Designing and Evaluating Zero-Dose Programs with Theory-Based Approaches: A Toolkit

November 2025

Zero-Dose
LEARNING HUB

Gavi Zero-Dose Learning Hub (ZDLH)

Funded by Gavi, the Zero-Dose Learning Hub (ZDLH) serves as the global learning partner and is led by JSI Research & Training Institute, Inc. with two consortium partners, The Geneva Learning Foundation and the International Institute of Health Management Research. Together, the consortium enables sharing and learning across four Country Learning Hubs in Bangladesh, Mali, Nigeria, and Uganda to advance the uptake of evidence by synthesizing and disseminating key learnings. The ZDLH also focuses on improving immunization equity and reducing the number of zero-dose and under-immunized children globally by facilitating high-quality evidence generation and uptake.

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Cover Photo Credit

Mali Country Learning Hub/Centre d'Apprentissage pour l'Equité en Vaccination

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Acronyms

BeSD	Behavioural and Social Drivers of Vaccination
CHV	community health volunteer
CLH	Country Learning Hub
CNI	Centre National d'Immunisation
CRW	Critical Reflection Workshop
DTP	diphtheria-tetanus-pertussis containing vaccine
EPI	Expanded Programme on Immunization
HCD	human-centered design
IEC	information, education, and communication
IIHMR	International Institute of Health Management Research
JSI	JSI Research & Training Institute, Inc.
MEL	monitoring, evaluation, and learning
MOH	ministry of health
NGO	non-governmental organization
PEA	political economy analysis
SBC	social and behavior change
TBE	theory-based evaluation
TOC	theory of change (or theories of change)
UIFHS	Universal Immunization through Improving Family Health Services
UI	under-immunized
WHO	World Health Organization
ZD	zero-dose
ZDLH	Zero-Dose Learning Hub

Executive Summary

This toolkit provides practical guidance for designing, implementing, monitoring, and evaluating immunization programs that focus on identification and reach of zero-dose (ZD) and under-immunized (UI) children using theory-based approaches. The toolkit demonstrates how using theory-based approaches can help guide immunization programs, using case studies and hypothetical examples. The toolkit equips program implementers and decision-makers with methods to assess whether programs achieved their goals and explain why and how they did or did not work, generating evidence to improve future strategies.

A Note on Definitions

A precise, technical understanding of the definitions of ZD and UI children is not required to use this toolkit. However, an understanding of the people involved in the programs described is important. We have provided both the general and operational definitions in Table 1 below, for clarity.

Table 1. Definitions of ZD, UI, and Missed Communities

Term	General Definition	Operational Definition
Zero-dose	A child who has not received a single vaccine.	A child who has not received the first dose of the diphtheria-tetanus-pertussis containing vaccine (DTP) or pentavalent vaccine series within their first year of life.
Under-immunized	A child who is not up to date with (i.e., is missing) one or more vaccines recommended for their age.	A child who has not received the third dose of the DTP or pentavalent vaccine series within their first year of life.
Missed communities	Communities, whether defined socially or administratively, that have groups of ZD and/or UI children.	N/A

Focus on ZD and UI

Routine immunization provides substantial health and economic benefits, with an estimated 50 million future deaths averted through immunization activities in 2000–2019 (Toor et al., 2021). However, reaching ZD children, or those who have not received even the first dose of essential vaccines, remains a critical challenge to achieving ambitious universal immunization coverage targets. Reaching these children requires targeted and effective programming that addresses their multilayered and compounding barriers to vaccination.

In response to this challenge, global initiatives, including those funded by Gavi, the Vaccine Alliance, have launched targeted efforts to reach these underserved populations. One of these initiatives is the Zero-Dose Learning Hub (ZDLH). The ZDLH project includes four Country Learning Hubs (CLHs) located in Bangladesh, Mali, Nigeria, and Uganda and aims to use evidence to better understand the factors influencing implementation and performance of approaches and interventions to identify and reach ZD and UI children and missed communities. More simply, the project aims to understand not only if programs reach ZD and UI children but also how and why they work or do not work.

To date, the CLHs have identified ZD and UI children in some of the most complex programming environments (e.g., mobile/migrant populations, areas with conflict or political upheaval, remote and hard-to-reach environments, and in communities with religious or other beliefs that limit engagement with health care services) where multiple barriers work to prevent access to and uptake of immunization services. Understanding how programs successfully overcome specific barriers—like distance, mobility, vaccine supply, or caregiver attitudes—can lead to more tailored and scalable solutions. Theory-based approaches are particularly well-suited to help frame assessments to answer the "how" and "why" questions. Ultimately, these insights can drive more equitable health systems and ensure that no child is left behind in immunization efforts.

The objectives of this toolkit are as follows:

1. **Describe theory-based approaches and explain why they are important for designing, implementing, and measuring programs that aim to reach ZD/UI children.**
2. **Discuss the importance of reviewing and revising program theories on a regular basis to improve the likelihood that programs and their associated activities are achieving their intended goals.**
3. **Provide guidance on how toolkit users can integrate theory-based approaches into their programs and present useful tools and resources.**
4. **Present current examples of ZD and UI initiatives using theory-based approaches and discuss how to overcome implementation challenges.**

Who Is the Intended User?

This toolkit has been developed for use by organizations and individuals designing, implementing, monitoring, and evaluating ZD and UI programs, which may include, but are not limited to, government stakeholders (e.g., health program managers and policymakers), international donors, and non-governmental organizations (NGOs). The toolkit is meant to serve as a plain language guide on how to better ground ZD and UI program measurement and evaluation plans in evidence, how to revisit and revise these plans throughout the course of implementation, and how to use this information to improve programs and measurement efforts.

I. Introduction to Theory-Based Evaluation

What Is Theory-Based Evaluation?

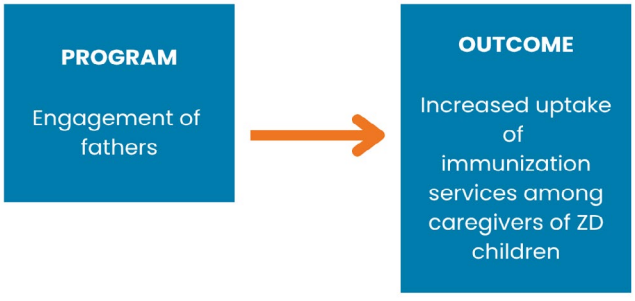
Theory-based evaluation (TBE) is a broad term encompassing methodological approaches that help in understanding and evaluating how and why a program or intervention functions by analyzing its underlying logic and assumptions (Funnell & Rogers, 2011). This approach helps evaluators and program staff not only determine whether a program works, but also explore *how* and *why* it does (or does not) work, thus offering actionable insights for improving program design and implementation (Rogers et al., 2000). TBEs require just that, a theory, to support how a program will move from inputs or activities to outcomes. Realist evaluations and developmental evaluations are common examples of TBE approaches, but most assessment and evaluation approaches can be modified to incorporate theoretical frameworks.

Why Are Theory-Based Approaches Important?

The move toward using more theory-based approaches is an acknowledgement of the complex environments in which immunization programming takes place and the need for more detailed information about how complex programs work (or don't work) to help inform future programming and policy efforts (Gugerty & Karlan, 2018). While these approaches have become more popular, implementation can be inconsistent and inadequate for providing the information needed to assist program and policy decision-makers.

During immunization program and measurement design, teams often focus overwhelmingly—or even exclusively—on inputs and outcomes, largely due to tight project timelines, limited resources, and competing priorities. As a result, the underlying theory and assumptions that should guide program activities are either overlooked or, more often, not clearly stated. This lack of information about how the program is intended to move from inputs to outcomes and, ultimately, impacts the causal pathways, is sometimes called the "black box" or "mystery box" of program evaluation (Funnell & Rogers, 2011). Figure 1 illustrates an overly simplified evaluation for a ZD intervention that aims to address both vaccine hesitancy and female caregivers' limited autonomy to access immunization services for their children. In this example, the program or intervention is the engagement of men through fathers groups, with the expected outcome being improved uptake of immunization among caregivers of ZD children.

Figure 1. Example ZD Immunization Program Evaluation Pathway



Note: Figure concept adapted from Sue Funnell and Patricia Rogers. Purposeful Program Theory: Effective Use of Theories of Change and Logic Models. San Francisco, CA: Jossey-Bass, 2011. https://www.researchgate.net/publication/259999058_Purposeful_Program_Theory_Effective_Use_of_Theories_of_Change_and_Logic_Models.

The "mystery box" in this case is everything that happens between the blue boxes, where the orange arrow is located. Without more detail about the steps between the input and the outcome, we lack the information to do a number of important things. Without more information about the causal pathway, we cannot develop a measurement strategy that captures different progress points. Subsequently, in the event that the program does not achieve the ultimate goal of a reduction in ZD children, we don't have the information to understand *why* or *how* it did not work. Alternatively, if the data show that immunization coverage did, in fact, improve and there was a reduction in ZD/UI children, we do not have the information needed to indicate *why* or *how* the intervention worked, which would be essential for scaling or replicating the intervention.

Source: Fresh Spectrum Evaluation Cartoons

Case Study 1: Uganda Learning Hub—Clarifying Pathways for Impact

The Uganda Learning Hub met to review their theory of change (TOC) and add more detail for an evaluation of a local partner's immunization intervention. The intervention focused on engaging local leaders to advocate for immunization programming to reach ZD and UI children. The discussion revealed the program hadn't articulated how it intended to reach ZD and UI children or the important assumptions behind its strategy. For example, how would leaders advocate for immunization? Would advocates focus on education and sensitization about the importance of immunization for caregivers of ZD and UI children? Or, if vaccine hesitancy due to fear of side effects was the main barrier, would the community leaders focus on issues of safety to help reassure caregivers? These are examples of a few of the many essential but unanswered questions. The team agreed that the best approach would be to work through these questions with the implementing partner, noting that this would be helpful not only from the evaluation/measurement perspective but also to guide the implementer's programming. Thinking through the causal pathways together would help the implementing partner design a more focused program that better met the community's needs.

Why Are Theory-Based Approaches Important for ZD and UI Program Measurement and Evaluation, and What Questions Can They Answer?

As noted in the introduction, theory-based approaches are particularly important for immunization programming targeting ZD and UI children for a number of reasons. First, ZD children and their caregivers often reside in areas and communities that require tailored programmatic solutions. For example, in Mali, ZD and UI children have been identified in communities that face both conflict and insecurity, which affect caregivers' ability to travel to health facilities to get their children immunized and impede vaccines and other necessary supplies from reaching these communities. This is further compounded by entrenched cultural beliefs and vaccine hesitancy that curtail demand for immunization.

Photo Credit: AFENET, Nigeria Learning Hub

Additionally, addressing these various, intersecting barriers requires multi-faceted programming along supply- and demand-side pathways. Increasing demand alone, without ensuring adequate supply and access to quality vaccination services, is unlikely to lead to the desired change in vaccination uptake. In such cases, theory-based approaches help explain how each part of the program contributes to the overall success of the CLH, or to identify which components of the program did not work.

Additionally, most theory-based approaches promote participatory development and review of the underlying theories or frameworks in the early stages of design. In the example of the Uganda Learning Hub (*see* *Case Study 1: Uganda Learning Hub—Clarifying Pathways for Impact*), the CLH's decision to engage the local program implementer in the evaluation process could lead to co-designing an intervention adapted to the local context and rooted in thorough, thoughtful discussions about barriers and specific causal pathways to overcome those barriers. Research on the use of the theory-based approaches indicates that stakeholder engagement improves not only program design but also the measurement, as teams are better able to develop context-specific indicators that better reflect the program's activities (De Silva et al., 2014). Using the Uganda CLH example, if an intermediate objective of the program is to reduce fears around the side effects of immunization, the measurement team, once they understand this pathway, could make sure to include a survey question about fears related to side effects or to include the topic in their key informant interviews.

Moreover, by using theory-based approaches that encourage regular reflection and updating of the underlying theory based on ongoing program monitoring, we are able to identify what is or is not working in a timely manner and provide useful feedback to the programs, allowing them to pivot and adopt alternative approaches/strategies. As noted earlier, ZD and UI children are commonly found in dynamic, rapidly changing environments. By encouraging adaptive learning and flexibility, TBEs help programs remain responsive to changing contexts and ensure that resources are directed toward the most effective solutions.

A recent analysis of published impact evaluations (Vadrevu et al., 2024) found that many interventions to improve routine immunization failed to explain their underlying theory, articulate assumptions, or detail the intervention's causal mechanisms. Without that detail, the findings and recommendations of these evaluations lack much of the necessary detail that enable stakeholders to effectively implement them, including vital information about context and causal mechanisms.

Case Study 2: Bangladesh Learning Hub—Rapid Adaptation in a Shifting Context

The Bangladesh Learning Hub experienced firsthand the need to pivot and adapt programming in 2024. The Learning Hub was supporting a number of programs to identify and reach ZD and UI children in various districts across the country using strategies such as expanded outreach and extended health facility hours. Additionally, the Learning Hub worked closely with the government's Expanded Programme on Immunization (EPI) counterparts to advocate for services for ZD and UI children by regularly presenting on evidence gathered through their work. In July and August 2024, the country experienced widespread political upheaval and violence, ultimately resulting in the prime minister's resignation and the fall of the ruling party. During the unrest, curfews and other restrictions on movement were implemented, preventing health workers from conducting the Learning Hub's additional outreach sessions and the cancellation or postponement of other program activities. Furthermore, shifts in top government leadership led to changes at EPI and other agencies where the Learning Hub had established relationships. In one case, the national EPI contact responsible for coordinating with the Learning Hub changed twice in a short period. As a result, the Learning Hub was forced to rapidly adapt their implementation plans and advocacy strategies. The team kept track of where sessions had been canceled and children may have been missed, and they conducted more focused outreach efforts in these areas once they received permission to move around. Additionally, the Learning Hub worked quickly to engage with new leadership as the turnover occurred to ensure that new staff were familiar with the Learning Hub and its objectives. The rapid action taken by the Learning Hub helped limit the impact of the conflict on ZD and UI children. Data from the quarter showed that while there was a noticeable dip in coverage during the unrest, immunization coverage rebounded in some areas to above where it had been before the unrest, suggesting that the response was effective.

Importance of TBE

1. **Helps to guide the decision-making process and provides a framework for understanding what works and what needs improvement.**
2. **Useful for assessing program progress toward intended objectives as well as gaps/challenges and solutions.**
3. **Promotes the development of solutions to meet actual needs.**
4. **Helps ensure that program activities are conducted in a way that will lead to desired results by considering the underlying theories that inform the program design.**
5. **Allows for the use of evidence-based strategies to achieve desired outcomes and adjust programming based on findings.**
6. **Provides an opportunity to consider the underlying assumptions on which the program is based and identify potential areas for improvement or expansion, which can help inform further development of the program and increase its overall success.**
7. **Facilitates the use of findings by documenting, in the form of a framework, how a program met objectives.**

What Questions Can TBEs Answer?

There are a number of questions that TBEs are well suited to answer. Below are examples of practical and actionable questions that are important to ask when considering the effectiveness of a program, whether it's to inform ongoing implementation or scale-up. The questions have been categorized by points along the program cycle where they may be useful, but most questions can be revised slightly to inform any/all stages.

Design and Adaptation

- What changes are needed to improve the program's effectiveness?

Evaluation

- How did the program lead to the observed outcomes?
- What are the key factors or processes that contributed to the success or failure of the program?
- What causal pathways explain the change in outcomes, and how do they unfold?
- What assumptions underpinned the program's design, and were they valid?
- How did contextual factors (e.g., cultural, political, socioeconomic) influence the program's outcomes?
- Does the program's TOC reflect the actual pathways and outcomes that occurred?
- What parts of the TOC worked as expected, and where did the assumptions fail?
- Why did certain components of the program succeed while others didn't?
- What factors helped certain activities achieve their intended outcomes, and which factors hindered progress?
- What unintended outcomes (both positive and negative) resulted from the program?
- How did the program impact the community in ways that weren't initially anticipated?
- What other factors, outside of the program, played a role in achieving (or not achieving) the intended outcomes?
- How did the program impact different subgroups (e.g., marginalized populations)?
- Were there unintended inequalities in how the program reached or benefited certain populations?

Sustainability and Scale

- How should the program be adapted for different contexts or target populations?
- What can be done to scale the program while maintaining its effectiveness?
- What factors will make the program sustainable in the long term?

Table 2. Key Concepts in TBEs

Theory of Change	A framework used for program implementation and measurement that provides an explicit description of how and why a program is expected to lead to specific results. It lays out the causal pathways from inputs and activities through intermediate outcomes to long-term goals, including the assumptions, contextual factors, and causal linkages along the way. (*See more about TOC in Section II*).
Causal Pathway	The overall process through which change is expected to occur from A to Z. TBEs can help determine if programs or interventions worked through these expected pathways (*e.g., did the program work in the way we thought it would?*) by examining the strength and validity of each causal linkage.
Causal Linkages	The individual steps along a causal pathway through which change is expected to occur (e.g. A to B, B to C, and Y to Z).
Contextual Factors	The external conditions or characteristics of the environment in which a program or intervention is implemented. These factors can influence whether and how the causal linkages hold—that is, whether the program works as intended.

What Are Some of the Challenges with TBEs?

While useful in many contexts, theory-based approaches may not be appropriate for every setting. Although these approaches can be combined with studies that measure impact, they do not inherently quantify the size of a program's or activity's contribution. Additionally, theory-based approaches can be time and resource-consuming, particularly during the evidence gathering and stakeholder engagement phases (Treasury Board, 2021). Proponents of the approach would argue that these evidence-informed approaches result in more contextually appropriate program designs and measurement strategies, which should lead to greater efficiency. Simply, the upfront costs should result in later savings due to more effective, sustainable programs. In this guide, we have prioritized approaches that may be more appropriate in settings where resources are scarce, but the resource requirements are an important consideration.

Now that we have a basic understanding of what theory-based approaches are and why they are important for ZD and UI programming, we will discuss how to develop and implement a TBE, beginning with development of theory-based frameworks, or TOCs. We will also cite existing resources, including tools and templates, that can be used to develop these frameworks.

Photo Credit: Infectious Diseases Research Collaboration, Uganda Learning Hub

II. Developing a Theory of Change

To measure or evaluate a program using a theory-based approach, a theory is needed. These theories or frameworks explain how the program designers anticipate that the program will achieve its goals, the assumptions that underlie the change pathway, and the factors that influence success. In an ideal world, when the measurement team begins to think through how to measure the program, they would meet with the program team or the implementing organization and would be handed a clear, up-to-date mapping of anticipated causal pathways, with relationships and causal links indicated and described in detail, along with detailed descriptions of assumptions and risks. Unfortunately, as is described in the first case study with the Uganda CLH, this level of documentation is rare.

This documentation of all program components—the activities, the casual linkages, the desired outcomes, and details about risks and assumptions to consider—is a required step when using a theory-based approach to design a program. It's also a common step when using a TBE approach to measure or assess programs because this step may not have been well thought-out, not well communicated or documented, or skipped altogether during the program design process. As such, we are often required to document the theory in order to develop the measurement approach. This can happen at a number of points in the project, depending on when the measurement is taking place. You may document the theory at the outset of the program if you are planning to do prospective monitoring, but you may also need to document the theory in the middle of the program implementation, if you come in to do a midterm assessment, or even after the project has ended, when you are doing an endline assessment. As the first case study with the CLH in Uganda illustrates, documenting a theory in the middle or the end of a project can be challenging, but it is important for developing a useful measurement approach.

The approach used to document a theory will vary slightly, depending on where the project is in implementation (at the outset vs. middle/end). We will discuss a general approach in the next section and make note of where the steps might change based on when the measurement or assessment is taking place in the program cycle. Additionally, in nearly all cases, it is important not only to document the theory, but also to regularly revisit and revise it based on data collected and new insights formed (a topic that we address in Section III). We'll begin by discussing one of the most commonly used tools for documenting a theoretical framework that supports a program: a TOC.

What is a TOC?

A TOC is a commonly used approach to document and visualize a theory that underpins a program, which maps out the various pathways that may take place to achieve change over time. TOCs generally contain a few similar fields: assumptions, activities, inputs, outputs, outcomes, and impact. The terminology may vary between organizations (e.g., long-term goals vs. impacts), but most importantly, the team developing and using the TOC should have a shared understanding of the terms being used and how they are defined. Some of the key TOC terms/concepts and their definitions are included in Table 3. Additionally, TOC visuals (the graphical representation of the framework that we often associate with TOC) are most useful when accompanied by a narrative to explain the causal links between the various fields.

Table 3. Key Concepts in a TOC

Concept	Definition
Inputs	The resources, investments, and foundational elements used to implement a program or intervention. Inputs are generally under the control of the implementing organization and are required to activate the causal pathways.
Activities	The intentional actions or processes carried out using program inputs to produce specific outputs. They are what the program does to bring about change.
Outputs	The direct and tangible results of a program's activities. Outputs represent what the program delivers or produces in the short term, typically components that are immediately observable and measurable.
Outcomes	Results that are likely achievable within the project's time frame and can be measured to clearly demonstrate the program's contributions. Intermediate outcomes can also be included in a TOC. These outcomes may fall after outputs, but precede more general outcomes and have time frames for (short-term, medium-term, etc.) when they are expected to be achieved in the program cycle.
Impacts	The long-term, high-level changes that a program ultimately aims to achieve (not necessarily within the project's time frame). Impacts represent the end goals or final effects of a causal pathway and may be influenced by factors outside of the program.
Assumptions	Conditions that must be present in order for the change pathway to be successful and are **within the program's control**.
Risks (or External Risks)	Potential threats to the program's success that are generally outside the control of the project (i.e., not just the inverse of assumptions).

Photo Credit: icddr,b, Bangladesh Learning Hub

Figure 2 shows a Gavi/UNICEF TOC for an intervention using geospatial technologies to improve immunization programming that features many of the traditional TOC categories: inputs, outputs, outcomes, and impacts. This example shows the program's planned sequence in a structured, linear format.

Figure 2. Example TOC from an Immunization Strengthening Program Utilizing Geographic Information System Technology

Theory of change

Use of Geospatial Technologies for Immunisation Programming

Health Impact	**Reduction in Childhood Disability and Mortality Due to Vaccine-Preventable Diseases**		
Immunisation Impact	≥80% of children fully immunised in all districts and equitable coverage across population subgroups based on geographic, socio-economic and cultural differences		
	Improved immunisation campaigns and routine immunisation programmes		
Immunisation Outcomes	Increased number of children immunised through improved target setting	Optimised immunisation resource distribution and location of services	Improved quality, timeliness and perception of immunisation services with equity in coverage between communities
Geospatial Data and Technologies Outputs	Improved **identification of zero dose and under-immunised children** through more accurate microplanning and identification of missed settlements to implement appropriate vaccination strategy	Improved **planning and allocation** of immunisation resources through strengthened use of geospatial data, analysis and visualisation	Improved **service delivery** through better planning, monitoring and tracking of immunisation activities for rapid problem identification and corrective action
Geospatial Data and Technologies Inputs	Produce and regularly update digital maps for health area planning based on health resources mapping through a participatory process involving local health staff to map immunisation resources	Optimize distribution of resources (workforce, funding, vaccines and supplies) based on more accurate target population distribution and identification of gaps in coverage and immunisation service accessibility based on geospatial accessibility analysis and coverage modelling	Track by location vaccinator activities, immunisation sessions, supervision and allocation of financial resources
Geospatial Data & Immunisation Foundations	**Health System Mapping (essential):** Develop and maintain master lists and data standards for health facilities, vaccination delivery sites and cold chain, settlements, infrastructure, health area boundaries and other core geographic objects **Population Estimation (essential):** Generate and use accurate population estimates (human density and distribution) to establish targets (denominators) in immunisation programme planning **Analytics & Modeling for Accessibility, Coverage, and Surveillance Planning and Monitoring (when possible):** Use modeling to understand geographic accessibility to services, vaccine distribution, and immunisation coverage with links to data (through HIS, IHRIS, and eLMIS) on vaccine-preventable diseases and AEFI		
Enablers	Clearly defined vision, strategy and plan for a geo-enabled HIS/immunisation programme Information system governance structure covering geospatial data and technologies Policies supporting and enforcing the strategy and governance, including data accessibility Necessary human and financial resources to ensure effective use and sustainability of geospatial data over the long-term		

Source: Gavi, UNICEF & HealthEnabled. "Leveraging Geospatial Technologies and Data to Strengthen Immunisation Programmes," April 2021. https://www.gavi.org/sites/default/files/evaluations/Leveraging-Geospatial-Technologies.pdf.

However, many practitioners in the field of TBE argue for a less linear and structured approach, allowing for more flexibility and documentation of causal links with non-standardized categories, which may provide a more holistic picture, particularly in more complex settings (Koleros et al., 2024). Additionally, these less structured theoretical frameworks can be helpful when there may be multiple possible pathways between the intervention and impact or where change is not necessarily linear. This approach may be more useful to document causal pathways for immunization interventions that target changes in community social norms around immunization or advocacy campaigns for broad immunization policy changes. An example of this is included in Figure 3. While this example largely follows the structured, linear pathway discussed earlier, it takes on a less linear format as we build on it throughout the guide.

The program aims to reduce the number of ZD children in communities by improving trust in the health system and to improve female caregiver autonomy to access children's immunization services. The graphic illustrates several intermediate steps between the output and outcome that are detailed in the graphic. Note that this example is included only to show the inclusion of causal links, or intermediate outcomes. We will build on this example throughout this toolkit, and a final TOC with narrative is included in Annex C.

Tip: The structure and level of detail of your TOC may vary depending on the audience and purpose.

Less detail ⟹ Gives a holistic, bird's-eye view of the program and pathways. May not capture details about specific target populations or provide details about intermediate changes.

> **Possible audiences:** Funders or other stakeholders who are not/will not be responsible for implementing the program or assessing it but need a basic understanding of the program and pathways.

More detail ⟹ More information, with more insight about intermediate causal links, specific target populations.

> **Possible audiences:** Program staff involved in implementation and assessment, as well as governments or other stakeholders who may ultimately be interested in or responsible for scaling or replication.

Note: When we refer to the "TOC" here, we are referring to the full TOC package (which includes the visual and the narrative). Step 5 (in Table 4) emphasizes the importance of a clear and concise TOC visual. The graphic should avoid excessive detail to remain practical and user-friendly. The narrative is the best place for expanding on the visual and providing more detail.

Figure 3. Example TOC for a ZD Social and Behavioral Change Intervention

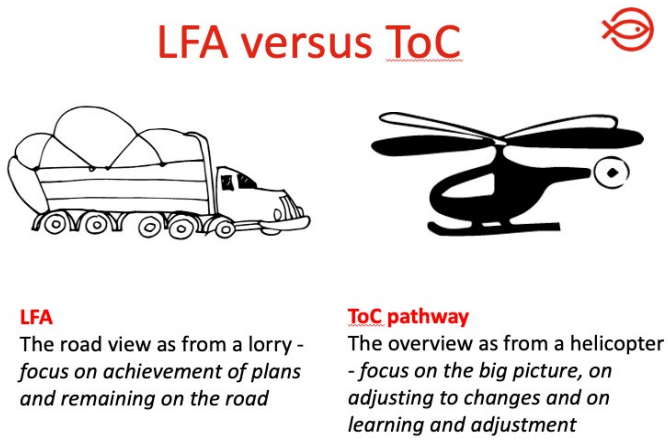
How is a TOC Different from a Log Frame?

While a TOC and a log frame are similar (outlining a project's outcomes, impacts, etc.), they tell a slightly different story. A log frame usually includes more program details, including what is planned/implemented and how it will be implemented, whereas a TOC focuses more on why and how change is expected to take place. Log frames are more structured and might include indicators, whereas the TOC may be less linear, identifying the different ways change may occur. Additionally, a TOC includes assumptions and information about context that should be considered. Log frames can be more useful for monitoring purposes, while a TOC tends to be more useful for program design as well as evaluation. That said, the TOC should help to inform the development of a log frame.

Figure 4 provides a helpful analogy for understanding the difference between a TOC and a log frame. The lorry (or log frame) is focused on the road (the program implementation plan) and should receive directions from the helicopter (the TOC), which has a higher-level view of the project. The helicopter can tell the lorry that a bridge ahead has been swept away and that a change of course is needed to reach the desired destination (outcomes and impacts).

Figure 5 provides an example of how a log frame might be structured for one of the interventions in the immunization TOC example.

Figure 4. Logical Framework Approach vs. TOC



Source: "Learning Site: Theory Of Change - Facilitator's Guide to Critical Reflection Workshop." Accessed February 14, 2025. https://fabo.org/dca/Theory_Of_Change_Facilitator%27s_Guide_to_Critical_Reflection_Workshop.

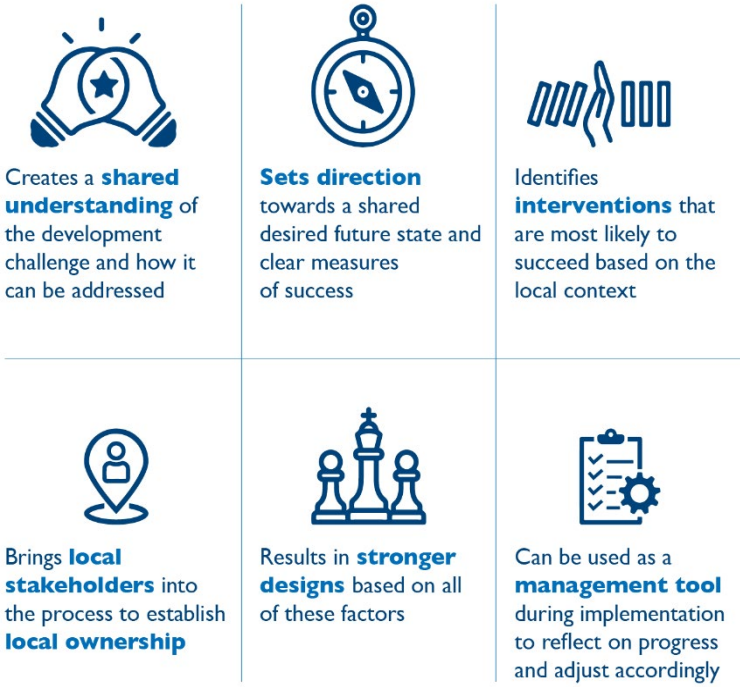
Figure 5. Example Log Frame for a ZD Social and Behavioral Change Intervention

Inputs	Activities	Outputs	Outcomes	Impact
Financial resources provided to support CHV time and travel Technical support to develop IEC materials *# of IEC materials developed*	CHVs conduct house-to-house outreach visits to ZD households and hold IEC sessions with caregivers, providing information about the importance of vaccines and vaccine safety *# of ZD households reached through outreach visits*	Caregivers of ZD children are informed about the importance of vaccines and vaccine safety Caregivers of ZD children are trusting of health services *% of caregivers who report trusting health services* *% of caregivers who rate vaccines as important or very important* *% of caregivers who believe that vaccines are safe*	Caregivers bring their ZD children for immunization services *% of households receiving CHV visits that bring their ZD children for vaccination*	Reduction in ZD children *# of ZD children in X community decreases* *% of children who are ZD in X community decreases* *% of children who are ZD across communities decreases*

How Do We Develop a TOC?

As noted earlier, how you develop a TOC will depend on the implementation stage of the program. For external evaluations, measurement teams often come in during the middle or end of the programs, but for measurement teams embedded in program teams, they are often engaged from the beginning. In this guide, we will discuss both scenarios and how they may vary. Regardless of the timing, it is always important to engage program implementers and other stakeholders in the TOC development process to understand the context, barriers, objectives, and causal pathways through which the program intends to address the barriers and lead to the end goal. Collaborative TOC design is essential to promote shared understanding and buy-in around the direction of the project. The graphic outlines additional benefits of the collaborative TOC development process. As others have pointed out, the process of bringing together stakeholders to discuss the TOC can be more important than the TOC itself (Salib, 2022).

Figure 6. Benefits of a Collaborative TOC Process



Source: Salib, Monalisa. 2022. Theory of Change Development: A Step-by-Step Process for Developing or Strengthening Theories of Change. USAID Learns. https://decfinder.devme.ai/dec/theory-of-change-development/.

Case Study 3: Mali Learning Hub, Collaborative TOC for Equity

Across the Gavi-funded CLHs, collaborative TOC processes have proven to be a valuable tool in ensuring ownership, alignment, and adaptability when designing country-led implementation research of targeted interventions to reach ZD children. In Mali, for example, the CLH coordinated a collaborative process under the leadership of the Centre National d'Immunisation (CNI) to design, refine, and validate the TOC which provided a framework for assessing the ZD interventions through their implementation research. The TOC provided the foundational step for understanding how the interventions were supposed to work. National and subnational workshops engaged government, district health teams, civil society, and partners to jointly map pathways. They identified barriers across different district typologies, and streamlined innovations such as Coach2PEV, a digital supportive supervision tool, and MEDEXIS, an electronic logistics management information system, with the country's Full Portfolio Planning, Gavi's framework for aligning national priorities with partner support. This participatory approach fostered ownership and ensured the TOC became a living framework that guides implementation research, learning products, and real-time adaptation. Mali's approach illustrates a principle that resonates across all CLHs: a TOC is most effective when co-created, grounded in country systems, and adaptable to new evidence. Similar collaborative approaches for developing TOCs of ZD interventions in Bangladesh, Nigeria, and Uganda demonstrate that this participatory process can guide real-time adaptation and ensure interventions are aligned with national priorities, a globally-relevant approach to advancing immunization equity.

In this section, we outline five steps to developing a TOC for ZD programming and measurement, illustrating questions that should be addressed in consultation with program implementers and other stakeholders. While these are presented as linear, the development of the TOC itself may not be a linear process. When the measurement team is coming in after the design phase, as happens in many cases and in the scenario presented below, it's common to combine steps, jump around between steps, or start by discussing the end objective first. The most important consideration is that all steps are visited at some point in the development process and revisited as needed. Additionally, the TOC should not be considered "final" or "finished." It is a living framework that should be revised on a regular basis and updated as new information becomes available. Guidance on how to review and revise the TOC is presented in Section III.

Table 4. TOC Development Process

Step 1	Document the problem and context.
Step 2	Identify entry points for change and articulate the desired outcomes.
Step 3	Map the pathways for change and identify interventions.
Step 4	Identify assumptions and risks and prioritize interventions.
Step 5	Document the TOC by developing a visual and narrative.

Note: In situations where the measurement team is separate from the program design team and is engaged after the program is designed or during/after implementation, the same Steps 1-5 should be taken. However, these discussions will require the teams to look back at decisions made in response to the context and decisions that informed program design and implementation to date. These conversations are also best conducted in meetings or workshops with stakeholders and should result in the development of a TOC. In this case, the focus will be on generating a measurement plan moving forward as opposed to designing an intervention.

Step 1. Document the Problem and Context

In this step, it is important to define the challenges or barriers the program aims to address and the context in which it is operating. The approach in this phase may vary based on the timing of TOC development, but generally should include collection, triangulation, and validation of information from a variety of sources, including existing literature and data sources as well as experiences of stakeholders. In this scenario, we assume that the impact of interest, reduction in ZD children, has been determined ahead of time and that the geographic focus of the program has been narrowed to a specific area (e.g., a particular country or region within a country).

Resource: In cases where the impact is not pre-determined, see USAID's TOC Workshop Step 3, Part A for guiding questions to identify an appropriate impact.

To use stakeholders' time efficiently, the program measurement and design team might take the lead in conducting a targeted literature review. This preparatory work will ensure that initial conversations with stakeholders are grounded in existing evidence and contextual understanding, enabling more focused and meaningful engagement throughout the participatory process. Below, we note example questions that could be explored through an initial literature review.

Note: This literature review is intended to provide important context for stakeholder discussions, but it should be treated as an iterative process. Because the direction of these conversations and the pathways that emerge cannot be fully anticipated, it will be important to revisit the literature after stakeholder consultations. Doing so will help align stakeholder experiences with existing evidence where relevant. For example, if a stakeholder indicates that a community that is home to a particular religious group known to be resistant to vaccines, the measurement and design teams could search for any literature supporting the idea that vaccine resistance was prevalent in this religious community in other areas or if it may be related to other factors.

- What is the scale and scope of ZD children in the geographic area of interest?
- What is the profile of a ZD child and their caregiver/s (e.g., demographics, geographic location, socioeconomic status)?
- What are some of the underlying barriers to vaccination faced by caregivers of ZD children (e.g., geographical constraints, economic hardships, sociocultural dynamics, systemic health inequities, political instability, and disruptions brought by pandemic, if any)? How might these barriers vary across geographies?
- What enabling factors and resources exist to address these challenges?
- What other programs are operating or have operated with a similar focus in a similar context? What did they do? What, if any, evidence exists on their process, outcomes, or lessons learned?
- Who are the vital stakeholders working on immunization and to address ZD children in the context? What are their respective roles (program implementers, funders, policy-makers, etc.) and areas of expertise? What geographic areas are they working in?

Once the design team has a basic understanding of the context, it is important to bring stakeholders together to discuss the background information collected by the team, to validate the information collected with stakeholders' experiences, to identify and discuss where information may be contradictory, and to identify information gaps that may need to be filled through other means. These conversations are used to begin piecing together the components of a TOC. While this process could be structured in a number of ways, in-person participatory workshops, where feasible, are useful to promote dynamic discussion and engagement and build connections among participants, which can be useful throughout the implementation process.

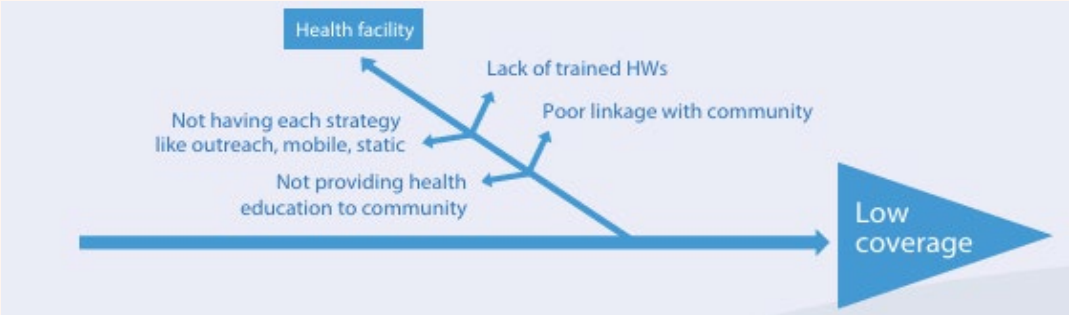
Resource: Where time and resources allow, conducting a political economy analysis (PEA) or stakeholder mapping exercise can be useful to better understand the various "players" in the ZD and immunization space as well as the wider health and non-health context. A PEA can provide more information about influence and power, which can be particularly useful when considering implications for sustainability. Links to tools are included in Annex A.

Resource: Human-centered design (HCD) approaches foster a greater understanding of the ZD context, including barriers and opportunities, and have been successfully employed to inform program design in a participatory manner. Additional documentation and resources related to using HCD to guide intervention design and TOC development for ZD programs can be found in Annex A.

Case Study 4: Bangladesh Learning Hub—Co-Creating Solutions through HCD

The Bangladesh Learning Hub conducted participatory workshops with EPI and other government stakeholders to discuss the ZD context and co-create context-appropriate solutions. The Learning Hub employed an HCD approach to better understand the ZD context in the country, particularly in urban, informal settlements and remote, hard-to-reach areas, which had been identified by workshop participants as ZD hotspots. The Learning Hub consulted implementation staff, caregivers of ZD children and children who had missed routine vaccination doses, and service providers, including health assistants, using methods such as empathy building, persona development, and journey mapping as part of creative ideation sessions to deepen understanding of the ZD context. These sessions surfaced key barriers to vaccination, including misinformation, fear of side effects, and the physical and financial challenges families face in accessing vaccination services. These insights informed a TOC for interventions that focused on context-specific solutions. The TOC design was shaped by local barriers identified during co-creation, including long travel times, limited information, and human resource shortages, and simplified to clearly communicate the program's overall objectives to a broad audience. The resulting high-level TOC (Annex B) highlights how context-specific challenges informed intervention choices and how feedback loops supported timely adaptation. More detailed pathways describing intermediate outcomes and causal linkages are documented elsewhere, but this version illustrates how a TOC can be used to translate local realities into program priorities in a way that is accessible to diverse stakeholders.

Resource: When discussing problems and context with stakeholders, a root cause analysis can be a useful tool to identify the precursors to outcomes, and in the ZD context, better understand the underlying reasons for why children are unvaccinated. The analysis can help pinpoint barriers and challenges and help stakeholders to develop program strategies to address these root causes effectively. This can be done in a participatory manner using a fishbone diagram. The example below illustrates what a fishbone diagram might look like for a session focused on finding the root causes of low immunization coverage. See Annex A for additional resources for conducting root cause analyses.



Source: Universal Immunization through Improving Family Health Services. Use a Fishbone Diagram to Find Root Causes and Effective Solutions. https://uifhs.jsi.com/wp-content/uploads/2018/08/Fishbone-Job-Aid_A1.pdf.

Once the context and problem are clearly defined and stakeholders have a shared understanding, the focus of discussions can turn to defining the outcomes of interest.

Step 2: Identify Entry Points for Change and Articulate the Desired Outcomes

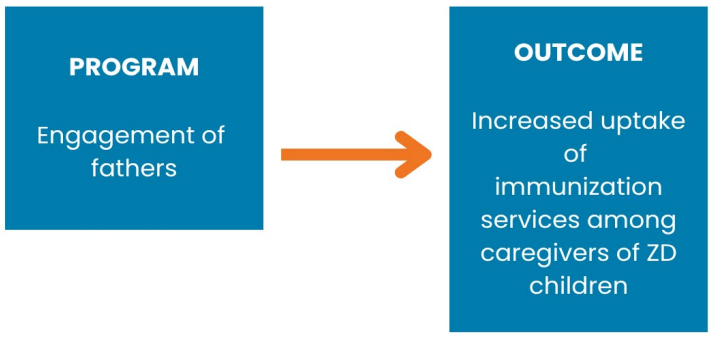
In this step, the measurement team will work closely with stakeholders to determine the outcome or outcomes that are most appropriate and realistic for the context. Remember, in this step you are considering outcomes, not impacts, so the team should be focusing on results that are likely to be achieved within the project's time frame and where the program's contributions can be clearly measured and demonstrated. An important first step in this process is to identify entry points for change. To do this, the team should closely examine existing immunization efforts (government led, private sector, and other external efforts) to identify barriers and gaps that a program or activity could help address. This exercise helps reduce the duplication of efforts and promotes the design of programs that address the specific needs of a population. Sample questions that can be used to guide this conversation include:

- What outcomes are being produced by existing programming in the geographic area of interest?
  - E.g., are current programs effective in encouraging caregivers of ZD children to seek immunization services, and are ZD children receiving vaccinations? If not, why not? Consider what precursors or barriers to vaccination might exist.
- Are existing programs addressing the barriers identified in the previous step?
  - E.g., caregiver fears of side effects, distance to health facilities, supply of vaccines, inability to track/identify ZD children.
- What outcomes do we want to achieve and how do they address existing gaps or barriers to reaching ZD children identified in the previous question?
- How do these outcomes align with broader health and equity goals?

Note: In the event that the TOC is developed after the program has been designed or is being implemented, the questions will be slightly different and, instead, document the intentions of the existing program. For example, the measurement team may ask implementers and stakeholders: What are the anticipated short-term, intermediate, and long-term outcomes of the existing ZD programming?

In some cases, you may find that a single outcome has been articulated, but more intermediate outcomes have not been identified. Working with program teams and other stakeholders to identify intermediate outcomes can help guide programming and measurement activities. For example, using the example presented earlier (Figure 7, same as Figure 1, repeated for reference), if the program aims to increase uptake of immunization services for ZD children, it's important to consider what some of the shorter-term or intermediate outcomes might look like. In this case, shorter-term outcomes may include changes in social norms or reductions in stigma.

Figure 7. Example ZD Immunization Program Evaluation Pathway



Note: Figure concept adapted from Sue Funnell and Patricia Rogers. Purposeful Program Theory: Effective Use of Theories of Change and Logic Models. San Francisco, CA: Jossey-Bass, 2011. https://www.researchgate.net/publication/259999058_Purposeful_Program_Theory_Effective_Use_of_Theories_of_Change_and_Logic_Models.

Resource: Outcome mapping can be a useful tool when working with stakeholders to consider the universe of potential outcomes. Outcome mapping is a participatory approach that assists with program implementation, monitoring, and evaluation by identifying and describing the universe of outcomes or changes anticipated or those that have been experienced by members of a program's target population. Outcomes suggested by participants can be tagged based on their likelihood of emerging during the program time frame (i.e., "expect to see," "like to see," and "love to see"). This approach not only helps to better understand the likelihood and timing but also may encourage participants to be more creative and open to contributing and documenting less-likely outcomes, even those that may not be targeted by the project specifically, without fully committing to achieving them. More information about outcome mapping can be found in Annex A.

Once the desired outcomes have been identified, the team can work with stakeholders to map the pathways of change to identify the best approaches to achieving the outcomes outlined in Step 2.

Step 3: Map the Pathways for Change and Identify Interventions

In this step, the team will engage with stakeholders to discuss and document potential pathways for change. In some cases, the intervention activities have been predetermined, and the team must work with stakeholders to better understand the pathways between inputs and activities. Ideally, however, the activities will not yet be determined, and the team and stakeholders can work backwards from outcomes to design inputs/activities that lead to the outcomes identified in the previous step. This scenario is preferable because it helps encourage the design of programs that more closely align with the local context and the needs of the target population/s, outlined in Steps 1 and 2. Discussion with stakeholders is essential in all steps, but during this step, it's particularly helpful if the program and measurement teams are prepared with any existing theoretical frameworks that might be useful resources to help guide the discussion.

Why should I use an existing theoretical framework?

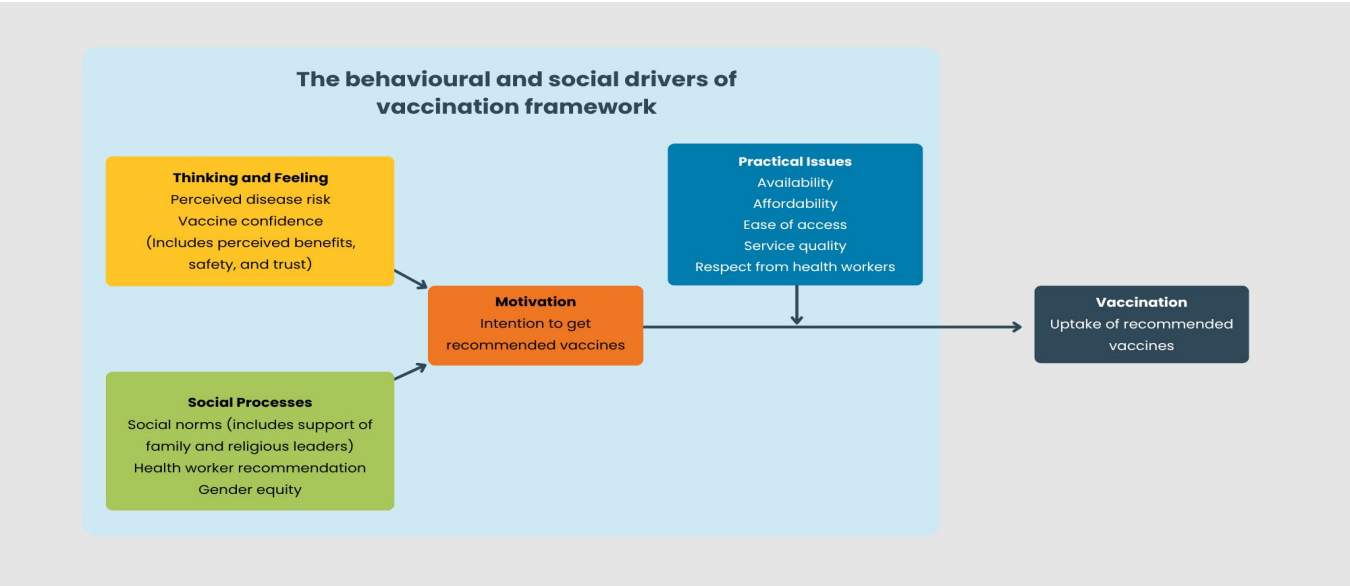
Existing theoretical frameworks can be helpful as draft maps for understanding the possible causal relationships to outline in a TOC. These frameworks are generally developed by experts in particular fields (to be discussed below) and are usually tested and validated over time to outline patterns that may be able to apply to a current effort. They can be especially useful in situations where the team may get stuck when identifying root causes. Note that the language used by many of these frameworks can feel overly academic and unapproachable, and using them may feel like an unnecessary step. However, they can be useful guides for designing a program and for understanding what is essential for measurement, particularly when the root cause boils down to behavior, which it often does.

Let's look at an example that draws from Social Cognitive Theory (Bandura, 1977). When reviewing the context and root causes of ZD children, the team realizes that caregivers aren't bringing their children to be vaccinated. The team decides to review an existing theoretical framework that has been applied to health seeking behavior for immunization (Askelson et al., 2010; Gichuki et al., 2024), like the Theory of Planned Behavior (Ajzen, 1991). This theoretical model suggests that, in order for someone to perform a certain behavior, like taking their child for vaccination, they need to have a positive attitude toward vaccination and subjective norms that align with vaccination (i.e., a belief that others in their family, community, etc., will approve of them vaccinating their children or will disapprove of them not vaccinating their children). This model illustrates that an intervention that only seeks to address a caregiver's attitudes about vaccines will likely not work if their family and community do not also approve. While a very basic example, it illustrates how using these theories can help guide programming and measurement approaches by suggesting pathways for change that may not always be clear.

There are several theoretical frameworks that can inform ZD programming. One commonly used framework is the World Health Organization (WHO) Behavioural and social drivers of vaccination framework (Figure 8). The framework highlights the importance of motivation or intention to vaccinate to immunization uptake, a step that could easily be overlooked when designing and monitoring immunization programs. However, by referring to this framework when designing an immunization program and developing the TOC, a team can attempt to incorporate these elements into programming and measurement.

The WHO framework and supporting documents as well as examples of frameworks that may be useful for immunization programming are summarized and linked in Annex A. Existing frameworks are adaptable and flexible, and design and measurement teams should not hesitate to modify them to better suit the needs of their context. While many existing frameworks are rooted in extensive research and analysis of programs over time, they should be viewed as resources to consult rather than as strict roadmaps. In fact, existing frameworks should be adapted by local implementers and stakeholders, whose contextual knowledge and experience are essential for tailoring these frameworks to ensure their relevance and practicality within the country or local context.

Figure 8. The Behavioural and Social Drivers of Vaccination (BeSD) Framework



Source: "Behavioural and Social Drivers of Vaccination: Tools and Practical Guidance for Achieving High Uptake." Geneva: World Health Organization, 2022. https://www.who.int/publications/i/item/9789240049680.

> **Note:** A theory-based approach does not have to be rooted in existing theoretical frameworks. It only requires that a framework is developed (by thinking through the causal pathways from activity to impact) and, ideally, documented.

Regardless of whether or not an existing theory is used, as with previous steps, consultation with stakeholders is essential to ensure that causal linkages documented in this step accurately reflect the population of interest. Additionally, the team can now begin brainstorming interventions that might bring about the changes identified in the TOC. During this phase, the following questions may be useful to help guide the conversation with stakeholders:

- What actions and underlying interventions are needed to achieve the desired outcomes?
  - If individual behaviors are identified as a challenge to reaching outcomes, what might motivate these individuals to change their behaviors?
  - Why do we think that this intervention will work?
  - What would be the appropriate sequence of these actions and interventions to lead from inputs to outcomes?
- How might the program build on existing work or collaborate with other activities to achieve the desired outcomes? (e.g., using the example above, if another organization is working in the same area with fathers groups to promote immunization services, perhaps engaging local leaders would build on/complement their activity).
- How can information collected at the various stages feed back into the program to allow for adjustments and adaptations?
- Activity: map out causal pathways that connect activities to outputs, outputs to outcomes, and outcomes to impacts.

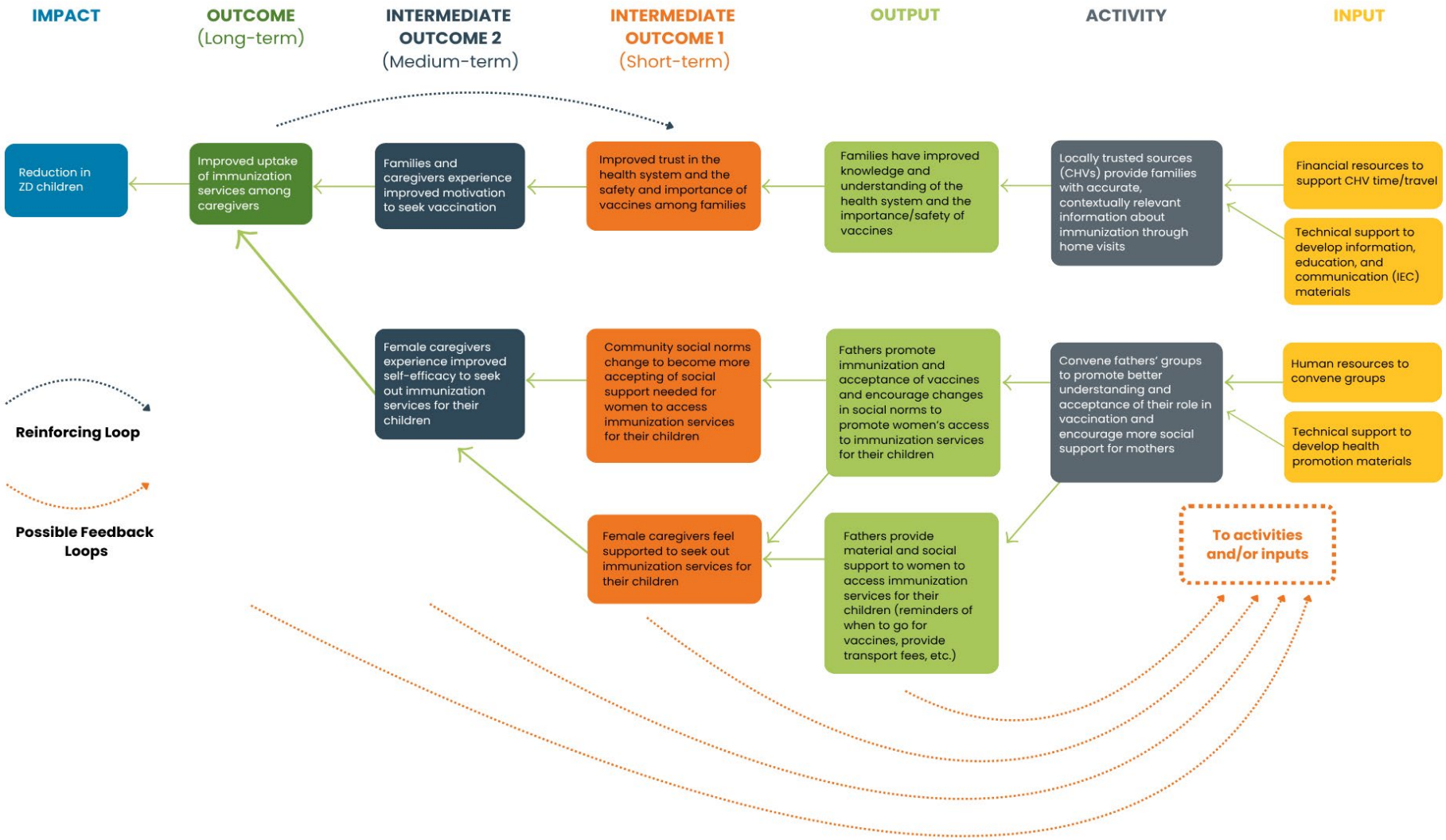
At the end of this process, a map of causal pathways, from activity to impact, should be drafted. Figure 9 shows what this map might look like for the ZD program discussed earlier. Please note that this graphic includes the impact on the left-hand side, which may help sinistrodextral readers (those who read from left to right) better process the causal pathways by starting from the impact and moving toward the activity on the right-hand side. However, a TOC can also be arranged from top to bottom or even bottom to top, depending on the preference of the project team (see Step 5 for more examples of visual representations of TOC).

The example framework on the next page shows only two activities, but, at this point in the TOC development process, the team may have identified a longer list of activities that could achieve the desired outcomes and impact. Identifying assumptions and prioritizing activities are an important part of the next step.

Photo Credit: AFENET, Nigeria Learning Hub

Tip: During TOC development, consider using a large wall space and sticky notes to map out the pathways. This makes the process more interactive and collaborative, everyone can see the full picture, suggest changes, and move elements around as the group's thinking evolves.

Figure 9. Example TOC for a ZD Social and Behavioral Change Intervention



Step 4: Identify Assumptions and Risks and Prioritize Interventions

In the first part of this step, the design and measurement teams should work together to identify assumptions about and risks to the change pathways outlined in the previous step. Assumptions represent the conditions that must be present in order for the change pathway to be successful and are **within the program's control**. External risks are potential threats to the program's success that are not just the inverse of the assumptions, but are threats generally outside the control of the project. For example, in the scenario above, an *assumption* might be that fathers are well-respected figures in the community and have the ability to change community social norms. Assumptions should be reviewed regularly, and adjustments can be made to programming in the event that they are not accurate (which we will discuss further in Section III). A *risk* might be that political instability prevents fathers groups from meeting or that it prevents caregivers from bringing children for vaccination services. Risks may or may not be mitigated through adjustments to the program.

Case Study 5: Bangladesh Learning Hub—Mitigating External Risks During Political Instability

The Bangladesh CLH was in its second year of implementing Learning Hub activities in 2024, actively monitoring a number of ZD interventions when political turmoil and protests erupted across the country that were met with violent force. Ultimately, the prime minister was ousted and an interim government took over, but for a period, curfews and restrictions on movement were in place, businesses and educational institutions were shut down, and the internet and other communication channels were restricted. Although Bangladesh has experienced political instability in the past, nearly eleven years had passed since the country had last experienced such serious and disruptive events. The external risk of political instability was likely moderate or low when the CLH was planning its ZD-focused activities and developing their TOC. At the onset of the instability in 2024, the CLH was able to review the programming and mitigate the effects of political disruption for some activities but not for others. For example, immunization sessions monitored by the CLH in some areas were cancelled due to health facility closures and a lack of human resources. However, the CLH was able to work with implementing partners to conduct catch-up immunization sessions when curfews were lifted and the situation allowed it. In this case, the impacts of the external risks could not be avoided completely, but the CLH was able to adapt and work to mitigate effects as much as possible.

While teams may find it helpful to generate an exhaustive list of assumptions and risks, using history and context as a guide and categorizing assumptions by confidence and risks by their likelihood may help create a more targeted, prioritized list. For example, if a country does not have a recent history of political instability and events that may have triggered instability in the past (like elections) are not scheduled to overlap with the implementation period, political instability may be categorized as "low likelihood."

Photo Credit: CAPEV, Mali Learning Hub

Questions that may help guide a conversation with team members and stakeholders about assumptions and risks include:

- What assumptions underpin the pathways of change (e.g., "communities will participate actively in immunization campaigns")? What level of confidence does the team have that these assumptions will hold (low, medium, high)?
- What external factors might influence the success of the program (e.g., political instability, funding availability, etc.)? How likely are these risks/factors (low, medium, high)?

Categorizing the risk likelihood and the confidence level in assumptions can be important when prioritizing interventions. The team may want to prioritize interventions with high confidence in assumptions and low likelihood of risk.

During the intervention prioritization process, the team should work to determine which interventions or activities are most important. "Important" in this case may mean which interventions are likely to have the greatest impact with the fewest resources or those that involve the least risk and fewest assumptions. The team will need to work with stakeholders to determine what combination of considerations to include in this decision-making process.

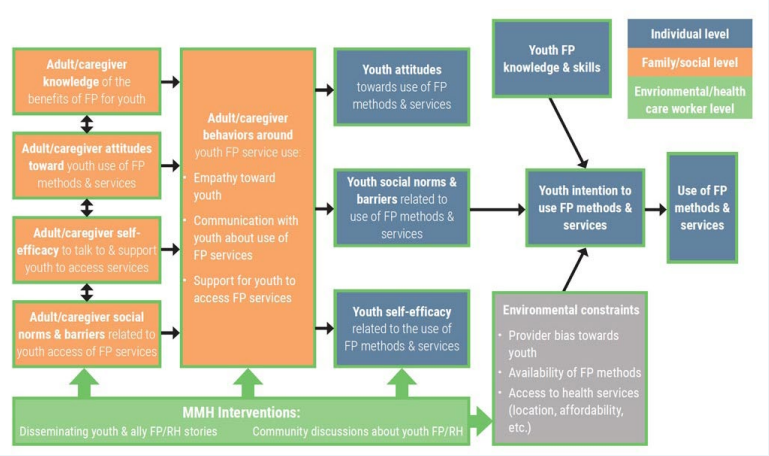
Step 5: Document the TOC, Visual and Narrative

The TOC should be documented as soon as Step 4 is complete, before time passes and important decisions are forgotten. The documentation has two key steps finalizing the visual and writing the narrative. The steps can be completed in the order the team prefers. Some teams may choose to develop the visual first, as graphics are often generated as part of Steps 1 and 4 through sticky notes or flip charts, and it can be a good approach for building consensus with stakeholders around a framework. Additionally, the final TOC visual will pull heavily from the causal map developed in Step 3, so it may be the easiest starting place.

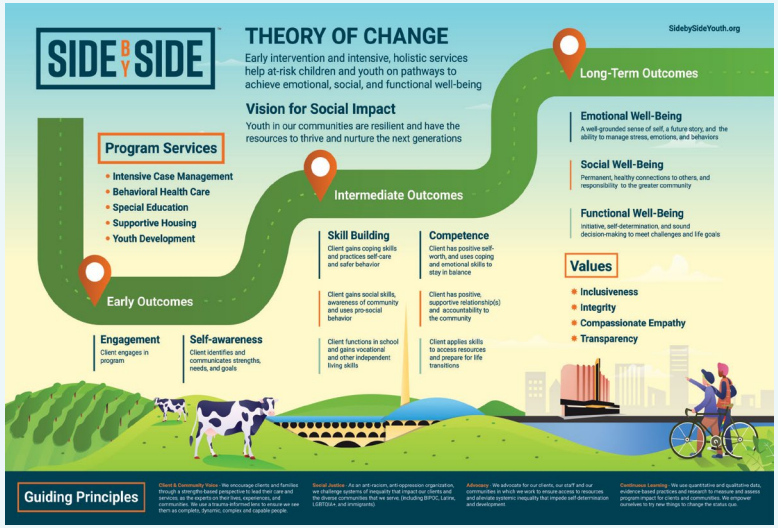
Tip: If the TOC development takes place over a multi-day workshop, consider engaging a rapporteur throughout the workshop to take note of discussions and key points as the team works through the various steps.

When developing the visual, remember that there is no one "correct" way to present a TOC. A quick search shows frameworks that move from all directions, including bottom to top and multi-directions. Some use roadmap formats, waves, or zig-zags; some are composed of text boxes and arrows; and others include icons and sophisticated graphics. See Figure 10 for diverse examples of how organizations have visualized their TOC.

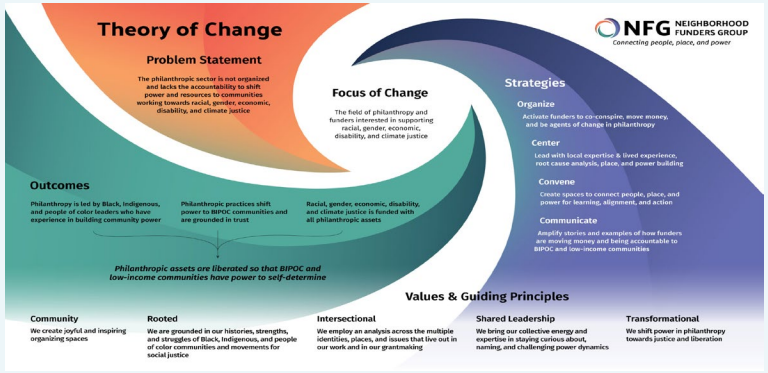
Figure 10. TOC Visual Examples



The Compass for SBC. "Merci Mon Héros Theory of Change." https://thecompassforsbc.org/how-to-guide/how-to-use-a-theory-of-change-to-monitor-and-evaluate-social-and-behavior-change-programs/figure-3-merci-mon-heros-program-theory-of-change/.



Side by Side. "Theory of Change." https://www.sidebysideyouth.org/about/our-approach/theory-of-change/.

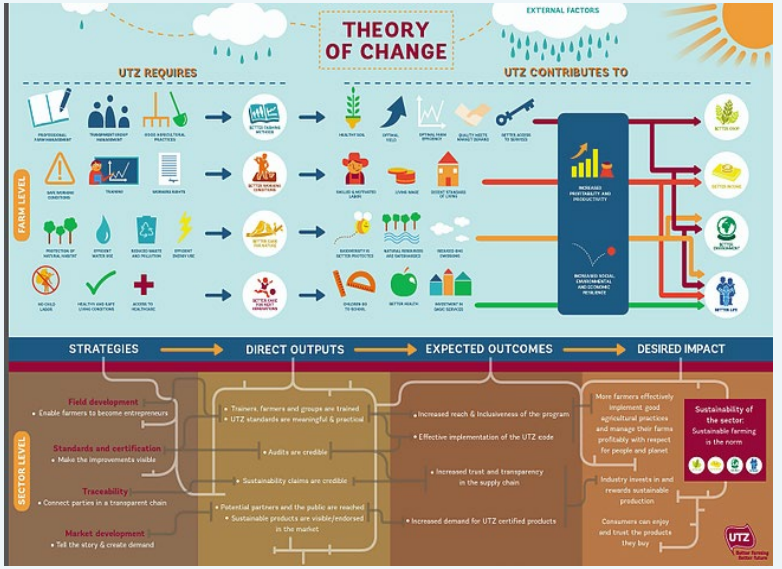


Neighborhood Funders Group. "Neighborhood Funders Group Theory of Change." https://nfg.org/theory-of-change/.

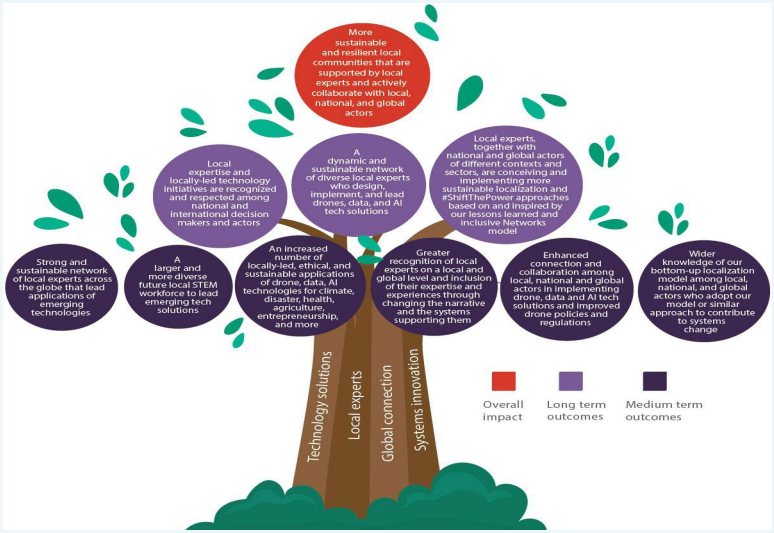
SCiP Alliance. "Theory of Change." https://www.scipalliance.org/theory-of-change.

Figure 10. TOC Visual Examples (Continued)

PANORAMA. "Participatory Theory of Change." https://panorama.solutions/en/building-block/participatory-theory-change.



Impact Academy. "Theory of Change." https://knihovna.impactacademy.cz/theory-of-change-3.



WeRobotics. "Theory of Change." https://werobotics.org/why/toc.

The best TOC format accurately represents the team's ideas. A person not involved in the decision-making should be able to look at it and come away with a general understanding of the activities and their relationship to outcomes and impact, as well as the assumptions, risks, and barriers.

Often, program design and measurement teams will develop the graphic and consider the TOC design process complete. Once the visual has been developed, there is excitement and anticipation to move forward with implementation and measurement. However, a TOC visual is insufficient to explain this carefully developed framework, which is why an accompanying narrative is important. Again, someone unfamiliar with the project should be able to review the TOC package (the visual and narrative) and understand the project as a whole, including the background or context in which the program is operating. The TOC visual should act as a blueprint and include important details discussed in conversations with stakeholders, and the accompanying documentation or narrative should walk the reader through the TOC and answer questions[1] including, but not limited to:

Source: Fresh Spectrum Evaluation Cartoons

- What is the **context** outlined in Step 1 that the program or activity will work in? What are the **needs** and **challenges**, and what are some of the reasons why they persist?
- What does the environment of **stakeholders** look like?
- What specific changes does the program or activity aim to achieve? What do the **outcomes** look like, and how might they be measured over time to track progress?
- What **activities** or **interventions** will lead to this change? How and why are they likely to contribute to these outcomes?
- What are the **assumptions** that underpin the framework and what are the **risks** that may challenge it? How likely are they? How will the team work to **mitigate** these risks?
- **Bonus**: What are the key points along the framework where evidence and learning will feed back into program design?

Measurement note: Throughout the TOC design process, the measurement team should actively consider various measurement approaches and indicators. During the last few steps of the TOC development and documentation, the team may choose to begin documenting a measurement strategy in the preferred format (a monitoring, evaluation, and learning [MEL] plan, study protocol, MEL framework, etc.). The measurement strategy should be closely aligned with the TOC, and, where possible, should identify a variety of data types, collection mechanisms, and subjects to measure progress for all outputs, outcomes, and impact. Additionally, if the program intends to continuously integrate evidence and adapt its strategies on an ongoing basis, the team should prioritize the most useful and usable data types and formats for this purpose.

1 These questions are adapted from the USAID TOC workbook: Salib, Monalisa. 2022. Theory of Change Development: A Step-by-Step Process for Developing or Strengthening Theories of Change. USAID Learns. https://decfinder.devme.ai/dec/theory-of-change-development/.

Once the TOC narrative and the visual are complete, stakeholders have had an opportunity to review and provide feedback, and the team feels confident that the documents accurately represent the thinking and evidence available at the time, the first draft of the TOC package can be considered complete. At any point in program implementation, and even during post-implementation measurement activities, the TOC should not be considered "final" as it represents the thinking of the team using information available at the point in time it was put together. Over time, as the situational context changes and program data emerges or as other key stakeholders are identified and included in discussions, the TOC will almost certainly evolve. As such, the program and measurement teams should plan to revisit the TOC on a regular basis to review and revise. In the next section, we discuss why and how this TOC revision should take place.

III. Revisiting and Revising a Theory of Change

All too often, TOCs are treated as a formality, created to demonstrate strategic thinking or planning rather than as a living blueprint that actively guides program implementation and measurement. TOCs are often developed at the outset of a program (or even during the proposal development period) and then tucked away, unused. For immunization and ZD programming in particular, the implementing environment changes rapidly, and if the TOC is not revisited and reviewed on a regular basis, it's possible that by the end of the project the TOC may no longer reflect the program's actual design, activities, or context.

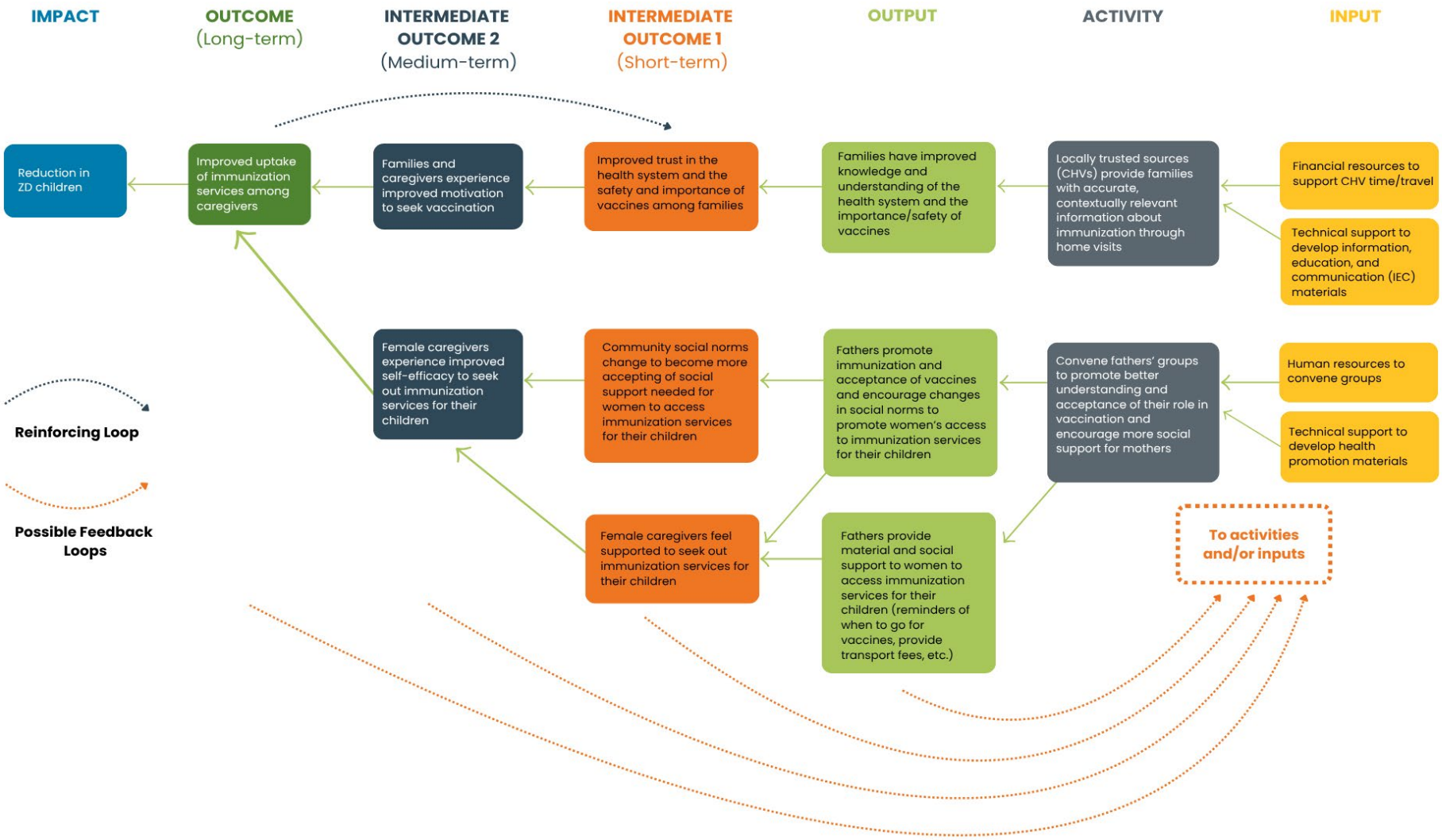
To keep the TOC up to date and reflective of the current thinking and programming, the team should try to schedule regular check-ins to review and revisit the TOC. The timing of the check-ins will depend on a number of factors, including the duration of the program, where the measurement team is coming into the process, resources, availability of staff, the complexity of the program, the volatility of the context, etc. A monthly hour-long check-in could suffice for one program, while another might benefit more from an annual two-day stakeholder workshop.

This section outlines the process for reviewing and revising a TOC, using the ZD TOC example (Figure 11) as a case study.

Source: Fresh Spectrum Evaluation Cartoons

Resource: Many of the graphics and content in this section are adapted from a TOC Critical Reflection Workshop (CRW) guide, developed by Fabo, an online learning community for NGOs. The CRW is structured as a two-day workshop, but the materials can be adapted, as the proposed steps for revisiting and revising a TOC remain the same. The extensive package of free resources (e.g., slide templates, facilitators guides, activity templates) are linked in Annex A.

Figure 11. Example TOC for a ZD Social and Behavioral Change Intervention



Revisiting and revising a TOC involves several recommended steps. As always, it is beneficial to include stakeholders in these discussions to complement the core team's information. Similarly, the team should use program data and wider contextual information to inform discussions.

Tip: One easy way to incorporate TOC review and revision into regular meetings would be to add TOC check-ins as a standard agenda item after program data is presented or discussed.

Note: The steps below provide guidance on revisiting and revising a TOC that has all of the elements discussed in Section II. In cases where these items may not have been included in the original draft, the program team may want to first work through Section II to ensure the important components of a TOC, like risks, assumptions, and causal links, are available so that the TOC has enough detail to inform programming and measurement decisions.

The following activities and guiding questions can facilitate the review and revision of the TOC and can be customized as necessary. While the suggested order of steps may help inform subsequent discussions, program teams may find alternative sequences more effective:

Step 1: Review the Most Recent Draft of the TOC as a Team

In this first step, the team should walk through the existing TOC together, noting impacts, outcomes, causal linkages, assumptions, and risks. This step ensures a shared frame of reference within the team, especially if the TOC hasn't been reviewed recently.

Tip: If the team used any tools during TOC development (e.g., root cause analysis, outcome mapping), it may be helpful to have these tools available during the review as a reminder of the original thought processes and to update if desired.

Step 2: Assess How the Program Context Has Changed Over Time

How has the context in which the program is operating changed over time? How do these changes in context affect change along the TOC pathway, assumptions, or risks?

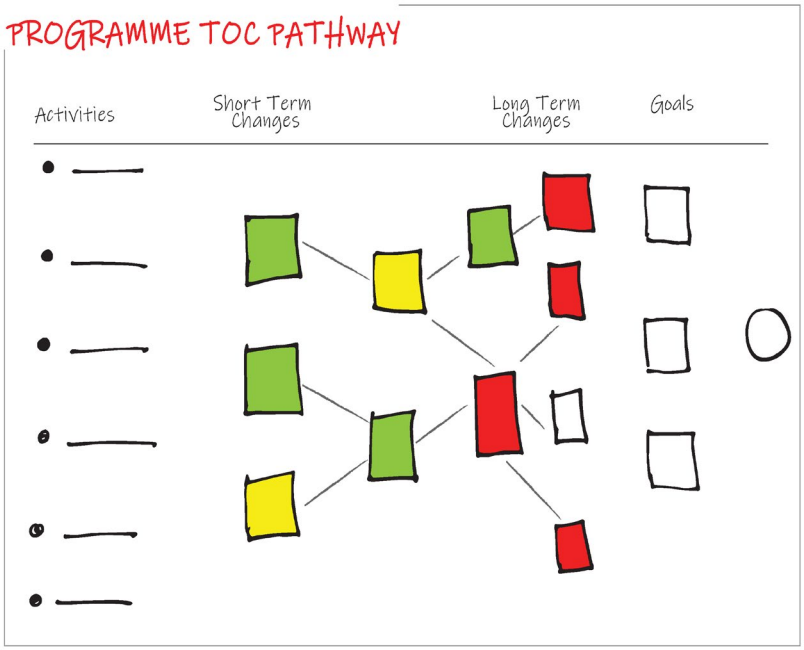
In this step, the program team should discuss any changes to the programming context. Using the ZD example above, perhaps since the last team discussion, the provincial health authority had passed a budget that reduced funding for the health facilities. The team would want to discuss the details of the budget cuts and how they anticipate the reductions would affect immunization services. Would the cuts affect staffing or reduce immunization service hours? The team should then consider how this might affect change along the TOC. How will the budget reductions affect community health volunteers (CHVs)? Will caregivers be able to access services when they arrive at the clinic? If this is a concern, the team might need to update risks to note that immunization services may not be readily available for caregivers who bring their children.

Step 3: Re-Examine Causal Pathways and How They Have Changed Over Time

How has the causal pathway changed over time? What changes have occurred and for whom? Are the changes positive, negative, expected, or unexpected?

In this step, the program team should work through the TOC systematically, from outputs to impact, to identify any changes that have occurred. Changes should include positive and negative changes as well as expected and unexpected changes. One helpful way to track and document change is to project the visual TOC and to color code changes as green (full change), yellow (some change), and red (no change) as the team works from one end to the other (Figure 12).

Figure 12. Color-Coded TOC Pathway



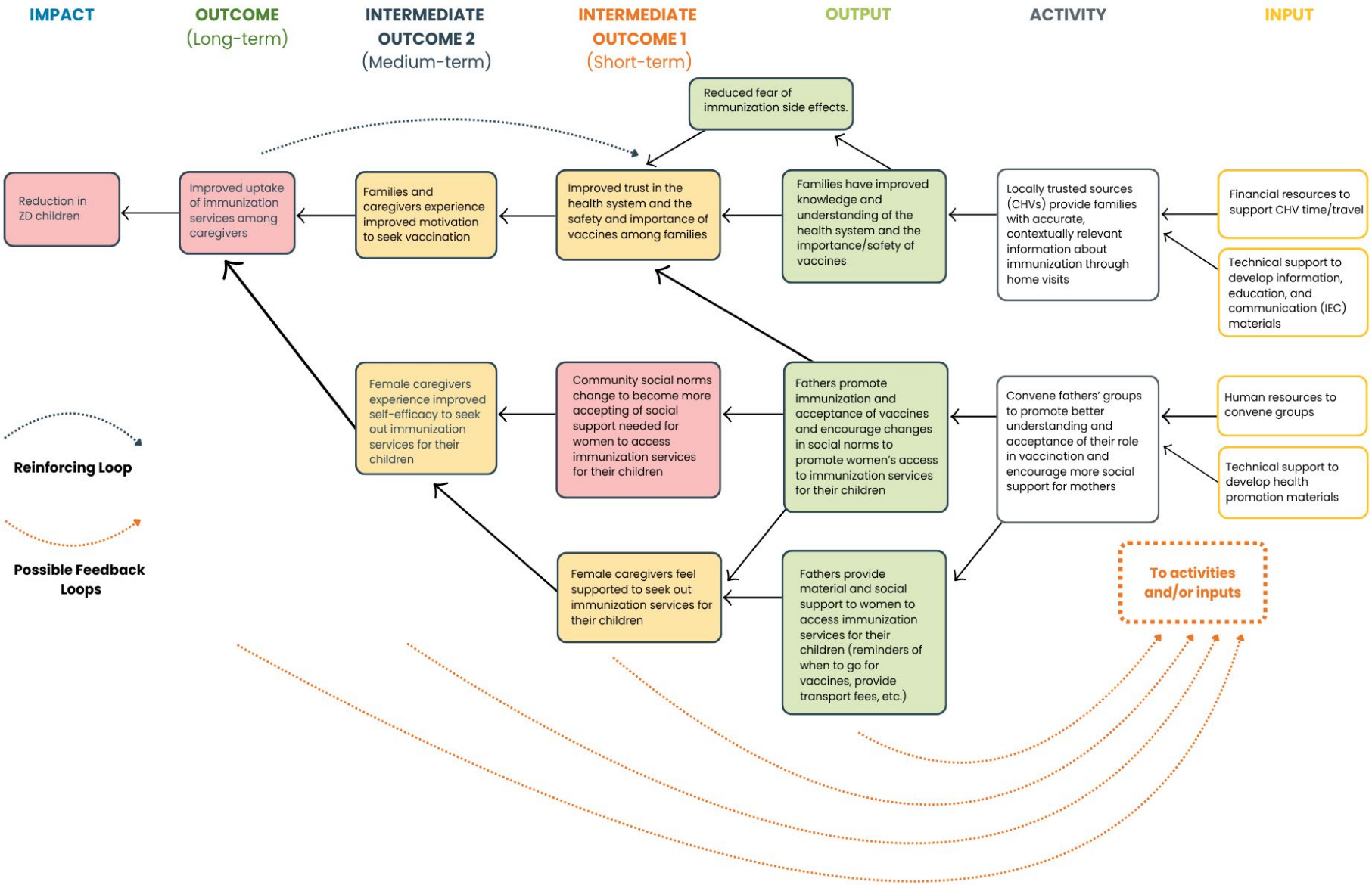
Source: Learning Site: Theory Of Change - Facilitator's Guide to Critical Reflection Workshop." Accessed February 14, 2025. https://fabo.org/dca/Theory_Of_Change_Facilitator%27s_Guide_to_Critical_Reflection_Workshop.

Figure 13 shows how this approach could be used with the example ZD Social and Behavioral Change Intervention. In this scenario, the team may have discussed and noted that there was evidence that the outputs had been achieved. For example, families had demonstrated improved knowledge and understanding of the health system and the importance and safety of vaccines. Fathers were promoting immunization and vaccine acceptance, encouraging changes in social norms and providing social support to caregivers to access vaccines. There was also some evidence of increased trust in the health system, with caregivers expressing greater motivation to access immunization services. However, this progress had not yet translated into expected outcomes; caregivers were still not bringing children for immunization and a reduction in the number of ZD children had not materialized.

When examining the second pathway, the team noted that while fathers were promoting changes in social norms, broader community norms had not yet shifted in support of vaccination. On the other hand, fathers were successfully providing social support to female caregivers, and some caregivers had begun reporting that they felt supported in accessing immunization services and reported improved self-efficacy to obtain these services.

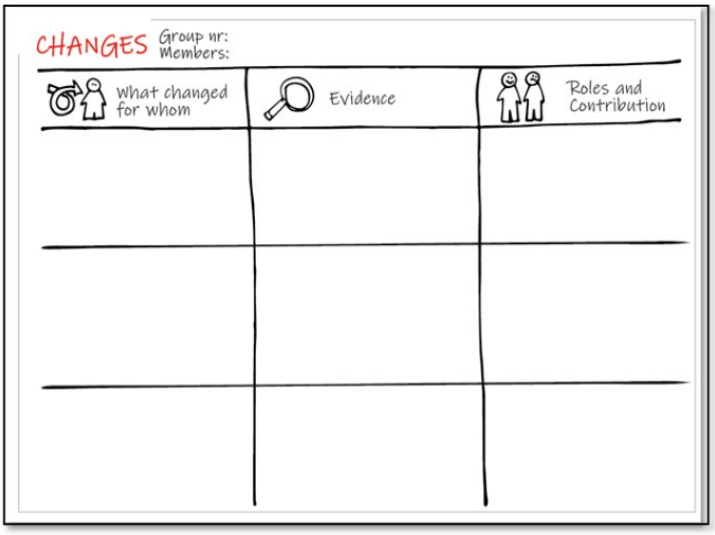
Perhaps in discussing the changes, the team noted that for the first activity, through implementation of the CHV home visits, the families gained knowledge and understanding about the health system, but also reported that their fears about vaccine side-effects had been reduced. The team may have collected qualitative data in which families were indicating that this reduction in fear was an important part of their increased trust in the health system. It would be important to note this finding and add it to the TOC as an essential precursor to trust so that it accurately reflects the sequence of change. With this information, the team may decide to come up with ways to measure fear, if they weren't already in place, or to note this as an important intermediate outcome or facilitator of trust.

Figure 13. Color-Coding TOC Progress for the Example ZD Intervention TOC



During this step, the team may also choose to create a list of the changes and whom they affected, the evidence supporting the changes, and the roles of different actors who may have contributed to the change (Figure 14).

Figure 14. Matrix for Assessing Change Areas



Source: "Learning Site: Theory Of Change - Facilitator's Guide to Critical Reflection Workshop." Accessed February 14, 2025. https://fabo.org/dca/Theory_Of_Change_Facilitator%27s_Guide_to_Critical_Reflection_Workshop.

At the end of this step, the team should have a comprehensive list of changes that have taken place. In the next step, the team will discuss how and why or why not changes have or haven't taken place.

Step 4: Validate and Identify New Assumptions

What are the drivers of or barriers to the changes that occurred?

In this step, the team should review the changes that have occurred and discuss why certain changes may have taken place (i.e., what drove change) and what some of the barriers to change may have been.

Using the ZD example, the team identified in an earlier step the importance of fear reduction for building trust in the health system. Perhaps, in this step, they build on this by noting that CHVs identified fear of side effects as a barrier in their meetings with families and began addressing it more directly in their discussions with families. The team may note this as a facilitator of fear reduction.

Alternatively, when discussing the lack of change in community social norms, a team member notes that in the program communities, female caregivers mentioned in interviews that while they appreciate the support of fathers, community elders and religious leaders still show significant resistance to allowing female caregivers to make decisions about accessing immunization services for their children. These leaders felt strongly that it was the responsibility of the father, as head of household, to make these decisions. This could be identified as an important barrier to changes in social norms.

In the next steps, the team will consider how the changes affect TOC assumptions and risks and, finally, consider the program implications.

Step 5: Identify Emerging Risks and Opportunities

How do these changes affect TOC assumptions and risks?

With important contextual and programmatic changes identified, the team should now consider how these affect the TOC's assumptions and risks. The team should revisit assumptions identified earlier and use program evidence to determine whether the assumptions have held, whether they should be revised, and/or whether new assumptions should be added.

In the ZD case study, perhaps one of the early assumptions made was that fathers were the main facilitators of social norms that prevented female caregivers from accessing services for their children. For that reason, the program chose to engage fathers and use them to promote change. Perhaps in reality, it isn't only fathers who uphold this social norm, but community leaders as well. And perhaps another assumption was that fathers had the power to influence community leaders, when, in this scenario, it is the reverse. Instead, community leaders, as respected elders, are able to influence the behaviors of fathers and community social norms more generally.

Step 6: Revise and Update the TOC

Considering these changes, how should we modify programming or measurement approaches?

This brings us to the final, and arguably most important, step. The team must critically review the changes and consider how the program and measurement approaches should be adapted to respond to changes. Questions to help guide this session include:

- What could we do differently based on the identified changes in context and other relevant information gathered?
- Moving forward, which, if any, components of the program should we consider scaling? Which, if any, components should we consider downscaling or phasing out?
- Are there opportunities to strengthen ties with other programming efforts and maximize programming effects?

In the ZD case study example, perhaps the team notes that, given the finding about reduction in fears as an interim step in building trust, it would be useful to adapt CHV information, education, and communication (IEC) materials to include guidance on discussing side effects with families. Additionally, the measurement team may decide to implement measurement activities to better understand the extent of caregivers' fear about side effects, how it changes over time, and the root causes underlying these fears.

For the community engagement activity, the team may decide that adding engagement of community leaders will be important for effecting changes in community social norms. In this scenario, perhaps another local organization is currently engaging local leaders on another topic and they agree to incorporate aspects of the immunization engagement activity into their own program. The team may also decide to develop additional measurement activities here to help better understand the perspectives of community leaders to craft more targeted engagement approaches.

Finally, based on these discussions, the team will likely want to closely monitor the change pathways moving forward. Specifically, the team will likely want to monitor causal pathways that have not yet been confirmed and where adjustments have been made to programming to inform the next TOC review and revision.

IV. Conclusion

TBE offers a robust and essential framework for understanding the intricacies of ZD and UI programming and measuring its progress and outcomes. As this toolkit demonstrates, moving beyond simple "did it work?" questions to delve into "how" and "why" programs succeed or fail is essential, especially in the complex, dynamic environments where ZD and UI children are often found.

The development of a clear and comprehensive TOC is the cornerstone of a theory-based approach. This involves a collaborative process of defining the problem and context, articulating desired outcomes, mapping pathways for change, identifying interventions, acknowledging assumptions and risks, and thoroughly documenting the TOC in both visual and narrative forms. This iterative process, continuously informed by stakeholder engagement and contextual understanding, ensures that the program's underlying logic is explicit and actionable.

Crucially, a TOC is not a static document. The regular revisiting and revision of a TOC, as outlined in this toolkit, are vital for adaptive learning and program responsiveness. By continuously reviewing changes in context, assessing the effectiveness of causal pathways, identifying drivers and barriers, and re-evaluating assumptions and risks, programs can remain agile and effective in achieving their goals. This adaptive approach ensures that resources are directed towards the most impactful solutions, leading to more equitable and sustainable immunization outcomes.

Ultimately, by embracing theory-based approaches, ZD and UI initiatives can gain deeper insights into their interventions, refine strategies, and contribute to the broader goal of leaving no child behind in immunization efforts. The commitment to understanding the "how" and "why" of program effectiveness is not just an evaluation best practice; it is a critical driver for achieving universal immunization coverage and improving child health globally.

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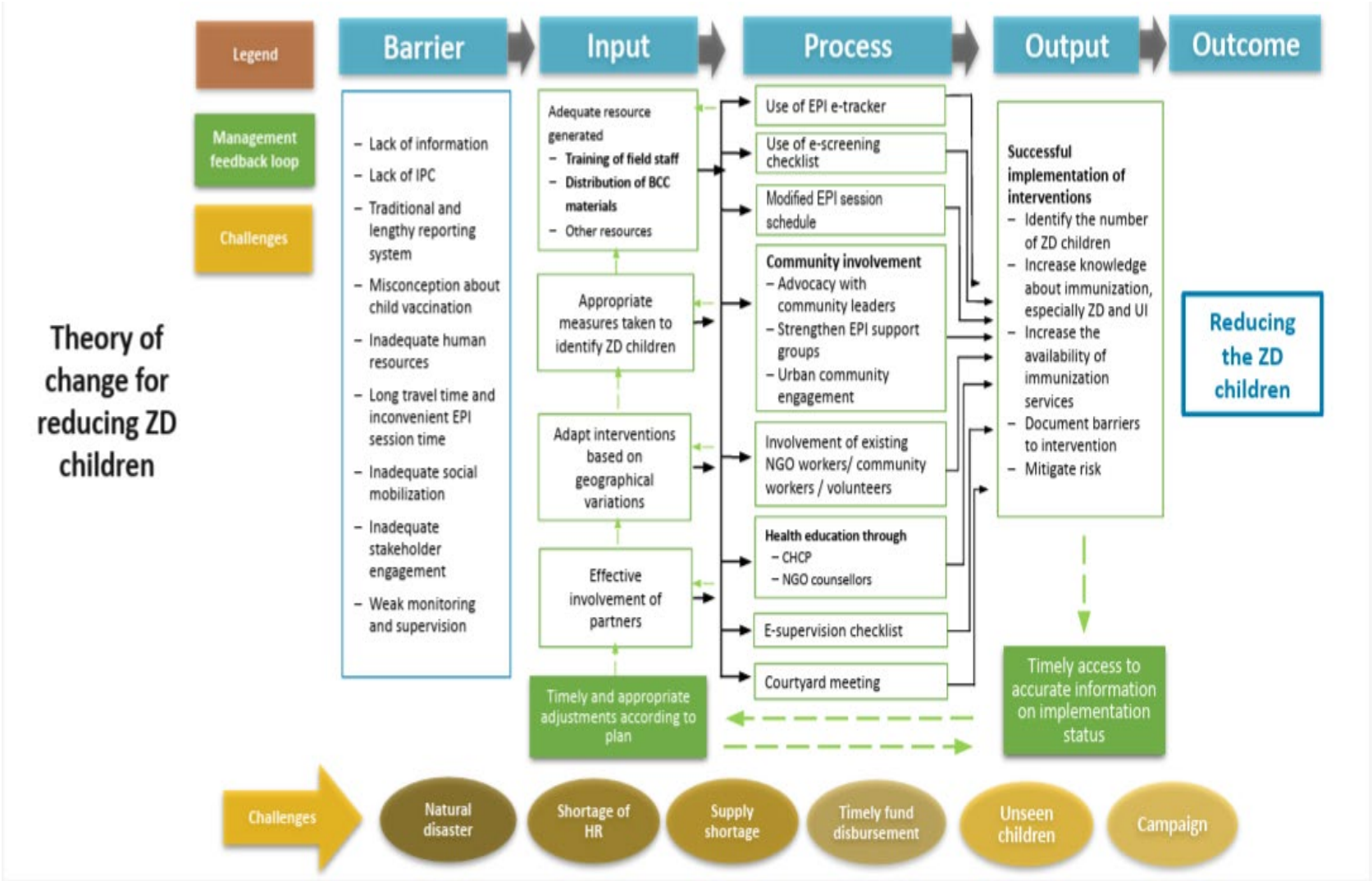
Annex A. Relevant Resources to Guide TBEs

Resource Name	Description
Theory of Change Workbook: A Step-by-Step Process for Developing or Strengthening Theories of Change	This USAID TOC development workbook provides tools and templates to walk implementing organizations and stakeholders through a five-step TOC development process.
Human-Centred Design for Tailoring Immunization Programmes	This WHO guide supports health and immunization actors to identify barriers, leverage drivers, and co-design tailored, human-centered immunization programs. It outlines a four-stage, cyclical process—Diagnose, Design, Implement, and Evaluate—to improve vaccination outcomes.
Applying Human Centred Design (HCD) to Increase Vaccination Rates in Zero-Dose Communities	This UNICEF case study shares insights from using HCD to improve vaccination rates in ZD communities in Nepal. It explores what HCD is, how it was implemented, the context of its application, its influence on practice, and key lessons learned.
Using Human-Centered Design to Bridge Zero-Dose Vaccine Gap: A Case Study of Ilala District in Tanzania	This document is a case study on using HCD to address the ZD vaccine gap among under-five children in Ilala District, Tanzania. It details the methodology, interventions, and outcomes of community-centric approaches, highlighting the success of house-to-house campaigns and advocacy strategies in increasing vaccine uptake and reducing vaccination hesitancy.
Uncovering the Drivers of Childhood Immunization Inequality with Caregivers, Community Members and Health System Stakeholders: Results from a Human-Centered Design Study in DRC, Mozambique and Nigeria	This case study highlights a project that applied HCD and intersectional approaches in the Democratic Republic of the Congo, Mozambique, and Nigeria to uncover the complex, overlapping barriers caregivers face in accessing childhood immunization. Through co-creation workshops, communities and health system actors collaboratively identified context-specific solutions to improve equity and responsiveness in vaccination programs.
A Theory of Change for Guiding the Integration of Human-Centered Design Into Global Health Programming	This article provides an actionable and relevant framework for creating a TOC when integrating HCD approaches into global health programming, including immunization. It explains HCD's core tenets (collaboration, people-centered approach, and iteration) and how these are linked to desired outcomes like strengthening health systems and promoting equity.
WaterAID - Political Economy Analysis Toolkit	This toolkit builds on existing resources to present four different types of PEA, including a simple "Everyday PEA."
Assessment of the Political Economy Context Surrounding Evidence for Zero-Dose Programming and Policies in Nigeria	This assessment from the ZDLH explores how political, institutional, and systemic factors influence the generation and use of evidence to support ZD immunization programming in Nigeria. It highlights challenges such as data fragmentation, weak accountability, and misaligned incentives and identifies opportunities to strengthen collaboration, data systems, and decision-making to better reach unvaccinated children.

Resource Name	Description
Assessing the Governance and Political-Economy Landscape for Evidence-Based Zero-Dose Programming and Policies in Bangladesh	This PEA explores how governance structures, institutional dynamics, and decision-making processes affect the generation and use of evidence for immunization in Bangladesh. Conducted by IIHMR and icddr,b, the study highlights how centralization, coordination challenges, and resource constraints impact efforts to identify and reach ZD/UI children and missed communities. The report offers actionable recommendations to improve data integration, support sub-national actors, and align financial and human resources with program needs as Bangladesh transitions to middle-income status.
WHO Implementation Guide Toolkit: Stakeholder mapping guide	This WHO toolkit was developed as part of an implementation toolkit to support contraceptive guideline implementation. However, the Stakeholder mapping guide includes helpful guidance on conducting the mapping as well as a template that can be easily customized for immunization programming.
A Toolkit For Engaging Non-Health Stakeholders In Supporting Routine Immunization In Uganda	This toolkit provides practical guidance for engaging local government, civic, and community leaders outside the health sector to strengthen routine immunization services in Uganda. It outlines roles, processes, and platforms at district, sub-county, and community levels to help integrate non-health stakeholders into planning, implementation, and accountability efforts for immunization programs.
WHO Behavioral and Social Drivers of Immunization	This guidebook, developed by WHO and UNICEF, provides tools and practical guidance for understanding the behavioral and social factors that influence vaccine uptake. It is intended for immunization program managers, research advisors, and others involved in collecting, analyzing, and using data for immunization program planning and evaluation, with the goal of achieving high vaccine uptake.
UNICEF'S Behavioral Driver's Model	This conceptual framework introduces the Behavioural Drivers Model, a comprehensive tool that synthesizes various theories of decision-making and behavior to inform social and behavior change (SBC) programming. Its primary purpose is to provide a common language and guide for operationalizing SBC interventions, helping practitioners understand and influence a wide range of behavioral drivers in real-world contexts, particularly for the protection and promotion of children's and women's rights.
Journey to Health and Immunization Framework	This study details the establishment of a Behavioral Science Center in Nepal by JSI Research & Training Institute, Inc. (JSI), UNICEF Nepal, and Dhulikhel Hospital-Kathmandu University School of Medical Sciences, aimed at increasing the capacity of practitioners to apply behavioral science to immunization programming. The initiative successfully engaged government stakeholders, who, through formative research using the Journey to Health and Immunization framework, identified and addressed BeSD challenges in Nepal, demonstrating a strong demand for such approaches in public health.
Getting Started: A Self-directed Guide to Outcome Map Development	This guide provides step-by-step instructions and tools for organizations to develop an outcome map, which visually articulates their TOC and promotes better understanding of causal linkages. The primary purpose is to enhance communication about their work to various audiences and to serve as a framework for evaluation planning.

Resource Name	Description
How to Guide: How to Conduct a Root Cause Analysis	This guide outlines a comprehensive four-step process for conducting a root cause analysis in social and behavior change communication projects, aiming to identify the fundamental, underlying sources of a problem rather than just superficial symptoms. For immunization programs, this approach can be used to uncover the core reasons for low vaccine uptake, enabling them to design more effective, targeted interventions based on a deeper understanding of behavioral and social drivers.
UIFHS Project Root Cause Analysis Job Aid	This resource from the Universal Immunization through Improving Family Health Services (UIFHS) project provides guidance on how to identify root causes of low immunization coverage using a fishbone analysis.

Annex B. Bangladesh Learning Hub TOC



Annex C. Example ZD TOC Visual and Narrative

Reader's Guide: This annex provides a fictional worked example of a TOC for a ZD immunization program. It is designed to help immunization experts who may be new to TOC methods see how a narrative can be written and used.

- **Not country-specific:** The example uses "Country A" to show how a TOC can be applied without tying it to a particular setting.
- **Structured like a real TOC narrative:** Sections include context, health system and community barriers, stakeholders, program objectives, pathways, measurement, and risks.
- **Shows how pieces connect:** Data, barriers, and stakeholder roles are linked to outcomes and indicators, making the causal linkages explicit.
- **Meant to be adapted:** Use this structure as a template: substitute your own data, challenges, and program details.
- **A living framework:** The version tracking highlights that a TOC should be revisited and revised as new evidence and lessons emerge.

TOC Narrative Background

In this section, we have developed an example of what a TOC narrative *might* look like for the fictional immunization program discussed in the toolkit.

In this example, we can assume that portions of the narrative were developed based on the background literature search, but that information was complemented by feedback from stakeholders in validation and TOC development workshops. Additionally, this is the version of the TOC narrative that resulted after the latest TOC review, so version tracking and some record of decisions and adaptations made are also included. Finally, this example includes detail to help the reader understand why certain decisions are being made, particularly around the background/context. However, this level of detail may not be required or useful for your own purposes.

For this example, we will refer to the local implementing organization as "Immunization Associates," a local NGO located in the capital city of Country A. Immunization Associates is planning to implement the proposed activity in Province A, District C within the country.

In the program timeline, we are assuming that this narrative was initially developed in January 2025, after the stakeholder workshop. It has been revised (in June 2025) after a TOC review and revision activity.

Please note that this example is entirely fictional. Organization names, report titles, and all data are for demonstration purposes only.

Context

In the wake of the COVID-19 pandemic, data from Country A EPI indicate that routine immunization coverage is declining. The "State of the Country's Children" report from 2025 showed that an estimated 10 percent of children ages 12–23 months have not received their first dose of the pentavalent vaccine series (ZD) and 15 percent of children of the same age have not received the third dose of the prevalent series (UI). This represents a notable increase from 2015, when the State of the Country's Children report indicated that only four and eight percent of children from the same populations were ZD and UI, respectively. The 2025 report suggests that up to half of the country's ZD and UI children are located in specific populations in three districts, within a single province (Province A): immigrant populations in border communities in conflict-prone District A, nomadic/herder populations in District B, and households in a remote, mountainous district (District C). Research on barriers to immunization conducted by Immunization Associates and other organizations shows that each of these districts have unique populations that face unique challenges. However, common challenges across the districts include lack of transport to health facilities, lack of awareness about the country's vaccine schedule, and gender barriers related to decision-making.

District and Community-Level Characteristics

District C, where the program is to be implemented, faces unique challenges. The district, with a population of 40,000 people, is home to one of the country's marginalized ethnic minority groups (the Zs) that has been subject to discrimination in the past and relocated from urban areas to a hard-to-reach rural mountainous region. The Zs who reside in the district speak a different language than the majority population outside of the district, adhere to strict religious law within a male-dominated culture, and are generally distrustful of outsiders. The 2024 DHS indicated that only 40 percent of women ages 15-49 had completed primary school and only 15 percent of women ages 15-49 were literate. A 2020 study by an NGO supporting child health programming in the district indicated that only 20 percent of women reported involvement in making decisions about seeking care for their children, and 70 percent of women required permission to travel outside of the home for health services for themselves and their children.

Health System

During the stakeholder workshop, representatives from the district EPI provided an overview of health services available in the district. The two publicly-run health centers in District C are the main source of immunization services. The health centers, staffed by nurses, offer in-person immunization services three days a week and conduct mobile vaccine outreach clinics twice a month to reach more remote areas. The chief nurse from one of the health facilities at the stakeholder workshop noted that there are many communities in the mountains beyond the reach of the current outreach sessions but that reaching them would require more resources and multi-day journeys. She also noted that the outreach sessions are not well attended, particularly by members of the Z community. The chief nurse also discussed some of the challenges with working with the Z community. She, and most of her fellow nurses, are from the majority ethnic group and given the difficulty placing nurses in this remote, rural district, she and the other nurses rotate in and out of the health facilities every two years. In fact, most of the nurses return home to their families in the provincial capital on weekends and holidays. She said that communication with members of the Z community is difficult because most of the nurses do not speak the same language as the Z community. She noted that she often cannot provide all of the information that she is supposed to provide about things like vaccine side effects and when to return and cannot answer most of the questions they have. Additionally, the immunization cards held by the families are not in the Z language, meaning that even literate families have difficulty reading them. Finally, the nurse mentioned that working with the Z community can be frustrating, as they often request that the health professionals that tend to women and children are female, and there are a limited number of female nurses in the facility.

The district EPI representatives described the large number of CHVs supervised by the health facility. CHVs receive training from the ministry of health (MOH), mostly on maternal and child health topics including immunization, and are responsible for providing information to community members as well as referrals to health facilities for services like antenatal care, nutrition support, and immunization services. CHVs serve in the communities where they reside, which means that in District C, the CHVs are mostly from the Z ethnic group. They are required to speak the country's primary language in order to communicate with nurses at the facility, but they also speak the local language. According to the national CHV policy, CHVs are supposed to receive a very small stipend for travel within their communities, but the CHV supervisor at the workshop said they are rarely paid, which limits their ability to conduct their activities. CHVs are provided with IEC materials, including flipcharts with images, to support their community visits. The District C CHV supervisor noted that while they appreciate the materials, they do not often use them in their visits because the messaging does not match up with the barriers faced in these communities, and the community governing council, made up of community leaders and elders, has complained that the images are inappropriate because they show women immodestly dressed.

Community

Two community representatives from the Z community in District C attended the workshop to discuss barriers to immunization services: a religious leader and a local elected official. The officials, both male, stressed the importance of the health of children in their communities. They discussed existing community-initiated efforts in a number of villages to support transportation of sick women and children to health facilities. On immunization, in particular, they noted that their community supports vaccines but that they are difficult to access. The distance to the health facilities is challenging, particularly when it means that men in their community must forgo their daily work to accompany women and children to the facilities, a religious requirement. Regarding outreach, they are not aware of the outreach sessions and when they occur. They noted that there have been times when they heard from the CHV that an outreach session would be taking place, only to show up and find that it was canceled.

The leaders also note that they do not know when their children are due for vaccines, and they cannot read the cards provided by the health facility. They prefer to bring all their children to a single visit for vaccination to save time but have been turned away and told that only some can be vaccinated. Additionally, in some cases, when they arrive at the facility and female nurses are not available to attend to women and children, which is a requirement, they feel disrespected and are turned away. Finally, the religious leaders mentioned that they have heard from families that the vaccines are making their children sick. These families have told them that children suffer from high fevers in the days after vaccination and that some families believe a child from a neighboring community died as a result of a vaccine.

The community leaders noted their positive relationship with the local CHVs, who they welcome into their homes and rely on for up-to-date information about health topics. They often schedule community-wide meetings around their visits to provide the CHV with a forum for presenting information.

Stakeholders

During the workshop in January 2025, Immunization Associates and other stakeholders used their experience with programming in these communities to map the various stakeholders working on health and immunization in District C. Government stakeholders, with the MOH and EPI at the national, provincial, district, and subdistrict levels, play a key role in providing immunization services, establishing and updating immunization policy, managing human resources, and planning and implementing information and advocacy campaigns to promote vaccination. At the district level, there are a number of NGOs supporting services related to immunization and child health more widely. A number of organizations are supporting interventions to improve vaccine supply and support outreach activities from the two health facilities. One organization is also supporting monthly groups with community leaders to discuss issues related to maternal health.

At the community there are a variety of local community groups: mother's/breastfeeding support, agricultural co-ops, micro-loans, religious studies, and an elder community council. The mapping noted that some groups, like the community governing council, meet regularly, while others, like the mothers group, meet on a more ad hoc basis.

Objective

The objective of Immunization Associates' programming in District C is to reduce the prevalence of ZD children. Through discussion with stakeholders and review of the context, the Immunization Associates team believes that in order to reach this goal, a number of preconditions must be met. First, families must feel motivated to seek out immunization services, and lack of trust in the health system is an important barrier to that. As such, community trust in the health system must be established and maintained. Secondly, in order to improve uptake, mothers and female caregivers need to not only be allowed to take their children unaccompanied to access immunization services, but also must feel empowered to do so. To promote their empowerment, women will need to feel supported by the individuals who hold decision-making powers in their households and communities. In their households, it is often husbands who have this power. As such, fathers will need to provide support to their wives/mothers of their children to advocate for their ability to access service, and promote the importance of immunizations with their partners and communities. The team also noted that if fathers promote immunization and acceptance of vaccines, that it may improve trust in the health system, specifically in the safety and importance of vaccines. Finally, women will need material support from their husbands, including money for transport and vaccine cards.

During discussions, stakeholders also suggested that behaviors might also drive changes in trust. For example, if members of the community saw others bringing their children for immunization services, perhaps it would influence them to be more trustful of immunization services and change their feelings about the importance of vaccines. For this reason, the reinforcing loop was added between outcomes and intermediate outcomes.

Update Based on TOC Revision

Based on review of the TOC and discussion in June 2025, the team also determined that, in order to change community social norms to be more accepting of women accessing health services independently, community leaders will need to play a role in promoting and advocating for change.

Additionally, based on discussion during the TOC review and revision, the team suggested that in cases where trust in vaccines had improved, participants had reported that CHV information about vaccine side effects had been impactful, reducing their fear. As a result, the TOC has been updated to include this casual link/mediator of trust.

Intervention

To achieve the outcomes identified in the previous section, the Immunization Associates team and stakeholders co-designed two activities to be implemented in program communities. These interventions aim to address a subset of vaccine barriers. The remaining barriers that will likely remain but not be directly addressed by this project are noted below.

To address the lack of trust in both immunizations and the health system more generally, it was decided that it was important to provide accurate information about vaccination to the target population using locally appropriate communication channels. CHVs were identified as trusted sources of information that also have accurate, up-to-date information about immunization services. CHVs are already well known to the community and, when appropriately funded, conduct visits to the community. One gap noted earlier was the lack of culturally appropriate IEC materials. As such, the intervention will focus on providing CHVs with culturally appropriate IEC materials and facilitating their travel.

The second activity aims to use fathers, as powerful decision-makers in the household, to promote immunization services and work to change community social norms around women' s access to immunization services for their children. In order to mobilize fathers in the community, the team will support CHVs to convene father's groups to discuss immunization and its importance and to encourage more social support for mothers and female caregivers to access services. Immunization Associates will also provide technical support to help develop promotional materials for CHVs to use as part of the father's groups.

NEW **Update Based on TOC Revision**

Based on review of the TOC and discussion in June 2025, the team also determined that in order to engage community leaders to support women's access to health services for their children, the intervention would need the CHVs to convene with community leaders. The team identified another program working in the same areas that was convening sessions with community leaders about maternal health issues, and that organization was open to sharing time in the sessions to discuss immunization. As such, Immunization Associates is now supporting CHVs to attend community leader groups to discuss immunization.

Additionally, the team noted the importance of reduction in fear of side effects as important for facilitating trust in the health system and vaccines. As such, the intervention was updated to provide IEC materials specifically addressing side effects.

For more information about which barriers to immunization are not addressed by the program and how the team decided on the program focus, see External Influencing Factors.

Measurement

A simplified measurement plan is included in Table A1, below. A more detailed description can be found in the project's monitoring and evaluation plan.

Table A1. Measurement Plan Summary

Outputs/Outcomes	Measurement
Immunization service uptake	Routine immunization data from facilities and outreach sessions
Motivation to seek vaccination	Semi-structured interviews, key informant interviews, and focus group discussions with mothers, fathers, and other family decision makers (mothers-in-law)
Trust in vaccines and the health system	Semi-structured interviews, key informant interviews, and focus group discussions with mothers, fathers, and other family decision makers (mothers-in-law) and CHVs
Community social norms changed	Focus group discussions with community leaders, mothers and fathers groups, and CHVs
Caregivers feel supported to seek out immunization services	Key informant interviews with female caregivers
Improved knowledge of health system and importance of vaccines	Semi-structured interviews and knowledge, attitude and practice surveys, key informant interviews with fathers, female caregivers, and CHVs
Fathers and community leaders promote immunization and acceptance of vaccines and encourage changes in social norms	Focus group discussions and key informant interviews with community leaders, father's groups, and CHVs
Fathers provide social support to women to access immunization services	Focus groups with fathers groups, mothers groups

Opportunities for Evidence-Based Adaptation

There are a number of points along the framework when the team will actively review program data and information collected and use it to feedback into the program. Table A1 identifies how data for each outcome and output will be collected. These data sources will be reviewed routinely alongside the TOC to better understand if and how the causal links are emerging. The team will also rely on experiences from Immunization Associates community team leads and the district team lead to report back on programming and progress and provide their recommendations about what changes should be made to the intervention or measurement activities.

Assumptions and Risks

A number of risks and assumptions have been identified by the team, in cooperation with stakeholders, and a monitoring plan or mitigation strategies have also been identified for each. The assumptions have been updated since the TOC review and revision in June 2025.

Table A2. Program Assumptions and Monitoring Approaches

Assumption	Monitoring plan
IEC materials developed by the team are culturally relevant and messaging is appropriate for the Z community.	Maintain regular contact with CHVs to collect their feedback on IEC content.
Fathers and community leaders are the individuals in the community who are best placed to catalyze changes in community social norms.	Continuous review of monitoring data and conduct rapid feedback sessions with communities to better understand power dynamics.
Long-standing social norms around women's travel and access to health can be changed through engagement of community leaders and decision-makers.	Continuous monitoring and review of program data, conversations with stakeholders and community members to determine if the causal link is valid.
The intervention, which focuses on strengthening demand for immunization services, will drive demand for services among caregivers of ZD children, specifically.	Review of routine immunization data trends over time, disaggregated by immunization status to determine if ZD children are being reached; interviews with ZD caregivers.

Table A3. Risks to the TOC and Mitigation Approaches

Risks	Risk Mitigation
Political instability around the upcoming election prevents groups from convening. *(Unlikely)*	Monitor the situation; consider holding more frequent sessions after the election.
Impassable roads during the rainy season result in vaccine stock-outs at the facility. *(Somewhat likely)*	Encourage CHVs to communicate with the CHV supervisor regularly to understand the stock situation and pass on updates to the community members so they know when vaccines are likely available.
Budget cuts at the provincial level remove all government funding for CHVs. *(Very likely)*	Convene meetings with other organizations working with CHVs to determine how to address the funding gap (e.g., combining parallel CHV programming efforts or advocating with the government).

External Influencing Factors

Given the context described above and the variety of barriers to immunization faced in District C, it is important to note which factors the program does not address but that likely contribute to the problem of ZD children.

Supply-Side Barriers

The intervention does little to address the supply-side barriers to immunization, which may include, but are not limited to, lack of respectful, culturally sensitive care by health providers, lack of female nurses, language barriers between providers and clients, inadequate number of facilities, and unavailability of vaccination cards in the local language. Additionally, the intervention does not address the issue of poor communication around timing and location of outreach sessions or budget constraints that prevent health staff from conducting outreach sessions that require overnight stays. Supply-side interventions with the facility staff were considered, but stakeholders noted in conversations that respectful care interventions were being implemented with health care providers through another organization's maternal health intervention. The team determined that the budget and advocacy work needed to address some of the barriers was not one of Immunization Associates' areas of strength or expertise and that this work should be considered by other organizations. The stakeholder group identified community engagement as an important gap and suggested that this work would complement programming with the providers.

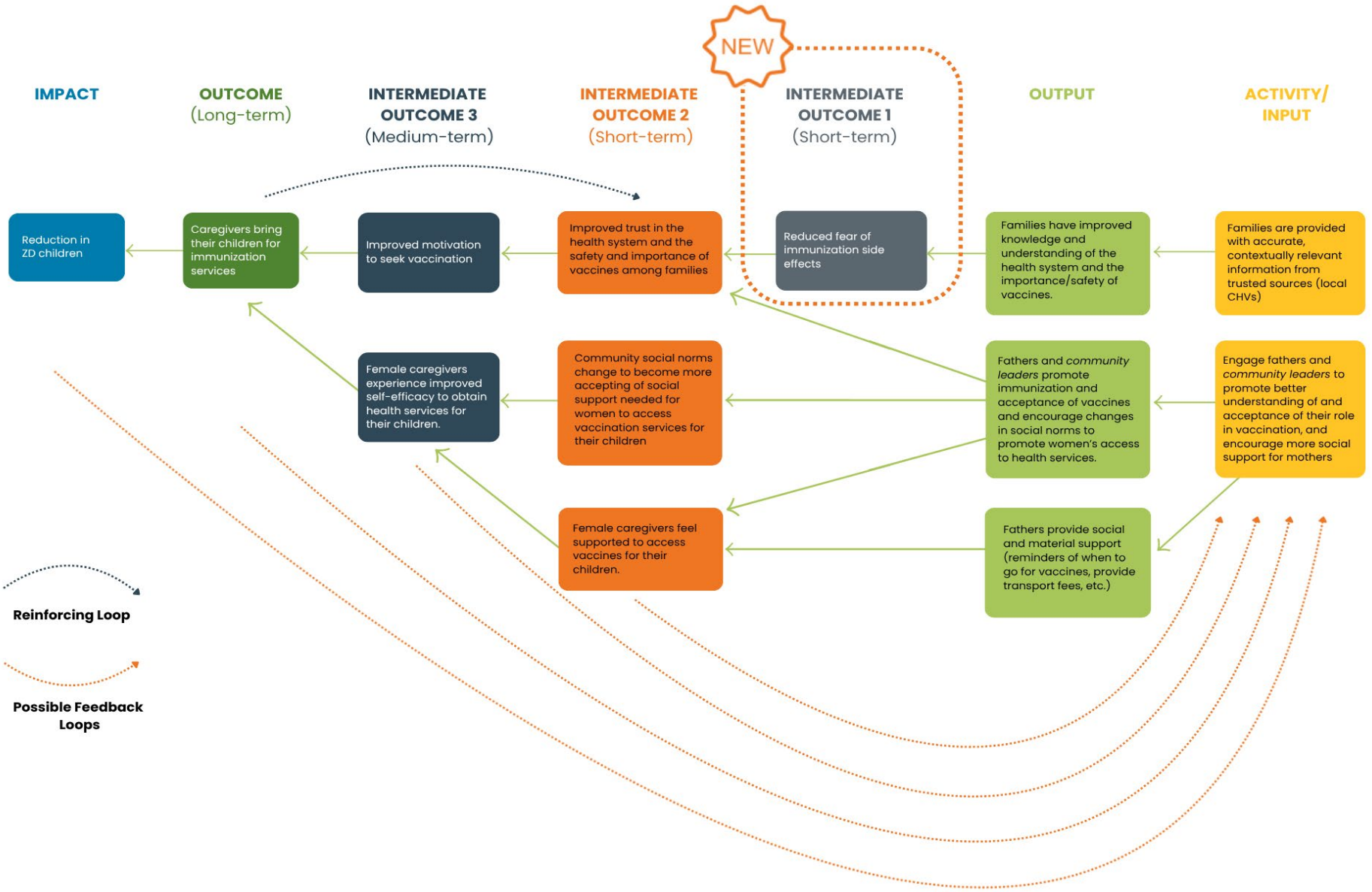
While it was not included in the final TOC, the team noted during the outcome mapping exercise that more personal interactions between the community and the CHVs might improve CHV understanding of the challenges and barriers to immunization. The team suggested that as a result, the CHVs, who are well-connected with the health facilities, might act as liaisons between the Z community and the health facility staff to improve relations. The team identified this as "low likelihood" and did not include it in the TOC but committed to revisiting the outcome mapping exercise in the future.

Demand-Side Barriers

Demand-side barriers that are important but not addressed by the project include the lack of transport and distance to health facilities. In discussions with community members, it was suggested that the existing community funds to support transport for maternal and child health might be expanded to support immunization services as well. Finally, the intervention does not address some of the common social determinants of health in the community, like low literacy, which the team considered to be outside of the scope of the project.

Final TOC Visual

Figure A1. Final ZD SBC TOC with Revisions Included



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