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# Public Health Challenges of Delivering COVID-19 Vaccines

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Scarcely a day has gone by in recent months when the issue of Covid-19 vaccine access has not played out in the news. Here we are, a year into the global pandemic. The number of Covid-19 cases globally approaches 130 million, and deaths, over 2.8 million. The grim totals tracked on the Hopkins' Covid-19 dashboard show that the United States leads in Covid-19 case counts, with over 30 million cases, double the 12 plus million cases seen in Brazil and India, each. In the U.S., the number of deaths now exceeds 550,000, a total greater than the number of lives lost in World War One, World War Two, and the Vietnam War combined, and a fifth of the world's total. A year later, our focus is on the hope that vaccines might help turn the tide on this pandemic.

Our Program—the Innovation + Design Enabling Access (IDEA) Initiative at the Johns Hopkins Bloomberg School of Public Health—took a snapshot in mid-November of last year as to where reservations of Covid-19 vaccines stood. The signs of the impending inequities were beginning to take shape even then. At that time, none of the Covid-19 vaccines had received emergency use authorization from the FDA, nor any market approval. Several countries had made pre-market purchase commitments totaling nearly seven and a half billion doses or 3.76 billion courses. Just over half of these doses were going into high income countries, which represented 14% of the world's population. Looking at projected production capacity, if all of the leading vaccine candidates at the time had successfully scaled to the

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projected manufacturing capacity, we would have come to nearly 6 billion courses by the end of 2021. Up to about 40% of these vaccine courses might have potentially remained for low- and middle-income countries. On a per capita basis, if these vaccine candidates had all successfully scaled, Canada, followed by Australia, the UK, Japan, the European Union and the U.S. had all reserved at least one vaccine course per person within their respective countries, and Canada topped the list with nearly five reserved COVID-19 vaccine courses per person.

Contracts between countries and the COVAX facility, which is the vaccines pillar of the World Health Organization's efforts to deliver vaccines, and the vaccine manufacturers were not fully transparent. We could glean in part details from press releases, the U.S. Securities and Exchange Commission disclosures, and heavily redacted Freedom of Information Act requests. As the pandemic emerged last year, the World Health Organization proposed a global, equitable allocation approach that would distribute vaccines to reach a percentage of the world's population, initially 3%, and then up to 20% in each country. The priority was to cover health care and essential workers, as well as vulnerable populations in every country, so that the backbone of our health care systems could withstand the coming wave of Covid-19 cases.

In the meantime, over half a dozen Covid-19 vaccines on various platforms came onto the market, typically under emergency use authorization. The Covid-19 vaccine market is unlike anything we have seen for biological products. There are 263 Covid-19 vaccine candidates in the Research and Development (R&D) pipeline currently. The delayed ramp up of the COVAX facility allowed bilateral agreements to proliferate, bypassing this global effort to supply Covid-19 vaccines. Thus, as the rollout has proceeded, stark inequities in vaccine administration have emerged. As our recently published perspective piece of *Cell Med* reveals, those vaccinated have reached nearly 300 million doses, 60% in high income countries and most of the rest in middle-income countries. But these vaccine doses have gone to very few countries. The U.S. and China alone comprise over 40% of the total.

Serving as the vaccines pillar of the World Health Organization's Access to Covid-19 Tools, or ACT accelerator, the COVAX facility seeks to bridge some of the gaps in global access to Covid-19 vaccines. It has taken shape with the stewardship of GAVI, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations, or CEPI, and

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WHO, among other partners. Boosted by recent pledges from G7 countries, the COVAX Facility has mobilized \$6.3 billion dollars for 92 lower income countries eligible to receive donor-funded doses of Covid-19 vaccines. The U.S. under President Biden has joined COVAX, pledging \$4 billion dollars of this total. And as of now, COVAX secured over their goal of 2 billion doses. However, in the first two quarters of this year COVAX will roll out about 240 million doses, 12% of its end-of-the-year goal of 2 billion doses. And as of April 1<sup>st</sup>, 2021, the initiative has rolled out only 32 million doses, leaving most lower income countries considerably short of achieving herd immunity through vaccination.

Covid-19 vaccine prices vary, not only widely across platforms, but also somewhat across different buyers. These price differences can make a huge difference in the rollout of these vaccines, particularly in countries where the economic downturn has hit hard and healthcare systems are strapped for resources. Switching from the AstraZeneca/Oxford vaccine to an mRNA vaccine could result in requiring a greater level of financing. Even for the same vaccine candidate, prices vary across the U.S., the European Union and the COVAX facility. Of note, the E.U. is paying even less for the AstraZeneca/Oxford vaccine per dose than the COVAX facility is. The U.S., however, is paying slightly less for the Moderna vaccine, but footed more than two and a half billion dollars in both push and pull financing to bring the mRNA vaccine to market.

While several vaccine manufacturers have pledged pandemic pricing, some reportedly at no profit, the question remains: when will pandemic pricing go away?

Now, the stark reality is that we are some ways off from supply meeting demand. So, share-and-exchange mechanisms might be critical to ensuring vaccines are deployed efficiently and more equitably across the globe. The landscape of vaccine access continues to change rapidly. While the vaccine doses may not yet be in hand, all the G7 countries have secured sufficient approved Covid-19 vaccines to cover their entire populations. Canada currently remains in the lead with over 11 doses reserved per person. The US now has close to 10 doses reserved per person, but also has a Covid-19 case burden of more than 30 million. As population coverage for these countries rises, the question now is: at what level of domestic vaccination efforts will national governments be prepared to share available vaccine supplies with other countries?

Our Program recently suggested a temporal trading of places in

the queue might also speed global access. For example, should the United States which has not yet approved the AstraZeneca/ Oxford vaccine make a temporal trade on its reserved doses with countries waiting and ready to use this vaccine now? In fact, the United States has begun to take steps in this direction by pledging some of its early AstraZeneca/Oxford doses to Canada and Mexico, while this vaccine still awaits FDA emergency use authorization here in the United States. We realize that there remains considerable uncertainty around the duration of immunity, both from infection and from the use of these vaccines. And we also cannot be sure of how effective all these vaccines will be against emerging Covid-19 variants, but now is the time to make clear public and principled commitments at least to share any surplus and to help mobilize the manufacturing capacity to make up for the difference for the world. We will only be as secure as the weakest link in our global vaccination efforts. But a share-and-exchange mechanism may face an uphill battle as export restrictions on Covid-19 vaccines fall into place from Europe to India. They are disrupting vaccination plans across the globe. Facing under-delivery of the AstraZeneca/Oxford vaccines destined to the European Union, Italy recently blocked 250,000 of these vaccine doses to Australia.

Other limits to share-and-exchange mechanisms have to do with the characteristics of vaccines. Two of the three mRNA vaccines—Pfizer/BioNTech and Moderna—are already on the market, with very similar levels of effectiveness. The third mRNA vaccine CureVac is on its way. A key difference already known across these vaccines is the cold chain storage requirements. Pfizer/BioNTech requires an ultra-cold chain and must, for part of its journey and storage, be kept at minus 70 degrees centigrade. Moderna also requires freezer temperatures, but only at minus 20 degrees centigrade. The CureVac vaccine, however, if it proves to be as safe and effective as the other two, only requires standard refrigerator temperatures and can be stored at least three months at these temperatures. This difference could be a critical one in ensuring broader distribution, particularly in low- and middle-income countries where an ultra-cold chain might be very difficult and expensive to maintain.

Manufacturing facilities will rapidly become locked up by the first comers among these mRNA vaccines, however. If the public sector were to invest more heavily in scale-up of such facilities, would it be possible to undergo the switching from scaling up the manufacture of one mRNA vaccine to a better second-generation mRNA vaccine? This can make a pivotal difference. And as new variants emerge, we might be better positioned to switch to a superior, second-generation

vaccine.

As the value of second-generation vaccines becomes more evident, so will the need to share intellectual property (IP). Just as the first-generation vaccines have depended on the ability to license a key patented, publicly funded invention to stabilize the spike protein, so may be the case for second-generation vaccines. Over 30 of these vaccines in the pipeline are based on the mRNA vaccine platform, yet a patent landscape of the mRNA vaccine space found the intellectual property holdings to be highly fragmented, with BioNTech, Moderna, CureVac and GSK collectively owning half of these patent applications. Concerns over the cross licensing of such IP have prompted proposals, such as the WTO TRIPS waiver, and the Covid-19 Technology Access Pool, or CTAP, to emerge. CTAP is a proposal by Costa Rica backed by 40 member states, calling upon the World Health Organization to launch a pooling of intellectual property to accelerate the development of technologies to tackle Covid-19. To ensure sustainable access to Covid-19 vaccines, particularly to address Covid-19 variants, we will still face challenges to scale production, maintain a stable supply until the pandemic subsides, and stockpile for the next resurgence.

Furthermore, we should not only pool intellectual property to enable innovation, but also pool procurement. Using monopsony, or demand-side, power, an intergovernmental facility for pooled procurement could forecast demand, assure drug manufacturers of secure payment, and provide technical assistance for scaling up these products. Fortunately, we have lessons to build upon: the Global Drug Facility has worked to ensure access to TB commodities. The PAHO Revolving Fund for Vaccine Access has purchased vaccines for the Latin American and Caribbean region for years, and UNICEF has done so globally. Beyond procurement, governments can also exercise greater control over the manufacture of technologies for Covid-19. The U.S. government has had the Defense Production Act on the books since the Korean War. Under this authority, the federal government can compel manufacturers to produce specific goods from ventilators to personal protective equipment to combat the pandemic. And the law has been used regularly to place thousands of orders, particularly by the military, to prioritize its orders to manufacturers over other clients, but not much so for COVID-19. However, President Biden announced in February that he would use the Defense Production Act to scale up manufacturing of the Moderna and Pfizer/BioNTech vaccines.

Finally, to break the pandemic, we have to lower the rate of

transmissibility  $R(t)$ . This goal will only be achievable if effective herd immunity is reached in the population, population coverage is sufficiently high, and pandemic social distancing measures hold while the other two aims are achieved. Herd immunity is reached both by those becoming vaccinated developing immunity, and by those infected by Covid-19 manifesting natural immunity. Vaccine hesitancy, particularly among certain parts of the population, may prove challenging, and outreach, especially to communities of color in the United States, will require particular attention. Hopefully, vaccine hesitancy over time will diminish as public confidence in the vaccine grows. But as we have seen, the road can be a bumpy one as possible vaccine adverse reactions emerge and have to be evaluated. The delays in getting vaccination campaigns moving in low- and middle-income countries also means that part of the herd immunity may result from widespread exposure to Covid-19. And we are seeing prevalence rates suggesting prior infection with Covid-19 in upwards of 50% in the population of Delhi in a recent serological surveillance survey. High-income countries have shown just how hard vaccination is to achieve, even in well-resourced settings. The financing of delivery of vaccines in countries, from cold chain to administration, must also fall into place if the last-mile challenges are to be surmounted. As the sprint turns into a marathon, will financial commitments from multilateral institutions and development banks hold and sustain financing on the road to recovery?

Pulling all these factors together, we constructed a triangle of equitable allocation for Covid-19 vaccines. Equitable allocation is a function of demonstrating vaccine candidate effectiveness, ensuring financing for healthcare systems and enabling efficient delivery. As these vaccines become available, three policy levers might help define the triangle of equitable allocation: development and production, procurement, and ultimately healthcare delivery. Development and production shape the supply side; healthcare delivery, the demand side; and procurement, demand against available supply. How we triangulate these factors will determine how well we achieve more equitable allocation of Covid-19 vaccines. Committing to global access for Covid-19 vaccines is key to avoiding a resurgence of the pandemic. As we have pointed out though, agreements between countries and vaccine manufacturers have undermined a globally coordinated approach, and the ongoing vaccine rollout highlights long-standing inequities in health. We believe the surest path out of this pandemic is one towards greater equity, and we hope that these remarks suggest some of the policy levers that might be used to achieve this.