

POLICY BRIEF

Enhancing Readiness for Large-Scale Distribution of the COVID-19 Vaccine



When a vaccine becomes available, priority will be given to health workers. Photo credit: ADB.
Advance country preparation and global collaboration are crucial to the efficient, effective, and equitable delivery of the future vaccine.

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Introduction

The death toll from the coronavirus disease (COVID-19) pandemic and its impact on lives and livelihoods continue to increase as the world waits for a vaccine.

Substantial resources have been deployed to accelerate vaccine development. While governments are heavily banking on these efforts to return life to normal, a safe and effective vaccine will likely be in limited supply initially. Therefore, a strategy for phased vaccine rollout and continued pandemic control using public health measures and other tools will be required.

Countries need to address their unique epidemiologic, demographic, infrastructure, and financing challenges in their national plan for introducing the vaccine in a manner that will reduce mortality, strengthen health system response, and build economic resilience. They also need to work with other countries to ensure equitable and speedy access to the vaccine for all.

This policy brief is based on [presentations by PATH](#), a global nonprofit organization dedicated to health for all, at the [Policy Actions for COVID-19 Economic Recovery \(PACER\) Dialogues](#) organized by the Asian Development Bank (ADB).

High Hopes amid the Challenges

Latest data from the *New York Times* shows that [more than 165 vaccines for the coronavirus disease \(COVID-19\) are under development and 42 of these are undergoing human trials](#). Several candidates are from Asian countries, including the People's Republic of China (PRC), India, Republic of Korea, and Thailand.

The extraordinary scale and speed of vaccine research and development efforts are fuelling high hopes, but expectations should be tempered as several prospects may fail. Previous experience has demonstrated that the probability of success for a vaccine in early stage development is around 7% in the preclinical phase and 17% in clinical trial stages. The absence of a blueprint makes the process even more complex for a first-of-its-kind vaccine.

If and when a vaccine comes to fruition, worldwide demand is undoubtedly going to exceed initial supply. Addressing the epidemiological needs globally requires massive doses for 215 states and territories, but the current best-case estimate is that only two billion doses will be available by end of the year. This shortage obviously raises a conundrum as a study conducted by epidemiologists David Dowdy and Gypsyamber D'Souza suggests that 70% or more of a population would need to be vaccinated to achieve herd immunity. On top of this, some products in the current pipeline will require more than one dose, and possibly larger amounts for adults and high-risk groups.

To meet demand, scaling up vaccine production will be imperative. However, the manufacturing facilities and technology transfer will depend on which vaccine will emerge successful. Although there are a few frontrunners that show promise against the virus, it is unclear which one will demonstrate efficacy against COVID-19 and gain safety approval in the quickest possible time.

Another issue lies in the divergence of regulatory requirements and processes across the world, which could be a hurdle for countries to quickly obtain access to the vaccine for their respective citizens. Additionally, the income disparity among countries could result in access inequities. Wealthy economies are well-positioned to directly secure deals with other governments and vaccine developers and to pay more for the much-needed supply—which may leave the low- and middle-income nations at a disadvantage.

Posing another challenge is the vaccine delivery—an equally daunting and resource-intensive endeavor as vaccine development. Effectively launching a new vaccine and its efficient delivery will be contingent

upon financing and the capacities of health systems, which may be lacking in most low-income countries.

Logistical considerations also come into play, with packaging and cold chain requirements conditional on a viable vaccine. The end-to-end temperature control and other storage and handling factors could be major implementation barriers for low-resource nations that likely have inadequate infrastructure.

Physical distancing, which is a necessary measure to limit transmission, and vaccine hesitancy could also affect delivery and uptake.

Obtaining the Vaccine

Funding for vaccines

With the staggering impact of COVID-19 on societies and economies, investments in vaccines must be rapidly mobilized. Along with government contributions, innovative finance mechanisms, such as vaccine bonds, should be leveraged to fund vaccines. Advance purchase commitments are also useful instruments designed to incentivize vaccine developers to produce enough eligible vaccines through demand guarantees.

Innovative regulatory processes

The crisis urges a rethink of the traditional course of vaccine development to expedite solutions while adhering to high standards of quality, safety, and efficacy. Innovative approaches, such as parallel and adaptive trials, could speed up testing and comply with safety protocols at the same time.

Assuming a vaccine is proven safe and efficacious, researchers will apply to regulatory bodies globally for production and distribution. However, the lack of alignment on regulatory standards from one country to another can cause inefficiencies, which could impede the immediate introduction of the vaccine across the globe. Therefore, countries need to take steps toward harmonization by coordinating on policies for vaccine approval by regulatory agencies.

Manufacturing scale-up plans

Action should be taken now to build production capacity while research and development are still underway. The facilities and equipment necessary for manufacturing depend on what will turn out to be the best vaccine. Thus, investing in manufacturing at this point could be a risky undertaking. However, there is a strong case for making this uncertain investment given the urgent need for universal access to the vaccine.

The expected high demand for lower-priced vaccines could stimulate local manufacturing, particularly in developing countries, where pharmaceutical or biological manufacturing capacity is in place. In Asia, countries should coordinate to harness the capabilities of neighboring nations with existing facilities.

Countries should evaluate timelines, financial and human resource investment needs, regulatory requirements, and technical risks associated with manufacturing biologics prior to exploring technology transfer options.

Delivering the Vaccine

Planning and communications

Successful vaccine delivery is rooted in proper strategic planning, which should encompass regular consultations with key stakeholders, prioritization of target segments, review of vaccine suitability, assessment of current delivery channels, and evaluation of resource requirements. It is important for countries to consider how to introduce the vaccine without disrupting existing routine immunization services.

Advocacy and communications will be an integral part of the vaccine introduction and delivery process, from ensuring the public is informed on the criteria used to allocate doses within the country to reaching target groups not normally part of vaccination programs. Crisis communication plans should also be put in place. Transparency will be essential to mitigate the effects of misinformation and mistrust around vaccines.

Mass campaigns that rely on large gatherings may not be possible or appropriate because of the need for physical distancing. As such, new delivery strategies will likely need to be designed and deployed.

Health systems strengthening

COVID-19 vaccine development, manufacturing, financing, and procurement need to be complemented by strengthening the capacity of countries on the development of an allocation methodology, administration of vaccines, reporting, and post-marketing surveillance. Following immunization, post-marketing surveillance will be essential to rigorously monitor outcomes and identify and investigate adverse events in relation to the vaccine.

Delivery costs

In addition to vaccine procurement, the financial implications of distribution should be evaluated. Because COVID-19 requires nontraditional approaches, any additional costs for new modes of distribution should be integrated into national financing plans. The supplies, personal protective equipment, and cold chain logistics, among many others, also need to be factored into the budgeting exercise.

Mobilizing Financing

Governments around the world have marshalled billions of dollars for vaccine research and development in response to COVID-19. Several arrangements between countries and companies have also been established to secure the supply of future COVID-19 vaccines. For example, the United States has committed to providing \$10 billion to several vaccine developers and vial and syringe manufacturers under Operation Warp Speed.

In July 2020, the International Finance Facility for Immunization (IFFIm) issued over \$220 million in

vaccine bonds to support the vaccine development efforts of the Coalition for Epidemic Preparedness Innovations (CEPI).

Alongside these initiatives, the Access to COVID-19 Tools (ACT) Accelerator was formed to serve as a framework for collaboration to make swift progress on the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

Within the ACT-Accelerator, COVAX, which stands for COVID-19 Vaccine Global Access, is driving the work on vaccine development, manufacturing, procurement and delivery at scale, as well as policy and allocation. The Global Alliance for Vaccines and Immunizations (Gavi), CEPI, and World Health Organization (WHO) lead COVAX. CEPI steers product development and manufacturing capacity efforts while Gavi manages global financing and procurement in collaboration with WHO on the delivery of any successful vaccine.

COVAX ensures that the most suitable candidate vaccines get the backing they need to maximize the probability of success. It invites global participation to pool demand and resources to support vaccine procurement. COVAX negotiates five to 10 advance purchase agreements at the highest possible volume and most reasonable price for vaccine candidates that meet the technical threshold criteria. There are nine vaccines that are part of the COVAX initiative, with an additional nine candidates under evaluation.

To address funding for developing economies, Gavi launched in June 2020 the COVAX Advance Market Commitment (AMC) to support the participation of low-income countries and lower-middle-income countries. Fundraising for COVAX is ongoing, with \$600 million raised against the goal of securing \$2 billion by the end of 2020 to fund the initial cost of the AMC. An additional \$3.54 billion will be required to procure two billion doses for all COVAX members and \$3.2 billion to cover delivery costs by the end of 2021.

This leaves a sizable funding gap that will need to be filled. It is also important to note that there are potential products that are not yet part of COVAX. In terms of supply, the facility will be designating doses for only 20% of the population of participating countries, thereby offering a partial solution to abate the global pandemic.

Given the need for universal coverage and the complexities of vaccine development, procurement, and delivery, countries have been pursuing initiatives apart from COVAX and forging bilateral deals with developers. Inclusive Vaccine Alliance, for instance, has been set up by France, Germany, Italy, and the Netherlands to solidify their negotiating positions and secure doses for the European Union. Bangladesh's Beximco Pharmaceuticals has entered a pact with Serum Institute of India (SII) to ensure the country receives an agreed quantity from the institute. Sinovac Biotech in the PRC has also signed a supply agreement with Bio Farma in Indonesia.

Ensuring Global Access

Through the COVAX Facility, doses will be distributed equitably to participating countries—giving priority to their health workers and then the most vulnerable segments of their population—as vaccines become available. Further amounts will be provided based on the country's need, vulnerability, and COVID-19 threats. A small proportion of the total doses may be kept in reserve for emergency and humanitarian response.

Self-financing high-income countries and upper-middle-income countries that are part of COVAX will be required to contribute a portion of the procurement amount upfront to support the facility's ability to negotiate supply agreements with companies and a speed premium. About 80 of these countries have submitted nonbinding expressions of interest to COVAX.

Doses for countries with a gross national income (GNI) per capita under \$4,000 or that are eligible for funding under the World Bank's International Development Association (IDA) will be subsidized through the COVAX AMC. With this facility, OECD donors make commitments to vaccine manufacturers through official development assistance funds in exchange for sufficient vaccines at a price affordable to these countries. There are 92 countries that qualify for AMC, including seven Southeast Asian countries: Cambodia, Indonesia, the Lao People's Democratic Republic, Myanmar, the Philippines, Timor-Leste, and Viet Nam.

Expanding Manufacturing Capacity

An estimated supply of one billion doses by end of the year will hinge on production expansion. COVAX will encourage manufacturers to invest in scaling up and help share the associated risks.

Twelve developers in Phase 2/3 trials have announced their vaccine capacity estimates. AstraZeneca and the University of Oxford are projected to have 700 million doses available in 2020, followed by Sinopharm with 200 million and ImmunityBio with 100 million doses.

Recently, Gavi and the Bill & Melinda Gates Foundation announced their collaboration with SII—the world's largest vaccine manufacturer by volume—to accelerate its production and distribution of up to 100 million doses to low-income countries and lower-middle-income countries, as part of the COVAX AMC.

Preparing for Vaccine Introduction

To guide countries in ensuring fair allocation of doses for their respective populations, the WHO has created a draft framework, outlining recommendations on initial doses to be given to health and social workers, then to the elderly and high-risk adults with co-morbidities.

As every region and country may be different, vaccination protocols should be reflective of the demographic context. For instance, intergenerational households are common in Asian countries and

the elderly should be given high priority in these locations since they could be at a greater risk when younger members of the family must return to work and schools.

Moreover, the pandemic severity in countries and their primary objectives—whether it is interrupting transmission, averting deaths and severe cases, or restarting the economy—have implications on the way they will shape their allocation systems and procurement investment plans.

For vaccine candidates and the product attributes that will be most appropriate for delivery in low-income contexts, WHO's Strategic Advisory Group of Experts (SAGE) will be issuing recommendations on specific vaccines with their safety and efficacy profiles as well as guidance on delivery approaches as data become available.

For its part, the Asian Development Bank (ADB) is supporting the strengthening of the health systems of its developing member countries as well as regulatory mechanisms of vaccines to facilitate regulatory approval processes of countries and the harmonization of regulatory decisions. ADB is also generating a vaccine knowledge-sharing portal to inform member countries of the latest developments and strengthen their decision-making on future vaccines.

Recommendation

Forge coalitions and partnerships for the common good.

Partnerships can offer a means for countries to catalyze innovation, coordinate approaches, and foster global solidarity. A framework should be put in place to ensure equity in access because monopolizing supply would run counter to the collective efforts of limiting transmission.

Countries also need to agree on regulatory policies for vaccine approval to reduce time lags. Regional cooperation can make this possible.

Plan for vaccine procurement in tandem with strengthening delivery systems.

In this crisis, delays mean more lives are put at risk. Hence, planning for obtaining vaccines should be done in parallel with preparing systems for distribution. It is crucial for countries to identify implementation barriers and bottlenecks, and invest in making improvements now to ensure safe, effective, and efficient rollout once a vaccine is ready. These investments will reap long-term gains even after the pandemic.

Use a phased approach for vaccine introduction.

With the anticipated scarcity of initial supply, a fair rationing system needs to be established. The first batch of vaccines should be provided in phases to different cohorts—immunizing health care workers first since they are essential to help preserve the health of others, as well as people at greatest risk of severe illness and death.

When countries apply their allocation framework, these key considerations should be considered: the available resources, the context, and the stage of the pandemic.

Commit to sharing of data.

Facilitating the timely development of safe and quality vaccines and efficient distribution will hinge on data. The exchange of information could advance the pace of vaccine research and development and enable arrangements on equitable allocation of doses and manufacturing expansion.

After distribution, it will be critical for countries to maintain data-sharing on vaccination outcomes to continuously monitor the vaccine's long-term safety and efficacy.

Build trust and cooperation through transparent communications.

Even before the pandemic, vaccine hesitancy has been rising in many parts of the world. Low confidence in vaccines, lack of health literacy, and other concerns about immunization need to be tackled through communication campaigns to cultivate trust and overcome behavioral barriers.

There should also be proactive communication strategies regarding the allocation model criteria,

adverse events after immunization, and any new findings on the vaccine.

Leverage innovative financing vehicles.

The investments needed to outpace the fast-moving pandemic are immense, and innovative financing instruments can amass the large sums of money that no single party could do alone. Mechanisms that crowd in financing could bring the necessary capital to back a diversified portfolio of vaccines and increase the likelihood of finding a viable solution. These could also consolidate demand for a guaranteed market, minimizing risks for manufacturers and encouraging them to supply countries with adequate doses.

Avoid crowding out other vaccines and health services.

There is a risk of disruption to routine immunization activities and health services when a vaccine for COVID-19 is introduced. Countries will need to design strategies to mitigate such risk. If COVID-19 negatively impacts other immunization services, a catch-up program should be initiated for missed vaccinations.

Once a COVID-19 vaccine is distributed, treatment, testing, and contact tracing services should be maintained, and individuals need to be reminded of the importance of upholding standards for COVID-19 infection prevention and control since only a small fraction of the population will be vaccinated in the early stages of the rollout.

Resources

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