

Global landscape of the COVID-19 vaccination policy: Ensuring equitable access to quality-assured vaccines

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Abstract: Ensuring equitable access to COVID-19 vaccines for all people has been challenging, hence, establishing relevant vaccination policies is required. This study delineates how vaccination policies have affected equitable access to COVID-19 vaccines. A situation survey was conducted in 201 countries and territories through 156 Japanese diplomatic missions abroad to capture the global state of COVID-19 vaccination policies. Questionnaire responses were received from 159 states (79%) as of March 31, 2021, and data from Japan were incorporated into the analysis. All questionnaire items were open-ended, covering the vaccines in use and five vaccination policies such as vaccine eligibility. Results reveal that first, 81 states (51% out of 160) had not started vaccinations as of February 24, 2021, but by March 31, this number had decreased dramatically to 37 (23%); in particular, the number of states in Africa without vaccination decreased from 40 to 16. Second, 43 (27%) states did not recommend the vaccine for pregnant women. Third, the vaccine was free of charge to the public in 116 states (73%), and 43 states (27%) offered no-fault compensation. Finally, vaccination was voluntary in 124 states (78%). In conclusion, the number of countries that had started vaccination increased by March 2021, especially in Africa, although many African countries seemed to lack access to the mRNA vaccine. To fix the uneven distribution, dose donations were accelerated since middle of July. Reviewing worldwide vaccine policies is useful not only for this pandemic but also to strengthen vaccination systems for preparedness for the next pandemic.

Keywords: vaccine policy, equity, COVAX Facility, mRNA, no-fault compensation, voluntary inoculation

Introduction

The year 2020 brought a global pandemic caused by the new coronavirus infection; on January 30, the World Health Organization (WHO) Director-General declared the virus a Public Health Emergency of International Concern (PHEIC) (1). In response to what was later declared a pandemic, vaccine development began worldwide, and pre-purchase negotiations for COVID-19 vaccine candidates heated up among developed countries from the early stages. To ensure equitable access to the COVID-19 vaccine for all regardless of national economic power, Gavi, the Vaccine Alliance (Gavi), Coalition for Epidemic Preparedness Innovations (CEPI), and WHO established a global mechanism known as "COVID-19 Vaccine Global Access Facility (COVAX Facility)" for pooled procurement and distribution of vaccines (2). The COVAX Facility aimed to ensure

equitable access to vaccines with guaranteed safety, efficacy, and quality for all nations, including developing countries. With this study, we aimed to assess the state of vaccine delivery worldwide and vaccine policy in each country as of March 31, 2021, using survey data; we selected the end of March because the COVAX Facility had begun delivering vaccines approximately one month earlier. Our aim was to understand the direction of vaccine policies and how to expand equitable access to vaccines both as an effective countermeasure against COVID-19 and to prepare for future global pandemics.

Methods

Generating the data

To determine the status of the global COVID-19 vaccination policy, the Ministry of Foreign Affairs in

Japan sent a survey request to the Japanese diplomatic missions abroad, which covered 201 countries and territories. As of March 31, 2021, the questionnaires were returned by 159 (79%) states. Besides incorporating these responses, we also include the status of the vaccination policy in Japan as of March 31, 2021. All survey items were open-ended questions on topics that had been developed by the International Affairs Division, Minister's Secretariat of Ministry of Health, Labour and Welfare and the Global Health Policy Division, International Cooperation Bureau, Ministry of Foreign Affairs. For this study, we selected several responses to questions that could be categorized into quantitative data from qualitative responses, such as which vaccine the country used and the start date of vaccination.

Measures

The vaccines: The vaccines were identified using the developers' names taken from the COVID-19 candidate vaccine landscape and tracker (3). Items and responses were based on the date from when the vaccine was available to public-facing essential workers, such as healthcare workers, who were usually prioritized for vaccination in each country, not by the clinical trial dates. The vaccine developed by AstraZeneca and the University of Oxford and the vaccine licensed by the Serum Institute of India, Covishield, were categorized as Oxford-AstraZeneca. Vaccines developed by Sinopharm with the Wuhan Institute of Biological Products or the Beijing Institute of Biological Products were not separately identified in this study.

The regional categories: The regional categories were based on countries and territories classified by the Ministry of Foreign Affairs of Japan (4).

The analysis items: We collected data on the vaccines used in each country and on the following five key policies: the option of vaccine type based on people's preference; vaccine eligibility for children, pregnant women, foreigners, and dignitaries under limited supply; vaccine cost; no-fault compensation programs; and regulations regarding immunization, such as voluntarily inoculation. For states that had not begun vaccination as of March, we used information about their planned or current policies or categorized them as "Do not know".

Results and Discussion

Uneven distribution of vaccine use

Figure 1 displays the vaccines by region that were in use worldwide as of March 31. Oxford-AstraZeneca was in widest use, in 112 states over 6 regions; it was much cheaper by dose, approximately 3 to 4 USD, than the vaccines based on mRNA, such as Comirnaty by Pfizer/BioNTech, which costs approximately 19 USD

in the E.U. and the U.S. (5). Although Pfizer/BioNTech was more expensive, in March 2021, it was in use in 71 states; this might reflect that it received the earliest approval besides reflecting higher efficacy; Pfizer/BioNTech was approved on December 2, 2020, by national regulatory authorities, such as the Medicines and Healthcare products Regulatory Agency in the U.K. (6).

The WHO assessed that sufficient data on Pfizer/BioNTech were available for an Emergency Use Listing (EUL) recommendation on December 31, 2020 (7). The EUL is a procedure for assessing unlicensed vaccines, therapeutics, and *in vitro* diagnostics during PHEIC, with the goal of expediting the availability of these products to people who need them (8). Also, the EUL was one of the COVAX Facility's product eligibility criteria for vaccine use recommendation (9).

At that time, Pfizer/BioNTech required storage at -90°C to -60°C for a six-month shelf life (10), which required expensive freezers to maintain the ultra-cold temperature. Conversely, Oxford-AstraZeneca could be stored under ordinary conditions at $2-8^{\circ}\text{C}$ (11). Based on its price and storage advantages, the COVAX Facility had expected that Oxford-AstraZeneca would be on EUL in the early stages.

There was uneven distribution of Pfizer/BioNTech by region. Specifically, it was used primarily in North America and Europe, where the Moderna vaccine was also in high use; both Moderna and Pfizer/BioNTech are mRNA vaccines. In December 2020, the COVAX Facility made available limited funding to support ultra-cold freezers in cases of emergency, but only 10 million USD was initially allocated (12). Therefore, it is highly possible that Pfizer/BioNTech was only in use in countries that could afford the vaccines and the freezers.

The U.S. government announced a donation of 500 million Pfizer/BioNTech doses for low-income countries through either the COVAX Facility or other mechanisms on June 10, 2021 (13), and on June 23, the COVAX Facility increased the funding for ultra-cold freezers to 775 million USD (14). These supports will contribute to reducing the inequitable distribution of the Pfizer/BioNTech vaccine and to increasing choice and availability in low- and middle-income countries that could not afford certain vaccines themselves.

Expanding vaccine availability

Figure 2 presents the changes in vaccine use by region from February 24, the first day the COVAX Facility delivered vaccines, to March 31. During that approximately one month, the number of states that had not started vaccination decreased from 81 to 37, and particularly in Africa, the number of states with no vaccine decreased from 40 to 16.

The COVAX Facility began vaccine delivery in

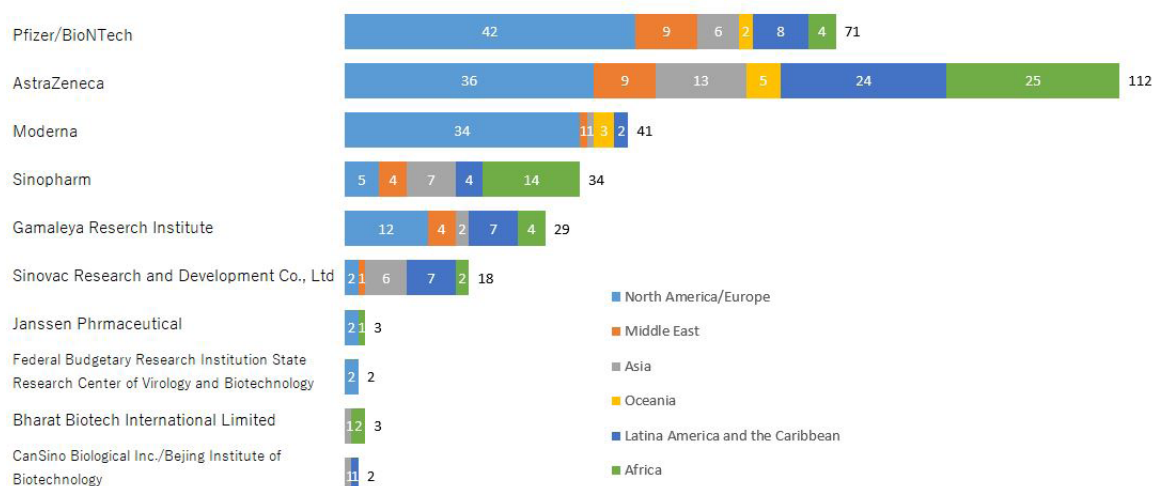


Figure 1. Nations' selected vaccines by region as of March 31, 2021.

Footnote: The figure described the number of countries or territories each vaccine was used by.

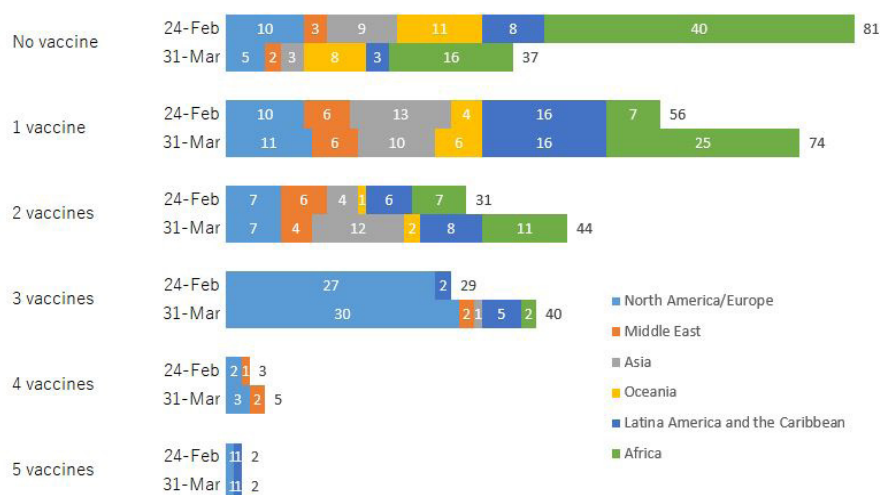


Figure 2. Changes in vaccine type and number by region between February 24 and March 31, 2021.

Footnote: The figure described the number of countries by the number of available vaccines in two time lines.

Ghana on February 24 and had reached over 100 states by April 8, 42 days later (15). To receive the vaccine supported by donor funding through the COVAX Facility, the states had to prepare a national vaccination plan; 92 states were eligible based on income. To develop an overall vaccination policy, a regional committee, including Gavi Independent Review Committee members, reviewed the vaccination plans of the 92 eligible economies (16), and because of these preparations, the vaccine administration progressed smoothly. The findings here clearly indicate that without the COVAX Facility, many more countries would not have started COVID-19 vaccination by March 31.

Overview for five vaccination policies

Supplemental Table S1 (<https://www.ghmopen.com/site/supplementaldata.html?ID=31>) presents the findings from our analyses regarding key COVID-19 vaccination

policies. In most of the states (87%), people did not have a choice regarding the vaccine type they would receive, when several vaccine types were available in the country. Concerning eligibility, children were eligible for vaccination in six states as of March 2021, and 43 states recommended against COVID-19 vaccination for pregnant women. In 59 countries, foreigners could receive the vaccine under the same conditions as domestic citizens, and political leaders in 31 states had begun discussing easing quarantine restrictions for vaccinated residents. Dignitaries had received the vaccine in approximately 50% of the states. Vaccination was voluntary in 78% of the states. Only one country required residents to pay for vaccination. Forty-three states had no-fault compensation programs.

Vaccine eligibility and prioritization

The WHO Strategic Advisory Group of Experts on

Immunization used available clinical data to provide guidance for overall vaccine program strategy, including prioritization by subpopulation. Children take priority for routine immunizations; however, COVID-19 rarely causes severe illness or death in children (17), and in our study, six states were administering the vaccine to children as of March 2021, although some clinical data on children were available on May (18). Evidence showed that pregnancy was associated with increased rates of hospitalization, ICU care, and mechanical ventilation (17); however, the available data on vaccine use in pregnant women of the first EUL vaccine, Pfizer/BioNTech, were insufficient to assess vaccine-associated risks in relation to pregnancy as of December 2020, and the WHO was not recommending pregnancy testing prior to vaccination at that time (10). The initial recommendations for the COVID-19 vaccine influenced how national plans prioritized vaccination; as of March 2021, 43 states recommended that pregnant women not receive the vaccine; however, 40 states were administering the vaccine with a doctor's consultation. In June 2021, the initial recommendations for several vaccines were updated with relevant data; for example, based on its benefits, the WHO recommended the use of Pfizer/BioNTech in pregnant women (19).

Each country has had to prioritize vaccine distribution given limited supplies despite sufficient data showing their safety and effectiveness. Considering the inequities in vaccination rates between high- and low- to middle-income countries, countries accelerated donating vaccines through the COVAX Facility since middle of July (20,21). Countries with high vaccination rates, in particular, should increase dose-donation for vulnerable countries before administering booster shots for the general population in the countries, because there was limited data that booster doses were efficient in September 2021 (22).

No-fault compensation

Before the pandemic, no-fault compensation programs were set up in a few high-income countries; we identified 39 states with such programs for vaccine injuries, and 3 had established the programs for the COVID-19 vaccine. In a prior study in 2018, only 25 states had no-fault compensation programs for vaccine injuries, with programs administered at the central government level in 15 states (23). The COVAX No-Fault Compensation Program started in April 2021 to protect the 92 eligible economies (24,25), and the COVAX Facility requested that all participating countries make indemnification and liability agreements with each manufacturer before they shipped the vaccine (16). The aims of vaccine injury compensation were to promote vaccination with fair compensation for individuals in the event of harm and to accelerate vaccine research and development while protecting manufacturers from liability. The latter was

especially important because the COVID-19 vaccines were developed at unprecedented speed, and there were uncertainties concerning severe adverse events or long-term effects.

COVID-19 vaccine fees

In the acute phase of an infectious disease, it is reasonable for any vaccine to be free of charge for all to promote vaccine access and prevent severe disease and death. In most of the surveyed countries, 72%, the governments administered the vaccines at no cost to the public. The COVAX Facility decided that the pledge for vaccine procurement by donors would cover at least 20% of a nation's population, excluding India because of its large population, during the acute phase of COVID-19 for the 92 eligible lower-income countries and that it would then introduce a cost-sharing mechanism both to ensure sustainability of vaccine distribution and encourage a sense of ownership (26,27). It is possible that COVID-19 vaccination will require a yearly booster shot in the same way as seasonal influenza vaccination and that people might need to pay for it. To avoid the situation where low-income individuals hesitate to get vaccinated or low-income countries do not purchase the vaccine, careful consideration should be given to covering out-of-pocket costs for the COVID-19 vaccine.

Vaccination regulations

The WHO stated that either governments or institutional policymakers or both should encourage voluntary vaccination against COVID-19 before contemplating mandatory vaccination (28). In our survey, the COVID-19 vaccination was voluntary in most states (78%). The ongoing COVID-19 pandemic is sufficiently dire that it necessitated drastic restrictions on social activity, including national lockdowns, but securing the public health had tremendous economic impacts, and the lockdowns were controversial. There were high expectations for vaccines to control COVID-19, and some national leaders focused on expanding their vaccinated populations.

For instance, most of the WHO EUL-approved vaccines, except for that of the Janssen Pharmaceutical, need two doses at intervals recommended according to clinical trial data; however, to extend access with limited supplies, some countries emphasized administering the first dose to as many people as possible before giving the second shot. For example, leaders in the U.K. elected to extend the interval between doses for Pfizer/BioNTech from 3 weeks to 12 (29), and similar decisions were made for Oxford-AstraZeneca, for which a longer gap between doses had shown improved efficacy in some age groups (30). We found only five countries prioritized to expand first shots before second shots were completed. Although governments attempted to maximize the public

health impact of the vaccine and the WHO recommended longer between-dose intervals given the limited supply of vaccine (10,11,19), most governments seemed hesitant to deviate from the recommended protocol and expand administration of single shots.

There was high demand from industries to reduce the COVID-19 restrictions on international mobility, especially from aviation industries, because international tourism fell by around 80% in 2020, and up to 174 million jobs were estimated to be at risk globally (31). However, easing restrictions carries risk of transmission, and indeed, some outbreaks occurred after quarantine restrictions were eased (32,33). Our survey only showed the eligibility of foreigners who were living within a given country, but some countries also offered the vaccine to foreign travelers (34,35). For example, the U.S. government offered travelers the Janssen Pharmaceutical vaccine, owned by Johnson & Johnson, which required only one shot (36). This type of vaccine tourism could increase the inequities in global vaccination because only countries with surplus vaccines can offer such services for rich people who can travel overseas given the limited global supply. Accelerating vaccination rates with policies such as longer intervals between doses before completing second shots was a sound decision with scientific evidences; however, we recommend against encouraging vaccine tourism or only easing regulations for vaccinated individuals. Such policies will only extend vaccine inequity given that few states had over 50% of their populations fully vaccinated by the end of June 2021 (37).

Strengths and limitations

For this study, we relied on information reported in the media and in press releases that was available by the end of March 2021 and COVID-19 conditions are changing dramatically from country to country depending on date; however, a particular strength of this study is that information was collected from people who understood the languages of original information. Although we could not produce a holistic view of the COVID-19 vaccination policies, we were able to highlight how these policies contributed to promoting and extending vaccination.

Conclusion

The suppression of economic activities, such as through restricted human movement during emergencies, is a major issue in many countries, and COVID-19 was not an exception; national lockdowns had tremendous social and economic impacts worldwide. Vaccines were considered crucial to reopening economies and lifting restrictions, and once these became available, most governments attempted to eliminate or decrease barriers to vaccination by making it voluntary and administering

the vaccines free of charge. The COVAX Facility comprehensive global system and relevant vaccine policies established in each country were highly effective at ensuring equitable access to the COVID-19 vaccine and protecting people. From February 24, 2021, when the COVAX Facility distributed the first vaccines to a low-income country, to the end of March, the number of countries that had not started vaccination decreased substantially, especially in Africa; the COVAX Facility supported 46 African nations in expanding vaccine access as 92 eligible low-income countries. This review of policies worldwide and accumulated data could make substantive contributions to countries' vaccination policies. The systems for adjusting uncertainties and making justifiable policies, such as emergency use approval mechanisms and no-fault compensation programs, for vaccine injuries are of great use during this ongoing pandemic and will contribute to preparedness for the next one.

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