

Executive summary

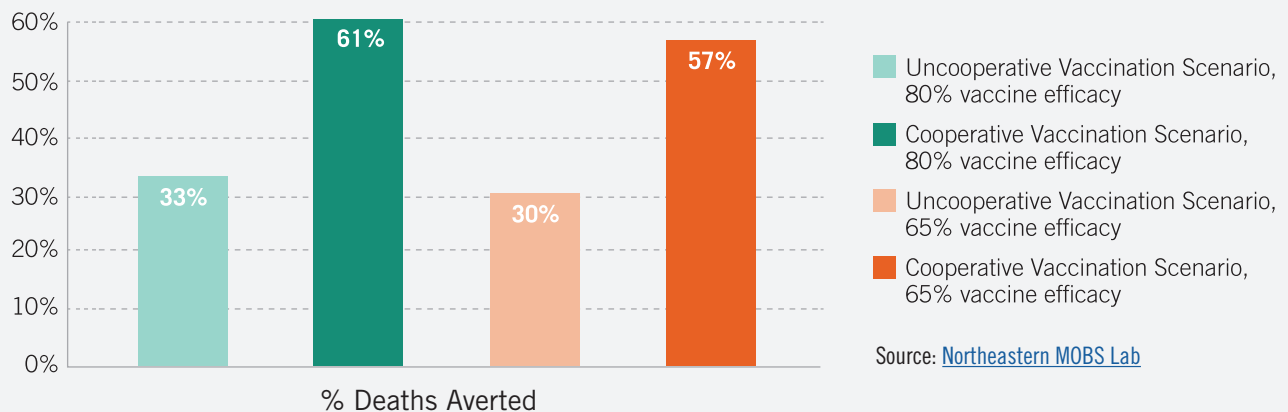
A global race is underway to develop vaccines that can help end the COVID-19 pandemic. An unprecedented effort involving researchers, advocates, governments and private industry has produced hundreds of COVID-19 vaccine candidates. As of November 2020, dozens of these are currently being tested in humans, and nine are in large-scale efficacy trials. Innovations in study timelines, long recommended by HIV advocates, are helping to accelerate these trials safely. Many people are hopeful that a COVID-19 vaccine will be the fastest ever developed. But developing a safe and effective vaccine is only the beginning.

To achieve actual public health impact against COVID-19, the world will need the largest global vaccine delivery effort ever. Both equity and the need for an effective, coordinated response demand that:

- Safe and effective COVID-19 vaccines are affordable and available to all.
- Access to approved vaccines is prioritized for those who need them most, especially immediately after licensing, when supply will be limited.
- Health systems are prepared to deploy vaccines equitably and efficiently.

A free market, profit-driven approach to access, in which wealthy countries and individuals monopolize the global supply of COVID-19 vaccines, would not only be unjust, but would fail to end the pandemic.

Comparing Vaccine Nationalism to Equitable Access



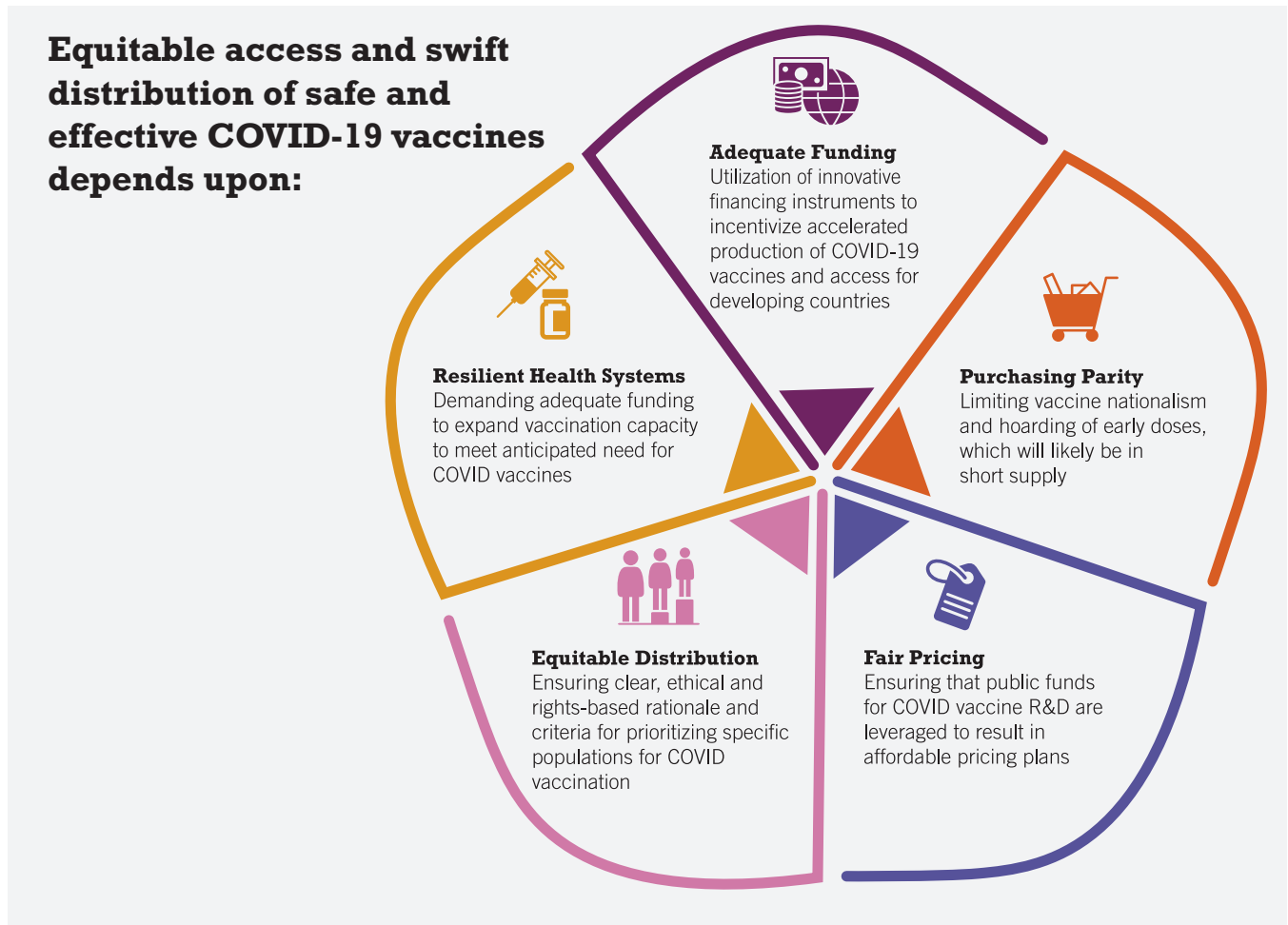
Using a counter-factual scenario, this model compares the impact of a vaccine distribution approach dominated by vaccine nationalism to one that prioritizes equitable access. In the 'uncooperative scenario' 2 billion (of an estimated 3 billion) doses are taken by high-income countries, compared with a 'cooperative scenario' where vaccines are distributed based on population size.

In an interconnected world, prioritizing vaccination for the people who are at the highest risk is key to controlling, containing and ending the COVID-19 pandemic. Risk of COVID-19 extends to frontline workers (responsible for protecting health and providing essential services), the elderly, those most likely to become seriously ill and those most likely to pass it to others. Connecting these people first to a safe and effective vaccine regardless of where they live or their ability to pay, is a priority in scaling back the pandemic. At the same time, there must be global agreement on strategies to produce and distribute proven vaccines in sufficient quantities to allow everyone, worldwide, to be vaccinated as quickly as possible.







Global cooperation is critical, but market forces, exacerbated by growing "vaccine nationalism"—in which countries reserve large quantities of vaccine doses for their citizens only—threaten to undermine rational and equitable access to COVID-19 vaccines.

Historically, HIV advocates have been at the forefront of demanding equitable access to lifesaving treatment and prevention. HIV activism has been a driving force in reducing drug prices, holding governments and pharmaceutical companies accountable, combating stigma and misinformation and securing funding to curb the epidemic. These are the same issues that threaten the COVID-19 response today.

Advocates can play a critical role. This guide outlines five factors that will govern access to a COVID-19 vaccine: adequate funding, low-/no-cost pricing, purchasing parity, equitable distribution and resilient health systems, (see Figure 1). This guide is designed to help advocates understand each of these factors so that they can dismantle barriers and leverage opportunities to secure equitable access. This guide is part of a package of resources for advocates, including [vaccine pipeline reviews](#) and a [Regulatory Approval Primer](#).



These five factors outline a framework for thinking about access issues. While there are multiple opportunities to become engaged, this document presents six near-term entry points where advocates can play a role to influence the way vaccines are distributed globally and locally.

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1. Supporting the COVAX Facility: Pressuring governments to join the COVAX Facility (see further description below) to maximize purchasing power and ensure equitable access to safe and effective vaccines as soon as they receive regulatory approval, with a commitment to donate any surplus vaccine doses in their national stockpiles to the Facility.
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2. Calling out vaccine nationalism: Highlighting the damaging impact of vaccine nationalism on global efforts to end the COVID-19 pandemic as quickly and humanely as possible.
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3. Calling for accountability and transparency on public investments in vaccine R&D: Demanding greater government and private sector transparency on the use of public funds for R&D, pre-purchase agreements, advanced market commitments for vaccines and pricing plans.
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4. Advocating for equitable and transparent vaccine pricing: Ensuring that distribution criteria are ethical and rights-based, with consistent metrics for prioritizing populations for COVID-19 vaccination.
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5. Demanding input from civil society on definitions for fair and equitable vaccine distribution: Insisting on participatory approaches and transparency to develop context-specific allocation frameworks.
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6. Engaging in planning for vaccine deployment and health system readiness: Demanding that governments adequately fund vaccination programs and share national deployment plans with the public.

1. Support the COVAX Facility

[COVAX](#) is the vaccine pillar of the ACT-Accelerator, a global collaboration to accelerate the development, production and equitable access to COVID-19 interventions, including tests, treatments and vaccines. COVAX is co-led by [GAVI: The Vaccine Alliance](#), the [Coalition for Epidemic Preparedness Innovations \(CEPI\)](#) and the [World Health Organization \(WHO\)](#). The COVAX Facility is a procurement mechanism that pools money from participating countries for the purchase of COVID-19 vaccines. Countries join the Facility to gain access to a portfolio of COVID-19 vaccines at set prices. Currently, 172 countries—representing 70% of the world’s population—have expressed interest in joining the COVAX Facility.

Because the COVAX Facility manages a large and diverse portfolio of vaccine candidates, participating nations ultimately have a better chance of accessing safe and effective vaccines than if they were to negotiate directly with each vaccine developer. As more nations sign up, the Facility has more purchasing power and thus can reduce vaccine prices for all participating countries. Notably, however, some countries, including the United States and Russia, are not participating.

COVAX FACILITY GOALS:

- Ensure equitable access to COVID-19 vaccines across countries, regardless of income level.
- Manage a portfolio of vaccine candidates across a broad range of technologies to maximize chances that the portfolio includes safe and effective vaccines.
- Accelerate the timeline to equitable access to a proven vaccine in order to end the epidemic as quickly as possible.

The COVAX Facility is open to countries at all income levels, but participation differs. Self-financing countries (with high- and upper middle-income) pay into a pool when joining the Facility, and funded countries (low-income) receive vaccines at no cost through GAVI. Self-financing countries can request vaccines to cover 10-50% of their populations; funded countries will receive vaccines for up to 20% of their populations. Through COVAX, no country can receive vaccines for more than 20% of their populations until every participating country has received enough vaccines to cover 20% of their own. Vaccines for funded countries will be purchased using a funding mechanism known as an advanced market commitment, or AMC. The funds for the AMC come from official development assistance, the private sector and philanthropy. Some middle-income countries that do not qualify for support from GAVI through the COVAX Facility face a unique predicament, and may not be able to afford to purchase vaccines directly from manufacturers.

Key Considerations for Countries Participating in the COVAX Facility

High-income	Middle-income	Low-income
<ul style="list-style-type: none">■ Offers an opportunity to expand portfolio of investment.■ Participation critical to ensure adequate pooled funding power.■ Does not preclude bilateral agreements in addition to COVAX participation.	<ul style="list-style-type: none">■ Access to vaccines at lower prices.■ Even at reduced prices, may be challenging to make upfront payments for large quantities of vaccines.■ Procurement challenges associated with purchasing a product not yet approved by national authorities.	<ul style="list-style-type: none">■ Participation dependent on COVAX Board approval.■ Potential cost-share of COVID-19 vaccines and delivery, (US\$1.60 – US\$2/dose).■ Additional funding needed to support deployment of vaccines.

Mechanisms such as the COVAX Facility are only part of the solution. While they may help ensure a supply of proven vaccines to countries with limited resources, the ability of COVAX to deliver on its promises is contingent upon funding and supply. COVAX cannot prevent high-income countries from receiving vaccines first through agreements made directly with manufacturers. The existence of COVAX also does not solve complex questions around which countries get vaccines first, an important consideration in the likely case that initial vaccine supplies will not be enough to meet global demand. It also does not address the logistical challenges that many countries will face in distributing a vaccine.

COMMITMENTS TO EQUITABLE ACCESS

The Bill & Melinda Gates Foundation (BMGF) and several pharmaceutical companies [have pledged](#) to ensure that COVID-19 vaccines, therapeutics and diagnostics are and will be available, affordable and fairly distributed in low- and middle-income countries (LMICs).

2. Call out vaccine nationalism

What is vaccine nationalism?

1. Large national investments in companies and their vaccine candidates to secure access.

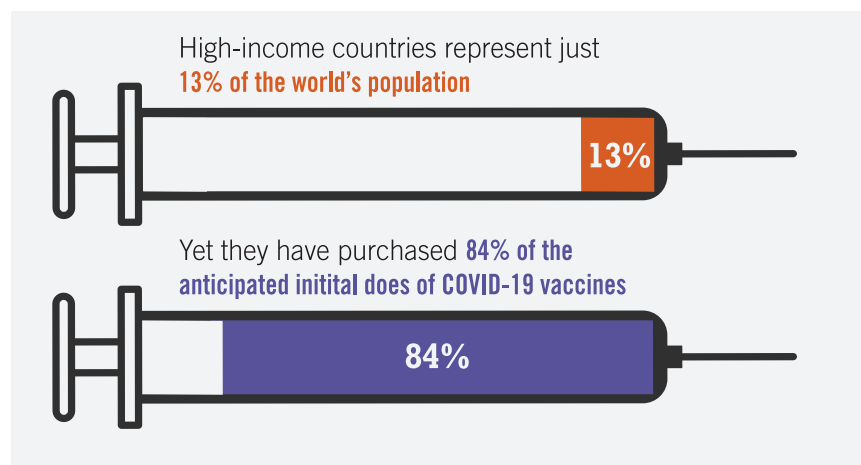
2. Limiting international patent transfers and prohibiting the export of a locally produced vaccine

3. Purchasing or pre-ordering doses to cover a country's own population's needs.

The rise of vaccine nationalism poses one of the greatest challenges to the equitable distribution of vaccines. If nations reserve vaccines for their own populations or prevent locally-produced vaccines from being exported, the global response to the pandemic will falter and fail. Australia, the European Union, Israel, Japan, the United Kingdom, the United States and others have directly funded pharmaceutical companies and manufacturers to ensure that their citizens receive the earliest access to approved COVID-19 vaccines. While these investments have spurred R&D, they may also:

- Make it more likely that a select few countries will be able to vaccinate significant portions of their populations, while other nations in need may receive little if any vaccine and/or may experience significant delays in vaccine access.
- Create discrepancies in access that result in a longer and more devastating pandemic, especially for poorer nations that cannot afford to make private deals to secure vaccines.
- Reduce the supply of vaccines and funding for collective efforts such as COVAX that focus on building the capacity for equitable vaccine access.
- Drive up COVID-19 vaccine prices, making it more difficult for others--especially middle-income countries--to afford vaccines.

Even before any COVID-19 vaccine has been approved for use, the influence to date of vaccine nationalism is chilling. Currently, high-income countries have pre-purchased 84 of every 100 doses of potential COVID-19 vaccines. This means that wealthy countries, which represent only 13 percent of the global population, could receive more than four out of five doses of future COVID-19 vaccines, leaving the remaining 87 percent of the world's population to scramble for access to just 16 percent of COVID-19 vaccine doses.



3. Call for accountability and transparency on public investments in vaccine R&D

National governments are investing billions of dollars in COVID-19 vaccine R&D as well as the pre-purchase of doses. But there is little to no public accountability attached to these public funds: there are no conditions on pricing, profits or the transfer of intellectual property and manufacturing knowledge to support broader production and access to vaccines.

This public investment in COVID-19 vaccine R&D and procurement is unprecedented and presents a unique opportunity to demand transparency from governments and pharmaceutical companies. Pressure from advocates can encourage vaccine developers and pharmaceutical companies to:

- Make public the actual cost of vaccine R&D and the share of costs paid for with public money.
- Waive exclusive licenses and enable technology transfer to increase vaccine production in a wider range of countries. (For example, India and South Africa have petitioned the World Trade Organization to suspend or waive patents to enable the transfer of COVID-19 vaccine technology.)

Establishing transparency on the use of public funds for COVID-19 vaccines sets a precedent for adopting these practices in relation to all public health priorities that involve public funds.

4. Advocate for equitable and transparent vaccine pricing

Vaccines are complex to make and usually expensive to manufacture. However, the unprecedented volume of COVID-19 vaccines needed could reduce production costs significantly.

Estimates on production costs vary widely, ranging from roughly US\$3 to \$20 or more per dose. Final prices are likely to be determined by R&D costs, manufacturing costs (including the cost of related supplies, such as syringes and glass vials), the number of doses required and the willingness of purchasers to pay.

The relative efficacy of a vaccine could also affect its price, resulting in higher prices for more effective vaccines. Additional factors that may impact pricing include whether COVID-19 requires repeat, seasonal vaccination like the flu and whether developers will agree to maintain at cost or no-cost prices once the pandemic is largely controlled.

Some large pharmaceutical companies, including Johnson & Johnson and AstraZeneca, have pledged to sell their COVID-19 vaccines without seeking profits. Transparency regarding R&D and production costs is essential in order to determine true at cost pricing. And it remains to be seen whether other manufacturers can be persuaded to make similar commitments and whether these commitments will be honored after priority populations are vaccinated.

THE PEOPLE'S VACCINE

The [People's Vaccine](#) is a coalition of organizations, including UNAIDS and civil society groups, calling for a free vaccine for everyone, everywhere. In recognizing a vaccine as a global public good, this movement urges governments and pharmaceutical companies to dismantle monopolies on vaccine production, to share knowledge and technology and to provide the vaccine at cost. The call to action also demands that civil society meaningfully participate in decisions around vaccine access.

5. Demand input from civil society on definitions for fair and equitable vaccine distribution

The question of who gets a vaccine first has implications for global public health and raises ethical, social and economic considerations. A consensus on clear guidelines for identifying priority populations for vaccination—both within countries and around the world—is essential; without it, distribution decisions may fail to meet public health priorities, may exacerbate inequities in healthcare and may ultimately reduce the impact of an eventual vaccine. Different global and national institutions have proposed frameworks to guide

decisions on vaccine allocation. Opportunities for civil society to participate in the development of these frameworks have been limited, but the WHO and the United States have shared drafts with independent observers, including civil society organizations, for public comment and validation.

- WHO has developed a [values framework](#) and [allocation framework](#) (adopted by COVAX) to assist countries in deciding which populations to prioritize for vaccination. WHO estimates that approximately 1.4B people meet the high-need criteria.
- The US National Academies of Sciences, Engineering, and Medicine (NASEM) published an [allocation plan](#). It proposes a phased approach to deliver vaccines to priority populations, including healthcare workers, individuals 65 years of age or older, other high risk adults with underlying conditions and essential workers.
- The recently published “Fair Priority Model”, developed by a group of bioethicists, proposes a formula that prioritizes first reducing premature deaths, then reducing severe economic impact and finally lowering high transmission rates.

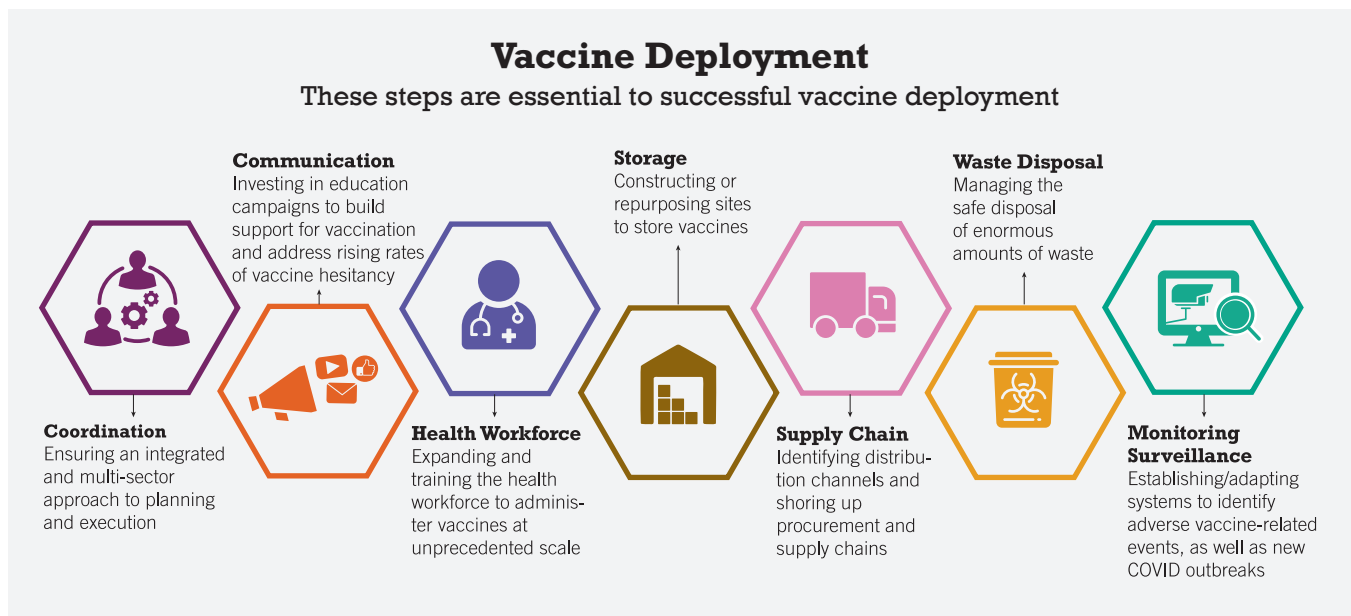
At the national level, fair and equitable vaccine distribution will only be possible in conjunction with efforts to counter the systemic racism and structural inequalities that place certain populations (such as Black, Indigenous and Latinx people in the United States) at higher risk for contracting or dying from COVID-19. Racial and ethnic health disparities have also been reported in Australia, Brazil and the United Kingdom, and they underscore the structural barriers to criteria and validate that they are clear, ethical, rights-based, and include metrics for ensuring global access.

Advocates can demand that normative bodies work with civil society to review distribution vaccine access for prioritized populations. Advocates can participate in national and local task forces to monitor fair and equitable vaccine distribution and respond rapidly to grievances.

6. Engage in planning for vaccine deployment and health system readiness

Once a vaccine is licensed, the world will embark on the largest vaccination effort in history. Historically, child immunization programs have been largely successful, yet adult vaccination programs have not fared as well. Delivering and rationing a vaccine across all ages poses unique challenges. This effort will happen in countries with health systems that have been overwhelmed by COVID-19, and, in many cases, were struggling even before this pandemic. The response to COVID-19 has severely hampered routine immunization, family planning and HIV treatment and prevention services. Vaccine deployment may further strain health systems that are struggling to provide basic services during the outbreak.

Vaccine distribution is complicated in any circumstance. To deliver a vaccine at scale will present a massive logistical challenge and will require health systems to overcome myriad barriers, including limitations and restrictions caused by the virus, limited infrastructure, politicization, consumer distrust of medical systems, poverty and racism. In addition, RNA-based vaccines require special handling unlike any other existing vaccines. This will demand new capacities in shipping and storage, a complicating factor globally and especially in LMICs. If multiple vaccines are eventually licensed, trade-offs between each product’s efficacy, ease of distribution and cost will need to be made.

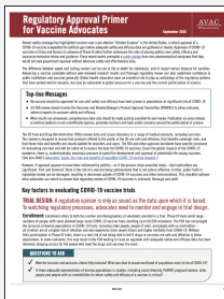


Some existing systems can be partially repurposed to support COVID-19 vaccination. New, innovative approaches for vaccine delivery will be necessary to reach everyone. Child immunization programs are well-established platforms that could be leveraged to deploy a COVID-19 vaccine, especially in LMICs. Expanding access points through mobile teams and pharmacies—a frequent practice for seasonal flu vaccines—will also be critical. Yet funding to support these efforts is not in place. Advocates can demand that governments expand the capacity to deliver vaccines and share national deployment plans with the public. Ultimately, the success of such plans depends on funding and political commitment. And the success of this endeavor will hopefully lay a foundation for equitable global vaccine delivery and more resilient immunization systems to respond to future pandemics.

Key reference documents:

- [COVAX](#)
- [WHO Fair Allocation Mechanism Framework](#)
- [NAESM report](#)
- [Facilitating Access to a COVID-19 Vaccine through Global Health Law](#)

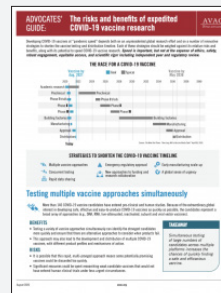
AVAC COVID Resources



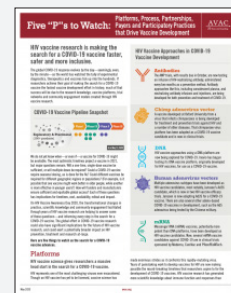
[Regulatory Approval Primer for Vaccine Advocates](#)



[COVID-19 Vaccine Pipeline Cheatsheet](#)



[Advocates' Guide: The risks and benefits of expedited COVID-19 vaccine research](#)



[Five "P's to Watch: Platforms, Process, Partnerships, Payers and Participatory Practices that Drive Vaccine Development](#)

Find these and other resources at www.avac.org/covid.

About AVAC

AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic. For more information, visit www.avac.org.