10 TIPS ON IMPLEMENTATION RESEARCH FOR DECISION MAKERS IN LOW- AND MIDDLE-INCOME COUNTRIES

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Ten Tips for Conducting Implementation Research

Why conduct implementation research?

Health interventions often do not fully achieve their intended results, especially in low- and middle-income settings facing complex challenges. Implementation research (IR) provides evidence that health decision makers can use to:

- Understand what is and is not working in implementing health programs
- Uncover and adapt to the contextual factors affecting implementation success
- Test approaches that ensure people receive needed health interventions

Implementation research can help stakeholders solve implementation challenges and identify needed programmatic adaptations to maximize results, using context-specific research findings. Moreover, IR can produce timely findings that provide good value for the money when used to improve the effectiveness of program interventions, and in turn, improve health outcomes. Findings are generally relevant to, and used by, policymakers, program managers, practitioners, and donors.

What are the IR Tips?

The IR Tips include ten briefs laying out the most important considerations for planning and conducting IR that achieves the study objectives and generates actionable findings.

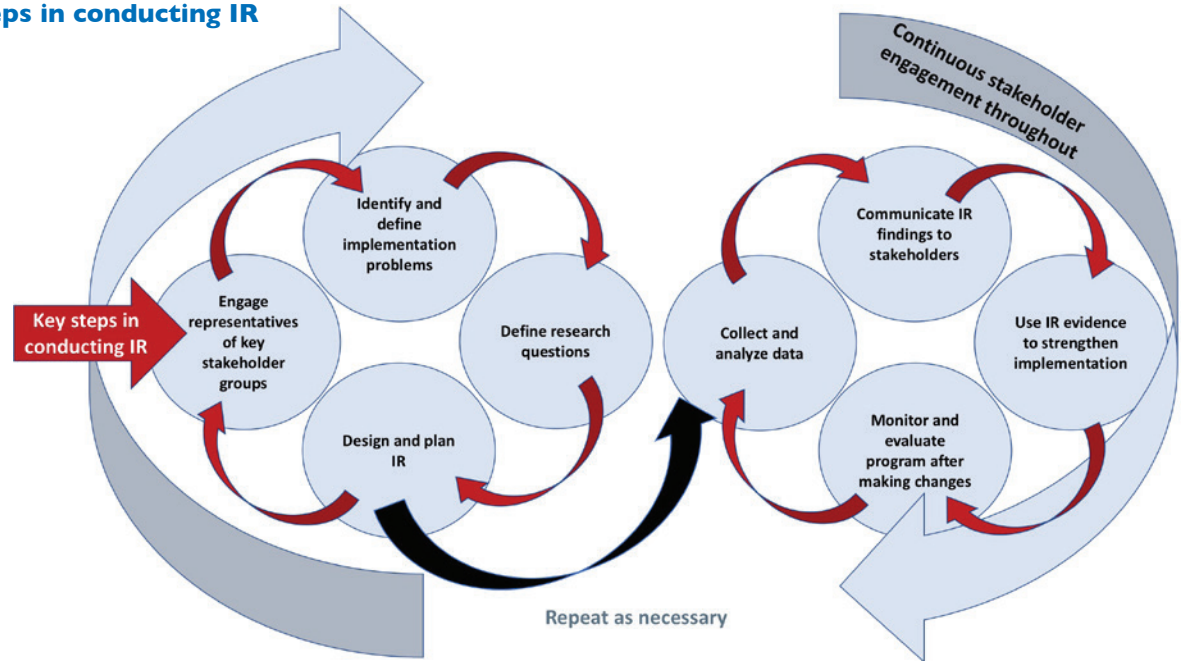
Who is the audience for the IR Tips?

These IR Tips were written for program planners and implementers in low- and middle- income countries who are planning to conduct IR or trying to decide whether IR is needed.

How can the IR Tips be useful to you?

The IR Tips are intended to guide decision makers to follow a systematic set of steps for conducting IR (see Figure), providing links to helpful resources along the way. Each IR Tip uses case examples to illustrate the material presented and includes links to guidance documents and planning tools to support the design and/or implementation of IR or the dissemination and use of study findings.

Key steps in conducting IR



Overview of the content of the IR Tips

	**IR Tip #1 - Introduction to IR: Real-time evidence to save lives** ▸ IR focuses on processes and outcomes of program implementation, addresses challenges and bottlenecks, and involves relevant stakeholders ▸ IR allows decision makers to apply evidence from research conducted locally to solve problems at all levels of the health system ▸ IR leads to more effective implementation
	**IR Tip #2 - How does IR work?** ▸ IR distinguishes between the intervention and the strategy used to implement it ▸ IR processes should be flexible and adapt to the complexity of local contexts ▸ Successful IR generates evidence that is used to improve implementation
	**IR Tip #3 - When to use IR** ▸ IR can be useful in some situations while other methods to strengthen programs may be more appropriate in other situations ▸ IR studies can vary greatly in size, scope, and cost and range from informal to very formal ▸ IR processes can be integrated with ongoing program or policy cycles or other data collection efforts
	**IR Tip #4 - Problem identification to guide IR** ▸ Reviewing and comparing existing data helps clarify the magnitude of an implementation problem ▸ Engaging diverse stakeholders helps to identify and clarify implementation problems ▸ Regular data review processes provide an opportunity to identify implementation challenges that would be good for further investigation
	**IR Tip #5 - Engaging stakeholders to form an IR partnership** ▸ Effectively engaging a diverse range of stakeholders contributes to a stronger IR effort and ensures that all relevant perspectives are included throughout the IR process ▸ Stakeholders can inform the IR methodology, contribute to data collection, help interpret and disseminate results, and support scale-up efforts ▸ An IR partnership should balance program knowledge, technical skills, decision-making, influence, and stakeholder representation
	**IR Tip #6 - Formulating IR questions** ▸ IR answers why or how an implementation is (or is not) working ▸ IR can address many challenges you may be facing ▸ IR gives priority to questions that are urgent, actionable and can improve operations
	**IR Tip #7 - Selecting and using a framework to guide IR** ▸ A framework provides a roadmap for the development, management, and evaluation of interventions or implementation strategies ▸ Selection of an appropriate IR framework and the fine-tuning of the research objectives/ questions often occur iteratively ▸ Frameworks should guide all phases of the research process from start to finish
	**IR Tip #8 - Research design methods and ethics** ▸ Choice of study design for conducting your IR study depends on the research objectives and questions ▸ Understanding the ethical considerations and challenges related to IR is important during all phases of the study
	**IR Tip #9 - Process documentation** ▸ Process documentation records how and why 'changes' are happening during implementation of intervention strategies and provides real-time reflection on the project's theory of change ▸ Enhances learning around an intervention strategy's context, systems, conditions for and drivers of change ▸ Provides critical information for adapting and scaling effective intervention strategies
	**IR Tip #10 - Translating learning for action** ▸ Dissemination of learning in real-time strengthens implementation, builds acceptance of change, ensures ownership, and can result in more sustained uptake ▸ Adaptive management helps systematize use of learning and respond to changes in the local context ▸ Multiple tools and approaches to translating and sharing learning must be matched with stakeholder audiences to communicate most effectively and to increase and accelerate impact

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IR TIP #1: INTRODUCTION TO IR: REAL-TIME EVIDENCE TO SAVE LIVES

INTRODUCING IMPLEMENTATION RESEARCH

Imagine that you are the national program manager for newborn health in an African country where newborn mortality is unacceptably high. Published research from Bangladesh has shown that providing postnatal home visits (PNHVs) to newborns can reduce newborn mortality. Three years ago, your department designed an implementation strategy to deliver PNHVs and scaled it up nationally. Routinely collected monitoring and evaluation data show that health workers report making PNHVs to most newborns. However, a recent survey revealed that neonatal mortality has not fallen. You wonder why your intervention has not achieved expected results. What can you do? Implementation research (IR) can help you find some answers.

WHAT IS IR AND WHAT DOES IT HELP US TO DO?

Implementation research is a systematic approach to understanding problems related to program implementation, then identifying and testing possible solutions in an adaptive or iterative process. **In IR, we study how to ensure interventions are successful by understanding and mitigating implementation challenges.** Implementation research recognizes that bottlenecks to achieving desired health outcomes are often found in the processes of program implementation. Therefore, IR focuses on identifying critical implementation problems in a setting, investigating why and how an intervention is—or is not—achieving good results, and then empowering decision makers to use the findings to adapt programs, solve problems, and improve population health (**Box 1.1**).

Box 1.1: IR can help decision makers to:

- Understand root causes of implementation problems
- Develop and test solutions to overcome problems
- Improve quality, effectiveness, and efficiency of programs
- Promote equity in service delivery
- Make sure that effective interventions are scaled up
- Establish successful and sustainable implementation

The "know-do gap" is the difference between the research-based results that we "know" can be achieved and the result that we achieve when we "do" the intervention. Implementation research is one way to understand the reasons for the "know-do gap" and find ways to overcome it, translating knowledge into action and improved programs.

HOW DOES IR LEAD TO MORE EFFECTIVE IMPLEMENTATION?

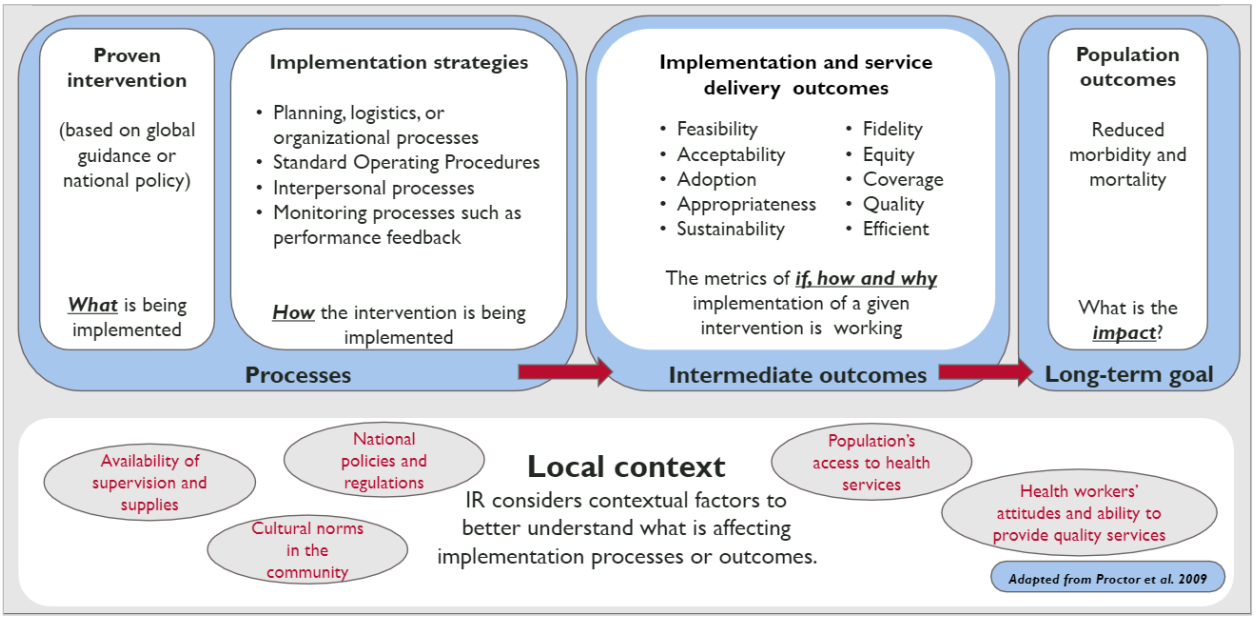
Why do health interventions like postnatal home visits that are proven to save lives in one setting fail to achieve similar results when they are implemented elsewhere? Why do some programs not perform as well as we thought they would (see **Box 1.2** for examples)?

Implementation research can help answer these questions by taking a critical look at the processes involved in implementing a program or policy, taking into consideration the importance of context. Implementation research investigates *how* these processes are carried out and what their effect is in a setting, helping to identify where the problems are. Like other research approaches, IR can help to answer questions of effectiveness, but its strength lies in uncovering why there are problems with implementation and how local factors affect implementation. This information can guide program managers as they develop locally appropriate, feasible, and effective strategies to overcome problems with implementation. **Figure 1.1** illustrates the focus of IR on studying contextual factors as well as implementation processes and outcomes to allow us to better understand why and how implementation succeeds or fails.

Box 1.2: Programs with implementation problems

- Monitoring data show that many pregnant women do not make all recommended antenatal visits
- Client surveys show that many women are not satisfied with family planning services
- Trained health workers resist shifting certain tasks to community health workers

Figure 1.1: Going from a "proven intervention" to improved population health: Issues or topics studied by IR to better understand implementation



WHEN IS IT APPROPRIATE TO ADOPT AN IR APPROACH?

Most decision makers are comfortable and familiar with monitoring and evaluation (M&E) of health program implementation. Simply put, monitoring is an ongoing process of counting, tracking, and collecting routine data that measure progress toward achieving program objectives over time. Is the program reaching the target group? Is the program being implemented as planned? Monitoring can be used to identify where activities may need to be adjusted during the intervention. Evaluation is the process to assess if a program has met its objectives by collecting data at the beginning and end of a program to see if certain indicators have changed. IR is a critical tool that should be used in conjunction

with routine M&E efforts because it embodies the key practices of real-time inclusive planning and data-driven solutions and it engages the key actors in the process of generating knowledge to answer a specific research question about the implementation outcomes.

While IR can be very useful in some circumstances, it may be neither necessary nor relevant in others. The first step in determining when IR is appropriate for your situation is to describe the problem by reviewing available data (see IR Tip #4). **Box 1.3** outlines key questions that a decision maker should consider before advocating for an IR approach. See IR Tip #3 for additional guidance on deciding if IR is appropriate for your situation.

Box 1.3: Questions to consider before deciding to conduct IR

- **Nature of problem:** Is the problem a divisive or controversial issue that will be difficult to change? Is the problem related to how an existing intervention is implemented?
- **Timing:** Do you have the time to develop and carry out the research?
- **Receptivity to research evidence:** Are key stakeholders open to using research evidence to inform decision making to improve implementation? Do they appreciate the value of IR? Do they accept that the iterative process of IR with regular "reflections" or reviews may take longer?
- **Availability of resources:** Do you have adequate financial and human resources to conduct the research and implement corrective actions as issues are identified?

WHAT ARE THE KEY STEPS IN CONDUCTING IR

While there is no single "correct way" to conduct IR, the action steps generally include the following:

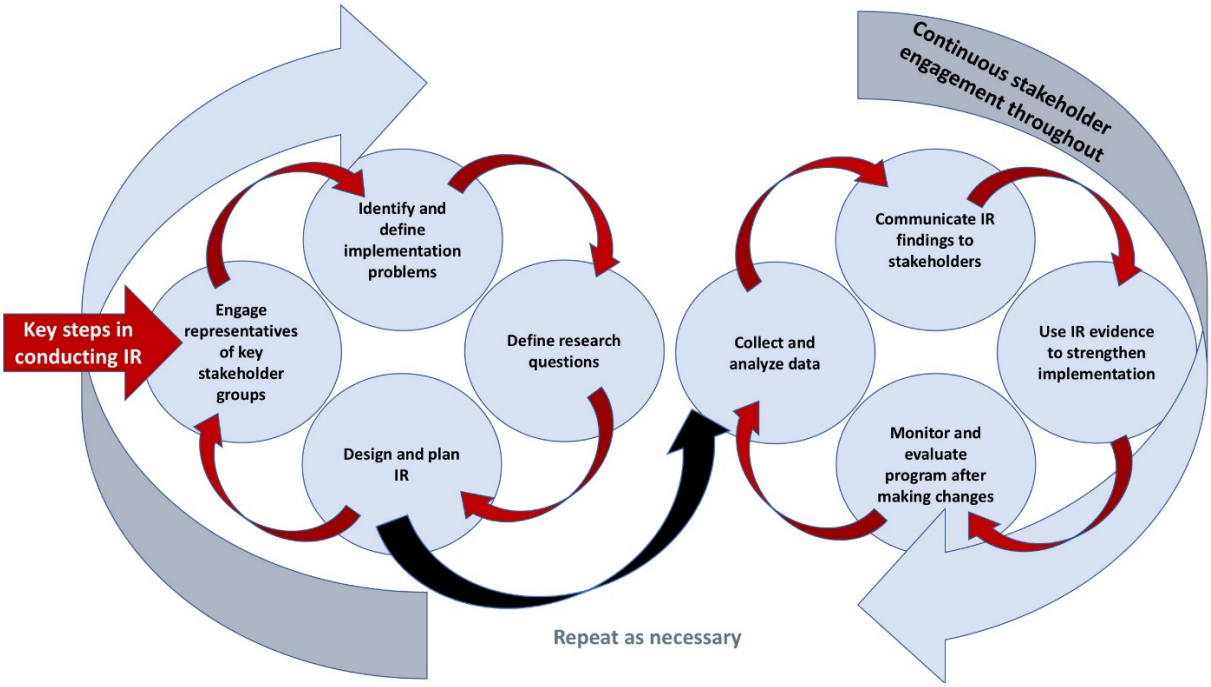
- **Engage key stakeholders** at the beginning and then throughout the IR initiative (see IR Tip #5)
- **Identify and define the priority implementation problems** that the IR will focus on (see IR Tip #4)
- **Define the research questions** (see IR Tip #6)
- **Design and plan** for the IR with key stakeholders (see IR Tip #6, IR Tip #7, and IR Tip #8)
- **Collect and analyze data** from the IR and document the findings to support decision making (see IR Tip #9)
- **Communicate** findings to stakeholder community (see IR Tip #10)
- **Use IR evidence** to develop solutions to improve implementation
- **Continue** to assess as part of routine M&E efforts
- **Repeat** this process as necessary

Box 1.4: Smallpox: An IR success story

Smallpox was eradicated by one of the most successful global health campaigns ever conducted. At one point during the campaign, a shortage of the smallpox vaccine in Nigeria threatened the mass vaccination strategy. Implementation research was used to test a different strategy of "ring vaccination" that targeted areas where new smallpox cases were reported. Ring vaccination contained the outbreak within a short time frame and has since been adopted across the region and worldwide. Most recently, it helped to contain the Ebola outbreak in Guinea (Theobald 2018).

These actions can be pursued efficiently with a strong partnership of implementers, researchers, and policymakers even in the most challenging circumstances. IR is iterative so the processes can overlap, changes can be made at any time, and using the results to strengthen implementation can lead to a new cycle of discovery (**Figure 1.2**).

Figure 1.2: Key steps in conducting IR



KEY TAKEAWAYS

- IR focuses on processes and outcomes of program implementation, addresses challenges and bottlenecks, and involves relevant stakeholders
- IR allows decision makers to apply evidence from research conducted locally to solve problems at all levels of the health system
- IR leads to more effective implementation

KEY RESOURCES

Health Systems Global. (2014) Statement on advancing implementation research and delivery science.

MEASURE Evaluation Implementation Research Technical Working Group. (2015) Fundamentals of implementation research.

Peters DH, Tran NN, Adam T. (2013) Implementation research in health: A practical guide.

World Health Organization. Implementation research toolkit.

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Peters DH, Tran NT, Adam T. (2013) Implementation research in health: a practical guide, Geneva: World Health Organization.

Proctor EN, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. (2009) Implementation research in mental health services: An emerging science with conceptual, methodological, and training challenges. Adm Policy Ment Health Jan;36(1):24-34.

Theobald S, Brandes N, Gyapong M, El-Saharty S, Proctor E, Diaz T, et al. (2018) Implementation research: new imperatives and opportunities in global health**,** The Lancet 392(10160):2214.

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IR TIP #2: HOW DOES IR WORK?

HOW DOES IR WORK?

Some health officials assume that if they introduce an evidence-based intervention—an intervention that has been proven to work through rigorous research and which is highly recommended by experts globally—that the health of the population will improve. They may not appreciate that the success of the intervention is dependent upon the implementation strategy used as well as the local context within which it takes place. They are then surprised when the intervention—due to problems with implementation—does not achieve the expected outcome (or has unintended consequences). Implementation research (IR) can improve the health of populations by strengthening the delivery of health interventions through routine services. Implementation research is especially useful for improving the implementation of interventions that—for unknown reasons—are not achieving expected outcomes.

THE DIFFERENCE BETWEEN AN INTERVENTION AND AN IMPLEMENTATION STRATEGY

Realizing the difference between an intervention and an implementation strategy is crucial to understanding how IR works (**Box 2.1**). In simple terms, the intervention is what you do, and the implementation strategy is how you do it. For example, research has shown that providing high-dose Vitamin A supplementation (VAS) to children twice a year can reduce under-five mortality significantly. VAS is thus the intervention. If a Ministry of Health takes a decision to introduce VAS, it will need to develop implementation strategies to deliver Vitamin A to children. There are many different ways to deliver this service, and depending on the local context, some will be more effective than others. We know that the VAS intervention can save lives—but if program managers find that the intervention is not achieving its expected outcomes, then IR can help them understand why.

Box 2.1: Intervention vs. implementation strategy

An **intervention** is a practice or service—usually evidence-based—that has been shown to be effective in ideal conditions. A clinical intervention may include a technology, innovation, or product (e.g., a vaccine). A public health intervention may include policies, programs, or practices intended to improve health care (e.g., a program to provide vaccines to children).

An **implementation strategy** is the approach used to implement the intervention or deliver its services (e.g., conducting a mass vaccination campaign, or providing vaccines at health facilities or in outreach clinics).

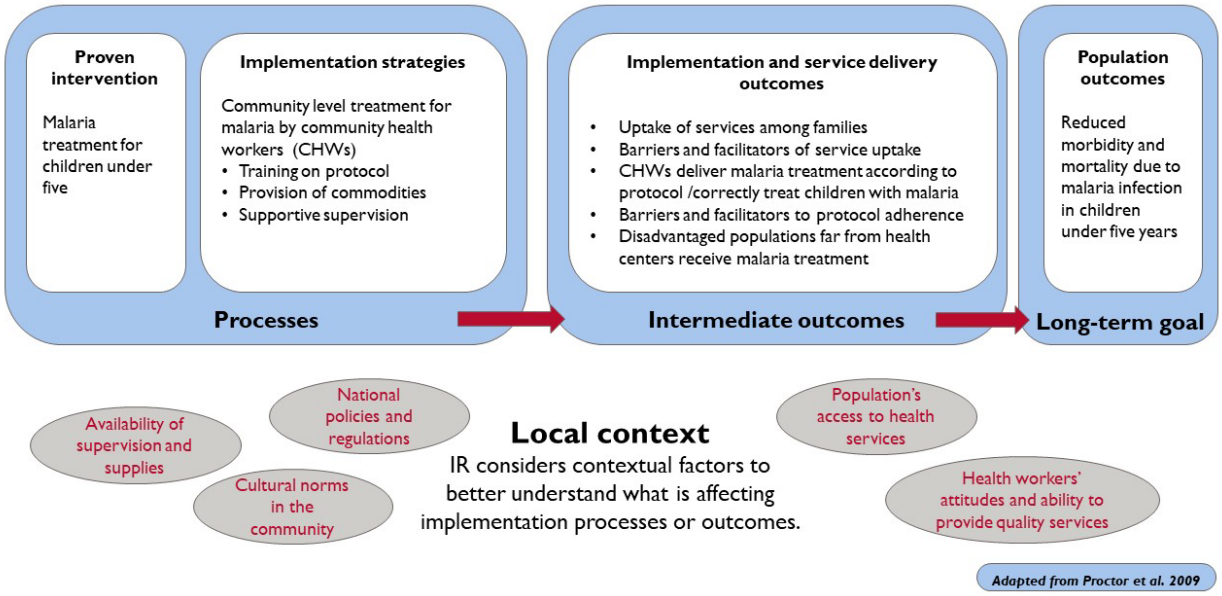
Implementation research's focus on implementation strategies (i.e., processes), implementation outcomes, and contextual factors is part of what differentiates it from other investigative techniques such as program evaluations or clinical trials, which often focus on higher-level outcomes such as population outcomes (i.e., impact). The focus on implementation processes and outcomes is similar to the focus in quality improvement. See IR Tip #3 to learn more about how IR compares with other commonly used methods to assess and strengthen health programs.

UNDERSTANDING HOW IR WORKS

We can better understand the IR process with a model of how IR can be used in the programming cycle to strengthen implementation and improve health outcomes. **Figure 2.1** shows the processes, outcomes, and goals related to the introduction and implementation of a health intervention within a specific local context. Typically, an intervention that has been shown to improve health outcomes in one context is introduced in a new environment using a specified implementation strategy ("processes" in **Figure 2.1**). Implementing this strategy leads to implementation and service delivery outcomes ("intermediate outcomes") which should then lead to positive population outcomes ("long-term goal"). While IR can be used to investigate the long-term goal, it typically concentrates on the implementation strategy as well as the relevant implementation or service delivery outcomes within a given context. **Figure 2.1** uses the delivery of malaria treatment for children under five as an example of these processes and outcomes for IR. Finally, IR does not truly "work" until its results have been used to change problematic policies and practices—changes that will usually take time to have a positive effect on the health of the population. Implementation research can produce information that:

- Shows whether an intervention is being implemented as planned
- Reveals contextual factors that affect implementation in the local setting
- Indicates which of two implementation strategies is more effective in a context
- Identifies aspects of the implementation strategy that may need to be adapted when scaling up the intervention

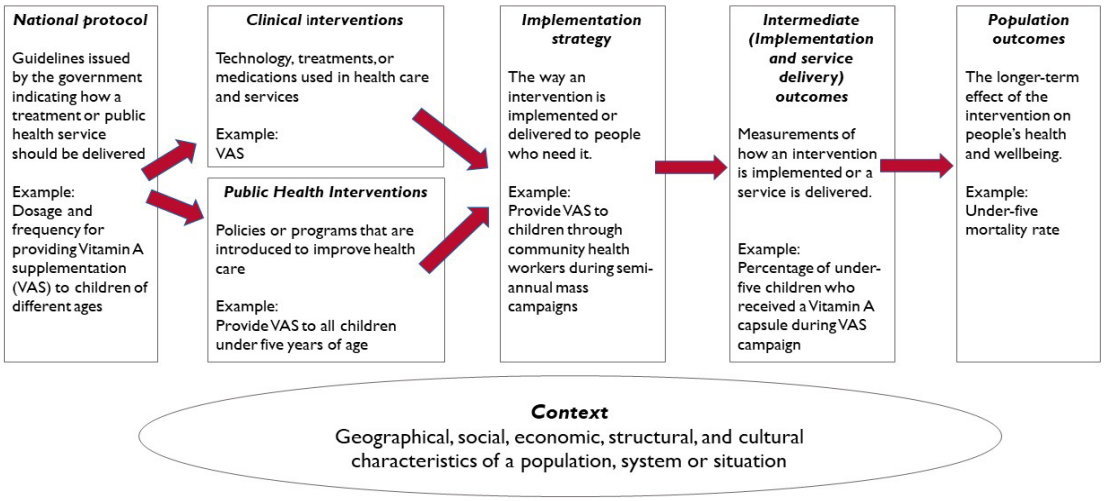
Figure 2.1: Going from a "proven intervention" to improved population health: How IR might inform implementation of an intervention to address malaria



DEFINING KEY TERMS ALONG THE CAUSAL PATHWAY

Defining specific terms can help understand how IR works. **Figure 2.2** uses a graphic format to explain the meaning of some of the terms that we use most often when discussing IR.

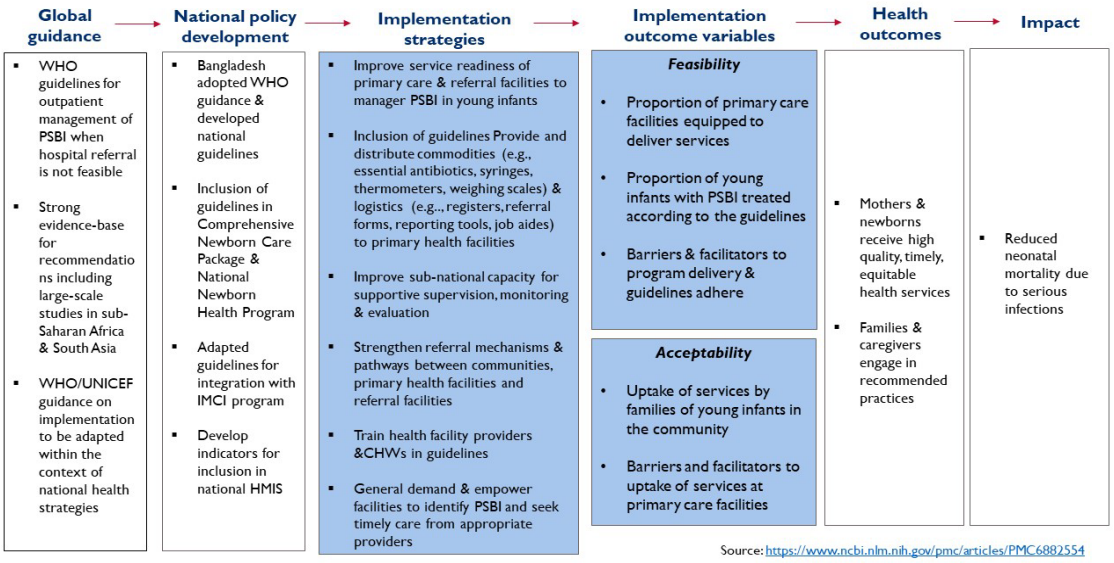
Figure 2.2: Key terms used in IR along the Causal Pathway



HOW IR WORKS: CASE STUDY OF AN INTERVENTION TO MANAGE POSSIBLE SEVERE BACTERIAL INFECTION

Building on the discussion above, the figure below presents the treatment of young infants for possible severe bacterial infection (PSBI) within a conceptual framework for IR to illustrate how Bangladesh used global guidance to develop national policy and then designed implementation strategies—which could be measured through indicators of implementation outcomes—that were intended to lead to improved health outcomes and population impact.

Figure 2.3: Conceptual framework for MaMoni Health Systems Strengthening Implementation Research case study



Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6882554

Implementation research focuses on the two blue columns in the center of the figure—implementation strategies and implementation outcome variables. Implementation research "works" in this example by identifying the implementation strategies that were used and developing variables, indicators, and domains to measure implementation outcomes that were critical steps toward improved health outcomes and impact. Examples of variables that measure feasibility and acceptability can be found in the framework. **Table 2.1** includes examples of other variables that can be measured using IR in the context of PSBI.

Within the context of this PSBI case study, how does IR help government officials and their partners to strengthen the PSBI intervention? By exploring issues such as service readiness at health facilities, capacity for and conduct of supervision, and PSBI training status of health workers and community health workers (CHWs), IR can show the extent to which the intervention was implemented as planned. Reviewing activities to generate demand for PSBI services among the community, and then comparing those findings with community perceptions regarding the PSBI service, will provide insights into contextual factors that affect implementation. Finally, a broad analysis of the study findings will reveal parts of the implementation strategy that not only should be strengthened in the study area, but also that will need to be adapted when scaling up the intervention elsewhere.

This case study illustrates how IR can be used to explore different aspects of implementation that may have a significant effect on health outcomes. By reviewing the different measures and variables that IR focuses on, we can better understand not only "how IR works" but also appreciate the power of IR to unpack the complexities of implementation.

Table 2.1: Measuring the outcomes of an implementation strategy

MEASURES	QUESTIONS TO ASK	OUTCOMES: PSBI TREATMENT EXAMPLE
OUTCOMES OF THE IMPLEMENTATION STRATEGY		
Appropriateness	Was the strategy suitable for the community, the health system, and the environment?	Health worker, CHW, and community members feelings and perceptions regarding how PSBI was treated
Adoption	Did CHWs treat PSBI?	Percentage of CHWs that treat PSBI
Feasibility	Was PSBI put into practice?	See **Figure 2.3** above
Acceptability	Did the community have confidence in and agree with PSBI as an approach?	See **Figure 2.3** above
SERVICE DELIVERY OUTCOMES		
Fidelity	To what extent did health workers and CHWs follow PSBI treatment guidelines?	Percentage of PSBI cases treated according to the national protocol
Equity	To what extent were disadvantaged groups reached during PSBI treatment provision?	Percentage of PSBI cases that came from disadvantaged groups compared to percentage in the population
Coverage	To what extent did all young infants with PSBI receive treatment (by CHWs)?	Percentage of anticipated cases of PSBI that received treatment (by CHWs)

SUMMARY: PUTTING IR INTO PRACTICE

Programs and interventions that work well in one setting can fail elsewhere (even within the same country) because of differences in the local context. Implementation research can help identify problems with the implementation strategy and suggest solutions that should lead to improved implementation outcomes—and, eventually, better population outcomes. Implementation research does this in part by revealing contextual factors that affect implementation. These can include political, economic, cultural, geographic, and structural considerations such as human resources.

KEY TAKEAWAYS

- IR distinguishes between the intervention and the strategy used to implement it.
- IR focuses on implementation strategies and their intermediate outcomes.
- IR processes should be flexible and adapt to the complexity of local contexts.
- Successful IR generates evidence that is used to improve implementation.
- Changes in implementation strategies based on IR studies often take time to achieve. measurable change in population outcomes.

KEY RESOURCES (see also *Key Resources* from IR Tip #1: Introduction to IR)

Proctor E, et al. (2011) Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda, *38*(2):65–76.

Proctor EK, et al. (2009) Implementation research in mental health services: An emerging science with conceptual, methodological, and training challenges. Adm Policy Ment Health 36(1):24-34.

Theobald S, Brandes N, Gyapong M, El-Saharty S, Proctor E, Diaz T, et al. (2018) Implementation research: New imperatives and opportunities in global health**.** The Lancet 392(10160):2214-228.

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IR TIP #3: WHEN TO USE IR

WHEN TO USE IR TO ADDRESS IMPLEMENTATION CHALLENGES?

Picture yourself as the Director of Reproductive Health (RH) in the Ministry of Health. A recent survey showed that women often wait many months following delivery to resume family planning and that birth spacing (or interpregnancy interval) is lower than what is considered optimal. The RH Technical Working Group wants to strengthen post-partum family planning services to address this problem. What is the best way to do this? Should you consider implementation research (IR)? Would quality improvement, program evaluation, or a collaborating, learning, and adapting (CLA) approach be a better choice? What do these terms all mean, and how do they differ from each other? We can use various approaches to strengthen programs that are not performing well. Implementation research is one of these approaches, but IR is not always the best way forward. This IR Tip will explain how IR compares to other approaches to address bottlenecks and when it is appropriate to use IR.

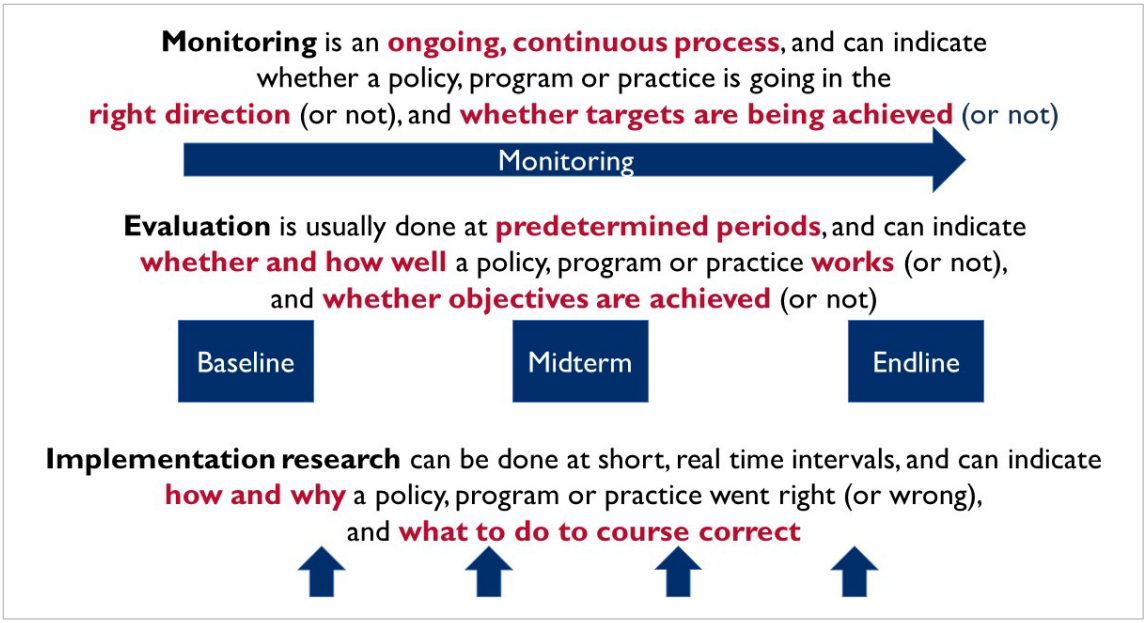
HOW DOES IR COMPARE WITH OTHER APPROACHES TO ADDRESSING PROGRAM CHALLENGES?

Comparing IR with other methods to strengthen programs should begin with accepted definitions of implementation and implementation research (see **Box 3.1** for definitions of the two terms). There is relative consensus on the definition of implementation; however, there are varying definitions of IR. Implementation research also tends to overlap with or include some related methods in these definitions. For example, in the situation of a program intended to improve maternal and neonatal outcomes, measuring the quality of antenatal care (ANC) can be applied both in quality improvement as well as in IR. Likewise, data from an end line survey in a program evaluation of maternal care could be used to identify problems with timeliness of ANC that could then be used as part of an IR study to strengthen the effectiveness of messaging to community members regarding ANC. **Table 3.1** describes several methods that are frequently used to assess and address program challenges. While the purpose of these strategies is focused on program improvement, the purpose of IR is to generate generalizable or contextually specific knowledge about a specific research question that should lead to program or policy development or change. **Figure 3.1** presents how these two purposes are complementary by illustrating the relationship between IR and routine monitoring and program evaluation (M&E) and the value added of IR to the M&E that has become a mainstream component of most health program efforts.

Box 3.1: Implementation and implementation research definitions

- "**Implementation** [is] the act of carrying an intention into effect…which can be policies, programmes, or individual practices (collectively called interventions)." (Theobald 2018)
- "**Implementation research** is the scientific inquiry into questions concerning implementation." (Theobald 2018)

Figure 3.1: The relationship between routine monitoring, program evaluation and IR



Using the ANC example above, program evaluation data collected might reveal that the program is not reaching the targeted beneficiaries and/or not being implemented as intended (process evaluation), and the expected results are not being achieved (outcome evaluation). By engaging stakeholders in a process of inclusive planning and review of program evaluation data, an IR question can be formed that seeks to generate knowledge as to why the program is not meeting expectations. For instance, IR might seek to understand if the implementation strategy being used is feasible in this setting or if it is acceptable to community members. Implementation research might test two or more different implementation strategies for improving outcomes. Implementation research supports a deeper understanding of the context when embedded within existing routine monitoring and program evaluation.

Table 3.1: Commonly used methods to assess and address implementation challenges

PURPOSE	SCOPE	EXAMPLE FOR ANC VISITS
ROUTINE MONITORING		
Counts or tracks indicators of program performance and measures progress toward achieving targets over time.	Involves ongoing collection of routine data that measures progress toward achieving objectives using pre-established indicators. Can reveal implementation problems that may require IR. Can be used to measure progress and results of IR.	By counting clients seen and collecting data on them, monitoring data can be used to measure the percentage of pregnant women (PW) receiving four timely ANC visits.
Collaborating, Learning and Adapting		
USAID's approach to organizational learning and adaptive management.	A set of practices that support strategic collaboration, continuous learning, and adaptive management throughout the Program Cycle. Learning includes data from	Periodic reflection with partners to identify successes, challenges, and learning questions. Acting on reflections with adaptive management

PURPOSE	SCOPE	EXAMPLE FOR ANC VISITS
	monitoring, portfolio reviews, stock takings, research findings (***including IR***), evaluations, analyses, and knowledge gained from experience.	approaches and finding answers relevant to decision making.
QUALITY IMPROVEMENT		
Formal assessment of performance and systematic efforts to improve it. Essential to enhancing patient experiences/outcomes as well as improving provider experience.	Supply-side program approach using a Plan-Do-Study-Act cycle. Utilizes both routine monitoring of service delivery and periodic assessments to focus on intervention-specific problems in individual sites. Can reveal problems that may require IR or be used as a method within IR.	Use record review or direct observation of care to measure percentage of PW who received all recommended services during ANC visits (i.e., assess adherence of service delivery to standard of care and responsiveness to patient).
PROGRAM EVALUATION		
PROCESS EVALUATION		
Assesses whether program met its objectives, focusing on processes.	Answers process questions related to who, what, when, and where the program was implemented. Can reveal problems that may require IR. Is an important component of effective IR.	Use program data to measure if the program was implemented as planned (e.g., did it reach the targeted number of PW? Did it implement the activities it set out to do?)
OUTCOME EVALUATION		
Assesses whether program met its objectives, focusing on outcomes.	Focuses on results—measures the direct effects of program activities on targeted recipients. Can reveal problems that may require IR.	Use survey data to measure change in percentage of PW satisfied with ANC care from before to after implementation.
HEALTH SERVICE PROVISION OR HEALTH SYSTEM PERFORMANCE ASSESSMENTS		
Diagnoses health service/system capacity and identifies solutions.	Focuses on "readiness" for service delivery (e.g., technical capacity) or health system domains (e.g., health workforce). Can identify problems with systems/services that may require IR.	Use survey data to measure percentage of health facilities with equipment to conduct blood tests.
IMPLEMENTATION RESEARCH (IR)		
Explores how or why a program functions to inform policy or program development or change.	Focuses on processes and outcomes of implementation, with varying scope depending on setting context.	Use IR data to measure timeliness and quality of ANC in outreach clinics vs. formal health facilities.

WHEN SHOULD YOU USE IR?

Program managers normally review data to identify problems in health programs. These data may come from routine monitoring, recent studies (e.g., quality of care studies or program evaluations), surveillance systems, or even implementers' knowledge regarding the program. Depending upon the problem and its context, the best way forward will depend on key considerations including available resources and time.

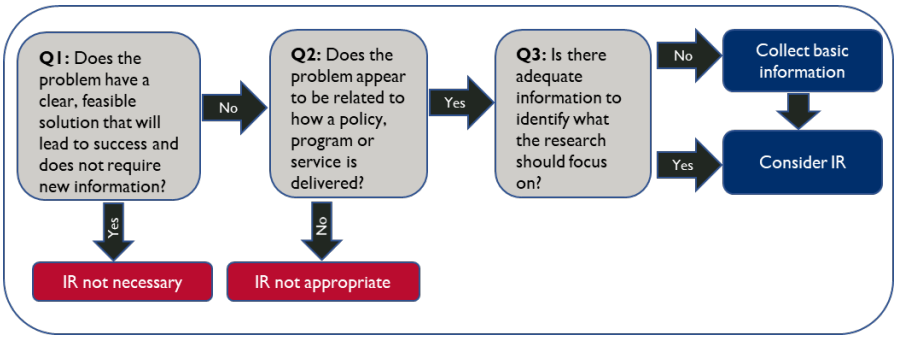
Implementation research may be useful when …

- Necessary managerial changes have been implemented, but the problem persists
- The root of the problem is not fully understood and there is no clear solution
- A potential solution has been identified, but its effectiveness or appropriateness in the local context is not known
- More than one possible solution has been identified, but it is not clear which is most appropriate for the local context

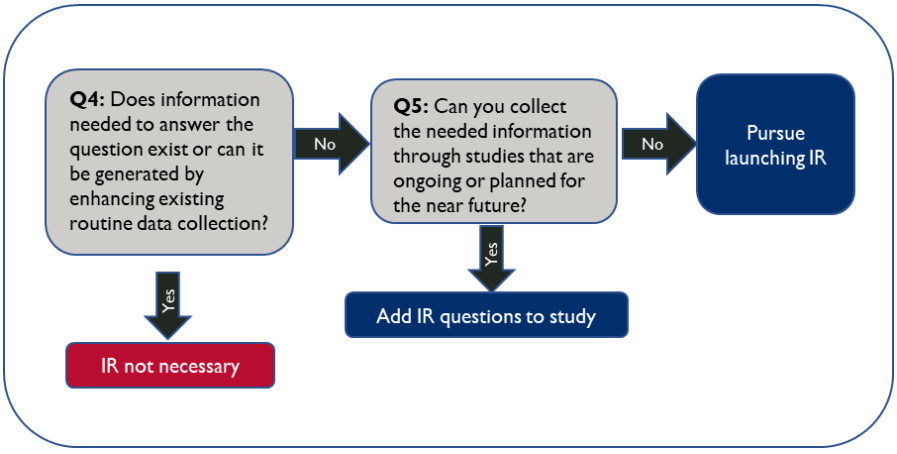
In addition, **Figure 3.2** presents a step-by-step approach to help you decide whether IR might be appropriate for your problem and context. It is important to acknowledge that some IR questions can be answered in part or fully through routine data collection mechanisms that may already be in place (e.g., service delivery records, supervision visit reports, client exit interviews, etc.). Where Ministry of Health buy-in and collaboration is strong, utilizing and enhancing these data collection mechanisms may eliminate the need for a larger IR study.

Figure 3.2: Deciding whether to use IR once the problem is identified

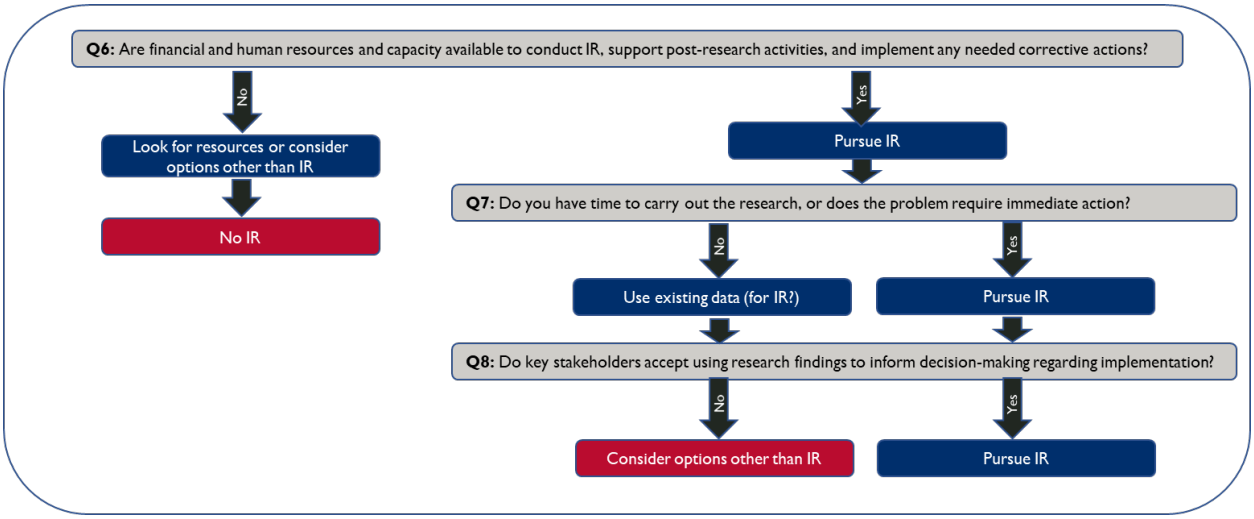
STEP 1: Understanding the problem overarching questions: What do you know about the nature of the problem based on available information? What can you detect about the source of the problem that might indicate which direction to take?



STEP 2: Clarifying your information needs overarching questions: What kind of information do you need to identify the root of the problem? To make decisions about changes to the program? To measure the size of the problem? To determine if the problem affects program outcomes?



STEP 3: Assessing feasibility overarching questions: Do you have time and resources to conduct an IR study? Will its results be useful?



KEY TAKEAWAYS

- IR is a type of research that strengthens health programs by focusing on implementation.
- IR can be useful in some situations while other methods to strengthen programs may be more appropriate in other situations.
- IR studies can vary greatly in size, scope, and cost and range from informal to very formal.
- IR processes can be integrated with ongoing program or policy cycles or other data collection efforts (e.g., quality improvement, program evaluation, etc.).

KEY RESOURCES

APPROACH	RESOURCE
Routine monitoring	USAID Learning Lab. USAID Monitoring Toolkit.
Collaborating, Learning, and Adapting	USAID Learning Lab. Collaborating, learning, and adapting (CLA).
Quality improvement	Rakhmanova N, and Bouchet B. (2017) Quality improvement handbook: A guide for enhancing the performance of health care systems. University Research Co, LLC. Quality improvement.

APPROACH	RESOURCE
Program evaluation	Centers for Disease Control and Prevention. (2011) Introduction to program evaluation for public health programs: A self-study guide. USAID Learning Lab. USAID Evaluation Toolkit.
Operations research	Zachariah R, Harries AD, et al. (2009) Operational research in low-income countries: What, why, and how? The Lancet Infect Diseases, 9(11), 711-717.
Implementation research	Peters DH, Tran NN, Adam T. (2013) Implementation research in health: A practical guide.
Health services research	Lohr KN, & Steinwachs DM (2002) Health services research: An evolving definition of the field. Health services research, 37(1):15.
Health program evaluation	MEASURE Evaluation. (2006) M&E Fundamentals (Free 2-hour online training).
Health policy and systems research	Gilson L (Ed.). (2012) Health policy and systems research: A methodology reader.

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IR TIP #4: PROBLEM IDENTIFICATION TO GUIDE IR

HOW TO IDENTIFY PROBLEMS THAT CAN BE SOLVED THROUGH IR

Implementation research seeks to answer an implementation question that explores, defines, or tests solutions for an implementation problem that has been identified by service providers, program managers and/or policymakers. But how are implementation problems identified, clarified, and prioritized? **Figure 4.1** illustrates the basic ways a problem is brought to attention, what that problem might look like, and suggestions for clarifying the magnitude of the problem.

Figure 4.1: Identifying and clarifying the problem (adapted from Lavis et al 2009)

A problem is brought to attention through…

A focusing event (such as with a specific political commitment or media coverage)	**A change in an indicator** (such as with the release of a national report)	**Feedback from a current program or policy** (such as from survey data or other stock-taking)

A problem may be related to…	For example…
A risk factor, disease or condition	High newborn mortality rates
Implementation strategies being used to address the risk factor, disease or condition	Ineffective services are being utilized to prevent newborn mortality
The health system within which those implementation strategies are being implemented	Insufficient resources are allocated to support full delivery of newborn care services
The level of implementation of an agreed upon or evidence-based intervention	Health care workers do not fully adhere to national policies and guidelines related to newborn care

It is important to clarify the severity and magnitude of the problem through…

Review of existing data (surveys, registries, administrative)	Comparison with other data: over time, between countries, against plans	Discussion with concerned stakeholders

Systematic identification, clarification, and prioritization of implementation problems is best done during regular data, health sector, or program reviews. These reviews are most complete if they have included opportunities for problem identification feedback from frontline workers or facility managers through observation of delivery challenges.

Some key steps to successfully identify implementation problems include (CDC 2019):

Box 4.1: A good problem statement answers:

- Who is affected?
- How big is the problem?
- What contributes to the problem?
- When and where is the problem most likely to occur?

- Involving technical experts and other relevant stakeholders to help define the problem
- Reviewing existing research and information about the problem
- Collecting new data from stakeholders, if necessary, to help identify root causes and other contextual information
- Framing the problem in a way that will help to identify possible solutions for testing

Widely supported by many low- and middle-income countries, processes such as joint annual reviews or mid-term reviews of health sector plans (WHO 2014) provide an opportunity to:

- Review trends related to key maternal, newborn, and child health indicators (**see Box 4.2**)
- Assess constraints or challenges encountered
- Solicit recommendations for implementation improvement

Box 4.2: Where to get the information to help identify your implementation problem

A good first place to start assessing and identifying your implementation challenge is your country's Countdown to 2030, the Country Profile and the Equity Profile. Using data accessible to the public from UNICEF and WHO, *Countdown* tracks:

- Progress in the 81 countries that account for the majority of under-five and maternal deaths
- Implementation of interventions that have been scientifically proven to reduce mortality among mothers, newborns, or children AND that are feasible for implementation in low- and middle-income countries
- Service delivery platforms that support delivery of multiple effective interventions
- Interventions and approaches that can be associated with a valid coverage indicator that is reliable, comparable across countries and time, nationally representative, clear and comprehensible to policymakers and program managers, and available regularly

While *Countdown* provides the most up-to-date snapshot of national (Country Profiles) and regional (Equity Profiles) data, access to district-level data is critical. Investigation of routine monitoring data (i.e., health facility and other administrative data) compiled through your district health information system (DHIS2) can provide important (and continuous) statistics to help in identifying the implementation challenge. Health facility data can be used (if the quality is sufficient) at the district level to understand the extent to which facilities are functioning as intended, and at the state/national levels to review policies and allocation of resources.

ESTABLISHING PRIORITY CHALLENGES

As part of the review process, multiple challenges will likely arise, and priorities for action will need to be identified. National (or sub-national) priority-setting processes are an important means of ensuring dialogue and engagement among researchers, policymakers, and managers that turns health system and policy problems into researchable questions, identifies priorities among them and, ultimately, supports the uptake of research findings (Gilson 2012). There are many tools available for establishing an effective priority-setting process, (COHRED 2006) including the Essential National Health Research (Okello

2000), priority setting Child Health and Nutrition Research Initiative (CHNRI) (Rudan 2008), Combined Approach Matrix (Ghaffar 2004), and the James Lind Alliance Method (2021).

As many countries are increasingly moving toward decentralization of health system management, it is essential, whatever review processes and priority-setting tool(s) are employed, to support sub-national decision makers (e.g., District Health Officer) to utilize routine monitoring data to detect implementation problems and advocate for investigation of questions to support solving them. Following the principles below will help to ensure that all stakeholder voices are heard throughout the problem identification and prioritization process. These include (COHRED 2010):

- **Capacity and quality assurance** all along
- **Prioritization** based on evidence, reasons and principles accepted as relevant
- **Transparency** ensured through documentation and communication of decisions and actions, reflecting the concerns of stakeholders at national and local levels
- **Inclusiveness** by ensuring that all interested parties are represented throughout the process
- **Promotion of equity** in health and development by ensuring the maximization of health for the greatest number of people, independently of individual financial resources, with special focus on the poorest

WHEN CAN AN IR APPROACH BE MOST USEFUL?

Health interventions are complex largely because of many unpredictable factors that can lead them off track. A systematic way to collect and use evidence to identify and act on implementation problems is the first step in the IR process. An IR approach is useful when (Peters 2013):

- Answering the research question will lead to:
  - positive population health outcomes
  - improved delivery of the target health intervention
  - a strengthened health system, *and*
- There is capacity to put results into practice to create change, *and*
- There is political and community support, *and*
- Results can be measured

Box 4.3: The Kampala Slum Maternal and Newborn Health (MaNe) Project

In Uganda, an effort to generate evidence on the most feasible and value for money approaches for improving maternal and newborn health (MNH) for the urban poor brought implementers, researchers, government partners, donors, and program beneficiaries and other stakeholders such as community leaders, health providers, and others together for a four-day co-design workshop to review formative research findings to support understanding of the contextual issues for those living in informal settlements of Kampala. The workshops utilized participatory methods to engage stakeholders in interpreting and synthesizing the formative phase research findings, identifying gaps and underlying issues, and generating ideas for possible implementation strategies to be tested using IR.

Once the implementation problem has been identified and clarified, you are ready to engage the key stakeholders to jointly formulate an IR question to help you address the problem (see IR Tip #5 and IR Tip #6).

KEY TAKEAWAYS

- Implementation problems are brought to light through focusing events, indicator changes, or feedback on an existing program or policy.
- Reviewing and comparing existing data helps clarify the magnitude of an implementation problem.
- Engaging diverse stakeholders helps to identify and clarify implementation problems.
- Regular data review processes provide an opportunity to identify implementation challenges that would be good for further investigation.

KEY RESOURCES

CLARIFYING IMPLEMENTATION PROBLEMS

BMC Health Research Policy and Systems. (2009) SUPPORT project Tools for evidence-informed health Policymaking (STP). This 18-article supplement in describes systematic processes to support evidence-informed policymaking. Article 4 focuses on clarifying problems.

PRIORITY-SETTING RESOURCES

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IR TIP #5: ENGAGING STAKEHOLDERS TO FORM AN IR PARTNERSHIP

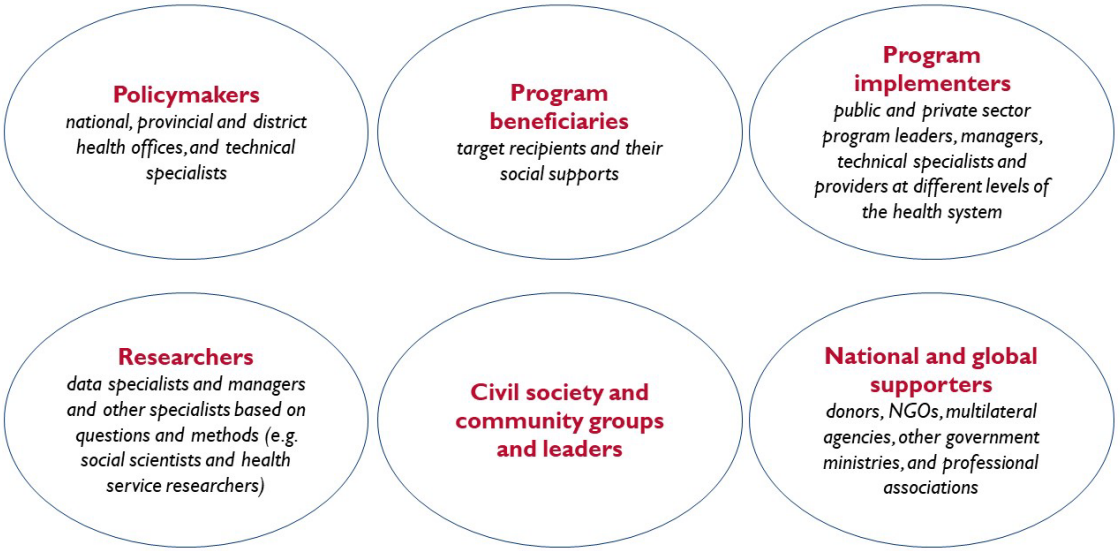
INVOLVING STAKEHOLDERS AND ESTABLISHING A STRONG IR PARTNERSHIP

Implementation research (IR) gathers data that describe how a program or intervention is being implemented and then uses that information to strengthen implementation and improve health outcomes. Program stakeholders play an important role in IR. Stakeholders are people or groups who have an interest or concern in the program. For example, the stakeholders in a newborn health program may include the Ministry of Health, health providers, patients, donors and other partners, community members, and professional societies, among others.

In the conduct of IR, it is important to consider which stakeholder groups should be involved in the IR or even represented in the partnership overseeing the IR ("IR partnership"). The IR partnership takes all decisions regarding the IR and is the focal point where stakeholder views on the IR are considered. Involving stakeholder representatives in the IR not only allows them to bring perspectives from their backgrounds to contribute to the IR effort, but also builds bridges to the stakeholder communities that they represent—bridges that can be important for communicating findings from the IR and creating support for changes that are made as a result of the IR. In some cases, failing to include key stakeholder groups can even cause the overall IR effort to fail, as unhappy stakeholder groups may refuse to support the research or resist changes that are introduced based on the IR findings.

WHO ARE THE STAKEHOLDERS FOR IR?

Figure 5.1: Implementation research stakeholders



Implementation research stakeholders include people and groups who have an interest or concern in the program that is being studied or the research itself. This might include individuals, groups, or organizations that are involved with implementing or overseeing the program, those who benefit directly from the program, and interest groups who are not directly involved with the program. Stakeholders also include organizations or individuals who are able to influence the program or the IR such as policymakers, donors and funding agencies, researchers, and technical experts.

Figure 5.1 presents categories of stakeholders for IR. Program beneficiaries (i.e., clients, or end-users) and other critical stakeholder groups such as professional associations should not be overlooked. (**Boxes 5.1 and 5.2.**)

Box 5.1: Program beneficiaries

Engaging beneficiaries in the IR process helps to maximize the benefits of IR. Approaches such as human-centered design (HCD) that focus on understanding the needs of the beneficiaries are important to achieving success in IR (Design Kit).

Box 5.2: Involving professional associations

In one country, the government used IR to compare the implementation of two different regimens for treatment of pneumonia in newborns at the household level by auxiliary health workers (AHWs). The government considered the Pediatric Association to be a key stakeholder and engaged them in the IR to build their support for treatment of pneumonia by AHWs at the household level—treatment that formerly could only be provided by physicians in health facilities.

BENEFITS OF INVOLVING STAKEHOLDERS

The IR leadership should identify key stakeholders early in the IR planning phase and develop systems to engage them throughout the IR process, which will help to:

- Identify factors that influence the success of the program (positively or negatively)
- Assess local health challenges (and opportunities) and the health system's readiness to respond
- Raise awareness about the health program, IR processes, and benefits of participating in IR
- Build commitment from the government and donors to support the intervention
- Create shared vision, health program ownership, political will, and accountability
- Reduce participants' fears of risks and harm from participating in a research process

ESTABLISHING A STRONG IR PARTNERSHIP

At the heart of successful IR lies a strong partnership made up of individuals committed to working together toward a common goal: producing relevant, reliable information in real-time that can be used to strengthen program implementation. Some stakeholders will be part of this core IR partnership that is directly responsible for preparing and conducting the IR effort, as well as engaging other stakeholders to make sure the study results are used for program improvement. All IR partners are key stakeholders and the distinction between these two groups may be fluid, with IR partnership roles evolving and adapting as the IR process proceeds.

TYPICAL ROLES ON AN IR PARTNERSHIP

Ensuring an effective IR process requires securing the participation of relevant actors. Ideally this would involve a partnership among researchers, implementers, and policymakers/government, while ensuring a voice for beneficiaries in the process. Because implementation efforts tend to be complex, IR partnerships often require diverse actors with a range of expertise, skills, and perspectives. While the composition of an IR partnership will depend on factors such as the focus, scope, and complexity of the research, the local context and customs, available budget, and any donor requirements, the IR partnership should represent a balance of program knowledge, technical skills (i.e., research/methodological or program area content expertise), and decision-making influence (**Box 5.3**).

Inclusion of appropriate Ministry/government officials is critical in ensuring the broader national (policy) and subnational (implementation) context is considered. These players will also be critical in informing eventual scale-up efforts to sustain successful interventions.

The IR partnership should be formed before research activities start, but additional or different partners should be added as needs are clarified and gaps are identified. The size of the IR partnership will vary by research project, and one partner may take on more than one role. Informal meetings with the managers and implementers of the program being studied, other local implementing partners, researchers experienced in IR, or key government counterparts can help gauge individual or institutional capacity to contribute to the partnership (both skills/expertise and resources) when considering additional partners. One place to start might be to build on and engage with entities that are part of existing national working groups that already include a cross-section of stakeholders interested in the IR being proposed.

Box 5.3: A diverse set of stakeholders brings value to the IR partnership

- Knowledge of broader intervention context—national plan or municipal programs—to ensure suitability of IR
- Familiar with local setting and cultural norms to inform improvement strategies
- Practice-based understanding about whether a research method or program solution can succeed
- Knowledge about system stakeholders' attitudes on key issues
- Understanding of how policies and regulations are implemented and enforced and how this might affect plans for improvements
- Leverage over processes needed for eventual scale-up or integration and sustainability of program changes
- Intuition about whether a research method or program solution will succeed

DEVELOP A PARTNERING AGREEMENT

Working with partners can be challenging—the larger the partnership, the more complex things become. Partners have their own perspectives, interests, and level of authority or influence. Each member may be under different sources of pressure due to organizational cycles and time constraints. The partners should plan and develop some ground rules so all members have a clear understanding of why, when, where, and how the partnership will work together. These ground rules should be documented in a partnership agreement or memorandum of understanding (Research+Practice Collaboratory 2015). **Box 5.4** lists some issues your partnership should consider including in the agreement. While these agreements do not need to be formal signed documents, the process of developing them together can provide an opportunity for identifying and solving potential areas of

conflict before they become a problem and for team-building that will strengthen the partnership throughout the IR.

Box 5.4: A partnering agreement should…

- State a vision of what IR results will generate
- Explain roles of all partners prior to, during, and following the research phase
- Establish how decisions will be made—e.g., governance and leadership structure
- Clarify resource contributions (in-kind, financial, or human) by each partner
- Develop initial schedule of IR partnership meetings, stating frequency and process
- Establish guidelines for conflict management and resolution
- Develop data ownership/sharing guidelines

GETTING THE PARTNERSHIP STARTED

Once members are selected and the partnership agreement is drafted, an initial meeting can be held to launch the IR project. Topics to discuss might include setting priorities, formulating initial research objectives, defining member responsibilities, identifying any capacity gaps within the partnership, preliminary planning and budgeting of the project, and strategies to set up your partnership for success. Prioritizing effective communication, encouraging participation by and interaction among partners, and capitalizing on the strengths of each partner are the keys to maintaining a strong collaboration throughout the IR process.

HOW TO ENGAGE STAKEHOLDERS AND THE IR PARTNERSHIP

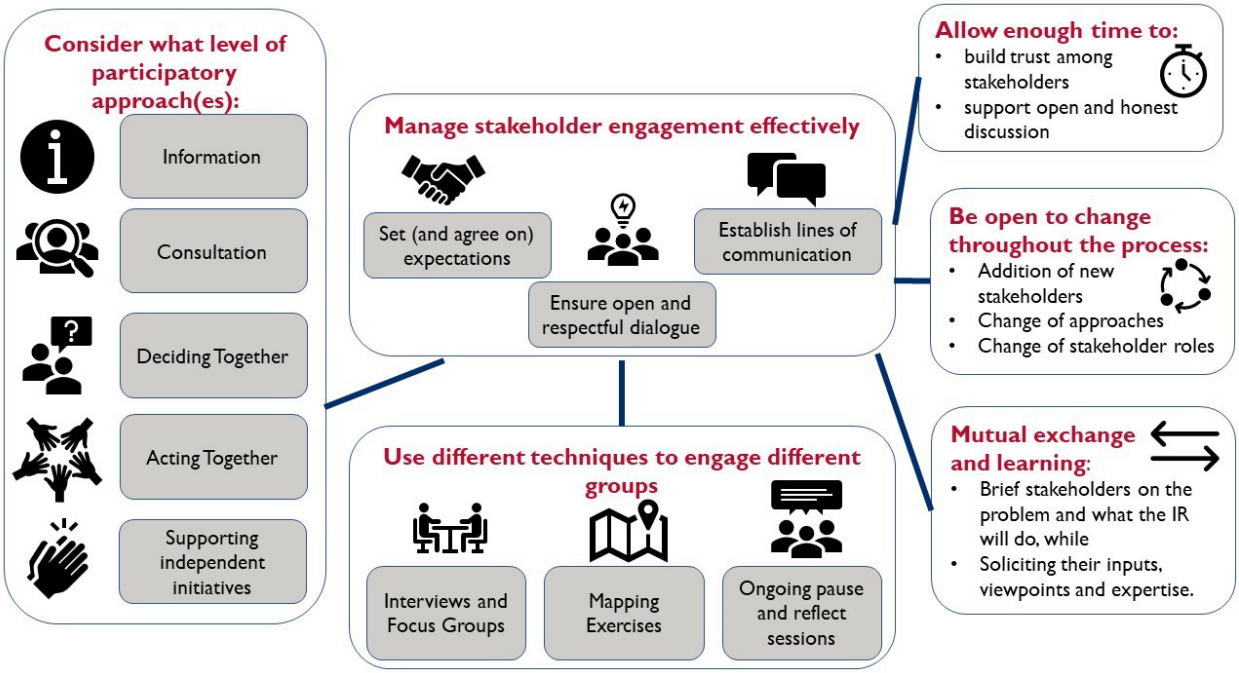
Once you have established the core IR partnership and identified the broader set of key stakeholders, a strategy for engaging them must be developed. While involving and mobilizing multiple stakeholders might seem challenging, tools such as the Stakeholder Analysis Matrix (Bullen 2014) can help to understand what each stakeholder group can contribute to the IR and clarify how to best involve them. Completing a tool such as this might require convening discussions with stakeholders, but taking the time to map each stakeholder groups' key characteristics will help you to:

- Understand their relationship with the program/intervention
- Realize what they value about the program and as well as their level of influence
- Identify what they can contribute to the IR effort (e.g., ideas, information, support, effort)
- Consider whether and how they might block or obstruct the IR process
- Develop ideas for how and when they can best be involved

You can then use this detailed stakeholder mapping to identify activities, roles, tasks, and goals that together will ensure each individual's/group's meaningful involvement in the IR effort from beginning to end. **Figure 5.2** presents a conceptual diagram of how to manage stakeholder involvement during IR. The IR partnership leadership should do this by agreeing upon expectations with stakeholders, using

appropriate techniques to establish communication and engage different groups, and taking time to create an open, respectful dialogue among stakeholders. The IR partnership should use different techniques to engage stakeholders and ensure that learning and exchange of information flows among stakeholders.

Figure 5.2: Ensuring meaningful stakeholder engagement throughout IR



One way to encourage participation is to arrange for interactions between partners where they can learn from each other and build trust. For example, team members involved in program implementation can invite other members to the field to observe or participate in program activities that will help them understand implementation-related processes. In turn, researchers can help other team members understand methodological issues more easily. Other regular opportunities for team members to interact—face-to-face meetings or informal social gatherings, such as dinner meetings—help to build relationships and trust so that all partners feel free to express their opinions, talk about their experiences, and disagree with other stakeholders. The process of stakeholder engagement is dynamic, and leadership should be open to change over the duration of the IR effort.

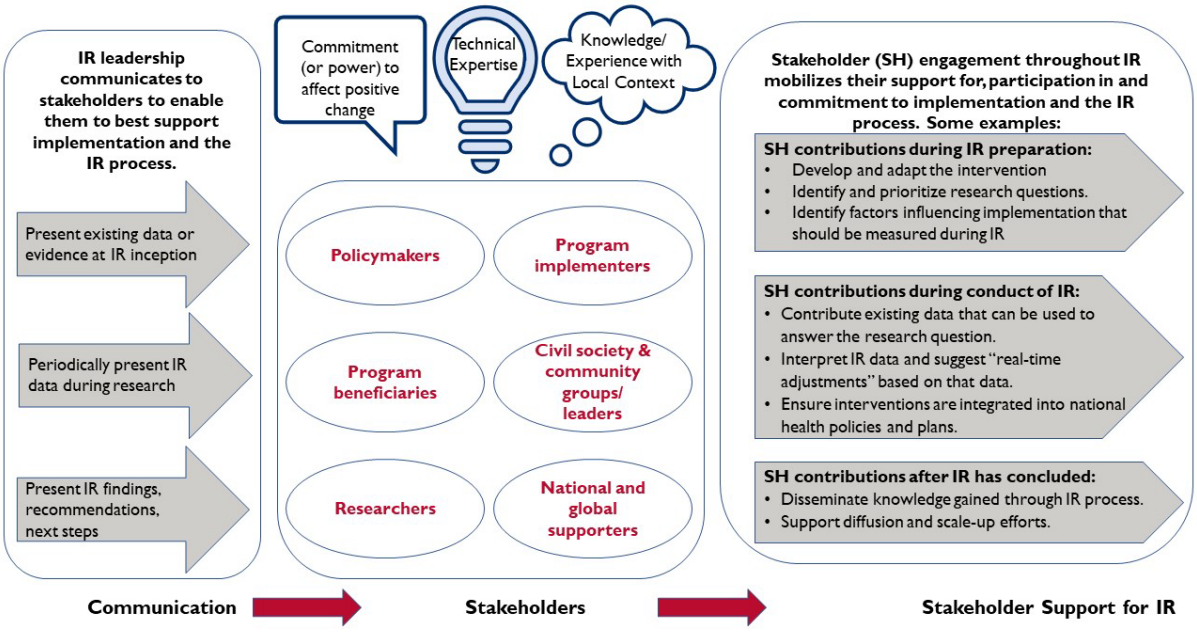
Often, particularly with large, complex IR projects that have the potential to significantly impact program practices, it is useful to identify a sub-group of stakeholders that can support the larger goal of using results to inform action. This group of actors is often identified following a stakeholder analysis and can be formalized into a research advisory committee.

HOW STAKEHOLDERS SUPPORT IR

Suppose that you are a partner in an IR effort that is about to start. You have just completed a stakeholder analysis and identified a set of key stakeholders who together have technical expertise, knowledge of and experience with the local context, and a commitment to (or power to) change the

program. In concrete terms, what can you expect them to contribute to IR? While the answer to this question will vary across IR efforts, **Figure 5.3** provides some insights/suggestions. The figure presents a graphic description of IR stakeholders (center box), the information that builds their capacity to contribute (left box), and some examples of tasks and roles that stakeholders may carry out during three time periods (right box): preparing for IR; conducting the IR; and following the conclusion of the research activities.

Figure 5.3: How can stakeholders contribute to IR



Before beginning, you will need to give stakeholders information that will enable them to support the IR effort. For example, you might bring stakeholders together to review DHS and other data, including the results of any formative data you conducted with program beneficiaries (see IR Tip #8 for more on conducting formative research with beneficiaries). You might ask stakeholders to interpret the data, suggest reasons for any problems or successes that the data show, and suggest changes to the program that would test solutions to any problems. Some stakeholders may even have data that could be used to inform the IR, reducing the need for additional data collection. Importantly, beneficiaries and other community stakeholders should be incorporated into the IR partnership as active participants—inserting their voice into the problem identification, proposed solutions, and regular review of findings. You will almost certainly provide stakeholders with updates during the data collection period, and then provide them with a summary of ultimate findings. Bringing key stakeholders together routinely to review the data can help to understand the findings and provide important perspectives on how the program might be adapted based on those findings. In addition, stakeholders have an important role to play in communicating (and acting on) results after the IR is completed.

KEY TAKEAWAYS

- Stakeholders are people or organizations that are involved in or affected—directly or indirectly—by the program.
- Effectively engaging a diverse range of stakeholders contributes to a stronger IR effort and ensures that all relevant perspectives are included throughout the IR process.
- Stakeholders can inform the IR methodology, contribute to data collection, help interpretate and disseminate results, and support scale-up efforts.
- The "right" IR partnership will differ for each project, but should include local government partners and local academic/research institutes experienced in IR.
- An IR partnership should balance program knowledge, technical skills, decision-making influence, and stakeholder representation.
- Collaboration within the IR partnership should be encouraged through open communication and sharing ideas and responsibilities.

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STAKEHOLDER MAPPING TOOLS

Bullen PB. (2014) Stakeholder analysis matrix template.

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MULTI-STAKEHOLDER PARTNERSHIPS (MSP)

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BUILDING COLLABORATION CAPACITY

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HUMAN CENTERED DESIGN

Design Kit. What is human-centered design? (Video).

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ESTABLISHING A STRONG COLLABORATION

Implementation research for universal health coverage in practice: A series of technical briefs based on lessons learned from the field in Myanmar and Indonesia. USAID Health Finance and Governance project.

- Part 1: Laying the groundwork (2015)
- Part 2: Defining and designing the IR (2017)

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- How do I find good partners?
- Structuring a partnership
- Developing data sharing agreements

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IR TIP #6: FORMULATING IR QUESTIONS

WHAT QUESTIONS SHOULD GUIDE THE IR?

Formulating the right research question is critical to making sure IR provides the learning you need to take action to address the identified implementation challenge. Because problems that arise when implementing health interventions often result from circumstances specific to a local context, engaging diverse stakeholders will help formulate the right question. This IR Tip provides guidance on how to formulate and prioritize a question for IR, which will in turn support decision makers to find out how and why a health intervention is not achieving what it set out to do and how to get better results.

For instance, in Malawi, policies leading to increased access to and utilization of health facilities for delivery did not produce equivalent gains in newborn survival. Later analyses concluded that facility quality fell substantially short of global standards of evidence-based care. Higher-quality facilities had substantially few neonatal deaths than other facilities (Godlonton 2016, Leslie 2016).

Box 6.1: IR can help to answer questions like…

- Why am I not seeing the results I expected from my program?
- How can I develop solutions to the challenges I'm seeing?
- How can I help my program get better results?
- How can I adapt or improve my program as it is being implemented?
- How can I ensure the program is reaching those that need it?
- How do I ensure the program is sustainable in the long-term?

Implementation research utilizes real-time data review and reflection to help decision makers to understand why interventions and investments are not achieving their goals in their unique context. **Box 6.1** provides some potential questions IR could help to answer.

HOW TO FORMULATE IR QUESTIONS

While more traditional research questions focus on the impact of an intervention—for instance, does presence of a skilled attendant at birth reduce maternal mortality—IR questions focus on:

- How an intervention is being implemented (implementation strategies)
- How those implementation strategies affect service outcomes and implementation outcomes (i.e., coverage, feasibility, acceptability)
- How contextual factors affect the intervention and its outcomes

Implementation research questions can explore, describe, influence, explain, or test how implementation is (or is not) working (Peters 2013). Additionally, IR questions can try to address challenges related to program scale-up, sustainability, replication and robustness, program integration, equitability, and real-life effectiveness, including cost (University of Washington).

Box 6.2: Examples of good IR questions

- What are the barriers to scaling up implementation of a vaccine program for children under five?
- Is it feasible and acceptable to utilize antenatal care services as a delivery platform to integrate other health services (i.e., HIV, malaria, or nutrition)?
- How and where at the household/ community level should multiple micronutrient supplements be made available for effective coverage during pregnancy?

Once you have identified some preliminary IR questions, you can refine and finalize those questions with the help of an IR framework (see IR Tip #7) and input from partners/stakeholders. Furthermore, IR Tip #5 addresses stakeholder engagement more specifically, but the Robert Wood Johnson Foundation (Preskill 2009) and the Canadian Institutes for Health Research (2009) have developed practical guidance on engaging stakeholders in developing research questions.

HOW TO PRIORITIZE QUESTIONS

Health interventions can produce multiple, simultaneous implementation problems and questions.

Figure 6.1: How to prioritize IR questions?

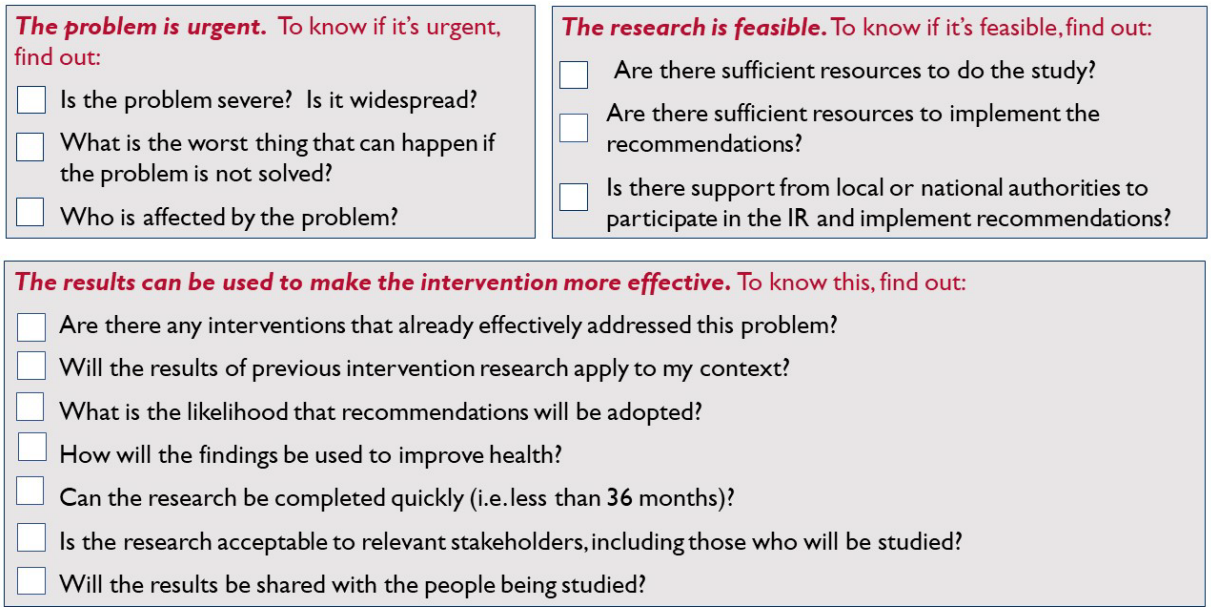

Figure 6.1 illustrates three criteria to utilize when prioritizing IR questions and some questions that will help to establish which IR questions should be prioritized. **Box 6.3** presents how Indonesia utilized a collaborative process to establish IR questions to support scale-up of a national insurance policy.

Box 6.3: How IR was used to strengthen financing reforms in Indonesia

In 2014, Indonesia began implementing a national health insurance initiative (JKN) aimed at covering the country's entire population by 2019. Implementation research was undertaken to provide crucial information about whether JKN was being implemented as intended. A consultative process with key stakeholders, including national and local policymakers and implementers, contributed to defining the IR questions. The first one-year cycle assessed how JKN regulations were being interpreted and implemented and implications for effectiveness. The second cycle sought to investigate health worker satisfaction and opportunities to strengthen the links that lead to improved service delivery (Eichler 2018).

KEY TAKEAWAYS

- IR answers why or how an implementation is (or is not) working
- Collaborating with diverse stakeholders helps to formulate the right IR questions
- IR can address many challenges you may be facing. For example:
  – How can coverage of your intervention be improved?
  – How can multiple interventions be effectively packaged and delivered?
  – How can the intervention be delivered more equitably?
- Give priority to questions that meet three criteria:
  – the problem is urgent
  – the questions can be answered and recommendations can be put in practice
  – the research can provide results that can make the intervention more effective

KEY RESOURCES

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IR TIP #7: SELECTING AND USING A FRAMEWORK TO GUIDE IR

SELECTING AND USING A FRAMEWORK TO GUIDE YOUR IR PROJECT

When you embark on a new endeavor, a roadmap is useful to guide the way. In implementation research (IR) (like other learning approaches), these roadmaps are called theories of change, models, or frameworks. Here they are collectively referred to as "frameworks," which capture the logic behind how an intervention or strategy is expected to function, how it leads to change, and what factors may affect how it works.

> *"There is nothing so practical as a good theory."*
> *(Kurt Lewin, 1951)*

WHY USE A FRAMEWORK?

A framework helps guide the process of designing, planning, implementing, and evaluating an intervention. In IR in particular, frameworks can map and break down complex processes to better understand factors that influence implementation of the program under study. The process of developing a framework can also help clarify the program's assumptions by making them more explicit for all involved in the IR. Frameworks also help ensure that IR findings can be used to improve the program under investigation.

In the context of IR, frameworks can help:

- Point to reasons why an intervention works or doesn't work (explanations)
- Highlight implementation strategies essential to study (process)
- Show what is important to measure (outcomes)
- Enhance how study findings are interpreted (analysis)

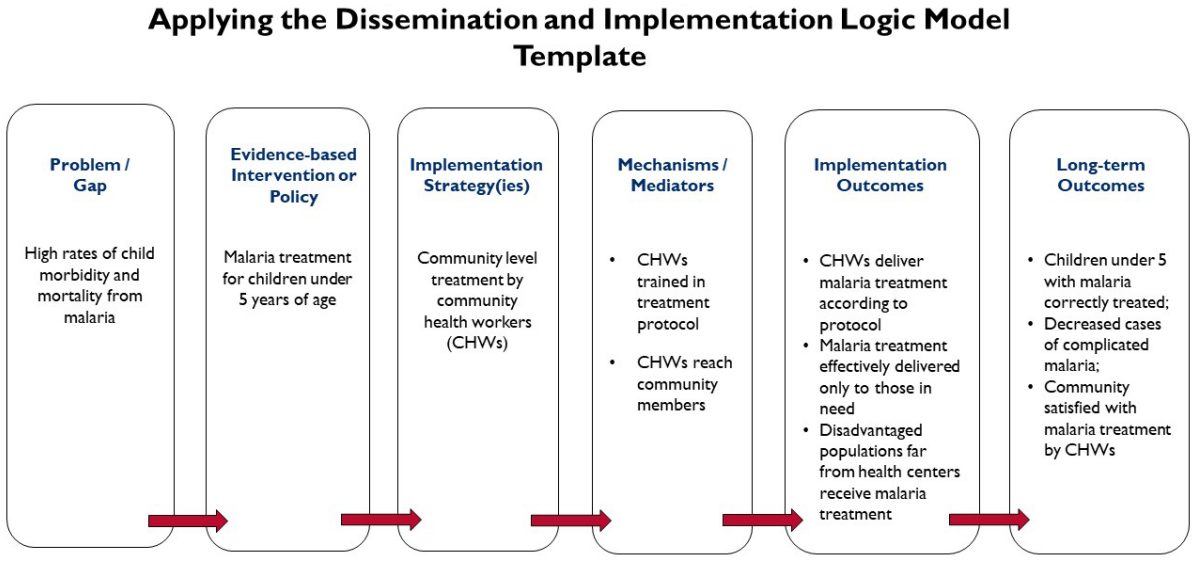
HOW TO SELECT OR DEVELOP A USEFUL FRAMEWORK

With the abundance of IR frameworks currently available, selecting an appropriate one for your research can be a daunting task. Defining preliminary study aims and research questions (see IR Tip #6 on formulating research questions) will help determine which framework is most appropriate. The chosen framework will then help to refine and finalize the research questions. Resources such as the Dissemination & Implementation Models in Health Research and Practice interactive webtool can help you through this process (D&I Science Project). Below we outline four key steps to developing a framework customized to your IR.

1. MAP WHAT YOU WANT TO STUDY

A first step is to map the overall logic of the health intervention and corresponding program under study. This will help identify key elements of the program you are studying and the factors that are known to influence it. Tools such as the Logic Model of Dissemination and Implementation Science Project can guide this process (D&I Science Project). **Figure 7.1** shows an example of how it can be applied to the malaria treatment example discussed in IR Tip #2. Another tool is the theory of change; see the last section of this IR Tip for more details.

Figure 7.1: Example Logic Model



2. SEARCH EXISTING FRAMEWORKS TO FIND A GOOD MATCH

You can then use this "map" to determine which existing implementation framework addresses the needs of your proposed research. While this repository of frameworks (D&I Science Project) is quite comprehensive, a brief review of the literature may also be useful. You may find multiple frameworks that could be used and fit the research purpose. It may be helpful to consult with stakeholders for insight into their experiences with and preferences for frameworks they have used. See **Box 7.1** for a brief description of two commonly used frameworks.

Box 7.1: Commonly used frameworks

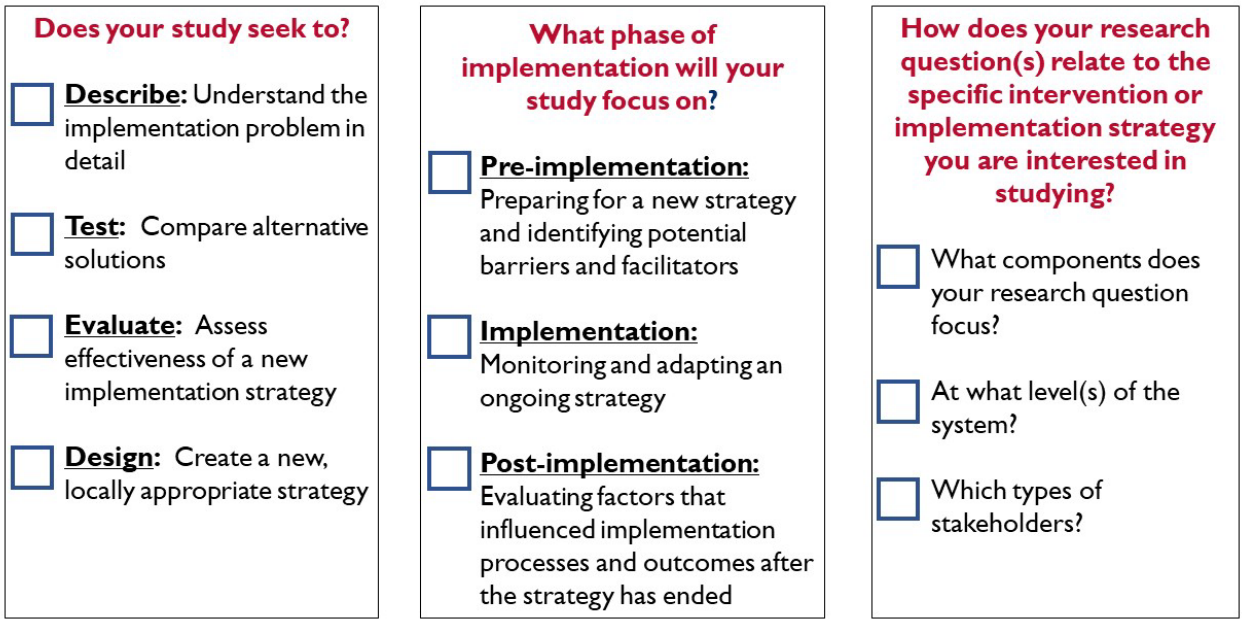
The Consolidated Framework for Implementation Research (CFIR) helps understand or explain how implementation outcomes are achieved. It provides a menu of constructs associated with effective implementation (i.e., intervention characteristics, individual characteristics, process, inner setting, and outer setting) that can be used to assess the potential barriers to and facilitators of implementation.

The Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework focuses on implementation strategies and program elements that support scale-up of evidence-based interventions. Each element is an opportunity for intervention.

3. ASSESS THE "FIT" OF A FRAMEWORK

Once you have a short list of viable options, you can use a tool such as the Theory, Model, and Framework Comparison and Selection Tool (T-CaST) for Implementation Practitioners, which helps to assess the "fit" of a framework based on its usability, validity, applicability, and acceptability (NC TraCS). See **Figure 7.2** for additional guidance on selecting a framework.

Figure 7.2: Questions to think about when selecting a framework



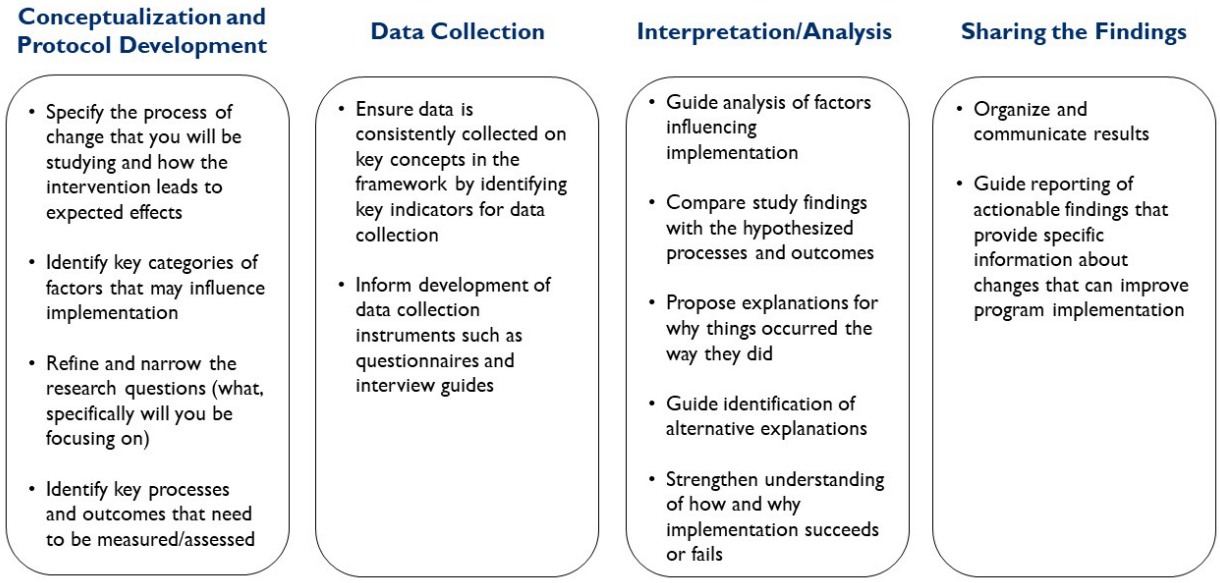
4. TAILOR THE FRAMEWORK

You likely will need to adapt an existing framework to address your questions, the local context, the nature of the specific intervention you are studying, etc. (See this example of how the Consolidated Framework for Implementation Research [CFIR] was adapted to identify implementation performance drivers for human papillomavirus vaccine delivery in Mozambique [Soi 2018]). Remember to document the steps taken in this selection process and the reasoning behind your decisions, an approach called process documentation (see IR Tip #9).

HOW TO USE THE FRAMEWORK IN A MEANINGFUL WAY

You can use your framework when you first conceptualize the IR and revisit it throughout implementation **(Figure 7.3)**. You can also use the framework to test the assumptions between causal steps on the pathway, for instance between inputs and activities or outputs and outcomes (Britt 2017).

Figure 7.3: Frameworks can be used in all stages of IR



THEORY OF CHANGE AS A RESOURCE

When preparing for your IR, one good resource to guide the development of your framework is the theory of change of the project under investigation. A theory of change is a model illustrating the causal pathway which depicts how an intervention or strategy is expected to function, how it leads to change, and what factors may affect how it works. In comparison, a conceptual framework helps us to understand how the various pieces fit together and is not necessarily linear.

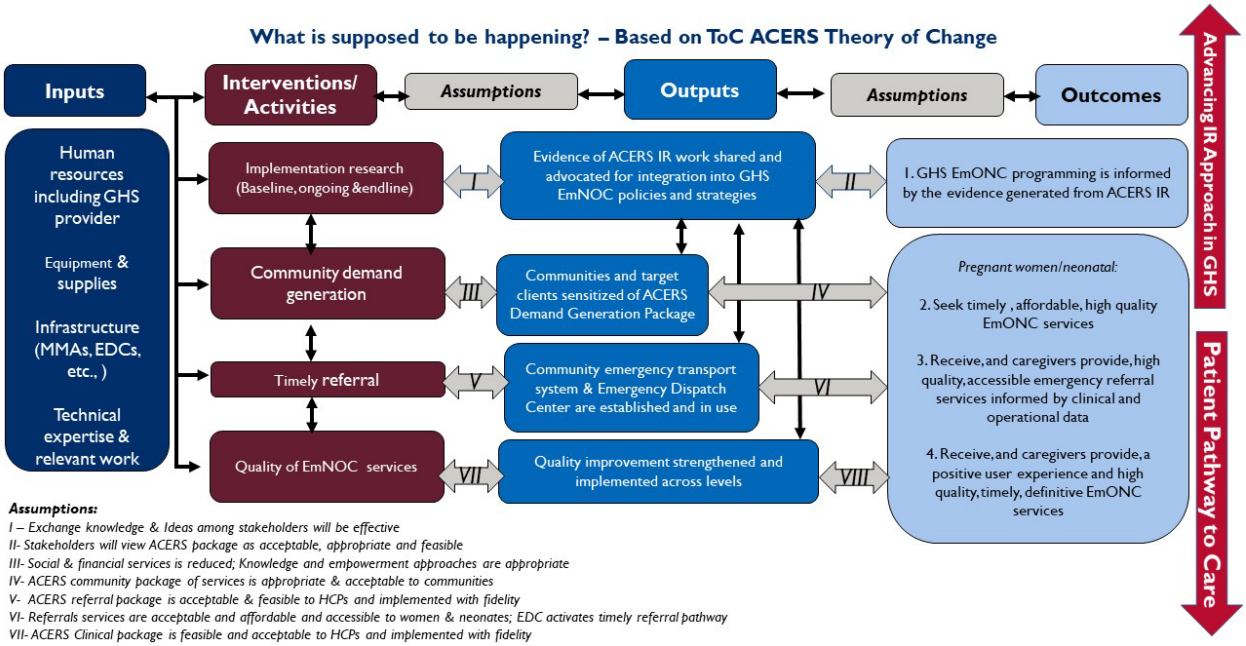
A theory of change describes and illustrates how and why an intervention strategy in a particular context will lead to certain outcomes (change). A narrative and a mapping is built by specifying the long-term goals and then working back, identifying the inputs and activities needed to get to each subsequent step. The pathway created will show how the steps relate to each other and lead to objectives, as in a theory of causation. All levels must include assumptions about context, other systems, and stakeholders.

A theory of change model has some key features that will help guide the development of your IR framework:

- It specifies the rationale of expected change
- It is put in the context of or linked with the broader system
- It identifies risks, as well as assumptions which can be tested

Figure 7.4 shows the theory of change that the Acute Care and Emergency Referral Systems (ACERS) project in Ghana developed. See also IR Tip #9, which references the importance of theory of change to process documentation.

Figure 7.4: Sample project theory of change



A good theory of change has:

- Long term outcome(s) for success
- Intermediate outcomes
- Dependent relationships that form pathways of change in the broader system
- The rationale behind how change is to be achieved
- Assumptions being made
- Potential barriers and risks
- Stakeholder activities

KEY TAKEAWAYS

- A framework provides a roadmap for developing and mapping your IR the development, management, and evaluation of interventions or implementation strategies
- Selection of an appropriate IR framework and the fine-tuning of the research objectives/questions often occur iteratively
- It is important to document the steps taken and reasoning behind selecting a framework
- Frameworks can (and should) guide all phases of the research process from start to finish
- Not all projects have a theory of change but it can be a good starting point, and may inform the selection of an IR framework

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IR TIP #8: RESEARCH DESIGN METHODS AND ETHICS

RESEARCH DESIGN METHODS AND ETHICS

Implementation research (IR) is conducted differently from other traditional research, such as clinical or epidemiological, because it is meant to investigate implementation under existing, real world conditions. As such, IR creates a blurring of the boundary between research and clinical care/public health practice.

Some distinguishing features of IR include:

- IR may be embedded in health care service delivery
- IR is an iterative and dynamic research approach
- IR focuses on the population or group level, rather than on the individual

These features, together with other factors such as available resources and desired level of rigor, influence the selection of a study design.

WHAT STUDY DESIGNS ARE APPROPRIATE FOR IR?

In addition to the features mentioned above, your research questions will further inform and narrow your IR study design. The questions in IR for health are often multifaceted, reflecting the complexity of the real world and the challenges of dynamic health systems and the need for adaptive interventions. Implementation research questions are not limited to the clinical setting or implementation of a treatment or prevention program itself. Questions can also address implementation process issues in health care delivery (especially implementation bottlenecks) as well as cost-effectiveness, policy uptake, etc.

In general, IR study designs can be grouped into two primary categories. The first aims to broadly capture the effectiveness, utility, and feasibility of an intervention; the second looks more specifically at program uptake (Curran 2012).

1. **Effectiveness implementation hybrid designs:**
   - Hybrid design type 1: Primary aim: determine effectiveness of an intervention. Secondary aim: better understand context for implementation
   - Hybrid design type 2: Primary aims: determine effectiveness of an intervention, and determine feasibility and potential utility of an implementation intervention/strategy
   - Hybrid design type 3: Primary aim: determine utility of an implementation intervention/strategy. Secondary aim: assess health outcomes associated with the implementation trial

2. **Pure IR designs:** Focuses on the adoption or uptake of interventions. Research outcomes are usually provider and/or system behaviors, for example, levels and rates of adoption and fidelity of the intervention.

Careful consideration should be given before deciding to assess both effectiveness and implementation; there are lots of factors to address. In many cases, it may be best to focus on implementation only—which brings us back to implementation outcomes, which were discussed in IR Tip #1.

Studies categorized as pure IR designs may be broad (examining many IR outcomes) or narrow (examining a small subset of IR outcomes) in focus and may use qualitative and/or quantitative designs and involve process documentation.

Box 8.1: Example of hybrid IR study that uses mixed methods: Ponya Mtoto project, Kenya

The Ponya Mtoto project manages possible serious bacterial infection (PSBI) in young infants in Kenyan facilities when referral is not feasible. The project is conducting IR to first identify service delivery and program barriers that prevent infants with PSBI from accessing care, and then develop solutions in partnership with local teams. These teams include the Newborn, Child and Adolescent Health Unit in the Ministry of Health, county, sub-county and facility-level health management teams, and community health unit teams. This hybrid type I IR study is measuring both IR outcomes, such as feasibility, acceptability, and sustainability of PSBI management strategies, as well as quality of care and health outcomes. Data collection methods include direct observation of care, client follow up surveys, and focus group discussions with clients. (See Ponya Mtoto brief)

RESEARCH DESIGN AND METHODS DETERMINED BY RESEARCH OBJECTIVES AND QUESTIONS

Formulating IR questions and using IR frameworks to guide the process of designing your IR are covered in IR Tip #6 and IR Tip #7 (Gopichandran 2016). As with other research and evaluation efforts, IR studies can include traditional trial designs as well as participatory action research, qualitative designs, and the hybrid designs described above. However, they most commonly employ quasi-experimental study designs such as stepped wedge and interrupted time series (Bernal 2017), or observational designs and mixed methods designs (which use qualitative and quantitative methods) (Kings College 2018). The methods used must allow for adaptation of the intervention or implementation strategies overall, or at individual levels. Given the multitude of possible IR designs, a decision tree can be a good tool to help IR partners (study team and stakeholders) hone in on the design that works in their context. The Academy Health guide to rigorous research designs presents detailed descriptions and examples of different study designs (AcademyHealth 2017).

SELECTING RESEARCH METHODS AND ANALYSES

After identifying your research question(s), determining appropriate research methods first entails identifying key outcome indicators related to your questions. The Better Evaluation website presents a Rainbow Framework that describes a wide menu of research and evaluation data collection methods and processes (Better Evaluation). The ImpRes tool offers a helpful matrix template that has been adapted

here (**Table 8.1**) to assist with linking data collection methods to outcome measures and research questions (Kings College 2018).

Table 8.1: Linking research methods to research questions and outcome measures

RESEARCH QUESTION #	OUTCOME MEASURES (SERVICE*, PATIENT** OR IR***)	DATA COLLECTION METHOD	LEVEL OF MEASUREMENT (INDIVIDUAL CLIENT, HEALTH CARE PROVIDER, HEALTH FACILITY)	MEASUREMENT FREQUENCY (ONGOING, QUARTERLY, ANNUALLY, BASELINE/ENDLINE)

*Service outcomes: Efficiency, safety, effectiveness, equity, patient-centered, timeliness
**Patient outcomes: Satisfaction, function, symptomatology (Kings College 2018)
***IR outcomes: Acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, sustainability

A mixed-methods research approach is preferable when conducting IR, as the combination of quantitative and qualitative data often provides a richer understanding of the issues that prompted the research question(s) and also allows for triangulation of data in using one method's findings to confirm (or refute) the other's.

While quantitative approaches tend to focus on whether an intervention was effective in achieving any number of outcomes, qualitative methods can enhance assessments by providing insight into the reasons behind those findings, including variability across contexts. Qualitative data can also help identify issues related to the degree to which the intervention is implemented as intended (implementation fidelity).

Box 8.2: Example of IR for emergency obstetric and newborn care referral and provision: ACERS project, Ghana

The Acute Care and Emergency Referral Systems (ACERS) project in Ghana used the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) approach to inform its IR design and identify metrics and measurement methods for implementation outcomes across the demand for care, timely referral, and facility-level quality of care for emergency obstetric and newborn care. This study employs a before and after quasi-experimental cluster design that uses mixed methods. Subdistricts serve as the cluster, with four receiving the "full" set of interventions (timely referral, demand generation, and facility-level quality of care interventions) and seven receiving only the timely referral interventions. The feasibility and acceptability of the ACERS package of interventions will be assessed from the perspective of frontline health workers and administrative staff in the health system, as well as community members, leaders, and volunteers within the study areas. Study tools include in-depth interview guides for district health management team members, a health facility readiness survey, a health worker survey, an emergency referral needs assessment, and a women's household survey. Secondary analysis of routine data form client charts and health facility registers is also planned. (ACERS Project brief)

ETHICAL CONSIDERATIONS FOR DESIGN AND REVIEW OF IR

Understanding the ethical considerations and challenges related to IR is important during all phases of the study, not only to ensure the study complies with ethical principles, but also to prepare for review by ethics review committees (ERCs) and institutional review boards (IRBs) (Gopichandran 2016).

KEY ETHICAL CONSIDERATIONS WHEN DESIGNING AND CONDUCTING IR

Important differences between traditional public health research and IR may require changes in the application of ethical principles when designing and conducting IR studies (Gopichandran 2016). While the researchers in your IR partnership may be aware of the basic ethical principles of research, they may not be as familiar with the nuanced differences in their application to IR. All members of the IR partnership (including the health decision makers, implementers, and managers) should participate in discussions about the possible ethical implications of their research in the design phase and throughout implementation.

While public health-focused IR is aimed at identifying the best process to implement and scale-up health interventions (programmatic evidence), clinical research, such as the gold standard randomized controlled trials, focuses on testing whether a health intervention has an impact on health status, and if so, the extent of that impact. WHO notes, "There is an ethical imperative to conduct IR as there is a need to understand access, acceptability, reach and utilization issues in a local context" as part of the process of putting clinical and public health evidence into practice (World Health Organization 2021). However, when an evidence-based intervention has already been successfully translated into practice, unless there are major concerns about potential contextual differences in implementation between one location and another, IR or other research may not be justified. Similarly, unless there is a local plan for sustaining or scaling a successful intervention, IR may not be justified.

When IR is justified, the nature of ethical considerations will depend on the specific study design, the implementation processes or intervention under study, and the local context, among others (Gopichandran 2016). **Table 8.2** presents a few examples of ethical issues that might arise. For example, acceptable standards of care, especially in control/comparison groups, must be accounted for as in traditional studies (Gopichandran 2016)**.** However, a key distinction of IR versus clinical research is that **interventions subject to IR have often already been proven to be effective in other settings, raising questions as to whether the use of control or comparison groups is ethical**. A stepped-wedge approach can help mitigate this conundrum. In a stepped-wedge design, an intervention is delivered sequentially to participant groups until all participants eventually receive the intervention. Those groups which do not initially receive the intervention serve as the control groups.

Table 8.2: Sample of ethical issues for consideration (adapted from Gopichandran 2016)

ENGAGING STAKEHOLDERS AND COMMUNITY MEMBERS IN ALL PHASES OF THE STUDY	"Scalability and sustainability are important ethical considerations at both planning and post-study phases, as ultimately these are the goals of IR" (Gopichandran 2016). Therefore, researchers must strive to ensure sustainability post-study of effective interventions by engaging and convening multiple stakeholders to promote these goals throughout the IR process. Implementation research may not be ethical if access to a proposed public health intervention cannot be ensured for a community after research has concluded.
ASSIGNING THE STANDARD OF CARE TO A CONTROL OR COMPARISON GROUP	This is important for IR studies with experimental or quasi-experimental designs. When comparing the effects of two implementation strategies, ensure an ethical "standard of care or prevention" for the control/comparison group (i.e., determine if it is ethical to assign the control/comparison group to the current standard of care or no care when an effective treatment might exist) (Macklin 2014).
ANCILLARY CARE OUTSIDE THE SCOPE OF THE STUDY FOR THOSE IN NEED	Establish clear processes and guidelines in case of encountering severe illness or the need for urgent medical attention. Identify which needs can and should be addressed in the field and how to meet other needs through collaboration with other organizations.
OBTAINING CONSENT, INFORMED CONSENT, ASSENT, AND/OR PERMISSION	Careful attention is needed to identify the study populations and weigh the relative risks of their participation in research. Possible risks should be clearly conveyed to both ERCs/IRBs (if review is required) and potential study participants. This process should involve discussions among the IR partners and other stakeholders. All study participants should be asked for consent, with participants in human subjects research undergoing a full informed consent process that meets established ethical guidelines. Minors may also offer assent, or be considered to be emancipated and provide informed consent per approval of an ERC or IRB. Withholding information can be justified in some circumstances. For example, some implementation strategies, such as those related to behavior change interventions, may need to conceal certain intervention details during the consent process with participants, particularly if there is a comparison or control group. While it maybe be prudent to seek "permission" from community or health facility gate keepers to conduct the IR in their area, they cannot under any circumstances provide consent or informed consent for another individual.
PLANNING FOR AND SHARING DIRECT AND INDIRECT BENEFITS OF IR	When possible, IR should be designed to strengthen research capacity of local individuals and/or institutions in conducting IR, strengthen local health information systems to track data, and build capacity to translate research findings into action or health policy.
DISSEMINATING AND SHARING RESEARCH FINDINGS	Privacy and confidentiality need to be protected when disseminating research findings. Avoid breaches of confidentiality by paying attention to situations where individuals, health facilities, or regions may be easily identifiable. Individual-level data should be de-identified before sharing with any public data repositories. Ownership of the data needs to be clear and accounted for in dissemination plans.
INTEGRATING IR FINDINGS INTO PUBLIC HEALTH PRACTICE	The goal of IR is to influence public health practice. As such, those conducting IR should strive to ensure the research is responsive to local priorities and systems and the results are communicated in timely and effective ways so that they can be readily used to improve health outcomes. Furthermore, researchers should endeavor to promote a culture of data-driven decision making throughout study implementation and beyond.

IR STUDIES THAT INVOLVE HUMAN SUBJECTS RESEARCH

Implementation research studies which include human subjects research are held to a higher standard of ethical conduct and must undergo external ethical review. You will need to clearly justify certain decisions in the research design to study stakeholders and research ethics committees, and show that you have carefully considered expected risks/benefits to study participants and the wider community and the potential impact on study quality. Upholding ethical standards often also requires periodic honest reflection and discussion among all IR partners throughout the implementation of the study (**Box 8.3**) (Patel 2017). Such dialogue can also help uncover and test the various assumptions that IR partners may have about different aspects of the research (e.g., the risks of a study to individuals or communities), as well as address any biases that emerge among researchers.

Human subjects research is a systematic investigation that obtains information about living individuals and is intended to produce generalizable knowledge.

Box 8.3: Cultivate ethical reflection among the IR partners by (Guillemin 2004)

- Acknowledging that ethically important decision points can arise at any time in the day-to-day conduct of research
- Recognizing the importance of one's intuitions about the appropriateness about a research situation— "not feeling quite right"
- Articulating what is ethically important in the practice of research through application of the principles of respect, justice, and beneficence
- Being reflective about one's experience in conducting research—i.e., thoughtful consideration of actions and their implications in the research process (such as the role of trust and power imbalances in research relationships)
- Exercising openness to assume new ways of thinking about research ethics and courage to critically challenge established research practice

The most important principles of ethical human subjects research are highlighted in **Box 8.4**.

When conducting research involving human subjects, you must submit a study application to at least one IRB or ERC, including in the country where the research will take place to ensure local laws and cultural issues are addressed (US HHS 2018) (US HHS 2020).

To determine whether your IR requires IRB/ERC approval, ask the following questions:

- Does it meet the definition of "research"?
- If yes, does it involve "human subjects"?
- If yes, is it human subjects research "exempt"?

Box 8.4: Ethical principles for the conduct of human subjects research

Respect for study participants' autonomy: Protect an individual's ability to choose freely whether to participate in the research based on transparent information about any risks and benefits involved and to decide to withdraw at any time.

Beneficence: Ensure the benefits of the research contribute to a public good and outweigh the risks to the study participant.

Justice: Ensure the equitable distribution of research costs and benefits.

If the results of an IR study will only be used by program stakeholders and will not be published or presented at scientific meetings or conferences, and especially if the activity is carried out in collaboration with a government health agency, it is almost always **public health practice**. Nonetheless, the risk of harm to participants should be assessed, with benefits deemed to outweigh possible risks and harm being a key criterion to proceed. Unintended consequences of public health practice, such as quality improvement activities, can result in punitive actions or perceived punitive actions. Thus, accountable knowledgeable oversight is needed even for practice.

You may encounter challenges when submitting IR studies to ERCs and IRBs for review (see **Box 8.5**). For example, ERCs and IRBs may not be as familiar and experienced with the oversight of studies that focus on health program and policy implementation.

Box 8.5: Common challenges of non-traditional research studies in the ethical review process (Pratt 2017)

- Identifying appropriate bodies for ethics review of IR
- Research ethics committee members lack familiarity with IR and the methods it uses
- Accounting for the flexible, dynamic nature of some forms of IR
- Variation in research ethics committee decisions across sites

KEY RESOURCES AND TOOLS

RESEARCH DESIGN AND METHODS

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IR TIP #9: PROCESS DOCUMENTATION

PROCESS DOCUMENTATION

Process documentation is an evaluation method to track meaningful events in projects or programs as they happen. This provides staff and stakeholders with insights into how implementation processes are working, allowing for course corrections, program adaptation, and innovation, which together enhance the prospect of program success and scale up. It may also help facilitate adaptation of program strategies and scaling up to other locations and contexts (Ross 2021). Process documentation should not capture everything that happens during program implementation but should include meaningful milestones that explain how and why a project or program made the decisions it did, and the subsequent outcomes associated with those decisions.

"Process documentation is a method of collection, collation, analysis and communication of experiences in contextually-appropriate ways. This set of activities is guided by a certain programme logic or 'theory of change' (see TIP 7): a representation of the underlying ideas and assumptions about how change is expected and/or foreseen to take place in each initiative. Hence, process documentation is an attempt to identify and bring to the fore the factors that affect the change process that the initiative aims to contribute to, whether these factors were expected or otherwise. To be more effective, process documentation must be considered a shared effort across the full spectrum of project participants." (da Silva 2011).

WHAT IS THE VALUE ADDED OF PROCESS DOCUMENTATION?

Process documentation is at the heart of implementation research (IR). By documenting the processes of implementation in real time, this method helps explain how and why interventions, strategies, and systems effect change. This information can then be used to clarify and adjust a project's theory of change (See IR Tip #7). Process documentation contributes information and insights in parallel to implementation, allowing for mid-course corrections and improvement. Beyond ongoing improvements to a given intervention, it can provide deeper understanding for replication and scale-up. Process documentation is a good complement to routine monitoring that typically provides data on inputs and outputs, and to qualitative assessment that is often performed at the conclusion of a project. Implementation of any program can be influenced by context and interactions of factors such as motivations, attitudes, power, decision making, and willingness to change. Process documentation can capture these more nuanced factors that may have an impact on program uptake and outcomes. In documenting perceptions, experiences, and changes as they happen from the multiple perspectives of those involved, process documentation contributes to a better understanding of what was done, what was changed, and why. The benefits of process documentation are not limited to the one program or

intervention under study; dissemination of lessons learned can enrich similar efforts and increase the likelihood of success by pointing to context-specific missteps that may not be captured in standard monitoring and assessment findings.

Very simply, process documentation starts with a project's theory of change or hypothesis (see IR Tip #7), and implementation strategy, and uses various tools—such as timelines, diaries, meeting notes, interviews, observations, dialogue, and videos—to document how change happens (or fails to). Process documentation captures a project's major events and milestones, not every minute detail.

Box 9.1: What do we lose without process documentation?

As part of work to mitigate the potential effects of COVID-19 on RMNCH services, the USAID-funded MOMENTUM Knowledge Accelerator project reviewed available evidence from Ebola and Zika outbreaks. While RMNCH outcomes (e.g., antenatal care coverage, contraceptive use) and some supply and demand effects (availability of services, trust in community health workers) were documented, little description exists on what was done or how interventions or implementation strategies were changed to work better. We know that adaptations were often made, but without process documentation we cannot learn and extrapolate from what worked in what context and why (MOMENTUM 2020, Hirschhorn 2020).

WHEN TO USE PROCESS DOCUMENTATION

Process documentation should be considered when trying to deconstruct what is happening as a result of a program or intervention. It can help unpack how and why strategies do or do not work at every stage of an intervention, including the start-up phase when they are first introduced and tested, during implementation when adaptations are being made and improvement measured, and at the point of project maturation when strategies are disseminated, replicated, or scaled up. It can also support and improve responses to context or systems stressors such as those experienced with COVID-19.

KEY QUESTIONS FOR PROCESS DOCUMENTATION AND PRIORITIZATION

One challenge with process documentation is determining where to start and what to focus on, given the complexity of implementation in the real world and the limitations of time and resources.

If you are planning to conduct IR and process documentation prior to program implementation, the following questions can help guide your effort:

- How is this program going to work? What is your theory of change/hypothesis and what are your operational assumptions?
- Who are the program's key stakeholders and what roles do they play in setting the agenda for the program?
- How will you systematically capture information about what is actually happening relative to your theory of change? How will you track important assumptions?
- How will you analyze and organize information so that all stakeholders can reflect on what is being learned and improve processes, during/throughout the intervention?

If you are conducting IR and process documentation for a program that is already underway, further questions to consider include:

- What do you understand about what is happening now? What are the most important unknowns or questions that relate to how implementation is going?
- Within the confines of resources and this understanding, and in consultation with stakeholders, what do you want to focus process documentation on now? Will the information:
  - Clarify appropriateness of underlying assumptions in the theory of change?
  - Explain progress related to a critical node on the pathway to outputs/outcomes (necessary step) in the current context?
  - Allow better and more rapid adjustments to implementation?
  - Allow for action on the information in the time available to the program or for later adoption?

USING PROCESS DOCUMENTATION TO ASSESS AND ADAPT THE THEORY OF CHANGE

Process documentation provides important information for reviewing the extent to which a program's theory of change or logic model is aligned with what is actually happening in the field. Along with other monitoring and evaluation data, it can help staff and stakeholders reflect on assumptions, planned versus actual outputs, linkages between change steps, and alignment of progress with goals and outcomes. This can then inform decisions regarding program adaptation, innovation, and needed improvements (Peek 2019).

STEPS TO CONDUCT PROCESS DOCUMENTATION

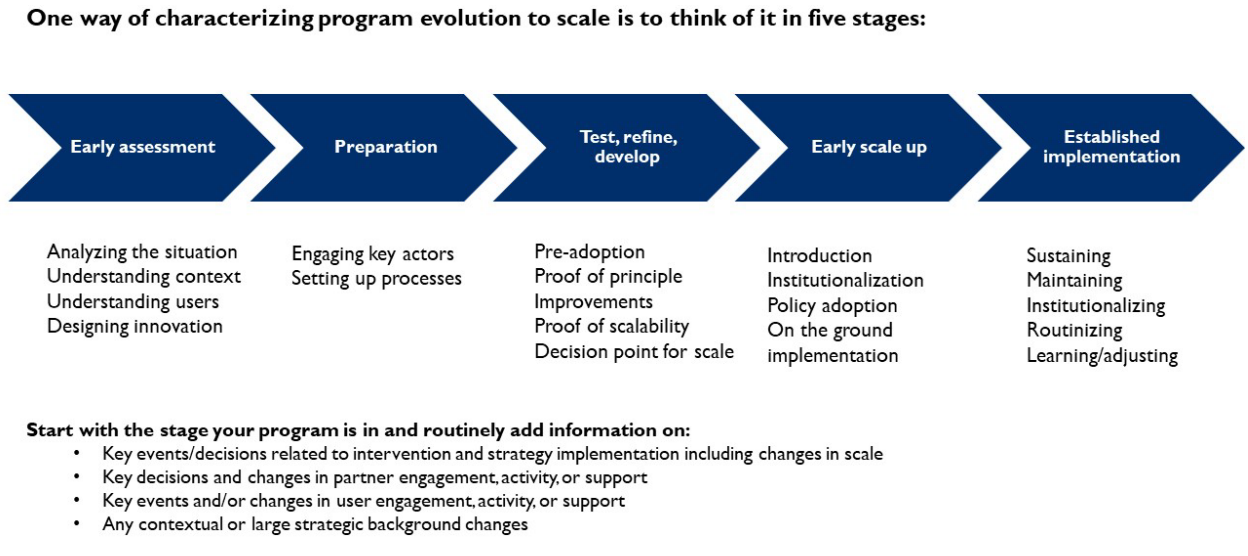
Process documentation needs to be integral to program or project plans and aligned with other monitoring and evaluation processes. It must be shaped by the theory of change or logic model (see IR Tip #7) which is guiding the intervention strategy. The following steps in Table 9.1 guide the development and application of process documentation (Nyangara 2015).

Table 9.1

STAGE	STEPS	DETAILS
PLANNING PROCESS DOCUMENTATION	Identify a documentation team and leader	• Plan how you will involve all key stakeholders • Assign person responsible for documenting
	Specify the intervention package	• Define technical content • Specify support/delivery strategies for intervention
	Map the program and draw its theory of change	• Draw a graphic depiction • Specify key causal pathways and actions • Write out hypotheses and assumptions • Be clear about how you expect it to work

STAGE	STEPS	DETAILS
	Identify possible contextual factors that may result in unanticipated impacts	• Consider external and internal factors • Prioritize them
	Define and prioritize documentation questions	• See section above, *Key questions for process documentation and prioritization*
	Identify appropriate methods and tools for data collection (checklists, screenshots, text, images, videos)	• Establish a process for keeping a basic implementation timeline (see **Figure 9.1**) • Develop tools matched to need • Align process data needs and analysis plans with other monitoring data systems
	Develop data collection plans	
COLLECTING & USING DATA	Collect data regularly from various sources using mixed methods	• Keep a timeline of program/project implementation that includes major activity milestones, key decisions, strategy adjustments, contextual changes, management changes • Other methods will depend on what is best suited to documentation questions
	Incorporate compilation, analysis, and reflection in improvement processes	• Document how information is brought into decision making • Consider along with other program/project monitoring and evaluation data • Continue to engage all stakeholder groups in reflection and improvement

Figure 9.1: How to keep a high-level timeline (adapted from Hodgins, S. Scale up Cheat Sheet, 2020)



CASE STUDIES

CASE STUDY 1: KUBORESHA AFYA MITAANI CASE STUDY IN KENYA (BENNETT 2020)

In the midst of change due to COVID-19 and the shift of health service management to a different government entity, the maternal and child health project - the USAID-funded Kuboresha Afya Mitaani project found process documentation allowed quicker and more strategic adaptation of activities. Ongoing stakeholder and decision maker mapping at multiple levels resulted in more effective engagement and progress through new requirements. The project has now built process data collection and collaboration on electronic platforms deepening participation and efficiency.

CASE STUDY 2: FROM RESEARCH TO NATIONAL EXPANSION: COMMUNITY-BASED MANAGEMENT OF CHILDHOOD PNEUMONIA IN NEPAL (DAWSON 2008)

In rural Nepal, local research was showing that community-based management of childhood pneumonia was highly effective. To scale up the intervention, the health system would need to engage female community health volunteers (FCHVs) in case management using oral antibiotics. A technical working group of government officials, local experts, and donor partners piloted two different models of delivery to determine whether this approach could be expanded nationally. The results were clear: community-based management of pneumonia by FCHVs doubled the total number of cases treated compared with areas served only by facilities. Process documentation was essential to explaining how and why this approach was so successful. Information on how implementation worked and the engagement of key decision makers in that process provided the foundation for rapidly moving delivery to national scale.

KEY TAKEAWAYS

Process documentation:

- Records how and why interventions are or are not leading to changes
- Provides real-time reflection on the project's theory of change
- Enhances learning around an intervention strategy's context, systems, and conditions for and drivers of change
- Provides critical information for adapting and scaling effective intervention strategies

KEY RESOURCES

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IR TIP #10: TRANSLATING LEARNING FOR ACTION

TRANSLATING LEARNING FOR ACTION

This IR Tip describes best practices for translating implementation research (IR) learning to ensure uptake by program managers, providers, policy makers, and communities to improve maternal, newborn, and child health in low- and middle-income countries (see IR process steps and **Figure 1.2** in IR Tip #1).

Implementation research (IR) is a systematic approach to understanding problems related to program implementation, identifying, and testing possible solutions in an adaptive or iterative process, and then actively sharing that learning.

Learning from IR can be used in a number of key ways that will be discussed in this brief:

- For adaptive management of programs in real time
- To plan for scale-up of feasible and effective interventions
- For national policy development or revision

This IR Tip draws on lessons of USAID projects which applied IR as part of a broader collaborating, learning, and adapting (CLA) approach. The CLA approach helps to ensure that programs coordinate efforts, are grounded in a strong evidence base, and iteratively adapt to remain relevant and effective over time (see IR Tip #3). In addition to applying learning systematically within a program, dissemination of IR findings allows the leveraging of solutions to more programs in more places to achieve better outcomes more quickly for more people.

PLANNING WITH STAKEHOLDERS FOR DISSEMINATION AND USE OF IR FINDINGS

A key principle of successful IR is the engagement of stakeholders throughout the entire design, implementation, analysis, and dissemination process (see IR Tip #5). Stakeholders are people or groups with an interest or concern in the program and its effects. Engaging a wide range of stakeholder representatives from the beginning allows them to bring important perspectives and local knowledge that builds bridges to their communities. These bridges are critical for establishing trust, communicating learning from the IR, and creating support for changes that improve implementation. The challenge of introducing stakeholders to information and ideas for change is to communicate them in a way that encourages stakeholders to support action based on research evidence rather than only on assumptions and beliefs.

SYNTHESIZING AND TRANSLATING DATA

Strong data analysis and documentation processes are the foundation for synthesizing and applying implementation learning to adapt and improve programs. The findings that emerge may prove or disprove underlying assumptions, confirm implementation strategies are working as planned or not, identify missing pieces, document changing outcomes, and reveal opportunities for enhancement.

Translating and disseminating IR findings in a compelling way that builds stakeholders' and key audiences' understanding of and appreciation for using evidence and sharing learning can result in two important outcomes. First, it can build commitment to changing the program as needed and contribute to scaling up of adapted approaches to other relevant communities and countries. Second, nurturing stakeholder capabilities to value and apply IR helps cultivate a broader culture of learning which continuously improves health systems over time and overall.

However, developing an effective dissemination process that meet the needs of a wide range of stakeholders can be challenging. From inception, identify stakeholder audiences and clarify what actions each group might be expected to take with IR learning. What information will they need and how can that information be best packaged and presented to be understood and actionable? Methods of communication and engagement will vary by stakeholder group and by stage of implementation from design to scale up, but participatory approaches and user-friendly materials are likely to be most effective. Last, how will you know what changes are resulting from sharing knowledge? Learn from dissemination by documenting when there is uptake of valuable practices and when non-valuable practices end.

Links for common communication tools are provided in **Box 10.1**.

Box 10.1: Making knowledge consumable, targeted, and diverse: Tools for IR findings for action

- Convene a stakeholder meeting (IR Tip #5)
- Initiate a policy dialogue (WHO 2015)
- Develop a policy brief or briefing document (CDC)
- Publish a blog (Blog Tyrant 2019)
- Create videos and infographics (Otten 2015)
- Host a webinar (USAID 2013)
- Share findings through a community of practice (QED Group 2013)
- Tell the story or narrative stories) (Downs 2014)
- Present at a conference (Petra 2016)

APPLYING IMPLEMENTATION RESEARCH FINDINGS FOR ACTION

The ultimate purpose of IR is to use the findings to make better decisions and adjustments to policies, plans, and programs to achieve, scale, and sustain morbidity and mortality reduction goals.

Adaptive management is central to IR. Prior to taking action to adapt and act, a program generally will have a pause and reflection to consider information, followed by decisions and adjustments in response to the information and/or changes in context. This intentional approach is called "adaptive management" (USAID 2021 and USAID 2018). Adaptive management is not about changing goals during implementation, but rather about changing the path being used to achieve the goals.

Implementation research starts as a study (data collection methods, selection of respondents or data sources, analysis), but as information is generated, flexibility and executing change become the most important features. Learning and the development of these capabilities can be applied to interventions, policies, and delivery systems. If successful, these will be reflected in leadership, decision making, and the spread of solutions. Building skill, confidence, and comfort with adaptive management, flexibility, and change or transformation will in turn enable more effective IR.

CASE STUDIES

CASE STUDY ON USING IR FOR ADAPTIVE MANAGEMENT: SINGLE PAYER NATIONAL INSURANCE REFORM IN INDONESIA

The USAID Health Finance and Governance Project supported a study in Indonesia to help the Ministry of Health (MOH) understand how its single-payer national insurance reform scheme was affecting primary care. During the study, program managers used research information to facilitate and follow the effects of real-time corrective actions. Cycle 1 study findings indicated uneven understanding of the insurance scheme's regulations, uneven readiness to implement it, and little change in productivity. This prompted the MOH to consult with district health officers to make written materials more understandable, and to set up a pay for performance incentive scheme to improve productivity. Cycle 2 of the study demonstrated increased primary care usage based on better application of the regulations but inconsistent application of pay for performance, leading to requests to adapt the system to pay for achievement of targets. Adaptive management was ongoing, with decision makers engaged throughout the process.

CASE STUDY ON USING IR FINDINGS FOR ADAPTIVE MANAGEMENT AND POLICY DEVELOPMENT: REVISIONS TO POLICY FOR MANAGEMENT OF PSBI IN BANGLADESH

In 2015, the Government of Bangladesh partnered with funding agencies, implementation groups, and research organizations to test how best to operationalize new guidelines for the management of possible serious bacterial infection (PSBI) in young infants when referral is not feasible. A group of partners including the Ministry of Health and Family Welfare (MOHFW), USAID's MaMoni Health Systems Strengthening Project, the Saving Newborn Lives Project of Save the Children, and Johns Hopkins Bloomberg School of Public Health conducted IR in several sites using an adapted action learning cycle approach [Plan-Do-Study-Act (PDSA)] to deliver a package of services and support for program scale-

up. Study activities embedded mixed methods data collection, and the IR team shared lessons around implementation in periodic stakeholder meetings with partners such MOHFW. Implementation strategies were adjusted in real time based on learning from efforts to build health facility readiness, measuring provider performance on applying the intervention algorithm, and monitoring the quality of program delivery. Routine stakeholder engagement was critical to cross-site learning and building confidence in the findings and ensured policy makers were ready to incorporate what was learned in the scale-up of policies, guidelines, and programs.

CASE STUDY ON USING IR FINDINGS FOR ADAPTIVE MANAGEMENT AND SCALE UP: TESTING A RESPECTFUL MATERNITY CARE PACKAGE OF INTERVENTIONS IN KENYA

Disrespect and abuse of women during labor and delivery strongly affect women's decisions to deliver in health facilities, which nonetheless are often are the best option them and their babies (Bohren 2019). The USAID-funded TRAction/Heshima project in Kenya used IR to implement an interactive three-pronged set of interventions at policy, health facility, and community levels. First, technical meetings, which included government, civil society, and professional associations, established continuous dialogue. At health facilities, staff were oriented and trained to provide respectful maternity care, and linkages with communities were strengthened for accountability. Communities were also trained, and mediated dialogues and counseling with providers were held. Heshima employed a learning-by-doing process from the outset, such that these new interventions were refined and extended to additional facilities. In addition, the process was adapted to reflect context-specific changes, including rapid devolution of health services and the initiation of free maternity service provision in public facilities. Reporting and observation during and after the intervention demonstrated decreased disrespect and abuse and greater satisfaction with facility delivery.

KEY TAKEAWAYS

- Involvement of all important stakeholders from the outset in planning for the learning, dissemination, and use of IR findings is critical to its success
- Dissemination of learning in real time from IR strengthens implementation, builds acceptance of change, ensures ownership, and can result in more sustained uptake
- Adaptive management helps systematize use of learning and facilitates responding to changes in the local context
- Multiple tools and approaches to translating and sharing learning must be matched with stakeholder audiences to communicate most effectively
- Audience-responsive packaging and sharing of learning from IR enables solutions to be shared effectively with more people and places, potentially increasing and accelerating impact
- Dissemination itself should also be subject to continuous review and improvement

KEY RESOURCES

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