

New Gavi Modalities for a Changing World

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INTRODUCTION

In its first 20 years, Gavi narrowly targeted its support to the 77 countries meeting its income-based eligibility criteria—specifically, GNI per capita under or equal a threshold (\$1,580 as of 2018), averaged over three years.¹ Historically, these countries housed the vast majority of under-vaccinated children and struggled with the most severe resource constraints, offering a natural target for immunization support. Some Gavi activities have also had positive spillovers for ineligible countries, including accelerated market entry of new vaccinations; a healthier supplier landscape; and the availability of global vaccine stockpiles for cholera, meningitis, and yellow fever.

Yet as the Board crafts its new five-year strategy—Gavi 5.0—it must confront a rapidly changing context in which many of the largest recipients of Gavi funds will soon become ineligible for support; the population of under-vaccinated children will become concentrated within Gavi-ineligible countries; and a wider range of countries will struggle to sustain and expand vaccination coverage amidst rapid urbanization, growing vaccine hesitancy, unaffordable vaccine pricing, and complex emergencies and displacement. For Gavi to maintain its relevance and effectively support progress toward universal vaccination, it will need to offer new modalities targeted toward the middle-income countries (MICs) ineligible for traditional support.

In this note, we summarize the changing context and its relevance for Gavi, exploring the specific issues relevant to transitioning countries, never-eligible MICs, and countries dealing with complex emergencies or large-scale protracted displacement. We then offer four recommendations to increase Gavi's relevance and effectiveness in a changing world.

¹ Countries that reach the threshold (averaged over three years) enter a state of accelerated transition; during this five-year period, co-financing requirements rapidly increase and Gavi gradually winds down its financial support. At the end of accelerated transition, countries become fully self-financing.

This note is part of a series of notes on the future of Gavi. For more, visit <https://www.cgdev.org/publication/gavi-5-0-five-challenges-and-five-ideas-reform>

CHALLENGES ON THE HORIZON

Large middle-income countries are poised to transition from Gavi support—but the vaccination agenda remains unfinished

Following 20-plus years of Gavi support, many of the largest recipients of Gavi funds are projected to transition to full self-financing by 2030. Yet transition is tied to national income (GNI per capita)—not vaccination-related outcomes. Many transitioning countries continue to struggle with low coverage rates, even for basic vaccines (see table 1). By 2030, 54 percent of under-vaccinated children (DTP3) will live in countries that have transitioned from Gavi support—most notably Nigeria, India, and Pakistan.² Transitioning countries will enjoy time-limited access to Gavi prices via manufacturer agreements, helping blunt immediate transition pains;³ yet in the long-run, experience from never-eligible MICs suggests transitioning Gavi countries are likely to face higher and more variable procurement prices (see next section). Historical evidence also suggests that IDA graduation—roughly coinciding with Gavi transition criteria in terms of GNI per capita—has been associated with a decline in World Bank lending for human development sectors, including health.⁴ Declines in other sources of health financing may further complicate countries' efforts to sustain vaccination programs following the loss of Gavi support.

TABLE 1. Top 10 recipients of Gavi funds, 2017, by projected transition and DTP3/MCV2 coverage

	2017 Gavi Disbursements	Projected Transition to Fully Self-Financing	DTP3 Coverage	MCV2 Coverage
India	\$149,505,531	2023	88%	77%
Pakistan	\$115,138,076	2026	75%	45%
Nigeria	\$109,071,924	2029	42%	N/A; 42% MCV1
DR Congo	\$84,260,014		81%	N/A; 80% MCV1
Bangladesh	\$67,075,861	2026	97%	96%
Ethiopia	\$63,776,700	2037	73%	N/A; 65% MCV1
Tanzania	\$40,235,603	2032	97%	79%
Côte d'Ivoire	\$39,073,165	2025	84%	N/A; 78% MCV1
Mozambique	\$37,305,378		80%	45%
Indonesia	\$35,290,409	2017	79%	63%

Source: Silverman (2018); UNICEF

Beyond the country-specific challenges, the shrinking Gavi portfolio will dramatically reduce the overall size of its vaccine procurement, potentially constraining its ability to shape markets through large-scale predictable and reliable tenders. (For more, see my colleagues' note, "[Gavi's Role in Market Shaping and Procurement: Progress, Challenges, and Recommendations for an Evolving Approach.](#)") Gavi will need

2 "Annex B: Supplementary Contextual Analysis." Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/>

3 "Vaccine Pricing: Gavi Transitioning Countries." World Health Organization, December 2017. <https://unct.global/wp-content/uploads/2018/02/Vaccine-Pricing-for-GAVI-Transitioning-Countries-1.pdf>

4 Gatti, Roberta and Aakash Mohpal. "Investing in Human Capital: What Can We Learn from the World Bank's Portfolio Data?" Policy Research Working Paper 8716. Human Development Global Practice, World Bank Group, January 2019. <https://openknowledge.worldbank.org/bitstream/handle/10986/31184/WPS8716.pdf?sequence=1&isAllowed=y>

to lean more heavily on other market-shaping tools to adapt to changing circumstances and sustain healthy vaccine markets.

MICs that were never eligible for Gavi support are still struggling. . . and sometimes backsliding

Beyond the challenges posed by Gavi transition, under-vaccination remains a major problem in countries that were never eligible for Gavi support. On average, never-eligible MIC governments see significantly higher expenditures on routine immunization—\$90 per live birth compared to \$25 in Gavi-eligible countries (current and former).⁵ Yet despite these substantial investments, vaccination-related outcomes remain suboptimal: never-eligible MICs accounted for 17 percent of the world's under-immunized children in 2017⁶ and have lagged behind Gavi-eligible countries in pneumococcal conjugate (PCV) and Rota introductions. Worse, trend lines are moving in the wrong direction, with a large majority (45 of 61) of never-eligible MICs experiencing stagnation or declines in DTP3 coverage between 2010 and 2017.⁷

High vaccine procurement prices stand out as a particular challenge among this cohort, limiting the reach of vaccination budgets, reducing cost-effectiveness, and therefore posing a substantial barrier to new vaccine adoption. Under the terms of its advance market commitment purchase agreements, for example, Gavi can purchase PCV on behalf of eligible countries for between \$3.05 and \$3.30 per dose; manufacturer commitments will also enable transitioning countries to sustain access at the Gavi prices through at least 2025.⁸ In contrast, even the most efficient non-Gavi procurement (through the PAHO revolving fund) accesses PCV at \$10 to \$15 per dose—three to five times the Gavi price. In Southern Africa, prices range between \$17 and \$20 per dose, and in Eastern Europe, MIC pay up to \$50.⁹ At these prices PCV may not be locally cost-effective in many non-Gavi MICs. For example, a 2013 cost-effectiveness analysis in Thailand recommend against PCV adoption at current market prices; it suggested that PCV would only become locally cost-effective following a 70 percent to 90 percent price reduction, e.g., prices between (roughly) \$10 to \$15 per dose.¹⁰

Refugee flows and emergencies confound income-based eligibility thresholds

Gavi's income-based eligibility thresholds are most sensible in stable, centrally governed nation-states—where per-capita income serves as an imperfect but useful proxy for the affordability of vaccination using government resources. Yet increasing protracted displacement and migration—sparked by conflicts, complex emergencies, and (increasingly) climate change—suggest the need for a more flexible and inclusive policy that supports refugee populations and their host communities, and which allows rapid response to emerging crises and sustained coverage in protracted situations.

5 “Annex B: Supplementary Contextual Analysis.” Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/>

6 “Annex B: Supplementary Contextual Analysis.” Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/>

7 “Annex B: Supplementary Contextual Analysis.” Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/>

8 “Vaccine Pricing: Gavi Transitioning Countries.” World Health Organization, December 2017. <https://inct.global/wp-content/uploads/2018/02/Vaccine-Pricing-for-GAVI-Transitioning-Countries-1.pdf>

9 “Annex B: Supplementary Contextual Analysis.” Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/>

10 Kulpeng et al. “Cost-Utility Analysis of 10- and 13-Valent Pneumococcal Conjugate Vaccines: Protection at What Price in the Thai Context?” *Vaccine* 31(2013): 2839-2847. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4667720/>

Gavi has already taken an important step in this direction with the Board’s 2017 adoption of a [policy](#) to permit certain operational flexibilities in fragile states, during emergencies, and to assist refugee populations. These flexibilities have helped Gavi more effectively serve refugees in Bangladesh and Uganda through additional vaccine and operational support.¹¹ However, current policies do not permit Gavi support to refugee populations housed in noneligible countries—even when the refugees have fled from countries that would otherwise meet Gavi eligibility criteria.

At present, Gavi-ineligible MICs host almost half of the world’s 18 million refugees; under current Gavi policy, there is no way to support vaccination among these populations, regardless of need.¹² And in Syria, unavailability of World Bank data on GNI per capita initially prohibited Gavi from offering support even as large measles and polio outbreaks spread across the country.¹³ (Ultimately the Gavi Board approved exceptional vaccine and cold chain support for Syria in 2017 and 2018; in mid-2018 the World Bank officially classified Syria as a low-income country, making it officially eligible for Gavi support.)¹⁴

RECOMMENDATIONS FOR GAVI’S FUTURE APPROACH

1. Link priority-setting and efficient procurement support for routine vaccination in middle-income countries

To a significant extent, high MIC vaccine prices and slow vaccine adoption are symptomatic of weakness in priority-setting, product selection, and procurement processes. To help extend the purchasing power of existing vaccination budgets, encourage introduction of new cost-effective vaccines, and inform advocacy for increased domestic budgetary resources, Gavi should partner with MICs—including both former Gavi countries and those that were never Gavi-eligible—to strengthen these core health system capacities.

As a first step, Gavi should work with National Immunization Technical Advisory Groups (NITAGs) and existing health technology assessment (HTA) agencies to evaluate WHO-recommended vaccines for local and/or subnational cost-effectiveness, accounting for the full cost of vaccine delivery (e.g., both vaccine procurement and health system costs associated with their delivery). Previous reviews of NITAG operations and effectiveness have noted insufficient use of and expertise in economic evaluation;¹⁵ where necessary, Gavi should therefore offer NITAGs technical assistance in

11 Operational support in Bangladesh only. See Berkley, Seth. “Report from Gavi, the Vaccine Alliance.” Meeting of the Strategic Advisory Group of Experts on Immunisation. Gavi, April 2018. https://www.who.int/immunization/sage/meetings/2018/april/Gavi_SAGE_presentation_Apr_2018_Final_SFB.pdf

12 “Annex B: Supplementary Contextual Analysis.” Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/>

13 Sharara, Sima L and Souha S Kanj. “War and Infectious Disease: Challenges of the Syrian Civil War.” *PLoS Pathog* 10(2014): e1004438. <https://doi.org/10.1371/journal.ppat.1004438>

14 “Consent Agenda: Ongoing and Planned Support for Syria.” Report to the Board. Gavi, November 2018. <https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/10f---consent-agenda---ongoing-and-planned-support-for-syria/>

15 Buffardi, Anne L and Susan Njambi-Szapka. “The Role of National Immunisation Technical Advisory Groups in Evidence-Informed Decision-Making.” ODI, February 2019. <https://www.odi.org/sites/odi.org.uk/files/resource-documents/12599.pdf>; Howard, Natasha, Helen Walls, Sadie Bell, and Sandra Mounier-Jack. “The Role of National Immunisation Technical Advisory Groups (NITAGs) in Strengthening National Vaccine Decision-Making: A Comparative Case Study of Armenia, Ghana, Indonesia, Nigeria, Senegal and Uganda.” *Vaccine* 36(2018): 5536-5543. <https://www.sciencedirect.com/science/article/pii/S0264410X18310727>; Howard, Natasha et al. “The Need for Sustainability and Alignment of Future Support for National Immunization Technical Advisory Groups (NITAGs) in Low- and Middle-Income Countries.” *Human Vaccines & Immunotherapeutics* 14(2018): 1539-1541. <https://doi.org/10.1080/21645515.2018.1444321>

the development and use of economic evidence to inform the cost-effectiveness studies and build long-term capacity. The results of this analysis should empower NITAGs to recommend adoption of locally cost-effective vaccinations, including through a larger vaccination budget if necessary. Gavi can subsequently use its extensive subject-matter expertise to provide technical support for vaccine introduction, including planning, budgeting, and procurement.

Likely, HTA will also identify WHO-recommended vaccines that are not locally cost-effective—at least at the prices currently accessible to MIC procurement agencies. For non-cost-effective vaccines, Gavi should work with the NITAGs and HTA agencies to evaluate the price at which vaccines would meet local cost-effectiveness criteria. Given the large gap between prices paid by non-Gavi MICs and those secured via Gavi/UNICEF pooled procurement, countries can identify a set of vaccines that would become locally cost-effective at Gavi-achieved prices. Gavi can offer its market-shaping expertise, technical assistance, and procurement support to help countries achieve price reductions for these marginally cost-effective vaccines, helping accelerate new vaccine introductions within the existing budget envelope.

In some settings, vaccines may narrowly exceed local cost-effectiveness thresholds even when efficiently procured. In such cases, Gavi could consider modest subsidies for priority vaccines in MICs, essentially funding the difference between the procurement price and each country's cost-effectiveness threshold. The latest work on cost-effectiveness thresholds suggests that a half a GDP per capita is the rule of thumb that corresponds most closely to budgets and opportunity costs for the use of public monies in lower-income countries.¹⁶

2. Support targeted “Immunization Challenges” to increase vaccination coverage in underserved populations

To address the growing concentration of under-vaccinated children in Gavi-ineligible MICs—often clustered within specific underserved geographies or population subgroups (for more, see my colleagues' note, “[Vaccine Introduction and Coverage in Gavi-Supported Countries 2015-2018: Implications for Gavi 5.0](#)”)—Gavi should support targeted “Immunization Challenges” to increase vaccination coverage within specific target populations. Drawing on previous global health experiences—specifically [Salud Mesoamerica](#) and the [Nigeria Governors' Immunization Leadership Challenge](#)—Immunization Challenges would provide high-level political recognition and flexible grant funds to national and/or subnational governments that achieve substantial and independently verified increases in vaccination coverage among underserved populations.

Immunization Challenges would be conducted in partnership with local and/or subnational governments, leveraging financing from multilateral development banks or other funders to support programmatic costs (procurement, campaign costs, etc.). Gavi itself would help build political will and momentum for each challenge; provide technical support (upon request) to national and subnational partners; and offer modest and flexible results-based grant funding linked to verified increases in vaccination coverage.

Gavi should allocate a certain portion of its budget to this modality; work with partners to set criteria for country and/or subnational eligibility; determine the set of vaccines and target populations

¹⁶ Ochalek, Jessica, James Lomas, and Karl Claxton, “Estimating health opportunity costs in low-income and middle-income countries: a novel approach and evidence from cross-country data,” *BMJ Global Health* 2018; 3:e000964, <https://gh.bmj.com/content/3/6/e000964>

that are eligible for results-based payments; and establish a structured application process with transparent evaluation. Gavi must take care to ensure that eligibility criteria do not create incentives for governments to underinvest in vaccinations using domestic funds. To ensure acceptability to donors, Gavi should also set an income-based threshold for vaccination challenges that is somewhat higher than the current threshold but comparable or below thresholds used by other providers of global health assistance; for example, immunization challenges could be open to countries categorized as lower-middle-income by the World Bank.

3. Create Innovation Partnerships with middle-income countries

As many large MICs transition from Gavi support, Gavi's purchasing power within the vaccine market will fall—as will its ability to unilaterally shape the innovation agenda for vaccine research and development. To sustain innovation as a core component of Gavi's mission and business model—and ensure continued relevance of Gavi-supported innovation across emerging markets—Gavi should engage MICs as partners in shaping a joint innovation agenda.

Within the framework of an Innovation Partnership, Gavi and MIC governments would:

- identify local innovation priorities
- calculate and signal willingness to pay and market size for desired innovative products (using value-based pricing principles and ensuring local affordability)
- create joint target product profiles between Gavi and MIC governments to aggregate and signal demand to industry
- compile joint Gavi and MIC demand estimates
- potentially, facilitate binding advance purchase commitments to accelerate priority innovation. Near-term opportunities may include the hexavalent vaccine including IPV or a universal flu vaccine, subject to assessment of their cost-effectiveness

4. Support vaccination in emergencies and for refugee populations, including in non-Gavi-eligible countries

The income-based Gavi eligibility criteria are no longer fit for purpose in certain conflict, displacement, and emergency situations, particularly in the context of refugee populations who may be displaced over long periods of time. In recognition that many refugees and displaced populations are housed outside of Gavi-eligible countries—and that conditions in non-Gavi-eligible countries can rapidly deteriorate during a complex emergency—Gavi should expand its current [policy](#) on fragilities, emergencies, and refugees to additional settings and populations, including those not eligible for traditional Gavi support.

The scope of Gavi support would necessarily be determined on a case-by-case basis based on an appraisal of need and close coordination with partners, including UNICEF, UNHCR, and the World Bank. When appropriate, this additional support could be offered to (1) non-Gavi-eligible hosts of refugee or displaced populations; and (2) in countries facing complex emergencies. When refugees are hosted in Gavi-ineligible countries, Gavi should permit and encourage vaccine assistance to be channeled through mainstream government health programs rather than through creation of parallel delivery platforms, helping build inclusive health systems that can effectively serve entire communities.



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