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EDITORIAL

Vaccines: global dimensions and local manifestations

This issue addresses the latest debates on Covid-19 by bringing together three important contributions that situate vaccine scarcity and access in a longer structural history of medical monopoly and corporate greed. The unequal global distribution of vaccines brings to sharp focus the situation of low- and middle-income countries who now find themselves in a hopeless scramble against the world's biggest economies that are, in keeping with their historical trajectories of development, once again engaged in a scientific race of discovery, patenting, and hoarding of vaccines, reflecting both power and geostrategic positioning at the expense of poorer countries. Matrich raises the emergent notion of 'vaccine nationalism' which denotes a widespread understanding of the fact that rich countries are hoarding doses far above their needs and leaving low-income countries without recourse. It is a vastly unequal and unfair distribution where, as we see in the contributions in this issue, developed countries such as Canada have acquired vaccines to inoculate its population five time over, and others such as the US, UK, Australia, New Zealand and the EU have acquired enough does to vaccinate their population at least twice. The fact, however, that countries with less resources cannot boast of similar achievements and are likely to continue suffering the devastating health, economic and social consequences of Covid-19 cannot be understood outside of the historically unjust, unequal nature of the global system. The social and political dimensions of this problem are also localised, evident in the discriminatory state policies and vaccine roll-out approaches being implemented in various countries of the South which map onto existing social disparities. As Garimella highlights in the case of India where the vaccine drive has been marred by a manipulation of the process, discrimination, and lack of transparency, a response to the question about vaccines has also to respond to the question regarding for whom it is being produced. That is, whether a country can be free from the spread of a virus if the largest segments of its vulnerable populations are not being accounted for. Valiani's contribution proposes an important lens through which to make sense of vaccine politics at this current conjuncture. She shows that the current divide being entrenched by rich nations to deny sufficient access to most of the world is a problem with much deeper roots in the monopolies created by the medical device, diagnostic industry and pharmaceuticals. It is a long history that begins from the late 19th Century and evolves into a tale of global hegemony that

has installed monopoly-driven healthcare against which the only viable alternative is a 'people-centered, No-COVID strategy' that centres decommodified universal health care. As Covid-19 continues to ravage vast populations of the globe in tandem with monopoly finance capitalism, all three contributions in this issue alert us to the dire situation being faced by millions of people, and the political task of resistance and mass mobilization that this moment requires. Blueprints already exist, as countries such as Cuba have already been demonstrating models of decommodified, universal healthcare since the onset of the pandemic which show what principled, ideological commitment and political will can achieve in a relatively short period and organised manner.

As always, we welcome enquiries and responses, which may be submitted to the editors at:

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ACCESS TO MEDICAL SUPPLIES AND DEVICES — THE LESSER KNOWN STORY OF COVID-19 AND MEDICAL MONOPOLY

Salimah Valiani [1]

Discussions around access to potential vaccines for COVID-19 are widespread, particularly in the global South. Much less discussed is the lack of access to already existing medical technology crucial to stemming the spread of the novel coronavirus and assisting its most severely affected victims. The latter is the outcome of the monopoly control of medical technology — a phenomenon stretching at least as long as the monopoly of Big PHARMA — though much less understood.

News of medical technology shortages have been reported around the world in the past months: from N95 respirators to protect healthcare workers from contracting and spreading the novel coronavirus, to COVID-19 testing materials, to ventilators for infected patients unable to breathe.

A well publicised example globally is the shortage of personal protective equipment (PPE). Since March, workers in rich as well as impoverished countries have demanded employers to provide protective gear including N95 respirators, gowns and gloves.

In the United Kingdom, when not on duty, public hospital workers demonstrated for PPE throughout March and April. By the end of April, the Guardian newspaper had recorded over 100 COVID-19 deaths [i]of healthcare workers in the UK.

Also in April, as Canada's largest privatised elder care sector was becoming a hotbed of the first wave of the pandemic, The Ontario Nurses' Association, the country's largest nurses' union, had to file a court petition to push[ii] private long term care homes to provide protective gear to nurses and other healthcare workers.

In Northern Italy in mid-March, during the height of the first wave of the pandemic there, factory workers staged wildcat strikes[iii] demanding protective gear. While most shops and public places were under lockdown by March, factories remained open and without income supports, workers were forced to continue working. Even if not reported in the media, workers' battles for PPE will continue to intensify around the world as workplaces reopen and stay open despite resurgence of the virus.

In late April and May, in public as well as private hospitals in the Eastern Cape[iv], South Africa, reproducing typical hospital hierarchies, management and doctors[v] were hoarding PPE. Nurses and other healthcare workers contracted the virus in large numbers. Similarly in the Peruvian Amazon city of Iquitos[vi], 80 per cent of hospital workers tested positive for

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COVID-19 by mid-May, largely due to a lack of PPE.

In Africa as whole, the World Health Organization (WHO)[vii] reported in late July that more than 10,000 health workers had contracted the corona virus, with lack of PPE being a major cause. In South Africa alone, by early August, 24,104 health workers had been infected[viii], with 181 losing their lives. Elsewhere in the global South, health worker deaths[ix] related to inadequate PPE as of early September amounted to 1,320 in Mexico and 634 in Brazil.

Another example receiving some media coverage is that of COVID-19 testing materials. As early as March, the WHO was admitting the emergence of a global[x] shortage of chemical reagents needed to process COVID-19 polymerase chain reaction (PCR) tests, the best WHO recommended test for clinical diagnosis.

In early June, toward the end of a crucial period for testing and contact tracing in South Africa, the Minister of Health finally acknowledged[xi] that both public and private South African labs were slow in processing tests due to a shortage of PCR test kits and the reagents required to read the tests in large number and quickly. By early July, the pharmacy group, DisChem, closed[xii] its testing facilities citing delays in receiving test results as the reason.

Speaking of the African continent, the Minister of Health of the Central African Republic, Pierre Somse, stated[xiii] in mid-July "…we are in a scarcity, a misery of tests," attributing the Africa-wide lack of testing materials to hoarding in rich countries and a shortage of "global solidarity."

Explaining medical technology shortages

High demand and in turn, local and global shortages, is the most commonly provided explanation for the chronic lack of PPE, testing materials, and other COVID-19 related medical technology. At best, governments are blamed for epidemic unpreparedness[xiv] and not stockpiling supplies despite long standing studies and recommendations from previous epidemics.

As I show in Rethinking Unequal Exchange[xv], however, the problem runs much deeper. The medical device and diagnostics industry — like the better known story of pharmaceuticals — is a monopoly, with all the attendant features of for-profit production dominated by a small few.

Baran and Sweezy define monopoly capital[xvi] as the central phenomenon of 20th century capitalism. They argue that in contrast to 19th century firms that produced small fractions of homogenous products for anonymous markets, the typical business unit of the 20th century was the large scale enterprise producing a substantial share of products of one or several industries. These enterprises were in turn able to control the production volumes of products, prices, and types and amounts of investment. In his 2013 book, The Implosion of Capitalism[xvii], Samir Amin updates and applies this analysis to the 21st century world capitalist economy, coining the notion of 'generalised monopolies' dominating globally in a range of industries including agriculture, communications and finance.

The makings of monopoly

In the instance of medical technology, the process unfolded from the late 19th century onward[xviii], largely in the USA. The process involved creating first local, then global markets for new medical commodities, patenting to maximise the price of these commodities by limiting production and supply, and controlling the direction and scale of technological innovation through the acquisition of firms with ideas that were investing in innovation.

Using such manoeuvres, US-based companies played a major role in establishing and leading the multinational medical device and diagnostics industry. Stretching into countries around the world, this history is part of what Giovanni Arrighi has termed US world hegemony[xix]. Where other major medical technology firms emerged, for instance in Western Europe, they necessarily had to use manoeuvres similar to those leading the industry.

Over time, some companies fared better than most. By 1999, 12 percent of firms came to dominate[xx] the US medical technology industry. More specifically, 733 of 5,998 companies accounted for 80 per cent of industry sales, with the top 2 per cent accounting for 48 per cent of these. Today, the total number of companies in the industry has gone down[xxi] to 1,083, suggesting deepening monopoly control. Along the same lines, according to a 2017 estimate[xxii], the top 20 medical technology companies controlled just under 55 per cent of the global medical technology market, the majority of which were US firms (see table below).

Further suggesting deepening monopoly control are the numbers of US medical technology firms figuring in Fortune Magazine's listings of top performing companies in the USA (Fortune 500) and internationally (Global 500) between 2005 and 2019. In 2005[xxiii], seven US medical technology companies (Baxter, Becton Dickinson, Boston Scientific, Medtronic, Guidant, Stryker and Danaher) figured in the Fortune 500, and one US medical technology company (Abbott) featured in the Global 500. By 2019[xxiv], five of these companies (Baxter, Becton Dickinson, Boston Scientific, Stryker, Danaher) figured in the Fortune 500, and two (Medtronic, Abbott) featured in the Global 500. Meanwhile, the market size of the US medical technology industry increased from 67.9 billion USD[xxv] in 1999, to 169.3 billion USD in 2018 and 425.5 billion USD[xxvi] globally. Two significant acquisitions occurred in this period. In 2006, Boston Scientific acquired Guidant[xxvii], for 27 billion USD, or just under 40 per cent of the industry's total market value in 1999. In 2015, Zimmer acquired Biomet, thus gaining a place in the Fortune 500. By 2019, Zimmer ranked 387, climbing from 431 in 2016.

The story[xxviii] of US-based multinational, Becton Dickinson — which ranked 187[xxix] in the 2020 Fortune 500 — illustrates the rise and reach typical of firms in the top 2 per cent since the late 1990s. Beginning back in 1898, Becton Dickinson acquired half rights to the patent on the all-glass syringe developed in France. The company went on to produce a range of syringes and other medical devices, surgical instruments, and sterile disposable products. Along the way, Becton Dickinson absorbed various enterprises involved in producing and distributing medical technology. These include

the Philadelphia Surgical Company in 1904, the Surgical Supply Import Company in 1913, the Toronto-based distributor, Norman S. Wright Company in 1951, Mexico-city based MAPAD S. A. CV in 1952, and AMI of France in 1955. Also in 1955, Becton Dickinson acquired the Baltimore Biological Laboratory, launching Becton Dickinson to become a leading force in two major changes in medical practice: conversion to sterile disposable products, and the emergence of diagnostic medicine.

Market Share of Top Global Medical Technology Companies, 2017

COMPANY	MARKET SHARE (%)
Medtronic*	7.4
Johnson and Johnson	6.6
Abbott	4.0
Siemens (Germany)	3.8
Becton Dickinson	2.7
Philips (Netherlands)	3.3
Stryker	3.1
Roche (Switzerland)	3.0
Boston Scientific	2.2
General Electric	2.5
Essilor International (France)	1.8
Danaher	2.1
B Braun Meisungen (Germany)	1.9
Baxter	1.8
Zimmer Biomet	1.9
Novartis (Switzerland)	1.5
Olympus (Japan)	1.4
3M	1.4
Terumo (Japan)	1.2
Edwards Lifesciences	0.8
TOTAL GLOBAL MARKET SHARE, TOP 20	54.4

Source: Statisca (based on company-reported sales data of the world's top 300 medical technology companies)

* All companies without countries indicated in brackets are USA-based.

Impact on hospitals

Through the 1980s, monopoly production of medical technology was the primary cause of cost escalation[xxx] for US hospitals, the major consumers of medical devices and diagnostics. Along with reductions in public financing, medical technology induced cost escalation led to the failure of 550 community hospitals in the USA, and mergers of several hundreds. Around the same time, the number of corporate-owned hospitals[xxxi] in the USA more than doubled, increasing from 445 in 1978 to 955 in 1984.

As hospital care became commodified in the USA, it quickly took on a monopoly[xxxii] structure like that of medical technology. Three companies — Hospital Corporation of America, Humana, and American Medical International — came to own just under three quarters of the 35.1 per cent of the country's hospital beds controlled by the private sector.

By the mid-1990s, two of these companies — after American Medical Holdings took over American Medical International — began ranking in the Fortune 500. This marked the beginning of multi-hospital systems becoming a high profit industry[xxxiii] in the USA. Between 1996 and 2020, Humana rose[xxxiv] steadily from 279th place in the Fortune 500 to 52nd.

Monopoly priced medical technology can be traced as a major cost pusher, over time, in public healthcare systems as well, for instance in Canada[xxxv].

Impact on nurses

In order to maintain high profitability, particularly given the monopoly-driven high costs of medical technology, the hospital industry looked to reduce labour costs through the 1990s. Nursing work and compensation were restructured[xxxvi], undoing the gains made by nurses and their unions with regard to professional autonomy and compensation. Part of the cost saving shift was the increased use of internationally trained nurses entering the US on temporary work permits and employed at inferior levels of wages and working conditions to local nurses.

Reduced professional autonomy, worsening working conditions and the overall devaluing[xxxvii] of nursing labour have been key causes of the dwindling supply of nurses in the USA and elsewhere in the world for the past several decades.

Full circle to COVID-19

The COVID- 19 pandemic has amplified the gravity[xxxviii] of the global nurse shortage. In the attempt to make up for the shortfall of nurses, Rwanda[xxxix], for instance, turned to using robots for COVID-19 screening and care delivery. These robots, another form of medical technology, are not produced in Rwanda and come at a monopoly price that is unlikely to be sustainable, to say nothing of the human touch crucial to healing and impossible to emulate.

Testing materials, N95 respirators, and ventilators are technologies that are far more crucial than robots to manage COVID- 19. All are produced by companies in the Fortune 500 and Global 500. Some have been in these lists since the 1990s, some since the early 2000s, and one since 2017.

Becton Dickinson and Danaher (the parent company of Cepheid) — ranking 187th

and 161st respectively in the US top 500 — produce reagents that are necessary to process COVID-19 PCR tests. Danaher/Cepheid reagents are designed to function only[xl] with Danaher/Cepheid diagnostic machines. Mixing and matching is not part of the design. Nor are the machines compatible with reagents made using a method provided[xli] free of charge by the World Health Organization early on in the pandemic, before Cepheid created COVID-19 PCR tests. Becton Dickinson uses the same strategy of market control for its PCR tests.

Though South Africa was among the first to procure Danaher/Cepheid's GeneXpert Systems diagnostic machines, it has not been able to access[xlii] adequate supplies of reagents. Many blame[xliii] state failure alone for delays in testing and contact tracing. Monopoly control of testing technology, however, is the more plausible, primary explanation for why South Africa — despite imposing one of the strictest, most extensive lockdowns globally — was not able to diagnose COVID-19 cases quickly enough to conduct contact tracing and stem the spread of the virus in the first wave. Peru, which was among the first in Latin America to impose a lockdown and conducted extensive testing from March, faced similar difficulty[xliv] accessing reagents to process the tests. This was a major part of Peru surpassing the USA and Brazil from May in terms of infections per 1 million population. As of mid-October, as this article goes to press, this trend has continued, with infections[xlv] of 25,900 per 1 million population in Peru, as compared to 24,057 per 1 million in Brazil, and 23,736 in the USA.

Thailand is another example. In Bangkok, three hospitals suspended testing as early as March because they had run out[xlvi] of reagents. Thailand then ramped up prevention through mass education[xlvii] and collective mobilisation as the major thrust of its COVID-19 strategy, an approach from which much can be learned. But that is another story for another time.

With ongoing innovation by non-profit bodies as well as smaller and larger companies, new testing technology is likely to emerge. Without decisive intervention, however — particularly as more waves of the virus unfold, underlining the importance of widespread testing and contact tracing — new tests are likely to fall into the same dynamics of monopoly control. An emerging example is Abbott's new rapid[xlviii] COVID-19 diagnostic test. Antigen-based and hence, less accurate than the PCR test, 120 million rapid tests will be distributed to 20 African countries through the WHO and players such as the Clinton Health Access Initiative and the Bill and Melinda Gates Foundation. These bodies have negotiated with the multinational to make available a portion of rapid tests at a lower price for a limited period while the company maintains its control of the market and continues earning monopoly profits.

The company 3M, producing medical as well as a range of other technology and ranking 103rd[xlix] in the Fortune 500 in 2020 is the largest[l] producer of N95 respirators in the USA. In early April, Kentucky state Governor Beshear[li] called on 3M to release the patent on the N95 respirator so that other companies could produce them. Shortly after, President Trump invoked the Defense Production Act to among other things, stop 3M from exporting N95 respirators and other medical devices. Later on that month, next door in Canada,

trade union and other activists called for a General Motors plant sitting idle[liii] for a year to be reopened to produce N95 respirators. Though the plant was reopened to produce masks, it was not the N95 respirators. This was undoubtedly related to the 3M patent.

Rather than releasing the patent, the CEO of 3M was quite public[liii] as early as March about the company's priority: working with large e-marketplace operators to identify and report counterfeiters and price gougers of N95 respirators and other 3M medical devices. By mid-July, 3M had filed[liv] 18 lawsuits after tracing 4,000 reports globally of fraud, counterfeiting and price gouging of its products.

Finally, Medtronic produces ventilators and technologies to treat some 40 medical conditions. It featured in the Fortune 500 from 2000[lv] to 2006[lvi], and in the Global 500 since 2017[lvii]. With the rise of COVID- 19, along with the creation of virtual training in the use of its ventilators, the company has opened a 'COVID-19 path for idea submissions' online. Medtronic's focus is securing further monopoly profit and control through pandemic-related training and innovation.

One big solution

As I have discussed in an article on Interferon 2b[lviii] and Cuba's other treatments for COVID-19, decommodified universal healthcare is the alternative to monopoly - driven healthcare ravaging countries around the globe. Not for profit production and delivery of all health related goods responding to general and specific human needs of the majority of any given country is the only means to assure quality health for all, in pandemic as well as non-pandemic times.

More concretely, decommodified[lix] universal healthcare is ecologically sound, public sector production of everything from food to psychological support, medicines to medical technology, as well as medical care. Rather than results based management and other corporate models adopted by most state owned enterprises globally in the past four decades, such public production should be designed and managed democratically by citizens, health professionals, scientists, and the range of other workers involved.

Taxation of corporations and rich individuals would be the primary means of financing decommodified universal healthcare. Due to the social importance of health related goods, and high employment potential given the extent of need in most countries, decommodified universal healthcare would constitute a significant segment of needs based, ecologically sound, nationally focused[lx] economies.

This contrasts with the narrow notion of 'universal health coverage[lxi] ' in the United Nations Sustainable Development Goals (SDGs). SDG- 3 pertains to health and embodies results based management, favouring public procurement of healthcare commodities produced for profit. In order to do this, the UN and other intergovernmental bodies encourage impoverished countries to accumulate further debt through loans from the International Partnership for Health. Rather than this, these global bodies should be supporting healthcare financing through general taxation by devising strategies to retrieve the trillions[lxii] of dollars of wealth lost

to the global majority through tax avoidance by rich individuals and corporations like the medical technology multinationals discussed here.

Amid disintegrating human as well as ecological health and a collapsing world economy, decommodified universal healthcare within needs based, nationally focused, ecologically sound production[lxiii] is central to rebuilding world society.

POSTSCRIPT TO ACCESS TO MEDICAL SUPPLIES AND DEVICES — THE LESSER KNOWN STORY OF COVID-19 AND MEDICAL MONOPOLY

https://www.southcentre.int/southviews-no-208-19-october-2020/

by Salimah Valiani
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Writing three months after original publication of my piece in SouthViews, rollout of COVID-19 vaccines has begun and 'vaccine nationalism' is only slightly more rife than the calls against it. With the focus on 'vaccine nationalism' by critical thinkers and activists, two key points revealed through the pandemic and elaborated in my October 2020 piece are missed.

First, that the underproduction of vaccines is at the root of so-called vaccine nationalism and both are systemic to monopoly capital. Only by rallying against commodified healthcare can the limited production of vaccines, masks, other medical technology and ultimately healthcare, be brought to an end. The commodification of healthcare is a reality in most countries. Rallying against it in national and subnational spaces is a path opened by the pandemic to mobilising concurrently and globally against world capitalism unlike any health issue has done previously.

Second, as Swati Thiyagarajan[lxiv] and others have argued, the extent of human incursion and destruction of the earth has exposed us to viruses with which we would otherwise not have had to interact. These viruses are powerful and able to transform themselves quicker than the conquering spirit of biomedical science. Focusing on vaccines as the primary means of preventing the spread of the novel coronavirus leaves countless people exposed to new, yet more destructive strains of the virus that are conceived while the excluded wait passively for vaccine roll-outs.

A people centred, Zero-COVID[lxv] strategy is the alternative around which it is crucial to mobilise. Such an approach to prevention challenges people to work together to eradicate the virus in their geographic spaces with the aid of popular education, grassroots target setting, decommodified testing[lxvi] technologies, tracing, and limited but strategic lockdowns that include income supports and nutritious food delivery to homes. The Zero-COVID strategy has been used successfully[lxvii]

in places like Cuba[lxviii], Vietnam and New Zealand.

If activists around the world fail to push for a Zero-COVID strategy in their local and national spaces, we risk seeing several more waves and new strains of COVID-19, further burnout of nurses and other health workers, and deeper stratification of the global health labour force already concentrated in richer countries.

* **The views contained in this article are attributable to the author and do not represent the institutional views of the South Centre, its Member States and the Agrarian South Network.**

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THE NEEDLE IN A MESS: COVID-19 VACCINATION POLICY IN INDIA AND THE LACK OF A CLEAR BLUEPRINT

Suresh Garimella[1]

The World Health Organisation (WHO) declared the spread of Covid-19 (novel coronavirus) as a global pandemic on March 11, 2020.[i] The confirmed cases were over 118000 cases and over 4000 deaths from 114 countries during the WHO's official declaration. Since then, various countries have registered a rapid surge in the number of positive cases and deaths. For more than a year, more than a hundred countries have been battling to break the coronavirus chain. More than a dozen biopharma companies have worked for several months to release a vaccine that can arrest the spread of the virus. On December 31, the WHO issued[ii] a statement confirming the validation for a Covid-19 vaccine under Emergency Use Listing (EUL) by granting emergency validation to the first company - the Pfizer BioNTech Covid-19 vaccine.

In India, the first Covid-19 immunisation drive started on 16 January 2021, with a sanitation staff[iii] from the All India Institute of Medical Sciences (AIIMS) reportedly receiving the first shot. The vaccine drive was administered for the frontline warriors (doctors/health care professionals) and the second phase of vaccine rollout started on 1 March 2021. Through a general guideline, the Ministry of Health and Family Welfare noted that the vaccine drive would be primarily for the senior citizens over 60 and those above 45 with comorbidities. The notice also mentioned that as of 24 February 2021, 12.3 million people were inoculated with the vaccine, with 10.9 million receiving the first dose and 1.4 million receiving the second dose of the vaccine. As of 12 March 2021, 28,218,457 vaccinations have been conducted, with 5,142,953 people getting two doses of the vaccine.[iv]

This paper raises a few concerns regarding India's vaccination drive and the Government of India's policy. The question it focuses on is whether India has a transparent policy on the Covid-19 vaccine. In this regard it raises question on the centre-state sharing of expenditure for the immunisation programme, showcasing how the lack of transparency in the disbursal of information is creating hurdles in the registration process for vaccination. The paper also highlights data showing that the government declared list of comorbidities is constricted.

Does India Have a Transparent Policy for Covid-19 Vaccines?

The Ministry of Health and Family Welfare (MHFW) provides a daily update on their website with the number of vaccinations conducted per day and a cumulative figure on the total number of vaccinations. The 'Cumulative Coverage of Covid-19 Vaccination' gives a list of doses administered to the beneficiaries with a state-wise break-up.

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However, the data does not indicate any other essential information regarding the composition of the beneficiaries. For example, there is no information regarding how many health workers - doctors, nurses, or the Accredited Social Health Activist (ASHA) and *Anganwadi* workers have received the vaccine to date.[v]

Under the Universal Immunisation Programme, the Centre is supposed to bear 60 per cent of the immunisation expenditure while the states are to pay the remaining 40 per cent. However, there is no clarity about what the sharing between the Centre and States would be specifically for the Coronavirus Immunisation programme. In the first and second phases of the vaccination, the Union Government has borne the vaccines' costs. However, government policy does not have a clear roadmap as to how to administer the procurement of vaccines, keeping in mind the need to vaccinate the entire India population.[vi] A report by *The Print*[vii] in early December 2020 quoting a senior official from the MHFW indicated the vagueness involved in the procurement policy. The percentage share of expenditure on the Coronavirus vaccines procurement that would fall on the states was unclear. Such a scenario raise concerns over the State resources in catering for the population. There is no understanding of the support mechanism for the States with limited resources. Further, as noted during the lockdown, if the Centre shifts the vaccine burden entirely to the States, the situation would leave the States with meagre resources more vulnerable. It seems that an effective and transparent blueprint of the immunisation programme to arrest the spread of the deadly coronavirus is still evolving and yet to be released in the public domain.[viii]

The Process of Approval of the Vaccine - What Went Wrong?

On 2 January 2020, the two vaccines, 'Covidsheild' – developed by Oxford-AstraZeneca and prepared by Serum Institute of India (SII), and 'Covaxin' – developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR), got permission for the 'restricted emergency approval' from the Central Drug Standards Control Organisation (CDSCO). By the time the regulatory agency under the union government had given permission, the third phase of testing was in progress. Understanding this process of approval of vaccines amidst ongoing trials puzzled Indian scientists. In an interview with the *Times of India,* Dr Gagandeep Kang, the Vice-Chair of the board of Coalition and Epidemic Preparedness and Innovations expressed her anxiety over the vaccine approval process. Kang said that she has never seen something like this: where the vaccine gets approval while a clinical trial is in progress. As she put it, "either you are doing a clinical trial, or you are not. I am confused."[ix]

The All Indian People's Science Network (AIPSN), in its statement on 6 January 2021, raised "serious doubts" in consonance with the apprehensions raised by the Subject Expert Committee (SEC). In the case of Covisheld, the SII got approval even before the confirmation of results came from the Phase III trial, while in the case of Covaxin, the matter was more serious. According to the AIPSN, "[t]he SEC had called for additional data from Phase-III trials, but appears to have been pressured overnight into reconsidering its decision and giving approval the next day, albeit hedged in by many conditions. CDSCO's

Statement[x] shows that the approval is based only on Phase-I and Phase-II data on safety and immune response without any efficacy data from Phase-III trials. Top-ranking officials of the Government and ICMR have been strenuously defending this decision by stressing safety and arguing, without any evidence, that the design of Covaxin might make it more effective against the new UK mutation. The opinion of ICMR, a co-developer of Covaxin, reflects possible bias and a conflict of interest, besides adding to perceptions of pressure on the regulator."[xi]

It is, therefore, clear that the Government has sidestepped procedures for vaccine approval by not providing scientific evidence. Such an act has raised concerns for many who were already under the threat of the deadly virus. It is also a violation of integrity to the scientific research and protocols set to test a vaccine before its rollout. In a hurried move to build an image merely for political gain amid its severe failures, the Union Government went ahead to risk the lives of millions of people. This has resulted in widespread confusion among the people[xii] and paved way for the spread of unscientific propaganda among the people. In the past, India has experienced issues with universal vaccination and immunisation programmes because of unscientific propaganda. For example, polio cases prevailed over the years despite vaccines' availability because of such propaganda. Many people in rural India did not take the polio vaccine as there were many confusions and superstitions attached to the vaccination.[xiii]

Several States in India have refused the use of Covaxin because the data on the clinical trials were not provided in the public domain. With the violation of procedures and protocols, one can raise questions with regards to the 22 deaths[xiv] in India after the Covid-19 vaccination, although the union health ministry had set that possibility aside.

In addition, the distribution policy set by the union government does not provide any clarity over the distribution mechanism. Besides, there is no uniformity over which vaccines are sent to the States and how many doses of each vaccine are administered to the citizens. There have been reports that consent forms were not provided to the citizens, and neither were they informed about the trails. Citizens are also yet to know if there have been attempts to study side effects of the vaccine. There are reports of people dying after taking the vaccine, though there has been no confirmation about whether the victims died because of the vaccination. The citizens of Bhopal, who have already been victims of the Great Bhopal Gas Tragedy, have been inducted into the trial process without any information regarding the trials or the deaths of the victims studied.[xv] Such a move by the government-monitored bodies are unethical and lack any sincerity and accountability to people. The lack of transparency about the clinical trials and the sheer irresponsibility of not getting consent and ensuring continuous medical check-ups have created widespread confusion, fear, and mistrust of the vaccine itself. While vaccines could be life saviour, a lack of scientific testing and evidence-based research may mean the opposite.

Registration for the Vaccine - Who Gets It?

The registration process for the vaccines is itself a process which is discriminatory. The people who want to be vaccinated have to get themselves registered

through the CoWin app or the Arogya Setu app.[xvi] The digital divide present in society has not been taken into consideration for the registration process. Reports from the recent past, during the lockdown, shows how millions of people passed through a miserable phase without having access to food, and they could not avail of the free rations that were being distributed by the Government of Delh, due to lack of access to digital devices or internet facilities.[xvii]

There have been no sincere efforts towards dissemination of information on the authority's part to reach out to the most vulnerable sections of the people with the vaccine-related updates. The middle classes or the elites who have information about the processes involved gobble up the bulk of the vaccines available. Thus, the most vulnerable populations – the large working-class people – are at a severe disadvantage. It is hard to keep a closed eye to the possibilities of further tensions. For instance, in a situation when there is a shortage of vaccines, how would a country as big as India cater to its citizens and bring all out of risk of infection? The apprehension becomes more potent when one reflects on the process of making vaccines, which would inevitably lead to a crisis when the demand for the vaccines goes high, owing to the complexities that may arise with the new stream of the virus hitting various countries. As per the present prevailing mechanism, there is a massive gap between the scale on which the vaccines are produced and the actual number of people in India.[xviii] This gap would inevitably put the sizeable poor population outside of the vaccination process. They would either be left entirely out or have to wait for years to get their vaccinations done.

Moreover, there is no information about whether the most vulnerable such as the homeless, TB patients living in the shelter homes, migrant labourers living on daily wages and the working poor such as the rag-pickers, home-based workers or the sanitation workers are included in a plan to provide vaccines.[xix]

The Government of India's publicity mechanisms is beyond appreciation. However, while it is repeatedly seen to champion the advertisement to showcase some of its schemes or propagate some of its agenda, it is almost absent in bearing the Covid-19 vaccine-related information. While a cumbersome process of registrations needs thorough assistance and supportive measures for the vulnerable sections to get registered, we witness apathy, or negligence, which is very hard to ignore. The ruling dispensation has largely ignored the digital divide prevailing in India and the upscale poverty on most occasions. A response to the question about vaccines has also to respond to the question regarding for whom it is being produced: that is, can a country be free from the spread of a virus if one of its largest contingent of people is not safe? What moral would we have as a country if we fail to care for India's most vulnerable citizens?

The Government's Narrow List of Comorbidity Conditions

The comorbidity conditions listed by the Government[xx] is very narrow and does not cover most of the ailments. As people have to prove that they have specific comorbidities to get the vaccines, this leaves most people without access to the vaccines despite having severe comorbidities. Several medical professionals have raised concerns on the

narrow list that leaves several high-risk patients out of the vaccination drive. Dr Giridhara Babu, an epidemiologist at the Public Health Foundation of India (PHFI) in Bengaluru, pointed out that "besides being restrictive, the focus is on people with more than one comorbidity. With each comorbidity increasing the chances of severe disease and death, focusing on people with more than one comorbidity would have been acceptable in case of a vaccine shortage. But with millions of doses of both vaccines already available in India, it is not clear why the focus is on diseases at an advanced stage."[xxi]

The discrepancies of age provided in the Aadhar card to get government scheme benefits are prevalent problems concerning a large section of the Indian population. Due to such discrepancies, people belonging to the margins remain beneficiaries on paper and not in reality. This also becomes a hurdle for the poor to get access to vaccines. The uneducated and unaware people are left on their own by the Government's process of vaccination. Again, what is the vision of a policy set to arrest a global pandemic whose vision does not cover the most marginalised people of a country? What does the policy of the Government offer to the poor people with comorbidities, and how does it guarantee hassle-free vaccinations to them?

Conclusion

A hurried projection of 'Atmanirbhar Bharat' or self-reliant India indeed is a successful move by the Government in lifting a bad image amid its successive failures to handle the Covid-19 pandemic. But in reality, a range of questions remain unanswered, which portrays a weak government image. The Government has not developed any blueprint about the vaccination process or how it plans to ensure that India's entire population is vaccinated. The Government has not cared to make a blueprint or feels there is no need to ensure transparency and share a well-chartered policy with its citizens. With disparities present in India with respect to class, region, religion, education etc., India needs a socially-sensitive approach to ensure that no one left behind or that no one will have to wait for years, leaving them vulnerable. The absence of data provided by the Government and the non-transparent way in which it is providing information about the vaccination policy raises doubts about the Government's intentions and work.

Any immunisation programme needs cohesive planning, and social realities need to be taken into consideration in making the policy. Immunisation is an essential programme for society as a whole, with health being one of the most important social indicators. Therefore, social sensitivity and concern need to be given priority and utmost importance in shaping a policy. The policy needs to be transparently shared, and wide propagation needs to be carried out to ensure that society's disparities can be overcome.

The Government's lackadaisical attitude in making the policy and the lack of importance given to ensuring that the disparities do not become a hurdle is visible. The Government should immediately make a blueprint by considering all these factors, and should be transparent by putting this information out in the public domain. The steps taken by the Government does not inspire any confidence that it is going in this direction.

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SCARCE VACCINES, UNEQUAL ACCESS AND THE USUAL DEFEATED

Evangelina Martich[1]

Since the World Health Organization (WHO) declared the coronavirus pandemic in March 2020, health systems have been forced to reorganize their services, infrastructure, human resources and supplies to focus on responding to an unprecedented demand at a certain level. But this crisis went beyond the strictly health question, spreading over the months and having an impact on politics and global economy.

From the beginning, the idea was installed that only a vaccine would be able to return world society to its "normality," and so we have been following in real time the scientific race that was unleashed. As a consequence of the pandemic situation many processes have been accelerated, shortened and/or some stages overlapped. The search for the vaccine for the Coronavirus has thus proceeded at unprecedented speed, also complying with the necessary steps to achieve good results: effective, quality and safe vaccines. Today we have 70 vaccines that are in the clinical research phase,[i] 20 that have already reached the final stages of research, and 10 that have been approved for use.[ii] Never before has a vaccine been developed in such a short time. Slowly it became possible to imagine the end of the cavalry.

The world´s biggest economies - the United States, the European Union, China, India and Russia - disputed amongst themselves this scientific race: all them wanted to make the headline of having discovered the vaccine to save us all. Deep down, they also disputed power and geostrategic positioning in a world that will undoubtedly no longer be the same.

This paper analyzes the unequal distribution of the COVID19 vaccine, focusing on the situation in low- and middle-income countries in Latin America. Possible causes of this situation are indicated, as well as the challenges faced by governments when it comes to acquiring doses and immunizing their population according to their economic resources, political capacity for international negotiation, and infrastructure of their health systems.

Scarce vaccines

The complexity and scale of the health crisis that we are experiencing means that it is not enough to discover the vaccine, but also answer the question: who

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has the capacity to produce it on a global scale? This is undoubtedly another of the great challenges, along with the logistics and adherence to massive vaccination campaigns throughout the planet to achieve group immunity.

Difficulties in accessing vaccines are directly associated with the way in which they are developed and produced. All of this is within the framework of a global Innovation and Development (R&D) model that only now, due to the magnitude of what we are experiencing and its multiple consequences, seems to show its distress:

• States allocating public money for R&D to later become clients and buyers of what they themselves contributed to developing;[iii]

• Private industries with minimum requirement of transparency who benefit from copies of public developments to finish products, patent them and thus place them on a monopolistic market structure (due to intellectual property rights);

• Researchers who reproduce the system by precarious labor conditions, amending garbage contracts and achieving some result that allow them to publish in important (prestigious) journals which increase their resumes and thus enable them obtain new funds for their projects;

• Focusing major resources on "potential profitability" of research's programs and leaving those diseases that are not "attractive" in terms of economic interest thus, often resulting in scarce or even non-existent offers of treatments; and

• In those cases where the products exist, they are often not available in the health systems due to multiple barriers, both economic and institutional, of the supply chains and deficiencies in public and private health coverage.[iv]

The above are just some of the many problems that today derive from the fact that the doses are scarce and the countries are fighting each other to obtain them. There is now talk of "vaccine nationalism," because rich countries are hoarding doses above their needs and leaving low-income countries without access.[v]

Faced with this scenario, some initiatives that seek to reverse it have emerged. Such include the proposal presented by India and South Africa in December 2020 on the World Trade Organization (WTO) to temporarily suspend intellectual property rights for diagnostics, treatments and vaccines for the Coronavirus for the duration of the pandemic,[vi] a move which would allow more companies to produce and accelerate the availability of doses and increase the speed of vaccination. The

response was as expected: most developed countries, including the United Kingdom, Canada, the United States and the European Union, are opposed to it, claiming that patents "incentivize" innovation for new treatments. The reality is that what patents do is create monopolies and block the possibility of new suppliers entering the market to compete for lower prices. Alternative initiative by WHO itself together with the Global Alliance for Vaccination (GAVI) have launched the COVAX mechanism,[vii] the objective of which is to provide diagnoses, treatments and the vaccine for COVID-19 to lower-income countries, ensuring access to the population regardless of the countries' wealth levels and their negotiating capacities.

There are alternative mechanisms such as these and others (voluntary licenses, technology transfer agreements, among others) that can help improve access. However, vaccines take time to arrive ...

Inequitable access

Much of the debate in recent months has focused on finding the vaccine for COVID-19. Now that there are already several that have proven to be safe and effective, the bottleneck has moved to another link in this complex chain through which drugs and vaccines go until they reach our hands: production. Producing vaccines to supply on a global scale is undoubtedly another of the great challenges in this crisis. Supplying the countries is becoming the new race.

Although obvious, it is worth point out that economic resources available to the countries play a central role, as well as the political, technical and strategic capacity of negotiation between producer and buyer states, and between them and the companies that produce them. The consequence of this complex network is that some high-income countries have supplied themselves while others continue to wait. General Secretary of the United Nations (UN), Antonio Gutérres has publicly stated that only 10 countries have supplied 75% of the vaccines in the world, while 130 countries have not yet received a single dose.[viii] We are faced with a completely unequal and unfair distribution, where developed countries benefit, while those countries with fewer resources continue to suffer devastating health, economic, political, social and even educational consequences. Massive vaccination of the global population, in addition to an enormous effort and challenge of production, economic and logistical is, above all, an ethical-political obligation. If countries move towards a "every man for himself" this will be increasingly complex and its

consequences more serious, because the virus will continue to expand and mutate. But there are other factors to take into account: 1) the infrastructure of the health systems themselves and their logistical organization so that the vaccines effectively reach the population; 2) available budgets (and often very limited); 3) the complex power relationships between the multiple agents that interact in the health systems of each country, and 4) the correct implementation of vaccination plans, the development of protocols that establish priorities by population and risk groups, and traceability that enable adequate recording of the vaccines applied.

Low and middle income countries

Latin America, one of the places most affected by the coronavirus pandemic, with Brazil leading the number of cases (10 million infected) and around 250,000 deaths,[ix] has also joined the unbridled race for the vaccine. However, the region is not having the same luck as developed countries in obtaining doses and immunizing their population, despite the fact that some countries have actively participated in clinical trials of the vaccine. Specific issues came mainly from large number of population with diverse demographic and epidemiological profiles; experience in clinical research, good research centers and qualified personnel; regulatory agencies with a recognized track record; low costs, and high virus circulation[x].

The vaccines most used in the region at the moment are the double-dose company Pfizer (acquired by countries such as Chile, Costa Rica, Ecuador and Mexico, while Colombia expects to start applying it at the end of February) and AstraZeneca. The Moderna vaccine has been left out of the purchase packages of Latin American countries, probably as a consequence of its high cost of around 30 dollars, with the exception of Colombia, which acquired 10 million doses. In addition, the Colombian Government went ahead with the vaccine developed by Johnson & Johnson, whose tests are still being practiced and for now shows encouraging results. The advantage of this vaccine is that it requires only a single dose.

Argentina opted for the Sputnik V vaccine from Russia, whose doses it has been receiving in a staggered manner, slowly advancing with the vaccination campaign in the country. In addition, Argentina reached production agreements with the AstraZeneca / University of Oxford company. This agreement implies that the mAbxience laboratory (belonging to the Insud Pharma group) in Argentina is in charge of producing the active

substance of the vaccine, while later in Mexico the production process is packaged and completed.[xi]

In December 2020 Brazil approved for emergency use the CoronaVac vaccine of Chinese origin and produced locally by the Butantan Institute, a public laboratory located in the State of São Paulo.[xii] In addition, the country signed two other production agreements between the state laboratory Bio-Manguinhos (Fiocruz) and the pharmaceutical company AstraZeneca, and a third agreement between the TecPar laboratory (located in the state of Paraná) and the Gamaleya institute of Russia to manufacture the Sputnik V.[xiii]

In addition to the agreements and purchases that individual countries manage to negotiate, the COVAX mechanism can be as essential for the region[xiv] as for many other middle and low-income countries. A large part of the doses would be destined for Brazil (10.7 million doses), Colombia (2.7 million doses) and Mexico (6.5 million doses).

South Africa has been perhaps the most affected when it comes to availability of vaccine doses. Strongly affected by the Conoravirus, reaching one and a half million infected and exceeding 40 thousand deaths,[xv] the government paid more than twice as much as the European Union for the Astrazeneca / Oxford vaccine, also receiving fewer doses than it needs.[xvi]

Generally speaking, low- and middle-income countries have reached agreements with pharmaceutical companies that at the moment assure them about 32% of the dose supply, being that they must immunize 84% of the global population. Meanwhile, Canada acquired vaccines to inoculate its population five times, and other high-income countries such as the United States, the United Kingdom, Australia, New Zealand and the European Union also acquired enough to vaccinate their population at least two times.[xvii]

Inequitable vaccination campaigns

At the moment, the Latin American countries that have begun to vaccinate their population are: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Panama and Peru.[xviii] Just as the quantity of vaccines acquired presents enormous differences between high- and low-income countries, in the same way there are important contrasts in the rhythm when it comes to immunizing the population.

Organizing vaccination campaigns is complex and requires great coordination efforts between different levels of government, especially in those countries where health systems are strongly

decentralized in their management. According to Our World in Data[xix] which carries out a survey of data on vaccination for COVID-19 in the world, there are important differences in this regard between countries and regions according to higher or lower income level. On the one hand is the case of Israel that has already managed to inoculate 35.5% of its population (who received a full scheme when it comes to two doses), the United States with 5.8%, Spain with 2.6% and Germany with 2.2%, while in Latin America, Argentina and Brazil are the ones that have managed to advance the most, immunized 0.6% of their population, followed by Chile with 0.3%.

Share and not accumulate

The displacement of the debate from the problem of vaccine development to the dispute for the access to it continues to reveal the unjust and unequal nature of the global system.

The expectation wasn't that pharmaceutical companies would become supportive solely because COVID-19 put the health of all humanity at risk. However, knowing which are the key actors involved and how each of them proceeds, we should ideally in the near future be able to have a global R&D model that works more adequately and with States, with greater organization and control capacity.

Meanwhile, cooperation between countries to improve access to the vaccine against COVID-19 should not be guided by criteria of charity (about whose benefits no one doubts), but mainly by epidemiological reasons. In the world in which we live, where the flow of goods and services and the (voluntary and forced) displacement of people is so intense, thinking about "every man for himself," in addition to being selfish, could be naïve, ineffective and extremely dangerous.

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