Worldwide Vaccination Issue
Group 3 Final Report
MFE634

SYRACUSE UNIVERSITY
ENGINEERING & COMPUTER SCIENCE

Zhaoning Song
Andrew Gagan
Silvio-Antonio Zallo
Shree Krishnan
Prathamesh Patil

Syracuse University Spring 2022

Table of Contents

1. Overview

1.1 Problem Statement

In 2019 the COVID-19 virus was spread around the world as millions of people got the infection. In the following months companies like ours have researched, developed and then successfully created a vaccine for the virus. However, there are various obstacles and roadblocks in the way of getting every person their vaccine, no matter where they are on the globe or what their living status is. It is the goal of our company to find the flaws or redundancies in our organization and fix them so that the systems run more efficiently and in turn more people are better protected against the virus.

This is a difficult process however as there are a number of factors that go into a patient successfully receiving their vaccination. Since a worldwide pandemic has not happened on this scale in the modern age, hospitals and governments were extremely unprepared to combat it and there was not enough staff to properly run the vaccination clinics. There was also no transportation systems set up to move the vaccines and not enough warehouse equipt to properly store them. To be effective the vaccine needs to be refrigerated from the moment it is made to a couple hours before it is used, meaning that from packaging, to being on the trucks or other vehicles, to then being stored near the clinic, the vaccines need to maintain a certain temperature or else become useless. This brings a lot of challenges as refrigeration units are sensitive and can fail for a number of different reasons, the biggest being that the vaccine needs to be distributed worldwide to all climates and elevations so that everyone could receive the same protection. This included third world countries that might not have the infrastructure or resources that countries such as those in North America and Europe. To take all of this into consideration and try to optimize the process is a large but necessary task to safeguard everyone from the pandemic.

1.2 Brainstorming

Populations at Risk	Before	Response	After
Elderly	Low vaccination rate	Hire and train new personnel	Proper documentation
Sick	High costs	Effective transportation	Public perception
Poor	Low public knowledge	Public Information Campaigns	Updated training
Isolated	No transportation/ supply network	Research and study lowers costs	
Biased people	Need training	Effective Clinics	
3rd World Countries	Low staffing		

Figure 1: Brainstorming

To start, our group thought of those most at risk, what challenges our organization faced, what we could do about it, and then what we could look to do after. We defined elderly, sick, and poor people as the most susceptible to the potentially deadly virus but also considered other factors such as where in the world a person could live and how close they lived to a vaccination clinic. The last group we considered were those who might be scared away from taking the vaccine either from possibly unverified sources or political allegiances as the more individuals that receive a vaccine the safer the entire population is. We then focused on the problems we faced before we started which included little to no infrastructure in transportation or clinics. This project is therefore going to cost a lot of money as our organization is going to need to buy vehicles and refrigeration units, hire staff, research and develop a more efficient vaccine, along with a number of other things. From there we came up with ways to combat these problems and then ways to measure and ensure that we were doing a satisfactory job. This would include properly documenting the patients after they were vaccinated and constantly updating training and clinic methods to reflect the most productive outcomes.

2. Define Phase

2.1 Flowchart

Figure 2: Flowchart

The flowchart is a pathway to follow and find failures in the system and recommend solutions to fix them. It is a kind of contingency plan for when things inevitably go wrong and the organization can't avoid like machines breaking down. All the different collared and differently shaped boxes mean something different. The diamonds are decision gates with multiple answers, the red boxes are the primary reason while the blue are the secondary and yellow represent anything after that, and finally the green ovals are suggestions of how to fix the problem inside the company. Starting at the top with the Orange diamond that simply asks if a hypothetical patient recive the vaccine and its effects and is followed by a yes or no gate. If the answer is yes then we proceed to the green oval and nothing needs to be done. If the answer is no then we need to follow the arrows and answer the questions to find a solution to our problem. For instance if someone wasn't vaccinated because we didn't have enough staff to process them, using this chart it is easy to follow and find the solution of hiring more staff or increasing

training. Although this chart doesn't answer every single small question it will get you in the right vicinity of the solution and if expanded even more is even more helpful to the organization.

2.2 Organization Chart

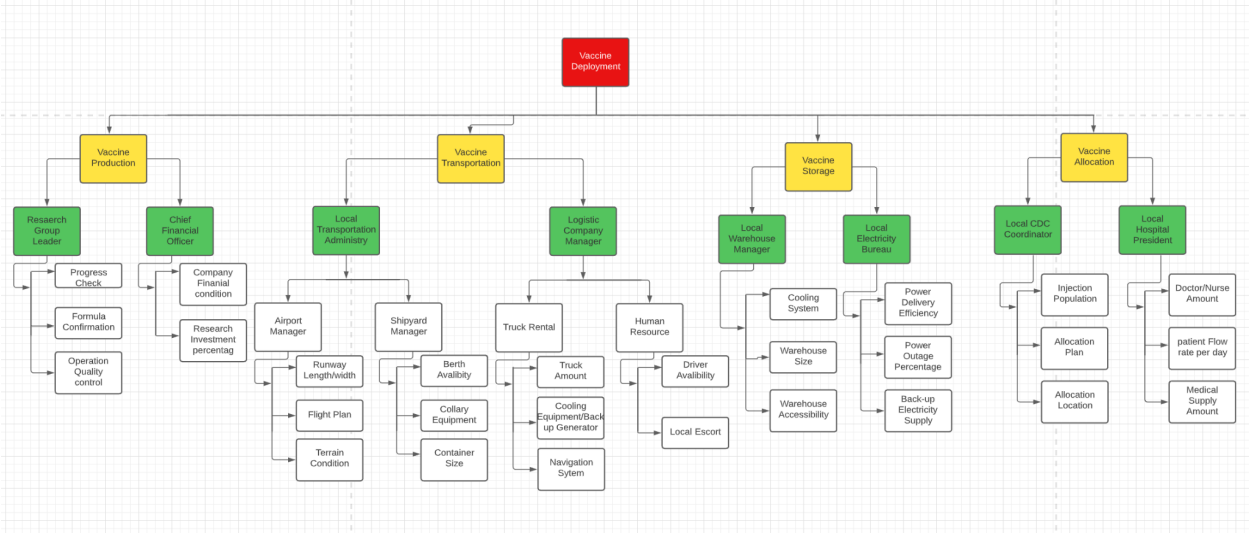


Figure 3: Organization Chart for Vaccine Allocation

The organization chart is a tool to help us determine the personnel who are responsible for each important procedure for our allocation process. It can help us figure out who we need to reach out to and discuss with them how this step works and what we need to prepare for each step. So we listed the person's response to each vaccine allocation process. We also prepared the interview for those persons. From vaccine production, the persons we are going to ask are research group leader and Chief Financial Officer. For vaccine production, these two people hold the power of research progress, quality, and company's cash flow. We can get information related to research progress and the company's financial condition. For vaccine transportation, we need to ask the local transportation ministry and logistic company manager. More detaily, we need to ask the local airport manager and shipyard manager to confirm the runway condition and berth availability. For example, is the runway long enough to land a large cargo plane and is the berth large and deep enough to park a large cargo ship. For airplanes such as An-124 and Boeing 747, we need at least 4000 meters of runway in order to let them land safely with heavy loads. We also need to confirm the flight plan with the local airport. About the logistics company, we need to ask them how many trucks they can provide and whether those trucks have a functional cooling system. Also, those trucks need to have navigation systems in order to avoid the bad road which may damage the vaccine. We also need to ask the human resource department of the logistic company to confirm how many truck drivers they can provide. For vaccine storage, we need to get in touch with the local warehouse manager to confirm warehouse location, size, and cooling ability. When talking about cooling, electricity is a vital part we can not afford to lose.

So we also need to contact the local electricity bureau to confirm the local power grid's stability and is there any back up power supply available. Finally for vaccine allocation, we need to reach the local CDC coordinator to get the data for the injection population to determine how many vaccines are needed per day. We also need to talk about the allocation plan with them. They need to help us find the allocation location. We also need the local hospital's help to get enough doctors and nurses for us to do the vaccine injection.

2.3 COPQ Analysis

Process	Internal Failure	External Failure	Appraisal	Prevention
Vaccine Development	Wrong Formula, management decision	Company Bankrupt, natural disaster		continue researching, test, hire the proper managers and researcher
Vaccine Transportation	Air-con failure,, Refrigerant leak, bad packaging, Lack of workers	Car accident, boat sink, plane crash, poor travel conditions		Better Packaging, back-up air-con, optimize navigation with weather
Vaccine Storage	Air-con failure, lack of space	Fire,natural disasters, power outage	Warehouse manager, system engineer	Back up cooling equipment, Generators, smoke detector, cctv system.
Vaccine Allocation	Poor time management, poor planning	Population estimation error, lack of medical staff	Medical Staff, project manager	Acquire extra allocation center, hire more medical staff
Vaccine Injection	Vaccine contaminate, wrong dose, poor paperwork recording	People change mind		Proper training, better disinfection method
Post Injection Screen	Allergic reaction, patient hide allergic history, poor health of patient	Unknown medical history or underlying conditions	Doctor and nurse	Double check medical record, update recording system

Table 1: Cost of Poor Quality Analysis

For the cost of poor quality, we can analyze them internally and externally. There are six major processes in our vaccine delivery. From development to final post injection screening. For vaccine development, the internal failure could be researchers using the wrong formula or putting the wrong concentration of one material into the mixture. It could also happen at the management level, with the wrong decision which could interrupt the researching process. The external failure could be stock falls down causing the company to go bankrupt or any natural disaster which causes the company to stop operating. To prevent those potential failures, we can

only try to fix the internal failure by hiring a proper manager or researcher to avoid quality issues and continue researching. For vaccine transportation, the internal failure could be air-con, refrigerant, packaging and driver shortage. The external failure could be a car accident, plane crash, boat sink and poor road conditions. To avoid those failures, we need to double check the packaging and use an advanced navigation system which has a weather forecast system. For vaccine storage, the internal failure could be air-con failure and lack of space, the space is not enough to store all the vaccines means the rest of the vaccine will just be exposed to higher temperature and become unusable. The external failure could be fire, natural disaster and power outage. The way to avoid those failures are equipping back-up cooling equipment, generators, smoke detectors and CCTV monitoring systems. For vaccine allocation, it could be poor time management and planning internally and over population for external failure. More people came in for vaccination means the medical staff and supply are not enough to handle. The way to solve those problems could be to keep a larger threshold for the allocation center and hire some back up medical staff for preparation. For vaccine injection, the contamination could be a serious problem. Furthermore, if the staff sends the wrong dose to the patient or doesn't check the medical record which causes the patient to have a serious allergic reaction, the consequence will be severe. To avoid those, better training and disinfection methods should be introduced. For post injection, it could be patients unaware or didn’t know their allergic history or patients having some background diseases which didn’t found by medical staff. What the doctor and nurse need to do is double check the medical record and we can update the recording system to make sure the correction of the medical record.

2.4 Affinity Diagram

Transportation	Storage	Allocation	Injection
Trucks breaking down	Lack of space	Not enough vaccines for area	Untrained workers
Refrigerator failure	Cooling System fail	Lack of certified medical staff to distribute vaccine	Poor needle or other material quality
No airports	Destruction of storage		Poor Disinfection
No Ports	Damaged vaccines		
Lack of Driver			
Road Damage			

Table 2: Affinity Diagram

The affinity diagram is a chart we used to organize and analyze our process by breaking down the metrics used into possible failures that can occur at each stage in our process. The four processes we focused on for this chart were transportation, storage, allocation and injection. Figure 1 is a depiction of the affinity diagram that we created where the first row is our metrics and each column represents failures within that metric that need to be accounted for. This easily shows us the problem we would have in our vaccine allocation which could occur mainly in the transportation and storage stage. Any of these failures occurring would cause a great hiccup in our allocation process if not causing total failure of the process in a region. We use the affinity diagram when creating our process to assure that each step is carefully planned out and plotted to avoid such failures which may stall our allocation.

2.5 Ishikawa Chart (Fishbone)

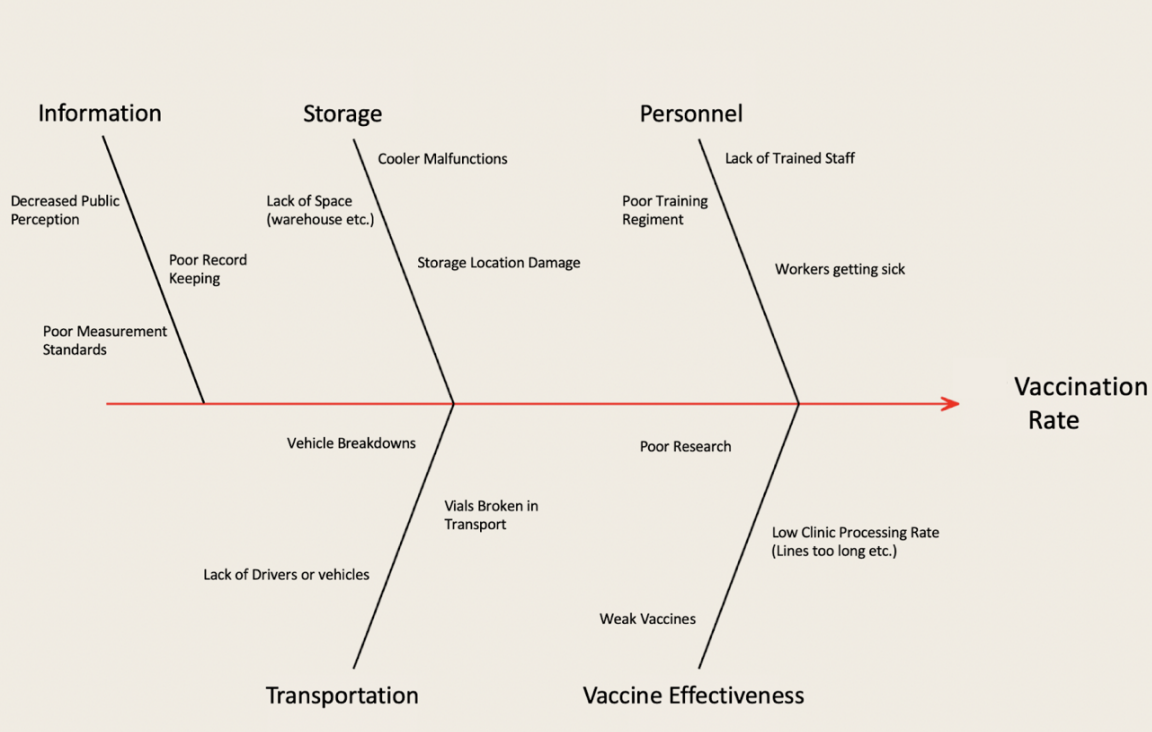


Figure 4: Fishbone Chart

Above is the Ishikawa or Fishbone chart that shows a type of cause and effect relationship that leads to a certain outcome. It is easiest to think of like an equation where all the factors on the black lines lead to impacting the final value of the end cause, which in our case is the vaccination rate. For example if in the transportation branch vehicles breakdown the overall vaccination rate would be impacted negatively and we would have a lowered vaccination rate. On the other side if something like training for personnel increased and the clinics became more efficient then there would be a higher vaccination rate. The key is that all of these elements are changing and impacting the final vaccination rate all at once making it a constantly moving metric. The purpose of this chart is to demonstrate where quality control issues might occur and devise a

response based on those issues. If we have multiple failures in one rib of the chart then we can focus on that section and make sure that we put more resources into fixing it's problems. (Hayes, 2022)

2.6 Interview Questions/Quality Assessment/Root Cause Analysis

The quality assessment is a crucial phase in establishing our process' ability to function. Here we diagnose issues that were presented in the COPQ (Cost of Poor Quality Analysis), Affinity Diagram and the other tools we used to analyze our process, and solutions to these issues. Firstly we interview the high level personnel in our organization with a list of questions and expected answers shown below.

Interviewees:

Research Group Leader, CFO, Local Transportation Administry, Logistic Company Manager, Local Warehouse Manager, Local Electricity Bureau, Local CDC Coordinator, Local Hospital President

Questions and Answer:

When did the COVID-19 Outbreak start?

According to the CDC, the outbreak was first documented at the tail end of 2019 in December in Wuhan, China.

What measures were taken to prevent it?

Lockdowns were enforced by many governments as well as masks and safety guidelines to prevent the spread of the disease.

How can we safely navigate distribution of vaccines and avoid the spread of the virus?

Safety measures and guidelines will be in place for every employee and patient that is dealt with to assure the overall health care of the community.

What tools will be necessary for the distribution of vaccines?

There will need to be a solid transportation system, storage system, and injection protocol in order to effectively distribute the vaccines around the world, as well as plenty of employees to staff all these processes.

What can you do about local government restrictions and protocols in every place?

Research will have to be done in every place that we wish to distribute as well as contacting the local health officials for their help and cooperation in our efforts to understand any local rules that need to be adhered to.

How will the variants be handled if the vaccine does no work?

There will be a research team at the headquarters looking for any news of variants and studying samples as soon as possible to understand them in collaboration with the World Health Organization.

What is the plan to stop the virus and get the vaccine out there?

We will allocate vaccines everywhere possible in order to stop the spread of COVID-19 as best as we can and hopefully stop any more harm from it and maybe prepare the world for any other outbreaks that might come about.

The quality assessment is based on the root cause analysis which shows where we should look to create improvement and effectiveness by naming what would be the main issue in each sector of the process.

The issues we proposed from our analysis come in many forms which will be shown in a list including the issue and the solution to that issue:

1. Vaccine Distribution and Effectiveness - We want to be sure our distribution is as quick as possible but also done in a manner which gives good quality to our patients. An increase in budget will be crucial to provide backup resources and extra personnel while also providing the ability to allow for overtime work.
2. Public Health Issues, Social Issues - To assure the safety of employees and patients there must be clear guidelines on how to operate this allocation. There will also be a team of employees researching social issues in each region we allocate in to avoid any possible hiccups in the allocation and be ready for any government guidelines we must follow. Ad's will direct people where to go and how to receive the vaccine in the the most efficient way.
3. Unclear or Poorly kept Documentation - Poor kept documentation could verily lead to misread results or bad quality in the allocation of the vaccine. There will be a centralized database and headquarters for keeping accurate records of all organized activity.
4. Miscommunication - In tandem with poor documentation, miscommunication must be corrected with an in depth communication system throughout the entire organization.
5. Extensive Public Health Codes and Regulations - Create rules and plans for public personnel and safety within the clinics for distribution.
6. Issues with Refrigeration Failure, Storage and Transportation - The shipping routes will be expedited so vaccines are on trucks and planes for less time.
7. Lack or Loss of Resources, Transport Vehicles, Medical Staff, Storage, Funds - - With an increased budget we shall also invest in better and more refrigeration units to mitigate loss of doses as well as backups in each category mentioned to avoid any bottlenecks in the process.

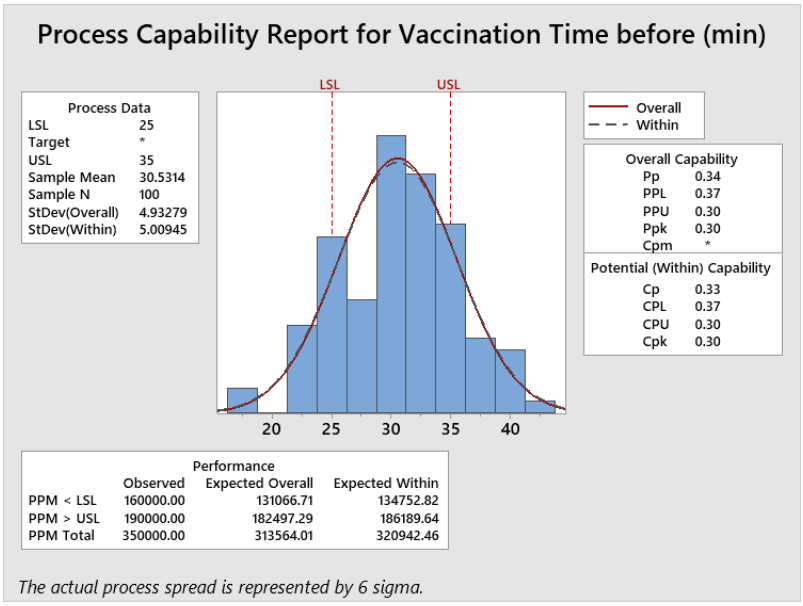
Within all of this there will be implementation of a better records system that will allow the organization to better track who is effectively receiving the vaccine and which nations or communities need further assessment and change. We will also track who gets the virus after the vaccine and what their symptoms are to measure if more research needs to be done. And also check to make sure that the number of vaccinated people keeps increasing at a sufficient and reasonable rate to insure effectiveness of our work.

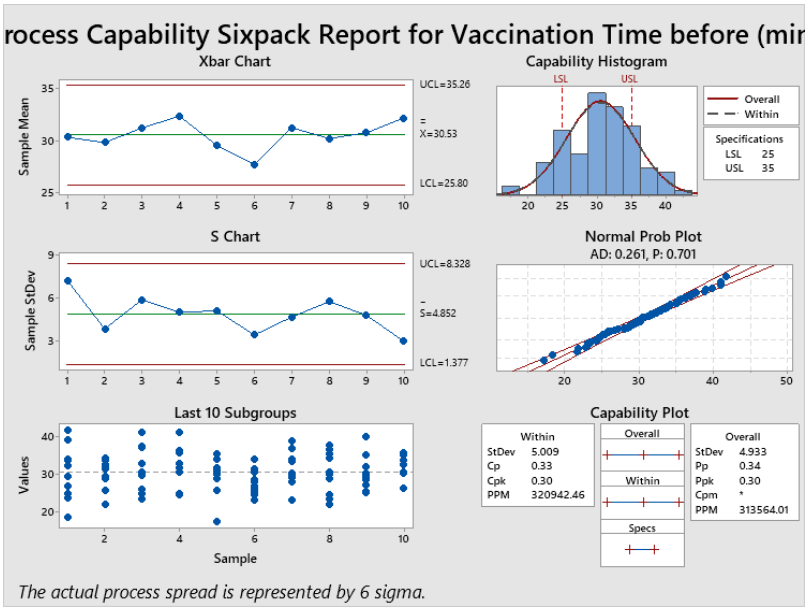
3.Measure Phase

3.1 Process capability

The process capability is a tool to check if a process is meeting its specifications and how well is the process meeting its requirement. In this project we are trying to use this method to improve our vaccine injection process. The whole process contains medical record check-in, disinfection, injection and post infection screening. We want to avoid the long waiting line and decrease the possibility of cross infection.

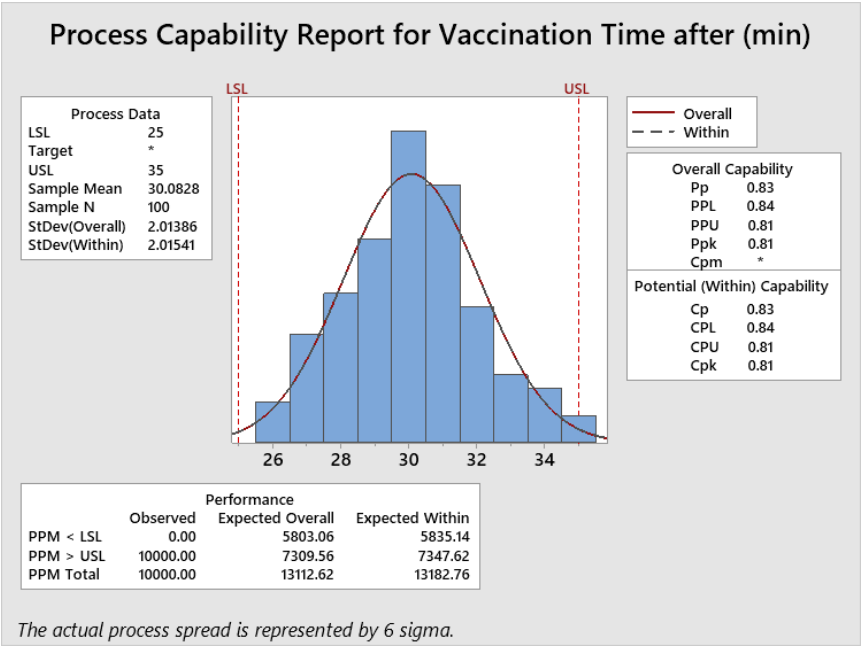
We originally plan to leave 25-35 min for each person, from patient check-in, a volunteer will check his appointment date, time and vaccine location is correct. Secondly a doctor will check his medical history and confirm the vaccine brand he will inject, in the meantime, double check the number of shots in case of putting the wrong dose. Next step is to perform disinfection and vaccine injection. After finishing injection, the patient needs to stay in the waiting area for post-injection screening. For this process, as the result shows, the process capability is only 0.33, which is totally unacceptable. As we can see from the plot, there are some people who didn't stay long enough for post-screening and some patients may get delayed due to poor training of medical personnel or there are some background diseases they didn’t tell doctors, which may cause some serious post-injection allergic or complex diseases.

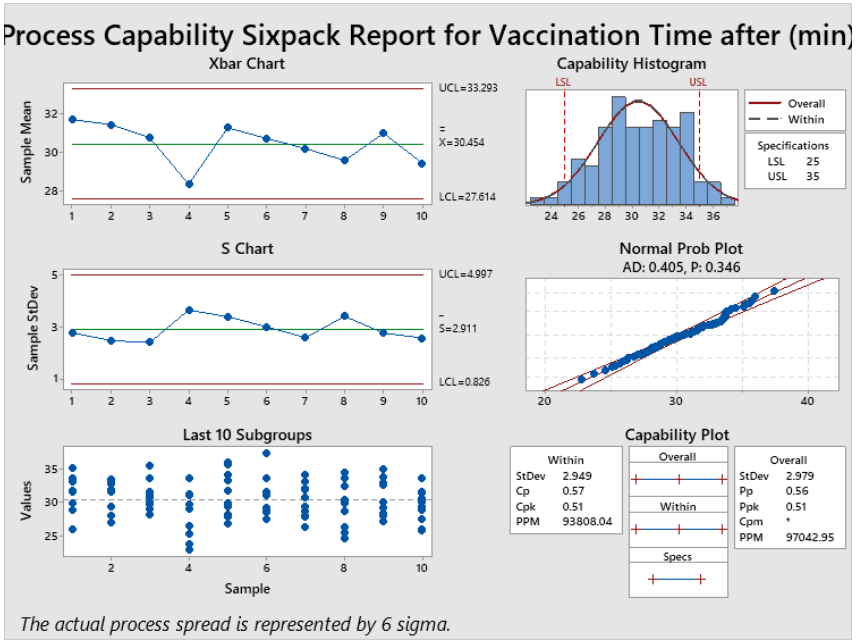




Figures 5 and 6: Original process capability

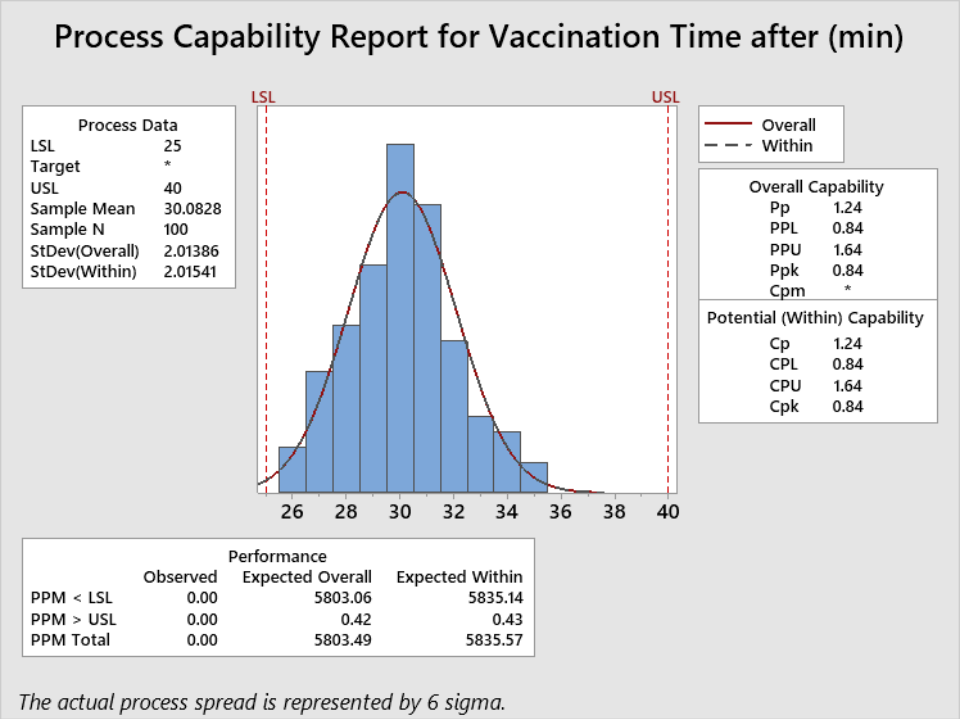
For our updated process, we perform more training to our medical staff and try to avoid some small mistakes such as missing the blood vessels. We controlled our standard deviation from 5 to 2. As a result, the process capability increased to 0.83 but it's still not good enough. We think the reason for low process capability is that we only considered adding more training to our medical personnels, we didn't fully consider our patient who may have some potential issues such as background disease and personal issues. We can still train our medical personnel to lower the standard deviation for their operation time, but we think it is better to put some effort on the patient side.

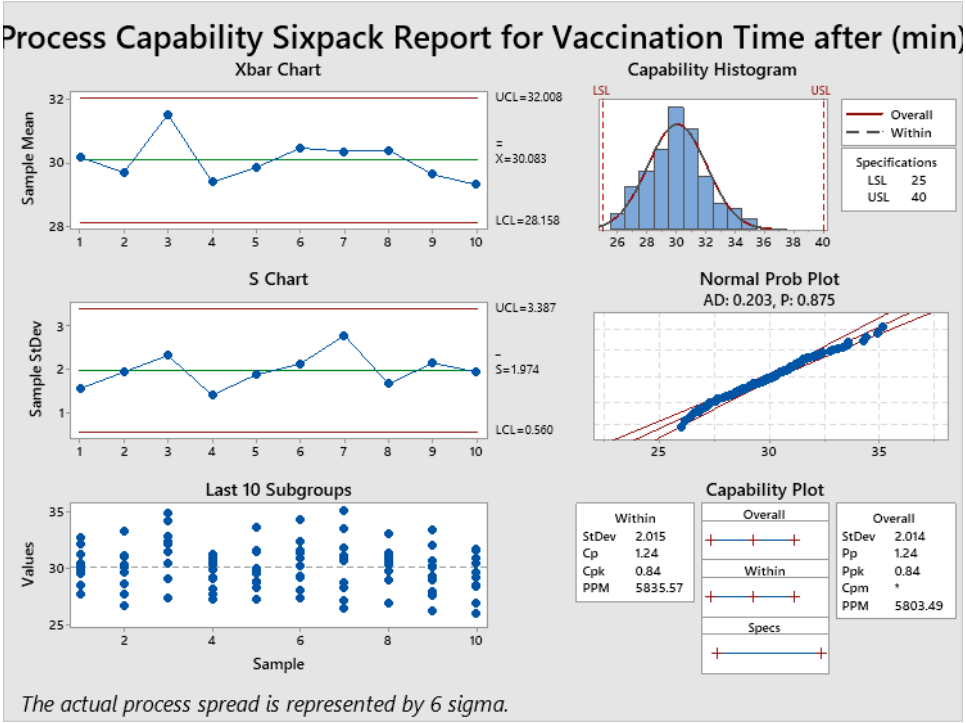




Figures 7 and 8: Updated Process Capability

In our last try, we tried to leave more time for each patient incase of emergency such as post injection effects. We extend our process time for each patient from 25-35 min to 25-40 min. If there is nothing happening, our medical staff could have some time to relax and keep focus for their next patient. As a result, we manage to make our process capability to 1.24, it is good enough to put it into practice.





Figures 9 and 10: Final Process Capability

By using process capability, we can find out the direction to make our process capable. By applying different trails with varying LSL, USL and standard deviation, we can find a pattern with better process capability. With the help of process capability, we can improve the process not only its reliability but also its efficiency.

3.2 Design of Experiment

3.2.1 Factor Definition

For the DOE our group defined three factors that would impact the regression; Personnel (A), Transportation (B), and Storage (C). All of these factors can directly impact the model that we created and therefore are the topics that we investigated. To make our model realistic we decided not to focus on a number of different clinics, but instead just one to see how efficiently it was operating. In this sense Personnel refers to the staff at the clinic like doctors, nurses, vollentiers, and others like custodians and other helpers to keep the facility moving. A lower score in this category could mean too little or too many workers or insufficient training for those workers while a higher score would denote the opposite, the optimal number of staff and the best degree of training. The second factor was the Transportation of the vaccines to the clinic. The more vehicles that the organization has safely and successfully delivered their cargo will drive up the score in this category. Any trucks that don't reach their destinations or arrive with damaged or unusable cargo will bring the score down. The last factor we defined was the Storage of the vaccines. Just like in the trucks the vaccines need to be carefully stored at the correct temperature to be effective. This means that just like transportation the score will increase with the number of vaccines that are successfully stored and delivered from the warehouses and a loss in the number of vaccines that reach the clinic would decrease the score. The difference between storage and transportation in terms of factor definitions is that we measured the transportation factor in the number of trucks and the storage factor by the number of vaccines, which can be seen in the chart below.

Factor	Low	High	Units	Range	Midpoint	Val(+)	Val(-)
Staff	40	100	Personnel per Site	60	70	1	-1
Transportation	400	950	Vehicles	550	675	1	-1
Storage	500,000	4,000,000	Units of Vaccines	3,500,000	2,250,000	1	-1

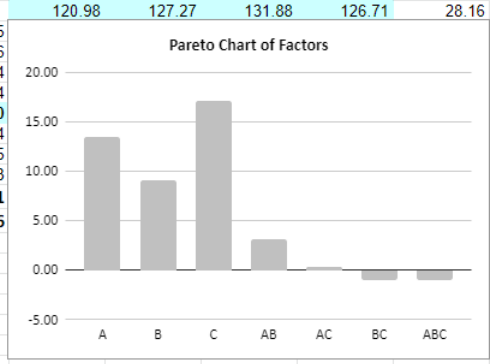
Table 3: Factor Definitions

3.2.2 Design of Experiment Data

Design of Experiments

Factorial Experiments 2^3 (Three Replications/Treatment)

Run	A	B	C	AB	AC	BC	ABC	Run Results Y1	Y2	Y3	Avg.	Var.
1	-1	-1	-1	1	1	1	-1	-2.56	-1.55	-2.59	-2.230	0.350
2	1	-1	-1	-1	-1	1	1	4.67	8.66	6.85	6.725	4.001
3	-1	1	-1	-1	1	-1	1	5.54	3.31	2.23	3.692	2.844
4	1	1	-1	1	-1	-1	-1	19.66	19.97	23.27	20.966	4.003
5	-1	-1	1	1	-1	-1	1	13.30	14.03	16.21	14.515	2.278
6	1	-1	1	-1	1	-1	-1	24.01	25.10	29.59	26.232	8.744
7	-1	1	1	-1	-1	1	-1	21.92	20.70	18.56	20.391	2.884
8	1	1	1	1	1	1	1	34.45	37.05	37.77	36.421	3.051
TotSum								120.98	127.27	131.88	126.71	28.16
SumY+	90.34	81.47	97.56	69.67	64.12	61.31	61.35					
SumY-	36.37	45.24	29.15	57.04	62.60	65.41	65.36					
AvgY+	22.59	20.37	24.39	17.42	16.03	15.33	15.34					
AvgY-	9.09	11.31	7.29	14.26	15.65	16.35	16.34					
Effect	13.49	9.06	17.10	3.16	0.38	-1.02	-1.00					
Var+	4.950	3.195	4.239	2.421	3.747	2.572	3.044					
Var-	2.089	3.843	2.799	4.618	3.292	4.467	3.995					
F	0.422	1.203	0.660	1.908	0.878	1.737	1.313					
regression	6.747	4.528	8.551	1.579	0.190	-0.512	-0.501					
SUM VAR	1.430	-0.324	0.720	-1.099	0.228	-0.948	-0.476					
Var. of Model		3.52		StdDv	1.88							
Var. of Effect		0.59		StdDv	0.77							
Student T (0.025;DF) =				2.473								
C.I. Half Width =				1.894								



Significant Factors & 95% CI Limits:

Factor	A	B	C	AB	AC	BC	ABC
Signific.	Yes	Yes	Yes	Yes	No	No	No
LwrLimit	11.60	7.16	15.21	1.26	-1.51	-2.92	-2.90
UprLimit	15.39	10.95	19.00	5.05	2.27	0.87	0.89

Figure 11: DOE Data

Figure 11 depicts our Design of Experiments Data using a factorial experiment of 2 to the power of 3 (2^3) which denotes three replications per treatment. Using the coded values for each combination we received average 'Y' values and the variation of them. These values were then used to find our significant factors which are highlighted in blue in the above data in the row named 'Effect'. The Pareto Chart depicts which of our factors are the significant factors. We received only factors A,B and C as significant since the others were so close to zero there significance in minute and therefore not included in our regression analysis.

3.2.3 Regression Equation

Regression Equation in Uncoded Units

Response = 15.840 + 6.748 A + 4.530 B + 8.551 C

Figure 12: Regression Equation

Based on our data, we got the average Y around 15.84. because we set the USL and LSL from 10 to 30, which means our target value should be 20 for better process capability. As we got our regression equation from minitab, we can try to manipulate our factors to make the response as close to 20 as possible. Changing the number of medical staff and trucks is easier, the unit of

vaccine in storage is not easy to change due to storage capacity. As the result, with A =0.3, B=0.3, C = 0. We got our response of 19.9912, which is close to 20. We find out the process capability Cpm is 1.311. We can base on those factors to get our real ABC values. Based on that, we think 79 medical staff per site, 758 trucks per day and putting 2,250,000 vaccines in storage per day is capable for our vaccine allocation process.

3.3 Quality Function Deployment

QFD is the voice of the customer. It is a process that interprets and allows understanding of customer needs and expectations and product or service features and functions. It was developed in the late 1960's by Professors Shigeru Mizuno and Yoji Akao. It involves several sequential phases, each phase needs one or several matrices, which can help project managers to plan and communicate critical product and process planning and design information. (Romeu, 2019)

For our QFD Matrix, we think there are 7 aspects that are vital for our vaccine allocation process. On the vertical axis, we give them priority points based on their importance. 7 is top priority, 1 is the least priority. On the horizontal axis are the factors which could affect the process of allocation. Inside the matrix shows the number for their relationship, 9 is strongly related, 3 is medium related, 1 is less related, 0 means no relationship. We believe vaccine research and funding are two most important factors for development. Furthermore, political power also played a vital role for research, without government approval, vaccine research can't proceed. For transportation, cooling equipment, vehicles and parking are most important. For storage, cooling and electricity are most important as well. For vaccine allocation, we believe the proper training to medical personnel and volunteers are really necessary because without proper training, we are putting the patients life in danger. This also applies for vaccine injection, without proper training, patients may suffer from extra pain when missing the blood vessels, or get infected due to improper disinfection. From CTQ priority score and percent of total, we can see that research and funding are two most important aspects in our vaccine allocation process, because without funding and research, we will not have vaccines, there is no need to talk about allocation.

On the top of our QFD matrix, we can see the correlation matrix. Those are factors that have a relationship between each other. With two plus signs means they have a strong positive relationship while two minus signs means they have strong negative correlation. As we can see from our matrix. There is no negative correlation between each factor. We can see the vaccine research related to funding; clinic location has a relationship to vehicles and parking spots because the size of the clinic decides the number of population it can handle, the corresponding parking lot needs to have enough size for patients who drive a car. It is obvious that the cooling equipment needs electricity to power them.

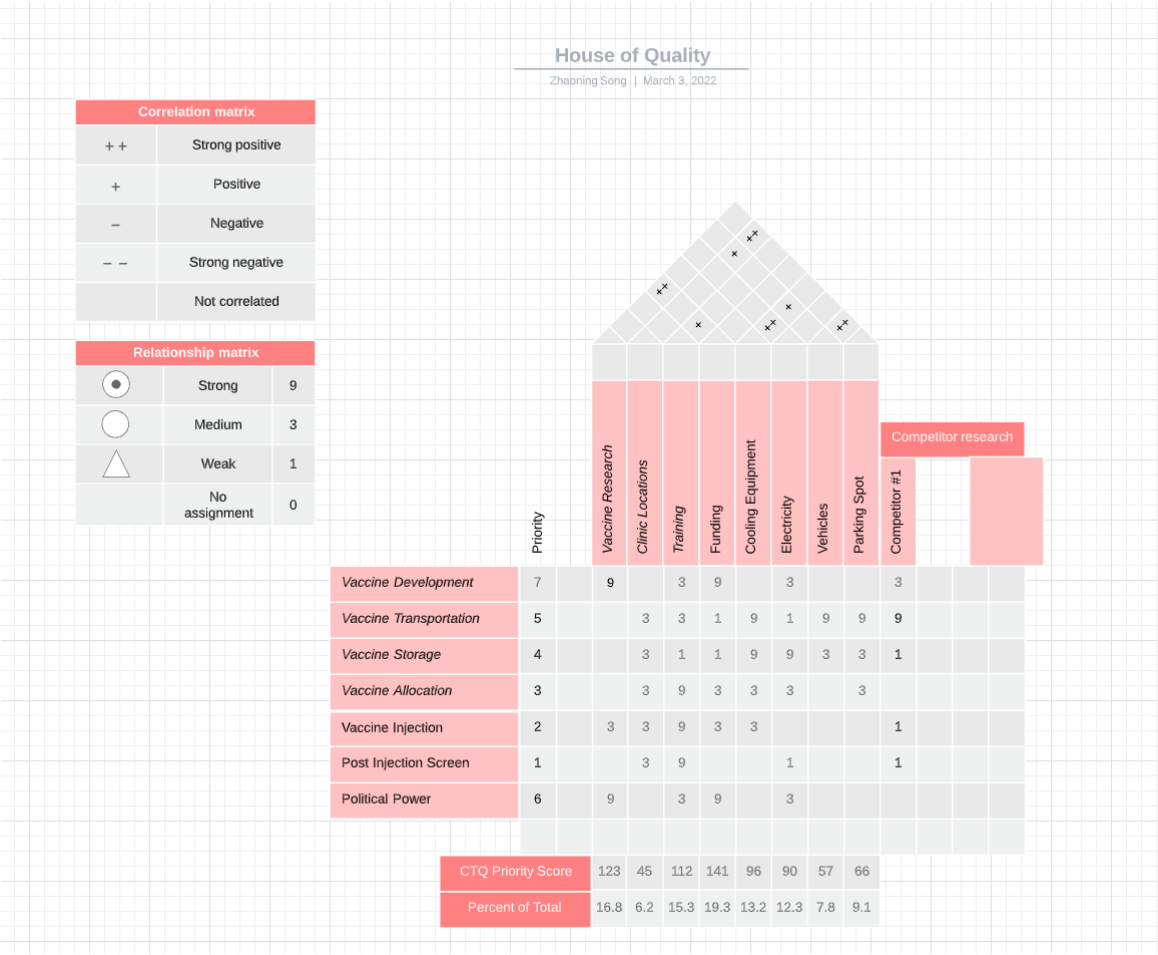


Figure 13: Quality Function Deployment Matrix

3.4 Failure Mode and Effect Analysis

Step	Description							
1	verify the order for the vaccination							
Failure Mode	**Causes**	**Effects**	**Occ**	**Det**	**Sev**	**RPN**	**Actions**	
No order for the vaccine	Provider did not order the vaccine	Patient could be given the wrong vaccine Insurance will not pay for the vaccination Patient could go without a vaccine that is needed	9	2	2	36	check the MCIR, verify the order with the provider	
Step	**Description**							
2	verify the right patient with name and identification							
Failure Mode	**Causes**	**Effects**	**Occ**	**Det**	**Sev**	**RPN**	**Actions**	
wrong patient	failure to check the patient's name or identification	vaccine given to wrong patient; getting unnecessary vaccines or omission of a needed vaccine	9	1	1	9	Always check name and identification of the patient prior to administering the vaccine	
Step	**Description**							
3	verify the insurance or no insurance							
Failure Mode	**Causes**	**Effects**	**Occ**	**Det**	**Sev**	**RPN**	**Actions**	
failure to choose the correct vaccine based on insurance (our stock) or no insurance (health department stock)	failure to verify the correct insurance selection	patient will end up paying or our office will have to pay the health department	7	2	5	70	Verify with patient about any insurance changes prior to selecting the vaccine from stock	
Step	**Description**							
4	verify the right vaccine							
Failure Mode	**Causes**	**Effects**	**Occ**	**Det**	**Sev**	**RPN**	**Actions**	
choosing the wrong vaccine	failure to verify the needed vaccination failure to double check with another staff member	administration of unneeded vaccination failure of administration of the proper vaccination	9	2	2	36	always double check vaccine with another staff member	
Step	**Description**							
5	verifty the right dosage of vaccine							
Failure Mode	**Causes**	**Effects**	**Occ**	**Det**	**Sev**	**RPN**	**Actions**	
giving the wrong dose of vaccine	drawing up the wrong dose not double checking with another staff member	wrong dose (too little or too much) vaccine given to patient	7	10	2	140	always double check with another staff member prior to administration	

Figure 14: Failure mode and effect analysis

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. In the Failure mode and effect analysis we identified potential failures and what actions should we take on that. In the covid vaccination drive we encounter failures like there is no order for vaccine for patients and effect of this could be the patient will receive the wrong vaccine and maybe he could go without vaccine. To avoid this failure we check and verify it with the provider.There could be more failures like wrong patient could receives the vaccine which effects would be that getting unnecessary vaccines or omission of a needed vaccine, so to avoid that we should always check the name and identification of the patient before administering the vaccine to them.By doing this we encountered another failure to choosing the correct vaccine based on insurance or no insurance,as this will affect the patient in such a way that the the patient will end up paying to the health department.The action needed for this is to verify with the patient about any insurance changes before selecting the vaccine.The another failure could be that the patient is getting wrong dose of covid vaccine.It would affect the health of the patient if he gets wrong dose of the vaccine.To avoid this failure we should always double check with another staff member prior to administration. (*Failure Modes and Effect Analysis to Develop Transfer Protocols in the Management of COVID-19 Patients*, 2020) (*Vaccine Support*, n.d.)

3.5 Fault Tree Analysis

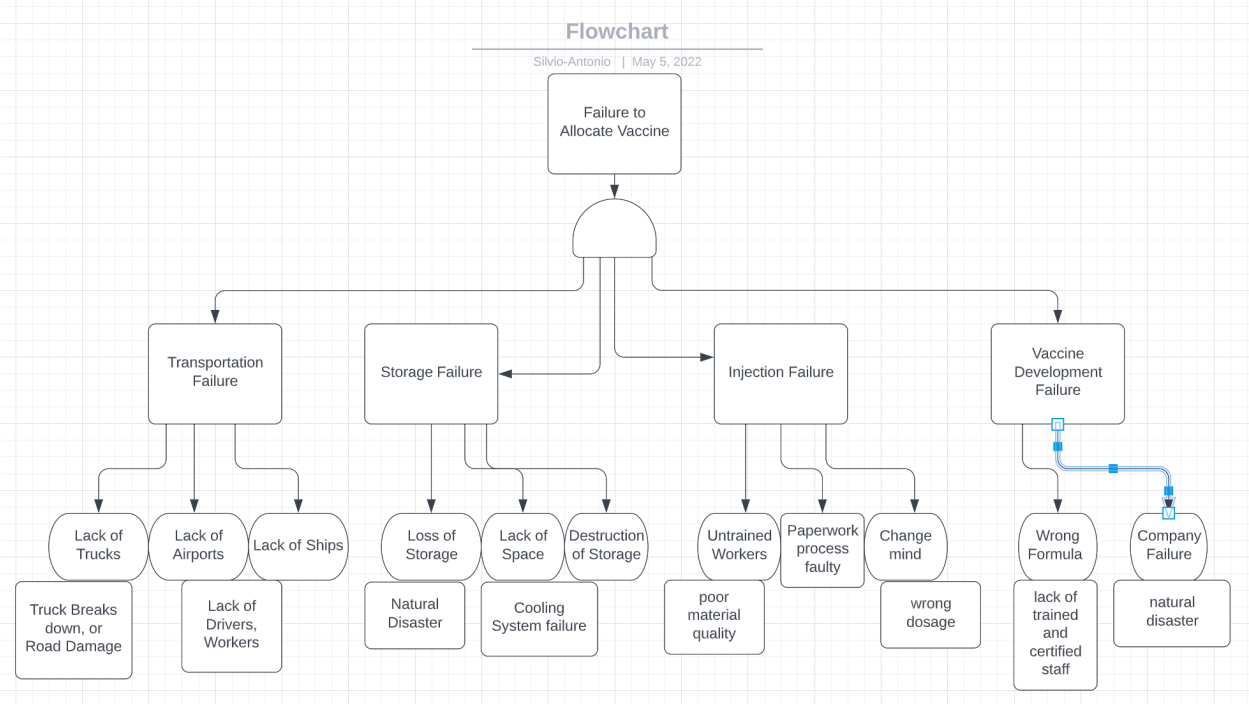


Figure 15: Fault Tree Analysis

The fault tree analysis helps us to identify any possible failures in our process that could happen and allows us to assess and plan for prevention of those problems. Our Analysis in Figure 9 shows the relationship of the problem to our process as a whole and how certain mishaps in any sector could compromise the entire process. In turn this also helps us understand our process and how it flows on a generic level.

4. Improvement

4.1 Lean Manufacturing

4.1.1 Lean Manufacturing In The Vaccine Supply Chain

The current situation has demanded the governments and institutions worldwide to adopt a lean manufacturing plan to expedite worldwide vaccination.

At present, the U.S. Government has limited visibility into the supply chain for most pharmaceuticals. Some of the factors affecting are:

1.Finished Dosage Form (FDF): Some FDF manufacturing occurs in the United States. On-demand manufacturing capabilities for API and fixed-dose formulation drugs have been established.

2. Therapeutic Development: During the COVID-19 response, new therapeutic development focused in part on mAb therapeutics. These require some of the same resources—such as glass vials—as vaccines to produce. Production is limited because of the difficulty in acquiring the glass vials required to fill doses.

3. Vaccines: The situation has led to the development of innovative manufacturing platform technologies that improve flexibility, mitigate cross-contamination risk, and reduce time and cost of cleaning between manufacturing campaigns.

FDA is working on many efforts to address the COVID-19 pandemic, using lean manufacturing principles, such as

- helping to expedite development programs for vaccines
- supporting product development and facilitating the scaling up of manufacturing capacity
- expediting the review of EUA requests and Biologics License applications for vaccines
- helping to ensure an adequate and safe blood supply;
- providing information to healthcare providers and researchers to help them submit expanded access investigational new drug application requests.

4.1.2 Current Actions to Address Supply Chain Vulnerabilities

The government is working to identify current product shortages, anticipate future shortages, and determine where and by whom the products are manufactured. The government will then institute mitigation measures to ease or eliminate the shortages through investments to bolster domestic production.

1. Developing Essential Medicines List:

50 to100 drugs that are most critical to have at all times due to clinical need are stocked. An evaluation of the critical drugs will define strategies to ensure domestic supply and production of essential medicines.

HHS (Human Health Services) is investing in technology and infrastructure development to improve domestic capacity to produce APIs for a variety of essential medicines.

2. Partnering with the National Academies:

   The United States government directed HHS recommendations to strengthen the medical products supply chain by addressing these dependencies. To examine critical dependencies within the supply chain, the committee held information-gathering sessions throughout 2021. The outcome of these sessions lead to the change in decision-making in order to inform strategies to mitigate the impact of failures in the medical product supply chain. Further exploration of this topic is now ongoing.

3. Partnering with the Interagency:

   In partnership with the Defense Advanced Research Projects Agency and the U.S. Air Force, two efforts are underway for drug substance and drug product production. The combined investments of approximately $105M are enabling advanced continuous synthesis of APIs, which is parallel tasking to save time and resources.

4. Advancing Manufacturing Capabilities:

   HHS is investing in the development of advanced manufacturing capabilities to lower the cost of domestic manufacturing of critical supplies. Additional innovations will spur development and deployment of novel manufacturing platforms; the scale-up of these technologies will help develop the domestic pharmaceutical industry.

   The goal is to establish the physical infrastructure, manufacturing platforms, and supply chains capable of producing enough vaccines for the entire U.S. population within 130 days and the global population within 200 days.

5. Creating a Rating System for Quality Management Maturity (QMM):

HHS and FDA are constructing a program for a rating system to incentivize drug manufacturers to invest in achieving QMM and sustainable compliance. The program's purpose is to recognize manufacturers that develop mature quality management practices, which focus on continuous improvement, business continuity plans, and early detection of supply chain issues. (Denyse Baker, Jeff Broadfoot, Steve Mendivil, Adam Caruso, and Sandra Lueken, (2021), *How to Measure Quality Management Maturity,*)

This will work as a rating system that includes hospitals, institutions and pharmacies. It involves getting feedback and changing as per feedback at every level, from production to end consumer.

6. Detecting and Managing Supply Chain Disruptions:

FDA's Center for Drug Evaluation and Research (CDER) has recently established the Pharmaceutical Supply Chain Governance Board to coordinate all supply chain initiatives across CDER and provide strategic guidance on major supply chain issues without data gaps and visibility across business partners.

7. Allocating and Distributing Pharmaceuticals:

HHS, through the HHS Coordination Operations and Response Element (H-CORE), is overseeing the allocation of drugs on a state and territorial-level basis. Post allocation, HHS will continue to monitor ordering and utilization at the facility and state levels to prevent excessive stockpiling and wastage of therapeutic inventory. HHS is planning for the distribution of and is monitoring inventory levels, which will allow for earlier detection of supply disruptions and shortages.

8. Coordinating Vaccine Supply Chain with Industry:

The vaccines require similar resources needed to manufacture other vaccine candidates that are still completing clinical testing. Balancing these priorities across the supply chain requires successful coordination between the federal government and private industry. Vaccine capacity is primarily domestically based; however, HHS monitors the supply chain for critical components.

(Public Health Support Chain, One Year Report, *Office of assistant secretary for preparedness and response*)

4.2 Value Stream Mapping

Value stream mapping is the process of viewing a process from start to finish with its resources and time taken so it may be best optimized and the waste can be kept to a zero. In the case of setting up a vaccination site, considering the time taken from receiving approval from the CDC to procuring vaccines and vaccinating the public, we go through many processes.

Current State VSM:

Here we see that permits and tenders are very crucial processes in the setting up of a vaccination site however the time they take is delaying vaccinating the public. Hence monitoring the plan before execution in a flow chart method helps us see where the resources can be saved.

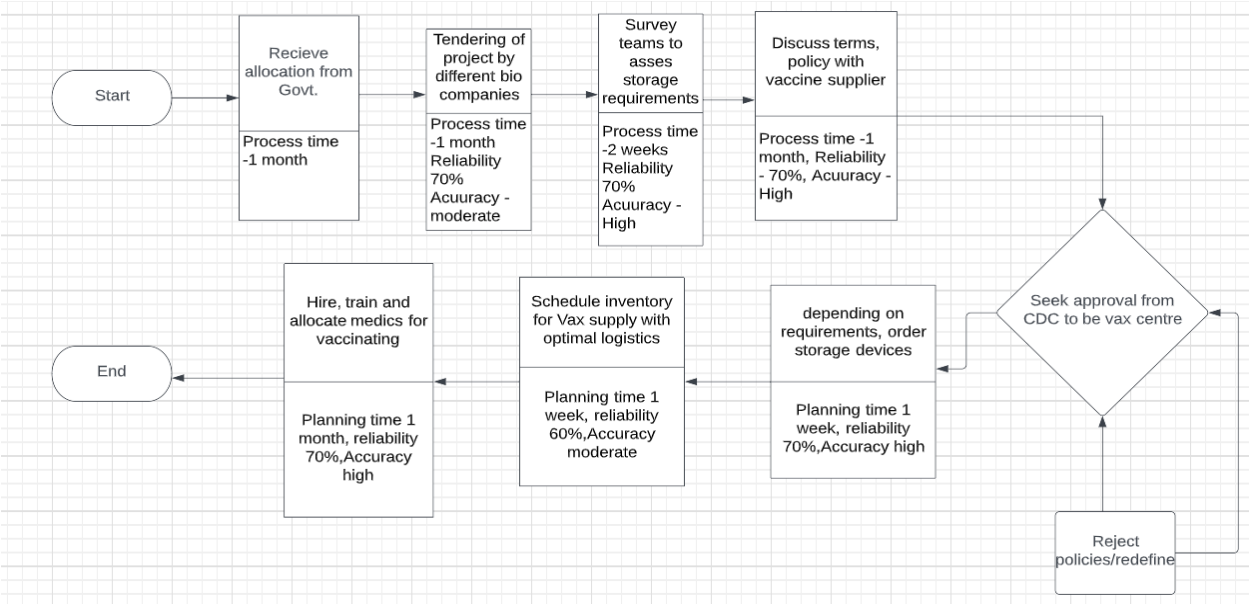


Figure 16: Current VSM

This sets the base for a future VSM to be established which will be much more efficient and can be executed. It creates the options for tasks to be done in a parallel manner so yield is quicker. Some factors when scheduling or planning tasks for a future VSM are:

- Biggest "bang for the buck"
- Largest reduction in lead time or inventory
- Biggest impact to the customer
- Highest probability for success
- Most visible to stakeholders
- New product or service line
- Volume or quantity efficiency

In the case of a vaccination center, here is a future VSM:

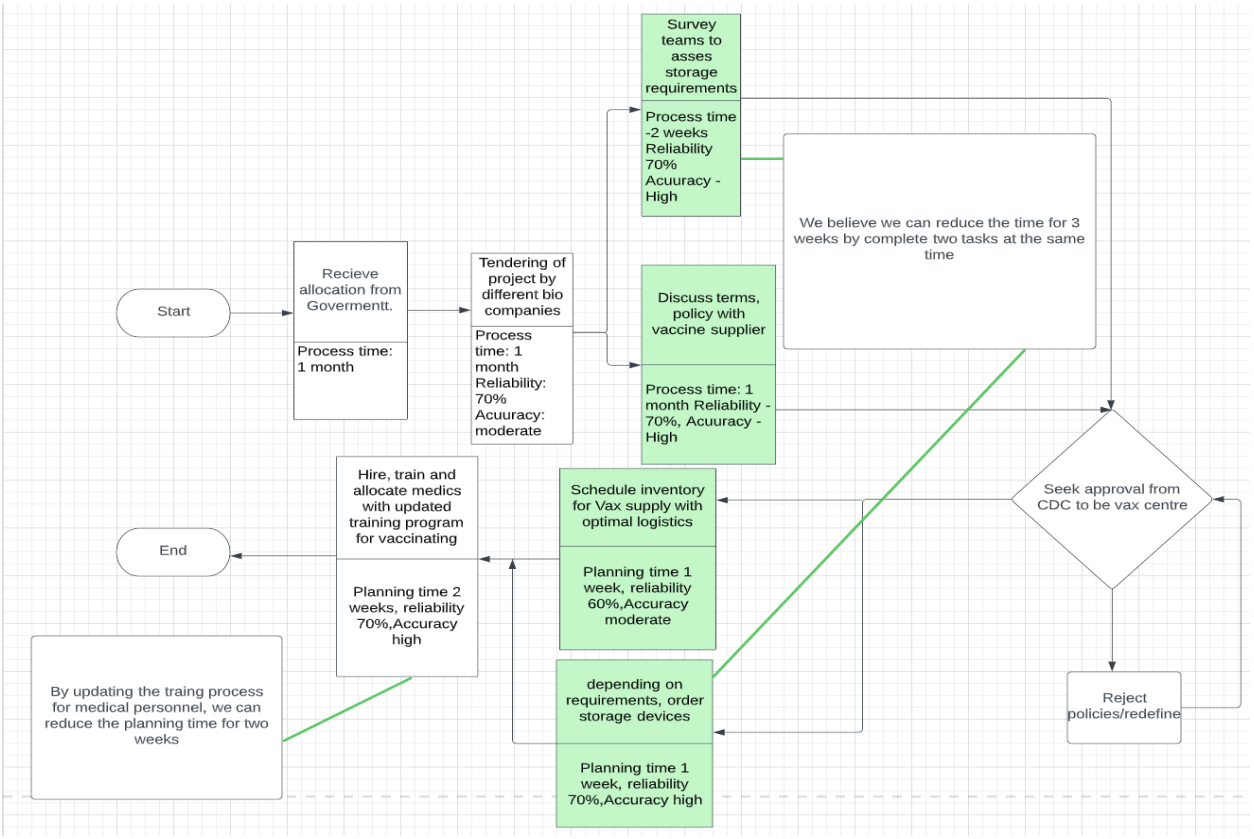


Figure 17: Future VSM

As we can see, survey teams sent out by the center can be scheduled at the same time as discussing terms and contracts with the supplier, which makes the process shorter by three weeks.

Also, planning inventory and storage of vaccines can be made many times more efficient by calculation of different takt times respectively for vaccinating each individual, vaccine to reach distribution center and clinic, etc. A cumulative study of takt times gives an idea of when the whole population will be vaccinated.

Takt time, T = Ta / D;

Where T is the time required for inventory,

Ta is the hours of work available,

D is the demand.

Here, we require the cycle time to be less than the process times so bottlenecks can be avoided and the ordering of vaccines, their storages and refrigeration and power supply can be

such that there is no queue time, wait time or shortage of resources. Takt time greatly helps in deciding and scheduling complex processes and in this case to come up with an efficient plan for the vaccination center.

---

5. Control Phase

5.1 Acceptance Sampling Plan

Acceptance sampling uses statistical sampling to determine whether to accept or reject a production lot of material. It has been a common quality control technique used in industry. It is usually done as products leave the factory, or in some cases even within the factory. Most often a producer supplies a consumer a number of items and a decision to accept or reject the items is made by determining the number of defective items in a sample from the lot. The lot is accepted if the number of defects falls below where the acceptance number or otherwise the lot is rejected.We used acceptance sampling method as it allows us to determine the quality of a vaccine by selecting a specified number for testing.

Acceptance sampling is "the middle of the road" approach between no inspection and 100% inspection. There are two major classifications of acceptance plans: by attributes ("go, no-go") and by variables. The attribute case is the most common for acceptance sampling, and will be assumed for the rest of this section.
The main purpose of acceptance sampling is to decide whether or not the lot is likely to be acceptable, not to estimate the quality of the lot.

<u>Advantages and Disadvantages of Acceptance Sampling</u>

- ADVANTAGES
  There is less damage due to inspection handling.
  It is more economical than doing 100% inspection.
  It takes much less time than doing 100% inspection.
- DISADVANTAGES
  There may be errors (Producer's and Consumer's risk) associated with the sampling
  The sample does not provide 100% accurate information of the condition of the vaccine.

- Operating Characteristic (OC) curve
  The Operating Characteristic Function (also known as OC
  Function) is one of the most useful tools in practical statistical applications. Unfortunately, it is also under utilized and

often misunderstood mainly because of confusing information. Some theoreticians think of the OC Function as the result of elaborate calculus-based manipulations, while some practitioners reduce it to a table of values, whose origins are obscure, but whose results are very useful. Missing the strong connections between theory and applications affects the use of the OC Function as the excellent design and analysis working tool that it is.An OC curve is a probability curve for a sampling plan that shows the probability of accepting lots with various lot quality levels(% defectives).

- Acceptable Quality Level (AQL): a percent defective that is the baseline requirement for the quality of the producer's product.
- Lot Tolerance Percent Defective (LTPD): a pre-specified high defect level that would be unacceptable to the consumer. (L, n.d.)

Method

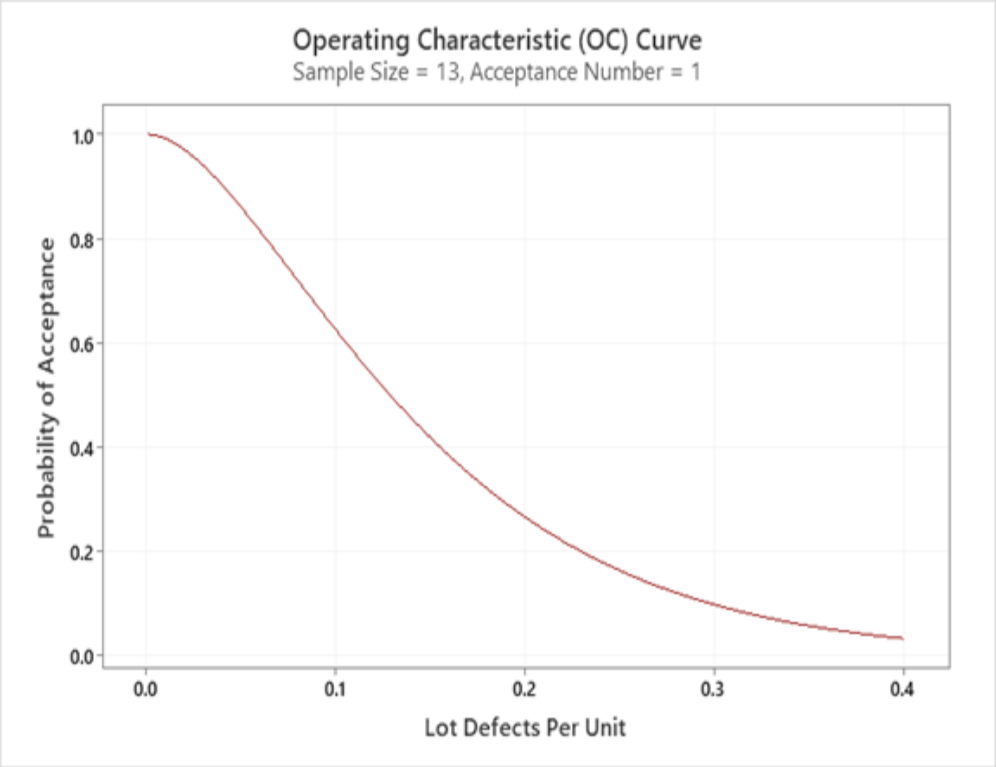
Acceptable Quality Level (AQL)	0.1
Producer's Risk (α)	0.5
Rejectable Quality Level (RQL or LTPD)	0.2
Consumer's Risk (β)	0.3

Generated Plan(s)

Sample Size	13
Acceptance Number	1

Accept lot if number of defects in 13 items ≤ 1; Otherwise reject.

Defects Per Unit	Probability Accepting	Probability Rejecting
0.1	0.627	0.373
0.2	0.267	0.733



Figures 18 and 19: OC Curve

- Nomogram

  By using Nomogram with our AQL and LTPD, we can find the intersection point of the two lines and project the point to sample size axis and number of occurrence axis to find our sampling plan.

  Sample Size(n) = 55 Occurrences(c) = 8

  Total Truck (N) = 950

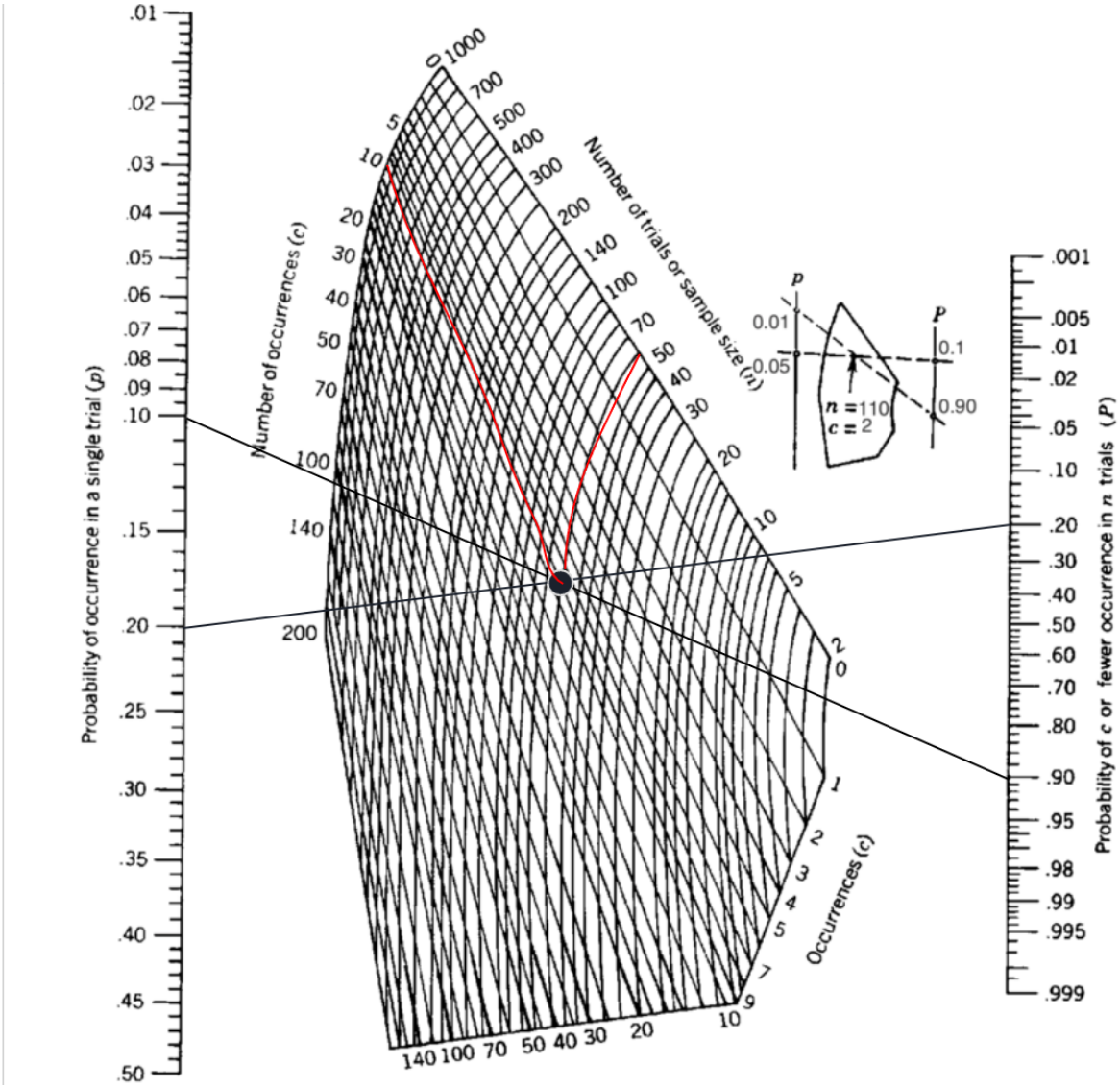


Figure 20: Nomogram

- ANSI Table

ANSI table is a tool to determine the sampling size for our sampling plan. The first step is to check ANSI master tables to determine the general inspection level based on the lot or batch size. Based on our project, we have 950 trucks that need to be inspected. So we need to select G,J and K as our inspection level. Then we move to the second table, which could give us the acceptance number and reject number for our sampling plan. From our nomogram, we got our sample size to be 55 trucks. However, the sample size for our AQL value couldn't give us a proper sampling plan, we have to seek a bigger sample size. With our AQL, we can use size code K as our sampling plan with acceptance number of defective 0 and reject the trucks if there is one truck defective.

Table I—Sample size code letters

(See 9.2 and 9.3)

Lot or batch size	Special inspection levels				General inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10000	C	D	F	G	J	L	M
10001 to 35000	C	D	F	H	K	M	N
35001 to 150000	D	E	G	J	L	N	P
150001 to 500000	D	E	G	J	M	P	Q
500001 and over	D	E	H	K	N	Q	R

Table II-A—Single sampling plans for normal inspection (Master table)

(See 9.4 and 9.5)

Sample size code letter	Sample size	Acceptance Quality Limits, *AQLs*, in Percent Nonconforming Items and Nonconformities per 100 Items (Normal Inspection)																									
		0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25	40	65	100	150	250	400	650	1000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↓	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑
D	8	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑	↑
E	13	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑	↑	↑
F	20	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑
G	32	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑
H	50	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑
J	80	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑
K	125	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
L	200	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
M	315	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
N	500	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
P	800	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Q	1250	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
R	2000	↑	↑	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

↓ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 percent inspection.
↑ = Use the first sampling plan above the arrow.
Ac = Acceptance number.
Re = Rejection number.

Figures 20 and 21: ANSI Tables

5.2 Gage R&R

Gage R&R provides our process a vaccine protection rate measurement. It allows us to identify what proportion of the variation for our data is caused by the actual variation of what is measured and the variation due to the measuring device. In other words we are checking to see if our measurement of vaccine allocation is a good measurement with a good quality measuring system. Our group uses gage R&R to evaluate the effectiveness of our vaccine protection rate and the quality of our system measuring that rate.

Gage R&R

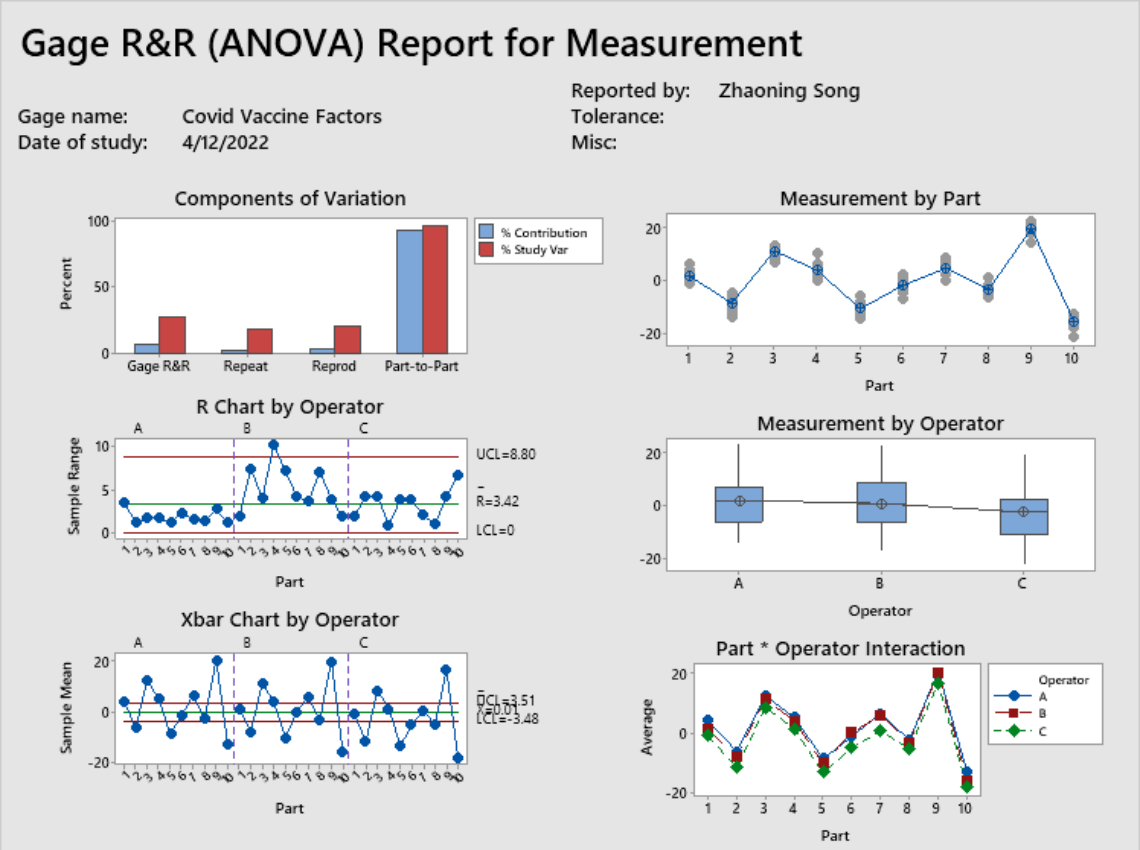
Variance Components

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	9.143	7.76
Repeatability	3.997	3.39
Reproducibility	5.146	4.37
Operator	5.146	4.37
Part-To-Part	108.645	92.24
Total Variation	117.788	100.00

Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)
Total Gage R&R	3.0237	18.1423	27.86
Repeatability	1.9993	11.9960	18.42
Reproducibility	2.2684	13.6103	20.90
Operator	2.2684	13.6103	20.90
Part-To-Part	10.4233	62.5396	96.04
Total Variation	10.8530	65.1180	100.00

Number of Distinct Categories = 4



Figures 23 and 24: Crossed Gage R&R Report

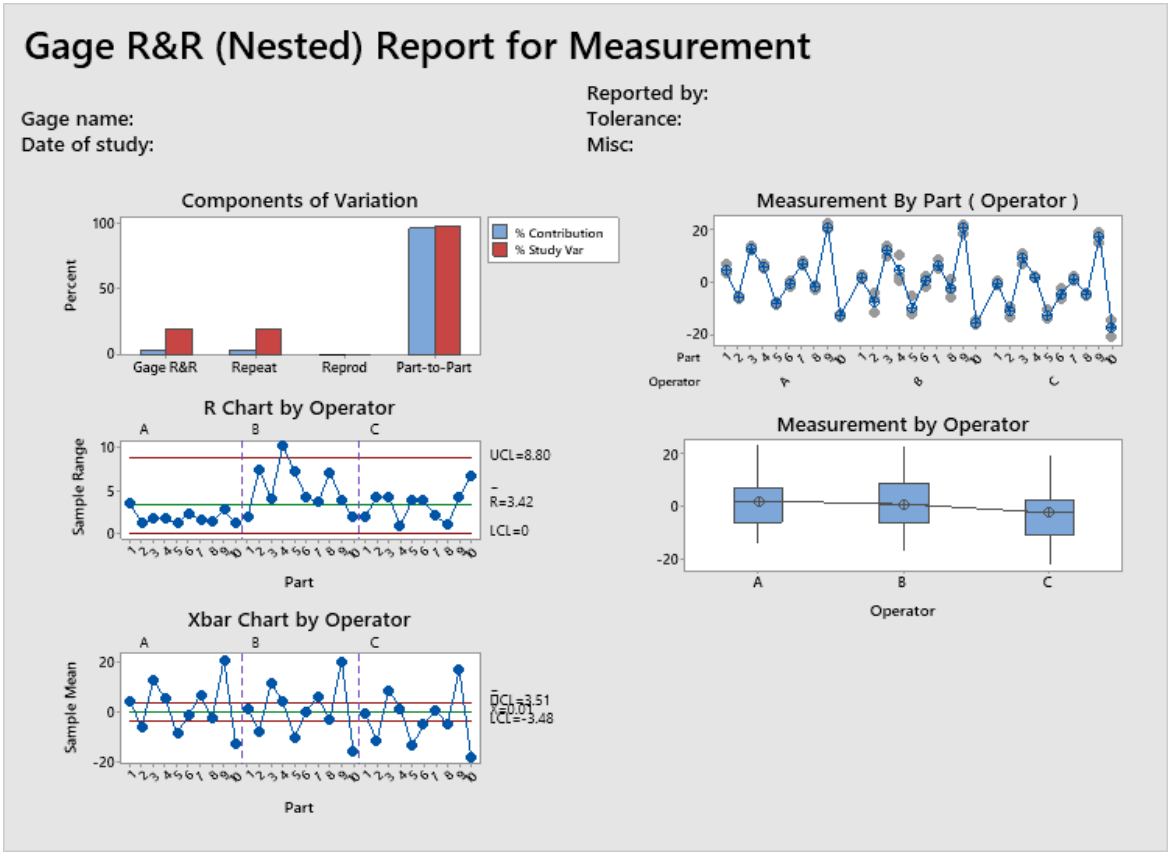
In Crossed Gage R&R we assume that the different parts measured are of different types, in which each part is measured independently multiple times.

Variance Components

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	4.598	4.08
Repeatability	4.598	4.08
Reproducibility	0.000	0.00
Part-To-Part	107.999	95.92
Total Variation	112.597	100.00

Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)
Total Gage R&R	2.1443	12.8661	20.21
Repeatability	2.1443	12.8661	20.21
Reproducibility	0.0000	0.0000	0.00
Part-To-Part	10.3923	62.3536	97.94
Total Variation	10.6112	63.6672	100.00



Figures 25 and 26: Nested Gage R&R Report

In Nested Gage R&R we assume that the different parts measured are of similar type. The difference here shows in the measurement by part of the operator. There is a good amount of variance within the graph shown implying that the parts of the process are not so similar and that this type of measurement might not be as suitable as others.

Each Appraiser vs Standard

Assessment Agreement

Appraiser	# Inspected	# Matched	Percent	95% CI
1	20	19	95.00	(75.13, 99.87)
2	20	18	90.00	(68.30, 98.77)

 # Matched: Appraiser's assessment across trials agrees with the known standard.

Assessment Disagreement

Appraiser	# no / go	Percent	# go / no	Percent	# Mixed	Percent
1	1	20.00	0	0.00	0	0.00
2	0	0.00	0	0.00	2	10.00

 # no / go: Assessments across trials = no / standard = go.
 # go / no: Assessments across trials = go / standard = no.
 # Mixed: Assessments across trials are not identical.

Fleiss' Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
1	go	0.856631	0.158114	5.41781	0.0000
	no	0.856631	0.158114	5.41781	0.0000
2	go	0.856631	0.158114	5.41781	0.0000
	no	0.856631	0.158114	5.41781	0.0000

Each Appraiser vs Standard

Assessment Agreement

Appraiser	# Inspected	# Matched	Percent	95% CI
1	20	19	95.00	(75.13, 99.87)
2	20	18	90.00	(68.30, 98.77)

 # Matched: Appraiser's assessment across trials agrees with the known standard.

Assessment Disagreement

Appraiser	# no / go	Percent	# go / no	Percent	# Mixed	Percent
1	1	20.00	0	0.00	0	0.00
2	0	0.00	0	0.00	2	10.00

 # no / go: Assessments across trials = no / standard = go.
 # go / no: Assessments across trials = go / standard = no.
 # Mixed: Assessments across trials are not identical.

Fleiss' Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
1	go	0.856631	0.158114	5.41781	0.0000
	no	0.856631	0.158114	5.41781	0.0000
2	go	0.856631	0.158114	5.41781	0.0000
	no	0.856631	0.158114	5.41781	0.0000

Each Appraiser vs Standard

Assessment Agreement

Appraiser	# Inspected	# Matched	Percent	95% CI
1	20	19	95.00	(75.13, 99.87)
2	20	18	90.00	(68.30, 98.77)

 # Matched: Appraiser's assessment across trials agrees with the known standard.

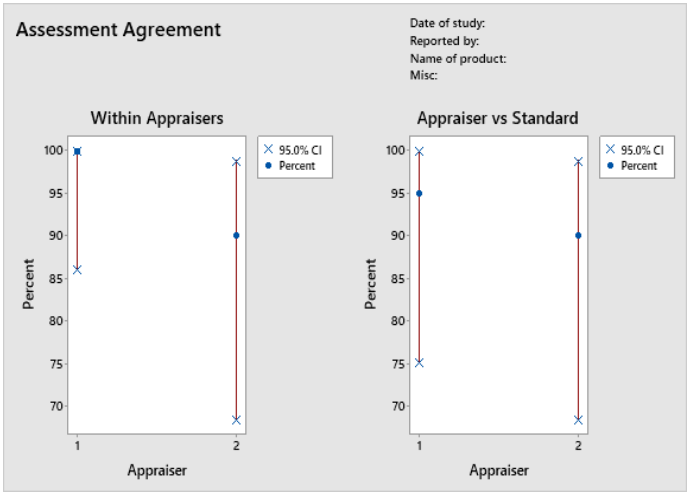
Assessment Disagreement

Appraiser	# no / go	Percent	# go / no	Percent	# Mixed	Percent
1	1	20.00	0	0.00	0	0.00
2	0	0.00	0	0.00	2	10.00

 # no / go: Assessments across trials = no / standard = go.
 # go / no: Assessments across trials = go / standard = no.
 # Mixed: Assessments across trials are not identical.

Fleiss' Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
1	go	0.856631	0.158114	5.41781	0.0000
	no	0.856631	0.158114	5.41781	0.0000
2	go	0.856631	0.158114	5.41781	0.0000
	no	0.856631	0.158114	5.41781	0.0000



Figures 27, 28, 29, and 30: Assessment Agreements for Appraiser vs. Standard

For our Gage R&R study we were happy with the confidence intervals received for each 'appraiser vs standard' chart and assessment. Despite some expected variance the measuring systems were well within the intervals for percent variation (1-10%) and the assessment agreement having a 95% confidence interval told us that our method of measuring was within the approved range in this category.

5.3 Control Chart

Quality Control Chart is a systematic plot and analysis of Product and Process Performance Measures. There are two types of performance measures, which are Quantitative and Qualitative. Charts to analyze Quantitative parameters are called variable charts, and charts

to analyze qualitative parameters are called attribute charts. For variable charts, Measurements are quantitative and are taken continuously, for example, sizes and weights can be measured by variable charts. Attribute charts mainly focus on qualitative aspects such as defective rate and failure rate. (Romeu, n.d.)

The standard chart for variables data, X-Bar and R charts can tell if a process is stable and predictable.An X-bar and R (range) chart used with processes that have a subgroup size of two or more. The p-chart is used to monitor the proportion of nonconforming units in a sample, where the sample proportion nonconforming the ratio of the number of nonconforming units to the sample size. The c-chart is a control chart used to monitor "count"-type data, typically the total number of defects per unit. Both P Chart and C Chart are used to visualize attribute data.

For our project, we are using the X-Bar Chart as a tool to visualize the variation of box of vaccine per truck, based on different truck size and human error, it could be slightly different in each truck. We also use an X-Bar chart to analyze the variation of turck number. Due to human instability, it is possible that the driver couldn't arrive on site in time or the truck is malfunctioning in the middle of the road. We use P charts to determine the percentage of defective trucks and vaccines per box and we also use C charts to determine the specific number of trucks defective per day and number of defective vaccines per box.

Range Chart

$$UCL = D_4\overline{R}$$

$$CL = \overline{R} = \sum R_i / k$$

$$R_i = Max(X_i) - Min(X_i)$$

$$LCL = D_3\overline{R}$$

Average (Xbar) Chart

$$UCL = \overline{\overline{X}} + A_2\overline{R}$$

$$CL = \overline{\overline{X}} = \sum_{i=1,k} \overline{X}_i / k$$

$$LCL = \overline{\overline{X}} - A_2\overline{R}$$

k = number of subgroups
n = number of samples in a subgroup
A_2, D_3 and D_4 are constants based on n

Figure 31: Formulas for X-Bar Chart

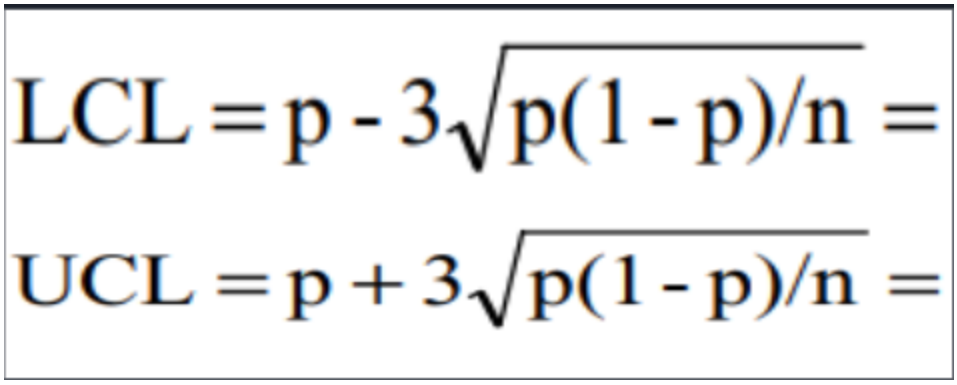
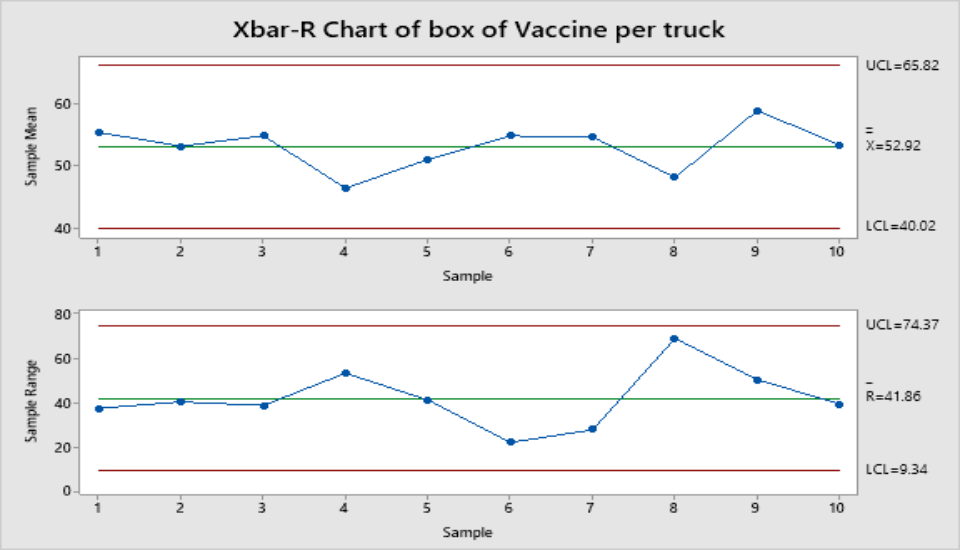
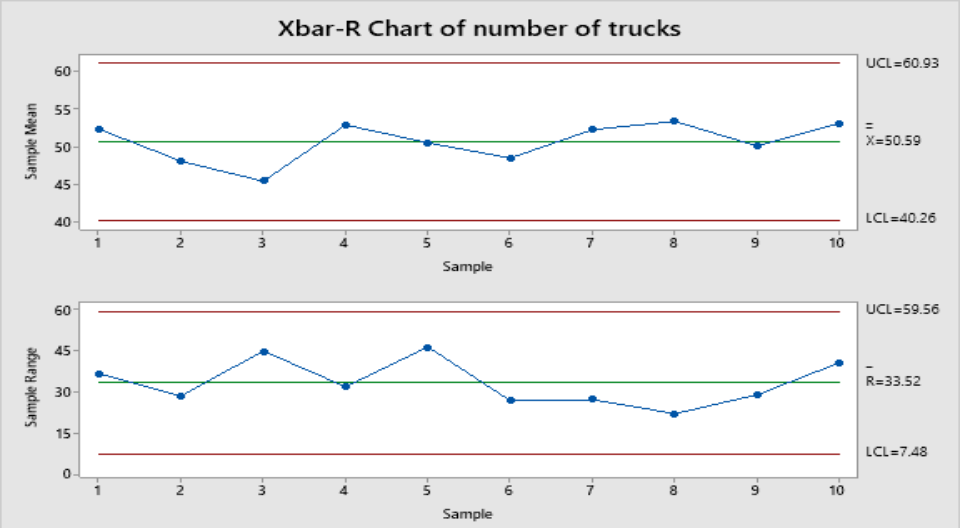


Figure 32: Formula for P Chart

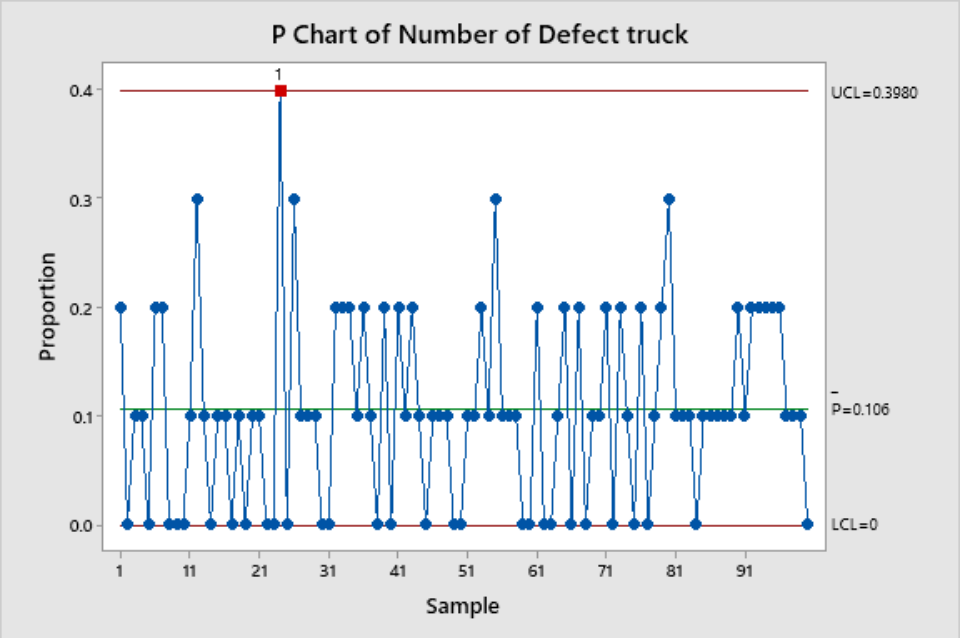
Mean (Target) = λ; UCL = λ + 3√λ; and
LCL = λ - 3√λ (if LCL is > 0; otherwise LCL = 0)

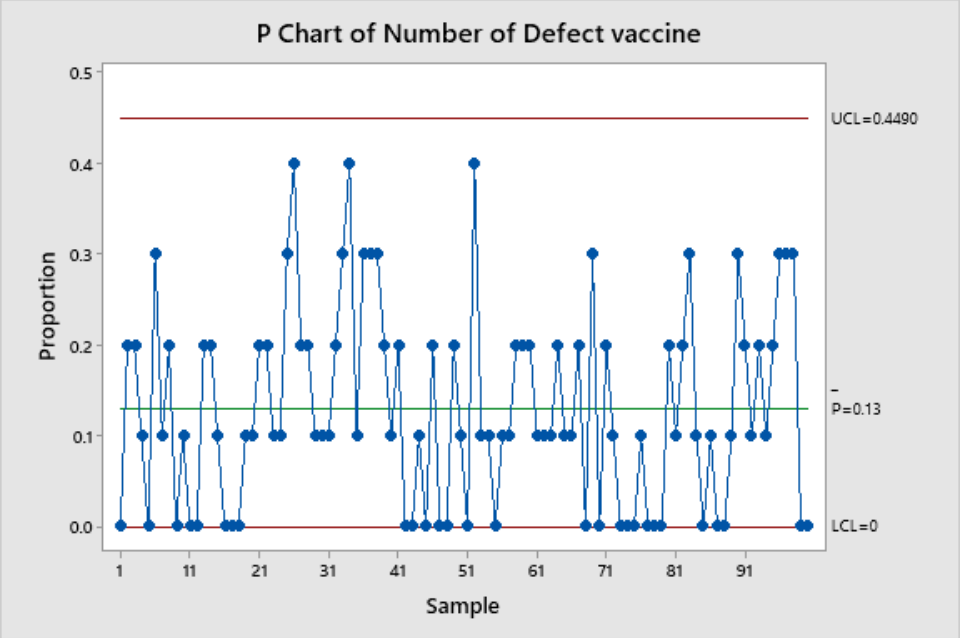
Figure 32: Formula for C Chart



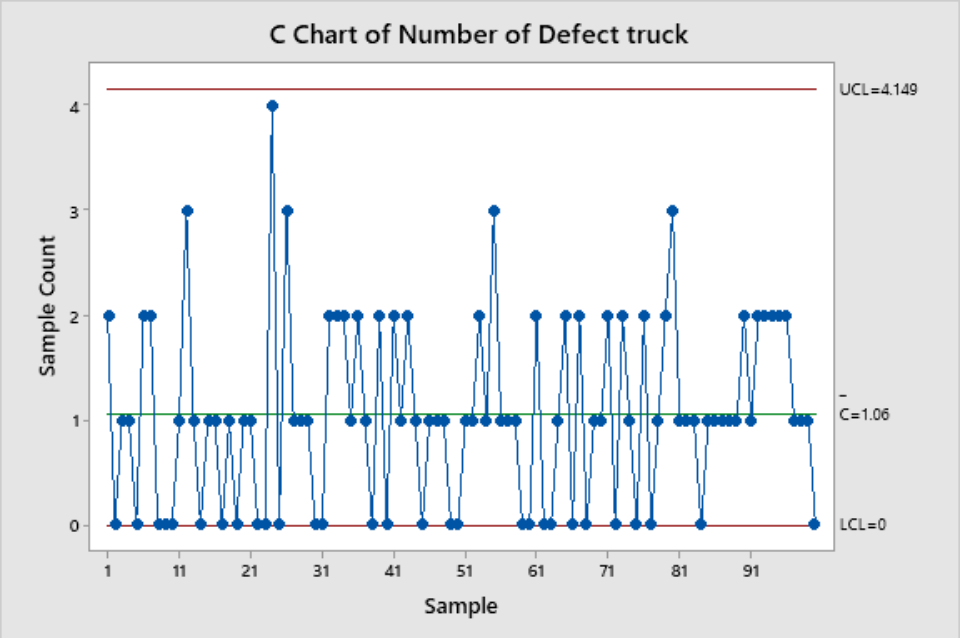


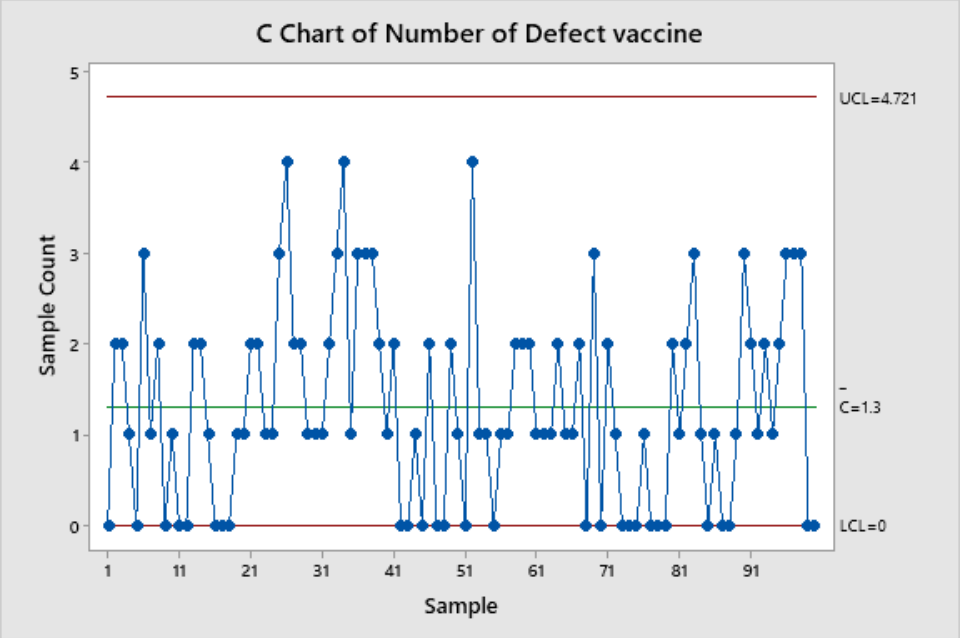
Figures 33 and 34: Results for X-Bar Chart





Figures 35 and 36: Results for P Chart





Figures 37 and 38: Results for C Chart

As we can see from the X-bar Chart, most of our data are lying between our control limits, data is very stable. But when we look at the P chart, which shows the percent defective. There is one data point exceeding the upper control limit, this means the process has fallen out-of-control. But for defect vaccines, things are still acceptable. For the C chart, we can see the number of defect trucks has the largest value of 4, which also corresponds to the 4% defective rate as shown in P chart. This means it could be possible to cause transportation delays due to vehicle malfunction.

5.4 Reliability

According to RAC START Sheet: "Reliability is the probability that a device will function according to its specifications, for a pre-established period, sometimes called "mission time" . If it is a one-shot device, reliability implies that it fulfills its prescribed function in the brief but crucial time that the device must work. The failure rate, for the exponential case, is the constant rate at which the device is failing, given in some time or operational domain or context." ("Reliability Estimations for the Exponential Life," 2003, 1)

In our project, the cooling system is vital for our vaccine transportation and storage. It is necessary to check the reliability of our refrigerator. There are three test methods, which are Complete sample test, failure censored test and time censored test. We take 15 refrigerators as samples to test their reliability.

Formula to calculate the confidence interval for Mean Time to Failure:

$$\left(\frac{2T}{X^2_{2n,1-\alpha/2}} ; \frac{2T}{X^2_{2n;\alpha/2}} \right)$$

Formula to calculate the confidence interval for Failure Rate:

$$FR = \frac{1}{MTTF}$$

Formula to calculate the confidence bound of MTTF:

$$\text{Mean} = \frac{2T}{\chi^2_{2n,1-\alpha}}$$

Confidence Interval for Reliability R:

$$R(T) = EXP(-T * FR)$$

The first test is to test all 15 refrigerators until they all fail. The total test time T is 16063 hours, which is too long and a waste of money. With 95% CI, we got our range of mean time to failure and failure rate. We also calculated our confidence bound based on 90% CI. As a result, with a complete sample test, we got our reliability of 57.9%.

Refrigenator Failure Time
34.0432661
88.65319939
101.7130879
172.3930781
195.4018529
235.1577889
649.6396429
952.7762964
999.3017379
1673.963027
1878.344751
1919.386942
1963.374842
2033.479886
3165.274591

Sample Size (N)	15	
alpha (Confidence Level)	0.05	
T (Sum of Failure Time)	16062.9	
a. 95% CI for MTTF and FR		
Chi-Square		
X^2 (2n, 1-alpha/2)	16.791	
X^2 (2n, alpha/2)	46.979	
	Lower	Upper
MTTF (95% CI)	683.8334	1913.275
FR (95% CI)	0.000523	0.001462
b. 95% Lower Confidence Bound for MTTF		
Develop 90% CI		
alpha (Confidence Level)	0.1	
Chi-Square		
X^2 (2n, 1-alpha)	20.599	
MTTF Lower Bound	1559.580949	
c. 95% Upper Confidence Bound FR		
Develop 90% CI		
FR Upper Bound	0.000641198	
d. 95% CI for Reliability		
Mission Time	850	
R	0.579831	

Table 4: Complete Test Results

The second test we conducted is failure censored. The test will be truncated at 3rd failure. It could save some time, but we will never know when the rest of the 12 refrigerators fail. We only used 1444 hours to finish our testing and get the reliability of 52.2%.

Refrigenator Failure Time
34.0432661
88.65319939
101.7130879
172.3930781
195.4018529
235.1577889
649.6396429
952.7762964
999.3017379
1673.963027
1878.344751
1919.386942
1963.374842
2033.479886
3165.274591

Sample Size (k)	3
alpha (Confidence Level)	0.05
T (Sum of Failure Time)	1444.967

a. 95% CI for MTTF and FR		
Chi-Square		
X^2 (2k, 1-alpha/2)	1.237	
X^2 (2k, alpha/2)	14.449	
	Lower	Upper
MTTF (95% CI)	200.0092	2336.244
FR (95% CI)	0.000428	0.005

b. 95% Lower Confidence Bound for MTTF	
Develop 90% CI	
alpha (Confidence Level)	0.1
Chi-Square	
X^2 (2k, 1-alpha)	2.204
MTTF Lower Bound	1311.221967

c. 95% Upper Confidence Bound FR	
Develop 90% CI	
FR Upper Bound	0.000762647

d. 95% CI for Reliability	
Mission Time	850
R	0.52296

Table 5: Failure Censored Test Results

The third trail is time censored. We set the test time for 500 hours to see how many refrigerators will fail. The problem is that we will never know how long the rest of the functional refrigerator will keep working. The total test time is 5327 hours and the reliability for this test is 53.7%. As we compare with these three test methods, the complete sample test gives us the highest reliability.

Refrigenator Failure Time
34.0432661
88.65319939
101.7130879
172.3930781
195.4018529
235.1577889
649.6396429
952.7762964
999.3017379
1673.963027
1878.344751
1919.386942
1963.374842
2033.479886
3165.274591

Sample Size (k)	6	
alpha (Confidence Level)	0.05	
T (Sum of Failure Time)	5327.362	
a. 95% CI for MTTF and FR		
Chi-Square		
X^2 (2k+2, 1-alpha/2)	5.629	
X^2 (2k+2, alpha/2)	26.119	
	Lower	Upper
MTTF (95% CI)	407.93	1892.827
FR (95% CI)	0.000528	0.002451
b. 95% Lower Confidence Bound for MTTF		
Develop 90% CI		
alpha (Confidence Level)	0.1	
Chi-Square		
X^2 (2k+2, 1-alpha)	7.79	
MTTF Lower Bound	1367.743844	
c. 95% Upper Confidence Bound FR		
Develop 90% CI		
FR Upper Bound	0.000731131	
d. 95% CI for Reliability		
Mission Time	850	
R	0.537159	

Table 6: Time Censored Test Results

---

6. Conclusion

In this project, we used different quality engineering methods. By Using Different methods we Analyze the problems and improve our project.

Flow chart : Flowchart is an effective tool to identify the cost of quality (COQ) by close analysis of frequencies within decision loops along with input, output branches involved. During the planning process of quality, i.e. “Plan Quality”, flowchart is used as a tool to improve processes that are selected for the project.It visually displays the sequence of activities of vaccine storage and transportation.

Organization chart: Organization chart lets us know about production of vaccines and distribution of vaccines. It also tells us about vaccine storage and vaccine allocation.

COPQ: By COPQ we understand the opportunities to improve the quality by reducing internal and external failure costs. Basically, by increasing the expenditure on prevention.It determines the costs that would disappear if all failures were removed from vaccines.

Affinity Diagram: Affinity diagram helps us with Transportation, storage, allocation and injections of vaccines.

Process capabilities:- Process capability analysis is a set of tools used to find out how well a given process meets a set of specification limits. In other words, it measures how well a process performs.It indicates the statistical quality control of the vaccine.

Design of Experiments:- We use DOE, one of the most powerful tools that statistics can provide to research, to screen and identify experimental Covid-19 treatments and characteristics that may affect Covid-19 patients. DOE helps identify which variables or factors, from a large variable pool, can be discarded as ineffective, and which ones should be examined more carefully, for they affect the responses.

FMEA:-Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. The FMEA leads the vaccination project to the right part.It describes what the possible failures are in the vaccination drive.FMEA can be usefully performed on a mass vaccination process to help identify potential failures. Safety strategies were recommended for each failure mode identified by our analysis and these recommended actions could be considered for practice and for further studies in the field.

Value Stream Map(VSM):- Value stream mapping (VSM) a lean tool that employs a flowchart documenting every step in the process. Many lean practitioners see VSM as a fundamental tool to identify waste, reduce process cycle times, and implement process improvement.VSM helps us to improve the vaccine transportation, allocation process of vaccine and makes the allocation faster and more efficient.

Acceptance Sampling Plan:-Acceptance sampling is a quality-control measure that lets us determine the quality of vaccine by testing randomly selected samples and using statistical analysis.When done correctly, acceptance sampling is effective for quality control of vaccines.And also by applying acceptance sampling plan we can sort out the factors we need to improve in Vaccine transportation.

Reliability:- Due to reliability test methods such as complete sample, failure censored and time censored we measure the quality of vaccine.In our project the refrigerator is the key factor to keep vaccine potency.It is necessary to find out the probability of refrigerator.

This project in turn was an immense learning experience and skill development for using these measuring and assessment tools mentioned to increase and develop better quality within a system as well as how to uphold that quality. It is clear that there is no limit on quality assessment and how crucial it is to implement and maintain to the benefit of a system and its participants.

7. References

1.Romeu, J. L. (n.d.). *Quality Control Charts*. https://blackboard.syracuse.edu/bbcswebdav/pid-7646704-dt-content-rid-82144845_1/xid-82144845_1

2.Romeu, J. L. (2019, January 1st). *On Quality Engineering*. Blackboard. https://blackboard.syracuse.edu/bbcswebdav/pid-7646589-dt-content-rid-82144700_1/xid-82144700_1

3.Reliability Estimations for the Exponential Life. (2003). *Selected Topics in Assurance Related Technologies*, *10*(Reliability Analysis Center), https://blackboard.syracuse.edu/bbcswebdav/pid-7646716-dt-content-rid-82144853_1/xid-82144853_1

4. Romeu, J. L (L, n.d.) Acceptance sampling plan, https://blackboard.syracuse.edu/ultra/courses/_464807_1/cl/outline

5**.** Denyse Baker, Jeff Broadfoot, Steve Mendivil, Adam Caruso, and Sandra Lueken, (2021), *How to Measure Quality Management Maturity,* https://www.pda.org/pda-letter-portal/home/full-article/how-to-measure-quality-management-maturity

6. Public health supply chain, one year report, from the office of assistant secretary, https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/Pharmaceuticals-and-Vaccines.aspx

7**.** (*Failure Modes and Effect Analysis to Develop Transfer Protocols in the Management of COVID-19 Patients*, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184001/

8. (*Vaccine Support*, n.d.), https://www.fema.gov/disaster/coronavirus/vaccine-support

9. Hayes, Adam. "Ishikawa Diagram Definition." *Investopedia*, Investopedia, 8 Feb. 2022, https://www.investopedia.com/terms/i/ishikawa-diagram.asp#:~:text=An%20Ishikawa%20diagram%20is%20a,are%20required%20at%20specific%20times.