**ASIAN**
**HORIZONS**
Special Issue 1, March 2022
Pages: 32-46

# COVID-19 AND THE CHALLENGES TO MEDICAL RESEARCH

**Rahul Sima**♦

**Abstract**

At present there is no effective therapy for COVID-19 and all current therapies based on previous evidence of drugs and hypotheses and are being used with limited evidence. This applies to the vaccine as well. Researchers face huge challenges in generating high-quality data while putting scientific and ethical principles into practice in the face of restriction of movement and lockdowns. It is clear that inequalities related to social determinants of health are actually magnified during a crisis. 'Sheltering in place' does not inflict hardship equally on all people. In this article we look at the challenges to medical research from an epidemiological perspective, including data collection and patient selection, choice of drugs for research, pharmaceutical challenges including those posed by governments and vaccines, and challenges to clinical research: consent, funding and the role of the doctors.

**Keywords:** Consent Process; Covid-19; Covid-19 Vaccine; Epidemiology; Healthcare Workers;

## Introduction

In December 2019 an unheard of virus in a small region called Wuhan in China spread in the human population and the outbreak that it caused rapidly spread across the world bringing the 21st century modern world to a standstill. This unheard of virus was officially named the Severe Acute Respiratory Syndrome (SARS)

♦**Dr Rahul Sima** is a Surgeon currently pursuing his Diplomate of National Board in Vascular Surgery at Kauvery Hospital, Chennai. He also teaches post graduate surgical students. He holds other degrees in the field of medicine and hospital administration, and has published extensively in medical journals. He has a background in theology and is avidly interested in the field of bioethics. He is currently a member of the Bangalore Bioethics Forum. Email: rahulsima@gmail.com

Corona virus and the disease it caused COVID-19 (previously known as the 2019 novel corona virus) by the WHO in its briefing on 11th February 2020, because of its similarity with already known Corona virus.[1]

## 1. COVID-19 and the Unknown

The COVID-19 pandemic has been marked with uncertainties across multiple domains from nature of the virus to treatment options, alternative therapies, clinical outcomes and preventive measures. The biggest question yet is will there be a third wave?

### 1.1. The Disease/Virus

By December 31st 2019, 27 cases of pneumonia of unknown origin were reported. The virus was thought to have spread from a non-human source. On 10th January 2020 after the death of the first patient, it was found to be the Corona virus. In less than a month there were over 3000 cases and almost 100 deaths - twenty months into the pandemic the official number of deaths has crossed 4.5 million worldwide and still counting.

### 1.2. Epidemiology

The Corona virus family is large and the diseases they cause range from common cold to severe sepsis and death (as seen in the COVID-19), which was previously unheard of. These are zoonotic viruses transmitted between animals and humans.

The source and mode of transmission was initially unclear and thought to be due to contact with animals, contaminated food or person to person spread. It was only after several health care workers had contracted the disease that person to person transmission was hypothesized. We have reached the stage of community spread where one can get infected without knowing the source of transmission.

The incubation period of the virus before the onset of symptoms is still a mystery. Initially it was thought that all the cases outside China were not transmissible from person to person. We now know for sure it is transmitted mainly via airborne droplets and can be caught from an asymptomatic infected person.

We have come a long way from just naming the virus to now identifying that this virus has multiple mutant strains which are more

[1] WHO briefing of Corona virus, https://www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-the-media-briefing-on-2019-ncov-on-11-february-2020

pathogenic than the initial strains. Such altered transmissibility and pathogenicity indicates evolution of the virus.

Like other RNA viruses, COVID-19, while adapting to its new human hosts, is prone to genetic evolution with the development of mutations over time, resulting in mutant variants that may have different characteristics from its ancestral strains. Several variants have been described during the course of this pandemic, among which only a few are considered 'variants of concern' (VOC) by the WHO, given their impact on global public health. Based on the recent epidemiological update by the WHO, as of June 22, 2021, four VOCs have been identified since the beginning of the pandemic:

**Alpha (B.1.1.7):** first variant of concern described in the United Kingdom (UK) in late December 2020

**Beta (B.1.351)**: first reported in South Africa in December 2020

**Gamma (P.1)**: first reported in Brazil in early January 2021

**Delta (B.1.617.2):** first reported in India in December 2020

Despite the unprecedented speed of vaccine development against the prevention of COVID-19 and robust global mass vaccination efforts, the emergence of these new SARS-CoV-2 variants threatens to overturn the significant progress made so far in limiting the spread of this viral illness.

In India overpopulation, poor execution of a coherent containment strategy and public health policy has been blamed for the substantial number of viral mutations to persist in the environment. These highly infectious strains or variants are less affected by current vaccine responses, and is a main cause of the COVID-19 surge in India.[2]

### 1.3. Prevention

Initially only suspected patients were required to wear masks; hand hygiene was only after contact with respiratory secretions. Contact with live animals was discouraged and meat and meat products were to be thoroughly cooked. Twenty months down the line most concerned people and healthcare workers wonder if it will ever be safe again to be without masks in public.

### 1.4. Changing Perspective

Even after twenty months of grappling with the pandemic we are still far from definitively understanding all modes of transmission,

[2] J. Cohen, "The Pandemic Surge at Home is Threatening an Indian Vaccine Maker's Bid to Protect the World," *Science* (2021) (published online May 14), https://doi.org/10.1126/science.abj4746

clinical features of the disease, its severity, the extent to which it has spread or its source, and now as time progresses, the complications and long term effects of the disease.

At present there is no clear effective therapy for the disease and all current therapies are based on previous evidence either from *in vivo* studies, based on drugs that have been used for similar viral infections in the past or based on the mechanism of effect that they have on various parts of the viral structure.

At the beginning of March 2021, India entered the second wave of the pandemic and this left a staggering trail of death and suffering which unfortunately can never be measured. There was no time to stop and take stock of where we were and where we were heading. Hence medical research unfortunately is evolving alongside our understanding of the virus and its manifestation.

Currently, a variety of therapeutic options are available under FDA issued Emergency Use Authorization (EUA) or being evaluated in the management of COVID-19.[3]

-antiviral drugs (e.g., remdesivir),
-anti-SARS-CoV-2 monoclonal antibodies (e.g., bamlanivimab/ etesevimab, casirivimab/imdevimab),
-anti-inflammatory steroids (e.g., dexamethasone),
-immunomodulators (e.g., baricitinib, tocilizumab).

The late phase of the illness is driven by a hyperinflammatory state induced by the release of cytokines and the coagulation system's activation that causes a prothrombotic state. Anti-inflammatory drugs such as corticosteroids, immunomodulating agents, or a combination of these therapies can help combat this hyper-inflammatory state.

However, the efficacy of these drugs is still questionable. For example, based on results from randomized, controlled clinical trials that showed remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with mild-to-severe COVID-19 infection. The U.S. Food and Drug Administration (FDA) approved remdesivir for clinical use in adults and paediatric patients. However, results from the WHO 'Solidarity Trial' conducted at 405 centres, spanning across 40 countries, enrolling 11,330 inpatients with

[3]C.M. Coopersmith, M. Antonelli, S.R. Bauer, C.S. Deutschman, L.E. Evans, R. Ferrer, J. Hellman, S. Jog, J. Kesecioglu, N. Kissoon, I. Martin-Loeches, M.E. Nunnally, H.C. Prescott, A. Rhodes, D. Talmor, P. Tissieres, D. De Backer, "The Surviving Sepsis Campaign: Research Priorities for Corona virus Disease 2019 in Critical Illness," *Crit Care Med*. 49, 4 (Apr 01, 2021) 598-622.

COVID-19 randomized to receive remdesivir (2750) or no drug (4088) and other antivirals, found that remdesivir had little or no effect on overall mortality, initiation of mechanical ventilation, and length of hospital stay.[4] There is no data available regarding the efficacy of remdesivir against the new SARS-CoV-2 variants; however, acquired resistance against mutant viruses is a potential concern and should be monitored.

Researchers conducting such trials face huge challenges in generating high-quality data while putting scientific and ethical principles into practice in this scenario. How do we assess the situation and look at the challenges they face?

The pandemic caused restriction of movement and people were confined to their homes. This has reinforced important truths that inequalities related to social determinants of health are actually magnified during such a crisis and 'sheltering in place' does not inflict hardship equally on all people. Economic instability and unsafe housing, neighbourhood violence, lack of safe, stable child care and social support, were during this period.

Rationing of resources in the time of pandemic whether it is of ICU beds and ventilators or even a hospital bed, brought to the forefront four fundamental values which need to be kept in mind:

-maximising the benefits when there are scarce resources
- treating people equally
- promoting and rewarding instrumental value
-priority to the worst off.

It is consistent both with utilitarian ethical perspectives that emphasize population outcomes and with non-utilitarian views that emphasize the paramount value of each human life.[5]

If we look at the challenges faced by medical research in the time of the COVID-19 pandemic we have to list challenges in various phases of planning and execution of studies and trials. We look at data available and how that may totally mislead us, and the caution needed even though time is of the essence.

**1.5. Logistics for Non COVID-19 Research**

Conduct of trials and research unrelated to COVID-19 faced difficulties, due to lockdown, quarantining and travel restrictions,

---

[4]R. Zhang, E. Mylonakis, "In inpatients with COVID-19, None of Remdesivir, Hydroxychloroquine, Lopinavir, or Interferon β-1a Differed from Standard Care for In-hospital Mortality," *Ann Intern Med.* 174, 2 (Feb 2021) JC17.

[5] Samuel J. Kerstein, "Dignity, Disability, and Lifespan," *Journal of Applied Philosophy* 34, 5 (November 2017) 635-50, https://doi.org/10.1111/japp.12158

limitations on production, distribution and dispensing of the investigational product together with constraints on other critical resources like healthcare and support staff. Unavoidable protocol deviations and efforts from sponsors, investigators, needed to be made for continuing these trials.[6] In most instances enrolment into studies was stopped and efforts made to continue and complete ongoing studies. Ethical clearances are not always required before the implementation of change in protocols but needed to be reported once done.

During the second wave in India, many otherwise rare diseases or complications like mucor mycosis, also known as the black fungus, thrombosis or clots in blood vessels were reported in patients at alarming rates. In addition to focusing research on drugs and vaccines to fight the pandemic, prediction models were essential to our understanding of why specific individuals are more vulnerable to developing certain complications. By monitoring probable outcomes based on recovery individuals, we could help save millions of COVID-19 patients worldwide by providing better-prioritised treatment.[7]

Worldwide there are about 5200 registered studies on COVID-19 according to the WHO database. Thousands of retrospective and meta-analysis papers have also been published without proper scrutiny or ethical committee approval.

Papers are being released pre-print without proper peer review, and even though they are not for treatment guidance there is nothing to stop physicians from trying them based on research. This can have disastrous effects on patients.

## 2. Epidemiological Challenges

### 2.1. Data Collection

While throwing the world off balance and putting all essential services on strain, a tidal wave of data is being generated and tech corporations with modern technology are used to collect data. Data is an essential tool for understanding opinion, response, resource allocation, and treatment and also to measure the effectiveness of these interventions.

---

[6]Pankaj Kumar Panda, Martin R. Stockler, Ashish Gulia, "Clinical Research during Corona virus Disease Pandemic: Challenges and Way forward," *Indian Journal of Medical Sciences* 72, 2 (2020) 101-6, doi:10.25259/IJMS_125_2020

[7]P. Asrani, M.S. Eapen, M.I. Hassan, "Implications of the Second Wave of COVID-19 in India," DOI:https://doi.org/10.1016/S2213-2600(21)00312-X

Incomplete/incorrect data can obscure important facts. Socioeconomic realities are not accurately assessed and either a false sense of security or panic can result. There is exposure to otherwise private information without any need for it.

No data or technology in this time can provide an accurate picture, as often there is lack of expertise in the subject matter. Tech companies have more access to this data than do academic researchers.

In the Indian scenario the vast majority of data we have is from urban cities and hospitals and not much from the rural areas. Since the data being generated is mainly from government organizations, we may doubt its reliability. We still lack basic facts and do not know how many patients have symptoms, immunity after infection, or possibility of reinfection. In the absence of reliable virological testing data, we cannot know confidently what the future of this pandemic will look like and yet numbers, and statistics are being presented to governments and the public with the appearance of certainty.[8]

It is very clear that right from the actual gravity of the situation, to the number of patients and even proposed lines of treatment, no data is completely reliable. When this is the only sure fact how do we go about framing questions that need to be answered in the form or research?

**2.2. Patient/Subject Selection**

COVID-19 has disproportionate effects on various ethnic groups as many studies done in USA have shown. COVID-19 mortality rates are more than twice as high in black, Latinx and indigenous populations, revealing a strong socio-economic gradient.[9]

Members of marginalized minority and immigrant communities are known to have more coexisting medical conditions and reside in conditions that impede social distancing. Many front line jobs that cannot be done remotely like transportation, emergency response, healthcare, agriculture, etc. which are functional for society and pay near the minimum wage continue to be done by people at a higher risk. Ignorance of the realities that shape the lives of minority populations contribute to health disparities. In Europe, Indians and

[8]S. Balsari, C. Buckee, T. Khanna, "Which COVID 19 Data can you Trust?" *Harvard Business Review*, May 2020, https://hbr.org/2020/05/which-covid-19-data-can-you-trust?

[9]https://covidtracking.com/race/dashboard

other ethnic minorities have higher mortality rates when compared to the general population.[10]

Same exposure leads to more severe in some disease due to disparities structured by the conditions in which individuals are "born, grow, live, work and age."[11]Hence we cannot say that the pandemic is the great leveller—it unequally affects people.

In the Indian scenario there is a projection that mortality rates would be less because we are a younger population, and the viral infectivity is different. But we do not have any data on how the less fortunate, rural, and underprivileged are affected by the disease. The reason this is important is that for any kind of medical research into the pandemic an accurate representation of the entire population is of paramount importance. Conditions in which people live and work need to be taken into consideration.

Biomedical research must include representative populations in COVID-19 studies, and it is ethically untenable to conduct or publish studies that do not clarify if the variables being studied affect minorities differently. In the case of a pandemic, we need to talk of public health ethics and move away from ethics that arise from treatment of individual patients.

**3. Selection of Investigational Products**

New drugs are not used but already pre-approved drugs are repurposed for COVID-19 treatment. A lot of studies are being done with drugs, of which the most noteworthy are chloroquine and hydroxycholroquine which in few initial trials showed to be effective. Even before these studies were peer reviewed and published in medical journals it was publicized resulting in a worldwide frenzy to acquire the drug. For example, some of these drugs produced in India were exported to treat western population. Recent studies have shown there is no superiority in treatment of patients with hydroxychloroquine but again other researchers have questioned the method in which these studies were conducted.

More and more trials are being conducted across the globe with costly drugs out of reach to common man rather than cheaper

---

[10] https://www.indiatoday.in/world/story/Corona virus-race-income-virus-impact-discrimination-1680629-2020-05-22

[11]E.G. Price-Haywood et al., "Hospitalization and Mortality among Black Patients and White Patients with COVID-19," *N Engl J Med* 382 (2020) 2534-43; Monica Webb Hooper, Anna María Nápoles, Eliseo J. Pérez-Stable, "COVID-19 and Racial/Ethnic Disparities," *JAMA* 323, 24 (May11, 2020) 2466-2467, doi: 10.1056/NEJMp2028535.

alternatives. Secondly, in India at least such trials are mostly be conducted in urban, private hospitals, leaving out a large majority of population who would not be represented in these studies.

Remdesivir, an antiviral used for Ebola is being tried. Vitamin D and C, too have all been shown in previous studies to work in severe infections and hence as an adjunct in treating people with COVID-19.

The standard of care for critically ill in rural areas as compared to urban, and private when compared to public hospitals, varies greatly. Trials in critically ill COVID-19 patients are likely to be conducted only in private hospitals, thus depriving representation of the socio-economically disadvantaged. With lockdown and travel restrictions a truly centralized wide-based study is difficult and almost unachievable.

**4. COVID-19 Complications**

COVID-19 is now regarded as a systemic viral illness based on its involvement in multiple major organ systems. In the past 20 months we have come across a wide range of manifestations of the virus and patients with COVID-19 are at increased risk of developing prothrombotic or clotting complications, cardiac complications, bowel complications, kidney failure and mucor mycosis or the black fungus all of which are associated with an increased risk of death. Unfortunately there is no registry or adequate documentation of the magnitude of these complications.

More recent data have emerged regarding prolonged symptoms in patients who have recovered from COVID-19 infection, termed "post-acute COVID-19 syndrome." A large cohort study of 1773 patients performed 6 months after hospitalization with COVID-19 revealed that most exhibited at least one persistent symptom: fatigue, muscle weakness, sleep difficulties, or anxiety. Patients with severe illness also had an increased risk of chronic lung issues.[12]

To add to these in early 2021, a new clinical syndrome characterized by blood clots at atypical sites (brain and intestine) combined with low platelet count was observed in multiple patients days after vaccination with some COVID19 vaccine. This added to the fear of people getting vaccinated. Here also there is no clear data

[12]C. Huang, L. Huang, Y. Wang, X Li, L. Ren, X. Gu, L. Kang, L. Guo, M. Liu, X. Zhou, J. Luo, Z. Huang, S. Tu, Y. Zhao, L. Chen, D. Xu, Y. Li, C. Li, L. Peng, Y. Li, W. Xie, D. Cui, L. Shang, G. Fan, J. Xu, G. Wang, Y. Wang, J. Zhong, C. Wang, J. Wang, D. Zhang, B. Cao, "6-Month Consequences of COVID-19 in Patients Discharged from Hospital: A Cohort Study," *Lancet* 397, 10270 (16 Jan 2021) 220-232.

of its actual prevalence as documentation of these complications is grossly inadequate. If this is the case how can we work towards unbiased ethical research?

## 5. The Research Process Itself

### 5.1. The Consent Process

Obtaining a valid informed consent in a pandemic setting from vulnerable participants with impaired decision making capacity is demanding. Consent process wearing full protective gear by the investigation team makes effective communication difficult.[13] An informed consent should include information, comprehension and voluntariness. The nature and scope of the risks and benefits must be assessed in a systematic manner and these must be effectively communicated to the participants.

Most of the trials are targeted at patients with moderate to severe symptoms and the sheer urgency in initiating treatment puts the entire consent process under question. Randomization which is the gold standard of research is ethically questionable in a pandemic scenario when consent to standard of care in the placebo arm forgoes a potentially beneficial therapy. High number of serious patients presenting simultaneously, and high mortality rate make random allocation of an experimental drug to patients from within the same family or location difficult. That is ethically unacceptable. Furthermore, critically ill patients would find randomization procedure difficult to understand. It would be considered unethical and impractical to conduct randomized controlled trial (RCT) asking the patients or family members to consent to standard care when a potentially beneficial therapy is available. For example, in LOTUS China open-label RCT, families of 31 patients (8.6%) did not give consent. The WHO has planned SOLIDARITY—a large global trial of four drugs—remdesivir, chloroquine and hydroxychloroquine, lopinavir—ritonavir, and lopinavir-ritonavir plus interferon-beta. Its simple design allows the physician to recruit a confirmed case of COVID-19 after obtaining informed consent and to administer any of the four drugs locally available according to randomization prescribed by the WHO. The physicians are required to enter patient's data at the start and at outcome assessment—recovery or death, the duration of the hospital stay, and requirement of oxygen or ventilation. This could be one way in which the hurdle of randomisation can be overcome.

---

[13]Bhatt, "Clinical Trials during COVID-19 Pandemic," 59-63.

### 5.2. Funding

Current role of funding and support into research of infectious diseases, their treatments and development of low cost drugs also deserve our attention. In developing countries like India, where even the data base of how many lives are lost due to communicable diseases is lacking it is almost impossible to find how much is being spent on research and development for possible treatment. While 15% of the Indian budget is supposed to be allocated for health spending India is still at 4%.In India, public financing for health research and development is unclear and we do not know how funds have been raised and resources allocated across different needs. This is important as we have a low overall public health spending and potentially high opportunity costs of resource use. The 2016-17 health spending was estimated at 3.8% of the GDP.[14]

## 6. Vaccines

Emergence of a vaccine will build immunity and significantly reduce the socio-economic burden of the disease. There is a sound economic rationale in fast-tracking the development of a vaccine. One of the main concerns about a vaccine is the need for public confidence in its safety and efficacy.

Operation Warp Speed, is an effort by some departments of the US government together with private sector providing financial investment, scientific support, regulatory expertise and logistic assistance to deliver vaccines, therapeutics and diagnosis for SARS-CoV-2.[15]

Predicting drug performance is difficult associated with many safety problems. In spite of this, it is suggested that the necessary financial risk be taken and scaling-up of supplies of such drugs be done so as to have them on hand to be used if results are positive, instead of waiting for results of clinical trials to start large scale production.[16]

Besides the importance of imposing public health and infection control measures to prevent transmission of COVID 19, the most crucial step to contain this global pandemic is through vaccination.

---

[14]Https://nhscrcindia.org

[15]Moncef Slaoui, Shannon E. Greene, Janet Woodcock, "Bridging the Gap at Warp Speed—Delivering Options for Preventing and Treating COVID-19," *New England Journal of Medicine* 383 (2020) 1899-1901, doi: 10.1056/NEJMp2028535.

[16]Centers for disease control and prevention, "Vaccines and Immunizations," https://www.cdc.gov/vaccines/basics/test-approve.html

Vaccination triggers the immune system leading to the production of neutralizing antibodies Extraordinary efforts by clinical researchers worldwide during this pandemic have resulted in the development of novel vaccines at an unprecedented speed to contain this viral illness. As per the WHO Corona virus (COVID-19) Dashboard, more than 2.4 billion doses of vaccine doses have been administered as of 22 June 2021 with approximately 22% of the world's population receiving at least one dose of the vaccine.

At present the vaccines that are being used include:

**BNT162b2 vaccine:** Results of an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial reported that individuals 16 years of age or older receiving two-dose regimen the trial vaccine BNT162b2 (mRNA-based, BioNTech/Pfizer) when given 21 days apart conferred 95% protection against COVID-19 with a safety profile similar to other viral vaccines.[137] Based on the results of this vaccine efficacy trial, the FDA issued a EUA on December 11, 2020, granting the use of the BNT162b2 vaccine to prevent COVID-19.

**mRNA-1273 vaccine**: Based on the results of this vaccine efficacy trial, the FDA issued a EUA on December 18, 2020, granting the use of the mRNA-1273 vaccine to prevent COVID-19.

**Ad26.COV2.S vaccine**: received EUA by the FDA on February 27, 2021, based on the results of an international multicenter, randomized, placebo-controlled multicenter, phase 3 trial showed that a single dose was sufficient.

**ChAdOx1 nCoV-19 vaccine:** an ongoing multicenter randomized control trial demonstrated an acceptable safety profile and has been approved or granted emergency use authorization in many countries across the world but not yet received a EUA or approval from the FDA.

**NVX-CoV2373 vaccine:** Preliminary results from a randomized, observer-blinded, placebo-controlled, phase 2 trial in South Africa was efficacious in preventing COVID-19

In addition to the vaccines mentioned above, as many as seven other vaccines, including protein-based and inactivated vaccines, have been developed indigenously in India (**Covaxin**), Russia (**Sputnik V**), and China (**CoronaVac**) and have been approved or granted emergency use authorization in many countries around the world.

*Emergency approval for vaccines:*

Emergency Use Authorization (EUA) is a regulatory mechanism to allow the use of vaccines and medicines to prevent and/or reduce the

impact of life-threatening diseases or conditions as caused by COVID-19. However, before grant of the EUA, rigorous assessments of laboratory and clinical trial data, including data on quality, safety, production of protective antibodies and efficacy is conducted. Safety is particularly critical aspect of this scrutiny and a risk-versus- benefit evaluation is done in the context of a public health emergency. Full licensure is obtained when the manufacturer submits the complete data. EUA by Indian regulators is aligned with global guidelines. While vaccines usually require phase III trials (i.e. large scale trials in human subjects) before being approved the ministry states "Both the Indian COVID-19 vaccines have completed their Phase I & II trials. Covishield has completed its Phase III trials in UK and the bridging trial in India.

Finally, we must remember that though vast investments have been made to develop and produce vaccines, it is the act of vaccination itself that prevents disease and saves live. It is not expert committee reports but successful communication to the public that will bring this about. This brings me to the last points of who will educate the patients and instil the trust in vaccination.

## 7. Ancillary Factors

### 7.1. Pharmaceutical Companies

Nine pharmaceutical companies on 8th September 2020 took an unprecedented step to state that they would not apply for approval for a vaccine until adequate data was available.[17] This is an unusual role reversal in a time of regulatory anomalies. Companies have understood the damage that can be caused by unanticipated consequences both to their reputation and also to a population already suspicious of the vaccine and immunization. With the US FDA stating that to be approved the vaccine should show 50% or greater reduction in incidence or severity of COVID-19 against a placebo, it is unlikely that any such agent would be found in the near future. Some sources say that in the United States, the FDA guidance document stipulation of "reasonably likely to predict" protection could be demonstrated before the national election.[18]

---

[17] K. Thomas, "9 Drug Companies Pledge to 'Stand with Science' on Corona Virus Vaccines," *New York Times*, September 8, 2020, https://www.nytimes.com/2020/09/08/health/9-drug-companies-pledge-coronavirus-vaccine.html

[18] Jerry Avorn, Aaron S. Kesselheim, "Up is down—Pharmaceutical Industry Caution vs Federal Acceleration of Covid-19 Vaccine Approval," *New England Journal of Medicine* 383 (2020) 1706-1708, doi: 10.1056/NEJMp2029479.

Emergency Use authorizations need only believe that, in a public health emergency, a product's known and potential benefit outweighs its known potential risks in order to be approved. In such situations, can political pressure actually outweigh the process of science?

**7.2. Media/Government Role**

We have already said that most of the information in the current pandemic is from tech companies and government statistics. The FDA has stated time and again that there will be transparency in ensuring safety and efficacy but in a setting where everything seems to be controlled by the government and media is this a possibility? Medical research should have complete and easy access to such data; how much of this is actually available?

Social media is today flooded with misinformation and surveys and studies show only about fifty percent of Americans willing to take the vaccine. Global health policy is usually guided by the WHO and with the USA withdrawing from it the uncertainty has increased.[19]"Vaccine nationalism" is a term being used to refer to deals being struck between powerful countries and manufacturers to get major and initial doses of vaccine.

*Challenges in government policy:*

India for a period of time had the highest number of daily cases than any other country in the world and the lockdown imposed during the first wave and a wide variety of administrative barriers affected the co-ordination among the state, centre and national institutes and contributed to the inadequate response to COVID-19 during the second wave.

India is a country with a huge population with regional variations in health literacy, health care inequity, and poor risk perceptions among the general people [2]. There is a challenge to vaccinate the whole population even though the country has the largest vaccine-producing units.

Large scale unpreparedness and a possibility large scale misinformation both from the government and media were some important factors that led to severe consequences in the form of spiralling cases, reduced supplies of essential treatments, and increased deaths particularly in the young population. Understanding why the second wave has been more dangerous than

[19]https://www.livescience.com/trump-exits-who-united-states.html

the first could help to identify the potential areas of diagnostics to target in future control strategies.

### 7.3. Role of Healthcare Workers

Healthcare delivery for the future, COVID 19 diagnostics, therapeutics and vaccines are being developed at pandemic speed. Technology is being used more and more for various procedures and processes from triage to prognostication and bed allocation. Demand for healthcare workers has increased from 2 to14 times and increasing technology without adequate staff is unlikely to succeed.[20]

Until most of the world's population gets vaccinated against this illness, COVID-19 will continue to remain a threat to global public health with the emergence of potentially treatment-resistant variants.

Continued viral surveillance of new variants is crucial at regular intervals with viral genomic sequencing given the possibility that more highly transmissible, more virulent and treatment-resistant variants could emerge that can have a more catastrophic effect on global health.

From personal experience it is clear that the personal "touch" of a healer has been reduced to being almost non-existent. When doctors are the ones to influence decisions of patients and relatives this is a practical challenge that the shielded, muffled "warrior" has to face.

## Conclusion

The process of research and the steps that will ultimately lead to the developing of a successful treatment and vaccine cannot be seen as the end of the fight. Having treatment and a vaccine does not end the pandemic or our striving to a better, healthier world. It is an ongoing effort that must challenge us to evaluate the motives behind every action whether is it in prevention, diagnosis, treatment and most importantly research that should lead to these changes.

[20] Eli M. Cahan, Lisa B. Levine, William W. Chin, "The Human Touch—Addressing Health Care's Workforce Problem amid the Pandemic," *New England Journal of Medicine* 383 (2020) e102, doi: 10.1056/NEJMp2020962.