

Gavi MICs Approach Theory of Change Narrative

Introduction

The Middle-Income Countries (MICs) Approach Theory of Change (ToC) presents the core of the MICs Approach. It sets out the logical pathways through which the key intermediate outcomes that the Approach seeks to achieve will lead to a longer-term set of outcomes that meet the objectives of the MICs Approach, and contribute overall to Gavi's goals for 5.0. The ToC will be used as a blueprint for the MICs Approach, helping to shape and assess potential investments, as well as to inform measurement of results, Gavi contribution, and accountability to delivering on these outcomes. The original ToC was developed in consultation with partners, CSOs, and relevant teams across the Secretariat (e.g., those working on the zero-dose agenda; Maintain, Restore, and Strengthen; Leadership, Management, and Coordination; Civil Society and Community Engagement) and has since been updated to reflect the refined approach. It is also aligned with, and will support the achievement of, the strategic priorities of the [IA2030 MICs Annex](#).

The driving force behind the MICs Approach is the need to address intra- and inter-country inequities. Thus, taking an equity lens throughout, the MICs Approach has two key objectives: (i) to drive the sustainable introduction of key missing vaccines in both former- and select never-Gavi eligible countries (the "new vaccine introduction objective"); and, (ii) to prevent backsliding in vaccine coverage in former Gavi-eligible countries (the "backsliding objective").

While the ToC sets forth overarching intervention areas, it specifically does not articulate explicit activities that contribute toward the intermediate and long-term outcomes due to the heterogeneity of MICs and the flexibility required to respond to country-specific needs. Gavi, partners and countries will work together to identify and prioritise the most relevant and impactful activities, in their contexts, that will make a clear contribution to the outcomes in the ToC. It is not expected that every country will prioritise every intermediate outcome in the ToC: each country's area of focus will depend on the local context and evidence-based analysis of need. It is also not expected that Gavi will necessarily fund activities against each Intermediate Outcome. Only those activities that can demonstrably address a clearly identified need and deliver a meaningful contribution to the desired outcomes of the MICs Approach will be funded.

Gavi 5.0 goals and impact

The MICs Approach contributes to Gavi's overall intended impact of leaving no one behind with immunisation. Specifically, the MICs Approach is expected to contribute substantively to Gavi 5.0's Strategic Goal 3: improved sustainability of country immunisation programmes. Both MICs objectives, preventing and mitigating backsliding and supporting sustainable new vaccine introductions, advance immunisation programme sustainability. Secondly, the MICs Approach contributes to Gavi 5.0 Goal 1, introduction and scale up of vaccines, as well as Goal 2, strengthening health systems to increase equity in immunisation, given the strong equity lens of the MICs Approach.

Objectives and long-term outcomes

New vaccine introduction objective

Long-term outcome 1 - PCV, rotavirus and HPV vaccines sustainably introduced in national immunisation programmes: Despite higher domestic immunisation investments on average, MICs lag behind in critical vaccine introductions, posing a significant threat to intra-country equity. Further, while these vaccines are available in many never-Gavi eligible countries, they are often only accessible through the private sector to those able to pay. Therefore, the children with the greatest need – the poorest and most vulnerable – are least able to access these life-saving vaccines. This presents a clear intra-country inequity concern. Against this backdrop, the intended long-term outcome under the new vaccine introduction objective is to *sustainably introduce PCV, rotavirus and HPV vaccines in national immunisation programmes* in former- and never-Gavi eligible countries eligible under the MICs Approach. This outcome has an equity lens: the MICs Approach will seek to promote equitable access to PCV, rotavirus and HPV vaccines across and within countries. Moreover, it has a specific zero-dose lens: countries supported through the MICs Approach will be encouraged to explore the ways in which new vaccine introductions can be utilised as an opportunity to identify and reach zero-dose children and missed communities.

Backsliding objective

Long-term outcome 2 - Immunisation system performance is maintained, sustainable, and resilient to shocks and stresses: Beyond addressing the immediate risks of backsliding brought on by the pandemic, the MICs approach also seeks to prevent any future backsliding among former-Gavi countries, protecting the legacy of Gavi's investments and ensuring immunisation system performance is maintained and sustainable. The second intended long-term outcome under the backsliding objective is thus to ensure *immunisation system performance is maintained, sustainable, and resilient to shocks and stresses*. If the MICs Approach is successful, we will see coverage rates and immunisation system performance stable (or potentially even increasing) over time. This outcome will also include an equity lens: as the MICs Approach supports immunisation systems to be resilient to shocks and stresses, it will help to ensure that services are maintained to the most vulnerable and hardest to reach, who would likely be the first to see disruptions when the system comes under strain.

Long-term outcome 3 - Coverage rates restored, including by reaching zero-dose children: Before the pandemic, the Alliance recognised the risk of backsliding in former-Gavi countries, some of whose immunisation systems were not sufficiently strong and sustainable to maintain the gains achieved through Gavi support following transition. The COVID-19 pandemic tested the resilience of these systems, and in fact caused backsliding in several former-Gavi countries. There continue to be former-Gavi countries in which coverage rates have dropped or where despite rebounds, there is still a need to make up for children missed during drops in coverage. In these countries, there is a need to *mitigate the backsliding* that has occurred to restore coverage rates to pre-pandemic levels. Thus, the first intended long-term outcome under the backsliding objective is to *restore coverage rates in former-Gavi countries, including by reaching zero-dose children*. Importantly, this outcome has an equity, and specifically a zero-dose, lens: the MICs

Approach will seek to restore coverage rates by, where feasible, starting at the periphery, with those who were never reached in the first place, with the intended outcome of reaching zero-dose children in addition to those who were missed due to COVID-19. Given the urgency of reversing drops in coverage, this long-term outcome was the initial priority of the MICs Approach. Note that it is relevant only in countries where backsliding has occurred and where targeted interventions are deployed to mitigate drops in coverage.

Intermediate outcomes

Four of the intermediate outcomes will contribute toward each of the long-term outcomes, ensuring that the key foundations are in place to sustainably and equitably introduce new vaccines, sustain immunisation performance, and restore coverage rates in countries that have experienced backsliding. The MICs Approach will seek to build and maintain *community demand for immunisation services*, including new vaccines, by countering vaccine hesitancy and restoring community confidence in immunisation services. It will also look to strengthen the *institutional capacities* necessary to plan and deliver equitable immunisation programmes as a platform for broader primary healthcare delivery. These institutional capacities could be cross-cutting in nature (e.g., strategic planning for National Immunisation Strategies, evidence-based decision making processes for new vaccine introductions, data access and analysis, EPI management capacity), or specific to key systems (e.g., information systems), depending on where the largest gaps exist in a given MIC context and based on diagnoses of key barriers. The MICs Approach will also seek to ensure *sufficient, sustained, and reliable domestic resources for routine immunisation programmes*, so that financing is mobilised, budgeted, secured, and reliably disbursed toward both new vaccine introductions and the strengthening of the routine immunisation system. Finally, the MICs Approach will seek to achieve *political commitment and accountability* for equitable routine immunisation, ensuring it is put and kept high on the political agenda. Note that these four intermediate outcomes are focused on the broader immunisation ecosystem, i.e. not just on zero-dose and missed children, but all do have an explicit equity lens, seeking to ensure new vaccine introductions as well as immunisation system performance are sustainable and equitable, with commitment, resources, and capacity to serve those who are often left behind.

Two intermediate outcomes contribute further toward the attainment of long-term outcome 1, the 'sustainable introduction of PCV, rotavirus and HPV vaccines in national immunisation programmes'. The MICs Approach will seek to create a more favourable environment for *sustainable access to PCV, rotavirus and HPV vaccines*, including sustainable pricing. In the context of new vaccine introductions, the MICs Approach will also support the *identification and targeting of zero-dose children*, recognising this as an opportunity to ensure that new vaccines, as well as routine immunisation services more broadly, reach the most vulnerable children and communities.

Similarly, two intermediate outcomes make additional contributions toward achieving long-term outcome 3, the 'restoration of coverage rates, including by reaching zero-dose children and missed communities'. The MICs Approach will look to support the *restoration*

of routine immunization services¹, including time-bound reinforcement where needed to boost reach and catch up those who were missed, either due to COVID-19 or due to more systemic exclusion. While seeking to restore and reinforce immunisation services, The MICs Approach will also support the *identification and targeting of zero-dose children*, helping to restore coverage rates overall, and to extend the reach of services to zero-dose children and missed communities. Associated investments will include and be informed by work to quantify and map both those missed due to COVID-19 disruptions and zero-dose children. It is expected that interventions draw heavily from Gavi's Maintain, Restore, and Strengthen guidance and approaches to identifying zero-dose children.

The intermediate outcomes necessarily support and reinforce one another – for example, political commitment can help to mobilise domestic resources, which can in turn help to strengthen institutional capacities, restore demand, identify zero-dose children, and restore and reinforce routine immunisation services. Strengthened institutional capacities can help to ensure sufficient, sustained, and efficiently used domestic resources.

Note that it is not expected that every country will prioritise every intermediate outcome. As described below, it is expected that countries will prioritise intermediate outcomes, and activities to attain each outcome based on individual country context and evidence-based analysis to identify gaps and inform priorities.

Modalities and country eligibility

Each long-term outcome, and the corresponding intermediate outcomes that contribute to it, will leverage a different set of tools and modalities that fall within two overarching intervention areas: *strengthen the enabling environment* and *provide responsive, targeted and catalytic tools*. Support will be differentiated, with type and intensity of engagement to vary based on need.

The MICs Approach is first comprised of a series of Foundational Building Blocks, investments made primarily to build and strengthen the enabling environment. The investments will contribute toward all three of the long-term outcomes, to *sustainably and equitably introduce new vaccines*, to *restore coverage rates*, and to *maintain immunisation system performance*. The tools and modalities will be focused on advocacy to galvanise political commitment, regional and multi-country Technical Assistance, as well as peer-to-peer learning and knowledge sharing. While all countries eligible under the MICs Approach will benefit from efforts to build and strengthen the broader enabling environment, investments focused on restoring immunisation coverage and maintaining immunisation system performance will be specifically tailored to former-Gavi countries.

The Foundational Building Blocks are complemented by Responsive and Catalytic Tools. These tools leverage the momentum generated by the Foundational Building Blocks by delivering country-specific, targeted actions toward achieving the MICs Approach

¹ See here for WHO recommended list of routine immunisations: https://cdn.who.int/media/docs/default-source/immunization/immunization_schedules/immunization-routine-table1.pdf?sfvrsn=c7de0e97_4&download=true.

objectives. To *sustainably and equitably introduce new vaccines*, support will be available through several channels for countries eligible under the MICs Approach, including:

- Vaccine Introduction Assistance comprised of both Technical Assistance via relevant core and expanded partners and flexible, one-off support for costs that are traditionally unfunded or challenging to fund;
- In partnership with UNICEF Supply Division and PAHO Revolving Fund, access to pooled procurement mechanisms as well as support to help alleviate barriers to participation (e.g., those related to pre-financing); and,
- Vaccine Catalytic Financing for the cost of half the first birth or target cohort to help secure commitment and sufficient domestic resources for new vaccine introductions.

It should be noted that support is not guaranteed, but rather based on a clear articulation of needs and specific barriers standing in the way of sustainable and equitable new vaccine introductions. The final component within the Responsive and Catalytic Tools is specific to the long-term outcome to *restore coverage rates*. These investments are focused on select former-Gavi countries with significant and sustained drops in coverage. The MICs Approach will deploy Targeted Interventions in these countries, which allow for the reinforcement of routine immunisation services and specific efforts to identify, target, and reach zero-dose children.

How this will be used to shape activities

Given the heterogeneity of MICs, the Theory of Change specifically does not articulate specific activities that contribute towards these intermediate and long-term outcomes, to allow space for countries to self-define and prioritize which activities are most relevant in their contexts, depending on where focus is most needed. Gavi will work with countries and partners, as part of the application process and part of MICs support, to identify the causes of backsliding in different country contexts and to identify and prioritise interventions to address them to contribute to the outcomes listed in the ToC.

As they explore opportunities for financing under the MICs Approach and propose specific activities to be funded, countries will need to consider their own strategies and objectives; where these overlap with MICs objectives and outcomes; and where there are otherwise unfunded, needed activities that contribute to both country-level and MICs objectives. They will also need to map potential partners and consider who is best placed to carry out planned activities. The shaping of activities will thus be a co-creation process among the country, the Alliance, and expanded partners.

It is not expected that Gavi-funded activities in a given MIC will contribute to every intermediate outcome in the ToC, nor that every country will prioritize the same types of activities to achieve the overall outcome; rather, it is expected that countries will diagnose and prioritize key gaps to identify where MICs support would be highest value. Gavi support will be targeted, will vary by country, and will be focused on where Gavi can add value relative to other actors and existing activities in these contexts. The MICs ToC thus creates a framework for shaping and assessing potential interventions, but does not

prescribe which activities can or cannot be funded. More detailed guidelines and application materials support countries in shaping their requests for support.

Assumptions

The Theory of Change rests on several assumptions, which will be monitored to understand whether the logical pathways through which the MICs Approach seeks to achieve its intended impact are valid. These assumptions are:

- Clarity on drivers of backsliding and barriers to sustainable new vaccine introductions in different contexts
- Targeted MICs have a sufficient foundation of immunisation infrastructure that can be built upon by the MICs Approach
- Countries have available domestic resources for routine immunisation
- Relevant partners, with the necessary technical skills, are available to support countries to develop and implement effective and efficient plans and strategies to achieve MICs Approach outcomes
- Countries are willing and able to prioritise routine immunisation, including new vaccine introductions and the zero-dose agenda, amid the ongoing impact of the pandemic
- Communities are open to efforts to rebuild trust in routine immunisation programmes
- Interventions lead to more sustainable PCV, rotavirus and HPV vaccine prices for MICs than could otherwise be achieved