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Towards a Global Covid-19 Vaccine Strategy

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Executive Summary

The search for a vaccine for Covid-19 concerns all of us. But finding an effective formula is only the beginning. The long-term goal must be a global strategy that will ensure population immunity on a worldwide scale. To do that, we need to address a series of key challenges that stretch from Research and Development to “needle in the arm” and beyond. And we need to do it together, to ensure the most vulnerable are not left behind.

RESEARCH

Currently vaccines take an average of 10 to 15 years to develop and manufacture. Covid-19 is compressing that process by piggybacking on previous research, eliminating or combining phases, and speeding up approvals. But there are several potential sticking points:

- Novel techniques like mRNA- and DNA-based vaccines are yet to be proven in humans. Previous experience with respiratory infections shows certain formulations could do more harm than good.
- There are problems recruiting enough and the right clinical trial participants, for example the elderly, who may have diminished immune systems, and those in developing countries, who may suffer multiple health issues, including malnourishment and exposure to diseases, which may affect the efficacy of the vaccine. Vaccines and populations interact differently than they do under clinical trial conditions. Moreover, different strains of Covid-19 may also predominate in these areas.

PRODUCTION

Not only do we need to produce billions of doses of a vaccine, but we need the equipment and people to store, distribute and administer it. However:

- There is very little spare vaccine manufacturing capacity in the world, and focusing on Covid-19 runs the risk of affecting production for other essential vaccines.
- Manufacturing is already hampered by scarcity of components like glass vials.
- In order to be ready for production, manufacturers need advance market commitment, which at the moment is very limited, as well as other measures to boost production in countries like China and India.
- While many vaccines need to be stored between 2 and 8 degrees centigrade, nucleic acid vaccines (RNA and DNA) require a temperature of -20 degrees centigrade. Many countries lack enough suitable storage facilities, partly because of poor electricity supply.
- The global shortage of health-care workers is set to increase from 12 to 18 million in the next 10 years, even as the population is set to increase, especially in developing countries.

EQUITABLE ACCESS OR VACCINE NATIONALISM?

Currently access to the vaccine appears to be being determined through a bidding war. If we're to achieve global population immunity, developing countries will need help to ensure access:

- Institutions and richer countries will need to provide partial financing, or options such as bond structures, repaid to investors over time.
- Frontline workers will need to be prioritised and given PPE.

- 1 billion residents of poor and developing countries lack any formal identity. Significant investment must be made to address this gap to keep track of who has received the vaccine.
- There also needs to be work on mapping vaccine coverage, and investment in implementing Electronic Immunisation Records (EIRs) in these countries.

PROPER CO-ORDINATION

The same problem that plagues treatment development and access affects vaccine development and access: lack of co-ordination. This is perhaps our biggest challenge of all. The US presidential election in November could prove pivotal to a more inclusive and co-operative approach. In the interim, EU countries and the UK are in a position to assume greater leadership for coordinating key aspects of how any vaccine is delivered, especially in poorer countries.

Once we find an effective vaccine, ensuring global population immunity is not an impossible task. Nor is it unaffordable. But countries and stakeholders must work together, and better, to make sure the world is protected.

CONCLUSION

We need a radical, fast and global approach in order to provide for all nations. And we need political leadership to create this framework and drive its adoption.

Introduction

We all have a stake in the development of a vaccine for Covid-19. And we've all watched as vaccine development – a process that usually takes at least 10 to 15 years – has had to compress exponentially as researchers race to find an effective candidate. This work is already showing promising results, but there is still some way to go. And a vaccine is, of course, only the beginning of the story.

Aside from the fact we're likely to end up with several contenders, it's not just a question of producing those vaccines safely and effectively. We need to ensure the funding and infrastructure is there to manufacture enough vaccine for everyone, and to distribute it to everyone. All on a global scale. And all as quickly as possible.

This raises some difficult issues: about who pays for this; about who gets access to the vaccine and when; and about who might miss out on access altogether if we don't address some key geopolitical inequalities. These are issues that need to be debated and resolved as a matter of urgency, and with the world watching.

This paper sets out those key challenges we're facing as a global community, and suggests ways forward, so that countries can work together more effectively towards a global vaccine strategy, and, ultimately, global population immunity.

The Vaccine Landscape

COMPRESSING THE TRADITIONAL LINEAR MODEL

Traditionally, vaccine development has been a linear model, following five discrete stages, and taking a total of ten to fifteen years minimum from research and development to needle in the arm. These are:

Discovery research (2-5 years) involves lab-based research to find ways to induce an immune response at a molecular level. Traditional methods include using inactivated or killed versions of the virus, while others develop a vaccine using small pieces of a virus protein. Another common approach is to use harmless viruses that contain virus genes that are then injected into cells in order to induce the immune system to identify the virus.

The **pre-clinical** stage (2 years) involves testing in animals to assess the suitability of potential human vaccines.

Clinical development (9-15 years) involves testing potential vaccines in humans in three phases: Phase I: testing for safety (10-50 people); Phase II: understanding the immune response (hundreds of people); and Phase III: assessing efficacy (thousands of people).

Regulatory review and approval (2 years) involves submitting data to gain approval.

Manufacturing and delivery require specialist facilities and components, all of which are highly regulated and expensive to develop and produce. In addition, manufacturing just one batch of a vaccine can take from 1 to 2.5 years.

In addition, researchers spend time between phases reviewing data and results and applying for approvals for the next phase.

The Covid-19 pandemic has upended this paradigm, effectively short-circuiting the process by combining phases, testing more candidates on people with less waiting, and compressing the process for securing regulatory approvals. Research scientists have benefited from previous work done on SARS and MERS, saving time in the pre-clinical phase.

Some processes have eliminated the animal-testing phase entirely. Finally, other developments in technology and breakthroughs in genetic sequencing have reduced development timelines, for example, the use of messenger RNA (mRNA). See [Table 1](#) for companies and phases of development.

Traditionally vaccines are made with either an inactive or attenuated disease-causing pathogen, or they use antigens (proteins made by the pathogen), all of which entail significant production times and constrained production capacity. In contrast, RNA vaccines trigger the body's immune system through the introduction of an mRNA sequence that encodes the disease's antigen. (DNA-based vaccines are a variant of this.) The question we must ask now is whether the pressing need to find a vaccine for Covid-19 necessitates an approach that departs further from the traditional model. An approach that could, potentially, be dangerous.

The vaccine may also make the recipient more susceptible to infection and/or severe illness, which happened with Dengvaxia. There is growing interest in "human challenge trials", in which volunteers would receive the vaccine then be deliberately exposed to coronavirus. The obvious ethical concern is that participants could become seriously ill or even die because we are yet to know for sure what therapeutics are effective in reducing acute illness and deaths. There is also a concern that a vaccine that works in artificial conditions may not in clinical practice. However, such a daring approach would be far faster than the traditional system (in which participants have to wait to be exposed – or not – as part of everyday life), enabling a rapid sorting of which vaccine candidates work and how well; the potential for alternatives if the virus mutates; and ensuring there's still enough active virus left in the population during testing (with MERS the virus was largely gone by the time the vaccine was ready).

A CURRENT COVID-19 VACCINE SNAPSHOT

Globally there are more than 100 Covid-19 vaccine development projects underway, with several candidates already being tested in human trials.

They are:

Inovio (US) had already been working on a DNA vaccine for MERS when Covid-19 appeared in December. This allowed the company to quickly develop a potential vaccine, which is already in Phase I clinical trial, with Phase II/III due to start this summer. However, the company is currently facing challenges with both its manufacturing partner and shareholders. China's Sinovac Biotech's Covid-19 vaccine candidate, CoronaVac, recently showed promising results in Phase I/Phase II clinical trials. The Beijing-based company has already submitted Phase III protocols to China's drug regulator and is seeking to collaborate with Brazil's Instituto Butantan for a Phase III clinical trial.

US-based clinical-stage biotechnology company, **Codagenix**, is collaborating with Serum Institute of India to develop CDX-005. Successful pre-clinical animal studies have cleared the way for the Institute to manufacture CDX-005 to be tested in a Phase I clinical trial that begins in the fall of this year. At the same time, the Indian manufacturer will scale production in preparation for large-scale efficacy and safety studies, while also planning to supply vaccines at the global level.

Pharmaceutical companies **Johnson & Johnson** and **Sanofi** are both working on vaccines, while **Pfizer** has teamed with a German company and began human testing in early May. **GSK** is manufacturing adjuvants "at risk" even as it seeks funding from global institutions and governments to support production. **Merck** has two vaccine development projects. One is through its recent acquisition, Themis, which is part of a consortium with The Center for Vaccine Research at the University of Pittsburgh and the Institut Pasteur, while the other is through its partnership with IAVI, which is leveraging the recombinant vesicular stomatitis virus (rVSV) technology.

Moderna (US) began testing its mRNA vaccine in March. The early safety test, in 45 human subjects, indicated the vaccine was safe and that it generated the right kind of immune response with only minor side effects. In early May, the company received FDA approval to start a Phase II study with 600 participants, half of whom are over 55, and expects to start a Phase III clinical trial in early summer.

The FDA has also agreed to fast-track regulatory review if this phase succeeds.

University of Oxford (UK) partnering with AstraZeneca began clinical trial with more than 500 participants in late April, using a modified virus to trigger the immune system. In May, they reported the vaccine was effective after success with six rhesus macaque monkeys (although this does not necessarily follow that the same result will be seen in humans). They expect to begin a late-stage clinical trial within weeks.

University of Queensland (Australia) researchers are developing a vaccine by growing viral proteins in cell cultures and began pre-clinical testing in early April.

WHERE MIGHT PROBLEMS ARISE?

There are potential sticking points at every phase of the vaccine development, manufacture and distribution process.

Early research and pre-clinical

Not only are mRNA and DNA-based vaccines novel techniques yet to be proven in humans, previous experience with respiratory infections suggests certain formulations could lead to adverse responses. Specifically, the vaccine could make the disease worse instead of preventing the infection, especially given the fast-track approach, which may mean serious problems are missed. The vaccine may also only ever be partially effective.

TABLE 1 Vaccines currently under development

Players	Stages	Manufacturing Process	Approach	Country	Capacity/Collaboration
Moderna	Phase III trials begin in July	Nucleic acid synthesis	RNA	US	Tech transfer to Lonza plants in Switzerland and the US is due to start in June, with production scheduled for July.
BioNTech and Pfizer	Phase I/II trials	Nucleic acid synthesis	RNA	Germany	BioNTech plans to manufacture supplies for clinical trials at its European mRNA facility, with the help of Polymun; “millions” of vaccine doses by the end of 2020 and hundreds of millions by end of 2021. Pfizer will activate its manufacturing network and product at risk an approved vaccine.
Imperial College London	Phase I/II trials under way	Nucleic acid synthesis	RNA	UK	\$8.4M funding from CEPI. Imperial’s supply chain and manufacturing partners will be ready to produce tens of millions of vaccines starting in early 2021.
CureVac	Starting Phase I/IIa clinical trials in June	Nucleic acid synthesis	RNA	Germany	The company is prepared to manufacture several hundred million doses per year at its facility in Germany.
Inovio Pharmaceuticals	Phase I trials	Nucleic acid synthesis	DNA	US	Inovio has a lawsuit pending against manufacturer, VGXI.
Applied DNA and Takis Bio	Starting clinical trials in autumn	Nucleic acid synthesis	DNA	US/Italy	Applied DNA began large-scale production of five vaccine candidates, using the company’s proprietary PCR-based DNA (“LinearDNA”) manufacturing systems.
Sinovac Biotech	Phase I/II trials	Biomanufacturing	Attenuated virus	China	Sinovac will produce up to 100 million doses of CoronaVac each year.
Wuhan Inst. of Biological Products and Sinopharm	Successful completion of Phase I/II clinical trials, Phase III imminent	Biomanufacturing	Attenuated virus	China	CNBG (Sinopharm’s subsidiary) will manufacture 200 million doses a year at two new vaccine production facilities in Beijing and Wuhan.
CanSino Biologics and the Chinese Academy of Military Medical Sciences	Phase II trials	Biomanufacturing	Non-replicating viral vector	China	Canada’s National Research Council will manufacture doses that can be administered in human tests and for emergency pandemic use.

Astra Zeneca and University of Oxford	Phase IIb/III trials	Biomanufacturing	Non-replicating viral vector	UK	Partnered with CMOs Halix (NL), Cobra, and Oxford Biomedical for initial manufacturing. Collaborating with AZ for global distribution. Millions of doses could be available by September. Wuxi and SRI are reportedly also getting rights. Intelligence suggest collaborating with Janssen.
J&J (Janssen)	Starting clinical trials September 2020	Biomanufacturing	Non-replicating viral vector	Belgium	With BARDA's support, Janssen will scale up to produce up to 300 million doses of vaccine in the US each year. Collaborating with Oxford, partnered with Catalent on manufacturing
Novavax	Phase I/II trials	Biomanufacturing	Protein	US	\$388m in funding from CEPI to boost manufacturing. In June 2020, US Department of Defense (DoD) provided a \$60m contract to Novavax to manufacture in June 2020. Novavax will supply 10 million doses to the DoD in 2020 to be used in Phase II/III clinical trials or under an Emergency Use Authorisation, if approved.
Symvivo	Phase I trials	Biomanufacturing	Other	Canada	In-house manufacturing
Clover Biopharma	Starting clinical trials in July	Biomanufacturing	Protein	China	
Vaxart	Starting clinical trials 2H 2020	Biomanufacturing	Protein	US	
University of Pittsburgh	Starting clinical trials in Q3	Biomanufacturing	Protein	US	
Sanofi and GSK	Starting clinical trials in 2H20	Biomanufacturing	Protein	France/UK	
Medicago	Starting clinical trials in summer	Greenhouse production (!)	Other	US	
Vir, AbCellera, Regeneron, etc.	Starting clinical trials in summer	Biomanufacturing	Non-vaccine proteins	NA	Partnered with Samsung, Wuxi, and Biogen

Clinical trials

At the clinical trial stage, there are potential issues with recruiting enough participants, and the right participants, without which the vulnerable could be left at a severe disadvantage.

Too few participants

Countries that experience success in reducing Covid-19 infections are at a disadvantage with respect to clinical trials as they have fewer people to populate them (as was experienced with the Zika and Ebola outbreaks). A cottage industry of disparate research groups has already arisen to test various therapies and have ended up competing for the same patients. With more than 100 separate efforts underway to develop a vaccine, similar issues may arise.

The vulnerable

Issues arise for the most vulnerable, e.g. the elderly, those living in poor and developing countries, and those in migrant and refugee camps. The elderly have diminished immune systems, meaning vaccines are less effective. While Gavi, the Vaccine Alliance; the WHO; and various UN agencies have impressive levels of success in vaccinating young children, their reach among both adults and the elderly in poor and developing countries is minimal. Finally, African countries are routinely underrepresented in clinical trials, and there is evidence from previous vaccine developments that lack of diversity at this stage can lead to dire consequences. For example, the anti-HIV drug Efavirenz is metabolised more slowly among people of African descent, leading to resistance issues. Population differences matter at the stage where identification of antigens occurs.

Production at scale and licensing

Once a vaccine is approved it must be manufactured quickly and at a huge scale. For Covid-19 live virus to be manufactured at scale this means 1,000-2,000 litre bioreactors, which are scarce. In addition, many of the lead developers are not the large, established pharmaceutical companies but small ones lacking experience and capacity in production.

The only way for demand to be met is for manufacturing preparation to take place alongside development, and worldwide, not just in developed countries.

Lack of advance market commitment

Drug makers need confidence that there is a market for their product, i.e. advance market commitment. While there will undoubtedly be demand for a Covid-19 vaccine (to the point where no single manufacturer could meet it), most of the commitments to date are for the US and other developed countries. There is no commitment from stakeholders to subsidise organisations in developing countries (which are already under pressure to produce vaccines for other diseases). There is also the wider issue that many countries simply do not commit to vaccination programmes at all.

Lack of components

It's not just the vaccine itself that's essential to the manufacturing process, but all the components for its storage and application – so vials, rubber stoppers and syringes. Billions are needed for global demand and there is already concern about the medical glass needed to make the vials because of difficulty accessing the right sand (this issue was reported as long ago as 2015). Janssen (the Johnson & Johnson subsidiary that is developing a Covid-19 vaccine) has pre-ordered 250 million but it is not clear that there is supply beyond this. In addition, much of the manufacture of components is done in India and China, which have seen declines in outputs due to export bans and lockdown. Ramping up production will require more overtime, more shifts and more co-ordination across trade authorities to shorten lead times and expedite shipments.

Licensing

A major concern is who will have access to the vaccine itself. The current published manufacturing agreements promise equity. Whether or not this becomes a reality remains to be seen.

AstraZeneca has an agreement with the University of Oxford, and will produce millions of doses if the vaccine is effective, including 30 million for the UK, which is part of an agreement for 100 million doses, and 300 million for the US. The US is also expected to have access to Sanofi and GSK's vaccine, with any excess capacity expected to go to the EU and then worldwide. In the past few weeks, there has been progress with providing access for developing countries. This includes agreements with CEPI and Gavi for the manufacturing, procurement and distribution of 300 million doses for low and middle-income countries and beyond, and a sub-licensing agreement with the Serum Institute of India (SII) to provide a billion vaccine doses for developing countries, with 400 million to be supplied before the year ends. AstraZeneca has also reached an agreement with Europe's Inclusive Vaccines Alliance (IVA), spearheaded by Germany, France, Italy and the Netherlands, to supply up to 400 million doses for Europe.

Type of vaccine

Finally, there are issues that may arise depending on the type of vaccine that eventually makes it through the regulatory gauntlet. While there is existing infrastructure to produce vaccines made from inactivated forms of virus, facilities with biosafety level 3 certification (BSL3) could be required to produce a Covid-19 vaccine. DNA and RNA platforms are likely to be easier to scale. Moreover, adjuvants (boosters) may require specific lipids that may be hard to find in a pandemic. GSK has deals to make a billion doses of its vaccine adjuvant, but many more will be needed to serve a global population.

Storage

There is another set of challenges that will affect poor and developing countries in particular.

In general, vaccines need to be kept within 2 and 8 degrees centigrade, while nucleic acid vaccines (RNA and DNA) require a temperature of -20 degrees centigrade. Intermittent and, in some cases, non-existent electricity sources pose an immense challenge to this requirement.

Usually, absorption refrigerators have been the standard choice for environments with spotty electricity access. However, it's difficult for these gas- and kerosene-powered appliances to maintain vaccine temperatures correctly; the risk of freezing them is quite high. Live vaccines, like adenovirus, are very sensitive to high temperatures. There are new technologies that could mitigate this issue – ice-line refrigerator technology and solar direct drive refrigerators – but planning, procurement, testing and deployment will be necessary.

Distribution

Numerous logistical challenges could hinder distribution. However, experience from the 2009 H1N1 flu vaccine can signpost potential bottlenecks:

Quality control

It is likely to be the case that several manufacturers will produce the vaccine and will need to be monitored for both safety and efficacy. There is currently insufficient capacity to handle this.

Vaccine supply

There could be unforeseen problems in the manufacturing process along with the reality that initial supplies of the first batch might be limited.

Application

Countries receiving the vaccine must have a plan in place that involves applying for it, developing usage plans, and providing both regulatory approvals and customs clearance.

Legal agreements

These will need to be developed and negotiated between recipient countries and the manufacturers, and the WHO if it's involved.

Changing level of urgency

The vaccine may not be ready until the peak of the pandemic has passed and cases drop drastically, thereby reducing the urgency of deploying the vaccine.

Reaching the last mile

Because of the nature of the virus, full global vaccinations are required as any pockets where the virus is unchecked risk rapid spread. The challenge is ensuring last mile distribution. Logistics experts (such as UPS) and tech (such as drones) are being explored as a means of delivering equipment.

Health systems and health-care professionals

The above challenges presuppose enough trained health-care workers both to be vaccinated and to administer the vaccine. But 46 out of the 47 countries within sub-Saharan Africa have significantly fewer than the 2.28 doctors or nurses per 1,000 people regarded as the minimum to deliver basic health-care services. And the WHO and Intrahealth International have predicted that, by 2030, the global shortage of health-care workers will increase from 12 million to 18 million, of which Africa's shortage will be 6 million. This region also carries nearly 24 per cent of the world's disease burden, while containing only 3 per cent of its health-care workforce and only 1 per cent of its financial resources for health care. On top of that is the further disparity in distribution between urban and rural areas. Finally, the effective vaccines are likely to require multiple doses or booster shots for some or all and may not confer immunity for longer than two years. In low health-care capacity countries, loss to follow up (LTFU) is a significant issue unless better systems are put in place. Without this, many people may receive one dose and not receive the vital second dose that provides full immunity, resulting in a waste of resource in public health terms and vulnerability for the individual.

EQUITABLE ACCESS OR VACCINE NATIONALISM?

The only way to achieve global population immunity is for there to be equitable access to and distribution of the vaccine.

However, this currently appears to be determined through a bidding war: The governments with money to fund immediate manufacture are the ones who have secured the vaccine.

Areas for investment

Equity and access on the ground in Africa and other developing countries are likely to be driven by both political and co-ordination issues and will need to consider several areas for investment.

Purchase of vaccines

Some poorer countries can pay in instalments, with institutions such as Gavi providing partial financing, as is the case with the recently announced agreement with AstraZeneca. Richer countries may still need to step up with options such as bond structures repaid to investors over time.

Priority of frontline workers

Frontline health workers who are at high risk of infection must be prioritised (a mass vaccination effort is literally impossible without them). They will also need personal protection equipment (PPE) and testing to ensure continuity of vaccine administration. Finally, routine immunisations should not be overlooked.

Identity issues

For the vaccination campaign to be successful, we need to ensure significant investment in identifying residents in poor and developing countries, 1 billion of whom lack formal identities. Without these it is difficult to know who has received vaccines. Accidental duplication and leakage cause waste and could be deadly. To mitigate this, biometric digital IDs can be linked to the vaccine registry, which is then embedded in health system information systems.

Hyperlocal level

Risk transmission at the hyperlocal level needs to be measured as well as the likelihood of following

vaccination programmes for specific groups and geographies. This can be done by leveraging data to predict behaviour. Digital conversations, satellite imagery and publicly available data can be used by artificial intelligence programmes to, for example, accurately predict which children will drop out of immunisation programmes.

Data capture

Finally, data capture systems are needed to understand the stock and flow of vaccines in the supply chain.

Together, these investments will go a long way to addressing issues of access and equity.

MAPPING VACCINE COVERAGE

Crucial to a successful global Covid-19 vaccination strategy is being able to map vaccine coverage. That means looking at current global coverage to help us plan, and maintaining up-to-date records when we do start vaccinating.

The current inoculation map

The WHO maintains data on global childhood immunisation programmes, from which we know there is wide coverage for a range of diseases including measles, mumps, rubella, meningitis, polio and tetanus (though there are, inevitably, some variations between regions).

There is no such database for adult immunisation programmes, and, while it isn't difficult to find information on countries' vaccination policies, it is much harder to access consistent data on adult vaccination rates. However, we do know from a review of the literature that Africa has fallen behind other regions in immunising adolescents and adults. Most adults in Africa remain unvaccinated despite the availability of vaccines. And most research about adult immunisation is on pregnant women.

Administering the Covid-19 vaccine will be relatively easy for children, given the extensive experience that low- and lower-middle-income countries (LMICs) and their international partners have with

childhood immunisation programmes. At issue will be immunising adults, which is not currently common practice. What is urgently needed is a map on adult vaccination coverage in LMICs, especially Africa; this is work that could be commissioned now. We also need to support African governments in developing delivery mechanisms.

There are partial exceptions. For example, between 2010 and 2015, Gavi supported 16 African countries located in the "meningitis belt" in vaccinating more than 220 million children and adults through mass vaccination campaigns. As of 2013 only four cases of the deadly disease were reported among unvaccinated people in the area. The experience of this campaign could provide a template for how a Covid-19 vaccine could be administered in sub-Saharan Africa. Planning and infrastructure should be put in place now.

Electronic Immunisation Records

Electronic Immunisation Records (EIRs) will be key in keeping track of who is vaccinated, increasing coverage as well as reducing the burden on frontline staff. However, the challenge is to introduce and expand their use in the developing world.

There is currently a patchwork of disparate initiatives designed to introduce EIRs to developing countries, funding and/or providing software solutions:

- The Bill and Melinda Gates Foundation, which funds many projects and much of the research on EIRs
- eHealth Africa, a US-based organisation founded on the premise that "communities in developing countries could have better healthcare when providers are able to make data-driven decisions"
- The Better Immunization Data (BID) Initiative created by PATH with Gates funding, which is a US-based team committed to accelerating health equity. BID is a significant player, with major EIR initiatives in Vietnam, Zambia and Tanzania
- UNICEF
- PAHO

- WHO
- Centres for Disease Control (CDC) in the US
- United States Agency for International Development (USAID)

What is needed now is better co-ordination, and more information.

There is a burgeoning literature on EIRs, but it is underdeveloped in terms of highlighting case studies from Africa and using them to identify challenges. The BID Initiative has established a learning network that convenes African countries to share experiences, but the outputs are piecemeal – periodic blogs, short articles and webinars.

However, we know from PAHO of the problems faced in Latin America. As of 2016, they found that only 24 per cent of implementations had been successful, with 44 per cent suffering difficulties and 32 per cent being failures. This literature helps us plan for similar challenges faced in implementing EIRs in Africa. On top of infrastructure issues, such as internet access and access to electricity, health ministries face:

- Multiple sources of data
- Poor data triangulation
- Multiple data collection tools
- Poor data handling, storage and archiving
- Staffing challenges including inability to provide ongoing training
- Financial sustainability for EIR maintenance and upgrades
- Planning to ensure operability among multiple different pilots
- Convening mechanism for relative stakeholders to drive successful implementation

What we need now is a robust, commissioned piece that evaluates the full range of experiences of African countries that have sought to implement EIRs, where they are in the process of scaling, what the challenges have been, and how they have been addressed.

INTERNATIONAL CO-OPERATION

The same problem that plagues treatment development and access affects vaccine development and access: lack of co-ordination. This is perhaps our biggest challenge of all.

Part of the issue is the complexity and array of actors and institutions that comprise the global health infrastructure: multilateral partnerships that often duplicate efforts; philanthropic organisations; government institutions; NGOs; and the private sector.

Under other administrations, we would have expected the US to assume leadership to drive global co-ordination for access and equity. But the current “America First” doctrine is palpable in the area of Covid-19, as evidenced by the announcement to withhold funding from the WHO, efforts to secure exclusive rights to a vaccine company, and the unveiling of “Operation Warp Speed”, which has a clear focus on securing a vaccine for the US alone. The American election in November could be pivotal, either deepening the “America First” doctrine or opening space for American re-engagement on a global level, including in the area of vaccine access and affordability.

In the interim, EU countries and the UK are in a position to assume greater leadership and responsibility for coordinating key aspects related to how any vaccine is distributed, especially in developing regions such as Africa and Asia. The WHO has launched C-TAP, the COVID-19 Technology Access Pool, which was championed by the Costa Rican president and met with disdain by the pharma industry. While at least 37 countries have signed up to this voluntary initiative, notable non-signatories to date are China, France, Germany, Japan, Turkey, the UK and the US – places where a significant proportion of vaccines are going to be made. In the absence of these economic and political powerhouses, it is not clear how effective the pool will be.

Conclusion

We need a radical, fast and global approach in order to provide for all nations. And we need political leadership to create this framework and drive its adoption.

High Income Countries (HICs) need to pool financing for manufacturing (a “Covid Buyers Club”) for “at risk” and “at scale” manufacturing in order to:

- Back a portfolio of candidate vaccines rather than back a single horse
- De-incentivise bilateral deals
- Efficiently manage tech transfers from R&D to MNC and smaller manufacturers to avoid capacity capture by a few deals
- Avoid bidding wars that raise prices
- Agree that a reasonable percentage of doses wherever they are manufactured go to LMICs priority populations

A partial example of this is the European Inclusive Vaccines Alliance (IVA), which includes Germany, France, Italy and the Netherlands, and is open to other European countries that want to participate. This “buyers’ club” hopes to improve its position through collective action and seeks to manufacture a Covid-19 vaccine in Europe. The Alliance recently closed a deal with AstraZeneca, which will provide 27 EU countries with up to 400 million doses, at a cost of €750 million. If the vaccine makes it through the clinical development process, it will be delivered at the end of this year, with EU countries receiving doses based on the size of their population. Catalent, the US manufacturer, will produce the drug at its facilities in Italy.

Low- and lower-middle-income countries (LMICs) need to supplement their own government budget, secure aid and philanthropic funding to:

- Finance advance market commitments for a portfolio of candidate vaccines rather than back a single one
- Agree that a reasonable percentage of doses allocated to LMICs are reserved for priority populations
- Upgrade and scale up manufacturing capacity
- Prepare their expanded programmes on immunisations (EPIs)

A significant aspect of this work for LMICs is being spearheaded by Gavi and CEPI.

The search for a vaccine for Covid-19 concerns all of us. When we do get an effective and approved vaccine, the current marketplace may not deliver for developed countries, nor for poorer countries. Hence, we need a global vaccine strategy for Covid-19.

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