Chapter 7 – Pandemic Response: The Logistics of COVID-19 Mass Vaccination
Book title – Immigration, the Borderlands, and the Resilient Homeland: A Critical Reader

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INTRODUCTION

The twenty-first century has seen novel infectious diseases challenge the response of nations and their medical systems, which has required investments in preparedness to build resilience for the critical infrastructure of the healthcare sector. Despite these incremental investments, the COVID-19 Pandemic demonstrated how the best of intention among planners resulted in the nation's inability to respond with the resources at hand and raises the question "What will it take to build resilience when the nation is confronted with a pandemic that rises to the level of a public health emergency of national significance?"

In this discussion of building resilience, it should be asked "what does resilience to a pandemic look like?" The National Security Strategy of 2017 definition for resilience states:

> *Resilience includes the ability to withstand and recover rapidly from deliberate attacks, accidents, natural disasters, as well as unconventional stresses, shocks, and threats to our economy and democratic system.*

The operative word in the definition is *rapidly* and it is only in recent months of 2022 that recovery has begun. Thus, did the nation, states, local communities and families "withstand and recover rapidly" to the COVID-19 Pandemic? Trillions of U.S. dollars have been authorized by Congress to aid recovery for families, communities and states. An unemployment figure of 3.6% in April 2022 matches the February rate before the pandemic was declared March 2020, suggests the nation is well on its way to recovery. While numbers indicate recovery, yet to be assessed and less apparent is the loss of schooling for those under 18, the mental health effects of job loss, mask mandates, small-business lockdowns and related non-pharmaceutical interventions (NPI).

The HHS Office of ASPR (Assistant Secretary for Preparedness and Response) defines community resilience as "the sustained ability of communities to withstand, adapt to, and recover

from adversity." The Federal Emergency Management Agency (FEMA) narrows its definition of resilience and refers to hardening of infrastructure to known threats or hazards.

The Center for Emerging Infectious Diseases Policy & Research asked the world's leading public health experts "How does the nation build resilience for the next pandemic?" While the contributions were many, Syra Mada summed them up best "We must maintain a state of readiness and look at pandemic preparedness as an active and ongoing process – not an afterthought, not a static state, and not as a 'once-in-a-century' problem."[1] The variation in definitions reflects the perspective of the source but all imply that the culture of preparedness is the basis for resilience, whether it's a nation, state, community or family. The challenge becomes how to maintain a high-level of preparedness that can achieve resilience, when vaccination is the most effective mitigation strategy and requires a public-private partnership that integrates the federal response with state, local, tribal and territorial governments (SLTT).

In 2003, SARS broke out in the major cities of Canada and demonstrated the inadequacy of hospital preparedness. In 2009, the H1N1 Pandemic revealed that federal agencies responsible for building resilience in the healthcare sector had failed to build a twenty-first century logistics system for mass vaccination. While the 2012 MERS outbreak was limited to the Middle East, Ebola in 2014, originating in Africa challenged both the Centers for Disease Control and the few hospitals that treated Ebola patients. In January 2020, the world was confronted with a novel coronavirus for which there was no vaccine, therapeutics effectiveness unknown and personal protective equipment demands overwhelmed supply availability. It was also learned that critical medical-supply chains were offshore, vaccine manufacturing facilities were inadequate and the nation's citizens and healthcare workers were left unprotected. To thwart the pandemic emergency would require a substantial mass vaccination campaign, one of which a logistics-

driven distribution plan had failed to be constructed given years of federal funding for pandemic and public health preparedness. Until then, despite a twenty-first century, high-technology and social media driven communications global networks, the nation found itself falling back on the centuries-old disease fighting tools of public health, hand washing, social distancing, contact tracing, isolation, quarantine, travel restrictions and the controversial donning of face masks.[2]

There can be little argument that the COVID-19 pandemic 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 and hospital preparedness as well as public health preparedness to a tune of over $21.2 billion dollars since 2002.[3] The pandemic's sudden onset caught government officials off-guard, both state and federal, and the all-encompassing frenzy to "flatten the curve" watched as Operation Warp Speed (OWS) produced a vaccine in ten months as the essential mitigation strategy. But OWS did not stop with vaccine production but recognized the significance of distribution logistics. As a result, the Department of Defense was recruited with its logistics capabilities, along with the Federal Emergency Management Agency and its federal, state and local logistics linkages. A critical question, the answer of which suggests a lifeline to normalcy, "what logistics are and were required to support a COVID-19 mass vaccination campaign?"

The logistics of vaccination is three-fold, vaccine, venues and vaccinators. Vaccine management once shipped requires cold-chain management from manufacturer to the venue. Venues are those clinics sites that represent the partnership of both public and private sectors. Finally, establishing the vaccinator corps; where to find enough trained vaccinators to administer vaccine? Once all three resources are present, then vaccine administration takes place.

This chapter discusses COVID-19 the logistics of mass vaccination in the context of the National Response Framework (NRF) and the Incident Command System (ICS). 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. The analysis includes developments and programs implemented in the interim, or the inter-pandemic decade. Finally, it takes a historical look at the nation's pandemic vaccine policy and the mass vaccination distribution model, once the sole domain of public health that has evolved over the past twenty years into a public-private partnership (PPP).

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.[4] 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 June 11, 2009 but CDC's new system was not ready.[5] Most states had abandoned their vaccine warehousing function, which meant pandemic supplies had no state home, nor the climate control functions essential to protect vaccine viability. Not only that, but 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.[6] The Act was reauthorized in 2013 and most recently reauthorized as the Pandemic and All-Hazards Preparedness and Advancing Innovation Act in June 2019.[7] A core element of these reauthorization acts has been hospital preparedness in collaboration with healthcare coalitions, members of which included public health and emergency management.

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.[8] It was recognized that with no vaccine currently available to mitigate the highly transmissible COVID-19 coronavirus and its crippling effects, its immediate impact would be on hospital systems, as well as public health systems. To track those impacts, the collection of hospital data was critical to understanding its impact but data inconsistences constantly plagued COVID-19 response efforts with competing data gathering technologies.

During a Pandemic, the purpose for tracking hospital data is to assess the pandemic's severity and its impact on the healthcare system. However, while positives can be noted, shortcomings became much more prevalent and especially in the states on the ground with local healthcare providers. Take for example, hospital-census data; the HHS Protect system was intended to collect that data, but the snapshot it presented, conflicted with the snapshot presented by other (local) hospital data reporting systems. A Wisconsin physician and chief quality officer for the University of Wisconsin health system reported that "The HHS Protect numbers 'are not real."[9] HHS Protect replaced the CDC's hospital tracking system, National Healthcare Safety

Network (NHSN), a system that the Trump administration found lacking for real-time, valid data and shut it down in July 2020.[10] Much turmoil ensued and CDC insiders blamed the Trump administration for essentially benching the agency. The impression was that the CDC was consumed by the allocation scheme while the administration sought logistic plans for COVID-19 distribution. HHS officials' later claim that drastic improvements were made in data-collection consistency. However, conflicts arise when untested, complicated technologies are rolled out in the midst of a national emergency. It became apparent that the CDC promise of achieving "big data" use with the functional products from hospital data had yet to be realized.[11] Yet, other federal agencies had achieved forecast capabilities by the use of big data, such as the National Oceanic Atmospheric Administration as seen with hurricane forecasting models.

Emergency managers along the east coast know that tropical storms are identified weeks out and as their threat to the mainland intensifies, forecast models monitor the storm's track. 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 from "big data" to forecast disease case rates, hospitalization requirements as well as fatality rates given a $21.2 billion investment in pandemic/hospital and public health preparedness.

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)[12] 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."[13] A more recent 2020 analysis by the Harvard Kennedy School

Belfer Center[14] 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 and nearly overwhelmed (even after the Ebola threat in 2014) 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 recent as 2009 with the H1N1 pandemic. It remains the most-effective mitigation strategy for creating herd immunity. Operation Warp Speed (OWS) engaged pharmaceutical companies globally, and U.S. vaccination rates are well over 70 percent. But before discussing how OWS got us there, along with its successor, the Countermeasures Acceleration Group (CAG), the chapter will briefly review traditional distribution models, and twenty-first century pandemic policy. It looks at two studies that researched mass vaccination distribution from a national defense perspective as well as a homeland security perspective. The conclusions underscore the absence of a clear distribution model, one that encompasses the logistics function, and presents both the rationale and performance-based criteria that should be reflected in mass vaccination campaigns.

PANDEMIC PLANS & VACCINE DISTRIBUTION

The two studies, representing the perspectives of both national defense (military) and homeland security, breakout and 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.[15]

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[16] may present quite similar and perhaps additional logistical challenges, whether military or civilian, as conveyed in the 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.[17] 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 (temperature-controlled supply chain) 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.

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.[18] 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 literature found that too often vaccine administration conflates 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.

This analysis 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 System (ICS), and structures 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 (See Figure 1). Each side represents a process, vaccine production, vaccine distribution and the most frequently referenced process, vaccine administration. Vaccine production is best understood as the task of federal government agencies to include the National Institutes of Health (medical research), Federal Drug Administration (regulation)

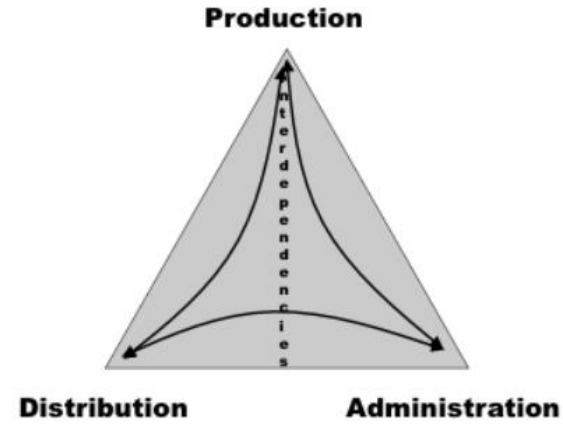

Figure 1. Mass Vaccination:
A Triangular Network of Interdependencies

and related-alphabet agencies such as BARDA or the (Biomedical Advanced Research & Development Authority) and private-sector pharmaceutical 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) that outlines Tier groups and priority groups, in itself a maze of complexity. But that poses a critical question with limited supplies: Who gets it first?[19] 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 distribution 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 becomes a critical link between manufacturers and dispensing sites. Its apparatus consists of the "how vaccine is distributed" (technology-process strategies), "where vaccine is distributed" (venues), and "by whom" (vaccinators).[20] The distribution matrix is straightforward. Applying the H1N1 centralized-distribution scenario to COVID, and the incorporation and use of technology, manufactured vaccine moves from five manufacturers to one contractor, four warehouse depots and then is dispersed to well over COVID-19 100,000 venues, probably approximating a million if one considers the mix of pharmacies, grocery stores, and big-box retail centers. The complexity comes into play with the federal to local logistics as government partners with the *retail* private sector for its mass distribution capabilities.

The 2019 Crimson Contagion Functional Exercise

This study would be remiss if it did not elude to the 2019 HHS-ASPR Crimson Contagion 2019 Functional Exercise and its results that influenced the Trump Administration's approach to the COVID-19 Pandemic in January 2020.[21] The functional exercise titled *Crimson Contagion* was conducted over a period of time with 19 federal agencies, 12 states (both public health and emergency management departments participated), the City of Chicago, 74 public health districts, 87 hospitals along with a number of nongovernmental and private sector organizations. The exercise scenario simulated an H7N9 influenza virus, which created 110 million illnesses, 7.7 million hospitalizations and 586,000 deaths. Key findings of the After-Action Report (AAR) were structured into one of six groups and included, statutory authorities and funding, planning, operational coordination, situational assessment resources, public information and risk communications. Given the timeframe between the exercise and onset of the pandemic and government's inability to turn on a dime, it is unrealistic to expect AAR items to be fully implemented prior to declaration of the COVID-19 Pandemic. However, findings did provide insights into the limitations of statuary authorities, HHS guidance and planning and provided a rationale for operational considerations in 2020. Shortfalls of the COVID-19 response described in this chapter, are identified in the AAR Draft report. Rather than belabor those points, the focus in this work is COVID-19 and the logistics of the vaccination campaign.

MASS VACCINATION MODEL ANALYSIS

To familiarize readers with the history of vaccine distribution, two prominent models show the evolutionary nature of mass vaccination defined as the Public Health Model and the Private Sector Model. The homeland security study used a subject matter expert panel and engaged the panel in a three-step process to identify model-evaluation criteria. The Delphi research method was used to conduct policy analysis of the two models.[22] Criteria were 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.

All panel members 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. The brief discussion of the two models provides context for understanding the COVID hybrid pandemic vaccination model and helps to tease out crucial variables that are merged into the COVID-19 pandemic vaccine distribution model.

THE PUBLIC HEALTH MODEL

The public health model (PHM) is a twentieth century *emergency-based mass vaccination model*, and the documented strategy for mass vaccination when a public health emergency is declared. The guidance dictated federal policy for mass vaccination, which 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 administering to the public. It required a logistics functions, manpower and facilities, such as warehousing that were no longer in place for day-to-day functions in most states.

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.[23] 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 reports the 2016 survey data; local departments numbered 2,795 while regional or district offices increased to 312 offices.[24]

The Delphi panel evaluated the public health model, concluding that it was dated, and no longer reflected the realities of the twenty-first century.[25] 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, compared to the number of local health departments (venues) in 2010 there were 2,790 sites while 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.[26] The CDC expanded its contract with McKesson Specialty Care Solutions to use its centralized distribution for vaccine distribution, supplementing the logistics distribution function with its retail healthcare capabilities to augment 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 a *non-emergency, distribution model*, driven by profit; vaccine is manufactured and sold to wholesalers and distributors who sell to frontline providers, both medical and retail. Manufacturers provide annually, an estimated 162 to 169 million doses of influenza vaccine for the U.S. market. Public Health manages, perhaps only 10 percent of that volume.[27] 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.[28] 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.[29] A 2017 *NCPA Digest* (National Community Pharmacists Association) numbered 22,041 pharmacies located throughout the nation in rural and isolated locations.[30] 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.[31] These retail outlets form the basis for a de-centralized community-based, emergency-

vaccine distribution network. The 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.[32] 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 lacked 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 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, such as the underserved, at-risk gaps and the most vulnerable to ensure all Americans are served.

As noted in the Private Sector Model, the government, SLTTs, accounts for less than 10 percent of seasonal flu vaccine purchase and administration. Physicians, medical groups as well, as 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

One only need look to COVID-19 and the frenzied confusion that persisted with the initial response if we are curious about an established, tested and documented U.S. pandemic policy for public health emergencies of national significance. 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 missed their mark. 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.[33] Though this was the published doctrine, the goal was insurmountable given the guidance, technology and resources. At the time, planners went through all sorts of mathematical computations to bring plans, including medical surge plans, into compliance yet this approach required vaccinator

manpower and clinic sites not suggested in that guidance. The question remains "has the revised distribution strategy been updated, guidance provided and readied to accomplish this goal?"

In 2008, the HHS plan lists 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.[34]

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."[35]

The 2017 Interim Guidance adds that an overarching *aim* for a national pandemic vaccination campaign is clear "to vaccinate all persons in the United States (U.S.) who choose to be vaccinated, prior to the peak of disease." The revised goal drifted from the specificity offered in the 2008 guidance declaring 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 NRF NIMS/ICS framework.

The homeland security study with its Delphi Panel concluded 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.[36] 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. In this model, 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. This recommendation remained a gap in preparedness from 2009 to January 2020 when COVID-19 struck the U.S.

This analysis describes a pandemic policy framework listing six goals to establish 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.[37] 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 model emergency vaccination after the annual flu campaign to encourage the public’s acceptance of and accessibility to vaccination (integration). The analysis underscores the latter as a critical factor, that *emergency* vaccination 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 that 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

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

Both models, that of the public sector, a government driven model and that of the private sector, a 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. Yet, COVID-19 presented a new challenge to not only public-private partnerships but one that would require a whole-of-government approach.[38]

The Trump administration concluded that the 2008 goals were not achievable nor did updated guidance provide a rationale that would meet COVID-19 challenges. The result was the creation of Operation Warp Speed (OWS) and a plan to *accelerate* development and distribution of COVID-19 vaccine through a partnership that coupled the Department of Health and Human Services (HHS) with the Department of Defense (DOD).[39] The administration looked to the DOD for its known logistics capabilities accompanied by FEMA's state and local logistics capabilities. The federal partnership teamed the science expertise of HHS with the military's expertise of logistics in a unity of effort that would yield the essentials for Pandemic response. Operation Warp Speed was launched May 2020 with a goal to produce 300 million doses of COVID-19 vaccines, with initial doses available by January 2021.

Not to be discounted is that the COVID-19 Pandemic response, in relation to vaccine development and distribution built on successes from the 2009 H1N1 Pandemic. These include CDC's VtrckS, or the Vaccine Tracking System, centralized distribution using McKesson and Biomedical Advanced Research and Development Authority's (BARDA) emergency authorization to procure the necessary biomedical supplies. An additional H1N1 lesson formed the basis for COVID vaccine allocation; H1N1 allocations tested the nation's ability to distribute and administer limited supplies of vaccines to prioritized groups and, using CDCs social vulnerability index, expanded CDCs ability to reach the most remote and vulnerable citizens.[40] Operation Warp Speed thus provided an overarching strategic vision for the nationwide mass vaccination campaign and incorporated huge logistics capabilities.

At its one-year anniversary (Operation Warp Speed), *USA Today* wrote that, OWS is considered the most successful public-private partnership since World War II.[41] Apparently, the new administration did not come to the same conclusion. On January 20, 2021, with the transition of administrations, President Biden dropped the OWS reference and adopted Countermeasures Acceleration Group, (CAG) to describe the continuous, national vaccination campaign.[42] By May, CAG became the HHS-DOD COVID-19 Countermeasures Acceleration Group and by December 31, 2021, CAG management transitioned from DOD to HHS.[43] Perhaps the most transparent, non-partisan and comprehensive analysis comes from the Government Accountability Office (GAO) dashboard where the many facets of OWS are explored and presented.[44] It even includes a comparison of H1N1 to COVID-19 of the various phases of mass vaccination and how lessons learned carried forward to COVID-19 response.

A brief note about vaccine production before discussing the efforts of OWS to put logistics capabilities on steroids. The Government Accountability Office (GAO) in an analysis of

Operation Warp Speed, graphically depicted the timeline for the traditional vaccine development versus that of OWS, which accelerated the process from approximately ten years to ten months.[45] However, the manufacturing process was not without challenges in a Pandemic environment.

A review of vaccine production reveals that cell-based technologies encouraged the pharmaceutical sector to establish U.S. based facilities. However, the accelerated timeline set by OWS underscored the reality that there remained a shortage and a limited production capacity of facilities. With the help of BARDA and the U.S. Army Corps of Engineers, existing facilities expanded to meet the OWS goal.[46] Also, global demands contributed to disruptions of supply chain-dependent materials, such as reagents and certain chemicals. Finally, gaps in the available workforce persisted. The OWS worked with the Department of State to expedite visa approvals for key technical personnel; OWS requested that 16 DOD personnel serve as quality control at two U.S. vaccine manufacturing sites until the manufacturers could hire the personnel.[47]

Thus, technology and facility limitations identified prior to the 2009 H1N1 Pandemic, were addressed by the private sector during the inter-Pandemic period. Vaccine manufacturing facility limitations were known in 2008 before the H1N1 Pandemic when a Congressional Budget Office (CBO) report called for both expanding production capacity and developing cell-based technologies to replace the chicken-egg based process.[48] The CBO report concluded that vaccine production self-sufficiency was not probable as long as the nation was dependent on offshore vaccine production. In 2009 of the five vaccine U.S. licensed suppliers, only one, had a U.S. based facility. By 2020, four pharmaceuticals had established U.S. based capabilities. What remained dormant from 2009 and, actually regressed, was the public sector ability to surge the logistics function for distribution when the Pandemic Severity Index (PSI) was high. The COVID-19 fatality count (900,000 – 1,800,000) sets the PSI at a level 4, where the range is 1-

(least severe) to Level 5 – most severe. By the first week of May 2022, the CDC reported over a million COVID-related deaths (1,002,242) on death certificates.[49]

PANDEMIC VACCINE DISTRIBUTION

In April 2020, CDC published a two-page schematic overview (Figure 2) 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.[50] It reveals a distribution model based not only on seasonal vaccine distribution but those vaccines used in immunization programs throughout the country. It expands the CDC public-sector centralized distribution

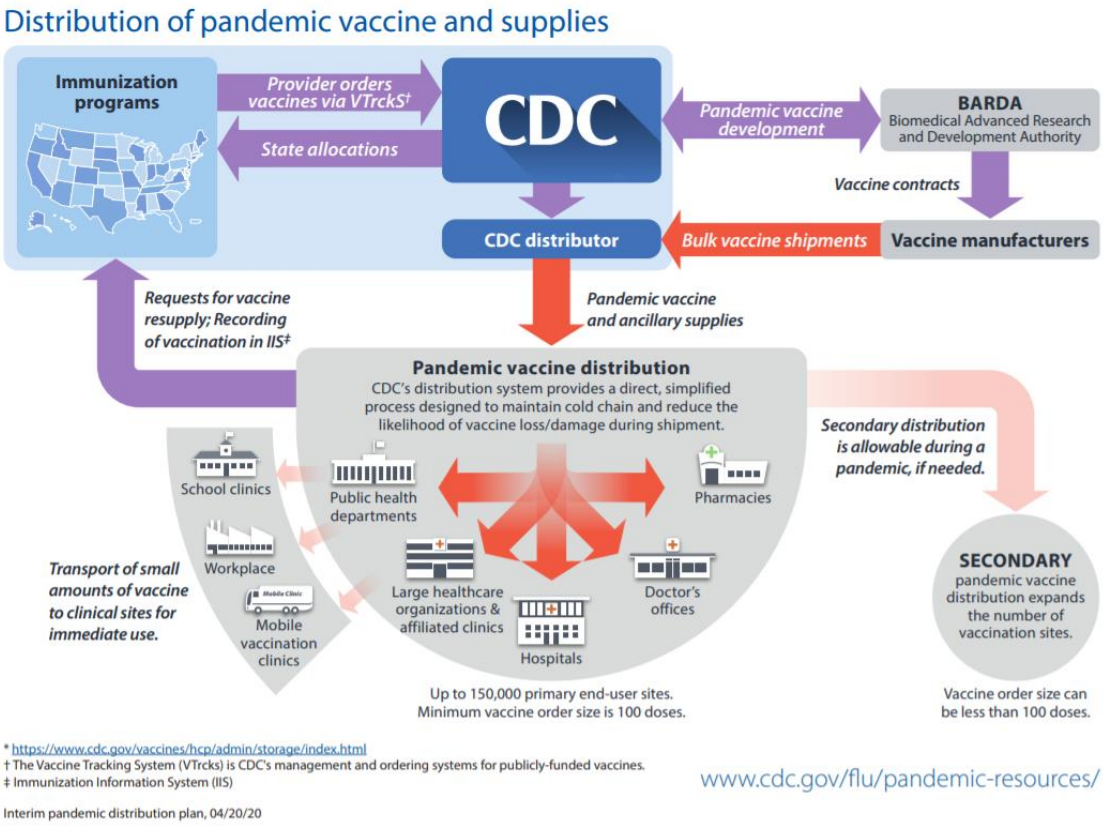

Figure 2. CDC Pandemic Vaccine & Supply Distribution

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 study's Delphi Panel's six-goal policy framework and offers metrics that can evaluate the CDC *conceptual* model.[51] It suggests an approach that incorporates criteria that frame an executable distribution plan. Those executable criteria in the Delphi framework include scalability, client-centered, provider-centered, federal guidance 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 whether 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) as well 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, fully rolled out 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.[52] However, the system at that point 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.[53]

Roll forward to the 2020 COVID-19 Pandemic. Operation Warp Speed was intended to not only expedite the production of vaccine but also oversee its distribution to the states, where allocation to local venues would remain with state authorities. The Trump administration approached the national emergency with a view that the then current pandemic response structure was inadequate for the expected demands whether vaccine production and dose volume or its distribution. U.S. Army General Gustave Perna who had served as Commanding General over the U.S. Army Material Command (logistics) was appointed as the Chief Operating Officer over Operation Warp Speed July 2020. A nationwide strategy for vaccine distribution logistics was then developed in cooperation with federal agencies (HHS/CDC and DHS/FEMA) and public sector partners such as McKesson for vaccine and related supplies, as well as FedEx and UPS for secure transport of vaccine.[54] Planning took into account various projections to include vaccine dose production schedules, state vaccine allocations, supplemental supplies, timeframes and available resources to secure, ship and meet the requirements. Reflecting the whole-of-government approach, a Pentagon spokesman stated "The Department of Defense has been clear in its role in Operation Warp Speed: We are providing the bandwidth of logistical expertise, including program management and contracting proficiency to this all-of-America effort. The development and delivery of over 300 million vaccine doses harnesses public-private partnerships, academia, and industry – no one entity can do this alone."[55]

The requirements and demands of the COVID vaccine campaign were described as Herculean by U.S. Army Lt. General Paul Ostrowski who was OWS's director of supply, production and distribution. Talking to medical officials and reported by MedPage, Ostrowski's

descriptive remarks frame the effort by the whole-of-government approach, federal, state, local and private sector partners.

> *The distribution of potentially six COVID-19 vaccines in the midst of a pandemic is a "Herculean task," said Ostrowski, and one that HHS lacks the personnel to manage on its own. The DOD's role in Operation Warp Speed will be to provide "the bandwidth and the enablers."*[56]

While OWS tapped DOD for its logistics capability, new software had to be developed to manage vaccine distribution and track dose administration. Palantir Technologies, Inc., a data-mining company, got the contract to build the distribution software that could track vaccine delivery by location, cold-chain management, or vaccine temperature during transport and at time of arrival. The software system was titled Tiberius, a name familiar to Trekkies… the middle name of Star Trek Captain James T. Kirk's! Of course, Gen X would claim Palantir follows as the "Lord of the Rings" reference! Palantir had worked with several federal agencies including HHS and its hospital data collection system, HHS Protect.

Palantir is considered one of the world's biggest surveillance companies and slammed by human rights groups for its exploit of sensitive data. The system, Tiberius, builds on the work the DOD used to track down Osama bin Laden and currently used to track undocumented immigrants by authorities. Initially, the Tiberius software was used for tracking COVID hospitalizations through HHS Protect as well as other demographic data. Later, data was used to identify demographic groups where there persisted gaps in vaccination rates, and used to target underserved populations to ensure vaccine equity.

Tiberius provides planners with data dashboards that tells them about vaccine production and its distribution to the states, essentially describing how many vaccine doses are produced, how many can be shipped and where are they headed. According to Palantir Technologies executive, Alexander Karp, the problem with the U.S. system compared to the U.K. (a

centralized healthcare system), is that with America's decentralized healthcare system, Tiberius reports the number of vaccine doses delivered to the state but does not tell us the actual doses that gets into arms.[57] Creating a national snapshot of local allocation, is compounded by fifty states and the various infrastructures used to administer vaccinations. This is borne out by the number of states that dropped federal vaccine management systems and created or upgraded their systems to manage vaccine ordering, distribution and interface with priority groups.[58]

While the Tiberius software provides additional capability for planners, the downside is its complexity. It came at a time when the healthcare workforce was consumed by the COVID-19 testing program, with limited time for training on a new system. Tiberius had a rocky deployment and exposed a lack of understanding of the U.S. public health system. According to Dr. Julie Swann, a professor at North Carolina State University who worked with the CDC on the H1N1 response, "Public Health – underfunded, understaffed and struggling amid a pandemic – could not be expected to adopt a new technology within weeks of its announcement."[59]

The rationale for Operation Warp Speed, when first announced, was the HHS collaboration with DOD to assist with "faster distribution and administration than would have otherwise been possible using wholly private medical infrastructure distribution" of vaccine to millions of Americans."[60] The scale of response required was such that the DOD model discussed earlier with its enhanced cold-chain logistics capability, may well have served as a primer to supplement the CDC Twenty-First Century Pandemic Vaccine Distribution model and hasten citizen vaccination. An October 2020 CDC planning document, intended for local jurisdiction operations, includes a worksheet template broken out by target groups and quantifies vaccine requirements by facility type.[61]

Noted earlier, an additional critical supply that required considerable attention was dry ice to maintain vaccine temperatures and ensure cold-chain management from manufacturer to shippers and arriving at venues with vaccine not compromised. The challenge of cold-chain management for shippers, their storage and shipping containers was and is to meet the COVID vaccine-maintenance requirements.[62] Temperature fluctuations during transport compromise vaccine efficacy. Thus, monitoring systems incorporated performance metrics to ensure private sector participants fulfilled public-sector contract requirements.

This analysis has shown that the COVID-19 distribution system built on the CDCs H1N1 response, while expanding to accommodate anxious-vaccination demands. The strategic federal distribution plan called for additional assets to meet OWS goals. McKesson's contract with CDC for child vaccine distribution included the option to distribute Pandemic vaccine. Thus, it was awarded the COVID-19 contract. Operation Warp Speed tapped the military for developing the logistics planning strategy, to include the security arrangements for all shipping containers. Despite this progress, a January 28, 2121 GAO study reported: "We remain deeply troubled by the lack of sufficient federal action on critical gaps identified and by the lack of clear plans to address these gaps. For example, a clear and comprehensive vaccine distribution plan remains a work in progress."[63] Initial federal logistic plans were intended to distribute vaccine to the states, where state plans would link distribution allocations according to priority needs. State plans have existed for the past two decades but reflect the attrition of public health resources to effectively execute those plans.[64]

EMERGENCY MANAGEMENT & COVID-19 LOGISTICS

It does not seem that long ago (2009 – H1N1 Pandemic) when mass vaccination clinics were the sole domain of public health. The steady erosion of the public health workforce along

with new missions that provided limited resources resulted in a critical infrastructure unable to meet the demands for a robust, COVID-19 Pandemic response. As a result, new partnerships were formed, not only between public and private but equally among federal government agencies. As previously discussed not only were the Department of Defense capabilities tapped, but equally, the Department of Homeland Security and, especially, the Federal Emergency Management Agency. Even emergency management prepared public health practitioners recognized that county and municipality emergency managers would be needed to meet surge requirements for the COVID-19 vaccination campaign.[65]

The HHS Secretary declared a national public health emergency January 31, 2020 and by March 19, 2020, President Trump declared a national emergency, thus activating the Federal Emergency Management Agency (FEMA). While HHS initially was the lead federal agency (LFA), with the activation of the Stafford Act, FEMA subsumed LFA and tasked with coordinating the federal response, established the Unified Command Group (UCG) and followed the methodology of its traditional response role – locally executed, state managed, and federally supported.[66] The impact on hospital capacity had surged and the immediate need called for FEMA to scour supply chains and locate ventilators and personal protective equipment. Soon to follow, its role would expand to assist with the nationwide vaccination campaign.

As of January 2021, FEMA, in cooperation with and local emergency management agencies, had stood up 440 mass community vaccination centers (CVC) that administered 61,000 shots per day, providing personnel, supplies and funding.[67] Once the vaccination center assets were deployed, states assumed management of the CVC, per a CDC vaccination program provider agreement. The agreement between FEMA, CDC and the state, ensured the vaccine allocation was sufficient to address the throughput targets.

To achieve these accomplishments, FEMA used its typing system to establish five types of community vaccination centers based upon the desired vaccination throughput target, or vaccinations per day.[68] Centers' throughput ranged from 6,000 a day (Type 1) to 250 a day (Type 4). A Type 5 was added as a mobile center that could administer 250 vaccinations a day. Additional Types set up included a Type 2 (3,000 a day), and Type 3 (500). Typically, the Type 1 vaccination centers were in huge venues (stadiums) with large capacities and wrap-around amenities. The agency uses the typing system to label all of its emergency response assets (facilities, equipment, personnel and related supplies) that are deployed to communities when disasters strike, whether its hurricanes, tornadoes, or flooding to include mass casualty and mass fatality. The intent is that *state and local* emergency managers know what response assets to expect, designed to match the disaster situation. The CVCs supplemented other FEMA, HHS or state assets that included mobile-vaccination units (MVU), Federal Medical Stations, Large-Format Alternate Care Sites and federal medical staff.

Once established, states could request a FEMA center, a state-led CVC, which supplemented the federally-managed FEMA centers. Site selection, or "pilot sites" for the federally-managed FEMA CVCs were determined on the basis of Social Vulnerability Index (SVI) as opposed to the state-led CVCs based on existing capabilities and location feasibility.

Federally-managed centers incorporated CDC's SVI to ensure that vaccine equity was merged into the selection of vaccination sites; essentially SVI was a "booster" to the vaccination campaign. The CDC's SVI uses a mix of demographics and economic data to identify, low income, poverty crowded housing, and lack of access to transportation, thus vulnerable to emergency situations that could result in community disasters. Public health authorities recognized to impact the spread of COVID-19, as well as overcome the Pandemic, labor-

intensive efforts must be made to reach the most vulnerable populations to include remote, rural and urban centers to address communities characterized with health inequities. To ensure the achievement of vaccination equity, the Biden administration stood up a COVID-19 Health Equity Task Force to ensure vulnerable populations were deliberately targeted for vaccination.[69] Tiberius software identified underserved, unvaccinated demographic groups, while SVI located vulnerable communities. The data overlays then, became the basis for the equitable distribution of vaccine, to underserved populations, high-priority, the elderly and others at high-risk to include immuno-compromised groups.

This process ensured the unity of effort among the federal agency members represented. Simultaneously, FEMA assimilated the pandemic vaccination campaign in the context of an ICS framework while synchronizing the logistics function. Emergency managers recognized the massive scale required at the community level to implement vaccine equity policies and effectively coordinated resources to address local, public health needs. The federal agencies recognized that the COVID-19 Pandemic, unless severely and quickly mitigated, could result in a cascading catastrophe for the nation.

As noted earlier, a major factor in a vaccination campaign is vaccinators, and where to draw from a pool of eligible healthcare workers to surge personnel for staffing CVCs. FEMA drew from not only its own personnel, but from National Guard units as well as U.S. Coast Guard reservists. The PREP Act, (Public Readiness and Emergency Preparedness) provided immunity from liability for non-traditional, allied health professionals serving as vaccinators.

The PREP Act, coupled with state emergency power laws, lifted licensure constraints to permit the use of allied health professionals and augment the vaccinator corps. State emergency powers relax the quagmire of professional licensure, statutory and state regulations that prevent

allied practitioners from needle sticks in arms in the *non-emergency* state of operations. For example paramedics; local medical control secured approval from state medical control for the purpose of vaccination. Once secured this resource was 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 (including pharm techs and interns); some states still required a physician's prescription to permit a certified-pharmacist to vaccinate.[70] Restrictions of this nature, had to be reconciled at the state level to permit the use of allied health professionals. As a result, the vaccinator corps was supplemented by an entire novel corps of vaccinators as licensure constraints were lifted from among medical professionals, phlebotomists, dentists, paramedics (EMTs) and even veterinarians.

When viewed from this macro perspective, emergency managers as members of healthcare coalitions, can readily recognize the critical nature of the coalition to serve as a primary information-sharing tool (local medical intelligence) during a pandemic and especially as the vaccine supply increases. 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), healthcare coalitions become the community's phalanx for executing the COVID-19 mass vaccination campaign.

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.[71] 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 be each state.[72] Emergency managers are key members of the coalition and their knowledge of community resources are 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. Thus, the COVID-19 vaccination response requires the knowledge and skills of emergency management to ensure the entire community is effectively served.

PANDEMIC VACCINE ADMINISTRATION

The Food and Drug Administration first granted emergency use authorization[73] (EUA) to the Pfizer-BioNtech vaccine December 10, 2020. Food and Drug Administration EUAs soon followed for the Moderna vaccine (December 17, 2020) and then Johnson & Johnson (February 27, 2021). Mass vaccinations began December 14, 2020 for selected priority groups, hospital workers and nursing home personnel. President Joe Biden took office January 20, 2021 and immediately set a goal of 100,000 vaccinations within the first 100 days (would be completed by April 26, 2021. The goal was surpassed March 19, 2021 and reset to 200 million doses in the first 100 days. April 22, 2021 the administration announced the nation had reach this goal. Despite the politics that surrounded the Pandemic, an issue in the Presidential campaign, Congressional funding differences and even vaccine hesitancy, the fact remains that vaccine administration goals were met and exceeded due to a unity of effort of federal agencies, state and governmental sources along with the private sector.

As of April 5, 2022, 217,882,466 citizens were fully vaccinated or 65.6 percent. Those 18 years of age and older, 75.5% are fully vaccinated while 65 years of age and older, 89.2% are fully vaccinated.[74] From a different perspective, 562,435,301 vaccine doses have been administered since mid-December 2020, or in 16 months, 562.4 million doses went into arms.

Pharmacies became a primary, critical and accessible pandemic response asset with most citizens (90%) living within five miles of a pharmacy. The history and role of pharmacies in mass vaccination campaigns was discussed earlier yet, for the COVID-19 vaccination campaign, recruitment expanded from the initial OWS Federal Retail Pharmacy Program (FRPP) to the Biden CAG-FRPP initiative, resulting in over 235 million doses administered through 21 pharmacy partners' retail stores with more than 41,000 locations nationwide.[75] The FRPP began with Phase 1; with limited supplies, 6,500 select pharmacies received dose allocation from state allocations and administered to priority groups, residents of nursing homes and long-term care facilities. The CAG enrolled additional pharmacies, expanding the network from the initial 6,500-17,000 to 41,000, with Phase 2 as supplies increased. The expansion opened up vaccination to the general population but also targeted the underserved, rural groups using the CDC's SVI. This came at a time when traditional healthcare providers were shut-down, pharmacies remained opened, caring for patients.[76] The effect was to throttle up the vaccination rollout, ensure vaccine equity and progress toward the goal of herd immunity.

The significance of logistics becomes apparent when the distribution timeframe from EUA to priority groups for vaccination occurred within days. However, allocation schemes for priority groups with changing guidance remained a challenge for state and local planners. The fact remains, as seen with H1N1, that states "get bogged down in the silos of priority groups."[77]

Public sector partners look to guidance to finalize venue vaccination plans that incorporate dose administrations, staffing requirements, and ensuring ancillary supplies match the target group size. One such model the Centers for Disease Control and Prevention (CDC) incorporated used various data sets, both demographics and epidemiological, and optimized a vaccine allocation strategy that concludes with the location of mass vaccination sites to the most vulnerable communities, thus guiding the allocation of vaccines. Authors report that this optimization is significant, saving an extra 20% of lives while eliminating pockets of COVID-19 transmission. [78] These efforts show, once again the unity of effort among federal agencies and how the DELPHI-V-OPT model was used to carry out the DHS mission to fully support access to COVID-19 vaccine allocation and distribution sites for underserved and rural communities as well as undocumented immigrants.[79]

Prior to the DELPHI-V-OPT model's emergence as a reliable methodology for vaccine allocation, venue selection was rather an ad hoc process, supplementing private sectors locations with public-sector run vaccination clinics. While states elect whether to follow CDC guidance and given the timing of the DELPHI-V-OPT model's effectiveness, states along with local health authorities, had already planned most vaccination venues that required Memorandum of Agreements, logistics support, as well as vaccinators. The DELPHI-V-OPT model came mid-Pandemic but demonstrated its utility to identify high-risk areas and locate vaccination clinics. For example, in rural areas, it was not uncommon to see a church bus, partnered with a vaccination "strike-team" consisting of nurses and administrative support personnel. Summarizing the contributions of the DELPHI-V-OPT model, the author's conclusion underscore the critical nature of distribution:

> *Whereas these limitations undoubtedly motivate further research, this paper lays one of the first data-driven bricks on the optimal distribution of COVID-19 vaccines at a*

macroscopic level. At a time where vaccine development and vaccine production are going full speed, the results from this paper highlight the critical role of vaccine distribution strategies to combat the pandemic.

States can elect to adopt federal guidance or modify as they see fit for their citizens. All of which underscores the quagmire between federal jurisdiction and state jurisdiction during a public health emergency of national significance.[80] The nation's citizens experienced that daily at the outset of the Pandemic when the lack of a national pandemic testing program, coupled with no FDA approved COVID-19 tests, caused anxiety, confusion and frustration.

Extensive guidance is published for the coronavirus pandemic by CDC, five pages with details for all the target populations. Guidance, based on H1N1, states vaccine administration will be dispensed by one of five Tier groups or target populations according to 2018 Interim Planning Pandemic Guidance[81] and updated for COVID-19.[82] Five 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 5. Guidance is adjusted to accommodate vulnerable, high-risk groups in congregate living facilities such as nursing home and seniors with underlying conditions. Adults 65 and older are Tier 4 and a group that will see adjustment in terms of Tier status, pandemic severity and vulnerability. Healthy adults 19-64 roll in at Tier 5.

The lack of pandemic preparedness, despite the enormous multi-agency response, public-private partnership, reveals the vulnerabilities that collectively stymied the nation's response to achieve resilience. The challenges of mass vaccination logistics is but one aspect of resilience discussed throughout the chapter. The technical challenges remain as states turned back to their own systems when they concluded the national systems, rolled out in the midst of a crisis, were too complex and not providing the data that match the data of their own systems. The GAO

described the challenge when it reported that when 40 million doses were distributed through the centralized distribution network to the states and local venues, only 11.1 million of those doses went into arms. The problem described by Open Access Government, was that public health had abandoned mass vaccination clinics, due to either resource limitations (staffers) or consumed by the COVID-19 testing program.[83] All vaccination models were based on one dose, while COVID-19 vaccination is a two-dose regimen and, for some a booster shot! None of which was anticipated prior to January 2020. During the same time period of these reports, Governor's complained that the allocations received were less than those estimated, thus disrupting plans for the state vaccination campaign. Then there are those that point to the registration/appointment systems consumers used to get a shot. Only nine states reported using CDC's $44 million VAMS (Vaccine Administration Management System) while other states used their own systems or developed systems that would integrate with existing vaccination systems.[84]

Yet, the COVID vaccination campaign is the beneficiary of decades of dedicated work. 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. Then there are the seasonal influenza vaccines, manufactured 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 has become complex and yet that complexity is not fully understood by the American public. CDC's experience with vaccine development and administration is extensive and should not be discounted in a pandemic.

CONCLUSION

This chapter has outlined the evolution of an *emergency-administered* vaccination campaign and described its transition from a public sector driven model to a public-private partnership driven model. As well, it has shown the quagmire of logistics for pandemic vaccine distribution and the vulnerability from COVID-19 required a huge lift for real-time logistics planning. Three distinct mass vaccination campaigns were used to reflect the evolutionary nature of mass vaccination, from the mid-twentieth century (polio and smallpox) where the public sector was the sole source, to the 2009 H1N1 when the public-private partnership was established for the current mass vaccination model, COVID-19, where necessity to address pandemic severity required a whole-of-government approach in cooperation with the mass capabilities of the private sector. It has also shown how the concerns of the public sector for vaccine equitable distribution has evolved throughout the twentieth-first century using new technologies and models that can target vulnerable population groups, as well as those difficult to access by a solely private-sector model.

The COVID-19 Pandemic strained the nation's resources beyond the healthcare sector, its workforce and the vaccine manufacturers, venues and vaccinators needed for response. Supply-chain issues, limited personal protective equipment, the absence of an established testing program at the onset of the pandemic, and not to omit, controversial, non-pharmaceutical interventions (NPI), politically-laden protocols and mandates, all of which required tremendous efforts to surge response capacity. A long-time public health tool, contact tracing, virtually unknown outside of public health, became a household name after January 1, 2020 as an NPI method to track the spread of COVID, coupled with isolation and quarantine measures. Equally noteworthy is that federalism played out in the courts as states took the White House to court

over state's rights while statutory authority for lead agency lacked clarity between HHS, FEMA and Department of Homeland Security.[85] The public's response; vaccine hesitancy and apprehensiveness of whose science to follow! Given twenty years of pandemic planning, is it not a surprise when citizens ask "Why were we not ready?"

The chapter began by arguing that resilience for pandemic response in the twenty-first century has seen novel infectious diseases challenge the response of nations and their medical systems, and has required investments in preparedness to build resilience for the critical infrastructure of the healthcare sector. The Department of Health and Human Services (HHS) has been under fire by the GAO for its lack of implementing GAO recommendations. In January 2022, GAO reported HHS has had "persistent deficiencies in its ability to perform this role, the role of preparing and responding to public health emergencies,"[86] adding that HHS deficiencies "have hindered the nation's response to the current COVID-19 pandemic."[87] As a result, the GAO designated HHS as *high-risk,* or a federal program needing transformation. One could conclude that the nation has yet to achieve resilience against biological threats when recognizing that new methodologies and technologies were introduced in the midst of a pandemic in an attempt to abate, what could have been, an existential catastrophe.[88] The CRS points out that once a disaster declaration is made and FEMA activates its Disaster Relief Fund, the cost for disaster assistance for the COVID-19 Pandemic categorizes it as a catastrophic incident.[89]

Earlier it was discussed that the private sector leveraged cell-based technologies to shorten the timeframe for producing new vaccines that mitigated the current bio-threat; followed by onshore production facilities that produced essential life-saving vaccines. The analysis also showed mass vaccination, once the domain of public health, had to be augmented to meet vaccination distribution requirements. The literature is strewn with citations regarding an

underfunded, understaffed public health system, both state and federal, unable to mount a mass vaccination campaign.[90] Federal funding programs keep public health missions on life support but frankly, failed to build resilience as shown throughout this analysis. Constitutionally, states are responsible for the police powers and protection of its citizens, including healthcare. The question needs to be addressed "When will states sufficiently fund their public health systems and build the necessary resilience for pandemic response?" Too many states were not prepared to administer "shots in arms" when distribution allocations were being delivered to states. Reasons are many but pending guidance for allocation schemes could well have contributed to these nagging issues of local preparedness. The Congressional Research Service comes to a similar conclusion suggesting "states and localities should assume more responsibility for funding their preparedness, and that the federal government should reduce its investment," adding that Congress assess the policy for funding two separate agencies for preparedness capabilities and synchronize preparedness with the lead federal agency for pandemic response.[91]

Federal funding is stop-gap funding. Anthony Downs explored this issue in 1972 with his "Issue-Attention Cycle" that "shed doubt on long-term federal funding for social conditions, when he turned his attention to ecology and the American public's limited ability to focus on more than one social issue."[92] In essence Downs theorizes that as public interest wanes for a particular social issue, the political environment responds with not only a declining level of interest, but that the funding levels diminish as well over time. As recently as February 2022, AMA President Gerald Harmon stated "State public health spending has dropped 16% over the last decade, resulting in the loss of nearly 340,000 jobs at state public health agencies."[93] One only need look at the Hospital Preparedness Program (HPP) and the Public Health Preparedness Program (PHP), and funding decreases since their inception in the early 2000s. Down's theory

has held true for most public sector social programs whether one considers the environment, mental health, public health and since the restructuring of federal agencies for homeland security, even raised for homeland security and its future.[94]

To further illustrate how attention to identified gaps in preparedness and their fixes get lost in the federal maze of new social programs competing with funding for past priority structures, consider the Strategic National Stockpile (SNS) and its role in the COVID-19 response. The GAO in its comprehensive review of the nation's COVID-19 Pandemic response made a number of recommendations. One set of recommendations relates to the role of the SNS and the Medical Supply Chain. The strategy "SNS 2.0 Strategy – Modernize the SNS" states that the SNS should be modernized and capable of addressing the challenges presented by the pandemic, specifically the vulnerability of the medical supply chain. The GAO reported that this "U.S. dependence on foreign manufacturers has increased over the past several decades in part because foreign manufacturers can produce their products at a lower cost." It noted "Federal agencies have identified this dependence as a national security issue."[95]

What can be done to change the trajectory of pandemic preparedness with institutions on stand-by for pandemic response? Consider the nation's response after it was drawn into two world wars and each time, unprepared. The National Security Act of 1947, put the nation on a war footing by consolidating the military services into the Department of Defense, establishing the Central Intelligence Agency (CIA) and creating the National Security Agency (NSA). Before passage of the Act, intelligence gathering was scattered among the military services and there lacked a centralized institution that could advise the President. The NSA brought together the nation's security agencies into a collaborative, coordinated effort to focus on national security.

The question should be explored, given the persistent emergence of novel infectious diseases and the performance of the nation's lead health agency, whether the time has come to put the nation on a warlike footing for pandemic response with a coherent, institutionalized, and tested Pandemic policy. Recall the GAO January 2022 report, that designated HHS as *high-risk*, or a federal program needing transformation.[96] The rational for a warlike footing for pandemics is that the nation needs emergency structures that are established legislatively rather than leave it to the petty whims of administrations and their partisan politics. It was recognized in 1947 with the passage of the National Security Act, that the nation needed continuity with its security institutions that can provide the commander-in-chief with informed council he or she needs in emergencies. Out of these concerns came not only the NSA, but the Defense Production Act of 1950,[97] used in 2019-20 to acquire Pandemic supplies during the Pandemic national emergency.

Recall that with COVID-19 and the transition of White House occupants during a national emergency the changing of response structures (i.e., OWS versus CAG), which is reminiscent of FDR and his reluctance to mobilize the nation for WWII and the naming of WWII emergency structures for the war emergency. In 1939 with Germany's attack on Poland, President Roosevelt appointed a commission to update the nation's industrial mobilization plan but did this to placate his detractors. Once completed and delivered to the President, he stuffed it away avoiding immediate implementation of its recommendations. The Pearl Harbor attacks surprised the nation, finding it as unprepared in 1941 as it was in 1916. FDR had avoided the establishment of emergency structures, quibbling over naming conventions, civilian-centralized authority and functionality (i.e., War Industries Board of WWI versus War Production Board of WWII, both industrial mobilization agencies).

As a result, Roosevelt in the midst of a war, spent precious time establishing numerous emergency agencies to ready the nation to meet war requirements, some of which were restructured due to missions that needed to be expanded and even missions inadequately conceived with their inception. There was the War Resources Board, the War Production Board, Office of emergency Management, Office of Production Management, the Supplies, Priorities and Allocations Board, Office of Economic Stabilization, Defense Plant Corporation (new facilities had to be built), Office of War Mobilization as well as the Shipping Board.

Readers were introduced to OWS and CAG as well as FEMA's Community Vaccination Centers but other emergency structures were created as well such as the Federal Retail Pharmacy Partnership Program (FRPP) accompanied by numerous task forces, PPP contracts and specialized structures to target vulnerable priority groups. The pandemic emergency also brought about other response measures that affect the way patient care was delivered; telehealth got a big boost and the industry saw the inclusion of the Telehealth Modernization Act in the Cures Act.

In March 2022, the Biden administration, published its *National COVID-19 Preparedness Plan*, essentially an effort to capture lessons learned from the COVID emergency and a pandemic plan moving forward. After a review of the plan, the question remains "Will the *National COVID-19 Preparedness Plan* build resilience?" A full analysis awaits further study but without institutionalizing through Congressional legislation, the plan will be shelved, and accompany those of prior administrations that date back to 2001 when the nation witnessed the anthrax attacks, its first biological threat. The only overtures to Congress in the Biden COVID plan are the requests for additional funding. The plan fails to address the GAO's key recommendation directed toward HHS that it be transformed to respond to Pandemics and related emerging infectious disease outbreaks.

One particular tool of the Biden COVID plan "Goal Two: Prepare for New Variants" works toward that effort and relates to this analysis, worthy of mention, and that would contribute to pandemic resilience. It states:

> *The U.S. government has established a permanent logistics and operational hub at HHS to ensure accelerated development, production, and delivery of COVID-19 vaccines and treatments.*

Likewise, the plan explains that the former emergency structure (CAG) *would* become a permanent agency structure with a new name "HHS Coordination Operations and Response Element (H-CORE)" within HHS and would incorporate the necessary tools for future infectious disease outbreaks.[98] But the tool, among others listed in Goal Two, are dependent on funding. Consider this operational aspect of the Biden COVID plan:[99]

> *FEMA has developed the operational model to stand up a federal mass vaccination site rapidly upon state request. With this successful playbook now in place, FEMA could launch mass vaccination sites, in the future, if needed. Similarly, HHS and FEMA have developed a playbook, a process, and the infrastructure to stand up surge testing sites quickly and efficiently upon state request.*

The volume of venues stood up for the COVID-19 vaccination campaign are impressive. Over 90,000 locations reached over 90% of American within five miles of a vaccination site. These sites included pharmacy locations, FEMA sites, FEMA's mobile clinics, federally-funded health centers, as well as physician offices, hospital systems and public health departments that also served as vaccination sites. Given the last pandemic, (H1N1 was a decade ago) can the federal government sustain the necessary partnerships and funding over another decade?

It is hopeful but what makes a discerning public believe the FEMA model will survive federal funding mechanisms any more than public health and the Public Health Preparedness (PHP) grants of 2002 that provided planners with similar emergency structures for pandemic response? The SNS scenario discussed previously was established in concert with the PHP and

hospital preparedness programs that provided oversight and the planning mechanisms for immediate response to chemical threats in cooperation with local first responders.

Furthermore, the plan's relationship to the National Response Framework (NRF) is absent, which would suggest that the response elements in the plan are isolated from the NRF. Yet clearly a whole-of-government approach embraces the NRF and its intent. It would seem that alignment needs to occur to synchronize pandemic response with a response structure used for other national emergencies, rather than isolate it outside the normal response framework. The federal government must work at the policy level to align pandemic response, to include vaccine distribution, with the National Response Framework and the system it directs first responders to use for all-hazard response, National Incident Command System (NIMS). Interestingly enough, some states that participated in ASPR's Crimson Contagion exercise, noted the inconsistent response structure for pandemics; plans did not reflect NRF/NIMS. For example, South Carolina AAR stated "none of the pre-existing plans adequately described the State's incident management structure for a public health emergency or provided strategies to prepare the State for the complex challenges of the COVID-19 response."[100] A National Homeland Security Consortium (NHSC) After-Action Report wrote that the initial federal response was problematic:

> *The federal government's messaging was neither unified nor consistent. The failure to implement a national strategy or plan led to states, localities, tribes, and territories (SLTTs) issuing guidance that was inconsistent with federal guidance. The guidance changed constantly, which further confused the public and led to lost credibility.... This event tested the limits of the national response doctrine—in particular NIMS/ICS—and agencies' understanding of how to implement it, for prolonged, nontraditional, complex incidents.*[101]

The point is, that unless Congress takes action to make permanent, the current emergency pandemic structures, they will remain temporary and subject to the cycle of eroding public interest, diminished funding and outside the purview of Congressional oversight, all reminiscent

of Down's "Issue-Attention Cycle." In a White Paper by the U.S. Senate Committee on Health, Education, Labor and Pensions, referring to the coordination of federal agencies, it states "it is Congress' responsibility to provide a foundational structure that administration after administration can build on instead of creating a new structure with each new emergency. The laws that Congress passed do not seem to have anticipated fully the scope of a pandemic such as COVID-19 and the need for a whole-of-government approach,"[102] Legislated actions, on the order of the National Security Act of 1947, would build the essential resilience to public health emergencies of national significance.

Finally, one redeeming lesson of the COVID-19 Pandemic is that government should now fully understand the national and homeland security implications of pandemics and the far-reaching impacts it had on the healthcare sector, the economy, the mental health aspects that result from lockdowns, and the toll on working families that suffered job loss from unprepared, impulsive actions of federal, state and municipal governments. Numerous gaps in preparedness were experienced and noted. The question remains whether Congress and state legislatures, through a unity of effort, can collaborate, legislate and unite with an incident structure, as they review the COVID-19 Pandemic response that advances the culture of preparedness and truly builds resilience for the nation, for communities and for families.

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