

Less than a Lifeline: Challenges to the COVAX Humanitarian Buffer

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PHOTO CAPTION: A medic prepares to administer a dose of the COVID-19 vaccine to a man at a camp for the internally displaced in northern Syria on June 14, 2021. (Photo by OMAR HAJ KADOUR/AFP via Getty Images)

Introduction

President Biden recently announced that the United States would convene the [Global COVID-19 Summit: Ending the Pandemic and Building Back Better](#) on September 22 on the margins of this year's United National General Assembly. That summit must prioritize efforts to assist the world's most vulnerable populations, many of whom are [being left behind](#) in the global COVID-19 response. Communities in conflict and humanitarian crisis zones have been hit hard by both the [direct and indirect effects](#) of the pandemic. Now, plans to ensure that these populations have access to vaccines are faltering.

The Inter-Agency Standing Committee (IASC) – the UN's highest-level humanitarian coordination forum – estimates that [167 million](#) people are at risk of being excluded from vaccination efforts because they live in hard-to-reach areas or are being omitted from national plans. [COVAX](#), a global mechanism for providing equitable access to vaccines, has established a Humanitarian Buffer. The buffer is designed to serve as an instrument of last resort – one that can help close the vaccine gap for populations in crisis, including the forcibly displaced. Yet nearly six months after its inception, not one vaccine has been distributed as part of the buffer.

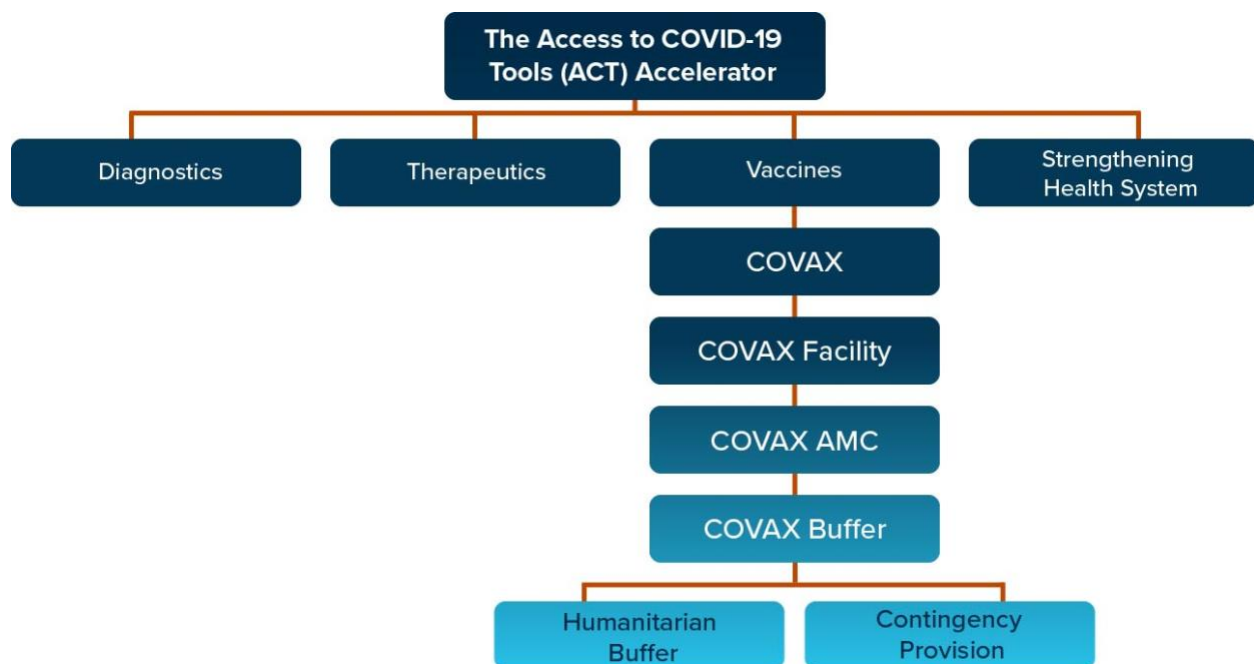
The major stakeholders in the global COVID-19 vaccination effort need to take steps urgently to help ensure that the Humanitarian Buffer fulfills its mandate. These include formally launching the buffer, addressing issues around vaccine liability, streamlining vaccine rollout in hard-to-reach areas, and providing funding for delivery operations. The upcoming global vaccine summit announced by President Biden provides an important opportunity to get the Humanitarian Buffer back on track.

Understanding the Access to COVID-19 Tools (ACT) and COVAX

The Humanitarian Buffer is part of a much larger global collaboration to combat COVID-19. In April 2020, global health organizations, governments, civil society groups, businesses, scientists, and other stakeholders came together to establish the Access to COVID-19 Tools (ACT) Accelerator. The ACT Accelerator is comprised of [four pillars](#):

diagnostics; therapeutics; strengthening health systems; and vaccines. The vaccine pillar – known as COVAX – was established to provide equitable access to vaccines.

COVAX is [co-led](#) by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization (WHO). It [focuses on](#) the development, manufacturing, and access of COVID-19 vaccines for 20 percent of every participating country’s population. As described below, high and low-income countries opt into COVAX either through agreement and/or eligibility. Initially, partners established COVAX with the goal to provide 2 billion doses to these countries by the end of 2021. But only [280 million](#) doses have been shipped to date, and COVAX has [reduced](#) its 2021 projections to 1.42 billion doses.



At the heart of COVAX is the COVID-19 Vaccine Global Access Facility ([COVAX Facility](#)) which focuses on procuring vaccines for all [COVAX participants](#) through commitments from self-financing (higher income) countries. The COVAX Facility gives these countries [options](#) to pay into purchase agreements to obtain access to a wide range of vaccines. These purchase agreements increase Gavi’s purchasing power, enabling it to work with manufacturers to negotiate lower prices and secure a large stock of various vaccines for all participants.

Under the COVAX facility is a funding mechanism is for low and low-middle-income countries (LMICs) and is called the Gavi COVAX Advance Market Commitment (COVAX AMC). The COVAX AMC is designed to ensure that [92 low-and middle-income eligible](#)

[countries](#) have equitable access to vaccines in the COVAX facility. It is [funded](#) by development aid from bilateral and multilateral donors, private sector donations, and philanthropy.

The COVAX Buffer Explained

As the race for a vaccine began, health officials [warned against vaccine nationalism and called on governments](#) to prepare for an equitable rollout across the globe. To overcome this challenge, COVAX was established to help provide “[fair and equitable](#)” access to a vaccine. Yet early on, it became clear that gaps were already emerging in vaccine access and coverage in vaccination plans. To meet this particular challenge, COVAX has established a two-pronged vaccine supply mechanism (known as the “[COVAX Buffer](#)”) made up of a Contingency Provision and the Humanitarian Buffer. The Contingency Provision facilitates the release [of vaccine doses](#) for emergency outbreaks with high mortality, and the Humanitarian Buffer is a [measure of last resort](#) designed for [high-risk](#) populations who might be left out of national vaccination plans. The COVAX Buffer is slated to receive [5 percent](#) of the total COVAX facility’s vaccine supply. Thus, the buffer could be up to 100 million doses.

Scenarios where the Humanitarian Buffer [could be deployed](#) include: 1) new humanitarian crises occurring after vaccination plans are finalized; 2) situations in which governments do not control an area of their territory; 3) situations where national authorities tried but were unable to support vaccination to populations of concern, and 4) situations where national authorities otherwise cannot or will not include certain groups. Populations of particular concern for the Humanitarian Buffer include [refugees, asylum seekers, stateless persons, internally displaced persons, and minorities](#).

Humanitarian agencies and all COVAX participants, both AMC eligible countries and self-financing countries, are eligible to [apply](#) for these doses. They must provide evidence that a population is excluded from national plans according to the possible scenarios previously listed and must substantiate their ability to distribute.

A Slow Start: Challenges Facing the Humanitarian Buffer

The COVAX Humanitarian Buffer could serve as an important instrument to ensure that the world's displaced and other vulnerable populations receive vaccines. Unfortunately, it has yet to become truly operational, despite the fact that the first COVAX vaccine was delivered in February 2021. Initial plans had called for allocations of up to [100 million doses](#) to the buffer by the end of 2021. However, to date, the current supply stands at [14.7 million doses](#) allocated to the Humanitarian Buffer¹ and no doses have been distributed. Gavi did not open buffer [applications](#) to governments and humanitarian agencies until June 1, 2021. As of July 27, only [3 applications](#) have been submitted. Since then, little information has been released about the approval of applications, and there have been no further public updates.

Governments and international organizations are leaving displaced populations behind in COVID-19 vaccination efforts. It was [clear from the start](#) that the COVID-19 pandemic would disproportionately affect the world's most vulnerable, among them refugees, asylum seekers, and internally displaced people (IDPs). The [pandemic](#) exacerbated preexisting crises and disrupted humanitarian response, and these negative impacts will continue and become more severe without more equitable vaccine access to displaced populations. As compared to the numbers for 2020, the large majority of countries experiencing humanitarian distress have in 2021 reported increases in COVID cases, and half of the countries with humanitarian response plans [have reported at least twice the number of cases](#).

COVAX Supply

The Humanitarian Buffer's slow start may in part be linked to some of the wider setbacks faced by COVAX. It is worth remembering that the some [100 million vaccine doses](#) slated for the Humanitarian Buffer are to be drawn from 5 percent of the overall COVAX supply. These doses are to be funded through the COVAX AMC. However, as noted above, COVAX has recently scaled back its 2021 vaccine distribution target from 2 billion to [1.42 billion doses](#). Part of the problem has been decisions by wealthy countries to enter into bilateral deals with manufacturers to purchase enough doses to

¹ Editor's Note: This report originally stated that "no doses" had been allocated to the Humanitarian Buffer. That is incorrect, and the text has been updated to state that "14.7 million have been allocated to the Humanitarian Buffer."

["vaccinate their populations several times over."](#) Participation from all countries, specifically higher-income countries, is essential to COVAX. Bilateral deals from these countries make up the [majority of COVID-19 vaccine doses](#) and have [reduced](#) the amount of global supply available for COVAX. In addition, India's [devastating COVID-19 surge](#) early this year forced the Serum Institute of India – one of the main suppliers for COVAX – to redirect its output to support [India's domestic vaccine campaign](#). While the implications are not immediately quantifiable, the shortfalls in COVAX vaccine supply [will negatively impact](#) the availability of doses for the Humanitarian Buffer.

Liability

The issues of liability and indemnity agreements around the COVID-19 vaccines have been major challenges facing the Humanitarian Buffer, creating hesitancy on the part of distributing parties, especially humanitarian organizations, which would apply for doses and have responsibilities for distribution. At the heart of the matter is a disagreement over which parties should assume the [risks of liability](#) in the event that a [serious adverse event](#), such as an unexpected medical occurrence resulting in injury as a result of the COVID-19 vaccine. This has been a unique issue for the COVID-19 vaccines because the rapid development of the vaccines and widespread rollout [shortened the time frame](#) for manufacturers to lock in insurance deals to protect them from the financial risk of potential lawsuits.

Typically, manufacturers receive insurance against potential legal action, but now it is unlikely that they will be able to [obtain insurance](#) until vaccines are granted full regulatory approval through WHO and national agencies in AMC countries. The lack of such approvals has impacted manufacturers' access to full insurance, which typically allows them to assume liability for their products. This has led manufacturers to require that any party receiving COVID vaccines, whether countries or [humanitarian agencies](#), assume liability for the vaccines through an [indemnity agreement](#), which requires countries and humanitarian agencies to pay costs related to injury claims that might be made against manufacturers.

The [COVAX No-Fault Compensation \(NFC\) Program](#) provides a partial solution to the problem by enabling individuals who received their doses in an AMC-eligible state through the Humanitarian Buffer to apply for financial compensation from the NFC instead of pursuing litigation. [ESIS](#), a subsidiary of the global insurance company Chubb, is responsible for reviewing NFC applications and administering compensation. The program is funded through a [tax on each vaccine](#) dose that is allocated to AMC countries. Compensation for injury is to be [based on a formula](#) involving each country's

GDP to reflect the cost of living in each country. The hope is that this process will reduce costly legal action and more easily enable humanitarian agencies and less-wealthy nations to enter into agreements with manufacturers.

However, many humanitarian organizations remain concerned that individuals may choose to forgo the compensation and instead pursue lawsuits. Several senior NGO officials have [expressed](#) deep concerns about their organizations taking on financial and [legal](#) risks that could conceivably lead them to bankruptcy. Furthermore, agencies would assume considerable risk should they choose to deliver vaccines in a non-AMC country, as these are not eligible for the NFC program.

Hard to Reach Areas

Up to [80 million people](#) live in areas controlled by non-state armed groups, and significantly more live in remote, inaccessible regions of the world. As noted above, these populations are at high risk of being left out of national vaccination plans. The Humanitarian Buffer was established in part to reach many of these populations – particularly those living in crisis zones. The humanitarian agencies, which would in theory partner with the buffer, have track records of delivering aid and other essential items like vaccines in these environments. However, there are early signs that this distribution system may face significant hurdles.

First, a significant [setback for COVAX](#) has been the number of unused doses left to expire in many low-income nations. This experience serves as a warning about the buffer. If national governments are failing to deliver and administer vaccine doses in areas they control, aid groups will likely face an uphill battle in crisis zones or other areas beyond the reach of the state. Part of the problem is that conflict adds risk, costs, and other complications to the distribution of any vaccine. Population centers or rural areas hit by fighting often have weaker infrastructure and less access to healthcare and other basic services, making aid delivery a challenge in general.

Second, the complexities of operating in crisis and conflict environments are exacerbated by specific attributes of the COVID-19 vaccines. For example, delivery of most of the available doses comes with [cold chain delivery requirements](#). This is particularly true for vaccines like those developed by Pfizer and Moderna. These vaccines require [extremely low storage temperatures](#), which means freezer storage rather than refrigeration. In addition, vaccines that must be administered in two doses,

such as Pfizer, Moderna, Sinovac, AstraZeneca, create rollout complications, as it may be difficult to get individuals to return for their second shot in crisis environments.

Third, humanitarian agencies applying for doses must provide evidence that they have the ability to deliver vaccines through previous evidence of vaccine distribution. They must also submit a full plan including transportation, human capacity, public health capability, and other logistical components. However, past performance may not be fully predictive of the capacity of an organization to execute a COVID-19 vaccine campaign since the funding from the humanitarian buffer does not include operational and delivery costs. As we shall see below, these costs can be quite significant.

Funding for Operational Costs

Insufficient financial support, particularly for operational costs, has been a major sticking point for the Humanitarian Buffer. While the buffer will cover the cost of doses and shipping to designated points of entry for implementing partners, it does not cover in-country operational and delivery expenses. These expenses include but are not limited to personal protective equipment (PPE), transportation, cold chain, and training. These are the responsibility of the receiving humanitarian agency or government and are not eligible for AMC funds. When applying for the buffer, recipients indicate the level of external financial support which they require for these operational costs, and must submit a budget showing which resources are already available to them.

Gavi has allocated [\\$7.5 million USD](#) to help cover these expenses in scenarios where alternate funding is unavailable, but this number pales in comparison to the full cost of delivery. Estimates of vaccine delivery in humanitarian contexts average [\\$3.00 per dose](#), almost double the \$1.66 per dose in stable settings. CARE estimates that for every [one dollar that is invested](#) in vaccine doses, it would need another \$5 for delivery of the vaccines. The United States has made significant contributions for [vaccine funding and donations](#), but the United States and other donors still have a long way to go. UNICEF'S ACT-A [Humanitarian Action for Children \(HAC\) appeal](#) is the central funding mechanism for the operational and delivery costs associated with the Humanitarian Buffer. Although the ACT-A (HAC) appeal aims to raise [\\$120 million](#) to support delivery and rollout costs of Humanitarian Buffer vaccines, and \$510 million for all of their vaccine efforts, as of June 30, 2021 it is only 40 percent funded.

Conclusion

The Humanitarian Buffer's creation signaled a more hopeful path toward the goal of vaccinating the displaced and other vulnerable populations. But logistical and financial issues are preventing the Humanitarian Buffer from reaching its potential. The risk of COVID-19 transmission for those living in conflict and other crisis zones increases the longer these barriers remain in place. Key stakeholders and donors must move quickly to ensure that the buffer is able to fulfill its mandate.

Recommendations

- ***The United States Global COVID-19 Summit must place the Humanitarian Buffer at the center of the world's agenda on COVID-19.***

A key agenda item is "Vaccinate the World," and the "world" must include those who are most vulnerable and at-risk. Senior officials from COVAX and partners like the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, WHO, UNICEF, and the Inter-Agency Standing Committee (IASC) should brief the summit on the state of the Humanitarian Buffer, challenges facing its operations, and plans to overcome them.

- ***The Agencies—GAVI, CEPI, WHO, UNICEF—that are partners in the Humanitarian Buffer must provide greater transparency and regular updates on its rollout.***

NGOs and others are concerned about the lack of transparency and information. In such circumstances, donors have less clarity on ways to strengthen the Buffer. COVAX should provide regular updates on buffer rollout, challenges, applications, and funding. These should be easily accessible to the public and widely disseminated.

- ***Manufacturers, GAVI, IASC, and international donors should seek ways to alleviate liability concerns among humanitarian agencies, and manufacturers should be prepared to accept liability on vaccine doses allocated to the humanitarian buffer.***

There is no simple solution to this challenge. But in light of the significance of the buffer, and the relative financial capacities of manufacturers, we support the expressed preference of an IASC working group that manufacturers be prepared to accept liability. Gavi should also work with insurance companies to explore other ways to provide protection for humanitarian agencies, such as developing insurance specific to Humanitarian Buffer doses.

- ***Donors must work to fully fund UNICEF's ACT-A Humanitarian Action for Children (HAC) appeal.***

UNICEF coordinates the centralized funding mechanism for operational and in-country costs of Humanitarian Buffer doses, and there is a shortfall of [\\$307 million](#). Without urgent financial support for this mechanism, many humanitarian agencies will be unable to afford delivery and operational costs.

- ***High-income and rich countries should prioritize COVAX.***

High-income and rich countries should increase their participation in COVAX's efforts in addition to their own bilateral deals. Donors should also increase funding and vaccine dose donations to COVAX in order to maximize the facility's supply and therefore the number of available doses via the Humanitarian Buffer.