How to develop an evidence-informed theory of change for health

WHO technical guidance

World Health Organization

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Preface

Global challenges ranging from health emergencies, such as the COVID-19 pandemic, to the health impact of climate change, stress the importance of responsive health systems and the critical role that research and evaluation[1] play in informing the design and implementation of health policies. Effective planning, implementation, monitoring and evaluation of policies, programmes and interventions are crucial for any organization working in the health sector and beyond. Timely, strategic and objective evidence relevant to health policies and interventions are needed to attain the highest possible level of health by all people.[2]

Theories of change (ToCs) are a critical method for achieving these goals, helping policies, programmes, and interventions to focus on outcomes (effects) rather than outputs, and strengthening the respective results chain. They allow policy-makers to plan, adapt and evaluate their interventions and engage stakeholders in defining, implementing and measuring the expected development change. They are the bedrock of management strategies focusing on performance. By helping to articulate the vertical and horizontal logic of interventions, they help demonstrate the effects of work to team members and stakeholders. This document provides guidance on how to integrate evidence into the processes of developing and updating a ToC in the health sector.

ToCs have become a common tool for policies, programmes, and interventions, and are often developed for results-based management of core components, such as in planning and evaluation. However, their formulation is often conducted in a non-systematic way. Sometimes ToCs rely heavily on one source of information, such as a previous study or insights from a particular group, while ignoring the wealth of knowledge available from other sources. Furthermore, up to this point, there were very limited resources that explicitly discussed how evidence should be used when developing ToCs.

[1] According to the United Nations Evaluation Group (UNEG) on norms and standards (2016) "An evaluation is an assessment, conducted as systematically and impartially as possible, of an activity, project, programme, strategy, policy, topic, theme, sector, operational area or institutional performance. It analyses the level of achievement of both expected and unexpected results by examining the results chain, processes, contextual factors and causality using appropriate criteria such as relevance, effectiveness, efficiency, impact and sustainability. An evaluation should provide credible, useful evidence-based information that enables the timely incorporation of its findings, recommendations and lessons into the decision-making processes of organizations and stakeholders."

[2] Which is a constitutional objective of WHO.

As a science- and evidence-based organization promoting evidence-informed policy-making (EIP), the World Health Organization (WHO) has thus undertaken the challenge of organizing a set of principles and steps to inform how to systematically use evidence while developing and updating ToC frameworks.

This guide, developed by the WHO Research for Health Department/Science Division, in collaboration with the WHO Evaluation Office, highlights the importance of using different kinds of evidence in health policies and plans. Its aim is to help everyone involved in health interventions – from local groups to international organizations – make better decisions. The steps presented here are a roadmap, helping us to learn from past experiences and from each other, and to make better choices for the future. We hope you find it useful and that it encourages you to think about how you can use evidence and research in your work.

Professor Sir Jeremy Farrar

Chief Scientist

World Health Organization

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About this guide

What is this guide for?

This guide aims to support efforts to use evidence in a systematic and transparent way for developing and updating theories of change (ToCs) in the health sector. While ToCs are widely used for policy design, implementation and evaluation, there is a lack of structured approaches to using evidence to inform ToCs. This guide is an attempt to fill this gap. . This guide focuses on how to use evidence to develop ToCs. For broader guidance on how to develop ToCs, we suggest readers also consult other resources, such as the ones listed in Annex 2.

Who is this guide for?

The target audience of this guide is health professionals, policy-makers, researchers, members of civil society, staff in international organizations such as WHO, and other stakeholders interested in promoting effective health policies through the use of ToCs and high-quality evidence. This guide can also be useful for project managers and planning, monitoring and evaluation officers in ministries of health and other ministries, as well as in civil society and nongovernmental organizations.

Why should I use this guide?

ToC frameworks can be applied to a range of objectives, such as designing and planning interventions, implementing interventions, monitoring and evaluation, promoting transparency, policy transfer and scaling up, as well as supporting institutional strategic plans. As such, ToCs are an important resource for evidence-informed health policies. By combining different types of evidence, a more comprehensive and nuanced understanding of the programme or intervention can be attained. The six-stage process for integrating evidence into ToCs presented in this guide offers a practical step-by-step approach to developing and updating ToCs, helping organizations to effectively plan, implement, monitor or evaluate policies, programmes, and interventions in the health sector. This guide aims to improve the capacity for developing and utilizing ToCs, ultimately empowering readers to devise more effective policies and interventions that significantly enhance the quality of people's lives.

How should this guide be used?

Each part of this guide is relatively independent from the others. Therefore, while it is possible to read the guide from beginning to end to have a complete introduction to the topic, it is also possible to use parts of it to deepen knowledge on specific topics when needed.

We have organized this guide into three chapters. The first chapter offers a definition of ToC and discusses its uses and relevance in health policies. The second chapter broadly addresses how to use evidence to develop and update ToCs, including specific discussions about participatory processes and equity. Finally, the third chapter presents how to design or revise a ToC systematically informed by evidence in the health sector. We provide methods and recommendations, as well as a sequence of six stages for incorporating evidence into ToC frameworks. The annexes contain extra resources complementary to the content of the guide. Annex 1 provides the relevant terminology and definitions for ToC, Annex 2 offers practical tools and resources to support ToC development. Annex 3 provides more detailed ToC applications, as well as a source for additional examples. Finally, Annex 4 describes the methods for development of the guide.

Before each section, we include a box with "key messages" to orient the reader. We also include "practice spaces" at the end of each section. In these spaces, we ask you questions to help you apply the insights from the guide to a practical problem of your choice. You can use a notebook or software for editing text or presentations to write down your answers. Throughout the guide, we highlight additional resources in the "learn more" boxes.

When describing the stages of evidence use in Chapter 3, we also include boxes with "step-by-step" guidance for implementing them. These boxes intend to provide a to-the-point, practical synthesis of the stage to support you when developing your own ToCs.

How was the guide developed?

The conceptual framework and guidance presented here are based on the findings of a rapid systematic review *(1)* complemented by supplementary resources and input provided by an expert group convened by the Science Division of WHO (more details can be found in Annex 4). This guide also draws on the lessons learned from the Independent Evaluation of WHO's Results-Based Management (RBM) Framework (2023): report – January 2023 *(2)*.

Chapter 1: Why use theory of change?

1.1 What is a ToC?

Key messages

- Programmes are based on policies, which, in turn, are built on expectations. These expectations can be presented through a theory of change (ToC).
- Analysis should determine if and how these expectations can be met.
- A ToC is a framework for depicting a sequence of causal steps that describe how an intervention, programme or strategic plan is expected to lead to outputs, outcomes and impact. It is presented as a diagram containing preconditions, expected results, rationales, assumptions, and indicators.
- A ToC is built from a flexible, interactive and participatory process.
- A ToC involves a continuous process of analysis and discussion, fostering critical questioning, incorporating diverse perspectives and helping to deal with uncertainties.
- A ToC is a living product that must be constantly updated and adapted as the intervention process unfolds and more is learned about what needs to be done.

According to Global Affairs Canada *(3)*, every programme or project is based on a "theory of change" – a set of assumptions, risks, and external factors that describe how and why the programme or project is intended to work. This theory connects the programme's or project's activities with its expected ultimate outcome. It is inherent in the programme or project design and is often based on knowledge and experience of the programme or project design team, research, evaluations, best practices and lessons learned.

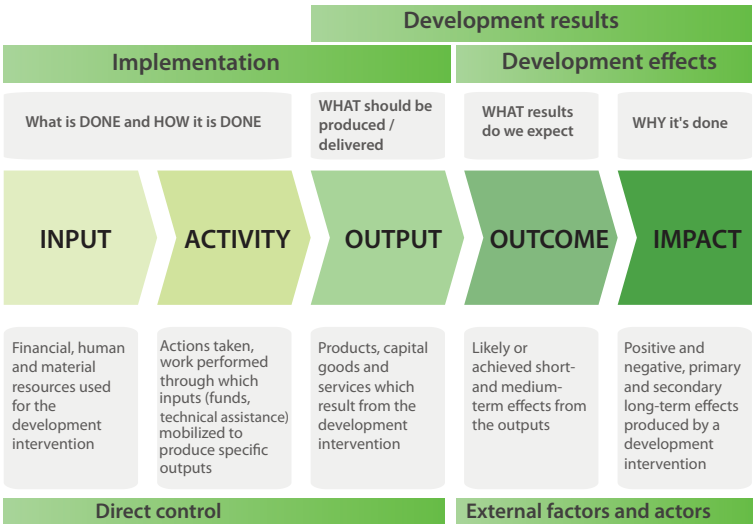
A ToC shares characteristics with various methodologies and frameworks, such as Logical Model, Program Theory, Programme Logic, Action Theory or Logical Framework *(4)*. A ToC is a framework that allows for a comprehensive description of how and why a desired change is expected to occur in a particular context. The framework involves identifying long-term goals and mapping out all the conditions that must be in place for those goals to be achieved. In this sense, ToCs make explicit assumptions of how determined resources and activities are expected to lead to intended outcomes *(5–14)*.

The framework explains why an intervention was chosen and how to measure the changes we would like to see. ToCs can be used to support specific policies and programmes, as well as overarching institutional strategies, comprising bundles of interventions and activities. A good ToC should be precise, rigorous, credible, and achievable.

Generally, ToCs are built through a flexible, participatory, and dynamic process. In this process, stakeholders continuously deepen their understanding of the local conditions for action, barriers, facilitators, risks and opportunities. A well-developed ToC should guide a group of stakeholders through an easy-to-understand explanation of how an intervention or programme will help solve complex social problems to achieve common long-term goals (*15*). As such, ToCs should be considered as living models that allow for multiple perspectives to be critically examined. At each phase of the project, ToCs provide the opportunity to assess whether adjustments or improvements are in place to better achieve the desired outcomes.

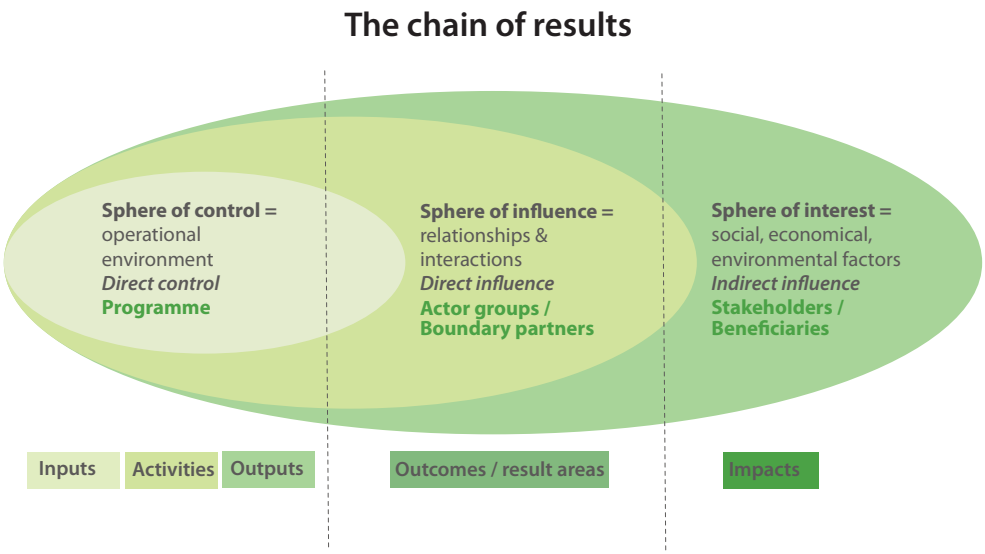
While ToCs are portrayed in countless formats and structures *(1)*, they commonly depict a diagram, showing the connections between interventions and outcomes (causal pathways) while explicitly stating assumptions and related evidence *(16)*. This diagram usually represents a working model containing preconditions, expected results, rationales, assumptions, indicators, and other relevant elements (Fig. 1). The ToC is also accompanied by a narrative description that explains its elements, assumptions, and the presumed causal links between parts. For a more detailed explanation of these terms, with references, please refer to Annex 1.

Fig. 1. Typical components of a theory of change



Within a typical ToC, it is possible to identify three spheres of responsibility, as per Fig. 2. The sphere of control involves what is under the direct influence of the responsible team. The sphere of influence relates to aspects that the team can influence, but that depend on other variables and stakeholders. Finally, the sphere of interest encompasses the elements that the intervention is trying to affect, but that are determined by a complex system of variables and processes.

Fig. 2. Results and responsibilities

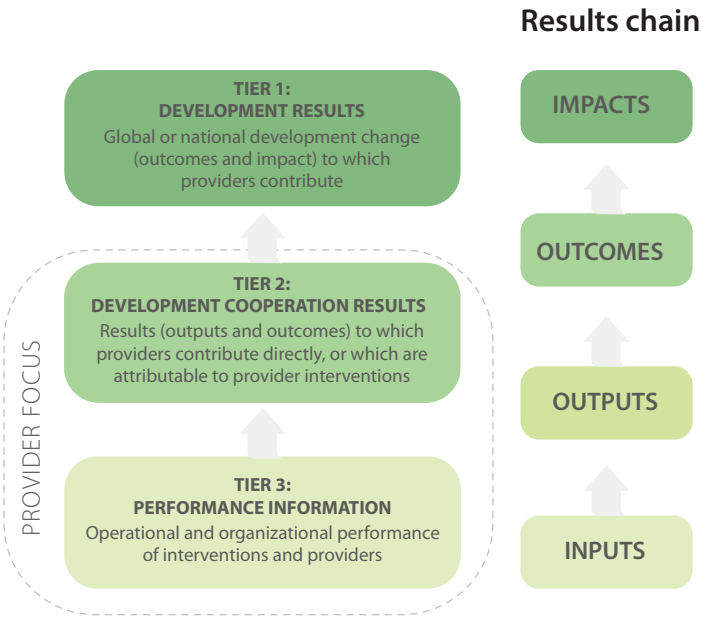


Source: Adapted from Buhl-Nielsen E, Gouzou J, Rao KBP, BlomhØj TI. Evaluation of Swedish International Training Programme (ITP): climate change – mitigation and adaptation (2007–2011). Stockholm: Sida and authors; 2015) *(17)*.

Furthermore, it is worth mentioning that the results depicted in a ToC can be classified in three tiers, as explained in Fig. 3.

- **Tier 1**: development results: global results, country results (impacts and outcomes)
- **Tier 2**: development cooperation results: direct results of interventions (outputs and outcomes)
- **Tier 3**: performance information: financial and performance information (inputs and management information) *(18)*.

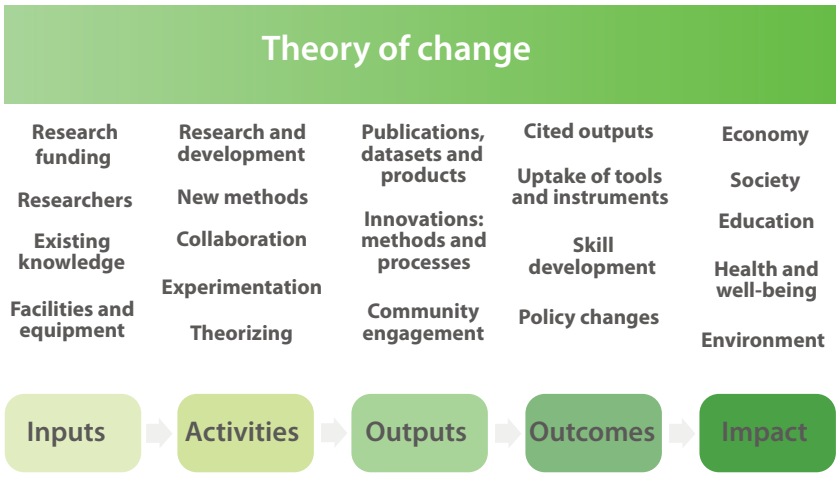
Fig. 3. Three tiers of results



Source: Adapted from Zwart R. Strengthening the results chain: synthesis of case studies of results-based management by providers. OECD Development Policy Papers No 7. August 2017 *(18)*.

In Fig. 4, a simple example of a ToC can be found. In Chapter 3, Stage 4 and in Annex 3, we present other examples that showcase how to display the complexity and the many elements that a complete ToC can include.

Fig. 4. Initial ToC of the Humanitarian Engineering and Energy for Displacement (HEED) project, which seeks to improve access to energy for displaced populations



Source: Adapted from Humanitarian Engineering and Energy for Displacement (HEED), 2023 *(19)*

Box 1. Other elements that a ToC should ideally cover

In addition to the basic elements described above, a ToC can become more useful by addressing:

- **"Change theory**: this identifies one or more causal mechanisms by which change comes about for individuals, groups and/or communities.
- **Action theory**: this explains how interventions are constructed to activate their theory of change in terms of the activities that will be undertaken and what level of success will be needed for each result to produce the final intended impact.
- how **other projects and programmes** contribute to producing impacts
  - those who are explicitly collaborating (these are referred to as 'boundary partners' in outcome mapping forms of theory of change)
  - others who have positive or negative influence;
- how **the particular contexts in which the intervention is implemented** affect activities and results;
- **potential unintended results**, both positive and negative;
- **assumptions** on which the theory of change is based – these are in addition to the cause–effect relationships shown in the logic model and often involve assumptions about the context;
- how participants **become engaged** in a project, programme or policy;
- how results are **expected to be sustained** after a project, programme or policy ends or participants' engagement ends."

Source: Manager's guide to evaluation. In: Better Evaluation [website] (https://www.betterevaluation.org/frameworks-guides/managers-guide-evaluation/scope-evaluation/describe-theory-change, accessed 6 February 2024) *(20)*.

Practice space

Consider an intervention, policy or programme of your interest. What would a first draft of its ToC look like?

1.2 When should a ToC be used?

Key messages

ToCs can be used for multiple purposes, including:

- designing and planning interventions;
- implementing, monitoring and evaluating interventions;
- transparency, policy transfer and scaling up;
- improving strategic plans.

A high-quality ToC can be a cornerstone for sound policy development and implementation and for robust evidence-informed decision-making. It is a useful tool for orienting policy design and implementation, informing budget allocation and producing high-quality evidence through monitoring and evaluation. Every public policy has some version of ToC or an equivalent of it, i.e. it has an explicit or implicit theory regarding how its actions will lead to outputs and the expected results. Sometimes, this theory is not publicly displayed or even institutionally registered. However, it does exist, even if only in the minds of the policy-makers involved in its design, and will be the backbone of future interventions. An explicit and rigorous ToC, therefore, is a requirement for transparent, accountable, and effective policy-making.

ToC is a versatile framework that can be used for multiple purposes in health policies. Due to its simple and clear visualization, ToCs are considered accessible and useful for various health areas and settings *(10, 21)*. Below, we list the primary purposes for which a ToC can be used to support a policy process.

Designing and planning interventions

While planning an intervention, ToCs help to clarify the expected causal mechanisms. When multiple intervention options are being considered, their respective ToCs can be a user-friendly way to present and compare them and facilitate a decision. Once a policy or programme is chosen, its ToC will be the backbone for the detailed plan.

Likewise, the ToC can assist the process of identifying key actors for the intervention's success, as it facilitates the mapping of who needs to contribute to each activity. ToCs can also support ex-ante evaluations of potential interventions, assessing feasibility, challenges and expected impacts before implementation. This type of evaluation supplies critical information for the design and planning of the final intervention.

Implementing, monitoring and evaluating interventions

ToC is a supportive approach to implementing interventions and for learning from these experiences. As the overall structure of how an intervention is meant to work, the ToC can serve as a compass for the implementation phase, expressing the intervention's logical structure as a coherent narrative and allowing for discussions about its design *(20,22)*. It depicts the main activities and how these are expected to lead to outputs and outcomes. In the implementation phase, the ToC is also an important reference for monitoring, evaluating and learning strategies. Based on the ToC, indicators can be constructed and selected to continuously generate evidence about implementation of the programme and its results. They can also be used as a base for implementation research studies and impact evaluations (*21,22*). When evaluating the impact of an intervention, a ToC helps to identify indicators that can be measured as part of the evaluation using experimental or quasi-experimental studies, such as randomized controlled trials. Hence, ToCs are an important tool for expanding the evidence base within a specific programme and the broader scientific literature about a topic. When absent, it can be reconstructed during the inception phase of an evaluation.

Transparency, policy transfer and scaling up

In representing how interventions are meant to work, ToCs are also useful frameworks for communicating with external actors. This increases the transparency and accountability of actions, as it is easier for interested parties to understand the intervention's mechanisms and expected results. It is also a relevant resource for transferring the policy to new settings. Transparently reporting the reasoning behind an intervention contributes to the existing body of knowledge on the field and helps to guide future initiatives. This is valuable information for scaling up an existing intervention within the same context or taking the intervention to a new setting.

Improvement of strategic plans

From an institutional point of view, a ToC can be used as a benchmark for strategic plans *(5)*. Organizations can produce overarching ToCs that depict how their combined set of processes and products concur to produce a specific change in the world. A ToC can serve as a basis for monitoring and evaluation as well as for communicating the organization's performance, while also helping to identify bottlenecks and the need for adjustments. Furthermore, developing a ToC is an opportunity to make explicit the links between inputs, activities, outputs and outcomes, often revealing existing gaps and problematic assumptions that need to be addressed.

Learn more

For more information about how to develop ToCs for an evaluation, see:

- How to develop a theory of change for evaluation *(25)*.
- Theory-based approaches to evaluation: concepts and practices *(23)*.
- Useful theory of change models *(24)*.

For more on scaling and sustainability, see:

- Scaling up development impact *(26)*.

Practice space

What reasons do you have for developing a ToC for your project or programme?

In what contexts could the ToC be used?

Chapter 2: Evidence for ToCs: where to start?

Key message

Incorporating the best available evidence into a ToC improves its quality and capacity to deliver good services and products to the target population.

As with any health policy tool, ToCs must incorporate the best available evidence to be rigorous and effective. A culture of regularly accessing, selecting, and evaluating evidence can greatly improve the quality of an intervention and its capacity to deliver good services and products to the population. Integrating evidence into ToCs is essential because it helps to ensure that the underlying assumptions and logic of the programme are grounded in empirical research and data. This leads to a ToC that is more likely to be accurate, reliable and effective.

Evidence-informed decision-making (EIDM) is an approach that applies structured, systematic, transparent and replicable methods to identify, assess and employ the best available evidence throughout all processes of the policy cycle *(27)*. This approach includes the production, search, selection and interpretation of evidence, as well as its critical appraisal. Evidence must be produced and summarized transparently and systematically to prevent biases in the evidence base, such as when a decision-maker "cherry picks" the evidence most aligned with their interests, while ignoring other relevant information.

Research and consultation can help refute or validate assumptions. Having a design team that includes both local and non-local participants can help to prevent unconscious assumptions from negatively influencing project design. Where assumptions are intentional, they must be based on evidence, and should be documented in the ToC narrative. You should use references, quotes and evidence from your analysis and consultations to justify the assumptions made at each level of the model.

Systematically developing an evidence-informed ToC for a policy or programme has many advantages. Creating a ToC invites exploration of the policy issue, context, and potential solutions. It demands a comprehensive assessment of the problem, its consequences, and the underlying assumptions of interventions. This paves the way for strategies that address specific needs, supporting efforts towards real change *(21)*.

In the following sections of this guide, we will use the principles and tools of EIDM to help you build ToCs grounded in the best available evidence.

Learn more

To learn more about EIDM, see:

- Evidence, policy, impact: WHO guide for evidence-informed decision-making *(27)*.

2.1 Types of evidence relevant for ToCs

Key messages

- There are several types of evidence relevant for EIDM and ToC development, including global and local evidence, colloquial and research evidence, and quantitative and qualitative evidence.
- The development of a ToC should use the best possible evidence.

For the purpose of this guide, a distinction between four types of evidence, based on their source and scope, is especially relevant. These are: scientific and tacit evidence, and local and global evidence. These distinctions are relevant because it is common, in the existing practice of ToC development, to value and include local and tacit evidence while neglecting scientific and global evidence *(1,5,28)*. Box 2 presents an explanation for each type of evidence.

Box 2. Overview of the different types of evidence used in EIDM

Scientific evidence is produced through formal, rigorous research processes of defined methodological standards, making it explicit, systematic and replicable. It includes primary studies (primary research), synthesis of existing evidence (secondary research), and evidence products such as guidelines or evidence briefs for policy (tertiary research).

Tacit (colloquial) evidence includes opinions, expertise, lessons learned, and organizational traditions, as shared by policy-makers, clinicians, patients or citizens. It is important for understanding the local context and to contextualize and interpret scientific evidence further.

Global evidence assembles the best available findings on a specific thematic or health issue from around the world, e.g. through a systematic review or an established, evidence-informed guideline.

Local evidence takes into account modifying factors in specific settings, e.g. through a primary study or programme monitoring data *(27)*.

These types of evidence can be obtained from a variety of evidence workstreams, supporting the policy cycle in different ways, as shown in the table below:

Box 2. Continued

Table 1: Evidence workstreams

Evidence workstreams	Definition	Phase(s) of the EIDM process
Data analytics, e.g. health information systems	Systematic analysis of raw data in order to make conclusions about that information	Clarifying problems, and monitoring implementation
Guidelines	Systematically developed statements that recommend a particular course of action with one or more evidence syntheses contributing to the assessment of effectiveness, values and preferences, and other factors	Selecting options and designing solutions
Health technology assessment (HTA)	Assessment of all relevant aspects of a "technology", including safety, effectiveness, and economic, social and ethical implications (technology assessment), with an evidence synthesis often contributing to the assessment of effectiveness	Selecting options, and designing solutions
Evidence-informed policy-making supports, e.g evidence briefs for policy (EBPs), policy dialogues	An approach that aims to ensure that policy-making is informed by the best available evidence from research	Clarifying problems, selecting options, and identifying implementation considerations
Modelling, e.g. economic modelling	Use of mathematical equations and existing data and research to stimulate real-world scenarios (i.e. what is likely to happen if we don't intervene) and options (i.e. what happens if we intervene) in a virtual environment	Selecting options, designing solutions
Implementation/ behavioural research	Study of methods to promote the systematic uptake of effective approaches into routine practices at the personal, professional, organizational and government levels (implementation research)	Implementation considerations
	Systematic examination of what people (citizens and professionals) do, what drives them to do it, and what can sustain or change what they do (behavioural research)	
Evaluation	Systematic assessment of the implementation (monitoring) and impacts (evaluation) of an initiative for the purpose of learning or decision-making	Designing evaluations, and monitoring implementation and evaluating impact

Source: Adapted from: Evidence, policy, impact. WHO guide for evidence-informed decision-making. Geneva: World Health Organization; 2021:7 *(27)*.

Another important distinction is between qualitative and quantitative evidence. Qualitative local evidence is especially relevant for purposes such as problem definition; assessing the political and social support for an intervention; identifying relevant social and cultural norms, values and preferences of stakeholders and the target population; and identifying barriers to and risks for the intervention. Quantitative local evidence, on the other hand, can be critical to understanding the magnitude and trends of the problem, or for taking stock of available resources. When assessing the potential effects of a programme, quantitative information can also be strategic. It is relevant to consider, for instance, the demographic and socioeconomic characteristics of the target population, the institutional capacity of implementing organizations, logistical issues, measures of corruption or resource waste, among others.

Both quantitative and qualitative evidence can also be found in the global literature. Global evidence can be provided by systematic reviews published in academic journals or institutional databases (grey literature). They can focus on different topics, such as problem definition, conceptual frameworks and theories, best practices, intervention effectiveness, etc. These review methods can provide an overview of the "state of the art" regarding a specific research question and are a critical starting point for using the current academic knowledge to help solve any local problem. Narrative reviews conducted without the proper systematic and transparent process should be avoided, though, due to their high risk of bias *(29)*.

Some examples of methods and study designs for evidence collection can be found in Table 2. This is not a comprehensive list but highlights some of the most common methods that can be applied to strengthen the evidence base of a ToC. The table's classification corresponds to the predominant application of each method or study design. However, the versatility of these approaches allows for their use in generating diverse types of evidence. For instance, interviews can be analysed qualitatively and quantitatively, and literature systematic reviews can focus on local topics.

Table 2: Examples of common methods and study designs for collecting different types of evidence

Qualitative local evidence	Quantitative local evidence	Global evidence (qualitative and quantitative)
Interviews Qualitative surveys Focus groups Debates Expert consultation Policy dialogues Programme observations	Analysis of institutional data or data from health systems Mechanisms and moderators' evaluation Feasibility or pilot studies Programme evaluations Structured surveys Cross-sectional surveys Data analytics and modelling Randomized controlled trials	Systematic reviews Rapid reviews Review or overview of systematic reviews Guidelines

For any policy question, it is important to seek answers from the best available evidence. Depending on the question, the type of best evidence might change (see more on this topic in the following "Learn more" box).

Learn more

For more information on how different study designs and methods can be applied to support answering policy questions, see:

- How to choose between the different types of research evidence, pp. 8–10. In: Evidence, policy, impact. WHO guide for evidence-informed decision-making *(27)*.

For a checklist on supporting the routine use of evidence during the policy-making process, see:

- A WHO checklist: supporting the routine use of evidence during the policy-making process *(30)*.

Practice space

Considering the ToC that you drafted above, what types of evidence did you take into consideration? What types of evidence would you need to improve it?

If you need more information or guidance, please refer to Evidence, policy, impact. WHO guide for evidence-informed decision-making *(27)*.

2.2 Who should participate in ToC development?

Key messages

- Developing a ToC is an opportunity to stimulate stakeholder involvement and gather local evidence.
- ToC development requires diverse and representative perspectives.
- A ToC expert can lead or facilitate the ToC development process.

Several reasons underscore the importance of stakeholder participation in any policy or programme. Broad social participation fosters legitimacy as it encourages stakeholders to engage and invest in the process. It also serves as a relevant source of local evidence, helping to understand the issue more clearly, identify potential interventions, and discuss practical aspects of implementation. Without the involvement of stakeholders, critical elements might be overlooked, risking the effectiveness of the intervention.

Developing a ToC can be an opportunity to stimulate stakeholder involvement and gather local evidence about the intervention setting. ToCs highlight the problem to be solved and the expected outcomes, promoting open discussions about priorities. Co-creating a ToC allows stakeholders to learn from each other, enhancing their understanding of the problem and potential solutions, supporting transparency and accountability *(9)*. Regularly monitoring and adjusting the ToC ensures effective adaptation and sustained stakeholder commitment. This collaboration can cultivate trust and cooperative efforts *(11)*.

It is beneficial if the ToC development can encompass the viewpoints of multidisciplinary groups representing a diverse range of perspectives on the policy topic. Whenever relevant, these groups can comprise staff members, programme managers, funders, service users, programme evaluators and implementers, community members, topic experts, methodological experts, among others.

There are several ways to promote participation during the different stages of ToC development. Meetings, policy dialogues and workshops are often held to discuss the ToC *(4,10)*. Qualitative research methods can also be applied to collect insight from larger groups, such as interviews, focus groups and surveys.

A ToC expert can potentially facilitate the ToC development process. The ToC expert can help plan the steps for building the ToC and facilitate activities to gather the relevant information. The expert can also support the analysis and interpretation of the evidence collected, turning it into a narrative that is suitable for a ToC.

It is also important to have a dedicated individual or group leading the effort of building the ToC. This champion should take ownership of the development and application of the ToC, overseeing the tasks involved and ensuring that all necessary conditions for the work are met *(31)*. This approach will promote accountability and clarity of roles, while also increasing the likelihood of achieving the desired outcomes. Policy champions are often associated with enthusiastic advocates of change proposals and can help promote and lead the implementation of health-care innovation *(32)*.

Finally, as with any policy, it is essential to carefully map the ToC's authorizing environment, and to act strategically on it. This includes all decision-makers whose authority is needed for the project to advance. Specific tools for mapping and managing the project authorizing environment can be of help here.

Learn more

For ToC workshop planning, see:

- Using theory of change in the development, implementation and evaluation of complex health interventions: a practical guide (*33*).

For strategies to promote citizen participation in EIDM in health policies, see:

- Implementing citizen engagement within evidence-informed policy-making: an overview of purpose and methods (*34*).

For tools to map stakeholders and manage the authorizing environment for a project, see:

- PDIA toolkit – building state capability (*35*).

Practice space

Considering the ToC that you drafted above, which stakeholders and social groups should be involved in the process? How would you involve them?

2.3 How does the ToC affect equity?

Key message

ToC development should also include an explicit and structured approach to equity considerations.

Equity considerations are another important dimension of the use of evidence for ToCs. When producing and using evidence, one needs to consider how this knowledge represents the different groups that will be directly and indirectly affected by a policy or programme. While some sources of evidence are extremely valuable, such as the academic literature, they might also have important blind spots when it comes to specific groups or needs. To avoid this, we need an explicit and structured approach to look at equity issues. This includes learning from academic publications that address equity considerations and also gathering evidence on the perspectives of multiple groups about the problem and possible interventions, and how these groups might be impacted.

Learn more

For investigating equity dimensions, see:

- PROGRESS-Plus tool *(36)*.
- Supporting equity-centred engagement: a step-by-step guide with tailored resources *(37)*.

Practice space

Considering the ToC that you drafted above, how may various social groups be differently affected by the intervention? Is there any group that might be left out or made worse off by it?

2.4 What is the best evidence for a ToC?

Key messages

- The evidence base for a decision is not static and must be updated constantly based on the development of any policy process.
- The appropriate type of evidence will depend on the policy question that needs to be answered.
- The process of incorporating evidence into ToCs needs to be systematic and transparent.

The different types of evidence discussed above should not be seen as mutually exclusive. Tacit evidence, for instance, is often used to support, complement or question the appropriateness of scientific evidence *(27)*. Likewise, while global evidence assembles the best available findings on a specific topic or health issue from a global perspective, its applicability to specific cases is completely dependent on local evidence that informs the characteristics of the concrete situation.

For a robust decision, it is important that all types of evidence are considered and integrated in a cohesive interpretation, always seeking the best possible evidence to answer the policy question at hand. In EIDM, the best evidence is the one that provides the most relevant information for supporting a good conclusion or decision, while striving for scientific rigour and applying the highest methodological standards *(27)*.

Importantly, the process of incorporating evidence into ToCs needs to be systematic and transparent, so as to guarantee its rigour and for others to easily understand what evidence was used and how. For that purpose, those working on ToCs should explicitly register how they are gathering, producing and using evidence.

At the same time, each organization will have to assess, given the available resources and constraints, whether only existing research will be sought and used or whether new research will be conducted to fill any gaps. On some occasions, it might be the case that more research could be beneficial for informing the ToC, but due to the lack of time and budget, this additional effort would be impossible. As long as the ToC process is undertaken in a systematic and transparent manner, and these limitations are appropriately reported, this should not be seen as an impediment to advancing with the work.

To ensure that the best available evidence informs ToCs, the next chapter details six stages for developing an evidence-informed ToC.

Learn more

For more on conducting systematic and transparent incorporation of evidence into decision-making, see:

- Evidence, policy, impact: WHO guide for evidence-informed decision-making (*27*).
- Evidence-informed health policymaking. SUPPORT tools for evidence-informed health policymaking (*38*).
- Conceptual background and case studies: introduction to EVIPNet Europe (*39*).

For more on how to deal with limited evidence, or limited capability to find evidence, see:

- Chapter 3 of Evidence, policy, impact: WHO guide for evidence-informed decision-making (*27*).

Practice space

Considering the ToC that you drafted above, how do you see different types of evidence providing complementary information for the ToC? If you were to use all types of evidence, can you identify any aspect for which you could find contradictory evidence? How would you deal with this contradiction?

Chapter 3: Developing evidence-informed ToCs

Key messages

We propose a six-stage approach to incorporating evidence into ToCs, consisting of the following:

1. Define the problem.
2. Define expected outcomes.
3. Define the interventions.
4. Define change mechanisms and build a model of the theory of change.
5. Validate the theory of change.
6. Revise the theory of change.

The order of implementation of these stages is rarely linear. They can be combined, revisited, or conducted simultaneously as the ToC takes shape.

This chapter presents how to design or revise an evidence-informed ToC in the health sector. We discuss strategies and recommendations and provide a sequence of six stages for developing evidence-informed ToC frameworks.

These six stages are inspired by the classical steps of the policy cycle. The policy cycle, in general, starts with agenda-setting, followed by problem definition, identification of policy options, assessment of local applicability, policy design, implementation, monitoring, evaluation, adaptation, and replication. Within the policy cycle, ToCs are often used to support policy design, implementation, monitoring and evaluation. For that purpose, they need to be robustly informed by the previous stages, when the policy problem is understood, and the policy options are discussed and assessed.

Even though the six stages are presented here in a logical and sequential order, it is important to emphasize that the elaboration of a ToC is essentially a dynamic and nonlinear process. The process can have multiple possibilities regarding its form and content and will frequently combine these stages in one activity or move forward and backward as the ToC matures. For instance, even though definition of the problem is the first step, it is common to revisit it many times as the ToC takes shape. Likewise, the definition of interventions and change mechanisms can be conducted simultaneously, combining a literature review with stakeholder consultation. Despite the complexity of this process in real life, we opted for a structured step-by-step presentation for didactic and visual purposes.

Similarly, the guidance provided below should not be understood as mandatory or normative regarding how evidence is to be incorporated into ToCs. As with any effort to use evidence in a policy context, there are many limitations that affect the extent to which

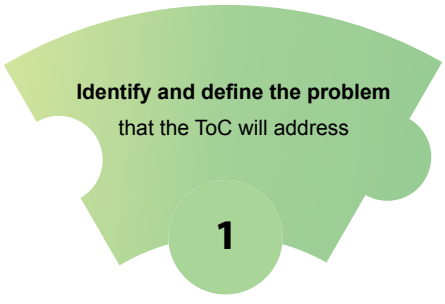
evidence can be obtained, produced and applied, such as insufficient budget, lack of time, gaps in the academic literature. In the face of these limitations, the team developing the ToC needs to make strategic choices to incorporate the best possible evidence, given the available resources and existing priorities. It is important for this process to be conducted in a systematic and transparent way, with a sound rationale that can be shared with the relevant stakeholders.

It is also worth mentioning that the group leading the ToC development will not always have all the skills necessary to produce, find and synthesize all the relevant pieces of evidence. In these cases, organizations and professionals specializing in knowledge translation, such as research institutions, evidence units or knowledge brokers, can be sought to support the process.

Finally, it is also important that future research papers and policy documents report the ToC development process adequately. Currently, this is rarely done, which leads to a lack of transparency and justification for the decisions made. Detailed reporting is relevant for future users, allowing for a critical understanding of the rationale behind each aspect of the ToC. Policy projects might want to consider *(5)* a proposed checklist for reporting ToC in public health interventions. It has five criteria: assessing the ToC approach, the ToC development process, presentation of the ToC, description of the intervention process, and use of the ToC for evaluating a policy. This checklist, however, has not yet been validated and might not be appropriate for all uses of a ToC, possibly requiring adaptations depending on the context.

Below, we describe the six stages for developing evidence-informed ToCs. For each stage, we also provide a step-by-step approach that can guide you in finding, producing and using the relevant evidence.

Stage 1: How do we define the problem?



A good definition of the problem is the most important step for designing the appropriate intervention. Even though the problem definition is not usually directly portrayed in a ToC, this stage is essential to set the target of where, when, and why to intervene. Complex social problems are composed of multiple causes. An appropriate problem definition identifies

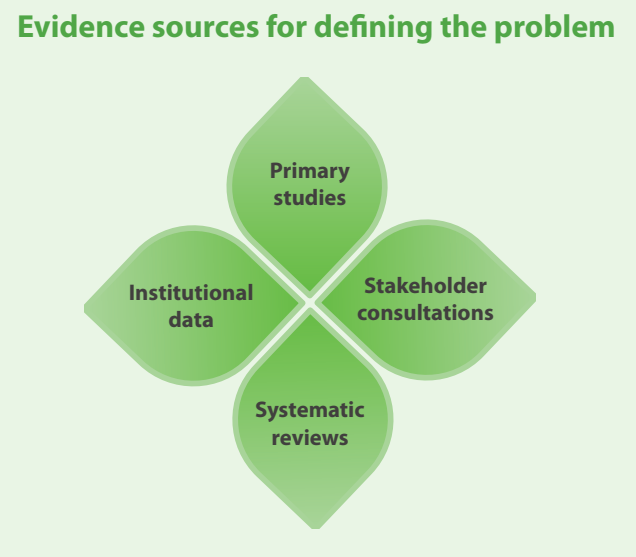
these causes and allows for structuring of intervention strategies targeting each of them. In this way, a gradual process for addressing the larger initial problem can be undertaken. The problem definition also lays the groundwork for choosing the relevant outcomes. For instance, if the problem we need to tackle is childhood obesity, we might find out that one of its most relevant causes is the high consumption of sugary and ultra-processed food. Based on this, we could choose to improve healthy eating among children as an outcome.

During the definition of the problem, new understandings of it often emerge. Sometimes this even points to the need for reframing the problem altogether. A root cause of the problem, for instance, might reveal itself as so central that it is then chosen to be the actual problem the policy will focus on. One example of this would be an attempt to reduce mental health issues in an organization (initial problem), which leads to the understanding that the organization's climate is severely deteriorated, leading to a harmful work environment (problem reframed). The deteriorated organizational climate might be then elected as the new problem for which an intervention is needed.

Lavis et al. *(40)* suggest a few guiding questions for developing an evidence-informed problem definition:

1. **What is the problem?**
2. **How did the problem come to attention, and has this process influenced the prospect of it being addressed?**
3. **What indicators can be used or collected to establish the magnitude of the problem and to measure progress in addressing it?**
4. **What comparisons can be made to establish the magnitude of the problem and measure progress in addressing it?**
5. **How can a problem be framed (or described) in a way that will motivate different groups?**

Problem definition should be supported by all the types of evidence previously mentioned. It is relevant to consider quantitative and qualitative evidence, global and local evidence, as well as scientific and tacit evidence. Therefore, different sources should be consulted, reflecting multiple perspectives, with special emphasis on descriptive qualitative and quantitative evidence and evidence syntheses, such as systematic reviews. Evidence briefs for policy, as presented in the following "Learn more" box, provide a good example of how to define a problem, with special focus on developing a "problem tree".



One way to initiate problem definition is through consultations with a diverse group of stakeholders, such as patients, health-care providers, policy-makers and researchers. This allows investigation of the main issues, perceived impacts, and understanding of their determinants from a local perspective. Undertaking interviews with key actors can also be applied to investigate contextual conditions.

In addition to these qualitative sources, it is also essential to investigate what the available literature says qualitatively and quantitatively about the problem. To do that, it is possible to conduct literature reviews based on the issues raised in the consultation with stakeholders. Next, it is advisable to search for systematic reviews on topics related to the problem and perform a narrative summary of the theories and data found. This allows the identification of the main concepts and their interrelationships, including assumptions, trends and specificities. Furthermore, primary studies, institutional databases, and reports can also be consulted.

Learn more

For more information on how to conduct an evidence-informed problem definition, see:

- Evidence briefs for policy. Using the integrated knowledge translation approach: guiding manual *(41)*, in particular, the sections "The problem tree" and "How to frame the problem".
- Chapter 2 of Evidence, policy, impact: WHO guide for evidence-informed decision-making *(27)*.
- Evidence synthesis for health policy and systems: a methods guide *(42)*.
- SUPPORT tools for evidence-informed health policymaking (STP) 4: using research evidence to clarify a problem *(40)*.

ToC in practice

Hartley et al. *(43)* present a study that designs and tests a support programme for kinship carers of teenage children in Scotland. They collect and analyse three types of evidence: literature reviews, beneficiary interviews, and stakeholder consultations.

The researchers initially conducted a literature review on interventions for reducing alcohol, drug, and tobacco use among adolescents. Findings highlight two key factors influencing kinship carers' roles: "connection" – the emotional attachment within family relationships, and "behaviour control" – encompassing boundary-setting and conflict resolution.

Recognizing that kinship carers might have additional needs, semi-structured interviews and stakeholder consultations were conducted. These sources of evidence revealed emerging themes that helped reframe the problem and support actionable strategies. One theme emphasized the impact of family circumstances on teenagers' emotions and behaviour. Looked-after teenagers require extra support in emotional, behavioural, and learning aspects due to challenging family circumstances. Interlinked issues often lead to problems with communication, conflict, and behaviour control. An excerpt from the interview is collated to illustrate how these findings were derived, shedding light on the research process.

> I (Interviewer): So can you tell me what it was like for you when you first became a carer of Shelly?
>
> Margaret: Well at first, I was grieving for Jenny [Margaret's daughter] and looking after Shelly [granddaughter]. And… with her being a bairn (child), how could you explain to her, ken, that her ma wasn't going to come back home to her. But, I mean, she's doing well now. She's 13. And she gets on well with everybody, ken… She's got a wee bit of learning difficulties and that just now, ken, her writing and that but she's getting a lot of help at the school.
>
> I: What is your relationship like with Shelly?
>
> Margaret: Aye, she's… ken, sometimes she goes into moods and, ken, stomps away up the stair, banging doors, kicking them, tearing the wallpaper, ken. But then she comes out of them as quick as she goes in them, ken.
>
> I: Yeah. And what do you do when she's in a mood like that?
>
> Margaret: I just sit down here and let her do it, ken… because once I tried to stop her and she hurt me… ken, and… she kicked me doon the stair, but I think she regretted it, ken. And she couldn't say enough, ken, oh granny, I'm sorry.

Step-by-step

Stage 1 – How do we define the problem?		
Main task		Identify and define the problem that the ToC will address. Include information on the relevance of the problem and the evidence base that supports it.
Why define the problem?		• to identify the main characteristics, magnitude, trends, causes and consequences of the problem. • to identify where, when and why to intervene. • to establish indicators appropriate for monitoring and evaluating an intervention.
Output		Narrative summary, including a clear definition of the problem, description of the context, identification of the main challenges to be faced, and sources of evidence.
Steps to define the problem		
Step 1	**Outline the questions that need to be answered to define the problem.**	What are its features, causes, consequences, context, main stakeholders involved, etc. For example: • What is the problem that needs to be addressed? • Who is affected by the problem? • What is the context in which the problem occurs? • What are the causes of the problem? • What are the consequences of the problem? • What indicators can be used to establish the magnitude of the problem and to measure progress in addressing it?
Step 2	**Collect and synthesize evidence to answer these questions.**	Collect and synthesize both qualitative and quantitative evidence to support your problem definition. This includes global and local evidence, as well as scientific and tacit evidence. Consider using: • *Stakeholder consultation*: conducting interviews, workshops, focal groups and surveys with key actors. • *Institutional data:* finding local data in institutional databases and existing reports. • *Primary studies:* primary studies can provide specific information about a context, and can also be resorted to when literature reviews are not available. • *Evidence synthesis:* different types of evidence syntheses can be either consulted or conducted, depending on the need, such as systematic reviews, overviews, rapid reviews, scoping reviews, evidence and gap maps. • *Tertiary research:* if possible, consult evidence briefs for policy, guidelines, health technology assessment. For further guidance on how to select the best sources of research evidence for different policy questions, see Tables 1.1, 3.1 and 3.2 of "Evidence, policy, impact: WHO guide for evidence-informed decision-making" *(27)*.
Step 3	**Define the problem.**	Based on the policy questions and on the evidence found, it is possible to outline the problem and its main features. As the ToC development advances and new information emerges, it is important to constantly update and reframe the problem definition.

Practice space

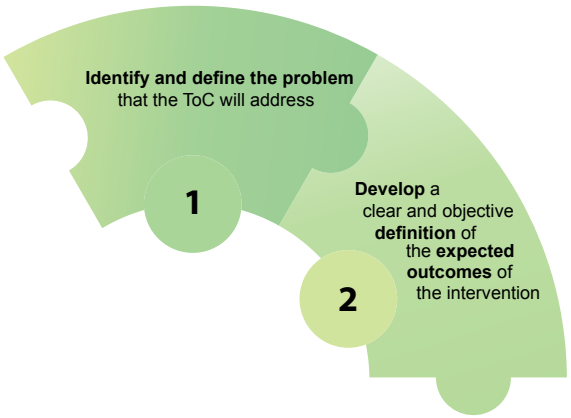
Choose a policy problem that you want to solve. How can you initially describe the problem? What sources of evidence can you use to understand the problem better?

If you need more information or guidance, please make reference to "Evidence, policy, impact. WHO guide for evidence-informed decision-making" *(27)*.

Using the sources of evidence described in the "Step-by-step" box, answer the following questions:

- What is the problem that needs to be addressed?
- Who is affected by the problem?
- What is the context in which the problem occurs?
- What are the main causes of the problem?
- What are the main consequences of the problem?
- What indicators can be used to establish the magnitude of the problem and measure progress in addressing it?
- How can you define the problem in a few words?

Stage 2: How do we define the expected outcomes?



The next step for developing a ToC is to envision how things would look if the initial problem was solved. This is the point to clarify the purpose of the ToC process, defining the desired change, why, and for whom *(44)*. The expected outcomes of the intervention are similar to an inverted mirror for the most relevant aspects of the problem. Based on the problem definition and its causes, one can identify what short-, mid- and long-term outcomes indicate that the problem has been addressed successfully.

In other words, the problem definition is the starting point for identifying the expected outcomes of the intervention.

It is important to think of the desired change before defining the steps to reach it. Often these might seem too challenging at first, but a broad perspective is helpful to identify all possibilities. The team responsible for the intervention may also realize that addressing all the elements of a problem is impossible given their current resources and mandate. In this case, it might be necessary to refine the scope of the intervention, while also strategically thinking how to acquire more resources and legitimacy to fully address the problem in the longer term, expanding the authorization environment for the initiative. If solving the problem requires the collaboration and protagonism of other stakeholders, it is necessary to identify this need and reflect on how to gather their support and promote their engagement.

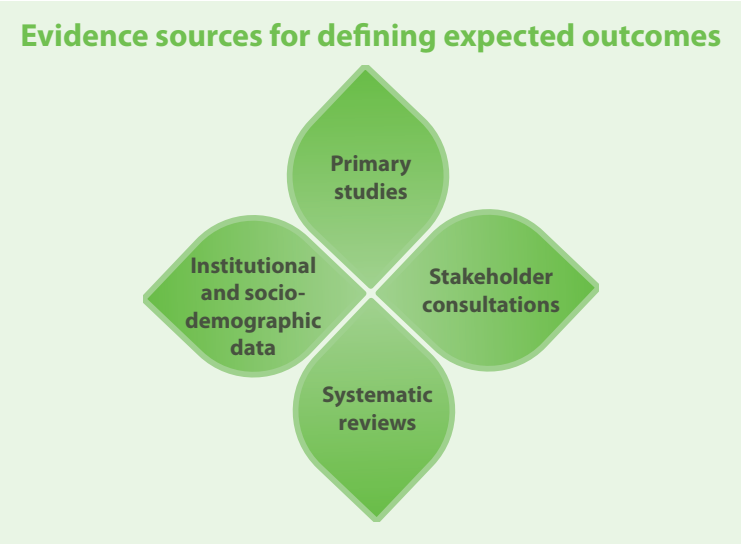
Based on an understanding of the expected impact, i.e. solving the problem or a part of it, it is possible to reverse engineer what is required for this to happen. This often leads to the identification of relevant intermediate outcomes. It is useful to differentiate between short-term, mid-term, and long-term outcomes (or impact). The expected outcomes should be stated clearly, following a logical and chronological order. It is also helpful to include them in the ToC diagram. For an example of a ToC displaying long-, medium-, and short-term outcomes, see the "ToC in practice" box.

Furthermore, the delimitation of expected outcomes is an important moment for alignment and engagement between stakeholders. When all relevant actors participate in the process of defining the outcomes of the policy, it is more likely that the results will actually be relevant and consequential for them and that they will engage with the process afterward. Therefore, a participatory process at this stage can be strategic for achieving the desired change.

The definition of outcomes is essentially a local task. It depends on the stakeholders' views, values, plans, and preferences. Thus, systematic ways for collecting and synthesizing these qualitative data should be applied. Focus groups, workshops, and deliberative dialogues are helpful to gather the relevant information and allow participants to debate and refine their views collectively. Ideally, this process would be iterative, with multiple opportunities for stakeholders to exchange and mature ideas. Surveys can be applied if many people need to be consulted. Through this process, short-, mid- and long-term outcomes can be identified and validated.

At this point, it might also be relevant to use institutional data, systematic reviews, and previous pilot studies to deepen the understanding of the chosen outcomes. This might lead to new perspectives on the initial problem definition. For example, in the case where the initial problem was the staff's mental health, the debate around outcomes might reveal that this problem has emerged because of complaints by service users. A rapid literature

review could potentially demonstrate that these are dense topics, with multiple options for intervention. In this case, the organization might consider exploring two avenues in parallel, one focusing on staff mental health and another one directly focusing on the need to improve service delivery.



We can define the expected outcomes by following three steps. First, goal-setting: identify the long-term expected results through an iterative process of consultations with stakeholders. Second, identify the evidence base through systematic reviews, primary studies, institutional and sociodemographic data. Third, combining the insights of the two previous stages, map potential short-term, mid-term, and long-term outcomes to connect them in a causal chain, allowing for the identification of potential mechanisms of change (see Stage 4 for more on the definition of change mechanisms).

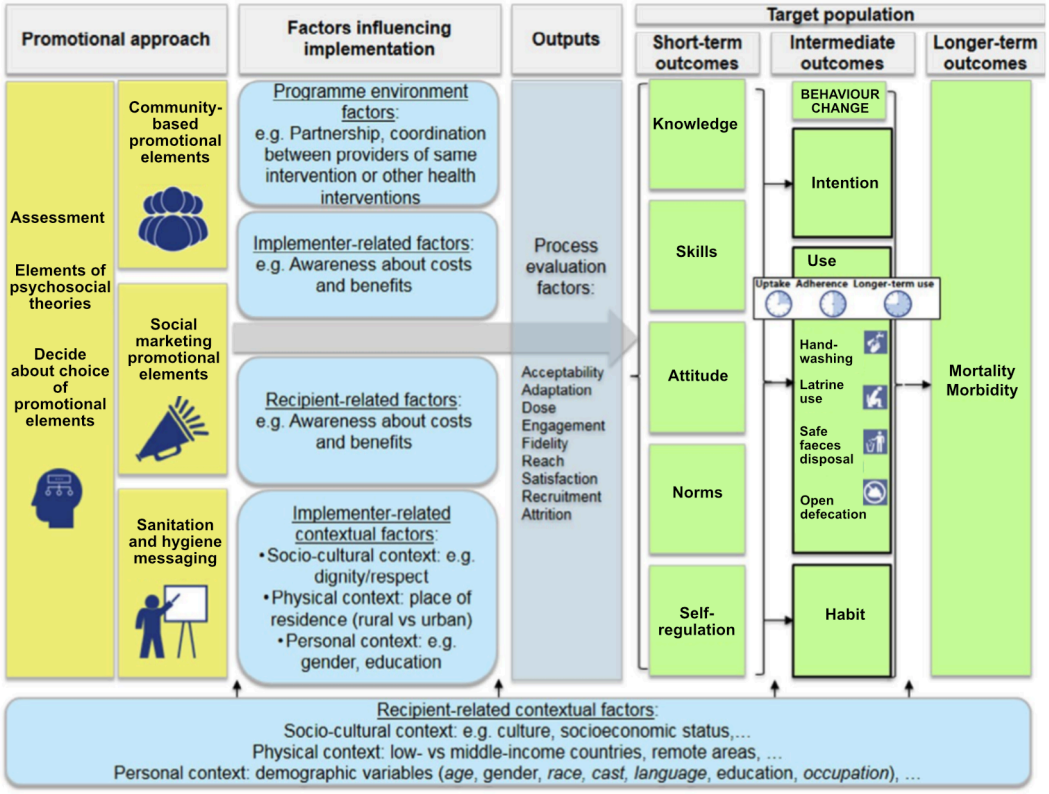
ToC in practice

De Buck et al. *(9)* developed a ToC to assess handwashing and sanitation promotional approaches in low- and middle-income countries, along with implementation factors. They collected and analysed evidence through literature reviews, stakeholder consultations, and external peer-review (Fig. 5).

The expected outcomes were initially proposed based on literature reviews and specialist consultations, which generated an initial ToC model. The long-term outcome was defined as reducing mortality and morbidity from waterborne diseases by decreasing incidence. Short-term outcomes included improved knowledge, skills, attitudes, norms, and self-regulation. Intermediate outcomes assumed sustained behaviour change leading to long-term health improvements. Moderating factors influenced the pathways towards the desired long-term outcome.

Working with a multidisciplinary panel of stakeholders enhanced the model by contributing to implementation, behavioural and contextual factors. This participatory approach also generated buy-in and ownership, improving the ToC's relevance for practice.

Fig. 5. Expected outcomes from a handwashing and sanitation behaviour change programme



Source: De Buck et al., 2018: 8 *(9)*. Reproduced with permission from Taylor & Francis Group.

Learn more

For an approach to identify relevant outcomes based on your problem definition, see:

- "Problem tree" and "Objective tree", in Project management toolkit: achieving results that endure in transition societies *(45)*.

For examples and definitions of outcomes relevant for development projects, associated with their respective ToCs, see:

- The outcomes and evidence framework *(46)*.

For more information on how to manage your authorizing environment, see:

- Chapter 9. Managing your authorizing environment, pp. 193–214, in Building state capability: evidence, analysis, action *(47)*.

Step-by-step

Stage 2 – How do we define the expected outcomes?		
Main task		Develop a clear and objective definition of the expected outcomes of the intervention.
Why define the expected outcomes?		• to clarify the desired change, for whom it is important, and why • to support the identification of the elements and mechanisms needed to bring about change
Output		Narrative summary, including definition and description of the expected short-, medium-, and long-term outcomes, clear and well-founded justification for the choice of outcomes, and documentation of the underlying evidence.
Steps to define the expected outcomes		
Step 1	**Reflect upon what needs to change for the initial problem to be solved.**	! Ensure that the problem is well-defined before moving to this stage. The following questions can guide your thinking: • What does the problem look like when addressed? • What is the desired change? • Why is this change necessary? • What are the short-, medium- and long-term outcomes that need to be achieved for this change to happen? • To whom is this change important? • How will this change impact the target population?
Step 2	**Collect and synthesize evidence to answer these questions.**	Outcomes should be defined primarily from the perspective of the local context, using global evidence as a framework to be adapted to the local needs. Consider consulting: • stakeholders: brainstorming possible goals and objectives collectively, through interviews, workshops, focus groups, deliberative dialogues and, if many people need to be consulted, surveys; • institutional reports; • evidence syntheses; • primary studies, such as policy evaluation and pilot studies.
Step 3	**Define the expected outcomes.**	Combine the insights from the problem definition and the investigation on possible outcomes to identify priority outcomes and the intended impact by: • differentiating between short-term, mid-term, and long-term outcomes, and connecting them logically and chronologically; • differentiating outcomes from potential mechanisms of change; • prioritizing the most relevant outcomes, to become part of the ToC; • defining and describing these outcomes.

Practice space

Considering the problem you chose and, using the sources of evidence described in the "Step-by-step" box, answer the following questions:

- What does the problem look like when addressed?
- What is the desired change?
- Why is this change necessary?
- To whom is this change important?
- How will this change impact the target population?
- What are the main short-term, mid-term and long-term outcomes relevant for solving the problem?

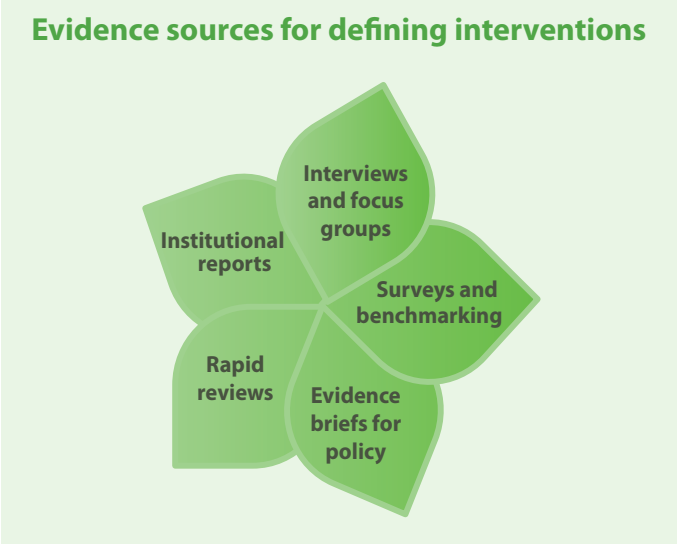
Stage 3: How do we define interventions?

Interventions are the central link between the problem and the expected outcomes. Thus, it is important to carefully design the intervention, examining its potential for impact, as well as barriers, facilitators, risks and equity considerations.

To find the appropriate interventions, it is important to identify the evidence base related to the problem and desired outcomes. The first step for that is to carry out systematic or rapid systematic reviews searching for effective interventions to tackle the problem and achieve the desired outcomes.

Complementary to systematic reviews, other sources can be used, such as institutional reports, interviews and focus groups with stakeholders and experts, surveys, and benchmarking with other relevant programmes. All these sources can help identify potential interventions, as well as causal mechanisms and contextual facilitators, barriers, and risks.

To inform this stage, it might also be interesting to commission an "evidence brief for policy" (EBP). An EBP includes a "summary of the best available evidence to clarify the size and nature of a problem, an assessment of the likely impacts of three key options for addressing the problem based on systematic reviews, considerations of potential barriers to implementing the options, and strategies for addressing these barriers" (WHO, 2021:ix–x) *(27)*. EBPs also often include equity considerations about the different policy options. EBPs can be developed in-house or can be commissioned from evidence units and knowledge translators. Based on the policy options discussed by the EBP, it might be easier to choose what is the best intervention for addressing the problem at stake.



Several dimensions of each potential intervention must be assessed, such as its potential benefits and harms, cost–effectiveness, equity, acceptability, and feasibility *(48)*. For instance, if an intervention is identified through literature searches, it might be the case that it was implemented in a very different location, and its effects could be different if transposed to different circumstances. To assess local feasibility, consultation with local stakeholders is a critical step, since they have the most knowledge about how things happen both in the implementing institution and in the delivery setting. Furthermore, the participation of stakeholders in this process is also important to promote their buy-in into the programme.

This stage can be understood as the moment of defining the scope of a project, from a project management perspective. Thus, specific tools and processes typical of project management can be applied here to refine the decisions around what intervention will be implemented and how.

When identifying the relevant interventions, in addition to expected outcomes, it is important to consider what values serve as the pillars to the initiative. For instance, as we strive to achieve the project's goal, we might want to cater for aspects such as equity, sustainability, safety, quality, efficiency, cultural sensitivity. These values must thus inform the choice of intervention.

Finally, when mapping potential interventions, it is important to always recognize how different stakeholders play critical roles in the health system where the problem occurs. An organization such as WHO often has the objective of gathering support for initiatives that will be implemented by national and local agencies. In such cases, it is important to map this system and relevant stakeholders, designing your ToC considering the relevant power relationships and different mandates.

Learn more

For more on how to design solutions see:

- Phase 2 – Design the solution (pp. 27–29) in Evidence, policy, impact: WHO guide for evidence-informed decision-making *(27)*.

For guidance on how to conduct systematic and rapid reviews, see:

- Cochrane handbook for systematic reviews of interventions version 6.3 *(49)*.
- Rapid reviews to strengthen health policy and systems: a practical guide *(50)*.
- WHO handbook for the development of normative products *(51)*.

For evidence briefs for policy, see:

- Evidence briefs for policy. Using the integrated knowledge translation approach: guiding manual *(41)*.

For assessing the benefits, harms, cost–effectiveness, equity, acceptability, and feasibility of interventions, see:

- The GRADE Evidence to Decision (EtD) framework for health system and public health decisions *(48)*.
- The WHO-INTEGRATE evidence to decision framework version 1.0: integrating WHO norms and values and a complexity perspective *(52)*.

For guidance on project management, see:

- Project management toolkit: achieving results that endure in transition societies *(53)*.

For stakeholder analysis, see:

- "Stakeholder analysis", in Project management toolkit: achieving results that endure in transition societies *(53)*.

For systems thinking, see:

- Systems thinking for health systems strengthening *(54)*.

For using ToCs in complex contexts, see contribution analysis in:

- Contribution analysis for adaptive management *(55)*.

Toc in practice

Roza and Martin *(56)* present a comprehensive roadmap for addressing sexual and gender-based violence (SGBV) in Latin America and the Caribbean (LAC) region. They identified six strategic areas of intervention aimed at both preventing and responding to SGBV.

To determine these areas, a thorough literature review was conducted, which revealed the primary barriers in the region. Based on these barriers, appropriate interventions were selected. The literature review focused on gathering impact evaluations from experimental or quasi-experimental studies conducted in developing countries, with a particular emphasis on the LAC region. Whenever there was a lack of evidence from developing countries or the LAC region, they considered evidence from developed countries.

The interventions were classified based on their effectiveness, ranging from effective and promising to those with mixed results, not effective, or insufficient evidence. The evaluated interventions had impacts on multiple variables, including victimization, perpetration of violence, attitudes, and social norms, among others.

Fig. 6 provides an example of one of the defined areas of intervention.

Fig. 6. Strategic intervention template for a programme to address sexual and gender-based violence in Latin America and the Caribbean

Strategic intervention 2. Institutional strengthening and capacity building

Description
Programs or interventions that strengthen the capacity of institutions and sectors, as well as their personnel, or which reform the provision of services to improve their quality, efficiency and cultural appropriateness.
Expected results
• Institutions improve access to and quality, coverage and multisectoral coordination of violence prevention, as well as mechanisms for filing formal complaints and response services. • More women and girls gain access to services for prevention and appropriate response.

Effectiveness	Prevention	Response
Effective	—	Training programs for police
Promising	—	Training programs for personnel of women's police stations
Mixed	Areas reserved for women on public transportation	—
Insufficient evidence	Improvement of public infrastructure to increase women's safety	Training programs for: • Judicial system personnel • Health service personnel • All public sector personnel

Source: Roza & Martin, 2021:58 *(56)*

Step-by-step

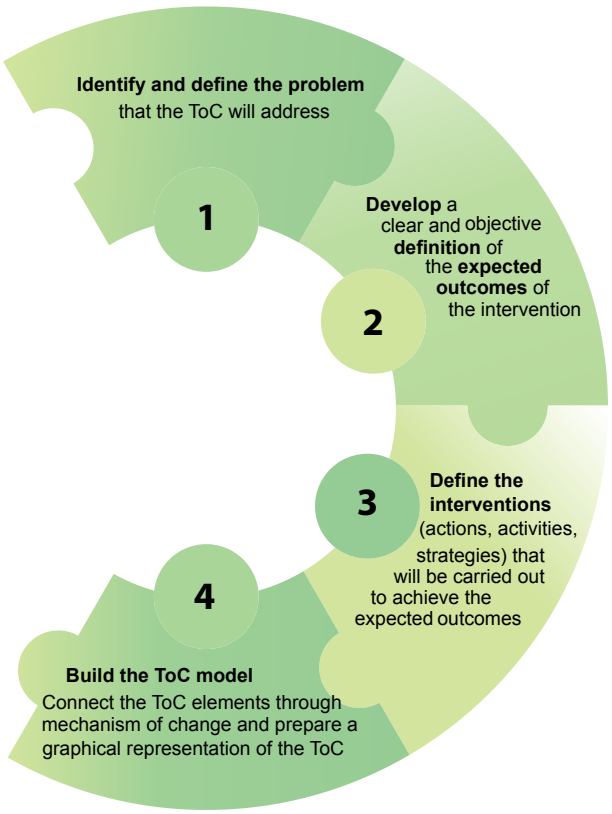
Stage 3 – How do we define interventions?		
Main task		Define the interventions that will be carried out to achieve the expected outcomes.
Why define interventions?		• to establish overall guidance for practice • to define the activities that will be necessary and their expected causal chain resulting in the desired outcomes • to ensure that stakeholders and the implementing team have a shared understanding of how the project or programme is expected to be conducted
Outputs		Narrative summary, including a detailed description of the intervention, outlining the logical sequence of activities and expected outcomes, as well as the identification of possible risks and limitations.
Steps to define the interventions		
Step 1	**Identify possible interventions.**	To identify possible interventions, it is important to consult different sources of local and global evidence. • Consult the academic literature, especially publications that measure and discuss policy impact (e.g. systematic reviews and impact evaluations), as a source of information on what interventions have been demonstrated to work, and what interventions have failed to show effectiveness. • Institutional data, benchmarking with similar organizations and stakeholder consultation, in turn, can be a source of ideas that are tightly connected and relevant to the local context. These methods can be used both to identify intervention options and to discuss options identified in the literature. ! The definition and design of interventions require the active participation of local stakeholders.
Step 2	**Assess the applicability of potential interventions.**	While identifying potential interventions, the same methods described in the previous point can be used to map causal mechanisms, contextual facilitators, barriers, risks, and equity considerations for each of them. Based on this information: • assess and compare interventions in terms of the potential impact and local applicability; • choose one or more interventions for implementation.
Step 3	**Detail the interventions.**	• Describe the chosen interventions. • Detail the intervention's logical sequence from activities to final outcomes.

Practice space

Considering the problem and outcomes you chose, and using the sources of evidence described in the "Step-by-step" box, answer the following questions:

- What are the possible interventions for addressing the problem?
- How are they applicable to the local context? What are the possible facilitators, barriers, risks, and equity considerations relevant for their implementation?
- How do the different interventions compare? Which one seems to be the best option?
- Considering the one that seems to be the best option, what are its main elements, from resources and activities to final outcomes?

Stage 4: How do we define change mechanisms and build a model of the theory of change?



Once an intervention is chosen as potentially relevant to solve the problem, then it is important to detail its logical sequence from activities to final outcomes, defining its change mechanisms. Change mechanisms refer to the causal steps that are expected to lead an intervention to achieve its intended outcomes (Van Es et al., 2015:43) *(44)*. They refer to how each step of an intervention is expected to create the necessary conditions for the next steps to succeed *(57)*. In the ToC, change mechanisms are presented as causal links, starting from the initial resources and activities, through outputs, outcomes, and finally impact. These elements must be described by their key concepts and the interrelationship between them, forming causal connections.

Detailing the mechanisms is a core part of the ToC development process. Special focus is necessary regarding the expected results of an intervention and the evidence supporting these links. Furthermore, the necessary levels of detail are flexible and need to be considered according to the decision-making process that the ToC will be supporting. For instance, if the ToC is being developed to compare a few potential interventions, and the different frameworks will be presented to decision-makers for consideration, it is probably better to have a more schematic presentation that easily contrasts the options. On the other hand, if the ToC will be used by the implementation team to design the intervention further, then it might be important to provide more details on how each mechanism is expected to work.

For each intervention, all its components need to be identified and discussed. If an intervention relies on concurring strategies, this might lead to parallel causal pathways in the ToC. For instance, one intervention can include a package of actions, such as institutional capacity development, behavioural change, and direct benefits. Each of these should be delineated as building blocks of the ToC.

The evidence collected about the intervention and the problem should inform the mapping of the relevant mechanisms. Policy reports or primary studies describing the intervention can provide detailed accounts of how an intervention works or has worked before. Previous ToCs can be used as a base. Systematic reviews sometimes also report the etiological aspects of a problem, and barriers, facilitators, and other relevant aspects of an intervention, which can inform the definition of the mechanisms. Similar to the previous stages, local evidence is critical to assess how an intervention can effectively be rolled out in a specific setting. Qualitative evidence from stakeholders and other key actors is essential for that purpose. Focus groups, deliberative dialogues, workshops, interviews, and surveys are possible tools to gather the relevant information.

Evidence sources for defining change mechanisms

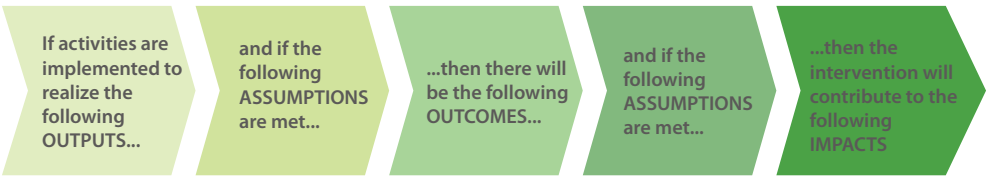
When discussing the ToC mechanisms, it is often beneficial to start at the expected outcomes and then reverse engineer all the steps necessary to get there. This helps to identify blind spots that a first intervention blueprint might overlook.

In addition to the change mechanisms, the ToC must also depict the assumptions that are made for each causal link. Assumptions refer to the conditions and contextual factors that are assumed to exist and that are necessary for the intervention to work. They can also refer to other policies and programmes that are assumed to be in place for the intervention to work. For instance, if the intervention involves sending emails to a group of people, some assumptions could be that the target audience is literate, has access to and uses email, that the emails will not be filtered out by spam detectors, and that the Internet providers of the region will reliably provide Internet when needed. It is important to identify and explicitly discuss all possible assumptions, which could be related to the context in which the intervention takes place, the initial resources and activities, outputs, outcomes and final impact. Based on these assumptions, it is possible to identify relevant risks for the project, and then discuss how to mitigate them.

Box 3. Identifying assumptions

The following diagram can help in recognizing relevant assumptions.

Fig. 7. ToC assumptions



Source: Adapted from UNICEF, 2020:4 *(58)*

Additionally, Van Es et al. (2015:59) *(44)* suggest a few questions that can help to identify assumptions:

- "If X changes, will Z really happen? Why? Under which conditions would it work?
- Are our assumptions about causality in the pathways valid for all stakeholders, or otherwise affected/interested people?
- How do our beliefs and preferences for specific types of change shape our thinking about the pathways? What are we taking for granted? What would challenge our assumptions?
- What evidence do we have that supports our assumptions about causality and the effectiveness of strategies?"

Through the process of defining the change mechanisms and assumptions, it is possible to start modelling the ToC. A ToC must graphically present the various causal links that lead to the intended result. These causal pathways must clearly and logically represent the interaction between the intervention elements, as well as the underlying assumptions, connecting each step up to the final results. ToC modelling puts together all the insights collected in the previous stages. This is when all the evidence and critical thinking put into the ToC development process will be materialized in a structured, logical, and realistic sequence of steps to guide implementation of the intervention.

The ToC designing process should be conducted by a group of people who understand the problem, the intervention, its mechanisms, and contextual conditions. It can start with either a blank page in a facilitated workshop with stakeholders, or with a ToC draft as a starting point in a discussion with stakeholders.

In any case, it is important that all relevant evidence is available, constantly considered and, whenever appropriate, incorporated into the final product.

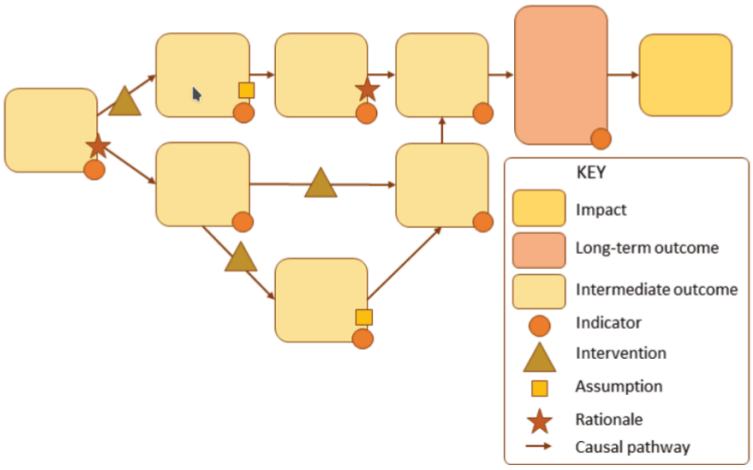
Overall, the final design of the ToC needs to account for three main domains: what resources are needed before the intervention starts (inputs), what the intervention will consist of (activities), and what the intervention will produce (outputs and outcomes). The results of the intervention are commonly differentiated by short-term, mid-term, and long-term outcomes. Often, short- and mid-term results are referred to as outcomes and long-term results as impact. Furthermore, it is important for the presentation of the ToC to highlight which causal connections are the most critical for the intervention's success and which components are needed to achieve each outcome.

As the structure of the ToC becomes clearer, it is necessary to develop the indicators that will be used to assess the progress and implementation of the ToC, as well as supporting the monitoring and evaluation process. When formulating the indicators for a ToC, one should consider what data are available and what information is the most effective for both internal and external audiences. It is also recommended to use indicators that are already defined and applied in other contexts to ensure consistency and comparability. As part of the measuring effort, one should establish when and how the indicator will be measured, and what study design will be used to ensure internal and external validity. For each indicator, it is necessary to define clear targets. The indicator should make clear what is considered a success for a specific outcome, so that everyone can understand and track the progress of the ToC *(12)*. For instance, in the Gender-based Violence programme conducted by the International Rescue Committee (IRC), two indicators are used to assess the outcome "Women and girls are protected from and treated for the consequences of Gender-Based Violence (GBV)": "% of female survivors who demonstrate an improvement in their

psychosocial well-being after three or more GBV case management sessions" and "% of GBV survivors who present for clinical care who receive assistance within 72 hours of an incident" *(59)*.

Graphic tools, such as a blackboard, post-its or a graphical software can be helpful at this stage. They facilitate the visualization of the ToC and allow for the dynamic manipulation of its elements, which can serve as a basis for debate and refining of ideas (see Fig. 8 for an example).

Fig. 8. Example of a ToC design



Source: De Silva et al., 2014: 4 *(33)*. Reproduced with permission from Mental Health Innovation Network.

ToC in practice

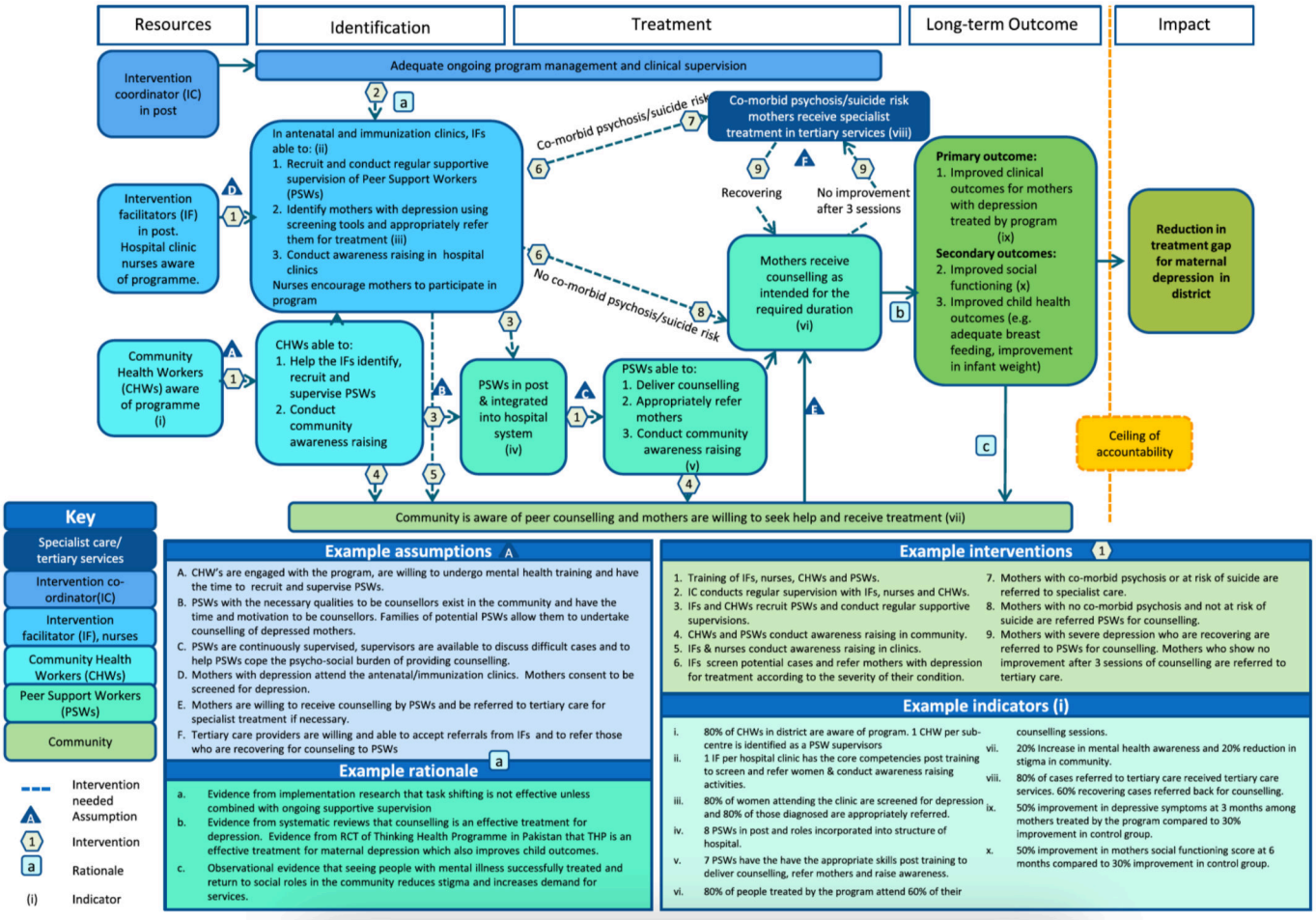
De Silva et al. *(10)* used ToC to enhance the Medical Research Council's (MRC) framework. This aimed to support implementers in developing more comprehensive and theory-driven health-care interventions. They tested the approach on the SHARE programme, which provides peer counselling for maternal depression in Goa, India.

The change mechanisms were defined through a participatory process, with stakeholder consultations in workshops. First, the programme's long-term outcome was defined. Then, participants identified causal pathways, considering available resources. Preconditions leading to outcomes were articulated as the pathway developed, while interventions and supporting evidence for each link were identified. The rationales were drawn from a range of sources, including research evidence, behaviour change theories, local knowledge and primary research conducted as part of the project. Based on these resources, key

assumptions, conditions and potential barriers for the ToC were highlighted.

Finally, indicators were defined for each precondition to evaluate the stages leading to the final impact. Drawing on a diverse range of evidence produced a more plausible intervention. In the end, the participants found that the ToC approach supplemented the MRC framework by providing guidance on integrating theory-driven approaches into complex interventions (Fig. 9).

Fig. 9. ToC diagram from the South Asian Hub for Advocacy, Research and Education on mental health (SHARE) trial



Source: De Silva et al., 2014: 3 *(10)*

Learn more

For more on how to identify assumptions and risks, see:

- Context analysis – PESTEL *(60)*

Step-by-step

Stage 4 – How do we define change mechanisms and build a model of the theory of change?		
Main task		Connect the ToC elements through mechanisms of change and prepare a graphical representation of the ToC.
Why define change mechanisms and model the ToC?		• to visually depict the causal relationships that lead the intervention to achieve the desired outcomes • to clarify how each step of the intervention is expected to work • to demonstrate how the components of the intervention relate to each other • to identify any gaps and failures in the planned intervention • to identify the specific needs and contextual assumptions of each step of the intervention • to guide the implementation effort • to coordinate and promote collaboration among those involved • to communicate the intervention and its results to other parties.
Outputs		• Visual model of the ToC that illustrates how the different elements are connected and how change occurs • Summary explaining the causal model and its mechanisms, as well as its assumptions, risks and indicators
Steps to define the change mechanisms and model the ToC		
Step 1	**Identify and discuss change mechanisms, assumptions and risks.**	Understanding the change mechanisms, assumptions and risks entails delineating: • each component of the intervention, including resources and activities; • how each component creates the necessary conditions for the next components to succeed; • what assumptions are made about how each component will work, and how they can be translated into risks to the project. To identify the change mechanisms and assumptions, consider: • Stakeholder consultation: →Discuss how each component contributes to achieving the desired outcomes. →Discuss how an intervention can effectively be rolled out in a specific setting. →Discuss what is assumed to be true for each step. • Consult academic and institutional publications that describe and assess similar policies. Impact evaluations, systematic reviews and implementation research reports can be particularly useful.
Step 2	**Define the mechanisms that will bring about the desired change.**	Based on the previous research, start creating the roadmap for the intervention. • Reverse engineer the steps: start at the expected outcomes and then reverse engineer all the steps necessary to get there. This helps to identify blind spots that a first intervention blueprint might overlook. • Validate this roadmap with key stakeholders to identify potential gaps. • These mechanisms should represent the interaction between the intervention elements and be clearly and logically connected to the final results.

Steps to define the change mechanisms and model the ToC (continued)

Step 3	**Draft the ToC.**	Based on the mechanisms identified in the previous stage, develop a first draft of the ToC: • Adopt a visual template to organize the information. • Develop a structured, logical, and realistic sequence of steps to guide implementation of the intervention and include them in the diagram. • Add contextual assumptions and other considerations as needed. • Include the most relevant risks and their respective mitigation strategies. • Add arrows and other graphical elements to indicate the causal links and the relationships between each part. • Emphasize which causal connections are the most critical for the intervention's success. • At least three main sections need to be included: → Inputs: account for the resources needed for the intervention (e.g. money, time, staff). → Activities: describe what the intervention will consist of. → Outputs and outcomes: describe what the intervention will produce. • Add the main indicators that will be used to assess implementation of the ToC. ! Depending on the decision-making process, different levels of detail are required for the ToC. ! If an intervention relies on multiple strategies, this might lead to parallel causal chains.

Practice space

Considering the intervention that you chose, and using the sources of evidence described in the "Step-by-step" box, answer the following questions:

» What are the change mechanisms necessary for the intervention to work?

» What are the assumptions of these mechanisms?

» What indicators can be used to monitor the intervention?

» Next, make a draft of the theory of change of the intervention, in a graphical form.

Stage 5: How do we validate the ToC?

Once a first complete draft of the ToC is ready, the Mechanism Mapping tool *(61)* can be applied for a more thorough examination and validation. Mechanism Mapping is a tool originally developed for policy adaptation, i.e. bringing a previously implemented policy to a new context. The tool focuses on assessing if an initial ToC is appropriate given the local contextual conditions, considering each of its mechanisms. Here, we suggest applying this tool even if the ToC has not yet been implemented before, because its structured process allows for a clear consideration of how contextual factors might require adjustments of an initial ToC.

Mechanism Mapping has five steps:

1. **Map out the policy's initial ToC.**
2. **Map the contextual assumptions that must hold for the ToC to work.**
3. **Map the actual characteristics of the context and compare them to the assumptions.**
4. **Adapt the policy to eliminate mismatches between assumptions and characteristics.**
5. **Repeat steps 1–4 for the adapted policy, iterating in more detail until satisfied that all major policy design decisions fit the local context.**

In this framework, evidence is key at all steps. In the first and second steps, research and tacit evidence must be combined to design a first version of the ToC. In steps 3 and 4, local, quantitative and qualitative evidence must be used to assess if the initial assumptions of the ToC are valid for the context of implementation and to raise hypotheses regarding potential barriers and risks.

The process of validating a ToC involves confirming that there is an alignment between the product taking shape, the expectations of the actors involved, and the possibilities of that context. The following three principles can be considered to guide this reflection *(12)*:

- **Plausibility**: this concerns the logic of the proposed pathways and outcomes. It aims to evaluate whether the ToC makes sense, whether the results are in a coherent order, and whether the preconditions are adequate for the expected outcomes. Possible gaps should be identified, and necessary adjustments made. The Mechanism Mapping method, described above, can be especially useful for this point.
- **Viability**: this concerns the actual possibility of achieving the proposed long-term results of the ToC. It should be evaluated whether there are sufficient resources to implement all the defined interventions, whether there is a need to seek additional resources and new partnerships, and whether adaptations need to be made to the scope.
- **Testability**: this concerns the development of consistent and measurable indicators that can be evaluated in a timely manner. It is important to evaluate whether the ToC has defined adequate indicators to assess the success or failure of the proposal.

These three principles can be applied continuously during the construction of the ToC, but it is important to have a protected moment to revisit them at the end of the process. By doing so, stakeholders can ensure that the ToC is well-designed, feasible, and can be evaluated effectively.

It is worth remembering that social participation must play a central part in the processes of formulating any public health policy. However, due to practical reasons, it is not always possible to conduct participatory processes for all stages of ToC development. When this is the case, it is especially important for the final ToC diagram to be then validated and agreed on by a wider range of stakeholders, particularly those whose actions matter for the intervention to work. This can include service users, staff members, policy-makers, members of the community, topic experts, among others. Community engagement, in particular, is a condition for effective interventions. The validation stage is an opportunity to allow the participation of other actors who will be affected by the desired change.

The relevant evidence for this stage is primarily colloquial and qualitative. It can be collected through workshops, interviews, surveys, deliberative dialogues, meetings, and similar methods. If consensus is needed, a technique such as the Delphi method can be applied.

After finalizing and validating the ToC, compile all records accumulated during each stage into a narrative text that describes each element of the ToC and identifies the various sources of evidence that informed it. If the resulting document is too extensive, prepare an executive summary using clear and concise language to make it accessible to a diverse audience *(12)*. Documenting the processes and resources used to build the ToC can ensure transparency and transferability, as well as being an important tool for accountability. Also, this document will be valuable for maintaining the memory of the processes and guiding the next steps of intervention review and implementation. A checklist, such as the one proposed by Breuer et al. *(5)*, can be used to guide the narrative process.

Learn more

For more information on how to conduct Mechanism Mapping, see:

- External validity and policy adaptation: a five-step guide to Mechanism Mapping *(61)*.

For the Delphi method, see:

- Research guidelines for the Delphi survey technique *(62)*.

For a checklist for reporting ToCs, see:

- Checklist for reporting ToC in public health interventions *(5)*.

For citizen engagement guidance, see:

- Implementing citizen engagement within evidence-informed policy-making: an overview of purpose and methods *(34)*.

Step-by-step

Stage 5 – How do we validate the ToC?	
Main task	Validate the ToC with relevant stakeholders to ensure its accuracy, acceptance, and plausibility.
Why validate the ToC?	• to ensure the accuracy and quality of the model • to identify possible gaps or flaws in the intervention design • to enable the participation and engagement of relevant stakeholders • to provide transparency and legitimacy to the ToC development process
Outputs	Final version of the validated ToC with supporting documentation explaining its key features such as problem definition, relevant outcomes, mechanisms, assumptions, indicators, and evidence base, as well as a description of the process conducted to develop the ToC.
Steps to validate the ToC	
Step 1 **Apply the Mechanism Mapping tool.**	Follow the five steps of Mechanism Mapping *(61)* to assess if an initial ToC is appropriate, given the local contextual conditions, considering each of its mechanisms. The tool can be used to refine the ToC and can be applied in a validation workshop, for instance. For each step of the process, collect and analyse the relevant evidence, including research and tacit evidence. The process consists of: • mapping out the policy's intended theory of change (i.e. mechanism); • mapping the contextual assumptions that must hold for the theory of change to work; • mapping the actual characteristics of the context and comparing them to the assumptions; ***Step 1 continued on next page***

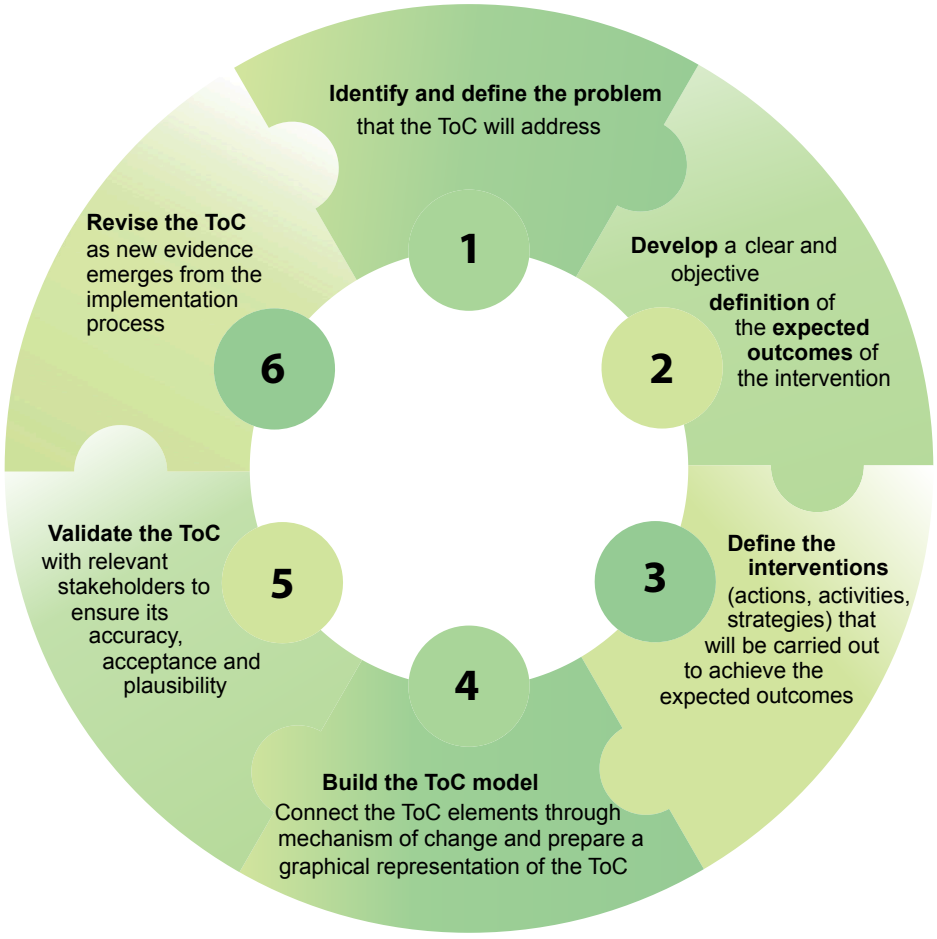
Steps to validate the ToC (continued)		
Step 1	Apply the Mechanism Mapping tool.	• adapting the policy to eliminate mismatches between assumptions and characteristics; • repeating steps 1–4 for the adapted policy, iterating in more detail until satisfied that all major policy design decisions fit the local context.
Step 2	Discuss and refine the ToC draft.	At this stage, it is critical that a diverse range of stakeholders has the opportunity to provide feedback on the ToC, so that any blind spots are identified, and the ToC is representative of multiple perspectives. → Consider inviting topic experts as well as stakeholders who will be involved in or affected by the intervention, such as service users, staff members, and members of the community. → Discuss the dimensions of plausibility, viability and testability of the ToC. There is a list of approaches that can be undertaken: • A facilitated workshop, conducted by a ToC specialist, can assist this process. • A blackboard, post-its, or graphical software can be used to discuss and visualize possible changes and adaptations. • Interviews, surveys and other qualitative methods can also be applied. • The draft ToC can be shared in advance so that participants have a first concept to react to and time to prepare. • During the validation, register feedback regarding the ToC diagram, its assumptions, and concerns and questions. ! In some cases, it may be appropriate to go through two or more validation rounds, depending on the degree of change prompted by the process.
Step 3	Revise and finalize the ToC.	Based on the feedback received during the validation process, revise and finalize the ToC diagram. • Make sure that the ToC reflects the concerns, suggestions, and feedback received. • Seek to ensure that the stakeholders have a sense of ownership and buy-in towards the intervention. • Compile all records accumulated during each stage into a narrative text that describes each element of the ToC and identifies the various sources of evidence that informed it. • Prepare an executive summary using clear and concise language to make it accessible to a diverse audience. • Make the complete and validated ToC available to relevant stakeholders, so as to support policy implementation, monitoring, evaluation, and dissemination.

Practice space

Considering the intervention you chose, and using the sources of evidence described above, apply at least two rounds of the Mechanism Mapping tool:

1. Map out the policy's initial ToC.
2. Map the contextual assumptions that must hold for the ToC to work.
3. Map the actual characteristics of the context and compare them to the assumptions.
4. Adapt the policy to eliminate mismatches between assumptions and characteristics.
5. What is your final ToC?

Stage 6: How do we revise the ToC?



While a ToC must be rigorously constructed, it should also be flexible. Social interventions in complex settings always imply unforeseeable circumstances, challenges, and barriers. It is naive to assume that the first design of an intervention will anticipate all of these barriers and challenges. When dealing with complex problems, the understanding about the problem and local conditions for action deepen throughout implementation. Thus, the ToC should not be an anchor that prevents adaptations and changes of route, but rather it should be a compass pointing to the desired direction and allowing for learning and adjustments on the way. If need be, the ToC should be completely revised to account for the new understanding of the problem and the intervention context.

However, too often a ToC is treated as a one-off exercise for the design phase. Once the implementation starts, the ToC is never revisited. There are two potential risks in this case: (i) new challenges arise, but the implementing team fails to adapt in the face of these (such as when there are contextual modifications that lead to changes in the assumptions of the ToC), or (ii) adaptations are made, but the ToC is not updated accordingly. In the first case, the implementation team might be overlooking important contextual factors that were not expected in the design phase, which could lead to the intervention not succeeding without the proper adaptations. In the second case, although the necessary adjustments are made, they are not incorporated into the normative description of the intervention, which might lead to misleading information in monitoring, evaluation, and future adaptation processes.

To prevent these problems, it is important to consider two key points in the ToC: (i) ToC is a process that promotes continuous learning, and (ii) ToC is an adaptive and iterative approach *(44)*. The use of ToC is not limited to the planning phase of a programme but should support the iterative process of implementation, making it a living process. Initial assumptions regarding the conditions, behaviours, or critical events do not necessarily hold throughout the lifetime of a programme *(63)*.

To bring the most value and facilitate learning, the underlying assumptions and theories of how change is expected to happen should be regularly reviewed and revisited. In a similar vein, ToCs often start with a relatively simple framework (given the limited evidence on how change is likely to happen) and gradually become more comprehensive, including different pathways, assumptions, and causal feedback loops (*64*). Revising the ToC with the support of key stakeholders is also an opportunity to ensure their engagement and promote overall alignment.

Monitoring and evaluation are also opportunities to revise the ToC. Often, ToCs are used as a base for monitoring, evaluation, and learning (MEL) efforts. The different steps depicted in the ToC can be a reference for the choice of appropriate indicator, as well as to establish when each measure will be relevant and what are the values of reference.

Based on the findings that are regularly generated by the MEL system, the ToC can be updated. If monitoring indicates that the intervention is not achieving the expected results, it is probably the case that some adjustment is needed. Similarly, if an impact evaluation

finds that the intervention has not led to the desired changes, it means that there was some kind of mistake or overlooked aspect in its ToC, which needs to be adjusted before a next iteration. The tools provided by the field of implementation research are particularly useful for this stage.

The ToC revision stage is the moment when adaptations, amendments, and suggestions can be introduced. The natural exercise of trial and error is the source of evidence for these adjustments. In this process, quantitative and qualitative evidence from the local level is the most important. MEL frameworks can be used to systematically collect evidence through the implementation process and feed it back to the responsible team. Quantitative databases and data collection forms can be used to track activities, outputs, and results indicators. Similarly, qualitative methods such as interviews, focus groups, and surveys can be used to gather narrative information about what is working and not and why this is happening. If possible, causal analysis of the impact of certain mechanisms and moderators can be very insightful to validate specific links in the ToC. Whenever appropriate, the revision of the ToC can also apply the Mechanism Mapping method, as described earlier in Stage 5, which provides a structured protocol for comparing the existing ToC with contextual conditions.

Learn more

For more information about MEL frameworks, see:

- Monitoring and evaluation: some tools, methods, and approaches *(65)*.
- Monitoring, evaluation and learning strategy and action plan *(66)*.
- A practical guide to measuring and managing impact *(67)*.
- Handbook for monitoring and evaluation *(68)*.
- WHO evaluation practice handbook *(69)*.

For more on adaptive management, see:

- Building state capability: evidence, analysis, action *(47)*. From real-time evaluation to real-time learning | ALNAP

For more on implementation research, see:

- Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda *(70)*.

Step-by-step

Stage 6 – How do we revise the ToC?		
Main task		Revise the ToC as new evidence emerges from the implementation process.
Why revise the ToC?		• to ensure that the ToC remains relevant and reflects new insights gained during implementation • to adapt to contextual changes • to avoid mistakes that could arise from following an outdated ToC • to ensure that key stakeholders are aligned and on board.
Outputs		• Plan for how the ToC will be updated as new evidence becomes available and how the underlying assumptions of the ToC will be tested and revised. • Updated ToC, explaining what changes were made, and documenting the process that led to these changes.
Steps to revise the ToC		
Step 1	**Gather evidence to update the ToC.**	• Use monitoring, evaluation, and learning (MEL) efforts as an opportunity to revise the ToC. • Whenever appropriate, use a framework or tool, such as the Mechanism Mapping method (*61*) to reflect on how new contextual conditions might affect the ToC. • Register learnings from the trial-and-error process of policy implementation. • Use both quantitative and qualitative evidence from the local level to inform the revisions. → Quantitative databases and data collection forms can be used to track activities, outputs, and results indicators. → Qualitative methods such as interviews, focus groups, and surveys can be used to gather narrative information about what is working, what is not working, and why.
Step 2	**Update the ToC.**	• Based on the new evidence, incorporate adaptations, amendments, and corrections to the ToC as needed. • Make the new ToC available for those who need it. ! Remember: the ToC should be seen as a living product, evolving over time in an iterative and adaptive way, as more insight is gained from the implementation process.

Practice space

Considering the ToC you drafted, and using the sources of evidence described in the "Step-by-step" box, answer the following questions:

- How would you monitor the implementation of the ToC?
- What evidence can you collect to adapt the ToC if needed?
- How would you go about collecting this evidence?
- Through what instruments would you do it?
- How often?
- With whom and how would you share your findings?

References

1. Romão DMM, Setti C, Arruda LHM, de Melo RC, de Araujo BC, Tan AR et al. Integration of evidence into theory of change frameworks in the healthcare sector: a rapid systematic review. PLoS One. 2023;18(3):e0282808. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0282808.
2. Independent Evaluation of WHO's Results-Based Management (RBM) Framework (2023): report – January 2023 (https://cdn.who.int/media/docs/default-source/evaluation-office/rbm-final-evaluation-report.pdf?sfvrsn=2663b1c1_3&download=true, accessed 6 February 2024).
3. Results-based management for international assistance programmimg at Global Affairs Canada: a how-to guide. Global Affairs Canada; 2022 (https://www.international.gc.ca/world-monde/assets/pdfs/funding-financement/how-to-guide.pdf, accessed 6 February 2024).
4. Funnell SC, Rogers PJ. Purposeful program theory: effective use of theories of change and logic models. San Francisco: Wiley; 2011 (http://au.wiley.com/WileyCDA/WileyTitle/productCd-0470478578.html, accessed 6 February 2024).
5. Breuer E, Lee L, De Silva M, Lund C. Using theory of change to design and evaluate public health interventions: a systematic review. Implement Sci. 2016;11(1):63. https://doi.org/10.1186/s13012-016-0422-6.
6. Yearwood AC. Applying a logical theory of change for strengthening research uptake in policy: a case study of the Evidence Informed Decision Making Network of the Caribbean. Rev Panam Salud Publica. 2018;42:e91.
7. Sapkota D, Baird K, Saito A, Anderson D. Interventions for reducing and/or controlling domestic violence among pregnant women in low- and middle-income countries: a systematic review. Syst Rev. 2019;8(1):79. https://doi.org/10.1186/s13643-019-0998-4.
8. Meiksin R, Melendez-Torres GJ, Falconer J, Witzel TC, Weatherburn P, Bonell C. Theories of change for e-health interventions targeting HIV/STIs and sexual risk, substance use and mental ill health amongst men who have sex with men: systematic review and synthesis. Syst Rev. 2021;10(1):21.
9. De Buck E, Hannes K, Cargo M, Van Remoortel H, Vande Veegaete A, Mosler HJ et al. Engagement of stakeholders in the development of a theory of change for handwashing and sanitation behaviour change. Int J Environ Health Res. 2018;28(1):8–22.
10. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C et al. Theory of change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials. 2014;15:267.
11. UNSDG. Theory of change: UNDAF companion guidance. UNSDG; 2017 (https://unsdg.un.org/resources/theory-change-undaf-companion-guidance, accessed 2 October 2023).
12. Taplin DH, Clark H. Theory of change basics: a primer on theory of change. New York, NY: ActKnowledge; 2012 (https://www.alnap.org/help-library/theory-of-change-basics-a-primer-on-theory-of-change, accessed 2 October 2023).

13. Stein D, Valters C. Understanding theory of change in international development. London, UK: Justice and Security Research Programme, International Development Department, London School of Economics and Political Science; 2012 (http://www.lse.ac.uk/internationalDevelopment/research/JSRP/jsrp.aspx, accessed 3 October 2023).
14. McLaughlin JA, Jordan GB. Using logic models. Chapter 3. In: Handbook of practical program evaluation. John Wiley & Sons, Ltd; 2015:62–87 (https://onlinelibrary.wiley.com/doi/abs/10.1002/9781119171386.ch3, accessed 3 October 2023).
15. Anderson AA. The community builder's approach to theory of change. A practical guide to theory development. New York: The Aspen Institute Roundtable on Community Change; 2009 (https://developmenteducation.ie/resource/the-community-builders-approach-to-theory-of-change-a-practical-guide-to-theory-development/, accessed 3 October 2023).
16. UK Aid Connect. Guidance note: developing a theory of change. 2017 (https://assets.publishing.service.gov.uk/media/5964b5dd40f0b60a4000015b/UK-Aid-Connect-Theory-of-Change-Guidance.pdf, accessed 3 October 2023).
17. Buhl-Nielsen E, Gouzou J, Rao KBP, BlomhØj TI. Evaluation of Swedish International Training Programme (ITP): climate change – mitigation and adaptation (2007–2011). Stockholm: Sida and authors; 2015 (https://cdn.sida.se/publications/files/sida61909en-evaluation-of-swedish-international-training-programme-itp-climate-change-mitigation-and-adaptation-2007-2011---final-report.pdf, accessed 6 February 2024).
18. Zwart R. Strengthening the results chain: synthesis of case studies of results-based management by providers. OECD Development Policy Papers No 7. August 2017. In: OECD ilibrary (https://www.oecd-ilibrary.org/docserver/544032a1-en.pdf?expires=1706198379&id=id&accname=guest&checksum=8661209554EF1F59676BEBBEEF12EC04, accessed 6 February 2024).
19. Humanitarian Engineering and Energy for Displacement (HEED). Theory of change. The HEED Project. 2018 (http://heed-refugee.coventry.ac.uk/theory-of-change/, accessed 3 October 2023).
20. Manager's guide to evaluation. In: Better Evaluation [website] (https://www.betterevaluation.org/frameworks-guides/managers-guide-evaluation/scope-evaluation/describe-theory-change, accessed 6 February 2024).
21. Vogel I. Review of the use of "Theory of Change" in international development: review report. UK Department for International Development; 2012 (https://www.theoryofchange.org/pdf/DFID_ToC_Review_VogelV7.pdf, accessed 3 October 2023).
22. Practical guide to evaluation for programme managers and evaluation staff. Geneva: World Health Organization; 2023 (https://cdn.who.int/media/docs/default-source/evaluation-office/final_the-practical-guide-on-evaluation-2023.pdf?sfvrsn=19b002e_3&download=true, accessed 6 February 2024).
23. Theory-based approaches to evaluation: concepts and practices. In: Government of Canada (website). 2021 (https://www.canada.ca/en/treasury-board-secretariat/services/audit-evaluation/evaluation-government-canada/theory-based-approaches-evaluation-concepts-practices.html (accessed 6 February 2024).

24. Mayne J. Useful theory of change models. Can J Program Eval. 2015;30.2:119–42.
25. Jones S. How to develop a theory of change for evaluation. In: EVAL Academy [website] (https://www.evalacademy.com/articles/how-to-develop-a-theory-of-change-for-evaluation, accessed 7 February 2024).
26. Guerrero I, Gokhale S, Fahsbender J. Scaling up development impact. 21 November 2023 (https://www.google.com/search?q=scaling+up+development+impact&oq=Scaling+up+deve&gs_lcrp=EgZjaHJvbWUqCggAEAAY4wIYgAQyCggAEAAY4wIYgAQyBwgBEC4YgAQyBwgCEAAYgAQyBggDEEUYOTIHCAQQABiABDIHCAUQABiABDIICAYQABgWGB4yCggHEAAYDxgWGB4yCAgIEAAYFhgeMggICRAAGBYYHqgCALACAA&sourceid=chrome&ie=UTF-8#ip=1, accessed 7 February 2024).
27. Evidence, policy, impact. WHO guide for evidence-informed decision-making. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/bitstream/handle/10665/350994/9789240039872-eng.pdf?sequence=1&isAllowed=y, accessed 3 October 2023).
28. Lam S, Dodd W, Wyngaarden S, Skinner K, Papadopoulos A, Harper SL. How and why are theory of change and realist evaluation used in food security contexts? A scoping review. Eval Program Plan. 2021;89:102008. https://www.sciencedirect.com/science/article/pii/S0149718921001038.
29. Callcut RA, Branson RD. How to read a review paper. Respir Care. 2009;54(10):1379–85.
30. Supporting the routine use of evidence during the policy-making process: a WHO checklist. Geneva: World Health Organization; 2023 (https://www.who.int/publications-detail-redirect/9789240056145, accessed 3 October 2023).
31. Lee L. Using theory of change? You need a champion. Mental Health Innovation Network; 2014 (https://www.mhinnovation.net/blogs/using-theory-change-you-need-champion, accessed 3 October 2023).
32. Santos WJ, Graham ID, Lalonde M, Demery Varin M, Squires JE. The effectiveness of champions in implementing innovations in health care: a systematic review. Implement Sci Commun. 2022;3(1):80. https://doi.org/10.1186/s43058-022-00315-0.
33. De Silva M, Lee L. Using theory of change in the development, implementation and evaluation of complex health interventions: a practical guide. London: The Centre for Global Mental Health at the London School of Hygiene & Tropical Medicine and The Mental Health Innovation Network; 2014 (https://www.medbox.org/document/using-theory-of-change-in-the-development-implementation-and-evaluation-of-complex-health-interventions-a-practical-guide, accessed 3 October 2023).
34. Implementing citizen engagement within evidence-informed policy-making: an overview of purpose and methods. Geneva: World Health Organization; 2022 (https://apps.who.int/iris/rest/bitstreams/1478266/retrieve, accessed 3 October 2023).
35. Samji S, Andrews M, Pritchett L, Woolcock M. PDIA toolkit. Building state capability. Cambridge, Mass: Center for International Development at Harvard University; 2018 (https://bsc.cid.harvard.edu/tools/toolkit/, accessed 3 October 2023).

36. Cochrane. PROGRESS-Plus. In: Cochrane Methods Equity. 2023 (https://methods.cochrane.org/equity/projects/evidence-equity/progress-plus, accessed 3 October 2023).
37. Ul Haq M, Dhamanaskar R, Tripp L, Rodgers J, Abelson J. Supporting equity-centred engagement: a step-by-step guide with tailored resources. Public and Patient Engagement Collaborative. Hamilton, Canada: McMaster University; 2023 (https://www.engagementinhealthpolicy.ca/supporting-equitycentred-engagement-guide, 3 October 2023).
38. Oxman AD, Hanney S, editors. SUPPORT Tools for evidence-informed health Policymaking (STP): guides. Health Res Policy Syst. 2009; 7(Suppl 1): S1. https://health-policy-systems.biomedcentral.com/articles/supplements/volume-7-supplement-1.
39. EVIPNet Europe. Introduction to EVIPNet Europe: conceptual background and case studies. Copenhagen: World Health Organization Regional Office for Europe; 2017 (https://www.who.int/europe/publications/m/item/conceptual-background-and-case-studies-introduction-to-evipnet-europe, accessed 3 October 2023).
40. Lavis JN, Wilson MG, Oxman AD, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 4: using research evidence to clarify a problem. Health Res Policy Syst. 2009;7(1):S4. https://doi.org/10.1186/1478-4505-7-S1-S4.
41. Evidence briefs for policy: using the integrated knowledge translation approach: guiding manual. Geneva: World Health Organization Regional Office for Europe; 2020 (https://apps.who.int/iris/handle/10665/337950, accessed 3 October 2023).
42. Langlois EV, Daniels K, Akl EA, editors. Evidence synthesis for health policy and systems: a methods guide. Geneva: World Health Organization; 2018 (https://ahpsr.who.int/publications/i/item/2018-10-08-evidence-synthesis-for-health-policy-and-systems-a-methods-guide, accessed 3 October 2023).
43. Hartley JE, McAteer J, Doi L, Jepson R. CARE: the development of an intervention for kinship carers with teenage children. Qual Soc Work. 2019;18(6):926–43.
44. Van Es M, Guijt I, Vogel I. Theory of change thinking in practice: a stepwise approach. Den Haag: Hivos; 2015 (https://hivos.org/assets/2020/10/hivos_toc_guidelines.pdf, accessed 3 October 2023).
45. Mintz S, Aldrete R, Mitchell C. Project management toolkit: achieving results that endure in transition societies. USAID: Booz Allen Hamilton; 2003 (https://pdf.usaid.gov/pdf_docs/Pnacy789.pdf, accessed 3 October 2023).
46. International Rescue Committee (IRC). The OEF: choose an outcome. [n.d.] (http://oef.rescue.org/#/outcomes?_k=o0xka0, accessed 3 October 2023).
47. Andrews M, Pritchett L, Woolcock M. Building state capability: evidence, analysis, action. UK: Oxford University Press; 2017 (https://bsc.cid.harvard.edu/publications/, accessed 3 October 2023).
48. Moberg J, Oxman AD, Rosenbaum S, Schünemann HJ, Guyatt G, Flottorp S et al. The GRADE Evidence to Decision (EtD) framework for health system and public health decisions. Health Res Policy Syst. 2018;16(1):45. https://doi.org/10.1186/s12961-018-0320-2.

49. Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M et al., editors. Cochrane handbook for systematic reviews of interventions. Cochrane Training. 2023 (https://training.cochrane.org/handbook/current, accessed 3 October 2023).
50. Tricco AC, Langlois EV, Straus SE, editors. Rapid reviews to strengthen health policy and systems: a practical guide. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/258698/9789241512763-eng.pdf, accessed 3 October 2023).
51. WHO Handbook for the development of normative products. Geneva: WHO; 2024 (In press).
52. Rehfuess EA, Stratil JM, Scheel IB, Portela A, Norris SL, Baltussen R. The WHO-INTEGRATE evidence to decision framework version 1.0: integrating WHO norms and values and a complexity perspective. BMJ Glob Health. 2019;4(Suppl 1):e000844. https://gh.bmj.com/content/4/Suppl_1/e000844.
53. Mintz S, Aldrete R, Mitchell C. Project management toolkit: achieving results that endure in transition societies. USAID: Booz Allen Hamilton; 2003 (https://pdf.usaid.gov/pdf_docs/Pnacy789.pdf, accessed 3 October 2023).
54. Systems thinking for health systems strengthening. Alliance for Health Policy and Systems Research, WHO; 2009 (update 2023) (https://evidence-impact.org/storage/165/Systems-Thinking-for-Health-Systems-Strengthening.pdf, accessed 8 February 2024).
55. Apgar M, Hernandez K, Ton G. Contribution analysis for adaptive management. Briefing note. USAID; 2020 (https://usaidlearninglab.org/system/files/resource/files/glam_-_contribution_analysis.pdf, accessed 8 February 2024).
56. Roza V, Martin C. Sexual and gender-based violence: road map for prevention and response in Latin America and the Caribbean. Washington, DC: Inter-American Development Bank, Gender and Diversity Division. Technical Note No. IDB-TN-02342; 2021 (https://publications.iadb.org/publications/english/document/Sexual-and-Gender-based-Violence-Road-Map-for-Prevention-and-Response-in-Latin-America-and-the-Caribbean.pdf, accessed 3 October 2023).
57. Mayne J, Johnson N. Using theories of change in the CGIAR Research Program on Agriculture for Nutrition and Health. Evaluation. 2015;21(4):407–28. (https://doi.org/10.1177/1356389015605198, accessed 3 October 2023).
58. United Nations Children's Fund (UNICEF). WCARO Technical Note # 2: the COVID-19 response theory of change. In: UNICEF Evaluation in UNICEF [website]. 2020 (https://www.unicef.org/evaluation/documents/wcaro-technical-note-2-covid-19-response-theory-change, accessed 3 October 2023).
59. International Rescue Committee (IRC). Women and girls are protected from and treated for the consequences of gender-based violence (GBV) [website]. Gender-based violence programme. [n.d.]. (http://oef.rescue.org/#/outcome/14?_k=8inj1s, accessed 3 October 2023).
60. European Commission: supporting tools. Context analysis – PESTEL. In: European Commission: EXACT External Wiki [website] (https://wikis.ec.europa.eu/pages/viewpage.action?pageId=50109048, accessed 8 February 2024).

61. Williams MJ. External validity and policy adaptation: a five-step guide to mechanism mapping. Oxford: Policy Memo, Blavatnik School of Government, Oxford University; 2017 (https://www.bsg.ox.ac.uk/research/publications/external-validity-and-policy-adaptation-0, accessed 3 October 2023).
62. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000;32(4):1008–15. https://pubmed.ncbi.nlm.nih.gov/11095242/.
63. Guide for planning long-term impact evaluations (LTIEs): utilizing the expertise of the Expanding the Reach of Impact Evaluation (ERIE) Program Consortium. United States Agency for International Development (USAID); 2018 (https://pdf.usaid.gov/pdf_docs/PA00T9HJ.pdf, accessed 3 October 2023).
64. Pasanen T, Barnett I. In: Institute of Development Studies [website]. Supporting adaptive management: monitoring and evaluation tools and approaches. Working paper 569. ODI; 2019 Dec (https://opendocs.ids.ac.uk/opendocs/handle/20.500.12413/15204, accessed 3 October 2023).
65. Monitoring and evaluation: some tools, methods, and approaches. Washington: The World Bank; 2004 (https://openknowledge.worldbank.org/handle/10986/23975, accessed 3 October 2023).
66. Chemicals and Waste Management Programme. Monitoring, evaluation and learning strategy and action plan. United Nations Environment Programme (UNEP); 2020 (https://wedocs.unep.org/handle/20.500.11822/35798, accessed 3 October 2023).
67. Hehenberger L, Harling A-M, Scholten P. A practical guide to measuring and managing impact. European Venture Philanthropy Association; 2015 (https://www.impacteurope.net/sites/www.evpa.ngo/files/publications/IMM_Guide_2015_EN.pdf, accessed 9 February 2024).
68. Handbook for monitoring and evaluation, first edition. Geneva: International Federation of Red Cross and Red Crescent Societies; 2002 (https://www.measureevaluation.org/resources/training/capacity-building-resources/basic-me-concepts-portuguese/IFRC_Monitoring%20and%20Evaluation%20handbook.pdf, accessed 9 February 2024).
69. WHO Evaluation practice handbook. Geneva: WHO; 2013 (https://cdn.who.int/media/docs/default-source/evaluation-office/who-evaluation-practice-handbook-2013.pdf?sfvrsn=2513394e_3&download=true, accessed 9 February 2024).
70. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65–76. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068522/.

Annex 1: Glossary

Terminology	Definition	Authors
Activity	Actions taken or work performed through which inputs, such as funds, technical assistance and other types of resources, are mobilized to produce specific outputs	UNEP, 2020 *(1)*; OECD, 2022 *(2)*
Adaptive management	A systematic process for continually improving management policies and practices by learning from the outcomes of previously employed policies and practices.	UNEP, 2020 *(1)*
	A structured management strategy that involves an ongoing process of working collaboratively and flexibly to learn, make decisions, test assumptions, and adjust actions on the basis of new information, lessons and changes in context.	OECD, 2022 *(2)*
Assumptions	Conditions and contextual factors that are assumed to exist and that are necessary for the intervention to work. Significant external factors or conditions that need to be present for the realization of intended results but are beyond the influence of the project and its partners. Assumptions are often positively formulated risks. (See also the concept of Drivers, below).	Taplin & Clark, 2012 *(3);* UNEP, 2020 *(1)*
	A set of (untested) factors and beliefs that form the basis of the intervention logic, and factors or risks, which affect its relevance, progress or success. Assumptions are the conditions necessary for the cause-and-effect relationships between the different levels of results (i.e. to move from activities to outputs, outputs to outcomes, and outcomes to impacts).	OECD, 2022 *(2)*
Baseline	The status of the indicator at the beginning of a programme or project that acts as a reference point against which progress or achievements can be assessed.	UNEP, 2020 *(1)*
	The conditions existing prior to an intervention or at the beginning of the period, against which changes can be measured, monitored and evaluated.	OECD, 2022 *(2)*
Change mechanisms	Causal steps or causal links that are expected to lead an intervention to achieve its intended outcomes. They refer to how each step of an intervention is expected to create the necessary conditions for the next steps to succeed.	Van Es et al., 2015 *(4)*; Mayne and Johnson, 2015 *(5)*
Drivers	Drivers are the significant external factors that, if present, are expected to contribute to the realization of the intended results. Drivers can be influenced by the project and its partners.	UNEP, 2020 *(1)*
Evaluation (continued on next page)	An evaluation is an assessment, conducted as systematically and impartially as possible, of an activity, project, programme, strategy, policy, topic, theme, sector, operational area or institutional performance. It analyses the level of achievement of both expected and unexpected results by examining the results chain, processes, contextual factors and causality using appropriate criteria such as relevance, effectiveness, efficiency, impact and sustainability.	

Terminology	Definition	Authors
Evaluation (continued)	An evaluation should provide credible, useful evidence-based information that enables the timely incorporation of its findings, recommendations and lessons into the decision-making processes of organizations and stakeholders.	UNEG, 2006 *(6)*
	Rigorous, science-based analysis of information about programme activities, characteristics, outcomes and impact that determines the merit or worth of a specific programme or intervention.	IHP & WHO, 2011 *(7)*
	The systematic and objective assessment of a planned, ongoing or completed intervention, its design, implementation and results. The aim is to determine relevance, coherence, effectiveness, efficiency, impact and sustainability. Evaluation also refers to the process of determining the worth or significance of an intervention.	OECD, 2022 *(2)*
Impact	Positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended.	UNEG, 2014 *(8)*
	The higher-level effects of an intervention's outcomes. The ultimate effects or longer-term changes resulting from the intervention. Such impacts can include intended and unintended, positive or negative higher-level effects.	OECD, 2022 *(2)*
	Long-term effects produced by an intervention, directly or indirectly, intended or unintended.	Taplin & Clark, 2012 *(3)*
Indicators	Quantitative or qualitative factor or variable of interest, related to the intervention and its results, or to the context in which an intervention takes place.	OECD, 2022 *(2)*
	Measurable and observable signals attached to each of the outcomes that verify whether an outcome has been reached. Indicators should clearly identify the subjects and objects of change, their quantity, the dimensions and the time span in which this should occur. They may be quantitative (e.g. number of citizens vaccinated) or qualitative (e.g. description of user's experience in hospital).	Taplin & Clark, 2012 *(3)*; UNEG, 2014 *(8)*
Inputs	The financial, human, and material resources used for the development of the intervention.	UNEG, 2014 *(8)*
	The financial, human, material (in-kind), and institutional (including technological and information) resources used for the intervention.	OECD, 2022 *(2)*
Interventions	The intentional activity or effort that is being evaluated (also called the evaluand or object of the monitoring or evaluation).	OECD, 2022 *(2)*
	Organized set of activities undertaken within a programme that leads to the desired outcomes.	Taplin & Clark, 2012 *(3)*

Terminology	Definition	Authors
Lessons learned	The new knowledge or understanding gained by the experience of implementing a project that is applicable to, and useful in, other similar contexts.	UNEP, 2020 *(1)*
	Generalization or extrapolation of findings and translation of analysis into relevant knowledge that supports decision-making, improves performance and promotes the achievement of better results in other settings (beyond the intervention being evaluated). Frequently, lessons highlight strengths or weaknesses in the preparation, design, and implementation of interventions that affect performance and results. A lesson may be positive, neutral or negative.	OECD, 2022 *(2)*
Long-term outcomes	The higher-order objectives or results to which a programme or project is intended to contribute.	UNEP, 2020 *(1)*
Logframe	A Logical Framework (logframe) is a tool for summarizing the project's intended results. It specifies project results, indicators and their baseline and target values. It also includes a milestone schedule to deliver the expected output(s) and/or achieve the intended result(s).	UNEP, 2020 *(1)*
	Management tool used to improve the design of interventions, most often at the project level. It involves identifying strategic elements (inputs, activities, outputs, outcomes, impacts) and their causal relationships, as well as indicators, and the assumptions or risks that may influence success and failure. It facilitates planning, execution, monitoring and evaluation of an intervention.	OECD, 2022 *(2)*
Logic model	A representation of a programme theory, usually in the form of a diagram.	Funnell & Rogers, 2011 *(9)*
Mechanism mapping	Systematic process of adaptation of a ToC through using empirical evidence to compare the assumptions of the ToC with the existing contextual conditions.	Williams, 2017 *(10)*
Monitoring	A continuous process of using systematic collection of data on project/programme parameters (e.g. expenditure, risk, milestone delivery, inclusive participation) to provide management with indications of the extent of progress against plans and targets.	UNEP, 2020 *(1)*
	A continuing process that involves the systematic collection or collation of data (on specified indicators or other types of information). Provides the management and other stakeholders of an intervention with indications of the extent of implementation progress, achievement of intended results, occurrence of unintended results, use of allocated funds and other important intervention and context-related information.	OECD, 2022 *(2)*

Terminology	Definition	Authors
Narrative	A summary of the theory that explains its overall logic and presents a case as to how and why the initiative is expected to work. A successful narrative should convey the theory's main elements easily and quickly to others.	Taplin & Clark, 2012 *(3)*
Outcomes	Outcomes represent the changes obtained due to the programme. Examples include changes in policy, behaviour, attitude, and knowledge. The short-term and medium-term effects of an intervention's outputs.	Taplin & Clark, 2012 *(3)*; UNEG, 2014 *(8)*
Outputs	The concrete products or services produced by the intervention. The products, capital goods and services that result from an intervention. Outputs may also include changes resulting from the intervention that contribute to the achievement of outcomes. Outputs include changes in knowledge, skills, or abilities produced by the activities.	UNEG, 2014 *(8)*
Primary research	Techniques of original data collection or research directly from the target respondents. Primary research is different from secondary research in that secondary research uses data or research that has already been collected. Primary research includes qualitative and quantitative research and can include surveys, focus groups, questionnaires, and interviews.	Oxford reference, (n.d.) *(11)*
Problem definition	Understanding of the problem that drives the need for an intervention.	McLaughlin & Jordan, 2015 *(12)*
Programme theory	An explicit theory of how an intervention is understood to contribute to its intended or observed outcomes.	Funnell & Rogers, 2011 *(9)*
Qualitative indicator	Verifiable indicators that use categories that can be ranked or compared to assess changes such as judgements, opinions, perceptions or attitudes.	UNEP, 2020 *(1)*
Quantitative indicator	Verifiable indicators that can be measured numerically, e.g. numbers, percentage, rate and ratio.	UNEP, 2020 *(1)*
Rapid systematic review	Type of literature review in which the steps of a systematic review are adapted to produce evidence in a shortened time frame.	Tricco et al., 2017 *(13)*
Rationale	Key beliefs that underlie why one precondition is a precondition for the next, and why you must do certain activities to produce the desired preconditions. Can be based on evidence or experience.	De Silva et al., 2014 *(14)*
Results	Results are intended changes in a state or condition that derive from a cause-and-effect relationship. Outputs, outcomes and impact are considered "results" (as opposed to inputs and activities). The outputs, outcomes or impacts (intended or unintended, positive or negative) of an intervention.	UNEP, 2020 *(1)* OECD, 2022 *(2)*

Terminology	Definition	Authors
Risks	Significant factors or conditions that may negatively affect a project.	UNEP, 2020 *(1)*
Stakeholders	Agencies, organizations, groups or individuals that have a direct or indirect interest in the problem and in the intervention.	UNEG, 2014 *(8)*
	Agencies, organizations, groups or individuals who have a direct or indirect interest in the intervention or its monitoring and evaluation.	OECD, 2022 *(2)*
Survey	Data collection tool used to gather information about individuals to learn about a more generalized phenomenon. It encompasses any measurement procedure that involves asking questions to individuals.	UNEG, 2014 *(8)*
Systematic review	Structured research process for literature review that applies rigorous and transparent methods to ensure that the results are reliable and meaningful to end users.	Aromataris & Munn, 2020 *(15)*
Targets	Measurement tool used to assess if outputs and outcomes are being achieved. A value that an indicator should reach by a specific date in the future.	UNEP, 2020 *(1)*
	An objective, usually quantitative, defined as a value on an established indicator. The target is generally set at the beginning of an intervention and is expected to be achieved by a specific point in time with available resources.	OECD, 2022 *(2)*
Theory of action	The ways in which programmes or other interventions are constructed to activate their theories of change.	Funnell & Rogers, 2011 *(9)*

Annex 2: Practical tools and other resources

Topic	Title	Reference
Actor and stakeholder analysis **Power analysis**	Hivos ToC guidelines – theory of change thinking in practice – chapter 8	Van Es et al., 2015 *(4)*
Gender analysis	Integrating human rights and gender equality in evaluations	UNEG, 2014 *(8)*
Building robust ToCs	Theory of change analysis: building robust theories of change	Mayne, 2017 *(16)*
Checklist for reporting ToC in public health interventions	Using theory of change to design and evaluate public health interventions: a systematic review	Breuer et al., 2016 *(17)*
Conduct an evidence-informed problem definition	Evidence Briefs for Policy. Using the integrated knowledge translation approach: guiding manual Evidence synthesis for health policy and systems: a methods guide	WHO, 2020 *(18)* Langlois et al., 2018 *(19)*
Deliberative dialogues	Deliberative dialogues as a strategy for system-level knowledge translation and exchange	Boyko et al., 2014 *(20)*
Delphi	Research guidelines for the Delphi survey technique	Hasson et al., 2000 *(21)*
Design solutions	"Phase 2 – Design the solution" (pp. 27–29). In: Evidence, policy, impact. WHO guide for evidence-informed decision-making	WHO, 2021 *(22)*
Evaluation	Norms and standards for evaluation UNEG ethical guidelines for evaluation Monitoring, evaluation and review of activities of the national health strategy RealWorld evaluation: working under budget, time, data, and political constraints	UNEG, 2008 *(6)* UNEG, 2008 *(23)* IHP & WHO, 2011 *(7)* Bamberger & Mabry, 2020 *(24)*
Evidence-informed decision-making	Evidence, policy, impact. WHO guide for evidence-informed decision-making	WHO, 2021 *(22)*
Evidence briefs for policy	Evidence Briefs for Policy. Using the integrated knowledge translation approach: guiding manual	WHO, 2020 *(18)*
Evidence-informed health policy-making	SUPPORT tools for evidence-informed health policymaking (STP)	Oxman & Hanney, 2009 *(25)*
MEL frameworks	Monitoring and evaluation: some tools, methods, and approaches Monitoring, evaluation and learning strategy and action plan	The World Bank, 2004 *(26)* UNEP, 2020 *(1)*

Topic	Title	Reference
Qualitative evidence synthesis	Qualitative evidence synthesis for complex interventions and guideline development: clarification of the purpose, designs and relevant methods	Flemming et al., 2019 *(27)*
Rapid reviews	Rapid reviews to strengthen health policy and systems: a practical guide	Tricco et al., 2017 *(13)*
Promote citizen participation in health policies	Implementing citizen engagement within evidence-informed policy-making: an overview of purpose and methods	WHO, 2022 *(28)*
Stakeholder meeting facilitation	Supporting the routine use of evidence during the policy-making process: a WHO checklist	WHO, 2023 *(29)*
Survey	Monitoring and evaluation: some tools, methods, and approaches	The World Bank, 2004 *(4)*
Systematic review	Cochrane handbook for systematic reviews of interventions version 6.4	Higgins et al., 2022 *(30)*
Knowledge translation	Chapters 2 and 3 of Evidence, policy, impact: WHO guide for evidence-informed decision-making	WHO, 2021 *(22)*
ToC adaptation to new contexts	External validity and policy adaptation: a five step guide to mechanism mapping	Williams, 2017 *(10)*
ToC and logic models, building and using	RealWorld evaluation. Chapter 10 Using logic models	Bamberger & Mabry, 2020 *(24)* McLaughlin & Jordan, 2015 *(12)*
ToC representation and logic models	Purposeful program theory: effective use of theories of change and logic models Chapter 9	Funnell & Rogers, 2011 (*9*)
ToC workshop planning/ToC building	Using theory of change in the development, implementation and evaluation of complex health interventions: a practical guide Purposeful program theory: effective use of theories of change and logic models. Chapter 6	De Silva & Lee, 2014 *(31)* Funnell & Rogers, 2011 *(9)*

Annex 3: ToC in action

In this annex, we present three final examples to demonstrate the ToC in action. Below, you can find the WHO's GPW13 ToC *(32)*, TDR's ToC *(33)*, and Project Superwoman's ToC *(34)*. Additional examples and other resources are also available on the webpage of the Center for Theory of Changes *(35)* and described in the article "Useful Theory of Change Models" *(36)*.

GPW13 ToC

The WHO General Programme of Work (GPW) is a strategic framework that outlines the Organization's priorities and goals for a specific period, typically spanning five years. This framework guides WHO's efforts in addressing global health challenges, setting out high-level objectives and targeted outcomes.

GPW13 (2019–2023) delineates WHO's approach to the pursuit of the health-related Sustainable Development Goals, primarily Goal 3 (to ensure healthy lives and foster well-being universally across all ages) and various other health metrics within additional Goals. It establishes the Triple Billion goal:

1. **ACHIEVING UNIVERSAL HEALTH COVERAGE**: 1 billion more people benefited from universal health coverage;
2. **ADDRESSING HEALTH EMERGENCIES**: 1 billion more people better protected from health emergencies;
3. **PROMOTING HEALTHIER POPULATIONS**: 1 billion more people enjoying better health and well-being *(37)*.

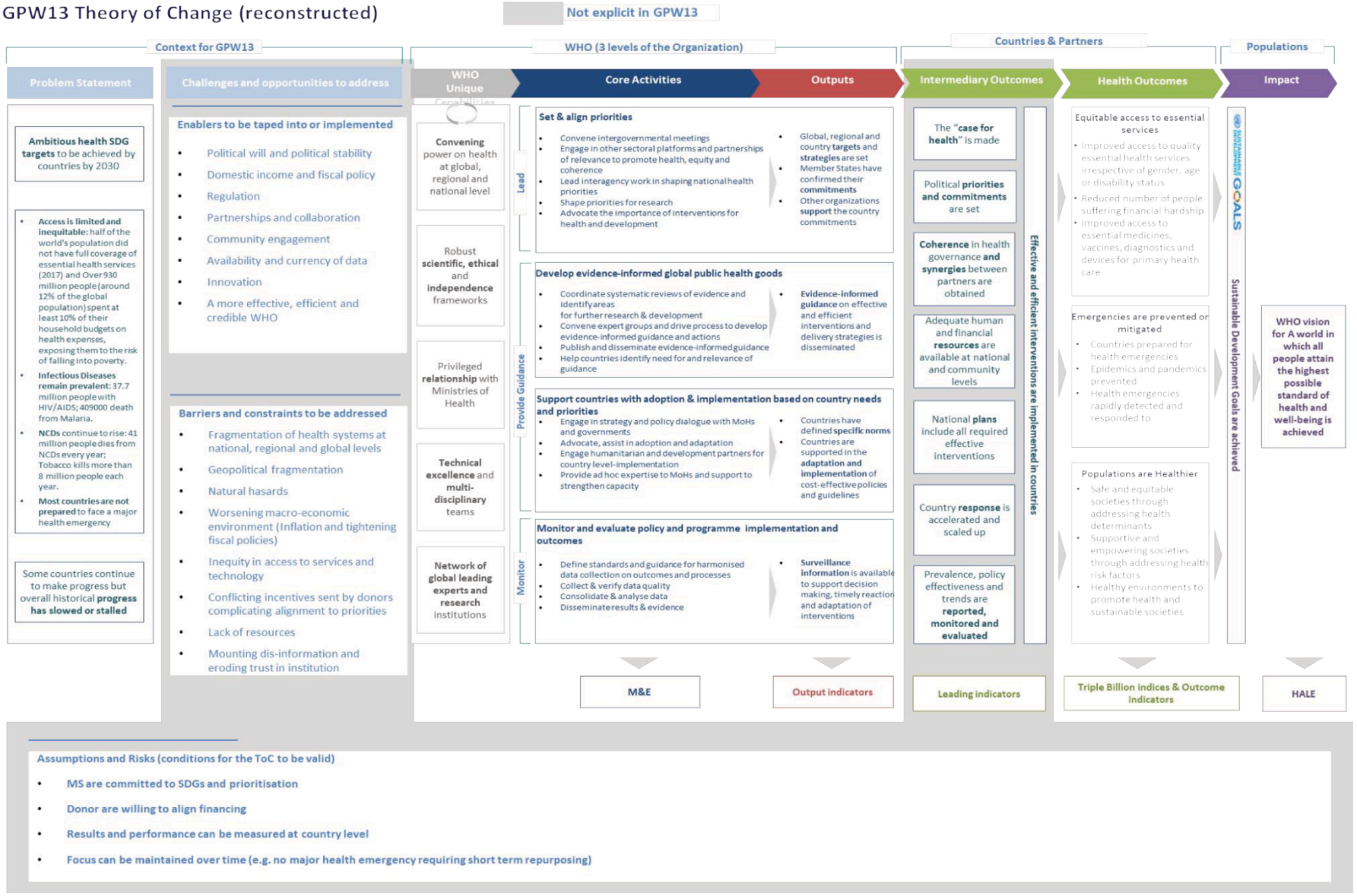
A recent effort to evaluate GPW13 *(38)* sought to develop a comprehensive ToC to demonstrate its rationale. The ToC was reformulated based on interviews, surveys, and extensive country analyses. This reconstruction (depicted in Fig. A3.1) underscores the need for contemplating key success factors, constraints, and risks to successfully fulfill the Triple Billion agenda.

TDR's ToC

The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and the World Health Organization (WHO). The Programme aims "to support effective and innovative global health research, through strengthening the research capacity of disease-affected countries, and promoting the translation of evidence into interventions that reduce the burden of infectious diseases and build resilience in the most vulnerable populations *(39)*."

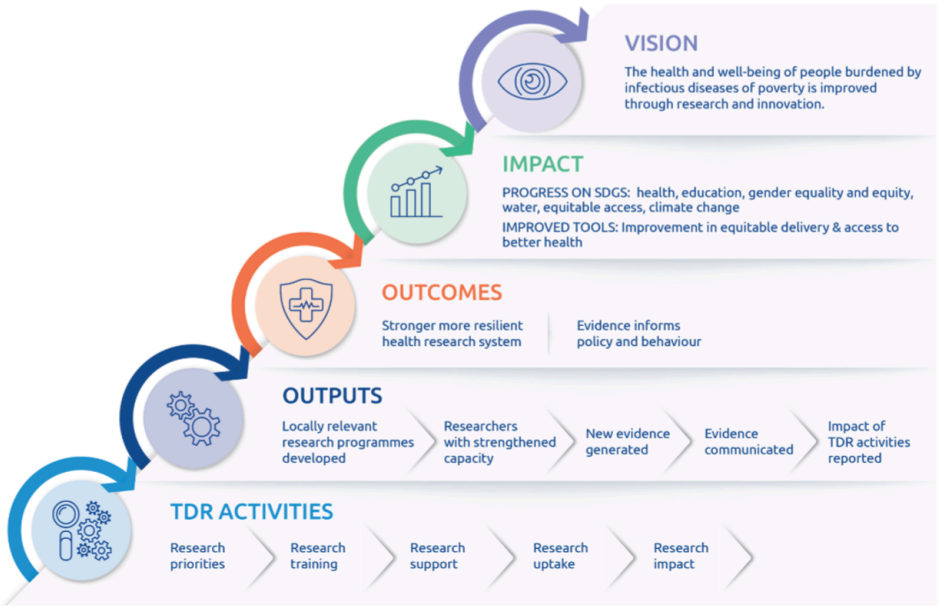
We present TDR's ToC (Fig. A3.2), in which its three approaches (research support, research training for capacity-strengthening, and global engagement) feed into outputs towards health impact.

Fig. A3.1: General Programme of Work 13 Theory of Change



Source: Evaluation of WHO's 13th General Programme of Work: report. Geneva: WHO: 2023 [prepublication version] *(38)*

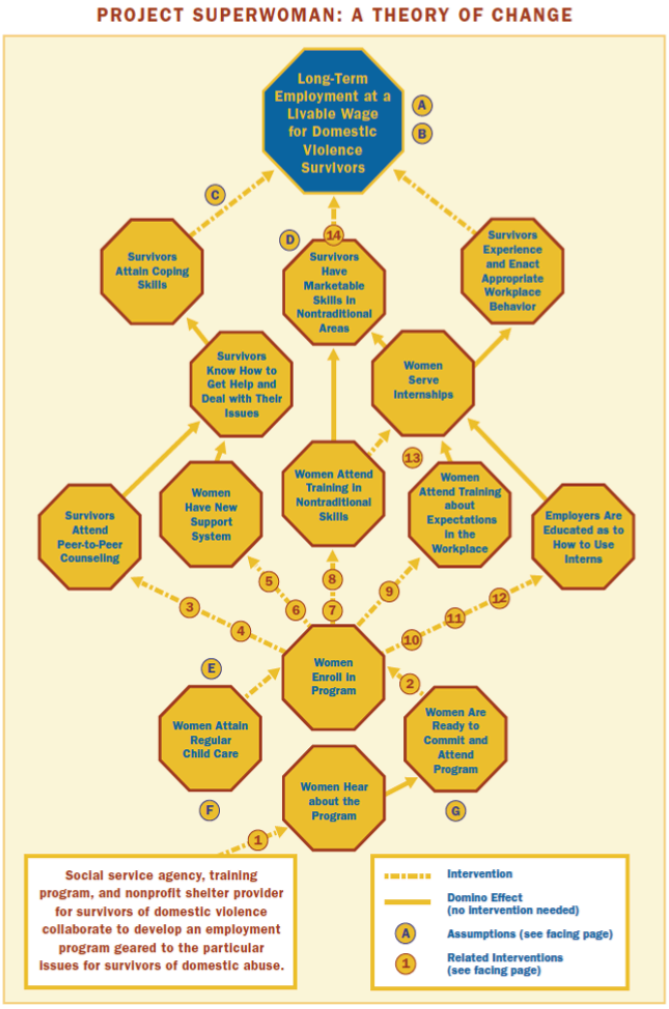
Fig. A3.2: TDR's ToC



Source: TDR's theory of change. In: Making an impact. TDR strategy 2024–2029: building local research solutions to improve global health. Geneva: WHO; 2023 *(33)*. Reproduced with permission from the World Health Organization.

Project Superwoman ToC

Fig. A3.3: Project Superwoman ToC



Source: Anderson AA. The community builder's approach to theory of change. A practical guide to theory development. New York: The Aspen Institute Roundtable on Community Change; 2009 *(34)*. Reproduced with permission from Aspen Institute.

Project Superwoman is a community-based programme designed to support women who have survived domestic violence and struggle to find stable employment at livable wages. It originated as a collaborative effort among a social service provider, an employment training centre, and a nonprofit shelter for women experiencing domestic violence. The programme aims to empower women by offering employment opportunities that provide financial stability and upward mobility (Fig. A3.3).

The long-term outcome is defined as the provision of long-term employment at livable wages for domestic violence survivors, as depicted in the upper section of the figure. In the lower section, the programme is briefly described as a social agency, training programme, and nonprofit shelter provider for domestic violence survivors. These entities collaborate to develop an employment programme tailored to address the unique challenges faced by survivors of domestic abuse. The middle segment of the figure outlines multiple pathways to achieve the desired change, which can be viewed as intermediate outcomes and preconditions leading to the final goal.

The project acknowledged the significance of providing training in nontraditional skills and engaging supportive employers. By offering programmes in electrical work, plumbing, carpentry, and building maintenance, Project Superwoman created opportunities for entry-level positions with the potential for career advancement. The initiative also placed emphasis on holistic support, recognizing that participants, often single mothers who have experienced abusive situations, require practical assistance and psychological support to thrive in the workforce. Addressing counterproductive adaptive behaviours is another crucial aspect. Participants with previous experiences in the courts, foster care, or the welfare system receive training in workplace expectations to overcome barriers to success. Strategic allocation of resources is another valuable lesson learned. The initiative focused on assisting with specific crises while implementing screening criteria to ensure that major issues such as substance abuse or foster care problems were addressed beforehand. By building on the available resources, Project Superwoman optimized its impact to empower women for sustainable employment opportunities.

The ToC approach here underscored the importance of locally adapted and contextually relevant plans developed in collaboration with stakeholders, including local policy-makers. The hypothesis is that such plans are more likely to be feasible, acceptable, and work within existing resource constraints. Additionally, it facilitated the dissemination of information about the intervention, as the visual map serves as a useful tool to describe the key components and outcomes. It also assisted other researchers in understanding how the intervention is set up for success and supported advocacy efforts with policy-makers to scale up successful interventions.

Annex 4: Methods for the development of the guide

To create this guide, the Evidence to Policy and Impact Unit of the Research for Health Department, Science Division at WHO, and the Veredas Institute (commissioned supplier) collaborated with numerous experts and stakeholders (listed in the Acknowledgements section of this Guide). The methodology utilized for the development of the guide contained the following steps:

1. Development and publication of a rapid systematic review *(40)*, with the following research questions: (i) "What are the available tools, methods, and recommendations to systematically incorporate research evidence into the development and adaptation of theories of change in the health sector?" and (ii) "What are the main principles, processes, and practical steps recommended by the literature on how to systematically incorporate research evidence into the development and adaptation of theories of change in the health sector?" This rapid review provided the conceptual framework for this guide, a first version of the stages relevant for evidence integration into ToCs, and a first map of the methods used for evidence integration into ToCs.
2. Collecting supplementary resources on ToC development based on expert recommendations and institutional website searches.
3. Based on the rapid systematic review and these additional resources, a first draft of the Guide was developed.
4. The draft was subsequently reviewed by an Editorial Board. The Board comprised four members, with balance over the following dimensions: gender, region, and practitioners and scholars. The Board conducted two rounds of revision of the guide. The first round included a meeting to allow open debate about the scope of the draft. The second round of revision was conducted through written feedback.
5. Two rounds of the draft were reviewed by two adult learning experts.
6. Simultaneously, along with the second round of revision by the Editorial Board and the adult learning experts, the guide was also reviewed by five independent peer-reviewers who were experts in ToC, and nine expert users, with proven experience in working with the tool.
7. Finally, the draft was submitted to a final round of revision by eight experts.

Annex references

1. Chemicals and Waste Management Programme. Monitoring, evaluation and learning strategy and action plan. United Nations Environment Programme (UNEP); 2020 (https://wedocs.unep.org/handle/20.500.11822/35798, accessed 3 October 2023).
2. Glossary of key terms in evaluation and results-based management, second edition (prepublication version). Paris: Organisation for Economic Co-operation and Development; 2022 (https://one.oecd.org/document/DCD/DAC/EV(2022)2/en/pdf, accessed 9 February 2024).
3. Taplin DH, Clark H. Theory of change basics: a primer on theory of change. New York, NY: ActKnowledge; 2012 (https://alnap.org/help-library/resources/theory-of-change-basics-a-primer-on-theory-of-change/#:~:text=Theory%20of%20change%20is%20a,graphically%20in%20a%20causal%20framework., accessed 2 October 2023).
4. Van Es M, Guijt I, Vogel I. Theory of change thinking in practice: a stepwise approach. Den Haag: Hivos; 2015 (https://hivos.org/assets/2020/10/hivos_toc_guidelines.pdf, accessed 3 October 2023).
5. Mayne J, Johnson N. Using theories of change in the CGIAR Research Program on Agriculture for Nutrition and Health. Evaluation. 2015;21(4):407–28. (https://doi.org/10.1177/1356389015605198, accessed 3 October 2023).
6. Norms and standards for evaluation. 2016. In: United Nations Evaluation Group (UNEG) [website] (https://www.unevaluation.org/document/detail/1914, accessed 9 February 2024).
7. International Health Partnership (IHP), World Health Organization (WHO). Monitoring, evaluation and review of national health strategies: a country-led platform for information and accountability. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/handle/10665/85877, accessed 3 October 2023).
8. Integrating Human Rights and Gender Equality in Evaluations. New York: United Nations Evaluation Group (UNEG); 2014 (https://www.unevaluation.org/uneg_publications/integrating-human-rights-and-gender-equality-evaluations, accessed 3 October 2023).
9. Funnell SC, Rogers PJ. Purposeful program theory: effective use of theories of change and logic models. San Francisco: Wiley; 2011 (http://au.wiley.com/WileyCDA/WileyTitle/productCd-0470478578.html, accessed 6 February 2024).
10. Williams MJ. External validity and policy adaptation: a five-step guide to mechanism mapping. Oxford: Policy Memo, Blavatnik School of Government, Oxford University; 2017 (https://www.bsg.ox.ac.uk/research/publications/external-validity-and-policy-adaptation-0, accessed 3 October 2023).
11. Oxford Reference [place unknown]: Oxford University Press [Internet]. [n.d.]. (https://www.oxfordreference.com/view/10.1093/oi/authority.20110803100345447, accessed 3 October 2023).

12. McLaughlin JA, Jordan GB. Using logic models. Chapter 3. In: Handbook of practical program evaluation. John Wiley & Sons, Ltd; 2015:62–87 (https://onlinelibrary.wiley.com/doi/abs/10.1002/9781119171386.ch3, accessed 3 October 2023).
13. Tricco AC, Langlois EV, Straus SE, editors. Rapid reviews to strengthen health policy and systems: a practical guide. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/258698/9789241512763-eng.pdf, accessed 3 October 2023).
14. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C et al. Theory of change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials. 2014;15:267.
15. Aromataris E, Munn Z. Chapter 1: JBI systematic reviews. In: Aromataris E, Munn Z, editors. JBI manual for evidence synthesis. JBI; 2020 (https://synthesismanual.jbi.global; https://doi.org/10.46658/JBIMES-20-02, accessed 3 October 2023).
16. Mayne J. Theory of change analysis: building robust theories of change. Can J Program Eval. 2017;32(2):155–73. https://doi.org/10.3138/cjpe.31122.
17. Breuer E, Lee L, De Silva M, Lund C. Using theory of change to design and evaluate public health interventions: a systematic review. Implement Sci. 2016;11(1):63. https://doi.org/10.1186/s13012-016-0422-6.
18. Evidence briefs for policy: using the integrated knowledge translation approach: guiding manual. Geneva: World Health Organization Regional Office for Europe; 2020 (https://apps.who.int/iris/handle/10665/337950, accessed 3 October 2023).
19. [1]Langlois EV, Daniels K, Akl EA, editors. Evidence synthesis for health policy and systems: a methods guide. Geneva: World Health Organization; 2018 (https://ahpsr.who.int/publications/i/item/2018-10-08-evidence-synthesis-for-health-policy-and-systems-a-methods-guide, accessed 3 October 2023).
20. Boyko JA, Lavis JN, Dobbins M. Deliberative dialogues as a strategy for system-level knowledge translation and exchange. Healthc Policy. 2014;9(4):122–31.
21. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000;32(4):1008–15. https://pubmed.ncbi.nlm.nih.gov/11095242/.
22. Evidence, policy, impact. WHO guide for evidence-informed decision-making. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/bitstream/handle/10665/350994/9789240039872-eng.pdf?sequence=1&isAllowed=y, accessed 3 October 2023).
23. UNEG ethical guidelines for evaluation. New York: United Nations Evaluation Group (UNEG); 2008 (https://www.unevaluation.org/uneg_publications/uneg-ethical-guidelines-evaluation, accessed 3 October 2023).
24. Bamberger M, Mabry L. RealWorld evaluation: working under budget, time, data, and political constraints. Thousand Oaks, California: SAGE Publications, Inc.; 2020 (https://methods.sagepub.com/book/realworld-evaluation-3e, accessed 3 October 2023).
25. Oxman AD, Hanney S, editors. SUPPORT Tools for evidence-informed health Policymaking (STP): guides. Health Res Policy Syst. 2009; 7(Suppl 1): S1. https://health-policy-systems.biomedcentral.com/articles/supplements/volume-7-supplement-1.

26. Monitoring and evaluation: some tools, methods, and approaches. Washington: The World Bank; 2004 (https://openknowledge.worldbank.org/handle/10986/23975, accessed 3 October 2023).
27. Flemming K, Booth A, Garside R, Tunçalp Ö, Noyes J. Qualitative evidence synthesis for complex interventions and guideline development: clarification of the purpose, designs and relevant methods. BMJ Glob Health. 2019;4(Suppl 1):e000882. https://gh.bmj.com/content/4/Suppl_1/e000882.
28. Implementing citizen engagement within evidence-informed policy-making: an overview of purpose and methods. Geneva: World Health Organization; 2022 (https://apps.who.int/iris/rest/bitstreams/1478266/retrieve, accessed 3 October 2023).
29. Supporting the routine use of evidence during the policy-making process: a WHO checklist. Geneva: World Health Organization; 2023 (https://www.who.int/publications-detail-redirect/9789240056145, accessed 3 October 2023).
30. Higgins J, Thomas J, Chandler J, Cumpston M, Li T, Page M et al., editors. Cochrane handbook for systematic reviews of interventions. Cochrane Training. 2023 (https://training.cochrane.org/handbook/current, accessed 3 October 2023).
31. De Silva M, Lee L. Using theory of change in the development, implementation and evaluation of complex health interventions: a practical guide. London: The Centre for Global Mental Health at the London School of Hygiene & Tropical Medicine and The Mental Health Innovation Network; 2014 (https://www.mhinnovation.net/sites/default/files/downloads/resource/ToC_A%20Practical%20Guide.pdf, accessed 3 October 2023).
32. Evaluation of WHO's 13th General Programme of Work: evaluation brief. Geneva: WHO; 2024 (https://cdn.who.int/media/docs/default-source/evaluation-office/gpw13-evaluation-brief_jan2024.pdf?sfvrsn=c8464521_3&download=true, accessed 9 February 2024).
33. TDR's theory of change. In: Making an impact. TDR strategy 2024–2029: building local research solutions to improve global health. Geneva: WHO; 2023 (https://tdrstrategy.org/making-an-impact/, accessed 9 February 2024).
34. Anderson AA. The community builder's approach to theory of change. A practical guide to theory development. New York: The Aspen Institute Roundtable on Community Change; 2009 (https://developmenteducation.ie/resource/the-community-builders-approach-to-theory-of-change-a-practical-guide-to-theory-development/, accessed 3 October 2023).
35. Center for Theory of Change. Publications [website]. Theory of Change Community (https://www.theoryofchange.org/library/publications/, accessed 3 October 2023).
36. Mayne J. Useful theory of change models. Can J Program Eval. 2015;30.2:119–42.
37. Promote health, keep the world safe, serve the vulnerable. Thirteenth General Programme of Work 2019–2023. Geneva: WHO; 2019 (https://iris.who.int/bitstream/handle/10665/324775/WHO-PRP-18.1-eng.pdf?sequence=1&isAllowed=y, accessed 9 February 2024).

38. Evaluation of WHO's 13th General Programme of Work: report. Geneva: WHO: 2023 [prepublication version] (https://cdn.who.int/media/docs/default-source/evaluation-office/evaluation-report-gpw13.pdf?sfvrsn=215b2a79_4&download=true, accessed 9 February 2024).
39. UNICEF, UNDP, World Bank, WHO. TDR: for research on diseases of poverty (website) (https://tdr.who.int/about-us, accessed 10 February 2024).
40. Romão DMM, Setti C, Arruda LHM, de Melo RC, de Araujo BC, Tan AR et al. Integration of evidence into theory of change frameworks in the healthcare sector: a rapid systematic review. PLoS One. 2023;18(3):e0282808. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0282808.

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