A Digression on Covid-19 Vaccine Rollout

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1.0 Introduction

The *search for the Covid-19 vaccine* was a complete *success*: at least three different, clinically tested and government approved vaccines were developed in less than a year! However, the US *rollout of such vaccines* has proven *a failure*. At the time of writing this article, this 75 years old analyst, who also teaches graduate school in college, has not been able to get an appointment.

In June of 1944 the Allied army successfully landed in *Normandy*: "Over 1,200 aircraft and more than 5,000 vessels carrying 160,000 troops, medical supplies, water, food, ammunition, etc. were moved in a few days"[1]. *Operations Research*, the new technique that made possible the essential Logistics, was born. Such a feat was accomplished without computers, internet, cell phones, etc. *The operation's* political and military *leaders*, Messrs. Roosevelt and Churchill, and Eisenhower and Montgomery *had the brilliance of establishing* the key *goals and objectives* of the operation *while letting the OR people take care of* all the *technical details enabling its implementation*.

Thence, with all the technological advances that we currently have, it was perfectly reasonable to assume that an equally efficient rollout of the new Covid-19 vaccines was also possible.

The *objective of this article* is to *provide* examples of *other techniques* that can be successfully applied *to improve the Logistics* of said *Vaccine Rollout*. This paper is part of our contribution (https://www.researchgate.net/publication/341282217_A_Proposal_for_Fighting_Covid-19_and_its_Economic_Fallout) to the struggle against Covid-19, as stated in our proposal. Our previous work is: https://web.cortland.edu/matresearch/CORONAVARUSListEn gNov2020.pdf

In the remainder of this paper we present and discuss Quality Engineering examples of Covid-19 analyses. First, three PPTs developed by our graduate course students. Secondly, more advanced tools that analyze and resolve other problems in the implementation of the vaccination process.

2.0 Some analyses using Quality Engineering tools

In March of 2020, at the beginning of Covid-19 lockdown in New York, *we were teaching* our graduate Quality Engineering course (https://web.cortland.edu/romeu/MFE634SylS17.pdf). We gave real life problems (https://web.cortland.edu/romeu/PastProjectTopics2018.pdf) to our MFE student groups, to develop their Final Projects. Thence, *we included discussions about Covid-19*.

[1] Operation Overlord: https://en.wikipedia.org/wiki/Operation_Overlord

The students implemented a *Cost of Poor Quality* (*COPQ) analysis* to address the problem of infections (https://web.cortland.edu/matresearch/Covid-19COPQGrp1.pdf), and how these could be prevented or controlled. In our occupation, *Quality* is the acceptable delivery of products or services; *COPQ* create problems that produce long-term costs, and prevent the above to be true.

In the *Covid-19 case, the objective is efficient delivery of the vaccine*. *COPQ discovers problems* that *curtail or impede* such *efficient delivery* or create further issues down the road. *For example*, not having enough *personnel* to vaccinate, or enough *storage* for vaccines, limits the number of persons served. Alternatively, *vaccinating the wrong people, or the right people in the wrong order of priority*, also creates further issues down the road. Let's give *an example* of the latter:

Assume, for example, that 100 individuals between 25 and 35 years of age are not vaccinated. Assume that 5 become infected, of which one ends in the hospital. Alternatively, assume these individuals are between 75 and 85 years of age, and 10 become infected, 5 end in the hospital and 3 die. In addition to the loss of life, such *COPQ includes* the possibility of *overwhelming hospital services*, thence indirectly causing more deaths by *lack of* adequate *medical treatment*.

Students also (https://web.cortland.edu/matresearch/Coronavirus_Assess_Grp2.pdf) dealt with assessment. We need to learn *the ins and outs of the process under study*. To identify such, we *interview key individuals* in the service delivery chain. Students dealt with virus spread; in our *Covid-19* case *we analyze vaccination process*. From the study of this problem, and interaction with other providers and users of this service, we *come up with a series of questions to ask*:

Why have *only 33% of the vaccines been delivered into people's arms*? Determine exact *causes*: lack of vaccinating *personnel* (e.g. nurses), lack of *support material* (e.g. syringes), lack of good *coordination* with users (e.g. defective appointment request process), etc. We then establish, its *main reasons and possible causes and consequences*, as well as *responsibility* levels (who has the authority to decide, not who is to blame; *playing the blame game* is the worst of mistakes).

The third student PPT (https://web.cortland.edu/matresearch/Covid-19FTAGrp5.pdf) deals with *FTAs*[2]. Students used, as *Top Event*, death of a patient. We use *Lack of Vaccination*. Why has an individual not been vaccinated? Lack of appointment? Lack of vaccines? Of syringes? Other?

In the next section we further develop Quality Engineering analyses. We include a *Fishbone or Ishikawa Chart*, and an *FMEA*[3], directly applied to the current Vaccination process.

3.0 Organization of the Vaccine Rollout

The *Logistics of Vaccination Rollout and its Implementation*[4], requires taking a thorough Quality Engineering (or other engineering specialties, such as O.R., civil, logistic, etc.) analysis.

In a previous paper we briefly discussed FMEAs and FTAs applied to assessing a Covid-19 ICU (https://www.researchgate.net/publication/342449617_Example_of_the_Design_and_Operation_

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[2] Fault Tree Analysis: https://en.wikipedia.org/wiki/Fault_tree_analysis
[3] Failue Mode and Effects Analysis: https://web.cortland.edu/matresearch/FMEA&FTASumaryS2017.pdf
[4] CDC rollout recommendations: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html

of_an_ICU_using_Reliability_Principles) and to the operation of said ICU. *We now apply* such Failure Mode and Effects Analysis/*FMEA* to identifying *Vaccination process* potential problems.

Consider the situation arising from the impossibility for an individual, aged 75 to 85 years, to get an appointment and become vaccinated. *An abridged FMEA* for this problem can include:

Function	Failure Mode	Effects	Severity	Causes	Detection	Actions
Vaccination	No Vaccine	Exposed	High	Transport	Freezer	Federal
	No Syringe	Exposed	High	Materials	Warehouse	County
	No Nurse	Exposed	High	Staff	Hospital	Health
	No Info Data	Exposed	High	Admin	Office	State

Unvaccinated individuals are therefore *still exposed* to becoming infected by the Covid-19. Such high risk is *due to four contingencies* that have different causes, and require different solutions.

Vaccine supply may be lacking because the delivery has not take place for lack of *transportation*. It is detected when searching in the *freezer,* to vaccinate more customers,. Said problem requires contacting the Federal agencies responsible with vaccine *distribution* to the local sites. *A system* should be set in place *to replenish* vaccines *before a stock-out* occurs.

There may be vaccines in stock, but no syringes (or *other required material*). It is detected when looking for more in the *warehouse*. County is responsible to provide such material and should be contacted. *A system* should be set in place to replenish support materials before stock-out occurs.

There are no *Nurses* (called in sick; became infected; must quarantine; need break time, to eat or perform other necessities) and no replacements were considered. *A system* should be set in place for *medical personnel* back-up to cover for scheduled or unscheduled breaks, when such occurs.

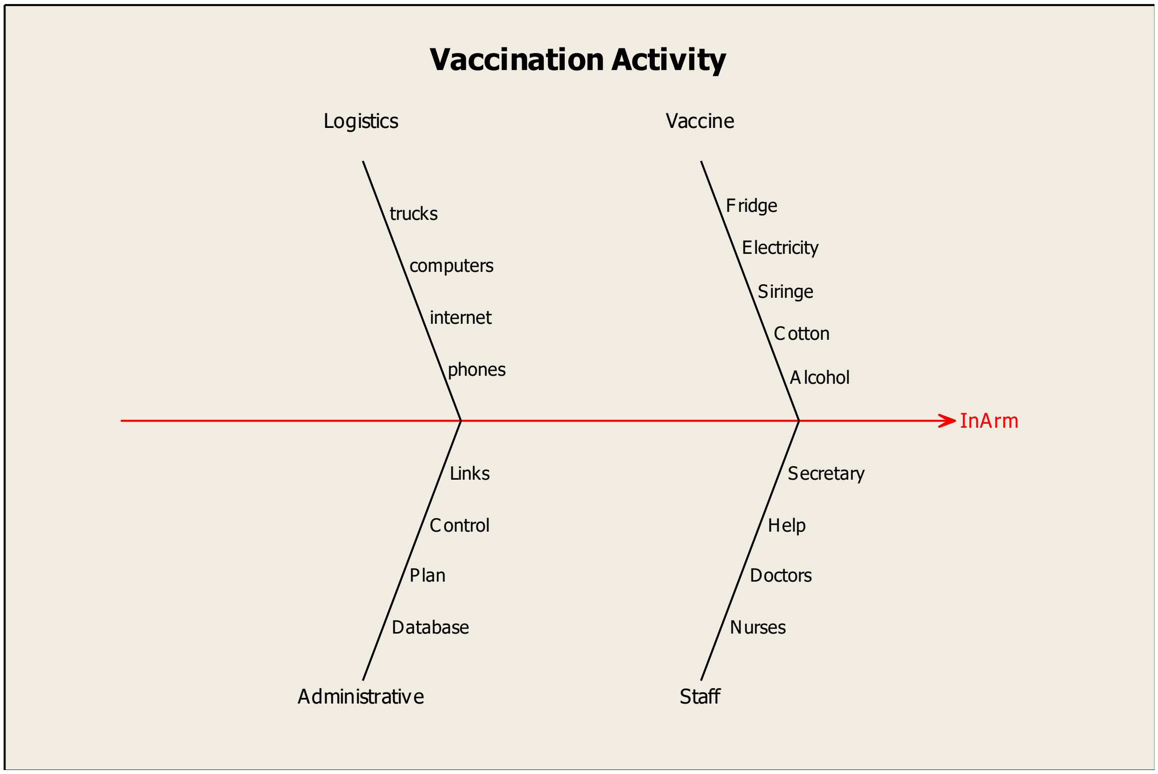
There is a failure in the *Data Collection* function (names, ssn, address, age, gender, contact, type of vaccine given, scheduled booster, etc.). Perhaps *the system*, *computer, internet* went down or the *operator* had a problem. *Backup or redundant elements* should provide *adequate reliability*.

In an *FMEA*, *which is a bottoms-up* approach to systems analysis, one *considers every important function of the system*, *how* it fails, *why and what* is the consequence, what can be done to avoid, or to survive such failure, etc. Since it is not necessary for an FMEA that the system is complete and operating, *they can be implemented during system creation and organization, saving time*.

For example, *if during the FMEA analysis it was* acknowledged that the available personnel was insufficient to carry out the vaccination of all individuals, then training sessions *could have been organized before* the vaccination started. If problems were caused by lack of transportation, or of materials, storage, etc. more trucks, freezers, and so on could have been purchased. *A thorough Quality Engineering analysis* of the system, prior to (or during) its implementation, would have identified and resolved many of the existing issues, pointed above.

With all the *information from the COPQ*, Brainstorming sessions, quality assessments, FMEAs and FTAs, we can *build an Ishikawa or Fishbone Chart*, a *qualitative tool* that helps identify *what data* we need *to collect*. Once data collection is available, Ishikawa Charts help *determine the regression and ANOVA models* that will be used *to quantify* these important relationships.

The *Ishikawa Chart below illustrates* some key issues involved in the vaccination activity:



We have *considered four main factors*: Logistics, Vaccine elements, Administrative elements and Medical and related Staff involved. Each one has several, *important, sub-elements*:

Logistics involves transportation of the vaccines (trucks), computer and communication systems, including internet, phones, etc. and its related data bases. These *system components* must be completely *established and operating*, at the beginning of the vaccination effort.

Vaccine itself involves *storage facilities* (fridge), power to operate them (electricity, lines etc.), medical equipment involved (syringes, sterilizers, PPEs, etc). Such important material must exist in sufficient quantities, and its re-supply must be consistent and reliable.

Administrative involves the control of the operation (including *the master plan* and *eligibility*), and the *data bases to store all this information*, including SW, operators, Internet, etc.

Staff involves *all personnel related to* the vaccination effort: doctors, nurses, administrative, support staff, etc. *Healthcare providers are humans*: get sick, burn out, need to rest, rotate, etc.

With this device we can build *a useful Discrimination Function* between environments that are successfully vaccinating the population, and those who are not. Response *variable InArm* defines the *number of persons* vaccinated, given existing staff, logistics, administrative and vaccine used. Discrimination *function identifies the requirements* to meet a specified number of vaccinations.

4.0 Discussion

The *rollout of the Covid-19 vaccine* was a failure because of *defective implementation*. It is easy to criticize, without a complete knowledge of all the facts. But, as the popular saying goes: *the proof of the pudding is in the eating*: only about 33% of vaccine availability is put into arms.

Systems are not perfect: they may fail. *Redundancy* helps increase *system reliability*. Assume a vaccination system is composed of five independent subsystems: production, distribution, first and second dose and control, each one having 0.99 Reliability, per day (which may seem pretty good). Then, *daily system reliability* would be (0.99)^5 = 0.95, or 1/20. This means that, *in the long run*, the system *would fail to perform one day out of every twenty* (not very good). If some *redundancy is introduced*, as suggested in the FMEA above, *reliability will improve*.

Selection of vaccine candidates is another concern. Individuals having suffered *mild Covid-19* may acquire some immunity. Others, are *young* and do not have co-morbidities. These could be *moved to later stages*, to prioritize more aged individuals, and/or those with co-morbidities. Data shows (https://www.syracuse.com/coronavirus-ny/) how *over 87% of Covid-19 deaths* occur in *persons aged 60 and above*, and how *less than 5%* occur *in those 49 years* of age *or younger*.

Debate exists on whether *to give both required vaccine shots, versus a single one*, vaccinating more people. However, vaccine *clinical trial results are based on giving both shots*. *We don't know what vaccine protection will be,* or whether its life length decreases, *under a single shot.*

5.0 Conclusions

The main tenant of *Quality Engineering, a statistics-based* endeavor, is that *adequate operation* of a system (its quality*) is expensive*. *Inadequate operation* (poor quality) is *cheaper in the short term*. But *in the long run*, the costs derived from a poor quality system runs up to *a much more expensive final cost*, among other things, *due to the Cost of Poor Quality*.

We have used *previous Quality Engineering experiences in Epidemiology*, analyzing first Ebola: https://web.cortland.edu/matresearch/EbolaGageR&R2016.pdf and later the Zika health crises: https://web.cortland.edu/matresearch/2017ZikaVirusFinPres.pdf with our MFE634 students.

There is a *new Administration coming in tomorrow*. It will bring *change in the Leadership* of the Covid-19 organization. It may also prove *useful to evaluate the logistic plans used* in the current vaccination effort. Its *current poor rollout suggests the need to re-examine their approach, and redefine some of the methods* currently being implemented. Moreover, even *considering to use* some of the *methodology presented in this paper*, to *help improve Vaccine rollout performance*.

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About the Author:

Jorge Luis Romeu retired Emeritus from the State University of New York (SUNY). He was, for sixteen years, a Research Professor at Syracuse University, where he is currently an Adjunct Professor of Statistics and Quality Engineering. Romeu worked for many years as a Senior Research Engineer with the Reliability Analysis Center (RAC), an Air Force Information and Analysis Center operated by IIT Research Institute (IITRI) and Quanterion Solutions (QSI). Romeu received seven Fulbright assignments: in Mexico (3), the Dominican Republic (2), Ecuador, and Colombia. He holds a doctorate in Statistics/O.R., is a Chartered Stat. Fellow, of the Royal Statistical Society, a Senior Member of the American Society for Quality (ASQ), and a Member of the American Statistical Association. He is a Past ASQ Regional Director (currently a Deputy Regional Director), and holds ASQ Reliability and Quality Professional Certifications. Romeu created and directs the Juarez Lincoln Marti International Ed. Project (JLM, https://web.cortland.edu/matresearch/), which (i) supports higher education in Ibero-America and (ii) maintains the Quality, Reliability and Continuous Improvement Institute (QR&CII, https://web.cortland.edu/romeu/QR&CII.htm) applied statistics web site.