TRAINING MANUAL ON IMPLEMENTATION RESEARCH

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INSTITUTE OF TROPICAL MEDICINE ANTWERP

TRAINING MANUAL ON IMPLEMENTATION RESEARCH

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PREFACE

It gives me immense pleasure to present this "Training Manual on Implementation Research", developed by the Nepal Health Research Council (NHRC) with the support of Institute of Tropical Medicine (ITM), Belgium. Implementation research plays a significant role in bridging the gap between research evidence and real-world practice, identifying effective strategies to ensure that proven health interventions are successfully adopted, scaled up, and sustained across diverse settings.

This manual has been designed as a practical resource to strengthen the knowledge and skills of health professionals and researchers on implementation research. It provides clear systematic guidance on the process of conducting implementation research. By offering step-by-step approaches, real-world examples, and context-specific guidance, this manual aims to empower participants to translate evidence into action for improving the health and wellbeing of the people.

In recent years, the importance of evidence-based decision-making has become even more evident. The growing burden of non-communicable diseases, and the challenges of emerging infectious diseases such as dengue highlight the need for evidence-based research and competent researchers at all levels. This training manual represents an important step toward building a stronger research culture, one that is inclusive, multidisciplinary, and aligned with national and global development goals.

I take this opportunity to express my sincere appreciation to all the experts, facilitators, and contributors who have devoted their time and expertise in preparing this manual. I am confident that it will serve as a valuable resource for trainees and institutions alike, supporting the development of competent researchers. I extend my best wishes to all researchers and encourage them to apply the knowledge and skills gained from this manual to advance implementation research for the betterment of our society.

Prof. Dr. Narayan Bikram Thapa

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Implementation research plays a vital role in bridging the gap between what is known through evidence and what is practiced in real-world settings. While numerous evidence-based interventions have been developed to improve public health and development outcomes, their effectiveness ultimately depends on how well they are implemented. This is where implementation research becomes essential, as it helps identify and address the practical challenges of applying interventions in routine contexts.

This training manual has been developed to support trainers by providing clear and structured guidance on planning training sessions, designing instructional content, and applying effective teaching methods. It emphasizes systematic and practical approaches to help trainers achieve specific learning outcomes and enhance the effectiveness of capacity-building efforts.

Foremost, I would like to express my heartfelt gratitude to Prof. Dr. Ruth Müller (Institute of Tropical Medicine, Belgium) for her expert guidance and continuous encouragement throughout the preparation of this training manual. Her unwavering support was instrumental in shaping both the direction and quality of this work.

I am also thankful to Dr. Meghnath Dhimal, Chief of the Research Section at the Nepal Health Research Council (NHRC), Prof. Dr. Archana Shrestha, Dr. Megha Raj Banjara, and Dr. Sabitri Sapkota for their invaluable inputs and thoughtful suggestions, which have significantly enriched the content and enhanced the practicality of the manual. My special thanks go to Ms. Namita Ghimire, Chief, Ethical Review Monitoring and Evaluation Section; Ms. Sailaja Ghimire, Research Associate; and Mr. Bishal Dahal Khatri, Research Assistant, for their dedicated efforts and outstanding contributions, without which this manual would not have reached its present form.

I would further like to acknowledge the insightful contributions of Prof. Dr. Anand Ballabh Joshi, Prof. Madhusudan Subedi, Prof. Naveen Shrestha, Dr. Rajendra B.C., Dr. Prajwal Pyakurel, and Ms. Jyoti Nepal, whose feedback and expertise have added substantial value to the relevance and quality of this manual. I am also grateful to Mr. Rajesh Gautam, Ms. Prakriti Sharma, and Ms. Susmita Bhusal for kindly granting permission to reproduce their photographs, which have enhanced the visual presentation of this publication.

This initiative was made possible through the generous financial support of the Institute of Tropical Medicine (ITM) under a FA5 collaborative agreement with NHRC. Their commitment to advancing implementation research in Nepal is deeply appreciated.

It is my sincere hope that this training manual will serve as a practical and valuable resource for trainers and practitioners, supporting their professional development and contributing meaningfully to the advancement of implementation research in Nepal.

Sincerely,

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ACRONYMS

Abbreviations	Full Form
ADAPT-ITT	Assessment, Decision, Adaptation, Production, Topical Experts-Integration, Training, and Testing
ANC	Antenatal Care
BANANA	Basel Approach for coNtextual ANAlysis
BCW	Behavior Change Wheel
CBT	Cognitive-Behavioral Therapy
CFIR	Consolidated Framework for Implementation Research
CHW	Community Health Worker
COM-B	Capacity, Opportunities, Motivation- Behaviour
cRCT	Cluster Randomized Controlled Trials
EBI/EBIs	Evidence-Based Intervention/ Evidence-Based Interventions
EBPs	Evidence-Based Practices
ERIC	Expert Recommendation for Implementing Change
FCHV	Female Community Health Volunteer
FGD	Focus Group Discussion
FRAME	Framework for Reporting Adaptations and Modifications to Evidence-based Interventions
EHR	Electronic Health Record
HPV	Human Papillomavirus
HSR	Health System Research
IR	Implementation Research
ITS	Interrupted Time Series
mhGAP	Mental Health Gap Action Program
NCD	Noncommunicable Disease
OR	Operational Research
PHC	Primary Health Care
PRISM	Practical, Robust Implementation and Sustainability Model
RCT	Randomized Control Trial
RDD	Regression Discontinuity Designs
REAIM	Reach, Efficacy, Adoption, Implementation, and Maintenance
StaRI	Standards for Reporting Implementation Studies
TMF	Theory Model and Frameworks
TPB	Theory of Planned Behavior_
WHO	World Health Organization

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OVERVIEW OF THE TRAINING MANUAL

The implementation research training manual aims to strengthen the capacity of researchers, academicians, program implementers, and public health professionals to conduct high-quality implementation research in low- and middle-income settings like Nepal. It provides systematic guidance on planning, conducting, and facilitating implementation research to bridge the gap between research evidence and real-world practice.

The manual includes nine modules covering key topics such as implementation research concepts, outcomes, context, strategies, stakeholder engagement, ethics, and reporting. It emphasizes a hands-on, interactive approach through group activities, case studies, and practical tips for facilitators. The manual helps trainers and participants design and conduct implementation research that is contextually relevant and can make a real difference in routine healthcare practice and policy.

Goal

The goal of the manual is to explain key concepts of implementation research and demonstrate their practical application to strengthen the capacity of researchers, trainers, and public health professionals in planning and conducting implementation research.

Objectives

1. To introduce the fundamental concepts, frameworks, and principles of implementation research.
2. To build the capacity of researchers, trainers, and public health professionals to design and conduct high-quality implementation research.
3. To enhance understanding of how contextual factors influence implementation processes and outcomes.
4. To promote skills in selecting and applying appropriate implementation strategies and measuring implementation outcomes.
5. To strengthen abilities in stakeholder engagement, ethical conduct, and effective reporting of implementation research.

Guidelines for the use of manual

This training manual is a practical guide for researchers and program implementers interested in learning about implementation research. It is designed for interactive, group-based training sessions that can be completed over six days. The manual is especially useful for those who want to build their knowledge and skills in implementation research within the Nepali context. Facilitators are encouraged to review each module carefully before the sessions. Being familiar with the content will help them lead engaging discussions and create an effective and meaningful learning experience for all participants.

Guidelines for facilitators

Facilitators play a crucial role in making training programs effective and successful. Their job is not just to share information, but to create a respectful, inclusive, and interactive space where participants feel comfortable asking questions, sharing ideas, and taking part actively.

To do this well, facilitators should be well-prepared, know the subject thoroughly, manage time effectively, and encourage positive group interactions. By promoting participation, guiding discussions, and focusing on key concepts, facilitators help participants understand, remember, and apply what they learn both during and after the training.

Guidelines on training approach

This training is interactive, hands-on, and focused on the learner. Rather than relying only on lectures, it encourages participants to share ideas, reflect on their experiences, and work together to solve problems.

Facilitators guide the session while creating space for everyone to take part openly. Respect and a non-judgmental environment are important, every voice is valued, and different perspectives are welcomed.

Using tools like cards, markers, flip charts, soft boards, and pin boards is encouraged to make the learning more visual and practical.

Key methods for the training

Icebreakers: Short, interactive games at the beginning will create a relaxed atmosphere and help participants feel more comfortable with one another, especially important when people are meeting for the first time.

Group work: Participants are divided into smaller teams (ideally 4 to 8 people) to complete specific tasks. This setup encourages more focused discussion, teamwork, and shared problem-solving.

Group discussions: Open discussions allow participants to express their thoughts, listen to others, and possibly rethink their own views. These exchanges help understand personal values, attitudes, and behaviors. Facilitators ensure everyone gets the chance to speak, and often designate a rapporteur to summarize the key points of the groups.

Case studies: Real or hypothetical stories will spark discussion and draw lessons. These can be delivered through text, images, video, or storytelling. Facilitators prepare guiding questions, give participants time to analyze the case, and lead a debrief to capture key insights.

Energizers: These quick and fun activities will break up monotony and keep energy levels high during longer sessions. These helps refresh participants and maintain engagement.

Classroom exercises: These activities are conducted within the full group, without breaking into smaller teams. They often involve individual reflection or collective brainstorming.

Group exercises: Conducted in smaller, mixed-background groups (ideally 5 to 8 people), these exercises encourage diverse contributions and active collaboration.

COURSE STRUCTURE OF THE MANUAL AND TRAINING SCHEDULE FRAMEWORK

This training manual is structured into 9 modules lasting for 6 days as mentioned below.

Table 1: Schedule of the training

Time	Activities/ content
Day 1	
9:00-9:45	Registration, opening session
9:45-10:00	Pre-test assessment
10:00-11:00	Introduction to implementation research
11:00-11:15	Tea break
11:15-1:00	Group work on introduction and evidence-based intervention
1:00-2:00	Lunch break
2:00-3:00	Implementation outcomes
3:00-3:15	Tea break
3:15-5:00	Group work on implementation outcomes
Day 2	
9:00-9:45	Registration
9:45-10:00	Recap of day 1
10:00-11:00	Contextual determinants
11:00-11:15	Tea break
11:15-1:00	Group work on contextual determinants
1:00-2:00	Lunch break
2:00-3:00	Implementation strategies
3:00-3:15	Tea break
3:15-5:00	Group work on implementation strategies
Day 3	
9:00-9:45	Registration
9:45-10:00	Recap of day 2
10:00-11:00	Implementation research logic model (IRLM)
11:00-11:15	Tea break
11:15-1:00	Group work on IRLM
2:00-3:00	Lunch break
3:00-4:00	Stakeholder engagement
4:00-5:00	Group work on stakeholder engagement

Time	Activities/ content
Day 4	
9:00-9:45	Registration
9:45-10:00	Recap of day 3
10:00-11:00	Implementation research to identify contextual determinants
11:00-11:15	Tea break
11:15-12:15	Implementation research to identify contextual determinants (Contd.)
12:15-1:00	Group work on proposal on identifying contextual determinants
1:00-2:00	Lunch break
2:00-5:00	Group work on proposal on identifying contextual determinants and presentation
Day 5	
9:00-9:45	Registration
9:45-10:00	Recap of day 4
10:00-11:00	Implementation research for testing implementation strategies
11:00-11:15	Tea break
11:15-12:15	Group work on proposal development for testing implementation strategies
1:00-2:00	Lunch break
2:00-5:00	Group work on proposal development for testing implementation strategies and presentation
Day 6	
9:00-9:45	Registration
9:45-10:00	Recap of day 5
10:00-11:00	Hybrid approach in implementation research
11:00-11:15	Tea break
11:15-12:15	Ethics in implementation research
12:15-1:00	Reporting of implementation research
1:00-2:00	Lunch break
2:00-5:00	Closing

Users of this manual

Facilitators or trainers who would like to conduct basic training on implementation research should use this manual as a guide or reference material. This is reading material for researchers, ethics committee members, program managers, and learners.

Target participants for training

The target participants for this training are the researchers and program managers who have completed at least a master's degree or experience in the health sector.

Module 1: Introduction to Implementation Research

INTRODUCTION TO IMPLEMENTATION RESEARCH

Background

Implementation Research (IR) is essentially the study of how to get proven health interventions, guidelines, and policies into everyday healthcare systems. Even when strong evidence exists, these solutions may not be adopted, delivered as intended, or sustained over time showcasing the implementation gap. Implementation research helps explain why this gap between evidence and practice occurs and identifies practical strategies to support the adoption, integration, and scale-up of evidence-based interventions in real-world contexts.[1-3]

Why do we need implementation research?

Implementation research is needed because even when a health intervention is proven to work in clinical trials, it often does not reach the people who need it most or is not used properly in real-life healthcare settings. This gap may occur due to challenges within health systems, limited resources, and barriers faced by healthcare providers and patients.[4,5] Traditional effectiveness research usually focuses on whether an intervention works, but it does not explain why it succeeds in some settings and fails in others. Implementation research helps by identifying real-world barriers and facilitators, developing strategies to overcome these challenges, and testing whether those strategies improve adoption, delivery, and long-term use of interventions.[6-8]

Importantly, when an intervention does not show the expected benefit during scale-up, implementation research helps determine whether the problem is with the intervention itself (intervention failure) or with how it was delivered (implementation failure).[8] By doing so, implementation research ensures that proven interventions are not only adopted but also sustained, reach more people, and lead to better and more equitable health outcomes.

Research-to-practice gap (Know-do gap)

The research-to-practice gap, often called the “know-do” gap, is a significant and persistent delay or failure in translating evidence-based research findings and interventions into routine healthcare practice. It describes the gap in ‘what we know’ and “what we do actually”. Studies estimate that it takes an average of 17 years for evidence-based practices (EBPs) to become routine in healthcare.[20] (Figure 1)

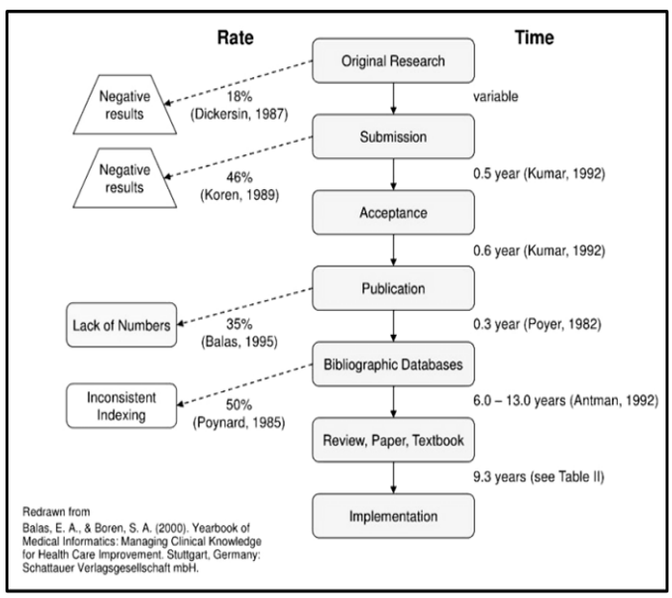


Figure 1: Research-practice gap

The gap exists because simply establishing that an intervention is effective (through efficacy and effectiveness trials) does not guarantee it will be widely adopted or correctly used in real-world settings. There is a fundamental disconnect between the highly

controlled, resource-rich environment of research (where interventions are developed) and the complex, resource-constrained environment of practice (where interventions must be implemented).

Example of scurvy

A classic example of this gap is the discovery of vitamin C as a preventive measure for scurvy. In 1601, a Scottish surgeon, James Lind, experimented on scurvy. He divided sailors with scurvy into different groups and gave them various treatments, including citrus fruits, vinegar, and seawater. The group that received citrus fruits, including lemons, recovered rapidly, and Lind concluded that citrus fruits contained a substance that could prevent scurvy. Despite this discovery, it took another 194 years for the Royal Navy to implement Lind's findings and include lemon juice in the sailors' diets on ships in 1795, effectively preventing scurvy.[9]

Closing the know-do gap is the primary goal of implementation research. Implementation research systematically closes the know-do gap by treating the translation of evidence into practice as a scientific process, rather than a passive event. It achieves this by first using theories and frameworks like Consolidated Framework for Implementation Research (CFIR) or Reach, Effectiveness- Adoption, Implementation, and Maintenance (RE-AIM) to rigorously analyze the determinants (barriers and facilitators) to adopting an evidence-based practice within a specific organizational context. Next, researchers and practitioners co-develop and test specific implementation strategies, the deliberate, tailored actions such as peer-to-peer facilitation or audit and feedback designed to overcome those identified barriers. Finally, it uses specialized implementation outcomes (e.g., fidelity, feasibility, and sustainability) to rigorously evaluate how effectively the new strategy and intervention are integrated, thereby generating generalizable knowledge on how to achieve high-quality, sustained use of evidence.

Evidence based intervention

An evidence-based intervention (EBI) is a program, practice, policy, or treatment that has been proven to work through strong scientific research. High-quality studies show that it improves health outcomes when used as intended, and it is therefore recommended for use in real-world practice or policy.[10,11] EBIs are the "what" that implementation research seeks to integrate into routine use.

Table 2: Examples of EBIs

EBIs (What)		Health effects
Policy	Smoke-free environment[12]	Showed to reduce acute myocardial mortality by 8 %[13]
Programs	Community health worker (CHW)-led community health program	Among registered pregnancies, 19% in the intervention group and 2% in the control group received at least eight ANC visits.[14]

EBIs (What)		Health effects
Practices	Infection control practices in hospitals	Showed to reduce healthcare-associated infections by 35-70 %[15]
Health-related behaviors	Increased physical activity	Showed to lower risk of death from cardiovascular disease by 28-38 %[16]
Procedures	Laparoscopic appendectomy	Laparoscopic surgery significantly reduces the risk of wound infections compared to open surgery (0.48 (95%-CI: 0.36; 0.65)).*
Tests	Human papillomavirus (HPV) testing	Showed to reduce cervical cancer mortality by 41-92 %. [17]
Treatment	Anti-hypertensive medication	Showed to reduce systolic blood pressure by 10-3 - 22.2 mmHg over 8-12 months.[18]

Evidence hierarchy

The evidence hierarchy (Figure 2) is used to rank research studies based on the strength and reliability of the evidence they provide. It helps researchers, clinicians, and policymakers decide how much confidence to place in study findings when selecting or scaling up interventions. At the top of the hierarchy are systematic reviews and meta-analyses, followed by randomized controlled trials (RCTs), which offer strong evidence of cause and effect. Below these are quasi-experimental studies, commonly used when randomization is not feasible, and observational studies such as cohort and case-control studies, which are more prone to bias. At the bottom are case reports and expert opinion, which provide the weakest evidence. While useful as a guide, the hierarchy should be applied flexibly, as the most appropriate evidence depends on the research question and real-world context, particularly in implementation research.[19]

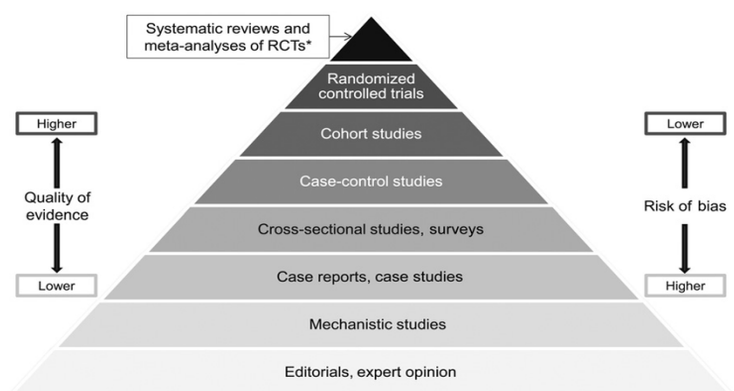


Figure 2: Evidence hierarchy

Typology for classifying interventions by level of scientific evidence

Table 3 presents the typology of interventions, based on their purpose and the level of scientific evidence they generate. This typology helps researchers, practitioners, and policymakers decide which interventions are ready for implementation, which require further testing, and which should be used with caution.[20]

* Gorenoi V, Dintsios CM, Schönermark MP, Hagen A. Laparoscopic vs. open appendectomy: systematic review of medical efficacy and health economic analysis. GMS Health Technol Assess. 2007 Jan 29;2:Doc22.

Table 3: Typology of interventions by level of scientific evidence

Category	How the intervention is established	Considerations for the level of scientific evidence	Typical data source
Evidence-based interventions	Demonstrated effectiveness through multiple rigorous studies, often across different settings and populations.	High internal validity and strong causal inference; consistent findings across studies; evidence of effectiveness, safety, feasibility, and often cost-effectiveness; high potential for scalability and generalizability.	Community guide Cochrane reviews Narrative reviews
Effective interventions	Shown to work in at least one well-designed study or real-world program but with more limited replication or contextual testing.	Moderate to high quality evidence; effectiveness demonstrated but may be context-specific; limited information on long-term outcomes, cost, or scalability.	Research articles Research-tested intervention programs
Promising intervention	Written program evaluation without formal peer review	Preliminary evidence of effectiveness; limited sample sizes or short follow-up; uncertainty about sustainability, generalizability, and unintended effects; requires further testing.	Government reports Conference presentations
Emerging intervention	Ongoing work, practice-based summaries, or evaluation works in progress	Minimal empirical evidence; focus is on plausibility and relevance rather than proven impact; high uncertainty regarding effectiveness and safety; appropriate for exploratory or formative research only.	Evaluability assessment Pilot studies Formative qualitative studies Cases studies

What level of evidence is necessary for implementation research?

The level of evidence needed depends on how developed the intervention is and what the study aims to do. Strong evidence-such as systematic reviews, meta-analyses, or multiple high-quality randomized controlled trials-is preferred for well-established interventions. However, implementation research also values practice-based and context-specific evidence to help adapt and deliver interventions in real-world settings.[21,22]

High-level evidence is desired but not always required to make decisions, especially when evidence is limited or action is urgent. Researchers and policymakers must therefore judge the appropriate level of evidence based on available data, the local context, and practical constraints. For example, during the early stages of the COVID-19 pandemic, decisions were made using expert judgment and emerging local data rather than waiting for strong trial evidence.[23,24] Similarly, when governments roll out new programs, it is

often appropriate to conduct implementation research alongside implementation to assess feasibility, fidelity, reach, and equity and to improve programs as they are delivered. Over time, this work can develop into hybrid effectiveness-implementation studies, which strengthen evidence on both outcomes and delivery, supporting timely and practical decision-making in resource-limited or rapidly changing settings.[22,25]

Operationalizing evidence-based intervention while initiating IR

Before initiating implementation research, it is essential to identify and clearly define the EBI that addresses a specific health problem. This involves articulating specifics of the intervention:

1. Who will deliver it? The implementer
2. Who are the beneficiaries? The target
3. What are the essential components? Core functions[26]
4. How will it be delivered? Forms
5. How much? Dose and duration
6. What is the intended effect? Health outcomes

Example of mental health gap(mhGAP) as an evidence-based intervention

To operationalize the world health organization (WHO) Mental health gap action program (mhGAP), the intervention must be clearly defined for use in routine health services.

Intervention: WHO mental health gap action program (mhGAP)[27]

- ❑ Who delivers it (Implementers): Primary health care workers, such as medical officers, nurses, or health assistants
- ❑ Who benefits (Target population): People with priority mental, neurological, and substance use conditions (e.g., depression, psychosis, epilepsy, alcohol use disorders)
- ❑ Essential components (Core components): Identification and assessment using the mhGAP intervention guide, basic psychosocial support, use of first-line medications when indicated, referral of severe or complex cases, follow-up and continuity of care
- ❑ How it is delivered (Form): Structured clinical consultations guided by the mhGAP intervention guide, use of job aids, algorithms, and supervision support
- ❑ How much is delivered (Dose and duration): Approximately 20-30-minute consultations during routine outpatient visits, follow-up visits every 2-4 weeks, depending on the condition
- ❑ What is the intended effect? (Health outcome): The intended benefit is a reduction in symptoms of mental health disorders, such as depression and anxiety.

Example of a group care ANC intervention as evidence based intervention

Intervention: Integrated community health worker-led intervention to improve antenatal care utilization, implemented by Nyaya health

- Who delivers it (Implementers): Community health workers and nurses/supervisors together with government clinic nurse-midwives
- Who benefits (Target population): Pregnant women from six rural village clusters in Achham
- Essential components (Core components): Facilitate gestation-specific group ANC visits that combine clinical assessment, participatory education, documentation, and referral and care coordination.
- How it is delivered (Form): Reduced visit schedule, joint facility-based sessions, expanded diagnostics, fixed scheduling with larger or mixed-age groups, and mobile supervisory checklists.
- How much is delivered (Dose and duration): Once per month, for a year
- Evidence of effectiveness (Health outcome and effect size): Women receiving CHW-led interventions were 41% more likely to attend at least four ANC visits compared with controls (risk ratio = 1.41, 95% CI: 1.26-1.58).

Adaptation of evidence based intervention

Adaptation of an EBI is making planned changes so the intervention fits a new setting or population, while keeping the key parts that make it work. These changes usually affect how the intervention is delivered (such as who delivers it, where it is delivered, or how often), not what the intervention is meant to do.[29] Adaptation is often necessary to improve feasibility, acceptability, and sustainability in real-world settings. However, adaptations should be intentional and documented to make sure the intervention remains effective and does not lose its core purpose.

A key early step in adaptation is clearly separating core functions from forms. Core functions are the essential purposes or mechanisms of the intervention that must stay the same, while forms are the specific activities or delivery methods that can be changed. By adapting the form while protecting the core functions, implementers can tailor interventions to local needs without weakening their proven effectiveness.[29]

Example: Adapting WHO mhGAP from rural Nepal to urban refugee clinics in a high-income country

- Original Nepal context: mhGAP delivered by primary health care workers in rural health posts with limited specialist support.
- Core functions (remain the same):
  - Identify priority mental health conditions
  - Provide basic psychosocial support and first-line treatment
  - Refer severe cases
  - Ensure follow-up care

- ❑ Adapted forms in the new context:
  - ➲ Delivery by nurse practitioners and social workers instead of health assistants
  - ➲ Use of translated screening tools and cultural mediators for refugee populations
  - ➲ Longer appointment times to address trauma and migration-related stress
  - ➲ Integration with social services and legal aid referrals
- ❑ Rationale for adaptation: Different workforce composition, cultural needs, and service structures, while keeping the same clinical purpose of mhGAP.

Example: Adapting group antenatal care (group ANC) from rural Nepal to urban slum settings in sub-saharan Africa

- ❑ Original Nepal context: Group ANC delivered in village clinics by CHWs and nurse-midwives, with fixed schedules and expanded diagnostics.
- ❑ Core functions (remain the same):
  - ➲ Provide antenatal care in group settings
  - ➲ Integrate clinical care, health education, and peer support
  - ➲ Promote participation, learning, and birth planning
- ❑ Adapted forms in the new context:
  - ➲ Sessions held in community centers or churches instead of clinics
  - ➲ Groups organized by time availability rather than gestational age due to mobility
  - ➲ Use of visual aids and peer facilitators for low-literacy populations
  - ➲ Inclusion of male partners or family members in some sessions
- ❑ Rationale for adaptation: High population mobility, space constraints, and different social norms require flexible delivery while preserving the benefits of group-based care.

Adaptation process

In implementation research, evidence-based interventions (EBIs) can be adapted in different ways depending on the setting, goals, and stage of implementation. Some adaptations are planned in advance, based on local needs, resources, and culture, while others are made during implementation to address practical challenges.

Adaptations may include:

- ✓ Changing language or examples to fit local culture,
- ✓ Adjusting where and by whom the intervention is delivered,
- ✓ Simplifying content to match local capacity while keeping the key elements intact.
- ✓ how the intervention is delivered, such as task shifting or using digital tools, or
- ✓ Changing the dose or intensity to make the intervention more feasible. Involving stakeholders and communities in the adaptation process helps ensure the intervention is acceptable and relevant.

Across all approaches, good practice requires clearly identifying what must stay the same, documenting any changes, and monitoring outcomes to make sure the intervention remains effective.

There are several frameworks to guide the adaptation of evidence-based interventions (EBIs), most of which follow a structured, step-by-step process. A systematic review by Escoffery et al. identified 11 common steps across adaptation models. These steps begin with assessing the local context and fully understanding the original EBI, followed by engaging experts and stakeholders to decide what changes are needed. After modifying the intervention, the process includes training implementers, pilot testing the adapted materials, and then implementing and evaluating the EBI to ensure it remains effective in the new setting.

A critical principle underlying adaptation is distinguishing between core functions and forms. Core functions are the essential purposes or mechanisms that make the intervention effective and must be preserved. Forms are the specific activities or delivery methods used to achieve those functions and can be adapted to fit the local context. By modifying forms while maintaining core functions, implementers can tailor EBIs to local needs without undermining their effectiveness.

Existing research provides several process frameworks for guiding EBI adaptation, which typically follow a structured, multi-step approach.30 little is known about the reasons for adaptation, the adaptation process, and outcomes of adapted EBIs. To address this gap, we conducted a systematic review to answer the following questions: (1) A systematic review by Escoffery et al.30 little is known about the reasons for adaptation, the adaptation process, and outcomes of adapted EBIs. To address this gap, we conducted a systematic review to answer the following questions: (1) synthesized these models and identified 11 common steps necessary for effective adaptation: (1) assess the community and implementation context; (2) thoroughly understand the original EBI and its evidence base; (3) identify the intervention's core functions and distinguish them from adaptable forms; (4) assess the fit between the EBI and the local context; (5) engage key stakeholders and experts; (6) define adaptation goals and priorities; (7) decide which forms require modification while preserving core functions; (8) adapt and revise intervention materials and protocols; (9) train implementers on the adapted EBI; (10) pilot test the adapted intervention to assess feasibility, acceptability, and fidelity; and (11) implement and evaluate the adapted EBI to ensure its effectiveness and sustainability in the new context.

Assessment, Decision, Adaptation, Production, Topical Experts-Integration, Training, and Testing (ADAPT-ITT)

Building on the general 11-step adaptation process described above, the ADAPT-ITT model provides a practical, theory-informed framework for systematically adapting evidence-based interventions while preserving their core functions. ADAPT-ITT consists of eight phases: Assessment of the target population and context; Decision on whether adaptation is needed and which EBI to use; Administration of the intervention components (often through theater testing or demonstrations) to gather feedback; Production of adapted materials; Topical experts consultation to review adaptations; Integration of feedback into the revised intervention; Training of implementers; and Testing of the adapted intervention

through pilot implementation. Consistent with the core functions-forms distinction, ADAPT-ITT emphasizes adapting the form of intervention components based on stakeholder input and contextual fit, while maintaining the core functions responsible for effectiveness.[31]

Framework for Reporting Adaptations and Modifications to Evidence-based Interventions (FRAME)

- ✓ FRAME provides a standardized way to document what parts of an intervention were modified. In practice, FRAME is used as a checklist to systematically record how an evidence-based intervention changes as it is implemented in real-world settings. When an adaptation occurs, implementers document.[32]
- ✓ what was changed (e.g., content, delivery method, frequency, personnel),
- ✓ when the change happened (before implementation or during delivery), and
- ✓ who initiated it (such as frontline providers, program managers, or community members).
- ✓ why the change was made, for example to improve cultural relevance, reduce burden on staff, address resource constraints, or increase participant engagement.
- ✓ whether the change was planned or reactive, and
- ✓ whether it is consistent with the intervention's core functions or represents a deviation that could affect effectiveness.

Implementation research

Implementation research (IR) is the scientific study of how to promote the adoption, delivery, and long-term use of EBIs or policies in routine public health and clinical settings.[33] Because IR focuses on how interventions are delivered in practice, it asks why and how an intervention works-or fails to work-outside controlled research settings. Typical IR questions include which delivery strategies increase coverage, what barriers prevent frontline workers from following guidelines, whether an intervention is acceptable to users and providers, which adaptations preserve effectiveness while fitting local constraints, and what strategies improve adoption in primary health care. These questions are closely linked to key program outcomes such as fidelity, coverage, equity, sustainability, and cost-effectiveness.

The key characteristics of implementation research are:[34,35]

- ✓ **Systematic:** IR uses rigorous qualitative and quantitative methods to study implementation challenges and test solutions in a structured way.
- ✓ **Multidisciplinary:** It draws on multiple disciplines, such as public health, social sciences, health economics, and systems thinking, to address the social, organizational, and financial aspects of implementation.
- ✓ **Contextual:** IR places strong emphasis on local context, recognizing that health system structures, culture, resources, and policies shape how interventions work.
- ✓ **Practical:** Finally, IR focuses on real-world complexity, developing practical strategies that remain effective despite variation in settings, stakeholders, and service delivery conditions.

Implementation research within different phases of research

Figure 3 illustrates the progression of research phases on an intervention, moving from early exploratory work to real-world application, with increasing relevance as the research advances. The first phase, Pre-Intervention, focuses on exploring whether a relationship exists, asking the research question: "Is there a relationship?" Next, Efficacy Studies test whether the intervention could work under ideal, controlled conditions, with the question: "Could this program work?" Following that, Effectiveness Studies examine if the program does work in typical, real-world settings, asking: "Does this program work?" Finally, Implementation Studies investigate how and why the program works in practice by identifying barriers and facilitators to successful use, guided by the question: "What makes the program work in practice settings?" The figure also highlights the importance of considering implementation early, even during pilot testing, to collect data that supports effective translation of evidence into practice. This staged approach ensures that interventions move from theoretical promise to sustainable, practical impact.[36]

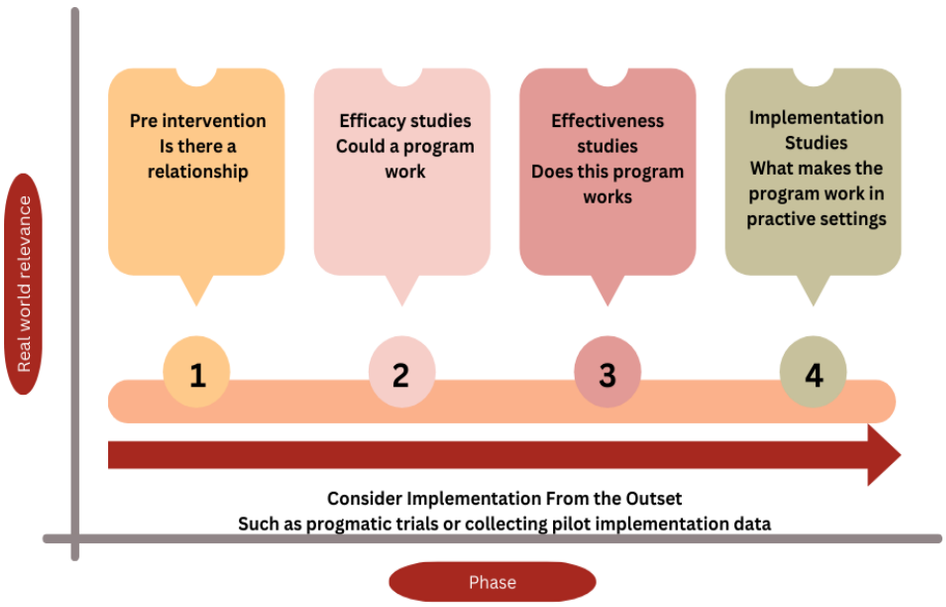


Figure 3: IR in different phases of research

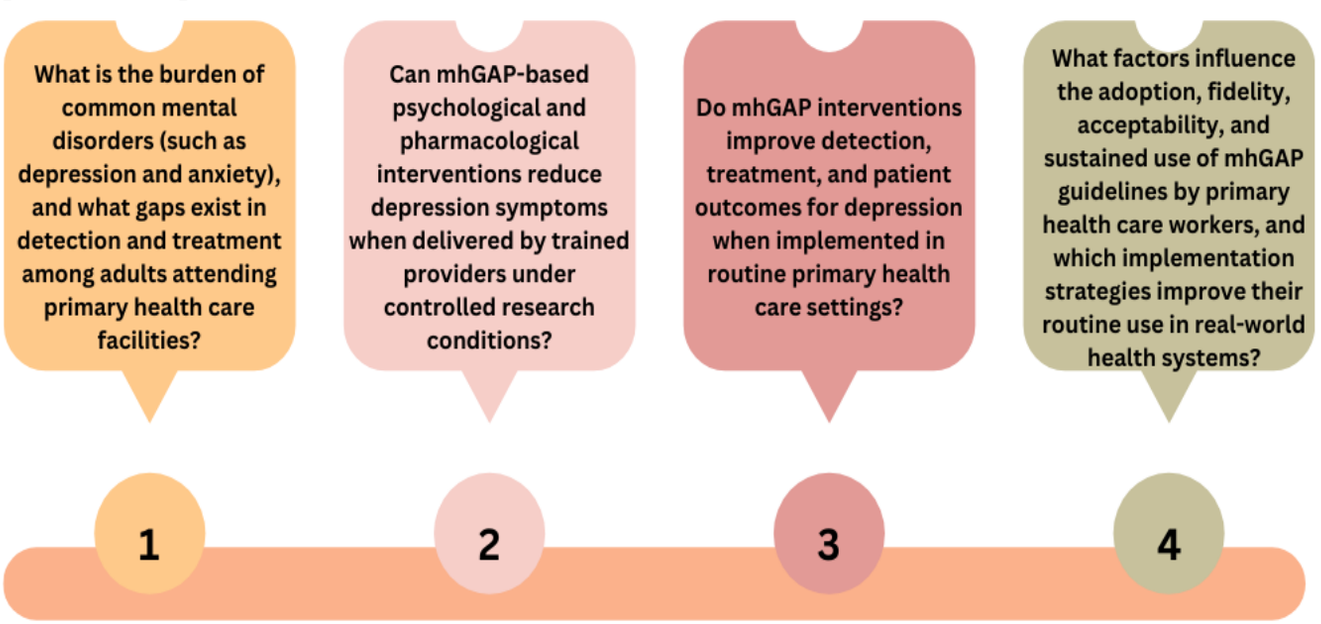


Figure 4: Example of phases of IR

What is not implementation research?

- ✓ Not about discovering new diseases, drugs, or biological mechanisms (that is basic research)
- ✓ Not a tightly controlled clinical trial testing whether something can work (that is efficacy research)
- ✓ Not simply routine program monitoring or basic evaluation
- ✓ IR goes beyond counting activities to explain causes and test solutions
- ✓ Not the same as operational research or health systems research, though there are overlaps

Distinction between implementation research, operational research and health system research

Table 4: Distinction between implementation research, operational research, and health system research.

Research type	Primary focus	Core question asked	Typical scale / utility
Implementation research (IR)[1]	Strategies to integrate proven interventions into practice.	"How best can we get people or places to do the thing?"	Generates generalizable knowledge about implementation strategies across different contexts.
Operational research (OR)[37]	Efficiency and optimal management of ongoing programs or services.	"What is the most effective and efficient way to run this specific program?"	Provides immediate, context-specific solutions for program managers (local utility).
Health systems research (HSR)[38]	Structure and function of the health system and its policies as a whole.	"How can we improve the whole health system to better achieve its goals?"	Produces broad, policy-level evidence for system-wide reform and decision-making.

Example of group ANC

Evidence shows that group ANC can improve maternal satisfaction, knowledge, social support, and in some settings maternal and newborn outcomes. Based on this evidence, many countries are exploring ways to expand the delivery and coverage of Group ANC within routine maternal health services. Implementing this proven model presents valuable opportunities for three complementary areas of research: OR, IR and HSR.

- ➲ OR question: Which health facilities or catchment areas should be prioritized for introducing group ANC to maximize reach among pregnant women?
- ➲ IR question: What implementation strategies can improve the adoption, fidelity, and sustained delivery of group ANC by health care providers and facilities?
- ➲ HSR question: What are the effects of scaling up group ANC on the health system, including workforce workload, service organization, costs, and equity in access to antenatal care?

Theories, models and frameworks in implementation research

Theoretical approaches which aim at understanding and/or explaining influences on implementation outcomes (i.e., the second aim) can be further broken down into determinant frameworks, classic theories and implementation theories based on descriptions of their origins, how they were developed, what knowledge sources they drew on, stated aims and applications in implementation research. Thus, five categories of theoretical approaches used in implementation research can be delineated.[39]

1. Process models
2. Determinant frameworks
3. Classic theories
4. Implementation theories
5. Evaluation frameworks

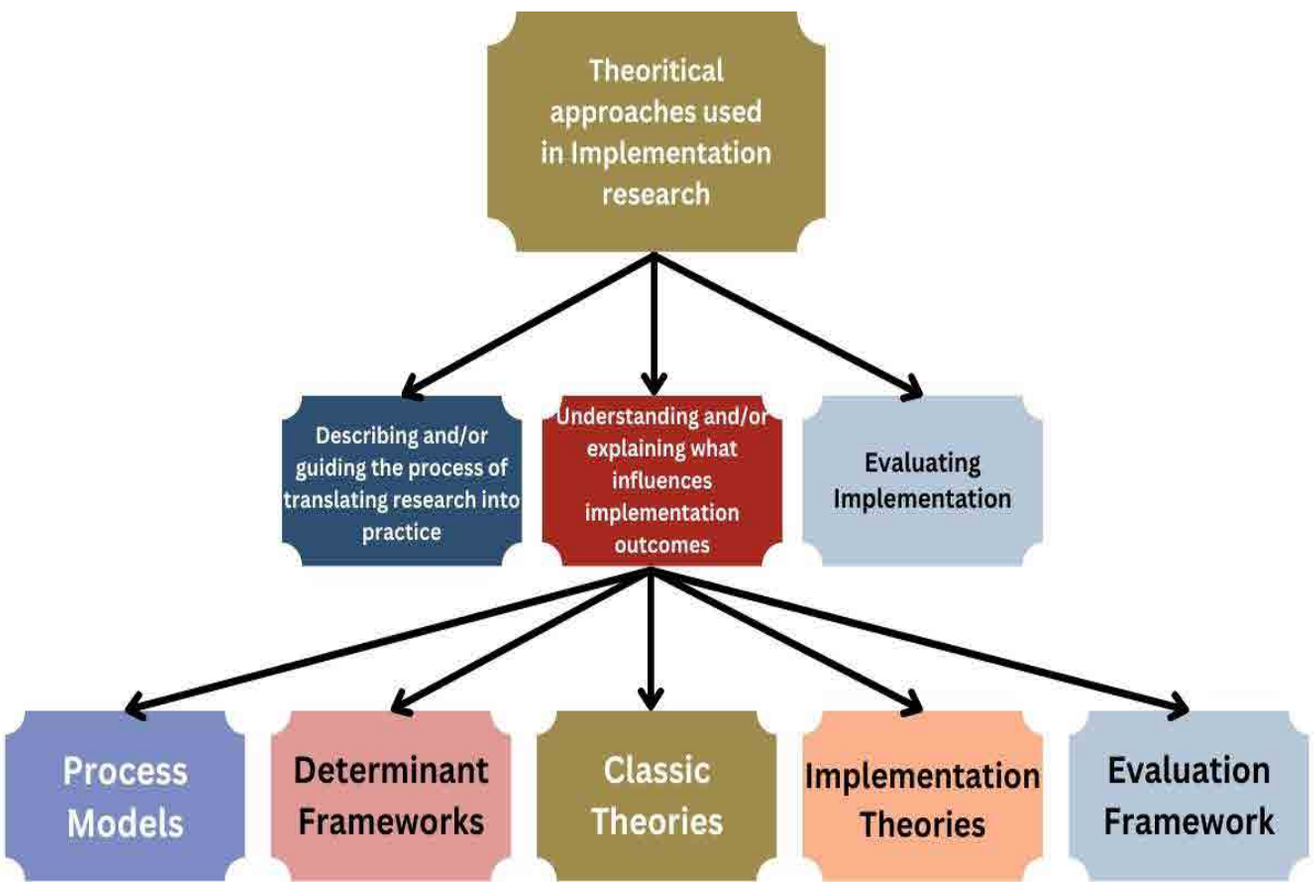


Figure 5: TMF in IR

Process models guide researchers and practitioners through the steps of implementing an intervention, helping structure the sequence of activities from planning to sustainment. Example: The Knowledge-to-action (KTA) Framework outlines stages such as knowledge adaptation, implementation, monitoring, and sustaining change.

Determinant frameworks identify why implementation succeeds or fails by highlighting barriers and facilitators across multiple levels of a system. Example: CFIR helps researchers assess factors like organizational culture, individual attitudes, and external policies that influence implementation.

Classic theories explain individual, social, or organizational behavior, offering insight into the mechanisms that drive change. Example: Theory of planned behavior (TPB) helps explain how attitudes, subjective norms, and perceived control shape clinicians' intentions to adopt a new practice.

Implementation theories specifically describe mechanisms or processes through which implementation strategies bring about change in practice. Example: Normalization process theory (NPT) explains how new interventions become embedded in routine practice through processes like sense-making, engagement, and collective action.

Evaluation frameworks guide what should be measured to determine implementation success and how to assess both processes and outcomes. Example: reach, effectiveness, adoption, implementation, maintenance (RE-AIM) helps evaluate real-world impact by examining both implementation quality and population-level outcomes.

*****END OF MODULE 1*****

Module 2: Implementation Outcome

IMPLEMENTATION OUTCOMES

Implementation outcomes are the key indicators to evaluate how well an EBI is implemented. They represent the success or failure of the implementation process itself, rather than the clinical or health effects of the intervention. Proctor and colleagues first introduced the concept of implementation outcomes in 2011 that serve key functions:[6] they indicate the success of implementation efforts, mark progress along the implementation process, and act as intermediate outcomes linking implementation efforts to clinical or service results. Because interventions must first be implemented effectively, these outcomes are essential preconditions for achieving desired clinical impact.

It is important to differentiate between implementation effectiveness and clinical effectiveness. Sometimes a treatment fails because it was not delivered properly (implementation failure), not because the EBI itself doesn't work (intervention failure). To avoid this confusion, researchers need to define and measure implementation outcomes clearly. Doing so helps us better understand how implementation works, compare different strategies, and make implementation research more effective and efficient.

Proctor's Implementation Outcome

Proctor et al. (2009) proposed a model in implementation research that distinguishes between evidence-based interventions (the treatments themselves) and implementation strategies (the methods used to apply them). The model identifies three outcome levels: implementation, service, and client outcomes which are linked but distinct. Implementation outcomes, such as adoption or fidelity, are the earliest indicators of success and are expected to lead to better service quality and improved client health, though these relationships are not always straightforward. Service outcomes reflect care quality across six dimensions safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.[22]

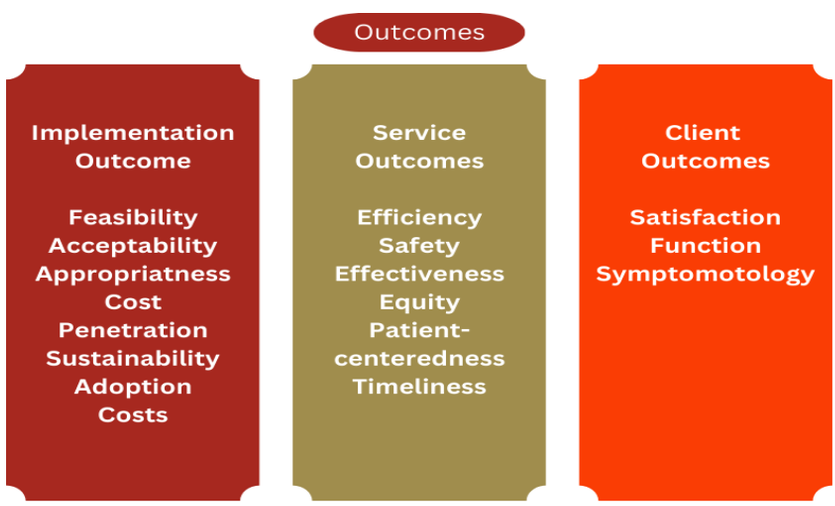


Figure 6: Implementation Outcome, Service Outcomes, and Client Outcomes [Proctor et al., 2011]

Proctor et al. (2011) developed a taxonomy of eight key implementation outcomes to clarify and standardize how implementation success is defined and measured. Using a narrative review and collaborative discussions among a multidisciplinary team, they identified and refined core concepts used in implementation research. The resulting framework included eight constructs: acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration, and sustainability. These are considered the most fundamental outcomes for assessing implementation.[22]

Acceptability

Acceptability is the perception among implementation stakeholders that a given EBI is agreeable, palatable or satisfactory.

Acceptability is different from the 'service satisfaction' that measures the overall experience of the intervention. Acceptability is measured based on knowledge or direct experience at different levels: consumers, providers, payers, administrators, etc. It can be evaluated using qualitative methods, such as in-depth interviews and focus group discussions, or quantitative methods, such as surveys. Acceptability is typically measured at multiple stages: early (pre-implementation) to inform adoption, during implementation to inform penetration, and at the endline to inform sustainability.

Example of defining and measuring acceptability of group ANC care intervention

Acceptability among pregnant women refers to the extent to which women perceive group ANC as comfortable, satisfactory, and preferable to individual ANC visits, including comfort with group discussions, satisfaction with session content and frequency, perceived peer support, and willingness to continue or recommend the model.

Quantitative acceptability can be assessed using an adapted acceptability of intervention measure (AIM) (e.g., "I feel comfortable participating in antenatal care sessions with other pregnant women"; "Overall, I am satisfied with group antenatal care," 5-point Likert scale).

Qualitative acceptability can be explored through interviews or FGDs (e.g., "How did you feel about receiving antenatal care in a group?"; "What did you like or find uncomfortable about Group ANC?"). [40]

Example of defining and measuring acceptability of community health worker

Acceptability among community health care workers refers to the extent to which CHWs perceive group ANC as agreeable, satisfactory, and compatible with their roles and routine work. This includes comfort in facilitating group sessions, satisfaction with training and session content, perceived value of group ANC for improving communication and engagement with pregnant women, and perceived burden on time and workload.

Quantitative acceptability can be assessed using an adapted acceptability of intervention measure (AIM)[41] (e.g., "Delivering antenatal care through group sessions fits well with my routine work"; "Overall, I am satisfied with providing Group ANC," 5-point Likert scale).

Qualitative acceptability can be explored through interviews or FGDs (e.g., "How acceptable is group ANC within your daily responsibilities?"; "What aspects of facilitating group ANC did you find helpful or challenging?").

Appropriateness

Appropriateness is the perceived fit, relevance or compatibility of an EBI for a given practice setting, provider or consumer and/or perceived fit of the innovation to address a particular issue or problem.

While related to acceptability, appropriateness focuses more on how well an intervention aligns with the context or goals of implementation. An intervention can be appropriate but not acceptable, or vice versa. This construct is important because it helps explain resistance to implementation when providers feel a new program does not align with their organization's mission or practices.

It is typically assessed at both the individual (provider or consumer) and organizational levels. Appropriateness can be measured using surveys, focus groups, qualitative interviews, or brief rating scales. Although it is often evaluated early before or during the initial consideration of an intervention it can also provide valuable insights during the piloting phase.

Example of defining and measuring appropriateness of group ANC intervention

Appropriateness among pregnant women refers to the extent to which women perceive group ANC as a suitable and relevant way to receive antenatal services given their needs, preferences, and social and cultural context. This may include perceptions of whether the group format meets their informational and emotional needs, aligns with cultural norms and privacy expectations, and is appropriate for discussing pregnancy-related concerns with peers.

Quantitative appropriateness can be assessed using an adapted intervention appropriateness measure (IAM)[41] (e.g., "Group ANC is an appropriate way for me to receive antenatal care"; "Group ANC fits well with my needs during pregnancy," 5-point Likert scale).

Qualitative appropriateness will be explored through interviews or focus group discussions (e.g., "Do you think group antenatal care is the right way to receive care during pregnancy?"; "In what ways did group ANC fit or not fit your needs and expectations?").

Example of defining and measuring appropriateness of community health worker

Appropriateness among community health care workers refers to the extent to which CHWs perceive group ANC as a suitable, relevant, and good fit for their roles, the local context, and the needs of pregnant women. This includes perceptions of whether group ANC aligns with community norms, ANC guidelines, and CHW scope of practice; whether the group format addresses women's informational and psychosocial needs; and whether the model fits with existing workflows and health system structures.

Quantitative appropriateness will be assessed using an adapted intervention appropriateness measure (IAM)[41] (e.g., "Group ANC is an appropriate way to deliver

antenatal care in my community"; "Group ANC fits well with my role as a community health worker," 5-point Likert scale).

Qualitative appropriateness can be explored through interviews or FGDs (e.g., "In what ways is group ANC a good or poor fit for your community?"; "How well does group ANC align with your responsibilities and local practices?").

Feasibility

Feasibility measures the degree to which an intervention is effectively implemented within a certain organization or environment.

While related to appropriateness, feasibility is distinct: a program may align well with an organization's goals but still be unfeasible due to limited resources or capacity. For example, deploying telemedicine services in remote regions may be highly appropriate, as it aligns the service modality with the region's needs. However, its feasibility depends on sufficient telecommunications infrastructure.

It can be evaluated before adoption when factors like cost, training, or resources may limit implementation or afterward, to understand success or failure through indicators such as recruitment or participation rates. Feasibility is typically measured at both the individual provider and organizational levels.

Example of defining and measuring feasibility of community health workers

Feasibility among community health care workers refers to the extent to which CHWs can realistically deliver group ANC within their existing roles, skills, and time constraints. This includes whether CHWs have adequate training, confidence, and supervisory support to facilitate group sessions; whether group ANC can be integrated into their routine workload; and whether required materials and coordination with facility staff are available.

Quantitative feasibility can be assessed using an adapted feasibility of intervention measure (FIM)[41] (e.g., "I am able to deliver group ANC sessions within my regular work schedule"; "I have the resources and support needed to facilitate group ANC," 5-point Likert scale).

Qualitative feasibility can be explored through interviews or FGDs (e.g., "What makes it easy or difficult for you to deliver group ANC sessions?"; "What additional support would make group ANC more workable for you?"). Feasibility will be measured prior to implementation (anticipated feasibility following training), during implementation (experienced feasibility), and post-implementation (overall assessment of practicality). Feasibility at the health facility level refers to the extent to which facilities where CHWs are based can support the delivery of group ANC within existing infrastructure, staffing, and operational systems. This includes availability of adequate space for group sessions, alignment with clinic schedules and patient flow, staffing coverage, supply availability, and managerial support. Quantitative feasibility can be assessed using facility-level FIM[41] items (e.g., "Our facility has sufficient space and staff to support Group ANC sessions"; "Group ANC can be delivered without disrupting routine services," 5-point

Likert scale). Qualitative feasibility will be examined through key informant interviews with facility managers and staff (e.g., "How feasible is it to run group ANC within current facility operations?"; "What system-level barriers or facilitators affect feasibility?"). Facility-level feasibility will be assessed before implementation, during implementation, and after implementation to inform decisions about continuation and scale-up.

Feasibility can be assessed prior to implementation (anticipated feasibility), during implementation (experienced feasibility), and post-implementation (overall judgment of practicality and sustainability).

Adoption

Adoption is the intention or initial decision to try or use an EBI. It is also called "uptake". It can be measured from the perspective of providers or organizations. Measurement methods include observations, structured interviews, pre- and post-intervention surveys, and administrative records. Adoption is typically measured early, shortly after the intervention begins, during the first month, and again after the intervention ends.

Example of defining and measuring adoption of group ANC intervention

Adoption at the health facility level refers to the extent to which a health facility decides to initiate and use group ANC as part of routine service delivery. This may include whether facility leadership and staff agree to introduce group ANC, allocate space and staff time, integrate it into clinic schedules, and formally begin offering group sessions to eligible pregnant women.

Quantitative adoption can be measured using facility records and administrative data, such as whether or not they have provided orientation to the CHW or initiated the Group care.

Qualitative adoption can be explored through key informant interviews with facility managers and senior staff (e.g., "What factors influenced your decision to start group ANC at this facility?").

Adoption at the community health worker (CHW) level refers to the extent to which individual CHWs decide to begin using group ANC in their routine work after it is introduced. This includes CHWs' willingness to facilitate group sessions, actively recruit and enroll pregnant women, and consistently use the group ANC model as intended. Quantitative adoption can be assessed using program monitoring data, such as the proportion of trained CHWs who initiate group ANC. Qualitative adoption will be explored through FGDs with CHWs (e.g., "What influenced your decision to start facilitating group ANC?"; "What factors made it easier or harder for you to adopt group ANC in your routine work?").

Implementation cost

Implementation or incremental cost is the additional cost of carrying out an implementation effort. These consider three cost factors: (a) administering the EBI, (b) administering the implementation strategy, and additional cost within the context in which the EBI is delivered.

Implementation cost is typically expressed as the cost per item, household, person, or activity, or as the total cost for the population protected or benefited. It is usually measured at the provider, program, or organizational level, depending on the scope of the analysis. Measurement tools include administrative finance data, time logs, and budget records. Costs can be assessed early to plan budgets and evaluate feasibility, midway as uptake increases, and later to examine penetration and sustainability.

Example of defining and measuring implementation cost of group ANC intervention

Implementation cost for group ANC refers to the additional (incremental) resources required to introduce and deliver the group care model beyond standard individual ANC services. This includes costs related to administering the EBI (e.g., staff time for facilitating group sessions, educational materials, refreshments, and space use), administering the implementation strategy (e.g., CHW and provider training, supervision, coaching, and monitoring), and context-specific costs (e.g., adapting schedules, minor facility modifications, or community mobilization activities). Implementation cost may be expressed as cost per group session, per pregnant woman enrolled, per facility, or total cost for the population served, and is typically measured at the CHW, facility, or program level. Costs will be estimated using administrative financial records, time-motion or activity logs, and program budgets, and assessed early to inform budgeting and feasibility, midway to capture costs as uptake increases, and later to evaluate affordability, penetration, and sustainability of group ANC.

Fidelity

Fidelity assesses the extent to which an intervention is implemented as intended by its original design or protocol.

It is typically assessed by examining adherence to the program components: (a) the content delivered; (b) the amount or dose delivered; and (c) the quality of delivery. High fidelity indicates that the intervention was carried out as planned.

Fidelity is typically assessed at both the individual provider and organizational levels. It can be measured using fidelity rating scales, observation checklists, audits, reviews, or qualitatively through in-depth interviews and focus group discussions. Fidelity is often evaluated early to ensure proper delivery of the intervention and reassessed periodically to monitor any deviations from the original design over time.

Example of defining and measuring fidelity of group ANC intervention

Fidelity will be defined as the extent to which the integrated community health worker-led group ANC intervention is delivered as intended across its core components, delivery form, and planned dose. Fidelity will be assessed across three domains-content fidelity, dose fidelity, and quality of delivery at the individual implementer level (CHWs) level.

Content fidelity will assess whether the essential components of the intervention are delivered according to protocol during each gestation-specific group ANC visit. These components include: (a) completion of required clinical assessments by nurses or

nurse-midwives; (b) delivery of participatory, gestation-appropriate health education by CHWs; (c) accurate documentation of services; and (d) appropriate referral and care coordination for identified risks. Content fidelity will be measured using structured observation checklists completed by supervisors during randomly selected group ANC sessions and through mobile supervisory checklists embedded in routine monitoring systems. Checklist items will document whether each core component was delivered (yes/no) and allow calculation of component-level and overall fidelity scores.

Dose fidelity will assess whether the intervention is delivered at the intended frequency and duration-specifically, monthly group ANC sessions across the full year of pregnancy following the reduced visit schedule. Dose fidelity will be measured using session logs, attendance registers, and facility ANC records, capturing the number of sessions conducted versus planned, the number of sessions attended per woman, and continuity of participation across gestational stages. Facility-level dose fidelity will be summarized as the proportion of planned sessions delivered and the average number of sessions received per participant.

Quality of delivery will assess how well CHWs and nurses deliver group ANC, focusing on facilitation skills, participant engagement, teamwork between CHWs and clinical staff, and adherence to participatory group care principles. Quality will be measured using fidelity rating scales completed by supervisors during direct observations, with items assessing facilitation style, clarity of communication, inclusiveness, and responsiveness to participants. To complement quantitative ratings, qualitative in-depth interviews and focus group discussions with CHWs, nurses, and supervisors will explore perceived challenges, adaptations, and factors influencing high- or low-quality delivery.

Penetration

Penetration refers to the extent to which an intervention is integrated into a service setting and its subsystems.

Penetration can be assessed at various levels, including the community or geographic area, health system, organization, and workforce. For example, it may be measured as the proportion of providers delivering a specific service compared to the total number trained or expected to do so. Common measurement tools include checklists and program records. Penetration is typically evaluated from the mid to later stages of implementation, as the intervention expands and becomes more integrated across providers and settings.

Example of defining and measuring penetration of group ANC intervention

Penetration refers to the extent to which group ANC is integrated into routine service delivery and reaches the intended target population within participating health facilities and communities. For this intervention, penetration reflects how widely group ANC is delivered across eligible facilities, CHWs, and pregnant women in the six rural village clusters in Achham. This includes the proportion of eligible health facilities offering group ANC, the proportion of trained CHWs actively delivering group ANC sessions, and the proportion of eligible pregnant women who are enrolled in and attend at least one group ANC session.

Penetration will be measured quantitatively using program monitoring data, facility ANC registers, and CHW activity logs, including indicators such as: (a) the percentage of facilities implementing group ANC out of all eligible facilities; and (b) the percentage of trained CHWs who conduct at least one group ANC session.

Sustainability

Sustainability is the degree to which an implemented intervention continues to be maintained and integrated into the routine operations of a service setting over time.

It reflects how organizational rules and routines integrate the EBI into standard care and identifies key steps that influence long-term sustainability and potential for scale-up, including: (a) Transitioning from short-term to long-term funding, (b) Embedding the EBI into organizational or community practices, including assessment criteria and budgeting, and (c) Achieving niche saturation, or full integration across the organization's subsystems.[6]

Sustainability is typically measured at the organizational or setting level and may involve administrators or policymakers. Measurement methods include documentation of funding and roles, checklists, interviews with administrators, questionnaires, and policy reviews. It is usually evaluated in the later stages of implementation, once routine practice or institutionalization is expected.[42]

Example of defining and measuring sustainability of group ANC Intervention

Sustainability refers to the extent to which group ANC is maintained and continues to be delivered over time after initial implementation support is reduced or withdrawn. For this intervention, sustainability reflects whether health facilities and community health workers (CHWs) continue to offer group ANC as part of routine antenatal services, whether core components are preserved, and whether the model is supported by ongoing resources, supervision, and local ownership. Sustainability also includes the extent to which group ANC is institutionalized within facility workflows, staffing patterns, and local health system structures in the six rural village clusters in Achham.

Sustainability will be assessed using a combination of quantitative and qualitative methods. Quantitative indicators will include the proportion of facilities continuing to deliver group ANC at 6- and 12-months post-implementation, the number of group ANC sessions conducted without external project support, and the proportion of CHWs who continue facilitating sessions over time. Qualitative assessment will involve interviews with CHWs, facility managers, and local health officials to explore factors influencing continued delivery, such as leadership support, integration into routine budgets and schedules, and perceived value of group ANC.

Table 5: Proctor's implementation outcome

Implementation Outcome	Definition	Focus	Level of measurement	Methods/ tools	Timing
Acceptability	The perception among implementation stakeholders that a given EBI is agreeable, palatable, or satisfactory.	Perception of the intervention's satisfaction/agreeableness among consumers, providers, etc. (Different from 'service satisfaction').	Consumers, providers, payers, administrators	Qualitative methods (interviews, FGDs), Quantitative methods (surveys).	Early (pre-implementation), During implementation, Endline (to inform sustainability).
Appropriateness	The perceived fit, relevance, or compatibility of an EBI for a given practice setting, provider, or consumer, and/or perceived fit to address a particular issue.	How well the intervention aligns with the context, goals, mission, or needs. (An intervention can be appropriate but not acceptable, or vice versa).	Consumer, Provider, Organization	Surveys, Focus Groups, Qualitative Interviews, Brief Rating Scales, Policy Review.	Early (before or during initial consideration), Piloting phase.
Feasibility	The degree to which an intervention is effectively implemented within a certain organization or environment.	Whether the program can be carried out successfully with the given local resources, capacity, and infrastructure. (Different from appropriateness due to resource/capacity limits).	Provider, Organization	Program records (attendance, staffing), Checklists, Mobile Supervisor reports, Qualitative interviews about operational challenges.	Before adoption, After adoption (to understand success/failure), During the pilot.
Adoption	The intention or initial decision to try or use an EBI. Also called "uptake".	The initial decision or uptake by providers or organizations to use the EBI.	Provider, Organization	Observations, Structured Interviews, Pre- and Post-intervention Surveys, Administrative Records.	Early (shortly after the intervention begins), During the first month, After the intervention ends.
Implementation Cost	The additional cost of carrying out an implementation effort, including administering the EBI and the implementation strategy.	The incremental cost of implementing the EBI, often expressed per-unit (person, household, activity) or as a total cost.	Provider, program, organization, per-participant	Administrative Finance Data, Time Logs, Budget Records, Itemized Cost Accounting.	Early (to plan budget/evaluate feasibility), Midway (as uptake increases), Later (to examine penetration/sustainability).
Fidelity	The extent to which an intervention is implemented as intended by its original design or protocol.	Adherence to the program's core components: content, amount/dose delivered, and quality of delivery.	Individual provider, organization	Fidelity Rating Scales, Observation Checklists, Audits, Reviews, Qualitative Interviews, Structured Checklists.	Early (to ensure proper delivery), Periodically (to monitor deviations over time).
Penetration	The extent to which an intervention is integrated into a service setting and its subsystems.	The proportion of the setting (community, organization, workforce) that is using or being reached by the intervention.	Health system, organization	Checklists, Program Records, Administrative/Session Logs, Census data, Questionnaire Surveys.	Mid to Later stages of implementation.
Sustainability	The degree to which an implemented intervention continues to be maintained and integrated into the routine operations of a service setting over time.	The process of institutionalization, embedding the EBI into organizational rules, long-term funding, and standard practice.	Organization, setting,	Documentation of funding/ roles, Checklists, Interviews with administrators, Questionnaires, Policy Reviews.	Later stages of implementation (once routine practice is expected).

RE-AIM framework implementation outcomes

The RE-AIM framework evaluates implementation outcomes across multiple dimensions, focusing on how interventions are adopted, delivered, and sustained in real-world settings. RE-AIM is an implementation science framework which is used to evaluate public-health intervention across five dimensions. The framework provides five steps for translating research into action, which are considered as implementation outcomes:[21,43]

- ✓ **Reach -** Engage the target population.
- ✓ **Effectiveness/Efficacy -** Assess the impact of the intervention.
- ✓ **Adoption -** Promote uptake by staff, settings, systems, and communities.
- ✓ **Implementation -** Ensure consistency, track costs, and document adaptations during delivery.
- ✓ **Maintenance -** Sustain intervention effects in individuals and settings over time.

Reach

Reach is the absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program.

Assessment approaches for Reach vary by implementation phase (planning, implementation, and evaluation) and by the availability and quality of data. Common quantitative methods include calculating the percentage of participation using a valid denominator (i.e., all eligible individuals, not only volunteers), using program or administrative records and enrollment logs, and comparing participant characteristics with non-participants or the broader target population using demographic surveys, electronic health records, or census and registry data to assess representativeness. Documentation of exclusion criteria and reasons for exclusion, obtained from screening forms and eligibility logs, further clarifies who is not being reached and why. Qualitative approaches complement these measures by examining recruitment processes and experiences, using focus group discussions, in-depth interviews with participants and implementers, and observation notes. Even when Reach cannot be directly quantified, participant and stakeholder perceptions, expectations, and perceived barriers to participation can be assessed through surveys, interviews, or focus groups to inform planning and refinement of future interventions.

Example of defining and measuring reach of mhGAP intervention

Reach of the mhGAP intervention refers to the extent to which individuals with priority mental, neurological, and substance use (MNS) conditions in the target catchment areas are identified and receive mhGAP-based services in primary care, and how representative these individuals are of the broader population in need. Reach will be assessed by calculating the proportion of eligible individuals who receive at least one mhGAP-based assessment or treatment, using a valid denominator derived from facility outpatient registers, community screening records, or population estimates of MNS conditions, rather than counting only self-referred patients. Participant characteristics (e.g., age, sex, caste/ethnicity, socioeconomic status, and distance to facility) will be compared with those of non-participants and the underlying service population using routine health records and demographic surveys to assess representativeness and equity. Reasons for non-identification, non-enrollment, or exclusion (e.g., stigma,

referral barriers, provider capacity constraints) will be documented using screening and referral logs. Qualitative methods, including interviews with service users, community health workers, and primary care providers, will explore pathways to care, barriers to identification and engagement, and perceptions of mhGAP services, helping to interpret quantitative reach estimates and inform strategies to improve access and coverage in future implementation phases.

Effectiveness

Effectiveness (or efficacy) in the RE-AIM framework refers to how well an intervention achieves its intended outcomes, considering both primary and broader stakeholder-relevant outcomes. Assessment depends on the implementation phase (planning, implementation, evaluation) and available data.

Some of the effectiveness assessment includes

- ✓ **Primary outcomes -** Compare results to a public health goal or baseline. Methods such as surveys, clinical records, biometric measures are used for measuring primary outcomes.
- ✓ **Broader outcomes -** Quality of life, potential negative outcomes, or multiple criteria. Methods such as standardized questionnaires, patient-reported outcome measures are used for measuring broader outcomes.
- ✓ **Robustness across subgroups -** Analyze intervention effects by subgroup (e.g., age, sex, socioeconomic status). Methods such as statistical moderation analyses, subgroup comparisons are used for measuring robustness across subgroups.
- ✓ **Attrition and differential participation -** Track dropouts and differential rates by participant characteristics. Methods such as program records, attendance logs, follow-up tracking are used for measuring attrition and differential participation.

Even when effectiveness is not directly measured, participant and stakeholder perceptions and expectations can be assessed through methods such as surveys, interviews, and focus groups, providing valuable insights to guide planning for future interventions.

Example of defining and measuring effectiveness of group mhGAP intervention

Primary effectiveness outcomes will be assessed by comparing changes in clinical indicators-such as symptom severity for depression or anxiety, seizure control for epilepsy, or treatment initiation and adherence for priority conditions-to baseline levels or predefined public health targets, or a control group, using clinical records and standardized symptom screening tools administered through routine care. Broader effectiveness outcomes will include improvements in functioning, quality of life, and patient satisfaction, as well as potential unintended or negative outcomes (e.g., stigma, treatment burden), measured using validated patient-reported outcome measures and structured surveys.

Effectiveness will also be examined for robustness across subgroups, including age, sex, socioeconomic status, and geographic access, through subgroup analyses and moderation models to assess equity in intervention effects.

Adoption

Similar to Proctor's definition[6], adoption refers to the decision to initiate or use an intervention and can occur at both the setting (organization) and staff/provider levels. Assessment should capture all relevant levels and consider not only the proportion adopting the intervention but also the representativeness of adopters and reasons for adoption or non-adoption. Methods vary by implementation phase (planning, implementation, evaluation) and available data. Some examples of adoption measurement include:

Setting level:

- ✓ Percent of eligible settings that participate and reasons for exclusion.
- ✓ Comparison of participating settings' characteristics to non-participants or relevant benchmarks. Methods: Administrative records or program documentation, interviews

Staff/provider level:

- ✓ Percent of invited staff who adopt the intervention and reasons for exclusion. Methods: Administrative records, surveys
- ✓ Comparison of characteristics between participating and non-participating staff. Methods: Administrative records, surveys
- ✓ Participation and barriers. Methods: qualitative interviews
- ✓ Even when adoption is not directly measured, stakeholder perceptions and expectations of adoption at the setting and staff levels can be assessed through surveys, interviews, or focus groups to inform planning for future projects.

Example of defining and measuring adoption of mhGAP intervention

Adoption of the mhGAP intervention refers to the decision by health facilities (settings) and individual providers to initiate and use mhGAP guidelines for the identification and management of priority mental, neurological, and substance use (MNS) conditions in routine primary care.

At the setting level, adoption will be defined as the proportion of eligible primary health care facilities that agree to implement mhGAP and begin delivering mhGAP-based services. Adoption will be measured using administrative and program documentation to calculate the percentage of eligible facilities that initiate mhGAP implementation and to document reasons for non-participation or exclusion. Characteristics of participating facilities (e.g., patient volume, staffing levels, rural-urban location) will be compared with non-participating facilities using routine administrative data and supplemented by interviews with facility managers to understand contextual factors influencing adoption decisions.

At the provider level, adoption will be defined as the proportion of invited primary care providers (e.g., medical officers, nurses, CHWs) who begin using mhGAP protocols in clinical practice after training. Adoption will be assessed using training records, supervision reports, and brief provider surveys to estimate the percentage of trained providers who conduct mhGAP-based assessments or initiate treatment, and to document reasons for non-adoption (e.g., lack of confidence, time constraints, perceived scope-of-practice issues). Characteristics of adopting and non-adopting providers will be compared using administrative data. Qualitative interviews with providers and supervisors will explore perceived facilitators and barriers to mhGAP adoption.

Implementation process

Implementation process is the extent to which intervention agents deliver the key components of an intervention as intended, including consistency, fidelity, time, cost, and any adaptations made. Assessing implementation is a multidimensional process that examines how an intervention is delivered, including its fidelity, adaptations, costs, consistency, and stakeholder feedback.

Fidelity or adherence evaluates the degree to which the intervention is delivered as intended, such as the percentage of "perfect" delivery completed, and is typically measured using observation checklists, structured fidelity rating scales, session logs, or audits.

Adaptations capture any modifications made to the intervention during implementation and are assessed through document reviews, field notes, qualitative interviews with staff, or meeting minutes.

Costs involve tracking the time and financial resources required to deliver the intervention, using methods such as time logs, administrative finance data, itemized cost accounting, and budget records.

Consistency examines how uniformly the intervention is delivered across staff, time points, settings, or participant subgroups, using program records, observation checklists, monitoring reports, and cross-site comparisons.

Even when projects do not directly measure implementation, participant and stakeholder perceptions and expectations can be evaluated using surveys, interviews, or focus groups, providing insights to guide planning for future projects.

Example of defining and measuring implementation of mhGAP intervention

Implementation refers to the extent to which primary health care providers deliver the WHO mhGAP Intervention guide as intended, including fidelity to core components, consistency across providers and facilities, time and cost required for delivery, and any adaptations made to improve contextual fit. Implementation will be assessed as a multidimensional construct capturing how mhGAP is delivered in routine practice rather than whether it is effective.

Fidelity (Adherence to mhGAP protocols): Fidelity will assess the degree to which trained health workers adhere to mhGAP clinical algorithms and psychosocial management protocols for priority mental health conditions (e.g., depression, psychosis, epilepsy, alcohol use disorders). Fidelity indicators will include the proportion of consultations in which providers correctly complete key mhGAP steps-such as symptom assessment, diagnosis, treatment initiation, referral decisions, and follow-up planning-without deviation. Fidelity will be measured using structured observation checklists, clinical record audits, and session logs completed by providers. Periodic supervisory observations will generate fidelity scores reflecting the percentage of "complete and correct" mhGAP delivery.

Costs: Implementation costs will assess the time and financial resources required to deliver mhGAP within routine primary care services. Cost components will include

provider time for consultations, training and refresher sessions, supervision time, and use of medications and referral services. Data sources will include provider time logs, administrative and finance records, and itemized cost tracking. These data will inform estimates of per-facility and per-patient implementation costs, supporting future scale-up and budgeting decisions.

Consistency: Consistency will examine how uniformly mhGAP is implemented across providers, facilities, time periods, and patient subgroups. Consistency indicators will include variation in fidelity scores across health workers, differences in mhGAP delivery between facilities, and stability of implementation over time. Program monitoring data, observation checklists, and cross-site comparisons will be used to assess whether mhGAP is delivered equitably and reliably within the health system.

Maintenance

Maintenance is the extent to which a program or policy becomes institutionalized within organizational practices (setting level) or produces long-term effects on participants after program completion (individual level). Assessment of maintenance examines both individual- and setting-level sustainability of an intervention over time, typically at least six months after program completion or funding ends.

At the setting level, maintenance focuses on whether the program continues post-funding, long-term adaptations and which components are retained, alignment with organizational mission or business model, and qualitative assessments of institutionalization to explain why and how the intervention was sustained. Methods: program records, documentation of retained components, interviews with administrators, surveys, and policy or workflow reviews.

At the individual level, maintenance involves measuring primary and broader outcomes (e.g., quality of life, negative outcomes), evaluating robustness across subgroups, tracking long-term attrition and differential effects by participant characteristics, and using qualitative methods to understand sustained effects. Methods: follow-up surveys, assessments of primary and secondary outcomes, subgroup analyses, and interviews or focus groups with participants.

Even when projects cannot directly measure maintenance due to short timelines, participant and stakeholder perceptions and expectations of both individual- and setting-level maintenance can be assessed using methods such as surveys, interviews, and focus groups, providing insights to inform planning for long-term sustainment.

Example of defining and measuring maintenance of mhGAP intervention

Maintenance refers to the extent to which the WHO mhGAP is sustained over time at both the health system (setting) and individual levels after initial implementation support or external funding ends. Maintenance will be assessed at least six months after the completion of active implementation or withdrawal of project support to capture longer-term sustainability and institutionalization.

Setting-Level Maintenance (Institutionalization)

At the setting level, maintenance will examine whether mhGAP continues to be delivered as part of routine primary health care services after the study period. Key indicators will include continued use of mhGAP clinical algorithms, retention of trained providers, integration of mhGAP into standard clinical workflows, supervision structures, and health facility reporting systems. Maintenance will also assess which mhGAP components are retained, adapted, or discontinued over time and how these changes align with facility priorities, national mental health policies, and organizational missions.

Setting-level maintenance will be assessed using program records documenting post-project service delivery, reviews of facility guidelines and workflows, and documentation of retained or modified mhGAP components. Qualitative interviews with health facility managers, district health officers, and policymakers will explore reasons for sustainment or discontinuation, perceived value of mhGAP, and contextual factors such as staffing, financing, leadership support, and policy alignment that influence long-term institutionalization.

Individual-Level Maintenance (Sustained Participant Outcomes)

At the individual level, maintenance will assess whether mhGAP produces sustained benefits for service users beyond the active intervention period. Outcomes will include continued symptom improvement, treatment adherence, and broader indicators such as quality of life, functional status, and reduction in negative outcomes (e.g., relapse, hospitalization, or social impairment). Maintenance analyses will examine robustness of outcomes across key subgroups (e.g., sex, age, diagnosis, socioeconomic status) and track long-term attrition from care.

Individual-level maintenance will be measured through follow-up surveys and clinical assessments conducted at least six months post-intervention, supplemented by routine health records. Subgroup analyses will identify differential sustainment of benefits, while qualitative interviews or focus groups with service users and caregivers will explore perceived long-term impacts, barriers to continued care, and factors that support ongoing engagement with mental health services.

Perceived Maintenance and Planning for Sustainment

In settings where long-term follow-up is not feasible due to project timelines, perceived maintenance will be assessed through surveys and qualitative interviews with providers, administrators, and service users. These data will capture expectations regarding continuation of mhGAP services, perceived likelihood of institutionalization, and anticipated barriers and facilitators to sustainment. Such insights will inform the design of future implementation strategies aimed at strengthening long-term maintenance and scalability of mhGAP within the health system.

Valid and reliable tools to measure implementation outcomes

Valid and reliable measurement of implementation outcomes remains a key challenge in implementation research. In a comprehensive systematic review, Lewis et al. (2015)[44]

examined 104 instruments designed to measure implementation outcomes and assessed their validity, reliability, norms, responsiveness, and usability. Overall, the quality of available tools was modest and highly variable, with a median quality score of approximately 8 out of 24. Nearly 50% of tools lacked basic reliability evidence, about 75% lacked structural validity, and most instruments had not been assessed for predictive validity or responsiveness; notably, only one tool met all six quality criteria.

Coverage varied substantially by outcome

- ✓ Acceptability was the most frequently measured, with roughly 50 tools available, though many lacked evidence of responsiveness
- ✓ Adoption was covered by approximately 19 tools with limited psychometric support
- ✓ and appropriateness, feasibility, penetration, and sustainability were poorly represented, with only a handful of tools available and few rigorously validated.

Measures of implementation cost often relied on economic formulas rather than direct assessment of underlying constructs, and fidelity was not included in the review.

Recommendations for tool selection:

Based on these findings, Lewis et al. (2015) recommend:

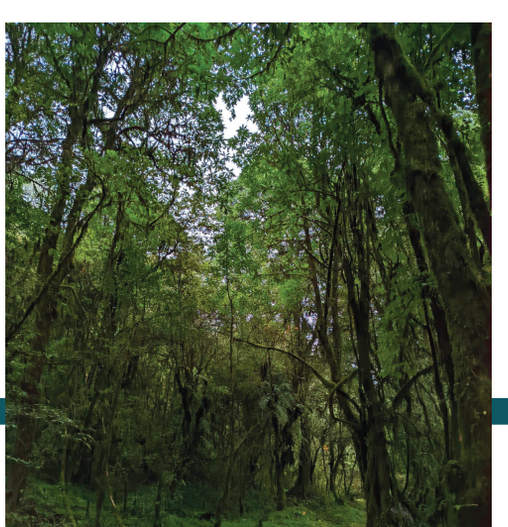
- ✓ Align tool content with research objectives, not just the title.
- ✓ Prefer tools with internal consistency, structural validity, and norms.
- ✓ If invalidated, conduct psychometric testing (factor analysis, test-retest, predictive validity, responsiveness).
- ✓ Consider practical factors: respondent effort, scoring complexity, obtaining permissions, and stakeholder acceptability.

Implementation outcome tool repository

A most widely used resource is the implementation outcome repository (IOR) developed by the society for implementation research collaboration (SIRC). The IOR is a publicly available database of quantitative tools that measure key implementation outcomes, including acceptability, adoption, appropriateness, feasibility, fidelity, penetration, sustainability, and cost. Each tool is catalogued with information on the construct measured, setting, respondent, psychometric properties, burden, and permissions. By making tools transparent and comparable, the repository addresses gaps in measurement quality and supports more rigorous and consistent implementation research. It also encourages researchers to select instruments based on conceptual fit with implementation outcomes rather than tool names alone, while promoting ongoing validation across diverse settings, including low and middle-income countries.[44,45]

*****END OF MODULE 2*****

Module 3: Contextual Determinants



CONTEXTUAL DETERMINANTS

Context in implementation research

In IR, context means the different factors that affect how an intervention is adopted, implemented, and sustained. These factors can be organizational, environmental, social, or political, and they interact and change as the intervention is carried out.[46,47] Context is dynamic; it changes over time and can either support or obstruct the success of an intervention.[47,48] Context is important because it can affect how well an intervention works. For example, a program that succeeds in one setting might fail in another if factors like organizational culture, leadership support, or available resources are different.[46,49]

Context influences implementation outcomes by acting as either a facilitator or barrier. For example, strong leadership support, sufficient resources, and a supportive organizational culture (inner setting) can enhance outcomes such as adoption, fidelity, and sustainability of an intervention. Conversely, inadequate resources, poor communication, or misalignment with external policies (outer setting) can hinder implementation, leading to low uptake, inconsistent application, or early discontinuation.

Example community health worker led activities

For community health worker (CHW)-led activities embedded within health facilities, strong leadership support, clear role definition, adequate supervision, and access to necessary resources within the facility (inner setting) can enhance CHW engagement and enable consistent delivery of services, leading to higher adoption, fidelity, and sustainability. Conversely, insufficient staffing, unclear task allocation between CHWs and facility-based providers, weak communication, limited supervision, or misalignment with facility priorities and external policies (outer setting) can hinder implementation, resulting in low uptake of CHW activities, inconsistent service delivery, reduced motivation, or early discontinuation of CHW-led interventions.[50]

For implementation of the WHO mhGAP within health facilities, strong leadership commitment, availability of trained staff, regular supervision, and integration of mhGAP protocols into routine clinical workflows (inner setting) can support provider uptake and consistent use of mhGAP guidelines, thereby improving adoption, fidelity, and sustainability of mental health services. In contrast, shortages of trained personnel, high staff turnover, limited time for consultations, weak supervision, or misalignment with national mental health policies, referral systems, and financing mechanisms (outer setting) can constrain implementation, leading to low utilization of mhGAP protocols, variable quality of care, and premature.[27]

Assessing and understanding context

Assessing context is critical in implementation research because context shapes how interventions are adopted, implemented, and sustained. EBIs rarely operate in a vacuum; factors such as organizational culture, leadership support, available resources, policies, and social dynamics can either facilitate or hinder successful implementation. By understanding context, researchers can identify barriers and facilitators that affect outcomes like adoption, fidelity, reach, and sustainability.

Assessing context helps explain why an intervention works in one setting but fails in another, allowing for adaptation to local conditions and more effective scaling of evidence-based practices. It also informs the design of implementation strategies, ensuring they are tailored to the unique characteristics of the environment and the people involved. Without a clear understanding of context, interventions risk being ineffective, poorly adopted, or unsustainable, even if they are evidence-based.

However, assessing context in implementation research (IR) is challenging because it is complex and dynamic. Common problems include:

- ✓ Unclear definitions: Different studies define "context" in different ways, which causes confusion and inconsistency in how it is measured and analyzed.
- ✓ Weak methods: Many studies use narrow methods that focus only on individuals instead of looking at the larger social and organizational systems.
- ✓ Ignoring change: Traditional approaches often treat context as fixed, rather than something that changes and interacts with interventions, leading to incomplete understanding and poor implementation.

These challenges can make it hard to adapt and apply EBIs effectively in different settings.

Different Theories, Models, and Frameworks can help to Structure our Thinking about Context.

Consolidated Framework for Implementation Research (CFIR)

The CFIR framework directly emphasizes the role of context in implementation. Context is embedded in several of its domains:[46]

Intervention characteristics: The first domain, intervention characteristics, refers to the features of the intervention itself that can affect its adoption and success. This includes

- ✓ evidence strength and quality (how convincing the supporting evidence is),
- ✓ relative advantage (perceived benefit over existing practices),
- ✓ adaptability (ability to be modified to fit local needs),
- ✓ trialability (extent to which it can be tested before full implementation),
- ✓ complexity (difficulty of use or understanding),
- ✓ design quality and packaging (presentation and usability), and cost (financial impact).

Outer setting: Outer setting covers the external context in which the organization operates. Key subdomains include

- ✓ patient needs and resources (how well the intervention addresses target population needs),
- ✓ cosmopolitanism (networking with external organizations),
- ✓ peer pressure (influence from similar organizations), and
- ✓ external policies and incentives (regulations, funding, or mandates that affect implementation).

Inner setting: Inner setting, focuses on the internal organizational context that can facilitate or impede implementation. Its subdomains include:

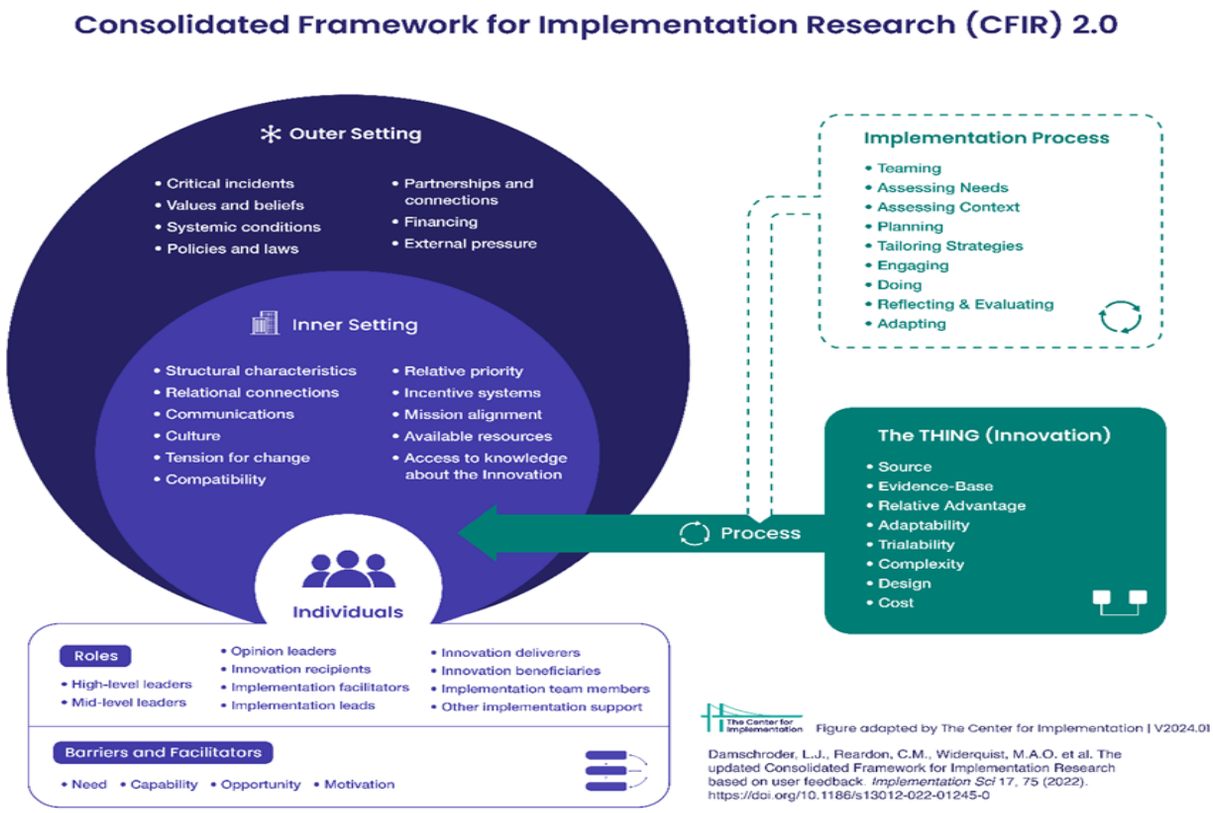


Figure 7: CFIR 2.0

- ✓ structural characteristics (size, age, and social architecture of the organization),
- ✓ networks and communications (quality of relationships and information flow), culture (norms, values, and basic assumptions),
- ✓ implementation climate (tension for change, compatibility, relative priority,
- ✓ organizational incentives and rewards,
- ✓ goals and feedback, learning climate), and readiness for implementation (leadership engagement, available resources, access to information and knowledge).

Characteristics of individuals: It addresses the attributes of people involved in implementation. Subdomains include

- ✓ knowledge and beliefs about the intervention (attitudes, values, and familiarity),
- ✓ self-efficacy (confidence in performing required tasks),
- ✓ individual stage of change (readiness to change behavior),
- ✓ individual identification with organization (commitment and sense of belonging), and
- ✓ other personal attributes (motivation, learning style, tolerance for ambiguity).

Process: Process relates to the activities that guide the implementation of an intervention. Key subdomains are

- ✓ Planning (developing a roadmap for implementation),
- ✓ Engaging (attracting and involving appropriate individuals such as opinion leaders, champions, or external change agents),
- ✓ Executing (carrying out the implementation according to plan), and reflecting and
- ✓ Evaluating (assessing progress, gathering feedback, and making necessary adjustments).

CFIR highlights that context is multidimensional and dynamic. By explicitly considering inner and outer settings, as well as individual and process-related factors, CFIR provides a structured way to understand how context influences the adoption, implementation, and sustainability of interventions. This helps explain why the same intervention can have different outcomes in different settings.

For more information on the definition of constructs, refer to Annex-I.

Table 6: Example of CFIR guided determinants of group ANC in Nepal (selected constructs included)

CFIR Domain	CFIR construct	Operational definition (group ANC context)	Facilitators	Barriers	Data sources
Intervention Characteristics	Relative advantage	Perceived benefits of group ANC compared with routine individual ANC (e.g., efficiency, peer learning, improved education)	CHWs and providers report group ANC saves time and improves client engagement	Providers perceive group ANC as more time-consuming than individual visits	CHW and provider interviews; session observations
	Complexity	Degree to which group ANC is perceived as difficult to deliver (facilitation skills, group management, documentation)	Clear facilitation guides; simple session structure	Difficulty managing group dynamics; complex reporting formats	Observations; CHW interviews; document review
	Adaptability	Ability to modify session timing, group size, and examples while preserving core ANC content	Flexible scheduling; locally relevant examples	Unclear boundaries of acceptable adaptations	Training materials; supervision notes
Outer Setting	Patient needs & resources	Extent to which group ANC addresses pregnant women's needs, constraints, and preferences	Peer support; shared learning; culturally acceptable format	Transport barriers; competing household duties	Participant interviews; FGDs
	External policies & incentives	Alignment of group ANC with national ANC guidelines, reporting systems, and incentive structures	National endorsement of group ANC	Lack of incentives tied to group sessions	Policy review; administrator interviews
Inner Setting	Leadership engagement	Degree of facility in-charge support for CHW-led group ANC (planning, supervision, resource allocation)	Active leadership support and problem solving	Passive or inconsistent leadership involvement	Facility manager interviews
	Available resources	Availability of space, time, materials, and staffing for group sessions	Dedicated room and scheduled time for sessions	Inadequate space; staff shortages	Facility assessments; observations
	Communication	Quality of information exchange between CHWs and facility-based providers	Regular coordination meetings	Poor coordination; unclear role expectations	Meeting minutes; interviews
Characteristics of Individuals	Knowledge & beliefs	CHW understanding of group ANC goals and perceived value	Belief that group ANC improves maternal outcomes	Skepticism about effectiveness	CHW interviews; pre/post training assessments
	Self-efficacy	CHW confidence in facilitating groups and addressing sensitive ANC topics	Confidence increases with mentoring	Low confidence among newly trained CHWs	Interviews; supervision records
	Motivation	Willingness of CHWs to deliver group ANC consistently	Recognition and community respect	Burnout; competing responsibilities	CHW interviews
Process	Planning	Degree to which group ANC implementation was proactively planned	Clear session schedules and roles	Ad-hoc planning	Implementation documents
	Engaging	Involvement of CHWs, providers, and community leaders	Early stakeholder engagement	Limited community involvement	Interviews; meeting notes
	Reflecting & evaluating	Use of feedback and reflection to improve delivery	Regular review meetings	No structured feedback mechanisms	Supervision logs; reflection notes

Practical, Robust Implementation and Sustainability Model (PRISM)

The PRISM framework emphasizes the role of context in implementation by linking intervention characteristics, organizational and recipient perspectives, the external environment, and implementation infrastructure to practical outcomes. Context is embedded in several of its domains:[51]

Intervention/Program

Characteristics: This domain refers to features of the intervention itself that can influence adoption and sustainability. Key subdomains include design quality and packaging (clarity, usability, and presentation of the intervention), adaptability (ability to tailor the intervention to local needs), complexity (ease of use and understanding), relative advantage (perceived benefit over existing practices), and evidence strength and quality (credibility of supporting research). Interventions that are simple, flexible, and clearly advantageous are more likely to be adopted and sustained.

Recipients/Organizational perspective: This domain focuses on characteristics of individuals and organizations involved in implementation. Subdomains include organizational culture and climate (norms, values, and readiness for change), leadership support and engagement, staff knowledge and attitudes (beliefs, motivation, and confidence in performing tasks), capacity and resources (availability of staff, time, and infrastructure), and alignment with organizational priorities. Positive attributes act as facilitators, whereas resistance, limited capacity, or misalignment with priorities can be barriers.

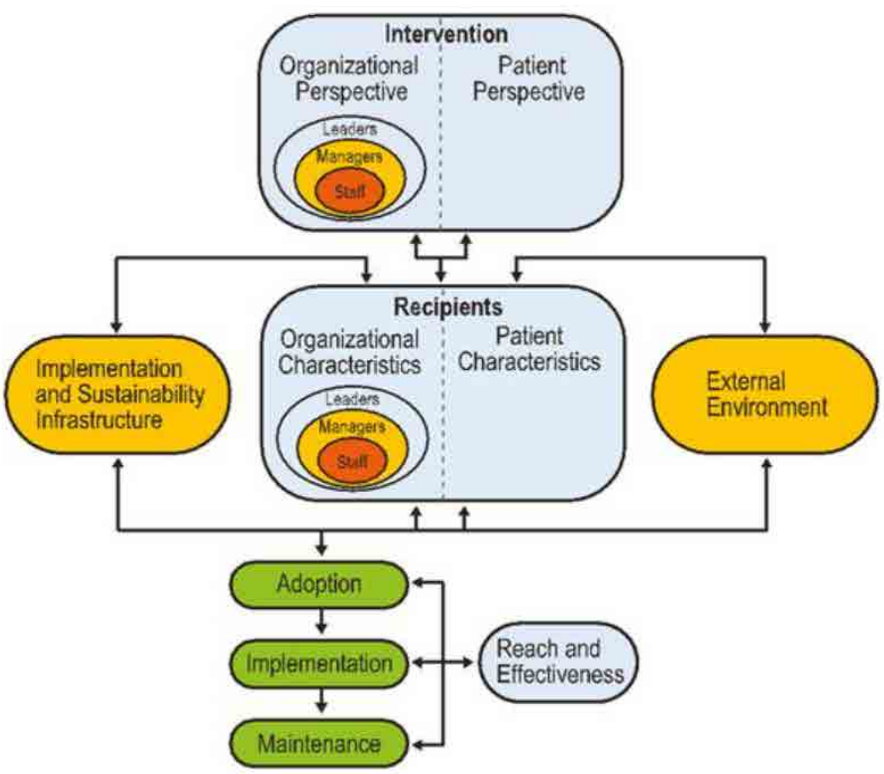


Figure 8: PRISM [Feildstein and Glasglow, 2008]

External environment: The external context encompasses factors outside the implementing organization that influence adoption and sustainability. Subdomains include policies and regulations, funding and incentives, community needs and preferences, and inter-organizational networks. Supportive policies, external partnerships, or funding facilitate implementation, whereas restrictive regulations or misaligned incentives may pose barriers.

Implementation and sustainability infrastructure: This domain relates to the systems and processes that support effective implementation. Key elements include training and technical assistance, workflow integration, monitoring and feedback mechanisms, and continuous quality improvement processes. Well-developed infrastructure facilitates consistent implementation and long-term sustainability, while gaps or weak support systems act as barriers.

Table 7: Example of PRISM guided determinants of mhGAP intervention in Nepal

PRISM Domain	Contextual focus	Facilitators	Barriers
1. Perspectives on the intervention	Organizational & provider perspectives	• mhGAP perceived as credible and evidence-based (WHO-endorsed)	• Algorithms perceived as complex or lengthy
		• Structured algorithms and job aids increase provider confidence	• Concerns about increased consultation time and documentation burden
		• Task-sharing aligns with PHC mandate	• Perception of mental health as an added responsibility
	Patient (recipient) perspectives	• Mental health services delivered in PHC reduce stigma	• Persistent stigma around mental illness
		• Care closer to home improves accessibility	• Low mental health literacy
		• Trust in PHC providers encourages disclosure	• Uncertainty about benefits of treatment
2. Characteristics of implementers, settings, and recipients	Organizational characteristics	• Supportive facility leadership promotes prioritization of mhGAP	• High patient volume and staff shortages
		• Positive organizational culture toward task-sharing	• Competing clinical priorities
			• Limited private consultation space
	Implementer characteristics	• mhGAP training improves knowledge and skills	• Limited prior mental health training
		• Ongoing supervision increases self-efficacy	• Low confidence managing complex cases
		• Job aids support correct application	• Fear of making diagnostic or treatment errors
	Patient & family characteristics	• Family support enhances adherence and follow-up	• Social vulnerability and poverty limit follow-up
		• Community awareness activities improve acceptance	• Gender and cultural norms restrict care-seeking
			• Low health literacy

PRISM Domain	Contextual focus	Facilitators	Barriers
3. External environment	Policy & system context	• National endorsement of mhGAP and PHC integration	• Policy–practice gaps
		• Policy support for task-sharing	• Limited budget allocation for mental health
	Referral environment	• Availability of some referral pathways for severe cases	• Shortage of mental health specialists
			• Long waiting times and weak referral feedback
	Medicines & supplies	• Inclusion of psychotropic medicines in essential drug lists	• Frequent stock-outs of psychotropic medicines
			• Weak supply chain management
	Sociocultural context	• Community engagement initiatives reduce stigma	• Stigma, discrimination, and misconceptions about mental illness
4. Implementation and sustainability infrastructure	Training & supervision systems	• Structured mhGAP training programs	• Irregular supervision
		• Supportive supervision improves fidelity	• Staff turnover leading to loss of trained personnel
	Workflow integration	• mhGAP embedded into routine outpatient consultations	• Parallel reporting systems
		• Use of standardized documentation	• Poor integration with routine HMIS
	Monitoring & feedback	• Use of service data for feedback and quality improvement	• Weak mental health indicators in routine data systems
	Financing & sustainability	• Short-term project or donor funding supports initial implementation	• No dedicated budget line post-project
			• Lack of long-term sustainability planning

Using frameworks for exploring facilitators and barriers to EBI implementation

CFIR or PRISM frameworks can be used to explore facilitators and barriers by systematically identifying contextual factors that influence implementation and sustainability. Facilitators may include leadership engagement, strong training and support systems, intervention adaptability, and alignment with organizational priorities, whereas barriers may involve limited resources, staff resistance, complex interventions, or external policy constraints. To investigate these facilitators and barriers, researchers can use qualitative interviews or focus groups with staff and stakeholders, surveys assessing perceptions and attitudes, process mapping to understand workflow integration, and document reviews to examine policies, infrastructure, and organizational capacity. Using PRISM or CFIR in combination with these methods enables a comprehensive understanding of contextual determinants and supports the development of strategies to enhance facilitators and mitigate barriers, thereby improving the likelihood of successful and sustainable implementation.

The Basel Approach for coNtextual ANAlysis (BANANA)

The Basel Approach for coNtextual ANAlysis (BANANA) is a comprehensive, multi-component methodology designed to systematically guide researchers in planning, conducting, and reporting contextual analysis within implementation research projects.

A central principle of BANANA is continuous stakeholder engagement, which cuts across and informs all components of the approach. BANANA explicitly recognizes context as multilevel, multidimensional, and dynamic, and positions contextual analysis as a core scientific activity rather than a secondary or descriptive task.[52]

BANANA consists of six core, interrelated components, which are often conducted iteratively and in parallel rather than sequentially.

Component 1: Choosing a Theory, Model, or Framework (TMF)

This component involves selecting one or more TMF to systematically identify and organize contextual factors. TMFs should be appropriate for contextual analysis, recognize context as multilevel and dynamic, provide guidance on operationalization, and fit the intervention and setting. Multiple TMFs may be combined to increase analytic depth.

Example: For mhGAP implementation, CFIR was selected to examine facility- and provider-level determinants such as leadership engagement, workflow, and readiness for change, while PRISM was used to assess health system alignment and sustainability. Combining these frameworks allowed for a comprehensive examination of both short-term implementation and long-term sustainment of mhGAP within primary health care.

Component 2: Using empirical evidence to identify contextual factors

Relevant contextual factors are identified using multiple sources of empirical evidence, including local data, professional experience, patient perspectives, and existing research. Using diverse evidence sources strengthens validity and ensures the analysis reflects real-world conditions.

Example: Contextual factors influencing mhGAP were identified using routine health facility data on service utilization, provider experiences delivering mental health care, patient perspectives on stigma and care-seeking, and prior mhGAP implementation studies. This evidence highlighted gaps in training, medication availability, and referral capacity.

Component 3: Stakeholder Involvement

This component focuses on identifying, mapping, and engaging stakeholders who influence or are affected by the intervention across micro, meso, and macro levels. Continuous stakeholder engagement ensures relevance, feasibility, and ownership of the implementation process.

Example: Stakeholders engaged in the mhGAP contextual analysis included primary care providers, facility managers, district health officers, mental health specialists, policymakers, and service users. Stakeholders were mapped by role and influence and engaged through interviews and consultation meetings to identify implementation barriers and priorities.

Component 4: Developing a study design for contextual analysis

A study design tailored specifically to contextual analysis is developed, guided by theory, empirical evidence, stakeholder input, and research questions. Qualitative, quantitative, or mixed methods may be used, with attention to capturing context over time.

Example: A mixed-methods design was used to examine mhGAP context, including interviews and observations to explore provider workload and stigma, and facility surveys to assess staffing, space, and supervision structures. Data were collected at multiple time points to capture changes during implementation.

Component 5: Determining the relevance of context

Findings from contextual analysis are used to inform intervention adaptation, selection of implementation strategies, interpretation of outcomes, and sustainability planning. This component ensures context informs action.

Example: Contextual findings informed adaptations to mhGAP training schedules, selection of supportive supervision strategies, and integration of mental health screening into routine workflows. Findings were also used to interpret variation in adoption and fidelity across facilities and to plan for long-term sustainability through policy alignment.

Component 6: Reporting on contextual analysis

This component emphasizes transparent reporting of contextual analysis, including definitions of context, TMFs used, evidence sources, stakeholder involvement, methods, and how findings informed implementation and sustainability.

Example: The mhGAP contextual analysis was reported as a core component of the study, detailing frameworks used, stakeholder engagement processes, data sources, and how contextual findings guided intervention adaptation and implementation strategies. Results were positioned as essential for understanding implementation outcomes and informing scale-up.

*****END OF MODULE 3*****

Module 4: Implementation Strategies

IMPLEMENTATION STRATEGIES

Implementation strategies are the practical methods or techniques used to integrate effective EBIs into routine health care and other settings. They represent the "how to" of implementation, the deliberate actions taken to enhance the adoption, implementation, and sustainability of clinical programs or practices.[53]

Implementation strategies differ widely in scope, complexity, and targets ranging from simple actions like sending printed materials to multifaceted approaches addressing multiple levels of an organization. In this context, the term "implementation strategy" refers specifically to discrete strategies, such as reminders or educational meetings, which aim to support and sustain the use of EBIs in practice.

While EBIs are the proven health interventions themselves, implementation strategies are the actions or processes that help organizations put those interventions into routine use. These strategies can range from simple steps like sending printed materials to complex, multi-level efforts within health systems. In this chapter, "implementation strategy" refers specifically to discrete actions (e.g., reminders, educational meetings), not bundled or multifaceted approaches.

Example:

EBI: Group ANC

The intervention was an integrated community health worker-led program to improve antenatal care (ANC) utilization, implemented by Nyaya Health in rural Nepal. The intervention was delivered by community health workers and nurses/supervisors in collaboration with government clinic nurse-midwives, and targeted pregnant women from six rural village clusters in Achham district. Core components included gestation-specific group ANC visits that combined clinical assessment, participatory health education, standardized documentation, and referral and care coordination. The intervention was delivered through a reduced visit schedule, joint facility-based group sessions, expanded diagnostic services, fixed scheduling with larger or mixed-age groups, and use of mobile supervisory checklists to support quality and consistency. Group ANC sessions were conducted monthly for one year.

Implementation strategies and targeted implementation outcomes for group ANC

These are the strategies used to improve the implementation success (implementation outcomes) of group ANC. They may include

- Training CHWs and facility providers: Training CHWs and providers in group facilitation, ANC clinical protocols, and respectful maternity care. Targeted outcomes: Adoption, fidelity and appropriateness
- Scheduling and reminder systems: Establishing fixed group ANC schedules and using registers, phone calls, or SMS reminders to support attendance and session continuity. Targeted outcomes: Reach, Feasibility
- Supervision and audit & feedback: Conducting regular supervisory visits and providing feedback on session delivery, attendance, and adherence to group ANC protocols.

Targeted outcomes: Fidelity, Adoption, Sustainability

- Role clarification and task allocation: Clearly defining roles and responsibilities of CHWs, nurses, and midwives in organizing, facilitating, and documenting group ANC sessions. Targeted outcomes: Acceptability, Feasibility.
- Workflow and space redesign: Modifying clinic workflows to allocate protected time and space for group sessions, integrate clinical assessments into group visits, and align documentation with routine ANC records.

Targeted outcomes: Feasibility, Penetration, Sustainability

Table 8: Difference between EBI and implementation strategies

Dimension	EBI	Implementation strategy
What it is	The intervention or innovation itself - "the thing"	The methods or processes used to help people do "the thing"
Question addressed	What improves health outcomes?	How do we deliver the intervention effectively in real-world settings?
Purpose	Improve clinical or population health outcomes	Improve adoption, fidelity, reach, and sustainability
Nature	Clinical, behavioral, or public health program or practice	Organizational, behavioral, or system-level actions
Focus of evaluation	Health outcomes and effectiveness	Implementation outcomes
Example: Group ANC	Group antenatal care model combining clinical assessment, education, and peer support	Training CHWs in group facilitation; supervision and audit-feedback; workflow and space redesign
Example: mhGAP	WHO mhGAP clinical guidelines for managing priority mental health conditions in primary care	Training non-specialist providers; supportive supervision; integration into routine workflows and reporting systems

Implementation strategy taxonomies

Implementation research taxonomies provide structured ways to classify implementation strategies so researchers and practitioners can design, report, compare, and synthesize implementation efforts consistently. Without a shared structure, researchers and practitioners may use different words for the same strategy or the same word for different strategies making it difficult to compare studies, replicate effective approaches, or select the most suitable strategies for a specific context. A clear taxonomy provides a common language and organized framework for naming, grouping, and understanding strategies. It helps teams systematically review their options, align strategies with identified barriers, and make better-informed decisions during implementation planning.

Multiple taxonomies have been developed to classify implementation strategies, helping researchers understand different types of strategies and compare evidence on their effectiveness on implementation success.[54] Early taxonomies focused on changing physicians' behavior, such as Davies et al.'s (1992)[55] categories like education, reminders, and audit and feedback. Oxman et al. (1995)[56] expanded this to all health professionals, adding strategies like outreach visits, opinion leaders, marketing, and multifaceted interventions.

Building on this, Cochrane's Effective Practice and Organization of Care (EPOC) group developed taxonomies that moved beyond individual behavior change to include strategies targeting health care organizations, systems, and regulatory environments. The EPOC taxonomy was revised during 2013-2015 and now includes four broad categories of health system interventions: delivery arrangements, financial arrangements, governance arrangements, and implementation strategies.[57]

Other taxonomies take a theory-driven approach. The RURU taxonomy (Walter et al., 2007)[58] categorizes strategies based on their underlying mechanisms of change such as dissemination, education, social influence, incentives, reinforcement, and facilitation highlighting the importance of connecting strategies to theory. Grol and Wensing (2005)[59] organized strategies along a continuum from voluntary, motivation-based approaches to compulsory, regulatory ones.

Powell et al. (2012) later consolidated existing literature to create a comprehensive list of 68 strategies, refined through the ERIC project into 73 discrete implementation strategies, establishing a common language and a menu of "building blocks" for practice.[53]

The Expert Recommendations for Implementing Change (ERIC) implementation strategies are a standardized, well-defined set of discrete strategies designed to promote the adoption, implementation, and sustainment of evidence-based interventions (EBIs). Developed by Powell et al. (2015), the ERIC project brought together implementation research experts to consolidate and clarify terminology because the field had become fragmented, with over 70 strategies described in the literature under inconsistent names and definitions. Implementation strategies have often faced problems such as unclear terminology, overlapping definitions, and vague descriptions. These issues make it hard to compare studies, repeat interventions, or choose the right strategies for a specific setting.[53]

ERIC provides a common langague, allowing researchers and practitioners to clearly plan, select, and report strategies, as well as compare and synthesize evidence across studies. The strategies target multiple levels, clinicians, organizations, and health systems and can be used individually or combined into multi-component implementation efforts. Examples include audit and feedback, educational meetings, reminders, tailoring interventions to context, using opinion leaders, and developing implementation teams. By offering a structured "menu" of strategies, ERIC addresses the confusion and inconsistency in reporting implementation efforts, ultimately improving the rigor, replicability, and effectiveness of implementation research.

Table 9: Lists of the nine broad ERIC categories with short description and example of strategies from the ERIC menu

ERIC Category	Description	Example of ERIC strategies
Use evaluative and iterative strategies	Strategies that help teams assess needs, evaluate implementation, and continuously refine their approach. These strategies emphasize learning, feedback loops, and ongoing improvement.	Assess readiness; Audit and feedback; Needs assessment; PDSA cycles; Develop implementation blueprint; Rapid-cycle evaluation

ERIC Category	Description	Example of ERIC strategies
Provide interactive assistance	Strategies that offer hands-on guidance and real-time problem-solving support to implementers. Often involve external or internal experts providing facilitation.	Centralized technical assistance; Local technical assistance; Facilitation; Learning collaborative; Clinical supervision
Adapt and tailor to context	Strategies that adjust interventions or implementation processes to fit local needs, culture, or resources. Focus on improving the fit between the innovation and the setting.	Adapt the intervention; Promote adaptability; Tailor strategies to barriers and facilitators
Develop stakeholder interrelationships	Strategies that strengthen relationships among stakeholders, build coalitions, and leverage social networks to support implementation.	Identify and prepare champions; Academic detailing; Engage opinion leaders; Build coalitions; Create implementation teams
Train and educate stakeholders	Strategies that build knowledge and skills among those responsible for implementation. Training may be one-time or ongoing.	Educational meetings; Ongoing training; Standardized training materials; Train-the-trainer programs; Peer-to-peer learning
Support clinicians	Strategies that modify tools, workflows, roles, or systems to help clinicians deliver the EBI effectively and efficiently. Focused on practical support for day-to-day practice.	Clinical reminders; Change record systems; Revise professional roles; Develop tools; Workflow modifications
Engage consumers	Strategies that involve patients, families, or community members in supporting implementation often to increase uptake, adherence, or demand for the EBI.	Mass media; Patient involvement; Prepare patients to participate; Consumer interviews
Use financial strategies	Strategies that use funding, incentives, or financial structures to encourage adoption or sustainment of EBIs.	Access new funding; Adjust incentives; Contract for the innovation; Add intervention to fee schedules
Change infrastructure	Strategies that modify organizational, regulatory, or environmental structures to support long-term implementation. Often involve high-level or system-level changes.	Change accreditation standards; Modify physical structures; Update technology infrastructure; Mandate change; Revise workflows

The details of each strategy are presented in Annex-II.

Specifying and reporting implementation strategy

Clearly specifying the implementation strategy is essential because it strengthens the rigor, transparency, and usefulness of research. It allows others to understand exactly what was done and why, supports reproducibility, and helps reviewers and readers assess the validity of the methods and findings. Detailed reporting also builds credibility and contributes to the broader knowledge base, enabling future studies to learn from, replicate, or build on the work.[60]

- ✓ Name it: Provide a clear, concise, and distinctive name for the implementation mapping. Ensure the name is aligned with the terminology used in existing literature to maintain consistency and clarity.
- ✓ Define it: Clearly define the implementation strategy and its discrete components, spelling out exactly what the strategy is and is not. Operationally describe how the strategy works, what it entails, and the expected outcomes.
- ✓ Specify it: This is used for full transparency and replicability, describing who, what, when, how much, what change is expected, and why.
- ✓ Who enacts the strategy? / Actor: Identify the individuals or groups responsible for carrying out the strategy. These may include managers, healthcare professionals, patients, or other relevant stakeholders.
- ✓ What actions or steps need to be enacted? / Action: Specify the precise actions, steps, or processes involved in implementing the strategy. This includes the specific behaviors or procedures that need to change.

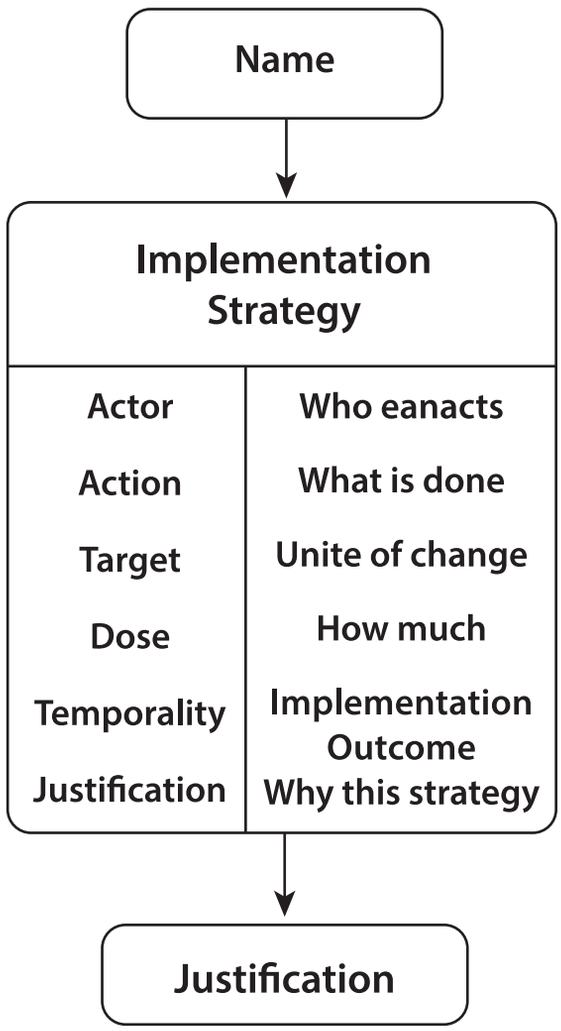


Figure 9: Specifying and reporting implementation strategies

- ✓ What are the intended targets of the strategy? / Action target: Define what behaviors, practices, or systems the strategy aims to change or improve. Identify the specific aspects of practice or systems that need to be addressed.
- ✓ When is the strategy used? / Temporality: Specify the timing of the strategy's implementation, including the stage of the intervention (e.g., initiation, follow-up), frequency, and duration of use.
- ✓ What is the dosage of the strategy? / Dose: Define the intensity and frequency of the implementation strategy. This could include the number of sessions, hours of training, or frequency of meetings necessary for successful implementation.
- ✓ What are the expected implementation outcomes? Identify the key outcomes that the strategy aims to affect, such as changes in practice, behavior, or organizational processes. Define the metrics for measuring success and how these will be tracked.
- ✓ What is the justification? Provide empirical, theoretical, or pragmatic justification for the selection of the strategy. Explain why this particular strategy is appropriate based on evidence, existing research, or theoretical frameworks.

Example of Implementation strategy

Table 10: Specifying implementation strategies of group ANC

Strategy (Name it)	Definition (Define it)	Actor (Who enacts?)	Actions (What is done?)	Action Target (What is changed?)	Temporality (When?)	Dose (How much?)	Primary Implementation Outcome	Theoretical justification (with citation)
Training CHWs and facility providers	Structured capacity-building activities to improve providers' knowledge, skills, and confidence in group facilitation, ANC clinical protocols, documentation, and respectful maternity care.	Trainers	Deliver standardized training; provide manuals and job aids; conduct role-plays and supervised practice	Frontline providers (CHWs, ANMs): provider capability (knowledge, skills, self-efficacy) to deliver Group ANC as intended	Pre-implementation with early refresher	Initial 2-3-day training; 1-day refresher within 6-12 months	Adoption	The behavior change requires sufficient capability (knowledge and skills). Training directly increases psychological and physical capability, enabling adoption of new practices.[61]
Scheduling and reminder systems	Organizational systems that establish fixed group ANC schedules and use registers, phone calls, or SMS reminders to support attendance and continuity.	Auxiliary Nurse Midwife (ANM)	Develop ANC group calendars; maintain registers; send reminders	Patient attendance and continuity of participation	Initiation and throughout implementation	Reminders sent 1-3 days before each session	Reach	Reminders reduce cognitive and logistical barriers that limit participation. This addresses patient needs and resources and access to care, improving reach[62,63]
Supervision and audit & feedback	Ongoing oversight involving observation of sessions, review of records, and structured feedback to providers on performance and adherence to protocols.	Auxiliary Nurse Midwife (ANM)	Observe sessions; review documentation; provide feedback; support problem-solving	Provider adherence to core components of group ANC	Early implementation and maintenance	Monthly visits for 3-6 months, then quarterly	Fidelity	Timely, task-focused feedback improves performance. Audit & feedback is also a core ERIC strategy shown to enhance fidelity across settings[53,53,64]

Strategy (Name it)	Definition (Define it)	Actor (Who enacts?)	Actions (What is done?)	Action Target (What is changed?)	Temporality (When?)	Dose (How much?)	Primary Implementation Outcome	Theoretical justification (with citation)
Role clarification and task allocation	Explicit definition and communication of roles and responsibilities among CHWs, nurses, and midwives for organizing, facilitating, and documenting group ANC sessions.	Health facility in-charge	Develop role descriptions; clarify responsibilities; integrate into routine job expectations	Team coordination and accountability	Pre-implementation with reinforcement during rollout	One-time clarification with periodic reinforcement	Acceptability	Role clarity reduces ambiguity and conflict, increasing staff acceptance of new practices. This addresses networks and communications and implementation climate.[62,65]
Workflow and space redesign	Structural modifications to clinic workflows and physical space to integrate group ANC into routine services, including protected time, designated space, and aligned documentation.	Health facility in-charge	Adjust clinic schedules; allocate group space; integrate assessments into group visits	Compatibility of group ANC with routine service delivery	Pre-implementation with early refinement	One-time redesign with iterative adjustment	Feasibility	Emphasizing alignment between tasks, people, and infrastructure. In CFIR, this targets structural characteristics and compatibility, which are critical for feasibility of EBIs in routine care.[62,66]

Implementation Research Logic Model

An implementation research logic model (IRLM) is a structured, visual framework that links implementation determinants, implementation strategies, and implementation outcomes, while keeping the EBI and clinical/public health outcomes explicit. It helps answer the core implementation research question:[67] "What strategies will address which barriers, to achieve which implementation outcomes, and ultimately improve health?"

Example of determinants, implementation strategies and outcomes logic of aroup ANC

In health facilities implementing group ANC, fidelity challenges often arise due to limited provider skills in group facilitation, unclear roles among CHWs and facility staff, competing clinical demands, and uncertainty about how group sessions should be delivered while maintaining ANC quality. To address these barriers, clinics can use targeted implementation strategies such as training and education to build provider competence in group facilitation and ANC protocols, role clarification to ensure consistent responsibilities across CHWs, nurses, and midwives, and workflow and space redesign to create protected time and appropriate settings for group sessions. Ongoing supervision and audit and feedback further reinforce fidelity by monitoring adherence to core components and providing corrective guidance.

When these strategies effectively address identified barriers, providers are better prepared and supported to deliver group ANC as intended, resulting in higher fidelity, with consistent delivery of core components, appropriate session structure, and adherence to clinical and facilitation protocols across providers and facilities.

Example of determinants, implementation strategies and outcomes logic of mhGAP

In primary health care settings implementing the WHO mhGAP, adoption of mhGAP guidelines by general health workers may be limited due to several determinants, including low provider confidence in managing mental health conditions, limited prior mental health training, competing clinical priorities, and skepticism about the feasibility of delivering mental health care in routine primary care. Additional barriers may include unclear referral pathways and lack of leadership endorsement for mhGAP integration.

To address these barriers, facilities can apply targeted implementation strategies. Structured mhGAP training and refresher sessions can increase providers' knowledge and confidence in identifying and managing priority mental health conditions. Identification of facility-level mhGAP champions can promote uptake by modeling mhGAP use, reinforcing its relevance, and encouraging peers to apply the guidelines in daily practice. Workflow integration strategies, such as embedding mhGAP screening and decision-support tools into routine outpatient visits and patient registers, can further lower practical barriers to use. Supportive supervision and audit and feedback can reinforce adoption by tracking mhGAP utilization and sharing data on screening and treatment initiation.

When these strategies effectively address the identified determinants, providers are more likely to adopt mhGAP, reflected by increased use of mhGAP screening tools,

documentation of mental health diagnoses, initiation of guideline-concordant treatment, and appropriate referrals within routine primary care services.

IRLM helps to plan, describe, and evaluate implementation strategies. It shows how and why an implementation strategy is expected to produce desired implementation outcomes.

The key components of the IRLM form a clear logical chain that begins after identifying an evidence-based intervention to be implemented.

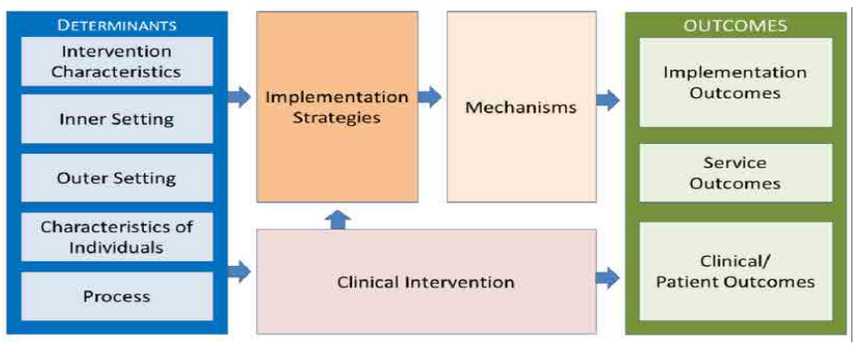


Figure 10: Implementation research logic framework [Smith JD, Li DH, Rafferty MR, 2020]

First, teams assess the context to identify determinants, the barriers and facilitators that could influence whether the intervention is successfully integrated into practice.

These determinants then guide the selection of implementation strategies, which are the purposeful actions chosen to overcome barriers or leverage strengths. The strategies work through specific mechanisms of action such as improving knowledge, increasing motivation, enhancing skills, or streamlining workflows that explain how and why the strategies are expected to produce change.

They lead to improved implementation outcomes, such as increased adoption, higher fidelity, better acceptability, greater feasibility, and stronger sustainability of the intervention.

Ultimately, successful implementation supports improved intervention or service outcomes, like better patient health or more efficient care delivery.

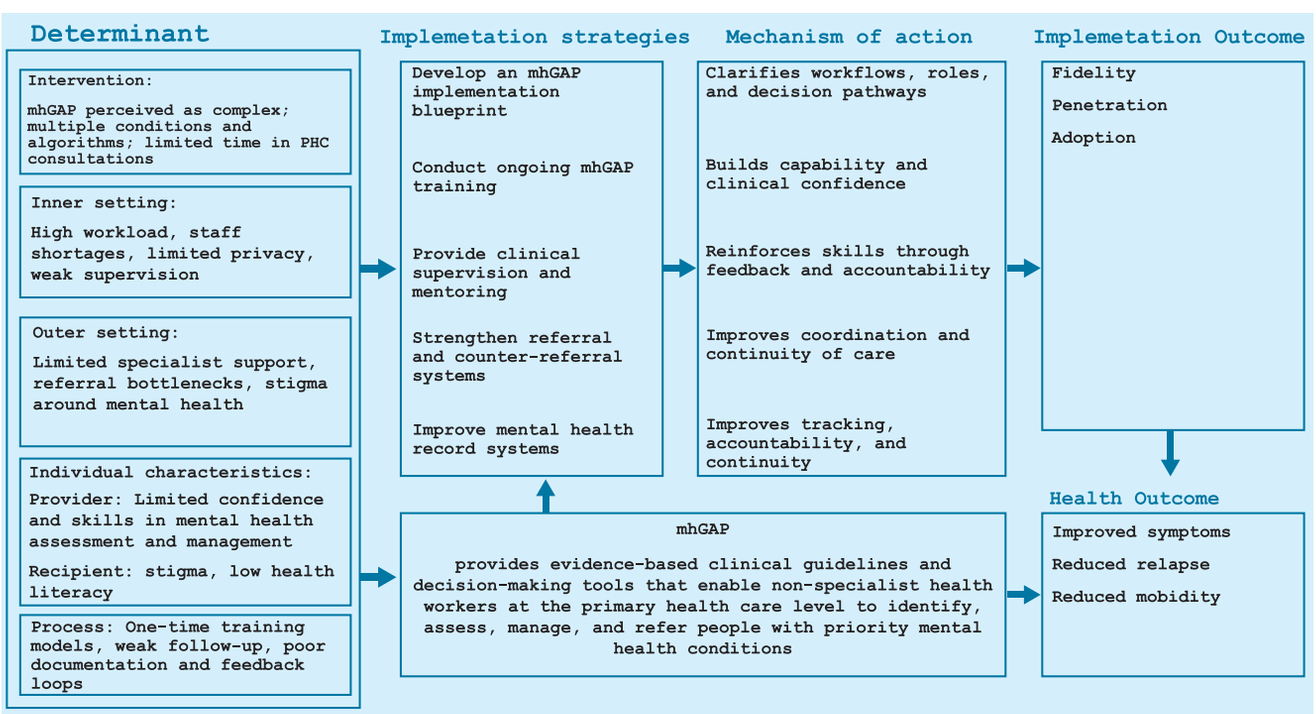


Figure 11: Example of IRLM for Implementing mhGAP

Systematically selecting implementation strategies

Selecting implementation strategies systematically is important because it ensures that the chosen strategies directly address the real barriers and needs within a specific context, rather than relying on guesswork or convenience. A structured process helps align strategies with relevant barrier along with stakeholder input and improve EBI adoption, implementation or sustainment. It also promotes efficient use of resources by focusing efforts on actions most likely to produce meaningful change, while improving transparency and making it easier to evaluate and replicate.

Theory driven approaches

One of the theory-based approaches to select implementation strategy is behavior wheel with Capability, Opportunity, Motivation, Behavior (COM-B) model. The COM-B model identifies the behavioral determinants: Capability, Opportunity, Motivation affecting Behavior. The Behavior Change Wheel (BCW) builds on COM-B by linking each determinant to intervention functions (types of strategies) and policy categories to systematically select strategies. [61]

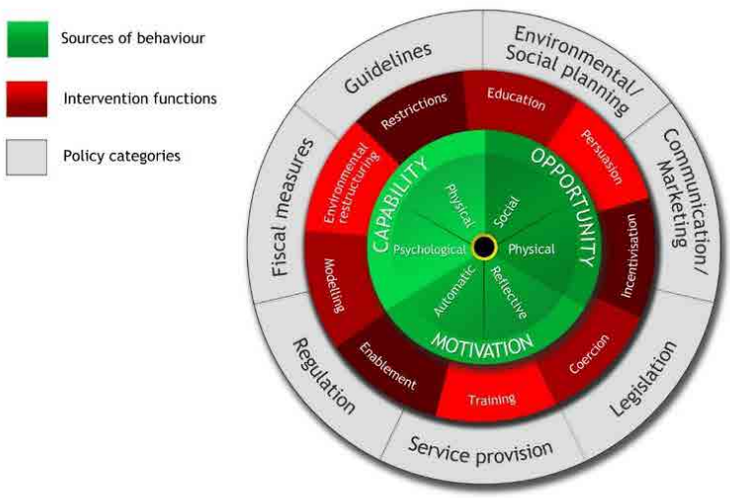


Figure 12: COM-B [Michie S, van Stralen MM, West R, 2011]

Table 11: Example of COM-B model

COM-B Component	Barrier	BCW intervention function	Implementation strategies
Capability (psych./ physical)	Staff lack knowledge/ training	Education, training	Training sessions, workshops, skill-building exercises
Opportunity (social/physical)	Limited time, unclear workflow, electronic health records (EHR) issues	Environmental restructuring, enablement	Workflow redesign, EHR prompts, clinical champions, peer support
Motivation (reflective/ automatic)	Clinician skepticism, low engagement	Persuasion, incentivization, modeling	Audit and feedback, motivational communication, incentives, role-modeling by respected peers

Evidence-based strategies lists and tools

The CFIR-ERIC implementation strategy matching tool is designed to help implementers systematically select strategies based on the specific context of their setting. By combining the CFIR, which identifies contextual determinants such as organizational culture, resources, or clinician attitudes, with the ERIC taxonomy, which lists 73 evidence-informed implementation strategies, the tool provides a structured way to match strategies to barriers or facilitators identified in a context assessment.

For example, if a clinic assessment using CFIR reveals that limited leadership engagement is a key barrier, the tool can suggest ERIC strategies such as involving executive boards, developing formal implementation leaders, or identifying clinical champions to directly address this determinant. This systematic mapping ensures that strategy selection is evidence-based, targeted to the local context, and increases the likelihood of successful implementation outcomes.

Implementation mapping

Implementation mapping (IM) is a systematic, step-by-step protocol for developing, selecting, and tailoring strategies to promote the adoption, implementation, and sustainment of EBIs, practices, or policies in real-world settings.[68]

Implementation mapping is an iterative process consisting of five main tasks. These tasks guide planners to systematically apply theory, empirical evidence, and stakeholder input to ensure implementation strategies are robust, context-appropriate, and feasible.

Task 1: Conduct an implementation needs and assets assessment: The initial task of Implementation mapping involves a deep needs and assets assessment to thoroughly understand the context and the key players. This requires identifying the adopters (those who decide to use the EBI) and the implementers (those who deliver the EBI), and then systematically assessing the specific barriers and facilitators (known as determinants) that influence their behavior toward the EBI. By employing established frameworks, such as the CFIR, planners gather data from multiple levels (individual, organizational, and environmental) to form a comprehensive picture of the factors that will either hinder or support successful integration of the evidence-based intervention.

Task 2: Identify outcomes, objectives, and determinants: Task 2 translates the findings from the assessment into a structured roadmap for change. First, planners define the desired, measurable implementation outcomes (e.g., fidelity, penetration, sustainability) using taxonomies like the Proctor model. Next, they specify the detailed performance objectives the observable actions that adopters and implementers must perform to achieve those outcomes. Finally, the core of this task involves creating matrices of change objectives by combining these performance objectives with the key determinants (barriers/facilitators) identified in Task 1, defining precisely what needs to change in the environment or in individual behavior.

Task 3: Choose theoretical methods and select strategies: This phase focuses on selecting the practical actions necessary to achieve the change objectives defined in Task 2. Planners first choose theoretical change methods (e.g., modeling, persuasion, reinforcement) which

are evidence-based techniques known to influence the specific behavioral determinants (e.g., self-efficacy, knowledge, attitude). These theoretical methods are then translated into concrete, real-world implementation strategies (e.g., 'conducting an in-person training session' or 'providing performance feedback'). This critical step ensures that the chosen strategies are not random, but are directly matched to the identified determinants to maximize their effectiveness.

Task 4: Produce implementation protocols and materials: Once the implementation strategies have been selected and finalized, Task 4 is dedicated to operationalizing the plan by developing detailed resources. This involves creating comprehensive implementation protocols that specify exactly who will deliver each strategy, when it will be delivered, and the exact steps to follow to ensure consistent application. Furthermore, planners produce all necessary materials required to support the strategies, such as training manuals, communication guides, clinical flowcharts, and checklists, ensuring that the implementation team has the necessary tools for flawless execution.

Task 5: Evaluate implementation outcomes: The final task involves establishing a comprehensive plan for evaluating the implementation effort itself, not just the health outcome of the intervention. This requires developing metrics and processes to measure whether the chosen implementation strategies successfully improved the specified implementation outcomes (e.g., did the strategy increase fidelity, acceptability, or adoption?). The results of this evaluation are then used as a crucial feedback loop, allowing planners to identify which strategies worked, refine the protocols, and adapt the overall plan for continuous quality improvement and long-term sustainability of the evidence-based intervention.

Example: Implementation mapping to implement a new standardized clinical protocol for type 2 diabetes management in a PHC in a rural or semi-urban setting in Nepal.

The intervention is defined as a standardized clinical protocol for Type 2 diabetes management delivered at the primary health care (PHC) level. The protocol is implemented by primary care providers, including medical officers, health assistants, and staff nurses, with support from auxiliary health workers and Female Community Health Volunteers (FCHVs) for patient education and follow-up. The target population includes adults diagnosed with Type 2 diabetes, including newly diagnosed individuals and those with suboptimal glycemic control. Core components of the protocol include standardized screening and diagnosis using blood glucose or HbA1c where available; stepwise pharmacologic management beginning with first-line oral agents such as metformin; lifestyle counseling focused on diet, physical activity, weight management, and tobacco cessation; routine monitoring of blood glucose, blood pressure, and weight; assessment and referral for diabetes-related complications; and ongoing patient education and self-management support. Care is delivered through structured outpatient consultations guided by national or World Health Organization (WHO)-adapted treatment algorithms, supported by job aids, clinical checklists, standardized registers, and supervision. Initial consultations typically last 20-30 minutes, with follow-up visits every 4-12 weeks depending on glycemic control, reflecting the chronic nature

of diabetes management. The intended effect of this intervention is improved glycemic control, prevention or delay of diabetes-related complications, and improved quality of life among people living with Type 2 diabetes.

Task 1: Conduct an implementation needs and assets assessment

Identified Adopters/Implementers:

- Adopters: Medical Officer In-Charge, Health Post Management Committee.
- Implementers: PHC Medical Officer (MO), Health Assistants (HAs), and Auxiliary Nurse Midwives (ANMs) who provide initial screening, patient education, and follow-up care.

Key barriers (determinants) identified: Individual (PHC Staff): Low knowledge of the new, updated protocol and its specific dosage/referral criteria. Low self-efficacy in counseling patients on lifestyle changes. Negative attitude among staff that patients won't comply due to economic constraints.

Organizational (PHC facility): Limited resources (e.g., lack of essential medications listed in the protocol, irregular supply of blood glucose strips). Poor workflow for chronic disease follow-up (current focus is acute care).

Contextual (Patient/Community): Financial barriers to treatment/dietary compliance. Low health literacy about diabetes.

Task 2: Identify outcomes, objectives and determinants

This task defines the change needed by linking the desired behavior (performance objective) to the identified obstacle (determinant).

Table 12: Example of identifying outcomes, objectives, and determinants

Implementation outcome	Performance objective (Implementer must do)	Key determinant (Barrier)	Change objective (What must change)
Fidelity (Accurate use of protocol)	MOs/HAs must follow the protocol's 4-step treatment algorithm	Low Knowledge and skills of the new treatment algorithm.	Increase MOs' and HAs' knowledge of the precise 4-step treatment algorithm.
Acceptability (Staff willingness)	ANMs/HAs must dedicate 10 minutes to deliver structured dietary counseling to all new patients.	Negative Attitude that patients won't comply with counseling.	Increase ANMs'/ HAs' belief that their counseling can lead to patient compliance.
Sustainability (Long-term operation)	PHC In-Charge must ensure a continuous, 95% stock of essential diabetes medications.	Lack of reliable Resources and supply chain.	Increase the In-Charge's confidence/self-efficacy in managing the chronic disease medicine supply chain.

Task 3: Choose theoretical methods and select strategies

Strategies are chosen specifically to influence the determinants that block the Performance Objectives.

Table 13: Example of chosen theoretical methods and selected strategies in implementation mapping

Change objective	Theoretical method	Selected implementation strategy (ERIC taxonomy)
Increase knowledge of treatment algorithm.	Instruction (knowledge transfer)	Conduct training: Deliver hands-on, case-based training using local examples.
Increase belief that counseling helps compliance.	Modeling/persuasion (influencing beliefs/ confidence)	Utilize clinical champions: Identify a respected, motivated HA to demonstrate successful patient counseling sessions to peers.
Increase In-charge's confidence in managing the supply chain.	Reinforcement/ restructuring (process improvement)	Develop a medicine stock management system: Institute a bi-weekly checklist/ logbook specifically for diabetes medications and assign a dedicated staff member.
Overcome patient financial/literacy barriers.	Information provision/ facilitation	Provide patient education materials: Develop culturally appropriate visual job aids in Nepali and link patients to government subsidized medicine schemes.

Task 4: Produce implementation protocols and materials

- Training materials: Create a laminated, pocket-sized, protocol flowchart in Nepali summarizing the 4-step treatment algorithm for MOs/HAs.
- Supply chain protocol: Create a bi-weekly inventory logbook and set explicit reorder points for diabetes medications (e.g., when stock hits a 4-week supply, trigger an order).
- Counseling materials: Design a simplified, pictorial diet counseling card (focusing on local foods like Dāl-Bhāt and seasonal vegetables) for ANMs to use with patients to address low health literacy.

Task 5: Evaluate implementation outcomes

Evaluation Focus: Measure the effectiveness of the chosen implementation strategies.

Metrics:

- Fidelity: Audit a sample of patient charts monthly to track the percentage of times the 4-step treatment algorithm was correctly followed (measuring the impact of the training strategy).
- Acceptability: Conduct a post-implementation survey with ANMs/HAs to measure changes in their perceived self-efficacy and attitude toward providing counseling (measuring the impact of the clinical champion strategy).
- Sustainability: Track the percentage of days over the month that all essential diabetes medications were in stock at the PHC (measuring the impact of the stock management system strategy).

Concept mapping with stakeholders

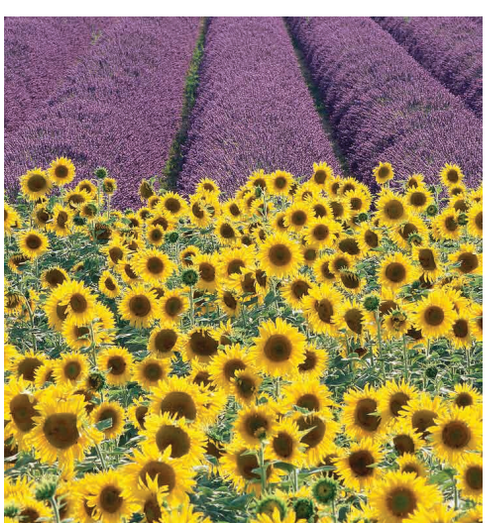
The process of concept mapping with stakeholders to decide implementation strategies begins by clearly defining the objective of the session, such as selecting the most effective strategies for a new program. Next, diverse stakeholders including frontline staff, managers, and clients are identified and invited to ensure multiple perspectives are represented. Preparation involves gathering materials or digital tools and developing guiding questions to focus discussions. During the session, participants brainstorm potential strategies, which are then organized into clusters or themes, highlighting relationships and dependencies. Stakeholders collaboratively prioritize strategies based on feasibility, impact, and alignment with needs. The ideas are visualized in a concept map, and the map is reviewed and validated by all participants to ensure accuracy and consensus. Finally, the concept map is used to guide the implementation plan, assign responsibilities, and monitor progress.[69]

Table 14: Example of implementation of type 2 diabetes protocol in PHC, Nepal

Step	Description	Example: Type 2 diabetes protocol in PHC, Nepal
Define objective	Clarify the goal of the session a	Goal: Implement a standardized diabetes management protocol.
Identify stakeholders	Include diverse perspectives (staff, managers, patients).	PHC doctors, nurses, health assistants, community health volunteers (FCHVs), district health officers, and patient representatives.
Prepare materials and tools	Gather physical or digital tools; prepare guiding questions.	Whiteboard or flip charts, sticky notes, markers; guiding questions like “What challenges prevent staff from following the protocol?” or “What support do patients need?”
Generate ideas	Brainstorm all possible strategies without judgment.	Conduct staff training workshops, create easy-to-use flowcharts, provide patient education leaflets, ensure availability of glucose testing kits and essential medications, involve FCHVs for follow-up, use mobile reminders for appointments.
Organize and categorize concepts	Group similar ideas and identify relationships.	Clusters: Staff capacity (training, flowcharts), resources and infrastructure (glucose kits, medications), patient engagement (education leaflets, mobile reminders), community support (FCHV follow-ups).
Prioritize strategies	Decide which strategies are most feasible and impactful.	Prioritize strategies that address the most critical barriers first: staff training and medication supply for immediate needs, then patient education and mobile follow-ups.
Create concept map	Visualize the clusters, connections, and priorities.	Map linking staff training to proper protocol use, medication availability to treatment adherence, and FCHV follow-ups to improved patient outcomes.
Review and validate	Share the map with stakeholders and revise as needed.	Stakeholders confirm that the map accurately reflects critical barriers, feasible strategies, and local priorities.
Plan next steps	Use the map to guide implementation and assign responsibilities.	Assign training sessions to nurses, manage procurement of medications, coordinate FCHV follow-ups, and schedule evaluation after 3-6 months.

*****END OF MODULE 4*****

Module 5: Stakeholder Engagement



STAKEHOLDER ENGAGEMENT

Stakeholder engagement is a cornerstone of successful implementation research, ensuring that research findings are relevant, feasible, and sustainable in real-world settings. It involves actively involving individuals or groups who are affected by, responsible for, or have an interest in the implementation process, such as patients, healthcare providers, policymakers, community leaders, and organizational staff. Engaging stakeholders helps identify barriers and facilitators to implementation, informs the selection and adaptation of strategies, and fosters buy-in and shared ownership of interventions.

Effective stakeholder engagement is iterative and collaborative, involving consultation, co-design and ongoing communication throughout the research process. By incorporating diverse perspectives, implementation research can produce context-sensitive strategies, improve intervention uptake, and enhance the likelihood of sustained impact in practice.

A key principle for engaging stakeholders is to "begin with the end in mind." IR benefits from multiple perspectives, so involving a diverse group of people early is important. Some useful guidelines for stakeholder engagement include:[35]

- ✓ Engage stakeholders early and frequently
- ✓ Include underrepresented groups and a variety of perspectives
- ✓ Present issues in ways that align with stakeholders' values and mission
- ✓ Recognize stakeholders as valuable sources of information and connectors to others

Purpose of stakeholder engagement in implementation research

Stakeholder collaboration is a two-way exchange of information:

- ✓ Stakeholders to researchers: Stakeholders contribute essential contextual knowledge about workflows, cultural norms, resources, and constraints that shape how interventions function in real-world settings. They help identify key barriers and facilitators, improve access to and quality of data, and support timely problem-solving and iterative adaptation during implementation. Their input strengthens feasibility and uptake, refines research questions and methods, enhances interpretation of findings through contextual nuance, and promotes ethical legitimacy and equity by ensuring the perspectives of diverse and marginalized groups are meaningfully represented.[70-72]
- ✓ Researchers to stakeholders: Researchers provide evidence and analytic insights that support informed programmatic and policy decisions. By sharing implementation-relevant findings, they help stakeholders improve delivery, plan for scale-up, and sustain interventions in routine practice. Researchers also build local capacity in data use, monitoring, and evaluation, foster trust and ownership through transparent communication, and support stakeholders in acting as champions who translate evidence into policy and practice.[62,73]

Stakeholder engagement process

Stakeholder engagement in implementation research is continuous, iterative process aligned with the stages of implementation rather than a single activity. John M. Bryson and colleagues (2011) has recommended the following structured stepwise stakeholder engagement process:[74]

Step 1. Start with a broad definition of stakeholders: Begin by identifying all individuals, groups, or organizations who affect or are affected by the program or its evaluation. Do not limit stakeholders only to program staff or funders. Include decision-makers, implementers, beneficiaries, community members, and others who may have an interest in or be impacted by the findings.

Step 2. Identify and map key stakeholder groups: Systematically list stakeholder groups and categorize them (e.g., decision authority, implementers, beneficiaries, those indirectly affected). The goal is to ensure no important perspective is overlooked before narrowing the focus.

Step 3. Analyze stakeholder interests, influence, and perspectives: Assess each stakeholder group's interests, concerns, expectations, power, and influence related to the program and the evaluation. This analysis helps reveal where support, resistance, or conflict may arise and which voices carry decision-making authority.

Step 4. Identify primary intended users of the evaluation: From the broader stakeholder list, identify a smaller group of primary intended users-those who are most likely to use the evaluation findings for decision-making. Because no evaluation can answer all questions equally well, this step helps focus the evaluation on the most relevant uses.

Step 5. Engage stakeholders in shaping the evaluation design: Use the stakeholder analysis to inform key evaluation design decisions, including evaluation questions, methods, outcomes, and interpretation plans. Engagement at this stage increases relevance, feasibility, and eventual use of findings.

Step 6. Select and apply appropriate stakeholder engagement techniques: Choose practical techniques (e.g., workshops, interviews, influence diagrams, prioritization exercises) based on the stage of the evaluation and stakeholder needs. These techniques should support dialogue, clarify assumptions, and surface diverse perspectives.

Step 7. Use stakeholder insights during implementation and analysis: Continue engaging stakeholders during data collection and analysis to help interpret findings, explain unexpected results, and provide contextual understanding. This supports both technical rigor and political realism.

Step 8. Validate and interpret findings with stakeholders: Share preliminary findings with stakeholders through validation or co-interpretation sessions. This helps confirm accuracy, refine interpretations, and ensure findings align with lived experience and contextual realities.

Step 9. Support use of findings and learning: Finally, work with stakeholders to apply findings in decision-making, program improvement, or policy change. Attention to stakeholder engagement throughout the process increases the likelihood that evaluation results will be used, not just reported.

Stakeholder matrix

A stakeholder matrix is a practical planning and management tool used to systematically identify, analyze, and engage stakeholders who can influence or are affected by a program or research initiative. The matrix helps researchers and program teams move

beyond simply listing stakeholders to understanding their roles, interests, capacities, and constraints, and to designing appropriate engagement strategies for each group. In implementation research, a stakeholder matrix is especially useful for anticipating implementation challenges, aligning strategies with system realities, and strengthening ownership and use of findings.

The matrix has the following components

- ✓ **Name of stakeholder:** Identifies the organization or group involved in or affected by the program. This ensures transparency about who has a stake in implementation and outcomes.
- ✓ **Stakeholder description:** Briefly explains who the stakeholder is and their position within the health system or community (e.g., national policymaker, frontline provider, community volunteer, beneficiary).
- ✓ **Potential role in program implementation:** Describes how the stakeholder contributes to implementation, such as policy approval, service delivery, supervision, coordination, or community engagement. This column clarifies who does what in practice.
- ✓ **Level of knowledge of the issue:** Assesses how familiar the stakeholder is with the health issue or intervention. This helps identify where training, orientation, or information sharing is needed.
- ✓ **Level of commitment:** Indicates the stakeholder's motivation or willingness to support the program. High commitment suggests readiness to engage, while moderate or variable commitment signals the need for targeted engagement or incentives.
- ✓ **Available resources:** Lists resources the stakeholder can contribute, such as staff, funding, infrastructure, technical expertise, or social capital. This helps leverage strengths already present in the system.
- ✓ **Limitations:** Identifies constraints that may affect participation or performance, such as workload, limited funding, bureaucratic processes, or capacity gaps. Recognizing limitations early helps design realistic implementation strategies.
- ✓ **Engagement activities:** Specifies tailored strategies for engaging each stakeholder, such as consultations, trainings, workshops, feedback sessions, or community meetings. This ensures engagement is intentional rather than ad hoc.

The stakeholder matrix supports strategic engagement by matching engagement approaches to stakeholder roles, capacities, and constraints. For example, high-level actors like the Ministry of Health and Population may require policy dialogues and formal consultations, while frontline providers benefit more from hands-on training and feedback sessions. Community volunteers and patients may need empowerment, education, and trust-building activities rather than technical briefings.

Overall, the stakeholder matrix serves as a living tool that guides planning, implementation, and evaluation. It helps ensure that stakeholders are engaged in ways that are appropriate, feasible, and meaningful, thereby increasing the likelihood of successful implementation, sustainability, and use of results.

Table 15: Stakeholders' matrix example

Name of stakeholder	Stakeholder description	Potential role in program implementation	Level of knowledge of the issue	Level of commitment	Available resources	Limitations	Engagement activities
Ministry of Health and Population (MoHP)	National government, responsible for health policy and funding	Provide guidance, approve protocol, allocate resources	High - develops and oversees national health programs	High - strong supporter of standardized care	Staff, program frameworks, budget allocation	Bureaucratic delays, limited local oversight	Regular consultations, program briefings, feedback on draft protocol
District Health Office (DHO)	Regional administration of MoHP	Monitor implementation, coordinate PHC activities	Medium - familiar with diabetes care but may need updates on new protocol	Moderate - generally supportive but balancing multiple priorities	Staff for monitoring, reporting systems	Limited funds, workload pressure	Meetings, training sessions, progress reviews
PHC doctors and nurses	Local healthcare providers delivering care	Implement protocol, provide feedback	High - clinical knowledge, but may need training on new guidelines	Moderate to High - supportive if feasible and practical	Clinical staff, patient records, basic equipment	Staff shortages, limited time, resistance to workflow changes	Workshops, hands-on training, refresher sessions, feedback sessions
FCHVs	Community-level health workers	Educate patients, support follow-up and adherence	Medium - some knowledge of diabetes management	High - motivated to support community health	Volunteer network, local connections, community trust	Limited formal training, no compensation	Training workshops, community meetings, home visits
Patients with type 2 diabetes	Beneficiaries of the program	Follow treatment, provide feedback on acceptability	Low to Medium - may know general care but not standardized protocol	Variable - some motivated, some indifferent	Personal experience, adherence feedback	Literacy barriers, travel distance, financial constraints	Patient education sessions, focus group discussions, reminder calls/ SMS
Local NGOs / Health programs	Non-governmental organizations active in health	Support training, provide technical expertise, community outreach	Medium - knowledge of local context and health programs	High - supportive of improving care quality	Staff, funding, health education materials	Limited reach, project-specific funding	Collaborative workshops, community campaigns, monitoring support
Local government / municipality	Local administrative body	Facilitate logistics, infrastructure support	Low - not directly involved in clinical care	Moderate - supportive if aligns with local priorities	Meeting spaces, coordination support	Competing priorities, limited health expertise	Coordination meetings, advocacy briefings

Reporting evaluating stakeholder engagement

Evaluating stakeholder engagement: Evaluating stakeholder engagement involves assessing how well the engagement process meets stakeholders' expectations and needs. It examines whether all relevant groups were adequately represented, the extent to which stakeholders were actively involved, and whether the methods and channels used for engagement were effective and accessible. It also considers stakeholders' future expectations, as well as the benefits they gained and barriers they faced during the process. [57,5]

Stakeholder engagement in IR should lead to improved relevance, adoption, and sustainability of intervention in the practice setting. The process builds trust, enhances understanding of local needs, and increases the likelihood of research being effectively translated into practice. At each stage of engagement, the process (stakeholders' representation, channel of engagement, frequency, duration) and outcomes/benefits and challenges are documented. Also, the recommendations made by the stakeholders for future similar engagements are documented.

*****END OF MODULE 5****

Module 6: Identifying Contextual Determinants in Implementation Research

DESIGNING IMPLEMENTATION RESEARCH TO IDENTIFY CONTEXTUAL DETERMINANTS

Implementation research seeks to understand how, why, and under what conditions EBIs can be effectively adopted, integrated, and sustained in real-world settings. Central to this mission is the identification of contextual determinants, the barriers, facilitators, and environmental conditions that shape implementation outcomes. Because health systems are dynamic, multi-level, and influenced by political, social, cultural, and economic factors, IR must be intentionally designed to uncover these contextual realities rather than treat them as background noise. Contextual analysis is an important domain of IR. The insights from the contextual analysis will shape the design and help to adapt the intervention, choose the best strategies for rolling it out, guide in making sense of implementation and effectiveness results, and even inform on how to keep the research project going over the long term.

Step by step process for designing IR to identify contextual determinants

Step 1. Provide a clear problem statement including context, evidence-based intervention and implementation gap

When introducing an implementation research study, first clearly name the EBI or policy that will be implemented so readers understand exactly what is being studied and summarize the evidences supporting the EBI's effect on the health outcome. Next, describe the implementation gap, such as low adoption, poor fidelity, limited reach, lack of sustainability, or inequitable uptake, and explain why this gap matters for health outcomes or system performance. Then specify the context, including the country, level of the health system, types of facilities, and the key actors involved as implementers and beneficiaries. Finally, explain why contextual uncertainty is central to the study by identifying which features of the setting-such as resources, workforce capacity, organizational culture, governance, or social norms-are likely to influence implementation success or failure.

Example: Determining contextual barriers to HPV vaccination in Nepal

This proposal focuses on the HPV vaccination program, a well-established evidence-based intervention for the prevention of cervical cancer. Operationally, the EBI consists of administering the WHO-recommended HPV vaccine to adolescent girls aged 9-14 years prior to sexual debut. The vaccine is delivered through school-based vaccination sessions, with primary health care workers responsible for vaccine administration, cold-chain maintenance, documentation, and completion of the recommended dosing schedule in accordance with national immunization guidelines.

The effectiveness of HPV vaccination is strongly supported by randomized controlled trials and population-level evidence. Clinical trials have demonstrated greater than 90% efficacy in preventing persistent HPV infection and high-grade cervical precancerous lesions associated with vaccine-type HPV among HPV-naïve girls and young women.[75,76] Real-world evidence from countries with high vaccination coverage shows substantial reductions in HPV infections, cervical intraepithelial neoplasia, and invasive cervical

cancer, confirming the long-term public health impact of HPV vaccination[17,77] Based on this robust evidence, the World Health Organization recommends HPV vaccination as a core pillar of cervical cancer prevention and elimination, particularly in settings with a high burden of diseases.[78]

Despite the strong evidence supporting HPV vaccination and its inclusion in national immunization policies, coverage and completion of the HPV vaccine remain suboptimal in many low- and middle-income settings. In school-based delivery models, gaps persist due to incomplete reach among eligible girls, particularly those who are out of school or irregularly attending, missed or delayed doses, and inequities by geography, socio-economic status, and school type. Additional challenges include variability in caregiver awareness and acceptance, inconsistent school-health system coordination, and constraints in primary health care workforce capacity during vaccination periods. These gaps limit the population-level impact of an otherwise highly effective intervention and underscore the need to understand how contextual factors shape real-world delivery and uptake of HPV vaccination.

Contextual uncertainty is central to this study because HPV vaccination is delivered within a complex implementation environment shaped by multiple interacting factors. These include variability in primary health care workforce capacity, competing service delivery demands during vaccination periods, and challenges in coordination between schools and the health system. Additional contextual influences include caregiver knowledge and acceptance of HPV vaccination, social norms related to adolescent girls' health and sexuality, and local governance and municipal-level planning capacity. Together, these contextual features are likely to shape adoption, reach, fidelity, and equity of HPV vaccine delivery. Understanding how these determinants operate in real-world settings is essential to closing the gap between the proven effectiveness of HPV vaccination and its population-level impact.

Step 2. Select and justify implementation research TMF

Choose a primary determinant framework and explicitly justify its selection in relation to your setting, EBI, and implementation outcomes of interest. Different frameworks focus on different themes or approaches. For example,

- ✓ **Consolidated Framework for Implementation Research:** Focuses on organizational and system-level factors, such as leadership support, resources, and culture. Useful for understanding how the environment shapes implementation.[46]
- ✓ **Theoretical Domains Framework:** Focuses on behavioral determinants, like knowledge, beliefs, skills, and motivation of the people delivering or receiving the intervention. Useful for identifying why individuals behave in certain ways.[79]
- ✓ **Practical, Robust Implementation and Sustainability Model:** Combines contextual factors with RE-AIM outcomes (Reach, Effectiveness, Adoption, Implementation, Maintenance). Helps connect context to measurable implementation results.[51]
- ✓ **Capability, Opportunity, Motivation-Behavior:** Focuses on three key drivers of behavior: whether people have the capability to perform the behavior, the opportunity to do so in their environment, and the motivation to engage in it. Useful for designing interventions that address behavioral barriers. The complete list of theories, models, and frameworks can be found in the following website.[61]

Select a framework that can capture the multilevel contextual factors most relevant to how the EBI is delivered in routine practice (e.g., individual, organizational, and system-level determinants) and that aligns with the specific implementation outcomes being examined, such as adoption, fidelity, reach, equity, or sustainment. Clearly explain how the chosen framework will guide the study design, including (a) tool development, by informing the domains and constructs incorporated into interview guides, surveys, and observation tools; (b) sampling, by supporting purposive selection of stakeholders, sites, and system levels that reflect key contextual variation; and (c) coding and analysis, by providing a deductive structure for organizing and interpreting data while allowing inductive identification of context-specific determinants. This ensures that the assessment of contextual barriers and facilitators is systematic, theory-informed, and directly linked to implementation outcomes.

Example of CFIR for identifying contextual barriers and facilitators

For this study, we will use the CFIR[46] as the primary determinant framework to examine contextual barriers and facilitators to the implementation of the school-based HPV vaccination program. CFIR is well suited to this EBI because HPV vaccination is delivered through routine public-sector systems and requires coordination across multiple levels, including the national immunization program, primary health care facilities, and schools. In this setting, implementation outcomes such as adoption of school-based delivery, fidelity to vaccine administration and cold-chain procedures, reach among eligible adolescent girls, and equitable coverage across geographic and socio-demographic groups are shaped by interacting individual-, organizational-, and system-level factors, which CFIR is designed to capture.

CFIR will guide tool development by informing the content and structure of qualitative and quantitative data collection instruments, including interview guides for health workers, school staff, and caregivers; observation checklists for vaccination sessions; and surveys assessing organizational readiness and perceived barriers. The framework will inform sampling through purposive selection of stakeholders across CFIR domains (e.g., frontline vaccinators, supervisors, school administrators, local health managers, parents, and adolescents) and selection of schools and health facilities that vary by urban-rural context, workload, and prior vaccination performance. For coding and analysis, CFIR will be applied as a deductive analytic framework to organize data into predefined domains and constructs, while allowing inductive identification of context-specific determinants. This approach will enable systematic comparison across sites and clear linkage of contextual determinants to observed variation in HPV vaccination implementation outcomes, generating actionable evidence to inform subsequent adaptation and scale-up.

Step 3. State aims and research questions

Select two-four implementation outcomes to detect meaningful variation in the implementation of the school-based HPV vaccination EBI, such as adoption, fidelity, reach, and acceptability. Variation in these outcomes across schools, facilities, and geographic settings will be used as an analytic lens to reveal underlying contextual determinants, including differences in workforce capacity, school-health sector coordination, community norms, and system support.

Guided by these outcomes, the study aims are framed to identify, explain, and prioritize contextual determinants of implementation. Specifically, the aims are to (1) identify multilevel contextual barriers and facilitators influencing the implementation of the school-based HPV vaccination program; (2) explain how interactions among individual-, organizational-, and system-level determinants shape variation in adoption, fidelity, reach, and acceptability; and (3) prioritize key contextual determinants that are most amenable to change within real-world immunization system constraints, based on their importance, feasibility, and implications for equity. This integrated approach ensures that assessment of context is directly linked to observable implementation performance and generates actionable evidence to inform subsequent implementation strategy selection and scale-up.

Example research questions are:

- To identify multilevel contextual barriers and facilitators influencing the adoption of the school-based HPV vaccination program delivered by primary health care workers to adolescent girls aged 9-14 years.
- To assess differences in contextual determinants of HPV vaccine adoption
- To prioritize the most salient and actionable contextual determinants for targeting with future implementation strategies to improve HPV vaccination adoption.

Step 4. Choose study design

When the primary objective of implementation research is to identify contextual determinants (barriers and facilitators) of an EBI, select a study design that prioritizes explanation over causal attribution and is explicitly aligned with determinant frameworks (e.g., CFIR, TDF/COM-B). Begin by confirming that the study is positioned in the formative or early implementation phase, where understanding why implementation varies across settings is the central goal, rather than testing the effectiveness of an implementation strategy.

Choose observational, qualitative, or mixed-methods designs that can capture natural variation in implementation outcomes (e.g., adoption, fidelity, reach, acceptability) across sites, populations, or time. Appropriate designs include cross-sectional or longitudinal qualitative studies, comparative case studies across multiple sites, embedded process evaluations, or convergent or sequential mixed-methods designs that integrate quantitative implementation outcome data with qualitative inquiry. Avoid experimental designs unless they are explicitly needed to create variation; randomization is not required to identify determinants and may obscure real-world contextual influences.

The list and short description of study designs are listed in Annex III.

Example of study design

We will conduct a multisite comparative mixed-methods determinants study using a convergent design to identify and explain multilevel contextual barriers and facilitators influencing adoption, fidelity, and reach of the school-based HPV vaccination program delivered by primary health care workers to girls aged 9-14 years. We will purposively select districts and schools to maximize contextual variation by geography (urban vs. rural)

and school type, and we will ensure representation of equity-relevant subgroups (caste/ethnicity and socioeconomic strata). Quantitatively, we will compile routine program data and/or facility-school records to measure variation in adoption (implementation of school sessions), fidelity (adherence to delivery, cold-chain, documentation, and dosing procedures), and reach (coverage among eligible girls), stratified by the contextual dimensions above. Qualitatively, we will conduct in-depth interviews and/or focus groups with key stakeholder groups (vaccinators/primary health care workers, supervisors, local health managers, school administrators and teachers, parents/caregivers, and adolescents where appropriate) and conduct structured observations of vaccination sessions to document workflow, coordination, and contextual influences. Guided by a determinant framework (e.g., CFIR), we will integrate quantitative and qualitative findings through joint displays and cross-case comparison to explain how determinants differ across contexts and how they relate to observed implementation performance. Finally, we will prioritize determinants using a structured prioritization process (e.g., stakeholder co-interpretation workshop and/or a Delphi-style ranking) that rates determinants by importance, feasibility/actionability within current system constraints, and equity impact, generating a short list of high-priority determinants to target with future implementation strategies.

Step 5. Define study population and sampling

Define the study population to include multiple stakeholder groups who directly or indirectly influence the adoption and delivery of the evidence-based intervention (EBI), ensuring a comprehensive assessment of contextual determinants. Include implementers (e.g., frontline providers, community health workers, or clinical staff responsible for delivering the EBI), recipients (patients or community members whose experiences and perceptions shape uptake and adherence), managers and supervisors (facility or program leaders who influence organizational processes, resource allocation, and support), and, where relevant, policymakers or decision-makers who affect program design, financing, and system-level support. Use a purposeful sampling strategy to ensure rich and relevant information, applying maximum variation sampling to capture heterogeneity across key contextual dimensions such as geographic setting (urban vs. rural), facility type, provider role, training or experience, and participant demographics (e.g., age, gender, socioeconomic status).

For qualitative components, apply purposive and maximum variation sampling to capture diverse perspectives, continuing data collection until thematic saturation is achieved. As a guideline, plan for approximately 15-25 in-depth interviews per stakeholder group or 3-5 focus groups per group, with final sample sizes adjusted based on emerging data.80,81 For quantitative components, draw on larger samples to assess the prevalence and magnitude of contextual determinants, using stratified or cluster sampling to ensure representation across facilities, provider types, and population subgroups. Calculate sample size using standard statistical methods to detect meaningful differences or associations with adequate power (e.g., 80%) and significance (e.g., $\alpha = 0.05$), accounting for clustering and design effects as appropriate.

Example

Quantitative component: participants, sampling, and sample size

Unit of analysis and participants: The primary quantitative unit of analysis will be the school, with adoption defined as whether an eligible school initiated at least one school-based HPV vaccination session during the implementation period. Quantitative data will be extracted from routine program records rather than individual recruitment, including school vaccination registers/logs, EPI session reports, immunization registers, and administrative records maintained by the vaccinating health facility and municipal EPI teams.

Sampling frame and selection: We will construct a sampling frame of all eligible schools in Kathmandu District and select schools using stratified random sampling to ensure representation of community (government) and private schools, as well as variation by municipality/ward (urban and peri-urban areas). Each selected school will be linked to its corresponding vaccinating health facility (health post/PHCC) and EPI team to ascertain adoption status through documentation review.

Sample size estimation: Assuming an expected prevalence of adoption of 70% ($p = 0.70$), a 95% confidence level ($Z = 1.96$), and a desired absolute precision of 8 percentage points ($d = 0.08$), the required sample size was calculated using the single-proportion formula: $n_0 = Z^2 \times p \times (1 - p) / d^2$. Substituting values yields $n_0 \approx 127$ schools. To account for clustering by municipality and potential correlation in adoption decisions across schools served by the same health facility, we applied a conservative design effect of 1.10, resulting in an adjusted sample size of approximately 140 schools. Allowing for up to 15% incomplete or missing documentation, we will target a final sample of approximately 160 schools for the quantitative adoption analysis.

Qualitative component: participants, sampling, and sample size

Participants (who and why)

To identify multilevel contextual determinants influencing adoption, we will recruit stakeholders who directly influence or experience decisions to initiate school-based HPV vaccination in Kathmandu District, including:

- **Implementers:** vaccinators/ANMs and extended program on immunization (EPI) staff responsible for initiating and delivering school sessions;
- **Supervisors and managers:** health facility in-charges, EPI focal persons, and municipal public health officers (palika health section);
- Education-sector actors: school principals, management committee representatives, and designated teachers involved in approval, scheduling, and coordination;
- **Recipients and influencers:** parents/caregivers (including both consenters and refusers) and, where ethically approved, adolescent girls aged 9-14 years using appropriate assent procedures.

Sampling strategy

We will use purposive, maximum-variation sampling anchored to quantitative adoption status. Schools will be purposively selected from the quantitative sample to represent

high-adoption and low-/non-adoption schools, across community and private school types and different geographic areas. Stakeholders linked to these schools and their vaccinating facilities will then be recruited. This approach is designed to surface CFIR-based determinants that plausibly explain variation in adoption decisions.

Qualitative sample size

We anticipate conducting approximately 45-60 in-depth interviews (IDIs), distributed across stakeholder groups to capture perspectives at multiple implementation levels (e.g., ~15-20 implementers/supervisors, ~15-20 school actors, and ~15-20 parents/caregivers; with optional adolescent interviews if approved). Final sample size will be guided by thematic saturation within key stakeholder groups and by the analytic need to explain quantitative differences in adoption across schools and contexts.

Step 6. Data collection

Describe that data collection tools will be theory-informed, systematic, and aligned with an established implementation research framework. Begin by naming the primary framework (e.g., CFIR) and explaining that it guides tool development to ensure comprehensive coverage of contextual determinants across levels. State that qualitative tools (interview and FGD guides) will be explicitly structured around the framework domains. For example, specify that interview and FGD guides will be organized according to the five CFIR domains-intervention characteristics, outer setting, inner setting, characteristics of individuals, and implementation process-to enable systematic assessment of barriers and facilitators influencing implementation at individual, organizational, and community levels. Indicate that probes within each domain will be adapted to the local context and stakeholder group (e.g., implementers, supervisors, caregivers) while maintaining consistency with the underlying framework.

Describe the procedures used to ensure that all data collection tools are valid, reliable, and contextually appropriate for the study setting. Begin by explaining how validity will be established. State that expert review will be conducted with implementation science researchers, subject-matter experts, and local practitioners to assess content validity, confirm alignment with the selected theoretical framework (e.g., CFIR), and ensure contextual appropriateness for the Nepali primary health care setting. Indicate that tools will be pre-tested using cognitive interviewing and pilot testing to assess clarity, cultural relevance, and correct interpretation of items by intended respondents. Note that construct validity will be examined by assessing whether individual items map coherently onto predefined theoretical domains and behave as expected within those domains.

Next, explain how reliability will be ensured. State that all quantitative tools will be piloted to assess internal consistency (for example, using Cronbach's alpha for multi-item scales) and, where feasible, test-retest reliability. Describe steps to minimize measurement error, including standardized training of data collectors, use of detailed field manuals, and calibration exercises to reduce inter-observer variability, particularly for observation and checklist-based tools. Emphasize ongoing supervision and quality control procedures, such as routine data checks and field monitoring, to ensure consistency across sites.

Conclude by describing pilot testing and refinement as an iterative process. State that all qualitative and quantitative instruments will be piloted with a small sample of participants representing key stakeholder groups. Explain that feedback from pilot testing will be used to refine wording, sequencing, probes, and response options, ensuring that tools are understandable, culturally appropriate, and capable of accurately capturing contextual determinants across diverse implementation settings.

Example of HPV vaccine

Data collection tools for this study will be systematically developed using the CFIR, with a specific focus on identifying contextual determinants of adoption of the HPV vaccination program. Adoption is defined as the decision and initial action by implementers and organizations (e.g., health facilities, schools, and local authorities) to initiate and support delivery of HPV vaccination as intended. Using CFIR ensures that data collection tools comprehensively capture multilevel factors influencing adoption across individual, organizational, community, and policy contexts.

Qualitative tools, including in-depth interview and FGD guides, will be structured around the five CFIR domains, with questions explicitly oriented toward understanding why, how, and under what conditions HPV vaccination is taken up by implementers and institutions. Under Intervention Characteristics, questions will explore perceived relative advantage, complexity, and adaptability of HPV vaccination and school-based delivery models, such as: “What makes your school or facility willing or unwilling to initiate HPV vaccination sessions?”, “Which aspects of planning and delivering HPV vaccination make it easier or harder to start implementation?”, and “How does HPV vaccination compare to other immunization or adolescent health activities in terms of effort and benefit?”

The outer setting domain will examine external influences on adoption, including caregiver demand, social norms, and policy signals, with questions such as: “How do community perceptions and parental consent affect decisions to initiate HPV vaccination sessions?”, “What national or municipal policies, targets, or reporting requirements influence whether schools and facilities adopt HPV vaccination?”, and “Are there external incentives or pressures that encourage or discourage early uptake?”

The inner setting domain will focus on organizational readiness and support for adoption, including leadership engagement, implementation climate, and coordination mechanisms. Example questions include: “How do leadership support and municipal planning influence the decision to introduce HPV vaccination in your school or facility?”, “How well do existing workflows and coordination between schools and health facilities support starting HPV vaccination?”, and “What resource constraints (staffing, time, transport, cold chain) affect your ability to initiate sessions?”

Under characteristics of individuals, questions will assess implementers’ knowledge, beliefs, self-efficacy, and motivation related to adoption, such as: “How confident do you feel in initiating HPV vaccination activities?”, “What beliefs about vaccine safety, effectiveness, or community response influence your willingness to adopt the program?”, and “What training or experience would increase your readiness to begin implementation?”

The process domain will examine planning and engagement activities that enable or hinder adoption, with questions including: “How were schools, health workers, and local leaders involved in planning HPV vaccination?”, “What steps were taken to prepare for the first vaccination session?”, and “How does early feedback or monitoring influence decisions to continue or expand HPV vaccination activities?”

Quantitative tools will include structured surveys and adoption readiness checklists mapped to CFIR constructs to quantify determinants of adoption across sites. These may measure leadership support, perceived priority of HPV vaccination, training exposure, clarity of roles, availability of start-up resources, perceived caregiver acceptance, and initial willingness to conduct sessions. Facility- and school-level adoption indicators (e.g., decision to conduct at least one HPV vaccination session, timeliness of first session, and proportion of planned schools initiating delivery) will be linked to these determinants. Together, the qualitative and quantitative tools will enable systematic identification and prioritization of contextual factors that influence the adoption of HPV vaccination, informing the selection of targeted implementation strategies to improve early uptake and scale-up.

Step 7. Data analysis plan

Quantitative data analysis

Quantitative analysis measures the magnitude, distribution, and relationships among key implementation determinants identified through structured surveys and checklists. After establishing the validity and reliability of the tools, the analysis typically begins with descriptive statistics to summarize variables such as frequency of supervision, availability of essential medications, perceived workload, or confidence in delivering the intervention. Inferential statistics-such as chi-square tests, t-tests, ANOVA, or regression models-help assess associations between determinants and implementation outcomes like fidelity, reach, or acceptability. Composite scores may be created for constructs such as organizational readiness or self-efficacy, followed by internal consistency checks (e.g., Cronbach’s alpha). Fidelity checklist data can be quantified to score adherence to core intervention components, allowing comparisons across facilities or over time. These quantitative findings allow researchers to prioritize determinants based on their strength, prevalence, and impact.

Qualitative data analysis

Qualitative data analysis is guided by the chosen implementation framework. Using CFIR, the analysis typically begins with deductive coding, where the CFIR domains and constructs serve as the initial coding structure. This systematic approach enables the classification of facilitators and barriers into predefined, theory-informed categories. It also supports transparency, consistency, and comparability across settings and studies. When a single framework does not fully capture the mechanisms underlying certain determinants, additional theories can be integrated. For example, if low self-efficacy emerges as a barrier (CFIR: Characteristics of Individuals), incorporating Social Cognitive Theory helps explain the mechanisms driving self-efficacy and points to more targeted solutions. Synthesizing and presenting findings by CFIR domains-such as Intervention Characteristics, Inner Setting, and Outer Setting-provides a coherent narrative and allows

stakeholders to quickly identify which categories of determinants are most influential. Linking identified barriers directly to theory-informed implementation strategies ensures that findings translate into practical guidance for improving adoption, delivery, and sustainability of interventions.

Mixed-methods integration

Mixed-methods integration strengthens interpretation by combining numerical trends with contextual explanations. Integration may occur through merging (comparing qualitative themes with quantitative results), connecting (using one dataset to inform the analysis of the other), or embedding (using qualitative insights to explain unexpected quantitative findings). For example, survey results may show high reported availability of medications, while interviews reveal frequent stock-outs due to supply chain delays-highlighting implementation gaps that numbers alone cannot capture. Joint displays, which align CFIR constructs, quantitative indicators, and implementation outcomes, help visualize convergence, divergence, and complementarity across data sources. This integrated approach yields a comprehensive understanding of barriers and facilitators and supports the development of more nuanced, targeted, and theory-informed implementation strategies.

Example data analysis plan

This study will use a convergent mixed-methods approach, guided by the CFIR, to examine multilevel contextual determinants influencing adoption of the school-based HPV vaccination program delivered by primary health care workers to adolescent girls aged 9-14 years in Kathmandu District.

Quantitative analysis: Quantitative analysis will assess the magnitude and distribution of adoption and its association with CFIR-informed contextual determinants. Adoption will be operationalized at the school level as initiation of at least one HPV vaccination session during the implementation period (yes/no). Survey and checklist items will be mapped a priori to relevant CFIR constructs across domains, including Intervention Characteristics (e.g., perceived complexity, adaptability), Outer Setting (e.g., policy support, parental acceptance, school-health sector coordination), Inner Setting (e.g., leadership engagement, available resources, implementation climate), Characteristics of Individuals (e.g., knowledge, self-efficacy, beliefs about HPV vaccination), and Process (e.g., planning, engagement of school leadership and parents). Descriptive statistics will summarize adoption prevalence and CFIR determinants overall and by geography (urban vs. peri-urban), school type (community vs. private), and equity-relevant subgroups (caste/ethnicity and socioeconomic status). Bivariate analyses (chi-square tests and t-tests or non-parametric equivalents) will examine unadjusted associations between CFIR constructs and adoption. Multivariable logistic regression models will then be fitted to estimate independent associations between prioritized CFIR constructs and adoption, adjusting for prespecified covariates and accounting for clustering at the municipality or health facility catchment level using robust standard errors or mixed-effects models. Interaction terms will be used to assess whether associations differ by equity-relevant subgroups, with stratified results presented were meaningful.

Qualitative analysis: Qualitative data from in-depth interviews, focus group discussions, and observations will be analyzed using directed content analysis, with CFIR domains and constructs serving as the initial coding framework. Coding will focus on identifying how determinants within each CFIR domain function as barriers or facilitators to adoption, such as school leadership engagement, alignment with school calendars, parental consent processes, workload and staffing constraints, intersectoral coordination, and clarity of planning and communication. Transcripts will be coded by at least two analysts, with discrepancies resolved through discussion and analytic memoing to enhance rigor. Findings will be synthesized by CFIR domain and compared across school types, geographic contexts, and equity-relevant groups to identify differential mechanisms influencing adoption decisions.

Mixed-methods integration: Quantitative and qualitative findings will be integrated by mapping results from both strands onto shared CFIR constructs and the adoption outcome. Joint displays will be developed to compare quantitative associations with qualitative explanations, allowing assessment of convergence, complementarity, and divergence. Qualitative findings will be used to explain quantitative patterns, particularly where adoption varies across contexts or equity-relevant subgroups.

Step 8. Validate findings with stakeholders

Preliminary findings should be shared with stakeholders to obtain meaningful feedback and ensure interpretations align with local realities. This can be done through member-checking, co-interpretation sessions, or validation workshops that invite participants, implementers, and community representatives to review and reflect on the results. Through these collaborative processes, researchers can refine or adjust their interpretations to better capture lived experiences, contextual nuances, and practical considerations, ultimately strengthening the validity and relevance of the study's conclusions.

Step 9. Use the findings from the contextual determinants research

Once contextual barriers and facilitators have been identified, the next step is to move from understanding context to acting on it in a systematic and deliberate manner. Rather than attempting to address all determinants simultaneously, teams typically begin by prioritizing those that are most likely to influence implementation success. Structured approaches such as ranking exercises, facilitated voting, or consensus-building techniques-including the Nominal Group Technique or Delphi method82-are commonly used to support this process. These approaches encourage transparent discussion and collective judgment about which determinants are most important, feasible to address, modifiable within existing constraints, and urgent, ultimately producing a focused and actionable set of priorities.

With prioritized determinants in hand, attention then turns to selecting implementation strategies that are well matched to the local context. Methods such as the ERIC-CFIR matching tool or implementation mapping68 can support this step by helping teams systematically link specific barriers and facilitators to strategies that have been used to address similar challenges in other settings. Importantly, this alignment process is not purely technical; it benefits greatly from the active involvement of stakeholders. Engaging

practitioners, community members, managers, and policymakers in the co-design of implementation strategies helps ensure that selected approaches are realistic, culturally appropriate, and responsive to everyday workflows, while also fostering ownership and long-term sustainability.

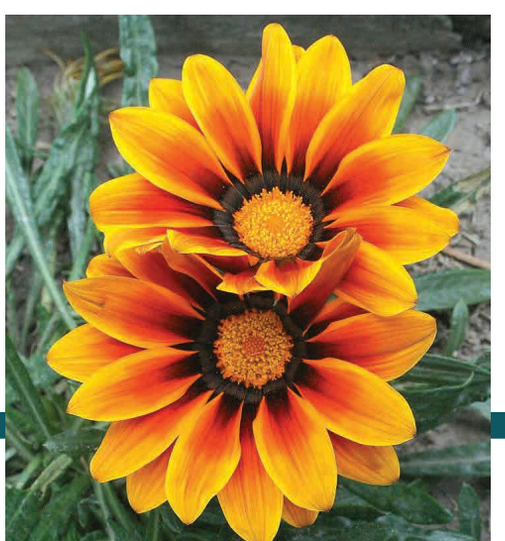
Throughout this process, it is essential to clearly document the rationale for strategy selection. Articulating why particular strategies were chosen-how they respond to prioritized contextual determinants, and how they draw on existing evidence-enhances transparency, supports learning across settings, and strengthens the interpretability of implementation findings. Insights gained from contextual analysis should also be used to adapt workflows, training, supervision, communication channels, and, where necessary, policies to better support implementation in the local environment. Finally, context identification should not be treated as a one-time activity. Because implementation settings evolve over time, ongoing monitoring and periodic reassessment of contextual determinants are critical. Viewing context as part of a continuous learning process allows teams to refine strategies as conditions change, increasing the likelihood of sustained and effective implementation.

Stakeholder engagement in designing and conducting implementation research to explore contextual determinants

Stakeholder engagement is a cross-cutting and essential element in designing implementation research to identify contextual determinants, as it ensures that studies are grounded in real-world systems, practices, and priorities. Engaging stakeholders-including implementers, managers, educators, caregivers, community members, and policymakers-from the outset strengthens problem definition by aligning the implementation gap with lived experience and local realities. Throughout study design, stakeholder input informs framework selection, sampling strategies, outcome prioritization, and tool development, ensuring that contextual factors at individual, organizational, and system levels are meaningfully captured. During data collection and analysis, stakeholders enhance validity by helping interpret variation in implementation outcomes, explain unexpected findings, and contextualize quantitative and qualitative results. Engagement in validation and co-interpretation activities further ensures that identified barriers and facilitators accurately reflect local conditions rather than external assumptions. Finally, stakeholder participation is critical for prioritizing contextual determinants and selecting feasible, acceptable, and equity-sensitive implementation strategies, supporting adaptation, scale-up, and sustainability. Treating stakeholder engagement as an ongoing partnership rather than a discrete activity strengthens both the scientific rigor and practical impact of implementation research.

*****END OF MODULE: 6*****

Module 7: Assessing Implementation Strategies on Outcome



DESIGNING IMPLEMENTATION RESERCH TO ASSESS EFFECTS OF IMPLEMENTATION STRATEGIES ON IMPLEMENTATION OUTCOME

A central goal of implementation research is to understand not only how evidence-based interventions are delivered in real-world settings, but also which implementation strategies work, for whom, and under what conditions. While descriptive studies are essential for identifying implementation challenges, progress in the field depends on rigorous research that tests the effects of implementation strategies on key implementation outcomes such as adoption, fidelity, reach, and sustainment.

Testing implementation strategies goes beyond simply describing how an intervention is delivered. The focus shifts to whether and how a specific strategy improves implementation success, operationalized in terms of implementation outcomes. In this approach, implementation strategies are treated as the independent variables, implementation outcomes (e.g., adoption or fidelity) are the primary dependent variables, and the evidence-based intervention itself is held constant. The explicit goal is to support causal inference, allowing researchers to determine whether observed changes in implementation outcomes can be attributed to the strategy being tested.

Step by step process for designing studies to test implementation strategies

Step 1. Clearly define the EBI and the implementation gap

As in all implementation research, the first step is to clearly define the evidence-based intervention (EBI) whose implementation is to be improved. The EBI should be described in practical terms, including its core components, who delivers it, where it is delivered, who it targets, and the expected dose or intensity. The EBI should be stable and already supported by evidence, as the purpose is not to test its effectiveness. The EBI is designed to address a clearly defined health problem, such as a high burden of preventable disease, poor health outcomes, or persistent health inequities in the target population. However, despite the availability of an effective intervention, the health problem often persists because the EBI is not consistently implemented in routine practice, leading to gaps such as low adoption, delayed initiation, or uneven uptake across settings or populations. Researchers must therefore clearly articulate both the underlying health problem the EBI addresses and the specific, measurable implementation problem that warrants the use of targeted implementation strategies.

Example:

Cervical cancer is a major public health problem that can be prevented through HPV vaccination. The HPV vaccine is a proven, evidence-based intervention that is effective when given to girls aged 9-14 years. In Nepal, the vaccine is delivered through school-based programs by primary health care workers under the national immunization system.

Despite this, cervical cancer risk remains high because HPV vaccination is not adopted in all eligible schools. Some schools do not initiate vaccination sessions due to poor

coordination between the health and education sectors, parental concerns, and health system constraints. As a result, many eligible girls miss timely vaccination. This reflects an implementation problem of low and uneven adoption, not a lack of evidence for the vaccine, highlighting the need for targeted implementation strategies to improve HPV vaccine adoption.

Step 2. Identify implementation determinants and select theory-informed implementation strategies and operationally define the strategy bundle

The second step is to identify implementation determinants, meaning the modifiable barriers and facilitators that explain why the implementation gap exists. These determinants should be identified using established frameworks such as CFIR, TDF, or COM-B, and informed by formative research or prior descriptive studies. Once determinants are identified, they should be explicitly linked to implementation strategies. Strategy selection should be theory-informed and based on how each strategy is expected to address specific determinants. For example, gaps in provider knowledge may be addressed through training, while weak accountability may require audit and feedback.

Implementation strategies should be clearly specified by describing who delivers the strategy, what is done, who or what is targeted, when and how often it occurs, its intensity, and the expected mechanism of action. This step ensures that implementation strategies are clearly defined and testable, rather than loosely described activities.

Example

We have already identified key implementation determinants influencing adoption of school-based HPV vaccination using the CFIR, informed by prior formative assessments, descriptive studies, and program experience. These determinants span multiple CFIR domains, including Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process, and represent modifiable barriers and facilitators explaining low and uneven adoption across schools.

Based on these identified determinants, we have selected implementation strategies using the CFIR-ERIC matching tool, ensuring systematic alignment between specific CFIR constructs and evidence-informed implementation strategies. The preliminary strategy package was then validated and refined through a structured co-design workshop with key stakeholders, including vaccinators, health facility in-charges, municipal EPI focal persons, school representatives, and program managers. This co-design process allowed stakeholders to assess the relevance, feasibility, and acceptability of each strategy within existing immunization system, workforce, and policy constraints, and to suggest context-specific adaptations.

All selected implementation strategies are fully specified to support rigorous testing. For each strategy, we clearly define the actor, action, target, temporality, dose or intensity, and expected mechanism of action. This approach ensures that the strategy package is theoretically grounded, contextually validated, and operationalized as a set of testable interventions designed to improve adoption of school-based HPV vaccination.

Table 16: Logical flow from determinants to implementation strategy, mechanism of action and implementation outcomes

CFIR domains	Priority determinant	Matched implementation strategy (ERIC)	Mechanism of action	Implementation outcomes
Intervention Characteristics	Perceived complexity of school-based HPV vaccination delivery	Develop and distribute educational materials; Create implementation protocols and tools (ERIC: #15, #28)	Simplifies processes, clarifies steps and roles, reduces uncertainty	Increased adoption
Outer Setting	Parental concerns and low community trust	Use mass media; Conduct local consensus discussions; Involve patients/consumers (ERIC: #37, #2, #13)	Improves knowledge, trust, and social acceptance	Increased adoption
Inner Setting	Weak coordination and variable leadership engagement across health and education sectors	Promote interorganizational collaboration; Identify and prepare champions (ERIC: #54, #18)	Strengthens leadership support, coordination, and shared accountability	Increased adoption
Characteristics of Individuals	Low confidence and knowledge gaps among vaccinators	Conduct educational meetings; Provide ongoing consultation (ERIC: #19, #32)	Builds self-efficacy and readiness to initiate school sessions	Increased adoption
Process	Limited advance planning and stakeholder engagement	Develop formal implementation blueprint; Conduct cyclical small tests of change (ERIC: #23, #14)	Improves planning, ownership, and timely initiation	Increased adoption

Table 17: Specification of the implementation strategies selected to improve adoption of school-based HPV vaccination.

Strategy (Name)	Definition	Actor (Who enacts?)	Actions (What is done?)	Action Target (What is changed?)	Temporality (When?)	Dose (How much?)	Theoretical Justification
Standardized HPV vaccination protocols and job aids	Development and dissemination of clear, standardized protocols, checklists, and job aids to guide school-based HPV vaccination delivery	Municipal EPI focal person; Health facility in-charge	Develop micro-plans; distribute protocols and job aids; orient vaccinators and school focal persons	Perceived complexity and clarity of vaccination delivery	Pre-implementation with reinforcement at rollout	One set of tools per school and facility; one orientation per cycle	Reducing perceived complexity increases compatibility and usability of EBIs, improving adoption[4]6
Parent and community engagement sessions	Structured engagement activities to improve parental knowledge, trust, and acceptance of HPV vaccination	Vaccinators; School leadership	Conduct school-based parent meetings; use standardized IEC materials; address myths and concerns	Parental attitudes, trust, and social norms	Pre-implementation and early implementation	One session per school per cycle; additional sessions if needed	Addressing patient and community needs and social influence increases acceptance and adoption[4,6,6]3
Joint health-education planning and local champions	Formal coordination between health and education sectors supported by identified champions	Municipal EPI focal person; School principals	Hold joint planning meetings; clarify roles and timelines; identify and support champions	Leadership engagement, coordination, and accountability	Pre-implementation with reinforcement during rollout	One planning meeting per school per cycle; ongoing champion engagement	Leadership engagement and networks enhance readiness and implementation climate, driving adoption[4]6

Strategy (Name)	Definition	Actor (Who enacts?)	Actions (What is done?)	Action Target (What is changed?)	Temporality (When?)	Dose (How much?)	Theoretical Justification
Refresher training and supportive consultation for vaccinators	Targeted capacity-building to strengthen vaccinators' knowledge, confidence, and problem-solving skills	District/ municipal trainers; Supervisors	Conduct refresher training; provide mentoring and on-call consultation	Vaccinator self-efficacy and readiness to initiate sessions	Pre-implementation with early follow-up	One half- to one-day refresher; ongoing consultation during rollout	Improving capability and confidence increases adoption of new practices[61,83]
Formal implementation blueprint and micro-planning	Written plans specifying timelines, roles, milestones, and monitoring for HPV vaccination initiation	Municipal EPI team; Health facility in-charge	Develop implementation plans; set timelines; review progress; adapt plans	Planning quality, preparedness, and stakeholder engagement	Pre-implementation with iterative refinement	One plan per school	Reducing perceived complexity increases compatibility and usability of EBIs, improving adoption[46]

Step-3 Define implementation outcome operationally

Once the evidence-based intervention and implementation strategies have been specified, the next critical step is to define the implementation outcome operationally. In implementation research, outcomes such as adoption, fidelity, reach, or sustainment are not abstract concepts; they must be translated into clear, observable, and measurable indicators that reflect real-world practice. Operational definitions ensure that implementation outcomes are interpreted consistently across settings, time points, and studies, and they are essential for valid comparison and causal inference.

Operationalizing an implementation outcome requires explicit decisions about the unit of analysis, the timing of measurement, and the data sources used to capture the outcome. For example, adoption may be defined at the level of organizations, teams, or providers, and measured as a binary indicator (e.g., yes/no initiation), a proportion, or a count of implementation events. These choices should align with how implementation decisions are made in practice and with the level at which implementation strategies are applied. Importantly, the operational definition should reflect meaningful action-such as initiation of delivery-rather than intent or self-reported readiness.

Example

The primary outcome will be adoption, defined as initiation of at least one school-based HPV vaccination session during the implementation period. Adoption will be calculated as the proportion of eligible schools that initiated HPV vaccination during the implementation period.

Adoption = Number of schools that initiated at least one HPV vaccination session/Total number of eligible schools

Step 4. State research aims and objectives

After clearly defining the evidence-based intervention and implementation gap, and identifying implementation strategies and implementation outcomes, the next step is to explicitly state the research aims and objectives. In implementation research, aims and objectives must be tightly aligned with the implementation strategies being tested and the implementation outcomes of interest, rather than with clinical or health outcomes alone.

Well-specified aims and objectives provide a direct link between theory, strategy design, study design, and data analysis, and they are essential for interpretability and causal inference.

Implementation research objectives often extend beyond a single question. In addition to testing whether an implementation strategy improves an implementation outcome, studies may aim to (1) understand variability in effects across contexts or subgroups, and (2) examine mechanisms through which strategies operate.

Example

- To evaluate the effect of an implementation strategy bundle on adoption of school-based HPV vaccination.
- To explore the mechanisms through which the implementation strategies influence adoption, using mixed-methods analyses to understand how and why specific strategies worked or did not work in different school and health system contexts.

Step 5. Select an appropriate study design for testing implementation strategies

When the goal is to test an implementation strategy, the study design must support causal inference, allowing researchers to determine whether observed changes in implementation outcomes are attributable to the strategy rather than to external factors.[6,25] Unlike descriptive studies, testing implementation strategies requires comparative designs that examine differences across groups, time periods, or strategy conditions while holding the EBI constant. Increasingly, implementation research combines these designs with mixed-methods approaches to answer not only whether a strategy works, but also what is the mechanism of action such as why some strategies work, why others do not, and why effects vary across contexts.[45,84]

Experimental designs allow researchers to test the causal effects of implementation strategies on implementation outcomes, such as adoption, fidelity, reach, and sustainment. In these studies, the implementation strategy-rather than the EBI is treated as the experimental factor. The EBI is held constant across study conditions, and differences in implementation outcomes are attributed to differences in the implementation support provided. The most commonly used experimental design is the cluster randomized controlled trial (cRCT).[85] Clusters-such as schools, health facilities, provider teams, or communities-are randomized to receive an implementation strategy or a comparison condition (e.g., usual implementation support). Cluster randomization is particularly appropriate when strategies operate at organizational or team levels or when there is a high risk of contamination across individuals. cRCTs provide strong internal validity and clear causal interpretation, especially when paired with appropriate analytic methods to account for clustering. Stepped-wedge cluster randomized designs[86] are a variant of experimental designs in which all clusters eventually receive the implementation strategy, but the timing of rollout is randomized. This design is useful when withholding a potentially beneficial strategy is ethically or politically challenging. The staggered implementation allows each cluster to contribute both control and intervention data, supporting causal inference while accommodating real-world constraints. Stepped-wedge designs are especially well suited for system-wide implementation efforts and policy-driven rollouts. When implementation strategies are multicomponent or when there is interest in optimizing strategy packages, factorial and fractional factorial designs[87] offer an efficient experimental approach. Used within frameworks such as the Multiphase Optimization Strategy (MOST), these designs allow researchers to test the individual and combined effects of multiple strategy components, identify synergistic or redundant elements, and select an optimized strategy package based on prespecified criteria such as effectiveness, cost, or feasibility. Sequential Multiple Assignment Randomized Trials (SMART)[88] are experimental designs used to test adaptive implementation strategies. In SMART designs, clusters or providers are re-randomized at decision points based on their initial response to a strategy. This approach allows researchers to evaluate sequences of strategies and to determine how implementation support should be intensified, modified, or switched over time. SMART designs are particularly valuable in complex or heterogeneous settings where a single strategy is unlikely to be effective for all sites.

Mixed-methods designs incorporate explanatory qualitative components alongside experimental or quasi-experimental comparisons. For example, in cluster randomized

trials, qualitative interviews, observations, and document reviews can be conducted in clusters with high versus low adoption to examine differences in contextual determinants such as leadership engagement, implementation climate, and compatibility with workflows, as conceptualized in the CFIR.[46] In stepped-wedge designs, repeated qualitative data collection across rollout phases can explain how learning effects, contextual shifts, or policy changes influence implementation outcomes over time.[89] In SMART, qualitative inquiry is particularly valuable for understanding why certain sites or providers respond to initial strategies while others require adaptation, thereby informing interpretation of adaptive implementation pathways.[90,91]

Across these designs, it is essential to distinguish what is assigned and what is tested. The study design assigns the implementation strategy or strategy bundle, while the EBI remains constant. What is tested is the causal effect of the implementation strategy on predefined implementation outcomes, such as adoption, fidelity, reach, or sustainment.[6] Quantitative analyses estimate whether the strategy improves implementation outcomes, while qualitative analyses explain how the strategy interacted with context to produce the observed effect-or lack thereof. By intentionally designing studies to integrate causal estimation with explanation, mixed-methods implementation research generates actionable knowledge about which strategies work, for whom, under what conditions, and why, thereby supporting adaptation, scale-up, and sustainability of evidence-based interventions.[39,45]

Study design example

To evaluate the effect of an implementation strategy bundle on adoption of school-based HPV vaccination and to explore the mechanisms through which the strategies influence adoption, we will conduct a cluster randomized controlled trial (cRCT) with an embedded mixed-methods explanatory component.

Schools will serve as the unit of randomization and primary analysis because decisions to initiate HPV vaccination and the associated implementation activities occur at the school level in coordination with linked primary health care facilities, and because individual-level randomization would pose a high risk of contamination. Eligible schools will be randomly assigned in a 1:1 ratio to either (1) an implementation strategy bundle designed to improve adoption of school-based HPV vaccination or (2) routine implementation support currently provided through the national immunization program. The evidence-based intervention (HPV vaccination for girls aged 9-14 years) will be held constant across both study arms; only the implementation support will differ.

The primary implementation outcome will be adoption, operationalized as whether a school initiates at least one HPV vaccination session during the implementation period. Quantitative analyses will compare adoption between intervention and control schools using methods that account for clustering at the school and municipality levels, thereby estimating the causal effect of the implementation strategy bundle on adoption.

To address the second study objective-understanding how and why the implementation strategies work or fail across contexts-we will embed a mixed-methods explanatory component within the trial. We will purposively select schools from both study arms that demonstrate high and low adoption and conduct in-depth interviews, focus group

discussions, and structured observations with key stakeholders, including vaccinators, school administrators, health facility managers, municipal EPI focal persons, and caregivers. Guided by the Consolidated Framework for Implementation Research (CFIR), qualitative data will be used to examine contextual determinants and mechanisms such as leadership engagement, intersectoral coordination, parental trust, and workforce capacity that shape adoption.

By integrating a rigorous experimental design with qualitative inquiry, this study will generate both causal evidence on the effectiveness of the implementation strategy bundle and in-depth understanding of the mechanisms and contextual conditions influencing adoption. This design will support refinement of the strategy bundle and inform future scale-up of school-based HPV vaccination within Nepal's immunization and education systems.

Step 6. Define study population and sample size

When testing the effects of implementation strategies on implementation outcomes, careful definition of the study population and sample size is essential to ensure valid causal inference while also supporting explanation and learning. Unlike clinical trials that focus primarily on individual patients, implementation research often targets organizations, teams, or systems as the units of analysis and intervention. This step therefore requires explicit attention to multiple stakeholder groups and the integration of both quantitative and qualitative sampling strategies.

Defining the study population

Begin by defining the population at the level where the implementation strategy operates. If strategies are delivered at the organizational or team level—such as schools, clinics, or health facilities—these units typically serve as the primary population and unit of randomization for quantitative analyses. Clearly specify eligibility criteria for these units, including setting, service scope, and linkage to delivery systems. In addition, identify the stakeholder populations that influence or experience implementation, such as frontline implementers, supervisors and managers, partner organizations, and beneficiaries. Including these groups is essential for understanding how strategies work in practice and for interpreting variation in implementation outcomes.

Quantitative sample size for testing effects

For the quantitative component, base sample size calculations on the primary implementation outcome (e.g., adoption, fidelity, reach, sustainment) rather than clinical outcomes. Select the outcome metric (binary, continuous, count, or rate) and calculate the required sample size to detect a minimum detectable effect (MDE) that is meaningful for decision-making. Because implementation strategies are frequently assigned at the organizational level, account for clustering using an appropriate intra-cluster correlation coefficient (ICC) and adjust for design effects. If outcomes will be measured repeatedly over time, incorporate assumptions about within-unit correlation to improve efficiency or to adjust required sample size accordingly. These decisions should align with the study design (e.g., cluster randomized trial, stepped-wedge design) and analytic plan.

Qualitative sampling for mechanisms and context

Qualitative sampling serves a different but complementary purpose. Rather than statistical power, qualitative sampling aims for depth, diversity, and explanatory richness. Use purposive and maximum-variation sampling to select sites and participants that represent meaningful contrasts, such as high versus low implementation performance, different organizational types, or varying levels of readiness and resources. Include representatives from each key stakeholder group to capture multiple perspectives on strategy delivery and response. Continue data collection until thematic saturation is reached within and across groups, adjusting sample size iteratively as analysis proceeds.

Integrating quantitative and qualitative sampling

Integrate quantitative and qualitative sampling plans from the outset. Use quantitative results to inform qualitative case selection, such as choosing clusters with high and low outcomes or divergent responses to the strategy. This linkage allows qualitative findings to directly explain quantitative effects and heterogeneity. Conversely, insights from early qualitative work can inform refinement of quantitative measures or analytic subgroups. Together, these integrated sampling strategies support both rigorous testing of strategy effects and deep understanding of mechanisms and context.

In practice, document the study population and sample size decisions transparently, including eligibility criteria, assumptions used in power calculations, and rationale for qualitative sampling targets. Revisit these decisions as the study progresses, particularly in adaptive or phased designs. By thoughtfully defining populations and integrating quantitative and qualitative sampling, implementation research can generate evidence that is not only statistically robust but also actionable and transferable to real-world settings.

Example:

The study population will include eligible schools in Kathmandu District (clusters) and the stakeholders who influence or experience adoption of school-based HPV vaccination. The cluster-level population will include community (government) and private schools that are eligible for school-based HPV vaccination for girls aged 9–14 years and are linked to a vaccinating primary health care facility (health post/PHCC) and municipal EPI team. Stakeholder groups will include: implementers (vaccinators/ANMs and EPI staff delivering school sessions), managers and supervisors (health facility in-charges, municipal EPI focal persons, public health officers), education-sector actors (principals, teachers, school management committee representatives), and recipients/influencers (parents/caregivers; and adolescent girls only if ethically approved).

Quantitative component (primary aim: effect on adoption)

Unit of randomization and analysis: The unit of randomization and primary quantitative analysis will be the school (cluster). Schools will be randomized to either the implementation strategy bundle or routine implementation support.

Sample size (schools): To estimate school-level adoption with adequate precision and power to detect a meaningful improvement, we will target approximately 160 schools

(clusters) total. This sample size is consistent with a single-proportion estimate based on an expected adoption prevalence of ~0.70 with 95% confidence and ±0.08 precision (n≈127), inflated for design effects and incomplete documentation (≈15%), yielding a target of ~160 schools. Schools will be stratified by school type (community vs private) and municipality/ward to ensure representation of key contextual strata. This cluster sample will provide sufficient information to compare adoption between trial arms and examine variation by school type and geography while accounting for clustering.

Qualitative component (secondary aim: mechanisms and "why")

Sampling approach: We will use purposive, maximum-variation sampling anchored to quantitative outcomes and trial arm assignment. Schools will be selected from both arms to represent: (1) high adoption vs low/non-adoption, (2) community vs private schools, and (3) geographic variation (urban/peri-urban). Stakeholders linked to these schools and their vaccinating facilities will then be recruited to explore mechanisms through which strategies influenced adoption.

Qualitative sample size (targets): We anticipate approximately 45–60 in-depth interviews (IDIs) distributed across stakeholder groups, for example:

- ✓ 15–20 implementers and supervisors (vaccinators/ANMs, EPI staff, facility in-charges, municipal EPI focal persons)
- ✓ 15–20 education-sector actors (principals/teachers/SMC representatives)
- ✓ 15–20 parents/caregivers (including consenters and refusers)

Where feasible, we will also conduct 6–10 structured observations of strategy-related activities (e.g., joint planning meetings, parent orientation sessions, initiation processes) across contrasting school contexts. Final qualitative sample size will be guided by thematic saturation within stakeholder groups and the analytic need to explain heterogeneity in adoption outcomes.

Mixed-methods integration (linking "effect" to "mechanisms") Quantitative results will estimate whether the implementation strategy bundle increases adoption, while qualitative findings will explain how and why adoption changed and why effects varied across contexts. Integration will occur by selecting qualitative cases based on quantitative adoption patterns (high/low adoption and arm assignment) and by using joint displays that link adoption outcomes to CFIR-informed mechanisms and contextual determinants across school and health system settings.

Step 7. Data collection

In this step, you will design and implement data collection procedures that allow you to accurately estimate the effects of implementation strategies on implementation outcomes and to interpret why those effects occurred. Data collection in strategy-testing studies must go beyond outcome measurement to include rigorous assessment of strategy delivery, exposure, fidelity, and adaptations, as these elements are essential for causal inference.

Begin by selecting or adapting tools with evidence of reliability and validity whenever possible.

Prioritize established instruments for implementation outcomes such as adoption, fidelity, acceptability, feasibility, penetration, and sustainment. When validated tools are not available or require contextual modification, document all adaptations and provide a clear rationale. Explicitly map each measure to the targeted implementation outcome and relevant CFIR constructs to ensure conceptual alignment.

Pilot all data collection tools before full implementation.

Conduct pilot testing in non-study or early-run sites to assess clarity, feasibility, respondent burden, and logistical challenges. Use pilot findings to refine item wording, response options, and administration procedures. Provide standardized training to all data collectors and observers, including detailed operational definitions and practice exercises. For observational fidelity measures, formally assess inter-rater reliability (e.g., percent agreement or kappa statistics) prior to data collection and conduct refresher training as needed to maintain consistency.

Establish robust data quality assurance and supervision procedures.

Develop standard operating procedures for data collection, entry, and storage. Implement routine data checks for completeness, logic, and outliers; verify key variables through double entry or random audits; and conduct regular supervisory reviews to identify and correct errors early. These procedures are essential to ensure comparability across clusters, implementers, and time points.

Measure implementation strategy fidelity and dose as core study variables.

Treat the implementation strategy as an intervention that must be measured with the same rigor as any clinical or public health intervention. Track whether each strategy component is delivered as intended, including the number, timing, and content of activities such as trainings, facilitation visits, consensus meetings, or feedback cycles. Measure the dose received by target actors, such as attendance, participation intensity, and exposure to strategy components. These data are critical for distinguishing between a strategy that is ineffective and one that was inadequately delivered.

Systematically document adaptations to the implementation strategy.

Use structured logs, checklists, and qualitative field notes to record what changes were made to the strategy, why they occurred, when they were introduced, and who initiated them. Clearly distinguish between planned adaptations and reactive changes made in response to contextual challenges. Documentation of adaptations is essential for interpreting outcomes and informing future replication or scale-up.

Collect baseline and follow-up data on implementation outcomes using consistent timing.

Measure implementation outcomes at baseline, prior to strategy rollout, to characterize pre-existing implementation levels and contextual differences across sites. Collect follow-up data at clearly defined and consistent time points across all clusters. Align measurement windows with the expected timing of strategy effects-for example, short-term follow-up to capture changes in adoption and longer-term follow-up to assess sustainment. Consistency in timing is essential to avoid bias and to support valid comparisons.

Example

To evaluate the effect of an implementation strategy bundle on adoption of school-based HPV vaccination and to explain how and why the strategies worked (or did not) across contexts, we will use a convergent mixed-methods data collection approach that combines routine records, structured surveys, implementation tracking, and qualitative inquiry.

To evaluate the effect of an implementation strategy bundle on adoption of school-based HPV vaccination and to explain how and why the strategies worked (or did not) across contexts, we will use a convergent mixed-methods data collection approach that integrates routine program records, structured quantitative tools, implementation tracking, and qualitative inquiry.

1) Adoption outcome measurement (quantitative).

We will measure adoption using routine program documentation and structured record abstraction. We will use a School Adoption Record Abstraction Form to extract whether each eligible school initiated at least one HPV vaccination session during the implementation period, including the date of initiation and session type (planned or mop-up), based on school vaccination registers and EPI session reports. We will verify adoption status using an Adoption Verification Checklist that triangulates information across school registers/logs, EPI session reports, health facility immunization registers, and municipal EPI records, applying predefined rules to resolve discrepancies. We will define the adoption denominator using a School Eligibility and Denominator Roster that lists all eligible schools and their key characteristics. We will rely on systematic document review and cross-verification to minimize misclassification of adoption.

2) Measurement of contextual determinants (quantitative, CFIR-based).

We will assess contextual determinants using structured tools mapped to CFIR constructs. We will administer an Implementer Survey to vaccinators and EPI staff to measure perceived intervention complexity, leadership support, self-efficacy, workload, planning quality, and coordination processes. We will administer a School Readiness and Coordination Survey to school principals or designated focal persons to capture engagement, scheduling feasibility, coordination with health facility teams, and perceived parental acceptance. We will also complete a Facility and Municipality Readiness Checklist to document system-level factors such as staffing availability, micro-plans and communication materials, supervision arrangements, and coordination structures. We will administer all tools using standardized training, piloting, and quality control procedures.

3) Implementation strategy fidelity and dose (strategy exposure).

We will prospectively track fidelity and dose for each implementation strategy component. We will use Strategy Delivery Logs to document whether specific activities occurred as planned (e.g., joint planning meetings, champion identification, refresher trainings, parent orientation sessions, and protocol dissemination), including timing, duration, facilitators, and outputs. We will capture dose received by target actors using Attendance and Participation Sheets. We will document supportive supervision contacts

and follow-up actions using Supervision and Consultation Logs. We will record changes to strategy content or delivery using an Adaptation and Issue Log, noting what changed, when, and why. This prospective tracking will allow us to distinguish strategy failure from implementation failure or appropriate contextual adaptation.

4) Mechanisms and "why" (qualitative component).

We will collect qualitative data to explain mechanisms underlying adoption and heterogeneity in strategy effects. We will use CFIR-guided in-depth interview guides with vaccinators, EPI staff, facility in-charges, municipal EPI focal persons, school principals or teachers, and parents or caregivers to explore barriers, facilitators, and experiences with strategy components. Where appropriate, we will conduct focus group discussions with parents or community members to examine shared beliefs, trust, consent concerns, and information pathways influencing adoption decisions. We will conduct structured observations during joint planning meetings, parent sessions, and initiation activities to document coordination processes, leadership engagement, communication quality, and practical constraints. We will purposively select participants and sites from both high- and low-adoption schools across trial arms.

5) Timing and alignment with trial phases.

We will align data collection with key trial phases to ensure clear interpretation of findings. We will collect baseline data on the school eligibility roster, baseline adoption status (if any), and baseline CFIR determinants before strategy rollout. We will track strategy fidelity and dose continuously during rollout and conduct targeted observations. We will collect endline data on adoption using consistent time windows across clusters, administer follow-up determinant measures as needed, and conduct qualitative interviews or FGDs to explain why adoption occurred or did not occur. Together, this integrated approach will support robust estimation of strategy effects on adoption and provide contextual explanations for differential performance across schools and health system settings.

Step 8. Data analysis plan

This step focuses on translating the study design and data collection into an analytic approach that produces valid causal estimates and meaningful explanations. A well-specified data analysis plan aligns analytic models with the study design, the implementation outcomes of interest, and the level at which implementation strategies are assigned and measured, while also integrating qualitative evidence to explain how and why observed effects occur.

Selecting models aligned with design and outcome type: The choice of statistical models should reflect both the nature of the implementation outcome and the design features of the study. For adoption, which is typically measured as a binary outcome (e.g., whether a school initiated at least one HPV vaccination session), mixed-effects logistic regression models or generalized estimating equations (GEE) are appropriate, as they account for clustering at the school, facility, or municipality level. For fidelity, often measured as a continuous score reflecting adherence to core components, linear mixed-effects models allow estimation of strategy effects while accounting for repeated measures and

hierarchical data structures. Reach, commonly expressed as counts or rates (e.g., number of eligible individuals reached), can be analyzed using Poisson or negative binomial regression models with appropriate offsets to account for differing denominators. When outcomes are measured over time, particularly in quasi-experimental or stepped-wedge designs, segmented regression or interrupted time series (ITS) models enable estimation of level and trend changes associated with implementation strategies. Across all analyses, investigators should explicitly account for clustering, time effects, and design-specific features to avoid biased inference.

Testing heterogeneity and equity effects: Beyond estimating average strategy effects, implementation research should examine whether effects vary across contexts and populations. We will test heterogeneity of effects by evaluating whether the impact of the implementation strategy differs by geography (e.g., urban vs. rural), facility or school type, baseline readiness, and equity-relevant characteristics such as caste/ethnicity and socioeconomic status. Analytically, this can be achieved through interaction terms between the strategy indicator and subgroup variables or through stratified models. Because subgroup analyses may be underpowered, results will be interpreted cautiously and in conjunction with qualitative evidence to avoid overinterpretation of chance findings.

Testing mechanisms of change (mediation): To strengthen causal explanation, the analysis should examine mechanisms through which implementation strategies produce change. Guided by the study's theoretical framework or theory of change, we will measure hypothesized mediators such as provider knowledge, self-efficacy, leadership engagement, coordination quality, or workflow fit. When data and assumptions permit, we will conduct mediation analyses to assess whether changes in these mediators explain the observed effects of the strategy on implementation outcomes. Even when formal mediation is not feasible, descriptive and correlational analyses can inform which mechanisms are most plausibly responsible for observed effects, guiding refinement of the strategy and improving its transportability to other settings.

Integrating qualitative methods to explain "how" and "why": Quantitative analyses alone cannot fully explain why an implementation strategy succeeds or fails. Therefore, we will integrate qualitative data from interviews and focus group discussions with implementers, managers, and beneficiaries to explore acceptability, feasibility, contextual constraints, adaptations, and unintended consequences. Using a convergent mixed-methods approach, we will compare and integrate qualitative explanations with quantitative findings to identify areas of convergence and divergence. This integration will clarify how contextual factors and implementation processes shaped outcomes and will provide actionable insights for adapting and scaling implementation strategies in diverse real-world settings.

Example

We will implement a data analysis plan that aligns analytic methods with the study design, implementation outcomes, and level of strategy assignment, while integrating quantitative and qualitative evidence to support causal inference and explanation. We will estimate the effect of the implementation strategy on adoption using mixed-effects logistic regression models or generalized estimating equations to account for clustering at the school and health system levels, and we will use appropriate mixed-effects,

count, or time-series models for other implementation outcomes as relevant, explicitly accounting for clustering, time, and design features. We will assess heterogeneity of effects by geography, school or facility type, baseline readiness, and equity-relevant characteristics such as caste/ethnicity and socioeconomic status using interaction terms or stratified analyses, interpreting subgroup findings cautiously and in conjunction with qualitative data. Guided by the study's theory of change, we will test mechanisms of action through mediation analysis by (1) measuring pre-specified mediators (e.g., vaccinator knowledge and self-efficacy, leadership engagement, coordination quality, workflow fit, parental trust) at baseline and follow-up, (2) estimating the effect of the strategy on each mediator using mixed-effects models that account for clustering, and (3) estimating the association between each mediator and adoption while adjusting for strategy assignment and key covariates. We will then decompose total effects into direct and indirect effects using causal mediation methods (e.g., product-of-coefficients or counterfactual-based natural direct/indirect effects) with clustered standard errors and bootstrapped confidence intervals, and we will interpret mediation results cautiously, recognizing assumptions such as no unmeasured mediator-outcome confounding and correct model specification. We will triangulate mediation findings with qualitative evidence on how strategy components changed determinants (or failed to do so) and use convergent mixed-methods joint displays to integrate mechanisms with observed strategy effects, producing actionable guidance for refining the strategy bundle and improving its transportability for scale-up.

Stakeholder engagement

Stakeholder engagement should function as a cross-cutting process across each step of this implementation research sequence, ensuring that the EBI definition, implementation gap, determinants, strategies, outcomes, and interpretations reflect local realities and remain feasible within system constraints. In Step 1, stakeholders (vaccinators, EPI managers, school leaders, caregivers, and policymakers) should help define the HPV vaccination EBI operationally and validate the implementation gap (e.g., low school-level adoption) by clarifying how decisions are made, which bottlenecks matter most, and why the gap persists. In Step 2, stakeholders should contribute to identifying CFIR-based determinants and should co-design and refine strategy options-such as joint health-education planning, parent engagement, and supportive supervision-so that the selected bundle fits existing workflows, resources, and norms; they should also validate the CFIR-ERIC matched strategies for acceptability and feasibility through co-design workshops. In Step 3, stakeholders should ensure that the operational definition of adoption (numerator/denominator, timing, and data sources) captures meaningful action in practice rather than intent. In Step 4, stakeholders should shape aims and objectives so they address decision-relevant questions, including equity concerns and variation across school types and geography. In Step 5 and Step 6, stakeholder input should guide site selection, sampling, and recruitment to ensure representation of key contexts and vulnerable groups, and to anticipate practical constraints in a cluster randomized design. In Step 7, stakeholders should help tailor and pilot data collection tools, improve clarity and cultural appropriateness, and support access to routine records while strengthening trust and participation. In Step 8, stakeholders should participate in co-interpretation

and validation sessions to confirm whether findings accurately reflect implementation realities, explain unexpected results, and identify actionable determinants. Finally, in Step 9, stakeholders should lead or co-lead prioritization of determinants and selection of next-step implementation strategies, ensuring that resulting recommendations are realistic, equity-sensitive, and scalable within the immunization and education systems.

Hybrid effectiveness and implementation research

Hybrid implementation research designs combine questions about whether an intervention works and how it can be implemented in real-world settings within a single study. These designs recognize that decisions about scale-up and sustainability require evidence on both effectiveness and implementation. Instead of conducting effectiveness trials and implementation studies separately over many years, hybrid designs speed up translation by examining health outcomes alongside implementation processes and outcomes at the same time.

Hybrid designs are commonly categorized into three types. Hybrid type I prioritizes testing the effectiveness of an EBI while collecting limited data on implementation (e.g., feasibility, acceptability, or contextual barriers) to inform future implementation planning. Hybrid type II gives equal weight to testing the effectiveness of the EBI and testing one or more implementation strategies, allowing researchers to assess whether the intervention improves health outcomes and whether the implementation approach improves outcomes such as adoption, fidelity, or reach at the same time. Hybrid type III prioritizes testing implementation strategies on implementation outcomes, while still monitoring clinical or population health outcomes to ensure that effectiveness is maintained during real-world delivery.

Hybrid type I

Hybrid Type I approach focuses on testing the effectiveness of a clinical intervention while at the same time gathering information on how it can be implemented in real-world settings. The primary goal is to determine whether the intervention works, but researchers also collect data on factors that may help or hinder its delivery. This design combines a traditional effectiveness study with a process evaluation, which explores:

- What parts of the intervention worked well or didn’t work?
- How the intervention needs to be adapted to fit the setting.
- What resources or support are required for successful implementation?

Researchers often use interviews, surveys, and observations to gather this information, helping to identify barriers and facilitators to implementation early on. When planning a Hybrid type I study, using frameworks such as CFIR or the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) can help guide the study design, while frameworks like RE-AIM support clear reporting of outcomes.

Examples of Hybrid type I studies

The CALM study, funded by the national institute on mental health, tested an anxiety intervention in primary care while using the promoting action on research implementation

in health services (PARIHS) framework to guide interviews and gather implementation insights.[92]

A study by Hagedorn et al. tested contingency management through a randomized effectiveness trial and combined it with a mixed-method, multi-stakeholder evaluation of how the intervention was delivered.[93] This design is especially valuable because it allows researchers to test interventions and start learning how to make them practical and scalable in real-world conditions at the same time.

Hybrid type II

Hybrid type II approaches place equal emphasis on both the clinical intervention and the implementation strategy. Unlike hybrid type I, where the focus is primarily on the effectiveness of the intervention, hybrid type II explicitly examines both the intervention's impact and the strategies used to implement it, giving them equal weight. These designs always include a clearly defined implementation strategy that is practical and suitable for real-world use. They also require the measurement of key implementation outcomes, such as adoption, fidelity, and acceptability.

It is important to distinguish between the components of the intervention itself and those of the implementation strategy, even though this can sometimes be challenging. For example, if an evidence-based intervention is delivered over the phone, the phone delivery is part of the intervention design. The implementation strategy, however, would focus on encouraging healthcare teams to adopt and deliver the intervention effectively, rather than treating phone delivery itself as an implementation strategy.

Hybrid type II designs are especially useful when an intervention has already been proven effective in other contexts or populations but has not yet been tested in the setting or group of interest. This creates uncertainty about whether similar clinical benefits will be achieved. They are also well-suited to situations where there is strong momentum to implement the intervention, driven by policies, systems, or organizational needs.

By using a hybrid type II design, researchers can take advantage of this momentum to simultaneously evaluate the clinical effectiveness of the intervention and study the effectiveness of implementation strategies. This dual approach supports a deeper understanding of how to deliver proven interventions successfully in new, real-world settings while continuing to assess their clinical impact.

Type II hybrid designs can be seen in various studies. For instance: Cully et al. (2012) conducted a study that combined a clinical trial of brief cognitive-behavioral therapy for depression and anxiety with the piloting of an implementation strategy.[94] A study by Garner et al. demonstrated dual randomization at both the organizational and client level. [77] Another study focused on assessing the Veterans Health Administration's response to intimate partner violence among women also utilized a type II hybrid design.[93]

Hybrid type III

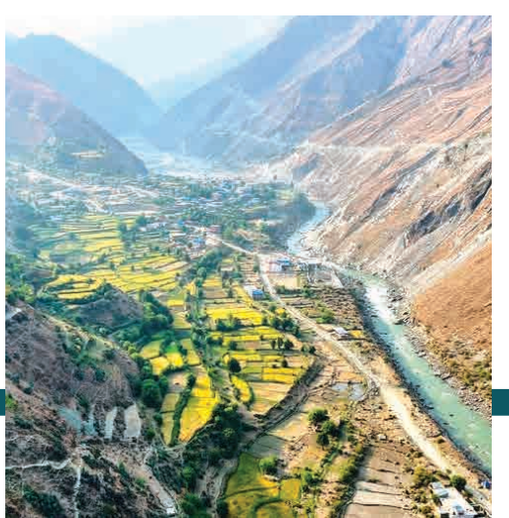
In a hybrid type III approach, the primary focus is on implementation outcomes, while clinical intervention outcomes are observed or collected as secondary measures. These designs integrate aspects of implementation trials with evaluations of patient outcomes. Key implementation outcomes such as adoption, fidelity, and sustainability serve as the main indicators of success.

Hybrid type III studies typically involve comparing different implementation strategies, which often target providers, clinics, or healthcare systems to assess their effects on implementation outcomes. Depending on the intervention, strategies may also be directed towards participants. Randomization in these studies usually occurs at the provider, clinic, or system level. For example, clinics can be randomly assigned to receive different sets of implementation strategies, which may vary in type, target, or intensity. The impact of these strategies on implementation outcomes can then be compared.

Clinical intervention outcomes are examined as secondary measures, generally through observational methods rather than participant-level randomization, and are analyzed in relation to the adoption and fidelity achieved by the implementation strategies. For example, in one study, researchers investigated how a bundle of implementation strategies affected the adoption and sustainability of an intervention aimed at improving physical function in community-dwelling older adults. Another study evaluated the impact of implementation facilitation to promote emergency department-initiated buprenorphine for opioid use disorder, comparing a standard educational dissemination strategy with facilitation. In this study, implementation outcomes were the primary focus, while effectiveness outcomes were secondary, assessed across four urban academic emergency departments.[25]

*****END OF MODULE: 7*****

Module 8: Ethics in Implementation Research



ETHICS IN IMPLEMENTATION RESEARCH

Ethics in implementation research is especially important because this type of research is different from other fields. It examines why, how, when, and where interventions are carried out, which creates unique ethical challenges. These challenges arise from the complex relationship between research, real-world practice, policy, and the many stakeholders involved. This topic discusses the main ethical issues in IR, based on the contexts provided. Before starting any study-and before publishing it-researchers must obtain approval from an ethical review committee. At every stage of IR, researchers should follow Nepal's National Ethical Guidelines 2022.[95]

Key ethical issues in IR

Planning phase

IR must first address problems that matter locally. This responsiveness means choosing questions and interventions seen by communities and health authorities as high priorities; otherwise, doing the research is ethically questionable.[96]

Equipose in IR

Ensuring equipoise in IR is different from clinical trials. In clinical trials, equipoise means there is genuine uncertainty about whether a drug works. In IR, the focus is on "contextual equipoise", being genuinely unsure whether an implementation strategy will work in a new setting. This uncertainty is essential to ethically justify any risks to participants. For example, a strategy proven in a large urban hospital may not work the same way in a small rural clinic.[97] Choosing a fair study design involves balancing scientific rigor with justice. Randomized controls or stepped wedge trials can withhold proven interventions from some groups, raising equity concerns; quasi-experimental or pragmatic designs may be more acceptable but can weaken validity. Stakeholder's and community engagement must begin during the planning phase. Researchers need to involve policymakers, health workers, and representatives of affected communities to select relevant questions, gain buy-in for scale up, and surface hidden risks.[98] Finally, risk assessment in IR demands thorough situational analysis. Health systems are complex, so risks can be difficult to predict. Researchers must identify potential harms (including benefits accruing to non-participants) and plan how to balance them transparently with communities.[99]

Implementation phase

During implementation, respecting autonomy and obtaining appropriate consent can be challenging when interventions occur at the community or cluster level. Traditional individual consent may not be possible (e.g., water supply changes), so researchers may need waivers, community agreement, or dual gatekeeper and individual consent but never skip meaningful engagement or oversight. [100,101]

Sometimes withholding information is used to prevent bias (e.g., behavior change trials), but this must be carefully justified against risks to participants and the integrity of consent.[99]

IR should also build local capacity from training community health workers to strengthening data systems without creating parallel, unsustainable programs. True capacity building empowers host institutions and benefits future research and service delivery.

Post-research stage

After the study ends, researchers have an ethical duty to disseminate findings widely and report back to the communities and stakeholders who participated, whether the results are positive or negative outcomes alike, to inform policy and practice elsewhere.[101] Moreover, the control group should be provided with the proven intervention if it's found successful during the implementation phase.

Data ownership and sharing arrangements should be agreed upon at the start. While donors or sponsors often claim data rights, transparent and fair agreements are essential to ensure local partners and communities can access and use the data, balancing privacy concerns with the public health value of open access.

Finally, IR should plan for sustainability and scale up from the beginning. Securing commitments from decision-makers to fund and integrate effective interventions into routine health services ensures that benefits continue beyond the research period.

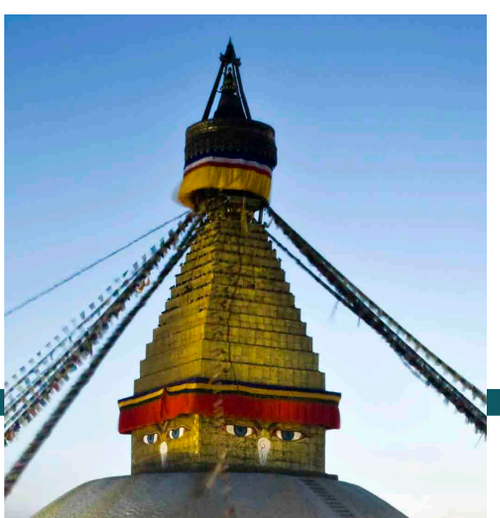
Table 18: Ethical issues related to IR design

IR design	Example	Ethical concerns
Cluster randomized trials (group randomized, place-based, community wide intervention trials)	Randomization of clusters of obstetrics unit staff to education on hand washing or usual practice, measurement of rates of puerperal sepsis in women delivering at study clinics	Different units of intervention and outcomes measurement Consent before and after randomization, whom to consent? Choice of gatekeepers No opt-out option within cluster Risk: benefit balance Ethics of randomization to known intervention, equipoise, Identification of vulnerable groups
Effectiveness-implementation hybrid trials	Evaluate the impact of ITN on reduction of malaria and assess robustness of availability and uptake of ITNs in the community	The trade-off between the scientific rigor required for effectiveness assessment and the realistic contextual considerations required for implementation is an important ethical consideration
Mixed-methods research	Integration of HIV and TB management in single clinics-patient experience (qualitative) and adherence (quantitative)	The trade-off between the scientific rigor required for quantitative methods and the realistic contextual considerations required for the qualitative component
Participatory action research	Peer support groups to improve adherence to ARV in HIV positive subjects	There is a need for community engagement to ensure responsiveness, sustainability, and scalability

IR design	Example	Ethical concerns
Pragmatic trials	Introduction of community health workers for home management of malaria	There may be concerns of standards of care and ancillary care, which in pragmatic conditions may be ethically debatable.
Quasi-experimental study	Open label demonstration project of effectiveness of self-reported use of pre-exposure prophylaxis for HIV infection	There is a concern regarding scientific rigor of the research
Realist view	Integration of traditional healers into home management of malaria strategies	Community engagement is of utmost importance to retain cultural and contextual sensitivity

*****END OF MODULE: 8*****

Module 9: Reporting



REPORTING

Reporting of IR processes and findings requires specific attention and format to better inform initiatives to improve healthcare services and improve the chances of indexing when published. Unlike traditional clinical trials, IR often involves complex, context-specific interventions where both the effectiveness of an intervention and the process of implementation are of interest. The common reporting follows Standards for Reporting Implementation Studies (StaRI) guidelines, developed by Pinnock et al. (2017), and provides a structured framework to improve the clarity, transparency, and completeness of reporting. The StaRI checklist helps authors capture and communicate various dimensions e.g., EBIs, context, implementation strategies, and outcomes effectively.[96]

Key features of the StaRI guidelines

Dual-Strand Reporting: StaRI emphasizes two strands of reporting: the intervention itself and the implementation strategy 27-Item Checklist: The StaRI statement includes a checklist covering all sections of a research report from title and abstract to methods, results, and discussion. It guides authors to describe:

- ✓ The context in which the study was conducted
- ✓ The characteristics of the intervention and implementation strategies
- ✓ Study design, implementation outcomes, and analytical methods
- ✓ Adaptations made during implementation
- ✓ Fidelity, reach, and sustainability of both the intervention and implementation

Focus on context and real-world relevance: StaRI stresses the importance of detailing the setting, stakeholder engagement, barriers and facilitators, and adaptation factors that are critical for replication and scaling.

Promoting reproducibility and utility: By providing a transparent account of both what was done and how it was implemented, StaRI enables other researchers, policymakers, and practitioners to better interpret, replicate, and apply findings in different contexts. For example, if a study is testing the implementation of a hypertension management program using community health workers, StaRI would require authors to report not only the outcomes (e.g., blood pressure reduction) but also how the health workers were trained and supported, how they were integrated into the health system, and whether any challenges or adaptations occurred during rollout.[96]

Table 19: STARI checklist

Checklist item	Reported on page #	Implementation strategy	Reported on page #	Intervention
		"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract				
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction				
Introduction	3	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	The scientific background and rationale for the implementation strategy (including any underpinning theory, framework and model, how it is expected to achieve its effects; and any pilot work).		The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description				
Design	6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		

Checklist item	Reported on page #	Implementation strategy	Reported on page #	Intervention
Targeted 'sites'	8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.		The population targeted by the intervention and any eligibility criteria.
Description	9	A description of the implementation strategy		A description of the intervention
Sub-groups	10	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation				
Outcomes	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets		Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy		Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Checklist item	Reported on page #	Implementation strategy	Reported on page #	Intervention
Results				
Characteristics	17	Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	22	Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23	Contextual changes (if any) which may have affected outcomes		
Harms	24	All-important harms or unintended effects in each group		
Discussion				
Structured discussion	25	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	Discussion of policy, practice, and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice, and/or research implications of the intervention (specifically including sustainability)
General				
Statements	27	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

Reporting and dissemination tools and methods

Research teams have a range of reporting and dissemination tools to reach different audiences and encourage uptake. These tools work best when combined as part of an integrated dissemination plan rather than used separately: each has distinct strengths and limitations, and material created for one format can often be adapted for another. Using multiple channels increases the likelihood that key audiences will act on the findings. This part covers tools such as research reports, peer-reviewed articles, press releases and policy briefs. Target audiences include stakeholders involved in the research (participants/end-users, implementers, policymakers, researchers and donors), and the choice of dissemination method should match the audience and the objective. For example, community members and beneficiaries benefit from interactive meetings with simple, concise messages, whereas implementers and policymakers prefer policy briefs focused on implications for practice and policy; researchers typically expect technical reports and journal articles. In implementation research, dissemination should be ongoing (not delayed until study end) and can be carried out through stakeholder meetings, workshops, seminars, symposia and conferences tailored to the intended audience.[34]

Important considerations while reporting and disseminating implementation research results

The following points should be considered while reporting and disseminating the results of IR.

- Who is the intended audience for the research findings, and how can the results be made accessible to diverse groups, including those who may not have academic or technical backgrounds?
- Are there barriers (e.g., language, technical jargon) that might prevent certain groups from understanding the research findings?
- Are the voices and perspectives of marginalized or underrepresented groups highlighted in the findings?
- How might the research findings impact different communities, particularly those that are historically or currently marginalized? Are there potential negative consequences of the findings, and how can these be mitigated?
- Are the methods, data, and analysis processes clearly and transparently reported to allow for scrutiny and replication?
- How will the research team be accountable to the communities involved in or affected by the research?
- What strategies will be used to disseminate the findings to ensure they reach and benefit the relevant communities? How will the research team engage with the community to discuss the findings and their implications?
- Are there ethical considerations related to privacy, consent, and the use of data that need to be addressed in the reporting? How will the research team ensure that the findings are used ethically and responsibly?

*****END OF MODULE: 9*****

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GLOSSARY

A

acceptability

Stakeholder perception of intervention's agreeableness or suitability, 7, 9, 16, 17, 18, 24, 31, 45, 50, 52, 55, 56, 57, 63, 68, 69, 74, 80, 90, 93, 94, 95, 96

adaptation

Deliberate modifications to interventions to enhance contextual fit, 7, 8, 9, 10, 13

ADAPT-ITT

Eight-step intervention adaptation framework facilitating systematic implementation adjustments, 9, 10, 109

adoption

Initial decision by organizations or individuals to employ an intervention, 2, 3, 10, 12, 14, 16, 17, 19, 20, 24, 25, 27, 31, 33, 34, 36, 38, 39, 42, 44, 45, 46, 47, 49, 51, 52, 53, 54, 55, 64, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97

B

barriers

Anything that restrains or obstructs progress, access, etc, 2, 3, 10, 11, 13, 20, 25, 26, 27, 30, 33, 37, 38, 39, 40, 41, 45, 47, 49, 51, 52, 53, 54, 56, 57, 58, 60, 63, 64, 66, 67, 68, 69, 72, 74, 75, 76, 77, 80, 92, 95, 103, 104, 107

C

cluster randomized controlled trial

Experimental design randomizing groups rather than individuals to control contamination, 85, 86

Cochrane reviews

Rigorous, peer-reviewed systematic reviews published by the Cochrane Collaboration, 5

co-design

Collaborative process engaging stakeholders in intervention design activities, 60, 77, 80, 94

contextual determinants

Conditions and factors within settings affecting implementation outcomes, 33, 44, 54, 66, 68, 69, 70, 71, 72, 73, 75, 76, 77, 86, 87, 89, 91

F

facilitators

Thing that makes an action or process easier, 2, 3, 8, 11, 13, 20, 27, 30, 33, 37, 38, 39, 40, 47, 52, 54, 60, 66, 68, 69, 72, 74, 75, 76, 77, 80, 91, 92, 95, 103, 104

feasibility

Practicality of implementing an intervention within a given setting, 3, 5, 6, 7, 9, 16, 19, 20, 21, 24, 31, 41, 44, 45, 50, 51, 52, 58, 60, 61, 69, 70, 80, 85, 90, 91, 93, 94, 95

Annexes

Framework Guidance:

The CFIR is intended to be used to collect data from individuals who have power and/or influence over implementation outcomes. See the CFIR Outcomes Addendum for guidance on identifying these individuals and selecting outcomes.

The CFIR must be fully operationalized prior to use in a project:

1) Define the subject of each domain for the project (see guidance for each domain below).
2) Replace broad construct language with project-specific language if needed.
3) Add constructs to capture salient themes not included in the updated CFIR.

I. INNOVATION DOMAIN	
Construct Name	**Construct Definition** *The degree to which:*
A. Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable.
B. Innovation Evidence-Base	The innovation has robust evidence supporting its effectiveness.
C. Innovation Relative Advantage	The innovation is better than other available innovations or current practice.
D. Innovation Adaptability	The innovation can be modified, tailored, or refined to fit local context or needs.
E. Innovation Trialability	The innovation can be tested or piloted on a small scale and undone.
F. Innovation Complexity	The innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps.
G. Innovation Design	The innovation is well designed and packaged, including how it is assembled, bundled, and presented.
H. Innovation Cost	The innovation purchase and operating costs are affordable.

II. OUTER SETTING DOMAIN	
Construct Name	**Construct Definition** *The degree to which:*
A. Critical Incidents	Large-scale and/or unanticipated events disrupt implementation and/or delivery of the innovation.
B. Local Attitudes	Sociocultural values (e.g., shared responsibility in helping recipients) and beliefs (e.g., convictions about the worthiness of recipients) encourage the Outer Setting to support implementation and/or delivery of the innovation.
C. Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation.
D. Partnerships & Connections	The Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks.
E. Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation.
F. Financing	Funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation.
G. External Pressure	External pressures drive implementation and/or delivery of the innovation. Note: Use this construct to capture themes related to External Pressures that are not included in the subconstructs below.
1. Societal Pressure	Mass media campaigns, advocacy groups, or social movements or protests drive implementation and/or delivery of the innovation.
2. Market Pressure	Competing with and/or imitating peer entities drives implementation and/or delivery of the innovation.
3. Performance-Measurement Pressure	Quality or benchmarking metrics or established service goals drive implementation and/or delivery of the innovation.

III. INNER SETTING DOMAIN	
Construct Name *Note:*	**Construct Definition** *The degree to which:* *Constructs A – D exist in the Inner Setting regardless of implementation and/or delivery of the innovation, i.e., they are persistent general characteristics of the Inner setting.*
A. Structural Characteristics	Infrastructure components support functional performance of the Inner Setting. Note: Use this construct to capture themes related to Structural Characteristics that are not included in the subconstructs below.
1. Physical Infrastructure	Layout and configuration of space and other tangible material features support functional performance of the Inner Setting.
2. Information Technology Infrastructure	Technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting.
3. Work Infrastructure	Organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting.
B. Relational Connections	There are high quality formal and informal relationships, networks, and teams within and across Inner Setting boundaries (e.g., structural, professional).
C. Communications	There are high quality formal and informal information sharing practices within and across Inner Setting boundaries (e.g., structural, professional).
D. Culture	There are shared values, beliefs, and norms across the Inner Setting. Note: Use this construct to capture themes related to Culture that are not included in the subconstructs below.
1. Human Equality-Centeredness	There are shared values, beliefs, and norms about the inherent equal worth and value of all human beings.
2. Recipient-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of recipients.
3. Deliverer-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of deliverers.
4. Learning-Centeredness	There are shared values, beliefs, and norms around psychological safety, continual improvement, and using data to inform practice.

Note:	*Constructs E – K are specific to the implementation and/or delivery of the innovation.*
E. Tension for Change	The current situation is intolerable and needs to change.
F. Compatibility	The innovation fits with workflows, systems, and processes.
G. Relative Priority	Implementing and delivering the innovation is important compared to other initiatives.
H. Incentive Systems	Tangible and/or intangible incentives and rewards and/or disincentives and punishments support implementation and delivery of the innovation.
I. Mission Alignment	Implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the Inner Setting.
J. Available Resources	Resources are available to implement and deliver the innovation. Note: Use this construct to capture themes related to Available Resources that are not included in the subconstructs below.
1. Funding	Funding is available to implement and deliver the innovation.
2. Space	Physical space is available to implement and deliver the innovation.
3. Materials & Equipment	Supplies are available to implement and deliver the innovation.
K. Access to Knowledge & Information	Guidance and/or training is accessible to implement and deliver the innovation
IV. INDIVIDUALS DOMAIN	
ROLES SUBDOMAIN **Construct Name**	**Construct Definition**
A. High-level Leaders	Individuals with a high level of authority, including key decision-makers, executive leaders, or directors.
B. Mid-level Leaders	Individuals with a moderate level of authority, including leaders supervised by a high-level leader and who supervise others.
C. Opinion Leaders	Individuals with informal influence on the attitudes and behaviors of others.
D. Implementation Facilitators	Individuals with subject matter expertise who assist, coach, or support implementation.
E. Implementation Leads	Individuals who lead efforts to implement the innovation.
F. Implementation Team Members	Individuals who collaborate with and support the Implementation Leads to implement the innovation, ideally including Innovation Deliverers and Recipients.
G. Other Implementation Support	Individuals who support the Implementation Leads and/or Implementation Team Members to implement the innovation.
H. Innovation Deliverers	Individuals who are directly or indirectly delivering the innovation.
I. Innovation Recipients	Individuals who are directly or indirectly receiving the innovation.

CHARACTERISTICS SUBDOMAIN	
Construct Name	**Construct Definition:** *The degree to which:*
A. Need	The individual(s) has deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation.
B. Capability	The individual(s) has interpersonal competence, knowledge, and skills to fulfill Role.
C. Opportunity	The individual(s) has availability, scope, and power to fulfill Role.
D. Motivation	The individual(s) is committed to fulfilling Role.

V. IMPLEMENTATION PROCESS DOMAIN

Construct Name	**Construct Definition** *The degree to which individuals:*
A. Teaming	Join together, intentionally coordinating and collaborating on interdependent tasks, to implement the innovation.
B. Assessing Needs	Collect information about priorities, preferences, and needs of people. Note: Use this construct to capture themes related to Assessing Needs that are not included in the subconstructs below.
1. Innovation Deliverers	Collect information about the priorities, preferences, and needs of deliverers to guide implementation and delivery of the innovation.
2. Innovation Recipients	Collect information about the priorities, preferences, and needs of recipients to guide implementation and delivery of the innovation.
C. Assessing Context	Collect information to identify and appraise barriers and facilitators to implementation and delivery of the innovation.
D. Planning	Identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance.
E. Tailoring Strategies	Choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context.
F. Engaging	Attract and encourage participation in implementation and/or the innovation. Note: Use this construct to capture themes related to Engaging that are not included in the subconstructs below.

1. Innovation Deliverers	Attract and encourage deliverers to serve on the implementation team and/or to deliver the innovation.
2. Innovation Recipients	Attract and encourage recipients to serve on the implementation team and/or participate in the innovation.
G. Doing	Implement in small steps, tests, or cycles of change to trial and cumulatively optimize delivery of the innovation.
H. Reflecting & Evaluating	Collect and discuss quantitative and qualitative information about the success of implementation. Note: Use this construct to capture themes related to Reflecting & Evaluating that are not included in the subconstructs below.
1. Implementation	Collect and discuss quantitative and qualitive information about the success of implementation.
2. Innovation	Collect and discuss quantitative and qualitative information about the success of the innovation.
I. Adapting	Modify the innovation and/or the Inner Setting for optimal fit and integration into work processes.

CFIR OUTCOMES ADDENDUM

I. ANTECEDENT ASSESSMENTS

Name	Definition
A. Acceptability	The extent to which an innovation is perceived as “agreeable, palatable, or satisfactory" (Proctor, 2009).
B. Appropriateness	The “perceived fit, relevance, or compatibility of the innovation […] for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem" (Proctor, 2009).
C. Feasibility	The extent to which an innovation “can be successfully used or carried out within a given agency or setting" (Proctor, 2009).
D. Implementation Climate	The extent to which the Inner Setting has an implementation climate.
E. Implementation Readiness	The extent to which the Inner Setting is ready for implementation

II. IMPLEMENTATION OUTCOMES	
Name	**Definition**
A. Anticipated Implementation Outcomes	Outcomes based on perceptions or measures of the likelihood of future implementation success or failure, i.e., implementation outcomes that have not yet occurred. These outcomes are forward-looking; constellations of CFIR determinants across domains predict these outcomes.
1. Adoptability	The likelihood key decision-makers will decide to put the innovation in place/innovation deliverers will decide to deliver the innovation.
2. Implementability	The likelihood the innovation will be put in place or delivered.
3. Sustainability	The likelihood the innovation will be put in place or delivered over the long-term.
B. Actual Implementation Outcomes	Outcomes based on perceptions or measures of current (or past) implementation success or failure, i.e., implementation outcomes that have occurred. These outcomes are backward-looking; constellations of CFIR determinants across domains explain these outcomes.
1. Adoption	The extent key decision-makers decide to put the innovation in place/innovation deliverers decide to deliver the innovation.
2. Implementation	The extent the innovation is in place or being delivered.
3. Sustainment	The extent the innovation is in place or being delivered over the long-term.
III. INNOVATION OUTCOMES	Outcomes that capture the success or failure of the innovation, based on the impact of the innovation on three important constituents: Innovation Recipients, Innovation Deliverers, and Key Decision-Makers. Impact is defined by: Reach ("The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program") x Innovation Effectiveness ("The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes" (Glasgow et al. 2019).
Name	**Definition**
A. Innovation Recipient Impact	Recipient Reach x Innovation Effectiveness
B. Innovation Deliverer Impact	Deliverer Reach x Innovation Effectiveness
C. Key-Decision Maker (or System) Impact	Key-Decision Maker Reach x Innovation Effectiveness

Annex II: Nomenclature for Implementation Strategy: ERIC Discrete Implementation Strategy Compilation

Strategy	Definitions
Access new funding	Access new or existing money to facilitate the implementation
Alter incentive/allowance structures	Work to incentivize the adoption and implementation of the clinical innovation
Alter patient/consumer fees	Create fee structures where patients/consumers pay less for preferred treatments (the clinical innovation) and more for less-preferred treatments
Assess for readiness and identify barriers and facilitators	Assess various aspects of an organization to determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort
Audit and provide feedback	Collect and summarize clinical performance data over a specified period and give it to clinicians and administrators to monitor, evaluate, and modify provider behavior
Build a coalition	Recruit and cultivate relationships with partners in the implementation effort
Capture and share local knowledge	Capture local knowledge from implementation sites on how implementers and clinicians made something work in their setting and then share it with other sites
Centralize technical assistance	Develop and use a centralized system to deliver technical assistance focused on implementation issues
Change accreditation or membership requirements	Strive to alter accreditation standards so that they require or encourage use of the clinical innovation. Work to alter membership organization requirements so that those who want to affiliate with the organization are encouraged or required to use the clinical innovation
Change liability laws	Participate in liability reform efforts that make clinicians more willing to deliver the clinical innovation
Change physical structure and equipment	Evaluate current configurations and adapt, as needed, the physical structure and/or equipment (e.g., changing the layout of a room, adding equipment) to best accommodate the targeted innovation
Change record systems	Change records systems to allow better assessment of implementation or clinical outcomes
Change service sites	Change the location of clinical service sites to increase access
Conduct cyclical small tests of change	Implement changes in a cyclical fashion using small tests of change before taking changes system-wide. Tests of change benefit from systematic measurement, and results of the tests of change are studied for insights on how to do better. This process continues serially over time, and refinement is added with each cycle

Strategy	Definitions
Conduct educational meetings	Hold meetings targeted toward different stakeholder groups (e.g., providers, administrators, other organizational stakeholders, and community, patient/consumer, and family stakeholders) to teach them about the clinical innovation
Conduct educational outreach visits	Have a trained person meet with providers in their practice settings to educate providers about the clinical innovation with the intent of changing the provider's practice
Conduct local consensus discussions	Include local providers and other stakeholders in discussions that address whether the chosen problem is important and whether the clinical innovation to address it is appropriate
Conduct local needs assessment	Collect and analyze data related to the need for the innovation
Conduct ongoing training	Plan for and conduct training in the clinical innovation in an ongoing way
Create a learning collaborative	Facilitate the formation of groups of providers or provider organizations and foster a collaborative learning environment to improve implementation of the clinical innovation
Create new clinical teams	Change who serves on the clinical team, adding different disciplines and different skills to make it more likely that the clinical innovation is delivered (or is more successfully delivered)
Create or change credentialing and/or licensure standards	Create an organization that certifies clinicians in the innovation or encourage an existing organization to do so. Change governmental professional certification or licensure requirements to include delivering the innovation. Work to alter continuing education requirements to shape professional practice toward the innovation
Develop a formal implementation blueprint	Develop a formal implementation blueprint that includes all goals and strategies. The blueprint should include the following: 1) aim/purpose of the implementation; 2) scope of the change (e.g., what organizational units are affected); 3) timeframe and milestones; and 4) appropriate performance/progress measures. Use and update this plan to guide the implementation effort over time
Develop academic partnerships	Partner with a university or academic unit for the purposes of shared training and bringing research skills to an implementation project
Develop an implementation glossary	Develop and distribute a list of terms describing the innovation, implementation, and stakeholders in the organizational change

Strategy	Definitions
Develop and implement tools for quality monitoring	Develop, test, and introduce into quality-monitoring systems the right inputthe appropriate language, protocols, algorithms, standards, and measures (of processes, patient/consumer outcomes, and implementation outcomes) that are often specific to the innovation being implemented
Develop and organize quality monitoring systems	Develop and organize systems and procedures that monitor clinical processes and/or outcomes for the purpose of quality assurance and improvement
Develop disincentives	Provide financial disincentives for failure to implement or use the clinical innovations
Develop educational materials	Develop and format manuals, toolkits, and other supporting materials in ways that make it easier for stakeholders to learn about the innovation and for clinicians to learn how to deliver the clinical innovation
Develop resource sharing agreements	Develop partnerships with organizations that have resources needed to implement the innovation
Distribute educational materials	Distribute educational materials (including guidelines, manuals, and toolkits) in person, by mail, and/or electronically
Facilitate relay of clinical data to providers	Provide as close to real-time data as possible about key measures of process/outcomes using integrated modes/channels of communication in a way that promotes use of the targeted innovation
Facilitation	A process of interactive problem solving and support that occurs in a context of a recognized need for improvement and a supportive interpersonal relationship
Fund and contract for the clinical innovation	Governments and other payers of services issue requests for proposals to deliver the innovation, use contracting processes to motivate providers to deliver the clinical innovation, and develop new funding formulas that make it more likely that providers will deliver the innovation
Identify and prepare champions	Identify and prepare individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization
Identify early adopters	Identify early adopters at the local site to learn from their experiences with the practice innovation
Increase demand	Attempt to influence the market for the clinical innovation to increase competition intensity and to increase the maturity of the market for the clinical innovation

Strategy	Definitions
Inform local opinion leaders	Inform providers identified by colleagues as opinion leaders or "educationally influential" about the clinical innovation in the hopes that they will influence colleagues to adopt it
Intervene with patients/ consumers to enhance uptake and adherence	Develop strategies with patients to encourage and problem solve around adherence
Involve executive boards	Involve existing governing structures (e.g., boards of directors, medical staff boards of governance) in the implementation effort, including the review of data on implementation processes
Involve patients/ consumers and family members	Engage or include patients/consumers and families in the implementation effort
Make billing easier	Make it easier to bill for the clinical innovation
Make training dynamic	Vary the information delivery methods to cater to different learning styles and work contexts, and shape the training in the innovation to be interactive
Mandate change	Have leadership declare the priority of the innovation and their determination to have it implemented
Model and simulate change	Model or simulate the change that will be implemented prior to implementation
Obtain and use patients/ consumers and family feedback	Develop strategies to increase patient/consumer and family feedback on the implementation effort
Obtain formal commitments	Obtain written commitments from key partners that state what they will do to implement the innovation
Organize clinician implementation team meetings	Develop and support teams of clinicians who are implementing the innovation and give them protected time to reflect on the implementation effort, share lessons learned, and support one another's learning
Place innovation on fee for service lists/formularies	Work to place the clinical innovation on lists of actions for which providers can be reimbursed (e.g., a drug is placed on a formulary, a procedure is now reimbursable)
Prepare patients/ consumers to be active participants	Prepare patients/consumers to be active in their care, to ask questions, and specifically to inquire about care guidelines, the evidence behind clinical decisions, or about available evidence-supported treatments

Strategy	Definitions
Promote adaptability	Identify the ways a clinical innovation can be tailored to meet local needs and clarify which elements of the innovation must be maintained to preserve fidelity
Promote network weaving	Identify and build on existing high-quality working relationships and networks within and outside the organization, organizational units, teams, etc. to promote information sharing, collaborative problem-solving, and a shared vision/goal related to implementing the innovation
Provide clinical supervision	Provide clinicians with ongoing supervision focusing on the innovation. Provide training for clinical supervisors who will supervise clinicians who provide the innovation
Provide local technical assistance	Develop and use a system to deliver technical assistance focused on implementation issues using local personnel
Provide ongoing consultation	Provide ongoing consultation with one or more experts in the strategies used to support implementing the innovation
Purposely reexamine the implementation	Monitor progress and adjust clinical practices and implementation strategies to continuously improve the quality of care
Recruit, designate, and train for leadership	Recruit, designate, and train leaders for the change effort
Remind clinicians	Develop reminder systems designed to help clinicians to recall information and/or prompt them to use the clinical innovation
Revise professional roles	Shift and revise roles among professionals who provide care, and redesign job characteristics
Shadow other experts	Provide ways for key individuals to directly observe experienced people engage with or use the targeted practice change/innovation
Stage implementation scale up	Phase implementation efforts by starting with small pilots or demonstration projects and gradually move to a system wide rollout
Start a dissemination organization	Identify or start a separate organization that is responsible for disseminating the clinical innovation. It could be a for-profit or non-profit organization
Tailor strategies	Tailor the implementation strategies to address barriers and leverage facilitators that were identified through earlier data collection
Use advisory boards and workgroups	Create and engage a formal group of multiple kinds of stakeholders to provide input and advice on implementation efforts and to elicit recommendations for improvements

Strategy	Definitions
Use an implementation advisor	Seek guidance from experts in implementation
Use capitated payments	Pay providers or care systems a set amount per patient/consumer for delivering clinical care
Use data experts	Involve, hire, and/or consult experts to inform management on the use of data generated by implementation efforts
Use data warehousing techniques	Integrate clinical records across facilities and organizations to facilitate implementation across systems
Use mass media	Use media to reach large numbers of people to spread the word about the clinical innovation
Use other payment schemes	Introduce payment approaches (in a catch-all category)
Use train-the-trainer strategies	Train designated clinicians or organizations to train others in the clinical innovation
Visit other sites	Visit sites where a similar implementation effort has been considered successful
Work with educational institutions	Encourage educational institutions to train clinicians in the innovation

Annex III: Study designs

Mixed- method

Mixed-method research is often preferred in implementation research because it provides a comprehensive understanding of contextual determinants. Qualitative data help explore the "why" and "how" of implementation-such as experiences, perceptions, and contextual influences-while quantitative data measure the "what" and "how much," including fidelity, reach, and costs.[1] In implementation research, mixed methods designs are essential for understanding the complex and multilevel factors that shape the uptake, feasibility, and sustainability of evidence-based interventions. Common designs include:

Convergent (concurrent) parallel, where qualitative and quantitative data are collected simultaneously to triangulate findings. For example, researchers may use a convergent mixed methods design by administering a facility readiness survey to assess quantitative indicators-such as availability of blood pressure devices, medication stockouts, staffing levels, and training coverage-while simultaneously conducting in-depth interviews with healthcare providers. The survey identifies "what" barriers exist and their magnitude across facilities, whereas the interviews help explain "why" these barriers persist. Providers may describe challenges such as unclear clinical protocols, lack of confidence in measuring blood pressure accurately, competing clinical demands, or weak supervision systems. When the two data sources are compared, the quantitative readiness scores reveal the scale of resource gaps, and the qualitative findings provide the underlying contextual and behavioral determinants. Together, these insights provide a more comprehensive understanding of barriers to implementing hypertension protocols than either method alone.

Sequential exploratory designs begin with qualitative inquiry to explore local context and inform subsequent quantitative measurement. For example: For example, researchers may begin with focus group discussions (FGDs) with community health workers to explore the determinants of guideline non-adherence in depth. During these discussions, workers may reveal issues such as limited confidence in using blood pressure devices, unclear documentation procedures, insufficient supervision, cultural beliefs influencing patient interactions, or heavy workloads that prevent full protocol adherence. These qualitative findings help identify the full range of contextual, organizational, and behavioral barriers that may not have been recognized beforehand. Using these insights, the research team then develops a structured survey that includes items reflecting the determinants identified in the FGDs. The survey is administered to a larger sample of health workers to quantify how common each barrier is, compare patterns across districts or facility types, and assess which determinants are most strongly associated with non-adherence. This sequential process ensures that the quantitative measurement is grounded in real-world experience and captures the most relevant contextual factors.

Sequential explanatory designs reverse the order, using quantitative results to guide qualitative follow-up. For instance, researchers may begin by analyzing quantitative fidelity scores across districts and find that some districts consistently perform lower than others

[1] R Burke Johnson and Anthony J Onwuegbuzie, 'Mixed Methods Research: A Research Paradigm Whose Time Has Come' (2004) 33 Educational Researcher 14 <https://journals.sagepub.com/doi/10.3102/0013189X033007014>.

in implementing hypertension protocols. To understand the reasons behind this variation, they then conduct qualitative interviews with healthcare providers, supervisors, and facility managers in both high- and low-performing districts. Through these interviews, they may uncover contextual explanations-such as staffing shortages, unclear role expectations, supply chain issues, weak leadership support, or differences in training quality. By linking these qualitative insights to the original fidelity data, researchers can explain why fidelity varies and identify which contextual determinants need to be addressed to improve implementation.

Embedded (nested) designs, one method supports a larger study using the other. For example, in a cluster randomized trial evaluating a task-shifting strategy for hypertension control, researchers may embed brief ethnographic observations to understand how implementation unfolds in practice. During routine site visits, qualitative researchers observe workflows, patient-provider interactions, and how community health workers perform newly assigned tasks. These insights reveal workflow disruptions-such as bottlenecks, role confusion, or equipment challenges-and help explain why the intervention is working or struggling, complementing the trial's quantitative outcomes.

Multiphase mixed methods design's involve iterative cycles across development. For example, when implementing a hypertension counseling intervention, researchers might begin with qualitative interviews to explore contextual determinants-such as provider workload, patient beliefs, or facility-level resource constraints-and use these insights to adapt the intervention for the local setting. They may then pilot the adapted intervention quantitatively to assess feasibility, fidelity, and early outcomes across multiple facilities. Based on these quantitative findings, researchers return to qualitative methods, such as follow-up interviews or observations, to understand why certain components worked better in some contexts than others and to refine implementation strategies accordingly. This iterative, multiphase approach ensures that both contextual determinants and emerging challenges are continuously integrated into the implementation process.

Mixed methods case study designs combine interviews, observations, and routine data to understand how and why implementation succeeds in a specific facility or district. For example, researchers may conduct a mixed methods case study of a high-performing primary care clinic to understand the contextual determinants of successful HEARTS program implementation. Quantitative data, such as patient outcomes, service coverage, and protocol fidelity, provide objective measures of performance. Simultaneously, qualitative methods-like interviews with providers and managers, observations of clinic workflows, and document reviews-explore how organizational culture, leadership support, staff motivation, training, and resource allocation contribute to success. By integrating these data, researchers can identify the key contextual factors, processes, and mechanisms that enabled high performance, offering lessons that can inform implementation strategies in other clinics or districts.

Qualitative methods

Qualitative methods are widely used in implementation research to explore the perceptions, experiences, norms, practices, and historical context that influence how interventions are

delivered and received. They provide rich, contextual insights that quantitative data alone cannot capture. Common qualitative methods include:

In-depth interviews: In-depth interviews are used to understand individual (implementers, leaders, planners, beneficiaries) perspectives and experiences.[2] For example, interviews with frontline health workers may explore challenges they face in adhering to hypertension management protocols, while interviews with facility managers may reveal organizational barriers to implementation.

Focus group discussions (FGDs): FGDs explore shared perceptions, norms, and group dynamics. For instance, a focus group with community health volunteers may uncover collective beliefs about patient engagement or cultural barriers to diabetes screening.

Observations: Direct observation helps researchers understand actual practices and interactions within the implementation setting. For example, observing patient flow in a clinic can identify workflow bottlenecks or discrepancies between protocol and practice.

Document review: Reviewing policies, guidelines, reports, and historical documents provides context for implementation decisions and helps track changes over time. For example, examining national hypertension guidelines and local facility protocols can reveal misalignments that affect fidelity.

Quantitative methods

Surveys / Questionnaires: Surveys and structured questionnaires are commonly used to assess individual- and organizational-level determinants that influence the implementation of evidence-based interventions. They measure attitudes, knowledge, perceptions, confidence, and perceived barriers or facilitators among implementers or recipients. For example, in a hypertension management program, a survey could be administered to primary care providers to assess their confidence in measuring blood pressure, adherence to treatment guidelines, perceived workload, and organizational support. The responses can identify specific barriers-such as insufficient training or limited access to equipment-that may hinder proper implementation and inform targeted strategies to address them.[3]

Fidelity Checklists / Implementation Logs: Fidelity checklists are quantitative tools designed to assess whether an intervention is being delivered as intended. They provide objective measures of adherence to protocols, which is a key determinant of implementation success. For instance, during a diabetes screening program conducted by community health workers, an observer may use a checklist to record whether each step of the screening protocol-patient consent, blood glucose measurement, risk counseling, and referral-is completed correctly for each patient. By analyzing these scores, researchers can identify components of the intervention that are consistently missed or modified, and relate them to contextual factors such as training adequacy, supervision, or workflow challenges.

Administrative or Routine Data Analysis: Analysis of administrative and routine data provides a quantitative overview of intervention adoption, reach, and sustainability across sites. For example, electronic health record (EHR) data can be used to calculate

[2] Alison B Hamilton and Erin P Finley, 'Qualitative Methods in Implementation Research: An Introduction' (2019) 280 Psychiatry Research 112516 <https://linkinghub.elsevier.com/retrieve/pii/S0165178119307917>.

[3] Luke Plonsky and Susan Gass, 'Quantitative Research Methods, Study Quality, and Outcomes: The Case of Interaction Research' (2011) 61 Language Learning 325 <https://onlinelibrary.wiley.com/doi/10.1111/j.1467-9922.2011.00640.x>.

the proportion of eligible patients receiving guideline-based hypertension management in multiple health facilities. Comparing these rates across districts can highlight patterns, such as low uptake in facilities with high staff turnover or limited medication supplies. These findings reveal structural and operational determinants that influence implementation and help prioritize areas for improvement

Performance Metrics: Performance metrics are used to track adherence to protocols and assess organizational determinants that affect implementation outcomes. For instance, monthly facility reports showing adherence rates to non-communicable disease (NCD) management protocols can be analyzed alongside staffing levels or the frequency of supervision visits. Facilities with lower adherence rates may reveal gaps in training, insufficient leadership support, or workflow inefficiencies. Providing feedback to staff based on these metrics can also serve as an implementation strategy to improve performance while identifying determinants influencing success.

Organizational / Facility Assessments: Quantitative facility assessments measure structural and contextual determinants that influence intervention implementation at the organizational level. These may include resources, infrastructure, leadership support, staffing, and readiness for change. For example, a facility readiness survey for a HEARTS program could assess availability of essential hypertension medications, functional blood pressure monitors, frequency of supervisory visits, and staff training coverage. Comparing scores across multiple facilities helps identify systemic barriers to successful implementation and informs site-specific strategies to optimize delivery.

Network Analysis / Social Network Survey: Network analysis quantitatively examines the influence of relationships, communication patterns, and collaboration among implementers on intervention uptake. For example, a social network survey could map referral pathways and communication flows among providers in a multi-facility diabetes care program. By identifying central actors, isolated providers, or weakly connected facilities, researchers can pinpoint relational determinants that may facilitate or hinder the consistent implementation of protocols, such as coordination gaps or lack of peer support.

Cost and Economic Analysis: Economic evaluation assesses financial determinants affecting the feasibility, scalability, and sustainability of an EBI For instance, in a task-shifting intervention for hypertension control, researchers may calculate the cost per patient for deploying community health workers to deliver counseling and follow-up visits. Comparing costs across clinics can reveal whether financial constraints, such as limited budgets for staffing or supplies, influence the extent and quality of intervention delivery. These analyses help inform decisions about resource allocation and scaling.

Time-Motion or Workflow Quantification: Time-motion studies quantitatively measure operational determinants, such as workflow efficiency, provider workload, or patient flow, that influence implementation fidelity. For example, in a primary care clinic implementing a cardiovascular risk screening protocol, researchers can record the average time health workers spend on each step-patient registration, history taking, measurements, counseling, and documentation. Identifying steps that take disproportionately long can reveal bottlenecks or workflow inefficiencies that hinder adherence to protocols. These insights help tailor strategies to optimize processes and improve fidelity.

Difference-in-Differences analysis

Differences-in-Differences regression (DID) is used to assess the causal effect of an event by comparing the set of units where the event happened (intervention group) in relation to units where the event did not happen (control group).[4]

Intervention effect (IE) or DID = (C-A)- (D-B)

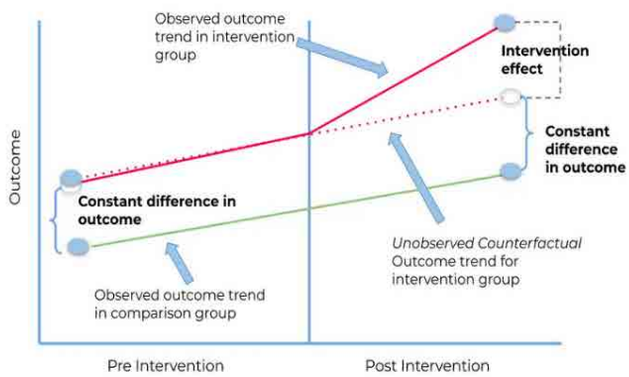
were,

A= Value at baseline in experimental group

B= Value at baseline in control group

C= Value at endline after intervention in experimental group

D= Value at endline after intervention in control group



Interrupted time series analysis

Interrupted time series (ITS) analysis in IR, is used to evaluate the impact of an intervention by analyzing data collected at multiple time points both before and after the intervention. This approach helps determine whether the intervention has produced an effect that goes beyond any existing trend in the data.[5] ITS is commonly applied to assess the effectiveness of interventions such as policy changes, quality improvement initiatives, or new treatments. By examining both the level and trend of outcomes before and after implementation, researchers can detect immediate effects, sustained impacts, and any shifts in the trajectory of outcomes over time. This analysis is especially valuable for studying interventions in real-world settings where randomization is not practical or feasible.

Regression discontinuity designs

Regression discontinuity design (RDD) is used to estimate the causal effects of interventions or strategies. In RDD, assignment to an intervention is based on whether a measurable variable crosses a specific cutoff point. This creates a clear threshold, allowing researchers to compare outcomes for individuals just above and just below the cutoff, closely approximating the conditions of random assignment. RDD is particularly valuable for evaluating strategies in situations where randomization is not feasible. By focusing on participants near the threshold, researchers can make strong causal inferences with reduced bias. This analysis is especially useful when interventions are assigned based on measurable criteria, such as implementation fidelity scores, training hours, or other continuous indicators. By leveraging these naturally occurring thresholds, RDD provides robust evidence on the effectiveness of implementation strategies in real-world settings.[6]

[4] Justin B Dimick and Andrew M Ryan, 'Methods for Evaluating Changes in Health Care Policy' (2014) 312 JAMA 2401 <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2014.16153>.

[5] James Lopez Bernal, Steven Cummins and Antonio Gasparrini, 'Interrupted Time Series Regression for the Evaluation of Public Health Interventions: A Tutorial' [2016] International Journal of Epidemiology dyw098 <https://academic.oup.com/ije/article-lookup/doi/10.1093/ije/dyw098>.

[6] Guido W Imbens and Thomas Lemieux, 'Regression Discontinuity Designs: A Guide to Practice' (2008) 142 Journal of Econometrics 615 <https://linkinghub.elsevier.com/retrieve/pii/S0304407607001091>.

Mixed-methods integration

The purpose of this method is to explain how qualitative and quantitative findings will be explicitly combined and synthesized to provide a more holistic and nuanced understanding than either method could achieve alone.[7]

Data collection and results presentation in mixed methods research

Combined qualitative and quantitative data collection

Triangulate findings, validate results, and provide a nuanced perspective on the research topic

Methods of results presentation

Separate presentation of quantitative and qualitative results (contiguous approach)

Integrated presentation of quantitative and qualitative results

The decision depends on research goals, the nature of data, and disciplinary conventions.

Separate presentations of results

A clear distinction between the quantitative and qualitative aspects of the study as per the objective.

This approach is suitable when research objectives differ significantly for each data type.

Tips for separate presentation of results

Rationale: Clearly explain in findings at the beginning the reason to present the data separately, highlighting the unique insights each data type provides.

Aims: At the beginning of each section, outline the specific aims related to quantitative and qualitative data collection.

Data presentation: Data should be presented meticulously, using tables, charts, and narrative descriptions effectively.

Transitions: Smooth transition between sections by summarizing what each section has revealed and addressing the questions it has answered.

Integrated presentation of results

[7] Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs—principles and practices. Health services research. 2013 Dec;48(6pt2):2134-56.

Annex IV: Data analysis

In IR, it is important to plan data analysis during the development of the protocol. The data analysis plan describes the specific procedures that will be used to process, summarize, and interpret the data collected from the chosen target populations to determine if and how the implementation strategies impacted the selected implementation outcomes.

Quantitative data analysis

The purpose of quantitative data analysis is to analyze numerical data. In quantitative data analysis, frequency distribution and summary statistics, relationships and confounding variables identification, sub-group analysis, statistical models or regression analysis, and trend analysis are performed to compute relationships between the implementation strategy and the implementation outcomes.

The following list provides the commonly used statistical measures in quantitative data analysis.

Univariate or descriptive analysis: Frequency, percentage, mean, median, mode, standard deviation, interquartile range, 95percentage confidence interval, skewness, kurtosis, quartile, percentile

Bivariate or inferential analysis: Correlation, chi-square test, t-test, Z-test, ANOVA, Mann-Whitney U-test, Kruskal-Wallis test, sign test, median test, Friedman two-way analysis of variance, diagrams, charts, line graphs.

Multivariable or regression analysis: Linear regression, binomial logistic regression, multinomial logistic regression, ordinal logistic regression, cox-hazard regression or survival analysis, poisson regression, negative binomial regression, Difference in Differences (DiD), Regression discontinuity design (RDD), Interrupted time series analysis (ITS).

Table 20: Choosing a significance test- difference between and within groups

Type of data	Unpaired observations	Paired observations
Categorical nominal data		
Small sample	Fishers exact test	Sign test
Large sample	Chi-square test	NcNemars Chi square test
Categorical ordinal data		
2 groups	Wilcoxon two-sample test or Mann Whitney U-test	Wilcoxon signed-rank test
More than 2 groups	Kruskal-Wallis 1 -way analysis of variance	Friedman 2-way analysis of variance
Numerical data		
2 groups	Independent sample t-test	Paired t-test
More than 2 groups	F-test (ANOVA)	

Table 21: Measuring associations between and within variables

Type of data	Tests	Measures
Categorical nominal data	Chi-square test	Odds ratio Relative risk
Ordinal or numerical data (no linear relation)	Significance of Spearman or Kendalls tau	Spearman's rank correlation coefficient
Numerical (linear relation)	Significance of Pearson's correlation coefficient	Pearson's correlation coefficient

Quantitative and qualitative data become interdependent in addressing common research questions and hypotheses.

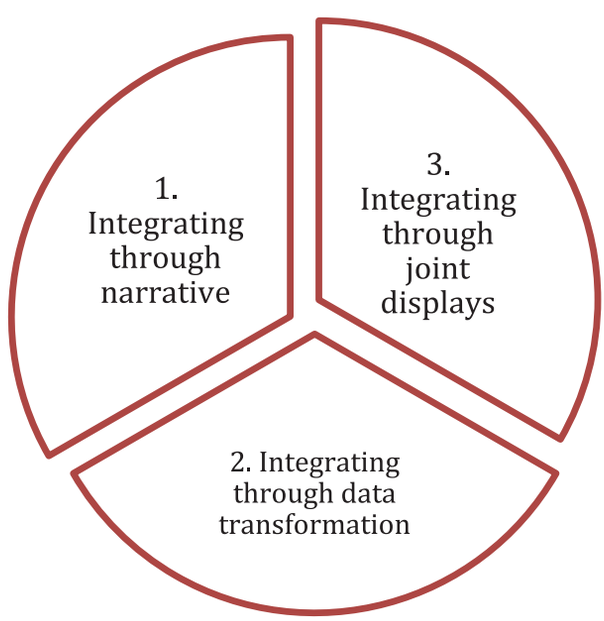
Meaningful integration allows researchers to "produce a whole through integration that is greater than the sum of the individual qualitative and quantitative parts

The qualitative data can be used to assess the validity of quantitative findings.

Quantitative data can also be used to help generate the qualitative sample or explain findings from the qualitative data.

Qualitative inquiry can inform development or refinement of quantitative instruments or interventions, or generate hypotheses in the qualitative component for testing in the quantitative component.

Three approaches of integrating results of qualitative and quantitative methods



Integrating through narrative

The weaving approach involves writing both qualitative and quantitative findings together on a theme-by-theme or concept-by-concept basis.

Integration through data transformation

Researchers sometimes code the qualitative data and then count the frequency of codes or domains identified; a process known also as content analysis. Merging in mixed methods goes beyond content analysis by comparing the transformed qualitative data with a quantitative database.

Integrating through joint displays

Researchers integrate the data by bringing the data together through a visual means to draw out new insights beyond the information gained from the separate quantitative and qualitative results. This can occur through organizing related data in a figure, table, matrix, or graph.[8]

Fits of data integration

Coherence of the quantitative and qualitative findings

1. Confirmation

Confirmation occurs when the findings from both types of data confirm the results of the other. As the two data sources provide similar conclusions, the results have greater credibility.

2. Expansion

Expansion occurs when the findings from the two sources of data diverge and expand insights of the phenomenon of interest by addressing different aspects of a single phenomenon or by describing complementary aspects of a central phenomenon of interest.

3. Discordance

Discordance occurs if the qualitative and quantitative findings are inconsistent, contradict, conflict, or disagree with each other. [85]

Options for reporting discordance findings

Looking for potential sources of bias, and examining methodological assumptions and procedures

Gathering additional data

Re-analyzing existing databases to resolve differences

Seeking explanations from theory

Challenging the validity of the constructs

Further analysis with the existing databases or in follow-up studies

Discussing:

Reasons for the conflicting results
Identifying potential explanations from theory

Laying out future research options

8 Lawrence A Palinkas and others, 'Mixed Method Designs in Implementation Research' (2011) 38 Administration and Policy in Mental Health and Mental Health Services Research 44 <http://link.springer.com/10.1007/s10488-010-0314-z>.

Annex V: Group Work

Cervical cancer is a major global public health problem and a leading cause of preventable cancer-related mortality among women. In 2022, an estimated 660,000 new cases and more than 350,000 deaths occurred worldwide, with approximately 94% of deaths concentrated in low- and middle-income countries (LMICs) (World Health Organization [WHO], 2025; International Agency for Research on Cancer [IARC], 2024). Cervical cancer is recognized as a disease of inequity, disproportionately affecting women with limited access to screening, timely diagnosis, and effective treatment [1, 2].

Cervical cancer is the leading cancer among Nepali women, with approximately 2,169 new cases and 1,313 deaths annually, corresponding to an age-standardized incidence rate of 16.4 per 100,000 women and a mortality rate of 11.4 per 100,000[3]. Recent modeling further indicates that without sustained improvements in prevention and care, cervical cancer will continue to impose a significant health and economic burden in Nepal for decades[2]. Women living in rural and remote areas, those with low socioeconomic status, and those with limited health literacy experience the highest risk due to structural and social barriers to care[4, 5] .

Cervical cancer is largely preventable in adults through secondary prevention through organized screening and timely treatment of precancerous lesions. WHO recommends HPV DNA testing as the preferred screening method, complemented by visual inspection with acetic acid (VIA) and a screenandtreat approach in lowresource settings to minimize loss to followup[1, 6]. These efforts are highly effective and costeffective when delivered with adequate coverage, quality assurance, and continuity of care [2, 6].

Despite the availability of effective interventions, cervical cancer screening coverage in Nepal remains low. Only 11.4% of women aged 30-49 years have ever been screened for cervical cancer[7]. Other studies report similarly low uptake, reflecting limited awareness, sociocultural stigma surrounding gynecological examinations, fear of diagnosis, and misconceptions about cervical cancer risk[4, 5]. Health system readiness for cervical cancer screening and treatment is also uneven. Only a minority of public health facilities in Nepal consistently provide cervical cancer screening services8,9. Even when screening is conducted, delays in diagnostic confirmation, referral, and treatment are common, leading to reduced program effectiveness[9]. These gaps contribute to late-stage presentation, increased treatment costs, and poorer survival outcomes[3].

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1 World Health Organization. (2020). *Global strategy to accelerate the elimination of cervical cancer as a public health problem.* WHO.

2 IARC. (2025). *Cervical cancer elimination tool: Nepal.* International Agency for Research on Cancer.

3 IARC. (2024). *Cervix uteri cancer fact sheet: Nepal (GLOBOCAN 2022).* International Agency for Research on Cancer.

4 Shrestha, A. D., et al. (2022). Utilization of cervical cancer screening services in Nepal: A systematic review and metaanalysis. *Cancer Causes & Control.*

5 Paneru, D., et al. (2023). Stigma and sociocultural barriers to cervical cancer screening in Nepal. *Journal of Cancer Education.*

6 World Health Organization. (2021). *WHO guideline for screening and treatment of cervical precancer lesions.* WHO.

7 Lamichhane, R., et al. (2024). Factors associated with cervical cancer screening uptake among women in Nepal. *PLOS Global Public Health.*

8 Lal, B., et al. (2024). Availability and readiness of cervical cancer screening services in Nepal. J*ournal of the Nepal Medical Association.*

9 Dangal, G., et al. (2024). Cervical cancer prevention and screening in Nepal: Current gaps and opportunities. *PLOS Global Public Health.*

In response, Nepal has demonstrated strong political commitment to cervical cancer elimination. The Government of Nepal has aligned national policies with the WHO Global Strategy to Accelerate the Elimination of Cervical Cancer, which sets ambitious 90-70-90 targets for HPV vaccination, screening, and treatment [1]. Cervical cancer screening and prevention services have been incorporated into national reproductive health and non-communicable disease programs and delivered primarily through the primary health care (PHC) system using a screenandtreat model (Family Welfare Division, cited in Lal et al., 2024).

However, a persistent implementation gap remains between policy commitments and routine service delivery. The variability in service availability, inconsistent provider adherence to guidelines, weak monitoring and reporting systems, and limited integration across levels of care undermine the effectiveness of cervical cancer prevention efforts[8,9]. These challenges are characteristic of implementation failures rather than deficiencies in scientific evidence. Addressing them requires implementationfocused approaches that account for multilevel contextual factors within Nepal's federal health system[1, 2].

	Activity	Time
Group discussion 1 **Evidence-based intervention and know-do gap**	Divide participants into three subgroups:	5 minutes
	Question 1 How would you explain the magnitude of the health problem in this context?	15 minutes
	How would you describe the evidence-based intervention? Operationalize the EBI for implementation research	15 minutes
	What is the know-do-gap that needs to be addressed?	15 minutes
	Presentation to larger group (5 minutes each)	15 minutes
	Plenary session by facilitator: synthesize key insights, clarify concepts and link the discussion to the learning objectives	15 minutes
Group discussion 2 **Implementation outcomes**	Q/A session	10 minutes
	Divide the participants into three groups	5 minutes
	Question 1 Operationally define implementation outcomes and identify data collection tool and technique from Proctor's framework: Acceptability, Appropriateness, Feasibility, Penetration, Sustainability	20 minutes
	Operationally define implementation outcomes and identify data collection tool and technique from RE-AIM framework	20 minutes
	Presentation to the larger group	20 minutes
	Plenary session	15 minutes
	Q/A	10 minutes
Group discussion 3 **Contextual determinants**	Divide the participants into three groups	5 minutes
	Question 1 Use CFIR framework to brainstorm and identify contextual facilitators and barriers to EBI adoption and fidelity: use all 5 domains of CFIR	40 minutes
	Question 2 Prioritize three most important barriers from group consensus (you can use general discussion or vote)	20 minutes
	Presentation to the larger group	20 minutes
	Plenary session	15 minutes
	Q/A	10 minutes

	Activity	Time
Group discussion 4 **Implementation Strategy**	Divide the participants into three groups	5 minutes
	Question 1 Identify an implementation strategy for each barrier (you may use CFIR-ERIC match table, or brainstorm based on experience and knowledge, literature search)	30 minutes
	Question 2 Describe each implementation strategy: name it, define it, specify it, actor, action, intended targets, temporality, dose, implementation outcome, justification	30 minutes
	Presentation to larger group	20 minutes
	Facilitator Plenary session	15 minutes
	Q/A	10 minutes
Group discussion 5 **Implementation Research Logic Model**	Divide the participants into three groups	5 minutes
	Question 1 Develop and IRLM connecting contextual determinants linking to implementation strategy, mechanism of action and implementation outcomes	40 minutes
	Question 2 Add service outcomes and effectiveness outcomes to this model	20 minutes
	Presentation to larger group	20 minutes
	Facilitator Plenary session	15 minutes
	Q/A	10 minutes
Group discussion 6 **Stakeholder analysis**	Divide the participants into three groups	5 minutes
	Question 1 Identify the major stakeholder to implement the EBI in your district	20 minutes
	Question 2 Create stakeholder engagement matrix	40 minutes
	Presentation to larger group	20 minutes
	Facilitator Plenary session	15 minutes
	Q/A	10 minutes

	Activity	Time
Group discussion 7 **Short proposal to conduct IR to identify contextual determinants**	Divide the participants into three groups	5 minutes
	Question 1 Develop a short proposal to conduct an IR to identify contextual determinants: provide clear problem statement, select and justify TMF, state your research question, choose study design, define study population, data collection technique and tool and data analysis	120 minutes
	Presentation to larger group	45 minutes
	Facilitator Plenary session	15 minutes
	Q/A	10 minutes
Group discussion 8 Short proposal to conduct IR to test implementation strategy	Divide the participants into three groups	5 minutes
	Question 1 Develop a short proposal to conduct an IR to assess effects of implementation strategies on implementation outcome, clearly defining the EBI, identifying implementation determinants, define implementation outcome, state research aims and objectives, select appropriate study design, define study population, and sample size, data collection technique, and analysis plan (Use the IRLM that was developed in the group discussion 5	120 minutes
	Presentation to larger group	45 minutes
	Facilitator Plenary session	15 minutes
	Q/A	10 minutes

Annex VI: Illustrative examples of implementation research applications in dengue control

Example of research-to-practice gap

The historical use of quinine mixed with tonic water and gin provides a clear early example of an implementation research problem. By the nineteenth century, the biomedical "knowledge" component was largely in place: quinine was known to be effective against malarial fevers. However, routine use failed because of poor adherence driven by extreme bitterness, the need for daily intake and the practical realities of life in tropical colonial settings. The key barrier was therefore not efficacy but implementation. Reformulating quinine into a palatable drink embedded in an existing social practice partially closed this know–do gap. Mixing quinine with sweetened tonic water and gin improved acceptability and compliance by aligning prophylaxis with daily routines rather than medical instruction. Although doses were often sub-therapeutic and benefits unequally distributed, the example illustrates a core principle of implementation research: effective interventions only achieve impact when delivery is adapted to behavioural, cultural and contextual constraints.[1,2]

Example of evidence-based dengue intervention in Asia

Intervention (what)	Evidence base	Implementation challenge	Key implementation insight
Community-based source reduction targeting household containers	Cluster-randomised trials and quasi-experimental studies in Vietnam, Thailand and Indonesia showed significant reductions in Aedes aegypti larval indices and dengue incidence when regular container management, covering and removal were implemented with community engagement[3]	Sustained participation declines over time; intervention effectiveness collapses without continuous engagement and local ownership	Efficacy depends on behavioural adherence and social organisation, not technical feasibility; long-term impact requires integration into daily household practices and local governance

Examples on measuring Proctor's implementation outcomes

Acceptability

What it measures: Whether stakeholders (health staff, volunteers, households) find the container-management intervention agreeable or satisfactory. For example, it gauges if households feel the container covers are easy and comfortable to use.

1 Achan, J., Talisuna, A.O., Erhart, A. et al. Quinine, an old anti-malarial drug in a modern world: role in the treatment of malaria. Malar J 10, 144 (2011). https://doi.org/10.1186/1475-2875-10-144

2 Simonetti O, Contini C, Martini M. The history of Gin and Tonic; the infectious disease specialist long drink. When gin and tonic was not ordered but prescribed. Infez Med. 2022 Dec 1;30(4):619-626. doi: 10.53854/liim-3004-18. PMID: 36482962; PMCID: PMC9714995.

3 Tun-Lin W, Lenhart A, Nam VS, Rebollar-Téllez E, Morrison AC, Barbazan P, Cote M, Midega J, Sanchez F, Manrique-Saide P, Kroeger A, Nathan MB, Meheus F, Petzold M. Reducing costs and operational constraints of dengue vector control by targeting productive breeding places: a multi-country non-inferiority cluster randomized trial. Trop Med Int Health. 2009 Sep;14(9):1143-53. doi: 10.1111/j.1365-3156.2009.02341.x. Epub 2009 Jul 14. PMID: 19624476.

Level measured: Organizational/system level and individual level
Measurement tools: Survey, interviews, group discussions
When measured: During piloting and early implementation

Adoption

What it measures: The initial uptake or intention to use the intervention. In this context, it means tracking how quickly and how many organizations or households begin to implement the source-reduction activities (e.g. covering containers and removing stagnant water).
Level measured: Organizational/system level and individual level
Measurement tools: Policy review, surveys, interviews, review of program records
When measured: During piloting and early implementation

Appropriateness

What it measures: It assesses whether stakeholders feel that covering household water containers addresses the community's dengue risk effectively and fits local customs (e.g. is it compatible with household routines and cultural norms).
Level measured: Organizational/system level and individual level
Measurement tools: Surveys, interviews, group discussions
When measured: During piloting and early implementation

Feasibility

What it measures: It examines whether households have the time and ability to cover/remove containers regularly, and whether health workers have the capacity to support the program (e.g. supply covers, train volunteers).
Level measured: Organizational/system level and individual level
Measurement tools: Surveys, interviews, observation, review of implementation plans
When measured: During piloting and early implementation

Fidelity

What it measures: Whether the intervention is being implemented as planned. This includes checking if households are managing containers as instructed and if volunteers and health workers are following the agreed procedures.
Level measured: Organizational/system level and individual level
Measurement tools: Observation checklists, activity logs, interviews
When measured: During early and ongoing implementation

Implementation Cost

What it measures: The costs involved in delivering the intervention. This includes costs for materials, training, supervision, transportation, and the time of health workers and volunteers.
Level measured: Organizational/system level and individual level
Measurement tools: Budget review, financial records, interviews
When measured: During piloting and early implementation

Penetration

What it measures: It measures the proportion of communities, households, or wards where container management activities are being practiced.

Level measured: Organizational/system level and individual level
Measurement tools: Program records, surveys, household coverage reports
When measured: During early to mid-implementation

Sustainability

What it measures: It examines if container management becomes a routine household practice and if local authorities include it in regular dengue control activities.
Level measured: Organizational/system level and individual level
Measurement tools: Policy review, follow-up surveys, interviews
When measured: During later stages of implementation and after the project period

Examples of measuring implementation outcomes using the RE-AIM framework

Reach

What it measures: It measures the number and proportion of households, especially high-risk groups, that participate in container management activities.
Level measured: Individual level and community level
Measurement tools: Household surveys, program records, community mapping
When measured: During early and mid-implementation

Effectiveness

What it measures: The impact of the intervention on key outcomes. This includes changes in mosquito breeding indicators, dengue cases, and household practices related to water storage and container management.
Level measured: Individual level and community level
Measurement tools: Routine surveillance data, household surveys, entomological assessments

When measured: During implementation and after a defined implementation period

Adoption

What it measures: The extent to which organizations and community actors decide to start the intervention. This includes adoption by local health offices, municipalities, community groups, and volunteers.
Level measured: Organizational/system level and community level
Measurement tools: Policy review, interviews with health officials and community leaders, program records
When measured: During piloting and early implementation

Implementation

What it measures: Consistency of household visits, correct use of container covers, quality of community engagement, and adaptations made during delivery.
Level measured: Organizational/system level and individual level
Measurement tools: Observation checklists, activity logs, interviews, supervision reports
When measured: During early and ongoing implementation

Maintenance

What it measures: Whether the intervention is sustained over time at both individual and system levels. This includes continued household practices and integration of source reduction into routine dengue control programs.
Level measured: Organizational/system level and individual level
Measurement tools: Follow-up surveys, policy review, interviews with local authorities and households
When measured: During later implementation stages and after the project period

Example of PRISM-guided determinants of community-based dengue source reduction intervention

PRISM Domain	Contextual Focus	Facilitators	Barriers
1. Perspectives on the Intervention	Organizational perspectives	• Dengue source reduction is perceived as an evidence-based and low-cost intervention • Alignment with national dengue control strategy and vector control guidelines • Visible reduction in mosquito breeding sites increases confidence among health staff	• Results are not immediately visible, reducing motivation • Perception that dengue control is mainly a municipal responsibility • Limited priority compared to curative health services
	Community / household perspectives	• Simple actions (covering, emptying containers) are easy to understand • Reduced mosquito nuisance motivates participation • Community clean-up activities promote collective responsibility	• Behavior change is difficult to sustain over time • Low risk perception during non-outbreak periods • Belief that dengue is a seasonal or “urban-only” problem
2. Characteristics of Implementers, Settings, and Recipients	Organizational characteristics	• Support from municipal health sections and FCHVs • Existing ward-level committees facilitate coordination • Integration with routine vector control activities	• Staff shortages and high workload at local level • Limited budget for continuous community engagement • Weak monitoring and supervision systems
	Implementer characteristics	• Training improves knowledge on dengue transmission and prevention • Use of simple checklists and job aids supports correct implementation • Supervision builds confidence among volunteers	• Limited experience in behavior change communication • Low confidence in motivating resistant households High turnover of volunteers

PRISM Domain	Contextual Focus	Facilitators	Barriers
	Household and family characteristics	• Family involvement supports regular container management • Awareness campaigns improve acceptance • School children act as change agents	• Irregular water supply increases water storage practices • Gender roles place burden on women without decision-making power • Low health literacy in some communities
3. External Environment	Policy and governance context	• National dengue guidelines support community-based prevention • Decentralized governance enables local action • Multisectoral collaboration opportunities (health, environment, education)	• Weak enforcement of environmental sanitation regulations • Inconsistent coordination between sectors • Limited accountability mechanisms
	Social and physical environment	• Dense communities allow peer influence and collective action • Media coverage during outbreaks increases awareness	• Rapid urbanization and unmanaged waste create breeding sites • Migration and rental housing reduce ownership and responsibility • Seasonal monsoon increases mosquito breeding
4. Implementation and Sustainability Infrastructure	Program design and delivery	• Community-led approaches increase ownership • Integration with routine outreach activities reduces additional burden Use of local leaders improves trust	• Dependence on external funding • Lack of long-term incentives for volunteers • Limited data use for local decision-making
	Sustainability capacity	• Potential for integration into routine municipal services • Community norms can sustain behaviour over time	• Behavior change declines without continued engagement • Political and leadership changes disrupt continuity • Absence of dedicated budget lines

Example of implementation strategies for community-based dengue source reduction intervention

Strategy (Name it)	ERIC Strategy Alignment	Definition (What is it?)	Actor (Who enacts?)	Actions (What is done?)	Action Target (What changes?)	Temporality (When?)	Dose (How much?)	Primary Implementation Outcome	Rationale / Justification
Competency-oriented training for dengue field workers	Conduct educational meetings; Develop educational materials; Provide ongoing training	A structured approach to build practical skills and confidence of front-line workers understanding dengue transmission and household-level source reduction	Public health inspectors, FCHVs, municipal health staff	Deliver interactive training sessions with demonstrations, field exercises, and practical job aids focused on identifying breeding sites and counselling households	Improved knowledge, skills, and self-confidence of implementers	Before rollout, with refreshers during implementation	Initial 2–3 days; refresher every 6–12 months	Adoption	Field workers are more likely to take up and correctly apply new practices when they feel competent and supported
Household reminder and follow-up system	Use reminders; Promote adherence to intervention protocols	A structured system to prompt households to routinely perform container management activities	FCHVs, ward volunteers, community mobilizers	Maintain household registers; deliver verbal reminders during visits; use cards, phone calls, or local announcements to reinforce regular actions	Increased regular household participation in container emptying and covering	Initiated early and continued through transmission season	Weekly or bi-weekly during high-risk periods	Reach	Reminders help overcome forgetfulness and competing daily priorities, especially when perceived dengue risk is low
Supportive supervision and field mentoring	Provide clinical supervision; Audit and provide feedback	A continuous process of observing practice and offering constructive guidance to improve delivery quality	Municipal supervisors, senior health staff	Conduct joint visits, observe interactions, provide feedback, discuss challenges, and jointly identify solutions	Improved consistency and quality of implementation	Early implementation onward	Monthly early; quarterly later	Fidelity	Supportive feedback strengthens adherence to agreed procedures and reduces variation in delivery

Strategy (Name it)	ERIC Strategy Alignment	Definition (What is it?)	Actor (Who enacts?)	Actions (What is done?)	Action Target (What changes?)	Temporality (When?)	Dose (How much?)	Primary Implementation Outcome	Rationale / Justification
Community leadership engagement and endorsement	Build a coalition; Involve local opinion leaders	Active involvement of respected local figures to legitimize and promote dengue source reduction as a shared responsibility	Ward chairs, community leaders, school heads	Hold orientation meetings; encourage public endorsement; involve leaders in community clean-up activities and messaging	Increased trust, social acceptance, and community participation	Before and during implementation	Periodic engagement	Acceptability	Endorsement by trusted leaders increases legitimacy and motivates community action
Integration of source reduction into routine municipal activities	Change service sites; Integrate services	Embedding dengue prevention tasks into existing municipal health and sanitation routines	Municipal health sections, sanitation units	Align container management with waste management, environmental inspections, and routine outreach	Institutionalization of dengue prevention practices	During scale-up and routine delivery	Continuous	Sustainability	Integration reduces reliance on short-term projects and supports long-term continuation
Use of simple monitoring and feedback tools	Develop and use quality monitoring systems; Facilitate relay of clinical data to providers	Practical tools to track progress and provide feedback to implementers and communities	Field workers, supervisors	Use brief checklists during visits; review data in meetings; share progress with communities	Improved accountability and data-informed adjustments	During implementation	Ongoing	Penetration	Simple feedback systems keep implementers engaged and allow timely course correction

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