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Schweizerisches Tropen- und Public Health-Institut
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Associated Institute of the University of Basel

Network Medicus Mundi Switzerland

Implementation Research

Step-by-step guide to a successful implementation research study

Guide for Medicus Mundi Switzerland network members

Draft 8.0 Submitted as final

Medicus Mundi Switzerland

Netzwerk Gesundheit für alle
Réseau Santé pour tous
Network Health for All

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Disclaimer

The views and ideas expressed herein are those of the author(s) and do not necessarily imply or reflect the opinion of the Institute.

Abbreviations

ACT	Artemisinin-based Combination Therapy
FGD	Focus group discussion
IR	Implementation research
ISPM	Institut für Sozial- und Präventivmedizin
KAP	Knowledge-attitude-practice
KII	Key informant interview
MMS	Medicus Mundi Schweiz (Medicus Mundi Switzerland)
MSF	Médecins sans frontières
NGO	Non-governmental organization
RDT	Rapid diagnostic test
SCIH	Swiss Centre for International Health
Swiss TPH	Swiss Tropical and Public Health Institute
TDR	Special Programme for Research and Training in Tropical Diseases
WHO	World Health Organization

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Executive Summary

A Medicus Mundi Switzerland (MMS) member organization-driven platform focused on Implementation Research (IR) asked the Swiss Tropical and Public Health Institute to prepare an IR Guide to support NGOs that are interested in embedding IR within their projects, and to help overcome typical barriers and challenges to carrying out IR studies.

Designed to be a "living document" that will be updated and improved at periodic intervals and based on feedback from MMS member organizations, the guide is informative, user-friendly and hands-on. It comprises five chapters, each of which includes some basic information, as well as links to existing documents, in particular the WHO Special Programme for Research and Training in Tropical Diseases (TDR) Guide on IR, videos, other resources and so-called "tips and tricks".

- **Chapter 1** describes the motivation behind the development of this guide.
- **Chapter 2** defines IR and describes why it is relevant.
- **Chapter 3** details the design and planning process for an IR study.
- **Chapter 4** focuses on key aspects for successful data collection and data analysis.
- **Chapter 5** discusses how to communicate results and dissemination strategies.

Throughout the guide, key concepts are highlighted, with definitions in the glossary, while for each chapter, resources, references and templates have been included in the appendices.

In **Chapter 2** IR is defined as research that addresses implementation bottlenecks and/or barriers to effectively delivering health system or health care interventions. The guide provides an overview of key characteristics of IR, as well as insights as to what it is not. A diagram has been developed showing the 3 main phases of IR (including the process and strategies), with main actors and key roles.

In short the 3 phases cover:

- **Phase 1**: Identifying and describing the **research problem**, in this case, bottlenecks to effective implementation of an intervention (analysis and assessment of already available information).
- **Phase 2:** Developing and **conducting the study** informed by findings from phase 1 and using standard research methods (systematic data collection, data analysis and interpretation of the findings)
- **Phase 3**: **Disseminating the results** among all stakeholders and uptake of the findings (communication plan, modification of the current implementation strategy)

Chapter 3 first takes the user through the steps of designing and planning an IR study – from identifying the problem, to conducting a literature review, formulating the research question and objectives and delineating suitable approaches and methodologies. Next it provides more detailed information on how to define IR outcome variables, aspects to think about related to the study population, sampling strategies and the design and testing of data collection tools. The guide also covers questions of timelines, data management and data analysis approaches, ethical clearance, as well as resource planning and ways in which quality assurance can be provided. Some of these aspects would most likely be outsourced to a research institution but have been included as the basis for discussions so they can take place at eye-level. Ideally, all involved partners have an overview of the main processes and their importance and rationale.

Chapter 4 takes the user through the whole process of actually conducting an IR study. This includes the recruitment and training of a data collection team, piloting of the data collection and analysis tools, and microplanning of the data collection team efforts in the field. It calls

out the importance of informing all relevant stakeholders so that the data collection can run smoothly, stresses mitigation of any potential safety and security risks, and elaborates the bigger issue of how to analyse the different types of data that are collected.

Finally, **Chapter 5** highlights how essential it is that the findings of IR studies can be conveyed in a clear way. As these findings relate to implementation challenges they implicate or require supportive action from a wide variety of stakeholders. For each of these stakeholders it is important to consider the format for sharing the findings in ways that will be clearly understandable to them - be these reports, policy briefs, posters, videos, press releases, conference abstracts, oral presentations, and/or manuscripts for the scientific literature. Getting for format right is critical for the take up of evidence into policy and to overcome the gap that too often exists between policy and practice.

As mentioned above, the aim of this guide is to support MMS member organisations and their partners in their IR undertakings. We hope you will enjoy using it and share your experiences, lessons learnt and examples with MMS so that this IR guide can be further improved and enriched going forward!

1 Introduction

1.1 Background

In 2015, a thematic working group of Medicus Mundi Switzerland (MMS) member organizations established a non-governmental organization (NGO)-driven platform for Implementation Research (IR) in international cooperation programs and projects in the health sector. The platform underlines the importance for Swiss NGOs to strengthen evidence-based decisions in their projects and programs. MMS's current and incoming (2020-2023) Strategy clearly stress the importance of IR for the network. Based on this recognition, various activities have been carried out including: a study/situation analysis on IR of Swiss NGOs working in the field of international health cooperation by the *Institute of Social and Preventive Medicine (ISPM)*; meetings and round tables at the 2015 *European Congress on Tropical Medicine and International Health (ECTMIH)*; and a visit to *Médecins Sans Frontières (MSF)* in Brussels for an **operations research**[1] dialogue day in June 2018. The aim of these events was to encourage exchange on IR amongst MMS member organizations.

On 21 February 2019, the Swiss Tropical and Public Health Institute (Swiss TPH) hosted a workshop with MMS member organizations to exchange IR experiences and lessons learnt, and discuss the idea of developing an IR guide for Swiss NGOs and their partners in the global South. There was a strong wish among the workshop participants for such a guide to be practical and for it to include typical examples, case studies and insider "tips and tricks". Subsequently MMS commissioned the guide's elaboration, as a way to support NGOs that are interested in embedding IR within their projects, and to help overcome typical barriers and challenges to carrying out IR studies.

1.2 Structure and use of the guide

The guide is intended to be informative, user-friendly and hands-on. As such it includes concrete examples and templates, highlights key concepts and take-away messages and points out important steps that must be considered for IR. Whenever possible it indicates the kind of timelines that should be taken into account. When consulting the guide it needs to be recalled that IR is a broad field particularly in health research, and that the design, planning and execution of IR studies highly depends on the research question, the context and the scope of the implementing organization. This guide focuses on aspects that are common for most IR activities related to health projects. For more specific insights, it is advisable to refer to a research institution for more in-depth consultations and advice.

The guide is comprised of five chapters. Each includes some basic information, as well as links to existing documents, videos and other resources.

- **Chapter 1** describes the motivation behind the development of this guide.
- **Chapter 2** defines IR and describes why it is useful.
- **Chapter 3** details the design and planning process for an IR research study.
- **Chapter 4** focuses on key aspects for successful data collection and data analysis.
- **Chapter 5** highlights how to communicate results and discusses dissemination strategies to target implementers, collaborators, local health authorities and affected communities.

[1] To add a call out box explaining that highlighted words are defined in the glossary in Appendix A (as the explanation only comes later down the page)

Throughout the guide, key concepts are **highlighted** and defined in the glossary in Appendix A. For each chapter, additional resources, references and templates can be found in the appendices.

2 Implementation research

2.1 Definition, goal and scope

Implementation research (IR) addresses implementation bottlenecks and/or barriers to delivering health system or health care **interventions**. Figure 1 shows how a health care intervention – the treatment of malaria infection with Artemisinin based Combination Therapy (ACT) that is close to 100% **efficacious** in a laboratory setting immediately starts to lose **effectiveness** in real life, such that in the end only 37% of malaria infected patients in a given context benefit from receiving the treatment. Various barriers and bottlenecks are encountered during the whole process (e.g. from ACT initiation to patient follow-up).

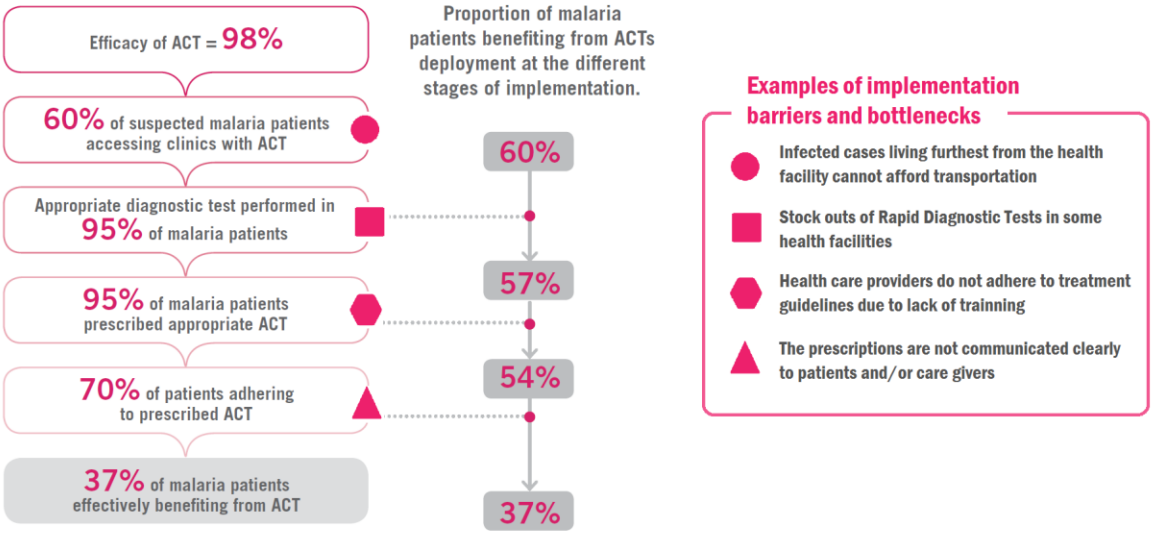

Figure 1 Example of implementation barriers and bottlenecks representing the difference between efficacy and effectiveness (Adapted from the TDR IR Toolkit)

The aim of IR is to identify solutions to overcome implementation problems. It addresses barriers or bottlenecks that decrease an interventions' efficacy. This later may be useful to inform the policy level and to scale-up efficacious interventions. Hence, IR contributes to better health outcomes by pointing to how health system deficiencies can be addressed and delivery mechanisms strengthened. Implementation research describes the scientific study of the activities related to an initiative as well as the contextual factors that affect them. It can address or explore any aspect of implementation, including contextual factors (such as poverty, geographical remoteness, or traditional beliefs), the activities related to the intervention itself (such as distribution of fully-subsidised insecticide-treated bednets (ITNs) through maternal health clinics, or the use of mass vaccination versus surveillance-containment), and the end-products of the intervention [1, 2].

Without implementation research we are at best committing valuable resources to implementation in the hope that things will work out [1].

IR can be best described by the key characteristics listed in **Error! Reference source not found.**.

Table 1. Key characteristics of implementation research [2].

Characteristic	Summary/description
Systematic	• IR systematically studies how evidence-based public health interventions are integrated and provided in a specific context, and how resulting health outcomes may vary across settings and communities. • IR balances relevance to real life situations with rigor, strictly adhering to norms of scientific inquiry.
Multidisciplinary	• IR analyses biological, social, economic, political, system and environmental factors that influence the implementation of specific health interventions. • IR fosters interdisciplinary collaborations between behavioural and social scientists, clinicians, epidemiologists, statisticians, engineers, economist, policy makers, and key stakeholders.
Contextual	• IR is demand driven. Framing of research questions is based on needs identified by implementers in the health system. • IR is relevant to local specifics and needs, and aims to improve health care delivery in a given context. • IR provides generalizable knowledge and insights that can be applied across various settings. • IR is 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.

What is an implementation strategy?

An **implementation strategy** is the planned approach to deliver or implement interventions and it provide solutions to overcome the bottlenecks and barriers. Implementation strategies need to be adapted to the sociocultural context, for example to reach increasing acceptability and therefore sustainable adoption of the intervention. Implementation strategies also consider aspects like the quality and cost of the services provided[1]. IR identifies and investigates problems that prevent effective implementation of the interventions. IR develops and tests implementation strategies that provide solutions for these implementation problems. Table 2 lists the main relevant actors and provides examples of implementation strategies.

Table 2. Main relevant actors and implementation strategies (Adapted from [3])

Main actor	Examples of implementation strategies
Government	Reorganize and/or integrate services Decentralize public service provision Policy reviews
Provider organization	Team problem solving Quality assurance Develop and apply guidelines Regular supervision
Individual provider	Continuing education and training Peer learning Job aids
Communities and households	Community Information and Communication Training community health workers Community mobilization Financial empowerment: in-kind subsidies and vouchers
Multiple actors	Situation analysis Engage powerful interest groups Coordination with community organizations

An example of IR findings translating into an implementation strategy [4]:

Onchocerciasis, often referred to as "river blindness", is an infection characterized by chronic skin and eye lesions. Ivermectin, a safe and highly potent microfilaricidal drug, has assumed a major role in the efforts to control and eliminate onchocerciasis. Annual administration of ivermectin to at least 65% of the population at-risk for about 15 years is an efficient approach to control onchocerciasis and eventually interrupt transmission. However, in the face of challenges like weak health systems and funding shortages that are prominent in most endemic areas, achieving and maintaining such a high coverage relying only on the health system is often not possible. As a consequence, the effectiveness of the intervention remained lower than expected. In an effort to identify a sustainable solution, several IR studies investigated the feasibility and effectiveness of community participation in: i) designing, ii) delivering and iii) monitoring the implementation strategy for ivermectin distribution. The findings shaped a community-directed strategy that has become the standard approach for onchocerciasis control. The underlying idea of entrusting the community with managing the delivery of basic health services has since been adopted by multiple other health programs.

IR is NOT: Basic biomedical research, clinical trials, replication of intervention efficacy trials in controlled setting, routine programme progress reporting or simple implementation of health interventions. (TDR IR Toolkit)

2.2 Relevance and process of Implementation Research

Looking back at the advances in medicine and public health over the last century highlights the relevance of conducting IR. A multitude of proven and **efficacious** health interventions have failed to deliver the expected impact. It is therefore imperative to understand and investigate existing bottlenecks, gaps or challenges obstructing **effective** implementation of such health interventions or strategies in order to address these failures.

Example: Measles and vaccination [5]:

Measles is a highly contagious viral infection. Complications of measles infection include pneumonia (the most common cause of death in children with measles), diarrhoea, encephalitis and ear infections that can lead to permanent deafness. A safe and very effective two-dose vaccination schedule has been available and widely deployed since the 1960s. However, the need for very high and consistent vaccination coverage to elicit herd immunity has limited the vaccine efficacy hence measles burden and harms remain substantial. WHO reports that globally in 2017, measles led to an estimated 110,000 deaths, most among the 20.8 million children under 5 years of age in low- and middle-income countries who had not received a single dose of measles vaccine through routine programmes in that year. IR could help identify bottlenecks and barriers preventing local vaccination programmes from reaching all children with the two necessary doses of the vaccine.

2.3 The process of Implementation Research

The process of IR consists of three phases:

- Phase 1: Identifying and describing the research problem, in this case, implementation problem (analysis and assessment of already available information).
- Phase 2: Developing and conducting the study informed by findings from phase 1 and using standard research methods (systematic data collection, data analysis and interpretation of the findings)
- Phase 3: Disseminating the results among all stakeholders and uptake of the findings (communication plan, modify the current implementation strategy)

Phase 1: Identification and description of the IR problem (see Chapter 3.1): Understanding the issue(s) negatively impacting implementation requires systematic analysis of the situation, setting and context. This involves understanding the socio-economic and political environment (outer setting), cultural or programmatic structures (inner setting), relevant stakeholders (individuals involved) and methods or strategies used for implementation (process for implementation) as shown in **Error! Reference source not found.**. It is i mportant to emphasize the need to involve all relevant actors in all phases of the IR process. Phase 1 provides the basis for framing the IR question.

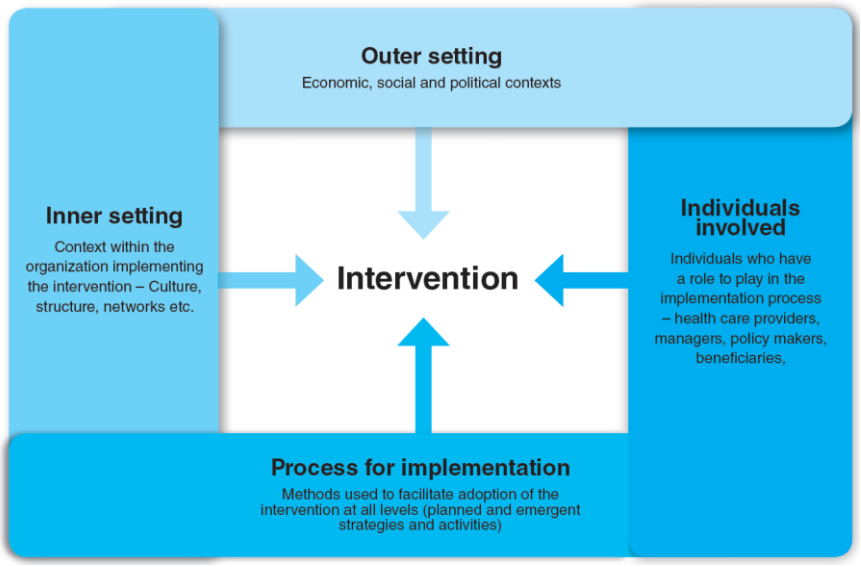

Fig. 2 Dimensions to consider when identifying/describing an IR problem during IR phase 1 [2].

Phase 2: Designing and conducting IR projects: typically, IR projects involve the collection of primary data. This is done based on a research **proposal** and **protocol** elaborated according to standard scientific research requirements and practices (see chapters 3 and 4). Data may be qualitative, quantitative or mixed depending on the research objectives (see sub-section 3.5). Phase 2 may require engagement of diverse stakeholders and multiple disciplines in order to adequately plan and address complex implementation challenges while adhering to good research practices.

Phase 3: The findings of an IR project need to feed back into the examined project, to inform decision-making and adaptation. An appropriate dissemination strategy ensures that the target audience has access to the findings (see Chapter 5). In most cases, recommendations for practical solutions to the identified issues may be formulated. Such recommendations must consider Implementation Research Outcomes (IRO), such as, local feasibility (technical, financial), acceptability and appropriateness that translate into potential for long-term adoption and sustainability. Reporting and dissemination of research findings beyond the project can involve a wide range of activities and formats such as meetings and conferences, briefings, publications and mass media. They can result in uptake and scale-up of interventions and strategies, guide decision-making and inform policy change or recommendations at local, national or international level.

The three phases are subdivided into different steps which cover critical questions to be asked before and during an IR project. The three phases are summarized in Figure 3.

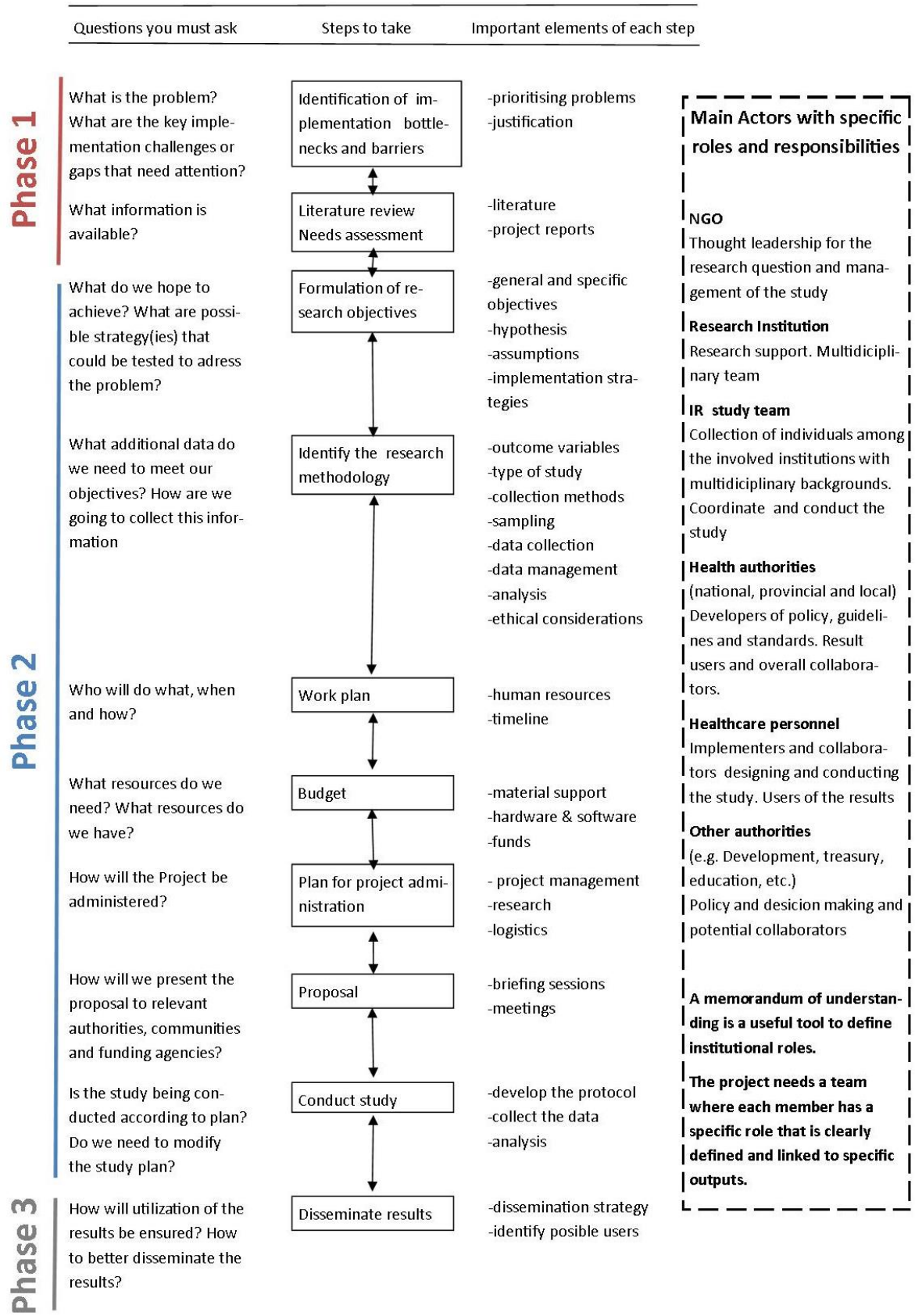

Figure 3: Three phases of the IR process showing the main actors, different steps and key questions. The process is iterative, indicated by the doubled-headed arrows (adapted from [6]).

3 Designing and planning an IR study

Designing and planning an IR study is in many cases a non-linear iterative process. It starts with the identification of a problem and the formulation of an informed research question, ideally after conducting a literature review. From there on, numerous steps need to be carefully taken and methodically documented in the core document of any IR study: the IR study **protocol**. An outline for a study protocol is provided in Appendix F. In addition, an example of a published protocol is available here [7]. The following section describes the steps needed to plan and design an IR study.

The TDR toolkit that provides guidance through key steps of designing and planning an IR study it is available at: TDR_IR process summary.

3.1 Identifying the research problem

The first step when planning an IR study is to formulate the research question. This must be done based on a thorough understanding of the **context**. Environmental, socio-economic, cultural, health systems, stakeholder and institutional culture determinants can affect the planning, the implementation, the monitoring and the outcome of an **intervention** and thus are key aspects to be taken into consideration when planning IR. Face-to-face interactions with relevant parties, site visits, sharing and reviewing of documents pertaining to the project, and a review of the scientific literature to identify related research (see Chapter 3.3) are fundamental sources of information.

Relevant factors to consider in the context assessment as well as a description of a stakeholder and institutional analysis, both illustrated by examples, can be found in the IR toolkit from TDR, available at: TDR_context.

Tips and tricks:

- **The end users are key to identify the problem and prioritize the research question as well as for making methodological choices.**

3.2 Identification of stakeholders and definition of IR roles and responsibilities

Once the research problem has been defined and the context is well understood, the main **IR stakeholders** must be identified and the core research team constituted. The composition of the research team is guided by the research question and setting, and will often need to be **multi-disciplinary** (e.g. epidemiology, anthropology/sociology, communication) reflecting all the expertise required to address the identified problem(s) and implement the study. Typically, this will mean collaboration with external consultants and/or research institutions and/or further local partners. Roles, responsibilities and deliverables must then be defined and detailed. An example of a memorandum of understanding (MoU) between an NGO and a research institution can be found in Appendix E.

Tips and tricks:

- **The project needs a team where each member has a specific role that is clearly defined and linked to specific outputs**

3.3 Conducting a literature review

A literature search is an important component of the design and planning process for any research study, including an IR study. A literature search can be a **scoping review** of published studies, project reports and other resources. Only rarely will time and resources allow conducting a full systematic literature review. Rather, the intention is to situate the research question in the current state of knowledge, to put the proposed research in a broader context, and to summarize the most up-to-date and relevant information.

A literature review helps avoid researching to find answers that have already been answered through other studies

Conducting a literature search consists of identifying, reviewing, categorizing and summarizing information on a topic. An effective literature review should present information from various sources grouped by topics, in a logical flow and providing all information about the references.

PubMed is a commonly used **search engine** to look for scientific literature on life sciences and biomedical topics (PubMed). It is free and offers intuitive search functions for general users and highly specialized search options for advanced reviews. Contacting relevant stakeholders such as program managers, health authorities and implementation partners will identify grey (unpublished) literature such as reports and previous studies in the area or in similar settings. This literature is critical to understanding the local context and history of the given project. Google scholar is one tool that provides access to literature beyond peer-reviewed scientific publications.

Reference management software such as Mendeley (open source) or EndNote facilitate the management of scientific articles, literature and reports. A reference manager ease tasks like storing, retrieving and referencing the source documents.

Several online courses focusing on literature search, PubMed and reference management software solutions are available. For example:

- Series of courses about literature search and PubMed by the Union: The Union_PubMed Short Course;
- Series of courses about reference management with Mendeley by the Union: The Union_Mendeley Short Course;
- One course about literature search and PubMed by SORT IT: SORT IT_PUBMED;
- One course about organizing and cite references by SORT IT: SORT IT_References;
- One course about reference management with Mendeley by SORT IT: SORT IT_Mendeley;

A literature review can be time-consuming. It is often advisable to **seek support and guidance from external resources** for conducting a literature search.

Tips and tricks:

- **Access the institutional memory of your own NGO and contact other NGOs that are likely to have faced similar issues in similar settings in the past.**
- **Use a reference management software**
- **Read with a purpose / be a critical reader**
- **Note insights and relevant findings as you come across them, and properly reference notes right from the start**
- **It is advisable to select literature where the research was developed in similar contexts to those of our concern**

3.4 Formulating the research question and research objectives

The literature review together with the internal project documentation provides the basis for framing the IR question. It is important to bear in mind that in IR, the "question is king" meaning that it is the question that determines the method used, rather than the method that determines the kinds of questions asked. An IR question should answer one or more of the following:

- Describe the contextual situation and **interventions** (already in place and potential ones): e.g. magnitude of the problem, distribution of the health needs, risk factors for specific problems, awareness for the problem, cost-effectiveness of available and potential/new intervention;
- Provide information to evaluate ongoing interventions or progress in order to adjust the intervention: e.g. better coverage of priority health needs or target groups, acceptability of services, quality of services, cost-effectiveness of the intervention, impact of the programme on health outcomes;
- Analyse possible causes for missed targets in order to find solutions: e.g. service availability, acceptability, affordability, delivery barriers.

An implementation research question should cover the characteristics listed in Table 3.

Table 3 Characteristics of an implementation research question [2]

Relevant	Should be of interest to the policy-makers, programme managers, health-care providers, and the communities.
Appropriate	Should be answerable, realistic (resource and time) with the IR approach and results shall be useable within the available health system.
Problem-driven	Should aim at reducing a gap in quality (e.g. of health care delivery) identified by the community, policy-maker and/or programme manager.
Action-oriented	Should identify underlying the causes of a problem in order to provide recommendations for practical solutions.
Specific	Should have a precise focus (issue under scrutiny and dimensions of the issue that must be addressed) and a well-defined target group (**target population** in a spatial and temporal context).
Innovative	Should complement previously studied and answered questions and should add important information and improve intervention implementation.
Generalizable	Should lead to findings applicable across various settings and contexts (even if intervention specific initially).

Once the research question has been formulated, the general and the specific objectives can be elaborated. While the general objective defines the main scope of the work, the specific objectives are a "breakdown of the general objective into **measurable action** statements"

(TDR). *Research objectives are not the same as programme objectives.* For example, a programme objective would be expanding a vaccination coverage (e.g. from x% to y%) whereas a research objective would be identifying the factors contributing to a low vaccination coverage and develop a strategy to overcome identified factors.

Research objectives are not programme objectives.

Examples of poorly formulated research question vs well formulated research question:

Example 1:

✘ Poorly formulated question: Is the intervention working?

✓ Well formulated question: What are the factors and agents for successful implementation of the intervention?

Example 2:

✘ Poorly formulated question: What is the context of the intervention?

✓ Well formulated question: What are the main factors influencing the implementation in a given context?

Tips and tricks:

- **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?**
- **It is better to have a limited number of objectives instead of studying a large number of different issues that will not result in a significant health impact.**
- **If several questions are identified, they could be grouped on separated research projects.**
- **Do not restrict the study to the descriptive analysis of implementation barriers but assess how and under which conditions implementation processes can be made more effective.**
- **Specific objectives: use action verbs (calculate, estimate, compare, etc.) and avoid vague non-action verbs (e.g. appreciate, understand, study, etc.)**
- **A conceptual framework could serve as a guide during the whole process (elaboration of the questionnaire, analysis, etc)**

3.5 Identifying suitable approaches and a research methodology

In order to design a study leading to valid results that can be trusted and are generalizable, the research methods must be planned systematically. **Each methodological choice must be justified by the objectives and context.** It is often advisable to mandate a research institution to support this process.

IR draws on a wide variety of qualitative, quantitative, and mixed-method research approaches, it makes little sense to talk in terms of a narrow set of 'implementation research-methods'. There are however a number of research approaches that are particularly useful to the implementation researcher [1].

1. Pragmatic trials (i.e. test new healthcare delivery strategies): described as explanatory or pragmatic, usually includes an extensive formative research phase that involves implementers, policy-makers and "end-users" in the design, including those who are affected by the outcome.

2. Effectiveness-implementation hybrid trials are designed to simultaneously assess both the effectiveness of an intervention and implementation strategy and the impact in the real-life settings.
3. Quality improvement studies are highly context-dependent, challenged by modifications (moving-target) and generally involves multi-component interventions. This is reflected in structured, cyclical processes e.g. plan-do-study-act (PDSA) cycle.
4. Participatory action research (PAR) describes a “bottom up” approach in which the targeted audience is actively involved in the research process. It uses mainly qualitative but increasingly quantitative and mixed method techniques.
5. Realist reviews (explanatory) inform the decision-makers on the potential of an intervention in different settings. Findings and analysis from i.e. literature reviews and audits generate evidence to guide changes in policy and programmes.
6. Mixed-method approach consists of qualitative and quantitative methods used in the same study and investigate causality and outcomes for a multitude of purposes.

Examples of research questions – approach – methodology match [1]:

Example 1:

Research question: What are the possible factors and agents responsible for good implementation of the intervention?

Approach: Mixed method

Methodology:

Qualitative methods: Grounded theory, ethnography, phenomenology, case-studies and narrative approaches; key informant interviews, focus groups, historical reviews

Quantitative methods: Network analysis, Cross-sectional surveys.

Example 2:

Research question: What describes the context in which implementation occurs? What describes the main factors influencing implementation in a given context?

Approach: Mixed method

Methodology:

Quantitative: Cross-sectional (descriptive) surveys, network analysis

Qualitative methods: Grounded theory, ethnography, phenomenology, case-studies and narrative approaches; key informant interviews, focus groups, historical reviews

3.6 Defining IR outcomes and variables

Once the research question has been formulated, it is time to start defining the kind of data needed to answer it and therefore the **variables** needed to assess the outcome (in agreement with the study objectives). Operational variables provide information on the implementation process while outcome variables measure the (intended) effect and lead to conclusions regarding the effect of a selected approach. Together, they enable project improvement and feedback. Commonly used outcome variables in IR are listed in table 4 [3, 8].

Table 4 Implementation research outcome variables [3]

Implementation outcome	Working definition	Related terms
Acceptability	The perception among stakeholders (for example, consumers, providers, managers, policy makers) that an intervention is agreeable	Factors related to acceptability (for example, comfort, relative advantage, credibility)
Adoption	The intention, initial decision, or action to try to employ a new intervention	Uptake, utilisation, intention to try
Appropriateness	The perceived fit or relevance of the intervention in a particular setting or for a particular target audience (for example, provider or consumer) or problem	Relevance, perceived fit, compatibility, perceived usefulness or suitability
Feasibility	The extent to which an intervention can be carried out in a particular setting or organisation	Practicality, actual fit, utility, trialability
Fidelity	The degree to which an intervention was implemented as it was designed in an original protocol, plan, or policy	Adherence, delivery as intended, integrity, quality of programme delivery, intensity or dosage of delivery
Implementation cost	The incremental cost of the implementation strategy (for example, how the services are delivered in a particular setting). The total cost of implementation would also include the cost of the intervention itself	Marginal cost, total cost
Coverage	The degree to which the population that is eligible to benefit from an intervention actually receives it.	Reach, access, service spread or effective coverage (focusing on those who need an intervention and its delivery at sufficient quality, thus combining coverage and fidelity), penetration (focusing on the degree to which an intervention is integrated in a service setting)
Sustainability	The extent to which an intervention is maintained or institutionalised in a given setting.	Maintenance, continuation, durability, institutionalisation, routinisation, integration, incorporation

Data can be broadly categorized into **quantitative** and **qualitative data**. This is reflected in the data collection methods which may focus exclusively on one of these categories or be mixed i.e. a combination of the two. The choice of the data collection method depends on the study question and the **variables** that are studied, e.g. qualitative data collection methods are preferable if feedback or knowledge-attitude-practice (KAP) questions are studied. Many IR studies use mixed methods to generate complementary data and thus arrive at a better understanding of a problem. Table 5 below summarizes the key characteristics of quantitative and qualitative methods.

Table 5 Quantitative and qualitative data characteristics (TDR IR Toolkit)

	Quantitative	Qualitative
Research question	What is happening?	How or why is it happening?
Purpose	Explanatory/causal	Exploratory, descriptive
Sample	Large **sample size** & mostly probability sampling (See subsection 3.6)	Small sample size and purposive sampling (See subsection 3.6)
Representativeness	Study population	Sample with rich information about the phenomenon of interest
Data collection methods	Questionnaires, **quantitative data**, systematic observations	**Key informant interview**s (KIIs), **focus group discussions** (FGDs), illustrative observations, narrative documents (e.g. diaries, historical documents), etc.
Tools and questions	Standardized tools with closed questions (determined prior to data collection) - Observation checklists - Questionnaires	Researcher asking open questions with support of a guide/checklist (flexible) - Interview and discussion guides - Observation checklist - Checklist and/or criteria to review document or media
Analysis	Numerical, statistical	Narrative, interpretive, establishing patterns and themes
Interpretation	Generalizable	Context specific

Additional resources about quantitative and qualitative methods are available in the TDR toolkit:

- Pros and cons for quantitative and qualitative methods: TDR_Methods_Pros&Cons
- Summary and examples of qualitative methods and tools: TDR_Qualitative_Tools
- Situations when various qualitative methods can be used: TDR_Qualitative_Situations
- Rationale and combination of mixed methods: TDR_Mixed Methods

Tips and tricks:

- **Use written specific definitions for all variables of interest, so that everyone involved in the research has the same understanding.**
- **Qualitative methods – good to combine several data collection methods**

3.7 Identification of the study population and sampling strategies

Possible targets for data collection include interviews with medical staff, **household surveys**, hospital records reviews, diagnostic test results, biomedical or anthropometric measurements, etc. The source of the data will determine the "study population". An IR "study population" often includes program implementers. Once the "study population" has been identified it is time to determine the size of the sample. In order to answer the research question with considerable certainty, how extensive does the study need to be?

Sample size and sampling strategy for quantitative studies

For quantitative studies, the **sample size** must be big enough to provide reliable estimates of the key **variables**. The calculation of the sample size depends on several factors including the frequency of the variable of interest, the **sampling strategy** and statistical power parameters. The formulas used for sample size calculations are different for the various study design. Many common sample size calculations can be completed using OpenEpi, an

open source online software for epidemiologic statistics (OpenEpi). However, asking advice and obtaining confirmation from a bio-statistician is highly advisable.

Quantitative studies require a sample that is representative of the study population. Therefore, probability sampling where everyone has the same probability to be selected to participate in the study is the standard (random sampling). Common probability strategies are the following: simple random sampling, systematic random sampling, stratified sampling, cluster sampling. More details are available here TDR_Probability_Sampling. In some situations, probability sampling is not feasible (e.g. due to time, cost, ethics) or desirable (e.g. survey among experts). Non-probability sampling strategies such as convenience sampling, successive sampling, purposive sampling, snowball sampling can be used. The consequences of the choice must always be considered when interpreting the results. More details are available here TDR_Non-probability Sampling.

Sample size and sampling strategy for qualitative studies

For qualitative studies, the **sample size** is less important than its composition. The aim is to reach enough individuals that can represent prevalent opinions, experiences and knowledge in the study population. Thus, the sample size is sometimes even not fixed at the beginning of the study but rather determined as data collection progresses, i.e. data collection is stopped as no further information not already represented in the collected evidence is identified in subsequent interviews (**data saturation**).

The sampling for **qualitative data** collection is different from that for quantitative studies as the aim of qualitative studies is not to have a representative sample but a sample providing rich and diverse information. Appropriate sampling strategies are: convenience, purposive, maximum variation, snowball and contrasting cases. More details are available here TDR_Qualitative_Sampling.

Tips and tricks:

- **Quantitative sample calculation: Account for non-response percentage when calculating the sample size.**
- **A rule of thumb for qualitative sampling: the more experienced/knowledgeable the respondents, the less people needed in a group discussion.**

3.8 Design your data collection tools

Once you identified your outcomes, the **variables** and the “study population”, you may develop the data collection tools. A basic decision (mainly for quantitative research) concerns the data collection format (paper based or electronic data collection).

The traditional paper based data collection tools consist of printed questionnaires and forms to collect data that is later entered in a database. Paper based data collection needs more time, is prone to data entry errors and is generally more expensive compared to the use of electronic data collection tools. The use of electronic platforms or electronic data collection tools usually allows better monitoring of data entry and therefore increases the quality of the data. When the setting provides reliable access to electricity (for charging tablets or smartphones) and to the internet at least once a week (to upload data), electronic data collection using smartphones or tablets is generally considered to be the better option compared to paper-based data collection. With electronic data capture, the data entry step is skipped, and logic controls (jumps, mandatory fields and possible ranges for answers) can be programmed. Remote supervision of data collection progress and interim analyses are also facilitated. Therefore, the risk of mistakes is reduced and time can be saved. The

combination of both is also possible especially when a paper trail is needed to validate electronic data collection. Several open source (free) and payable electronic data collection platforms are available, e.g. ODK, KoBo Toolbox, SurveyCTO and REDCap.

For **qualitative data**, particularly interviews, audio-recording is commonly used. In parallel, notes on key concepts and main topics may be taken. Transcription of the interviews is completed after the data is collected. Transcription is either verbatim or summarized (focusing on key messages). In addition, participatory tools are an innovative approach to guide focus groups discussions, which keep the respondents engaged and (depending on the tool) allow for real-time visualization of the discussion.

Attention: the systematic collection of personal data, including demographic and health data, is subject to stringent regulation in many countries. Local laws and regulations must always be considered when planning data collection, and relevant authorizations obtained! For details, see Chapter 3.11 Ethical considerations.

Once the data collection format has been chosen, the data collection tools can be designed keeping always in mind the outcomes and variables previously defined. Data collection often starts with a questionnaire. However, this is not always the case, as studies may be based on secondary analyses of existing data, measurements etc. Most quantitative variables will be obtained by asking a question. It is often preferable to specify answer options over asking open questions as free text answers require extensive analysis to later categorize them [9]. A useful overview of considerations for the preparation of a questionnaire, including practical guidance on how to formulate and present questions to the respondent is available in the document: Take good care of your data by Juul [10].

When developing a tool in a language different to the one that is going to be used in the data collection, special attention to the translation is needed. Questionnaires should be translated into the final language by staff not involved in the design of the original questionnaire, tested, and back-translated to ensure accuracy and adherence to the intended concepts.

Further useful information on how to develop and pilot a questionnaire can be found in the Handbook of Recommended Practices for Questionnaire Development and Testing in the European Statistical System [11].

Tips and tricks:

- **Try to use existing data collection tools as much as possible. You will save time and existing tools have already been tested, used and improved.**
- **Check translation quality by having someone else back translating**
- **Plan enough time to pilot your data in the local context (see also chapter 4.2)**
- **Pilot-test data collection tools in the field and adapt them if necessary**
- **Only collect data that you plan to analyze**
- **Use data edit checks when programming data collection tools**

3.9 Establishing data management and data analysis approaches

A data management and analysis plan is a standard component of a research methodology and must be prepared before starting data collection. Ideally, it already specifies the statistical analyses to be carried out for **quantitative data** or a thematic framework and codes for qualitative data. Designating a data manager for electronic data collection guarantees the collection of uniform data and safe storing.

Data management includes the following steps:

- Ensuring the collection of accurate data: this requires a strategy to check data for errors (completeness and consistency) during data collection

- Entering the data into a database (for paper-based data collection only): data entry requires a strategy to reduce and identify errors during when entering the data (e.g. double data entry)
- Securing data upload/transfer for data collected electronically
- Preparing data in a format that will allow analysis: coding and cleaning the data
  - Storing the data: location and duration of safe storage need to be determined for electronic and paper-based data. Confidentiality of the participants' needs to be ensured (e.g. locked cabinets, password-protected databases, anonymized questionnaires, etc.) and legal requirements observed (e.g. minimum time over which raw data need to be retained).
- Sharing the data: agreements for data ownership, sharing and publication/dissemination need to be in place. They must follow the regulation of your institution and/or country where data collection takes place.

Attention: some countries require raw/original data to remain in the country where data was collected and even electronic export of raw data without explicit permission is forbidden!

More details about data management are available in the TDR toolkit: TDR Data Management.

The data analysis methods depend on the study objectives and the types of **variables/indicator**s that have been collected. The data analysis plan needs to specify the outcomes of interest, a description of the variables to be collected, any variables that will be created by combining collected variables, the statistical tests to be conducted and the software to be used.

Analysis of quantitative data (descriptive and statistical tests), qualitative data and mixed method data are detailed here: TDR Analysis.

Tips and tricks:

- **Get familiar with the data ownership regulations in the study country**
- **Plan data storage location and duration (digital and physical) well in advance**
- **Consider the local conditions regarding internet connectivity (availability, bandwidth) if electronic data collection tools are to be used**

3.10 Ensuring the quality of the study

In order to meet scientific, ethical and regulatory standards, it is **mandatory** for all data collection activities to be quality assured. This is a shared responsibility among everyone involved in a research project. A quality management plan describes all the measures that are taken to monitor and ensure the quality and rigor of the work at all the stages of the study. Quality control and assurance also concerns the rights of the participants. Their anonymity and privacy must be protected, their interests duly considered (including not wasting their time) and any harm or disadvantage avoided. Some strategies that can be used to manage quality are (TDR IR toolkit):

- **Protocol** review and approval (A study protocol outline is available as Appendix F)
- Defining standard operating procedures (SOPs) and training
- Piloting and validating research instruments
- Quality control and monitoring during data collection and aggregation, data quality audits

- Evaluation of services provided and of the performance of service providers (e.g. access to servers and network in study sites)
- Review of reports

More details about quality management strategies are available in the TDR toolkit: TDR Quality Management.

Tips and tricks:

- **Plan for and build in quality assurance steps into all critical activities of the study**
- **When you are working with qualitative data and using verbatim transcripts, start early on with the transcription process to be able to check the questions asked (incl. probes and prompts) and the quality of the transcript.**

3.11 Ethical considerations

Any study that involves human subjects must protect participants' rights, dignity and safety before, during and after the study. Universal ethical values and international scientific standards need to be adhered to during the planning, implementation and evaluation phase of the research study. Key ethical considerations are:

- No harm: balance risks for participants against benefits
- Autonomy: voluntary participation and freedom to withdraw at any time without an explanation, negative consequences and/or prejudice
- Privacy: confidentiality and anonymity ensured at any time

Generally, ethical review is required from several committees e.g. from an institutional committee covering the lead institution and the competent national or regional committee where the research is carried out. In case of international projects, the competent agency is the ethics committee responsible for the study population but in case the responsibility for the study is with a principal investigator ("sponsor") in another country, an exemption (declaration that the proposed study complies with basic requirements but the competent agency is the one covering the study population) may be sought. Procedures may be particularly lengthy in the case of collaborative or multi-country projects where often approvals depend on other agencies, and all approvals are needed in order to start field work. Specific requirements (information and documentation) of the ethics committees are usually available on their website. It is highly advisable to submit an application through an institution with a proven track record in obtaining ethical approvals from the particular agency. In case of any changes in the **protocol** or tools, the committee needs to be informed and an additional approval or waiver must be obtained before the change can take effect. More information on seeking ethical approval is available in the TDR: TDR Ethical Issues

Informed consent to participate in the study needs to be obtained before any data collection. Informed consents consist of two parts, (i) an explanation about the study and how the participant will be involved, and (ii) a certificate of consent where the participant expresses agreement. Both sections should be clearly understandable for the participants. Therefore, it must be in a language fluently understood and spoken by the prospective participant, medical terminology should be avoided and the length must be acceptable. An option to ask all pertinent questions must be foreseen, and a contact to the study coordinator provided so that the responsible person can be reached at any time. Information may be provided in writing and explained orally, including the right of the participant to withdraw at any time. In illiterate societies, the oral format is most relevant, with the written text merely serving as back-up and to leave a paper trail for the participant. Consent is individual and

can be written, verbal or in another appropriate format. In case of minors, the parents or legal guardians must give their consent and children old enough to understand give their assent. Special procedures e.g. signature by an impartial witness, need to be put in place for persons with diminished autonomy, those speaking a different language or the illiterate.

Clear points of contact and referral pathways must be anticipated in case of physical or psychological need regardless of whether or not the study caused the need. Also, any costs associated with participation in the study must be covered by the project. However, compensation for participation in the study is discouraged to avoid **bias**.

A list of codes of ethics to be considered is available in the TDR toolkit: TDR Research Ethics

A list of items that should be in an informed consent is available in the TDR toolkit: TDR Informed Consent

Templates of informed consent forms are available on WHO website: WHO Templates for informed consent forms

Tips and tricks:

- **Ethics approval can take several months to receive, so apply as soon as possible.**
- **Informed consent should be taken at all levels. If there is a household interview and then individual interviews with family members, the head of household needs to give a household consent and then each family member need to give an individual consent.**
- **When possible, have one single page consent forms, with all information needed on the upper part (incl. Contact details for question) and the part to sign on the bottom that can be torn apart and kept by the research team.**
- **Adapt the information and informed consent forms to the local context and make sure to use language that is adapted to the target population.**
- **Consider using alternative information tools during the consenting process for hard to understand concepts (e.g. photos, pictograms, videos, etc.), such materials also need ethics approval**

3.12 Identifying needed and available resources

IR projects require adequate human, logistic, technical and financial resources that need to be secured prior to committing to the study and available in line with the needs of the project progress. While expert input is usually most critical in the planning, data analysis and dissemination phases, logistic and financial resource needs are biggest in the training and data collection phases. When assessing the resources that are needed, it is important to take into account what is **already available** in the programme/project.

3.12.1 Human resources

Human resources must be sufficient in terms of numbers and expertise. Some would be available from the partner research institute (i.e. statisticians or epidemiologists) and some from the NGO (i.e. logistics officer, data collectors). Typical positions include:

- Study coordinator: an expert with experience in managing projects of comparable size and complexity, ideally familiar with the research topic and study setting
- Experts/backstopping: resource persons in research, statistics etc. that are available to provide targeted technical input
- Quality control: to assure impartial data collection, an external quality control manager shall be included
- Data manager: specially needed when the data required extensive maintenance (data cleaning, archiving, etc.)

- Data collectors: their number depends on the data collection methodology (**sample size**, **sampling strategy**, data collection strategy). Data collectors should always work in pairs or larger groups
- Supervisor(s): could be hired as such or could be selected among data collectors at the end of the training based on knowledge, experience and motivation showed
- Data entry clerk/transcribers: in case of paper-based data collection or the need to transcribe audio-records
- Translators when interviews and focus group discussions have been done in local languages
- Logistics manager: an expert familiar with the logistics involved in data collection, including vehicle management, security, communication etc.
- Other roles might be needed depending on the study e.g. nurses, laboratory technicians
- A driver are usually essential for conducting a study, local drivers are familiar with the area and can easily navigate local roads

Tips and tricks:

- **Teambuilding activities before data collection could strengthen the team bonds and make for friendly environment during data collection.**
- **If possible, avoid staff turnover as this can be very disruptive to study conduct.**

3.12.2 Hardware and software

Hardware and software are going to be needed to plan and conduct the study, and to analyse and disseminate the results. Needs will vary depending on the research question, the methodology and data collection tools. A table of hardware and software commonly used for planning and conducting IR studies is available below (Table 6).

Table 6 Hardware and Software needed for quantitative and qualitative data collection along the IR study phases.

	Quantitative	Qualitative
Hardware		
Planning	Laptop, internet access and adequate server space for secured data storage	Laptop and internet access
Data collection	Tablets and/or smart phones, GPS receiver, printer, power banks, access to a photocopy machine, paper data collection forms, consent forms,	Audio recorder, tablets and/or smartphones, power banks camera, printer, access to a photocopy machine, paper data collection forms, consent forms
Data analysis	Laptop/ Desktop PC	Laptop/ Desktop PC
Data dissemination	Printer, projector	Printer, projector
Software		
Data planning	Word processor (Microsoft Word, Open Word, Google Docs), electronic spread sheet (Microsoft Excell), sample size calculator (Open Epi), email account	Word processor (Microsoft Word, Open Word, Google Docs), electronic spread sheet (Microsoft Excell), email account
Data collection	Electronic data collection platform (ODK, ODK briefcase)	Electronic data collection platform (ODK, ODK briefcase)
Data analysis	Statistical analysis software (STATA, R), geographic information system software (QGIS, ArcGIS),	Electronic spread sheet (Microsoft excell), qualitative analysis software (Nvivo, Atlas ti, MAXQDA, opencode)
Data dissemination	Presentation software (Microsoft power point), word processor (Microsoft word)	Presentation software (Microsoft power point), word processor (Microsoft word)

Tips and tricks:

- **Open source software is often available.**
- **Data collection technological requirements are often low therefore a basic and economic tablet or smartphone can do the job.**

3.12.3 Consumables and transportation needs

For each activity, the needs in terms of supplies and transportation must be established. It is important to plan ahead based on what is available on the local market. Unavailable goods need to be shipped from another country. This often applies for diagnostic tests, drugs and more sophisticated instruments. Electronic equipment such as tablets may be difficult to source locally if certain specifications need to be met. For shipments, transit times must anticipate customs and importation procedures that might be lengthy. Consider using a professional freight forwarding company also taking care of customs clearance. The following items are usually required:

- Stationary
- Photocopies
- Communication means
- Transportation means
- Other study-specific items such as drugs, diagnostics, medical devices (thermometers, rapid diagnostic tests, etc.), laboratory supplies
- Compensation for the participants when specified by the **protocol** (e.g. pens, soap, refreshments, biscuits)

Tips and tricks:

- **Prepare a plastic box with the most important stationary supply (scissors, tape, markers, sticky notes, spare paper, folders, etc.).**
- **Make sure to obtain any import / export licenses (particularly for biological samples) prior to study start**

3.12.4 Budget

A detailed budget must be established based on the study **protocol**. It is important to take into account the costs per unit, number of units/repeats of activities, per diems, person-time of staff, insurance etc. The main items/budget lines typically are:

- Personnel
- Travel (international and local)
- Meetings
- Transport (cars, gasoline)
- Data collection equipment
- Laboratory tests
- Communication (calls, data)
- Office costs
- Quality assurance
- Institutional overheads

Tips and tricks:

- **About 10% of a project budget should be reserved for unexpected events throughout the course of the study.**

3.13 Timeline

As any project, an IR study needs to be planned with a defined beginning and end, and a realistic schedule of activities including measurable milestones and deliverables. The duration of each activity should be realistic and it is important to take into account periods for **protocol** review and approval as well as time for staff recruitment and dissemination. The timeline should include (TDR toolkit):

- Description and sequence of the tasks to be performed
- Schedule, deadlines and deliverables within tasks
- People assigned to the tasks
- Number of person-days required to complete each tasks

Ideally, a timeline should be displayed in a visual format such as a graphic. The recommended format for time planning is a Gantt chart. Gannt Project is an open access software tool for producing Gantt charts.

Additionally, the availability of the study population needs to be taken into consideration well in advance when planning. It is crucial to avoid starting a **household survey** during a harvesting period etc. In general epidemiological and weather conditions also need to be taken into consideration.

Examples of timeline formats are available in the TDR toolkit: TDR Timeline Example

Tips and tricks:

- **Plan sufficient time for ethical review and administrative permissions**
- **In some countries, provisional approvals are available which allow conducting pilot testing of tools and procedures, training etc.**
- **Consider peer-review and revision periods (e.g. 4 weeks) when planning dissemination**

4 Conducting the IR study

4.1 Assembling the data collection team

IR studies often require a data collection team in addition to the core research team. When relying on paper-based data collection, data entry clerks will also be needed. Similarly, translation and transcription of **qualitative data** often is most efficiently done by specialized staff.

Data collectors are key to the systematic data collection. Usually they need to have a specific background (e.g. nursing), which depends on the kind of data that needs to be collected and the environment in which it is collected. Often, multidisciplinary IR data collection teams are most suitable to collect all necessary data. Consider the types of data that needs to be collected and make sure you have the right mix in your team to properly collect all the data. For instance, if you are using mixed methods that require collecting blood samples and qualitative data via FGDs make sure you have a nurse to collect the blood sample and an interviewer trained in social sciences to conduct the FGDs. When assembling your team also consider the sensitivity of the data and if you need a person with a specific profile to better collect this data. For instance, if your study requires extensive discussions on sensitive topics with pregnant women a female interviewer is strongly advisable. In some cases individuals from the same ethnic or religious group may be necessary to successfully access certain sub-populations, especially if they are minorities or marginalized. For data entry, make sure your team understands the research context and establish a communication channel to keep the team informed. Data collectors can often be recruited from universities (medical school, public health school etc.) or health research institutions. Ideally, at least some of the data collection team has previous experience with data collection.

Establishing the team structure early enough is also advised. Make sure all team members are aware of their role within the team and appoint a team leader with clearly defined duties and rights for each data collection team so that operational decisions can be taken on the spot.

Tips and tricks:

- **Clearly define required skills in the job advert**
- **Try to engage team members with previous experience in data collection, or a good mix of experienced candidate and beginners so they can learn from each other**
- **Follow standard interview procedures with personal interviews to test language skills and the candidates interview performance**
- **Engage at least 10% more candidates for the training than effectively needed during data collection to avoid HR shortages once the activities have started**
- **Cultural and gender sensitivity of data collection team (e.g. FGDs with women done by female researchers; seems obvious – but also making sure field assistants speak different local dialects**
- **Depending on the cultural context and the research question it is advised to employ local staff or people from the same cultural background speaking the local language**

4.2 Training the data collection team

Once your data collection team has been assembled it is time to train them. This is a crucial step that needs to be carefully planned and implemented. If overlooked, the quality of the data and hence the findings of the study might be jeopardized. Plan enough time to properly train your team. Consider their background and research experience for planning the

training. The first step is to make sure the team understands the research question and the rationale of the study. If the team is fully aware of the importance of their work, data collection is more likely to be successful and the team is more likely to stay motivated.

Then, introduce the study methods and carefully explain to them the content of the data collection tools, making sure all questions are clearly formulated and understood, including the motivation to ask each question. This is best achieved with a participative training style. Once they know the content of the data collection tool, the technicalities of the tool must be explained. Instruct them on how to follow it and fill the forms (paper based or electronic). A special focus should be on good interview techniques such as [12]:

- Reading the questions exactly as worded.
- If the respondent's answer is incomplete or inadequate, probe for clarification or elaboration in a non-directive way.
- Record the answers without interviewer's discretion.
- Do not provide any positive or negative feedback regarding the specific content of respondent's answers

When conducting electronic data collection introduce the collectors to the hardware. Make sure to cover all aspects of the maintenance, use and storage of the tablet or phone. Limitation of the use of the tablets and phones exclusively to data collection extends the battery life of your data collection device. Setting limitations to the use of the device also protects it from viruses and reduces the risk of loss or theft. Make sure the training also includes the upload of the data to a computer or server after it has been collected.

When conducting qualitative research, the interviewers will need extensive training in interview and discussion moderation techniques to ensure the focus of the conversation is on answering the research question. Introduce them to the data collection tools (e.g. Interview guide) and make sure they are well aware of the follow-up questions that need to be asked. Especially if you have more than one interviewer make sure there is uniformity in the data collection approach. Familiarity with technical devices (e.g. audio recorder) is also necessary.

Awareness for ethical considerations are vital in the training sessions. Find out the gaps in obtaining informed consent and train the team how to properly obtain it.

Training must include all the tools that are needed for data collection, including all forms, all devices and all the steps. If your study requires a variety of electronic devices (e.g. GPS), a specific kind of procedure (e.g. collecting a blood spot on filter paper) or other materials (e.g. visual signs or cues) make sure you introduce them to data collectors and practice using each, first separately and then in their intended context. Full data collection simulations among the team members could trouble shoot data collection problems before piloting the study.

Tips and tricks:

- **Provide manuals for each individual function in the team (interviewers, supervisors, etc.)**
- **Simulations of the field conditions are useful to introduce the team to the full data collection process**
- **Different parts of the training can be delivered by different members of your core research team**

4.3 Piloting your data collection and analysis tools

There are two main reasons to pilot a study. Firstly, you validate your tools (e.g. questionnaires or interview guides) and secondly you assess the effectiveness of the training. The IR study process is not linear but rather iterative. If you find an important issue

during the piloting stage, go back to revising the tool, reinforce training and pilot again. Smaller issues that can be easily fixed do not need repeated piloting. However, everyone in the team must be informed of any adjustment.

In broad terms; piloting means using the data collection tools on a group of people similar to the "study population" as a first level of quality control. Piloting tackles issues such as feasibility and acceptability of the intended **protocol**, internal consistency of data collection methods and interpretability of data. Moreover, if a questionnaire is translated into another language, a back-translation may help to ensure that the questions have been translated properly and capture the right meaning and nuances of the original questionnaire [9]. The use of **cognitive interviews** to validate and improve the data collection tools is also advisable [13]. Piloting is ideal under study conditions which means by the data collection team, in the study area and population, and simulating the whole procedure. Finalize your data collection tools after piloting them.

And finally, it helps to evaluate the candidates and to select those that will be part of the final team.

Attention: data collected in the frame of a pilot shall not be included in the final study database, and individuals taking part during the pilot shall not be approached for the study.

Tips and tricks:

- **The pilot test must take place in a community outside the study area**
- **Inform and obtain agreement with the village authorities several days before the pilot test**
- **Allow for every candidate to perform at least two interviews, and observe as many as possible**
- **Plan a feedback session for the next morning to exchange about experiences and to finalize the data collection tools**
- **Select the candidates that performed best during the training and pre-test for your final data collection team**
- **Dedicate sufficient time to pilot-test and adapt data collection tools before launching the study and to make sure that the tools don't have to be repeatedly modified making merging of the datasets rather cumbersome**

4.4 Draft your micro plan

Before deploying the team, make sure there is a detailed but flexible plan for them to follow while in the field. This plan is best managed by the field work coordinator who oversees the timeline and progress of the data collection, and is the person in contact with the authorities. This plan will help them stay on track and will be very useful to arrange accommodations, transportation and security. Some things to consider in your plan:

1. Number of people in the team
2. Expected length of the data collection
3. Number of sites
4. Transportation to each study site
5. Transportation within each study site
6. Accommodation
7. Daily activities (Specifying the expected outcome of the day, e.g. number of interviews)
8. Main milestones

4.5 Inform the relevant stakeholders

Before your team starts collecting the data make sure all relevant stakeholders are informed well in advance of the arrival of the study team in the area. When appropriate contact the

local authorities (e.g. health district authorities) and inform them about the study in detail. Stakeholders may include community leaders, religious leaders, school principals, hospital directors etc. When dealing with communities make sure to have a contact point that can introduce you to the community leaders. Have a formal meeting with the leaders and get their consent before approaching other stakeholders and ultimately informing the rest of the community. Be clear on what results are to be expected from the study since the first meeting. Take your time to explain the study in lay terms and take time to answer all questions. Advise them of the data collection team arrival dates. You can also ask them at this time to identify suitable local guides and, if necessary, translators. They can also be helpful in arranging accommodations and meals for the team. Once you have the consent of the village leaders, it may be necessary to hold a general meeting with the whole community even if your study population is only a sub-group within the community.

Announce the arrival of the data collection team beforehand and agree on a specific day and time. Choose a time for data collection that suits your informants and that interferes the least with their professional duties and private responsibilities.

Tips and tricks:

- **IR is usually carried out in the frame of an implementation project where local authorities and stakeholders are key partners. Therefore, they should be involved since project design**
- **Make sure you inform stakeholders before study start data collection and obtain their buy-in (when designing the study) and keep them informed (e.g. feedback of study results)**
- **Depending on where you conduct your study be mindful of any safety and security risks that the data collection team may be exposed to and take steps to mitigate them**

4.6 Collect your data

Data collection needs to be systematic and follow the procedures as described in the **protocol**. In addition, data collection often needs to be repeated over time or in different settings. Therefore a standard operation procedure (SOP) or field guide may be necessary. SOPs can be defined as "detailed, written instructions to achieve uniformity of the performance of a specific function". Some information to be included in an SOP for data collection can cover the following (but if needed the SOP can be extended) [9]:

1. Participant selection
2. Instructions on how to fill in the questionnaire
3. Overview of quality assurance steps
4. Possible answers to participants' doubts or "frequently asked questions".

Tips and tricks:

- **Plan enough meetings with data collection staff to feedback about data quality. Daily meetings are advisable in the beginning.**
- **Double data entry of the paper forms is a strategy to reduce errors during data entry**
- **All data collectors must clearly identify themselves before starting to collect data.**
- **Ensure that all data collectors can also be clearly identified as part of the study, e.g. with badges, if it is necessary**
- **Back up your data on a regular basis from the very beginning!**

4.7 Analyse your data

Data accumulated during a study will need to be summarized and presented in a structured format. Descriptive tools, such as tabulations, diagrams and figures can be used [14].

After summarizing and describing the data the next step is to analyse it. Through the analysis a clear message can be formulated, supported by quantitative (e.g. statistics) and/or qualitative (e.g. **framework method**) analysis [14].

Most IR studies use mixed methods in which qualitative and quantitative techniques are combined. Under the right circumstances, a mixed-methods approach can provide a more comprehensive understanding of the problem than either approach alone. To ensure that the analysis is undertaken in a comprehensive and targeted manner, an analysis plan should be created first. The analysis plan contains a description of the research question and the various steps that will be carried out in the process of answering it based on the collected data [2].

4.7.1 Analysis of quantitative data

Statistics help us in making inferences, and are therefore called inferential statistics. An inference is a generalization made about the “study population” from a subset of individuals (sample). It should be emphasized that if the study sample is not representative of the “study population” the inference we make from the results will be misleading. The statistical analysis cannot correct mistakes in the study design [14].

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

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

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

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

4.7.2 Analysis of qualitative data

There are many traditions of qualitative research and it has been argued that “there cannot and should not be a uniform approach to qualitative methods [15]. Similarly, there are few “agreed-on” canons for qualitative data analysis, in the sense of shared ground rules for drawing conclusions and verifying sturdiness [16]. Many qualitative studies adopt an iterative strategy – collect some data, construct initial concepts and hypotheses, test against new data, revise concepts and hypotheses, etc. This approach implies that data collection and analysis are embedded in a single process and undertaken by the same individuals (TDR IR Toolkit).

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

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

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

The three core requirements of qualitative analysis are:

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

Further details and information on data analysis for qualitative and quantitative data can be found at TDR Analysis.

5 Disseminating the results

Relevant individuals and institutions need to be aware of the IR study findings to realize the potential benefits from the effort. It is uneconomic and unethical to conduct research without at least trying to share findings with relevant parties. Being aware that sharing with relevant parties should not reveal data or references that could compromise participants' anonymity.

5.1 Communication and dissemination plan

The communication and **dissemination plan** is an integral part of the study **protocol**. The basis for the plan is a careful evaluation of the project objectives, expected outcomes and target audiences. While structured feedback to the project or program in the frame of which the IR study takes place will always feature in such a plan, additional stakeholders may also need to be considered, e.g. the Ministry of Health, local government offices, and the study community. If findings are of interest or relevant beyond the project/program, dissemination in appropriate format should be planned, with the choice depending on the nature of the study and potentially including popular media, (scientific) conferences and the peer-reviewed scientific literature. The following formats are commonly used: reports, policy briefs, posters, videos, press releases, conference abstracts, oral presentations, and/or manuscripts for the scientific literature. Standard quality guidelines for reporting are available in the following source http://www.squire-statement.org/index.cfm?fuseaction=page.viewpage&pageid=471. Examples of a video, a short study report are available in the following links:

- Video: https://vimeo.com/328443343
- Short study report: https://www.childhealthtaskforce.org/resources/report/2018/ieda-trial-findings-report-lshtm-2018

If a study established standard procedures, the production of a toolkit, (video) protocol, guideline, training instructions or standard operating procedures (SOP) should be considered. Dissemination of such instructions must be carefully planned so that they are widely and sustainably available to the target audience.

An important component of any dissemination plan is a description of the data ownership, assignment of rights to publications, internal decision and review processes related to publication products, and the identification of first and last authors as well as responsibility for the drafting of the anticipated dissemination products. For larger studies, a publication working group may be appointed, working according to written standard operating procedures. Ideally, the types and tentative titles of the key dissemination products are already defined at the protocol stage. This list may be periodically revisited and updated as the study progresses.

Tips and tricks:

- **Ensure to disseminate to key decision-makers.**
- **Develop different materials for different target audience; e.g. posters or leaflets to disseminate findings at community level, policy briefs for policy makers.**
- **Films and other promotion materials are also useful.**
- **Involve the local team to identify the most appropriate messages**
- **Adapt the language to avoid technical terminology when communicating with non-experts.**
- **Consider translation to local languages for communications targeted to local communities and authorities**

5.2 Uptake and implementation of IR findings

It is widely acknowledged that strong evidence of beneficial impacts is no guarantee for uptake and sustainable implementation [17]. In certain settings, the requirement for evidence-based procedures and policies will ensure eventual consideration of results if they are publicly accessible in standard format (usually as a scientific article in a peer-reviewed scientific journal). However, in many low-resource settings no such requirements exist, and uptake and implementation is only ensured if relevant stakeholders become aware, are convinced and have at their disposal the means to implement the innovation. Within organizations this information is usually no problem but impact on international or national policy is more difficult to achieve. However, this is the best way to ensure uptake and sustainable implementation of the **intervention**. This means that working with policy makers at national and international level is critical. Often, national research institutions are better placed than NGOs for such discussions.

The principles of ethical human subject research also require that results are being published irrespective of their outcomes. This means that study findings that are inconclusive or negative / unfavorable (from the point of view of the investigator) must be disseminated as the findings may still be relevant, be it to inform future research, be it to critically review the value of an intervention. Table 7 summarizes key strategies to maximize uptake and impact of research findings, both in terms of health outcomes and practice.

Table 7. Strategies for uptake of research findings with a view to improve health (top) and translation into practice (bottom; source: [17]).

Determine the user audience(s) for the research, define a user-oriented research agenda and appreciate the environment in which the users operate;
Utilize objective methods of data collection and analysis and present data with sufficient transparency to establish trustworthiness;
Package findings in a format appropriate for the audience and utilizing principles from graphic design, communication science, marketing, and the psychology of information processing;
Engage stakeholders that have interest in an outcome and give voice to those who will be most directly affected before the research begins;
Use effective communication science during interactions with decision makers, stakeholders and the public and reach the target audience(s) with the right message through the appropriate media.
Anticipate and address likely barriers to dissemination;
Appreciate and integrate multiple types of evidence;

Adopt research designs, such as practical clinical and behavioral trials across settings, that address concerns of clinicians and policymakers;
Conduct broader evaluations that include multiple outcomes, address generalizability, and report on contextual factors;
Do not expect a program to work perfectly initially, but plan for adaptation and refinement to fit local conditions and emerging issues that affect what constitutes effective **interventions**.
Engage stakeholders that have decision-making power

Appendix A: Definitions

Bias	Bias is defined as any tendency which prevents unprejudiced consideration of a question. In research, bias occurs when “systematic error is introduced into sampling or testing by selecting or encouraging one outcome or answer over others
Code	In qualitative research, coding is “how you define what the data you are analysing are about” (Gibbs, 2007). Coding is a process of identifying a passage in the text or other data items (photograph, image), searching and identifying concepts and finding relations between them.
Cognitive interview	Cognitive interviewing could be define as the administration of draft survey questions while collecting additional verbal information about the survey responses, which is used to evaluate the quality of the response or to help determine whether the question is generating the information that its author intends. (See Beatty and Willis, 2007)
Conceptual framework	A conceptual framework is an analytical tool with several variations and contexts. It can be applied in different categories of work where an overall picture is needed. It is used to make conceptual distinctions and organize ideas. Strong conceptual frameworks capture something real and do this in a way that is easy to remember and apply.
Data saturation	Saturation is used in qualitative research as a criterion for discontinuing data collection and/or analysis when no additional data are being found.
Dissemination plan	A dissemination plan is a plan for disseminating research findings or products to those who will use the information in practice. It is what will get the message out whether it is results of research or a successful intervention.
Effectiveness	Effectiveness can be defined as the performance of an intervention under 'real-world' conditions
Efficacy	Efficacy can be defined as the performance of an intervention under ideal and controlled circumstances
Exclusion criteria	Exclusion criteria are a set of predefined definitions that is used to identify subjects who will not be included or who will have to withdraw from a research study after being included. Together with inclusion criteria, exclusion criteria make up the eligibility criteria that rule in or out the participants in a research study. Similar to inclusion criteria, exclusion criteria are guided by the scientific objective of the study and have important implications for the scientific rigor of a study as well as for assurance of ethical principles.
Focus group discussion	A focus group discussion involves gathering people from similar. backgrounds or experiences together to discuss a specific topic of. interest. It is a form of qualitative research where questions are. asked about their perceptions attitudes, beliefs, opinion or ideas.
Framework method	The framework method is a frequently used tool in health research to manage and analyse qualitative data. Particularly, it is suitable for team work during the analysis. (See Gale et al., 2013)
Household survey	A 'Household Survey' is the process of collecting and analysing data to help understand the general situation and specific characteristics of individual household or all households in the population.

Implementation Strategy	Implementation strategies are the strategies needed to deliver or implement interventions. Implementation strategies may also be designed to improve the sociocultural aspects of implementation, for example by improving the acceptability or adoption of the intervention, or may affect things like the quality and cost of the services provided. Implementation research may focus on the implementation strategy itself, or incorporate consideration of the implementation strategy into a broader study of the health intervention
Inclusion criteria	Inclusion criteria are a set of predefined characteristics used to identify subjects who will be included in a research study. Inclusion criteria, along with exclusion criteria, make up the selection or eligibility criteria used to rule in or out the target population for a research study. Inclusion criteria should respond to the scientific objective of the study and are critical to accomplish it.
Indicator	An indicator is something that points to, measures or otherwise provides a summary overview of a specific concept. An indicator is an observable and measurable entity that serves to define a concept in a practical way. For example, an intelligence test is used as an indication of intelligence.
Informed consent	Permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits.
Intervention	An intervention is an activity or set of activities designed to produce behavior changes or improve health status among individuals or an entire population. Interventions may include educational programs, new or stronger policies, improvements in the environment, or a health promotion campaign.
Key informant interview	Key informant interviews are qualitative in-depth interviews with people who know what is going on in the community. The purpose of key informant interviews is to collect information from a wide range of people—including community leaders, professionals, or residents—who have first hand knowledge about the community.
Operational research:	The term “Implementation research” is sometimes used interchangeably with the term “operational research” (OR). In other instances; OR is defined more narrowly as pertaining only to issues under the control of program managers while IR deals with the uptake and implementation of interventions.
Proposal	In a proposal, all sections (background, methods, work plan and impact) are sufficiently detailed to allow any person to understand the planned study. Proposals are mainly used to get endorsement by stakeholders and apply for grants/funding or justify their release.
Protocol	A protocols is a detailed project plan with a focus on procedures and tools. The protocol needs to be sufficiently precise that anyone could repeat the study. The protocols thus is a reference when managing and monitoring the study and to answer questions that come up in the frame of the implementation. A protocol also is the core document to seek ethical approval
Qualitative data	Qualitative data is defined as the data that approximates and characterizes. Qualitative data can be observed and recorded. This data type is non-numerical in nature. This type of data is collected through methods of observations, one-to-one interview, conducting focus groups and similar methods. Qualitative data in statistics is also known as categorical data. Data that can be arranged categorically based on the attributes and properties of a thing or a phenomenon
Quantitative data	Quantitative data is data expressing a certain quantity, amount or range. Usually, there are measurement units associated with the data. It makes sense to set boundary limits to such data, and it is also meaningful to apply arithmetic operations and statistical methods to the data.

Sample size Sample size is a term used in research for defining the number of subjects included in a sample. By sample, we understand a group of subjects that is selected from the general population and is considered a representative of the true population for that specific study.

Sampling strategy Sampling is simply stated as selecting a portion of the population, in your research area, which will be a representation of the whole population. The strategy is the plan you set forth to be sure that the sample you use in your research study represents the population from which you drew your sample.

Scoping review Scoping reviews are "preliminary assessment of potential size and scope of available research literature. Aims to identify nature and extent of research evidence

Search engine A program that searches for and identifies items in a database that correspond to keywords or characters specified by the user.

Systematic review A systematic review summarises the results of available carefully designed healthcare studies (controlled trials) and provides a high level of evidence on the effectiveness of healthcare interventions. Judgments may be made about the evidence and inform recommendations for healthcare.

Target population The target population for a study is the entire set of units for which the survey data are to be used to make inferences. Thus, the target population defines those units for which the findings of the survey are meant to generalize..

Variable A variable is defined as anything that has a quantity or quality that varies. The dependent variable is the variable a researcher is interested in. An independent variable is a variable believed to affect the dependent variable.

Appendix B: Literature and resources

Literature

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18. Macías, Y.F. and P. Glasauer, *Guidelines for assessing nutrition-related knowledge, attitudes and practices*. 2014: Food and Agriculture Organization of the United Nations.

Resources

- **TDR Implementation Research Toolkit** (TDR IR Toolkit) aims at helping to conduct an implementation research project through a standard process in order to get high quality results that are reliable. It is an online toolkit including seven modules (introduction, understanding IR, proposal development, research methods and data management, IR planning and conducting IR, communications and advocacy, integrating IR into health system). The toolkit is not linear and allows jumping in to any specific module. It is extremely user-friendly. IR is well explained theoretically but also well illustrated with practical examples. It consists of text, key messages, case studies, illustrative figures and tables and hyperlinks to other resources.
  Available at: http://adphealth.org/irtoolkit/
-
- **TDR Massive Open Online Course (MOOC) on implementation research**
  https://www.who.int/tdr/capacity/strengthening/mooc/en/

- **Data collection resources:**
  https://opendatakit.org/
  https://www.kobotoolbox.org/
  https://www.surveycto.com/
  https://www.project-redcap.org/

- **Informed consent templates**
  https://www.who.int/ethics/review-committee/informed_consent/en/

Appendix C: Template consent form for adults

(This for was adapted from Macías et al 2014 [18])

Good morning/afternoon, Mr/Mrs _____. We are from *[insert the name of your organization].* We are working on a project concerned with *[insert project topic]* in which you could participate.

[Include the objectives and a short description of the project]. Now, the project is just starting and we are completing a *[insert the type of method you will use]* among participants to know more about *[insert main focus of the project]*. It will take about *[time estimated to conduct the study per participant]*. All the information we obtain will remain strictly confidential and your answers and name will never be revealed. Also, you are not obliged to answer any question you do not want to, and you may stop at any time.

The objective of this study is to *[main objective]*. This is not to evaluate or criticize you, so please do not feel pressured to give a specific response and do not feel shy if you do not know the answer to a question. I am not expecting you give a specific answer; I would like you to answer questions honestly, telling me about what you know and feel. Please answer questions at your own pace.

Do you agree to participate in this interview?

Yes ___ No ___ If yes, continue to the next question; if no, stop the interview.

Do you have any question before we start? (Answer questions).

May I start now?

Appendix D: Outline for a IR study proposal

Adapted from the TDR IR toolkit

1. **Title**

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

2. **Executive Summary**

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

3. **Introduction and background**

   An explanation of the issue(s) being examined.

4. **Literature review**

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

5. **Rationale**

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

6. **Objectives**

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

7. **Methodology/study design**

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

8. **Ethical issues**

   Issues about the autonomy, protection and confidentiality of the subjects need to be addressed.

9. **Budget/resources**

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

10. **References**

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

Appendix E: Template Memorandum of Understanding with an academic partner

(Adopted from globalengagement.berkeley.edu)

MEMORANDUM OF UNDERSTANDING

between

[NONPROFIT ORGANIZATION]

AND

[RESEARCH INSTITUTION]

on

[Subject of Research Collaboration]

This Memorandum of Understanding (MOU) is made between [INSTITUTION] ("Institution"), a [description of entity] located in [location] and [NONPROFIT ORGANIZATION ("NGO"), [description of NGO] located in [location]. [Institution] and [NGO] are each a "Party" and together are referred to as the "Parties".

Purpose

The purpose of this MOU is to state the intentions of the parties in undertaking a collaboration in the research and development of [research areas]. The Parties have common scientific and research interests and will cooperate in performing the activities stated below.

Types of Cooperative Activities

The scope of collaboration on research activities to be pursued through this MOU includes the following [*select those that apply*]:

1. [Research collaboration in the areas of mutual interest.]
2. [Exchange of academic materials which are made available by both parties.]
3. [Exchange of visiting research scholars.]
4. [Cooperative symposia, seminars, workshops and conferences.]

Specific Research Activities

Activity I: [Description of specific research activities]

Activity 2: [Description of specific research activities]

Activity 3: [Description of specific research activities]

Funding

The Parties intend to support the specific research activities stated above in the amount of $_____ CHF. The payment terms and schedule will be stated in a later, formal agreement. Until the Parties enter into a formal agreement, each Party will bear its own costs. [Modify as needed]

MOU is Non-binding

This MOU is not intended by the Parties to be legally binding. Any binding obligations will be the subject of later, definitive agreements negotiated between the Parties. Nothing in this MOU is intended to create a legal partnership or joint venture.

Formal Agreement

The Parties' intentions expressed in this MOU will be the subject of a future definitive agreement, which will contain detailed provisions stating the Parties' rights and obligations including:

a. Detailed statement of work
b. Milestones and schedule for deliverables
c. Funding arrangements, including allocation of funds both domestically and internationally as required
d. Intellectual property arrangements
e. Exchange of materials, data, and software
f. Disclosure of confidential information
g. Compliance with laws and regulations, including those applicable to human and animal subjects in research, disclosures of conflicts of interest, and export controls.
h. Roles and responsibility in administering and managing the project.

Publicity and Use of Names and Trademarks

Nothing in this MOU authorizes a Party to use the name of the other Party or its employees in any advertisement, press release, or publicity with reference to this MOU or any product or service resulting from activities contemplated by this MOU, without prior written approval of an authorized representative of the other Party.

Nothing in this Article is intended to restrict either Party from disclosing the existence of any nature of this MOU or from including the existence of and nature of this MOU in the routine reporting of its activities.

General Terms

1. This MOU is effective from the date when both parties have signed it ("Effective Date").
2. This MOU shall remain in force for a period of [duration] from the Effective Date. Either Party may terminate the MOU by providing at 60 days' advance written notice to the other Party. Termination or expiration of this MOU does not automatically terminate any separate agreement between the Parties related to the subject matter of this MOU.

3. The MOU may be amended or extended by mutual consent in writing signed by authorized representatives of the Parties.
4. Each party is liable for its own acts and omissions under this MOU, which, for the prevention of doubt, does not include any liability based on the acts or omissions of a third party.
5. Confidential information shall be exchanged only under the terms of a separate agreement, whether a non-disclosure agreement, sponsored research agreement, material transfer agreement, or data use agreement. No confidential information shall be disclosed pursuant to this MOU.
6. No export-controlled information shall be disclosed pursuant to this MOU.
7. This MOU is written in English and [language]. In the event of a discrepancy between the English and [language] version of this MOU, the English version will prevail.
8. This MOU may be executed in counterparts, which taken together will constitute one document.

Notice

Each Party must provide all required notices under this MOU in writing to the addresses set forth below or such other addresses designated by the receiving Party:

For [Institution]:	[Name of contact Title Unit or Department Partner Institution Address Phone Email:]
For [NGO]:	[Name of contact Title Unit or Department Nonprofit Organization Address Phone Email:]

Signed for and on behalf of

[Non-profit Organization]
by its authorized representative:

_____
Signature

_____
Name

_____
Title

_____
Date

[Partner Institution]
by its authorized representative:

_____
Signature

_____
Name

_____
Title

_____
Date

Appendix F: Outline for a IR study protocol

(Adapted from https://www.swissethics.ch/, a protocol template is available as separate document)

1 Background information

1.1 Introduction

2 Objectives and purpose

2.1 Study rationale and objectives

2.1.1 Study rationale

2.1.2 Primary objective

2.1.3 Secondary objectives

2.2 Scientific justification of study population

3 Study design

3.1 Primary and secondary outcomes

3.1.1 Primary outcome

3.1.2 Secondary outcome

3.2 Measures to minimize bias

3.3 Study duration and duration of participant's participation

3.3.1 Schedule of events

3.4 Amendments

3.5 Withdrawal and discontinuation

4 Selection of study participants

4.1 Recruitment

4.2 Inclusion criteria

4.3 Exclusion criteria

4.4 Criteria for discontinuation of study

4.4.1 Discontinuation of individual participants

5 Qualitative Analysis – use this section if the study used qualitative data

5.1 Determination of sample size

5.2 Description of qualitative methods – this section could refer to a separate analysis plan when available

5. Quantitative Analysis – use this section if the study collected quantitative data

5.1 Hypothesis

5.2 Determination of sample size

5.3 Description of statistical methods – use this section if a separate statistical analysis plan is written

5.3 Description of statistical methods – use this detailed section if no separate statistical analysis plan is written