

ASSESSING COUNTRY READINESS FOR COVID-19 VACCINES

FIRST INSIGHTS FROM
THE ASSESSMENT
ROLLOUT

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A person wearing a blue protective suit, a yellow hood, and yellow goggles is working in a laboratory or clinical setting. They are holding a syringe and are positioned behind a wooden table. On the table, there is a clear plastic bag containing medical supplies and a small glass vial with a green cap. The background is blurred, showing other people and equipment. A large, semi-transparent blue shape is overlaid on the right side of the image, containing white text.

The country readiness assessments for COVID-19 vaccines are undertaken jointly by governments; the World Bank; Gavi, the Global Vaccine Alliance; the Global Fund to Fight AIDS, Malaria and Tuberculosis; UNICEF and the World Health Organization. This report presents initial findings of 128 countries as of March 2021.

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Acronyms and Abbreviations

ACT-A	Access to COVID Tools Accelerator
ADB	Asian Development Bank
AEFI	Adverse events following immunization
AFE	Africa East, World Bank Region
AFW	Africa West, World Bank Region
AIDS	Acquired Immunodeficiency Syndrome
AMC	Advance Market Commitment
CCE	Cold chain equipment
CNCC	COVAX National Coordinating Committee
COVAX	COVID-19 Vaccine Global Access
COVID-19	Novel coronavirus disease
CoWin	COVID Vaccine Intelligence Work app
CRD	Country Readiness and Delivery
CSS	Closed source software
CTWG	COVAX Technical Working Group
CVIC	COVID-19 Vaccine Introduction and Deployment Costing tool
DFAT	Department of Foreign Affairs and Trade, Australia
DHIS2	District Health Information Software 2
EAP	East Asia and Pacific, World Bank Region
ECA	Europe and Central Asia, World Bank Region
EMR	Electronic medical records
EPI PM	Expanded Program of Immunization Program Manager
ESMAP	Energy Sector Management Assistance Program, World Bank
eVIN	Electronic Vaccine Intelligence Network platform
Gavi	Gavi, the Vaccine Alliance
GDP	Gross Domestic Product
GFF	Global Financing Facility for Women, Children and Adolescents
HCW	Healthcare Worker
HIS	Health Information Systems
HMIS	Health Management Information Systems
HR	Human Resource
HRIS	Health Resource Information Systems
HSIP	Health Systems Improvement Project
IBRD	International Bank of Reconstruction and Development
ID	Identification
IDA	International Development Association
IFC	International Finance Corporation
IHR 2005	International Health Regulations 2005
IIS	Immunization Information Systems

IP	Intellectual Property
IT	Information Technology
JEE	Joint External Evaluation
LAC	Latin America and Caribbean, World Bank Region
LEG	Legal, World Bank
MIGA	Multilateral Investment Guarantee Agency
MNA	Middle East and North Africa, World Bank Region
MOF	Ministry of Finance
MOH	Ministry of Health
MOHSP	Ministry of Health and Social Protection
MPA	Multiphase Programmatic Approach
NCC	National Coordinating Committee
NCD	Non-communicable disease
NDVP	National Deployment and Vaccination Plan
NGO	Non-governmental organization
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
NTWG	National Technical Working Group
OPCS	Operations Policy and Country Services, World Bank
OpenIZ	Open Immunize
OpenSRP	Open Smart Registry Platform
OSS	Open source software
R ²	R-squared
RCIP	Republican Center for Immuno-prophylaxis
RITAG	Regional Immunization Technical Advisory Group
SAGE	Strategic Advisory Group of Experts on Immunization
SAR	South Asia, World Bank Region
SARS-CoV-2	Severe Acute Respiratory Syndrome-Coronavirus 2
SOP	Standard Operating Procedures
The Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
TOR	Terms of Reference
UCC	Ultra-cold chain
UiO	University of Oslo
UNICEF	United Nations International Children's Emergency Fund
US	United States
USAID	United States Agency for International Development
VIRAT	Vaccine Introduction Readiness Assessment Tool
VIRAT-VRAF 2.0.	Integrated Vaccine Introduction Readiness Assessment Tool and Vaccines Readiness Assessment Framework
VRAF	Vaccines Readiness Assessment Framework
WHO	World Health Organization

Executive Summary

The global COVID-19 vaccination campaign, the largest public health initiative ever undertaken, presents challenges unprecedented in scale, speed and specificities, especially in low and middle-income countries. In November 2020, anticipating the availability of safe and effective vaccines for COVID-19, the World Bank together with WHO, UNICEF, the Global Fund, and Gavi rolled out readiness assessments in more than 100 low and middle-income countries. The key insights from the assessments to date present a high-level snapshot of country readiness to deploy COVID-19 vaccines based on initial findings from ongoing assessments in 128 countries. The World Bank is providing \$12 billion for developing countries to purchase and distribute COVID-19 vaccines, tests and treatments and strengthen health and vaccination systems to ensure that vaccines get to those who need them. The assessments provide highly valuable insights into countries' preparedness and will feed into World Bank projects.

Initial findings from the ongoing assessments show that the world's poorest countries are at varying degrees of readiness for the massive undertaking of vaccinating their populations against the deadly COVID-19 disease.

The assessments reveal that while 85% of countries have developed national vaccination plans and 68% have vaccine safety systems, only 30% have developed processes to train the large number of vaccinators who will be needed for the campaign and only 27% have created social mobilization and public engagement strategies to encourage people to get vaccinated. Given the worrying vaccine hesitancy levels, strategies to generate confidence, acceptance and demand for the vaccine are urgently needed.

The assessments further show that most countries are focusing on strengthening essential aspects of the vaccine delivery chain – enough to advance vaccination schedules and begin inoculating their populations. The pandemic's devastating toll on health and economies, fear of highly contagious variants and public pressure to start vaccinations have prompted many countries to prepare aggressive vaccine delivery schedules. Although countries have many gaps in readiness, most have prepared well enough in select essential areas to begin inoculating their populations as soon as vaccines become available. Most countries are approaching the COVID-19 vaccine rollout as an emergency and are emphasizing speed and expediency over deliberative system-strengthening. As a result, they are missing out on the benefits of long-lasting improvements that a systems approach could bring.

The assessments show that COVID-19 vaccination campaigns offer unique opportunities for countries to develop specialized digital systems to track vaccines and vaccinated individuals, and monitor vaccine safety and report adverse reactions. In addition, the large-scale vaccination mobilization provides opportunities to countries to sustainably strengthen the cold chain and introduce environmentally-friendly options that could be of use well beyond the current crisis.

Finally, it is noteworthy that in most countries the assessments have succeeded in elevating the importance of readiness to the highest levels of decision-making. The assessments have brought together government officers, healthcare professionals, the private sector and communities as well as global partners in the largest vaccination campaign in history, and have generated an unprecedented momentum as countries begin inoculating large swathes of the adult population to overcome the virus that has redefined the world in the last fifteen months.

1. Introduction

The novel coronavirus disease [COVID-19] pandemic has delivered an enormous shock to the global economy, exacting a large human toll, shutting down major economic sectors and deeply upending labor markets. The virus has already infected over 115 million people worldwide, killing over 2.5 million of them, and has disrupted millions of lives and livelihoods in the deepest global recession in eight decades.¹ As a result, per capita incomes in the vast majority of countries shrank in 2020, tipping approximately 100 million additional people into extreme poverty this year. This number is set to rise to as many as 150 million people by end-2021.²

Amidst this devastation and turmoil, and almost matching the unprecedented scale, speed and intensity at which the virus has convulsed the globe, the coronavirus pandemic motivated a huge flurry of global scientific activity in the quest to find a vaccine. Over 40 clinical trials were launched within months of the virus spreading across borders as scientists began seeking a vaccine for the SARS-CoV-2 coronavirus.³ They were not starting from scratch: scientists have been studying coronaviruses for over 50 years and have existing data on the structure, genome, and life cycle of this type of virus. Still, the task was daunting, as the fastest that any vaccine had previously been developed from viral sampling to approval was for mumps in the 1960s, which took four years.⁴ To hope for one in less than half that time seemed highly optimistic.

By start of December 2020, however, the developers of several vaccines had announced excellent results in large trials, with several more showing promise. And on December 11, a vaccine made by Pfizer and BioNTech became the first fully-tested immunization to be approved for emergency use.⁵

This speed of advance augurs well not only for how quickly the COVID-19 pandemic can potentially be brought under control once effective vaccines become available and deployed, but also for the future of vaccine science and how that could impact diseases affecting large populations.

Anticipating the imminent availability of safe and effective vaccines for COVID-19, several global and regional initiatives were introduced at early stages of the pandemic to assist low and lower-middle income countries in procuring and deploying vaccines. In April 2020, the World Health Organization (WHO), the European Commission and France launched Access to COVID Tools Accelerator (ACT-A). In June 2020, at the time of Gavi's replenishment, COVAX was launched with the aim of bringing together governments, global health organizations, manufacturers, scientists, private sector, civil society and philanthropy, to provide equitable access to COVID-19 vaccines to low and lower-middle income countries.⁶ A Country Readiness and Delivery (CRD) workstream led by WHO and UNICEF and including Gavi, the World Bank and the Bill & Melinda Gates Foundation, was established under COVAX.

¹ Data as of March 2, 2021

² <https://openknowledge.worldbank.org/bitstream/handle/10986/34496/9781464816024.pdf>

³ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-01-Bell.pdf>

⁴ <https://www.history.com/news/mumps-vaccine-world-war-ii>; accessed January 21, 2021 at 6a.

⁵ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>; accessed January 21, 2021 at 9a.

⁶ <https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines>; accessed January 25, 2021 at 2p.

In September 2020, CRD issued the Vaccine Introduction Readiness Assessment Tool (VIRAT) to support countries in developing a roadmap to prepare for vaccine introduction and identify gaps to inform areas for potential support. In October 2020, the World Bank's Board approved \$12 billion of fast-track financing to IBRD/IDA-eligible countries for purchasing vaccines as well as strengthening primary health care systems to deliver the vaccines. Building upon the VIRAT, the World Bank developed the Vaccine Readiness Assessment Framework (VRAF) to help countries obtain granular information on gaps and associated costs and program financial resources for deployment of vaccines. To minimize burden on countries, avoid duplication in information collection, and reduce workload, in November 2020, the VIRAT and VRAF tools were consolidated into one comprehensive framework, called VIRAT-VRAF 2.0.

Later that month, the World Bank, WHO, UNICEF, the Global Fund, and Gavi jointly reached out to over one hundred low and middle-income countries, declaring a commitment of assisting them in the next hundred days to get ready to safely and effectively deploy COVID-19 vaccines.

The COVAX facility expects to make available about 1.8 billion doses of the COVID-19 vaccine to the 92 economies of the Gavi COVAX Advance Market Commitment (AMC) in 2021, corresponding to approximately 28 percent coverage of AMC populations.⁷ As on March 2, 2021, COVAX forecasts a supply of 95 million doses of the COVID-19 vaccine within the first quarter of the 2021 (of which 85 million doses are earmarked for AMC countries) and a further 365 million doses in the second quarter of 2021 (285 million doses earmarked for AMC countries).⁸ Over 12 million doses have already been delivered to 19 low and lower-middle income countries and vaccination campaigns are already underway in Kenya, Nigeria and Rwanda.⁹ Concurrently, readiness assessments are being carried out in most low and lower-middle income countries. This note synthesizes the key insights from the assessment experience (as of mid-February 2021) and is organized as follows. Section 2 presents a high-level snapshot of status of country readiness to deploy COVID-19 vaccines based on findings from the ongoing assessments. Section 3 elaborates select key insights from the readiness assessments. Section 4 concludes.

2. Implementation of Vaccine Readiness Assessments

The VIRAT-VRAF 2.0 tool assesses country readiness to deploy COVID-19 vaccines across ten core programmatic areas: Planning and Coordination; Budgeting; Regulatory; Prioritization, Targeting, and COVID-19 Surveillance; Service Delivery; Training and Supervision; Monitoring and Evaluation; Vaccine, Cold Chain, Logistics, and Infrastructure; Safety Surveillance; and Demand Generation and Communication (Annex 1). Within these 10 core areas, the tool measures progress across 50 indicators along a 4-level scale which, individually and collectively, provide a functional assessment of country readiness to deliver the COVID-19 vaccine. Countries are encouraged to repeat the assessments as many times as necessary, until all functional areas are addressed, and the capacity gaps are filled.

⁷The 92 AMC-eligible economies include all economies with Gross National Income (GNI) per capita under US\$4,000, plus other World Bank IDA-eligible economies.

⁸<https://www.gavi.org/sites/default/files/covid/covax/COVAX%20Supply%20Forecast.pdf>; accessed March 9, 2021 at 2a.

⁹<https://www.gavi.org/covax-vaccine-roll-out>; accessed March 9, 2021 at 2a.

At any stage of the assessment, the VIRAT-VRAF 2.0 tool can be used to generate a running checklist of all pending and incomplete administrative and organizational actions as well as all unmet material and human resource requirements. Accompanying the VIRAT-VRAF 2.0 is a costing tool, which can be used to determine the associated price tag of an identified gap in readiness. In this way, the tool helps countries arrive at a granular quantification of financing needs, which may be met from own resources, bilateral loans and grants, as well as through World Bank-financed projects.

In most countries, the assessment exercise is being overseen by the Expanded Program of Immunization Program Manager (or the EPI PM), and is being carried out with guidance and assistance primarily by Gavi Senior Country Managers where available, and WHO/UNICEF officers entrusted with this task. Several countries have established committees and empowered them to collect data, liaise and coordinate across government ministries, departments and agencies, coordinate with global partners, and take decisions where necessary. At the country level, World Bank staff play an important role in co-ordinating and nudging the exercise toward completion and are strategic partners in financing and developing downstream returns from this investment. The World Bank has a long history of financing and working with EPI and polio programs to ensure that they are effective but also contribute towards building systems for universal health coverage. More recently, the World Bank has played a leading role in the Ebola response, both the West Africa and Democratic Republic of Congo outbreaks. The World Bank is also among the core Gavi Alliance partners and works closely across the partnership in the areas of immunization financing and sustainability, public financial management, health systems and equity. The recent announcement of \$12 billion support through Multiphase Programmatic Approach (MPA) Additional Financing reinforces the technical leadership of the World Bank in these areas.^{10,11}

Figure 1: Number of Countries that have Completed at least One Round of Assessment¹²



¹⁰ At the World Bank, the readiness assessment is coordinated and guided by a Vaccines Delivery Task Force, which draws expertise from the Health Practice from all Bank regions as well as from other Practices across the World Bank, including Digital Development, Energy, IT, LEG, OPCS, Poverty and Transport, in addition to IFC and MIGA.

¹¹ Expectedly, the assessment process at the country level depends a lot on specific partner relationships with country officials. Thus, different partner agencies are steering the readiness assessments in different countries, while others are providing support in areas of their comparative advantage. With travel limited due to COVID-19 restrictions, most of the hands-on support is provided by agencies that have strong country presence.

¹² The assessment is deemed to be completed if most indicators are assessed.

The rollout of the integrated readiness assessment tool, VIRAT-VRAF 2.0, started in November 2020 and since then, 127 IBRD/IDA countries and West Bank & Gaza have already completed at least one round of the assessment (Figure 1). We have summary scores for all 128 participants [AFW: 22; AFE: 25; EAP: 22; ECA: 15; LAC: 25; MNA: 11; SAR: 8] and detailed assessment records for 57 countries. All assessments are work-in-progress and are being regularly updated as information and data come in from World Bank teams, WHO, UNICEF, Gavi and others. A Country Readiness Core Indicators Dashboard is maintained by WHO and presents high-level global, regional and country level summaries. Regional offices of WHO maintain their own dashboards. Gavi maintains and coordinates detailed data on cold chain capacity, which is shared regularly with all partners, including the World Bank. Likewise, data on air and ground transportation as well as procurement of equipment and personal protective equipment (PPE) is maintained and coordinated by UNICEF and shared regularly with all partners. The World Bank's Vaccine Delivery Task Force secretariat collects, corroborates, and analyzes the data from various sources, and updates the assessment periodically.

Figure 2: Progress in Readiness Assessment across Select Key Indicators (128 countries reporting)

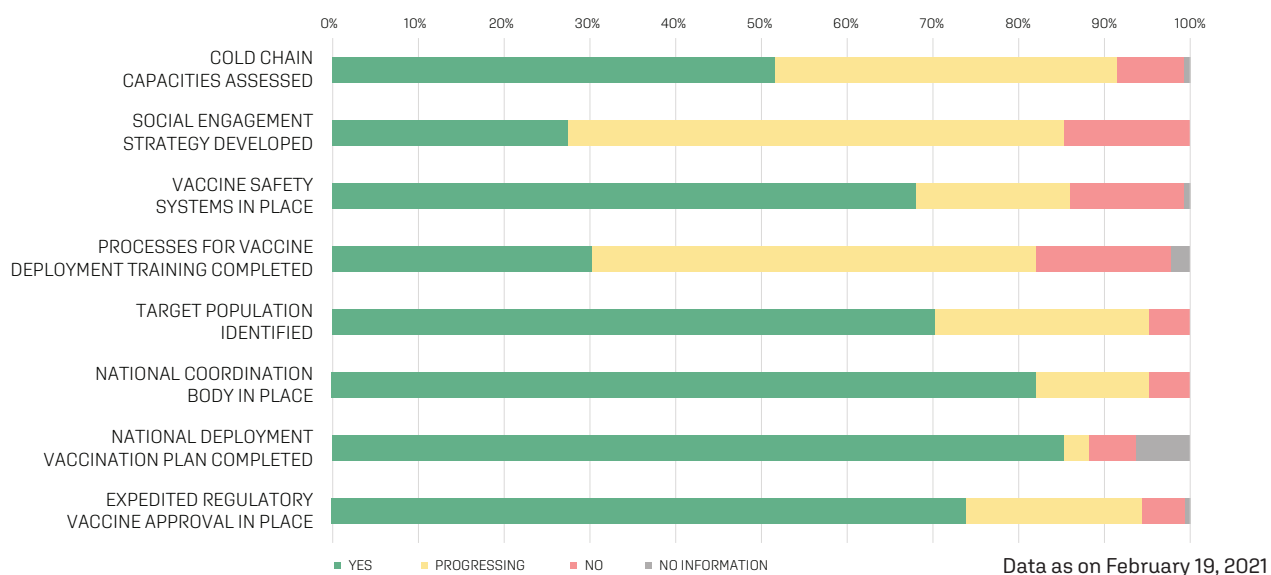


Figure 2 provides a summary view of readiness progress across select key indicators. Significant progress has been made in most countries in Planning and Coordination. Most countries have established a National Coordinating Committee (NCC) for COVID-19 and have set up a National Technical Working Group (NTWG) for COVID-19 vaccine introduction. Several countries have established NTWG subcommittees to assess progress on service delivery, cold chain & logistics, demand generation & communication, etc. Many countries have begun planning for vaccine access, through COVAX as well as through bilateral purchase agreements. Over one hundred countries have developed National Deployment and Vaccination Plans (NDVP) for COVID-19 vaccine, which contains specifics related to regulatory preparedness, planning and coordination, identification of target populations, preparation of supply chains, waste management, human resource management and training, vaccine delivery strategies, demand planning, safety monitoring and management of adverse events, and monitoring and evaluation – all key areas for successful deployment of the vaccine. Whereas the VIRAT-VRAF 2.0 gives a snapshot of country readiness, the NDVP details the key inputs and processes necessary for successful deployment and is therefore the most important indicator of assessing a country's readiness as well as for decisions on allocation of doses.

Likewise, most countries are reporting good progress in setting up a functional vaccine safety system. With help from WHO and Gavi, many countries have established guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities, such as adverse events following immunization (AEFI) reporting and investigation. Work is ongoing to establish coordination mechanisms between relevant stakeholders (including the National Regulatory Authority (NRA), Ministry of Health, WHO and others) for exchange of COVID-19 vaccine safety information. Several countries have specified regulatory pathways for the NRA to approve market access for COVID-19 vaccines and put in place regulatory instruments to ensure timely decision-making. Most countries have existing legal bases of regulatory approvals and are getting ready to deploy them for COVID-19 vaccines as well.

Early results from the assessment identify several areas where more needs to be done. Most countries have not finished preparing training materials and have yet to train the large number of vaccinators that would be needed for the delivery of COVID-19 vaccines. Likewise, most countries have not finalized master lists of service providers and points of delivery for effectively delivering COVID-19 vaccine to target populations. Progress on training of health staff to conduct surveillance of events attributable to vaccination is also slow. Social mobilization and public engagement strategies also have not been enunciated in most countries. As a result, advocacy, community engagement, and risk and safety communication remain largely unaddressed.

3. Key Insights

The analyses of the data from the early rounds of country-level readiness assessments provide several interesting insights that can help governments, development partners, communities and other stakeholders better understand and manage the complex task of vaccinating large adult populations in a very short timeframe.

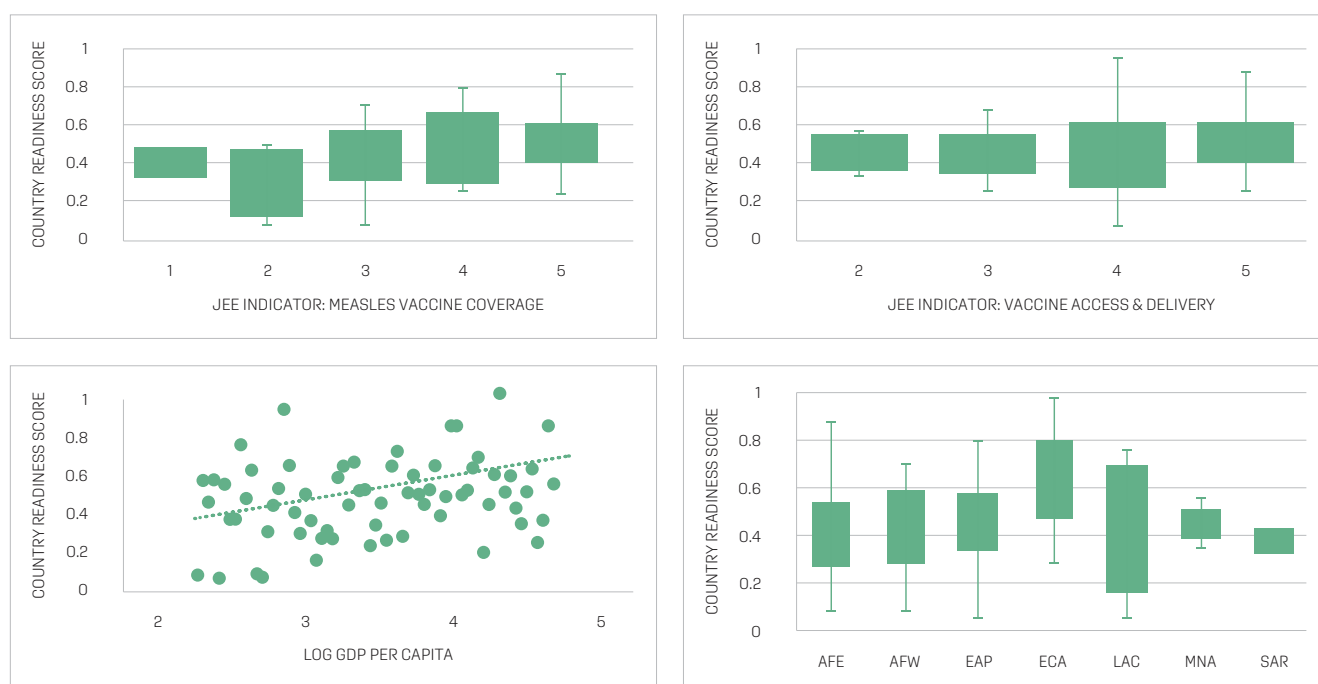
1. Existence of well-functioning child immunization national delivery systems is not a strong predictor of country readiness to deliver COVID-19 vaccines

Over a hundred countries have carried out Joint External Evaluations (JEE) in the last four years to determine their ability to find, stop and prevent epidemics. A consolidation of WHO's International Health Regulations 2005 (IHR 2005) Monitoring and Evaluation Framework and the Global Health Security Agenda country assessment tool, the JEE is an objective, voluntary, independent peer-to-peer multisectoral assessment of a country's health security preparedness and response capacity across 19 IHR technical areas. The JEE tool is divided into 4 public health functions relevant to health security: Prevention, Detection, Response and Other Hazards (including radiation emergencies and chemical events). Each public health function consists of several technical areas, each of which is assessed by one or more indicator. Each indicator in the JEE is scored on a five-point ordinal scale. A score of 1 reflects no pertinent capacity, 2 reflects limited capacity, 3 notes developed capacity, 4 connotes demonstrated capacity, and a score of 5 reflects sustainable capacity. One of the areas assessed under the public health function of 'Prevention' is whether the country has a functioning national vaccine delivery system that has a nation-wide reach and is able to respond to new disease threats.

Two indicators are used for this evaluation: vaccine coverage [measles] as part of national program; and national vaccine access and delivery.¹³

Figure 3 (upper panels) present the plot of country COVID-19 vaccine delivery readiness scores against each of the two indicators of immunization as assessed using the JEE tool. The median country readiness score varies from 0.36 for countries that were evaluated to have ‘limited immunization capacity’ (JEE score: 2) to 0.5 among those that were judged to have ‘developed capacity’ (JEE score: 3) [Figure 3, top left]. The difference in median readiness scores is even less when grouped by country capacity for vaccine access and delivery, ranging from 0.51 for countries with ‘developed immunization capacity’ to 0.44 for countries with limited capacity (Figure 3, top right).

Figure 3: Relationship between Country Readiness for COVID-19 Vaccine and JEE Immunization Scores and GDP per capita



These results are not surprising, since proficiency in traditional immunization programs – which in most low and lower-middle income countries focus on infants and are implemented gradually over the course of the year as children are born– does not directly translate to proficiency in vaccinating large adult populations in a very tight timeframe. The absence of correlation between JEE immunization scores and country COVID-19 vaccine readiness scores is suggestive of a whole new level of readiness that the COVID-19 vaccination program requires, both because of the scale and speed of the operation as well as because it targets adults, a population group for which vaccination experience is limited in most countries.

¹³ World Health Organization – Joint External Evaluation Tool; available at https://apps.who.int/iris/bitstream/handle/10665/204368/9789241510172_eng.pdf?sequence=1

¹⁴ The Readiness Score is computed as the average of scores across all assessment indicators, weighted by program areas (WHO methodology)

Figure 3 (lower left) presents the plot of country GDP per capita against readiness scores and shows a weak correlation between income and readiness score ($R^2 = 0.1$). Countries in ECA region have a higher median readiness score, followed by countries in LAC and MNA regions (Figure 3, lower right). Countries in the LAC region have the highest dispersion, with scores ranging from 0.06 (Haiti) to 0.76 (Colombia). This result is surprising, since a priori rich countries – that have strong health systems and greater and quicker access to financial and human resources relative to low-income countries – would be expected to be able to rapidly adapt and develop the high level of readiness needed for the rollout of COVID-19 vaccines. The novelty, extent and intensity of the COVID-19 pandemic – which has upended lives and livelihoods and redefined normality in high-income countries offer at least a partial explanation for the absence of this correlation.

2. Most countries are focusing on strengthening the most essential aspects of the vaccine delivery chain – enough to advance vaccination schedules and begin inoculating their populations

A strong and well-prepared vaccine delivery system would score very highly across all 50 indicators of the 10 core programmatic areas covered in the VIRAT-VRAF 2.0 assessments. Countries aiming for a high level of readiness would ensure that the key areas of readiness are strengthened, and the gaps are addressed. At the organizational level, all aspects of planning and coordination would be in place and all investments and operational expenditures would be provided for and well-accounted. The regulatory mechanism would follow internationally-accepted and endorsed levels of stringency. Target populations would be well-prioritized and identified. Cold chain and supply logistics systems would correspond to the highest standards of time-temperature management and safety surveillance systems would be well-established and functioning. Of immeasurable importance, the level of community engagement and public trust would be high. These achievements and more would constitute a substantive foundation for success. However, readiness assessments conducted so far show that many countries are not at that high level of readiness and that there are many gaps in readiness across several VRAF-VIRAT 2.0 indicators.

Yet, most countries are speeding up plans to vaccinate their populations against COVID-19. In the accelerating race between the virus and vaccinations, countries are hastening their vaccination plans in response to rising infections, public pressure, and fear of new, highly contagious variants of the coronavirus. The monthly economic costs of the pandemic are also very high, with one study finding that every month's delay would cost the African continent \$14 billion in GDP losses.¹⁵ Many IBRD/IDA AMC countries have already started rolling out the vaccine and some, like Uzbekistan, have launched vaccination drives without developing an NDVP. Several countries have announced plans to begin rolling out the vaccine in the first quarter of calendar year 2021,¹⁶ and several have tentatively scheduled COVID-19 vaccinations in the second quarter (data as of February 3, 2021).¹⁷ More than 50 countries have also expressed an interest in being part of the small, first-wave rollout of the Pfizer vaccine through COVAX.

¹⁵ Ahuja, A, J. Castillo, M. Kremer, G. Larson and J. Lee (2021): Purchasing COVID-19 Vaccines: Analysis of Costs and Benefits for Africa. Draft Paper produced for the World Bank, January 2021.

¹⁶ Afghanistan, Angola, Bangladesh, Benin, Bhutan, Cambodia, Chad, Congo Repub., Djibouti, Fiji, Guinea, Guyana, India, Indonesia, Kenya, Kiribati, Kosovo, Liberia, Maldives, Mali, Mauritania, Micronesia, Mongolia, Myanmar, Nepal, Nigeria, Pakistan, Sao Tome and Principe, Senegal, Solomon Islands, South Sudan, Tonga, Tunisia, Ukraine, Vanuatu, Vietnam, West Bank and Gaza, Zambia

¹⁷ Algeria, Bolivia, Burkina Faso, Cabo Verde, Central African Republic, Comoros, Cote d'Ivoire, Democratic Republic of Congo, Eswatini, Ethiopia, Ghana, Honduras, Lao PDR, Lesotho, Malawi, Moldova, Nicaragua, Niger, Papua New Guinea, Rwanda, Sierra Leone, Somalia, Sudan, Syria Arab Republic, Tajikistan, The Gambia, Timor-Leste, Togo, Uganda, Yemen

Notwithstanding the compelling economics of early and rapid rollout of COVID-19 vaccines, a country's ability to inoculate its population will depend on being well-prepared across at least the most essential areas of the delivery chain. Experience from previous vaccination campaigns as well as of countries that have already started rolling out COVID-19 vaccines suggest that in order to safely and efficiently deliver vaccines, countries advancing the delivery schedules must ensure that at the bare minimum: (i) the National Deployment and Vaccination Plan is finalized; (ii) first-phase targeted population is identified; (iii) supply chain, including cold chain and logistics, is established, tested and assured to handle a small number of doses (no larger than what the countries are used to managing in routine immunization programs albeit with a different population target group); (iv) vaccine safety surveillance and adverse effect identification and mitigation procedures and protocols are established and tested; and (v) frontline vaccination and supply chain teams have the resources and the spending authority to implement emergency measures in the event of any breakdown in the vaccination process. Readiness assessments conducted to-date show that most countries have done enough on at least the first four of these essential action areas to begin inoculating their populations as soon as the vaccines become available.

Most countries have finalized their NDVPs, and those that haven't finished are close to doing so. Following guidelines issued by WHO, most countries have identified priority populations to receive the first few rounds of the vaccine. Supported by Gavi and other international partners and reinforced over years of implementing immunization programs for children, most countries have cold chain equipment and systems in place enough to handle small quantities of vaccines at any point of time. Likewise, most countries have safety surveillance systems in place, at least for established childhood vaccines, that they will use for the COVID-19 vaccine as well. The readiness assessments have not provided much information on budgets and spending authority – as these are still being worked out – and weaknesses are likely to come to light at the first sign of a breakdown.

Advancing vaccination schedules to inoculate large swathes of population without having all the necessary systems in place is thus not a suggestion that countries are sidestepping caution. Rather, it is an indication that countries are choosing practical approaches to rolling out small quantities of the vaccine. Most countries are strategically choosing to deploy vaccines as they become available in the very near future instead of waiting to get better prepared across most dimensions of readiness before beginning to inoculate their populations.

3. Few countries are using the opportunity provided by the imminent deployment of COVID-19 vaccines to strengthen health systems and find long-lasting solutions for similar future challenges

In addition to building a stronger immunization program, the introduction of a new vaccine provides many opportunities for improving a country's health services and health systems. One of the key messages of the WHO-UNICEF "Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines" is that "in developing their national strategies for the deployment of COVID-19 vaccines, countries should include activities to strengthen immunization, health services and health systems with collaboration across programs."¹⁸

¹⁸ https://apps.who.int/iris/bitstream/handle/10665/336603/WHO-2019-nCoV-Vaccine_deployment-2020.1-eng.pdf

These include, but are not limited to, “strengthening human resource management; training for new vaccine introduction; establishing new contact points for vaccination across the life course, screening for noncommunicable diseases, establishing systems for managing NCDs, improving integrity and efficiency of supply chains, enhancing integrated disease surveillance and AEFI monitoring and reporting systems, conducting integrated advocacy and communications activities to promote demand for vaccination as part of increasing overall demand and acceptability of all essential primary health care services, and catalyzing the development of health information systems.”¹⁹

Most low and lower-middle income countries, however, are under pressure to approach the COVID-19 vaccine rollout as an emergency vertical operation. As a result, they are giving primacy to speed and expediency over deliberative system strengthening initiatives that could take more time to set up but would deliver more value for money.²⁰ For example, in targeting priority populations for the COVID-19 vaccine, countries could use this opportunity to develop comprehensive data management capabilities and ID systems or population registries. In all countries, frontline health workers are listed as the priority population to be immunized, but many countries do not have a current census of health workers, especially outside of the public sector. The deployment of COVID-19 vaccine provides a good opportunity for countries to quickly conduct a census of the health workforce, build planning capacity that informs human resources for health strategies and develop strong and functioning Health Resource Information Systems (HRIS). Unfortunately, analysis undertaken for this paper on several rounds of vaccine readiness assessments conducted to date does not identify the development of HRIS or any other systematic attempt at conducting a census of health workers as a priority area. If this is repeated across other areas, in addressing COVID-19 head-on and with speed, most countries would miss out the benefits of long-lasting improvements that a systems approach could potentially bring.

Early experience from countries of high vaccination rates, including Israel, United Arab Emirates and United Kingdom, demonstrates the critical role that robust health systems play in supporting vaccine delivery. The World Bank is taking broad, fast action to help developing countries addresses both emergency containment and mitigation needs for COVID-19, including strengthening health systems to treat severe cases and save lives and be better prepared to respond to future outbreaks.

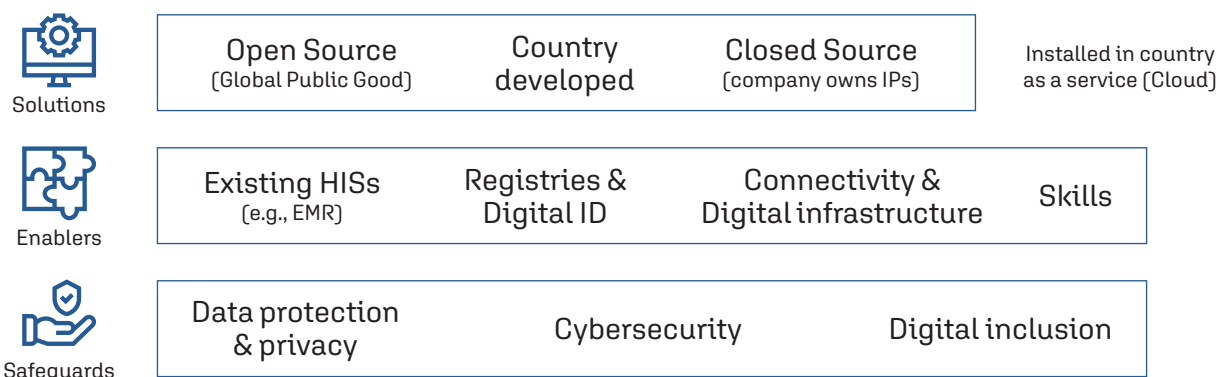
4. The COVID-19 vaccination campaign offers a unique opportunity to countries to digitize their information systems for tracking vaccines and vaccinated individuals, monitoring status, and reporting adverse reactions

The large-scale, multi-dose COVID-19 vaccination of the adult population offers a huge opportunity to low and lower-middle income countries to put specialized digital systems in place for monitoring of vaccination status and collecting data for post-vaccination safety surveillance. Such systems would optimize vaccine deployment across a range of capacities. They would help countries identify vaccine recipients, record and store individual immunization information, and monitor vaccination coverage and safety. To improve uptake and administration, the systems would notify patients to stay on the recommended delivery schedule for multiple doses. In addition, they would support logistics, including vaccine supply and stock management. These robust mechanisms would also play a critical role in follow-up campaigns in case the protection offered by immunization is limited in time.

¹⁹ Ibid

²⁰ In Papua New Guinea for example, a recent polio campaign expanded coverage quickly but at massive cost and with limited benefits for immunization coverage more broadly, let alone for health systems strengthening

Figure 4: Taxonomy for how Digital Technologies can help with Vaccine Delivery



The World Bank has developed a high-level taxonomy to understand how digital technologies can assist with COVID-19 vaccine delivery (Figure 4). In terms of solutions, some countries already have existing well-functioning Immunization Information Systems (IIS) at the national level, developed for child immunization programs or for elderly flu vaccination, which may relatively easily be expanded to the whole population for the COVID-19 vaccination campaign. For instance, Uruguay is planning to reuse its existing Vaccine Information System,²¹ which is linked to individuals' national ID number and records all type of vaccinations. Uruguay relies on a robust identification system with sufficient coverage of the population, which is an advantage that most countries do not have. Individuals will be able to make appointments for their vaccination, allowing hospitals and health centers to anticipate the demand and comply with the COVID-19 prevention measures to minimize crowds and long waits in closed places. The system also allows for the collection of additional relevant personal information and to keep track of the number of doses administered, which will be critical for COVID-19 vaccines dose schedule compliance.

Another example is CoWin, the COVID Vaccine Intelligence Work app launched by the Government of India on January 16, 2021, the day the nationwide COVID-19 vaccination drive started. An app like CoWin has been around since 2015 and was used for various immunization drives through the Electronic Vaccine Intelligence Network (eVIN) platform. The eVIN technology is already being routinely used for over 20,000 cold chain points across the country for efficient vaccine logistics management. The CoWin app, a scaled-up version of eVIN, offers authorities, vaccine administrators and the general public information on COVID-19 vaccine availability as well as temperature of the vaccine in the cold chain in real-time. The CoWin app has 4 modules: beneficiary tracker; beneficiary registration; vaccination beneficiary acknowledgment; and status updating. Beneficiaries can register on the app in several ways, including through pre-populated Aadhaar (unique ID) data, survey data or self-register with other details using 11 alternative IDs to Aadhaar. CoWin collects basic data on beneficiaries, including name, age, sex, comorbidities and residence, which it uses to monitor and track beneficiaries for adverse side-effects. Focusing on the 3Ps of the vaccination drive — namely Product, Place and People — CoWin is expected to help ensure enough availability of product, awareness about the place and time of vaccinations and that everyone is vaccinated. Aarogya Setu, India's COVID-19 contact tracing app, has been integrated with CoWIN and helps citizens find vaccine-related information and provides a vaccination certificate.

²¹ Ministry of Public Health, Vaccine Information System, <https://www.gub.uy/ministerio-salud-publica/tramites-y-servicios/servicios/sistema-informatico-de-vacunas>

Countries that do not have an existing, fully operational and scalable IIS can develop bespoke software, develop and tailor open source software (OSS) or deploy closed source software (CSS). The number of OSS and CSS options are growing as philanthropic actors and software companies recognize the opportunities and needs of countries. One well-established OSS health information management system for immunization programs that is being expanded for COVID-19 vaccination campaigns is the District Health Information Software 2 (DHIS2), developed by the University of Oslo (Universitetet i Oslo, or UiO).²² UiO, in partnership with WHO, has developed a suite of DHIS2 tools and metadata packages that support countries to adopt WHO immunization program standards into national Health Management Information Systems (HMIS). The DHIS2 toolkit includes packages for data quality, interoperability, electronic immunization registry, vaccine supply chain information systems, bottleneck analysis, tracking adverse events, case-based surveillance and immunization campaign monitoring mass campaigns. More than 45 countries in Africa and Asia have already installed DHIS2 dashboard packages into their national HMIS, empowering their EPI program managers and district staff to identify gaps in immunization coverage, reduce stock wastage and monitor cold chain metrics and follow up on facility reports.²³ Other OSS examples include Open Immunize (OpenIZ), which is currently being used in Tanzania for its Immunization Registry;²⁴ DIVOC, which is being used by India for its proof of vaccination certificate and is being considered by Bangladesh, Indonesia and Ethiopia;²⁵ and the Open Smart Registry Platform (OpenSRP), which allows for registration of clients with unique identifiers and is being used in Zambia, Bangladesh, Indonesia, Malawi and Pakistan.²⁶

The deployment of COVID-19 vaccines offers a unique opportunity to promote digital global public goods and build digital infrastructure for health systems and service delivery more broadly. The World Bank has an important role to play in this context by helping countries select, design and use digital technologies to ensure that vaccine delivery is safe, equitable and efficient.

5. The COVID-19 vaccine rollout is an opportunity to create a sustainable, environmentally-friendly cold chain that could be of use well beyond the current crisis

Cold chain refers to the linked system of infrastructure that allows a product to move from where it is produced to its final point of use via intermediate storage points – all the while remaining appropriately chilled. Traditional vaccines – as well as some COVID-19 vaccines such as AstraZeneca's Covishield – are usually stored between 2 and 8°C, but some of the leading COVID-19 vaccines need to be stored at much colder temperatures. Moderna's vaccine requires a storage temperature of -20°C, whereas Pfizer's vaccine requires a storage temperature of -70°C.

²²<https://dhis2.org/immunization/>

²³Examples include Rwanda (monitor vaccination activities, improve birth notification and vaccination schedule compliance, and improve vaccination coverage), Uganda (real-time data visualization to coordinate a country-wide mass immunization campaign targeting 18 million children for measles-rubella and 8 million for polio), Nigeria (improved reporting completeness rates), Ghana (managing immunization programs,) and Togo (improvements in reporting completeness). The DHIS2 toolkit is being expanded rapidly to support the equitable delivery of COVID-19 vaccines at scale, and is already operational in Myanmar and Sri Lanka, and in development in 7 other countries and territories (Cabo Verde, Timor-Leste, Lao PDR, Mozambique, West Bank and Gaza, Rwanda and Sao Tome and Principe). Source: <https://dhis2.org/covid-vaccine-delivery/>

²⁴<http://openiz.org/>

²⁵<https://divoc.egov.org.in/>

²⁶<https://smartregister.org/>

However, cold chain requirements are unlikely to hold back the distribution of most COVID-19 vaccines. In the last 10-15 years, Gavi has made significant investments in strengthening cold chain capacity at the health facility and district level in all 73 low and lower middle-income countries it has historically supported. In addition, it is providing catalytic support to countries to meet the incremental cold chain equipment needs associated with COVID-19 vaccine at the national and regional levels of the cold chain.

Despite the slow uptake of this support – only 21 submissions have been received so far of which only 8 have been reviewed²⁷ – Gavi estimates that this initiative, which includes deployment and installation, will more or less meet all the incremental cold chain equipment (CCE) needs for COVID-19 vaccines at national and regional levels. Further investments may of course be required at lower levels, including district, county or village, depending on target populations who need to be reached. On the whole, Gavi assesses that in most low-income countries, the cold chain will be able to hold up COVID-19 vaccines requiring temperatures as low as minus 20°C (which is the same storage temperature for measles and polio vaccines) in quantities not exceeding what would be needed for up to 5 percent of the country's population at any given time. This matches well with the phasing of expected vaccine deliveries to most low-income countries, which minimizes potential blockages in the cold chain.

Fifty-nine IBRD/IDA have so far expressed interest in procuring the Pfizer vaccine from COVAX and have begun readiness assessments.²⁸ COVAX is developing guidelines for ultra-cold chain (UCC) to help countries define their needs and plan for procurement of UCC freezers. It is worth noting however that Pfizer accounts for very few COVAX doses and is unlikely to be deployed at scale in many countries through the facility. In some countries, such as Lebanon, Pfizer is taking care of transporting the vaccine to key distribution points within the country, thereby alleviating some of the UCC requirements.

At the same time, the rollout of the COVID-19 vaccine provides a unique opportunity to identify financially and environmentally better ways of strengthening the cold chain. Long-term solutions imply substituting climate-warming hydrofluorocarbons with environmentally-friendly refrigerants, superior energy efficiency, and less reliance on polluting diesel generators that power fridges in places where electricity supply is expensive, fragile or non-existent.²⁹ In Mongolia, for instance, the modernization and expansion of the cold chain capacity is being carried out in cooperation with UNICEF, which is committed to ensuring an efficient and 'climate friendly' cold chain. Thus, the existing diesel generators will be replaced with batteries, including solar batteries, new cold-rooms will use environmentally-friendly refrigerants, and the expansion of the central store will involve construction of an environmentally-friendly building.

²⁷ Data current as of January 25, 2021. Countries that have completed the peer-review process are Bangladesh, Comoros, Ethiopia, India, Mongolia, Uganda, Nepal and Nigeria.

²⁸ This includes 12 countries in AFR, 3 in MNA, 5 in SAR, 8 in EAP, 11 in ECA, and 20 in LAC. Data current as of January 25, 2021.

²⁹ Gavi no longer supports refrigerators which require gas or kerosene and funds solar devices for off-grid locations.

Complementing the World Bank's efforts to assist client countries in addressing the COVID-19 pandemic by helping procure and deploy COVID-19 vaccines as well as developing reliable and sustainable health infrastructure, ESMAP,³⁰ through its 'Efficient, Clean Cooling' program, is supporting climate-friendly solutions for deployment of sustainable cold chains to help the strengthening of countries' health systems. ESMAP support extends to interventions in a variety of areas related to the vaccine cold chain, including CCE, buildings/facilities housing cold chain equipment and administering vaccines, cold chain planning and costing, transportation, sustainable operations and management, and capacity-building.

6. In terms of the process, countries that assigned dedicated staff, consolidated and facilitated data collection, convened joint sessions of responsible agencies, and that had gone through a similar exercise earlier were able to rapidly complete the assessments

A review of the process related to the conduct of readiness assessments points to 4 enabling factors that helped countries complete the assessments in a short time. First, countries that dedicated staff and subject-matter experts to this task have been able to complete the readiness assessments quickly and successfully. In Ecuador, for instance, the availability of dedicated Ministry of Health staff together with immunization experts has been fundamental to the success of the exercise. The team met every two days to review progress, agree on tasks for the following days, and repeat the process. In Tajikistan, having the Global Financing Facility (GFF) Liaison Officer on the ground to support this task and coordinate meetings between partners proved to be crucial. In Armenia, the hands-on support provided by the Program Manager for the National Immunization Program and Deputy Director General of the National Center for Disease Control linked the assessment to the development of the NDVP and was critical for timely and quality completion of both. Similar sentiments were echoed across the Africa and Latin America and Caribbean regions, where the people involved with this assessment noted the value of skills and experience needed in fully engaging in this task.

Second, countries where data were consolidated across one or two offices were rapidly able to complete the readiness assessment. Many countries reported having the required information to inform the assessments, but fragmentation across agencies and within ministries posed a huge challenge. In one country, technical agency teams have had to work around their primary counterparts to get the required data from other ministry agencies due to slow communication between units. In other situations, the authority for approving the release of information to partners is held at different levels of the ministry, adding authorization bottlenecks in accessing the required information. This was compounded by the need for information that was deemed "confidential" and working through strategies to attain this within tight timeframes.

³⁰ ESMAP, or the Energy Sector Management Assistance Program, is a partnership between the World Bank and 19 partners to help low and middle-income countries reduce poverty and boost growth through sustainable energy solutions. ESMAP's analytical and advisory services are fully integrated within the World Bank's country financing and policy dialogue in the energy sector. Through the World Bank Group, ESMAP works to accelerate the energy transition required to achieve Sustainable Development Goal 7 (SDG7) to ensure access to affordable, reliable, sustainable and modern energy for all. It helps to shape WBG strategies and programs to achieve the the World Bank Group's Climate Change Action Plan targets.

Box 1. Mongolia: Vaccines Readiness Assessment Provides Key Inputs to World Bank Project Financing

Mongolia was one of the first countries to seek World Bank support for an additional US\$50 million project to add to its COVID-19 response. The additional financing supports the purchase and deployment of vaccines, purchase of therapeutics and strengthening of the health system to counter disrupted services caused by the pandemic and prepare for future pandemics. Teams from the Bank, WHO and UNICEF country offices in Mongolia worked with the Ministry of Health to carry out a rapid assessment of vaccine readiness to inform the financing required to support vaccine rollout as well as the required health systems strengthening. The assessment tool was uniquely helpful in preparing the project as it formed a comprehensive checklist to ensure that all activities required to acquire and deploy vaccines were considered in the planning and budgeting of the project. It also helped bring different perspectives to the table and helped reach agreements and prioritize activities. Finally, it helped ensure that all partners arrived at a joint plan, synchronized implementation, and prevented funding overlaps.

Third, readiness assessments carried out jointly by all agencies concerned enhanced the quality and efficiency of the readiness assessments. In Papua New Guinea, for instance, the success of the WHO-UNICEF-World Bank partnership in the assessment process is built on the recognition of each partner's relative strengths and comparative advantages, and clear roles delineated for the exercise. The World Bank is conducting the analytics to support the National Department of Health, WHO and UNICEF to outline the key challenges and gaps in vaccine readiness and in facilitating discussions on potential solutions to support the successful rollout of the COVID-19 vaccine. WHO and UNICEF are also bringing their technical expertise and reach within the National Department of Health to enhance the quality of the discussion and socialize the results across technical leads in the government. In Sao Tome and Principe, the integrated tool provided a unique opportunity to ensure that all relevant stakeholders sat at the same table and contributed to the country's readiness assessment. This collaborative effort was key to maximizing investment efforts and avoiding duplication of activities. In Armenia, development partners met regularly in weekly meetings, and had very little difficulty in coordinating and completing the assessment.

Fourth, countries that had experience with vaccine readiness assessments found it relatively easy to complete the COVID-19 vaccines readiness assessment. In Honduras, for instance, the Ministry of Health had already prepared a detailed and robust planning exercise that identified and costed the gaps in readiness, so that when the VIRAT-VRAF 2.0 was initiated, the information was easily compiled. Ecuador launched the assessment while the NDVP and micro-planning of vaccines deployment were ongoing. The assessment therefore was well-informed by the ongoing exercises, and in turn it enhanced the development of the NDVP as well as the micro-planning process. In Tajikistan, the assessment began relatively early in October 2020, and provided an impetus for the government to start working on their vaccine deployment plan. At the same time, the consultations on the assessment led by the World Bank staff with key partners – WHO, Gavi/COVAX, UNICEF, USAID, Asian Development Bank (ADB), Agha Khan Development Network – initiated broader coordination and multi-donor alignment on vaccine support for the Government of Tajikistan.

Box 2: Tajikistan: Vaccine Readiness Assessment Strengthens Coordination

In Tajikistan, which has the lowest GNI per capita and lowest per capita health expenditure in Central Asia, close coordination with partners has been critical for successful COVID-19 vaccine deployment. The early launch of the COVID-19 vaccine readiness assessment triggered the first formal COVID-19 vaccine readiness discussions in Tajikistan with government and partners. Through regular update meetings, the assessment helped the Ministry of Health and Social Protection (MOHSP) and Republican Center for Immuno-prophylaxis (RCIP; the national immunization program) understand the importance of timely preparation and the need for immediate country action to ensure preparation for COVID-19 vaccination. Consultations in October 2020 on the assessment with key partners became a starting point of a broader coordination and multi-donor alignment on vaccine support for the Government of Tajikistan. The assessment collected substantial knowledge for project preparation and for partners and was used by the National Technical Working Group for COVID-19 vaccines to develop the NDVP. In addition, the consultant hired by the World Bank to conduct the assessment has now also been hired by WHO to prepare the NDVP, which will further share technical knowledge obtained through the assessment with partners.

Completing the readiness assessment required buy-in and engagement from the government and partners. Without political mobilization from the MOHSP and an intensive engagement from RCIP, it would have been difficult to finalize the assessment. The World Bank's work in partnership with Gavi, RCIP and partners over the last couple of years – through the Gavi co-financed Health Systems Improvement Project (HSIP) and through the GFF – had already helped establish a close working relationship that made it much easier to launch this effort.

7. Most countries are using indicative top-down methodologies instead of using the VIRAT-VRAF 2.0 framework and associated tools to cost gaps in readiness

Most countries are using indicative top-down methodologies based on global cost estimates per activity to get a sense of the overall resource envelope. While relatively fast and inexpensive, this approach produces crude estimates of average costs and does not use the rich information provided by the VIRAT-VRAF 2.0 assessment framework. Countries that are costing gaps using this approach include the Republic of Congo, Lesotho, Egypt, Ethiopia, Tajikistan, Eswatini, Indonesia, Myanmar, Bosnia and Herzegovina, Kyrgyz Republic, Moldova, Ukraine, and Honduras. In comparison, very few countries are using the VIRAT-VRAF 2.0 framework to identify cost centers or the COVID-19 Vaccine Introduction and Deployment Costing tool (CVIC) developed by WHO to compute detailed costs of readiness gaps. Papua New Guinea, Mongolia, Lao, Sudan and Egypt are among the few countries that have used CVIC to estimate the detailed costs of meeting the gaps in readiness. The COVAX Inter-Agency Costing Group has conducted a series of training sessions to promote and socialize the use of CVIC, but the uptake so far has been limited.

Box 3: Papua New Guinea: Use of CVIC strengthens Donor Coordination

Prior to the onset of COVID-19, Papua New Guinea's immunization program could cover only about 40 percent of most childhood vaccines. The main costs drivers for vaccine delivery in Papua New Guinea are health personnel and supply chain logistics management.

In using the CVIC to compute costs for delivery of COVID-19 vaccines, Papua New Guinea has used scenario-based planning to identify and cost the trade-offs of different delivery strategies and service delivery models. This process has raised awareness of the challenges, facilitated dialogue on alternative options, and fostered better coordination across donors and global partners in the country, especially DFAT, UNICEF, WHO, ADB, Gavi and USAID, and has provided them with a nuanced understanding of the various cost components. This has been particularly important as vaccine delivery costs are very high.

4. Conclusion

Most low and lower-middle income countries have come a long way in the last few months since a COVID-19 vaccine became imminent and the global community and countries started preparing for the deployment of the vaccine. When COVAX was launched 8 months back, little was known about the vaccine delivery capacity and capability in most countries. The first of the country readiness assessment tools was published only in September 2020, and it was only in November 2020 when the World Bank, WHO, UNICEF, Gavi and the Global Fund got together in an ambitious program of helping at least 100 countries in 100 days to get ready for the deployment of the COVID-19 vaccine that the readiness assessment process truly took off. The 100-countries-in-100-days target was met well in time to support the development of NDVPs and for the first of the low-income countries to receive vaccines which at this time is occurring primarily through COVAX.

The COVID-19 vaccine rollout is going to be unlike any other prior vaccine delivery effort. The sheer volumes of people, doses, locations, and human resources involved in the mammoth vaccination exercise will challenge the most resilient of systems, and even the best-laid vaccine deployment plans will be seriously tested. The scale of the operation is immense, and despite all efforts by governments and partners alike, not all countries will be fully ready in all respects to rollout the vaccines by the time they receive the first significantly sized consignments. Yet, we are cautiously optimistic that most countries have addressed the essential minimum requirements for safe delivery of vaccines, and that they are ready enough to successfully deploy the small quantities that they will receive in the next few months until June 2021. We are also cognizant of the fact that several things could go wrong as the rollout starts but are confident that the effort that countries and partners continue to put in assessing and addressing gaps in readiness will help governments plan and execute amid uncertainty and deliver for their populations. We hope that the insights outlined in this paper will help governments, partners, communities and all stakeholders improve and adapt as the crisis continues to unfold and be better prepared for future pandemic threats.

Finally, we note from the experience of the first 12 weeks of readiness assessments that the process of carrying out the assessments is almost as important as the results of the assessments themselves. In most countries, the assessments have elevated the importance of readiness to the highest levels of decision-making. In the process, the assessments have brought together government officers, healthcare professionals, the private sector, and communities as well as global partners in the largest public health initiative ever undertaken, and have generated an unprecedented momentum as countries hunker down to overcome the virus that has redefined the world in the last fifteen months.

ANNEX: VIRAT-VRAF 2.0

CATEGORY	ACTIVITIES
A. PLANNING & COORDINATION	A.1 Establish (or engage an existing committee) a National Coordinating Committee (NCC) for COVID-19 vaccine introduction with terms of reference, roles and responsibilities and regular meetings. The body and its leadership should be accountable and functional.
	A.2 Establish (or engage an existing working group) a National Technical Working Group (NTWG) for COVID-19 vaccine introduction with terms of reference, roles and responsibilities and regular meetings.
	A.3 Establish or engage existing NTWG subcommittees, if required, to cover the following workstreams: 1) service delivery 2) vaccine, cold chain & logistics, 3) demand generation & communication (4) prioritization, targeting and COVID-19 surveillance, (5) Monitoring and Evaluation: determination and proof of eligibility, proof of vaccination, monitoring of coverage among at-risk groups, and monitoring of vaccine impact (6) Safety, including injury prevention and AEFI detection and response.
	A.4 Brief key ministries, NITAG, stakeholders and partners about COVID-19 vaccine introduction and their expected roles. Inform regularly & disseminate global and regional guidance (i.e. SAGE) with NITAGs & RITAGs and support NITAG working groups on COVID-19 vaccines.
	A.5 Identify and plan for the national vaccine access/procurement approach (e.g. COVAX Facility, bilateral purchase agreement, procurement through UN agency, self-procurement), including costs of items, due diligence mechanisms; identify key needs, ensure regulatory compliance, and complete required paperwork. Ensure that the procurement plan and purchasing strategy includes vaccines, ancillary supplies, and Personal Protective Equipment. Budget has been approved; and monitoring arrangements are agreed and updated as needed.
	A.6 Plan and procure waste management supplies and equipment for appropriate implementation of waste management protocols.
	A.7 Ensure that program objectives are defined and agreed to by key stakeholders at the central and sub-national levels, including representatives of target populations, community leaders, religious leaders, etc., and reflect the epidemiological situation and are adaptable to vaccine supply scenarios (protection of vulnerable populations, continuity of essential services, equity).
	A.8 Develop the National Deployment and Vaccination Plan (NDVP) with input from relevant bodies (National COVID-19 Response Coordinating Committee, CNCC, CTWG, NITAG, National Immunization Program, National Regulatory Authority, AEFI committee and other relevant groups such as private sector). The NDVP should be in line with WHO guidance and SAGE recommendations (plan can be developed by adapting the Pandemic Influenza NDVP, if existing).
B. BUDGETING	B.1 Include COVID vaccine program costs (vaccine, operating costs, HR and capital costs) in government budgetary and/or planning documents approved by the appropriate authority; in addition, include appropriation or allocation (from MOF/treasury) in the cash planning as an additional means to ensure that financing is indeed readily available.
	B.2 Ensure management aspects of appropriations from the MOF/Treasury are in place.

CATEGORY	ACTIVITIES
C. REGULATORY	C.1 Confirm the existence of any expedited regulatory pathway for approval of COVID-19 vaccines (i.e. emergency use authorization, exceptional approval/approval mechanism based on reliance/recognition, abbreviated procedure, fast track, etc.). Timelines and maximum number of days should be mentioned.
	C.2 Ensure the national regulatory authority or other concerned authority has clarified the regulatory requirements, and documents needed for regulatory approvals of COVID-19 vaccines and related supplies.
	C.3 Ensure that regulatory procedures are in place for import permit of COVID-19 vaccines and related supplies, and identify the requirements and documents needed to import COVID-19 vaccines and related supplies, including for taxes and tariffs.
	C.4 Confirm to WHO the existence of an expedited import approval from appropriate authorities. Timelines and maximum number of days should be mentioned. (expected timeline: maximum 5 working days).
	C.5 Ensure COVID-19 vaccines can be released (lot release) in less than two days by reviewing the summary lot protocol only (testing is not required). Identify the requirements and documents needed for NRA lot release for COVID-19 vaccines. Timelines and maximum number of days for lot release/waiver process should be mentioned.
D. PRIORITIZATION, TARGETING & COVID19 SURVEILLANCE	D.1 Monitor progress of NITAG working groups on COVID-19 vaccines and interim recommendations focusing on prioritization and risk groups.
	D.2 Identify potential target populations that will be prioritized for access to vaccines, estimate their numbers, and identify their geographic location, i.e. prepare first to define, identify and estimate no. of HCWs.
	D.3 Coordinate with national COVID-19 disease surveillance group to ensure relevant epidemiological data will be collected to inform planning of subsequent rounds of COVAX vaccination, if applicable, including outbreak responses.
E. SERVICE DELIVERY	E.1 Update protocols for infection prevention and control measures including adequate personal protection equipment (PPE) to minimize exposure risk during immunization sessions.
	E.2 Identify potential COVID-19 vaccine delivery strategies and outreach strategies leveraging both existing vaccination platforms and non-vaccination delivery approaches to best reach identified target groups. Develop a master list and strategy of service providers, points of delivery, including fixed and outreach (e.g. health facilities, community centers, by appointments, house-to-house) and associated medical supplies that could effectively deliver COVID-19 vaccine to target populations, and ensure that the necessary planning for locations and logistics is carried out.
	E.3 Identify implementing agencies and establish contractual agreements to prepare for vaccine introduction (e.g., vaccine warehousing, transport, waste management, cold chain capacity, etc.) where applicable. For delivery through private facilities, develop and approve Standard Operating Procedures, including service quality and performance and reporting standards and mechanisms for complaints-handling, certification of facilities, financing, performance monitoring and integrity checks.
	E.4 Ensure existence of protocols regarding consent to vaccinations, process for agreeing to or refusing to be vaccinated, and measures to protect those that refuse to be vaccinated are in place.

CATEGORY	ACTIVITIES
F. TRAINING & SUPERVISION	F.1 Develop a training plan across all participating facilities to prepare for COVID-19 vaccine introduction that includes key groups of participants, content topic areas (including safe injection practices), key training partners and training methods (in-person or virtual). WHO will provide a template for guidance.
	F.2 Adapt and translate training materials developed by WHO and develop additional training materials as outlined in the training plan.
	F.3 Ensure availability of plans to safeguard the security of staff (e.g. during an emergency or major campaign) as well as security at the central and/or regional storage facilities and for in-transit of products. Ensure regulations are in place regarding personnel who will be carrying out vaccinations, including all staff/personnel/consultants etc. engaged in such activities (cover military personnel also, if relevant), and include requirements relating to chemical, physical and biological substances, not engaging in sexual exploitation and abuse and sexual harassment, participation in training, reporting and non-retaliation.
	F.4 Conduct virtual and/or in person trainings as outlined in the training plan.
	C.5 Ensure COVID-19 vaccines can be released (lot release) in less than two days by reviewing the summary lot protocol only (testing is not required). Identify the requirements and documents needed for NRA lot release for COVID-19 vaccines. Timelines and maximum number of days for lot release/waiver process should be mentioned.
G. MONITORING & EVALUATION	G.1 Develop or adapt existing surveillance and monitoring framework with a set of recommended indicators (coverage, acceptability, disease surveillance etc.) for COVID-19 vaccine, including gathering information from facilities and contractors participating in vaccine delivery, and ensuring necessary human resource capacity is in place. Determine whether registration and reporting will be individual or aggregate, and to what extent existing tools and systems can be re-used.
	G.2 Develop or adapt necessary paper-based and/or electronic monitoring tools and appropriate institutional arrangements, including vaccination cards/certificates, facility-based nominal registers and/or tally sheets, vaccination reports, medical records, immunization records, systems entry and analytical tools to monitor progress and coverage among different at-risk categories and facilitate vaccine delivery and timely reporting.
	G.3 Ensure measures are in place for data protection, and appropriate data governance regulation is in place to monitor legitimate, appropriate and proportionate use and processing of data which may be routinely collected and managed in health information systems.
	G.4 Produce and distribute monitoring tools to eligible vaccination providers, develop, test and roll-out any changes to electronic systems, provide training for use of these tools and processes to traditional and new providers.
	G.5 Ensure a mechanism with multiple intake points has been designed and is in place and is operational for feedback and grievances in relation to the vaccine program.

CATEGORY	ACTIVITIES
H. VACCINE, COLD CHAIN, LOGISTICS & INFRASTRUCTURE	H.1 Establish/strengthen the national logistics working group with appropriate terms of reference and standard operating procedures to coordinate COVID-19 vaccines and ancillary products deployment.
	H.2 Map key roles and responsibilities needed for vaccine and ancillary products deployment; collect and confirm contact information for key personnel and facilities.
	H.3 Create a distribution strategy, including mapping the potential port(s) of entry, points of storage (stores) and stocking, and fallback facilities in the country with their respective cold chain storage (2-8C, -20C, -60/70C) and transportation capacity for vaccines and ancillary products, and ensure necessary human resource capacity is in place.
	H.4 Map and develop plan to provide for infrastructure needs, including for energy (primary and back-up power, especially in cold chain), IT/communications (including internet connectivity) and water.
	H.5 Assess dry storage and cold chain capacity and infrastructure needs at all levels with regards to the COVID-19 vaccines characteristics and fill the identified supply and logistics gaps.
	H.6 Provide COVID-appropriate standard operating procedures (SOPs), protocols, or guidelines for collection and disposal of medical waste, both hazardous and non-hazardous, to the relevant stakeholders. Assure that properly-licensed waste management providers (especially for hazardous waste storage, transportation and disposal) are identified and can be operationalized.
	H.7 Update and implement systems and protocols for tracking and monitoring the stock management and distribution of vaccines and key supplies through the Government's existing Vaccine Logistics Management and Information System, including operating procedures to reflect the characteristics of COVID-19 vaccines (i.e. vial size, etc.).
	H.8 Disseminate delivery and acceptance protocols, ensure monitoring arrangements are in place, and identify supervisory focal points at each facility. Establish security arrangements to ensure the integrity of COVID-19 vaccines and ancillary products throughout the supply chain.
I. SAFETY SURVEILLANCE	I.1 Ensure that guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities (i.e. AEFI reporting, investigation, causality assessment, risk communication and response), have been developed and disseminated to surveillance facilities/sites.
	I.2 Ensure adequate and trained human resources are available to conduct surveillance of events attributable to vaccination.
	I.3 Expedite appropriate representation, well defined TORs and training the AEFI committee to review COVID-19 Vaccine safety data (e.g., causality assessment of serious AEFI, clusters of AEFI, emerging safety concerns etc.).
	I.4 Identify provisions that require manufacturers to implement risk management plans and collect and report COVID-19 vaccine safety data to the NRA.
	I.5 Plan active surveillance of specific COVID-19 vaccine related adverse events. If this is not possible, develop provisions that allow reliance on active surveillance data, decisions, and information from other countries or regional or international bodies.
	I.6 Define roles and responsibilities and establish a coordination mechanism between relevant stakeholders (NRA, EPI, MAH, MOH, WHO and others) for exchange of COVID-19 Vaccine safety information.
	I.7 Identify and secure channels of data sharing mechanisms to share COVID-19 vaccine safety data and findings with relevant regional and international partners.
	I.8 Establish compensation schemes in the event that there are unintended health consequences as result of vaccines, including no-fault liability funds, and ensure that associated policies are in place.

CATEGORY	ACTIVITIES
J. DEMAND GENERATION & COMMUNICATION	J.1 Design and distribute a social mobilization and engagement strategy/demand plan and information awareness program (including advocacy, communications, social mobilization, risk and safety comms, community engagement, and training) to generate confidence, acceptance and demand for COVID-19 vaccines, including for engaging with national and local media, NGOs, social platforms, etc. and human resources for community outreach and risk communication management that also explains how complaints may be lodged and how they will be resolved, are available at all levels. Must include crisis communications preparedness planning.
	J.2 Establish data collection systems, including 1) social media listening and rumor management, and 2) assessing behavioral and social data.
	J.3 Develop key messages and materials for public communications and advocacy, in alignment with demand plan.