Spring 2021

COVID-19 vaccine distribution: an intrinsic case study on coordinating vaccination efforts for long-term care facilities

Kelsey Hill

COVID-19 Vaccine Distribution: An Intrinsic Case Study on Coordinating Vaccination Efforts for Long-Term Care Facilities

By: Kelsey Hill

Disclaimer:

This is a study of a temporary work position in which I held with a company. The name of the position has been changed so as to not identify my employer. This study does not reflect my employer in any way and all ideas and discussions are strictly my own. I will not mention any names of Long-Term Care Facilities in which we were associated with. Any names of positions or people have been changed to protect and maintain their privacy.

Purpose:

In late 2020 I was approached by a regional manager within my company to help out with a major task; coordinating the vaccinations of some of our State's Long-Term Care Facilities in an attempt to protect some of our most vulnerable from the COVID-19 Pandemic. I was one of 10 people who were selected to take on this huge task within our region for our company (every region of the company had this coordinating position with varying participants depending on the size of the regional geography and number of facilities they were servicing). The coordinating position was one of the most difficult, yet most rewarding positions I have been a part of so far in my career. This is an intrinsic case study, meaning I am going to be exploring some of the challenges of the position I was in and is not to build any theories or study any abstract ideas (Baxter & Jack, 2008).

In this study, I will be briefly discussing what the COVID-19 pandemic is, give some background on the vaccines that were approved and in use for the clinics, how the vaccine was distributed, and some of the challenges I faced in the role while including some ways in which information systems solutions could help in the future planning and distribution of vaccines.

COVID-19:

With almost 31 million cases of COVID-19 in the U.S. since the pandemic began and over 558,000 deaths, SARS-CoV-2 as it is known has had devastating effects on people around the world ("COVID Data Tracker", 2021). According to the Mayo Clinic, coronaviruses are a group of viruses that cause respiratory illnesses such as "the common cold, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS)" and is how SARS-CoV-2 (COVID-19) got it's name; it stands for severe acute respiratory syndrome coronavirus 2

("Coronavirus disease 2019 (COVID-19) - Symptoms and causes", 2021). Common symptoms of this disease include fever, cough, shortness of breath and fatigue, and some experience a loss of taste and smell for varying amounts of time and can lead to other respiratory illness and even death (Adil et al., 2020). The main source of transmission is through droplets that are expelled from the infected person when they are talking, sneezing, or coughing (Omer, Malani & del Rio, 2020). The first case was reported in Wuhan, China in November of 2019, by May of 2020, the World Health Organization (WHO) declared it a global pandemic (Adil et al., 2020).

To combat the COVID-19 global pandemic, the Department of Defense (DOD), the Department of Health and Human Services (HHS), and the Centers for Disease Control and Prevention (CDC) have teamed up to "accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics to counter COVID-19" ("Coronavirus: Operation Warp Speed", 2021). The main goal of OWS is "ensuring that every American who wants to receive a COVID-19 vaccine can receive one, by delivering safe and effective vaccine doses to the American people beginning January 2021" (From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine, 2020). OWS assisted in the support of vaccine trials and ensuring a quick yet safe way for developing vaccines and had set out a plan to create a centralized distribution for when vaccines were approved by the FDA and get them send out to states and territories as quickly and efficiently as possible (From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine, 2020). OWS assisted in distributing vaccines and supplies to our stores, including the shipments of supplies for vaccination including diluent, syringes, vaccination cards, and more in every OWS shipment.

COVID-19 Vaccine:

At the time of my position only 2 vaccines were approved under the Emergency Use Authorization (EUA), the Moderna and Pfizer vaccine. For our Long-Term Care Facilities, we were allocated the Pfizer vaccine, which will be the focus of this paper. The Advisory Committee on Immunization Practices (ACIP) states that "On December 11, 2020, the Food and Drug Administration issued an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine" (Oliver et al., 2020). They also state that it is a 2 dose series in which the

doses should be given 3 weeks apart (21 days) and is able to be given to those aged 16 and up for the prevention of COVID-19 (Oliver et al., 2020). This allowed the vaccine to be utilized and shipped on plan with OWS.

One of the biggest challenges with the Pfizer vaccine was the ultra-cold temperatures in which it had to be stored and handled. According to the CDC, the ultra-cold temperatures in which the vaccine should be held is between -80°C and -60°C (-112°F and -76°F), meaning that our stores in which shipments were received either had to have shippers with dry ice or have ultra-cold freezers installed in the pharmacy ("Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary", 2021). Training of all employees was an essential part of ensuring that the vaccine was stored and handled properly.

Another challenge was that once the vaccine was thawed to refrigerated temperatures (2°C and 8°C (36°F and 46°F)), it had to be used within 120 hours ("Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary", 2021). This required a high level of coordination between us coordinators, the stores, and the Long-Term Care Facilities; if the facilities requested a number that was different from what was needed, we would either cause a shortage or a surplus, alternatively, if the store did not properly count the amount of vials they pulled, it could also cause issues. The factor that helped the most was having open communication, explaining why the numbers requested was so important, and always verifying the number before the clinic date. If there was a shortage or surplus, it was my responsibility to figure out where to send the vaccine so that it was utilized within that 120 hour window. To ensure the temperature was maintained, hourly temperature checks (for clinic visits), twice daily temperature checks (for ultra-cold freezer/shippers) and temperature alarms were placed with the vaccine and monitored.

Vaccine Distribution to Long-Term Care Facilities (LTCF):

To ensure effective distribution of the vaccine, and to keep in compliance with the cold chain (the storage and handling of the vaccine at the cold temperatures and verifying that the temperatures were maintained), my company utilized a hub-and-spoke model detailed in Figure 1 (Zäpfel & Wasner, 2002). There were some stores that were distributed throughout the state that were the ‘Hub’ stores and other stores, based upon geographical distance to a Long-Term

Care Facility, that were 'Spoke' stores. The Hubs were responsible for receiving the vaccine shipments, maintaining the ultra-cold temperature required, and distributing supplies that were shipped in to the stores through the OWS shipments. Spoke stores were then responsible for picking up the vaccine from the Hubs, fulfilling other supplies for the pharmacists (i.e. sharps containers, bandaids, vaccine and diluent, syringes, etc.), and supplying a support person to the clinics. This support person was responsible for the non-vaccination side of the clinics (ensuring paperwork was completed, filling out vaccination cards, and helping to observe patients for the allotted time after vaccination). While it was the Spoke stores' responsibility to send a support person, it was also my responsibility to ensure they were aware of their roles and responsibilities.

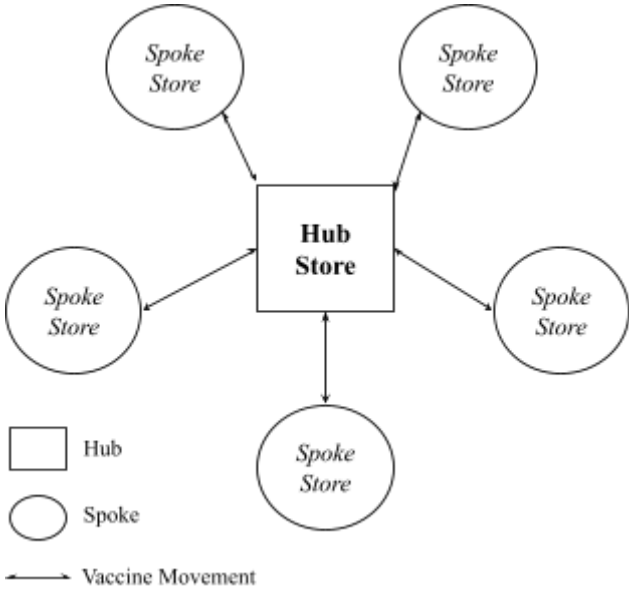

Figure 1 - Visualization of a Hub-and-Spoke model

Throughout the process, we had those in the coordination position, such as myself, as well as someone who was scheduling our pharmacists who were willing and able to go to the clinics (it was not required that all pharmacists assist with the clinics as not everyone was comfortable with the potential risks of going into these LTCF). In the first few days of my position I was responsible for contacting my Long-Term Care Facilities (broken up by Spoke stores, i.e. Store X was responsible for 10 clinics, Store Y was responsible for only 4 clinics, etc. based on geography and selected by someone at the corporate level), gaining information on the number of staff and residents wanting the vaccine, and creating a schedule for when we would hold our

clinics. Since we were dealing with the Pfizer vaccine, these clinics were to be held 21 days apart. The State of Iowa gave my company a deadline that all first-round clinics must be completed by the end of January 2021. This would make it so that all 3 clinics were completed by the middle of March and allow for the next phase of vaccine distribution to begin.

As part of our agreement with the State, we were to offer 3 vaccination clinics to the Long-Term Care Facilities. The reason behind this was that everyone needed to get 2 doses of the vaccine for it to reach the full efficacy. The first clinic was to get anyone at the facility (resident or staff) their first dose of vaccine. The second clinic was to finish the dose series for those at the first clinic, but also allow anyone who was new or changed their mind to get their first dose. Our third and final visit was to finish the vaccine series for everyone that had received their first dose either at the first or second visit (i.e. those who were ill at our second visit and didn't complete their vaccine, those who got their first dose at our second clinic, etc.). When scheduling I had to verify that the same Spoke store wasn't doing multiple clinics on the same day, as these clinics were generally 6-8 hour clinics, and that they would still have proper staffing at the store level to run paperwork and do their normal store responsibilities.

There were rules that needed to be followed for my company to complete these clinics and comply with State and Federal standards. I was responsible for ensuring that we were following these rules and communicating them with my teams at the store level as well as with my team going to the clinics. One of the biggest compliance standards was that anyone going to these LTCF had to be COVID-19 tested within 3 days of the clinics. This meant that both support persons and pharmacists had to be aware of the requirement. It also meant if they were not tested or if they tested positive then I would have to find someone else to replace them that had been tested and tested negative. Another compliance standard that I had to ensure was upheld was that HIPAA regulations were being followed and that everyone was aware of the proper billing process on the store side. Lastly, I was responsible and held accountable for entering the number of vaccines that were given for each clinic into different 'portals' that were used to create reports that were sent to the State and the CDC daily on these clinics. This information had to be accurate and submitted on time as it was used in daily reports provided by the Department of Health and the CDC on the COVID-19 Pandemic and vaccinations.

Throughout my time in the position there were 3 main difficulties I encountered throughout the distribution process and clinics; communication issues, rapid changes to the process, and ensuring accurate reporting. I will discuss each of these topics in detail and what I would recommend based on what I have learned throughout my academic career to alleviate or even prevent the issues from occurring in the future.

Communication:

One of the most important aspects of my coordinating position was communicating. I had to communicate with Hub/Spoke stores, Pharmacists, support persons, supervisors, other coordinators, schedulers, my LTCF contacts, etc. The main form of communication initially was through email. In the very beginning, back in December of 2020, my company had just begun to develop my position and had a few scripts initially made for when we reached out to the facilities. I used this script and customized it to each facility and waited for the response back. This initial contact was just to get who would be the LTCF point of contact, and to ensure that the facility had actually signed up to be a part of the Federal program to get vaccines. Once I established who the contact would be, I created an Excel spreadsheet with all of their information (facility name, facility address, contact name, position, phone number, email, the best form of communication, etc.). I quickly discovered that communication would have to be done on a case-by-case basis, as some facilities were very quick and responsive to emails, and others I would rarely get a reply from. With these experiences, I tailored communication to fit the needs of my contacts.

My main goal in my communication style was to be supportive. Supportive communication can clarify roles and expectations, assist in reducing uncertainty in situations, and can increase perceptions of personal control (Eileen, 1991, pg. 507). This was an unprecedented time and many facilities were wanting to get their residents and staff vaccinated as soon as possible to try and get back to "normal." My position was primarily to coordinate and work with the facilities to schedule their clinics, but I also answered any questions, ensured they were ready for the clinics, and communicated any changes. The more information I could communicate with the

facility, the smoother the process at the facility would be, and the more prepared the facilities felt for these clinics.

There were 2 very important steps that needed to be completed before every clinic; Vaccination Administration Record (VAR) forms completely filled out and staff and resident information needed to be entered into our portal that was used for State and CDC reporting. The VAR forms that had to be filled out for every patient prior to the start of the clinics included name, address, screening questions, consent, and signatures. It was extremely important to have this completed for every patient before the clinic so that the clinic process could be as streamlined as possible and so everyone's form could be properly processed at the store and reported to the State Health Department and the CDC. For the portal, every LTCF was registered in advance with standard information (name, address, phone, number of staff, number of residents, main contact) before each clinic. It was the responsibility of the facility to have all patients and staff registered with their information. This portal had two purposes; one was to cross-reference and properly report numbers to the CDC and IRIS (Iowa's Immunization Registry Information System) as well as create a profile in our pharmacy system to process the VAR form. In the case of an adverse event, the facilities could report the event to the Department of Health and Human Services Vaccine Adverse Event Reporting System (VEARS) or contact the pharmacy that processed their VARs to report the event. It was my responsibility to inform these facilities of the VAR form and to ensure everyone getting the vaccine was in the portal as this streamlined the process at the clinics and made it more efficient for the pharmacy at the store level.

For future vaccination clinics, I would recommend both an assertive yet supportive communication style. For assertive communication, you are balancing between what you want and what others want (Pipas, 2010, pg. 650) and doing so in a respectful, yet firm manner. This is extremely important as on occasion the facilities either didn't have time or understand the importance of what you are asking to be done. It seemed to work best when this issue arose to explain the why behind your request and explain the importance of the task needing to be done. To maintain a positive relationship, there does have to be some give where you listen to their frustrations and try to help the best you can. On occasion I would have to take the stress of uploading to the portal off of the facility and do it on my end when available. This assertive yet

supportive communication style helped create and maintain positive relationships, which is ideal for uncertain and challenging times.

Changes:

Change is inevitable, especially in a situation like a vaccine distribution during a global pandemic. One of the biggest challenges throughout my coordination position was dealing with the constant changes from both the State and Federal level and also within the corporation itself. After we went live with vaccinating LTCF, my corporation came out with nationwide "Vaccine Updates" in which a corporate team was responsible for announcing changes and updates to the program at a federal level. These meetings were over broadcast and were twice weekly.

An example of a major change was the VAR form itself. When we started there were only 6 screening questions, then a new VAR came out with 9 questions, and it currently contains 11 screening questions. While these questions were all vital and the reason for the change was necessary, they were not explicitly stated to us until after the changes were made, causing some confusion on the facilities end as they were then sent the new VARs to be completed. This caused frustration and annoyance with many facilities as they were trying to streamline their processes. I found if I explained the importance of the changes and communicated with them as soon as possible that many were understanding and were willing to make the changes.

Another change that caused confusion throughout the process was who was technically eligible for vaccination. In December of 2020, the Advisory Committee on Immunization Practices (ACIP) recommended phases in which vaccine distribution be allocated, their phases are shown in table 1 ("COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex", 2021). Phase 1-A included healthcare personnel and LTCF residents according to the ACIP recommendations but Iowa considered "paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials [and] Long Term Care Facility (LTCF) residents and staff," which would make anyone working or volunteering at the facility eligible for the vaccine as well (Curtiss, 2020). This meant that anyone working for the facility who was over 16 could get the vaccine at one of our vaccine clinics, but they were not eligible outside of our clinics.

Phase	Eligibility
1-A	Healthcare personnel and long-term care facility residents.
1-B	Persons ≥75 years of age and frontline essential workers (non-healthcare).
1-C	Persons 65–74 years of age, persons 16–64 years of age with high-risk medical conditions, and other essential workers.
2	Other persons aged ≥16 years of age not already recommended for vaccination in Phases 1a, 1b, or 1c.

Table 1 - ACIP Recommended Vaccine Phase Eligibility

Lastly, another major change that caused confusion was from our registration portal that the facilities used to enter staff and resident information. They were continuously working on improving the system as we were using it. The product life cycle includes the modeling, creation, updates, integration, and optimization of the product at hand, in this case the portal (W. He, 2006). It is expected that changes will happen as our corporate support team optimized the portal to better allow for ease of use, account for accurate information, as well as ensuring that information needed for State and Federal reporting is collected. A major factor of this system was to allow our support team to cross reference data in our pharmacy system and what was reported from the facilities to be reported to IRIS through a data exchange, where in Iowa, "approximately 90 percent of the data reported to IRIS is through [a form of] electronic data exchange" to ensure accurate vaccination information (Curtiss, 2020). The changes included verification of facility information (after the profile had been created and used), and the ability to only enter staff and resident information based on scheduled clinic date (when before it was put under the date the facility chose to place it under).

While change is expected in every environment, it is especially expected during a pandemic as new information is found on a continuous basis. Change can be hard on individuals and while they may not want to revert to how the process was before, too much change can make individuals resist future change (Galston, 2018). For this reason, organizations and governments

should be cognizant of the potential changes that will need to be made and either take more time to develop their product in the creation phase so as to reduce the amount of changes needed in the optimization phase. Governments should also ensure that the expectations are clear and understandable for those creating these systems to further reduce the need for changes after the systems have been implemented.

Reporting:

Throughout the vaccination process, data collection was extremely important for reporting according to Federal and State standards. The most important step in data reporting was that it must be completed within 24 hours of vaccination (Curtiss, 2020). The number of vaccines given was dependent upon staff, residents, the number of doses received, and the information reported to the coordinators by pharmacy staff at the store level once they completed processing the VARs. Since humans are involved with the data entry process, we can assume that there will automatically be human errors in the data (Barchard & Pace, 2011). This error could occur at the store level when entering VARs, at the reporting level when numbers were sent to the coordinators, or in the process of the coordinators of entering the data.

There were three locations in which we reported data on the number of vaccinations; one was a portal in which every clinic name was shown and we had to break down Dose 1 vs Dose 2 for staff and residents which fed to the State portal (we will call this portal A), another was a master Microsoft Excel datasheet we had shared among the coordinators to easily see how many vaccines were being administered and where, and lastly into our company portal that was used for outreach and held facility and contact information (we will call this portal B). Portal B was important for the scheduling of the clinics and was how the first portal got the facility names and clinic dates. The two portals, A and B, were important to update daily and portal A received information from portal B about the clinic date and facility name, but any vaccine administration numbers placed in either portal did not translate into the other, causing the need for multiple entries of the same data. This technological inability to communicate could potentially lead to misreported data to both State and Federal programs tracking the COVID-19 vaccinations across the U.S.

Personally, the way that I tried to reduce errors was to reiterate the importance of accurate numbers when collecting it from the store personale and double (and even triple check) the numbers I entered before completing the entry. This was due to my knowledge of how common human error is in the data entry process from my Undergraduate and Graduate studies. Visual checking is one of the most common methods to preventing data error (Barchard & Pace, 2011) and consists of entering the data and then visually cross-checking your entry with what you had read your data from (i.e. written piece of paper, email, etc.) to ensure it is correct. The reduction of the amount of times data had to be entered (i.e. bi-directional interfacing between the two portals) and a way to verify the data entry could greatly improve the data collection and reporting process for future vaccination clinics.

Conclusion:

While the pandemic changed the way of life for people across the globe, we are still not done fighting this disease. With the advancements of the vaccine and the push to get as many people vaccinated as possible, we are hopefully one step closer to getting back to 'normal'. Many things have changed since my time as a vaccine coordinator and assisting Long-Term Care Facilities with vaccination clinics, including a new vaccine being distributed, the Johnson & Johnson (also known as Janssen) COVID-19 vaccine that was approved for emergency authorization in late February (Oliver et al., 2021). While we will continue to see changes, having open, honest, supportive and assertive communication, minimizing the amount of changes needed, and ensuring accurate data reporting, the vaccination process can continue to be efficient and widespread, and hopefully we can all see the end to the pandemic.

References:

Adil, M., Rahman, R., Whitelaw, D., Jain, V., Al-Taan, O., & Rashid, F. et al. (2020). SARS-CoV-2 and the pandemic of COVID-19. Postgraduate Medical Journal, 97(1144), 110-116. doi: 10.1136/postgradmedj-2020-138386

Barchard, K., & Pace, L. (2011). Preventing human error: The impact of data entry methods on data accuracy and statistical results. Computers In Human Behavior, 27(5), 1834-1839. doi: 10.1016/j.chb.2011.04.004

Baxter, P., & Jack, S. (2008). Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers. The Qualitative Report, 13(4), 544-559. https://doi.org/10.46743/2160-3715/2008.1573

Coronavirus disease 2019 (COVID-19) - Symptoms and causes. (2021). Retrieved April 2021, from https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963

Coronavirus: Operation Warp Speed. (2021). Retrieved April 2021, from https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

COVID Data Tracker. (2021). Retrieved April 2021, from https://covid.cdc.gov/covid-data-tracker/#datatracker-home

COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex. (2021). Retrieved 11 April 2021, from https://idph.iowa.gov/Portals/1/userfiles/61/covid19/vaccine/COVID-19%20Vaccination%20Playbook%20Januar.pdf

Curtiss, R. (2020). COVID-19 Vaccination Strategy - Draft IOWA. https://idph.iowa.gov/Portals/1/userfiles/61/covid19/vaccine/V%202%20IOWA%20COVID-19%20VACCINATION%20STRATEGY%2012_4_20_FINAL.pdf

Eileen Berlin RayKatherine, I. M. (1991). THE INFLUENCE OF COMMUNICATION STRUCTURE AND SOCIAL SUPPORT ON JOB STRESS AND BURNOUT: THE NATURE OF SUPPORTIVE COMMUNICATION OUTCOMES OF SUPPORTIVE COMMUNICATION IN THE WORKPLACE A MODEL OF SUPPORTIVE COMMUNICATION, JOB STRESS, AND BURNOUT METHODS ORGANIZATIONS INSTRUMENTATION RESULTS DESCRIPTIVEANALYSES RELIABILITIES MODEL DISCUSSION APPENDIX ITEMS FOR PERCEPTUAL MEASURES REFERENCES. Management Communication Quarterly : McQ (1986-1998), 4(4), 506. Retrieved from https://search.proquest.com/scholarly-journals/influence-communication-structure-social-support/docview/232858404/se-2?accountid=10906

Galston, W. A. (2018, Jul 31). Slow down and try not to break things; change is inevitable, but policy makers should think about how to make it easier. Wall Street Journal (Online), Retrieved from https://search.proquest.com/newspapers/slow-down-try-not-break-things-change-is/docview/2080341799/se-2?accountid=10906

Oliver, S., Gargano, J., Scobie, H., Wallace, M., Hadler, S., & Leung, J. et al. (2021). The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. MMWR. Morbidity And Mortality Weekly Report, 70(9), 329-332. doi: 10.15585/mmwr.mm7009e4

Oliver, S., Gargano, J., Marin, M., Wallace, M., Curran, K., & Chamberland, M. et al. (2020). The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020. MMWR. Morbidity And Mortality Weekly Report, 69(50), 1922-1924. doi: 10.15585/mmwr.mm6950e2

Omer, S., Malani, P., & del Rio, C. (2020). The COVID-19 Pandemic in the US. JAMA. doi: 10.1001/jama.2020.5788

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary. (2021). Retrieved April 2021, from https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

Pipas, M. D., & Jaradat, M. (2010). ASSERTIVE COMMUNICATION SKILLS. Annales Universitatis Apulensis : Series Oeconomica, 12(2), 649-656. Retrieved from https://search.proquest.com/scholarly-journals/assertive-communication-skills/docview/856208387/se-2?accountid=10906

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. (2020). From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine [PDF].

W. He, X. G. Ming, Q. F. Ni, W. F. Lu & B. H. Lee (2006) A unified product structure management for enterprise business process integration throughout the product lifecycle, International Journal of Production Research, 44:9, 1757-1776, DOI: 10.1080/00207540500445453

Zäpfel, G., & Wasner, M. (2002). Planning and optimization of hub-and-spoke transportation networks of cooperative third-party logistics providers. International Journal Of Production Economics, 78(2), 207-220. doi: 10.1016/s0925-5273(00)00152-3