A VACCINE, NOT A CURE

WHERE THERE'S A WILL THERE'S A BARRIER

A Thesis Prospectus
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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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The outbreak of the novel coronavirus disease, COVID-19, presents an unparalleled disruption to public health systems, devastating impacts on economies worldwide, and a profound loss of human life. Analysis of the genetic lineage of COVID-19 reveals the disease combines unfavorable traits of other illnesses (Jaimes et al., 2020, p. 3309). An increase in severity with comorbidity is characteristic of the first SARS virus, SARS-CoV-1 (Jaimes et al., 2020, p. 3310). The high contagiousness and delayed onset or absence of symptoms is a trademark of the human coronavirus HCoV-HKU1 (Jaimes et al., 2020, p. 3311). The latter features complicate controlling the transmission of COVID-19, but some countries are doing so better than others. Gregory Poland, the director of the Vaccine Research Group at the Mayo Clinic, reveals swift national responses are a crucial factor in controlling the spread of COVID-19 (Burki, 2020, p. 1240).

The sluggish response of the United States to the pandemic has affirmed the country's title as a global leader—in COVID-19 cases and deaths. The conditions in the U.S. are under scrutiny because countries with fewer resources have more adequately protected their citizens from the virus (Yong, 2020, p. 1). Dennis Proffitt, a recently retired UVA professor, attributes the differences in COVID-19 responses amongst Americans to two competing and equally American ideals (Proffitt, 2020, p. 1). The country's motto, "E Pluribus Unum," emphasizes that national unity can overcome obstacles (Proffitt, 2020, p. 1). Conversely, Revolutionary War cries like "don't tread on me" embody the nation's dedication to upholding individual freedoms (Proffitt, 2020, p. 1). The function of the federal government navigates between these two notions to promote the well-being and functioning of society. However, a global pandemic prompts government entities to become more restrictive. The pushback on restrictions to advocate for freedom, a lack of government planning, and increasing accommodations to make

life appear more "normal" have disengaged Americans from the problem they face (Yong, 2020, p. 27-29).

A dynamic, aggregate forecast compiled by the Centers for Disease Control and Prevention predicts the United States is on track to report between 7,300 to 16,000 COVID-19 related deaths between November 19th and December 12th without intervention (Center for Disease Control and Prevention [CDC], 2020b). A similar forecast estimates an 810,000 to 2,300,000 increase in the number of COVID-19 cases over the same period (CDC, 2020c). These projections are underestimates. The United States reported at least 843 COVID-19 related deaths on November 22nd. If 843 daily cases were the basis of calculation, the U.S. would report 25,290 new deaths by December 12th (New York Times, 2020, p.1). As the disease continues to propagate, the competition between the two paths to herd immunity advances; natural infection and vaccination.

Herd immunity is a phenomenon that occurs when disease transmission is no longer probable, protecting every member of a population regardless of individual immunity (Mayo Clinic, 2020, p. 1; Metcalf et al., 2020, p. 755). According to Kwok et al. (2020), epidemiology experts estimate at least 70% of the U.S. population have to be immune to COVID-19 for immunity to confer (p. e32). The natural infection approach to herd immunity allows the disease to spread in communities with minimal interference. This method would result in an enormous death toll, runs the risk of overwhelming health care systems, and loses standing because of the possibility of reinfection (CDC, 2020a; Mayo Clinic, 2020, p. 2). Alternatively, vaccines create immunity without causing illness. Administering 230 million doses of a vaccine instead of withstanding 230 million cases of the disease is the ideal approach (Mayo Clinic, 2020, p. 2).

The technical research aims to bridge the gap between the innovation and production of a viable vaccine through the development of a yield-driven manufacturing process. The tightly coupled STS research focuses on the limitations of full immunization in the United States to infer excluded communities from the administration of a COVID-19 vaccine. The timetable for deliverables required for the completion of both projects is presented in Figure 1.

	Fall 2020			Spring 2021		
	September	**October**	**November**	**February**	**March**	**April**
STS 4500 & 4600						
Statement of Topics						
Annotated Bib.						
RRP #2						
Prospectus						
STS Research Paper						
CHE 4438 & 4476						
Tech Prospectus						
Design Basis Memo						
Design Project						

Figure 1: Gantt Chart of Deliverables for 2020-2021 School Year: Shows the completed and upcoming coursework needed for STS 4500, STS 4600, CHE 4438, and CHE 4476 (Acquaah 2020).

A VACCINE, NOT A CURE

The design team, comprising of Aba Acquaah, Paul Imbrogulio, Mucui Lin, Kevin Macera, and Sara Richardson, will focus on an inactivated vaccine as a solution to the COVID-19 epidemic. The design goal of the project is to create a novel production process for the inactivated whole-virion vaccine developed by Bharat Biotech in India (Ganneru et al., 2020, p. 1).

General knowledge of how the body fights infections is essential to understanding how vaccines benefit the immune system. The immune system uses white blood cells, primarily those identified in Figure 2, to destroy germs, produce unique remedies to the remnants of those germs, and destroy compromised cells in the body (CDC, 2018, p. 1).

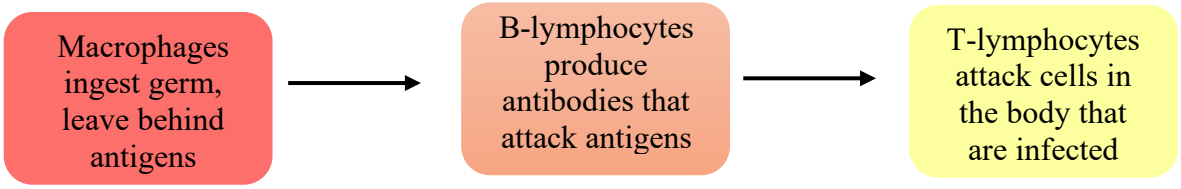

Figure 2: Visual Representation of the Immune Response: Shows the tools the immune system employs to fight infections (Acquaah, 2020).

After initial infection, the immune system promptly attacks similar antigens when they are detected (CDC, 2018, p. 1). Vaccines introduce weaker versions of viruses and bacteria into the body to trigger an immune response. More specifically, inactivated vaccines contain dead antigens (CDC, 2018, p. 1). Inactivated vaccines typically follow the three-step process laid out in Figure 3, but each step involves several stages, modified for specific pathogens.

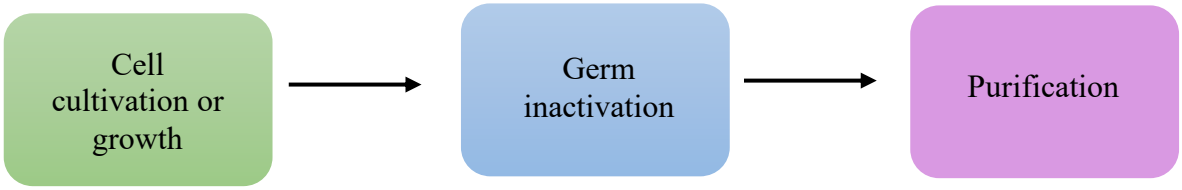

Figure 3: Schematic of Inactivated Virus Production: Reveals the general manufacturing process for an inactivated virus vaccine (Acquaah, 2020).

The process developed by the design team will encompass upstream and downstream processing. Upstream processing will include a step-wise cell growth process from a cell seed train and bioreactor to produce SARS-CoV-2 virus particles in Vero cells CCL-81 (Ganneru et al., 2020, p. 3). Kiesslich and Kamen (2020) report cells extracted from the kidney of African Green Monkeys establish Vero cell lines (p. 1). 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 serve as a platform for cell growth, a necessity for Vero cells (Kiesslich, 2020, p. 4). Low serum and low protein solution media allow for simplified downstream processing. Sufficient cell density prompts the inoculation of the mammalian cells in a

microcarrier-based bioreactor for monolayer growth (General Electric [GE], 2013, p. 110). Microcarriers are small bead-like particles allowing for Anchorage-based growth for suspended cell cultures (GE, 2013, p. 13). Adjusting agitation rate, oxygenation rate, and temperature will yield the optimal operating conditions for the bioreactor. The scale-up design includes the energy requirements and raw materials needed to sustain these conditions. The addition of virus stock seed to the reactor will infect the Vero cells in solution and cause them to burst, making cell lysing unnecessary (Kiesslich, 2020, p. 4). The solution exiting the reactor will undergo purification and inactivation in downstream processing to separate dead virus particles from the rest of the solution.

The lysed cell solution will first undergo centrifugation to remove cell debris. The supernatant will contain the virus particles, while larger cell debris will effectively pellet. The supernatant will be passed through a depth filtration system for further separation of cell debris from virus particles. Depth filtration is advantageous because traditional microfiltration allows cake accumulation in the membrane, which diminishes throughput. The optimal microfiltration method will be determined through simulation analysis. Membrane selection for either process will also follow this analysis. In either case, the principle of separation is size exclusion. The particle size of SARS-CoV-2 is approximately 50-200 nm; this value will guide filter/membrane selection (Chen et al., 2020, p. 512). The filtrate will be concentrated and further purified using an anion exchange chromatography column. Subsequently, the solution will be precipitated with polyethylene glycol and resuspended with inactivation solvent, rendering a concentrated virus stock (Hagan, 2000, p. 440). The stock will be coprecipitated with aluminum hydroxide adjuvant, allowed to settle, decanted, then resuspended again. The inactivation component utilized in the Bharat Biotech formulation is β-propiolactone (Ganneru et al., 2020, p. 14). The

company reports increased levels of neutralizing antibodies in their aluminum adjuvanted vaccines, signifying antigen immunogenicity (Ganneru et al., 2020, p. 2). Accordingly, the inactivated virus stock will be treated with aluminum hydroxide diluent to single-dose volumes. Dosages currently being studied are 3 and 6 μg (Ganneru et al., 2020, p. 2).

Monitoring of virus inactivation is essential at each step in the purification process for product safety, quality, and FDA compliance for US market distribution (U.S. Food and Drug Administration [FDA], 2019, p. 4). Inactivated virus samples will be assessed for cytopathic effects. Transmission electron microscopy (TEM) will be used to validate the intact structure and presence of inactivated virus particles. Western blot analyses will be used to characterize the identity of specific antibodies from the inactivated virus. Samples drawn from various processing stages will be probed for anti-Spike (S1 and S2), anti-RBD, and anti-N proteins, with their corresponding bands used to validate high product purity.

One drawback of inactivated vaccines is the multiple doses needed to build up or maintain immunity (Mayo Clinic, 2020, p. 2). However, the distribution of a vaccine with moderate efficacy is projected to dramatically curb the transmission of COVID-19 (Zimmer, 2020, p. 5). It is important to note that a viable vaccine will not take the place of the social-distancing measures that are in effect today, and the road to overcoming the coronavirus disease will not end once a vaccine is distributed (Zimmer, 2020, p. 5).

The design team will investigate the COVID-19 vaccine production process during the fall and spring semesters. A Design Basis Memorandum (DBM), an expository report, will be produced by the end of the fall semester, which contains a summary of the design work and the problem statement for the spring semester, as shown in Figure 1. Prior research, several provided by Lecturer Michael L. King, Department of Chemical Engineering and former Head of Science

at Merck & Company, will be the basis of design. The purification process will be modeled using ASPEN Plus software and with the recommendations of Professor Giorgio Carta, Department of Chemical Engineering.

The work will be divided into different sections and assigned according to each team member's strengths. There will be weekly meetings within the group to update the team on the progress and to ask the technical advisor, Professor Eric W. Anderson, Department of Chemical Engineering, for help on any problems that may arise.

WHERE THERE'S A WILL THERE'S A BARRIER

The effects of the pandemic have disproportionately impacted minority populations concerning race, ethnicity, age, socioeconomic status, geographic location, chronic illness, presence of a disability, and employment status (CDC, 2020a). These disparities are more pronounced in financially struggling communities, which begs the question of why a country with limitless resources is struggling so severely.

WHY IS THE UNITED STATES FAILING?

The United States accounts for four percent of the world population but a quarter of its confirmed cases as of September 2020 (Yong, 2020, p. 1). Yong (2020) concludes the coronavirus disease was able to gain a foothold because of underfunded public health research and education, an inefficient health-care system, racist policies that disproportionately impact minorities, and the shredding of the nation's social safety net (p. 2). Although the negative impacts of the pandemic affect the majority of Americans, opposition to vaccination exists.

WHAT BARRIERS EXIST TO IMMUNIZATION IN AMERICA

Anderson (2014) argues barriers to immunization comprise of system barriers, healthcare provider barriers, and parent and patient barriers (p. 345). Respectively they represent inadequate healthcare systems, improper education, and fears of immunization-related adverse effects (Anderson, 2014, p. 345).

Before COVID-19 was a thought in the minds of Americans, an anti-vaccination demographic emerged from citizens obstinate in the expression of their free will. In particular, a COVID-19 vaccine has received public resistance. Only 58% of Americans are willing to take a vaccine in November 2020, which is an improvement from earlier polls (Opam, 2020, p. 1).

The scientific method results in the constant development of accepted scientific knowledge. While this cannot be changed, measures to ensure Americans understand the practice could encourage vaccine compliance. The best courses of action for improving compliance with the Center for Disease Control and Prevention are interventions (Ventola, 2016, p. 436).

The rejection of master protocol, where all vaccine candidates compete with one another, and adoption of a harmonized approach impact the quality of the vaccine and complicate efficacy studies of pending vaccines. The master protocol, backed by Dr. Fauci, the director of the National Institute of Allergy and Infectious Diseases, entails testing vaccine candidates at once, against one another (Zimmer, 2020, p. 2-3). The idea was rejected by pharmaceutical companies because “these mega-trials pose a business risk for any given vaccine maker because they reveal how a vaccine stacks up against its competitors” (Zimmer, 2020, p. 4). This decision complicates the vaccine vetting process because it produces vaccines on a rolling basis instead of one, verified vaccine. Americans already skeptical of the information that experts distribute can be justified in their hesitation to take one when multiple versions of vaccines are on the market. A

harmonized approach, where manufacturers run their trials, and muddy F.D.A. guidelines prohibit the actual effectiveness of these drugs to be known. The small population sizes in these studies prompt unjustified causal relationships (Zimmer, 2020, p. 5). Or vaccines can underperform outside of clinical trials (Zimmer, 2020, p. 5). These intimidating results will deter prospective Americans from taking these vaccines.

Why should children be the focus?

Children do not possess the same level of autonomy as adults do in society. Additionally, they do not act on or lack a level of trust in officials, removing two factors in Figure 5. The responsibility of their welfare and health resides with their caregivers. Therefore, the medical attention they receive should depend solely on their well-being, and the well-being of their collective group. According to Ventola (2016), childhood vaccines have been one of the most effective ways to mitigate childhood morbidity and mortality (Ventola, 2016, p. 427-430).

Why this case study?

Wood et al. (1998) sought to assess the effectiveness of case management on immunization levels of African American infants residing in inner-cities (p.1). The results of this study determine the necessity and associated costs of intervention methods of this nature in a plan to mitigate vaccination non-compliance.

THE ENGINEER: THE INITIATOR

To create a COVID-19 vaccine distribution plan that compensates for the barriers that exist to full immunization, the intricacies of legislation, decisions of government entities, and the level of autonomy reserved for individuals must be analyzed, emphasized by Figures 4 and 5. The engineers and the vaccines they develop for the public are impacted by social groups that influence the production and demand for a vaccine. Accordingly, the Social Construction of

Technology (SCOT) approach recognizes technology as a social construct and technological development as a social process (Pinch & Bijker, 1984, p. 399-441). Interpretive flexibility, the idea that an artifact can mean different things to different social groups, and the ongoing development of technology are fundamental to the SCOT approach (Kline & Pinch, 1996, p. 766).

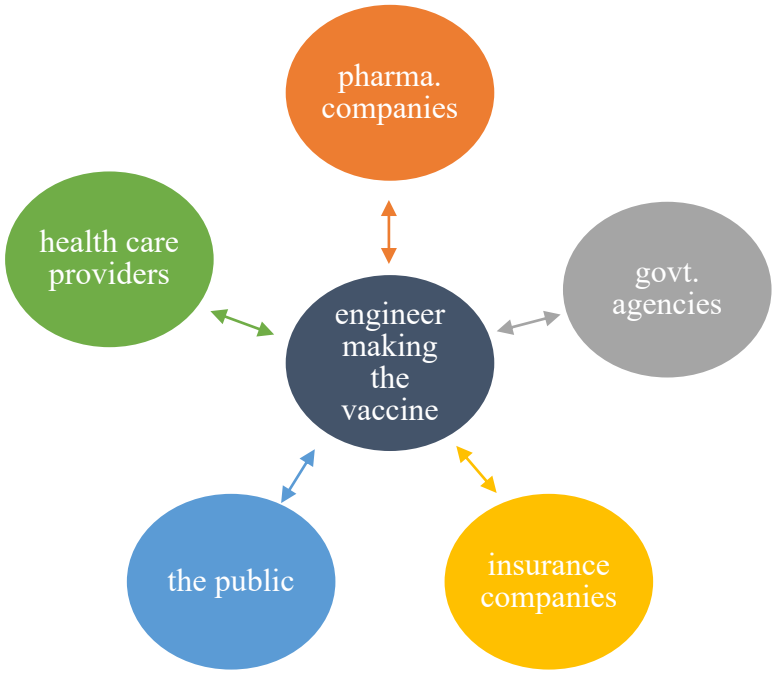

Figure 4: Social Construction of Vaccinations: The engineer does not impact the diffusion of the vaccine produced but they are necessary to allow the social groups to plan what to do with the artifact once it is developed. The engineer and the vaccine serve as a connection between pharmaceutical companies, healthcare providers, government agencies, insurance companies, and the public (Adapted by Aba Acquaah 2020 from W. Bernard Carlson 2009).

To pharmaceutical companies, the development of a vaccine is a potential source of revenue and distinction, the methods they use to create the vaccine impact its efficacy and formulation. To government agencies, a vaccine is a necessity to promote societal well-being and functioning. Their decisions hold other social groups accountable to facilitate immunization. Insurance companies decide whether or not a COVID-19 infection is a pre-existing condition, impacting the finances of those who contract the disease and increasing the popularity of vaccination for those who don't want their plans or potential plans to change. Healthcare

providers influence the popularity of vaccines by administering the ones they prefer to their patients. Ultimately, the public determines the extent of immunization in a community, impacting trends of supply and demand. This reliance on public interest requires a deeper understanding of the influencers of immunization compliance.

Expanding the Current Social Construction of Vaccinations Model

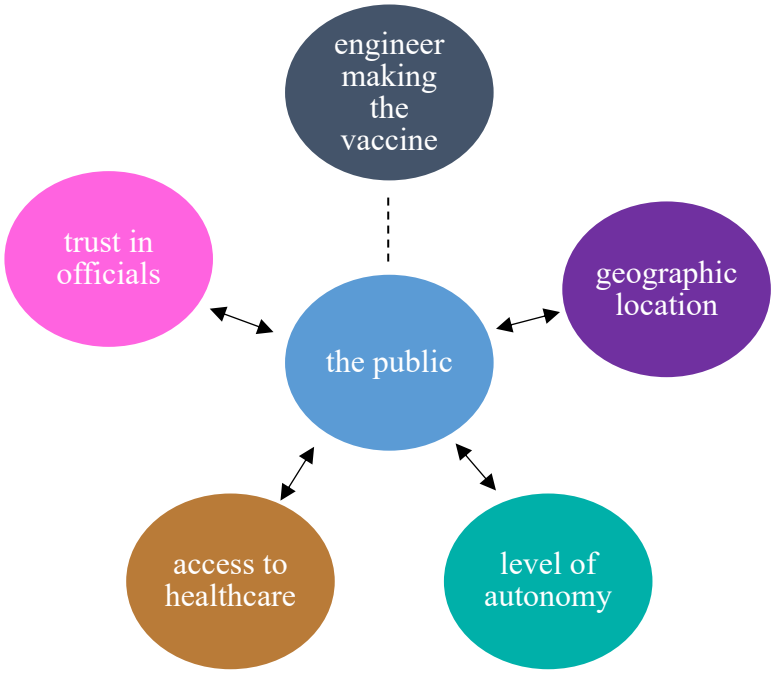

Figure 5: Social Construction Vaccinations: Updates the current model to account for the difference contexts recipients of the vaccine live in. The engineer and vaccine are still fundamental to connecting the public with other social groups, but the characteristics of the public alter how a vaccine is viewed (Adapted by Aba Acquaah 2020 from W. Bernard Carlson 2009).

In the updated model, the geographic isolation of some members of the public could require vaccine formulations to be more durable. Plans to achieve full immunization need to inquire about public access to and individual inclination towards vaccines and champion flexible formulations. The STS research project will be a scholarly article relating the barriers that undermine the full immunization of low-income, African American children in Los Angeles, CA to serve as a basis for a plan to immunize marginalized communities. Expansion of this plan to promote immunization in other American regions and middle and low-income countries can be the aim of future research applications.

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