

COVID-19 Vaccination and the Ethics of Global Health

Luxi (Lucy) Yu

Author Bio:

Luxi (Lucy) Yu is a 16-year-old rising senior at Boston Latin School where she is actively engaged in many clubs and extracurriculars, such as Science Olympiad, Red Cross, Dance Club, and the Boston Latin Fencing Team. Outside of school, she enjoys playing the violin, running a Youtube music channel, and spending time with her pet beagle. Lucy is passionate about the intersection between Social Justice Advocacy and Healthcare. In college, Lucy hopes to study Biomedical Studies and Health Policy.

ABSTRACT

The development of COVID-19 vaccines in the face of the global pandemic has been an unprecedentedly quick process, resulting in the release of a number of new vaccines in under a year. However, the global distribution of such vaccines faces major roadblocks, especially concerning questions of equity. This paper investigates governance and procedural processes for conducting human trials and developing vaccines, with a US-centric focus; it compares different COVID-19 vaccine candidates and their attributes, and it examines challenges around COVID-19 vaccination roll-out from a global justice perspective. The paper discusses current initiatives for global distribution, such as COVAX, as well as the need for improvements further down the road. This review paper includes personal observations regarding the challenges of COVID-19 vaccination, focusing on questions of ethics and global justice. Not only do some vaccine characteristics limit global distribution (e.g. low storage temperatures), but issues such as wealth inequality and vaccine availability also present additional challenges. As seen in the 2020 pandemic, wealthy countries largely take an individualistic approach towards vaccination, thus limiting access to inoculation for underdeveloped and less wealthy countries. Although there has been significant progress in vaccine development since the beginning of the pandemic, there is still much work to be done to ensure effective roll-out in a way that promotes global justice to help boost global immunity and protect populations from the devastating effects of this virus.

Keywords: COVID-19, Governance, Global Justice, Equity, Distribution, Vaccination

Introduction

Global pandemics have devastated global populations over the course of human history, and the COVID-19 pandemic is no different. Despite the development of effective vaccine technology, this ever-changing disease continues to present a host of ongoing challenges regarding distribution and public health. Although the world has come a long way since March 2020, there is still a long way ahead and many facets to consider before the world can reach global herd immunity. This paper presents an overview of research carried out over the span of three months, focusing on COVID-19 vaccination, ethics, and the governance of public health.

Overall, this research project was designed to achieve four major goals, the first of which is an understanding of governance. To better understand the technical procedures of vaccine development, the first goal sought to explore the legalities and guidelines surrounding clinical trials. The analysis of these procedures was then expanded to further understand which COVID-19 vaccines had either already undergone, or were being subject to, such guidelines. This meant understanding which vaccines were on the market, which phase of development they were in, as well as their various characteristics. The next major goal was to take a more global perspective by examining the various roadblocks or challenges to distributing said vaccines after approval. Last but not least, the fourth and final aim was to research and understand the barriers surrounding global justice, or why these vaccines may not reach all populations equally, even after approval.

The significance of this research project is connected to the date March 11, 2020, also known as the date that the World Health Organization (WHO) declared the COVID-19 situation to be a pandemic. COVID-19 is undoubtedly a reality that the world has been living with for more than a year and has claimed the lives of more than 2.7 million people globally (*Cumulative Confirmed COVID-19 Deaths, 2021*). Thus, naturally, the topic of vaccination and reaching a solution holds a constant relevance and will continue to for the next few months or even years as the world tries to recover from the current situation. Additionally, one specific figure that contributed to an interest in this research is linked with the United States. Overall,

COVID cases in the US seemed to be on a general decline as of March 2021 (*Coronavirus in the U.S.: Latest Map and Case Count, 2020*), while global cases seemed to be rising again (*COVID Live Update, 2021*). This figure prompted further research to address not only the cause of these statistics but also what the world was doing wrong from a justice standpoint to ensure equal access to COVID-19 relief.

Before going further into an explanation of the research itself, four baseline realities of the research must be addressed to better frame the findings. The first is that there exists inequity regarding vaccine distribution in the first place. It would be ignorant to assume that this inequity is common knowledge, and yet it is something that not many people think about or even realize, especially in more wealthy countries such as the United States, which has a lot of resources compared to many other countries. Secondly, another reality is that no two vaccines are identical and that different vaccines have different advantages based on their individual distinctions (which will be explained further on). The third reality is that the world does indeed face many roadblocks in equally distributing these vaccines. Lastly, although this project looks at certain instances of distribution and social justice beyond the United States, the rest of this project adopts a largely US-centric focus for simplicity's sake.

Method

This project included a sample literature review using search engines such as Google Scholar, PubMed, and The Lancet, choosing articles to help with my analysis. When searching for sources, there was no initial date restriction due to the fairly current topic of research. However, the end date was restricted to March 31, 2021, as it would be unrealistic to try to constantly keep up with every piece of new information. Important keywords that were used to locate references included: COVID vaccines, vaccine approval, for-profit, efficacy, medical governance, medical ethics, clinical ethics, and clinical governance. Lastly, to categorize the research, a Qualitative Thematic Analysis method was employed to find commonalities between sources that guided the conclusions.

Findings

Governance

One of the first steps to understanding vaccines is to understand the basic governance and ethics of clinical research. The root of ethics and governance is to protect subjects of clinical trials as well as their communities from being harmed by the research. A big part of this is transparency and making sure that the subjects know what they're agreeing to as well as potential consequences (physical, or in their wider community) that could result from their participation. Furthermore, a major priority when talking about governance and ethics is the idea of patient consent. After the Nuremberg trials after WWII, the world needed to prevent anything so criminal from happening ever again, particularly regarding human experimentation.

In an industry as essential yet risky as clinical medicine, measures must be established to ensure the safety of participants in clinical trials as well as the general public. Even for those who may not be directly participating in the trial, due to larger potential social or cultural impacts of trials, communities are generally at risk of being adversely impacted. Specifically, in the case of America, due to a significant amount of clinical trials being outsourced to other countries with fewer regulations, this puts the participant and wider society at risk of being exploited and treated unsafely. That then is where the Institutional Review Board (IRB) comes in. An Institutional Review Board according to the Food and Drug Administration (FDA) is a "group that has been formally designated to review and monitor biomedical research involving human subjects" (Center for Drug Evaluation and Research, 2019, para.1). IRBs have jurisdiction over the approval, modification, monitoring, or in some cases the disapproval of proposed clinical research involving human participation. These decisions are made primarily to ensure the safety and protection of such subjects and are measured by the standards of ethical principles. Federal regulations include a host of different guidelines, mostly from the FDA (regarding research in the United States), the Office for Human Research Protections, and other branches of government under the United States Department of Health and Human Services (U.S. Department of Health & Human Services, 2016).

After approval by an IRB, the most widely accepted method of clinical research, called Randomized Controlled Trials (RCTs), is most often used to collect data concerning the safety and efficacy of the intervention of interest. RCTs are considered the most reliable method of research due to their ability to "minimize the risk of confounding factors influencing the results" (Akobeng, 2005, p. 840). During RCTs, research participants are randomly split into two groups, typically, either two treatment options or a treatment and a placebo, observed for a specific amount of time with all other factors being held constant. Thus, any observable differences would be able to be attributed to the difference in treatment. The reliability of RCTs can be attributed to the randomization of participants placed in each group, which can minimize the impact of participant variability on the results (Kabisch et al., 2011).

Lastly, on a more macro level, clinical research has to go through 4 different phases of clinical trials to gather data on safety and efficacy (*Types and Phases of Clinical Trials*, 2020). In the first phase, according to the American Cancer Society, the treatment is tested on "up to a few dozen" participants (*Types and Phases of Clinical Trials*, 2020). In this phase, the most important factor is whether the new treatment is safe to use on humans, this being the first few trials that are conducted on humans (*Types and Phases of Clinical Trials*, 2020). Then in the second phase, the sample group increases to a few hundred, and further research is carried out to determine safety and efficacy. Then in the third phase, the sample size increases to a few thousand, and it is also compared to standard-of-care treatment. Often, in this phase, double-blind studies are utilized to minimize biases and ensure randomization on both the conducting end as well as the subject end. After Phase III trials are completed (e.g., in the United States) with sufficient efficacy data that demonstrates an advantage, a new drug application is submitted to the FDA for approval. Finally, the fourth phase, which takes place after FDA approval, is carried out in the early stages of roll-out for additional data collection, mostly for safety surveillance.

Vaccine Candidates

Despite aiming for a unified objective, every vaccine is different and has different characteristics. In this paper, the focus is on accessibility, convenience,

and distribution. Four of the major characteristics to consider when analyzing and comparing vaccines are vaccine type, storage temperature, number of doses, and cost per dose. As for the type, there isn't much evidence of an advantage provided by certain types, but there is more of a precedent and knowledge surrounding certain types more than others. For example, regarding the new mRNA technology used in Pfizer and Moderna's vaccines, this method is relatively more novel in comparison with inactivated viral vaccines, which are a lot more commonplace. This is significant because, from a distribution standpoint, it could serve as an influencing factor that could increase vaccine hesitancy. Particularly when the Pfizer and Moderna vaccines first received emergency approval, there was an initial sentiment of skepticism among many who were wary of this supposedly "never done before" method.

Another important consideration is temperature: the lower the temperature required for vaccine storage, the harder it is to store and distribute the vaccine. This is why Astra-Zeneca is seen as a more convenient and widely distributable vaccine than Pfizer, which is required to be stored at lower than -70 degrees Celsius. Furthermore, the number of doses is also an important consideration when looking at vaccines. Only administering one dose is certainly more convenient than administering two, each a month apart, which is why the development of the J&J vaccine was almost revolutionary in vaccine production, as it only requires the administration of a single dose (Wouters et al., 2021).

The final consideration is cost, and although vaccines are generally free to the public, the cost is a vital factor, especially when looking at this from a social justice lens. Poorer countries that don't have the money to spend on vaccines naturally cannot afford more expensive vaccines without financial assistance.

Distribution

The development and approval of vaccines for use in controlling the spread of Covid-19 is undoubtedly a major step. However, it is one thing to develop vaccines, and it is another challenge to get these vaccines into the arms of people around the world. When talking about vaccine distribution and

its intersection with social justice, the critical issues are affordability, physical distribution, supply, and healthcare infrastructure (Wouters et al., 2021). Each country has varying levels of each of these components, and it is important to look at them from an intersectional perspective because vaccine distribution can only run well if every criterion is accounted for.

Currently, the premier initiative focusing on this issue is the COVID-19 Vaccines Global Access (Covax) program, which is an organization launched by the Coalition for Epidemic Preparedness Innovations (CEPI), WHO, and The Vaccine Alliance (Gavi) to serve as a platform for global vaccine allocation. Not only does this program support the research of vaccine candidates, but it also helps to provide funding for such research to benefit lower-income nations or self-operating nations that won't have access to vaccines otherwise (*COVAX Explained*, 2021). Under this Covax initiative, countries can request enough vaccines to vaccinate between 10-50% of their population. On the Covax distribution side of things, the Covax Facility, or the pooling mechanism of participating nations, concluded deals with various vaccine manufacturers to allocate doses before these vaccines were approved in their countries of production.

While the Covax Facility runs on a pooling system, a lot of Covax's money used to buy these vaccines has "been donated mostly by Western governments and charitable groups, such as the Bill & Melinda Gates Foundation" (Steinhauser, 2021, para. 2). Thus far in 2021, Covax has made deals with companies such as Johnson and Johnson, Novavax, and Pfizer. However, most of the vaccines being distributed will be AstraZeneca, which is expected to make up around a third of Covax's COVID supplies (Steinhauser, 2021). In terms of the United States, the Trump administration denied participation in the initiative. However, with the advent of the Biden administration, the United States has pledged a four-billion-dollar contribution to the Covax facilities.

Despite the benefits of Covax, wealthier countries are sometimes scrambling to buy up all the vaccines before Covax can get to them, causing rollout to slow down significantly. As summarized by Wouters et al. (2021, p.1027), "Scarcity in supply coupled with the large volumes of pre-orders made by richer countries creates challenges to achieving timely, universal access". Even if Covax were to accomplish

its goal of vaccinating 20% of every country by the end of 2021, there would still be a long road ahead to achieving herd immunity in a timely fashion (Katz et al., 2021). Although these wealthy countries think they are getting an upper hand, the reality is that no one is safe until everyone is safe, which is a call for a more unified approach that every country must heed before the world can overcome this pandemic. This sentiment is equally reflected by the Access to COVID-19 Tools Accelerator (ACT-A) initiative, in which the governments of 28 different countries came together to pledge international cooperation, agreeing that, “at a time when COVID-19 has exploited our weaknesses and divisions, we must seize this opportunity and come together as a global community for peaceful cooperation that extends beyond this crisis” (*COVID-19 Shows Why United Action Is Needed for More Robust International Health Architecture*, 2021, para. 10).

Inequalities that are present globally right now can be illustrated by a quick comparison of the United States, a very wealthy country, and Brazil, a country of similar size but less wealth. According to data from the Centers for Disease Control and Prevention (CDC, 2020), almost one-fifth of the United States population has been fully vaccinated, and about one-third of the US population has received at least one dose [at the time of writing]. This is a huge step toward overcoming COVID in the United States and stands in stark contrast to vaccination rates in Brazil. Even under the aid of Covax, at this rate, it will take Brazil more than 46 more days to vaccinate a mere 10% of its entire population (Bhatia et al., 2021), which is a huge issue for them as well as for the world’s pandemic efforts.

Although there is still a long road ahead to herd immunity, there are several steps that countries can take to lessen the current disparities in distribution. Looking forward, vaccine companies need to focus on expanding production capacity. Now that several vaccines have been proved, and many more are well on their way toward approval, it is imperative to ensure that the production process picks up speed and can be efficiently delivered to distribution sites across the world. Secondly, to promote accessibility, vaccine companies must ensure the affordability of the vaccines. According to Wouters et al. (2021): Mechanisms are needed to ensure the affordability and sustainable financing of COVID-19 vaccines in low-income and middle-income countries, which are home to about 85% of the global population and which

might lack the resources to buy adequate quantities of vaccines. Even in high-income countries, it is important to ensure access to COVID-19 vaccines for poor and marginalized populations. (p. 1025)

Similarly, governments must strive for equal global allocation as well as adopting a more global approach. Although in the short term it may appear to more wealthy countries that prioritizing their own countries over the rest of the world will lead to quicker normalcy, in the long run, this is not the case.

Eventually, as the world begins to open back up, the disparities between COVID conditions in less wealthy countries and world leaders will become an even bigger issue. This is why right now governments, as well as the private sector, must move forward together and prioritize the global community rather than individual countries that have the funds to secure large amounts of vaccines. Moving forward, governments should also secure further funding for Covax. Despite limitations, Covax is a gateway for global distribution that is opening the door for more equitable allocations to countries with less access. Lastly, governments and vaccine companies must build public trust. This means being transparent with the non-scientific community and the general public, releasing adequate information, and building confidence in the private sector.

Significance

Amid a pandemic as devastating as this, it is important to work together on a global scale to combat the virus and to protect as many people as possible, and not just in well-to-do countries, but in poorer countries as well. Although the world has come a long way since the beginning of the pandemic in terms of vaccines and solutions to the pandemic, there is still a lot of work to be done to ensure global health, justice, and immunity from the virus.

Vaccine companies have never produced or innovated vaccines as quickly as they have during the 2020 pandemic. This new speed of vaccine production is promising for the future of drug and vaccine development because from this past year, collaboration and sharing of resources have resulted in greater efficiency, which will undoubtedly benefit future drug development. While it will be future generations that are responsible for dealing with the aftermath of the pandemic, including the burden of debt, there is still much more work to be done as a society to overcome this pandemic and its lingering effects. However, if governments come together as a global society, the process will become less burdensome and more productive as a means of promoting global public health.

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