Pandemic Vaccine Distribution Policy for the Twenty-first Century

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ABSTRACT

Over this past decade, Congress has responded to the growing threat of bioterrorism and risks to US national security with increased funding for biosecurity and public health preparedness. This has included investment in domestic vaccine manufacturing capacity by the United States government. As a result, a policy of vaccine production self-sufficiency has emerged that should cause policy makers to pause and ask: “what is the next step?” In the near future, this policy may create a surge of efficient vaccine production that current emergency distribution models are ill equipped to manage. This article presents the results of a research project aimed at developing a model that could serve as a strategy for pandemic vaccine distribution. It argues that as the nation readied for its first pandemic in forty years, it benefited from investments in preparedness but still found itself unprepared for the 2009 H1N1 Pandemic vaccination campaign.

BACKGROUND

Congressional action has responded to the growing threat of bioterrorism and the associated risks to US national security by increasing funding for biosecurity and public health preparedness. Among these actions has been the investment in domestic vaccine manufacturing capacity by the United States government. As a result, a policy of vaccine production self-sufficiency has emerged that should lead policymakers toward the next steps in developing a vaccine distribution strategy. In the near future, this production strategy will create a surge of vaccine production efficiency that current emergency distribution models are ill equipped to manage. This gap between production and distribution capabilities was witnessed in the 2009 H1N1 Pandemic when the limitations of the public health mass vaccination model were recognized and a distribution infrastructure was assembled to support a vaccination campaign. As a result, public health planners were encouraged to pursue agreements with private sector providers to support pandemic vaccine distribution. This guidance came after the confirmation of the H1N1 virus on the North American continent in April of 2009.

THE PROBLEM

The HHS Pandemic plan for mass vaccination is non-executable, inadequately resourced, and lacks a staffing strategy to fulfill the goal of vaccinating 300 million Americans in six months. The US General Accountability Office (GAO) has reported to Congress that the Health and Human Services (HHS) Pandemic Plan lacks clarity...
regarding the roles and responsibilities of states versus the federal government in regards to vaccine distribution. As the nation prepared for H1N1, its first mass vaccination campaign in nearly forty years, the GAO reported to Congress that GAO recommendations had not been implemented. This report came in the midst of a declared public health emergency. The Association of State and Territorial Health Officers (ASTHO) reported, in the aftermath of H1N1 Pandemic, that states experienced difficulties with vaccine distribution. Why does the nation not have a proven vaccine distribution system after spending billions on pandemic preparedness?

The HHS mass vaccination plan is based on the public health model, established in the 1950s and 1960s, which was successful in eliminating infectious diseases while controlling numerous other childhood diseases. The plan assumed state and local public health personnel would fulfill the distribution function, as they did in the 1957 and 1968 pandemics. However, over the past twenty years, the public health vaccinator corps has declined, and in the past decade has continued to lose workforce capacity due to state and local budget cuts. Thus, as the nation readied for the H1N1 vaccination campaign, public health no longer had the workforce to sustain an ambitious, prolonged vaccination campaign. In seeking to mitigate the effects of a gap in the public health workforce, Congress passed the Public Health Emergency Response grant to purchase the H1N1 vaccine and support state and local response efforts to hire a temporary vaccinator workforce. When attempting to use the grant funds to support a range of vaccine distribution strategies, states reported several policy barriers, such as bureaucratic state procurement and hiring practices that lacked a “fast track” mechanism to expedite the filling of vacancies during emergency operations. Additional challenges resulted from the introduction of web-based applications, databases, and vaccine ordering applications that were new to providers and lacked interoperability with seasonal influenza vaccine administration systems.

In contrast to the 80 million doses of H1N1 Pandemic vaccine dispensed in 2009, the private sector routinely distributes 135 to 140 million doses of influenza vaccine each flu season. Given the limitations of the public health model and government’s greater reliance on the private sector to accomplish a “rapid response” H1N1 pandemic vaccine distribution, the time has come for a strategic study of strengths and weaknesses of all vaccine distribution logistics. This research project sought to answer the question “How could a new model be designed to support pandemic vaccine distribution for a public health emergency of national significance?”

If the current public health model experiences difficulties managing vaccine distribution when dose volumes are less than 100 million, then how can the nation expect its public health system to meet the goal of the HHS to distribute 300 million doses? This article proposes a hybrid public/private policy that could serve as the basis for pandemic vaccine distribution and compliment the current policy of vaccine production self-sufficiency.

METHODOLOGY

Policy analysis was used to evaluate two existing vaccine distribution models and, from that analysis, suggest a new hybrid model for pandemic vaccine distribution (PVD). The analysis examined weakness in the current public and private sector models, identified strengths of those models, and developed a new model that could better achieve the policy goal of vaccinating 300 million people in six months. Three steps were used to evaluate existing private and public sector distribution models and develop a new hybrid model.

1. The first step was to identify, shape, and validate model evaluation criteria using the Delphi method. Subject matter experts (SME) were interviewed in two rounds: the initial round was used to identify criteria and a second round was used to validate the criteria identified from the first round. In the second round, SME were asked to rate the relative importance of each criterion, rank order all criteria, and discuss their rationale for the ranked order of each criterion.
2. The second step was to evaluate the two distribution models using the model evaluation criteria, which were identified in the Delphi study.

3. The final step was to develop a new distribution model for pandemic vaccine distribution. The new model incorporates desirable attributes from the two existing models; a comparative analysis of the literature provided context in which to frame the new model.

**SAMPLE**

The Delphi panel consisted of eleven individuals with professional vaccine distribution experience. Individuals selected served as subject matter experts and represented stakeholders who were involved in either non-emergency (seasonal) or emergency (pandemic) vaccine distribution. These SME were drawn from policy, administration, academic (medical), state-level program operations, federal operations, and national policy levels. They represented local, state, and federal levels of government, non-government organizations and the private sector, and the disciplines of medicine (as physicians, nurses, or pharmacists), emergency preparedness, and business. All had extensive experience with the vaccine supply chain, including production, distribution, ordering, and administration. As a group, their perspectives represented policy and operations, and the public and private sectors. It is worth noting that several SME had extensive experience in one sector but worked in another sector at the time of this study, thus offering insight from both sectors as it relates to vaccine supply, administration, and distribution.

**DATA COLLECTION**

The survey instrument consisted of a series of sixteen questions. Questions were grouped into one of four segments and each interview consisted of the four segments: (1) SME background information; (2) private sector model and SME involvement with seasonal influenza vaccination; (3) pandemic influenza vaccination and the public health model; and (4) the ethics of vaccine distribution during public emergencies. The first segment established the SME’s experience and familiarity with vaccination policy, both seasonal and pandemic. It also offered an opportunity to understand the SME’s expertise, with in-depth follow-up provided in the subsequent sections of the interview. The second segment focused the discussion on knowledge of and familiarity and experience with the private sector model and its outcomes. The third segment focused on the public health model and provided an opportunity to contrast strengths and weaknesses of this model with the private sector model. The fourth segment solicited discussion of the ethics surrounding vaccine distribution.

**ANALYSIS**

Survey data were analyzed to determine those themes that emerged from the interviews and resulted in the identification of enablers (the how) and criteria (the what). An enabler was defined as a process that supported a particular outcome or criteria. Enablers were sorted based on the interview discussions that related to a major theme. Criteria and enablers are depicted in Figure 1.
The epidemiological model “web of causation” was used to model and illustrate the inter-relationships among the enablers and criteria (see Figure 1). First introduced in the 1960s by MacMahon, Pugh and Ipsen, the web of causation model showed relationships among causal factors of disease. The survey conducted for this study revealed that several factors contributed to the understanding of the dynamics of vaccine distribution. The application of the epidemiological model helped to conceptualize how the criteria relate to each other and associated enablers for vaccine distribution. The next step was to use these model evaluation criteria to evaluate two current models of vaccine distribution: the public health model and the private sector model.

**TWO MODELS OF VACCINE DISTRIBUTION**

**THE PUBLIC HEALTH MODEL**

The public health model (PHM) is the current, documented strategy for mass vaccination when a public health emergency is declared. This guidance, which dictates federal policy for mass vaccination, dates to the 1950s and 1960s when mass vaccination clinics were used to defeat childhood infectious diseases such as polio, smallpox, etc. In the first decade of the twenty-first century, the guidance was revised and updated, and then pushed to state and local jurisdictions. This public health model is described in numerous public health mass prophylaxis planning guidance documents.
Figure 2 depicts the public health model, in which the federal government is the purchaser and distributor of pandemic vaccine and has the sole responsibility for procurement and distribution to the states. This model is labor intensive and dependent upon state, local, and tribal departments for distribution. It requires logistics functions, such as warehousing, that are no longer in place for day-to-day functions in most states. In 2009, this model was modified dramatically for H1N1 pandemic distribution plans, which had an impact on routine functions. For example, centralized distribution was incorporated for vaccine distribution and the private sector was recruited to supplement vaccination.

The evaluation of the PHM revealed that, while the Delphi panelists rated the planning guidance high (see Figure 1), most model evaluation criteria were rated low, including the extent to which the guidance was executable, scalable, and provider-centered. The criteria of client-centered and integration were assessed as medium. During the rating of these criteria, comments were offered by SME that provided insights to their assessments based on experience. Generally, they believed the public health model is dated and no longer reflects the realities of the twenty-first century. This view was stated in the context of the attrition of the public health workforce, low dependence on and integration of untested technologies for logistics support, and a consumer-oriented retail service sector.

Consider the attrition of the public health workforce and its capacity to manage a sustained mass vaccination campaign. Enumeration methodologies used by departments of health to assess the public health nurse workforce across the nation lack consistency, but states with centralized public health systems have reported declines in that workforce. For example, in 2009, South Carolina reported that its workforce over the past decade decreased from an estimated 1,200 nurses to 461 nurses, a decrease of nearly two-thirds.
workforce have further impacted vaccination support requirements and the capacity to sustain a campaign.

The public health model is built around few technologies; however, subject matter experts cited examples of technologies introduced during the H1N1 pandemic and described how technologies used in the private sector would aid in vaccine distribution. For example, two SME pointed out that the distribution logistics to support H1N1 should have been managed by a Supply Chain Inventory Management system. Another SME described the Centers for Disease Control's (CDC) use of technology as “untested,” while another reported her state had been using pen, paper, and fax machine to manage vaccine distribution prior to the H1N1 pandemic. The pandemic caused the state to develop and roll out a new web-based technology ordering system for physician practices willing to administer the H1N1 vaccine. This was one state’s experience, but there was no one system used by all states for vaccine ordering and distribution. There also was no system in place for use by CDC’s contractor, McKesson Medical Specialties, which was responsible for distributing pandemic vaccine to the 90,000 registered providers.21

Finally, the public health model incorporated limited strategies when compared to those of a twenty-first century consumer-oriented retail service sector. The mass vaccination clinic, according to planning guidance, delivers service at large centers. Clients who seek vaccination must travel to this site for a single service (which is not to say that many departments of health have not instituted alternative delivery methods such as drive-thru clinics, rural clinics located in solo-owned pharmacies and mall clinics, but this is not necessarily a component of the traditional public health model).

THE PRIVATE SECTOR MODEL

A vaccine is manufactured for profit and sold to wholesalers and distributors who sell to frontline providers. Over the past decade, this provider network has expanded to include not only physician practices, but retail pharmacies (chain-owned), grocery stores, and big box retail outlets as well. It is estimated that a third of all annual flu vaccine is administered through the retail sector.22 The balance is administered through physician practices and community clinics. While the ability of this model to distribute vaccine is powerful, its ability to respond to public health emergencies is limited. For example, during periods of vaccine shortage, the system lacks the responsiveness to retrieve vaccine and distribute 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.

Figure 3 shows the private sector model (PSM) and illustrates the complexity and redundancy of production, distribution, and wholesaler and provider relationships. The government – federal, state, and local – accounts for less than 10 percent of the activity in this model.23 Physicians, at the provider level, purchase a vaccine directly from either a manufacturer or from a wholesaler. That purchase can include auxiliary supplies such as syringes, alcohol swabs, and cotton balls.
In evaluating the PSM, Delphi panelists rated it high for three criteria (see Figure 1): it is executable, scalable, and client-centered. With regards to two criteria – provider-centered and integration – the PSM was rated as medium, while the federal planning guidance was rated as low. The limitations of this model to serve as public policy are twofold: it fails to reach population targets that are either geographically remote and/or high-risk. The model offers limited reach into remote rural areas not served by large corporations with franchise networks. For example, while corporate retail pharmacies (such as CVS, Walgreens and Rite Aid) are members of the network, locally owned pharmacies in remote areas are not served by the pharmaceutical corporate structure. Therefore, these communities, in all likelihood, are not served by this service delivery model and would also be underserved in emergency distribution. The second limitation of the model is that it does not incorporate a community outreach component that serves high-risk population groups, such as the homebound or uninsured. Vaccination rates among the uninsured, underinsured, and geographically remote population groups are underachieved by this model due to limited accessibility.

RESULTS OF THE DELPHI PANEL

Three major findings were drawn from this analysis of the public health model and the private sector model: (1) the PHM is not executable; (2) there are statutory, regulatory and licensure barrier to using alternative healthcare professionals as vaccinators; and (3) the United States lacks a comprehensive policy for pandemic vaccine distribution.

1. THE HHS PANDEMIC VACCINATION PLAN IS NOT EXECUTABLE

The evaluation of the public health model illustrated the limitations of pandemic vaccine distribution (PVD) due primarily to insufficient public health workforce capacity. The weaknesses of the current federal pandemic plan for distribution were revealed when the nation responded to the 2009 H1N1 pandemic. Public health did not have the expected infrastructure to support mass vaccination as called for in the federal guidance to meet the HHS goal. It is the public health nurse workforce that has served...
as the key personnel in past mass vaccination efforts. As a result, Public Health Emergency Response (PHER) grants were used to supplement the staffing limitations of state and local departments of health (DoH) and the private healthcare sector was recruited to assist with vaccination.

2. THERE EXIST STATUTORY, REGULATORY, AND LICENSURE BARRIERS TO USING ALTERNATIVE HEALTHCARE PROFESSIONALS AS VACCINATORS

An alternative workforce capacity must be identified and readied for emergency mass vaccination to supplement the decline in the public health nurse workforce. But regulatory complexities (such as limited scope of practice) restrict recruitment of alternative health professionals as vaccinators, especially during an emergency. The pharmacy profession has been readying pharmacists for the role of vaccinator over the past sixteen years, and this has been coupled with the expansion of retail pharmacy flu clinics. While public health was slow to adopt the pharmacist vaccinator as a partner for emergency mass vaccination during the H1N1 campaign, other factors also limited the adoption of pharmacists as vaccinators. These issues – scope of practice and medical control – limit the ability of other allied health professions (dentists, paramedics, or veterinarians) to serve as vaccinators as well. States have authority over issues of medical control and could resolve such barriers. But each state must identify and address barriers that surround the statutory regulatory issues that limit the use of allied healthcare professionals as vaccinators.

3. THE NATION LACKS A COMPREHENSIVE POLICY FOR PANDEMIC VACCINE DISTRIBUTION

While the United States is progressing toward vaccine production self-sufficiency, little progress has been made on the distribution side. The CDC has distribution projects underway, such as the Vaccine Management Business Improvement Project (VMBIP), begun in 2003. Elements of VMBIP were adapted for the H1N1 pandemic. But federal planning guidance for mass vaccination is driven by US dependency on traditional vaccine production techniques and offshore sources that traditionally have produced an unreliable vaccine supply. As the US policy of vaccine production self-sufficiency produces a more reliable supply of vaccine, consideration of alternative policy implementation strategies will be merited. Policy strategies should be amended for a time when vaccine distribution will not be based on scarce allocation schemes or vaccine rationing, but instead will be based on vaccine self-sufficiency. In light of the 2009 H1N1 pandemic and as new vaccine production technologies come online, the discussion of distribution policy ought to consider what the nation’s pandemic vaccine system should look like.

A policy for pandemic vaccine distribution should include strategies that strengthen the distribution model and enhance herd immunity. Extensive guidance exists for vaccine administration to target groups; this achieves the ethical principle of social justice while managing who gets vaccinated. What is absent in the model and its guidance is how a vaccine is distributed (strategies), where the vaccine is distributed (venues), and by whom (vaccinators).

A NEW MODEL FOR PANDEMIC VACCINE DISTRIBUTION

Based on this evaluation of the public health and the private sector models, a new model can be developed. It is a public-private partnership that builds upon current private sector relationships by incorporating the distribution component for pandemic events where vaccination is the mitigation strategy. It builds on decades of the United States government and state governments partnering with the private sector to implement a cost-effective, policy-based vaccine supply for such programs as Vaccine for Children (VFC), and the more recent response to H1N1. A partnership with the pharmaceutical industry has existed in one form or another since the 1950s but has been limited to the supply of vaccines. The pharmaceutical industry has the production capacity; what has been missing is a private sector-driven medical logistics capability. The
2009 H1N1 mass vaccination campaign demonstrated a core competency of the private sector – its centralized distribution capability – that had been a key component in seasonal flu campaigns.

Figure 4 depicts the public-private partnership model for pandemic vaccine distribution (PVD). The federal government is the purchaser but contracts with the private sector for both vaccine production and distribution logistics in pandemic events. The federal government, in concert with state and local departments of health, collaborates with, recruits, and registers the provider network in advance of a public health emergency. This last element was introduced during the 2009 H1N1 pandemic vaccination campaign. However, the wholesalers and, to a great extent, the large purchasers (shown in Figure 3) critical for distribution to providers in the private sector model were removed from the supply chain. This hybrid model restores, to some extent, the private sector components of the distribution network that are missing in the public health model but prominent in the private sector model. It expands vaccination venues by incorporating retail sector in-store clinics, pharmacies, grocery stores, and big box sites – a concept supported by retail executives.28

Centralized distribution is critical in this model because it replaces the labor-intensive distribution function inherent in the public health model that, due to attrition, is either diminished or no longer operational. Central distribution includes a warehousing function, where product is received, an inventory and data system, and a shipping and transport function. An additional essential component is cold-chain management;29 the ability to monitor temperature fluctuation during transport may compromise vaccine efficacy. Finally, this system incorporates performance metrics to ensure private sector participants fulfill contract requirements.
To distribute the H1N1 vaccine, McKesson Specialty Care Solutions assembled four depots in six weeks, strategiically located throughout the United States. The five pharmaceutical manufacturers shipped vaccine to these locations, where it was inventoried and stored. The CDC provider network orders were pulled from depot inventory but the data systems used by states were a patchwork of systems that fed into the CDC. As explained by Delphi panelists, the supply-side ordering system (a pull system) competed with the manufacturing system (a push system). What was missing from the H1N1 application was a supply chain management system. Aspects of the CDC VMBIP project had yet to be implemented but project elements will eventually standardize an ordering system to be used by all states and US territories. (McKesson filled H1N1 vaccine orders the day they were received and delivered vaccines the next day. This metric was assessed daily, weekly, and monthly.)

The hybrid model leverages private sector resources to achieve the goal of herd immunity during a public health emergency of national significance. The public and private sectors both work toward delivering a public good by building on their core competencies. The public sector, through the federal government, serves as the lead partner coordinating activity among federal agencies, state governments, vaccine advisory committees, and pharmaceutical manufacturers. The private sector uses its production capabilities, the strength of its logistics support technology, and a contracted reasonable cost to the public sector to accomplish the public health goal. The private sector is protected legally and fulfills its social responsibility as a contributing corporate citizen. The public sector meets its mandate to provide for the common good.

Planning doctrine, published for public health emergencies of national significance, should be written to support this hybrid model. It builds on the network of providers used for seasonal influenza vaccinations and leverages the full scope of the private sector for both distribution and administration of vaccine. Additionally, it recruits, prepares, and readies a network of “emergency” vaccinators or non-traditional vaccinators supplementing traditional providers (illustrated in Figure 4) as the provider network. The new hybrid model integrates the public health system and its emphasis on target populations with the broad net cast by the private sector to maximize vaccine distribution. This policy strategy ensures the emergency distribution of vaccine by maximizing geographical reach and using a full range of venues for vaccine administration in a given community. It also follows the policy and practice of emergency management for preparedness, response, and recovery and reflects National Incident Management System (NIMS) guidance.

**Barriers to Implementation**

There currently exist several barriers to implementing the hybrid model. These include scope-of-practice restrictions on potential vaccinators, the lack of an integrated distribution system that works for seasonal and pandemic vaccines, and the need for a formal public-private partnership for pandemic response. This section presents three recommendations for removing or mitigating those barriers.

**Recommendation 1.** States, in cooperation with HHS and health and medical specialty associations, should change scope of practice restrictions that block disciplines from serving as vaccinators in declared public health emergencies where vaccination is the mitigation strategy.

The nation has a corps of health and medical professionals with the skill set and desire to assist during emergency operations. The limitations and barriers to deploy health and medical personnel in the aftermath of Hurricane Katrina revealed the legal, licensing, and practice constraints. These issues were visited again in an attempt to deploy vaccinators for the 2009 H1N1 pandemic.

State statutes define the scope of practice for these professionals. However, there are legal, regulatory, and licensure restrictions that limit health and medical professionals from serving as vaccinators in public health
emergencies. These became apparent during the H1N1 mass vaccination campaign.

This recommendation addresses the quagmire of restrictions. It expands the non-traditional vaccinator’s scope of practice to include this skill set for public health emergencies. The scope of practice is a state responsibility, but HHS should serve as lead facilitator (which would be not unlike its role in the past), providing the incentives and mechanisms for states to upgrade laws pertaining to state emergency powers.

**Recommendation 2.** The United States government should support an integrated vaccine distribution infrastructure that works for both seasonal influenza and pandemic influenza.

An integrated vaccine distribution infrastructure could be used each influenza season and when a public health emergency requires a mass vaccination strategy. This recommendation has been made in the past, serves as recommended policy in Canada, and is currently practiced in the Province of Ontario. The Department of Health and Human Services must understand that its investments on the supply side are insufficient if, in an event, supplies are not efficiently distributed to those in need. Delphi panelists described how their family members could not get an H1N1 shot, despite warehouses they managed full of vaccine doses. The public health model has distribution barriers that should be addressed and resolved if the intended outcome is improved uptake rates and biosecurity. Thus, an integrated distribution infrastructure offers dual-purpose application.

**Recommendation 3.** The United States government should establish a comprehensive public-private partnership for pandemic vaccine distribution that achieves the HHS goal and facilitates a rapid response.

Pandemic response should not stop at vaccine production self-sufficiency. It should incorporate a distribution policy that supports the vaccine supply chain from production through distribution and administration to individuals. A policy of vaccine distribution would complement the policy of vaccine production self-sufficiency.

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**A STRATEGIC POLICY FOR PANDEMIC VACCINE DISTRIBUTION**

The new hybrid model serves as the implementation strategy for a strategic policy that targets pandemic vaccine distribution (PVD). This final section describes the strategy and the six strategic goals drawn from the findings of this analysis. Finally, a framework is presented that outlines a policy for pandemic vaccine distribution.

**The Policy Strategy**

The United States government has invested $7.1 billion in pandemic preparedness, of which $3.2 billion was invested in enhancing vaccine production, including expanded capacity and new technology for cell-based vaccine. In the near future, the return on investment will be realized, but funding investments should be redirected into PVD infrastructure projects. For example, $176 million is used annually for egg embryos to sustain the egg-based vaccine production process of the 1940s. Once cell-based vaccine technology is proficient, these investments could be redirected to offset costs to improve distribution strategies. One such project could assist states and medical associations to review statutory and licensure barriers that prohibit non-traditional professionals with vaccination skill sets from administering vaccinations in a declared public health emergency.

A policy strategy directed toward distribution, accompanied by similar investments and initiatives, should be pursued. It should incorporate six key goals that draw from this analysis. The recommended policy parallels the Congressional Budget Office (CBO) document *U.S. Policy Regarding Pandemic-Influenza Vaccines,* which details the US strategy for achieving vaccine production self-sufficiency.

The strategy is to establish a comprehensive public-private partnership for PVD that can achieve the HHS goal. The objective of this approach is to incorporate an executable staffing strategy for the HHS goal stated in the 2005 pandemic plan and its claim “to facilitate rapid response.”
POLICY GOALS
Six specific policy goals offer guidance to policymakers and planners in the development of a new model.

1. Augment the current emergency mass vaccination plan with a staffing model sufficiently sized to meet the mass vaccination goal.

This first goal is predicated on a staffing strategy that supports the HHS goal to vaccinate 300 million Americans in six months. Three enablers are crucial to support an executable mass vaccination plan. These included a publicly funded vaccination campaign, a staffing strategy or model, and technology that would sustain the ordering, distribution, and metrics requirements. H1N1 was a publicly funded campaign and, while federal guidance implies that a campaign could be publicly funded, there is currently no policy that supports publicly funded campaigns. Actions of the government show that it will fund medical countermeasure purchase and distribution, but the key enabler is a staffing model sized for response.

2. Expand the vaccinator corps to support the staffing of multiple venues with a mechanism that permits capacity to expand or contract.

The second goal is to develop a vaccinator corps that can provide the workforce capacity for the staffing model called for in the first goal. It expands the current model to include non-traditional vaccinators such as pharmacists, paramedics, dentists, and even veterinarians. This goal advocates for primary care physicians with an emphasis on the medical home, but recognizes that, in a medical emergency, this network is insufficient to reach most Americans. Therefore, multiple venues must be incorporated in the network. This dependence builds on the traditional public health model and adds non-traditional venues such as pharmacies, in-store retail clinics, and the workplace.

The public health mass vaccination model is built around 3,036 local and tribal departments of health. In contrast, Walgreens reports 7,100 pharmacies and CVS boasts another 3,000 pharmacies, most of which give flu shots. This contrast illustrates the scalability of the private sector resources used for the seasonal flu campaign that could be tapped for pandemic mass vaccination.

3. Adopt client-centered strategies to maximize vaccination rates.

To maximize vaccination rates, mass vaccination campaigns should take advantage of client familiarity and routine behavior, convenience, and accessibility. Nations that have cultivated client-centered strategies experience greater vaccination uptake. For example, Canada reported the highest H1N1 vaccination rates in the world at 46 percent, while the United States reported 27 percent.

Customer convenience and accessibility has attracted the attention of retailers hosting in-store clinics and vaccination is a service that has become part of the retail mix. To illustrate this point, consider this statement published in a California Health Care Foundation report: “Retail companies are ready to cater to this new kind of healthcare consumer by offering what they believe their shoppers want: convenient basic medical service at a fair price, stated in advance.”

A strategy used in seasonal flu campaigns is point-to-point service. This is similar to the practice instituted by Southwest Airlines that has contributed to its success. Southwest and manufacturers understand that airline commuters seek transportation that will take them from home to their destination without layover and that smaller aircraft can accommodate increased frequency. Manufacturers build more, smaller aircraft. Southwest uses these aircraft to service the same routes with greater frequency to accommodate passengers. This contrasts with the current “hub-and-spoke” system used by most airlines.

Concentrating resources and setting up clinics only in public facilities or establishing a “mass vaccination center” is, from a client perspective, a hub-and-spoke system. In contrast, clinics in the workplace, pharmacy, or retail store are examples of point-to-point service. This is the essence of the client-centered strategies used to maximize vaccination rates in Canada.

The public health model is not built around client-centered strategies that
encourage high vaccination rates. The public image of a public health mass vaccination center involves long lines, lengthy wait times, traffic congestion, and few conveniences. As a result, this model may do more to discourage vaccination than to enhance uptake.

4. Adopt provider-centered strategies to recruit and expand the traditional provider network.

Explicit strategies to encourage and maximize both traditional and non-traditional provider participation in public health emergency mass vaccination campaigns must be developed. The seasonal flu campaign models a number of these strategies while, in contrast, the public health model (PHM) for mass vaccination is void of such innovations. As a result, the PHM was limited in its efforts to recruit participation by private physician practices until H1N1. The challenge for the public sector is how to incorporate incentives in a model for pandemic response that approximates the inherent strengths of the public sector model but encourages physicians, through incentives, to adopt immunization practices. For example, public funding is one incentive that could be strengthened by including an administrative reimbursement fee for patients whose insurance does not cover such expenses.

5. Adopt an implementation strategy that supports an integrated vaccine distribution infrastructure and view each seasonal campaign as an exercise for pandemic response.

It has been decades since public health last managed a pandemic using the public health model as its sole strategy and, at that time, it had the workforce needed for implementation. The integration concept argues that public health no longer has the capacity to sustain a separate model for pandemic vaccine distribution and must develop alternative strategies. The “blended” model incorporated for H1N1 was an alternative model, and the Vaccine for Children program (VFC) represents yet another model from which elements were adopted for the H1N1 campaign.

Integration suggests pandemic response be developed around a single model; this represents a philosophical shift of strategy from that described in current planning guidance. In a review of H1N1 barriers,45 the Association of State and Territorial Health Officers (ASTHO) recommended use of normal distribution channels. According to ASTHO, the initial limited supplies could have been sent to the public health departments using the CDC identified priority vaccination providers (e.g., those participating in VFC).

6. Expand federal planning guidance to incorporate proactive distribution strategies.

Most published federal planning guidance for mass vaccination is driven by US dependency on traditional production techniques and offshore sources that contribute to unreliable vaccine supplies. Thus, considerable emphasis is placed on vaccine rationing, such as the CDC priority targets. This article argues that with the establishment of the US policy of vaccine production self-sufficiency, a time will come when vaccine production will be more reliable. Future strategies should be accompanied by federal planning guidance to assist state and local planners with the development of plans that are both comprehensive and identify the resources necessary to accomplish the goal.

A POLICY FRAMEWORK

The framework for the development of a policy for US pandemic influenza vaccine distribution, depicted in Figure 5, provides a starting point for discussion. It represents a composite of strengths identified from the analysis of vaccine distribution models used in the United States for either emergency vaccination (e.g., pandemic) or the seasonal influenza campaign.
1. **What Makes the U.S. Pandemic Plan Executable**
   a. A publicly funded campaign
   b. The staffing model strategy
   c. An implementation philosophy for an integrated system
   d. The use of new technology
      • Vaccine Management Business Improvement Project
      • Supply Chain Inventory Management System

2. **The Scalability for Pandemic Response**
   a. A robust vaccinator corps
      • Physicians and the emphasis of the medical home
      • Allied health professionals ready to serve in new roles
   b. How the plan uses multiple venues to maximize public outreach
      • Fixed facilities
      • Public facilities
      • Mobile facilities
      • Workplace clinics
   c. How technology may offer vaccine production scalability

3. **Adoption of a Client-centered Approach to Vaccination Practices**
   a. The medical home remains the first choice
   b. Point-to-Point service
      • The workplace clinic for most Americans
      • Retail sector in-store clinics, pharmacies
   c. The role of the Vaccine Injury Compensation Program

4. **Adoption of Provider-centered Approach to Maximize Vaccination Rates**
   a. Improved communication with an expanded provider network addresses issues of efficacy, safety and contraindications
   b. Insure a single vaccine ordering system compatible for states with electronic interfaces
   c. Expand provider network by offering tax breaks for registered participants who administer vaccine during a public health emergency

5. **An Integrated Vaccine Distribution System**
   a. A single vaccination distribution system
   b. Exercised annually through the seasonal campaign
   c. Optimal readiness at all times
      • Act of bioterrorism
      • Emerging infectious disease
      • Influenza pandemic

6. **Federal Planning Guidance**
   a. Vaccine Production: A policy for vaccine production self-sufficiency
   b. Vaccine Administration: A multidisciplinary, collaborative approach to provide guidance for safe and effective vaccine practices.
   c. Vaccine Distribution: A performance based system to transport vaccine from manufacturer to provider front door.

**Figure 5. Framework for U.S. Policy: Pandemic Vaccine Distribution**

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CONCLUSION

How does this new hybrid model fit into the current discourse on mass vaccination strategy? This article has briefly described the progress that has been made toward vaccine production self-sufficiency and demonstrated that vaccine administration guidance is well documented. What has not progressed is the process of vaccine distribution for emergencies. Three distinct processes should define a US pandemic response using vaccination as the mitigation strategy: production, distribution, and administration. These three processes are conceptualized in Figure 6 as a triangle, which illustrates the equivalency of the relationships among the three vaccination processes. The three sides form an interdependent triangular network, each equal but requiring a body of knowledge to support its execution.

Figure 6. Vaccination: A Triangular Network of Interdependencies

Each process is distinctive and warrants a body of work essential for success; however, the interdependency of all three is necessary to achieve herd immunity during a public health emergency. The public-private partnership for pandemic vaccine distribution offers a model for developing the distribution process. It becomes the building block that compliments the HHS pandemic plan and contributes to an executable vaccination model.

Vaccine distribution should be differentiated from vaccine administration in federal planning guidance. Too often in guidance, distribution is discussed in the context of vaccine administration while the discussion focuses exclusively on protocols for vaccine inoculation. If the discussion were framed in the context of the National Incident Management System (NIMS) and incident command (ICS), vaccine distribution would be a function of logistics, whereas vaccine administration is a function of the operations section. A public policy should be adopted that differentiates between these functions and establishes a deliberate course of action. It should build on current
capabilities while encouraging constructive change of distribution limitations.

This article has presented a new hybrid model that could serve as a conceptual framework for a pandemic vaccine distribution policy. Six goals were outlined based on the findings of the analysis of two existing vaccine distribution models: the public health model (pandemic influenza) and the private sector model (seasonal influenza). The new hybrid model builds upon the strengths and weaknesses within each of these and serves as the basis for a strategic implementation policy for pandemic vaccine distribution.

ABOUT THE AUTHOR

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3 Center for Biosecurity, “The 2009 H1N1 Experience.”


10 Public health nurses have historically served as the primary vaccination corps but their numbers have dwindled steadily. For example, it is estimated that in one state, nurses have decreased by 60 percent. See Russo, “Strategic Policy for Pandemic Vaccine Distribution,” 20-22.


12 Ibid.


15 Russo, “Strategic Policy for Pandemic Vaccine Distribution.”


17 ASTHO, *Assessing Policy Barriers to Effective Public Health Response*.


19 Ibid., 94, for a summary of strengths and weaknesses enablers as they relate to the model evaluation criteria.

20 Ibid., 21.


24 Ibid.

25 See Russo, “Strategic Policy for Pandemic Vaccine Distribution,” 117 for a summary of strengths and weaknesses as they relate to the model evaluation criteria.

26 Centers for Disease Control and Prevention, “Vaccine Management Business Improvement Project (VMBIP),” http://www.cdc.gov/vaccines/programs/vmbip/default.htm#what

27 Vaccine for Children (VFC) is a comprehensive childhood program to ensure all children are immunized against infectious diseases. VFC reflects federal policy as it relates to the provision of vaccine for children with eligibility under Medicaid, uninsured, underinsured or Native Americans. VFC is administered through the states by providers that register and agree to comply with federal program guidance.


29 Cold-chain management is “maintaining proper vaccine temperatures during storage and handling to preserve potency.” See Centers for Disease Control and Prevention, “Guidelines for Maintaining and Managing the Vaccine Cold Chain,” MMWR Weekly 52, no. 42 (October 24, 2003); 1023-1025, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5242a6.htm.

30 The four McKesson depots included Memphis, Tennessee; Sacramento, California; Suwanee, Georgia; and Fairfield, Ohio.

31 CDC contracts with McKesson Specialty Care Solutions, a division of McKesson Corporation for distribution of vaccine in support of the Vaccine for Children program. This contract was expanded to support distribution of the 2009 H1N1 pandemic vaccine.

32 The vaccine supply side was a push system (pushing vaccine from manufacturers to McKesson) while the state/CDC system was a pull system (pulling orders from the provider network). The private sector uses a supply chain inventory management system to manage this push/pull dynamic of distribution.


36 Ibid.

37 Ibid.

38 Ibid.

39 Family and pediatric physician specialties have adopted the patient-centered medical home. Public health has adopted this policy to support private sector, family-oriented practices.


42 Ken Scott, Public Health Agency of Canada, personal interview with the author, April 9, 2010.


47 Ibid., 43.