

IMPLEMENTATION RESEARCH TOOLKIT



IR-Planning and Conducting IR

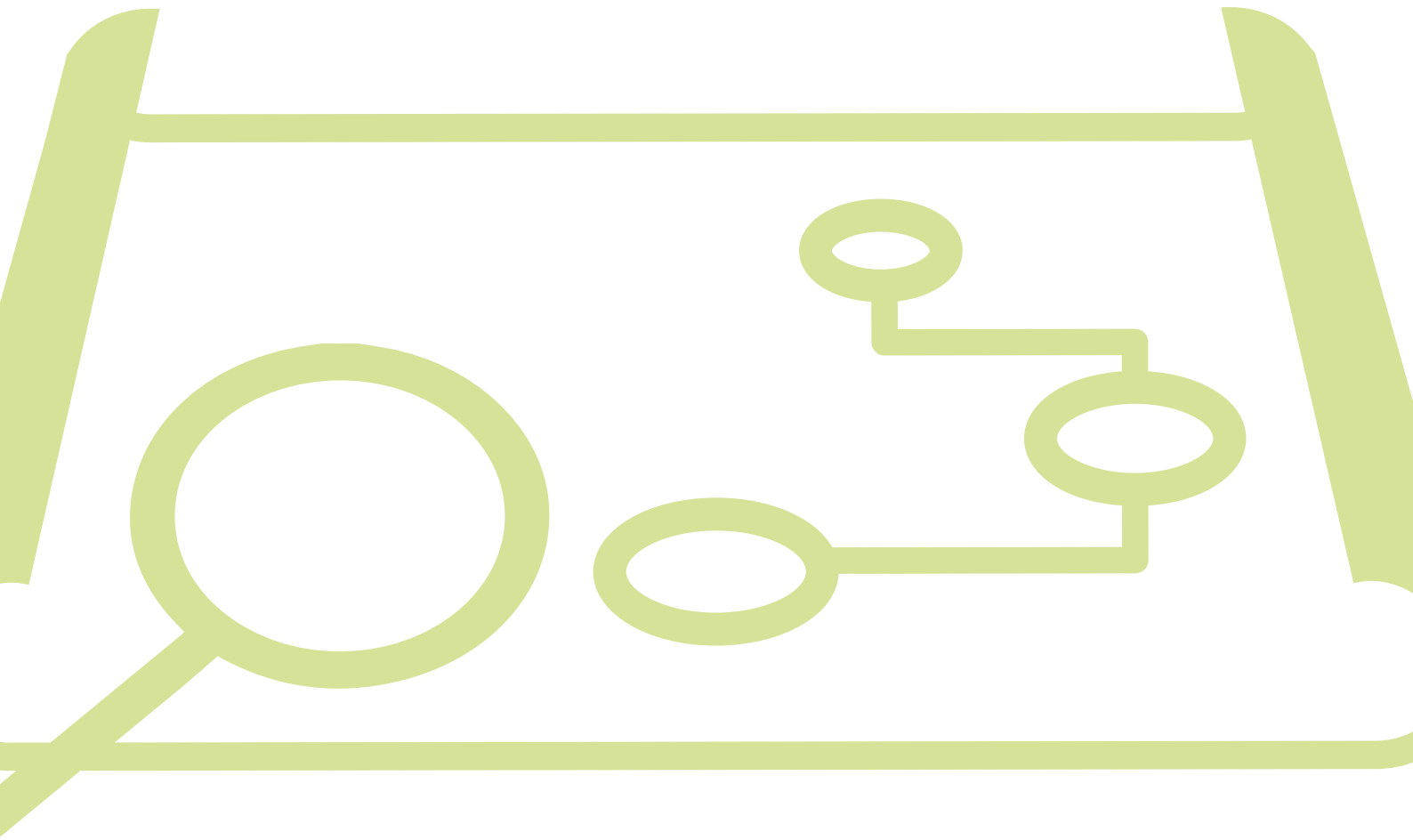
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IR-PLANNING AND CONDUCTING IR

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

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



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

SEE

**DEVELOPING
AN IR PROPOSAL**

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

SEE

**INTEGRATING
IR INTO HEALTH
SYSTEM**

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

Table 1: Key plans and components of IR project planning

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

Effective project plans have five primary characteristics, as follows:

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



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



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

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

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



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

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



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

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



Project Planning

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

Scope of the project

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

Project timelines

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

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

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

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

Figure 1: IR Project timeline (example)

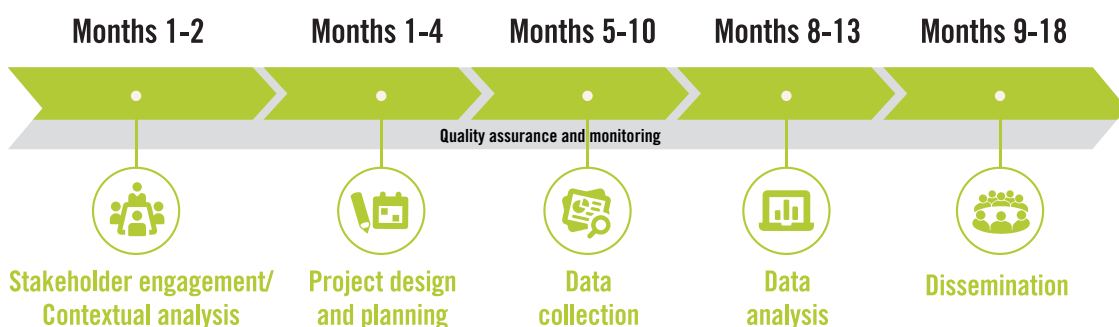




Figure 2: IR Project GANTT chart (example)





Resource management plan

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

SEE

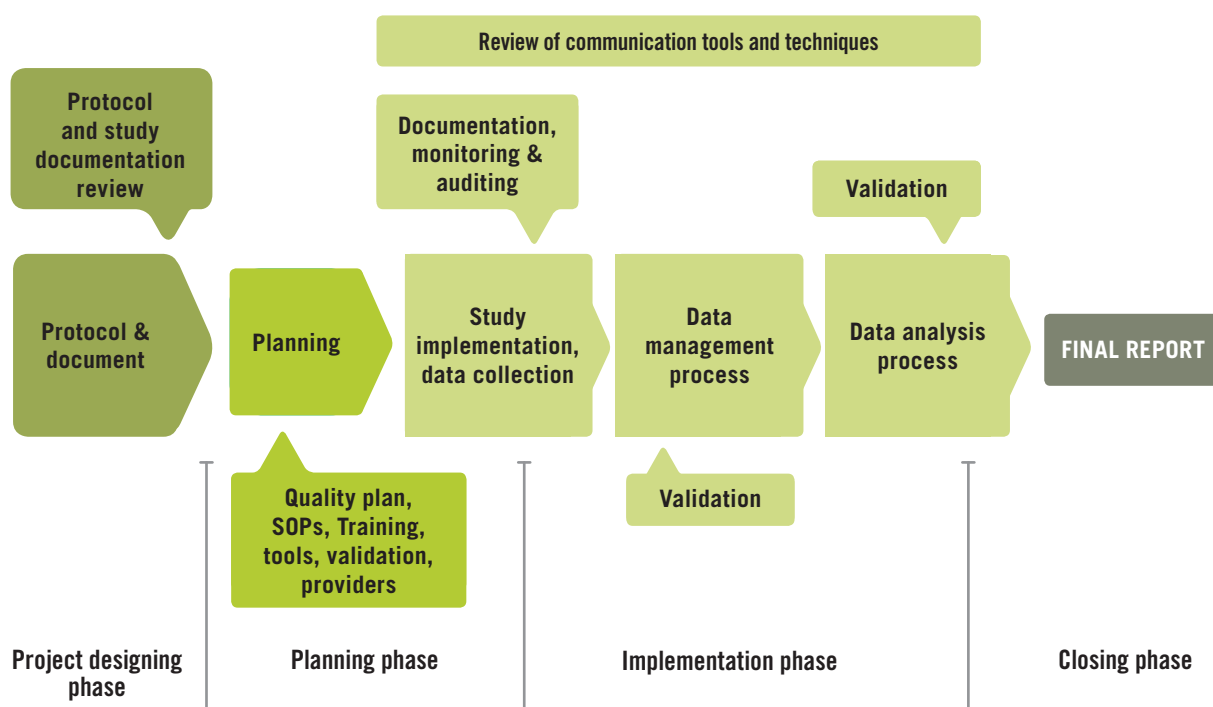
DEVELOPING AN
IR PROPOSAL
MODULE

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

Quality management plan

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

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



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

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

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

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



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

Table 3: Descriptions of various quality management strategies

Strategy	Description
Protocol review and approval	Research rigour consistency includes stipulating how you will protect the rights and welfare of research participants. Protocols may also be established to ensure approval consistency and diligence in data and collection procedures (standardized instruments, consistent interview protocols); as well as checklists and established protocols to ensure consistency and rigour of data analysis across sites/among researchers.
Standard operating procedures	A principal investigator must put protocols in place to establish rigour and consistency between and among researchers and research sites. This may include standardized research collection procedures (establishing a protocol or checklist); creating standardized instruments and interview protocols to be used across sites and among all researchers; constant checks to ensure procedures are diligently adhered to; and holding training sessions with researchers and research assistants.
Validation of research instruments	Indicate whether research instruments are standardized and whether they have been shown in previous studies and reports to have strong reliability and validity (with respect to content, criteria and construction).
Project team training	Adequate training is essential to research subject/participant safety, protocol implementation, and quality assurance and improvement. Training of researchers and assistants in data collection procedures to ensure safety of the participants, as well as to ensure consistency and research rigour between and across sites, is essential.
Quality control and monitoring	Quality control is important to ensure reliable and consistent findings. What procedures will be incorporated into the research design to ensure consistent data collection methods are implemented between and among research sites and among different researchers? The proposed methodology should help investigators identify data quality problems that can be corrected while data is still being collected, and also to identify biases in the data collection that might be adjusted at a later date.



Strategy	Description continue
Evaluation of services provided by the project	Monitoring and evaluation of service provision is essential for analyzing and, where possible, improving the effectiveness of service regimes. Establish 'critical limits' to measure the effectiveness and quality of the services provided to participants/clients/patients. Establish appropriate record-keeping and documentation systems. Make regular site visits to monitor progress and assess impact. Establish corrective actions. Evaluate, with relevant health care workers, achievements made and lessons learnt, and apply any lessons learnt to existing and new arrangements.
Evaluation of service provider performance	Generating and using information on the performance of service providers can lead to the substantial enhancement of transparency and accountability, which in turn fosters adherence to higher quality standards in service delivery. Assessment tools rely on external experts measuring quality and performance against a pre-determined set of indicators. Participatory monitoring and evaluation tools seek to engage service users beyond the provision of feedback, to also take an active role in the planning and implementation of the assessment. This helps to build the capacity of the local community to analyze, reflect and take action. Community scorecards envisage the active involvement of the group and allow participants themselves to identify indicators of quality and performance.
Review of reports	Reports should be drafted and shared in a timely manner to provide all the researchers and appropriate stakeholders with sufficient opportunity to read, react to, provide feedback on, edit, revise, and provide input into relevant reports. Various formats will be required for different review platforms (e.g. Powerpoint presentations and/or narratives).

Risk management plan

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

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



Some examples of risks in a research project are:

Poor data quality.

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

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

Table 4: Mitigation activities for risks in a research project

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

Monitoring plan

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

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



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



"What Gets Measured – Gets Done".

Communications and advocacy plan

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

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

**IR RELATED
COMMUNI-
CATION AND
ADVOCACY**

SEE

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

Primary and secondary target audiences

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

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



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

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

Table 6: Illustration of a communication plan for secondary audience

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



REFLECTION ACTIVITY

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

Evaluation plan

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

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



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

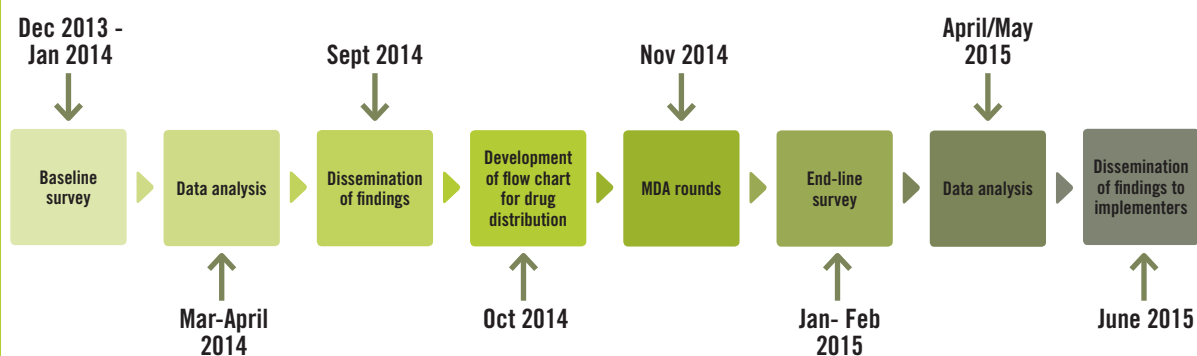
Background: Indonesia began its national lymphatic filariasis (LF) elimination programme in 2002, including conducting an annual mass drug administration (MDA) in endemic regions. By 2014, some regions had conducted at least five rounds of effective MDA and thus would qualify for Transmission Assessment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

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

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

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

Figure. Execution timeline for the overall project



Quality assurance:

To ensure quality of data:

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

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

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

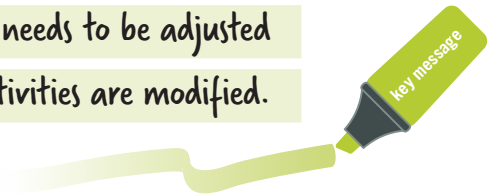
Source: Krentel A. et al. Improving coverage and compliance in Mass Drug Administration for the Elimination of LF in Two 'Endgame' Districts in Indonesia Using Micronarrative Surveys. PLoS Neglected Tropical Diseases. 2016; 10 (11): e0005027.



Project Monitoring Plan

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

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



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

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

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

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

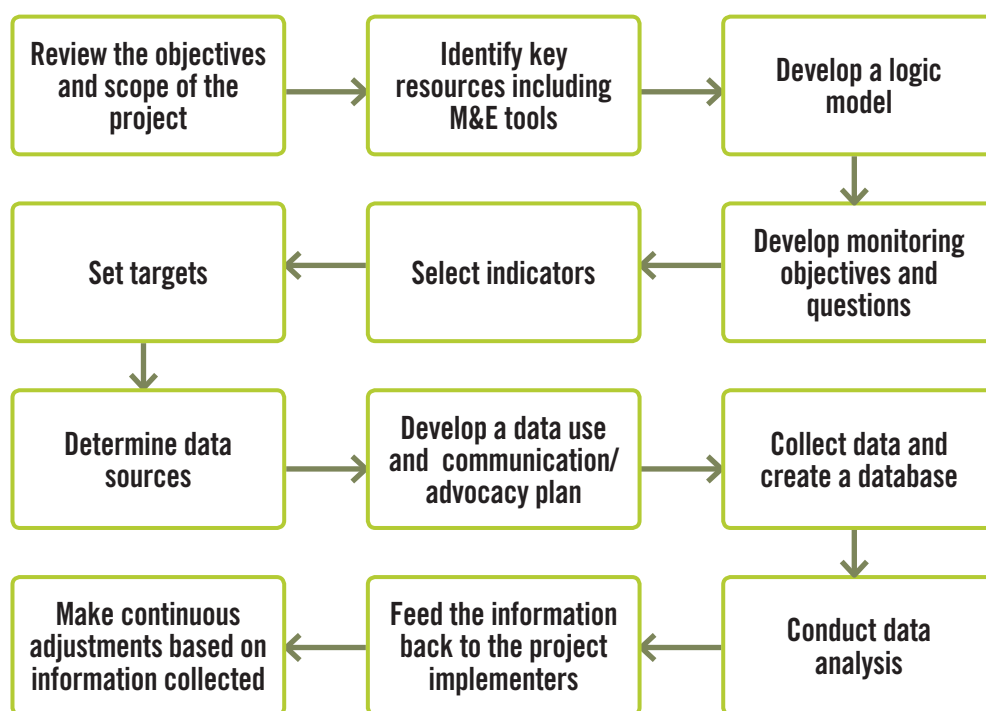
A set of useful key questions can help guide effective monitoring:

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

Key steps in developing a project monitoring plan

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

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



Reviewing the objectives and scope of the project

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



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

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

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



Case study 2

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

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

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

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

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

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

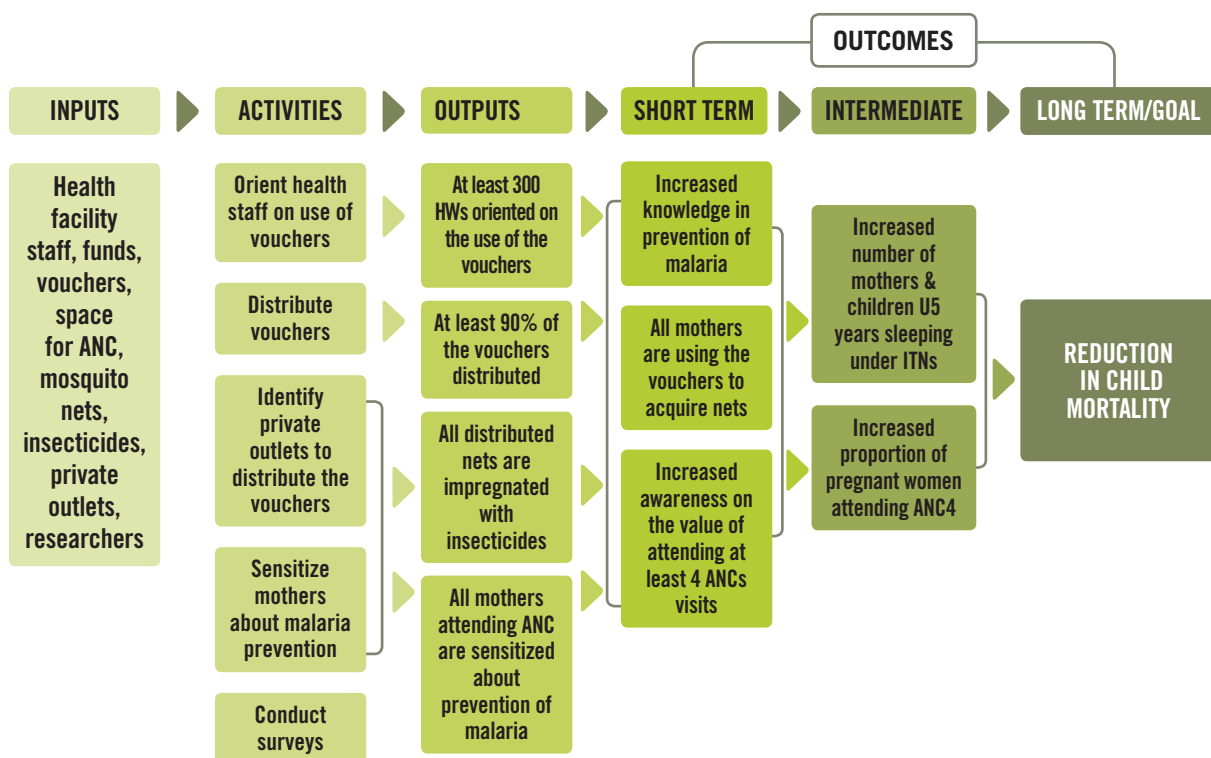
Source: Larson C.P., Saha U.R., and Nazrul H. Impact monitoring of the national scale up of zinc treatment for childhood diarrhea in Bangladesh: repeat ecologic surveys. PLoS Medicine. 2009; 6(11):e1000175.



Developing a logic model

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

Figure 5: Logic model of a research project



Assumptions relating to the external context



Definitions

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

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

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

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

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

Assumptions

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

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

Assumptions are of particular interest for IR because they are of specific relevance in relation to potential for replicating, scaling up or relocating the intervention in question. Some key questions to help improve the assumptions you document might include the following:

- Are the stated assumptions plausible in the existing context?
- How specific are the assumptions to the research context?
- Are there important implicit (unidentified) assumptions?
- What consequences might result from incorrect assumptions?
- During the course of the project, are any assumptions proven to be incorrect?

**REFLECTION ACTIVITY**

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

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

Developing Monitoring Questions

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

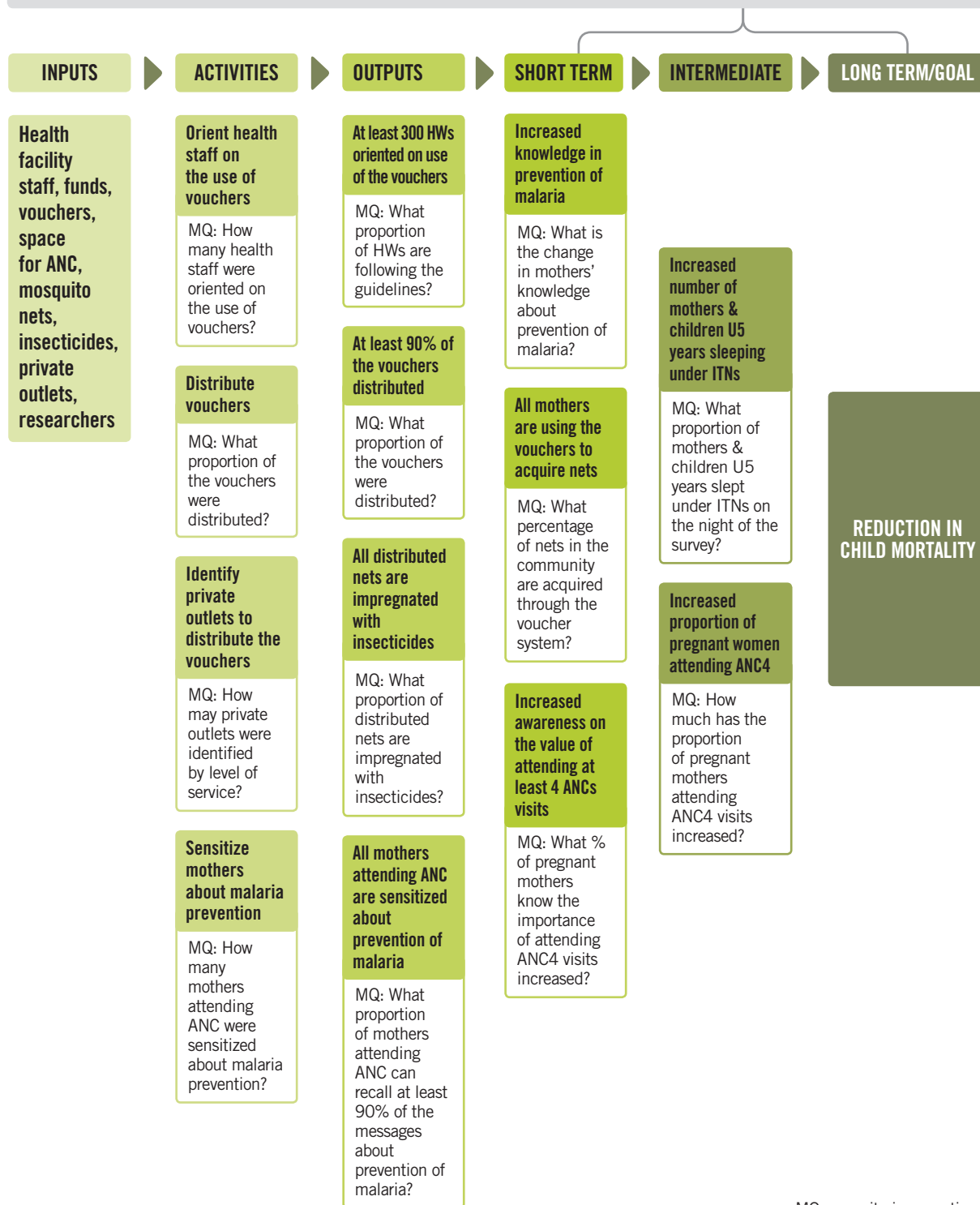
Identify the resources to implement the monitoring plan

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



Figure 6: Example of monitoring

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



MQ = monitoring question

**REFLECTION ACTIVITY**

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

Selection of key indicators

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



Table 8: Indicator matrix (example)

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



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

SMART questions and indicators facilitate monitoring.

key message



Setting targets

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

Establishing data sources, analysis and reporting systems

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

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

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



Examples of data collection for project monitoring purposes include:

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

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

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



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

key message



Data Use and Reporting

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

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



REFLECTION ACTIVITY

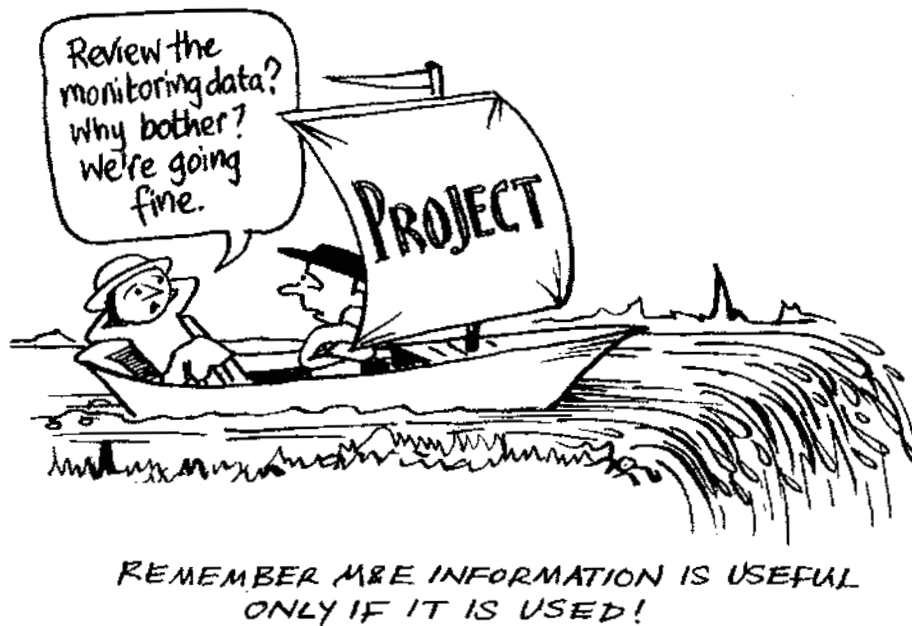
Develop a monitoring plan matrix for your research project. Include monitoring questions, indicators, data sources, data collection methods, how the findings will be disseminated, the target audience(s) for the respective findings and how these findings will be used.

Table 9: Illustration of data use and reporting plan

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



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



Project Execution

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

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

Starting execution of a research project

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

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

Case study 3 Analysis of constraints and facilitators of project execution

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

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

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



Case study 3 Analysis of constraints and facilitators of project execution

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



Case study 3 Analysis of constraints and facilitators of project execution

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

5. Usage characteristics

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

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

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



Monitoring Research Activities

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

Figure 9: Monitoring activities of a project

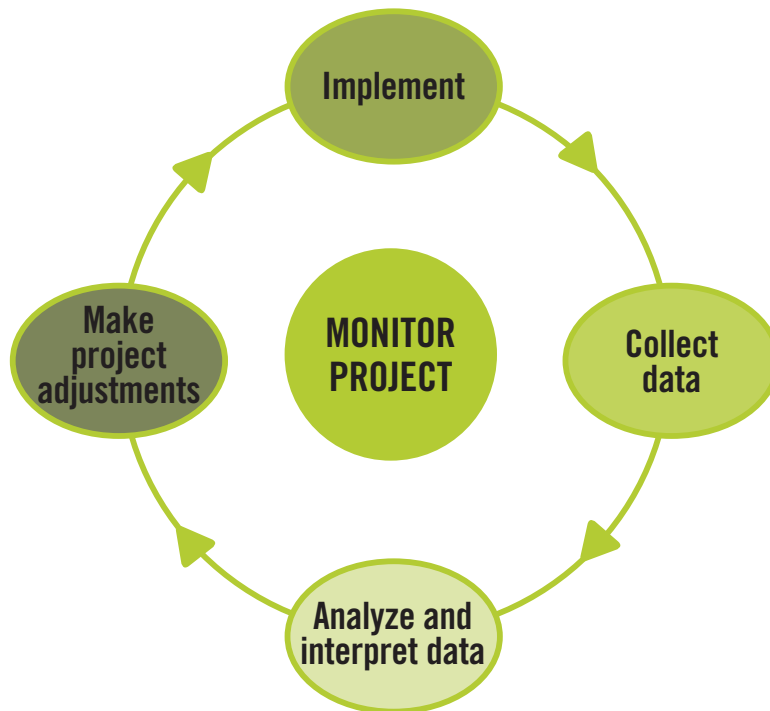


Figure 10: Parameters to monitor in a project



The monitoring process occurs in three stages, namely: i) checking and measuring progress; ii) analysing the situation; and iii) reacting to new events, opportunities and issues. These are described in detail below. Click on each of the headings to see details.

Checking and measuring progress

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

Analyzing the situation

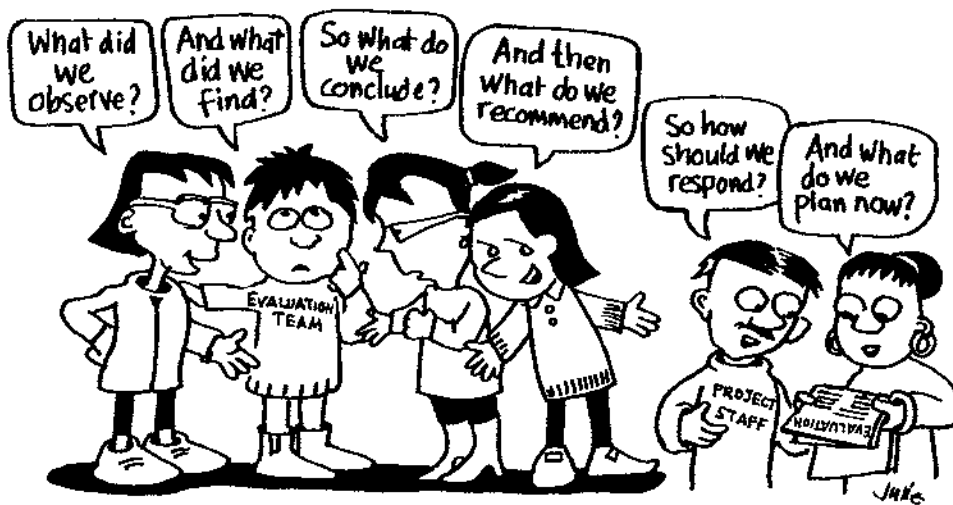
The second stage of monitoring consists of analyzing the situation. The status of project progress compared to the original plan – as well as causes and impacts of potential/observed deviations – are identified and analyzed. Actions are identified to address the causes and the impacts.

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



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

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



Reacting to new events, opportunities and issues

It is important to anticipate and react quickly to new situations, events, opportunities and issues, and to identify the possible actions to be taken. If appropriate, various options should be considered and discussed within the project team and a decision taken regarding the most appropriate action to take.

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

key message



Updating the project monitoring plan

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

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

Evaluation and closure of a research project

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

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

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



Every Project has a beginning and an end.



Ethical Issues

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

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

Ethical challenges associated with the review of IR protocols

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

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

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



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

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

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



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

Specific comments: Requires response and protocol amendments

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

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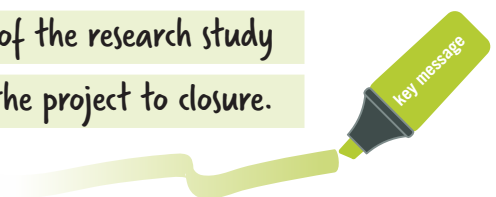
2.2.1	Under the section Participant Selection, please explicitly state that if the patient is a minor, then the interview will be conducted with her/his parents/caregivers.
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2.2.2	The consent form should reflect that children may be indirectly included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

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

It is important to consider the ethical aspects of the research study right from the initial planning stage of the project to closure.





Submission of the research protocol for ethical review

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

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

Table 11: Some documents to be submitted to ERCs

Cover letter briefly describing the research protocol and ethical issues involved, if any.
Full research protocol including rationale, research problem, literature review, methodology, data collection tools, procedures, budget and expected outcomes.
Analysis of potential risks and benefits, including protection of privacy and confidentiality.
Detailed human subject/participant recruitment process and target population.
Informed consent or assent for minors available in the local language.
Process of communicating the research findings to participants and communities.
Plan for addressing post-study obligations, such as: <ul style="list-style-type: none">• improvements in health care and facilities;• provision of new-proven interventions to participants;• long-term surveillance;• strengthening of local research expertise.
Curriculum vitae of the team leader/principal investigator and the other research team members.
Proposed dissemination of the study results.



Ethical practices during the execution of an IR project

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

Seeking informed consent

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

To have effective informed consent, the full information should be explained in the language of the participants. Furthermore, local/simplified words (i.e. rather than scientific and professional jargon) should be used. The consent form should also include information about the research, the procedure, expected outcomes and potential benefits as well as the consent certificate (see Table 12).



Table 12. Elements in an informed consent document

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

Privacy, confidentiality and anonymity

Protecting the anonymity and confidentiality of research participants is another practical component of research ethics. Disclosure of personal information may, in some circumstances, pose a risk of discrimination or prejudice. Research participants should have the right to remain anonymous and to have their rights to privacy and confidentiality respected. Protecting the privacy and confidentiality of participants is the investigator's responsibility.⁷ Protecting the anonymity and confidentiality of research participants involves adhering to ethical procedures during data collection, storage and analysis, as well as, during any subsequent publication process.



During data collection, the participant should be accorded as much privacy as possible to ensure that the information being provided is not shared with others without the participant's explicit permission. Unless the respondent gives their permission, at no time should the identity of the respondent be disclosed to any third party during data collection, storage or analysis, or even during dissemination or publication. The identity of the respondents may be associated with anonymous identifiers that cannot be linked to individuals. However, the standard of being anonymous throughout the lifecycle of the study may be a challenge, for example in situations where participants are measured at multiple time points (pre- and post-study) or where content of different databases (e.g. laboratory results and clinical records) need to be linked. Nevertheless, efforts should be made to guarantee the anonymity of all research participants.

Ethical clearance during the execution of an IR project

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

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



REFLECTION ACTIVITY

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

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

Anticipated responses:

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



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



Good Practices in Planning and Conducting IR

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

Documentation of processes

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

The following questions should underpin documentation of IR projects:

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

It is important to be objective when documenting processes, and to report both negative and positive experiences. This will facilitate learning and generate evidence to support previously anecdotal reports. Documentation of the various processes, adaptations, revisions and experiences that occurred and impacted the research will ensure that programme planners and policy-makers do not only receive the results of the study but also fully understand the process by which the results were obtained.

Training researchers

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

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



most up-to-date versions of the data collection tools and instruments. As with all research, IR carries a possibility of adverse events or unintended consequences arising as a result of the intervention. Adverse events can have a negative impact on the adoption and sustainability of the intervention, particularly when these events occur during the initial stage of implementing the project. Resistance to change, inertia and existing investment in the status quo – coupled with the inherently difficult and complex new task – may affect the adoption of a new practice.

Capacity building

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

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

UNDERSTANDING
IR

SEE

INTEGRATING
IR INTO HEALTH
SYSTEM

SEE

Continuous engagement with stakeholders

It is crucial to ensure that you gain stakeholders' trust so as to facilitate the implementation process and uptake of the research findings. The details of how stakeholders can be engaged is described in the Understanding IR and Integrating IR in the health system modules of this Toolkit.

Good practices during data collection

Pre-testing

In any research project, a pre-test is usually conducted to check the validity and reliability of a data collection tool. Pre-testing allows the research team to check whether the research instructions and questions are sufficiently clear, context specific, and that adequate time is provided to administer the questionnaire, etc.

RESEARCH
METHODS
AND DATA
MANAGEMENT

SEE

Data management

Collection and storage/documentation of accurately recorded and retrievable results are essential for any research. Good data collection practices will ensure that data can be traced to their source.

Data quality management

Data quality is key to having authentic and robust data. As such, it should be taken seriously. Activities such as staff training, support supervision and data feedback can be used to enhance the quality of data.



Data sharing

Data sharing is becoming mandatory in many fields as a way to ensure transparency, to avoid duplication and also reduce plagiarism. Since IR may involve different institutions/organizations, guidelines for data sharing and ownership should be clearly spelt out at the beginning of the project through formal agreements such as a memoranda of understanding. Data sharing should follow a clear process and can be done between research institutions (though not between individuals).

Communicating research findings

Communicating IR findings to relevant stakeholders must not wait until the closure of the project. On the contrary, in IR knowledge transfers and translation is an integral part of the research process and takes place throughout the project life cycle. Communication should be through appropriate communication channels, formats and language to targeted audiences. It should be timely and the information should be used to contribute to the improvement of health service delivery. Details are described in the IR related advocacy and communication module of this Toolkit.

Continuous monitoring and feedback

Continuous monitoring and feedback should be embedded in the project life cycle and the information generated should be fed back into the health system to inform the process for action. The details are discussed in the Integrating IR in the health system module of this Toolkit.

SEE**IR-RELATED
COMMUNICATIONS
AND ADVOCACY****SEE****INTEGRATING
IR INTO HEALTH
SYSTEM**



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