

**COVERING THE LAST 50 FEET OF THE
IMMUNIZATION SUPPLY CHAIN: LOGISTICS POINTS
TO CONSIDER FOR HEALTHCARE MANAGERS****AUTHORS**

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BACKGROUND

The COVID-19 immunization process continues to await approval of vaccine for this condition. Most would agree that this will be one of the largest mass immunization projects in US healthcare history. A significant challenge for health care managers arises from the fact that the alternative immunizations currently approaching approval all have different handling methodologies. Furthering that conundrum is that roles for health care provider organizations have not been delineated in many communities. While the Centers for Disease Control and Prevention (CDC) and several state departments of health have published preliminary guidelines for local healthcare providers on handling immunizations, it appears left to each community to determine the actual plan for immunizing local populations. In Colorado, over 1,100 providers have expressed interest in becoming a vaccination provider.¹

Dr. Julie Swann of North Carolina State University (and a CDC advisor) points out that providers may not have the infrastructure available to properly handle and store at a super-cooled temperature of -80 degrees Celsius.² Depending on the ultimately approved vaccine, hospitals may become instrumental in moving vaccines from the distributors to patients – that figurative “last fifty feet” of the supply chain. This work is intended to raise some points to consider for managers as they contemplate their role in this upcoming health care delivery challenge.

Health care providers – especially hospitals - do have a foundation to build potential community immunization plans. That foundation rests in existing mass casualty plans. While some elements of a mass casualty event would not

apply, such as organizing a medical triage, the establishment of supply handling and traffic flow will be essential elements to a mass immunization undertaking. Staffing plans, physical location, and monitoring of immunization materials will be essential variations to existing mass casualty plans. Using that structural foundation, managers should consider couching their plans in the areas of population, place, and process.

EVALUATING THE PATIENT POPULATION

The population perspective here presents two planning challenges. First, there is the question of which members of the community will want an immunization. Dr. Mario Macis of Johns Hopkins University noted that some community members might choose not to vaccinate for various reasons.³ Depending on factors ranging from political influence to concerns about efficacy and side effects, not all community members may seek vaccination. This could lead planners to over-estimate the population to be served.

Secondly, concerning the population served, the variability of vaccine supplies will also impact the volume of persons seeking immunizations. The CDC projects three phases of vaccine availability that will influence potential service demand, as illustrated in Figure 1.

As the number of vaccine doses available increases, the likely demand for those doses will also increase. However, the availability of those immunizations is unpredictable since there is little data on the expected production rate and distribution to earlier portions of the supply chain. Hence, the ability to predict the volume of vaccinations to be given becomes a challenge - veritably a conundrum where demand could depend on supply. While vaccinations’ priorities are relatively straightforward based on CDC guidelines, the CDC plan phases’ rate of change or progression is uncertain. Our ability to make decisions on the scale of actions in those places or process domains is constrained.

Furthering that decision constraint is that the allocation of doses geographically across the United States is also

THREE TAKE-AWAYS

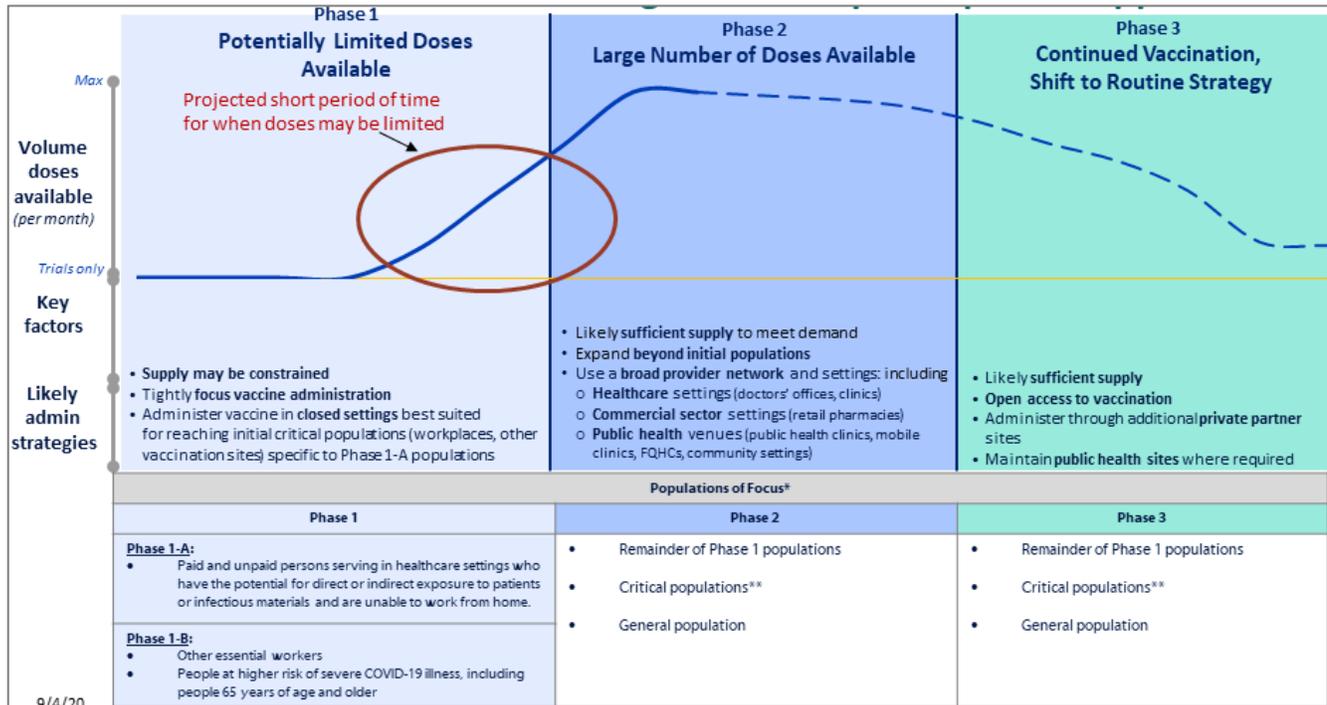
- Service volume depends on an unpredictable, independent variable (available doses)
- Location – provide for one-way throughput, safe hold areas, cold chain infrastructure, security
- The foundation exists in mass-casualty plans, adapt– processes to assess, prepare a dose, inoculate, document, observe, discharge while maintaining inventory – think “assembly line” here – because in this case, it is (or should be)

¹ Ingold, John. “Colorado Unveils Draft Plan for Who Will Get a Coronavirus Vaccine First.” *The Colorado Sun*, October 2020, 9AD. <https://coloradosun.com/2020/10/09/colorado-coronavirus-vaccine-priority-2/#bio-link-641>.

² Swann, Julie, Jeffrey Helton, and Mario Macis. “The Greatest Supply Chain Challenge: COVID 10 Vaccine- Webinar.” *University of Colorado Denver & The Business School Alliance for Healthcare Management*, 2AD. October 2020. Dr. Swann explains handling conditions of Pfizer/BioNTech mRNA COVID-19 vaccine. URL: <https://www.youtube.com/watch?v=tmGmsEWxe4s&t=752s>.

³ Mario Macis, Jeffrey Helton, and Swann, Julie. “The Greatest Supply Chain Challenge: COVID 10 Vaccine - Webinar.” *University of Colorado Denver & The Business School Alliance for Healthcare Management*, 2AD. October 2020. <https://www.youtube.com/watch?v=tmGmsEWxe4s&t=752s>.

FIGURE 1 – CDC VACCINATION AVAILABILITY PHASES (SOURCE: CDC, 2020)



unknown. Managers will, therefore, struggle with predicting how many doses will be available within each local jurisdiction and, thus, how to address local demand arising from local availability of vaccines.

A recommendation for dealing with this population element is to do some predictive modeling of multiple local scenarios based on local intelligence on population size, known attitudes toward vaccination, and input from state authorities who will likely be the most incredible predictors of possible vaccine allocation decisions.⁴ At a minimum, taking at least a low/medium/high sort of approach would set some boundaries around which further scalability plans could be made. The risk in any such projections is the availability of vaccines and where the country is among those three production phases. It seems the prudent manager would build scenarios appropriate for all three phases described in the CDC plans as a practical matter.

A necessary extension of this scenario analysis is to consider the potential variation in demand, depending on which vaccine gets approval first or which manufacturer’s vaccine is distributed in each local area. It is entirely possible that different areas of the country would receive different types of vaccines.^{5 6} As a result, there may be differentials in the community uptake of a particular vaccine based on public

perception of the product distributed in each local area, and those multiple products may be distributed to different areas of the country. This factor cannot be predicted, given the limited amount of available data on each of the current front runners for that initial wave of vaccinations. However, it may be prudent to evaluate different scenarios based on variations in public acceptance of a specific vaccine option.

THE “RIGHT PLACE”

Decisions in the place domain focus on physical space considerations in a mass immunization scenario. Should a mass immunization be needed, reliance on those previously mentioned hospital mass casualty event plans would be prudent. Indeed, site planning needs to have some context based on the local environment. It might be easy to think of a plan to set up outdoors and run a vaccination clinic unless the decision is being made for mass immunization in a northern climate during the winter. A hospital mass casualty plan would certainly consider inside operations for many parts of the country where such winter impacts must be accounted for.

Following that, guidance is helpful as a starting point. However, some other considerations should demand evaluation in the use of an “off-the-shelf” disaster plan. Given that we are dealing with vaccinations for a highly

⁴ USA. *From the Factory to the Frontlines, The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine*. By Department of Health and Human Services and United States Department of Defense. 202.

⁵ Kaur, Simran Preet and Vandana Gupta. 2020. "COVID-19 Vaccine: A Comprehensive Status Report." *Virus Research* 288: 198114-198114.

⁶ Slaoui, Moncef and Matthew Hepburn. "Developing Safe and Effective Covid Vaccines — Operation Warp Speed’s Strategy and Approach." *The New England Journal of Medicine* 383, no. 18 (2020): 1701-1703.

contagious disease with the possibility of asymptomatic carriers in a vaccination queue, space plans must have sufficient capacity that allows for an efficient throughput with adequate social distancing among patients.⁷ Creating a situation where immunization sites become a “super-spreader” event is a plausible risk in this situation. So, space planning must consider the need to protect the people seeking vaccinations, especially given the fact that there will be limited empirical data on the vaccine’s population-scale efficacy initially released for the general public. Space plans for mass immunization must consider throughput that involves a one-way patient flow through the site.⁸

FIGURE 2. CDC VACCINATION CLINIC LAYOUT
(SOURCE: CDC, 2020)



Another vital space consideration from a clinical perspective is the need to build into that traffic flow at least some minimal amount of time to observe the patient right after administering the vaccine for any immediate reactions. This is a concession to the limited amount of side-effect or reaction data that will accompany an initial vaccine release. That is undoubtedly going to be a constraint on any traffic flow planning. From the perspective of efficient traffic flow, an observation hold will also be a bit of a bottleneck that flow planning will have to work through. This hold step will require additional space with room to hold patients with appropriate spacing at a minimum. However, that hold step must also allow room for staff resources to monitor patients and simultaneously manage traffic flow to ensure patients’ timely movement into an observation queue, waiting for appropriate amounts of time for observation, and then clearing that queue space for other inbound traffic. A suggested traffic flow from the CDC is shown in Figure 2.

Planning in the space domain must also consider how to maintain that cold chain for the immunization doses. The

current vaccines in Phase III clinical trials and the likely first ones to enter the supply chain all have differing cold storage requirements.⁹ These constant temperature requirements range from refrigeration (2 to 8 degrees Celsius) to freezing (-15 to -25 Celsius) to an ultra-cold (-60 to -80 Celsius) and so may not be possible in some locations¹⁰. While ultra-cold storage can be maintained in a portable setting with dry ice, an option tied to a reliable availability of that cooling medium could be a logistics challenge in some parts of the country and a possible site option constraint. Again, because manufacturer or storage requirements vary among the current potential first-release vaccines, site planning should examine all three different storage requirement scenarios to ensure the adequacy of site storage.

A final space planning consideration is site security. Depending on the timing of the release of vaccine doses, it is conceivable that a “black market” could arise from the diversion of vaccines. If the immunization site is in a public place, this risk could be a concern. Vaccines should be secured in storage, and the site protected with access controls to limit admission to only patients and staff. Security concerns could also arise from community members attempting to obtain a vaccine before others are given a higher priority (such as health care workers or the elderly). As potential increases in cases arise over the upcoming winter season, securing vaccination doses will likely increase public health priority action.

PROCESS CONSIDERATIONS

The process domain entails input from both the population and place elements previously mentioned here. The logistics created by the number of people demanding vaccinations is a factor of CDC priority level-setting based on available vaccine doses. Demand-dependent volumes will further influence the decision to use places for mass immunization on supply volumes. Both factors will guide how the provider will design processes for this immunization effort. Providers would do well to consider the scalability of any process decisions made on the three phases of vaccine demand described in Figure 1.

In this context, the process entails designing workflows that will maintain efficient throughput in those areas where large populations could present seeking vaccines. Because of current uncertainty about vaccine efficacy (preliminary

⁷ Barati, Fatemeh, Mahdi Poursmaeili, Elena Ekrami, Sahar Asghari, Farzad Ramezani Ziarani, and Matin Mamoudfard. 2020. "Potential Drugs and Remedies for the Treatment of COVID-19: A Critical Review." *Biological Procedures Online* 22 (1): 15-15.

⁸ Centers for Disease Control and Prevention (U.S.). 2020. *Vaccination Clinic Planning Activities*. Version 1.0. ed. Atlanta, Ga.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Retrieved November 8, 2020 from: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/planning-activities.html>

⁹ Centers for Disease Control and Prevention (U.S.). 2020. *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*. Version 1.0. ed. Atlanta, Ga.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

¹⁰ Centers for Disease Control and Prevention (U.S.). 2020. *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*. Version 1.0. ed. Atlanta, Ga.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

results from Pfizer's 90% efficacy announcement¹¹ notwithstanding), bottlenecks must be avoided to minimize infection risk while a patient is developing immunity – or does not gain immunity from the vaccination. As researchers, we should also be cognizant of the risk we present to ongoing efficacy data by perhaps creating infections before a vaccine has a chance to take effect and possibly introducing noise into our clinical databases. So, throughput through process efficiency must be critical.

While we do not know yet which storage medium will be required for the immunization allocated to a given locale, managers must be prepared for three different vaccine handling protocols, which will lead to modifications in operational protocols. Processes to monitor and verify the integrity of storage cold chains must be developed and readied for implementation once the vaccine allocation is decided. Staff assignments will need to be made for persons to oversee and document tracking of cold chain integrity and remedy any breaks in such storage integrity. This will divert the resources needed from other parts of the vaccine effort. As such, managers will need to allocate additional staffing resources to cover this potential functional need.

Another vital process element arises from inventory management. Because of these vaccines' rapid deployment, there is no useful data available concerning these materials' shelf life. As a result, the CDC intends for vaccines to be distributed without a specified expiration date¹². Providers will need to be attentive to any updates in vaccine expiration dates and be prepared to address potential expired product problems in real-time. Specific tracking of lot numbers to associate with any rapid updates on expiration will be an additional inventory management challenge for managers as resource allocation decisions are planned. Further, it will be imperative for providers to anticipate the potential loss of available products based on non-expired product variability. As a result, recordkeeping provisions should be considered now before the distribution of these vaccines begins.

The CDC intends for immunizations to be distributed in packages with an allocation of syringes, diluent or adjuvant, and personal protective equipment (PPE) sufficient to handle only the number of doses in that shipping lot. This will handle any normal operations, but there is no information currently available about any spare numbers of these necessary supplies shipped with vaccine lots. Managers

should anticipate that potential losses from breakage or user errors have not been planned to allocate vaccine supplies. Therefore, our advanced planning should include additional PPE, diluent or adjuvant, syringes, needles, and sharps containers. In particular, PPE and sharps containers should be an advanced planning priority. Remembering that other ongoing patient care will be happening concurrently with this vaccination effort, managers should anticipate additional demand for everyday items such as sharps containers and PPE. To the extent possible, planning and securing of inventories of these goods will be valuable insurance against potential unplanned needs once the mass immunization effort has started. Considering the magnitude of the vaccine distribution effort on a national scale, the likelihood of having insufficient supplies shipped with vaccine lots should be an operations planning priority.

Once the immunization effort has started, staff resources' availability will be a significant challenge for many jurisdictions. Remembering that immunizations will be an additional workload over and above routine patient care, managers must plan to source additional staff or plan around routine care to free up existing limited staff to support the vaccination effort. Collaboration with community resources such as local pharmacies or other healthcare providers to identify staff qualified to administer vaccination injections should start now to develop a roster of available resources for deployment once vaccines come available. This will be an especially critical point in rural and underserved communities where staff resources may already be in short supply. Advance staff planning that is scaled based on the three vaccine deployment phases mentioned earlier will be a valuable management effort now.

Documentation of immunizations presents yet another process challenge to providers in this upcoming vaccination effort. This is especially true for those vaccines that require two doses.^{13,14} While the manufacturers will ship appointment reminder cards with the vaccines, providers will have a burden of monitoring who was given a vaccine first dose and will likely be relied upon to lead the reminder effort and second dose administration in their respective communities. Documentation of dispensed first doses will be necessary data for managers to plan for the logistics of handling that second dose.¹⁵ The potential liability for a provider who administers the first dose to have some

¹¹ Business Wire (2020). Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study. Retrieved November 9, 2020 from: <https://www.businesswire.com/news/home/20201109005539/en/>

¹² Centers for Disease Control and Prevention (U.S.). 2020. *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*. Version 1.0. ed. Atlanta, Ga.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

¹³ Falconer, Michelle Anne. 2013. "Improving Vaccine Uptake: An Overview." *Human Vaccines & Immunotherapeutics* 9 (6): 1368-1371.

¹⁴ Shimabukuro, MD, MPH, MBA, Tom T, Sapkota, MBBS, MPH, Sanjeeb, BS Nichols Barbara L, MPH Williams Warren G, Mullins, MIT, CSM, Shirley W, MPH Lee Leslie, Waite, MBA, PMP, Sarah, et al. 2012. "Tracking H1N1 Vaccine Doses Administered using CDC's Countermeasure and Response Administration System." *Journal of Emergency Management (Weston, Mass.)* 10 (4): 277.

¹⁵ Id

responsibility for seeking out the patient to administer the second dose is indeterminate.¹⁶ In this regard, a good risk management strategy is to plan on adding documentation of the immunization to the processes used in this effort. Tracking the time from the first immunization to the second dose will be a recordkeeping challenge for many providers. While most electronic health records can track immunizations¹⁷, integration of those systems on a perhaps broader scale is a question that managers should ask and secure an answer for now before the mass vaccination effort begins.

Further to this documentation challenge, providers must report dispensed vaccinations to state and federal authorities¹⁸. Processes will need to be put into place to make such reporting to government authorities a reality. Most electronic health records do not have the ability for automated vaccination reporting. However, it is unclear whether those reporting requirements differ from those for other routine vaccinations such as childhood vaccinations. Tracking any vaccine reactions that arise after injection is a part of that reporting and amplifies the need to establish a documentation protocol by providers serving in the immunization effort.¹⁹ Managers should proactively verify the ability of their systems to create those automated reports as needed. Otherwise, a reporting process must also be considered as part of participation in this mass immunization effort.

Our recommendations for managers whose organizations will participate in the COVID-19 immunization effort are:

- Develop processes and traffic flows at varying levels now – be able to scale up or down without much lead time
- Build reserves – PPE, diluent and/or adjuvant, sharps containers, syringes, needles
- Check with the EHR vendor now and verify the documentation and seamless reporting feasibility

Distributing an immunization to millions of people in the United States will be an unprecedented public health effort that will require advanced planning and coordination between many parties. Healthcare providers that will participate in this effort will be providing a valuable service to their communities and can do so successfully by anticipating needs now. Consideration of the volume of

people that will require vaccines spread across three different distribution phases is a valuable first step. Using that data, providers can then plan for the venue in which a mass immunization can occur. Using insights from consideration of population and place will inform important operational and process decisions that must be spelled out in advance of this work. Our healthcare system is well prepared to address this challenge using the foundation of existing mass casualty plans. Thinking about how those plans will be operationalized in this unique circumstance will represent a unique and worthwhile challenge to those in the healthcare management field today.

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¹⁶ The National Childhood Vaccine Injury Act of 1986 (9 42 U.S.C. Sect. 300aa-1 to 300aa-34) requires healthcare providers: “ensure the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine.” This law, however, only applies to minors. No such law exists on the national level for adults.

¹⁷ Health Information Management Systems Society, (2020). *Health IT Improves Immunization in the Time of COVID-19*. Retrieved November 11, 2020 from: <https://www.himss.org/news/health-it-improves-immunization-time-covid-19>

¹⁸ Centers for Disease Control and Prevention (U.S.). 2020. *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*. Version 1.0. ed. Atlanta, Ga.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.