IMPLEMENTATION RESEARCH TOOLKIT

Introduction

Understanding IR

Research methods and data management

IR-Planning and Conducting IR

Communications and advocacy

Integrating IR into health systems

Developing an Implementation Research Proposal

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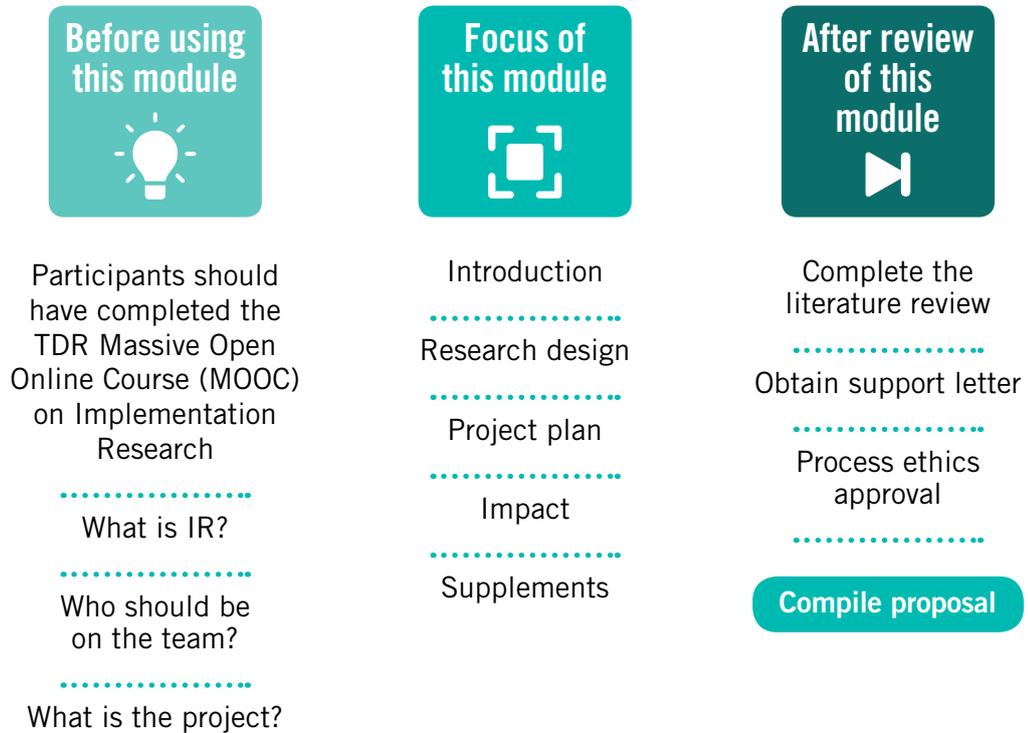# Developing an implementation research proposal

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

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

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

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

Before using this module	Focus of this module	After review of this module
Participants should have completed the TDR Massive Open Online Course (MOOC) on Implementation Research	Introduction	Complete the literature review
What is IR?	Research design	Obtain support letter
Who should be on the team?	Project plan	Process ethics approval
What is the project?	Impact	Compile proposal
	Supplements	

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

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

MOOC ON IR   SEE

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

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

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

The team and the research challenge

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

REFLECTION ACTIVITY

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

Structure of an IR proposal

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

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

A proposal is a requirement for most grant/funding applications, which are typically evaluated by a committee. To be effective, you need to know:

- what you are doing;
- why you are doing it;
- when you plan to do it;
- how you plan to do it.

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

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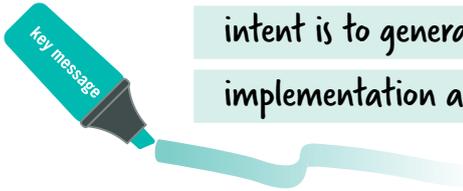
When developing an academic proposal, the intent is to generate new knowledge and ideas. However, when developing an IR proposal the intent is to generate research evidence to improve programme implementation and inform policy.

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

Writing a robust research proposal is probably one of the most challenging – and crucial – stages of research. You need to develop the research question(s), a rationale for why the study is necessary and important, and a conceptual framework. You need to conduct a review of existing literature. You need to design the research and specify what research methods you will be using to collect and analyse your data.[5]

What is different about an IR proposal?

WHAT IS DIFFERENT ABOUT AN IR PROPOSAL?

What?

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

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

How?

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

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

Contribute to the development of policy recommendations and practical solutions.

Why?

Better inform health care service quality improvement efforts;

Facilitate uptake of research results and outcomes by end users.

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

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

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

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

In general, IR projects:

- generate knowledge so it can be applied across settings and contexts;
- engage multiple sectors, including epidemiology, social science, anthropology, communication science and health economics;
- contribute to development of policy recommendations and practical solutions.

Because it can take years for research findings, guidelines and best practices to be completely integrated into practice, researchers, decision-makers and practitioners constantly seek ways to improve related knowledge transfer. To address this challenge, IR originates with a problem identified and prioritized by end users. Encouraging end-user uptake of research results requires end-user engagement in all steps of the research process, including proposal development.[6]

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

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Characteristics of an IR proposal

Characteristics of an IR proposal

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

Additional characteristics to consider:

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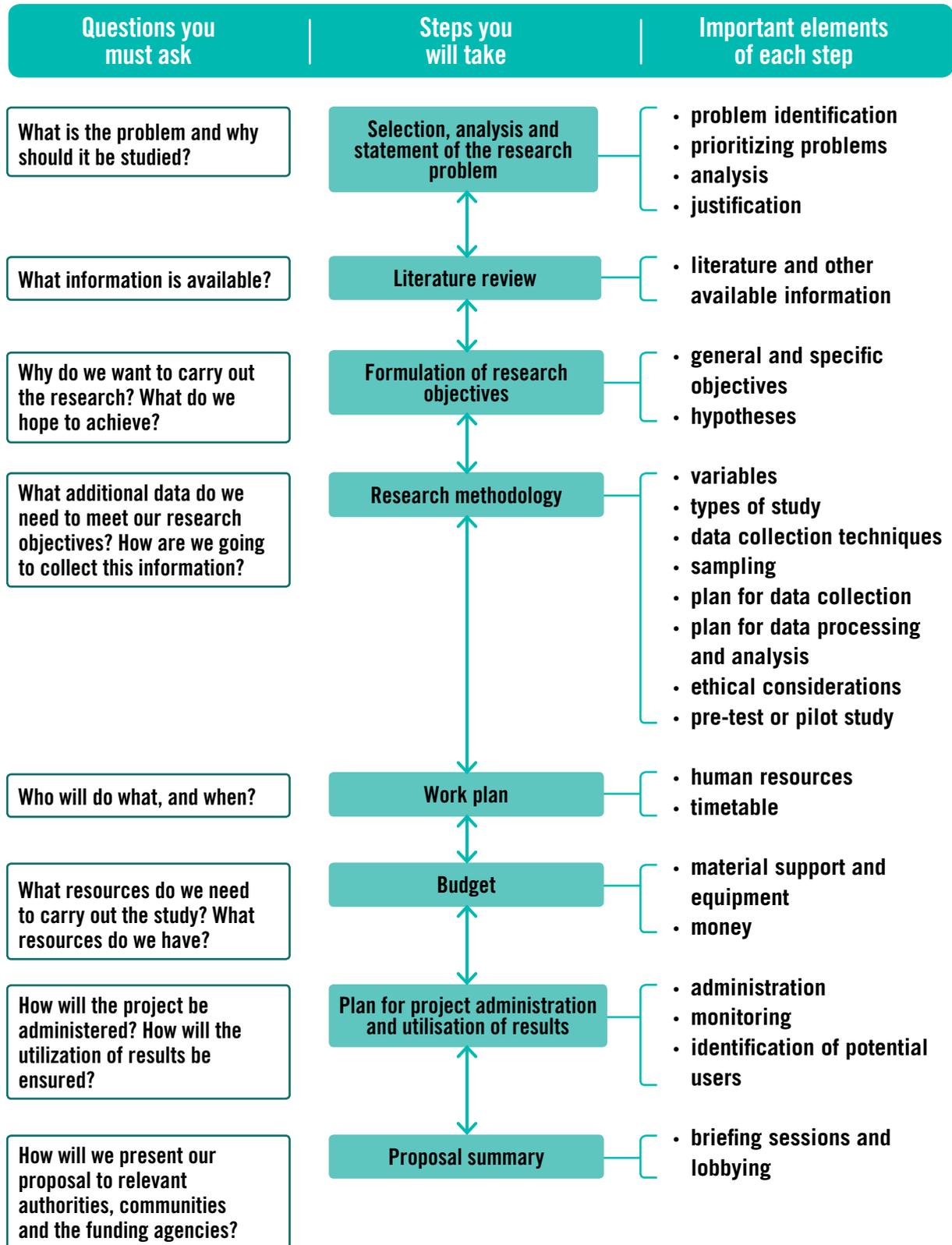
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Components of an IR proposal

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

The following section has been designed to be general enough so it can be adapted to fit the priorities of different users and various calls for proposals, recognizing that not all sections will be used in every proposal submitted for funding consideration. It is helpful to see the components of the IR proposal as being structured to respond to a series of questions that the research process aims to answer, as outlined in Figure 2.[7] The different steps are discussed briefly in this module and further elucidated in the other modules of the toolkit.

Figure 2: The IR framing process

Questions you must ask	Steps you will take	Important elements of each step
What is the problem and why should it be studied?	Selection, analysis and statement of the research problem	• problem identification • prioritizing problems • analysis • justification
What information is available?	Literature review	• literature and other available information
Why do we want to carry out the research? What do we hope to achieve?	Formulation of research objectives	• general and specific objectives • hypotheses
What additional data do we need to meet our research objectives? How are we going to collect this information?	Research methodology	• variables • types of study • data collection techniques • sampling • plan for data collection • plan for data processing and analysis • ethical considerations • pre-test or pilot study
Who will do what, and when?	Work plan	• human resources • timetable
What resources do we need to carry out the study? What resources do we have?	Budget	• material support and equipment • money
How will the project be administered? How will the utilization of results be ensured?	Plan for project administration and utilisation of results	• administration • monitoring • identification of potential users
How will we present our proposal to relevant authorities, communities and the funding agencies?	Proposal summary	• briefing sessions and lobbying

Source: Varkevisser et al.

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

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

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

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

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

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

Figure 3: Components of an IR proposal

Introduction
Title page
Rationale
Statement of the problem
Research questions
Literature review

Research design
Research design
Research method
Data collection
Data analysis
Study participants
Quality management
Ethics

Project plan
Project implementation plan
Research team
Budget and justification

Impact
Monitoring & Evaluation
Capacity building
Dissemination plan

Supplements
Project summary
Table of contents
References
Appendices CVs of research team members

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

Introduction

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

After completing this section, you will be able to:

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

The introduction to your proposal should:

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

The introduction content is summarized in Table 1.

Table 1: Sub-components of introduction section

Section	Description
Title page	Four components of a good title: • Use action words. • Reflect implementation and intervention themes. • Include specific target populations (adolescents, children under 5 years of age etc.)
Rationale	• Outlines what is being studied and why. • Summarizes expected outcomes, including the intended impact(s). • Provides a clear succinct rationale for why the project should be funded
Statement of the problem	• Summarizes the purpose of the study. • It is a paragraph rather than a single statement. • Establishes the direction and captures the essence of the study. • Should be clear and concise. • Incorporates your general objectives and uses action words to succinctly outline the purpose of the study. • Reflects the research design of the study. • Leads logically to the research question(s).
Objectives and research question(s)	• Should be of interest to the research community, researchers, policy-makers; decision-makers, funding agencies, health care providers, and the communities the research will ultimately affect. • Should be answerable. • Are shaped by the problem, and in turn should logically influence the research design. • Are clear and specific. • Are feasible. • Provide information required to evaluate interventions or progress. • Analyse possible causes for missed targets in order to find solutions. • Answering the question will result in important information or in developing relevant interventions.
Literature Review	• Demonstrates familiarity with the topic. • Summarizes what is not known about the topic. • Establishes credibility. • Places proposed research in a broader context. • Demonstrates relevance by making connections to a body of knowledge.

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

> The introduction provides critical information for funding and community support by:
> - Providing a foundation for the further development of the proposal (overview of the problem).
> - Facilitating access to background information on, and reports from, similar studies (systematic analysis and succinct review of literature).
> - Systematically stating why the proposed IR should be undertaken (rationale), what you hope to achieve (objectives) and expected results (outcomes).

key message

Guidelines for writing the introduction

- Begin by conducting a systematic analysis of the problem you intend to research and why it is important that this research is done.
- Once you have your initial ideas clarified, continually edit the introduction as you progress and discuss issues with your team.

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

What to write about

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

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

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

Developing the title

There are four components to a good title:

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

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

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

Example

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

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

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

Rationale

Every IR proposal needs a robust rationale to present the case to policy-makers and/or funding agencies outlining the benefits of committing scarce resources to the proposed research project. The introduction section of the proposal must therefore strongly justify why the research problem you have identified is important and worthy of support. Justification should also be provided explaining how the selected research problem aligns with the national research agenda. To provide this justification, it is useful to begin by providing evidence through a systematic analysis of existing information.

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

- local documentation (e.g. related project progress reports, theses, dissertations, seminar proceedings);
- programme progress, annual or evaluation reports;
- medical and social science literature, including reviews that outline gaps in research and/or programmes;
- research results in journal articles and scientific publications;
- abstracts/presentations/papers from scientific meetings and conferences;
- new ideas/recommendations from previous research;
- funding agencies' annual reports;
- questions asked by programme staff and/or students.

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

key message

Statement of the problem

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

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

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

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

How to know if the problem is worthy of research?

To confirm that the problem identified constitutes an appropriate research project, you can ask the following questions:

- Is there a perceived difference or discrepancy between the situation that exists and the ideal or planned situation?
- Is there a clear reason for the difference or discrepancy in relation to the problem?
- Is there more than one possible answer or solution to the problem?
- Do current programme implementers/policy-makers identify the problem as a priority?

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

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

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

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

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

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

Example 1:

In Vietnam, after the introduction of user charges in 1989, several provincial health insurance schemes were developed. In these schemes, industrial workers, constituting a minority of the population, were in principle insured on a compulsory basis, while other citizens (including farmers in the rural areas), could join on a voluntary basis. However, less than 2% of the rural target population was enrolled in the voluntary health insurance in 1999. The problem here was the low enrolment in the health insurance scheme and by extension, limited access to health care in the rural population.

Example 2:

In District Y (population 145 000), sanitary conditions are poor (5% of households have toilets) and diseases connected with poor sanitation such as hepatitis, gastroenteritis and worm infestations are very common. The Department of Health has initiated a sanitary project that aims to increase the percentage of households with toilets by 15% every year. The project provides materials and the population is expected to provide labour. Two years after the programme began less than half the target was reached. (adapted from Varkevisser et. al. 1991)

Case study 1   Is your research problem justifiable?

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

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

| Case study 1 | Is your research problem justifiable? |

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

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

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

The research team should now be able to develop an overview of the problem and, through a systematic analysis of existing resources and literature, provide a rationale for why conducting the proposed research would provide answers, solutions or alternative strategies to the identified problem.

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

a. Clarify the viewpoints of all stakeholders.

- List all the problems.
- Illustrate existing discrepancies.

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

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

b. Specify and describe the core problem.

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

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

- How widespread is the observation? Which regions/settings are persistently affected? Are there certain areas that may be potential low-compliant areas?
- Who is affected the most?
- How severe is the problem? What are the consequences? e.g. increasing morbidity, deaths, a waste of resources, development of multidrug resistance.
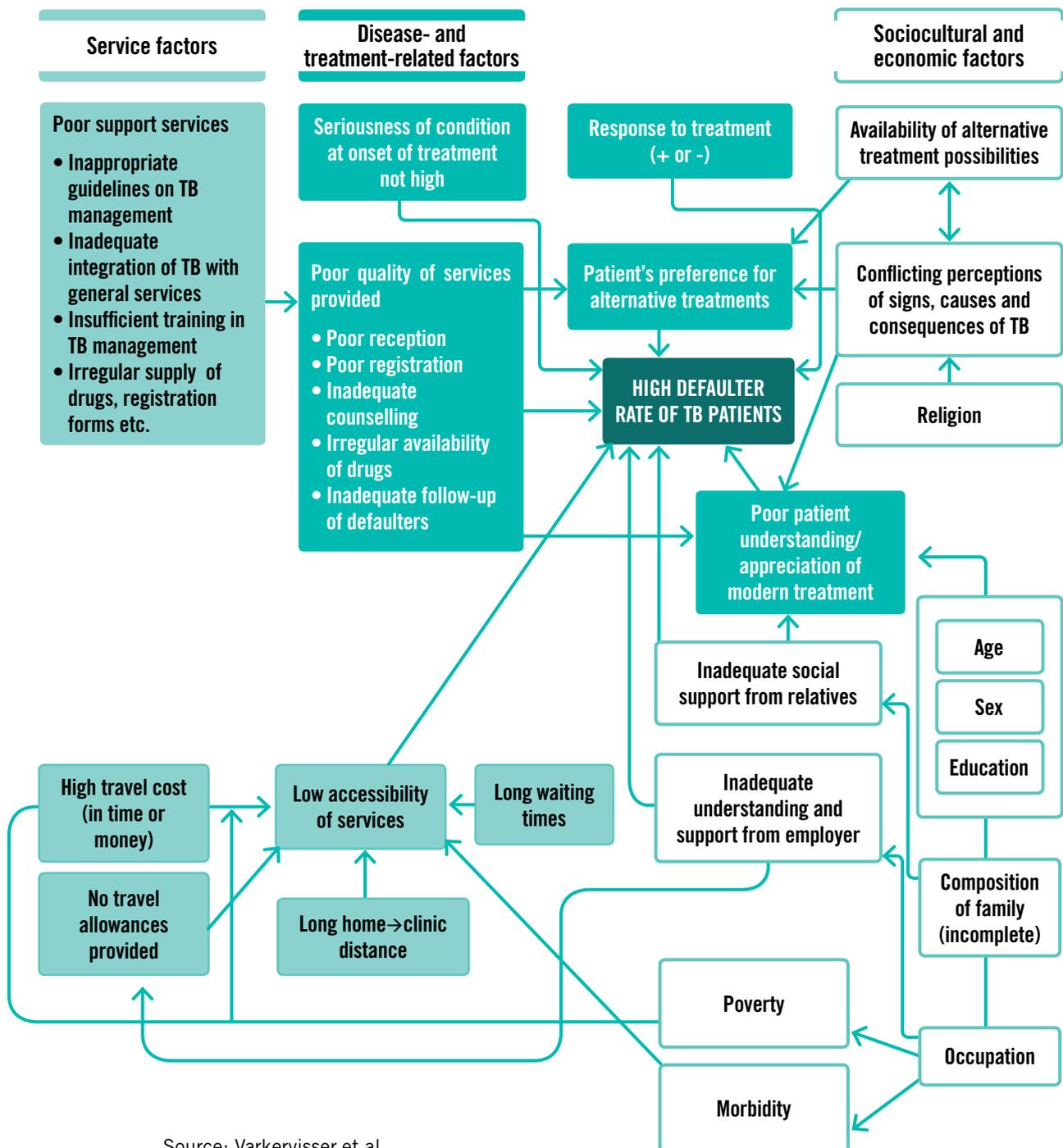
c. Identify the factors that may have contributed to the problem and clarify their relationship to the problem.

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

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

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

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

Service factors	Disease- and treatment-related factors		Sociocultural and economic factors

Poor support services
- Inappropriate guidelines on TB management
- Inadequate integration of TB with general services
- Insufficient training in TB management
- Irregular supply of drugs, registration forms etc.

Seriousness of condition at onset of treatment not high

Response to treatment (+ or -)

Availability of alternative treatment possibilities

Poor quality of services provided
- Poor reception
- Poor registration
- Inadequate counselling
- Irregular availability of drugs
- Inadequate follow-up of defaulters

Patient's preference for alternative treatments

Conflicting perceptions of signs, causes and consequences of TB

HIGH DEFAULTER RATE OF TB PATIENTS

Religion

Poor patient understanding/appreciation of modern treatment

Inadequate social support from relatives

Age

Sex

Education

Inadequate understanding and support from employer

High travel cost (in time or money)

Low accessibility of services

Long waiting times

No travel allowances provided

Long home→clinic distance

Composition of family (incomplete)

Poverty

Occupation

Morbidity

Source: Varkervisser et al.

Case study 2	Analysis of the research problem

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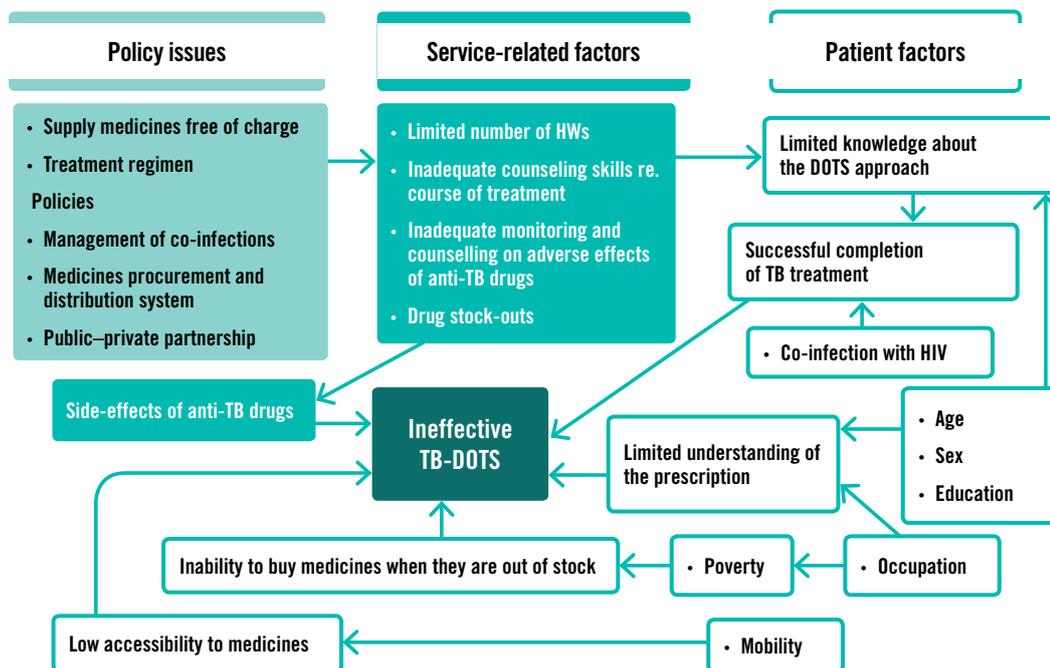
Lessons: A comprehensive analysis of the problem identified specific bottlenecks and their mutual relationships at the various levels of the health system. This was helpful in the development of research tools, as well as recommendations for targeted interventions.

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

Research objectives

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

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

In addition, you need to consider whether the research is:

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

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

- Is the research realistic? Describe the complexity of the proposed research. Are there adequate resources to carry out the research? Is it feasible to conduct and report the findings in 12 to 36 months?
- Is the research timely? You should provide a rationale for why your research is timely, and convince readers of the urgency for research in this area in order to generate information/solutions to problems affecting a specific community.
- How is the research relevant? Describe how large or widespread the problem is, who it affects and, and who considers it a problem. Also, refer to the potential for the disease/condition to spread/increase if not treated, the potential burden to the health system, and existing or potential economic impacts of the problem on the target population.

REFLECTION ACTIVITY

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

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

Possible responses:

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

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

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

Is the research *new* or *innovative*?

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

Example

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

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

Is the research *urgent*?

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

Example

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

Is the research *politically acceptable*?

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

Example

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

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

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

Example

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

Is the research *ethical?*

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

Example

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

a. Overall objectives

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

- state clearly what the study is expected to achieve in general terms;
- align with the broader social, economic and health concerns outlined in the overview of the introduction, and further focus the context of the research down to an essential purpose.

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

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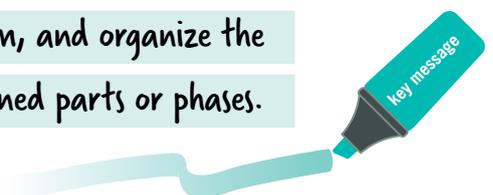
Different funding agencies use varying terminology to describe and characterize objectives, goals, aims etc. Sometimes these terms are used interchangeably.

b. Specific objectives

Specific objectives are a breakdown of general objective(s) into measurable action statements that outline what will be done, where and for what purpose. Here are some brief suggestions for framing specific objectives:

- Use action verbs when defining specific objectives (e.g. determine, compare, verify, calculate, describe, establish, evaluate).
- Avoid the use of vague, non-action verbs (e.g. appreciate, understand or study). Use verbs such as: train, supervise and distribute when describing project activities.
- Resist the temptation to put too many or over-ambitious specific objectives in your IR proposal that cannot be achieved.
- Ensure that the different aspects of the problem and its contributory factors are covered logically and in a coherent manner by the specific objectives.

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

Research question(s)

Should be of interest to the researchers, policy-makers; decision-makers, funding agencies, health care providers and the community the research will affect. In addition, research questions:

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

key message

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

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

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

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

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

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

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

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

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

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

In light of this, IR questions:

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

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

Table 2: Research domains and examples of research questions

Research domain	Research question
Epidemiological research	What is the association of zinc deficiency with the severity of diarrhoea? • Establishes an association between zinc and diarrhoea.
Clinical efficacy research	What is the association of zinc deficiency with severity of diarrhoea? What is the effect of zinc as an adjunct for the treatment of diarrhoea? • Examines how well zinc treatment works on the health outcome (diarrhoea).
Programme effectiveness research	What is the effect of a programme of promoting zinc as an adjunct treatment of diarrhoea • Examines how well a specific intervention or programme works in promoting the use of zinc treatment.
Implementation research	Why is the zinc promotion programme not reaching all children with diarrhoea? How can the barriers to scaling up zinc promotion programmes be overcome so that they reach all children with diarrhoea? • Uses findings from previous research in practical applications, examining implementation strategies to scale up the programme and treatment coverage.

Source: MEASURE Evaluation

Formulating IR questions

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

• How could it best be answered?

• How could it feasibly be answered?

• What data is available? What data is needed?

• What can be controlled?

key message

Once the problem has been identified, the next step is to formulate a question addressing that problem. Your approach depends on the particular context and availability of information.
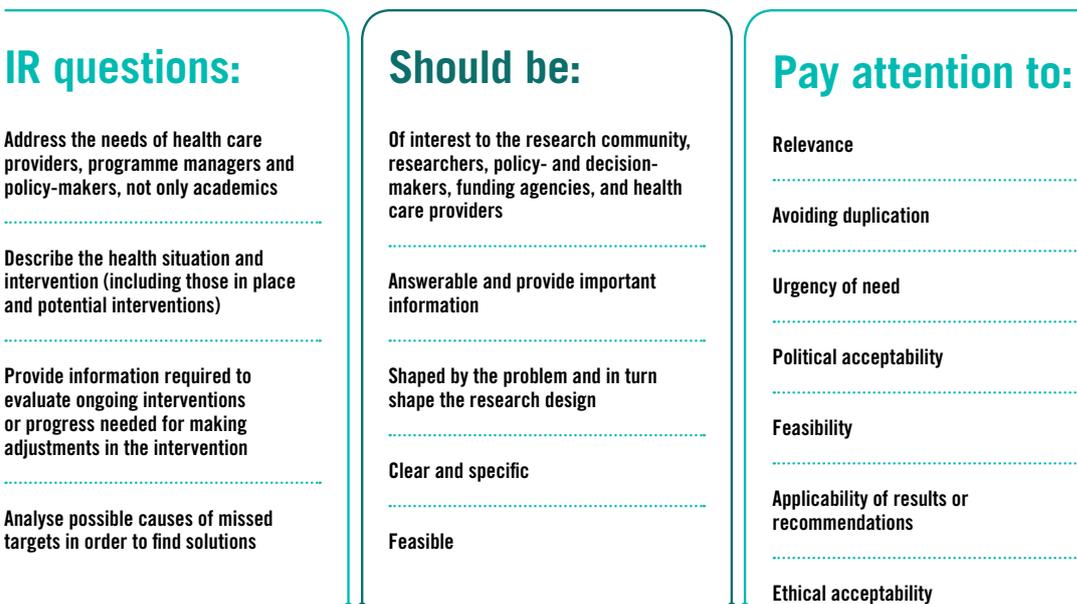
> **Remember that IR problems are programme embedded – they begin and end in programmes.**
>
> *key message*

Therefore, engage programme stakeholders early to formulate IR questions. The way questions are formulated drives research methods. These are helpful sources for formulating IR questions:

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

Figure 3F: Defining and prioritizing IR questions

IR questions:

Address the needs of health care providers, programme managers and policy-makers, not only academics

Describe the health situation and intervention (including those in place and potential interventions)

Provide information required to evaluate ongoing interventions or progress needed for making adjustments in the intervention

Analyse possible causes of missed targets in order to find solutions

Should be:

Of interest to the research community, researchers, policy- and decision-makers, funding agencies, and health care providers

Answerable and provide important information

Shaped by the problem and in turn shape the research design

Clear and specific

Feasible

Pay attention to:

Relevance

Avoiding duplication

Urgency of need

Political acceptability

Feasibility

Applicability of results or recommendations

Ethical acceptability

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

Table 3: Criteria for prioritizing IR questions

Criteria	Considerations
Relevance	• How large or widespread is the problem? • Who is affected by the problem? • How severe is the problem? • If the problem is not addressed, is there a potential for it to spread? • Who considers this a problem? • Is this problem a burden to the health system? How severe is the burden? • What is the economic impact of this problem on the population?
Avoidance of duplication	• Has this question or problem been researched before? • Are there any interventions that could effectively addressed this problem? • If yes, are there any major questions that deserve further research? • Is the context so different that I cannot use the results of previous intervention research?
Urgency of need	• How urgently do policy-makers, implementers and health care providers need results? • Will timeliness impact changing course, taking on new interventions or stopping what they are doing?
Political acceptability	• Is the implementation research problem of high interest and does it have the support of local or national authorities? • Would the study results generate sufficient political support that will more likely lead to their implementation? • Does the implementation problem have political acceptance that can engender the involvement of the policy-makers in the study?
Feasibility	• How complex is the research? • Are there adequate resources to carry out the study? • Is it possible to conduct and report the findings in 12 to 36 months?
Applicability of results or recommendations	• What is the likelihood that recommendations will be adopted? • How will the findings be used to improve health and health care? • Are there available resources for implementing the recommendations?
Ethical acceptability	• How acceptable is the research to those who will be studied? • Does the target group share the implementation problem? • Can informed consent be obtained from the research subjects? • Will the condition of the subjects be taken into account? • Will the results be shared with those who are being studied?

Review of literature

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

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

A literature review:

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

You should strategically situate your research problem in the existing knowledge and literature, in order to establish a rationale for why it is important that your identified problem should be researched. Writing this kind of rationale is the first step in developing the synthesis of existing knowledge for an IR proposal.

Conducting a literature review involves reviewing the existing knowledge and carrying out library searches to find relevant resources (i.e. research articles, research studies, reports, government documents, and white papers), reading, and then organizing and synthesizing the information into a succinct overview of the topic. You may find that you need to read about the topic for several days or weeks before beginning to compile or collate available information. At some point, however, you do need to begin to draft the review content. Often you will find that once you begin to write, the process can feel overwhelming and you need to go back and do some more reading. You need to look for major concepts, read with a purpose, be a critical reader and try to write while still reading and

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

Ultimately, a literature review should aim to:

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

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

It may have been acceptable previously for proposals not to provide a strong synthesis of the existing knowledge due to the research team's location and lack of access to libraries and resources. That is no longer the case now that anyone who has access to the Internet can explore most of the existing literature. Several search engines, such as Pubmed (http://www.ncbi.nlm.nih.gov/pubmed), Hinari (http://www.who.int/hinari/en/) and Google Scholar (http://scholar.google.com) will be helpful in this regard. You can also work with a librarian, or assign a specific member of the project team to help you find and access the information you need.

Referencing

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

It is essential that you use and cite references properly and consistently, and in accordance with the applicable style guide. Not adhering to the conventions of proper referencing suggests sloppy organization and may hamper the chances of a proposal being successful. Moreover, if you do not reference properly, you run the risk of plagiarizing content and/or ideas, which can have severe career and academic ramifications. There are programmes that can help you check against plagiarism during your write up. An example is Desktop Plagiarism Checker (https://desktop_plagiarism_checker.en.softonic.com/).

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

REFLECTION ACTIVITY

At the end of this section your team should be able to develop the following for your team's project:
- **Working title**
- **Statement of the problem for your IR proposal (1/2 page)**
- **Research question(s)**
- **Specific objectives for your project (4 to 6 objectives)**

Research design

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

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

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

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

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

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

SEE MODULE ON RESEARCH METHODS AND DATA MANAGEMENT MODULE

Table 4: Sub-components of the research design section

Section	Description
Research design	• Describes the nature or structure of the planned research. • Describes whether it is an intervention or non-intervention study design.
Research methods	• Comprises the various methods you will use to obtain and analyse data – qualitative, quantitative or mixed. • Justifies what you will do, when and how. • Provides a rationale for your research design. • Justifies how your methodology will enable you to produce results that are new or unique. • Comprises a number of sub-sections such as research design, participants, data collection, and data analyses.
Data collection	• Explains how you intend to gather the information that will be used to answer the research question(s). • May involve the use of quantitative (e.g. surveys, recording the number of times an incident occurs, laboratory experiments), qualitative (e.g. interviews, observations).
Data analysis	• Describes exactly how you plan to compile the data you collect and how you will organize and interpret the data to make sense of your findings. • Identifies themes, developing tables and charts, identifying relationships, and/or calculating frequencies.
Participants	• Provides a full description of the subjects (sample) or participants involved in the research. • Describes the selection of participants. • Lists the criteria for becoming a participant.
Quality management	• Describes the system to ensure the quality of the research project. • Helps provide confidence that the conduct of the study and data generated optimally fulfil applicable requirements. [NOT OPTIONAL – You must have a quality management plan].
Ethics	• You must apply to an ethics board/committee if you intend to collect information/data from human participants (directly or indirectly). • If you are collecting data from more than one site, you may need to apply to more than one board. • Stipulate that you intend to apply for ethics approval. • Ethics approval may take several months to receive, so apply as soon as you submit your proposal for funding. • Most agencies will not release funds until ethics clearance has been received in writing.

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

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

Status of knowledge regarding problem	Type of research question	Appropriate research study design
Knowing that a problem exists but knowing little about its characteristics or possible causes.	• What is the nature/ magnitude of the problem? • Who is affected? • How do the affected people behave? • What do they know, believe, think about the problem and its causes?	• Descriptive studies: • Cross-sectional surveys
Suspecting that certain factors contribute to the problem (or are associated with it)	• Are certain factors indeed associated with the problem? (e.g. lack of pre-school education related to low school performance? Is low-fibre diet related to carcinoma of the large intestine?)	• Analytical (Comparative) studies: • Cross-sectional comparative studies • Case control studies • Cohort studies
Having established that certain factors are associated with the problem: Establishing the extent to which a particular factor causes or contributes to the problem	• What is the cause of the problem? • Will the removal of a particular factor prevent or reduce the problem? (e.g. stopping smoking, providing safe water).	• Cohort studies Experimental or quasi-experimental studies
Having sufficient knowledge about cause(s) to develop and assess an intervention that would prevent, control or solve the problem	• What is the effect of a particular intervention/ strategy? (E.g. treating with a particular drug; being exposed to a certain type of health education) • Which of two alternate strategies gives better results? • Which strategy is most cost-effective?	• Experimental or quasi-experimental studies

Once the overall study design has been determined, it informs the choice of participants, research methods and data collection/analysis approaches that are used/adopted. In your proposal, you will need a strong justification for your choice of research design for your study. Click on each of the headings below to explore each of the sections individually.

Study participants

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

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

REFLECTION ACTIVITY

Study participants

With members of your team discuss who you think your research population will be. Will you have one site or multiple sites? Why will you choose the site(s) you select? Discuss how many participants you will need. What will be the criteria for becoming a participant? Will you need a variety of participants in order to get different perspectives on an issue (e.g. patients, physicians, family members, members of the community)? Will you have a control group of participants? Do you need to choose a representative population for certain aspects of data collection? For example, if you are conducting individual interviews do you want your participants to vary in age, gender, education, experience etc., in order to represent the sample population?

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

> **Example**
>
> *For the key informant interviews for a study on TB in the prison system of country X, a comprehensive list of officials to be interviewed will be developed based on the stakeholder analysis and on consultations with the national TB control programme (NTBCP) personnel. A preliminary list of officials has been compiled and includes the following:*
>
> - *Minister of Health (or their deputy).*
> - *Deputy of the Minister of Health, responsible for epidemiology and infection control.*
> - *Director of the NTBCP.*
> - *Chair of the sanitation and epidemiological services committee.*
> - *Ministry of Justice.*
> - *Deputy of the Minister of Justice responsible for the prison system.*
> - *Chief medical doctor, who oversees the prison system.*
> - *Ministry of Internal Affairs.*
> - *Deputy responsible for detention centres.*
> - *Chief TB medical doctor (detention centres).*
> - *Ministry of Social Security (head administrator).*
> - *Ministry of Finance (head of budgeting department).*
> - *Head of regional political authority*
> - *Head of health department of that authority.*

Research methods

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

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

Qualitative methods

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

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

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

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

Quantitative methods

Quantitative methods involve the collection and analysis of objective data, often in numerical form. They are used when it is necessary to establish cause and effect relationships, where the researcher can manipulate a particular variable (experimental research) or in instances where no attempt is made to influence the variables (correlational research). The research design is determined prior to the start of data collection and is not flexible. The research process, interventions and data collection tools (e.g. questionnaires) are standardized to minimize or control possible bias.

In your proposal, explain where the data will come from (e.g. health centres, district hospitals, regions); how surveys will be delivered, who will facilitate delivery; how you will ensure anonymity; time required to complete survey; length of survey; number of questions in the survey; sample size; how the survey will be designed; is the survey validated, etc.

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

Mixed methods

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

MODULE ON
RESEARCH
METHODS
AND DATA
MANAGEMENT
MODULE

SEE

If your research team decides to use mixed methods in your study, you will need to describe why you chose this approach, explaining how the combination of qualitative and qualitative methods will provide information that helps you to address your research objectives and research questions. For example, using a mixed methods approach may be appropriate because you require a better understanding of the problem than either a quantitative or qualitative research approach could achieve alone. Your explanation may state that you want to create a design that provides the optimal combination and sequence of both approaches. Additional justification for using a mixed methods approach may be

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

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

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

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

Plan for data analysis

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

You should outline/highlight the following as they relate to your study:

- Demonstrate appropriate analysis procedures.
- Provide a general plan for data analysis and justify its technical and theoretical soundness.
- Describe what information is needed to complete the analysis, the potential sources of this information and the instruments that will be used for its collection.
- Provide sufficient detail to demonstrate the technical soundness of all data collection instruments and procedures.
- Identify and justify procedures for analysis, reporting and utilization.
- Identify any anticipated constraints on the analysis.
- Discuss who will be responsible for analysis, and the roles of any consultants or external personnel.

Research design

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

Example

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

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

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

For the fourth objective, the study will compare bacteriological and clinical data with quantitative and qualitative social data collected from patients and family members in order to identify biosocial determinants and effects of MDR-TB emergence and persistence. The study will obtain the life histories of patients with MDR-TB and TB on video, if possible.

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

REFLECTION ACTIVITY

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

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

Quality management

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

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

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

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

SEE

MODULE ON RESEARCH METHODS AND DATA MANAGEMENT MODULE

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

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

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

Case study 3	Quality management plan

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

Case study 3	Quality management plan

Table. Data quality management measures

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

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

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

Research ethics

Any research study that collects data from or involves human subjects must undergo an ethics review. You must stipulate that you intend to apply for ethics approval if you have not done so already. You should have an ethics section in your proposal that describes the steps you will take to ensure the protection, dignity, rights and safety of potential research participants before, during and after the research takes place. In addition, your IR proposal should describe how you will ensure that universal ethical values and international scientific standards will be adhered to in terms of local community values and customs in planning, conducting and evaluating the research. You may also be required to apply for a research permit in addition to ethical clearance in certain countries or disciplines. In some cases, you may be required to submit your protocol to the funding agency for ethical review by the agency ethical clearance unit in addition to obtaining local ethical review/research permit.

In the ethics section of your proposal, state explicitly how the research will address the following codes of ethics (it may, however, be worth going to the website of the review board to whom you are submitting your proposal, to make sure you have complied with all their specific requirements, including for example, evidence of having completed an online ethics course).

- Balance potential harm to participants against potential benefits. Possible harms fall into several categories such as physical injuries, loss of privileges, inconvenience (including wasted time, psychological injuries (e.g. embarrassment), economic loss, or legal risks).
- Maintain privacy, anonymity, and confidentiality:
  - when health care providers are research participants;
  - when reviewing medical records;
  - by maintaining the boundary between researchers and physicians;
  - when collecting data in field settings.

- Construct the informed consent letter and form (include in the proposal appendices). [The consent form has two parts: (a) a statement describing the study and the nature of the subject's involvement in it; and (b) a certificate of consent attesting to the subject's consent. Both parts should be written in sufficiently large letters and in simple language so that the subject can easily read and understand the contents. As far as possible, medical terminology should be avoided in writing up the consent form. (These should be included in the proposal appendices)].
- Where necessary, include a translation of the consent form in the appropriate local language(s) as this may be required by some ethical review committees.
- Obtain voluntary consent from all human subjects/participants. In the case of minors, parental/ guardian consent must be obtained, and in the cases where the information is to be obtained from a patient by a non-health worker, state the process to be followed.

- Subjects must be informed that their participation is voluntary and that they are at liberty to withdraw from the research at any time without explanation and/or prejudice.
- Research will be terminated at any stage if there is any reason to believe harm is being caused to the subjects/participants.
- Adequate provisions must be taken to protect participants.
- Demonstrate that results cannot be obtained by other methods or means.
- Avoid all unnecessary physical and mental suffering and injury.
- Risks do not exceed the humanitarian importance of the problem the research will solve.
- Cultural diversity must be considered to ensure participants understand the purpose of the study.
- Special attention should be paid if the research involves vulnerable subjects.
- Teams should involve scientifically qualified, well trained and properly supervised individuals.
- Protocols should be submitted for approval to the appropriate ethical and scientific review committees.
- Research procedures involving human subjects should be submitted for approval to an independent ethics committee before research begins.
- Research and related procedures must be conducted in adherence to the protocol that received scientific and ethical approval.
- Any subsequent alterations to the protocol should be re-submitted for ethics approval.
- Research results should be made freely available as a public good.
- Participants should be provided with the option to receive the results of the study in which they are participating.

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

Example

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

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

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

Protocols for social science research involving human participants are subject to review, and IRB approval, of both a local and national institutional review board and where the research is funded by WHO, WHO's Research Ethics Review Committee (ERC) ERC's website can be consulted at http://www.who.int/ethics/en/.

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

Ethics checklists

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

REFLECTION ACTIVITY

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

Project plan

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

Table 6: Sub-components of the project plan section

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

Research team

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

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

The membership of a research team typically includes:

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

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

Example

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

Composition of the research team

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

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

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

REFLECTION ACTIVITY

In your research team, review the content of the planning module of this toolkit and draft the following sections in relation to your own project:

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

Budget and Justification

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

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

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

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

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

REFLECTION ACTIVITY

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

Impact and measuring project results

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

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

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

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

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

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

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

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

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

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

> **SEE** MODULE ON IR RALATED COMMUNICATIONS AND ADVOCACY

The dissemination section of the IR proposal should include:

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

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

REFLECTION ACTIVITY

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

Example

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

A stakeholder analysis will be conducted at the beginning of the project and involve the following:

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

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

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

Example (continued)

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

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

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

REFLECTION ACTIVITY

Work in your teams to develop the following aspects of your team's IR proposal:
- **Monitoring and evaluation plan.**
- **Capacity building plan.**
- **Dissemination plan.**
- **Make any changes necessary to improve, update, or align all sections of your proposal.**

Supplements

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

Table 8: Sub-components of the supplements section

Section	Description
Project summary	• Briefly describes the entire proposal.
	• Although this is read first, you should write it last.
	• Includes a description of the problem under investigation, a rationale (situated in the existing literature) for why the research is needed and/or important, the participants, the methodology, and the implications of conducting the research.
	• This section is your 'first impression' with reviewers and may influence whether reviewers choose to fund your proposal.
	• Makes it very easy for reviewers to understand and evaluate your proposed project according to the review criteria.
Table of contents	• Organizes the proposal by outlining where each item can be found.
	• Presents a convenient list of the topics and sections in a logical sequence 'at a glance.'
References	• Lists all references cited in the text of your proposal (in a recognized referencing style).
	• If a reference is not cited in the text of your proposal, it should not be included in your reference list.
Appendices	• May include CVs of team members.

Project summary

An IR project summary (sometimes called an abstract or an executive summary) briefly describes the entire proposal. Researchers often write their summary or abstract last, when they are best able to concisely describe their research proposal. The summary should include a description of the problem under investigation, a rationale for why the research is needed or important (situated in the literature), the participants, the methodology, the research activities to be undertaken and the expected outcomes or implications of conducting the research. Depending on the requirements of the funding agency, your summary/abstract may be limited to anywhere from 150–200 words (abstract) to a page (summary). Like a research report or journal article, your proposal summary or abstract might be the most important paragraph/page of your proposal because it will be the first thing most

reviewers come into contact with when reviewing your proposal. The summary will create the 'first impression' with reviewers and may influence whether reviewers choose to fund your proposal or not.

Example

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

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

Specific objectives

- *To carry out a situation analysis of perceived needs for rural health insurance and strengths and weaknesses of existing schemes.*

- *To develop and implement pilot rural health insurance schemes that are feasible and meet the perceived needs of their target populations.*

- *To monitor and evaluate the effects of the new schemes from the perspectives of equitable coverage, user satisfaction, efficient service utilization and provision, poverty reduction and sustainability.*

- *To support the design and implementation of sustainable, equity-oriented rural health insurance schemes by effective dissemination of the research findings.*

Abstract

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

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

Project summary checklist

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

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

Table of contents

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

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

Appendices

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

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

Usually agencies have a limit of 1–3 pages for an investigator's short curriculum vitae. Therefore, investigators will need to shorten their CVs and highlight the

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

REFLECTION ACTIVITY

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

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

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

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

Funding an IR project

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

In-country sources

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

Multilateral organizations

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

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

Bilateral donors

For example, the Canadian Government, United Kingdom Government (DFID), United States Government (USAID, National Institutes of Health, Fogarty International Center), Norway Government (Norad), Sweden Government (SIDA) Australia Government, and the International Development Research Centre (IDRC).

An increasing number of bilateral organizations, such as IDRC, NIH/FIC, DFID, USAID, CDC and NORAD have supported IR. Almost all bilateral organizations have aid projects/programmes in LMICs with a certain part of the programme budget allocated to monitoring and evaluation. A case could be made for using such resources for IR if such research will significantly improve the delivery of their programmes.

Private foundations and trusts

For example, the Bill & Melinda Gates Foundation, Rockefeller Foundation, Ford Foundation, Wellcome Trust.

Private foundations and trusts have a tradition of supporting health research, among other issues. Implementation research is a potential area of interest for these entities.

To find a good donor match for your proposal, consider:

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

Other related resources

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

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

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

Do your searching…

- Go to a library where good internet access is available.
- Talk to your institution's Office of Research Administration, if you have one.
- Search comprehensive databases such as COS, eRACommons and Spin.
- Set up alerts from your database searches.
- Search US government grant websites such as OER or Grants.gov, or individual agency websites.

- Search association and foundation websites.
- Search specialized research websites such as AuthorAID (http://www. authoraid.info/en/).
- Find out what projects related to your subject area were already funded.

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

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

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

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

Preparing your application

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

When applying for a research grant, take advantage of the resources available to you. Most universities in Europe and North America have an Office of Research with trained staff to assist researchers with large grant applications. This may not

be available in institutions and health agencies in LMICs, but there may also be resources available online that can be helpful. It is important to visit the website of the funding agency to which you plan to submit your proposal. They will usually have full instructions on what to do and when to submit your proposal.

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

What reviewers look for

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

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

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

- Scientific merit and policy relevance.
- Scientific 'soundness.'
- Synthesis of existing knowledge (which could include a literature review) – make it concise; pertinent; complete; appropriate.
- Research questions – make them appropriate and feasible.
- Analytical framework – apply as appropriate and make it sound.
- Proposal should be in accordance with IR principles outlined in the call for proposals.
- Proposal should address issues relevant in the country/community where the research will be conducted.
- Proposal should fit the specific call for proposals.

Methodology

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

Other considerations

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

Additional critical issues

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

Common problems with applications

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

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

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Recommended readings

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- The NIH Office of Extramural Research free tutorial on Protecting Human Research Participants available at https://phrp.nihtraining.com/users/login.php?l=3