

GLOBAL ECONOMIC GOVERNANCE INITIATIVE



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Three Pillars of Vaccine Equity

TRIAGING THE GLOBAL VACCINATION CHALLENGE

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EXECUTIVE SUMMARY

Severe vaccine inequality continues to undermine efforts to end the COVID-19 pandemic, but a focus only on vaccine distribution eludes a deeper problem: the world is simply not making enough to meet the global vaccination challenge. Ramping up global vaccine production is a complex but necessary task that can also be an opportunity to build a more equitable response to global health emergencies. Doing so requires attention to the three pillars of vaccine equity that must be advanced simultaneously:

- A TRIPS Waiver to cut through the intellectual property rights that deter new production
- Technology transfer from vaccine originators to regionally distributed manufacturing hubs
- Robust financing measures to upgrade production facilities and improve vaccine distribution worldwide

Alone, each of these initiatives is not sufficient to meet the moment. Only a comprehensive approach that advances on all three fronts will transform the outlook for vaccine equity and build the resilience and collaboration needed to survive.



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Introduction

There is no shortage of challenges the international community has faced in the last 18 months of the COVID-19 pandemic, but the failure to achieve global vaccination sufficient to end the pandemic shall be remembered for generations. Severe inequality both between and within countries has hampered the public health response since the beginning, but the manifestation of these asymmetries in the global production and distribution of vaccines has and will continue to have deadly and costly consequences. As of this writing, the United States of America (US) has administered at least one dose to around 60 percent of their population, the European Union (EU) around 64 percent and the United Kingdom (UK) just over 70 percent. Compare this to low-income countries who have administered at least one dose to only 1.4 percent of their people (Our World in Data 2021).

We do not have a vaccine problem, we have a system problem. With the support of tens of billions of public funds, multiple viable COVID-19 vaccine candidates were developed in less than a year (Torreele, Mazzucato and Li 2021). But severe vaccine scarcity meant that advanced economies cornered the market, often buying many times their need (Oxfam 2020), leaving few for lower- and middle-income countries (LMICs) to purchase (EIU 2021). Meanwhile, health systems that have been severely under-resourced after subsequent structural adjustment measures and debt distress buckled under the strain (Munevar 2020; Forster et al 2020). Advanced economies did not need these doses more – in fact, analyses have shown that LMICs have suffered more deaths (The Economist 2021) and more economic hardship from the pandemic without the same fiscal and public health buffers as their wealthier counterparts (UNCTAD 2020). But fixating on how to divide available vaccine doses also eludes the obvious solution: the world needs more vaccines, and fast.

Making more vaccines is not a simple task. There are issues of production, development, vaccine hesitancy and politicization, as well as regular logistical problems with supply chain bottlenecks, difficulty with storage, transport and staffing (Wouters et al 2021). No single policy will address these manifold challenges and relying only on our current set of tools will not vaccinate the world fast enough. Failing to meet the moment now will also leave the global community facing the same disasters in vaccine distribution in the next pandemic or global emergency.

There is no choice but to advance efforts on multiple fronts. First, more of the vaccines that are currently available must get to under-vaccinated regions, and one way to accomplish this is immediately ramping up donations from vaccine-hoarding and producing countries. G7 countries are far from reaching their 1 billion donation target (Group of Seven 2021), and perhaps more importantly, this target was too small and unambitious from the outset.

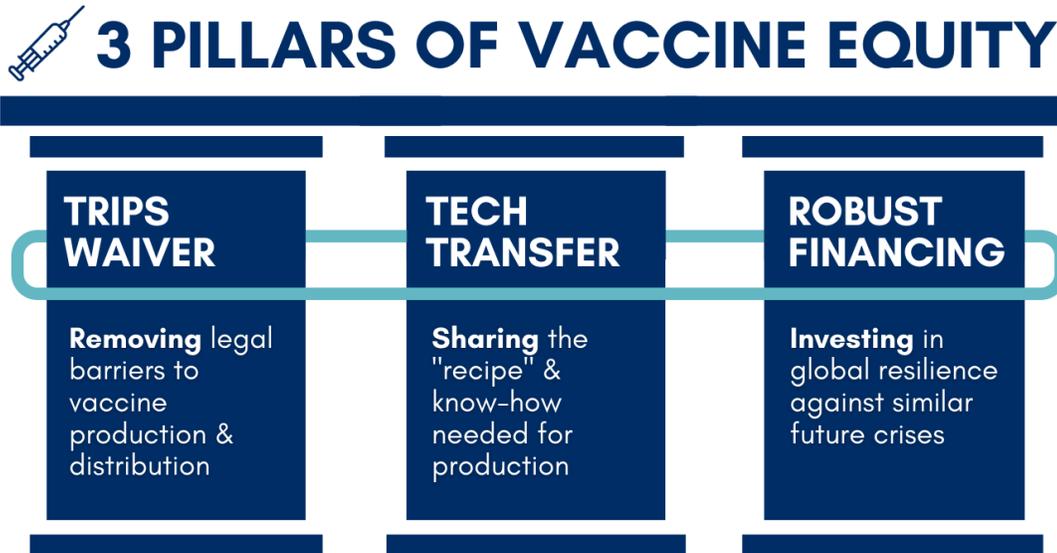
The flow of newly produced shots must be redirected. So far, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator (COVAX), a worldwide initiative aimed at equitable access to vaccines directed by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations and the World Health Organization, has achieved roughly 10 percent of its commitment, far short of the 2 billion doses pledged by the end of the year (UNICEF 2021). What's more, some of these doses have ended up in the hands of wealthy countries who have already vaccinated a majority of their population¹ (Cheng & Hinnant 2021a). The WHO's proposed moratorium on booster shots (UN News 2021) must be supported and extended until broader vaccine equity has been achieved in order to stem the rise of resistant new variants.

However, while these initiatives are unequivocally necessary to begin the slow backpedal away from over a year of self-defeating vaccine nationalism, they do not alter the mechanics of a system set

¹ In June 2021 alone, COVAX sent 530,000 doses to Britain – more than double the amount sent that month to the entire continent of Africa (Cheng & Hinnant 2021a).

up for inequity. The complex challenge of transitioning to a more equitable approach to global vaccine production can be concentrated into three broad pillars that must be advanced simultaneously: implementing a waiver to cut through the intellectual property (IP) rights that deter new production, compelling vaccine originators to transfer technology and know-how and robust financing of the necessary measures to upgrade manufacturing facilities.

Figure 1: Three Pillars of Vaccine Equity



Source: Boston University Global Development Policy Center, 2021.

Without any one of these three tactics, it will be difficult to seriously increase the scale of affordable manufacturing needed to end the pandemic. If achieved together, however, the world would be in a much better position to scale up vaccine production and meet global needs. If leaders had taken these steps at the outset of the pandemic, it is likely there would already be a number of additional facilities producing billions more vaccines. The world cannot afford to be in the same position in 2022.

The TRIPS Waiver: Clearing the Legal Barriers

Nearly six months into the pandemic, as shortages of medical equipment squeezed struggling healthcare systems but vaccine optimism grew, South Africa and India drafted a proposal for waiving certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) at the World Trade Organization (WTO) (WTO 2020). The undergirding rationale for the TRIPS Waiver is that traditional IP protection has no place in a global pandemic, particularly when every vaccine candidate benefited from different degrees of public investment to get their development off the ground (Torreele, Mazzucato and Li 2021). This proposal now has the backing of almost every WTO member, including the US.

While this support is a substantial win, negotiating a comprehensive waiver text remains the necessary first step to combatting vast vaccine inequity. Though much of the conversation has centered around IP as it relates to vaccines, this scope is too narrow. A broader waiver would free producers in developing countries from fear of patent infringement lawsuits and provide the opportunity for accelerating production of COVID-19 related products, as well as vaccines.

The most recent version of the proposal put forth by the African Group, India and others, lays out a broad-based waiver with regard to the rules governing IP rights as well as the enforcement of those rules for a minimum of three years (WTO 2021). This covers the protection of copyrights, industrial designs, patents and undisclosed information (e.g., trade secrets). Such a waiver would allow countries to temporarily waive their domestic IP laws, which protect these types of knowledge and innovation. In countries where IP protection is waived, domestic producers could begin to manufacture and sell patent-protected products, for example, without negotiating a license with the originator firm, and without fearing domestic or international legal repercussions.

The US has not publicly stated its preference regarding the scope of the waiver, though public statements on the subject have been limited to vaccines and their associated patents – evidencing support for a narrow vaccine patent waiver over a bona fide TRIPS Waiver (Leonard et al. 2021). The EU on the other hand, continues to block the waiver and has submitted their own proposal that amounts to a clarification of the existing compulsory licensing rules already in place under the TRIPS Agreement and its amendments (Baker 2021a). The clarification proposal asks that WTO members agree:

- (1) that “the pandemic is a circumstance of national emergency,” thus waiving the requirement to negotiate with the right holder first before issuing such a license,
- (2) that members must “support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory license, the remuneration for [which] should reflect such affordable prices,” and that
- (3) “the compulsory license could cover any exports destined to countries that lack manufacturing capacity.”

The TRIPS Waiver has not been without its critics, who have argued that removing IP rights, even for a time, will undermine responses to future pandemics and, in the alternative, that compulsory licensing already provides the necessary policy space to deal with patent obstacles (Kilbride 2020, Wong 2020). While the rebuttals to these critiques have been rehashed numerous times, the EU has single-mindedly latched onto the idea that compulsory licensing is the right tool for the job (Gallogly-Swan et al. 2021; Thrasher 2021, Baker 2021b).

Why Compulsory Licenses are Not the Solution

There are several issues with the EU proposal. Compulsory licenses (CLs) have been shown not to be effective in the pandemic context (MSF 2021). Generally speaking, CLs must be issued on a case-by-case, patent-by-patent basis, obstructing coordination across jurisdictions. Additionally, given the thicket of patents surrounding the major COVID-19 vaccines, the approved CL process would require a license for every related patent in the production of those products (Gaviria & Kilic 2021). CLs issued for export also require an additional step in the importing country, and this process has taken place only once before when Canada issued a CL for an antiretroviral to export to Rwanda, which took five years to complete (Hestermeyer 2007).

Finally, even if countries were successful in implementing laws to issue CLs for various COVID-19 related products, they are likely to find themselves up against retaliatory measures by affected countries (Gallogly-Swan et al. 2021). The US has claimed that India is ‘diluting’ IP rights and violating the TRIPS Agreement by issuing a CL on an expensive cancer drug and threatened sanctions through its Special 301 Report, an annual U.S. Trade Representative review of global IP protection and enforcement aimed at protecting US innovator interests (MSF 2015). When Colombia took the first steps toward issuing a CL for a leukemia treatment called Glivec, both the Swiss government and Novartis,



the patent holder, argued forcefully that CLs are “tantamount to expropriation” – code for exercising a sort of eminent domain through regulation (Goldman & Balasubramaniam 2015). Even during the COVID-19 crisis, the pharmaceutical industry has been lobbying for countries pursuing CLs - including Hungary, Colombia and Chile – to face punitive sanctions (Fang 2021).

Concomitantly, critics are correct in pointing out that the TRIPS Waiver is unlikely to be effective on its own. In addition to the IP, prospective manufacturers of vaccines and other products will need a transfer of key technologies and (often intangible) know-how to kick-start production. Moreover, financing will be needed prior to, during and after the technology and know-how are transferred in order to enable the start of effective production. Nevertheless, the TRIPS Waiver offers the first pillar of action for wider, cheaper vaccine development.

Technology Transfer: Sharing the Recipe and Know-How

It is widely accepted that the world needs geographically diverse regional hubs to increase vaccine supply and make distribution cheaper, easier and more equitable (WHO 2021a, Miriri & Obulutsa 2021, Kis & Rizvi 2021, Maybarduk 2021a). In order to build up a broad range of regional hubs and have them effectively produce new vaccines, firms need new technology and know-how from vaccine originators. Technology transfer to regional manufacturing hubs is thus the second pillar towards increasing vaccine production.

With a record number of successful, relatively cheap and fast technology transfers already undertaken during the pandemic, the mRNA technology of the COVID-19 vaccine is a particularly suitable candidate. Despite criticism from pharmaceutical companies, and even the Gates Foundation, that building up capacity is too difficult (Byrne 2021), the WHO have identified 19 manufacturers from more than a dozen countries in Africa, Asia and Latin America that have expressed interest in ramping up mRNA vaccine production but lack access to the technology (WHO 2021b). Many of these firms are in regions that are severely under-vaccinated, such as Vietnam and Bangladesh (Viet Nam News 2021, Cheng & Hinnant 2021b).

The Role of Technology Transfer

Technology transfer is much more involved than simply sharing the machines needed to produce a vaccine. Rather, it aims to “equip a receiving site with the knowledge needed to produce doses” (WHO 2011). To best make use of an expansive TRIPS Waiver, vaccine originators need to actively engage in technology transfer, granting licenses with a global territorial scope to all relevant knowledge and equipment needed for product manufacturing.

The information disclosed by a patent publication alone is inadequate to permit effective and commercially viable production (Garrison 2020). Three corresponding types of IP rights – patents, know-how and ‘data exclusivity’ – form an ‘IP stack’ and access to all three elements is required to scale up production of COVID-19 related diagnostics, therapies and vaccines (Garrison 2020). This level of knowledge sharing requires willful collaboration to be most effective, but can be hampered with more complex technologies where different elements of the ‘stack’ are retained by different actors across different countries.

Firms have historically been happy to engage in technology transfer when it enabled them to expand their supply into new markets. Producing goods closer to consumers yields numerous financial benefits to firms, including jumping tariff walls, as well as lowering transportation costs and labor costs. However, these same firms are less likely to transfer prized technology and know-how to others viewed as competitors. This is especially true with mRNA technology, which is likely to form the

basis of a new generation of therapeutic treatments. For this reason, traditional technology transfer often relies on carefully crafted contracts and strict IP protection (Kowalski et al. 2017).

Research has shown that industry-led technology transfer, even for the most complex vaccine technologies, has happened relatively quickly and with relatively few resources during the pandemic (Kis & Rizvi 2021; Rizvi et al. 2021). Nevertheless, voluntary technology transfer has been insufficient to scale up production worldwide. A handful of Indian firms, for example, have manufacturing licenses to produce the key vaccines currently available - AstraZeneca, Moderna and Pfizer/BioNTech (Ghosh 2021). South African firms, on the other hand, have only acquired “fill and finish” contracts and the bulk of the manufacturing will still take place elsewhere (Erman et al. 2021). Even then, the finished product in South Africa has to be shipped to the EU to fulfill orders, due to a contractual requirement preventing South Africa from introducing vaccine export controls, such as those initiated by the EU and India (Mueller & Robbins 2021; Peters and Prabhakar 2021). In a situation where South Africa had little bargaining power, they were forced to accept the terms, highlighting the systemic problem of contractual opacity that has made vaccine accountability even more difficult during the COVID-19 pandemic (Transparency International 2021).

How Would Technology Transfer Happen?

Appeals to patent holders to facilitate technology transfer have not yielded results (Stacey 2021). Allowing the pharmaceutical industry to retain all the power in licensing technologies, which are needed to end the pandemic, will only lead to more time wasted and more lives lost (Baker 2021c). It is time for countries to act together to secure the needed transfer and increase the total pool of vaccines available, but current tools and the industry-led model limit the possible avenues of government intervention. One possible route is public technology buyouts, but this may be prohibitively expensive and inappropriate, considering the public funding that supported initial vaccine development (kENUP 2020).

A more transformative route that should be pursued is for those states which host firms - the US (Moderna, Pfizer, Johnson and Johnson); the UK (Oxford-AstraZeneca), Germany (BioNTech), China (Sinovac, Sinopharm), Russia (Gamaleya) and India (Bharat) (UNICEF 2021) - to use their privileged position to share their own know-how and use incentives to compel vaccine originators to share technology with the WHO's COVID-19 Technology Access Pool (C-TAP).²

The US, for example, could use the rights the Biomedical Advanced Research and Development Authority (BARDA) gained in supporting the development of the Moderna vaccine to share the recipe and data to other potential manufacturers (USHHS 2020),³ and it could go further in enforcing technology transfer under the auspices of the Defense Production Act (DPA) (Maybarduk 2021b; Rizvi et al. 2021; Kapczynski & Ravinthiran 2021). As new variants sweep the globe, scaling up vaccine production could be considered “critical infrastructure” to keep Americans safe, as well as an “emergency preparedness activity” - both well within the scope of the DPA. Additional positive and negative incentives could be developed, such as a suggested windfall tax on the profits of firms that refuse to participate in technology transfer. Ideally, states would work in concert to overcome

² The COVID-19 Technology Access Pool (C-TAP) is a WHO-sponsored initiative that has been under-funded and undermined at every step. C-TAP seeks to provide a “one-stop shop for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data, with quality-assured manufacturers through public health-driven voluntary, non-exclusive and transparent licenses”. Initiated by Costa Rica at the beginning of the pandemic, it sought to create a collaborative approach for governments, private funders of research and development, holders of intellectual property or other knowledge about COVID-19-related products, researchers and other stakeholders (WHO 2020).

³ The contract award was announced publicly on April 16, 2020, but the funding was disbursed April 3, 2020. Summary of Moderna-BARDA Definitive Contract 75A50120C00034, USA Spending (Apr. 3, 2020). <https://tinyurl.com/5h6b3x5e>.

blockages in sharing the 'IP stack' by virtue of knowledge being held by different actors in different regions. With the right set of incentives and the political will to increase production, it could take less than a year to ramp up production around the world (Kis & Rizvi 2021).

Some countries that are developing their own vaccines, like Cuba and Mexico, are leading the way by already committing to open collaboration in vaccine technology and pooling manufacturing capacity with other national partners (Progressive International 2021). Moreover, according to the WHO, there are "many, many vaccines" in the final stages of the pipeline for WHO approval (Times of India 2021). However, while these candidates await approval, existing viable vaccine technology can and must be shared.

The Long Game

Compelling vaccine originators to share their technology and know-how is urgent and necessary, but one-off and uncoordinated forced technology transfers are not a long-term solution. If and when another pandemic arises, the global community will once more find itself battling the realities of profit-driven vaccine inequity, endangering the world with greater and greater health risk. In addition, the compensation required to rely on such laws may be prohibitively expensive.

Technology access pools (like C-TAP) offer a collaborative and coordinated model for governments and scientists to work together on future innovation challenges. As has been proven in the last 18 months, when they own patent rights, pharmaceutical giants cannot be relied upon to voluntarily share their knowledge or IP or keep medicine prices affordable. Instead, governments establishing large-scale investment in new research and development for global public goods, such as a COVID-19 vaccines or low-cost green technologies, can instead institute stronger rights to open-sourcing developed technologies to ensure critical life-saving innovations are not exploited to profit the few.

The need for government intervention to both advance scientific research and promote technology transfer is not surprising or new (Mazzucato 2021). Domestic firms in developing countries have often relied on government policymaking to make sure they can develop or access more advanced technology (Chang 2002). It is the key mechanism by which developing countries have adopted new technologies and continued on their path toward development (Kowalski et al. 2017). Moreover, technology transfer has also been a core promise of foreign direct investment for developing countries - the bargain being that if a country allows foreign investors to access their markets, the country will acquire access to state-of-the-art technologies.

The TRIPS Waiver and technology transfer will not stand alone, however. Robust financing is also needed to enable countries to take advantage of these policy changes.

Robust Financing: Investing in Global Resilience

A globally equitable vaccination drive will need robust financing behind it, but there are options on what and how much is needed. As it stands, financial support for global vaccination has primarily been funneled into the COVAX facility which works to purchase doses on behalf of participating countries, sometimes at a higher price than bilateral purchase agreements (Oxfam 2021a). This ensures patent-holders continue to gain a high price for their product. Many pharmaceutical firms are already taking advantage of their market dominance by increasing prices, even charging poorer countries more than advanced economies (Dyer 2021). These vaccine monopolies are making global vaccination at least five times more expensive than it could be if products were sold at cost price (Oxfam 2021a). Firms Pfizer/BioNTech and Moderna, for example, have charged governments as much as \$41 billion above the estimated cost of production (Oxfam 2021a). Pandemic super-profits

reaped from the global crisis have led to at least nine new vaccine billionaires with a combined wealth greater than the cost of vaccinating low-income countries (Oxfam 2021b).

The global community faces a choice: continue this model and drain much needed public resources while maintaining lower levels of vaccine production, or, armed with the TRIPS Waiver and the right basket of incentives to get technology transfer off the ground, significantly invest in regional production hubs for cheaper, generic versions of COVID-19 products. The former route promises to delay reaching sufficient vaccination rates for many years, costing the global economy as much as \$9.2 trillion (Cakmaklı et al 2021). The latter route has the potential to shift power away from a few dominant companies, achieving greater regional accountability for production while building future resilience to new strains or pandemics.

A recent study from Public Citizen demonstrated in detail what this project would entail, projecting a total cost of \$23 billion to upgrade facilities and produce 8 billion additional doses by the summer of 2022 - enough to vaccinate 80 percent of people in LMICs (Kis & Rizvi 2021). Alternatively, the International Monetary Fund's (IMF) analysis puts achieving 60 percent global vaccination through the existing approach at \$50 billion (Agarwal and Gopinath 2021). Rapid investment in upgrading and retrofitting available facilities for production with the help of a TRIPS Waiver and technology transfer is not only a globally transformative strategy, but also rock-bottom cheap when compared with the alternative.

How Can We Afford It?

Regardless of whether the status quo or a transformative approach is chosen, there is no excuse for under-investing in a global vaccination drive. As many have noted, it is the best stimulus package the global economy can get, saving humanity from untold needless deaths and trillions of dollars of costs in prolonged economic disruption (US Department of the Treasury 2021).

One such potential source has recently been released into the accounts of IMF member countries. An unprecedented allocation of US\$650 billion worth of Special Drawing Rights (SDRs), the IMF's special reserve asset, have been distributed according to members' quota shares (IMF 2021). Wealthy countries who are unlikely to use their allocated share have already signaled plans to recycle at least US\$100 billion of their SDRs (G7 UK 2021). Channeling a portion of these SDRs into financing the necessary scale up of vaccine manufacturing is a no-brainer: costing advanced economies nothing but providing a global public good for all of humanity's benefit. Project-based financing like this is likely best delivered through the supranational central banks, regional monetary authorities and development institutions that are authorized holders of SDRs, indicating the need to bring these actors into the plans for recycling (Bradlow & Gallagher 2021).

Another proposal is to use a one-off taxation on those who have benefitted from a pandemic wind-fall. Proponents argue that a one-time emergency COVID-19 billionaire tax would raise \$5.4 trillion and still leave the world's 2,690 billionaires US\$55 billion richer than before the coronavirus struck (Oxfam 2021c).

Conclusion

There are no excuses for ongoing inaction. The international community has the tools, but continues to lack the political will to end this pandemic for good. There are no simple solutions, but there are obvious routes. The world must work towards the three pillars of vaccine equity to accomplish a transformative vaccination drive: a TRIPS Waiver to clear the legal restraints for producing generics, enforced technology transfer to share the knowledge to tackle the virus with the world and robust

financing to get new production off the ground. Alone, each of these initiatives is not sufficient to meet the moment. Only a comprehensive approach that advances on all three fronts will transform the outlook for vaccine equity and build the resilience and collaboration we all need to survive.

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