative methods can improve the strength of an IR project.

Table 4: Strengths and limitations of quantitative and qualitative research methods

	Strengths	Limitations
Quantitative methods	Provide wide coverage of a range of situations.	The methods can be inflexible and artificial (e.g. RCT).
	Can be fast and economical.	Not effective for understanding processes or the significance that people attach to actions.
	Statistics from large samples can provide considerable relevance for policy decisions.	They are not very helpful in generating theories.
Qualitative methods	Data gathering methods seen more as natural than artificial.	Data collection can be tedious and require more resources.
	Ability to look at change processes over time.	Analysis and interpretation of data may be more difficult.
	Ability to understand people's meaning.	Harder to control the pace, progress and end-points of the research process.
	Ability to adjust to new issues and ideas as they emerge.	Policy makers may give low credibility to result from qualitative approach.
	Captures a wide range of relevant themes through purposive sampling.	Lack of external validity/generalizability.

(Adapted from Amaratunga D et al 2002)⁸

Assessing the quality of quantitative and qualitative studies

Quantitative and qualitative studies have fundamentally different criteria to assess the rigor of the study due to the paradigm used and the nature of the methods. The criteria are analogous but not interchangeable. Each has its own appropriate and no less rigorous standards. There are four analogous criteria that are comparable to assess the quality of both quantitative and qualitative studies i.e. truth-value, applicability, consistency and neutrality.⁹

Table 5: Comparable criteria in quantitative/qualitative methods, and questions addressed

Issues	Quantitative	Qualitative	Question
Truth value	Validity	Credibility	Do we measure what we are supposed to measure?
Applicability	Generalizability	Transferability	Could the research be repeated in different subjects or contexts?
Consistency	Reliability	Dependability	Could the research be repeated with the same result?
Neutrality	Objectivity	Conformability	How far does the personal interest of the researcher influence the result?

(Adapted from Krefting L, 1991)⁹

Truth Value

The quality of study depends on how effective the researcher is in measuring the concept being studied. In a quantitative method, this means the extent to which the measurement reaches the concept it intends to measure. Validity assumes correct operational measures for the concepts being studied. The validity of the study can be improved by ensuring that there are no selection and measurement biases (through the use of standardized instruments and procedures).

Credibility is the corresponding criterion of validity in qualitative research. It focuses on whether the investigator has achieved in seeing the truth according to the informants' eyes and in understanding of the context in which the research is conducted. Credibility can be accomplished by triangulation of informants, data collection methods or analysis; prolonged engagement with people; continual observation in the field; the utilization of peer researchers; researcher reflexivity; and participant checks, validation or co-analysis.

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.¹⁰



Applicability

Applicability refers to how we can apply the research findings to a wider population, beyond that under study. In a quantitative study, it is known as the external validity or generalizability of the findings. Generalizability is a goal of quantitative studies. It is accomplished by selecting large enough random samples to minimize the probability of error and to be able to statistically represent the population from which the samples are drawn.

Transferability is the qualitative analogue to the concept of generalizability. Transferability is the degree to which the results of a study can be applied to other contexts and settings or other groups. It also means the level to which the audience will be able to generalize the study findings into his or her own context. The audience that requires to transfer the findings into different situations are responsible to assess the transferability of the study, rather than the researchers of the original study. Transferability can be achieved when the researcher gives adequate information about researchers' backgrounds, any prior knowledge and possible bias, as well as the research context, processes, members and researcher-participant connections so that the reader can decide to what extent the findings of the study is transferable to their own contexts.

Consistency

Consistency refers to whether the study conclusions would be similar if replicated with the same subject matter or in a similar context at a different time. In a quantitative study consistency refers to the reliability of measurement. When we measure variables under study, all measurements involve some degree of error. When the amount of error is low, the reliability of the measurement is high.

Consistency is defined as dependability in qualitative research. Dependability refers to the way researchers ensure that the study is conducted consistently across time, researchers and analysis techniques and that the procedures of the study are explicit and repeatable. This can be achieved by an audit trail, which is a process of keeping a detailed chronology and description of the research activities, including: an explanation of the choices and justification for the different research designs, data collection and analysis, emerging themes, and an analytic memo.

In summary, 'reliability' in a quantitative study is the repeatability and independence of findings from the specific researchers generating those findings. While in qualitative research, reliability implies that given the data collected, the results are dependable and consistent.



Neutrality

Neutrality implies that the researcher maintains objectivity, minimizing any possible bias due to the researcher's values or interests. In a quantitative study, objectivity can be achieved by avoiding selection bias (by randomization) and measurement bias (by standardized instruments, procedures and masking participants' status during measurement). In a qualitative study, however, these same strategies would be counterproductive. To be able to capture reality as accurately as possible according to participants' perspectives and experiences, the researcher needs to be inseparable from the study participants. Furthermore, the researcher can act as an instrument during data collection. As a result, the researcher cannot be fully objective. Objectivity (or conformability) is therefore a way of knowing that the researchers have maintained the distinction between their own personal values and those of the study participants. The readers should be able to see that the integrity of the study findings is based on the data, and not the researchers' beliefs or biases. Conformity can be achieved through the use of a reflexive diary.

Mixed methods: Combining quantitative and qualitative methods

After understanding the strengths and weaknesses of both quantitative and qualitative approaches to research, it is possible that your IR team will consider using a combination of these two approaches. In fact, many IR projects use mixed methods to provide a better understanding of the problem than either a quantitative or qualitative research approach can do alone. Before making this decision, it is important to review why you may want to combine the two kinds of research approaches. Table 6 (adapted from Bryman 2006¹¹ and Greene et al 1989¹²) can help to guide the decision-making process.



Table 6: A Guide to the decision-making process on whether to use mixed research methods

Question?	Explanation regarding your research design	Terminology
Do you wish to confirm the accuracy of your findings?	You want to see the convergence of results from different methods in order to confirm what you have found with one method is valid through the use of another method.	Using two research approaches to ask similar questions is called triangulation .
Do you want to elaborate the results from one approach with another approach?	It is important to elaborate, enhance, illustrate or clarify the results from one method with the results from another.	Using one research approach to further elaborate the results from a different approach is called complementarity .
Do you want to use the results from one research method to inform the development of additional data collection?	When results from one method help to develop the subsequent data collection method, by informing the sample as well as measurement decisions (e.g. questions to ask, scales to use).	Using one research method to sequentially inform the other is called development .
Have you have discovered or expect to discover something new or contradictory with one method, and you want to try and understand that new or contradictory thing better?	When one data collection method reveals results that are unexpected or contradictory to what is understood to be true, re-asking the same questions using a different methodological approach can lend more understanding.	Using one research method to further explore contradictory results from another research method is called initiation .
Do you want to maximize your understanding?	Extending the range of enquiry by using different methods for different components of enquiry.	This combination of approaches, called expansion , will allow you to extend your data collection methods more widely.

After considering how a mixed methods approach might contribute to your research, you will also need to justify the sequence and weight given to the two approaches. The four most common types of mixed methods research are: sequential explanatory; sequential exploratory; concurrent triangulation; and concurrent embedded (Table 7).

Table 7: Main mixed methods research approaches

Sequence	Description
Sequential explanatory	<p>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.</p>
Sequential exploratory	<p>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.</p>
Concurrent triangulation	<p>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.</p> <p>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.</p>
Concurrent embedded	<p>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.</p>



When designing mixed methods research, the IR team will need to consider the following elements when planning data collection and analysis:

- **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 quantitative and qualitative data to arrive at new variables or new themes (Creswell 2009). 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.

If your research team decides to use mixed methods in your study, you will need to describe why you chose this approach, as discussed in Proposal Development Module.

SEE

DEVELOPING AN
IR PROPOSAL

Case study 2

Use of mixed methods to explain malaria persistence in remote Central Viet Nam

Background: Malaria remains a major global threat despite the availability of efficacious tools. Its effective control requires consistent action from both *health care systems* and *community* and an understanding of features that precipitate risk. The Viet Nam National Malaria Control Programme (NMCP) introduced in 1991 has controlled malaria through the provision of free anti-malarial drugs, impregnated bed-nets, bi-annual home insecticide spraying and early diagnosis and treatment. Overall, the number of clinical cases declined from 1.2 million and 4646 recorded deaths in 1991 to 185 529 clinical cases and 50 deaths in 2002. However, over 90% of severe cases and deaths occurred in mountainous, forested and largely ethnic minority areas of central Viet Nam, where populations are impoverished, poorly educated, culturally and linguistically distinct and living in dispersed, less accessible settlements. The researchers therefore considered it both instructive and timely to investigate persistent malaria in such settings.

Methods: Mixed methods (qualitative and quantitative) were used to collect data, in order to explore the complex interrelations between the various actors and system elements. Data was collected in two stages. The formative stage used mainly qualitative tools (e.g. community meetings, observation of bed-net use, and focus group discussions/semi-structured interviews) while health managers, providers and the community helped to define and expand thematic areas of enquiry. Outcomes informed the quantitative approaches (e.g. a provider quiz, structured surveys with community members and village health workers, and quality check of microscopy facilities and health records at district and commune levels). The table describes the methods that were used.

Conclusion: Use of the mixed methods informed researchers and the NMCP about the contextual factors that acted as bottlenecks to effective malaria control in the affected region.

Lessons: The complexity of contextual factors coupled with poverty, low education levels, cross-border mobility, and cultural diversity, made it appropriate to use mixed methods.



Case study 2

Use of mixed methods to explain malaria persistence in remote Central Viet Nam

Table. Summary of mixed methods used during the project

Formative stage		
Method	Objective	Participants
Community meetings	To explore beliefs, attitudes, awareness, care seeking/providing and circumstances relevant to malaria exposure and control	Malaria control officials, local government, mass organizations, hospitals
Focus group discussion		Provincial and district malaria control managers and Commune Health Station staff, village health workers, and community members
Semi-structured interviews		Provincial malaria control officials, district malaria control secretaries, district hospital staff, commune health staff, village health workers, community members
Informal group discussion		District hospital managers
Observation	<ul style="list-style-type: none"> To identify antimalarial drugs on the market 	Drug selling points
Observation	<ul style="list-style-type: none"> To describe village environment/context 	Villages/community
ASSESSMENT STAGE		
Tests/quiz	To obtain an impression of provider knowledge and guidelines adherence	District hospital staff
Observation checklists	To assess visibility and currency of malaria treatment guidelines	Health service points
	Quality of microscopy	
	Bed-net quality during KAP survey home visits	Homes
Review of treatment records/logs		Malaria patient records
Structured questionnaire	To determine community knowledge, attitudes and practices(KAP)	Village health workers Community members

Source: Morrow M. et al. Pathways to malaria persistence in remote central Vietnam: a mixed-method study of health care and the community. BMC Public Health. 2009; 9(1):1.



REFLECTION ACTIVITY

In relation to your team’s IR question, and the study design that you have chosen, consider and discuss/agree which research methodology (or combination of both methods) you will use in your research.

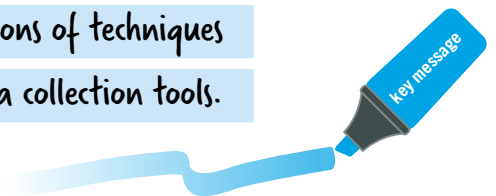


Research tools and techniques

Introduction

This section describes the tools and techniques that are used in quantitative and qualitative methods.

IR projects use a wide range and combinations of techniques and data collection tools.



Quantitative research tools

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. Table 8 provides an overview of quantitative data collection strategies.

Table 8: Quantitative data collection tools

Type of instruments	Summary
Observation checklist	<p>The researcher directly observes (watches and listens to) some phenomenon and then systematically records the resulting observations.</p> <p>Tool: Observation checklist is the instrument used for structured observation. The checklist consists of pre-determined specific categories of behaviours/arrangement/processes/procedures that will be observed.</p>
Questionnaires	<p>Survey instruments comprising a series of questions, designed to measure a given item or set of items.</p> <p>Tool: Questionnaires can be used for structured interviews, offline or online self-administered data collection, and telephone interviews. 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.</p>
Performance based instruments	<p>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, the use of these approaches is fraught with technical difficulties. They are often time-consuming and may require equipment or other resources that are not readily available.</p>

Type of instruments	Summary
Diary	A diary is a self-completed record of experiences during the study period (e.g. alcohol consumption, episode of sickness, or travel).
Electronic data capture	Electronic data capture is a method for collecting data entered directly into a computer or other electronic device (i.e. rather than paper forms). The instrument can be in web based, handheld/smartphone or computer format.

Qualitative research techniques and tools

Qualitative research is generally used to explore values, attitudes, opinions, feelings and behaviours of individuals and understand how these affect the individuals in question. Researchers using qualitative methods 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 generating theory, developing policy, improving educational practice, justifying change for a particular practice, and illuminating social issues. It may also be used to explain the results of a previous quantitative study or to prepare for the development of a quantitative study.

If your research team decides to use qualitative methods in your study, you will need to describe how qualitative methods will provide the information to help you address your research objectives and research question(s). For example, qualitative research may be appropriate because you intend to explore the values and behaviours of individuals in the study area in relation to a public health intervention, and to understand how these affect the phenomena in question. For example, why do some households have bed nets but do not use them? Or, why do individuals in a study area decline services from a specialized antenatal clinic? Qualitative methods can provide context, a deeper understanding of stakeholders' needs and participants' perspectives.

When collecting qualitative data, it is preferable to use more than one data collection method. Obtaining information on the same phenomena in a variety of ways allows the researcher to triangulate the data, adding rigour to the research. By nature, qualitative data collection is emergent and the design is intentionally flexible to enable the researcher 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 and analyse. The following table may be helpful to you as you decide which qualitative tools and techniques are most appropriate for your IR project (Table 9).

**Table 9: Qualitative data collection tools**

Summary and examples	
Participant observation	<p>The researcher participates in/observes 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 is collected by observing, interviewing, note taking and/or journaling. The researcher develops a relationship with the participants, which may affect the data collected.</p> <p>Tool: Participant observation checklist</p> <p>Example: 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. In this setting the observer can participate in the interaction between the health staff and the patients and can act as part of the health providers' team or as a client to the health providers.</p>
Non-participant observation	<p>The researcher does not participate in any activity in the natural setting. Data is collected by observing, note-taking and/or journaling. The 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.</p> <p>Tool: Participant observation checklist</p> <p>Example: The same study setting as the example above, but this time the observer does not participate in the interaction between health staff and the patients. He or she will independently observe the encounters.</p>
Field observation during a 'transect walk'	<p>Detailed descriptions of events, actions, behaviours, people and objects in a natural setting. Field observations are written in the form of field notes.</p> <p>Tool: Transect walk checklist</p> <p>Example: To understand the day-to-day activities, practices, and interactions in a village, a researcher walks through the village cross-sectionally and observes villagers activities, structures of houses, buildings, and interactions among villagers.</p>

Summary and examples	
In-depth interviews	<p>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).</p> <p>Tool: In-depth interview guide</p> <p>Example: 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 the services; health policy-makers at national and local levels; and rural health insurance scheme managers.</p>
Review of documents and artefacts	<p>Written or printed records of past events (e.g. letters, anecdotal notes, diaries). Material objects and symbols of a current or past event, groups, organizations, or a person that can reveal social processes, meaning, and value (e.g. diplomas, awards, papers, logos etc.).</p> <p>Tool: Checklist or other criteria to review documents</p> <p>Example: Analysis of printed posters, commercials etc. to understand values, messages and meanings for targeted audiences.</p>
Video/film/photographs	<p>Media that captures the daily life of an individual, group or event under study. Can be captured and viewed repeatedly to record behaviours.</p> <p>Tool: Checklist and/or criteria to review that media</p> <p>Example: Review photographs taken by community members showing the areas of public health need in their community.</p>
Focus group discussion	<p>A 1–2 hour discussion, guided by a trained moderator, in which 6 to 10 similar respondents (e.g. by 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 among participants.</p> <p>Tool: FGD topic guide</p> <p>Example: 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.</p>



Unlike quantitative data collection, qualitative data collection can be more flexible allowing the research to incorporate emerging themes in the ongoing data collection. This allows the researcher to test and validate findings as they collect the data. For example, perhaps in one in-depth interview, the researcher learns that people do not attend the lymphatic filariasis mass drug administration because they use traditional medicines and therefore feel that they are already under treatment. The researcher may then add a related question to subsequent in-depth interviews to see how prevalent this phenomenon is in the study population.

Table 10 describes situations when various qualitative data collection techniques can be used.

Table 10: When to use various qualitative data collection techniques

Data collection technique	Situation
Observation	<ul style="list-style-type: none"> • When the unit of analysis is individual or a group. • When verification is needed. • Anytime and in any situation where researchers want to understand first-hand phenomena under study.
In depth Interviews/ Key informant interviews	<ul style="list-style-type: none"> • At the beginning of the research as a stepping stone to FGDs. • When preliminary knowledge on a particular issue is needed. • When research interests are being defined. • When individuals or social settings are difficult to access. • To understand subjective experiences. • Where subject matter may be sensitive and people will not speak in FGD settings.
Focus Group Discussions	<ul style="list-style-type: none"> • When a single subject is being explored in depth. • When enough is known about the subject to develop a topic guide for discussion. • When the subject matter is not sensitive so that people will not mind talking in a group. • Quick results are needed but the research project has limited funding. • Acceptable number of people can be assembled to participate in a discussion group.



Case study 3 Data collection tools: Case of the NIGRAAN project

Background: Data collection tools enable a systematic collection of data about participants in any given study. The exact tool employed depends on the objective of the study. Due to the potentially complex nature of implementation research (IR), mixed methods – and hence different data collection tools – are often used as in the NIGRAAN project in rural Pakistan. The project was conducted by the department of community health sciences of the Aga Khan University (AKU) (Karachi) in collaboration with the Sindh Provincial Department of Health. Nigraan is an Urdu word meaning ‘supervisor’. The two-year IR project sought to identify ways the structured and supportive supervision of lady health workers (LHWs) by lady health supervisors (LHSs) could be strengthened, and to improve community case management of pneumonia and diarrhoea in children under five years of age in Badin district, in Sindh. The study was conducted in three sequential phases. The study participants included LHWs, LHSs, community caregivers of children under the age of five and policy-makers. Quantitative data was collected using structured questionnaires, a knowledge assessment questionnaire and a skill assessment questionnaire (Table 1), while qualitative data was collected using in-depth interviews (IDs), focus group discussions (FGDs) and narrative interviews (Table 2).

Table 1: Quantitative data collection tools

Tool	Study participants	Purpose of the tool
Household survey questionnaires	Primary caregivers	To record socio-demographic information, caregiver practices regarding diarrhoea and pneumonia of the population under study, as well as to document the morbidity due to diarrhoea and pneumonia.
Knowledge assessment questionnaires	LHSs and LHWs	To assess the theoretical understanding and knowledge of LHSs and LHWs regarding community case management of diarrhoea and pneumonia.
Skills assessment scorecard ‘A’	LHSs and LHWs	To assess the practical/clinical skills of LHSs and LHWs regarding community case management of diarrhoea and pneumonia.
Skills assessment scorecard ‘B’	LHSs and LHWs	

Table 2: Qualitative data collection tools

Tool	Study participants	Purpose of the tool
Narrative interviews	Community caregivers	Explore caregiving practices and decision making for childhood diarrhoea and pneumonia.
FGDs and IDs	LHSs, LHWs	To record HWs’ perspectives, knowledge and skills regarding community case management of childhood diarrhoea and pneumonia in rural Pakistan.
IDs	Policy-makers	Establish their opinions on the causes of the observed structural gaps.

Lessons: Data collection should be designed specifically, in accordance with the study population and objective.



Pre-testing

All study instruments (quantitative and qualitative) should be pre-tested to check the validity and reliability of data collection tools. Pre-testing allows the research team to check whether the research instructions and questions are clear, context specific, and that adequate time has been allowed to administer the questionnaire, etc. Pre-testing should be conducted from a comparable study population and environment. 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, in order to incorporate changes into the final design of the tool and facilitate the 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 ensure the appropriate variables are collected.

Example

Table 11 summarises the range of research methods used in the different phases of an IR project in Bangladesh. It describes a cluster randomized controlled trial designed to test a home care and community health worker intervention in comparison to established neonatal care services.

Table 11: Research methods used in the different phases of an IR newborn care project in Bangladesh

Phase of the research	Methods	Objective
Pre- intervention phase	Quantitative household survey	Provided estimates of existing neonatal mortality and levels of skilled attendance.
	Formative qualitative research	Explored home care practices that put newborns at risk of death, and the barriers for safe delivery and postnatal care.
	Observation of newborn care	Demonstrated that community health workers could diagnose newborn illness.
Intervention phase	Household surveys and in-depth interviews	Demonstrated that the intervention was being implemented as planned.
	Surveys, observations and in-depth interviews	Established whether the newborn package was being implemented consistently (“implementation fidelity”).
Post intervention phase	End-line household	Assessed both neonatal mortality and service coverage levels
	Qualitative research	Explained in detail how and why delivery and post-natal practices changed, largely because of the engagement of the local community in the programme, and the supportive supervision of the community health workers (“meaning enhancement”).

Adapted from Baqui et al, 2008;¹³ Baqui et al, 2009;¹⁴ Choi et al, 2010;¹⁵ Shah et al, 2010.¹⁶

**REFLECTION ACTIVITY**

In relation to your team's research problem and question(s), discuss and agree which data collection tools you will use in your IR project. As you reflect on this, you must take into account the selected study design, your IR questions, and also the time and budget available to your IR team.

Sampling

Now that you have chosen the most appropriate techniques and tools to collect your research data, it is important to know how many people you need to approach to participate in your research. This is called the 'sample size'. In general, when using quantitative research tools, you need to ensure that you recruit enough people to provide an accurate and reliable estimate of what you are studying. When using qualitative research tools, the aim is to reach enough individuals that you can represent the prevalent opinions, experiences and knowledge in the study population. In this section, we review the sampling designs used in both quantitative and qualitative research tools.

Sampling design in quantitative methods

Quantitative studies require a representative sample of the study population to be able to accurately portray the characteristics of the population and to yield maximum precision of such population parameters. The following criteria are critical when designing a sampling strategy: (1) What are the research objectives? (2) What are accurate estimates of sampling variability? (3) Is it feasible to apply the sampling strategy and obtain the calculated sample size? (4) Is it possible to minimize costs (or to achieve research objectives for minimum cost). As these criteria can conflict with each other, research teams must find a balance between them.

Sample size

A representative sample requires an adequate sample size, taking into account statistical power parameters. Power is the probability of rejecting the 'null' when an alternative hypothesis is true. In simple terms, this is the probability of actually detecting an effect under study. Different sample size calculations should be used for the various study design types. Sample size calculation formula and calculation procedures can be found in standard biostatistics reference materials.¹⁷ Further discussion with a statistician will also help to confirm and calculate the appropriate sample size needed for various types of research methods.

Sampling strategy

As quantitative studies require a representative sample with regard to population characteristics, a ‘probability’ sampling is preferable. This enables every individual in the population to have a certain chance of being included in the sample. Probability sampling also allows estimates of sampling error to be calculated. There are several probability sampling strategies (Table 12).

Table 12: Probability sampling strategies

Sampling strategy	Summary
Simple random sampling	The ideal sampling strategy because each element of the population has equal probability of being included in the sample. The sampling procedure is to assign a number to each element in the sampling frame and use a random number to select elements from the sampling frame. Most statistical packages can generate random numbers.
Systematic random sampling	This sampling strategy uses a list of population elements. We assume that the elements are randomly listed. The first element included in the sample is randomly identified and the subsequent elements are selected using sampling interval. The sampling interval is calculated by dividing the desired sample size by the number of elements in the sampling frame.
Stratified sampling	Stratified sampling can be used in a population that consists of mutually exclusive sub-groups (e.g. school population with classes). A random sampling procedure is then used to select elements from each stratum/sub-group. Sample size can be selected proportionately to the stratum size.
Cluster sampling	Cluster sampling is commonly used when the population is very large or dispersed across a large geographical area. The goal of cluster sampling is to increase sampling efficiency. However, cluster sampling reduces the population variability in the sample since a group of individuals in the same geographical area is to some extent more homogenous and the probability of each element to be selected in the sample is not equal. To address this limitation, sample size calculation in a cluster sampling strategy needs to take into account design effect, which will increase sample size. Furthermore, the researcher can use the ‘probability proportionate to size’ procedure to correct the difference in cluster size and adjust the chance that clusters will be selected. A common example is the Expanded Programme for Immunisation (EPI) cluster sampling framework.




In some situations, random sampling is not the preferred option due to lack of specific resources (e.g. a list of the entire population), time, costs or ethical constraints. In other situations, the research requires some ‘weighting’ to the information being collected (e.g. a survey among experts). In this scenario, nonprobability sampling is preferable. There are several commonly used non-probability sampling strategies (Table 13).

Table 13: Non-probability sampling strategies

Sampling strategy	Summary
Availability or convenience sampling	Availability sampling refers to the technique in which the selection of sample is due to researcher accessibility. The limitation of this strategy is selection bias. An example of this strategy is sample from facility or institution where the researcher is employed.
Successive sampling	Successive sampling is when individuals are selected successively, for example, an exit interview with patients after an encounter with the health provider. All patients who just met with the doctor are offered the opportunity to participate in the study. If the study involves multiple sites, a combination with stratified sampling can be used. However, the patients are selected successively in each stratum.
Purposive sampling	Purposive sampling is used when the elements are selected based on the researcher’s judgment regarding the desired information being collected. Participants are being selected on their knowledge of the topic being studied. The example of purposive sampling is a survey using a panel of experts.
Snowball sampling or respondent driven sampling	This type of sampling strategy is suitable to recruit participants who are members of a hidden population (e.g. victims of domestic violence, drug users). Snowball sampling is started when a researcher can identify the first participant that met selection criteria. The researcher then asks these participants to identify people with similar experiences or characteristics. To increase the variability of characteristics of the study participants, the researchers can ask the subsequent participants to find the next participants with the same experience but with different socio- demographic characteristics, for example with different gender, age group, socio-economic

Sampling in qualitative methods

Sampling strategy



Sample size determination is an important step in IR as it informs how many people you need to approach to participate in your research.

Sampling in qualitative research uses quite different approaches to those used in quantitative studies. The aim in qualitative research is not to have a representative sample, but rather one that reflects the characteristics and richness of the context and/or study population. Whatever sampling method is used, the IR team will need to justify their sampling frame selection. Table 14 reviews the different kinds of sampling techniques used in qualitative research.

Table 14: Sampling techniques used in qualitative research¹⁸

Kinds of sampling	Explanation
Convenience	Studies the units that are available at the time of the research. It is more convenient than a random sample because the researcher uses what is available, rather than what is selected. There is however, a risk of measurement bias. If interviewing households in the morning is most convenient, which populations might be overrepresented (housewives, elderly) and which may be underrepresented in the sample (employed, men, students)?
Purposive	Used when the elements are selected based on the researcher's judgment regarding the desired information being collected. For example, researchers may decide to identify respondents according to their involvement in a particular health programme.
Maximum variation	Selects units that represent as wide a range of variation as possible (e.g. gender, socioeconomic status, population density, etc.).
Snowball	Identifies a few people who will be involved with the study and then asks them to identify more people who would be relevant to include in the research. Best to start with at least two individuals so as to reach different networks of individuals. This is the most common form of sampling in qualitative research methods.
Contrasting cases	Involves two or more units with distinct characteristics so that comparisons can be made when explaining problems and understanding the factors that influences them. For example, researchers may decide to study individuals living in a site where a health programme has been successful and another site where the programme has been less optimal.

**REFLECTION ACTIVITY**

Working together with the other members of your IR team, devise the sampling strategy for your study and the tools you will use. Think about the respondents you hope to recruit as you plan your study. How can they be reached? What time of day should you interview people? How much time will they have to participate in your study? Remember that IR takes place in real-life settings, so if you want to interview nurses in a health clinic, Monday morning may not be the best time!

Data collection

Now that you have a sampling framework, you can start to think about collecting your data. Before data collection begins (e.g. interviews, focus group discussions, survey, etc.), you must receive ethical approval from the bioethics committee in your country. In this process, you will have to develop an information sheet and informed consent form that will need to be read to each study participant. Before any data is collected, the participant must give his/her informed consent to the process. This information is outlined in detail in the module entitled Planning and Conducting an IR Project.

While planning your data collection, you will need to identify people who will actually carry out the data collection. A short training will need to be conducted prior to the start of the survey so that the enumerators understand the entire process, the data collection instruments as well as the sampling strategy that you will use. At this time, role plays can be carried out with the enumerators to ensure that they understand the research process and instruments.

Finally consider how you will supervise the data collection process. How will problems in the field be rectified? For example, what if people aren't home on the days that you start your surveys? What if key informants do not have the time for an in-depth discussion? How will you work with the local head of the health centre if he or she does not agree with using a performance-based instrument?

Regular meetings with the enumerators/field staff can help address some of these issues that may arise in the data collection process. These regular meetings will also provide an opportunity to amend topic guides if using qualitative data collection tools. For example, if you discover new and unexpected phenomena on the first day of FGDs, you will want to add the topic to your next planned FGDs to ascertain how common it is within your respondent population.

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Data management

Most research projects generate a significant amount of data. This data should be of good quality because it underpins the quality of the study. Therefore, good data management is fundamental for high quality research. Good practice in data management also helps researchers ensure that the required processes of data collection and analysis are organized, understandable, and transparent.

The main data management responsibilities include:

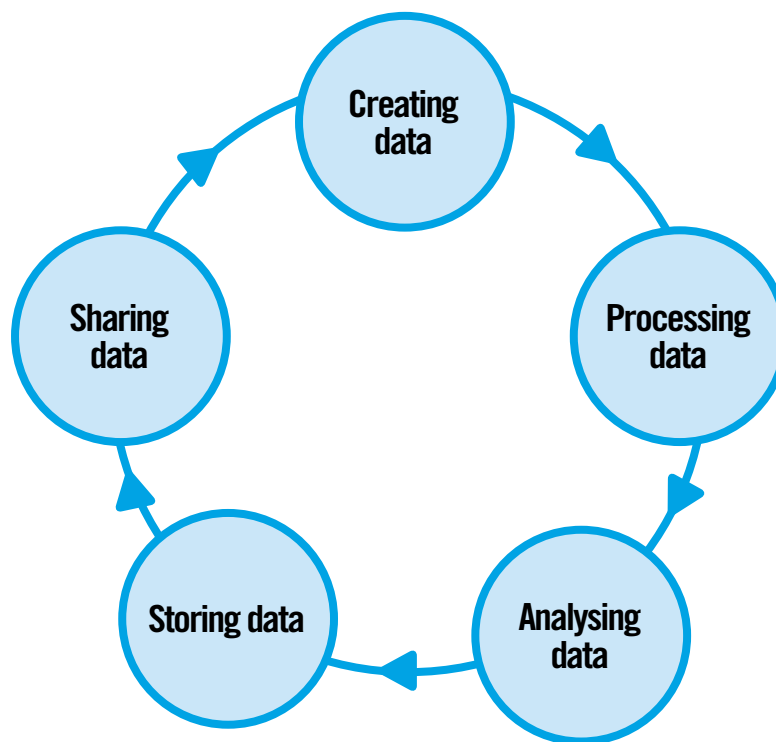
- Organizing and ensuring the collection of accurate data.
- Capturing the data on a database.
- Validating and correcting the data.
- Providing data in a form that will enable analysis.
- Storing and sharing the data.

It is important to remember that the confidentiality of the respondents' identities must be guaranteed at all times in the data management process. This is usually stipulated in the ethical approval you will receive (e.g. keeping files on a password-protected computer, locked cabinets, limited number of persons with access to any anonymized data). In addition, you will outline how long you will keep the data after the research has been completed. You must ensure that these ethical criteria are maintained throughout the course of your IR project.

Data management is a cyclical process (Figure 4). The data life cycle starts with creating data, followed by processing and using data for analysis. The last two stages of the cycle are storing and sharing the data.



Figure 4. Data management cyclical process



Adapted from Surkis & Read, 2015.¹⁹

Creating data

Creating data is the first step in the data management processes. In quantitative studies, this stage consists of defining what type of data will be collected, their format and the procedure to create them. The researcher must ensure that all the collected data reflect the realities, using standardized instruments, data collection procedures, checking error rates during data collection (e.g. checking the completeness and consistency of respondents' responses in the questionnaires, checking the validity of the responses by random re-interview process).

In a qualitative study this stage starts with defining different types of information the researcher intends to gather, different tools (e.g. interview or FGD guidelines) and data collection activities. The researcher needs to ensure that all recording devices are placed in a way that will best record the conversation or discussion, and that the space for interview or discussion creates a safe atmosphere for open discussion while ensuring privacy.



Processing data

This is the course of translating information from the rawest form to a form that is ready for analysis to the researcher. In quantitative study this means creating an electronic database that is appropriate to manage different types of data (e.g. multiple responses, numerical data, visual analogue scale data, etc.). It involves creation of file and coding structures that are understandable, the development of a codebook, making decisions on which data can be kept in the database which should be discarded. As data is entered, data entry errors should be prevented by double entry and checking the consistency of responses. In qualitative studies, this means that all the recorded data are transcribed verbatim and in some cases transcripts can be shared with respondents to verify content. It also entails the development of a codebook particularly when more than one researcher is conducting the analysis. All collected qualitative data should be saved in a qualitative data management application.

Analysing data

Data analysis in quantitative studies consists of identifying patterns through descriptive analysis, comparing data, hypothesis testing and finding relationship between variables. In qualitative studies, this process consists of identifying, understanding meaning and assigning code to the data, identifying patterns and emerging themes, and constructing framework to explain certain phenomena. This activity will be described in a subsequent section.

Storing data

Storing data involves activities not only during the study period, but also in the long term by archiving data in a repository or data centre. Presently, electronic data storage/repository is the medium of choice as it requires little space and is simple to back up. However, a data storage strategy is needed as digital storage media also have several limitations e.g. quality and life cycle of storage media, software interoperability, relevant data reading equipment and power supply. Data security is another issue in storing data. Security issues include physical data security (e.g. locked room or cabinet, access log book), and electronic data security (e.g. secure access using password, level of access, and data encryption for sharing and transmission). The WHO Good Clinical Practice Guideline recommends that data and essential documents should be stored for at least two years after the research project has ended.²⁰

Sharing data

Sharing data is particularly important in collaborative multi-centre/country studies. Data sharing, together with data transfer, data storage and access for all collaborative partners or institutions can be challenging as it may involve different regulations. Cloud-based file sharing may be preferable, although it may not be suitable for all types of data, particularly identifiable, confidential data. Furthermore, researchers do not have control over where data is actually stored.



Data sharing is becoming mandatory in many fields as a way to ensure transparency, avoid duplication as well as plagiarism. Since IR may involve different institutions/organizations, the guidelines for data sharing and ownership should be clearly spelt out at the beginning through agreements such as a memorandum of understanding. Data sharing should follow a clear process and can be carried out between two research institutions though not between two individuals. Please check your own institutional and national guidelines before designing any data sharing agreements.

Data quality 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 their original form (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; Accuracy is therefore a critical part of the integrity of the study.
- **Legibly:** Hand-written data should be clearly written and 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.

Data quality is key to having authentic and scientific data and therefore should be taken seriously. Activities such as staff training, supportive supervision and data feedback can be used to enhance the quality of data. Refer to the planning of an IR project module for details.

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Data analysis

Introduction

Depending on the research questions you want to answer and the type of data you have collected (i.e. quantitative or qualitative data), different types of analysis can be performed. Before we begin to analyse the data, we need to remember the different audiences to be reached with the results and recommendations of the IR project. What are their needs for information, and what is the best way to reach them? Click on each of the headings below for an explanation on each type of analysis.

Data analysis plan

To ensure that the analysis is undertaken in a systematic manner, an analysis plan should first be created. The analysis plan should contain a description of the research question and the various steps that will be followed in the research process. It is best practice to develop your data analysis plan at the start of your project, in order to capture the hypotheses you have about your research question. You may amend the data analysis plan as your research progresses.

Designing data analysis in an IR project is based on the premise that IR aims to: (i) understand the implementation processes for a given intervention, 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, policy and/or programming.

Most IR proposals use mixed methods in which quantitative and qualitative techniques are combined. Under many circumstances, mixed-methods approaches can provide a better understanding of the problem than either approach can achieve alone. However, few of the stakeholders in the IR project team are likely to have specialized knowledge of both quantitative and 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.²¹ Data analysis should take place along with the data collection process. This continual data analysis process facilitates regular sharing and discussion of findings.



Designing analysis by purpose

An important preliminary consideration when designing your 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 its nature, intended not only to simply describe an 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.

When preparing your data analysis plan; it is important to remember your research audience. Different audiences have different information needs, understanding of data presentation, interests and knowledge. Plan and present your analysis accordingly.



Quantitative data analysis

Before any statistical analysis is undertaken, some factors need to be taken into account in order to select the most appropriate statistical analysis approach. These are described briefly below.

Measurement scale and different statistical techniques

Measurement scale is a way to define and categorize variables. There are four different measurement scales (nominal, ordinal, continuous and ratio scale). Each measurement scale has different properties, which are required for different statistical analysis. Table 15 summarizes the properties for different measurement scales, described in detail below.

Table 15: Summary of measurement scale properties

Measurement	Category/ difference	Rank/order	Meaningful number	Meaningful number scale
Nominal	+	-	-	-
Ordinal	+	+	-	-
Continuous	+	+	+	-
Ratio	+	+	+	+

The nominal scale can only differentiate the category. We cannot say that one category is higher or better than the other category. An example of a nominal scale is gender. If we code Male as 1 and Female as 2 or vice versa (i.e. when we enter the variable into the computer), it does not mean that one gender is better than the other. The numbers 1 and 2 only represent categories of data.

Ordinal scales represent an ordered series of relationships or rank order. However, we cannot quantify the difference between the categories. We can only say that one category is better or higher than the other categories. An example of an ordinal scale is the level of a health facility (e.g. primary, secondary, tertiary).

Continuous scales represent a rank order with equal unit of quantity or measurement. However, in this scale, zero simply represents an additional point of measurement not the lowest value. An example of such a scale is a temperature scale in Celsius or Fahrenheit. In this scale, zero (0) is one point on the scale with numbers above and below it.

Ratio scale is similar to the continuous scale, in that it represents a rank order with equal unit of quantity or measurement. However, ratio scale has an absolute zero, in which zero is the lowest value. An example of ratio scale is body mass index (BMI) in which the lowest value (theoretically) is zero.

The continuous and ratio data are referred to as parametric as these types of data have certain parameters with regards to distribution of the population as a whole (assumption of normal distribution with mean as a measure of central tendency and variance as a measure of dispersion). Parametric also means that the data can be added, subtracted, multiplied and divided. The statistical analysis for these types of data is referred to as parametric test.

On the other hand, nominal and ordinal scales are referred to as non-parametric. Non-parametric data lacks the parameters that the parametric data have. Furthermore, it lacks quantifiable values and as such nonparametric data cannot be added, subtracted, multiplied or divided. Nominal and ordinal data are analysed using non-parametric tests.

A parametric test is considered to be more robust than a non-parametric test. Furthermore, there are more statistical options available for analysing parametric data. However, most parametric tests assume that the data is normally distributed.



Research questions

The way we formulate research questions also determines what kind of statistical techniques need to be used for analysis. Examples of IR questions include:

- Describing patterns/distributions of study variables in terms of “What, Who, Where, and When”.
- Comparing differences between groups.
- Exploring possible associations/correlation between independent variables (exposures) and dependent variables (study outcomes).
- Exploring a possible causal relationship between independent variables (exposures) and dependent variables (study outcomes).

Descriptive statistics

Quantitative research generates large volumes of data that require organizing 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 to estimate the extent to which they relate to other variables.

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.).



The different data presentation formats help to reach different target audiences. Tables are a useful presentation format when you want to communicate within the scientific community. Graphical data presentations help to communicate with a wider, less scientific, audience in the community or policy makers. You can read further about data presentation and how to present data to different audiences in the Advocacy and Communication module of this Toolkit.

Defining intervals for frequency distributions

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

- Ordinal: Level of health facility (e.g. primary, secondary, tertiary).
- Continuous: Body temperature (e.g. below normal, normal, above normal).
- Ratio: 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.

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

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 (e.g. mean, variance) that are intended (but often fail) to capture the essential features of a distribution.

Summary statistics usually focus on deriving the measures indicating the overall tendency location of a distribution (e.g. how sick, poor or educated a study population is, on average) or on indicating 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.



Measure of central tendency

Example

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 the proportion of five year-old children in village falling below the predetermined minimum calorie requirement?

The criteria for making such choices include:

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

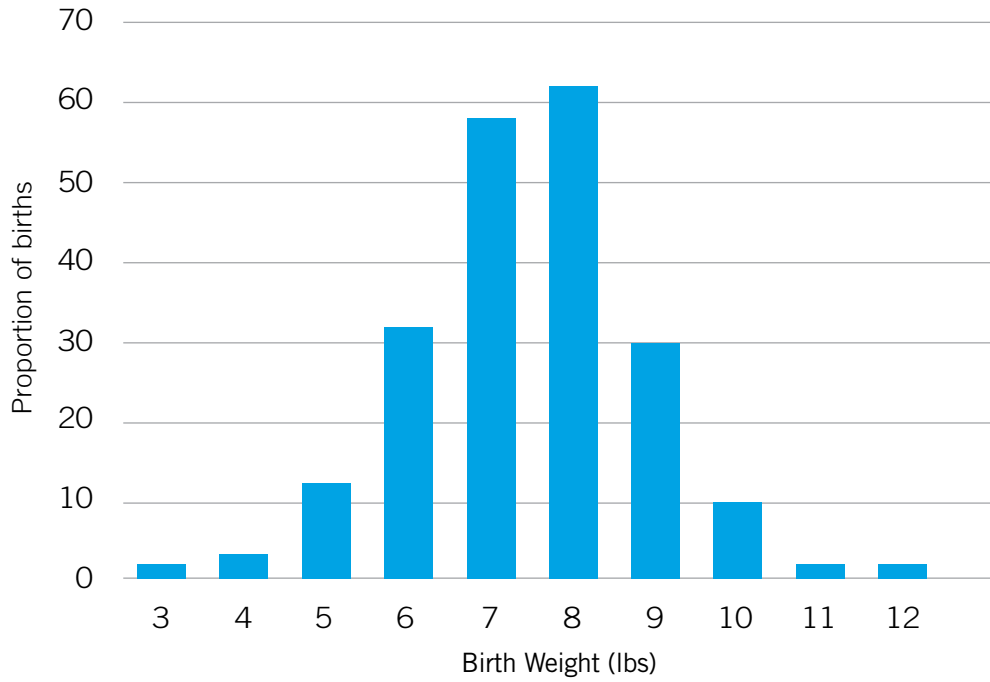
The central tendency measures the central location of a data distribution. The mean, or average, is the most commonly used parameter because the mean is simple to calculate and manipulate. For example, it is straightforward to combine the mean of sub-populations to calculate the overall population mean. However, the mean is often inappropriately used. It can also be misinterpreted as the typical value in a population.

Example

The GDP of a certain middle-income country was calculated as 3200US\$. Interpreting this as the income of an ‘average’ person in that country does not reflect the reality (in fact, it was closer to 1200US\$). The mean is often unrepresentative when the underlying distribution is skewed.

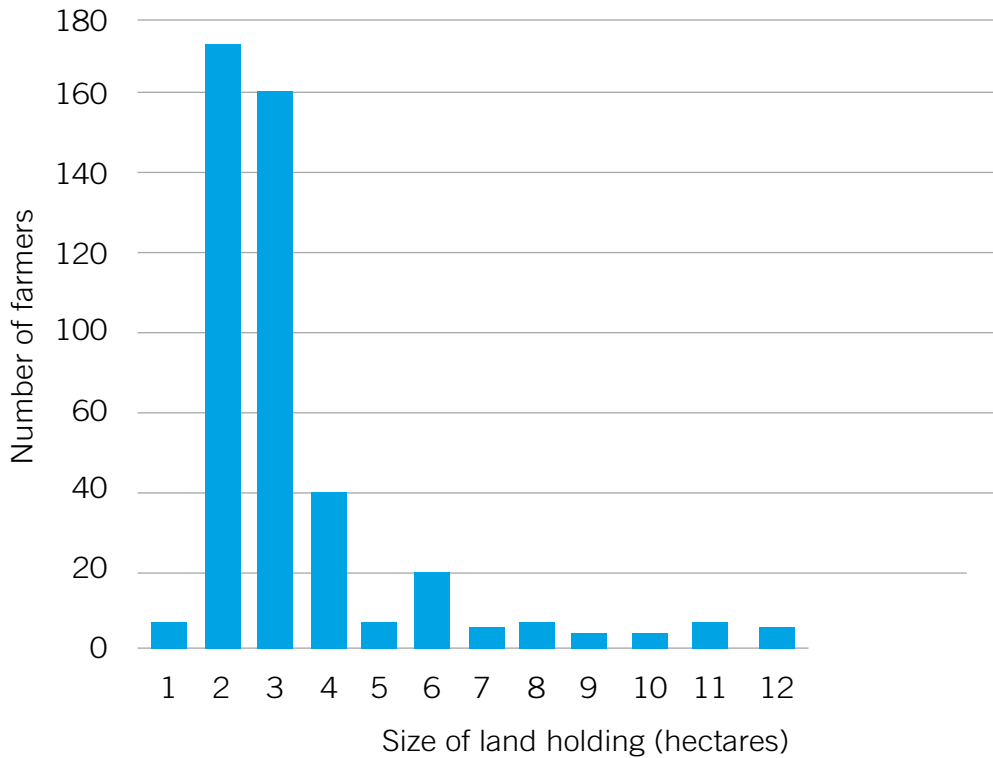
The median, defined as the middle value, is relatively easy to explain. The magnitudes of other values are irrelevant. For example, if the largest value in a given range increases or the smallest value decreases, the median remains unchanged. When a data set is not skewed (or when data is distributed ‘normally’), the mean and the median are the same (Figure 5). It is therefore preferable to use median as a measure of central tendency when the data set is skewed as the value is independent to the shape of the data distribution.

Figure 5. Normal distribution: the mean is the measure of central location



In a skewed distribution, the mean is difficult to interpret (Figure 6).

Figure 6. Skewed distribution





Measure of dispersion

Measure of dispersion denotes how much variability occurs in a given population, as follows:

- **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:** 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), with 25% of available data in each:

- Q2 is the median.
- Q1 is the median of the data points below the median.
- Q3 is the median of the data points above the median.

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).

Other descriptive statistics

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 simply 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 16. For meaningful interpretation of the results, the type of chronic illness and the background of the patients experiencing them will be important variables to consider.

Table 16: Background variables of patients with chronic illness

Age group	Chronic illness prevalence	
	Males	Females
15-24	0.55	0.80
25-44	1.79	4.01
46-64	4.91	12.28
65	12.86	20.00
All	1.77	4.25

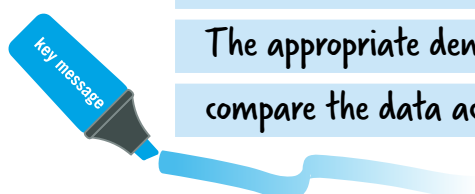
Measures of risk

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 they do not mean the same thing:

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

The denominator is very important in descriptive analysis.

The appropriate denominator helps the audience understand and compare the data across different groups/characteristics.





Statistical tests

A statistical test is performed so that we can make inferences concerning some unknown aspects of a statistical population from the sample that we have collected from a study. There are different types of statistical tests that we can use depending on the research questions, type of measurement scale and assumptions about data distribution. A Simple univariate and bivariate analyses should be done before a sophisticated analysis such as the multivariate analysis, is undertaken.

Finding association/correlation

Association is a relationship between two variables which are statistically dependent. The two variables are equivalent; there are no independent and dependent variables. Correlation can be considered as one type of association where the relationship between variables is linear. There are several statistical tests to assess the correlation between variables (Table 17).

Table 17: Different statistical tests for finding associations according to existing assumptions

Measurement scale	Assumption of distribution	Analysis
Nominal or Ordinal	-	Chi square test
Continuous or Ratio	Normally distributed Avoid outliers data	Pearson correlation
	Not normally distributed	Spearman rank correlation

Finding causality: group comparison

Group comparison analysis is used to explore the statistically significant difference of study outcomes between groups. The groups can be categorized by exposures under study. When there is a significant difference between groups we assume that the difference is due to the exposures (Table 18).

Table 18: Different statistical tests for group comparison according to the existing assumptions

Measurement scale	Assumption of distribution	Type of group	Analysis
Nominal or Ordinal	-	Independent	Chi square test
	-	Paired (before-after)	Sign test
Continuous or Ratio	Normally distributed	Independent	Independent t test
		Paired (before-after)	Paired t test
	Not normally distributed	Independent	Mann Whitney
		Paired	Wilcoxon

Finding causality: prediction

Regression analysis is the type of analysis used to predict study outcome from a number of independent variables. If the outcome variable is on a continuous or ratio scale and has a normal distribution of data, we can use linear regression. If the outcome variable is dichotomous i.e the variable has only two possible values such as “yes” or “no”, we can use logistic regression.

Qualitative data analysis

There are many traditions of qualitative research and it has been argued that there cannot and should not be a uniform approach to qualitative analysis methods (Bradley et al 2007).²² Similarly, there are few ‘agreed-on’ canons for qualitative data analysis, in the sense of shared ground rules for drawing conclusions and verifying sturdiness.²³ Many qualitative studies adopt an iterative strategy: collect some data, construct initial concepts and hypotheses, test against new data, revise concepts and hypotheses. This approach implies that data collection and analysis are embedded in a single process and are undertaken by the same individuals. However, with the increasing use of qualitative research in health research, objectives are often pre-defined prior to the start of data collection, as opposed to being developed as information for the data collected emerges.

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

- AtlasTi (<http://www.atlasti.com>) deals with large data sets, unstructured coding, and mimics paper code and sort functions.



- MAXQDA (<http://www.maxqda.com>) provides powerful tools for analysing interviews, reports, tables, online surveys, videos, audio files, images and bibliographical data sets.
- QSR NVivo (<http://www.qsrinternational.com>) (previously called Nud*ist 6) caters for unstructured coding, finds patterns/relationships in codes.
- EZ-TEXT 3.06C (<http://www.cdc.gov/hiv/topics/surveillance/resources/software/ez-text/index.htm>).

Researchers should feel free to use whatever analysis method (with or without software) they are comfortable with. Whatever approach is used, all qualitative analyses involve making sense of large amounts of data, identifying significant patterns and communicating the essence of what the data reveal.

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 the links that exist between them. As mentioned, there is no set formula for analysing qualitative data, but there are three core requirements of qualitative analysis to adhere to:

- A. Detailed description of techniques and methods used to select samples and generate data.
- B. Carefully specified analysis, paying attention to issues of validity and reliability.
- C. Triangulation with other data collection methods.

The following steps describe these three core components in more detail:

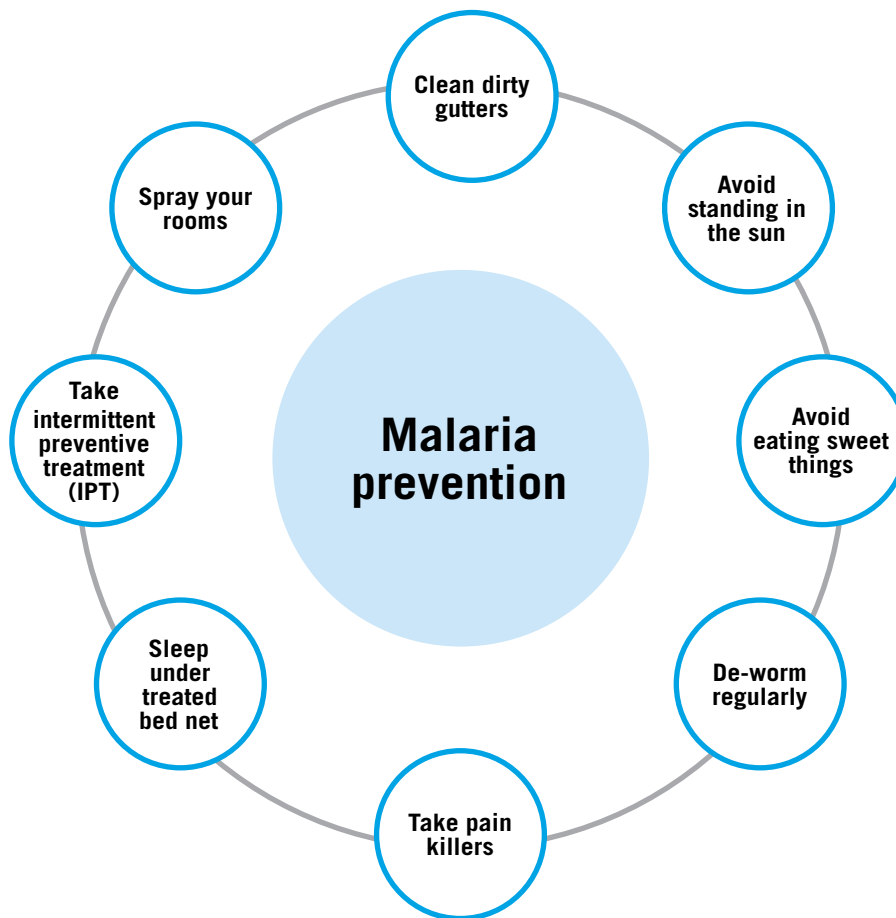
- A. Detailed description of techniques and methods used to select samples and generate data
 - If conducting interviews or focus group discussions, all sessions are recorded (preferably with a recording device, although where this is not accepted by the participants, with hand written notes).
 - All recordings have to be transcribed verbatim (i.e. typed out in full, word-for-word).
 - If observation has been done, document the times, locations and important events (e.g. interruptions, significant events, etc.)
 - All background information about the participants should be appended to each transcript.
- B. Carefully specified analysis, paying attention to issues of validity and reliability
 - 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).
 - While reading the data, the researchers should 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.²⁴ A list of these categories is compiled and attached to the data.

- 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 is grouped into categories and a list of the categories is 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.
- These categories are then given names. Category names may emerge from the researcher, from the participants or from the literature. According to Merriam (1998),²⁴ 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.
- 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.
- 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 participants' pseudonym, the date of data collection, and the page number.²⁵
- 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, a number of prevention themes emerged (Figure 7).



Figure 7. Diagram to describe reported methods of preventing malaria



C. Triangulation with other data collection methods

- Review your results against those collected using other data collection methods to determine the validity or truthfulness of your findings.
- Review if routine data sources confirm your findings.

Rigour in qualitative research

The research team must ensure scientific rigour in qualitative methods analysis. For example, will your study provide participants with a copy of their interview transcripts to give 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 (called inter-rater reliability)? Will you triangulate the data to increase the rigour? Will you report disconfirming evidence?

Validity and reliability in analysing qualitative research

In quantitative studies, reliability means repeatability and independence of findings from the specific researchers generating those findings. In qualitative research, reliability implies that given the data collected, the results are dependable and consistent.¹⁰ The strength of qualitative research lies in validity (closeness to 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. When analysing your qualitative data, look for internal validity, where an in-depth understanding will allow you to counter alternative explanations for your findings.

Analysis of textual material

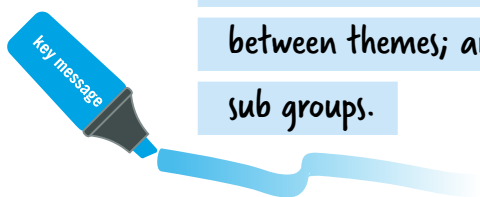
The basic process for the analysis of text derived from qualitative interviews or discussions is relatively straightforward and includes:

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

As far as possible, outputs of focus group discussions (FGDs) should be verbatim records. The notes taken by the recorder (a person) 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 differences between sub groups.





Domain/theme analysis

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

There are four stages in domain/theme analysis:

- A. Identify main issues raised by the interviewees – the domains /themes.
- B. Group more detailed topics within each of these domains to construct a taxonomy of sub-categories.
- C. Specify what was actually said and the components within each sub-category.
- D. Explore the of interrelationships between the various domains.

A. 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.

After listing the domains, 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.

Example²

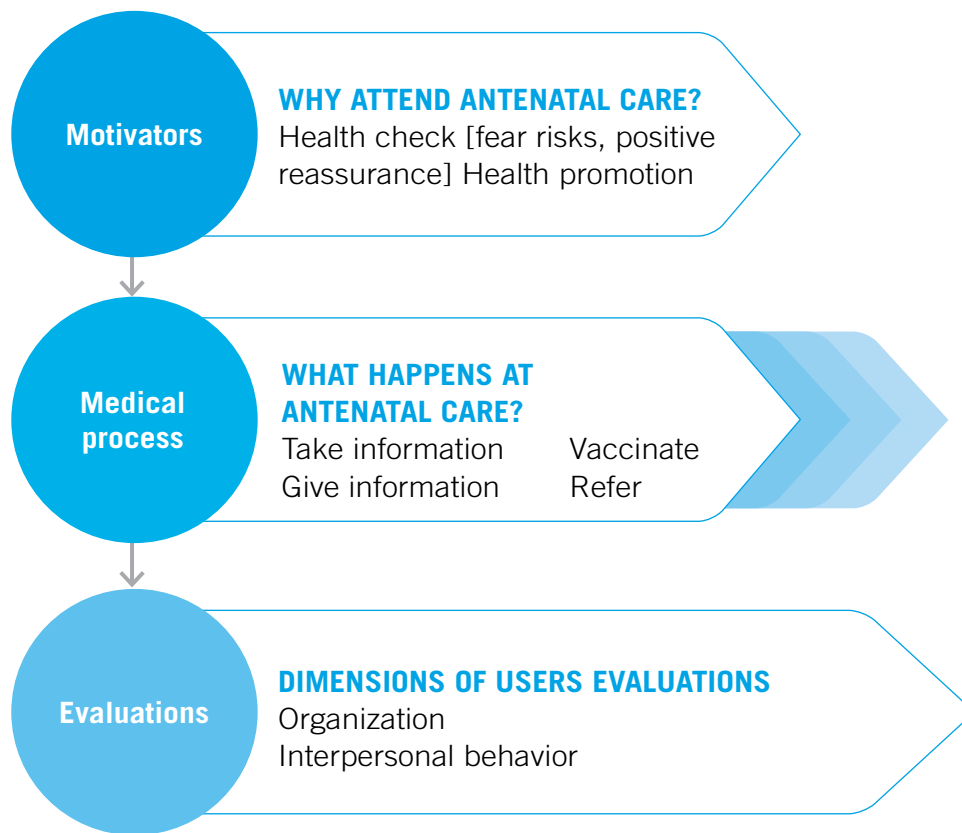
- **Getting and being pregnant:** Signs of pregnancy, danger signs, physical problems.
- **Feelings during pregnancy:** Anxiety, anger/fright, worries, embarrassment, inconvenience, impressions.
- **Family planning:** Methods.
- **Advice/activities to promote health:** Exercise, activities, smoking, 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.

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.

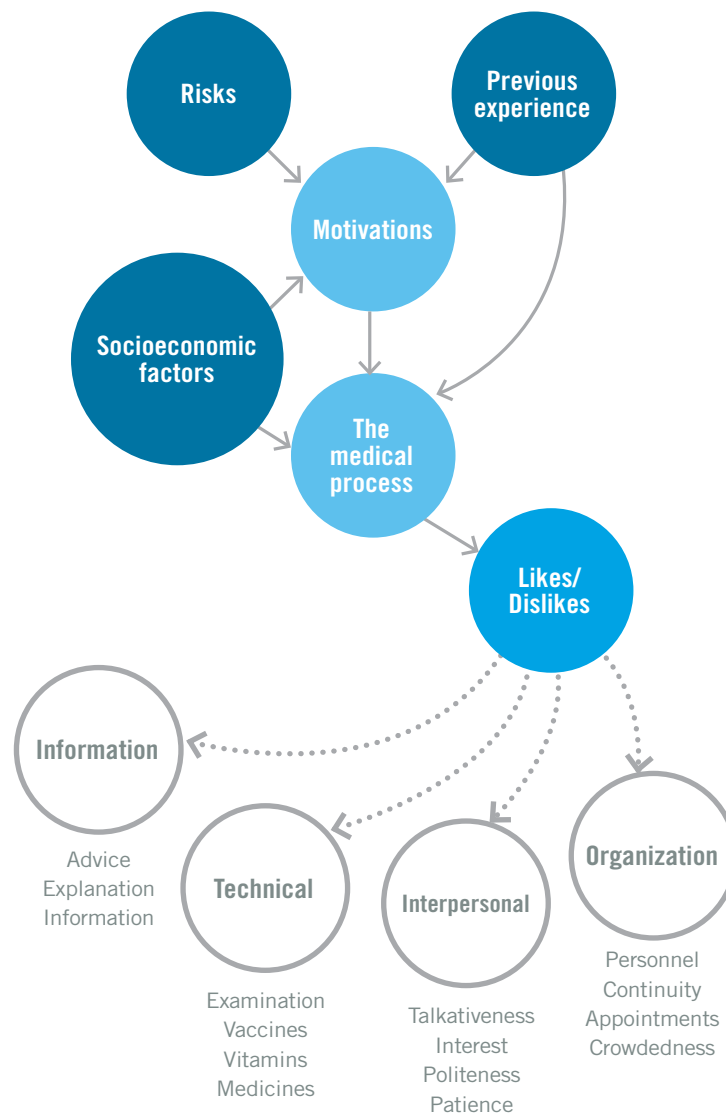
These domains are represented in Figure 8.

Figure 8. Taxonomy of sub-categories²



B. 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 and their evaluations of health services (Figure 9).

**Figure 9. Relationship between domains²**

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.²³ These codes are then assigned to specific occurrences of words or phrases, highlighting patterns within the text while preserving their context, as in Table 19.

Table 19: Matrix of perceived causes and signs of malaria

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

Description of qualitative data analysis

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.

Coding of focus group interviews, ethnographic field notes and interviews with health workers using Atlas-TI software will enable the analysis of emerging themes and presentation of data in the form of narratives or frequency tables.

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 with 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.



Mixed methods data analysis

In a mixed methods IR project, demonstrating 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.

Before beginning the analysis, consider how the mixed method study was designed. Refer to Table 7 on mixed methods approaches to review the order in which data was collected. This will guide the process indicating which data (qualitative or quantitative) should be analysed first.

One of the important aspects of mixed methods analysis is the capability in the presentation of these data to have the different methodologies 'speak' to each other. For example if the quantitative survey results show that 45% of mothers do not attend antenatal services, adding a direct quotation from a mother collected in a FGD will add a real-life and tangible element to this result.

Data presentation for your audience

When working through the analysis of the data collected in the IR project, it is important to remember who will receive the results of the research. This will determine how the research findings are presented. For example, if the results are disseminated in community meetings, it is important to use simple infographics and quotations or stories; in contrast during a workshop style meeting with high level policy-makers, more detailed information and numerical explanations will be required. This is dealt in more detail in the Communications and advocacy module of this Toolkit.

SEE
COMMUNICATION
& ADVOCACY
MODULE

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IMPLEMENTATION RESEARCH TOOLKIT



IR-Planning and Conducting IR

Edward Mberu Kamau and Robinah Najjemba

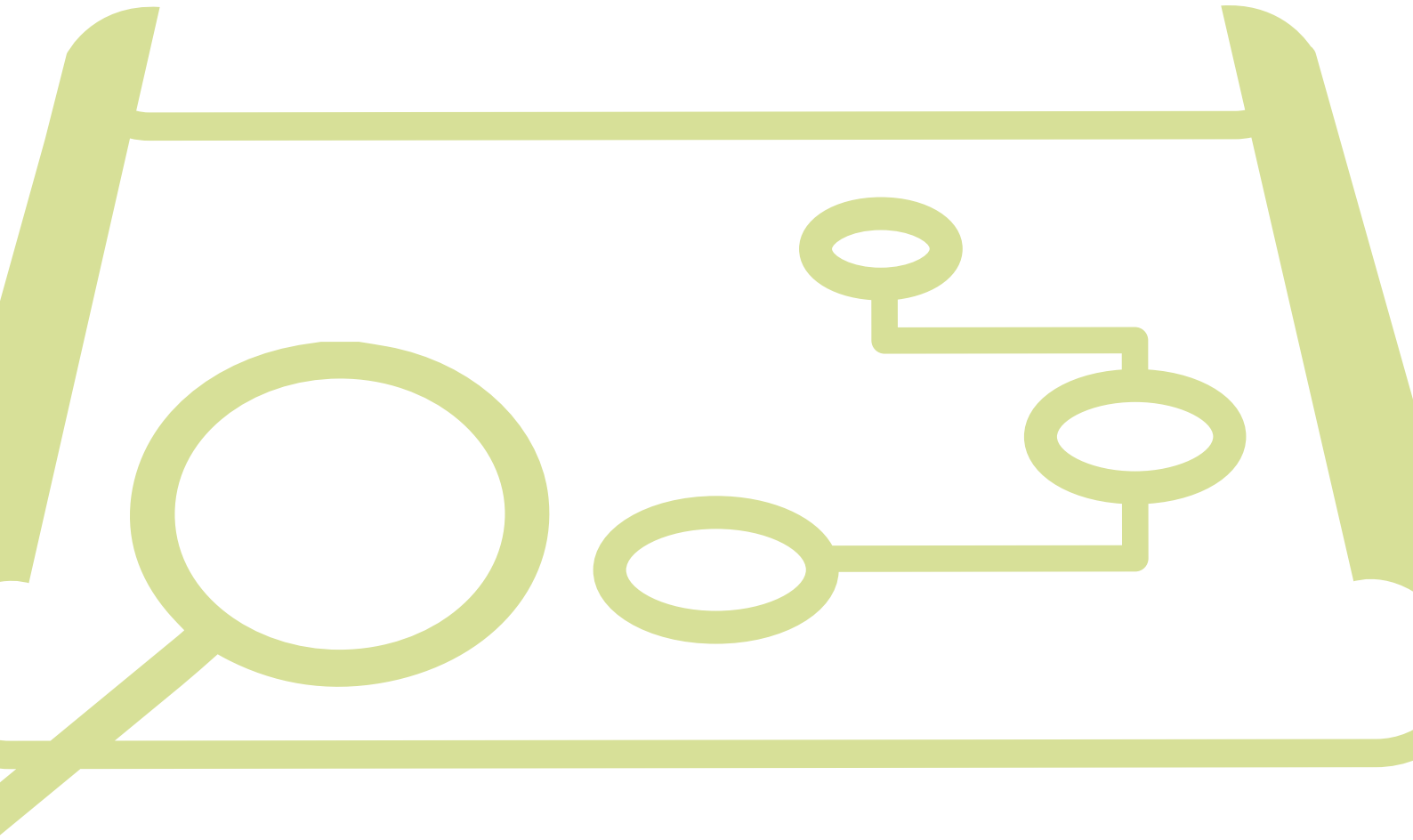


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IR-PLANNING AND CONDUCTING IR

The key to a successful implementation research project is good planning.

A project plan should be: rational, objective, justified, coordinated, team-driven as well as meet the expectations of stakeholders. In addition, it should have adequate resource allocation. The planning process, requires team work, clear project goals, deliverables and timelines in addition to supporting plans for: human resources, costing and budgets, monitoring and evaluation, communication, quality and risk management, as summarized in Table 1. The project plan must be as explicit as possible with enough information describing the processes and procedures including roles and responsibilities of the respective stakeholders. Before a project plan is implemented, a consensus on its major components must be reached with all stakeholders including sponsors.



The success of a project execution relies profoundly on the project plan, a competent and coordinated team and well-managed resources. The composition of the research team and details of budgeting are addressed in the Proposal development and Integrating IR into Health Systems modules.

SEE

**DEVELOPING
AN IR PROPOSAL**

It is also critical that while executing the research project, the project manager supports and monitors the execution of the other components of the project plans (i.e. human resources, budget, communications and the risk management plan) through interactions with the project team and stakeholders.

SEE

**INTEGRATING
IR INTO HEALTH
SYSTEM**

This module provides information on the activities involved in developing a project plan, and the steps taken once funding/resources for the IR protocol are secured. It covers the concepts of: (i) Project planning; (ii) Development of a monitoring plan for a research project; (iii) Project execution; (iv) Ethical issues in an IR project; and (v) Good practices in IR.

Table 1: Key plans and components of IR project planning

Plans	Components
Stakeholder map	Relevant stakeholders and research team, including respective roles and responsibilities.
Project scope	Project goal and objectives, coverage, target populations.
Project time lines	Work schedule, tasks, deadlines for activities, milestones and deliverables.
Resource management plan	Human resources, logistics, technical, finances.
Costing plan	Comprehensive budget for inputs and activities.
Quality management plan	Protocol review and approval, standard operating procedures (SOPs), project team training, tool and data validation, monitoring, report review.
Communication plan	Communication objectives, information needs of the stakeholders, types of knowledge products tailored for different audiences, target audience, communication tools, timing/frequency of communication.
Risk management plan	Threats to project objective & opportunities to improve.
Monitoring plan	Project objectives, Logic model, resources for monitoring, indicators, targets, data sources, data analysis and reporting system, on-going data dissemination and utilization.
Evaluation/Closure of project plan	Evaluation objectives, resources, project report (technical and financial).

Effective project plans have five primary characteristics, as follows:

- Describes a project process with a clearly defined beginning and end, a well-defined schedule of activities and milestones, and outlines the step-by-step approach that will be adopted.
- Allocates specific resources to distinct activities.
- Defines end results with specific implementation goals (e.g. in relation to time, cost, performance/quality).
- Demonstrates a planned and organized approach to the project implementation, and uses information generated from continuous monitoring to make planning adaptations.
- Development ideally involves and engages a broad team of people.



**A project plan is a consolidation of several sub-plans
and NOT just a typical project schedule.**

A project plan for IR is just like any other plan: A formal, approved document used to guide both project execution and control. Its primary uses are to document planning, assumptions and decisions, facilitate communication among project stakeholders and record approved scope, cost and schedule. It describes the research problem being addressed, activities and related deliverables, who is involved and their specific roles and responsibilities, project timelines, indicators and milestones. An effective project plan provides a very clear vision spanning what needs to be done and why, the standards to which it should be carried out, who will do it, how much it will cost and how those costs will be met.

Effective planning facilitates the ongoing strengthening of project focus and ensures consensus around a project development strategy and plan. It also helps to ensure ownership of the project, that all stakeholders understand who is doing what, when, and how each action impacts the project as a whole. Good planning enhances teamwork and transparency, facilitates project monitoring and identification of issues, and provides management and donors with key information for reviewing project progress.

**“Proper Planning and Preparation Prevent
Poor Performance” (Stephen Keague).**



The project plan establishes the scope of the project as well as appropriate timelines and budget to carry it out. It helps stakeholders to anticipate and/or identify potential barriers or constraints in adhering to the timetable, implementation and/or completion of the project. A project plan also facilitates communication between and among stakeholders, coordinates procedures, teamwork and collaboration.

Project plans are generally presented in four major phases: designing, planning, implementing and follow-up (see Table 2).

Table 2: Main activities associated with planning for a research project

Phase	Main activities
Designing the project	<ul style="list-style-type: none"> • Determine issues/problems to study and frame the research question(s). • Identify relevant stakeholders. • Identify funding sources and obtain support. • Develop a research protocol. • Obtain ethical clearance.
Planning	<ul style="list-style-type: none"> • Organize the research group and advisory committee. • Establish budget and financial management procedures. • Develop a monitoring plan. • Develop a dissemination plan. • Plan for capacity building and technical support.
Implementing	<ul style="list-style-type: none"> • Gain the approval of appropriate stakeholders to begin execution. • Pre-test all research tools. • Implement the new idea. • Ensure continuous monitoring of the implementation process. • Establish and maintain data management and quality control. • Communicate findings. • Explore with stakeholders' interpretations and recommendations arising from the research findings. • Monitor changes in the revised project.
Follow up	<ul style="list-style-type: none"> • Disseminate results and recommendations. • Document any changes in policy and/or guidelines that resulted from the research. • Consider ways of improving the project that can be tested through further research. • Project closure.

Project Planning

The process of developing a project plan should be systematic and must involve all team members and relevant stakeholders. The key steps are described below. Click on each heading for details.

Scope of the project

Establishing the scope of the project includes reviewing the project goal, objectives, study area, level of health system, target population and sample size, tasks and deliverables. By this time, you should have the research project protocol, an established research team and stakeholders plus the necessary resources including the required budget.

Project timelines

The project duration should realistically reflect the time needed to carry out each phase of the project plan. Be sure that the plan takes into account the time required for staff recruitment and logistics. The project timelines should outline:

- a description of the tasks to be performed;
- schedule and deadlines within tasks;
- people assigned to the tasks;
- 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 and as such, project planning must follow rigorous project management standards. There are commercial software packages such as the Microsoft Project, available to help prepare and monitor the implementation of a work plan.

Work plans/timelines are most effectively displayed in a graphic, table or spreadsheet. If done correctly, the timeline will help visually demonstrate the feasibility of the project. Ideally, the work plan should include clear details, identifying specific tasks and outlining when the activity will take place and responsibilities. Figures 1 and 2 show some of the formats project timelines can adopt. Choose the most appropriate style for your project.

Figure 1. IR Project timeline (example)

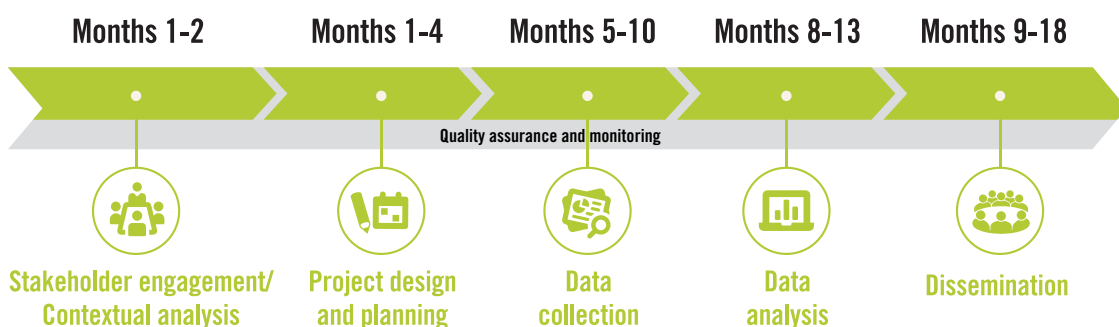




Figure 2. IR Project GANTT chart (example)





Resource management plan

A successful research project, requires adequate and well managed human, logistic, technical and financial resources. All resources should be mobilized prior to the execution of the project. Potential funding sources such as multilateral agencies, bilateral donors, private foundations and trusts, as well as in-country sources, are discussed in the Developing an IR Proposal Module.

SEE

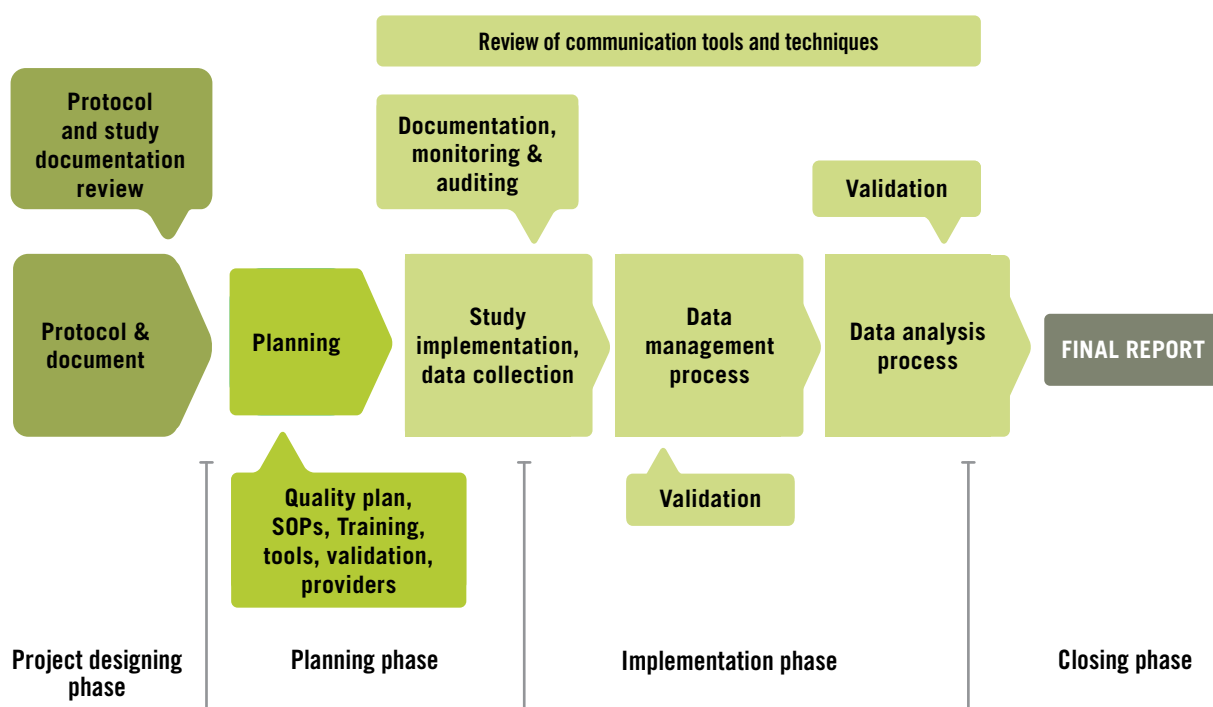
DEVELOPING AN
IR PROPOSAL
MODULE

It is advisable to conduct a detailed assessment of all resources required to accomplish the project goal(s). Human resources should be sufficient in terms of both number and experience/capacity. For each activity, requirements for equipment/materials should be established. Likewise, the financial requirements for each item – as well as the total cost to undertake each activity within the project plan – must be mapped out and budgeted in detail. In addition, management plans for human resources, logistics, and budget must be developed. Team members' technical capacities should match the identified tasks/requirements as closely as possible. In cases of a mismatch, efforts to enhance their capacity should be built into the project plan.

Quality management plan

Quality assurance is integral to all research activities and it is essential to embed quality management into your protocol/planning. Quality management is the responsibility of everyone engaged in the project and is essential to ensuring that the project meets or exceeds the applicable scientific, ethical and regulatory standards. The quality management plan should explicitly outline how your research team will take consistent, ongoing measures to monitor and evaluate quality and rigour of the research. It should indicate how you will evaluate quality at various stages. For example, if the project lasts more than one year, you may want to stipulate that you intend to have annual quality monitoring evaluations and reports. In order to facilitate rapid adjustments and corrections, the quality standard procedures should be communicated with all stakeholders. Quality management should also express a constant and consistent concern for research participants, such as how you will protect their privacy, and measures you will take to protect them from harm. Figure 3 provides a visual example of how continuous and consistent quality management activities can be ensured.

Figure 3. Activities to address quality issues in a research project



Some of the key activities you can integrate into your IR project to enhance its quality include:

- protocol review and approval;
- standard operating procedures (SOPs);
- 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.

Monitoring and evaluation strategies that can help to facilitate the quality of your research project include (see also Table 3):

- Information log to keep track of feedback from stakeholders, news stories published and articles written about the project, and the number of times research has been cited in the academic literature.
- Detailed documentation: Many of the observations made during the continuous monitoring of activities are contextual and critical to the interpretation of the results.

- A survey can be conducted with members of the target audience(s) in order to generate feedback. For example, questionnaires can be distributed using appropriate and affordable means.
- A series of key informant interviews with stakeholders at various levels of the health system can provide an insight into whether, and how the research was used.

Table 3: Descriptions of various quality management strategies

Strategy	Description
Protocol review and approval	Research rigour consistency includes stipulating how you will protect the rights and welfare of research participants. Protocols may also be established to ensure approval consistency and diligence in data and collection procedures (standardized instruments, consistent interview protocols); as well as checklists and established protocols to ensure consistency and rigour of data analysis across sites/among researchers.
Standard operating procedures	A principal investigator must put protocols in place to establish rigour and consistency between and among researchers and research sites. This may include standardized 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 is essential to research subject/participant safety, protocol implementation, and quality assurance and improvement. 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 is still being collected, and also to identify biases in the data collection that might be adjusted at a later date.

Strategy	Description continue
Evaluation of services provided by the project	Monitoring and evaluation of service provision is essential for analyzing and, where 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 service provider performance	Generating and using information on the performance of service providers can lead to the 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 analyze, reflect and take action. Community scorecards envisage the 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 a timely manner to provide all the researchers and appropriate stakeholders with sufficient opportunity to read, react to, provide feedback on, edit, revise, and provide input into relevant reports. Various formats will be required for different review platforms (e.g. Powerpoint presentations and/or narratives).

Risk management plan

Project risks include both threats to the project's objectives and opportunities to improve on those objectives. Risk management is a systematic process of anticipating, identifying, analysing and responding to project risks/threats, and should be considered throughout the project lifecycle. A risk management plan describes the process of risk identification, analysis, response planning, how monitoring and control will be structured and performed during the project.

Risks should be prioritized according to the level of potential impact on the project. The tools and techniques for risk identification include document review, information gathering techniques such as brainstorming, interviewing and strengths, weaknesses, opportunities and threats (SWOT) analyses, etc.¹

Some examples of risks in a research project are:

Poor data quality.

- Lack of resource commitment.
- Unexpected budget cuts.
- Loss of some research team members before completion of the tasks.
- No stakeholder inputs.
- Poor communication within the team.
- Key pieces of equipment break down.
- Inadequate team training.

Table 4 outlines some of the approaches that can be adopted to mitigate risks in a research project.

Table 4: Mitigation activities for risks in a research project

Risk mitigation approach	
Poor data quality	<ul style="list-style-type: none"> • Pilot testing/pre-testing. • Review data frequently. • Training.
Loss of staff	<ul style="list-style-type: none"> • A contingency plan. • Training of other project staff.
Equipment break down	<ul style="list-style-type: none"> • Maintenance/inventory of spare parts. • Identify alternative sources.

Monitoring plan

Project monitoring is not only important to identify implementation challenges, but also to take account of gaps identified during execution and make project plan modifications accordingly. Taking time to monitor project progress allows researchers and other stakeholders to systematically and thoughtfully compare progress made with agreed milestones, and to make any necessary adjustments. The monitoring plan outlines how project activities are to be tracked, and links strategic information from various data collection systems to ongoing decisions about how to improve the project. The monitoring plan also helps with standardization and coordination, making procedures more transparent and helping keep implementation on track.

Although monitoring and evaluation (M&E) activities are important components of IR, you should be cognizant that M&E and IR are not equivalent.² While most M&E plans provide a guide for monitoring an entire project, the monitoring plan in this context is intended to monitor only the processes involved in the implementation of the research and not health outcomes. Whereas an IR project is often part of a health programme – and includes wan M&E system itself – researchers should

make an effort to develop a monitoring plan tailored specifically to measure the immediate implementation outcomes of the project. The process of developing a monitoring plan is described in detail in the following section.



“What Gets Measured – Gets Done”.

Communications and advocacy plan

The direct aim of project-focused communications and advocacy is to ensure that the right information is communicated to the right audience, with a clear rationale, and in a timely fashion. The overall goals are to promote ownership and engagement in the research by key stakeholders, and ultimately to help promote and facilitate uptake of research results into related policies and programmes.

Before you develop a communications and advocacy plan, you should have clear project objectives, as well as a clear understanding of the information needs of various stakeholders. The communication plan presents the communication goals, tools, timings and audiences. The primary target audience are the direct beneficiaries of the information, while the secondary audience are the direct influencers of the primary target audience. To help facilitate uptake of your research findings, your plan should indicate how you intend to inform all stakeholders of your research findings at specific stages of the research. The process of developing a communication plan is described in more detail in the Communications and advocacy module of this toolkit.

IR RELATED
COMMUNI-
CATION AND
ADVOCACY

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Table 5 demonstrates an outline of a communication and advocacy plan for a project providing circumcision as an HIV prevention strategy and Table 6 demonstrates an example of a secondary target audience for the same project.

Primary and secondary target audiences

An intervention to promote safe circumcision for HIV prevention had a goal of encouraging men to come forward for circumcision. The primary audience was uncircumcised men at risk of HIV infection; the secondary audiences included health workers, opinion leaders, and female sexual partners. In this setting/context, each audience required its own targeted communications plan.

However, the same intervention also had a goal of mobilizing policy-makers to incorporate circumcision policies into the existing national health policy framework. In this context, ministry of health officials and legislatures, plus other opinion leaders, also constituted a primary audience.

Table 5: Illustration of a communication and advocacy plan for primary audience

Communication objective	Primary audience	Communication strategy	Dissemination tools	Timeline	Resources	Responsible person
Persuade men to go for safe medical circumcision	Men	Sensitization workshops	Pamphlets, Drama skits, Change champions	3 months	Health workers, Community mobilizers, Funds	Project communication officer
Seek support of policy-makers to incorporate male circumcision into the post-natal care services	Policy makers	Seminar	Policy brief	9 months	Principal investigator Program researchers funds	Principal Investigator

Table 6: Illustration of a communication plan for secondary audience

Communication strategy	Secondary audience	Communication strategy	Dissemination tools	Timeline	Resources	Responsible person
Seek support of opinion leaders to support medical circumcision in their communities	Opinion leaders	Sensitization campaigns	Change champions Videos	3 months	Health officers, films, funds	Project communication officer
Persuade men to seek safe medical circumcision	Sexual partners	Partner-counseling	Pamphlets	6 months	Counsellors, Rooms for privacy, funds	Project counsellor



REFLECTION ACTIVITY

Using a similar format to Tables 5 and 6, develop a communication plan for the primary and secondary target audiences of your research project.

Evaluation plan

The evaluation plan demonstrates how the research objectives will be met. It also indicates how you intend to keep close track of changes in the project plan and problems encountered and (not) solved, so you can inform the stakeholders and include this information in all preliminary/intermediate reports. An evaluation plan also serves the following purposes: (i) identifies who will use the evaluation findings; (ii) describes information needed, sources and evaluation methods/instruments used; (iii) examines how the project objectives will be met; (iv) tracks the expected impact of the intervention; and (v) demonstrates that the scope of the evaluation is appropriate.

Research teams often hire consultants to conduct project evaluations and the associated cost is about 10% of total budget. In your plan, indicate whether the evaluation will be conducted by an internal team member or an external consultant. Furthermore, the evaluation plan should include a sense of concern for what will happen following the conclusion of the funding period. For example, how will the initiatives started under the project be sustained? How will other cooperating agencies assist in continuing the project after the conclusion of the funding period?



Case study 1 Planning an IR project, its execution and quality assurance measures

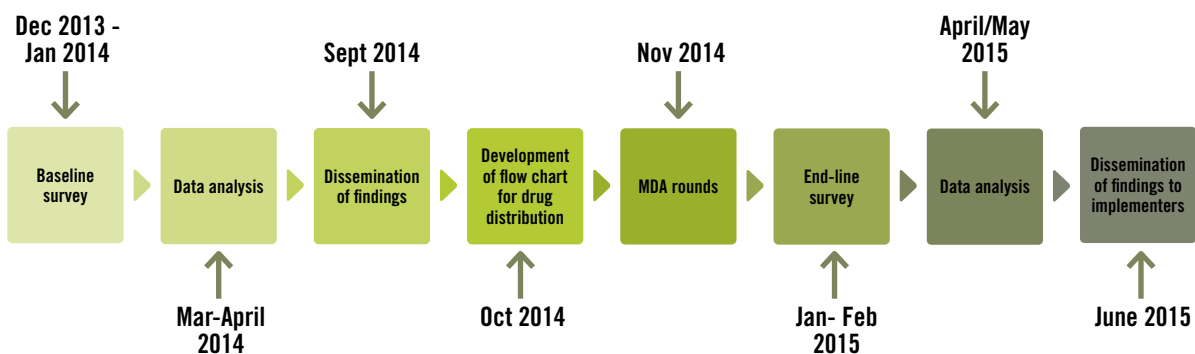
Background: Indonesia began its national lymphatic filariasis (LF) elimination programme in 2002, including conducting an annual mass drug administration (MDA) in endemic regions. By 2014, some regions had conducted at least five rounds of effective MDA and thus would qualify for Transmission Assessment Surveys (TAS) to determine if MDA could be halted. In the Agam District, despite multiple MDA rounds, drug coverage was insufficient and persistent LF transmission was observed. In Depok City, the programme could not qualify for TAS because of insufficient drug coverage for multiple MDA rounds. The reasons for the insufficient coverage in Depok City and the presence of ongoing LF transmission in Agam District were not understood. It was against this background that researchers sought to increase their understanding of how to guide and assist these areas to implement additional MDA rounds beyond the 4–6 rounds initially suggested by the programme. This was done through the development of a novel survey designed to collect short stories about people's direct experiences with MDA for LF.

Planning phase: Working with the programme implementers, the research team developed a study tool to establish the factors that might be responsible for the sub-optimal coverage in the two study sites. Through a collaborative process, research themes were identified, a project implementation plan was developed and data collection tools were designed. This process involved regular communication with the district health teams to ascertain important dates for the enumerator training, community surveys, MDA awareness activities and the dates for MDA itself. Before surveys were conducted, the research team sought ethical approval from the Faculty of Health at the Universitas Indonesia for the research in both study sites.

Execution phase: The project was implemented in three phases: A first (baseline) phase where data was collected, analyzed and interpreted and feasible recommendations shared among the stakeholders before the next MDA. The second phase (execution) involved adopting MDA using the recommendations based on the baseline survey findings. These recommendations were used to develop a flow chart to aid those carrying out drug distribution. The third phase (evaluation) involved another round of data collection (end-line survey) to assess the changes that may have occurred as a consequence of the baseline survey recommendations. The figure shows the timelines for project execution.

Case study 1 Planning an IR project, its execution and quality assurance measures

Figure. Execution timeline for the overall project



Quality assurance:

To ensure quality of data:

- questionnaires were pre-tested with a cohort of individuals in Depok City prior to data collection;
- data collectors were trained on the survey methodology;
- all questionnaires were administered by trained enumerators;
- supervisors checked completed questionnaires at the end of each day;
- the same sampling frame and methodology were used in both baseline and end-line surveys;
- data was double entered (using Epi-Info);
- data was checked for response bias, range and consistency.

Conclusion: Through the collaborative process described, researchers and implementers developed a valid and effective tool that was able to detect operational issues within MDA programmes. They were also able to draw up an effective implementation plan.

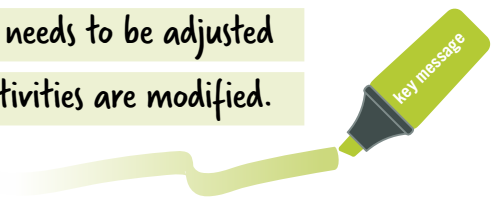
Lessons: Planning requires team work and close collaboration between programme implementers and researchers. This close collaboration enables research activities to be aligned with programme activities. Quality must also be maintained throughout the life cycle of the project.

Source: Krentel A. et al. Improving coverage and compliance in Mass Drug Administration for the Elimination of LF in Two 'Endgame' Districts in Indonesia Using Micronarrative Surveys. PLoS Neglected Tropical Diseases. 2016; 10 (11): e0005027.

Project Monitoring Plan

IR takes place in complex environments. As a result, project execution does not always proceed as planned. This makes development of a monitoring plan all the more important for IR projects. As with the development of the overall project plan, developing a monitoring plan should be as iterative and participatory as possible. It should take into consideration the information needs of all stakeholders. You should be mindful of the project objectives and the assumptions that underpin its success or failure.

A monitoring plan is a 'living document' that needs to be adjusted whenever project activities are modified.



The monitoring plan should be developed in a transparent way so that all team members/stakeholders are aware of the plan, and also understand their respective roles and responsibilities. An effective monitoring plan must guard against any potential errors in practice, and conform to several related standards:

- *Utility*: It must be useful and serve the practical and strategic information needs of the intended users for action, these may range from assessing project performance to allocating resources, etc.
- *Feasibility*: It must be realistic and practical. Given the scarcity of resources, the 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 be carefully considered.
- *Ethics*: Monitoring involves data collection, storage, analysis and communicating information about participants. The entire process should therefore abide by ethical principles with regard to those involved in and/or affected by the monitoring activities.
- *Accuracy*: Data should measure what it is intended to measure and the monitoring plan should provide technically accurate and useful information for decision-making and project improvement.

The key components on which the monitoring plan must be built are:

- *Scope of the monitoring*: specifying the project goals and developing the conceptual framework that integrates inputs, activities, outputs and outcomes.
- *Methodological approach*: describing the methodology, indicators, data sources and analysis plan.
- *Implementation plan*: describing roles and responsibilities and timelines for monitoring activities.
- *Dissemination plan and use of results*: describing the dissemination strategy including feedback to relevant stakeholders.

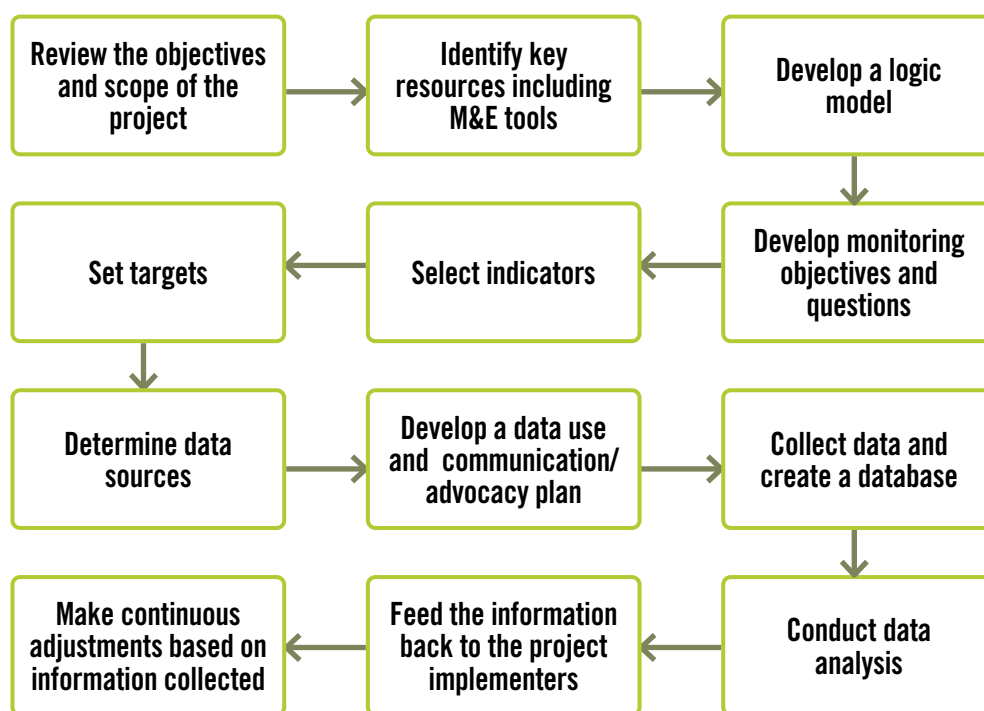
A set of useful key questions can help guide effective monitoring:

- What information is needed and what are the sources?
- Who should be involved in the monitoring?
- When should the monitoring be conducted?
- What is its communication strategy and data use?

Key steps in developing a project monitoring plan

Before you develop a monitoring plan, you must define the overall project goal and objectives, the context in which the project is operating and the key stakeholders. Sufficient resources and technical capacity to conduct the proposed monitoring activities and realistic timelines also need to be established. Since monitoring activities involve data collection from, or about human subjects, ethical principles must be observed throughout the entire process, and should be an integral part of the original protocol. Figure 4, summarizes 13 key steps for consideration when developing a monitoring plan. However, note that these steps are not necessarily independent of each other and may substantially overlap.

Figure 4. Key steps in developing a monitoring plan for an IR project



Reviewing the objectives and scope of the project

The review of project objectives and how their success can be defined helps the generation of a road map for monitoring the activities. The monitoring plan must consider the key activities, target audience(s), primary monitoring activities and realistic timelines. The scope of the project refers to: i) coverage/geographical area; ii) level of health system at which the project is being implemented (e.g.

health facility, community); iii) target population; and iv) stakeholders. Table 7 illustrates the objectives and scope of a research project that aimed to improve polio vaccination coverage in a county of Nigeria, through mobilizing state and local government authorities in a grass roots mobilization campaign ‘Majigi’, a road- side film show conducted in communities through mobile vans.³

Table 7: Objectives and scope of a research project (example)

Objectives	
Main objective	To improve polio vaccination coverage through the mobilization of state and local government authorities.
Specific objectives	To actively engage traditional, religious and political leaders at all levels in sensitization and mobilization activities.
Project scope	
Geographic area	Gezawa local council in Kano state, Nigeria.
Level of health system	<ul style="list-style-type: none"> • Health facility • Community level
Target population	<ul style="list-style-type: none"> • Opinion leaders • Community gate keepers
Key stakeholders	<ul style="list-style-type: none"> • Ministry of Health • Opinion leaders • Community gate keepers: <ul style="list-style-type: none"> • political leaders • traditional leaders • religious leaders • traditional healers • birth attendants • traditional surgeons
Key activities for the project and time lines	<ul style="list-style-type: none"> • Grass roots mobilization • Grass roots campaign ‘Majigi’ • Monitoring of monthly supplemental regular vaccination activities • Documentation of cumulative uptake in each settlement for 6 months
Monitoring description	
Monitoring activities and time lines	<ul style="list-style-type: none"> • Monitoring of polio vaccine uptake for the subsequent 6 months. • Documentation of the number vaccinated at each site. • Documentation of the number of children who never received polio vaccination.



Case study 2

Importance of continuous monitoring of the national scale up of zinc treatment for childhood diarrhoea (Bangladesh)

Background: Diarrhoeal diseases are still one of the major causes of childhood morbidity and mortality, especially in low- and middle-income countries. Clinical trials show that zinc, as part of a treatment for childhood diarrhoea, not only helps to reduce the severity and duration of diarrhoea but also reduces the likelihood of a repeat episode in the future. In 2004, the WHO/UNICEF revised their clinical management of childhood diarrhoea guidelines to include zinc.

The “Scaling Up of Zinc for Young Children” (SUZY) project was established in Bangladesh in 2003 to provide zinc treatment for diarrhoea in all children under the age of five. The project was supported by public, private and nongovernmental organizations, as well as multinational agencies. The scale-up campaign included production and distribution of zinc tablets, training of health professionals to provide zinc treatment and creation of media campaigns (TV and radio) to raise awareness and promote the use of zinc for diarrhoea treatment. To establish the effectiveness and success of the national campaign, and to highlight any potential problems during the implementation of health care initiatives in areas with deprived health systems, four survey sites were set up to monitor results from the first two years of the SUZY campaign. Each of the survey areas represented a different segment of the population across Bangladesh: urban slums, urban non-slums, municipal (small city) and rural settings. The study population across these sites was approximately 1.5 million children under the age of five years. At each site, seven surveys were conducted between September 2006 and October 2008. During each survey, about 3200 children with diarrhoea were studied from randomly selected households.

Findings: At baseline, awareness of zinc treatment was less than 10% in all communities. 10 months later, this peaked at 90%, 74%, 66%, and 50% in urban non-slum, municipal, urban slum, and rural sites, respectively. After 23 months, only 25% of urban non-slum, 20% of municipal and urban slum, and 10% of rural children under the age of five were using zinc for treatment of childhood diarrhoea. Use of zinc was shown to be safe, with few side-effects, and did not affect the use of traditional treatments. However, many children were not given the correct ten-day course of treatment and 50% of parents were sold seven or fewer zinc tablets. The findings further showed that although the first national campaign to promote zinc treatment for childhood diarrhoea in Bangladesh generated some success, the high awareness of zinc did not translate into high use. The scale-up campaign did not have any adverse effect on the use of oral rehydration salts (ORS). However, there were disparities in zinc coverage favouring higher income, urban households.

Conclusions: The study identified areas where more work was needed to ensure higher levels of coverage. For example, there was a need to link mass media messages with information from health care providers to help reinforce and promote understanding of the use of zinc. A change in focus of media messages from awareness to promoting household decision-making aided the adoption of zinc treatment for childhood diarrhoea and improved adherence.

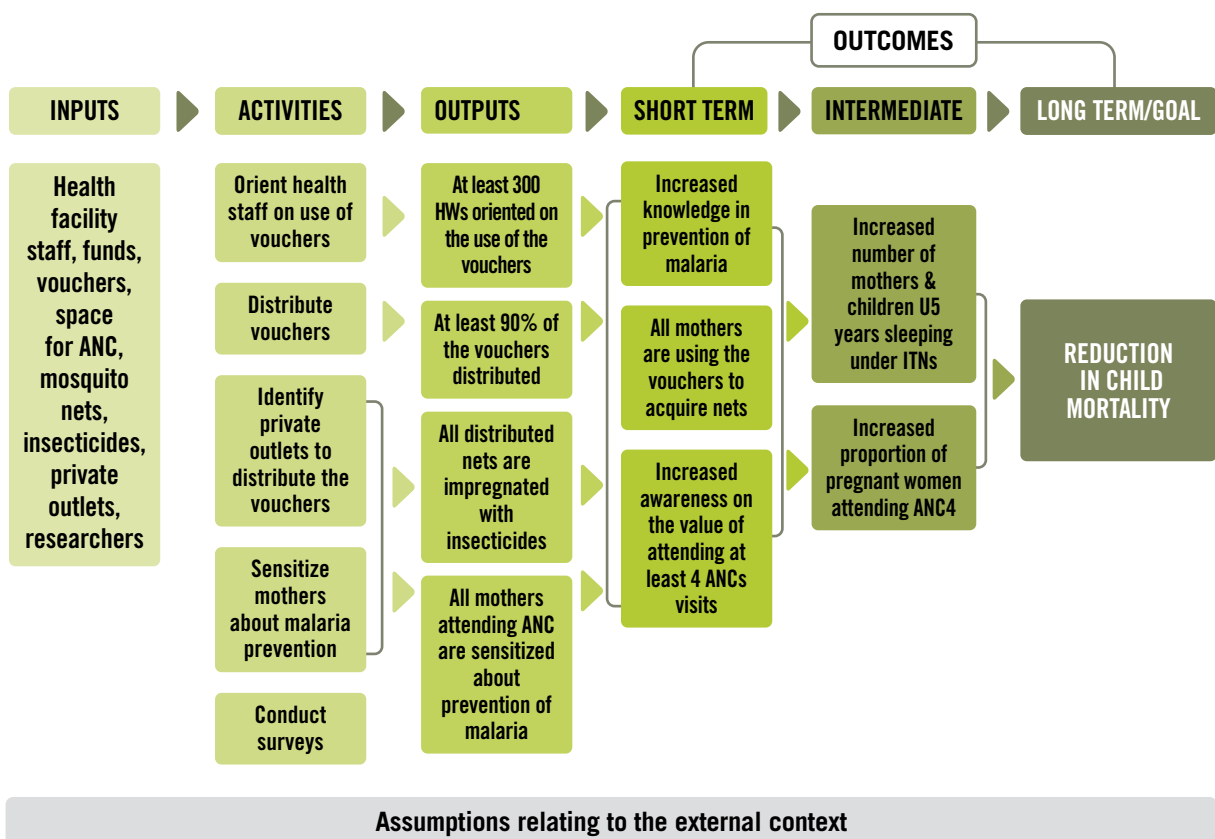
Lessons: Long-term monitoring of scale-up programmes can identify important gaps in coverage and provide the necessary information about both intended and unintended outcomes, which consequently guides further decision-making.

Source: Larson C.P., Saha U.R., and Nazrul H. Impact monitoring of the national scale up of zinc treatment for childhood diarrhoea in Bangladesh: repeat ecologic surveys. *PLoS Medicine*. 2009; 6(11):e1000175.

Developing a logic model

The logic model (sometimes referred to as the conceptual framework) links the project goal and objectives to the project parameters. It provides a reference for why the monitoring exercise is being done and what it intends to accomplish. The guiding parameters to develop the logic model are as follows: i) Defining the intervention, coverage, and target population. This helps the team to focus its monitoring efforts and provides an ‘anchor’ for the identification of required resources and processes; ii) Specifying the expected achievements (i.e. outputs and immediate outcomes); and iii) Defining the timeline (for the implementation of the project, not the monitoring exercise). However, you should be aware that a ‘linear’ description of a complex problem/approach may restrict flexibility and continual improvement if not updated during implementation. Figure 5, shows the different levels of a logic model for a research project in Tanzania where pregnant mothers attending antenatal care used vouchers to redeem mosquito nets from private outlets.⁴

Figure 5. Logic model of a research project





Definitions

Outcomes: The ultimate effects or changes anticipated as a consequence of the project:

- **Long-term/Goal(s):** The higher-level objectives the project is expected to achieve and/or contribute to. These may be beyond the scope of the project (e.g. reduced infant mortality rate).
- **Intermediate outcomes:** Changes in behaviour, actions, practice. Often only visible some time after project implementation (e.g. increased: use of treated mosquito nets, utilization of immunization services).
- **Short-term outcomes:** Immediate results/consequences of project outputs (e.g. increased knowledge, awareness, motivation (e.g. use of immunization services)

Outputs: Observations/parameters that can be directly influenced by the project, and for which the research/implementation team are responsible (e.g. improved access to immunization).

Activities: Specific actions/undertakings that will be performed as part of the project, in order to produce the intended outputs (e.g. training, developing brochures, training, survey, sensitization etc.).

Inputs: Key resources needed to support the project (e.g. personnel, equipment, funding).

Assumptions

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

- 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 specific relevance in relation to potential for replicating, scaling up or relocating the intervention in question. Some key questions to help improve the assumptions you document might include the following:

- 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?
- During the course of the project, are any assumptions proven to be incorrect?

**REFLECTION ACTIVITY**

Develop a logic model, describing each of the following for your IR project:

- **Inputs.**
- **Activities.**
- **Outputs.**
- **Outcomes.**
- **Assumptions.**

Developing Monitoring Questions

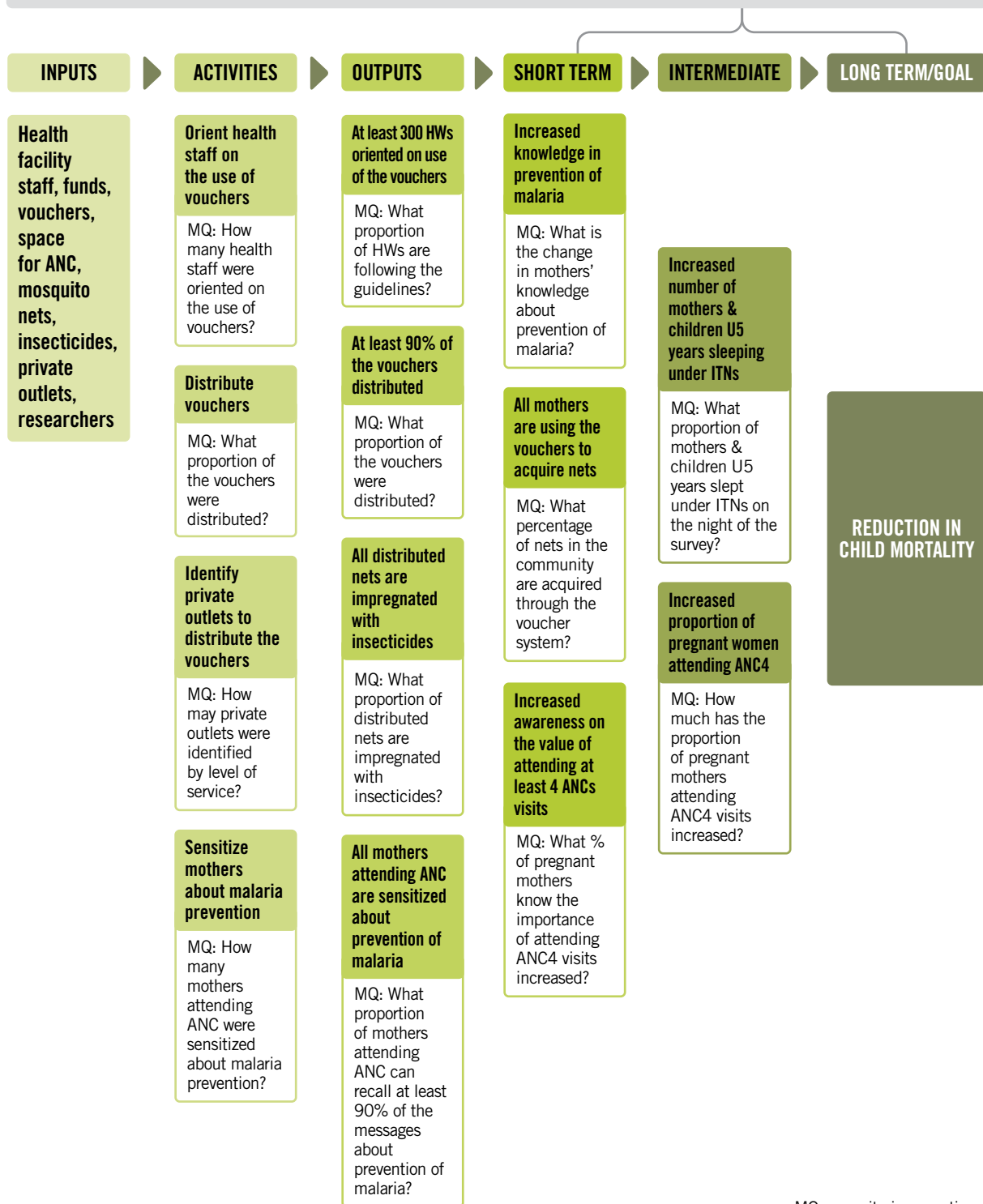
Monitoring objectives and questions help you to objectively assess whether the project is progressing according to the agreed time lines, budget and quality criteria. The monitoring objective is the overall purpose of conducting monitoring activities. This should be specific, realistic and within the specified period/scope of the project. Use the project logic model as a guide to identify relevant monitoring objectives and questions at the various levels of the model. Figure 6, illustrates some of the monitoring questions (by logic model level) for a project with the goal of reducing child mortality through the distribution of treated mosquito nets to pregnant woman using a voucher system in a public–private partnership in Tanzania (as mentioned in the Developing a logic model section).

Identify the resources to implement the monitoring plan

The development and implementation of the monitoring plan requires sufficient human and financial resources, as well as information management systems. It is recommended that you assess available resources for the coordination of activities, data collection, quality management, analysis and dissemination of information before commencing of any monitoring activities. However, given typical resource constraints, it is generally wise to take advantage of readily available resources for M&E such as indicator guides, M&E materials and communication tools rather than developing new ones to implement the project monitoring plan.

Figure 6. Example of monitoring

Monitoring objective: To determine the use of vouchers by pregnant mothers to claim mosquito nets from private outlets, by the end of 1 year



MQ = monitoring question

**REFLECTION ACTIVITY**

Add relevant and specific monitoring questions to the logic framework you already developed for your project in the previous section.

Selection of key indicators

One of the essential steps in developing a monitoring plan is to translate research objectives into variables that can be readily and objectively measured. These should be defined prior to the commencement of the project implementation and comprise a blend of those that focus both on processes and outcomes. They should be based on the research question and objectives of the project and their rationale should be based on the logic model and information needs of decision-makers. The indicators should be relevant, accurate, feasible, distinctive, useful, and consistent with international/national standards. Selection of suitable indicators is iterative and participatory, and should involve relevant stakeholders. It is helpful to develop an indicator matrix, summarizing the indicators in the monitoring plan. Table 8 describes, data sources for the indicators at various levels of the logic model.

Table 8: Indicator matrix (example)

Level in the logic model	Monitoring Question Indicator	Data	Source
Inputs			
• Vouchers	How many vouchers were purchased?	Number of vouchers purchased.	Project records
• Mosquito nets	How many mosquito nets were purchased?	Number of mosquito nets purchased.	Project records
Activities			
• Orienting health staff	How many health staff were oriented on the use of vouchers?	Proportion of health staff oriented.	Activity log
• Distribution of vouchers	What proportion of vouchers were distributed?		Project records
• Identify private outlets to distribute mosquito nets	How many private outlets were identified?	Proportion of private outlets were selected by level of service?	Project records survey
• Sensitize women attending ANC about malaria prevention	How many women attending ANC were sensitized about malaria prevention?	Number of mothers attending ANC that were sensitized about malaria prevention.	Exit interviews
• Conduct surveys	Were the surveys conducted as planned?	Number of surveys conducted.	Project records
Outputs			
• 300 health staff oriented on use of vouchers	What proportion of oriented staff are following guidelines when distributing vouchers?	Percentage of health staff following guidelines.	Health facility survey
• At least 90% of the vouchers distributed	What proportion of vouchers are distributed?	Percentage of vouchers distributed.	Project records
• All distributed nets are impregnated with insecticides	What proportion of distributed nets are impregnated with insecticides?	Number of distributed nets that are impregnated with insecticides.	Survey project records

Level in the logic model	Monitoring Question Indicator	Data	Source
Outcomes	Has community knowledge about preventing malaria improved?	Percentage of the community with knowledge about preventing malaria.	Survey
Short term (Immediate)			
<ul style="list-style-type: none"> Increased knowledge about malaria prevention 	What is the change in mothers' knowledge in preventive measures of malaria?	Levels of knowledge compared to baseline.	Exit interviews
<ul style="list-style-type: none"> 90% of nets are purchased through the voucher system 	What proportion/number of the nets are acquired through the voucher system?	Proportion/number of nets acquired through the voucher system.	Survey, Facility survey
<ul style="list-style-type: none"> Increased knowledge on the value of attending at least 4 ANC visits 	What proportion of pregnant mothers understand the importance of attending at least 4 ANCs visits?	Proportion of pregnant women attending at least four antenatal visits.	Survey
Intermediate (1-2 years)			
<ul style="list-style-type: none"> Increased number of mothers and children sleeping under bed nets 	What is the coverage of mosquito nets in the community?	Proportion of mothers and under-5 children sleeping under mosquito nets.	Survey
Increased number of mothers attending at least 4 ANC visits	By how much has the proportion of mothers attending at least 4 ANCs visits changed?	Proportion/number of pregnant women making 4 or more ANC visits.	Survey

SMART questions and indicators facilitate monitoring.





Setting targets

Target setting is a critical part of M&E planning. In order to determine variance (the percentage of target reached), it is necessary to not only measure the indicator but pre-determine a target for that indicator. Targets 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 or whether it may be essential to adjust the implementation or timeframe. Targets should be realistic, but they should also be challenging enough to encourage staff and stakeholders to think about the potential achievements within the project life cycle. Factors for consideration when setting targets include: Baseline levels; past trends; expert opinions; research findings; what has been achieved elsewhere; client expectations; the capacity and logistics to achieve targets. The targets set at the time of protocol development – which may have been based on secondary data information – may be refined after baseline values are collected. Furthermore, the targets may continue to change during the implementation, due to external influences beyond the researchers' control. In all cases, any modifications to targets should be communicated to stakeholders and any changes made should follow proper procedures and approval.

Establishing data sources, analysis and reporting systems

In order to make evidence-based decisions, decision-makers require information from various sources. Despite many potential sources of data for monitoring, these may not be sufficiently comprehensive or appropriate to inform an IR project, particularly given contextual considerations. The data may also be collected from several different levels within the health system, depending upon the specific objectives of the project. Data existing sources and data collection tools might include: Service statistics; administrative or programme records; geographical information systems; facility assessments; qualitative interviews; observations; and questionnaires/surveys.

In general terms, the monitoring of the implementation process should be relatively quick and simple, with larger and more costly data collection reserved for measuring outcomes or impact. The power of qualitative data should also not be overlooked. In establishing the primary targets' perceptions and experiences from the project, success stories, key lessons and experiences from stakeholders, photographs can be valuable complements to facts and figures, filling data gaps and providing insight and understanding into the statistics. Generally, monitoring the process may require using different data sources other than what is often used for monitoring project outcomes (See Table 8).

The frequency of data collection should be sufficient to support management decisions, but not so frequent to over-burden team members. Furthermore, the same data sources should be used to measure indicators throughout the monitoring cycle.

Examples of data collection for project monitoring purposes include:

- Review of routinely collected data (e.g. HMIS) (example number of malaria treatments among children under the age of five).
- New data collected to monitor the project implementation (e.g. interviews with health workers involved in a project to provide counselling to mothers with sick children under the age of 5).
- Review of data collected specifically for the IR project (e.g. focus group discussions with traditional healers in malaria treatment and referred to health centres for children under the age of 5).

A monitoring system should be able to link data collection, its analysis and usage. It must also systematically and reliably store, manage and access the M&E data. Thus, the monitoring plan should have a detailed data analysis component indicating how the results will be analysed and presented. This procedure requires critical review of the resources for data analysis and storage. For effective decision-making, data management should be timely, secure, and in a format that is practical and user-friendly.

Figure 7. A light-hearted look at overdoing the monitoring system⁵



only monitor and evaluate what is necessary and sufficient
for project management and accountability.

key message

Data Use and Reporting

Although the ultimate aim of monitoring is to enhance the effectiveness of the implementation process, the findings from monitoring efforts should not be squandered or misused. Data should be processed appropriately and subsequently shared both within the project team and with other stakeholders. The information should be tailored to the specific stakeholders' interests and needs so it can be fed back into the project in a timely fashion to support decision-making and project adjustments.

Effective use of data/information depends on recipients' decisions about when and how to put it to use. Strategies such as holding stakeholder dialogues, management action plans/meetings, decision and action logs can all be adopted to enhance knowledge uptake and the eventual utilization for action. The timing of data/information dissemination has a significant bearing on its uptake, and so the most conducive frequency and opportunities for data reporting should be identified. Table 9 illustrates data use and reporting plan for the mosquito nets project example.

REFLECTION ACTIVITY

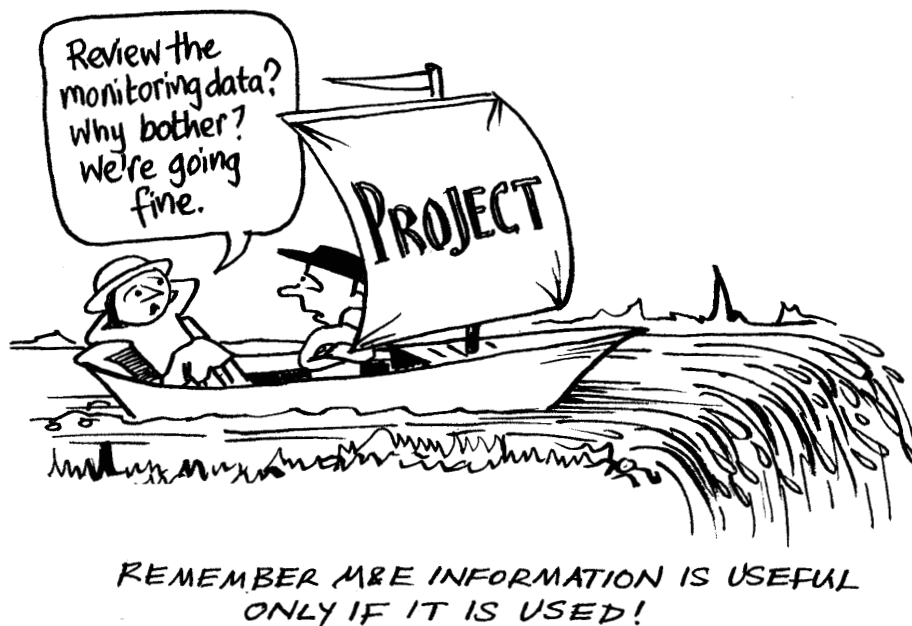


Develop a monitoring plan matrix for your research project. Include monitoring questions, indicators, data sources, data collection methods, how the findings will be disseminated, the target audience(s) for the respective findings and how these findings will be used.

Table 9: Illustration of data use and reporting plan

Indicator	Responsible person	Who will collect the data?	How will the finding be presented?	How will findings be disseminated?	Target audiences	Use
Proportion of vouchers redeemed	M&E officer	PI and research team	Research reports	Meetings	Ministry staff and private outlet owners	Adjust according to results
Proportion of pregnant mothers sleeping under mosquito nets	M&E officer	PI and research team	Bar charts	Community Meetings	Community leaders and mothers	Enhance sensitization campaigns

Figure 8. The importance of using and acting upon M&E data



Project Execution

Execution of the research project involves both conducting and monitoring the proposed activities, as well as updating and revising the project plan according to emerging lessons and/or conditions. The activities include assembling the research team(s), applying for the logistical needs and allocation of tasks. The choice of research sites, the timeline for each research activity, and the procedures for the data collection must all be well established. The project execution phase should also include the closure and evaluation of the project, as well as reporting and disseminating the processes and findings of the research.

As already emphasised in his module, the project monitoring process should take place continuously throughout the research project. Similarly, regular and effective communication among the team members is crucial throughout the entire process. The research team should meet on a regular basis to discuss project progress and any potential issues and solutions as they emerge. The following section covers the process of starting project execution and monitoring the project.

Starting execution of a research project

Once the project work plans are complete, agreed upon by all involved parties and approved by relevant management groups and ethical committees, the execution of the research project can begin. It is recommended that the entire research team (including stakeholders, partners and front-line workers) participate in the launching of the project. Their involvement enhances ownership and promotes accountability. During the launch, the team members can, once again, review the project goal, objectives, indicators and work plans. They may also address any remaining potentially contentious issues and set up mechanisms for

communication and conflict resolution, to help enhance teamwork during the execution phase. The team leader must ensure that work begins on time and the agreed standards of performance are followed within the approved budget limits. Related details of developing a budget are discussed in the Proposal development module.

Case study 3 Analysis of constraints and facilitators of project execution

Background: Execution of IR projects encounter numerous potential constraints, particularly in resource-limited settings. Therefore, it is essential that such constraints are identified before research commences. Several frameworks and guidelines have been developed to help identify specific constraints and facilitators at the various levels of project execution. One such framework, developed by Gericke and colleagues, can be applied to a wide range of interventions to help identify potential constraints to project execution. The framework describes: (i) Intervention characteristics (e.g. product design, supplies and equipment); (ii) Delivery characteristics (e.g. facilities, human resources, communications and transport); (iii) Government capacity (e.g. regulation, management systems, collaborative action); and (iv) Usage characteristics (e.g. easy to use, pre-existing demand and black market risks). This framework – with an additional category to address private sector capacity (e.g. manufacturing, marketing, health care providers, households) – was used to establish the constraints and facilitators to the success of the scale up of zinc treatment for childhood diarrhoea in Bangladesh. These constraints and some facilitators found to influence the zinc project scale up are summarized in the table below.

Table. Summary of constraints and facilitators influencing the scale up of zinc treatment for childhood diarrhoea in Bangladesh

Category	Criteria	Intervention status	Level of constraint
1. Intervention characteristics			
1.1 Product design	Stability	<ul style="list-style-type: none"> Stable under conditions of high humidity and temperatures for up to 3 years in aluminium-PVC blister packs 	Low
	Easy of storage	<ul style="list-style-type: none"> No special requirements 	Low
1.2 Supplies	Supply needs	<ul style="list-style-type: none"> Must maintain a filled pipeline with regularly scheduled re-supply of retail outlets or health care facilities under conditions of uncertain product demand 	Moderate
1.3 Equipment	Technology equipment	<ul style="list-style-type: none"> No high technology equipment or infrastructure needed Households require a spoon or small container 	Low
2. Delivery characteristics			
2.1 Facilities	Retail sector levels	<ul style="list-style-type: none"> Feasible, given an existing distribution system is in place Feasible at all facility levels of care and in homes 	Low

Case study 3 Analysis of constraints and facilitators of project execution

Category	Criteria	Intervention status	Level of constraint
2.2 Human resources	Knowledge	<ul style="list-style-type: none"> Requires provider orientation and training, aided by a frequently asked questions repository with standardized responses 	Moderate
	Professional services	<ul style="list-style-type: none"> Requires individuals skilled in monitoring and in maintaining product supplies 	Moderate
2.3 Communications and transport	Infrastructure	<ul style="list-style-type: none"> Requires a product promotion and distribution infrastructure that reaches retail outlets and supplies health facilities 	Moderate
3. Government capacity			
3.1 Regulation/legislation	Regulation	<ul style="list-style-type: none"> Several regulatory considerations: e.g.: <ul style="list-style-type: none"> registration of the zinc tablet formulation registration/approval of product branding and packaging over-the-counter sales approval or waiver approval for mass media advertising 	Low
3.2 Management systems	Monitoring	<ul style="list-style-type: none"> Capacity required to effectively monitor the quality of the zinc products available over the counter 	Moderate
3.3 Collaborative action	Inter-sectoral	<ul style="list-style-type: none"> Must be able to maintain equitable, socially responsive pricing that reaches the poor 	Moderate
	External funding	<ul style="list-style-type: none"> If a high demand for zinc occurs in the government sector, the purchase of zinc will require external funding (unless passed on to the consumer) 	Moderate
4. Private sector capacity			
4.1 Manufacturing	Production	<ul style="list-style-type: none"> Requires a pharmaceutical laboratory that can maintain good manufacturing practices (GMP) certification, preferably in-country 	Moderate
	Distribution	<ul style="list-style-type: none"> Distribution systems that reach drug and general retail outlets required 	Moderate
4.2 Marketing	Communication networks	<ul style="list-style-type: none"> Widespread access to mass media networks (TV, radio), especially among poor and rural households, is needed 	Moderate
	Expertise	<ul style="list-style-type: none"> Requires professional skills in preparing and delivering marketing messages that target households at greatest risk (urban slums and rural poor) 	Moderate



Case study 3 Analysis of constraints and facilitators of project execution

Category	Criteria	Intervention status	Level of constraint
4.3 Health care providers	Regulation/ continuing education	<ul style="list-style-type: none"> The vast majority of health providers in Bangladesh are not licensed and are poorly regulated, but are represented by special interest groups that can organize continuing education Primary source of information is through private sector medical representatives (drug salesmen) 	Moderate
	Access	<ul style="list-style-type: none"> Easy access and widespread availability of unregulated providers at little cost 	Low
4.4 Households	<ul style="list-style-type: none"> Cost Health seeking Demands Expenditure 	<ul style="list-style-type: none"> Licensed private providers limited to urban settings Caregivers overwhelmingly seek help in the private sector Consumers demand and expect a curative treatment If burden to pay for zinc is passed onto households, then likely not to reach many of the poorest households 	Moderate

5. Usage characteristics

5.1 Ease of use	Information	<ul style="list-style-type: none"> Zinc as a treatment for childhood diarrhoea will be universally unknown to caretakers and most providers, thus requiring comprehensive education of providers and caretaker orientation Caretaker adherence with instructions regarding preparation is high (98%), but to duration given is low (<50%) 	High
5.2 Pre-existing demand	Need for promotion	<ul style="list-style-type: none"> This is a largely unknown intervention, therefore requiring large-scale provider and mass media promotion 	Moderate
5.3 Black market risks	Resale/ counterfeiting	<ul style="list-style-type: none"> If product is provided free of charge in public sector facilities, then risk of resale exists (MOHFW supplied blister packs are labelled 'not for sale') The dispersible tablet formulation can be counterfeited, with lower quality products jeopardizing the reputation of the intervention 	Low

Lessons: The various categories of constraints to project execution should be identified before research takes place in order to devise mitigation measures for a comprehensive execution plan.

Source: Larson C.P., Koelmoos T.P. and Sack DA,. Scaling Up of Zinc for Young Children (SUZY) Project Team. Scaling up zinc treatment of childhood diarrhoea in Bangladesh: theoretical and practical considerations guiding the SUZY Project. Health policy and planning. 2012; 27(2):102–14.

Monitoring Research Activities

As soon as you begin executing the research project, start using your monitoring plan. As monitoring measures progress and establishes any deviance from the project plan, it is imperative that baseline indicators are established prior to the start of the project. These are used as reference points to gauge progress towards the goal and objectives and also to measure the level and direction of any change. Monitoring activities include data collection, analysis, interpretation, dissemination and use of data for decision making (Figure 9). Furthermore, the research project should be monitored for timeliness, cost effectiveness and quality (Figure 10).

Figure 9. Monitoring activities of a project

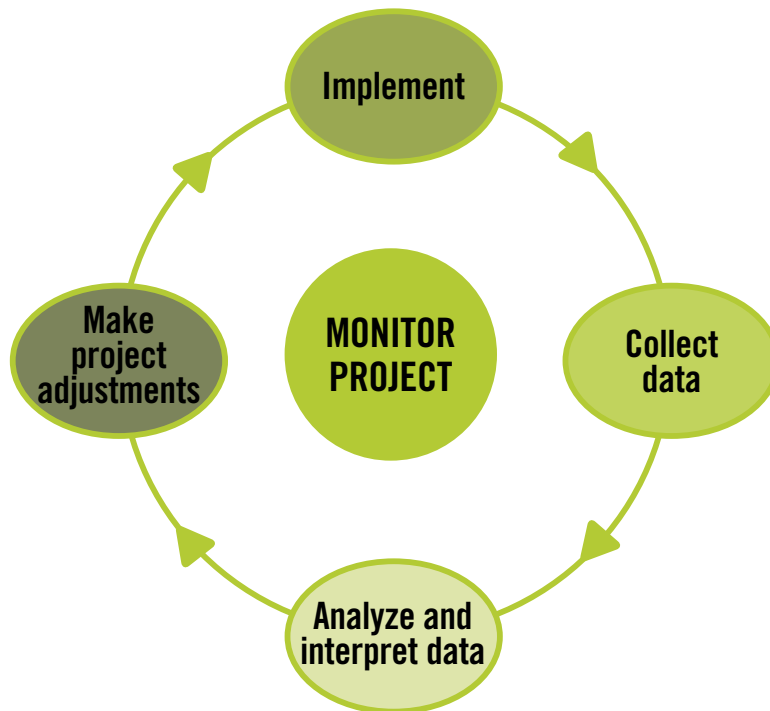


Figure 10. Parameters to monitor in a project



The monitoring process 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. Click on each of the headings to see details.

Checking and measuring progress

Ideally, monitoring focuses on the three main characteristics of any project: quality, time and cost. The team leader coordinates the project team and should always be aware of the status of the project. When checking and measuring progress, the team leader should communicate with all team members to assess whether planned activities are implemented on time and within the agreed quality standards and budget. The achievement of milestones should be measured as the information will reflect the progress of the project.

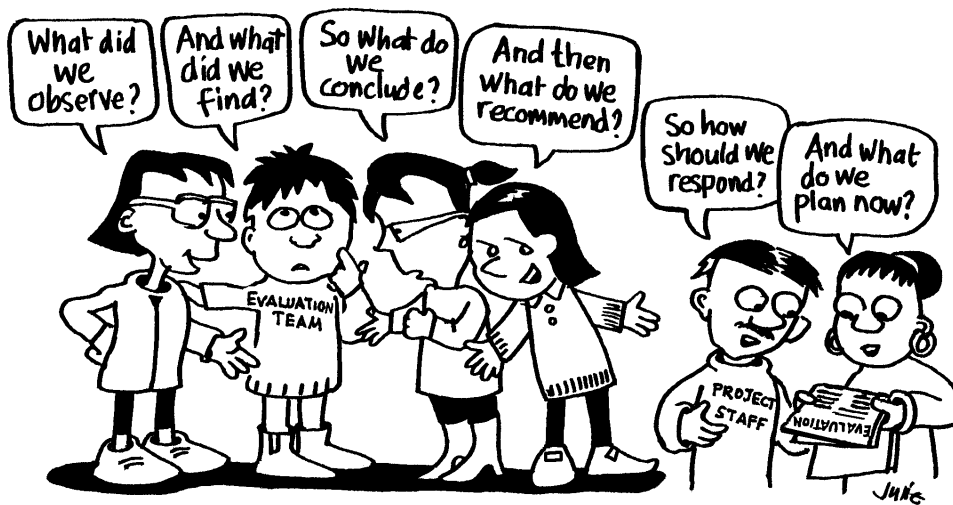
Analyzing the situation

The second stage of monitoring consists of analyzing the situation. The status of project progress compared to the original plan – as well as causes and impacts of potential/observed deviations – are identified and analyzed. Actions are identified to address the causes and the impacts.

Below are examples of questions that can help your research team analyze progress of your research project.

- Are project activities progressing as planned?
- Are the monitoring questions being answered sufficiently?
- Are there any outside factors (political, environmental) that are affecting the execution process?
- Are appropriate resources including staff still available to implement the monitoring activities?
- Are monitoring findings being disseminated and used by stakeholders for decision-making and project improvement?

Figure 11. analyzing causes and impacts of deviations from the project plan



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 should be considered and discussed within the project team and a decision taken regarding the most appropriate action to take.

Collecting data is a waste of resources unless it is analyzed, interpreted and acted upon to make project adjustments.



Updating the project monitoring plan

The monitoring plan should be seen as a dynamic document that continuously reflects the reality of what is known and understood. Each time a deviation from the original plan is identified – regardless of whether or not it requires any further action – the plan should be revised and changes documented accordingly. The revised plan should reflect the new situation and also demonstrate the potential impact of the deviation on the whole research project.

For effective execution, good communication is essential across the research team, donors and all stakeholders. Ongoing adaptation of the plan also facilitates management of the project finances. The entire project team and other key stakeholders should be involved in updating the plan, revising the work plan (including costs) and decision-making should all be meticulously documented. The revised plan should be circulated to all stakeholders including the relevant Ethics Review Committees/Boards as well as the Institutional Review Board(s), highlighting the changes and their potential impact on the project. The research team must obtain approval for project plan amendments from all relevant parties.

Evaluation and closure of a research project

The decision as to whether a final end-of-project evaluation of the research project will be conducted depends on the objectives of the project and the timeframe. Evaluation can be either formative or summative in nature:

- *Formative evaluation* is intended to improve performance and is mostly conducted during the design and/or execution phases of the projects.
- *Summative evaluation* is conducted at the end of an intervention to determine the extent to which the anticipated outcomes were produced.

In IR projects, formative evaluation is conducted most. The processes for evaluation should be determined during the planning phase of the project, and about 10% of the project budget allocated accordingly. Evaluation can be conducted internally by the project team or independently by external evaluators. Once the project is completed it should be formally closed, including final technical and financial reports, written and submitted to stakeholders and to donors (as required). The final technical report should be distributed to the research team members and all other stakeholders.



Every Project has a beginning and an end.



Ethical Issues

Like all research involving human subjects (participants), IR should protect participants' rights, dignity and safety. By adhering to ethical norms, IR promotes scientific integrity and helps to ensure that researchers are accountable to the public. Furthermore, since IR involves a great deal of cooperation and coordination among many stakeholders, rigorous ethical standards to promote collaborative working are essential. IR should strictly follow the principle of autonomy to allow participants to participate voluntarily without any coercion and their privacy should be protected by observing confidentiality and anonymity. However, researchers should be cognizant that IR presents a unique ethical perspective as it involves – in most cases – multiple stakeholders and interfaces with health system and/or care services. In light of this, IR researchers may find differentiating between routine health care and the research process challenging. If the lines are not clear between research and routine activities, it may be difficult to identify potential risks associated with the research, especially in participatory research.

The established ethical principles such as autonomy/respect for research participants, risk/beneficence, and justice should be adhered to throughout the project life cycle, and these are outlined in the following section. Click on each of the headings below to explore each of the ethical principles.

Ethical challenges associated with the review of IR protocols

As part of IR project planning and research implementation, ethical considerations likely to be of concern to Institutional Review Board(s) (IRBs)/Ethics Review Committee(s) (ERCs) must be anticipated, identified and possible solutions clearly articulated. Even though the majority of ethical challenges for IR projects will be context specific, there are some generic issues associated with IR. This includes the need to make a very clear distinction between what is done under routine care and what is being proposed as components of the research study. This is often difficult since IR is conducted within the health system and is expected to provide direct feedback and utilization of the research findings. This distinction also highlights the importance of providing detailed information and justification for the involvement (if any) of health care personnel in IR-related activities.

Another challenge often encountered during the review of IR protocols is the general lack of IR expertise among most IRB/ERC panels. In addition, the protocol review tools/forms (guidelines) are generally designed to assess the quality of more 'mainstream' biomedical and clinical research. When such guidelines are used for IR protocols, the outcome may be unfavourable: not necessarily due to quality of proposals, but as a result of inappropriate assessment.

The other most common limitation is failure on the part of the research team to explain sample size calculation for qualitative (or mixed methods) research. This drawback is closely related to the multidisciplinary, and at times, inter-sectorial nature of IR protocols. Delays in the review of such protocols can be minimized by starting with less complex studies and sensitizing ERC/IRC members on the methodologies and

expected outcomes applicable in IR. To address these challenges, efforts must be made by the research team to develop research protocols that identify and propose solutions to ethical issues well before submission to IRB/ERC. It is also prudent for research ethics committees to expand their membership to include key IR expertise in the review panels. In some settings, IRBs have established a parallel review panel and tools for assessing the quality of IR related protocols. Examples of the ethical challenges associated with IR protocols submitted for ethical review are illustrated in table 10.

Table 10: Examples of comments from an Ethics Review Committee on an IR protocol

General comment: The committee considered this an interesting study that may help optimize current preventive approaches and improve the clinical algorithm for cystic echinococcosis (CE) in the country.	
Specific comments: Requires response and protocol amendments	
1. Protocol	
1.1	Please provide an amended proposal specifying the version number and/or date on each page.
1.2	It is understood from the protocol that only adults will be included in the study and that for the collection of information on paediatric patients, their parents/caregivers (above the age of 18) will be asked to take part in the interview. Please specify the actions that the study team will take in cases where the parent/caregiver of the child is below the age of 18 (e.g. will another family member above 18 be asked to take part in the interview? Will information on that child not be collected? etc.).
1.3	According to the protocol, women have more exposure to domestic animals and are therefore at higher risk of CE. In order to ensure that the risks and benefits of the study are fairly distributed in the population:
1.3.1	Please describe the steps that the research team will take to promote adequate representation of women among the 50 patients that will participate in the interviews per province.
1.3.2	Please explain how the sample size of 50 was determined.
1.3.3	Please specify whether gender-based analysis on the data obtained will be applied in order to inform the development of gender-sensitive CE control programmes in the future.
1.4	Please specify the measures that researchers will take cases where interviewed patients have not yet received adequate care and treatment of CE.
1.5	In terms of data confidentiality:
1.5.1	As per the protocol, “an in-depth assessment in five provincial hospitals to register newly diagnosed cases” will be conducted. Please specify whether researchers will be given access to this data or whether health personnel whose daily activities relate to clinical record management will extract this information, anonymize it and thereafter provide it to the study team.

General comment: The committee considered this an interesting study that may help optimize current preventive approaches and improve the clinical algorithm for cystic echinococcosis (CE) in the country.

Specific comments: Requires response and protocol amendments

1.5.2	Please specify where data collected in the study will be stored, who will have access to it and when it will be destroyed.
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2. Informed Consent Forms

2.1	The consent documents use technical words that may not be understood by lay people (e.g. CE, zoonosis, ultrasonographic imaging, etc.). These terms should be defined and/or replaced so that prospective participants can fully understand the study.
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2.2	Consent form for patient-based survey:
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2.2.1	Under the section Participant Selection, please explicitly state that if the patient is a minor, then the interview will be conducted with her/his parents/caregivers.
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2.2.2	The consent form should reflect that children may be indirectly included in the study. For example, the sentence: “I consent voluntarily to be a participant in this study” could be replaced by: “I consent voluntarily to be a participant in this study [and to respond to the interview regarding my health or that of my child]”.
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Seeking ethical clearance prior to project execution

Research funding agencies require the approval of research protocols by the appropriate ethics review committees 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 the case of collaborative projects. The ethics committee(s) will review the study protocol and require full details of the study plan and procedures. The committee(s) will pay particular attention to how consent will be obtained from prospective study participants, and carefully scrutinize all informed consent documents. 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. As a result, any changes in the study, during the project life cycle 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 the research study right from the initial planning stage of the project to closure.



Submission of the research protocol for ethical review

This section provides information on the preparation for submission of the study protocol for ethical review. The ethics review process is essential to ensure that the research project will protect research subjects'/participants' dignity, rights, safety and well-being. Therefore, before initiating a study, written ethical approval of the protocol should be obtained from the appropriate IRBs/ERCs. The team should search from appropriate resources (e.g. institutional websites) to establish the submission requirements, the IRB review process as well as what is involved or the next steps required once the initial ethical approval has been granted. It is the team leader/principal investigator's responsibility to ensure that the protocol is submitted and also to ensure compliance with the study protocol as agreed by the sponsor and regulatory authority (if appropriate), and as approved by the scientific and ethical committees.

Table 11 outlines the documents generally required to be submitted to ERCs. The researcher should be cognizant that requirements may vary between committees. It is important to check the specific documentation and protocol requirements with the ethics committee(s) to whom you are applying.

Table 11: Some documents to be submitted to ERCs

Cover letter briefly describing the research protocol and ethical issues involved, if any.

Full research protocol including rationale, research problem, literature review, methodology, data collection tools, procedures, budget and expected outcomes.

Analysis of potential risks and benefits, including protection of privacy and confidentiality.

Detailed human subject/participant 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 team leader/principal investigator and the other research team members.

Proposed dissemination of the study results.



Ethical practices during the execution of an IR project

The ethical principles of autonomy, risk/beneficence and justice must be observed during the execution of the research project. This section discusses issues regarding seeking informed consent, privacy and confidentiality and ethical issues during project execution.

Seeking informed consent

Informed consent (IC) is recognized as a fundamental ethical requirement for conducting research involving human subjects.⁶ Informed consent ensures that individuals can freely make decisions to participate according to personal interest, values and priorities. IC is more than a contractual obligation and should be understood as a process that begins with the initial contact with the research participant (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: i) Provision of accurate and appropriate information; ii) Participant's ability to understand the purpose of the procedures in the research process; iii) participant's capacity to consent; and iv) voluntary participation and withdrawal.

To have effective informed consent, the full information should be explained in the 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, the procedure, expected outcomes and potential benefits as well as the consent certificate (see Table 12).

Table 12: Elements in an informed consent document

Part 1: Information sheet
Introduction of the team leader/principal investigator and his/her institution.
Purpose of the research.
Type of research intervention.
Participant selection.
Voluntary participation.
Procedures (interview, focus group discussions (FGD), where interviews 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 present particular challenges to confidentiality, because once something is said in the group, it becomes common knowledge, and can be linked to a person).
Sharing of research results (process that will be used to share the research results) with all stakeholders.
Right to refuse or withdraw.
Who to contact (e.g. for any additional information or in case of complaints).
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 the information 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 and date the consent form.
The researcher or person going over the informed consent must sign and date each consent form.

Privacy, confidentiality and 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. Research participants should have the right to remain anonymous and to have their rights to privacy and confidentiality respected. Protecting the privacy and confidentiality of participants is the investigator's responsibility.⁷ Protecting the anonymity and confidentiality of research participants involves adhering to ethical procedures during data collection, storage and analysis, as well as, during any subsequent 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 others without the participant's explicit permission. Unless the respondent gives their permission, at no time should the identity of the respondent be disclosed to any third party during data collection, storage or analysis, or even during dissemination or publication. The identity of the respondents may be associated with anonymous identifiers that cannot be linked to individuals. However, the standard of being anonymous throughout the lifecycle of the study may be a challenge, for example in situations where participants are measured at multiple time points (pre- and post-study) or where content of different databases (e.g. laboratory results and clinical records) need to be linked. Nevertheless, efforts should be made to guarantee the anonymity of all research participants.

Ethical clearance during the execution of an IR project

Questions of ethics are embedded in every aspect of IR processes and steps. Once the protocol has been reviewed and approved by the ERC(s), the approval certificate informs the team leader/principal investigator of any subsequent steps, which may include a need for regular reviews or follow-up ethical reviews. Whereas in most study designs the original research protocol is followed precisely, in IR the research team continuously monitors and reviews the intervention activities to ensure meaningful and practical outcomes for project planning and execution. 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 protocol submitted for ethical review. Therefore, the IR team must inform the ethical committee of any changes to the original research protocol or procedures. For example, during the initial submission of the protocol for ethical review, the research team may indicate that patients will be given daily injections by the nurse in charge of the facility. However, during the research process, the planned administration of daily injections may not be feasible due to unanticipated problems. When such issues arise, the ethics committee must be informed of any proposed change(s) in procedure and those unanticipated problems. The three types of follow-up ethical reviews include periodic, interim and end-of -project (final) ethical reviews:

- Periodic reviews may be requested since most ERCs require follow up to ensure compliance with planned procedure, to evaluate any protocol deviation. Most ethical approvals are given a limited period, commonly one year. However, the frequency and procedures for follow-up and review of operations is on a case-by-case basis.
- Interim ethical review may be needed in special circumstances due to significant changes in the study design or when information used for the original approval of the protocol has changed.
- Final ethical review is a process whereby the project team leader/principal investigator communicates the conclusion of the project to the ERC, through a progress report since last approval, a summary of study results and dissemination plans.



REFLECTION ACTIVITY

An anthropologist was conducting an ethnographic study on Buruli ulcer patients in a half-way home. Buruli ulcer is an infectious debilitating necrotic skin disease caused by *Mycobacterium ulcerans*. Early treatment with a combination of antibiotics can greatly improve the disease outcome. The study was designed in such a way that a health worker from a nearby health facility was required to make a daily visit to administer injections. However, due to the long distance between the half-way home and the nearest health facility, the health worker was unable to make the necessary daily trips. (Note, the anthropologist was staying within the community where the halfway home was located). Discuss the ethical issues raised by the scenario described above and how they would be handled by your team. For example:

- Should the health worker train the anthropologist to administer the daily injections to the patients?
- What ethical issues should the project research team consider?

Anticipated responses:

- The health worker should not train the anthropologist to give the daily injections.
- The entire research team should consider and discuss the implementation challenge and take appropriate measures.
- Ethical clearance should be sought from the relevant ERCs, informing them of the implementation challenges, the proposed actions (e.g hiring another competent health worker to administer the daily injections).
- Budgetary implications should be communicated to donors, as appropriate.
- The research should only continue after seeking guidance from the ERCs.



Plan properly, document, monitor continuously and use the information to make appropriate decisions.

Good Practices in Planning and Conducting IR

IR is no less of a science (or art) than any other type of research and hence must generate credible data. Good research practice can ensure credible data by reducing the risk of obtaining inconclusive results due to uncertainty. Uncertainty arises when the intervention is ineffective or the implementation procedures are unclear.⁸ Good practices must be enshrined throughout the entire process in order to produce valid, reliable, precise, complete and timely data, which can be used to contribute to improved health care services. This section describes some of the most important research-related good practices. Click on each of the headings below to see details.

Documentation of processes

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

The following questions should underpin documentation of IR projects:

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

It is important to be objective when documenting processes, and to report both negative and positive experiences. This will facilitate learning and generate 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 also fully understand the process by which the results were obtained.

Training researchers

Plans do not always proceed as anticipated in IR projects. Adaptations are frequently required as the execution process proceeds and more information is obtained and understood. Designated procedures (e.g. sampling and data tools) should be reviewed regularly to compare what is happening in practice with the original planned procedure and expected observations, so that any necessary adjustments can be made. Staff training is a critical part of this process and helps to ensure that the procedures are understood and adhered to. Training for all essential procedures should be standardized and targeted to the appropriate staff.

To ensure a continuous learning process, training should be followed by mentoring and/or support supervision activities. Researchers need to ensure that the set procedures are adhered to during training, and use the prescribed materials and

most up-to-date versions of the data collection tools and instruments. As with all research, IR carries a possibility of adverse events or unintended consequences arising as a result 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 implementing the project. Resistance to change, inertia and existing investment in the status quo – coupled with the inherently difficult and complex new task – may affect the adoption of a new practice.

Capacity building

A successful project depends on the technical capacity of the research team, and any identified capacity gaps should be addressed promptly through training, mentoring and/or support supervision. Nonetheless, limited research capacity has been identified as one of the constraints to addressing health care priorities in LMICs.⁹

Generating appropriate, trustworthy evidence depends on the existence of good research infrastructure. Capacity-strengthening strategies need to focus on the comprehensive needs of institutions, including the overall skills and career development of individual researchers, the development of leadership, governance and administrative systems, and strengthening networks among the research community, both nationally and internationally.

UNDERSTANDING
IR

SEE

INTEGRATING
IR INTO HEALTH
SYSTEM

SEE

Continuous engagement with stakeholders

It is crucial to ensure that you gain stakeholders' trust so as to facilitate the implementation process and uptake of the research findings. The details of how stakeholders can be engaged is described in the Understanding IR and Integrating IR in the health system modules of this Toolkit.

Good practices during data collection

Pre-testing

In any research project, 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 sufficiently clear, context specific, and that adequate time is provided to administer the questionnaire, etc.

RESEARCH
METHODS
AND DATA
MANAGEMENT

SEE

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.

Data quality management

Data quality is key to having authentic and robust data. As such, it should be taken seriously. Activities such as staff training, support supervision and data feedback can be used to enhance the quality of data.

Data sharing

Data sharing is becoming mandatory in many fields as a way to ensure transparency, to avoid duplication and also reduce plagiarism. Since IR may involve different institutions/organizations, guidelines for data sharing and ownership should be clearly spelt out at the beginning of the project through formal agreements such as a memoranda of understanding. Data sharing should follow a clear process and can be done between research institutions (though not between individuals).

Communicating research findings

Communicating IR findings to relevant stakeholders must not wait until the closure of the project. On the contrary, in IR knowledge transfers and translation is an integral part of the research process and takes place throughout the project life cycle. Communication should be through appropriate communication channels, formats and language to targeted audiences. It should be timely and the information should be used to contribute to the improvement of health service delivery. Details are described in the IR related advocacy and communication module of this Toolkit.

Continuous monitoring and feedback

Continuous monitoring and feedback should be embedded in the project life cycle and the information generated should be fed back into the health system to inform the process for action. The details are discussed in the Integrating IR in the health system module of this Toolkit.

SEE IR-RELATED COMMUNICATIONS AND ADVOCACY

SEE INTEGRATING IR INTO HEALTH SYSTEM

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IMPLEMENTATION RESEARCH TOOLKIT



IR-Related Communications and Advocacy

Tim France, Margaret Gyapong and Olumide Ogundahunsi



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IR-RELATED COMMUNICATIONS AND ADVOCACY

IR-related communications and advocacy range from productive dialogue and engagement throughout research planning and implementation, through to translation and sharing of results through broad-based advocacy or awareness-raising materials, and ultimately to the uptake and integration of research conclusions into local, national or international policies and practices.¹ This broad scope highlights how communications and advocacy take place at all stages of an IR project and comprise many kinds of specific communication approaches, including thought leadership, data visualization, mentoring, facilitation of proposal development and social media messaging, as well as and specific information products such as research reporting guidelines, peer-reviewed papers, press releases, web sites, meeting/conference presentations and policy briefs.²



Transparency, openness and engagement – among IR team members, and with broader project stakeholders and participants – are critical. They underpin accurate recognition of the problems that impede health interventions, support the development and sharing of research questions and approaches, and promote continuous dissemination of experiences, lessons and findings. Going beyond traditional ‘one-way’ research dissemination – through ongoing ‘two-way’ dialogue, targeted advocacy and strategic communications – helps to transfer IR-related awareness, knowledge and capacities to stakeholders and participants, and allows existing barriers to research evidence uptake to be more readily identified.³

This ongoing nexus between the research process and open communication is a defining characteristic of IR. This approach is essential to promoting ownership of the research process, to facilitating the uptake of research outcomes and conclusions, and to their ultimate translation into sustainable action and health improvements.

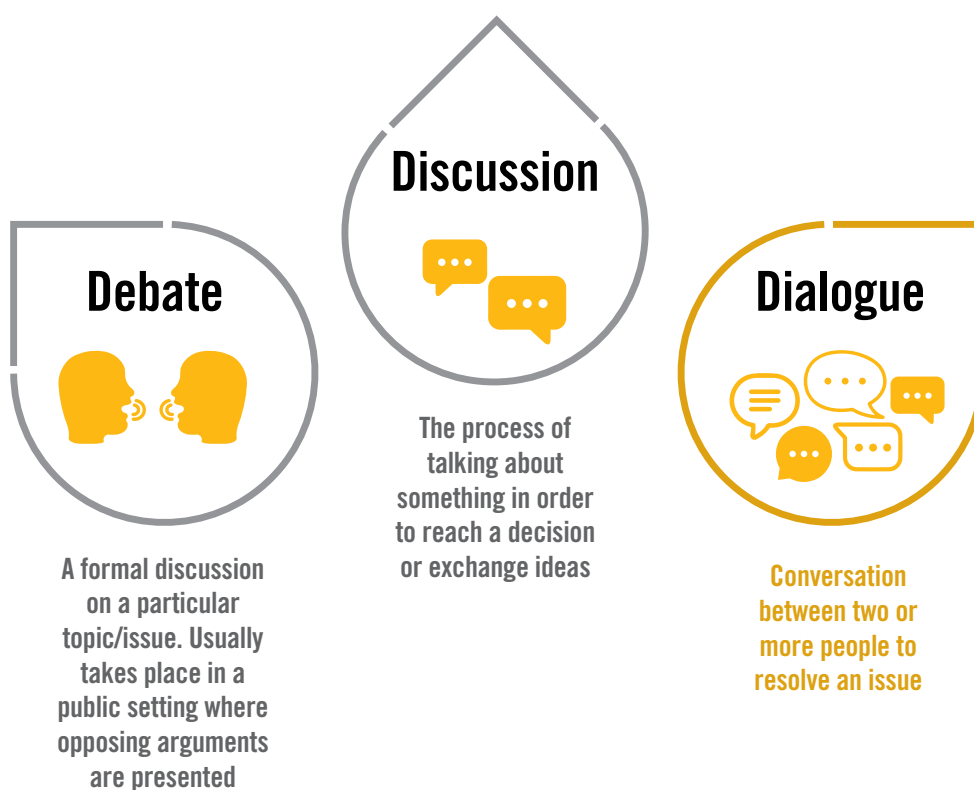
The specific goals of this module are to enable you to:

- Appreciate the importance of continuous stakeholder engagement and communication to the ultimate application and utilization of IR results.
- Recognize the value of developing a comprehensive communication strategy as an integral part of the overall IR process.
- Understand the importance of tailored advocacy and communication tools for engaging and sharing results with specific stakeholders and audiences.

Productive Dialogue

The critical quality of productive dialogue is that the IR team and key stakeholders come together to understand each other's viewpoint,⁴ in order to develop new options to address a commonly identified and owned problem. **Dialogue** is distinct from the other two 'D's – **discussion** and **debate** – in as much as it aims to promote a conversation with a centre, rather than sides.

Figure 1. The distinction between debate, discussion and dialogue





In the setting of an IR team, productive dialogue is essential for joint prioritization and evidence-based decision-making, the cornerstones of integrated knowledge translation. Genuine collaboration and dialogue can only take place when IR team members share common goals, yet acknowledge underlying differences and fragmentation in their respective approaches. Trust builds when team members recognize these challenges and are willing to jointly address them to achieve their common goals. Read more on productive dialogue in the section on Integrating IR into the health system.

Knowledge Translation

Knowledge translation (KT) techniques can help researchers become more active, context-aware, and collaborative in sharing the planning, implementation and results of research. Application of these techniques helps make research and its conclusions more relevant to stakeholders and target audiences, and ultimately more useful.⁵

There are essentially two types of KT activities: integrated knowledge translation (iKT) and ‘end-of-grant’ KT.

Integrated KT approaches (iKT) allow for greater innovation and are effective in providing timely solutions to implementation problems, including while research is being planned and/or taking place. This approach is a mixture of art and science, and illustrates some core features of IR itself. For example, it is multi-stakeholder and multidisciplinary, as well as dynamic and interactive.⁶ The integrated approach requires team members and other stakeholders to share new knowledge and data with key end-users as they are generated, and to invite their interpretation and input. Because the findings then reflect the needs of knowledge users, they have a much higher likelihood of being acknowledged, augmented and used.

iKT also includes ongoing activities such as priority setting and adjustment, development of interim information products, advocacy with policy-makers, and the development/deployment of knowledge translation platforms/rapid response services, as appropriate. Integrated approaches do not treat knowledge as something that is generated, disseminated and then applied. Rather, iKT views research knowledge – from its creation through to its application – as a collective, co-productive undertaking.⁷ It respects the two-way dynamic and broader environment in which research evidence is created, shaped and ultimately used by many different stakeholders, participants and programme implementers.

This approach largely reverses the typical default ‘authority’ of researchers: IR teams do not possess exclusive control of research evidence, but operate in a much more transparent and accountable way. In order to make research evidence and conclusions 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 IR as a tailored, context-sensitive process that is responsive to stakeholder/participant needs and demands.



End-of-grant KT activities are more typical to various mainstream types of biomedical research, and are often built into funding proposals.⁸ As the name suggests, such activities are typically conducted at the end of the research, or ‘knowledge creation’ process. They are focussed on translating knowledge into more conventional information products and disseminating those to generally broader audiences, and over a longer time period. These include peer-reviewed papers, guidelines, conference presentations, press releases, radio spots, and so on. These activities essentially present completed findings, appropriately summarized for a given audience. Although end-of-grant KT activities can be conducted as part of IR, it is generally a limited activity⁹ as it tends to lag behind the conclusion of research, and findings may not be applied in time to address the implementation challenge in question.

Research Evidence: Barriers and Facilitators to Uptake

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, they operate within challenging and dynamic environments driven by multiple in-country and external factors and stakeholders, and their expertise in applying or balancing different inputs to solve problems may be limited.

Barriers that have been identified range from access barriers to data and research; lack of enabling institutional systems and support mechanisms for research and individual barriers as described below.

- Perception about research evidence among practitioners: How do practitioners balance evidence with other competing influences?¹⁰ 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.¹¹ After all, “evidence speaks with many voices,” and any one piece of evidence might have multiple different (and even contradictory) interpretations and implications.¹² Findings may also be ambiguous and lack precise estimates of intended effects.¹³
- Organizational culture: How does an organization make decisions? How does information flow within an organization? What are its abilities to interact with research evidence?^{14,15} ‘Groupthink’ or an attitude of “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 researchers’ advocacy, and they may feel no accountability to the broader community.
- 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.



- The perceived cost and timeliness 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.
- 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).
- Separation of specific fields into ‘silos’. Across health and development sectors/silos, institutional competition and rivalry is often rife. Not only are organisations forced by donors to compete for funding, some institutions may be required to compete for credibility and/or mandates in a given area. Different topic-based silos, sectors and institutions also frequently lack a common culture or language that are essential to collaborate more effectively. This may provoke hesitation or reluctance by some institutions for inter-sectoral collaboration, for fear of exposure to informed peers or valid criticism.

Facilitators leading to wider adoption of the research evidence may include:

- National necessity is frequently observed to be the critical driver for the uptake and application of research evidence. When a national or provincial health system undergoes a specific change of policy or experiences new/emerging health needs, the exigencies of the situation frequently lead to an active search for relevant research evidence to guide implementation in new areas.
- Researchers may also ‘reframe’ current practice issues to align with the existing evidence base or emerging national priorities. Framing an implementation problem is often an essential step in 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.
- 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.¹⁶
- Researchers collaborating with practitioners to generate essential information, to encourage active sharing, and identify pressing priorities.
- 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.¹⁷ 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.
- Researchers pursuing personal contact with practitioners and developing trust. Trust built from personal relationships can be a vital ingredient connecting the worlds of research and practice.

Policy Advocacy and Strategic Communications

Advocacy

Although there are many possible interpretations, we focus here on advocacy approaches adopted by IR teams to modify (or maintain) implementation approaches or programmes. This specific goal is frequently referred to as ‘policy advocacy’ and comprises the process of awareness-raising and sensitization through which opinion leaders and decision-makers take ownership of research evidence and conclusions, and ultimately act upon them.¹⁸ Policy advocacy can be characterized as:

- A strategy to affect policy (or implementation) change or action — designed specifically to start and direct, or prevent, a specific change in implementation policy.
- A process to influence those who hold decision-making power, and/or those who inform them.
- A deliberate process of persuasive communication — intended to help the primary audience(s) to understand, be convinced by, and take ownership of the evidence presented. Trying to make a change in public policy can be a relatively slow process as changing attitudes and positions may require ongoing engagement, dialogue and negotiation.

In essence, advocacy in the context of IR is focused on building ownership of new research evidence, core ideas and implementation recommendations.

Strategic communications

The traditional basis for research and scientific communication is to share research results accurately and objectively, as a means to facilitate its rational and detailed scrutiny by peers – the peer review process. While peer review remains a valid component of IR (as described above as part of end-of-grant KT activities), strategic communications involves the sharing of information and ideas with a distinct goal or intention in mind.

As already mentioned, the goal may be raising awareness or policy advocacy, for example, and the specific strategic communication approach adopted will be determined according to how best that goal can be achieved. It goes beyond the simple ‘delivery’ of research evidence, to bring together the optimal approach to selecting, designing and promoting specific types or areas of information in order to make the achievement of the desired goal more probable.

Strategic communication may be regarded as the antithesis of traditional forms of scientific reporting and the rigours of peer review, and may therefore not be the first instinct of researchers. For this reason, it is important to include communications professionals in the IR team from the outset, as appropriate.



Data Presentation and Visualization

IR frequently generates large volumes of data that require organization, summarizing and visualization so they can be used for various kinds of communication and advocacy, and for different purposes and/or audiences. To help people understand and interpret the significance of specific data it is frequently transformed from raw numbers, to be presented in various visual formats. This often makes previously subtle or invisible patterns, trends or correlations within the data more readily perceived. Like any form of visual presentation, the method you choose to visualize data can emphasize specific characteristics of a given data set, and so care must be taken to choose an objective approach that meets your goal and the needs of a specific audience, and does not affect the integrity of the data itself or present a biased perspective.

A series of examples are provided to illustrate varying data visualization approaches, and the influence this has on how a relatively simple data set is interpreted. Tables 1a to 1b and 2c to 2e present and disaggregate a single set of quantitative data in various ways. Figures 2a to 2c are examples of how the same data can be visualized.

Table 1a: Client educational levels expressed as frequency table

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 2a. Client educational levels expressed as a histogram/bar chart

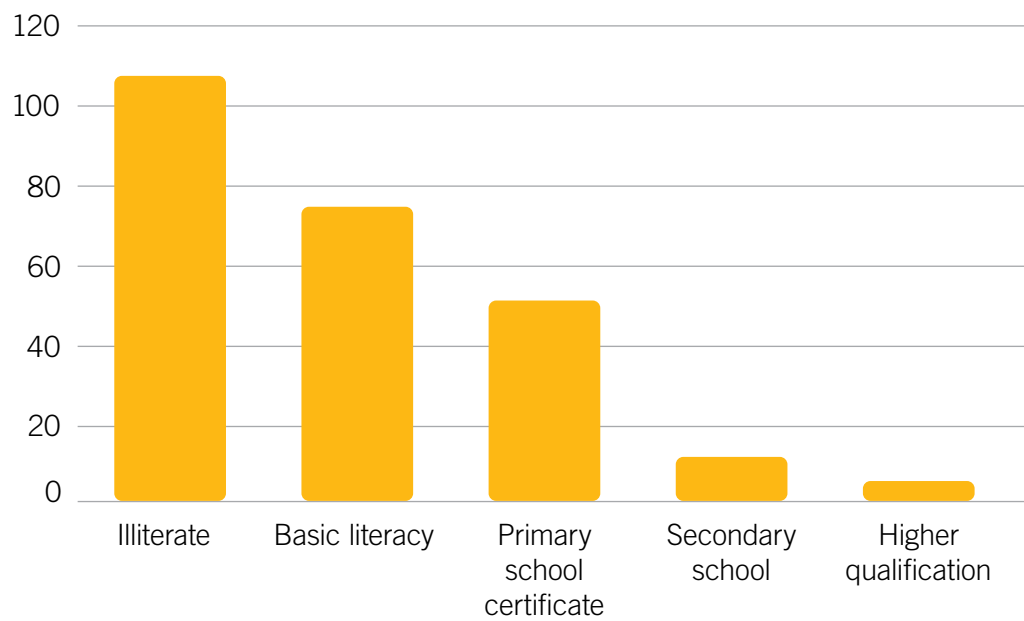


Table 1b: Client educational levels expressed as proportion, percentage and cumulative percentage

Level of education	Proportion	Percentage	Cumulative percentage
Illiterate	0.424	42.4%	42.4%
Basic literacy	0.296	29.6%	72%
Primary school	0.228	22.8%	94.8%
Secondary school certificate	0.044	4.4%	99.2%
Higher level	0.008	0.8%	100.0%
Total	1.00	100.0%	



Figure 2b. Client educational levels expressed as a pie chart

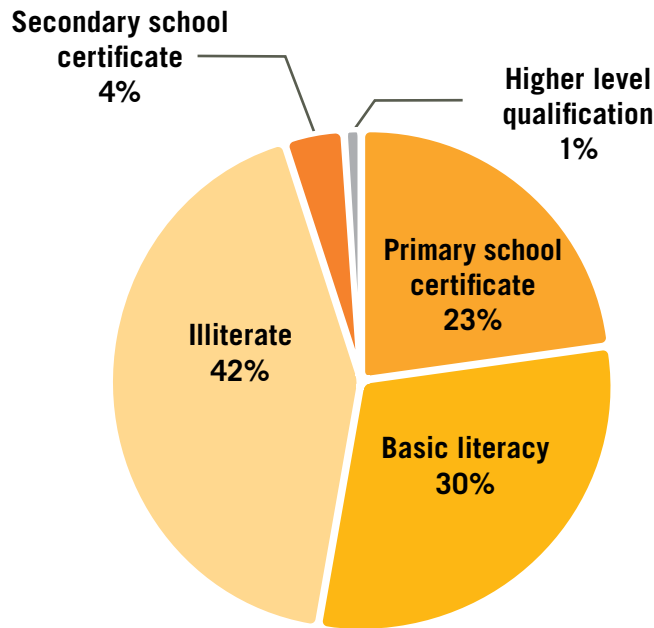


Table 2c: Client educational levels expressed as frequency distributions for two or more variables

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

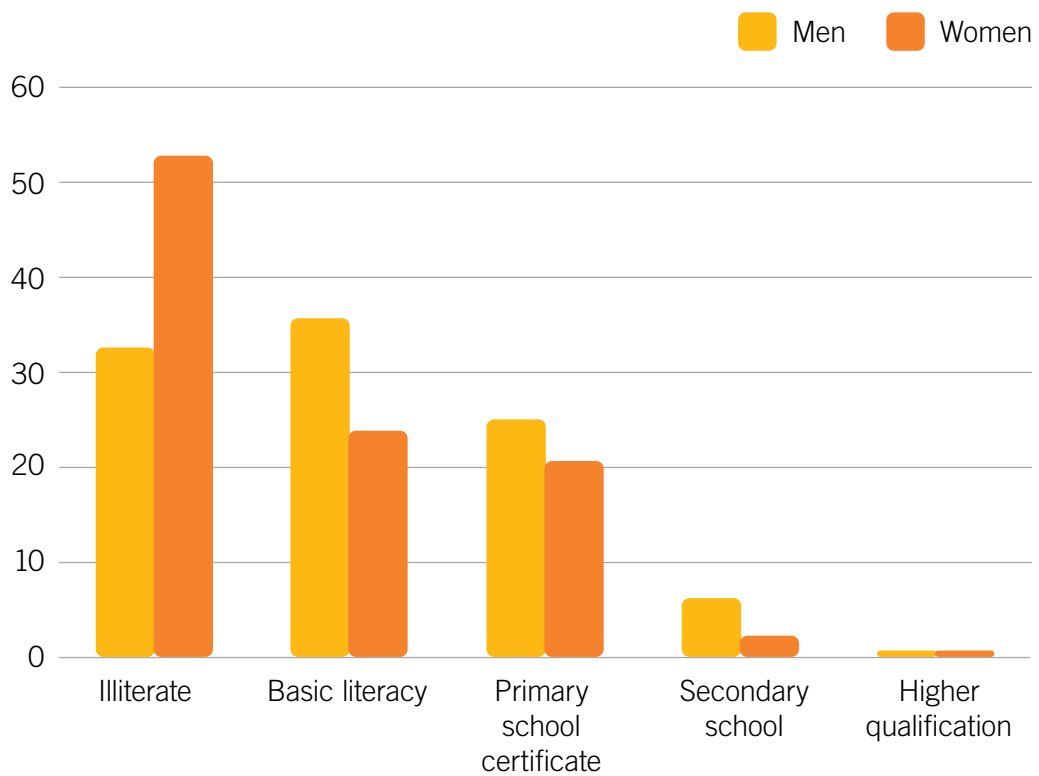
Table 2d: Client educational levels expressed as row percentages

Highest level	Men	Women	All
Illiterate	39.6%	60.4%	100.0%
Basic literacy	60.8%	39.2%	100.0%
Primary school certificate	56.1%	43.9%	100.0%
Secondary school certificate	72.7%	27.3%	100.0%
Higher level qualification	50.0%	50.0%	100.0%
Total	51.2%	48.8%	100.0%

Table 2e: Client educational levels expressed as column percentages

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	100.0%	100.0%	100.0%

Figure 2c. Client educational levels expressed as a histogram depicting two variables





Case study 1 Dissemination of research findings to different audiences

Background: Implementation research (IR) frequently generates large volumes of data that require organization, summarizing and visualization in order that they can be used for various kinds of communication and advocacy for different purposes and/or audiences. To help people understand and interpret the significance of specific data, it is frequently transformed from raw numbers and presented in various visual formats. The method you choose to visualize data can emphasize specific characteristics of a given data set, and so care must be taken to choose an objective approach that meets your goal and the needs of a specific audience, and which does not compromise the integrity of the data itself or present a biased perspective. The choice of how to present the data should depend on simplicity and interpretability because stakeholders need to understand the information provided and to be able to interpret it correctly.

The following example illustrates how the target audience dictates the data visualization approach. The same data from a survey to assess community drug distributors' (CDD) performance in the provision of integrated community case management, using malaria rapid diagnostic test kits, is presented in different formats for the various priority audiences. Performance data was stratified by sex, age and education level. The table format is appropriate for a scientific audience; the bar graph for lay literate audiences (e.g. policy-makers and project implementers), while the diagram may be used for illiterate audiences at community level.

Conclusion: Large volumes of data can be organized and summarized as figures, tables or diagrams/graphics and used as varied communication tools.

Lessons: The presentation of findings should be carefully considered to avoid potential misinterpretations that could lead to inappropriate conclusions and/or responses. The choice of format should be simple, clear and appealing to the target audience.

Table: CDD characteristics and adherence to malaria treatment guidance

CDD sex	Male number (%)	Female number (%)	Total
Correct case management	130 (89.0)	486 (97.6)	616
Incorrect case management	16 (11.0)	12 (2.4)	28
Total	146	498	644
(Fisher's exact test two-sided P value <0.0001)			
CDD Age	< 36 years number (%)	>36 years number (%)	
Correct case management	294 (92.7)	322 (98.4)	616
Incorrect case management	23 (7.3)	5 (1.6)	28
Total	317	327	644
(Fisher's exact test two-sided P value = 0.0004)			
CDD education	Primary number (%)	Secondary + above number (%)	
Correct case management	83 (92.2)	533 (96.2)	616
Incorrect case management	7 (7.8)	21 (3.8)	28
Total	90	544	6434
(Fisher's exact test two-sided P value = 0.0947)			

Case study 1 Dissemination of research findings to different audiences

Figure CDD characteristics and adherence to malaria treatment guidance

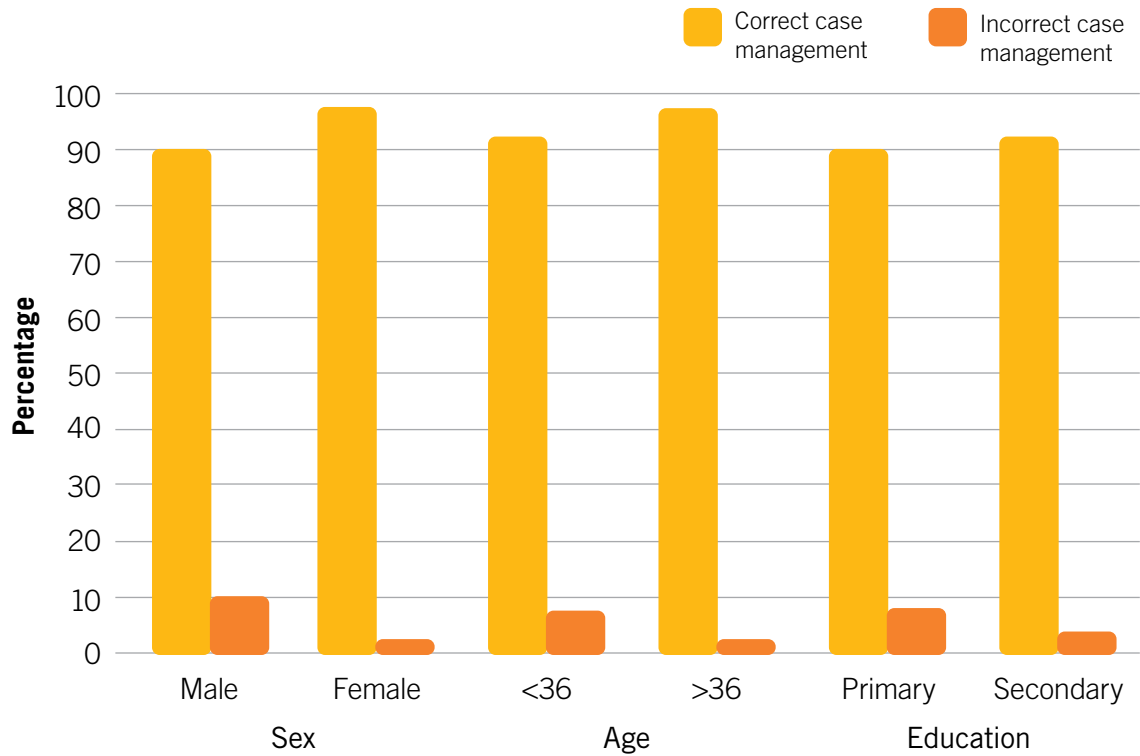
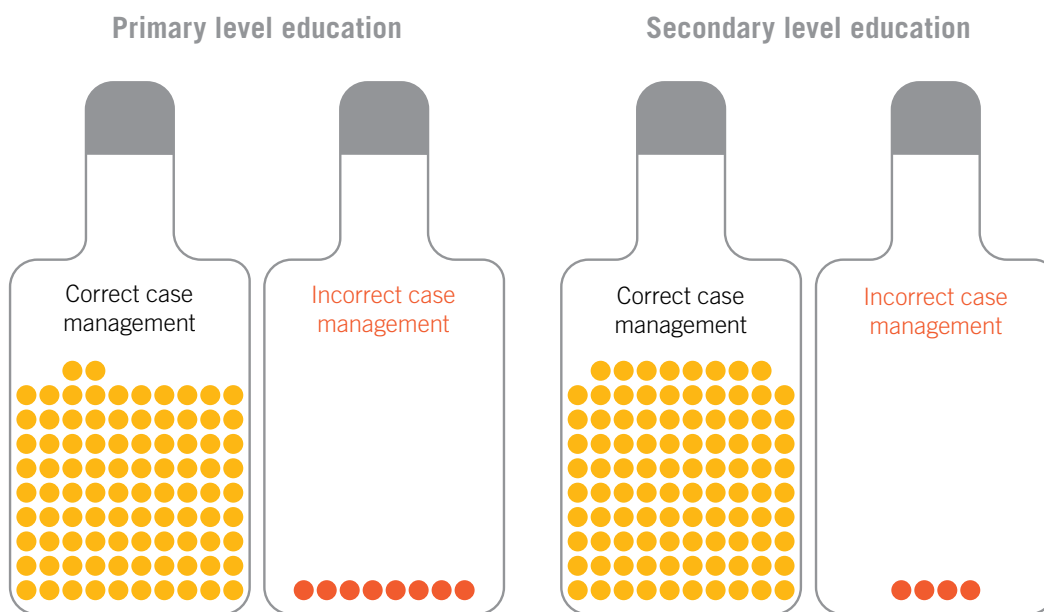


Diagram Percentage of CDDs who adhered to treatment guidance by education level



Source: Orji BC, et al. Community health workers provide integrated community case management using malaria rapid diagnostic test kits. *Research in Social and Administrative Pharmacy*. (2016); 13(4):875–879.

**REFLECTION ACTIVITY**

Using the case study outlined below, consider what were the main barriers and facilitators to uptake of the evidence that zinc was an effective treatment for diarrhoea in children. It will help if you identify the essential stakeholders who were involved in the productive dialogue leading to policy change, and why they might resist/accept such a new body of evidence.

An example of implementation research supporting KT from Bangladesh

The scale up of zinc use for childhood diarrhoea in Bangladesh illustrates the use of KT strategies in encouraging the uptake of implementation research by policy-makers. Systematic reviews of the research literature and on a joint UNICEF/WHO recommendation established that zinc provides a very effective treatment for diarrhoea among children under the age of five, by reducing the severity and duration of diarrhoea as well as the likelihood of future episodes of diarrhoea and the need for hospitalization. It was estimated that zinc treatment could save the lives of 30,000 to 75,000 children per year in Bangladesh alone.

As a first step towards implementing this promising intervention two committees were established: A National Advisory Committee, headed by the Health Secretary, and a Planning and Implementation Committee, headed by the Joint Secretary, Public Health and WHO. These committees acted as platforms for collaboration between policy-makers and researchers, facilitating the sharing of tacit knowledge and policy positions and the setting of common priorities and goals.

Based on available evidence, the National Advisory Committee approved the policy on using zinc in addition to oral rehydration solution (ORS) for under-five children suffering from diarrhoea and incorporated zinc into a revised National Diarrhoea Treatment Guideline. Research also guided the development of the product, a dispersible zinc tablet, as well as its pricing, leading to the following national evidence-based policy changes being approved:

- Zinc tablet formulation by the Bangladesh Drugs Administration.
- Branding the product as 'Baby Zinc'.
- Over-the-counter sales waiver.
- Mass media promotion of Baby Zinc.

Developing a Communication Strategy

The communication process must be an ongoing and continuous component of the overall IR project process from pre-implementation, throughout implementation and in the final evaluation stage. Involving stakeholders in the development process early will enhance ownership of the process and the ultimate uptake of the research findings and conclusions. Specific steps are recommended for research teams as they discuss and identify their communication strategy and related stakeholder needs. This is intended as generic guidance that can be adapted and customized for specific projects. The end result should be a context-sensitive strategy designed to intentionally engage and communicate with specific stakeholders and disseminate information products to pre-determined target audiences.

There are no short-cuts to facilitating and promoting advocacy and communications around an IR project. The research team could be tempted, for example, to focus on the creation of specific information products and simply disseminate those. However, single one-way products do not constitute a communication strategy.

Strong communication strategies help promote and facilitate:

- productive dialogue within the IR team and with key stakeholders and partners;
- active two-way exchange of experience and learning (not just from researchers/ key stakeholders to given audiences, but also actively inviting feedback and engagement by specific audiences, including IR participants and end users);
- precisely tailored and targeted messages and information products that are appropriate to particular audiences; and
- mechanisms to evaluate relevant indicators and outcomes, so that the strategy and its products can be revised and improved.



Steps in Developing a Communication Strategy

The ten separate steps research teams should consider in developing a communication strategy are summarized in Figure 3. In the sections below, the ten steps are described in more detail.

Figure 3. Steps in developing a dissemination strategy





Step 1: Reviewing past communication efforts

When developing a communication strategy, it is prudent to begin by looking at what has been done in the past. How did the research team share 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 communication efforts (often conducted by a third party) can assess performance and, more importantly, gauge perceptions among key stakeholders about the team's research, and of the context surrounding the research, including current or forthcoming opportunities. This type of information can significantly influence the selection of future tools and communication channels.

Step 2: Devising communication priorities and objectives

The research team should brainstorm around what it hopes to achieve by sharing IR results and engaging with key stakeholders and decision-makers. Why does the team wish to communicate specific processes or findings to particular audiences? Is the purpose of the communication to increase awareness, understanding, action, or to support local stakeholder involvement? These may be separated into short- and medium-term priorities.

Step 3: Identifying key audiences

Determining the appropriate primary and secondary audiences is a critical aspect of the communication strategy. The research team must understand who the audiences are, how they prefer to absorb information (including, but not exclusively, research evidence), their typical timelines, needs, etc. This will greatly increase the likelihood that the communication strategy will achieve its objectives.

Every IR project has multiple audiences with unique abilities and needs. Communication approaches and messages must be appropriately tailored to take these into consideration.

One tested way to ensure your team addresses the needs of all stakeholders in the communication process is to classify them into primary and secondary audiences. Primary audiences are those who need to ultimately make an implementation/policy decision or a related 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) determines the communication objectives, and each of these audiences is distinct from IR team members, but may include key stakeholders.

Step 4: Developing messages

Messages are at the heart of any communication strategy. Messages should be direct, simple and explain the problem the research sets out to address. In addition, the research approach as well as 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 messages. IR projects often result in multiple 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 agreed, concise words and phrases.

Messages should be audience oriented and written exclusively for one audience, bearing in mind the audience's needs, literacy capacities with respect to the research and the evidence it generates.

Step 5: Deciding on communication approaches

One way of choosing communication approaches is by initiating several stages or layers of 'conversation' with each specific audience. The 'graded-entry' approach¹⁴ offers one such option. As an initial outcome of this approach, the research team develops a short document (i.e. one page or less) for a major audience. The document should focus exclusively on the most important aspects of the research problem and/or findings for that specific audience, and their major implications. Assuming the audience's positive reaction, a more detailed three-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. This approach can be adapted to achieve a blend of printed and online approaches, social media or face-to-face presentation approaches, depending on the nature of each audience and foreseeable opportunities or strategic moments.

Step 6: Assessing and managing communication-related risks

However detailed and considered your communications planning, there are likely to be unanticipated questions, responses or criticisms of the project, and these can detract from – or even undermine – the goals of your communication strategy. It is worth investing some time identifying and analysing what those potential threats might be.

Carry out some discussion/analysis within the IR team to identify any potential risks in targeting specific audiences with certain messages. For example, is there any potential for messages to be misinterpreted as criticisms of decision-makers or current approaches? Could discussion of a current problem or challenge be taken as openly critical of the local or national authorities? Are there opportunities that may have been overlooked to explicitly praise current/past achievements that might be helpful in fostering a constructive relationship with primary audiences? Also think about barriers to success, difficult timescales and other stakeholders' activities that may make actions on your priority difficult at a given time or change it entirely.

Reconsider these potential threats each time you embark on a new aspect of your communication strategy. Each time you do so, examine the likelihood of a possible threat occurring and the impact that it might have on your communication activities and eventual success.



Step 7: Identifying opportunities and/or strategic moments to deliver messages

Based on what you know of the key audiences you are aiming to reach, it may also be possible to identify/predict strategic opportunities for key messages to be positioned or delivered. This might include forthcoming national planning processes or events, high-profile meeting or gatherings of key audience members, or strategic dates on which specific issues are likely to be highlighted and/or discussed.

Bear in mind that while these are most likely to include national or sub-national events or other opportunities, access to decision-makers may be easier during meetings taking place in the capital city or even in another country, when key stakeholders are away from the day-to-day pressures of work, and where local or provincial priorities are considered in a national, regional or international context.

The benefits of having a clear timeline for developing and sharing information products may be obvious, but is worth reiterating. The use of the existing channels/structures may highlight specific strategic opportunities and may reduce costs and workload. For instance, an upcoming event may be an opportunity to achieve several communication objectives and/or arrange face-to-face interactions.

Overall, the IR team must pay attention to issues of communication timing. This involves being aware of shifts within an audience (suggesting greater receptivity to your team's work, for example), strategic opportunities that might emerge suddenly and to which the team must respond quickly. Also, the activities of like-minded researchers and institutions may help in advancing your team's agenda.

Step 8: Determining communication channels

No matter how well messages or information products have been developed and refined, their impact will be compromised if they are not disseminated via the most relevant and effective channels. For example, a well-written paper is unlikely to be read by a high-level decision-maker unless it is succinct and to the point, and unless an adviser has already read and been impressed by it. A beautifully produced video that captures the detail and magnitude of a research project's impact will not be viewed if members of the intended audience do not have DVD players or unless a suitable viewing opportunity is identified, such as including it on a specific meeting agenda.

Dissemination of messages and information products must be specific, intentional and active, so that the IR team knows, with a good degree of certainty, how and when they will be delivered and presented. In the current context of information overload, relying on any channel as a means of passive dissemination – and simply putting information products 'out there' for audiences to see them – will not achieve the desired outcome and engagement.

Similarly, relying solely on single language and/or on-line distribution may incorrectly assume the access and/or connectivity status of specific stakeholders, and may exclude certain audiences.



The consideration of appropriate channels is an essential step as it helps to narrow down, in very realistic ways, the platforms and 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. Please note, you may need to adopt multiple channels and approaches to suit the needs of even your main target audiences. Furthermore, varying the platform/approach is likely to increase your chances of success.

Step 9: Reviewing available resources and capacities

It is important to consider the resources and capacities available to the IR team for communication 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 communication approaches require significant resources, including time, 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 at the strategy planning stage, the more realistic the expectations for this work will be. This is best achieved by drawing up detailed budgets for each part of the strategy from the outset.

Step 10: Taking stock, evaluating progress/impact and identifying gaps

As with all aspects of the IR process, communication about health service implementation bottlenecks, research priorities, results and their implications requires careful evaluation and feedback. Communication should be carefully planned so that the intended audiences are specifically reached. During implementation of the communications strategy, adjustments will be needed to ensure a maximum return on investment and stakeholder interest and attention. One question that can usefully guide the entire communication approach 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, and possibly even given individuals, 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 communication, you need to be clear that you have used the right messages, struck the right balance across available platforms/channels, and received sufficient end-user feedback. This can be collected via some formal surveying and key informant interviews, and be invaluable for planning future communications approaches. An 'impact log' 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. The research team can then synthesize all of this information into a ‘lessons learned’ summary 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.

It is important that the resulting communications and advocacy plan is regarded as an integral part of the research process itself. Embedding communications and advocacy activities in this way is described in the Planning and conducting an implementation research project module of this Toolkit.

IR-PLANNING
AND
CONDUCTING
IR

SEE

Case study 2

A dissemination strategy for an IR Project: A case of the NIGRAAN project, Pakistan

Background: Dissemination of research findings is crucial to facilitate uptake of research findings and for translating them into action. If the dissemination is to be effective, the tools should be appropriate for the target audience, and the message should be clear and succinct. Furthermore, the message must be timely. Moreover, if the health improvements are to be observed, the dissemination should go beyond just communicating by aiming to transfer new knowledge and understanding to the target audience, so that they are empowered to take the necessary actions.

Methods: NIGRAAN, a community-based implementation research (IR) project in rural Pakistan, was conducted by the Department of Community Health Sciences at the Aga Khan University (AKU) in Karachi, in collaboration with the Sindh Provincial Department of Health. Nigraan is an Urdu word meaning ‘supervisor’. This two-year IR project aimed to identify ways to strengthen structured supportive supervision of lady health workers (LHWs) by lady health supervisors (LHSs), in order to improve community case management of pneumonia and diarrhoea in children under the age of five in the Badin district of Sindh Province. Effective dissemination and knowledge translation enhances the execution process of a given IR project, as well as the use of the findings. A dissemination strategy should be developed during the planning phase of the project and should involve the relevant stakeholders. The research findings should be shared with stakeholders on a continuous basis throughout the project cycle using appropriate dissemination tools. The dissemination strategy for the NIGRAAN project was developed based on the TDR/WHO IR Toolkit dissemination framework. The relevant target audiences (community members, LHWS, LHSs, programme managers and implementers and the scientific community) were engaged at the appropriate timelines of the project lifespan.

Conclusion: A dissemination strategy was developed during the project planning phase and relevant stakeholders were actively involved. Furthermore, the dissemination tools were specific to the dissemination objectives and target audience.

Lessons: In creating a dissemination plan, researchers should consider the project goal, target audience, medium and execution plan. Developing an explicit dissemination strategy in advance guides the process of knowledge translation. Secondly, to enhance the use of the research findings, dissemination must not be an end-of-project activity but must adopt a continuous and integrated knowledge translation approach. Additionally, the multidisciplinary and collective approach used to disseminate results on an on-going basis builds the trust of stakeholders.



Case study 2

A dissemination strategy for an IR Project: A case of the NIGRAAN project, Pakistan

Table. NIGRAAN project dissemination strategy

Dissemination Objective	Content	Dissemination Tool	Target audience	Timeline
Creating awareness about the project among the community	<ul style="list-style-type: none"> Value of project Potential benefits for the community 	<ul style="list-style-type: none"> Community meetings Electronic media (newspapers, radio) 	Community members	From outset of the project
Creating awareness among policy-makers about the project	<ul style="list-style-type: none"> General and technical overview of the project Integration into existing systems/ structures 	<ul style="list-style-type: none"> Executive Project Management Team Meeting (EPMT) Project brochure Policy briefs 	Policy Makers at district and provincial level	At the launch of the project
Sensitization of the community about the progress of the project	<ul style="list-style-type: none"> What's happening? Community response to the project Field challenges and support requirements from the community 	<ul style="list-style-type: none"> Local electronic media (newspapers radio) LHSs' appraisal meetings 	<ul style="list-style-type: none"> Community Community-based organizations 	Ongoing
Sensitizing the Lady Health Supervisors (LHSs) and Lady Health Workers (LHWs) about the project	<ul style="list-style-type: none"> Overview of project and intervention What to expect? Roles and responsibilities Expectations from stakeholders 	<ul style="list-style-type: none"> Training workshop Formal dissemination seminars for LHSs at AKU 	<ul style="list-style-type: none"> Lady Health Supervisors Lady Health Workers 	Intermittent
Updating policy-makers and community leaders on the progress of the project	<ul style="list-style-type: none"> Field updates (what's happening? /progress) Any issues arising from within the system and/or community affecting the technical structure of the project Support requirements 	<ul style="list-style-type: none"> Project Support Team meetings District Project Management Team meetings 	Policy makers, community representatives other stakeholders with an active interest in the project	Intermittent periods
Updating the funding agency about the progress of the project	<ul style="list-style-type: none"> Progress of project activities Any technical issues arising finances 	<ul style="list-style-type: none"> Progress reports Emails, telephone calls 	World Health Organization	Yearly and end of project
Add to existing scientific knowledge	<ul style="list-style-type: none"> Process of the research Research findings 	<ul style="list-style-type: none"> Published articles 	Scientific community	Ongoing basis
Inform the AKU staff on the progress	Activities, successes, challenges and recommendations	<ul style="list-style-type: none"> Faculty meetings Departmental presentations 	AKU staff	Intermittent
Contribute to LHW-P curriculum	Trainer's manual to improve community case management of pneumonia and diarrhoea in children under five years	<ul style="list-style-type: none"> Trainers manual 	Lady health supervisors	After the formative phase

Source: Rabbani F et al. Improving community case management of diarrhoea and pneumonia in district Badin, Pakistan through a cluster randomised study--the NIGRAAN trial protocol. *Implement Science*. 2014; 9:186.



Case study 3

Innovative participatory health education: promoting reproductive health in post-conflict settings in Sudan

Background: Despite efforts to improve maternal health, South Sudan has one of the highest maternal mortality ratios worldwide. The decades of war, poor infrastructure, shortage of health workers and scarcity of resources, has negatively impacted the health system in general and reproductive health specifically, as also reflected in generally poor health care-seeking behaviour. A two-year Global Health Through Education, Training and Services-funded project was conducted in the Upper Nile State, Renk County in South Sudan. Previous participatory ethnographic studies on reproductive and child health provided a better understanding of contextual issues surrounding the problem, perceptions towards maternal health and interacting dynamics influencing patient decisions. An intervention (health education) was designed targeting the entire community by addressing maternal health issues within the post-conflict context. The intervention integrated the *Women Health Learning Package* (WHLP) in a participatory approach involving local women, non-governmental organizations and theatrical band members.

Results: Context-friendly materials were jointly developed and disseminated in the form of songs, drama and pictograms to promote the communities' knowledge about maternal health issues among various audiences. All materials/outputs were developed in local dialects.

Conclusion: The effective engagement of the community in the project – right from the initial problem identification and message development – enhanced the local sense of ownership. It also culminated in the development of context-friendly educational materials to promote women's health in a post-conflict setting.

Lessons: For a communication to be effective, innovative dissemination approaches should be adopted, community engagement is vital and the message and dissemination tools must be adapted to the local context.

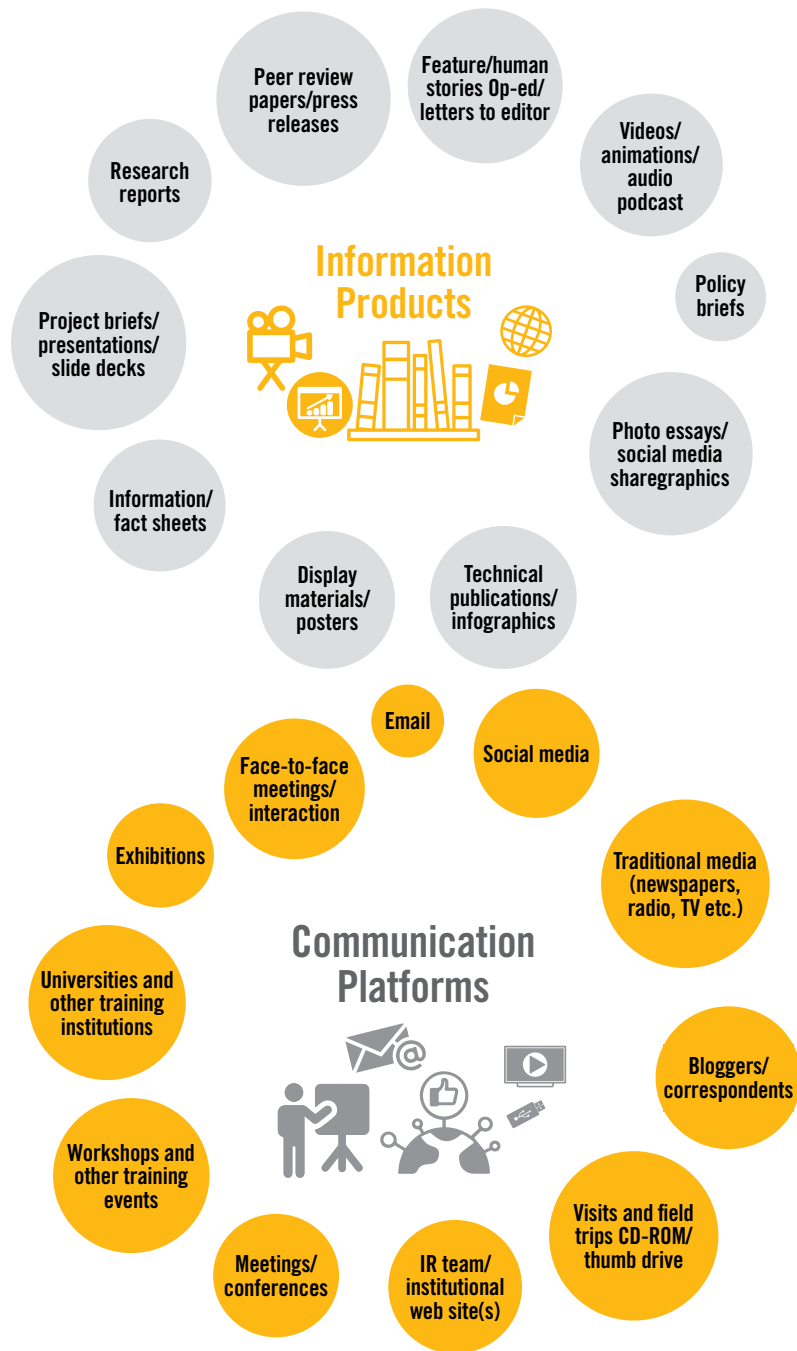
Source: Elmusharaf K. et al. Innovative Participatory Health Education (video). Available at: https://www.webmedcentral.com/View_video/225.

Information Products and Communication Platforms

Numerous products and platforms are available to research teams pursuing the uptake of research-related information and findings. These should be considered in light of priority audiences and messaging, and less as individual pieces than as parts of a whole approach. Each product and platform has different strengths and weaknesses in reaching audiences and therefore by using more than one, they can complement one another to produce a strong communication 'footprint'. In many cases, the work that goes into the development of one product, or for a given platform, can be readily replicated or modified for alternative platforms etc. Increasing the number of ways that research findings reach key audiences increases the chances of uptake and action.



Figure 4. Various complementary options for information products and dissemination channels



REFLECTION ACTIVITY



Follow the ten steps outlined in this module to develop a communication and advocacy plan for your research project.

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IMPLEMENTATION RESEARCH TOOLKIT



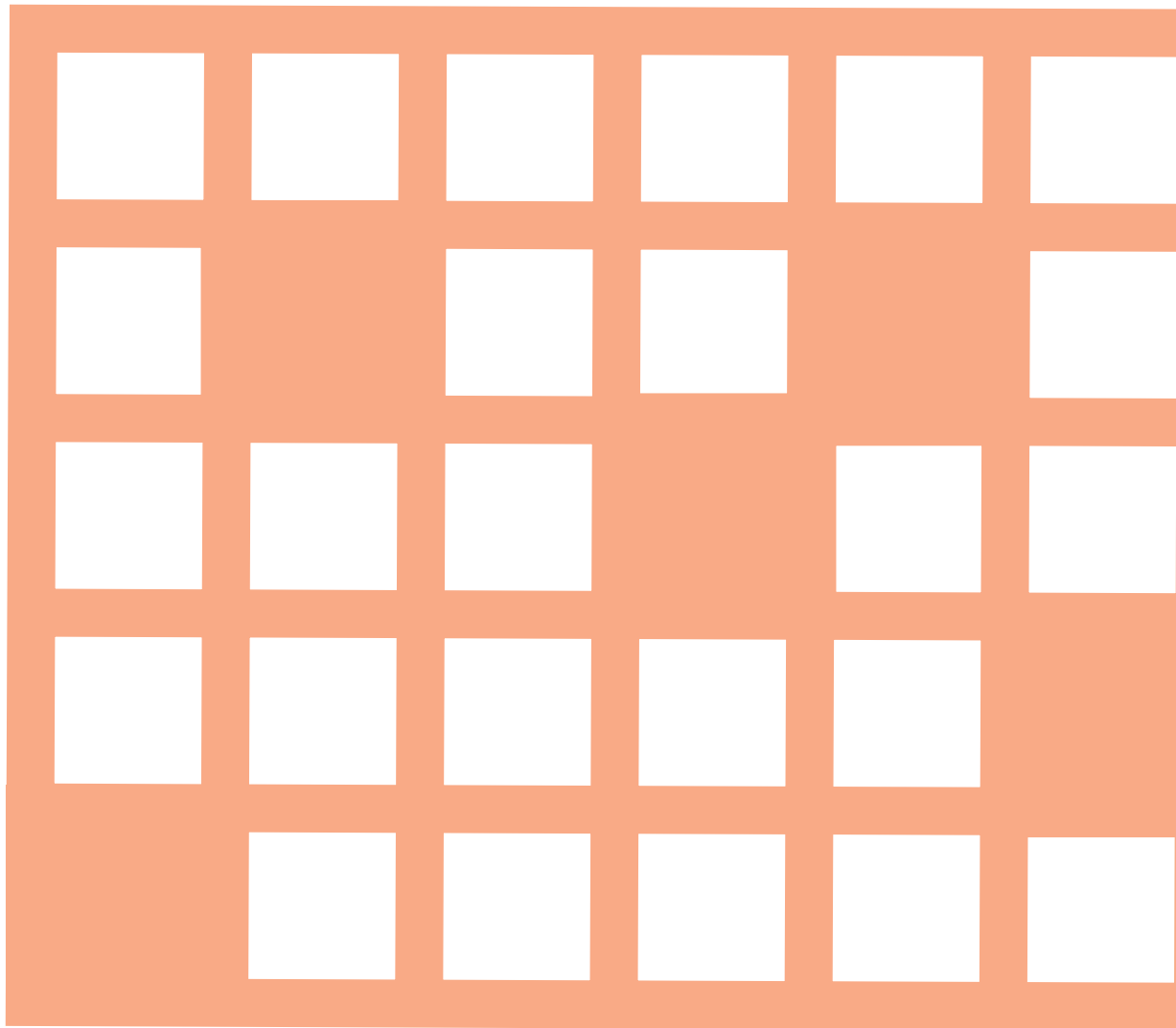
Integrating Implementation Research into the Health System

Tim France, Alison Krentel, Margaret Gyapong and Edward Mberu Kamau



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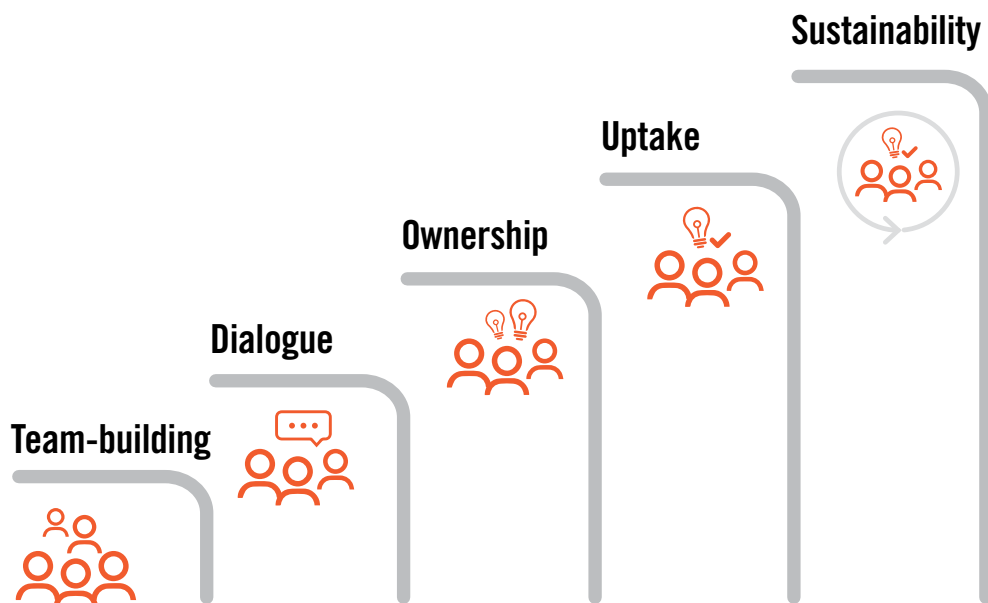
Integrating Implementation Research into the Health System



Within health systems, implementation research (IR) is embedded in real-life settings and its goal is to improve health interventions by helping to highlight specific implementation bottlenecks and barriers, and by suggesting solutions identified through close collaboration with those who deliver health programmes. Ideally, these solutions will become part of the intervention, lending sustainability to the research and improved delivery.

With uptake and sustainability of solutions as the ultimate goals of IR, there are a series of steps that must be completed to attain them. This module outlines each of these steps in a progressive fashion, where each step builds upon the success of the preceding one.

Figure 1. Progressive steps towards IR ultimate goals



Building an IR Team

Despite the potential value of new IR knowledge, technologies and approaches, a general lack of authentic coordination, cooperation and dialogue among various health-/science-related disciplines and community stakeholders limit their application. This continually hampers accessibility of innovations in many contexts, holding back the progress necessary to reach health-related goals and commitments. To be truly successful, IR requires effective multi-stakeholder coordination, cooperation and dialogue to take place from the outset – when the research question and goals are defined – through planning of the research, and continuing throughout the local implementation, sharing and actions based on research results. In this sense, IR teams require more integrated approaches and are quite distinct from – and more broad-based – than those set up to conduct most other forms of biomedical or social research.

More than most other types of research, the collaborative and deliberative nature of IR requires people with a broad range of skills, experiences and backgrounds to think together in order to address an implementation challenge that is experienced – in a given context – by health care providers, programme managers, implementers or other service providers. In other words, conducting IR implies close and consistent teamwork.



Outside of IR, however, intersectoral and multidisciplinary collaborations are typically limited to critical moments when pivotal decisions are being made. But with their longer-term approach, IR teams bring together stakeholders from various disciplines so they can engage in ongoing, authentic dialogue around existing local challenges and appropriate potential solutions. Depending on the specific research question it addresses, an IR team must be appropriately multidisciplinary and diverse in order to meet the project objectives.

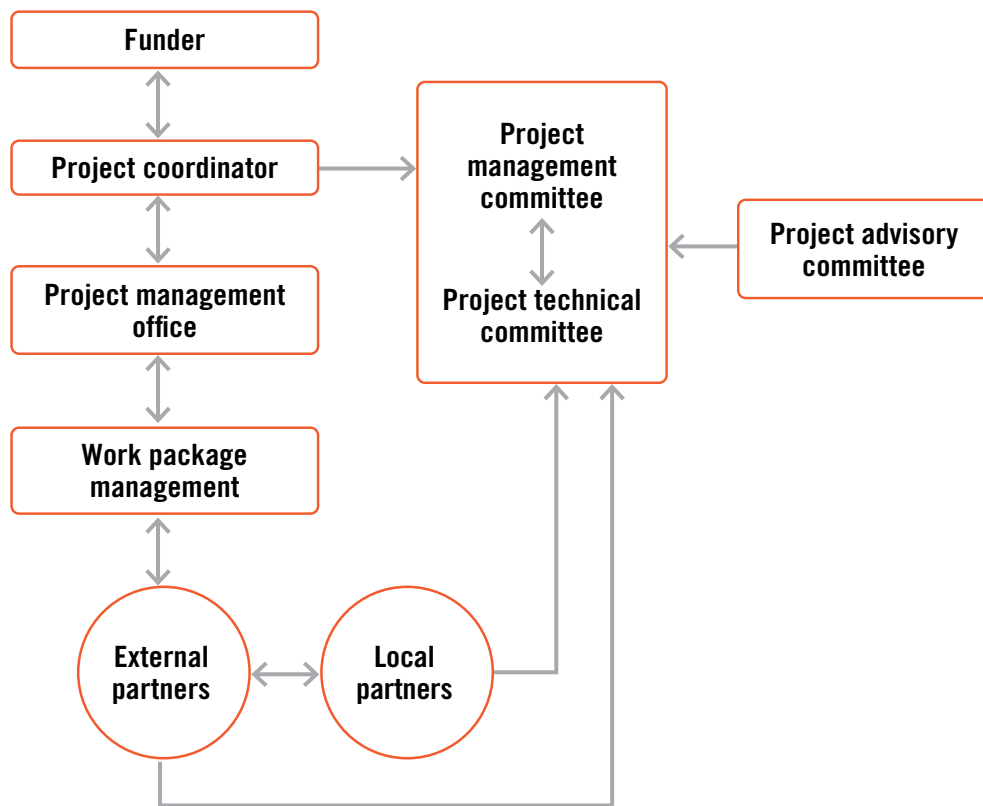
Team building includes both enhancing the ability of team members to contribute as individuals as well as enhancing the ability of the group to function as a team. Individual competencies are the essential foundation to building the core of an IR team. Team building is often complicated when individual team members are accountable to both a functional/line manager as well as the IR team leader. Effective management of this dual reporting is essential for the success of an IR project. However, each IR team should integrate appropriate expertise with local understanding to design, conduct and communicate the proposed research effectively. A typical IR core team includes the following functions (note that one person could perform multiple roles):

- Team leader.
- Investigator(s)/implementer(s)/health care provider(s).
- Project manager(s).
- Scientific/technical leader
- Other researchers (multidisciplinary, depending on the IR question).
- Media/communications specialist(s)
- Programme M & E/data specialist

In some circumstances, additional IR team members might include community members/health care recipients and advisory committee/policy-makers, and other research collaborators.

In addition to including the appropriate expertise, an IR team must adopt a suitable team management approach (Figure 2).

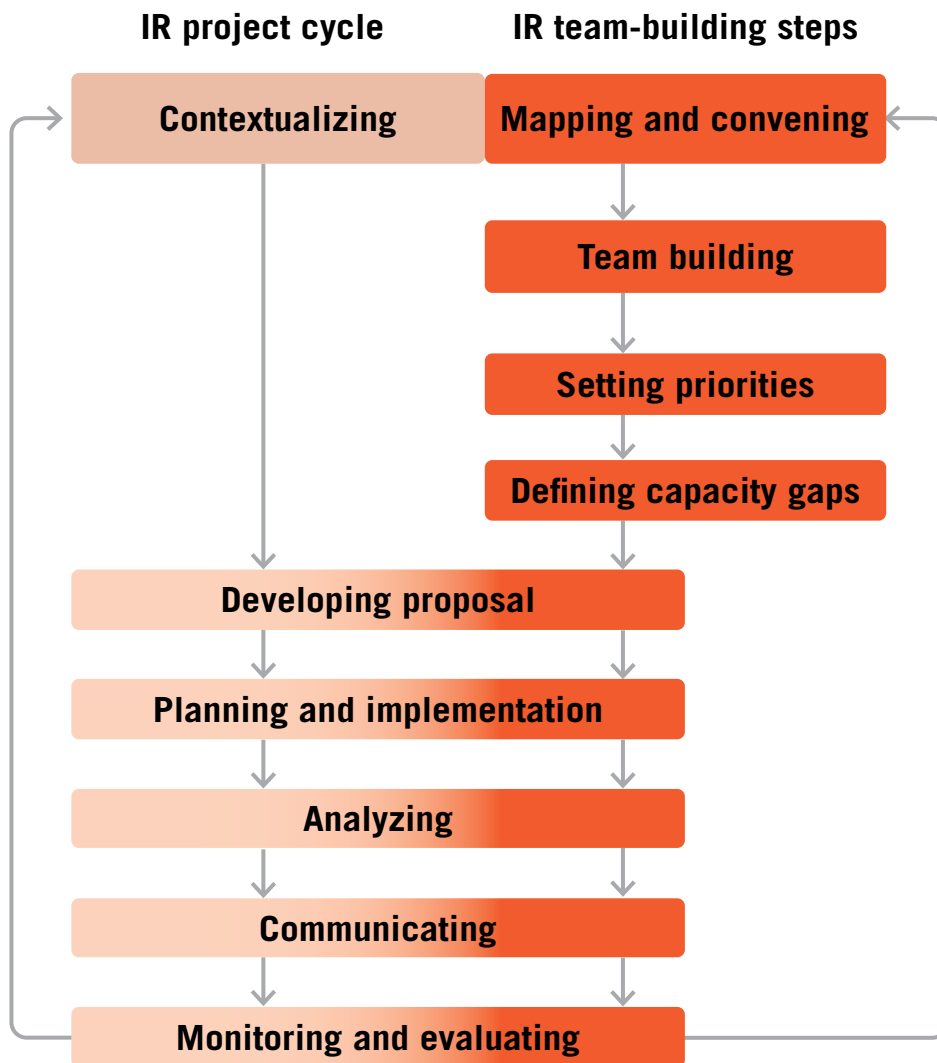
Figure 2. Research team management structure (example)



Based on various current models for team and partnership development, four specific steps are outlined for the establishment of IR teams (Figure 3). In accordance with local and team considerations, not all teams will need to go through each individual step. For some existing teams, a renewed focus on specific or incomplete steps may also be helpful.



Figure 3. Parallel processes of the IR project cycle and IR team-building steps



Start up, mapping and convening

As you will have read in several other modules, the physical, socioeconomic and cultural environments, health systems, stakeholders and institutional culture are key aspects of the IR context. As the first of the pre-implementation steps of an IR project, the IR team must be brought together from this preliminary contextualizing stage to jointly analyze and agree on relevant contextual factors.





In addition to building a common understanding of the research context, this initial step also represents an ideal opportunity for the core IR team to achieve several team-related objectives:

- Understanding the opportunities and challenges of existing research Partnerships/collaborations.
- Identifying potential team members and additional project stakeholders.
- Gathering issue status information and data mapping (e.g. desk research).
- Consulting with relevant stakeholders and with external resource providers (including donors).

Convening team members often requires time and patience, and cannot be hurried. A good understanding of existing power relationships between stakeholders may also be essential. Clear and equal communication among team members is an important principle from the outset, and one potential challenge at this stage is the lack of human resources to dedicate to the team-building process.

The mapping and convening step might include exploring potential interest and partner ‘readiness’ through initial one-to-one meetings, as well as initial IR core team brainstorming meetings, as the collaboration takes shape. This first stage frequently involves consultation leading to development of a preliminary conceptual framework for a research question and/or early consensus surrounding a common challenge or priority.

Productive dialogue

In the setting of an IR team, productive dialogue is essential for joint prioritization and evidence-based decision-making, the cornerstones of integrated knowledge translation. Genuine collaboration and dialogue can only take place when IR team members share common goals, yet acknowledge underlying differences and fragmentation in their respective approaches. Trust builds when team members recognize these challenges and are willing to jointly address them to achieve their common goals.

Many commentators have defined the key characteristics of authentic dialogue:¹

- *Inclusiveness*: Individual team members have key pieces of the expertise and knowledge required to address a shared problem, as well as the processes or structures for addressing it.
- *Joint ownership*: There must be something real and common at stake in identifying optimal solutions.
- *Learning*: Rather than being about talking, productive dialogue is about learning together, and listening to those we might not hear otherwise. It is also about individual team members realizing what they don’t know.
- *Humanity*: Showing empathy for others’ positions.
- *Long term perspective*: Recognizing that there are no quick fixes, dialogue is intentionally open-ended.



By its nature, IR takes place in the real, complex adaptive systems of non-experimental settings, and understanding of specific contextual factors and the perspectives of all team members directly influences the planning, design and conduct of the research.



For this reason, productive dialogue is often the best way – indeed the only way – for the IR team to jointly: identify research questions; determine methodologies; conduct the research; interpret findings; disseminate and apply the findings. In practice, dialogue is founded on four key skills that IR team members must cultivate, as summarized in Table 1.

Table 1: Four practices of productive dialogue²

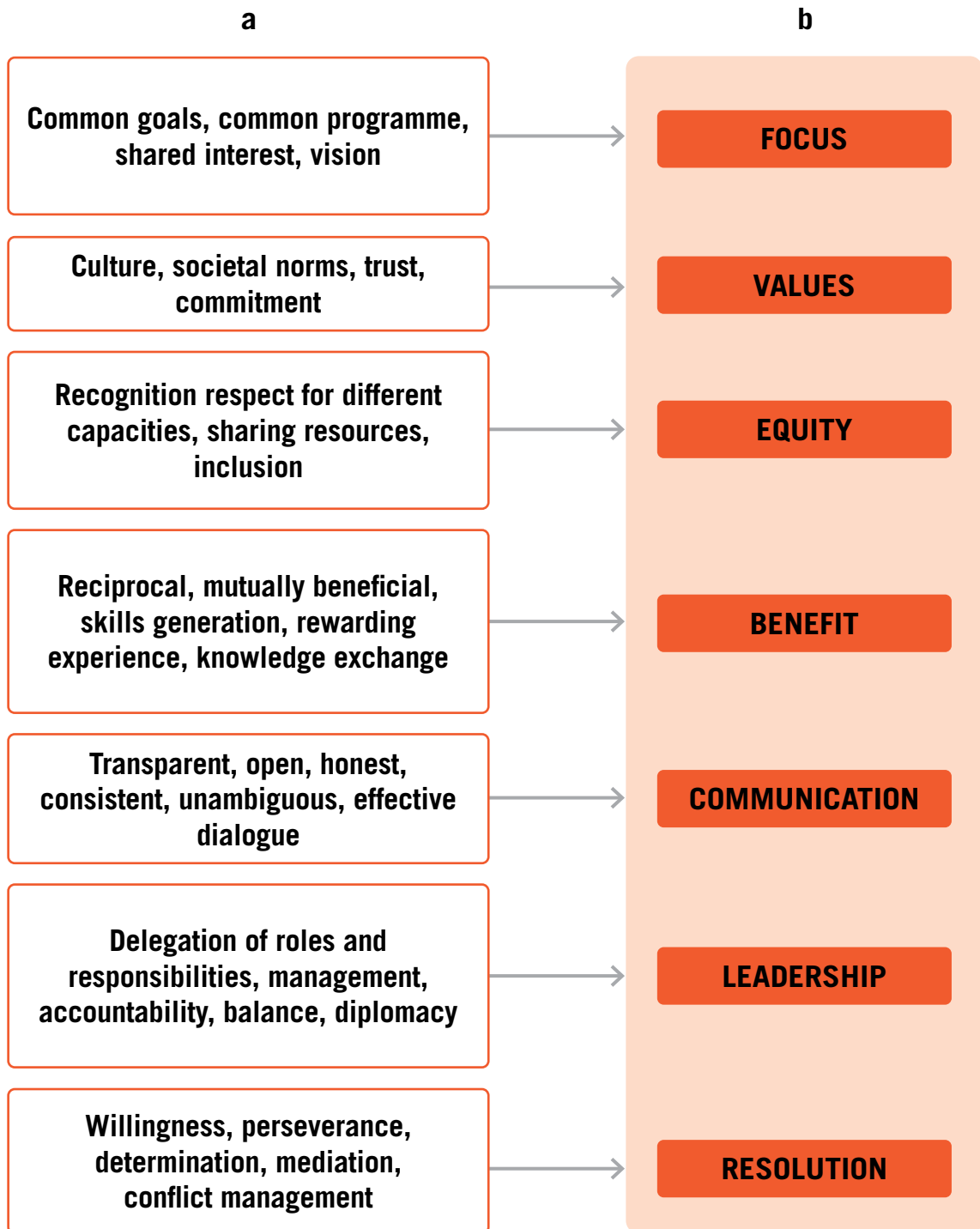
Practice	Summary
Active listening	Requires stakeholders/participants to not only hear the words, but also different points of view.
Respecting	Begins with accepting and acknowledging that others have things to teach us, and may involve highlighting what seems different or impossible to understand.
Suspending	When we listen to someone speak, we begin to form an opinion, and face a choice: to defend our view and resist theirs; or, we can suspend our opinion and the certainty that lies behind it. Suspension means neither suppressing what we think nor advocating it with unilateral conviction. The opposite of suspension is dogmatism.
Voicing	Revealing what is true for you regardless of other influences that might be brought to bear

With time and a safe environment, IR team members can learn to let go of personal or organisational biases, and turn to IR methods to jointly design pragmatic, contextual approaches, rather than falling back on generic or familiar ones. In this way, a new paradigm – one of thinking and working together – can be established within IR teams, where contextual learning, dialogue and collective implementation become the norm. Genuine collaboration and accountability can only be generated when IR team members are able to reach this new level of openness with one another. Accountability can also be generated as a by-product of team dialogue – an understanding of what team members can expect from one another – as opposed to being an outcome of ‘enforced’ monitoring or evaluation.

Ownership, trust, responsibilities and roles

Recent work on health system strengthening has identified some useful common requirements and characteristics of research teams and partnerships. Among other criteria, Larkan et al³ have suggested that complex partnerships require all parties to agree to a common minimum programme, should involve all major stakeholders from the design stage, and have resources clearly allocated. Summary attributes (a) and core concepts (b) for successful research teams are proposed in Figure 4.

Figure 4. Summary attributes (a) and core concepts (b) for successful research teams in global health



Adapted from Larkan et al.



Figure 4. Summary attributes (a) and core concepts (b) for successful research teams in global health (adapted from Larkan et al). At an early stage in the IR team establishment process, an initial team/partnership meeting is essential. The first meeting should involve as many potential stakeholders as possible, and is an opportunity to bring partners together – possibly for the first time – to begin defining a common research question and approach, and to commit to continue working together to develop an IR proposal. As far as possible, it should create a neutral, inclusive space where all potential IR stakeholders have the opportunity to understand and question the IR approach, as well as gauge and agree to their own involvement and roles.

This is also an occasion for team members to explore the division of labour and any critical capacity needs or gaps across the team. The topics that might be covered during the initial meeting might include:

- Decision-making mechanisms clarified and agreed.
- Agreement on core objectives.
- Team member commitments and responsibilities defined and agreed, e.g.:
 - networking with other potential stakeholders;
 - initial publicity/advocacy for the IR study;
 - strengthening/complementing existing team members' capacities;
 - IR team coordination and conflict resolution;
 - monitoring, evaluation and review;
 - learning and sharing;
 - resource mobilization.

Following the meeting, a concept note should be created that captures the discussion and decisions, and begins to lay out the vision, goals and design/methodology for the IR project, and should refer to the shared values, strategic objectives, IR core team members, collaboration and ways forward. One or two individuals need to be assigned this task during the initial team meeting, preferably the scientific leader.

Setting priorities, defining problems and research questions

By now, the research team should be able to develop a 'Statement 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 problem identified.

In developing the 'Statement of the problem' that the IR project addresses, the team should reach a shared understanding of the purpose of the study and the research question(s) it will focus on.

Once again, reaching this point should not be rushed and should take into account the varying positions and capacities of different team members and broader stakeholders. Building team ownership at an early phase of the project will yield invaluable engagement in subsequent stages of the study.



Capacity strengthening

If the team is aware of specific capacities that the IR project requires, but that cannot be identified within the team, steps should be taken to identify additional team members, either locally or remotely, who can contribute those capacities. In specific cases, where local capacity is essential but cannot be identified, it may be necessary to devise an option for developing specific skills or capacities within the team, time and resources permitting.

Case study 1

Capacity building for sustainable health research: analysis of four African case studies

Background: Despite substantial investment in health capacity building in developing countries, evaluations of capacity building effectiveness are scarce. By analysing projects in Africa that had successfully built sustainable capacity, we aimed to identify evidence which could indicate that capacity building was likely to be sustainable. Four projects were selected as case studies using pre-determined criteria, including the apparent achievement of sustainable capacity. By mapping the capacity-building activities in each case study onto a framework previously used for evaluating health research capacity in Ghana, we were able to identify activities that were common to all projects. We used these activities to derive indicators that could then be used in other projects, including to monitor progress towards building sustainable research capacity.

Results: Indicators of sustainable capacity building increased in complexity as projects matured and included: (i) early engagement of stakeholders; explicit plans for scale up; strategies for influencing policies; quality assessments (awareness and experiential stages); (ii) improved resources; institutionalization of activities; innovation (expansion stage); and (iii) funding for core activities secured; management and decision-making led by southern partners (consolidation stage). Projects became sustainable after a median of 66 months. The main challenges to achieving sustainability were high turnover of staff and stakeholders, and difficulties in embedding new activities into existing systems, securing funding and influencing policy development.

Conclusions: It takes many years for capacity building projects to become sustainable therefore indicators : i) should be both generic and context specific; ii) should evolve and increase in sophistication as projects mature; iii) need buy-in from stakeholders and should be revised regularly.

Source: Bates I. et al. Indicators of sustainable capacity building for health research: analysis of four African case studies. *Health Research Policy and Systems*. (2011); 9(1):1.



Uptake of Findings

The findings and solutions identified in an IR project need to be accepted by the health personnel delivering the health intervention. If these key stakeholders are willing to take up the recommendations suggested by the IR project, then the research will add value and improvement to the health intervention. Without uptake, the IR project has not achieved its intent and its findings will not be used. As discussed earlier in this module, identifying the right people for the IR team is an essential step in this process. This team will work directly with the health personnel throughout the project. The quality and frequency of their interaction will determine how likely the health personnel will utilize the IR project findings and recommendations.

Explanation of Continuous Monitoring

As highlighted throughout the toolkit, the aim of IR is to identify bottlenecks and barriers to implementing health interventions. Data collection in IR investigates why these barriers exist and in its analysis, proposes solutions to address them. Throughout this process, engagement of health personnel who deliver the interventions is key. IR is not ‘monitoring and evaluation’ of a health intervention, and health personnel should not feel that they are being evaluated while participating in an IR project. This will not encourage the ownership and uptake of the project results by the very people who need to use them.

IR uses an ongoing process of feedback and dialogue between the IR team and health personnel involved in the delivery of the intervention. At the outset of any IR project, this process should be designed so that health personnel understand that they are a critical part of the research and the IR team. Effective feedback should be constructive, tangible, transparent, actionable, user-friendly, specific, timely and ongoing. Feedback can be delivered in various formats: reflection meetings, supportive supervision visits, frequent data review meetings and sharing of research results and updates.

During the process of continuous monitoring, it is possible that adjustments may be made to the health intervention before the IR project has been completed. For example, if education about malaria prevention offered to a cohort of mothers of children <5 years is shown to reduce malaria cases, then the health personnel may decide to offer education to all mothers coming to the health centre at a midpoint in the IR project cycle. Involving the health personnel in the analysis of those early data findings may help them to improve the interventions under study before waiting until the final conclusion of the IR project. Continuous monitoring differentiates IR from other scientific studies, where a researcher traditionally waits until all of the results are compiled and analyzed before providing recommendations. Because IR occurs in real-life settings, the ability to adapt to ongoing findings can have the potential to save lives and improve population health.

Throughout the project cycle, continuous monitoring should be built into the team's activities. These interactions between the research team and the health personnel on the IR team provide opportunities to engage key health personnel in the data collection process, the data analysis and its interpretation. Each of these steps is outlined below.

Health personnel's input into data collection is essential. They often provide most of the local knowledge that the IR team needs prior to starting data collection. For example, what times of the day are best to interview community members? Who are key informants in this locality? What cultural parameters exist in this area that may affect data collection (e.g. women must be interviewed by women, religious holidays, etc.)?

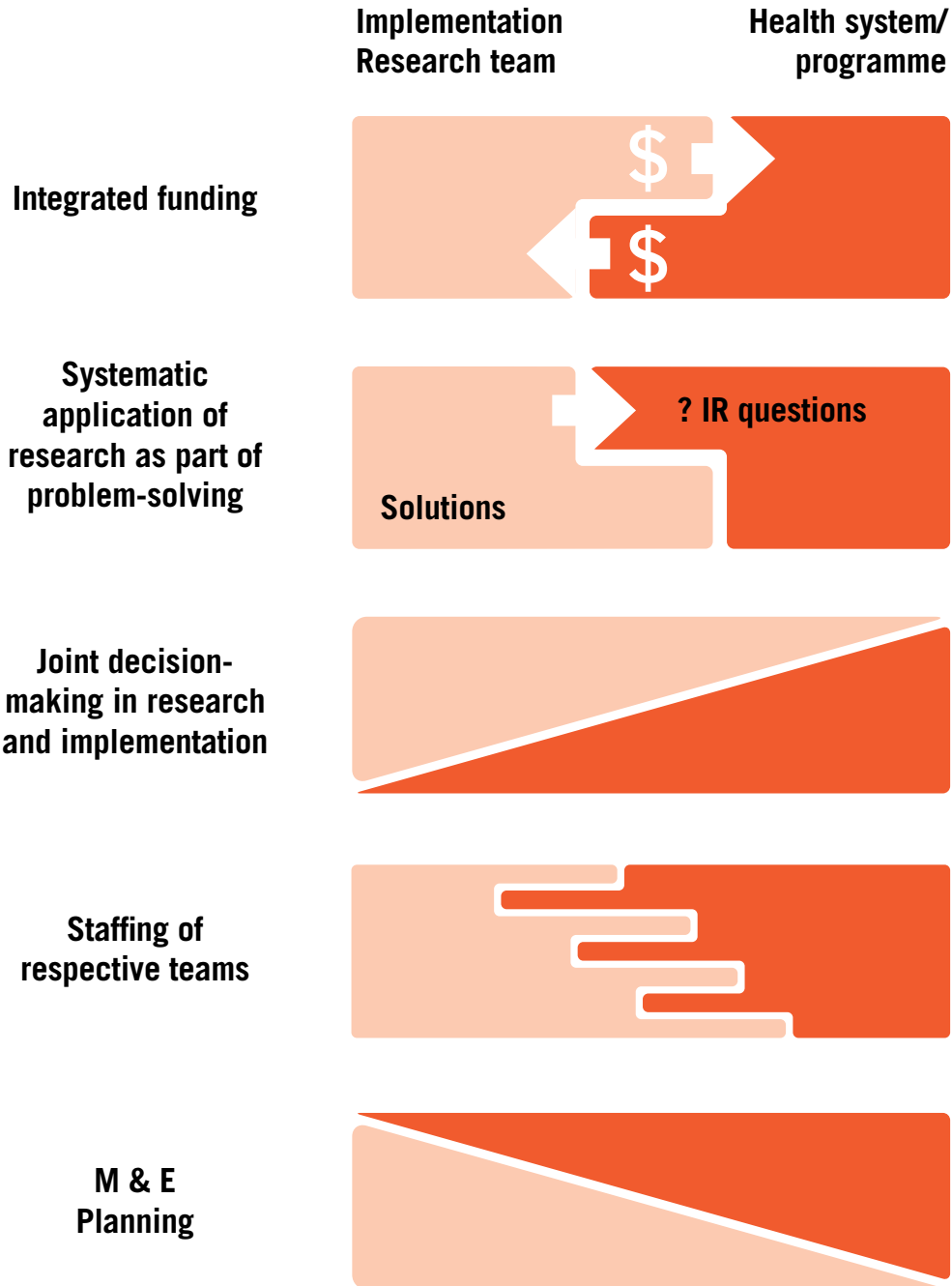
By involving health personnel in the design of the data collection, the IR team creates an expectation of responsibility that continues throughout the project. With this, health personnel will take more ownership of the IR project, even ensuring that their reports are accurate, complete and prompt, thereby improving the quality of the data collected during the project. Their willingness to engage with the information improves if they feel involved in the process. Throughout data collection, the IR team should guarantee the quality of data so that health personnel staff can be confident about its value, thereby increasing their likelihood of them using the information for learning and decision-making. Regular communication during this stage of the IR project will provide an opportunity to address any challenges in the fieldwork and allows the health personnel to participate in the interpretation of some of the early findings, thereby offering the chance to revise the data collection as needed.

During the data analysis and interpretation phase of the IR project, the involvement of the health personnel is critical. By providing opportunities that encourage health personnel to interpret the IR project findings, they are able to identify their own successes, challenges, and solutions to bottlenecks. This dialogue reinforces health personnel ownership rather than forcing "top-down" interpretations and solutions. Furthermore, health personnel provide that important contextual explanation for research findings that the IR team may not be familiar with. As discussed above, at different times throughout the project cycle, the IR findings may be adapted into the existing health intervention.

At the end of the project, when the results are being disseminated to relevant stakeholders, it is important that the IR team work together with the health personnel to identify the best people to deliver messages as well as those people that need to be targeted for knowledge translation. Feedback of this process to the team will be important so that reactions and interpretations of the findings can be understood and where necessary, the message can be adapted. Furthermore, involving key health personnel in the dissemination of the results can be an empowering process.



Figure 5. Infographic to demonstrate the interaction between health personnel and the IR team, showing the embedded nature of IR within the health system





Documentation

Implementation research is a dynamic process that often requires adaptation, flexibility and innovation during the execution of the project. As we have seen, the process of continuous monitoring may bring changes to the IR project and the IR team should be prepared to make these adjustments as they arise. For example, health personnel may decide to implement a solution identified through the IR project in the middle of the research process, once it has been shown to be effective. Or they may decide that the modification proposed to the health intervention in the IR project needs to be amended. It is crucial that such changes or adaptations to the research process are well documented, coordinated and monitored to ensure credibility and fidelity.

The following questions should underpin the documentation the team carries out:

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

The IR team must be objective when documenting processes and report both the 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 were obtained.

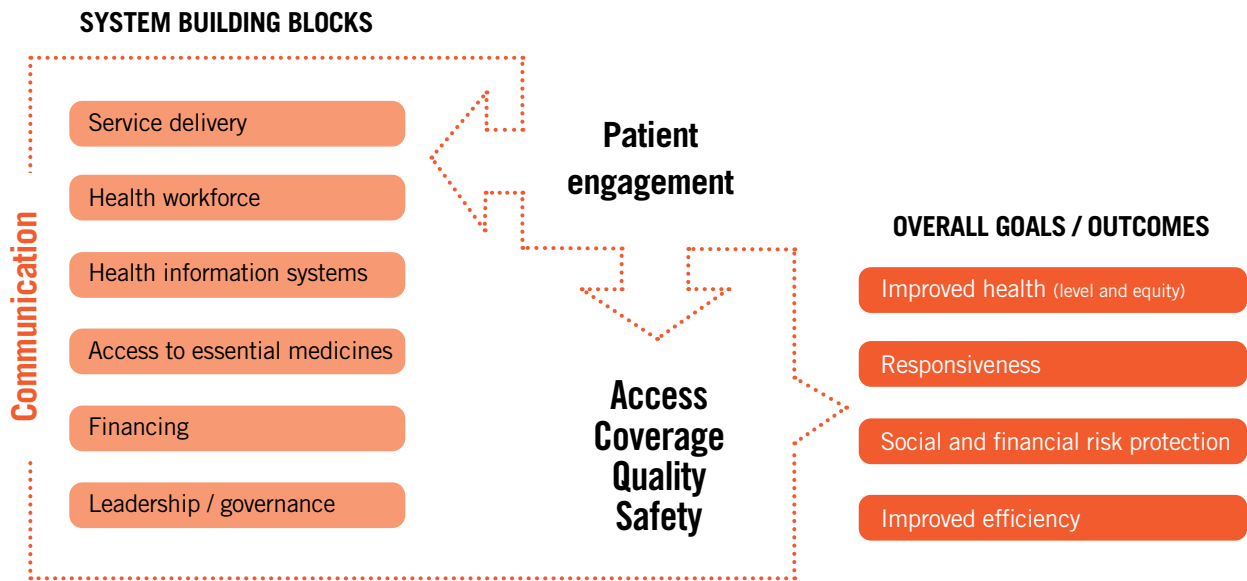
Using the WHO Health Systems Framework in IR

As stated, during the IR process health personnel are involved in the development of the research questions, the data collection as well as the interpretation of results and identification of recommendations. At the same time, they are responsible for the delivery of the intervention, whether it be mass drug administration for onchocerciasis, promoting better sanitation to reduce transmission of intestinal helminths or other health interventions. For reasons of operational feasibility, human resources and funding, IR is often conducted in only a selection of districts or health centres. However, the implications of the IR might apply to the wider health system. How then, do we ensure that these results are integrated and sustained within the health system?

The WHO Health Systems Framework (Figure 6) provides a guide to IR practitioners on how the wider health system can be involved in implementation research. Before the IR project begins, the IR team can review the framework to assess how each of the building blocks might be implicated in the health intervention under study as well as in the solutions to identified barriers.



Figure 6. The WHO health systems framework⁴



Let’s consider an example to understand how the six building blocks in the WHO framework can serve as a guide for integration of IR into the health system:

Your IR project aims to understand and reduce barriers to uptake with insecticide-treated bed nets (ITN) in families with children under the age of 5 in two districts using a mixed methods study. Barriers to ITN use included: fathers were not supportive of bed net use for children; and mothers needed more understanding and skills to ensure their children slept under a net every night. The IR project tested two solutions to these barriers: 1) text messaging to fathers; and 2) the use of counselling to mothers in MNCH clinics. IR results demonstrated the utility of both actions to improve compliance with ITN use in two districts, confirmed with a reduction in cases of malaria in children < 5 years as treated by local health staff. These results and actions are applicable to several other districts in the health system, so how will you ensure that these new practices are integrated into existing health service delivery so that they can be sustained over time?

With this example, each health system building block contributes to integration of results and increased sustainability:

- *Service delivery:* These IR recommendations provide a solution to reduce the cases of malaria in children under the age of 5 by improved use of ITNs. These actions have been shown to be effective, safe and with a minimum of additional resources. As a result, these IR actions can be recommended for improved service delivery in more than the two districts under study.

- *Health workforce:* In order to ensure that mothers are counselled in each district, appropriate health personnel working in MNCH clinics need to be identified for training so that they can provide counselling to mothers. These activities can be added to the regular staff training programmes as well as supervision checklists to ensure that staff have the resources and skills they need to carry out the activities. Consider if further upstream training is required to sustain the activities, e.g. at nursing or midwifery schools.
- *Health information systems:* How can the recording of these activities be integrated into the routine data collection at the health centre and/or the district health office?
- *Medical products, vaccines and technologies:* If the IR project demonstrated the use of a job aid (e.g. brochure, poster, Frequently Asked Question sheet) to guide the health staff as they counselled mothers, how can this be reproduced and distributed on a wider scale?
- *Health financing:* Can the training of health personnel be integrated into existing training activities to reduce financial pressure on the health system? How can routine text messages to fathers be financially maintained?
- *Leadership and governance:* In order to ensure effective oversight of these activities, regular monitoring and evaluation of the counselling, text messaging and reported malaria cases can demonstrate the impact of these activities over time.

Without considering the health system, IR risks producing results that have limited and time-bound implications. Sustainability in IR is efficient. Without sustainability, the same IR question may be researched again in several years, as the barrier or bottleneck may have only been temporarily removed. Working within the health system improves the equity of the reach of IR so that those areas not originally in the research project may also benefit from its results. Health interventions need to benefit all those in need. Considering sustainability, equity and the rational use of resources should be a part of all IR projects.

**Case study 2****Use of WHO health systems 'building block' framework to analyse how IR can be integrated and sustained within the health system?**

Background: Although IR may be conducted in only a limited geographical area or health facility for reasons of operational feasibility, human resources and funding, the implications of the IR might apply to a wider section of a given health system. The WHO has recommended use of a health systems 'building block' framework for comprehensively examining how interventions can operate more successfully and effectively in complex, real-world settings. This approach analyses the six WHO health systems building blocks, which define the essential components of a health system. This approach was used in the analysis of the barriers and motivators of voluntary medical male circumcision (VMMC) in 14 priority countries that were tasked with scaling-up VMMC services to 80% of HIV-negative men aged 15–49 years by 2016. Although the programme started in 2008, by July 2014 only two countries had achieved over 50% of the target, while the rest had <30%. This review used the WHO health systems building block framework to examine the factors influencing the scale-up of the VMMC programmes from 2008–2013 in 14 priority countries. The influence of each respective health system building block is summarized below.

- (i) *Leadership and governance:* The success of the intervention was facilitated by sustained country ownership and political will. However continued commitment and engagement of the stakeholders is also key.
- (ii) *Health workforce:* The activities of the proposed intervention should not compromise the already overstretched work force and the overall quality of health services provided. Thus, any innovations should ensure efficiencies to minimize human resource constraints. In VMMC, task shifting and task sharing appeared to facilitate scale up. Appropriate training of non-physician health workers was essential.
- (iii) *Health service delivery:* Expanding access and improving demand for VMMC are essential to service utilization. Mobile or outreach services to expand access to VMMC were successful in countries such as Kenya. However, experience from Zimbabwe revealed understanding the barriers and motivating factors related to the uptake of VMMC was necessary to determine service demand.
- (iv) *Medical products, vaccines, and technologies:* Availability of commodities and supplies in good quantities, on time and of acceptable quality is critical for the success of an intervention. Successful VMMC implementation requires coordinated partnerships that are effective and efficient in meeting commodity requirements. However, 10 of the 14 countries reported challenges related to inadequate supplies and delayed procurement. In addition, in most cases, VMMC waste management activities were not costed.
- (v) *Health system financing:* In the scale-up of VMMC, availability of external funding was a major facilitator. However, reliance on donor funding for scale up proved to be a barrier in countries where achievements of VMMC targets had been low. To close such funding gaps, several countries are currently generating and directing national funds specifically to HIV programmes, including VMMC activities.



Case study 2

Use of WHO health systems 'building block' framework to analyse how IR can be integrated and sustained within the health system?

(vi) Health information: Quality information is needed to guide evidenced-based decisions on how to allocate limited resources for HIV prevention, including the VMMC programmes. Standardized sets of indicators agreed upon by technical and funding agencies was one factor that strengthened the monitoring and the evaluation of VMMC services. However, since ensuring that the data collected through the national health information systems are of sufficient quality for meaningful interpretation is a challenge, the VMMC monitoring systems in most of the countries are parallel to national health information systems.

Conclusion: Use of WHO health system building blocks to analyze implementation bottlenecks can explicitly identify barriers and facilitators to integrating IR into the health system.

Lessons: Understanding of contextual barriers and facilitators of demand for a given intervention are essential in enhancing integration and sustainability of IR into the health system.

Source: Ledikwe J.H. et al. Scaling-up voluntary medical male circumcision – what have we learned? HIV/AIDS (Auckl). 2014; 6:139–46.

Principles of Sustainability

The approach advocated in this module closely mirrors that articulated by the Sustainable Development Goals (SDGs). In particular, SDG goal #3 that aims to ensure healthy lives and promote well-being for people at all ages. The need to address sustainability challenges in a more comprehensive, multi- and interdisciplinary manner is key. A better understanding of the factors and determinants that delay progress or, in some instances, set countries off-track highlights the need to better address health system bottlenecks with applicable and tailored approaches.

Lessons learnt from the Millennium Development Goals (MDGs) and challenges anticipated in the SDG era emphasize the importance of a more hands-on approach in addressing and designing interventions that are better suited to a modified and adapted context, where one-size-fits-all approaches are widely recognized as being obsolete.

The integrated framework for implementing SDGs recognizes the role of local action, community buy-in, local leadership and coordination at all levels of governance. The health-related SDG targets, along with other global platforms, highlight the importance of acting now; the need to enhance research; increase the quality implementation of services; promote partnership and stakeholder roles, while tailoring sustainable solutions to local realities and challenges. IR fits into these as a way to reach the anticipated aims and targets.



Making sure that health interventions benefit all those in need is a key challenge for LMICs.

**Case study 3****Building sustainable implementation research in the Ghana Health Service.**

Background: Ghana has steadily embedded implementation research (IR) in its health system through sustained country-led capacity building and sustained efforts by the Ministry of Health (MoH) and the Ghana Health Service (GHS). Over a period of almost 20 years, successive leadership has engaged stakeholders at the national and international levels to identify bottlenecks in the health system and address them with varying degrees of success. Most recently, the GHS led the development of a national health research agenda and an IR capacity plan for some key disease control programmes, with support from a multilateral partnership on access and delivery of health interventions.

In order to strengthen capacity within the GHS for implementation and operational research to identify and address country-specific health system needs for effective access to and delivery of new health technologies, a series of national workshops and stakeholder activities were conducted serially over a period of 18 months by the Research and Development Division (RDD) of the GHS. These included the development of a National Health Research Agenda so that the priority research areas identified by the GHS, its stakeholders and other collaborators could develop and provide evidence to support decision-making. Over one hundred and fifty development partners, GHS Directors and Deputy Directors, MoH Directors, Scientists from GHS research institutions, the Noguchi Memorial Institute for Medical Research, staff of the School of Public Health, Staff of non-GHS research institutions, policy-makers, disease control programme managers, Regional Directors, District Directors, Regional and District level Health Staff, Academics, and Health Administrators all contributed to the development of the research agenda, and participated in various workshops and stakeholders' meetings to review and refine the emerging research priorities. The resulting *National Health Research Agenda* included a list of barriers and problems impeding the effective delivery of health programmes and implementation of policies. The list provided a practical point at which IR can begin and focus.

A second series of workshops were conducted after the initial stakeholder consultation on the research agenda. These workshops were designed to:

- sensitize policy-makers at the GHS on the importance of IR to address priority programme needs;
- sensitize key players of the African Regional Training Centre (RTC) at the University of Ghana on the value of IR to address priority programme needs;
- build capacity in cohorts of research teams for the conduct of IR and dissemination of research findings in public health; and
- promote teamwork and functional partnerships among researchers, disease programme implementers and policy-makers.



Case study 3

Building sustainable implementation research in the Ghana Health Service.

Development of a national health research agenda for Ghana

Ghana has a rich history of health services research, with strong institutional arrangements for the coordination of research efforts in the country. The Health Research Unit, established in 1990 serves as the main coordination mechanism for health research and has evolved over time to the Research and Development Division (RDD) of the GHS. Research has always been accorded a high priority to support the successive *Health Sector Five-Year Programmes of Work*, starting with the first programme of work in 1996. In 1998, the Government published *Policy guidelines for strengthening research* in support of the *First Medium-Term Health Strategy* in Ghana. The second five-year Programme of Work (2002–2006) had its own five-year research programme, aligned with the Medium-Term Health Strategy for Ghana (2002–2006). Successive health sector programmes had strong research components, and in 2008, a health research agenda was published to accompany the programme of work.

In 2004, the GHS/RDD developed a health research agenda for 2015–2018 with the support of partners (WHO/TDR and the United Nations Development Programme) to underpin the 2014–2017 Health Sector Medium Term Development Plan. The process involved high-level stakeholders' meetings organized by the GHS in collaboration with other partners, in order to obtain input on a draft national health research agenda covering 2015 to 2018. A draft document was produced and reviewed at a subsequent stakeholders meeting. The revised document was finalized and published by the GHS as the *Ghana National Health Research Agenda 2015 – 2019*.

Sensitization workshops for policy-makers and Regional Training Centre staff

A one-day workshop was convened for Directors and Deputy Directors of the various divisions in the GHS. The workshop sensitized and familiarized top management of the GHS to the key concepts of and approaches to IR and its potential value in addressing the key health system challenges in the country. Being slightly removed from the implementation level, it was imperative that policy-makers appreciated the value of IR in addressing implementation challenges encountered by programme managers at the district level. The second component of the sensitization process was to engage academia at the School of Public Health, University of Ghana and to sensitize key players on the content and processes of IR.

Training workshop for national control programmes

Following the sensitization of policy-makers, attention shifted to front-line practitioners of three priority programmes of the GHS: the National Malaria Control Programme (NMCP), National Neglected Tropical Diseases Control Programme (NTDCP), and the National Tuberculosis and Leprosy Control Programme (NTLP). Workshops were designed to equip programme teams to undertake IR on obstacles to the effective and efficient delivery of programme interventions. These obstacles were previously identified during the stakeholder consultations for the development of the national health research agenda.

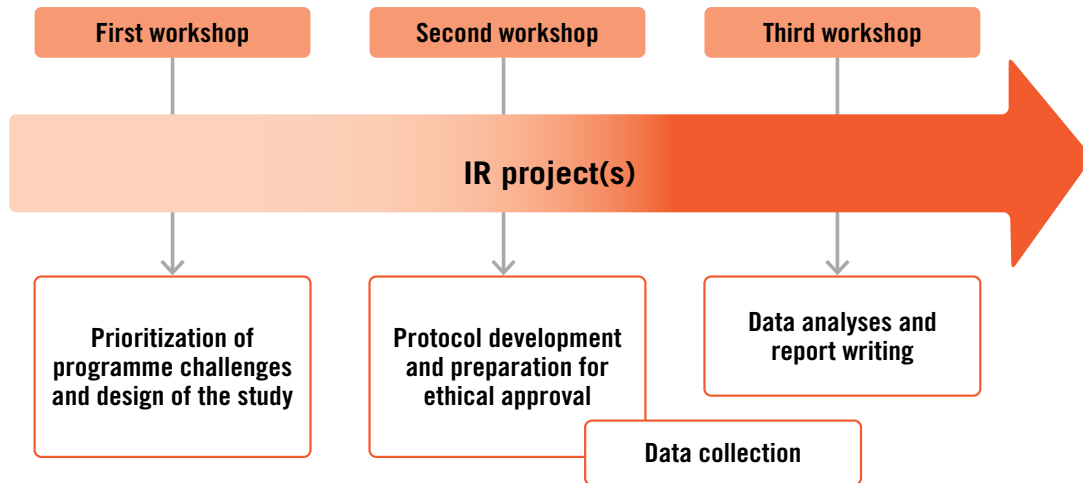
A comprehensive plan was put in place to equip the research teams constituted by the priority control programmes through a series of national workshops – from the identification of research problems through to the development of robust study protocols, conduct of the research, data analyses, and preparation and dissemination of results (Figure).



Case study 3

Building sustainable implementation research in the Ghana Health Service.

Figure. Planning for building IR capacity among priority programme managers



The programme managers constituted teams for the workshops on training and proposal development. Teams comprised a key member of the control programme, respective information officers, and researchers with quantitative and quantitative skills and an interest in the programme.

The workshop helped research teams to start the process of executing IR to address priority problems identified by national control programmes in Ghana. A number of programmes were able to provide funding within their programme budgets to support the resulting research projects.

Lessons: Engagement of key stakeholders in the health sector and research community in the identification of barriers, and development of the national health research agenda, facilitated wider appreciation of the value of IR in achieving national health outcomes. Funds were allocated within the national programme budget(s) to support IR without dependence on external sources.

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IMPLEMENTATION RESEARCH TOOLKIT



Developing implementation research projects
with an intersectional gender lens

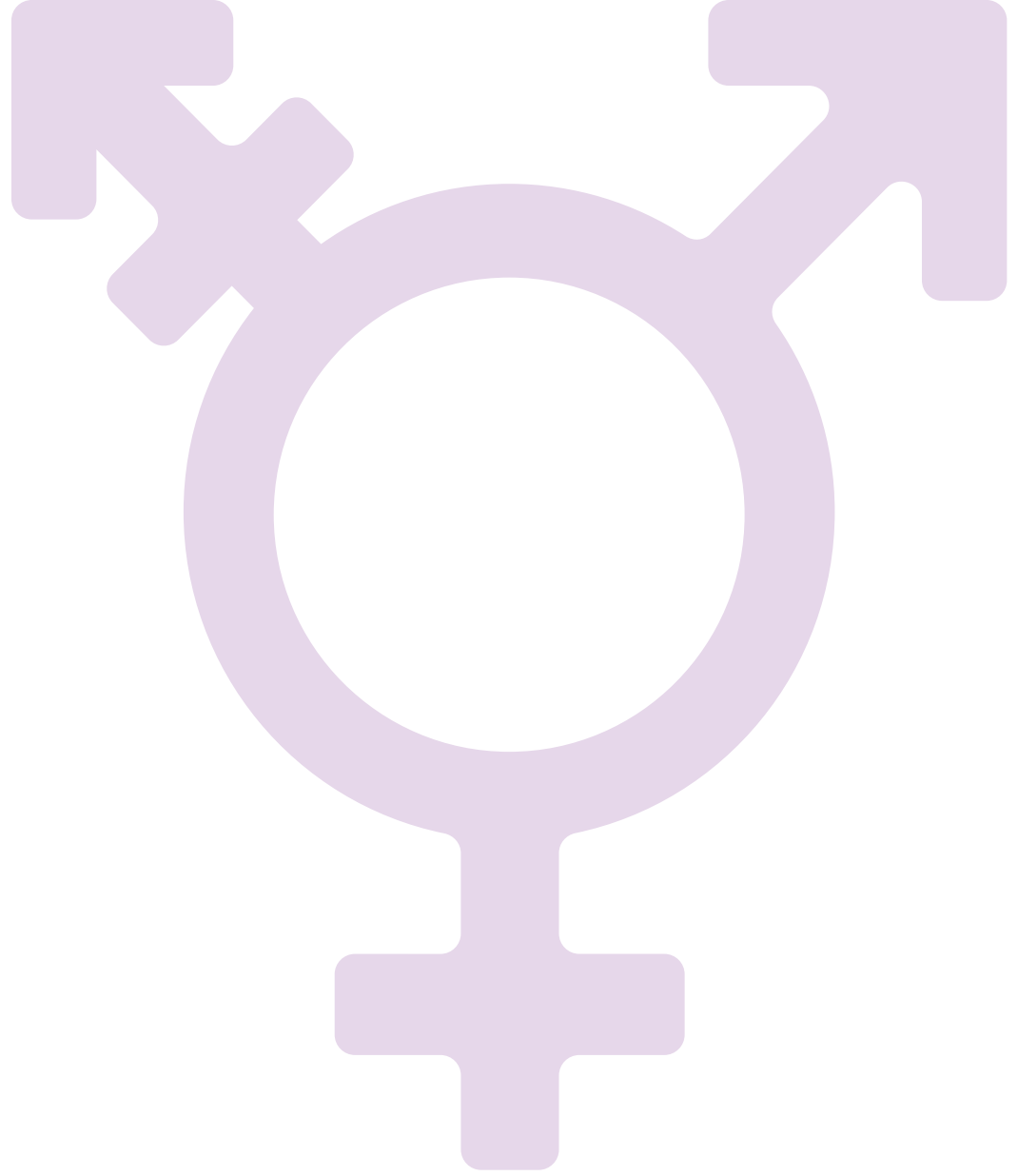
Mariam Otmani del Barrio, Chandani Kharel, Robinah Najjemba and Edward Mberu Kamau

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DEVELOPING IMPLEMENTATION RESEARCH PROJECTS WITH AN INTERSECTIONAL GENDER LENS

Definitions

Sex	The biological attributes that separate males, females and intersex people. Sex is assigned at birth and may differ from a person's gender identity (1).
Gender	<p>Gender refers to the socially constructed roles, behaviours, activities, attributes and opportunities that any society considers appropriate for men and women, boys and girls and people with non-binary identities (1–3).</p> <p>Gender is often relational, shaping how men/boys, women/girls and people with non-binary identities interact with each other and the world around them. As a social construct, gender varies from society to society and can change over time, as individuals construct differing roles and identities that are shaped by broader political, social, and economic circumstances (4).</p> <p>Gender influences people's experience of and access to health care (5).</p>
Gender identity	Gender identity refers to a person's deeply felt, internal and individual experience of gender, which may or may not correspond to the person's assigned sex at birth (4).
Intersectionality	<p>Intersectionality is an analytical lens that examines how different social variables (such as gender, class, race, education, ethnicity, age, geographic location, religion, migration status, ability, disability, sexuality, etc.) interact to create different experiences of privilege, vulnerability and/or marginalization within structures of power (6).</p> <p>Intersectionality and its application in health research is an emerging research paradigm, that seeks to “move beyond single or typically favoured categories of analysis (e.g. sex, gender and class) to consider simultaneous interactions between different aspects of social identity, as well as the impact of systems and processes of oppression and domination.” It embraces the complexities that are essential to understanding social inequities, which in turn are manifested in health inequities (7).</p> <p>Intersectionality is not additive; consider how human and social characteristics such as age, gender, sex, ability, disability, ethnicity, sexuality, etc. interact to shape individual experience at a given point or time (1).</p>



Gender analysis The process of analysing how gender power relations affect the lives of women, men and people with non-binary identities, how differences are created in their needs and experiences, and how policies, services and programmes, can help to address these differences (1).

Intersectional gender analysis The process of analysing how gender power relations intersect with other social stratifiers to affect people's lives, create differences in needs and experiences, and how policies, services and programmes can help address these differences (1).

While intersectional gender analysis aims to move from one dominant social category of analysis and resist essentializing, it does not follow a pure intersectional approach. In this type of analysis, gender is used as an entry point for analytical purposes with an intersectional lens.

Introduction

This module aims to strengthen the capacity of researchers by incorporating an intersectional gender perspective in implementation research (IR). It is a step-by-step guide for researchers to develop an IR proposal incorporating an intersectional gender lens. It aligns with the format of the current World Health Organization (WHO)/ Special Programme for Research and Training in Tropical Diseases (TDR) *Implementation research toolkit* (8), and draws from the WHO/TDR *Incorporating intersectional gender analysis into research of infectious diseases of poverty toolkit* (1).

After completing this module, researchers will be able to:

- understand the relevance and importance of gender and intersectionality in IR;
- develop an IR proposal incorporating an intersectional gender lens;
- plan to implement IR projects using an intersectional gender lens.

Although there are certain elements that are common to other IR toolkit modules, some aspects in this module are emphasized to guide both IR project development *and* addressing implementation challenges for interventions using an intersectional gender lens. The aim of the process is to contribute to the optimization of a given health intervention while ensuring equity in its coverage, thereby contributing to the 2030 agenda for sustainable development and the objective of “leaving no one behind”.

Before using this module, researchers should have already reviewed the Introduction and Understanding IR modules of the IR toolkit (8). Furthermore, you should be familiar with the process of stakeholder analysis and community engagement. It is important that researchers work through the current module *before* designing research questions, as this will help in incorporating an intersectional lens into research questions formulation. For further guidance, refer to the WHO/TDR intersectional gender analysis toolkit (1).

This module comprises four sections:

- Introduction to the concepts of gender, intersectionality and intersectional gender analysis.
- Relevance and importance of incorporation of an intersectional gender approach in IR.
- Development of an IR proposal using an intersectional gender lens.
- Implementation of an IR project using an intersectional gender approach.

Introducing gender

Gender refers to the roles, behaviours, activities, attributes and opportunities that any society considers appropriate for men, women, girls, boys and people with non-binary identities. It is often relational, as it shapes how men/boys, women/girls and people with non-binary identities interact with each other and the world around them. Gender is hierarchical and produces inequalities that intersect with other social and economic inequities. Due to its social construction, gender frequently varies through spaces, contexts and time, as individuals construct differing roles and identities shaped by broader political, social, historical, and economic circumstances (1–3). Gender, as a social determinant of health and a relational construct of power, manifests in different ways to influence peoples’ experience and access to health care at different levels of the health system (9). For example, at an individual level, women’s lack of access to resources can limit the affordability of health services. At a societal level, physical access to health care may be



hampered by social norms that require married women to obtain permission from their husbands/partners before they can seek health care. At the system level, how the health services are organized can either facilitate or limit one's access to health services, for example, if the opening hours do not favour their use by women (10) or the sex of the health provider (e.g. due to religious reasons).

The intersection of gender with an individual's social variables (e.g. ethnicity, class, socioeconomic status, disability, age, geographical location, sexual orientation and sexual identity etc.) with wider social processes (e.g. ableism, racism etc.) and structural processes (e.g. politics, economy, globalization etc.) culminate in individual life experiences of discrimination, marginalization and social exclusion – all of which have complex effects on an individual's health and response to interventions. For further guidance on how gender intersects with other social variables refer to the WHO/TDR intersectional gender analysis toolkit (1).

Introducing intersectionality

The term “intersectionality” was first coined by Kimberlé Crenshaw in 1989 (11). Historically speaking, the concept emerged from various theoretical foundations on feminism (6,12). Intersectionality is an analytical lens that examines how different social variables (such as gender, class, race, education, ethnicity, age, geographic location, religion, migration status, ability, disability, sexuality etc.) interact to create different experiences of privilege, vulnerability and/or marginalization within structures of power (6). An intersectionality approach supports health researchers to understand the drivers of social inequality through due consideration of real-world complexity (13) in which inequities are rarely the result of single, distinct factors but are the outcome of intersections of different social locations, power relations and experiences (6, 14).

The visual representation of intersectionality shown in Figure 1 describes what intersectionality means in practice. It includes three concentric layers that surround each person's unique circumstances of power, privilege and identity: the inner ring describes an individual's characteristics (e.g. age, occupation, religion etc.); the middle ring describes social processes (e.g. ableism, racism, discrimination etc.); and the outer ring describes the structural processes (e.g. politics, legal system, capitalism etc.). It highlights how multiple individual social variables (age, gender, education, etc.) interact within wider social processes (ableism, racism, discrimination, etc.) and structural factors (politics, capitalism, etc.) to shape an individual's position, privilege or disadvantage within society, culminating in an individual being either in a privileged or disadvantaged social category (15). In practice, the use of an intersectionality approach aids researchers to examine power relations, understand the social variables of research participants and how they interact with systemic structural factors to shape their life experiences (7).

Figure 1. Intersectionality wheel. Extracted from (15).

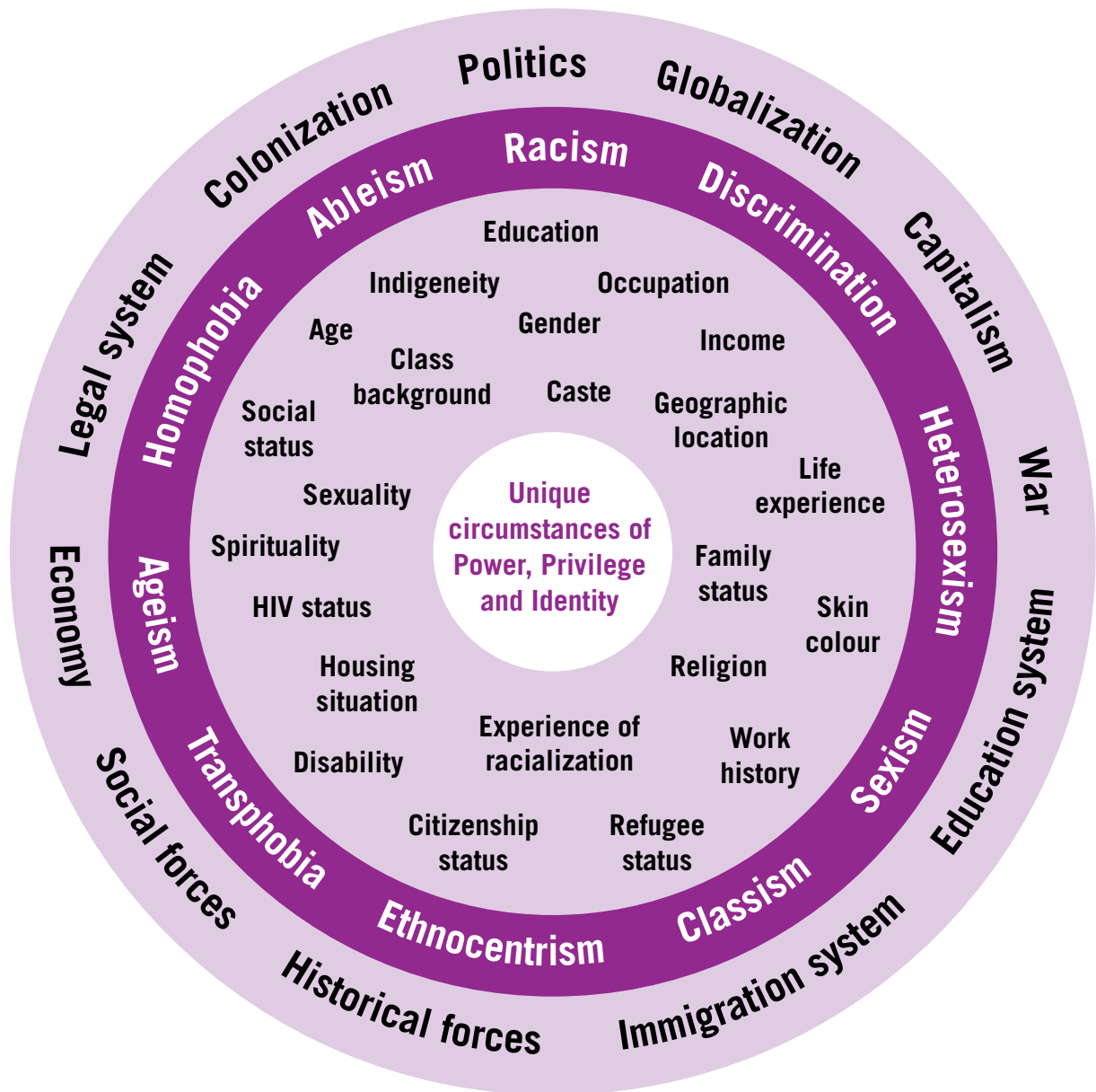




Table 1 presents key considerations regarding intersectionality, including a focus on social inequality and its implications, power dynamics of social relations, the structural and political context, and researchers’ reflexivity (13).

Table 1: Key elements of intersectionality. Extracted from (13).

Focus of intersectionality	What it is...	What it is not...
Social inequality	Based on mutually constituted and intersecting social categories	Based on adding up advantages and subtracting disadvantages assuming equivalence between them
Dynamic nature of inequality	A way of understanding inequalities as dynamic relationships	A static examination of inequalities that omits relational aspects
Contextual dependency	Based on the understanding that power configurations are time and location dependent	A group of <i>a priori</i> assumptions regarding the importance of any one or multiple social categories
Structural and political context	Focus on structural and political factors that shape inequalities	Focus on individual behaviour without consideration of structural and political constraints
Power relations	Explores how social inequalities are shaped by power relations	Ignores the impact of power relations on social inequalities
Implications for most disadvantaged	Focus on implications for vulnerable and marginalized within a group	Focus on implications for those whose status are protected or elevated with a group
Researcher reflexivity	Researchers reflect upon how their own background identity shapes research process and interpretation of results	Researchers attempt to completely remove themselves from the research and analysis process

From an intersectionality perspective, inequality is never the result of a single, distinct factor. Rather inequality is the outcome of intersections of an individual’s characteristics, power relations and experiences with the social systems and structures of power they are embedded in.



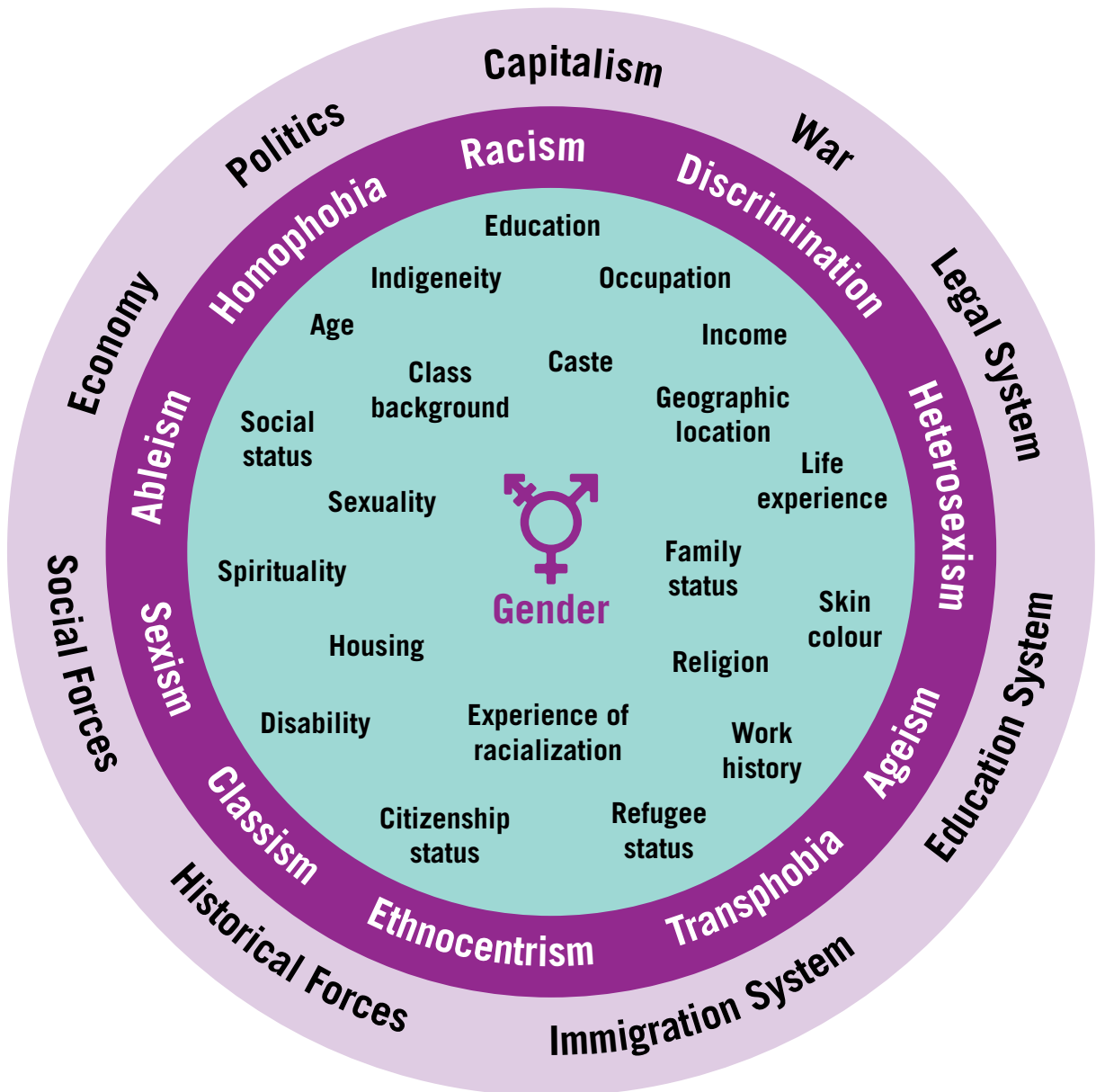
Why an intersectional gender lens in implementation research?

To incorporate an intersectional gender lens in IR, we have selected gender as our entry point to analyse and understand access to health care and how people experience and respond to ill-health and health services, as well as other health-seeking experiences. Gender roles, norms and relations intersect with other axes of inequality (e.g. age, experience of racialization, social status and disability) and these intersections, under connected systems and structures of power, influence why and how health is shaped in specific ways. Understanding how gender intersects with other axes of inequality is important in all stages of the IR process, to avoid neglecting the social dynamics that exist in the community context and how these impact on how and for whom a health implementation strategy works (5).

An intersectional gender analysis in research enables understanding of within-group differences at community level and the complex contexts that drive gender and other social inequalities. Figure 2 below shows the modified intersectional gender analysis wheel where gender is considered as the entry point for doing intersectional gender analysis. This figure helps researchers to think about how gender intersects with other social variables of an individual (for example, age, gender identity, occupation, religion etc.) and interacts within wider processes of social (e.g. ableism, racism, etc.) and structural (e.g. politics, capitalism, etc.) discrimination and privilege to shape an individual's position within society. This approach helps researchers to examine the inequities created at the intersection of such social factors under specific systems and structures of power, which are also influenced by policy processes that are, in turn, shaped by the contexts in which they operate. In addition, as gender is relational, its intersection with other variables within the intersectionality wheel can culminate in privileges or disadvantaged positions in society. It also enables researchers to understand how gender power dynamics and other contextual factors within the community influence implementation and uptake of a given intervention at the different levels of the health system (1).

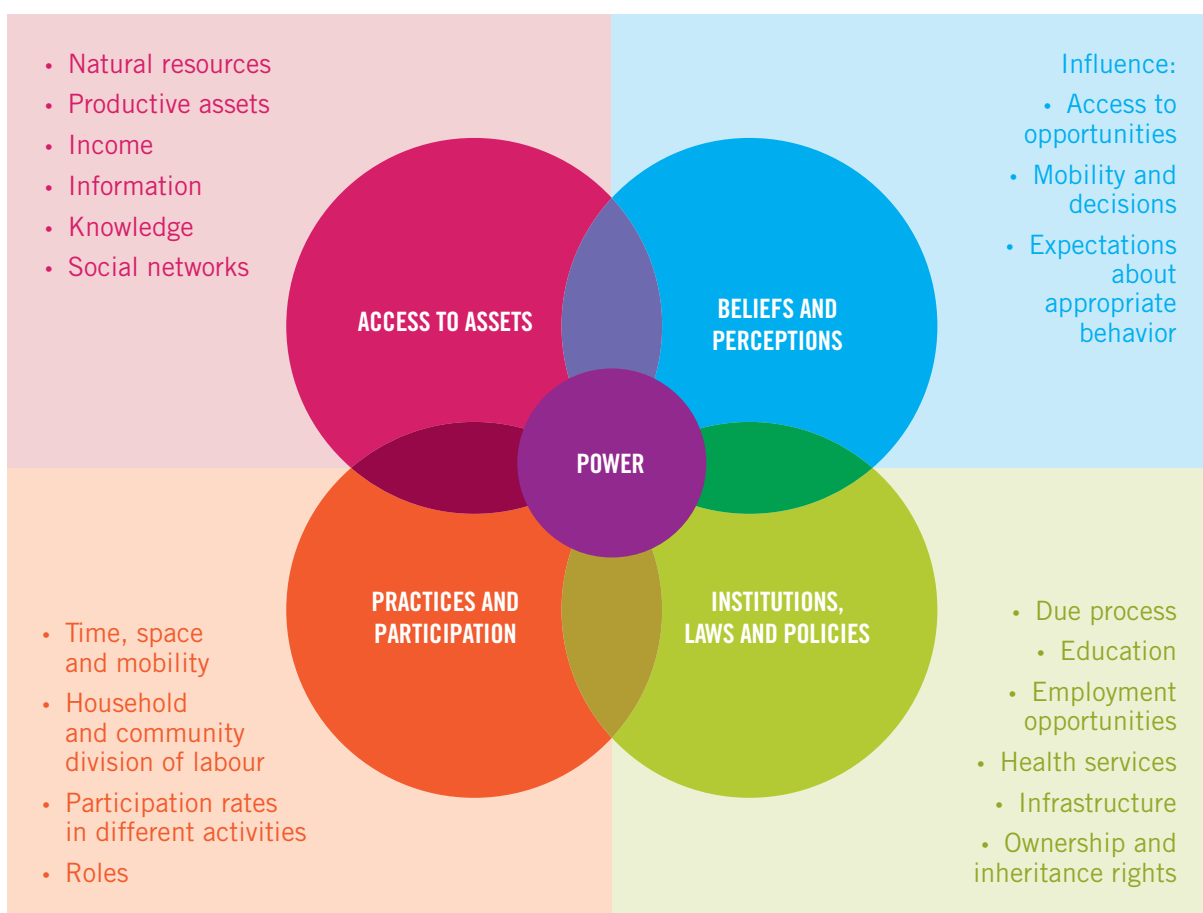


Figure 2. Modified intersectional gender analysis wheel. Extracted from (1).



Various gender analysis frameworks (16–18) can be used as a starting point for incorporating gender analysis within research. These frameworks systematize information about gender-related dimensions across various domains of life and examine how these differences affect the lives and health of men, women, boys, and girls, as well as people with non-binary identities. The *Jhpiego Gender Analysis framework* (17) (Figure 3) describes four gender relation domains: access to assets; beliefs and perceptions; practices and participation; and institutions, laws and policies. Power pervades each of these domains and is key to understanding how gendered hierarchies exist and how these can be a driver of inequality.

Figure 3. Jhpiego Gender Analysis Framework. Extracted from (17).



Intersectional gender analysis frameworks help researchers to explore how gender intersects with other social variables to influence access to specific health interventions (19).

For further details on gender analysis frameworks and guidance on how to conduct intersectional gender analysis, refer to the WHO/TDR intersectional gender analysis toolkit (1). In implementation research, applying an intersectional gender approach enables researchers to understand how gendered power relations and other contextual factors within the community influence implementation and uptake of the intervention at the different levels of the health system.

Evelyn Kabia et al (20) conducted a qualitative study in Kenya to explore how the interaction of personal factors (gender, disability, and poverty) of women living with disabilities and environmental factors influenced their experience while accessing health care (Box 1). Corroborating their findings using the Jhpiego gender framework shows that the intersection of disabled (individual's social variables) women who were also living in/under poverty conditions with household division of labour (practice and participation), limited mobility (access to opportunities), being dependent (access to assets) and negative attitude of the health workers (institutions, laws and policies) influenced their health-seeking behaviours.



Box 1. Example of intersectional gender analysis in health

How do gender and disability influence the ability of the poor to benefit from pro-poor health financing policies in Kenya? An intersectional analysis (20)

A qualitative cross-sectional study in Kenya used an intersectional approach to explore how gender, disability and poverty interact to influence if and how women living in/under poverty conditions in Kenya benefit from pro-poor financing policies that target them. In-depth interviews were conducted with women with disabilities living in poverty who were beneficiaries of the health insurance subsidy programme and those in the lowest wealth quintiles residing in the health and demographic surveillance system.

Results: Women with disabilities living in poverty often opted to forgo seeking free health care services because of their roles as the primary household providers and caregivers. Due to limited mobility, they needed someone to accompany them to health facilities, leading to greater transport costs. The absence of someone to accompany them and unaffordability of the high transport costs made some women forgo seeking antenatal and skilled delivery services, for example, despite the existence of a free maternity programme. The layout and equipment at health facilities offering care under pro-poor health financing policies were not disability friendly. In addition, negative health care workers' attitudes towards women with disabilities discouraged them from seeking care. Negative stereotypes against women with disabilities in the society led to their exclusion from public participation forums, thereby limiting their awareness about health services.

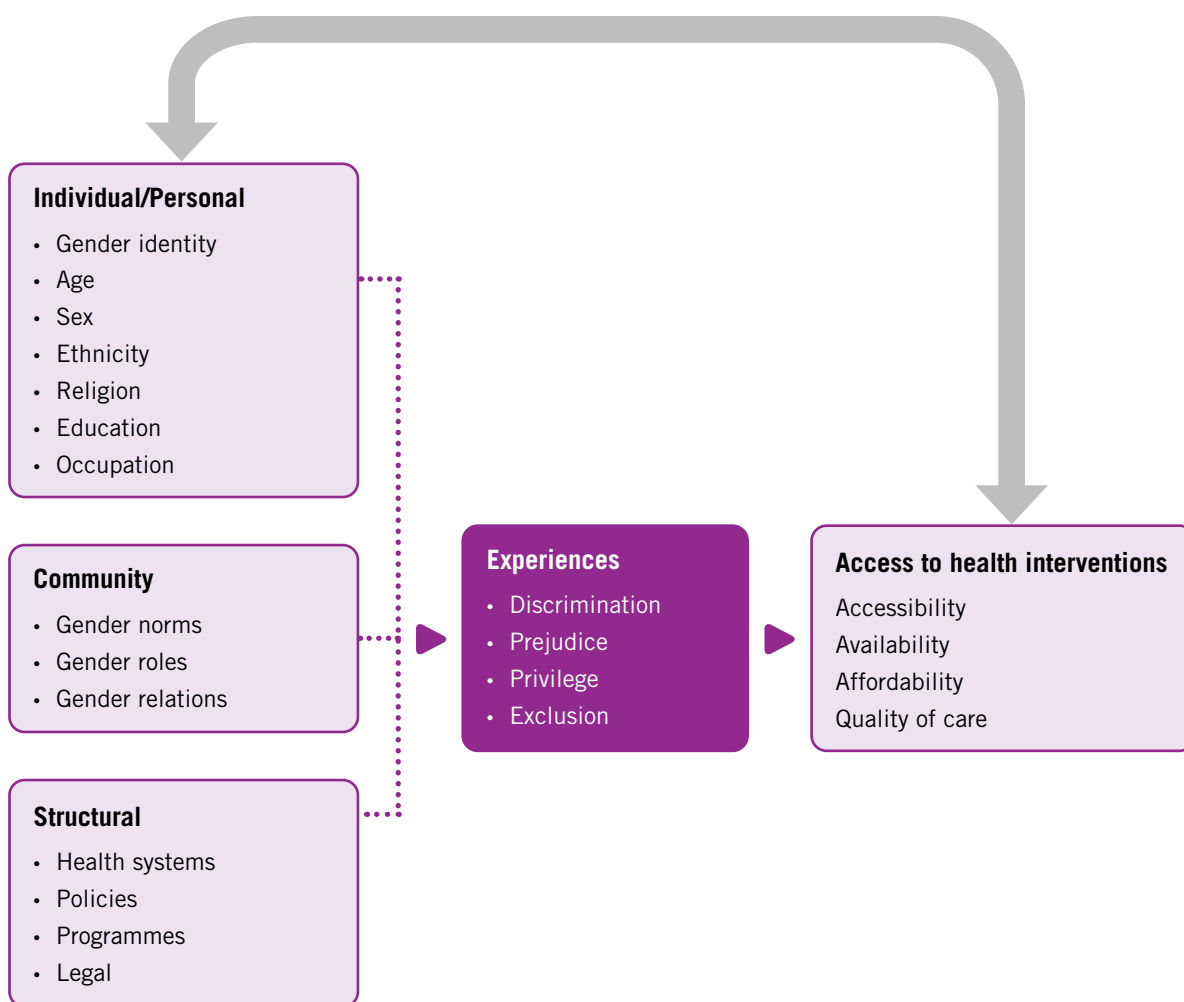
Conclusions: Intersections of gender, poverty and disability influenced the experiences of women with disabilities benefiting from pro-poor health financing policies in Kenya. Addressing the health care access barriers they faced might include ensuring availability of disability-friendly health facilities and public transport systems, building cultural competence in health service delivery, and encouraging the women to engage in public participation.

Using an intersectional gender lens in IR contributes to our understanding of what factors contribute to disadvantaged people within the study population being left behind or neglected while accessing health care, thus enabling researchers to provide evidence based recommendations for policy change.



An individual's social variables interact with local community and structural forces to produce an experience that subsequently affects access to the IR health interventions (Figure 4). If an individual's gender identity influences their access to resources and decision-making, then this can contribute to the individual being in either a privileged or disadvantaged position, which can subsequently influence access to an IR health intervention. In this way, access to, use of and response to health interventions at a community level are significantly influenced by gender power relations with regards to resource availability, resource allocation, societal values and structural systems (1,20).

Figure 4. Intersectional gender analysis framework showing intersection of gender with other social variables. Adapted from (20).





REFLECTION ACTIVITY

Consider the following questions, where possible in relation to your IR project:

- **What is gender and intersectionality?**
- **What is the relevance of gender and intersectionality in implementation research (IR)?**
- **Reflect on the different intersectional gender analysis frameworks.**
- **Reflect and consider why incorporating an intersectional gender perspective is important and its relevance to your IR project.**

Key resources for intersectionality

Hankivsky O. Intersectionality 101 (https://www.researchgate.net/publication/279293665_Intersectionality_101, accessed 3 April 2022) (6).

Larson E, George A, Morgan R, Poteat T. 10 Best resources on... intersectionality with an emphasis on low- and middle-income countries. *Health Policy and Planning*. 2016; 31(8): 964–969 (<https://academic.oup.com/heapol/article/31/8/964/2198131>, accessed 30 March 2022) (13).

Lucas H, Zwarenstein M. A practical guide to implementation research on health systems. Brighton: Institute of Development Studies; 2016 (<https://opendocs.ids.ac.uk/opendocs/handle/20.500.12413/14383>, accessed 3 April 2022) (19).

Integrating an intersectional gender lens in implementation research

Implementation research is neither a single nor linear activity but a continuous, cyclical process that adopts the six steps outlined in this Toolkit.

Although an intersectional gender lens may be incorporated throughout the IR cycle, it should be incorporated as early as possible, such as during the study problem identification and proposal development phases. Further, it is recommended that an intersectional gender perspective is sustained throughout the entire IR cycle (Fig. 5) i.e., from contextualization of the research to dissemination and utilization of the research findings) (21).

Figure 5. Incorporating an intersectional gender lens into the IR cycle
Adapted from (8).



Since IR operates in real-life contexts where several factors including gender and other social factors intersect, researchers should adopt an intersectional gender approach during the IR stakeholder and community engagement processes, project execution and dissemination of research findings (Table 2).



Table 2: Key elements for incorporating an intersectional gender lens in the IR cycle. Adapted from (1,8,12 and 22).

IR process	Issues for consideration
IR study inception	
Setting up a multidisciplinary team	<p>How will you ensure that there is adequate opportunity for participation of men, women and people with non-binary identities in the research team in order to form a diversified team?</p> <p>How might your research teams' personal values, experiences, interests, beliefs and political commitments play a role at each stage of the research process?</p>
Problem identification	<p>What are the perspectives of the target population/ community of interest?</p> <p>What social variables are relevant in the study context?</p> <p>What inequities (between and within groups of people) exist in relation to the health issue/intervention to be researched?</p>
Setting goals and objectives	<p>What are the living experiences of the study participants and how do their social variables intersect to influence these experiences at different levels of the health system?</p>
Stakeholder consultation	<p>How gender and other social variables impact on who wants to be involved; who is able to be involved; how those who are involved interact with each other, and how that affects their contributions (e.g. are power dynamics influencing who is able to speak up in your meetings). These factors can be subtle (e.g. men speaking more often and for longer; hierarchical position amongst men with juniors not speaking in the presence of seniors) or unsubtle (e.g. men speaking on behalf of or over women).</p> <p>How will you identify and select stakeholders to include diverse representation of the community, especially considering that women or marginalized people may be selected as tokenistic representatives.</p>
Proposal development	
Study design	<p>What methodology is appropriate for your study?</p> <p>What data needs to be collected and disaggregated (e.g. age, gender identity, sex, social demographics of study participants) to enable an intersectional gender analysis?</p>
Data collection	<p>Who is involved in the data collection and how will data be collected?</p> <p>How will interview questions be formulated to explore intersecting social variables, including how gender intersects with other axes of inequality (e.g. age and disability, among others)?</p>

IR process	Issues for consideration
IR study inception	
Data analysis	<p>Plan data analysis keeping in mind that different groups of people may be affected variably by the same health condition or issue.</p> <p>How can the findings be interpreted within the wider community context?</p> <p>Are there any unexpected findings (e.g. social variables that only emerge as important during the data analysis?)</p>
Communication of research findings	<p>What do the findings mean for policy, practice and the community, especially in relation to addressing inequalities and vulnerabilities?</p> <p>How to present findings that are sensitive, inclusive and unbiased? What gender-sensitive (responsive) communication products and derivatives will be developed?</p> <p>How do you ensure research findings reach vulnerable and disadvantaged groups?</p>
Project planning	<p>What are the sociocultural and gender relation domains of the study context?</p> <p>What are the sociocultural values and gender dimensions of the implementers?</p> <p>What are the researcher biases and power dynamics within the team and the various project areas, and how can they be mitigated?</p> <p>How do participants with the social identities under research want to be involved in the implementation of the IR project?</p>
Ethical issues	<p>How to address issues of confidentiality and anonymity especially where a given social identity is not recognized by law?</p>

Inception of an IR project

For a successful IR project, a competent interdisciplinary research team (with expertise in biomedical and social sciences) must be assembled, and relevant stakeholders/community members must be identified and actively engaged.

Study team

A multidisciplinary team comprising researchers, policy-makers, programme implementors and health care providers is the core requirement for any IR project. The team should include social science researchers with the knowledge, experience and expertise needed to incorporate and apply an intersectional gender approach in health research. While designing the study, adopt an 'insider perspective' that relates to and identifies with the lived experiences of the study participants. This is important because it promotes empathy, trust and rapport-building,



and ensures the research project is sensitive to the needs and experiences of participants (23). To achieve this, all research team members should reflect upon and recognize how their own values, experiences, knowledge and social positions may influence the research process and outcomes. Researchers can accomplish this through a reflexivity process, which is a cultivated awareness of the influence of relevant identity and power differentials. Reflexivity can help to transform the process of public involvement in health research when both researchers and engaged public research partners bring critical self-awareness about the assumptions and truths in their work (12) (Table 3).

Furthermore, as researchers, you should be cognizant that reflexivity is a continuous process of engaging with and articulating the position of the researcher and the context of the research. The process involves the researcher exploring how their own social variables such as gender identity, ethnicity, level of education, age, religion etc., may affect fellow researchers, study participants and the entire research process. Therefore, an intersectional gender approach calls for a reflexive and continuous examination of the research context, including recognition of how biases influence researcher's activities, and analysis of how multi-level factors interact during the research process and influence forces shaping health-related conditions (14).

Table 3: Reflexivity process: Questions for research project team. Extracted from (12).

Questions for research project team

- a. What are my own personal values, experiences, interests, beliefs and in the area of health we will be researching?
- b. How does my social position (e.g. gender identity, race, ethnicity, indigeneity, socioeconomic status, gender expression, age, sexual orientation, migrant status, religion etc.) and my personal opinions/experiences of oppression (e.g. patriarchy, colonialism, capitalism, racism, heterosexism, ableism) influence the research process, and research outcomes?
- c. What are my personal values, assumptions, perspectives and experiences regarding participants' living experiences?
- d. While working together, how can team members become more aware of and take advantage of opportunities where they can challenge each other's ideas and work towards achieving equality within their project team?
- e. What do you think are some of the ways to ensure that everyone feels "comfortable" when working together on this research project? What are some of the best ways to work together to address the research problem?
- f. How do you think people with lived experience in this area of health would prefer to be involved in research and why? What types of challenges would need to be addressed to make it easier for them, as well as their families and communities to become involved in research?



REFLECTION ACTIVITY

The purpose of this activity is to help:

- (i) individual researchers pay attention to their research context, dynamics within the research team, and potential biases through critical self-reflexive practice;**
- (ii) team members work collaboratively to become more aware of power imbalances and take advantage of opportunities to challenge assumptions towards more equal team dynamics.**

Each team member should individually answer the reflexivity questions in Table 3 and analyse your answers. As a team, reflect and analyse how the interplay of individual identities, the research context and team dynamics may affect your IR project overall.

Stakeholder identification and engagement

Stakeholders have been defined as individuals, organizations and communities that have a direct interest in the process and outcomes of a project, research or policy endeavour (24,25). Stakeholders include those people for whom the research will be beneficial. The type and number of stakeholders will vary depending on the nature of the research problem, but typically include research participants and other community members, policy-makers, government officials, health workers, funding agencies, programme officers, development workers and the researchers themselves. Since IR and intersectional gender analysis are participatory in nature, researchers should pay special attention to engaging stakeholders so that the group is diverse enough to include all stakeholders relevant to your IR study. Conducting a stakeholder analysis helps to understand the context of the intervention as well as to identify all relevant stakeholders, assess how they are likely to be affected by the research, and how they might respond to the research outcome. Similarly, it helps you as a researcher to identify their needs, understand their priorities and plan how to respond to them. The process of stakeholder identification and engagement should be iteratively led by the researchers and incorporated throughout the IR project cycle.

An intersectional gender perspective should be considered while selecting stakeholders from all relevant organizations and segments of the population. To ensure diversity of participants, consider how gender and other social variables



impact on who wants to be involved, who can be involved, how those who are involved interact with each other and how that affects their contributions. As researchers, it is good to be cognizant that gender-related power dynamics influence stakeholder participation. During stakeholder meetings, the moderator has a key role in identifying stakeholders who are shy or being overridden by other participants, and encouraging them to engage and participate in the discussions. For example, female participants might not speak up if male participants consistently override them while speaking, but the moderator can encourage the female participants to speak. Power and position of a participant can also influence the engagement of other participants. For example, if two persons from the same organization with different hierarchical positions are involved, the junior person might not speak and shy away from taking leadership even when they have better knowledge and competence than their senior colleague(s). The key steps for conducting a stakeholder analysis are:

- a. Define the purpose of the analysis.
- b. Generate a list of potential 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).
- c. Collect necessary data (e.g. using interview guides and semi-structured questionnaires).
- d. Analyse and present 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).

In addition, you should be mindful that the social variables of individuals involved in designing the study, recruiting participants, collecting, analysing and disseminating data are critical to effectively respond to the specific needs of the study participants.

Community engagement

Community engagement is vital throughout an IR project, building on the strengths and resources within the community. ‘Community’ may be understood as a group of people who live in the same local geographical area or who have some other non-spatial element of shared social identity, such as a similar trade or group membership, or organized entities that operate within a community such as local government, district health teams, or other community-based organizations, such as religious or civil society groups (26, 27). Community engagement is the meaningful, respectful and fit-for-purpose involvement of community members in one or more aspects of an IR project (27).

Actively engage the community throughout the entire IR cycle (i.e. from problem conceptualization during the design and development of the research proposal, project planning and implementation, data collection, analysis, and interpretation of results). This involves consultation, communication, participation, partnerships

and raising awareness. Community engagement also provides a conducive co-learning environment for both the researchers and the community, which is based on the communities' experiences, historical and current social cultural context. In addition, it builds trust and rapport that aids the entire research process, enhancing a timely balance between research and action (28, 29). Table 4 summarizes the role of community engagement at the different phases of the IR cycle, and also highlights potential opportunities to incorporate an intersectional gender perspective.

Table 4: Potential roles of community engagement at different points throughout the IR cycle Adapted from (25).

Phase in the IR cycle	Input on key problems or issues to be addressed
Problem identification	Understanding context, needs and priorities of the community; conceptualizing key issues; identifying key stakeholders to involve; conducting stakeholder mapping and intersectional analysis.
Design and planning	Shaping key research aims; questions to meet local objectives; input into methodology especially contextually appropriate approaches for data collection (including those for intersectional analysis); review of research documents and tools (e.g. protocols, consent forms, instruments that include intersectional variables).
Implementation	Generating awareness and ownership of research project; potential involvement in an intervention being studied; pilot testing of instruments; participating as data collectors or respondents; formal partnership and collaboration with community groups that go beyond single or favoured social categories/identities.
Analysis and interpretation	Interpreting findings; discussing implications; adding contextual depth and sensitivity to recommendations.
Knowledge translation	Discussing implications of findings; issue prioritization, planning and implementation of follow-up actions; tailoring evidence to enhance community voices of diverse social identities.
Iteration and adaptation	Establishing ongoing community participatory monitoring and evaluation (M&E) and social accountability mechanisms to increase transparency of key service delivery outcomes.

Box 2 provides an example describing how engaging the community enabled implementers to identify the appropriate and effective medicine distribution points in a mass drug administration (MDA) programme for neglected tropical diseases (NTDs) in four west African countries.

**Box 2. Example of community engagement in implementation of a health intervention*****Understanding who is left behind and why in mass drug administration (MDA) initiatives: Lessons from four country contexts***

Background: A study by Dean et al (2019)(30), established that active engagement of the community is critical for the success of an IR project. They used participatory community mapping methods across, Cameroon, Ghana, Liberia and Nigeria and identified key medicine distribution methods during MDA.

Results: Across all contexts, both house-to-house and fixed-point distribution methods were called for by community members. In Liberia, house-to-house methods were preferred in some rural areas because it allowed community drug distributors (CDDs) to identify those who were reluctant to take medicines and to ensure appropriate spread of awareness messaging. On the other hand, in Nigeria and Cameroon both house-to-house and fixed-point distribution methods were indicated to minimize cost and time for community members. However, in other rural areas, fixed point distribution was preferred as group distribution was thought to have the potential to increase medicine acceptability especially among women who felt more comfortable taking medicines in the presence of their friends.

Conclusion: Intersectional factors that guided preference for fixed-point distribution locations across contexts included geography (urban/rural), religion, gender, presence of clinics, existing community meeting points, religious structures, and marketplaces. The social position of chiefs in Cameroon and Nigeria enhanced their house to be selected as distribution points.

Box 3 presents an example describing how community engagement with the Indigenous people in Australia was key in linking them with the health system, improving local health services, increasing their trust and access to care.

Box 3. Example of effective engagement between community and health services for the improvement of health care for Indigenous population in Australia

Background: In 2016, the study entitled “Improving healthcare for Aboriginal Australians through effective engagement between community and health services” from Durey et al (31) evaluated a unique strategy of community engagement between local Indigenous populations and health providers across five districts in Perth, Western Australia to improve local health service delivery for Indigenous Australians. This qualitative study aimed to identify whether this Indigenous community considered the community engagement strategy effective in identifying their health service needs, translating them to action by local health services and increasing their trust in health services.

Methods of community engagement: Community consultations were conducted to identify key health areas of concern for this community, to strengthen existing relationships and build the community’s trust through transparent communication. Forums were held with up to 80 Indigenous Australians attending area-wide gatherings to share, review and exchange information with the community, and using community feedback to improve practice. The Aboriginal Health Team (AHT) coordinated and brought together local Indigenous citizens, Indigenous community-controlled health services, representatives from the Department of Health Western Australia, public hospitals, mental health and community health services, and divisions of general practice. These interactions resulted in the establishment of five District Aboriginal Health Action Groups (DAHAGs) located within the organizational structure of the Department of Health in Western Australia.

Results: Findings from 60 participants suggested the engagement process was effective: it was driven and owned by the Indigenous Australian community, captured a broad range of views, and increased community participation in decisions about their health care. It built community capacity through regular community forums and established DAHAGs comprising local Indigenous community members and health service representatives who met quarterly, and were supported by the Aboriginal Health Team at the local Population Health Unit. Participants reported health services improved in community and hospital settings, leading to increased access and trust in local health services.

Conclusions: The evaluation concluded that this process of actively engaging the Indigenous community in decisions about their health care was a key element in improving local health services, increasing their trust and access to care.



Key resources for stakeholder analysis and community engagement

Glandon D, Paina L, Alonge O, Peters DH, Bennett S. 10 Best resources for community engagement in implementation research. *Health Policy and Planning*. 2017; 32(10):1457–1465 (<https://academic.oup.com/heapol/article/32/10/1457/4582360>, accessed 30 March 2022) (27).

De Weger E, Van Vooren N, Luijkx KG et al. Achieving successful community engagement: a rapid realist review. *BMC Health Serv Res*. 2018;18:285 (<https://doi.org/10.1186/s12913-018-3090-1>, accessed 30 March 2022) (32).

Hyder A, Syed S, Puvanachandra P et al. Stakeholder analysis for health research: case studies from low- and middle-income countries. *Public Health*. 2010;124(3):159–66 (doi: 10.1016/j.puhe.2009.12.006, accessed 30 March 2022) (33).

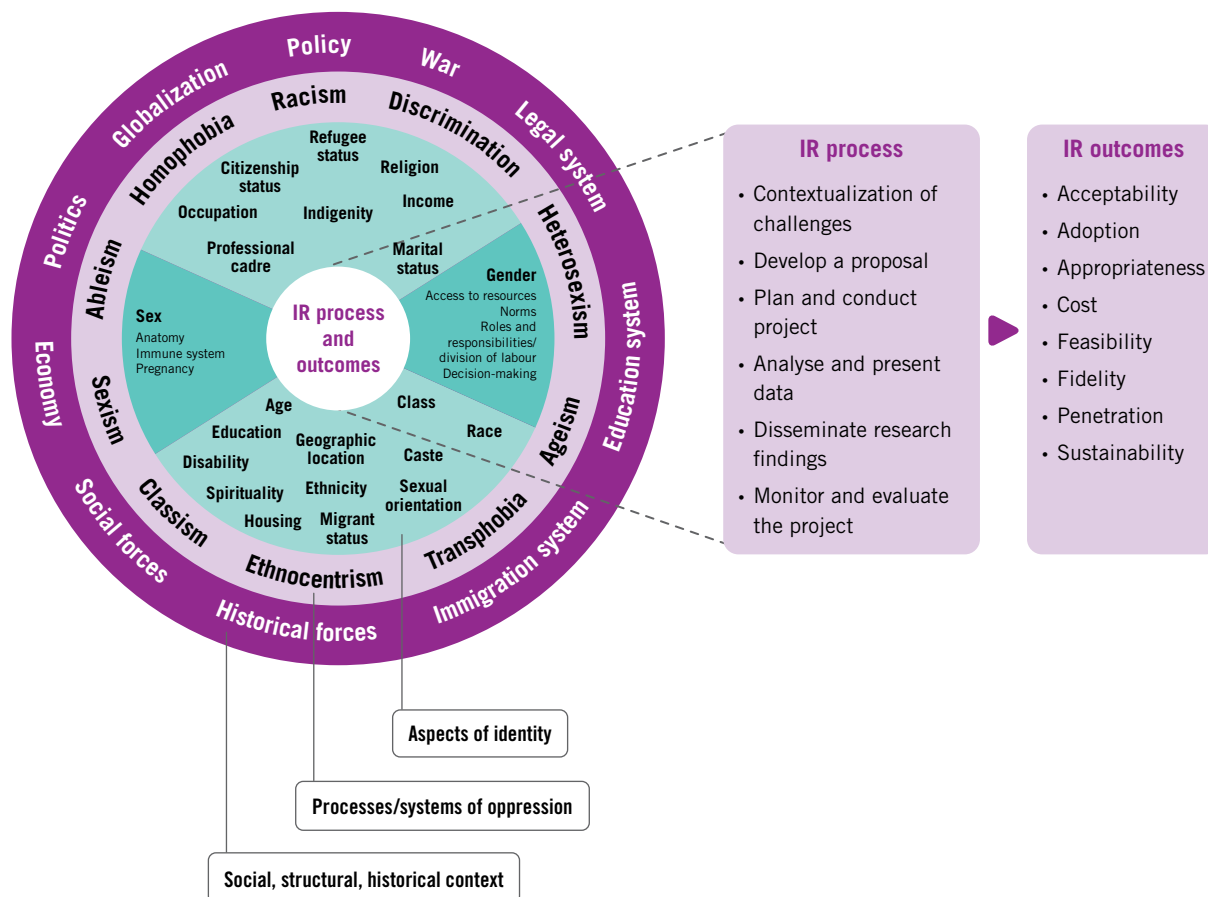
Conceptualization of research

Study conceptualization that is rooted in gender and intersectionality analysis frameworks can examine the complex systems of feedback loops and interactions between different levels of the intersectionality wheel (34). The first step to incorporate an intersectional gender lens or approach in IR should be during the conceptualization of the research project (22). This can be systematically carried out through the collective engagement of relevant stakeholders. To avoid any potential conflicts arising later in the research process regarding interpretation of concepts, the definitions of social variables and research outcomes should be clear and concise from the outset. The definitions should be in alignment with the social, cultural, economic, political and historical context of the selected community or geographic location. You may start the process by brainstorming through the concepts and terminologies. It is also helpful to consult prior work done in that region to understand how the local community members perceive certain terminologies. It is critical for all team members to clearly understand the concepts and definitions before you proceed.

After your team has agreed on the relevant concepts and definitions, incorporating an intersectional gender approach allows for critical reflection about how gender intersects with other social variables in the context in which the study participants live and where the health interventions would ultimately be implemented. This enables exploration and understanding of these intersections and the societal and institutional factors that facilitate or impede a given IR study. Further guidance on incorporating an intersectional gender analysis throughout the six steps of the IR process to achieve the desired outcomes is highlighted in Figure 6.

Due consideration should be given to gender domains and social variables that are relevant to a specific research problem. Such an intersectional gender analysis process is a critical step and if it is skipped, then important social variables – that may play a significant role within a given study context – could be overlooked (35).

Figure 6. Modified intersectional gender analysis framework for IR. Adapted from (1,8).



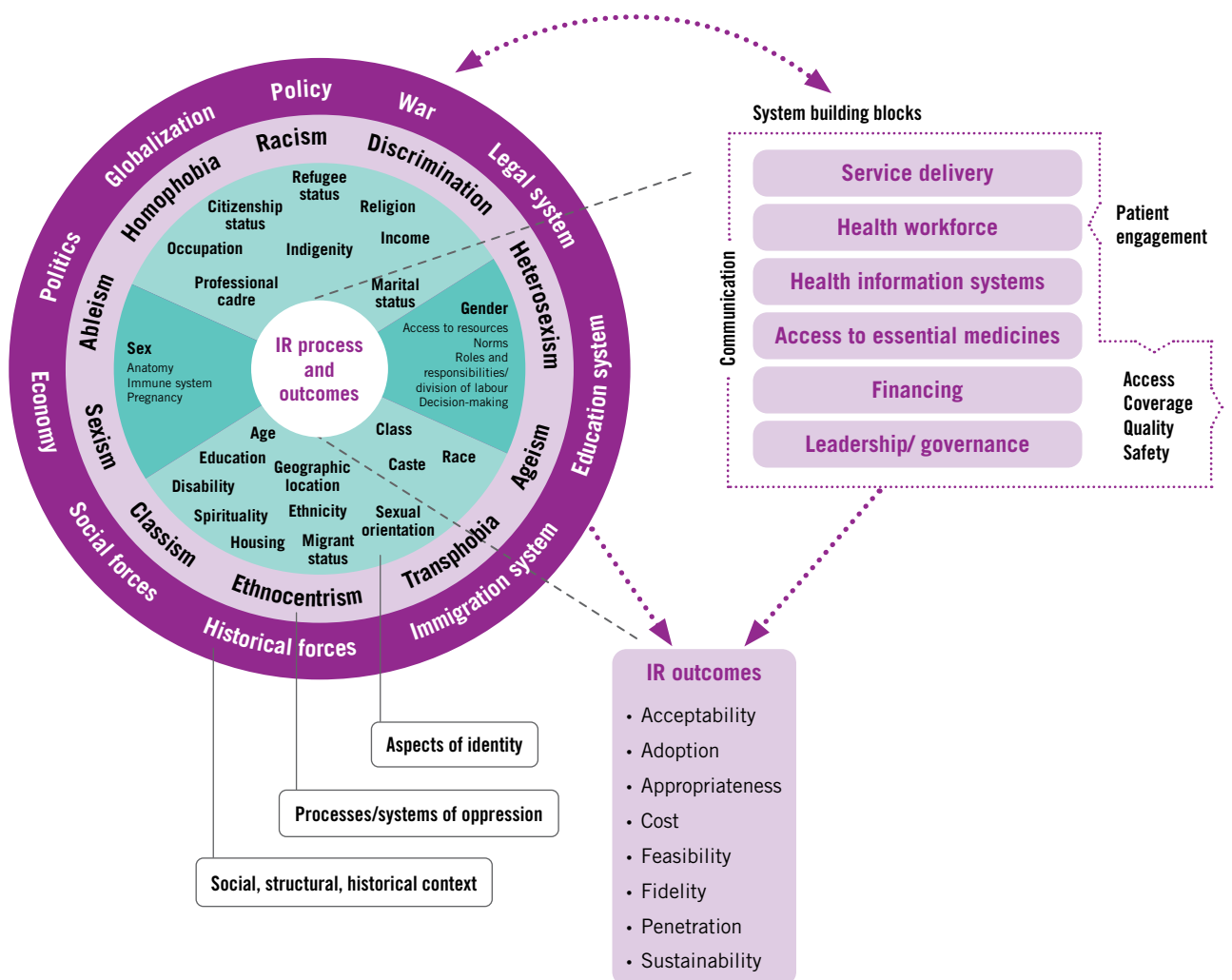
Various health system frameworks have evolved over time. WHO defines a health system as: “All organizations, people and actions whose primary intent is to promote, restore or maintain health” (36,37). The ‘building blocks’ of the WHO *Health Systems Framework* can be used as a guide by IR teams to assess how each of the building blocks might be implicated in the health intervention under study, as well as in the solutions to identified barriers.

Health systems are not gender neutral; gender is a key social variable and affects health system needs, experiences and outcomes (19,38). When designing and implementing health systems interventions, it is often assumed that an intervention will be equally effective for men, women and people of other gender identities across all socioeconomic strata (39). It is important to be cognizant that implementers often fail to recognize how power relations related to gender can affect how someone interacts with, accesses, uses or generally responds to a specific health intervention (19).



An individual's experiences while accessing health services also shape their decisions regarding utilizing a health intervention. For example, if an adolescent unmarried girl visiting a health facility for information on oral contraceptives is ridiculed or judged by a health worker for seeking such information, she will prefer not to seek care from that health facility irrespective of the best intervention rolled out in the future targeted for adolescent girls. Figure 7 shows how the intersectionality wheel is intrinsically linked to the health system, and can also affect the uptake of a health intervention in a given IR project.

Figure 7. Interlinkages between the intersectionality wheel, health system and IR outcomes. Adapted from (1 and 8).





Participatory community engagement is key for study conceptualization as it helps identify community problems or concerns, understand their priorities and needs, identify relevant stakeholders, and ensure continuous participation throughout the research process.



REFLECTION ACTIVITY



In your teams:

- 1. Define the social variables relevant for your IR project.**
- 2. Discuss how gender can interact with the social variables selected for your IR study.**
- 3. Brainstorm about how you will engage the community and conduct a stakeholder analysis in the selected geographic location.**
- 4. Discuss which intersectional gender analysis framework is appropriate for your study in alignment with your selected IR outcomes.**

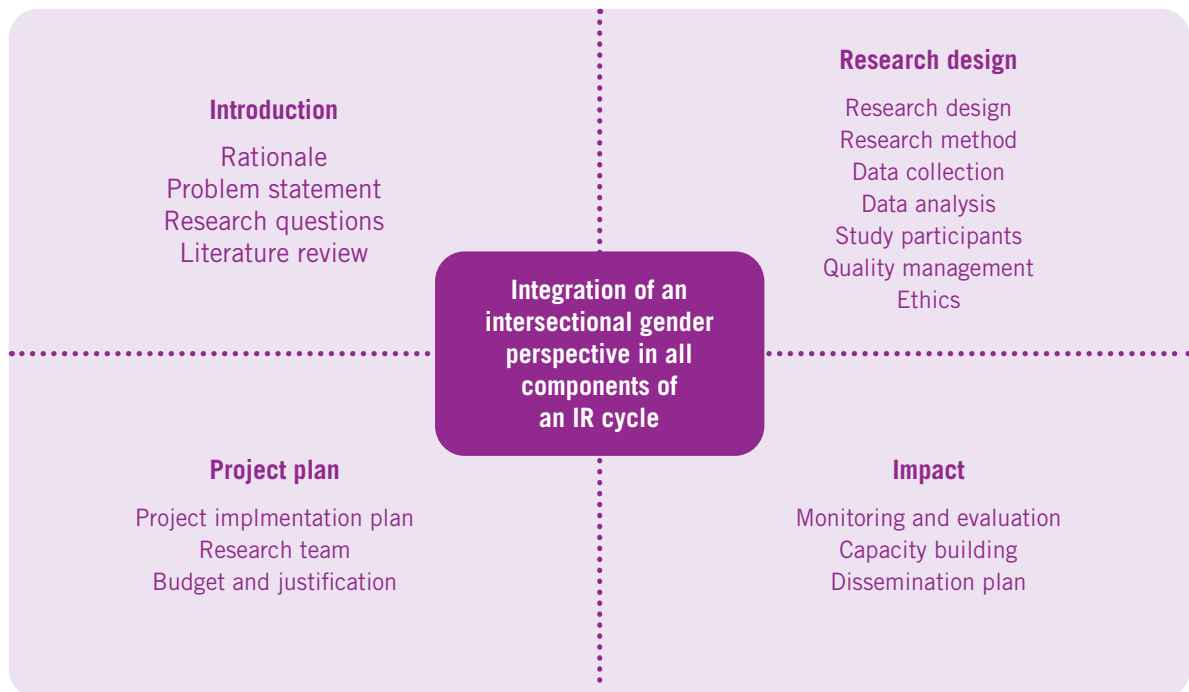
Proposal development with an intersectional gender lens

Proposals for IR projects differ from those used in other types of research primarily because IR originates from a problem identified and prioritized by end-users – so that the research findings can be used within the available health system framework and implemented appropriately for end-users' immediate benefit. Developing an IR project proposal from an intersectional gender perspective is critical for addressing implementation bottlenecks (Figure 8).

Integration of the intersectional gender perspective should start at proposal development stage of the IR process (22), which includes conceptualization of the research, problem analysis, research design and plans for data collection, analysis and implementation, and dissemination of research findings.



Figure 8. Integrating an intersectional gender perspective within all components of an IR proposal. Adapted from (8).



Study rationale

The rationale of an IR study should be convincing to relevant funding agencies and policy-makers, so they will potentially commit resources to your IR project and make relevant policy decisions or changes informed by the results of the study. In the rationale of an IR proposal, the importance of the research – in relation to existing local and national research agendas or policies – should be clearly described and justify why the study needs to be conducted. State how the ‘voices’ of the vulnerable population will be incorporated and harnessed to draw the necessary recommendations that will enhance their access to the intervention, including at different levels of the health system (40, 41). This can be achieved by clearly describing how participants will be selected during stakeholder and community engagement steps to ensure diversity and representation of vulnerable populations in the study context.

Research problem statement

The research problem should be of interest and justifiable to all stakeholders (e.g. researchers, policy-makers, decision-makers, funding agencies, care providers and the community affected by the research). In your problem statement, describe the problem, its magnitude, the current health practices, health-seeking behaviours of vulnerable populations and factors preventing them from accessing

the intervention. Describe what might be the gender-related challenges and opportunities for the proposed IR solutions. Specifically, using an intersectional gender lens, explore how gender dimensions interact with other social variables (e.g. socioeconomic status, sexuality, age, refugee status, geographic location or religion, among others), to influence implementation of your IR study.

Research questions

Research questions should be of interest and relevance to all project stakeholders.

Informed by gender frameworks, intersectional gender analysis questions can be developed to guide researchers in the overall direction of the study, including informing research objectives, developing research questions and hypotheses. These questions help researchers move beyond describing the differences between men/boys, women/girls, and people with non-binary identities, to examine and critically interpret how gender inequities manifest within a particular context, how they intersect with and are influenced by other drivers of inequality, and their effect on IR (1).

When developing intersectional gender-informed IR questions, consider the different social variables within the inner circle of the intersectionality wheel (15), that interact to shape individual experience under the contextual factors in which the IR project is being conducted. Key contextual factors – such as physical factors, political environment, economic, social and cultural structures, health systems etc. – should be analysed objectively to ensure that the research questions are formulated and framed considering such factors.

IR questions must be sensitive to the diverse characteristics of the IR project target population (e.g. gender identity, age, social status, (dis)ability, sexual orientation etc.). An intersectional gender perspective does not assume the same experience across population sub-groups (e.g. not all pregnant women in the same geographic area experience similar barriers to access health care). This reflects that decision-making is influenced by different systems and structures of power as well as other factors that influence access to social, economic and political resources. For example, Morgan et al (42), established that at a societal level, pregnant women with disabilities in a Ugandan community were shunned by the men who were responsible for their pregnancy, while at the health facility level, the health workers' poor attitudes and behaviours towards them were derogatory, which consequently negatively affected their maternal health-seeking behaviours.

This also highlights differences between gender analysis and intersectional gender analysis research questions, as illustrated in Table 5.



Table 5: Examples of gender analysis and intersectional gender analysis research questions. Adapted from (1).

Gender relations domains	Gender analysis questions	Intersectional gender analysis questions
<p>Access to resources (e.g. education, information, skills, income, employment, services, benefits, time, space, social capital, etc.)</p>	<p>How does access to financial resources affect men's and women's abilities to access the IR intervention?</p> <p>How does access to health information affect men's and women's abilities to access the IR intervention?</p>	<p>To what extent does access to financial resources differ between the different social categories of men, women, people with non-binary identities (e.g. education, migration status, age, ableism etc) to influence their access to the IR intervention?</p> <p>To what extent does access to health information regarding the IR intervention differ between the different social categories of men, women, people with non-binary identities (e.g. ethnicity, marital status, geographical location, education, migration status, age, ableism etc)?</p>
<p>Division of labour (within and beyond the household and everyday practice)</p>	<p>To what extent does men's and women's household work role affect their ability to access the IR intervention?</p>	<p>How do socially assigned household roles/responsibilities influence access to the IR intervention between the different groups of men, women, people with non-binary identities (e.g. class, migrants, education level, age etc.)?</p>
<p>Social norms (ideologies, beliefs, and perceptions)</p>	<p>How do social/cultural norms affect women's ability to seek the IR intervention?</p>	<p>How do the social norms in relation to seeking the intervention in your IR project differ between different groups of women by (e.g. age, education, class, ethnicity etc)?</p>

Gender relations domains	Gender analysis questions	Intersectional gender analysis questions
Decision-making power <i>(e.g. seeking permission to leave the house, on how financial resources will be used)</i>	Do women have autonomy to access the intervention in your IR project? Do women make decisions on how to use finances to access the intervention in your IR project?	How does autonomy to seek the intervention in your IR project differ between different groups of women (e.g. age, education, religion, class etc.) How does autonomy to use finances to seek the intervention in your IR project differ between different groups of women (e.g. age, education, religion, class, occupation, disability etc.)

To develop gender analysis questions for IR, recognized implementation outcome variables should be used to develop related gender analysis questions. Various implementation outcome variables have been devised that act as indicators of how well the intervention is working (43,44). The variables are acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration and sustainability.

While constructing intersectional gender analysis questions, it is important to ask: How does this differ between different groups of men, women and non-binary people? How does gender intersect with other social variables (e.g. age, gender identity, education) to create differences between different groups of men, women and non-binary people? Table 6 shows an example of intersectional gender analysis questions informed by a gender framework (16), mapped against feasibility, one of the implementation outcome variables.



Table 6: Examples of intersectional gender questions linking a gender domain and an implementation research outcome. Adapted from (1, 19).

Implementation outcome variable: Feasibility (i.e. the extent to which an intervention can be carried out in a particular setting or organization)	
Gender power relations domain	Examples of intersectional gender questions
Access to resources	To what extent do women and men (or other marginalized categories of people) have the same access to material resources and opportunities for education and training? To what extent do family support and roles help or limit opportunities for training by gender identity, marital status, age or other social variables? How might this affect stakeholder engagement within an intervention?
	To what extent do women (or other marginalized categories) have sufficient literacy, autonomy and access to technology to effectively use an intervention?
	To what extent is protective health equipment and gear made available and does it fit bodies that are not the male standard?
Division of labour and roles	To what extent are women more or less likely to work in frontline health service delivery in poorly compensated (including volunteer) or less-supported positions than men? How does this affect who implements an intervention and how?
	How do men's and women's roles and responsibilities affect the use of products used within the intervention (e.g. bed nets, vaccinations)?
	What are the challenges different groups of women and men might face in adhering to long-term treatment (e.g. for tuberculosis, HIV or diabetes)? Are they appropriately supported, or stigmatized within health systems and community-based structures?
Social norms	How do women and men within households and communities prioritize individuals' access to medical technologies or commodities used within an intervention (e.g. are boys or girls more likely be prioritized for oral rehydration therapy)?
	How do social norms and notions of masculinity and femininity influence men's and women's decisions to use the protective equipment required in an intervention?
Rules and decision-making	To what extent does regulation stand in the way of making services used within the intervention more widely accessible for women or marginalized groups (e.g. medical abortion, family planning)?
	What is the effectiveness of regulatory mechanisms to ensure that medical products for women or other marginalized groups are not misused (e.g. oxytocin to augment labour)?



REFLECTION ACTIVITY

How will you identify the problem relevant for your IR study?

What are the gender relations domains you have selected for your study?

What are the implementation outcomes you plan to achieve?

Using Tables 5 and 6 to guide you, develop your research question incorporating an intersectional gender lens that is relevant to your IR study.

Example of an intersectional gender analysis research question

To what extent does access to mass drug administration (MDA) for lymphatic filariasis differ between men, women and people with non-binary identities, and how do their social variables (e.g. ethnicity, geographical location, education, migrant status, age, ableism etc.) intersect to influence their access?

Literature review

A literature review provides a foundation of knowledge on a given research topic.

To incorporate an intersectional gender perspective, focus the literature search on exploring how gender intersects with other social variables or axes of inequality in relation to your IR problem (1). Use keywords sensitive to gender and intersectionality. For example, O'Neill et al (45) explored the utility of using an acronym PROGRESS (i.e. place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status, and social capital) while conducting 11 systematic reviews and methodological studies published between 2008 and 2013 to assess effects of interventions on health equity. Box 4 shows examples of keywords for intersectional variables that can be used while conducting a literature review.



Box 4. Example of intersectional variables used as keywords for a literature review. Adapted from (45 and 46).

Intersectional variables at the:

- *Individual level:* (age, sex, gender, gender identity, “race”, ethnicity, income, education, employment status, professional status, socioeconomic status/class indicator (SES-indicator), marital/partnership status, single-parent household, migrant status, religion, dis/ability, sexual orientation, region of residence, urbanity/rurality).
- *Area level:* (age, sex, gender, gender identity, “race”, ethnicity, migrant status, income, education, employment status, SES-indicator, marital/partnership status, social capital, urbanity/rurality).
- *Regarding contextual inequality indices:* (gender inequality, indices of multiple deprivation) as well as occupational segregation (sex, gender identity, “race”, ethnicity).

Consult multiple sources of data including specific community-based research, published and grey literature. Much of the community-based research might not be published in peer-reviewed journals. Therefore, it will be useful to conduct internet searches for the information posted on the respective websites of community organization (47) that are active in the geographic area of your IR project. You can also enrich your literature review by citing prior studies that highlight significant similarities and differences between the different social identities, which in turn can inform the thinking behind the research project design.

Research objectives

Research objectives should be specific, measurable, achievable, realistic and time bound. While developing your research objectives, think about which implementation outcomes are appropriate for your study and how they can be measured. IR study objectives with an intersectional gender lens should be aligned with the corresponding research questions and sufficiently strategic to help reduce implementation bottlenecks, thereby promoting access and intervention coverage among the vulnerable target population. In other words, the objectives should contribute to the elimination or alleviation of the negative experiences by the vulnerable target population. Box 5 shows examples of research studies in which research objectives denote an intersectional gender approach.

Box 5. Examples of research objectives with an intersectional gender lens.

To assess barriers to VL [visceral leishmaniasis] diagnosis and treatment for different groups of men, women, and people with non-binary identities in endemic districts with a high burden of VL (48).

To assess the extent of disparities in health expectancy among the elderly from different ethnic groups using quality-adjusted life expectancy (49).



REFLECTION ACTIVITY

Using the examples in Box 4, brainstorm among team members to develop your research objectives adopting an intersectional gender lens that is relevant for your IR project.

Research design

Research design is the conceptual blueprint or strategy within which research is conducted (50). Various study designs can be employed in IR projects. The different study designs and factors guiding appropriate study design selection have been described in detail elsewhere in this Toolkit.

In this section of your IR proposal, specify the study design and the justification for its adoption. While deciding on your study design, adopt an intersectional gender lens to explore and reflect upon ‘what’, ‘why’ and ‘how’ questions, to uncover how different social variables intersect to influence the implementation of and access to the intervention under consideration (43). The WHO *Gender responsive assessment scale* (4) is a framework used to help determine the extent to which gender is incorporated into research. The scale includes five types of research:

- a. *Gender unequal research* perpetuates gender inequality by reinforcing unbalanced norms, roles and relations.
- b. *Gender-blind research* ignores gender norms, roles and relations.
- c. *Gender-sensitive research* considers inequality generated by unequal gender norms, roles and relations but takes no remedial action to address it.
- d. *Gender-specific research* considers inequality generated by unequal gender norms, roles and relations and takes remedial action to address it, but does not change underlying power relations.
- e. *Gender-transformative research* addresses the causes of gender-based health inequities by transforming harmful gender norms, roles and relations through the inclusion of strategies to foster progressive changes in power relationships between women and men.

For conducting IR studies and/or health interventions, the gender continuum framework (5,51) is useful to help determine how gender is addressed within intervention design and implementation. The framework classifies interventions into:

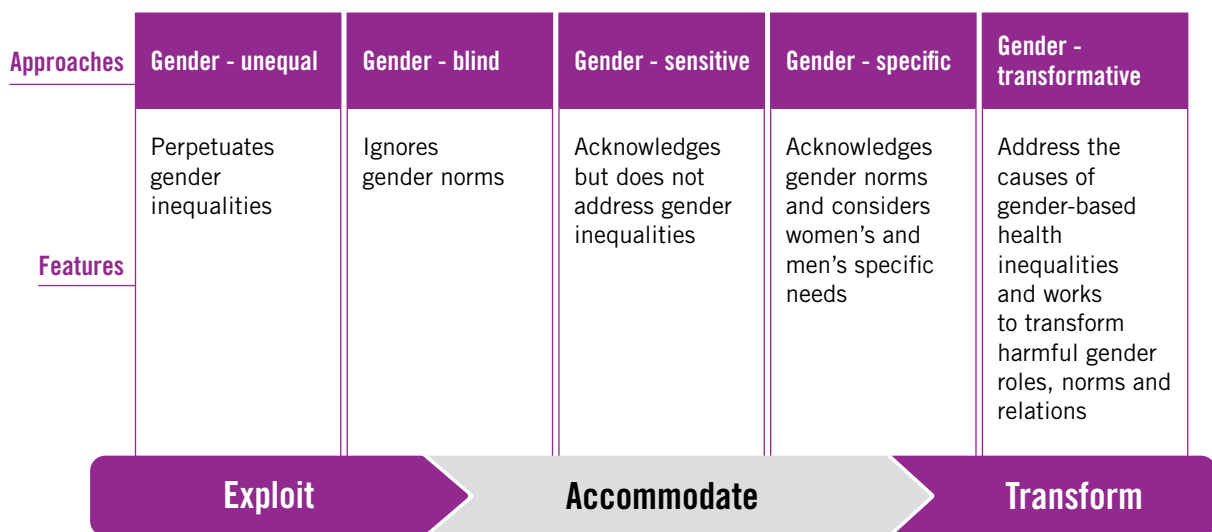
- a. *Gender-exploitative interventions* that take advantage of existing and prevalent gender inequities, norms, behaviours or stereotypes in order to achieve programme outcomes.
- b. *Gender-accommodative interventions* that adjust or compensate for existing gender inequities, norms or behaviours to achieve programme outcomes.



- c. *Gender-transformative interventions* that attempt to challenge or change existing gender power relations that reinforce gender inequities.

Figure 9 helps researchers to assess their planned activities against each approach/level to determine the extent to which their research and/or interventions are currently integrating sex and gender (1).

Figure 9. A continuum of approaches for integrating sex and gender.
 Reproduced with permission from: Greaves L, Pederson A, Poole N (Eds).
Making it better: Gender transformative health promotion. Toronto: Canadian
 Scholars’ Press – Women’s Press; 2014. Extracted from (5 and 52).



While conducting your research design exercise, reflect on the data that needs to be collected and disaggregated according to various intersecting variables to facilitate intersectional gender analysis. To be more precise with the results, focus specifically on social variables that can be disaggregated to create meaningful group-level variables (53). The inclusion of such reliable and valid measures allows researchers to explore the complex factors that shape and influence the experiences of individuals influenced by different gender dimensions.

Research methods

Study designs used in IR can be interventional (e.g. experimental, quasi-experimental, before and after, cohort studies or randomized controlled trials) or observational (e.g. exploratory, descriptive and comparative) studies. For your IR project, you can use quantitative, qualitative research methods or a combination of the two (i.e. mixed methods).



Key factors to consider while choosing your research methods include:

- Strengths and limitations of the research method considering the objectives of your study.
- Validity of the study.
- Applicability of the study results to the wider population.
- Consistency of the study findings.

IR focuses on identifying the challenges and bottlenecks related to the roll out of health interventions, as well as on developing and testing effective strategies designed to overcome them. If the health intervention is new, you can test the acceptability, adoption, appropriateness, feasibility and sustainability of that intervention. For example, if your IR explores barriers and facilitators of access to the intervention by the intended participants in the community, an intersectional gender approach helps to understand the magnitude as well as the contributing factors that influence barriers to access the intervention. Participatory research methods (PRM) place the most vulnerable populations at the centre of research (40,47). PRMs are collaborative and equitably engage all partners in the research process, for example during problem identification and action planning for change, thereby increasing participants' likelihood of using the research findings for appropriate actions (54,55).

Furthermore, engaging vulnerable populations enables researchers to appreciate the gender relations at play and how these intersect with other social variables to influence access to the intervention. If the health intervention is well established, you can test its fidelity, cost and coverage. If your study is to learn about the bottlenecks of the implementation of the intervention, then understanding the implementers perspective (e.g. doctors, nurses, community health workers delivering care or treatment) will be helpful for researchers to see how gender differences influence the implementation. The three commonly used research methods that you can employ in IR with an intersectional gender lens are briefly described in the following section.

Qualitative methods

The use of an intersectional gender lens in qualitative research methods allows greater understanding of people's lived experiences, and how practices, policies and programmes are responding to the needs of women/girls, men/boys, and people with non-binary identities. You can consider PRM while designing your qualitative study. Some of the different PRM include participatory mapping (e.g. community maps, transect walks), timelines (e.g. life histories, daily activity) as well as priority ranking, Venn diagramming, matrix scoring and use of problem trees. In recent years, participatory action research (PAR) has been used as a tool to encourage both communities and health system actors to recognize their own problems and create solutions that can promote social change (56).



In your IR proposal, you should describe the qualitative data collection methods your study will use, including the process followed to identify the study sample. Qualitative research instruments used for data collection in IR include key informant interviews (KIs), focus group discussions (FGDs), observations, documents (e.g. diaries and historical documents), among others.

Quantitative methods

Quantitative methods involve the collection and analysis of objective data, often in numerical form and used to examine relationships between variables. The research process, interventions and data collection tools (e.g. questionnaires, observation check lists, performance-based instruments) are standardized to minimize or control possible bias (53).

Mixed methods

The majority of IR research questions require answers to both the ‘what’ and the ‘why’ aspects and, as a result, require use of mixed methods that include both quantitative and qualitative approaches. If you use a mixed methods approach, you should explain why your team chose the approach, and how the use of qualitative and quantitative methods will provide information to address the research question and objectives.

Study participants

Under this section of your proposal, describe: (i) the individuals in the social category of interest; (ii) how gender dynamics and various gender domains interplay in the implementation and outcome of the intervention; (iii) how other axes of inequality and structures of power such as social background, education, sexism, classism, homophobia, or any relevant combination of these, impact on their experience with the health care system. For example, if your study is to test the uptake of an intervention for any noncommunicable disease in primary health care settings, you may wish to consider the differences between men and women who will use the intervention and whether their religion, education, income status, age etc. – given their specific context – intersect to influence their decision to use the intervention.

Recruitment of study participants

People often face unique barriers while accessing interventions due to interpersonal, societal and/or structural power dynamics and discriminatory practices. This is especially common for those who may not be socially or legally respected in certain contexts, for example in the case of gender identities beyond the binary gender categories. It is important to intentionally develop and implement a strategy to identify and meet appropriate respondents, avoid any harms their participation might cause them, and ensure key respondents are not being excluded.

For example, in societies with acute health and social inequities across populations, if you are identifying participants from a database of health facility patients, there is a chance you will lose the most vulnerable community members as they may not be accessing services at health facilities. In areas of east Ethiopia, for example, where gender norms dictate son preference, more than 50% of households had increased odds of preferential care-seeking for boys, but decreased odds for girls, compared with communities in which fewer than 50% of households were Muslim (57).

You should be mindful not to focus the recruitment entirely from traditionally recognized institutions such as health care facilities and training institutions, and broaden your strategy to other institutions, civil society organizations and human rights networks that can contribute to the recruitment phase of your research project. Other sources to consider for recruitment include advocacy organizations, religious centres, empowerment groups, community centres, unions/fraternities, and web-based locations such as social media, chatrooms, blogs and support groups (58,59).

In case of hard-to-reach populations, you can consider using venue-based sampling or time-location sampling (TLS). The TLS strategy assists researchers to intercept hard-to-reach populations in places and times where they might gather (60,61). For example, it can be used for adolescents who may come together to access services provided to them in specific social venues at certain times of the day. Community gatekeepers exist who can be excellent sources to help identify participants. However, selection bias may occur as these gatekeepers have the potential to rule out key participants who might have a language barrier, who are hesitant to speak or for those who might have to seek permission from family members to participate in the study. To ensure that there is no selection bias, it is better to approach different community gatekeepers, preferably of different gender identities and social locations, so that a heterogenous group of people is included in your study.

Sampling

Under this section of the proposal, describe the steps of your sampling process. The main steps are (62):

- i. Defining the target population.
- ii. Selecting the sampling frame.
- iii. Choosing the sampling technique.
- iv. Determining the sample size.



In general, sampling techniques can be divided into two types:

Probability or random sampling	Non-probability or non-random sampling
Simple random	Quota sampling
Stratified random	Snowball sampling
Cluster sampling	Judgment sampling
Systematic sampling	Convenience sampling
Multistage sampling	

In general, probability sampling techniques are typically used in quantitative research methods and non-probability sampling techniques in qualitative research methods. Overall, ensure that the sample is as heterogeneous as possible to allow diversity within the study population. This facilitates representation of those who would have been overlooked (58). Before sampling, it is important to define the inclusion and exclusion criteria for your study.

Quantitative study

As quantitative studies require a representative sample in relation to population characteristics, a probability sampling is preferable. This enables every individual in the population to have a certain chance of being included in the sample. While planning your sample size, consider how data will be disaggregated in your study. For example, if your study explores barriers to access a health intervention by adolescents residing in a specific geographic location, you will want your sample size to be representative of adolescent boys and girls. In order to incorporate an intersectional gender perspective, it will be helpful to also consider social variables such as education status, religion, marital status etc. as relevant to your study while considering your sample size, so that it is possible to collect disaggregated data for analysis.

Qualitative study

In qualitative research, the use of purposive, quota and snowball sampling strategies from an intersectional gender perspective, strengthens the study design and promotes diversity and inclusivity of participants (60,63).

With qualitative research, the sample should be designed to allow for in-depth understanding of the role of gender and its intersection with other social variables. Consider the similarities and differences within the study population. The sampling strategy will depend on the objective of the study and the type of analysis (i.e. inter-categorical or intra-categorical) you plan to do.

For inter-categorical analysis, you can divide your sample into different groups according to the relevant social variable that you are studying. For example, to do an intersectional gender analysis of how gender intersects with economic status between different groups of people while seeking health care, your sample will have to be diverse enough that data can be disaggregated into poor men vs poor

women vs rich men vs rich women. The sample needs to be as representative as possible with respect to a community or population of interest, while being heterogeneous enough to allow for inductive explorations (e.g. interrogating how various categories can intersect to differentially shape experience) (64). An intra-categorical analysis focuses on one specific group at the intersection of multiple social variables to explain within-group differences and larger social structures influencing their lives. For example, if your IR is exploring barriers and facilitators for adolescent girls to seek reproductive health services, then your sample will remain homogenous as you are identifying only adolescent girls. However, while conducting intersectional gender analysis, you have to be mindful that different social variables such as education, religion, etc. of an adolescent girl will intersect to influence her experience of seeking reproductive health services. Thus, within your sample of adolescent girls, you should be able to analyse the differences in their experience arising because of their different social variables and other structural or contextual factors.

Data collection plan

As a researcher, you should be cognizant of how power relations, biases and other key factors can influence the quality and validity of the data collected (Table 7).

Table 7: Key factors to consider for data collection. Adapted from (1 and 22).

As a power relation gender influences...	Key considerations	Actions
Who participates as respondents	Respondents may be excluded due to differential levels of education, literacy, proficiency in national languages or proficiency with technology.	Implement an intentional strategy to identify and access appropriate types of respondents and ensure that key respondents are not being excluded.
	Respondents who are women/girls may need to have additional permissions to participate within the research and/or travel to research locations to participate in focus group discussions, have less free time to participate in research or privacy, and will often have more gatekeepers inhibiting their involvement.	Ensure that participants are not being overburdened through participation in research.
	Sampling may be skewed towards respondents who are the most visible subjects, without including the less visible gatekeepers or decision-makers that frame the contexts in which those subjects live and work.	Include gatekeepers and/or decision-makers within sample; ensure inclusion does not further disempower women and girls or other marginalized groups.



As a power relation gender influences...	Key considerations	Actions
<p>When data is collected and where</p>	<p>Men/boys and women/girls have different responsibilities within and outside of the home, which affects when they are available.</p> <p>Context may affect the extent to which individuals have privacy.</p> <p>Participants who have been affected by infectious diseases of poverty may experience increased stigma because of participation within research, which may be exacerbated by gender relations and the intersection with other social variables.</p>	<p>Schedule data collection at a time that does not inconvenience participants.</p> <p>Where possible, ensure that interviews or surveys are conducted in a private setting.</p> <p>Include participants in a confidential manner; where participation might increase stigma, ensure data is collected in a neutral location.</p>
<p>Who is present during data collection</p>	<p>Power relations between and among respondents can affect the quality and accuracy of data collected (e.g. women may respond differently in the presence of men and may remain silent, even if they disagree or if inaccurate information is given or adolescent girls (and boys) may respond differently in the presence of parents or guardians).</p>	<p>If conducting focus group discussions, conduct separate discussions for men and women, boys and girls.</p> <p>Consider the power dynamics that may exist between participants and structure focus group discussions or other data collection methods accordingly, (i.e. disaggregate participations by age, occupation etc.).</p>



As a power relation gender influences...	Key considerations	Actions
Who collects and analyses data	The position of researchers may influence respondents' responses or ability and/or willingness to participate (e.g. in some contexts it may be important for respondents to be interviewed by a researcher of the same sex).	Where possible, use data collectors that are the same sex as the respondents.
	The sex of the researcher may affect the ability to get access to collect data; for example, in many contexts only data collectors who are women will be allowed to enter homes or will be allowed to collect anthropometric measurements of women and children.	Use local data collectors where relevant.
	Researchers will have gender biases that influence the data collection and analysis process.	Ensure that all data collectors receive training and supervision to become aware of their own gender or other biases and how they can address them.
		As a research team, reflect on own power dynamics and position within the data collection and analysis process. Be prepared to challenge each other's assumptions and questions asked of the data. Be flexible to reconstitute data collectors if necessary.
		Use joint reviews of transcripts and debriefing meetings among team members to identify potential bias and check assumptions.

To increase participation during data collection, outline the measures you will use to give every participant the same opportunity to be involved. Also describe how the research team will ensure confidentiality throughout the entire research process. Privacy, safety and confidentiality should be ensured during data collection, and the research team should be sensitive to existing gender dynamics. For example, in certain contexts or circumstances, women may feel uncomfortable if the data collector/researcher is not a woman. Similarly, the institutional hierarchy may influence junior officers responses during focus groups in the presence of their



supervisor or senior manager. At the household level or school setting, adolescent boys or girls might be fearful to participate openly in the presence of a parent, guardian or teacher.

Be aware of the gender dimensions (e.g. gender roles, norms, and relations) that influence the division of labour at the household and community levels. For example, in some communities, gender norms dictate women do unpaid work within the household while men are expected to work outside home to earn a living. Thus, it may be difficult to collect data during certain hours of the day, since both women and men may not be available during the day or season.

Therefore, it is pertinent to be sensitive to gender norms, roles and relations in a given community, to ensure availability of target respondents and confidentiality of responses during the data collection process. Research proposals should describe the process of participant identification, the time periods, and the convenient places for data collection to ensure comprehensive information including from those who tend to be less centrally engaged in the participatory process.



REFLECTION ACTIVITY

- **What is the appropriate sampling strategy for your study methodology?**
- **How does gender intersect with other social variables to create differential levels of power within the data collection process? How might this affect your data collection?**
- **What key gender-related factors need to be considered during the data collection process?**
- **How might you minimize ways in which gender power relations impact the quality, accuracy and validity of your data?**

Developing intersectional gender indicators for an IR project

During the planning phase, it is important to establish baseline indicators to contribute to monitor and measure the progress of your IR project. These should be developed in collaboration with the community and the study population. The intersectional gender analysis questions already considered/developed can be used to inform these indicators. Gender-sensitive indicators can be sex-specific, sex-disaggregated and/or indicators for gender equality. In general terms, indicators

should: (i) guide collection of data that can be disaggregated by the relevant social variables; (ii) measure and monitor the achievements of expected results; (iii) measure any gaps in the experiences of the study participants; (iv) avoid large group categorizations that may miss intra-group differences; and (v) be gender sensitive (i.e. measures gender equality directly or is a proxy for gender equality).

Within the data collection tools and indicators, consider gender-related variables/proxies in alignment with the gender domains that are integral parts of your IR study. Table 8 shows examples of gender proxies/variables that support analysis of gender power relations domains against relevant implementation health outcomes.

Table 8: Gender proxies used to understand gender relation domains.

Adapted from (1).

Gender relations domains	Gender-related variables/proxies
Access to resources	<ul style="list-style-type: none"> • Cash earnings • Ownership of land • Education • Information Access (e.g. to what extent are marginalized populations able to access relevant information and care related to an intervention?)
Distribution of labour	<ul style="list-style-type: none"> • Works outside home • Time spent doing housework • Employment (e.g. from an implementers' perspective, how might costs of accessing an intervention affect women and men differently?)
Social norms, beliefs and values	<ul style="list-style-type: none"> • Women delivering at home • Unmarried young girls should be in the company of their kinsmen when accessing care • All household earning belong to the man in the house
Decision-making autonomy	<ul style="list-style-type: none"> • Decision-making related to the health intervention (e.g. who decides whether or not it is acceptable for someone to participate in an intervention?) • Control over household's earnings/resources

To develop gender equality indicators explore the role of gender power relations specific to your IR project as included in your gender framework.

While developing indicators, consider the relevant IR outcomes that you will measure. For example, if your study is exploring how decision-making influences acceptability of a given health intervention (i.e. IR outcome) for married women, your intersectional gender equality indicator could be:



Proportion (%) of married women aged 15–49 who usually decide to accept the health intervention either by themselves or jointly with their husbands, disaggregated by income, age, education, etc.

Table 9 shows examples of differences between gender-sensitive indicators and intersectional indicators.

Table 9: Comparison of gender-sensitive and intersectional indicators.

Adapted from (1).

Type of indicators	Examples of sex and gender-sensitive indicators	Examples of intersectional indicators
<p>Sex-specific indicator: a type of gender-sensitive indicator that pertains to only females or only males.</p>	Proportion of females or males who are living with HIV.	Proportion of females or males who are living with HIV disaggregated by income, age, education, etc.
<p>Sex-disaggregated indicator: a type of gender-sensitive indicator that measures differences between females and males in relation to a particular metric.</p>	Proportion of females and males who are living with HIV.	Proportion of females and males who are living with HIV disaggregated by income, age, education, etc.
<p>Gender equality indicator: a type of gender-sensitive indicator that measures gender equality directly or is a proxy for gender equality.</p> <p>Indicators that can act as a proxy for gender equality include those that explore the different domains included in a gender framework. These may include access to resources, distribution of labour/roles, norms and values and decision-making.</p>	Proportion of married women aged 15–49 who usually decide about their own health care – either by themselves or jointly with their husbands.	Proportion of married women aged 15–49 who usually decide about their own health care either by themselves or jointly with their husbands disaggregated by income, age, education, etc.
	Proportion of women who are able to leave the house without permission.	Proportion of women who are able to leave the house without permission disaggregated by income, age, education, etc.
	Proportion of women who decide how their own income will be used.	Proportion of women who decide how their own income will be used disaggregated by income, age, education, etc.



REFLECTION ACTIVITY

Case scenario example: In one country, the majority of pregnant women deliver their child(ren) at home because social norms dictate restrictions for delivering at a health facility. An IR project has developed an intervention to promote deliveries at health facilities.

Activity: Formulate intersectional gender indicators to measure uptake of institutional delivery by pregnant women in that country.

Data analysis plan

It is important to clearly outline the plan for data analysis in your IR proposal. Both the techniques and models for data analysis should be in accordance with the study objectives, research methods used and the types of anticipated IR outcome variables. The data analysis plan should have the target audience in mind with a focus on simplicity and interpretability. Clearly explain the analyses you intend to conduct on the data. Indicate the appropriate software you may use in the data analysis.

To analyse data effectively using an intersectional gender lens, the IR team should have taken preparatory steps from the initial stages of the study design. This includes disaggregation of data or sampling frameworks by sex and other social variables, the use of gender frameworks and the incorporation of intersectional gender analysis questions into data collection tools.

It is useful to develop an intersectional gender analysis matrix relevant to your study at the beginning of the proposal development process. Because it is difficult to ask about gender power relations directly, gender frameworks are used to break down the ways in which they manifest and then develop proxies to indirectly analyse gender relations against relevant health or other outcomes. An intersectional gender analysis matrix can be used to help you think about which domains might be most relevant for your study. Researchers should begin by filling in the matrix by identifying how the different gender relations domains may affect areas of interest relevant to your study, and which social variables are likely to intersect with gender to influence a person's marginalization or vulnerability regarding these domains.

Table 10 illustrates an example of using the intersectional gender analysis matrix while conducting research in infectious diseases. This helps researchers to identify how gender relations domains affect the infectious diseases domains, and helps to identify which social variables can potentially intersect with gender to influence an



individual's vulnerability. It is important to develop an intersectional gender analysis matrix specifically for the relevant gender domain, study domain and social variable relevant to your research. For example, if you are planning to conduct IR on access to bed nets by adolescent boys and girls in a dengue endemic area, to ascertain their ability to prevent exposure to mosquito bites, you can identify the contextually-relevant gender norms, relations and values and also consider which specific social variables intersect with the boys/girls access to bed nets. If gender norms allow only adolescent boys to wear shorts (i.e. unprotected clothing), this will decrease their ability to prevent mosquito bite exposure as compared to girls. In this scenario, the possible social variables that can be considered to influence risk of exposure may include age, sex, race/ethnicity, education status and socioeconomic status.

Table 10: Intersectional gender analysis matrix for infectious diseases of poverty. Extracted from (1).

Infectious diseases of poverty domains	Biological and social stratifies					Gender relations domains			
	Sex	Age	Race/ethnicity	Income	Disability	Access to resources	Distribution of labour and roles	Norms and values	Decision-making power
Vulnerability to disease/illness	x	x	x	x	x		Women care for sick family members. Women wash clothes outdoors.	Boy permitted to swim in infected bodies of water	
Ability to prevent exposure		x		x		Women lack knowledge of how to prevent exposure.	Men unable to reach health facilities during opening hours due to employment.		Men decide whether to buy bed nets.
Response to illness		x		x		Women lack access to financial resources to access health facilities			

Data can be analysed in two different ways:

a) *Intra-categorical* focusing on one social group only and analysing experiences of that one group (e.g. focusing only on adolescent boys and analysing how their age, sex, race/ethnicity, education status and socioeconomic status intersect to influence their access to bed nets, thus affecting their ability to prevent exposure).

b) *Inter-categorical* (e.g. analysing data for differences between both adolescent boys and girls and across social variables such as age, sex, race/ethnicity, education status and socioeconomic status). For example, you can identify and compare differences and experiences in terms of vulnerability to disease exposure across social groups such as poor uneducated boys and poor uneducated girls.

Quantitative data analysis incorporating an intersectional gender lens

Before analysing quantitative research data using an intersectional gender lens, your data should be disaggregated by variables relevant to your IR study. Depending on your research design, analysis can be intra-categorical or inter-categorical. In both approaches, the analysis focuses on the intersection of selected social variables to understand how these variables interact to create different experiences of marginalization and discrimination, which in turn shape health outcomes related to your IR study.

It is also possible to conduct a gender analysis on secondary quantitative data, such as demographic health surveys, population-based surveys or own quantitative data sets. Generally, the secondary data sets help further sex-specific (males or females) and sex-disaggregated (males and females) analysis. For example, if you are studying the prevalence of malaria in a population residing in an endemic area, you can conduct a sex-specific analysis for males and females separately. To conduct a sex-disaggregated analysis, the differences in prevalence between males and females diagnosed with malaria are considered. However, to conduct an intersectional sex-specific analysis, you must disaggregate this data by the relevant variable chosen for your study (e.g. age, education, ethnicity etc.). Intersectional sex-disaggregated analysis explores the prevalence of malaria between and among groups of males and females, against the different variables chosen as relevant for your IR study.

Generally, data cannot be disaggregated by gender in the same way it can be disaggregated by sex. Therefore, relevant gender relations domains need to be included within data collection tools and interrogated separately; these are sometimes referred to as gender variables and are used as proxies to understand gender relations (1). Refer to Tables 8 and 9 to identify gender variables/proxies and intersectional gender indicators, respectively.

Unlike traditional quantitative methods, intersectionality-informed analysis uses an additive approach, using an initial 'baseline' upon which further analyses are applied using multiplicativity (e.g. regression coefficient) to account for effects of intersecting categories on health or social outcomes.

Qualitative data analysis incorporating an intersectional gender lens

Intersectional gender analysis begins during data collection, when researchers are gathering and reflecting iteratively on the data and practicing reflexivity throughout the coding process as well as subsequent interpretation and reporting. Regardless of the level of analysis or approach, it is important to note that expectations and potential biases of the researcher must be open, particularly those resulting from the interaction between the data and the researchers' backgrounds. Caution should be taken to avoid reproducing inequality within the data coding and analytic processes (65). A multi-stage analysis is needed to enable moving from additive towards interactive analysis. When analysing



data, you will therefore need to go beneath the surface of what is being stated/said to understand how gender intersects with other social variables to influence different experiences, relating this to the larger social, political and cultural context. Data analysis often occurs on one level, the semantic level, which involves analysing data at face value, only considering what participants have articulated or written. However, to conduct an intersectional gender analysis, researchers must go deeper to understand and identify assumptions, beliefs, thought patterns and conceptualizations that characterize semantic content. This is particularly true in instances where a person's identity may be so normalized/ingrained, they may not see how their experiences are shaped by systems or structures of privilege and/or oppression resulting from that identity, therefore, it is the researcher's responsibility to make these connections. This interpretative analysis helps achieve a more comprehensive analysis (22,66).

Gender frameworks can be used to develop coding frameworks that facilitate the analysis of qualitative data. In terms of analysis, the type of coding methodology is often based on the types of framing used. As such, inductive analysis should be used, when possible, as it allows for codes to be derived from existing data. To facilitate intersectional gender analysis within qualitative research, a multi-stage analysis is needed. There are three main levels of coding:

Open coding, which involves analysis of data that codes a passage using multiple and overlapping codes (e.g. access to resources, gender norms, gender roles, decision-making, age, etc.).

Axial coding, which focuses on inductively refining each separate code into more distinct codes (e.g. a code for the intersections of gender roles with age, one for intersection of gender roles and poverty, etc.). These codes are often developed following identification of relationships and patterns that emerge during the open coding stage. Grouping open codes into different themes that help explain what is going on can facilitate identification of axial codes.

Selective coding is used to further refine codes to reflect a specific aspect of intersectional experience (e.g. how married women's experience of assigned domestic responsibilities influences her access to a health intervention). These codes often link the intersections of different social variables to experiences of advantage or disadvantage in relation to the implementation outcome of a given IR study.

Box 6 illustrates an example of how gender domains can influence men's health-seeking behaviours.

Box 6. Example showing the influence of gender norms on men's health seeking behaviours.**Masculinity and men's health-seeking behaviours in Nigeria (67)**

Aim: To investigate men's health-seeking behaviours and to examine the extent to which gender/masculinity impede their acceptability of and accessibility to available health care facilities in Nigeria.

Method: Case study research design incorporating eight in-depth interviews conducted with men volunteers over seven weeks. The socio-demographic variables and inclusion criteria of the participant selection were age, academic status, religion, occupation, location of residence, marital status and financial status.

Results: Hegemonic masculinity built into the society's classification of men as the stronger sex and women as the weaker sex is an influencer of men's health care. Seven of the eight participants argued that men conform to the belief of masculinity identity in seeking health care. It was observed that there was no difference in perception of health-seeking behaviours among the respondents, despite their educational and the employability status. Men express some form of masculinity and sentiments that men should not be sick. The 'masculinity factor' is reflected in the rejection of medical help because of the feeling that being treated by women, labelled "the weaker sex", is a taboo. The majority of the respondents reiterated the importance of their religious beliefs and doctrines as compared to seeking adequate health attention when the need arises. To them, as long as these beliefs are in place, their health status/stability is guaranteed.

Conclusion: Cultural and patriarchal norms/beliefs that often characterize men as being resilient and brave among other socially constructed expectations still play vital roles in determining the health-seeking behaviours of men, regardless of their educational and professional attainments.

Key resources for intersectional data analysis

Fehrenbacher AE, Patel DR. Translating the theory of intersectionality into quantitative and mixed methods for empirical gender transformative research on health. *Culture, Health & Sexuality*. 2019;22:145–160. doi: 10.1080/13691058.2019.1671494 (68).

Bauer G, Bowleg L, Rouhani S, Scheim A, Blot S. Harnessing the power of intersectionality: Guidelines for quantitative intersectional health inequities research. London, Canada; 2014 (https://www.researchgate.net/publication/343140477_Harnessing_the_Power_of_Intersectionality_Guidelines_for_Quantitative_Intersectional_Health_Inequities_Research, accessed 3 April 2022) (53).

Jasmine A. Abrams, Ariella Tabaac, Sarah Jung, Nicole M. Else-Quest. Considerations for employing intersectionality in qualitative health research. *Social Science & Medicine*. 2020; 258:113138. doi: 10.1016/j.socscimed.2020.113138 (69).



Selecting appropriate intersectional gender analysis frameworks helps guide development of data analysis plans. Developing an intersectional gender analysis matrix during proposal development is a facilitating factor in achieving IR outcomes.



REFLECTION ACTIVITY

- What are the intersectional gender indicators relevant to your IR study?
- Based on your study design, select the appropriate intersectional gender analysis framework and develop the best applicable data analysis plan.
- Using the example in Table 10, develop an intersectional gender analysis matrix for your planned IR intervention to help conduct intersectional gender analysis.

Quality Management

Embedding a quality management plan in an IR proposal is essential in ensuring that research meets (or exceeds) scientific, ethical and regulatory standards.

Research ethics

As in other forms of research, ethical considerations are of vital importance to IR with an intersectional gender perspective. Respecting the dignity of all research participants and avoiding causing any physical, emotional or psychological harm to study participants are essential throughout the entire research process. It is important to take extra caution to minimize the risks that may be associated with working with vulnerable populations. It is also essential to be cognizant of sensitive issues in relation to the local context, for example, and to use the language of the participant community and respect how the community identifies itself. This communicates respect for their right to self-determination and respects their lives (70). Participatory approaches may be particularly useful, as they can allow individuals who represent the population of interest to work with researchers to ensure linguistic and cultural appropriateness of written or verbal

consent documents, for example. Research should be approached with ‘cultural humility’ in communities where any lingering historical mistrust of researchers may exist, as in many marginalized communities for example, due to past unethical research practice (71).



REFLECTION ACTIVITY

In your research team, identify the context specific ethical issues to consider in your research project and the strategies you can use to conduct an ethically sound research project.

Dissemination plan

Communicating research plans and findings are among the good research practices in IR. Communicating research findings makes you accountable to participants and to the research process itself. Disseminating research findings – especially to the research participants – not only provides them with data, but also sensitizes them to related issues, and enables them to utilize the findings to improve their health-seeking practices (28). Your proposal should include a section on your dissemination plans, including where and to what audiences you intend to disseminate your research findings. As much as possible, you should aim to communicate the results and findings of your research to all the stakeholders engaged in the research effort, using the most appropriate and relevant channels.

The dissemination plan should include:

- a. A communication goal, which aims to promote ownership and engagement in the research by key stakeholders, and ultimately to help promote and facilitate uptake of research results into related policies, practices and programmes.
- b. Your primary and secondary audiences.
- c. Clear timelines for your dissemination to take place.
- d. Dissemination channels/tools you plan to use (e.g. educational or informal community presentations; information sessions; policy briefings; press conferences; slide shows etc.), an estimate of the number of refereed and other planned publications (including the names of journals and newsletters, printed hand-outs, policy reports etc.), and the number and names of the academic and professional conferences the team will attend each year.



During proposal development, it is also important to consider how a gender lens will be used in reporting of study findings. The first step is to ensure development of gender-sensitive reports considering how men, women and people with non-binary identities will be differently affected by the results. While writing a gender-sensitive report, be cautious that potentially harmful gendered stereotypes are not replicated. When conducting gender analysis, common pitfalls that may bias research include (1,72):

- a. *Overgeneralization*: Occurs when only one sex is studied but the data are presented as if they were of general (rather than sex-specific) applicability. Over-generalization can be represented in the language used to discuss results, such as when only the terms ‘he’ or ‘man’ are used when both sexes are intended. Within health reporting, generic terms are often used for all-women or all-men groups, such as patients, community members, community health workers or single parents, which masks any gender-related differences that might exist. Groups should always be distinguished by sex or gender identity, even when only one sex or gender identity is included within the sample.
- b. *Sex and gender insensitivity*: Occurs when sex and gender are not addressed in the research, although they are related to the research content.
- c. Harmful gender stereotypes and/ or norms: May be replicated/perpetuated.
- d. *Double standards*: Occur when similar behaviours, traits or reactions are experienced by men and women but are reported differently.

Some key questions to be considered while generating gender-sensitive reports are:

- Is data reported in a gender-sensitive way (i.e. have you avoided common pitfalls)?
- If the result of the research includes policy recommendations, have the outcomes been considered in relation to equal opportunity of men, women and people with non-binary identities?
- Are images of different gender identities projected within the reports or publications? Do these images reproduce stereotypical gender roles or harmful gender stereotypes and/or norms?
- Do the findings replicate harmful gender stereotypes and/or norms? How can people of different gender identities use the results in different ways?
- Are results and conclusions about gender and sex outcomes reported even if no differences were found?

Execution of an IR project with an intersectional gender lens

Execution of an IR project involves implementation and monitoring of the proposed research activities as well as updating and revising the project plan according to emerging lessons and/or conditions. This phase should also include the closure and evaluation of the project, as well as reporting and disseminating the processes and findings of the research.

This section introduces important activities that will enable your research team to plan and execute an IR project with an intersectional gender lens . These include:

- i. Reflexivity process.
- ii. Development of data collection tools.
- iii. Pilot testing of the tools and methods.
- iv. Project implementation.
- v. Good research practices.

Planning for IR project execution

Reflexivity process by the implementation team

The composition of the implementation team and meaningful stakeholder/community engagement are both vital to inform your project design and implementation activities. Researchers should be self-aware of their own biases to avoid any social prejudices against the study participants. Thus, before implementing your project, use the questions in Table 11 to guide your research team to critically reflect on your own biases and power dynamics might impact the project activities.

Table 11: Reflexivity process by research team. Adapted from (12).

Questions for the research team
1. How can we ensure that we do not reinforce existing stereotypes or biases or produce further inequities (i.e. avoidable and unjust inequalities) for some people and populations?
2. What is the best way for people with lived experience, their families and communities to be involved in making sure that the outcomes/results of the research lead to a reduction in inequities (i.e. avoidable inequalities between and within groups of people)?
3. In what ways we can work together to make sure everyone on the research team (as well as any people involved in the research project) feel “comfortable”?
4. (a) How do people with lived experience in the project area prefer to be involved in research and why? (b) What types of challenges would need to be addressed to make it easier for people living with the experience – as well as their families and communities – to become involved in research?
5. How do we make sure that interpersonal interactions promote a sense of belonging for ALL members of the research team (as well as any participants in the research study)? What makes me feel psychologically safe? What types of interactions do not make me feel safe and should be avoided?



Development of data collection tools with an intersectional gender lens

Collaborate with the research participants when designing the research tools for your study. It is important to include some research participants in your research team. This participatory approach will not only enhance the relevance and sensitivity of the questions in your study tools, but also minimize power imbalances in the research process, as well as the risk of perpetuating stigma and social injustice (22). Use gender frameworks as a basis for developing questions with an intersectional gender lens to explore how the different social variables under analysis intersect with the relevant gender domains to shape participants' experiences with the IR intervention. Use the information from the intersectional gender analysis matrix to design the data collection tools.

Below are some tips for designing questions for data collection tools incorporating an intersectional gender lens (73–75):

- Ensure that the questions capture details of the different social variables (e.g. sex, gender identity, education level, ethnicity etc.) so data can be disaggregated as relevant to your study.
- Consider gender relations domains that are most relevant in the context of your study.
- While developing the data collection tools, consider the differences between the needs of women, men and non-binary people and how such differences vary in specific situations relevant for your study.
- Start questions by asking about one social variable first (i.e. avoid combining two variables in a single question). For example, do not ask: “How do you think your age or gender identity influence your decision to seek health care?” Rather, begin the question with: “How do you think that your gender identity influences your decision to seek health care?” The other intersecting social variables such as age, sex, ethnicity, sexual orientation, education etc. can be asked subsequently so all the variables – as adequate to your study – can be included.
- Questions must allow for intersectional gender interactions to be investigated. For example, how does being a woman and being a migrant affects one's access to health care in a specific context?
- The data collection tools/methods must be sensitive to the participant's identity. For example, be sensitive to the different social variables of the study participants' and formulate questions paying extra attention to the wording of the questions, avoiding gender stereotypes, misconceptions or stigmatizing terms.
- Include some open questions about the participants' experience with the intervention.



Pre-testing of the data collection process

All study instruments (quantitative and qualitative) should be pre-tested to check the validity and reliability of data collection tools. Pre-testing allows the research team to check whether the research instructions and questions are clear, context-specific and that adequate time has been allowed to administer the questionnaire, etc. Ideally, pre-testing with individuals from the population of interest ensures that potential participants understand the questions and helps the research teams to design questions that are sensitive to the needs and experiences of participants (76). If this is not feasible, pre-testing should be conducted from a comparable study population and environment.

Pre-testing the research methodology with participants, and using their feedback, can make the research design more robust. It assists identification of ideal data collection sites, time periods for data collection and any other related requirements that may have been overlooked during the planning phase, such as compensation of participants (70). Since data management is critical to the success of the research, the research team should be available during discussions that follows the pre-test, in order to incorporate changes into the final design of the tool and facilitate the 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, as well as planning dummy tabulations to ensure the appropriate variables are collected.

Implementation of the project plan

The implementation of the overall research project involves both conducting and monitoring the proposed activities, as well as updating and revising the project plan according to emerging lessons and/or conditions. You should be aware that the planning and start-up phases of an IR project can take a considerable amount of time, especially when the project is intentional about ensuring gender inclusion aspects. You should take this into consideration while developing your project timeline. As mentioned, your implementation team should be interdisciplinary in nature with expertise in health, gender and intersectionality research, and should be self-aware of their own biases. Use participatory approaches, methods and tools and be respectful and accountable to research participants and the community at large.

Consider the following tips to incorporate an intersectional gender lens when implementing your IR project:

- Ensure a robust study design that allows analysis of why and how relevant social variables intersect to influence implementation.
- Determine what intersecting social variables are most relevant to the implementation context and why.
- Conduct activities during times and spaces when respondents are likely to be available and free to interact with the project team.



- Use formats that are readily accessible to participants (e.g. meetings, surveys on paper, online, phone calls).
- Explore how the study participants with different social variables are impacted by the IR problem in question.
- Provide the research team with adequate capacities, expertise and resources on approaches to enable them to conduct intersectional gender analysis.

Project monitoring

The main objective of monitoring is to assess whether the project implementation is aligned with the IR project objectives and plan.

IR teams should conduct monitoring continuously, with the aim of improving project implementation processes. Use your baseline indicators to monitor both the process as well as the progress of the project activities. Seek feedback and adjust accordingly. Assess indicators for different groups of people in each project area, for example:

- Obtain feedback from team members and project participants on whether the project is meeting their needs and request their suggestions for improvement.
- If all project stakeholders are unable to participate, ascertain the reasons why not. For example, in certain contexts, women may not have been able to participate because they needed permission from their spouses.
- Adjust your research plan as necessary to enable you to achieve the IR project objectives.

Dissemination and uptake of research findings

Communication must be an ongoing and continuous component of the overall IR project process from initial planning stages, throughout implementation and during the final evaluation. Involving stakeholders in the development process early enhances ownership of the project, drives engagement in the process and promotes the ultimate uptake of the research findings and conclusions. Transparency, openness and engagement among IR team members, and with broader project stakeholders and participants are vital elements. Implementation research is different from other forms of research because the IR study can be adjusted according to the bottlenecks identified during the phases of the IR cycle. As new knowledge and data are being generated from your study, it is important to share them with stakeholders and key end-users during interactive collaborative sessions. This integrated knowledge translation approach will not only help researchers become more active and context-aware but also creates a much higher likelihood of the research findings being acknowledged, augmented and used by stakeholders and end-users. End-of-study knowledge translation activities are typically conducted at the end of the research and are focused on translating knowledge into more conventional information products and disseminating those to generally

broader audiences, and over a longer period. The information should be accessible, simple to comprehend and clear, and communicated widely in an effective way through use of appropriate language, formats and technologies. Focus on the needs of the target audience, including the scientific community, nongovernmental organizations, policy-makers, technical staff and service providers, participants, and beneficiaries of the study. During dissemination consider the following points from an intersectional gender lens:

1. All forms of communication must avoid the reinforcement of gender stereotypes as well as harmful gender norms, roles and relations.
2. Present findings that are relevant to the study participants and, in doing so, highlight how the intersection of social variables influence an individual's experience at the household, community and health system levels.
3. Report disaggregated results, ensuring participants' confidentiality and anonymity.
4. Use inclusive, bias-free language, that is sensitive to the local geographical setting and cultural context.
5. Images and the type of media used to communicate health messages can and should be used to challenge gender-based stereotypes that may harm health. Avoid use of images depicting stereotypes or fostering stigma.
6. Highlight varying individual experiences in relation to gender power dynamics and at the different levels of the health system, household, community and institutional levels.
7. During the policy-making process, information should be presented to ensure decision-makers understand how the information impacts various populations, and how they are linked to inequalities in health outcomes. For example, highlight differences between vulnerable and non-vulnerable populations, and how information affects their access to health interventions, and how results differ in their health outcomes.

Evaluation and closure of a research project

At project closure, your project team should reflect upon and discuss successes, failures and lessons learned and re-plan accordingly.

Some contemplative questions on the lessons learned include the following:

- a. Was the time allocated to complete the various IR project activities sufficient/adequate?
- b. Did the project achieve desired, anticipated and/or unexpected outcomes?
- c. What difference did the project make for the participants and their communities?
- d. Did the project change or reinforce any gender-specific outcomes/attributes?
- e. What could be designed differently in a future IR project to enhance the inclusion of an intersectional gender lens ?



Good practices in IR projects with an intersectional gender perspective

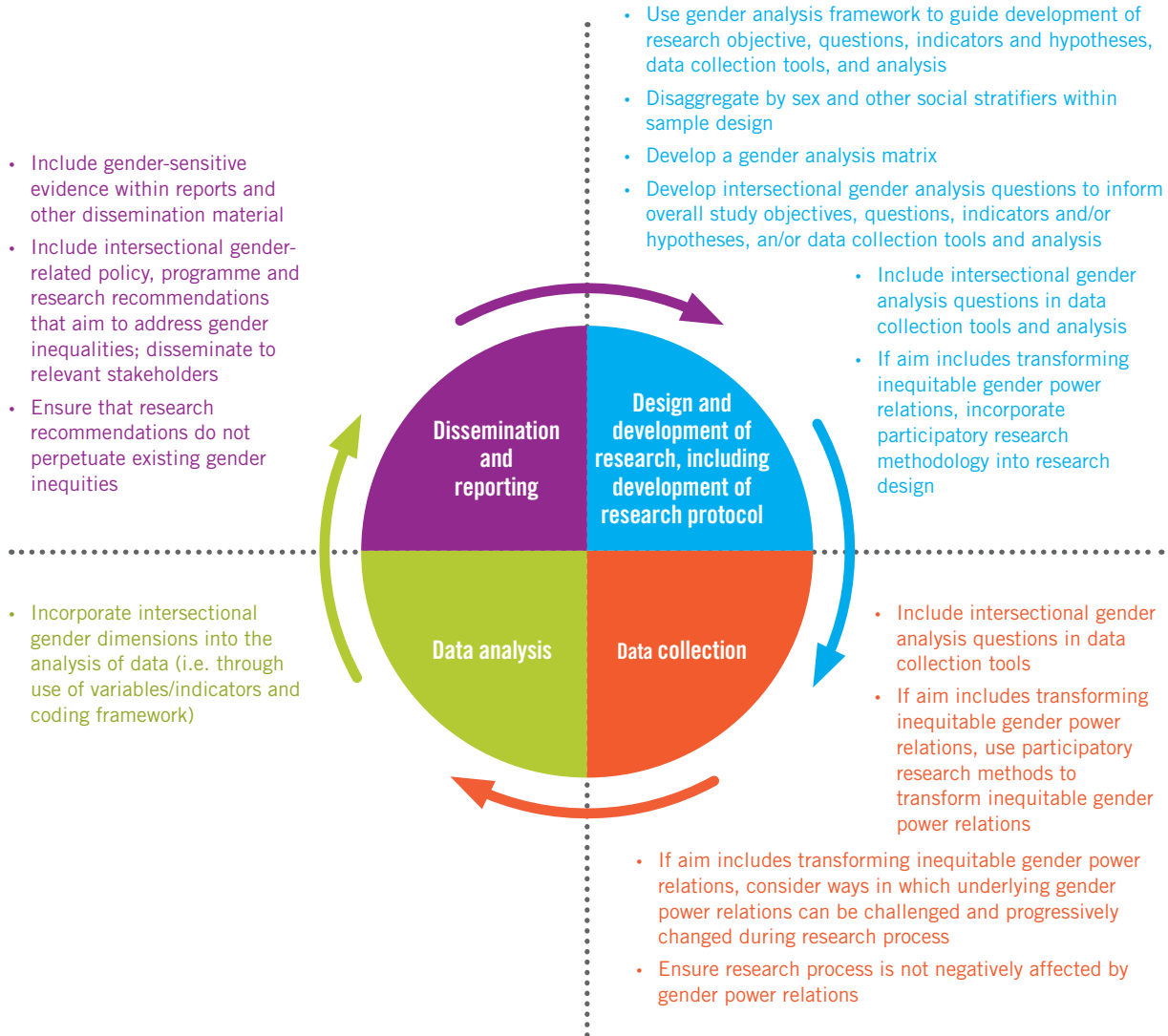
Good research practices must be embedded throughout the entire process to ensure credible and timely data (6).

Consider some of the good research practices below to incorporating an intersectional gender lens into your IR project.

- a. *Disaggregate data* at different levels of the research cycle (e.g. data collection, analysis, implementation, and dissemination). This facilitates a more informed understanding of an issue or situational differences and inequalities to be identified.
- b. *Promote inclusion and diversity* by paying special attention to including the voices of marginalized groups.
- c. *Analyse power hierarchies* to address power inequalities between researchers and participants, as well as among participants.
- d. *Use local taxonomies* that various communities use to identify themselves.
- e. *Use the language of the participant community* to convey respect for their right to self-determination and respects their lives (70).
- f. Strengthen capacities of the project teams and communities in areas of intersectional gender analysis.

Figure 10 summarizes the various activities to incorporate an intersectional gender lens within the various IR phases.

Figure 10. Summary of intersectional gender analysis activities in research.
Extracted from (1).



Incorporating intersectional gender analysis as part of IR will help researchers to understand context and the ways in which gender, power and other social stratifiers shape systemic, individuals and/or households abilities to access and use interventions.





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IMPLEMENTATION RESEARCH TOOLKIT



Implementation Research Case Studies

Compiled by Ayat Abu Agla and Robinah Najjemba

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INTRODUCTION TO IMPLEMENTATION RESEARCH

Case study 1

Identifying barriers to accessing integrated community case management services

Background: Integrated community case management (iCCM) is an equity-focused strategy adopted by WHO/UNICEF to improve access to essential treatment services for children. In 2010, the Government of Ethiopia used its health extension workers (HEWs) programme to scale up the iCCM of childhood illness strategy throughout the country. However, after two years, utilization of HEWs remained low despite the presence of a service delivery strategy that focused on minimizing several common access barriers related to cost, distance and quality of services. For instance, HEWs were trained and facilitated, volunteer community health workers were deployed in the villages, the preventive and curative services for children below five years of age are free. In addition, the HEW's community mobilization and education activities were part of existing national child health initiatives to promote community engagement and programme sustainability. Research was undertaken to elucidate perceptions and experiences of caregivers and to better understand the reportedly low utilization of iCCM services. The parameters used to define accessibility were availability of qualified health providers and health commodities at the health post; geographic accessibility; affordability of the services; and acceptability of the providers and services.

Rapid ethnographic assessments in eight rural health post catchment areas of Jimma and West Hararghe zone were conducted using focus group discussions (FGDs) and in-depth interviews (IDIs). FGDs focused on social norms of care-seeking and community perceptions regarding HEWs and iCCM services. IDIs focused on care-seeking experiences of caregivers over the course of the most recent illness of a child, including perceptions relating to barriers and facilitators to utilizing HEWs delivering iCCM services at the health post. The study participants were mothers, fathers, (either ever used or never used iCCM) HEWs and community health workers.

Findings: HEWs were frequently absent. Although the services were free, many caregivers could not access services due to related social and transport costs. Long distances to the health posts, bad terrain coupled with inadequate transportation frequently rendered the health posts inaccessible. Lack of ownership of the health posts due to insensitive HEWs, lack of trust of the quality of care provided and lack of decision-making power of the primary caregiver regarding care choices for their child were also cited as prohibiting factors. However, caregivers also had limited awareness of child illness and the services provided at the health posts.

Conclusions: In spite of the conducive and supportive health policies, the use of iCCM services was suboptimal due to challenges at the personal and systems level.

Lessons: Innovative approaches are needed to address challenges identified and in order to reduce barriers and promote utilization of iCCM services for all caregivers and children in need.

Source: Shaw B et al. Access to integrated community case management of childhood illnesses services in rural Ethiopia: A qualitative study of the perspectives and experiences of caregivers. *Health Policy and Planning*. 2015; Nov 24:czv115.



Case study 2 Key characteristics of implementation research

Background: Implementation Research (IR) in comparison to other research domains, is demand-driven and research questions are based on the needs identified by the implementers in the health system. It is context-specific and is mindful of cultural and community-based influences. Furthermore, although IR is dynamic and adaptive, it takes place within real-life settings and there is no attempt to manipulate the setting within which the intervention is taking place. It engages with the relevant stakeholders including the beneficiaries. Since IR is especially concerned with the users of the research and not purely the production of knowledge, it aims to promote the uptake of research findings into routine practice. The process of knowledge translation is promoted through active involvement of the relevant actors in the identification, design and execution of research and should not be used only as targets for dissemination of study findings.

Example of an IR project: To inform a planned mass drug administration (MDA) for lymphatic filariasis (LF) in two districts of Indonesia, a micro-narrative survey tool was developed to capture community members' experiences with MDA and the social realms where drug delivery and compliance occur. The goal of the project was to enhance coverage and compliance in MDA for the elimination of LF in two 'endgame' districts. It was a three-phase study involving a baseline survey, implementation of the identified recommendations and an end-line survey. The systematic approach began with the multidisciplinary research team collaborating with the stakeholders and programme implementers to identify barriers related to delivery of MDA. The relevant stakeholders were involved in the selection of the study sites, development of the survey tool, analysis of both the baseline and end-line surveys, discussion of research findings and resulting recommendations, dissemination of research findings and identification of feasible actions to improve delivery and access.

The barriers to effective coverage of MDA identified included: Men and 15–24 years old youths lacked appropriate information about the programme; misconceptions about drug safety were common; ineligibility criteria were not clear; and there were limited distribution points. The findings were discussed with the relevant stakeholders and feasible recommendations and interventions were executed using existing health system structures. The recommended interventions were implemented within the local sociodemographic context. For example, social media and texting were used for reaching young people, specific messaging was developed for 'systematic non-compliers', and flow charts were produced to guide drug distributors. The illegibility criteria were adapted to the local context. Specific messages addressing drug safety, drug-taking procedure, information on illegibility, benefits of compliance by all people and where to go for assistance, were carefully crafted on the packaging of the medicines. Both districts were responsible for implementing the identified recommendations and the end-line survey showed an improvement in coverage of MDA in both sites.

Conclusion: The research conducted was demand-driven and the findings were used by the local health offices to improve delivery and access of MDA services. Furthermore, the research did not manipulate the routine health services. Active involvement enhanced stakeholders' ownership and enabled them to mobilize local resources and relevant networks to promote drug uptake, improving compliance.

Lessons: The research team profile should reflect the skill sets required to address an implementation challenge and the team should actively engage relevant stakeholders to further understand the context where the intervention occurs.

Source: Krentel A et al. Improving Coverage and Compliance in Mass Drug Administration for the Elimination of LF in Two 'Endgame' Districts in Indonesia Using Micronarrative Surveys. *PLoS Neglected Tropical Diseases*. 2016; 10 (11): e0005027. doi:10.1371/journal.pntd.0005027.

**Case study 3****Sustaining PMTCT in real life settings: challenges in Mother Infant Retention for Health**

Background: Although services to prevent mother-to-child HIV transmission (PMTCT) have increased in sub-Saharan Africa throughout the past decade, with HIV testing and anti-retroviral treatment (ART) improving, retention in PMTCT care remains a challenge. Kenya, one of the countries in the region facing this barrier, has committed to eliminate new paediatric HIV infections. In 2014, the country had a 5.6% national HIV prevalence, including an estimated 75 000 women living with HIV who become pregnant annually. Although HIV testing in pregnancy is >90%, only 64% of HIV-exposed infants (HEI) received ART for PMTCT. To increase the proportion of infants protected from HIV exposure, the barriers preventing pregnant women and their infants from being identified, linked to and followed up/referred to care services are significant obstacles.

The US National Institutes of Health (NIH) and the President's Emergency Plan for AIDS Relief (PEPFAR) and the Implementation Science (IS) Alliance funded the current study (MIR4H). A combination intervention was designed to reduce loss-to-follow-up for women entering PMTCT services in ten health facilities in Kenya using an individual randomized trial approach. The aim was to evaluate the effectiveness of standard of care (SOC) with active patient follow-up among pregnant women living with HIV and their infants at six months postpartum. The SOC included antenatal care (ANC) and HIV services, while the intervention delivered by lay counsellors included four additional components: individualized health education; retention and adherence support; SMS appointment reminders; and follow-up and tracking of missed for missed clinic visits. Routine data and questionnaires were used to collect the data for the study. The study results highlighted that pregnancy complications, infant deaths, and transfer out of specific facilities increased loss-to-follow-up among women and infants in PMTCT care.

Conclusion: This study encountered many of the realities encountered on the ground when conducting implementation research. The MIR4H study faced real-life challenges – such as delays in funding, health-care worker strikes, shortage of rapid HIV test kits, slow uptake of new HIV guidelines – that together led to evident delays and resulted in adaptation to the project implementation.

Lessons: Implementation research must be adaptive to any challenges.

Source: Fayorsey R. N. et al. Mother and infant retention for health (MIR4Health): Study design, adaptations, and challenges with PMTCT implementation science research. *Journal of Acquired Immune Deficiency Syndrome*. 2016; 72:Supplement2.



UNDERSTANDING IMPLEMENTATION RESEARCH

Case study 1 Importance of involving stakeholders throughout an IR project

Background: The distinguishing features of IR include the importance given both to the context within which a programme operates, as well as the populations that are affected by the project. It seeks to involve implementers and populations affected by an intervention in all aspects of research right from research design, the process of research, and as users of research outcomes. The emphasis on involving 'local' populations and groups in research to enable a 'bottom-up' approach ensures that local priorities and participants have a voice. This subsequently makes research and the actions that result from it more relevant and acceptable locally. Incorporating programme implementers' perspectives makes the research process sensitive to the complexity of the world the programme implementers inhabit and are trying to change.

The IR approach was used to ascertain how the nature of emerging questions differed in focus when compared to those found in the literature on evaluation of health insurance programmes in low- and middle-income countries (LMICs). The context was one of the longest serving government-funded insurance schemes in India, the Rajiv Aarogyasri Scheme (RAS) in the state of Andhra Pradesh. The RAS has been operating since 2007 and covers the cost of inpatient care for people below the poverty line. The programme has around 70 million beneficiaries. The IR approach comprised a series of meetings during 2012, involving various groups of stakeholders. Staff from the Aarogyasri Health Care Trust, the Public Health Foundation of India and the Indian Institute of Public Health, Hyderabad met to identify research questions that could serve as a guide for evaluation of the RAS. The derived research questions were compared with the ones identified by a literature review.

Findings: Around 60% of the research questions in the published literature pertained to programme outputs and outcomes while 40% were related to programme input/process. This was in contrast with the questions generated through IR, where 81% of questions were related to input/processes and only 19% focused on outputs and outcomes. Furthermore, the majority of the studies in published literature that sought to evaluate health insurance programmes were researcher-driven. They also had a stronger tendency to evaluate the insurance programme against a set of outcomes rather than to the process and input aspects of the programme.

Conclusions: The research questions identified through the collaborative approach established and offered a more comprehensive view of programme performance and were more closely aligned to implementers' needs. Furthermore, involving implementers/stakeholders gave insight into the programme activities. If implementers are not involved, it becomes difficult for external researchers to independently achieve or incorporate the implementers' tacit knowledge into the research process or research questions that are more relevant to the research needs of policy-makers.

Lessons: The set of research questions resulting from IR were much broader in scope and put more emphasis on processes and inputs. The collaborative process also enabled the researchers to appreciate the heterogeneous nature of implementers, a fundamental characteristic of IR.

Source: Rao, K.D. et al. An implementation research approach to evaluating health insurance programs: insights from India. *International Journal of Health Policy and Management*. 2016; 5.5: 295.

**Case study 2****Community engagement: *Majigi* educational intervention for polio eradication in Northern Nigeria**

Background: Over two decades ago, the global polio eradication effort was launched. It sought to end the disease through an efficacious polio vaccine that is delivered through routine vaccinations and supplementary campaigns among susceptible populations. To date, however, Nigeria is yet to be declared polio free. This is mainly because of the low polio vaccine coverage in northern Nigeria despite the repeated polio campaigns in the region. The main bottleneck is low community acceptance due to misconceptions, distrust and myths around the cause of the disease and the safety of the vaccine, inadequate social mobilization, improper channels of communication, and lack of programme commitment and ownership at the local government level. Thus, to enhance effective of the intervention, there is a need to actively engage community gatekeepers with a special focus on political, traditional and religious leaderships, traditional healers, birth attendants, town criers and traditional surgeons. A pilot trial using a mass media campaign was launched in 2008 in four northern communities within the same local council. This campaign, dubbed the 'Majigi' educational intervention, targeted the beliefs about the disease and the negative attitudes towards polio vaccination. Majigi involved a road side film show in communities using mobile vans. Community leaders encouraged attendance and participation in subsequent vaccination activities through their circles of influence. Regular polio supplemental vaccination activities were conducted and the outcomes monitored for six successive months.

Results: The campaign resulted in a 310% increase in polio vaccination uptake and net reduction of 29% of never-vaccinated children in the targeted region. 'Majigi's successful innovative contextually- sensitive approach enhanced community ownership and cleared misconceptions around the polio vaccine.

Conclusions: Targeting the community gatekeepers facilitated the implementation as well as the outcomes of the intervention. Furthermore, polio vaccination uptake was enhanced by a locally adapted programme that promoted effective communication with and within the community.

Lessons: To promote a given intervention, communities need to be empowered so that they are able take informed decisions.

Source: Nasiru, S.-D. et al. Breaking community barriers to polio vaccination in Northern Nigeria: the impact of a grass roots mobilization campaign (Majigi). *Pathogens and Global Health*. (2013); 106(3):166–71



Case study 3

Contextual factors leading to persistence of malaria in remote Central Viet Nam

Background: The persistence of malaria in Viet Nam is related to complexities within the health system, sociocultural, economic and environmental contexts. The establishment of the National Malaria Control Programme with a strategy to distribute bed nets, as well as diagnosing and treating confirmed cases free of charge, dramatically reduced the malaria incidence rate from 1.2 million clinical cases in 1991 to 185 529 in 2002. Despite these efforts, however, the central province of Quang Tri – with poor, low-educated and culturally diverse minority populations – had one of the highest malaria burdens in the county. A study aiming to strengthen malaria control sought to identify how the health system and community factors are linked to malaria persistence. A multidisciplinary team conducted the study from March 2004 to April 2005. A mixed-methods approach was used in two of the districts with the highest malaria burden. In the formative stage, qualitative approaches were used to inform the later quantitative part of the study. Semi-structured interviews and focus group discussions were conducted with purposively selected health care managers, village heads and villagers to explore beliefs, attitudes, awareness, health care-seeking behaviour and circumstances relevant to malaria exposure and control. A knowledge attitude and practices (KAP) survey was conducted in the assessment stage, face-to-face with the village health workers (VHWs) and community members. Checklists were used to assess visibility and status of malaria treatment guidelines, quality of microscopy, as well as bed net quality (during KAP survey home visits). To determine actual bed net use, unannounced night visits to the homes were also conducted.

Findings: The main deficiencies at a health facility level were understaffing, unqualified staff, lack of in-service training, inaccessible treatment guidelines and lack of equipment and supplies. At a community level, socioeconomic and cultural factors impeded access to and effective use of interventions. Although diagnosis and treatment of malaria were free, patients were unable to afford the related indirect costs and this led to early self-discharge and failure to honour review appointments. Furthermore, although bed nets were supplied free of charge, the target of 80% coverage (i.e. one net per two people) was not met due to cultural sleeping norms, as well as low education and poverty. Overnight socializing among male neighbours is typical and yet the majority of homes did not have spare nets for guests. Risks to exposure were also increased due to the high mobility, which is culturally and economically driven. Whereas the geographical access to health services was addressed by having community health workers (CHWs), many of them had insufficient training and this greatly affected their capacity to cope with all expected tasks. In addition, due to delays in rolling out the new guidelines for some of the medicines included in VHW kits, some CHWs did not follow prescribed treatment guidelines. Language barriers and mistrust between the ethnic minorities in western Quang Tri and service providers was also reported, and this may have contributed to the community's lack of responsiveness to medical advice. Geographical inaccessibility due to poor roads, and shortage of telephones, were among the contextual barriers identified.

Conclusion: Deficiencies were established throughout the continuum of care from the health facility all through to the community level. These observations were used as a basis of the proposed intervention.

Lessons: A comprehensive analysis of context is critical for the effectiveness and ultimate success of any proposed intervention.

Source: Morrow M. et al. Pathways to malaria persistence in remote central Vietnam: a mixed-method study of health care and the community. *BMC Public Health*. 2009; 9:85.



DEVELOPING AN IMPLEMENTATION RESEARCH PROPOSAL

Case study 1 Is your research problem justifiable?

Background: Any worthy research should be preceded by a knowledge gap. Accordingly, in implementation research, the knowledge should be used to overcome any identified bottlenecks to improve health service delivery. Therefore, any proposed research should address the discrepancy between the observed status and what is desired. Furthermore, a successful research project should be able to garner support of the relevant stakeholders. Hence it must be acceptable, relevant, a priority, politically acceptable, timely, ethically sound, urgent and feasible. The table presents an analysis of the above variables for a study that set out to determine the barriers and motivators to voluntary medical male circumcision (VMMC) uptake among various age groups of men in Zimbabwe. The aim of the analysis is to establish if the research was justifiable.

Variable	Explanation
Was there a discrepancy between the situation that exists and the ideal?	Yes: The programme started in 2009, but as of September 2013, only 170 000 men were reached against a five-year target (2013–2015) of 1.9 million.
Was the research a priority ?	Yes: In 2009, Zimbabwe was one of the priority countries identified by WHO/UNAIDS to scale up VMMC. But after four years of implementation, a coverage of only 4.8% of the target population was achieved. Therefore, understanding and addressing the barriers and motivators to VMMC uptake will inform effective demand creation as an urgent priority.
Where there a clear reason for the difference or discrepancy to the problem?	No.
What factors could explain this difference?	Negative attitudes towards circumcision; fear of pain; fear of complications; perceived threats to masculinity; costs.
Were the results urgently required by stakeholders e.g. policy-makers, implementers, health care providers	Yes: There was a need to establish why the programme was not achieving its set targets.
Was the research politically acceptable?	Yes: The project was run by the Ministry of Health (MoH) and Population Services International (PSI), and would therefore get support. The topic was of high interest to local and national authorities.
Was the research ethically sound?	Yes: Results were shared with the stakeholders, research group and were beneficial to the community. Furthermore, informed consent was obtained from the research participants?
Were the recommendations applicable to the target community?	Yes: The recommendations were used to craft context specific IEC messages. Specific goodwill ambassadors were identified within the community. [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].



Case study 1 Is your research problem justifiable?

Variable	Explanation
Is the research relevant ?	Yes: HIV is a public health problem affecting a significant proportion of the population, in terms of health as well as social and economic impacts.
Is the research new or innovative ?	Yes: The results identified other target populations such as women for the information, education and communication messages. Other modes of dissemination were also identified.
Is the research feasible ?	Yes: Human resources to collect the information and implement the recommendations were available and WHO and PSI were willing to support the research.

Conclusion: The study to determine barriers and motivators to VMMC uptake among different age groups of men in Zimbabwe was justifiable because there was a discrepancy between the status and the desired state, the information was needed urgently, it was politically acceptable to the stakeholders, was ethically sound and feasible to conduct in terms of human resources, time and funding.

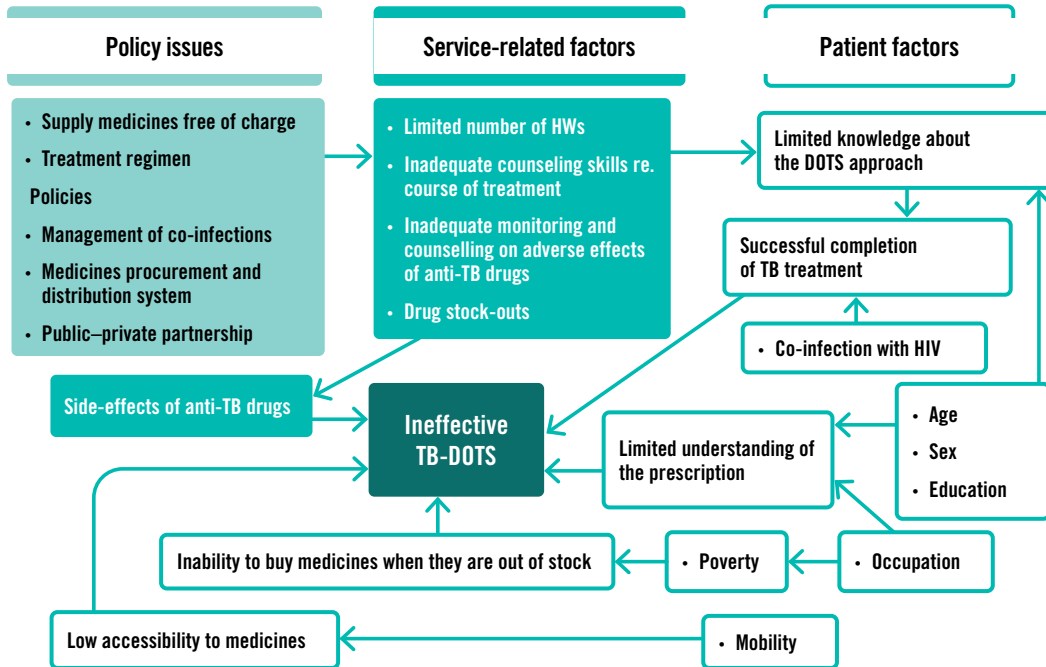
Source: Hatzold K. et al. Barriers and motivators to voluntary medical male circumcision uptake among different age groups of men in Zimbabwe: results from a mixed methods study. PLoS One. 2014; 9(5):e85051.

Case study 2 Analysis of the research problem

Background: The directly-observed treatment strategy (DOTS) short-course approach has been adopted as an effective strategy for management of tuberculosis (TB) and is reported to have significantly improved TB disease detection, treatment and control. In Nigeria, however, neither the set target for TB detection rate nor the cure rate has been achieved nationwide. This has been due to several challenges at various levels of the health system (i.e. policy, health service delivery, community and individual levels). To analyse the research question and to also establish the relationships of the factors at the different levels within the health system, the problem was critically analysed. The process involved a brainstorm session on the different factors impeding the core problem, description of the cause-effect relationships between the different factors and grouping them under the relevant thematic areas (see diagram). The process also actively involved relevant stakeholders. A previous study by Bello et al, examined the challenges of DOTS implementation strategy in the treatment of TB patients with the view to determining the obstacles to effective implementation. Associated patient-level factors included a lack of knowledge about the DOTS strategy, poor adherence to medicines, co-infection with HIV, poverty and sex of the patient. At the health facility level, poor counselling by the health personnel and medicines stock-outs were established, as well as side-effects of medicines. These observations were encountered despite the existence of national policies intended to improve uptake of the DOTS programme.



Case study 2 Analysis of the research problem



Lessons: A compressive analysis of the problem identified specific bottlenecks and their mutual relationships at the various levels of the health system. In addition, identification of specific bottlenecks assisted in the development of research tools, as well as recommendations for targeted interventions.

Source: Bello SI. Challenges of DOTS implementation strategy in the treatment of tuberculosis in a tertiary health institution, Ilorin, Nigeria. African Journal of Pharmacy and Pharmacology. 2010;;4(4):158-64.



Case study 3 Quality management plan

Table: Data quality management measures

Study phase	Variable	Quality control measure	
Design	Study design	Mixed methods enabled the capture of both quantitative and qualitative aspects	
	Sample size	Scientifically derived (i.e. based on prevalence, power of study, degree of error, design effect)	
	Study area	Randomly selected	
	Sampling of participants	Participants were selected purposive sampling and convenient sampling for key informants	
	Study tools		Structured questionnaire for quantitative methods
			FDG guide and KI guide for qualitative methods
			Data collection tools translated into Bengali
	Ethical concerns	Sought ethical approval from the Ethical Review Committee of James P. Grant School of Public Health	
		Pilot testing of the tools to ensure that are accurate and culturally sensitive	
Data collection	Data quality	Training of data collectors	
		Field protocol with all the instructions, including skipping and probing	
		Supervision of the data collectors	
		Notes were taken during FGDs and IDIs	
		Recording of interviews and discussions done to avoid information loss	
	Ethical concerns	Informed verbal consent, observation of confidentiality and privacy	
Data Management	Qualitative data	Data was cleaned	

Lessons: Quality processes should start right from the study design stage and continue throughout the project life cycle. These should be succinctly described and justified in every research proposal.

Source: Paul S. et al. Knowledge and attitude of key community members towards tuberculosis: mixed method study from BRAC TB control areas in Bangladesh. BMC public health. 2015; 15(1):1.

RESEARCH METHODS AND DATA MANAGEMENT

Case study 1

Community-directed education intervention: Quasi-experimental study in malaria endemic areas of Sarpang District, Bhutan

Background: Malaria remains a public health problem in spite of the efficacious interventions such as long lasting insecticidal nets (LLINs) and artemisinin-based combination therapy. The Kingdom of Bhutan has achieved notable success in the prevention and control of malaria, and the country is moving towards the malaria elimination phase. For example, in 2011 only 194 malaria cases were registered compared to 5935 cases in 2000. To attain the elimination goal, current efforts need to be reinforced by community-directed interventions in order to empower the community to enhance their health-seeking and other preventive behaviours. Community-directed interventions have proved to be useful in the prevention and control of public health infections such as onchocerciasis. This study was conducted to elucidate the effectiveness of the community-directed educational intervention on malaria prevention and control in malaria-endemic areas of Sarpang District, Bhutan. A quasi-experimental study design was adopted, using both qualitative and quantitative methods (Figure). The study district (Sarpang) was purposively selected from seven malaria endemic districts. The study basic health units (BHU) were Umling and Chuzerganga (intervention arm), and Jigmeling (control arm). These were purposively selected. These BHUs were similar in population size and other relevant contextual criteria. Baseline data was collected during the formative phase using in-depth interviews and focus group discussions (FGDs), household surveys and document/data review. The training tool was developed in collaboration with the BHU staff. Health workers and community action groups (CAGs) were trained on malaria transmission, care and use of LLINs, proper use of indoor residual spraying, control of mosquito breeding sites, and the importance of early diagnosis and treatment. The intervention package was implemented in addition to the regular programme activities in the intervention BHUs while in the control BHU, only regular programme activities were conducted. To assess the effectiveness of the intervention, it was evaluated using household survey, FGDs, in-depth interviews and review meetings. Comparison of the pre- and post-intervention group, showed a significant improvement in knowledge, attitude and practice of the community intervention arm as compared to the control arm.

Conclusion: The quasi-experimental study design was able to elucidate the effectiveness of the community-directed educational intervention on malaria prevention and control in malaria-endemic areas.

Lessons: Quasi-experimental study design is an appropriate approach to establish the impact of a given intervention. However, to ensure reliable results, the intervention and control arms should be as similar as possible in terms of population characteristics and context. The only distinguishing variable should be the intervention in question.

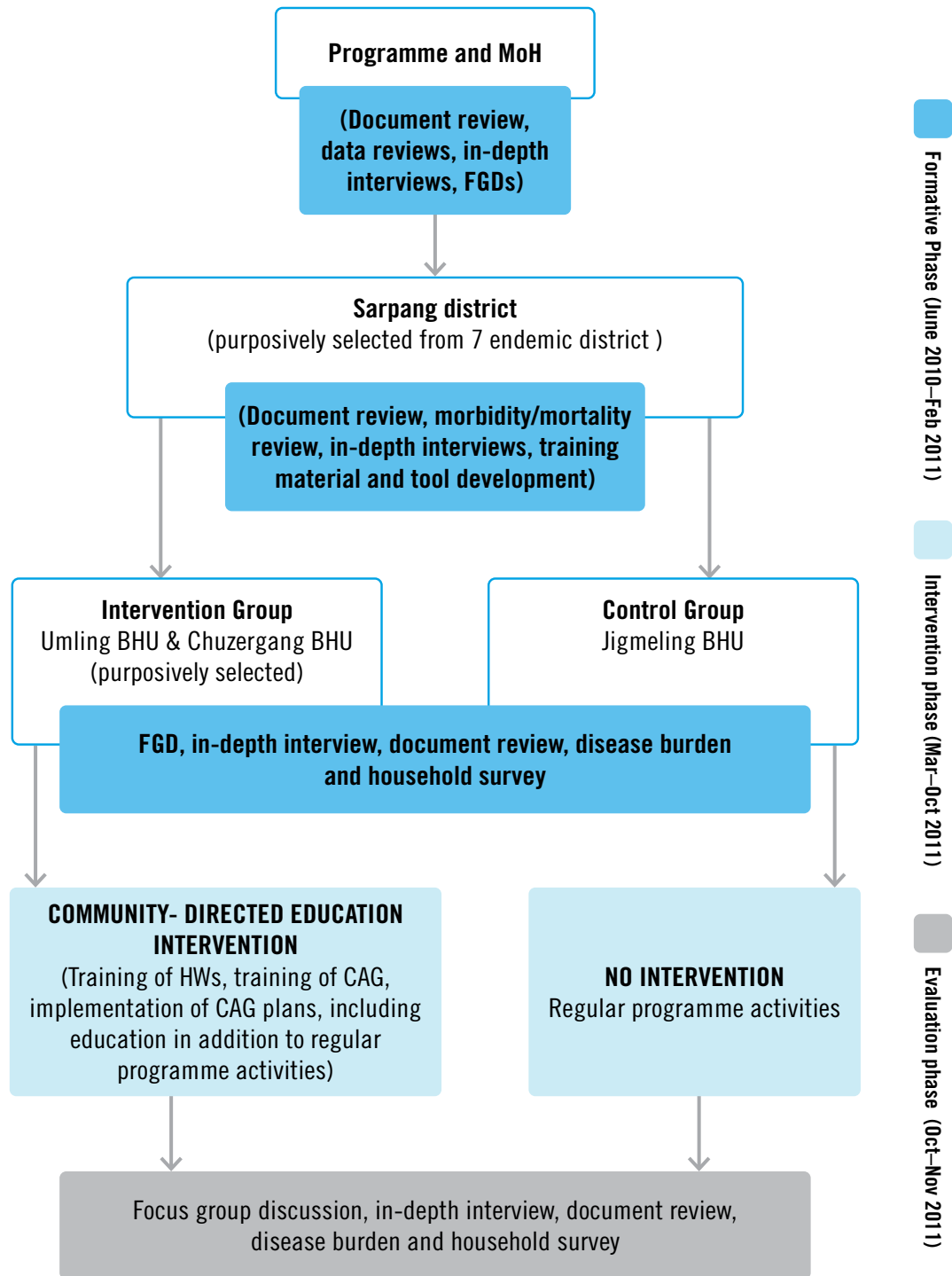
Source: Tobgay T. et al. Community-directed educational intervention for malaria elimination in Bhutan: quasi-experimental study in malaria endemic areas of Sarpang district. *Malaria Journal*. 2013; 12(1):1.



Case study 1

Community-directed education intervention: Quasi-experimental study in the malaria endemic areas of Sarpang District, Bhutan

Figure. Schematic diagram of research activities



**Case study 2****Use of mixed methods to explain malaria persistence in remote Central Viet Nam**

Background: Malaria remains a major global threat despite availability of efficacious tools. Its effective control requires consistent action from both *health care systems* and *community* and an understanding of features that precipitate risk. The Viet Nam National Malaria Control Programme (NMCP) introduced in 1991 has controlled malaria through the provision of free anti-malarial drugs, impregnated bed-nets, twice-yearly home insecticide spraying and early diagnosis and treatment. Overall, the number of clinical cases declined from 1.2 million and 4646 recorded deaths in 1991 to 185 529 clinical cases and 50 deaths in 2002. However, over 90% of severe cases and deaths occurred in mountainous, forested and largely ethnic minority areas of central Viet Nam, where populations are impoverished, poorly educated, culturally and linguistically distinct and living in dispersed, less accessible settlements. The researchers therefore considered it both instructive and timely to investigate persistent malaria in such settings.

Methods: Mixed methods (qualitative and quantitative) were used to collect data, in order to explore the complex interrelations between the various actors and system elements. Data was collected in two stages. The formative stage used mainly qualitative tools (e.g. community meetings, observation of bed-net use, and focus group discussions/semi-structured interviews) with health managers, providers and community helped to define and expand thematic areas of enquiry. Outcomes informed the quantitative approaches (e.g. a provider quiz, structured surveys with community members and village health workers, and quality check of microscopy facilities and health records at district and commune levels). The table describes the methods that were used.

Conclusion: Use of the mixed methods informed researchers and the NMCP about the contextual factors that acted as bottlenecks to effective malaria control in the affected region.

Lessons: The complexity of contextual factors coupled with poverty, low education levels, cross-border mobility, and cultural diversity, made it appropriate to use mixed methods.



Case study 2

Use of mixed methods to explain malaria persistence in remote Central Viet Nam

Table: Summary of mixed methods use during the project

Formative stage		
Method	Objective	Participants
Community meetings	To explore beliefs, attitudes, awareness, care seeking/providing and circumstances relevant to malaria exposure and control	Malaria control officials, local government, mass organizations, hospitals
Focus group discussion		Provincial and district malaria control managers and Commune Health Station staff, village health workers, and community members
Semi-structured interviews		Provincial malaria control officials, district malaria control secretaries, district hospital staff, commune health staff, village health workers, community members
Informal group discussion		District hospital managers
Observation	<ul style="list-style-type: none"> To identify antimalarial drugs on the market 	Drug selling points
Observation	<ul style="list-style-type: none"> To describe village environment/context 	Villages/community
ASSESSMENT STAGE		
Tests/quiz	To obtain an impression of provider knowledge and guidelines adherence	District hospital staff
Observation checklists	To assess visibility and currency of malaria treatment guidelines	Health service points
	Quality of microscopy	
Review of treatment records/logs	Bed-net quality during KAP survey home visits	Homes
		Malaria patient records
Structured questionnaire	To determine community knowledge, attitudes and practices	Village health workers
		Community members

Source: Morrow M. et al. Pathways to malaria persistence in remote central Vietnam: a mixed-method study of health care and the community. BMC Public Health. 2009; 9(1):1.



Case study 3 Data collection tools: Case of the NIGRAAN project

Background: Data collection tools allow a systematic collection of data about participants in any given study. The exact tool employed depends on the objective of the study. Because of the potentially complex nature of implementation research (IR), mixed methods – and hence different data collection tools – are often used as by the NIGRAAN project in rural Pakistan. The project was conducted by the department of community health sciences of the Aga Khan University (AKU) (Karachi) in collaboration with the Sindh Provincial Department of Health. Nigraan is an Urdu word meaning ‘supervisor’. The two-year IR project sought to identify ways the structured and supportive supervision of lady health workers (LHWs) by lady health supervisors (LHSs) could be strengthened, and in order to improve community case management of pneumonia and diarrhoea in children under five years of age in Badin district, in Sindh. The study was conducted in three sequential phases. The study participants included LHWs, LHSs, community caregivers of under five children and policy-makers. Quantitative data was collected using structured questionnaires, a knowledge assessment questionnaire and the skill assessment questionnaire (Table 1), while qualitative data was collected using in-depth interviews (IDs), focus group discussions (FGDs) and narrative interviews (Table 2).

Table 1: Quantitative data collection tools

Tool	Study participants	Purpose of the tool
Household survey questionnaire	Caregivers	To record the socio-demographic information and caregiver practices regarding diarrhoea and pneumonia of the population under study, as well as to document the morbidity due to diarrhoea and pneumonia.
Knowledge assessment questionnaire	LHSs and LHWs	To assess the theoretical understanding and knowledge of LHSs and LHWs regarding community case management of diarrhoea and pneumonia.
Skills assessment scorecard ‘A’	LHSs and LHWs	To assess the practical/clinical skills of LHSs and LHWs regarding community case management of diarrhoea and pneumonia.
Skills assessment scorecard ‘B’	LHSs and LHWs	To assess the supervisory and clinical mentoring skills of LHSs in terms of providing feedback and supportive supervision to LHWs.

Table 2: Qualitative data collection tools

Tool	Study participants	Purpose of the tool
Narrative interviews	Community caregivers	Explore caregiving practices and decision making for childhood diarrhoea and pneumonia.
FGDs and IDs	LHSs, LHWs	LHWs’ perspectives, knowledge and skills regarding community case management of childhood diarrhoea and pneumonia in rural Pakistan.
IDs	Policy-makers	Establish their opinions on the causes of the observed structural gaps.

Lessons: Data collection should be designed specifically, in accordance with the study population and objective.



IR-PLANNING AND CONDUCTING IR

Case study 1 Planning an IR project, its execution and quality assurance measures

Background: Indonesia began its national lymphatic filariasis (LF) elimination programme in 2002, including conducting annual mass drug administration (MDA) in endemic regions. By 2014, some regions had conducted at least five rounds of effective MDA and thus would qualify for Transmission Assessment Surveys (TAS) to determine if MDA could be halted. In Agam District, despite multiple MDA rounds, drug coverage was insufficient and persistent LF transmission was observed. In Depok City, the programme could not qualify for TAS because of insufficient drug coverage for multiple MDA rounds. The reasons for the insufficient coverage in Depok City and the presence of ongoing LF transmission in Agam District were not understood. It was against this background that researchers sought to increase their understanding as to how to guide and assist these areas to implement additional MDA rounds beyond the 4–6 rounds initially suggested by the programme. This was done through a development of a novel survey design to collect short stories about people's direct experiences with MDA for LF.

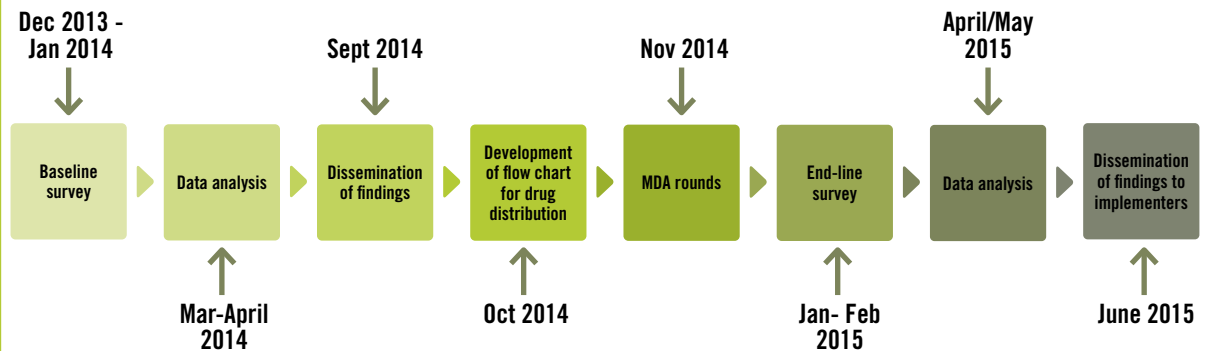
Planning phase: Working with the programme implementers, the research team developed a study tool to establish the factors that might be responsible for the sub-optimal coverage in the two study sites. Through a collaborative process, research themes were identified, a project implementation plan was developed and data collection tools were designed. This process involved regular communication with the district health teams to ascertain important dates for the enumerator training, community surveys, MDA awareness activities and the dates for MDA itself. Before surveys were conducted, the research team sought ethical approval from the Faculty of Health at the Universitas Indonesia for the research in both study sites.

Execution phase: The project was implemented in three phases: A first (baseline) phase where data was collected, analysed and interpreted and feasible recommendations shared among the stakeholders before the next MDA. The second phase (execution) involved adopting MDA using the recommendations based on the baseline survey findings. These recommendations were used to develop a flow chart to aid those carrying out drug distribution. The third phase (evaluation) involved another round of data collection (end-line survey) to assess the changes that may have occurred as a consequence of the baseline survey recommendations. The figure shows the timelines for project execution.



Case study 1 Planning an IR project, its execution and quality assurance measures

Figure. Execution timeline for the overall project



Quality assurance:

To ensure quality of data:

- questionnaires were pre-tested with a cohort of individuals in Depok City prior to data collection;
- data collectors were trained on the survey methodology;
- all questionnaires were administered by trained enumerators;
- supervisors checked completed questionnaires at the end of each day;
- the same sampling frame and methodology were used in both baseline and end-line surveys;
- data was double entered (using Epi-Info);
- data was checked for response bias, range and consistency.

Conclusion: Through the collaborative process described, researchers and implementers developed a valid and effective tool that was able to detect operational issues within MDA programmes. They were also able to draw up an effective implementation plan.

Lessons: Planning requires team work and close collaboration between programme implementers and researchers. This close collaboration enables research activities to be aligned with programme activities. Quality must also be maintained throughout the life cycle of the project.

Source: Krentel A. et al. Improving coverage and compliance in Mass Drug Administration for the Elimination of LF in Two 'Endgame' Districts in Indonesia Using Micronarrative Surveys. *PLoS Neglected Tropical Diseases*. 2016; 10 (11): e0005027.



Case study 2

Importance of continuous monitoring of the national scale up of zinc treatment for childhood diarrhoea (Bangladesh)

Background: Diarrhoeal diseases are still one of the major causes of childhood morbidity and mortality, especially in low- and middle-income countries. Clinical trials show that zinc, as part of a treatment for childhood diarrhoea, not only helps to reduce the severity and duration of diarrhoea but also reduces the likelihood of a repeat episode in the future. In 2004, the WHO/UNICEF revised their clinical management of childhood diarrhoea guidelines to include zinc.

The “Scaling Up of Zinc for Young Children” (SUZY) project was established in Bangladesh in 2003 to provide zinc treatment for diarrhoea in all children under five years of age. The project was supported by public, private and nongovernmental organizations, as well as multinational agencies. The scale-up campaign included production and distribution of zinc tablets, training of health professionals to provide zinc treatment and creation of media campaigns (TV and radio) to raise awareness and promote the use of zinc for diarrhoea treatment. To establish the effectiveness and success of the national campaign, and to highlight any potential problems during the implementation of health care initiatives in areas with deprived health systems, four survey sites were set up to monitor results from the first two years of the SUZY campaign. Each of the survey areas represented a different segment of the population across Bangladesh: urban slums, urban non-slums, municipal (small city) and rural settings. The study population across these sites was approximately 1.5 million children under the age of five years. At each site, seven surveys were conducted between September 2006 and October 2008. During each survey, about 3200 children with diarrhoea were studied from randomly selected households.

Findings: At baseline, awareness of zinc treatment was less than 10% in all communities. 10 months later, this peaked at 90%, 74%, 66%, and 50% in urban non-slum, municipal, urban slum, and rural sites, respectively. After 23 months, only 25% of urban non-slum, 20% of municipal and urban slum, and 10% of rural children under five years of age were using zinc for treatment of childhood diarrhoea. Use of zinc was shown to be safe, with few side-effects, and did not affect the use of traditional treatments. However, many children were not given the correct ten-day course of treatment and 50% of parents were sold seven or fewer zinc tablets. The findings further showed that although the first national campaign to promote zinc treatment for childhood diarrhoea in Bangladesh generated some success, the high awareness of zinc did not translate into high use. The scale-up campaign did not have any adverse effect on the use of oral rehydration salts (ORS). However, there were disparities in zinc coverage favouring higher income, urban households.

Conclusions: The study identified areas where more work was needed to ensure higher levels of coverage. For example, there was a need to link mass media messages with information from health care providers to help reinforce and promote understanding of the use of zinc. A change in focus of media messages from awareness to promoting household decision-making aided the adoption of zinc treatment for childhood diarrhoea and improved adherence.

Lessons: Long-term monitoring of scale-up programmes can identify important gaps in coverage and provide the necessary information about both intended and unintended outcomes, which consequently guides further decision-making.

Source: Larson C.P., Saha U.R., and Nazrul H. Impact monitoring of the national scale up of zinc treatment for childhood diarrhea in Bangladesh: repeat ecologic surveys. *PLoS Medicine*. 2009; 6(11):e1000175.



Case study 3 Analysis of constraints and facilitators of project execution

Background: Execution of IR projects encounters numerous potential constraints, particularly in resource-limited settings. It is essential that such constraints are identified before research commences. Several frameworks and guidelines have been developed to help identify specific constraints and facilitators at the various levels of project execution. One such framework, developed by Gericke and colleagues, can be applied to a wide range of interventions to help identify potential constraints to project execution. The framework describes: (i) Intervention characteristics (e.g. product design, supplies and equipment); (ii) Delivery characteristics (e.g. facilities, human resources, communications and transport); (iii) Government capacity (e.g. regulation, management systems, collaborative action); and (iv) Usage characteristics (e.g. easy to use, pre-existing demand and black market risks). This framework – with an additional category to address private sector capacity (e.g. manufacturing, marketing, health care providers, households) – was used to establish the constraints and facilitators to the success of the scale up of zinc treatment for childhood diarrhoea in Bangladesh. These constraints and some facilitators found to influence the zinc project scale up are summarized in the table.

Table: Summary of constraints and facilitators influencing the scale up of zinc treatment for childhood diarrhoea in Bangladesh

Category	Criteria	Intervention status	Level of constraint
1. Intervention characteristics			
1.1 Product design	Stability	<ul style="list-style-type: none"> Stable under conditions of high humidity and temperatures for up to 3 years in aluminium-PVC blister packs 	Low
	Easy of storage	<ul style="list-style-type: none"> No special requirements 	Low
1.2 Supplies	Supply needs	<ul style="list-style-type: none"> Must maintain a filled pipeline with regularly scheduled re-supply of retail outlets or health care facilities under conditions of uncertain product demand 	Moderate
1.3 Equipment	Technology equipment	<ul style="list-style-type: none"> No high technology equipment or infrastructure needed Households require a spoon or small container 	Low
2. Delivery characteristics			
2.1 Facilities	Retail sector levels	<ul style="list-style-type: none"> Feasible, given an existing distribution system is in place Feasible at all facility levels of care and in homes 	Low



Case study 3 Analysis of constraints and facilitators of project execution

Category	Criteria	Intervention status	Level of constraint
2.2 Human resources	Knowledge	<ul style="list-style-type: none"> Requires provider orientation and training, aided by a frequently asked questions repository with standardized responses 	Moderate
	Professional services	<ul style="list-style-type: none"> Requires individuals skilled in monitoring and in maintaining product supplies 	Moderate
2.3 Communications and transport	Infrastructure	<ul style="list-style-type: none"> Requires a product promotion and distribution infrastructure that reaches retail outlets and supplies health facilities 	Moderate
3. Government capacity			
3.1 Regulation/legislation	Regulation	<ul style="list-style-type: none"> Several regulatory considerations: e.g.: <ul style="list-style-type: none"> registration of the zinc tablet formulation registration/approval of product branding and packaging over-the-counter sales approval or waiver approval for mass media advertising 	Low
3.2 Management systems	Monitoring	<ul style="list-style-type: none"> Capacity required to effectively monitor the quality of the zinc products available over the counter 	Moderate
3.3 Collaborative action	Inter-sectoral	<ul style="list-style-type: none"> Must be able to maintain equitable, socially responsive pricing that reaches the poor 	Moderate
	External funding	<ul style="list-style-type: none"> If a high demand for zinc occurs in the government sector, the purchase of zinc will require external funding (unless passed on to the consumer) 	Moderate
4. Private sector capacity			
4.1 Manufacturing	Production	<ul style="list-style-type: none"> Requires a pharmaceutical laboratory that can maintain good manufacturing practices (GMP) certification, preferably in-country 	Moderate
	Distribution	<ul style="list-style-type: none"> Distribution systems that reach drug and general retail outlets required 	Moderate
4.2 Marketing	Communication networks	<ul style="list-style-type: none"> Widespread access to mass media networks (TV, radio), especially among poor and rural households, is needed 	Moderate
	Expertise	<ul style="list-style-type: none"> Requires professional skills in preparing and delivering marketing messages that target households at greatest risk (urban slums and rural poor) 	Moderate



Case study 3 Analysis of constraints and facilitators of project execution

Category	Criteria	Intervention status	Level of constraint
4.3 Health care providers	Regulation/ continuing education	<ul style="list-style-type: none"> The vast majority of health providers in Bangladesh are not licensed and are poorly regulated, but are represented by special interest groups that can organize continuing education Primary source of information is through private sector medical representatives (drug salesmen) 	Moderate
	Access	<ul style="list-style-type: none"> Easy access and widespread availability of unregulated providers at little cost 	Low
4.4 Households	<ul style="list-style-type: none"> Cost Health seeking Demands Expenditure 	<ul style="list-style-type: none"> Licensed private providers limited to urban settings Caregivers overwhelmingly seek help in the private sector Consumers demand and expect a curative treatment If burden to pay for zinc is passed onto households, then likely not to reach many of the poorest households 	Moderate

5. Usage characteristics

5.1 Ease of use	Information	<ul style="list-style-type: none"> Zinc as a treatment for childhood diarrhoea will be universally unknown to caretakers and most providers, thus requiring comprehensive education of providers and caretaker orientation Caretaker adherence with instructions regarding preparation is high (98%), but to duration given is low (<50%) 	High
5.2 Pre-existing demand	Need for promotion	<ul style="list-style-type: none"> This is a largely unknown intervention, therefore requiring large-scale provider and mass media promotion 	Moderate
5.3 Black market risks	Resale/ counterfeiting	<ul style="list-style-type: none"> If product is provided free of charge in public sector facilities, then risk of resale exists (MOHFW supplied blister packs are labelled 'not for sale') The dispersible tablet formulation can be counterfeited, with lower quality products jeopardizing the reputation of the intervention 	Low

Lessons: The various categories of constraints to project execution should be identified before research takes place in order to devise mitigation measures for a comprehensive execution plan.

Source: Larson C.P., Koehlmoos T.P. and Sack DA., Scaling Up of Zinc for Young Children (SUZY) Project Team. Scaling up zinc treatment of childhood diarrhoea in Bangladesh: theoretical and practical considerations guiding the SUZY Project. Health policy and planning. 2012; 27(2):102–14.



IR-RELATED COMMUNICATIONS AND ADVOCACY

Case study 1 Dissemination of research findings for different audiences

Background: Implementation research (IR) frequently generates large volumes of data that require organization, summarizing and visualization in order that they can be used for various kinds of communication and advocacy for different purposes and/or audiences. To help people understand and interpret the significance of specific data, it is frequently transformed from raw numbers and presented in various visual formats. The method you choose to visualize data can emphasize specific characteristics of a given data set, and so care must be taken to choose an objective approach that meets your goal and the needs of a specific audience, and which does not affect the integrity of the data itself or present a biased perspective. The choice of how to present the data should depend on simplicity and interpretability because stakeholders need to understand the information provided and to be able to interpret it correctly.

The following example illustrates how the target audience dictates the data visualization approach. The same data from a survey to assess community drug distributors' (CDD) performance in the provision of integrated community case management, using malaria rapid diagnostic test kits, is presented in different formats for the various priority audiences. Performance data was stratified by sex, age and education level. The table format is appropriate for a scientific audience; the bar graph for lay literate audiences (e.g. policy-makers and project implementers), while the diagram may be used for illiterate audiences at community level.

Conclusion: Large volumes of data can be organized and summarized as figures, tables or diagrams/graphics and used as varied communication tools.

Lessons: The presentation of findings should be carefully considered to avoid potential misinterpretations that could lead to inappropriate conclusions and/or responses. The choice of format should be simple, clear and appealing to the target audience.


Case study 1 **Dissemination of research findings for different audiences**
Table: CDD characteristics and adherence to malaria treatment guidance

CDD sex	Male number (%)	Female number (%)	Total
Correct case management	130 (89.0)	486 (97.6)	616
Incorrect case management	16 (11.0)	12 (2.4)	28
Total	146	498	644
(Fisher's exact test two-sided P value <0.0001)			
CDD Age	< 36 years number (%)	>36 years number (%)	
Correct case management	294 (92.7)	322 (98.4)	616
Incorrect case management	23 (7.3)	5 (1.6)	28
Total	317	327	644
(Fisher's exact test two-sided P value = 0.0004)			
CDD education	Primary number (%)	Secondary + above number (%)	
Correct case management	83 (92.2)	533 (96.2)	616
Incorrect case management	7 (7.8)	21 (3.8)	28
Total	90	544	6434
(Fisher's exact test two-sided P value = 0.0947)			

Case study 1 Dissemination of research findings for different audiences

Figure CDD characteristics and adherence to malaria treatment guidance

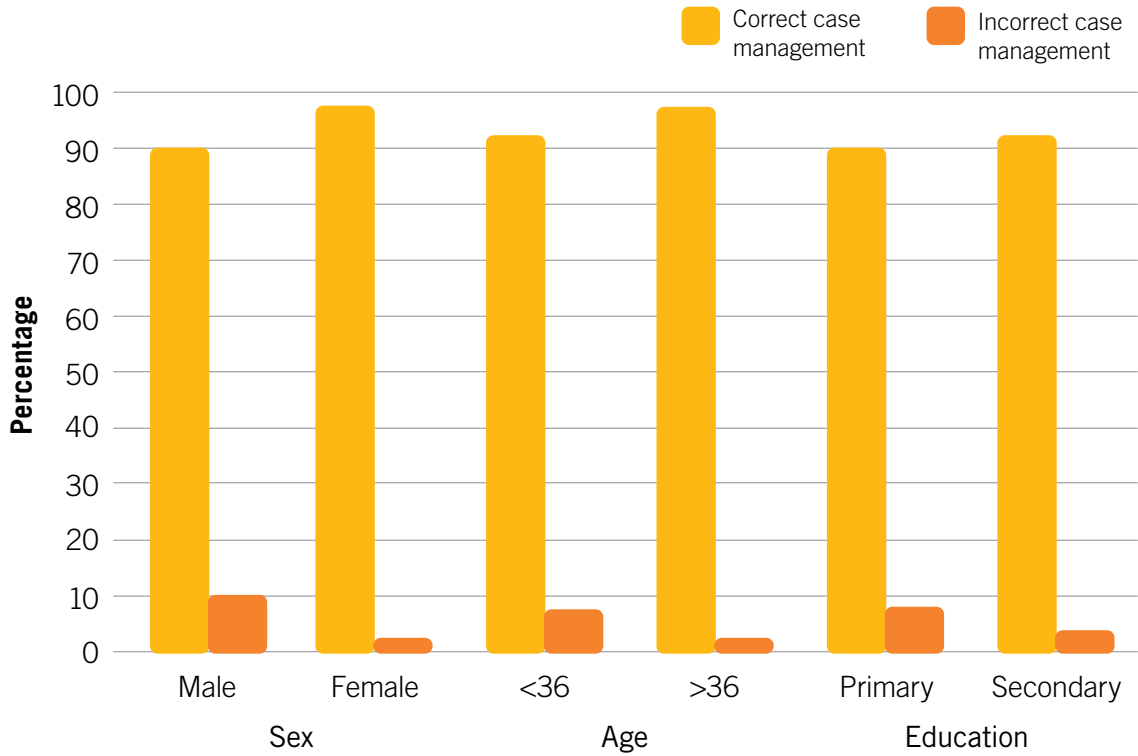
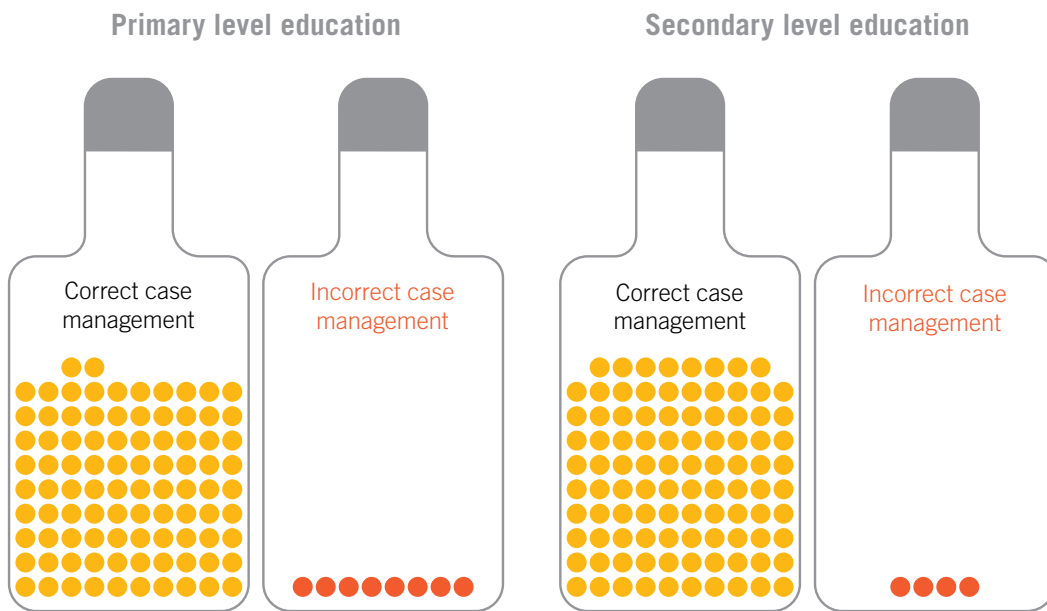


Diagram Percentage of CDDs who adhered to treatment guidance by education level



Source: Orji BC, et al. Community health workers provide integrated community case management using malaria rapid diagnostic test kits. *Research in Social and Administrative Pharmacy*. (2016); 13(4):875–879.

**Case study 2****A dissemination strategy for an IR Project: A case of the NIGRAAN project, Pakistan**

Background: Dissemination of research findings is crucial to facilitate uptake of research findings and for translating them into action. If the dissemination is to be effective, tools should be appropriate for the target audience, the message should be clear and succinct. Furthermore, the message must be timely. Moreover, if the health improvements are to be observed, the dissemination should go beyond just communicating by aiming to transfer new knowledge and understanding to the target audience, so that they are empowered to take the necessary actions.

Methods: NIGRAAN, a community-based implementation research (IR) project in rural Pakistan, was conducted by the Department of Community Health Sciences at the Aga Khan University (AKU) in Karachi, in collaboration with the Sindh Provincial Department of Health. Nigraan is an Urdu word meaning 'supervisor'. This two-year IR project aimed to identify ways to strengthen structured supportive supervision of lady health workers (LHWs) by lady health supervisors (LHSs), in order to improve community case management of pneumonia and diarrhoea in children under five years of age in Badin district of Sindh Province. Effective dissemination and knowledge translation enhances the execution process of a given IR project, as well as the use of the findings. A dissemination strategy should be developed during the planning phase of the project and should involve the relevant stakeholders. The research findings should be shared with stakeholders on a continuous basis throughout the project cycle using appropriate dissemination tools. The dissemination strategy for the NIGRAAN project was developed based on the TDR/WHO IR Toolkit dissemination framework. The relevant target audiences (community members, LHWS, LHSs, programme managers and implementers and the scientific community) were engaged at the appropriate timelines of the project lifespan.

Conclusion: A dissemination strategy was developed during the project planning phase and relevant stakeholders were actively involved. Furthermore, the dissemination tools were specific to the dissemination objectives and target audience.

Lessons: In creating a dissemination plan, researchers should consider the project goal, target audience, medium and execution plan. Developing an explicit dissemination strategy in advance guides the process of knowledge translation. Secondly, to enhance the use of the research findings, dissemination must not be an end-of-project dissemination activity but must be adopt a continuous and integrated knowledge translation approach. Additionally, the multidisciplinary and collective approach used to disseminate results on an on-going basis builds trust of stakeholders.



Case study 2

A dissemination strategy for an IR Project: A case of the NIGRAAN project, Pakistan

Table: NIGRAAN project dissemination strategy

Dissemination Objective	Content	Dissemination Tool	Target audience	Timeline
Creating awareness about the project among the community	<ul style="list-style-type: none"> Value of project Potential benefits for the community 	<ul style="list-style-type: none"> Community meetings Electronic media (newspapers, radio) 	Community members	From outset of the project
Creating awareness among policy-makers about the project	<ul style="list-style-type: none"> General and technical overview of the project Integration into existing systems/ structures 	<ul style="list-style-type: none"> Executive Project Management Team Meeting (EPMT) Project brochure Policy briefs 	Policy Makers at district and provincial level	At the launch of the project
Sensitization of the community about the progress of the project	<ul style="list-style-type: none"> What's happening? Community response to the project Field challenges and support requirements from the community 	<ul style="list-style-type: none"> Local electronic media (newspapers radio) LHSs' appraisal meetings 	<ul style="list-style-type: none"> Community Community-based organizations 	Ongoing
Sensitizing the Lady Health Supervisors (LHSs) and Lady Health Workers (LHWs) about the project	<ul style="list-style-type: none"> Overview of project and intervention What to expect? Roles and responsibilities Expectations from stakeholders 	<ul style="list-style-type: none"> Training workshop Formal dissemination seminars for LHSs at AKU 	<ul style="list-style-type: none"> Lady Health Supervisors Lady Health Workers 	Intermittent
Updating policy-makers and community leaders on the progress of the project	<ul style="list-style-type: none"> Field updates (what's happening? /progress) Any issues arising from within the system and/or community affecting the technical structure of the project Support requirements 	<ul style="list-style-type: none"> Project Support Team meetings District Project Management Team meetings 	Policy makers, community representatives other stakeholders with an active interest in the project	Intermittent periods
Updating the funding agency about the progress of the project	<ul style="list-style-type: none"> Progress of project activities Any technical issues arising finances 	<ul style="list-style-type: none"> Progress reports Emails, telephone calls 	World Health Organization	Yearly and end of project
Add to existing scientific knowledge	<ul style="list-style-type: none"> Process of the research Research findings 	Published articles	Scientific community	Ongoing basis
Inform the AKU staff on the progress	Activities, successes, challenges and recommendations	<ul style="list-style-type: none"> Faculty meetings Departmental presentations 	AKU staff	Intermittent
Contribute to LHW-P curriculum	Trainer's manual to improve community case management of pneumonia and diarrhoea in children under five years	Trainers manual	Lady health supervisors	After the formative phase

Source: Rabbani F et al. Improving community case management of diarrhoea and pneumonia in district Badin, Pakistan through a cluster randomised study--the NIGRAAN trial protocol. *Implement Science*. 2014; 9:186.

**Case study 3****Innovative participatory health education: promoting reproductive health in post-conflict settings in Sudan**

Background: Despite efforts to improve maternal health, South Sudan has one of the highest maternal mortality ratios worldwide. The decades of war, poor infrastructure, shortage of health workers and scarcity of resources, has negatively affected health system in general and reproductive health specifically, as also reflected in generally poor health care-seeking behaviour. A two-year Global Health Through Education, Training and Services-funded project was conducted in the Upper Nile State, Renk County in South Sudan. Previous participatory ethnographic studies on reproductive and child health provided some better understanding of contextual issues surrounding the problem, perceptions towards maternal health and interacting dynamics influencing patient decisions. An intervention (health education) was designed targeting the entire community by addressing maternal health issues within the post-conflict context. The intervention integrated the *Women Health Learning Package* (WHLP) in a participatory approach involving local women, nongovernmental organizations and theatrical band members.

Results: Context-friendly materials were jointly developed and disseminated in the form of songs, drama and pictograms to promote the communities' knowledge about maternal health issues among various audiences. All materials/outputs were developed in local dialects.

Conclusion: The effective engagement of community in the project – right from the initial problem identification and message development – enhanced the local sense of ownership. It also culminated in development of context-friendly educational materials to promote women's health in such a post-conflict setting.

Lessons: For a communication to be effective, innovative dissemination approaches should be adopted, community engagement is vital and the message and dissemination tools must be adapted to the local context.

Source: Elmusharaf K. et al. Innovative Participatory Health Education (video). Available at: https://www.webmedcentral.com/View_video/225.



INTEGRATING IMPLEMENTATION RESEARCH INTO THE HEALTH SYSTEM

Case study 1

Capacity building for sustainable health research: analysis of four African case studies

Background: Despite substantial investment in health capacity building in developing countries, evaluations of capacity building effectiveness are scarce. By analysing projects in Africa that had successfully built sustainable capacity, we aimed to identify evidence that could indicate that capacity building was likely to be sustainable. Four projects were selected as case studies using pre-determined criteria, including the apparent achievement of sustainable capacity. By mapping the capacity-building activities in each case study onto a framework previously used for evaluating health research capacity in Ghana, we were able to identify activities that were common to all projects. We used these activities to derive indicators that could then be used in other projects, including to monitor progress towards building sustainable research capacity.

Results: Indicators of sustainable capacity building increased in complexity as projects matured and included: (i) early engagement of stakeholders; explicit plans for scale up; strategies for influencing policies; quality assessments (awareness and experiential stages); (ii) improved resources; institutionalisation of activities; innovation (expansion stage); and (iii) funding for core activities secured; management and decision-making led by southern partners (consolidation stage). Projects became sustainable after a median of 66 months. The main challenges to achieving sustainability were high turnover of staff and stakeholders, and difficulties in embedding new activities into existing systems, securing funding and influencing policy development.

Conclusions: Indicators of sustainable capacity building need to be tested prospectively in a variety of projects to assess their usefulness. For each project, the evidence required to show that indicators have been achieved should evolve with the project and they should be determined prospectively in collaboration with stakeholders.

Source: Bates I. et al. Indicators of sustainable capacity building for health research: analysis of four African case studies. *Health Research Policy and Systems*. (2011); 9(1):1.

**Case study 2****Use of WHO health systems 'building block' framework to analyse how IR can be integrated and sustained within the health system?**

Background: Although IR may be conducted in only a limited geographical area or health facility for reasons of operational feasibility, human resources and funding, the implications of the IR might apply to a wider section of a given health system. The WHO has recommended use of a health systems 'building block' framework for comprehensively examining how interventions can operate more successfully and effectively in complex, real-world settings. This approach analyses the six WHO health systems building blocks, which define the essential components of a health system. This approach was used in the analysis of the barriers and motivators of voluntary medical male circumcision (VMMC) in 14 priority countries that were tasked with scaling-up VMMC services to 80% of HIV-negative men aged 15–49 years by 2016. Although the programme started in 2008, by July 2014 only two countries had achieved over 50% of the target, while the rest had <30%. This review used the WHO health systems building block framework to examine the factors influencing the scale-up of the VMMC programmes from 2008–2013 in 14 priority countries. The influence of each respective health system building block are summarized below.

- (i) *Leadership and governance:* The success of the intervention was facilitated by sustained country ownership and political will. However continued commitment and engagement of the stakeholders is also key.
- (ii) *Health workforce:* The activities of the proposed intervention should not compromise the already overstretched work force and the overall quality of health services provided. Thus, any innovations should ensure efficiencies to minimize human resource constraints. In VMMC, task shifting and task sharing appeared to facilitate scale up. Appropriate training of non-physician health workers was essential.
- (iii) *Health service delivery:* Expanding access and improving demand for VMMC are essential to service utilization. Mobile or outreach services to expand access to VMMC were successful in countries such as Kenya. However, experience from Zimbabwe revealed understanding the barriers and motivating factors related to the uptake of VMMC was necessary to determine service demand.
- (iv) *Medical products, vaccines, and technologies:* Availability of commodities and supplies in good quantities, on time and of acceptable quality is critical for the success of an intervention. Successful VMMC implementation requires coordinated partnerships that are effective and efficient in meeting commodity requirements. However, 10 of the 14 countries reported challenges related to inadequate supplies and delayed procurement. In addition, in most cases, VMMC waste management activities were not costed.
- (v) *Health system financing:* In the scale-up of VMMC, availability of external funding was a major facilitator. However, reliance on donor funding for scale up proved to be a barrier in countries where achievements of VMMC targets have been low. To close such funding gaps, several countries are currently generating and directing national funds specifically to HIV programmes, including VMMC activities.



Case study 2

Use of WHO health systems 'building block' framework to analyse how IR can be integrated and sustained within the health system?

(vi) Health information: Quality information is needed to guide evidenced-based decisions on how to allocate limited resources for HIV prevention, including the VMMC programmes. Standardized sets of indicators agreed upon by technical and funding agencies was one factor that strengthened the monitoring and the evaluation of VMMC services. However, since ensuring that the data collected through the national health information systems are of sufficient quality for meaningful interpretation is a challenge, the VMMC monitoring systems in most of the countries are parallel to national health information systems.

Conclusion: Use of WHO health system building blocks to analyse implementation bottlenecks can explicitly identify barriers and facilitators to integrating IR into the health system.

Lessons: Understanding of contextual barriers and facilitators of demand for a given intervention are essential in enhancing integration and sustainability of IR into the health system.

Source: Ledikwe J.H. et al. Scaling-up voluntary medical male circumcision – what have we learned? HIV/AIDS (Auckl). 2014; 6:139–46.

Case study 3

Building sustainable implementation research in Ghana Health Service.

Background: Ghana has steadily embedded implementation research (IR) in its health system through sustained country-led capacity building and sustained efforts by the Ministry of Health (MoH) and the Ghana Health Service (GHS). Over a period of almost 20 years, successive leadership has engaged stakeholders at the national and international levels to identify bottlenecks in the health system and address them with varying degrees of success. Most recently, the GHS led the development of a national health research agenda and an IR capacity plan for some key disease control programmes, with support from a multilateral partnership on access and delivery of health interventions.

In order to strengthen capacity within the GHS for implementation and operational research to identify and address country-specific health system needs for effective access to and delivery of new health technologies, a series of national workshops and stakeholder activities were conducted serially over a period of 18 months by the Research and Development Division (RDD) of the GHS. These included the development of a National Health Research Agenda so that the priority research areas identified by the GHS, its stakeholders and other collaborators could develop and provide evidence to support decision-making. Over one hundred and fifty development partners, GHS Directors and Deputy Directors, MoH Directors, Scientists from GHS research institutions, the Noguchi Memorial Institute for Medical Research, staff of the School of Public Health, Staff of non-GHS research institutions, policy-makers, disease control programme managers, Regional Directors, District Directors, Regional and District level Health Staff, Academics, and Health Administrators all contributed to the development of the research agenda, and participated in various workshops and stakeholders' meetings to review and refine the emerging research priorities. The resulting *National Health Research Agenda* included a list of barriers and problems impeding the effective delivery of health programmes and implementation of policies. The list provides a practical point at which IR can begin and focus.



Case study 3 Building sustainable implementation research in Ghana Health Service.

A second series of workshops conducted after the initial stakeholder consultation on the research agenda. These workshops were designed to:

- sensitize policy-makers at the GHS on the importance of IR to address priority programme needs;
- sensitize key players of the African Regional Training Centre (RTC) at the University of Ghana on the value of IR to address priority programme needs;
- build capacity in cohorts of research teams for the conduct of IR and dissemination of research findings in public health; and
- promote teamwork and functional partnerships among researchers, disease programme implementers and policy-makers.

Sensitization workshops for policy-makers and Regional Training Centre staff

A one-day workshop was convened for Directors and Deputy Directors of the various divisions in the GHS. The workshop sensitized and familiarized top management of the GHS to the key concepts of and approaches to IR and its potential value in addressing the key health system challenges in the country. Being slightly removed from the implementation level, it was imperative that policy-makers appreciate the value of IR in addressing implementation challenges encountered by programme managers at the district level. The second component of the sensitization process was to engage academia at the School of Public Health, University of Ghana and to sensitize key players on the content and processes of IR.

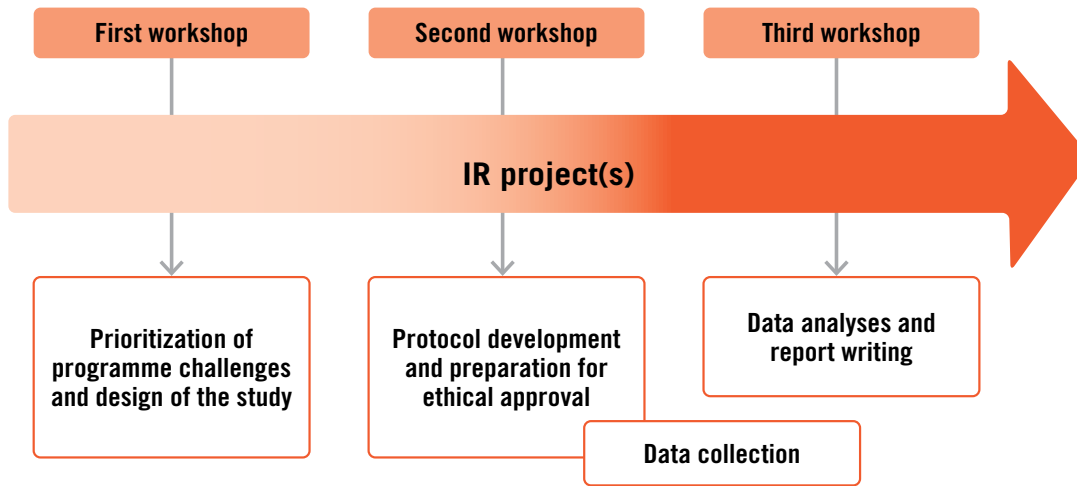
Training workshop for national control programmes

Following the sensitization of policy-makers, attention shifted to front-line practitioners of three priority programmes of the GHS: the National Malaria Control Programme (NMCP), National Neglected Tropical Diseases Control Programme (NTDCP), and the National Tuberculosis and Leprosy Control Programme (NTLP). Workshops were designed to equip programme teams to undertake IR on obstacles to the effective and efficient delivery of programme interventions. These obstacles were previously identified during the stakeholder consultations for the development of the national health research agenda.

A comprehensive plan was put in place to equip the research teams constituted by the priority control programmes through a series of national workshops – from the identification of research problems, through the development of robust study protocols, conduct of the research, data analyses, and preparation and dissemination of results (Figure).



Case study 3 Building sustainable implementation research in Ghana Health Service.



The programme managers constituted teams for the workshops on training and proposal development. Teams comprised a key member of the control programme, respective information officers, and researchers with quantitative and quantitative skills and an interest in the programme.

The workshop helped research teams to start the process of executing IR to address priority problems identified by national control programmes in Ghana. A number of programmes were able to provide funding within their programme budgets to support the resulting research projects.

Lessons: Engagement of key stakeholders in the health sector and research community in the identification of barriers, and development of the national health research agenda, facilitated wider appreciation of the value of IR in achieving national health outcomes. Funds were allocated within the national programme budget(s) to support IR without dependence on external sources.



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