

Fundamentals of Implementation Research

MEASURE Evaluation



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Fundamentals of Implementation Research

Please take a moment to consider the following:

- Each year, over 8 million children die from preventable causes, including diarrhea, pneumonia, measles, malaria, HIV/AIDS, malnutrition, and causes leading to neonatal deaths.¹ Inexpensive, evidence-based interventions for all of these preventable causes are available in some form.
- 8 million cases of pneumonia and meningitis and 371,000 deaths per year are attributed to Hib disease. Safe and effective Hib vaccines have been available since the 1980s, and where the vaccine is adopted, routine use has led to virtual elimination of Hib disease.² Poor infrastructure and lack of coordination prevent vaccine adoption in many countries.

Today, more than ever, the public health sector has effective interventions and experience with practical ways to adapt them to local context.³ Implementation research examines strategies to use this knowledge and scale up innovations into sustainable programs that can solve health problems for more people. Implementation research attempts to take what we know and turn it into what we do.

Purpose

This module, *Fundamentals of Implementation Research*, is an introduction to the language, concepts, tools, and strategies used in implementation research (IR). The information is intended to be practical and useful for researchers and program implementers as an orientation to IR.

Objectives

After successfully completing this course, learners will be able to understand key implementation research (IR) terminology, identify IR core concepts, research frameworks, program components, and appropriate IR questions. Specific objectives include:

- Identify characteristics of IR
- Describe implementation/scale-up and relate implementation research to these processes
- Classify research questions and associated research that falls under the umbrella of IR
- Summarize framework characteristics and identify strategies for applying them to IR
- Recognize how IR is applied to different implementation problems
- Classify IR priorities for grant applications

¹ Jones, G., Steketee, R. W., Black, R. E., Bhutta, Z. A., Morris, S. S., & Bellagio. (2003). "How many child deaths can we prevent this year?" *Lancet* 362 (9377): 65-71.

² Hajjeh, R. (2011). "Accelerating introduction of new vaccines: Barriers to introduction and lessons learned from the recent haemophilus influenzae type b vaccine experience." *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences* 366(1579): 2827-2832.

³ Jones, G., Steketee, R. W., Black, R. E., Bhutta, Z. A., Morris, S. S., & Bellagio. (2003). "How many child deaths can we prevent this year?" *Lancet* 362 (9377): 65-71.

- List the roles of various stakeholders in IR and identify appropriate means for integrating stakeholders in the planning of IR and in communicating and disseminating results

Time

Approximately 2-3 hours

Audience

- Participants in the 2012 USAID Implementation Research workshops (this on-line course is a prerequisite).
- Researchers and program personnel who are considering/conducting implementation research.
- Individuals interested in gaining an introductory understanding of implementation research.
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Table of Contents:

Sub-Module 1 Defining Implementation Research

Sub-Module 2 Implementation Research Frameworks

Sub-Module 3 Implementation Research Questions/Application

Sub-Module 1: Defining Implementation Research

Objectives

- Identify the goal and function of implementation research (IR)
- Identify characteristics of IR common to the definitions currently used
- Differentiate IR from other forms of research and evaluation activities
- Understand the role of implementation research in the implementation process
- Differentiate problems that can be solved with IR from problems for which IR would be inappropriate
- Identify relevant IR questions

Overview

- Purpose of IR
- Defining characteristics of IR
- What IR is and is not
- The Implementation Process
- IR Problems
- IR Questions

Purpose of Implementation Research

"Implementation science is the study of methods to improve the uptake, implementation, and translation of research findings into routine and common practices (the 'know-do' or 'evidence to program' gap)."⁴

Implementation research rests on the public health value of applying what we already know to achieve long-term health benefits that are within reach. A review by Jones et al. suggests that about two-thirds of child deaths could be prevented by interventions that are available today and feasible for implementation in low-income countries at high levels of population coverage.⁵ In their discussion of translational research, Kottke et al. use the term optimizing practice through research.⁶ This is a good way to think of IR, which addresses challenges at the intersection of public health research and practice. According to Leroy et al., "The main challenge today is to transfer what we already know into action; deliver the interventions we have in hand to [those] who need them."⁷ As funding makes a departure away from short-term goals and pilot projects, IR works to meet that challenge and move toward long-term goals, sustainability, and scale-up. IR aims to integrate evidence-based interventions and research findings into health policy and practice. So, IR moves results from effectiveness studies and efficacy trials to real-world settings, obtaining information to guide scale-up and sustainability. One example of this is tobacco research and policy.

The function of IR includes

- Identifying implementation problems that hinder access to interventions, and delivery of services, as well as usability of evidence-based interventions, and their main determinants
- Developing and testing practical solutions to these

Example of tobacco policy challenges in IR

Tobacco control, cessation, and prevention are addressed through a variety of interventions and policies. Recently, policy has included increased taxation on tobacco products and bans on cigarette smoking in commercial and public spaces.

These policies have met with varying degrees of success, depending on the support they have and barriers they face. Unfunded mandates or policies that are approved with insufficient funding or enforcement mechanisms are classic IR policy challenges.

While the policy or intervention itself has proven efficacious, implementation is failing to realize expected benefits. Somewhere, something in the implementation process or local context is inhibiting success of the policy as written.

IR can explore this and address the challenges to improve the effectiveness of the policy on changing tobacco-smoking behaviors.

⁴ Padian, N. S., C.B. Holmes, S.I. McCoy, R. Lye, Bouey, P. D., & Goosby, E. P. (2011). "Implementation science for the US president's emergency plan for AIDS relief (PEPFAR)." *Journal of Acquired Immune Deficiency Syndromes* 56(3): 199-203.

⁵ Jones, G., Steketee, R. W., Black, R. E., Bhutta, Z. A., Morris, S. S., & Bellagio. (2003). "How many child deaths can we prevent this year?" *Lancet* 362 (9377): 65-71.

⁶ Kottke, T. E., Solberg, L. I., Nelson, A. F., Belcher, D. W., Caplan, W., Green, L. W., et al. (2008). "Optimizing practice through research: A new perspective to solve an old problem." *Annals of Family Medicine* 6(5): 459-462

⁷ Leroy, J. L., Habicht, J. P., Pelto, G., & Bertozzi, S. M. (2007). "Current priorities in health research funding and lack of impact on the number of child deaths per year." *American Journal of Public Health* 97(2): 219-223.

problems that 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 to achieve sustained health impacts in real-world settings, including low- and middle-income countries
- Determining the best way to introduce practical solutions into health systems and facilitating their full-scale implementation, evaluation and modification

Examples of IR projects and research questions can be found on page 14 of *Implementation Research in TDR: Conceptual and Operational Framework* (available at www.who.int/entity/tdr/publications/documents/ide_framework.pdf.)

IR studies factors that affect the uptake, adaptation, and adoption of evidence-based health interventions. Even the best interventions have been adapted over time. Whether findings indicate that a program doesn't fit, it's only viable with major adaptations, or a few minor adaptations are enough, these are all useful, beneficial findings. Successful IR integrates these findings into practice, improving program implementation. This success often relies on support from stakeholders and policy makers. So, engaging stakeholders early is essential to successful integration of IR findings.

Take-home Message

IR uses contextual knowledge to study processes to improve practice. It applies research findings and methods to real-world contexts and settings. The outcome of a successful IR project is integration of findings into practice or policy.

Knowledge Check

Select the best option from the choices listed below.

Q: Successful implementation research:

- A. Must support existing evidence
- B. Integrates findings into practice or policy
- C. Uses innovative methods
- D. Relies on programs with a history of moderate success
- E. Earns funding awards for continued work

Defining Characteristics of IR

There are many accepted definitions of IR, which vary by region and discipline. Different organizations adhere to different definitions. Here are some commonly used definitions:

Implementation Research is the scientific study of methods to promote the **systematic uptake of research findings and other evidence-based practices into routine practice** [by developing and evaluating practical solutions to common, critical problems in the implementation of these interventions] and, hence, to improve the quality and effectiveness of health services and care.⁸⁹

Implementation Research is the scientific study of methods to promote the **integration of research findings and evidence-based interventions into health care policy and practice**.¹⁰

More definitions are available in Appendix 1.1. For your research, it will be useful to select the definition that best matches your purpose and that of your funding organization. While there are differences between the different definitions, they all share similar, defining characteristics. Common characteristics of IR include:

IR Characteristic	Application for use
Systematic	<ul style="list-style-type: none"> The systematic study of how a specific set of activities integrate an evidence-based public health intervention within specific settings and how health outcomes vary across communities Balances relevance with rigor, strictly adhering to norms of scientific inquiry
Multidisciplinary	<ul style="list-style-type: none"> Analysis of biological, social, economic, political, system, and environmental factors that impact implementation Interdisciplinary collaborations between behavioral and social scientists, clinicians, epidemiologists, statisticians, engineers, business analysts, policy makers, and stakeholders
Contextual	<ul style="list-style-type: none"> It is relevant to local specifics and need Generates generalizable knowledge that can be applied across contexts Culture, community
Complex	<ul style="list-style-type: none"> Dynamic and adaptive Multi-scale: occurs at multiple levels of health care systems and community practices Analyzes multi-component programs and policies Non-linear, iterative, evolving

⁸ Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. (2005). "Changing the behaviour of healthcare professionals: the use of theory in promoting the uptake of research findings." *J Clin Epidemiol* 58:107-112.

⁹ Eccles, M. P., Hrisos, S., Francis, J. J., Steen, N., Bosch, M., & Johnston, M. (2009). "Can the collective intentions of individual professionals within healthcare teams predict the team's performance: Developing methods and theory." *Implementation Science* 4: 24.

¹⁰ National Institutes of Health Fogarty International Center. Implementation Science Information and Resources. <http://www.fic.nih.gov/RESEARCHTOPICS/Pages/ImplementationScience.aspx>.

	<ul style="list-style-type: none">• Addresses complex, important problems (see here)• Includes many variables, introducing unintended consequences
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Take-home message:

The *characteristics* of IR (systematic, multidisciplinary, contextual, and complex) are paramount to the exact definition. Selecting a specific definition may be determined by the funding organization

Knowledge Check

Select the best option from the choices listed below.

Q: Which of the following characteristics does NOT describe IR?

- A. Systematic
- B. Multidisciplinary
- C. Contextual
- D. Complex
- E. Routine

What IR is and is Not

IR involves looking at barriers and constraints, identifying potential solutions to those barriers, testing the solutions, and integrating those solutions. IR addresses scale, feasibility, cost-effectiveness, sustainability, health maintenance, acceptability, equity, coverage, access, and compliance of programs and interventions.

To review, IR is:

- Systematic
- Multidisciplinary
- Contextual
- Complex

IR is NOT:

- Routine, applied operations research
- Basic biomedical research (e.g., discovery of a new gene pathway or etiology research)
- Initial or replication of intervention efficacy trials in a top-down controlled setting
- Routine program progress reporting

It should be noted that monitoring and evaluation (M&E) activities are an important component of IR, but M&E and IR are not the same. IR does not refer to standard program delivery or ‘business as usual’. To better understand the difference between IR and other types of research, we consider the example of zinc deficiency and diarrhea. The research questions are shown below:

Epidemiological research: *What* is the association of zinc deficiency with severity of diarrhea?

Clinical efficacy research: *What* is the effect of zinc as an adjunct for treatment of diarrhea?

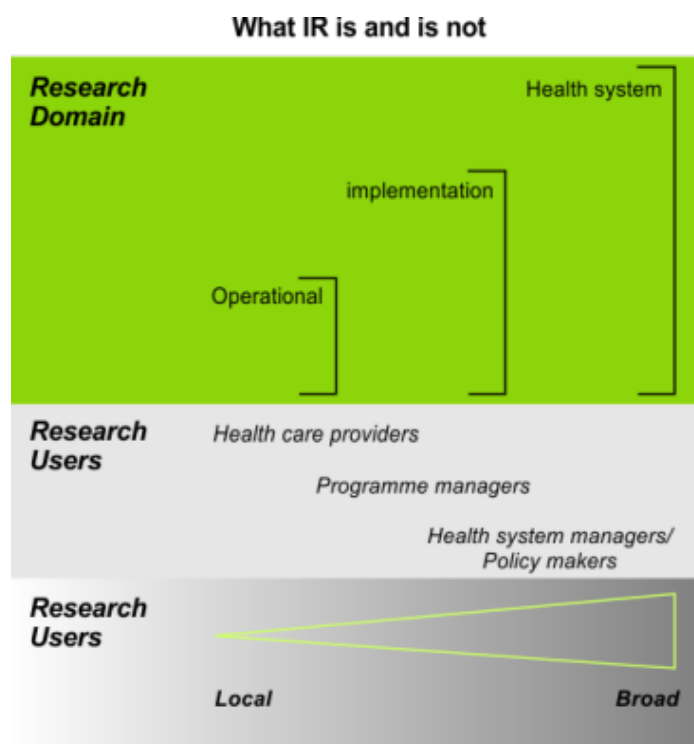
Program effectiveness research: *What* is the effect of a program of promoting zinc as an adjunct treatment of diarrhea?

Implementation research: *How* can the barriers to scaling up zinc promotion programs be overcome so that it reaches all children with diarrhea?

First, epidemiological research is used to establish an association between zinc and diarrhea. Then, clinical efficacy research examines how well zinc treatment works on the health outcome (diarrhea). Program effectiveness research examines how well a specific intervention or program works in promoting the use of zinc treatment. So far, all of these research questions aim to determine whether or not an effect or association exists between exposure and outcome (in this case, zinc and diarrhea). IR uses findings from previous research in practical applications, examining implementation strategies to scale up the program and treatment coverage.

IR should not be confused with operational research or health systems research, though they overlap. It may be helpful to consider these different types of research as a continuum from local and specific to broad. IR links the ends of the spectrum together.

- **Operational research** focuses on a specific, local, clearly defined setting and context.
- **Implementation research** starts with a specific setting and applies findings to broader contexts through scale-up and other implementation processes.
- **Health systems research** focuses on a broader context, covering many settings under the umbrella of an entire system.



The following example applies the spectrum of research domains to a male circumcision intervention designed to reduce HIV transmission in Africa:

Male Circumcision Scale-up in Eastern and Southern Africa

With evidence that male circumcision (MC) reduces the risk of HIV transmission in specific settings, countries in Eastern and Southern Africa are working to scale up MC service delivery and coverage. Delivering this evidence-based male circumcision intervention includes opportunities for operations research, implementation research, and health systems research.

OR question: Which locations should be targeted for delivering MC services in Eastern Africa?

IR question: How can access to MC services among populations who are currently not reached by MC services be improved?

HSR question: What has been the impact of the rapid scale-up of MC programs on fragile health

Take-home message:

IR is not an umbrella term for activities related to program monitoring and evaluation. Rather, IR aims to resolve implementation challenges so that programs may be expanded or optimally implemented across contexts and settings.

Knowledge Check

Select the best option from the choices listed below.

Q: Which of the following research topics fits under the umbrella of Implementation Research?

- A. Routine monitoring and evaluation activities
- B. Randomized trials to determine efficacy
- C. Health systems research questions
- D. Studies to assess unintended consequences of programs
- E. Formative research to determine the distribution of a disease in a specific region

The Implementation Process

Because IR has to fit, be embedded, and influence implementation programs, it is imperative to understand the implementation process. Engaging stakeholders, which will be discussed later, is an essential component of implementation and IR. Stakeholder engagement should begin as early as possible, and continue for the duration of the implementation process.

Implementation is the use of strategies to adopt, adapt, and integrate evidence-based health interventions and policies, changing practice patterns within specific settings. That is to say that implementation is a specified set of activities and policies designed to be put into practice. Relevant stakeholders will provide valuable input for all of these activities and policies at each stage. IR studies these activities using an iterative, ongoing process (not a one-time event), and can take place at a number of levels: practitioners, agency, or community.

Implementation seldom succeeds perfectly when it is first attempted – adaptations are required as more knowledge is gained. IR attempts to understand barriers that inhibit implementation in different environments.

Achieving sufficient program **fidelity** is a frequently encountered challenge in implementation. It is critical to balance fidelity and fit. Fidelity refers to maintaining key components and principles and fit refers to adaptation to local culture. Striking this balance is the art of implementation science. Adaptation to context is important, but remember that whatever is implemented needs to be measured. More on the importance of fidelity is available in Appendix 1.2. The following points on fidelity are relevant to implementation and IR:¹¹

- Implementation fidelity is the degree to which a program is delivered as intended.
- Implementation fidelity affects the credibility and utility of research.
- A high level of adherence to an intervention, or its essential components, is not achieved easily. Factors that influence the degree of implementation fidelity include: complexity of intervention, quality of delivery, practitioner training, and participant responsiveness.
- By measuring implementation fidelity, one can begin to understand how and why an intervention works, and the extent to which outcomes can be improved. So, implementation fidelity should be evaluated as part of any IR study.

Scaling up is one area of IR that addresses equity, sustainability, and health maintenance. It is intended to "increase the coverage of services based on the evidence derived from experimental research, leading to improved health outcomes in the target population". Its primary objective is to deliver "more quality benefits to more people over a wider geographical area more quickly, more equitably and more lastingly". An example of community-based health planning and services scale-up in Ghana is available in Appendix 1.3.

Not all health interventions should be or can be scaled up. A decision to scale up should consider:

¹¹ Carroll, C., M. Patterson, S. Wood, A. Booth, J. Rick and S. Balain. (2007) "A conceptual framework for implementation fidelity." *Implementation Science* 2:40.

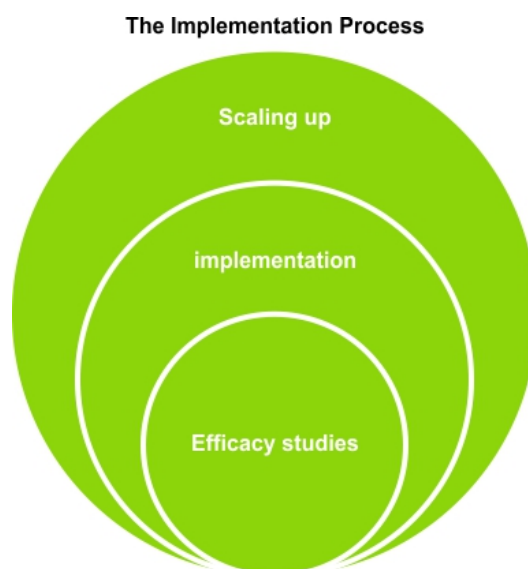
- Size of programs, resources needed, and effect size
- Evidence available
- Potential sustainability judgments
- Fit for an intervention and the setting in the general population, and fit for sociocultural context

In addition, scaled up interventions should not always last indefinitely. Some interventions have a natural time limit or shelf life. For example, a vaccination program may have limited coverage and require scale-up. Expanding efforts to achieve necessary coverage is appropriate for a specific time period. Once a coverage threshold has been reached, it is not useful or sustainable to continue to run the program at scaled up levels. Then, the program may return to routine maintenance levels. ExpandNet's detailed framework on scaling up is provided in Appendix 1.4.

Challenges frequently occur in the planning and implementation of scaling up, including:

- Creating an environment to allow flexibility in the process of scaling up
- Mobilizing adequate resources and ensuring that they are in place for implementation
- Addressing conflicting orientation, mandates, and capacities of stakeholders
- Developing robust health information systems for M&E of the implementation process
- Improving institutional capacity and infrastructure to sustain scaling up of program efforts or shift towards health maintenance (e.g., communication, logistics, transportation, supply of medicines and other techniques)
- Unintended consequences and externalities
- Right-size scaling to sustain scaling up or attain the appropriate level of the intervention

Many promising health interventions have had limited impact on the burden of diseases in low- and middle-income countries because implementation problems were not identified and dealt with in a timely manner. For example, the impact of insecticide-treated-nets to reduce malaria was diminished because IR on scaling up did not follow effectiveness trials. It is critical to include IR as an extension of the efficacy study phase when testing a new intervention.



Take-home message:

IR can improve implementation practice by understanding and systematically addressing barriers to implementation. Some interventions do not render themselves to scale-up.

Knowledge Check

Select the best option from the choices listed below.

Q: IR systematically studies implementation challenges. A teen pregnancy intervention is successful at lowering pregnancy rates, but interpartner violence and abortion complications increase in the program delivery area. What type of implementation challenge does this describe?

- A. Achieving sufficient program fidelity
- B. Unintended consequences and externalities
- C. Improving institutional capacity and infrastructure to sustain scaling up
- D. Mobilizing adequate resources
- E. Right-size scaling for sustainability

Implementation Challenges

Much like IR itself, challenges that IR addresses are systematic, multidisciplinary, contextual, and complex. IR seeks to solve the following types of issues and programmatic challenges:

- Scale-up
- Sustainability and health maintenance
- Replication
- Program integration
- Equitability
- Real-life effectiveness, cost-effectiveness, and impact
- Efficiency
- Unintended consequences

Examples of problems that are suitable for IR to address include:

- Learning about management, administrative, cultural, social, behavioral, economic and other factors that exist as bottlenecks to effective implementation
- Testing new, more effective, efficient approaches to programming (e.g., task shifting)
- Identifying and solving program problems in a more timely or equitable manner
- Helping policy makers and program managers make evidence-based program decisions
- Improving program quality and performance using scientifically valid methods
- Helping program staff understand how their programs work and how to improve them

These are just a few types of IR problems – they will be discussed further in sub-module 3. It is important to note that all of these problems arise within programs and are directed towards finding action-oriented solutions or improvements that can be applied to future implementation practices. IR problems can be thought of as program embedded – *they begin and end in programs*.

Take-home message:

By nature, IR problems are applied and arise from contextual factors within programs that inhibit implementation.

Knowledge Check

Select the best option from the choices listed below.

Q: Implementation research problems are unique from problems in other research domains because they are always:

- A. Specific
- B. Related to underserved populations
- C. Program embedded
- D. Interdisciplinary
- E. Based on previous research

IR Questions

As you conduct your own IR, remember that *the question determines the methods, and the purpose determines the framework*. IR questions address the design, implementation, and outcomes of programs. IR also asks “Are there unintended consequences?” and “Why is it happening as it is?” The following questions are derived from key bottlenecks facing those who implement programs:

Challenge	IR Question
Scale-up	How can coverage and usage of a proven intervention be improved to meet set targets?
	How can a program be scaled up to broader regions or populations?
Sustainability	Why do established programs lose effectiveness over time?
	How can sustainability or health maintenance be achieved?
Replication and robustness	Why do tested programs exhibit unintended effects when transferred to a new setting or problem?
	Why don't tested programs work when transferred to new settings or work in some settings and not others?
	How can implementation be improved to assure replicability?
Program integration	How can multiple interventions be effectively packaged and delivered within health systems?
	How can interventions be delivered to assure integration?
Equitability	How could program or service delivery be more equitable in settings where financial and human resources are low, or where cultural and social norms affect health-seeking behaviors?
	What is the impact across issues of race, class, education, gender, age, geography (urban-rural) and other relevant factors?
Real-life effectiveness	Are there unintended consequences (positive or negative) of the program?
	Under what conditions does the program work?
	Is the tool, intervention, or strategy worth it? Is it cost-effective?
	Does the program achieve the intended public health impact?

- Specific examples of HIV-related IR questions that the CDC is working to address are available in Table 1 in Appendix 1.5.
- Table 2 in Appendix 1.6 provides examples of questions relevant to different types of IR.

- IR questions for a variety of public health challenges are available in Table 3 in Appendix 1.7.

Take-home message:

IR questions are driven by implementation problems and should be designed for action-oriented research in collaboration with stakeholders.

Knowledge Check

Select the best option from the choices listed below.

Q: Please select the best example of an implementation research question.

- A. What is the effect of zinc as an adjunct for treatment of diarrhea?
- B. What is the effect of distributing insecticide-treated nets to prevent malaria in vulnerable populations?
- C. How can tuberculosis treatment be delivered effectively in rural areas?
- D. Does a health education program increase access to antiretroviral therapy?

Sub-Module 2: Implementation Research Frameworks

Objectives

- Identify essential components common to all frameworks presented
- Identify relevant criteria for selecting a framework that relates to their IR

Overview

- IR Frameworks
- Selecting Frameworks

IR Frameworks

There are many frameworks for conducting IR. Depending on the context you work in, some frameworks may be more useful than others. While frameworks vary in some ways, there are common characteristics present in many of them:

- Proven effectiveness – an evidence-based intervention with demonstrated effectiveness
- Proven efficiency – delivering services at low cost and most sustainably
- Context – local determinants of program adoption and impact
- Implementation – a plan for implementation, adaptation, innovation, and dissemination
- Sustainability – assessed through monitoring, evaluation, and impacts
- Stakeholder input – involvement of stakeholders early and throughout the entire process

Frameworks are useful for developing research questions, and can guide the way you think about your work and come up with questions. In this introductory course, we will consider the following five frameworks. More information on each framework is available through the hyperlinks.

1. **Diffusion of Innovation:** This model represents the context within which IR is being conducted. Rogers' diffusion of innovation theory, developed from naturalistic studies across content areas and countries, is the earliest and most widely applied. It indicates that the rate at which an innovation spreads is a function of the intervention itself and the setting it is implemented in. More information in Appendix 1.8.
2. **PEPFAR Implementation Science Framework:** This framework is an organizational representation of implementation research. It incorporates monitoring and evaluation, operations research, and impact evaluation. More information in Appendix 1.9.
3. **CDC REP Framework:** This framework specifies steps needed to maximize fidelity to effective interventions while allowing opportunities for flexibility (i.e., community input) to maximize transferability. More information in Appendix 1.10.
4. **ExpandNet Scaling Up Framework:** This framework identifies conditions that lead to success, articulates strategic choices that have to be made for successful scaling up, and highlights actions that enhance the potential for success and sustainability. More information in Appendix 1.4.
5. **RE-AIM Framework:** This is a useful research framework that focuses on external validity, which can improve sustainable adoptions and implementation of effective, generalizable, equitable, evidence-based interventions. More information in Appendix 1.10.

We have chosen to introduce these frameworks because they are widely used in IR. Depending on program parameters, you may want to consider a framework beyond this list. Additional frameworks can be found here:

- **The Community Toolbox** - <http://ctb.ku.edu/en/default.aspx>
- **Consolidated Framework for Implementation Research (CFIR)** - <http://www.implementationscience.com/content/pdf/1748-5908-4-50.pdf>.

- **Promoting Action on Research Implementation in Health Services (PARIHS) Framework** - <http://www.implementationscience.com/content/pdf/1748-5908-5-82.pdf>.
- **Quality Enhancement Research Initiative (QUERI)** - <http://www.queri.research.va.gov/>.
- Yano, E.M. (2008) "The role of organizational research in implementing evidence-based practice: QUERI Series." *Implementation Science* 3: 29.
- Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: Systematic review and recommendations. *The Milbank Quarterly*, 82(4), 581-629.
- Ward, V, House, A, Hamer, S. Developing a framework for transferring knowledge into action: A thematic analysis of the literature. *J Health Serv Res Policy*. 2009;14:156-164.

Take-home message:

There are differences between the frameworks, but they all retain some common characteristics: an evidence-based intervention with demonstrated effectiveness, guided implementation and innovation, evaluation, sustainability, and stakeholder input. Regardless of which framework you select, adhering to it consistently and maintaining its key components is essential.

Knowledge Check

Select the best option from the choices listed below.

Q: Regardless of which framework you select, it is essential that you:

- Adhere to it consistently and maintain its key components
- Use only the components that benefit your research
- Modify your context to fit every single framework component
- Ignore the context when working within a framework
- Modify the framework to fit your methods

Selecting Frameworks

When selecting which framework to use for your research, your **purpose** will guide which framework your research will readily fit with. In some cases, a **funding agency** may endorse a specific framework. Consult the funding announcement for this information when selecting a framework. Remember, frameworks can help guide your IR question and process. Implementation frameworks will emphasize guiding you through phases of implementation, whereas IR frameworks will emphasize steps for evaluation. Regardless of which framework you choose, it is important to follow it closely and consistently.

A framework is a tool to help achieve more relevant and meaningful results. Here are some other useful tools to assess implementation challenges. These tools can be used to help select an intervention or choose among alternatives before much time and money are invested.

CORRECT Criteria (ExpandNet)

Innovations with the “CORRECT” criteria (**C**orrect, **O**bservable, **R**elevant, **R**elative advantage, **E**asy to install and understand, **C**ompatible, **T**estable) are most likely to be successfully scaled up. For more information, please see Appendix 1.12.

Scalability Checklist (Management Systems International)

This scalability checklist is an aid for prioritizing alternatives and identifying actions to simplify the scaling-up process. It is not a scorecard to determine what can be scaled up and what can't. The scalability checklist can guide analysis of relevant issues for scaling up. For more information, please see Appendix 1.13.

Evaluability (Robert Wood Johnson Foundation)

Evaluability assessments are pre-evaluations that allow for making needed modifications before full-scale implementation. In addition, evaluability assessments in the public health sector aid in developing a research question and identifying a specific purpose, which will in turn influence methods and framework selection. For more information, please see Appendix 1.14.

Viability (CDC)

In public health, viability is the extent to which a program is viable in the real world. Viability alone does not guarantee an intervention's efficacy or effectiveness, but in real-world settings, viability is essential to an intervention's overall success. Regardless of an intervention's efficacy or effectiveness, that intervention should be practical, suitable to community organizations' capacity for implementation, and acceptable to clients and implementers, to ensure survival in a community. For more information, please see Appendix 1.15.

Considering these issues can prevent future implementation problems. Not all interventions should be scaled up or sustained, and these tools can help you determine whether or not your intervention is a candidate for scaling up or sustaining.

Take-home message:

Selecting an appropriate framework for IR depends on research purpose, funding parameters, and contextual determinants.

Knowledge Check

Select the best option from the choices listed below.

Q: Which of the following will most likely determine which framework you use?

- A. Planned methodology
- B. Timeline and logistics
- C. Context and culture
- D. Purpose and funding agency
- E. Political support and stakeholder preference

Sub-Module 3: Implementation Research Questions and Application

Objectives

- Identify four approaches to identifying IR problems
- Identify three methods for formulating IR questions
- Identify 7 criteria for prioritizing IR problems and questions
- Identify major potential stakeholders and strategies for engagement in IR

Overview

- Identifying IR problems
- Formulating IR questions
- Prioritizing IR questions
- Engaging stakeholders in IR
- Disseminating IR results

Identifying IR Constraints

Problems in the implementation process arise at different times and places for many reasons. The tools discussed earlier help to anticipate implementation challenges. Examples of common implementation constraints that are specific to access challenges are available in Appendix 1.16. Information on implementation constraints specific to scale-up is available at: <http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2011/presentations/Aug4/YANO%20Scale%20Up%20Spread%20Jul%2023%202011.pdf>.

IR Constraints to Scale-Up: funding, stakeholder access to information at different levels, lack of political support, frequent changes in staff or policies at any level, lack of skilled facilitators, influence and relationship of different contextual levels (individual, organization, community, policy).¹²

Consider the example of interventions with skilled birth attendants to address the Millennium Development goals of improving maternal, newborn, and child health. The table below shows how identifying constraints improves intervention effectiveness and delivery:

Level of constraint	Types of constraints	Potential interventions
Community/household	Perceptions of SBAs, decision-making	Community level promotion of services and behavioral modifications to increase demand for services
Health services delivery	Shortage and distribution of appropriately qualified staff (of appropriate gender) Adequate drugs and medical supplies Lack of equipment and infrastructure	Task-shifting and redistribution of personnel
Health sector policy and strategic management	Employment systems, supply procurement processes	Task-shifting and redistribution of personnel
Public policies cutting across sectors	Poor availability of communication Poor transport infrastructure	Quality assurance and monitoring Transportation vouchers
Environmental and contextual characteristics	Corruption, weak government Geographic barriers	Transparency Transportation vouchers

Source: Tran, N. Global Applications of Implementation Research. Presentation, Training Institute for Dissemination and Implementation Research in Health.

¹² Yano, EM. *Scale-Up and Spread*. Presentation, Training Institute for Dissemination and Implementation Research in Health.

Identifying these, and other, implementation problems is essential to improved program delivery. Here, we introduce four approaches for identifying IR constraints:

- I. Systematic analysis
- II. Discussion with concerned stakeholders
- III. Routine monitoring of health sector activities
- IV. Annual health sector review meetings

I. Systematic analysis to identify IR constraints:

1. Enable researchers and stakeholders to **critically evaluate existing knowledge**, pool this knowledge, and identify gaps that IR projects should fill
2. **Clarify the constraint** and the possible factors that may be contributing to it
3. Facilitate decisions concerning the **focus and scope** of IR by relating significance to specific project aims

These tools may be helpful in conducting your own systematic analysis:

- **The Cochrane Collaboration** - <http://www.cochrane.org/>
- **Realist Review** - a new method of systematic review designed for complex policy interventions - <http://pram.mcgill.ca/seminars/i/Pawson-2005-Realist-Review-Essay.pdf>
- **RE-AIM situation analysis tool** - <http://cancercontrol.cancer.gov/IS/reaim/pdf/PlanningTool.pdf>
- **RE-AIM self-quiz tool** - <http://tools.re-aim.org/quiz/intro.html>
- **Implementation Science for the US President's Emergency Plan for AIDS Relief (PEPFAR)** - <http://www.pepfar.gov/documents/organization/157942.pdf>

II. Discussion with all concerned stakeholders

Stakeholder input is a necessary component of conducting IR, and it is best to engage stakeholders early and often in the process. Facilitating a discussion with all concerned stakeholders to list the constraints they are facing during early implementation is essential to identifying IR constraints.

1. Specify and describe the constraint
2. Quantify and elaborate on the constraint
3. Identify contributing factors and their relationships to the constraint

To illustrate how to best facilitate discussion with stakeholders, we will use an example about tuberculosis control:

1. Specify and describe: Help stakeholders word constraints properly. Wording should be specific and avoid ambiguity. Well-defined constraints are exhaustive and exclusive – they have all relevant information without any excess information.

A discussion of tuberculosis (TB) control with stakeholders might identify increasing defaulter rate of TB patients as a constraint. Possible causes might include poor health services management, social stigma associated with TB, or negative attitudes of health workers towards TB patients.

2. Quantify and elaborate: Guide stakeholders to quantify and elaborate on the constraint and its consequences.

If TB control stakeholders identify increasing defaulter rate as a constraint, they should elaborate on how widespread the problem is, in which regions it occurs more persistently, potential areas of low compliance, who is most affected, and consequences of the problem. For increasing defaulter rate of TB patients, consequences include increasing morbidity, deaths, waste of resources, development of multi-drug resistance, etc.

3. Identify contributing factors: Guide stakeholders to suggest factors that may contribute to the constraint. Once these factors have been identified, clarify the relationships between the constraint and contributing factors.

Increasing defaulter rate of TB patients may be a result of poorly trained staff. Lack of proper training may lead to inadequate TB health education materials, limited patient understanding of treatment, or failure to provide systematic advice and counseling to patients. These factors may inhibit patient understanding of treatment requirements, causing the high defaulter rate.

III. Routine monitoring of health sector activities

Health management teams routinely monitor their activities. Through monitoring, the national level identifies constraints at the regional level, the regional level identifies constraints at the district level and the district level identifies constraints at the sub-district level.

IV. Annual health sector review meetings

Health management teams and program directors evaluate their performance against health sector objectives, identifying reasons for poor performance or other results. Unanswered questions are potential IR constraints. For example, the following questions might arise:

- Maternal and child health: Why don't women fully utilize free maternal health services, including antenatal care and skilled attendance at delivery?
- Financial access to health care: Why have national health insurance coverage rates declined despite the obvious benefits of insurance coverage?

- Adolescent health: Why is the rate of teenage pregnancy increasing when the overall fertility rate among other age groups is decreasing?

Take-home message:

When identifying IR constraints, it is important to engage stakeholders early and cast a wide net, considering many sources of information, many different perspectives, and underlying causes of problems. Efforts should be made to include those not usually involved and from groups who historically have been left out.

Knowledge Check

Select the best option from the choices listed below.

Q: Is the following statement about identifying IR problems true or false: When identifying an IR problem, researchers should collaborate with only the stakeholders who are experienced in research to make sure that the problem is feasible and well-defined for use in a research setting?

- A. True
- B. False

Formulating IR Questions

Once the implementation problem has been identified, the next step is to formulate a question addressing that problem. When formulating an IR question, you'll want to consider the following:

- How could it best be answered?
- How could it feasibly be answered?
- What data is available? What data is needed?
- What is there control over?

These questions can all be addressed by thinking about study design, measurement, and evaluation. More information on these issues and research methods is available at:

<http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2011/presentations/Aug2/TIDIRH%20Presentation%20Proctor%20and%20Chambers%20v47.pdf>.

We will consider the following three ways to formulate IR questions:

1. Describe the relevant health situation:
 - Magnitude of the problem
 - Distribution of population health needs
 - Risk factors for the problem
 - Awareness of the problem
 - Utilization patterns of services
 - Cost-effectiveness of other interventions
2. Evaluate on-going interventions and access to these interventions:
 - Coverage of priority health needs
 - Coverage of target groups
 - Acceptability of the services
 - Quality of services
 - Cost-effectiveness of available and potential interventions
 - Health impact of the intervention
 - Sustainability
3. Analyze possible causes for missed targets:
 - Availability
 - Accessibility
 - Acceptability
 - Affordability
 - Lack of fit for key subgroups
 - Sustainability (financial and institutional)

Your approach for formulating an IR question depends on context and availability of information. Remember that IR problems are program embedded – *they begin and end in programs*. So, engage program stakeholders early to formulate IR questions. The way you formulate your question will drive your research methods. These are helpful sources for formulating IR questions:

- Program progress or evaluation reports from monitoring and evaluation activities
- Medical literature, meta-analyses, and literature reviews
- Scientific meetings and conferences
- New ideas from previous research or formative qualitative studies (e.g., interviews)
- Funding agencies' annual reports
- Questions asked by program staff and students
- Local documents – project progress reports, theses, dissertations, seminar proceedings
- Analyzing GIS data to identify geographic location and distribution of problems

Resources: Table of IR Questions in Appendix 1.17.

Knowledge Check

Select the best option from the choices listed below.

Q: Who should be involved with formulating IR questions?

- A. Researchers
- B. Program managers and staff
- C. Policy makers
- D. Health professionals
- E. All of the above

Prioritizing IR Questions

A program may generate multiple, simultaneous implementation problems and questions. This can be overwhelming, so it is important to prioritize IR questions, ensuring efficiency and responsible practice of IR. The following seven criteria should help with prioritizing IR questions:

Criteria	Considerations
Relevance	<p>How large or widespread is the problem?</p> <p>Who is affected by the problem?</p> <p>How severe is the problem?</p> <p>If the problem is not checked, is there potential for spread?</p> <p>Who considers this a problem?</p> <p>Is this problem a burden to the health system? How severe is the burden?</p> <p>What is the economic impact of this problem on the population?</p>
Avoidance of duplication	<p>Has this question or problem been researched before?</p> <p>Are there any interventions that have effectively addressed this problem?</p> <p>If yes, are there any major questions that deserve further research?</p> <p>Is my context so different that I cannot use the results of previous intervention research?</p>
Urgency of need	<p>How urgently do the policy makers, implementers and health care providers need results?</p> <p>Will timeliness impact changing course, taking on new interventions or stopping what they are doing?</p>
Political acceptability	<p>It is advisable to do study implementation problems of high interest and those that are supported by local or national authorities</p> <p>Study results for salient issues with political support are more likely to be implemented</p> <p>Politically accepted implementation problems can likely rely on involvement of the policy makers in the study</p>
Feasibility	<p>How complex is the research?</p>

Applicability of results or recommendations	Are there adequate resources to do the study?
	Is it feasible to conduct and report the findings in 12 to 36 months?
	What is the likelihood that recommendations will be adopted?
	How would the findings be used to improve health and healthcare?
Ethical acceptability	Are there available resources for implementing the recommendations?
	How acceptable is the research to those who will be studied?
	Does the target group share the implementation problem?
	Can informed consent be obtained from the research subjects?
	Will the condition of the subjects be taken into account?
	Will the results be shared with those who are being studied?
	<i>Public Health Code of Ethics</i> , available at: http://www.apha.org/NR/rdonlyres/1CED3CEA-287E-4185-9CBD-BD405FC60856/0/ethicsbrochure.pdf .

These criteria are particularly useful for writing proposals or applications to conduct IR. You may choose to emphasize specific criteria based on parameters your funding organization provides.

For more information on how to structure an IR proposal for the Global Fund, please find further guidance here: www.theglobalfund.org/documents/rounds/10/R10_OperationsResearch_Checklist_en/. More information on USAID funding opportunities for IR projects can be found here: http://cfar.duke.edu/wysiwyg/downloads/2011-08-16_PEPFAR_aps-oaa-11-000002-1.pdf.

While specific research methods are beyond the scope of this course, it is useful to think about study design, measurement, data sources, and evaluation techniques when formulating and prioritizing IR questions. There are a variety of research methods available to address IR constraints and questions.

- **Pragmatic trials**, designed to understand if an intervention works under usual, ‘real-life’ conditions (as opposed to ideal conditions) are often appropriate for IR. These types of trials are useful in evaluating effectiveness and feasibility, emphasizing reach, generalizability (across settings, staff, and subgroups), context, replication, and transparency. More information on pragmatic trials is available at: http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2011/presentations/Aug5/Glasgow_Pragmatic%20Trials_TIDRH_FINAL.pdf.

- **Mixed methods**, which combine quantitative and qualitative data sources, often enrich the results of research that is context-dependent. Ideally, when using mixed methods, the whole picture gained from using multiple sources simultaneously is greater than the sum of its parts. These informational sources might include medical record abstraction, stakeholder preference surveys, community level data, interviews, and more. Additional information on mixed methods is available here:
<http://conferences.thehillgroup.com/OBSSRinstitutes/TIDIRH2011/presentations/Aug2/TIDIRH%20Presentation%20Proctor%20and%20Chambers%20v47.pdf/>.

Take-home message:

The complexity of IR necessitates prioritizing IR questions. Using systematic criteria helps ensure that we act responsibly to address important priorities in IR.

Knowledge Check

Select the best option from the choices listed below.

Q: At a stakeholder meeting identifying challenges around prevention of mother to child transmission of HIV, two barriers are identified. First, many women in rural areas don't tend to deliver their babies in health facilities. Second, some women won't get tested unless their partners grant permission. They chose to address delivering in health facilities because it affects more women. Which criterion for prioritization does this example illustrate?

- A. Relevance
- B. Urgency of need
- C. Avoidance of duplication
- D. Feasibility
- E. Political acceptability

Engaging Stakeholders in IR

A good rule of thumb to engage stakeholders from the very beginning is ‘*Begin with the end in mind.*’ IR relies on many perspectives, so it helps to get a lot of people involved. Some useful principles for engaging stakeholders include:

- Engage early and often
- Engage underrepresented groups and multiple perspectives
- Frame issues in ways that are congruent with the mission and values of stakeholders
- Stakeholders are valuable sources of information, and they can link you to other stakeholders

Collaborations with stakeholders involve exchange of information in two directions. Stakeholders provide information to researchers, offering their insight into implementation problems, contextual factors, constraints, assets, and other ideas. Stakeholders are a valuable resource throughout the process, and especially during the formative research phase while identifying IR questions. The other direction of information is information that researchers provide to stakeholders to help inform their decision making. Collaborations with stakeholders are illustrated in this example about maternal mortality in Nigeria.

Example on Maternal Mortality in Nigeria

Efforts in Nigeria aim to reduce maternal mortality and birth-related injuries by addressing a variety of contributing factors. These factors include ineffectual government, under-resourced hospitals, gender inequalities, pressure on girls to marry early and give birth to numerous children, preferences to deliver children at home, and mistrust of family planning services. The collaboration involves researchers from universities in Nigeria and the United States, and is administered by a Nigerian advisory group made up of researchers, medical practitioners and other experts. Additionally, community-based research supported by the project has led to a partnership with village parent-teacher associations, schools, and religious groups, with the goal of promoting the education of girls and increasing the age of marriage.

The collaboration has already had an impact—introducing new postpartum drugs that help stop bleeding, addressing some infrastructure limitations, and promoting education for girls. They also determined that lack of electricity in rural areas seriously impairs the ability of hospitals to deliver care, leading to the development of solar energy systems that now power blood bank refrigerators, ultrasound machines, communications equipment and lights in operating rooms. Engaging stakeholders from local and national government, research institutions, hospitals, schools, and religious groups is essential to the success of each program component. In this example, local context and culture define some of the critical implementation constraints, and engaging a variety of stakeholders has allowed program administrators to address these barriers.

For more information on efforts to avert maternal mortality in Nigeria, please see here:

http://www.fic.nih.gov/News/GlobalHealthMatters/Pages/0410_maternal.aspx.

Engaging stakeholders is an essential part of all types of IR, though it may look different for different types of studies. Work that relates to policy change or policy implementation depends heavily on stakeholder support. Coordination among the various key partners or stakeholders is crucial to ensure the transition from policy to implementation. If policy makers and analysts aren't involved from the outset, it will prove nearly impossible to implement a policy change later. Time spent early in the process to consider who the relevant decision makers and stakeholders are is time well spent. Investing this time early, and following through with stakeholder engagement, will greatly improve the likelihood of successful IR and integration of policy findings. This example of a successful vaccine initiative in Pakistan shows the utility of stakeholder engagement.

Example on GAVI Hib Vaccine Initiative in Pakistan

Haemophilus influenzae type b (Hib) is a common cause of bacterial meningitis and pneumonia in children under 5 years of age in developing countries. In 2006, a team from the Hib Vaccine Initiative visited Pakistan and met with key officials of the ministries of Health, Finance, and Planning and Development. While the Ministry of Health was aware of the health benefits of the vaccine, the other ministries were not informed about the disease or the potential role of the vaccine in meeting Millennium Development Goals. Once the Hib Vaccine Initiative team framed the health and social costs of Hib disease and the benefits of prevention, Ministry of Planning and Development staff began advocating for vaccine adoption. Together, all three ministries played an important role in the final decision making. The Hib Vaccine Initiative team brought important officials in this process together, and worked closely with pediatricians and immunization officers in the country, delivering clear and consistent messages.

Source: Hajjeh, R. (2011). "Accelerating introduction of new vaccines: Barriers to introduction and lessons learned from the recent *haemophilus influenzae* type b vaccine experience." *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences* 366(1579): 2827-2832.

Take-home message:

Engaging many relevant stakeholders throughout the IR process is essential to conducting IR. Beginning with the end in mind, stakeholders should be engaged as early as possible and throughout the process.

Disseminating IR Results

Disseminating information is a strategy to integrate IR findings into practice through policy and program decisions. Data are disseminated to respond to policy and program-related issues and contribute to decisions about change in program implementation. Even ‘negative’ results are important because we don’t want to invest in things that don’t work. Not every intervention should be sustained, and knowing which interventions aren’t sustainable is just as important as knowing which ones are. Stakeholders need to know if a program is not working, so all results (negative and positive) should be disseminated.

Dissemination should occur according to a well-planned strategy. As new technology and social media become more pervasive, consider new dissemination strategies (e.g., Facebook, Twitter, MHealth, EHealth). Better dissemination plans will yield greater benefits, strengthening the impact of IR. Benefits of disseminating results include:

- Strengthening programs
- Engaging stakeholders
- Ensuring evidenced-based decisions for program improvement
- Advocating for additional resources
- Informing scale-up and policies
- Contributing to global lessons learned

The goal of disseminating information to stakeholders is that they will use it for decision making. Information and an example of decisions in IR for prevention of mother-to-child transmission (PMTCT) services are available in Appendix 1.18. The following questions can guide which stakeholders to target for information dissemination:¹³

- Who will benefit from the data, and what questions are they seeking to answer?
- Who has influence and resources that can support this project?
- Who needs to be targeted to get the intervention or data into action?
- Who will be directly or indirectly affected by the outcome of this initiative?
- Who will support our plan? Who will oppose it? Why? How do we deal with it?
- How can we best leverage their insights or assuage their objections?

Stakeholders have different information needs because they make different types of decisions. When determining information needs of stakeholders, consider the objectives of the communication strategy, the target audiences, appropriate channels of communication and how will you assess information use. A table of specific informational needs is available in Appendix 1.19.

¹³ Foreit, K, S. Moreland, S., A. Lafond, (2006). *Data Demand and Information Use in the Health Sector: strategies and tools*. MEASURE Evaluation, Carolina Population Center. University of North Carolina at Chapel Hill.

Resources:

Foreit, K, S. Moreland, S., and A. Lafond, (2006). *Data Demand and Information Use in the Health Sector: Conceptual Framework*. MEASURE Evaluation, Carolina Population Center. University of North Carolina at Chapel Hill.

Foreit, K, S. Moreland, S., A. Lafond, (2006). *Data Demand and Information Use in the Health Sector: strategies and tools*. MEASURE Evaluation, Carolina Population Center. University of North Carolina at Chapel Hill.

Take-home message:

Disseminating information is an avenue to get IR results into policy and practice. To do this effectively, dissemination should be planned and tailored to stakeholder needs.

Knowledge Check

Select the best option from the choices listed below.

Q: Which of the following choices is NOT a benefit of disseminating information:

- A. Engaging stakeholders
- B. Ensuring evidenced based decisions for program improvement
- C. Advocating for additional resources
- D. Contributing to global lessons learned
- E. Improving program reputation by selectively disseminating results

Appendices

1.1 Other Implementation Science Definitions in Use

Definition	Origin
Implementation Science is the scientific study of methods to promote the integration of research findings and evidence-based interventions into healthcare policy and practice. It seeks to understand the behavior of healthcare professionals and support staff, healthcare organizations, healthcare consumers, and policy-makers <i>in context</i> as key variables in the sustainable uptake, adoption, and implementation of evidence-based interventions	Fogarty International Center /International Clinical, Operational, and Health Services Research and Training Award
Implementation is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings. Research on implementation addressed the level to which health interventions can fit within real-world public health and clinical service systems. (Dissemination is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread knowledge and the associated evidence-based interventions. Research on dissemination addresses how interventions can fit within real-world public health and clinical service systems).	-National Institutes of Mental Health -Dissemination and Implementation Conference
Any research producing practically-usable knowledge (evidence, findings, information, etc) which can improve program implementation (e.g., effectiveness, efficiency, quality, access, scale-up, sustainability) regardless of the type of research (design, methodology, approach) falls within the boundaries of operations research.	World Health Organization-Special Programme for Research and Training in Tropical Diseases (WHO-TDR)
Implementation research is that subset of health services research (HSR) that focuses on how to promote the uptake and successful implementation of evidence-based interventions and policies that have, over the past decade, been identified through systematic reviews.	Sanders, D. and A. Haines. (2006). "Implementation Research Is Needed to Achieve International Health Goals." <i>PLoS Med</i> 3(6): e186.
Implementation research is used as a general term for research that focuses on the question 'What is happening?' in the design, implementation, administration, operation, services, and outcomes of social programs. Implementation studies can have multiple purposes, such as supporting the impact study by describing the precise nature of the program being tested and explaining the pattern of impact findings over time or across program sites.	Werner, A. (2004). <i>A Guide to Implementation Research</i> . Washington, DC: The Urban Institute Press.
Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services. It includes the study of influences on healthcare professional and organizational behavior.	Eccles M.P., and B.S. Mittman. (2006) "Welcome to Implementation Science." <i>Implementation Science</i> 1(1): 1-3.

1.2 The Importance of Fidelity in the Implementation Process

There is compelling evidence that technological advances in treatment, which are often the target of research funding, must yield unrealistic increases in efficacy to outweigh the benefits realized by improving fidelity.¹⁴ According to one analysis of interventions for children in 42 low-income countries, improving fidelity would save almost 3 times as many lives as providing new drugs or care.¹⁵¹⁶ In many low-income countries, child mortality research continues to center on improving technology, with less emphasis on IR principles like delivery, utilization, and sustainability. A shift toward these IR principles may improve the health profiles of these countries dramatically.

¹⁴ Woolf, S. H., & Johnson, R. E. (2005). "The break-even point: When medical advances are less important than improving the fidelity with which they are delivered." *Annals of Family Medicine* 3(6): 545-552.

¹⁵ Leroy, J. L., Habicht, J. P., Pelto, G., & Bertozzi, S. M. (2007). "Current priorities in health research funding and lack of impact on the number of child deaths per year." *American Journal of Public Health* 97(2): 219-223.

¹⁶ Woolf, S. H., & Johnson, R. E. (2007). "Inattention to the fidelity of health care delivery is costing lives." *American Journal of Public Health* 97(10): 1732-3; author reply 1733.

1.3 ExpandNet example on Community-Based Health Planning and Services initiative in Ghana¹⁷¹⁸¹⁹

The Community-based Health Planning and Services (CHPS) initiative in Ghana is an example of a strategy for scaling up a field trial to become a national program. Overcoming the complexity of organizational change requires phasing in change in small, manageable units. Pilot trials are useful, not only at the experimental phase, but also in the course of scaling up. Pilots build experience with the change process, permitting adaptation of the new organizational system to local realities. The original Navrongo experimental trial and the Nkwanta replication site produced scientific evidence and sites where visiting implementation teams could see the model in action. The CHPS initiative employs strategies tested in the successful Navrongo experiment to guide national health reforms that mobilize volunteers, resources, and cultural institutions to support community-based primary health care. A progression from field trials to scale-up is shown below.

Phases in the Scaling Up Process

PHASE	POLICY DEBATE AND PILOT PROJECT 1990-1993	NAVRONGO TRIAL 1994-2000	NKWANTA VALIDATION 1998-2002	NATIONWIDE EXPANSION (CHPS) 200-Present
QUESTION	What is appropriate?	Does it work?	Can it be validated?	Is scaling-up progressing
APPROACH	Micro-pilot and social research	Factorial trial	Operations research	Quantitative and qualitative system appraisal
PRODUCT	Alternative models	Successful system	Consensus for change	Changed programme

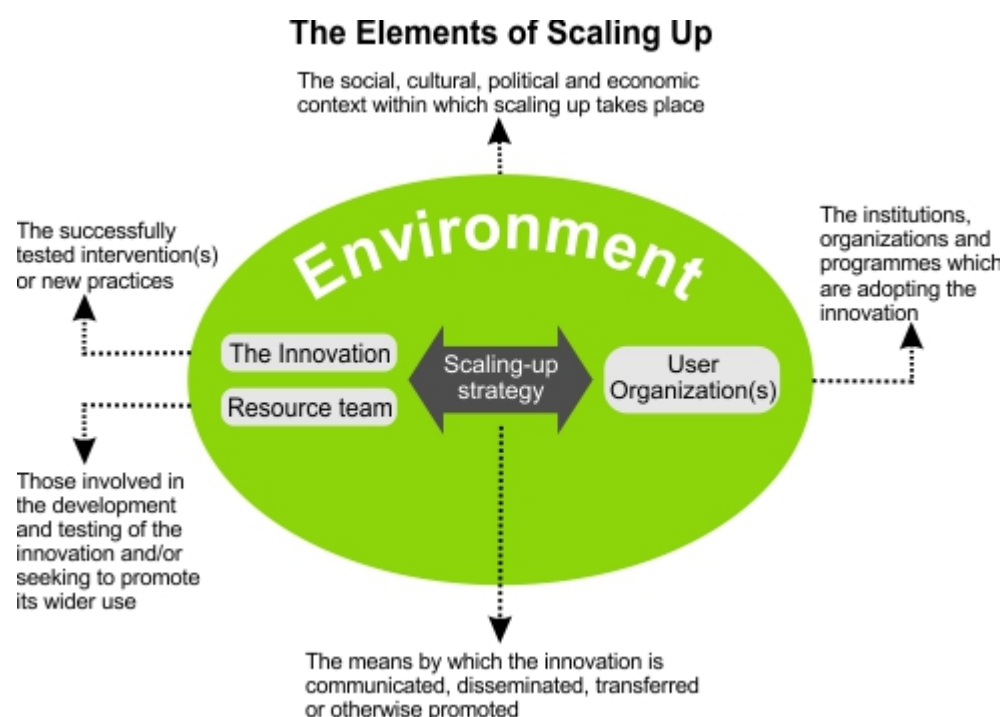
¹⁷ Nyongator, F. K., Awoonor-Williams, J. K., Phillips, J. F., Jones, T. C., & Miller, R. A. (2005). "The Ghana community-based health planning and services initiative for scaling up service delivery innovation." *Health Policy and Planning* 20(1): 25-34.

¹⁸ World Health Organization/ExpandNet (2007). *Practical guidance for scaling up health service innovations*. Edited by Simmons, R. and Fajans, P. Geneva: WHO.

¹⁹ Nyongator, FK., Akosa, BA., Awoonor-Williams, JK., Phillips, JF., Jones, TC. (2007). "Chapter 5: Scaling up experimental project success with the Community-based Health Planning and Services initiative in Ghana." In *Scaling up health service delivery: from pilot innovations to policies and programmes*. Edited by Simmons, R., Fajans, P., Ghiron, L. Geneva: WHO.

1.4 ExpandNet Framework for Scaling Up

Scaling up has multiple dimensions - institutional, spatial, economic, temporal and technological – involving multiple stakeholders with different perspectives. ExpandNet's framework for scaling up demonstrates the multiple dimensions involved in scaling up.²⁰ We have chosen this framework because it is well-known, widely used, and endorsed by the World Health Organization. The ExpandNet framework will be discussed further in sub-module 2.



Scaling up can take place through three different organizational path:²¹

1. **Expansion** is ramping up a pilot to scale within the organization that developed it.
2. **Replication** is scaling up by entities other than the organization that originally developed the pilot or model intervention, or those in different settings or for different problems.
3. **Spontaneous diffusion** is the spread of ideas or practices largely of their own accord.

²⁰ World Health Organization. (2003). *Implementation Research in TDR: Conceptual and Operational Framework*. Geneva: WHO.

²¹ World Health Organization/ExpandNet (2007). *Practical guidance for scaling up health service innovations*. Edited by Simmons, R. and Fajans, P. Geneva: WHO.

1.5 Table 1. Examples of HIV-related IR questions

Specific examples of HIV-related IR questions that the CDC is working to address are below.²²

Research Area	IR Question
HIV/AIDS Prevention	How do we improve uptake of available prevention interventions by couples where one partner is HIV-positive and one is HIV-negative?
Prevention of Mother-to-Child Transmission (PMTCT)	How do we optimize effective approaches to infant feeding and nutrition among HIV-exposed children to maximize PMTCT and HIV-free survival?
HIV Treatment and Care	Which intervention is most cost effective in reducing early mortality in patients initiating antiretroviral treatment (ART)?
Health Systems	What are the effects of task-shifting (i.e., shifting tasks from one type of health care worker to another, such as from a doctor to a nurse) for prevention, care, and treatment service delivery on quality, outcomes, and cost-effectiveness?

²² CDC Implementation Science. More information available at <http://www.cdc.gov/globalaids/support-evidence-based-programming/implementation-science.html>.

1.6 Table 2. Questions for Different IR Types

Type of IR	Example IR Questions
Needs Assessment	<ul style="list-style-type: none"> • What practices and interventions have been proven to be effective? • What contextual factors contribute to the success or failure of identified interventions? • How might existing policies affect the intervention? • What are the needs and priorities of the different stakeholders and target population?
Formative Research	<ul style="list-style-type: none"> • How and to what extent do contextual and cultural factors influence the desired change? • What factors hinder or facilitate the delivery of the intervention? • What adaptations are necessary to achieve the desired goal? • What changes need to be made to the protocol to address these issues?
Effectiveness Study	<ul style="list-style-type: none"> • Did the intervention do more good than harm when delivered under real-world conditions? • Does the intervention/program meet its goals under typical conditions? • For whom was the intervention effective and for whom was it not? • Under what conditions or context does the intervention prove effective?
Dissemination	<ul style="list-style-type: none"> • What is the social structure of the system, community, or organization we want to affect? • Which types of information and delivery or access modalities are effective for selected target groups? • How can we harness technology or existing networks to achieve widespread dissemination?

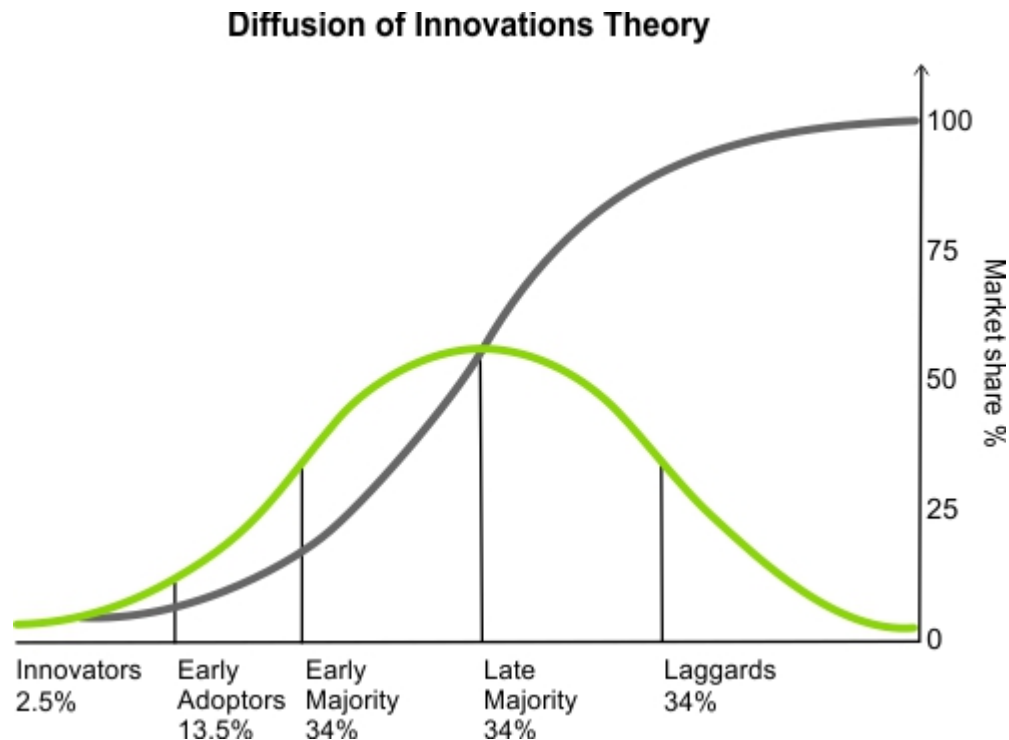
1.7 Table 3. Example IR Projects and Questions

Project Title	Main Research Question
Scale-up of effective home management of malaria	<p>What factors hinder/promote scaling up of home management of malaria?</p> <p>What is the most cost-effective and sustainable distribution system at large scale?</p> <p>Which factors determine sustainability?</p> <p>What adaptations are needed for information and education campaigns (IEC) in urban settings?</p> <p>Is home management equally feasible/acceptable using more effective/expensive drugs?</p>
Integrated management of childhood fevers at the community level	<p>Is an integrated intervention for malaria and pneumonia in children feasible and acceptable to communities?</p> <p>How should it be implemented to achieve high coverage and adherence by caregivers?</p> <p>How to make the intervention sustainable?</p>
Strategies and impacts of deployment of rectal artesunate in highly-endemic malarious areas	<p>How and where at household/community level should the drug be made available for optimal access?</p> <p>What training/supervision is needed for persons who diagnose, treat, provide referral advice, and monitor treatment?</p> <p>What health education supports referral and treatment advice?</p>
Scale-up of “Immunization Plus” with UNICEF in 4 countries of West Africa	<p>What is the effect of adding intermittent preventive treatment in infants (IPTi) on acceptability of, and compliance with expanded program of immunization (EPI) (including EPI coverage) and how can it be optimized?</p> <p>What is the cost-effectiveness of IPTi?</p>
Strategies for integration of leprosy control into the regular public health services	<p>What are the major obstacles to integration of leprosy services and what are possible solutions that can sustain adequate levels of access, case detection, compliance, disability prevention, and referral?</p>
Cost-effective delivery strategies for new drugs against visceral leishmaniasis	<p>What are the most appropriate and cost-effective ways for detecting patients, delivering miltefosine to the most affected groups, and ensuring high levels of compliance?</p>

Drug delivery strategies for lymphatic filariasis elimination in urban areas	<p>What are the main reasons for low treatment coverage in urban areas?</p> <p>Can these problems be overcome with a community development and partnership strategy?</p>
Strategies for sustainable and affordable management of lymphoedema and associated adeno lymphangitis (ADL)	<p>How can simple methods for lymphoedema/ADL management be brought to scale?</p> <p>How feasible, cost-effective, and sustainable are alternate strategies?</p>
Community-directed integrated delivery of interventions for major health problems in Africa	<p>Is Community-directed treatment (ComDT) a feasible and effective approach for the integrated delivery of community-based interventions?</p> <p>What are the advantages and disadvantages, and what modifications are needed?</p>
Strategies for improved delivery of praziquantel at the community level	<p>How can praziquantel treatment be scaled up in different endemic regions in Africa?</p> <p>How feasible/cost-effective is the use of existing mechanisms</p>
Scaling-up mapping of urinary schistosomiasis for nationwide planning of control	<p>How can the educational system be involved in mapping schistosomiasis using the red urine questionnaire?</p> <p>What mapping/spatial analysis strategy should be used?</p>

For more information on this table, please see page 14 of the document available at http://www.who.int/tdr/publications/tdr-research-publications/ide_framework/en/index.html.

1. 8 Diffusion of Innovations



In IR, an innovation is a new or improved tool (vaccine, drug, diagnostic), intervention, strategy, policy, guideline, or protocols. Rogers' diffusion of innovation theory is the earliest and most widely applied.²³ It was developed from naturalistic studies across content areas and countries, originating out of agricultural research. This framework indicates that the rate at which an innovation spreads is a function of the intervention itself and the setting it is implemented in. The four essential elements of diffusion of innovation are:

1. **Innovation** – characteristics influencing diffusion:

- Relative advantage: is the innovation perceived as better than the current practice?
- Compatibility: is the innovation perceived as being consistent with the existing values, experiences, and needs of potential adopting units?
- Complexity: is the innovation perceived as being difficult to understand and use?
- Trialability: can the innovation be experimented with on a limited basis?
- Observability: are the results of the innovation observable?

2. **Communication channels** – two-stage model:

²³ Rogers EM. (2003). *Diffusion of Innovations*. 5th ed. New York: Free Press.

- Stage 1: creating awareness and knowledge of innovations in the mass media
- Stage 2: getting people to change their behaviors through interpersonal networks

3. **Adopters** – modeling by near-peer adopters leads to imitation by potential adopters.

Adopter	Characteristics
Innovator	<ul style="list-style-type: none"> • Venturesome and imaginative
Early adopter	<ul style="list-style-type: none"> • Have means to know about innovations • Have means to make well-informed decisions about adopting innovations • Opinion leaders • Usually quick rate of adoption
Early majority	<ul style="list-style-type: none"> • Trust opinions of early adopters • Responsible for making innovation normative
Late majority	<ul style="list-style-type: none"> • Feel normative pressure from early majority adoption • Love conformity • Fear loss of social standing
Laggard	<ul style="list-style-type: none"> • Traditional, socially isolated, rejecters • Suspicious of innovation • Usually slow rate of adoption

4. **Time** – rate of adoption:

The length of time required to complete the innovation decision process varies for different adopter types and their relative speed of adoption (see figure above)

More information on Diffusion of Innovations is available here: <http://rds.epi-ucsf.org/ticr/syllabus/courses/67/2011/01/27/lecture/readings/dearing%202008a.pdf>.

1.9 PEPFAR Implementation Science Framework

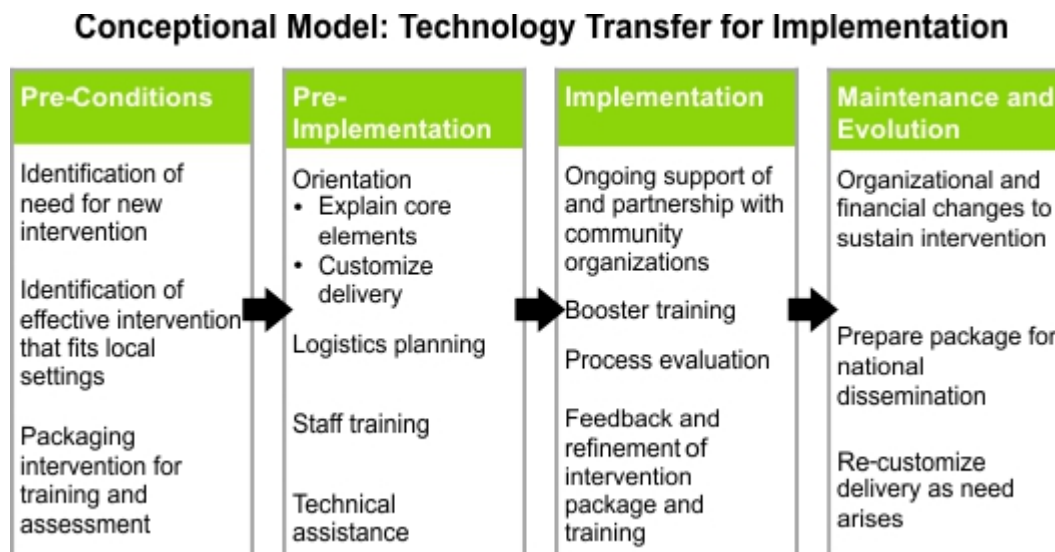
The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Implementation Science framework is designed to provide structure, methodological rigor and diversity, and knowledge generation to meet the needs of the PEPFAR program and the global community. It incorporates monitoring and evaluation, operations research, and impact evaluation (including modeling and cost-effectiveness analyses).

- **Monitoring and evaluation** activities support program effectiveness, efficiency as well as sustainability, country ownership, and program integration.
- **Operations research** focuses on increasing the efficiency of implementation and operational aspects of a particular program, allowing planners to design, implement, and test solutions to improve program delivery. Operations research often uses mathematical modeling to improve decision-making in resource allocation.
- **Impact evaluation** compares observed changes in outcomes to a particular program to what would have happened had the program not been implemented (the counterfactual scenario). This is also used to assess comparative efficiencies and cost effectiveness of different programs.

More information on the PEPFAR Framework is available here:

<http://www.pepfar.gov/documents/organization/157942.pdf>.

1.10 CDC Replicating Effective Interventions (REP) Framework



Replicating Effective Programs (REP) is a US Centers for Disease Control and Prevention (CDC) project that identifies and packages HIV/AIDS prevention interventions with demonstrated evidence of efficacy in reducing risky behaviors or encouraging safer ones, developing systematic and effective strategies to prepare HIV interventions for dissemination.²⁴ REP specifies steps needed to maximize fidelity to effective interventions while allowing opportunities for flexibility (i.e., community input) to maximize transferability. The REP framework consists of four major components, shown in the above diagram.

More information on the REP Framework is available here:

http://www.cdc.gov/hiv/topics/prev_prog/rep/.

²⁴ Kilbourne, A., Neumann, M., Pincus, H., Bauer, M., & Stall, R. (2007). "Implementing evidence-based interventions in health care: application of the replicating effective programs framework." *Implementation Science* 2(1): 42.

1.11 RE-AIM Framework

The goal of RE-AIM is to encourage program planners, evaluators, readers of journal articles, funders, and policy-makers to pay more attention to essential program elements including external validity that can improve the sustainable adoption and implementation of effective, generalizable, equitable, evidence-based interventions,²⁵

The five key issues to translate research into action are:

- **Reach** the target population
- **Effectiveness** or efficacy, including unintended consequences and equity of results
- **Adoption** by target settings or institutions and delivery agents
- **Implementation**, consistency, and costs of delivery of intervention
- **Maintenance** of intervention effects in individuals and settings over time

More information on the RE-AIM framework is available here:

<http://cancercontrol.cancer.gov/IS/reaim/index.html>.

²⁵ Glasgow R.E., T.M. Vogt, and S.M. Boles. (1999). "Evaluating the public health impact of health promotion interventions: the RE-AIM framework." *Am J Public Health* 89(9):1322-7. Review.

1.12 CORRECT Criteria (ExpandNet)

Innovations with the “CORRECT” criteria listed below are most likely to be successfully scaled up.

- **Credible** –based on sound evidence or advocated by respected persons or institutions
- **Observable** – to ensure that potential users can see results in practice
- **Relevant** – for addressing persistent or sharply felt problems
- **Relative advantage** – over existing practices so that potential users are convinced that the costs of implementation are counteracted by the benefits
- **Easy to install and understand** – not complex and complicated
- **Compatible** – with potential users’ established values; fits into larger programs and context
- **Testable** – without committing potential users to complete adoption before results are seen

For more information on ExpandNet, see http://whqlibdoc.who.int/publications/2009/9789241598521_eng.pdf. For specifics on the CORRECT criteria, please see page 20 of the document.

1.13 Scalability Checklist (Management Systems International)

Many successfully scaled up programs involve a clear and replicable technology and self-generate financial resources for expansion. Assessing your program informs decisions about whether and how to scale up. This scalability checklist is an aid for prioritizing alternatives and identifying actions to simplify the scaling-up process. It is not a scorecard to determine what can be scaled up and what can't. The scalability checklist can guide analysis of relevant issues for scaling up.

For more information on the Scalability Checklist, please see page 22 of the document available here: <http://www.msiworldwide.com/files/scalingup-framework.pdf>.

1.14 Evaluability (Robert Wood Johnson Foundation)

Evaluability assessments are pre-evaluations that allow for making needed modifications before full-scale implementation. In addition, evaluability assessments in the public health sector:

- Provide rapid, constructive feedback to program staff
- Develop clear objectives that assist core public health planning and assurance
- Improve demonstration of reporting requirements
- Translate research into practice by assessing evidence-based practices in new settings and populations
- Translate research into practice by identifying promising approaches to achieve public health goals

This tool may be helpful in developing a research question and identifying a specific purpose, which will in turn influence methods and framework selection.

For more information, please see <http://www.rwjf.org/pr/product.jsp?id=58470>.

1.15 Viability (CDC)

In public health, viability is the extent to which a program is viable in the real world. These five dimensions are assessed by stakeholders and researchers to determine an intervention's viability:

- **Practical:** can practitioners implement a program adequately, and is the program suitable for management by a service delivery organization such as a community clinic
- **Affordable:** whether decision makers view the intervention program as affordable
- **Suitable:** can the program recruit clients without paying them to participate, does it have a clear rationale connecting an intervention to expected outcomes, and do stakeholders regard the intervention as helpful in alleviating problems or enhancing their well-being
- **Evaluable:** whether the intervention can feasibly be evaluated
- **Helpful:** can stakeholders notice or experience progress in alleviating a problem

For more information, please see: http://www.proval-services.net/download/Chen_presentation.pdf

1.16 Table of Constraints to Improving Access to Priority Health Interventions²⁶

Level of constraint	Types of constraint
I. Community and household level	<p>Lack of demand for effective interventions</p> <p>Barriers to use of effective interventions (physical, financial, social)</p>
II. Health services delivery level	<p>Shortage and distribution of appropriately qualified staff</p> <p>Weak technical guidance, program management and supervision</p> <p>Inadequate drugs and medical supplies</p> <p>Lack of equipment and infrastructure, including poor accessibility of health services</p>
III. Health sector policy and strategic management level	<p>Weak and overly centralized systems for planning and management</p> <p>Weak drug policies and supply system</p> <p>Inadequate regulation of pharmaceutical and private sectors and improper industry practices</p> <p>Lack of inter-sectoral action and partnership for health between government and civil society</p> <p>Weak incentives to use inputs efficiently and respond to user needs and preferences</p> <p>Reliance on donor funding that reduces flexibility and ownership</p> <p>Donor practices that damage country policies</p>
IV. Public policies cutting across sectors	<p>Government bureaucracy (civil service rules and remuneration; centralized management system civil service reforms)</p> <p>Poor availability of communication and transport infrastructure</p>

²⁶ Hanson, K., M. Kent Ranson, V. Oliveira-Cruz, and A. Mills. (2003). "Expanding access to priority health interventions: a framework for understanding the constraints to scaling up." *Journal of International Development* 15: 1–14.

V. Environmental and contextual characteristics	<p>Governance and overall policy framework</p> <ul style="list-style-type: none"> • Corruption, weak government, weak rule of law and enforceability of contracts • Political instability and insecurity • Low priority attached to social sectors • Weak structures for public accountability • Lack of free press <p>Physical environment</p> <ul style="list-style-type: none"> • Climatic and geographic predisposition to disease • Physical environment unfavorable to service delivery
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1.17 Questions for Different IR Types

Type of IR	Example IR Questions
Needs Assessment	<ul style="list-style-type: none"> • What practices and interventions have been proven to be effective? • What contextual factors contribute to the success or failure of identified interventions? • How might existing policies affect the intervention? • What are the needs and priorities of the different stakeholders and target population?
Formative Research	<ul style="list-style-type: none"> • How and to what extent do contextual and cultural factors influence the desired change? • What factors hinder or facilitate the delivery of the intervention? • What adaptations are necessary to achieve the desired goal? • What changes need to be made to the protocol to address these issues?
Effectiveness Study	<ul style="list-style-type: none"> • Did the intervention do more good than harm when delivered under real-world conditions? • Does the intervention/program meet its goals under typical conditions? • For whom was the intervention effective and for whom was it not? • Under what conditions or context does the intervention prove effective?
Dissemination	<ul style="list-style-type: none"> • What is the social structure of the system, community, or organization we want to affect? • Which types of information and delivery or access modalities are effective for selected target groups? • How can we harness technology or existing networks to achieve widespread dissemination?

1.18 IR Decisions in PMTCT services

The following table provides examples of decisions in IR for prevention of mother-to-child transmission (PMTCT) services.²⁷²⁸

Monitoring and mid-course correction for an ongoing PMTCT Program

Entry point	Decisions around continuation of the program
Data	PMTCT program monitoring indicators on the program monitoring plan
Decisions and Use of data	Assessment of project's success in reaching program goals; whether any mid-course corrections to program strategies are warranted.
DDIU tools/approach	In connection with the development of the program's PMP, a DDIU approach would include use of the decision calendar to link the PMP data to program strategy changes; a constraints to data use assessment might be performed to ascertain what technical assistance of capacity building might be useful, e.g. data analysis techniques. Other technical assistance approaches may be determined by the DDIU Assessment.
Expected result	A revised PMTCT strategy based on the monitoring data.

²⁷ Foreit, K, S. Moreland, S., and A. Lafond, (2006). *Data Demand and Information Use in the Health Sector: Conceptual Framework*. MEASURE Evaluation, Carolina Population Center. University of North Carolina at Chapel Hill.

²⁸ Foreit, K, S. Moreland, S., A. Lafond, (2006). *Data Demand and Information Use in the Health Sector: strategies and tools*. MEASURE Evaluation, Carolina Population Center. University of North Carolina at Chapel Hill.

1.19 Table of Informational Needs

Different stakeholders contribute different perspectives and resources. They also have different requirements or restrictions for decisions. It is important to know their informational needs at the beginning so that that the work you do is as informed and efficient as possible.

Stakeholder group	Information needs	Communication channels
Policy makers and government officials	Limited time availability Limited technical/content expertise Involved in decisions regarding policy, resource allocation, strategic planning Concise information with reference to the bottom line	Dissemination workshops, face-to-face meetings, policy forums, policy briefs, executive summaries, public web sites
Program managers	Use information for program design, planning, improvement, management, and operations decisions Detailed information specific to their area of responsibility	Monthly/quarterly reports, summary reports, executive summaries, audiovisual presentations
Civil society groups	Use evidence-based research to advocate for specific policies, programs, or issues Action-oriented research Plain language (not research jargon)	Fact sheets, brochures, audiovisual presentations
Private sector	Clear recommendations and action items Financially-oriented documents and recommendations	Fact sheets, audiovisual presentations, political endorsements
Mass media	Use research information to increase public awareness about health issues Topic is highly relevant to their own audiences and/or in some way timely	Network with journalists, dissemination meetings, press releases
Funders and donor agencies	Typically assess accountability and program effectiveness and inform investment decisions	Personal communication, research report, audiovisual presentations

	Type of information needed varies	
Researchers and international agencies	<p>Information used for strategic purposes, should be presented concisely with recommendations relevant to ongoing/future work</p> <p>Program officers are familiar with programmatic issues</p> <p>Full research report in addition to audiovisual presentation</p>	Peer-reviewed article, research databases, oral and poster presentations, web sites, CD-ROM

Once you've determined what information is relevant to a stakeholder group, you'll need a strategy to communicate that information. Effective stakeholder communication strategies include:

- Know your stakeholders
- Not all results are equally important to each stakeholder
- Key messages should be tailored for each audience for maximum effect

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Final Exam

1. Select the set of characteristics that best describes IR?
 - A. Efficacy, Effectiveness, Health systems, Operations
 - B. Systematic, Multidisciplinary, Contextual, Complex
 - C. Proven, Evidence-based, Cost effective, Embedded
 - D. Routine, Monitoring, Evaluation, Scaling up
2. Which of the following research questions is program embedded?
 - A. Is oral rehydration therapy distributed equitably in low-income countries?
 - B. Which subpopulations lack access to family planning services?
 - C. How can a community-based breastfeeding education program reach more single mothers?
 - D. Does standard tuberculosis treatment work effectively?
 - E. Which antiretroviral therapy is most effective at preventing mother to child transmission of HIV?
3. Successful implementation research integrates findings into practice or policy. Which example illustrates integration of findings into practice or policy?
 - A. A clinical trial shows no effect of treatment, so the treatment is studied further before it's available to the public.
 - B. A successful new cholera vaccine is added to the government's list of required vaccines before children can enroll in school.
 - C. Text message reminders are tested as a new intervention to improve antiretroviral therapy adherence.
 - D. A nutrition education program isn't scaled up because it works well at the current size.
 - E. An anonymous donor contributes free condoms for distribution in local health centers.
4. Sometimes IR yields unexpected or negative results about a program or policy. Select which statement about IR and negative results is TRUE.
 - A. Negative results should be minimized to avoid termination of program funding.
 - B. Negative results may be important, and whether or not to disseminate them should be determined by policy makers.
 - C. Negative results are usually the fault of the investigator, and should not be reported until a second attempt has been made.
 - D. Negative results are important and useful. They should be reported to inform decision-making.
 - E. Negative results diminish trust in research, and the public should not find out about them.

5. IR addresses many different issues in program delivery. Which of these is NOT an issue that is relevant to IR?
 - A. Sustainability and health maintenance
 - B. Program integration
 - C. Equitability
 - D. Intervention efficacy
 - E. Real-life effectiveness, cost-effectiveness, and impact
6. The extent to which a program can succeed in the real world is known as:
 - A. Feasibility
 - B. Efficacy
 - C. Practical application
 - D. Viability
 - E. Utility
7. Research frameworks are useful for:
 - A. Identifying programs to focus IR on
 - B. Finding funding organizations
 - C. Developing research questions
 - D. Anticipating challenges in conducting IR
 - E. Determining who relevant stakeholders are
8. Which of the following best describes the domain of implementation research?
 - A. Implementation research focuses on a specific, local, clearly defined setting and context.
 - B. Implementation research starts with a specific setting and applies findings to broader contexts through scale-up and other implementation processes.
 - C. Implementation research focuses on a broader context, covering many settings under the umbrella of an entire system.
 - D. Implementation research focuses on finding useful, action-oriented solutions at any scale.
9. When considering whether or not to scale up a program, one should consider:
 - A. Which stakeholders you have existing connections with
 - B. Program size and resources, evidence available, sustainability, and fit
 - C. Economic conditions and overall climate for funding programs
 - D. Political support and popularity of the issue
 - E. How innovative the issue is
10. The IR question, “Why do established programs lose effectiveness over time?” addresses which implementation challenge?
 - A. Scaling up
 - B. Sustainability
 - C. Replication and robustness
 - D. Program integration
 - E. Equitability
 - F. Real-life effectiveness

11. Which research framework is credited as being the most widely used framework, originally setting the context for IR?
- A. Diffusion of innovation theory
 - B. PEPFAR Implementation science framework
 - C. CDC REP framework
 - D. ExpandNet framework for scaling up
 - E. RE-AIM
12. Which is NOT a suggested approach to identify an IR problem?
- A. Systematic analysis
 - B. Discussion with concerned stakeholders
 - C. Review of unsuccessful efficacy trials
 - D. Routine monitoring of health sector activities
 - E. Annual health sector review meetings
13. Achieving sufficient program **fidelity** is a frequently encountered challenge in implementation. Which of the following statements does NOT describe implementation fidelity?
- A. Fidelity refers to the level of adherence to an intervention, or its essential components
 - B. Fidelity is honesty with stakeholders about findings, regardless of their implications
 - C. Fidelity is the degree to which a program is delivered as intended
 - D. Fidelity should be evaluated as part of any IR study
 - E. Fidelity affects the credibility and utility of implementation research
14. Select the only characteristic that is NOT common to most research frameworks:
- A. Proven effectiveness – an evidence-based intervention with demonstrated effectiveness
 - B. Context – local determinants of program adoption and impact
 - C. Sustainability – assessed through monitoring, evaluation, and impacts
 - D. Precedent – this exact problem and solution have been tested before, so the research is likely to succeed
 - E. Stakeholder input – involvement of stakeholders early and throughout the entire process
15. While trying to identify an IR problem, researchers meet with program managers, policy makers, end users, and local leaders to get their input. This is an example of:
- A. Outsourcing
 - B. Pilot testing
 - C. Disseminating information
 - D. Engaging stakeholders
 - E. Evidence-based research

Knowledge Check Answers

Sub-Module 1 Defining Implementation Research

Title: Purpose of IR

Q: Successful implementation research:

- A. Must support existing evidence
- B. Integrates findings into practice or policy**
- C. Uses innovative methods
- D. Relies on programs with a history of moderate success
- E. Earns funding awards for continued work

A: The outcome of a successful IR project is integration of findings into practice or policy. IR uses contextual knowledge to study processes to improve practice. It applies research findings and methods to real-world contexts and settings.

Title: Defining characteristics of IR

Q: Which of the following characteristics does NOT describe IR?

- A. Systematic
- B. Multidisciplinary
- C. Contextual
- D. Complex
- E. Routine**

A: Routine

Title: What IR is and is not

Q: Which of the following research topics fits under the umbrella of Implementation Research?

- A. Routine monitoring and evaluation activities
- B. Randomized trials to determine efficacy
- C. Health systems research questions
- D. Effectiveness studies to assess unintended consequences of programs**
- E. Formative research to determine the distribution of a disease in a specific region

A: Effectiveness studies to assess unintended consequences of programs in real-life settings.

Title: The Implementation Process

Q: IR systematically studies implementation challenges. A teen pregnancy intervention is successful at lowering pregnancy rates, but interpartner violence and abortion complications increase in the program delivery area. What type of implementation challenge does this describe?

- A. Achieving sufficient program fidelity
- B. Unintended consequences and externalities**
- C. Improving institutional capacity and infrastructure to sustain scaling up
- D. Mobilizing adequate resources
- E. Right-size scaling for sustainability

A: Unintended consequences and externalities

Title: IR Challenges

Q: Implementation research problems are unique from problems in other research domains because they are always:

- A. Specific
- B. Related to underserved populations
- C. Program embedded**
- D. Interdisciplinary
- E. Based on previous research

A: Program embedded. All of these problems arise within programs and are directed towards finding action-oriented solutions or improvements that can be applied to future implementation practices. IR problems can be thought of as program embedded – *they begin and end in programs*.

Title: IR Questions

Q: Please select the best example of an implementation research question.

- A. What is the effect of zinc as an adjunct for treatment of diarrhea?
- B. What is the effect of distributing insecticide-treated nets to prevent malaria in vulnerable populations?
- C. How can tuberculosis treatment be delivered effectively in rural areas?**
- D. Does a health education program increase access to antiretroviral therapy?

A: How can tuberculosis treatment be delivered effectively in rural areas?

Sub-Module 2 Implementation research (IR) frameworks

Q: Regardless of which framework you select, it is essential that you:

- A. Adhere to it consistently and maintain its key components**
- B. Use only the components that benefit your research
- C. Modify your context to fit every single framework component
- D. Ignore the context when working within a framework
- E. Modify the framework to fit your methods

A: Regardless of which framework you select, adhering to it consistently and maintaining its key components is essential.

Title: Selecting frameworks

Q: Which of the following will most likely determine which framework you use?

- A. Planned methodology
- B. Timeline and logistics
- C. Context and culture
- D. Purpose and funding agency**
- E. Political support and stakeholder preference

A: Purpose and funding agency

Sub-Module 3 Implementation research (IR) questions/application

Title: Identifying IR problems

Q: Is the following statement about identifying IR problems true or false:

When identifying an IR problem, researchers should collaborate with only the stakeholders who are experienced in research to make sure that the problem is feasible and well-defined for use in a research setting.

- A. True
- B. False**

A: FALSE. When identifying IR problems, it is important to engage stakeholders early and cast a wide net, considering many sources of information, many different perspectives, and underlying causes of problems. Efforts should be made to include those not usually involved and from groups who historically have been left out.

Title: Formulating IR questions

Q: Who should be involved with formulating IR questions?

- A. Researchers
- B. Program managers and staff
- C. Policy makers
- D. Health professionals
- E. All of the above**

A: All of the above, including as many perspectives as possible. IR questions should be identified through analysis of the situation and evidence, addressing the needs of policy makers, program managers and healthcare providers. Remember that IR problems are program embedded – *they begin and end in programs*. So, engage program stakeholders early to formulate IR questions.

Title: Prioritizing IR questions

Q: At a stakeholder meeting identifying challenges around prevention of mother to child transmission of HIV, two barriers are identified. First, many women in rural areas don't tend to deliver their babies in health facilities. Second, some women won't get tested unless their partners grant permission. They chose to address delivering in health facilities because it affects more women. Which criterion for prioritization does this example illustrate?

- A. Relevance**
- B. Urgency of need
- C. Avoidance of duplication
- D. Feasibility
- E. Political acceptability

A: Relevance includes questions of how large or widespread the problem is, who is affected by it, and how severe the problem is. With regard to these questions, a problem afflicting more people is more relevant than one that is less common. Remember, there are many other criteria to consider as well when prioritizing IR questions.

Title: Engaging stakeholders in IR

Q: When is it important to engage stakeholders?

- A. **Early and often, maintaining contact throughout the process**
- B. Right before you disseminate results, so they are prepared to receive results
- C. At the beginning, before you're too burdened with research activities
- D. After you've reviewed preliminary results, so you know which stakeholders are most important
- E. Stakeholder engagement is only necessary for policy-focused IR

A: Early and often. Stakeholders should be involved from the very beginning, to help identify problems and develop a question. They should remain involved throughout the process. For stakeholder engagement, begin with the end in mind.

Title: Disseminating in IR

Q: Which of the following choices is NOT a benefit of disseminating information:

- A. Engaging stakeholders
- B. Ensuring evidenced based decisions for program improvement
- C. Advocating for additional resources
- D. Contributing to global lessons learned
- E. **Improving program reputation by selectively disseminating results**

A: Improving program reputation by selectively disseminating results is not an advantage or benefit of disseminating information. For dissemination to yield its intended benefits, all results (positive and negative) should be disseminated.

Final Exam Answers

A1: Systematic, Multidisciplinary, Contextual, Complex

A2: *How can a community-based breastfeeding education program reach more single mothers?* is program embedded. IR problems arise within programs and are directed towards finding action-oriented solutions or improvements that can be applied to future implementation practices. IR problems can be thought of as program embedded – *they begin and end in programs*.

A3: *A successful new cholera vaccine is added to the government's list of required vaccines before children can enroll in school.* The outcome of a successful IR project is integration of findings into practice or policy. IR uses contextual knowledge to study processes to improve practice. It applies research findings and methods to real-world contexts and settings.

A4: Even 'negative' results are important because we don't want to invest in things that don't work. Not every intervention should be sustained, and knowing which interventions aren't sustainable is just as important as knowing which ones are. Stakeholders need to know if a program is not working, so all results (negative and positive) should be disseminated.

A5: Intervention efficacy. IR occurs **after** efficacy trials have determined the effect size of the program or intervention.

A6: Viability. In public health, viability is the extent to which a program is viable in the real world. Viability alone does not guarantee an intervention's efficacy or effectiveness, but in real-world settings, viability is essential to an intervention's overall success.

A7: Frameworks are useful for developing research questions, and can guide the way you think about your work and come up with questions.

A8: Implementation research starts with a specific setting and applies findings to broader contexts through scale-up and other implementation processes.

A9: Size of programs, resources needed, and effect size; Evidence available; Potential sustainability judgments; Fit for an intervention and the setting in the general population, and fit for socio-cultural context.

A10: Sustainability

A11: Diffusion of Innovation theory

A12: Review of unsuccessful efficacy trials

A13: 'Honesty with stakeholders about findings, regardless of their implications' does NOT describe implementation fidelity.

A14: Precedent – the problem and solution have been tested before, so the research is likely to succeed. This is not essential to the frameworks. The other characteristics listed are common to most research frameworks. In addition, proven efficiency and implementation are essential components.

A15: Engaging stakeholders. Stakeholders should be involved from the very beginning, to help identify problems and develop a question. They should remain involved throughout the process. When thinking about stakeholder engagement, begin with the end in mind.