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Operation Warp Speed: implications for global vaccine security

*Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force Members**

Several global efforts are underway to develop COVID-19 vaccines, and interim analyses from phase 3 clinical testing have been announced by nine organisations: Pfizer, the Gamaleya Research Institute of Epidemiology and Microbiology, Moderna, AstraZeneca, Sinopharm Group, Sinovac Biotech, Johnson & Johnson, Novavax, and CanSino Biologics. The US programme known as Operation Warp Speed provided US$18 billion in funding for development of vaccines that were intended for US populations. Depending on safety and efficacy, vaccines can become available through mechanisms for emergency use, expanded access with informed consent, or full licensure. An important question is: how will these Operation Warp Speed vaccines be used for COVID-19 prevention in global health settings? We address some key questions that arise in the transition from US to global vaccine prevention efforts and from ethical and logistical issues to those that are relevant to global vaccine security, justice, equity, and diplomacy.

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Introduction

At the end of January, 2021, 16 SARS-CoV-2 vaccine candidates around the world were in phase 3 clinical trials, with five of these vaccines funded by a US programme called Operation Warp Speed (OWS).[1] Nine announcements of safety and efficacy have been made, ranging from 50% to 95% efficacy,[2] several vaccines have been granted emergency approval, and vaccines from Pfizer, AstraZeneca, and Moderna have received recommendations from the Strategic Advisory Group of Experts in Immunization. OWS has invested an estimated US$18 billion mostly in the late-stage clinical development and early manufacturing of COVID-19 vaccines and has agreements in place to buy 455 million doses.[3,4] OWS is the largest of the global efforts for development of COVID-19 vaccines; by comparison, the Coalition for Epidemic Preparedness Innovations (CEPI) invested $1·4 billion in support of the development of COVID-19 vaccines. CEPI funding carries commitments to ensure global access and affordable cost. Recipients of OWS funding also have clear commitments: to the USA. Companies that are supported by OWS, and manufacturers in Russia and China, have approached countries and organisations independently, creating a complicated ecosystem for COVID-19 vaccines that is comprised of a patchwork of countries that have and do not have vaccines.

There were eight vaccines in the original OWS programme (but not all have entered phase 3 trials). The OWS vaccines that reached phase 3 testing included two non-replicating adenovirus-vectored vaccines (the AstraZeneca–Oxford chimpanzee adenovirus and the Johnson & Johnson adenovirus type 26 vaccine); one vesicular stomatitis virus-based vector (Merck–International AIDS Vaccine Initiative); two mRNA vaccines from Pfizer–BioNTech and Moderna; and two protein vaccines from Novavax and Sanofi–GlaxoSmithKline.[1] The vaccine from Merck–International AIDS Vaccine Initiative has since been withdrawn. Vaccines from Pfizer, Moderna, and Johnson & Johnson have received US Food and Drug Administration approval for emergency use. The European Medicines Agency has approved vaccines from Pfizer–BioNTech, Moderna, and AstraZeneca. WHO has given emergency use listing to Pfizer–BioNTech, AstraZeneca, and Johnson & Johnson. Additionally, the adenovirus type 5 (Ad5) vaccine from the Gamaleya Research Institute of Epidemiology and Microbiology has been approved by the ministry of health in Russia, the whole inactivated vaccines from Sinopharm Group and Sinovac Biotech and the CanSino Ad5 vaccine have received approval in China, and the whole inactivated vaccine from Bharat Biotech has received approval in India. Other countries, for example the United Arab Emirates, Indonesia,

Key messages

- The USA should accelerate the rejoining of WHO, expand its role in COVID-19 Vaccines Global Access, and contribute funding and vaccines to this global effort.
- Countries with excess vaccines (which were developed through funding from Operation Warp Speed or the Coalition for Epidemic Preparedness Innovations) through preorders should consider assignment of excess vaccines to COVID-19 Vaccines Global Access and support the mechanisms for logistics, implementation, and follow-up of vaccinated populations.
- As a continuation of the work of Operation Warp Speed, research into efficacy against COVID-19 variants; optimisation of schedule, dose, and boosters; correlates of protection; effectiveness and herd immunity; long-term safety and adverse events after immunisation; and global surveillance for mutations should also be used as an opportunity to strengthen health systems and research capabilities in low-income and middle-income countries as a part of pandemic preparedness and global health security.
- Operation Warp Speed funding should be followed by support for optimising vaccination practice and vaccine acceptance worldwide, to counter misinformation and vaccine hesitancy.

Turkey, Brazil, and India (among others), have also granted approvals.

Nearly 400 million doses of COVID-19 vaccines have been administered, primarily in high-income countries that had preordered vaccine but now in other countries as well. In the USA, vaccination started in December, 2020, and slowly increased to roughly 10% of the US population.

The OWS programme is focused on the USA and approval by the US Food and Drug Administration. The USA continues to lead globally in the number of COVID-19 cases, and its deaths due to COVID-19 are approaching 560 000 people in March, 2021. However, the global toll of infection (ie, approaching 121·2 million people) and deaths (ie, nearly 2·7 million) means that vaccines that are developed under OWS should also be considered for global distribution. Interestingly, several of the companies that are supported by OWS also received funding from CEPI, which should require global access. Failing to provide equity in the early distribution of SARS-CoV-2 vaccines, according to modelling by Chinazzi and colleagues, could result in a doubling of global mortality.[5] Leveraging the efforts of OWS for global health and bringing safe and effective vaccine solutions to people around the world in a timely manner is a crucial endeavour and too important to fail.[5,6]

The global access gap

Equity and access have been a focus of a previous *Lancet* Commission report on essential medicines.[7] The biomedical innovation system does not prioritise disease that is found predominantly in low-income and middle-income countries (LMICs), and innovation that is fostered in high-income countries, for reasons of cost, complexity, or intellectual property restrictions, typically has delays in global introduction.[7,8] Vaccine technology is not different.

Often it takes years, and sometimes decades, for new vaccines to achieve the same level of uptake in LMICs as in high-income countries. Rotavirus vaccine, approved in 2006 by the US Food and Drug Administration and approved and recommended by WHO in 2009, rapidly achieved 70% uptake in the USA. Worldwide, in 2020, less than 40% of children receive three doses of rotavirus vaccine.[9] Gavi, the Vaccine Alliance, provides vaccines at low or no cost to the poorest countries; sadly the greatest burden of unvaccinated children is found in middle-income countries. To address the gap in access to COVID-19 vaccines, Gavi, WHO, and CEPI lead an international plan for access to COVID-19 vaccines, known as the COVID-19 Vaccine Global Access (COVAX) Facility, an activity of the Access to COVID-19 Tools Accelerator.[6,10] 189 countries have expressed interest in COVAX, and the partnership is working to procure 2 billion doses of safe and effective COVID-19 vaccine that has been granted emergency use listing by WHO by the end of 2021, which is roughly 20% of the vaccine needs of participating countries. $2 billion of investment are needed to purchase these vaccines. Over 90 LMICs will be eligible to receive 1 billion doses of COVID-19 vaccines at low (ie, up to $1·60 per dose) or no cost through this mechanism.[6]

Most of the members of the G20, including China, have joined COVAX. The Biden administration announced its participation and a $4 billion commitment. Through financial support for COVAX and integration of timelines for vaccine delivery under OWS into COVAX, US participation could be decisive. Although there is broad support for COVAX, questions persist. The USA, the EU, the UK, Japan, and Canada have preordered 8·8 billion doses of vaccine, far in excess of need.[3,11] To some extent, this excess reflects contingent purchasing, but it dwarfs the planned purchase of 2 billion doses through COVAX and potentially decreases the ability of COVAX to negotiate on costs for large bulk purchases.

LMIC challenges and opportunities

Additional scientific issues related to vaccines that are now undergoing interim analyses—eg, the emergence of mutant SARS-CoV-2 viruses that are less sensitive to vaccines than are the original virus, dose and schedule optimisation, new adjuvants, correlates of protection, and improved surveillance of emerging pathogens—are beyond the scope of this Viewpoint. There are, however, many questions regarding the relevance of new vaccines that are being generated through OWS to target product profiles that are required for use in LMICs.

Many deficiencies complicate programmes for COVID-19 prevention in low and lower-middle income countries worldwide: diagnostic testing; personal protective equipment; good epidemiological data; logistical systems to vaccinate all segments of society; and systems for reporting adverse events after vaccination. Social, political, and religious unrest can also complicate all prevention efforts. Even as OWS vaccines are applied to the global campaign against COVID-19, strengthening of health-care services in low-resource settings will be a key element for successful implementation.

CEPI estimates that 2–4 billion doses of global vaccine production can be used for COVID-19 in 2021; modelling by the Duke Global Health Innovation Center suggests that it could be 2023–24 before enough vaccine can be manufactured.[12,13] Several companies that were supported by OWS have licensed production to other manufacturers, including members of the Developing Countries Vaccine Manufacturing Network, which provides hundreds of millions of doses of vaccines worldwide that are prequalified by WHO.[14] AstraZeneca–Oxford (UK and Sweden) has manufacturing arrangements with Serum Institute of India (India), SK Bioscience (South Korea), and the Oswaldo Cruz Foundation (Brazil), whereas Novavax (USA) has manufacturing arrangements with Serum Institute of India (India) and SK Bioscience (South Korea). Sinovac (China) has agreements for vialling with Instituto Butantan (Brazil) and BioFarma Innovations (Indonesia). Johnson & Johnson (USA) will work with

Biological E (India) and Merck (USA). Moderna (USA) has partnered with Lonza Group (USA and Switzerland). Sanofi (France), whose vaccine is delayed, will make the Pfizer–BioNTech (USA and Germany) vaccine under licence. The global distribution of manufacturing COVID-19 vaccine is unprecedented and represents an important development not only for supply of COVID-19 vaccine but also for the recognition and use of vaccine manufacturers in LMICs.

mRNA vaccines can be a particular problem as the Pfizer–BioNTech vaccine can be stored at –70°C for up to 6 months, –20°C for 2 weeks, and 2–8°C for 5 days, whereas the Moderna vaccine can be stored at –20°C for 6 months and 2–8°C for 1 month. Despite improvements, at listed temperatures, neither vaccine would be practical in many LMICs. Other approved vaccines and many vaccines that are still in phase 3 testing can be stored at temperatures that are consistent with the target product profile that was developed by WHO (ie, 2–8°C for at least 2 weeks, with long-term storage at –20°C or higher). The costs and formidable logistics around cold-chain requirements for mRNA vaccines will compound routine access and supply challenges.[15] Could cold storage containers that are used effectively for –60°C storage of vesicular stomatitis virus-based Ebola virus vaccine be scalable for Pfizer–BioNTech and Moderna mRNA vaccines in LMICs?

The 80–85% global uptake for childhood WHO extended programme on immunisation vaccines has saved 2·5 million lives annually.[9] The target population for SARS-CoV-2 vaccines includes all age groups, although most vaccination programmes do not routinely target adults. Due to probable shortages in vaccine supply, particularly in the immediate period after approval, prioritisation of risk groups will be necessary.[10,16,17] Countries might adopt multiple COVID-19 vaccines; however, data do not yet exist for mixing of different vaccines as primary series or booster doses. Adult vaccination records might become important in this regard.[15]

The ongoing OWS trials (and those of other manufacturers) are large, phase 3, randomised, blinded clinical trials. These trial designs eliminate confounding biases and are excellent for establishing the protection of individual participants so that, by intention, community protection is not evaluable. If the ultimate goal is reduction of the morbidity and mortality that are associated with COVID-19, then information on community protection, or effectiveness, is necessary.[18,19] Evidence of community protection is crucial; it could inform government vaccination strategy and policy around ancillary protective measures or justify the lifting of pandemic restrictions. Planning for effectiveness trials should begin now.

OWS has accelerated the development of COVID-19 vaccine without compromising efficacy, safety, or quality.[1] There are, however, long-term safety issues that might arise. For example, three Ad5-vectored vaccine trials for HIV showed excess HIV infections in vaccine recipients; could Ad5-based vaccines for COVID-19 enhance HIV infections? Similarly, the use of the AS03 adjuvant was thought by some to be associated with the development of narcolepsy.[20] Rare events, such as intussusception after the use of oral rotavirus vaccines, might not be apparent, even in trials of 30 000–60 000 people.[21] Vaccine-associated enhanced respiratory disease and antibody-dependent enhancement were reported in animals given vaccines against SARS-CoV and MERS-CoV;[22] fortunately, these effects have not been reported in small animal, non-human primate, or human studies of SARS-CoV-2 vaccines.[23] However, a long-term effect, similar to the enhancement that was observed for the Sanofi dengue virus vaccine, cannot be ruled out.[24] Disregarding safety can undermine public confidence in COVID-19 vaccines and decrease vaccination uptake.[25] Strengthening of systems in LMICs to monitor, record, and report adverse events after immunisation will be important given the multiple vaccines in use.[26]

For all of its potential benefit, OWS is a form of so-called vaccine nationalism: a country prioritising its own needs over the legitimate needs of others.[27] Some countries have laws that allow them to appropriate vaccine that is produced within that country in times of emergency, regardless of contractual commitments. High-income countries and wealthier middle-income countries have confirmed purchases of 5·4 billion doses, whereas LMICs and low-income countries have 1·2 billion doses.[13] COVAX is a novel solution, but if COVAX fails to secure the necessary doses and distribute equitably, it could precipitate a scramble for COVID-19 vaccines that will heighten inequity, increase mortality, and extend the crisis.[5,11] Concern has arisen that the Chinese, Indian, and Russian governments and manufacturers might be using the pandemic for geopolitical purposes. Given the inward focus of OWS and concerns about the remainder of LMIC needs for COVID-19 vaccine, a more robust multilateral approach to COVAX needs to be pursued.[27,28] Can CEPI, WHO, and Gavi give COVAX the crucial leadership that it needs to become the first international effort to provide concurrent access to a "global public good":[29] safe and effective COVID-19 vaccines?

Finally, an unintended consequence of OWS is its potential effect on vaccine hesitancy. Although overall vaccine confidence is robust globally,[25] there is now a strong element of hesitancy regarding COVID-19 vaccines in the USA. Among the reasons for vaccine hesitancy is the so-called warp speed messaging, which has been interpreted by some people to imply that these vaccines are being rushed or not adequately tested for safety, combined with activities that are connected to committed anti-vaccine opposition groups and activists who are based in the USA and in western Europe.[30] Increasingly, WHO and other UN agencies will be called

on to address a growing infodemic (ie, the deluge of information and worryingly inaccurate information) that is seeking to discredit vaccines, masks, and other COVID-19 interventions.

COVID-19 vaccine security as a global public good

According to UNICEF and WHO vaccine security is the timely, sustained, and uninterrupted supply of affordable vaccines of assured quality.[31] Equitable vaccine distribution, transnational collaboration (including LMICs) in development of COVID-19 vaccines, and international mechanisms for sharing of data for clinical trials and vaccine efficacy in real time will undermine the appeal and legitimacy of vaccine nationalism.

The role that intellectual property limitations could play in limiting the full provision of COVID-19 vaccines is a concern for vaccine security, especially for LMICs. Vaccines differ from drugs in several aspects of relevance to intellectual property. Vaccines are biological products, which are more complex and costly to manufacture than are drugs, and for much of the world, are priced for use in the public sector.[8] Additionally, the involvement of several major vaccine manufacturers in LMICs in contract manufacturing, in primary vaccine development, and under access agreements with CEPI could ensure that global supply, once full-rate production is achieved, should be sufficient. Crucially, will this production be timely and accessible to all countries?

Conclusions

Purchasing data suggest that OWS vaccines, and vaccines that are funded by other organisations, are more likely to be allocated according to national rather than global priorities for vaccine security.[11] The supply of vaccines to COVAX cannot be an afterthought. As the access gap example of rotavirus vaccine reminds us, 11 years to 40% uptake worldwide of a COVID-19 vaccine will be unconscionable failure, and the cost in illness, deaths, and disruption will be substantial. Bringing the COVAX Facility to a successful launch, crucial vaccine technology to LMIC populations concurrent with high-income populations, and closure to a pandemic through a co-ordinated, multilateral solution will be an unprecedented expression of support for global vaccine security. In showing safety and efficacy of SARS-CoV-2 vaccines and preparing companies for large-scale manufacturing, OWS has, by accident or design, provided an important opportunity. The key to its success will be enabling the COVAX Facility to exploit and use this opportunity for the benefit of global health and working collaboratively to end the COVID-19 pandemic.

Contributors

JHK wrote the first draft of the manuscript. PH, MEB, and BL managed the process of review. All authors contributed equally and provided critical feedback, reference sources, and critical revisions for intellectual content and verified the information presented here.

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Declaration of interests

JHK reports personal fees from SK Biosciences. MEB and PH are developers of a COVID-19 vaccine construct, which was licensed by Baylor College of Medicine to Biological E, a commercial vaccine manufacturer, for scale-up, production, testing, and licensure. MG participates in one of eight SARS-CoV-2 vaccine development projects supported by the Scientific and Technological Research Council of Turkey since March, 2020. JPF and GK are members of the WHO Strategic Advisory Group of Experts in Immunization Working Group on COVID-19 vaccines. GK is independent director of Hilleman Laboratories and vice chair of the board for CEPI. SG is cofounder of Vaccitech and has a patent on ChAdOx1 nCoV-19 licensed to AstraZeneca. MH is founder and managing director of SaudiVax. HL reports grants and honoraria from GlaxoSmithKline for training talks and from Merck as a member of the Merck Vaccine Confidence Advisory Board, outside the submitted work. TS reports grants from National Institute of Allergy and Infectious Disease and Fast Grants and research contracts from GlaxoSmithKline and ViiV Healthcare. SS reports grants from Ansun BioPharma, Astellas Pharma, Cidara Therapeutics, F2G, Merck, T2 Biosystems, Shire Pharmaceuticals, Shionogi, and Gilead Sciences, outside the submitted work; and personal fees from Amplyx Pharmaceuticals, Acidophil, Janssen Pharmaceuticals, Reviral, Intermountain Healthcare, Karyopharm Therapeutics, Immunome, and Celltrion, outside the submitted work. All other authors declare no competing interests.

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