A reliability engineer takes a hard look at Operation Warp Speed's COVID-19 vaccine distribution

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December 29, 2020

As 2020 comes to a close, we reflect back on a year of uncertainty that impacted all corners of the world. As of the writing of this article, the current international Coronavirus cases are just below 80-million with the number of deaths at about 1.75-million[1]. With those numbers, the worldwide fatality rate *[(# of deaths / # of cases) * 100%)]* is right around 2.2%. These are alarming numbers considering at the close of 2019, we were only just beginning to hear about the COVID-19 virus. However, we end 2020 with hope in the form of vaccine emergency use authorizations (EUAs) and distribution rollouts beginning around the world. Initial study results indicate an effective rate between 90%-95% for the two vaccines currently authorized.

The current thought process on herd immunity requires 75-85% or so of the population to receive the vaccine[2], which seems achievable on the surface. This will require two key aspects to work: robust public policy to encourage adoption of the vaccine and the ability to get every possible vaccine from the lab into the arm of willing recipients. Our focus for this paper will be on the latter, specifically from storage at the distribution centers to injection.

Background

While the vaccine distribution network is a worldwide issue that will require coordination and cooperation across governments as well as funding and support from wealthier nations, this white paper focuses only on the United States (US) Operation Warp Speed (OWS) COVID-19 vaccination roll-out program. This reliability engineer has been truly impressed by the dedication of scientists, technology leaders, and medical personnel in their response and rapid advancement during this pandemic. Which had me thinking: "Until there are enough vaccines to be widely available to all, what is the likelihood that there is a failure in the distribution system that results in a failure to deliver vaccines to the neediest?"

I want to emphasize that I am in no way connected to the field of medicine, nor am I a scientist working on the vaccine or affiliated with any of the OWS participants working on the distribution supply chain. I am, however, a reliability engineer who wanted to discuss the complex machinery of humans and processes that will make the dream of putting this pandemic behind us a reality. To do this, I would like to discuss the OWS process from storage, to transport, to the receiving facility, and finally, to injection. In this analysis, you will see how the failure of any part of this complex chain could result in the loss of

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[1] Worldometer. *COVID-19 Coronavirus Pandemic,* updated December 24th, 2020 at 20:47 GMT. [online] accessed December 24th, 2020. https://www.worldometers.info/coronavirus/?utm_campaign=homeAdvegas1?

[2] Jagannathan, M. *How many people have to get vaccinated against COVID_19 to reach herd immunity?,* MarketWatch [online] accessed December 24th, 2020. https://www.marketwatch.com/story/how-many-people-have-to-get-vaccinated-against-covid-19-to-reach-herd-immunity-the-faster-we-do-it-the-faster-we-get-back-to-life-11608740335.

efficacy of a given vaccine vial(s), which contain multiple doses. Before we get started, I would like to make some additional clarifications:

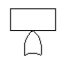
1) I am not a vaccine skeptic.

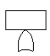
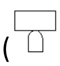
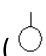
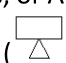
2) I have the utmost respect for the many millions of workers around the world who have worked tirelessly in this fight to protect the 7 Billion+ world citizens.

In summary, I have written this to broadly touch on general failure mechanisms to show the power of Fault Tree Analysis as a methodology to take a complex situation/system and break it down to the component level to assess the overall reliability of complex systems.

Much of the details surrounding OWS are kept secret for obvious security concerns, and with no OWS involvement, this white paper draws on publicly available sources for information. Furthermore, I have not addressed every potential failure nor the mitigations that I mention below.

Failure to Deliver Viable Vaccine Vial(s)

My job as a reliability engineer is to look at different failure modes that can result in a given dangerous outcome, which in this case is the ***loss of vaccine efficacy*** (i.e., the top event). Some may see me as a pessimist; however, it is important to identify the weak link in a complex system chain so that it can then be strengthened. To understand the reasons of a failure, all credible causes of failures are identified and put under a giant OR gate (like you would see in a binary logic ).

An OR gate indicates that if one failure cause occurs, the top event occurs. Each cause can then be further divided into more gates (combination of events) and events (root cause or probabilities). Gates can be either OR () gates, or AND gates (), which mean that each event () must occur for the cause to occur. Transfer gates () are used when further detail needs to be shown.

To simplify this analysis, let us separate out the three key places where failure could occur as shown in Figure 1:

- Failure of vaccine efficacy (vaccine) at storage
- Failure of vaccine during transport
- Failure of vaccine during handling (i.e., receipt and injection process)

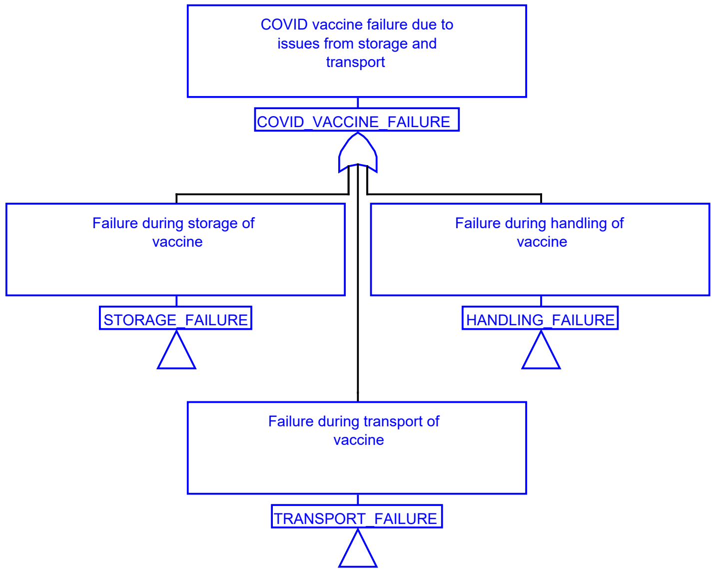


Figure 1. COVID Vaccine Efficacy Top Event

The most likely scenario of failure at storage is due to loss of temperature control. The Pfizer-BionTech as well as the Moderna vaccines need to be maintained at low temperatures to be effective. While I recognize Moderna needs to be kept at temperatures achievable by standard freezers and the Pfizer-BionTech needs to be stored at -70C, I have treated them the same in this simplified analysis. The breakdown of causes for failure at storage are summarized in Table 1 and Figure 2.

Table 1. Vaccine Failure at Storage

Cause	Event	Description	Mitigation
Freezer Malfunction	Loss of Power to Freezer	This can be sitewide power loss or loss to a particular freezer unit. Some of the pictures of these storage facilities indicate that they are fairly large with rows of freezer units sitting side-by-side. The efficacy of the vaccine may also depend on the duration of power loss. For short duration power loss, there may not be an effect, while for longer duration, utility power loss may result in those vaccines becoming ineffective.	For critical operations like these, a backup power system is typically provided. Monitors detect loss of power and temperature rise; move vials to other freezers with capacity.
	Natural Hazards at Storage Site	Thunderstorms, snowstorms, heavy wind, tornados, etc. can affect the entire site.	Design buildings and housing freezers and associated critical controls to withstand likely natural hazard events.
	Loss of Seal in the Freezer Units	This would result in loss of cooling to the vials. Typically, this type of failure would be limited to a single freezer, but multiple freezers can also be affected if there is a manufacturing defect.	Monitors detect temperature rise and move vials to other freezers with capacity (temperature monitoring

Cause	Event	Description	Mitigation
			depends on the instrument successfully measuring temperature, the signal being sent to central control room and the operator's response to a loss of cooling alarm). If common cause failure affects multiple freezers, mitigate with dry ice on hand.
	Development of Frost in the Freezer	Affects the overall temperature and humidity control, which is critical to keep the vaccine safe.	Monitors detect seal failure; move vials to other freezers with capacity.
Loss of Temperature Monitoring and/or Controls (may be extremely critical)		Freezer units have temperature monitors and/or controls, which may fail. This event can be further sub-divided into many more gates and events.	Each package also has individual temperature monitor(s), which are being monitored and tracked in central control rooms.

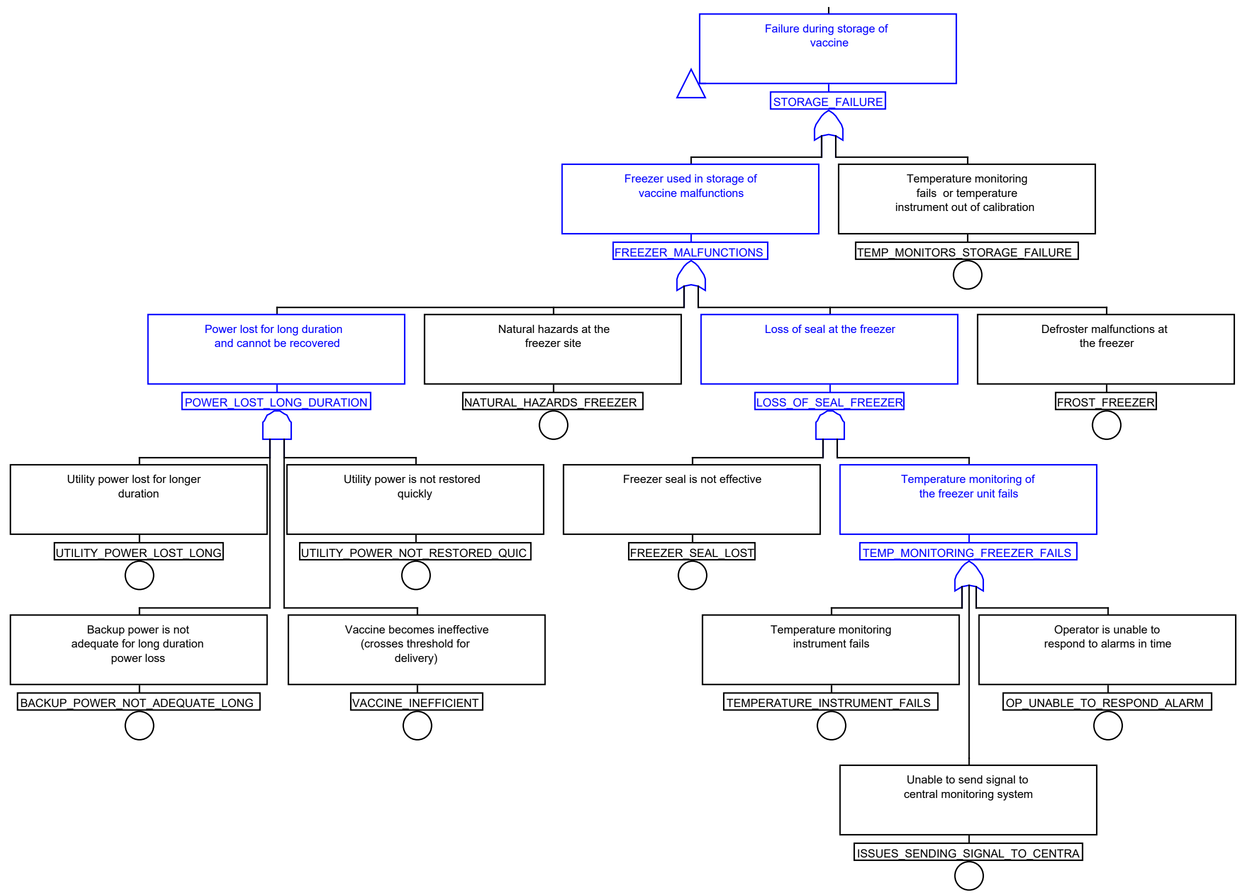


Figure 2. Vaccine Failure at Storage

From a US perspective, one can imagine the logistical nightmare of transporting a vaccine that must be stored at low temperatures. The vaccines, which are currently only produced in a handful of cities, have to be distributed nationally from Los Angeles to New York and Minneapolis to Houston. This requires a significant amount of care to transport these vaccines via air, road, and possibly over water in some cases. As I mentioned above, this logistical puzzle is one of the reasons the governments of the world (friendly or not) will need to work together if herd immunity is to be achieved.

The complexity of transport is not only in the distribution, but also in keeping the vaccine safe while enroute. The key causes of failures during transportation are shown in Table *2* and Figure *3*, which can be summarized as needing the proper delivery equipment as well as keeping the vaccines at the required temperature.

Table 2. Vaccine Failure During Transport

Cause	Event	Description	Mitigation
Dry Ice Refill Failure (Figure 4)	Dry Ice Supply Issue	Dry ice must be refilled regularly to maintain temperature. Supply is unavailable when neither the anticipated dry ice nor the backup supply is available.	Hazard analysis conducted with personnel familiar with perishable logistics (i.e., produce and medical supplies). Pre-identified freezer locations throughout distribution network to provide "buffer" storage until dry ice is obtained.
	Dry Ice Not Added When Needed	Failure to add when needed could be either failure of temperature monitors to alert or the handler is unable to refill with dry ice in time.	Set a maximum refill time. Secondary temp. monitor as backup. Transport with two handlers.
Transfer Truck Failure (Figure 5) *Note: this applies for other ways of transport as well.*	Refrigerated Truck(s) are Unavailable	Refrigerated trucks are necessary to maintain temperature. Trucks are unavailable when neither the original trucks nor backup trucks are available.	Pre-identify other means of emergency transport in case of failure. Pre-identified freezer locations throughout distribution network to provide "buffer" storage until dry ice is obtained.
	Refrigerated Truck(s) Malfunction	Trucks may malfunction at some point during the distribution route. If the trucks cannot be repaired in a timely manner, vaccines could be impacted by loss of cooling.	Have backup refrigerated trucks available for quick deployment.
Rural Infrastructure and Rough Terrain Challenges		Not all transportation will be possible with large aircraft and trucks on highways. If it takes multiple days to reach a given destination and the dry ice needs to be refilled, that may not be possible.	Potential for drone delivery. Back-up dry ice. Specially designed vehicles with freezer capacity. Military transportation support.
Vibration and Shocks During Transport		Stability is required to ensure the structure of the vaccine remains intact.	Additional packaging and padding materials in potentially rough transportation conditions.
Loss of Temperature Monitoring and/or Controls		Each package also has individual temperature monitor(s), which are being monitored and tracked in central control rooms. Mislabeling can result in tracking, sending, and receiving of incorrect vaccine vials.	Set a maximum time outside of freezer and/or dry ice resupply. Monitor inside container holding vials as well as in the storage box with dry ice.

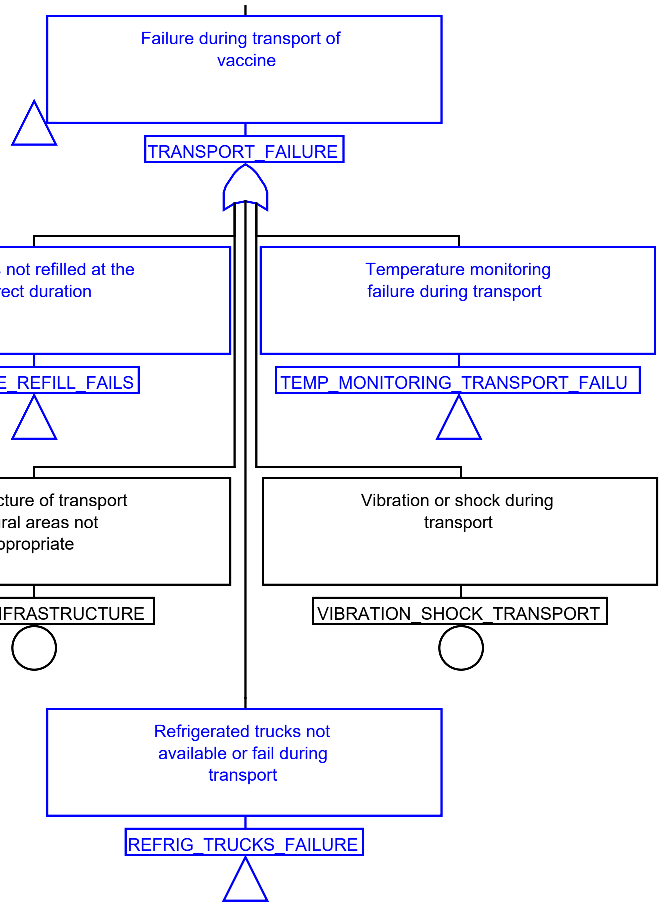


Figure 3. Vaccine Failure During Transport

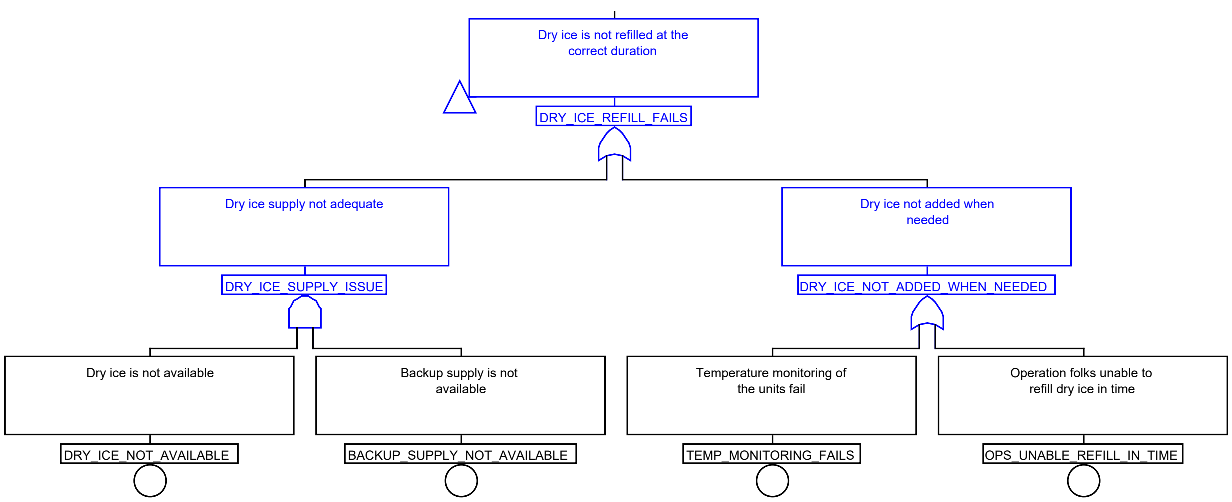


Figure 4. Dry Ice Refill Failure

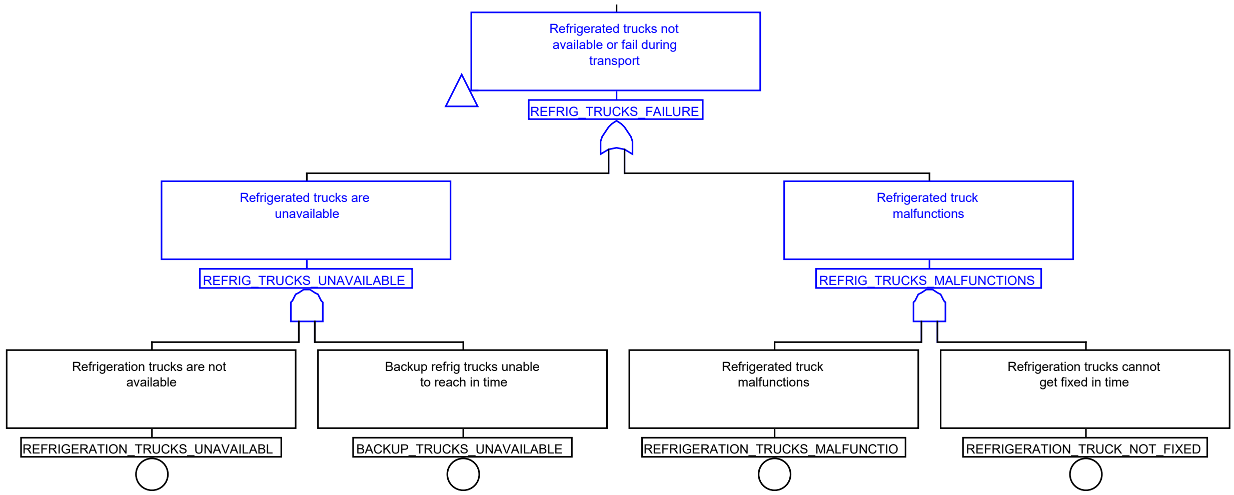


Figure 5. Refrigerated Trucks Not Available

The hard work of scientists and manufacturers, warehouse and storage teams, and transport personnel result in the vaccines being received at the receiving facility in good condition. The job is not yet done. It still needs to be stored, managed, and administered correctly. The major vaccines in circulation require two doses, from the same manufacturer, to be administered a few weeks apart.

Key causes of failures during handling are shown in Table 3 and Figure 6:

Table 3. Vaccine Failure during Handling

Cause	**Event**	**Description**	**Mitigation**
Other Supplies Not Available (Figure 7)	Supplies to Support Vaccine Injection Not Available	Required supplies include, but are not limited to, needles and syringes to administer the vaccine, PPE (masks and face shields), storage/ handling equipment, and storage/packing materials.	In preparation of the vaccine disbursement, most facilities have stocked up on supplies so that this is one of the least contributors to the failure of the overall process.
	Supplies Cannot be Procured in Time	Most facilities have arrangements with manufacturers to order and receive supplies on a short notice.	Identify back-up providers in case of emergency.
Lack of Trained Staff to Administer Vaccine		Arguably the most important part of the chain as failure to administer can make the efforts of all the people in supply chain upstream irrelevant. Also key is trained staff who can keep detailed records of dosage administered to individuals.	Pre-verification of staff in area to administer and track vaccinations. Have redundancy in employees on call in case of employee failure to show.
Infrastructure Failure at Vaccination Centers		The infrastructure at the facility receiving and administering the vaccines must be well equipped to store and manage the vaccine as well as have the supplies to administer and track. Many locations where these vaccines will be received and administered will be mobile units, home facilities, schools, etc. and will not be high tech clinics or hospitals.	Audit facilities for adequacy on a routine basis. Deploy standardized mobile units where hospitals and clinics are unavailable to limit external influences.
Management of 2nd Dose in a Timely Manner		Ensuring members of the public, especially the elderly, return on the vaccine schedule is a tall order. Lack of literacy, awareness, access to internet, and computer record keeping are all hinderances to success.	Manual back-ups. Assign case workers to each vaccinated person. Local clinic or in-home vaccine distributions for those at risk of slipping through the cracks.

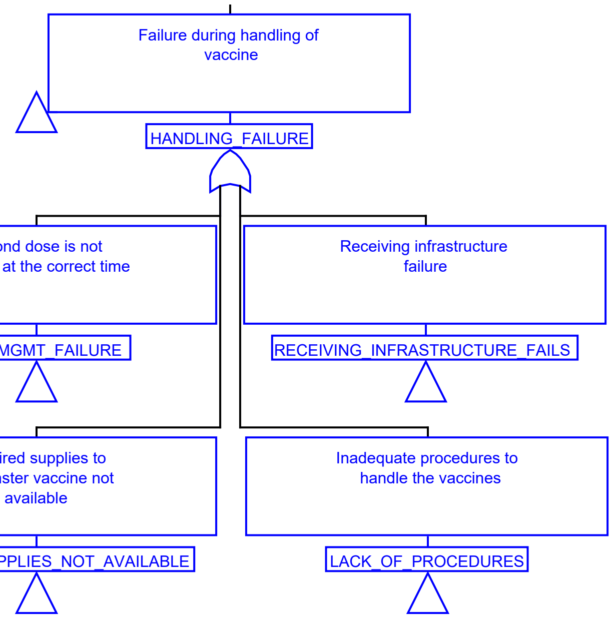


Figure 6. Vaccine Failure During Handling

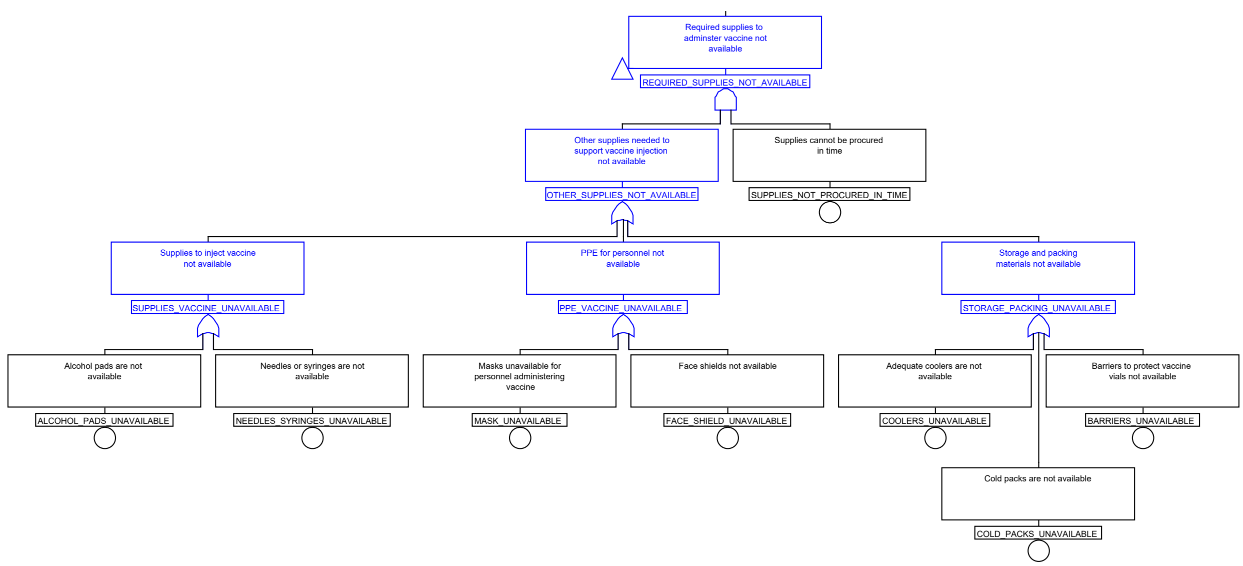


Figure 7. Supplies for Personnel Administering Vaccines are Not Adequate

In Summary

As stated above, the intent of this analysis was to identify how FTA can help to identify failure modes within complex systems. The analysis presented is intentionally simplistic, as a more thorough analysis would require intimate knowledge of the full supply chain and further work with the various components and participants in the OWS supply chain. While researching this topic and developing these models, it was clear that the models will differ widely depending on the country. Typically, the next step of fault tree development is the assignment of frequency numbers so the frequency of vaccine failure per person can be determined as well as to identify key contributors to overall failure. In addition, available and proposed backup mechanisms can be analyzed within fault tree analysis to determine the impact on success as a function of the cost of investment.

However, it is worth noting that the failure of the vaccine distribution system is only in the early stages of deployment since there is a shortage of vaccine vs the demand for it. With time, the supply will overshoot the demand and while loss of vaccine may be costly, will no longer be critical. In fact, it may be argued that the common mode failure in putting the pandemic behind us will be the lack of vaccination adoption, both in the US and abroad. As of the date of this paper, 60% of Americans said they would "definitely or probably" take the vaccine when made available to them[3]. Unfortunately, that is tens of millions of Americans short of the required number to reach herd immunity.

While there may be debate as to whether those who have been infected need the vaccine, one thing is likely – herd immunity is going to require higher rates of vaccine adoption. This reliability engineer knows that if there is one thing 2020 taught us, it is that we cannot predict what will happen next; with more information, adaptations to how to achieve herd immunity to COVID-19 will continue to occur.

I want to close this by giving my utmost and sincere thanks to the medical staff who have been protecting and treating people for the last year, to the scientists worldwide who collaborated to create vaccines in an expedient and safe manner, and to the millions of men and women who will work to store, transport, and administer the available vaccines safely to the world citizens.

Closure

To discuss how fault tree analysis (FTA) can assist with identifying failure modes in your complex systems, contact me today at MGandhi@BakerRisk.com.

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