

Thesis Portfolio

Novel Design of the RTS,S Malaria Vaccine Process Train Employing Single Use Systems

(Technical Report)

Vaccines, Politics, and Logic: Why Science Failed to Quell the Antivaccination Movement

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

In 2018 alone, about 228 million people contracted malaria, and 405,000 were killed by malaria (World Health Organization, 2018). There are a few different types of drugs used to treat malaria once infected, but the parasites that cause the disease are quickly becoming immune to most of them. Although new treatments are constantly being researched and developed, progress is often hindered parasite evolving drug resistance. Therefore, scientists are now looking into more preventative measures, such as vaccination, to combat the spread of malaria. In July 2013, GlaxoSmithKline's (GSK) malaria vaccine, Mosquirix, was approved by the EMA for use in Sub-Saharan Africa, particularly in babies aged 6 weeks to 17 months. The technical portion of my thesis is a design for a Mosquirix pilot plant to be built onto another GSK facility in Belgium. The facility will produce enough doses to fully vaccinate 3,500,000 babies per year. While the technical portion of my thesis focuses on producing the vaccine, the STS research portion discusses the reasons why some people may resist taking the vaccine. Since so much scientific literature has been written debunking the connection between vaccines and autism, my STS research paper discusses how effective that literature was at convincing the general public of the safety of vaccines, and details many other reasons why they may be apprehensive to vaccination.

In the technical portion of my thesis, my team designed a Mosquirix vaccine pilot plant intended to provide the Mosquirix vaccine for 3,500,000 babies in Sub-Saharan Africa. This pilot plant is a part of GlaxoSmithKline's (GSK) Mosquirix trial, which will provide the vaccine to seven Sub-Saharan African countries. My team assumed a 50% penetration rate, with a total annual birth rate of 7,000,000 babies in the seven countries, to arrive at an annual production rate of 3,500,000 vaccines (UNICEF, 2018). The manufacturing process involves fermenting

Saccharomyces Cerevisiae, baker's yeast, in a 1,000 Liter reactor. The yeast is genetically modified to overproduce a particle (RTS,S) that induces an immune response to the malaria virus, which is the active ingredient in Mosquirix. The yeast then undergoes various purification processes, such as homogenization, ultrafiltration, and chromatography, to isolate and purify the RTS,S antigen. The purified product is then filled into vials and lyophilized, or freeze dried, to ensure the antigen lasts long enough to be administered.

In my STS research paper, I determined and analyzed many of the reasons why people may be opposed to vaccination, and determined if the outpouring of scientific literature refuting the connection between the MMR vaccine and autism was effective at convincing people that vaccines were safe. I determined that the scientific papers refuting the connection between the MMR vaccine and autism were not the most effective method in persuading people of the safety of vaccines. People have many other reasons for avoiding vaccines, such as political or religious reasons. Many people also fall victim to a number of logical fallacies, such as omission bias, the anecdotal fallacy, and confirmation bias. My research indicated that other methods besides publishing scientific literature must be done to curb the antivaccination movement.

Although I could have chosen to work on the projects above separately, I chose to complete them simultaneously I thought that each project would put the other project into perspective. I was correct. Designing a factory that manufactures vaccines allowed me to learn exactly how many safety precautions are designed into a normal vaccine manufacturing process so that they are not harmful. Each vaccine batch is filtered at least a dozen times throughout the process, and each critical quality parameter is measured at each step throughout the process. In addition, the regulations regarding the manufacture of pharmaceuticals are extremely stringent. I believe that every person who is exposed to the vaccine manufacturing process would be

persuaded of their safety and efficacy. In addition, researching reasons why people may be opposed to vaccines showed me some potential limitations of the manufacturing facility. The target population of Mosquirix may have some of the same objections to vaccines as the population studied in the STS research paper: they may oppose vaccination for religious reasons, or for political reasons. The target population may even object to Mosquirix for reasons not mentioned in the research paper. I would not have had these insights about either project without working on them at the same time and analyzing them together. This shows the value of sociotechnical analysis: society and technology are always intertwined, and one cannot be analyzed without fully considering the other.

References

UNICEF. (2018). Data Warehouse. Retrieved December 10, 2019, from UNICEF DATA

website: https://data.unicef.org/resources/data_explorer/unicef_f/

World Health Organization. (2018). *Malaria*. WHO; World Health Organization.

<https://www.who.int/ith/diseases/malaria/en/>