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Global Access to COVID-19 Vaccines

Challenges in Production, Affordability, Distribution and Utilisation

Andreas Stamm Christoph Strupat Anna-Katharina Hornidge

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Abstract

The COVID-19 pandemic and the ongoing vaccination process calls for decisive, internationally coordinated and forward-looking action. We propose short-, medium- and long-term actions and emphasise that the political pressure for action should not only focus on short-term management, but on building long-term structures that are crucial to prepare for future epidemics or pandemics. Four key challenges need to be addressed in order to achieve global control of COVID-19 by using vaccines. First, vaccines need to be produced at scale; second, they should be priced affordably; third, they have to be allocated globally so that they are available where needed; and fourth, they have to be deployed and utilised in local communities. Challenges in production are producing some of the main bottlenecks, but the others – in particular vaccine scepticism and utilisation – need to be considered early enough to enable smooth global vaccination campaigns. Addressing the four key challenges, we recommend the following short, medium- and long-term actions. In the short term, we advise accelerating global vaccination efforts by scaling up financial support for the COVAX initiative. In the medium term, we suggest establishing regional production centres in priority countries, providing the necessary intellectual property through voluntary patent pools and fostering information campaigns and civil society participation to increase vaccination willingness and utilisation. In the long term, we recommend establishing Global Pandemic Centres of Excellence in all world regions - analogous to the CGIAR system in the agricultural sector - that are responsible for medical research, vaccine production, distribution and delivery.

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Abstract

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Abbreviations

ACT	Access to COVID-19 Tools
AMC	Advance Market Commitment
C-TAP	COVID-19 Technology Access Pool
CEPI	Coalition for Epidemic Preparedness Innovations
CGIAR	Consultative Group on International Agricultural Research
COVAX	COVID-19 Vaccines Global Access
EIU	Economist Intelligence Unit
EU	European Union
GPCC	Global Pandemic Competence Centre
IFFIm	International Finance Facility for Immunisation
IP	intellectual property
IPD	Institut Pasteur de Dakar
IPR	intellectual property right
MPP	Medicines Patent Pool
PPP	public-private partnership
R&D	research and development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UNICEF	United Nations Children's Emergency Fund
US	United States

1 Introduction

Several COVID-19 vaccines have now been approved for human use by national and regional agencies (e.g. the European Medicines Agency) agencies. However, having licensed vaccines is not in itself sufficient to gain control over COVID-19. Getting the pandemic under control globally and permanently is key to mitigating its impacts on health, society and the economy. To do this, a large part of the world's population must be vaccinated against COVID-19 as soon as possible. However, the current data does not allow for very optimistic projections.

At the end of January 2021, the Economist Intelligence Unit (EIU) published a forecast of the expected accessibility to the COVID-19 vaccine worldwide (Economist Intelligence Unit, 2021). In its forecast, the EIU rather optimistically assumed a scenario in which

- the countries at the top of the queue for example the United States (US), the United Kingdom (UK) and many European Union (EU) countries had vaccinated the prioritised populations by the end of March 2021; other relatively affluent countries had vaccinated them by the end of July 2021. By the end of the year, vaccination campaigns could be largely completed for the entire populations of these countries.
- Some of the middle-income countries either produce vaccines themselves (Russia, China and India) or have sufficient purchasing power to procure vaccines (Mexico, Brazil). At the same time, if the infrastructure works, these countries' vaccination campaigns could be well-advanced by mid-2022.
- Other middle-income countries, but also all low-income countries, are essentially dependent on international solidarity and action. From today's perspective, the COVAX Facility (COVID-19 Vaccines Global Access) of the World Health Organization (WHO) has an important role to play here (see below).

It is now clear that some assumptions cannot be maintained in this way. As of July 2021, some countries (UK, US) have made significant progress in their vaccination campaigns, but most countries have not yet achieved full coverage of priority populations, which was projected in the EIU scenarios for the end of March. The massive COVID-19 outbreak in India has exhausted or overwhelmed that country's production capacity, leading the government to impose an export ban on vaccines from licensed production. Recent evidence also suggests that, for vulnerable groups, a booster vaccination may be needed fairly soon after being completely vaccinated in order to maintain full immunity.

This would mean that the point at which developed countries will be ready to share vaccines on a large scale with poorer countries – beyond the relatively limited donations to the COVAX Facility (see Box 1) – is even further in the future than projected in the EIU scenarios. To date, progress on immunisation has depended heavily on countries' income levels. As of 15 May 2021, 30.8 per cent of the population in high-income countries had received at least one dose of a COVID-19 vaccine, 5.8 per cent in lower-middle-income countries and 4.8 per cent in upper-middle-income countries. Barely 0.4 per cent of residents in low-income countries had received one dose of a vaccine. Recent projections, mostly based on calculations by the International Monetary Fund, confirm that vaccines will not reach the world's poorest countries in significant quantities until 2023 (Padma, 2021).

2 The four dimensions of a successful global vaccination campaign

COVID-19 vaccines need to be produced on a large scale, offered at an affordable price, distributed globally and utilised across each country. Wouters et al. (2021) identify four dimensions of the global vaccination challenge: 1) development and production, 2) affordability, 3) global distribution and 4) utilisation. This approach is a good basis for analysing key issues affecting the utilisation of COVID-19 vaccines and allows for the formulation of policy recommendations for development cooperation. Currently, the first dimension is the main bottleneck, but the others, in particular vaccine utilisation, need to be considered early enough to enable smooth global vaccination campaigns.

2.1 Development and production

The development of an effective vaccine against the coronavirus was extremely rapid; normally it takes many years to develop and approve a vaccine. The shortening to only a few months was possible because:

- Companies of different sizes and characteristics (relatively young and innovative, established multinationals) and public research institutes (Oxford University, Gamaleya Center) quickly started research and development (R&D) and shifted their research focus, for example, in the case of BioNTech, from cancer to COVID-19 research;
- Substantial public funds were mobilised to support this R&D, mostly at the national but also the regional (EU) and multilateral levels, through the Coalition for Epidemic Preparedness Innovations (CEPI);
- Research was able to draw on an existing body of knowledge from existing vaccines (viral vector technology) or advanced research, for example on cancer medication (mRNA technology);
- Innovative procedures ("rolling reviews") shortened the approval procedures.

Currently, the main bottleneck of a global vaccination campaign is the sufficiently rapid production of quality vaccines. Various sources estimate that between 11 and 14 billion doses of COVID-19 vaccine need to be produced and applied before global herd immunity can be achieved. By far the largest quantities of vaccine doses are produced in the US, Europe (including the UK), Russia and China. Each month, 400 to 500 million doses of the vaccines are produced by Moderna, Pfizer and Johnson & Johnson. There is a great deal of uncertainty in the projections about future demand, such as the need for additional vaccinations in response to mutations. The relevance of this can be seen in the fact that the EU recently signed a contract for 1.8 billion additional COVID-19 vaccines to be procured between the end of 2021 and 2023. It is very likely that occasional or even regular booster vaccinations will be necessary, as is the case with influenza vaccinations. This implies that a significant increase in global production capacities will be required on a permanent basis. This is also necessary to reduce the risk of production capacity being shifted towards COVID-19 vaccines and at the expense of vaccines for other infectious diseases relevant to developing countries, such as Ochropyra (yellow fever).

Given the significant demand for COVID-19 vaccines, access to the relevant patent information alone will not solve the problem in the near future. An opportunity was simply missed here in 2020. As early as March of that year, it was proposed to set up a patent pool for COVID-19-related technologies. Its successful implementation would have ensured the necessary lead time to build up and scale up production capacities before, for example, the case numbers in India – or more recently, Argentina – increased massively.

Looking at the countries that have requested a TRIPS (Trade-Related Aspects of Intellectual Property Rights) waiver for COVID-19 vaccines at the WTO, we see that while production capacity in these countries is relatively high, it is far below the level required to make access to the necessary information to produce the vaccine a real potential game changer:

- In India, there is an indigenous vaccine known as Covaxin, produced by Bharat Biotech, and licensed production of the vaccine by AstraZeneca at the Serum Institute. The Serum Institute currently has a production capacity of 70 million doses of AstraZeneca per month and plans to expand this to 100 million doses. Since the vaccination campaign began in mid-January, India has injected a total of 123 million doses of vaccine, including nearly 11 million doses of domestically developed Covaxin. Without a doubt, India has the greatest potential in the southern hemisphere to relevantly expand the global production capacity for COVID-19 vaccines, as the country has an established industry for manufacturing generic products for the international market. However, as of July 2021, just 22 per cent of India's population had received at least one vaccination (Our World in Data, s.a.). The number of cases and deaths jumped in the second quarter of the year. Assuming uninterrupted production of 100 million doses per month, this would mean that relying on domestic production alone, it would take about 10 months for at least 70 per cent of India's population to be vaccinated once - the minimum at best to achieve herd immunity. However, since most vaccines require two injections, late 2022 is the most likely date by which herd immunity could be achieved. Before then, it is unlikely that India could return to its role as the "pharmacy of the world" and start exporting significant quantities of COVID-19 vaccines to Africa, for example.
- South Africa is another country that is often mentioned as a possible production site in the "Global South". However, it has much less experience in drug production. Pfizer South Africa is the largest pharmaceutical company in the country, followed by the indigenous Aspen Pharmacare. At the end of April 2021, Aspen said that it could produce 200 million doses of Johnson & Johnson's vaccine annually. However, it should be noted that this is "fill and finish" capacity. The active ingredients would have to be supplied by Johnson & Johnson to Aspen and mixed or diluted and filled there under sterile conditions. This capacity is relevant because fill and finish is often a bottleneck in the mass production of vaccines.
- In Senegal initial preparations as well as financial commitments for the construction of a new production site have already been made. Initially, a filling plant for the portioning of imported vaccines (against COVID-19 and other diseases) is envisaged, with an expected construction phase of two years and an estimated cost of US\$200 million. The expansion to a production line for mRNA vaccines is planned for later.

- Furthermore, it is reported that the United Arab Emirates, in cooperation with the Chinese pharmaceutical company Sinovac, can "fill and finish" up to 200 million doses per year.

Box 1: COVAX Facility: Global solidarity on a voluntary basis

COVID-19 Vaccines Global Access is a global initiative aimed at achieving equitable access to COVID-19 vaccines. It is led by Gavi the Vaccine Alliance, WHO and CEPI, together with key delivery partner the United Nations Children's Emergency Fund (UNICEF). To date, US\$6.3 billion has been pledged to support COVAX. Team Europe – the EU with its member states and the European Investment Bank – is the largest contributor, having provided more than US\$4 billion to date. Germany contributed US\$1.9 billion. Underfunding of the most urgent needs for the COVAX campaigns was averted. In April 2021, it was estimated that approximately an additional US\$2 billion would be needed to meet the targets. An international donor conference attended by 21 countries and international foundations raised additional US\$2.4 billion in June 2021.

COVAX includes a mechanism – the Gavi COVAX Advance Market Commitment (AMC) – that enables low- and middle-income countries to access donor-funded doses of vaccine. AMC-eligible countries have the opportunity to purchase vaccines according to a cost-sharing principle that works as follows. Initially, donor-funded, fully subsidised doses (i.e. free vaccines) are distributed to eligible countries until each country has enough vaccines to cover 20 per cent of its population (or until donor funds are exhausted). After reaching 20 per cent coverage, eligible countries can purchase the vaccines at a price equivalent to 15 per cent to 20 per cent of the cost (according to the cost-sharing principle).

The first shipments of COVID-19 vaccines by COVAX started on 24 February 2021, and COVAX has so far delivered 95 million COVID-19 vaccine doses to 125 countries in the developing world (as of July 2021). By the end of 2021, at least 1.3 billion COVAX doses are expected to reach the 92 countries eligible for AMC support.

Sources: Chutel (2021), European Commission (s.a.), Gavi (2020a), Schnirring (2021), and WHO (2021c)

Intellectual property rights and TRIPS waivers: Longer-term perspective needed

The current debate on a temporary suspension of intellectual property rights (IPRs) for COVID-19 vaccines – and possibly other items related to the fight against the SARS CoV-2 virus – highlights a conflict between the global public interest in overcoming the pandemic on the one hand, and private-sector interests in innovation and product development on the other.

The main arguments *in favour* of a possible waiver on COVID-19-related patents are obvious: *First,* the accelerated development of effective vaccines has been strongly supported by public spending on R&D in both North America and Europe. This should be taken into account when assessing an appropriate return on innovation for manufacturers. *Second*, the companies involved in the global vaccination campaigns have already had sufficient opportunity to recoup their private R&D expenditures and make a profit. *Third*, COVID-19 is a global pandemic with persistently high fatality rates, and the need to combat it thus arises from a "*force majeur*", which also justifies a temporary suspension of IPRs under WTO rules.

Box 2: Medicines Patent Pool

The Medicines Patent Pool (MPP) is a United Nations-supported health organisation that works to increase access to and promote the development of life-saving medicines in low- and middle-income countries. MPP works with civil society, governments, international organisations, industry, patient groups and other stakeholders to prioritise and license needed medicines and pool IPRs to promote the production of generic medicines and the development of new formulations.

MPP was founded by Unitaid, which continues to be MPP's main funder. Between 2010 and 2018, public and private patent holders granted 18 licences to MPP for highly effective medicines. MPP sub-licensed 24 manufacturers (e.g. in India and South Africa) to produce low-cost generic versions of the drugs and distribute them in 136 countries. To date, MPP has signed agreements with ten patent holders for thirteen HIV antiretroviral drugs, one HIV technology platform, three direct-acting hepatitis C antiviral drugs and one tuberculosis treatment.

On 31 March 2020, MPP temporarily expanded its mandate to include all health technologies that could contribute to the global response to COVID-19. In May 2020, WHO invited MPP to join the C-TAP (COVID-19 Technology Access Pool) initiative, a global collaboration to accelerate the development, production and equitable access to COVID-19 tests, treatments and vaccines. In September 2020, MPP became part of the Access to COVID-19 Tools (ACT) Accelerator Therapeutics (see Box 3).

MPP is currently in discussions with a number of original equipment manufacturers and research organisations about potential licences for COVID-19 healthcare technologies, including a potential licence for molnupiravir, a promising candidate drug that mitigates the progression of COVID-19 after infection.

Source: Medicines Patent Pool (s.a.-a; s.a.-b)

Opponents of such a move argue that a waiver would provide a disincentive for private investment in vaccine R&D. Drug development is – under normal conditions – a long-term (often 10-15 years) and risky business: Depending on the type of drug and the approval process, only between 7 and 45 per cent of all drugs that enter the clinical trial phase receive approval for marketing.¹ How quickly certain vaccines (e.g. using the new mRNA method) can be adapted by third parties to the now numerous mutants once access to patent information is guaranteed is unclear. First, however, it appears to be of fundamental importance to obtain a reliable basis of cooperation with the patent holders. They not only have scientifically developed the biochemical formulations, but they also have the corresponding knowledge about the procedural basis for mass production and quality assurance as well as about the supply chains, including sources of supply for critical ingredients.

It is regrettable that vaccine providers did not respond to patent pool solutions proposed early in the pandemic, based on the MPP established by Unitaid in 2010 (see Box 2). This would have meant that they would have voluntarily provided their patented knowledge in recognition of a global emergency and the substantial public subsidy they had received for their R&D. Licensing to third parties within the MPP could then have been conditional, for example, on the possibly cheaper generics being offered exclusively in developing countries, which would not have been a problem given the massive need. In March 2020, WHO and its partners launched the C-TAP initiative (see Box 3) to facilitate timely,

¹ In this specific case, however, the data suggest that successful vaccine developers have already made significant profits and will continue to do so, given the high demand for vaccines in Europe and North America.

equitable and affordable access to COVID-19 health products by providing a platform for sharing intellectual property (IP) on COVID-19 therapeutics.

Box 3: COVID-19 Technology Access Pool

In March 2020, the government of Costa Rica approached WHO to lead a global effort to pool intellectual rights to technologies useful for the detection, prevention, control and treatment of COVID-19. Costa Rica itself is working on scientific contributions to COVID-19 treatment based on the use of blood plasma (Stamm & Orozco, 2020). A global call for solidarity, supported by nearly 40 WHO member states, has backed this initiative. In May 2020, WHO and its partners launched the C-TAP initiative to facilitate timely, equitable and affordable access to COVID-19 health products by promoting their provision. C-TAP provides a global one-stop shop for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their IP, knowledge and data with quality-assured manufacturers through voluntary, non-exclusive and transparent public health-based licences.

Source: WHO (s.a.)

In the following, we formulate recommendations for *short-term* (some already taken), *medium-term* and *long-term measures* to (a) address the immediate situation and (b) prepare for future health crises.

Short-term: The COVID-19 Vaccines Global Access (COVAX) initiative

In May 2021, the World Health Summit adopted the Rome Declaration. The declaration expresses commitment to a multilateral health architecture and trading system to ensure undisrupted supply chains for the production of COVID-19-related devices and commodities. Page two of the declaration states (European Commission, 2021): "Promote the use of instruments such as voluntary IP licensing agreements, voluntary technology and know-how transfers and patent pooling on mutually agreed terms."

Box 4: Global collaboration to fight the pandemic: Access to COVID-19 Tools (ACT) Accelerator

Launched in April 2020 by WHO, the European Commission, France, Germany and the Bill & Melinda Gates Foundation, the ACT Accelerator brings together world-class knowledge in R&D, manufacturing, policy development, regulatory processes, market design, procurement and delivery. The framework for collaboration among all partners consists of three pillars (diagnostics, treatment, vaccines) supported by a Health Systems Connector and a Country Allocation & Access Workstream. Each ACT Accelerator pillar is led by two to three partner organisations. Civil society and community engagement is integrated across all pillars, including the central coordinating secretariat.

The ACT Accelerator's mission is based on the assumption that investments in the three pillars of the Accelerator bring much higher benefits to donor countries than unilateral fiscal stimulus programmes: If just 10 high-income countries (Canada, France, Germany, Japan, Qatar, South Korea, Sweden, the United Arab Emirates, the UK and the US) invested the US\$19 billion that the ACT Accelerator still needs in 2021, this investment would create more than US\$466 billion in economic benefits over five years.

Source: WHO (2021b)

For immediate action on the urgent need for significant quantities of vaccines, the Rome Declaration refers to the COVAX Facility and the ACT Accelerator (Box 4) and proposes to close the still large ACT Accelerator funding gap. The ACT Accelerator (WHO, 2021b, p. 8) itself cites a funding gap of around US\$19 billion for the remaining period until the end of 2021. Germany has so far provided \notin 2.2 billion for the ACT Accelerator, of which more than \notin 1.6 billion goes to COVAX. The contribution enables COVAX to procure

vaccines, distribute the doses and advance vaccine research on viral mutations. Germany is thus currently the second-largest donor country. We support strengthening the COVAX initiative as an immediate measure and recommend advocating for a further increase in financial support from Germany, other European countries and the EU. This is the most effective way to ensure that larger quantities of vaccines are available in the short term (see more details in Section 2.2).

Medium-term: Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa

As a medium-term measure to ensure local manufacturing and supply, several European countries launched the "Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa" at the G20 Health Summit on 21 May 2021. The initiative plans to mobilise $\notin 1$ billion to

- increase the supply of vaccines by establishing regional production centres in priority countries;
- consolidate demand by helping African countries coordinate their needs;
- strengthen the enabling environment in the region, improving regulations and facilitating trade procedures; through
- transfer technology and know-how; R&D, education and training;
- strengthen national and regional authorities; and
- establish digital supply chain management systems for vaccines and medicines.

The Team Europe Initiative is a response to the biggest challenges of the pandemic, namely the lack of production capacity for a rapid and widespread vaccination campaign. However, it cannot solve the shortage of vaccines in the short term. Building capacity to produce quality vaccines in the required quantities will most likely take longer than an "emergency response" would require. Clearly, the mass production of vaccines for low-income groups in developing countries cannot compromise high and stable quality standards. This implies a complex undertaking and the need to build infrastructural and human capacity, not only in the production of pharmaceutical products, but also in industrial process engineering and inbound and outbound logistics.

We believe that such a complex undertaking can best be implemented through a public– private partnership (PPP). It is no coincidence that research-oriented entities (BioNTech, Oxford University) have partnered with established pharmaceutical companies that are experienced in mass production and related logistics (Pfizer, AstraZeneca). We argue that, with international support, advanced developing countries – for example Chile or Costa Rica in Latin America, and Senegal, South Africa or Kenya in Africa – could also build up significant production capacities. However, as this is expected to be time-consuming, we consider it to be only a possible medium-term measure. If a PPP model is chosen, this would mean giving up the waiver option and seeking direct cooperation. At the same time, companies should be invited to contribute their IP to the MPP and/or C-TAP (Boxes 2 and 3).

This step could and should be voluntary. Companies should be encouraged by policy to go for this solution, in recognition of the public money that has supported the development of

patent-relevant knowledge. Vaccines produced in new centres to be established in developing countries should be distributed exclusively in Africa, Latin America, Asia and the Pacific, for reasons of simplicity referred to as the "Global South". This would allow patent holders to continue to recoup their investments through the "Northern" market. If no cost-neutral options for these PPPs in developing countries can be found in negotiations with the patent holders, *reverse auctions* could be an option: The vaccines to be produced are based on the IP whose patent holder demands the most favourable terms for licensing to the centres. This could be a "flat rate" payment made by the international community or a royalty for each dose of vaccine produced. Given the pressure built up in recent months to obtain a waiver for COVID-19-related patents, voluntary licensing to centres in the Global South could also be a viable option for patent holders. It is important here that their cooperation should not be limited to sharing the chemical code of their vaccines, but also include active knowledge transfer (e.g. about the supply chains) and technology transfer (high-quality industrial mass production).

Properly designed and implemented with sufficient financial support, the establishment of production centres in the Global South can help make health systems much more resilient to external shocks such as the COVID-19 pandemic and future ones. First steps in this direction have already been taken by several Team Europe Initiative countries. For example, German development cooperation is financially supporting the Institut Pasteur de Dakar (IPD) in Senegal to set up a vaccine production facility. The IPD is one of the few institutions in Africa already producing a WHO-certified yellow fever vaccine. The concept envisages the filling of vaccines in the first phase, in parallel with the construction of a production facility for COVID vaccines. Currently, Africa imports 99 per cent of its vaccines and 94 per cent of its medicines. This should be fundamentally changed before the next pandemic hits the societies in Africa, Latin America, Asia and the Pacific.

Long-term: Global Pandemic Competence Centres

In the following, we propose to further develop Team Europe's concept and consider establishing a series of "Global Pandemic Centres of Excellence" on all continents. It is not only Africa that lacks the capacity to deal with a pandemic. The same is true for large parts of South and Southeast Asia, Latin America and the Pacific, with the exception of some advanced countries. Building on the proposal of the Team Europe approach, we propose a model based on the 15 research centres of the Consultative Group on International Agricultural Research (CGIAR) system. These Global Pandemic Competence Centres (GPCCs) could combine the following functions:

- **Research and development**, for example assessing risks of new pathogens, analysing spread pathways, preventive measures, developing vaccines, conducting clinical trials, negotiating approval of vaccines with national and regional authorities;
- **Production**: Vaccines, drugs and diagnostic tools can be produced on a cost basis to deliver to the populations most in need and/or to prevent massive outbreaks that have the potential to develop mutations. Developed vaccines could be channelled through the COVAX Facility.
- Global monitoring of new variants of virus- and bacteria-based diseases;

- *Issue early warnings* on a purely scientific basis when a disease outbreak has the potential to develop into a pandemic, directly to national governments and/or through WHO;
- *Capacity-building* with national and regional disease control centres and health authorities; this can range from short laboratory courses to the development of relevant higher-education studies at universities;
- *Provision of services* to national and regional health authorities and public institutions, for example DNA sequencing of pathogens.

GPCCs can help strengthen small, less-established pharmaceutical companies and development centres in a pandemic situation. In non-pandemic times, the facilities could be used for various activities, for example vaccine development and production for dengue fever, Chagas or any of the 13 other neglected tropical diseases described by WHO and/or regional mutations of viruses such as SARS-CoV-2 (Aagaard-Hansen & Chaignat, 2010).

Following the CGIAR model, GPCCs could be located in different regions of the world to be close to different ecosystems and cultural contexts and to allow for frequent interaction with national and regional authorities. One option could be to locate GPCCs near WHO regional offices (without giving WHO the task of running the centres). Where comparable regional institutions that perform certain functions already exist, it is necessary to examine how to cooperate with them without creating redundancies. The Africa Centres for Disease Control and Prevention (Africa CDC) should be mentioned here in particular. This is a specialised technical body of the African Union, created in 2016 to support member states' public health initiatives and strengthen the capacity of their public health institutions (Africa CDC, s.a.).

Close interaction, knowledge exchange and joint research between the GPCCs would have to be ensured. Here, too, the CGIAR system could serve as a model, in which programmatic cooperation between the centres is already being carried out. The GPCCs would be funded globally from public budgets and/or donations. The knowledge generated should be open source, and the vaccines developed would be channelled exclusively based on scientific criteria and out of the reach of national authorities. It is important to emphasise that the GPCCs cover more than just pandemic prevention and early warning, such as the Early Warning Centre opened by WHO in Berlin to pool pandemic data and make it available to the scientific community and other institutions ("Berlin gets WHO early warning centre", 2021).

2.2 Affordability

Limited financial resources and poorly functioning health systems hinder the ability of lowincome countries to offer COVID-19 vaccines free of charge. The current limited supply of COVID-19 vaccines means that we will be dealing with a supplier market in the near future. Consequently, one task for governments is to develop and implement well-designed pricing policies to ensure affordable access to COVID-19 vaccines. At market prices, the procurement of vaccines involves significant expenditures. According to UNICEF data from the COVID-19 vaccine dashboard (UNICEF, s.a.), a one-dose vaccination costs US\$2.70-US\$13.30 for AstraZeneca/Oxford; US\$3-US\$10 for Sputnik V; US\$7-US\$19.50 for Pfizer-BioNTech; US\$10.30-US\$29.70 for Sinovac; US\$15-US\$37 for Moderna and US\$18.60-US\$44 for Sinopharm. For a country with a GDP per capita of US\$1,000, procuring two doses of vaccine worth US\$40 per capita would cost 4 per cent of GDP, which is likely to be prohibitively expensive for many low-income countries (Agarwal & Reed, 2021).

There are three options for how the international community could address these challenges and support low-income countries in particular:

An *immediate, first option* is to continue expanding financial support to the global public procurement mechanism COVAX (see Box 1) to increase their purchasing power and reduce transaction costs. Gavi estimates that about US\$8 billion is needed to provide free vaccines to 30 per cent of the population in COVAX-AMC-eligible countries (Agarwal & Reed, 2021). In April 2021, it was estimated that approximately an additional US\$2 billion would be needed to reach the target of 30 per cent coverage. This gap was successfully closed during an international donor conference with 21 countries and international foundations in June 2021. Germany is providing US\$1.6 billion to COVAX so far, making it the second-largest donor. In addition, the COVAX AMC needs additional funding to achieve vaccine coverage in lower-middle-income countries beyond the 30 per cent threshold, which is clearly too low to achieve herd immunity. The simplest way to secure this amount would be for donors to provide these funds directly.

The *medium-term*, second option is a financing mechanism that provides funding for the COVAX Facility while reducing the requirements for donors to make advance payments. The main idea is to use an existing multilateral financing institution – the International Finance Facility for Immunisation (IFFIm). IFFIm is backed by long-term, legally binding commitments from donor governments, issues vaccine bonds on the international capital markets and provides Gavi with funds for the delivery of vaccines in advance over many years. IFFIm currently has only 10 donors - Australia, Brazil, France, Italy, the Netherlands, Norway, South Africa, Spain, Sweden and the UK. Of these countries, Australia, Norway, Spain and the UK have already provided money through IFFIm to fund the COVAX AMC for COVID-19 vaccines (IFFIm, s.a.). The main advantage of this funding mechanism is that IFFIm contributes the missing liquidity directly to COVAX while receiving the funds back in small annual payments (estimates are between US\$500 and US\$800 million per year over five years) in the form of grants (plus interest payments) from high-income donor countries. This option ensures the frontloading of funds, resulting in long-term donor commitments that translate into immediate liquidity for COVAX. However, the number of donors to the financing facility is too small. The G20 countries should coordinate and ideally provided further financial support to the global public procurement mechanism COVAX directly (immediate, first option). However, if this is not possible, as donors are hesitant to fund COVAX, IFFIm should be expanded and more donors added.

Another medium-term, third option discussed is in-kind donations of pre-purchased vaccines to COVAX. In many countries, pre-purchases of COVID-19 vaccines are many times larger than the respective populations. In June 2021, the US government announced it would donate 75 per cent of its unused COVID-19 vaccines – 19 million doses – will go

to COVAX, including about 6 million for South and Central America, 7 million for Asia and 5 million for Africa (O'donnell & Mason, 2021). In addition, Japan, Belgium, Denmark, Spain and Sweden have made new commitments to donate another 54 million doses of vaccine to COVAX in June 2021 (Schnirring, 2021). As part of the EU approach, the German government has declared that it will deliver 100 million doses of vaccine – the vast majority of which will be delivered via COVAX as soon as possible so that low-income countries also have access to COVID-19 vaccines and current supply shortages (see India above) are bridged.

In addition to financing COVID-19 vaccines, the cost of distribution within countries must also be considered. Low-income countries will need significant national revenue or external financial support to manage these costs; otherwise, they will not be able to offer the vaccines for free. Experiences from previous health crises, such as the Ebola and HIV/AIDS epidemics, have shown that countries need additional financial support to reach all societal groups. Especially in large territorial states or even island groups in Southeast Asia or the Pacific, these are enormous logistical challenges. Many low-income countries have already provided funding to cover the cost of introducing the first batches of vaccines, but funding shortfalls pose a growing threat, as the number of people to be reached increases and the areas to be served are farther away from major cities. In some African countries, the lack of funding is already causing delays, in addition to shortages of qualified medical staff and problems collecting important data or printing and distributing immunisation cards (WHO Africa, 2021). These problems are likely to worsen in the future, as many low-income countries are facing economic crises and have high levels of debt. One approach would be to support the G20 initiative to suspend debt servicing in order to create additional fiscal space.

2.3 Global distribution

COVID-19 vaccination on a global scale and at a rate that will halt the rapid progression and spread of COVID-19 mutations requires an enormous effort. Countries therefore need significant logistical support. In 2018, 74 out of 194 WHO member states had no adult immunisation programme. Less than 11 per cent of countries in Africa and South Asia reported having such a programme (Williams et al., 2020). These countries often lack adult immunisation registries and the systems needed to administer vaccines at this scale. In addition, establishing and maintaining cold or ultra-cold supply chains is a challenge, especially for low-income countries. There is an urgent need for technical and financial support for partner countries to deal with these logistical challenges. COVAX already has responded to this need with its own COVID-19 vaccine logistics programme, which includes US\$775 million and is mainly implemented through COVAX partners WHO and UNICEF.

In terms of policies to speed up vaccine delivery, countries waiting for vaccine supplies could start investing in logistics, regulatory approvals and staff training for efficient vaccine distribution. The logistics of distribution, especially in remote areas, will be important here. According to WHO, countries need to focus on the following areas to ensure the smooth distribution of vaccines (WHO, 2021a):

- Developing and strengthening supply chain strategies for receiving, storing, distributing and managing COVID-19 vaccines and their adjuncts;
- Ensure the quality, efficacy, proper tracking and reporting on COVID-19 vaccine use and safety throughout the supply chain;
- Strengthen appropriate cold chain and logistics requirements, including reverse logistics, and provide tools to support country preparedness activities;
- Assess, design and implement appropriate waste management mechanisms to safely handle and dispose of waste while protecting the environment and the public.

Germany should support the countries in providing vaccines, both in the short and medium term. Rapid distribution without loss of quality of larger quantities of vaccines is a considerable logistical challenge. Even from Colombia, a member of the Organisation for Economic Co-operation and Development since 2020, there are anecdotal reports that vaccines are transported on mules when remote settlements need to be reached. Institutions such as the German Federal Agency for Technical Relief (THW) and the German Armed Forces, but also German development cooperation through their implementing agencies GIZ and KfW, could support partner countries in their logistical efforts. Deutsche Post DHL also has established disaster response teams that could contribute their capacities in a PPP approach. In addition, German development cooperation could further support the training of personnel for the efficient distribution of vaccines. Germany already supports the strengthening of vocational training in many developing countries. Existing capacities could be used to increase the number of people trained for vaccination campaigns in the short term; studies show that a lack of personnel might be a factor that hinders high-quality vaccination campaigns.

In addition to logistical challenges within countries, there are serious supply shortages of COVID-19 vaccine materials, such as ingredients, packaging materials and equipment, which limits production. Such shortages and constraints may result in COVID-19 vaccine manufacturers being unable to meet their commitments. Such systemic supply chain risks at various stages of the vaccine manufacturing process may materialise in the future and jeopardise the speed of vaccine deliveries. To minimise these risks, the COVAX Manufacturing Task Force, among others, was established. The task force includes CEPI, WHO, Gavi and UNICEF, as well as the Bill & Melinda Gates Foundation, the International Federation of Pharmaceutical Manufacturers and Associations and the Developing Countries Vaccine Manufacturers' Network. One goal of the working group is to map all relevant supply chains for vaccine production worldwide and analyse them for their vulnerabilities. Where weaknesses have been identified, efforts are being made to eliminate them by, on the one hand, possibly increasing supply capacities, and on the other hand, bringing manufacturers with supply bottlenecks together with manufacturers who still have production-relevant stocks of ingredients and other precursors. Furthermore, the working group advocates the acceleration of export licences and customs clearance for critical primary products. In the long term, in addition to building up further vaccine capacities, the establishment of a global monitoring system for supply chains should be aimed for.

2.4 Utilisation of vaccines

Limited willingness to utilise COVID-19 vaccines can delay the achievement of herd immunity, and thus allow time for further mutants to emerge. Vaccine scepticism is therefore a challenge of global importance. A meta-study using surveys to examine COVID-19 vaccination preparedness in 33 countries shows an average of 70 per cent vaccination preparedness (Sallam, 2021). In the case of sub-Saharan Africa, based on interviews with at least 1,000 respondents, the average willingness to be vaccinated was 79 per cent in 15 countries, with a high of 88 per cent in the case of Ethiopia and a low of 59 per cent in the case of the Democratic Republic of the Congo (Africa CDC, 2021; Strupat, Shigute, Rieger, & Bedi, 2021). Despite this high level of willingness to be vaccinated, several African countries suspended their vaccination campaigns due to safety concerns (WHO Africa, 2021). Much of this concern was caused by fears of adverse side effects reported in Europe and the US. The suspension of the utilisation of AstraZeneca's vaccine in South Africa and among younger adults in Europe has also significantly affected the uptake of the vaccine among younger healthcare workers in some African countries. Kenya received one million doses of AstraZeneca's vaccine in March 2021 and planned to vaccinate all health workers by June 2021, but it has so far reached only 99,000 of the total 300,000 health workers (Shimanyula, 2021). In South Africa, fewer than 300,000 health workers had been vaccinated by May 2021, out of a total workforce of more than one million. Concerns about the safety and efficacy of COVID-19 vaccines, as well as myths and misinformation, are spreading rapidly on social media. This has contributed significantly to vaccination scepticism. Some countries reported that they had destroyed some of their COVID-19 vaccines because they had passed their expiry date. Malawi destroyed nearly 20,000 doses of AstraZeneca's vaccine, while South Sudan announced it would destroy 59,000 doses (Odhiambo, 2021).

To prevent a decline in COVID-19 vaccine demand and reduce vaccination scepticism, trusted sources of information and advice are critical. Engaging stakeholders from the local community, for example traditional opinion leaders and religious leaders, can help counteract misreporting about the COVID-19 vaccine and further ensure health education about the benefits of the COVID-19 vaccine. In this context, the role of local health workers is crucial (Afolabi & Ilesanmi, 2021). Targeted education should ensure that local health workers are vaccinated with the available COVID-19 vaccines in a timely manner, thus enabling them to act as role models for the rest of the population. In addition, highlighting the benefits of COVID-19 vaccination from a societal perspective can promote its uptake. Nationwide information campaigns to counteract fears of vaccination and possible side effects are particularly important for at-risk groups. Other important factors are significant investments in local health infrastructure and the integration of COVID-19 vaccines into existing health services. The possible coverage of costs by existing health insurances through domestic revenues should be promoted and represents a promising strategy to increase vaccination readiness.

German development cooperation should support the following activities to increase vaccination readiness: (1) immunisation education initiatives and information campaigns; (2) targeted cooperation with local communities to reduce concerns and counter misinformation through the involvement of local institutions, health workers and religious institutions. The involvement of civil society institutions through Gavi (with German support) in key working groups of the COVAX initiative is a first step towards building

targeted collaborations with local communities. The involvement of civil society has been crucial in promoting access to new health products in recent years (Gavi, 2020b). Finally, (3) make financial and technical investments in health systems and support the integration of COVID-19 vaccines into existing health services/insurance schemes so that future COVID-19 vaccination campaigns and boosters are better received.

3 Conclusion: Learning from COVID – preparing for future pandemics

The COVID-19 pandemic and the ongoing vaccination process in some, but not all, regions of the world call for decisive, internationally coordinated and forward-looking action. In the text presented, we propose short-, medium- and long-term actions. We emphasise that the political pressure for action should not only focus on short-term management, but also on building long-term structures, which are crucial to prepare for future pandemics.

The four key challenges include 1) development and production, 2) affordability, 3) global distribution and 4) utilisation of vaccines. In dealing with them, we recommend the following short-, medium- and long-term actions.

- Short-term: Accelerate global vaccination efforts by scaling up support for the COVAX initiative.
- Medium-term: Establish regional production centres in priority countries, provide the necessary IP through voluntary patent pools, build logistics and delivery infrastructures, and foster information campaigns and civil society participation to increase vaccination willingness and utilisation.
- Long-term: Establish Global Pandemic Centres of Excellence, analogous to the CGIAR system, as centres for medical research, vaccine production, distribution and delivery.

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