

Covid-19: Access to medical products

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Procurement and distribution

Shortages of medical products in the early weeks of the pandemic were inevitable in the face of explosive transmission and a novel virus. The Wuhan response was severely impacted by shortages of personal protective equipment (PPE) in the early weeks but under a national mandate production was rapidly scaled up and stern warnings issued to potential hoarders and price gougers [207].

By late January WHO (through its Operations Supply and Logistics team, OSL) had (with the World Economic Forum) established the Pandemic Supply Chain Network to scale up production, procurement and distribution for a range of medical products starting with PPE. By early March the OSL team had shipped more than 584,000 surgical masks, 47,000 N95 masks, 620,000 gloves, 72,000 gowns and 11,000 goggles to 57 countries [432].

While production was ramping up, getting supplies to hospitals in need was complicated by national stockpiling (and restrictions on exports), hoarding and profiteering. By early March prices had surged. Surgical masks had seen a sixfold increase, N95 respirators had trebled and gowns had doubled. [806]

The diligence of national authorities in ramping up production and addressing hoarding and price gouging has varied widely. By late June there were still reports, from the US, of health workers being infected and dying after being denied access to PPE [668].

By 18 January the Wuhan health authorities were using a nucleic acid test for surveillance and diagnosis and on 19 January WHO published the protocols for the first WHO approved nucleic acid test, developed by the Institute of Virology on Campus Charite Mitte in Germany. Testing started to ramp up as test reagents became more widely available. The procurement and distribution of the reagents for the new test was a core focus for WHO's OSL team from February.

Use of the WHO / German test was not approved for use in the US as the US CDC proceeded with its own test kit production [798]. The CDC kit was distributed in early February but laboratories reported false positives which was found to be due to contamination of one of the reagents. By late February a revised test protocol was in place and uncontaminated reagents were distributed.

A big challenge in relation to procurement and distribution of ventilators was the price with standard units costing in excess of \$20,000. In response there was a flurry of innovation directed to producing cheap and mobile ventilators which were affordable in low and middle income countries. A number of different designs were developed for local manufacture.

Some preliminary conclusions may be drawn from this review of Covid procurement. Shortages are to be expected in the early stages of a new pandemic. Some level of stockpiling could ameliorate such early shortages. Local production capacity which can be rapidly scaled up can assist in meeting local needs. Countries dependent on global supply chains may expect

delays owing to production bottlenecks and host countries demanding priority access. Countries without domestic production capability will be more vulnerable to hoarding and price gouging.

The ACT Accelerator

Meanwhile the search for medicines, vaccines and more useful diagnostics is ramping up. The mix of policy proposals, fund raising initiatives, global partnerships, and vested interests is complex; the main policy objectives are contested and the likely outcomes uncertain. In terms of equitable access to medical products in accordance with needs, the stakes are very high.

Much of the debate, in global policy terms, centres around the Access to Covid-19 Tools Accelerator (ACT-A or 'the Accelerator').

ACT-A, launched at the end of April 2020 [387, 496] describes itself as “a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines”. It is sponsored by the Bill and Melinda Gates Foundation (BMGF), the Consortium for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Initiative, the Global Fund for AIDS, TB and Malaria, UNITAID, the Wellcome Trust, WHO, the International Red Cross and Red Crescent Movement (IFRC), the International Federation of Pharmaceutical Manufacturers (IFPMA), the Developing Countries Vaccine Manufacturers' Network (DCVMN), and the International Generic and Biosimilar Medicines Association (IGBA) [710, 755]. As of late June US\$3.4 billion had been pledged, out of the target figure of US \$31.3 billion [644].

The Accelerator has four 'pillars': diagnostics, therapeutics, vaccines, and health systems.

The diagnostics pillar [814] is co-led by the Foundation for Innovative New Diagnostics (FIND) and the Global Fund to Fight AIDS, Tuberculosis and Malaria, and promises to save 9 million lives and avoid 1.6 billion further infections by ensuring equitable access to simple, accurate and affordable tests. Assuming it is fully funded, it plans to bring to market 2–3 high-quality rapid tests, train 10,000 healthcare professionals across 50 countries, and establish testing for 500 million people in low- and middle-income countries.

The gold standard tests are nucleic acid tests, using PCR amplification to detect viral RNA. These are accurate but sampling is uncomfortable and the tests are relatively expensive and require a fully equipped laboratory. Antibody tests are of uncertain value clinically because of uncertainty regarding the strength and duration of the antibody response; they may be better suited to prevalence surveys than diagnosis and clinical monitoring. Tests which detect viral antigens are easy to collect, relatively cheap, fast and can be used at point of care. Several are in development but none yet routine.

The pillar [814] offers support for research, development and evaluation; advanced purchase agreements (or 'similar mechanisms'), local capacity building and technology transfer; large volume pooled procurement, and support for roll out of testing. As of 26 June only 2% of the estimated \$6b needed had been pledged [644]. The pillar makes no reference to how intellectual property will be treated.

The therapeutics pillar is led by Unitaid and the Wellcome Trust with close involvement of BMGF, and promises to accelerate the development and equitable delivery of treatments at all stages of disease, ensuring they are accessible to all, regardless of geography and level of

economic resource. It targets development, manufacture, procurement and equitable distribution of 245 million courses of treatment for populations in Low and Middle Income Countries within 12 months. The pillar will provide grant support for research and development, including phase 3 trials as well as support for scaling up production capacity, procurement and deployment support [815]. As of late June, only 10% of the \$7.2b ask had been pledged [644].

So far two drugs have been shown to have some therapeutic efficacy in severe cases of Covid-19: dexamethasone and remdesivir.

Dexamethasone is reported [479] to have reduced deaths by one-third in ventilated patients (rate ratio 0.65 [95% confidence interval 0.48 to 0.88]; $p=0.0003$) and by one fifth in other patients receiving oxygen only (0.80 [0.67 to 0.96]; $p=0.0021$). There was no benefit among those patients who did not require respiratory support (1.22 [0.86 to 1.75]; $p=0.14$).

Working with other partners in the therapeutics pillar, [UNICEF and Unitaid](#) have agreed to an initial purchase of oral and injectable dexamethasone to secure quality treatment [702]. This move will support access for patients in low- and middle-income countries, where it is expected that up to 4.5 million patients could benefit from dexamethasone based on preliminary projection of needs. Initial funding has been committed equally by UNICEF and Unitaid, with additional funding to come from pledges made to the therapeutics pillar. It is not clear how these supplies will be distributed or on what terms.

Remdesivir. In results released in late April and later published in the New England Journal of Medicine, remdesivir reduced the median time it took a patient to recover from 15 days to 11 days with a 10 day course of treatment. The mortality rate in the remdesivir group was 7.1%, compared to 11.9% among those who received placebo, but the difference was not statistically significant. [660]

It is not clear how the therapeutics pillar is going to engage with remdesivir, first, because in June the US government purchased the entire foreshadowed production run of remdesivir for July, August and September [676]; and second, because Gilead has already licensed generic producers in India, Pakistan and Egypt to supply remdesivir to 127 mainly low- and middle-income countries [671]. However, this network of licensing agreements excludes more than 70 large middle-income countries, including Brazil, Mexico and China [673].

Gilead's pricing policies in the rich world are aggressive [660, 673]. For all governments in the developed world, including the U.S. government's Indian Health Services and the Department of Veterans Affairs, Gilead will charge \$2,340 for a five-day course. U.S. insurers, in addition to Medicare and Medicaid, will pay 33% more, or \$3,120. Estimates by Hill et al [823] suggest that the cost of production per treatment course may be as little as \$9. Cipla has announced [824] that it will be pricing remdesivir in India at less than INR5,000 (USD66).

The vaccines pillar builds on CEPI's involvement in vaccine development and manufacturing and GAVI's involvement in vaccine procurement and delivery in low income country settings. The objective of the pillar is "to ensure that vaccines are developed as rapidly as possible, manufactured at the right volumes without compromising on safety and delivered to those that need them most" [813].

The pillar plans to deliver 2 billion doses by the end of 2021, at a cost of US\$18.1 billion, assuming a safe and effective vaccine is developed in the near future. An additional, 950 million doses would be procured by self-financing high-income countries and upper middle-income countries through the COVAX Facility.

According to Gavi's [press release](#) (4 June), COVAX is "a new innovative financing instrument to provide access to COVID-19 vaccines for low- and middle-income countries" with the aim of establishing a "global mechanism to ensure equitable access to future COVID-19 vaccines." Fifteen donors have provided seed funding of just over \$US500 million; the goal is to raise \$US 2 billion. [[541](#), [586](#), [609](#), [615](#)]

Gavi explains that the COVAX Facility is "a risk-sharing mechanism – reducing risk for countries concerned about failing to secure access to a viable vaccine and reducing risk for manufacturers concerned about investing without assured demand." [cited in [586](#)] Seth Berkley (GAVI CEO) said, "The worry we have is that unless we scale up production dramatically right now, and do that at risk, when the vaccines are available, they could be bought up by wealthy countries" [[208](#)].

It is useful to understand the Covax Facility as comprising two sets of 'advanced purchase agreements' (APAs). There will be one set of agreements between Gavi and the vaccine suppliers (perhaps 5-10 suppliers), and one set of APAs between Gavi and participating countries.

The agreement between Gavi and the vaccine supplier will specify a price and a total volume (of individual doses). In sum the total volume of doses which Gavi agrees to buy, from all suppliers, will aim to cover up to 20% of the total population of participating countries. It is understood that Gavi will only take delivery of vaccines that meet WHO standards with respect to efficacy and safety. However, there is no suggestion that participating suppliers will be required to return forward payments if their vaccine turns out to be ineffective or unsafe.

Two subsets of agreements will be struck between Gavi and participating countries; one for 'self-funded countries' (upper middle income and high income countries) and one for 'funded countries' (low income and lower middle income countries).

The agreement with self-funded countries will specify a volume (based on doses needed to vaccinate the highest priority populations, limiting these to around 20% of total population for each country) and a price range (recognising that the agreed prices of the actually effective vaccines to be delivered may vary). The June 11 design document [[816](#)] indicates that vaccine suppliers will be asked to restrict their prices to "validated cost of production plus a small margin". However, the document also notes that suppliers may insist on tiered pricing. The relationship between the price which is agreed between Gavi and the vaccine supplier and the price actually charged when supplies to individual countries are delivered is quite obscure at this stage. Self-funded countries will be required to pay a down payment, of around 10% of the total agreed purchase, on joining the facility.

The agreement between Gavi and the funded countries will specify a volume of doses calculated on an agreed minimum 'high priority' population which is likely to be limited to well below the ball park figure of around 20% of the total population adopted for the self-funded countries. The cost of supply will be paid out of donations to the Covax facility. The mix of vaccines and unit prices will be determined by Gavi.

It is understood that the Covax facility will only operate in the short to medium term and that, once participating countries have been supplied agreed doses for their ‘high priority’ populations, supply arrangements (prices, volumes and delivery dates) will revert to bilateral arrangements between individual countries (or purchasing consortia) and the vaccine suppliers [541]. It is also understood that individual countries (or purchasing consortia) may engage directly with vaccine suppliers even while they are participating in the Covax arrangements.

It is estimated that the proposed Covax Facility will require funding of up to USD 18.1 billion for the 2020/2021 vaccine supply. Of this total, USD 11.3 billion is sought urgently to cover investments within the next 6 months including USD 2 billion in funding for advance market commitments to secure doses for low and middle income countries. [670]

In early June AstraZeneca announced that it had reached a deal with Gavi and Cepi under the Covax facility for \$750m to supply 300m doses of the Oxford vaccine candidate (AZD1222). [827] This was the first agreement involving the Covax facility but the competition to secure vaccine supplies has been fierce.

What is emerging before any of the vaccines have been shown to be efficacious is a fierce competition between the US and Europe and the Covax facility to seal supply agreements with the most promising of the candidate vaccine suppliers.

As well as its deal with the Covax facility AstraZeneca has also sealed advance purchase agreements with Britain [825], the US [826], and the European Inclusive Vaccine Alliance [641, 700].

As well as its deal with AstraZeneca the US also has a deal with Novavax for \$1.6b for 100m doses [733]. In March the US was rebuffed by the German government and vaccine developer, CureVac [777, 780, 776, 778, 781] when Trump sought to negotiate exclusive access to their vaccine.

The arrangements being put in place by Gavi and CEPI as leaders of the ACT Accelerator vaccine pillar have been criticised by a range of commentators. The criticisms may be grouped as follows:

- vast amounts of public money (from UMICs as well as HICs) are being channelled to the vaccine developers (including those whose vaccine candidate will not ultimately prove effective) with no binding agreements on future prices and no restrictions on the IP status of the technologies so produced;
- once the ‘funded’ countries participating in Covax have received their ‘high priority’ doses (enough for perhaps 10% of their population) they will be dependent on the good will of the suppliers for affordable prices; the suppliers are likely to use tiered pricing from this point;
- once the self-funded UMIC countries have received their ‘high priority’ doses (enough for up to 20% of their populations) they will also need to strike bilateral deals with the vaccine suppliers, again based on unaccountable tiered pricing;
- deep conflicts of interest are embedded in the Covax arrangements; while the BMGF is a major donor to Gavi, CEPI and to the Covax facility, the foundation is also a share and bond holder with a number of vaccine manufacturers who may receive funding from Covax;

- while vaccine distribution to the priority populations in ‘funded’ countries will be in accordance with WHO’s allocation guidelines, self-funded countries will not be so bound;
- despite repeated calls from the global South for the Covid vaccine to be produced as a ‘global public good’ (implying available at cost), it is apparent that the Covax arrangements are designed to prevent this happening; the China vaccine candidates may be exceptions in this regard [[669](#), [760](#)];
- the Covax strategy includes no conditions governing the open pooling of intellectual property and knowhow; it appears to be designed to prevent even the modest C-TAP proposal (see below) from being implemented.

The health systems ‘connector’ is the fourth pillar of the ACT-Accelerator and is expected to support the other three by ensuring that health systems and local community networks can fully utilize these and other tools in their battle against COVID-19. This pillar is led by the World Bank and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

It promises to build capacity – such as laboratory capacity, training for laboratory and health staff and management of protective equipment for health workers – needed to deploy the new tools effectively when they are ready. It also works on system innovations to complement the rollout of products, such as contact tracing, social distancing and isolation approaches as well as community engagement needed to sustain them.

The appointment of the WB and the Global Fund to ‘lead’ the health systems connector is astonishing. The WB has for decades promoted health systems dominated by private providers and financed through competitive health insurance markets. The Global Fund has for years contributed to health systems fragmentation and inefficiency through its narrow vertical funding programs.

WHO has been completely excluded from the governance of the ACT A pillars, including the connector.

[The Covid-19 Technology Access Pool \(C-TAP\)](#)

The Covid-19 Technology Access Pool takes an approach which is very different from that of the ACT Accelerator.

The C-TAP [[521](#)] is a ‘technology platform’ through which data, knowhow and intellectual property regarding existing or new COVID-19 health products will be pooled (by universities and corporations) in order to accelerate the discovery of vaccines, medicines and other technologies through open-science research, and to fast-track product development by mobilizing additional manufacturing capacity. This will help ensure faster and more equitable access to existing and new COVID-19 health products.

There are five key elements to the initiative [[861](#)]:

1. Public disclosure of gene sequences and data;
2. Transparency around the publication of all clinical trial results;
3. Governments and other funders are encouraged to include clauses in funding agreements with pharmaceutical companies and other innovators about equitable distribution, affordability and the publication of trial data;

4. Licensing any potential treatment, diagnostic, vaccine or other health technology to the Medicines Patent Pool - a United Nations-backed public health body that works to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries.
5. Promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity, including through joining the Open Covid Pledge and the Technology Access Partnership (TAP).

WHO, Costa Rica and all the co-sponsoring countries have also issued a “Solidarity Call to Action” asking relevant stakeholders to join and support the initiative, with recommended actions for key groups, such as governments, research and development funders, researchers, industry and civil society.

As of late May the C-TAP was supported by the following countries: Argentina, Bangladesh, Barbados, Belgium, Belize, Bhutan, Brazil, Chile, Dominican Republic, Ecuador, Egypt, El Salvador, Honduras, Indonesia, Lebanon, Luxembourg, Malaysia, Maldives, Mexico, Mozambique, Norway, Oman, Pakistan, Palau, Panama, Peru, Portugal, Saint Vincent and Grenadines, South Africa, Sri Lanka, Sudan, The Netherlands, Timor-Leste, Uruguay, Zimbabwe.

Civil society responses to C-TAP have been ambivalent, largely because of the voluntary nature of the proposed pooling. Health GAP [\[672\]](#) commented:

Government funders and charities like the Gates Foundation and Wellcome Trust investing billions of euros must demand that (1) all data and research findings be made public, (2) all exclusive rights (patents, data protections, manufacturing know-how, trade secrets, software, cell lines and other biological materials) be licensed to the new WHO COVID-19 Technology Access Pool on terms that allow open licensing to other qualified manufacturers, and (3) that resulting supplies will be distributed equitably worldwide to meet epidemiological need. In addition, activists globally and low- and middle-income countries must pressure Big Pharma and rich countries to ensure equitable access to COVID-19 health products instead of allowing an unregulated market to prioritize nationalistic hoarding by the U.S. and other rich countries.

The South Centre has also criticised the restriction of technology sharing in C-TAP to voluntary [\[478\]](#).

On 10 July, the European Parliament adopted a resolution regarding the EU’s public health strategy post-COVID-19 [\[875, 818\]](#). This resolution paves the way for the creation of a European Health Union and the establishment of a European Health Response Mechanism; the resolution contains strong language in support of C-TAP, de-linkage mechanisms, transparency, and compulsory licensing.

The resolution envisages the use of compulsory licensing in the event that third countries (non-EU member states) do not share COVID-19 vaccines, therapeutics and know-how and calls for dialogue and cooperation with third countries and urges Member States to issue compulsory licences, in the event that third countries do not share the vaccine and/or therapy or the respective knowledge.

Mogha Kamal-Yanni comments [609] that the UK and USA are transferring huge amounts to pharmaceutical companies to secure high numbers of doses for their populations, but they have shown no interest in supporting C-TAP. The chief executive of Pfizer described the pool as 'nonsense' and 'dangerous' [877].

Even in the US Congress there is support for greater transparency. A bill introduced in June [606] would allow Americans to monitor tax dollars used by federal agencies to research Covid-19 medical products by creating a single database. The database would include all financial and non-financial federal support provided to drug makers, along with associated clinical trial data, patent information, and the full terms of agreements made between the federal government and manufacturers.

Intellectual property

The gulf between the ACT Accelerator and C-TAP concerns the role of intellectual property. The Accelerator is mobilizing billions of dollars of public and philanthropic money to accelerate the development of diagnostics, medicines and vaccines while protecting the IP regime established in the TRIPS Agreement and made more extreme through various 'free trade' agreements.

The Accelerator promises some downwards pressure on prices in the short term while protecting IP regime which provides monopoly power over prices.

C-TAP does not seek to dismantle the TRIPS Agreement but argues for greater transparency, pressure on patentees and owners of industrial knowhow to license their technologies to the Medicines Patent Pool and to promote technology transfer and local manufacturing. The threat to pharma associated with C-TAP is that it might give rise to increasing pressure, even regulatory pressure, to make such licensing compulsory.

Civil society organisations have repeatedly highlighted the role of public funding in yielding private patents. Public Citizen estimates that taxpayers contributed \$70.5 million to government agency work that helped lead to the discovery of remdesivir [606].

Countries call for attention to TRIPS barriers at. Many developing countries participating in the informal meeting of WTO Trips Council in late June [642] expressed sharp concerns over the barriers imposed by the WTO's TRIPS Agreement on affordable access to vaccines and therapeutics that are being currently developed for combating the Covid-19 pandemic, as well as the likely emergence of so-called "vaccine nationalism".

In relation to TRIPS flexibilities, South Africa noted [587] the importance of TRIPS flexibilities in facilitating access to medical products which might otherwise be not available or affordable. South Africa pointed to the barriers that many developing countries face in using TRIPS flexibilities.

South Africa also highlighted the inadequacies of the provisions in the TRIPS Agreement allowing countries without local manufacturing to access the benefits of compulsory licensing in the COVID-19 response.

At a subsequent meeting in July sponsored by the Africa Union, African health ministers underlined their concern that patents and other technology barriers could negatively impact the ability of developing countries to access of future COVID-19 vaccines. [678]

A further risk associated with trade and investment agreements is the possible use of investor state dispute settlement (ISDS) to thwart various initiatives taken by governments as part of their Covid response. An open letter to governments co-sponsored by 630 civil society organisations lists a range of government initiatives undertaken as part of their Covid response which could be challenged under ISDS provisions. The letter points out that the damages could be immense. [\[619\]](#)