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The 'Vero Cell' COVID-19 vaccine rollout in Nepal: What we know about the Chinese vaccine development and access?

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The world has changed dramatically from the impact of the COVID-19. It has impacted the normality of daily life, highlighting the failure of rich and poor nations alike, which is evident from the high number of human lives lost in rich and powerful countries like the USA with total deaths of 32,735,704 and Europe with 43,708,958 until April 24, 2021, as per Worldometer.¹ The COVID-19 pandemic has shown that all of us 'have and have-not', no one can escape from the effects of the lockdowns, disruption of normal life including education, businesses, etc. reminding all of us that equitable access to vaccines is the best possible choice not to further exacerbate the challenges because 'no country is safe until every country is safe'.² It is a remarkable scientific achievement that within a year of the identification of the virus, we have COVID-19 vaccines, albeit available mostly in rich countries. The benefit of research is possible only with solidarity, by sharing the available resources, vaccine included, for the control of the ongoing COVID-19 pandemic.

Modern science and technology, including the development and marketing of COVID-19 vaccines, have been focused in the USA and Europe. China joined this club of elites of science following the Chinese FDA approval of Sinopharm (the subsidiary of state-owned China National Pharmaceutical Group- CNPG), first COVID-19 vaccine (inactivated Sars-Cov-2) based on the results of the phase-3 clinical trial in UAE and Bahrain showing up to 86% efficacy of the vaccine in preventing COVID-19.³

Detail of trials of Sinopharm inactivated COVID-19 vaccines (Vero Cells) available on two early trials in China (Phase I/II [ChiCTR2000031809](#), enrollment 1,456) and later 4 trials outside China (phase III, [NCT04510207](#) Bahrain, Egypt, Jordan, United Arab Emirates- enrollment of 45,000; [ChiCTR2000034780](#) United Arab Emirates, enrollment of 15,000; [NCT04612972](#) Peru, enrollment of 6,000) show the progress of research and approval in China and UAE.^{4,5}

Four Chinese vaccines (from among more than 10 in different stages of trials), two from Sinopharm CNBG, one from Sinovac Biotech, and one from CanSino Biologics have been authorized for public use. A 5th candidate (based on protein) from the Institute of Microbiology of the Chinese Academy of Sciences has the green light for emergency use.⁶ A 3rd vaccine candidate from Sinopharm, the protein-based recombinant vaccine that includes parts of the Coronavirus spike protein got approval on April 10, 2021, for the human trial in China.^{6,7} The protein-based vaccine cultivation does not require facilities with high biosafety levels involved in the use of active virus during the production.

The World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE), based on submitted data from Sinopharm and Sinovac, indicates that levels of efficacy are compatible with the WHO requirements for this vaccine, and have over 50% efficacy along with all the safety required of a vaccine.^{8,9}

The vaccine from Beijing Biological Products Institute (BBPI), a unit of Sinopharm subsidiary of CNBG, has been approved in several countries including China, Pakistan, and the UAE. CoronaVac from Sinovac has shown efficacy between 50.65% and 83.5% from trials from Brazil, Turkey, and Indonesia.⁹ In a Chilean study based on data obtained 14 days after the second dose, Sinovac's CoronaVac was found to be 67% effective in preventing symptomatic COVID-19 infections and preventing 80% of fatalities from the disease. It was 85% effective against hospitalisation and 89% in preventing intensive care units (ICU) admissions.¹⁰

Chinese vaccines from Sinopharm and Sinovac are in demand and have now been exported to >70 countries. They have been approved for emergency use by most of the developing nations, and some European countries like Hungary and Serbia. Most of these countries have limited access to shots from the USA and Europe.⁹ By the end of April, these two Chinese vaccines will be included in the list of vaccine of COVAX.⁸

China joined COVAX (co-led by Coalition for Epidemic Preparedness Innovations CEPI, Gavi, and WHO, alongside the United Nations Children's Fund UNICEF) in October 2020 for global distribution of COVID-19 vaccine backed by the WHO.^{11,12} Gavi, the Vaccine Alliance (previously the GAVI Alliance, and before that the Global Alliance for Vaccines and Immunization) is a public-private global health partnership for increased access to immunization in resource-poor countries.^{13,14}

Virus replication anywhere is a threat everywhere. Virus mutations arise during replication, and so, preventing infection and transmission will stop virus evolution/mutation. Viruses less neutralized by vaccines may in theory have a selective advantage over viruses more susceptible to vaccine-induced immunity. However, this selection pressure on the virus leading to a meaningful vaccine escape is unknown and circulating strains mutate from genetic drifts with or without vaccination. Thus, vaccination and public immunity to the virus are important to stop the transmission and virus mutation. Debating and demanding 100% efficacy from a vaccine, and arguing not to vaccinate, is unscientific. Even for the mutant virus, the South African variant, two vaccines developed by Sinopharm and Chongqing Zhifei Biological Products were found to be effective.^{15,16}

The WHO calls for solidarity in the fight against the COVID-19 pandemic is more than a slogan. There is a huge gap between countries for vaccine access. The high-income countries with 16% of the world's population have stockpiled the vaccines which amount to more than twice their population. The stockpile of vaccine by few richest countries is 1 billion more doses than they require, whereas the rest of the world struggles for vaccine access and have only 2.5 billion doses, far less than they need for their populations. This is unethical, for example, for the USA to have a vaccine surplus, and it should seriously consider sending the excess vaccines to the needy countries, because, it can't stop production and continue to sit on the excess vaccine supply.¹⁷ The COVID-19 pandemic has

taught us important lessons to be humble, to be ethical, and to practice equitable healthcare delivery within and outside countries, and to come together collectively to minimize the loss of lives. The virus does not respect boundaries in today's interconnected world. The COVID-19 does not discriminate against people by their socioeconomic status, race, or ethnicity. To protect everybody, we need a critical mass of [herd immunity](#) (>70%) to stop the pandemic, which not possible as long as we allow the virus to transmit unchecked and kill millions. The analyses show >12 billion doses of vaccine will be produced in 2021 to cover 70% of the world population and it will be possible only by 2023 to vaccinate the world's population if all goes well.¹⁷

The mechanism of COVAX to make vaccines available globally is a much-needed effort from countries around the world. Vigilance, surveillance of circulating Coronavirus, and population immunity are essential to update the vaccines and to keep up with the virus evolution. Prioritization to supply the vaccines to COVAX, instead of bilateral (commercial) deals among countries, is not only an essential step for equitable access to vaccines globally to prevent the virus from mutating and taking over the world, it's more of a humanitarian move.¹⁸ The COVAX Advanced Market Commitment (AMC) needs to break the 'superiority complex' of a few countries that produce vaccines and should stand up beyond the vaccine politics to make it available to 92 lower-middle and low-income economies participating in COVAX.¹⁹ Multinational studies show China's COVID-19 vaccines are effective²⁰, and more than 80 countries have received China's emergency assistance.

The director-general of the Chinese CDC (CCDC) George Gao, on 11 April 2021, at a Chengdu conference on COVID-19 vaccines, mentioned the problems of efficacy faced by all COVID vaccines. He highlighted the current problem is global and not just an issue with China's vaccine²¹, and that "we will solve the problem that current vaccines don't have very high protection rates and consider whether we should use different vaccines from different

technical lines for immunization." Also, Chinese health official, Wang Huaqing, mentioned that "The mRNA vaccines developed in our country have also entered the clinical trial stage." This is challenging for China to meet the demand and supply (have already supplied 80 million doses) of the vaccine around the world to >60 countries that have approved Chinese COVID-19 vaccines. As per health official Wang Huaqing, China expects to manufacture about three billion vaccine doses in 2021.²¹

Ongoing pandemic and evolution of virus with new strains is a challenge to all countries. Precautionary measures together with vaccination are needed. As per USA CDC-Centers for Disease Control and Prevention Report, some people (5,800) became infected after vaccination, and about 7% (396) of those re-infected required hospitalizations, and 74 died.²²

In an interview on Jan 15, 2021, the chairman of Sinopharm, Liu Jingzhen explained that Vero Cell was the first COVID-19 vaccine in the world to be approved for phase I/II clinical trial in China. It was China's first approved vaccine for adults >18y of age. As mentioned in the vaccine leaflet, this was based on initial clinical trials on the age group 18-59 years. Further trials conducted in >60y and then age 3-17y (in 3 sub-groups, age 12-17, 5-12, and 3-5), will cover whole age groups above 3y.²³ The inactivated vaccine is based on the traditional and widely accepted technology, like earlier vaccination data which show it is a safe and effective technology, proven by polio vaccine, hand foot mouth disease and, tick-borne encephalitis vaccines. Since June 2020, based on Phase III trial in 7 countries (UAE, Bahrain, Egypt, Jordan, Peru, Argentina, and Morocco), the vaccine was approved officially by China and the UAE. This vaccine is convenient to store and transport at 2-8°C. One important aspect of this vaccine is the cross-neutralization tests with the novel Coronavirus strains from different sources around the world (as per phase III trial data from UAE included 50,000 volunteers in 125 countries

from different parts of the world), meaning it provides wider protection.²³

The latest update to expand the vaccination for a wider population, a randomized double-blind placebo parallel-controlled Phase III Clinical Trial ([NCT04560881](#)) with inactivated SARS-CoV-2 Vaccine (Vero Cell) on 3,000 Argentine healthy population of 18-85 years will be complete on December 1, 2021.²⁴ The earlier timeline show Sinopharm BBIBP-CorV inactivated vaccine was made of virus particles grown in culture developed by Sinopharm's Wuhan Institute of Biological Products Co and the Chinese CDC, using SARS-CoV-2 strain (genome sequencing of WIV04 strain and number [MN996528](#)) isolated from a patient in the Jinyintan Hospital, Wuhan, China. As per the vaccine information, it was approved by China's National Medical Products Administration as an experimental vaccine on December 31, 2020.²⁴

The BBIBP-CorV, one of the two inactivated vaccines of the Sinopharm, reported efficacy of 86% (UAE) and 79% (Sinopharm interim analysis) in Dec 2020. This was based on Phase III trials from Argentina, Bahrain, Egypt, Morocco, Pakistan, Peru, and the United Arab Emirates-UAE with over 60,000 participants. The vaccine has been used widely in Asia, Africa, South America, and Europe.^{25,26} Sinopharm's Chairman Yang Xioyun reveals the company's plan of production in collaboration with local facilities outside China, like Abu Dhabi G42, Egypt's VACSERA, while Serbia and Belarus plan to produce BBIBP-CorV locally for their local markets.^{26,27} The effective, affordable cost and ease of transport of vaccine fulfills the need of the populations in developing countries around the world.²⁸

Another inactivated Chinese COVID-19 vaccine, the CoronaVac, made by Sinovac, a private Chinese company, had shown effectiveness in phase I and II clinical trials.^{21,29} The phase III trials in Brazil, Chile, Indonesia, Turkey, and the Philippines, show the efficacy

of 83.5% by Turkish³⁰, 56.5%-67% by Chilean^{10,31}, 50.7%, and 62.3% (with longer dosing intervals) by Brazilian²¹ studies. The data based on the earlier randomized, double-blind, placebo-controlled, phase 1/2 clinical trials, on healthy adults aged 18–59 years in Suining County of Jiangsu province, China²⁹ led to the use of the 3 µg dose in phase III trial (phase I trial seroconversion after the second dose in 24 of 24 participants 100% [95% CI 85.8–100] and in phase II seroconversion in 96 of 98 participants 98% [92.8–99.8]). A similar randomized, double-blind, placebo-controlled, phase 1/2 clinical trial of CoronaVac in Renqiu, Hebei, China³² investigated the vaccine efficacy in healthy adults aged 60 years and older. Also, Brazil data has shown persistent efficacy for the P.1 variant with the administration of at least one dose of CoronaVac against symptomatic infection.³³

Currently, five vaccine candidates are in use for mass immunization campaigns in China.^{4,27,34-36} Three inactivated-virus vaccines (Vero Cells), two vaccines from Sinopharm, and one from Sinovac require two shots. The 5-vaccines are: 1st Sinopharm BBIBP CorV - Beijing Institute of Biological Products – UAE, approved for emergency use in September 2020 followed by full approval in December by Bahrain and China; 2nd Sinopharm Wuhan Institute of Biological Products; 3rd Sinovac's CoronaVac inactivated two shots vaccine authorized by China for emergency use in July 2020; 4th CanSino Beijing Vaccine, developed by Sino Biologics in collaboration with the Beijing Institute of Biotechnology is a weakened adenovirus one-shot vaccine; 5th Gao's team in partnership with Anhui Zhifei Longcom.

Also, the China clinical trial registration data are awaited on mixing of COVID-19 vaccine doses from CanSino Biologics ([6185.HK](#)), and Zhifei Biological ([300122.SZ](#)).³⁷ Sinopharm's two vaccines have an efficacy of 79.4% and 72.5%, based on interim results. Indonesia's phase III Sinovac trial shows the efficacy of 65%.^{27,34}

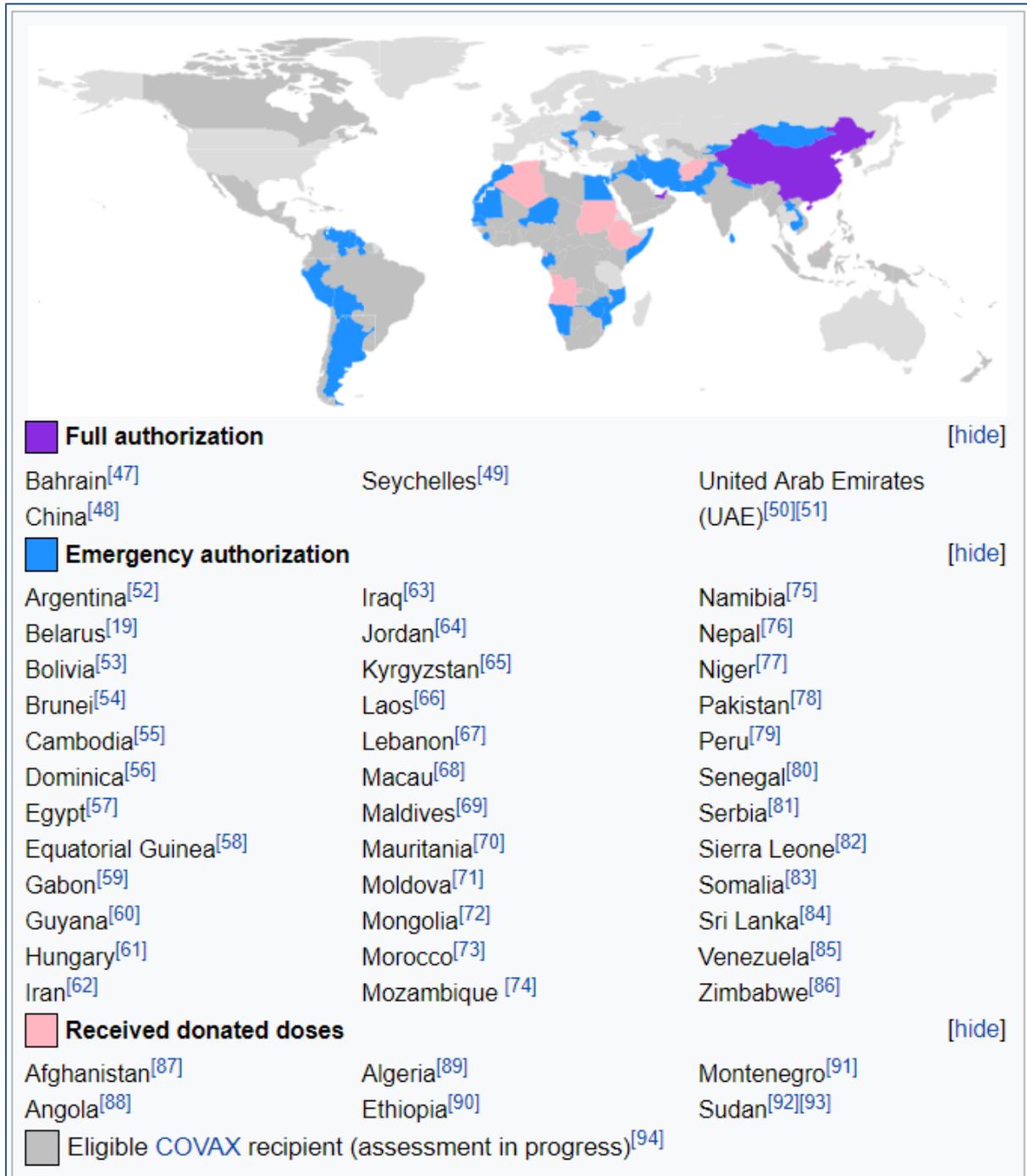


Figure 1. Authorization and deployment of Sinopharm vaccine by country (the numbers in parenthesis [] indicates the country data source).²⁶

In Nepal, the Vero Cell, Chinese COVID-19 vaccines developed by Sinopharm was donated on March 29, 2021.³⁸ The Chinese vaccines arrived in Nepal when the Himalayan country has been struggling to continue its vaccination drive, which started on Jan 27 (with COVISHIELD donated by India). Nepal has inoculated over 1.7 million people as per Nepal's Ministry of Health and Population.³⁹

According to the ministry, the 800,000 Chinese jabs (Vero Cell) were targeted at people involved in emergency services, traders working across the Sino-Nepal border and Nepali students studying or preparing to study in China. This vaccine is within WHO's Emergency Use Listing Procedure Pre-Qualification (EUL/PQ) evaluation process and

had reached the "in progress" stage as of January 20, 2021.^{40,41}

On February 17, 2021, the Department of Drug Administration (DDA) ministry of health and population, the government of Nepal, approved the emergency use of the Sinopharm COVID-19 vaccine (Vero Cell). The Vero Cell developed by China's Beijing Institute of Biological Products (BIBP) Co. Ltd. was approved for administration at designated hospitals in Kathmandu Valley. This coincides with the rise in cases that had gone down in March.^{42,43} Nepal, home to 28 million people, has recorded 277,944 COVID-19 infections and 3032 deaths, granted conditional emergency approval for use of Vero Cell.⁴⁴

The COVID-19 vaccines should be available for everyone, everywhere who could benefit from it. For such, the WHO, through COVAX, is supporting the vaccine introduction readiness assessment tool (VIRAT) to prepare countries for vaccine introduction and to develop a National Deployment and Vaccination Plan (NDVP) for COVID-19 vaccines.⁴⁵

Preventive measures of hand hygiene, social distancing, masking, together with extreme steps for 'quarantine, isolation, and lockdown'⁴⁶ in the context of Coronavirus continue to play important role in the new-normal life during this ongoing COVID-19 pandemic. Nepal went into the second lockdown effective from 0600 on Thursday, April 29 until May 05, 2021, in Kathmandu (and other provinces outside has also implemented different measures of lockdown) to slow the spread of COVID-19.⁴⁷ Government of Nepal implemented the first partial lockdown on 18 March 2020 and countrywide lockdown on 24 March, 2020.⁴⁸ The new lockdown is for the fear that an uncontrolled number of people may have contracted the virus of infectious mutant strains from across the open border in neighboring India where the situation is out of control.⁴⁹

The COVID-19 vaccines rollout is the ultimate step in the control of pandemics. Nepal approved for emergency use of the Sinopharm

COVID-19 vaccine (Vero Cell) from China's BIBP for administration at designated hospitals in Kathmandu Valley on February 17, 2021. In the countries with resources, the vaccine elites have to consider that 'no country is safe until every country is safe'.

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