IMPLEMENTATION RESEARCH TOOLKIT

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Understanding Implementation Research

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IMPLEMENTATION RESEARCH TOOLKIT: UNDERSTANDING IMPLEMENTATION RESEARCH

This section is designed to help you understand the processes involved in implementation research (IR). Before starting, you should have already completed the TDR Massive Open Online Course (MOOC) on Implementation Research[1] and worked through the Introduction section of this Toolkit.

This module comprises six sections:

1. *The need for IR*: Highlights the central importance of a real-life problem in framing the research questions, the composition of the research team and the range of stakeholders to engage.

2. *Implementation*: Describes the three possible levels at which implementation outcomes can be measured, and stresses the underlying point that IR ultimately optimizes an intervention for better outcomes.

3. *Characteristics of IR*: Outlines the defining characteristics of IR.
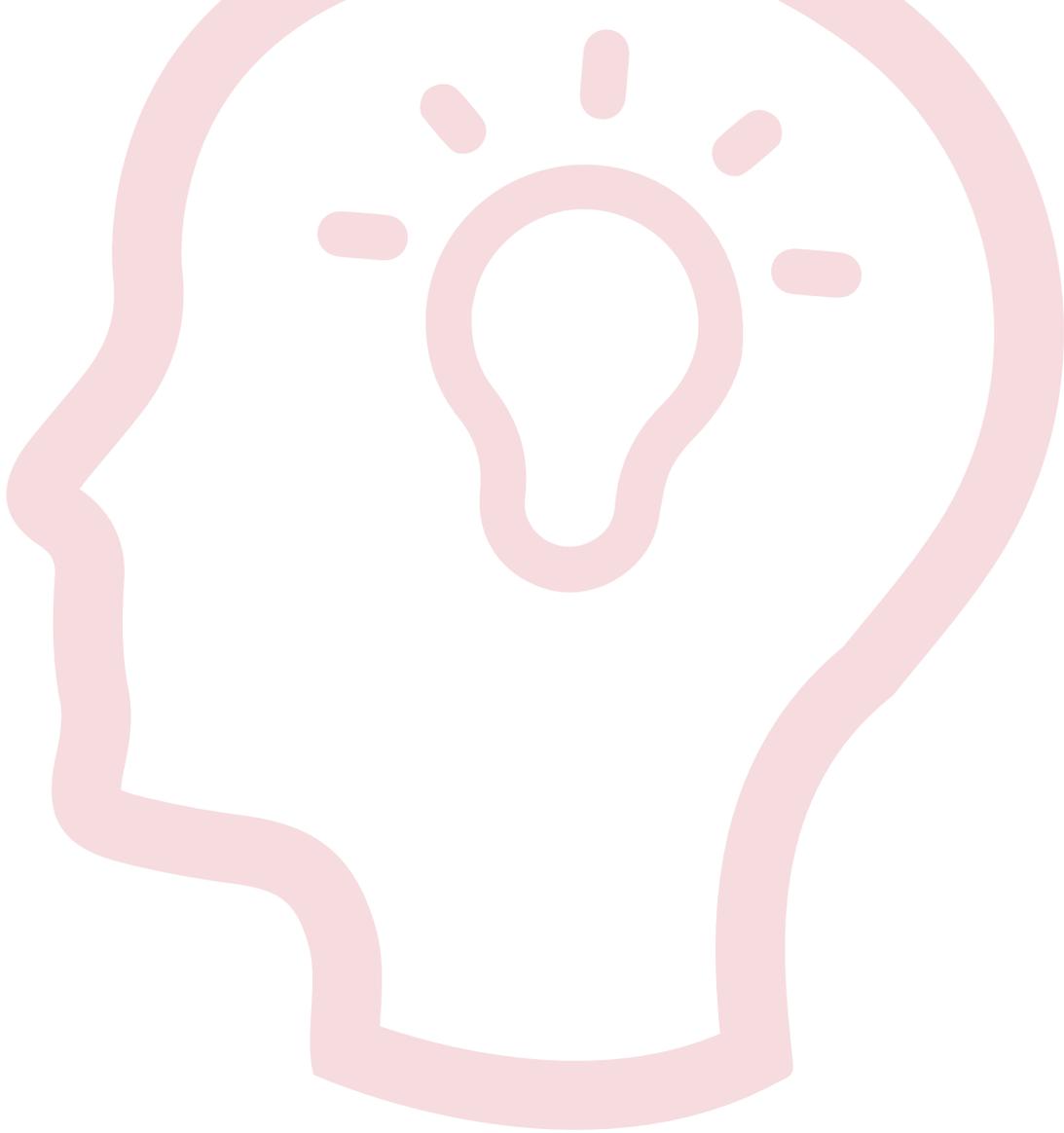
4. ***How IR works***: Maps out eight key activities in the IR process, considers the role of contextual factors and describes the crucial role of stakeholders in more detail.

5. ***Community engagement***: Focuses on the community as a key stakeholder in the IR process.

6. ***Ethical challenges in IR***: Employs case studies to illustrate some of the potential ethical issues surrounding IR.

The need for IR

The importance of research in identifying solutions and options for overcoming implementation barriers and bottlenecks (problems) in health systems and programmes is now widely recognized.[2] These problems are typically identified in the course of implementing a health programme and may be anchored in factors related to the local community, national, regional or health system contexts, for example. Identifying, understanding and characterizing the problem are the foundations of the research methodology and experimental design of IR.

IR is the systematic approach to understanding and addressing barriers to effective and quality delivery of health interventions, strategies and policies. Implementation barriers are best identified by health workers and programme managers, who have direct experiential knowledge of such problems and of the contexts in which they are encountered. The module "developing an implementation research proposal" of this Toolkit describes the process of identifying the problem and formulating corresponding research questions in greater detail.

key message

IR is demand-driven and the research questions are framed based on problems identified through engagement with relevant implementers and stakeholders in the health system.

Problems are best identified by health workers and programme managers

Introducing innovation (technology, policy, programming)

Implementation barriers and bottlenecks are variable and can occur at any point

Access and delivery

Many efficacious disease control tools (e.g. bednets and artemisinin-based combination therapies for malaria; praziquantel for schistosomiasis; ivermectin for lymphatic filariasis and onchocerciasis; oral rehydration solution (ORS) for treating diarrhoea; vaccinations for human papilloma virus, polio, influenza, hepatitis B); or strategies (preventing the transmission of HIV from mother to child, testing, tracking and treating malaria) are available. Despite Phase I–III clinical trials that have shown the potential of such tools and strategies to be effective at the community level, impact on health outcomes frequently fall below expectation after scale up and system-wide implementation. In order for a 'proven' intervention to be effective, it must be accessible to the target group, health care providers/service providers must comply with the relevant national or local policies, and patients must adhere to the intervention. However, there are several challenges that affect these requirements, including issues related to inequity.

Non-compliance or poor adherence can ultimately render a proven intervention ineffective. There is evidence that after integration into health systems and/or communities, interventions lose impact due to various factors (see Introduction module for example of rapid diagnostic tests for malaria).

IR focuses on identifying the challenges and bottlenecks related to the roll-out of health interventions, as well as on developing and testing effective strategies designed to overcome them, and determining the best way to introduce innovations into the health system, or to promote their large-scale use and sustainability.[3]

What does implementation research involve?

- Identifying implementation problems that hinder access to interventions, the delivery of services, as well as usability of effective, evidence-based interventions and their main determinants.

- Developing and testing practical solutions to address these problems, which are specific to particular health systems and environments or that address a problem common to a region.

- Identifying how evidence-based interventions, tools, and services should be modified or adapted to achieve sustained health impacts in real-world settings.

- Determining the best way to introduce practical solutions into health systems and facilitating their full-scale implementation, evaluation and modification.

The need to address implementation bottlenecks is often greatest in settings where health systems are weakest or non-existent, as illustrated by studies on health system effectiveness designed to understand reasons for the loss of the impact of a proven intervention. Loss of impact was associated with individual and systemic behaviour, including access to the intervention, diagnostic targeting, provider compliance and patient adherence (Figure 1).

Figure 1. Sequentially decreasing efficacy of artemisinin-based combination therapies (ACTs) when implemented at a local level
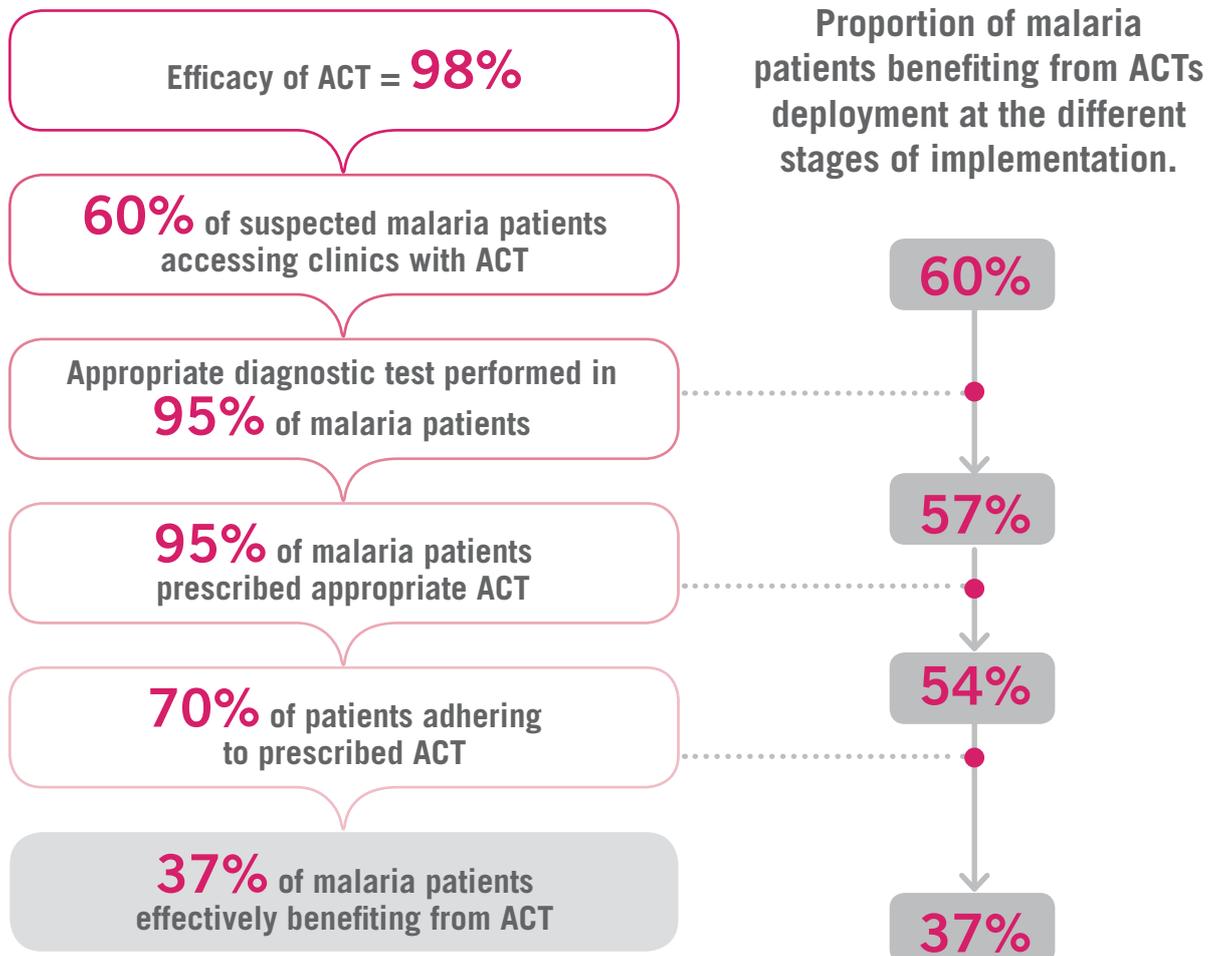
Studies on health system effectiveness

Figure 1 summarizes the outcome of studies conducted in Tanzania to determine why highly efficacious anti-malarial treatments low effectiveness when implemented at the community level.

Clinical trials show that artemisinin-based combination therapies (ACTs) have very high efficacy for the treatment of uncomplicated malaria: About 98% of patients who receive treatment within carefully conducted efficacy trials were cured of malaria. A community-based survey found that only 60% of suspected malaria patients accessed treatment at a clinic that had ACTs. Studies within the clinics showed that 95% of those who came to the clinics had an appropriate diagnostic test performed, and that 95% of those diagnosed with malaria were prescribed the correct treatment. Further studies showed that only 70% of patients who received the correct prescription of ACT adhered to the treatment as recommended.

Taken together, these series of studies showed that less than 40% of people with uncomplicated malaria in the community were effectively treated, despite the availability of ACTs, an intervention with an efficacy of 98%. Such studies not only document and measure the failings in the health system, but can also be used to investigate the reasons behind these problems and the potential actions that can be taken to address them.

REFLECTION ACTIVITY

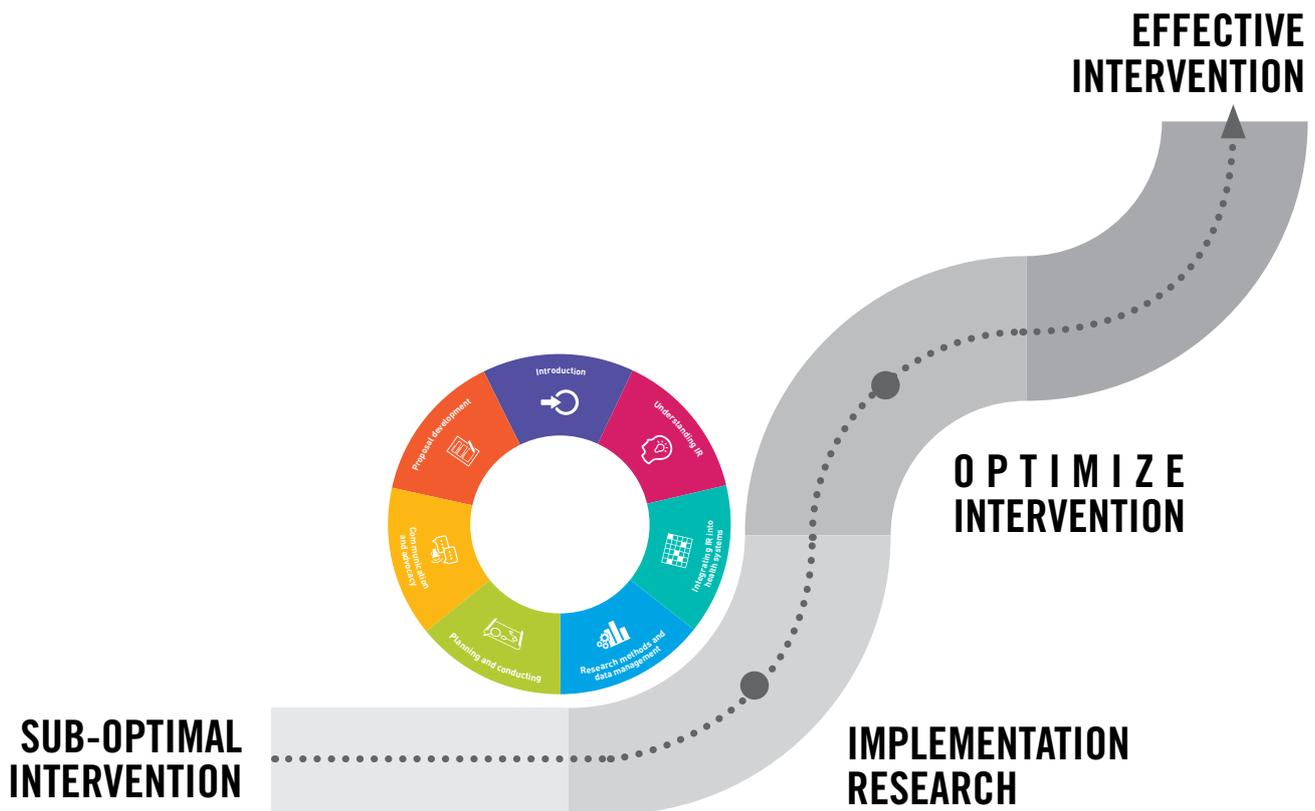**In relation to your IR project, address the following questions:**
- **What is the real-life problem or intervention bottleneck to be addressed?**
- **How was the problem identified? Is it demand-driven?**

Outcomes of IR

key message

Implementation research ultimately aims to optimize an intervention for better health outcomes.

IR uses scientific inquiry to guide the problem-solving process, with a view to providing evidence for policy and programmatic decisions. In this way, IR lends itself to change through continuous learning and, where necessary, adaptation. Such change can be best achieved when implementers or programme personnel:

- identify and describe an implementation problem clearly;
- are engaged in the process of formulating research question(s) to address the problem;
- work closely with researchers and specialist academics to conduct related IR.

The IR must have clear measurable outcomes.[4] These can be conceptualized at three levels:[5]

1. **Client outcomes:** Individual level; can be measured from client satisfaction whilst accessing the services, improvement in performance of the service provider / personnel and/or symptoms experienced.

2. **Service outcomes:** Measured using the following quality dimensions: efficiency, safety, effectiveness, equity, patient-centeredness and timeliness.[6]

3. **Implementation outcomes:** Measured using indicators of acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability (See Table 1).

Table 1: Definition of implementation outcomes

| Outcomes	Definition
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable, or satisfactory.
Adoption	The intention, initial decision or action to try/employ an innovation or evidence-based practice. Adoption also may be referred to as "uptake".
Appropriateness	The perceived fit, relevance or compatibility of the innovation or evidence based practice for a given practice setting, provider or consumer; and/or perceived fit of the innovation to address a particular issue or problem. "Appropriateness" is conceptually similar to "acceptability".
Cost	The cost impact of an implementation effort. Implementation costs vary according to the complexity of three components: the intervention, the implementation strategy, and the setting(s).
Feasibility	The extent to which a new treatment or an innovation, can be successfully used or carried out in a given agency or setting.
Fidelity	The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the programme developers.
Penetration	The integration of a practice within a service setting and its sub-systems. Penetration can be calculated in terms of the number of providers who deliver a given service or treatment, divided by the total number of providers trained in or expected to deliver the service.
Sustainability	The extent to which a newly implemented intervention is maintained or institutionalized within a service setting's ongoing, stable operations. There are three stages that determine institutionalization: 1) passage (a single event such as transition from temporary to permanent funding); 2) cycle or routine (i.e. repetitive reinforcement of the importance of the evidence-based intervention through inclusion in organizational or community procedures and behaviours, such as the annual budget and evaluation criteria); and 3) niche saturation (the extent to which an evidence-based intervention is integrated into all sub-systems of an organization).

Adapted from Proctor et al (2011)

In the IR context, an 'intervention' is broadly defined as any health technology (medicine, vaccine or diagnostics), treatment and/or prevention practice and strategy, or efforts executed at the individual, community or institutional levels. Interventions include policy changes, strategies or scaling up health innovations that have demonstrated efficacy in the laboratory, clinical trials or small-scale pilot studies.[7] Lack of compliance awareness or contextual issues related to culture, politics and geography can constitute barriers to the effective delivery of these interventions. It is critical to identify the intervention outcome indicators of key relevance to an IR project (see Table 2).

Table 2. Stages of an intervention and examples of main outcome indicators

Stage of intervention	Examples of main outcome indicators
New (introduction and scale up)	Acceptability, adoption, appropriateness, feasibility and sustainability
Well established intervention	Implementation as originally designed (fidelity), cost and coverage

key message

For IR, it is important to describe the process of introducing an intervention (in the context of a specific environment), and the intervention itself in sufficient detail.
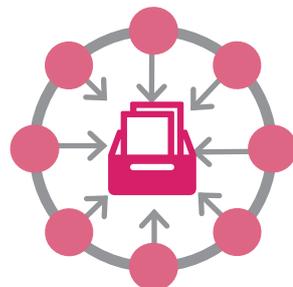
Describe the process of introducing the intervention in context and the intervention itself.

REFLECTION ACTIVITY

In relation to your IR project, address the following questions:

1. **What is the proposed intervention in your IR project?**

2. **Describe the intervention as it is currently being implemented. How will the proposed IR improve the intervention?**

3. **List the main outcome indicators for the IR.**

Characteristics of IR

An IR process can optimize interventions available to address health problems.[8] Thus, while bed nets and artemisinin-based combination therapy are key examples of available, affordable and life-saving interventions for preventing and treating malaria, access to and proper use of these interventions remain suboptimal (See Figure 1).[9]

IR is characterized by the complex, iterative, systematic, multidisciplinary and contextual processes that take place at multiple levels in order to identify and address implementation problems (Table 3).

Table 3: Key characteristics of IR

| Characteristic	Description
Systematic	The systematic study of how evidence-based public health interventions are integrated and provided in specific settings, and how resulting health outcomes vary across communities. Balances relevance to real life situations with rigor, strictly adhering to the norms of scientific inquiry.
Multidisciplinary	Analysis of biological, social, economic, political, systemic and environmental factors that impact implementation of specific health interventions. Requires interdisciplinary collaborations between behavioural and social scientists, clinicians, epidemiologists, statisticians, engineers, business analysts, policy-makers, community leaders and key stakeholders.
Contextual	Demand-driven. Framing of research questions is based on needs identified by implementers and other stakeholders in the health system. Research is relevant to local specifics and needs, and aims to improve health care delivery in a given context. Generates generalizable knowledge and insights that can be applied across various settings. Mindful of cultural and community-based influences.
Complex	Dynamic and adaptive. Multi-scale: occurs at multiple levels of health systems and communities. Analyses multi-component programmes and policies. Non-linear, iterative, evolving process.
Real Life Situations	Takes place within real-life settings. There is no attempt to manipulate the setting within which the intervention is taking place. Engages with populations of interest including the actual implementers (e.g. health practitioners, policy-makers) and beneficiaries (communities, target population).

A simple paradox that IR acknowledges is that the more rigidly the implementation is controlled to ensure fidelity of a proven intervention, the more likely it is that local factors will reduce its effectiveness. Similarly, the more adapted an intervention is to local conditions the more effective it is likely will be.

As an intervention is tailored or adapted for a specific context, it becomes more difficult to argue that findings can be generalized to other localities or populations. It is important to apply scientific rigor to an IR project. The implication is that processes leading to outcomes must be well documented to be understood. As any other type of scientific investigation, IR must comply with good research practices, Including:

- Access to data collection and analysis methods and clear presentation to allow replication.
- Concepts and propositions should be logically consistent, clearly defined, and, in general, lead to empirically verifiable hypotheses.
- Methods and concepts should be intentionally subjected to criticism and evaluation by subject area experts.

IR is NOT:
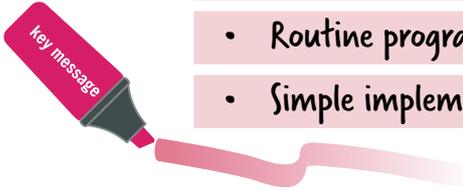
- Basic biomedical research (e.g., discovery of a new gene pathway or aetiology research).
- Initial or replication of intervention efficacy trials in a top-down controlled setting.
- Routine programme progress reporting.
- Simple implementation of health interventions.

REFLECTION ACTIVITY

Analyse your proposed IR project using the key characteristics of IR (see Table 3). Does the proposed approach align with the characteristics listed?

1 Systematic

2 Multidisci-plinary

KEY CHARACTERISTICS OF IR

3 Contextual

4 Complex

5 Real-life situations

How IR works

key message
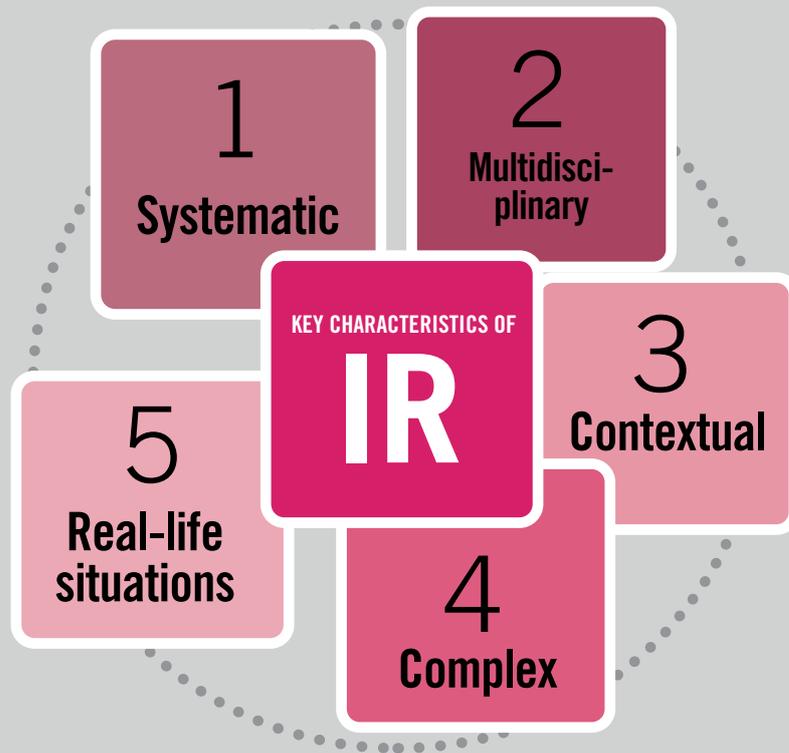
Implementation research is not a single or a linear activity, but a continuous process.

Each aspect of the IR process is crucial to project success, and the degree to which individual steps are interconnected in practice increases the dissemination and uptake of the IR findings (see Figure 2). For this reason, the composition of the IR team should be multidisciplinary, bringing together people with relevant skills, backgrounds and experiences.
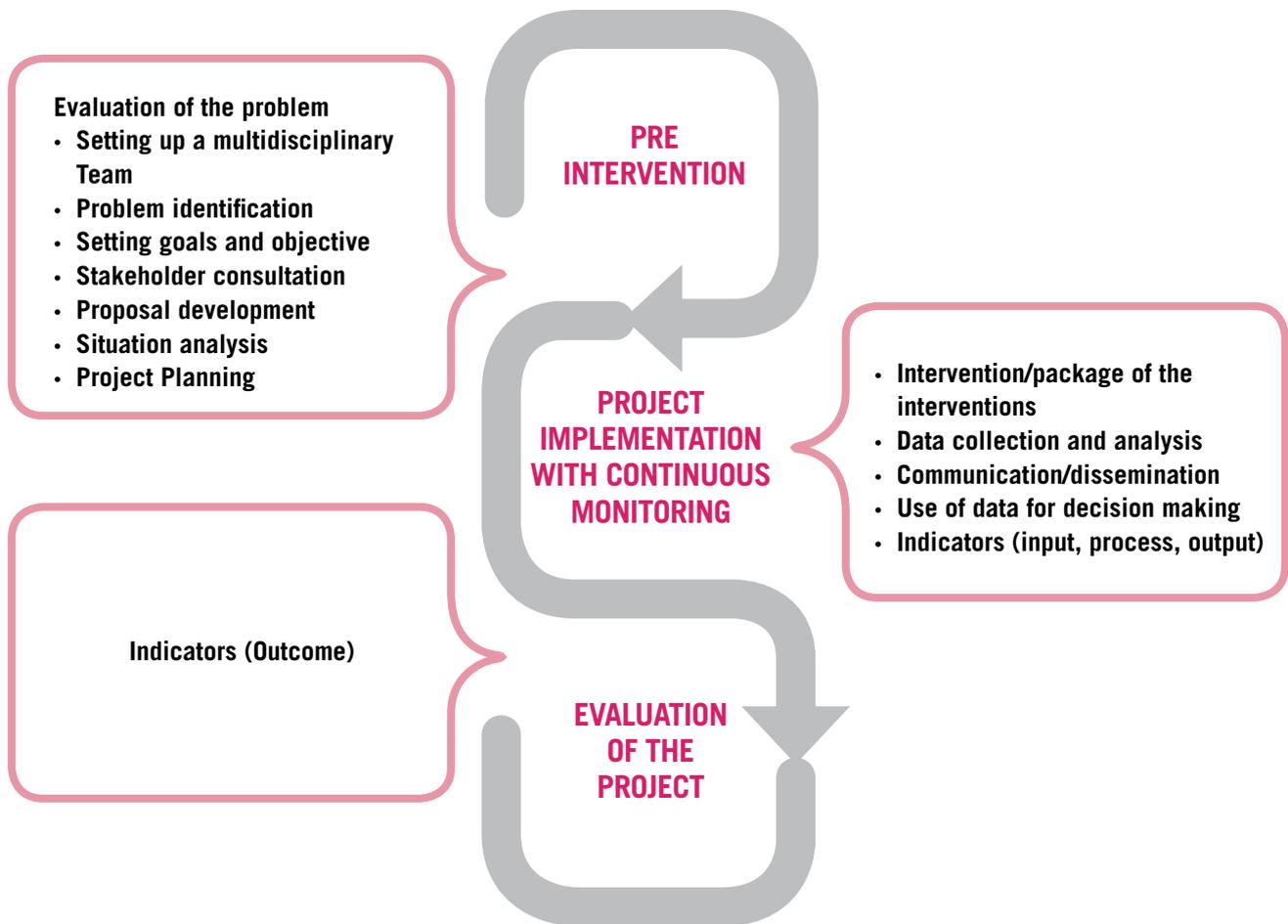
Key steps in the IR process

- Identify barriers/problem preventing optimization of a defined intervention.
- Form the research team. Should reflect the skill sets needed to address the implementation problem.
- Identify other key stakeholders. Engage relevant stakeholders (e.g. the community) to understand the context where the intervention occurs.
- Discuss the implementation problem(s) and generate pertinent research questions that provide important insights and identify feasible solutions.
- Identify an appropriate study design to address the research question.
- Develop a detailed proposal and research plan, mobilize resources and conduct the study aimed at addressing the question(s) using good management practices.
- Continuously monitor and document processes throughout the research and provide feedback to key stakeholders to maximize the value of the research.
- At the end of the research project, the team has an obligation to document and disseminate the knowledge generated through the appropriate media, including publication in indexed scientific literature.

Stakeholders can play a crucial role in disseminating the IR findings through their own networks, supporting any recommended changes in the delivery of the intervention and promoting uptake within their networks.
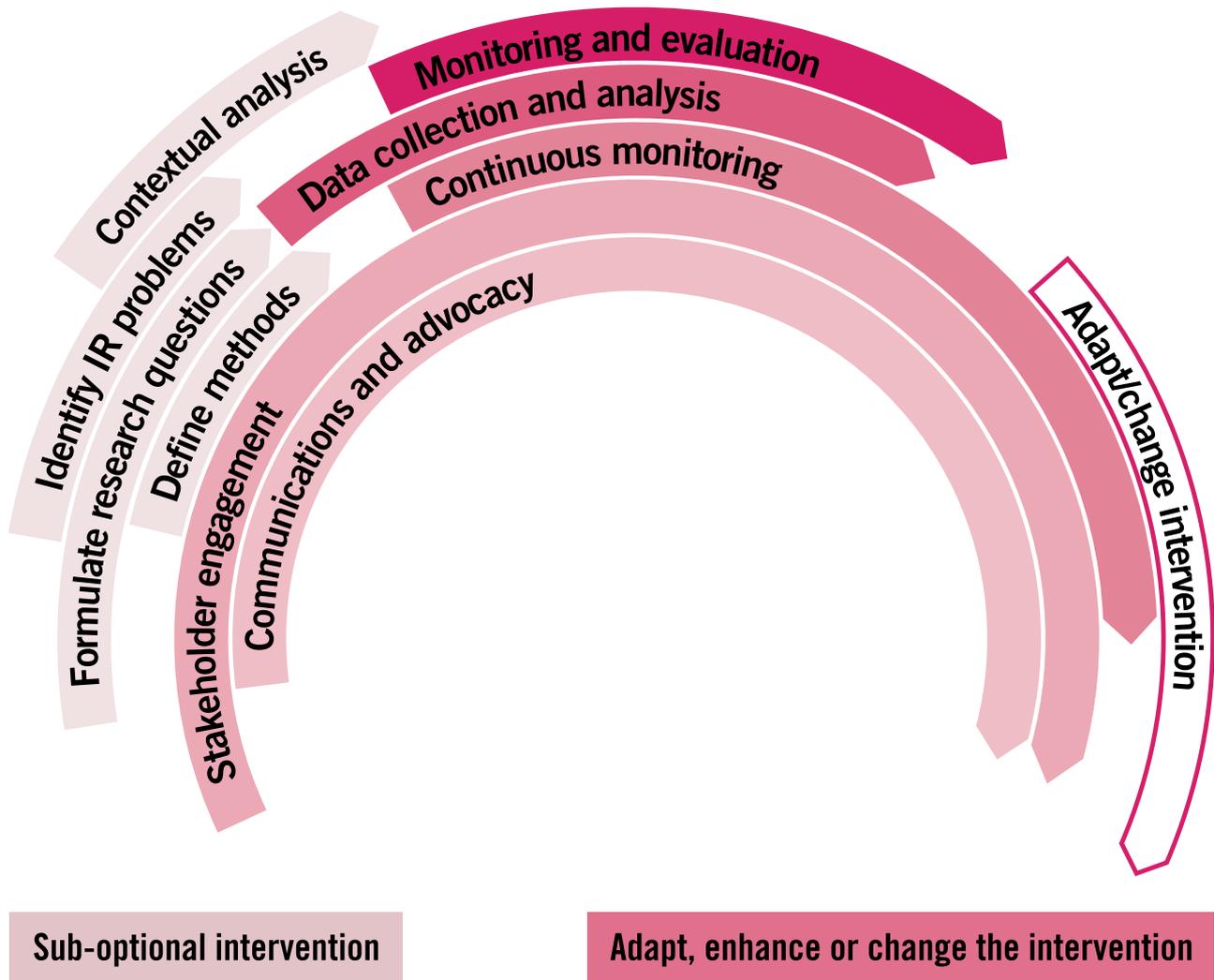
Figure 2: Key steps in the IR process

Evaluation of the problem
- **Setting up a multidisciplinary Team**
- **Problem identification**
- **Setting goals and objective**
- **Stakeholder consultation**
- **Proposal development**
- **Situation analysis**
- **Project Planning**

PRE INTERVENTION

PROJECT IMPLEMENTATION WITH CONTINUOUS MONITORING

- **Intervention/package of the interventions**
- **Data collection and analysis**
- **Communication/dissemination**
- **Use of data for decision making**
- **Indicators (input, process, output)**

Indicators (Outcome)

EVALUATION OF THE PROJECT

An IR project has many overlapping steps that do not necessarily occur in a linear manner. The roadmap in Figure 3 illustrates the timings and steps in the IR process. Remember that each context is different and has its own complexities, so this roadmap should be adapted to your situation. The timing for an IR project will depend on the intervention problem and research methods chosen. This sample roadmap indicates some of the key overlapping activities that occur throughout an IR project.

Figure 3: Road map of an IR project

Contextual analysis

Monitoring and evaluation

Data collection and analysis

Continuous monitoring

Identify IR problems

Formulate research questions

Define methods

Stakeholder engagement

Communications and advocacy

Adapt/change intervention

Sub-optional intervention

Adapt, enhance or change the intervention

key message

IR uses contextual knowledge to study processes to improve practice, it applies research findings and methods to real-world contexts and settings.

Unlike other types of research – where the setting is controlled to create an ideal situation for success – IR is conducted in real life contexts and must necessarily address problems identified in the course of delivering an intervention in context. The research team does not manipulate the setting in any way and allows life to go on "as usual". Factors such as political changes, health staff circumstances (e.g. staff changes or transfer), physical settings (e.g. natural disasters and geographic terrain), tradition (cultural, religious, institutional), stakeholder characteristics and public health related issues (e.g. disease outbreaks and epidemics) influence the real-life context in which an intervention takes place. These factors, which can be broadly classified as physical, socioeconomic and cultural environments, health systems, stakeholders and institutional cultures are key aspects of the research context in IR and require critical analysis to ensure that the research questions are framed in context. Together they contribute to and affect the planning, implementation, monitoring and outcomes of any intervention.

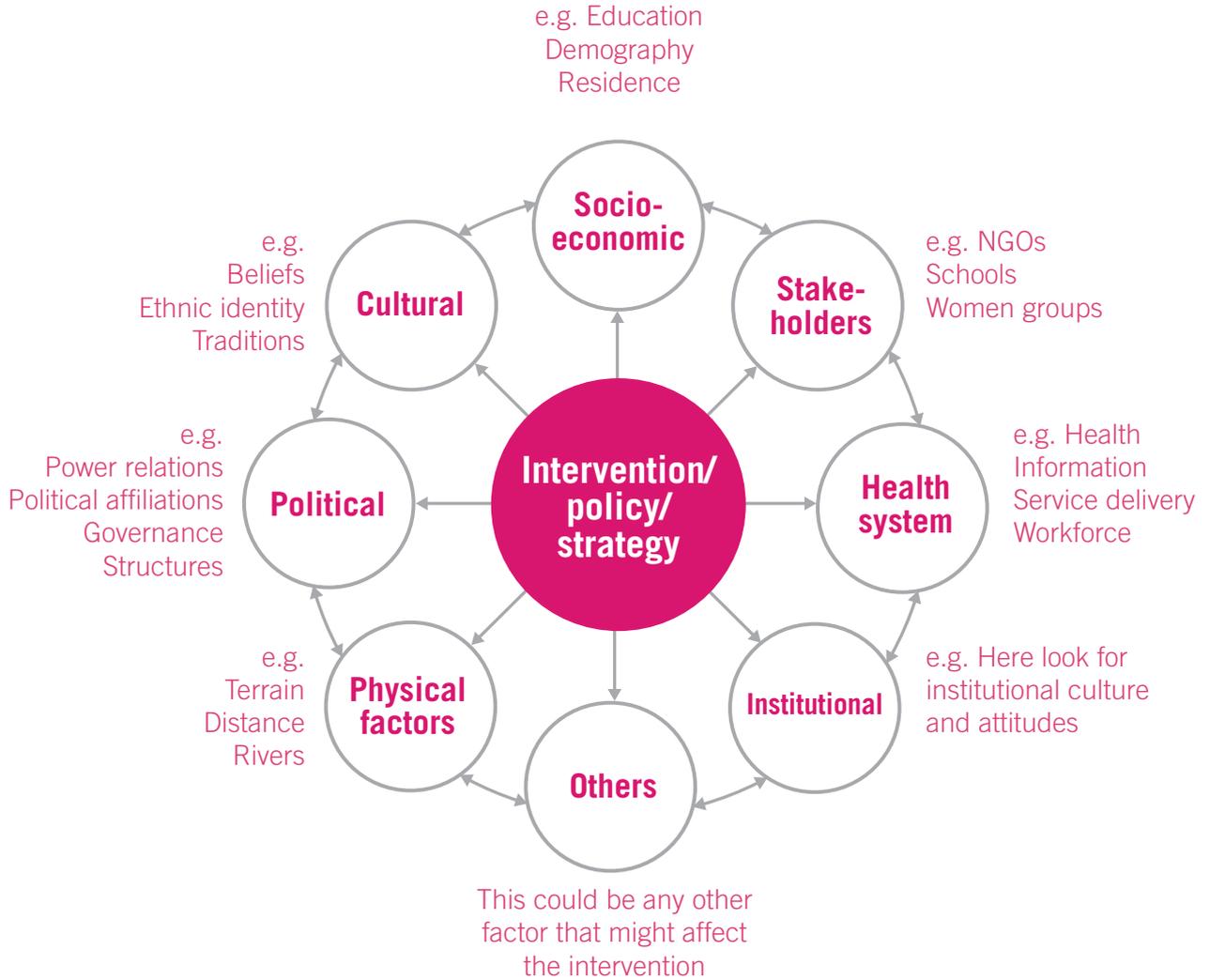### Political context and successful sustained policy implementation

Thailand is one of the countries that succeeded in meeting several Millennium Development Goal (MDG) targets, i.e. poverty and hunger reduction, universal primary education, gender equality, fight against HIV/AIDS, access to clean drinking water and sanitation, improving the lives of people in slums and participation in global partnerships.[10]

Thailand achieved the health-related MDGs and introduced the concept of 'MDG plus'. A review of the Thailand health system highlighted key factors underpinning the success. Although there were multiple changes in political context during that period, technocrats in the relevant government departments were stable and thus able to maintain focus on achieving the long-term plan of strengthening the health system. Health managers at provincial and district levels had the authority and flexibility to implement policies and regulations set at national level. This allowed them to respond to local context and needs, especially where financial and human resources were concerned. Financial managers were able to retain revenues generated from user fees to purchase medicines at the best possible price. Human resources were managed to enhance programme integration and avoid vertical duplication. For example, HIV prevention programme services were integrated with the antenatal care clinic delivered by nurses after training and piloting.[11]

During an IR project, the key contextual factors should be analysed objectively (Figure 4). These factors vary considerably from one location to another and can be impacted by international, regional, national and local events.

Figure 4. Contextual Factors in IR[12]

e.g. Education
Demography
Residence

e.g. NGOs
Schools
Women groups

e.g.
Beliefs
Ethnic identity
Traditions

e.g. Health
Information
Service delivery
Workforce

e.g.
Power relations
Political affiliations
Governance
Structures

e.g. Here look for
institutional culture
and attitudes

e.g.
Terrain
Distance
Rivers

Socio-economic

Cultural

Stake-holders

Political

Intervention/policy/strategy

Health system

Physical factors

Institutional

Others

This could be any other
factor that might affect
the intervention

Socioeconomic and cultural context

Cultural context plays an important role in treatment decisions and health seeking behaviour.

key message

Various aspects of the socioeconomic and cultural context can impact the delivery of an intervention such that an intervention that was effective in one locale could well be ineffective due to constraints inherent to the culture or circumstances. These factors also change over time as societies transition.

Traditional beliefs influence treatment decisions and behaviour

This is especially so in transitional societies where traditional and modern medicine are employed with the choice of one or the other determined by changing belief systems. Geographic distance and associated costs also come into play. In some cultures, the traditional health belief system places responsibility and blame on women and imposes a system of social control over the adult female population. Changing health beliefs are less the result of the introduction of a new health philosophy than of the retreat of traditional beliefs under the impact of other societal factors embodied in the older health philosophy.[13]

Physical and demographic factors

Geography can have a profound effect on the delivery of an intervention especially when related to access to health services and health interventions. Location of a target population (rural/urban), distance from the central facility or capital, physical barriers (such as mountains, rivers), extreme weather conditions, infrastructure (transport systems, electricity and water) and demographics (population size, distribution by location, gender and age) must be analysed where relevant to put the problem in context.

Socioeconomic status

The general standard of living and level of inequality, as well as identification of vulnerable groups and socioeconomic status based on income levels, assets, educational status and occupation should analysed. The main types of dwellings (e.g. communal huts, apartments or gated communities), by location, food consumption, nutrition, access to clean water and sanitation etc. should also be analysed.

REFLECTION ACTIVITY

In relation to your IR project, address the following questions regarding context:

- What are the sociocultural and political systems in your project area?
- What are the contextual issues currently affecting (positively and negatively) the intervention of interest.
- How might these contextual issues impact aspects of your study?

1 Cultural or other contextual issues surrounding the study?

2 Sociocultural and political systems?

3 How might contextual issues impact your study?
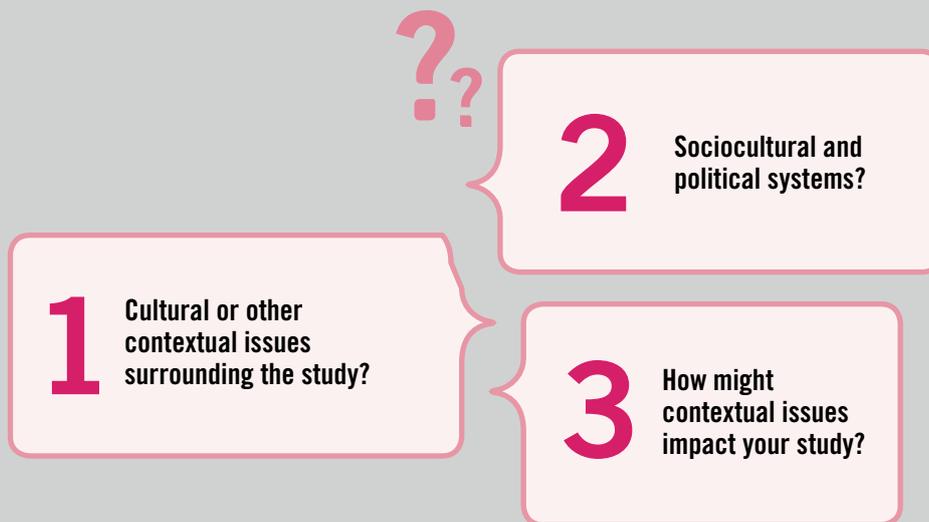
Cultural and political factors

Analysis of cultural beliefs related to health, gender equality, literacy rates, ethnicity/tribal segregation related to the following should be conducted;

1. policy environment and political factors, including the level of support for social services and health care services;
2. government capacity to provide services
3. ongoing or recently introduced health interventions should be conducted.

Stakeholders

Engaging stakeholders in an IR project involves face-to-face consultations and discussions from the national to the community level – not just briefing the stakeholders and seeking their approval for the study, but actively involving them in the various discussions, decisions and negotiations.[14]

A stakeholder is anyone whose involvement is crucial to the success of an activity. In practice, IR involves multiple stakeholders who should be identified in the developmental stages of the project.

key message

Involving stakeholders throughout IR projects

One of the distinguishing features of IR is the importance of involving implementers in all aspects of the research process. Researchers worked with the programme implementers of an insurance scheme in India, the Rajiv Aarogyasri Scheme (RAS), in the state of undivided Andhra Pradesh. One of the objectives of the collaboration was to identify research questions that could serve as a guide for an evaluation of the RAS. Meetings were held over a period of one year to identify appropriate research questions. The results of this collaboration were compared with those published in the literature on evaluations of insurance programmes in other low- and middle-income countries. The results showed great disparity in the types of questions that were generated through the collaboration and those that were published in literature. Whereas in the published literature, 60% of the research questions pertained to the output/outcome of the programme and the remaining 40% related to processes and inputs, in the RAS participatory research process, 81% of the questions generated looked at programme input/processes, and only 19% on outputs and outcomes. The study therefore concluded the implementation research approach of involving implementers can lead to a substantively different emphasis of research questions, which are more relevant to the research needs of policy-makers, and therefore contribute to greater translation of the research findings.[15]

Conducting a stakeholder analysis is one of the most important activities undertaken by researchers in terms of understanding the context of the intervention, and should be done in a systematic and comprehensive way.[16] [17] [18]
The objective of the stakeholder analysis is to identify all relevant stakeholders, assess how they are likely to be affected by the research, and how they might respond to the research outcome. Stakeholder identification requires careful judgment, should not be exclusive (limiting the breadth of perspectives) or over-inclusive (diluting essential focus).

Steps in a stakeholder analysis process

1. Define the purpose of the analysis.

2. Generate a list of potential stakeholders (an initial list can be constructed by brainstorming relevant issues and further additions to the list can utilize a 'snowball' technique, during which stakeholders identify additional stakeholders).

3. Collect necessary data (e.g. using interview guides and semi-structured questionnaires).

4. Analyse and present data in matrices (i.e. type of stakeholder, levels of interest and influence, and the roles they will be or are playing in the implementation of the proposed intervention).

Depending on the IR issue of interest, stakeholders could include (but are by no means limited to):

1. **Policy-makers and political leaders**. Representatives who will ensure that health workers and end-users of the study are properly informed of any shift in policy.

2. **Health care providers at facility and community level.** Include health professionals in government and private medical facilities, traditional healers and drug sellers, managers of drug shops etc. who have been providing health care in a particular way for a long time. Since change does not come easily, it is critical to involve them in the design and implementation of any strategies that will enhance programme implementation.

3. **Media specialists**. Consulting this group of stakeholders is critical since with their capacity to communicate, they can help to share the results of an IR project widely.

4. **Community members.** It is at the community/village level that all health care interventions are implemented. In this light, community members can help ensure maximum support. Consultations at the community level should cut across all social, political and religious lines. Constant interaction is crucial for success and to ensure that the activity or proposed intervention is not discredited.

SECTION ON BUILDING AN IR TEAM (INTEGRATING IMPLEMENTATION RESEARCH INRO HEALTH SYSTEMS)

SEE

Engaging stakeholders often requires a similar approach and set of skills as creating a successful IR team, and the two activities can be usefully seen as forming a continuum (see "Module on Building an IR Team").

The box highlights how stakeholder analysis was used in one instance to assess the perceptions, aspirations and expectations of a range of stakeholders in order to assess the policy environment prior to the introduction of a series of health service innovations.

Case study 1	Importance of involving stakeholders throughout an IR project

Background: The distinguishing features of IR includes the importance given both to the context within which a programme operates, as well as the populations that are affected by the project. It seeks to involve implementers and populations affected by an intervention in all aspects of research right from the research design, the process of research, and as users of research outcomes. The emphasis on involving 'local' populations and groups in research to enable a 'bottom-up' approach ensures that local priorities are recognized and participants have a voice. This subsequently makes research and the actions that result from it more relevant and acceptable locally. Incorporating programme implementers' perspectives makes the research process sensitive to the complexity of the world that the programe implementers inhabit and are trying to change.

The IR approach was used to ascertain how the nature of emerging questions differed in focus when compared to those found in the literature on the evaluation of health insurance programmes in low- and middle-income countries (LMICs). The context was one of the longest serving government-funded insurance schemes in India, the Rajiv Aarogyasri Scheme (RAS) in the state of Andhra Pradesh. The RAS has been operating since 2007 and covers the cost of inpatient care for people below the poverty line. The programme has around 70 million beneficiaries. The IR approach was comprised of a series of meetings during 2012, involving various groups of stakeholders. Staff from the Aarogyasri Health Care Trust, the Public Health Foundation of India and the Indian Institute of Public Health, Hyderabad met to identify research questions that could serve as a guide for evaluation of the RAS. The derived research questions were compared with the ones identified by a literature review.

Findings: Around 60% of the research questions in the published literature pertained to programme outputs and outcomes while 40% were related to programme input/process. This was in contrast with the questions generated through IR, where 81% of questions were related to input/processes and only 19% focused on outputs and outcomes. Furthermore, the majority of the studies in published literature that sought to evaluate health insurance programmes were researcher-driven. They also had a stronger tendency to evaluate the insurance programme against a set of outcomes rather than to the process and input aspects of the programme.

Conclusions: The research questions identified through the collaborative approach established and offered a more comprehensive view of programme performance and were more closely aligned to with the implementers' needs. Furthermore, involving implementers/stakeholders gave an insight into the programme activities. If implementers are not involved, it becomes difficult for external researchers to incorporate the implementers' tacit knowledge (which are often more relevant into the needs of policy-makers) in formulating the research questions and the subsequent research process

Lessons: The set of research questions resulting from IR were much broader in scope and put more emphasis on processes and inputs. The collaborative process also enabled the researchers to appreciate the heterogeneous nature of implementers, a fundamental characteristic of IR.

Source: Rao, K.D. et al. An implementation research approach to evaluating health insurance programs: insights from India. International Journal of Health Policy and Management. 2016; 5.5: 295.

Institutional assessment

An institutional analysis (a systematic study of the behaviour of organizations) is another important dimension to consider in planning for an IR project. This can be achieved through an analysis of strengths, weaknesses, opportunities and threats (or 'SWOT') associated with institutions that could potentially interact with the IR team in the course of the project, and with the intervention under study. A SWOT analysis will help establish the institutional factors with a potential impact on the success or failure of a given intervention.

Qualitative assessment of stakeholders

A study in the Santiago Metropolitan region of Chile used stakeholder analysis to assess the related policy environment prior to the introduction of a series of ambulatory care innovations for acute lower respiratory disease in children (pneumonia and obstructive bronchitis), as well as prevention of stroke.

Priority stakeholders were defined according to the knowledge of the researcher about the Chilean health sector. They included policy-makers, doctors, nurses, managers and professions allied to health care.

The study mainly involved the collection of qualitative data about the perceptions, aspirations and expectations of a range of stakeholders. It also gathered material on the perception of local power and authority, as this was seen as likely to affect implementation processes.

While this methodology did not permit statistical inference, it was seen as providing an understanding of the context and probable responses of stakeholders to the planned innovations. The research was intended to provide data on the negotiation and understanding perceptions within social interaction. It considered domains such as experience, knowledge and action.[19]

REFLECTION ACTIVITY

In relation to your IR project, address the following questions:

1. Who are the relevant stakeholders, what institutions do they belong to and how will you engage them?

2. What skills and knowledge are required in your team in order to implement a successful IR project?

3. What specific knowledge and (or) skills will each stakeholder bring to the research project?

1 Relevant stakeholders, what institutions do they belong to? How will you engage them?

2 What skills and knowledge are required in your team in order to implement a successful IR project?

3 What specific knowledge and (or) skills will each stakeholder bring?

SWOT analysis to identify issues affecting a mosquito control programme[20]

Mosquito control programmes in seven urban sites in Costa Rica, Egypt, Israel, Kenya and Trinidad were compared. Site-specific urban and disease characteristics, organizational diagrams, and SWOT analysis tools were used to provide a descriptive assessment of each mosquito control programme. They also provided a comparison of the factors affecting the resulting reductions in mosquito populations.

The information for the SWOT analysis was collected from surveys, focus group discussions and personal communications. The SWOT analysis identified various issues affecting the efficiency and sustainability of mosquito control programmes. The main output of the study was the description and comparison of mosquito control programmes within the context of each study site's biological, social, political, management and economic conditions.

The issues identified in the study ranged from a lack of intersectoral collaboration to operational issues of mosquito control efforts. A lack of sustainable funding for mosquito control was a common problem across all sites. Many unique problems were also identified, which included lack of mosquito surveillance, lack of law enforcement, and negative consequences of specific human behaviours.

Identifying common merits and shortcomings of mosquito control programmes was useful in identifying best practices for mosquito control operations, thus leading to better control of mosquito biting and mosquito-borne disease transmission.
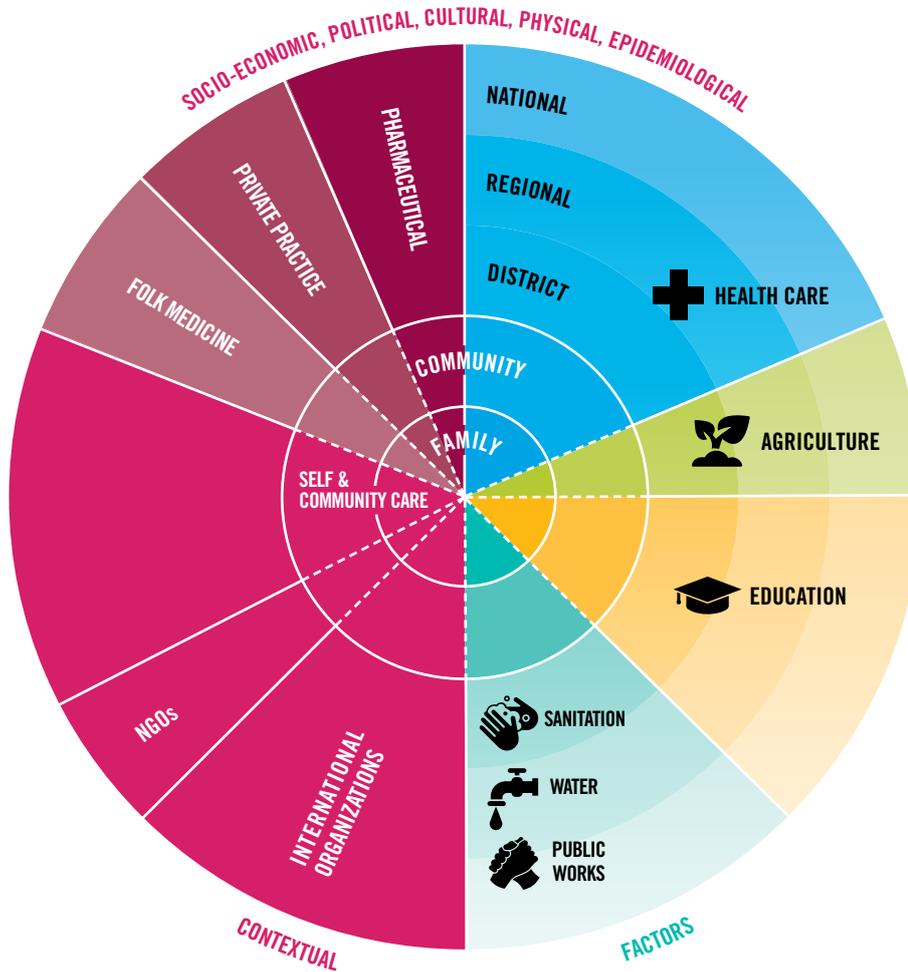
Health systems

Core research questions of IR projects are driven by implementation problems/ issues and should be formulated in collaboration with stakeholders, including implementers, programmes or decision-makers in the health system, and should be designed to suit action-oriented research. As a result, IR is typically conducted within the health system, at least in part. One of the main purposes of analysing the health system is to predict how specific considerations might potentially affect the viability and impact of an intervention.

Figure 5 illustrates the many components of a health system beyond the health centres, clinics or hospitals that are found in the formal health sector.[21] For example, community members may have a strong belief in the informal health sector and access it alongside the formal health system. From the community level, right up to the national level, there are various non-health ministries, departments and agencies whose work directly or indirectly impacts health care provision. The critical roles these stakeholders play must be fully considered in any IR study. For each component that is relevant to a specific IR project, it is helpful to undertake a systematic descriptive analysis to help identify the relevant decision-making agents and both the formal and informal institutions that govern its operation. All these complex, real-life interactions need to be considered when addressing IR. These complex interactions of individuals, groups, institutions, the family and society and the pluralistic health care systems that are available in many countries not only influence the health of people, they also affect the health services and health care provision in the formal and informal sectors.

Figure 5: Elements of a typical health system

REFLECTION ACTIVITY

Address the following questions in relation to your IR project:

1. **How is the health system in your project area structured (public, private and other related sectors)?**

2. **How might the various components of the health system impact your project?**

?
?
1 How is the applicable health system structured (public, private and other related sectors)?

2 How might the various components of the health system impact your project?

Complex adaptive systems

Many health initiatives give rise to what can be described as 'complex adaptive systems' (CAS), a theory based on relationships, emergence, patterns and iterations.[22] [23] [24] The underlying idea being that a myriad of complex systems continuously interact and trigger subsequent adaptations in their immediate environment. A CAS involves a large number of interacting agents, which have adaptive capabilities. They adapt in response to a changing environment, the context and to changes induced by a given intervention. The implication of this notion is that it is difficult to 'control' agent behaviour in real life situations. CAS are intrinsically unpredictable and unintended responses to interventions often occur. Therefore, understanding the CAS phenomena is important for better awareness, planning, implementation, monitoring and evaluation of approaches to scaling up health services.

Health interventions and complex adaptive systems

|		
Pilots/trials may not be effective on a larger scale because of contextual differences. e.g. levels of health system development, ecological factors, social and cultural differences.	**HEALTH INTERVENTIONS AND COMPLEX ADAPTIVE SYSTEMS (CAS)**	Inputs/impacts disproportionate in many cases
Implementation rarely proceeds according to plan and often has to be rapidly adapted to suit an alternative and/or changing context.	Behaviour of providers, communities and staff are often highly constrained.	Multiple stakeholder groups and independent factors interact → CAS.

- Interventions that were shown to be successful on a small scale in a controlled research context may not be effective on a larger scale because of contextual differences, such as levels of health system development, ecological factors, social and cultural differences.

- The process of implementing an intervention rarely proceeds according to plan and often has to be rapidly adapted to suit an alternative and/or changing context.

- The ability of implementation managers to exercise control over the behaviour of providers, communities and even their own staff is, in practice, often highly constrained by the organizational environment.

- Apparently simple technical interventions can exhibit CAS behaviours when multiple stakeholder groups and independent factors interact.

- Substantial interventions can sometimes result in very limited outcomes and conversely, relatively small inputs can have major positive/negative consequences.

CAS can result in unexpected behaviours in the context of health interventions through, for example, feedback loops, path dependence and emergent behaviours.

Feedback loops positively/negatively influence demand for immunization services[25]
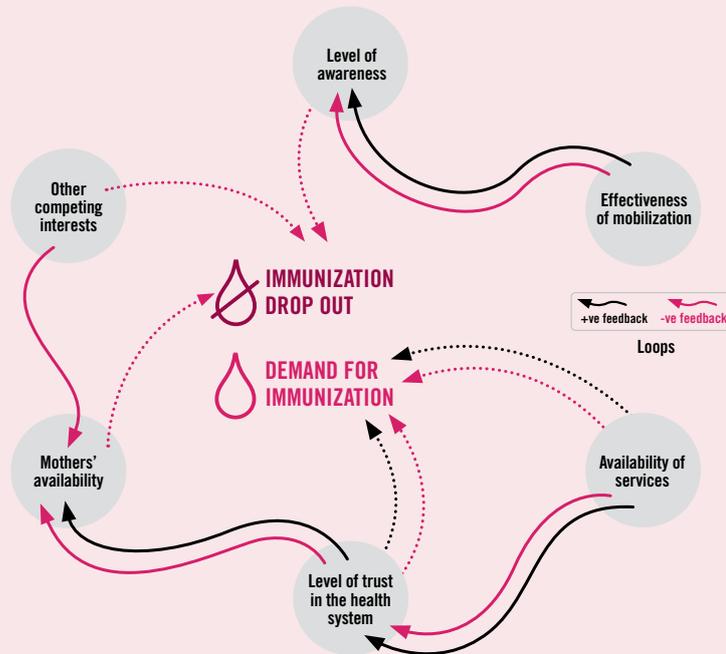
Demand for immunization services is positively influenced (i.e. increased) by high levels of community awareness about immunization, which is in turn also enhanced by effective community mobilization, high literacy levels of mothers, media campaigns and the extent of health education activities. On the contrary, misconceptions about immunization reduce levels of community awareness about immunization, subsequently reducing demand for immunization services. In addition, whereas mothers' availability increases demand for immunization, maternal family responsibility and low socioeconomic status can negatively affect their availability.

Furthermore, the quality and availability of health services can affect the demand for immunization services either positively or negatively. For example, availability of immunization services increases the number of children immunized, thereby increasing the herd immunity in the community, which reduces the risk of outbreaks of vaccine preventable diseases. This reduction in morbidities due to vaccine-preventable diseases contributes to an increase in confidence of the community in the immunization programmes, which subsequently increases the demand for immunization services. On the other hand, poor quality health services – for example lack of vaccines, long waiting hours, children developing abscesses after vaccinations etc., discourage mothers from bringing their children for immunization. This contributes to high drop-out rates and the proportion of unimmunized children in the community, leading to low immunity and an increased risk of outbreaks of vaccine-preventable diseases. The result is lost confidence in the health system, which contributes further to the reduction in demand for the immunization services.

REFLECTION ACTIVITY

This section considered the complex interactions of culture, politics, stakeholders, organizational culture (for example) on health-related interventions. Taking all these into consideration, summarize the environmental and contextual factors that are currently affecting (positively or negatively) the implementation of your intervention of interest.

1. To what extent are the outcomes of the intervention affected?

2. How should this knowledge influence your IR question(s) and project approach?

1 Outcomes affected?

2 Influence on IR question(s) and approach?

Community engagement in IR

> **Delivery of interventions will not be effective if the community does not trust the health authorities.**

key message

Invariably, most if not all health care interventions are targeted at community members – engaging them throughout the IR process is critical. Engagement is a process that involves consultation, education, communication, participation, extension work and partnerships. For example, by:

- Informing the community of policy directions of the government.
- Consulting the community as part of a process to develop government policy, or build community awareness and understanding.
- Involving the community through a range of mechanisms to ensure that issues and concerns are understood and considered as part of the decision-making process.
- Collaborating with the community by developing partnerships to formulate options and provide recommendations.
- Empowering the community to make decisions and to implement and manage change.

> **One of the critical outcomes of community engagement is literacy – a situation where individuals in the community are sufficiently informed to engage meaningfully in dialogue and discussions on the intervention.**

key message

Engagement allows the IR team to draw on the collective contextual knowledge of the community, as well as their understanding of existing strengths and resources within the intervention area. Community engagement should therefore be facilitated throughout the entire IR cycle – from pre-intervention, to intervention and continuous monitoring to the final evaluation – and not only during the IR design or conceptualization process (Figure 6).

Too often, unfortunately, researchers simply present an idea or approach to the community that they think will work and expect them to 'buy in'. In engaging the community, it is best to first discuss the problem at hand, as well as strengths and resources existing within the community, and then seek their opinions on the optimal interventions and IR approaches that will address the problem.

Figure 6: Reasons for community engagement in an IR project

8 reasons for community engagement in an IR project

- Demonstrates respect for the community.
- Ensures good research ethics.
- Integrates existing community strengths and resources into the IR project.
- Promotes greater community self-esteem (self-reliance, self-determination).
- Facilitates acceptability of ideas, research approach and related intervention(s).
- Creates trust and mutual understanding.
- Ensures shared responsibility in the research endeavour.
- Ensures community ownership of the research and interest in the research outcome(s).

'Gatekeepers' in the communities where IR will be conducted are particularly important research stakeholders. They can be considered de facto experts in the field, and an invaluable source or conduit of local information and knowledge, as well as of innovative solutions.

Community engagement: A process of working collaboratively with and for groups of people affiliated by geographical proximity, special interest, or similar situations, to address issues affecting the well-being of those people.[26]

key message
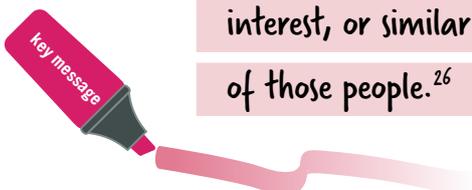
A frequent barrier to effective community engagement is the use of complicated informed consent forms, typically employed in a bid to follow principles of good research ethics. Complicated material with a lot of research jargon and fragmented information leaves the community wondering if they are safe or not. All materials provided to community members should be presented simply, with the critical information designed to make the community comfortable and to reassure them of their safety. Complex technical language – and the confusion and mistrust it can potentially generate – are critical barriers that should not be overlooked.

REFLECTION ACTIVITY

Address the following questions in relation to your IR project:

1. **Who are the community 'gatekeepers' in your project area?**
2. **How will you engage them?**

?

1 Who are the community 'gatekeepers'?

2 How will you engage them?

Case study 2	**Community engagement:** *Majigi educational intervention for polio eradication in Northern Nigeria*

Background: Over two decades ago, the global polio eradication effort was launched. It sought to end the disease through an efficacious polio vaccine that is delivered through routine vaccinations and supplementary campaigns among susceptible populations. To date, however, Nigeria is yet to be declared polio free. This is mainly because of the low polio vaccine coverage in northern Nigeria despite the repeated polio campaigns in the region. The main bottleneck was low community acceptance due to misconceptions, distrust and myths around the cause of the disease, the safety of the vaccine, inadequate social mobilization, improper channels of communication, and lack of programme commitment and ownership at the local government level. Thus, to enhance the effectiveness of the intervention, there was a need to actively engage community gatekeepers with a special focus on political, traditional and religious leaders, traditional healers, birth attendants, town criers and traditional surgeons. A pilot trial using a mass media campaign was launched in 2008 in four northern communities within the same local council. This campaign, dubbed the 'Majigi' educational intervention, targeted the beliefs about the disease and the negative attitudes towards polio vaccination. Majigi involved a road side film show in communities using mobile vans. Community leaders encouraged attendance and participation in subsequent vaccination activities through their circles of influence. Regular polio supplemental vaccination activities were conducted and the outcomes monitored for six successive months.

Results: The campaign resulted in a 310% increase in polio vaccination uptake and net reduction of 29% of never-vaccinated children in the targeted region. 'Majigi's successful innovative contextually- sensitive approach enhanced community ownership and cleared misconceptions around the polio vaccine.

Conclusions: Targeting the community gatekeepers facilitated the implementation as well as the outcomes of the intervention. Furthermore, polio vaccination uptake was enhanced by a locally adapted programme that promoted effective communication with and within the community.

Lessons: To promote a given intervention, communities need to be empowered so that they are able to make informed decisions.

Source: Nasiru, S.-D. et al. Breaking community barriers to polio vaccination in Northern Nigeria: the impact of a grass roots mobilization campaign (Majigi). Pathogens and Global Health. (2013); 106(3):166–71

Ethical challenges in IR

As with all research, ethical and scientific integrity is an essential good practice in IR. In the context of IR, there may be specific ethical dilemmas because the studies are often conducted within the routine activities of the health system, and without the level of control associated with most clinical research studies especially clinical trials. The autonomy and understanding of volunteers are likely to be limited if the studies are conducted in high-burden and vulnerable populations with limited access to health care. In some IR projects, individual observations or personal interviews risk generating psychological distress when sensitive issues are discussed or recorded, or if there are any potential breaches of confidentiality.[27]

Ethical issues associated with IR can generate controversy. This may affect both quantitative and qualitative research approaches, across a broad range of disciplines such as epidemiology, statistics, anthropology, sociology, health economics, health promotion and education, political science and others. Although research protocols are applied in real-life settings there are nevertheless inherent ethical pitfalls and risks.

For example, participants in IR may be burdened by the loss of privacy, time spent in interviews and examinations, and by possible adverse psychological effects. Such risks can be minimized by careful attention to study procedures, limiting the length of questionnaires or additional clinical examination and sampling, and considerate timing of observations. IR also poses specific ethical challenges, given that it frequently requires collection of information from a large number of subjects in diverse situations, and involving a broad range of stakeholders.

Research ethics committees are often more familiar with the protocols developed for more mainstream clinical studies and trials. Study protocols developed by IR teams should inter alia take special note to address issues such as power relationships, illiteracy, disruption of routine health services, inequitable selection of participants, raising expectation of participants and over-burdening staff in the health system with research responsibilities, diverting their time and efforts from health care provision.

REFLECTION ACTIVITY

Critically reflect on the ethical challenges that might be associated with your IR project considering the principles of autonomy, beneficence and justice. How will you minimize the impact of these challenges?

Ethical challenges in obtaining informed consent in IR

In general, the ethical codes of biomedical research – such as those prescribed in the Declaration of Helsinki, the Nuremberg Code and as espoused by the Council for International Organizations of Medical Sciences – do not provide adequate insight to guide IR projects. Nevertheless, with a robust research protocol, appropriate study design, a competent and skilful research team and rigorous review by the relevant scientific and ethics committees, ethical interests of the participants and the community can be safeguarded.

Because IR is conducted in real-life situations, researchers face changing sociocultural, economic and political context. Hutton et al[28] argue that: "The level at which an intervention is delivered may determine whether patients can opt in or out;" and further state: "For interventions delivered at the level of the health care facility, it is unclear whether one could ever reasonably seek consent for randomization to intervention and control arms from individual patients who may be affected by the trial interventions".

Example: Voluntary medical male circumcision as an HIV prevention strategy

In 2007, the World Health Organization (WHO) and the Joint United Nations Programme on HIVAIDS (UNAIDS) issued recommendations on medical male circumcision as an HIV prevention strategy, based on strong and consistent scientific evidence. In many settings, however, it has proven difficult to translate this research into policy and practice due to economic, sociocultural and ethical challenges. Thus, specific factors ought to be considered when planning to implement/scale up voluntary male circumcision as a public health intervention.[29]

Context: For an intervention to be successful, it is important that researchers understand the context in which the intervention will be implemented. Since IR is complex and involves multiple stakeholders, policy-makers, programme implementers, health workers, the community and the prospective beneficiaries should be identified and their respective roles assessed. Furthermore, voluntary male circumcision is a public health intervention impacting cultural dynamics and the health system. For example, in communities where circumcision part of a boy's right of passage into manhood, introducing neonatal circumcision may be difficult to implement. In addition, power relations in the community should be explored. The level of organization of the health services and capacity of existing human resources to provide safe circumcision will influence decisions to either integrate neonatal male circumcision into postnatal services or as a stand-alone service. At a policy level, the country's existing policies on male circumcision (such as the age at which a child should not be circumcised or if there are specialized circumcision surgeons, or designated places where circumcision takes place) should be analysed to guide the implementation process.

Ethical challenges: Ethical issues at both individual (neonates and minors under the age of consent) and community level that influence the intervention feasibility:

What should be done in cases where the child refuses to consent but the parents want the circumcision to take place, or where the child wants circumcision but the parents refuse to provide consent?

What if the very notion of obtaining consent for circumcision is culturally absent?

Ethical challenges in obtaining informed consent in IR (continued)

Should only populations at risk of HIV acquisition/transmission such as truck drivers, soldiers, migrant workers be targeted for circumcision? If yes, how can the subsequent stigmatization of this specific population be minimized?

What is the optimal age at which circumcision should be implemented?

Should it be offered only to men who test negative for HIV or be extended to men living with HIV?

To have an ethically sound implementation of voluntary male circumcision as a HIV- prevention strategy, elements of acceptability of different approaches among currently circumcising and non-circumcising groups should be comprehensively assessed.

Example: Improving the coverage of the PMTCT programme in South Africa

This intervention comprised a data-driven participatory quality improvement approach implemented in a high HIV prevalence district in South Africa.[30] It was designed in three phases: i) a participatory assessment to build capacity of the local programme managers; ii) a feedback and planning phase, during which weaknesses in the system were identified and a corresponding intervention was developed; iii) a 12-month implementation and monitoring phase, during which the intervention to prevent mother-to-child (PMTCT) HIV transmission was implemented, and related output indicators were monitored. Data were collected using structured interviews from the managers and counsellors, observation of the health facilities, review of documents and routine PMTCT data. The data showed large improvements in all key PMTCT output indicators.

Context: The population in the study area, the components of the PMTCT programme, the current PMTCT policy, South Africa's district health system, the referral system and the core activities of the health care providers were described in the IR proposal. The documents reviewed included country health review reports, protocols on PMTCT care, PMTCT programme implementation policy guidelines, and HIV seroprevalence survey reports. The baseline PMTCT indicators were extracted from routine district PMTCT data. The stakeholders included mid-level managers in the health system (e.g. facility managers, the primary health care supervisors and district programme coordinators) and the community. Their various roles were described accordingly.

Intervention: The conceptual framework used in developing the intervention was based on an expanded health systems approach. The researchers further acknowledged that the weaknesses identified during the assessment were due to the complex interaction between the clients' lack of information and fear of disclosing their HIV status, and the health system factors of lack of ownership of the PMTCT programme among nurses, unclear roles and responsibilities, lack of knowledge of the protocol, as well as poor recording systems and continuity of care.

Ethical challenges:

- Should being part of the routine health care system qualify the intervention for expedited ethical review?

- How to minimize interference with routine health care?

- How and at what level of interaction do you draw a line between routine care services and/or research?

Case study 3 — Contextual factors leading to persistence of malaria in remote Central Viet Nam

Background: The persistence of malaria in Viet Nam is related to complexities within the health system, sociocultural, economic and environmental contexts. The establishment of the National Malaria Control Programme with a strategy to distribute bed nets, as well as diagnosing and treating confirmed cases free of charge, dramatically reduced the malaria incidence rate from 1.2 million clinical cases in 1991 to 185 529 in 2002. Despite these efforts, however, the central province of Quang Tri – with poor, low-educated and culturally diverse minority populations – had one of the highest malaria burdens in the country. A study aiming to strengthen to malaria control sought to identify how the health system and community factors are linked to malaria persistence. A multidisciplinary team conducted the study from March 2004 to April 2005. A mixed-methods approach was used in two of the districts with the highest malaria burden. In the formative stage, qualitative approaches were used to inform the later quantitative part of the study. Semi-structured interviews and focus group discussions were conducted with purposively selected health care managers, village heads and villagers to explore beliefs, attitudes, awareness, health care-seeking behaviour and circumstances relevant to malaria exposure and control. A knowledge attitude and practices (KAP) survey was conducted in the assessment stage, face-to-face with the village health workers (VHWs) and community members. Checklists were used to assess the visibility and status of malaria treatment guidelines, quality of microscopy, as well as bed net quality (during KAP survey home visits). To determine actual bed net use, unannounced night visits to homes were also conducted.

Findings: The main deficiencies at a health facility level were understaffing, unqualified staff, lack of in-service training, inaccessible treatment guidelines and lack of equipment and supplies. At a community level, socioeconomic and cultural factors impeded access to and effective use of interventions. Although diagnosis and treatment of malaria were free, patients were unable to afford the associated costs and this led to early self-discharge and failure to attend follow up appointments. Furthermore, although bed nets were supplied free of charge, the target of 80% coverage (i.e. one net per two people) was not met due to cultural sleeping norms, as well as low education and poverty. Overnight socializing among male neighbours is typical and yet the majority of homes did not have spare nets for guests. Risks to exposure was also increased due to the high mobility, which is culturally and economically driven. Whereas the geographical access to health services was addressed by having community health workers (CHWs), many of whom had insufficient training and this greatly affected their capacity to cope with all expected tasks. In addition, due to delays in rolling out the new guidelines for some of the medicines included in VHW kits, some CHWs did not follow prescribed treatment guidelines. Language barriers and mistrust between the ethnic minorities in western Quang Tri and service providers was also reported, and this may have contributed to the community's lack of responsiveness to medical advice. Geographical inaccessibility due to poor roads, and shortage of telephones, were among the contextual barriers identified.

Conclusion: Deficiencies were established throughout the continuum of care from the health facility all through to the community level. These observations were used as a basis of the proposed intervention.

Lessons: A comprehensive analysis of context is critical for the effectiveness and ultimate success of any proposed intervention.

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