AN EXPLORATORY STUDY OF THE TRANSFORMATION OF THE VALUE CHAIN AND ISSUES DURING COVID-19 VACCINE DEVELOPMENT

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ABSTRACT

During a pandemic, the time frame to develop a vaccine can shrink to merely 5-9 months. Countries are shortening the normal value chain for vaccine development to mitigate the death toll during a global health crisis. An expedited process, politics, varying distribution priorities, Phase 1, 2 & 3 testing disparities, minimal oversight, financial incentives, and a lack of transparency are all issues that impact trust and the quality of a vaccine. The value chain for developing a COVID-19 vaccine is explored along with possible ethical/quality issues that could arise during this process. Descriptive statistics, chi-square tests and results from Marascuilo pairwise comparison procedures were used to analyze surveys about trust, concerns, and vaccinations amid a pandemic. The results indicate that more respondents were worried about getting COVID-19 than getting the seasonal flu and that respondents from the US were less willing to get a COVID-19 vaccine as compared with other countries.

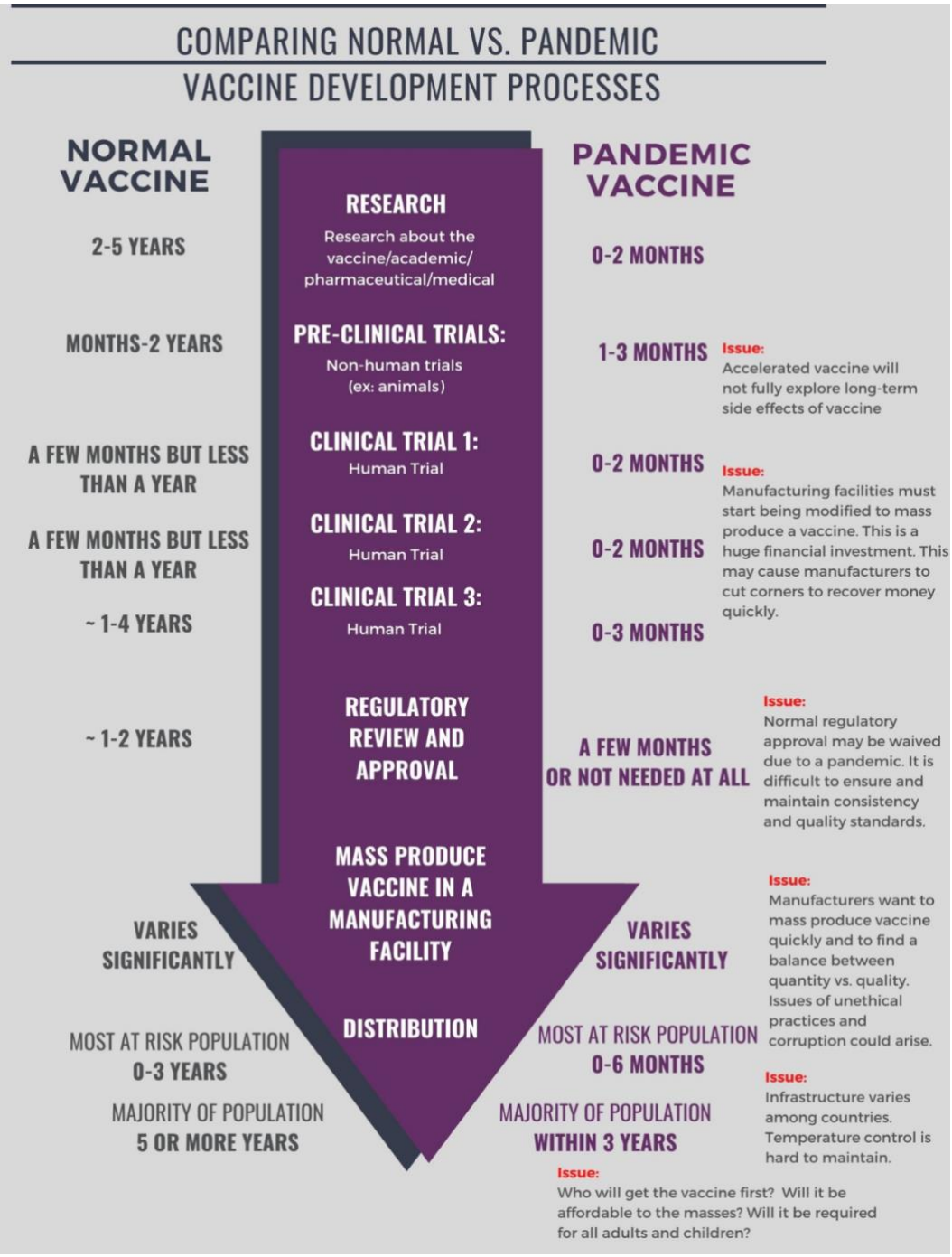
Keywords: COVID-19, Value chain for vaccines, Pandemic drug therapies, Public opinion about vaccines

INTRODUCTION

Supply chain management is a rapidly evolving field. Constant changes in the socioeconomical, political, regulatory, technological, and environmental landscape (Wieland, Handfield., & Durach, 2016) drive companies to continuously improve their processes. Optimal supply chain strategies aim to be demand driven, reduce costs, eliminate waste, and incorporate just-in-time practices (Baghalian, Rezapour & Farahani, 2013). A supply chain is typically comprised of a complex mix of companies and people who are tasked with getting the right product to the right customer at the right time. The supply chain for vaccines is even more complex. In addition to managing normal components of a supply chain (e.g. suppliers, manufacturers, logistics companies, distributors, retail stores), vaccines require pre-clinical trials, three clinical trial phases and a regulatory review process. The supply chain for vaccines also involves effectively storing vaccines, managing the inventory, meeting rigorous temperature control requirements in the cold chain as well as maintaining adequate logistics management information systems (World Health Organization, 2016). The distribution process requires meticulous management and logistics support, forecasting the vaccination schedule, and utilizing various logistics tools currently used with the World Health Organization.

In our research, we discuss the typical value chain for vaccine development. We compare this ordinary process to the projected value chain amid the COVID-19 pandemic. Figure 1 shows the normal process to develop and distribute vaccines to the public as compared with the current trajectory for COVID-19. The major difference is the expedited time frame that shrinks from 5-10 years to merely 5-9 months during pandemics. We also discuss issues which commonly arise during an expedited vaccine development process. As we highlight these issues, we attempt to

Figure 1. Displays the timeline to develop a vaccine normally vs. during a pandemic.



gain insight about the varying attitudes concerning vaccines during a pandemic. In the final part of our paper, we peruse several surveys about different pandemics to better understand respondents' knowledge about contraction, confidence in the government and vaccination attitudes. While we do not attempt to ascertain causation/correlation for these varying survey responses, we do want to explore if there are noticeable differences in the responses depending on the type of pandemic or country.

This paper is organized as follows: Section 2 outlines the value chain for vaccine development. Section 3 highlights possible ethical and quality issues that could arise during the pre-clinical trials, Phase 1, 2 and 3, regulatory approval, mass production, storage, or distribution stages for developing a COVID-19 vaccine. In section 4 several surveys about concerns, trust and vaccines during a pandemic are explored and analyzed. Finally, in section 5 the conclusion and future research directions are discussed.

VACCINE DEVELOPMENT

Vaccine Development for Past Pandemics

Vaccines are used to protect adults and children from serious illnesses or complications related to preventable diseases. Typically, vaccines undergo stringent development and testing protocols to ensure that a safe and effective drug is distributed. US vaccine manufactures must attain a license to develop the vaccine and face reviews by the National Vaccine Program, the Advisory Committee on Immunization Practices (ACIP) and other key vaccine committees (Centers for Disease Control and Prevention, 2018). The first vaccines were developed in the 1850s to eradicate smallpox. The success of these drugs served as the impetus behind continued research to prevent future pandemics. A measles outbreak in the 1950s led to sweeping legislative changes in the US. By the 1990's, all 50 states required children (with some religious and philosophical exemptions) to obtain certain immunizations before attending school. These mandates for school aged children highlighted issues with requiring, developing, and distributing vaccines (Malone & Hinman, 2007); these issues ranged from the research/testing procedure flaws to apparent access disparities (Centers for Disease Control and Prevention, 2018; Krosin, Klitzman, Levin, Cheng, & Ranney, 2006).

Over the past 20 years, there have been several pandemics with a significant global impact – specifically H1N1, MERS, Zika, Ebola, and SARS. H1N1 first emerged in April 2009. By September 2009 four H1N1 vaccines were developed and approved by the US Food and Drug Administration (FDA) (Centers for Disease Control and Prevention, 2020). According to the Immunization Action Coalition, "The 2009 H1N1 influenza vaccines are being produced by the same companies using the same procedures used to produce seasonal influenza vaccines. The 2009 H1N1 vaccines are exactly the same as seasonal influenza vaccines except for the strain of influenza virus they contain" (Immunization Action Coalition, n.d.). The vaccine development and approval processes were collectively 5 months, which is far shorter than the average 5-10 years that the normal vaccine process takes. In comparison, vaccines for Ebola, SARS and Zika took considerably longer to develop (Lurie, Saville, Hatchett & Halton, 2020).

Middle East Respiratory Syndrome (MERS) was first reported by health officials in Saudi Arabia in September 2012. As of December 2019, there were approximately 2500 confirmed cases of MERS reported from 27 countries. This virus is transmitted through dromedary camels to humans and occasionally through human-to-human contact. Currently, researchers in the United Kingdom and Saudi Arabia are in Phase 1 (human clinical trials) for developing a MERS vaccine (German Center for Infection Research, 2020).

In 2016, there were more than 36,000 cases of the Zika virus found in the US Virgin Islands, Puerto Rico, and American Somoa. By 2018, the vaccine was still in Phase 2 of the clinical trial (Grennell, 2018). To date, there is still not a readily available vaccine for the Zika virus. Since the number of cases has drastically dropped since 2016, there is not an urgency to develop a vaccine. Because the development process is long, cumbersome, and costly, many manufactures never recouped the money from their initial investment and are struggling for ways to streamline their methods.

Ebola outbreaks have been documented since the 1970s in sub-Saharan Africa. In 2014, Liberia, Sierra Leone, and Guinea experienced a rash of new cases and deaths attributed to Ebola outbreaks. Between 2014 and 2016 over 11,000 deaths were attributed to this virus. Ebola is transmitted through direct contact with infected blood, body fluids and surfaces. In December 2019, approximately 5 years after the onset of the global pandemic, Ervebo was approved as a vaccine for Ebola. This vaccine, developed by Merck Sharp & Dohme Corp., will be available for individuals 18 years of age or older. Ervebo consists of a live, genetically engineered vaccine that contains a protein from the Zaire Ebola virus. The FDA, "granted this application Priority Review and a Tropical Disease Priority Review Voucher under a program intended to encourage development of new drugs and biologics for the prevention and treatment of certain tropical diseases". After a 6-month review process, the FDA approved Ervebo as a safe and effective drug to prevent Ebola outbreaks (US Food and Drug Administration, 2019).

Severe Acute Respiratory Syndrome (SARS) was first discovered in Asia in February 2003. It spread to the US, South America, Europe, and other Asian countries within a few months. SARS is a viral illness that attacks your respiratory system. This airborne virus can be transmitted through small droplets of saliva -similar to COVID-19, a cold or influenza. According to the World Health Organization (WHO), 774 people have died worldwide from SARS. Seventeen years later, the vaccine is still in the developmental stage (Centers for Disease Control and Prevention, 2017).

Timelines for developing COVID-19, H1N1, MERS, Zika, Ebola, and SARS vaccines vary tremendously. The development process is significantly impacted by whether a vaccine is DNA/RNA based or a traditional one (microbial protein or inactive microbe) (Vanderbilt University Medical Center, 2020). To combat COVID-19, Moderna and Pfizer developed mRNA vaccines, while Johnson & Johnson developed a more traditional virus-based technology (VCU Health, 2021). DNA/RNA vaccines are quicker to develop because it is easier to produce DNA/RNA molecules vs. the right type of proteins needed in traditional vaccines. According to Hensley (2020), "Instead of injecting a weakened form of a virus or bacteria into the body as with a traditional vaccine, DNA and RNA vaccines use part of the virus' own genetic code to stimulate an immune response. In other words, they carry the genetic instructions for the host's cells to make antigens." As we explore the vaccine development process, it is worth noting that there are a

variety of factors (some scientific and others socio-economic) that may impact the development timelines.

Legal Implications of Vaccinations

As with any new drug therapy, people occasionally experience adverse side effects after being vaccinated. Since many vaccinations were mandated (and not necessarily wanted) in the 1980's in the US, people sought financial compensation for any complications they endured; consequently, a plethora of lawsuits against manufacturers ensued. The legal process was long, arduous, and expensive and often led to manufacturing companies shelling out an exorbitant amount of money. The government intervened and instituted the National Childhood Vaccine Injury Act (NCVIA) and the Vaccine Injury Compensation Program (VICP) in 1986.

The NCVIA formalized the process of providing financial compensation to citizens injured as a result of getting required vaccines. The act preserved a citizen's right to sue a manufacturer if federal compensation is denied or too small (Rockwell, 2017). This act also led to more transparency and information sharing; all healthcare providers are required to distribute vaccine benefit and risk information before children are vaccinated, keep written records of vaccine manufacturer names and lot numbers, enter serious health problems following the administration of the vaccine into a child's permanent record, and report any injury (or serious health problem) to the Vaccine Adverse Event System (Rockwell, 2017).

Historically, when a manufacturer paid a vaccine related claim, it would make them more vulnerable to additional lawsuits because there was an implied admission of fault and liability associated with the settlement. Hence, many companies refused to produce vaccines, to mitigate future lawsuits and liability claims. The VICP was created to provide no-fault, compensation for people experiencing adverse effects scientifically linked to vaccines. Although citizens can file a lawsuit after going through the VICP, special rules make those suits extremely difficult to win. Initially, the VICP parameters only included vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. More recently, the VICP expanded their coverage to include smallpox, trivalent influenza vaccines, and injuries to adults as well (Mello, 2007). Since vaccines that are new and/or are being licensed have historically been included in the VICP, we assume that COVID-19 vaccines in the developmental stage would also be included in this fund.

The Public Service Act authorizes the Health and Human Services Secretary to lead all public health and medical responses during a pandemic and to also declare a public health emergency (US Department of Health and Human Services, 2020). The Pandemic and All-Hazards Preparedness Act of 2006 was amended in 2019 and changed to the Pandemic and All Hazards Preparedness and Advancing Innovation Act. This act has more broad and flexible implications for response activities (US Department of Health and Human Services, 2020). The new legislation allows manufactures of pandemic vaccines to have near total immunity from civil lawsuits and claims ineligible for compensation via the VICP (Mello, 2007). Thus, we surmise that the manufacturers of the COVID-19 vaccine will have near total immunity from being legally and financially responsible for any adverse side effects.

Pre-Clinical Trials and Phase 1, 2 and 3

Several stages are required to develop an effective and safe vaccine. Initially, epidemiologists must understand the pathology behind any virus/disease before they can begin working on a vaccine. As their research progresses, scientists can start pre-clinical trials with animals. Typically, pre-clinical trials last for years until researchers can identify and mitigate adverse side effects of the drug therapies. After the pre-clinical trials, there are 3-phases which utilize human subjects to test the efficacy of a vaccine. Researchers often disagree about who should be included in the human vaccine trials (Centers for Disease Control and Prevention, 2018). Vaccine developers typically target healthy people with strong immune systems (Boyle, 2020) for the Phase 1, 2 and 3 trials. This approach could skew the results and lead developers to overestimate the efficacy of the drug therapy. Conversely, if the vaccine was administered to people with compromised immune systems, researchers run the risk of clinical trial participants being irreparably harmed or even dying. Also, children typically do not participate in the clinical trials, because there are concerns regarding their immune systems not being fully developed and their ability to tolerate possible side effects (College of Physicians of Philadelphia, 2020).

In Phases 1 and 2, the vaccine is given to humans. Phase 1 typically involves giving 20-80 healthy volunteers the vaccine to ensure that it is safe and induces an immune response against the virus. Phase 2 commonly utilizes double-blinded and placebo-controlled clinical trials of a few hundred healthy adults to ensure the vaccine is tolerable, produces the necessary antibodies and has minimal side effects. CEPI and Moderna Biotech Company began working on a COVID-19 vaccine soon after the first gene sequence was posted (CEPI, 2020; Lurie et al., 2020). CEPI is an alliance to finance and coordinate the development of new vaccines to prevent and contain infectious diseases. This company is also an international-private organization funded by the Bill and Melinda Gates Foundation, European Commission, Wellcome Trust, and the following countries: Japan, Norway, United Kingdom, Australia, Canada, Belgium, Ethiopia, and Germany (Lurie et al., 2020). Moderna entered Phase 1 of clinical trials in March 2020 and received regulatory clearance to start Phase 2 studies within two months (Park, 2020).

Phase 3 usually has several thousand participants and it provides more definitive data on the safety and effectiveness of the vaccine as well as its adverse effects (Institute of Medicine, 2003). When companies move into Phase 3, they must begin planning how the vaccine will be mass produced and distributed to the public. Essentially, this planning process occurs prior to getting regulatory approval. According to Lurie et al. (2020), "Manufacturing will need to be scaled up to commercial levels before substantial safety and immunogenicity data are available. Building manufacturing capacity can cost hundreds of millions of dollars". Time is a commodity when developing a vaccine amid a pandemic. Since companies are racing to be the first ones with a readily available vaccine that can stave off death and other complications related to the pandemic, they do not have the luxury of going through each Phase of the vaccine development process sequentially. Instead, companies work on different part of the value chain simultaneously. According to Lurie et al. (2020), "…for novel platform technologies, most of which are unlicensed, large-scale manufacturing has never been done, so facilities capable of producing large quantities of product must be identified, technologies transferred, and manufacturing processes adapted, all without knowing if the vaccine candidate is viable". Phase 3 clinical trials will be produced in a facility that will be uniquely suited for mass production once the vaccine is approved (Institute of

Medicine, 2003). As a result, manufacturers must frequently invest more than $30 million in the production facility prior to final product approval (Grabowski & Vernon, 2001).

Regulatory Approval and Mass Production

Manufacturers must obtain a product license application (PLA) and complete an establishment license application (ELA) before they can start the approval process to ascertain whether they are eligible to mass produce a vaccine. The ELA ensures that the facility, equipment used to produce the vaccine, and all personnel involved in the manufacturing process meet FDA standards (Hay & Zammit, 2002). This could be a long, costly, and laborious process that may not ultimately result in regulatory approval to produce a vaccine. There are only 5 companies that routinely supply vaccines to the United States - Aventis Pasteur, GlaxoSmithKline, Merck, Wyeth and Powderject (Rockwell, 2017). Merck and Wyeth are located in the US while Aventis Pasteur, Powderject and GlaxoSmithKline are based in Europe. Each company can potentially secure several licenses to produce vaccines. For example, while Wyeth and Merck have 16 and 13 licenses in the US respectively, seven other manufacturers have only 1 license to produce a vaccine for the COVID-19 virus (Rockwell, 2017). Since there are a limited number of manufacturers that are licensed to produce a COVID-19 vaccine, disruptions in their supply chain or production will almost guarantee shortages and a limited ability to distribute the vaccine to targeted populations. Scientists have been concerned that, "…the number of vaccine manufacturers seems to be declining as the number of single-suppliers increase" (DeBrock, 1985; Arnould & Debrock 1993).

Companies typically seek regulatory approval before mass producing a vaccine. China and Russia did not follow this normal process. In July 2020, China bypassed the clinical trial phases and began distributing their non-regulatory approved vaccine to high-risk groups throughout the country. According to the NY Times, "Three vaccine candidates are being injected into workers whom the government considers essential, along with many others, including employees of the pharmaceutical firms themselves" (Wee, 2020). Similarly, in August 2020, Russia became the first country to approve a vaccine for acute respiratory syndrome Coronavirus 2 (SARS-CoV-2). According to Burki (2020), "At the time of approval, the vaccine had not even started Phase 3 trials, nor had any results on the earlier stage trials been published." In September 2020, Phase 1 and 2 results from a study of 76 participants were released. With such as small number of participants, many question whether the vaccine is safe -especially without Phase 3 results and regulatory approval (Burki, 2020).

After a vaccine receives regulatory approval, manufacturing companies attempt to achieve a delicate balance between speed and quality to mass produce the drug. Manufacturing facilities must ensure that the vaccine is produced in a consistent manner and is free of contamination. Numerous samples must be taken in every step of the production process. Then, both internal and external laboratories must continuously check that proper quality and safety protocols are followed (Lemmens, Decouttere, Vandaele & Bernuzzi, 2016; Smith, Lipsitch, & Almond, 2011). Regulatory requirements may vary widely depending on each country's regulations; thus, it can be difficult to maintain similar manufacturing and testing processes. (International Federation of Pharmaceutical Manufacturers & Associations, 2014).

Manufacturing companies must forecast the demand for the vaccine (based on historical data and current trends) and make sure that the quality of the drug is maintained throughout the distribution process. Vaccines must be stored in regulated temperature-controlled facilities, known as cold storage units. The Cold Chain Equipment Inventory and Gap Analysis Tool is commonly used to help manage inventory. The EPI Logistics Forecasting Tool provides scenario analysis and projects multi-year forecast needs of vaccines and safe injection equipment. This tool also forecasts the cold chain and ambient storage capacities for national immunization distribution. The Immunization Supply Chain Sizing Tool is used to forecast the required cold-chain capacity at each level and facility. It takes into consideration the introduction of new vaccines, changing formulations of vaccines, elimination of vaccines, etc. (World Health Organization, 2016). Vaccine Vial Monitor Infographics and Vaccine Volume Calculators are used to monitor color changes in vials that could impact the efficacy of the drug and how national immunizations effect cold chain capacity, respectively. These tools and technologies are used collectively to maintain the integrity of the vaccines while being stored and distributed.

Manufacturers have a vested interest in mass producing vaccines quickly. Oftentimes the increase in production speed leads to decreased quality control measures. The speed of mass production is dependent on adequate machinery, labor, supply chain partner collaboration, effective communication, reliable logistics companies, machine capacity and improved technological systems (Allwood et al., 2016). A sterile and temperature-controlled environment is needed throughout the production, warehousing, and distribution process. If all temperatures are not consistent and maintained for any reason (including broken equipment, human error, and technological issues), the vaccine quality could be negatively impacted. Vaccines approved by the Food and Drug Administration (FDA) are subject to very stringent safety/quality standards and review procedures (Hay & Zammit, 2002). Each batch must be tested and approved before it can be released and distributed to the masses. If Moderna's COVID-19 vaccine does prove to be safe and effective, the company's CEO Stephane Bancel stated that, "…the company will not immediately have enough for everyone. We will all be supply constrained for quite some time, meaning we won't be able to make as many products as will be required to vaccinate everyone on the planet" (Feuer, 2020a). He stated that the company will work closely with the US government to determine who will receive the first doses In May 2020, Moderna announced that they would be partnering with Swiss Pharmaceutical company, Lonzo, to accelerate the production of the COVID-19 vaccine; they hoped to begin manufacturing in July 2020. Lonzo and Moderna are planning to manufacture approximately 1 billion doses per year (Feuer, 2020a).

Managing, Storing and Distributing a Vaccine

Many believed the FDA would manage and monitor the efficacy of vaccines distributed throughout the world. However, according to the Institute of Medicine (2003), "FDA resources for vaccine regulation have not kept pace with the growth and complexity of vaccine products. FDA regulation has shifted from a focus on science to a focus on enforcement. This shift may increase the risks and costs associated with vaccine production without increasing safety" (Institute of Medicine, 2003). If the FDA is not able to keep up with the demands and processes involved to rapidly develop a vaccine, how can people trust the effectiveness and quality of the drug?

To manage a vaccine effectively, workers need adequate training, strict process controls, and the proper equipment readily available (Lemmens et al., 2016). Vaccine management can be classified as managerial or operational. The operational functions of vaccine management include sorting the vaccines and the immunization equipment, updating inventory records and monitoring storage temperatures and other conditions. This function also includes performing maintenance duties on the cold-chain equipment, sharing challenges with management and troubleshooting ways to mitigate issues. The managerial functions of vaccine management include conducting a needs assessment, developing projections for vaccine usage, estimating equipment needs, ordering vaccine related equipment, keeping meticulous records, and providing support for workers and managers. It also includes developing a maintenance schedule for the cold-chain equipment and transportation/distribution plan for the vaccine. Many vaccines utilize a Controlled Temperature Chain (CTC) (World Health Organization, 2016). The CTC allows vaccines to be stored at varying temperatures while still maintain its antigen. A license must be attained to use a CTC. Additionally, there needs to be a vaccine vial monitor on each vial as well as a peak threshold indicator on each vaccine carrier (World Health Organization, 2016). Maintaining the cold chain from production until final consumption is an expensive and complex task that is exacerbated in warm-climate areas or developing countries (Lemmens et.al, 2016). Whether a vaccine is developed during a pandemic or not, the same steps are required to manage and store the drug therapy.

The distribution process for vaccines requires rigorous oversight, meticulous management practices, logistics support, accurate forecasting of the vaccination schedule, and utilization of various logistics tools currently used by the WHO. It is estimated that it will cost over $8 billion to distribute the COVID-19 vaccine throughout the US (Higgins-Dunn, 2020). These prohibitive costs and a lack of the proper infrastructure in many developing countries, will make the task of distributing a COVID-19 vaccine even more daunting. According to the US Department of Health and Human Services, "State health departments will distribute the doses to appropriate hospitals in their states because state and local health departments have the greatest insight into community-level needs in the COVID-19 response" (Facher, 2020). The CDC, WHO and other reputable agencies have agreed that health care personnel, other non-medical essential workers, those with high-risk medical conditions and adults aged 65 years or older should have priority and receive the COVID-19 vaccine first. Currently, there is still not a national policy that governs the distribution of the vaccine in the US (Stulpin, 2020).

TRUST, QUALITY AND ETHICAL ISSUES THROUGHOUT THE VALUE CHAIN FOR VACCINE DEVELOPMENT

From the onset of the pandemic to October 2020, over 1.1 million COVID-19 related deaths were reported worldwide. Because countries have struggled to contain the virus and mitigate the steadily rising death toll, pharmaceutical companies have been scrambling to rapidly produce a vaccine. It commonly "takes seven to ten years or more and about 1 billion U.S. Dollars" to develop a reputable and effective vaccine (Boyle, 2020). During a pandemic, normal timelines for vaccine development and testing are shortened. An expedited process, politics, varying distribution priorities, Phase 1, 2 & 3 testing disparities, minimal oversight, financial investments influencing decision making and a lack of transparency are all issues that impact trust and the quality of a vaccine.

Allwood et al. (2016) discusses how many companies prioritized production speed over more time-consuming quality-controlled processes (Allwood et al., 2016). Millions of dollars are invested in manufacturing equipment, adequate storage containers, warehousing facilities, labor hours and supplies before a manufacturer receives regulatory approval to mass produce a vaccine (Grabowski & Vernon, 2001). So, if the Phase 1, 2 and 3 trials are not completed expeditiously, this can result in a substantial financial loss. Also, because time is of the essence, some companies (and countries) skip the regulatory approval step; this step ensures that there are quality-controlled processes in place to produce a safe and effective drug (Wee, 2020). Numerous companies rushed to develop a vaccine for COVID-19 within the first year of the first known cases worldwide. Conventional thinking leads one to surmise that faster development, approval and distribution of a vaccine would translate to an increased market share. Burki (2020), Wee (2020) and OECD (2021) highlight several concerns about the hurried process. Some of these concerns, led to the following questions: 1) Are the vaccines safe and have they been tested adequately?; 2) Have the proper steps been taken to mitigate side effects?; 3) Can consumers trust that manufactures are being completely forthright about the efficacy of their vaccine given their tremendous financial investment? Ultimately, when you review articles about China giving thousands of their citizens a COVID-19 vaccine in July 2020 and Russia approving their vaccine in August 2020 without even completing Phase 3 testing, many of the aforementioned questions have merit (Burki, 2020; Wee, 2020; OECD, 2021).

In the US, there have been contentious battles between republicans and democrats for control of the legislative and executive branches of the government. Both politicians and scientists have been leading discussions about ways to combat COVID-19. Oftentimes, party affiliation heavily influences whether voters get vaccinated or adhere to suggested guidelines such as wearing a mask, social distancing, and rapid testing (Friedman, Gershon & Gneezy, 2021; Colvin & Whitehurst, 2021). In July 2020, President Trump's administration charged the US Department of Health and Human Services with collecting (and reporting) data about COVID-19. The CDC had been the premier organization tasked with researching, reporting, and leading the discussion about infectious diseases and pandemics since 1946 (Huang, 2020; Feuer, 2020b; Fox 6, 2020).

The polarizing nature of the pandemic response has led some minority groups, conservative conspiracy theorists and liberal democrats to ask the following questions: 1) How infectious is this virus?; 2) Is this virus a hoax that has been overhyped for political gain?; 3) How safe will a vaccine be?; 4) Can politicians be trusted to lead the discussion on the best practices to mitigate the impact of the COVID-19?; 5) Are the reported number of contracted cases and deaths accurate or made up for personal/political gain? A person's trust and willingness to take a vaccine is often tied to their political affiliation or race (Douglas, 2021; Ojikutu et al., 2021; Colvin & Whitehurst, 2021).

Phase 1, 2 and 3 trials are typically conducted on healthy subjects. Thus, the results may be skewed and more favorable, than if the vaccine was administered to sick or more at-risk patients. More information needs to be released about the age, ethnicity, co-morbidities, health status, gender etc. of subjects used for Phase 1, 2 and 3 trials. Initially, Russia approved their COVID-19 vaccine without releasing the results from the clinical trials; in subsequent weeks they published limited results for a study with 76 participants. The lack of transparency leads to questions about whether the clinical trial results are accurate and whether they can be trusted (Burki, 2020; Wee, 2020; OECD, 2021).

Distribution strategies and accessibility to a vaccine vary by country and region. These apparent disparities have led to questions regarding how the vaccine will be distributed and how people in rural areas will get vaccinated. World health organizations agreed that health care personnel, other non-medical essential workers, those with high-risk medical conditions and adults aged 65 years or older should receive the COVID-19 vaccine first (Stulpin, 2020). However, for the masses there is not a national policy in the US for distributing the vaccine. This uncertainty highlighted in Stulpin's (2020) and Sigalos'(2020) articles prompt the following questions: 1) Will the COVID-19 vaccine be affordable to the masses?; 2) Will wealth or socioeconomic class impact how vaccinations are prioritized?; 3) Will vaccinations be mandatory for adults and/or kids?; 4) Since VICP funds are restricted during a pandemic, how will citizens be compensated for adverse reactions to a drug if vaccinations are mandated? A contentious political climate in the US and the lack of a centralized response to the COVID-19 pandemic has eroded public trust and confidence that the government can adequately mitigate the virus (Stulpin, 2020; Sigalos, 2020).

ANALYSIS AND DISCUSSION OF SURVEYS ABOUT CONCERNS, TRUST AND VACCINES DURING A PANDEMIC

Epidemiologist were able to quickly develop a COVID-19 vaccine (within 9 months instead of 5+ years) because of how easily the mRNA molecules in the vaccine could be produced. According to Friedman et al. (2021) and Douglas (2021), many remain wary of the expedited vaccine development timeline and apprehensive about being vaccinated. Politics, the socioeconomic environment, distribution disparities and deviations from the normal development process, have led to inherent biases, fears, and concerns about the efficacy of the vaccines and the severity of the virus. These attitudes and beliefs are reflected in various surveys that capture respondents' views about contracting a virus, confidence in the government and attitudes about vaccinations amid a pandemic.

The purpose of this analysis and discussion is to review surveys about pandemics and highlight differences in the responses. The surveys in this section were retrieved between June-September 2020. Although analyzing correlating factors that impact the responses is beyond the scope of this research, the quality and ethical issues highlighted throughout this article could provide insight about why disparities exist in the survey results.

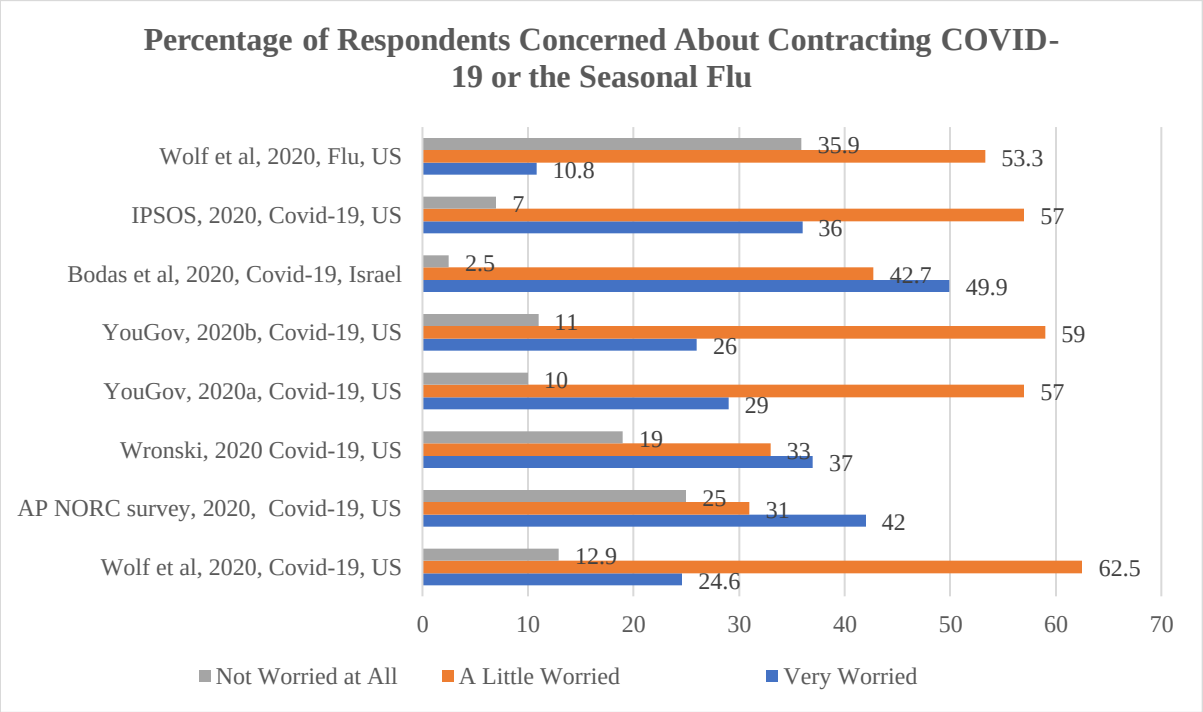
Initially, hundreds of articles were perused about surveys during pandemics over the past 20 years. Information was collected about the demographics, questions, and responses. It was challenging to compare the results for different surveys because varying Likert scales (and questions) were used and oftentimes the raw data was inaccessible. Ultimately, there were numerous questions in these surveys that could be definitively placed in 1 of the 3 groups -specifically, views about contracting a virus, confidence in the government or attitudes about vaccinations. Tables 1-3, list specific surveys about H1N1, MERS, Zika, Ebola, and SARS that have questions which fall into these three groups and have readily available data. By no means is this a comprehensive list. It is simply a snapshot of articles googled between June 2020 and September 2020. The types of questions slightly vary from article to article but the responses are still comparable.

In tables 4 and 5, the count and percentage of respondents who answered they were very worried (VW), A little worried (LW) or not worried at all (NW) about contracting COVID-19 or the

seasonal flu are listed. Since all of the surveys did not initially have these three distinct survey response categories, some categories were merged together if there were more than three possible answer choices in the original survey. Table 5 and figure 2, show that while 24.6-49.9 percent of the respondents were concerned that they (or their family members) would contract COVID-19, only 10.8 percent were worried about the seasonal flu. Most people were only moderately concerned about contracting either of these viruses. In order to further explore whether there was a significant difference in the proportion of respondents who were very worried about contracting these viruses, a chi-square test was conducted; this test revealed the p-value<0.001(χ^2=1053.71) and that there were significant differences in the proportions for these 8 surveys collectively.

Table 6A shows the results from a Marascuilo pairwise comparison procedure for the 8 population proportions. Of the 28 pairwise comparisons, 18 revealed significant differences in the proportions. The results illustrate that the differences in the proportion of respondents who were very worried about contracting the flu (Wolf et al., 2020, Flu) vs. COVID-19 in all but one pairing (3, 8) were significant. The disparities in the responses for questions about contracting the flu vs. COVID-19 are not unexpected; COVID-19 is still relatively new and people are processing how to understand the long-term impact and implications of this virus. As with any new global health crises, it is normal that people would have a heightened level of concern about the unknown. With more

Figure 2. Shows the percentage of people who answered that they were very worried (VW), a little worried (LW) or not at all worried (NW) that they or a family member would get COVID-19.

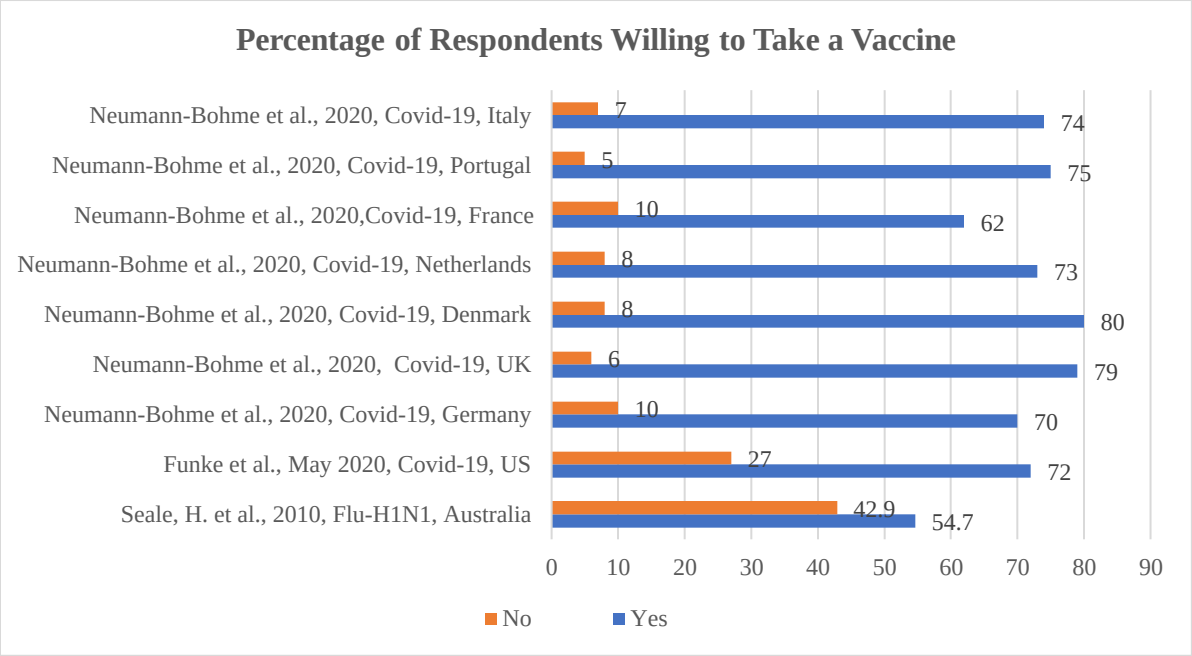


research and scientific studies, it would be interesting to track how these responses evolve over time.

Table 7, table 8 and figure 3 display the count and/or percentage of respondents who answered

that they would take a vaccine for COVID-19 or the flu-H1N1. While 62-80% of those surveyed revealed that they would take a vaccine for COVID-19, only 54.7% would get a flu-H1N1 vaccine.

Figure 3. Shows the percentage of respondents who are willing to take a vaccine for COVID-19 or the flu-H1N1.



Also, if only the surveys about willingness to take a COVID-19 vaccine are examined, an interesting dichotomy exists between respondents in the US vs. European countries; in European countries 5-10% indicated that they would not take a vaccine, whereas 27% were against taking it in the US. A chi-square test was conducted to explore the differences in the proportion of respondents who were willing to take a COVID-19 vaccine; this test revealed the p-value<0.001 (χ^2=882.79) and that there were significant differences in the proportions for these 9 surveys. Table 6B shows the results from a Marascuilo pairwise comparison procedure for the 9 population proportions listed. Of the 36 pairwise comparisons, 18 revealed significant differences in the proportions. Also, the differences in the proportion of respondents willing to take a vaccine for the flu-H1N1 (Seale, H. et al., 2010, Flu-H1N1) vs. COVID-19, were statistically significant. Similarly, the pairwise comparison procedure reveals a significant difference in the proportion of respondents willing to take a COVID-19 vaccine in the US vs. other European countries.

There are a multitude of factors which influence whether a person is concerned about contracting a virus or willing to get vaccinated during a public health crisis. Epidemiologists, politicians, and individuals are still in the early phases of understanding the trajectory of COVID-19 and its global impact long-term. Thus, this analysis is not comprehensive because surveys and data collection is on-going.

CONCLUSION AND FUTURE WORKS

In our research, we compare the typical supply chain for vaccine development to the current value chain used for many pharmaceutical companies developing a vaccine for COVID-19. While we focus on the expedited time frame to develop the COVID-19 vaccine, we also mentioned the rapid vaccine development for H1N1 as well. An H1N1 vaccine, "…was developed relatively rapidly, largely because influenza-vaccine technology was well developed and key regulators had previously decided that vaccines made using egg- and cell-based platforms could be licensed under the rules used for a strain change" (Lurie, 2020). Similarly, the mRNA based COVID-19 vaccine was also rapidly developed because it is relatively easier and faster to produce DNA/RNA molecules. Both the H1N1 and COVID-19 vaccines were developed within 5-9 months vs. the timeline for other pandemics, which normally spans 5+ years; although there are scientific reasons that support the expedited timeline to develop these vaccines, skepticism about the efficacy of the drug is understandable because the typical process was not followed.

Throughout this paper, we emphasize ethical and quality issues that could arise throughout the pre-clinical, phase trials, manufacturing, and distribution stages. We also perused various surveys about pandemics to understand how responses about contraction concerns and getting vaccinated vary. Descriptive statistics, chi-square tests and results from Marascuilo pairwise comparison procedures yielded insightful information. Significantly more respondents were worried about getting COVID-19 than getting the seasonal flu. Given the novelty of the COVID-19 and the familiarity with the seasonal flu, it is understandable that the heightened level of concern is different. Also, more people were willing to get vaccinated for COVID-19 than the flu-H1N1. It is also interesting to note that a pointedly greater number of respondents from the US were unwilling to get a COVID-19 vaccine as compared with individuals in other countries.

In the future it would be interesting to explore what factors have the most significant impact on respondents' attitudes about vaccination and virus contraction.

Table 1. Lists articles that discuss people's views about contracting a virus during a pandemic.

KNOWLEDGE ABOUT CONTRACTION			
Topic	**Reference**	**Question Wording**	**Explanation of Measurements**
Belief in disease contraction	Wolf et al, 2020; AP NORC Center survey, 2020; YouGov, 2020a; Wronski, 2020; Jang, WM et al, 2020; Bodas et. al, 2020; IPSOS Group, 2020	How worried are you about getting the Coronavirus?; How worried that or someone in your family will be exposed to the Coronavirus?; How worried are you about getting the flu?; How worried are you that you could get MERS?; Are you worried by the COVID-19 outbreak?	These measures indicate the degree to which people are worried about contracting the disease.
Belief in severity of disease	Wolf et al., 2020	Do you think you will get sick from the Coronavirus?	These measures indicate how likely it is that a person thinks they will get sick from a disease.
Belief in disease contraction amongst friends	Wolf et al., 2020	Do you think someone you know may get sick from the Coronavirus this year?	These measures indicate the degree to which people believe their friend, family member or associates are susceptible to obtaining the disease.

Table 2. Lists articles about people's confidence in the government or elected officials' ability to manage various pandemics.

CONFIDENCE IN THE GOVERNMENT			
Topic	**Reference**	**Question Wording**	**Explanation of Measurements**
Confidence in federal government	Wolf et al, 2020; Safford. T. et al., 2017; Bodas et al., 2020	How confident are you that the federal government can prevent a nationwide outbreak of the Coronavirus?; How confident are you in the federal government's ability to respond to Zika?; Do you trust the public health instructions of the MOH during the COVID-19 outbreak?	These measures indicate the confidence level in the government's ability to control of a disease outbreak.
Confidence in government officials	Wronski, 2020; IPSOS, 2020	Do you approve or disapprove of the way your governor is handling your state's response to the Coronavirus?; Do you approve or disapprove of your governor's handling of the Coronavirus outbreak?; Do you approve or disapprove the way of Congress' handling of the Coronavirus outbreak?; Do you approve or disapprove of the way President Trump is handling the federal government's response to the Coronavirus?	These measures indicate how the respondents feel about elected officials' abilities to handle a pandemic.
Longevity of the outbreak	YouGov, 2020a; YouGov, 2020b	Do you think the Coronavirus outbreak will have a lasting effect on the United States, or do you think things will soon get back to normal?	These measures indicate people's belief about the lasting effect of the Coronavirus.
Vaccination obtainment after government recommendation	Seale, H. et al., 2010	Will you get the vaccine if the government recommends it?	These measures indicate the respondents' confidence in government regulation and vaccine development.

Table 3. Lists articles about the attitudes and beliefs people have toward pandemic vaccinations.

VACCINATION ATTITUDES			
Topic	**Reference**	**Question Wording**	**Explanation of Measurements**
Vaccination side effects (Flu-H1N1; Flu-Seasonal;Covid-19)	Seale, H. et al., 2010; Cheney, M. et al., 2013; Wellcome, 2019	I am concerned about the side effects of the vaccine; I worry about side effects from the flu shot; Do you strongly agree that vaccines are safe?; Serious side effects from the flu shot are common.	These measures assess the concern level ofpotential side effects.
Safety of vaccination (Flu-H1N1; Flu-Seasonal;Covid-19)	Seale, H. et al., 2010; Cheney, M. et al., 2013; Wellcome, 2019	I am concerned that the vaccine has not been tested adequately; I wonder about the safety of the flu vaccine; Do you strongly agree that vaccines are effective?	These measures assess the concern level of the safety of various vaccinations.

Protection of vaccination (Flu-H1N1)	Seale, H. et al., 2010	The vaccination will protect me from the pandemic (swine flu); The vaccination will stop the spread of the swine flu.	These measures assess people's confidence in the protection levels of a pandemic vaccine.
Getting Vaccinated (Flu-H1N1; Covid-19)	Seale, H. et al., 2010; Funk et al. 2020; IPSOS 2020; Neumann-Bohme et al.2020	If a vaccine was made available to the general public, would you get vaccinated?; Would you be willing to take a vaccine if it were developed inside of the US?	These measures assess the probability of vaccine obtainment in a pandemic era.

Table 4. Focuses on questions and answers about how worried the respondents are about getting either COVID-19 or the Seasonal Flu.

CONCERNS ABOUT CONTRACTING COVID-19 OR THE SEASONAL FLU						
Exact Question	**Reference**	**Pandemic**	**Sample Size (n)**	**Survey Results and Scale**	**Survey Date**	**Country of Respondents**
How worried are you about getting the corona virus?	Wolf et al, 2020	Covid-19	630	24.6% Very worried, 39.1 % Somewhat worried, 23.4% A little worried, 12.9% Not worried at all	March 2020	US
How worried are you about you or someone in your family infected with the flu and Coronavirus?	AP NORC Center, 2020	Covid-19	1056	21% Extremely worried, 21% Very worried, 31% Somewhat worried, Not too; 18% not too worried, 7% Not at all worried	May 2020	US
How worried that or someone in your family will be exposed to the corona virus?	Wronski, 2020	Covid-19	46450	37% Very worried, 33% Somewhat worried,19%, Not too worried, 1% No answer	July 2020	US
How concerned are you that you or someone in your family will contract the coronavirus	YouGov, 2020a	Covid-19	997	29% Very concerned, 36% Somewhat concerned, 21% Not very concerned, 10% Not all concerned, 5% Not sure	May 2020	US
How concerned are you that you or someone in your family will contract the coronavirus	YouGov, 2020b	Covid-19	989	26% Very concerned,36% somewhat concerned, 23% Not very concerned, 11% Not at all concerned, 4% Not sure	June 2020	US
Are you worried about the Covid-19 outbreak?	Bodas et al, 2020	Covid-19	563	2.5% Not at all, 13.9% A little, 28.8% Moderate, 26.1% A lot, 23.8% very much	April 2020	Israel
How concerned are you that you or	IPSOS, 2020	Covid-19	500	36% Very concerned, 42%	May 2020	US

someone you know will be infected by the Coronavirus?				Somewhat, 15% Not so concerned, 7% Not concerned at all		
How worried are you about getting the flu?	Wolf et al, 2020	Seasonal Flu	630	10.8% Very worried, 26.8 % Somewhat worried, 26.5% A little worried, 35.9% Not worried at all	March 2020	US

Table 5. Shows the number (and percentage) of people who answered that they were very worried (VW), a little worried (LW), or not at all worried (NW) that they or a family member would get COVID-19.

	CONCERNS ABOUT CONTRACTING COVID-19 OR THE SEASONAL THE FLU-H1N1				
	Reference	**VW Percent (Count)**	**LW Percent (Count)**	**NW Percent (Count)**	**Total**
1	Wolf et al, 2020, n=630[c], COVID-19, US	24.6 (154.98)	62.5 (393.75)	12.9 (81.27)	**100% (630)**
2	AP NORC survey, 2020, n=1056*[c], COVID-19, US	42 (443.57)	31 (327.40)	25 (264.03)	**98% (1035)**
3	Wronski, 2020, n=46450*, COVID-19, US	37 (17360.07)	33 (15483.30)	19 (8914.63)	**89% (41758)**
4	YouGov, 2020a, n=997*[c], COVID-19, US	29 (289.09)	57 (568.22)	10 (99.69)	**96% (957)**
5	YouGov, 2020b, n=989*[c], COVID-19, US	26 (257.02)	59 (583.24)	11(108.74)	**96% (949)**
6	Bodas et al, 2020, n=563*[c], COVID-19, Israel	49.9 (280.72)	42.7 (240.22)	2.5 (14.06)	**95.1% (535)**
7	IPSOS, 2020, n=500[c], COVID-19, US	36 (180)	57 (285)	7 (35)	**100% (500)**
8	Wolf et al, 2020, n=630[c], Flu, US	10.8 (68.04)	53.3 (335.79)	35.9 (226.17)	**100% (630)**

VW- Very worried or concerned, **LW**- A little worried or concerned, **NW**- Not worried or concerned at all

[c] *Columns were merged. Responses of **somewhat** and **not very** were lumped together and summed. Responses of **very much concerned** and a **lot concerned** were lumped together and summed.*

** Responses that were left blank, or such as **not sure** or **don't know** were not included in these total counts and percentages.*

Table 6A. (left) Shows the results from a Marascuilo pairwise comparison procedure for eight population proportions very worried about contracting COVID-19. Table 6B. (right) Shows the results from a Marascuilo pairwise comparison procedure for nine population proportions who are willing to take a vaccine for COVID-19 or the flu-H1N1.

Pairwise Comparisons	$\lvert p_i - p_j \rvert$	CV_{ij}
1, 2	0.18257	0.08643
1, 3	0.16973	0.06499
1, 4	0.05608	0.08509
1, 5	0.02483	0.08408
1, 6	0.27871	0.10344
1, 7	0.11400	0.10307
1, 8	0.13800	0.07933
2, 3	0.01284	0.05840
2, 4	0.12649	0.08017
2, 5	0.15774	0.07909
2, 6	0.09614	0.09943
2, 7	0.06857	0.09905
2, 8	0.32057	0.07402
3, 4	0.11365	0.05640
3, 5	0.14490	0.05486
3, 6	0.10898	0.08148
3, 7	0.05573	0.08102
3, 8	0.30773	0.04725
4, 5	0.03125	0.07763
4, 6	0.22263	0.09827
4, 7	0.05792	0.09788
4, 8	0.19408	0.07246
5, 6	0.25388	0.09739
5, 7	0.08917	0.09700
5, 8	0.16283	0.07126
6, 7	0.16471	0.11419
6, 8	0.41671	0.09332
7, 8	0.25200	0.09291

	References
1	Wolf et al, 2020, n=630c, Covid-19, US
2	AP NORC survey, 2020, n=1056*c, Covid-19, US
3	Wronski, n=46450*, Covid-19, US
4	YouGov 2020a, n=997*c, Covid-19, US
5	YouGov 2020b, n=989*c, Covid-19, US
6	Bodas et al, 2020, n=563*c, Covid-19, Israel
7	IPSOS, 2020, n=500c, Covid-19, US
8	Wolf et al, 2020, n=630c, Flu, US

Pairwise Comparisons	$\lvert p_i - p_j \rvert$	CV_{ij}
1, 2	0.16682	0.08078
1, 3	0.31454	0.09144
1, 4	0.36895	0.08625
1, 5	0.34863	0.08774
1, 6	0.34078	0.08914
1, 7	0.30065	0.09390
1, 8	0.37704	0.08589
1, 9	0.35312	0.08805
2, 3	0.14773	0.04903
2, 4	0.20214	0.03848
2, 5	0.18182	0.04171
2, 6	0.17396	0.04458
2, 7	0.13384	0.05347
2, 8	0.21023	0.03767
2, 9	0.18631	0.04237
3, 4	0.05441	0.05759
3, 5	0.03409	0.05980
3, 6	0.02623	0.06184
3, 7	0.01389	0.06853
3, 8	0.06250	0.05706
3, 9	0.03858	0.06026
4, 5	0.02032	0.05151
4, 6	0.02818	0.05386
4, 7	0.06830	0.06142
4, 8	0.00809	0.04830
4, 9	0.01583	0.05204
5, 6	0.00786	0.05622
5, 7	0.04798	0.06350
5, 8	0.02841	0.05091
5, 9	0.00449	0.05448
6, 7	0.04012	0.06542
6, 8	0.03627	0.05329
6, 9	0.01235	0.05671
7, 8	0.07639	0.06092
7, 9	0.05247	0.06393
8, 9	0.02392	0.05145

	References
1	Seale, H. et al., 2010, Flu-H1N1, Australia
2	Funke et al., May 2020, Covid-19,US
3	Neumann-Bohme et al., 2020, Covid-19, Germany
4	Neumann-Bohme et al., 2020, Covid-19, UK
5	Neumann-Bohme et al., 2020, Covid-19, Denmark
6	Neumann-Bohme et al., 2020, Covid-19, Netherlands
7	Neumann-Bohme et al., 2020, Covid-19, France
8	Neumann-Bohme et al., 2020, Covid-19, Portugal
9	Neumann-Bohme et al., 2020, Covid-19, Italy

Table 7. Focuses on questions and answers about whether respondents would be willing to get a vaccine for COVID-19.

WILLINGESS TO TAKE A VACCINE FOR COVID-19 OR THE FLU-H1N1						
Exact Question	**Reference**	**Pandemic**	**Sample Size (n)**	**Survey Results and Scale**	**Survey Date**	**Country of Respondents**
If a vaccine to prevent COVID-19 were available today, would you get it?	Funk et al., 2020	COVID-19	10,957	42% Definitely, 30% Probably, 16% Probably not, 11% Definitely not, 1% No answer	May 2020	US
Would be willing to get vaccinated against COVID-19 if a vaccine would be available?	Neumann-Bohme et al., 2020	COVID-19	1000	70% Yes, 10%, No, 20% Unsure	June 2020	Germany
"	"	COVID-19	1000	79% Yes, 6% No, 15% Unsure	June 2020	UK
"	"	COVID-19	1000	80% Yes, 8% No, 12% Unsure	June 2020	Denmark
"	"	COVID-19	1000	73% Yes, 8% No, 19% Unsure	June 2020	Netherlands
"	"	COVID-19	1000	62% Yes, 10% No, 28%	June 2020	France
"	"	COVID-19	1000	75% Yes, 5% No, 21% Unsure	June 2020	Portugal
"	"	COVID-19	1000	74% Yes, 7% No, 19% Unsure	June 2020	Italy
If a vaccine was made available to the general public would you get vaccinated?	Seale, H. et al., 2010	Flu-H1N1	n= 627	54.7% Yes, 42.9% No, 2.3% Not specified	September-October 2009	Australia

Table 8. Shows the number (and percentage) of people who answered that they would (Yes) or would not (No) get a COVID-19 vaccine when it became available.

	WILLINGESS TO TAKE A VACCINE FOR COVID-19 OR FLU			
	Reference	**Yes Percent (Count)**	**No Percent (Count)**	**Total**
1	Seale, H. et al., 2010, n=627*, Flu-H1N1, Australia	54.7 (343)	42.9 (269)	**97.6% (612)**
2	Funke et al., May 2020, n=10957*, COVID-19, US	72 (7888.73)	27 (2958.27)	**99% (10847)**
3	Neumann-Bohme et al., 2020, n=1000*, COVID-19, Germany	70 (700)	10 (100)	**80% (800)**
4	", COVID-19, UK	79 (790)	6 (60)	**85% (850)**
5	", COVID-19, Denmark	80 (800)	8 (80)	**88% (880)**
6	", COVID-19, Netherlands	73 (730)	8 (80)	**81% (810)**
7	", COVID-19, France	62 (620)	10 (100)	**72% (720)**
8	", COVID-19, Portugal	75 (750)	5 (50)	**80% (800)**
9	", COVID-19, Italy	74 (740)	7 (70)	**81% (810)**

Responses that were left blank, or such as **not sure or **don't know** were not included in these total counts and percentages.*

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