Global Immunization and Gavi

Five Priorities for the Next Five Years

Center for Global Development

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The Center for Global Development is grateful for contributions from the Bill & Melinda Gates Foundation and individual CGD funders in support of this work.

Introduction

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Child vaccination remains among the most cost-effective uses of public and aid monies. In a highly contested funding environment where priorities must be set for the allocation of scarce concessional resources, investment in expanding the availability and coverage of cost-effective vaccination must come at the top of the list.

Gavi's mission—saving children's lives and protecting people's health by increasing equitable use of vaccines—remains highly relevant. Gavi and its partners have made enormous progress towards increasing equity in the introduction of vaccines; children living in the lowest-income countries now have access to the same set of vaccines as those living in high-income countries. Gavi and partners have also contributed to increased coverage; immunization rates are higher in Burundi and Rwanda, for example, than in many places in the United States and Europe. Yet the effects of under-immunization anywhere can have global implications everywhere, as recent outbreaks illustrate. New or dormant threats are also a new reality—newly vaccine-preventable diseases like Ebola or virulent flu strains can spread swiftly and lethally in an interconnected world.

These global realities require a new approach. A country crossing an income threshold does not signal mission accomplished for an organization that aims to save lives and protect health with vaccines. *Vaccines can only deliver on their health impact and value-for-money promise if herd immunity is attained and sustained.* Gavi 5.0 needs a new model to deliver on its laudable mission.

This overview note lays out five challenges and summarizes some of our ideas to address them; backing up each is a standalone note that provides greater detail and options for action.

Primary Challenges

1. Immunization coverage remains low in too many places. Increasing immunization coverage and equity have been part of Gavi's mission since its founding. Yet coverage rates of Gavi-funded vaccines are highly variable, particularly among those countries with the largest birth cohorts that are poised to or have already transitioned away from eligibility. In Ethiopia, for example, the pneumococcal conjugate vaccine was introduced in 2011 but coverage of a third dose of PCV among children 12–23 months had only reached half of children as of 2016, and less than 40 percent of children had received all basic vaccinations. Too often, the new vaccines reach the same children that already receive services and actually *increase* inequities as the same vulnerable populations are missed by more interventions and services. *While there are important success stories, there are just as many cases of stagnation and several egregious cases of very low coverage more than a decade after a vaccine is introduced.*

Drivers of under-immunization vary but are linked in the literature to the distribution and training of health workers, high staff turnover, and salary payment delays; shortfalls in funding created by macroeconomic changes, weak demand forecasting, or lack of budget priority to immunization; procurement and supply chain issues (e.g., global shortages of IPV and high wastage rates); and low demand, in part driven by parental beliefs or economic constraints as well as unfounded fears about vaccine safety and the intent behind immunization efforts, among others.

2. Country eligibility and transition criteria don't fit with mission and expected results. In its first 20 years, Gavi targeted its support to the 68–77 countries

Figure 1. Coverage rates for four vaccines vs. years since countries introduced those vaccines nationally

Note: Last dose refers to Hep B 3, Hib 3, MCV 2, and PCV 3
Source: WHO/UNICEF Year of Introduction of Selected Vaccines database from February 2019

meeting its income-based eligibility criteria over the period—specifically, GNI per capita under or equal to a threshold ($1,580 as of 2018, averaged over a three-year period since 2015). Historically, these countries housed most under-vaccinated children and struggled with the most severe resource constraints, offering a natural target for immunization support. Now, many of the largest recipients of Gavi funds will soon become ineligible for support under current rules; 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 financing and coverage amidst rapid urbanization, competing priorities for health spending, growing vaccine hesitancy, and complex emergencies and displacement. Further, there is historical evidence that Gavi-ineligible countries pay much higher procurement prices for many vaccinations (see below); that aid overall drops once the GNI threshold has been crossed and particularly affects the social sectors; and that public expenditure does not increase sufficiently to compensate for these declines. Together, these forces suggest that a more nuanced and less ad hoc approach to transition extensions and modalities is required.

3. Vaccine price, quality, and supply constraints are a problem for the growing number of countries transitioning from or not eligible for Gavi support and make Gavi's market shaping tools weaker. Gavi non-eligible countries pay high—and highly variable—prices for vaccines, with self-procurers doing

significantly worse. Unaffordable vaccine prices not only limit a country's ability to expand coverage but also deter new introductions. Further, market constraints related to supply and competition—due in part to insufficient production capacity, reliance on a small number of manufacturers, or safety missteps in own-manufacturing—continue to limit access to vaccines, with implications for Gavi and non-Gavi countries alike. Incentives and markets for future vaccines remain ill-defined, despite promising vaccine candidates that could potentially represent large-scale coverage gains such as hexavalent including IPV, universal flu vaccine, or Ebola vaccine. Further, the effectiveness of Gavi's own market shaping is under threat as current country eligibility rules will dramatically reduce the overall size of its vaccine procurement, potentially constraining its ability to drive lower prices and innovation through regular and predictable large-scale tenders alone.

4. Health system support creates limited incentives for coverage gains and is insufficient and overly complex for implementing partner countries. Gavi's support to health systems has swung from lesser to greater complexity over the past 10 years, but neither approach has proven clearly effective in solving coverage shortfalls. The current approaches and requirements makes it hard for countries to understand the exact offer, and the health systems grants are generally small-scale—less than $5 million per year. HSS and related support finances inputs into the delivery of vaccines—such as refrigerators, motorbikes, and training manuals—or technical assistance support via international agencies. Fully two-thirds of HSS funds are now channeled to partners rather than through country systems (See Nov 2018 board paper 6b). While the 2016 Full Country Evaluations led by IHME made a series of recommendations for reform, it is unclear whether the Gavi Secretariat has made progress in implementation. Likewise, countries do an HSS evaluation at the end of their grant, and several evaluations have been done previously – it is not possible to discern impact on the outcomes that matter from these materials.

5. Delivery in conflict and fragile settings is constrained by Gavi rules. Gavi's income-based eligibility thresholds are 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—challenge this approach, and more low-income country focus means more concentrated money in fragile and conflict settings. Gavi has taken a step toward a more inclusive policy with the Board's 2017 decision to permit certain operational flexibilities in fragile states, during emergencies, and to assist refugee populations. However, current policies do not permit Gavi support to refugee populations housed in non-eligible countries—where almost half of the world's 18 million refugees live—regardless of need. Further, even when vaccine delivery through government does not make operational sense, Gavi is obliged to operate through this channel, missing opportunities to increase access and coverage through other partners. The attention to supporting governments in their quest to establish sustainable immunization programs is right, and in some fragile states—like Liberia or South Sudan, where programs can work—this makes sense. However, in other settings, it is unlikely that government will be able to execute and expand coverage in the near or even medium term.

Recommendations for Gavi's Future Approach

1. Conserve the mission, double down on increases in equitable coverage within countries

Gavi's mission is more important than ever and many of its activities, such as vaccine procurement and introduction support, remain valuable. But with a changing context, Gavi funding must also contribute to the outcome that is meaningful for health impact: full immunization for age with existing and new cost-effective vaccines in the places where need is greatest,

and coverage is lowest. Introduction on its own without equitable coverage is no longer meaningful for the mission.

2. Match mission with new modalities

Gavi should engage selected middle-income countries under new modalities of cooperation that address the drivers of slow introduction and under-immunization, as well as changes in the broader aid landscape that will directly affect immunization program performance. Options include:

- adjusting eligibility, transition, and co-financing criteria to allow for bespoke support to middle-income countries and a measurable impact on full immunization rates, particularly in the poorest communities (see recommendation 4)
- supporting evidence-based priority-setting and procurement services (see recommendation 3)
- articulating more clearly and gradually with middle-income procurement and facilitation mechanisms such as the Vaccine Independence Initiative (VII)
- taking on support of key immunization program functions—vaccine-preventable disease surveillance, immunization program expertise, IPV financing—that are being affected by the scale down of GPEI and other aid transitions linked to GNI per capita eligibility
- taking advantage of the significant flexibilities of being a mission-driven public-private partnership to assure the delivery of vaccines in fragile settings in partnership with nongovernmental partners, while still working with government to work towards transition as soon as circumstances allow

3. Modernize and build on evidence for vaccine selection, market shaping, and procurement

There are significant cost savings and coverage gains to be made through pooled purchasing and/or framework agreements (negotiated access pricing) for price and quality. As more countries transition, Gavi and partners will need to create incentives and build political will for more economical strategies for procurement by clearly demonstrating potential efficiency gains and, in turn, making the problems of self-procurement and corruption/safety issues more visible in the public domain. Expanding VII's capital base and clearly articulating VII procurement with Gavi procurement is one option to create stronger incentives for country buy-in. Quality challenges and shortages can also be addressed through a broader set of market shaping tools and strategies. For example, where appropriate, auction and other procurement methods to assure supply security of affordable high-quality products should be tested and used more widely. Advance purchasing or market commitments should also be a regular feature of Gavi given the importance of new vaccines in the pipeline, and an explicit relationship with the vaccine development pipeline, particularly at CEPI, should be established.

4. Reset health system support to create strong and clear incentives for vaccine delivery and coverage with rigorous evaluation

For an organization with limited staff, Gavi should shift from purchasing specific inputs and addressing micro-barriers, and towards reforming policy frameworks and incentives for coverage. Supported interventions should directly address the drivers of under-immunization, including public spend-need mismatches, low demand for immunization, vaccine refusal or hesitancy, health worker shortages, and other major constraints on delivery. Support for interventions that have not been rigorously evaluated or have only limited evidence should hinge on the addition of an independent evaluation. Advocacy and information interventions to address vaccine hesitancy may be one interesting avenue to pursue, for example, or a clearer evaluation of the costs and impact of campaign versus routine immunization, and when to use each strategy. Another option is to support targeted "immunization challenges"

to subnational (state or provincial) authorities to increase vaccination coverage in underserved populations, modelled on the successful Nigeria Governor's Immunization Leadership Challenge, the Polio Debt Buy-Down, or Salud Mesoamerica. As Gavi continues to work on vaccine introduction and consider potential additions to its portfolio (e.g., the hepatitis B birth dose and booster vaccines for DTP), it should also consider testing what strategies may prove useful in minimizing the cost of introducing and routinizing new vaccines as part of health systems support.

5. Add money to deliver on the expanded agenda, including global health security

In addition to its role as a health and development organization, Gavi should be a substantive and financial part of the humanitarian system and the global health security agenda, and part of global strategies to eliminate polio and to prevent and control influenza. Exact amounts need to be evaluated. Silverman (2018) has estimated that the funds made available from 2018 country transitions was equivalent to about $57 million, or 5 percent of Gavi's 2017 disbursements. If new middle-income modalities are less expensive, or continued progress is made in co-financing, an additional amount may be released from subsequently transitioning countries. However, our suggestions for an expanded mandate, more important now than ever—including vaccine-preventable disease surveillance, more significant vaccine delivery support/incentives, and market incentives for new cost-effective vaccines—will require additional funding. The exact amounts should be assessed by the Gavi secretariat and partners; but, from an external view, it is apparent that the replenishment should be at least the same or larger than previous iterations.

Notes

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Vaccine Introduction and Coverage in Gavi-Supported Countries 2015-2018:

Implications for Gavi 5.0

Roxanne Oroxom and Amanda Glassman

Introduction

With a vision of "creating equal access to new and underused vaccines," Gavi set several coverage-specific targets for 2020 as part of its Phase IV strategy, including the immunization of an additional 300 million children, increased pentavalent 3 and measles-containing vaccine (MCV) 1 coverage, and greater equity in coverage across wealth quintiles.[1] The strategy also called for broadening protection through improved routine coverage and the introduction of new vaccines.[2]

Gavi's Mid-Term Review laid out progress to date on these targets. In 2016 and 2017, Gavi-supported countries vaccinated 127 million additional children through routine immunization and roughly 200 million people through campaigns.[3] Gavi also supported more than 100 introductions and campaigns of eight vaccines.[4] The proportion of districts in Gavi-supported countries where DTP 3 coverage reached or surpassed 80 percent improved modestly as well.

While this progress is laudable, coverage data from official and survey sources paint a more worrying picture of stagnation in coverage at suboptimal levels. Furthermore, coverage seems to be backsliding in some countries currently and formerly supported by Gavi.

In this note, we explore these coverage challenges in greater detail and offer recommendations for how Gavi can address them in its 5.0 strategy.

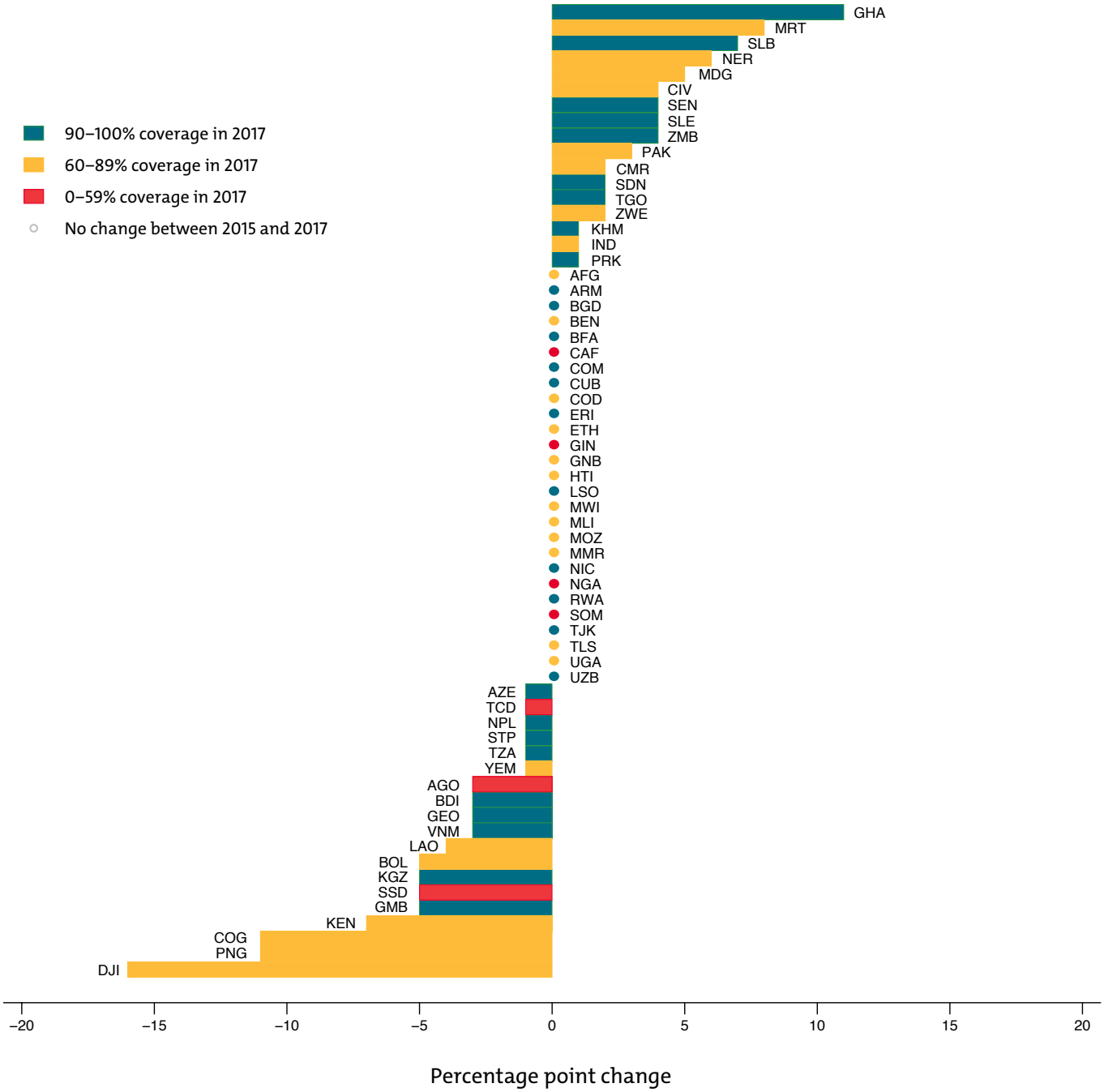
Challenges

Estimates aggregated across all Gavi-supported countries show modest gains in vaccine coverage between 2015 and 2017 based on WHO-UNICEF data. For example, DTP 3 and pentavalent 3 coverage increased only one percentage point, while drop-out after pentavalent 1 decreased one percentage point.[5] Coverage did not change at all in some cases. MCV 1 and pentavalent 1 coverage across the Gavi portfolio, for example, remained constant. Similarly, 27 of 64 Gavi-supported countries in the initial self-financing, preparatory transition, or accelerated transition stages in 2017 had the same DTP 3 coverage in 2017 as in 2015 (figure 1), although coverage was already relatively high in some of these settings.[6]

Coverage also varies widely across countries, even among those in the same co-financing stage (figure 2). Countries with sizeable birth cohorts but low and inconsistent levels of coverage present particularly troubling cases. For example, Pakistan (preparatory transition) and Indonesia (fully self-financing) had the third and fourth largest birth cohorts, respectively, in 2018, but MCV 2 coverage below 65 percent in 2017.

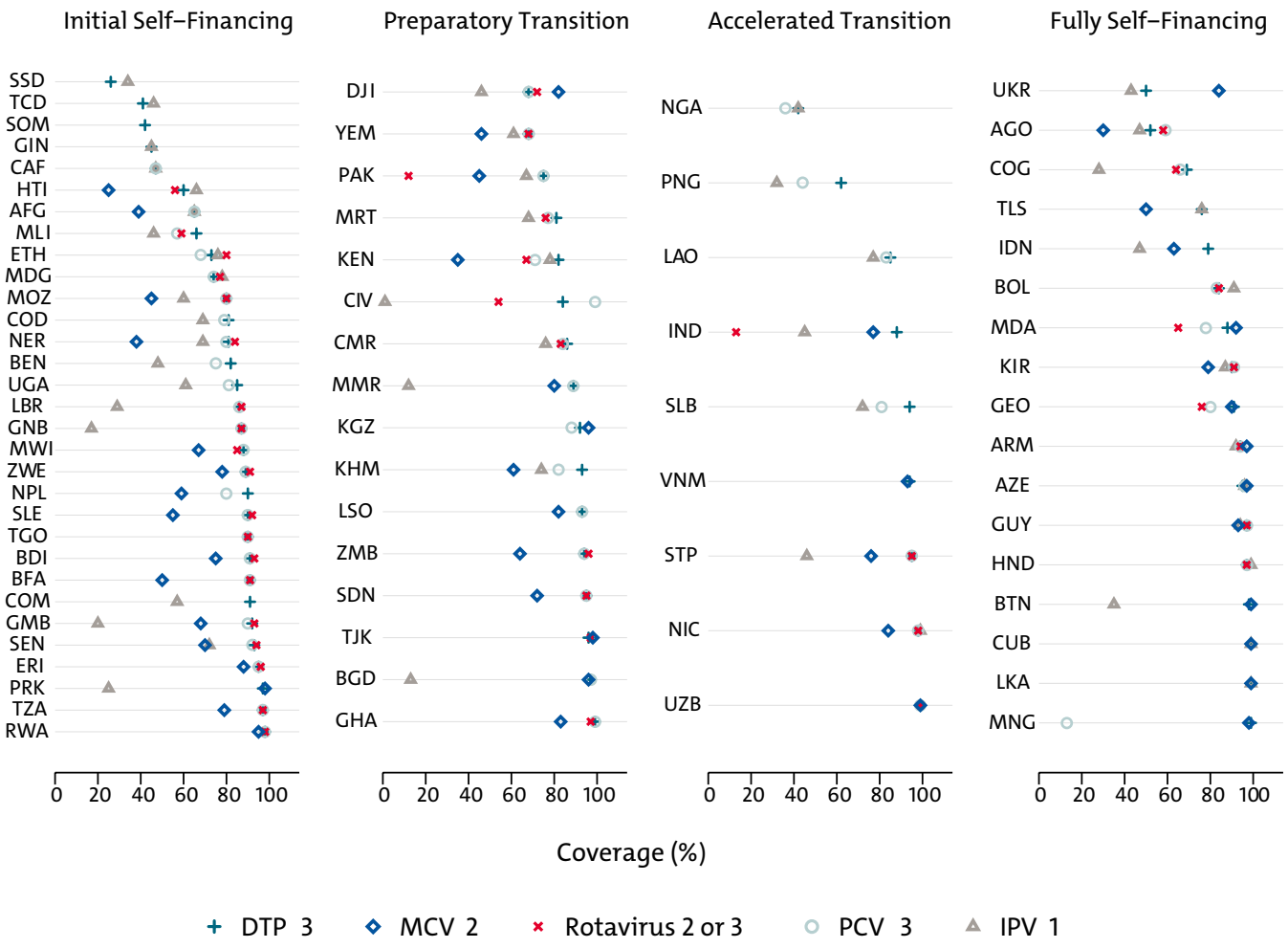
Recent Demographic and Health Survey (DHS) data for countries currently and formerly supported by Gavi depict similar variability in coverage (figure 3).[7] For example, pentavalent 3 coverage among children 12–23 months old ranged from a low of 39.6 percent in Angola (fully self-financing) to a high of 96.5 percent in Burundi (initial self-financing). Likewise, the

Figure 1. Percentage point change in DTP 3 coverage between 2015 and 2017



Note: For display purposes, the figure omits Liberia (34 percentage point increase in coverage between 2015 and 2017 to achieve 86 percent coverage in 2017)
Source: WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) data from November 2018

Figure 2. Coverage rates in 2017 by country and co-financing group at the time



Note: Sorted by DTP 3 coverage
Source: WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) data from November 2018

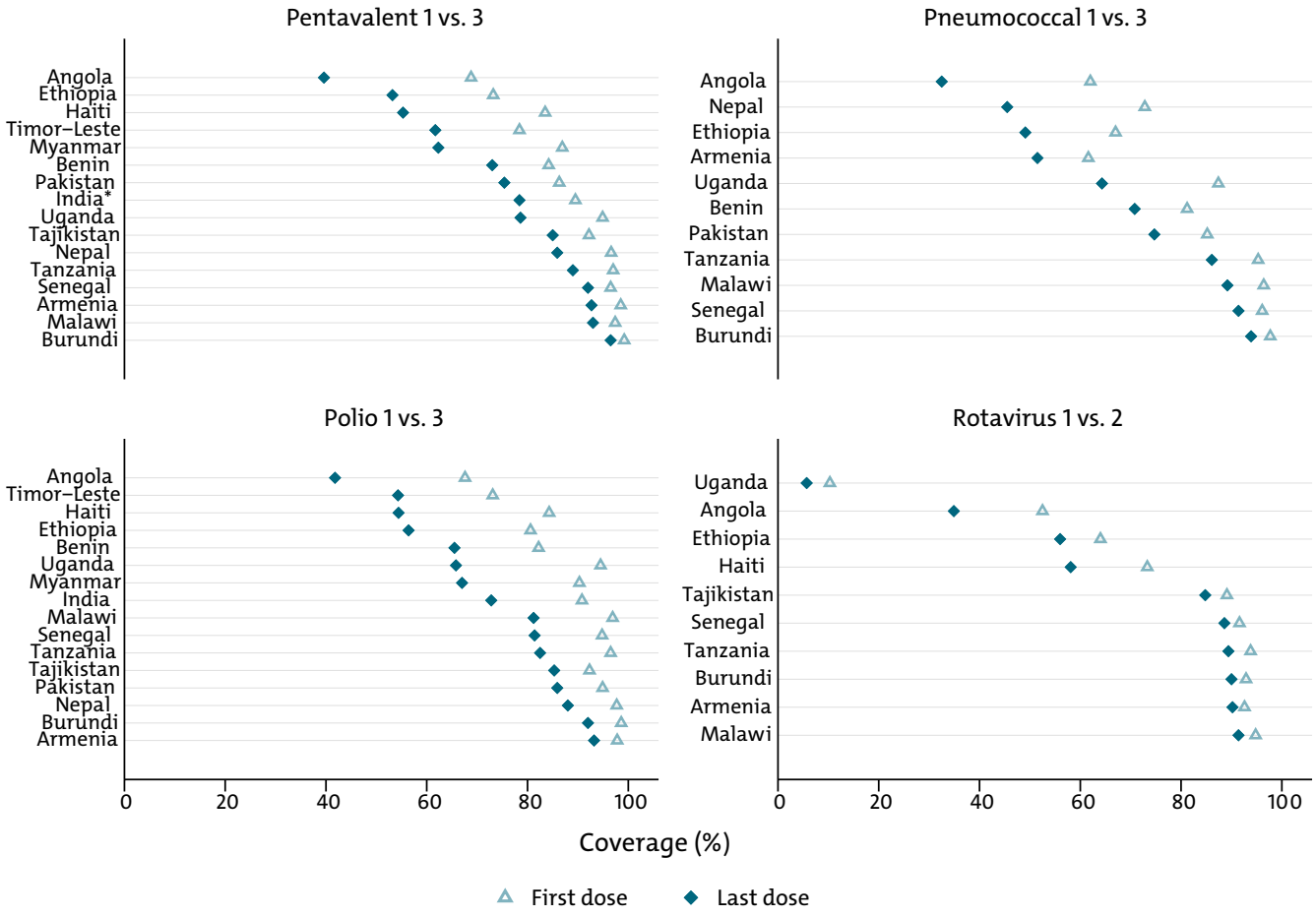
proportion of children in the same age group without any vaccinations ranged from 0.3 percent in Burundi to 19.2 percent in Timor-Leste (fully self-financing).

Within-country variation is also an issue, with children from poor households, living in rural areas, and with mothers who have less education least likely to be vaccinated, according to DHS reports. Gaps in immunization, no matter how small, have important implications for disease prevalence and incidence rates. Vietnam, for example, has had a national coverage rate for measles above 90 percent since 2014, but experienced a large outbreak around that time and reported 227 cases of measles in 2017 compared to 46 in 2016.[8]

There are numerous drivers of under-immunization. Frequently cited factors in Joint Appraisals and other case studies include:

- Inequitable distribution and poor training of health workers, high staff turnover, and salary payment delays[9]
- Shortfalls in funding created by macroeconomic changes (e.g., currency depreciation and changes in commodity prices), poor demand forecasting, or lack of prioritization for immunization[10]
- Procurement and supply chain issues (e.g., global shortages of IPV and high wastage rates)[11]

Figure 3. Coverage rates for the first and last doses of four vaccines



* India's values refer to DTPSources: Angola, Armenia, India, Malawi, Myanmar, Tanzania (2015-16 DHS); Ethiopia, Nepal, Timor-Leste, Uganda (2016 DHS); Burundi, Haiti (2016-17 DHS); Senegal, Tajikistan (2017 DHS); Benin, Pakistan (2017-18 DHS)

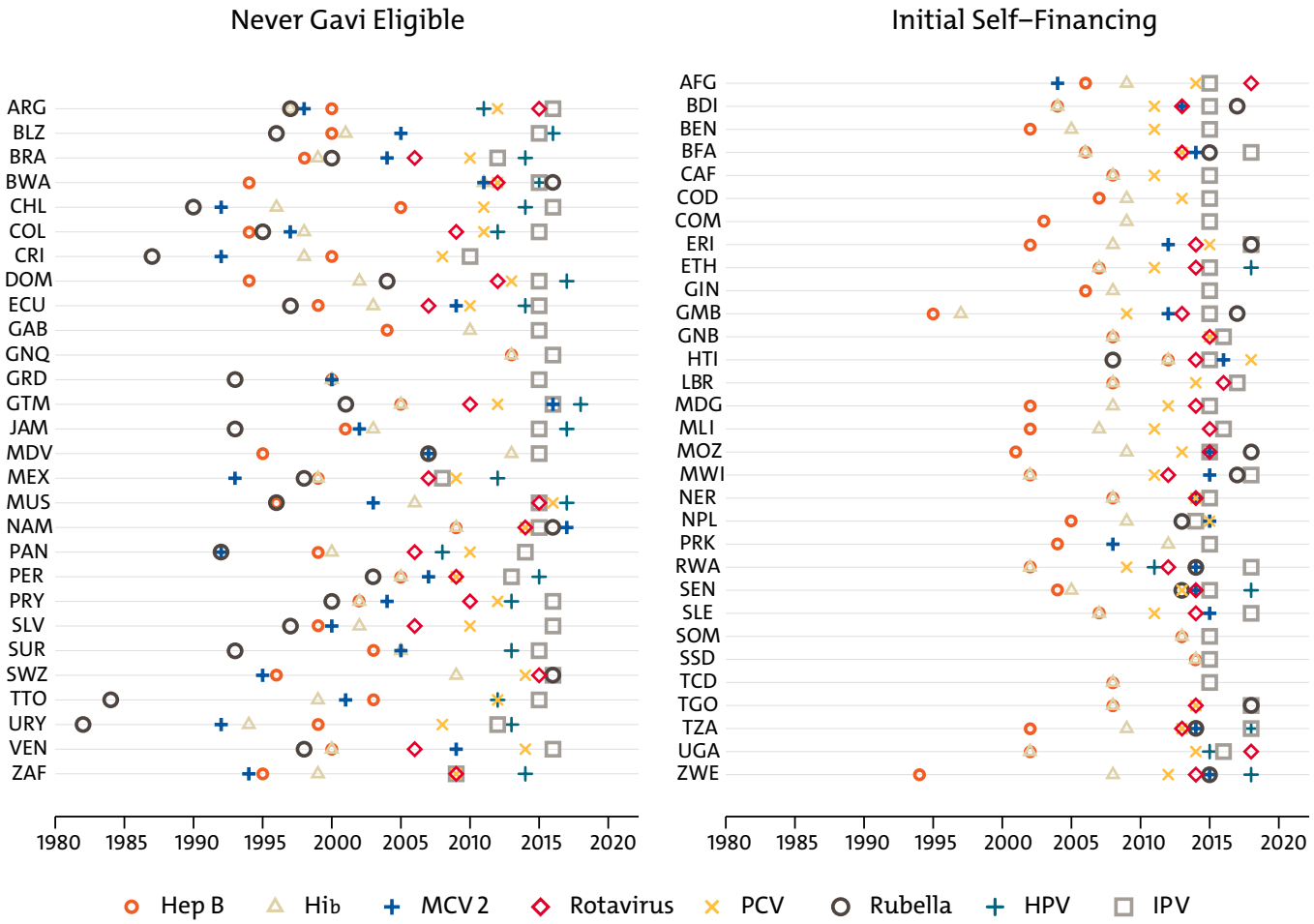
- Fears about vaccine safety and the intent behind immunization efforts, as well as reasons unrelated to fear[12]

Challenges on the Horizon

Increased reliance on immunization campaigns may draw time and resources away from routine vaccination efforts

Gavi saw the proportion of applications for campaigns rise from 15 percent in 2016 to 31 percent in 2017 and 55 percent in 2018.[13] Increased reliance on immunization campaigns may have unintended consequences. Immunization campaigns can be costly in terms of diverting health workers' time away from routine activities, as well as requiring funding for transportation, hiring, and overtime.[14] In addition, they may consistently miss key population groups if not designed well.[15] Coverage rates for vaccines not provided through campaigns may also suffer if routine immunization remains or becomes weak. For example, India's 2005–2006 DHS attributes differences in coverage of at least 17 percentage points for polio and DTP, which are given on the same schedule, to the Pulse Polio campaign.[16] Though Gavi acknowledges the potential hazards posed by frequent campaigns, documents from its November 2018 board meeting classify those risks as "outside of appetite."[17]

Figure 4. Year various vaccines introduced nationally



Source: WHO/UNICEF Year of Introduction of Selected Vaccines database from February 2019

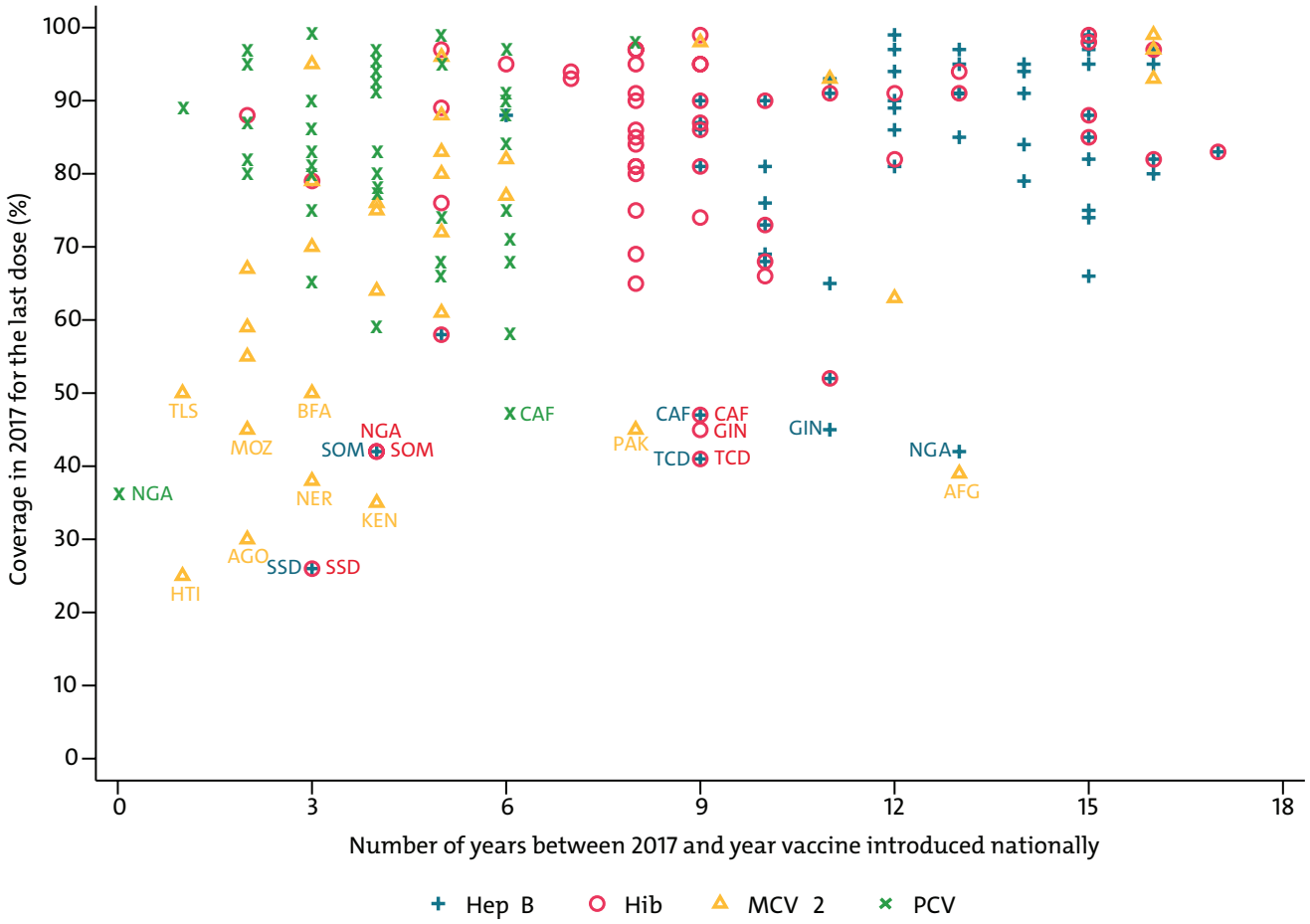
The fiscal space for immunization remains highly variable

As noted above, many factors have affected domestic funding for immunization activities. While volatility in funding is unlikely to completely cease in the future, inefficiencies in country spending—as evinced by the inconsistent relationship between spending on routine immunization and DTP 3 coverage—remain.[18] Improving the value-for-money achievable with current resources should be prioritized, particularly since studies have found that the costs of vaccination programs relate more to the delivery of vaccines than their cost.[19] Additionally, an analysis of global health transition from the major donors identified 11 countries that could undergo one or more transitions at the same time, and 9 of those countries receive support from Gavi.[20]

Current approaches to vaccine introductions may be inefficient

Gavi-eligible countries have made important strides in the introduction of new and underutilized vaccines. For example, 85 percent of middle-income countries (MICs) eligible for Gavi had introduced PCV in 2017 compared to just 3 percent of eligible MICs in 2010 and 50 percent of never-eligible MICs in 2017.[21] Nonetheless, introducing many disparate vaccines over a short time period, as many lower-income countries have done (figure 4), may create costs that affect the efficacy and scale-up of newly introduced vaccines.[22] For example, the concurrent launch in Mozambique of MCV 2 and IPV, which target different age groups, negatively influenced the degree to which social mobilization activities for each could be tailored.[23] Vaccines introduced nationally several years ago still had variable

Figure 5. Coverage rates for four vaccines vs. years since countries introduced those vaccines nationally



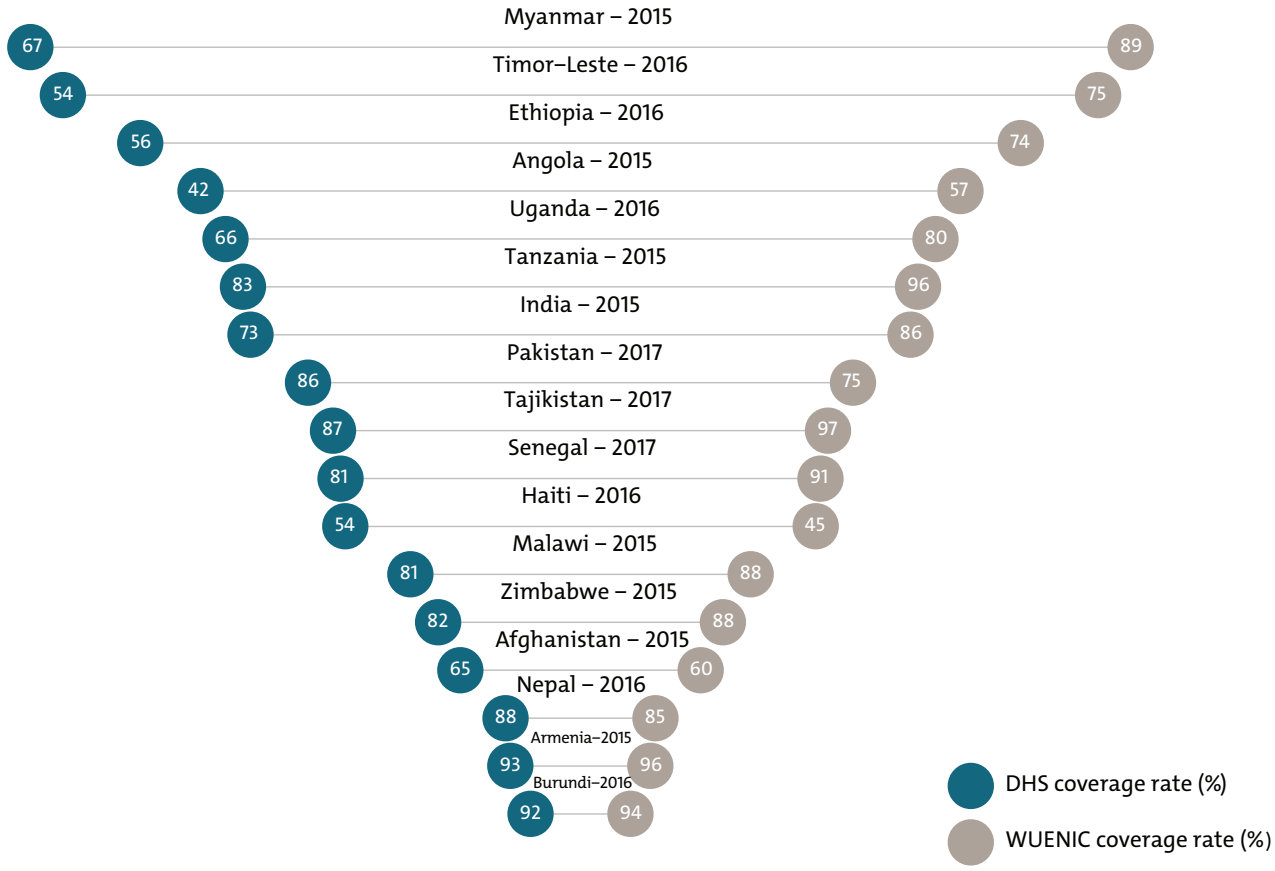
Note: Last dose refers to Hep B 3, Hib 3, MCV 2, and PCV 3
Source: WHO/UNICEF Year of Introduction of Selected Vaccines database from February 2019

coverage rates in 2017 (figure 5), possibly indicating that current approaches to introduction more broadly may be insufficient. That some transitioned countries have not introduced all WHO-recommended vaccines also remains a key topic of interest to Gavi.[24] It requires further exploration, though stakeholder interviews suggest that the availability of financing plays a significant role in vaccine introduction.[25]

Coverage estimates can be inconsistent

Variation in estimated coverage rates stemming from the use of different data sources (e.g., surveys or routine administrative reports) remains a widely acknowledged but persistent challenge. Gavi has introduced a data quality indicator that measures the percentage of Gavi-supported countries with a recent household survey and less than a 10-percentage point difference between survey and administrative estimates.[26] Though the indicator will compare estimated coverage rates for pentavalent 3 (or DTP 3 in some cases), significant inconsistencies also endure for other vaccines, such as polio (figure 6). Moreover, issues with caregiver recall or health card completeness, which many surveys rely on to calculate coverage, may lead to overestimates. In Nicaragua, measles coverage calculated based on caregiver recall or child health cards indicated an 82 percent coverage rate while dried blood spot samples revealed an effective coverage rate of just 50 percent.[27]

Figure 6. Comparison of Polio 3 coverage rates according to the Demographic and Health Surveys (DHS) and WUENIC data



Note: For countries with DHS that span two years - Angola, Armenia, India, Malawi, Myanmar, Tanzania (2015-16 DHS); Burundi, Haiti (2016-17 DHS); Pakistan (2017-18 DHS) - the figure compares WUENIC data to the first survey year (e.g., 2015 WUENIC to 2015-2016 DHS)
Source: DHS Program STATcompiler accessed March 2019 and WUENIC data from November 2018

The drivers of vaccine hesitancy, vaccine refusal, and low uptake—and how to address them—are very context-specific

Addressing household fears and concerns around vaccination is a priority, but evaluations often focus on interventions in high-income countries.[28] Lessons and tools based on those settings may not be generalizable owing to the context-specific nature of fears.[29] Low demand for immunization services also stems from more than just fears about side effects. According to the most recent assessment of the Global Vaccine Action Plan, 87 percent of countries reported some levels of hesitancy, but concerns about the risks of immunization represented only a third of reported reasons for low demand.[30] Research suggests a lack of awareness about the need for vaccination/subsequent doses, distance from clinics, lack of vaccinators, and affordability are all reasons for incomplete or non-vaccination.[31] More research is needed to understand the drivers of low demand and to rigorously test promising interventions to improve coverage (e.g., cash transfers) in different settings.

Recommendations for Gavi's Future Approach

1. Reconsider the scope of eligibility and transition criteria to account for low or backsliding coverage rates

Given stark coverage issues faced by some countries that have already transitioned (e.g., Angola), Gavi should revisit the issue of expanding its eligibility criteria. Expanding the set of eligibility criteria may allow Gavi to more effectively target its resources to areas with the highest need. If those conversations proceed, it may prove beneficial to make access to certain streams of funding contingent on coverage rate improvements.

2. Support specific vaccine delivery interventions that rigorous impact evaluations have identified as effective and cost-effective

Supported interventions could address low or decreasing demand for immunization, vaccine refusal or hesitancy, health worker shortages, and other key issues. Support for interventions that have not been rigorously evaluated or have only limited evidence should hinge on an independent evaluation. The limited number of studies considering costs should also expand to evaluations of the relative cost-effectiveness of campaigns versus routine immunization and specific ways those approaches can be more complementary.[32]

3. Work with other donors to understand the broader macro fiscal context in supported countries

Gavi should monitor indicators of potential economic vulnerability/volatility, such as oil prices for commodity exporters, that may affect the availability of domestic funding for immunization activities. This work should be completed in coordination with other donors, such as the Global Fund, since findings may have implications for their programming efforts and thus donor alignment.

4. Explore strategies to minimize the cost of introducing and routinizing new vaccines

As Gavi continues to work on vaccine introduction and discuss additions to its portfolio (e.g., the hepatitis B birth dose and booster vaccines for DTP), it should consider what strategies may prove useful in minimizing the cost of introducing and routinizing new vaccines. For example, improvements in DTP, Hib, and Hep B coverage since 2000 suggest that combinations like pentavalent may be an effective way of improving coverage rates for numerous vaccines at once.[33] There may be scope for the hexavalent vaccine that includes IPV, which alone has variable coverage rates.

5. Support improved data collection

Given the time lag between most Demographic and Health Surveys, Gavi should support smaller-scale data collection efforts that focus on measuring effective coverage and improving the robustness of data documented in child health cards. Introducing intermittent but rigorous data checks in subnational areas with low coverage/high concentrations of under-immunized children may prove particularly useful since some newer Health System Strengthening grants already target those areas.

Notes

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2. Gavi, "2016-2020 Strategy Indicator Definitions" (Gavi, the Vaccine Alliance, 2015), https://www.gavi.org/library/gavi-documents/strategy/gavi-2016-2020-strategy-indicator-definitions/.

3. Gavi, "2016-2020 Mid-Term Review Report" (Gavi, the Vaccine Alliance, November 2018).

4. Seth Berkley, "Mid-Term Review Presentation" (December 11, 2018), https://www.gavi.org/library/audio-visual/presentations/dr-seth-berkley-mid-term-review-presentation/. Page 23 lists vaccines introduced and supplied via campaigns since 2016: pneumococcal, rotavirus, measles, measles-rubella, meningitis A, human papillomavirus (HPV), Japanese encephalitis, and inactivated polio vaccine (IPV).

5. Gavi, "2016-2020 Strategy: Progress, Challenges, and Risks," November 2018.

6. Comparisons of the percentage point change in DTP 3 coverage between 2010 and 2012 show positive changes more often than negative or no changes.

7. Only some countries ever supported by Gavi had Standard DHS (not MIS or AIS) data available for 2016, 2017, or 2018: Angola, Armenia, Burundi, Ethiopia, Haiti, India, Malawi, Myanmar, Nepal, Pakistan, Senegal, Tajikistan, Tanzania, Timor-Leste, and Uganda.

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New Gavi Modalities for a Changing World

Rachel Silverman and Amanda Glassman

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.

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

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	2027	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	2025	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%

Sources: Silverman (2018); UNICEF

complicate countries' efforts to sustain vaccination programs following the loss of Gavi support.

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 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 2017[6] 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.

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 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 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.

Notes

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.

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Gavi's Role in Market Shaping and Procurement:

Progress, Challenges, and Recommendations for an Evolving Approach

Janeen Madan Keller and Amanda Glassman

Introduction

Market shaping and procurement constitute a core approach to achieve Gavi's mission to accelerate access to and increase equitable coverage of vaccines. Gavi drives lower prices and ensures the supply of high-quality vaccines[1] through a range of tools such as pooling demand with assured funding, offering multi-year contracts, and encouraging new suppliers to enter the market, among others.[2] Gavi has made notable progress, including securing a sustainable and affordable supply of pentavalent, pneumococcal conjugate (PCV), and rotavirus vaccines;[3] expanding and diversifying the manufacturer base;[4] and developing demand forecasts to give manufacturers longer-term market visibility.[5] These efforts have no doubt provided benefits to Gavi-supported countries, and they have also had some positive spillovers in Gavi-ineligible countries.

Yet several challenges—stemming in part from countries transitioning from Gavi support and an evolving vaccine manufacturer landscape—may impede Gavi's ability to effectively deliver on its mission in the future. The next five-year strategy (Gavi 5.0) is an opportunity to evolve—and possibly broaden—Gavi's role in market shaping and procurement. Looking ahead, Gavi will need to more carefully assess the implications of its market shaping strategies beyond Gavi-supported countries—and consider ways to potentially extend its benefits to the entire universe of low- and middle-income countries. And as more countries transition, a scaling back of Gavi's role in directly financing and purchasing vaccines will merit a concurrent scaling up of efforts to strengthen the procurement enabling environment. Supporting countries today to access affordable, high-quality vaccines through targeted market shaping and enhanced procurement support will empower them to make existing budgets go further in the future, freeing up resources to expand coverage and introduce new vaccines.

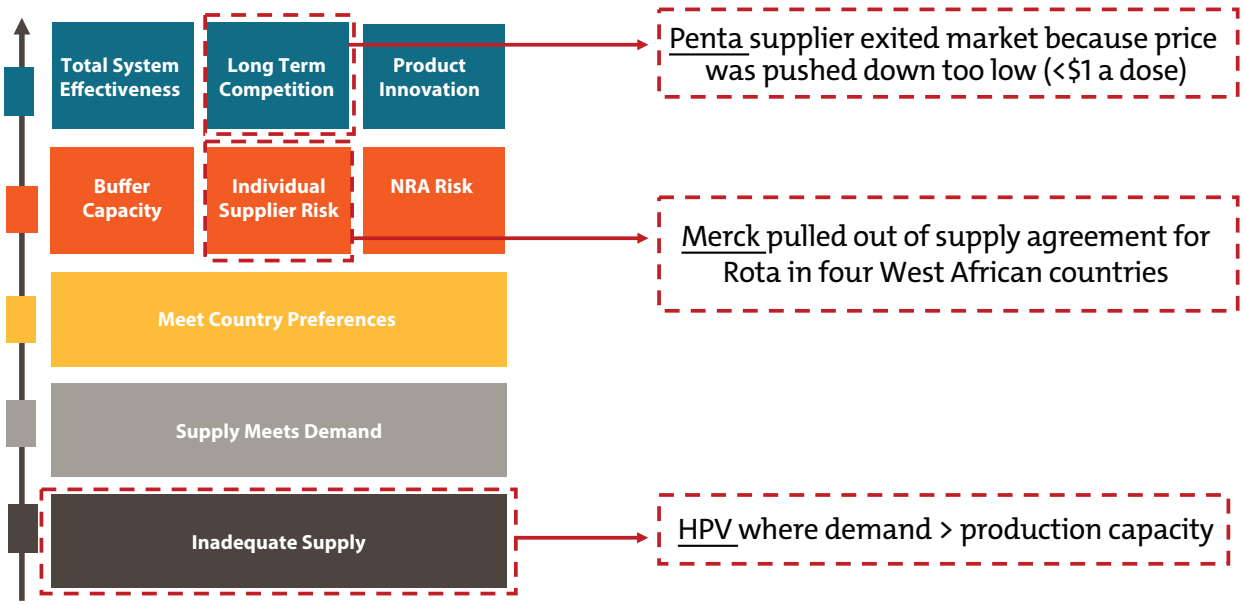
In this note, we diagnose key challenges that will strain Gavi's model during the 2021–2025 period and beyond. We then offer recommendations for an evolving approach, which closely align with Gavi's goal to maximize the impact of countries' current and future domestic investments.

Challenges on the Horizon

Constraints in specific vaccine markets are putting pressure on Gavi's market shaping tools, with broad-reaching implications for Gavi countries

Market constraints at the global level hinder countries' abilities to access a timely, stable, and affordable supply of high-quality vaccines to meet their needs. Procurement inefficiencies and supply breakdowns can lead to disruptions in immunization programs and can be an important driver of under-vaccination; they may also contribute to delayed or deferred introductions.[6] Nevertheless, some Gavi-supported countries are

Figure 1. Illustrative examples of pressures on Gavi's market shaping tools, based on the healthy markets framework



Source: Authors, based on the 2015 Healthy Markets Framework developed by Gavi, UNICEF, BMGF, available here.

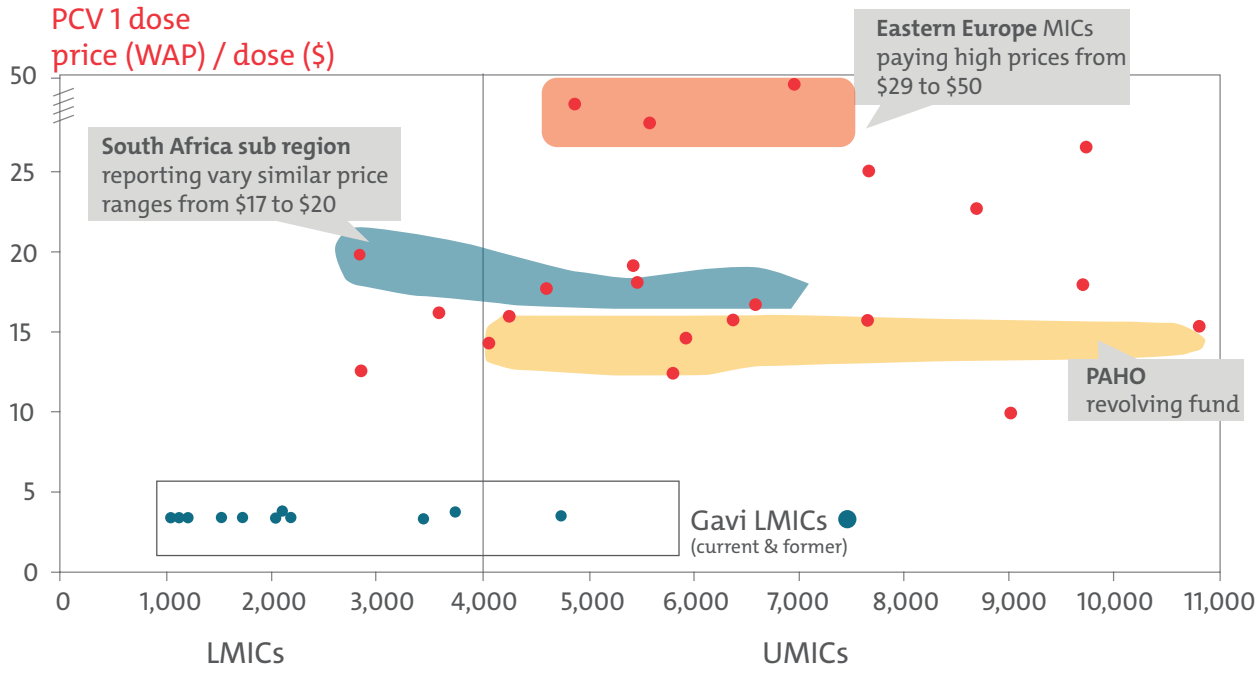
introducing vaccines, even as data reveal a stagnation in coverage rates of basic vaccines and/or earlier-introduced new and underused vaccines at suboptimal levels.[7] One hypothesis suggests that Gavi's approach to demand consolidation may emphasize new introductions to achieve sufficient volumes across countries to access favorable prices, underscoring the need to carefully balance trade-offs across priorities.

Further, constraints related to supply and competition for specific vaccines at the global level are putting increasing pressure on Gavi's market shaping tools (see figure 1). In the case of the human papillomavirus vaccine (HPV), increased demand from countries, driven in part by Gavi's own efforts to boost introduction, is outstripping production capacity.[8] For the pentavalent vaccine (Penta), where prices have been pushed below $1 per dose, one manufacturer exited the market in 2017.[9] While other manufacturers remain, this nevertheless illustrates the importance of balancing trade-offs between price and supply security. Last year, Merck pulled out of its agreement with Gavi and UNICEF to provide rotavirus vaccine (Rota) to four West African countries,[10] potentially redirecting product to the more lucrative market in China, as some reports suggested.[11] This case underscores certain risks of nonbinding agreements where there may be little or no recourse when manufacturers renege on commitments.[12] Ultimately, it also highlights the need to better understand the implications of Gavi's market shaping strategies on the broader market landscape.

Countries that are not eligible for Gavi support face high and unpredictable vaccine prices, undermining coverage and new introductions; this may be indicative of future challenges for transitioning countries

High vaccine prices pose a critical problem in many middle-income countries—and notably among the cohort of never-Gavi eligible countries. Figure 2 illustrates significant variation in prices paid across lower-middle and upper-middle income countries for a single dose of PCV. In comparison to the multi-year

Figure 2. High—and highly variable—vaccine prices for PCV across middle-income countries



Source: Gavi Report to the Board, Annex B: Supplementary contextual analysis, available here. Data represent 2016 prices reported to the V3P database (country names are anonymized).

Table 1. 2016 price per dose for PCV across middle-income countries, by Gavi eligibility and procurement mechanism

PCV 2016	Gavi/Non-Gavi	Procurement	Average Price	Price Range	N
LMIC	Gavi	UNICEF SD	$3.58	$3.05 - 7.89	24
	Non-Gavi	Self-procurement	$16.19	$12.51 - 19.83	4
UMIC	Gavi	UNICEF SD	$3.41	$3.14 - 3.68	5
	Non-Gavi	UNICEF SD	$20.50	$16.00 - 25.00	2
	Non-Gavi	PAHO Revolving Fund	$13.71	$7.62 - 15.58	8
	Non-Gavi	Self-procurement	$25.81	$9.85 - 49.99	15

Source: Authors based on 2016 price data for PCV reported to the V3P database (country names are anonymized).

supply agreement price of $3.03 to $3.30 per dose available to Gavi countries, non-Gavi middle-income countries in Southern Africa pay $17 to $20 for a single dose, while those in Eastern Europe pay as much as $28 to $50.[13] While the underlying cause of price dispersion is not immediately obvious, it may suggest a tiered pricing strategy by suppliers. In theory, tiered pricing can help improve access, however in practice, higher prices have proven to be locally cost-ineffective in some middle-income country contexts (e.g., Thailand).[14] Other potential factors that may contribute to price variation include small purchase volumes, the type and length of contracts, and specific payment modalities or payment delays.[15]

Data also suggest that self-procuring middle-income countries may pay higher—and more variable—prices than those procuring through UNICEF Supply Division

or PAHO's Revolving Fund (see table 1). (The reasons why countries choose to self-procure are many-fold and may include laws or other political economy factors that prevent the use of external procurement agents; cash flow constraints to meet UNICEF's pre-payment requirement;[16] the desire to exercise country preferences in product choice; and national industrial policies that favor local producers, among others.[17])

High prices are an important driver of underperformance on vaccine coverage, and may also deter new introductions. For example, never-Gavi countries lag behind current and former Gavi countries on PCV introduction.[18] This may be because PCV is locally cost-ineffective at current market prices, though it would be cost-effective at the Gavi price; it may also be an issue of limited fiscal space.

This reality may be indicative of future problems for Gavi graduates. Transitioned countries can access multi-year supply agreement prices through manufacturer commitments via UNICEF or PAHO (Gavi's designated procurement agents). This support helps smooth the transition process. However, it applies to select vaccines, is time limited with varying lengths, and has many exceptions, and the nonbinding nature of commitments can create uncertainty.[19] Moreover, the unpredictability of vaccine prices offered in response to national tenders affects budgeting and planning for self-financing countries. For example, India's recent domestic inactivated polio vaccine (IPV) tender saw an unexpected 80 percent price increase, prompting the government to request 50 percent cost-sharing support from Gavi of $40 million over 2019–2021.[20] This is a unique case, but it may illustrate the nature of challenges to come.

Several large middle-income countries that are top recipients of Gavi support—notably Nigeria, India, Pakistan, and Bangladesh—are projected to be fully self-financing by 2030.[21] Accordingly, Gavi's leverage in negotiating lower prices through pooling demand alone may become constrained. This could exacerbate pricing challenges, as manufacturers may, for example, face greater unpredictably related to payments and tendering; in some cases, they could raise prices to account for higher transaction costs to serve more fragmented markets.

Many middle-income countries have weak capacity in procurement and related functions

The sustainability of Gavi's approach to transition will ultimately hinge on countries being able to manage the procurement process and related functions themselves.[22] Yet numerous impediments to successful procurement remain. Key barriers, as identified by CGD's Working Group on the Future of Global Health Procurement[23] and other studies,[24] include weak capabilities, institutions, and processes to assume self-procurement, as well as weak regulatory capacity, most notably in transitioning countries. Furthermore, Gavi-supported technical assistance, delivered by Gavi partners, appears more geared toward vaccine delivery. While downstream supply chain issues certainly pose a critical barrier to effective and equitable coverage, procurement processes further upstream merit greater attention.

Recommendations for Gavi's Future Approach

1. Offer stronger incentives to manufacturers to ensure a stable vaccine supply and assure that market shaping efforts prioritize outcomes achieved beyond Gavi markets

Gavi should continue to broaden the scope of its market analyses to better understand the (positive and negative) implications of its market shaping strategies on non-Gavi markets, with priority to limited competition vaccine markets. Similarly, Gavi should also continue to prioritize a wide range of market shaping tools to attract new suppliers to market and drive innovation, including advance purchase commitments and volume guarantees, where applicable. One possibility could be an AMC/APC-type mechanism for an IPV-containing hexavalent vaccine, though attention should be paid to creating the kinds of incentives that would enable adequate and growing future supply while still

assuring viable markets for pentavalent and standalone IPV as hexavalent is gaining acceptance and adoption.

At the same time, Gavi should invest in strategically expanding the menu of procurement modalities, in collaboration with partners such as UNICEF. As one example, Gavi could systematically pilot, evaluate, and adopt auction-like tools in vaccine markets with adequate supply and competition. (Currently, only the Penta market has adequate supply and competition but Gavi and partners could look to apply auction designs to other vaccine markets that meet this description in the future.) A range of design instruments could help achieve supply security and lower prices—such as a phased approach where portions of total forecasted quantities are awarded in multiple rounds (as was the case with the 2016 pentavalent tender[25]) or allocation of quantities across multiple suppliers.

Finally, Gavi could expand demand forecasts to include self-financing and/or self-procuring middle-income countries in select vaccine markets where demand predictability may be an issue. This could be built into the existing Vaccine Product, Price, and Procurement (V3P) platform, managed by WHO, which aggregates vaccine purchase data for some 150 countries.[26] This may also be relevant within the framework of an Innovation Partnership with one or more middle-income countries to drive vaccine research and development.[27]

2. Consider a better-adapted set of modalities related to vaccine support for transitioning and, where relevant, ineligible countries

Where specific vaccines exceed local cost-effectiveness thresholds, Gavi could consider providing a modest subsidy to fill the gap between the vaccine price and the level at which it becomes locally cost-effective. This modality would be relevant to self-financing transitioned countries—and in certain never-Gavi countries—for specific high-priority vaccines. It would help ensure adequate volumes to be sustained to enable further market shaping work that relies on aggregated volumes to achieve sustainable pricing.[28]

For limited competition vaccines, Gavi could also enable buy-ins from noneligible countries and secure appropriate tiered pricing tied to local affordability and cost-effectiveness through globally negotiated agreements. This could potentially help address constraints to vaccine introductions in some Gavi-ineligible countries where market prices exceed local cost-effectiveness thresholds.

In collaboration with UNICEF, Gavi could expand the Vaccine Independence Initiative (VII) to make bridge funding available to a greater number of self-financing countries that face liquidity constraints to pre-payment. The VII—whose scope was expanded to all essential commodities in 2015—has a current capital base of $100 million; pre-financing requests are expected to reach an estimated US$225 million by 2020.[29]

In a similar vein, Gavi could work with partners and manufacturers to achieve greater predictability in pricing agreements available to transitioning and transitioned countries to facilitate more accurate, reliable budgeting and planning.

3. Taking a longer-term view, prioritize the underlying enabling environment for vaccine procurement in transitioning, transitioned, and potentially never-Gavi countries

Incorporating a standardized assessment of procurement bottlenecks and performance indicators (see below) into multi-partner Transition Assessments, as Gavi and partners are working to do, would help ensure barriers are sufficiently addressed during the transition planning processes. Where applicable, Gavi should continue to prioritize greater investments in targeted assistance for procurement and procurement-related functions (e.g., product selection, regulatory capacity, etc.) through existing modalities, including Gavi Transition Plans and Post-Transition Engagement. A more deliberate focus on building capacity over the long-term is a necessary complement to short-term support. This support could include trainings to boost demand for and use of data and market information currently available through the V3P/MI4A project to improve

decision-making. Gavi's targeted support in this area could consider a results-orientation, linking financing to the achievement of measurable outcomes.

In collaboration with partners, Gavi should also consider extending technical assistance for priority-setting around adoption/introduction, product selection, and procurement processes to never-Gavi countries that are lagging in these capacities.

Finally, working closely with partners and funders (e.g., UNICEF, WHO, PAHO, BMGF, and the World Bank), Gavi should prioritize the provision of procurement-related public goods available to all countries, such as:

- standardized procurement performance indicators (KPIs)
- building an evidence base of strategic practices for vaccine procurement to achieve price reductions while also maintaining supply security (recommendation 1, above)
- support for expedited drug registration processes at country-level to lower transactions costs and barriers to entry.

Notes

1. See the accompanying note in this series, "Gavi's Approach to Health Systems Strengthening (HSS): Reforms for Enhanced Effectiveness and Relevance in the 2021-2025 Strategy," which focuses on delivery platforms to ensure those vaccines reach their target populations—another key pillar of Gavi's vaccine support.

2. Market shaping is the fourth strategic goal in the 2016–2020 strategy. See: https://www.gavi.org/about/strategy/phase-iv-2016-20/market-shaping-goal/

3. The weighted-average-price of immunizing a child with a full course of pentavalent, pneumococcal conjugate, and rotavirus vaccines fell from $35 in 2010 to less than $17 in 2017. ("Supply and Procurement Strategy 2016-20." Gavi, the Vaccine Alliance, n.d. https://www.gavi.org/library/gavi-documents/supply-procurement/supply-and-procurement-strategy-2016-20/; "2016-2020 Mid-Term Review Report." Gavi, the Vaccine Alliance, November 2018. https://www.gavi.org/library/publications/gavi/gavi-2016-2020-mid-term-review-report/)

4. The number of manufacturers supplying Gavi-eligible countries has increased from 5 in 2000 to 17 in 2017. ("Supply and Procurement Strategy 2016-20."; "2016-2020 Mid-Term Review Report.")

5. "Supply and Procurement Strategy 2016-20."

6. "Pre-empting and Responding to Vaccine Supply Shortages." WHO SAGE, April 2016. https://www.who.int/immunization/sage/meetings/2016/april/1_Mariat_shortages_SAGE_2016.pdf

7. For more details, see the accompanying note in this series titled, "Vaccine Introduction and Coverage in Gavi-Supported Countries 2015-2018: Implications for Gavi 5.0."

8. "2016-2020 Mid-Term Review Report."; "Report to the Board—2016 -2020 Strategy: Progress, Challenges, and Risks." Gavi, the Vaccine Alliance, November 2018. https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/03---2016-2020-strategy---progress-challenges-and-risks/

9. "2016-2020 Mid-Term Review Report."

10. "2016-2020 Mid-Term Review Report."; "Report to the Board—2016 -2020 Strategy: Progress, Challenges, and Risks."

11. Doucleff, Michaeleen. "Merck Pulls Out of Agreement to Supply Life-Saving Vaccine to Millions Of Kids." National Public Radio (NPR), November 2018. https://www.npr.org/sections/goatsandsoda/2018/11/01/655844287/merck-pulls-out-of-agreement-to-supply-life-saving-vaccine-to-millions-of-kids

12. We acknowledge that the current structure of agreements can have benefits and drawbacks. In some instances, nonbinding agreements can be of good service to stewardship of donor funds, by not requiring Gavi to procure doses it may not need if there is a delay in country readiness pushing out a vaccine introduction date, for example.

13. "Report to the Board—Annex B: Supplementary Contextual Analyses." Gavi, the Vaccine Alliance, November 2018. https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---annex-b---supplementary-contextual-analyses/

14. See Thailand example cited in the accompanying note in this series titled, "New Modalities for a Changing World."

15. Silverman, Rachel, Janeen Madan Keller, Amanda Glassman, and Kalipso Chalkidou. "Tackling the Triple Transition in Global Health Procurement." June 2019. Final Report of CGD's Working Group on the Future of Global HealthProcurement. https://www.cgdev.org/better-health-procurement; Kaddar, Miloud, Helen Saxenian, Kamel Senouci,Ezzeddine Mohsni, and Nahad Sadr-Azodi. "Vaccine procurement in the Middle East and North Africa region: Challenges and ways of improving program efficiency and fiscal space." Vaccine, volume 37, issue 27 (2019): 3520-3528. https://doi.org/10.1016/j.vaccine.2019.04.029

16. UNICEF's Vaccine Independence Initiative (VII), discussed later in this note, helps address this issue.

17. Note that a country may choose to use an external procurement agent such as UNICEF or PAHO for certain vaccines but opt to self-procure others. (Arias, Daniel, Cheryl Cashin, Danielle Bloom, Helen Saxenian, and Paul Wilson. "Immunization Financing: A Resource Guide for Advocates, Policymakers, and Program Managers." Washington, DC: Results for Development. 2017. https://www.r4d.org/resources/immunization-financing-resource-guide-advocates-policymakers-program-managers/)

18. Report to the Board—Annex B: Supplementary Contextual Analyses."; "Report to the Board—Gavi 5.0: The Alliance's 2021-2025 Strategy." Gavi, the Vaccine Alliance, November 2018. https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/11---gavi-5-0---the-alliance-s-2021-2025-strategy/

19. "Vaccine Pricing: Gavi Transitioning Countries." WHO Vaccine Product, Price and Procurement (V3P) project, December 2017. http://lnct.global/wp-content/uploads/2018/02/Vaccine-Pricing-for-GAVI-Transitioning-Countries-1.pdf; Saxenian, Helen, Robert Hecht, Miloud Kaddar, Sarah Schmitt, Theresa Ryckman, and Santiago Cornejo. "Overcoming Challenges to Sustainable Immunization Financing: Early Experiences from Gavi Graduating Countries." Health Policy and Planning, volume 30, issue 2 (2015): 197-205. https://doi.org/10.1093/heapol/czu003

20. Although Gavi eligible, the government of India agreed to self-fund its IPV program. The India IPV decision was approved by Gavi's Board in November 2018. See: https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/presentations/12---gavi-s-support-for-ipv-post-2020/

21. See the accompanying note in this series titled, "New Modalities for a Changing World."

22. Kallenberg, Judith, Wilson Mok, Robert Newman, Aurélia Nguyen, Theresa Ryckman, Helen Saxenian, and Paul Wilson. "Gavi's Transition Policy: Moving from Development Assistance to Domestic Financing of Immunization Programs." Health Affairs: Vaccines, vol 35, no. 2 (2016): 250-258. https://doi.org/10.1377/hlthaff.2015.1079

23. Final report forthcoming. For more details see:
https://www.cgdev.org/working-group/ working-group-future-global-health-procurement

24. Cernuschi, Tania, Stephanie Gaglione, and Fiammetta Bozzanic. "Challenges to sustainable immunization systems in Gavi transitioning countries." Vaccine, vol 36, issue 45 (2018): 6858-6866. https://doi.org/10.1016/j.vaccine.2018.06.012; Kallenberg et al 2016; Saxenian et al 2015.

25. "Supply of Children's Five-in-One Vaccine Secured at Lowest-Ever Price." UNICEF, October 2016. https://www.unicef.org/supply/files/UNICEF_release_penta_pricing_19OCT16.pdf

26. "Global Vaccine Market Report." WHO V3P project, October 2018. https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/MI4A_Global_Vaccine_Market_Report.pdf?ua=1

27. See accompanying note in this series titled, "New Modalities for a Changing World."

28. See accompanying note in this series titled, "New Modalities for a Changing World."

29. "The Expansion of the Vaccine Independence Initiative (VII): Protecting Children with Life-Saving Supplies." UNICEF Financial Innovation Lab, n.d. https://www.unicef.org/supply/files/INNOVATION_LAB_LFLT_Ver1_Single_Pages.pdf; Arias et al 2017.

Gavi's Approach to Health Systems Strengthening:

Reforms for Enhanced Effectiveness and Relevance in the 2021–2025 Strategy

Cordelia Kenney and Amanda Glassman

Introduction

Delivery of Gavi's mandate—saving children's lives through equitable access to vaccines—requires both access to vaccines and effective platforms to deliver vaccines to target populations. Broadly, investments to improve these platforms fall into two categories: upstream assistance for procurement and product selection, and downstream support for vaccine delivery.[1] Gavi has historically approached the second category under the auspices of health systems strengthening (HSS) and through technical assistance.

Gavi has steadily increased HSS commitments over time and currently supports a range of activities under its Health System and Immunization Strengthening (HSIS) framework, launched in January 2017.[2] The HSIS framework primarily encompasses HSS, vaccine introduction grants (VIGs), product and presentation switch grants, and operational support for campaigns (Ops), in addition to other broadly defined systems-related support.[3] The HSIS framework was amended in June 2018 to increase flexibility in countries' HSS support ceilings[4] and, in November 2018, to support measles and rubella routine immunization activities.[5]

The HSS window began as flexible support with minimal monitoring (a "light touch") and has over time adjusted the stated purpose of, and guidance for, HSS support.[6] Investments in HSS now target health system "bottlenecks" (cold chain, data systems) across four key strategic focus areas (SFAs) measured by five related key indicators, with signs of progress across most (see table 1).[7]

Despite these adjustments, Gavi's approach to HSS support remains cumbersome for recipient countries and has not demonstrated an obvious or evident causal relationship between investments made and improved coverage rates or stronger health systems.[8] While it is difficult to measure and attribute outcomes at the system level, and although investments to address specific bottlenecks are important, they are small-scale efforts that are affordable within countries' own budgets and may fail to address systemic incentives issues.

Many of the countries that will be eligible for Gavi support under its next five-year strategy (Gavi 5.0), moreover, have very weak health systems that constrain development and implementation of robust immunization programs.[9] Weak implementation and planning capacity coupled with a growing prevalence of conflicts and displacement further strain health systems and government budgets. Strengthening health systems is a task that presents complex, intertwined challenges, some of which may not fall within Gavi's mandate or even control. The development of Gavi 5.0, therefore, presents an opportunity to reimagine how Gavi's HSS support is defined and allocated while complementing efforts towards universal health coverage and strong primary health care.

In this note, we highlight the results of Gavi HSS evaluations, how Gavi has responded to identified challenges and limitations in the HSS proposal and implementation process, and what options are available to enhance the effectiveness of HSS support for Gavi's core

TABLE 1. 2016–2020 Health systems strategic focus areas (SFAs) and key indicators

SFA	Data	Supply chain	In-country leadership, management, and coordination of immunization programs	Demand promotion and community engagement	
Key Indicators	**Data quality** measured by the proportion of Gavi-supported countries with a less than 10 percentage point difference between different estimates of immunization coverage	**Supply chain performance** measured by the average score achieved by Gavi-supported countries that have completed WHO's effective vaccine management assessment	**Integrated health service delivery** measured by the percentage of Gavi-supported countries meeting Gavi's benchmark of coverage levels for four interventions—antenatal care and administration of neonatal tetanus, pentavalent and measles vaccines—within 10 percentage points of each other, and all above 70%	**Civil society engagement** measured by the percentage of Gavi-supported countries that meet Gavi's benchmarks for civil society engagement in national immunization programs to improve coverage and equity	**Coverage** with a first dose of pentavalent vaccine and drop-out rate between the first and third dose
2020 Targets[11]	**53% (47%)**	**72% (68%)**	**42% (44%)**	**63% (18%)**	**90% PENTA1; 5% Drop-out (86%; 7pp)**

Source: Authors, based on Gavi website.

mandate. We also discuss the importance of 4G (Gavi, the Global Fund, the Global Financing Facility, and the World Bank Group) collaboration.

HSS Support in Practice: An Ever-Moving Target

The HSS window was formally launched in 2007, thanks in part to evidence from evaluations that indicated weak health systems adversely affected Gavi's performance.[10] Gavi's HSS window has evolved significantly since then, demonstrating both a responsiveness to the need for adjustments in scope and approach as well as an indication of the inherent difficulty in identifying appropriate and feasible mechanisms for strengthening health systems across a range of diverse contexts. Gavi's focus on supply chain performance, data quality, access and demand, integrated service delivery, and engagement with civil society organizations in the 2016–2020 strategy has helped move the HSS window in the right direction towards more targeted, outcome-oriented support to countries (see table 1). It also positively reflects Gavi's receptiveness to critiques raised in evaluations and a willingness to take recommendations on board.

The 2016 and 2018 meta-reviews of evaluations of HSS support, however, as well as recent Independent Review Committee and Full Country Evaluation (FCE) reports, indicate that issues with Gavi's design, implementation, and monitoring of HSS support have not been sufficiently addressed over time, and ongoing challenges continue to undermine the effectiveness of this window[11] (see box 1).[12] The Institute for Health Metrics and Evaluation's (IHME) 2016 FCE Annual Dissemination Report, for example, cited "complex, time-consuming, and poorly understood processes of applying for HSS support" as a key ongoing issue for all four FCE countries that adversely affect the outcome of HSS grants throughout the entirety of the application, approval, and implementation phases.[13]

Since the publication of the first meta-review in 2016, Gavi has introduced a series of changes in its guidelines as well as mechanisms for HSS-related support

(broadly defined) that attempt to address identified weaknesses (namely recommendations 2, 5, and 7 in Box 1). The introduction of the HSIS framework in 2017, for example, along with the Country Engagement Framework and Targeted Country Assistance under the Partner Engagement Framework, are intended to enable greater tailoring of support to individual country needs, greater stakeholder participation, and streamlining of application processes to overcome recurrent challenges identified in evaluations. Box 2 summarizes several key adjustments Gavi has made since 2016, which broadly reflect an attempt at clearer design and implementation guidelines for recipient countries relative to pre-2016 guidelines.

Although these changes reflect Gavi's acknowledgement of the underlying challenges with the HSS window, issues remain with Gavi's HSIS framework. The most recent meta-review, published in early 2019, renews several of the preceding meta-review's findings, including the ubiquitous challenge of financial sustainability beyond Gavi support.[14] And although the new meta-review highlighted enhanced collaboration and engagement with stakeholders during the proposal process, it also identified a growing problem of "channeling funds through Alliance partners…[which] may undermine national ownership and oversight."[15] None of the six countries' HSS support evaluations analyzed in the last meta-review are able to document the impact of the investments made under the HSS window nor the modifications introduced since 2016 (the HSIS framework, PEF, and JA).[16] While this may simply be a result of these reforms occurring too late in the evaluation period to make a difference or be accounted for, the continued absence of information as well as the lag in the implementation of changes nevertheless signals that the process has not yet generated a measurable impact on health systems or vaccination coverage rates.

Box 1. Recommendations from 2016 meta-review

1. Gavi to critically consider key aspects of the scope and objectives of HSS support.
2. Gavi to provide complete information and improve clarity on HSS window, requirements, and processes for countries.
3. Gavi to consider the most appropriate delivery model for HSS support and whether a more "hands-on approach" may be required for some countries.
4. Gavi to conduct a critical assessment of how best to circumvent implementation delays.
5. Gavi to consider the appropriate monitoring of HSS grants.
6. Where HSS funding is channeled through partners, greater clarity is required on processes.
7. Gavi to proactively clarify and provide guidance on reprogramming and reallocation of funding.

Source: Meta-Review of Country Evaluations of Gavi's Health System Strengthening Support

Challenges on the Horizon

HSS support remains poorly defined with health system "bottlenecks" difficult to pinpoint

A total of 56 countries currently have active HSS grants, of which 10 countries have been approved for HSS support through the new Country Engagement Framework process introduced in 2016.[17] A coherent articulation of what activities are supported by the HSS window, however, remains elusive, and on a fundamental level, it is unclear what HSS support is intended to achieve. Although health system "bottlenecks," or principal barriers to achieving vaccine coverage and equity, are referenced as areas countries should prioritize

in their proposals for Gavi support, bottlenecks are primarily and somewhat vaguely defined in terms of Gavi's strategic focus areas as well as in terms of specific populations and geographies.[18] The 2016 FCE cross-country report recommended Gavi explore "concrete and user-friendly tools and processes that support evidence-informed assessments of immunization bottlenecks" to inform HSS design; it is unclear whether Gavi has made progress in this area since 2016, though it has been reported that the greater difficulty lies in developing appropriate solutions for the bottlenecks identified.[19] Notably, for many countries—including FCE countries—these procedural changes will have a limited impact on existing HSS grants; that leaves 46 countries, or 82 percent of countries with active HSS grants, that are not necessarily benefitting from Gavi's reforms and that may be experiencing ongoing challenges in implementation and monitoring of HSS support.[20]

In practice, what Gavi supports under the HSS banner is difficult to pinpoint and varies significantly depending on when an HSS application was submitted and what countries identify as priorities (which, again, is influenced by Gavi's guidance in effect for HSS support). Liberia, for example, applied for HSS and Cold Chain Equipment Optimization Platform (CCEOP) support in September 2016 using the new Program Support Rationale (PSR) with five clearly articulated strategic objectives in line with Gavi's core strategic focus areas and HSS key indicators.[21] Each strategic objective identifies the health system bottlenecks it intends to address. India, meanwhile, submitted a proposal in April 2017 for HSS support that focuses on routine immunization strengthening through four implementing partners, UNDP, WHO, JSI, and UNICEF.[22]

On the other hand, Zimbabwe's HSS support, approved in the 2016–2017 period, is referenced in Gavi's Mid-Term Review report as an exemplar of better targeting support towards low-coverage subnational areas. There are no HSS proposal documents in Zimbabwe's country hub for this period, however, making it difficult to ascertain the funding mechanism and core objectives for this support.[23] Indeed, four of the 10 countries that have used the CEF process in this period do not have the pertinent HSS support proposal documents on Gavi's website as of March 2019, and four others are either primarily or exclusively for CCEOP support.[24]

Box 2. Key changes since 2016

1. Introduction of Health System and Immunization Framework (HSIS)
2. Introduction of Country Engagement Framework (CEF), or portfolio planning
3. Introduction of Partners' Engagement Framework (PEF), which includes Targeted Country Assistance (TCA)
4. Transition to Joint Appraisals from Annual Progress Reports, an in-country annual review of implementation progress
5. Addition of Grant Performance Frameworks (GPF) with standard and tailored indicators
6. Streamlining of HSS, vaccine, and CCEOP support through introduction of Programme Support Rationale (PSR) template
7. Introduction of Program Capacity Assessments (PCA), a financial assessment tool

Frequent changes to frameworks and implementation delays undermine the clarity and relevance of HSS support

Even as guidance has improved, the inherent complexity of efforts to strengthen health systems combined with poor planning and implementation capacity in-country presents a quandary for the relevance of Gavi's HSS support as a whole.[25] In particular, the prevalence of reprogramming or reallocation

of HSS funds—reported in 9 of the 14 evaluations in the 2016 meta-review—indicates that HSS grants do not maintain relevance over time. While priorities and needs may evolve significantly over the lifespan of an HSS grant (making flexibility in programming of funds important), applications for new HSS support under the Programme Support Rationale now require countries to take a three- to five-year view of Gavi support.[26] Requiring countries to take this long-term view while also knowing that implementation is likely to be delayed by a year or more creates potentially ex ante irrelevant programming. With some countries repurposing their HSS grants for cold chain equipment (CCEOP) and with technical assistance via Targeted Country Assistance[27] to complement Gavi's HSS support and New Vaccine Support, it is evident that HSS support applies to challenges in routine immunization and vaccine introductions. The definition of HSS support, however, has been tweaked nearly annually, making it hard for countries to understand what the HSS window covers.[28]

Ongoing process-related issues, as well as gaps in communication regarding delayed timelines, also contribute to frequent disbursement and implementation delays. In Uganda, for example, the 2016 FCE Annual Dissemination Report projected that disbursement delays (and lack of clear communication about the delays) would result in temporary cessation of HSS-funded activities due to HSS funding gaps.[29] Gavi HSS support has also, in some instances, supplanted domestic financing for operational costs, meaning that disbursement delays can hinder service delivery. These frequent changes and lack of clear indicators of success also make it difficult to monitor the impact of HSS investments over time. For example, the supply chain performance and civil society engagement indicators' 2020 targets were only developed at the end of 2018, with no 2015 baseline available for the civil society engagement indicator. And while the introduction of Grant Performance Frameworks and the Program Support Rationale template may eventually provide a clearer window into the impact of HSS investments, subnational indicators feature in less than half of the 56 countries' active HSS grants.[30]

The under immunized and underserved will overwhelmingly reside in Gavi-eligible countries with weak health systems in the next strategic period

Among the 50 countries that remain Gavi-eligible during the next strategic period,[31] 19 are identified as having a weak health system (38 percent).[32] More than half of the under-immunized population (57 percent) and nearly 40 percent of the eligible birth cohort will live in just four countries in 2025, which have also been identified as having weak systems: Nigeria, DRC, Ethiopia, and Pakistan.[33] These weaknesses can but are not always reflected in vaccination rates — Nigeria, a country with 197 million people, had an estimated 42 percent DTP3 coverage rate as of 2017, for example.[34] Pakistan, however, had an estimated DTP3 coverage rate of 75 percent in 2017 (though of course, at the provincial levels, variances may be more significant, as is the case with Ethiopia[35]).[36]

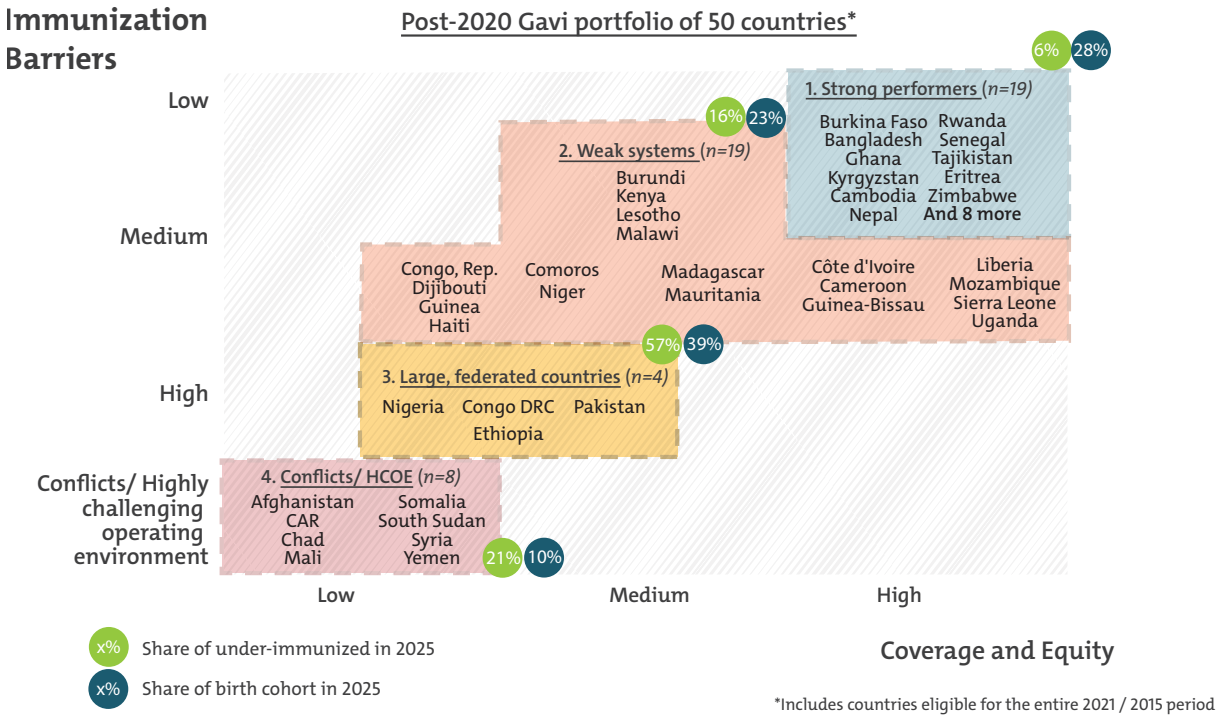
As Gavi doubles down on its aim to reach the "fifth child," it will have to do so in the context of increasingly fragile and weak governance settings. Country-level challenges affect all aspects of the health system; according to WHO, there is a global shortfall in excess of four million health workers and only 11 percent of African country governments adequately allocate resources for health in national budgets.[37]

The question therefore is how to address the challenge of under immunization in countries with weak health systems and where government may or may not be the best entity to deliver.

HSS support is small, slow to disburse, and channeled mainly to international partners

The majority of HSS grants are less than $5 million (per year),[38] representing a relatively small fraction of many countries' health budgets. It is unclear whether these grants can be truly catalytic as envisioned. The stronger oversight mechanisms and guidance frameworks mentioned above have also resulted in disbursement delays due to country program management and capacity issues; HSS grants take, on average, more than

Figure 1. High concentration of under-immunized in countries with weak systems



Source: March 2019 Gavi Board Retreat, segmentation presentation.

12 months to be disbursed after they are approved.[39] To prevent potential implementation delays, Gavi now channels two-thirds of HSS support through WHO and UNICEF and places partner staff in-country through Targeted Country Assistance, posing risks to country ownership and sustainability.[40] This reliance on external actors to oversee HSS support necessitates a rethink of the Gavi's positioning of HSS support, including a more clearly articulated framework for collaboration with partners in-country.

Recommendations for Gavi's Future Approach

1. Increase clarity, focus, and relevance by reframing Gavi investments as Vaccine Delivery Support

Creating an enabling environment for vaccine delivery is essential for achieving Gavi's mission. Vaccination is a vertical program, however, and Gavi's current HSIS framework should focus on vaccine delivery more explicitly, given that activities supported by the HSIS framework in practice constitute vaccine delivery and immunization systems. As an obvious starting point, Gavi 5.0 should reframe HSS support as "Vaccine Delivery Support" to better speak to the purpose of this window and eliminate the multiple and confusing windows and acronyms. Gavi's current guidelines for requesting new support, published in February 2019, include a definition of HSS support closer to this reality, while also indicating that Gavi will work towards a "portfolio view" of all Gavi support in-country.[41] While this portfolio view is critical to ensure all of Gavi's support makes sense from a 10,000-foot view and contributes to sustainability in programming and financing, the purpose and intended outcomes of HSS funding itself also need to be made more explicit and intentional from an institutional perspective.

In the next strategic period, Gavi should articulate a more clearly defined and coherent scope and approach to the HSS window that enables greater investment in sustainable vaccine delivery through this reframing. This should include revisiting both the problem definition underlying Gavi's HSS window and the Alliance's thinking around how to solve the problem so that the HSS window creates strong and clear incentives for vaccine delivery and coverage.

2. Develop and implement a clear set of criteria and framework for how Gavi makes allocation decisions under a health systems window

With total HSS support disbursements steadily increasing, Gavi should also consider developing a clearer and more transparent framework for how it makes allocation decisions for the total available funding under the HSIS umbrella and what kinds of activities HSS funding is intended to support. In the 2016–2020 strategic period, $1.3 billion has been allocated to HSS out of $2.1 billion total for HSIS programs (14 percent and 22 percent, respectively, of Gavi's entire forecasted expenditure for this strategic period), yet it is difficult to discern what that money will in practice support given both the lack of insight into and lack of consistency in outcome and activity tracking across countries.[42]

To overcome the limited leverage and impact of existing funds, a possible solution could expand on performance-based funding in Gavi's toolkit of modalities, looking to Salud Mesoamerica or the Nigeria Governor's Immunization Leadership Challenge as examples.[43]

Gavi should also be explicit and transparent about how and when it decides to channel HSS support through partners and should develop a clear framework for when significant amounts of funding will be diverted from country governments.[44] This could also enhance clarity on timelines and implementation plans from the country perspective.

This increased clarity in what HSS support covers would ensure alignment with countries' health budget allocations tailored to individual country needs and challenges at the subnational level, maintaining flexibility in approach while also introducing a greater degree of accountability (as Gavi has done with the Fragility Policy[45]). It would also assist with articulating the concrete problems HSS support is meant to solve while maintaining enough flexibility when course corrections are needed.

3. Develop a policy framework with the Global Fund and the Global Financing Facility to ensure the Vaccine Delivery Support framework aligns with their broader HSS programmatic and financial priorities

While a systems-level perspective is needed in Gavi's approach to ensuring coordination and complementarity of investments across the global health ecosystem, the broad goal of health system strengthening is beyond the scope of Gavi's core mandate. Enhanced collaboration among the biggest funders in global health—including the Global Fund and the World Bank's Global Financing Facility—will be essential in addressing the complex challenges ahead, with coordinated approaches in different countries key to successful interventions.[46]

While the Gavi Board has identified the "HSS agenda" as a promising ingredient in reaching the under-immunized and achieving universal health coverage, it should also carefully weigh its unique value add against the total HSS pot.[47] Of the Global Fund's overall support, for example, 27 percent goes towards "building resilient and sustainable systems for health," with many overlapping priorities.[48]

Gavi 5.0 should pursue a more coordinated approach with other HSS donors to ensure complementarity of investments, looking to recent examples such as the 4G Initiative (of which Gavi is a part), potentially even specific HSS-related commitments as part of 4G. Gavi should also examine its sharp increase in funding for in-country staff, partner or otherwise, to ensure that its technical assistance does not supplant training and capacity building of local staff.[49] Gavi could do this by working with countries to develop more robust

planning processes for eventual transitions (as recommended in the 2016 FCE Annual Dissemination Report).

For example, the Global Polio Eradication Initiative's (GPEI) anticipated winding down of vaccine-preventable disease surveillance support (among all other forms of support) has potentially enormous implications for certain countries with increasing emerging disease threats. As part of Gavi's involvement in the global health security agenda, it could work with partners to invest in surveillance systems, which HSS support does (in theory) fund already. As part of a menu of what HSS support can cover, and in line with what Gavi decides HSS support is intended to achieve, targeted investments in surveillance could bolster preparedness and response in some of the most vulnerable countries in the next strategic period.

4. Consider demand-side approaches to address constraints and drive coverage improvements

In a recent study of 15 countries transitioning from Gavi support, 92 percent reported vaccine hesitancy, indicating that this dangerous growing trend warrants attention in Gavi 5.0.[50] Although the study was limited to transitioning countries, vaccine hesitancy[51] and other demand-related issues are likely to loom large in the next strategic period, including potential opportunity costs that may be poorly understood and/or reflected in HSS proposal design. If immunization is to serve as a primary platform for achieving universal health coverage and primary health care aspirations, and if hard-won gains in coverage and equity are to be sustained, it will be imperative for issues on the demand side to be identified and addressed in designing Vaccine Delivery Support grants.

Recent evidence suggests that vaccination uptake-focused interventions, such as education campaigns, financial incentives, task-shifting, and laws, can have a sizable impact on immunization.[52] Gavi should work with country governments and other partners to scale up proven interventions to accelerate coverage rates and attain and sustain herd immunity. Gavi should also consider developing relevant indicators at the subnational level in partnership with countries that will help identify barriers to vaccination and potential context-appropriate behavioral interventions, among others.

Conclusion

The Gavi Board has acknowledged that a more tailored and country-specific approach is needed to deliver on Gavi's mission of providing access to life-saving vaccines. The Board has also acknowledged that fiscal and programmatic priorities should be coordinated across mechanisms to better advance shared goals and to achieve the Sustainable Development Goals. To better align with Gavi's core mandate and to better reflect the activities it supports, Gavi 5.0 should rename and redefine the HSS window to more explicitly orient it around vaccine delivery, develop a more coordinated framework for engagement with other global health funders, and work with countries to understand and address demand-related barriers to vaccine delivery.

Notes

1. This note will focus on the latter; for a discussion of procurement and market shaping issues, see the accompanying note in this series, "Gavi's Role in Market Shaping and Procurement: Progress, Challenges, and Recommendations for an Evolving Approach."

2. HSS support was introduced in 2007, with US$200 million disbursed in 2007-8. The Board has approved $1.3 billion for HSS support in 2016–2020. Health Systems: Scaling Up," Gavi, The Vaccine Alliance, accessed 18 March 2019, http://gotlife.gavi.org/data/health-systems-scaling-up/.

3. "Health System and Immunisation Strengthening Support Framework," Gavi, The Vaccine Alliance, accessed 18 March 2019, https://www.gavi.org/about/programme-policies/health-system-and-immunisation-strengthening-support-framework/.

4. Specifically, "to increase an individual country's allocation ceiling for HSS support by up to 25% beyond the total amount of the ceiling calculated based on the HSS Resource Allocation Formula." Gavi Board Meeting Minutes, 6-7 June 2018, https://www.gavi.org/about/governance/gavi-board/minutes/2018/6-june/minutes/02j---consent-agenda---modifications-to-gavi-s-hsis-support-framework-and-gavi-s-fragility,-emergency-and-refugees-policy/.

5. Specifically, "operational costs support for M/MR follow-up supplementary immunization activities (SIAs)." Gavi Board Meeting Minutes, 28-29 November 2018, https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/10g---consent-agenda---gavi-supported-measles-and-rubella-immunisation-activities---amendment-to-hsis-support-framework/.

6. Gavi, "Health Systems: Scaling Up."

7. Systems strengthening is the second strategic goal in the 2016-2020 strategy. Strategic focus areas include supply chain, data quality and use, demand generation, and leadership, management, and coordination. "The Systems Goal," Gavi, The Vaccine Alliance, accessed 18 March 2019, https://www.gavi.org/about/strategy/phase-iv-2016-20/systems-goal/.

8. Gavi claims nine countries have transitioned from Gavi support after receiving HSS support (second graphic in this link: http://gotlife.gavi.org/data/health-systems-scaling-up/) without any substantiation of this implied direct link (or even specification of which countries).

9. Many countries are anticipated to transition from Gavi funding by 2030, including India, Pakistan, Nigeria, and Bangladesh, which are among the largest recipients of Gavi support; Gavi's portfolio by the end of this period will be composed of—on average—countries with weaker systems (Silverman, Rachel. "Projected Health Financing Transitions: Timeline and Magnitude." Washington, DC: Center for Global Development, 2019). For a discussion of the impact of projected transitions, see accompanying note in this series, "New Gavi Modalities for a Changing World."

10. Storeng, Katerini T. "The GAVI Alliance and the 'Gates Approach' to Health System Strengthening." Global Public Health vol. 9,8 (2014): 865-79. http://dx/doi.org/10.1080/17441692.2014.940352.

11. Parenthetical percentages indicate progress against these targets as reported by Gavi in November 2018. Gavi Board Meeting Minutes, 28-29 November 2018, https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/minutes/03---2016-2020-strategy---progress-challenges-and-risks/.

12. The 2016 meta-review analyzes 14 evaluations of HSS support completed in 2013-2015 for HSS grants approved before 2012. It also notes that the Independent Review Committee and Full Country Evaluation reports completed more recently support findings of the meta-review, though Gavi's newer interventions may not be fully reflected in these reports. "Gavi, the Vaccine Alliance: Meta-Review of Country Evaluations of Gavi's Health System Strengthening Support." Cambridge Economic Policy Associates Ltd, March 2016. https://www.gavi.org/results/evaluations/hss/health-system-strengthening-evaluations-2013-2015/. The updated meta-review published in 2019 analyzes six additional evaluations of HSS support completed in 2016-2017. "Update to the 2015 Meta-Review of Gavi HSS Evaluations." Gavi Evaluation Team, 2018. https://www.gavi.org/library/gavi-documents/evaluations/gavi-hss-meta-review--update/.

13. FCE countries include Bangladesh, Mozambique, Uganda, and Zambia. Gavi Full Country Evaluations team. "Gavi Full Country Evaluations: 2016 Annual Dissemination Report. Cross-Country Findings." Seattle, WA: Institute for Health Metrics and Evaluation, 2017. http://www.healthdata.org/sites/default/files/files/policy_report/2017/Gavi-FCE_Cross-Country-Report_2017.pdf..

14. "Update to the 2015 Meta-Review of Gavi HSS Evaluations," Gavi Evaluation Team.

15. "Update to the 2015 Meta-Review of Gavi HSS Evaluations," Gavi Evaluation Team.

16. "Update to the 2015 Meta-Review of Gavi HSS Evaluations," Gavi Evaluation Team.

17. Many of these countries submitted applications before Gavi's introduction of Country Engagement Frameworks and Program Support Rationales, making it somewhat difficult to understand how the rollout of changes impacted these 10 countries. Gavi, the Vaccine Alliance. "2016-2020 Mid-Term Review report." November 2018. https://www.gavi.org/library/publications/gavi/gavi-2016-2020-mid-term-review-report/.

18. "Application Guidelines: Gavi's Support to Countries." Gavi, The Vaccine Alliance, February 2019. https://www.gavi.org/library/gavi-documents/guidelines-and-forms/application-guidelines/.

19. "Gavi Full Country Evaluations: 2016 Annual Dissemination Report," IHME.

20. "Gavi Full Country Evaluations: 2016 Annual Dissemination Report," IHME.

21. Liberia's total HSS ceiling for the 2017-2021 period is $11.84 million. "Proposal for PSR (HSS & CCEOP) Support 2017: Liberia." https://www.gavi.org/country/liberia/documents/proposals/proposal-for-psr-(hss---cceop)-support-2017--liberia/.

22. India's phase two of its HSS is for US$100 million. "Proposal for HSS Support 2017: India." https://www.gavi.org/country/india/documents/proposals/proposal-for-hss-support-2017--india/.

23. https://www.gavi.org/library/publications/gavi/gavi-2016-2020-mid-term-review-report/

24. The 10 countries are: Comoros, Côte d'Ivoire, Guinea, Haiti, India, Liberia, Malawi, Sierra Leone, Togo, and Zimbabwe. "Health Systems: Targeting the Underimmunised." Gavi, The Vaccine Alliance, accessed 18 March 2019, http://gotlife.gavi.org/data/health-systems-targeting/.

25. "2016 Full Country Evaluations – Alliance Management Response." Gavi, the Vaccine Alliance, 2016. https://www.gavi.org/library/gavi-documents/evaluations/fourth-annual-fce-report-(2016)---gavi-response/.

26. "Apply for health system strengthening support." Gavi, the Vaccine Alliance, accessed 18 March 2019, https://www.gavi.org/support/process/apply/hss/.

27. See accompanying note in the series, "Gavi From the Country Perspective: Assessing Key Challenges to Effective Partnership," for a discussion of challenges with Targeted Country Assistance support.

28. Indeed, Gavi guidelines as of February 2019 note the countries must "identify opportunities for integration and complementarity of HSS investments with vaccine introductions/campaign activities and other donor funding." "Application Guidelines: Gavi's Support to Countries." Gavi.

29. "Gavi Full Country Evaluations: 2016 Annual Dissemination Report," IHME. Uganda is an unusual case: it was approved by Gavi in May 2017 for another round of HSS funding ($30 million committed and $13 million approved), yet no disbursements are reported in the period of 2016–2019 (and only $129,515 disbursed of $6 million committed in 2015). "Disbursements and commitments." Gavi, the Vaccine Alliance, accessed 18 March 2019. https://www.gavi.org/results/disbursements/. However, on Uganda's country hub, $1.3 million of the $13 million approved for HSS 2 is reported by Gavi as being disbursed. "Uganda." Gavi, the Vaccine Alliance, accessed 18 March 2019. https://www.gavi.org/country/uganda/.

30. "Health systems: measuring, learning & adapting." Gavi, the Vaccine Alliance, accessed 18 March 2019. http://gotlife.gavi.org/data/health-systems-measuring/.

31. See "New Gavi Modalities for a Changing World" in this series for a discussion of the implications of Gavi's eligibility policies and projected transitions.

32. 27-29 March 2019 Gavi Board Retreat, segmentation presentation.

33. 27-29 March 2019 Gavi Board Retreat, segmentation presentation; See Gavi Board Meeting Minutes, 28-29 November 2018, for earlier version of Figure 1, which identifies Nigeria, Congo DRC, Ethiopia, and Pakistan as having weak systems. https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/presentations/11---gavi-5-0-the-alliance-2021-2025-strategy/.

34. "Nigeria: WHO and UNICEF estimates of immunization coverage: 2017 revision," 7 July 2018. https://www.who.int/immunization/monitoring_surveillance/data/nga.pdf. Official country estimates are even bleaker at 33 percent for 2017.

35. Glassman, Amanda and Liesl Schnabel. "Gavi Going Forward: Immunization for Every Child Everywhere?," Center for Global Development, 7 February 2019. https://www.cgdev.org/blog/gavi-going-forward-immunization-every-child-everywhere.

36. "Pakistan: WHO and UNICEF estimates of immunization coverage: 2017 revision," 7 July 2018. https://www.who.int/immunization/monitoring_surveillance/data/pak.pdf.

37. Adequate in this context is defined as 15% of domestic expenditure, per the 2001 Abuja Declaration. "Health systems: key expected results." World Health Organization, accessed 18 March 2019. https://www.who.int/healthsystems/about/progress-challenges/en/.

38. Gavi, "Health Systems: Scaling Up."

39. While these mechanisms are an important tool for preventing improper use of funds, the disbursement delays they create illustrate the potential trade-offs with which Gavi must grapple. "Health Systems: Challenges and Lessons Learned." Gavi, the Vaccine Alliance, accessed 18 March 2019. http://gotlife.gavi.org/data/health-systems-challenges/.

40. "Approximately two-thirds of funding is now being channelled through partners to manage fiduciary risk." "Health Systems: Challenges and Lessons Learned," Gavi.

41. HSS support as currently defined by Gavi's guidelines aims to "facilitate sustainable improvements in immunization coverage and equity by targeting and tailoring investments to drive immunization outcomes," which is an update to the definition included in guidelines published in February 2018. "How to Request New Gavi Support." Gavi, the Vaccine Alliance, February 2019. https://www.gavi.org/library/gavi-documents/guidelines-and-forms/how-to-request-new-gavi-support/.

42. Gavi Board Meeting Minutes, 7-8 December 2016. https://www.gavi.org/about/governance/gavi-board/minutes/2016/7-dec/minutes/05---financial-forecast-and-programme-funding-envelopes/.

43. See "New Gavi Modalities for a Changing World" in this series.

44. Afghanistan's March 2019 decision letter for HSS support, for example, includes the clause: "a proportion of the Annual Amount may be disbursed directly to an agreed implementing agency, such as WHO and UNICEF, rather than to the Country," yet it is unclear what factors would trigger disbursement of funds directly to partner agencies and what proportion of funds would be affected. "Decision Letter, Afghanistan Health Systems Strengthening Programme." Gavi, the Vaccine Alliance. 19 March 2019. https://www.gavi.org/country/afghanistan/documents/dlpas/decision-letter-afghanistan-hss-2019/.

45. "Fragility, Emergencies, and Refugees Policy." Gavi, the Vaccine Alliance, accessed 18 March 2019. https://www.gavi.org/about/programme-policies/fragility-emergencies-and-refugees-policy/.

46. See the Global Action Plan for Health Lives and Wellbeing for All, a joint initiative of 12 global health organizations: https://www.who.int/sdg/global-action-plan/.

47. Gavi Board Meeting Minutes, 28-29 December 2018. https://www.gavi.org/about/governance/gavi-board/minutes/2018/28-nov/presentations/11---gavi-5-0-the-alliance-2021-2025-strategy/.

48. "Resilient & Sustainable Health Systems for Health." The Global Fund, accessed 18 March 2019. https://www.theglobalfund.org/en/resilient-sustainable-systems-for-health/.

49. "How We Work Together: Quick Start Guide for New Members of the Vaccine Alliance." Geneva, Switzerland: Gavi, The Vaccine Alliance, 2018. https://www.gavi.org/library/publications/gavi/how-we-work-together/.

50. Cernuschi, Tania, Stephanie Gaglione, and Fiammetta Bozzani. "Challenges to sustainable immunization systems in Gavi transitioning countries." Vaccine vol. 36,45 (2018): 6858-6866. https://dx.doi.org/10.1016%2Fj.vaccine.2018.06.012.

51. See accompanying note in this series, "Vaccine Introduction and Coverage in Gavi-Supported Countries 2015-2018: Implications for Gavi 5.0."

52. Brenzel, Logan. "Can Investments in Health Systems Strategies Lead to Changes in Immunization Coverage?" Expert Review of Vaccines, 13:4, 561-572, 2014. DOI: 10.1586/14760584.2014.892832.

Putting Global Health Security on the Gavi 5.0 Agenda

Liesl Schnabel and Amanda Glassman

Introduction

The global disease landscape has shifted considerably in recent years. Climate change, forced migration, greater urban population density, and increased conflict all make it easier for infectious diseases to spread. Within this evolving landscape, the West Africa Ebola pandemic of 2014 ignited a new era of emergent global health security concerns.[1]

Over the past five years, major global health funders, including Gavi, the Vaccine Alliance, have grappled with strategies for preparing and responding to the world's next global pandemic. While Gavi serves a wide array of functions for the countries it supports—providing financing for specific vaccines while shaping vaccine delivery, health systems, and the global vaccine market—its business model was not designed to combat global outbreaks, as it aims primarily to provide support that will enhance the ability of countries to develop sustainable and self-financed immunization programs. This raises the question: How should Gavi frame its next five-year strategy to ensure vulnerable countries are prepared when confronted with a global pandemic?

Gavi-eligible countries face a variety of challenges, from impending aid transitions to global health security threats. A projected 26 countries[2] will undergo full Gavi transition by 2025, with only 27 countries still eligible for Gavi financing in 2040.[3] While this may be viewed as a positive change—an indication of economic development in lower-income countries—it also means Gavi-supported countries need to build strong fiscal strategies to self-finance their immunization systems and programmatic and institutional capacities. Moreover, prioritizing health spending is more difficult in countries facing conflict, refugee crises, disease outbreaks, and other emergency scenarios. Given significant global health security risks, country-level fiscal strategies should include financing for pandemic preparedness and response, including through vaccination and stockpiling where applicable, but this is a difficult task to balance with other pressing priorities.

Gavi's 5.0 strategy process presents an opportunity to assess Gavi's effectiveness in addressing these competing pressures and to align processes and priorities with the health security needs of country governments. In this note, we explore certain global health security considerations and propose procedural improvements or adaptations to Gavi's mandate to better support the needs of country governments and other partners.

The Challenge

The 2018 Ebola outbreak in the Democratic Republic of the Congo (DRC) is the second largest in its history and the first in an active conflict zone.[4] The DRC has 45 percent full immunization coverage nationally,[5] indicating an already-struggling health system. Gavi's primary response to the Ebola outbreak included mobilizing 300,000 investigational doses of the rVSV-ZEBOV Ebola vaccine, providing $3.9 million in support of the country's response plan, and supporting neighboring countries through WHO for preventative vaccination.[6] About

87,000 people have received the vaccine, which has proved highly effective in helping control the epidemic, but the supply is expected to run out by mid-September 2019.[7] Given limited vaccine availability, strategies for continuing to ramp up Ebola response in the DRC and preparedness in neighboring countries is vital.[8]

The DRC is just one of many examples of a country grappling with real or potential disease outbreaks, some of which require emergency response. Without health security capacities, including surveillance systems, laboratories, a health workforce, strong information systems, and multisectoral collaboration, it is unlikely that countries will be prepared to detect and respond to a pandemic.[9] However, financing for global health security capabilities and outbreak response adds additional financial burdens to lower-income countries, many of which are already struggling to prepare for transition from multiple sources of global health financing.[10]

Global health security efforts remain underfunded even though estimates show high payoffs for investing in these efforts now. In 2017, the International Working Group on Financing Preparedness (IWG) estimated $4.6 billion is required per year to finance preparedness,[11] significantly less than the predicted economic loss of $60 billion per year if a pandemic occurs.[12],[13] Considering one aspect of pandemic preparedness, a 2018 study, using WHO's National Comprehensive Multi-Year Plans (cMYPs), found spending for vaccine-preventable disease surveillance is minute but varies widely between countries, with a median expenditure of $0.04 per capita.[14] In some countries, such as Nigeria ($0.15 per capita), spending is explained by the urgent need for surveillance of specific diseases (e.g., polio). In other cases, however, there is little analysis or explanation of expenditures (e.g., $0.34 per capita in Zambia and $0.01 per capita in Pakistan),[15] indicating the need for further investigation of countries' expenditure decision-making around preparedness. In countries that rely on the Global Polio Eradication Initiative (GPEI) for surveillance,[16] the potential phasedown of GPEI support may create increased urgency for domestic funding of preparedness.

Gavi has exhibited growing recognition that preparedness is a critical issue. It currently has three active vaccine stockpiles (yellow fever, meningitis, and cholera) ready for emergency response and invests in measles outbreak response efforts and the Ebola vaccine stockpile. Moreover, Gavi developed a Fragility and Immunization Policy in 2012, which allows the organization to increase funding for countries with emergency and protracted circumstances (e.g., Yemen in 2015, Chad in 2013).[17] Gavi's Board continued these efforts by approving a Fragility, Emergencies, and Refugees (FER) policy in June 2017, which allows Gavi to provide flexible financial, administrative, and programmatic support to Gavi-eligible fragile states[18] and countries facing emergencies and/or hosting refugees.[19] However, this policy does not extend to global health security and preparedness, which is particularly relevant for the neighbors of countries managing emergencies, fragility, and displacement.

Between 2016–2018, Gavi reportedly provided $1.1 billion in disease outbreak prevention, detection, and response funding. Of this response, $790 million counted as "prevention" has gone to routine immunization campaigns; $72 million to surveillance through health system strengthening (HSS) investments and the Partner Engagement Framework (PEF); and $185 million in vaccine stockpiles for response in the case of an outbreak.[20] Gavi's disease prevention strategy highlights the need to prevent disease outbreaks in emergency settings. Specifically, the Rohingya refugee situation in Cox's Bazar, Bangladesh, is featured as a prime example of Gavi's success in preventing widespread cholera through a swift and comprehensive response.

In the coming years, Gavi may be responsible for filling a key role within the global health security landscape: introducing and supporting countries in deploying new preventative vaccines. For example, the National Institute of Allergy and Infectious Diseases is currently

developing a universal influenza vaccine,[21] which, if cost-effective, could be delivered across the world by Gavi. Controlling for negative regional externalities,[22] including disease outbreaks, can also be considered a global public good (GPG). Although only one-fifth of global health funding goes towards GPGs,[23] there are high returns for investing in them, as seen with HIV vaccine development ($67 return for every dollar invested in vaccine development).[24]

Overall, Gavi has shown progress in supporting countries that face emergencies, but there is still much ground that should be covered regarding the organization's role in the global health security landscape. The big question remains: What should Gavi's role be in financing large-scale preparedness efforts in countries that want to improve their global health security capacities, but are not facing an immediate threat of outbreak? The following recommendations outline steps that Gavi should take to adapt to the global health security landscape, beyond its current prevention, detection, and response framework.

Recommendations for Gavi's Future Approach

If countries are not prepared to prevent and respond, a global pandemic could erase Gavi's years of progress toward global immunization coverage. Although financing health security capacities is an additional financial ask during 2020 replenishment, Gavi should present pandemic preparedness as a framing for many of its current activities in its investment case. Significant updates on Gavi's role in global health security should be reported to Gavi's Board on a semi-annual basis and/or when major crises occur. The following recommendations provide ways that Gavi's current activities should adapt to a global health security framing:

1. Expand the Fragility, Emergencies, and Refugees (FER) policy to include preparedness

As a starting point, Gavi should engage in more analysis and discussion of health security within its fragility and emergencies policies. Gavi's FER policy could be revised to include a percentage investment (from Gavi) in preparedness as a requirement for granting additional support to fragile states and emergency settings. For example, in countries with large refugee populations, a percentage of grant funding should be designated for disease surveillance. In the case of the Rohingya crisis in Bangladesh, Gavi was effective in preventing cholera through mass vaccination campaigns, but did not anticipate the diphtheria outbreak that has now spread to 8,640 reported cases.[25] Gavi's FER policy should be adjusted to ensure preparedness, including surveillance, labs, and a strong health workforce, are funded and implemented at the onset of Gavi's engagement with fragile or refugee-hosting states.

2. Encourage country alignment with the Global Health Security Agenda, and fund immunization and surveillance components of costed JEE plans

To support countries in developing robust preparedness systems, Gavi should be considered an integral part of the Global Health Security Agenda[26] architecture by the global health community. New tools, such the Global Health Security Agenda's Joint External Evaluation's (JEE)[27] and the Global Health Security (GHS) Index (which uses technical assessments, health system strength, global goal commitments, socioeconomic circumstances, and more),[28] can be used by countries to develop costed plans and by Gavi to guide financing for preparedness in vulnerable countries. The JEE includes specific immunization targets, utilized to measure countries' prevention capacity.[29] Currently, 96 of 199 countries have completed JEEs, and most countries currently score below a four on the indicators, "indicating non-sustainable or underdeveloped capacities."[30] National Action Plans for Health Security (NAPHS) have been designed by countries to respond to gaps identified in JEEs, but only 45 have been completed.[31] If countries submit a costed plan for national health security, Gavi should provide a share of financial support for capacities that are related to existing HSS grants and programming in the country, as well as

additional financing for surveillance capacities. This could incentivize lower-income countries to invest in developing costed NAPHS, while strengthening Gavi's influence in GHS.

3. Integrate JEE indicators into Gavi vaccine support and HSS grants

Using the JEE country reports to understand varying country challenges, Gavi should require all countries that receive funding, including middle-income countries that have received transition extensions,[32] to include preparedness indicators in vaccine support and HSS grant proposals. As discussed above, the JEE includes immunization targets and indicators; Gavi should ensure that these indicators align with vaccine support grant indicators. Moreover, Gavi should encourage countries to include JEE targets outside of immunization in their HSS grants and strategies. For example, real-time surveillance, part of the JEE's "detect" targets,[33] is extremely important for all countries, regardless of income status or fragility. Strengthening vaccine-preventable disease surveillance is currently included in Gavi's strategic focus on data within its Partners Engagement Framework (PEF).[34] However, this only applies to the 20 countries that receive PEF support, and should extend to all. Global health security should be prioritized in Joint Appraisal discussions, and integration of preparedness targets in cMYPs and national plans should be encouraged. Gavi's senior country managers should work closely with recipient countries to ensure understanding and identification of appropriate and achievable preparedness indicators.

4. Prioritize equity in vaccine delivery in prevention activities and during complex emergencies

Gavi's assistance in preparedness and emergency response should be carefully constructed to avoid inequities in vaccine delivery. For example, at Gavi's June 2017 Board meeting, DRC Minister of Health Félix Kabange expressed appreciation for Gavi's assistance during the Ebola outbreak, yet noted the equity challenges that accompany decision-making around vaccine delivery in crises.[35] In an illustrative case, pregnant and lactating women were excluded from receiving rVSV-ZEBOV until February 2019.[36] This lapse in providing vaccination for a vulnerable population highlights the need to design approaches to preparedness and disease surveillance that consider equity and ethics. Ensuring equity[37] will prove particularly important if and when Gavi begins to deliver preventative vaccines, including for universal influenza. Gavi should carefully assess lessons learned from the 2018 Ebola outbreak in the DRC and share findings with high-risk countries.

5. Complete a mapping exercise to assess Gavi's comparative advantage in the global health security space and invest more in health security capacities

Gavi is facing a challenging replenishment year, with many competing priorities for financing. Along this vein, in November 2018, Gavi's Board approved support for inactivated poliovirus vaccine (IPV) with country financing arrangements. This decision will add to Gavi's 5.0 replenishment request, as IPV support alone will cost an estimated $848 million that was not included in Gavi's 2015 replenishment.[38] Given differing stakeholder viewpoints, it may be difficult for Gavi to add health security capacities, including surveillance, to its investment case. In order to make the case for its inclusion, Gavi or key partners should conduct a mapping exercise of the current actors in the GHS space and closely analyze Gavi's comparative advantage in supporting prevention activities. For example, an assessment could show Gavi is well-placed to support the immunization and surveillance components of the JEE, while other partners should address health workforce development. Beyond making the case for more financial investment from its funders, Gavi could redirect funding from transitioning countries towards additional resources for global health security capacities.

Notes

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