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DEPARTMENT OF SUPPLY CHAIN AND INFORMATION SYSTEMS

Applying Lessons Learned From The COVID-19 Vaccine Distribution To Future Public Health Emergencies

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ABSTRACT

Since the discovery of the Covid-19 virus, the development and distribution of the COVID-19 vaccine has been a global priority. After interviewing professionals in the industry, a clear picture of the COVID-19 vaccines has developed. Measures that can help speed people's access to a COVID-19 vaccine are presented by comparing supply chains and distribution strategies for influenza (flu) vaccines and COVID-19 vaccines thereby helping the future vaccine supply chain face to adapt to new emergencies. Flu vaccines are produced by private manufacturers. Their production mostly relies on egg-based methods, with a five-to-eight-month production time, and manufacturers often start producing vaccines in January through "at-risk early production." During transportation, flu vaccines are carefully transported in insulated containers with cold packs and heavy wrapping paper to maintain refrigerated temperatures. The COVID-19 vaccine is more sensitive to temperature changes and requires more careful handling. The COVID-19 vaccine faced supply chain constraints initially, but the pro rata formula was used to distribute limited vaccines equally based on population. In the early pandemic, states decided opened mass vaccination centers, and vaccines were shipped through UPS and FedEx. Once supply reached full capacity, vaccines were expected to be delivered from manufacturers every fifteen days. Over time, as demand is less than supply and each state has different problems. For example, there is not enough space to store the COVID-19 vaccine, and the funds are not enough to re-distribute. Distributors have to make changes to the distribution according to the situation. Overall, manufacturing and distribution challenges were faced due to the unprecedented speed and scale of vaccine production, but strategies were developed to ensure equitable distribution and on-time delivery. This can be implicated for future supply chains and help improve vaccine distribution.

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I also want to thank my parents for keeping me motivated during this long process and for proof reading each of my chapters even though they are not familiar with the topic. Their constant encouragement helped me succeed.

Finally, I would like to thank Megan and Aaron from LMI for supporting me throughout the whole thesis process. They helped keep me on schedule and were always checking on my progress.

Chapter 1 : Introduction

Vaccines have saved more human lives than any other medical invention in history. They play a vital role in protecting us from disease. Vaccines provide good protection against previously deadly diseases. The development of vaccines stems from knowledge from around the world. People have been using antiviral techniques for centuries. Hundreds of years ago in Asia and Africa, people applied pus from infected people to healthy people to make them mildly infected. In the 1700s, Edward Jenner discovered that people exposed to vaccinia could avoid contracting smallpox. Using the Latin word “Vacca,” he called the process "vaccination." By 1900, vaccines had been invented for cholera, rabies, typhoid, and plague. Flu vaccines began in the 1930s and were widely used in the United States in 1945 (World Health Organization, n.d.). Scientists then discovered the complexity of the flu virus. Flu viruses mutate and create new strains every few years, making vaccines less effective. Since it is impossible to predict which new strains of flu will emerge in the future, new flu vaccines need to be made through careful monitoring and annual production. The coronavirus first broke out in Wuhan, Hubei Province, China, in late 2019. And it quickly spread to many countries around the world in early 2020, gradually turning into a global disaster. Millions of people lost their lives during the pandemic. As time goes by, the COVID-19 pandemic has had a huge impact on the world economy and triggered a global economic crisis. It is urgent for countries to develop a vaccine to prevent their citizens from getting sick and dying from the virus. The development of COVID-19 vaccine was an important tool to help countries defeat the pandemic. For decades, scientists have been working on another type of vaccine, which is an mRNA vaccine. The Covid-19 vaccine used this

technology. The mRNA in the Covid-19 vaccine enters the body and instructs cells to produce a small part of the novel coronavirus (Centers for Disease Control and Prevention, 2022). This small fragment does not cause harm, but the human immune system can learn and recognize it. And when it is infected with the coronavirus in the future, the immune system can attack the real coronavirus. In 2020, U.S. FDA authorizes the emergency use of the mRNA vaccine. The vaccine is called the Pfizer-BioNTech COVID-19 vaccine. Although many new strategies like cold chain and thermal shippers were involved during the pandemic and can be used in the future, people still need to get prepared to deal with future pandemics.

The purpose of this thesis is to analyze what new strategies that were developed during the COVID-19 pandemic by comparing traditional and COVID-19 vaccines and how can institutions apply those strategies in the future when a similar situation happens again. The next section, Background, will demonstrate the Food and Drug Administration approval process, flu vaccines' history and the Pfizer-BioNTech COVID-19 vaccines' history. And the following section, Methodology and Analysis, will analyze the difference between flu vaccines and COVID-19 vaccines in detail.

Chapter 2 : Background

FDA Approval Process

Over the years, the global economy has accelerated national demands on national supply chains. In the past few years, uncertain factors such as earthquakes, floods and international trade disputes have superimposed disruptions in supply chains. In addition, the traditional supply chain has been greatly impacted in the face of the new crown. More and more enterprises are feeling the pressure of supply chain transformation. The supply chain of the vaccine bears the brunt. Before the vaccine can be manufactured and distributed, it needs to be tested and approved. A typical vaccine development timeline takes five to ten years, and sometimes longer. In the U.S., vaccines are regulated by the Food and Drug Administration's (FDA's) center for biologics evaluation and research (U.S. Food and Drug Administration, n.d.). The FDA works to ensure all new vaccines on the market are safe, effective, and have minimal side effects by carefully monitoring each stage of testing. Once the sponsor decided to make a new type of vaccine, the sponsor needs to submit an Investigational New Drug Application to the FDA. This application describes what is the vaccine, how it is made and how it is been tested for quality control. After the FDA approved the application, there are three phases needed to go through. The first phase uses small trials with around twenty to eighty subjects and focuses on testing safety of a vaccine and strength of an immune response. The second phase uses a larger group, with around several hundred participants, and different dosages will be tested to find the most effective vaccine. And the third phase includes thousands to test against a placebo, long-term efficacy, and rare side effects. After a vaccine completes all three phases, the manufacturer must submit a Biologics License Application to the FDA. This provides safety and efficacy information they need to

assess the risks and benefits of the vaccine for the FDA team to review. And based on the information, the FDA can decide whether they recommend it to be approved. Then the FDA and vaccine sponsor will present their data to Vaccines and Related Biological Products Advisory Committee (VRBPAC). Once the vaccines are approved, the FDA continues to oversee its production with periodic facility inspections and tracking the quality control performed by the manufacturer. The FDA also maintains the Vaccine Adverse Event Reporting System, which allows healthcare providers and patients for reporting extremely rare health events that may be a result of receiving the vaccine.

History of Flu Vaccine

The first flu vaccine was approved for military use in the U.S. in 1945 and civilian use in 1946 (Midwest Express Clinic, 2021). Today, there are three different flu vaccine production technologies approved by the FDA. The egg-based flu vaccine is the most common way that flu vaccines are made. It uses an egg-based manufacturing process. It requires large numbers of chicken eggs to produce the vaccine and may take longer than other production methods. There also is a cell culture-based production process for vaccines that was approved by FDA. The cell culture-based flu vaccine production does not require chicken eggs because the vaccine viruses used to make the vaccine are grown in mammalian cell cultures, which means there are no animals harmed by this process. It also has the potential for a faster start-up of the flu vaccine manufacturing process. The third production technology for flu vaccines involves using recombinant technology. It does not require the use of candidate vaccine virus (CVV) for production. Instead, recombinant vaccines are created synthetically. While there are other

vaccines that use similar recombinant manufacturing processes, only one flu vaccine is FDA approved for use in the United States now. Approximately eighty percent of the projected vaccine supply produced for the 2022-2023 flu season will be produced using egg-based manufacturing technology. The remaining vaccine will be produced using cell-based or recombinant technology (Centers for Disease Control and Prevention, 2022). All commercially available flu vaccines in the United States are made by private sector manufacturers. Although different manufacturers use different production technologies, all flu vaccines meet FDA safety and effectiveness requirements.

History of COVID-19 vaccine

While COVID-19 vaccines were developed rapidly, all steps have been taken to ensure their safety and effectiveness. SARS-CoV-2, the virus that caused COVID-19, was identified in December 2019. Although SARS-CoV-2 was a new virus, scientists were not starting from scratch. The new virus belongs to a family of viruses with similar traits. Scientists had studied other coronaviruses like SARS and MERS for fifty years and knew the spike protein could be targeted by a vaccine. After the World Health Organization declared COVID-19 a pandemic, Pfizer signed a letter of intent to BioNTech to co-develop a potential COVID-19 vaccine. The Pfizer-BioNTech COVID-19 vaccines was approved by the FDA on August 23,2021 as the first approval of a COVID-19 vaccine (U.S. Food and Drug Administration, 2021). As of January 2022, the Pfizer-BioNTech COVID-19 vaccine is manufactured in eleven sites across five countries, including the U.S., Germany, Belgium, Ireland, and Croatia, and engages more than

twenty suppliers. Pfizer is activating its extensive U.S. and European manufacturing network, including thousands of highly skilled U.S. workers in multiple states and localities (Pfizer, n.d.).

Chapter 3 : Methodology and Analysis

Methodology

While some information about the COVID-19 vaccines supply chain is publicly available, other information such as the distribution plan and process are considered confidential. Most of the research for this thesis was gleaned from interviews with industry experts and the sponsor company. Interviews were held to discuss the distribution process and identify the potential factors that could impact the distribution of COVID-19 vaccines. The interviews were conducted with professionals who were involved in the COVID-19 vaccine distribution process. This mix of professionals helped to create a clear picture of the distribution process and plan. Additional research was also conducted using internet articles and reliable resources from government to gain background on Food and Drug Administration approval process, flu vaccines, and COVID-19 vaccine supply chain.

Analysis

According to WHO (World Health Organization, 2021), In 2015, the global production capacity for seasonal influenza vaccines was estimated to be 1.5 billion doses with the ability to expand, in a best-case scenario, to 6.4 billion doses in the event of an influenza pandemic. Most seasonal influenza vaccines licensed for use are produced using egg-based methods, which rely on supplies of eggs and candidate vaccine viruses (CVVs). Egg-based vaccines can take as long as five to eight months to produce. For this reason, pharmaceutical firms often start production before the Vaccines and Related Biological Products Advisory Committee of the U.S. Food and

Drug Administration selects the composition of the flu vaccine (i.e., which strains to include) each February. To insist on production after knowing the selected composition would mean a nontrivial likelihood of late delivery. To ensure on-time delivery, flu vaccine manufacturers such as GlaxoSmithKline PLC and Sanofi often start producing flu vaccines in January, well before the FDA determines which strains to produce (Dai & Tang, 2020). This practice is known as "at-risk early production." Unfortunately, in the event that such production does not match the FDA recommendation, the manufacturers must discard entire batches of vaccine strains. Thus, supply chain pressures cause manufacturers to balance between improving on-time delivery performance and reducing the likelihood of producing the wrong strains. In order to reduce manufacturers' financial risks of producing vaccines that do not match the FDA recommendations, flu vaccine manufacturers sign early or "pre-book" contracts with their customers (Dai & Tang, 2020). And these committed pre-book orders provide guaranteed payments.

The flu vaccine is produced by private manufacturers, and the supply is depending on manufacturers. Manufacturers and distributors are encouraged to use a distribution strategy, which providers receive smaller shipments to allow as many providers as possible to begin vaccination activities early in the vaccination season. During the transportation, flu vaccines will be carefully transported in insulated containers with cold packs on the bottom and top of the container. There are four layers of heavy wrapping paper between the cold packs and the box of vaccine because vaccines cannot be touching the cold packs during shipping (South Dakota Department of Health, n.d.). The storage temperature requirement is refrigerated at a temperature between 35° to 46°F (2° to 8°C) and cannot be frozen (Centers for Disease Control and Prevention, 2022). And it has two types of vial supply. One is single dose, which contains 0.5mL

and the wastage rate is three percent (Fig. 1). The second one is a multi-dose vial, and each vial contains 5mL, which has ten doses per vial. The wastage rate is thirty-two percent, which is higher than the single dose. And the opened vials of multi-dose must be discarded twenty-eight days after the first puncture.

Step 1. Demographic Parameters

1.1 Select the year: 2023

1.2 Facility density (population per service point): 10,000

1.3 Select country groups or individual countries

WHO Region	IST /AFRO	PEF Tiers	Gavi Status	UNICEF Regions	Income class	Countries
AFR	West	Tier 3	Preparatory Phase 1	ECAR	High income	Sao Tome and Principe
AMR	Central	Tier 1	Accelerated Phase 2	ESAR	Low income	Senegal
EMR	Southern East	Tier 2	Fully self-financing Phase 3	LACR	Lower income	Seychelles
EUR	(blank)	(blank)	Initial self-financing	MENA	Not Applicable	Sierra Leone
SEAR			Not Eligible	ROSA	Upper middle income	South Africa
WPR				(blank)	(blank)	South Sudan
						Swaziland

Step 2. Immunization parameters

2.1 Select the vaccine: Influenza (Quadrivalent)

Full name: Influenza, seasonal Quadrivalent

2.2. Enter number of dose(s) scheduled for the vaccine: 2

2.3 Coverage*: 90%

2.4 Number of service points:

Estimated number of service points*: 5,067

2.5 Total population of selected countries:

Estimated total Population*: 25,336,244

2.6 Surviving infants for selected countries: 1,000,000

Estimated annual surviving infants*: 1,000,000

2.7 Enter the number of supply chain levels: 3

Avoidable opened vial wastage rate: 3%

Maxi closed vial wastage per supply chain level: 1%

2.8 Indicate the frequency of sessions:

	a. Percentage	b. Number of days	
% daily sessions	10%	dailly	1
% weekly sessions	60%	weekly	2
% monthly sessions	30%	monthly	4

Estimated vaccinations: 1,800,000

	dailly	weekly	monthly
Number of service points:	507	3040	1520
Estimated average session size:	14.8	6	25
Vaccinations per service point:	3552.2	592	1184

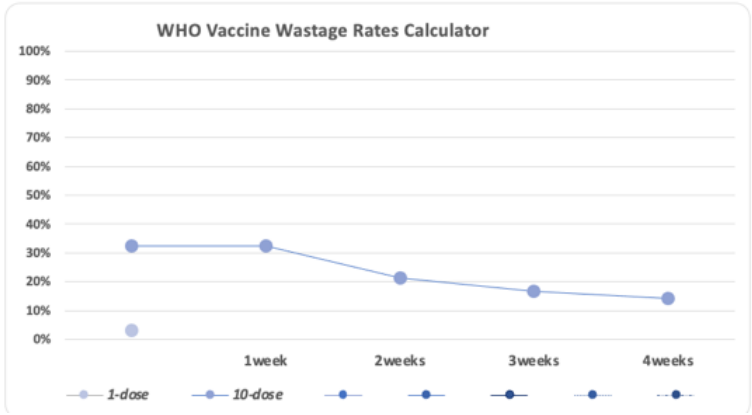
Results

Estimated anticipated wastage rates for the selected parameters:

schedule: 2-dose

Multi-Dose Vial Policy Status

Doses/vial	Re-use: No re-use	1week	2weeks	3weeks	4weeks
1-dose	3%				
10-dose	32%	32%	21%	17%	14%



Additional results

Figure 1: Estimated Wastage Rates for Influenza (flu) Vaccine

In 2019, the Covid virus was discovered, and it took approximately two years to develop a vaccine. The Covid vaccine was finally developed in February 2021. However, there was a supply chain constraint, and initially, there were not enough vaccines available for everyone. By November 2021, the supply issue had been resolved. This means there was a window of about seven to eight months between the realization that more vaccines would be needed to address the ongoing pandemic and the vaccine becoming available (Wetzel, LMI, March 2023).

The pro rata is an important basis for establishing the distribution of the Covid vaccine. The pro rata formula is often used in vaccine distribution plans to ensure that vaccines are distributed equitably among different population groups. From February 2021 to November 2021, the pro rata formula for COVID-19 vaccines refers to what was available and what was the population the state made up of the nation as a whole. Each population group receives a proportion of the available vaccine doses that is proportional to their share of the total population. For example, New York is six percent of U.S. population and current available vaccines are five million doses. Under the pro rata formula, New York will get six percent of those five million doses. And every time a new lot of vaccine became available, it got distributed in that same amount. In this way, limited vaccines were able to be distributed equally based on the population across the board. If there were not enough vaccines for one state to get their number of vaccines, then the number for all the states will be reduced. Based on the pro rata formula, bigger states will get impacted more. Once the vaccine supply reaches full capacity, vaccines are expected to be delivered from manufacturers every fifteen days. After November 2021, the supply was available for everyone. At that point, the state could ask for more vaccines if they needed them. And the extra doses that the state can get were based on the vaccine

admitted rate. It was not acceptable if a state only has ten percent vaccine admitted rate, but it asked for more vaccines (Wetzel, LMI, March 2023).

In the early stages of the pandemic, the state decided to open the mass vaccination center. It could be a community center or hospital, as long as it has the capacity to store the vaccines and be able to support large scale vaccine operations. Each state enrolled the site in the system on their own and order vaccines. And the distributor will ship vaccines to those sites. FedEx and UPS worked together and did the same role to distribute vaccines. They used flights to ship to each state, then used local transportation to re-distribute to other specific locations within the state. Pfizer-BioNTech COVID-19 vaccines were mostly shipped through UPS because Pfizer's manufacturing facilities were closer to UPS depot (Pfizer, 2022). However, as time went by, the state did not have money for the re-distribution. Although the state still had enough vaccines, the state will ask the distributor to ship more vaccines to the specific locations like CVS and Walgreen.

At the beginning, in terms of manufacturing the vaccines, there were some challenges due to the unprecedented speed and scale at which they needed to be produced. There was not enough infrastructure in place to support such a large quantity of vaccines, and while storage was not a major issue at the beginning, transportation was impacted by the pandemic. Overall, the main difficulty was simply the sheer volume of vaccines that needed to be produced, which exceeded the existing capacity. But distribution plans have suffered as states have more vaccine stocks and demand has dwindled. The need for certain parts of the country were not as high as before, or the state did not have enough storage room, which led to the situation that the state only ordered for the amount that they needed. However, the distributor expected the state to take the same amount every time. At that point, the supply exceeded the demand. Due to the

expiration date and the temperature requirements of vaccines, distributors reduced the maximum ordering fresh hold for states that required states/jurisdictions to utilize in field supply and started relying on states that asked for more. Furthermore, the distributor kept more vaccines in the distribution center to have better management and started the international donation campaign (Wetzel, LMI, March 2023).

According to WTO, the Pfizer-BioNTech COVID-19 vaccine is supplied in a multiple-dose vial with an orange cap and a label with an orange border. Each vial contains a frozen suspension of the vaccine that does not contain any preservatives (World Health Organization, 2021). The Pfizer-BioNTech COVID-19 vaccine has specific storage requirements. Unpunctured vials must be stored in an ultra-cold freezer at a temperature between -130°F and -76°F (-90°C and -60°C) until the expiration date and refrigerator at a temperature between 36°F and 46°F (2°C and 8°C) for up to ten weeks. The punctured vials can be stored between 46°F and 77°F (8°C and 25°C) for up to twelve hours prior to first puncture. Each vail contains 1.3mL, which can provide six doses of 0.3 mL each. For Pfizer-BioNTech COVID-19 vaccines designed for individuals between the ages of five and eleven, multi-dose vials must be used within twelve hours after being punctured. For individuals aged twelve years-old and above, multi-dose vials must be used within six hours after being punctured (Centers for Disease Control and Prevention, 2022). As the demand for COVID-19 vaccines decreased, the use of multi-dose vials resulted in the wastage of vaccine doses. These vials contain multiple doses, and once opened, the vaccine must be used within a specific timeframe to maintain its effectiveness. If there are not enough people seeking vaccination during that period of time, it may be challenging to use all the doses in the vial before they expire, leading to the disposal of the remaining doses. The storage capacity is also a reason of the wastage of vaccine doses since some places may to have the

ability to handle the large amount of doses. According to the WTO Vaccine Wastage Rates Calculator, the estimated anticipated wastage rates for Pfizer-BioNTech COVID-19 vaccines is twenty-two percent (Fig. 2). In order to decrease wastage, vaccine manufacturers should develop single-dose formulations to reduce the need for multi-dose vials in the future.

Step 1. Demographic Parameters

1.1 Select the year: 2023

1.2 Facility density (population per service point): 10,000

1.3 Select country groups or individual countries

WHO Region	IST /AFRO	PEF Tiers	Gavi Status	UNICEF Regions	Income class	Countries
AFR	West	Tier 3	Preparatory Phase 1	ECAR	High income	Sao Tome and Principe
AMR	Central	Tier 1	Accelerated Phase 2	ESAR	Low income	Senegal
EMR	Southern East	Tier 2	Fully self-financing Phase 3	LACR	Lower income	Seychelles
EUR	(blank)	(blank)	Initial self-financing	MENA	Not Applicable	Sierra Leone
SEAR			Not Eligible	ROSA	Upper middle income	South Africa
WPR				(blank)	(blank)	South Sudan
						Swaziland

Step 2. Immunization parameters

2.1 Select the vaccine: 9-Pfizer Tris/Sucrose (orange cap)

Full name: Covid-19 vaccine

2.2. Enter number of dose(s) scheduled for the vaccine: 2

2.3 Coverage*: 90%

2.4 Number of service points:

Estimated number of service points*: 5,067

2.5 Total population of selected countries:

Estimated total Population*: 25,336,244

2.6 Surviving infants for selected countries: 1,000,000

Estimated annual surviving infants*: 1,000,000

2.7 Enter the number of supply chain levels: 3

Avoidable opened vial wastage rate: 3%

Maxi closed vial wastage per supply chain level: 1%

2.8 Indicate the frequency of sessions:

	a. Percentage	b. Number of days	
% daily sessions	10%	dailly	1
% weekly sessions	60%	weekly	2
% monthly sessions	30%	monthly	4

Estimated vaccinations: 1,800,000

	dailly	weekly	monthly
Number of service points:	507	3040	1520
Estimated average session size:	14.8	6	25
Vaccinations per service point:	3552.2	592	1184

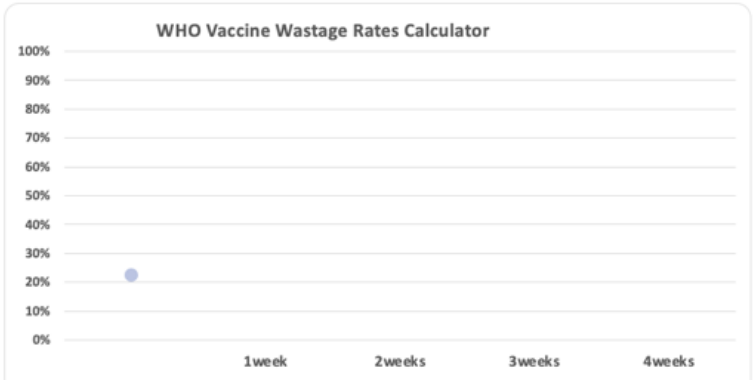
Results

Estimated anticipated wastage rates for the selected parameters:

schedule: 2-dose

Multi-Dose Vial Policy Status

Doses/vial	Re-use: No re-use	1week	2weeks	3weeks	4weeks
6-dose	22%				



Additional results

Figure 2: Estimated Wastage Rates for Pfizer COVID-19 Vaccine

For the Covid-19 vaccine, many new strategies were involved. First, to speed up the process of the development of Covid-19 vaccine, the FDA gave emergency use authorization to the Pfizer-BioNTech vaccine. Due to the urgent need for Covid-19 vaccines and the FDA's vaccine approval process which can take months to years, the FDA first gave emergency use authorization to COVID-19 vaccines based on less data than is normally required. In order to get the emergency use authorization from the FDA, Pfizer must provide data that show the vaccines are safe and effective. Secondly, Pfizer has developed packaging and storage innovations to be fit for purpose to meet the needs of global network. Pfizer has specially designed temperature controlled thermal shippers utilizing dry ice to maintain recommended temperature conditions for up to ten days unopened. These specialized thermal shippers are roughly the size of an eighty-one pounds. fully loaded. And the GPS enabled thermal sensors are utilized in every thermal shipper with a control tower that will track the location and temperature of each vaccine shipment across the pre-set routes. These GPS-enabled devices will allow Pfizer to proactively prevent unwanted deviations and act before they happen (Pfizer, 2022). Those strategies can utilize Pfizer strategic transportation partners to ship by air to major hubs within a country and region and by ground transport to the dosing location. Third, the use of enterprise resource planning (ERP) systems. During the COVID-19, ERP was significant in the continuance and sustaining of manufacturing operations worldwide. ERP is an analytic tool that can help determine where the vaccines are, the lot numbers, and the distribution network. It allows business operations through digital data exchange and remote access of the covid vaccines. People in different roles will have different levels of access on the ERP information, and they will use this information to make decisions. After integrating all the information from the ERP, CDC will receive a file that shows the number of vaccines that need to be given. Then the CDC

will load it in the Vaccine Tracking Systems (VTrckS) and order vaccines on the VTrckS. VTrckS is a robust vaccine management application that allows CDC, awardees, and providers to order and manage publicly-funded vaccines more efficiently (Centers for Disease Control and Prevention, 2022). It is owned by the CDC and hosted in the CDC data center. It has been in used by all immunization programs for vaccine ordering and management since 2010 (Centers for Disease Control and Prevention, 2022). Fourth, the cold chain plays an important role to manage the Covid-19 vaccines. Vaccine characteristics and physical supply chain capacity will significantly affect the feasibility and efficiency of distribution. A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain cannot work without the capacity of personnel. An effective cold chain relies on well-trained staff, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management (Centers for Disease Control and Prevention, 2020). The Center for Disease Control (CDC) recommends that "every facility that receives, distributes, or administers influenza vaccines maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures and train staff on those procedures." This will help to get personnel and cold chain ready when an emergency happens again. In addition, there is a need to determine effective ways to resource in-country distribution and delivery. The operational cost of getting influenza vaccines to people is significant, placing a high burden on some lower middle-income country budgets. Beyond standard transportation and distribution costs, human resource capacity for distribution and delivery is a major challenge. There are significant gaps for these operational expenses. There is a way to lower the cost in the future, which is using vaccination sites that established during COVID-19 to serve as central points of administration. The benefits of this model include easier delivery of vaccines and critical components to one centralized

location, rather than dividing the same volume of resources among multiple, smaller health care settings. In this way, it will be easier to manage the cold chain, the wastage of vaccine doses will decrease, and the throughput will increase. Moreover, the strong global cooperation is needed to effectively respond to a pandemic. It truly requires a global multi-stake- holder response. Manufacturers, regulators, and global agencies all need to be coordinated for there to be a sustainable and viable system. For example, supply chain that supports vaccine manufacturing and distribution. The ensures the supply life-saving vaccines can be produced.

The distribution plan, temperature and storage requirements, and transportation methods are all important factors that need to be carefully considered in the distribution of vaccines, including the flu vaccine and the Pfizer-BioNTech COVID-19 vaccine. The pro rata formula is used for both vaccines and it can ensure vaccines are distributed fairly and efficiently based on the population's need. Each state can order vaccines on VTrckS based on the pro rata data. The only difference is that due to the urgency of the COVID-19, a system called ERP has been involved to collect and store information about the vaccine. Temperature control is also critical for both vaccines, but the range of temperature requirements is different. The flu vaccine needs to be stored between 35° to 46°F, while the COVID-19 vaccine requires much lower temperatures. The COVID-19 vaccine needs to be stored between -130°F and -76°F until expiration date and between 36°F and 46°F for up to ten weeks. This means that special equipment and procedures need to be in place to ensure that the vaccines are kept at the right temperature during transportation and storage. For the transportation, both vaccines use air transportation and ground transportation. The flu vaccine has less stringent temperature requirements than the COVID-19 vaccine. Unlike the COVID-19 vaccine, the flu vaccine cannot be frozen, as freezing can damage the vaccine and make it less effective. The COVID-19 vaccine

is sensitive to temperature, and it requires precise temperature control during transportation to maintain the efficacy. Therefore, distributors must implement cold chain management, temperature monitoring and security measures like GPS tracking to ensure that the recommended storage temperature range is maintained.

Chapter 4 : Conclusion

The development and distribution of the COVID-19 vaccine have been crucial in fighting the pandemic. Due to the time restriction and urgency, it was important to develop and distribute the vaccine as soon as possible. The COVID-19 vaccine development process was much faster than the traditional flu vaccine development process due to advancements in technology and global cooperation. And the emergency use authorization has played an indelible role in accelerating the advancement of a COVID-19 vaccine. In addition, the FDA approval process also played a critical role in ensuring the vaccine's safety and efficacy before distribution.

There has been much attention put on the vaccine supply chain since the COVID-19 pandemic began. The new strategies developed in the U.S to deal with the difficulties of COVID-19 vaccine distribution have garnered significant interest. The pro-rata formula, ERP system, and VTrackS system were used to manage vaccine distribution. The distribution process was complicated due to the need for a cold chain to maintain the vaccine's efficacy. The flu vaccine is also temperature sensitive, but the COVID-19 vaccine requires a more stringent temperature control condition. To ensure safe distribution, COVID-19 vaccines were transported using specialized equipment and methods. The GPS thermal sensors helped to monitor temperature conditions transportation, ensuring that the vaccine was not exposed to unsuitable temperatures.

The COVID-19 vaccine's distribution plan and the methods used have overcome several challenges, including cold chain management, logistical challenges, and supply chain disruptions. However, there are still areas for improvement in the distribution plan and method. In the future, manufacturers should consider using single-vial or similar amounts to prevent waste. Additionally, better communication between different stakeholders in the vaccine

distribution chain is necessary to improve transparency and ensure that the vaccine reaches those who need it most. The global community must continue to work together to ensure the safe and equitable distribution of the COVID-19 vaccine. The importance of global cooperation and the need for a strong cold chain cannot be ignored.

Despite the urgency of the situation and time restrictions, the development and distribution of the COVID-19 vaccine has been successful due to the emergency use authorization, new strategies, careful planning and execution of the distribution process, and global cooperation. The development and distribution of the COVID-19 vaccine have demonstrated the importance of preparedness and effective management of the vaccine supply chain.

Appendix

Interview Guide

1. Walk me through the vaccine's distribution process.
2. Were there any difficulties in this process?
3. What is the time window between the availability of a vaccine and the recognition that a new vaccine is required to address the pandemic?
4. How did you develop the distribution plan? What were the factors that you concerned about?
5. What were the risks associated with the distribution process and what mitigation plans were in place to address them?
6. Was the distribution plan developed based on population?
7. If both areas have same amount of people, what other elements would affect your decision for the distribution amount?
8. How did you decide on the number of vaccines that needed to be distributed?
9. How did you decide the location for the vaccines that needed to be sent out? Ex. Hospital, retailer, etc.
10. After the situation stabilized, the demand decreased. How did the demand change over time and how did it impact the distribution plan?
11. What methods did you use for distribution?
12. Did any new strategies or technologies get involved in the distribution?
13. Were there any difficulty in transporting COVID-19 vaccines compared to traditional vaccines?

14. How will you improve the process if you can do it again?

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ACADEMIC VITA

Peiqi Huang

EDUCATION

The Pennsylvania State University — **University Park, PA**
Smeal College of Business — *May 2023*
Bachelor of Science in Supply Chain and Information Systems — Dean's List 7/7 semesters
Minor in Communication Arts and Mass Media
Minor in International Business
Schreyer Honors College

Queen Mary University of London — **London, United Kingdom**
Semester Study Abroad Program — *Jan 2022 – Jun 2022*

Experience

Shenzhen Daybetter Optoelectronics Co., Ltd. — **Remote**
Operation Intern — *May 2022 – Aug2022*

- New Media Operations, Distribution Operation, and Data Collection.

Coffee Bean & Tea Leaf — **Honolulu, HI**
Barista — *Jun 2016 – Apr 2017*

- Participated day-to-day business operations, prepared beverages, managed the cash register, and resolved customers' issues

Leadership

Rockwell Automation — **University Park, PA**
Student Member — *Aug 2021 – Feb 2022*

- Analyzed sales data for common ordering quantities for the Top 5K SKU
- Researched overpack options for best transportation optimization and increased revenue opportunities

APICS- The Supply Chain Organization — **University Park, PA**
Member — *Aug 2021 – Current*

- Participated in corporate events with Apple and Amazon
- Strengthen Supply Chain Management expertise by debating business topics with fellow outstanding members

Capital College Honors Program — **Harrisburg, PA**
Member — *Aug 2019 – May 2021*

- Participated in monthly featured and educational events

International Business Plan Competition — **Singapore**
Team Member — *Dec 2019 – Jan 2020*

- Collaborated with others to propose ideas to start a business, found solutions to implement the plan, and wrote a business proposal

Distributive Education Clubs of America, DECA — **Honolulu, HI**
Vice President — *Aug 2018 – May 2019*

- Prepared meeting agenda, organized club events such as fundraisers, business programs and competitions, and provided options to improve the club

AWARDS/SKILLS/INTERESTS

- *Awards:* Penn State Provost Award
- *Skills:* Native Fluency in Mandarin and Cantonese, Microsoft Excel, Video Editing
- *Interests:* Musical, Yoga, Gym, Board Game