

## Phase 1: Formative Research of the Problem

### Step 1: Establish a planning group

Begin by convening a small, purpose-built group that brings together (a) members of the target population, (b) stakeholders such as decision-makers, (c) those who will implement the program, and (d) content experts. Invite representatives of the at-risk group, prospective implementers, and organizational decision-makers to ensure lived experience, operational realities, and authority are all present in early planning (IntM). Clarify roles and accountabilities from the outset and establish a standing team responsible for guiding adoption, implementation, improvement, and communication with leadership (AIF). Keep the core team small and skilled (e.g., ~3–5 expert members) that works closely with executive leadership and is accountable for “making it happen,” while engaging broader stakeholders as needed (AIF). Use the group to systematically think through who must do what at each stage of adoption, implementation, and maintenance so early design choices reflect context, barriers, and facilitators identified with those who will adopt or use the program.

### Step 2: Understand and Define the Problem

Identify at-risk populations and define who the program will target during early scoping (REP). Meet with participating organizations to gather data through needs assessments, interviews, and environmental scans (Core) to identify patterns, root causes, and feedback loops (Systems Thinking).

Determine the highest priority needs and related goals for the population. This involves identifying social issues and desired outcomes that align with community priorities and are realistically achievable within existing constraints (QUERI, IM).

To gain a deeper understanding of the problem and the determinants associated with the problem, speak to a broad range of stakeholders and utilize methods from human-centered design, such as immersion, group activities, analogous inspiration, and other techniques (HCD). Identify key variables and formalize them in causal loop diagrams to show dynamic interrelationships and reinforcing/balancing loops, highlighting how policy, environment, and behaviors interact to shape the issue. Sketch a rich picture of the situation that captures elements, relationships, emotions, and interactions, and build it iteratively with key stakeholders (System Thinking).

Ground the issue in contextual data by defining the problem and the know-do gap, drawing on sources such as audits, needs assessments, and population data; use structured root-cause tools (e.g., Five Whys, cause-and-effect) and actively surface different perspectives to avoid bias (KAF). Critically reflect with an equity lens by engaging stakeholders to assess needs and assets and co-create plans that broker diverse perspectives and address power differentials (CORE).

### Step 3: Develop a Problem Logic Model

Creating a problem logic model requires in-depth assessments to understand determinants and influences on health behaviors. This model can help identify where interventions should focus. The problem logic model traces how environmental and behavioral factors contribute to health and well-being outcomes. An example of a problem logic model can be seen in Figure 1, below. For a more detailed description of how to create a problem logic model, review Step 1 of Intervention Mapping ([here](#)).

List the primary problem(s) that you will address in the final column of the problem logic model. Then consider the behavioral causes of the problem you will address (IntM, PRECEDE). Ask the target population and stakeholders to explain the various causes of the problem(s). List the behavioral causes of the problem in the column of the problem logic model labeled, Behavioral Outcomes. Then, identify the environmental and behavioral determinants that cause or influence the behaviors that you want to change. Analyze the determinants that predispose, reinforce, and enable the

target behaviors (PRECEDE, BCW, SEM). List the determinants in the column of the problem logic model labeled, Environmental/Behavioral Determinants.

Figure 1. Example Problem Logic Model

Environmental/Behavioral Determinants	Behavioral Outcomes	Primary Problem(s)
<p>Caregivers lack knowledge of responsive caregiving and stimulation practices</p> <ul style="list-style-type: none"> <li>- Limited access to early learning materials</li> <li>- Poor nutrition and food insecurity</li> <li>- Inadequate maternal mental health support</li> <li>- Lack of clean, safe play environments</li> <li>- Low parental engagement due to economic demands</li> </ul>	<ul style="list-style-type: none"> <li>- Caregivers do not engage in daily play or talk with children</li> <li>- Infrequent use of early stimulation activities (e.g., storytelling, singing)</li> <li>- Poor feeding practices</li> <li>- Low attendance at community health or ECD sessions</li> </ul>	Delayed cognitive, emotional, and physical development in children under age 5
<ul style="list-style-type: none"> <li>- Weak linkages between home and early childhood centers</li> <li>- Irregular attendance in community-based preschool programs</li> <li>- Poorly trained early educators</li> <li>- Cultural norms undervaluing early education</li> </ul>	<ul style="list-style-type: none"> <li>- Children enter school without basic language, social, or motor skills</li> <li>- Families do not prioritize preschool participation</li> </ul>	Low school readiness among children entering primary school
<ul style="list-style-type: none"> <li>- Lack of access to preventive health services</li> <li>- Unsafe water/sanitation</li> <li>- Poor vaccination coverage</li> <li>- Lack of routine child health monitoring</li> </ul>	<ul style="list-style-type: none"> <li>- Caregivers miss key child health visits</li> <li>- Children are frequently ill or undernourished</li> </ul>	High incidence of preventable illness

## Phase 2: Intervention Design

### Step 4. Develop a Logic Model of Change

Creating a logic model of change will help determine what needs to occur to address the problems described in the problem logic model. It defines the objectives that need to be accomplished for the intervention to be successful. The exercise will help with the design of the intervention by specifying who and what will need to change to improve the problem. With the planning group, determine the expected outcomes, objectives, and potential barriers of the intervention (IntM). For each step, consider each ecological level (individual, interpersonal, organizational, environmental) (SEM). Aligning planned activities with expected outcomes in a logic model framework will help with tracking and evaluation (IM Adapt, QUERI). An example of a logic model of change can be seen in Figure 2, below. For more information on creating a logic model of change, review Step 2 of Intervention Mapping ([here](#)).

Define the behavioral and/or environmental outcomes that are expected to change as a result of the intervention. The behavioral/environmental outcomes can be drawn from the problem logic model created in the previous step. List the outcomes on the right side of the logic model to reflect the consequences of the theory of change. Then, specify what needs to occur to address or improve the behavioral/environmental outcomes. These objectives usually represent improvements in the performance of local actors and systems that will lead to improved behavioral outcomes. These objectives will be the focus of the intervention. They will also be a key part of monitoring and evaluating the intervention. List the objectives in a column to the left of the behavioral/environmental outcomes, labeled, Performance Objectives.

Determine what needs to take place to accomplish the performance objectives. This provides a more detailed description of who and what needs to change to improve the performance and quality of services. Each performance objective should include a list of changes that need to occur for the objective to be accomplished. List the changes that need to occur in the column labeled, Change Objectives.

Specify the determinants (barriers and facilitators) that could hinder the accomplishment of the change and performance objectives. Further research will be conducted in later steps to better understand the determinants (barriers and facilitators), however, identifying determinants now will help to choose an appropriate intervention. Barriers are factors that could hinder implementation or the positive change created by the intervention. Facilitators are factors that will help the accomplishment of the objectives. The intervention and implementation process should be designed to eliminate or reduce the influence of the barriers and take advantage of the facilitators.

Figure 2. Logic Model of Change

Determinants (Barriers / Facilitators)	Change Objectives	Performance Objectives	Behavioral/Environmental Outcomes
<ul style="list-style-type: none"> <li>-Barrier: Lack of knowledge about child development</li> <li>-Facilitator: Respect for community health workers (CHWs)</li> <li>- Barrier: Belief that children “learn when older”</li> <li>-Facilitator: Familiarity with local cultural storytelling traditions</li> </ul>	<ul style="list-style-type: none"> <li>-Increase caregiver knowledge about the benefits of daily stimulation</li> <li>-Improve CHW skills in delivering key messages</li> <li>-Shift caregiver beliefs to value early learning</li> <li>-Promote traditional stories as tools for brain development</li> </ul>	<ul style="list-style-type: none"> <li>-Caregivers talk, play, and read with their children daily</li> <li>- Caregivers use storytelling and songs in local language</li> </ul>	Caregivers engage in responsive caregiving and stimulation
<ul style="list-style-type: none"> <li>-Barrier: Lack of money for toys</li> <li>-Facilitator: Creativity and resourcefulness in communities</li> <li>-Barrier: Competing work/family responsibilities</li> <li>Facilitator: Social support from other caregivers</li> </ul>	<ul style="list-style-type: none"> <li>-Train caregivers to create learning tools from local materials</li> <li>-Increase perceived value and convenience of parenting sessions</li> </ul>	<ul style="list-style-type: none"> <li>-Households use homemade toys or learning materials</li> <li>-Caregivers attend parenting group sessions regularly</li> </ul>	Improved home stimulation environments
<ul style="list-style-type: none"> <li>- Barrier: Limited nutrition knowledge</li> <li>-Facilitator: Presence of local clinic</li> <li>-Barrier: Irregular clinic visits due to distance</li> <li>-Facilitator: Trust in community health volunteers</li> </ul>	<ul style="list-style-type: none"> <li>- Improve caregiver understanding of balanced child diets</li> <li>Strengthen links between caregivers and health services</li> <li>- Raise awareness of importance of timely check-ups</li> <li>Engage volunteers to support household follow-up</li> </ul>	<ul style="list-style-type: none"> <li>- Caregivers feed children diverse meals and access growth monitoring services</li> <li>- Caregivers ensure vaccination and health check-ups are up to date</li> </ul>	Improved health and nutrition of children under 5

### Step 5: Conduct a Resource Assessment

Conduct a thorough resource assessment before defining the intervention to align resources with potential solutions to the identified needs. Identify the resources available to address the problem, including organizational capacity (staffing, skills, funding, infrastructure), community assets, and existing programs. Examine fit between candidate solutions and local resources. (QIF)

### Step 6. Select the intervention

Review available evidence-based practices (EBP) or innovations to determine which interventions best align with the problem. Interventions should be matched to behavioral targets, change objectives, and the underlying problem theory (QUERI, IntM). Interventions should be logically connected to the behavioral mechanisms they aim to change and be tailored to the local context (BCW). Focus effort on changeable, high-impact leverage points (QIF).

Determine if the intervention has been shown to be effective in similar populations. Assess if the potential interventions are feasible and relevant for the specific context (IM Adapt, ISF, QIF). Consider if they align with local needs, capacity, and infrastructure (REP). Bringing in individuals with expertise in developing usable innovations and involving local stakeholders further strengthens the selection process (AIF, EPIS). The Hexagon Tool can support this step by helping assess program indicators such as evidence, usability, and support, as well as local factors like fit, need, and capacity ([Hexagon Tool](#)) (AIF).

If no suitable intervention exists, consider adapting an existing one or developing a new approach. This should be grounded in research evidence and a clear understanding of the problem (MRCG).

Before finalizing the selection of the intervention, consider organizational readiness. Consider preparedness of leadership at all levels, including middle management and frontline staff, to ensure there is capacity and motivation to implement the intervention (PRISM, QIF). Make an assessment to determine if the level of readiness and organizational capacity that is needed for the intervention is feasible to achieve. Finally, decide whether to adopt the intervention with the planning group and local stakeholders (EPIS).

## **Step 7. Program development**

Once an intervention has been identified, define the program themes, components, scope, and sequence of intervention activities. Select theory-driven, evidence-based behavior change methods that align with the intervention's performance objectives (IntM, BCW). Developers should select or design practical application methods to create the intended changes.

Drawing from social and behavioral science theories can help identify which behavior change techniques will be most effective. For example, social cognitive theory and the theory of planned behavior can guide the design of strategies that influence individual beliefs, intentions, and actions (IntM, SCT, TPB).

Program elements must be tailored to fit local settings and populations. Adapt the knowledge material to the local context, reflecting cultural norms, language, and dialect. Engage with the end users of the intervention to ensure local relevance (KAF, IM Adapt). Include design activities with the end users to adapt all aspects of the program. Human-centered design practices, particularly the ideation phase, offer a structured way to engage local stakeholders in designing or refining interventions. Activities such as sharing inspiring stories, creating insight statements, brainstorming, and integrating feedback can generate innovative approaches that align closely with community needs and preferences ([HCD Ideation Phase](#))(HCD).

Consider that the population will adopt the intervention in stages and plan for the program to address the needs of each stage. The stages include: awareness of the need for an innovation, decision to adopt (or reject) the innovation, initial use of the innovation to test it, and continued use of the innovation (DOI).

Simplification of the program is a critical step. To increase usability and efficiency, interventions should be streamlined to include a minimum of non-essential elements, while also planning for long-term sustainability. Avoid burdensome, unessential tasks and instead leverage existing structures and workflows (PRISM).

Assess the usability and adaptability of the program. Conduct usability testing with local stakeholders before distributing more widely (AIF).

## **Step 8. Create Program Material**

Create a package of intervention material for the implementers that includes a description of what is being implemented and the overall vision and purpose for doing so (StrategEase). Provide a clear explanation of the "what" and "why." Findings from previous research should be distilled and existing experiences synthesized to translate insights into accessible, actionable language. The messaging should also highlight benefits to the organization, such as return on investment or value to end users (ISF, REP).

Convert the intervention into a usable format. This includes simplifying technical protocols into a user-friendly manual that outlines the intervention's theory, core components, and methods. The package should clearly define the intervention's essential functions and goals, while allowing for context-specific adaptations through menu options (AIF, REP). This flexibility helps maintain effectiveness while supporting scalability across diverse settings.

The package should contain all necessary implementation materials: a technical manual, training guides, verbatim scripts, session workbooks, staff roles and qualifications, supervision guidelines, and printable support tools such as pocket cards and flowsheets. These elements ensure the intervention is teachable, doable, and assessable in practice (REP, AIF, OMRU). Clarifying which elements are essential and which can be adapted further supports consistent delivery.

To ensure appropriate reach, the package should also define inclusion and exclusion criteria for the target population (AIF). Clearly identifying the intended audience enhances program relevance and effectiveness.

Before finalizing, the package must be pilot-tested and refined with feedback from early users. This step ensures clarity, usability, and fit with local contexts. Adjustments may be needed to improve delivery or materials. Finally, identify where to adapt specific elements of the intervention to support successful implementation in varied environments (REP, IntM, IM Adapt).

## Phase 3: Study Program Setting

### Step 9. Engage Stakeholders to review program

Begin by building partnerships with a range of stakeholders—researchers, healthcare professionals, policymakers, patients, community organizations, and government agencies (Core competencies). Form a Community Working Group composed of representatives from organizations serving the target population. This group should meet regularly during pre-implementation to review materials, refine core and adaptable components, advise on staff training and technical assistance, and help coordinate logistics (REP).

Identify individuals within organizations who have authority to lead change. These agents of change should be engaged across all levels of leadership—executive, middle management, and frontline—to build broad support for the intervention (OMRU, PRISM, QIF).

Appoint a program champion at each implementation site to mobilize support and coordinate internal activities. Champions help identify implementation staff, promote the intervention, and serve as key links to the Community Working Group (REP). Their leadership is essential to encouraging adoption and ensuring alignment within their organization.

### Step 10. Assess readiness, barriers and facilitators to implementation

Begin by specifying the behaviors that need to change. Use documentary analysis or research to define who needs to do what differently to support intervention uptake (TDF). Meet with staff at participating organizations to introduce the intervention and explore potential barriers. Focus on understanding users' needs, preferences, and experiences (QUERI, StrategEase, PRISM). Walk through the steps of the intervention with staff to identify what is required for delivery (MLSKT, REP). Ask what makes it easy or difficult to comply with the intervention requirements (MLSKT).

Conduct a multilevel assessment of the system, organization, providers, and clients' characteristics. Use semi-structured interviews to gather information about staffing, workflows, patient volume, and technology. This helps to benchmark current practice and identify technical support needs (REP). Also map out behaviors, decision points, and processes that influence practice delivery, engaging frontline staff to capture variations across settings (REP, QUERI, OMRU).

Assess barriers and facilitators using CFIR to understand multi-level determinants related to implementing the intervention at various levels of the local setting (CFIR). The list of CFIR domains can be found [here](#). Use TDF to explore what types of behaviors could be problematic to implementation or success of the intervention, such as skills, motivation, or social support (TDF). The list of TDF domains can be found [here](#). Apply these frameworks for the creation of interview or focus groups guidelines to identify challenges to implementation.

### Step 11. Assess Readiness of implementing organizations

Assessing readiness is a critical step in designing a public health program, ensuring that conditions are favorable for successful and sustained implementation. Conduct a thorough assessment of organizational readiness to evaluate current strengths and potential challenges, including motivation, innovation-specific capacities (skills and tools necessary for the specific intervention), and general capacities (staffing, infrastructure, resources) (RTT).

At the system level, work with system and agency leaders to determine if prerequisite structures and supports are in place. This includes evaluating broader infrastructure and administrative alignment that will enable effective execution and long-term integration of the intervention (DAP).

At the organizational level, assess both practical and structural factors that may influence readiness. These include training space, staff availability, resource adequacy, proximity to clients, and transportation access. Equally important are internal organizational factors, such as the engagement of senior and team-level leadership, organizational culture, and climate (DAP, Action, Core). Surveys and interviews can be conducted to diagnose overall health, culture, and readiness for change within the organization. Understanding these contextual elements helps tailor the implementation approach to the organization's strengths and needs (QUERI, PRISM).

The provider-level assessment focuses on the individuals who will deliver the intervention. Use staff surveys to assess experience with similar services, work attitudes, and openness to innovation. This includes measuring personal innovativeness—such as willingness to try new procedures or adopt new tasks—as well as attitudes toward evidence-based practices. Organizational factors like team climate, leadership support, and communication can also influence readiness at this level. Together, these insights reveal both individual and collective preparedness to adopt and sustain the intervention (DAP).

Once barriers and facilitators have been identified, the next step is to analyze the data to guide implementation planning. Begin by setting clear goals and identifying both behavioral and environmental targets that need to change. Compare current practices to the desired state to uncover key gaps (IM Adapt, OMRU).

Through the analysis, identify the barriers that are most relevant to implementation and plan for those barriers with context-relevant, behavior specific solutions. Prioritize 3–5 of the most critical or high-impact barriers to address first, based on who is affected and what behavior needs to change (StrategEase, QUERI).

## Phase 4: Implementation Design

### Step 12. Design a Program Implementation Plan

Creating a comprehensive implementation plan involves outlining specific strategies to ensure that the intervention is accepted, adopted, and delivered with fidelity. The implementation plan should reflect the diagnostic assessment of barriers, facilitators, and readiness conducted in the previous phase (QUERI, IRLM). Based on these factors, adapt the program and implementation strategies to align with the unique needs and structure of each setting (QUERI, OT). Include plans to build staff knowledge and skills, increase understanding of the innovation, and develop motivation to implement new practices. Whenever possible, integrate community resources and assess how the local environment may help or hinder implementation efforts (OMRU, PRISM, Core, QUERI).

Create a change matrix to link each program user type to the objectives they need to accomplish, implementation outcomes, and strategies that will be used to address them (IM, IRLM). Start by identifying the program users—those being asked to change—and the roles they will play (StrategEase, IRLM, IM). Define the implementation outcomes that are important for each actor. Define the performance objectives for each group to accomplish the implementation outcomes, such as delivering training, supervising staff, or conducting outreach. These will define what the implementors need to do to implement the program. Then determine the implementation strategies that will be used to accomplish the performance objectives. The strategies should address the barriers that were identified for each actor and ensure the objectives will be achieved (EPIS, OMRU). An example of an implementation mapping matrix with outcomes, objectives, and strategies can be seen in **Figure 3**. More information on conducting implementation mapping can be found [here](#).

Consider the REAIM dimensions as objectives or outcomes for the implementation strategies: reach, effectiveness, adoption, implementation consistency, and maintenance/sustainment (REAIM). Also consider Proctor's outcomes for implementation research as potential outcomes for the implementation plan, including acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability (PROCTOR).

Co-design the implementation strategies with stakeholders, using continuous engagement to ensure they are feasible and contextually appropriate. Include local representatives and champions in the creation of the implementation

strategies (IM). Continuously engage with them and other frontline stakeholders to ensure the proposed strategies are feasible for the local context (QUERI). Integrate community resources when possible (PRISM).

Target participants acceptance of the program when designing strategies (OT). Include strategies to increase awareness and understanding of the intervention (OMRU). Use strategies to support stakeholders at all levels to develop a shared understanding of the problem and the steps to address it (Core).

Create capacity building strategies for the implementers to be able to carry out the intervention (QIF, OMRU). Provide education in modifiable areas, such as knowledge, beliefs, and perceived risk of inaction (PRISM). Include a coaching service delivery plan to support the implementors (AIFs).

Include staff recruitment and maintenance strategies in the implementation plan (QIF). Create new job descriptions, establish interview methods, preparing interviewers to select practitioners and staff to do the new work (AIFs). Include a timeline for the implementation of the intervention (IM Adapt).

The ERIC refined list of implementation strategies can be referred to generating ideas for diverse strategies (ERIC, IM). Link the barriers identified in the previous phase to evidence-based change techniques in the implementation and/or intervention design (TDF, QUERI). To support strategy selection, the CFIR-ERIC Matching Tool can help align barriers with appropriate implementation strategies, improving the likelihood of program success (CFIR-ERIC).

To build long-term capacity, include strategies for coaching, staff training, and recruitment. This may involve developing job descriptions, preparing interview processes, and offering education on modifiable factors like knowledge, beliefs, or risk perception. Provide a delivery schedule for the intervention and create a menu of flexible adaptations that program managers can implement after rollout (AIFs, PRISM, IM Adapt, QUERI).

Plan for sustainability and ongoing improvement. Avoid adding nonessential tasks to staff workload and aim to embed the intervention into existing systems (PRISM). Build sustainability capacity among staff and organizations. Prepare action plans to address potential and unforeseen implementation issues, including the process for resolving challenges and making decisions. Maintain feedback loops to support continuous learning and refinement of the implementation plan (Core, QIF).

Develop detailed protocols and materials for each strategy (IM). Describe who will deliver each strategy, when, in what setting, and what barrier or facilitator each strategy is intended to address.

Adapt implementation strategies based on feedback from stakeholders (QUERI, Core, CHANGE). Create a menu of adaptations that can be done by program managers after implementation begins. The menu will show what activities are flexible and what alternatives can be used if they need to be changed (QUERI).

Plan for pre-testing materials and implementation activities (IM Adapt).

Figure 3. Implementation Mapping Matrix Example

Actor	Implementation Outcome	Performance Objectives	Implementation Strategies
Home Visitor	Adoption	1. Feel confident to use in the app during their visits 2. Agree to use the app during their visits/meetings 3. Access to a phone that can run the app	1. Conduct trainings with the CHWs to teach how to use the App. 2. Survey the CHWs after training to assess their confidence and readiness to use the App during the visits/meetings 3. Identify the CHWs that have low levels of readiness. Offer coaching to those individuals from local champions
	Acceptability	1. Feel confident using the app 2. Contact the intervention champion/supervisor when they have trouble	Implementation Strategies 1, 2, and 3 7. Conduct an improvement survey at mid-line to receive feedback from CHWs regarding how the App can be improved. 8. Conduct an improvement survey at mid-line with caregivers to receive feedback regarding the visits/meetings
	Fidelity	1. CHWs observe how the visits/meetings should be conducted 2. Participate in on-going training to ensure quality 3. Receive constructive feedback on how their visits/meetings can have greater fidelity	Implementation Strategies 1, 2, and 3 9. Simulate and video record a high-quality home visit with each age group and cultural group. 10. Share the home visit videos with the CHWs during training. 11. Make the home visit videos available online so the CHWs can view the videos when needed 12. Conduct a mid-line training session with CHWs 13. Request that the program supervisor or champion conduct home visit/meeting observations and fill-out an observation checklist, then share the checklist to the research team.

### **Step 13. Develop Evaluation Plan**

Develop a process evaluation and outcome evaluation plan to capture changes created by the intervention and implementation strategies (IM Adapt). The evaluation should determine which implementation strategies are successful, for whom, and under which conditions success occurs (QUERI, AIFs). The evaluation should determine if the program successfully achieves the intended outcomes and captures the implementation process (Core).

A logic model can guide the evaluation planning process to determine what to evaluate, key questions, data sources, timing, and methods (QUERI, Core, IRLM). Leverage the implementation mapping matrix from Step 12 to determine what needs to be measured to assess implementation quality (IM). The Logic Model of Change from Step 4 can be used to identify what needs to be measured to assess the success of the intervention, intermediate processes, and ultimate clinical outcomes (IRLM, Core).

The barriers, implementation strategies, implementation outcomes, service outcomes, and clinical outcomes can be organized in an Implementation Research Logic Model. The IRLM specifies the relationships between determinants of implementation, implementation strategies, the mechanisms of action resulting from the strategies, and the outcomes affected (IRLM). Proctor's implementation research outcomes help explain the differences between implementation, service, and clinical outcomes, and provided a list of implementation outcomes that can be used to monitor and evaluate the implementation and success of the intervention (PROCTOR).

When identifying measures of success and data sources, include implementation outcomes, consumer outcomes (client-level changes), system and service outcomes (improved service quality and efficiency), and measures that are meaningful to frontline staff (QUERI). The implementation outcomes help to evaluate if the intervention is being delivered as expected. Service outcomes and performance measures are used to evaluate if the intervention is being delivered as expected and creates the desired changes in the system, such as if the quality of the service has improved (MLSKT). Include measures to evaluate if patient outcomes have improved (client and clinical outcomes) (PROCTOR, MLSKT).

Establish a practical plan for data collection. Specify who will collect the data, when, and how. Integrate data collection into existing workflows and electronic systems whenever possible, making the process efficient for frontline staff. Encourage system improvements to enhance both the collection and use of the data to enhance clinical decision support whenever possible (PRISM).

Design a continuous improvement process that will leverage the monitoring and evaluation data being collected. Utilize short-cycle improvement processes – such as the Monitoring, Evaluation, Research, Learning, and Adaptation (MERLA) Cycle – to create and evaluate changes systematically.

## **Phase 5: Initial Implementation**

### **Step 14: Create Organizational Readiness**

Strong stakeholder relationships are a cornerstone of successful implementation. Begin by intentionally cultivating trust with those inside and outside the organization, including frontline staff, leaders, and community members (Core). Trust is built through transparency, authenticity, and respect—by genuinely listening to others and acknowledging both their words and emotions (Core).

Form a coordinated implementation team by collaborating with stakeholders, define their roles and responsibilities, create shared goals, and establish clear decision-making processes and timelines (Core, QIF). Consider utilizing existing staff, as this can accelerate implementation (PRISM). Develop clear work plans and communication structures that keep team members aligned, supported, and aware of their individual and collective responsibilities, timelines, and expected outcomes (QIF).

When organizational capacity gaps are identified from the readiness assessment, proactively strengthen internal structures, developing formal procedures and policies, writing and obtaining grants, investing in leadership and team training, and creating strong external partnerships (ISF).

Establish robust leadership capacity capable of navigating logistical and technical issues. Champions should be identified and engaged at all levels of the system. These individuals—in leadership roles, departments, or direct service

positions—can help mobilize support and influence others' attitudes toward change (Core). Champions serve as advocates who foster positive attitudes, drive momentum, provide guidance, and help navigate resistance across the organization (Core).

To ensure long-term success, implementation must include strong internal communication. Create structured feedback mechanisms that encourage continuous learning, adaptation, and improvement. Cultivate a psychologically safe organizational climate by regularly soliciting feedback, welcoming innovative ideas, and providing spaces where all team members feel comfortable voicing concerns or suggesting enhancements (QUERI, Core).

### **Step 15: Train and Support Staff at Participating Organizations**

Training is a critical preparatory step for implementation. Staff at participating organizations should receive hands-on training before implementation begins and ongoing technical assistance once the program is underway (AIFs, ISF). Training, coaching, and supervision can be delivered in various formats depending on staff needs and organizational context (AIFs, ISF). High-quality pre-implementation training should be provided, including skill-building and supervision strategies to prepare staff effectively (Core, QIF). Implementation teams play a key role in developing these necessary competencies (AIFs).

Educate staff by disseminating accessible summaries of scientific evidence and connecting them explicitly to the team's daily work, thereby promoting deeper understanding of the intervention's purpose and benefits. Use persuasive messaging techniques and storytelling to motivate and inspire staff at every level (MLSCT).

Continuous training and coaching should be embedded in the action plan to ensure skills are retained and applied in practice (CHANGE). Practical exercises—such as reviewing program manuals and practicing role-playing scenarios—can enhance communication and real-world preparedness (REP). Booster sessions should be included later in the implementation to reinforce knowledge and address any emerging challenges (REP).

Capacity-building should be supported with assessments to track teaching effectiveness and learning (CHANGE).

### **Step 16: Pilot the Implementation Package**

Before scaling up implementation, the program package should be reviewed and piloted within a limited number of intervention sites to test for clarity, functionality, and fit with the target setting (REP, AIFs). This stage allows the team to examine how well the intervention integrates with existing practitioner behaviors, organizational processes, and system influences. By observing the alignment—or misalignment—between the new approach and the current environment, the team can identify potential challenges early and address them before wider rollout.

During this pilot period, data should be collected on feasibility, acceptance, adoption, and any challenges encountered with the intervention, the implementation process, or the evaluation design (REP, MRCG). Usability and adaptability should also be explicitly assessed to ensure the program is realistic and practical for its intended context (PRISM). Findings from this assessment inform decisions about whether the package is ready for broader evaluation or requires additional refinement. The goal is to ensure the intervention is not only effective in principle but also workable in practice.

An iterative testing process should be used, beginning with a small trial group. Outcomes are reviewed immediately after implementation, adjustments are made based on the findings, and the next iteration is planned and executed (AIF). This cycle is repeated until the intervention demonstrates credible and consistent results. Throughout, feedback from the trial sites should be used to tailor practitioner behaviors, adapt organizational routines, and adjust system practices to improve fit and usability (AIFs). By embedding this rapid-cycle improvement approach, the program is strengthened, risks are reduced, and the likelihood of successful large-scale implementation is significantly increased.

### **Step 17: Maintain Organizational Capacity for Implementation**

Ongoing organizational readiness is vital to sustaining implementation success. This involves managing staffing levels, developing leadership, and ensuring that the organization remains connected with broader systems and community partners (ISF, ORT).

Identifying and addressing gaps in staff satisfaction and performance helps build internal support for the change effort (PRISM). Administrators should be supported in adjusting internal roles and structures to align with the intervention's

goals (AIFs), while organizational leaders should be equipped to champion the innovation and embed the necessary implementation supports (AIFs).

During implementation, it is important to maintain momentum while recognizing that deep change—especially in hospitals or large systems—may take over a year and must account for staff turnover and cultural shifts (TRIP).

Adaptation at the system or organizational level should be planned and expected, as it is a continuous part of the implementation process (DAP).

Technical assistance (TA) should continue beyond the training phase to ensure long-term fidelity and integration. TA typically includes follow-up phone calls or meetings with a representative from the implementing organization within the first month after training (REP). The TA specialist should guide staff on how to maintain program fidelity by helping distinguish essential core components from optional features, support integration with existing services, and troubleshoot implementation issues as they arise (REP).

Specialists are encouraged to help organizations explore the balance between fidelity and adaptability, ensuring that essential components are preserved even when delivery methods differ (REP). Throughout this process, it's critical to emphasize that the program's effectiveness is rooted in delivering it as originally designed, and changes should be minimal and justified (TRIP).

### **Step 18: Foster Learning, Empowerment, and Continuous Improvement**

Consistently recognize and affirm the implementation team's strengths and celebrate their successes to sustain motivation, engagement, and confidence (Core). Promote a supportive culture by explicitly highlighting team contributions, fostering shared pride in progress, and regularly reinforcing the positive impacts of their collective efforts (Core). Provide regular updates and visible demonstrations of executive support, linking team successes directly to organizational expectations and strategic objectives to continually reinforce program relevance and value (AIFs, PRISM).

Address resistance proactively by openly acknowledging and discussing potential concerns, perceived losses, shifts in loyalty, or competing priorities at individual, team, and organizational levels. Foster open, non-judgmental dialogue, and actively involve resistant stakeholders in collaborative problem-solving to create shared ownership of solutions (Core).

These structured reflection and improvement processes ensure sustained organizational growth and program success over the long term.

## **Phase 6: Implementation Monitoring, Adaption, and Quality Improvement**

### **Step 19: Monitor and Evaluate Implementation Progress**

Establishing a robust monitoring and evaluation (M&E) system ensures that implementation is on track, informs necessary adaptations, and measures effectiveness. After pilot testing is completed, baseline performance should be measured to identify improvement opportunities and estimate the size of change expected once the intervention is implemented (QUERI, MLSKT). Regular evaluation helps determine if there is a “voltage drop”—a decline in effectiveness—and whether the evidence-based practice should be adapted, reversed, or discontinued (IDEA Adaptation). It's important to assess whether the innovation is producing the intended effects (AIF).

Monitoring progress also requires evaluating whether the intervention is reaching the intended population and achieving its stated goals (CIFR, REAIM).

Conduct feasibility studies to identify if barriers persist and how they affect implementation (CIFR). Additionally, assess sustainability factors, including barriers and enablers, to inform strategies for scale-up and long-term success (Core).

Evaluate implementation quality using diverse data sources and metrics, and track any adaptations to understand how they may impact outcomes (QUERI, MERLA, IDEA, PRECEDE, Core).

Use REAIM assessments or Proctor's Implementation Outcomes to monitor program adoption and spread within the organization (REAIM) and assess patient usability and service experience to ensure the program is feasible in practice (PRISM).

Ongoing use of implementation data helps refine programs in real time. This includes providing data feedback to coaches and leadership to support understanding of fidelity and client satisfaction (DAP). Regular fidelity assessments should ensure alignment with the innovation's core elements and essential functions (AIF).

Once implementation has started, it's essential to evaluate how well knowledge translation strategies are working. Determine whether current strategies are sufficient for adoption or whether additional or revised approaches are needed (OMRU, AIF). Use pre- and post-tests to measure knowledge gains and learning needs (CHANGE). A structured summary of knowledge gaps should be created, including the questions these gaps raise and potential ways to address them (MERLA).

### **Step 20: Conduct Continuous Improvement Cycles and Adaptation**

Use quality improvement cycles throughout implementation to continually enhance the intervention and its outcomes. These cycles require reflection and adaptation of implementation plans and strategies using data gathered during routine M&E (Core).

Identify evidence gaps and frame operations research questions that address them (MERLA). Use a combination of formal studies, rapid assessments, and informal stakeholder conversations to guide improvements (MERLA). Create feedback loops between local stakeholders—such as technical experts, program staff, clients, and donors—to ensure iterative improvements (MERLA).

Adaptations should preserve the intervention's core elements while addressing barriers or local contextual needs (IDEA). Adaptations can also be culturally tailored to maximize consumer impact (QUERI).

Before full rollout, conduct pilot testing of any adapted version of the program, measuring key outcomes to evaluate its effectiveness. Assess whether the adapted version maintains clinical impact and aligns with implementation goals (IDEA).

Report all adaptations transparently using structured tools such as the Framework for Reporting Adaptations and Modifications (FRAME) to document what changed, why, and with what effect (IDEA).

Refine the monitoring and Evaluation Systems. Learning from implementation should inform how monitoring and evaluation are conducted in the future. Adjust monitoring systems and data collection practices based on program experience and learning agendas (MERLA). These adaptations help improve both the M&E process and the relevance of operations research.

## **Phase 7: Full Implementation**

### **Step 21: Support Staff and Retain High-Fidelity Practitioners**

Maintaining a skilled and consistent workforce is a critical component of program sustainability. High-fidelity practitioners are central to achieving and maintaining desired outcomes (AIFs). Organizations should provide continuous learning opportunities through refresher training and advanced coaching to prevent skill decay and reinforce adherence to the intervention model (AIFs). This can be achieved by supporting local stakeholder teams in engaging in ongoing cycles of reflection, innovation, and problem-solving (QUERI, KAF). Ongoing coaching strengthens technical skills and fosters practitioner engagement and satisfaction, which supports long-term retention (AIFs).

Organizations should ensure practitioners receive recognition, support from leadership, and are embedded in an environment that reinforces their roles, further strengthening their commitment to the program (AIFs).

The administration of the program should proactively remove barriers and maintain decision support systems that provide real-time data for improvement (AIFs). These systems reduce friction for new staff and promote consistent, high-quality delivery.

### **Step 22: Institutionalize Implementation Supports**

To embed the intervention into long-term practice, implementation supports must become part of the organization's structure. Integrate monitoring, training, and quality improvement processes into everyday workflows so that they continue without reliance on external supports (PRISM). At the same time, leadership, data use, and coaching must remain active and adaptive as conditions change (AIFs).

Continuous alignment of people, processes, and systems around the program's goals is necessary to protect fidelity and ensure that future staff receive the same support as those during initial implementation (AIFs, PRISM).

### **Step 23: Transition Ownership to Local Stakeholders**

As a program enters full implementation, assigning responsibility for core implementation activities is essential to sustainability. Transitioning roles from external change agents to internal staff, ensuring that tasks such as monitoring fidelity, updating procedures, and onboarding new staff are integrated into routine operations (PRISM). Transitioning program ownership to internal stakeholders is essential to long-term sustainability. Management should provide dedicated support and use an implementation playbook to clarify the processes, expectations, and responsibilities for sustaining the program (QUERI).

Responsibilities should be explicitly assigned and tracked using feedback systems such as implementation dashboards or routine supervision check-ins (PRISM). Without these mechanisms, the program is at risk of fading over time due to unclear accountability or loss of momentum (PRISM).

## **Phase 8: Evaluation**

### **Step 24: Evaluate Program**

To determine whether an intervention was successful, teams should compare post-intervention performance data with baseline data collected before and during implementation (REP).

Conduct an interpretative evaluation by collecting qualitative data through interviews with providers and consumers to understand how the intervention was implemented and its usefulness to the organization (REP). Include notes from training sessions and technical assistance (TA) visits as part of this review to capture implementation context (REP).

Measure intervention fidelity at both the organizational and patient levels to assess whether core components of the program were delivered as intended (REP). This determines the degree to which the intervention retained its integrity and allows for interpretation of effectiveness outcomes. Assess implementation strategies by measuring the implementation outcomes of each. Also measure the implementation outcomes of the intervention. This will often result in measuring adoption/reach, fidelity, acceptability, and other outcomes for multiple implementation strategies and intervention mechanisms of the program. Measure the implementation outcomes, service outcomes, and clinical outcomes along the theory of change of the program (Proctor).

Assess patient-level outcomes, focusing on clinical and functional measures that align with the intervention's original objectives (REP). These should include outcomes related to processes of care, such as access, adherence, or health status improvement, based on the targeted change.

Teams should also assess changes in public health behavior or outcomes. For example, determine whether there was a reduction in the prevalence of negative behaviors or an increase in positive behaviors that the intervention targeted (PRECEDE-PROCEED).

Evaluate practitioner- and system-level impacts to understand how the innovation influenced organizational practices, workflows, and staff behavior (OMRU, MLSKT, MRCG). This broadens the evaluation lens beyond individual patients to the infrastructure supporting sustained delivery.

Evaluation should include an economic perspective, assessing the return on investment (ROI) by comparing the costs of implementing the intervention with any savings realized, particularly in terms of patient care and system efficiencies (REP).

### **Step 25: Facilitate Feedback and Continuous Refinement**

Following the completion of evaluations, results should be shared with a committee working group for review and feedback (REP). The group can provide critical insights for refining the intervention and its implementation strategy. Vetting the evaluation findings with this group allows for discussion on barriers, potential improvements, and opportunities for wider dissemination. This step is critical to ensuring that future iterations of the program are even more effective and better tailored to local contexts (REP).

## Phase 9: Sustainment

### Step 26: Engage Stakeholders in Sustainability Planning

To ensure program longevity, stakeholders with decision-making authority over financial and operational aspects of care must be engaged in sustainability planning (REP). These individuals should use evaluation findings to assess whether the intervention can be integrated into standard operations and supported through existing or new funding streams.

Sustainability planning must include a clear business case that justifies the program's continued investment. Begin by assessing the costs, benefits, and return on investment (ROI) of maintaining the program over time, accounting for both financial and clinical impacts (QUERI).

Conduct budget impact analyses and break-even analyses to forecast the operating costs and identify how both local and shared resources will be allocated (QUERI).

### Step 27: Monitor Contextual Supports and Adjust Systems Accordingly

Sustainment requires attention to both internal and external organizational factors. Program leaders must monitor for changes in staffing, funding, organizational structure, and other contextual variables that may impact the intervention's viability (EPIS, REP). This includes incorporating program responsibilities into job descriptions, securing sustained funding, and training new personnel as needed (EPIS, REP).

Local teams should continue to monitor fidelity and conduct testing of adaptations to ensure changes do not undermine the intervention's integrity (QUERI).

As external and internal conditions shift, the intervention should be refined to maintain fit and effectiveness. Use a structured approach to identifying risks to sustainability, guiding teams to reflect every three months on team performance, emerging challenges, and necessary actions (LTST).

If the intervention is to be scaled, teams must prepare a refined implementation package, including updated training and technical assistance materials, for dissemination (REP).

Monitoring should also include assessment of whether a new or revised EP is needed, or whether de-intensification or de-implementation might be appropriate based on changing circumstances (QUERI).

Sustainability planning committees should review these dynamics regularly and advise on adaptive strategies to maintain alignment between the program and the evolving system context (EPIS).

## Implementation Theories, Models, and Frameworks

AIF – Active Implementation Frameworks

BCW – Behavioral Change Wheel

CFIR-ERIC – CFIR-ERIC Matching Tool

Core – Core Competencies for Implementation Practice

Change – Change Model (customized, holistic, analytical, network-building, grassroots, evaluator)

DOI – Diffusion of Innovation

DAP – Dynamic Adaptation Process

EPIS – Exploration, Preparation, Implementation, Sustainment Framework

ERIC – Expert Recommendations for Implementing Change (ERIC) Project

HCD – Human-Centered Design

Hexagon Tool – Hexagon Tool

IDEA – IDEA Adaptation

IM – Implementation Mapping

IM Adapt – IM Adapt

IntM – Intervention Mapping

IRLM – Implementation Research Logic Model

ISF – Interactive Systems Framework

KAF – Knowledge to Action Framework

MLSCT – Model for Large Scale Knowledge Translation

MRCG – Medical Research Council Guidance

OMRU – Ottawa Model of Research Use

ORC - A theory of organizational readiness for change<sup>2</sup>

OT – Organizational Theory

PRECED - PRECEDE–PROCEED Model

PRISM – Practical, Robust Implementation and Sustainability Model (PRISM)

PROCTOR – Proctor's outcomes for Implementation research

QIF – Quality Implementation Framework

QUERI – Quality Enhancement Research Initiative

REAIM – RE-AIM

REP – Replicating Effective Programs

RTT – Readiness Thinking Tool

SEM – Social economical model

SCT – Social Cognitive Theory

StrategEase – StrategEase Tool

TDF – Theoretical Domains Framework

TPB – Theory of Planned Behavior

TRIP – Translating Research Into Practice