Prospectus

Industrial Scale Production of an Inactivated COVID-19 Vaccine
(Technical Topic)

The Theory of Technological Politics and Vaccine Success Considering the Racial Disparities in Healthcare
(STS Topic)

By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Socio-technical Research Problem

The Coronavirus Disease-19 (COVID-19) was declared a pandemic by the World Health Organization on March 11, 2020 (Cucinotta & Vanelli, 2020). As of November 1, 2020, there have been 46.3 million cases of COVID-19 across the globe, 1.2 million of which have resulted in death (Dong, Du, & Gardner, 2020). In addition to the severe death toll, the coronavirus has posed enormous economic, environmental, and social challenges to the entire human population. Business shutdowns due to the pandemic have led to the highest unemployment rate in the US since the Great Depression (Dadyan et al., 2020); many have struggled to afford housing and food, and have lost employer-sponsored health insurance. In order to address this pandemic, I will be designing an industrial scale vaccine production process to manufacture millions of doses of the COVID-19 vaccine to be distributed within the United States.

Many believe that the invention of a COVID-19 vaccine will yield the demise of this pandemic, but it is important to realize that a vaccine is only effective when the vast majority of the population receives the drug to create herd immunity. Herd immunity is defined as "protection from infection conferred to susceptible individuals when a sufficiently large proportion of the population is immune". The proportion of the population needed to create herd immunity from the COVID-19 disease is estimated to be 70%. (Randolph & Barreiro, 2020) Considering that racial and ethnic minority populations have disproportionate access to quality healthcare, the threshold for herd immunity will not be reached unless the significant political aspects of vaccine distribution are addressed (Lu et al., 2015). Further, the lack of adequate vaccine coverage among minority populations will only advance the social dynamics regarding power and privilege introduced by the Coronavirus pandemic. Ignoring the social aspects of this

technical solution will result in the undue suffering of racial/ethnic minorities per the COVID-19 disease.

I argue that although the COVID-19 vaccine will benefit many, a better understanding of the social problem of racism in the American healthcare system is needed to achieve herd immunity and end the pandemic. In this paper I will propose a novel process to produce a COVID-19 vaccine in an effort to solve the technical engineering problem at hand. I will also consider Langdon Winner's Theory of Technological Politics (1980) in order to gain a greater understanding of how vaccines empower certain groups over others based on race and ethnicity.

Technical Research Problem

The development of a safe and effective vaccine has become a global priority as nations struggle to slow COVID-19 disease transmission. Currently, 47 vaccine candidates are in the human trial phase of development, however, meeting the global need for billions of doses of COVID-19 vaccines is an additional challenge (WHO, 2020). This technical project aims to scale-up the production process of a promising vaccine candidate to accommodate global demand to eventually end this pandemic. The design team will focus on an inactivated (killed) viral vaccine as a solution to the pandemic.

A number of licensed vaccines on the market are created using an inactivated, or killed, virus molecule. Inactivated vaccines are used to protect against Hepatitis A, the Flu, Polio, and Rabies. (Vaccines.gov, 2020) The majority of all inactivated viral vaccines follow a similar production process. First, the virus is cultivated and grown on a substrate to produce large quantities of the disease-causing toxin (also known as antigens). (Sanders et al., 2014) A widely accepted substrate used to grow several viral vaccines is called the Vero cell line, which

continuously grows Vero cells which originate from the kidneys of the African green monkey. (Barret et al., 2009). Once the virus has been propagated, it is purified and concentrated. Then, the virus must be inactivated so it can no longer cause harm to those who receive the vaccine. Inactivation can be achieved using chemical or physical methods. Finally, safeguards must be put in place to scientifically prove the virus has been completely inactivated before being distributed and given to patients in a specific dosage. (Sanders et al., 2014)

To date, no vaccine has been approved for protection for the novel SARS-CoV-2 coronavirus which causes the COVID-19 disease. This allows the virus to rampage through almost every country on earth causing suffering and death. By redesigning the process of making inactivated viral vaccines to accommodate the SARS-CoV-2 molecule and mass producing the COVID-19 vaccine, we stand to make significant strides towards the end of this pandemic.

The design goal of the project is to create a novel production process for the inactivated virus bulk of a whole virion inactivated SARS-CoV-2 vaccine being developed by Bharat Biotech in India (Ganneru, 2020). The process will encompass upstream and downstream processing (i.e. virus cultivation, purification, concentration, and inactivation). A complete process capable of producing 200 million doses of an inactivated COVID-19 vaccine will be available as my senior research design-based thesis in May 2021. Our technical project design team will draw on the knowledge from faculty in the UVA Dept. of Chemical Engineering, including Prof. Michael King, a world-renowned expert on the COVID-19 disease, Prof. Giorgio Carta, an expert on bioprocess separation engineering, and Mr. Eric Anderson, who has guided many vaccine development design projects in his tenure at UVA since 2010.

Thus far, the team has decided to support our design using the following scientific research. Upstream processing will include a stepwise cell growth process from a cell seed train

and bioreactor to produce SARS-CoV-2 virus particles in Vero cells CCL-81 (Ganneru, 2020). Vero cells for a cell seed train will come from frozen stock and will be scaled using multiple scale-up apparatus such as NUNC cell factories. NUNC cell factories provide a platform for cell growth due to the necessity for Vero cells to adhere to a surface during growth. Post cell growth that meets the criteria for inoculation of the virus, the virus stock seed will be added to infect the Vero cells in solution (Kiesslich, 2020). The solution containing virus particles will be passed to downstream processing for purification and inactivation of the virus. The lysed cell solution will first undergo centrifugation to remove cell debris. Next, the solution will go through multiple filtration units to purify and concentrate the virus. The concentrated virus will be repeated suspended in a viral inactivation solution to kill the virus, then an adjuvant will be added to the solution to increase the inactivated virus's power to induce immunity once injected. Finally, the inactivated virus stock will be diluted to the proper single-dose volumes. Dosages currently being studied are 3 and 6 μg. (Ganneru, 2020)

STS Research Problem

The negative effects of the coronavirus have disproportionately affected racial and ethnic minority groups, specifically communities of color (George, 2020). Therefore, it is paramount that an equitable solution be made widely accessible as soon as possible. A vaccine may seem like a clear medical solution to solve the pandemic, but unfortunately the American healthcare system is deep-rooted in racism and does not equally help all people. Historically, epidemiological data has shown that racial and ethnic minorities are at greater risk of contracting seasonal and pandemic influenza, and of experiencing more negative consequences as a result, as compared to white persons (Uscher-Pines et al., 2007). Additionally, it was found that 13.8% of black people received the 2009-H1N1 vaccine compared to 20.4% of white people (Uscher-Pines

et al., 2011). In the 2019-2020 annual flu season, flu vaccination coverage was 53% among non-Hispanic white persons, 41% among non-Hispanic Black persons, and 38% among Hispanic or Latino persons. (CDC, 2020) Current studies suggest that these statistics reflect negative attitudes toward vaccination, distrust in the medical system, and perceived risk of side effects within minority communities. (Uscher-Pines et al., 2011) The worries of ethnic and racial minorities regarding American healthcare is not unfounded; a group of researchers found in 2015 that the implicit biases of healthcare providers against black, Hispanic, and dark-skinned people were significantly related to patient-provider interactions, treatment decisions, and patient health outcomes. (Hall et al., 2015) Although scholars recognize that discrepancies in disease outcome and vaccine uptake exist due to tangible evidence of racism in the American healthcare system, they do not give adequate attention to the further social division that these discrepancies cause. It is clear that good health and immunity to disease increase quality of life. By recognizing the ways in which minorities are further marginalized due to discrepancies in vaccine uptake compared to white persons, I hope to shed light on how the upcoming COVID-19 vaccine will unintentionally define social relations of power and privilege.

Langdon Winner's Theory of Technological Politics (1980) will be used to analyze this case and determine how novel drug innovations such as vaccines privilege certain populations and negatively affect others based on race and ethnicity. Technological Politics describes how particular technologies reflect and shape social relations of power and privilege intentionally or unintentionally (Winner, 1980). Ultimately, the Theory of Technological Politics will allow the reader to understand that while developing novel vaccines is imperative to preventing undue suffering and death from a disease, some communities will be excluded from vaccine uptake, therefore preventing herd immunity and magnifying the discrepancies in access to quality

healthcare for all Americans. Specifically, I will analyze the development and uptake of the Seasonal Influenza vaccine and the 2009 Swine Flu pandemic vaccine and how they affected different United States racial and ethnical populations. I will research the cost of vaccinations, number of adverse effects per patient, percentage of populations who are vaccinated, people participating in vaccine trials, and racial/ethnic backgrounds of patients to identify potential disparities of vaccine development and distribution between races within the United States. I will also research the socioeconomic trends between different races/ethnicities after the release of these two vaccines. Thus, novel vaccine technology creates a political divide between those who have access to and/or are willing to receive the vaccine versus those who do not.

Conclusion

Within the next few months, I will design a COVID-19 vaccine production process to mitigate the effects of the coronavirus pandemic currently devastating the globe. The science, technology, and society aspects of this design project, including racial/ethnic biases that exist in American healthcare and power relations created by disparities in vaccine uptake between minority groups will be researched to gain a better understanding of how these issues will affect the production, distribution, and success of the COVID-19 vaccine. In understanding the greater political implications of a COVID-19 vaccine, the results of this project will allow the reader to gain insight of how the COVID-19 vaccine can be made a more equitable solution to achieve national herd immunity and end this pandemic.

Word Count: 1770

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