Final Report

COVAX Facility and AMC Formative Review and Baseline Study

Date: 15th March 2023

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Acknowledgments

Thank you to Gavi's Centralized Evaluation Team (CET) —in particular, Leslie Moreland and Jean Zampalegre —for their support in the process of collecting data and producing this report, and to all stakeholders and key informants who generously gave their time and insights.

The authors are also grateful to Anita Deshpande, Shola Dele-Olowu, Pär Eriksson and Juliette Gautron for their contributions to the report, and to Raimundo Eyzaguirre Ducci, Debrupa Bhattacharjee, Shriya Samani, Tarmini Mootoosamy, Shalini Eragoda and Viktoria Beran for their work supporting data collection and analysis.

The evaluation team would also like to thank Priscila Neves Silva, Fernanda Pinheiro Sequeira, Mateo Echeverry Angel, Marta Lucia Ramirez, Eric Mafuta, Aastha Dang, Ritwik Sarkar, Dominique Gomis, Nam Nguyen, Duong Minh Duc, Pham Cong Tuan and Bich Thao Nguyen for their work on the six country case studies. We are also grateful to the respective Senior Country Managers at Gavi for their support on coordination.

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List of acronyms

AFC	Audit and Finance Committee
AMC	Advance Market Commitment
APA	Advance Purchase Agreement
API	Active Pharmaceutical Ingredient
AVAT	African Vaccine Acquisition Trust
BMGF	Bill & Melinda Gates Foundation
CCE	Cold Chain Equipment
CDS	COVID-19 Delivery Support
CEPI	Coalition for Epidemic Preparedness Innovations
CET	Centralized Evaluation Team
CRD	Country Readiness and Delivery
CSO	Civil Society Organization
DCVMN	Developing Countries Vaccine Manufacturers Network
DRC	Democratic Republic of the Congo
EQ	Evaluation Question
EU	European Union
EUL	Emergency Use Listing
EvLU	Evaluation and Learning Unit
GNI	Gross National Income
HIC	High-Income Country
HSRC	Health Systems and Response Connector
I&L	Indemnity and Liability
IAVG	Independent Allocation of Vaccines Group
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
J&J	Johnson & Johnson
JAT	Joint Action Taskforce
LIC	Low-Income Country
LMIC	Lower-Middle-Income Country
MIC	Middle-Income Country
MoU	Memorandum of Understanding
MPA	Multiphase Programmatic Approach
NDVP	National Vaccine Deployment Plan
NFCS	No-Fault Compensation Scheme
NGO	Non-Governmental Organization
ODA	Official Development Assistance
PAHO	Pan American Health Organization
PEF	Partners' Engagement Framework
PPC	Program and Policy Committee
PPP	Public–Private Partnership

RAG	Regulatory Advisory Group
RDMIC	Research and Development and Manufacturing Investment Committee
SAGE	Scientific Advisory Group of Experts on Immunization
SCM	Senior Country Manager
SFP	Self-Financing Participant
SII	Serum Institute of India
TA	Technical Assistance
ToC	Theory of Change
TRG	Technical Review Group
UCC	Ultra-Cold Chain
UK	United Kingdom
UMIC	Upper-Middle-Income Country
UN	United Nations
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US	United States (of America)
WHO	World Health Organization

Executive Summary

Introduction

At the beginning of the COVID-19 pandemic in April 2020, the Access to COVID-19 Tools Accelerator (ACT-A) was launched to convene governments, multilateral organizations, private sector and civil society partners to coordinate, fund, develop and equitably deploy COVID-19 tools to bring about the end of the COVID-19 pandemic. Its four technical partnerships, led by nine partners, consisted of three vertical pillars (vaccines, therapeutics and diagnostics) and a cross-cutting health systems connector. As initiated in 2020, the vaccines pillar – known as the COVID-19 Vaccine Global Access Facility (COVAX) – was co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organization (WHO), and Gavi, the Vaccine Alliance (Gavi). UNICEF joined in 2021 as a formal COVAX partner.

The instruments through which COVAX was operationalized – including the COVAX Facility and Advance Market Commitment (AMC) – had the specific aim of enabling equitable global access to COVID-19 vaccines. Gavi is the legal administrator of the COVAX Facility. Since mid-2020, 1.9 billion doses have been delivered through the mechanism, 1.7 billion of which have gone to the world's poorest countries – the latter supported by fundraising efforts worth over $12 billion. It is critical to acknowledge that the COVAX Facility and AMC was a global first and that the highly-charged, dynamic and incredibly fast-moving global context in which these instruments were established was unprecedented. Decisions were necessarily made rapidly as the operating environment and context shifted, based on imperfect information, with the financial resources, teams, capacities and skills that existed at the time. The learning from the COVAX experience is invaluable at this juncture as major global health players deliberate future pandemic preparedness and response. This report aims to provide independent, robust evidence toward this effort.

Building on an evaluability assessment conducted in 2021, the COVAX Facility and Advance Market Commitment (AMC) Formative Review and Baseline Study was initialized in March 2022, as the first stage of the multi-phase evaluation of the COVAX Facility and AMC. The COVAX Facility and AMC Formative Review and Baseline Study assesses what has worked well and less well to date in the design, implementation, and results of the COVAX Facility and AMC. Conceived as the first stage of a multi-phase evaluation, it focuses on the time period since COVAX was conceptualized in 2020 through to the end of 2021, although it recognizes subsequent changes and results where these are particularly relevant. The evaluation, commissioned by the Gavi Board, focuses on Gavi's role in administering the COVAX Facility, but considers the links to and ways of working with other agencies in meeting the COVAX Facility and AMC's objectives. The evaluation questions (EQs) were agreed with Gavi at the outset of the assignment and structured around four modules: design, implementation, results, and lessons learned.

Findings

Design

The COVAX Facility and AMC was a bold and ambitious proposal to avoid the unequitable allocation of vaccines experienced in previous pandemics.

Many elements of the design were innovative and untested. A global procurement and allocation mechanism had never been attempted and it was unclear whether and to what extent richer countries

would participate. The COVAX AMC was an innovative approach to raising resources for vaccine purchase on behalf of low-income countries (LICs) and lower-middle-income countries (LMICs) while sending a signal to vaccine manufacturers. The indemnity and liability (I&L) provisions, the no-fault compensation scheme (NFCS), the Humanitarian Buffer, and the allocation mechanism were untested areas for Gavi and its partners. Moreover, while Gavi and UNICEF had used Advance Purchase Agreements (APAs) before, neither had experience with deal-making on the scale and with the urgency that COVAX required. While most stakeholders considered these design risks worth taking, some aspects were questioned. Some design elements, such as the COVAX Facility's role in supporting country readiness and vaccine roll-out, were unclear.

The strategic decision to operate within the global vaccine ecosystem rather than seeking to reshape it more fundamentally in the interest of equitable access was – and remains – contentious. In retrospect, some assumptions underpinning the design turned out to be overly optimistic. The COVAX Facility's designers understood that high-income countries (HICs) would buy vaccines outside of the mechanism, but they did not anticipate the scale and aggressiveness of this bilateral procurement or its impact on vaccine markets. The design underestimated the extent to which countries serve their own populations first and companies pursue their commercial interests, despite expressions of global solidarity. Including high- and middle-income countries as both self-paying and demanding beneficiaries in some ways undermined the achievement of equity goals.

The original design process was driven by a small subset of stakeholders, notably donors and industry of the Global North, without the meaningful engagement of beneficiary countries and civil society organizations (CSOs). This was a conscious decision taken by Gavi staff in the interests of quickly finalizing an approach to deal with an emergency, and, although the later stages of the design process were characterized by improved engagement of AMC countries and civil society, the final design in a large part reflected the priorities of those engaged in the early design process. The lack of initial engagement of low and middle-income countries and CSOs led some to feel a lack of ownership over COVAX and likely fed criticism during 2021, when COVAX was not able to meet expectations on vaccine deliveries.

The evidence supporting these findings on design is strong, comprising multiple sources of good quality data, enabling an acceptable level of triangulation.

Implementation

Over the course of 2020 and 2021, despite a very difficult operating environment, Gavi and its partners successfully launched and implemented the COVAX Facility and AMC. With 193 confirmed participants, establishing the mechanism involved a host of challenging processes. These included: setting up the Office of the COVAX Facility; engaging with those AMC participants that had never been Gavi-eligible; engaging with self-financing participants (SFPs), who had only worked with Gavi as donors or had not worked with Gavi at all; establishing I&L agreements and the COVAX NFCS; setting up the Humanitarian Buffer; negotiating APAs with vaccine manufacturers; administering dose donations; setting up cost-sharing; operationalizing the allocation mechanism; and providing vaccine delivery support in its various guises. A number of these had never been done before or were firsts for Gavi and the Alliance partners. Many required adaptation as the COVAX Facility and AMC sought to respond to an evolving context.

However, the scope of innovation and the speed of implementation created a heavy burden for Gavi and COVAX, with implications for the Office of the COVAX Facility's management capacity, efficiency and effectiveness. It also led to a perception by some stakeholders that COVAX's ways of working were too 'top-down', although COVAX Facility staff contend that this was necessary, given the importance of rapid decision making.

In terms of the operational aspects of the COVAX Facility:

- **Governance**

  Gavi is well placed to facilitate good governance of a multi-stakeholder effort to rapidly scale up global vaccination. However, the scope and scale of the COVAX Facility and AMC placed a heavy

burden on Gavi's existing governance arrangements and partner working relationships. A range of new structures established for the COVAX Facility and AMC added significant complexity and administrative burden without fully fulfilling stakeholder needs and expectations for engagement – these expectations grew over time, particularly as vaccine deliveries to countries were delayed.

- **Management**

  While a strong management team was created, it was under-resourced for the scale of its responsibilities, with staff stretched across multiple roles, overworked, and in some cases burned out. Despite this, and some inefficient ways of working, the very strong mission-driven culture of the Office of the COVAX Facility contributed to its ability to rapidly implement a hugely ambitious agenda.

- **Risk**

  The initial design was agreed in mid-2020 without a full analysis or understanding of risks and their implications. This led to some design decisions being taken which were considered in retrospect to be overly risk averse, limiting the COVAX Facility and AMC's programmatic progress. Nonetheless, strong risk management systems and processes have been established over time, notably drawing on the Gavi Audit and Finance Committee's (AFC's) engagement to supplement the Secretariat's capacity.

- **Communications**

  External communications were used to support several strategic objectives, including for resource mobilization and to secure supply in 2021. However, despite urging global solidarity and warning against excessive bilateral procurement, Gavi was intentionally restrained in the way it called out stakeholder behavior where it was inconsistent with the objective of equitable access. This had implications for the way in which COVAX (and Gavi specifically for its role in administering the COVAX Facility and AMC) was perceived during a time when country experiences did not match the global rhetoric. There was a notable shift in approach in late 2021, partly to address this and to respond to public criticism.

The COVAX Facility and AMC are active in several linked program areas that contribute to the overall outcome of fair and equitable global allocation of vaccines:

- **Resource mobilization**

  A strong resource mobilization function was established for the COVAX AMC, drawing on Gavi's pre-existing capacity and donor relationships to implement a need-based, opportunistic and ambitious fundraising strategy. While it was not possible to raise cash resources immediately in 2020 for the COVAX AMC due to the time many donors require to gain internal approvals, resource mobilization was successful. Dose donations and cost-sharing also became important sources of funding and vaccine supply during 2021.

- **Market shaping**

  In the initial design, it was anticipated that COVAX, and Gavi specifically, would play a major role in shaping vaccine markets to scale up manufacturing capacity, achieve affordable prices and ensure timely supply to LICs. Robust engagement in technology transfer was not a focus of the market-shaping strategy for COVAX as a whole. Further, funding for CEPI to do this at scale was limited and Gavi did not play a proactive role outside of the SII deal. As a result, the COVAX Facility's approach to market shaping relied on negotiating APAs with manufacturers on the basis of pooled demand and resources. The COVAX Facility ultimately lacked the market power to meet its market-shaping objectives in the early phase of the COVID-19 pandemic, although its important early deal with the Serum Institute of India (SII) expanded global supply and some other manufacturers eventually established additional manufacturing capacity to supply COVAX. The COVAX Facility did, however, achieve lowest-in-market prices for LMICs and LICs.

- ## Securing supply

  The negotiation of APAs with manufacturers produced some early successes, including the delivery of doses to India in January 2021 and other AMC participants in February 2021. This represents a historically short delay in access for LICs and LMICs, which typically wait years for new vaccines. However, after India halted vaccine exports, leaving the COVAX Facility without its most important supplier (SII) for AMC countries, COVAX deliveries increasingly lagged behind targets and expectations. Although supply picked up in the last few months of the year with the United States (US)-Pfizer-facilitated purchase/donation, other bilateral donations, and additional APAs, total COVAX deliveries in 2021 were less than 1 billion doses – far short of the 2 billion dose target. While the target of delivering 950 million doses to AMC participants in 2021 was only just missed, most of the doses were delivered in late 2021, and the shortfall in early and mid-2021 had dire consequences for recipient country efforts to immunize their populations. In addition, slow vaccine delivery from COVAX led to great frustration and encouraged many countries to seek vaccines from other sources. Although Gavi and the COVAX Facility did not have sufficient cash in hand at first to sign big purchase commitments, it is not clear whether this constraint strongly affected the timing of deal-making or whether deal timing was a primary determinant of delivery schedules. Ultimately, COVAX's ability to secure supply for participating countries through APAs was undermined by the overwhelming market power of HICs, exacerbated by vaccine hoarding and export restrictions, particularly the halt of exports in India.

- ## Allocation

  Dose allocation in 2021 was not conducted as anticipated, with no two rounds conducted in the same way and with each round involving several different processes. The approach evolved as a pragmatic response to a challenging operating environment, although it is considered to have been overly complex and difficult to understand. Until Round 7, conducted in September 2021, the allocation was broadly in line with the World Health Organization (WHO) Allocation Framework and the principle of proportional allocation. It did not factor in other, non-COVAX, sources of vaccine supply, and as a result did not optimize global equality (equal access to vaccines) or equity (prioritization of those most in need) as much as it could have. After Round 7, the approach was modified to allow greater prioritization of countries with low coverage and to allow a more equitable allocation of COVAX doses.

- ## Vaccine delivery support

  Throughout 2020 and into mid-2021, there was an expectation that other partners would be responsible for funding (notably the World Bank) and implementing (e.g. UNICEF) vaccine delivery support. During this time, Gavi did not take on a substantial role in this area but did provide $150 million in support for cold chain equipment and technical assistance (TA), which supported roll-out of COVID-19 vaccines in many countries. Amid substantial concern in early to mid-2021 about the lack of vaccine delivery support, Gavi mobilized and approved $775 million to support vaccine delivery in June 2021. This was provided through two main windows of support and TA in areas identified as particular risks. Only a small amount of Gavi funding had been made available to countries by the end of 2021, however, and many stakeholders noted that in spite of vaccine supplies being limited country needs were not met in a timely way.

The evidence in support of these findings is generally strong, comprising multiple data sources of good quality, with country case study insights reinforcing global evidence.

Results

Vaccine supply and coverage: COVAX has made a substantial contribution to the supply of vaccines to, and vaccine coverage in, LICs. Its contribution has been moderate in LMICs and marginal in upper-middle-income countries (UMICs) and HICs. This finding is based on analysis of the following:

- **Quantity of vaccine supplies:** By the end of 2021, the COVAX Facility had distributed almost 1 billion doses to 144 countries and played an important role in ensuring that these doses could be delivered in-country. Although this was well below the target of 2 billion doses by the end of 2021, 87% (833 million) of these doses went to AMC participants – close to the target of 950 million doses for these countries. Vaccines supplied by COVAX accounted for 79% of all vaccines delivered to AMC participating LICs in 2021, as compared to 38% for AMC LMICs excluding India, 37% for AMC UMICs, 2% for SFP UMICs and 1.3% for SFP HICs.
- **Timing of vaccine supplies:** While supply started to reach COVAX AMC participants in early 2021, deliveries were small and sporadic for the first six months, rising slowly but steadily in Q3 and picking up significantly in Q4. Given their reliance on COVAX, LICs received vaccines much later and in lower volumes than HICs throughout 2021.
- **Linkage between vaccine supplies and vaccine coverage:** Although it is not possible to have full confidence in the linkage between vaccine supplies and vaccine coverage, analysis suggests that COVAX vaccine supplies played a major role in scaling up coverage in LICs, as compared to a more modest role in LMICs and a small role in UMICs and HICs.

Enabling and hampering factors: Limited vaccine supplies constrained vaccine coverage in LICs, as compared to HICs, which had greater access; but other factors were also important. LICs noted inadequate country readiness and capacity to roll out vaccination as constraining factors, as well as issues with receipt of doses close to expiry. These issues were also noted in AMC participating LMICs but appeared to be less severe. In some of these countries, inadequate political commitment to vaccine roll-out and lack of community demand were cited as constraining factors in 2021. Countries from all income groups developed strong preferences for some vaccine products and were reluctant to accept others.

Respondents from AMC participating countries widely acknowledged the value of Gavi and Alliance partner support in strengthening country readiness for vaccine roll-out, particularly for cold chain capacity. However, a number commented that this support would have been more helpful if it had been received earlier and if application processes for vaccine delivery support had been less burdensome. The coordination of related types of financial support for vaccine roll-out were also noted as a challenge in some countries.

Equity: In spite of COVAX vaccines being distributed mostly towards LICs and LMICs, global vaccine distribution and coverage were highly inequitable. As discussed above, access to vaccine supplies and vaccine coverage was strongly associated with country income and remained highly unequal throughout 2021. Despite this, the distribution of vaccines *within* countries appears to have been broadly equitable, with groups at highest risk being prioritized and without significant differences in vaccination rates for men and women in most countries.

The COVAX Facility and AMC had some unintended consequences. SII's manufacturing capacity, substantially augmented by Gavi and Gates's investment to provide vaccine supplies to AMC participants, enabled the Government of India to directly purchase COVID-19 vaccines from SII during the period when exports were halted in 2021. This facilitated a higher vaccination coverage of population in India than could have been otherwise possible. In addition, delays in the supply of vaccines through COVAX in 2021 contributed to increased interest in regional procurement elsewhere by agencies, with implications for a global initiative in future pandemics. On the other hand, there is some evidence to suggest that Gavi's repurposing of existing health system strengthening (HSS) funds for the COVID-19 response without offering additional funds to protect RI contributed to lowered prioritization of RI in some countries.

These findings are made with generally strong evidence.

Conclusions

The following are the main overall conclusions emerging from the evaluation. These conclusions are developed and explained in greater detail in Section 3.

Conclusion 1

The overall design of the COVAX Facility and AMC is coherent, ambitious, and has responded to a rapidly evolving context. Significant elements were also innovative and untested, and as such it was unclear at the outset whether the COVAX Facility and AMC would work as intended. The design also suffered from too little engagement of LICs and LMICs and was too optimistic regarding the behaviors of HICs and vaccine manufacturers. Vaccine nationalism, vaccine diplomacy and commercial interests undermined the potential of market-based solutions to global vaccine equity challenges in a public health emergency context.

Conclusion 2

The COVAX Facility was successfully established and made substantial progress toward its core objectives. These include the rapid setting up of the COVAX Facility and AMC, the raising of significant resources, progress in market shaping and securing of supply, the equitable allocation of COVAX doses and the mobilization of vaccine delivery support funding (see further details below). However, given the complexity, scope and scale of these endeavors, the governance and management of the COVAX Facility and AMC has been challenging.

Key COVAX Facility and AMC achievements

- Establishing a highly effective resource mobilization function to enable one of the fastest and largest fundraising campaigns in global health history
- Securing deals for more than 4 billion doses of 10 different vaccine candidates at reasonable, generally lowest-in-market prices for AMC participants, and contributing to the expansion of manufacturing capacity for LICs & MICs through the deal with SII
- Allocating COVAX doses in a highly flexible and generally equitable manner
- Delivering the first COVAX doses internationally to Ghana on 24 February 2021 and 38 million doses to 100 countries 42 days later.

Conclusion 3

The COVAX Facility design and business model has evolved considerably in the face of a highly dynamic and uncertain environment, and this flexibility has been a core strength of the response. The evolution of COVAX has continued beyond the scope of this evaluation.

Conclusion 4

Despite its successes, COVAX fell well short of its target of delivering 2 billion doses for 2021,[1] and while it came close to meeting its target of delivering 950 million doses to AMC participants in 2021,[2] most of these were delivered in late 2021. This shortfall was due primarily to its inability to secure supply.

Conclusion 5

The COVAX Facility did not have sufficiently strong levers in 2020 and 2021 to influence the market and market actors to the extent intended. This can, in part, be seen as a failure of international solidarity to restrain the behavior of powerful stakeholders acting in their own interests. In this environment, the COVAX Facility did not have sufficient market power to compete successfully for vaccines against HICs with far greater resources at their disposal or to dramatically influence manufacturers' decisions on manufacturing capacity.

Recommendations

The COVID-19 pandemic has reminded us that the window of opportunity for scaling up vaccination in a pandemic is very short. The recommendations presented below therefore focus on how a future initiative can learn from the COVAX Facility experience and respond effectively in the first 24 months of a pandemic or within the first 12 months of a global vaccine roll-out.

An initiative to ensure equitable access to vaccines in a pandemic must have an end-to-end approach, addressing a full, integrated range of functions and processes required to bring vaccines in a timely fashion to those at risk. In this light, we offer recommendations in the following areas: 1) design (process and high-level choices); 2) governance and management; 3) market shaping and supply; 4) allocation; 5) vaccine roll-out. An end-to-end initiative must be, as COVAX was, a joint undertaking of agencies with different mandates and capabilities. Although our main focus is on *what* a "future COVAX" should do rather than *who* should do it, we do make some recommendations on roles in certain areas where the evidence from our evaluation supports this. As our evaluation has mainly focused on Gavi's role in COVAX, not those of other partners in the mechanism, our suggestions on future responsibilities also primarily concern Gavi. These recommendations are more fully articulated in the full report.

Recommendation area 1 – Design

High-level design principles and features

- The overall design approach to ensuring equitable access to health technologies in a health emergency should be based on the understanding that stakeholder behaviors will echo those seen in the early stages of the COVID-19 pandemic. In particular, HICs will serve their own national interests first in seeking to secure scarce commodities, and manufacturers will in most cases give priority to markets in HICs. While the international community works towards agreements based on global solidarity and effective regulations for knowledge sharing, pandemic preparedness and response mechanisms should plan for and proactively mitigate the negative effects of vaccine nationalism and commercial interests.
- A future international vaccine procurement and allocation mechanism should be clear that its primary focus is to support those countries with the least ability to procure independently and most likely to be dependent on such a mechanism. If countries with the ability to self-finance are allowed to opt into the mechanism, care must be taken that this does not jeopardize access for the lowest-income countries.

  Before the next pandemic, WHO, WTO, or other agencies with a normative mandate, should assess the best way to address the liability risk to manufacturers and enable them to provide new health products in emergencies, without shifting liability to recipient LICs, LMICs or humanitarian agencies.

Design process

- The process of designing an international vaccine procurement and allocation mechanism for the next pandemic should be more inclusive, transparent and accountable than was the case for the COVAX Facility and AMC. Global south countries, regional bodies, civil society and humanitarian agencies must have a meaningful role from the earliest design stages.
- The design of a future mechanism should begin well before the next pandemic, thereby allowing the time for broader engagement of global south countries, regional bodies, civil society and humanitarian agencies.
- Decision making after a pandemic has begun, when speed is critical, should be overseen by a robust and participatory governance function.
- The assumptions underlying the design of a future mechanism should be made explicit so the corresponding risks can be assessed and mitigation measures be in place where possible.

Recommendation area 2 – Governance and management

- Establish a governance mechanism that: 1) oversees the entire initiative, including the actions of all participating agencies; and 2) balances participation with transparency and accountability. Governance should be as inclusive as the need for rapid decision-making permits. Where broad engagement is not possible, full transparency and public accountability on processes and outcomes become even more important.
- Build management structures that draw on the established systems, processes, staff and culture of one or more existing organizations without allowing these structures and processes to impede unnecessarily the speed and flexibility required in emergencies.

Recommendation area 3 – Market shaping and supply

- Play a stronger role in expanding global supply, including through investment to expand vaccine production capacity in preparation for future outbreaks and greater support for technology transfer during an outbreak. Other agencies should have primary responsibility for tech transfer and building supplier capacity, but Gavi should align its actions as a buyer with these investments by others.
- Refine the approach to APAs through: greater access to at-risk funding at the start of future outbreaks in order to allow purchase agreements with product developers to be struck earlier and at greater scale; making transparency on delivery queues a condition of APAs; and considering the role of price in affecting access to supply in the context of competition with HICs.
- Ahead of the next pandemic, put arrangements into place for facilitating and efficiently managing other sources of vaccine supply, including dose-sharing commitments (e.g. Berlin Declaration), donations of excess vaccine procured by HICs and others, and facilitated purchases on the model of the arrangement with the US and Pfizer.
- Make greater use of soft power to seek to influence the behavior of vaccine manufacturers and HICs. This influence, which should be exercised in cooperation with LMICs and civil society, could involve public communication, transparency indices and other tools.

Recommendation area 4 – Allocation

Design a framework for global allocation of scarce commodities based on a set of guiding principles. As with the COVID-19 WHO Fair Allocation Framework, this should set out principles for equitable allocation across countries and population groups. Principles should not be interpreted as rules and trade-offs between principles should be considered at the outset. The framework should be flexible enough to apply in an uncertain context while maintaining focus on global objectives.

Recommendation area 5 – Vaccine roll-out and delivery support

Strengthen coordination among global partners to ensure the timely availability of financial and technical support for vaccine roll-out. Responsibility for coordination should sit with one agency, with others taking responsibility for different aspects of the work, such as financing, procurement and delivery of TA. As well as at the global level, roles and responsibilities at the regional and national level should be set out and defined in advance of the next pandemic.

Pandemic preparedness should be strengthened before the next pandemic, but if this does not take place to the extent required, substantial funding for delivery should be available early and on a no regrets basis, the terms of which should be defined up front. This will be especially important if greater vaccine supplies reach LMICs and LICs more quickly than was the case for COVID-19 vaccines. This support should be used to promote equitable distribution of vaccines within countries.

Section 1: Introduction

1 Overview

This draft final study report is organized into four main sections:

- this **introduction** (Section 1) contains information on the evaluation context (1.1), objectives and scope (1.2), methodology (1.3), strength of evidence guide (1.4) and risks and limitations (1.5)
- the **findings** (Section 2) are organized by the three evaluation modules: Module 1 – Design (2.1); Module 2 – Implementation (2.2), and Module 3 – Results (2.3). Module 4, which examines the lessons learned from the experience to date of the COVAX Facility and AMC, is detailed in Annex H, but snapshot lessons are summarized next to their corresponding findings within Section 2
- evaluation **conclusions** (Section 3)
- **recommendations** (Section 4).

Further detail, located in the annexes, is signposted throughout the report. These are available in a separate document, Draft Final Study Report Annexes (Vol. 1). This volume contains more information on the evaluation methodology and data collection strategies (Annex A), additional detail per each module (Annexes B, C and D), and lists of documents reviewed and stakeholders interviewed (Annexes F and G).

The full list of ten lessons learned and supporting analysis are included in Annex H. These lessons are also placed within this report adjacent to the findings they most closely relate to. In Annex H the lessons are ordered according to where they sit along the end-to-end continuum from working to secure global supply, through to country delivery support.

1.1 Evaluation context

At the beginning of the COVID-19 pandemic in April 2020, the Access to COVID-19 Tools Accelerator (ACT-A) was launched to convene governments, multilateral organizations, private sector and civil society partners to coordinate, fund, develop and equitably deploy COVID-19 tools to bring about the end of the COVID-19 pandemic. Its four technical partnerships, led by nine partners, consisted of three vertical pillars (vaccines, therapeutics and diagnostics) and a cross-cutting health systems connector. As initiated in 2020, the vaccines pillar – known as the COVID-19 Vaccine Global Access Facility (COVAX) – was co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organization (WHO), and Gavi, the Vaccine Alliance (Gavi). UNICEF joined in 2021 as a formal COVAX partner. Gavi is the legal administrator of the COVAX Facility.

The instruments through which COVAX was operationalized – including the COVAX Facility and Advance Market Commitment (AMC) – had the specific aim of enabling equitable global access to COVID-19 vaccines. Since mid-2020, 1.9 billion doses have been delivered through the mechanism, 1.7 billion of which have gone to the world's poorest countries – the latter supported by fundraising efforts worth over $12 billion. It is critical to acknowledge that the COVAX Facility and AMC was a global first and that the highly-charged, dynamic and incredibly fast-moving global context in which these instruments were established was unprecedented. Decisions were necessarily made rapidly as the operating environment and context shifted, based on the imperfect information, with the financial resources, teams, capacities and skills that existed at the time. The learning from the COVAX experience is invaluable at this juncture as major global health players deliberate future pandemic preparedness and response. This report aims to provide independent, robust evidence toward this effort.

The intentions of the baseline study expressed in Gavi's Request for Proposals in April 2021 were to inform potential course correction through early assessment of core design elements and to enable appropriate measurement over time of the effectiveness and performance of the COVAX Facility and COVAX AMC. This evaluation is the first phase of a multi-stage evaluation of the COVAX Facility and AMC. Given the timing of this study, almost two years since the COVAX Facility and AMC were launched, the study was reframed as a formative review and baseline component, with the aims of providing 1) a review

of what has worked well and less well to date in the design, implementation and results of the COVAX Facility and AMC and 2) an opportunity to test the early stages of the Theory of Change (ToC), taking a snapshot of progress against critical areas of the ToC.

As part of this framing, the formative review and baseline aimed to consider COVAX Facility and AMC design, implementation and results in the context of wider external factors, given the rapidly shifting context within which the mechanism was designed and operationalized. As such, the evaluation has taken into consideration factors both within Gavi's control – for which it can be held accountable – and over which it had little or no control.

1.2 Objectives and scope

1.2.1 Objectives

Given the clear appetite in the Office of the COVAX Facility and among Gavi stakeholders and the wider global health community for learning from the COVAX Facility and AMC experience to date, the Formative Review and Baseline Study phase was designed to provide lessons and recommendations for: 1) COVAX Facility and AMC course correction; 2) Gavi 5.0/5.1 and future strategy considerations; 3) future pandemic preparedness. However, as documented in Section 1.5 and Annex A1.4, COVAX has moved on significantly since the start of the evaluation, especially during 2022, which means that the evaluation conclusions, recommendations and lessons speak primarily to the design of a future pandemic response. These are, however, relevant for the Gavi 5.1 context, for which the Gavi Board is currently deliberating on Gavi's role in future pandemic scenarios.

1.2.2 Scope and complexities

The evaluation period is March 2020–December 2021. However, acknowledging the considerable shifts in COVAX Facility and AMC strategies and contextual shifts in the first two quarters of 2022, against which the main thrust of data collection was happening, separating the time periods within informants' responses was not always feasible. References to the post-December 2021 context are therefore highlighted where they are relevant to findings.

The evaluation focuses on Gavi and, specifically, the COVAX Facility and COVAX AMC. However, it is very difficult to evaluate these components in isolation, as there is a need to take in to account the interconnectedness of roles, responsibilities and ways of working between implementing partners to facilitate COVAX Facility and COVAX AMC results. We have approached this consideration in two ways:

- Not evaluating other COVAX implementing partners directly but, rather, drawing on the findings, conclusions and recommendations of other evaluation processes and evidence on the design, implementation and results of their work – i.e. the Coalition for Epidemic Preparedness Innovations' (CEPI's) role in research, development and manufacturing, the World Health Organization's (WHO's) role in policy, allocation and delivery coordination, and the United Nations Children's Fund's (UNICEF's) and the Pan American Health Organization's (PAHO's) roles in procurement and delivery
- Exploring the 'contribution' of Gavi to areas that multiple COVAX partners jointly administer, particularly those areas that Gavi is not primarily responsible for (e.g., allocation, vaccine delivery support, procurement and delivery).

The evaluation also considers the COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally and of the geopolitical and wider contextual factors at play. While not in direct scope, a thorough understanding of the following factors has been important for the evaluation:

- The geopolitical context of vaccine manufacturing and bilateral procurement
- Global and country-level pandemic preparedness and response strategies (self-financing participants (SFPs) and AMC)
- Bilateral and multilateral development bank support for vaccines and programming.

As such, this has necessarily involved taking into consideration factors both within and outside of Gavi's direct control and factors over which Gavi has both higher and lower levels of control and for which it can be held accountable.

1.2.3 Timeline

An interim findings report was shared with Gavi and a wide group of stakeholders in August 2022. This garnered extensive feedback and interest in the context of a busy evaluation space.[3] A draft final study report was then submitted to Gavi in December 2022. This represented the culmination of data collected and analyzed during the period March–November 2022 (see Section 1.3), including stakeholders' feedback. This again attracted extensive feedback from Gavi and a broad stakeholder group which has been responded to in this final version of the study report, shared with Gavi in March 2023.

1.3 Methodology

The design and methodology for the formative review and baseline was outlined in detail as part of the evaluability and evaluation design work that preceded this assignment. The methodology used for this evaluation phase broadly adhered to the outline shared in this report, and is detailed further in this section.

1.3.1 Overarching evaluation design

The Formative Review and Baseline Study employed a mixed-method and complexity-aware design, necessitated by the scale of the evaluation, different types of evaluation questions (EQs) and the varied expectations and requirements for information of different evaluation users. Given the complex nature of the COVAX Facility and AMC and its mechanisms to achieve change, the evaluation design is underpinned by a theory-based approach, enabling the evaluation team to systematically surface evidence related to the causal linkages in the ToC, test it, and understand and verify the underlying theory. More detail on the evaluation ToC is in 2.1.1 and Annex B.1.

The evaluation has adopted a generative causation approach to establish whether and how implementation of the COVAX Facility and AMC has contributed to observed results. In so doing, the design identifies a theory on how the mechanism interacts in the prevailing context to achieve the intended outcomes, seeks patterns within the evidence pertaining to the outcomes, and provides the most complete approach possible to a causal explanation.

Four evaluation modules provided a framework to organize the EQs and employ different methods:

- **Module 1: COVAX Facility and AMC design** – A political economy analysis was used, and the development and in-depth analysis of an overall Theory of Change and nested theories of change for five programmatic sub-areas. These analyses were mainly based on information collected using in-depth desk reviews of relevant articles, reports and studies, as well as from Key Informant Interviews (KIIs) and the six country case studies.
- **Module 2: COVAX Facility and AMC implementation** – Program implementation process tracing, benchmarking and contribution analysis methods were used as was root cause analyses based on in-depth information collected through desk reviews of relevant COVAX reports and other documents, individual and small group KIIs; consultations with global experts as well as experts based in countries with experience implementing COVAX, including through the six country case studies.
- **Module 3: COVAX initial results** – Secondary data analysis was conducted on key indicator data reported by COVAX and collected from other relevant data sources, as well as in-depth desk review of critical reports to determine impressions of the COVAX Facility and AMC contribution to the overall initial results regarding allocation, supply, distribution and vaccine coverage. Contribution analysis supported an understanding of COVAX Facility and AMC contribution

relative to ToC components. A rapid literature review was also used to discuss the COVAX Facility and AMC contribution to reduction in morbidity and mortality.

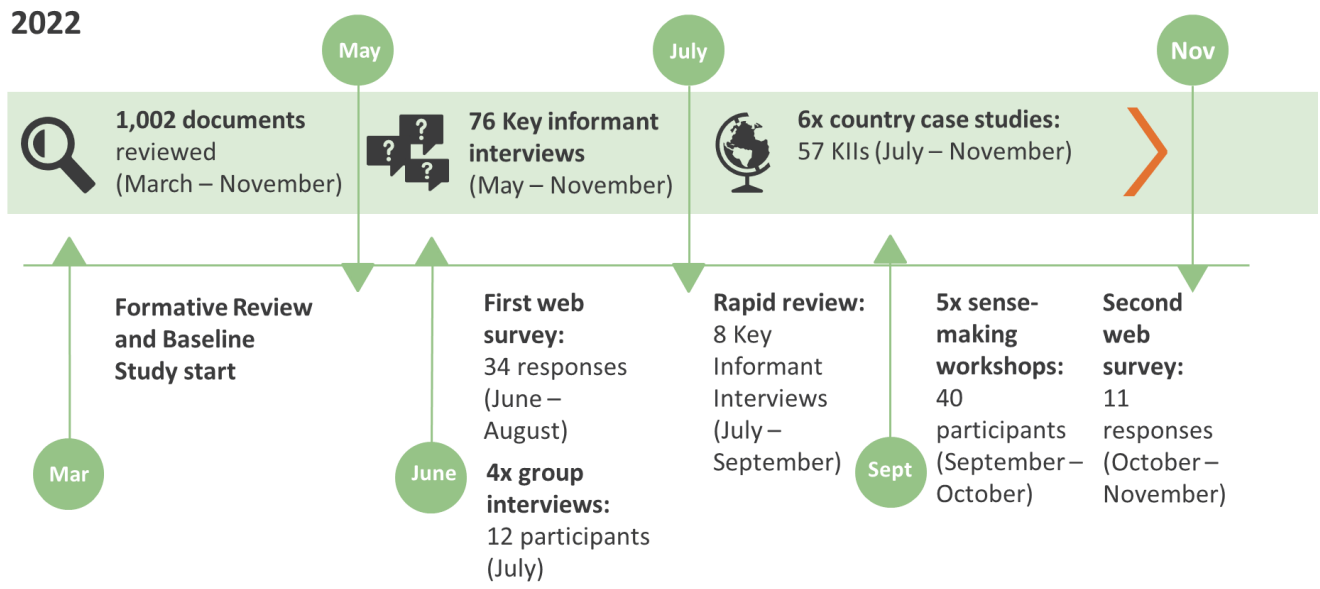
- **Module 4: Lessons learned** – An in-depth systematic review of the findings across all three modules was conducted and several consensus building meetings were had among the whole team to identify the top lessons learned that would be relevant for course corrections and well as planning for future pandemics. A priority list of lessons was developed further through sense-making workshops in October and November with key COVAX stakeholders to obtain their inputs and pressure test the lessons generated by the evaluation team.

The methods per each module are detailed further in Annex A1.2, Table A2.

1.3.2 Data collection

Data collection took place between March and November 2022. It involved a broad review of documentation and literature and relevant quantitative information sources, purposively sampled KIIs, engagement with stakeholder groups, web surveys and country case studies. These data collection methods are described in more detail in Annex A1.3 and are summarized Figure 1 below. Given their importance for the evaluation's ability to collate and analyse country-specific intelligence, the country case study data collection approach is detailed in Section 1.3.3.

Figure 1: Data collection methods and number of stakeholders engaged

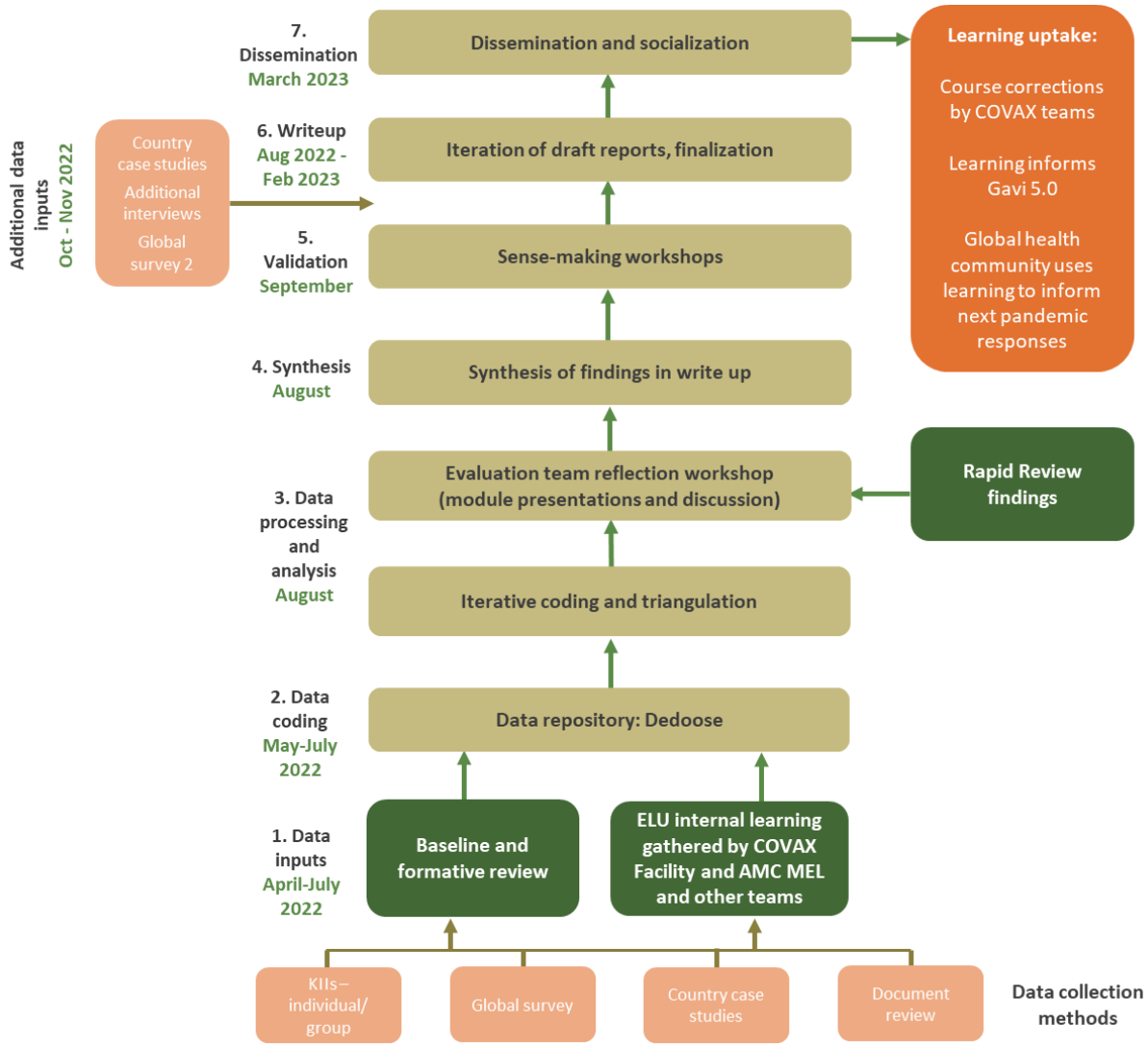


1.3.3 Country case studies

Fifty-seven stakeholders were interviewed and a large number of documents were reviewed across six evaluation case studies between July and November 2022. Six countries – Brazil, Colombia, the Democratic Republic of the Congo (DRC), India, Senegal and Vietnam – were selected for 'deep-dive' data collection, with the country case studies intended to 1) triangulate data collected from other sources, 2) capture country-specific experiences and contexts to enrich study findings (including exploring the programmatic components of the ToC), and 3) ensure that the views and perspectives of a broad range of country stakeholders are captured. As such, the countries selected for case studies were not intended to provide a representative sample across COVAX Facility and AMC participating countries. Using a criteria matrix[4], Itad proposed a list of Option A and Option B countries to Gavi in April and May 2022. Input was then sought from country-facing Gavi teams on feasibility and any additional aspects for consideration. The evaluation team took this feedback into consideration and arrived at the final list of countries for case studies.

The six country case studies began sequentially to ease pressure on evaluation team resources, with Brazil and Colombia initiated first in late July. Vietnam, DRC and Senegal all took place between September and November 2022, and the India case study began in October, following the program audit exercise in-country, concluding in mid-November 2022. Country-based consultants were hired in each of the six countries to lead data collection. Stakeholders were mapped by each country lead and were reviewed in collaboration with the respective Gavi Senior Country Managers (SCMs) to ensure alignment and inclusion of key stakeholders.

Figure 2: Data synthesis and analysis evaluation timeline



1.3.4 Synthesis and analysis

Given the breadth of the EQs and the large body of evidence and data generated, the team used a synthesis and analysis approach flexibly across key points in the evaluation timeline, detailed in the following bullet points. Figure 2 demonstrates how the synthesis and analysis processes came together.

- **Qualitative coding** – interview transcripts were uploaded to Dedoose qualitative coding software and coded against EQs. Excerpts per EQ were downloaded weekly and shared with relevant module and/or programmatic leads.
- **Triangulation and team interpretation** – following module leads' initial analysis of the evidence, a series of online and in-person workshops were held by the evaluation team, creating an intentional space to 1) engage with and challenge emerging findings across all modules; 2) look for areas of convergence and areas of divergence, and 3) look for strengths, weaknesses, lessons and appreciation

of equity. The lessons that resulted from this process consisted of generalized statements drawing on the strengths and/or weaknesses of the COVAX Facility and AMC, as observed by the evaluation team.

- **Feedback and sense-making** – following the submission of the Interim Findings Report, 250+ written comments were received from COVAX Facility and AMC stakeholders. Comments were categorized under four headings: factual inaccuracies; adjustments to framing and structure; broader issues meriting further discussion; issues out of scope. The first two categories of comments were then addressed for the final Interim Findings Report, which was submitted to Gavi on 30 September 2022. Comments relating to 'broader issues' were taken into consideration for this draft final study report and informed some areas of further analysis or data collection. Sense-making workshops provided a further opportunity to unpack comments and reactions from stakeholders, and supported the evaluation team to prioritize lessons learned and advance recommendations in areas of importance.
- **Triangulation of country data and recommendation development** – several online team workshops were held during the development of this report to discuss 1) learnings, 2) recommendations and 3) country case study findings. Country-level findings were organized thematically and mapped to existing findings where possible; where such mapping was not possible, 'outlier' findings were synthesized. Insights were thereby used to nuance, deepen or reshape report findings and to add new findings and insights elsewhere in the report. Insights emerging from the sense-making workshops were synthesized thematically and used to guide the development of recommendations, which are put forward in this report for further iteration following stakeholder engagement in Q1 2023.

1.4 Strength of evidence

The strength of evidence for our findings has been assessed based on the level of triangulation that was possible within each area of analysis. Table 1: (below) presents our approach to ranking the strength of evidence, which is used throughout the findings section of this report and indicated by a numeric and color key – as per the ranking below – next to each finding.

Table 1: Strength of evidence framework

Rank	Justification
1	Evidence comprises multiple data sources (both internal and external) (good triangulation), which are generally of good quality. Where fewer data sources exist, the supporting evidence is more factual than subjective.
2	Evidence comprises multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation) of decent quality but that are perhaps more perception-based than factual.
3	Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based, or generally based on data sources that are viewed as being of lesser quality.
4	Evidence comprises very limited evidence (single source) or incomplete or unreliable evidence.

1.5 Risks and limitations

A comprehensive list of limitations and/or risks to the evaluation are detailed in Annex A1.4, Table A3. The key risks and mitigation actions taken are summarised below. These have been submitted and reviewed by Gavi's Centralized Evaluation Team (CET) at regular intervals and in quarterly progress reports throughout the evaluation.

1 **Limitation/risk:** Key contextual shifts in the implementation of the COVAX Facility and AMC in the first quarter of 2022 are not captured by the evaluation period, risking the perception among stakeholders that the evaluation is less relevant to ongoing discussions and thinking. Concerns around the influence the

	evaluation is able to have in terms of informing Gavi Board discussions also persist, given the reporting schedule. **Mitigation:** References to key events and contextual shifts outside of the evaluation scope are highlighted in this report where relevant. In line with the context in which this evaluation report is being received, the evident focus of stakeholders' minds towards the next pandemic, and Itad's emphasis on utility, the recommendations of the report focus on future pandemic scenarios. Stakeholder engagement opportunities in Q1 2023 will support the refinement and targeting of these recommendations, with a view to the 2023 Gavi Board cycle.
2	**Limitation/risk:** Given the breadth of stakeholders interested in the evaluation of the COVAX Facility and AMC, there is an ongoing risk around expectation management and scope (e.g., the focus of this evaluation on Gavi's role only), and that this may impact the perceived utility and credibility of findings within certain stakeholder constituencies. The busy COVID-19 evaluation space also risks stakeholders conflating respective evaluation findings and critical insights being 'lost'. **Mitigation:** A clear articulation of scope has been included in this report and the previous Interim Findings Report, and Itad welcomes the support of Gavi's Centralized Evaluation Team (CET) and the Evaluation Advisory Committee (EAC) on stakeholder expectation management, particularly in light of multiple evaluation reports emerging in a similar time period. Periodic opportunities for engagement have been sought in order to increase stakeholders' understanding of the evaluation work (e.g. sense-making workshops, and an interactive evaluation session with key stakeholders in March 2023).
3	**Limitation/risk:** With many different stakeholder constituencies involvement in the evaluation, there has been an ongoing risk of limited or unbalanced involvement of stakeholder groups in data collection. **Mitigation:** The evaluation team has gone to considerable effort to ensure balance across key informant groups, and coordinated with other evaluation teams to avoid duplication and overburdening stakeholders. Purposive sampling in each stakeholder group has promoted balance capture of views. Low response rates have been observed among AMC92 representatives, despite further engagement initiatives in Q4 2022 prior to this report, suggesting a general lack of bandwidth among this group. Where findings are not supported by a wide breadth of stakeholders, we have highlighted in this in lower strength of evidence score for these findings.

Section 2: Findings

2 Overview

In this section we provide an overview of the finding for this assignment. They are organized by the three evaluation modules: Module 1 – Design (2.1); Module 2 – Implementation (2.2), and Module 3 – Results (2.3).

2.1 Module 1: Design (Right things)

This section addresses the main EQ 1: Is the design of the COVAX Facility and AMC appropriate to enable achievement of intended outcomes? Appropriateness is interrogated based on several criteria: 1) articulation of a problem analysis and clarity of ToC and objectives (EQ1.1); 2) responsiveness to beneficiary needs, and consistency with sustainable development goals and principles (EQ1.4); 3) adaptability to changes in context and needs (EQ 1.2). The section begins with findings on overall design considerations (2.1.1) before exploring the COVAX Facility and AMC design process (2.1.2). Assessment of 'right design' draws on the ToC for the COVAX Facility and AMC developed for this evaluation (Annex B).

Findings on overall design and design process are presented here; detailed findings on the design of particular program areas are presented in the pertinent section of Chapter 2.

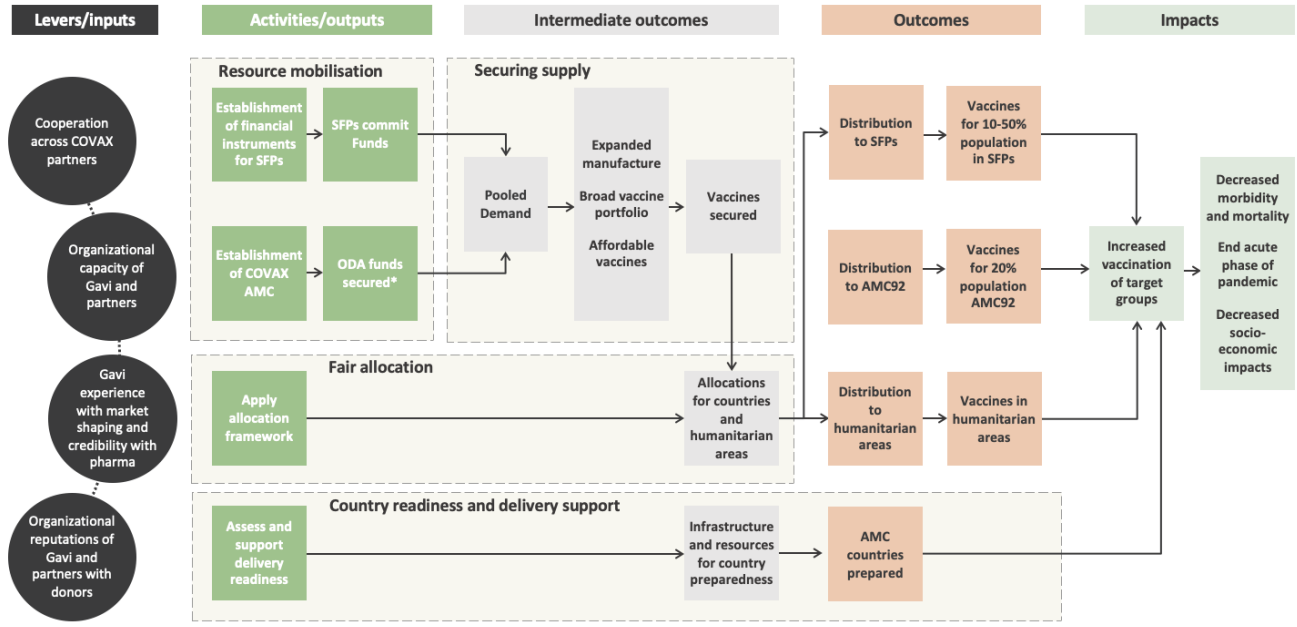
2.1.1 Overall design considerations

1 **Finding 1: COVAX, and specifically the COVAX Facility and AMC, was a bold and ambitious proposal to avoid the problem of unequitable allocation of vaccines experienced during previous pandemics.** Almost all interviewees commended the ambition of the COVAX Facility and AMC's design, which represented a bold attempt to address an unprecedented global crisis. COVAX's designers recognized the inequity and ineffectiveness of allocating scarce vaccines during a pandemic according to ability to pay. Instead of accepting this and waiting for surplus doses to be donated late, as happened during the H1N1 pandemic, COVAX would be a mechanism with a global scope, pooling resources from rich and poor countries to jointly procure vaccines and allocate them according to need.

1 **Finding 2: The COVAX Facility and AMC design was clearly articulated across a range of documents, with a ToC and indicator framework developed during implementation.**[5] Objectives were generally consistently articulated, from the earliest discussion papers to the initial COVAX investment case.[6] Gavi drafted a ToC in December 2020 to inform their monitoring and evaluation framework. COVAX Facility objectives were defined as being: 1) to support the largest actively managed portfolio of vaccine candidates globally; 2) to guarantee fair and equitable access to COVID-19 vaccines for all participants; 3) to deliver 2 billion doses by the end of 2021; 4) to offer a compelling return on investment by delivering COVID-19 vaccines as quickly as possible; 5) to end the acute phase of the epidemic by 2021.[7]

The COVAX Facility and AMC involves activities in several program areas, each with a distinct strategy and intervention logic: 1) resource mobilization; 2) market shaping and securing supply; 3) allocation; 4) vaccine delivery support.[8] As part of the evaluability assessment, a time-stamped ToC was developed that includes nested ToCs for each program area (Figure 3: and Annex B.1).

Figure 3: COVAX Facility and AMC program areas in the Theory of Change (December 2021)



* ODA in the form of dose donations added from 2021

1 **Finding 3: Significant design components were new, innovative and untested, and as such it was unclear at the outset whether the COVAX Facility and AMC would work as intended. While most stakeholders considered it a risk worth taking, some aspects of the design were heavily contested.** In particular, the design of a *global* procurement and allocation mechanism was new and it was unclear whether richer countries would participate. The concept of an AMC was not new, but previous iterations included a greater focus on incentivising vaccine manufacturers than was intended by the COVAX AMC. The use of Advance Purchase Agreements (APAs) on this scale was also new to Gavi and UNICEF, as were the indemnity and liability (I&L) and no-fault compensation scheme (NFCS) provisions, the Humanitarian Buffer and the allocation mechanism. A number of design components were unclear and/or contentious, as articulated in findings 4 to 6.

1 **Finding 4: COVAX aims to achieve fair access within the global vaccine ecosystem rather than seeking to fundamentally reshape this system.** The COVAX Facility and AMC design seeks to remedy the failure of market forces to ensure equitable access to vaccines through push and pull incentives to industry, collective action, and donor funding for procurement on behalf of the poorest countries. A number of commentators have argued that a longer-term vision of the market and global health system – based on the principle that in a pandemic, medical countermeasures and the knowledge needed to create them should be considered global public goods, as articulated in UN General Assembly and WHO resolutions – should have been embedded in the design.[9] The ongoing process to draft a pandemic treaty is a possible path toward a more sweeping transformation of current arrangements for developing and sharing vaccines and other tools in a pandemic (see Box 1). However, Gavi is also not a political organization, nor is it a mechanism through which these types of global agreements and grand bargains are struck. While this has led some to state that Gavi is ill-placed to deal with geopolitical and structural barriers to equitable access to vaccines, others posit that given the lack of global preparedness for a pandemic such as COVID-19, designing a mechanism to work within the existing global vaccine ecosystem was the quickest and most realistic option to best deal with the pandemic.

1 **Finding 5: Assumptions underlying the vision of the COVAX Facility and AMC as a channel for global joint procurement were revealed to be too optimistic.** Although the COVAX Facility and AMC's designers understood and acknowledged that better-off countries would procure bilaterally outside of COVAX, they hoped that many would also join the mechanism as SFPs, as an

insurance policy against failure of the candidates they had invested in. However, by the time the design was finalized, the United States (US), the European Union (EU), China and Russia had already indicated that they would not participate in COVAX joint procurement. Further, Gavi did not anticipate the speed and scale of bilateral deals made by high-income countries (HICs) or their impact on vaccine markets, nor the threat that the Indian government's decision to halt exports could pose to COVAX's vaccine supply. Several commentators have argued that despite what was known at the time, assumptions on the behavior of countries and manufacturers were overly optimistic, gave insufficient weight to national and commercial interests, and failed to anticipate the full impact of vaccine nationalism on the mechanism's prospects (see Annex C1.4 and Section 2.2.2).[10] Specifically, the hope that the COVAX Facility and AMC would play a larger role in procuring vaccines for countries *across income categories* also led to an overestimation of the initiative's power to shape markets for COVID-19 vaccines (see Section 2.2.2).[11]

Box 1: Emerging thinking on design for future pandemic preparedness and response

Global health stakeholders, including COVAX and Gavi Alliance partners, have started to discuss the design of a mechanism for ensuring timely and equitable access to vaccines in future pandemics. Proposals for pandemic preparedness and response reflect varying assessments of COVAX design and implementation. One set of proposals is around financing, including calls for a contingency 'pandemic response fund' large and rapidly available enough to enable early vaccine procurement and greater leverage in competition with HICs, while accepting that vaccine nationalism and the general outlines of a market-based global vaccine ecosystem are here to stay.[12] Manufacturers have proposed a voluntary commitment to allocate an unspecified proportion of all vaccines produced to low and middle-income countries, with certain conditions.[13] Most stakeholders support increasing regional capacity for vaccine manufacturing and/or procurement. Another set of proposals put forward for a pandemic treaty and/or IHR are more fundamental, treat knowledge and commodities needed in health emergencies as global public goods, and commit United Nations (UN) member states to act in support of global equity and human rights and to apply – or, where needed, amend – agreed flexibilities in trade-related intellectual property agreements.[14,15]

Lesson A

The experience of COVID-19 and other pandemics reminds us that HICs will prioritize national interests when securing vaccine supply. Commitment to global solidarity and equity will be secondary concerns.

1 **Finding 6: While equity is a guiding principle of COVAX, the COVAX Facility and AMC design focuses on cross-country distribution of vaccines. Its role in ensuring within-country distribution and in relation to human rights and gender equality is not clearly articulated or understood.**

From the earliest proposals for a new international initiative on access to COVID-19 vaccines, equity has been a guiding principle. This comprised the objectives of ensuring 1) equal access to vaccines *across countries* irrespective of ability to pay and 2) equitable allocation *within countries*, prioritizing the most vulnerable populations. Despite the latter being critical to meeting COVAX Pillar objectives, staff of the Office of the COVAX Facility stated unanimously that this was beyond Gavi's (and the COVAX Facility and AMC's) feasible remit and responsibility. Early COVAX documents also do not explicitly mention the principles of health as a human right[16] and gender equality, despite their impact on COVID-19 impact and policies. This is not, however, aligned to many stakeholders' perceptions or to Gavi's core business approach (e.g., the Zero Dose agenda). While it is implied that those COVAX partners with a country presence are responsible for working with countries to ensure equitable distribution in-country, this was disconnected from the work Gavi was primarily responsible for: design and operationalisation of the COVAX Facility and AMC; securing supply; allocation and administering vaccine delivery support.

2.1.2 Design process[17]

2 **Finding 7: The COVAX Facility and AMC were designed by a relatively small group of people with a shared vision, principles and sense of urgency.** This lean process helped the COVAX Facility and AMC design to come together with remarkable speed, which was necessary in early 2020 as the pandemic and its potential implications began to unfold, particularly given the internal understanding at that time that the pandemic would last for around 12 months. However, it probably also contributed to overly optimistic assumptions that affected design and later implementation. A review of design decisions found that many design decisions were taken by the Gavi Secretariat without Board input, and for others it was unclear where the decision making took place.[18]

1 **Finding 8: COVAX Facility and AMC design decisions reflected the disproportionate influence of donor countries.** This is to some extent related to Gavi taking a proactive role in the design process and the governance structure of Gavi itself – see Section 2.2.1. Countries represented on the Gavi Board and the PPC – notably a small group of Gavi and COVAX AMC donor countries, referred to as the 'Friends of COVAX' – used their position to influence the design of the COVAX Facility and AMC in a number of ways[19] by aligning the objective interests of the COVAX Facility with their own, such as the United Kingdom's (UK's) intervention to push for inclusion of SFPs in the COVAX Facility and for the subsequent decision to allow SFP 'optional agreements'. This decision was widely considered to be inequitable: not only could SFPs achieve higher coverage than AMC countries, but SFP countries with more resources benefited most.[20]

- Donors used incentives to reward actions and behavior they approved of and to punish those they did not approve of. It is understood that not only did the adoption of the Optional Purchase Agreement guarantee the participation of a number of influential donors, it was also linked to cash donations by some of these donors. The US also linked some of its support to the procurement of Pfizer vaccines, rather than a previously discussed cash donation.[21] Offers of surplus vaccines from Canada, France and other HICs also pushed COVAX to accommodate dose donations against early design principles. While this arrangement helped COVAX achieve delivery targets, it also allowed donating countries to minimize accountability for over-procurement and to count related expenditure as official development assistance (ODA) while earmarking donations to support vaccine diplomacy.[22]
- The Gavi Board, often led by the donor constituency, has also sought to exert/enhance its control over the Gavi Secretariat and Office of the COVAX Facility by reducing the asymmetry of information between them and by tightening their monitoring over the agency's work and outcomes, including through a rapidly scaled up governance function, as discussed below.

While these examples refer to the influence of donor countries, we understand that in some instances the changes were driven not by the development agencies of these countries but by the agencies responsible for procurement of vaccines for their national populations.

1 **Finding 9: The pharmaceutical industry was represented in the COVAX design process and governance, influenced design decisions, and did not always work to further the COVAX Facility's ultimate objective: equitable access to COVID-19 vaccines.**[23] Again, this can be related to the presence of these bodies in Gavi's governance structure – see Section 2.2.1. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents the multinational pharmaceutical industry on the Gavi Board, as does the Developing Countries Vaccine Manufacturers Network (DCVMN), and individual manufacturers were heavily involved in the early design of the COVAX Facility. A key example of industry influence is around I&L, which from the first concept note was identified as 'a perennial concern of private sector partners'. Industry demands for indemnification resulted in I&L clauses transferring liability to governments and establishment of the NFCS. The I&L arrangements contributed to the problems with the COVAX Humanitarian Buffer due to delayed waivers (see also Annexes B.2 and B.3).[24] Other potential signs of industry influence are COVAX's support for—or inability to challenge—the secrecy surrounding deals, its decision not to include intellectual property provisions in deals with manufacturers, and its reluctance to play a larger role in facilitating technology

(tech) transfer to increase supply and regional capacity and independence.[25] The perception of the COVAX Facility and AMC (and COVAX as a whole) making concessions to vaccine manufacturers in design and implementation, in a context of large public funding and large private profits, drew much criticism from public health experts, civil society, academics and media alike.

1 **Finding 10: COVAX leadership was slow to engage low and middle-income countries, resulting in public criticism of COVAX.** Low- and middle-income countries participated minimally in the original design of COVAX, either directly or through regional political groupings such as the African Union. Gavi has channels for engaging on routine immunization with its partner countries, who are represented on the Board and who were consulted and engaged in decision making on COVAX design from the outset. However, knowledge of country needs and capacities related to COVID-19 vaccines relied mostly on the input of WHO and UNICEF. Gavi's main justification for this is that comprehensive country engagement would have slowed down the design process. The establishment in mid-2020 of the AMC Engagement Group provided AMC countries with a platform for information exchange but little influence on COVAX Facility and AMC strategy. In retrospect, some COVAX leaders admitted that COVAX, including the Facility and AMC, was designed in a top-down fashion. Lack of engagement may have contributed to AMC countries and upper-middle-income SFPs feeling less ownership of the COVAX Facility and AMC compared to regional procurement mechanisms such as the African Vaccine Acquisition Trust (AVAT)[26].

2 **Finding 11: There was hesitation to engage civil society in the early design discussions on the COVAX Facility as it was thought that this would delay decision making.** Civil society and community representatives were largely absent at the early design stages, although independent scholars and experts were involved in the design of market shaping strategies. Nonetheless, high-profile voices and dissenting opinions were not invited or heeded. COVAX was slower to engage civil society compared to ACT-A and other pillars. For about a year, the COVAX Facility relied mainly on civil society representatives on the Gavi Board until civil society organizations (CSOs) were engaged more systematically in working groups. Despite informal consultations and regular updates to civil society representatives, there was little meaningful engagement in problem analysis and strategic planning. In some cases this may have contributed to delays in implementation (e.g. the Humanitarian Buffer – see Box 3 below), and certainly it resulted in some reputational damage to Gavi and the COVAX Facility.[27]

2.2 Module 2: Implementation (Right ways)

This section addresses EQ 2: 'Have the COVAX Facility and AMC been successfully set up and implemented thus far?' Following a finding which responds to this overall finding, the section is split into two subsections on: governance and operational areas, which responds to EQ 2.1 ('Are COVAX Facility and AMC operations appropriate and working to facilitate implementation as intended?'); programmatic areas, which responds to EQ 2.2 ('Have COVAX Facility and AMC programmatic areas been successfully set up and implemented thus far?').

1 **Finding 12: Over the course of 2020 and 2021, despite a very difficult operating environment, Gavi and partners successfully launched and implemented the COVAX Facility and AMC.** Establishing the COVAX Facility and AMC, with 193 confirmed participants, involved a host of different processes, each of which brought challenges and implications that had to be rapidly thought through.[28] These processes included: setting up the Office of the COVAX Facility; engaging with the subset of AMC participants that had never been Gavi-eligible and with SFPs, who had only worked with Gavi as donors or not at all; establishing I&L agreements[29] and the COVAX NFCS;[30] establishing the Humanitarian Buffer; negotiating APAs with vaccine manufacturers; administering dose donations; setting up cost-sharing; operationalizing the allocation mechanism; and providing vaccine delivery support in its various guises.

As noted above, a number of these activities had never been done before or were firsts for Gavi and the Alliance partners (see lesson F below, and relatedly Box 2, which shares learning from Brazil and Colombia on set-up and engagement of upper-middle-income countries (UMICs)). Many processes and systems

required adaptation as the COVAX Facility and AMC sought to respond flexibly to the uncertain and evolving context.[31] The time it took to set up such processes and systems with UMICS, for example, did not allow for rapid engagement. 0 presents a timeline of COVAX Facility and AMC design discussions and decisions by the Gavi Board, demonstrating the pace of decision-making and associated challenge. Box 3 discusses two design revisions in particular that demonstrate 1) the responsiveness of design to emerging needs and context and 2) issues experienced in implementation.

Lesson F

Management systems and processes that allow for rapid and smooth engagement with all types of countries, including those that Gavi does not ordinarily engage with in routine immunization operations, take time to put in place.

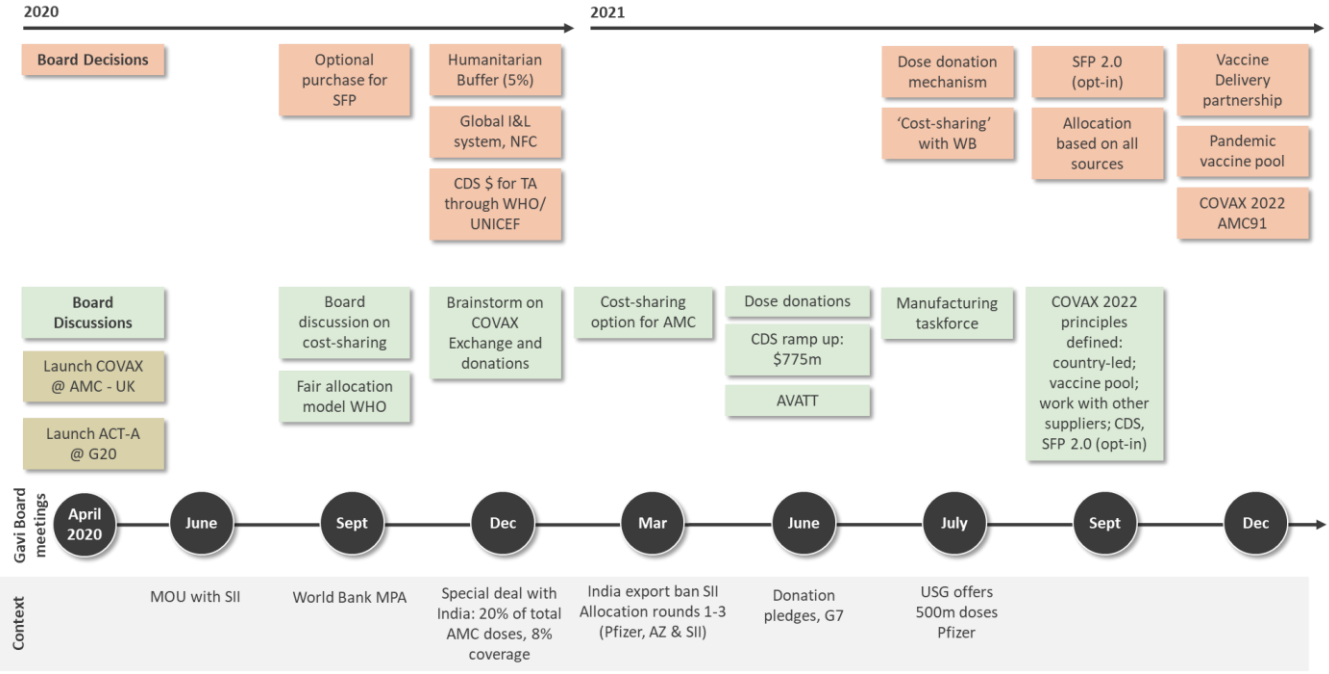
Box 2: UMIC engagement – Lessons from the experiences of Brazil and Colombia

UMICs can benefit from initiatives such as the COVAX Facility, but experiences from Brazil and Colombia show that the necessary processes need to be set up ahead of time for agreements to be reached quickly during a pandemic. The two case studies show the COVAX Facility's contribution to their vaccination coverage to be limited, but participation was nevertheless important for different reasons. In Brazil, the COVAX Facility was perceived to be an important insurance policy. In Colombia, participation in the framework of a multi-stakeholder initiative such as the COVAX Facility proved to be legally simpler than direct procurement. In both countries, engagement was also perceived as geopolitically important.

- **What can be learned from the Brazil case study?** When the COVAX Facility was launched, the necessary systems were not in place to enable rapid and smooth engagement between the government of Brazil and Gavi, resulting in delays. For example, a legal framework had to be set up to enable Brazil to join the COVAX Facility and, later on, to enable the country to donate COVAX doses. These systems and processes need to be put in place ahead of the next emergency.
- **What can be learned from the Colombia case study?** The COVAX Facility and similar mechanisms can facilitate the acquisition of vaccines and other medicines where processes for domestic procurement make rapid purchase of vaccines through other channels difficult. For example, where there are important issues around government corruption and where any purchase made by the government must be published, mechanisms such as the COVAX Facility or the PAHO Revolving Fund can play an important role.

Additionally, both countries noted communication challenges with the COVAX Facility, which are perceived to have impaired trust. Stakeholders attributed limited staff bandwidth within the Office of the COVAX Facility, lack of clarity on delivery dates, availability of vaccines,[32] and complexity of processes to some of these challenges.

Figure 4: COVAX Facility and AMC design revisions and timeline



Box 3: Promoting design revisions

Humanitarian Buffer: Developed for populations in humanitarian settings not adequately reached through government programs, but aspects of its design limited its impact.[33] As of late 2020, most national vaccination plans did not comprehensively include vulnerable groups, such as refugee populations. The Gavi Board agreed to the principle of a humanitarian buffer.[34] COVAX Facility partners finalized policy frameworks and design, approved in March 2021, and allocated 5% of AMC funding to the buffer[35] as a measure of 'last resort' (inclusion of populations in humanitarian settings in national vaccination plans remained the preferred approach).[36] The design assumed that additional funding for delivery costs would be available from other sources and that I&L waivers would be forthcoming from manufacturers for humanitarian agencies unable to indemnify manufacturers. These assumptions were not realized, and delivery funding and liability turned out to be barriers to implementation. Several reviews[37] recommend improvements for course correction and the next pandemic.[38] See Annex B.3 for more detail.

NFCS: Designed and added to further indemnify vaccine manufacturers for damage related to side effects, but evidence suggests it has been very costly to administer and hampered vaccine delivery. An NFCS was developed because some countries do not have the required credit rating to comply with indemnification clauses in the COVAX agreement, leaving manufacturers at some residual risk. The NFCS is a centrally administered scheme, which provides compensation for serious adverse events resulting in permanent impairment or death in full and final settlement. Since December 2020, AMC countries participate in the NFCS as part of the INL agreement which may require countries to pass complex legislation. The costs were high to design the NFCS and for implementation through WHO, an administrator and an international insurance firm.[39] Uptake of the scheme has been very low, with few payouts up to December 2021,[40] due to low prevalence of side effects and reluctance of countries to promote the scheme.[41] See Annex B.4 for more detail.

The scope of innovation and the speed at which the initiative was implemented created a heavy burden for the Office of the COVAX Facility and had implications for management capacity, efficiency and effectiveness. It also led to a perception by some stakeholders that ways of working were too centralized and 'top-down'. Stakeholders within the Office of the COVAX Facility acknowledge the issue but mostly consider it to have been necessary, given the need for speed and the scale and complexity of the issues at hand. These themes are explored in the following sections, which first cover the operational areas of the COVAX Facility and AMC (i.e. governance and management, risk management, set-up costs and stakeholder engagement) and then turn to the programmatic areas (i.e. resource mobilization, market shaping and securing supply, allocation and vaccine delivery support).

2.2.1 Governance and operational areas

This section considers operational aspects of the COVAX Facility and AMC related to EQ 2.1 and sub-EQs 2.1.1–2.1.4. Annexes C1.1–1.4 provide more in-depth analysis.

Governance

2 **Finding 13: Gavi, as a public–private partnership (PPP) with broad-based stakeholder governance and engagement, was a legitimate body to lead an international, multi-stakeholder effort to rapidly scale up vaccination programming.** The COVAX Facility and AMC is administered by Gavi, and as such one must consider the legitimacy of Gavi as a PPP in health governance. As elaborated in more detail in Annex C.1.1, Gavi derives legitimacy from a governance structure that is not representative of all stakeholders but does include state as well as non-state actors (non-governmental organizations (NGOs), the private sector and philanthropies), with strong conflict of interest policies and a strong track record of delivering health impact in low-income countries (LICs).[42, 43] The COVAX Facility and AMC derives further legitimacy from the engagement of various UN agencies (which are representative of a vast majority of states) in its design and implementation and from its broad-based membership of participant countries.

2 **Finding 14: Gavi was created, in part, to be able to take action quickly and at scale. Its structure and governance model are perceived by stakeholders to offer a number of comparative advantages for responding to the COVID-19 pandemic.** These include its ability and willingness to take on a greater degree of risk than other global health and UN agencies; expertise in vaccine market shaping; experience of working with LICs and LMICs to improve access to and utilization of vaccines; and the ability to take decisions quickly – a function of its slim governance structure. These features are important for an emergency pandemic response where agile and timely decision making is required, alongside strong working relationships with a breadth of stakeholders and constituency groups to influence change. Alternative host organizations were perceived by key stakeholders interviewed (mostly internal to Gavi) to have more complex and challenging governance arrangements than Gavi, as well as even more limited ability than Gavi to assume higher levels of risk than for their core work.

2 **Finding 15: The scope and scale of the COVAX Facility and AMC posed a challenge to Gavi's existing governance arrangements.** The decision to utilize Gavi's existing governance mechanisms was justified, in part, based on the need to establish the COVAX Facility quickly on the internal understanding that the pandemic would last for around 12 months. Nonetheless, the inclusion of countries in the COVAX Facility that were never eligible for Gavi support introduced the need to rapidly establish new relationships and adapt governance arrangements to enable their participation.[44] This was more of a problem for SFPs than for AMC participants, with most of which Gavi was already familiar. The operational complexity of establishing and implementing new structures, along with the substantial increase in the level of funding and the volume of vaccine doses being administered by Gavi, placed a significant burden on Gavi's existing governance structures. For example, it had to meet much more frequently and had to make decisions quickly and sometimes without a full understanding of the risks involved.[45] To partly mitigate this burden and ensure that decisions could be taken quickly, a number of additional executive powers were granted to the Gavi CEO and Board Chair.[46, 47]

1 **Finding 16: A range of governance structures were established for the COVAX Facility and AMC to meet different purposes, broadly focused on stakeholder engagement, soliciting external expertise and guidance, and accountability to donors.** A guiding principle of the ACT-A was not to establish new entities, and for governance arrangements to have to build on existing bodies wherever possible.[48] However, while the COVAX Facility is governed by the Gavi Board and its existing committees,[49] 18 separate bodies were also created and at least nine others adapted for the COVAX Pillar.[50, 51] These bodies have included more than 550 members. As shown in Annex C1.1, the COVAX Facility governance model is effectively an extension of Gavi's PPP model, with engagement and membership of participating countries, AMC donors and foundations, Gavi Alliance and COVAX implementing partners, research and

health institutes, the private sector and civil society. These governance structures report to and advise the Office of the COVAX Facility rather than the Board directly, and there are fewer members from some stakeholder groups (e.g. civil society) than from others.

1 **Finding 17: COVAX Facility governance arrangements have been overly complex, with a lack of clarity over roles and with overlapping responsibilities between bodies. These arrangements have created a huge administrative burden and have not provided an effective forum for genuine stakeholder engagement in decision making.** This view was widely shared by stakeholders and is aligned to Gavi's own internal reflections and learnings.[52] In particular, stakeholders pointed to a lack of clarity over roles and responsibilities across the many different bodies established, such as for allocation[53] and decision making on the vaccine portfolio.[54] Several stakeholders noted that COVAX Facility governance arrangements became a channel for communication rather than genuine stakeholder engagement. This is partly a function of how many stakeholders would join some groups. For instance, up to 400 participants would attend calls for the self-organizing AMC Engagement Group in 2021, making it impossible to offer all an opportunity to provide feedback and guidance to the Office of the COVAX Facility. Nonetheless, other external stakeholders reported a lack of willingness within the Office of the COVAX Facility to genuinely seek country and civil society input and incorporate it into decision making. There is also reported to have been some confusion and resulting frustration on the purpose of some governance bodies. For instance, members of the Shareholders Council would seek to engage in strategic discussion on such issues as the potential design of a COVAX dose exchange, although this was not the purpose of this group and it had no formal mandate to feed into Board decisions.[55] Box 4 considers the evidence on these themes in relation to the ACT-A guiding principles.

Box 4: Assessing the evidence on COVAX Facility and AMC governance arrangements against ACT-A principles

Assessed according to the three principles embedded in the mission statement of ACT-A and used by others, governance structures broadly meet stakeholders' needs for some form of *participation*, yet many expressed dissatisfaction that important information is not provided in a *transparent* and timely manner and that the governance structures do not enable stakeholders, other than donors through the AMC Investors Group, to hold implementers to *account*. This is principally because these structures are advisory to the Office of the COVAX Facility rather than to the Board.[56, 57]

Lesson I

Genuine participation in and transparency and accountability around decision making are crucial for engagement and effectiveness, especially if the involvement of all relevant multi-sectoral stakeholder groups is not feasible in the early stages of designing a pandemic response.

2 **Finding 18: Partner working relationships for the COVAX Facility have at times been challenging and blurred the usual lines of accountability for Gavi business.** In its usual course of business, Gavi funds partners, notably WHO and UNICEF, through the partners' engagement framework (PEF). This defines key performance indicators for activities at all levels, with progress against indicators monitored to ensure Gavi investments deliver results, helping to set expectations and ensure accountability for partner performance. During the implementation of the COVAX Facility and AMC, organizational relationships were organized differently through the following configuration:

- The COVAX Pillar is co-led by CEPI, Gavi and WHO (with UNICEF initially described as a procurement partner and later as a co-lead, itself reflecting a lack of clarity over UNICEF's intended role) and situated within ACT-A, which is in turn co-convened by UNICEF, WHO, the World Bank and others.
- WHO, UNICEF and other partners have been heavily involved in designing and implementing many aspects of the COVAX Facility's operations, with Gavi bearing ultimate responsibility given its legally binding contracts with manufacturers, donors and recipient countries.

- Gavi has also funded large parts of WHO and UNICEF's work within the COVAX Pillar, especially for country-level technical assistance (TA) and vaccine delivery support (although, as explored in findings 54 to 58, this was not the intended nature of the relationship).

A number of stakeholders suggest that this configuration compromised the Gavi Secretariat's ability to oversee and ensure appropriate implementation of Gavi resources and, as a consequence, the Board's ability to hold the Secretariat to account. On a more operational level, stakeholders reported that the complexity of working relationships and lack of clarity on roles and responsibilities resulted in all partners wanting to comment on all things, which created an additional management burden. One example is the communication of allocation offer letters: a straightforward process that should not require review by multiple partners. This should, however, be balanced by the acknowledged need to take greater risks and move fast in an emergency period, within which such issues may be deemed acceptable for a time-limited period.

Stakeholder engagement and communications

1 **Finding 19: Stakeholder engagement and external communications posed significant challenges for the COVAX Facility and AMC.** It was recognized early on that establishing and implementing the COVAX Facility and AMC would require 'extensive coordination, collaboration, stakeholder engagement and outreach with many partners involved with varying interests'.[58] Despite this, many stakeholders reflected that such engagement would slow down decision making and no plan or strategy was developed, at least initially, for comprehensive stakeholder engagement to meet specific purposes – which, best practice suggests, would be helpful.[59] Instead, different practices have been adopted by different teams, for instance with a wide array of stakeholders engaged in resource mobilization but engagement in other areas through governance structures only.

External communications were used as a tool to promote resource mobilization and to secure supply in various ways in 2020 and 2021. Resource mobilization and securing supply objectives required communications outputs to project a positive storyline while being careful not to impede progress by calling out stakeholder behavior where it was inconsistent with the objective of equitable access. Challenges were faced with donors, on whom COVAX was reliant for funds and dose donations; with vaccine manufacturers (and the governments of the countries where they are based), who provided the vaccines; and with partners responsible for aspects of implementation and support. Some stakeholders argued that these considerations, and a fundamental choice not to use public communication as an advocacy tool, prevented the Office of the COVAX Facility from explaining to participating countries the scale of the challenges it was facing and why it was not able to provide more timely and useful information on vaccine supplies and delivery timings during 2021.[60] There is anecdotal evidence that this absence of a complete explanation affected public perception and fed the frustration many countries felt in not receiving the volume of doses through the COVAX Facility and AMC that they expected and needed (see Box 7).[61] Alongside the country lines of communication via Gavi SCMs, COVAX/Alliance partners and weekly WHO member state communications, the fortnightly COVAX Data Briefs that were released from March 2022 onwards may have helped to ease this issue had they been released earlier.

Based on the substantial body of evidence on the effects of transparency on individual and organizational behavior, it is plausible and likely that public criticism (from Gavi/COVAX directly or via civil society) of pharma – or, at least, greater transparency on industry's progress in meeting commitments to the COVAX Facility and/or AMC – would have had some effect in influencing industry behavior, in particular given Gavi's status and the sensitivity of multinational pharma companies to reputational damage.[62] Greater use of public communication may also have been useful in influencing the behavior of HICs, whose political leaders were keen to use the COVAX brand to demonstrate their commitment to global vaccine access. This is, however, contested by senior Gavi/Office of the COVAX Facility staff, who note that: (a) a significant level of work was undertaken to discreetly influence external reporting on the COVAX Facility and AMC, such as through the CEO's social media presence, by reviewing draft reports and articles and responding to publishers to correct errors; (b) comprehensive non-disclosure agreements left little scope for publicly commenting on specific dealings with manufacturers; and (c) they did not believe that public

criticism would have much impact, especially on HICs, given the strong political pressures they faced to prioritize the needs of their own populations.

There were, however, shifts in communications approaches over time, notably with the establishment in mid-2021 of a communications team within the Office of the COVAX Facility,[63] and in late 2021 with more open criticism of country and industry behavior, including language that explicitly referenced vaccine hoarding, export bans, and the need for manufacturers to prioritize supplies to the COVAX Facility and AMC.[64] This shift stemmed from widespread criticism of COVAX, the need to more transparently communicate the issues to stakeholders, and the need to build momentum for a further programmatic and fundraising push in 2022.[65]

Lesson C

Influencing HICs and pharmaceutical industry decisions to consider public health and social responsibility alongside national and commercial interests is very challenging. Advocacy combined with transparency and exposure (e.g., publicly sharing vaccine doses sharing commitments or forecast deliveries by suppliers) can be effective in influencing behavior, alongside complementary strategies including political agreements.

Management

2 **Finding 20: While a strong management team was created, it was under-resourced for the scope and scale of its responsibilities.** Established within the Gavi Secretariat, the Office of the COVAX Facility is a dedicated team that supports the operations of the COVAX Facility and AMC. The caliber of staff, drawn from Gavi Secretariat staff and newly recruited short-term consultants, is generally perceived to be high, although some have raised concerns about:

- rapidly recruiting a new team within an organization without experience in managing emergency responses and employing surge capacity
- hiring from similar backgrounds, notably management consultancies and the pharmaceutical industry, which, in combination with a lack of country input in design, some external stakeholders perceived as contributing to 'groupthink' and an unwillingness to consider alternative viewpoints
- a lack of capacity in key skill areas, notably deal-making, I&L agreements and emergency response, none of which were areas of Gavi's core expertise.

Moreover, the Office of the COVAX Facility has been very lightly staffed for the scope and scale of the COVAX Facility's activities, linked to the set-up and management costs of the COVAX Facility being very low (funded mostly from the administrative charges levied on SFP deals). As a result, staff were stretched across multiple roles, overworked and, in some cases, burned out. Some stakeholders linked this lack of bandwidth in late 2020 and early 2021 to the Office of the COVAX Facility's inability to move quickly and with a sufficient level of depth and rigor. Despite this, there was a reported reluctance within the Gavi Secretariat to recruit more staff or accommodate the terms on which senior staff would be willing to join. This rigidity was described as a legacy of Gavi's traditional ways of working.

2 **Finding 21: A very strong mission-driven culture within the Office of the COVAX Facility has enabled it to rapidly implement a hugely ambitious agenda, though the extent to which inclusivity in decision making has influenced the speed of implementation is unclear.** Stakeholders universally noted the exemplary attitude of COVAX Facility staff in spite of the heavy workload and the challenges imposed by the pandemic. There is strong evidence that team members worked collaboratively and inclusively (of internal staff, partners and external stakeholders) for the attainment of shared goals. However, there were mixed views on the implications of inclusivity in decision making. While decision-making authority is highly centralized in the Gavi Board, the Board Chair and the CEO, decisions are often discussed at all levels of the hierarchy before being taken. Country-facing staff and some others pointed to this internal inefficiency and noted that decision making often took too long.

Other stakeholders reflected positively on the consensual nature of decision making and its appropriateness to decisions involving high levels of risk, while acknowledging the time required to seek external advice and strive for consensus.[66]

Risk management

1 **Finding 22: The initial COVAX Facility design was agreed in mid-2020 without a full understanding of the associated risks. Strong risk management systems and processes have been established over time.** The approach to risk management has been broadly translated from Gavi's core business, where risks are generally well understood and stable, with the emphasis on assurance (i.e. to ensure compliance with the Risk Policy and processes). The dynamic context of the COVID-19 pandemic and the administration of the COVAX Facility have involved much greater risks and required a heightened attention to risk identification, impact assessment, prioritization and mitigation. However, the risks associated with establishing the COVAX Facility were not fully understood during much of the design phase, and there are examples of decisions being taken without full appreciation of their implications. Some of these decisions were considered to be overly risk averse, which limited the scope and scale of deals struck with vaccine manufacturers, and the number of APAs entered into for different vaccine products (see Finding 24 below and Annex C1.2). This is something that the application of a more formal risk management lens might have prevented.

Gavi's governance structures were aware of this, and the Audit and Finance Committee (AFC) in particular was proactive in its engagement around risk, setting up a sub-committee in 2021 with additional programmatic expertise to supplement its primarily financial in-house expertise. Alongside the recruitment of a risk specialist for the COVAX Facility and the hiring of external expertise (e.g. CitiGroup, which developed a financial risk management framework for the COVAX Facility) in late 2020, systems and processes were formalized and risk analysis became more thorough and nuanced.[67] Through 2021 risk management was integrated into the working and operations of the Office of the COVAX Facility. This includes having standing agenda items in many meetings, with identified risks feeding into a risk tracker/matrix, with risk owners identified to monitor and mitigate particular risks. As such, some stakeholders noted that these processes added management burden and slowed decision making down. Although it took some time, Gavi's usual tools, processes and governance were eventually right-sized to the COVAX Facility's mandate and external and internal context. A remaining issue, however, has been in relation to Gavi's risk appetite, which was not initially spelled out. Despite the Board seeking to clarify its position in mid-2021 some uncertainty remains.[68]

Some stakeholders also noted that the COVAX Facility's senior management did not fully engage with risk management, with risk specialists not being sufficiently senior and nor were they invited to high-level strategy discussions. This was also linked to the need for the AFC to take an operational role in risk management, something that would normally be handled by the Secretariat. On balance, it is important to acknowledge the tension between senior management being able to take decisions quickly and according sufficient time and weight to risk management, especially in a highly dynamic operating environment.

Analysis suggests that most of the significant strategic risks faced by the COVAX Facility in 2021 were identified and mitigating actions were put in place. Even where substantial risks were not fully mitigated (e.g., supplies from the Serum Institute India (SII) not materializing), it is mostly unclear what could have been done differently given what was known at the time and a lack of alternative options. As such, these issues were not necessarily a failure of the risk management system but the result of external factors largely beyond COVAX's control.

2.2.2 Programmatic areas

This section considers the programmatic aspects of COVAX Facility and AMC implementation, related to EQ 2.2 and sub-EQs 2.2.1–2.2.5 – resource mobilization, market shaping, securing supply, allocation and vaccine delivery support. Annexes C2.1–2.5 provide more in-depth analysis.

Resource mobilization

1 **Finding 23: A strong resource mobilization function was established around the COVAX AMC.** This is essentially a financing instrument bound by terms and conditions to secure funds for COVID-19 vaccines for a 10-year period. The function drew on Gavi's pre-existing capacity and built on continuous fundraising efforts and three distinct fundraising rounds:

- an initial investment opportunity of $2 billion, announced at the UK-hosted Global Vaccine Summit in June 2020 to raise 'seed funding'
- significant resource mobilization activities surrounding the G7 Early Leaders' Summit in February 2021 and throughout 2021, through which $5 billion was sought to secure access to 1 billion vaccine doses
- a further investment opportunity for $3 billion ($2 billion in donor funding and $1 billion in cost-sharing) to secure access to 1.8 billion vaccine doses for the COVAX AMC in 2022 and cover 30% of the population of AMC participants, released in April 2021.

A fourth 100-day campaign seeking $5.2 billion was launched in January 2022, which is outside the scope of this evaluation.

The timing and target amounts of fundraising efforts were driven mostly by the deals struck with vaccine manufacturers and the volume of supply being received. For instance, in early 2021, when expected supply from SII was blocked by Indian government restrictions, there was a need to raise further resources to strike new deals.[69]

A wide range of stakeholders reflected that the fundraising function worked professionally and effectively to implement a need-based, opportunistic and ambitious fundraising strategy. This was supplemented by engagement of a wide range of stakeholders to advocate for the COVAX AMC and support resource mobilization around key events. This included COVAX and ACT-A partners, civil society, and public declarations of support from many political leaders and public figures.

Fundraising for the COVAX AMC was also supported by the design of the AMC as a fundraising vehicle that provided something tangible for donors to support, and by the inclusion of SFPs in the COVAX Facility. In particular, a number of stakeholders suggested that the latter created a *global* model which gained traction and appealed to a broad donor base. It is, however, noted that while the COVAX AMC attracted funding from a broad donor base, including many from the private sector that were new to Gavi, the vast majority of funding came from Gavi's traditional donor base.

However, while resource mobilization has been broadly positive, there is evidence that points to some of the resource mobilization materials having unintended consequences. Specifically, the consistently positive messaging of resource mobilization materials (which often echoed other materials prepared by the Office of the COVAX Facility) prepared throughout 2021 did not match the experiences of SFP or AMC participant countries, which had not received the volume of doses that they expected, and this likely contributed to the level of frustration many felt with COVAX as a whole (see Finding 51 and Box 7).

1 **Finding 24: The COVAX AMC was not able to access sufficient financial resources immediately in 2020.** As shown in Figure 4, by December 2020, nine months after WHO had characterized COVID-19 as a pandemic and the first vaccine had gained emergency use listing (EUL), and six months after the first investment opportunity of $2 billion was released, $2.4 billion had been pledged to the COVAX AMC, with $2.3 billion in signed donor agreements, but only $400 million had been received. The implications of this for deal making are explored below. For the most part, this simply reflects the time required by donors to obtain the required parliamentary or other approval before making formal commitments and disbursing cash. As such, this situation could have been predicted and would occur again in similar circumstances. It could, however, have been avoided if Gavi had been willing to use its core funds for the COVAX Facility and AMC, even if this had only been to cover the period of time between donor pledges being converted to cash – but this was initially prohibited by the Gavi AFC.

Lesson D

A dedicated fundraising vehicle, supported by a strong investment case, a credible host agency and a multi-pronged fundraising approach, can raise substantial amounts of money in a short space of time: almost $10 billion within 12 months in the case of COVAX.

1 **Finding 25: COVAX AMC resource mobilization in 2021 was highly successful.** This included cumulative pledges totaling $10.1 billion, $9.1 billion in signed donor agreements and $8.2 billion in cash, well above the $9.3 billion target for the end of 2021.[70] As shown in Figure 5, this met the highly ambitious resource requests that were set out in the investment opportunities. The scale and speed with which these resources were raised is unprecedented for a global health initiative.[71] Resources were raised in a number of ways, with around 80% from direct donor and other partner contributions, an additional 7% in direct contributions for vaccine delivery support; 11% from IFFIm; and the remainder from a transfer of unused funds from the pneumococcal vaccine AMC and ancillaries. Stakeholders noted three issues with resource mobilization:

- while there was a strong case for using IFFIm to frontload resources for large-scale procurement of vaccines, this was not strongly supported by existing IFFIm donors, and its potential was not fully utilized[72, 73]
- there was competition for donor resources, including between ACT-A and COVAX Pillar partners
- the US did not engage in or support the COVAX AMC financially early on but made very significant contributions of cash and vaccine doses in 2021 (see Annex C2.1).

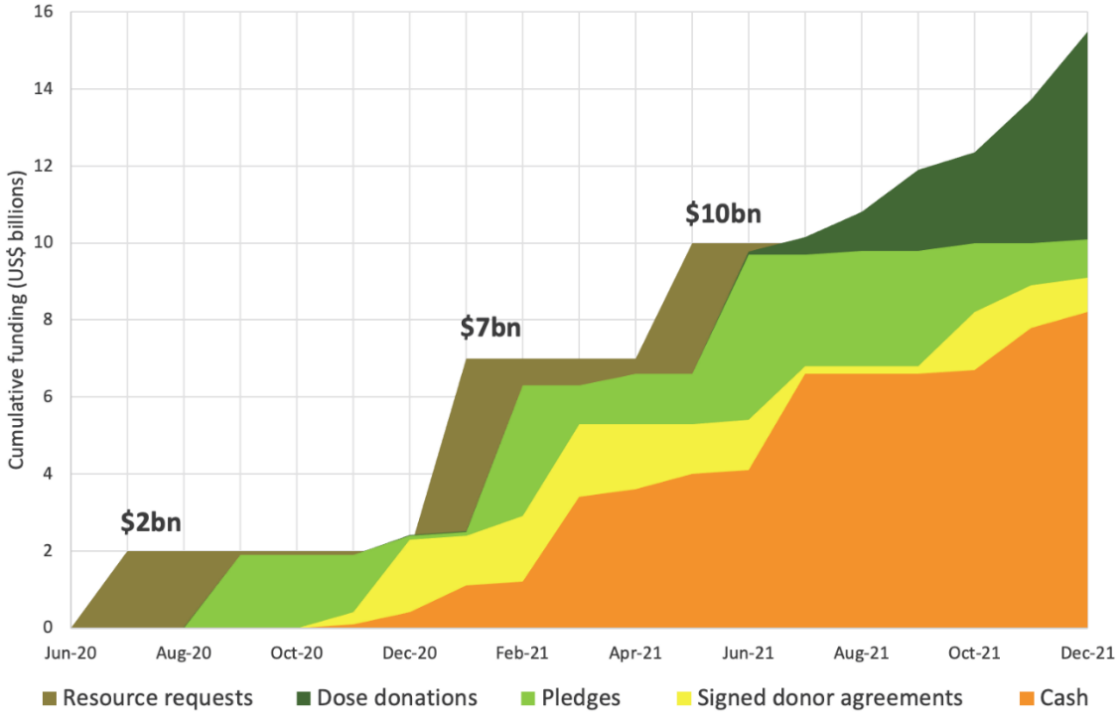
1 **Finding 26: Dose donations were handled primarily by the Resource Mobilization Team and became an important source of supply, but this created some tensions internally and with receiving countries.** Reflecting the frustration with the H1N1 response – which relied entirely on surplus dose donations from HICs – as well as long-standing Gavi policy and the level of optimism on HIC behavior which the COVAX Facility and AMC design assumed, dose donations were purposefully not included in the original design as in-kind resources. Despite dose donations only being accepted and received at scale from mid-2021 onwards, more than 900 million doses were donated and 470 million shipped and received via COVAX by the end of 2021.[74, 75, 76] The speed and scale of donations facilitated by the COVAX Facility and AMC was supported by the pre-existing relationships and contractual agreements with SFPs and AMC participants, although substantial additional negotiation and legal arrangements were necessary.

Using the prices paid by the COVAX Facility through APAs (see below), the estimated value of dose donations donated in 2021 is in excess of $5 billion. Including the estimated value of dose donations, the COVAX AMC raised $15.5 billion by the end of 2021 (see Figure 5 on next page).

While stakeholders have reflected that it made sense to utilize the Resource Mobilization Team's established working relationships with donor countries to enable dose donations via the COVAX Facility and AMC, this caused a degree of separation from the Deals Team (responsible for securing supply via APAs) which, reportedly, created some communications challenges with those responsible for allocation, procurement and other functions.

The manner in which dose donations were communicated to countries has also raised issues. Some stakeholders noted that in much of 2021 the Office of the COVAX Facility would 'not be the one to say no' to a donation, implying that most or all were offered to countries, even where the terms were unfavorable or not aligned to country preferences. Country-facing staff further reported feeling under pressure to ensure countries accepted donated doses even when there was a lack of demand. This was considered to have had negative consequences for the way in which Gavi and COVAX was perceived in some countries. The evidence on this point is contested by some stakeholders within the Office of the COVAX Facility, who further noted that practices improved over time.

Figure 5: COVAX AMC funding sought, pledged and received, as well as estimated value of dose donations[77]



1 **Finding 27: The shifting supply–demand context in late 2021 may have limited the potential of the cost-sharing arrangement introduced in mid-2021, which allowed AMC countries to purchase doses beyond the fully donor-subsidized doses they were already due to receive from COVAX.** This arrangement, alongside the provision of predictable financing from the World Bank and other multilateral development banks, was designed to enable the COVAX Facility to enter into new or expanded APAs with vaccine manufacturers on behalf of AMC participants. However, in practice it is unclear if the cost-sharing resources raised were used in this manner. A number of stakeholders nonetheless reflected that this was an important step for the COVAX Facility to take toward countries gradually assuming responsibility for vaccine financing, separate but aligned to the objectives of the Gavi Co-Financing Policy. By the end of 2021, 41 AMC participants had signed framework agreements to hear about cost-sharing supply offerings. Fifteen of these countries signed binding confirmation agreements for $800 million of domestic and multilateral development bank financing to purchase 140 million extra doses, representing about a 3% boost to their population coverage, of which 70% were shipped in 2021.[78,79] While significant, this was below the $1 billion requested in the April 2021 investment opportunity. Stakeholders attributed this to several reasons, including a reluctance of some countries to procure vaccines with loans and the continued availability of fully subsidized COVAX doses toward the end of 2021 as supply expanded relative to demand. As one stakeholder in Senegal put it, “Buying when you have the possibility of being given it, in a context where there were not enough vaccines [globally], was a bit difficult”. For those countries that did purchase doses via this mechanism, there is some evidence that it contributed to a situation of excess supply going into 2022, such as in Madagascar.

Market shaping

Market shaping and securing supply are overlapping activities and involve some of the same interventions. This section focuses on COVAX Facility (including the AMC) efforts to increase the total supply of COVID-19 vaccines, accelerate their availability and ensure their affordability, while the next section focuses on efforts to secure supply for the COVAX Facility and participating countries.

Vaccine development and the establishment of large-scale manufacturing capacity are expensive and risky. These risks are even greater in the early stages of a pandemic, when its epidemiology, and therefore the demand for a vaccine, is highly uncertain. In the face of these risks, private sector vaccine developers

may not choose to invest in bringing a vaccine to market or in scaling up manufacturing capacity, especially before the vaccine's safety and effectiveness are known. Governments and other stakeholders can use a range of tools to influence the decisions of manufacturers in order to achieve their goals, including adequate, timely and affordable supply.

1 **Finding 28: In the initial design, it was anticipated that COVAX would play a significant role in market shaping, increasing total supply through a combination of direct funding to product developers and manufacturers ('push') and the incentive effects of purchase commitments ('pull').** The Gavi Board recognized as early as March 2020 that Gavi, with its established reputation, credibility with vaccine manufacturers and its experience with market shaping and procurement financing, was well suited to play a role in COVID-19 vaccine market shaping.[80, 81] In April 2020, one of Gavi's key deliverables under the nascent COVAX arm of ACT-A was to facilitate manufacturing and availability of vaccines by efficiently managing supply and demand.[82]

Among the goals set for the COVAX Facility and AMC were:

- to invest early in a broad portfolio of vaccine candidates to mitigate the risk of vaccine failure and create additional manufacturing capacity for the benefit of LICs
- to use the market power of 190 countries in the COVAX Facility to achieve better terms than would be available to countries acting on their own.

1 **Finding 29: Within the broader market shaping effort, the division of labor between Gavi's role in administering the COVAX Facility and AMC (focused on 'pull mechanisms') and CEPI's (focused on 'push mechanisms') played to respective organizational strengths. However, the distinction between push and pull was not always completely clear.** Within the broader market shaping effort, the COVAX Facility and AMC, administered by Gavi, focused on pull mechanisms – purchase commitments intended to reduce risk to manufacturers by making demand more predictable – while CEPI (also a core COVAX partner) took responsibility for push funding or direct investments in product developers and manufacturers. Gavi's experience and comparative advantage was in procurement financing, whereas CEPI had been set up to support R&D and was already funding some COVID-19 vaccine developers, albeit at a relatively small scale compared to others.[83, 84] The distinction between push and pull is not always completely clear, however, as in the case of Gavi's deal with SII (see Box 6).

The COVAX Facility had four main tools available to shape the COVID-19 vaccine market:

1. **Pooling of resources for vaccine procurement:** The COVAX Facility intended to pool resources from several sources, including donor contributions to the AMC, prepayments and commitments from SFPs and, later, cost-sharing payments. This pool of funds would enable it to enter into large purchase agreements and give it far more market power than all but a few participating countries would have on their own.
2. **Pooling of procurement:** By aggregating demand and procuring on behalf of all participating countries, the COVAX Facility and its procurement partners could enter into consolidated agreements with manufacturers, reduce transaction costs, and allow manufacturers to benefit from economies of scale.
3. **Market-wide guarantees:** In the original design, the COVAX Facility and AMC anticipated establishing a market-wide purchase incentive, providing a commitment to manufacturers as a group that there would be demand for successful vaccine candidates. This was inspired, in part, by the success of the pneumococcal vaccine AMC.
4. **Bilateral APAs:** The market-wide guarantee would be complemented by bilateral purchase commitments – agreements negotiated with individual manufacturers committing the COVAX Facility to buy, and manufacturers to supply, a certain number of doses of a vaccine when it achieved regulatory approval and WHO EUL.

As an early Gavi document stated, the COVAX Facility was expected to 'pool demand and resources toward securing access to future supply of COVID-19 vaccines. All countries are invited to participate in this global Facility, which will utilize a mix of manufacturer-specific volume guarantees and market-wide demand guarantees'.[85] The Board also expected that the COVAX Facility and AMC would secure lower prices.[86]

Another potentially important market shaping tool is *tech transfer*. Tech transfer, which can take a variety of forms and is generally linked to IP licensing, is a way to increase the total supply of vaccines by allowing additional manufacturers to produce vaccines developed by other firms. Depending on the particular intervention, this could fall under the mandate of either CEPI or the COVAX Facility.

1 **Finding 30: Ultimately a market-wide guarantee, backed by secure funding and formal legal and operational machinery, was not put in place.** While the COVAX AMC may originally have been intended to be such a mechanism (as suggested by the use of the term 'Advance Market Commitment' and as proposed by some),[87] it evolved instead into a fundraising mechanism for non-SFP countries.[88] A true market-wide guarantee or AMC would have required a large pot of secure funding and a detailed set of rules and conditions backed by legal agreements in order to give it credibility to manufacturers. The pneumococcal vaccine AMC, for its part, was backed by a dedicated $1.5 billion fund and legal machinery that took years to put in place; the decision not to try to replicate this model in the context of the pandemic was thus a reasonable one. Although no such formal AMC or guarantee was put in place, it is certainly possible that the creation of COVAX and the AMC, and the early commitment to raise large amounts of resources for vaccine procurement did provide a signal to manufacturers and may have influenced the decisions of some. This signal would probably have been stronger had the COVAX AMC had access to a large pot of contingent financing from the outset.

Although the COVAX AMC was not a market-wide guarantee in the same sense as the pneumococcal vaccine initiative, it did involve legal agreements between donors and Gavi. Moreover, the use of the term 'AMC' was useful, in that it lent a degree of credibility to the mechanism and enabled the donors to the pneumococcal vaccine AMC to repurpose $187.5 million in unused funds from that initiative to the COVAX AMC in June 2020.[89]

1 **Finding 31: The COVAX Facility did not engage in or seek to incentivize tech transfer, with the exception of an early deal with SII (see Box 6).** A substantial role for COVAX in facilitating or requiring or advocating for tech transfer was not anticipated in the original design – tech transfer is mentioned only once, and in passing, in an important design document for the initiative as a whole – and any engagement in this area would fall under CEPI in connection with its push funding.[90] There was an assumption that market forces would be enough to encourage manufacturers to quickly develop manufacturing capacity that would make supply available to LMICs and LICs in a timely way.

Consistent with the original design, Gavi did not directly invest in manufacturing scale-up and did not include provisions on tech transfer or IP sharing in its purchase agreements with manufacturers. The one important exception to this is the funding provided by Gavi, with the assistance of the Bill & Melinda Gates Foundation (BMGF), to SII to support expansion of its vaccine manufacturing capacity (see Box 6). CEPI, for its part, has included support for manufacturing scale-up in some of its R&D funding partnerships, although the scope of its funding in this area has been quite limited.

The COVAX Facility's lack of emphasis on IP sharing and tech transfer has been a major focus of criticism from civil society, notably for making too many concessions to industry and of neglecting a critical route to increased production.[91] In particular, some civil society critics insisted that sharing of IP and tech transfer should be a condition of receiving any COVAX funds, including through purchase agreements.[92] It is doubtful, however, that the COVAX Facility and AMC had the leverage to impose IP or tech transfer conditions on manufacturers, especially early in the pandemic. Some stakeholders have also noted that Gavi and the Office of the COVAX Facility staff lacked the necessary expertise to broker or assist with tech transfer.

It is important to recognize that a great deal of voluntary tech transfer for COVID-19 vaccine production occurred as vaccine developers engaged with other manufacturers to expand supply of, and meet demand for, their products – one report from early 2021 counted 150 such partnerships.[93] Brazil's success in establishing local production of COVID-19 vaccines through tech transfer from AstraZeneca and Sinovac, documented in a case study for this evaluation (see Box 5), demonstrates the potential of this approach. It should be noted, however, that COVAX was not involved in these arrangements, nor did the arrangements contribute to additional supply to the COVAX Facility and AMC. This does not mean that additional measures to facilitate, incentivize or require tech transfer on the part of COVAX could not have accelerated expansion of COVID-19 vaccine supply. This will be an important area to explore in preparing for future pandemics. Further, a lack of direct involvement in tech transfer does not necessarily imply that Gavi did not recognize its importance, at least in retrospect.[94]

Box 5: Brazil's experience with tech transfer

Diversifying its vaccine supply through tech transfer to national manufacturers was important for Brazil to reach its current vaccination coverage rate. In June 2020 the government of Brazil signed two tech transfer agreements: 1) with the Chinese company Sinovac to allow Butantan Institute of the state of São Paulo to produce the CoronaVac vaccine, and 2) with the University of Oxford and AstraZeneca to allow the Immunological Technology Institute of Oswaldo Cruz Foundation (Bio-Manguinhos/Fiocruz) to produce the AstraZeneca vaccine. Brazil achieved its vaccination targets by the end of December 2021, securing 55% of vaccine doses through these tech transfer arrangements, 42% through bilateral purchase agreements and 3% through COVAX.

Brazil's tech transfer agreements eventually ensured 100% national production of the vaccine. Tech transfer from AstraZeneca[95] was in two stages: first enabling final processing of the vaccine ('fill and finish') by BioManguinhos and, subsequently, local manufacture of the Active Pharmaceutical Ingredient (API), thereby enabling 100% national production of the vaccine. To make this possible, the government of Brazil invested around $350 million.[96] Tech transfer in this case also helped Brazilian manufacturers to modernize their laboratories and production lines, resulting in increased production capacity and improved quality control standards, and has improved their capacity to produce other vaccines using the same technology.

Several lessons can be drawn from the Brazilian tech transfer experience, including:

- Tech transfer requires a certain level of baseline capability and infrastructure
- Tech transfer is expensive and, in the case of Brazil, required substantial investment from the government. However, these investments have improved national vaccine manufacturing capacity and resulted in the autonomy of Brazil in COVID-19 vaccine production.
- Tech transfer can be slow, an important challenge in a fast-moving epidemic.

Countries that are producing vaccines can benefit from support to secure the relevant certifications that will allow them to export what they produce.

1 **Finding 32: The COVAX Facility's market-shaping efforts relied on bilateral APAs with manufacturers, along with pooling of resources and procurement.** Funds raised through the COVAX AMC and from SFPs were used to back APAs with manufacturers and, when vaccines came to market, to purchase doses. Procurement was pooled, coordinated and implemented by UNICEF (and PAHO for the Latin American region) on the basis of the deals negotiated by Gavi for the COVAX Facility and AMC.

2 **Finding 33: The COVAX Facility and AMC ultimately lacked the market power to meet its market-shaping objectives in the early phase of the COVID-19 pandemic.** HICs, including the US, the UK and the EU, invested heavily and early in COVID-19 vaccine R&D and manufacturing.[97] Many of these HIC investments, notably those of the US Operation Warp Speed, were made while COVAX was still developing a strategy in early to mid-2020.[98] Linked to these investments or in addition to them, HICs and many MICs went on to make large bilateral purchase commitments outside of COVAX. These separate deals undermined the COVAX Facility and AMC's market power and reduced the impact of the

APAs it signed with manufacturers in late 2020 and in 2021. The influence of the COVAX Facility and AMC's APAs over manufacturers' decisions may also have been weakened by its pursuit of low prices, as the lower prices negotiated may have led some manufacturers to accord the COVAX Facility and AMC lower priority in allocating scarce supply.

Box 6: Case study – The COVAX AMC and Serum Institute of India

An important exception to the general conclusion that the COVAX Facility and AMC probably had only a modest effect on total vaccine supply is the case of SII. In 2020, BMGF and Gavi (the COVAX Facility and AMC was still in the design phase at this time) decided to make a specific investment to increase manufacturing capacity dedicated to LICs and LMICs. SII, the world's largest vaccine manufacturer and a long-time Gavi supplier, was selected as the partner for Gavi's and BMGF's investment. In June 2020, SII and AstraZeneca announced a licensing and tech transfer agreement that would allow SII to produce its own branded version of AstraZeneca's vaccine, COVISHIELD. The role, if any, played by either Gavi or BMGF in brokering this deal is not clear, but the partnership was a natural one for both participants as well as for Gavi and BMGF. SII had unmatched experience in high-volume, low-cost manufacturing as well as a business model focused on supplying LICs and LMICs through Gavi and UNICEF. AstraZeneca was looking for manufacturing partners and was committed to supplying LICs and LMICs by its agreement with Oxford University, the original IP holder. The process of tech transfer apparently went smoothly. SII also entered into an agreement with Novavax to produce a version of its vaccine, to be called COVOVAX.

The Gavi investment in SII took the form of prepayments on APAs. An initial deal for 100 million doses (of whichever of the two vaccines came to market first) was signed in July 2020; a second 100 million dose deal was signed in September of that year. The price of the vaccines to COVAX was set at $3/dose, and half of the total cost – $150 million in each deal or $300 million in total, was paid in advance. It was understood that this money would be used to build additional manufacturing capacity that could accommodate multiple types of vaccines and which would be dedicated to COVAX AMC participants.[99] Thus, this arrangement can be considered a form of push funding tied to a purchase commitment. As Gavi did not have the necessary resources on hand at that time, the payment was made possible by at-risk financing from BMGF to Gavi. This partnership was touted as 'manufacturing for the global south by the global south'. It is not clear if some of this support was also used to support the tech transfer from AstraZeneca or Novavax.

Eventually more substantial procurements of the two vaccines from SII were planned, amounting to over a billion doses (with over 110 million due before May 2021).[100] By early April 2021, however, India faced a deadly second wave of COVID-19, and the Indian government imposed a ban on vaccine exports.[101] Ultimately most of the doses produced by SII in 2021 ended up being distributed within India.[102] Although the COVAX AMC did not receive the doses it expected from SII in 2021 – with serious consequences for its efforts to supply participants in Africa and elsewhere – the SII vaccines contributed greatly to immunization coverage within India, with over 1.5 billion doses administered.

The decision to halt exports notwithstanding, the SII–COVAX deals demonstrate the power of tech transfer to increase vaccine supply when a willing technology donor and a ready recipient are at hand. Although more of these arrangements have been made during the current outbreak than ever before, greater use of tech transfer faces important constraints. On one hand, only some originating firms are willing to license their IP and transfer their technologies. Unlike in the case of small-molecule drugs, a waiver of IP related to pandemic vaccines, even if it could be achieved, would in general not be sufficient to allow additional manufacturers to make vaccines developed by others without accompanying tech transfer. On the other hand, the number of manufacturers capable of producing a range of new vaccines to international standards remains limited, and in fact almost all such firms were engaged in COVID-19 vaccine manufacturing. To relieve this second constraint will require substantial investments over several years to build the capacity of additional manufacturers, especially in the global south.[103]

2 **Finding 34: With the exception of the deals with SII, the influence of the COVAX Facility and AMC's APAs on manufacturing capacity was probably modest in the early stages of the pandemic.** In interviews, manufacturers did not directly credit the COVAX Facility and the AMC or its APAs with influencing their decisions on manufacturing capacity, and other stakeholders agreed that this influence was modest at best. The APAs were probably too late to have much influence, at least on

the firms that appeared likely to reach market first and had already signed large deals with HICs (see findings 34–52). By the time the COVAX Facility and AMC was in a position to sign APAs in late 2020–early 2021, manufacturers were already gearing up to supply HICs and were highly motivated to find and develop additional manufacturing capacity. In this sense, the efforts of the COVAX Facility and AMC probably had little additional impact at least on these manufacturers, because they already had greater demand for their products than they could satisfy, at least in the short term.

The deal with SII clearly contributed to a substantial increase in global vaccine supply, although India's decision to halt exports meant that little of this supply went to COVAX AMC participants until late 2021. The COVAX Facility's APAs may have helped some later-to-market manufacturers to de-risk their investments in manufacturing. Two examples are Clover and Novavax. Both manufacturers had already received push funding for R&D from CEPI and subsequently signed APAs with the COVAX Facility for large volumes of vaccine, subject to the products achieving WHO EUL. The deal with Clover made the COVAX Facility and AMC one of this firm's largest potential customers, and it is likely therefore that the APA was helpful in justifying its investments in manufacturing capacity.

Aside from any effects on manufacturing capacity, the COVAX Facility and AMC's pooling of demand through the APAs and subsequent pooling of procurement did bring an important market shaping benefit by reducing transaction costs for both manufacturers and participating countries.[104]

1 **Finding 35: The COVAX Facility and AMC was successful in achieving reasonable pricing for LICs and LMICs.** The COVAX Facility was able to secure the lowest prices in the marketplace – see Annex C2.2. The weighted average price of all vaccines procured by the COVAX Facility (AMC and SFP) during 2021 was $5.79, with prices for individual products ranging from $3 for vaccines from SII to up to an estimated $6.75 for the Pfizer product.[105] The weighted average price increased as the total share of APA product shifted toward the Pfizer vaccine in 2021.[106] Some vaccine manufacturers charged a flat rate to all customers, which they referred to as a not-for-profit price, while others adopted a tiered pricing strategy, offering AMC participants a lower price than for other customers.[107]

For those products with tiered pricing, the prices negotiated for the COVAX AMC were considerably lower than those achieved through direct procurement by HICs and UMICs, but broadly equivalent to prices paid by LICs and AVAT. Using the prices paid for Pfizer doses as an example, the COVAX AMC is estimated to have paid $6.75 per dose, as compared to an average price of $20.85 in HICs, $12.33 in UMICs, $7 in LMICs and $6.75 through AVAT.[108]

It is difficult to say, however, to what extent the relatively low prices made available to AMC countries should be attributed to Gavi/the COVAX Facility and AMC and its market-shaping activities, as offering a lower price to LMICs and LICs and international organizations procuring on their behalf is an established norm.[109]

Securing supply

This section focuses on the COVAX Facility's efforts to secure supply for its participating countries. It should be read in conjunction with the preceding section on market shaping.

1 **Finding 36: The COVAX Facility and AMC design relied primarily on negotiation of APAs with manufacturers to secure supply.** The initial design, which relied on the COVAX Facility and AMC's market power to secure supply, did not consider donations as a potential source of vaccine doses and put no mechanism in place for handling donations should they become available.

A feature of the design, significant in light of current interest in regional manufacture, was its highly centralized nature: deals would be made on behalf of all participating countries by Gavi and supply secured from manufacturers offering the best products on the best terms, with no provisions for regional procurement or supply.

It is also worth noting that negotiation of deals for the COVAX Facility and AMC by Gavi constituted a departure from Gavi's normal practice, in which UNICEF conducts tenders, allocates demand across

successful bidders, and works with manufacturers on behalf of Gavi. Although Gavi and UNICEF had previously used APAs in some circumstances, they are not part of UNICEF's normal procurement process and neither organization had experience with deal-making on the scale and with the urgency that the COVAX Facility and AMC required.

A second lever employed by COVAX to secure supply for AMC countries was access provisions attached to funding from CEPI to vaccine developers. CEPI was not a major funder of the vaccines that came to market first, but it did provide substantial support to Novavax and Clover, and conditions associated with support may have influenced the terms on which the COVAX Facility and AMC was able to obtain access to these vaccines.

This design was initially implemented as planned. As COVAX came together in summer 2020, Gavi built a deal team and pursued discussions with manufacturers. By December 2020, according to a Board paper, discussions were underway with several manufacturers to provide 'up to 2 billion doses' in 2021. By the end of 2020, however, only two binding APAs had been signed, with SII in August (and expanded in September) for 200 million doses and with AstraZeneca in December for 170 million doses.

1 **Finding 37: The approach to securing supply produced some early successes, but deliveries from the COVAX Facility and AMC quickly and increasingly lagged behind targets and expectations.** APAs with AstraZeneca, SII and Pfizer (signed in January 2021) allowed the COVAX Facility and AMC to deliver some doses to India in January 2021 and to other participating countries from February 2021. As HICs had begun to vaccinate their populations only in December 2020, this constituted a historically short delay in access for LICs and LMICs, which had typically waited years for new vaccines. However, a ban on vaccine exports imposed by India in April, which halted supplies from SII, along with slower than expected supplies from other manufacturers, greatly affected supply. By mid-2021, it was increasingly clear that the COVAX Facility would fall far short of its goal of distributing 2 billion doses by the end of the year. Although supply picked up in the last few months of the year, notably due to the US-Pfizer facilitated purchase/donation, other bilateral donations, and additional APAs, total COVAX Facility deliveries in 2021 were somewhat less than 1 billion doses – far short of the 2 billion dose target. While the target of delivering 950 million doses to AMC participants in particular in 2021 was only just missed, most of these doses were delivered in late 2021. The shortfall had dire consequences for recipient country efforts to immunize their populations. In addition, frustration with slow delivery from the COVAX Facility and AMC led many countries to seek other sources of vaccine, weakening the COVAX Facility and AMC's market power.[110]

2 **Finding 38: The COVAX Facility and AMC's supply shortfall in 2021 has been attributed to several causes, including India's decision to halt exports, regulatory and manufacturing delays, limited cash in hand in 2020, lower priority accorded to the COVAX Facility and AMC by some manufacturers, and lack of pre-established arrangements for handling dose donations.** An underlying cause was the difficulty of competing for limited doses with HICs, whose aggressive and early deal-making tied up much of the available supply. Each of these factors is analyzed below.

2 **Finding 39: Although in the first months the COVAX Facility and AMC had limited cash in hand to commit to deals with manufacturers, it is not clear that this constraint substantially delayed the signing of APAs or affected supply.** As discussed above, APAs are binding commitments to purchase vaccine doses, and Gavi's rules required that any such commitments be backed by available resources. As fundraising for the COVAX AMC began only in July 2020, this meant that until late 2020 the COVAX Facility had limited resources to back APAs, most of which were sourced from SFPs. In part for this reason, and due to Gavi's unwillingness to use its core resources to bridge the period between donor pledges being converted into cash, non-binding agreements, described as memoranda of understanding (MoUs) or letters of intent, were signed with some firms. Only some of these softer agreements were later translated into binding APAs.

While some interviewees—and Gavi itself—have argued that a lack of available resources impeded deal-making, other stakeholders suggested that the COVAX Facility's own risk appetite, as well as

manufacturers' willingness to engage and the time required to put basic processes in place and finalize commercial terms, were more important causes of delay. Some senior internal interviewees went as far as to state that at no time was a finalized deal held up by a lack of cash on hand, although others insist that availability of resources was a binding constraint. Furthermore, large agreements with several key manufacturers with early-to-market vaccines (Pfizer, Moderna and Johnson & Johnson (J&J)) were not reached until months after substantial resources were available, again suggesting that a shortage of cash was not the primary cause of the delay in these cases.

Even if financial constraints had some effect on the timing or volume of APAs signed with manufacturers, the impact of any such delays on supply available to the COVAX Facility and AMC in 2021 is far from clear, as delivery of agreed doses was often quite delayed (see below).

1 **Finding 40: The halt to vaccine exports imposed by India in April 2021 was a major blow to COVAX's supply during a critical period.** Although agreements with other manufacturers had been put in place by time of the ban, the COVAX Facility had bet heavily on SII – agreements had been signed with SII for 240 million doses of its version of the AstraZeneca vaccine as well as for 300 million doses of Novavax's vaccine, which SII had also arranged to produce but which had not yet received regulatory approval, as well as options for 100's of millions of additional doses. In the first three COVAX allocation rounds, covering the first five months of 2021, 64% of doses secured by the COVAX Facility were intended to come from SII, with 30% from AstraZeneca and 6% from Pfizer, the other firms with which the COVAX Facility had APAs in place in Q1 2021.[111]

Although, in hindsight, the bet on SII turned out badly for the COVAX Facility and AMC, it was a reasonable decision at the time. SII had been Gavi's most important supplier for years, it had vast experience as a high-quality, high-volume manufacturer, and it was offering two vaccines well suited for delivery in low-resource environments at low prices. Although the risk of an export ban was highlighted by others at the time, and UNICEF had experienced similar issues in sourcing PPE from India, the COVAX Facility and AMC may have had little choice, as it is not clear that there were alternative sources that were willing and able to supply comparable volumes in the first half of 2021.[112]

After the imposition of the export ban, the COVAX Facility and AMC had to find other sources of vaccine. In May 2021, it signed APAs with Moderna, Novavax and J&J, followed in June and July by deals with three Chinese firms: Clover BioPharmaceuticals, Sinovac and Sinopharm (see Annex C2.3). These agreements did not completely fill the gap, however. While some of the suppliers were able to make doses available quickly, some had not yet received EUL from WHO; others (Moderna) only agreed to supply small volumes in 2021; and others were slow to deliver agreed doses.

2 **Finding 41: Some manufacturers may have accorded a lower priority to the COVAX Facility and AMC than to other customers, particularly HICs.** Decisive evidence of deprioritization is hard to come by – no manufacturer has acknowledged short-changing the COVAX Facility and AMC – but multiple interviewees, both within and outside the COVAX Facility and AMC, stated that this was a factor. Some firms were said to have delayed signing APAs with the COVAX Facility, while others were slow to deliver committed doses. Many factors contributed to slow deliveries, including R&D and manufacturing delays, the need to put liability and indemnification agreements in place, country readiness to accept vaccine doses, inexperience on the part of many suppliers in working with Gavi and the UN system, and Gavi's and the Office of the COVAX Facility's own relative inexperience in deal-making on this scale and with this urgency. The COVAX Facility's late start in signing APAs also contributed: one analysis concluded that timing of deal signing was the most important determinant of timing of delivery to different customers, although the analysis did not include COVAX.[113] Many interviewees, however, perceived commercial considerations, including the lower prices paid for most vaccines by the COVAX Facility and AMC and many suppliers' broader focus on HIC markets as well as direct pressure from HICs themselves, to have played an important role. A range of stakeholders expressed the view that many manufacturers had not operated a queue on a 'first come, first served' basis and that the COVAX Facility and AMC was deprioritized relative to other purchasers throughout 2021. Whether or not some firms treated the COVAX Facility and AMC unfairly in allocating limited supply, to ensure equitable access there is a clear

need for greater transparency on how queues for vaccine supplies from manufacturers are managed in a pandemic.

The APA signed with Pfizer in January 2021 is an important case. Although, once the US government stepped in (see below), Pfizer became the most important source of vaccines for the COVAX Facility and AMC, its initial deal was for only 40 million doses, struck mostly with SFP funds which were available first. It is not completely clear why the agreed volume in this deal was so low. Although some sources suggested that the limit came from the COVAX Facility and AMC's side and stemmed from concerns about delivery challenges for this vaccine, which required ultra-cold chain (UCC), others stated that Pfizer only offered a very limited quantity of doses in 2021, the period of greatest competition for limited supply and the critical period for scaling up vaccination. Key informants did, however, note that this and other initial deals did provide a proof of concept for the COVAX Facility's ability to sign APAs which helped with later stakeholder engagement, resource mobilization and deal-making.

An emerging sense that some important manufacturers deprioritized supplying the COVAX Facility and AMC, while not definitive, has critical implications for the COVAX Facility and AMC's design and for the design of future initiatives, as it suggests that a COVAX Facility and AMC-like mechanism may not have sufficient market power to secure supply in the face of determined competition from HICs, even with greater resources available earlier in a pandemic.

2 **Finding 42: Most of the COVAX Facility and AMC APAs did not include enforceable clauses on delivery timing.** Many or most contracts with suppliers included indicative delivery schedules, and some included penalties for egregious failure to supply, but in general the COVAX Facility and AMC was left with little practical recourse when delivery was delayed. In theory, stricter contractual provisions might have allowed the COVAX Facility and AMC to better defend its place in the delivery queue (as, for example, the EU sought to do in taking legal action against AstraZeneca).[114] It is not clear, however, that the COVAX Facility and AMC had the leverage to impose or enforce such provisions. Especially during the chaotic and unpredictable period of scale-up, firms would have been understandably reluctant to agree to binding timing commitments. Evidence points to a critical question for future exploration: whether suppliers favored other customers over the COVAX Facility and AMC when they were not able to meet all of their commitments in a timely fashion.

In the absence of enforceable legal commitments, it is possible that Gavi and the COVAX Facility might have used public communication about delivery delays as a way to pressure manufacturers (see Section 2.2.1 for more detail on external communications).

2 **Finding 43: The COVAX Facility and AMC ultimately lacked the market power to meet its supply objectives in the face of aggressive competition from HICs.** The COVAX Facility and AMC's designers clearly understood, at least by the summer of 2020, that HICs would act on their own to secure vaccines for their populations. But they do not seem to have anticipated the scale and speed of this activity or that it would result in much of the available supply being tied up, at least during the first half of 2021. By August 2020, when the COVAX Facility and AMC had only the APA with SII in place, the US government's Operation Warp Speed had already signed funding deals with at least six vaccine developers that entitled it to 800 million doses if and when these vaccines came to market, and by March 2021 it had tied up at least 1.2 billion doses.[115] The UK, for its part, ordered more than five vaccine doses per person. Although the COVAX Facility and AMC had raised sufficient resources by early 2021 to purchase much of the vaccine it needed at the prices agreed with suppliers, it had limited leverage over suppliers in an environment of shortage. Even with greater resources in hand from early in the pandemic, it is doubtful that the COVAX Facility and AMC could have won an outright bidding war with HICs.

To 'vaccine hoarding' was added another form of vaccine nationalism: export bans. In addition to India's halt to vaccine exports, the US government is also widely perceived to have impeded global vaccine supply by preventing the export of critical inputs to vaccine production in early 2021.[116]

1 **Finding 44: In response to the supply crisis stemming from the decision in India to halt exports, the COVAX Facility and AMC gave greater priority to donations, which became a critical source of supply for much of 2021.** This was a major departure from the original design, as well as from Gavi's traditional policy, which had frowned on vaccine donations. In the first half of 2021, however, the COVAX Facility and AMC's supply shortfall coincided with growing supply surpluses in many HICs, which had hedged their bets by signing deals with multiple manufacturers and which now found themselves with many more doses than their populations needed or wanted. As it became clear that the R&D success rate would be high and excess supply loomed, HICs approached Gavi in late 2020 to discuss donation or resale of unneeded doses to the COVAX Facility and AMC. The Office of the COVAX Facility released a set of principles to govern donations in December 2020 but did little to prepare for handling them. In the second quarter, however, motivated by the ban and prompted by donation commitments by France and other countries, and later by the G7, the Office of the COVAX Facility began with greater urgency to develop the mechanisms for accepting and allocating donated vaccines.

2 **Finding 45: Lack of pre-established arrangements for donations slowed supply from this source.** The procedures were complicated, involving tripartite agreements between Gavi, manufacturers and donating countries that addressed liability and other issues, as well as consideration of the preferences, regulatory requirements and health system capacities of recipient countries. Some donated doses had little remaining shelf life, leading to refusals by countries and in some cases to vaccine expiry. Although pre-existing APAs with manufacturers formed a crucial foundation, many of these procedures had to be developed from scratch. Responsibility for the resulting delays falls as much on the donating countries as well as on the COVAX Facility, but these could have been minimized if the COVAX Facility and AMC design had anticipated the possibility of donations and included mechanisms for handling them.

In June 2021, donations of surplus vaccine originally ordered for HICs' own populations were dramatically supplemented by 500 million doses of Pfizer's vaccine, to be produced specifically for the COVAX Facility and AMC through a deal with the US government. This already very large commitment was then doubled to 1 billion doses in September. The deal had a complicated structure: some doses were bought by the US government and donated, while others were paid for by the COVAX Facility and AMC within the framework of Pfizer's agreement with the US government. The latter component of the deal is sometimes referred to as a facilitated purchase.[117]

The US-Pfizer donation/facilitated procurement, which constituted the single largest source of vaccine available to the COVAX Facility and AMC, had several consequences. First, it made a substantial contribution to filling the gap left by the decision in India to halt exports. Second, it made the COVAX Facility and AMC's supply much more predictable than it had been when the initiative relied on deliveries from AstraZeneca and on piecemeal, and sometimes last-minute, donations of excess vaccine. Third, it forced the COVAX Facility to focus on the in-country investments necessary to allow countries with weaker health systems to successfully make use of this vaccine (e.g., by installing UCC capacity), while scrambling to resolve shortages of the special syringes the vaccine required and negotiating with the US on allocation.

There is no doubt that dose donation was, on balance, a great boon to the COVAX Facility and AMC, given the difficulty it had encountered in securing supply through its own market action – donations accounted for about half of the COVAX Facility and AMC's delivered supply in 2021. Moreover, the COVAX Facility and AMC played a crucial role in facilitating donation and ultimately serving as the channel for 70% of the nearly 800 million vaccine doses donated in 2021.[118]

Lesson B

The COVAX's experience shows the importance of a multi-pronged, balanced approach to ensuring equitable vaccine supply in the next pandemic. Increasing global vaccine supply through tech transfer; securing access for LICs and LMICs through conditions attached to push funding; securing funding to enable early signing of APAs; examining trade-offs between price and timely access and putting in place arrangements for efficient management of donations are all important.

1 **Finding 46: By the end of 2021, the COVAX Facility had built a broad portfolio of vaccines and could project abundant supply for 2022.** By the start of 2022, the COVAX Facility had secured access to up to 4 billion doses of 10 different vaccines, of which almost 3 billion doses were available for delivery by mid-2022.[119] This projection was conditional on regulatory approval for some vaccines, but there is no doubt that by Q1 2022, the COVAX Facility had sufficient supply of first-generation COVID-19 vaccines.

Although the COVAX Facility's strategy of seeking to sign APAs with many firms to build a diverse portfolio did not enable it to overcome the obstacles to equitable access in the critical period of early 2021, it was a sensible approach. Supply from other sources partially compensated for the interruption in supply from SII, and a broad portfolio made the COVAX Facility's supply more resilient to R&D failure, manufacturing problems (exemplified by Novavax) and delivery delays. For more analysis of the portfolio approach, see Annex C2.3.2.

1 **Finding 47: Going into 2022, the COVAX Facility faced significant oversupply.** The COVAX Facility's successes in securing supply in the second half of 2021, including through donations, coupled to dramatically shrinking demand from participating countries, has left it with more vaccine than it needs. This excess supply amounts to a substantial liability, potentially reaching several billion dollars. It is understood that the COVAX Facility is negotiating with several suppliers on how to reduce some of these commitments, but the nature of these negotiations is considered confidential at this time. On the whole, overbuying can be seen as an acceptable risk, given the need to secure supply in the face of unpredictable demand. However, it can be argued that Gavi and the COVAX Facility, in signing APAs with so many suppliers in mid-2021 and exercising options into the fall, bears some responsibility for the current problem of oversupply.

Allocation

1 **Finding 48: Relying on WHO and SAGE for a normative allocation framework was appropriate, given COVAX partners' mandates and the sensitivity around global allocation decisions.**[120] From the outset it was recognized that the allocation of scarce resources was going to be political and that normative agreement would be crucial.[121] WHO as a normative agency was the appropriate partner to set fair and equitable allocation principles, as it did through the Fair Allocation Framework. This proposed an equal allocation of vaccines, with each country receiving enough to protect the most vulnerable 20% of each country's population. Specifically, it was envisaged that all countries must first be offered the doses needed to vaccinate 20% of their population before any countries can increase their coverage beyond this (there was, however, some lack of clarity with the design where SFPs with Optional Purchase Agreements could order vaccines for up to 50% of their populations – see Finding 8 – although this was clarified in September 2021 to expressly limit allocation of vaccines to HICs, partly in response to negative publicity).[122] After agreement on the normative principles of allocation, further operational design involved development of an Allocation Mechanism, including an allocation algorithm to be applied by the Joint (Gavi–WHO) Allocation Taskforce to allocate vaccines to COVAX Facility and AMC participant countries in intermittent rounds as vaccines became available.

1 **Finding 49: Dose allocation in 2021 and for Phase 1 was not conducted as anticipated, with no two rounds conducted in the same way and with several different processes being involved. The approach evolved as a pragmatic response to a challenging operating environment.** While stakeholders reflected that defining robust processes for allocation up front gave the process legitimacy and credibility, these processes were time-consuming and not agile enough to respond to the real-world issues encountered. The biggest challenge was the unpredictability of vaccine supplies from both APAs and dose donations, which often required allocation processes to be conducted at short notice for small volumes of one or two vaccine products.[123] This did not always allow time for the algorithm to be run and the results reviewed by the Independent Allocation of Vaccines Group (IAVG), nor did it give countries the desired three months from allocation to delivery in order to plan for vaccine roll-out.[124] It also meant that allocations were conducted without taking account of product preferences as much as would have been desirable, or the need to cover second dose requirements. These factors resulted in 14 allocation rounds, all implemented differently, plus 13 separate 'administrative adjustments' and numerous processes for dose donations being conducted.[125, 126]

As set out in Annex C2.4, a range of other factors also affected the operationalization of the allocation mechanism. These included contextual factors such as the geographical earmarking of doses by manufacturers and donating countries, limited country readiness to accept doses, and the need to maintain stable supplies of vaccines so as not to interrupt deployment programs in countries. Allocation was also affected by factors related to how the mechanism itself was operationalized, such as:

- a lack of clear ways of working between the various bodies, governance structures and working groups engaged in the allocation process, and different perspectives between agencies as members of some of these groups on how to operationalize the mechanism
- the principle of minimizing the number of vaccine products allocated to countries, which became unworkable through 2021 given the unpredictable availability of some products and the volume of dose donations
- limited understanding of absorptive capacity and country preferences, which – in combination with dose donations (and some APA-supplied doses) being provided with a short shelf life – led to refusals and returns[127]
- a lack of clarity on how to deal with dose donations, particularly whether these superseded other sources of supply and whether and how the allocation should be adjusted when geographical earmarking threatened to skew the overall allocation away from its equity objectives
- small states not fitting the model and requiring greater allocations per capita to meet manufacturers' minimum batch sizes
- difficulties in explaining the justification for Joint Action Taskforce (JAT) actions to the IAVG, given the complexity of considerations and limited time available for the IAVG to meet and engage in the process.

These issues were largely overcome by staff at Gavi within the Office of the COVAX Facility and WHO, acting as the JAT, who were committed to implementing allocation processes as quickly as possible.

Lesson E

In uncertain and complex circumstances, it is most helpful for the design to set out broad operating principles rather than fixed rules for operationalization. Clarity on decision-making processes within those broad principles is also important for transparency and efficiency.

1 **Finding 50: Most stakeholders outside of the JAT consider the allocation mechanism, and the algorithm in particular, to have been overly complex and difficult to understand.** The allocation mechanism has been referred to as a 'black box', the results of which cannot be fully explained post hoc. While members of the JAT and other staff engaged in the allocation process acknowledge this

criticism and consider that the process may have been too 'theoretical' at the outset, most feel that the algorithm works well to solve a complex optimization problem. Nonetheless, the inability to explain to countries how their allocations were arrived at is reported to have had implications for how the allocation process was seen by external stakeholders, including participating countries (see Box 7 for further insights on country communications regarding allocations).

1 **Finding 51: Until Round 7, conducted in September 2021, the allocation mechanism was operationalized broadly in line with the WHO Allocation Framework and the principle of proportional allocation. This did not factor in other, non-COVAX, sources of vaccine supply, and as a result did not optimize global equality (equal access to vaccines) or equity (prioritization of those most in need) as much as it could have.** Almost 500 million[128] doses were allocated in rounds 1–6, conducted in early to mid-2021 for supply up to September 2021, under the principle of proportional allocation, albeit with some countries excluded for not meeting readiness requirements.[129, 130, 131] This in effect meant that all countries included in these allocation rounds, usually a broad mix of SFP and AMC participants across income categories, received equal priority in doses allocated. Since most people live in LMICs or LICs, the result was pro-poor. Many countries, however, notably higher-income SFPs, had already secured large supplies of vaccine through bilateral deals and achieved high vaccination coverage by this time. For instance, the UK, which was allocated 270,000 doses in Round 3 (for supply between April and June 2021) through an Optional Purchase Agreement, had already achieved first-dose coverage of approximately 20% in February 2021, and reached 60% by June.[132] In contrast, in many LICs and AMC countries, first-dose vaccination coverage remained below 10% through the end of 2021.[133]

Despite clear evidence of global inequity in access to vaccines, the availability of vaccine doses from other (i.e., non-COVAX) sources was not factored into the allocation over this period. This was partly justified by data on alternative sources of supply not being available or required of participants, as per the terms and conditions and participation, and other data being of poor quality. However, stakeholders in many countries (as confirmed by AMC country representatives from CAR, Liberia, Mozambique and Vietnam) were frustrated by this, and many stakeholders questioned whether this was a reasonable justification, given the wealth of publicly available information on related measures, such as WHO-reported vaccination coverage. Key informants also suggested that there were tensions between the institutional leads of Gavi and WHO within the Access and Allocation Working Group on whether and how the allocation mechanism should factor in non-COVAX supply, given the COVAX Facility's legal obligations to SFPs and AMC participants.[134] A further consideration concerned the optics of penalizing countries for securing vaccines through other channels, particularly as the COVAX Facility and AMC was struggling to meet country needs during much of 2021.[135]

With the benefit of hindsight, early- and mid-2021 offered a critical window to scale up vaccination coverage among the highest risk populations in LICs and LMICs, when political will and community demand was at its highest. The choice to distribute the limited supply of doses equally across countries with high and low vaccination coverage limited the COVAX Facility and AMC's ability to maximize progress toward this goal. This contributed to the frustration many countries, particularly those that were very dependent on COVAX supplies, felt in not receiving as much vaccine through the COVAX Facility and AMC as they expected, as well as to widespread public criticism of COVAX and Gavi's role in administering the COVAX Facility and AMC.[136, 137, 138] Some have suggested that this and the relatively low (20%) COVAX Facility vaccine coverage targets for 2021 are factors that led countries to seek alternative sources of supply.[139]

Box 7: Communication of vaccine allocations to countries

The central question that countries had for the COVAX Facility was how many doses they would receive and when. While the Office of the COVAX Facility wanted to be transparent and timely in its communications to countries, the lack of predictability of vaccine supplies made it difficult. This created a dilemma about what to communicate and when, and how to balance the need to be accurate and timely while also conveying the degree of uncertainty. A few approaches were adopted, including the communication of interim distribution forecasts and indicative allocation ranges. While these included clear caveats and were non-binding, stakeholders reported that they set country expectations, against which the COVAX Facility's performance was later judged. The approach to providing indicative allocations was later dropped although interim distribution forecasts continued.

The inability to communicate vaccine allocations to countries in a timely manner also had implications for participant countries and their ability to prepare communities to receive the vaccine.

Lesson G

The content (accuracy, transparency, clarity of messaging) and quality (timeliness) of communication with countries on allocation details and forecast deliveries can significantly affect relationships with countries, confidence in the mechanism, and public perception of success.

1 **Finding 52: The allocation of doses from September to December 2021 did factor in other sources of vaccine supply, which gave the COVAX Facility and AMC more flexibility to prioritize countries with low vaccine coverage and led to a more equitable allocation.** Despite differing opinions within the JAT and despite technical challenges, steps were taken from Round 7 to prioritize the allocation of doses to countries with low vaccination coverage. In particular, Rounds 7, 8 and 9 prioritized a significant volume of doses for participants with low vaccination coverage. As supply increased toward the end of 2021, especially with the availability of 120 million Pfizer doses in Round 10, country absorptive capacity became a more prominent factor in allocation decisions.

Reflective of the shift in approach away from the original methodology (and given the presence of other factors, such as demand and absorptive capacity), the proportion of the population covered through COVAX Facility doses allocated varied from 71% in Dominica to less than 10% in 11 countries (including India, which was subject to separate allocation rules) (see Annex C2.5).

Analysis conducted as part of this evaluation (see Annex C2.4.3) supports the findings of others that the overall allocation of COVAX Facility doses in 2021 was broadly in line with the objective of equitable access.[140] Nonetheless, a number of interviewees indicated that the overall approach could have been more 'forward-leaning' and the decision to shift away from the original methodological approach could have been made earlier and more aggressively.

Vaccine delivery support

1 **Finding 53: Throughout 2020 and into mid-2021, there was an expectation that other partners would be responsible for funding and implementing vaccine delivery support. During this time, Gavi did not envisage taking a substantial role in this area.** The Country Readiness and Delivery (CRD) workstream within the COVAX Pillar was established in April 2020 to make available global guidance and TA for the implementation of COVID-19 vaccine delivery support. This was a joint initiative by WHO, UNICEF, Gavi and partners. While CRD was intended to support vaccine roll-out, the Gavi Secretariat operated throughout 2020 on the understanding that COVAX Pillar and Alliance partners would be responsible for providing finance for vaccine delivery.[141] In particular, there was an expectation that the World Bank (also a co-lead for the ACT-A Health Systems and Response Connector) would play a major role through its $12 billion (later increased to $20 billion) COVID-19 Strategic Preparedness and Response Program using the Multiphase Programmatic Approach (Global COVID-19 MPA2), designed to finance vaccine purchase and deployment.[142]

Acknowledging that World Bank and other substantial financial support would come only after the first vaccine deliveries, Gavi did approve $150 million in catalytic support for 57 Gavi-eligible participants in September 2020. This was intended to finance the procurement of cold chain equipment (CCE) at $50 million and implement TA via the CRD workstream with $100 million to ensure country readiness to accept and administer the first vaccine shipments.[143, 144]

Lesson J

Clarity and agreement on partnership working principles, roles and expertise required and responsibilities for areas of work to support a pandemic response cannot be underestimated.

1 **Finding 54: Despite initial delays in implementation, which meant that very little support was received before the first vaccines were delivered, Gavi's CCE support was used to procure over 5,900 cold chain units for more than 40 countries in 2021.** CCE needs were defined and supported by the Supply & Logistics subgroup within the CRD workstream with priority given to 57 Gavi-eligible participants. This support was focused on regular cold chain capacity rather than on UCC, based on the expectation in late 2020 that mRNA vaccines would not comprise a substantial proportion of the Gavi portfolio.[145, 146] By the end of 2021, Gavi had funded the procurement of more than 5,900 units of CCE (fridges, freezers and cold rooms) for over 40 countries, and through a later package of support (see finding 56 below) also funded around two-thirds of the 800 UCC freezers that UNICEF delivered to 70 countries – enough to store up to 200 million doses of mRNA vaccines.[147, 148] Evidence, including from country case studies, suggests that this support was extremely useful, such as in Vietnam, where additional UCC capacity was critical to the country's rapid vaccination scale-up with Pfizer vaccines between August and December 2021.

1 **Finding 55: Gavi funds, alongside WHO and UNICEF resources, were used to deploy more than 400 TA providers at the country level for the development of NDVPs and to support planning for the delivery of COVID-19 vaccines in eligible AMC92 economies.** This was operationalized through WHO, UNICEF and other partners from December 2020 onwards. The scope of TA included supporting AMC participants to develop and gain approval for NDVPs, which provided strategic and operational guidance on vaccine introduction, and conducting vaccine introduction readiness assessments.[149] These processes were overseen by country EPI managers with support from country partners and Gavi's SCMs.

These TA providers, embedded within partner country offices (along with UNICEF and PAHO as procurement agents and Gavi's SCMs) have continuously engaged with countries to overcome hurdles to getting COVID-19 vaccines to ports.[150] This has included the development and approval of NDVPs and subsequent plans, I&L, regulatory approvals, import permits/clearances, shipping, freight and logistics (during a global supply chain crisis), and storage arrangements, as well as additional readiness checks for some manufacturers.[151] Stakeholders described these roles as critical to enabling the successful receipt of COVID-19 vaccines in many countries, including both COVAX Facility and non-COVAX doses. The TA providers were also widely used to support vaccine roll-out, including to support coordination mechanisms and working groups (e.g. for National Immunization Technical Advisory Group decision making on prioritization of risk groups), to establish vaccine cold chain and logistics strategies and systems, to strengthen COVID-19 surveillance systems and for demand generation activities.[152]

Although there is only weak evidence on implementation progress, interim reporting to Gavi suggests that the provision of Gavi-funded TA proceeded mostly as planned, with nearly 90% of milestones achieved.[153] The most significant delays were for demand generation and communication activities (linked to the need for government approvals for communication materials) and cold chain and logistics activities (linked to delayed recruitment of consultants).

1 **Finding 56: Amid substantial concern in early to mid-2021 from countries, donors and partners on the lack of vaccine delivery support in the near and medium term, Gavi mobilized and approved $775 million to support vaccine delivery in June 2021.** By this time, there was substantial evidence that delivery funding from external sources was limited while domestic budgets were under unprecedented strain.[154] Support from other funders, notably the World Bank, was more weighted toward vaccine procurement than anticipated by Gavi; other financial institutions were slower to administer substantial volumes of support (although some implementers such as UNICEF have claimed to have disbursed funds to countries more quickly); and delivery costs were substantial. In hindsight, many stakeholders have questioned whether it was reasonable to expect others, particularly multilateral development banks, to provide emergency response funding, given that their loans and grants require some form of government approval which is known to take time to obtain.

Nonetheless, faced with this realization and the recognition that mRNA vaccines would feature more prominently in the COVAX Facility portfolio than originally thought, requiring strengthened UCC capacity in many countries, the Gavi Board approved $775 million for COVID-19 Delivery and System Strengthening. The new funding was operationalized through two main windows of support and dedicated TA in areas identified as particular risks:

- **COVID-19 Delivery Support (CDS) Early Access Window ($270 million):**[155] Launched in June 2021, this window provided grants of between $0.5 million and $15 million to fund vaccine roll-out costs. In line with the principle of providing funds on a no regrets basis, light-touch application processes were used which, stakeholders reported, were quick and simple.[156] The high degree of flexibility over how funds could be used was also widely appreciated and considered a key added value at the country level. In total, 82 applications were approved and disbursements made quickly, the first within 35 days of the application being received and some in as little as 48 hours, compared to what is normally for Gavi a three-month process. As of December 2021, countries had applied for $225 million in Early Access support and $190 million had been disbursed.[157, 158]
- **CDS Needs-Based Window ($330 million):** Launched in September 2021, this provided larger grants for the rapid roll-out and scale-up of COVAX Facility vaccines. More robust application processes were put in place that required more time for countries to prepare (which, many noted, were overly burdensome during a difficult time) and the Secretariat to review. This was partly linked to ongoing uncertainty over the Board's risk appetite, with stakeholders reporting that despite earlier funds being provided on an agreed no regrets basis, questions related fiduciary risk were still being asked internally (see finding 22). It was also due to the Secretariat's decision to request expressions of full country demand, the budgets for which exceeded the available resource envelope and which created a heavy administrative burden to prioritize requests. This also caused delays in approval and disbursement of funds to countries. By the end of 2021, 10 applications had been approved.
- **Other funding envelopes:** These included $77 million in Additional Direct Country Support, comprised of $20 million for management surge capacity, $25 million for UCC support from UNICEF, $16 million for building vaccine confidence, and $16 million for stock management. In addition, $85 million was earmarked for cross-cutting delivery investments and $10 million for unallocated buffer and operating expenditure.

The COVID-19 Vaccine Delivery Partnership was established in December 2021 by UNICEF, Gavi and WHO to further boost the financial resources available to and coordinate TA to the 34 countries that were at or below 10% COVID-19 vaccine coverage in January 2022.

Lesson H

The provision of flexible funding on a no regrets basis can be extremely useful in a range of country contexts during emergency situations.

2 **Finding 57: By the end of 2021, only a small amount of Gavi funding had been made available to countries, with many stakeholders noting that country needs were not met in a timely way.** Out of a total of $400 million requested by countries through 2021, Gavi approved around 60% (over $243m), much of which was through the Early Access Window.[159] These resources were not, however, in place for the first deliveries of vaccines to countries, for which countries were described as ill-prepared by a number of stakeholders. Evidence collected as part of this evaluation, including through a rapid review on this topic, suggests that while the CCE, TA and CDS funding through the Early Access Window positively supported vaccine roll-out, the level of external support was far below what was required and intended by the ACT-A Health Systems and Response Connector (HSRC) and Gavi through the course of 2021. While Gavi is not solely responsible, its own resources could have come earlier. In particular, multiple stakeholders in DRC pointed to the delay in Gavi funding as having an impact on the timeliness of implementation of vaccination campaigns.

However, it is also likely that the delays were not as damaging in many countries as they could have been, given limited vaccine supplies throughout most of 2021 and other contextual constraints.[160] For instance, in Burkina Faso, DRC and Ethiopia political and social instability, as well as health system capacity and community demand, also constrained vaccine roll-out, even when funding for vaccine roll-out and vaccine supplies were available in 2021 (see Box 8 for further detail on barriers to vaccine delivery in DRC and Senegal). A number of countries, including Ghana, reported issues in coordinating funding for the COVID-19 response, including for vaccine delivery, across a host of funders, requiring the need for resource mapping to understand what support was being used for.

Box 8: Operational and contextual barriers to vaccine delivery and uptake in DRC and Senegal

Vaccine distribution in DRC was described by a number of key stakeholders as 'following the presence of logistics' – namely, the locations of CCE capacity, which was good in some provinces following previous Ebola vaccination campaigns. Given the size of the country, vaccines were deployed to provinces on often extremely long journeys, or using multiple aeroplanes where road quality to rural locations was considered to be bad. Once the vaccines had reached their destination, it was then logistically near-impossible for them to be redirected to other locations. Given these constraints, and generally low uptake, vaccines were sometimes allocated to provinces in smaller quantities and a 'wait and see' approach was employed, observing whether vaccines were consumed, and then following up step-by-step with more deliveries if demand appeared to be high enough. In this context, vaccine duration and expiry became problematic.

In Senegal, stakeholders reported a high level of suspicion over external and foreign initiatives, which severely impacted the demand for vaccination. Fears about an initiative to curb African demography, or that vaccines procured through COVAX or donations were lesser quality were commonplace.

While Gavi CDS funding was considered to be critical and highly welcome in both countries, the two case study examples highlight the importance of timing of disbursements to coincide with imminent vaccine deliveries *and* funding flexibility (e.g. for operational delivery resources or timely messaging and awareness campaigns) in future responses.

There are, however, some success stories. In India for example, $21.8 million was used for TA through UNICEF, WHO and the United Nations Development Programme (UNDP) for training and supervision, demand generation and communication, vaccine cold chain and logistics, and monitoring and evaluation. This enabled more than 366,000 staff to be trained in safely administering COVID-19 vaccines, supported outreach and communication strategies for target populations, and strengthened the logistics and information system.[161] Respondents in India and Liberia highlighted how they had used the funding for planning roll-out as well as for innovation in digitization and certification of vaccine recipients. They also welcomed the flexibility in use of funding. Pakistan utilized Gavi support and TA to expand its cold chain storage capacity, strengthen its supply chain systems, and recruit additional vaccinators to ensure concurrent routine and COVID-19 immunization. This is reported to have enabled the rapid scale-up of vaccination coverage.[162] Similarly, Togo received its first delivery of doses in March 2021, and at the end of May had fully immunized 93% of the country's health care staff, supported by Gavi-funded TA to develop communications materials to stem misinformation and generate demand for COVID-19 vaccines.

2.3 Module 3: Results (Right results)

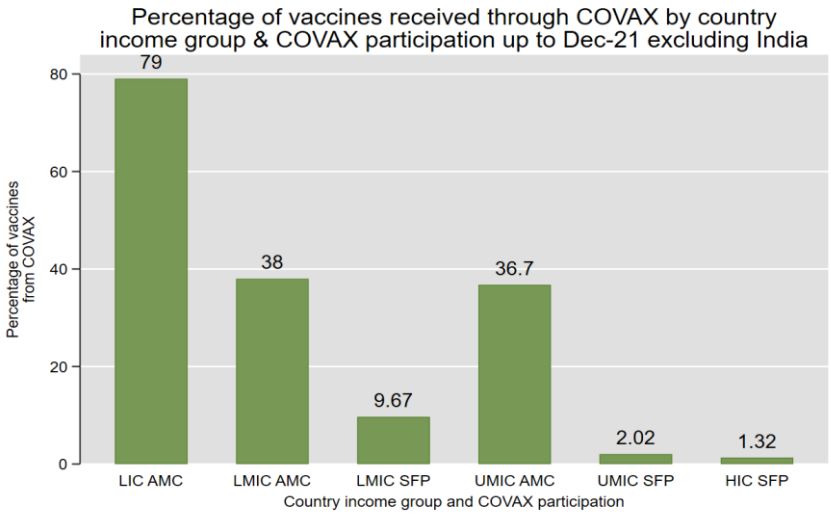
Following from Module 2, which addresses 'the extent to which the early emerging evidence suggests that intended intermediate outcomes of programmatic areas as per the ToC are likely to be achieved' (EQ 3.1), this section focuses on EQ 3.2 and 3.4. It assesses 'to what extent does the early emerging evidence suggest that the intended outcomes and impacts in the TOC are likely to be achieved and how has the COVAX Facility and AMC contributed to them' by analysing outcomes like quantity of vaccine supplies to AMC and SFP countries, their timing, vaccine coverage and impacts like vaccine coverage of targeted high-risk groups. In addition, the impact indicators on decrease in morbidity and mortality were assessed through a rapid review of secondary literature. The whole assessment has been done separately for LICs and LMICs, where possible, since income level proved to be a good way to classify and analyse the set of COVAX AMC countries. The analysis of LMICs mostly excludes India and other outliers such as island economies. The barriers and enablers to achieving intended outcomes have been discussed throughout the section as relevant (EQ 3.5). This section ends with an outline of the unintended consequences beyond those identified in the ToC (EQ 3.3).

1 **Finding 58: The COVAX Facility and AMC has made a substantial contribution to the supply of vaccines to and vaccine coverage in LICs. Its contribution has been moderate in LMICs and marginal in UMICs and HICs.** This finding is based on analysis in a number of areas.

Quantity of vaccine supplies:

- By the end of 2021, the COVAX Facility had distributed 957 million doses to 145 countries, including 28 LICs, 46 LMICs (which account for most of the global population and doses allocated), 47 UMICs and 24 HICs. While impressive, this is significantly below the target of 2 billion doses by the end of 2021. Importantly, however, 833 million (87%) of these doses were shipped to AMC participants, which is close to the target of shipping 950 million doses to these countries.[163] By the end of 2021, about 110 million doses were shipped to SFPs (from a target of 950 million) and 3.2 million to the Humanitarian Buffer (from a target of 50 million).[164]
- By December 2021, AMC participants (excluding India) received 41.7% of their vaccine doses from the COVAX Facility, while SFPs received only 2.1% of their total doses from this source. As shown in Figure 6:, 79% of all vaccines delivered to LICs were through the COVAX Facility, whereas the corresponding share for LMICs, excluding India, was 38%. For SFP UMICs, only around 2% came from the COVAX Facility, and for SFP HICs 1.3%.[165]

Figure 6: COVAX Facility share in vaccines delivered to participating countries (excluding India) by participation type and income group

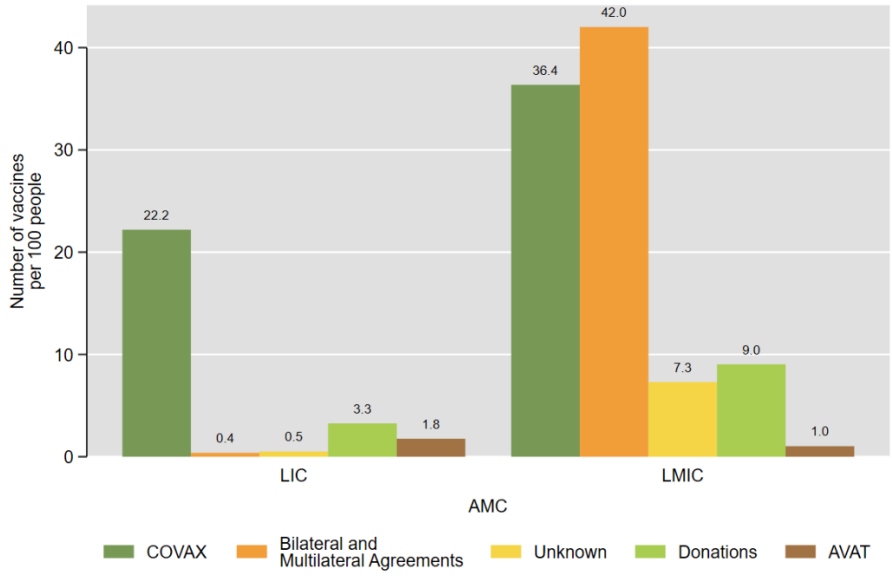


Source: UNICEF COVID-19 vaccine delivery data, accessed August 2022

Note: Iran and Belize constitute SFP LMICs. UMICs that are part of the COVAX AMC are Fiji, Republic of Moldova, Tonga, Grenada, Guyana, Kosovo, Maldives, Tuvalu, Saint Lucia, Dominica, Saint Vincent & The Grenadines, and Marshall Islands

- As shown in Figure 7, by the end of 2021 the COVAX Facility had delivered enough vaccines to vaccinate more than 20% of the population with at least one dose in LICs and AMC participating LMICs, excluding India. Even though the COVAX Facility contributed to a much smaller share of total doses in LMICs compared to those in LICs, it actually provided more doses per person in LMICs. There is a large variation within the country groups. Among AMC participating LMICs, Haiti received sufficient doses from the COVAX Facility to vaccinate 5% of population whereas Bangladesh received enough to vaccinate 75% of its population by December 2021.

Figure 7: Vaccine doses per 100 people delivered through the COVAX Facility and other sources to AMC countries, excluding India, as of December 2021

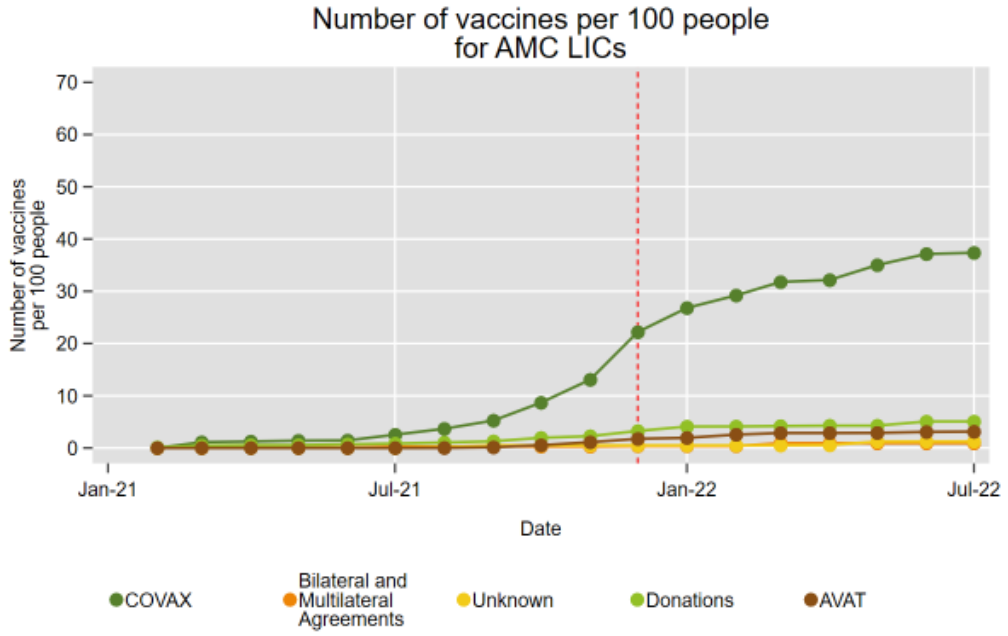


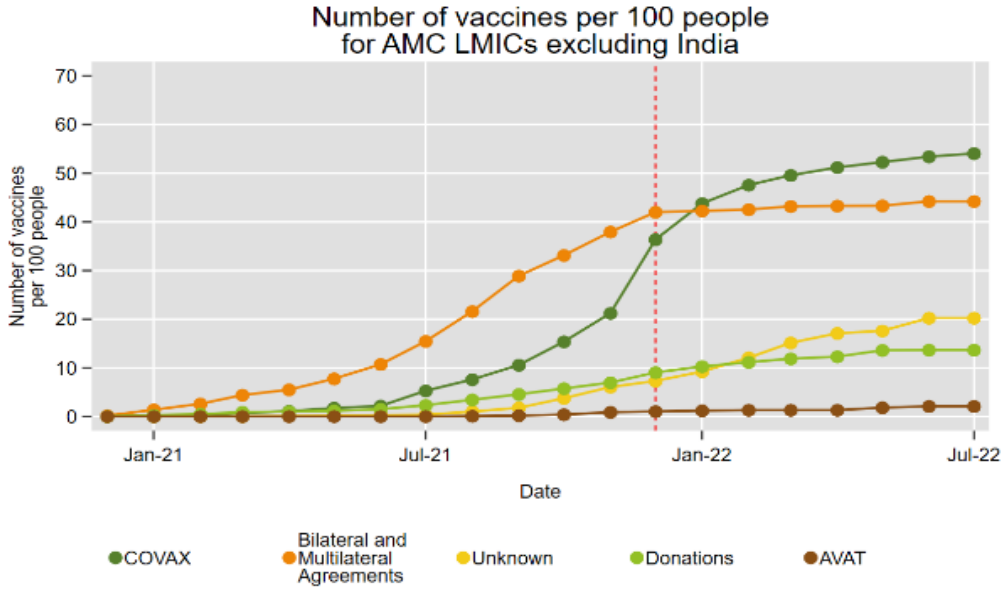
Source: UNICEF COVID-19 vaccine delivery data, accessed August 2022

Timing of vaccine supplies:

- While the COVAX Facility started to supply AMC participants in early 2021, deliveries were small and sporadic for the first six months, rising slowly but steadily from Q3 onwards and picking up significantly in Q4 of 2021.
- As shown in Figure 8:, vaccines were received much later in LICs than in HICs, and the volumes were also significantly lower. Further, AMC participating LMICs (and SFPs, but not shown) were able to access vaccines from bilateral and multilateral agreements before COVAX Facility supplies started picking up, but vaccines from these sources plateaued after December 2021, and in 2022 delivery of vaccines from the COVAX Facility surpassed that from other sources.

Figure 8: Number of vaccines per 100 people over time

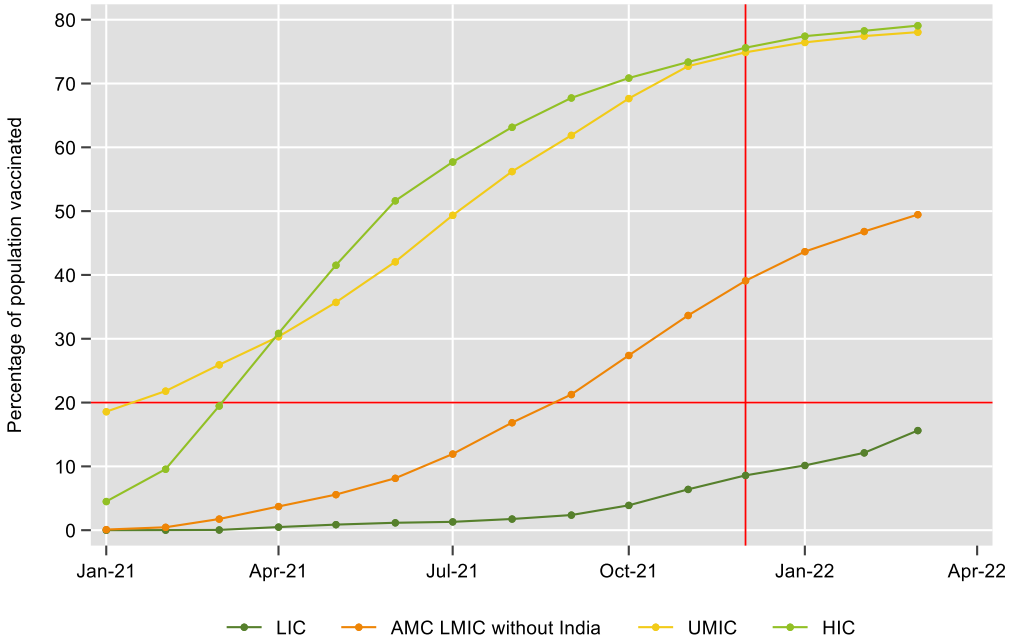




Vaccine coverage and its link with vaccine supplies:

- Figure 9: illustrates the vaccination coverage for at least one dose over time for the countries in different income groups. The rate of vaccination in LICs has remained considerably lower compared to that in LMICs, UMICs and HICs. Similar trends are observed for full vaccination coverage, as seen in Annex D1.1, Figure D1.

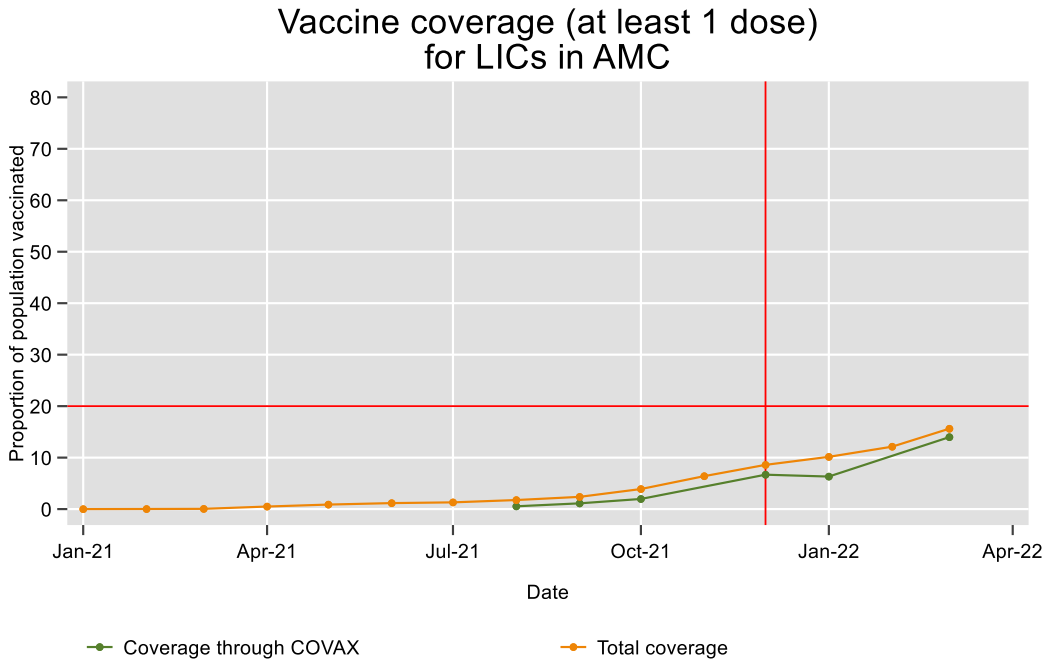
Figure 9: Vaccination coverage (at least one dose) over time, by country income group

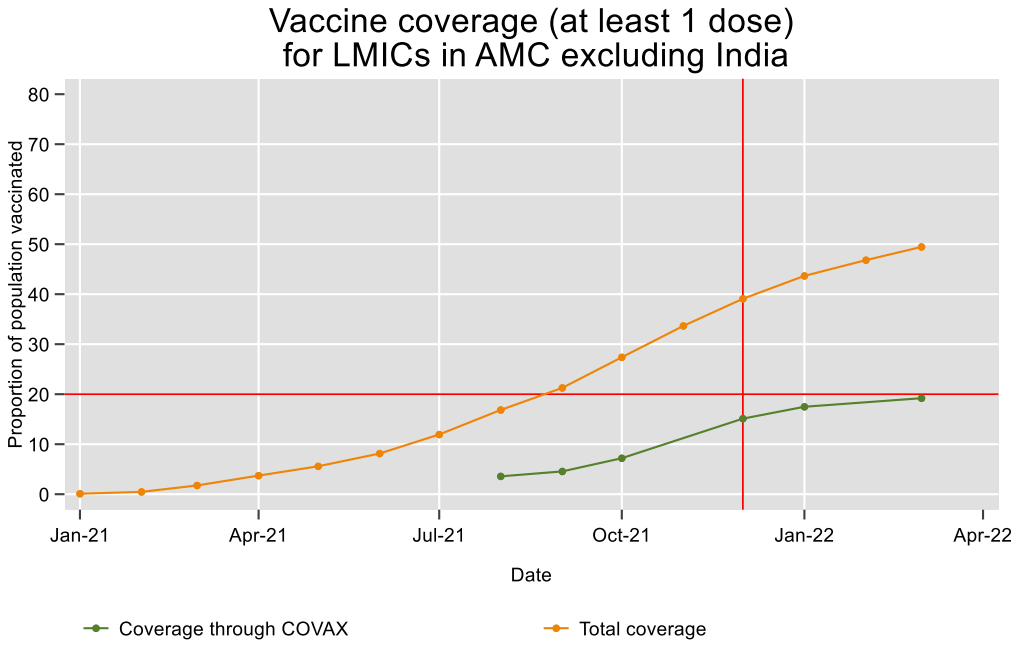


Source: COVID-19 Data Dashboard, https://infohub.crd.co/ accessed August 2022

- The extent of contribution of the COVAX Facility to vaccine supplies does not have a one-to-one mapping to the extent of its contribution to coverage in AMC participating countries. For instance, while COVAX Facility supplied doses equivalent to covering 22% of the population in LICs with at least one dose, the actual coverage was only 9% (about 5% population was fully vaccinated) during the evaluation period (Figure 9:). This gap reflects mediating factors such as country capacity to roll out vaccination before expiry and vaccine demand at the time of roll-out (discussed in more detail in the next finding).

Figure 10: Vaccination coverage through the COVAX Facility





Source: COVID-19 Data Dashboard, https://infohub.crd.co accessed August 2022.

Note: Country-level estimates of COVAX Facility-supported coverage is available through the COVAX Monitoring Framework. Countries in AFRO and EMRO directly report the number of doses administered attributable to COVAX. For most of the remaining countries, a country's average rate of COVID-19 vaccine utilization since vaccine roll-out (in doses administered per day) was used to determine an estimated number of COVAX Facility doses administered. Data is not available for months prior to August 2021, for December 2021 or for March 2022 due to various delays in data sharing.

- While coverage rates in LICs were relatively low, the COVAX Facility was the main contributor to what was achieved (as seen in the top graph of Figure 10:). For AMC participating LMICs, excluding India (as seen in the bottom graph of Figure 10:), COVAX Facility supplies played a more modest role in coverage, while other sources played a more significant role: there was an almost 25 percentage-

point gap between total vaccination coverage (at least one dose) and coverage through COVAX Facility-delivered doses as of December 2021. For UMICs and HICs on average, COVAX Facility vaccine supplies were a small share of the total, and hence played a small role in vaccination coverage.

- Evidence further suggests that the COVAX Facility's contribution to vaccination coverage overall and in high-risk populations supported a reduction in COVID-19-associated morbidity and mortality – see Box 9.

Box 9: Contribution of the COVAX Facility to decrease in mortality and morbidity based on rapid literature review

A rapid but intensive search for papers on the impact of COVAX on mortality and morbidity was conducted from 3-7 November 2022, and abstracts and full texts of relevant papers were screened. Most papers were focused on HICs. Only three papers were identified as being relevant for LMICs and one for UMICs; they have been summarized here. All the three papers for LMICs used mathematical modeling and simulations to assess the impact of COVID-19 vaccination on mortality and two assessed impacts on morbidity. While one paper conducted the analysis at the global level and for COVAX AMC countries separately, the other two papers were country-specific and focused on India and Pakistan. The fourth study was conducted for Brazil (UMIC) and assessed the impact on mortality rates of the elderly by comparison of death rates between different age groups.

Watson et al. (2022) used officially reported COVID-19 deaths and found that COVID-19 vaccination reduced 79% of deaths globally (14.4 million deaths averted, out of the predicted 18.1 million) in 2021. Substituting excess mortality data with officially reported deaths, they conclude that 19.8 million out of the predicted 31.4 million deaths were averted in 2021 due to vaccination. For COVAX AMC countries, they found 7.4 million out of the predicted 17.9 million deaths were averted.

A modeling exercise was carried out by Pearson et al. (2021) in Sindh Province in Pakistan. They predicted that if the COVAX target of vaccinating 20% population is achieved within a year using a vaccine with 70% efficacy and 2.5-year duration of protection, it may avert 900,000 cases and 10,000 deaths. Through another mathematical modeling exercise for India, Foy et al. (2020) found that prioritizing population aged 60 years of age and above for vaccination can lead to the greatest reduction in deaths. They also suggest that prioritizing the younger population is a better strategy for infection prevention, although the reduction in incidence of infection will be marginal.

In the Brazil study by Victora et al. (2021), the authors point out that proportionate mortality for the elderly population (70–79 years and 80+ years) hovered around 25%–30% in 2020 but was reduced to below 13% in May 2021. Moreover, decline at 80+ years happened before the same happened for the 70–79 age group. According to the authors, this was consistent with the vaccination schedule followed in Brazil.

To the extent that COVAX contributed to vaccination coverage of overall and high-risk population in LMICs and UMICs, the analysis in the above studies indicate that it would have contributed to reduction in mortality and morbidity.

Qualitative data collected and analyzed as part of the evaluation further supports the finding, albeit with some nuances across country experiences. Among LICs, key informants in DRC stated that the COVID-19 vaccine roll-out could not have started without COVAX Facility doses. In Ethiopia, the COVAX Facility provided 80% of all available doses to scale up coverage. Even for the four countries who signed bilateral agreements (Guinea, Mozambique, Rwanda and Somalia), the COVAX Facility provided supplies first and in larger quantities. On the other hand, respondents in CAR highlighted that the supplies from the COVAX Facility were sporadic and did not always take country vaccination needs into account.

Among LMICs, respondents from Senegal reported that the COVAX Facility vaccine supply was delayed and came after supplies from other sources. The delay led to the COVAX Facility supplies arriving at a time when vaccine demand had fallen, resulting in overall coverage remaining low in Senegal by the end of the evaluation period. Respondents in Vietnam highlighted the importance of the early supply of vaccine doses from the COVAX Facility in April 2021, but shared that the slow supply from the COVAX Facility due to global vaccine shortages caused a lot of difficulties for the Ministry of Health in planning vaccination

roll-out between March and August 2021, as they did not know when, how many and what type of vaccines would be received.

Most SFPs had access to alternative supplies, although some, such as Colombia and Brazil, highlighted that the COVAX Facility enabled access to a diversified pool of vaccines at a time when HICs were rapidly absorbing available supply. However, both countries pointed to the delay in vaccine deliveries from the COVAX Facility in mid-2021, with priority groups being vaccinated with other supplies. While Colombia received 34% of its vaccine doses from the COVAX Facility (including through donations) as of October 2022, Brazil ultimately received only 3% of its vaccine doses from the COVAX Facility, donating the rest of the allocation back to the COVAX Facility.

1 **Finding 59**: **Limited vaccine supplies in LICs relative to HICs constrained vaccine coverage rates, but contextual factors were also important constraints.** All AMC participating LICs from which qualitative data was collected noted that limited and unpredictable supplies of vaccine and associated products (e.g. syringes and CCE) affected vaccine roll-out and ultimately vaccine coverage rates in 2021. Informants in the LICs, including in CAR, DRC and Ethiopia, also noted inadequate country readiness and capacity to roll out vaccination as constraining factors, as well as issues with receipt of doses close to expiry. These issues were also noted in AMC participating LMICs such as Senegal and Vietnam, but appeared to be less severe.

For some of the participating countries, sources also placed greater emphasis on the lack of early political commitment to vaccine roll-out (as in Brazil and Vietnam, where vaccines were not initially prioritized) and a lack of community demand (as in Senegal) as constraining factors in 2021. Countries from all income groups developed strong preferences for some vaccine products and were reluctant to accept others. In Senegal, respondents highlighted that low coverage was also attributable to factors other than delayed supply, such as inadequate engagement of community and local government, low perception of pandemic risk, and misinformation around the AstraZeneca vaccine type by the time COVAX Facility supplies started scaling up.

Respondents from AMC participating countries, including LICs such as CAR, DRC, Ethiopia, Gambia, Liberia and Mozambique and LMICs such as Vietnam, acknowledged the value of vaccine delivery support from Gavi and Alliance partners in strengthening country readiness for vaccine roll-out, particularly for cold chain capacity. Stakeholders in Vietnam noted that the rapid scale-up in coverage after a late start owed in part to vaccine delivery support focused on strengthening cold chain capacity, alongside strong political commitment and existing health system capacity.

However, a number of respondents across AMC participating countries commented that the vaccine delivery support would have been more helpful if it had arrived earlier and if administrative application processes had been less burdensome. The coordination of related types of financial support for vaccine roll-out was also noted as a challenge in some countries, such as Burkina Faso, Ghana and Senegal. Enablers of and barriers to country readiness to turn vaccine supplies into administered doses are summarized in Box 10, below, and discussed in more detail in Annex D1.2.

Box 10: Summary of contextual factors affecting vaccine coverage rates

Enablers

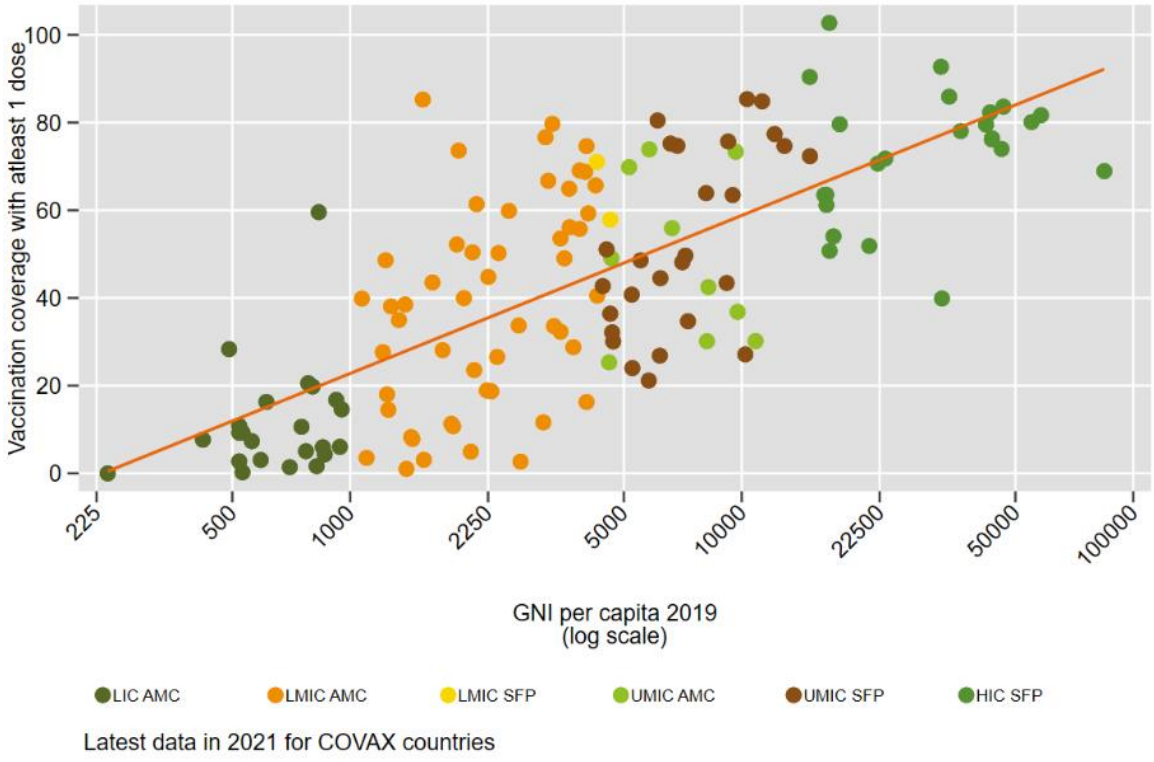
- Strong pre-existing health system capacity, including cold chain
- Strong political commitment
- High initial demand for vaccines

Barriers

- Weak administrative and regulatory processes for accessing and coordinating delivery support funding
- Lack of supplies of associated products, e.g. cold chain equipment and syringes
- Stretched health system capacity
- Low political priority accorded to vaccination in early 2021 in some contexts
- Inadequate engagement of local stakeholders
- Drop in demand linked to misinformation and perceptions around vaccine types and pandemic risk

1 **Finding 60: Despite the fact that the COVAX Facility and AMC's support was strongly targeted to LICs and LMICs, global vaccine coverage was highly inequitable across countries.** As shown in Figure 11:, vaccination coverage is strongly correlated with country gross national income (GNI) per capita, albeit with considerable variance among countries, especially LMICs, at the same GNI. LICs have the lowest vaccination rates, followed by LMICs. Both groups lag behind UMICs and HICs.

Figure 11: Vaccination coverage (at least one dose) vis-à-vis GNI per capita, as of December 2021



Source: COVID-19 Data Dashboard, https://infohub.crd.co/ accessed August 2022. Note: Each dot represents vaccine coverage rate (percentage of population with at least one dose) in a country.

2 **Finding 61: Within-country equity is harder to define and measure, but available data[166] suggests that high-risk groups were prioritized and that women and men had equal access to vaccines in most countries.**

- *Age*: Almost all countries across income categories that report data[167] on vaccination coverage for different age groups prioritized the elderly (population aged 60 and above) for vaccination in the initial few months of vaccination campaigns. Annex D Figure D2 shows vaccination coverage for population aged 60 and above relative to that of its general population.
- *Healthcare workers*: As with the elderly population, all countries which report data on vaccination of healthcare workers prioritized it, as illustrated in Figure D3 in Annex D.
- *Gender*: On average, there is no significant difference between vaccination rates (coverage with at least one dose) for men and women, irrespective of COVAX participation status and country income group, for countries reporting gender-disaggregated data. Figure D4 in Annex D represents the ratio of vaccination coverage of women to that of men. While on average the coverage rates between male and female populations are equal, there are countries such as Yemen, Gabon, Somalia and Pakistan with relatively lower vaccination coverage of their female population.

Almost all key informants and case study respondents confirmed that the initial scarce supplies were provided to frontline workers and the elderly. In Senegal, for example, respondents highlighted that while

the overall coverage remained low, frontline workers and the elderly had been fully covered. In the Philippines, too, respondents noted using strict prioritization criteria to vaccinate with the scarce supplies.

However, as far as the COVAX Facility's contribution is concerned, the experience across AMC countries differs. Despite prioritizing groups at high risk, LICs struggled to cover all those at high risk (see Annex D.1.1). While acknowledging the COVAX Facility's contribution to the coverage that was achieved in LICs, respondents in CAR and DRC respectively mentioned delays in COVAX Facility supply and also country capacity as key constraints. Respondents in DRC also cited barriers to reaching seniors and those with comorbidities, and also highlighted that misinformation acted as an obstacle to vaccine demand and hence coverage among these groups.

Among the LMICs, Vietnam, India and the Philippines highlighted the important role of the early supplies from the COVAX Facility for vaccination of high-risk groups. On the other hand, Senegal (and also SFP UMICs Brazil and Colombia) noted that due to delays in COVAX Facility supply, it was non-COVAX sources that enabled coverage of the population at highest risk in their respective countries.

2 **Finding 62: Implementation of the COVAX Facility and AMC through the course of 2020 and 2021 resulted in a few unintended consequences.** Stakeholders interviewed pointed to three examples in particular.

- SII's manufacturing capacity, substantially augmented by Gavi and Gates's investment (see Box 6 and Box 11) to provide vaccine supplies to AMC participants, enabled the Government of India to directly purchase COVID-19 vaccines from SII during the halt on exports in 2021. This facilitated a higher vaccination coverage of population in India than was otherwise possible. Up to October 2021, SII had supplied an estimated 866.9 million doses to India's vaccination program,[168] much higher than the 179.9 million doses committed by COVAX to India.[169]

Box 11: Case study contribution of COVAX to COVID-19 response in India

As Box 6 highlights, the COVAX Facility and AMC contributed to total vaccine supply in India and the world through the SII APA. Key informants also noted the contribution of the initial 10 million COVAX Facility doses received in January 2021 to vaccinate health workers in India. Another critical contribution highlighted by key informants related to Gavi's $30 million country delivery support, which was perceived to be very timely and flexible. It contributed to readiness to vaccinate in India through digitization of vaccine tracking and certification (COWIN) with UNDP support, as well as TA and community mobilization.

- There is some evidence that not offering additional funds to protect RI while repurposing existing HSS funds for COVID-19 response may have contributed to lowered prioritization of RI in some countries. A recent evaluation of Gavi's COVID-19 response[170] uses data from case studies to note that apart from the challenge at country level of focusing on both RI and COVID-19 response, there was evidence that 'shifting roles under COVID-19 response (e.g. ACT-Accelerator, Health Systems accelerator and the COVAX Facility) have disrupted [Gavi's] existing roles and responsibilities'. Citing instances of funds and staff shifting away from routine immunization in some countries, the authors add that the decision to allow countries to reprogram existing health system strengthening funds for COVID-19 response without offering additional funds to protect routine immunization led to routine immunization being deprioritized in at least three case study countries (Niger, Sudan and Pakistan). However, the authors note that reprogrammed support helped to identify innovative mechanisms, such as digital vaccination tracking, that might be useful for routine immunization in the future.
- The perception that the COVAX Facility did not adequately engage with pre-existing regional procurement mechanisms and the eventual delays in the supply of vaccines through the COVAX Facility contributed to increased interest in regional procurement by agencies such as PAHO and AVAT in 2021 (see Finding 10 and Finding 31). This view was widely held by stakeholders interviewed. A number also attributed this interest in regional (and bilateral) procurement to a perception among countries that the COVAX Facility would only supply vaccines to cover up to 20% of their populations, meaning that it would not fully meet their needs.

Section 3: Conclusions

This section details five key conclusions drawn from the evaluation findings, presented as headline conclusions (in bold) with explanatory paragraphs below. The 'line of sight' from findings to conclusions, recommendations and lessons is presented in Table E1, Annex E. Lessons learned from the COVAX Facility and AMC experience to date are summarized and explained in Annex H, and Section 4 offers a number of recommendations to evaluation users.

Conclusion 1

The overall design of the COVAX Facility and AMC is coherent, ambitious, and has responded to a rapidly evolving context. Significant elements were also innovative and untested, and as such it was unclear at the outset whether the COVAX Facility and AMC would work as intended. The design also suffered from too little engagement of LICs and LMICs and was too optimistic regarding the behaviors of HICs and vaccine manufacturers. Vaccine nationalism, vaccine diplomacy and commercial interests undermined the potential of market-based solutions to global vaccine equity challenges in a public health emergency context.

The design of COVAX was coherent. A global mechanism where all participating countries, rich *and* poor, jointly procure COVID-19 vaccines, which are then allocated equitably across countries, is bold and simple. Two aspects that were less clearly defined, yet critical to the achievement of objectives, were the provision of vaccine delivery support and equitable distribution of vaccines within countries – responsibility for these within the COVAX Pillar and ACT-A architecture was to be held by agencies other than Gavi, but specific mechanisms and responsibilities were unclearly defined.

The COVAX Facility and AMC design was ambitious but assumed an unrealistic degree of global solidarity, and has been criticized by some key stakeholders as being too embedded in status quo. The fact that assumptions regarding global solidarity were overly optimistic was clear even as the COVAX Facility and AMC was being established, as several major economies (USA, China, EU and Russia) did not participate in joint procurement, and many better-off countries moved aggressively to reserve vaccine for their own populations, undermining the COVAX Facility's ability to obtain doses for participating countries. Although COVAX Facility and AMC designers recognized that some countries would procure outside the mechanism, they did not anticipate the scale of vaccine hoarding and other forms of vaccine nationalism and developed no strategy to counteract them.

At the same time, some LICs and CSOs have criticized COVAX's design for not being ambitious enough in challenging the status quo and for relying on the existing global vaccine ecosystem to develop, produce and distribute vaccines rather than treating pandemic vaccines as a global public good. These critics also assert that the COVAX Facility has excessively accommodated commercial interests, including on I&L and deal transparency and by not pushing more aggressively for IP sharing and tech transfer.

In terms of engagement, the design process was highly centralized and included limited direct input from stakeholders external to the Gavi Alliance, notably representatives of LIC ministries of health, health workers and humanitarian agencies. The centralized process was driven by the need to establish the COVAX Facility and AMC rapidly as the pandemic was unfolding in 2020. By the time more adequate stakeholder engagement mechanisms were established, reputational damage had already been done. In contrast, donor countries and industry were substantially engaged in the design and are perceived by some to have had disproportionate influence.

The inclusion of UMICs and HICs within the COVAX Facility as SFPs has, however, offered some benefits, such as through the provision of financial resources sooner than the AMC was able to generate, which enabled earlier and larger deals, giving proof of concept to the use of APAs. The inclusion of SFPs also supported dose sharing through the COVAX Facility and funded the majority of COVAX Facility operational and management costs, effectively cross-subsidizing the administration of the COVAX AMC.

Conclusion 2

The COVAX Facility was successfully established and made substantial progress toward its core objectives. These include the rapid setting up of the COVAX Facility, the raising of significant resources, progress in market shaping and securing of supply, the equitable allocation of COVAX doses and the mobilization of vaccine delivery support funding. However, given the complexity, scope and scale of these endeavors, the governance and management of the COVAX Facility and AMC has been challenging.

Over the course of 2020 and 2021, in a highly dynamic and unpredictable geopolitical and epidemiological context, Gavi launched and implemented the COVAX Facility and AMC, incorporating 193 countries into a single mechanism. This involved setting up governance and management arrangements and a host of operational systems, processes and capacities. In spite of these challenges, the COVAX Facility was responsible for the delivery of more than 800 million doses to AMC participants in 2021—a central contribution to the fastest and broadest global vaccine roll-out in history. These successes are owed to the entire COVAX architecture, including the roles of partners, but also due in substantial part to Gavi's strengths, including its ability to convene partners, the strength of its governance and management team, and the faith of donors in its ability to competently manage large volumes of ODA.

Drawing on Gavi's strong pre-existing capacity and donor relationships, the design of the COVAX AMC enabled a highly effective resource mobilization effort, one of the fastest and largest fundraising campaigns in global health history. A convincing investment case for donors aided fundraising but also created very high expectations that the COVAX Facility and AMC subsequently struggled to meet.

Progress was also made in terms of objectives around market shaping and securing supply. Through the BMGF-supported deal with SII, the COVAX Facility was able to meaningfully influence the scale-up of manufacturing capacity to meet the needs of LMICs, and other APAs probably influenced capacity decisions, especially later in the outbreak. The COVAX Facility was also able to secure lowest in-market prices for AMC participants. By the end of 2021, deals had been struck for more than 4 billion doses of 10 different vaccine candidates.

The allocation mechanism was implemented in a highly flexible manner in the face of daunting obstacles, notably the unpredictability of vaccine supplies. While this flexibility created challenges, overall, an equitable allocation of COVAX Facility doses was achieved by the end of 2021.

Within the time frame of the evaluation, less progress was made in relation to vaccine delivery support. Gavi's initial $150 million investment in TA and CCE appears to have been helpful, although it was delayed in some instances and insufficient to meet country needs for vaccine roll-out. A larger package of support, initially anticipated to be provided by others, did not come in time to support countries receiving the first shipments of vaccine doses. By the end of 2021, while more than $240 million had been approved through the various funding windows established for delivery support, few of these resources had actually been used at the country level.

The governance and management of the COVAX Facility and AMC has, however, been challenging. A common feature across the areas of the evaluation is one of complexity, with a lack of resource within the Office of the COVAX Facility to deal with the scope and scale of its responsibilities; and a lack of clarity over roles and responsibilities between governance bodies and implementing partners. In the midst of an emergency response, where speed is of the essence, these issues have reduced the efficiency of internal processes and added to the management burden of administering the COVAX Facility and AMC.

Conclusion 3

The COVAX Facility design and business model has evolved considerably in the face of a highly dynamic and uncertain environment, and this flexibility has been a core strength of the response. The evolution of the COVAX Facility has continued beyond the scope of this evaluation.

Notable adaptations to the COVAX Facility and AMC design include: the adoption of cost-sharing and the incorporation of dose donations as mechanisms to raise additional resources and secure supply; the development of I&L and NFCS to remove obstacles to the use of new vaccines; the Humanitarian Buffer as a way to reach the most vulnerable populations; the changing approach to allocation; the evolving mechanisms for supporting vaccine delivery. In part, these shifts were a reflection of the need to build the ship while sailing it. Nonetheless, while shifts did not always occur as quickly as they might have, this flexibility should be seen as a strength, particularly in a highly dynamic and uncertain environment.

Conclusion 4

Despite its successes, COVAX fell well short of its target of delivering 2 billion doses for 2021,[171] and while it came close to meeting its target of delivering 950 million doses to AMC participants in 2021,[172] most of these were delivered in late 2021. This shortfall was due primarily to its inability to secure supply.

India's decision in March 2021 to curtail vaccine exports, exacerbated by slow delivery from some manufacturers, dramatically curtailed COVAX Facility and AMC supply during a critical phase of the pandemic. Vaccine donations and purchase agreements with additional manufacturers only partly and belatedly closed this gap.

The COVAX Facility's support was particularly important to LICs, for which it was the main source of vaccine supply, accounting for about 79% of doses delivered to these countries. Nonetheless, during the evaluation period the COVAX Facility's supply remained below the number of doses necessary to vaccinate 20% of the population in most LICs. For LMICs (excluding India) as a group, in contrast, only 38% of total vaccine supply came from the COVAX Facility, as these countries were able to obtain a much greater share of vaccines through other bilateral and multilateral channels than the poorest countries.

Conclusion 5

The COVAX Facility and AMC did not have sufficiently strong levers in 2020 and 2021 to influence the market and market actors to the extent intended. This can, in part, be seen as a failure of international solidarity to restrain the behavior of powerful stakeholders acting in their own interests. In this environment, the COVAX Facility did not have sufficient market power to compete successfully for vaccines against HICs with far greater resources at their disposal or to dramatically influence most manufacturers' decisions on manufacturing capacity.

The difficulty that the COVAX Facility encountered in securing supply in 2021 can, in part, be seen as a failure of international solidarity to restrain the behavior of powerful stakeholders acting in their own interests. These economic and geopolitical factors were, to a large extent, beyond Gavi's control: while Gavi aims to influence the market for vaccines, it cannot be expected on its own to address fundamental barriers to equitable access such as vaccine nationalism, policies on intellectual property rights, and the concentration of vaccine development and manufacturing capacity. Nonetheless, in this environment the COVAX Facility and AMC's reliance on APAs (and later dose donations) was insufficient

to simultaneously achieve the three related objectives of scaling up manufacturing capacity, securing rapid access to large volumes of vaccines, and affordable prices. The COVAX Facility and AMC did not have sufficient market power to compete successfully for vaccines in the face of highly aggressive buying by HICs with far greater resources at their disposal or to dramatically influence manufacturers' decisions on capacity.

Analysis suggests that the COVAX Facility and AMC's early market signals and APAs had limited impact on scale-up of manufacturing capacity, given the much greater scale of deals signed by HICs, and that the link between the timing of signing APAs and securing supply from manufacturers was weak. This finding, and a finding that lack of access to at-risk funding in the first months after launch was only one of several factors that delayed deal signing, casts doubt on the hypothesis that having earlier access to greater resources would have substantially improved the supply situation in the first half of 2021. This analysis also suggests that a greater use of push funding and support for tech transfer, tied to access guarantees, might have effectively complemented APAs as a way to expand capacity and secure supply, as illustrated by the SII deal. Our analysis also highlights potential trade-offs among the three objectives. In particular, the low prices agreed with some manufacturers may have played a role in the COVAX Facility, and the COVAX AMC specifically, being accorded a lower priority than other buyers, and thus may have contributed to the COVAX Facility's inability to secure timely supply.

While external communications was used as a tool to mobilize resources, it was not actively used to influence, and likely had only a marginal effect on influencing, HIC procurement and vaccine manufacturer sales decisions during most of 2021. Gavi is understandably reticent to criticize donor countries and manufacturers directly, given its dependence on them for funds and vaccine supply, but its decision to not call out behavior where it hampered COVAX Facility and AMC objectives was also based on the assumption that doing so would not be effective. The evidence upon which this assumption rests is unclear. This decision was a missed opportunity to make use of Gavi's soft power, and it prevented the COVAX Facility from accurately portraying to participating countries and other observers the challenges it was facing during most of 2021.

Section 4: Recommendations

The COVID-19 pandemic has reminded us that the window of opportunity for scaling up vaccination in a pandemic is very short. The time to prevent widespread illness, death and economic loss may be very limited, and political will and community demand may also fade before the danger is over, as has happened with COVID-19. For this pandemic, the critical window was during 2020 and 2021. The recommendations presented below therefore focus on how a future initiative can learn from the COVAX Facility experience and respond effectively in the first 24 months of a pandemic or within the first 12 months of a global vaccine roll-out.

An initiative to ensure equitable access to vaccines in a pandemic must have an end-to-end approach, addressing the full, integrated range of functions and processes required to bring vaccines in a timely fashion to those at risk. In this light, we offer recommendations in the following areas: design (process and high-level choices), governance and management, supply, allocation and vaccine roll-out.

Such an initiative must be, as COVAX was, a joint undertaking of agencies with different mandates and capabilities. An end-to-end initiative must be, as COVAX was, a joint undertaking of agencies with different mandates and capabilities. Although our main focus is on *what* a "future COVAX" should do rather than *who* should do it, we do make some recommendations on roles in certain areas where the evidence from our evaluation supports this. As our evaluation has mainly focused on Gavi's role in COVAX, not those of other partners in the mechanism, our suggestions on future responsibilities also primarily concern Gavi.

Recommendation area 1 – Design

High-level design principles and features

- **1.1: Design choices should be based on the understanding that stakeholder behaviors will largely echo those seen in the early stages of the COVID-19 pandemic.** In particular, HICs will serve their own national interests first in seeking to secure scarce vaccines, and other commodities and manufacturers will in most cases give priority to markets in HICs. As such, any future multilateral pandemic response should be as robust as possible to the effects of vaccine nationalism and commercial interest, while at the same time working to strengthen global solidarity and promote cooperative behavior.
- **1.2: Noting that a future international vaccine procurement and allocation mechanism may be one of many such mechanisms, it should be clear that its primary focus is to support those countries with the least ability to procure independently and most likely to depend on such a mechanism.** Although there are benefits from including HICs, the experience of COVAX suggests that these benefits were outweighed by added complexity and dilution of the core mission. If better-off countries such as UMICs are allowed to opt into or procure through the mechanism, care must be taken that this does not jeopardize access for LICs and LMICs.
- **1.3: Before the next pandemic, WHO, WTO, or other agencies with a normative mandate, should assess the best way to address the liability risk to manufacturers and enable them to provide new health products in emergencies, without shifting the liability risk to recipient LIC, LMIC or humanitarian agencies**. The evaluation found wide disagreement among stakeholders on whether the standardized I&L agreements and NFCS put in place by COVAX were an efficient solution or an unnecessary burden on country governments and donors.

Design process

- **1.4: The process of designing an international vaccine procurement and allocation mechanism for the next pandemic should be more inclusive, transparent and accountable than was the case for the COVAX Facility and AMC.** By more fully involving LICs, LMICs, regional bodies and civil society, including representatives of affected communities where

relevant, the future mechanism can benefit from more varied perspectives, avoid a perception of complicity with commercial and donor-country interests, and build a broader base of support.

- **1.5: The design of a future mechanism should begin well before the next pandemic, thereby allowing the time for broader engagement, by global south countries, regional bodies and civil society.** Decision making after a pandemic has begun, when speed is critical, should be overseen by a robust and participatory governance function.
- **1.6: The assumptions underlying the design of a future mechanism should be made explicit so the corresponding risks can be assessed and mitigation measures put in place where possible.**

Recommendation area 2 – Governance and management

- **2.1: Establish a governance and engagement mechanism that balances participation with transparency and accountability.** Governance of a pandemic vaccine procurement and allocation initiative should be as inclusive as possible and as the need for rapid decision-making permits. Where broad engagement is not possible, full transparency and public accountability on processes and outcomes become even more important. In line with recommendation 3.3, efforts should be made to increase the level of transparency over dealings with vaccine manufacturers.
- **2.2 Ideally, a future governance mechanism should oversee the entire initiative, including the actions of Gavi and other participating agencies.** In practice, this may be difficult to put in place. Whether or not a supra-organizational governance mechanism is established, any elements of the initiative hosted by Gavi should be overseen by a small but representative sub-committee of the Gavi Board, which should operate with a high degree of transparency and should be supported by working groups of each engaged constituency and for each technical area (e.g., supply, allocation, delivery).
- **2.3: Build management structures that draw on the established systems, processes, staff and culture of one or more existing organizations without allowing these structures and processes to impede unnecessarily the speed, flexibility and level of risk taking required in emergencies.** A number of the specific characteristics of future pandemic response initiative are suggested in the box below:

Key organizational and management characteristics for a future pandemic response

A future pandemic response initiative should be able to:

- Rapidly recruit sufficient staff, including by providing incentives and in-kind benefits to secure the right personnel at the right time
- Quickly bring in supplementary external expertise in areas where the in-house capacitated is insufficient
- Take risks, including financial risks, which requires acknowledgment and enabling guidance from the Board and senior management and delegation of decision-making authority from the Board to the management team
- Clarify roles, responsibilities and ways of working with financing agencies and implementing partners to minimize approval processes, both internally and between partners – this may be through a cross-partner, multi-disciplinary management team
- Draw on the systems, processes, expertise and capacities of organisations that specialise in emergency response, such as humanitarian agencies

Recommendation area 3 – Market shaping and supply

- **3.1: Play a stronger role in expanding global supply, through increasing R&D and manufacturing capacity and placing greater emphasis on tech transfer.** Given the daunting challenge of competing directly with HICs for scarce vaccine doses, increasing total supply as rapidly as possible to alleviate shortage should be a central priority for future outbreaks that strongly affect HICs. To achieve this, greater emphasis should be placed on tech transfer in order to bring as much production capacity online as quickly as possible. This will be particularly important if R&D success rates are lower than was the case with COVID-19 vaccines, leaving the world dependent on a small number of successful candidates. Specific recommended actions are suggested in the box below.[173]

  Investment in capacity and expanded tech transfer for future pandemics

  Specific actions should be taken in four areas:

  - In preparation for future outbreaks, significant investment should be made to expand vaccine production capacity by assisting additional producers to meet international quality standards and acquire capacity in specific vaccine platforms likely to be important in future outbreaks, such as RNA vaccines. In allocating investment, the benefits of greater geographic dispersal of vaccine production capacity, including for regional supply security, must be balanced against considerations of cost, time to readiness, and economic viability.
  - Capacity-building investments – and push funding for vaccine R&D during a pandemic – should be accompanied by access provisions that guarantee that if a relevant product comes to market, lower-income countries and/or an international mechanism buying on their behalf will have access to it at a reasonable price.
  - Vaccine developers should be pressed to commit to greater use of tech transfer – accompanied by sharing of relevant IP – as a means of rapidly expanding supply in an outbreak.
  - Substantial funding should be made available for facilitating tech transfer during the early stages of an outbreak.
  - Where possible, tech transfer requirements should be included in any deals struck with vaccine manufacturers (see below).

  It is recognized that responsibility for tech transfer and for building supplier capacity does not fall primarily to Gavi, as these functions are more suited to the mandates and capabilities of other agencies, notably CEPI and WHO. However, Gavi can do more in a future pandemic to integrate its activities as a buyer with the direct investments of others in tech transfer: the deal with SII can serve as one model towards this. Moreover, greatly expanded investments in supplier capacity and tech transfer will in turn require greater capacity to fulfil these functions than is now available in the international system. Filling this gap and further defining roles in this area should be a priority.

- **3.2: Refine the approach to APAs through greater access to at-risk funding at the start of future outbreaks in order to allow tech transfer and purchase agreements with product developers to be struck earlier and at greater scale.** This should be designed to cover the initial lag in the availability of resources at the outset of a pandemic, after which a dedicated fundraising vehicle could meet resource mobilization needs, as was the case with the COVAX AMC. Although such funding would probably not be sufficient by itself to overcome the buying power of HICs in a global pandemic, it could enable supply to be reserved from some manufacturers, as well as incentivizing vaccine development and supply in outbreaks that do not strongly affect HICs. Conditional funding commitments from donors or via IFFIm that

would be triggered during an outbreak may be the most efficient way to ensure early availability of funding. Greater flexibility to use donor pledges and other available resources (e.g. core or loaned funds) to enter into APAs would also support this objective.

- **3.3: Transparency on delivery queues should be a condition of APAs, and manufacturer behavior should be called out when transparency is not forthcoming or agreements on prioritization of delivery relative to other buyers are not honored.** During a period of supply shortage, it may not be possible to impose delivery timing conditions on suppliers, who may also be reluctant to make such commitments in the face of manufacturing and regulatory uncertainty. But greater transparency should be sought on supply capacity, commitments to other buyers and prioritization of deliveries. This information could then be used to hold manufacturers accountable, and to enable countries to plan for roll-out with greater certainty over vaccine supply.
- **3.4: The importance of price in affecting access to vaccine supply in competition with HICs paying higher prices should be carefully analyzed, and consideration given to paying more competitive prices in certain circumstances.** Such a policy should consider risks to the well-established tiered pricing model for routine vaccines, the differences between stable markets with adequate supply and supply-constrained outbreak vaccine markets, implications of pricing policies for self-financing UMICs, and the importance of price relative to other sources of HIC market power in influencing supply allocation.
- **3.5: Dose-sharing commitments should be spelled out and broadened in order to facilitate other sources of vaccine supply ahead of the next pandemic.** The IFPMA Berlin Declaration is an initial step in this direction, although crucial elements of the proposal remain to be clarified, including who would fund the vaccine doses earmarked for LMICs. Voluntary dose-sharing initiatives from pharma, in any case, can only be one arm of a comprehensive strategy to ensure equitable access.[174] Ideally, such a strategy would also involve commitments on the part of HICs and other countries with manufacturing capacity, perhaps embedded in a pandemic treaty.
- **3.6: Consolidate in advance processes for efficiently managing donation of excess vaccine procured by HICs and other buyers**. Although such donations cannot be counted on, as there is no guarantee that substantial excess supply will emerge in future outbreaks, they can be an important source of supply. The processes developed during the COVID-19 pandemic – which involve agreements among and actions by donor nations, manufacturers and recipient countries, as well as Gavi – should serve as a useful model. Purchases facilitated by HICs, as exemplified by the US arrangement with Pfizer and COVAX, can also be a useful model although, like donations, it depends on the availability of spare manufacturing capacity.
- **3.7: Make greater use of soft power to influence the behavior of vaccine manufacturers and HICs**. This influence, which should be exercised in cooperation with funding and implementing partners (e.g. Gavi, WHO, UNICEF, World Bank), LMICs and civil society, could involve public communication, advocacy, transparency indices,[175] translation of commitments to measurable targets, and other tools. As well as helping to improve the transparency over the issues being experienced with stakeholder behaviour in support of recommendation 2, it could be used to pressure manufacturers to make supply available in a timely fashion to LMICs and to COVAX or a successor initiative, promote tech transfer and IP sharing when this is important for expanding supply rapidly, and demand greater transparency from manufacturers and buyers alike on purchase agreements and delivery queues. These tools could also be used to discourage vaccine hoarding and export bans by HICs and other countries with manufacturing capacity. Other tools may also have some leverage, such as restricting the list of speakers at global events to representatives from only those countries whose behaviors and practices align to the initiative's stated principles. It is, however, acknowledged that an initiative's

ability to influence decisions made by national governments under pressure to protect their own populations will always be limited.

Recommendation area 4 – Allocation

- **4: Design a framework for global allocation of scarce commodities based on a set of guiding principles.** For a supply-constrained period of a future pandemic, an agreed normative framework for allocation is required. As with the COVID-19 WHO Fair Allocation Framework, this should set out the definitions and principles for 'equitable' allocation across countries and/or population groups. Principles should not be interpreted as rules, and trade-offs between principles should be considered at the outset. The objective should be to have a framework that can be applied quickly and flexibly to an uncertain context so as to maintain focus on global objectives. WHO, with its unique normative legitimacy, should play the leading role in the development of such a framework, which would ultimately rest on international human rights agreements, as well as a pandemic treaty, should such an accord be agreed. Additional considerations for an effective framework are detailed the box below.

Considerations for an effective framework for global allocation of scarce commodities:

- All sources of supply to countries must be taken into account in allocating supply from an international vaccine procurement mechanism such as COVAX. This will require data to be made available in line with recommendation 3.3.
- In designing an allocation mechanism, the objective of optimally allocating scarce resources should be balanced against the benefits of speed, simplicity and transparency, so that countries and other stakeholders can understand how allocation works.
- Without compromising the principles of speed and simplicity, product preferences and information on country absorptive capacity should be sought early and on a continuous basis and used to inform country allocations. Clear principles should be in place to ensure that countries have the option of other products if these become available earlier than preferred products.
- Different pathways for allocation should be designed to meet special circumstances, such as situations in which doses must be used quickly or are geographically restricted by a donor.
- Members of governance bodies should be accorded sufficient time to understand proposed allocations as well the challenges faced by those operationalizing the mechanism. This will enable appropriate oversight and fully informed decision making.
- Communication of decisions should seek to provide countries with short-term, medium-term and long-term forecasts of anticipated vaccine availability and allocation, while seeking to manage expectations and communicate the level of uncertainty attached to each.

Recommendation area 5 – Vaccine roll-out and delivery support

- **5: Strengthen coordination among global partners (donors, MDBs, multilateral agencies and TA providers) to ensure the timely availability of financial and technical support for vaccine roll-out.** Responsibility for coordination should sit with one agency, likely WHO working on behalf of the Alliance, with others taking responsibility for different aspects of the work, such as financing, procurement and delivery of TA. As well as at the global level, roles and responsibilities at the regional and national level should be set out and defined in advance of the next pandemic. The COVAX Facility's experience of providing vaccine delivery support suggests that substantial volumes of funding should be provided to strengthen preparedness before the next pandemic, but if this does not take place to the extent required, funding for delivery support should be provided as early as possible and on a no regrets basis, or at least with predetermined processes for application, compliance and monitoring to meet basic risk requirements, the terms of which should be defined up front. This will be especially important if much greater vaccine supplies are to reach LMICs and LICs more quickly than was the case for COVID-19 vaccines. Critically, this support should be used to promote equitable distribution of vaccines within countries, and greater accountability for achieving this outcome should rest with the providers of financial and technical support. Investments should also seek to protect Gavi's routine immunization investments, both in the short term and longer-term.

Itad is a global organisation. Our strategy, monitoring, evaluation and learning services work to make international development more effective. We generate evidence on important issues – from malnutrition to migration – to support our partners to make informed decisions and improve lives.

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Endnotes

[1] Delivering just under 1 billion to mostly AMC countries
[2] Delivering 833 million doses to AMC countries
[3] At the same time as this Itad evaluation was being implemented, a number of other evaluation projects were active in/around the ACT-A, Gavi and COVAX pillar space, including the Gavi COVID-19 Response evaluation by Euro Health Group; IEG's evaluation of the World Bank's Early Support to Addressing COVID-19 - Health and Social Response, and the External Evaluation of the ACT-Accelerator.
[4] The criteria matrix included: income level, WHO region, COVID-19 vaccination coverage (initial protocol as a % of population; absorption rate, reliance on COVAX vaccine supply (as a % of total vaccines), level of CDS funding, feasibility (security, consultant networks) and whether the country was selected by EHG for the COVID-19 Response evaluation and/or other programmatic audits or evaluation work. A range of countries across these criteria were selected.
[5] This section relates to EQ 1.1: 'To what extent are the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, and is the overall design clear and coherent?'
[6] https://www.gavi.org/sites/default/files/2020-06/Gavi-COVAX-AMC-IO.pdf
[7] Gavi Board Papers. (2020, December). Accessed at: https://www.gavi.org/governance/gavi-board/minutes/15-december-2020
[8] Delivering vaccines from manufacturers to countries is the role of UNICEF (and PAHO) and outside of the scope of this evaluation.
[9] Ducharme, J. (2021, September 9). COVAX Was a Great Idea, But Is Now 500 Million Doses Short of Its Vaccine Distribution Goals. What Exactly Went Wrong?. Time. Accessed at: https://time.com/6096172/covax-vaccines-what-went-wrong/
[10] Médecins Sans Frontières Access Campaign. (2021, December 21). *COVAX: A Broken Promise to the World*. Accessed at: https://msfaccess.org/sites/default/files/2021-12/Covid19_IssueBrief_Covax_1708_ENG_21.12.2021.pdf
[11] Gavi Board Presentation.(2020, December). Accessed at: https://www.gavi.org/governance/gavi-board/minutes/15-december-2020
[12] e.g. World Bank Group. (2022, May 17). A Proposed Financial Intermediary Fund (FIF) for Pandemic Prevention, Preparedness and *Response Hosted by the World Bank: White Paper.* Accessed at: https://thedocs.worldbank.org/en/doc/018ab1c6b6d8305933661168af757737-0290032022/original/PPR-FIF-WB-White-Paper.pdf; Agarwal, R. and Reed, T. (2022, May). *Financing Vaccine Equity: Funding for Day-Zero of the Next Pandemic.* World Bank. Accessed at: https://openknowledge.worldbank.org/handle/10986/37488
[13] International Federation of Pharmaceutical Manufacturers & Associations. (2022, May). *Applying Lessons Learned from Covid-19 to Create a Healthier, Safer, More Equitable World*. Accessed at: https://www.ifpma.org/wp-content/uploads/2022/05/IFPMA_Covid-19_Pandemic_Lessons_Learned_May_2022.pdf
[14] Hannon, E., Hanbali, L., Lehtimaki, S. and Schwalbe, N. (2022, July 13). Why we still need a pandemic treaty. *The Lancet*, 10(9), pp.E1232-E1233. Accessed at: https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(22)00278-9/fulltext; Bruce Aylward in Cullinan, K. (2022). *Covid-19 Support Steady Despite Global Partnership's 'Transition'*. Health Policy Watch. Accessed at: https://healthpolicy-watch.news/covid-19-support-steady-despite-global-partnership-transition/; Moon, S. *et al.* (2022, January 29). Governing the Access to Covid-19 Tools Accelerator: towards greater participation, transparency, and accountability. *The Lancet*, 399. Accessed at: https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(21)02344-8.pdf
[15] Hunter, D. et al. (2022, March 24). Addressing Vaccine Inequity — Covid-19 Vaccines as a Global Public Good. *New England Journal of Medicine*, 386(12), pp.1176-1179. Accessed at: https://www.nejm.org/doi/full/10.1056/NEJMe2202547; The Independent Panel for Pandemic Preparedness and Response. (2021, May 12). *Covid-19: Make it the Last Pandemic*. WHO. Accessed at: https://reliefweb.int/report/world/covid-19-make-it-last-pandemic-enarruzh; Yunus, M. (2022, May 28). *Preparing for the next pandemic: Time to follow a social business model for patent-free global medicine production*. STAT. Accessed at: https://www.statnews.com/2022/05/28/social-business-model-global-drug-production/?; Yamey, G. et all. (2022, March 24). It is not too late to achieve global covid-19 vaccine equity. *BMJ*. Accessed at: https://www.bmj.com/content/376/bmj-2022-070650; Moon, S. *et al.* (2021, September 20). Embedding global access in development of future pandemic vaccines. *BMJ*. Accessed at: https://www.bmj.com/content/374/bmj.n2256
[16] Office High Commission of Human Rights, 2020, Human rights and access to covid-19 vaccines. Accessed at: https://www.ohchr.org/sites/default/files/Documents/Events/COVID-19_AccessVaccines_Guidance.pdf
[17] These findings relate to EQ 1.3: 'How did external stakeholders and COVAX partners contribute to the original design, and subsequent design revisions of the COVAX Facility and AMC, and what impact did this have?'
[18] MM Global Health Consulting. (2021, August). Documentation Project: To synthesis core design decisions taken on the COVAX Facility and AMC.
[19] Friends of COVAX was co-chaired by Singapore and Switzerland, and comprised the following countries and the European Union: Australia, Canada, Iceland, Israel, Japan, Kingdom of Saudi Arabia, New Zealand, Norway, Qatar, the Republic of Korea, Singapore, Switzerland, the United Arab Emirates and the United Kingdom.
[20] Yoo, K. *et al.* (2022). COVAX and equitable access to Covid-19 vaccines. *Bulletin of the World Health Organization*, 100(05), pp.315-328. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9047429/pdf/BLT.21.287516.pdf; Médecins Sans Frontières Access Campaign. (2021, December 21). *COVAX: A Broken Promise to the World*. Accessed at: https://msfaccess.org/sites/default/files/2021-12/Covid19_IssueBrief_Covax_1708_ENG_21.12.2021.pdf
[21] Some stakeholders noted that this decision was linked to the Market-Sensitive Decisions Committee's decision to incorporate two Chinese-manufactured vaccines into the COVAX Facility portfolio, although this has not been confirmed by the Evaluation Team.
[22] de Bengy Puyvallée, A. and Storeng, K. (2022, March 5). COVAX, vaccine donations and the politics of global vaccine inequity. *Globalization and Health*, 18(26). Accessed at: https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00801-z
[23] This section relates to EQ 1.3: 'How did external stakeholders and COVAX partners contribute to the original design, and subsequent design revisions of the COVAX Facility and AMC, and what impact did this have?' See also earlier findings on the engagement of AMC beneficiary countries and civil society in the original design process.
[24] COVAX. (2020, November 29). *Breifing Note: Additional information on indemnification for COVAX AMC participants.* WHO. Accessed at: https://www.who.int/docs/default-source/coronaviruse/act-accelerator/briefing-note-indemnification-and-compensation-covax-amc-countries.pdf
[25] Civil society letter on COVAX Facility Preliminary Technical Design, 23 June 2020. Available at https://msfaccess.org/open-letter-gavi-board-members-urgent-changes-covax-facility-design-required-ensure-access-covid-19
[26] See also country case studies.

[27] Bentley, A. and Zerie, B. (2021, September). *Less than a Lifeline: Challenges to the COVAX Humanitarian Buffer*. Refugees International. Accessed at: https://static1.squarespace.com/static/506c8ea1e4b01d9450dd53f5/t/614b8fce68e7f5475d4e719d/1632341967411/Humanitarian+Buffer+Issue+Brief+FINAL%5B7%5D.pdf.; Gavi. (2022, June). *Discussion Paper: Taking stock of humanitarian access to pandemic vaccines.* Accessed at: https://www.gavi.org/sites/default/files/covid/covax/taking-stock-of-humanitarian-access-to-pandemic-vaccines-dp.pdf

[28] Eritrea did not join the COVAX AMC in 2021 and Marshall Islands opted out of the COVAX AMC as its needs were sufficiently met through other means). At the end of 2021, Burundi was in the process of joining as an AMC participant. Gavi. (2021). *2021 End of Year COVAX Reporting Framework Report.*

[29] Manuel Barroso, J. (2021, August 3). *Intellectual Property and Covid-19 vaccines*. Gavi. Accessed at: https://www.gavi.org/vaccineswork/intellectual-property-and-covid-19-vaccines

[30] Gavi. (2021, July 20). *The COVAX No Fault Compensation Programme: Explained*. Accessed at: https://www.gavi.org/vaccineswork/covax-no-fault-compensation-programme-explained

[31] This section relates to EQ 1.2: 'Recognizing the dynamic nature of the pandemic and geopolitical context, what design revisions were made since the original design, and why?'

32 Not licensed for use at the time country agreements were being put in place

[33] Gavi COVAX Allocation explainer version 3.

[34] e.g. the FER policy in Gavi 4.0. Source: GCDOC38_08 - COVAX Facility Operationalisation and Vaccine Programme.pdf

[35] IASC HB website updated 16 May 2022. Accessed at: https://interagencystandingcommittee.org/system/files/2022-05/Frequently%20Asked%20Questions-%20The%20COVAX%20Humanitarian%20Buffer%2C%2016%20May%202022.pdf

[36] At a later stage, $7.5 million would be allocated for special needs in AMC countries only.

[37] MSF, press release, 27 April 2022: 'Broken humanitarian vaccine system delays vaccinations'.

[38] 2022 Preparing for the next pandemic - lessons from COVAX, and CE report 2021.

[39] KII Gavi.

[40] Analysis of NFCS data.

[41] 2022 Preparing for the next pandemic - learnings from COVAX.

[42] The Gavi Board is comprised of four permanent seats for representatives of the Gates Foundation, UNICEF, WHO and World Bank, and 18 rotating seats, 5 from developing country governments, 5 from donors, 1 from research health institutes, 1 from developing country vaccine industry, 1 from industrialised country vaccine industry, 1 from civil society, and 9 independents.

[43] Jaupart, P., Dipple, L. and Dercon, S. (2019, December 3). Has Gavi lived up to its promise? Quasi-experimental evidence on country immunisation rates and child mortality. *BMJ Global Health, 4(6).* Accessed at: https://gh.bmj.com/content/4/6/e001789.citation-tools

[44] In addition, although a number of SFPs are in theory represented as donors, representatives tend to come from donor country development agencies and not the health ministry responsible for vaccine procurement.

[45] We understand that 6 additional Board meetings, at least 1 PPC meeting, 13 AFC and 2 Governance Committee meetings were held in 2020 and 2021 than would normally have been scheduled, with analysis suggesting that the COVAX Facility was discussed or the main agenda item in 83% of meetings where minutes are available.

[46] Gavi. (2020, May 11). *Review of Decisions: Board Meeting*. Accessed at: https://www.gavi.org/sites/default/files/board/minutes/2020/11-may/Board-2020-Mtg-2-Review-of-Decisions.pdf

[47] Gavi. (2021, November 30 – December 2). *Review of Decisions: Board Meeting*. Accessed at: https://www.gavi.org/sites/default/files/board/minutes/2021/30-nov/Board-2021-Mtg-4-Review%20of%20Decisions.pdf

[48] Dalberg. (2021, October 8). *ACT-Accelerator Strategic Review: An independent report prepared by Dalberg*. WHO. Accessed at: https://www.who.int/publications/m/item/act-accelerator-strategic-review

[49] The Gavi Board decided at its December 2021 meeting to establish a temporary Steering Committee of the Board with delegated authority over delivery related strategy and decisions of the COVAX Facility, and to oversee COVID-19 vaccine delivery support provided by COVAX. This is intended to include representation of key partners not on the Gavi Board (e.g. AU/AVATT) to maximise coordination.

[50] This includes: the Research and Development and Manufacturing Investment Committee (RDMIC); the Technical Review Group (TRG); SWAT teams, including Clinical Development and Operations SWAT, Enabling Sciences SWAT, Manufacturing SWAT, and Regulatory Advisory Group (RAG); WHO Strategic Advisory Group of Experts (SAGE) Working Group on Covid-19 vaccines; Policy and Allocation Working Groups, including Vaccine Strategy Sub-Working Group, and Vaccine Policy Sub-Working Group.

[51] COVAX. (2020, November 9). *COVAX: The vaccines pillar of the access to Covid-19 tools (ACT) Accelerator Structure and Principles*. WHO. Accessed at: https://www.who.int/publications/m/item/covax-the-vaccines-pillar-of-the-access-to-covid-19-tools-(act)-accelerator

[52] Gavi. (2022, February 28). 2021 COVAX Learning Synthesis: Shifting from programme design to delivery & demand.

[53] For instance with the JAT, IAVG and four working groups of the Access and Allocation Sub-Working Group

[54] For instance, the RDMIC provides investment oversight for the COVAX R&D portfolio, accountable to the CEPI Board. While distinct from the COVAX Facility (procurement) portfolio, it frequently considered issues across the R&D portfolio in view of the potential impact on downstream procurement. However, the COVAX Facility also had a separate scientific and technical advisory group (the Independent Product Group) to ensure objectivity in procurement decisions. The lack of clarity over the scope of each body's responsibility and decision-making pathways was described by stakeholders interviewed for this evaluation, from the perspective of the COVAX Facility, as duplicative and unnecessarily bureaucratic. MM Global Health Consulting. (2021, August 1). *Documentation Project: To synthesis core design decisions taken on the COVAX Facility and* COVAX *AMC.*

[55] Nonetheless, it is understood that feedback such as this was fed up into the PPC and other existing Gavi governance bodies, including through the same members being on both the Council and Gavi Board (again reflecting an issue with duplication between bodies).

[56] Moon, S. *et al.* (2022, January 29). Governing the Access to COVID-19 Tools Accelerator: towards greater participation, transparency, and accountability. *The Lancet*, 399(10323), pp.487–-494. Accessed at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02344-8/fulltext

[57] Development Tracker Foreign, Commonwealth and Development Office. (2022). *COVID-19 vaccine funding for the COVAX Advance Market Commitment using IFFIm – Annual Review*. Accessed at: https://devtracker.fcdo.gov.uk/projects/GB-GOV-1-301271/documents

[58] Gavi. (2020). *Risk* and *Assurance Report 2020*. Accessed at: https://www.gavi.org/sites/default/files/document/strategy/Risk-and-Assurance-Report-2020.pdf
[59] AccountAbility. (2015). Accessed at: *AA1000 Stakeholder Engagement Standard 2015.* https://www.accountability.org/static/940dc017198458fed647f73ad5d47a95/aa1000ses_2015.pdf
[60] For instance, Sridhar Venkatapuram (Senior Lecturer in Global Health and Philosophy at King's College, London) was quoted as saying that communications were used 'essentially [to] speak to rich country leaders and rich countries, and to try to get them to join and cooperate, while not giving us a really good indication of the kind of precarious situation that we were in'. Browne, G. (2021, December 20). *2021 Revealed the Depths of Global Vaccine Inequity*. WIRED. Accessed at: https://www.wired.co.uk/article/2021-vaccine-inequity
[61] Gavi's internal learning points to anecdotal evidence of some people losing their jobs for not getting access to doses and/or being held responsible for delayed timelines for receipt of vaccines. Gavi. (2022, February 28). *2021 COVAX LEARNING SYNTHESIS: Shifting from programme design to delivery & demand.*
[62] The relationship between Gavi and international civil society, and the access to medicines community in particular, has been and remains complicated. However, it appears that these organizations have often been more focused on criticizing Gavi and COVAX for having a too-close relationship with industry rather than with holding industry accountable for short-changing COVAX.
[63] This included providing regular briefing sessions, FAQs, biweekly newsletters and situation reports, in addition to official notification letters on dose allocations and frequent bilateral exchanges. Gavi. (2021, June 16). *Report of the Chief Executive Officer: Report to the Board*
[64] Gavi. (2022, February 28). 2021 COVAX LEARNING SYNTHESIS: Shifting from programme design to delivery & demand.
[65] For instance, Médecins Sans Frontières Access Campaign. (2021, December 21). *COVAX: A broken promise to the world.* Accessed at: https://msfaccess.org/sites/default/files/2021-12/COVID19_IssueBrief_Covax_1708_ENG_21.12.2021.pdf; Furneaux, R., Goldhill, O. and Davies, M. (2021, October 8). *How Covax failed on its promise to vaccinate the world*. The Bureau of Investigative Journalism. Accessed at: https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world
[66] These features accord with two established patterns of collaborative dysfunction, typical of a system that is both 'overwhelmed' and suffering from 'priority overload.' Typical solutions to these patterns will be considered in the development of recommendations.
Cross, R. and Carboni, I. (2021, December 8). *When collaboration fails and how to fix it*. MIT Sloan Management Review, Winter 2021. Accessed at: https://sloanreview.mit.edu/article/when-collaboration-fails-and-how-to-fix-it/
[67] As of December 2020, the risk matrix was still described by the Governance Committee as 'incomplete and that many of the risks described do not have any proposed mitigation'. Gavi. (2020, December 10). *Governance Committee Meeting*.
[68] However, there is now, in mid-2022, uncertainty as to whether and to what the Board's expressed risk appetite still applies, with different teams appearing to take different approaches.
[69] Once an APA was struck, sufficient resources required to fulfil the firm order commitment are 'set aside' and cannot be used for other purposes until either they are provided to the manufacturer in exchange for the agreed vaccine supply or the contractual obligation to purchase the doses no longer applies. This does not apply to any doses where Gavi has an option to purchase.
[70] Gavi. (2021). *2021 End of Year COVAX Reporting Framework Report.*
[71] While this must be interpreted in the context of there being an incredibly strong investment case for scaling up global COVID-19 vaccination, the scale and timing of fundraising can be compared to the Global Fund, which raised $14 billion for the 2021–2023 grant cycle ($4.7 billion p.a.) through its sixth replenishment, and Gavi, which raised $8.8 billion for the period 2021–2025 ($1.8 billion p.a.) through the Global Vaccine Summit.
[72] IFFIm was used to support CEPI's vaccine research and development for COVAX.
[73] Development Tracker Foreign, Commonwealth and Development Office. (2022). *COVID-19 vaccine funding for the COVAX Advance Market Commitment using IFFIm – Annual Review*. Accessed at: https://devtracker.fcdo.gov.uk/projects/GB-GOV-1-301271/documents
[74] Some donations were accepted earlier, including 1.7 million doses from New Zealand earmarked for the Asia-Pacific region.
[75] Gavi. (2021). COVAX: *Resource Mobilisation Update. Report to the Board*. Accessed at: https://www.gavi.org/sites/default/files/board/minutes/2021/30-nov/07b%20-%20COVAX%20Resource%20Mobilisation%20Update.pdf.
[76] Gavi. (2021). *2021 End of Year COVAX Reporting Framework Report.*
[77] Data as of December 2021, taken from the Gavi COVAX AMC 2022 Investment Opportunity, released in January 2022. Subsequent data provided by Gavi appears to suggest that some further pledges and cash contributions were received by the end of 2021. The value of dose donations is estimated by multiplying the volume of doses administered through the COVAX Facility in 2021 by the estimated prices paid, as reflected elsewhere in the report.
[78] Gavi. (2021). *COVAX: Resource Mobilisation Update. Report to the Board.* Accessed at: https://www.gavi.org/sites/default/files/board/minutes/2021/30-nov/07b%20-%20COVAX%20Resource%20Mobilisation%20Update.pdf
[79] Gavi. (2021). *2021 End of Year COVAX Reporting Framework Report.*
[80] Gavi. (2020, March 19). *Gavi Alliance Board Meeting: Minutes.*
[81] Berkley, S. (2020, July 30). *Gavi COVAX AMC & COVAX Facility Structure and Governance: Board Meeting. Gavi.*
[82] Gavi. (2020, May). *Gavi Alliance Programme and Policy Committee Meeting: Minutes.*
[83] Gavi. (2020, July 30). *COVAX Facility Structure and Governance: Report to the Board.*
[84] Volta Capital. Pandemic Action Network. Africa Centres for Disease Control and Prevention. (2021, September 8). *Addressing Market Failures: The Role of CEPI in Bridging the Innovation Gap to Prevent the Next Pandemic.* Accessed at: https://africacdc.org/download/addressing-market-failures-the-role-of-cepi-in-bridging-the-innovation-gap-to-prevent-the-next-pandemic/
[85] Gavi. (2020, June). *COVID-19 Vaccine Development, Access and Deliver: Report to the Board.*
[86] Gavi. (2020, July). *GAVI COVAX AMC: Report to the Board.*
[87] Snyder, C.M. *et al.* (2020); Designing pull funding for a Covid-19 vaccine. Health Affairs 39:1633-1642.
[88] Volta Capital. Pandemic Action Network. Africa Centres for Disease Control and Prevention. (2021, September 8). *Addressing Market Failures: The Role of CEPI in Bridging the Innovation Gap to Prevent the Next Pandemic.* Accessed at: https://africacdc.org/download/addressing-market-failures-the-role-of-cepi-in-bridging-the-innovation-gap-to-prevent-the-next-pandemic/
[89] Gavi. (n.d.). *The Gavi COVAX AMC An Investment Opportunity.*
[90] COVID-19 Vaccine Global Access (COVAX) Facility: Preliminary technical design document. June 2020. Available at https://www.keionline.org/wp-content/uploads/COVAX-Facility-Preliminary-technical-design-061120-vF.pdf

[91] Furneaux, R., Goldhill, O. and Davies, M. (2021, October 8). *How Covax failed on its promise to vaccinate the world*. The Bureau of Investigative Journalism. Accessed at: https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world. ; See also June 2020 civil society letter on COVAX design. (complete citation to come).
[92] Civil society letter on COVAX Facility Preliminary Technical Design, 23 June 2020. Available at https://msfaccess.org/open-letter-gavi-board-members-urgent-changes-covax-facility-design-required-ensure-access-covid-19
[93] Hatchett R., Saville M., Downham M. (2021). Towards vaccinating the world. Landscape of current COVID-19 supply chain and manufacturing capacity, potential challenges, initial responses, and possible "solution space". Chatham House Discussion Document.
[94] The document *Break Covid Now: The Gavi COVAX AMC Investment Opportunity* (January 2022, Gavi) states, "If we [the global health community] are to be prepared for the next pandemic, we need to increase global manufacturing capacity too, particularly in regions with low manufacturing capacity. And while COVAX supports any measures that increase the sharing of intellectual property, encouraging the further use of tech transfers is the best way to ensure there is adequate supply, without removing the incentives for manufacturers to develop the vaccines we desperately need."
[95] Fiocruz. (2020)Technology Transfer Agreement. Accessed at: https://agencia.fiocruz.br/sites/agencia.fiocruz.br/files/u34/contrato_etec.pdf
[96] Senado Federal (2021) Relatório final da Pandemia. Brazil, 1288 p.
[97] Volta Capital. Pandemic Action Network. Africa Centres for Disease Control and Prevention. (2021, September 8). *Addressing Market Failures: The Role of CEPI in Bridging the Innovation Gap to Prevent the Next Pandemic.* Accessed at: https://africacdc.org/download/addressing-market-failures-the-role-of-cepi-in-bridging-the-innovation-gap-to-prevent-the-next-pandemic/
[98] Congressional Research Service. (2021, March 1). *Operation Warp Speed*. US Department of Health & Human Services.
[99] KII, Gavi Secretariat.
[100] Furneaux, R., Goldhill, O. and Davies, M. (2021, October 8). *How Covax failed on its promise to vaccinate the world*. The Bureau of Investigative Journalism. Accessed at: https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world
[101] It was also noted by those involved in the deal that COVAX did not approach the government of India to mitigate any potential export control risks before the ban was put in place, despite confidential memos from UNICEF warning them of the risks and in addition to the India-specific special session held by the PPC to discuss AMC implementation in late 2020 which highlighted the need to work with the government of India and acknowledge their importance to overall vaccine manufacturing in the allocation strategy.
[102] During the period of the export ban, however, *COVAX-funded* doses were not distributed in India.
[103] Future pandemics will not always involve the same successful manufacturers, and that introduces a lot of uncertainty. Norms established specifically with COVID-19 vaccine manufacturers may not apply to a new set of manufacturers in the future unless codified in some way with the global community.
[104] BLT.21.285761.pdf. (complete citation to come).
[105] Some vaccine prices are public (https://www.unicef.org/supply/media/11336/file/Covid-19-vaccine-prices.pdf); the Pfizer price is an ITAD estimate based on public information.
[106] Gavi. (2022). *Gavi Secretariat Report.*
[107] AstraZeneca publicly committed to providing non-profit pricing of $4/dose for the first 3 billion doses, regardless of procurer.
[108] Some vaccine prices are public (https://www.unicef.org/supply/media/11336/file/Covid-19-vaccine-prices.pdf); the Pfizer price is an ITAD estimate based on public information.
[109] The UN also includes a clause in their procurement contracts obligating manufacturers to provide them the lowest negotiated market price.
[110] d41586-022-00809-w.pdf. (complete citation to come).
[111] Gavi. (2020, March 19). *Gavi Alliance Board Meeting: Minutes.*
[112] AstraZeneca. (2021, April 26). *Statement on EU legal action*. Accessed at. https://www.astrazeneca.com/media-centre/statements/2021/statement-on-eu-legal-action.html
[113] Agarwal, R. & Reed, T. (2022): Financing vaccine equity: Funding for day-zero of the next pandemic. IMF working paper.
[114] AstraZeneca. (2021, April 26). *Statement on EU legal action*. Accessed at. https://www.astrazeneca.com/media-centre/statements/2021/statement-on-eu-legal-action.html
[115] Congressional Research Service. (2021, March 1). *Operation Warp Speed*. US Department of Health & Human Services.
[116] Bollyky, T. and Bown, C. (2021, June 24). *The Real Vaccine Procurement Problem: Why America Should Make Its Supply Chain More Transparent.* Foreign Affairs. Accessed at: https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/bown_pres3.pdf
[117] The doses purchased by COVAX are sometimes referred to as 'US-facilitated purchases', although in some US communications they are bundled with US-purchased doses as donated doses.
[118] de Bengy Puyvallée, A. and Storeng, K. (2022, March 5). COVAX, vaccine donations and the politics of global vaccine inequity. *Globalization and Health*, 18(26). Accessed at: https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00801-z
[119] DFID COVAX AMC end of year report & COVAX Vaccine Outlook for 2022 (presentation, 13 January 2022). (complete citation to come).
[120] Strategic Advisory Group of Experts.
[121] Hatchett, R. (2020, March 25). *A proposal to establish a globally fair allocation system for COVID-19 vaccines.*
[122] Gavi Board Decision. (2021, September). Accessed at: https://www.gavi.org/governance/gavi-board/minutes/28-september-2021
[123] In contrast, Pfizer doses sourced through the US government-facilitated purchase were much more manageable in this regard, providing good visibility of supply up to five months in advance.
[124] Sharafudeen, M. (2021, December 14). *From availability to arrival: How COVAX doses make it to countries*. Gavi. Accessed at: https://www.gavi.org/vaccineswork/availability-arrival-how-covax-doses-make-it-countries
[125] While the initial design did not specify how many rounds would be conducted, we understand that significantly fewer rounds were envisaged for larger volumes of doses from multiple manufacturers.
[126] Administrative adjustments are intended to address swift operational issues for a limited number of doses which must be quickly allocated to participants due to a variety of reasons, including short shelf life issues, closing out Optional Purchaser SFPs, and some cost-sharing doses procured exceptionally by some participants. These processes, along with the processes for dose donations, were conducted by the JAT, and while the IAVG was updated on these adjustments, they were not subject to the IAVG's formal review or the WHO DDG's approval as they were considered outside of the WHO Fair Allocation Framework. This was not anticipated in the original design.

[127] For instance, doses to the DRC and South Sudan were returned and most redeployed to other countries in Africa. Furneaux, R., Goldhill, O. and Davies, M. (2021, October 8). *How Covax failed on its promise to vaccinate the world*. The Bureau of Investigative Journalism. Accessed at: https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world
[128] This number was later substantially reduced due to supply issues and reallocations.
[129] In particular, this relates to Round 2 (allocation of 237 million AstraZeneca and SII COVISHIELD doses across 143 countries), Round 4 (allocation of 17 million second dose needs from Round 2 in 43 countries), Round 5 (allocation of 127 million Pfizer, AstraZeneca, Moderna and Janssen doses across 99 countries) and Round 6 (allocation of 100 million Sinovac and Sinopharm doses across 60 countries).
[130] Over this time and for rounds 1–6 there was little information held centrally on, and consideration paid to, country absorptive capacity and the implications of this for allocation. This was acknowledged by the AFC to be a 'delicate and politically sensitive [issue] that required a clear process for unblocking doses', linked to the need for vaccine delivery support. [REF AFC-20~1.PDF]. (complete citation to come).
[131] This is well visualized in Figure 2 of GCDOC111, where after stripping out dose donations for rounds 1–5, countries have been allocated very similar volumes of doses per capita, except for some small countries where logistical reasons led to a decision to increase the allocation size.
[132] Similar situations occurred for other HICs, such as Australia and Canada.
[133] CoVDP data suggests that by the end of 2021, 25 out of 208 countries had vaccine coverage less than 10% – 23 of which were AMC participants, 16 of which were LICs and 7 of which were LMICs.
[134] The Access and Allocation Working Group, led by WHO, brings together a range of COVAX partners who work together to design the operationalization of the WHO-developed Fair Allocation Framework, the governance of the Allocation Mechanism, and the scope, governance and operationalization of the COVAX Emergency Buffer.
[135] Development Tracker Foreign, Commonwealth and Development Office. (2022). *COVID-19 vaccine funding for the COVAX Advance Market Commitment using IFFIm – Annual Review*. Accessed at: https://devtracker.fcdo.gov.uk/projects/GB-GOV-1-301271/documents
[136] For instance, Médecins Sans Frontières Access Campaign. (2021, December 21). *COVAX: A broken promise to the world.* Accessed at: https://msfaccess.org/sites/default/files/2021-12/COVID19_IssueBrief_Covax_1708_ENG_21.12.2021.pdf; Furneaux, R., Goldhill, O. and Davies, M. (2021, October 8). *How Covax failed on its promise to vaccinate the world*. The Bureau of Investigative Journalism. Accessed at: https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world
[137] This is identified in Gavi's internal learning, which points to anecdotal evidence of some people losing their jobs for not getting access to doses and/or being held responsible for delayed timelines for receipt of vaccines. Gavi. (2022, February 28). *2021 COVAX LEARNING SYNTHESIS: Shifting from programme design to delivery & demand.*
[138] WHO. (2021, May 6). *Emerging lessons from Africa's COVID-19 vaccine rollout.* Gavi: VaccinesWork. Accessed at: https://www.gavi.org/vaccineswork/emerging-lessons-africas-covid-19-vaccine-rollout
[139] The Independent Panel for Pandemic Preparedness and Response. (2021, May). *Access to Vaccines, Therapeutics, and Diagnostics: Background paper 5.*
[140] Yoo, K. *et al.* (2022). COVAX and equitable access to COVID-19 vaccines. *Bulletin of the World Health Organization*, 100(05), pp.315–328. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9047429/pdf/BLT.21.287516.pdf
[141] The ACT-A investment case included a preliminary estimate of $1.5 billion to deliver the first 1 billion doses to AMC92 economies in 2021, with a view to rolling out support as early as Q2 2021.
[142] World Bank. (2020, October 13*). International Bank for Reconstruction and Development and International Development Association Project Paper on a Proposed Additional Financing to the Covid-19 Strategic Preparedness and Response Program using The Multiphase Programmatic Approach (Global Covid-19 MPA) with an Additional IBRD And IDA Financing of up to US$12 Billion (of which up to US$6 Billion from IDA and up to US$6 Billion from IBRD).* Accessed at: https://documents1.worldbank.org/curated/en/882781602861047266/pdf/World-COVID-19-Strategic-Preparedness-and-Response-Program-SPRP-using-the-Multiphase-Programmatic-Approach-MPA-Project-Additional-Financing.pdf
[143] Nguyen, A. (2020, September). *COVAX FACILITY OPERATIONALISATION AND VACCINE PROGRAMME: Board Meeting*. Gavi. Accessed at: https://www.gavi.org/sites/default/files/board/minutes/2020/29-sept/03%20-%20COVAX%20Facility%20presentation.pdf
[144] UNICEF. (2020, November 5). *UNICEF Supply Division & Gavi: CCE Programme and Market updates on COVID-19 and Gavi 5.0.* Accessed at: https://www.unicef.org/supply/media/5721/file/CCE-Industry-consultation-05112020.pdf
[145] UNICEF. (2022, January 24). *Going ultra-cold: How UNICEF is supporting countries for COVID-19 vaccine roll-out*. Accessed at: https://www.unicef.org/supply/stories/going-ultra-cold-how-unicef-supporting-countries-covid-19-vaccine-roll-out
[146] Hein, D. (2020, October, 30). *UNICEF Logistics Industry Consultation*. Accessed at: https://www.unicef.org/supply/media/5826/file/Update-COVAX-Facility-logistics-meeting-Nov2020.pdf
[147] Gavi. (2021, September 28). *COVAX: KEY STRATEGIC ISSUES: Report to the Board*. Accessed at: https://www.gavi.org/sites/default/files/board/minutes/2021/28-sept/04a%20-%20COVAX%20Key%20Strategic%20Issues.pdf
[148] UNICEF. (2022, January 24). *Going ultra-cold: How UNICEF is supporting countries for COVID-19 vaccine roll-out*. Accessed at: https://www.unicef.org/supply/stories/going-ultra-cold-how-unicef-supporting-countries-covid-19-vaccine-roll-out
[149] (n.d). *Key highlights from 2021 COVAX Reporting Framework Report: Based on data compiled 30 December 2021—14 January 2022.*
[150] Sharafudeen, M. (2021, December 14). *From availability to arrival: How COVAX doses make it to countries*. Gavi: VaccinesWork. Accessed at: https://www.gavi.org/vaccineswork/availability-arrival-how-covax-doses-make-it-countries
[151] UNICEF Supply Division. (2021, October 14). *Delivering COVAX supplies during a supply chain crisis, the HOPE Consortium steps up support to UNICEF.* Gavi: VaccinesWork. Accessed at: https://www.gavi.org/vaccineswork/delivering-covax-supplies-during-supply-chain-crisis-hope-consortium-steps-support
[152] Gavi. (n.d). *Gavi-57: Guidance for Technical Assistance for COVAX Preparation and Readiness.*
[153] COVAX TA reporting across Gavi-57 countries by programmatic area.
[154] While vaccine delivery costs were estimated to be about $8.4 billion for 133 countries, the total confirmed external financing for COVID-19 vaccine delivery as of 12 November 2021 was $2.5 billion. Based on pre-COVID-19 health budget trends for many countries, it was estimated that most countries would have to increase their health budgets at least tenfold to meet up with the cost for vaccine delivery – an unrealistic feat within a short time. Griffiths, U. *et al.* (2022, January 10). *Costs and predicted financing gap to deliver COVID-19 vaccines in 133 low- and middle-income countries*. UNICEF. Accessed at: https://www.unicef.org/media/114216/file/Costs-and-Predicted-Financing-Gap-to-Deliver-COVID-19-Vaccines-in-133-Low-and-Middle-Income-Countries.pdf.

[155] This incorporated $20 million in Bridge Funding to support near term needs until the wider window launched in June 2021. All 14 bridge funding requests were approved by Gavi by the end of June 2021.
[156] Countries were able to access a simple application form through the WHO COVID-19 Partners Platform, which was used to submit National Deployment and Vaccination Plans for COVID-19 vaccine delivery.
[157] COVAX. (n.d). *Key highlights from 2021 COVAX Reporting Framework Report: Based on data compiled 30 December 2021 – 14 January 2022.*
[158] COVAX. (2021, December 14). *Delivery Situation Report #13*. Gavi.
[159] COVAX. (n.d). *Key highlights from 2021 COVAX Reporting Framework Report: Based on data compiled 30 December 2021 – 14 January 2022.*
[160] In the Philippines, scarce supply was administered according to strict criteria prioritizing frontline healthcare workers, senior citizens, and people with certain underlying health conditions. This limited supply and prioritization strategy masked the effect of the delayed support for vaccine delivery. Early, C. (2021, October 18). *Mass vaccination: COVID-19 protection for the many, not the few.* Global Government Forum. Accessed at: https://www.globalgovernmentforum.com/mass-vaccination-covid-19-protection-for-the-many-not-the-few/
[161] COVAX. (2021, December 14). *Delivery Situation Report #13*. Gavi.
[162] Gavi. (2022, January). *Break Covid Now: The Gavi COVAX AMC Investment Opportunity.*
[163] COVAX. (n.d). *Key highlights from 2021 COVAX Reporting Framework Report: Based on data compiled 30 December 2021 – 14 January 2022.*
[164] 50 million buffer + 50 million for contingencies
[165] Other countries are Anguilla, Cook Islands, Montserrat, Niue, Saint Helena and Wallis & Futuna Islands.
[166] The data on in-country equity is available only for a subset of countries and therefore the strength of evidence is 2.
[167] These countries are:
LICs: Burkina Faso, Chad, DRC, Ethiopia, Gambia, Guinea-Bissau, Madagascar, Malawi, Mali, Mozambique, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Sudan, Syrian Arab Republic, Uganda, Yemen, Zambia.
LMICs: Bangladesh, Benin, Bhutan, Bolivia (Plurinational State of), Cabo Verde, Cambodia, Cameroon, Comoros, Côte d'Ivoire, El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Iran (Islamic Republic of), Kenya, Kyrgyzstan, Lao People's Democratic Republic, Lesotho, Micronesia (Federated States of), Mongolia, Myanmar, Nepal, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, Sao Tome and Principe, Senegal, Tajikistan, Timor-Leste, Ukraine, United Republic of Tanzania, Uzbekistan, Vietnam, occupied Palestinian territory.
HICs: Andorra, Antigua and Barbuda, Australia, Austria, Bahamas, Barbados, Belgium, Bermuda, British Virgin Islands, Brunei Darussalam, Canada, Chile, China, Hong Kong SAR, China, Macao SAR, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, French Polynesia, Germany, Greece, Guam, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Northern Mariana Islands, Norway, Oman, Panama, Poland, Portugal, Qatar, Republic of Korea, Romania, Saint Kitts and Nevis, San Marino, Saudi Arabia, Seychelles, Slovakia, Slovenia, Spain, Sweden, Switzerland, Trinidad and Tobago, United Arab Emirates, United States of America, Uruguay.
UMICs: Albania, American Samoa, Argentina, Armenia, Azerbaijan, Belarus, Belize, Bosnia and Herzegovina, Botswana, Brazil, Bulgaria, Colombia, Costa Rica, Dominica, Ecuador, Fiji, Gabon, Georgia, Grenada, Guatemala, Guyana, Iraq, Jamaica, Kazakhstan, Kosovo (in accordance with UN Securit.), Malaysia, Maldives, Marshall Islands, Mexico, Montenegro, Namibia, North Macedonia, Palau, Paraguay, Republic of Moldova, Saint Lucia, Saint Vincent and the Grenadines, Serbia, Suriname, Thailand, Tonga, Turkmenistan.
[168] Nair, G. (2021, October 19). *Serum Institute of India contributes most to vaccination drive as others lag*. The Financial Express. Accessed at: https://www.financialexpress.com/lifestyle/health/serum-institute-of-india-contributes-most-to-vaccination-drive-as-others-lag/2352000/
[169] Using allocation estimates.
[170] Euro Health Group's Evaluation of Gavi's COVID-19 response (forthcoming).
[171] Delivering just under 1 billion to mostly AMC countries
[172] Delivering 833 million doses to AMC countries
[173] As explained above, these recommendations would not necessarily be implemented by Gavi. CEPI in particular would presumably play an important role in supporting tech transfer.
[174] Among the aspects of the Declaration that need to be clarified are:

- *The set of countries that would qualify for the doses.* Restricting the commitment to LICs would clearly be unacceptable.
- *The volume that would be set aside.* Some reports have suggested that the share of doses to be shared could be as low as 10%.
- *How the 'shared doses' would be paid for.* Would the offer only hold if HICs were willing to buy the doses on behalf of LMICs, as was the case for the larger share of the Pfizer donation to COVAX? If this is the case, it's not clear what manufacturers are actually committing to. Would participating manufacturers donate the doses for free? Or would they merely commit to making the available for purchase by qualifying countries or a buyer acting on their behalf?
- *The price.* If the doses would be bought by COVAX or a successor initiative, how would the price be set?

[175] Substantial work on how to monitor HIC contributions to global Covid-19 health equity has already been conducted. Samman, E (2022) Monitoring G20 contributions to global Covid-19 health equity: issues and options. Policy brief, ODI. Accessed at: https://cdn.odi.org/media/documents/ODI-LT-VaccineEquity-PB-Mar22-Proof05.pdf