Coronavirus pandemic: the vaccine as exit strategy

A GLOBAL HURDLE RACE AGAINST TIME WITH A SPLIT JURY

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Sars-CoV-2, a novel pathogen, submits a stern warning, a clarion call, on the huge human costs of shortsightedness, inaction and lessons lost in the face of common predicaments at the global level. Yet, a number of key actors remain oblivious, including ethically-challenged politicians seeking to elbow their way to the front of the queue at the expense of the poorest and most vulnerable nations and communities. Contrary to expectations being formed, a safe and effective vaccine for the Covid-19 strain once, if ever, attained, is the best way out but unlikely to do as a silver bullet in the midst of the complexities and unknowns at play.

As a result of the harmful impact of the pandemic and ensuing policy aftermath, the world runs the risk of squandering the gains barely made in the fight against poverty over the last few decades - a looming scenario of egregious global governance failure, in view of the eight close calls recently received (three flu epidemics or near-flu epidemics, two Sars episodes, one Mers episode, Zika & Ebola). A promptly and universally distributed vaccine promises to prevent future disease outbreaks. However, many scientific, economic and distributional hurdles stand in the way. Whilst each day counts, the survival of hundreds of millions of lives hangs in the balance as health issues and those pertaining to livelihoods, nutrition, schooling and deprivation are so closely interdependent. Can we rule out the need to resort to internationally sanctioned legal remedies as an inescapable response?

For the first time in living memory, the wealthy countries have done worse than the low- and middle-income countries during the initial phase of a global pandemic - the epicenter has now shifted towards the latter, particularly Latin America. Largely because of policy failures, many regions in the developed world, particularly the U.S., are suffering sharp relapses and tipping over into negative turns in transmission dynamics.
This evolutionary pattern has given an acute sense of urgency to the launching of response strategies in the wealthy countries - leading to piecemeal and fragmented approaches, including bountiful subsidies to support the quest for a vaccine, mostly at the national level. This approach crowds out truly global efforts towards a widely produced and promptly, affordably and equitably distributed vaccine accessible to everyone.\textsuperscript{4, 5}

This predicament only highlights the value and timeliness of efforts by the World Health Organization (WHO) and various governments, as well as non-state agents such as foundations and other civil-society and non-profit organizations, that have adhered to the principle that a vaccine must be conceived of as a global public good, and are swiftly acting on it.\textsuperscript{6}

In view of the uncertainties and challenges surrounding the quest for a novel vaccine, along with the huge stakes involved in terms of human lives, pursuing multiple parallel tracks of scientific and technological endeavor is no doubt the wisest thing to do in order to minimize the time and risks involved. But to infer from this that an open, consensual and highly coordinated global cooperation approach is not the best course to pursue is an absolute non-sequitur. Indeed, in view of a predicament indivisibly shared by all, the opposite is the case.\textsuperscript{7}

It is worth recalling that, if two or more rounds of the vaccine are to be administered to the world population, a minimum of some fifteen billion doses would eventually be needed, along with the whole gamut of complementary inputs (e.g. vials, needles, syringes, kitting and logistics infrastructure, particularly cold chains).\textsuperscript{8} However, pervasive “vaccine nationalism” suggests that shortages of a vaccine in the developing countries during substantive periods cannot be ruled out at all.\textsuperscript{9}

The markets of the poorest countries, those most affected by prior pandemics thus far, are not profitable enough for wealthy countries-based multinationals to justify engaging in vaccine R&D.\textsuperscript{10} Beyond health-related imperatives, the large subsidies being swiftly granted by wealthy countries now in order to not just shorten schedules but also, perhaps for the most part, to ensure domestic production capacity and control of intellectual property rights, are a glaring recognition of the market failures involved and the ensuing need for public intervention -- albeit often tinted by a narrow-minded nationalism. However, it is not quite clear if, in deciding to grant such subsidies, due note has been taken that the older segment of the population in rich countries, the one that bears the brunt of the pandemic in terms of mortality, is largely amongst the ones that offer the most profitable market. This circumstance, coupled by national rivalries, is leading to market segmentation and tiered pricing policies by the pharmaceutical multinationals, as confirmed by the design of actions already underway for the marketing of the future Covid-19-related vaccines and therapeutics.\textsuperscript{11}

A primary reason for the prompt government response in the wealthy countries is the mounting human and economic losses accumulated at very short notice. This is aggravated by the uncertain prospects looking forward that strongly suggest that achieving a sustained recovery may take up to a decade.\textsuperscript{12}

And yet, the developing countries are the ones that suffer most of the burden in relative terms and those to undergo the most lasting scars because of pre-existing human, social, budgetary and monetary vulnerabilities, overwhelming foreign indebtedness with very limited scope for alleviation, unfavorable primary export prices, lost jobs and poverty surges.\textsuperscript{13} This only pre-announces an exacerbation of their already worsening catching-up prospects these countries suffer ever since the aftermath of the 2007-08 financial crisis if not before.\textsuperscript{14}
A great deal of the failing response to the pandemic ensues from the ongoing decline of multilateralism and globalization, along with an incipient prevalence of government-induced just-in-case over just-in-time management policy strategies in the private sector with a view to defensibly restructure global value chains. On top of this, in various quarters national and competitive rivalries are glaringly taking pride of place over health-related considerations.

This relates closely to "vaccine nationalism", whereby a science and technology contest, whose outcome may affect the balance of economic and political power, is enticing spurs of narrow-minded "me-first" policies, export bans, questionable incentives for contestant firms to shift country allegiance and location and discretionary supply and demand-related decisions.

Likewise, it is common knowledge in the pharmaceutical industry that front-running companies involved anticipate that, if and when a vaccine does prove effective, countries will heavily influence, if not block, trade flows resorting to various means on grounds of regulatory-, intellectual property- and standard-related issues, national security and so on, as was the case with tests, personal protective equipment and experimental drugs very recently. Leading contestants fear being trapped inside national borders, for which reason they are planning to split future production facilities across various continents, which in the end might end up being a blessing in disguise.¹⁵

This rarified environment is only likely to heighten the need, already felt and acted upon in more "normal" times, in connection to various drugs, for developing countries to resort to the flexibilities contemplated by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its addenda and amendments, on grounds of public health emergencies, i.e., government use and compulsory licenses.¹⁶ Thus, developing countries may enable generic manufacturers to produce the vaccine at affordable prices either domestically or by other countries that have the necessary capabilities. Non-exclusive voluntary licensing should not be ruled out either.

It is also worth recalling in this regard that there is legislation at the national level in the advanced industrial countries themselves to an analogous effect. In the case of the U.S. for instance, the Bayh-Dole Act of 1980, codified in 35 USC§ 203, may be invoked in case of threats to public safety. Thus, the "March-in rights" enable the federal government to grant patent licenses to parties other than the patentee or such parties take licenses for themselves in case a patented invention has partly relied on federal funds and if a significant benefit to the public is expected.

In the meantime, why is the scope for attaining a safe, effective and stable vaccine so uncertain and the decision to impose mandatory deadlines to its development so imprudent? Here are the key hurdles faced by the contenders in this race.

In the first place, at the moment, scientific knowledge is not sufficient to predict the level of immunity to be attained by the vaccine (nor is it possible to predict how long it will take to lift the relating unknowns). What is involved is in fact a high stakes heuristic and serendipitous process where uncertainty cannot be done away by decree or political will.

Secondly, discords rooted in national rivalries are likely to spring up with respect to the scientific, technological, legal and regulatory standards to be recognized (efforts at delegitimizing WHO and WTO can be regarded as steps in that direction). It cannot be ruled out that a given nation may challenge a successful contestant from another nation on those grounds - thus turning the achievement into a subject of geopolitical dispute.
Third, moves towards weakening global innovation systems will only slow down advances in the knowledge frontier in general and regarding the coronavirus vaccine in particular, and thus pose further hindrances along the way.\(^1\)

In addition, there are various reasons why the current and expected impact of the pandemic is being wrongfully recorded and predicted, particularly with regard to the developing countries.

In the first place, there appears to be a gross under-recording of the contagiousness of the pandemic, even in the most resourceful countries.\(^2\)

Secondly, and most concerning, there is the loaded issue of coinfections and comorbid conditions, along with spillover effects and negative health externalities, largely affecting children\(^3\). These effects entail what may be called the *disease and health-risk multiplier*, particularly concerning the poorest countries and most vulnerable communities everywhere, whereby pre-existing health conditions prompt a compounding of health risks. Scientists are realizing that the coronavirus is not a single-, but a multiple-target virus, one which, once transmitted, translates into a greatly amplified array and multiplicity of health- and related consequences.\(^4\) Furthermore, the impact of the coronavirus does not appear to be time-bound. Evidence is mounting that it may lead to the development of chronic conditions, with the ensuing impact on the quality of life and the need to undergo lengthy and costly rehabilitation treatments, if and when available and affordable, for the many who appear to convalesce.

Third, there is the diversity/immunity nexus. There appear to be grounds to hypothesize that, rather than a single pathogen, what is at play in the evolution of the coronavirus pandemic is indeed the impact of myriad physical and social interacting parameters, whereby the conventional frontiers between communicable and infectious diseases get blurred, yielding the so-called "biosocial contagion". This expresses a "syndemic" world, i.e., one where a synergy of epidemics "co-occur in time and place, interact with each other to produce complex sequelae, and share common underlying societal drivers".\(^5\)

These factors more than offset the assumed demographic advantages of countries with younger populations. These countries may end up experiencing less deaths but also higher transmission rates and stronger and lengthier health-related disruptions than those of the wealthy countries. This is greatly aggravated by the relatively higher share of the population in the informal and service sectors as well as in tight agglomerations, which face greater difficulties in work-digitalization and in engaging in social-distancing. Clearly, weak public health, digital and governance infrastructures can hardly keep up with the surging number of cases in the developing world, currently most acutely in Latin America.

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Although the race for a vaccine is a science-based one, the political, socioeconomic, institutional and policy intricacies involved suggest that, in discerning access by the ultimate beneficiaries, medical science is unlikely to prevail over the balance of political and economic forces.

The current global health emergency is leaving devastation in its wake in terms of lives and livelihoods. But the impact is extremely asymmetric. The onset of a vaccine is highly unlikely to correct this, and might well aggravate it.

In a global economic environment undergoing abrupt falls in output, world trade and foreign direct investment, odds are that the equivalent to some 400 million jobs will be lost, extreme poverty will
augment by 420 to 580 million people, and extreme hunger will double to overcome the 260 million mark. All this is undermining the United Nations (UN) Sustainable Development Goal (SDG) of ending poverty by 2030, with some regions backtracking some 30 years. Needless to say, multiple other SDGs, particularly those relating to health and education, are also under serious threat.\textsuperscript{22}

The virus ought not be seen as much as an enemy to be defeated as an imperative call of nature to adapt. Adapting in this case means above-all co-operatively resorting to scientific knowledge-based innovation. This appears to be the best way to respond and the only way to address the root causes of the pandemic in all their multiplicity, complexity and diversity, with the future in sight.

A vaccine is a necessary but by no means a sufficient condition to bring the pandemic and its aftermath under control. As with climate change, there are no quick fixes. Responding to it requires knowledge, effort, innovation, cooperation, collective will and ethical leadership. Whilst a safe, effective and affordable vaccine at the reach of everyone in the globe is the best hope to control the pandemic, it is by no means the only tool or a panacea on its own. The means to diagnose and treat the disease, along with appropriate social innovations and governance, will continue playing a critical role.

These are good reasons to warn against laying excessive hope in the immediacy and marvels of a future vaccine - which may lead to taking a holding attitude in the meantime, and relying on mild and/or purely defensive measures. What if there is no vaccine efficacious enough, let alone safe enough, for much longer than anticipated? Critically, swift action needs to be taken to strengthen the public health systems, and push forward with the development of therapeutics & drugs that can prevent and treat the infection, rolling out better diagnostics, and addressing comorbid conditions, climate change, a looming hunger pandemic\textsuperscript{23} and other public bads. The international community should not bet on any single one of them.

References:


Endnotes:

1 Expanded and updated version of “Coronavirus -- Carrera global de obstáculos con jurado dividido” by the author, published on June 6th, 2020 (https://www.perfil.com/noticias/coronavirus/opinion-francisco-colman-sercovich-carrera-global-de-obstaculos-con-jurado-dividido-coronavirus.phtml). This piece was submitted to the South Centre on 17 July 2020. The author thanks Carlos Magaríños for his comments. The usual caveat applies.

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3 This is observed, for example, in many U.S. states (including Arizona, California, Florida and Texas). The U.S. currently accounts for one fourth of confirmed infection and death cases at the global level. The daily number of new cases in Arizona alone is higher than that of the European Union as a whole.

4 WHO has launched a US$18b bid to ensure global distribution of various versions of a vaccine in cooperation with GAVI, the vaccine alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI), having managed to raise

5 There are more than 100 vaccines for COVID-19 currently in the works just in the U.S. (10 at clinical and 115 at preclinical stages) and some 200 around the world, along with over 1000 clinical trails, of which over 70 are registered with the U.S. Food and Drug Administration (FDA) alone. Considering that progress -- which entails, for instance, rushing through the approval process by using interim data from earlier trials to expedite later stage trials without waiting for final data -- is approaching phases 2 or 3 in the best of cases, uncertainties and unknowns tend to be played down or ignored by politicians, such as ambivalent tentative results from trials on safety and particularly on effectiveness and unclear prospects about the enrollment of the required critical mass testing of subjects. Operation Warp Speed in the U.S., at an initial cost of US$ 10 billion, is intended inter alia to support production of 300 million doses of the Covid-19 vaccine for the US population by the end of 2020 relying heavily on relatively newer gene-based routes, i.e. those of Moderna & Oxford/AstraZeneca-AZ. These routes are still experimental. They lack the track record of traditional protein-based vaccines, based on inactivated or attenuated viruses, in terms of potency and durability of immune response (although they do have advantages in scalability & versatility), which rises their odds of failing to end up as the winning technologies and eventually falling by the wayside in a relay race. The U.S. National Institutes of Health (NIH) is currently conducting a scientific review of more than 50 vaccine candidates.

6 In fact, pharmaceutical companies, no matter how big, are engaging into a web of partnerships in order to get complementary resources, speed up projects and hedge bets. Thus, for instance, Sanofi has teamed up with GlaxoSmithKline-GSK and, separately, with U.S.-based Translate Bio; AZ with Oxford University (Jenner Institute) and U.S. Biomedical Advanced R&D Authority (BARDA), which is reportedly the most advanced (AZ also plans to provide up to 300m vaccine doses to CEPI & Gavi, as well as to license its vaccine to Serum Institute of India for production of up to 1 billion doses for low & middle-income countries); Pfizer with German mRNA company BioNTech - which in turn is cooperating with Chinese company Fosun and has financial support from the European Investment Bank and Temasek, an investment vehicle of the Singaporean government; Johnson & Johnson-J&J with BARDA and Boston-based Beth Israel Deaconess Medical Center; and Moderna with NIH & BARDA. Merck, which refused to embark in a 12-18 months quest for a vaccine as an unrealistic schedule, envisions advancing along two tracks; the first one with Themis Biosciences (Vienna), which is in turn collaborating with the Pasteur Institut and with Pittsburgh University, and the second track in association with International AIDS Vaccine Initiative (IAVI) (New York). It is worth recalling that less than 10% of medicines that clear phase 1 stage of human testing end up making it to the market.

7 It is hard to think of anything more alien to 'me-first' and 'me-only' national policy approaches than the underpinnings of the concept of a public good; namely, non-excludability and non-rivalry in consumption. For this reason, the protection of intangible assets such as the scientific and technological knowledge and related information and data relating to the production of vaccines cannot be regarded as akin to that for private goods, particularly in the context of global public health emergencies. See further below.

8 Reuters (2020)

9 A six-months delay in vaccine delivery to the populations of Latin America and Africa alone would put at risk, at the current rate, the life of additional 420,000 people. (Own estimate based on the Our World in Data COVID-19 Dataset at https://ourworldindata.org/coronavirus, accessed on July 3rd, 2020.)

10 It is important to recall that, in the pharmaceutical industry, unit production costs are negligible compared to those of performing Research and Development (R&D) activities. This is why, once the bulk of R&D costs is recovered in the wealthiest nations, pharmaceutical multinationals are able - although hardly willing - to charge much lower prices in the poorer nations. But, in order for them to recover R&D disbursements first, advanced-country markets are prioritized, whilst supplies to the lower income countries are left for latter. For this reason, the key rationale for the large subsidies currently being granted by wealthy country governments to develop Covid-19 vaccines should be precisely ensuring that this pattern of market selection does not occur by swiftly enabling the location of production facilities by generic producers in the developing world. Unfortunately, though, this is not the case. By the way, as admitted by a large pharmaceutical multinational, the cost of actually producing each dose of a vaccine is equivalent to that of a cup of coffee. See The Economist (2020).

11 For instance, Pfizer’s Chief Executive Officer (CEO) is reported to have acknowledged that, in the case of a future Covid-19 vaccine, it will be hard for the company to apply the blanket approach of pricing it according to its value to society and the economy (in other words 'what the market will bear', FCS) since, in that case, it would be in "very, very high numbers". Instead, Pfizer will use the price of other vaccines as benchmark, while cutting prices in places.... Still, they do anticipate making a profit. In preparation for inter-country conflicts over the distribution of the future Covid-19 vaccine, Pfizer is developing two separate manufacturing supply networks in different continents. See Financial Times (2020a), (2020b).

12 See, particularly, U.S. CBO (2020). See also CBS News (2020), OECD (2020), IMF (2020), and The World Bank (2020). The U.S. Congressional Budget Office projects that the current pandemic would detract 3% off the U.S. Gross Domestic Product (GDP) during the course of the next decade -- a cumulative US$ 7.9 trillion in constant prices relative to its January projections. In a similar vein, IMF projections indicate that, by the end of 2021, the world economy as a whole will have a size similar to that of 2019 whilst both the U.S. and EU economies will be about 4% smaller (IMF, 2020). Based on hard facts, the US Federal Reserve and the OECD. share the gist of these predictions, by predicting a collapse of output followed by a slow recovery. Weak balance sheets, waves of bankruptcies, precautionary behavior
resulting from fundamental uncertainty, policy mistakes and, above all, human capital destruction are leading to a resumption, with a vengeance, of the pervasive preference towards lasting preventative reductions in expenditures by households and firms originated by the Great Recession of 2007-08. On the other hand, the pre-existing secular decline of productivity growth will be buttressed by a greater emphasis on human-focused vis-à-vis productivity-enhancing innovations prompted by the pandemic at least until and if it comes fully under control. This circumstance will most likely lead to an additional drive towards automation and labor-saving innovation. These trends, in conjunction with a negative impact on income distribution and other monetary and structural factors, will most likely aggravate the secular stagnation syndrome already suffered by the wealthy economies since well before the outset of the pandemic. See Sercovich (2016).

13 See, particularly UN (2020a). Also see the World Bank (2020) and IMF (2020).
14 See Sercovich (2016).
15 See The Financial Times (2020a).
16 On this see: Correa and Velásquez (2019), Correa (2020), Muñoz Tellez, V. (2020), Vawda and Shozi (2020) and Velásquez (2019a and b). For a detailed account of the countries that have resorted to TRIPS’ public health emergency provisions, including medicines involved and respective dates, see South Centre (no date). See, also, Sercovich (2008).
17 This contrasts sharply with the paradigm underlying the stand adopted by the 36 developed and developing countries that have so far decided to support the WHO proposal to pool knowledge, intellectual property rights and data relating to the vaccine. See: https://www.who.int/news-room/detail/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19, retrieved on July 3rd, 2020.
18 Robert Redfield, head of the U.S. Centers for Disease Control and Prevention, has stated that, in the U.S., the number of coronavirus cases may be 10 times higher than reported, so that the current number would be 29 million rather than 2.9 million — 9 per cent of the population would be infected so far, which suggests that the pandemic remains in its early stages. See https://www.washingtonpost.com/health/2020/06/25/coronavirus-cases-10-times-larger/, retrieved on July 3rd, 2020.
19 See UN (2020b), Roberton et al. (2020), UNESCO (2020). For educational spillovers from Covid-19 in Britain see Andrew et al. (2020).
21 See Swinburn et al. (2019).
22 See Maganíños (2020), ILO (2020), Sumner et al. (2020) and World Food Programme (2020).
23 See Beasley (2020).

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