

# IMPLEMENTATION RESEARCH TOOLKIT



## Introduction to Implementation Research


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# INTRODUCTION TO IMPLEMENTATION RESEARCH

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

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



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

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


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

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

### What is implementation research?

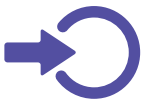
The importance of research in identifying solutions and options for overcoming implementation obstacles in health systems and programmes is widely recognized. This form of research addresses implementation bottlenecks, identifies optimal approaches for a particular setting, and promotes the uptake of research findings. Ultimately, it leads to improved health care and its delivery.

While IR has been defined in various ways by different institutions, common interpretations focus on a systematic approach to understanding and addressing barriers to effective and quality implementation of health interventions, strategies and policies. IR is demand-driven and the underlying research questions are framed around and based on needs identified together with relevant stakeholders and implementers who are themselves embedded in the local context. Uniquely, programme implementers are an integral part of the research process itself.



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

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



## The audience for this toolkit

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

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



## Relevance of IR for improved access and delivery of interventions

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

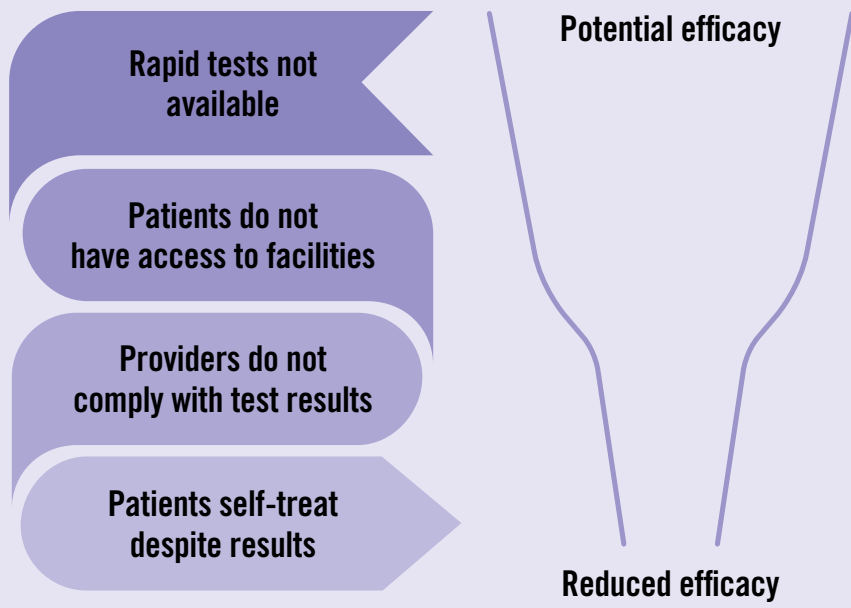
**Summary of the malaria ‘Test, Treat, Track’ initiative**

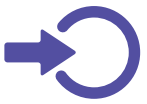
After several laboratory and clinical studies, the value of rapid diagnostic tests (RDTs) as efficacious tests for the timely identification of malaria infection was established. Malaria RDTs became an important component of malaria diagnostic testing in the clinical management of febrile illness.

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



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





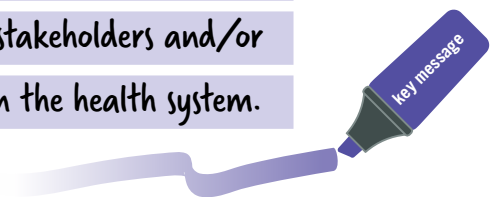
An intervention that has proven efficacious in a trial settings, may not perform as well as expected within a given health system due to wide-ranging potential contextual factors, such as issues of accessibility and/or acceptability, health care providers' adherence to policy recommendations and patient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

**Figure 1: Influence of health system factors on intervention effectiveness and impact<sup>4</sup>**



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

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



Essential elements of conducting meaningful IR include:

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

### Case study 1

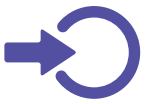
### Identifying barriers to accessing integrated community case management services

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

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

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



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

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

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

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

## The purpose of this Toolkit

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

The Toolkit helps IR teams:

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

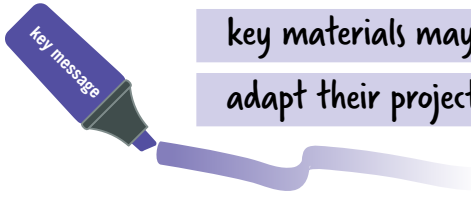
Many of the concepts presented in the Toolkit are cross-cutting and interrelated throughout the different modules.

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

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



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



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

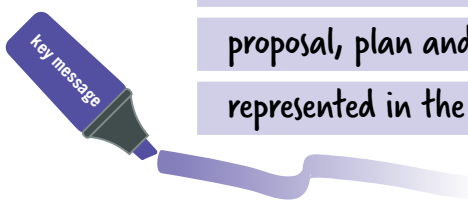
## Research teams

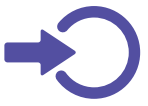
The research team assembled to address a specific IR question or implementation challenge should reflect the full range of disciplines required to address related research question(s). Members of the team have varied roles, they may work in diverse sectors (for example health, finance, planning, academia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

THE BUILDING  
AN IR TEAM  
MODULE

SEE

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





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

SEE

'MOOC ON IR'



## Case study 2 Key characteristics of implementation research

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

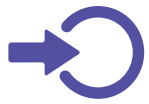
**Example of an IR project:** To inform a planned mass drug administration (MDA) for lymphatic filariasis (LF) in two districts of Indonesia, a micro-narrative survey tool was developed to capture community members' experiences with MDA and the social realms where drug delivery and compliance occur.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

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

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

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

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

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

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

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

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

**Lessons:** Implementation research must be adaptive to any challenges.

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

## Self-assessment and reflection activities

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

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

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

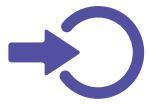
**Table 1: Self-assessment framework for IR awareness and competence**

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



### REFLECTION ACTIVITY

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



## References

1. SDG 3: Ensure healthy lives and promote well-being for all at all ages. New York: United Nations; 2017 (<http://www.un.org/sustainabledevelopment/health/>, accessed 16 October 2017).
2. Status report 2017: Access and Delivery Partnership (ADP). New York: United Nations Development Programme; 2017. ([http://adphealth.org/upload/resource/ADP\\_Status\\_Report\\_2017.pdf](http://adphealth.org/upload/resource/ADP_Status_Report_2017.pdf), accessed 16 October 2017).
3. Guidelines for the treatment of malaria. Third edition. Geneva: World Health Organization; 2015 (<http://www.who.int/malaria/publications/atoz/9789241549127/en/>, accessed 16 October 2017).
4. Adapted from de Savigny D. and Kuepfer I. (2015). Phase IV Studies. In: Field Trials of Health Interventions: A Toolbox. 3rd Edition. Eds. Smith P.G., Morrow R.H., Ross D.A. Chapter 22. Oxford: Oxford University Press; 2015.
5. In reality, some steps may occur simultaneously.
6. For further reading and in-depth discussion on IR see: Implementation research in health: a practical guide. Geneva: World Health Organization; 2013 (<http://www.who.int/alliance-hpsr/resources/implementationresearchguide/en/>, accessed 16 October 2017).

