



# A New Playbook for Gavi: Advancing Equitable and Sustainable Immunization in an Evolving Global Landscape

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This paper is a draft and may be revised following the Gavi December 2023 board meeting. It is part of a series of research and analysis on the future of Gavi. For more, visit: <https://www.cgdev.org/priorities-policy-options-gavi-vaccine-alliance>.

## Key Takeaways

Several imminent disruptions are exerting pressure on Gavi’s ability to deliver results across three primary levers: new vaccine introductions; increasing equitable immunization coverage; and country eligibility. For Gavi to be as successful going forward as it has been to date, its leadership and board need to reevaluate and adjust its operational model.

For the upcoming 2026–2030 strategic period (known as “Gavi 6.0”), Gavi should adopt a new playbook to leverage its strengths, mitigate the impacts of disruptions associated with the three levers, and enable greater agility and effectiveness in Gavi’s model going forward. We offer a series of policy recommendations for consideration by Gavi’s board for implementation during the next strategic period and beyond. These include:

1. incorporating “life course platform building” as an explicit objective for Gavi 6.0;
2. replacing existing financing arrangements with an envelope financing approach that is driven by local priorities;
3. recalibrating the global-regional balance in vaccine manufacturing and procurement;
4. creating a mechanism across Gavi and other global health initiatives to assure integrated approaches to disease control that optimize value for money and simplify implementation for countries;
5. establishing a stand-alone subsidiary that operates in fragile and conflict-affected settings with high-risk appetite;
6. leveraging Gavi’s experience, including in market shaping, to accelerate innovations for immunization systems and primary health care more broadly; and
7. revisiting its eligibility policy to better align with countries’ ability to pay and disease burdens.

## Introduction

Since its launch in 2000, Gavi, the Vaccine Alliance (Gavi) has made significant progress in its mission to “increase equitable and sustainable use of vaccines,” including by supporting immunizations for more than one billion children and contributing to the prevention of more than 16 million future deaths.<sup>1</sup> Yet, even before the COVID-19 pandemic, an evolving global landscape—marked by rapid urbanization, increasing vaccine hesitancy, a rise in complex emergencies and protracted displacement, shifting macroeconomic trends, and added pressure on aid budgets from wars and climate change—was impeding countries’ efforts to sustain and expand immunization coverage.<sup>2</sup>

The pandemic further set back global immunization efforts, with historic levels of backsliding marked by an increase in un- and under-vaccinated children. As countries continue to recover from the pandemic, increasingly face fiscal challenges, and embrace growing regionalism, among other trends, Gavi needs to adopt a new playbook to maximize impact and remain fit-for-purpose in its next five-year strategic period (2026-2030) and beyond.

Gavi’s impact is—and will be—a function of how well it delivers across three primary levers. First, Gavi facilitates the *introduction of new and underused vaccines* in eligible countries. Second, alongside adding vaccines to country portfolios, Gavi helps increase *equitable immunization coverage*. Third, *country eligibility* determines Gavi’s geographic reach with big implications for overall impacts on global immunization coverage and vaccine preventable disease burden.

In this note, we examine Gavi’s track record across these three levers and take stock of the current and anticipated challenges it will face on each front. We then offer policy recommendations for Gavi’s board and leadership to consider as it gears up for its next strategic period, known as “Gavi 6.0”.

## Gavi’s Track Record Across Three Levers: Introductions, Coverage, and Country Eligibility

*Gavi’s model for introducing new and underused vaccines has driven progress over the last two decades*

Gavi’s current model has effectively driven introductions of new and underused vaccines, increasing immunization in lower-income countries where access may otherwise be delayed or restricted. Gavi’s portfolio has grown significantly since it was set up, expanding from supporting vaccines against four infectious diseases in 2000 to 19 during the current strategic period.<sup>3</sup>

Gavi’s approach to market shaping is core to successful vaccine introductions in eligible countries. By consolidating demand for vaccines among lower-income countries and facilitating pooled purchasing

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<sup>1</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf); <https://www.gavi.org/news/media-room/vaccine-alliance-reaches-more-one-billion-children#:~:text=About%20Gavi%2C%20the%20Vaccine%20Alliance&text=Since%20its%20inception%20in%202000,in%2073%20lower%20income%20countries>.

<sup>2</sup> <https://www.cgdev.org/sites/default/files/global-immunization-and-gavi-five-priorities-next-five-years.pdf#page=23>

<sup>3</sup> <https://www.gavi.org/our-alliance/strategy/vaccine-investment-strategy-2024>

through assured funding, Gavi has driven predictability and sustainability in the vaccine market, expanded and diversified the manufacturer base, and helped lower vaccine costs.<sup>4</sup> To date, Gavi has deployed its market shaping tools to deliver a range of benefits for Gavi-eligible countries.<sup>5</sup> But there is also a need to carefully assess the implications of market shaping approaches—both positive *and* negative spillovers—on the global vaccine market, including for countries outside of Gavi eligibility.<sup>6</sup>

Going forward, Gavi should lean into its comparative advantage in expanding access to new and underused vaccines. But to do so effectively, it will need to adapt existing approaches to confront emerging challenges.

### ***Despite bright spots, Gavi has been less successful historically at driving equitable immunization coverage at-scale***

To date, Gavi’s efforts to optimize equitable coverage at-scale have been mixed at best. The overall track record has been particularly underwhelming in several countries with large birth cohorts and in specific fragile and conflict-affected settings.

The average coverage across key vaccines (known as “breadth of protection”) has increased among Gavi eligible countries from 47 percent in 2019 to 56 percent in 2022—and now exceeds non-Gavi countries (at 53 percent).<sup>7</sup> Still, aggregated statistics tell an incomplete story; full immunization-for-age varies widely *across* countries, including ones in the same phase of Gavi support. For example, coverage of the third dose of diphtheria-tetanus-pertussis-containing vaccine (DTP3) coverage in Papua New Guinea and Kenya—both in Gavi’s accelerated transition phase— was estimated at 42 percent and 86 percent in 2022, respectively.<sup>8</sup> Coverage rates *within* a handful of countries, particularly those with large birth cohorts, are highly inequitable and variable.<sup>9</sup> In 2021, Nigeria, with the world’s third largest birth cohort, had coverage of DTP3 and the second dose of measles-containing vaccine (MCV2) below 60 percent and 40 percent, respectively.<sup>10</sup>

Further, coverage also remains unacceptably low for certain critical vaccines. One stand-out example is coverage of the last dose of the human papillomavirus (HPV) vaccine, which has only increased by three percentage points over the last four years (2019-2022), in part due to the COVID-19 pandemic, and remains at ten percent in Gavi-eligible countries.<sup>11</sup> Alongside vaccine supply issues, this low coverage level could, at least in part, reflect challenges in reaching new populations like adolescents.

Complex humanitarian crises and instability have further complicated efforts to sustain and increase coverage levels. As one example, routine immunization rates in Myanmar fell from 87 percent in 2020 to

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<sup>4</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=34](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=34)

<sup>5</sup> <https://www.cgdev.org/sites/default/files/global-immunization-and-gavi-five-priorities-next-five-years.pdf#page=31>

<sup>6</sup> <https://www.cgdev.org/sites/default/files/global-immunization-and-gavi-five-priorities-next-five-years.pdf#page=31>

<sup>7</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf);

<https://www.gavi.org/sites/default/files/programmes-impact/our-impact/apr/Gavi-Progress-Report-2022.pdf>

<sup>8</sup> <https://worldhealthorg.shinyapps.io/wuenic-trends-2023/>

<sup>9</sup> <https://www.cgdev.org/blog/gavi-going-forward-immunization-every-child-everywhere>

<sup>10</sup> <https://ourworldindata.org/grapher/number-of-births-per-year?tab=table&time=earliest..2021&country=~AFG>;

<https://worldhealthorg.shinyapps.io/wuenic-trends-2023/>

<sup>11</sup> <https://worldhealthorg.shinyapps.io/wuenic-trends-2023/>

45 percent in 2021 due to the ongoing humanitarian crisis.<sup>12</sup> Further, the movement of refugee populations across country borders cuts across Gavi’s income-based eligibility rules.<sup>13</sup> The recent Syrian crisis with large flows of refugees fleeing to nearby Jordan and Lebanon, which are not eligible for Gavi support, exemplifies the need for greater operational flexibilities, beyond one-off exceptions, to adequately reach displaced populations as well as host communities in non-eligible countries.

Still, there are success stories where Gavi has taken a targeted approach to address key gaps in vaccine delivery systems by blending a “health systems” focus with its comparative advantage in pooled procurement and demand consolidation. For example, 40 Gavi-supported countries installed critical cold chain equipment between 2021–2023 through the Cold Chain Equipment Optimization Platform to bolster facilities’ reliability for services and reach missed communities with critical immunization interventions.<sup>14</sup> Notably, the rollout of COVID-19 vaccines during the pandemic demonstrated the pay-off from earlier efforts to strengthen in-country delivery infrastructure.

Yet, to drive sustained coverage improvements at-scale, Gavi will need a new model going forward that is tailored to operationally challenging settings and able to systematically tackle bottlenecks in delivery systems.

***Gavi’s income-based eligibility model and co-financing approach has advanced self-financing for vaccines and worked reasonably well to date***

Amongst other global health mechanisms, Gavi has a particularly explicit policy for eligibility and transition, defined based on a country’s income per capita. Alongside, its approach to co-financing incentivizes countries to incrementally increase domestic financing for immunization, setting countries on a time-bound path to transition away from Gavi support. Its GNI-based eligibility approach enables Gavi to target support to countries that have historically housed most of the world’s under-vaccinated children.

The approach to transition countries away from support once they exceed the GNI threshold has worked seemingly well during periods when lower-income countries have seen sustained growth. To date, Gavi’s model has supported 19 countries to become fully self-financing.<sup>15</sup> There has also been a steady increase in domestic financing for vaccine procurement; according to Gavi’s own reporting, the share of financing for vaccines from country governments has increased from 8 percent (\$416 million) of total vaccine financing for Gavi-supported countries during the Gavi 3.0 period (2011–2015) to 39 percent (\$3.4 billion) during the current strategic period (Gavi 5.0; 2021–2025)—an increase of 31 percentage points in the share of total vaccine financing.<sup>16</sup>

But the current cohort of soon-to-transition countries face harsher prospects compared to earlier ones.<sup>17</sup> For example, countries that are poised to transition fair less favorably on immunization coverage

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<sup>12</sup> <https://worldhealthorg.shinyapps.io/wuenic-trends-2023/>

<sup>13</sup> <https://www.cgdev.org/sites/default/files/global-immunization-and-gavi-five-priorities-next-five-years.pdf#page=23>

<sup>14</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=44](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=44)

<sup>15</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=28](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=28)

<sup>16</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=26](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=26)

<sup>17</sup> [https://centerforpolicyimpact.org/wp-content/uploads/sites/18/2018/03/Transition-from-foreign-aid\\_DukeCPIGH-Working-Paper-final.pdf](https://centerforpolicyimpact.org/wp-content/uploads/sites/18/2018/03/Transition-from-foreign-aid_DukeCPIGH-Working-Paper-final.pdf)

indicators, with DTP3 coverage below 85 percent in 38 percent of countries currently in or entering the accelerated transition phase, compared to only 25 percent in previously transitioned countries.<sup>18</sup>

In addition, current macro-fiscal conditions, marked by rising debt and high inflation, are likely to create additional challenges for countries. Some transitioning countries are likely to face a decrease in Gavi financing, and therefore increasing obligations for self-financing vaccine, under strained fiscal conditions. And others may face challenges meeting and progressively increasing co-financing requirements in the current macro-fiscal climate. Indeed, current projections for country vaccine financing are at least \$200 million lower than original projections for the current strategic period (2021-2025) due in large part to slower economic growth.<sup>19</sup>

Given the prevailing fiscal outlook and related shifts in the broader development landscape, Gavi will need to evolve its eligibility and transition model more substantively going forward.

## Challenges on the Horizon

Several existing gaps and future disruptions are putting—and will continue to exert—pressure on Gavi’s current model, with important implications for its ability to deliver progress towards its mission. To remain fit-for-purpose in the next strategic phase and beyond, Gavi will need to address these challenges head-on and adapt to multiple shifts in the global health and broader development landscapes.

### *Potential disruptions to Gavi’s approach to vaccine introductions*

To maintain its core strength in vaccine introductions, Gavi must confront the aftershocks of the COVID-19 pandemic; adequately prepare for novel vaccines in the pipeline; adapt to the need for greater alignment across global health mechanisms amidst an evolving architecture; and emphasize prioritization and value for money.

First, as a consequence of vaccine nationalism during the COVID-19 pandemic, countries in Africa and elsewhere are increasingly skeptical of Geneva-based solutions and are calling for investment in regionally diversified manufacturing, regional procurement mechanisms, and greater power in global alliances. Following the fraught experience with COVID-19 vaccine distribution, realigning the global/regional balance for key health system functions such as manufacturing and procurement, including through advancing efforts under Gavi’s 4 Pillar Strategy, would help bolster Gavi’s relationship with partner countries, especially in Africa.<sup>20</sup>

Second, the prospects of successfully developing novel vaccines against high burden infectious diseases are high. Turning those scientific breakthroughs into reduced disease burden will require new and different

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<sup>18</sup> <https://www.gavi.org/sites/default/files/board/minutes/2022/7-8-dec/11b%20-%20FPR%20-%20Eligibility%20and%20Transition%20Policy%20and%20Co-Financing%20Policies.pdf#page=2>

<sup>19</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=26](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=26)

<sup>20</sup> [https://www.gavi.org/sites/default/files/programmes-impact/our-impact/Final-Report\\_COVAX-Facility-and-COVAX-AMC-Formative-Review-and-Baseline-Study.pdf](https://www.gavi.org/sites/default/files/programmes-impact/our-impact/Final-Report_COVAX-Facility-and-COVAX-AMC-Formative-Review-and-Baseline-Study.pdf); <https://www.gavi.org/sites/default/files/document/2022/Gavi-Expanding-Sustainable-Vaccine-Manufacturing-in-Africa-2022.pdf>

approaches for effective vaccine introduction and delivery. Many critical vaccines are in the pipeline, with several new vaccines—including a tuberculosis vaccine—projected to launch during Gavi 6.0 (2026-2030).

Gavi and alliance partners will need to start to lay the groundwork *now* for future novel vaccines, which will require building new platforms to reach target populations beyond children. As one example, a new tuberculosis vaccine would require platform building to administer vaccines to adults and adolescents, who account for almost 90 percent of disease transmission, yet are outside of Gavi’s historical emphasis on childhood immunization.<sup>21</sup> To unlock these health and economic gains, Gavi must ensure its systems and approach are equipped to reach new target demographics.

Third, the evolving global health architecture and rapidly shifting development landscape is, in turn, amplifying calls for greater alignment to maximize efficiency among the global health mechanisms.<sup>22</sup> And new and upcoming vaccines for diseases like malaria and tuberculosis will raise the stakes for these organizations to reduce duplication and realize opportunities for greater alignment in their overall approach in areas like value for money. For instance, in the absence of a more integrated and coherent approach at the global level, each mechanism will assess the cost effectiveness of new technologies through their specific purview, with Gavi weighing investment in malaria vaccines against other vaccines in its portfolio, while the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund) compares it with other interventions to combat malaria.<sup>23</sup>

Finally, the growing portfolio of new and potentially more expensive vaccines will likely create additional challenges for countries already facing fiscal constraints. For comparison, the lowest price through Gavi for the rotavirus, pentavalent, inactivated polio, and pneumococcal conjugate vaccines in 2022 were \$0.60, \$0.75, \$1.50, and \$2, respectively, whereas the price for the R21 malaria vaccine is estimated at \$2-4 per dose.<sup>24</sup> A greater focus on prioritization and value for money will be critical considering these overall shifts in the vaccine portfolio.

### ***Potential disruptions to Gavi’s ability to drive equitable immunization coverage***

Gavi faces a key obstacle to reaching un- and under-immunized communities and increasing equitable coverage, most notably in unstable, fragile, and conflict-affected settings. This reality is especially troubling given recent trends around forced displacement, conflict, and instability.<sup>25</sup> Indeed, estimates suggest that the number of displaced people is set to double between 2015 and 2024, with the majority of newly displaced people living in sub-Saharan Africa.<sup>26</sup> Climate change, alongside other ongoing and new crises, is likely to continue to lead to record numbers of refugees. Most notably, nearly half of Gavi-supported countries (25/54; 46 percent) are currently classified as fragile or conflict-affected—including the majority (17/28; 61 percent) of countries in the initial self-financing stage (see Figure 1).<sup>27</sup>

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<sup>21</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=26](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=26)

<sup>22</sup> [https://d2nhv1us8wflpq.cloudfront.net/prod/uploads/2023/09/FGHI\\_final\\_report\\_designed.pdf](https://d2nhv1us8wflpq.cloudfront.net/prod/uploads/2023/09/FGHI_final_report_designed.pdf)

<sup>23</sup> <https://www.cgdev.org/blog/malaria-vaccination-era-how-endemic-countries-and-donors-can-make-most-r21>

<sup>24</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=33](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=33);

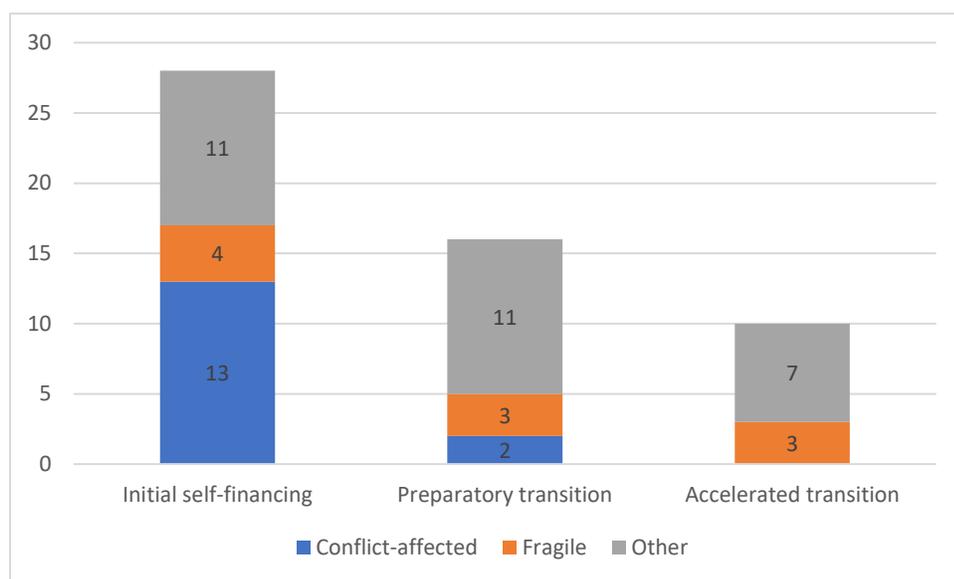
<https://www.washingtonpost.com/health/2023/10/03/malaria-vaccine-r21-oxford/>

<sup>25</sup> <https://www.unhcr.org/us/global-trends>

<sup>26</sup> [https://pro.drc.ngo/media/4c5hxa5c/230310\\_global\\_displacement\\_forecast\\_report\\_2023.pdf](https://pro.drc.ngo/media/4c5hxa5c/230310_global_displacement_forecast_report_2023.pdf)

<sup>27</sup> <https://www.worldbank.org/en/topic/fragilityconflictviolence/brief/harmonized-list-of-fragile-situations>

Figure 1. Breakdown of Gavi eligible countries by the World Bank's conflict and fragility classification



Source: <https://www.gavi.org/types-support/sustainability/eligibility>;  
<https://www.worldbank.org/en/topic/fragilityconflictviolence/brief/harmonized-list-of-fragile-situations>

Gavi has taken steps to address the unique challenges for immunization presented by conflict and fragility. Gavi's model has, for the most part, served well for working with relatively stable and centrally-governed nations. By contrast, Gavi funding has often been delayed with suboptimal targeting in humanitarian settings, due in part to the complexity of application and approvals processes and concerns about risk in these operational contexts.<sup>28</sup> Importantly, Gavi's Fragility, Emergencies, and Displaced Populations policy, last updated in June 2022, calls for more flexibility and mandates a higher risk appetite in these settings, though operationalization of these shifts is still in progress.<sup>29</sup> Gavi's recently established Zero-dose Immunization Program also enables a new model of engaging directly with humanitarian partners to reach zero-dose children in two regions in Africa that are currently unreached by governments.<sup>30</sup> Still, these efforts are in the early stages of implementation and could be complemented by further modifications to Gavi's approach in fragile and conflict-affected settings. To remain fit-for-purpose and relevant, Gavi needs to contend with these realities and adapt to these operationally complex settings.

Lastly, critical gaps in delivery infrastructure will continue to undermine efforts to expand vaccine coverage. Gavi has had a dedicated funding window for health systems strengthening support since 2007. To date, however, financing has been small-scale, specific results have been difficult to parse, and support has been slow to disburse and channeled via international partners.<sup>31</sup> Still, bolstering delivery systems and providing necessary equipment is essential. Going forward, Gavi should systematically leverage its market shaping capabilities for specific innovations that contribute to health systems strengthening and building more robust delivery systems.

<sup>28</sup> [https://www.gavi.org/sites/default/files/programmes-impact/our-impact/Final-Report\\_Annexes\\_Final-Report\\_COVAX-Facility-and-COVAX-AMC-Formative-Review-and-Baseline-Study.pdf#page=21](https://www.gavi.org/sites/default/files/programmes-impact/our-impact/Final-Report_Annexes_Final-Report_COVAX-Facility-and-COVAX-AMC-Formative-Review-and-Baseline-Study.pdf#page=21); <https://www.csis.org/analysis/reaching-people-fragile-and-conflict-affected-settings-immunization-services>

<sup>29</sup> <https://www.gavi.org/programmes-impact/programmatic-policies/fragility-emergencies-and-displaced-populations-policy>

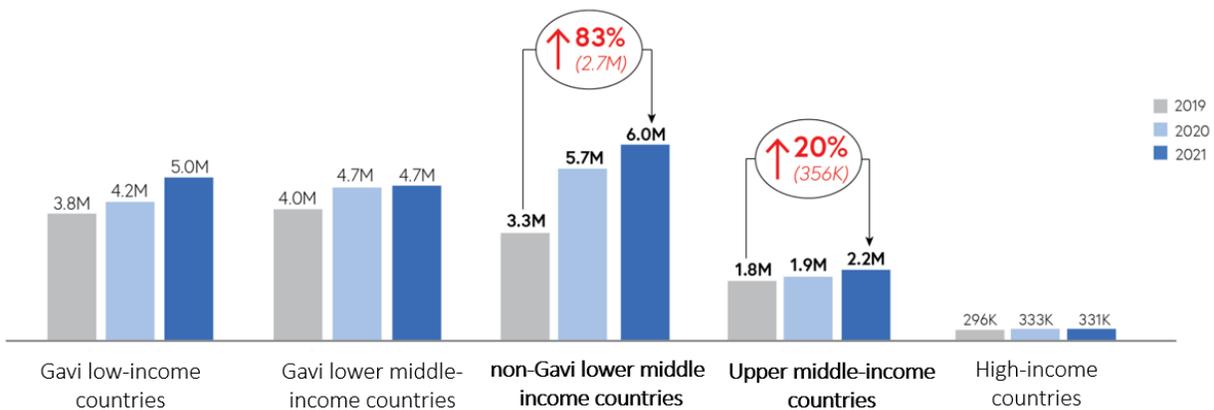
<sup>30</sup> <https://coregroup.org/gavi-funded-zero-dose-immunization-program/>

<sup>31</sup> <https://www.cgdev.org/sites/default/files/global-immunization-and-gavi-five-priorities-next-five-years.pdf>

### Potential disruptions to Gavi's eligibility model

Middle-income countries (both never-Gavi eligible and formerly eligible) have continued to face challenges in sustaining and advancing progress against immunization outcomes. This exposes a mismatch between Gavi's income-based eligibility threshold and its overarching goal to drive improvements in equitable coverage. Indeed, nearly half of zero-dose children in 2021 were in middle-income countries that are not eligible for Gavi support (see Figure 2). Although the overall number of zero-dose children declined by 2.2 million between 2021 and 2022, the higher density of zero-dose children in non-Gavi eligible countries—especially non-Gavi lower middle-income countries—should motivate greater focus on these populations.<sup>32</sup>

Figure 2. Number of zero-dose children in 2021



Source:

[https://www.immunizationagenda2030.org/images/documents/IA2030\\_Performance\\_of\\_MIC\\_Draft\\_Summary\\_for\\_Comment\\_July\\_2023\\_.pdf#page=6](https://www.immunizationagenda2030.org/images/documents/IA2030_Performance_of_MIC_Draft_Summary_for_Comment_July_2023_.pdf#page=6)

Note: The above figure presents a snapshot of a recent 3-year period and may not be representative of longer-term trends.

Further, Gavi's current GNI-based eligibility criteria does not adequately reflect countries' ability to pay. Nor does it provide a good proxy for transition readiness, as measured by a country's capabilities across different health system functions, including the ability to conduct, plan, and manage procurement. Current macro-economic realities, including mounting levels of debt, together with the fiscal outlook point to serious challenges with Gavi's current eligibility model. To ensure its approach is fit-for-purpose in a rapidly evolving global landscape, Gavi should substantively reexamine its model, going beyond the GNI per capita measure and more accurately reflecting countries' fiscal and programmatic readiness for transition (see CGD forthcoming analysis on Gavi eligibility and transition trajectories).

Gavi's income-based eligibility criteria that targets immunization support to lower-income countries also does not align well with the burden of certain diseases such as tuberculosis and HIV, for which we might soon have new vaccines. For instance, the four countries with the highest burden of tuberculosis, which collectively accounted for more than half of global tuberculosis cases in 2021, are middle-income countries

<sup>32</sup> <https://www.gavi.org/sites/default/files/programmes-impact/our-impact/apr/Gavi-Progress-Report-2022.pdf#page=7>

that are not eligible for support under Gavi’s standard eligibility and transition policy.<sup>33</sup> (India and Indonesia transitioned to fully self-financing vaccines in 2021 and 2016, respectively<sup>34</sup>; China and the Philippines have never been eligible). This mismatch between disease burden and eligibility for support reinforces calls to adjust Gavi’s overall approach.<sup>35</sup>

Gavi has demonstrated its willingness to adapt its eligibility model in response to shifts in countries’ needs and the broader macroeconomic environment, including with the Middle-Income Country Approach, last updated in June 2022.<sup>36</sup> Although this approach offers critical support to some middle-income countries, it is not comprehensive, relatively smaller-scale, and excludes some notable countries with high disease burdens and sub-national inequalities, such as India.<sup>37</sup> Closing immunization gaps will require evolving Gavi’s model and more substantively retooling its policies, going beyond tailored support at a relatively small-scale and one-off exceptions.

## Recommendations for Gavi’s Future Approach

We offer a series of policy recommendations for consideration by Gavi’s Board for implementation during the next strategic period (Gavi 6.0) and beyond. These recommendations are designed to leverage Gavi’s strengths, mitigate the impacts of disruptions associated with the three levers, and enable greater agility and effectiveness in Gavi’s model going forward. Implementation of some larger strategic shifts could likely stretch over multiple years, but the next strategic period is an opportunity to the groundwork for these reforms. Table 1 illustrates the links between impact levers, existing strengths, anticipated disruptions, and policy recommendations.

*Table 1. Summary of the strengths and challenges motivating the proposed policy recommendations for Gavi 6.0*

Impact levers	Gavi’s track record to date	Challenges on the horizon	Policy recommendations for 6.0
Introductions	Largely successful in accelerating new vaccine adoption at scale	Next wave of highly impactful new vaccines requires immunization platforms that reach beyond infants to include adolescents and adults	1. Incorporate “life course platform building” as an explicit objective for Gavi 6.0
		Countries are demanding more say in setting priorities following vaccine inequities that occurred during the COVID-19 pandemic	2. Replace existing financing arrangements with an envelope financing approach that is driven by local priorities
		Vaccine security is focusing increasingly on regional manufacturing and procurement mechanisms	3. Recalibrate the global-regional balance in vaccine manufacturing and procurement

<sup>33</sup> [https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022/tb-disease-burden/2-1-tb-incidence#:~:text=In%202021%2C%20eight%20countries%20accounted,Congo%20\(2.9%25\)%20\(Fig.;](https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022/tb-disease-burden/2-1-tb-incidence#:~:text=In%202021%2C%20eight%20countries%20accounted,Congo%20(2.9%25)%20(Fig.;)

<https://www.gavi.org/sites/default/files/programmes-impact/gavi-eligibility-and-transition-policy.pdf>

<sup>34</sup> [https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23\\_Report\\_FULL\\_eng.pdf#page=28](https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf#page=28)

<sup>35</sup> [https://www.cgdev.org/sites/default/files/1425581\\_file\\_Glassman\\_Duran\\_Sumner\\_MIC\\_global\\_health\\_FINAL.pdf](https://www.cgdev.org/sites/default/files/1425581_file_Glassman_Duran_Sumner_MIC_global_health_FINAL.pdf)

<sup>36</sup> <https://www.gavi.org/types-support/sustainability/gavi-mics-approach>

<sup>37</sup> <https://www.gavi.org/sites/default/files/programmes-impact/support/Countries-and-economies-eligible-for-support-under-Gavi-MICs-Approach.pdf>

		Increasing overlap across global health mechanisms in specific disease areas may distort funding priorities and complicate country programming	4. Establish a mechanism across Gavi and other global health initiatives to assure integrated approaches to disease control that optimize value for money and simplify implementation for countries
Coverage	Investments in broader systems development have generated less impact in fragile and conflict-affected settings	The number of displaced people living in fragile and conflict-affected settings is likely to increase	5. Establish a standalone subsidiary that operates in fragile and conflict-affected settings with high-risk appetite
	Market shaping capabilities have successfully helped fill specific gaps in health systems infrastructure	Critical gaps in delivery systems infrastructure	6. Leverage Gavi's experience, including in market shaping, to accelerate innovations for immunization systems and primary health care more broadly
Eligibility	Transition, eligibility, and co-financing model has supported progress on self-financing	Eligibility criteria is not well aligned with fiscal realities and disease burdens	7. Revisit Gavi's eligibility policy to better align with countries' ability to pay and disease burdens

### *Box 1. Trade-offs across three levers*

Importantly, the three levers do not operate in silos. Since its launch, Gavi's mandate and overall complexity has increased—and Gavi will need to carefully consider trade-offs across these levers going forward, especially in instances where adjusting one lever could have unintended consequences for other priorities.

Gavi's board and leadership will need to be explicit and realistic about these potential trade-offs when modifying individual policy levers—and further consider prioritizing across them. Below we highlight three illustrative examples:

1. As Gavi considers the potential benefits for supply resilience through an increasingly regional approach, it must anticipate and mitigate risks. Leaning into a regional approach to procurement could have multiple benefits, including promoting supply chain resilience and potentially helping to facilitate a more rapid and equitable rollout of new vaccines during future pandemics. However, regionally organized purchasing platforms that enable greater regional procurement, including of locally manufactured vaccines, could shrink Gavi volumes and hinder its market shaping capabilities at the global level. This could lead to higher vaccine prices in exchange for greater vaccine supply security regionally.
2. Even while increasing its focus on and support for developing platforms to deliver new vaccines to different age-groups, namely a tuberculosis vaccine to adults and adolescents, Gavi must adequately resource efforts to expand coverage of existing childhood vaccines.
3. Providing a fixed envelope of Gavi financing to governments may help align countries' introductions with local need, increase ownership, and build trust; however, in doing so, countries' portfolios may be reshaped in ways that impact progress towards increasing coverage of existing vaccines, with implications for vaccine markets and global outbreak risks.

## **1. Incorporate “life course platform building” as an explicit objective for Gavi 6.0**

To date, Gavi’s success and impact has been largely driven by accelerating uptake of life-saving new vaccines administered to infants or through mass campaigns targeting people of all ages. While a number of more recent vaccines approved in the 2018 Vaccine Investment Strategy also target different age groups (e.g., DTP boosters), coverage has remained a challenge. The next wave of impactful vaccines will require immunization programs to build on experiences and lessons learned from vaccinating different age groups, such as reaching adolescents with HPV and adults through mass campaigns. Strategic, at-risk investments are needed to assure high, rapid uptake in Gavi 6.0 and the first half of Gavi 7.0. For example, a tuberculosis vaccine would have the highest impact among adolescents and adults—the population with the highest burden.

Even while vaccine candidates are still in development, Gavi together with its partners will need to start laying the groundwork during the 6.0 phase to ensure primary health care systems and delivery channels at the country level are primed to reach relevant populations as soon as new life-course vaccines are available. Alongside, it will be critical for Gavi’s board to further assess the health system investments required to target these different age groups and drive equitable coverage of these vaccines going forward. Deferring platform building for these critical vaccines coming up in the pipeline to a subsequent strategic period, beyond Gavi 6.0, would be a missed opportunity.

## **2. Replace existing financing arrangements with an envelope financing approach that is driven by local priorities**

Currently, Gavi reviews vaccines in development through its Vaccine Investment Strategy, then allocates Gavi resource envelopes to a vaccine program (e.g., the 2021-2025 Investment Strategy proposed \$1.3 billion for pneumococcal vaccines, \$348 million for pentavalent vaccines, etc.).<sup>38</sup> Subsequently, Gavi offers countries the option of introducing any of the approved vaccines. Gavi should consider an alternative approach in which it allocates a consolidated envelope of financing for each country. One portion of that envelope could include financing for vaccine procurement, enabling countries to prioritize the use of those resources across different vaccines. Gavi would then aggregate countries’ priorities into bottom-up Gavi vaccine programs. The second portion could include consolidated resources across Gavi’s existing funding streams, including its health systems strengthening investments grants and vaccine introduction grants, among others. Operationally, these two portions of financing would need to be managed in support of each other to ensure programmatic linkages across these resources. The exact amount for each country’s envelope would be based on population and scaled according to different criteria, including a country’s eligibility and co-financing levels. It could also be adjusted during crises, natural disasters, or other disruptions.

Such an approach should also be linked with country-level priority setting platforms, including National Immunization Technical Advisory Groups (NITAGs) and national and regional health technology assessment efforts to evaluate the cost-effectiveness of new and existing vaccines. Further, to help build core capacities in priority setting, Gavi should work with partners, including Africa CDC’s health economics program, to offer technical assistance to NITAGs to make recommendations for vaccine introductions based on cost-effectiveness analyses, alongside other economic evidence.

Allocating a fixed-amount resource envelope to each country reflects a significant departure from Gavi’s current model. This shift would also understandably take some time to fully operationalize, and certain aspects, including the potential effect that country-driven priorities will have on Gavi’s market shaping

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<sup>38</sup> <https://www.gavi.org/sites/default/files/publications/2021-2025-Gavi-Investment-Opportunity.pdf#page=41>

capabilities, will need further consideration. Still, such an approach offers multiple benefits. Notably, increasing partner countries' ownership of Gavi investments can help drive greater alignment between vaccine portfolios and country priorities and needs, all while moving away from a centralized approach that could help rebuild trust with government partners. This approach should be carefully designed to bake in incentives for country financing, which would, in turn, contribute to greater programmatic sustainability.

To support country decision making within this arrangement, Gavi, alongside other partners, could develop regionally adapted menus of cost-effective vaccines.<sup>39</sup> This arrangement could also lean into innovative approaches to global health and development financing, such as “marginal aid.”<sup>40</sup> In this approach, countries could focus their domestic financing on the highest priority interventions including vaccines, then allocate the envelope of Gavi and other donor financing to supplemental immunizations at the “margin.”

### **3. Recalibrate the global-regional balance in vaccine manufacturing and procurement**

Through its proposed African Vaccine Manufacturing Accelerator (AVMA), Gavi is rapidly advancing its support for diversified manufacturing capabilities on the African continent.<sup>41</sup> This includes a new financial mechanism, in the form of an advanced market commitment, to help “pull” African-made vaccines to market. But an effective enabling ecosystem to support a nascent African vaccine manufacturing industry will be a key success factor for AVMA. And Gavi should work closely with partners to help create this enabling environment. Gavi should also address regulatory issues as part of the design of the proposed financial mechanism by supporting regulatory authorities through earlier milestone payments and considering alternate regulatory pathways (see CGD forthcoming analysis on regulatory considerations for AVMA).

Further, as African stakeholders—including several of African Union's vaccine manufacturing Member States, Regional Economic Communities, international organizations—explore and pilot a regional pooled procurement mechanism, Gavi should proactively consider ways to support this mechanism as part of the overall efforts to support more geographically diverse vaccine supply and resilience.<sup>42</sup> While it may still take some time for such a mechanism to fully operationalize and encompass Gavi-supported countries, Gavi should lay the groundwork to adapt its procurement policies to support purchasing of Gavi-supported vaccines by a new African pooled procurement mechanism and mitigate potential trade-offs (see Box 1).

### **4. Create a mechanism across Gavi and other global health initiatives to assure integrated approaches to disease control that optimize value for money and simplify implementation for countries**

Gavi should formalize a close partnership with other global health mechanisms—including the Global Fund, CEPI, and the World Bank/Global Financing Facility, among others—to avoid duplication and maximize impact. Perhaps most notably, building on nascent efforts to increasingly work together, Gavi and the Global Fund should explore a mechanism dedicated to systematically integrating approaches to value for money and evidence-based prioritization, as the potential for overlap between these organizations' mandates is increasing as new technologies come online. The rollout of malaria vaccines provides a case-in-point where a more integrated approach and coherent framework to evidence-

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<sup>39</sup> <https://www.cgdev.org/sites/default/files/prioritizing-public-spending-health-lower-income-countries-role-global-financing.pdf#page=38>

<sup>40</sup> <https://www.cgdev.org/blog/putting-aid-its-place-new-compact-financing-health-services>

<sup>41</sup> <https://www.cgdev.org/blog/gavis-amc-african-vaccine-manufacturing-start-these-three-foundational-questions>;

<https://www.cgdev.org/blog/accelerating-vaccine-manufacturing-africa-three-considerations-gavi>

<sup>42</sup> <https://africacdc.org/wp-content/uploads/2023/10/MINISTERIAL-WORKING-GROUP-MEETING-AT-THE-FIRST-MANUFACTURERS-MARKETPLACE-FOR-AFRICAN-UNION-MEMBER-STATES.pdf>

informed priority setting is critical. Similarly, an eventual tuberculosis vaccine further exemplifies the need for a more integrated health systems approach that assesses value for money and prioritizes across different interventions in relation to these global health mechanisms and country priorities. Increasing the alignment between Gavi and the Global Fund on these crucial axes, and especially in disease areas like malaria and tuberculosis, will also help streamline processes for eligible countries.

Global health funders should play a key role in incentivizing this kind of reform, alongside efforts to align donor financing flows with government budgets, which could potentially be advanced through the ongoing Future of Global Health Initiatives process. They should not only signal the need for greater alignment, but also underscore the importance of each global health initiative demonstrating how they are shifting approaches in practice. This approach will be critical to assure future efforts yield meaningful change compared to previous attempts to drive greater alignment.

#### **5. Establish a stand-alone subsidiary that operates in fragile and conflict-affected settings with high-risk appetite**

Gavi's current model is designed for long-term sustainable development, and it has been successful in areas like increasing domestic financing of vaccine procurement. However, this development model is not well-suited to improve immunization coverage amid humanitarian crises and fragile and conflict-affected settings, where both policy and operational challenges impact the current approach. In these settings, it is often important to work with non-governmental actors, take risks that would not generally be justified in stable settings, and define success differently.

Gavi and partners, including UNICEF, should consider setting up a distinct entity to operate in fragile and conflict-affected settings with high-risk appetite and greater agility. Effective modes of operation in humanitarian settings will be increasingly important since these settings are—and will continue to be—important to achieving Gavi's mission of delivering equitable immunization. A walled-off subsidiary could house and manage funds for immunization efforts in conflict-affected and fragile settings. Further, it could operate with different governance arrangements and risk profiles on several fronts—including accountability, potential vaccine losses, and liability and indemnification challenges—to further enhance speed, agility, and scope for partnerships with non-government entities required to effectively deliver vaccines in the face of conflict and instability. Working with non-government partners such as humanitarian organizations can also help address vaccine hesitancy since trust in governments may be lower in these settings.

This effort would build on the foundation provided by Gavi's Fragility, Emergencies, and Displaced Populations Policy and the Zero-dose Immunization Program and should apply important lessons from the recent COVAX experience. Setting up such an entity would also necessarily require close collaboration with other partners and mechanisms that support humanitarian responses to avoid duplication and align objectives.

#### **6. Leverage Gavi's experience, including in market shaping, to accelerate innovations for immunization systems and primary health care more broadly**

Gavi's leadership and board should consider if Gavi's contribution to health systems could be improved by focusing on systematically leveraging Gavi's comparative advantage in scaling new technologies and in market shaping and demand consolidation to fill gaps in critical infrastructure needs. The needs of health systems go beyond infrastructure challenges, so Gavi's contributions would need to be coordinated with other efforts and tailored to be responsive to country needs. Further, the extent to which market shaping tools may be relevant will vary across innovations.

Looking to the examples set by the Cold Chain Equipment Optimization Platform, Gavi can advance systems strengthening efforts by establishing explicit strategic and fundraising objectives for infrastructure and technological needs to bolster the effectiveness and sustainability of global immunization efforts and, in some cases, primary health care more broadly.

One way to operationalize this approach would be for Gavi to create accounts for each country that are pre-loaded with financing redeemable in an online “store” that contains a selection of pre-approved innovations that strengthen immunization systems and primary health care. Gavi can use this approach to scale up narrower, immunization-specific outcome like environmentally conscious immunization waste disposal methods or broader primary health care needs like solar-powered health facilities or interoperable digital health records.

Additional products could include an e-learning suite that could be used for on-the-job training of health care workers; a contract for geospatial data on vaccine coverage; and/or other innovations with proven effectiveness. This method would enable countries to drive decisions on how to allocate funding for systems investments based on local needs and priorities. It would also create a marketplace with sustainable value for countries and support for innovators.

#### **7. Revisit Gavi’s eligibility policy to align criteria with countries’ ability to pay and disease burdens**

Gavi’s leadership and board should evolve its approach to transition and eligibility to better target support to countries, including to identify criteria that better reflect a country’s fiscal situation and align with the highest burden of disease.

Possible options range from more incremental changes to more radical rethinking. As an incremental step, Gavi could supplement the GNI per capita criterion with alternate metrics that better capture countries’ ability to pay for immunization. In parallel, Gavi’s leadership and board should examine other indicators that could complement the ability-to-pay-based indicator to capture other salient factors, such as programmatic readiness and other core health system capabilities, including but not limited to priority setting, procurement, and supply chain management.

Down the line, Gavi could also consider shifting from a country-based transition model to a vaccine-based model, in which eligible countries could receive time-bound financing for a particular vaccine following introduction. This approach could help Gavi better tailor its support based on vaccine and disease priorities. On the other hand, the potential implications of this change for programmatic and operational complexity as well as equity would need further examination and appropriate plans for mitigating unintended consequences. Finally, the trade-offs between a vaccine-based transition model and the approach of allocating a fixed-amount resource envelope to each country, discussed earlier (see recommendation 2), would require further assessment.

Building on recommendation 4, one particularly important area for alignment between Gavi and the Global Fund is around eligibility policies. Currently, these financing mechanisms use different sets of criteria and thresholds to determine country eligibility, which can result in limited clarity and fragmentation for countries. Gavi and the Global Fund should work together to align overarching principles and criteria that guide their respective eligibility policies to facilitate a more coherent approach for countries. As an initial step, Gavi could adopt the existing eligibility criteria of the Global Fund for upcoming areas of overlap (i.e., malaria, tuberculosis, and possibly HIV in the longer-term), then participate jointly in relevant revisions.



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