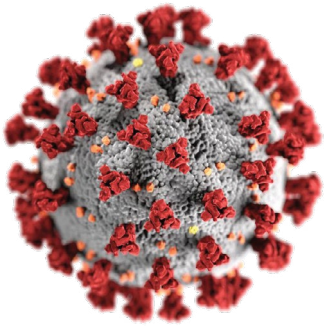
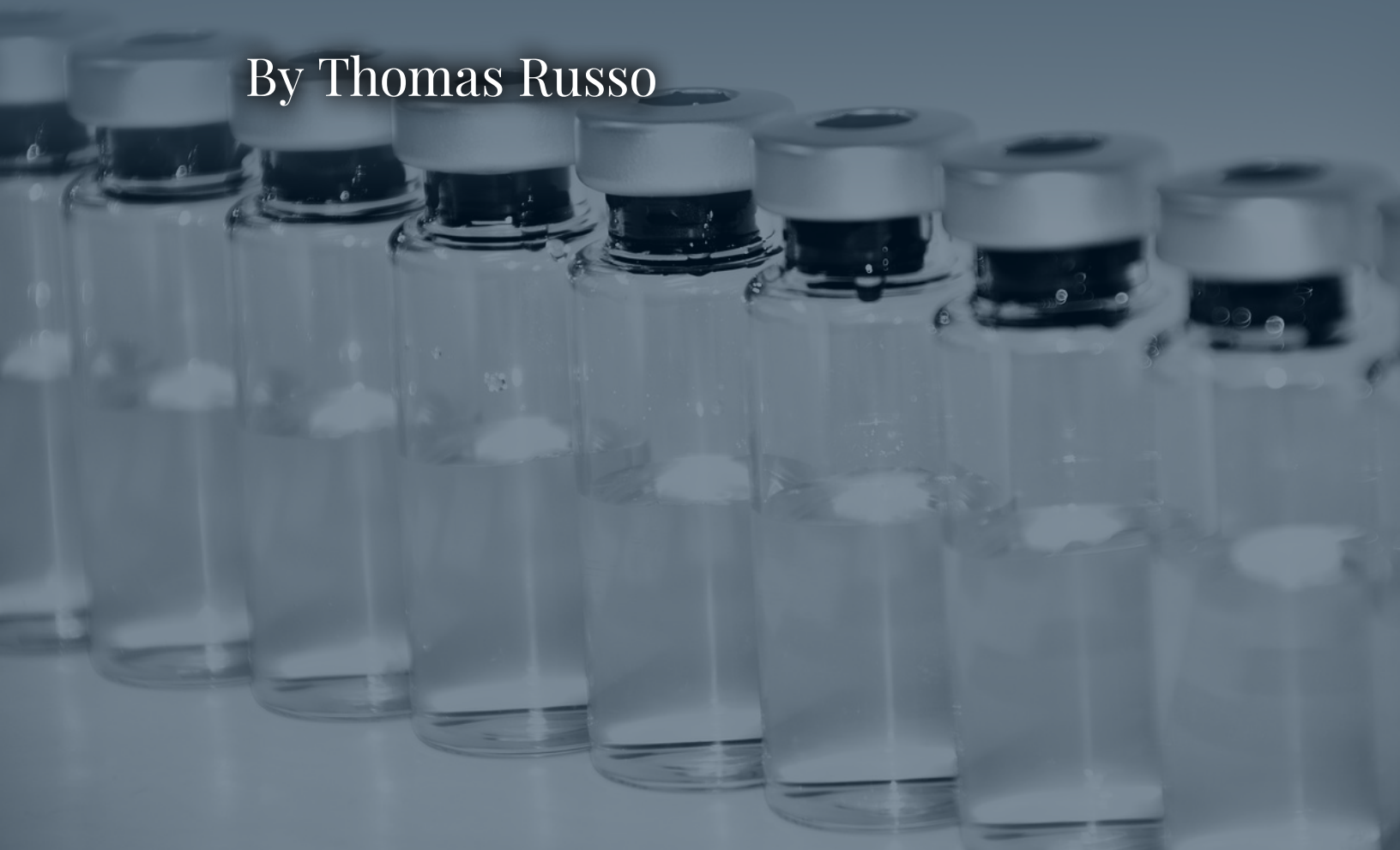


Homeland Security Affairs Journal
SPECIAL COVID-19 ISSUE

Pandemic Policy and the Logistics of COVID-19 Mass Vaccination

By Thomas Russo



Abstract

The sudden emergence of the H1N1 Pandemic in 2009 tested the nation's pandemic plans. It was learned that the nation did not have a well-defined, tested and reliable twenty-first century vaccine distribution system. The existing planning model, the public health model of the 1950s and 1960s served as the basis for published planning guidance. In 2020, once again the nation finds itself in the throes of a pandemic, scrambling to limit exposure and infection to a novel coronavirus, COVID-19. Meanwhile, all efforts are being exerted to produce an effective and safe vaccine. What remains to be seen is what mass vaccination will look like, given that a proven model has yet to be tested, and as new federal guidance is developed and published. This essay explores the status of a COVID-19 vaccination campaign from a distribution perspective or in the context of the Incident Command System, the Logistics Section. It draws from H1N1 and surveys developments implemented in the interim, or the inter-pandemic decade. Finally, the essay takes an historical look at the nation's pandemic vaccine policy and distribution models over the past twenty years. From this analysis, a blended-hybrid model emerges for COVID-19 vaccine distribution whose basis is a public-private partnership.

Suggested Citation

Russo, Thomas. "Pandemic Policy and the Logistics of COVID-19 Mass Vaccination." *Homeland Security Affairs* 16, Article 13 (December, 2020) www.hsaj.org/articles16514.

Introduction

There can be little argument that the COVID-19 pandemic has disrupted normalcy, creating chaotic circumstances throughout the world. In the United States, the lack of preparedness for the COVID-19 pandemic is especially disheartening given the investment in pandemic, hospital and public health preparedness approximating $21.2 billion dollars since 2002.[1] The pandemic's sudden onset caught state and federal government officials off-guard in the all-encompassing frenzy to "flatten the curve" and now the drumbeat to produce a vaccine as the essential mitigation strategy, all of which obscures a critical question: "what logistics are required to support a COVID-19 mass vaccination campaign?"

Emergency managers must be engaged in logistical planning that is closely coordinated with operational plans for administering vaccine to priority groups by public and private providers to ensure clinic sites are ready and operating within the Centers for Disease Control and Prevention guidance. The logistics of vaccination is three-fold: vaccine, venues and vaccinators. Vaccine distribution demands cold-chain management from manufacturer to the venue. Venues are those clinics or sites that represent the partnership of both public and private sectors. Finally, mass vaccination requires enough trained vaccinators to administer vaccine. All three of these elements must be in place for vaccine administration to take place. Emergency planners, hospital systems and healthcare coalitions must work collaboratively to ensure that vaccine distribution comes together with vaccine administration.

This essay explores what a COVID-19 mass vaccination might look like from a distribution perspective or in the context of the Incident Command System (ICS), the Logistics Section. It draws from H1N1, the last mass vaccination campaign and what was learned from the 2009 pandemic: a time when the nation was not quite ready for mass vaccination despite federal funding initiatives to support pandemic readiness. It surveys developments implemented in the interim, or the inter-pandemic decade. Finally, we take an historical look at the nation's pandemic vaccine policy and the vaccine distribution models that derive from that policy over the past twenty years. From this analysis, along with a preliminary CDC conceptual construct, the essay describes how the campaign might develop. The premise is that during a novel coronavirus pandemic, vaccination is critical to public safety, national security and herd immunity.

Background

It was April 2012 and the 2009 H1N1 Pandemic was in the rearview mirror as the Centers for Disease Control and Prevention (CDC) sped forward with development of its twenty-first century centralized vaccine distribution system.[2] It had just launched the final deployment of a system expected to transform the methods CDC had used to distribute vaccines to nearly 40,000 healthcare providers. The system it replaced was an uncoordinated, manual network of public health departments: 50 states and 14 territories and urban centers, or the 64 public-sector awardees. It was a hodgepodge of Excel worksheets and manual operations with each awardee performing public-sector vaccine management and distribution function a different way.

A wake-up call came when the 2009 H1N1 Pandemic was formally declared by the World Health Organization on June 11, 2009 but CDC's new system was not ready.[3] Most states had abandoned their vaccine warehousing function, which meant pandemic supplies had no state home, and lacked the climate control functions essential to protect vaccine viability. Additionally, the public health workforce, including public health nurses, the vaccinator corps, and the frontline for vaccination offense, had been decimated by state budget cuts over several decades.

Fortunately, the nation had begun a campaign for pandemic preparedness with the passage of the Pandemic and All-Hazards Preparedness Act, (PAHPA) signed December 2006 by President Bush.[4] The Act was reauthorized in 2013 and most recently reauthorized as the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of June 2019.[5] A core element of these reauthorization acts has been hospital preparedness in collaboration with healthcare coalitions.

A Nation Unprepared: A Failure of Imagination?

The World Health Organization first learned of COVID-19 cases in Wuhan City on December 31, 2019 and by early January, the CDC had begun tracking COVID-19. A month later, the White House convened its White-House-level task force with Vice President Mike Pence as the chairman. Emergency managers along the East Coast know that tropical storms are identified weeks out and as their threat to the mainland intensifies, forecast models track the

storm's path. Those "hurricane watchers" who live along the Atlantic Coast found it ironic that the sophistication of model forecasting with precision tracking for natural disasters, such as hurricanes, had yet to be replicated for emerging infectious diseases. One would have expected that forecast modeling would have been in place to forecast disease case rates, hospitalization requirements and fatality rates given a $21.2 billion investment in pandemic/hospital and public health preparedness.

Given the shortcomings of pandemic response thus far, government officials at all levels must be ready to roll-out a mass vaccination campaign once an effective vaccine is ready. A campaign for COVID-19 can rebuild confidence that assures bio-preparedness investments are worthy of American public confidence. Strategies must not only build on the initial COVID-19 testing program but must also build on the last pandemic vaccination campaign, the 2009 H1N1, its lessons-learned and the work of CDC to ready the nation for such a campaign.

In January 2019, the threat of a global pandemic was briefed to the U.S. Senate Select Committee on Intelligence by the Director of National Intelligence (DNI)[6] in the "Worldwide threat assessment of the U.S. Intelligence Community." Previously in 2018, the Center for Health Security delineated four categories of health events with a global pandemic included as a "catastrophic health event."[7] A more recent 2020 analysis by the Harvard Kennedy School Belfer Center[8] looked at the crisis-driven reactive nature of emergency management to the COVID-19 pandemic, noting "the United States made inadequate investments to prepare for a global pandemic." The nation had no nation-wide testing plan in place. Hospital systems were unprepared (even after the Ebola threat in 2015) and medical supply chain shortfalls were a surprise, with limited pre-development work completed for a SARS-CoV vaccine that could have served as the basis for a COVID-19 vaccine.

Vaccination is the ultimate "Hail-Mary" pass for fighting novel, infectious disease outbreaks and has proven its effectiveness historically as recently as 2009 with the H1N1 pandemic. It remains the most-effective mitigation strategy for creating herd immunity. Moreover, while a new campaign entitled "Operation Warp Speed" to manufacture an effective vaccine has engaged pharmaceutical companies globally, the public discourse regarding the distribution campaign remains unclear. However, by reviewing pandemic policy, vaccination distribution models and past performance, emergency managers can begin to conceptualize what the distribution strategy will look like.

Pandemic Plans and Vaccine Distribution

Two studies, representing the perspectives of both national defense (military) and homeland security, illustrate the essential nature of logistics, or the distribution function for mass vaccination. One study, (pre-H1N1 2009 pandemic) looked at the vulnerability of the Department of Defense (DoD) operational readiness given its dependency on the civilian medical logistics supply chain and specifically for pandemic vaccine distribution.[9] Vulnerabilities were identified with use of conventional, commercial carriers and how a pandemic could render them ineffective to transport vaccine to military personnel stationed globally. Those vulnerabilities included closed international borders, inability of commercial carriers to

transport due to civilian personnel absenteeism, and in a worse-case scenario, economic and political instability. Of course, the continental United States is not immune from these vulnerabilities with the exception of closed borders. In fact, the state of Hawaii, U.S. territories, as well as Alaska[10] may present quite similar and perhaps additional logistical challenges as conveyed in the DoD study.

After a review of federal pandemic planning documents, the study found a void in the distribution strategy for pandemic influenza vaccine for both military and civilian sectors in the National Strategy for Pandemic Influenza – Implementation Guide published by the Homeland Security Council in 2006.[11] The study adds, "Currently, no vaccine distribution plan exists."

The study concludes by recommending a distribution model for DoD and used the Pacific Command (PACOM) to illustrate its application. The intent was that the model be used as a planning mechanism for the nine DoD command groups (today 11 with cyber and space commands) and describes the parameters to identify a hub (military installation), military airfield availability, transport vehicles (cargo aircraft and helicopters), cold-chain management and related training to sustain the distribution model. The model elaborates on the critical significance of cold-chain management and ties it to exact real-time temperature and location data by using radio frequency identification (RFID) and global positioning satellites (GPS) technology as vaccine transports around the globe. The study defines the components of distribution and differentiates these components from vaccine administration, found overlapping in federal 2005-06 pandemic guidance.

A similar lack of coherent pandemic vaccine distribution guidance caught the attention of a researcher from a homeland security perspective when the H1N1 Pandemic was declared in April 2009.[12] The clarity defined in the DoD cold-chain logistics model, is not unlike the delineation sought in distribution guidance published for the civilian population. A review of the literature found that too often, vaccine administration is conflated with vaccine distribution, and federal guidance confused these two processes. Using the National Incident Management System (NIMS) framework, the researcher worked to clarify, define and differentiate the three processes for a pandemic vaccination campaign that under CDC/HHS guidance had remained muddled.

The study distinguished the tasks of vaccine distribution from those of vaccine administration and incorporated vaccine procurement or production, using a triangle to illustrate the interdependent relationships. The discussion was framed in the context of NIMS and incident command (ICS), and considers vaccine distribution as a function of the logistics section while vaccine administration is a function of the operations section.

The use of a triangle conceptualized the network of interdependencies absent in guidance documents. Each side represents a process: vaccine procurement, vaccine distribution and the most frequently referenced process, vaccine administration. Vaccine procurement is best understood as the task of federal government agencies to include the National Institutes of Health (medical research), Federal Drug Administration (regulation) related-alphabet agencies such as BARDA or the (Biomedical Advanced Research & Development Authority), and private-sector pharmaceutical companies (manufacturers).

Vaccine administration is needle sticks, or the act of dispensing vaccination shots, and in an ICS system, is the responsibility of the operations section. As the second side of the triangle, this function incorporates current CDC guidance, working in cooperation with the Advisory Committee on Immunization Practices (ACIP), which outlines Tier groups and priority groups. This answers a critical question with limited supplies: who gets it first?[13] Essentially, administration begins when there is a venue, vaccinator, vaccine and a receptive client. Getting vaccine to the clinic from the manufacturer entails the logistics function, as understood by the DoD study researchers. Logistics are subject to the vulnerabilities identified in that study.

The logistics function is the least understood and least referenced step in a mass- vaccination campaign, and it becomes a critical link between manufacturers and dispensing sites. Its apparatus consists of "how vaccine is distributed" (technology process strategies), "where vaccine is distributed" (venues), and "by whom" (vaccinators).[14] The distribution matrix is straightforward. With the incorporation and use of technology, manufactured vaccine moves from five manufacturers to one contractor, four warehouse depots and then is dispersed to over 100,000 venues. COVID-19 will more than likely expand that venue network. The complexity comes into play as government partners with and depends on the retail private sector for its mass distribution capabilities.

Method

To familiarize readers with the history of vaccine distribution, two prominent and documented vaccination distributions models are briefly introduced here: the Public Health Model and the Private Sector Model. We used the The Delphi research method to conduct policy analysis of the models.[15] A subject matter expert panel was recruited and engaged in a three-step process to identify model-evaluation criteria. Those criteria were then used in a second step to evaluate both models, using criteria that were deemed most critical to a pandemic vaccination campaign. In the final step, criteria were used to develop and analyze a hybrid model. In the final analysis, the Delphi panel evaluated each model based on these criteria.

Panel members all had extensive seasonal and pandemic vaccine experience and represented either administration, academics, distribution, manufacturing or policy and were subject matter experts representing either public (public health, BARDA) or private sectors (medical and pharmaceutical). An introduction of these models provides insights into history, intent, target audience and source of funding followed by a brief synopsis of the Delphi panel's evaluation. As stated earlier, when the last pandemic called for mass vaccination, neither model was readily available nor suitable, given their structures for the H1N1 vaccination campaign.

The brief introduction of the two models provides context for the discussion that follows on the emerging CDC hybrid pandemic vaccination model: a model yet to be tested in a pandemic scenario. Its full implementation guidance awaits publication. The discussion of the models teases out crucial variables that are merged into what, in all likelihood, will become the COVID-19 pandemic vaccine distribution model.

The Public Health Model

The public health model (PHM) is a twentieth century mass vaccination model, and the documented strategy for mass vaccination when a public health emergency was declared. The guidance dictated federal policy for mass vaccination, but dates to the 1950s and 1960s when mass vaccination clinics were used to defeat childhood infectious diseases such as polio, measles, smallpox, etc. As the pandemic threat rose to the top of national security concerns in the first decade of the twenty-first century, the guidance was revised, updated, and then pushed to state and local jurisdictions.

In this traditional model, the federal government is the purchaser and distributor of pandemic vaccine and has the sole responsibility for procurement and distribution to the states. Because of its emergency nature, all vaccine is distributed through public health departments and that called for few but large-scale, centralized vaccination clinics. The model was labor intensive and dependent upon local, and tribal departments for distribution and dispensing to the public. It required logistics functions, manpower and facilities, such as warehousing, that were no longer in place for day-to-day functions in most states.

However, additional resource limitations existed as well. To illustrate, in 2010, the Association for State and Territorial Health Officers (ASTHO) reported that throughout the nation and its territories, there were 2,790 local departments of health (DoH) and 261 regional or district offices.[16] Vaccination clinics were administered through the local departments. The governance structure of DoHs vary as well with only 30 percent (n=14) that have a centralized system with state employees overseeing the local departments. In contrast, over half the states (n=27), the department reports to a county official who is the decision-maker. Other states use a mix of centralized/decentralized systems. In 2016, The ASTHO Volume 4 reported the 2016 survey data; local departments numbered 2,795 while regional or district offices increased to 312 offices.[17]

The Delphi panel evaluated the public health model, concluding that it was dated and no longer reflected the realities of the twenty-first century.[18] Panelists' comments added that the attrition of the public health workforce, low dependence on the integration of untested technologies and a consumer-oriented retail service sector contributed to the inability of this model to distribute pandemic vaccine in a public health emergency. For example, as noted above, in 2010 there were 2,790 local health departments. In contrast, CVS and Walgreens each had pharmacies that numbered in excess of 9,000 sites, illustrating the convenience for consumers to access consumer-oriented retail stores as a one-stop shop. It also reveals the extent to which the private sector had restructured seasonal flu vaccination using the retail outlets.

In 2009 the Public Health Model was modified dramatically for H1N1 pandemic distribution plans, which impacted routine public health functions.[19] The CDC expanded its contract with McKesson Specialty Care Solutions to use its centralized organization for vaccine distribution, supplementing the logistics distribution function with its retail healthcare capabilities to supplement emergency mass vaccination. State departments of health then recruited from the retail sector, contracting venues (clinic sites) to administer H1N1 Pandemic vaccine according to the state's selected priority groups.

The Private Sector Model

The Private Sector Model is driven by profit; vaccine is manufactured and sold to wholesalers and distributors who sell to frontline providers, both medical and retail. Manufacturers provide an estimated 162 to 169 million doses of influenza vaccine for the U.S. market annually. Public Health manages, perhaps only 10 percent of that volume.[20] Over the past two decades, this provider network expanded beyond physician practices and outpatient medical specialty groups, to include retail pharmacies (chain-owned), grocery stores, and big box retail outlets as well. A third of all annual flu vaccine is administered through the retail sector.[21] Physician practices and community clinics dispense the balance.

Today, chain and independent pharmacies have established a network of over 88,000 pharmacies with CVS and Walgreen cornering a market share among chains with nearly 20,000 stores.[22] A 2017 NCPA Digest (National Community Pharmacists Association) numbered 22,041 pharmacies located throughout the nation in rural and isolated locations.[23] A recent article by the Healthcare Industry Association reported that while emergency room use decreased by 10 percent, urgent care centers have increased by 20 percent over the past decade and number 8,774.[24] These retail outlets form the basis for a de-centralized community-based, emergency-vaccine distribution network. These numbers fluctuate but offer a perspective on the role of pharmacies as a primary care provider, an alternative to the physician practices.

Since 1996, the American Pharmacist Association (APhA) has trained pharmacists throughout the franchise networks to vaccinate, providing and bringing online thousands of venues for vaccination. Today over 300,000 certified vaccination pharmacists, collectively account for 25 percent of seasonal flu vaccinations.[25] The delivery of healthcare services changed dramatically from the solo practitioner of fifty years ago to medical group practices, hospital systems and retail outlets along with numerous outpatient care facilities such as urgent care centers. The variety and range of vaccinations has changed as well and the private sector has transformed what was a public-sector medical service to a private-sector retail service.

While the ability of the private-sector model to distribute vaccine is robust, its ability to respond to public health emergencies is limited. During periods of vaccine shortage, (such as the 2005 flu vaccine shortage) the private-sector system lacks the responsiveness to retrieve vaccine and distribute it to high-risk population groups. Distribution of the first doses of vaccine goes to high-profit margin, bulk buyers. Under normal distribution, vaccine administration is offered through retail outlets before the healthcare sector begins to offer vaccine to its client base, which includes both physicians and public sector providers. The most vulnerable, at-risk groups are not priority groups in the Private Sector Model.

The Delphi panel evaluated the Private Sector Model as powerful but noted that it fails to reach population groups that are either high risk, underserved or geographically confined to remote locations. In addition, corporate retail pharmacies, such as CVS and Walgreens are networked into the large corporate structures but locally owned pharmacies in remote areas are not served by the pharmaceutical corporate structure. In emergency vaccine distribution, it is public health's duty to address the ethics of distribution, including issues such as the underserved, at-risk gaps and the most vulnerable to ensure all Americans are served.

As noted in the Private Sector Model, federal, state and local government accounts for less than 10 percent of seasonal flu vaccine purchase and administration. Physicians, medical groups and individual practices purchase vaccine from either a manufacturer or wholesaler. The federal government has limited input into the distribution dynamics of this model. Thus, distribution inequities persist unless the public health sector intervenes and redirects distribution.

U.S. Pandemic Vaccination Policy

If one is curious about U.S. pandemic policy for public health emergencies of national significance, one only need look to COVID-19 and the frenzied confusion that persists with the current response. The policy goals that moved the nation to a state of pandemic readiness in the first decade of the twenty-first century — whether it is the use of non-pharmaceutical interventions (NPI), vaccine supply chains, vaccine procurement, or as learned in 2020, medical personal protective equipment (PPE) supply chains—have all been missed. One could reasonably conclude that despite years of funding, a coherent policy driving a robust plan of action to supplement the nation's policy of vaccine self-sufficiency for pandemic response remains to be articulated.

With the passage of the 2006 PAHPA, planners were challenged by the CDC mass vaccination policy goal: to vaccinate 300 million Americans in six months.[26] Though this was the published doctrine, the goal was insurmountable given the guidance, technology and resources. Planners went through all sorts of mathematical computations to bring plans into compliance, yet this approach required vaccinator manpower and clinic sites not laid out in that guidance. The question remains: "has the revised distribution strategy been updated with the proper guidance provided to accomplish this goal?"

In 2008, the HHS plan listed two specific goals that relate to a policy of vaccine self-sufficiency. The first goal was to have in place by 2011 domestic production capacity sufficient to supply influenza vaccine to the entire U.S. population within six months of the onset of a pandemic. A secondary goal was to stockpile enough doses of vaccine to inoculate 20 million people as soon as possible after the onset of a pandemic.[27] In contrast, Operation Warp Speed, the Trump administration's plan to fast track development of a COVID-19 vaccine, suggests that the 2008 goals were not achievable and remain elusive.[28]

According to CDC's Interim Vaccine Guidance, and its 2017 Pandemic Influenza Plan, the goal for vaccination in a pandemic "is having sufficient pandemic influenza vaccine available for an effective domestic response within four months of a pandemic declaration with first doses available within 12 weeks of the President or the Secretary of Health and Human Services declaring a pandemic."[29] As of fall, 2020, COVID-19 vaccine was not available and is not expected to be readied for distribution before the end of the year.

The 2017 Interim Guidance adds that an overarching aim for a national pandemic vaccination campaign is "to vaccinate all persons in the United States (U.S.) who choose to be vaccinated, prior to the peak of disease." The revised goal drifts from the specificity offered in the 2008 guidance declaring that once COVID-19 reaches its peak, sufficient vaccine will be available for

all those who wish it. The definitive vaccination goal of 2008 has become generalized aims in the interim between H1N1 and COVID, with federal guidance lacking in specificity and structure, and remains outside the NIMS/ICS framework.

The homeland security study with its Delphi Panel concludes with a policy strategy recommendation that a comprehensive public-private partnership be established for pandemic vaccine distribution that can achieve the HHS goal, essentially creating a hybrid, third model.[30] The objective stated then, as it is today is to achieve an executable staffing plan, (i.e., logistics function) to "facilitate a rapid response." This becomes the challenge for local healthcare coalitions, including emergency management. The role of Public Health transitions from its role as vaccinator to one of essentially a logistics function in collaboration with the healthcare coalition to recruit vaccination sites, staffed with a surge of multi-disciplinary healthcare personal that serve as the pandemic vaccinator corps.

The study describes a pandemic policy framework listing six goals, establishing an executable, and publicly funded model for pandemic vaccine distribution. The model draws from the analysis by the Delphi Panel of the traditional Public Health Model and the Private Sector Model.[31] The policy goals included expansion of the vaccinator corps by recruiting the retail healthcare sector (scalability), as well as allied health professionals; engage both traditional and non-traditional medical providers in vaccine administration (provider-centered methods); and make emergency vaccination like the annual flu campaign to encourage the public's acceptance of and accessibility to vaccination (integration). The study underscores the latter as a critical factor that emergency vaccination should look more like seasonal vaccination offered through a full range of medical and retail venues (client-centered approach).

Finally, the policy framework called for structuring federal guidance along the lines of ICS, which the first responder community (i.e., emergency management, whether civilian or healthcare based) outside public health use daily for all-hazards response. In other words, bifurcate the traditional approach to vaccine administration into two independent processes simultaneously, recognizing their interdependencies, using the NIMS/ICS framework.

The COVID Model: A Public Private Partnership

Among the many lessons learned in 2009, federal pandemic guidance for vaccine distribution remained based on a dated twentieth century model. Yet in some fifty years, the private sector had progressed with a privatized model for flu vaccine distribution to protect the public, virtually bypassing public health and government agencies to mass produce and mass distribute through technology, adapted for centralized distribution of flu vaccine. The private sector had integrated seasonal flu vaccination effectively into its healthcare model as an additional retail service.

Yet, both the public sector, government-driven model and the private sector, profit-driven model offer strengths and limitations when the nation is confronted with a public health emergency of national significance where mass vaccination becomes the primary mitigation strategy. COVID-19 presents the challenge to partner for emergency response.

Pandemic Vaccine Distribution

In April 2020, CDC published a two-page schematic overview (Figure 1) for pandemic vaccine distribution which depicts nearly fifteen years of the agency's efforts to integrate the federal publicly funded vaccine programs with essential private sector entities and conveys a surge of vaccination sites and vaccinator corps for a pandemic scenario.[32] It reveals a distribution model based not only on seasonal vaccine distribution but also those vaccines used in immunization programs throughout the country. It expands the CDC public-sector centralized distribution system and brings onboard private sector entities through a vaccine contract process to build a public/private pandemic vaccination distribution system.

For the sake of comparative analysis, the emerging CDC pandemic distribution concept approximates that outlined in the homeland security Delphi Panel's six-goal policy framework and offers metrics that can evaluate the CDC distribution model.[33] It suggests an approach that incorporates criteria that contribute to an executable distribution plan with the exception of federal guidance. Those executable criteria include scalability, client-centered, provider-centered, and a model that integrates with seasonal and day-to-day vaccine distribution. The challenge then becomes the extent to which local planners can replicate the model at the community level and where federal planning guidance facilitates the model's implementation.

The schematic depicts two additional critical elements crucial to vaccine production and distribution: cold-chain management (vaccine handling) and vaccine tracking (route location). The distribution plan builds on the CDC VtrckS, or the Vaccine Tracking System, a critical component of the Vaccine Management Business Improvement Project (VMBIP), which is CDC's publicly-funded vaccine supply chain system. VTrckS, first launched December 2010, as the H1N1 Pandemic faded and subsequently rolled out fully in 2013.

The VMBIP began with the Vaccines for Children (VFC) program. This program served as the basis for the 2009 H1N1 pandemic vaccine mass vaccination campaign. In 2008, CDC had transitioned 64 departments of health (CDC awardees) onto the centralized vaccine distribution system.[34] However, at that point the system had not been prepared to incorporate the tens-of-thousands of private healthcare providers or private-sector retail entities that would become H1N1 vaccination sites. As a result, CDC's centralized distributor, McKesson expanded its contract from the 40,000 providers to an estimated 90,000 sites across the country shipping vaccine along with syringes, alcohol swabs and cotton balls.[35]

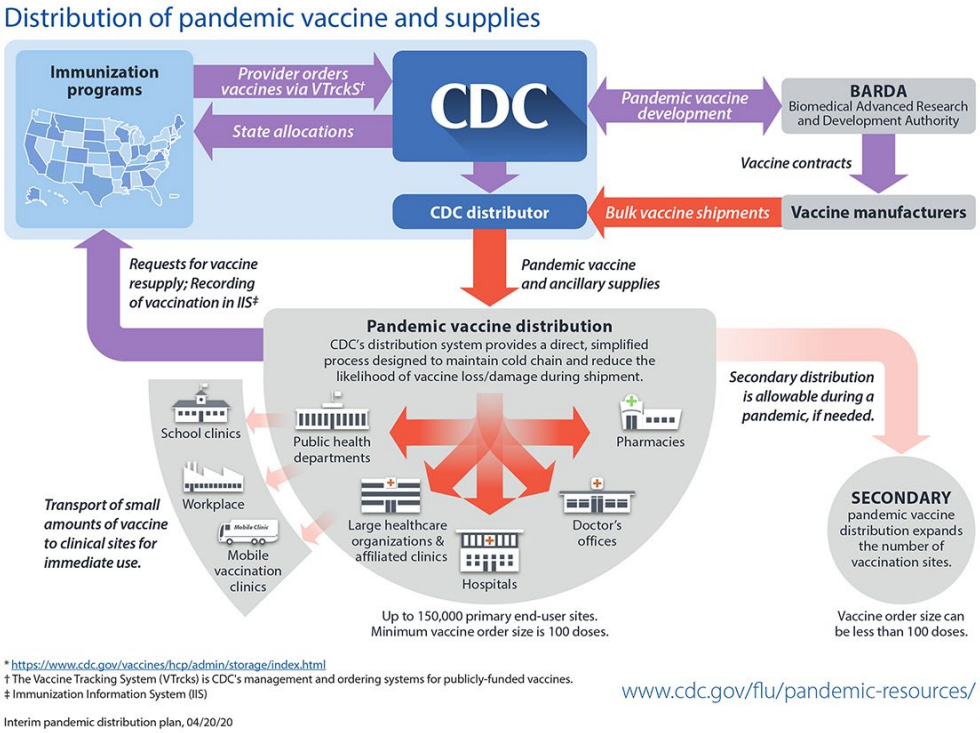


Figure 1. CDC Pandemic Vaccine & Supply Distribution

A DHHS Press Release, Operation Warp Speed announced that in collaboration with the private sector, the Department of Defense will assist with "faster distribution and administration than would have otherwise been possible using wholly private medical infrastructure distribution of vaccine to millions of Americans."[36] The scale of response is such that perhaps the DoD model, discussed earlier with its logistics capability, will supplement the CDC Twenty-First Century Pandemic Vaccine Distribution model to hasten citizen vaccination along with herd immunity. A recent CDC document targets jurisdiction operations and includes a worksheet template broken out by population group that can serve to quantify vaccine requirements by facility type.[37]

Today, the 2020 CDC schematic emerges as a blended-hybrid model, or a public-private partnership where centralized distribution is critical and replaces the labor-intensive distribution function inherent in the traditional public health model. Central distribution includes a warehousing function (or depots) where product is received, an inventory and data system, and a shipping and transport function. An additional essential component is cold-chain management.[38] The ability to monitor temperature fluctuation during transport and fluctuation beyond a narrow parameter can compromise vaccine efficacy. Finally, this system incorporates performance metrics to ensure private sector participants fulfill public-sector contract requirements.

Pandemic Vaccine Administration

The CDC has not published updated guidance regarding COVID-19 priority target groups, nor is it known how closely individual states will follow the CDC guidance when it is provided. However, a review of this summer's ACIP meeting agendas reveals that work is progressing on this front. The

health and protection of a state's citizens come under that state's policing powers as defined by the U.S. Constitution. Thus, a CDC recommendation is precisely that…a recommendation. States must either adopt those federal recommendations or elect to modify as they see fit for their citizens. This underscores the quagmire between federal jurisdiction and state jurisdiction during a public health emergency of national significance.[39] The nation's citizens experience that gulf daily with the lack of a national pandemic testing program.

The Administration has published guidance for its influenza vaccine Tier groups, but this guidance is based on an influenza pandemic and not a coronavirus pandemic. However, as published, the guidance states that vaccine administration will be administered by Tier groups or target populations according to the updated 2018 Interim Planning Pandemic Guidance.[40] Four broad categories are delineated. Within each category are Tier groups, vaccinated by tier assignment, depending on the availability of vaccine. For example, healthcare workers, first responders and public health are Tier 1 while the general population is Tier 4. Expect this guidance to be adjusted to accommodate vulnerable, high-risk groups in congregate living facilities such as nursing home and seniors with underlying conditions. Presently adults 65 and older are Tier 4 and this is a group that will see adjustment in terms of Tier status, pandemic severity and vulnerability. Healthy adults 19-64 roll in at Tier 5.

Regarding CDC and vaccine availability, the variety of vaccines currently distributed through the CDC numbers in the eighties with dose-specific formula by age groups. Doses are manufactured for children, adults, travelers and healthcare workers. There are also seasonal influenza vaccines manufactured to be dose specific, as well as vaccines for refugees and immigrants. Disease-specific vaccines also exist. It was in 2003 when CDC set about the task for merging what had become multiple vaccine management databases into a single system, funded as the VMBIP. Vaccine production, distribution, and management to keep Americans healthy and safe have become complex and yet that complexity is not fully understood by the American public. The COVID vaccination campaign is the beneficiary of decades of dedicated work.

Emergency Management and COVID-19 Vaccination Logistics

Emergency management can serve its community by subsuming the pandemic vaccination process in the context of an ICS framework while overseeing development of the campaign's logistics. In all likelihood, emergency management cannot control the contracting process through the bureaucratic public health, federal/private sector/state to local network, but clearly some entity needs to understand the extent to which its citizens are being served. Emergency managers recognize the massive scale required at the community level to address a localized public health emergency. Yet to be determined is the distribution network. Healthcare coalitions should become the community's phalanx for the COVID-19 mass vaccination campaign.

Equally, worthy of consideration is the use of allied health professionals to serve as vaccinators. The downside is that the bureaucratic quagmire of professional licensure and statutory and state regulations prohibits allied practitioners from needle sticks in arms. Consider for example

paramedics; local medical control must secure approval from state medical control in order for paramedics to be able to engage in vaccination. Once secured, this resource can be used in a county/municipality as either an open or closed point of distribution vaccination site. Or consider APhA, and its two-decade program to certify pharmacists as vaccinators; some states still require a physician's prescription to permit a certified-pharmacist to vaccinate.[41] An entire corps of vaccinators could be created if the maze of licensure constraints were lifted among medical professionals, pharmacists, phlebotomists, dentists, paramedics (EMTs) and even veterinarians, all of whom could serve as vaccinators. The question remains whether state emergency power laws are sufficiently robust to permit the use of allied health professionals in a pandemic when raised to the level of a catastrophic health event.

When viewed from this macro perspective, emergency managers can readily recognize the critical nature of the healthcare coalition to serve as a primary information-sharing tool during a pandemic especially as a vaccine becomes available. With all sectors of the healthcare industry integrated vertically from local to state and horizontally among healthcare facilities (hospitals, nursing homes, urgent care centers) as well as medical groups, chain pharmacies, state funded clinics (DoHs) and federal-funded sites (community health centers,) emergency managers may conclude that the coalition representation is incomplete and work to ensure all healthcare sectors with vaccination capabilities are engaged.

The PAHPA legislation in 2005 created healthcare coalitions to broaden the rationale for region-wide medical preparedness in the wake of Hurricane Katrina and the threat of pandemic. A report in 2009 by the Center for Biosecurity revealed that while hospitals were better prepared, regional capabilities had not improved but healthcare coalitions promise a foundation for healthcare system preparedness.[42] DHHS guidance has sought to ready coalitions for operational status throughout its service region. The limitation is that coalitions depend upon voluntary cooperation among healthcare facilities and public sector partners. Not all facilities participate and most have limited full-time staff. The Trust for America's Health (TFAH) revealed that only 89 percent of hospitals were in a coalition. TFAH breaks those percentages down by state.[43] Emergency managers are key members of the coalition and their knowledge of community resources is critical to an effective, broad-based, well-orchestrated COVID-19 campaign. Healthcare coalitions are not all equal with differences in configuration, leadership, operational capabilities and funding. The COVID-19 vaccination response requires the knowledge and skills of emergency management to ensure the entire community is effectively served.

Conclusion

This essay has outlined the logistics of pandemic vaccine distribution, and the current vulnerability to the COVID-19 requires immediate logistics planning. Meanwhile, the federal government must work at the policy level to align pandemic vaccine distribution guidance with the National Response Framework and the Incident Command System.

The scale of preparedness for the COVID-19 mass vaccination campaign cannot wait until vaccine is ready. To illustrate, consider the scale of the private sector flu model where it distributes an estimated 162 to 169 million doses annually. The U.S. population is an estimated 331 million and,

as of July 2020 the Trump administration has contracted for 600 million doses. This may indicate that vaccination will be a two-shot regimen.

As a result, emergency planners must consider the number of clinic sites a locality can muster, whether retail sector, medical practices including urgent care centers, community health centers or departments of health. In 2009, the CDC administered an estimated 100,000 contracts. The demand for COVID-19 vaccination could easily exceed that number.

The logistics of pandemic vaccination is three-fold: vaccine, venues and vaccinators and the responsibilities for both private sector and public sector differ, with each having a unique role to fill in this emergency public-private partnership. For example, the private sector must ensure compliance with CDC guidance and follow cold-chain management protocols to ensure vaccine viability as it arrives, is stored, and distributed. For the public sector, cold-chain management and CDC guidance (as adopted by the state) is standard practice, but the sector assumes responsibilities for the gaps in service distribution, reaching out to those who live in congregate living such as nursing homes, assisted living facilities, etc. It also fills the logistics gaps. A facility serves as venue and may have an on-site clinical staff, thus requiring vaccine and consultation services to complete logistical requirements. The public health sector also serves in a support role to private sector entities for consultation, vaccinator training, and pandemic protocol guidance.

COVID-19 vaccination clinics will incorporate not only traditional walk-through clinic sites at physician offices, pharmacies, public health departments and big box stores, but will also include college campuses, schools, churches, mobile sites (drive-through), community centers, and outdoor tents (parking lots) to name a few. The Centers for Disease Control and Prevention has published online a full range of guidance including a resource library for planning the administration of vaccine at local clinic sites and in concert with COVID-19 precautionary measures, much of which is currently pushed out through the CDC vaccine awardees.

Finally, the demand for vaccination will more than likely overwhelm available resources and require the marshaling of reserves to meet the demand. One only need to look at lines for the "optional" coronavirus test. To close, vaccination will be a protracted process. How long will it take to vaccinate 331 million Americans? In 2008, the DHHS goal was to vaccinate 300 Americans in six months! If healthcare resources are weary today, the vaccine is estimated to arrive 2020-21, and vaccination is projected to be a six-month project, then managers must plan for the various scenarios today.

About the Author

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