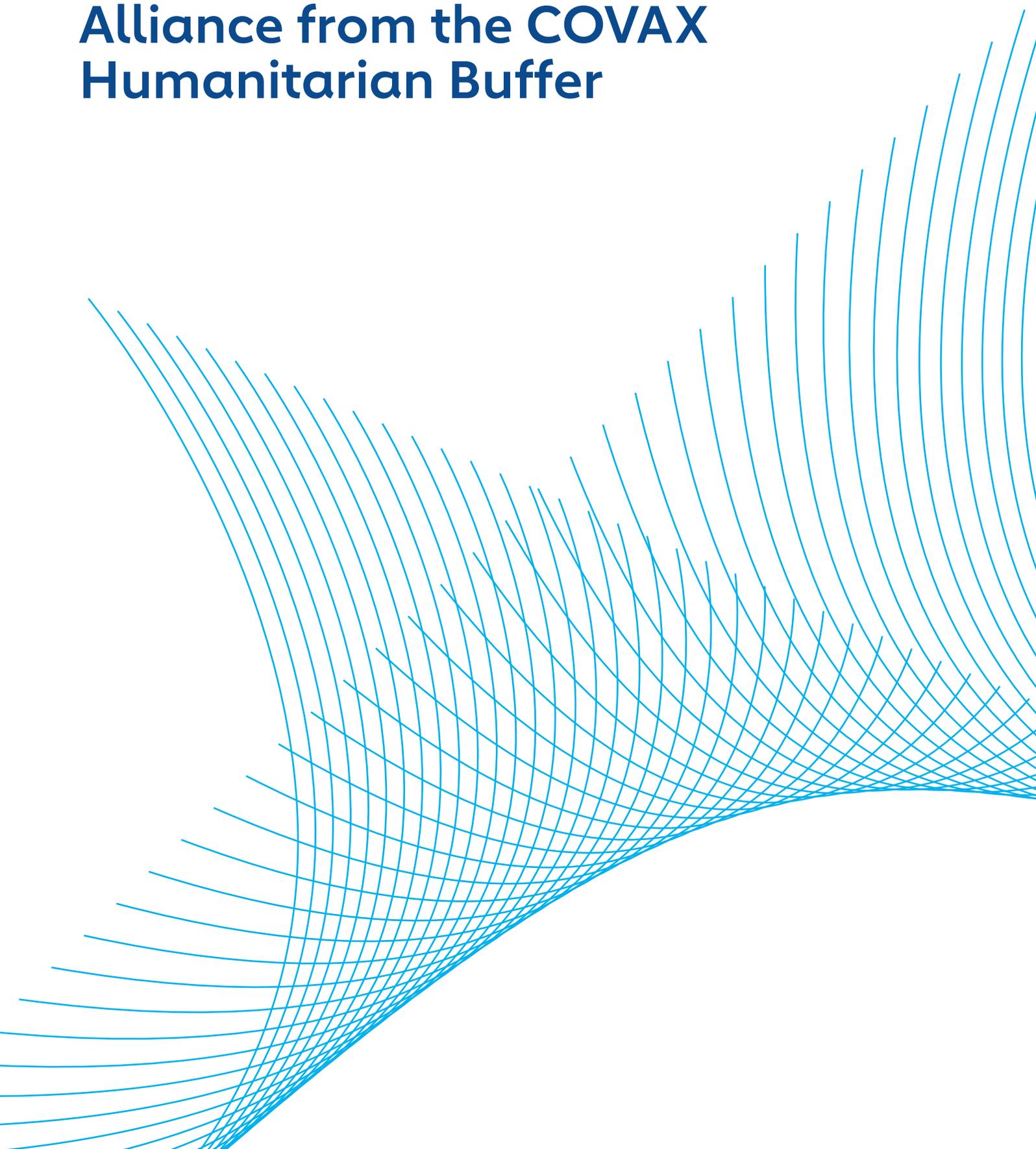


Discussion Paper

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10 Learnings for the Alliance from the COVAX Humanitarian Buffer



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In line with its commitment to constant innovation and leaving no one behind with immunisation, Gavi, the Vaccine Alliance continues to work on strengthening its model and strategies for operating in emergency and complex humanitarian settings. Experience gained through COVAX's efforts to reach the most vulnerable population groups can inform these efforts. Expanding Gavi's modalities, experience, and partnerships to work in these contexts will be key if the Alliance is to reach zero-dose children across

a growing number of humanitarian contexts, and be prepared for future pandemics.

The following 10 learnings highlight the ways in which the [COVAX Humanitarian Buffer \(HB\)](#) and COVAX's broader learnings in reaching humanitarian settings can contribute to both the Alliance's work in routine immunization, future preparedness and response efforts.



Design

1 **Establishing adequate resourcing, end-to-end processes, and design frameworks ahead of any future pandemics could generate significant efficiencies.**

Given this had never been attempted before, a great deal of time was required to get the HB mechanism and corresponding policies established both within Gavi and between COVAX partners. This included problem solving and navigating complex design components such as indemnification, liability, and broader legal agreements at the height of an unprecedented global emergency.

The following design considerations should be made in the future to build upon the experience of the COVAX HB:

- Given the fast pace of change in pandemics and often volatile operational context in fragile settings with competing priorities, the window of opportunity for deliveries could narrow quickly, making speed of action critical to success. Proactively identifying an operational blueprint and identifying internal resources for potential “surge support”—while simultaneously understanding the limitations of such processes—could be highly beneficial to responding in a timelier manner.
- Alongside the Inter-Agency Standing Committee's (IASC) – particularly civil society organization (CSO) expertise, future design could be strengthened through more extensive consultations, including with CSOs with a range of expertise and knowledge of national contexts, to better understand the full scope of needs and challenges.

- Response efforts in the future should be designed and communicated as part of a holistic response package to partners and participants (e.g. not just “vaccines”), understanding the importance of a multisectoral approach.

2 **The Alliance should better define and unpack comparative advantages and roles across its different agencies for vaccination in humanitarian settings, particularly in pandemic situations.**

Lack of definition and consensus of roles and responsibilities across the partnership at times proved challenging for HB coordination. Clear delineation of roles across WHO, UNICEF, and Gavi took months to establish given the new challenges presented by the pandemic setting – and may have contributed to misunderstandings and lost time. The standard decision-making landscape within the Alliance structure and IASC processes contributed to a lack of clarity around how to get decisions made, which forums should be used, and who should be brought into discussions.

Focal points and decision-making processes must be defined in advance to strengthen shared accountability (avoiding the “bystander effect” when so many partners are involved) and stalled decision-making. Building on the HB experience, it is now an opportune time to establish foundation/s for future Alliance ways of working in these contexts, supported as necessary by draft Memorandums of Understanding, agreed Standard Operating Procedures and documented roles and responsibilities.



Supply

- 3 Understanding the needs of humanitarian agencies with respect to novel or complex indemnification and liability (I&L) scenarios and compensation schemes is required at the outset, and must be built into other key pandemic response structures that impact supply.**

During the COVID-19 pandemic, where manufacturers required countries to provide indemnification for product liability for new vaccines, Gavi set about securing I&L waivers for doses to enable humanitarian agencies to directly deliver via the HB. The waivers were essentially given since humanitarian agencies do not possess the ability to take on additional I&L risk in the way sovereign states can. While most manufacturers

were willing to grant waivers, some of these waivers required lengthy negotiations with manufacturers. Furthermore, the COVAX No-Fault Compensation (NFC) scheme for Advance Market Commitment (AMC) participants—the world’s first international vaccine injury compensation mechanism—became a critical requirement for some non-state entities to deliver novel pandemic vaccine products; this was not at the forefront when Gavi and WHO designed this mechanism.

This is why it is critical to mainstream and anticipate the delivery needs and concerns of humanitarian agencies ahead of Advance Purchase Agreement (APA) discussions and other design considerations. This requires ample time, and much of this work could be ideally front-loaded in advance of future pandemics.



Demand

- 4 Proactive communications and targeted outreach could be required to generate demand and boost confidence in accessing vaccines.**

While the HB was grounded on a set of design assumptions, largely driven by the supply-constrained environment early in the pandemic, these assumptions may have hampered overall demand once supply was available. The conservative socialization approach adopted in 2021, to implement the mechanism as a “measure of last resort” (with national government-led response advocated as the primary response mechanism), likely contributed to lower-than-expected demand for Buffer doses over the course of 2021-2022.

This exacerbated the difficult position potential applicants often found themselves in with authorities (de facto or legitimate) given the perceived implication of a level of “state failure” in reaching all populations, which made CSOs uncomfortable in approaching governments to support this programme – and led to further operational issues down the line.

For future humanitarian engagements, a more active sensitization and outreach approach — complemented by new ways of working with governments and CSOs to

avoid politicization — is important to ensure demand and greater confidence in the ability to deliver to vulnerable populations.

- 5 Collaborating with diverse humanitarian actors and CSOs helps provide greater information and expertise to drive decision-making in complex contexts, and establishes greater credibility.**

While concerted engagement efforts across in-country health clusters, UN (including WHO and UNICEF) offices, IASC agencies and implementing partners, and Gavi country-facing teams could not markedly increase the number of applications to the COVAX HB, working closely with the UN Global Health Cluster (GHC) did prove effective in identifying potential gaps.

These included highlighting contexts that needed additional support at a sub-national level, potential humanitarian partners operating in low-coverage areas, and a clearer understanding as to where populations with humanitarian needs were located. These relationships and connections could be more broadly beneficial to Gavi’s zero-dose agenda and future pandemic response programs to improve data and understanding of active humanitarian actors and contexts.



Decision Making

6 Governance, and the potential role of external decision-making bodies or committees, requires thoughtful consideration of benefits, transparency, and potential trade-offs.

The COVAX experience of engaging humanitarian agencies and CSOs through formal process via the IASC also generated important learnings. The IASC was tasked with assessing HB applications against a clear set of criteria and to uphold humanitarian principles in its assessment and practice; this provided a neutrality that Gavi would have struggled to maintain alone given its role as a cross-stakeholder convenor. In addition, the IASC was perceived to bolster the credibility of the HB mechanism for donors and potential applicants, given

this group's highly valued expertise and experience in humanitarian delivery.

However, this partnership also presented some challenges. For example, the IASC and Gavi country teams did not engage as actively as they could have, in many cases due to confidentiality and bias concerns on both sides. As a result, there was a perception from some that certain decisions were made based on incomplete evidence or information. Whether and how to engage external groups, the level of responsibility to be delegated and how to ensure appropriate information sharing between actors, and the decision-making authority to be granted to each should be carefully weighed and all trade-offs considered.



Delivery

7 The COVAX experience has provided a sound foundation for future legal considerations associated with supply of vaccines across diverse settings and actors, particularly in a pandemic environment.

Legal aspects, such as I&L, import, regulatory, and sanction checks, required exceptionally lengthy negotiations and are incredibly challenging when attempting to delivery quickly via humanitarian agencies in humanitarian settings.

Emergency Use Authorisation of the pandemic vaccines played a vital role in global vaccine rollout; this is a State-owned process, as is importation, which requires that the COVAX HB applicants engage with country governments (including de facto) to access doses directly through the HB. While it is not suggested that state-based processes be subverted, there is a need to more thoroughly understand the

limitations or opportunities for humanitarian agencies when importing or engaging with national regulatory bodies. Thorough mapping of importation processes under emergency settings is required, and if needed advocacy and technical assistance provided, at a country-by-country level to resolve and understand these bureaucratic challenges to pandemic response.

Operating in cross-border environments creates grey areas, including issues linked to geographically bound regulatory authorization and tenuous coordination/ approvals from de facto authorities or decentralized government officials. This will require a sound risk assessment by all partners, and at times, this risk will need to be equally shared by partners – either in the Alliance or in future pandemic response efforts. A principled and conflict-sensitive method of ensuring distribution of vaccines across borders—which does not breach national or international sanctions—is required to already be in place in the very early stages of an application to ensure no delays or complications.



Implementation and Partner Coordination

8 Delivery funding is necessary for humanitarian agencies and planning for a holistic package of support is essential.

Providing vaccine doses alone is not enough to ensure vulnerable populations get vaccinated. Sources of delivery funding—whether through engaging with partners providing support or clarifying potential flexibilities in Gavi grants—should be clearly defined, mobilized, and communicated externally as early as possible. Embracing flexibility in funding and building in responsiveness and agility to changing needs and contexts is highly encouraged. Anticipating the need for eventual integration of activities and shared costs is necessary to adapt to both the phases of a pandemic and reality of competing needs in humanitarian settings. Gavi aims to further reflect on this vital learning as the Alliance forges new multisectoral partnerships in efforts to reach zero-dose children.

9 Investing in landscaping and relationship building in advance of the next pandemic would be beneficial.

Establishing relationships with more diverse implementers, particularly with non-traditional partners, is admittedly complex and time intensive: while certain processes and tools, such as application forms and review/approval mechanisms, can be relatively standardized ahead of time, establishing more robust mapping of expanded partners and potential context-specific requirements will be essential to providing effective tailored interventions rather than a “one size fits all”. Developing a solid and coordinated overview of (or establishing shared access to) mapping of populations and implementers across identified fragile, conflict, or unique humanitarian settings may help expedite outreach and response in the future.



Reporting

10 Further reflection and potential investments may be warranted in monitoring and data collection.

The utilization of doses for vaccination of approved target population groups specifically provided via the HB (and any broader support) has been challenging to demonstrate, even when recipients have submitted reporting. There may be no incentive to report, or no consequence associated with non-reporting.

Furthermore, data and learning on “what delivery modalities work in different scenarios and settings” remain limited from the COVAX experience. Exploring complementary monitoring approaches, such as use of third-party monitoring / standardized spot-checks and investing in more real-time learning, could be warranted and more successful in the future. Consulting humanitarian agencies ahead of time on the implications and value-add of these investments could prove beneficial.

In parallel with the shift in focus to reaching zero-dose children and communities, Gavi will continue to embrace an adaptive approach that is based on continuous learning. The cross-partner team working on the HB demonstrated a strong commitment to course correction and continued improvement throughout the course of its work, responding as

best possible to evolving contexts and feedback from applicants. The ability to move quickly and iterate where necessary is critical to success, as are having design, process, and operational frameworks that reflect a broad range of expertise and learnings. This experience provides an example for the Secretariat as it continues efforts around agile ways of working.

