ONE WORLD PROTECTED

COVAX: KEY LEARNINGS FOR FUTURE PANDEMIC PREPAREDNESS AND RESPONSE

COVAX

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BACKGROUND

This white paper outlines three key COVAX learnings for future pandemic preparedness and response. Drawing upon COVAX's unique experience enabling an unprecedented global rollout at scale during a pandemic, it highlights challenges encountered and subsequent impact on equitable access to COVID-19 vaccines, the actions COVAX took in response and recommendations for the future.

This paper is the result of a broad internal exercise to capture detailed learnings from COVAX partners and is intended to provide a framework for COVAX engagement in critical global pandemic preparedness and response discussions.[1] It is accompanied by an annex that documents the more than 50 workstreams and innovations that had to be developed during the pandemic in order to successfully implement COVAX, their impact, as well as associated challenges that will need to be considered in future efforts.

INTRODUCTION

The COVID-19 pandemic has demonstrated the clear need for the world to be better prepared the next time a public health emergency of this scale strikes. Rapid and equitable global access to medical interventions, such as therapeutics, diagnostics and, in particular, vaccines, which offer the best line of defense for vaccine preventable diseases, will be key to this. However, if future global health architecture is to be more agile and effective at responding to pandemic threats and bringing them under control, it will need to anticipate – and be built to overcome – all potential barriers to equity.

As the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A), COVAX was created at the beginning of the pandemic to enable access to potential COVID-19 vaccines to the most vulnerable everywhere, regardless of income level. Bringing together the expertise and resources of four established institutions across the global vaccine ecosystem – the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance (Gavi), the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) – COVAX has sought to protect lives and livelihoods and expedite an end to the acute phase of the pandemic through equitable access to vaccines. COVAX doses began to be shipped worldwide in late February 2021, and since then the partnership has delivered more than 1.7 billion COVID-19 vaccine doses to 146 countries.

Based on COVAX's unique experience implementing a historic global rollout during a pandemic – including the challenges it faced along the way – it is clear that critical global governance, policy and funding considerations must be taken into account when designing future pandemic preparedness and response architecture. While it is impossible to know the nature of the next pandemic threat, these considerations are based on the best empirical evidence the world has to-date, and must be treated as reasonable assumptions of global realities during any pandemic. It is critical to global health security that they are acknowledged, anticipated, analyzed and responded to – with improvements made and solutions put in place in advance of the next pandemic.

[1] COVAX partners are also conducting several evaluations into the effectiveness of COVAX's strategy, governance and processes in the response to the COVID-19 pandemic, which will be published separately.

KEY LEARNINGS

1. EQUITABLE ACCESS REQUIRES AN END-TO-END SOLUTION THAT CENTRES ON PUBLIC HEALTH, AND THE NEEDS OF THE MOST VULNERABLE, AT EVERY STEP

THE CHALLENGE

Achieving equitable access is critical during a pandemic: not only for moral reasons, but because this is the only way to limit the duration and impact of the emergency, for all countries and individuals. However, securing supply and turning those vaccines into vaccinations requires complete end-to-end solutions, backed by investments – from early R&D, scaling-up manufacturing, securing deals, consistent policy guidance and setting up operational, logistical, regulatory and legal frameworks and further along the value chain to shots-in-arms. This applies not just to the vaccines themselves but also ancillary supplies, such as cold chain and safe injection equipment, international freight and logistics as well as in-country delivery needs, including personal protective equipment (PPE) for healthcare workers.

An end-to-end solution must centre on public health and the needs of the most vulnerable – high risk groups, lower-income countries and populations in humanitarian settings – at every step. Implementing that solution to rapidly and equitably reach billions of people in countries across the world at the same time requires incredible real-time planning and coordination across all stakeholders in the value chain. Practically speaking, this means making sure the right supplies are allocated at the right times to those who both need them and are ready to receive them, that all countries get the tailored delivery support, equipment and resources they need to enable rollout – and that those supplies are available, have the right characteristics for the setting and arrive in the right countries in the right quantities at the right times. Helping countries turn vaccines into vaccinations means all of this must be done in a predictable and reliable manner, to the extent possible.

However, the most predictable factor in a pandemic is that there will be unpredictability throughout: despite best efforts, working assumptions will shift. At the beginning of the vaccine value chain, there will be uncertainty around R&D, a broad range of candidates in various stages of development, and multiple efforts to scale up manufacturing – with uncertain regulatory and efficacy outcomes and continuously evolving science and data. Throughout the chain, epidemiology, the evolution of the pandemic and subsequent impacts on policy recommendations and best public health approaches will require constant recalibration, impacting all activities. Simultaneously, the needs of countries and vulnerable populations must be kept in mind at every turn, but these too will be dynamic and varied. Each country will have its own unique and ever-changing political, cultural and socioeconomic realities, policies, legal and regulatory frameworks, evolving strategies, needs and rollout plans. Reaching the most vulnerable in humanitarian, fragile and conflict settings will pose additional difficulties. The push to deliver supplies, turn vaccines into vaccinations and successfully protect those at highest risk everywhere must contend with each country and context's unique logistics, infrastructure and delivery systems challenges.

Navigating this uncertain environment requires complex and agile stakeholder management and problem solving, as well as rapid decision-making. Successfully doing so relies on coordination, collaboration, information sharing and transparent real-time data made available across the value chain, particularly on countries' needs and priorities, as well as clear processes for handling data asymmetries between sources. It also requires building in fail-safes that take into account inevitable global realities, and ensuring response mechanisms have resources, flexibility and the ability to take risks built-in: this is the subject of the key learnings discussed in sections 2 and 3, below.

THE RESPONSE

Creating and implementing COVAX required data, information and continuous communication across several sources including each of its partners, other global, regional and national organizations, its participant countries and industry – covering everything from R&D, policy guidance, vaccine portfolio development, regulatory status and progress, allocation inputs and country readiness assessments, transport logistics, administration and usage, coverage and absorption rates and more – updated in real-time, or as close to it as possible.

COVAX was able to achieve this and deliver at scale because it was built around a networked approach that could draw upon the pre-existing expertise, resources, stakeholder relationships and infrastructure of its core partners, who could leverage deep experience working together to deliver vaccines at scale. Importantly, that work focused on decades of collaboration with lower-income country governments to immunize the most vulnerable. This meant each organization could focus on its core strengths and experiences, quickly set-up cross-cutting teams and functions where needed, monitor and understand lower-income countries' needs and draw on the expertise of other global actors as relevant – ensuring hand-offs between each step and no gaps along the value chain. Staff and teams had established relationships and ways of working that could be rapidly leveraged. The approach to leverage pre-existing networks was critical to COVAX's success in rapidly setting up a response mechanism during the emergency itself, and its ability to evolve as needed.

Thanks to this familiarity, COVAX partners were able to collaborate to rapidly set up cross-organizational workstreams, develop innovative mechanisms, tools and processes, expand existing initiatives as needed, monitor and understand lower-income countries' needs, consult and engage a broad range of stakeholders and take quick decisions – thus continuously evolving the COVAX model to remain fit-for-purpose as working assumptions and policy targets changed. Significant examples of this include the development and implementation of a dose donation model to fill urgent supply gaps, consistently increasing ambitions and fundraising to match shifting global targets and adapting to fill downstream gaps through increased country-support and funding when it became clear sufficient global financing for delivery from other sources had not materialized.

RECOMMENDATIONS

- **Prioritize strengthening end-to-end capabilites during non-pandemic periods, thereby ensuring that a resilient ecosystem is already in place when an emergency strikes.** Countries' health systems and infrastructure must be strengthened, including **a dedicated focus on response/surge capacity, emergency processes and systems**. Countries must be able to rapidly scale up during a pandemic or health emergency of a similar nature (e.g. surge health worker capacity, pre-positioning health system infrastructure and supplies, potential deployment plans, etc.) and the resources and pre-planning required to do this must not be underestimated. This dedicated response capacity must be underpinned by **serious and consistent investments in primary healthcare services, cold chain, vaccine track and trace, human resources and data monitoring systems, particularly in low-income countries**. In parallel, **regulatory readiness, harmonization, policy development and other activities must continue to be a focus** of preparedness.

- **Build access for the most vulnerable into the pandemic architecture**, from the outset. This means **acknowledging that, despite best efforts, there will be disparities in countries' readiness levels, infrastructure and capacity when the next pandemic strikes** – a successful response must be ready to navigate these disparities, and minimize the barriers to access they represent.

- In particular, **an end-to-end solution focused on equity must account for the disproportionate impact of such an emergency on hard-to-reach populations in fragile, conflict and humanitarian settings**. Response frameworks must be created with the unique contexts of these communities – where access to even the most basic services is a challenge a majority of the time – in mind. Successfully reaching these groups means understanding and overcoming the limitations to working outside state-based architecture – limitations that pose barriers that are not unique to public health or emergency response, but can be further heightened during a pandemic. These barriers can be mitigated by building humanitarian contingencies and waivers into various parts of pandemic response architecture, including financing, risk,

liability, importation and regulation.

- To avoid duplication of efforts, maximize the impact of investments made to-date and increase the likelihood of a successful response, **map out existing global health mechanisms, networks, expertise, policies, frameworks and tools – and retain, incorporate and evolve these as needed**. This includes established innovations that have already proven themselves during COVID-19, such as Emergency Use Listing, model indemnification and liability agreements and the No-Fault Compensation Scheme.

- To ensure end to end access can be successfully prioritized from the very beginning of the response, **sufficient resources, with rapid disbursement mechanisms, should be available for all aspects of the vaccine and ancillary product value chain from R&D, procurement and in-country delivery – in parallel**.

- Establish **clear standards, processes and expectations for rapid and agile end-to-end governance, decision making, communication, transparency and risk sharing** within a pandemic response mechanism, ahead of time. These must be underpinned by pre-established **frameworks for comprehensive and reliable information sharing, data transparency and solutions for addressing data asymmetry** – including when it comes to country demand as well as the prioritization of specific pandemic response strategies, and other health interventions and essential services. These frameworks are critical for coordinating efforts during non-pandemic periods where preparedness is the focus, but become absolutely fundamental during a pandemic response. During this time the work will be fast-moving, technically and politically complex and rapid decisions must be made based on best available information – and the buy-in of all stakeholders will be key to successful implementation of the response.

- **Set up processes and expectations – in advance – for the systematic consultation and updating of all relevant stakeholders**, particularly lower-income countries and civil society organizations, during both preparedness and response. Agreeing clear guidelines for collaboration outside of the fraught environment and power dynamics of an emergency will enhance buy-in from all stakeholders, further enhancing effective implementation of response activities (while also avoiding duplication of processes by various stakeholders in a resource-constrained environment).

- Similarly, **processes and expectations for transparency should be carefully considered in advance**. Transparency must be an organizing principle. However, effective solutions must recognize the challenges posed by unreliable, constantly shifting or non-existent data – and being reliant on many stakeholders to share this data. These solutions must also acknowledge and account natural tensions between the need for transparency, the need to act with urgency and the need to ensure stakeholder buy-in. Consultation of all stakeholders is key to inclusive decision making, but in the complex and politically sensitive environment of a global emergency, it is also highly likely stakeholders will have differing views. Reaching consensus can cost valuable time or lead to impasse, while being proactive without consultation may disincentivize many actors from coming to the table and sharing critical data and insights. In some situations consensus may be impossible. Rather, it is useful to have these discussions outside of an emergency environment. Careful consideration must be given to understanding needs, challenges and competing incentives – to identify where there may be gaps or areas for improvement, as well as to manage expectations across the value chain as to what can and will be shared, how, with whom and when – and who makes those decisions.

KEY LEARNINGS

2. HOARDING, EXPORT RESTRICTIONS AND NATIONALISM SHOULD BE EXPECTED

THE CHALLENGE

During a global crisis, and when there is great uncertainty about which medical interventions will become available, governments will always seek to protect their own citizens first. Both during the 2009 H1N1 pandemic and with COVID-19, this led to the wealthiest governments leveraging their resources to hedge against unknowns – ordering large volumes of doses, and leaving the majority of the world at the back of the queue. Similarly, during both these pandemics other forms of nationalism had negative impacts on global supply, including export restrictions imposed by governments around the world. This not only affected the free flow of vaccines, but also vital components and materials needed to make them.

However, this systemic hurdle is not easy to overcome. Players within the pandemic ecosystem (including countries, private sector actors and global organizations) will always respond to their incentives. These incentives – protecting domestic populations first, prioritizing the fastest and highest bidder to help de-risk investments and focusing on entrenched priorities, processes and stakeholder requirements – are rooted in a clear rationale and cannot be disrupted overnight, nor guaranteed by agreements established during "peace-time". Efforts in climate change and peace negotiations have faced similar hurdles for decades.

THE RESPONSE

Anticipating this, COVAX's solution was to pool demand, not just for lower-income economies, but also from wealthier nations that had resources but still lacked the power to secure bilateral deals in a supply-constrained environment. This included, for example, upper-middle income countries that had also missed out on doses during the 2009 H1N1 pandemic. COVAX's goal was to leverage the fair allocation mechanism to ensure doses were available to cover 20% – or high-risk groups – in all countries, as a public health imperative. Alongside fully-funded doses supplied through the COVAX AMC to lower-income countries, COVAX created a self-financing model that gave these countries access to the same insurance mechanism in the face of uncertainties around R&D successes and failures. This combined approach, developed in consultation with countries, resulted in more than 160 countries joining COVAX within months, eventually reaching more than 191 participants in total – an unprecedented show of global solidarity in an environment where political buy-in was critical to success.

This pooled demand, as well as self-financing participant and donor funding, gave COVAX the ability to make large-scale investments and build a diverse portfolio. In the end, COVAX was able to secure agreements for access to 11 vaccine candidates across four technology platforms, of which ten received regulatory approval, and more than 4 billion doses in total – the largest portfolio in the world.

However, despite rapid global solidarity, designing, consulting, implementing and raising funds for COVAX still took several crucial months during which the race to secure early access to vaccines was on. The lack of advance and early at-risk funding meant that COVAX still came to the table later than countries with resources readily at hand at the start of the global emergency, putting COVAX several months behind in building a broad portfolio. This meant that, with a limited set of approved products in the early stages of global rollout, COVAX was disproportionately impacted by manufacturers prioritizing earlier bilateral customers for early supply – as well as by export restrictions that further impacted supply of the majority of the volumes expected to be available to COVAX in the first half of 2021.

RECOMMENDATIONS

- Institute models – in advance – that **ensure volumes supplied to high income countries (HICs) are accompanied in parallel (not sequentially) by proportionate doses for lower-income countries**, to ensure equitable and timely distribution of available supply. These must be accompanied by reliable sources of **at-risk financing**, and **increased standards for transparency and coordination on how limited global supply is being allocated** in a pandemic, so that this decision does not solely lie within the hands of for-profit entities.

- **Increase and geographically diversify vaccine manufacturing** – broadening global supply capacity from the beginning while ensuring that all countries have access to viable regional suppliers, particularly across Africa – thus potentially minimizing the impact of export restrictions. Support **tech transfer** to further this goal, including contingencies in the event of limited R&D success. Consider new **demand-side financing** to support a sustainable diversified manufacturing base.

- **Strengthen multinational trade-facilitation measures to ensure the free flow of vaccines, manufacturing supplies and other life-saving equipment during health emergencies**. For example, an exemption/waiver model that allows agencies involved in global health response to ship life-saving medical countermeasures and materials to low- and middle-income countries as well as humanitarian contexts exempt from any trade barriers.

KEY LEARNINGS

3. A SUCCESSFUL GLOBAL PANDEMIC RESPONSE INVOLVES TAKING RISKS

THE CHALLENGE

During a pandemic, delays cost lives. Rapid response is a vital part of reducing the duration and impact of the emergency. Rapid response in an inherently uncertain environment requires end-to-end coordination, but also agility, flexibility and, crucially, an increased ability to take risks. Being prepared to mount a response in all scenarios means expending resources to put in place insurance mechanisms and redundancies – with the near-guarantee that some scenarios, if not many, will not come to pass. Furthermore, this is an iterative process – as working assumptions change, implementing a response must take place in parallel with constantly planning for the future.

Contingent funding needs to be in place at the outset, and available throughout the response – to ensure that global health agencies can mount a global response as soon as the crisis strikes, have the surge capacity to pivot and can readily invest in new solutions as needed. We accept this redundancy in other sectors – defense, for example – when it is deemed the cost of failure is too great. A similar approach must be taken for pandemics. That means contingent funding doesn't just need to be in place before outbreaks occur, it also needs to be immediately deployable and at-risk.

No funding of any kind existed when COVAX was set up. In addition to this – global health organizations and other international development agencies are not naturally built to take on the kind of risks sovereign states, especially those with large budgets, can. In the context of COVID-19, even before it was known if any vaccines would prove to be safe and effective, wealthy governments were willing to flex their sizeable budgets to secure advance deals for doses, even knowing there was a risk that any specific vaccine might fail. Those who cannot easily tolerate this size of risk are at an immediate disadvantage when securing early access to doses.

THE RESPONSE

Not only did COVAX not have any funding in place at the outset – having to raise money as it went – but it also had to break new ground to increase organizational risk tolerance while putting in place risk sharing and mitigation measures.

Recognizing the need for investment in R&D and manufacturing to create a large portfolio of vaccines with the volumes required, COVAX partners provided at-risk "push" funding to manufacturers in the form of forgivable loans, when no other funding was available, and at-risk "pull" funding to enable large-scale procurement. This meant rapidly taking on huge risks, in the face of unknowns related to R&D success and the trajectory of the pandemic. Similarly, COVAX partners invested in readiness and delivery from core budgets, financed the set-up and staffing of COVAX before any dedicated funding was raised and underwrote financial and legal agreements with Facility participants.

Faced with uncertainties and the need to plan with limited or yet-to-be-determined resources, COVAX partners built risk sharing and mitigation into the model, frequently innovating and adapting as needed. These measures included bringing together more than 190 participants to pool demand, investing in a broad portfolio of diverse candidates and putting in place safeguards such as the cost-sharing mechanism in the event sufficient donor funding did not materialize or additional doses were needed – giving countries the ability to still purchase doses at COVAX-negotiated prices. COVAX partners leveraged existing innovative financing mechanisms and created new ones to de-risk investments or make contingent funding available for earlier investments.

A key part of risk mitigation was the ability to act urgently and decisively, with flexibility: when faced with urgent supply challenges in the second and third quarters of 2021, COVAX identified

an alternate source of doses. It urgently called for dose donations from countries with excess supply, within months setting up a mechanism and establishing legal agreements between COVAX, manufacturers and donors to secure, plan for, allocate and ship donated doses to countries.

These early at-risk investments, combined with high risk tolerance, risk sharing and mitigation measures, flexibility and innovative financing allowed COVAX to start from nothing to successfully secure access to billions of doses, and deliver more than 1.7 billion doses around the world. However, this was not easy – development agencies whose processes revolve on aid budgets are not built for this kind of risk tolerance. Although COVAX partners were able to take on these risks thanks to the support of their governance mechanisms and stakeholders, negotiating risk tolerance and risk sharing, including between partners still took time.

RECOMMENDATIONS

- **Ensure that response mechanisms are flexible and agile, with appropriate funding and risk tolerance they need to successfully operationalize a response**. Mechanisms must be able to constantly update working assumptions related to epidemiology, policy recommendations, supply, demand, R&D, manufacturing, country-level challenges and other factors – and freely evolve to meet shifting goals.
- **Outline a clear, shared understanding of risk thresholds and risk sharing** within and across relevant organizations in advance – **recognizing that higher risk thresholds are necessary** for rapid decision-making, evolution and action in a fast-paced and uncertain environment. A successful pandemic response mechanism must have the ability to plan successfully for multiple scenarios, some of which may never materialize, making at-risk investments inevitable.
- **Make available, in advance, contingent at-risk funding for global health agencies and mechanisms that is immediately deployable when needed** (end-to-end, from R&D to procurement of medical countermeasures and ancillary supplies, as well as in-country delivery needs). This funding **should include a proportion that can be used with no regrets to secure vaccines that are at any R&D stage, even with the risk of vaccine failure.**
- **Sustain and leverage existing financing mechanisms** (e.g. the International Finance Facility for Immunization (IFFIm), contingent capacity, EIB liquidity facilities, DFC Rapid Financing and MedAccess Risk Sharing) **or create new mechanisms that focus on flexibility in response and help ensure sufficient scale of at-risk capital on day one of the pandemic**.

ANNEX

KEY WORKSTREAMS AND INNOVATIONS

The following list outlines over 50 critical workstreams and innovations that needed to be developed to implement COVAX and make it fit-for-purpose to enable rapid access to vaccines and deliver at a global scale during a pandemic.

It captures the solutions developed by COVAX partners across the value chain in real-time, their impact and outlines additional challenges in each area that should be considered when designing effective preparedness and response mechanisms for future pandemics. These experiences have informed the recommendations highlighted in the main text of this report.

This list was developed through extensive engagement and dedicated sessions across the leadership, technical teams and staff of the four COVAX co-lead organizations.

A. SET UP

Activity	Impact	Challenges
Unprecedented level of political support	◦ Collaboration across governments and within governments to enable a global rollout through COVAX, sustained across multiple years – including participation, funding and political support	◦ Managing distributed engagement with political leaders across multiple platforms and fora, and multilayered governance set ups ◦ Aligning political support with action
End-to-end partnership across four main actors of the vaccine ecosystem	◦ Experience across partners from R&D to delivery, enabling a holistic/comprehensive solution ◦ Previous collaboration between agencies centred on partnership with lower-income countries to reach the most vulnerable ◦ Rapid set up of collaboration enabled by existing familiarity and coordination between agencies/entities ◦ Leveraging existing governance, staff/expertise, increased speed and reduced the need for capacity build up ◦ Partner agencies could step up where additional resources/capabilities were needed ◦ Cross-partner mechanisms set up for rapid and frequent decision making (e.g. Workstream Conveners, SWAT, Pillar Leadership Team) ◦ Cross-partner data sharing and information systems set up	◦ Limited resources for effort of massive scale, speed and intensity – pushing limits of partner organizations and staff ◦ "Build while doing", under intense pressure and uncertainty of pandemic response needs ◦ Level and frequency of communication needed between interdependent parts of the value chain ◦ Newly formed coalition structure can result in overlap in mission of each entity, leading to lack of full clarity in roles and responsibilities – that must then be aligned ◦ Clarifying interplay between newly set up leadership and governance bodies and existing governance mechanisms across the partners

Activity	Impact	Challenges
>191 eligible and confirmed participants (HICs, MICs and LICs) included in rapid set up of the COVAX Facility in 2021	◦ COVAX AMC launched early as first building block of Facility, enabling access to fully donor-funded doses to a broad group of 92 lower-income countries ◦ A critical mechanism at the heart of COVAX, the Facility took on a high-level of financial, legal and operational risk to rapidly bring together HICs, MICs and LICs into the same initiative – with models, legal and financial agreements and payments negotiated and finalized within a few months ◦ Self-financing participant model provided countries with an insurance mechanism to ensure protection of most vulnerable everywhere in the face of uncertain R&D outcomes, gave access to scale and early funding and successfully built in options for countries to forgo COVAX supply if it was not needed (likelihood of bilateral deals) ◦ Many innovative financial risk mitigants were developed to support the scope ◦ Made investments across a broad portfolio of promising vaccine candidates (including those being supported by CEPI) and signed 11 advance purchase agreements (APAs) for candidate vaccines. ◦ Guided by a fair allocation framework developed with WHO, the Facility could equitably distribute doses to help protect the most at-risk groups in all participating countries. ◦ The Facility was able to continually evolve models processes to meet the needs of a dynamic pandemic environment. ◦ To date has provided more than 1.7 billion doses to 146 participants	◦ Many different and often conflicting interests and voices across stakeholders ◦ Extreme complexity to accommodate the needs/secure buy-in of different stakeholders while also rapidly implementing a viable solution ◦ Competing views combined with difficulty predicting what lies ahead can mean that the compromises that are necessary to move forward may result in suboptimal situations in the future ◦ Parallel pursuit of individual solutions undermines the impact of collective, pooling approach, and favors actors with greater resources – but is hard to avoid in an emergency situation
Flexibility in adapting existing mechanisms, and establishing new mechanisms, to engage a wide range stakeholders	◦ Enabled COVAX to regularly solicit input from a broad range of stakeholders, e.g. countries, CSOs, industry and extended partners – allowing for rapid consultation and decision-making, as well as collective ownership and engagement	◦ Managing competing interests and pushing for transparency in a heightened political environment, while securing buy-in of each stakeholder critical to the overall goal is extremely complex

Activity	Impact	Challenges
Flexibility in adapting existing mechanisms, and establishing new mechanisms, to engage a wide range stakeholders *(continued)*	• Existing governance mechanisms (such as the Gavi Board, CEPI Board and input from WHO Member States and regional offices) were leveraged to make decisions in consultation with a wide range of stakeholders, especially countries. Where needed or requested, existing governance structures were adapted (e.g. expansion of board committees). This is unprecedented for an initiative with a budget of over US$ 12 billion • Where needed or requested, new mechanisms were created • Additional groups specifically created for COVAX Facility participants to engage in COVAX governance (AMC and self-financing) • COVAX Coordination Mechanism to link cross-partner governance bodies, as well as COVAX working groups – with representatives from countries, civil society and industry associations (IFPMA and DCVMN), among others • Monthly participant and CSO briefings to listen, inform and engage • Dedicated staff to handle each critical stakeholder (countries, manufacturers, CSOs, donors, etc.)	• Balancing speed with engagement, given time and capacity constraints within organizations • Significant challenges to speak with one clear voice in service of goals • Challenges to discussing all issues openly when there may be conflicts of interest across stakeholders • Complexity, resource limitations and need for rapid decision-making in a fast-moving emergency response all compete with the need for frequent and deep engagement, discussion and debate, consensus building and trust across an extended range of stakeholders • Inclusion of stakeholder groups may not always influence specific actors' behavior (e.g. industry associations and individual manufacturers) • Inclusion, as well as the accountability of each organization towards their respective board/constituencies can result in complex and sometimes duplicate decision-making structure, despite best efforts
Establishment of Country Communications Team (CCT) to streamline and coordinate country-facing communications and processes	• CCT made COVAX better able to respond to country needs, keep participating economies informed and engaged on key issues in a timely manner • COVAX Participant Briefing for country-level/facing staff (MoH, WHO RO/CO, UNICEF CO, Gavi SCM/PM, C19 Strategic Liaisons and CoVDP Desk Officers) to regularly inform and engage • Increased effectiveness of communications through proactive identification and mapping of country information needs • Created an information and coordination hub for country communications and as liaison point for country-facing staff • Facilitating a steady flow of COVID-19 delivery success stories/challenges, in particular to support knowledge sharing between countries and partners	• Coordinating communications and messaging across multiple partners and initiatives across areas of work that are moving in parallel and constantly evolving • High volume and complexity of communications to countries due to the nature of the work • Avoiding delays in information sharing, ensuring appropriate review from all stakeholders, avoiding duplication of efforts across agencies/teams

Activity	Impact	Challenges
Centralized, cross-agency coordination body (COVAX Strategic Coordination Office, SCO)	• Unique team at the heart of the COVAX partnership providing neutral, COVAX-first strategic coordination support across Cepi, Gavi, UNICEF, WHO and broader COVAX ecosystem • Convened all governance meetings of the partnership (CCM, RSSET/PLT, WSC, SWAT) and supported decision-making through analytics, extensive stakeholder engagement and capability building • Provided end-to-end as well as targeted project management and coordination support to COVAX workstreams, especially for operations and product management • Coordination and surge support for time-critical, strategic projects, such as the COVAX transition	• Continuity of resourcing of the team with secondments from each COVAX partner • Balancing the priorities of individual partners (if divergent) with the priorities of the partnership, while maintaining a continuous dialogue between all stakeholders around shared goals and commitments

B. FUNDING

Activity	Impact	Challenges
Specific and focused fundraising for COVAX/ COVID-19	• Reduced resource competition against other potentially competing priorities within each agency	• Maintaining public/political focus and sufficient funding for other health emergencies
Large and rapid resource mobilization for AMC	• Allowed the development of and full funding of an AMC of unprecedented scale through more than US$ 12 billion in funding, of which US$ 9.8 billion for the procurement of vaccine doses • Created front loading financing structures to improve liquidity and optimize grants	• Managing to secure early access due financial constraints (donor funding not available in time, no rapidly available bridge financing from banks and limited willingness from international organizations to take the risk on their balance sheets) • Significant delays between commitments and actual funding, which constrained the ability of partnership to effectively execute contracts
COVID-19 Delivery Support funding	• COVID-19 Delivery Support (CDS) delivered through Office of the COVAX Facility provided time-sensitive, medium-sized, country needs-based funding to help countries address critical funding gaps for delivery scale-up – including with high risk tolerance given emergency situation • Directly funded countries for a wide range of needs including service delivery, health workforce, demand generation, data and monitoring, waste management and supply chain systems	• Rapidly changing country needs as the pandemic and virus evolved resulted in continuous iteration of funding applications and reprogramming of grants as country strategies evolved • CDS became a primary source of funding for many countries as opposed to gap-filling and supplementary (to multi-lateral development bank or country self-financing) as fiscal environments became more constrained and countries less willing to tap into MDB funding

Activity	Impact	Challenges
COVID-19 Delivery Support funding *(continued)*	• Funding both enabled scale-up of COVID-19 vaccine delivery and left a lasting legacy for immunization programmes through installation of cold chain capacity to store more than 1 billion doses of vaccine, build-up of supply chain and data management systems and efforts to advance vaccine safety and confidence	• Fragmented funding landscape across Alliance partners, MDBs and bilaterals created confusion and high transaction costs for countries to navigate • Costing of need and tracking funding gaps for in-country vaccine delivery have been an ongoing challenge, in part because of complex assumptions needed and multiple financing/funding flows
Aligning multiple funding streams to address urgent funding gaps	• COVID-19 Delivery Support (CDS) - Funding in two streams: (i) urgent requests (lower hurdle to application and quicker review and disbursement) (ii) needs-based funding • Established a global ACT-A Humanitarian Action for Children (HAC) appeals in 2021 and 2022 to support COVID-19 vaccine and other tools, providing a flexible and rapid disbursement mechanism for funding to country-level • Through the funding alignment working group, agencies identified funding that was fully flexible that can be deployed with 10-15 working days to the country level once urgent funding requests had been received	• New processes had to be set-up to identify new funding requests and to review them • Challenging to identify and reserve "flexible funding" to address different processes in institutions that needed alignment • Changing context (with advent of Omicron, reduced risk perception, competing priorities and corresponding lower demand for COVID-19 vaccines at country level) means that funding needs to shift from short-term humanitarian to multi-year primary healthcare strengthening/integration

C. RESEARCH AND DEVELOPMENT (R&D)

Activity	Impact	Challenges
Rapid development of global R&D Blueprint	• Reduced time between PHEIC and availability of effective vaccines • Facilitated rapid knowledge sharing between scientists, created investigation protocols, established local capacities to test samples, prioritized criteria for vaccines and developed Target Product Profiles	• Some developers followed alternative protocols and guidance
Ambitious but realistic Target Product Profile (TPP)	• Brought clarity to manufacturers on product requirements at a crucial time during development process • Allowed for earlier commercial agreements, accepting the need for product improvement over time	• Striking the balance between efficacy, cost, ease of use etc. to ensure that the products are available as early as possible, without compromising safety • Product characteristics may not be ideal for low-resource settings • Early anticipation of future trajectories to inform investments, development and procurement (e.g. variant-adapted vaccines)

Activity	Impact	Challenges
Early R&D support with grant funding (that led to early procurement)	• Combination of R&D push funding (e.g. grants), creating a pipeline of priority candidates for pull funding through APAs • Investments were made before PHEIC declaration, which allowed COVAX to move quickly • Pivoted between platforms during development to maximize success • Leveraged pre-existing relationships with pharmaceutical companies	• Limited impact when early winners are large established multinationals less in need of support • Even when investments are made early on, risk of losing exclusivity remains if players with greater resources invest in the same candidates
Continuous R&D investment	• Throughout the pandemic, addressed gaps (e.g. evidence among pregnant women) and emerging needs (e.g. variants) • Created multi-partner SWAT team for enabling sciences and clinical development	• Competing funding priorities with other procurement activities • Effectively linking R&D investment decision-making to procurement decision-making
Innovative financing (forgivable loans)	• Innovative financing tools such as forgivable loans, repayable based on sales of vaccines, to advance at-risk manufacture of products and establish relationships with manufacturers	• Alignment of at-risk funding terms across partners is required to leverage the full arsenal of at-risk funding potentially available • Access commitments may reduce manufacturer willingness to engage
Matchmaking between small bio-techs and large MNCs/CDMOs	• Partnering of small biotechs with large MNCs and Contract Development and Manufacturing Organizations (CDMOs) facilitated tech transfer	• Timelines for tech transfer not matching the speed at which vaccines needed to be manufactured

D. POLICY/REGULATORY/SAFETY/LEGAL

Activity	Impact	Challenges
Emergency Use Listing (EUL) vaccines for global use	• Provided expedited, comprehensive and thorough product-by-product global recommendation on which country regulatory authorities could rely	• Early/timely submission by manufacturers of dossiers to WHO for urgent recommendation • Lack of efficient regulatory harmonization across agencies leading to some manufacturers prioritizing some regulatory agencies over other options including WHO EUL

Activity	Impact	Challenges
No Fault Compensation (NFC) programme for AMC participants	◦ Landmark achievement providing no-fault lump-sum compensation in settlement of any claims for any COVAX AMC participant who suffers a serious adverse event associated with a COVAX-supplied COVID-19 vaccine ◦ Facilitated vaccine access for AMC participants and helped de-risk the I&L agreements, required by manufacturers ◦ Produced a fair, efficient global system for claimants ◦ Serves as an example beyond its own use case, by demonstrating how to set up an NFC system without "breaking the bank"	◦ Necessitated agreements (and liabilities) for financial and information flows between relevant organizations ◦ Required global organizations and aid funding to assume risk of SEA claims (as opposed to manufacturers) ◦ Resolving risk allocation in relation to third-party claims ◦ With limited Serious Adverse Event (SEA) claims it can be difficult to identify what role limited awareness among potential claimants might play
Model I&L language	◦ Landmark achievement that facilitated the conclusion of indemnity agreements between 91 AMC-eligible countries and manufacturers ◦ Negotiated and developed pre-agreed uniform language across most manufacturers ◦ Enabled more rapid access to vaccines, as well as access from manufacturers that might have not otherwise made their product available	◦ Some manufacturers still requiring bespoke agreements on handling etc. ◦ Certain manufacturers reserving the right to ask for additional protections (e.g. financial) ◦ While not a challenge, it is important to note that this approach to I&L was intended as a stop-gap measure during this pandemic, with manufacturers ideally eventually assuming liability themselves ◦ Overall approach to I&L in this pandemic resulting in high burden/ risks/operational complexities –for the coordinating mechanism (e.g. COVAX), lower-income countries and access in humanitarian contexts
Unprecedented regulatory collaboration and harmonization across agencies	◦ Convening of Regulatory Advisory Group (RAG) that assembled SWAT teams to review science ◦ Establishment of collaboration between Regulatory agencies such as FDA, MHRA, EMA, regulatory forums such as AVAREF and WHO PQ worked together on regulatory preparedness activities to ensure availability of regulatory standards for assessment of quality, safety and efficacy data, sharing expertise and aligning processes across COVID-19 vaccines pipeline	◦ Different processes and guidelines amongst regulatory agencies ◦ Maximizing collaboration across all relevant agencies to maximize impact of WHO recommendations ◦ Manufacturers needing to submit data in different formats to different regulatory agencies creates additional work and bottlenecks for deal-making
Enhanced global vaccine safety monitoring system with weekly updates	◦ Enhanced safety during global roll-out of vaccines through real-time data collection and assessment and greater coordination/joint action (e.g. through regulatory networks)	◦ Difficulties aligning across national and regional health agencies on safety recommendations ◦ Complex process to combine data across different monitoring systems

Activity	Impact	Challenges
Policy innovations and frequent interim guidance delivered through SAGE	◦ Scientific Advisory Group of Experts on Immunization (SAGE) timely policies on diverse issues	◦ Incomplete information and inconsistency across products over time ◦ Policy updates must be translated into operational and programmatic shifts, on every level including supply/procurement, demand planning, no-fault compensation scheme, etc.

E. MANUFACTURING

Activity	Impact	Challenges
Manufacturing task force and SWAT team	◦ Paradigm shift from sequential, risk-averse manufacturing to rapid manufacturing with maximum compression of time-to-market (enabled with public investments and innovative technology) ◦ COVAX manufacturing task force established to: (i) Tackle vaccine supply challenges, addressing shortages of raw materials and single-use materials (ii) Expedite cross-border transit of these materials (in partnership with BMGF, IFPMA, DCVM and BIO) ◦ Related SWAT team provided support to COVID-19 vaccine developers for drug substance and drug product scale-up and scale-out, supply chain and release assays	◦ Import/export restrictions ◦ Limited geographic diversity in global manufacturing capacity means disruptions or delays have broader impact ◦ Majority of supply in initial supply-constrained environment going to a few countries, with significant supply shortages in vaccines for majority of countries ◦ Shortage in consumables (e.g. glass vials), especially in optimal products for lower-income contexts
Establishment of COVAX Marketplace	◦ Actively engaged manufacturers, fill-finish facilities and suppliers to matchmake partners ◦ Accelerated the global production of COVID-19 vaccine doses for COVAX by matching existing suppliers of critical inputs with vaccine manufacturers ◦ Enabled the production of an additional ~90 million vaccine doses, of which over 40 million were dedicated for COVAX ◦ Supported WTO to instigate free flow of goods measures to improve import/export permits, border control measures and a harmonized coding system for critical consumables/materials	◦ Requires building trust with pharmaceutical companies to exchange private/potentially sensitive information on supply shortages ◦ Supply/demand mismatch for consumables (e.g. glass vials) during demand surge ◦ Limited visibility/ability to reliably forecast demand hinders planning

Activity	Impact	Challenges
Manufacturing scale-up support	• Increased manufacturing capacity for select candidates (e.g. SII, Clover and Novavax) • Global access agreements that dedicated volumes to the 92 COVAX AMC-supported countries	• Lack of timely/early funding constraints impact of newly established manufacturing facilities once they are developed, manufacturing facilities not already built/in use risk missing demand window • Larger, well-funded and/or country-backed candidates are less interested in scale-up support tied to access commitments • Sovereign states can offer benefits beyond funding, including industrial sites, established national manufacturers to partner, R&D support and knowhow • Political factors, such as export bans can override early access commitments
mRNA tech transfer hub	• Created a centre that will build capacity in L(M)ICs to produce mRNA vaccines through a centre of excellence and training (the mRNA vaccine technology hub in Cape Town) • Issued EOIs to manufacturers interested in receiving technology transfer and to establish a global biomanufacturing workforce training hub • Biomanufacturing workforce training hub established in Republic of Korea to increase capacity of LMICs to absorb biomanufacturing technology	• Mapping of IP and monitoring of freedom to operate (FTO) is challenging for novel technologies with emerging IP • Limited access to the right tools and information makes it challenging to measure/follow tech transfer • Skilled human resources in LMICs a barrier to receiving and absorbing technology • NRA maturity levels in many LMICs a barrier to infrastructure investment and technology transfer

F. PROCUREMENT

Activity	Impact	Challenges
Early commercial agreements with manufacturers	• First COVAX dose administered within 39 days of the first dose in the world (HIC) • Provided access to portfolio of 11 vaccines/candidates across four technology platforms • Achieved high overall volume commitments (~4.2 billion doses through APAs) - secured initially through MoUs and later APAs, some of which gave preferential access • Secured commitments in advance of complete development/regulatory approval on "at-risk" basis	• Securing access to large volumes of early doses requires making investments early, at scale and at-risk (lack of early funding and taking time to shape, agree and regularly update on risk appetite means lagging behind sovereign states with greater resources and risk tolerance) • Short, one-year or ad hoc funding cycles make it challenging to carry out longer term agreements with potentially higher volumes, especially vis-à-vis countries with greater and more predictable resources

Activity	Impact	Challenges
Early commercial agreements with manufacturers *(continued)*	• Integrated financing mechanisms with R&D and manufacturing push funding	• In a competitive environment, higher-income countries have comparative advantages in terms of ability to fund R&D and manufacturing sites in exchange for preferential access, ability to pay higher prices, higher risk tolerance, longer term funding and less stringent terms for regulatory approval • Limited knowledge of the trajectory of pandemic at early stage when early commitments need to be made, e.g. scientific recommendations, product characteristics, regimens and long-term efficacy, absorptive capacity and demand • Difficult to accurately gauge demand signals and align supply, especially with unclear demand or estimated/communicated demand that may not align with highly aspirational political targets • Delayed submission of regulatory dossiers by manufacturers, particularly to WHO PQ, diminishes the impact of this innovation in practice
Rapid and successful establishment of dose sharing principles and mechanism	• Rapidly addressed the acute supply shortage issue and allowed doses to flow to COVAX participants • Enabled access to donor country surplus dose volume in a novel way, helping doses that may have been wasted to be put to good use to protect people • To-date, more than 800 million doses delivered to over 100 countries through dose sharing via COVAX	• Supply rapidly sourced through donations of supply that was originally procured by others resulted in volumes often coming at short notice, on an ad hoc basis and with very short expiry dates that limit their usefulness/ability to be absorbed • Legal, logistical and technical complexities exacerbated by the above factors – resource intensive to operationalize for all stakeholders, including recipient countries, in an emergency response environment. E.g. requiring agreements signed between donors, manufacturers, Facility – and multiple communications with recipient countries to ensure readiness • Other channels for donations to countries, and lack of clear visibility on subsequent impact on demand/ distribution planning
Cost sharing (streamlined access to doses with multi-lateral development bank financing)	• AMC participants benefited from a streamlined process for accessing both donor-funded doses to cover high risk groups and more, as well as cost-shared doses to protect a higher proportion of their population if desired, using multilateral development bank (MDB) or domestic financing	• MDBs unwilling to take the risks of advance purchase agreements, required COVAX to take on additional risks under cost sharing • Need to maximize speed and minimize complexity of/harmonize disbursal processes

Activity	Impact	Challenges
Cost sharing (streamlined access to doses with multi-lateral development bank financing) *(continued)*	• Development of the cost sharing allowed hedging of supply against funding risks (e.g. failure to fundraise) and countries' potential increased needs in the future	• Shifting supply versus demand dynamic as the pandemic evolves, combined with supply of donor funded doses and cost shared doses at sub-optimal times, can contribute to supply-demand mismatch and presents additional risks
COVAX Humanitarian Buffer	• Co-created a mechanism alongside the humanitarian sector to enable access to COVID-19 vaccines for high-risk, vulnerable populations in humanitarian settings • Secured liability waivers from several manufacturers for the benefit of humanitarian agencies to facilitate access in humanitarian settings • Delivered doses in support of governments seeking to reach more people in humanitarian settings	• Legal and political limits in different organizations and contexts outline why solutions to reach these populations are so difficult to implement • Importation/cross-border movement of doses, regulatory approvals are challenging when working outside state-based system and with novel products • Precedent set for this pandemic re: manufacturer requirements for I&L, along with lack of WHO PQ products created roadblocks and delays: model I&L/waiver for I&L not applicable in all instances throughout delivery chain, necessitating complex negotiations on ownership of residual risks • Complexities reflected in a complex application process (including the need for a legal entity to sign on behalf of humanitarian populations) • Products available may not always optimally match needs of populations concerned • Logistical challenges planning for demand/distribution in highly-uncertain and hard-to-reach contexts • Given the sensitivity of working with groups outside of government in sensitive settings, there is need for confidentiality, which makes transparency challenging.

G. ALLOCATION

Activity	Impact	Challenges
Global values framework for vaccine allocation	◦ Created mechanism that could calculate vaccine allocation based on dynamic supply and demand inputs (including country infrastructure/ absorptive capacity, vaccine preferences, etc.) to equitably and optimally allocate doses globally ◦ Provided specification of trade-offs in priorities for products with supply shortage ◦ The mechanism evolved over time to adapt to complex and ever-changing realities to take into account the role of bilateral deals, to ensure countries with lowest coverage were prioritized, to adapt to country preferences and expressed demand	◦ Evolutions in the pandemic requiring several rounds of changes to complex allocation algorithm methodology. ◦ These include: Nature of the pandemic leading to willingness of countries to assume unprecedented risk, and increased supply from other sources; Shifting supply situation (low or high) impacting decision metrics; different product types and characteristics; shifting country preferences; changing epidemiology/new variants; evolving policy recommendations; interdependency with complex supply chain/order and shipment management process underneath it ◦ Shifting model to accommodate high levels of donations in response to supply shortages ◦ Dose donations present additional complexity for allocation, in terms of unpredictable shelf lives, short notice of availability, potential earmarking, with these elements also leading to refusals by some countries ◦ Uncertainties, evolutions and complexities led to challenges clearly communicating updates and processes to countries ◦ Ethically complex decision-making required, especially with limited supply – for example, equity versus 16 prioritizing countries that could absorb doses
Population Prioritization Roadmap (through SAGE)	◦ Guided countries/provided standard guidelines on which populations should receive vaccine doses first (e.g. patients with co-morbidities, elderly, healthcare workers)	◦ Incentivizing countries to follow guidelines in a rapidly changing epidemiological environment ◦ Focusing on highest risk populations versus those that are more readily accessible
Formalized Joint Allocation Taskforce (JAT), along with mechanisms to enable rapid redeployment and reallocation	◦ Formal JAT taskforce with clear mandate and set objectives, focused on implementing allocation mechanism that was able to be agile in response to changes in SAGE guidance ◦ Taskforce constructed with high-level of clarity on expectations and decision-making ◦ Additional flexible COVAX mechanisms allowed for rapid redeployment and reallocation in initial stages of rollout, as needed – critical when supply was limited	◦ Effectively communicating changes/ frequent updates in allocation methodology to 90+ countries ◦ Limited data availability and delayed, ad hoc input, plus unknowns on supply and demand impacts the effectiveness of the allocation algorithm and adds complexity ◦ Resource intensive and complex rapid reallocation/redeployment process

Activity	Impact	Challenges
COVAX Allocation 2.0 and country demand-driven planning	• Switch to allocation 2.0/demand-driven approach, implemented in 2022 once scale up occurred and supply was no longer limited • Country-driven demand planning process and tools implemented helped identify countries' product and timing needs • New cross-agency demand planning working group rapidly created a process that was quickly adopted by countries	• While process was adopted, implementation required resources and capacity building at country level • Frequency and reliability of information in a dynamic demand environment where countries' needs may change constantly

H. COUNTRY READINESS

Activity	Impact	Challenges
Implementation of large scale assessment for country readiness	• Readiness assessment performed across 80+ countries using the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) • Implemented VIRAT through country working groups, and managed it through country-led governance mechanisms • Developed an assessment tool based on best practices and experiences of new vaccine introductions, aligned with the NDVP	• Lack of early alignment on coordination responsibilities across broader global stakeholders (beyond COVAX) leading to confusion and unmet needs • Managing and aligning parallel processes/multiple efforts aimed at the same task, e.g. readiness assessments undertaken by multilateral development banks • Determining a source of truth for data inputs when there are contradictions between readiness assessments • Lack of real-time data to inform assessments
Development of dedicated regional and global coordination mechanisms	• Aligned resources, support across several coalitions and coordination structures and platforms, including COVAX Country Readiness and Delivery Global Working Group (CRD), Regional COVID-19 Vaccine Delivery Working Groups, Implementer Action Network, Funders Forum, COVID-19 Vaccine Delivery Partnership, etc. • Region-specific partner coordination mechanisms were set up to support countries in preparedness and roll out	• High transaction costs, including staff fatigue, associated with constant coordination across multiple processes and mechanisms • Difficulty in engaging in a structured manner with non-traditional immunization actors (e.g. humanitarian actors, CSO) at speed, particularly incorporating their existing coordination mechanisms • Challenge accurately/regularly communicating guidance across countries • Numerous stakeholders contributing to country delivery, at times without transparent processes and strong country-level coordination mechanisms, resulting in inefficiencies and confusion

Activity	Impact	Challenges
Increasing cold chain capacity in countries to absorb large deliveries of vaccines	• Previous investment in cold chain equipment during Gavi Alliance 4.0 strategic period, left countries in a better place in terms of cold chain capacity • This was supplemented with dedicated resources for countries to apply for investment in cold chain equipment (2-8°C) to increase storage capacity at national and sub-national level • 73 countries/economies applied for support and received cold chain equipment (including low- and middle-income countries)	• Challenges scaling manufacturing, shipping and installing equipment in a limited time frame
Ultra-cold chain (UCC) capacity scale up	• Largest UCC scale up in history, financing, coordinating and delivering 800 ultra-cold chain freezers to nearly 70 countries in 2021 that enabled delivery of mRNA vaccines to L(M)ICs • Built vaccine management capacity (e.g. deployment of vaccine management specialist to countries, outsourcing installation and maintenance of cold chain equipment) • COVAX partners built on experience from Ebola response	• Challenges introducing new type of technology to countries with no previous experience • Infrastructure investment needed in countries for smooth operation of UCC (electric power stabilization, backup power supply, ambient temperature environment, etc.) • Logistical challenges securing flights due to the size of the equipment and dangerous goods nature of refrigerant gas, coupled with global transport disruptions

Technical guidance to prepare for COVID-19 vaccine introductions	• Technical teams (COVAX Country Readiness and Delivery Working Group) developed guidance for vaccine management for each of the EUL approved vaccines, demand generation, community engagement, data monitoring, safety monitoring and vaccine delivery planning and strategies to reach target populations forming the basis for:
	  ◦ Dedicated capacity building of in-country implementers (OpenWHO courses with 75,000+ participants and numerous global, regional and country level workshops)
	  ◦ National training programmes (e.g. e-learning modules)
	  ◦ National Deployment and Vaccination Plans (NVDP)
	• Leveraged experience of developing guidance for new vaccines over last two decades
		• Identifying experts and ensuring they have sufficient time to develop guidance, while operating in an urgent emergency context
		• Complex project management to ensure guidance is developed, reviewed and approved on time
		• Developing guidance in advance despite unknowns (e.g. whether a product would be qualified, and the cold chain profile it qualified as) requiring frequent updates.
		• Lack of willingness to "take a position" on vaccines that may be better suited for developing countries (due to product characteristics, cost, availability, etc.) whilst wanting to remain neutral.

Activity	Impact	Challenges
National Deployment and Vaccination Plans (NDVPs)	• Comprehensive guidance document that provided a step-by-step approach for countries on how to develop NDVPs • Leveraged best practices of previous vaccine introductions and detailed Country Readiness and Delivery Global Working Group (CRD) technical guidance (mobilizing over 200 immunization experts from all major health agencies) • COVAX requested countries to submit NDVPs to ensure adequate planning on how to reach 20% coverage (initial target). In addition, many additional LMICs developed NDVPs for their own benefit • 200+ immunization experts dedicated staff time to write and review guidance, creating co-ownership • In total, 124 NDVPs were uploaded to the Partners Platform for review and approval as well as transparency for global health actors to tailor their support to country ambitions • COVAX partners collaborated with regional COVID vaccination working groups to review, provide recommendations and approve NDVPs • Reviewed and approved at record speed – completing approvals within a few days	• Countries have limited time and capacity to develop comprehensive deployment plans given inherently compressed timelines of pandemic, i.e. starting this during a pandemic was already too late • Variations in quality of the NDVP across different countries • Difficulty of costing these plans given the uncertainties on optimal vaccination strategy • Difficulties in coordinating with agencies such as the World Bank, who had their own processes for assessments • Complex and human resource intensive process to manage rapidly in a constrained environment
Country level support for vaccine rollout (human resources surge capacity and technical assistance)	• Mobilization of support across key areas (supply, communication for development, financing, data monitoring, surveillance) especially in AMC-supported countries through CDS funding • Supported countries to strengthen in-country deployment of vaccines through training, development of national guidance, technical assistance, operational coordination and funding • Provided surge capacity through newly hired staff/consultants • Supported shift of in-country level staff capacity to support preparation for vaccine deployment (including recruitment of retired staffs, recruiting volunteers and engaging medical and health science students) • Institutions raised surge financing to provide urgent support	• Limited mechanisms at the country level for sudden human resources (HR) surge at sub-national levels, highlighting current limits of public health HR – particularly for adult immunization – in lower-income countries • Limited availability/delays of timely funding, including from in-country and multilateral funds and funding mechanisms • Short notice from suppliers on availability and delivery of doses limits ability to plan campaigns in advance, straining limited resources • Competing country level health priorities, vaccine hesitancy and hesitancy in health workforce given risks of working during pandemic • Limited experience and plans for reaching high risk groups including HCWs, elderly and those with co-morbidities given that they are normally not targeted for vaccination.

Activity	Impact	Challenges
Digital remote working and training tools	• Developed remote training modules on products for healthcare workers and community workers – successful decision from early stages of the pandemic • Leveraged adult education best practices, working directly with WHO open training architecture	• Resourcing of additional experts able to translate paper-based guidance into e-learning modules • Access challenges when some in-country healthcare workers do not have access to computers/internet

I. GLOBAL TRANSPORT AND IN-COUNTRY DELIVERY

Activity	Impact	Challenges
Securing shipment solutions during global shut-down	• Rapid global shipment of vaccines during a time when few options were available • First 100 countries reached within six weeks of COVAX's unprecedented global rollout • Dedicated team identified solutions including providing vaccines via multi-country charter flights	• Dependency on countries providing export licenses for international shipments • Transport logistics - securing adequate volume during global transport disruptions (limited commercial availability of sea transport and commercial flights) • Increased costs associated with expensive alternative options (charter flights)
Real time data monitoring of countries' coverage, vaccine rollout, etc. through Electronic Joint Reporting Form (eJRF)	• Enhanced daily data sharing of countries coverage and COVID-19 vaccine administration • eJRF enabled monthly COVID-19 vaccine rollout data collection and monitoring, weekly implementation monitoring review on delivery risks • Monitoring dashboards/short message reminders were leveraged for dose reminders	• Getting timely/accurate data from countries • Change in dose regimen makes data capture more complex • Proliferation of public data/dashboards using parts, but not always the same, "source of truth" • Lack of regular reporting from some countries • Managing discrepancies between country administrative data and other reporting forms (eJRF)
Syringes scale up	• Funding and coordination of largest ancillaries scale up of auto-disable syringe procurement in history, (2.4 billion in 2021 and 2.8 billion in 2022), enabling safe administration of vaccines	• Logistical challenges due to global transport disruptions • Non-traditional/bespoke safe injection devices required for some products, increasing complexity to model demand and procure in advance and ensure availability ahead of vaccine arrival in country

Activity	Impact	Challenges
Joint platform for coordination of delivery support	• Improved coordination among partners/ funders, (Global Immunization Partner call, Implementers Forum, CSO engagement, regional working groups and partner coordination, Thematic Implementation Monitoring reviews between partners) bringing a joint view on country applications, National Deployment and Vaccination Plans (NVDPs) and partner support	• Partners outside of the construct remaining partly uncoordinated (e.g. multilateral development banks)
Development of global costing tool to influence vaccine delivery resource mobilization needs	• Created a centralized single source of information, using a consistent costing methodology and country-specific assumptions to estimate the resource requirements for vaccine delivery. Findings calibrated and incorporated in resource mobilization approach within COVAX • Costing exercise conducted to inform resource envelope needs	• Aligning on common sets of assumptions, many of which had significant cost implications • Backing up hypotheses with real-time country data • Estimating the share of domestic, bilateral and multilateral development banks funding allocated for delivery
Establishment of global financing tracker for delivery funding	• Developed and maintained a dedicated database to track financing/funding from multilateral, bilateral sectors as well as private sector contributions made available to countries to support vaccine rollout activities • Database tracks financing/funding flows from over 30 sources of financing to 133 low- and middle-income countries, creating visibility across countries and partners, aiding global, regional and country coordination efforts	• Lack of routine/regular updates from funders on allocations/disbursements • Challenges in obtaining data on fund utilization impeded an understanding of fund availability in country • Estimating global financing/funding flows and identifying a shared target on vaccine delivery costs
Creation of Funders Forum to engage COVID-19 vaccine delivery funders	• Regular meeting with major funders (bilateral, private, multilateral) that support COVID-19 vaccine delivery with resources, technical assistance and political support • Engaged funders on a regular basis – and discussed progress, bottlenecks and potential solutions	• Ensuring decision-making and funding disbursement timelines fully align • In the absence of structure, platforms may be utilized for information sharing rather than focused more clearly on raising needed delivery funds to overcome bottlenecks at country level
Adoption of Partners Platform to connect countries' budget needs with available donor resources	• Partners Platform where countries were able to submit their budget needs and donors could share information on available resources (Funders Forum and Implementers Action Network)	• Instituting tools to match country demand with donor funding earlier in the process will maximize their impact

Activity	Impact	Challenges
Innovation Working Group – scale innovations with focus on vaccine delivery	◦ Project Extension for Community Healthcare Outcomes (ECHO) e-training sessions to enable rapid training on health and vaccinations and an exchange of best practices across countries ◦ Data-driven Implementation Monitoring Report (IMR) process to identify and solve bottlenecks ◦ GIS-based digital mapping to target previously untargeted groups for vaccination ◦ Barcode enabled tracking for counterfeit vaccines ◦ COVID-19 served as a means of accelerating HSS by advancing GS1 barcoding standards; scanning capabilities and supply chain/regulatory collaboration on vaccine verification and visibility, including establishment of the traceability and verification system (TRVST), which can be applied to RI, ARVs and other pharmaceuticals. ◦ Community level digital monitoring of dose delivery with DHIS2 and uniquely identified QR codes ◦ Novel social listening and engagement tools for demand generation in areas with vaccine hesitancy	◦ Limited access to data and limitations of data collection infrastructure in L(M)ICs ◦ Multiple private sector initiatives and singular solutions for COVID-19 vaccines adopted despite advice to build interoperable systems from scalable known systems already in countries.
Targeted engagement with private sector to fill identified delivery needs	◦ Private sector engagement provided financial support, gap filled cold storage, transportation vehicles, helped raise awareness and establish mass vaccination sites.	◦ Level of private sector engagement varies by country ◦ Limited capacity to engage the private sector adequately across regions
Innovation focused on vaccine service delivery and service resumption and recovery	◦ New vaccination delivery approaches helped to reach parts of the population that might have otherwise remained unreached, employing several innovative delivery strategies (e.g. mass vaccination sites, workplace and school vaccination, extended hours and moonlighting) ◦ Mix and match use of different vaccines to complete vaccination cycles ◦ Quick service resumption and recovery interventions, such as catch-up campaigns and multi-antigen campaigns	◦ Disruption of other essential services including immunization, requiring follow-on and corrective actions to reduce loss of progress in immunization campaigns

Activity	Impact	Challenges
Leveraging existing emergency assets (e.g. EOCs), including systems built for polio response	• Leveraged existing polio assets – staff, technical assistance and infrastructure linking emergency operating centres (EOCs) that were used to deploy COVID-19 vaccines	• Ensuring sustainability over the long-term when capacity cannot be leveraged indefinitely
Establishing CoVDP (COVID-19 Vaccine Delivery Partnership) with global lead coordinator	• Enhanced coordination of country readiness and delivery operational support across COVAX partners as well as Africa CDC, World Bank and many other partners • Provided targeted support to 34 countries requiring concerted effort • Progress from 34 AMC countries with a COVID-19 vaccine coverage rate under 10% in January 2022, to just nine countries as of September 2022 • Improved global level coordination and advocacy between COVAX partners, countries, Africa CDC, WorldBank and many other by clarification of roles, coordination of global advocacy efforts (e.g. RCCE Summit) and high-level missions to countries. • Mechanism for improved data monitoring and reporting, keeping partners updated on the progress and priorities across countries • High-level leadership to increase focus on delivery challenges and promote political engagement	• Decrease in risk perception for COVID-19 with the emergence of Omicron created challenges in gaining traction for CoVDP with countries • Difficulties for countries to prioritize COVID-19 delivery programmes given other health and economic priorities