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STRATEGIC POLICY FOR PANDEMIC VACCINE DISTRIBUTION

by

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September 2010

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This thesis explores pandemic vaccine distribution, contrasting Department of Health and Human Service guidance with pandemic gap analyses and the recent H1N1 vaccination campaign. An analysis of the literature revealed that unresolved state and federal distribution issues contributed to distribution delays during the H1N1 call for mass vaccination.

Policy analysis was used to evaluate public health and private sector vaccine distribution models, and a third hybrid model was proposed to improve support for public health emergencies. Adoption of the hybrid model will enhance the vaccination process from production through distribution along with administration to support U.S national security interest in biosecurity. The hybrid model offers a strategic solution for pandemic vaccine distribution and proposes a new approach for efficient, rapid distribution of biological countermeasures.

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STRATEGIC POLICY FOR PANDEMIC VACCINE DISTRIBUTION

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ABSTRACT

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TABLE OF CONTENTS

LIST OF FIGURES

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LIST OF TABLES

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LIST OF ACRONYMS AND ABBREVIATIONS

ACIP	Advisory Council on Immunization Practices
ACOG	American Congress of Obstetricians and Gynecologists
ASPR	Assistant Secretary for Preparedness and Response
ASTDN	Association of State and Territorial Directors of Nursing
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Agency
CBER	Center for Biologics Evaluation and Research
CBO	Congressional Budget Office
CD	Centralized Distribution
CDC	Centers for Disease Control and Prevention
CICP	Countermeasure Injury Compensation Program
CI/KR	Critical Infrastructure/Key Resources
DHS	Department of Homeland Security
DoH	Department of Health
ECDC	European Centre for Disease Prevention and Control
EUA	Emergency Use Authorization
FDA	Department of Food and Drug Administration
Flu	Influenza
GMU	George Mason University
HHS	Department of Health and Human Services
HIT	Health Information Technology
HSEEP	Homeland Security Exercise and Evaluation Program
HSPD	Homeland Security Presidential Directive
ICS	Incident Command System
IOM	Institutes of Medicine
NCIRD	National Center for Immunization and Respiratory Diseases
NIMS	National Incident Management System
NSPD	National Security Presidential Directive
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office

OB/GYN	Obstetrics and Gynecology
OSHA	Occupational Safety and Health Administration
PCAST	President's Council of Advisors on Science and Technology
PHAC	Public Health Agency of Canada
PHE	Public Health Emergency
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHM	Public Health Model
PHN	Public Health Nurse
PVD	Pandemic Vaccine Distribution
PPP	Public Private Partnership
PPP4PVD	Public Private Partnership for Pandemic Vaccine Distribution
PREP Act	Public Readiness and Emergency Preparedness Act
SARS	Severe Acute Respiratory Syndrome
SME	Subject Matter Expert
UCC	Urgent Care Centers
USG	United States Government
VFC	Vaccine for Children Program
VICP	National Vaccine Injury Compensation Program
VMBIP	Vaccine Management Business Improvement Project
VTrckS	Vaccine Tracking System

EXECUTIVE SUMMARY

The traditional public health model for mass vaccination, which is based on the assumption that workforce will be sufficient to mount a campaign, is flawed. Funding initiatives by Congress while addressing certain inadequacies, have failed to consider workforce capacity that continued to decline resulting from state and local budget cuts. Thus, as the nation prepared for its first pandemic in 40 years and first of the twenty-first century, it found itself unprepared for a mass vaccination campaign.

Two questions guide the research methodology for this thesis: What criteria should be used to evaluate a model to support pandemic vaccine distribution and drive policy development? How could a new model be designed to support pandemic vaccine distribution for a public health emergency of national significance?

Policy analysis was used to examine weaknesses in the current models, identify strengths and develop a hybrid model that could contribute to achieving the policy goal. Each model contains methods, technologies and outcomes that may likely be essential in support of mass vaccination for a public health emergency. Subject matter expertise was used to identify, shape and validate evaluation criteria (see Figure 1, introduced in Chapter IV) that were used to evaluate existing models and the proposed hybrid model. Subject matter experts represented stakeholders involved in vaccine distribution for either and/or both non-emergency (seasonal) and for emergency (pandemic).

Two current models of vaccine distribution were evaluated. A new hybrid model for pandemic distribution (depicted in Figure 1) was developed that addresses implementation difficulties that came to light during the nation's response to the 2009 H1N1 pandemic. Limitations of the two existing distribution models were found during the analysis. The findings that resulted from the evaluation and analysis of the existing models are threefold:

1. The Department of Health and Human Service pandemic vaccination distribution plan (PVD) is not executable.

2. There exists statutory, regulatory and licensure barriers to the use of alternative healthcare professionals as vaccinators

3. The nation lacks a comprehensive pandemic policy for pandemic vaccine distribution during public health emergencies of national significance.

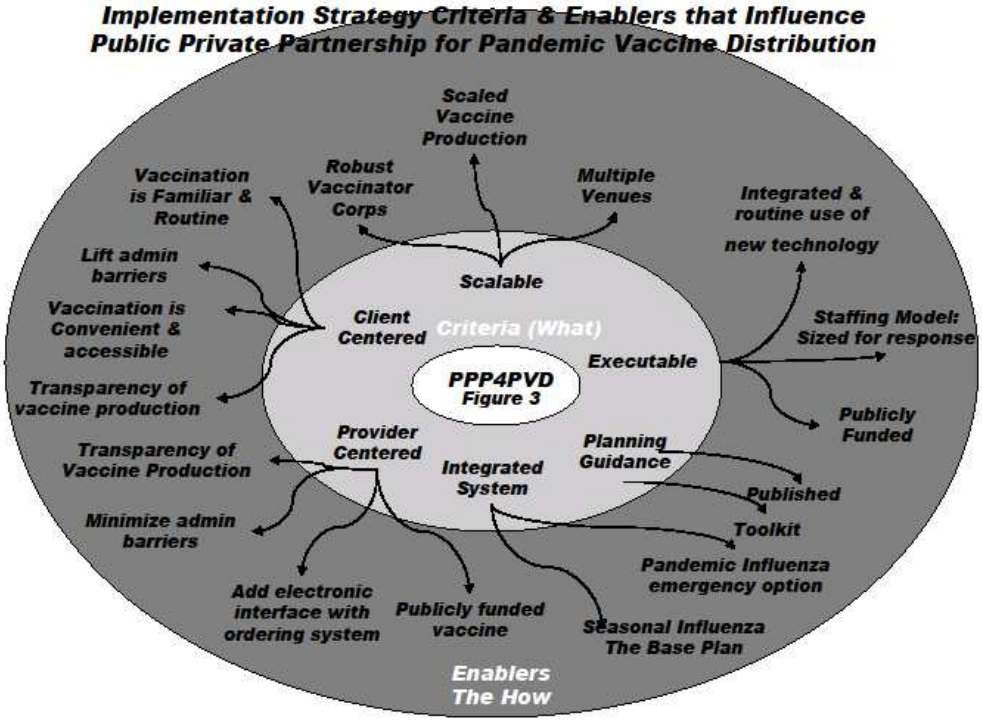

Figure 1. Criteria & Enablers that Influence Pandemic Vaccine Distribution

Three recommendations resulted from the analysis support development of a new hybrid model for PVD that leverages the use of a public private partnership. The first recommendation, change scope of practice restrictions that prohibit disciplines from serving as vaccinators in declared public health emergencies where vaccination is the mitigation strategy, targets the pre-pandemic period. Its aim is to extend the scope of practice among those disciplines whose professionals could also serve as vaccinators during a public health emergency for vaccination services. The second recommendation would be used during the inter-pandemic period and advocates the use of a single, integrated vaccination distribution system in which pandemic response is exercised

through each seasonal flu campaign. The third recommendation proposes the adoption of a policy for pandemic vaccine distribution during public health emergencies. A framework for the development of such a policy is outlined and comparable to the United States established policy of vaccine production self-sufficiency. A distribution policy brings congruence to the process of vaccination from production through distribution and includes administration. Pandemic response should not stop at vaccine production self-sufficiency but conclude with a distribution policy that supports the vaccine supply chain from production through administration and offers a comprehensive strategic solution for pandemic vaccine distribution.

Finally, the sudden emergence of the 2009 H1N1 Pandemic tested the nation's pandemic preparedness plans. The genesis for this thesis emerged in the early summer of 2009 as the nation announced plans for a mass vaccination campaign, the first in nearly 40 years. Planning efforts were not without confusion as conveyed by state and federal public health authorities as they debated strategies for vaccine distribution. Discussions between state and federal public health authorities proposed an alternative model of distribution that was unfamiliar to planners. This alternative model departs from the flu model used each season by the private sector and also departs from the public health model documented in federal planning guidance, which is used by planners to develop mass vaccination scenarios. The new hybrid model for pandemic distribution offers a new approach for efficient, rapid distribution of biological countermeasures.

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Execution is the chariot of genius.

William Blake

How insignificant William Blake's quote was before I began this venture, how central it is today with the conclusion of this endeavor. But the genius is the dependency on so many others that share a deep passion for the profession in which they work and their willingness to share their deepest convictions, thoughts and experiences with great candor. Their counsel and dedication is deeply appreciated.

There are two individuals in particular who pass me in the hallways each day, Dr. Covia Stanley and Faye Dorman, and for whom I have the utmost respect for their commitments to work, public health and the support of colleagues. Dr. Covia Stanley is not only supportive and encouraging but dedicated to the view that staff members pursue advance training opportunities. Without his support, I would not have either begun or continued this effort, especially in light of this past year's events. He is truly a leader who understands the professional's role to make a contribution to the profession, the discipline and/or the greater community. It is in this context that he doggedly pushes staff to advance professional and academically. I am one, but there are many that thank him for his persistence.

Then there are those that fill our shoes in our absence, and we all know them. Faye Dorman is a fellow colleague and was thrust into multiple leadership roles with expectations and performed with superb execution. During my first NPS in-residence, our agency was called to action in support of Horry County's largest forest fires but soon the H1N1 pandemic followed in its footsteps. How do you beat that? I thank her for stepping up and instinctively understanding the public health response and providing the leadership that our public health colleagues sought. Thank you, Faye.

Our public health region is supported by seven others regions and what is affectionately called "central office." Only 45 percent of states have an integrated system that consists of a state department of health and county units organized by regions like

that of South Carolina. I was able to call on multiple resources throughout this project with niche expertise to assist and to provide the wide range of background information that supported this project. I thank DHEC colleagues, Joanne Epley, Wendell Gulledge, Rebecca Morrison, Matthew Penn and Susan Smith for their counsel and insights, which contributed immensely to the didactic detail, inspiring further research and study.

A network of colleagues representing public, private, state and federal were extremely instrumental in sharing their pandemic knowledge, expertise and impassioned biases that leant much perspective and instigated some very robust discussions. I refer to this group as "stakeholders" but each made it personal and felt this project was a significant contribution and story that must be told. They committed 45 minutes for an interview but most ran 90 minutes. I thank each for their passion, candor and enthusiasm.

Two members of this network of colleagues are local physicians who represented both public and private sectors. They symbolize bookends of perspective, both strong proponents of pandemic preparedness, uniquely different professional experiences but united in patient care under extreme emergency conditions. Have to love them for that and their patients and colleagues do. I thank both Dr. Robert Ball and Dr. Gerald Harmon for their generous time, medical insights and strategic perspective of the pandemic operational environment that we confront in these unique public health emergencies. My hope is this project does justice to the perspectives they so candidly shared.

While I recognize and thank many, I cannot forget my thesis co-advisors, Lauren Fernandez and Richard Bergin, who are both faculty of the Naval Postgraduate School. Their yeoman support and constructive comments over six months shaped, clarified and challenged this project to keep it tight. My pace and their response kept this effort on track through each research aspect, and I am grateful and thankful.

Finally, sincere thanks to my family of friends (who were many) who showed much patience, picked up the slack in my absence and were very gracious with their support throughout this experience. They were there when I was not but equally present when I was, although my mindset was absent and focused elsewhere. After all this, Andie will look forward to more romps on the beach with her Kong toy. Love her for that unconditional love and always welcoming tail wag and whine.

I. THE NEED FOR AN IMPROVED PANDEMIC VACCINE DISTRIBUTION SYSTEM

A. PROBLEM STATEMENT

The United States has invested billions of dollars in pandemic preparedness including twenty-first century cell-based vaccine production, disease surveillance systems, laboratory facilities and planning at all levels of government; however, efforts to improve vaccine distribution had been sidelined and remained insufficient to meet the Department of Health and Human Service's goal (HHS) of vaccinating 300 million Americans in six months. A United States Government Accountability Office (GAO) report in 2004, underscored the limitations of the DHS (Department of Homeland Security) Pandemic Influenza Preparedness and Response Plan in regards to the lack of guidance for vaccine distribution and administration. It states, "The draft plan does not establish a definitive federal role in the purchasing and distribution of vaccine" (United States Government Accountability Office [GAO], 2004, p. 10). A recent gap analysis by the GAO of the nation's pandemic preparedness in 2009 point to continued gaps with vaccine distribution (GAO, 2009b, p. 7).

The HHS mass vaccination goal for a public health emergency is to vaccinate the population (300 million) in six months (HHS, 2005b). The implication is that vaccine supply is sufficient throughout that six month interim. A critical infrastructure protection analysis of the U.S. vaccine supply and distribution priorities by George Mason University (GMU) wrote:

> Under the currently existing capabilities for manufacturing vaccine, it is likely that more than 90% of the U.S. population will not be vaccinated in the first year" (2007, p. 16). The GMU analysis described the current pandemic vaccine distribution in the U.S. as "the inescapability of rationing. (GMU, 2007, p. 16)

Even as the nation works toward vaccine production self-sufficiency (Congress of the States Congressional Budget Office [CBO], 2008), the issues of distribution remain

unclear. The interest directed toward production capacity has overlooked and limited attention to the attrition of public health mass vaccination distribution capacity.

The current pandemic plan for mass vaccination revealed its weaknesses when the nation responded to the 2009 H1N1 pandemic. Public health did not have the infrastructure[1] to support mass vaccination as called for in federal planning guidance to support the HHS goal. As a result, staffing limitations of state and local departments of health (DoH) were supplemented through the Public Health Emergency Response grants to hire personnel to fulfill vaccinator roles and logistical support. The federal response depended upon state and local jurisdictions for pandemic vaccine distribution as a state-managed process. The assumption underlying federal mass prophylaxis plans is that state and local DoH staffing will be adequate for executing mass vaccination campaigns.

To understand the limited capacity of public health agencies in vaccine distribution, a useful distinction is to contrast seasonal influenza vaccine response by the private sector with the pandemic vaccine distribution by the public health sector during a national emergency such as the 2009 H1N1 pandemic. Public health[2] distributes and administers seven percent of seasonal influenza (flu) vaccine (Department of Health and Human Services [HHS], 2005, p. 4), but in a national emergency, such as the 2009 H1N1 pandemic, it distributes 100 percent of the volume or approximately 150 million doses. Distribution is dependent on the mass vaccination clinic using public health facilities, public schools and community centers. In contrast, the private sector[3] manages flu vaccine distribution for tens of thousands of frontline providers using its business process of centralized distribution, a portion of which was adopted for the H1N1 2009 pandemic.

[1] Public health infrastructure refers to workforce capacity including nurse vaccinators, personnel for logistical support and management team for command and control functions. In its broadest scope, it also includes federal and state laboratory system.

[2] Public Health refers to the system of state and local departments of health and the U.S. Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS).

[3] The private sector is defined as the five pharmaceutical companies that produce vaccine for the U.S. market, wholesalers and distributors along with their business processes of distribution.

This mix of distribution models deployed for a national emergency lacks a systematic, coordinated approach to pandemic vaccine distribution. Three problems persist and contribute to the current complexities of pandemic vaccine distribution:

1. Public health capacity has shrunk in terms of manpower and infrastructure.

2. The federal response targets priority groups for vaccination versus the mass prophylaxis guidance model used in planning and exercise scenarios. This causes a preoccupation with vaccine administration and retards distribution planning and logistical support requirements.

3. The private sector distribution model used for seasonal vaccine is sidelined when there is a public health emergency of national significance. As a result, private sector core competencies are not included in pandemic planning and exercise preparedness.

After years of pandemic preparedness, the nation in a public health emergency does not have a well defined, tested and exercised vaccine distribution system that will achieve the HHS goal and facilitate a rapid response. Each year, the private sector distributes vaccine to a broad network of healthcare providers, retail pharmacies and department stores, including state and local departments of health. Yet, this network is not used in a public health emergency. Each model has strengths that could be used in the development of a new model for emergency vaccine distribution.

B. RESEARCH QUESTIONS

What criteria should be used to evaluate a model to support pandemic vaccine distribution and drive policy development? How could a new model be designed to support pandemic vaccine distribution for a public health emergency of national significance?

C. ARGUMENT

The current public health infrastructure cannot adequately manage emergency vaccine distribution, and the public health distribution model is flawed. Effective public health programs have shifted vaccine distribution roles to the private sector while dismantling logistical support capacities such as vaccine refrigeration. HHS has

depended upon the mass vaccination clinic using public health facilities, public schools and community centers as the primary method of pandemic vaccine distribution. Yet, the public health sector has lost capacity over past decades. In contrast, the private sector manages seasonal vaccine distribution for tens of thousands of frontline providers using the business process of centralized distribution.

HHS should change the pandemic vaccine distribution strategy to incorporate a public private partnership. It should build upon the private sector seasonal influenza distribution system for public health emergencies of national significance. Furthermore, this strategy should consolidate distribution applications and publish doctrine that can serve as planning guidance for state and local public health jurisdictions.

The application of centralized distribution technologies demonstrates the ability of the private sector to manage vaccine distribution. This is witnessed annually as it distributes over 140 million doses to healthcare providers and retail outlets, both pharmacy and "big box" department stores (Health Industry Distributors Association [HIDA], (2009a). The feasibility for such a partnership exists technologically and financially as well. The public sector has partnered with the pharmaceutical industry over the last 50 years to produce critical vaccines. In this decade, the federal government has supported cell-based vaccine production technologies through countermeasure research and development authorizations.

After years of pandemic preparedness, the nation in a public health emergency of national significance does not have a defined, tested and exercised vaccine distribution model. The current public health infrastructure cannot adequately support emergency vaccine distribution and the distribution model is flawed. HHS must establish a strategic solution for pandemic vaccine distribution built upon a public private partnership for public health emergencies. This model should consolidate distribution applications and publish doctrine that can serve as planning guidance for public health jurisdictions.

D. SIGNIFICANCE OF THE RESEARCH

The literature defines the limitations of current vaccine distribution models but stops at providing suggestions for improving vaccine distribution during public health

emergencies of national significance. This research will look at current models and make recommendations, given the assumption that current problems due to vaccine production issues will be solved, and describe what a future distribution model should look like. In addition, the first decade of the twenty-first century has witnessed the nexus of biosecurity and public health as a focal point of national security policy discourse. This research will add to the literature of strategic solutions for pandemic vaccine distribution and seek to help protect the nation from public health emergencies; this requires a new approach to efficient, rapid distribution of biological countermeasures.

Future research efforts should revisit policy analysis research into countermeasure distribution given new technologies and an environment of public-private partnerships. Specifically, this research should inspire the development of planning guidance for state and local jurisdictions with the operational responsibility to distribute countermeasures to healthcare partners, high-risk groups, critical infrastructure sectors as well as the general public. The immediate consumer/customer of this research is policy makers responsible for public health emergencies including both federal and state practitioners.

Furthermore, the emerging role of biosecurity as a national security topic and the role of public health in the national security policy debate will grow as an area of interest for homeland security practitioners and national leaders. This research will describe the history of vaccine distribution under emergency conditions, the limitation of current distribution models and recommend a new model to support a nation where biosecurity takes a prominent role in the national security debate.

E. OVERVIEW OF CHAPTERS

Chapter I outlines the need for an improved pandemic vaccine distribution system in the United States. Chapter II reviews the literature that supports Chapter I, including an overview of related public health emergency response legislation, federal agencies and the public health infrastructure. It also introduces the limitations of current mass vaccination models. Chapter III describes the policy analysis methodology used to develop the model evaluation criteria and then used to evaluate current vaccination models presented in Chapters V and VI.

Chapter IV presents the results of stakeholder interviews used to identify, shape and validate the criteria used for the evaluation of the two models of vaccine distribution discussed in Chapters V and VI. The purpose of the survey was to use public health and private sector expertise to identify the desired outcomes of a mass vaccination strategy, whether pandemic or seasonal, and the strengths, weaknesses and the policies that drive each strategy.

Chapters V and VI are assessments of the respective models using the criteria presented in Chapter IV. Chapter V evaluates the current U.S. policy and implementation strategy for public health emergencies defined as the public health model. The chapter traces the historical basis for this model that has its roots in the polio and smallpox mass vaccination campaigns of the 1950s and 1960s. The chapter also describes the limitations of this model for public health emergencies where mass vaccination is the response strategy. Finally, the chapter explores the issue of limited vaccine production in the U.S., and the consequences for distribution options.

Chapter VI defines the vaccination strategy the U.S. uses each flu season as the private sector model. Approximately 90 percent of seasonal flu vaccine is distributed through the private sector and is a for-profit venture. The model is contrasted with the public health model, to show how the strengths of both should be blended into a new policy strategy for public health emergencies.

A new strategy for a public health emergency of national significance emerges in Chapter VII based on the criteria identified in Chapter IV and the analysis of the public health and private sector models reviewed in Chapters V and VI. This policy strategy is the public private partnership distribution for pandemic vaccine distribution model (PPP4PVD) and blends the strengths of the public health model and the private sector model. This chapter also shows how this strategy and the public private partnership model leverage the experiences learned from the 2009 H1N1 pandemic vaccine distribution campaign, outlines six goals to support this model and provides a framework for development of a pandemic vaccine distribution policy.

Finally, Chapter VIII explores strategic innovations essential to develop, support and implement PPP4PVD and lists three recommendations to sustain this model for vaccination distribution. This thesis will depict the limitations of current U.S. vaccine production, describe the U.S. policy of vaccine production self-sufficiency and advocate support for a policy of pandemic vaccine distribution. The premise of this thesis is that vaccine supply problems will improve and that policymakers and planners should begin to address vaccination distribution.

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II. LITERATURE REVIEW

A. INTRODUCTION

The nation's interest in biosecurity and bioterrorism in the twenty-first century has broadened the literature base as it relates to medical countermeasures,[4] mass prophylaxis, public health infrastructure and the role of public health in medical emergency response. Less represented in the discourse for vaccination distribution is the introduction of new methodologies, technology use or infrastructure expansion for addressing the vaccination goal of HHS.

This literature review incorporates Congressional legislation and testimony, government reports and studies, scholarly works both current and historical and documents representing the private sector who participate in vaccine distribution. It is divided into four major sections and several sub-literatures. The first section, Legal Authorities, provides an overview of Congressional legislation and its recent history to prepare the nation for a public health emergency of national significance. Sub-literatures within this section are public health preparedness legislation and the federal agencies and departments responsible for vaccine development, approval, procurement and distribution. It also includes an overview of vaccine program advisory groups.

The second section, Public Health Infrastructure, describes the public health system in the context of emergency preparedness and limits the discussion to federal, state and local government structures. The section reviews public health's capacity for mass vaccine distribution, manpower and, specifically, a review of those charged with vaccination, public health nurses. It explores the literature from government studies, testimony, scholarly works and professional associations that represent the disciplines of public health. Subsequent chapters consider the role of other public health partners,

[4] Countermeasures generically describe medical devices used to prevent and or protect individuals from chemical, biological, radiological or nuclear threats. Countermeasures in this thesis refer to vaccine and antivirals used to neutralize biological threats.

hospitals, healthcare providers and volunteer organizations, such as the American Red Cross (Congressional Research Service [CRS], 2005), during pandemic response.

B. LEGAL AUTHORITIES

1. Public Health Preparedness Legislation

Throughout the first decade of the twenty-first century, biosecurity topics became a major contributor to the discourse of national security. Public health legislation shaped the ability of the nation to respond to not only bioterrorism threats but emerging infectious disease outbreaks, producing a synergistic, dual-purpose benefit of investments and necessitating partnership with the private sector. Legislation has defined these relationships and how federal agencies managed the process in cooperation with the private sector pharmaceutical industry. Ironically, this is the same industry whose production capacity on United States soil has contracted over the last two decades of the twentieth century.

Legislation has addressed the limitations of the U.S. market economy and pharmaceutical countermeasure production, such as facilities, stockpiles or inventories, and the modernization of production processes in preparation for a public health emergency.[5] It is significant because it directs spending to incentivize pharmaceutical manufacturers to conduct research and produce pharmaceuticals of relatively small quantities in the event of biological threats with little market other than the U.S. government. U.S. national security interests have served as the basis for this legislation and resulted in contractual arrangements between the business sector and the federal government with public-private partnerships (PPP) being the end result.

Public health preparedness was the domain of state and local jurisdictions until The Public Health Improvement Act, was passed in 2000 by the Clinton Administration (Public Law 106–505). The 2000 Act expanded the federal role in state and local public health preparedness and response. A series of legislative acts throughout the first decade

[5] The Project Bioshield Act Public Law 108-276 of 2004 authorized the FDA to move forward with development and deployment of "unapproved medical products" or biological countermeasures.

of the twenty-first century continued this expansion of federal authority in state and local issues of health protection (Public Law 107-188, 2002; Public Law 108–276, 2004; Public Law 109-148, 2005; Public Law 109-417, 2006).

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), referred to as "The Bioterrorism Act," followed and established the public health infrastructure as critical to the nation's security (Frist, 2002). It worked to rebuild infrastructure and listed four primary provisions:

- preparedness for bioterrorism and other public health emergencies;
- control biologic agents;
- protect the food safety and water supplies;
- secure drinking water; and other provisions.

The 2002 Act legislated numerous changes to public health and medical response from the national level to local level. It established the office of the Assistant Secretary for Preparedness and Response (ASPR) whose role was to coordinate response with other federal agencies. It resurrected development of the smallpox vaccine and readied healthcare workers around the nation by organizing smallpox response teams and vaccinating its members. It expanded the Strategic National Stockpile along with the national disaster medical system response system. The Act touched not only HHS but the Food and Drug Administration (FDA) and U.S. Department of Agriculture. Countermeasures were developed and stockpiled, such as potassium iodide, anthrax vaccine and smallpox vaccine.

In 2004, the Project Bioshield Act of 2004 (Public law 108-276) was passed, amending section 564 of the Federal Food, Drug and Cosmetic Act (21 U.S.C 360bbb-3). This legislation authorized the FDA to move forward with development and deployment of "unapproved medical products" or biological countermeasures during a declared public emergency under Emergency Use Authorization (EUA). The H1N1 vaccine was developed and produced under the EUA. The Bioterrorism Act was followed by the Project BioShield Act.

The limitations of the BioShield Act were soon realized and in 2005, a BioShield Two or the Biodefense and Pandemic Vaccine and Drug Development Act of 2005 was introduced and passed by the Senate. It failed the journey through the House, but its provisions to address the limitations of BioShield Act found their way into P.L. 109-417, Title IV of the Pandemic and All-Hazards Preparedness Act. It established the "Biomedical Advanced Research and Development Agency (BARDA) within the Department of Health and Human Services (HHS)…to coordinate and oversee activities that support and accelerate advanced research and development of qualified countermeasures" (Gronvall, 2006, p. 175). Its scope was broad and targeted hazardous agents such as chemical and biological agents including bioterrorism as well as infectious diseases. It also included pharmaceutical products that may be required to combat either a "qualified" epidemic or pandemic. The act refers to not only vaccines, but antivirals and antibiotics, both those currently known as well as future products that may be required in the event of a new threat. It was BARDA that secured H1N1 vaccine from five pharmaceutical manufacturers in response to the 2009 pandemic under EUA.

The Public Readiness and Emergency Preparedness Act (PREP Act) was passed as part of the "Department of Defense, Emergency Supplemental Appropriations to address hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006" (Public Law 109-148, 2005). It provided liability protection and compensation for individuals who received a pandemic or epidemic countermeasure.

In summary, initially legislation strengthened the nation's public health capabilities to respond to bioterrorism. Subsequent legislation worked to broaden the scope to an all-hazards approach incorporating mass casualty and emerging infectious diseases. This section explored the role of legislation to shape, direct and fund the development, stockpiling and deployment of countermeasures in response to an act of bioterrorism or an emerging infectious disease. Vaccine production for the H1N1 pandemic of 2009 demonstrated a record series of actions resulting from legislative mechanisms introduced during the legislative period described above. More vaccine was produced than ever before, expedited by departments established for precisely this purpose while still addressing issues of safety, efficacy and contraindications.

2. Federal Agencies, Departments and Centers

Vaccine production is complex as witnessed by the myriad of federal agencies involved prior to application for licensure by a private sector pharmaceutical manufacturer. The limitations of distribution are understood by placing it in the context of the legal authorities over vaccine development, procurement, production and administration in the United States and the intricate role of federal agencies. The goal is safe but effective products that support the national vaccination plan.

The roles of federal agencies their missions, objectives and activities compliments congressional legislation introduced in the previous section and relates specifically to biological countermeasures. The mechanisms that support and contribute too many pharmaceutical public private partnerships begin to emerge as we understand vaccine production (GAO, 2004).

The Department of Health and Human Services' (HHS) National Vaccine Program Office (NVPO) is responsible for coordinating the roles and responsibilities of federal agencies and partners defined in the national vaccine plan (HHS, n.d. (d)). It is the plan that defines the numerous roles of federal partners, which lists 24. The HHS Secretary also is responsible for administration of contracts with manufacturers to purchase pandemic vaccine when an Emergency Use Authorization is authorized by the Food and Drug Administration (FDA).

The National Vaccine Advisory Committee (NVAC) is made up of federal agency representatives, members of academia and manufacturer representatives (HHS, n.d. (b)). NVAC was established to comply with Section 2105 of the Public Health Service Act (42 U.S. Code 300aa-5), assists with development of the national vaccine plan and serves in an advisory capacity for vaccine development and production to HHS. Members are appointed by the Director of NVPO.

The NVPO coordinates the many federal agencies tasked with vaccine and immunization activities and is responsible for implementation of the National Vaccine Plan. The goal of the plan is to prevent infectious diseases through immunization. This office works closely with the NVAC.

BARDA, also located within HHS, is responsible for "the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies" (Gronvall, 2009). This includes not only pandemic countermeasures, but all biologicals, chemical, radiological and nuclear countermeasures. It manages Project BioShield and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). PHEMCE coordinates communication and procurement between public stakeholders, stakeholders in industry and the research and development community and the federal government.

A vaccine is licensed by the U.S. FDA's Center for Biologics Evaluation and Research (CBER) (FDA, n.d.). CBER administers licensing over all biologic products distributed in the states. Manufacturers apply for licensing through CBER and must comply with applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. Four of five pharmaceutical manufacturers are licensed to distribute vaccine for the U.S. market but produce vaccine in plants located in Europe. Their products must comply with U.S. Customs' laws and therefore pass through the U.S. Customs Service.

The Centers for Disease Control and Prevention (CDC) has broad and numerous roles in addition to vaccine administration and distribution (The Centers for Disease Control and Prevention [CDC], n.d. (b)). Essentially, CDC is the operational unit and provides program implementation for the vaccination plan. Completing a restructure in 2008 after nearly a quarter center since its last restructure, CDC's "centers" encompass global health, health promotion, Occupational Safety and Health Administration (OSHA) and even health marketing. This discussion is limited to those roles in which it plays a role in pandemic vaccine distribution (PVD) such as the use of centralized distribution for the H1N1 pandemic.

A key initiative of the CDC is the Vaccine Management Business Improvement Project (VMBIP) begun in 2003. It represents "the first ever 'top-to-bottom' review of vaccine ordering and distribution (CDC, n.d. (e)),," and its purpose is "to improve current vaccine management processes at the federal, state, and local levels (CDC, n.d. (e))." One major component of the VMBIP is "Centralized Distribution (CD):"

> The centralized distribution of vaccine from two or three locations eliminates the need for multiple state and local depots. It reduces storage risk and distribution costs, while allowing more visibility into vaccine supply. The centralized distribution contract is held at the Federal level. (CDC, n.d. (e))

The National Center for Immunization and Respiratory Diseases (NCIRD), formerly known as the National Immunization Program, is charged with administration of the nation's immunization program (CDC, n.d. (f)). It is structured in the Coordinating Center for Infectious Diseases within CDC, which includes several companion disease control National Centers. It assists state and local DoHs with planning, development and implementation of immunization programs.

The Advisory Council on Immunization Practices (ACIP) is a key advisory body of immunization experts who advise and provide guidance to HHS and CDC on the administration of vaccination programs. According to CDC:

> The role of the ACIP is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. (CDC, n.d. (a))

ACIP advises CDC while the NVAC advises HHS and CDC. A third advisory group is the President's Council of Advisors on Science and Technology (PCAST), who advise the President on a wide range of science and technology issues including vaccine policy and practices (PCAST, n.d.). PCAST was announced by President Obama in April 2009 to advise the President on science and engineering. Administrations have formed experts in science, health and engineering to advise administrative officials since 1933.

An additional partner is the Laboratory Response Network (LRN), and it is grouped within the public health critical infrastructure. The mission of LRN, the network of federal and state laboratories is "to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies" (CDC, n.d. (d)). These federal agencies, departments and centers represent the federal

portion of the public health infrastructure. Collaboratively, they implement national policy and legislative actions to protect the nation against the threats of bioterrorism and emerging infectious diseases.

C. PUBLIC HEALTH INFRASTRUCTURE

A 2000 CDC report presented to the Appropriations Committee of the United States Senate called for strengthening the public health infrastructure to address emerging new global health challenges (CDC, 2000). Those challenges would come with the anthrax attacks in 2001, SARS in 2003, the aftermath of Hurricane Katrina in 2005, preparations for the threat of an avian influenza pandemic and, finally, the 2009 H1N1 pandemic that surprised health authorities around the world. But what exactly is meant by the public health infrastructure and what makes up public health at state and local levels of governments? The previous section introduced the federal structure. This section takes up the topic and looks at state and local jurisdictions and the affects of federal legislation and funding have had on those structures. Figure 2 illustrates the public health infrastructure for emergency response and describes three basic structures that support response:

- Workforce capacity and competency
- Information and data systems
- Organizational capacity

Federal funding, described in the previous section, funded primarily the middle of the pyramid, surveillance, laboratory practice and epidemic investigation along with initiatives for preparedness. It also permitted CDC preparedness grants to invest in the information and data system structures of public health. Workforce capacity and competency issues were left to the states. It is this structure that is described in the literature, before 2000 and continuing through 2009, as inadequate to take on the new demands of public health emergency response while continuing to provide core public health services. The CDC report provides a unique historical perspective:

> In part, this is the cumulative result of budget cuts, lack of staff training, and outmoded information systems and laboratories. But the gap has persisted and widened because in addition to this attrition, the demands on the public health system have grown. For both reasons, the public health infrastructure has not been able to keep pace. (CDC, 2000, p. 12)

With the exception of "outmoded information systems and laboratories" this statement could have been written in 2009 (CDC, 2000, p. 12). In 2008, the ASTHO workforce survey wrote, "a recent 2007 survey of ASTHO members confirm that little has changed in the past several years and that state governmental public health still faces a workforce crisis" (CDC, 2008, p. 3). It went on to state that the ratio of public health workers to 100,000 Americans had decreased by 10 percent over the past decade (CDC, 2008, p. 5).

Figure 2. Public Health Infrastructure Pyramid (From CDC, 2008, p. 6)

This thesis describes how legislation instituted mechanisms that expedited procurement of vaccine to mitigate the effects of the 2009 H1N1 virus. Other federal initiatives funded programs to develop capacities for pandemic preparedness and response to include mass vaccination. But governments at all levels were challenged by the complexities to deploy a workforce sufficient to support logistics and operational

requirements of the 2009 mass vaccination campaign called for by health authorities and the administration. These challenges were compounded by the impact of the economic downtown and the spiraling budget reductions for state and local jurisdictions. These budget reductions impacted public health by perpetuating the loss of workforce capacity. While there are several forces that impact public health and that discussion is beyond the scope of this thesis, it is important to frame and define those structures relevant to the discussion of pandemic vaccine distribution.

1. Workforce Capacity for Vaccine Distribution

Testimony presented to a Congressional committee by Cleveland's health commissioner illustrates the new demand on public health, such as preparedness. His testimony describes a city without adequate resources, a shrinking public health infrastructure and the lack of capacity to adequately respond to the 2009 H1N1 pandemic.

> Since 2005, community funding for public health preparedness in Cuyahoga County, including the City of Cleveland, has dropped from a high of $2.2 million to the current level of $1.3 million as the public's concern about a potential influenza pandemic has waned. Notably, funds for pandemic preparedness have been zeroed out in the coming grant year, which begins in August of 2009. This amounts to a 36% cut, with the likelihood of further cuts on the horizon. Over time, this trend is eroding our existing capacity and preventing us from developing the ability to meet our required target capabilities for local public health response. A compounding disadvantage emerges in the increasing list of local expectations in the face of these losses. Reversing this trend and sustaining funding levels for public health emergency preparedness must become a national priority. (Allan, 2009)

While specific public health disciplines have prospered due to targeted federal investments, the sheer numbers of workforce has decreased dramatically as a result of declining budgets throughout the twenty-first century. It is this workforce that vaccinates, completes paperwork, provides logistical support, fills antiviral and vaccine pharmaceuticals in compliance with DEA requirements, staff call centers, make appointments, staff clinics and numerous other activities that support a nationwide vaccination campaign, jurisdiction by jurisdiction.

A series of scholarly works, professional association studies and reports, historical enumeration studies and government testimony, conclude that the public health infrastructure is inadequate. For example, a 2002 report by the Institutes of Medicine, *The Future of the Public's Health in the 21st Century*, reinforced the inadequacy of the public health infrastructure first published in a 1988 landmark report (Institutes of Medicine [IOM], 1988). The 2002 report is significant because it established a baseline prior to legislation introduced after the 9/11 attacks. Fourteen years after the 1988 report, the IOM stated the situation had not improved (IOM, 2002).

Reports that followed the publication of the IOM 2002 report describe the continuing trend throughout this decade. For example, the Association of State and Territorial Health Officials (ASTHO) reported that a loss of 1600 public health jobs resulted in 2008 and another 2600 loss of jobs was projected for 2009 due to declining state revenue budgets (Association of State and Territorial Health Officials [ASTHO], 2009). Much of these job losses were public health nurses and administration personnel.

Public health professional associations call for an enhanced capacity at the state and local levels and recommend this expansion come from an expanded federal role in public health (ASTHO, 2009). Absent in the literature is the role of state government to support public health though states have examined their public health system status and report a need to increase capacity (Santiago, 2006). Equally absent is the role of the federal government in cooperation with professional associations to support and incentivize local and state expansion of public health capacity.

Limited capacity has undermined public health's ability to mount mass vaccination campaigns, yet planning scenarios call for this strategy. A review of the New Jersey TOPOFF exercise revealed the inherent weaknesses of its planning scenarios: "In point of fact, NJ [New Jersey] does not have enough manpower to meet its needs as demonstrated by the exercise, but officials ignore this lesson as they engage new plans based on old assumptions" (Santiago, 2006, p. 38). After nearly a decade of public health infrastructure investment, the sector continues to contract, losing staffing capacity

essential for emergency response. However, the foundation of the public health workforce is the corps of nurses who symbolize public health workers and represent the greatest shortage of all.

2. Public Health Nurses

The decimation of the public health workforce is best understood when exploring the public health nurse corps and its declining percent representation among all public health workers. Public health nurses have served as vaccinators for mass vaccination centers, an essential component for emergency response (Association of State and Territorial Directors of Nursing [ASTDN], 2008, p. 22; Quad Council of Public Health Nursing Associations [QCPHNA] 2007, p. 4). Enumeration has been inconsistent but does offer insights into the vaccinator corps that are depended upon to support mass vaccination clinics (ASTDN, 2008, p. 4).

Table 1 summarizes ratios of public health nurses tracked over the decades. In 1947, there was one nurse per 10,329 Americans or a ratio of 9.6 nurses per 100,000 populations. In 1968, the peak for mass vaccination campaigns, there was one nurse per 4,703 or a ratio of 21.3 nurses per 100,000. Forward to 2000 and the data shows another high point with 17.5 nurses per 100,000 or one nurse per 5,716 populations (ASTDN, 2008). By 2005, we see ratios begin their decline with 13.0 and 7,719 nurses per 100,000 (ASTDN, 2008).

Home health services delivered by public health peaked around 2000 and the private sector increased their involvement in home health services. As a result, public health nurses were siphoned off into the private sector and counts decreased. By 2005, we see a trend that continues through 2010 as the economy falters and public health budgets are cut. Table 1 shows this impact by contrasting nurse counts in South Carolina for 2000 and 2008, reflecting a 60 percent attrition of the state public health nurse workforce (W. A. Hucks, personal communication July 16, 2009).

The classic role of the public health nurse (PHN) was a trained nurse that worked in the community delivering a variety of patient care services such as communicable disease control, sexually transmitted disease control, tuberculosis control, maternity and

child hygiene, school hygiene and bedside care (home health for chronic diseases such as cancer and heart disease). The waning decades of the twentieth century through the first decade of the twenty-first century saw a dramatic decrease in the public health nurse workforce while simultaneously their expected role expanded to support public health emergency response for both pandemics and bioterrorism. In emergencies, sheltering or vaccination clinics, it is the public health nurse that is assigned emergency duty.

Nursing associations attempt to track numbers of public health nurses over many years but gaps remain. The difficulty with accurate enumeration has been all 50 states reporting numbers for any given survey year. ASTHO noted that in 2000, there were 36,000 public health nurses (ASTHO, 2007). But 16 states had not reported and ASTHO concluded that as of the report date, enumeration of the PHN workforce did not exist (2007). However, the same report writes that public health nursing experienced the most staffing shortages in contrast to other disciplines, with an estimated shortage of 28 percent (ASTHO, 2007, p. 20).

Table 1. Public Health Nurse to Population Ratio (After ASTDN, 2008, p. 9; Gebbie & Merrill, 2001, p. 14; U.S. Census Bureau, 2005)

Full-time nurses employed by state and local agencies for public health to population year	**Public Health Nurse (PHN)**	**U.S. Population**	**PHN per 100,000**	**Population per Nurse**
1947			9.6	10, 329
1950	15,867	150,720,000	10.5	9,500
1957			8.9	11,199
1960	16,341	178,729,000	9.1	10,937
1964	17,572	190,092,000	9.2	10,818
1968			21.3	4,703
1970			13.7	7,322
2000	49,232	281,422,000	17.5	5,716
2005	38,400[6]	296,410,404	13.0	7,719
		SC Population		
2000	1110	4,012,012	27.7	3,614
2008	464	4,479,800	10.4	10,158

[6] Workforce enumeration referenced 160,000 with nurses making up 24 percent of the workforce (National Association of City and County Health Officials, 2005, p. 2).

Professional nurse associations maintained ratios that date back to the early 1900s. In 1927, the recommended ratio of nurse (public health) to population was 1:2000 (ASTDN, 2008, p. 5). In 1943, the public health nurse to population ratio recommendation was changed to one public health nurse per 5000 population ASTDN (2008). The 1:5000 ratios were still recommended in 2008 by ASTDN (2008, p. 49). According to the report, the ratio is within reason of other health and medical professional ratios recommended by professional associations. For example, the recommended ratio for dentistry is 1:4000, mental health, 1:6000 and for physicians 1:3000 (ASTDN, 2008, p. 51). However, since the later part of the twentieth century, the number of nurses in public health has been reduced by 50 percent, according to ASTDN (2008, p. 49).

D. SUMMARY

Federal planning guidance for public health emergencies has emphasized the public health model with a decades-long planning assumption that states would have sufficient workforce capacity. Yet, this past decade has seen a continued, progressive decline in capacity as the nation was poised to address its first pandemic in 40 years. A consensus views the public health infrastructure as underfunded and inadequately resourced. It gains attention and focus with the events of 2001 but found lacking with the 2009 H1N1 pandemic, an incident of limited severity. Infused with $1.35 billion dollars of federal funds through the Public Health Emergency Response grants, state and local departments of health hired, contracted and supplemented existing full-time equivalent employees to execute the H1N1 pandemic mass vaccination campaign (Milner, 2009).

III. METHODOLOGY

This chapter describes the research methodology, sample population, data collection methodology and data analysis methods used to assist in answering the research questions posed in this study. This chapter also provides a discussion of the interviewee biases that emerged during the process.

A. RESEARCH METHODOLOGY

1. Policy Analysis

This thesis utilized policy analysis to evaluate two existing vaccination models and synthesize a new, third model for pandemic vaccine distribution. Policy analysis was selected to examine policy weakness in the current models, identify strengths (criteria) of those models and develop a new model that will achieve the policy goal. Each model contains methods, technologies and outcomes that can be essential in support of mass vaccination for a public health emergency. Subject matter experts (SME) were used to identify desired outcomes and shape evaluation criteria expected from implementation of these models. These model evaluation criteria were used to evaluate two existing models.

Three steps were used to evaluate existing models and develop the new model.

1. The first step was to identify, shape and validate evaluation criteria using an interview method. SMEs were interviewed in two rounds, the initial round to identify criteria and a second round to validate the criteria identified from the first round. In the second round SMEs were asked to rate 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 models using the model evaluation criteria that were identified, shaped and validated in step one.

3. The final step was to construct a model for pandemic vaccine distribution on the basis of the model evaluation criteria identified in step one, the evaluation of two models in step two. A comparative analysis of the literature provided context to frame the development of the new model.

The two existing vaccine distribution models evaluated were:

1. The public sector model is the policy and strategy for mass vaccination when a public health emergency is declared. It is the U.S. implementation strategy documented by federal planning guidance. This model dates to the 1950s and 1960s when mass vaccination clinics were used to defeat childhood infectious diseases such as polio, smallpox, etc.

2. The private sector model is represented by the seasonal influenza campaign and is a for-profit approach used each flu season. Vaccine is manufactured by the private sector, sold mostly to for-profit providers and distributed via the private sector. Its provider network is limited to the for pay sector, of which 74 percent includes physician practices (HHS, 2005a).

2. Delphi

The Delphi technique was selected to develop and establish the interview strategy and met the four features qualifying for Delphi. These key features are anonymity, iteration, controlled feedback and a statistical aggregation of the group's response (Rowe & Wright, 1999, p. 354).

Two interview rounds were conducted with each interviewee and interactions from each round limited to the researcher ensured anonymity during both rounds. A questionnaire was used to guide the interviews and provided controlled feedback from each SME. The questionnaire was scripted to ensure iteration from one interviewee to the next. Prior to round two interviews, evaluation criteria were developed from round one responses grouped by common themes (criteria) and factors (enablers) that supported those themes. A worksheet for use in round two was developed and distributed to each interviewee; it summarized the collective responses and described criteria and related enablers. The worksheet guided round two interviews in which respondents were asked to rate the relative importance of each criteria group and then rank order those criteria. From the round two interviews, six criteria were ranked and a median was calculated representing a modest statistical aggregation.

B. SAMPLE POPULATION

Sample selection consisted of individuals with vaccine distribution professional experience that served as the common characteristic among the interviewee group. Individuals selected served as subject matter experts and represented stakeholders involved in vaccine distribution for either and/or both non-emergency (seasonal) and for emergency (pandemic). SME experience represented policy, administration, academic (medical), state-level program operations, federal operations and national policy levels. SMEs represented local, state and federal levels of government, non-government organizations and the private sector. In addition, it included the personal experience of the author who serves as an emergency manager for a state public health agency and oversees regional and county preparedness, response and recovery efforts.

C. DATA COLLECTION

Subject matter expert interviews were used to answer the research question, "What criteria should be used to evaluate a model to support pandemic vaccine distribution and drive policy development?" The round one interviews were used to identify and shape evaluation criteria and evaluation criteria enablers. The round two interviews were used to validate the criteria.

The purpose of the research project was explained to each subject matter expert followed by an overview of the three sections of the interview consisting of nine questions. At the conclusion of the round one interview, each SME was reminded that round two interviews would be scheduled in a few weeks and that the round two interviews would explore the collective responses among SMEs interviewed.

The interviews were divided into four sections: 1) SME background information, 2) private sector model and the SMEs 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 SMEs experience and familiarity with vaccination policy, both seasonal and pandemic. It also offered an opportunity to understand the SMEs expertise and provide in-depth follow-up

in either of the subsequent sections of the interview. The second segment focused the discussion on knowledge, 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 discussion of the private sector model. The fourth segment solicited discussion of the ethics surrounding vaccine distribution.

The survey instrument consisted of a series of 16 questions and paralleled the four groups described above. Table 2 maps the primary research question to one of four segments groups and to a question reference number.

Table 2. Research Question Mapping to Survey Instrument

Research Question	Questionnaire Segment Group	Question Reference
What criteria should be used to evaluate a model to support pandemic vaccine distribution and drive policy development?	Vaccination policy and practice background	Q1, Q2a, Q2b
	Seasonal influenza and the Private Sector Model	Q3, Q4, Q4a, Q4b, Q4bi, Q4bii
	Pandemic Influenza and the Public Health Model	Q5, Q5a, Q5b, Q5c, Q6, Q7
	The ethics of vaccine distribution	Q8

The survey instrument guided in-depth interviews conducted in a conversational format either in-person or telephone with 45 minutes scheduled for each interview. Most interviews took about 60 minutes to complete with a few that further extended by 15 to 20 minutes. Interviews consisted of two rounds. The purpose of the first round was to identify criteria while the second round asked interviewees to validate the relative importance of the criteria and rank order them from one to six. Respondents were asked to describe their rationale for ranking each criterion's against the other criteria.

An open-ended question format was used, accompanied by a script for an overview to describe the purpose of the research project. Interviewees were instructed that the objective was to identify key criteria or outcomes that should be included in a

pandemic vaccine distribution system. Interviewee responses served as qualitative data that documented each interview. Responses were coded as enablers for a particular criteria consideration and grouped under a criteria heading using, in most instances the phrases and/or words of respondents.

Three biases became apparent during the SME selection process and subsequent interview process. The first bias unexpectedly occurred as a reflection of the 2009 H1N1 pandemic experience. All respondents were steeped in H1N1 response and, as a result, respondents defaulted to talking about their H1N1 pandemic experience. Most shared personal stories that contrasted what should be happening versus what was happening on the front lines of public health response. Their experience and passion made the discussion rich and robust but also biased the discussion to one pandemic experience. The limitation of this discussion was that it dealt with the reality of H1N1 versus state and federal implementation plans. However, H1N1 brought realism to the notion of "pandemic" that would otherwise have been an academic exercise without the realism or substance of what that experience was really like. H1N1 anchored their responses in terms of what is needed for a better pandemic vaccine distribution model.

The interviewer worked to adjust as it became apparent this would be the trend among respondents. The interviewer listened and documented the responses because they underscored a limitation or strength of the H1N1 vaccination model. In effect, these discussions revealed limitations of a public health model or equal limitations of elements of a private sector model that had been introduced to supplement the inherent inadequacy of the public health model. Eventually, the researcher would bring the respondent back to the target question in the context of the model being studied and reiterated the question.

A second bias was that state-level interviewee selection was limited to one state, South Carolina. The state has a centralized public health system with 46 counties organized into eight public health regions that delivered services to a network of counties. State departments of health are structured in one of three ways, centralized (South Carolina), decentralized or hybrid. States that have a decentralized system may have county departments of health reporting to a municipality or county governmental unit. Such is the case in North Carolina. The purpose of the survey was not to collect data on

state systems for responding to pandemic but to understand the mechanics and logistics of how those states integrated with the federal response under emergency response conditions. The research aim is to understand the strategic implications of pandemic vaccine distribution rather than the tactical decisions that direct a state-managed vaccine distribution process. In essence, vaccine distribution is managed 50 different ways.

Finally, the third bias is confirmation bias (Gardner, 2008). Confirmation bias is when a belief is held and content, information or experience that may subsequently be seen or heard is screened in such a way that it supports the belief. As a result of the literature review, the interviewer drew certain preliminary notions based on the analysis of the literature. The interviewer controlled for this by following the pre-planned questionnaire (Appendix A) and by avoiding interjection of information that would lead the respondent to state something that fit the researcher's preconceived notions. Rephrasing follow-up questions worked to probe a response and gain further insight into the significance or intent of the respondent. At the conclusion of the interview, a discussion ensued that shared findings from the literature review with the respondent.

D. DATA ANALYSIS

The objective in the first round was to identify evaluation criteria. At the conclusion of the first round interviews, responses were summarized and assessed for common phrases, words or descriptions that occurred with frequency. Key elements were tagged as enablers if they described how a process (the how) influenced an outcome (the what). Respondents described an enabler in the context of a vaccination campaign desired outcome. This context was preserved for subsequent coding of responses. Enablers were grouped and associated with a particular evaluation criterion.

At the conclusion of the interviews and during the subsequent analysis, the researcher introduced relevant criteria from the literature review and included criteria based on personal and professional experience. The purpose was to make certain all desired outcomes for a pandemic vaccine distribution campaign were included for discussion in the second round of interviews. The objective was to ensure that the evaluation criteria dataset and supporting enablers were comprehensive and that

interviewee's responses reconciled with the qualitative analysis of the literature. The results served as a standard reference point for round two interviews and analysis of results.

The objective of the second round of analysis was to validate evaluation criteria and enablers that support each criterion. Respondents weighed the relative importance of each criterion and the enablers associated with that criterion. Respondents assigned the value of each criterion as high, medium or low. Respondents were than asked why they assigned a particular weight to each criterion. The discussion was comparative, as respondents contrasted a particular score with another criterion. Once all criteria were assessed, respondents rank ordered evaluation criteria from one to six.

It became apparent to the researcher that the rating and discussion of relative importance had a calibration affect with each interviewee. The time lapse between the round one interview and the round two interviews ranged from two to six weeks. Thus, the discussion caused the interviewee to calibrate their focus on the topic of vaccine distribution and reassess both enablers and its related criterion. The outcome was a thoughtful, comparative and deliberative ranking of each criterion with a discussion about why they ranked each criterion as they did.

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IV. SURVEY AND INTERVIEW DATA

A. OVERVIEW

The results from two rounds of interviews and the development of the model evaluation criteria are presented in this chapter. The chapter synthesizes the comments offered by SMEs in response to the two rounds of interviews that were used to indentify and validate model evaluation criteria. Section B summarizes responses for each round of interview by question reference and develops the model evaluation criteria. Section C discusses the model evaluation criteria in the context of pandemic response and supporting literature. Finally, Section D defines the evaluation criteria used in Chapters V and VI to evaluate the public health model and the private sector model respectively.

B. DATA RESULTS AND ANALYSIS

This section summarizes the results of subject matter expert interviews. The first sub-section describes SME responses to the round one questionnaire. The second sub-section synthesizes the interview data into a set of model evaluation criteria and evaluation criteria enablers. Finally, the third sub-section describes how round two interviews were used to validate model evaluation criteria.

1. Round One—Identification of Evaluation Criteria

The survey of SMEs contributed to a comprehensive perspective on the limitations of current pandemic vaccine distribution models and the institutional barriers that prevent innovative solutions to problems inherent within distribution implementation. The data collected during the interviews resulted in the identification of evaluation criteria that were used to evaluate current models and strategies that support those models. Data collection also assisted to identify desired outcomes of a vaccination campaign, how best to maximize vaccination uptake and achieve herd immunity for the U.S. population and critical infrastructures. Below is a description of the interview

process, possible interviewee biases and a listing of round one interview questions used to better understand SME perspective, accompanied by a summary of responses.

Twelve first round interviews were completed and averaged about one hour each. The recent occurrence of the 2009 H1N1 pandemic colored the interviewee responses. As an example, when the first round the interview progressed into the second section where questions were directed toward the seasonal flu campaign, respondents referenced the H1N1 experience because two flu vaccine distribution initiatives were being pushed simultaneously. The H1N1 pandemic brought home the realty of a pandemic, testing pandemic plans at all levels. The level of detail may not have been as rich if the survey had been only an academic exercise without the benefit of a pandemic that had preceded it and having tested the public health system for emergency response. Table 3 provides a timeline of key vaccination events in 2009 that respondents referenced during the interview process.

Table 3. H1N1 2009 Pandemic Timeline of Events

Date	**Event**
24 Apr 09	Confirmation of first H1N1 case by CDC
01 Jun 09	First batches of H1N1 vaccine were produced
11 Jun 09	WHO declares H1N1 a Phase 6 Influenza Pandemic
15 Sep 09	H1N1 Clinical trials were underway
15 Oct 09	H1N1 Vaccine allocations begin to arrive in prioritized states and major cities
01 Jan 10	CDC recommends offering vaccine to all ages, all groups

a. Vaccination Policy and Practice Background

This section provided information on each SME's background in vaccine policy, supply and distribution both seasonal and/or pandemic that offered functional insights into the strengths and weaknesses of each model. It offered an opportunity to explore the SMEs expertise, especially if it related to a model weakness identified in the literature review. In addition, it provided a baseline for in-depth follow-up in either of the subsequent sections of the interview to explore factors that were either present or absent

as they relate to desired outcomes of a vaccination campaign. The section also frames the discussion for each SME in the context of policy as it relates to pandemic vaccine distribution.

- Q1: Tell me briefly your day-to-day duties.

Physicians were more likely to provide direct patient care than other disciplines interviewed. Other roles included professional association governance, education and consultation with both public and private sector physicians and a medical technical advisory role with the Department of Defense. Nurses served in a state program management role and involved with both seasonal and pandemic policy and budget. They also supported regional and local mass vaccination efforts. Those SMEs with roles in public health emergency management had responsibilities for critical infrastructure protection (CIP), coordination across federal specific sector agencies (lead agencies for CIP) and working closely with pharmaceutical vaccine manufacturers. Pharmacists had extensive experience in the private sector and public sector though their roles are now reversed. Each respondent understood how his or her counterpart sector worked, its limitations, strengths and contributions to pandemic emergency response. Roles and knowledge of pharmacists were not limited to vaccine distribution but applied equally to antivirals and other biologics. The ethicist that participated serves as a member of hospital bioethics committees and has chaired several pandemic ethics committees at local, regional and state levels. Operational personnel representing both the public and private sector understood clearly the mechanics of logistics and described the inter-workings of the systems they managed. Most SMEs had advanced academic degrees or extensive experience in a particular sector.

The backgrounds of SMEs included professionals from both public sector and private sector serving in local, state and national roles for pandemic preparedness and response. Academic credentials included physicians, nurses, pharmacists, emergency preparedness and business expertise. All have extensive experience with the vaccine supply chain from production, distribution, ordering, administration, including policy and operational perspectives. As a group, they represent pandemic vaccine procurement and distribution from both public and private sector perspectives. It is worth noting that

among the SMEs, several had extensive experience in one sector but now worked in the other sector, thus offering insights from both sectors as it relates to vaccine supply and distribution.

- Q2a: In your view, please describe the U.S. or federal policy for pandemic vaccination.

Several respondents were hesitant initially when the question was asked but generally, the range of responses revealed the lack of clarity regarding U.S. pandemic policy. One respondent referenced the executive order by the Obama administration and the subsequent funding by Congress of the order for H1N1 preparedness and response activities. This authorized the production and purchase of H1N1 vaccine and Public Health Emergency Program grants to states for response and staffing H1N1 mass vaccination clinics. Another respondent stated there is no policy for vaccination, only recommendations. When this respondent's answer was probed, the respondent stated that policy would have dollars associated with it and referenced the Vaccine for Children program. A similar response (no pandemic policy) was echoed by another respondent, adding that there was a clear change in distribution methodology (regarding H1N1) as the mechanics of distribution were worked out over the course of time. The respondent's point was that given a policy, operational and contractual issues would more likely have been worked out in advance of an incident.

- Q2b: Describe the U.S. or federal policy for seasonal vaccination.

A consensus of the SME panel expressed the view that there is no known federal policy as it relates to seasonal flu vaccinations. Several noted that the CDC Vaccine for Children program (VFC) reflects federal policy as it relates to the provision of vaccine for children with eligibility under Medicaid, uninsured, underinsured or Native Americans. It includes an element of seasonal influenza vaccine, administered through the states by providers that register and agree to comply with federal program guidance. One respondent noted that the policy relates to priority groups in the event of vaccine shortages.

b. Seasonal Influenza and the Private Sector Model (PSM)

This section narrows the discussion to the seasonal flu model of distribution. It asks SMEs to identify strengths, weaknesses and desired outcomes for the seasonal flu campaign that assisted in developing model evaluation criteria. This section also serves to frame the discussion for the next section.

- Q3: What has been your involvement (role) with seasonal influenza vaccine distribution?

Responses ranged from no involvement to the management and administration of seasonal influenza vaccines. Physicians were more likely to be involved in vaccination issues throughout the year while those in program administration and policy development were equally involved but as it relates to program development and implementation strategy.

- Q4: What is your familiarity with the Private Sector Model? (See definition below) Would you add anything to my brief description of the model?

> The Private Sector Model is represented by the seasonal influenza campaign and is a for-profit approach used annually. Vaccine is manufactured by the private sector, sold mostly to for-profit providers and distributed via the private sector. Its network is limited to the "for pay" sector, of which 74 percent includes physician practices. Public health distributes less than ten percent of seasonal flu vaccine in this model.

A consensus of respondents agreed with the definition of the private sector model. A few added footnotes as federal policy relates to seasonal flu vaccine distribution. For example, states can elect to expand coverage for children. State policy defines the parameters and the state funds vaccine purchase that covers those ages. The vaccine is distributed to providers who subscribe to the program.

- Q4a: What does it (private sector model) accomplish?

The general consensus of respondents is that the seasonal flu campaign prevents the spread of disease by distributing lots of vaccine rather quickly. A few respondents offered responses that conflict in terms of the profitability of vaccine production and distribution. One respondent stated that vaccine is not a profitable

industry and suggested this as one of many underlying reasons that there is no U.S. owned vaccine manufacturers. The sole U.S. based pharmaceutical manufacturer located in Swiftwater, Pennsylvania, Sanofi Pasteur, is French owed. Another respondent stated that it makes money for the private sector but the margins are low. Although Chapter VI explores the supply chain in detail, it basically begins at the plant, flows through wholesalers, distributors and eventually physician offices as well as retail outlets. Physicians report that for physician practices, due to the administrative time, required documentation and vaccine cost, it is a break even service provided to their patients. A few respondents offered the view that CDC does a pretty good job in promoting flu shots and educating the public that it is time to get protected against the season's top bug strains.

Several respondents also reported that as seasonal flu campaign has grown with an increase of vaccine manufacturers entering the U.S. market, non-traditional providers have gotten involved, which has expanded the provider network. For example, franchise pharmacies were referenced several times and that this sector is one that should be expanded further in support of both seasonal and pandemic campaigns. While there are regulatory limitations, some of which were worked through during H1N1, others remain. In South Carolina, a bill has been introduced that would allow pharmacists to provide vaccination without a physician's prescription. Currently, a pharmacist in a retail establishment must have a prescription by a physician to vaccinate. The workaround is for a standing order signed by a physician (in some remote area) to permit nurses to vaccinate in a retail pharmacy facility. During H1N1, it was learned that health insurance does not pay for prescription administration, an injection, while it does pay for vaccine. This would have to be addressed state by state to ensure 50-state coverage for pharmacists. The South Carolina example describes the work that must be done and its collaboration with legislative bodies and state medical associations.

- Q4b: What does it (Private Sector Model) not accomplish?

While the private sector model gets lots of vaccine into the provider network quickly, it leaves gaps for specific target groups. It was stated that public health

fills these gaps by having the ability to conduct vaccination clinics in offsite locations. The example of the public school vaccination campaign for the H1N1 response was referenced several times.

A few respondents reported that seasonal influenza is a limited service that physicians provide their clients due to the cost of product, administrative time and documentation. A state manager stated that due to the short vaccination period, large pediatric practices contracted for additional nurse services to assist with vaccination services. They cannot handle the volume in such a short period of time but the medical home does make arrangements on behalf of their clients. Another respondent described the current system as reactionary rather than proactive and advocated for a system that better approximated a universal vaccination program. The respondent suggested that a proactive system would push vaccine out to the provider network rather than wait for orders. Too often, physician orders arrive late in the vaccine ordering period resulting in vaccine that does not get into the distribution supply chain once the marketing campaign "that it's time" has begun.

- Q4bi: Are there important outcomes that must be included in a policy?

A few respondents stated, "Required vaccinations for critical infrastructure sector employees." This comment was made during the discussion as it relates to a pandemic in the context of sectors specifically healthcare workers who took an oath have a duty protect patients.

- Q4bii: Are there criteria in this model that should be re-evaluated?

Physicians strongly expressed the view that vaccinations for critical infrastructure sector employees should be required, especially for healthcare workers. In addition, the Vaccination Injury Compensation Program (VICP)[7] (HHS, n.d. (c)) should be expanded and incorporated into both seasonal and pandemic influenza programs. A few respondents, representing both public and private sectors, remarked that a publicly funded universal type program would push vaccine out to the provider network with

[7] October 1, 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Injury Compensation Program (VICP). VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines.

greater efficiency without the encumbering administrative workload placed on physician practices. One respondent stated that programs of this nature are measurable and would expect the results to be greater vaccination rates among the general public.

In summary, most respondents believed that the private sector model gets vaccine out to a growing provider network. The sector reflects innovation as the model expands to include non-traditional forms of vaccination both manpower and venues. Pharmacy was the non-traditional partner that was mentioned most often.

Vaccination service gaps were recognized among selected population groups (i.e., minorities), and all respondents recognized the role of public health to fill those gaps. Several noted the public health program VFC program that targets young children to ensure all children have access to the full scope of vaccinations that offer protection against childhood diseases.

Likewise, other limitations were noted. For example, the model is reactionary rather than proactive. Orders must be submitted by providers rather than vaccine being pushed out proactively in anticipation of a national seasonal flu campaign, which happens each year.

c. Pandemic Influenza and the Public Health Model (PHM)

This section focuses the discussion on the public health model of vaccine distribution. The questions in this section parallel those in the previous section but ask SMEs to contrast the public health model (PHM) to their experience with the private sector model (PSM) to help shape model evaluation criteria. Questions asked SMEs to identify strengths, weaknesses and desired outcomes for a pandemic vaccination campaign and not necessarily the H1N1 campaign. Most respondents answered this series of questions in the context of their most recent pandemic experience or the H1N1 response rather than on the basis of state and federal pandemic preparedness plans whose guidance describes the public health model.

- Q5: What is your familiarity with the Public Health Model for mass vaccination? Would you add anything to my brief description of the model? (See definition below)

> The Public Health Model is the federal policy and strategy for mass vaccination when a public health emergency is declared. It is documented by federal planning guidance that dates to the 1950s and 1960s when mass vaccination clinics were used to defeat childhood infectious diseases such as polio, smallpox, etc. but updated to address 21st century biological and emerging infectious disease threats.

Most respondents agreed with the definition of the public health model. Several respondents provided clarifications such as in the 1950s and 1960s the public health workforce was dramatically larger in proportion to the population it had to vaccinate. Respondents also noted that the workforce during that period was much more efficient, conducting mass vaccination on a routine basis. Several made comments about the adequacy of the public health workforce to support the model. A physician stated that the federal plan is a "non-executable plan" referring to the model as one without an adequate staffing component. Another respondent stated, "We no longer have nurses in blue uniforms that can do mass vaccination clinics." A third respondent noted that public health vaccination programs have been subjected to dismantling over the decades, much of which has been pushed into the private sector for routine vaccinations. This respondent underscored the point several times that public health is no longer the "medical home" for vaccinations. The implication is that today's public health workforce no longer has the capacity to vaccinate on the scale it did during an earlier period. In contrast, today's vaccinator corps is much smaller with training or "calibration of technique" required before vaccination. This held true for the 2003 smallpox campaign and for the 2009 H1N1 campaign.

Two state public health respondents commented that the public health model also includes a vaccine distribution management function that adds a significant logistics support function. The logistic function stems from the federal purchase of pandemic vaccine and than using CDC, state and local DoHs for the distribution function, which supplants the wholesaler/distributor function inherent to the private sector model. This creates a bottleneck for other providers (hospitals and physicians) that must go through public health for vaccine, as well as creating a burdensome workload for the public health administrative workforce as demonstrated by the H1N1 campaign. The

bottleneck results from a function that is not a routine capability for public health, does not have the staff infrastructure, nor supported by data management systems and for which there exists little to no training, exercising or methods on this scale.

- Q5a: What does it (public health model) accomplish?

A number of accomplishments were referenced by respondents but with no clear consensus. A few of these were presented in the context of the recent H1N1 experience.

- Gets a lot of vaccine out there in a relatively short period of time.
- Uses facilities that are familiar and routine, suggesting the public knows public locations and serves as a convenience factor. This was referenced as an example of why the public school campaign for H1N1 worked so well in so many states.
- It sends a message to the public that this emergency vaccination is important.
- Targets high risk groups through early prioritization.
- The private medical sector becomes dependent on the public medical sector for guidance and education.
- Keeps patients in their medical home.
- Tracks vaccine administration and vaccine adverse events.

A few respondents commented on the speed with which vaccine was produced and pushed out to states for mass vaccination—an unprecedented series of events that came together in an attempt to mitigate the H1N1 pandemic. The event was the first time clinical trials were conducted on an influenza vaccine in an attempt to assure vaccine safety. Another respondent commented that much emphasis by the federal government is on the vaccine supply side as demonstrated by this event. In contrast, less emphasis has been placed on the distribution side of vaccination. Another respondent added that federal purchase of vaccine assures manufacturers that they would sell all their vaccine during pandemic. In contrast, during seasonal vaccinations manufacturers must estimate what the market will bear, charge appropriately and than discard unused vaccine. The government pays for vaccine both what is used and what is discarded when it purchases it under emergency authorization use.

- Q5b: What does it (public health model) not accomplish?

Several respondents commented on communications that were inadequate whether those communications targeted the general public, health care workers or providers who served as vaccinators. As a result were required to interface with the state/CDC vaccine ordering system. Many viewed the low percentage vaccination rates among healthcare workers as due to inadequate education or lacking confidence in the H1H1 production process. Others made the point that federal officials did not make a positive case to refute the negatives of vaccine production that grew as vaccine got into the marketplace. A few commented on the positive aspects of the strategy; while, in contrast, several commented on failed messages that could have averted negative messages, which resulted in a mistrust of the H1N1 vaccine.

For example, one respondent referenced the early vaccine shipments that went to financial institutions, specifically Goldman Sachs. What the media did not report at the time was that these doses were earmarked for priority groups, pregnant women and children. The view was expressed that HHS/CDC officials should have intervened on behalf of not only Goldman Sachs, but other critical infrastructure sector partners who received vaccine early and had it earmarked for priority groups. Respondents felt a constructive message from CDC would reinforce the targeting of vaccine for priority groups through a variety of venues to reach those at greatest risk of infectious disease.

A few respondents commented that H1N1 kept patients in their medical home, and this was a tribute to the strategy deployed for this event. Conversely, the public health model (historically) did not include a strategy to reinforce medical home patient retention.

Several respondents commented on the inadequate data management system used for H1N1 to manage vaccine inventory. State level respondents remarked on technology strategies that they deployed early on to manage communications with participating providers. Two respondents with extensive private sector experience described a data management system as essential to support a vaccination campaign on this scale as a Supply Chain Inventory Management System. The comment was made that the data management function was fulfilled by using an “Excel spreadsheet,” but this did not prohibit job performance. As explained by respondents, states have one system that

was used to collect vaccine orders from providers. Some states elected to submit data daily while other states submit order data weekly. The data was uploaded to CDC where it was transferred to McKesson Corporation[8] for fulfillment and distribution to the provider network. As explained by a few respondents, the supply side management system competed with the distribution system. 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. It was pointed out that this type of a system is a routine function in the private sector, fulfilling pharmaceutical orders and distributing to a vast customer base of providers.

- Q5c: Are there important outcomes that must be included in a policy? Or, are there elements in this model that should be re-evaluated?

While education was cited by several respondents as a critical factor in a vaccination campaign, one respondent stated that a successful campaign is dependent upon a public that elects to participate, referencing the H1N1 effort. Another stated that pharmacists and their venues are not used as efficiently as they could be due to regulatory limitations. Many communities may not have a physician, but they do have a pharmacy and their use is too often discounted by other medical disciplines.

The use of technology was mentioned by several respondents throughout each interview, in reference to its application during the H1N1 vaccination campaign. Two respondents described how the CDC system competed with the application used to manage vaccine from manufacturers to McKesson. A few others mentioned that from their perspective, CDC was trying new systems out but it was apparent not all the bugs had been worked out. Another respondent stated that this model "needs to be responsive." The respondent defined responsive as a measure or a metric that assesses the movement of product quickly into the distribution supply chain. For example, a metric used in the H1N1 distribution was orders were filled the day they were received and delivered the next day. This measure was assessed daily, weekly and monthly.

[8] 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 contracted was expanded to support distribution of the 2009 H1N1 pandemic vaccine.

Probing respondents about technologies or strategies that may not have been effective as they could have been, respondents acknowledged that this (H1N1) was a tremendous response capitalizing on many systems that had been put into place over the last several years. Yet, a few respondents stated, “It caught us by surprise!” The next pandemic was to have come over from Asia. H1N1 came up quickly through Mexico. It was mentioned by several respondents that CDC adapted its VFC centralized distribution system to distribute H1N1 vaccine to a provider network that had yet to be recruited. This placed state and local departments of health in a position to build state and local vaccinator provider networks…without computer applications in place. These were adapted as well. A few respondents stated that instead of database management systems being used to manage data, Microsoft Excel worksheets were used. They stated that investment needed to be made in a supply chain inventory management system. A follow-up question was raised “why do we not have these now,” and the response was that “scientists have been involved rather than personnel experienced in business practices.”

One respondent commented on the nexus that occurred between “immunization” and “preparedness” throughout the planning stages for the H1N1 vaccination campaign among state and federal planners. This researcher found this to be a significant insight because it gets at “who is in charge during a public health emergency?” among other issues of command and control. H1N1 served as the first public health emergency of national significance in which public health served as lead in an emergency in which agencies operated within the NIMS environment. This becomes a tactical planning issue more so at a state level than federal level but plays out at the local operations level.

- Q6: What has been your involvement (role) with pandemic vaccine distribution, tactical or strategic?

Respondents were evenly divided between responsibilities that were identified as either tactical or strategic. Those respondents with roles at the federal level

identified their roles as strategic while those at state or regional (local) were more likely to describe their role as tactical. Private sector and national association respondents operated at the strategic level.

- Q7: What do you see as the desired outcomes for a pandemic campaign? Are there outcomes that either of these distribution models is not addressing that should be included in a pandemic vaccine distribution policy?

Responses ranged from strategic to tactical, depending on the role and experience of the responder. Generally, the desired outcomes of a pandemic vaccination campaign were described as population health and stability and critical infrastructure protection. Population health, or the prevention of disease, should be accomplished by achieving a high vaccination rate. Follow up questions probed what was meant by "high percentage rate," and several respondents identified the range of 60–80 percent as a rate that would achieve herd immunity.

Most respondents, at some point in the interview, commented that a pandemic vaccination campaign should be based on familiarity and routine or what is normal for the public and for those who would care for them. Physicians were more likely to comment on the burdensome of vaccine ordering and administration while others directed comments to how the public is served. For example, one respondent commented that a desired outcome should be to "lift administrative barriers" to improve vaccination response. Some consensus surrounded the notion that either vaccine availability or vaccine distribution should integrate both pandemic and seasonal flu into a single system. A pandemic vaccination campaign should layer into a seasonal vaccination campaign and minimize the confusion during the 2009 H1N1 campaign when two vaccines were seen as competing for the public's attention.

Most respondents offered personal stories that reflected a story that could have been told by any member of the general public; they were frustrated with their inability to get an H1N1 flu shot for a family member or themselves. The irony is that due to their work role, they had access to thousands or millions of doses, yet vaccine was not in the distribution network, and therefore, inaccessible to family members, target group individuals or the general public. Their point was that a distribution system "must

get vaccine out there" which respondents contrasted with the private sector model that, for the most part, gets it out there. Several respondents voiced the view that vaccine distribution should be conducted as efficiently as possible and draw upon the core competencies of the public sector and the private sector. Most expressed the view that the distribution model should reflect a partnership of sectors building on the core competencies of each sector and the model should be proactive rather than reactionary.

Several respondents suggested that pandemic campaigns must tailor distribution strategies to accommodate the lifestyles of today's public. One respondent's comment captures the consensus view expressed by most respondents:

> The public wants a fast food approach, convenience and accessibility which, is why the public school vaccination campaign (H1N1) worked so well, a captive audience, with no waiting, and minimal parental involvement.

In summary, H1N1 brought into focus the limitations of the public health model to support pandemic response from several perspectives. All respondents noted the limitations of staffing to support the public health model, with several noting that the model is not executable as currently resourced. The assumptions on which the model was established have changed dramatically but implementation strategies do not reflect decades of devolution. A companion issue is the limited use of technology as a strategy incorporated into the model. The H1N1 response brought about several implementation strategies from national and state to support distribution. Respondents noted that technologies had to be adapted or created to support vaccine distribution and contended this issue contributes to a non-executable plan. The other observation that surfaced by several respondents was the need for a separate distribution structure to manage, distribute and administer a vaccine during a public health emergency. Several suggested there should be a single system that simply scales for emergency response when vaccination is the response strategy, in contrast to one system for seasonal flu and another for pandemic. It was noted that VFC represents a third model upon which the H1N1 vaccination response was constructed.

Finally, several respondents noted a federal preoccupation with supply-side issues and less emphasis on distribution limitations. This was discussed often in the context of vaccine allocation, target groups and who gets first choice of limited vaccine doses. Then in the end, allocation priorities changed, which resulted in confusion among critical infrastructure planning partners and the general public. In the end, the public grew weary and moved on.

d. The Ethics of Emergency Vaccine Distribution

Vaccine distribution during public health emergencies is intended to allocate vaccine fairly and equitable to groups at greatest risk. Much discussion ensued throughout the interview process. This section captures that discussion while by asking each SME to assess whether or not these models are achieving the intended results and what evaluation criteria should be used to determine if candidate models fit with ethical concerns or issues.

- Q8: What ethical principles do you think are involved in these respective models?

The consensus by most respondents was that the implementation of priority groups, targeting those at greatest risk, was the most ethical allocation of limited vaccine resources. A few stated the utilitarianism principle of "the greatest good for the greatest number" and that allocation of vaccine pits public health versus clinical practice in conflict. But these views were based on the H1N1 experience so the premise of the question (U.S. vaccine production self-sufficiency) was articulated and respondents asked again. Most respondents conveyed the notion that vaccine would not be plentiful immediately but would be distributed via batches. Thus, in the early stages of vaccine distribution, there may still be a need to allocate based on initial pro-rata allocation schemes.

The topic of the CDC vaccination priority groups was introduced early by several respondents. This topic provided the opportunity to explore the ethics of balancing vaccination of those at greatest risk in contrast to all who wish to be vaccinated in order to achieve herd immunity. When respondents were probed to give a percentage

of a population vaccinated to achieve herd immunity (protection of the community), several respondents offered a range from 60–80 percent. One respondent did convey the view that even vaccinating those at greatest risk achieves herd immunity. He claimed that those at greatest risk serve as primary vectors and can infect many others due to the proximity of social distance. Public school children sequestered in a classroom for seven hours a day illustrates this concept. One respondent statement captured the collective discussion:

> To provide the maximum prevention and protection for the public, and articulate the reasoning for logistical reasons, distribution priorities and target groups.

As presented earlier, several respondents remarked on the need to educate healthcare workers, particularly nurses, with the implication that education would work to overcome their reservations about pandemic vaccine and vaccination. A few remarked that medical professionals take an oath with an obligation to provide care, knowing the risks that they may face in their professional career. This speaks to the ethical principle of "duty of care" and, conversely, the responsibility of society to protect those who put themselves in harm's way. This is reflected in the CDCs priority ranking with healthcare workers at the top of the list.

Finally, the broader ethical perspective was expressed by one respondent and stated the current medical model of medicine is that the sickest patients get first claim on medical resources. Medical system structures support this view such as legal, insurance and physician scope of practice. Yet, in a pandemic the view shifts to patients with the best chance of recovery get first claim on limited medical resources. The challenge becomes how to engage partners in a collaboration process to lay a foundation that will support these ethical principles before a public health emergency of national significance. The discussion of the ethical principle of "duty of care," thus far, is centered on the individual healthcare worker. But it equally applies to the institutions (i.e., professional associations) that support healthcare workers and maintain policies or credential practices that prohibit the use of scarce skill sets in a public health emergency.

2. Development of Evaluation Criteria

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). Data that represented a particular vaccination outcome was tagged a "what" while data representing a "how" was tagged an enabler. An enabler was defined as a process that supported a particular outcome or criteria (see Table 4). Enablers were sorted based on the interview discussions that related to a major theme. For example, several respondents described the "need to educate" selected groups, such as the public or nurses. Those discussions or themes were associated with a particular group such as client or provider. Another example, "publicly funded vaccine," was associated with the nation's ability to execute a plan, recruit providers or incentivize clients to participation in vaccination.

The epidemiologic model of "web of causation" was used to model and depict the inter-relationships among the enablers and criteria (see Figure 3). The web of causation was introduced in the 1960s to show relationships among causal factors of disease and especially the chronic diseases as research sought methodologies to understand cause and affect (Duncan, 2007). The web of causation model was used to explain heart disease and cancers (such as lung cancer) whose causal factors were not limited to a single cause but reflected other influences such as behavior, heredity and social circumstances. The model contrasted disease causation from multiple factors versus disease that results from a single agent (i.e., H1N1 virus) illustrative of the germ theory of disease. The survey revealed that several factors contributed to more fully understanding the dynamics of vaccine distribution. Figure 3 summarizes the relationships among enablers and criteria and conceptualizes how criteria relate to a model of vaccine distribution. The development of the evaluation criteria and the enablers that supported each criterion served as the next step in preparation for the validation interview or round two.

Table 4. Desirable Criteria for a Pandemic Vaccine Distribution Strategy

Evaluation Criteria	Brief description	Evaluation Criteria Enablers
Executable	A pandemic plan developed from a policy implementation strategy must be sufficiently resourced that it can be efficiently executed	Integrated & routine use of technology Staffing model: Sized for response Publicly funded vaccination campaign
Scalable	A policy implementation strategy must be scalable upward or downward in response to an intelligence-based biological threat	Scaled vaccine production Robust vaccinator corps Multiple venues
Client-Centered	A policy implementation strategy must maximize client-centered strategies to achieve the vaccination campaign goal	Vaccination is familiar & routine Vaccination is convenient & accessible Transparency of vaccine administration and production Lift and/or minimize administrative barriers
Provider-Centered	A policy implementation strategy must maximize provider-centered strategies to support and achieve the vaccination campaign goal	Minimize administrative barriers Electronic interface with ordering system Transparency of vaccine production Publicly funded vaccination campaign
Integration	A policy implementation strategy must build on a seasonal strategy and exercise pandemic response	Seasonal influenza: The base plan Pandemic influenza: Emergency option VFC Program: Special needs population
Federal Planning Guidance	A policy implementation strategy must reflect federal guidance and frame planning continuity from local, state to federal levels	Published guidance Administrative toolkits

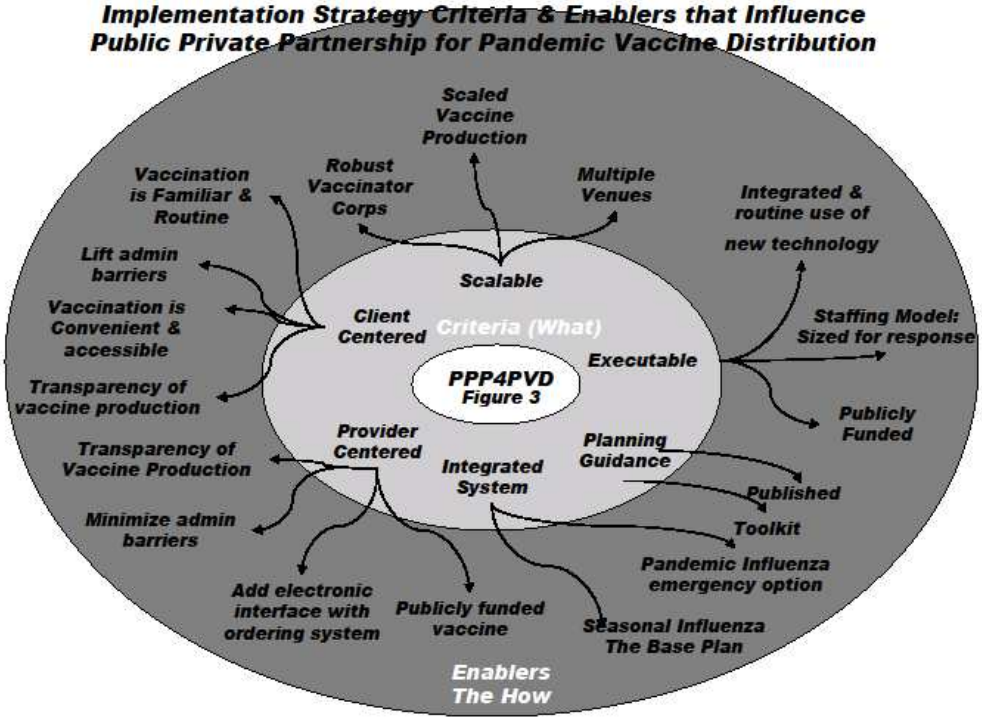

Figure 3. Criteria & Enablers That Influence Pandemic Vaccine Distribution

3. Round Two—Validation of Evaluation Criteria

Round two interviews used a criteria evaluation worksheet (Appendix B) to guide the discussion that accompanied the assignment of relative importance for each criteria and a rank ordering all six criteria. The worksheet grouped enablers by criterion and supplemented with a narrative description. The worksheet was electronically distributed in advance of the interview to allow each respondent to review the collective results from round one. Each respondent was directed to consider each criterion and its enablers and then rate its relative importance as high, medium or low. Discussion was encouraged, and the researcher asked why the respondents rated as they did. This process was completed for all six criteria.

The second step was then to rank order all six, from one through six, from most important to least important. The rank ordering usually led to further discussion of the importance of one criterion over another, and the respondents weighed each criterion in make that assessment. Once the assessment concluded, the respondents were asked if there were any criteria that had not been included but all respondents reported that they felt the list was rather comprehensive.

Tables 5 and 6 reflect round two assessment of the evaluation criteria. Table 5 shows the relative importance of each criterion in terms of the respondent's view of its importance while Table 6 shows the rank order of each criterion. Table 5 lists respondent's rating of each criterion, as high, medium or low. Respondents were asked why they rated the criterion as they did, and their comments follow the tables. The discussion by respondents revealed many interdependencies among the criteria and the enablers that support those criteria. The discussion that follows reflects their comments.

Table 5. Evaluation Criteria: Relative Importance

Respondent	Evaluation Criteria: Relative Importance					
	Scalable	Integration	Client	Executable	Provider	Guidance
1	High	Med	High	High	Med	Med
2	High	Med	High	High	High	High
3	High	Med	High	High	High	High
4	High	Low	High	High	High	High
5	High	High	Med	High	High	Med
6	High	High	High	High	High	Low
7	High	High	Med	Med	Med	Med
8	High	High	Med	High	Med	Med
9	Low	High	High	High	High	Med
10	High	High	High	Med	Med	High
11	High	Med	High	Med	High	Med
Median	High	High	High	High	High	Med

Table 5 lists the relative importance assessments by the SMEs from round two interviews. The criterion scalable was rated high most often followed by executable and client-centered. The median value for each criteria shows five of the six were rated high. Only the median value for guidance was a medium.

Table 6. Evaluation Criteria: Rank Order

Respondent	Evaluation Criteria: Rank Order					
	Executable	Scalable	Client	Provider	Integration	Guidance
1	2	1	3	4	5	6
2	1	3	5	4	6	2
3	1	5	4	3	6	2
4	1	3	4	2	5	6
5	1	6	2	3	4	5
6	1	4	3	2	5	6
7	4	2	3	5	1	6
8	1	2	5	4	3	6
9	2.5	6	4	5	1	2.5
10	5	4	2	6	3	1
11	4	3	1	2	5	6
Median	**1.00**	**3.00**	**3.00**	**4.00**	**5.00**	**6.00**
Range	**1-4**	**1-6**	**1-5**	**2-5**	**1-6**	**1-6**

Table 6 lists the rank order scoring of the evaluation criteria by respondent. The median score for the evaluation criteria revealed that "executable" (1.00) was viewed as the most important criterion followed by "scalable" (3.00) and "client-centered" (3.00). These were followed by provider-centered (4.00), "integration" (5.00) and "federal planning guidance" with the lowest ranked criterion at 6.00. The discussion that follows highlights enablers that resonated with respondents and the views expressed to either support or express reservation about a particular enabler.

C. DISCUSSION OF EVALUATION CRITERIA

Respondents were generally unanimous that executable was a key criterion for policy development but often would draw relationships between it and scalable. Two criteria, integration and guidance, showed the most variance in respect to both relative importance (Table 5) and variation in the ranking scores for each. The criteria are discussed in their rank order as displayed in Table 6.

1. Executable

Most respondents viewed this criterion and its enablers as critical to the success of a pandemic policy. One respondent shared the anecdote that his wife went to a local

department of health only to learn that it was not a vaccination clinic day; no staff were there to give shots and she would have to come back. To this respondent, vaccinators sufficient to staff multiple venues were seen as significant to support a vaccination policy. While respondents supported a staffing model sufficient to meet the goal, its interdependency with scalable was noted due to the staffing component. Discussions were introduced covering the use non-traditional providers and venues to support executable; those discussions continue in the scalable section.

Public funding was seen as critical for activation of an emergency plan and mobilization of the nation for mass vaccination. The act of a publicly funded emergency vaccination campaign sends the message that this is important and readies the population for vaccination. A contrasting message, stated by several respondents, was that while the public gets the message, the bureaucrats, who are responsible for administration of those funds at both federal and state levels of government, did not get the same message. Much frustration was expressed concerning the hiring of personnel for critical positions, which took too long, procurement of supplies, the processing of memorandum of agreements and the simple mobilization of logistical support for which public health was neither staffed, trained nor equipped to direct. One respondent noted that an objective was set to fill a critical H1N1 coordinator by September 1, 2009; however, it was well into November before the individual came on board. Another respondent stated, “It took too long to hire people,” and “we added more bureaucrats than we added vaccinators.”

Public dollars also fund ancillary supplies, such as syringes, alcohol swabs, cotton balls and medical waste buckets, which were described from both a strategic (national) and tactical (state) perspective as “huge.” Even though both state and federal respondents stated that they encountered bureaucratic hurdles, their view was that the ancillary supplies to support a campaign were keys to recruiting and expanding the provider network. One respondent shared a contrasting view that the time it takes to work through bureaucratic hurdles, “we lose capacity.” For example, when the funding request was submitted to the Office of Budget Management, it was initially rejected. In the interim, Canada went into the market place and bought six million syringes. Canada, with a population of 30 million, purchased one-fifth of its requirements. The U.S. government

(USG) competes in a world economy for resources that become scarce quickly, and in a national emergency, bureaucratic dithering does not support emergency response.

Federal planning guidance issued to the states described key planning issues for planners and states that vaccine would be purchased by the USG: “Pre-pandemic and pandemic vaccines was purchased by the federal government and distributed to project areas, who was to determine allocation of vaccine within their jurisdictions” (CDC, 2006, p. 6).

Less certainty surrounded the purchase of ancillary supplies in early guidance (CDC, 2006, p. 11), but as revealed in the survey, the USG did purchase these supplies and distributed through its contract with McKesson.

2. Scalable

The three enablers that support the scalable criteria were viewed as key to a successful pandemic policy and represented interdependencies with other criteria. One respondent noted that these two criteria (executable and scalable) represent both sides of the same coin.

A few respondents were most troubled by the “scaled vaccine production” enabler, viewing it as most likely unachievable due to two key factors. Otherwise, they rated the other two enablers that support scalable as high. The two factors pointed out were:

1. The fact that response is driven by the epidemiology of the infectious disease.

2. Due to long production cycle required for vaccine production and factors uncontrollable, this is not doable.

The basis of the first factor, vaccine insufficiency, drives who gets vaccine first. H1N1 revealed how pandemic plans for vaccine distribution can be changed weeks before vaccine is set to arrive at provider’s front doors. One responder noted that “change of target groups” caused consternation when the Tier Group Targets were changed from critical infrastructure private sector partners (i.e., financial) to pregnant women and

children. It caused confusion among federal agencies responsible for communicating this information to private sector CI/KR partners. This illustrates how the epidemiology of a disease, given scarce sources of vaccine, can rather quickly change who gets vaccine first. The planning guidance did alert planners to account for a shift in target group priorities (CDC, 2006).

The context for factor two was the H1N1 pandemic vaccine whose production cycle was impressive given the timeframe to produce a vaccine. But this experience is shaping actions and corrective actions for the next pandemic, so it must not be discounted and, therefore, it enters into the discussion. The severity of H1N1 in Mexico was extremely high initially, in addition to the attack rate. The case fatality rate exceeded 65 percent.[9] A U.S. National Center Medical Intelligence (NCMI) disease intelligence estimate stated:

> NCMI assesses with medium confidence 2009-H1N1 influenza illness rates two to five times higher than those caused by typical seasonal influenza are possible in areas where vaccination and other countermeasures are not applied (United States National Center Medical Intelligence. [NCMI], 2009, p. 2)

The President's Council of Advisors on Science and Technology (PCAST) (The White House [TWH], 2009) laid out the strategic implications for the While House with H1N1 that supported the decision to protect the nation against the H1N1 threat. These documents, among others, supported the decision to produce vaccine to protect most of the nation's population on the basis of the known epidemiology of the disease. Once production was set into motion, scaled vaccine production was not possible given the methodology used to produce vaccine or chicken and egg vaccine methodology. The timeline, production phases and investment required for vaccine production was the basis for which respondents were troubled by the concept of vaccine production scalability.

One respondent described the lengthy production cycle, which requires the purchase of embryonated eggs and the harvesting of eggs and vaccine. This is followed

[9] Case Fatality rate (CFR) is calculated by dividing the number of deaths by all who contract the disease, confirmed by laboratory tests.

by readying it for bulk shipment before finishing. The testing and approval by FDA follows, and the lab-testing is conducted by both the manufacturer and FDA. Finally, each lot is approved by FDA.[10] A manufacturer would not take on this task unless a contract was in place or the product can be sold and a return on investment can be made. Operations must be scaled up, resources committed, and a lead time of six months does not permit scaled vaccine production.

These were the issues raised by respondents, but this was in the context of today's conventional methodology for producing vaccine and demonstrates the rationale that supports the U.S. government's decision to invest in cell-based vaccine production, which eliminates the need for eggs. The respondents with apprehensive views about scaled vaccine production were reminded that the premise for this set of criteria was that the U.S. was near vaccine production self-sufficiency and producing cell-based vaccine. A refocus on a future with cell-based technology modified their views in support of scaled vaccine production. One respondent stated, "Yeah, much easier." Cell-based technology eliminates egg requirements and shortens the process time. Once the discussion was framed in the context of cell-based methodology, then apprehensive respondents recalibrated the relative importance of scalable to high.

Several respondents drew relationships between scalable, executable and provider-centered, with sufficient staffing as the thread to tie the three criteria together. A few respondents noted that "scalable makes the plan more executable." Reference was made to the use of non-traditional providers to provide the necessary scalability. Barriers were noted with use of non-traditional providers, indicating the resistance of other health professional associations that have lobbied against the use of non-traditional providers to vaccinate. One respondent noted these are the "force multipliers we should be using." To address the use of non-traditional providers across the nation and state by state would require the effort that it took states to upgrade their public health emergency laws

[10] Lot sizes differ dependent on the container size used by a manufacturer. For example, one manufacturer uses a bulk container that can hold a lot size of 660,000 doses of vaccine. When vaccine is shipped initially by a manufacturer, it is shipped in bulk. Finishing plants ready vaccine for vaccine administration such as multi-dose vials (10–15 doses), pre-filled syringes or nasal spray formulations (anonymous survey interview, May 19, 2010).

following 9/11. States that have updated their emergency health power laws have conditions that permit use of other disciplines to vaccinate but require a state declaration of public health emergency. For example, in South Carolina, there was no such declaration and therefore activation of other health professionals to vaccinate did not occur. One public health association did publish and disseminate to state and local DoHs a framework for partnering with pharmacies just before the H1N1 vaccination campaign began; this serves as one example of the suggested guidance (ASTHO, 2009).

A scalable staffing model is significant. The consensus of respondents felt strongly, including physicians that pandemic plans must finds ways to get vaccine out and into arms if indeed this is the objective. Efforts to establish a staffing model must include provider incentives and the recruitment of non-traditional providers and non-traditional venues. It was clear this group acknowledges, that public health no longer has a workforce to conduct mass vaccination campaigns, nor will future planning models that depend on a public workforce offer this capacity. These must be abandoned in favor of models that will expand the provider network beyond public health. Several respondents described the legal, regulatory and credentialing barriers that had to be addressed during the H1N1 response to recruit non-traditional vaccinators. Yet, it remained insufficient. One respondent stated that these barriers were encountered when the nation deployed its smallpox vaccination campaign in 2003. Professional institutions continue to resist the use of non-traditional disciplines for vaccination purposes.

When respondents stated that much effort has been expended on the supply side but not the distribution side, they referred to the lack of attention directed to the manpower required to staff and support mass vaccination campaigns. This discussion is descriptive of the project scope required to address scalable staffing and the modifications to the credentialing process to permit those with the skill set to serve as vaccinators during a public health emergency. This illustrates the relationship between scalable to the enabler “robust vaccinator corps” and a plan that is executable. It also conveys the high ranking for provider-centered and its complimentary role to support scalable and executable criteria.

3. Client-Centered

Most respondents expressed the view that if the public was not on board, then a campaign would be unsuccessful, referencing the 2009 H1N1 vaccination campaign. While this criterion ranked third overall, most respondents rated it high. One respondent saw this criterion linked with the integration criterion, explaining that if clients are not sufficiently motivated to participate, then integration would not being successful. Another referenced public health messaging and stated that public health is viewed as the authority and primary information source by the public in these matters. Similar statements were made by several respondents in the round one interview that both CDC and states do this well whether it was the H1N1 pandemic or the seasonal flu campaign. However, a couple respondents believed that some states and CDC failed to address emerging issues, causing confusing. This was compounded by states not sufficiently proactive with messaging and, as a result, the public's distrust of public health grew.

A few respondents noted that there would always be a need for some minimum level of documentation, and therefore make it unlikely that administrative barriers would be totally lifted. The rationale is that with the federal purchase of vaccine, accountability was required to demonstrate to the general public that indeed priority groups were served first. It equally serves the purpose of measuring herd immunity for any given target group.

Several respondents commented on the transparency or lack thereof of vaccine production as practiced during the H1N1 incident and suggested it be expanded to include vaccine administration as it relates to the communication of priority groups, who gets vaccine and when. There was confusion at national, state and local levels. No jurisdiction seemed to be immune from the lack of transparency regarding priority group allocation. The confusion stemmed from the inconsistent application of the allocation and target guidelines across state borders and county lines. One respondent described how one public health department was saving its vaccine for a public school vaccination campaign but was not offering it to pregnant women. Pregnant women who wanted to be vaccinated were advised to visit a neighboring county, several hours away. Eventually,

the public grew weary and gave up on its attempts to get vaccinated. One respondent saw transparency as one side of a two-sided coin with the flip side representing publicity. The implication is that while "media relations" is revealing production issues and allocation schemes, it must also conduct those messages in sufficient volume and timeliness to be effective.

Another respondent, who shared this view, suggested that a set of standardized triggers be developed and instituted so that once some threshold of vaccination was achieved for a particular target group then the jurisdiction could move on and offer vaccine to the next tiered target population. Several respondents described CDC vaccine allocation and target guidelines as administrative barriers to vaccination. In an effort to achieve the ethical principle of fairness, USG established a complex system of vaccine allocation but which raises the question, "The system is intended to achieve fairness, but is it achieving herd immunity?" However, the current allocation system is based on the scarcity of the vaccine. Until the nation achieves some level of production self-sufficiency, it is unlikely to disappear.

4. Provider-Centered

Generally, respondents expressed the view that if physicians were not on board, then "execution won't happen." It was pointed out by non-physicians that physicians have a significant influence on the decision clients make and it is critical that they understand and support the rationale for mass vaccination. Support should be demonstrated as well, by getting a shot. A medical practice where nurses reserve judgment on vaccine safety, efficacy and contraindications undermines a client's willingness and desire to seek vaccination. Clients use these views, reservations and behaviors as the calculus in their decision-making of whether to seek vaccination. But not all physician specialties are involved in vaccination activities, and the question arises what incentives can be offered to enlist their support as a vaccination venue under emergency conditions. The appeal may be no more than a message that reinforces the practice of "patient-centered medical home." Another strategy may be to enlist physician

specialty associations (i.e., ACOG)[11] that serve a defined priority group (pregnant women) to support emergency vaccination. For example, through a targeted association campaign its members could be encouraged through duty to client and country, serve as a core group of vaccinators during only emergency vaccination campaigns.

Physician practices do provide the bulk of seasonal flu vaccinations and serve as the cornerstone of a vaccination campaign. One physician respondent sought to divide the ranking between provider-center and client-centered, viewing both criteria as equally important. After some deliberation, the respondent ranked provider-centered higher and stated, "If I get it, they get it!" This perspective is seen in the average ranking with provider-centered ranked slightly higher than client-centered. Other respondents shared the view that client participation was more critical than that of providers, and campaigns should be biased in favor of the public.

Often during discussions, respondents would refer to a particular enabler grouped under one criterion as critical to another criterion. The example of public funding, previously described in the discussion of executable, was also a significant rationale for the high ranking of the provider-centered criterion. Another respondent, commenting on the Narrative Description (Appendix B) listed under the "executable" criterion (H1N1 ordering was cumbersome for physician practices-not the normal system), cited the results of a Zoomerang survey to show physicians' favorable response South Carolina's initiative to address physician communication using electronic methods. Over 90 percent agreed or strongly agreed with the statement that the "Vaccine Management System VMS) is an effective and efficient tool to use" (South Carolina Department of Health and Environmental Control, [DHEC], 2010).

5. Integration

The integration criterion ranked fifth but rated high by most respondents. One respondent viewed this criterion as a strategic companion to executable and federal planning guidance and saw integration of vaccination strategies as key to execution.

[11] American Congress of Obstetricians and Gynecologists (ACOG) is the professional association for OB/GYNs.

Several viewed it in the context of supporting the client-centered criterion. The respondent who rated the relative importance of this criterion low added that seasonal flu vaccine is a commodity, and it should be marketed as such and permit people to buy it. Another respondent commented that the enablers described to support this criterion did not come as a surprise and viewed them as significant factors. She explained that we "must pattern behavior on what we expect normally, rather than learn a new behavior." Her view was that the pandemic vaccination for the public should be familiar and that public health "must do it (respond) like first responders where they train as they respond." This perspective was supported by respondents during the round two interviews when the discussion described the role of a client's medical home. Respondents viewed this as a very important factor that must factor into mass vaccination campaign planning. In contrast, a few respondents stated in round one that public health is no longer viewed as the medical home for vaccination. The emerging strategy in public health is to implement tactics that encourage clients to seek health care services from their medical home. Yet in contrast, respondents stated that the physician specialty of obstetrics and gynecology (OB/GYN) is moving away from delivering vaccination services, and it was a tough sell to engage them in H1N1 vaccination. An OB/GYN practice is more likely unfamiliar with cold-chain management and may not have the dedicated refrigeration capacity required to properly store vaccine, in contrast to a pediatrics practice.

6. Federal Planning Guidance

The average rank order score for the guidance criterion ranked it sixth overall, yet its relative importance scored about half mostly high rating. A few respondents interpreted guidance to mean the recommendations that flow from the CDC Advisory Committee on Immunization Practices (ACIP). Others saw federal guidance as the *National Strategy for Pandemic Influenza: Implementation Plan*, published in May 2006 by the Bush Administration's Homeland Security Council (HSC, 2006). And another respondent stated that rather than a federal plan, referring to the *National Strategy*, that the U.S. needs a national plan that represents the views of all partners, including state and

local stakeholders as well as critical infrastructure private sector partners. The rationale referenced here is that under the system currently deployed, and when inviting private sector partners to participate, private sector partners are asked to adapt to 64 different state and jurisdictional plans. A national plan would provide guidance so that state plans are relatively consistent across the board. The respondent viewed this criterion along with scalable and executable as legs of a three legged stool that supports pandemic response.

One respondent rated guidance high and ranked it first among all criteria. When probed why, the respondent revealed that "guidance sets priority and strategic direction for the states" and that "you can't have 60 ways to do things."[12] The worksheet listed guidance last, yet this respondent initially identified another criterion as first but when the discussion came to guidance, the respondent recalibrated the ranking leaving guidance first. The theme of 50 state plans for regional and national private sector partners was a comment that emerged in several discussions among the various criteria. This respondent's comment was the first that associated with planning guidance. When probed, the underlying perspective was stated as "Who is the driver here?" (referring to either the federal government or state governments and the H1N1 incident). The respondent added, after some discussion, that many different plans retard implementation and cause loss of efficiency. An example cited was that once the system for ordering was established there was a lack of immediacy among states to place vaccine orders.

D. DEFINING EVALUATION CRITERIA

The criteria validated for evaluating each vaccine distribution model were: executable, scalable, federal planning guidance, client-centered, provider-centered and integration. Chapters V and VI used these evaluation criteria to evaluate two models for vaccine distribution, the public health model and the private sector model. This established the basis to identify the strengths and weaknesses of these models and form the foundation for a third model of implementation, a public private partnership for pandemic vaccine distribution (PPP4PVD). Figure 3 illustrated the relationship of

[12] The respondent was referring to the number of CDC Project areas, which number 64 states, territories and cities.

enablers to each criterion and how the survey identified these as desirable to support a strategic policy for pandemic vaccine distribution. In this section the criteria, which were identified, shaped and validated by the survey, are defined. Also identified was the rating scale used in Chapters V and VI for the model evaluations. The scale used to assess each criterion (stated as a performance measurement) was whether it was present (high), absent (low) or potential for improvement (medium).

It is understood that these criteria represent only a few that could be considered for inclusion is a model policy. But they represent those identified by respondents that should be incorporated in a policy implementation strategy for a vaccine distribution campaign.

1. Federal Planning Guidance

Federal guidance for vaccination may originate from policy but may also originate from advisory groups, as was learned in the survey and presented in Chapter III. The advisory groups affiliated with national immunization programs provide guidance on the basis of policy and equally best practices. Federal policy, as it relates to pandemic influenza vaccine, addresses vaccine supply and targets vaccine production self-sufficiency (CBO, 2008). There is no established policy that relates to the distribution mechanism for pandemic vaccine, but there is extensive guidance that targets who gets vaccine and in what order. There also exists a federal policy that relates to children as defined by the Vaccine for Children Program, and it was identified by several respondents in the survey. VFC is a comprehensive childhood immunization program to ensure all children are immunized against a number of infectious diseases and includes seasonal influenza. Some states elect to expand this basic federal program beyond the minimum federal requirements of age and vaccine type.

As an evaluation criterion, federal planning guidance represents a multitude of goals, strategies, tactics, tasks and job descriptions to direct, assist and aid state and local jurisdictions with preparedness actions. Planning doctrine documents the roles and responsibilities of partners. It outlines the administrative and logistical support crucial to support essential duties. It also specifies command and control and how it changes as

incidents expand and contract. The survey revealed limitations with current planning guidance as it relates to vaccine distribution in the context of an H1N1 response. This included lack of published guidance for the "blended" model, and respondents believed that the pandemic model should be integrated with seasonal flu campaign.

Another suggestion is to place planning guidance in the context of the National Incident Management System (NIMS) and an incident command system (ICS). Vaccine administration falls into the operations section while distribution issues fall within the purview of the logistics section. Guidance should be sufficient to support ICS functions and could be expanded to detail the planning section as well as the finance section.

2. Executable

Three enablers' support an executable plan and include funding, a staffing model sufficient to support the goal and the use of new technology that is used routinely. An executable plan becomes one in which these enablers are identified and adequately resourced to meet the plan's objective. In the evaluation of the two models, each was evaluated on the basis that it exhibits characteristics consistent with the enablers assigned to the executable criterion. The collective assessment of enablers that support executable was evaluated as high (present), low (absent) or medium (has the potential for improvement).

3. Scalable

This criterion is supported by three enablers defined to provide flexibility in response depending on pandemic severity. They include scaled vaccine production, a robust vaccinator corps and multiple venues. The purpose is to clarify capacity of the model to expand, contract and accommodate pandemic severity requirements[13] for emergency response. In a less severe pandemic, the number of providers responding would not be the same as that required in the most severe pandemic. What are the triggers

[13] The Pandemic Severity Index (PSI) was established by CDC and links appropriate actions for communities to take based on grade of severity. It ties to the category scheme used for hurricane and resembles the Saffir-Simpson Hurricane Scale classification scheme.

for activating additional vaccinators, and what are the sources? This enabler looked at not only traditional vaccinators, nurses and doctors but the potential to recruit non-traditional vaccinators such as dentists and vetenarians to expand the vaccinator corps. But for any public health emergency where vaccine is the recommended countermeasure, the process and the model should provide synergist capabilities.

Scalable describes venue and provider diversity, traditional providers and non-traditional providers. It includes a dispersion of venues, considering factors such as geographic, demographic, retail and healthcare settings essential to provide vaccination. It targets not only healthy, mobile population groups but uninsured, underinsured, residential care population groups as well. It delineates the provider network required to reach a diverse population and achieve some measure of herd immunity, given a pandemic's severity.

Finally, there is the challenge of scaled vaccine production that can only be considered when the nation achieves some level of vaccine production self-sufficiency. Self-sufficiency will progress as new production technologies, such as cell-based vaccine production increase vaccine production capacity. In the evaluation of the two models, each was evaluated on the basis that it exhibited characteristics consistent with the enablers assigned to the scalable criterion. The collective assessment of enablers that support scalable was evaluated as high (present), low (absent) or medium (has the potential for improvement).

4. Integrated System

An integrated system is a vaccine distribution infrastructure that works for both seasonal influenza and pandemic influenza. It is a strategy that would be used each influenza season but equally is intended for use in a public health emergency that requires a mass vaccination strategy. Each flu season becomes an exercise for an infectious disease outbreak or pandemic when a mass vaccination is the response strategy.

This strategy is documented by planning guidance that describes the integration principal and the mechanism that makes this option viable for either season or pandemic. For example, contracts are made with pharmacy franchise chains for seasonal flu

campaigns, but those contractual relationships are exercised for pandemic response. The H1N1 pandemic defined the limitations of insurance and licensure that presented barriers for using pharmacists as vaccinators; some of which were worked out during the course of the campaign. Integration would assist identification of barriers for either scenario. In the evaluation of the two models, each was evaluated on the ability of the model to support a policy of integration. The model was evaluated as high (present), low (absent) or medium (has the potential for improvement).

5. Client-Centered

Consensus among respondents underscored the significance of enablers that support a client-centered strategy for pandemic vaccine distribution. This strategy is not unlike social marketing strategies designed to affect behavior of customers when a customer centered strategy is the objective. This thesis views the individual who seeks vaccination as one who is healthy, proactive and seeking a risk reducing behavior in an effort to avoid illness. The individual is therefore seeking a service that consists of a specific product, administered by a credentialed health professional. In contrast, the medical model refers to the individual who seeks medical services as the patient, with the underlying premise that one who is sick, exhibit symptoms sufficient to determine a diagnosis that can be treated. Likewise, a consumption driven economy views a customer as one who seeks a product to meet some need. It is in this context that this criterion is labeled as “client-centered” versus patient- or customer-centered.

Client-centered describes a set of strategies used by planners to reach prospective clients who seek vaccination services. Strategies should minimize barriers that prohibit or discourage vaccination-seeking behavior and administer the service where those prospective clients conduct normal and routine day-to-day activity. One example, cited frequently by respondents, is that of the medical home. This is a strategy that has taken hold over the past decade to ensure that every child has a medical home, a health and medical professional practice where the child can receive the full range of wellness services including immunization.

The survey identified four key enablers that would facilitate vaccination seeking behavior by adults during an emergency in which the response is vaccination. Much discussion focused on behavior that was familiar to clients rather than new venues that are not likely part of their routine. Those enablers are: vaccination venues that are routine and familiar; that are convenient and accessible; transparency about the process of vaccine production and vaccine administration; and lifting administrative barriers. In the evaluation of the two models, each was evaluated on the basis that it exhibited characteristics consistent with the enablers assigned to the client-centered criterion. The collective assessment of enablers that support client-centered was evaluated as high (present), low (absent) or medium (has the potential for improvement).

6. Provider-Centered

Many family and pediatric physician specialties have adopted the concept of the patient-centered medical home, thus institutionalizing this practice. The relationship between provider-centered and client-centered strategy is supported in the literature as a wellness strategy incorporated into medical practices. Provider-centered enablers, described by respondents in the survey, aim at the government's relationship with providers who agree to serve in the vaccination network during an emergency. Thus there a continuity of practice between the government, provider and client to maximize support for vaccinations, whether it is seasonal or pandemic. But as discussed by respondents, this practice does not carry across all physician practices nor does it reach all adult population groups. Rather, family and pediatric practices reach those medical home adopters but other physician specialties, such as OB/GYN have yet to fully embrace vaccination practices.

Most likely, the healthy adult population, which consumes limited medical services but spends much of its time in a work setting, are less likely to be in contact with a medical provider. Because of this, alternative strategies must be established to reach this segment of the population in an emergency vaccination campaign. For example, recruiting Urgent Care Centers (UCC), that provide acute care and injury care services into the network, could serve as one strategy to reach this population group. It might be

important to learn what population sector uses UCCs. Another would be distribution through the work setting, but then this requires a strategy that is deployed annually rather than a strategy that waits for the next emergency vaccination campaign. The interdependency of this criterion, provider-centered methods with that of integration methods illustrates the rationale for a strategy of distribution based on a single vaccination distribution network for both seasonal and pandemic campaigns.

Thus, provider-centered enablers as discussed in this chapter, represent a set of strategies that emphasize those processes that facilitate participation of providers, expand the network and maximize penetration and reach into the various population targets. The enablers identified in the survey, transparency of vaccine production and administration; publicly funded vaccine; minimizing administrative barriers and electronic interfaces to facilitate communication, represent a few of those enablers to make this strategy a provider-centered approach. This is not to say there are not others that would facilitate a provider-centered approach. It simply says that in the context of this discussion, where the focus was pandemic vaccine distribution, specifically with the recent experience of H1N1, these four enablers are those that surfaced most often and for which there was a consensus of perspective. In the discussion of two models, each was assessed on the basis that they exhibit characteristics consistent with the enablers assigned to the provider-centered criterion. The collective assessment of enablers that support provider-centered was evaluated as high (present), low (absent) or medium (has the potential for improvement).

In summary, results of data analysis were displayed in Figure 3. The schematic represents enablers and criteria that will be used for the assessment of each model in Chapters V and VI. Table 7 will be used in Chapter V, VI and VII to summarize model evaluation results from the two existing distribution models and contrast a new model.

Table 7. Policy Evaluation Criteria Matrix

POLICY MODEL	EXECUTABLE	SCALABILITY	PROVIDER CENTERED	CLIENT CENTERED	PLANNING GUIDANCE	INTEGRATION
Public						
Private						

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V. THE PUBLIC HEALTH MODEL: THE CURRENT POLICY AND PANDEMIC IMPLEMENTATION STRATEGY?

A. OVERVIEW

The literature reflects a federal dependence on the public health model for mass vaccination with an underlying assumption that the public health workforce will be sufficient to staff mass prophylaxis operations. This guidance calls for the traditional public health model for mass vaccination clinics, which was introduced in the United States in the 1950s and 1960s. This guidance is found in numerous mass prophylaxis planning guidance documents, including smallpox, pandemic, strategic national stockpile and mass casualty guidance documents.

Missing in the literature is discussions of alternative distribution models or supplemental distribution methods in the event that mass prophylaxis is not feasible, and/or the event is large and requires additional resources. The literature suggests the use of dentists and veterinarians, but little planning guidance can be found that calls for a partnering with the public sector in a public health emergency or for an administrative mechanism to secure these partnerships. This absence in the literature is significant because it reveals a void in the planning guidance of alternative models that is available to state and local public health jurisdictions. The public health model is limited to 3,036 local and tribal departments of health in 50 states, and it has been confronted with a shrinking infrastructure over several decades (HHS, 2007, p. 11).

Contemporary pandemic planning for the United States began with the publication of the *National Strategy for Pandemic Influenza* (Homeland Security Council [HSC], 2005). It was soon followed by the *Implementation Plan* (HSC, 2006) for the *National Strategy* published in 2006. Since then, numerous plans and guidance have been published by the USG, including a pandemic preparedness plan for each critical infrastructure sector specific agency. Federal planning guidance has also been developed

and published to assist states and local jurisdictions with state and local pandemic plans based on the national strategy. Guidance also assists states with evaluation of those plans with the intention to improve their operational aspects.

B. THE PUBLIC HEALTH MODEL

The public health model (PHM) depicted in Figure 4 is the current documented strategy for mass vaccination when a public health emergency is declared. It is documented historically through federal planning guidance and implies federal policy for mass vaccination when there is a public health emergency. This guidance 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, guidance was revised, updated and then pushed to state and local jurisdictions. This model is described in numerous mass prophylaxis planning documents.

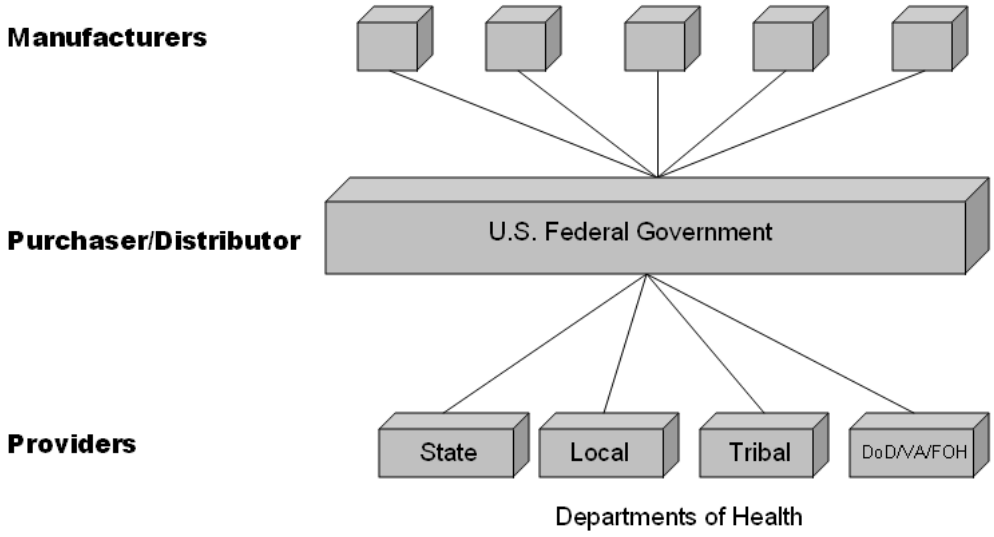

Figure 4. Public Health Model

Figure 4 depicts the public health model. The federal government is the purchaser and distributor of pandemic vaccine. It has the sole responsibility for procurement and distribution to the states. This model depends on state, local and tribal departments for distribution. This adds a logistics function for these entities no longer in place for day-to-

day functions in most states. The 2009 H1N1 pandemic distribution plans were modified dramatically from this model and impacted routine functions (Association for State and Territorial Health Officers, 2010).

Vaccine shortages, both seasonal influenza and pandemic, have demonstrated this approach is encumbered by numerous operational limitations such as a shrinking public health infrastructure, greater demand for vaccination and the ambitious goal for vaccination of a jurisdiction's population set by the CDC. While public policy is set to expand production capacity (CBO, 2008) public policy does not exist to improve distribution.

The advantage of this option is that public health has trained for, exercised for and implemented mass vaccination campaigns on a limited basis. However, this baseline of experience does not rise to the level of proficiency with which public health professionals conducted routine mass vaccination campaigns of the 1950s and 1960s. The model's planning doctrine has evolved over 50 years and is well established at federal, state and local levels. For example, job descriptions for all defined roles have been written, published and widely disseminated. In addition, these duties are even tailored for specific biological threats such as small pox, and pandemics.

However, the model is limited to 3,036 local and tribal departments of health across the United States and is confronted with an infrastructure that has been shrinking over several decades (HHS, 2007). In contrast and according to the HHS Public Health Critical Infrastructure, the public health sector consists of over 370,000 providers capable of vaccination (HHS, 2007. p. 11).

C. FEDERAL PLANNING GUIDANCE

The survey in Chapter IV revealed that the public health model, as defined in federal planning guidance, is not "executable" due to the inadequate staffing resource upon which it is based. Federal guidance fills many roles, but this thesis explores guidance as it relates to pandemic vaccination distribution before the 2009 H1N1 pandemic. Published federal guidance has targeted the threat of H5N1 or avian influenza. The guidance reviewed stems from strategic documents, national planning documents

and even the 10 national planning scenarios of which a pandemic is ranked third of 10.14 All of the guidance emphasizes attention to priority groups, and one guide is dedicated solely to allocation and targeting of pandemic vaccine for priority groups. Other guidance addresses various aspects of vaccination planning. Key phrases that were searched for in the guidance were "distribution planning" and/or "vaccine distribution." Typically, a reference to allocation suggests that vaccine is incorporated into guidance as "distribution" but refers to a vaccine inoculation strategy based on ethical principles when vaccine is a limited or scarce resource.

There exists numerous pandemic vaccination guidance documents published by, not only the USG, but other entities as well. This section will discuss a few key federal guidance publications that have served as the basis for state and local pandemic vaccination planning. A definitive document for pandemic vaccine allocation is the Guidance on Allocating and Targeting Pandemic Influenza Vaccine (HHS, n.d. (a)).15 Essentially, this document outlines who gets vaccine and in what order. The document provides the clearest guidance for pandemic vaccination based on categories (e.g., homeland security), tiers and target groups (e.g., pregnant women). The premise of this allocation strategy is that vaccination will not be sufficient, and therefore initial key target groups are those at-risk and those who will serve others. The document is not intended to address how a vaccine is distributed, where it is distributed or by whom.

Another set of documents assesses the influence of planning guidance on state plans by using a methodology of survey analysis to review those plans. The intended product from the analysis is to provide additional guidance in an effort to improve plans. These instruments are used to gauge how well federal plans have come to convey strategic goals, objectives and strategies. For example, the Congressional Research Service surveyed the pandemic plans of 50 states (51 plans) and reported its results in 2007 (CRS, 2007). The analysis was conducted 10 years after avian influenza was

14 The number three National Planning Scenario is for a "Biological Disease Outbreak – Pandemic Influenza" with an estimated attack rate of 15 percent causing 87,000 fatalities and 300,000 hospitalizations (Homeland Security Council, 2004).

15 The Center for Biosecurity at UPMC press release dated July 28, 2008 announced the final version was released by DHHS July 23, 2008 but document is undated (Center for Biosecurity, 2008).

confirmed in Asia and two years after pandemic preparedness funds began flowing to the 64 project areas.[16] Of the eight topical categories one is "Vaccine Management," which describes the findings of the reviewed plans in respect to priority groups, storage, security, vaccine tracking, etc. Of the 51 plans reviewed, 36 plans were noted to have met the evaluation criterion phrased as "describes plan for vaccine distribution (CRS, 2007, p.12)." The "36" was the high score of any vaccine management activity surveyed (CRS, 2007). CRS wrote this finding about vaccine distribution:

> While about three-fourths of state plans discussed vaccine procurement and distribution, 12 states appear to have kept their options open, and have planned to distribute vaccine, or coordinate its distribution, according to several different possible procurement scenarios. (Congressional Research Service [CRS], 2007, p. 13)

The conclusion drawn from this statement is that there was a wide range of planning elements rather than a set of consistent methods that reflect strategies articulated in federal guidance. If 12 states "appear to have kept their options open," does that mean that the distribution planning has yet to be reconciled? While the Trust for America's Health reported progress in its review of H1N1 preparedness and response among states, it equally notes gaps persist (Trust for America's Health [TFA], 2009). The report highlights a key concern is that while all states have plans to distribute vaccine, resources fall short to execute those plans:

> Despite years of planning, many state health departments have struggled with limited resources to develop mass vaccination plans to receive, distribute, and administer the H1N1 vaccine, raising concerns about the ability of the public health sector to collaborate with the health care system. (TFA, 2009, p. 5)

Another guidance document published by HHS in 2008 was the Federal Guidance to Assist States in Improving State-Level Pandemic Influenza Operating Plans (United States Government [USG], 2008). Its purpose was to review state operations for pandemic preparedness and note areas for improvement. This document was a tool for

[16] Projects are CDC Preparedness Grantees (or areas) and include states and metropolitans areas. For example, South Carolina, a centralized system would be one grantee while Illinois would have at least two grantees, the state and city of Chicago. Collectively, there are 64 project grants (CDC, n.d. (e)).

both states and federal agencies to assess state plans and give feedback on 26 operating objectives—one of which was "Ensure Mass Vaccination Capability during Each Phase of a Pandemic" referenced as Appendix B.6 (USG, 2008, pp. 81–82). Appendix B.6 asks if the plan included a number of support activities, two of which are shown in Figure 5. The descriptions reflect venue locations and staffing activities but are quantitative assessments versus a qualitative assessment.

Description of Supporting Activity	Citation to Supporting Document	If Not Applicable, Please Explain
Does the plan determine number and location of clinics based on planning assumptions? Does it include: - MOA's (or other appropriate document) - Points of contact identified		
Does the plan identify sources of staffing and develop memoranda of agreement with the following? - Backups identified - Job descriptions		

Figure 5. Ensure Mass Vaccination Capability (From USG, 2008, p. 82)

Appendix B.6 also refers the reader to two additional guidance documents: Pandemic Influenza Vaccination: A Guide for State, Local and Territorial and Tribal Planners (CDC, 2006) and Status of Pandemic Influenza Vaccine Manufacturing Capacity, Pre-Pandemic Stockpile, and Planning for Vaccine Distribution (CDC, 2007).

The guidance, Status of Pandemic Influenza Vaccine Manufacturing Capacity, Pre-Pandemic Stockpile, and Planning for Vaccine Distribution, is an update for planners on "vaccine distribution planning, current planning assumptions and a brief discussion of key planning considerations" (CDC, 2007, p. 1) as well as a discussion of ship-to-sites. This guidance, distributed to state projects, suggests it was directed to immunization program personnel rather than guidance for those responsible for the logistics function and planning for vaccinators, venues and the assembly of material in support of a campaign. Its only reference to distribution planning is this statement:

> CDC has been working with HHS, the Department of Homeland Security (DHS), and vaccine manufacturers to develop a vaccine distribution plan for pre-pandemic and pandemic influenza vaccines. At this time, planning and exercises are underway with vaccine manufacturers for distribution of pre-pandemic and pandemic influenza vaccines. (CDC, 2006, p. 2)

The implication is a strategic distribution plan would incorporate after action items that result in a corrective actions improvement plan. Less clear are the implications for state and local jurisdictions? Another exercise reviewed earlier, the New Jersey TOPOFF exercise, revealed inherent weaknesses of its planning scenarios: "In point of fact, NJ [New Jersey] does not have enough manpower to meet its needs as demonstrated by the exercise, but officials ignore this lesson as they engage new plans based on old assumptions" (Santiago, 2006, p. 38). The implication is that operational awareness and planning limitations becomes more astute by those on the ground or on the frontline than perhaps those that developed and published the guidance. The survey in Chapter IV noted that a national plan would incorporate state and local input while federal plans are more likely to not include this input. Really good guidance becomes a collaborative process where both federal and state/local partners learn from one another through the process, and the guidance product improves as a result.

Another document referenced earlier is the *Pandemic Influenza Vaccination: A Guide for State, Local, Territorial and Tribal Planners* (CDC, 2006). Its purpose is "to assist state, local, territorial, and tribal officials in developing pandemic influenza vaccination plans" (CDC, 2006, p. 1). The document continues and adds that in an attempt to provide guidance "in a pandemic scenario—notably those caused by the current limited capacity to manufacture vaccine—and provides detailed guidance on working with those challenges to conduct large-scale vaccination efforts" (CDC, 2006, p. 1). The document identifies the premise "limited vaccine availability" and recognizes the challenges inherent to a mass vaccination campaign.

Statements in the guidance show awareness of the challenges such as, "Over time, project areas may elect to shift control from public health departments to the private sector" (CDC, 2006, p. 5). While an apparent challenge, this is one that requires pre-planning and H1N1 provided a perspective of the elaborate collaboration that takes place

at national, state and local levels to arrange these partnerships. Section II. B. Vaccine distribution and allocation references ship-to-sites, allocation responsibilities, but it offers little direction on making plans executable. In fact, the discussion stop shorts of the ship-to-sites and leaves it to planners to imagine the process from storage sites to the arms of clients.

In general, the guidance in this document reflects a dependence on public health to serve as not only lead for incident management but also fulfilling the logistics, planning and operational aspects of plan execution with the implication that workforce capacity fulfillment would be sufficient to execute these functions. For example, the following statement demonstrates the assumption (insufficient workforce capacity) and dependence on public health as the vaccine manager. The statement implies the expectation that public health will activate a logistics responsibility to consist of repacking vaccine from a centralized depot and than distribution to vaccination clinics. The wisdom of using scarce public health personnel to vaccinate other healthcare workers would probably come under scrutiny by a public health operations section chief responsible for clinic operations.

> Due to the large number of outpatient offices in most localities, it may be impractical for public health agencies to deliver vaccine to individual offices. Therefore, planners should designate distribution sites where medical office staff may pick up vaccine stocks. Public health may elect to vaccinate staff from small practices at the distribution site to help limit wastage that could occur with vaccinating staff in small practices since vaccine will be provided in multi-dose vials. (CDC, 2006, p. 9)

Of course, the H1N1 response departed from this guidance as vaccine was dropped shipped to those providers who registered through the state and with CDC to serve as pandemic vaccinators. Also, VMBIP dramatically changed a state's centralized vaccine storage depot from a single, centralized distribution ship-to-site to direct shipments to registered providers. Other references in the guidance suggest this dependence but also recognize the need to recruit non-traditional providers:

> The identification of professional partners and volunteers who can help run these clinics is a critical aspect of pandemic planning. Potential partners include: Community Health Centers, the Visiting Nurse

> Association, and other community vaccinators, nursing and medical students and pharmacists, dentists and veterinarians. (CDC, 2006, p. 11)

The guidance proposes local planners think outside the box and consider non-traditional sources to address its needs for vaccinator staffing needs. But as the survey concluded, there are barriers with the use of non-traditional professionals that must be addressed in advance of an emergency and the guidance is quiet in this respect.

These documents represent a sampling of technical guidance for pandemic vaccine distribution disseminated to state and local planners. Pandemic plans have been referenced elsewhere in this thesis but do not provide the level of detail that these guidance documents provide. Yet, guidance stops short of taking vaccine distribution to the next level. They reflect pre-occupation with the limitations of vaccine supply and who should get vaccine first and in what order. The documents emphasize the ethics of vaccine distribution. But these ethical distribution concerns do not go far enough to recognize the operational limitations that are nestled with legal, licensure and credentialing. These limitations become barriers to using the full range of community resources to mount a campaign and deploy all of its available resources to address a biological threat. Guidance should address these limitations and improve execution.

The dependence on the public health model for pandemic vaccine distribution is not limited to federal guidance but trickles down through state public health and medical authorities as well. The South Carolina Pandemic Ethics Task Force (2009) wrote, “We expect that rationing of available vaccine will be necessary. In periods of limited vaccine supply, public health clinics will be the predominant locations for influenza vaccine administration” (p. 11). The HHS plan also describes this assumption that vaccination clinics will be operated by public health in the Vaccine Production, Procurement and Distribution section. It guides DoH to be prepared to “Identify locations for vaccination clinics that will be operated by health departments and enter into memoranda of agreement with organizations that agree to provide vaccinators or other staff” (HHS, 2005b, p. S6-5). The H1N1 response illustrated how plan working assumptions change (i.e., sufficient workforce capacity) as the realities of the incident becomes apparent.

In summary, less attention is directed toward development of a distribution network consisting of identifying multiple venues or recruitment of a robust vaccinator corps such as described in the survey. Several conclusions are drawn from this brief review of federal guidance for pandemic vaccine distribution

- An assumption that local DoH clinics will be the primary venue for conducting mass vaccination campaigns.
- The complexity of legal, licensure and credentialing among professional medical associations prohibits the integration of these disciplines into a readily activated vaccinator corps.
- Insufficient guidance is provided to support the logistical requirements of conducting mass vaccination campaigns using the Public Health Model.
- Generally, guidance is limited in respect to how vaccine is distributed (strategies), where it is distributed (venues), and by whom (vaccinator).

D. EVALUATION

The evaluation of the public health model considers those elements consistent with the criteria identified and validated by subject matter experts in Chapter IV. The criteria become a framework to analyze model elements in light of survey data, qualitative analysis from the literature and the 2009 H1N1 pandemic. Each criterion is stated in a performance measurement (i.e., is the public health model executable?), a discussion follows and rating assessed. The assessment was made based on the extent to which each criterion is supported by its enablers. The rating scale is either present (high), absent (low) or potential for improvement (medium). The assessment offers an indication of the strength of this criterion as exhibited in the model.

As reported in the survey and the ASTHO H1N1 project report (2010), the H1N1 pandemic response recognized that the public health infrastructure was inadequate to manage vaccination response and introduced strategies to address operational gaps. In essence, the H1N1 event exercised the nation's pandemic response including vaccination. As a result, it serves as a dataset to contrast with the public health model defined in federal planning guidance. The PHM is differentiated from the H1N1 vaccination distribution model rolled out for the 2009 pandemic. It is viewed by public health

authorities as a “blended model” that combines elements of public and private sectors and for which planning guidance did not exist. The researcher acknowledges that elements of the blended model were adopted from VFC, as described in the survey. As the survey revealed, lessons learned from H1N1 offers insights into operational issues that can be strengthened and built into PVD.

1. Is the Public Health Model (PHM) Executable?

Chapter IV identified, shaped and validated three enablers that support the criterion executable. This framed the evaluation and discussion of the PHM. Elements of the model illustrative of evaluation criteria enablers were evaluated using interview data and qualitative analysis from the literature review. The criteria represented by these elements was as rated high (present), low (absent) or medium (potential for improvement).

a. Integrated and Routine Use of New Technology

There are two perspectives that relate to this enabler. This is described in the context of the H1N1 pandemic but reveals the intricacies of moving product and the data processing that must accompany that movement. These are systems the survey described, but these are not systems fully described in federal guidance as those systems planners should expect for a pandemic.

The first is a state vaccine management system that is used to interface with its provider network and whose order data is used to upload to the CDC. The other perspective is that from the centralized distribution (CD) contractor (McKesson) to the customer or the provider registered with a state. The latter perspective relates to a system managed by CDC but operated by the private sector contractor or in this instance, McKesson. The federal involvement, coordinated by BARDA, is to manage vaccine shipments from the four offshore plants and one onshore plant to one of four McKesson CD depots. This was described as the “push” portion of the system. BARDA, working directly with manufacturers, pushed vaccine to McKesson, where the contractor awaited for the orders to arrive from CDC through its pull system.

This enabler considers technology deployed for the management, distribution and tracking of vaccine data. PHM depended upon public health systems in place for routine infectious disease outbreaks. Some states had robust systems in place that support the vaccination programs used routinely. Other states had traditional ordering systems in which providers ordered vaccine using paper, pen and fax machine. Some were integrated with the CDC's VAXMAN vaccine ordering system. As described in the survey, these are systems designed to support the VFC program for children. These are not systems used for working with the private sector during seasonal influenza campaigns, nor were they intended to support a pandemic in which a state DoH would administer some 72 percent of the doses allocated to the state. These technologies were not intended to scale upward and states had not intended for them to be used for pandemic vaccination response. While the CDC's VMBIP will eventually be the technology solution of choice, it is years from full implementation but portions of it were used for vaccination response. As revealed in the survey, SMEs noted it was apparent to them that the application of these technologies was unfamiliar to the users.

Federal guidance describes vaccine distribution that would ship from manufacturers to state and local depots (warehouses) where workers would manually repackage vaccine in the necessary quantities and ship to local DoHs or its network of providers. One estimate put the number of depots at more than 400 before VMBIP began implementation in 2008 (K. Lane, personal communication May 9, 2010). Depots began being dismantled once VMBIP was implemented; therefore, for H1N1, many states were no longer in a position to support the warehousing portion of distribution. Today, immunization grantees number 64, depots number three (one in Alaska and two with McKesson, CDC third party distributor) and the application of centralized distribution for H1N1 has eliminated the need for many of these by drop shipping directly to the provider network (K. Lane, personal communication May 9, 2010).

Technology became essential in distributing pandemic vaccine during the H1N1 response. The survey described the use of centralized distribution, electronic communication interfaces with a provider network, to name a few applications that were introduced for pandemic response. Conversely, these are technologies that were not

incorporated into the traditional PHM. To reference the example of VMBIP, this is new technology is not fully operational, and segments of it were adopted for the H1N1 response. Thus, planning based on guidance would have been incomplete.

This overview shows that the PHM, in terms of technology, was limited; and although H1N1 pandemic required new applications for distribution, it was still found cumbersome (ASTHO, 2010). The survey data supports the notion that this enabler was marginally executable.

b. Staffing Model: Sized for Response

The PHM references the mass vaccination clinic staffed by public health personnel and volunteers and was conducted in public facilities. As described above, DoHs are limited to 3,036 units and additional offices those units may be able staff. However, the public health workforce needed to support a mass vaccination campaign is limited by public health nurses, logistics support personnel and an incident management team sufficient to meet the vaccination goal. Additional evidence is the grants[17] that are administered by HHS for the H1N1 pandemic in which state and local DoH were infused with funds to hire part-time personnel, contract with private sector, turnkey vaccination clinics and recruiting and expanding the private and public sector physician provider network. The survey also revealed that most respondents viewed the public health infrastructure as inadequate to support a mass vaccination campaign. This perspective reflects both the PHM as well as the H1N1 response.

c. Publicly Funded Vaccine

According to the CBO (2008), the USG vaccine policy of production self-sufficiency does call for the purchase of pandemic vaccine. In addition, federal planning guidance, which preceded the CBO report, states that pandemic vaccine will be purchased by the federal government. As experienced with the 2009 H1N1 pandemic,

[17] Public Health Emergency Response grants were administered in three phases to state and local public health grantees for implementation of vaccine distribution. Separate sources were used for the purchase of vaccine and ancillary supplies administered through BARDA.

emergency funding authorizations were executed, proposed by the President, approved by Congress and then directed to HHS for procurement, purchasing, fulfillment and distribution. A few of the complications were described in Chapter IV. The consensus is that a pandemic necessitates emergency funding and the public purchase of vaccine, ancillary supplies and the personnel, which are essential to execute the campaign. H1N1 witnessed these funding elements in addressing the H1N1 threat.

But, there is an ethical principle integral to this discussion. Once a vaccine is publicly purchased, then government is compelled to make the necessary arrangements and offer it to all citizens. This is the principle of fairness:

> A principle of fairness suggests that all persons who are in a similar situation will have similar access to the medication that is available from public sector stockpiles. Availability of treatment will not be based on gender, race, ethnicity, citizenship or ability to pay. (SCPETF, 2009, p. 14)

There must be some mechanism in place that assures the public this will happen. Yet, guidance does not provide a staffing component nor sufficient venue settings that assure distribution under this model can happen. This planning component is left to state and local jurisdictions but provides little assurance of continuity of implementation from one state to another, and from one county to another. Confusion among the public was described in the survey as states and counties opened up the offering of H1N1 vaccine to other target groups but a neighboring state/county had not done so. The public was confused and asking, “Why can’t I get it here but I can drive six hours to get it?”

Is the public health model executable? Pandemic planning guidance called for public purchase of vaccine and the H1N1 pandemic witnessed the purchase of H1N1 vaccine under the Emergency Use Authorization. However, the staffing model is missing from the PHM guidance. According to the survey, recruitment was left to states. The survey documented a few of the difficulties experienced by one state, but difficulties were equally observed at the national level as well. Federal planning guidance also leaves vaccine distribution to the states without specifying a distribution methodology. While

public funding is assessed as high, it is limited by a mechanism to assure the principle of fairness is achieved. Both staffing and technology enablers were assessed as low, and the evaluation of the traditional public health model was as assessed low for this criterion.

2. Is the Public Health Model Scalable?

Chapter IV identified shaped and validated three enablers that support the criterion scalable. This framed the evaluation and discussion of the PHM. Elements of the model illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

a. Scaled Vaccine Production

As revealed in the survey, scaled vaccine production that uses traditional vaccine production technology has drawbacks. Until the USG has achieved production self-sufficiency and ceases its dependency upon offshore vaccine manufacturers, scaled vaccine, production is not possible. The premise of the model guidance is production insufficiency, and therefore vaccine rationing and related allocation schemes follow.

b. Robust Vaccinator Corps

Given the literature review and the discussion of public health nurses, the primary means of vaccination, the PHM is limited in terms of a vaccinator corps. ASTHO recognized this limitation when it published its framework for incorporating pharmacists as vaccinators for H1N1, and the survey also revealed state and national efforts to use pharmacists as vaccinators. But such a framework does not exist in federal planning guidance for the traditional public health model. And while a recommendation is made to use volunteers as experienced during the H1N1 pandemic, barriers persist that prevent the immediate assimilation of non-traditional professionals into the corps of vaccinators. The survey revealed a consensus of respondents, who believed this as an inherent weakness of this model and therefore noted the model non-executable. This enabler is assessed as low.

According to critical infrastructure/key resource planning guidance (HHS 2008), the public health sector includes 300,000 ambulatory care providers (physicians, veterinarians and dentists); 70,000 pharmacies, in addition to the 3,036 local and tribal departments of health. This network has the capability to provide 373,036 providers (HHS 2008). If the assumption is made that nearly 50 percent includes administrators, academicians and policy writers, it leaves a distribution network of 180,000, which is double the current structure. The survey revealed that a framework must be established and recruitment of both traditional and non-traditional providers to expand the vaccinator corps. One such framework was introduced by ASTHO and provided a detailed recruitment methodology to recruit pharmacists.

c. Multiple Venues

In the context of the PHM, this enabler parallels robust vaccinator corps but distinguished by the facility type where vaccination can occur. Venues under the PHM are unlimited and quite flexible, as demonstrated by the number of venues where public health conducts seasonal flu clinics to ensure board coverage. These venues include not only onsite public health clinics, but also offsite facilities such as workplace settings, nursing homes, churches and municipal recreation centers. Mobile units were referenced in the survey and saw modest use around the nation as a method to reach rural communities. For example, one West Virginia DoH partnered with its emergency management authority to use its mobile command vehicle to provide mobile vaccination capability (Kiley, 2010). Public health works to ensure the principle of fairness in its daily business and its leadership understand this mission. The limiting factor is vaccinators. This enabler could be assessed high in support of the model that was demonstrated by its ability to reach many population groups in a multitude of venues but limited by staffing.

Is the public health model scalable? There are elements of the model that could be scaled upward, given a robust staffing model, but as it stands and defined in federal guidance, it is not a model that is scalable. It is assessed low in respect to scalable.

3. Is the Public Health Model Provider-Centered?

Chapter IV identified shaped and validated four enablers that support the criterion provider-centered. This framed the evaluation and discussion of the PHM. Elements of the model were illustrative of the evaluation criteria enablers that were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

In general, this is a challenging criterion to evaluate, given that most federal guidance is directed toward public health as the lead planner and responder. The fact of the matter is that the PHM did not have a mechanism to incorporate private physicians nor non-traditional providers but left it to local jurisdictions to make those arrangements. But that was the rationale for titling the H1N1 vaccination response a "blended model" because it encouraged recruitment of the private sector physician community. So, given the H1N1 emergency, federal authorities did provide guidance to states to recruit the private sector. Ironically, those providers with familiarity with the public system through VFC had a base of experience that could be built upon, and therefore this group was among the "early adopters" of the blended model strategy. In addition, they served priority groups. This speaks to the criterion of integration and explored in that section.

a. Minimize Administrative Barriers

As discussed, federal planning guidance is directed toward public health as the primary mechanism for pandemic vaccine distribution, and therefore, there were few administrative tasks in the guidance for medical providers. However, the strategy of H1N1 vaccination response targeted, selected medical specialties, especially those that reached priority groups such as children and pregnant women.

The guidance does direct planners to provide protection for critical infrastructures, such as the healthcare providers, which includes medical practices. A review of the *Federal Guidance to Assist States in Improving State-Level Pandemic Influenza Operating Plans* reveals a strategic goal is to protect critical infrastructure and

names the public health and healthcare sectors. However, “the focus of this document is on the operations of the State government” (USG, 2008, p. 6). The document describes planning efforts to reach at-risk populations and even citizen preparedness but only as guidance. Statements, such as written in Appendix B.6 titled *Operating Objective: Ensure Mass Vaccination Capability during Each Phase of a Pandemic*, asks if the plan identifies sources of staffing and job descriptions but this guidance is directed toward public health roles rather than private sector physician participation (see Figure 5).

The survey revealed that administrative requirements of providers electing to participate in the H1N1 vaccination were somewhat burdensome. Vaccine orders were placed each week, and weekly vaccination activity was reported to the state, etc. These administrative requirements were not defined in guidance, but due to the necessity to recruit additional vaccinators were implemented prior to the H1N1 campaign.

b. Transparency of Vaccine Production

Planning guidance emphasizes communication strategies throughout guidance doctrine but the strategies are generally directed toward the public.

c. Add Electronic Interface with Ordering System

Planning guidance rarely refers to technology, let alone electronic interfaces with ordering systems in support of physician practices that elect to participate in a public mass vaccination campaign. In traditional federal planning guidance, this enabler does not exist but leaves it to state and local planners. The analysis of the executable criterion, and its enabler addressing technology, described the dependences, complexities and limitations of technology used to distribute H1N1 vaccine. In today’s market driven economy, technology is central and connects, providers, states, federal administrative agencies and private sector partners. The survey described how one state integrated electronic communications with its online ordering system. One respondent described this component as a significant source of support for its provider network throughout the mass vaccination campaign.

d. Publicly Funded Vaccine

The discussion of publicly funded in the section executable supports this enabler in the context of the provider-centered criterion and shows the interdependency among criterions with an enabler such as publicly funded.

In summary, the provider-centered criterion as applied in the PHM is assessed as low and in particular in the absence of strategies that target providers for recruitment and sustainment of public health emergencies. This evaluation reveals that work must be done if the public health model were adopted to recruit private physicians. This criterion is provider-centered. While most seasonal flu vaccine is distributed though private physician practices and is suggested in the survey, the model must expand the vaccinator corps to include non-traditional types.

4. Is the Public Health Model Client-Centered?

Chapter IV identified shaped and validated four enablers that support the criterion client-centered. This framed the evaluation and discussion of the PHM. Elements of the model illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

a. Transparency of Vaccine Administration and Production

This enabler is quite specific and while federal guidance provides a full-range of communication strategies, transparency of vaccine administration and production is not apparent in those documents reviewed for this thesis. This activity (vaccine production) may be appropriate for message mapping,[18] which is a strategy that breaks down a task and identifies the salient message components. Federal guidance recommends communication strategies across all planning doctrine and incorporates it into the guidance that evaluates state pandemic plans. For example, it includes the use of

[18] "Message mapping is a science-based risk communication tool that enables members of the emergency response and environmental protection communities to quickly and concisely deliver the most pertinent information about an emergency" (Homeland Security Research, n.d.).

technology (radios, HAN)[19] as well as staffing call centers. It also describes the pre-developed use of crisis communication and risk reduction messages.

b. Vaccination is Familiar and Routine, Convenient and Accessible

Vaccination that is familiar and routine and convenient and accessible refers to an enabler that is customer-service based. A strategy that emerged from H1N1 vaccination was to emphasize the medical home as a place where clients could get their influenza vaccination. But the survey also revealed that the PHM traditionally did not emphasize the medical home, rather it established offsite public facilities where clients would be instructed to go for their pandemic vaccination. Public school locations are familiar, and they are routine for families who transport children whether daily or occasionally. The fact is the public knows where schools are and many county emergency management points of distribution are based around the location of public schools. However, public facilities do not reach the entire population and probably omit most adults in the workforce. Familiarity with a clinic location is more likely where resident's evacuation and sheltering operations are routine such as coastal states threatened by hurricanes. Options must be considered where the use of public schools is limited to the purpose of education and may not serve as sites in emergency response.

This enabler contributes to the criterion client-centered approach; however, much more can be done as experienced with H1N1 and what the private sector has accomplished through the seasonal flu campaign.

c. Lift and/or Minimize Administrative Barriers

The survey reported that in general, administrative barriers included medical screening requirements, documentation and even fee charges. Pandemic vaccine is purchased by the federal government, and there is no charge for the vaccine administered through the provider network. But there is variation in the "administration" fee charged by providers, which can serve as a barrier for clients. A shot in a public

[19] The Health Alert Network (HAN) is a public health electronic alert system that communicates with healthcare providers registered throughout a state. States are connected through HAN to CDC.

health managed clinic has no administrative fee when those clinics are held in public schools, onsite clinics or other venues. Chain pharmacies charged a minimal $5.00 per shot while reports of providers administering shots to Medicare eligible clients billed up to $19.00. A recent analysis of insurance concludes:

> To date no state mandates coverage of vaccine administration fees during public health emergencies as a basic aspect of public health preparedness, thereby raising questions of how accessible private sector immunization services would be, particularly for larger families. (Rosenbaum, Lopez & Margulies, 2009, p. 3)

Messages that state on one hand, "there is not charge for a flu shot," but then retail facility charges a fee, though administrative, is a conflicted message, which compounds confusion and becomes a barrier that minimizes immunization uptake.

5. Can the Public Health Model Support Integration?

Chapter IV identified shaped and validated two enablers that support the criterion integration. This framed the evaluation and discussion of the PHM. Elements of the model that were illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

The PHM is a staple of public health practice in the United States and has been given much credit for the eradication of polio, smallpox and controlling numerous other infectious disease breakouts. In fact, in many developing countries today, the model is still deployed and based on very robust public health systems with the resources to marshal against disease agents.[20]

The likelihood of the U.S. public health system returning to the workforce capacity in proportion to the population is not likely given the multitude of demands on

[20] Conversation with Sheldon Jacobson on his statement in *Vaccine* to use the pediatric vaccination model for pandemic vaccination. He stated the limitation for the U.S. is a public health system with an inadequate infrastructure to support vaccination on this scale (S. Jacobson, personal communication, June 3, 2010).

states and the federal government. Thus, alternatives must be sought that can accomplish the mission expected of a nation during a public health emergency of national significance but are unencumbered by barriers described in Chapter IV. Public health offers the nation a system and a workforce that knows and practices partnering routinely with the healthcare private sector, as witnessed during the H1N1 pandemic response. What is missing from the model for state and local jurisdictions is partnering with the non-healthcare sector to expand the vaccinator and venue base for emergency response.

The U.S. Public Health System has demonstrated its ability to partner at all levels, as described throughout this thesis. For example the VFC program serves as an example of federal, state and local public health jurisdictions that partner with physician providers to ensure every child receives the full compliment of childhood vaccinations. The federal government partners with pharmaceutical manufactures to establish onshore production facilities and bring to fruition "high-tech" cell-based vaccine production. The 2009 H1N1 response saw many of these elements come together; this demonstrates the willingness of public and private sectors, local, state and federal to address this particular biological threat. Can the public health model support a policy of integration? The evaluation assessed this criterion as high.

6. Is the PHM Supported with Federal Planning Guidance?

Chapter IV identified shaped and validated two enablers that support the criterion planning guidance. This framed the evaluation and discussion of the PHM. Elements of the model that are illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

Extensive guidance was in place before the 2009 H1N1 pandemic as described previously in this chapter. Numerous checklists (HHS n.d. (e)) were developed by sector and by target groups, as described in *Guidance on Allocating and Targeting Pandemic Influenza Vaccine* (HHS, n.d. (a)). For example, there is a published pandemic preparedness checklist for nursing homes that outlines very specific steps a nursing home

should take to prepare for a pandemic. Likewise, the same checklist format is used to provide guidance for utilities, workplace and individual and families. The national planning scenario illustrates the threat of a pandemic to the nation by ranking it number three of the 10 scenarios and is well supported with exercise and evaluation methodology (Homeland Security Council, 2004).

Respondents in the survey acknowledged awareness of federal guidance as it relates to pandemics, whether or not it supported what most thought would be the H5N1 pandemic or the 2009 H1N1 pandemic. Most could speak to its strengths and its limitations, and therefore their knowledge base served as a particular area of expertise. In the review of guidance in this chapter, reference was made to several documents that serve as evaluation instruments for state and local pandemic plans. There does exist, for the most part, a continuity of plans from the federal, to state and to local public health jurisdictions—though in any state there may be much variation, as discussed in the guidance section. Is the public health model supported with federal planning guidance? The evaluation assesses this criterion as high.

E. SUMMARY OF RESULTS

This summary itemizes the narrated strengths and weaknesses by criterion for the PHM. Table 8 summarizes the rating of the model evaluation criteria for the PHM while Table 9 summarizes the strengths and weaknesses by rating and criterion.

Table 8 summarizes the evaluation of the public health model using the criteria defined in Chapter IV. The criteria executable, scalable and provider-centered were rated low; client-centered rated medium and planning guidance and integration rated high.

Table 8. Model Evaluation Criterion Matrix: Public Health Model

MODEL	EXECUTABLE	SCALABLE	CLIENT CENTERED	PROVIDER CENTERED	INTEGRATION	PLANNING GUIDANCE
Public	**Low**	**Low**	**Medium**	**Low**	**Medium**	**High**

Table 9. PHM: A Summary of Strengths and Weaknesses

Model Evaluation Criteria	Rating	Model Strengths	Model Weaknesses
Executable	Low	✓ Publicly funded campaign	✗ Lacks a staffing model sufficient to support mass vaccination ✗ Lacks description of technology used to support distribution o Distribution to provider network o Ordering system from network to centralized distribution
Scalable	Low	✓ Venues are a strength but limited by staffing	✗ Lacks staffing model sufficient to support mass vaccination ✗ Lacks multiple venues to support mass vaccination ✗ Vaccine production offers no scalability
Client-Centered	Medium	✓ Venue familiarity through public school selection ✓ Emphasis on communications ✓ Advocates for range of venues ✓ Publicly funded campaign	✗ Staffing does not support a range of venues ✗ Little to no guidance for charging administrative fee ✗ Lacks advocacy for medical home
Provider-Centered	Low	✓ Publicly funded campaign	✗ Lacks advocacy for medical home ✗ Directed toward the public health planner ✗ Mechanism to recruit private sector absence ✗ Most communication directed toward the public
Integration	Medium	✓ Demonstrated partnering through VFC ✓ Demonstrated through federal level and vaccine supply issues ✓ Demonstrated through H1N1 response	✗ Advocacy for partnering with private sector providers to expand network
Federal Planning Guidance	High	✓ Published guidance for planners ✓ Published guidance vaccine administrators ✓ Guidance reflects consensus among ACIP, NVAC and PCAST advisory committees ✓ Guidance continuity : federal to state & local jurisdictions ✓ Admin tools to guide planning	✗ Guidance does not reflect operational implementation of planning issues such as technology, distribution, provider network expansion.

F. DISCUSSION OF RESULTS

The reference is made to the public health model, and the survey revealed the limitations of the federal pandemic plan. The survey revealed three limitations with the PHM staffing model: sized for response, inventory management database and publicly funded.

Historically with the PHM, vaccine would be shipped from CDC to state pharmaceutical depots where states would than parcel out product, label and ship it to its provider network. As revealed in the survey, many state depots have been disassembled, including fixtures, equipment and personnel essential to support a depot operation. An element of this logistics function is the inventory management for which most states no longer have a current vaccine inventory management system. Therefore, inherent in this model is the lack of a provider network that places full dependency upon the public health infrastructure to vaccinate its state population. Without this logistics infrastructure, a states pandemic plan would fail to support its execution.

Support of the public health model requires an infrastructure that includes multiple venues, staffing, and a management team to support incident response. It was stated earlier that there are over 3,036 departments of health in the United States, which represents at least 3,036 venues and probably many more (HHS, 2007). Plans call for public health to establish offsite clinics at public schools, mass gatherings and other venues. But the limitation of staff prohibits an aggressive campaign in the event mass vaccination is called upon to protect the population. An element of this limitation is the management infrastructure to support a robust campaign that includes logistics support, incident command structure as well as operations or nurse clinic managers. Nurse clinic managers are essentially to direct clinic operations in offsite locations while ensuring the safety of attendees and protection of workers as well as maintaining cold-management of vaccine.

A critical component in the execution of pandemic plans, whether they are federal, state or local, is funding. There currently are no funding mechanisms in place to support federal, state or local pandemic plans in their execution phase. The survey

revealed that policy carries with it funding but there exists no pandemic policy. Pandemic plans that have been developed are dependent upon a funding mechanism to fall into place before response begins.

Three enablers were identified in the survey as key support for scalability in a pandemic plan. These enablers were described as a robust vaccinator corps, scaled vaccine production and multiple venues.

At one time, the PHM was staffed with a robust vaccinator corp. Public health personnel were skilled, efficient and the staffing model sufficient to wipe out smallpox, eliminate polio and dramatically reduce infectious diseases that afflicted children of the period. Today's public health staffing numbers are no longer sufficient to support the PHM as implemented during the middle of the twentieth century.

Accompanying public health staff are facilities, but these must be viewed from two perspectives, both onsite and offsite. Onsite facilities are those sites where immunization clinics are held and managed by public health. These sites have been reduced in an effort to consolidate, reduce cost and conserve staff. Many of these sites were established in rural, remote locations in an effort to support the public health needs of those constituents. As public health funding contracted, so did remote facilities, which required citizens to travel further for fewer services. As a result, this venue network has contracted and can no longer serve as a viable element of the vaccination provider network. It must be resurrected in some form to provide vaccination services.

The other component of multiple venue criteria is those offsite clinics that have served as the hallmark of mass vaccination efforts over the decades. Today, these are a robust component of pandemic vaccination plans and one that many public health jurisdictions have exercised in recent years. They include public schools, municipal recreation centers and convention centers. There are several limitations such as vaccinator corps, logistics support and the incident management structure to support multiple vaccination venues. While many public health jurisdictions have exercised a

mass vaccination center, how many have exercised multiple venues over an extended period of time? This is a goal of CDC, a prolonged, sustained vaccination campaign, requiring six months to vaccinate a nation.

Four enablers were identified from the survey that contributes to a client-centered model: 1. vaccination that is routine and familiar, 2. vaccination that is convenient and accessible, 3. lifting administrative barriers, and 4. transparency of the vaccine production.

If the PHM calls for standing up special clinics in venues that are the planned response, while convenient and accessible, this would not qualify as routine and familiar. When those plans call for a public school setting, this would meet the qualification as routine and familiar while also being convenient and accessible. The likelihood is that most local plans have factored in these two enablers and, therefore, would meet these qualifications.

The lifting of administrative barriers to maximize vaccination rates are considerations that are determined once a suspect novel virus is confirmed and the full scope of response is understood. The PHM, when initially introduced in the mid 1950s, did not have the vaccine safety concerns, the litigious society and the anti-vaccine movement as is present in the twenty-first century. On the other hand, the model evolved, it failed to include compensation mechanisms that would have protected the public while demonstrating confidence in vaccine products by incorporation programs, such as the vaccine compensation injury program described in Chapter IV.

Transparency of vaccine production was identified as an education strategy to compromise the skepticism that surrounds “quickly” developed vaccine. The PHM does include robust communication strategies with sufficient funding but as the survey revealed, there is room to use new technologies and improve communication messages.

G. CONCLUSION

The public health model for pandemic vaccine distribution, evaluated on the basis of the model evaluation criteria, is mixed with high marks for federal planning guidance and integration. On the other hand, it is assessed as low for criterions executable, scalable

and provider-centered. The model reflected an assumption that DoH clinics will be the primary venue for conducting mass vaccination clinics. The H1N1 response showed much divergence from this assumption and suggests this assumption is no longer valid. An additional implicit assumption is that the logistical requirements to support mass vaccination would be sufficient; yet the H1N1 response revealed many of these mechanisms are no longer in place and, as a result, was supplemented for the H1N1 response (ASTHO, 2010).

Two findings result from the evaluation and analysis of the public health model:

1. The HHS pandemic vaccination distribution plan (PVD) is not executable.
2. There exists statutory, regulatory and licensure barriers to the use of alternative healthcare professionals as vaccinators.

A model for PVD should identify and incorporate strategies that will strengthen the implementation of the model to achieve its goal of mass vaccination and herd immunity. The evaluation highlighted the extensive guidance for vaccine administration to target groups, achieve the ethical principle of justice and manage who gets vaccine. What is absent in the model and its guidance is how vaccine is distributed (strategies), where vaccine is distributed (venues) and by whom (vaccinators).

VI. THE PRIVATE SECTOR MODEL: AN ALTERNATIVE IMPLEMENTATION STRATEGY

A. OVERVIEW

The private sector model (PSM) is represented by the seasonal influenza campaign and is a for-profit approach used annually. A vaccine is manufactured by the private sector, sold mostly to for-profit providers and then distributed via the private sector. Its provider network is limited to the "for pay" sector, of which 74 percent includes physician practices (HHS, 2005a). In the two seasonal flu years (2007-08) that preceded the H1N1 season, this sector model distributed vaccine doses in the range of 135 to 140 million doses (Health Industry Distributors Association [HIDA], 2009a, p. 5). It is supported by a wholesaler/distributor network that approximates 200,000 distributors (HIDA, 2009a, p. 3). It distributes or re-distributes vaccine to not only private sector physician practices but also hospitals, retail pharmacies and big box department stores. Big box stores and pharmacies contract with private sector "flu teams" who manage and administer vaccine using sound vaccine management practices. In contrast, during the H1N1 pandemic, centralized distribution technology, inherent to the PSM, was expanded to manage vaccine distribution to 90,000 providers (McKesson, 2009).

A review of the literature in relation to a private sector vaccine distribution model reveals its omission for use in public health emergencies. It is well documented for seasonal influenza distribution but there is a gap regarding its application for emergency response. This brief literature review includes the "real time" events of H1N1 as captured through conference calls between CDC and the states and minutes as well as the government online resources that describe the use of the public sector distribution model (ACIP, 2009). It is the 2009 H1N1 incident in which the federal response leveraged the public sector distribution model. For example, in a July meeting of the Advisory Committee on Immunization Practices (ACIP, 2009), CDC introduced the expansion of its contract with McKesson to distribute H1N1 vaccine based on the Vaccine for Children program. A significant event, it underscores the absence of planning guidance for state

and local public health jurisdictions in rolling out new methodology. This chapter will show how elements of the private sector model (PSM) were tapped for the 2009 H1N1 pandemic, its first foray into the emergency realm.

B. THE PRIVATE SECTOR MODEL

A vaccine is manufactured for profit, 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. It is estimated that a third of all annual flu vaccines are administered through the retail sector (Lien, Maldin, Franco & Gronvall, 2006). 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. As a result, 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 6 shows the private sector model and illustrates the complexity and redundancy of production, distribution, wholesale and provider relationships. The role of government, federal state and local, accounts for less than 10 percent of activity in this model (HHS, 2005a). It shows that 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.

The limitations of this model to serve as public policy are twofold: failure to reach both geographically remote and high-risk population targets. The model offers limited reach into remote, rural areas, which are not served by large corporations with franchise networks. For example, while corporate retail pharmacies are members of the network, such as CVS, Walgreen's and Rite-Aids, those 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 distributions.

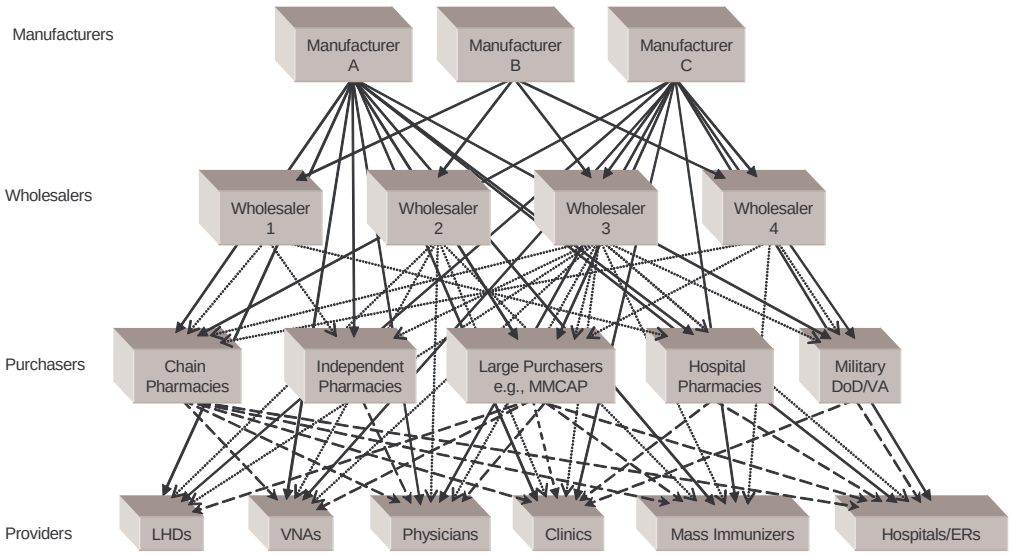

Figure 6. Private Sector Model (From HHS, 2005a, p. 5)

A second limitation of the model is that it does not incorporate a community outreach component that serves high-risk population targets. Vaccination rates among the uninsured, underinsured and geographically remote population groups are underachieved by this model, due to limited accessibility.

The public sector's sole responsibility in this model is as a buyer of vaccine, which accounts for less than 10 percent of total vaccine sales. The U.S. Department of Health and Human Services bulk contracts for cost-effective vaccine pricing and permits state, tribal and local Departments of Health (DoH) to purchase vaccine from the contract price. In periods of shortage, crisis or emergency, without the intervention of the federal government, population groups at greatest risk persist with unmet medical needs.

C. EVALUATION

The evaluation of the private sector model considers those elements consistent with the criteria identified and validated by subject matter experts in Chapter IV. The criteria become a framework to analyze model elements in light of survey data, qualitative analysis from the literature and the 2009 H1N1 pandemic. Each criterion is stated in a performance measurement (i.e., is the private sector model executable?), a discussion follows and rating assessed. The assessment was based on the extent to which each criterion is supported by its enablers. The rating scale is either present (high), absent (low) or potential for improvement (medium). The assessment offers an indication of the strength of this criterion as exhibited in the model.

As the PSM is examined, important considerations are those strategies developed by health and medical associations to transform their practice in the context of solving twenty-first century healthcare delivery issues. It is a transformation internally to adjust to external healthcare dynamics and to provide patient care in new ways to solve complex systematic problems. A practice referred to throughout this thesis has been that of pharmacy. This section explored how the discipline is reinventing itself, in such a way, that for the pharmacists of the future, their practice becomes provider-centered, client-centered and contributes to a staffing model that increases the ability of the model to be executable. The example shows how the discipline was poised to serve as vaccinators in their local communities but it took the H1N1 crisis for other practices to take note. Even then, institutional barriers persisted. This case study refers to one discipline, yet other disciplines are working with similar innovations, which are worthy of further study.

1. Is the Private Sector Model (PSM) Executable?

Chapter IV identified shaped and validated three enablers that support the criterion executable. This framed the evaluation and discussion of the PSM. Elements of the model that were illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

a. Integrated and Routine Use of New Technology

The PSM is technology driven and uses the centralized distribution, which made it attractive to adopt for the H1N1 vaccination. The survey reported that the pharmaceutical industry uses supply chain inventory management system routinely to run operations. More importantly, the PSM is not built around one vendor, such as the CDC contract with McKesson, but all approved influenza manufacturers/distribution chains would operate similarly. Thus, while there is redundancy in the private sector system, each distributor becomes responsible for performance measurements with each customer and that can vary from one distributor to another.[21]

Vaccination is a process that does not occur in a healthcare vacuum. A transformation is occurring in the industry by retailers who have begun to "cherry-pick the most profitable services" (Malvey & Fottler, 2006, p. 170). This issue will be revisited in subsequent analysis of the PSM, but retailers have demonstrated the ability to use technology, gain market share and provide value to the customer. One observation describing Walmart's[22] entry into healthcare delivery wrote, "Walmart uses information technology (IT) to facilitate organizational innovation for critical processes that leverage productivity and customer satisfaction" (Malvey & Fottler, 2006, p. 170).

While this comment addresses the use of technology for improving productivity, it also suggested its use for attracting customers through value and convenience. This topic will be revisited in the analysis of client-centered, but this observation and the example of centralized distribution illustrates that external forces influence the PSM and its delivery of vaccine. The PSM is not a medical model, driven by healthcare organizations in the traditional sense. Rather, it is a model driven by the private sector that leverages resources and technologies to deliver a good and, in this

[21] There are tradeoffs, redundancy versus accountability. McKesson expanded its performance measurement metrics with CDC for H1N1to ensure same day fill or 100 percent of orders were filled day of receipt. In contrast, VFC is a three to five day fill (80 percent orders filled in three days, 100 percent filled in five days (Survey Interview, May 18, 2010).

[22] The branding of Walmart was refreshed from Wal-Mart to Walmart June 30, 2008 (Walmart 2008).

instance, a service/good. This brief overview shows that PSM in terms of technology is robust; it demonstrates the power of the private sector system, and, with the capacity to distribute 140 million doses, it is executable.

b. Staffing Model: Sized for Response

The evaluation of the enabler staffing model addresses the distributor network as well as a provider network, which receives and distributes vaccine into the arms (or noses) of clients. Figure 6 illustrated the distributor network that supports the provider network and gets vaccine into the system.

According to a 2008–09 industry report, the two seasonal flu years that preceded the H1N1 season saw flu vaccine doses that were manufactured in the range of 135 to 140 million doses (HIDA, 2009a, p. 5). The provider network, in place to administer those doses, is challenging to quantify due primarily to the proprietary nature of the customer database. But open source documents do provide some indication of a network that supports the seasonal flu campaign. For example, according to HIDA, the wholesaler/distributor network approximates 200,000 distributors (2009a, p. 3). These distributors buy vaccine and sell it direct, redistribute or package it with vaccination ancillary supplies and sell the package.

Three major pharmaceutical/medical centralized distributors[23] account for an estimated 85 percent of vaccine distribution. Thirty additional regional distributors provide the balance of distribution. It is the major specialty groups that redistribute vaccine to other regional and smaller distributors. Finally, a HIDA 2007 industry market profile described the distribution network and wrote that it served "more than 50,000 points of care across the country and more than 12,000 U.S. medical practices with six or fewer physicians" (2008, p. 3).

The known customer base served by the distribution network is propriety, but open source documents do provide a feel for the range and types of vaccinators that

[23] Three major pharmaceutical medical specialty groups are McKesson Medical Specialty, AmerisourceBergen Specialty Group and Cardinal Health.

makeup this network. Consider the 100,000 pharmacists poised to staff community-pharmacy based clinics in chain pharmacies, supercenters and grocery stores and supplement medical practices that have served as the core for vaccination services throughout the decades (M.C. Rothholz, personal communication, June 9, 2010). Walmart offers 15,000 pharmacists in 3,000 in-store clinics (C. Aliger, personal communication, June 15, 2010), nearly the same number of DoH sites referenced in the public health model. The staffing model enabler is explored further in the evaluation of the scalable criterion but we learn this enabler supports an executable PSM.

c. Publicly Funded Vaccine

The funding mechanism with which the PSM operates is self sufficient; however, as reported in the survey, profit margins are low but the PSM provides a service to those at greatest risk and those who wish to get a flu shot. However, once cell-based technology comes to production, its technology development investment will have been underwritten by the USG. While this is a shared investment, the technology will have dual-purpose; one, pharmaceutical manufacturers having a contractual obligation to produce pandemic vaccine, and two, other vaccine countermeasures as a result of the public investment.

Is the private sector model executable? Each season this model gets vaccine out through its distribution network. The limitations over the years have been the vulnerability of vaccine production to contamination such as in 2004–05 with Chiron (GAO, 2004). In 2007–08, the PSM distributed an average 135–140 million doses, over 45,000 more doses than were distributed in the 2009 pandemic (HIDA 2008).. The redundancy of its centralized distribution works and it gets vaccine out to multiple venues and a provider network representing both traditional and non-traditional providers. The staffing and technology enablers are assessed as high, and the evaluation of the PSM is high for this criterion.

2. Is the Private Sector Model Scalable?

Chapter IV identified shaped and validated three enablers that support the criterion scalable. This framed the evaluation and discussion of the PSM. Elements of the model illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

a. Scaled Vaccine Production

Vaccine production that uses egg-based technology has drawbacks as described in the survey and discussed in the evaluation of the public health model. This affects either model equally. The difference in this evaluation is that the wholesale/distributors are holding the orders and the customers are the private sector provider network versus the USG. Until the nation has achieved production self-sufficiency and while it is dependent upon offshore vaccine manufacturers, scaled vaccine production is not likely.

b. Robust Vaccinator Corps

One respondent in the survey, with a pharmaceutical industry background, described seasonal vaccine as a commodity and that when coupled with service, should be sold as a product. This perspective contrasts with that of public health/medical that views vaccine as a medical/patient curative. A significant reason the executable criterion was rated high among respondents is because the provider network is not limited to physician practices. While physicians administer 74 percent of seasonal flu shots, the retail portion has grown steadily over the last several years (HHS, 2005a). The PSM is expanding its provider network through retail outlets, including community-based pharmacies, grocery stores and big-box department stores or supercenters. It is the later that supports not only food, clothing, garden supply and hardware but pharmacy as well. In fact, it is the bulk buyers who pay premium prices for vaccine that get the first shipments and, therefore, get vaccine into the market place before physician practices. Consider this press release from the Walgreen's newsroom:

> The retail pharmacy channel continues to play an increasingly important role in trying to drive higher rates for flu immunizations in all 50 states. Pharmacist-administered seasonal flu shots grew 36 percent this flu season, accounting for approximately 10 percent of the total administered nationwide. A recent study by the Centers for Disease Control and Prevention (CDC) found that approximately 12 percent of those surveyed said they received their seasonal flu shots from a drugstore or pharmacy. (Walgreen, 2010)

Equally attractive to the growing segment of retailers is that "flu shots" serve as marketing strategy to make the supercenter a one-stop-shop for all needs at great value. Chain pharmacies also use this as a marketing ploy to attract customers as well. Factors of this nature contribute to physician specialties, such as the OB/GYN described in the survey, moving away from offering vaccination in their practices. The Walgreen's newsroom also reported, "According to the American Pharmacist Association, there are now more than 100,000 pharmacists nationwide who have completed a certificate-training program in pharmacy-based immunizations" (2010).

c. Multiple Venues

While physician practices provide an estimated 74 percent of seasonal vaccinations, the retail sector is growing its market share as a marketing strategy and expands the number of venues offered through the PSM (HHS, 2005a). Retailers have been aggressive to enter the vaccination market and use vaccination to get customers into their storefronts. Other models are also being used to deliver vaccination services: "Pharmacies, supermarkets and other retailers are jockeying to become the go-to provider for swine-flu vaccinations, in a bid to attract more customers and, in many cases, promote their in-store health clinics" (Martin, 2009).

Walgreen's reports 7,100 pharmacies (Martin, 2009) and CVS boasts another 3,000 pharmacies that give flu shots (CVS, 2009), in contrast to local DoHs at 3,036 venues. But this shows the scalability of the private sector tapped for seasonal flu and poised for pandemic response.

An additional corporate competitor in this market is Walmart with its presence in 4,300 communities (Walmart, 2010a). Its pharmacies are present in 49 states

and it recently introduced its in-store health clinics, which currently numbers 73 (Walmart, 2010b). Walmart leverages its 4,300 storefronts with a pharmacy presence and extends it with 15,000 pharmacists (C. Aliger, personal communication, June 15, 2010),

Other private sector flu shot providers are the retail contract services such as CIGNA, Maxim Healthcare and Flu Busters. Described as "onsite, multi-service wellness programs" (CIGNA, 2010), these services are adjunct taking their business model to workplace, supercenters (e.g., Costco) and even physician practices to assist with flu shots during the seasonal campaign. They were used during the H1N1 response as a contract service provider. Their vaccine was still provided through public health, the gate keeper for all pandemic vaccine. What drives the sector interest to expand the venue network is the market forecast for vaccine production stimulated by USG investment.

> While prescription drug sales are forecast to rise by a third in five years, vaccine sales should double, from $19 billion last year to $39 billion in 2013, according to market research firm Kalorama Information. That's five times the $8 billion in vaccine sales in 2004. (Associated Press, 2009)

The growth of the vaccine market illustrates the interest in innovation that is driving the private sector to use vaccination as a strategy to grow their service portfolio and therefore expand its venue base. Equally important to consider are the wholesalers/distributors that supply a broad-based, multi-level distribution system. An industry market profile in 2007 reported, "more than 600 distributors operating 800 distribution centers" (HIDA, 2008, p. 3). It added that this distribution network served "more than 50,000 points of care across the country and more than 12,000 U.S. medical practices with six or fewer physicians" (HIDA, 2008, p. 3).

Is the private sector model scalable? It offers the capacity for scalability but is limited by vaccine availability and marginal profit returns. But this brief overview shows that the private sector identifies strategies to leverage vaccine distribution within a corporate marketing strategy and grow the market for vaccinations. The survey indicated a strength of the PSM is that it gets lots of vaccine into the supply chain quickly, which speaks to the strength of its distribution network. The PSM is rated high for scalable.

3. Is the Private Sector Model Provider-Centered?

Chapter IV identified shaped and validated four enablers that support the criterion provider-centered. This framed the evaluation and discussion of the PSM. Elements of the model are illustrative of evaluation criteria enablers that were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

Over the past two seasons, prior to H1N1, 135–140 million doses of flu vaccine have been pushed out through a provider network, 74 percent of which are represented by physician practices (HHS, 2005a). Seasonal flu vaccinations have become routine for most providers. It was described earlier, in the evaluation of the scalable criterion, that there are many new comers to the network. The model attracts innovation expanding the network beyond traditional vaccinators, including non-traditional vaccinators.

a. Minimize Administrative Barriers

The private sector model, through innovation, has expanded its network of providers and has done it with minimal government oversight of vaccine distribution and administration, which is not to say that current documentation requirements are not burdensome. As described in the survey results in Chapter IV, physician practices find government directed services burdensome. Yet to understand the difference of administration and documentation, the analysis of this enabler will contrast similar tasks under a pandemic and how those tasks are present or absent during administration of seasonal flu vaccine. For example, a significant factor as described in the survey is that during H1N1, providers were required to order vaccine weekly. In contrast, for seasonal vaccine, the order is submitted once unless there is a re-order. Providers agreed to provide an information packet to vaccinees that included not only a patient medical screening page but the 2009 H1N1 Vaccine Information Statement (VIS). If the provider offered flu-mist, then the packet would include the “Influenza Vaccine Live, Attenuated” statement. If the offering was the injectable, then an “Inactivated” or “flu shot” statement was included. VIS is required for all vaccinations.

An additional administrative expectation from private sector providers who participated in the H1N1 vaccination campaign was a set of registration documents. A registration packet precludes vaccine ordering and with H1N1, physician practices were required to register twice. First a practice registered with the state then once qualified, registered with the CDC. The typical packet included an enrollment form, memorandum of agreement (provider agreement), order and activity worksheet plus sets of instructions regarding cold-chain management of vaccine, filling out order forms, etc. Also included would have been guidance regarding vaccine adverse events[24] and their point of contact such as the DoH. Finally, the "dose administration report" forms were to be completed on a weekly basis by the practice and then reported to the project area (state or other jurisdictional DoH). With the exception of the VIS, these forms and activities are not required for seasonal flu administration even if the provider is a VFC program provider. The rationale is that they are already enrolled with VFC. These public sector administrative requirements depart from the customary administrative requirements a private sector practice completes when offering seasonal vaccine. It is this public sector process that providers find burdensome.

b. Transparency of Vaccine Production

Planning guidance emphasizes communication strategies throughout guidance doctrine but the strategies are generally directed toward the public.

c. Electronic Interface with Ordering System

This enabler is embodied in a broader context of system dynamics that temper the adoption of technology among healthcare providers by organizational structure type. For example, ambulatory clinics (in-store clinics) participating in the provider network are more likely to adopt health information technology (HIT) to maximize productivity and cost efficiencies than traditional physician practices (Siddharta, Battott, Beasley, Nadkarni, Gertner, & Holmbae, 2010). In contrast,

[24] A vaccine adverse event is an adverse change in health that is initially assumed to result from the vaccination. National surveillance is conducted through the Vaccine Adverse Events Reporting System (VAERS) and is hosted by the CDC and FDA to report adverse events, as well as vaccine safety.

traditional healthcare organizations would "primarily use IT [information technology] to improve financial reporting" (Malvey & Fottler 2006, p. 170). In recent years, healthcare providers have been challenged with electronic health record (EHR) mandates and its associated Computerized Physician Order Entry (CPOE) system. Several factors contribute to the reluctance among providers to adopt technology with the changing dynamics of healthcare delivery, cost reimbursement and legislative mandates all contributing factors. For example, the Medical Group Management Association (MGMA) reported in October 2009 that 75 percent of its members had not made the investment in EHR due to expense, return on investment and reduction in Medicare reimbursement (Healthcare IT News Staff [Healthcare], 2009).

Surveys have also been conducted to understand the factors that lead to adoption of these technologies, especially EHR. For example, a recent survey found that predictors of adoption included physician age, prior technology experience, years experience, system support, and clinical specialty (Morton & Wiedenbeck, 2009, p. 14). In general though, physician practices have been slow to adopt electronic systems with the exception, as noted to use for maintaining financial records (Bechham, 2002). The survey in Chapter IV revealed one state's application of technology for H1N1 providers did address communications and a Zoomerang survey reported high levels of satisfaction.

d. Publicly Funded Vaccine

As described previously under executable, this enabler is not a factor when distribution through the private sector is administered as the private sector model.

4. Is the Private Sector Model Client-Centered?

Chapter IV identified shaped and validated four enablers that support the criterion client-centered. This framed the evaluation and discussion of the PSM. Elements of the model illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

a. Transparency of Vaccine Administration and Production

When vaccine is readily available through the private sector model, there is no rationing and vaccine administration and production are not issues that become barriers to vaccination. The model is supported by an extensive public information campaign with four key messages, similar to those adopted for the H1N1 campaign that is managed by CDC in cooperation with state DoHs.

b. Vaccination is Familiar and Routine, Convenient and Accessible

The PSM has evolved and adapted to the changing strategies for delivering health care services, especially vaccinations. Physician-directed care is the core for vaccination services, especially with the institutionalization practice of the patient medical home. But this strategy reaches only a segment of the population and leaves a significant portion looking for convenience in healthcare.

Other segments of the system have responded with alternative strategies to deliver non-critical care as introduced earlier. Consumer-driven health care is an emerging trend that is expected to grow as the insured become more responsible for financing healthcare as a result of higher co-pays and higher premium deductibles. Consumers are making decisions based on value and convenience when care is not urgent, and vaccination services are becoming a commodity widely offered by retailers. These are attributes of the consumer profile that have attracted the attention of retailers as they adapt the retail, customer-driven model for healthcare delivery.

Customer convenience and accessibility has attracted the attention of retailers hosting in-store clinics. Vaccination is a service that has become part of the service mix as retailers have explored this service. Consider this statement published in 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” (Scott, 2007, p. 18).

Over 90 percent who visited a retail clinic were satisfied according to a 2007 study and 83 percent reported satisfied with the convenience (Bright, 2007). A

factor of high satisfaction is the point-to-point service aspects of vaccination at these locations, not unlike the strategy adopted by Southwest Airlines that contributed to its success (Kim & Mauborgne, 2005 p. 39). The point-to-point service concept refers to air travel that takes a customer from home to destination without layover. Getting a shot at a retail in-store clinic where the customer is visiting for other products and services is a variation of point-to-point service.

Convenience and accessibility found application in other customer-centric strategies used during the H1N1 response. For example, public health clinics provided "drive-thru flu clinic" (Sullivan, Trapnell, Muller, Kehler, & Stoops, 2006, p. 1). Clients remained in their vehicle, completed a form, and once medical screening was conducted, the vaccination was administered while the client remained seated in the vehicle. This strategy grew out of the 2004–05 vaccine shortage when high-risk, ambulatory client was unable to stand in long lines to get a flu shot. Clients report high levels of satisfaction with an average of 12 minutes to get a shot.

c. Lift and/or Minimize Administrative Barriers

Clients report high levels of satisfaction as the PSM has evolved, increasing convenience and accessibility and simultaneously minimizing administrative barriers to improve vaccination uptake. The administrative documentation differential is evident between public sector and private sector for the seasonal campaign. The PSM minimizes required documentation while the public sector seasonal vaccinations follow the documentation regimen used for any vaccination campaign, pandemic, seasonal or other.

In summary, this assessment of the criterion client-centered targeted the specific enablers defined in Chapter IV. The discussion reveals the extent to which interdependences among the scalable, executable and integrated criterions in this model supports a client-centered approach to vaccination. For example, a variety of venues, both traditional and non-traditional address client-centered enablers of convenience and accessibility in terms of no or minimal waiting, 24/7 access, and great value (in contrast to traditional provider cost structures).

5. Can the Private Sector Model Support Integration?

Chapter IV identified shaped and validated two enablers that support the criterion integration. This framed the evaluation and discussion of the PSM. Elements of the model illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

Can the private sector model support a policy of integration? Given that elements of the PSM were adopted for the H1N1 vaccination campaign, this suggests the model can support a policy of integration. The providence of Ontario uses its seasonal influenza model as the basis for its pandemic response. The Ontario strategy is the administration of a single integrated vaccine distribution system for both seasonal influenza and pandemic vaccinations. Distribution depends not only on the public health sector but works closely with the private healthcare sector, retail pharmacies and related retail outlets.

> Ontario has a vaccine distribution system in place to support its Universal Influenza Immunization Program (UIIP). A similar system may be used to distribute vaccine during a pandemic, with some changes. (Ontario Ministry of Health and Long-Term Care [OMHLTC], 2008, p. 9–4)

The difference is that the UIIP, as implemented in Ontario, is the purchaser of vaccine, both seasonal and pandemic by the government. This flexibility permits the government to distribute vaccine to its provider network, both public and private. This is the Ontario, Canadian vaccine distribution network. In contrast, the U.S. strategy presents at least three barriers or limitations with the private sector model as currently configured to support a policy strategy of integration. These are:

- Publicly purchased seasonal vaccine distributed to private providers
- Availability of vaccine to all who want a shot
- Federal guidance to support a policy of integration does not exist

There is distrust among public sector providers of the private sector when vaccine is distributed and administered via the private sector model. This perspective was

described in Chapter IV. As the model is currently configured, and while it offers several elements that are desirable for a mass vaccination campaign, it would require a partnership with the public sector before it could be assessed to support integrations. The evaluation assesses this criterion as medium.

6. Is the PSM Supported with Federal Planning Guidance?

Chapter IV identified shaped and validated two enablers that support the criterion planning guidance. This framed the evaluation and discussion of the PSM. Elements of the model that were illustrative of evaluation criteria enablers were evaluated using the interview data and qualitative analysis from the literature review. The criterion represented by these elements was rated high (present), low (absent) or medium (potential for improvement).

The private sector model is built around market forces and the exchange of goods in a free market. It works with what appears to be a great deal of efficiency and capacity to distribute 140 million doses of vaccine and it does this with a minimal degree of government interference (HIDA 2009a). However, it could be argued that federal regulation of vaccine production does incorporate a certain amount of interference. But in contrast to the public health model, there is minimal strategic planning guidance by the federal government that provides oversight of this model to distribute millions of doses each year. It is understood that actors involved in supply, distribution and consumption more than likely have business plans and strategic initiatives, several of which were described in discussions of other criteria, such as scalable and executable.

Private sector planning guidance was identified through open sources, designed for vaccine buyers and incorporates vaccine administration guidance from CDC via ACIP. Guidance of this nature is supported by industry associations but is directed to the individual vaccine administrator rather than a planning body, such as a state or local DoH responsible for mass vaccination efforts. For example, the online Flu Supply News published guidance titled *Flu Vaccine Planning Kit for the Healthcare Supply Chain* and reflects CDC guidance for both the seasonal flu vaccine and the H1N1 vaccine (HIDA, 2009b). This particular guidance is published by a coalition of pharmaceutical

manufacturers and distributors whose interest is to convey accurate information regarding vaccine administration to its collective customer base. It is one example of how the industry serves itself with planning guidance tailored for the customer-provider.

The performance measurement stated, “Is the private sector model supported with federal planning guidance?” The criterion was based on a definition of federal planning guidance that is published by HHS, and it included the need for administrative toolkits such as the “pandemic checklists” used by planners with responsibility for mass vaccination campaigns. The guidance offered by the private sector could support vaccination when administered during an emergency. However, the limitation of guidance of this nature is that it is not sufficient for strategic planning of a campaign but does support the customer-provider. The evaluation assesses this criterion as low.

D. SUMMARY OF RESULTS

This summary itemizes the narrated strengths and weaknesses by criterion for the PSM. Table 10 summarizes the rating of the model evaluation criteria while Table 11 lists the strengths and weaknesses by rating and criterion. The criteria executable, scalable and provider-centered were rated high, client-centered and integration rated medium and planning guidance rated low.

Table 10. Model Evaluation Criterion Matrix: Private Sector Model

MODEL	EXECUTABLE	SCALABLE	CLIENT CENTERED	PROVIDER CENTERED	INTEGRATION	PLANNING GUIDANCE
Private	**High**	**High**	**High**	**Medium**	**Medium**	**Low**

Table 11. PSM: A Summary of Strengths and Weaknesses

Model Evaluation Criteria	Rating	Model Strengths	Model Weaknesses
Executable	High	✓ Model self-funded through the private sector ✓ Use of technology for centralized distribution is integrated and routine ✓ Technology integrated to support provider network ✓ Staffing model sized for distribution response	✗ No weaknesses were noted
Scalable	High	✓ A robust vaccinator corps sufficient to support mass vaccination ✓ Multiple venues to support mass vaccination	✗ Current vaccine production offers no scalability
Client-Centered	Medium	✓ Venue access and venue familiarity ✓ Robust vaccinator corps support variety of venues ✓ Medical home is practiced ✓ Supported through both public and private sectors ✓ Administrative barriers not apparent	✗ Model is limited to the insured or clients with sufficient cash funds ✗ Not a publicly funded campaign
Provider-Centered	High	✓ Model capacity to distribute 140 doses ✓ Model self-funded through private sector ✓ The practice of medical home is institutionalized for selected medical specialties. ✓ Providers set practice administrative requirements ✓ Industry (Pharma) communication directed toward the provider network ✓ Model expands through non-traditional providers	✗ Traditional provider network slow to adopt HIT ✗ Traditional provider network slow to adopt EHR
Integration	Medium	✓ Model elements adopted for H1N1 response ✓ Demonstrated partnering through VFC and H1N1 ✓ Availability of vaccine for all who want it	✗ Requires a publicly funded mechanism ✗ The Model not supported by guidance ✗ General distrust of private sector motives by public sector
Federal Planning Guidance	Low	✓ Published guidance for vaccine administrators ✓ ACIP advisory committee recommendations incorporated into guidance for industry partners	✗ Guidance limited to ACIP ✗ Limited guidance for federal to state and local jurisdiction planners ✗ Administrative tools to guide local planning ✗ Guidance does not reflect implementation of planning issues such as technology, distribution, provider network expansion.

E. DISCUSSION

Three criteria were assessed high for the private sector model; executable, scalable and client-centered. The free market of the U.S. economy provides a scalable feature of the model that permits it to expand when vaccine availability is high and prospective providers can leverage vaccination services with other product offerings. This holds true whether the product offering is a medical service in a physician's office or a customer product that can be purchased from a retail pharmacy, grocery store or big-box supercenter. The base for the model is the medical provider whose advantage is that their medical practice serves as the medical home to families, particularly children and families. But other population targets find this traditional model has limitations and therefore seek alternative models of healthcare delivery to include both non-traditional providers and non-traditional venues. Scalability makes the PSM model executable, given that it offers a capacity to distribute 140 million doses of vaccine in any given year (HIDA, 2009a). The provider network is sufficient to support these criteria as well.

Innovation was referenced in the evaluation of the criteria executable, scalable and client-centered. Retailers exhibited innovation toward customers by providing strategies that would attract those customers to healthcare service products that offered convenience, value and familiarity. The criterion client-centered was assessed high though its limitations to serve the underserved, uninsured groups warranted a medium. The model demonstrates a propensity for clients, and it also operates with the knowledge that the role of public health is to fill gaps. Survey respondents reported the view that public health fills gaps well. The public health role is to reach out to population sectors not currently served by the private sector, such as was accomplished with H1N1. Yet, the model revealed innovations that over time, these strategies may reach and offer limited healthcare services to special need populations.

Both client-centered and integration were assessed as medium, and the rationale for the assessment of client-centered described in the previous paragraph. The PSM offers a base from which an integrated model can be constructed, and therefore it was assessed as medium. If one were to place the two models of distribution on a continuum

and be able to quantify them both in some statistically, meaningful way, the conclusion may very well be that they represent the polar ends of vaccine distribution strategies for the nation. A conclusion, drawn in Chapter V, was that federal guidance reflects a preoccupation with target allocation for at-risk groups to ensure the ethical principle of fairness. The PSM contrasts with the PHM using a disease-prevention biologic (flu vaccine) that serves as a commodity to draw customers to a retail establishment and earn profit. This strategy is dual-purpose as it is leveraged to entice return visits by the customer and sell additional products and services. As a result, it is a variation but draws upon the point-to-point service concept.

F. CONCLUSION

The private sector model for pandemic vaccine distribution was evaluated using the model evaluation criteria, and it rated high for executable, scalable and client-centered. On the other hand, it was assessed as medium for provider-centered and for integration and assessed low for the planning guidance criterion. The PSM has demonstrated the capacity to distribute 140 million doses of vaccine through multiple venues and both traditional and non-traditional provider network (HIDA, 2009a). Surveys showed that clients are receptive and satisfied with the introduction of non-traditional providers and that the PSM supports client-centered enablers of convenience and accessibility.

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VII. A NEW POLICY STRATEGY FOR PUBLIC HEALTH EMERGENCIES OF NATIONAL SIGNIFICANCE WHEN VACCINATION IS THE MITIGATION STRATEGY

A. OVERVIEW

This thesis began with two research questions. The first research question was addressed in Chapter IV; it identified, developed and validated model evaluation criteria, which were used to evaluate two current models of vaccine distribution. These results were presented in Chapters V and VI. The first question set a framework to explore the second research question:

> How could a model be designed to support pandemic vaccine distribution for a public health emergency of national significance?

While the U.S. is progressing toward vaccine production self-sufficiency, little progress has been made on the distribution side. The premise of this thesis is the USG policy of vaccine production self-sufficiency. Its intent was to conduct analysis for a period in the future when vaccine distribution is not based on scarce allocation schemes or vaccine rationing but instead based on vaccine self-sufficiency. As a result, the analysis contributes to the discourse of what the nation's pandemic vaccine distribution system ***should*** look like.

In respect to vaccine, partnerships in the past have been either supply-related or vaccine administration-related. Supply-related refers to vaccine manufacturing while administration-related refers solely to the protocol of inoculating humans with vaccine. The historical relationship has been on the supply side; however, due to the increased interest in bioterrorism and national security in this century, vaccine production capacity was renewed between the federal government and the pharmaceutical industry. As described in the survey, HHS/ASPR/BARDA managed H1N1 vaccine procurement with the manufacturers while CDC managed vaccine administration issues including distribution.

Other vaccine related partnerships have a historical basis and include advisory committees such as the ACIP, established in 1964, which connects federal agencies with the private sector medical community. The nature of this partnership is probably not commonly perceived as a partnership but it is a defined relationship between government agencies and the private and public sector medical community (Smith, 2010). The ACIP advisory group consists of "15 experts in fields associated with immunization" that represent both public and private sector and liaisons from 26 health-related associations. Most experts represent medical specialties such as infectious diseases, pediatrics, internal medicine, family medicine, virology, immunology, public health, preventive medicine, vaccine research, but some included policy, economics and cost effectiveness and a consumer representative. ACIP represents the private sector, professional associations and federal agencies. Its role defines its scope of responsibility:

> The Committee **develops written recommendations** for the routine administration of vaccines to children and adults in the civilian population; recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations. (CDC, n.d. (a))

Vaccine distribution is tasked to the CDC, but the ACIP advisory committee makeup is essentially medical professionals. An additional perspective of the ACIP role comes from within the medical academic community and is reflected in the Annals of Internal Medicine. Distribution is not discussed as a role of ACIP, nor does the word "distribution" appear in the academic journal article (Smith, Snider, & Pickering, 2009). So, what group represents the logistics of vaccine distribution? What is missing, as described in the survey, is representation from the business retail sector and/or the distribution sector. This is the logistics support for public vaccination campaigns that was expanded for H1N1. Until H1N1, this function was an assumed responsibility of the states, which was described in federal guidance but seen as ambiguous by others (GAO, 2009b).

As presented in previous chapters, a paradigm shift has occurred in relation to the public health workforce capacity, state public health budgets reductions and the

expectation that the USG will fund an expansion of a state workforce. In all likelihood, the federal budget will not grow to expand or to sustain a state's public health workforce. H1N1 response showed partnerships are essential to improving the efficiency of PVD, but the nation must get ahead of the paradigm shift and shape the system.

This thesis has explored the complexities of vaccine distribution and proposes that solving systematic constraints will require a collaborative effort. It should include those state and national health and medical associations that influence scope of practice and credentialing for those professionals with the skill set to vaccinate. Involvement of state governments is also needed as they set the statutes and regulatory apparatus that permit professionals to practice.

This chapter used the evaluation criteria developed in Chapter IV to frame the discussion for a new model of pandemic vaccine distribution. Each model evaluation criterion, discussed in the context of the evaluations from Chapter V and VI, described the gap that existed and proposed strategies to strengthen or adopt the criterion to earn a rating of high for a new model. What should a new hybrid model for PVD look like?

Section B narrates a theoretical description of the new model and six goals to support it. Section C proposes a policy for pandemic vaccine distribution accompanied by a framework that outlines its format and suggested legislative solutions. Section D presents barriers to implementation of the proposed policy.

B. THE PUBLIC PRIVATE PARTNERSHIP DISTRIBUTION MODEL

A public private partnership (PPP) leverages private sector resources to achieve the goal of herd immunity during a public health emergency of national significance. The public sector and private sector work toward delivering a public good by building on their core competencies. The public sector, federal government serves as the lead partner coordinating activity among federal agencies, state governments, vaccine advisory committees and pharmaceutical manufacturers. It funds the project and works toward those benefits that ensure and protect the manufacturers, such as indemnification of a new product. The private sector uses its production capabilities, the strength of its logistics support technology and reasonable cost 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.

Figure 7 illustrates the PPP model for pandemic vaccine distribution. The federal government is the purchaser and distributor for all pandemic vaccine. Removed from the supply chain, as shown in Figure 6, are the wholesalers and to a great extent the large purchasers all of which are critical for distribution to providers in the private sector model. This hybrid model restores the distribution network, missing in the public sector model but prominent in the private sector model. It expands vaccination venues by incorporating retail sector in-store clinics, pharmacy, grocery and big box sites, a concept supported by retail executives (Lien, Maldin, Franco & Gronvall, 2006).

The PPP model is defined by planning doctrine, used for public health emergencies of national significance. 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. It integrates the public health system and its target population emphasis with the broad net cast by the private sector to maximize vaccine distribution. This policy solution ensures emergency distribution of vaccine is routine by maximizing geographical reach and use of several sources for vaccine administration.

The role of the public sector is to serve as lead throughout the emergency, and it coordinates procurement, purchase and distribution of vaccine in cooperation with pharmaceutical manufacturers. It works to network the public health sector with providers at state and local levels, establishing those partnerships before emergency operations commence. It uses each influenza season to train, exercise, test and update plans. This follows the policy, practice and methodology of emergency management authorities for preparedness, response and recovery and reflects National Incident Management System (NIMS) guidance.

1. A New Model for Pandemic Vaccine Distribution

This new model for pandemic vaccine distribution is a public private partnership. It builds on decades of the USG partnership and state governments partnering with the

private sector to implement cost effective, but policy based vaccine distribution programs, such as VFC and recently H1N1. This partnership with the pharmaceutical industry has persisted in one form or another since the 1950s but limited to the supply side of vaccine availability until its deployment for H1N1. The partnership must now expand and blend a distribution model for emergency response when vaccination is the mitigation strategy. This section narrates a theoretical description of the new model for PVD.

The model is **executable**, publicly funded with a staffing model sufficient to meet the vaccination goal. It is supported by technology that is used routinely for vaccine ordering and distribution fulfillment. The two systems do not compete. Rather, the two technology systems are complimentary and sufficiently intuitive that provider orders are based on historically ordering. They push product out to the provider with minimal administrative involvement.

It is a **scalable** model, capable of sizing vaccine production upward or downward without sacrificing vaccine yield or production time. More importantly, a robust vaccinator corps has been readied at multiple venues throughout communities to administer vaccine without the encumbrances of regulatory or licensure limitations. Clients have the choices of venue setting and time of day without waiting. The scalability of the model offers options, point-to-point service and encourages vaccination.

The model is **client-centered,** and its strategies parallel those for scalability. It offers multiple venues staffed by a multi-disciplinary team of vaccinators who administer point-to-point vaccination services. The venues where clients go are familiar, routine and convenient. They use them for seasonal flu campaign, whether it is a physician's office, workplace clinics, retail clinic or a public school setting where children participated in a mass vaccination clinic. The model is geographically dispersed, urban, rural, and suburban with venues that are fixed or mobile but still sufficient to reach most population targets.

The **provider-centered** network builds around physician practices It emphasizes the patient-centered medical home but expands to incorporate non-traditional providers to

provide client convenience and accessibility. The network consists of fixed facilities, temporary facilities and mobile facilities. It is intended to provide surge capacity and use traditional public facilities for mass vaccination clinics. Pre-registered providers use familiar technology since they already serve as providers for the seasonal flu campaign.

Integration has been achieved, and there exists a single vaccine distribution system that is layered with similar technologies, administrative protocol and program support used for VFC, seasonal and pandemic. The seasonal flu campaign has been used to exercise pandemic response in local communities with public sector and private partners. These exercises help partners work through the mechanics of ordering, documentation, billing and memorandum of agreements that define the scope of service during a public health emergency. Exercises are not limited to healthcare providers but work toward incorporating the non-traditional provider network into the public private partnership.

Federal planning **guidance** provides the strategic direction, funding priorities and describes the mechanics of the integration philosophy. States have a choice whether or not they wish to adopt integration, but there are incentives that encourage adoption and are codified by public policy. The pandemic plan reflects not only vaccine administration but includes annexes that describe vaccine distribution with administrative tools to execute actions.

The model is embodied in a new policy and shaped by collaboration of state and federal government in cooperation with state and national health and medical associations. The effect is to shape policy that sheds the encumbrances of statutory, regulatory or licensure constraints. Control of vaccination activities are in the hands of local communities unconstrained by the quagmire of state and/or federal licensure issues. It is these manpower and distribution issues that frustrated the general public who sought H1N1 vaccination but grew weary and moved on unprotected.

Figure 7 depicts the new hybrid model. When this model is compared to the PSM (see Figure 6), the USG becomes the purchaser and distributor of pandemic vaccine. The difference between this model and the PHM (Figure 4) is the expansion of the provider

network and distribution separated from the CDC role as purchaser/distributor. It underscores the prominence that distribution assumes in this model, and that differentiates it from the PHM where DoHs served in a lead role for distribution fulfillment.

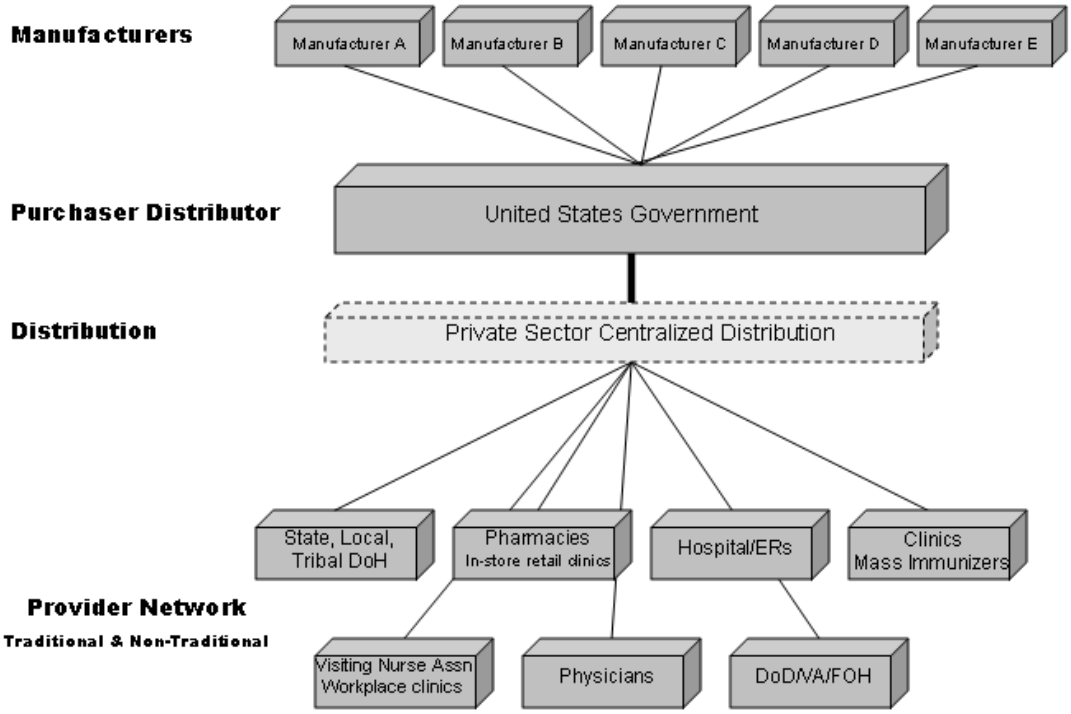

Figure 7. Public Private Partnership Model

Table 12. Model Evaluation Criterion Matrix: Public Private Partnership

MODEL	EXECUTABLE	SCALABLE	CLIENT CENTERED	PROVIDER CENTERED	INTEGRATION	PLANNING GUIDANCE
Public	**Low**	**Low**	**Medium**	**Low**	**Medium**	**High**
Private	**High**	**High**	**Medium**	**High**	**Medium**	**Low**
PPP	**High**	**High**	**High**	**High**	**High**	**High**

2. Goals of the New Model and Gaps with Current Models

What are the policy goals of the new hybrid model, and what gaps exist between this model and current models for vaccine distribution? How does this model build on the

strengths of each model evaluated in Chapters V and VI and, conversely, minimize weaknesses inherent in each model? This section describes policy goals, gaps and presents issues, strategies and/or actions that could guide policymakers and planners toward a new model. Table 12 summarizes results from PHM and PSM evaluations and provides a comparative analysis of gaps between the criterion of those models and the hybrid model. Table 13 itemizes strengths and weaknesses of the PPP model.

The model is executable and supported by a publicly funded campaign and a staffing model sufficiently sized to meet the HHS vaccination goal. Evaluation of the PHM assessed the criterion as low, in contrast to the evaluation of PSM that assessed it high. This new model will retain its publicly funded component. Portions of VMBIP were introduced during the 2009 H1N1 pandemic and show promise to become a technology that will drive future pandemic response while becoming integrated with routine vaccination distribution. H1N1 revealed the necessity of a supply chain inventory management system. The gap that persisted and identified is a staffing model sized for response.

Table 13. PPP: A Summary of Strengths and Weaknesses

Model Evaluation Criteria	Rating	Model Strengths	Model Weaknesses
Executable	High	✓ Publicly funded campaign ✓ Use of technology for centralized distribution is integrated and routine ✓ Technology integrated to support provider network ✓ Staffing model sized for distribution response	
Scalable	High	✓ A robust vaccinator corps sufficient to support mass vaccination ✓ Multiple venues to support mass vaccination ✓ Progress toward vaccine production self-sufficiency	✗ Scalable vaccine production dependent on application of new technologies
Client-Centered	High	✓ Point-to-point service: Venue access and familiarity: ✓ Robust vaccinator corps support variety of venues ✓ Medical home is practiced ✓ Supported through both public and private sectors ✓ Administrative barriers not apparent	
Provider-Centered	High	✓ Model capacity scalable to distribute 220 mil doses ✓ Publicly funded campaign ✓ The practice of medical home is institutionalized for selected medical specialties. ✓ Incentives to recruit traditional providers ✓ Partnership for communication with provider network ✓ Model expands through non-traditional providers	
Integration	High	✓ A single national strategy for mass vaccination ✓ Demonstrated partnering through VFC and H1N1 ✓ Availability of vaccine for all who want it ✓ Collaboration builds trust relationships	✗ Requires a mechanism (i.e., publicly funded) to maximize point-to-point service fulfillment (i.e. workplace clinics)
Federal Planning Guidance	High	✓ Distribution: Policy for pandemic vaccine distribution ✓ Administration: ACIP advisory committee recommendations incorporated into guidance for industry partners ✓ Production: Compliments self-sufficiency policy ✓ Advocates for concept of a triangular network	✗ Time for implementation of new policy ✗ Timeframe for clearing the critical path for scope of practice and medical control of non-traditional providers during emergency vaccination operations

The PHM advocates for the use of non-traditional providers to supplement the vaccinator corps; yet the analysis revealed that 1) no staffing model is described in guidance and 2) barriers persist that prohibit the use of non-traditional vaccinator types. The USG, in concert with professional and medical associations, must work toward the reduction of those barriers as part of a broader strategy for vaccine distribution during a public health emergency.

For example, much discussion throughout this thesis has described the use of pharmacists as vaccinators. The profession of pharmacy has worked through its professional organization, like APhA, to prepare pharmacists at the state and national level to serve as vaccinators, a campaign that has taken 16 years to achieve the authority in all 50 states (M.C. Rothholz, personal communication, June 9, 2010). It is estimated that "there is a retail pharmacy within five miles of 95 percent of the population" (Lien, Maldin, Franco & Gronvall, 2006, p. 179). Yet, H1N1 revealed that selected disciplines within public health were apparently unaware of the readiness of this vaccinator group to serve. This reflects a lack of inclination to reach out and recruit other professions for the manpower to staff mass vaccination efforts during the pandemic preparedness phase. Pharmacy represents one profession that has worked to expand its scope of practice. Yet, other branches of medicine, such as dentists, could serve as members of the vaccinator corps, but their scope of practice confines their skill set. The question arises what must be done to ready this profession for its role as vaccinator?

Dentistry serves as an example of a branch of medicine whose practice is limited to the oral cavity, maxillofacial area and adjacent structures. The American Dental Association (ADA) references this definition as its scope of practice:

> The evaluation, diagnosis, prevention and/or treatment (nonsurgical, surgical or related procedures) of diseases, disorders and/or conditions of the oral cavity, maxillofacial area and/or the adjacent and associated structures and their impact on the human body; provided by a dentist, within the scope of his/her education, training and experience, in accordance with the ethics of the profession and applicable law. (American Dental Association [ADA], n.d.)

Dentists have the skill set to perform needle sticks, as anyone who has ever required dental care can attest. But the profession's scope of practice is limited to the facial area while vaccination involves the upper arm in adults and legs in small children. This thesis has described how federal guidance suggests recruitment of other professions as vaccinators, but the process to ready a profession for vaccination is complex. For example, to use dentists as vaccinators would require a modification to the scope of practice for dentists during public health emergencies, state by state. It may also involve changing statutory regulations regarding medical control. This could be encouraged by the national association if it adopted a recommendation that state dental associations consider a recommendation that broadened scope of practice. The recommendation would target public health emergencies where the mitigation strategy is vaccination with the mechanism, such as governor declaration, that would permit dentists to perform intra-muscular injection. The process requires further analysis of state statues that may prohibit other medical professions from practicing outside their scope of practice. Regulatory, governing and licensing boards would also be included in the review process as well.

What other health and medical professions should be represented in the staffing model for PPPVPVD? Physician practices must serve as the cornerstone for vaccine distribution but work must continue in recruiting and readying other medical specialties for emergency response. Hospitals have played significant roles during the seasonal flu campaign by using not only nurses in community settings for mass vaccination clinics but equally deploying pharmacists as well. Their role was much more limited during H1N1 response due primarily to the vaccine pro-rata allocation scheme and the limited availability of vaccine. Hospitals are viewed in local communities as centers for health and medical care and, therefore, must be incorporated into pandemic response.

While dentistry and pharmacy has been discussed, other professionals with the desired skill sets include paramedics, veterinarians, nursing school students and allied health professionals, such as a phlebotomist.[25] Scope of practice is set by the professional

[25] Phlebotomists are trained to draw blood and relieve physicians and nurses from this task. At one time, phlebotomists were trained on the job, but technical schools offer certification courses that develop the finger stick and venipuncture technique along with patient interaction skills and blood collection legalities.

association responsible for licensure. Each requires a gap analysis to determine constraints to the scope of practice during a public health emergency where vaccination is the mitigation strategy. This analysis should identify medical control conflicts and recommendations to modify those controls for emergency response. Equally important is to determine who will the professional turn to in the event of a vaccine-related adverse event. In public health vaccination campaigns, such as the recent H1N1 or the smallpox vaccinations of 2003, public health infectious disease medical specialists serve as consultants to private sector physicians. This would be one option to be addressed. Each profession requires involvement of its professional association.

Expand the vaccinator corps to support the staffing of multiple venues with a mechanism that permits capacity to expand or contract. Three criteria have been discussed and recommended for inclusion in a scalable model, but the analysis shows that the critical path is a robust vaccinator corps. The evaluation of the PSM illustrated how retail is expanding the non-traditional venues market for vaccination sites. The premise of this thesis is that vaccine production self-sufficiency will progress and USG policy has invested heavily to ensure self-sufficiency. The evaluation of the PSM explored the range of venues established to support the seasonal flu campaign. The analysis showed the growth and range of network venues and providers and why portions should be adopted for pandemic response. Venues are accompanied by vaccinators and could be pharmacists, visiting nurses or a third party contractor. As discussed previously, elements of the PSM were recruited by public health for the H1N1 response such as pharmacies.

According to the American Pharmacists Association (APhA), there are 175,000 pharmacists in the U.S. and 95 percent of the population lives within five miles of a pharmacy (M.C. Rothholz, personal communication, June 9, 2010). The practice transformed itself from that of a dispensing pharmacist to a clinician pharmacist or the primary care pharmacist (American Pharmacists Association [APhA], 2007, p. 1). The profession is transitioning from a product-centered profession to a patient-care centered profession. Academic institutions train pharmacists in this new role, and APhA has offered a 20-hour course to licensed pharmacists who wish to upgrade their skill set to

serve in a vaccinator role. This prepares the pharmacist for the full range of vaccination services defined for age groups including flu vaccinations.

Consider, for example, the use of veterinarians in rural areas of the nation. Veterinarians use mobile clinics to serve clientele not unlike what was described as an innovation during the H1N1 response where command vehicles were deployed as mobile H1N1 clinics. Greater use of veterinarians could incorporate this strategy into pandemic response. This would offer scalability that incorporated a venue, vaccinator and outreach to a remote, population group. Of course, the use of vets to immunize humans would present perception issues, but it may be more acceptable to those target populations where the economy is agrarian-based. This aspect would be worthy of further study.

Adopt client-centered strategies to maximize vaccination rates. The evaluation of the two models rated each criterion medium in relation to the application of client-centered approaches. Collectively, these two models target a significant portion of the population especially for the seasonal flu campaign. An additional study could identify the precise percentage covered, but that is beyond the scope of this research. The gap lies within the pandemic response with the general population, as experienced during the H1N1 campaign. Each model targets different segments of the population, but there exists synergism between the two models. Public health strategies for mass vaccination have adopted private sector strategies, such as deployment of vaccination clinics in private sector settings during the H1N1 campaign. Within the context of the seasonal flu campaign, public health provides service coverage through outreach to remote, uninsured or underinsured segments of the population. Though it could be argued, rightfully so, that the private sector does not deliberately plan for public health to fill these voids during the seasonal flu campaign, there is collaboration. Public health understands its role and is intuitive to find and serve under-represented groups.

What specific strategies, discussed in the evaluation of the two models in Chapter V and VII, would improve client-centered approaches during pandemic response as described by the four enablers?

- Continued emphasis on the medical home
- A greater role for workplace clinics
- Greater use of urgent care centers and ambulatory care centers
- Greater use of non-traditional venues represented by pharmacies, in-store clinics
- Greater use of drive-thru clinics
- Greater use of mobile clinics to include veterinarians, hospital-based mobile clinics and first responder command center vehicles.[26]

Collectively, these strategies describe the "point-to-point" service concept adopted by some airlines (i.e., Southwest) and supported by airline manufacturers.

> Point-to-point service is defined in terms of passenger experience. Any flight that takes a passenger nonstop from point of origin to destination is a point-to-point flight. Point-to-point service does not eliminate hubs; it reduces the need to change planes at an intermediate airport. (Boeing, 2005, p. 2)

Airlines and manufacturers understand that airline commuters seek transportation that will take them from home to their destination without layover, and therefore a smaller aircraft can accommodate increased frequency. Manufacturers build more smaller aircraft. Airlines run the same routes with greater frequency to accommodate passengers. This contrasts with the current "hub and spoke" system used by most airlines. In terms of mass vaccination, setting up clinics in public facilities, from a client perspective is a hub and spoke system. In contrast, workplace clinics, pharmacy visits and in-store clinics are examples of point-to-point service. This is the essence of client-centered strategies.

Finally, a key policy consideration that would offset the public's apprehensiveness about the pandemic vaccine is coverage under the National Vaccine Injury Compensation Program (VICP) for any pandemic vaccine. This is not unlike other vaccines used to protect children, healthcare workers and DoD personnel. As revealed in

[26] The assumption is that mobile command centers are not deployed for other incidents.

the survey, H1N1 was not covered under VICP but individuals who sought a claim found contradictory guidance. Consider these two statements from the HHS webpage:

> The 2009 pandemic H1N1 influenza vaccine (swine flu vaccine) is not covered under the VICP. If you received the 2009 pandemic H1N1 influenza vaccine (swine flu vaccine) or drugs to treat or prevent H1N1 influenza such as Tamiflu, Relenza or Peramivir and think that you have been seriously injured by this vaccine or these drugs, see the Countermeasures Injury Compensation Program. (HHS, n.d. (c))

The above statement, cited at the Health Resources and Services Administration webpage on VICP, refers the reader to the Countermeasure Injury Compensation Program (CICP). Yet, once the reader arrives at CICP, it refers the reader to the VICP.

> Seasonal influenza vaccines are not covered countermeasures under the CICP. If you received the seasonal influenza vaccine or other vaccines covered by the National Vaccine Injury Compensation Program (VICP) such as tetanus or the human papillomavirus vaccine and think that you had an adverse reaction from one or a combination of these covered vaccines, see the VICP. (HHS, n.d. (c))

The contradiction of these two statements regarding injury compensation does not suggest that this issue supports a client-centered strategy in two ways: 1) H1N1 was not covered; and 2) the contradictory statements lack clarity, causes confusion and fuels apprehensiveness. What is needed is clear guidance that covers pandemic vaccines during a public health emergency (PHE). These strategies and venues represent convenience and accessibility with sufficient incentives for vaccine-seeking clients.

Adopt provider-centered strategies to recruit and expand the traditional provider network. The evaluation of the two models rated this criterion low for the PHM and high for the PSM. Historically, the PHM model was limited in its efforts to recruit participation by private physician practices until H1N1. In contrast, the PSM evolved around the physician practice until recent years, when the non-traditional sector expanded to provide greater access to vaccination services. The challenge for the public sector is how to incorporate incentives in a model for pandemic response that approximates the strengths inherent with the PSM but encourages physicians, through incentives, to adopt immunization practices. For example, public funding is one incentive, but it could be

strengthened by including an administrative reimbursement fee for patients whose insurance does not cover such expenses. Other improvements include:

- Improved communication with an expanded provider network addresses issues of efficacy, safety and contraindications.
- Insure a single vaccine ordering system is used by all states with the necessary electronic interfaces. For example, expand VFC program but also use it for pandemic response.

Adopt an implementation strategy that supports an integrated vaccine distribution infrastructure. Each seasonal campaign is an exercise for pandemic response.

The evaluation of the two models rated this criterion medium for the PHM and medium for the PSM. It has been decades since public health last managed a pandemic, and at that time, it had the workforce to implement its sole strategy, the public health model. 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 VFC program 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 planning guidance. In a review of H1N1 barriers, ASTHO (2010, p. 107) recommended use of normal distribution channels: An approach that follows normal distribution channels could have been used, and the initial limited supplies could have been sent to the public health departments and identified priority vaccination providers (i.e., those participating in VAFAC).

The concept of integration is not new but has been incorporated into pandemic response by the United States' northern neighbor Canada. It was tested in 2003 with SARS and again in 2009 with H1N1. While not all providences implement integration, Canada reported the highest H1N1 vaccination rate of all countries in the world at 46 percent (K. Scott, personal interview, April 9, 2010). In contrast, the United States reported an estimated 24 percent (Morbidity and Mortality Weekly Report [MMWR], 2010).

Canada has established a framework for an integrated vaccine distribution infrastructure, and it advocates for universal vaccination. The strategy is supported by agreements and procedures that worked for both seasonal influenza and pandemic influenza. Two additional policy strategies that support Canada's integration strategy are its Universal Influenza Immunization Program (UIIP) and policy of vaccine production self-sufficiency. The Canadian plan states the goal of UIIP is "Universal vaccination has the advantage of creating a population that is highly resilient to the pandemic virus because of both individual protection and potential herd immunity" (Public Health Agency of Canada [PHAC], 2008, p. 12).

The providence of Ontario used the federal infrastructure to establish a distribution infrastructure to achieve high vaccination rates and prepare for pandemic vaccine distribution. Ontario pioneered UIIP in 2000, and its distribution system was designed to support UIIP. The Ontario plan states, "Ontario has a vaccine distribution system in place to support its Universal Influenza Immunization Program. A similar system may be used to distribute vaccine during a pandemic" (OMHLTC, 2008, p. 9-4). Today, it serves as a mature model for the integrated strategy. It uses this strategy each year as a test of its pandemic response for mass vaccination. The European Union called this a "best practice" (Osterhaus, 2006, p. 6802) that should be incorporated into the European Centre for Disease Prevention and Control (ECDC) pandemic plan.

The strategy illustrates the Canadian policy as described in the *Ontario Health Plan for an Influenza Pandemic* (MOHLTC, 2008). The Ontario plan lists many elements such as the public private partnership, public sector responsibilities and expectations of providers on the private side. Several features of the plan are consistent with enablers that support private-centered and client-centered criteria. A unique feature of the pandemic plan is that it details how the seasonal flu season builds toward pandemic response and incorporates a variety of non-traditional venues such as workplace flu clinics.

For example, the Ontario UIIP recruits workplace settings to establish flu clinics during the inter-pandemic period by providing vaccine at no charge. Employers are encouraged to provide the service at no cost to employees. The incentive is a partnership

with Ontario who provides vaccine at no cost. The benefit to the employer is employees reporting to work and being productive rather than out of work and collecting sick leave.

> The flu vaccine is provided to employers by the MOHLTC (Ministry of Health and Long-Term Care) free of charge. If a corporation requires a nursing agency to administer the program the nursing agency will charge, on average, a fee of $12.00 per person. It is important to put this number in perspective against potential lost time due to sick days. If a company has 100 employees and 40% of these employees opt to take the flu immunization, the total cost to the company is $480.00. Given that the flu-related absences can range between one and five days, the cost of the immunization program can pay for itself if influenza illness is avoided in one employee. (MOHLTC, 2004, p. 5)

This thesis has argued that there should be one vaccine distribution system, and it should be exercised for pandemic response. But what would it take to bring the resources and capacities of the public sector and the private sector into a single system for vaccine distribution during emergency response? The initiative must rival that legislated in support of vaccine production self-sufficiency and will require a policy implementation strategy to include program support and funding. The recommendation is a policy strategy that clearly describes the strategy with a distribution plan and guidance that can guide state and local planners, supported with funding incentives for state and local DoH. It must be optional for states but with incentives for those that elect to participate, similar to the arrangement between Canada and its providences such as Ontario.

Expand federal planning guidance to incorporate proactive distribution strategies. Vaccine distribution should be differentiated from vaccine administration in planning guidance. Too often in guidance, distribution is discussed in the context of vaccine administration, and the discussion is exclusively about vaccine administration. If the discussion were framed in the context of ICS, distribution would be a function of logistics while administration is a function of the operations section. A public policy should be adopted that differentiates these functions and will establish a deliberate course of action. It should build on current capabilities while encouraging constructive change of distribution limitations. What strategies should this policy establish?

- It has been established that pandemic vaccination campaigns will be publicly funded. While stated in guidance, public policy is not clear.

- Establish a single, national strategy for vaccine distribution in contrast to an estimated 64 different strategies.

- Establish a single, integrated distribution system, used annually but exercised for pandemic response.

- Establish funding mechanisms that will encourage national health and medical associations to work with state association and state regulatory agencies to identify statute, regulatory, and/or licensure restrictions that prohibit those professionals with the skill set to vaccinate.

The USG should adopt a new strategy given the limitations of the public health model as defined in this thesis. The gap that must be bridged is a philosophical gap of how two different models operate. The private sector is represented by technical know-how, innovation and the capacity to expand and contract as presented in Chapter VI. The public sector should extend the principle of justice by maximizing venue sites and ensuring those venues are staffed with skilled vaccinators.

C. U.S. POLICY FOR PANDEMIC VACCINE DISTRIBUTION

1. The Policy Strategy

The USG has invested $7.1 billion in pandemic preparedness, of which $3.2 billion was invested in enhancing vaccine production (CBO, 2008), both expanded capacity and new technology. In the near future, the return on investment will be realized but funding investments should be redirected into pandemic vaccine distribution infrastructure projects. Considering, for example, the $176 million set aside each year for egg embryos that are used for nurturing the 1940s egg-based vaccine production process (CBO, 2008). Once cell-based vaccine production is proficient, these investments will expire and could be invested into distribution strategies.

Just as a USG policy evolved to develop pandemic-influenza vaccines, a policy accompanied by similar investments and initiatives should be directed toward distribution strategies. A goal of the 2005 HHS pandemic plan was to “facilitate a rapid response.”

This thesis has argued this is not likely given the current infrastructure. Options should be explored to establish a viable and executable rapid response structure. A policy for PVD should address goals presented in the previous section but must also describe strategies for incorporating several key elements discussed throughout this thesis. The policy should match the comprehensiveness of the CBO (2008) document "U.S. Policy Regarding Pandemic-Influenza Vaccines," which describes in detail the USG strategy regarding pandemic vaccine production self-sufficiency.

The policy strategy is to establish a comprehensive public private partnership for pandemic vaccine distribution that achieves the HHS goal and facilitates a rapid response. The objective of this policy is the HHS goal of the 2005 pandemic plan and its claim "to facilitate rapid response" (CBO, 2008). The plan must be achievable; it must be executable. As a result, it is supported by public funding, describes a staffing model sized for response, offers scalability and improves vaccination rates by integrating client-centered and provider-centered strategies. Finally, the policy is defined in planning doctrine and achieves the goals introduced in the previous section. These goals are:

1. The model is executable supported by a publicly funded campaign and a staffing model sufficiently sized to meet the HHS vaccination goal.

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

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

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

5. Adopt an implementation strategy that supports an integrated vaccine distribution infrastructure. Each seasonal campaign is an exercise for pandemic response.

6. Expand federal planning guidance to incorporate distribution strategies.

Figure 8 presents a framework for the development of a U.S. policy for pandemic influenza vaccine distribution and is a starting point for a discourse on the subject. Two topics are described here, based on previous discussions, as examples of subjects to be developed and included in a comprehensive policy that addresses distribution issues.

Staffing is a key issue. Therefore, the policy must address how suggested entities are working the issue of statutory, regulatory and licensure barriers that frustrate health professionals from serving as vaccinators during public health emergencies. This could be encouraged by national associations if recommendations were put forth and adopted by state associations. This should be conducted in collaboration with medical boards. Issues of medical control and scope of practice should be studied, modified and defined for public health emergencies. For example, as recommended above, dental associations could consider incorporation of a recommendation that during public health emergencies where the mitigation strategy is vaccination that a mechanism, such as a governor's declaration, would permit dentists to perform intra-muscular injection. The process requires further analysis of current state statues that may prohibit the profession from practicing outside its scope of practice. Regulatory, governing and licensing boards are among those entities that should be included in the review process and the policy should describe this process.

Another example of a topic that should be addressed is how technology is used to support distribution. Chapter IV suggested that a supply chain inventory management system was needed to distribute and track vaccine from its point of distribution throughout the provider network. While this would be relatively easy to accomplish, the greater challenge are vaccine ordering systems since they originate from states. While some states have made great progress, others still use paper, pen and fax machines. CDC, in cooperation with state DoHs, has made great strides with disease surveillance and syndromic surveillance systems. CDC has been instrumental in providing states with system architecture, compatible with the CDC system, to support the integration of state disease surveillance data with national surveillance data. Similar strategies should be adopted to encourage all states to upgrade their vaccine ordering to comply with current CDC projects such as VMBIP and Vaccine Tracking System (VTrcks). VTrckS is the vaccine ordering component of VMBIP. The projects were begun in 2004 and were not ready for H1N1 and efforts should be expended to expedite their implementation. These two topics are suggestive of the content to include in a policy strategy. In general, the policy should describe how these systems will be used in a pandemic and, specifically,

their role to support pandemic vaccine distribution. Furthermore, the analysis should describe gaps and actions being taken to move those toward a rapid response.

2. Possible Legislative Solutions

The USG should consider various legislative solutions to develop the PVD system—several of which have been used to develop supply side production limitations (CRS 2005). These include financial incentives, efforts to improve coordination, public private partnerships and identifying alternatives to the administrative bottlenecks that delay issues of readiness, response and capacity.

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
      i. Vaccine Management Business Improvement Project
      ii. Supply Chain Inventory Management System

2. The Scalability for Pandemic Response
   a. A robust vaccinator corps
      i. Physicians and the emphasis of the medical home
      ii. Allied health professionals ready to serve in new roles
   b. How the plan uses multiple venues to maximize public outreach
      i. Fixed facilities
      ii. Public facilities
      iii. Mobile facilities
      iv. 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
      i. The workplace clinic for most Americans
      ii. 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
      i. Act of Bioterrorism
      ii. Emerging infectious disease
      iii. 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 8. Framework for U.S. Policy: Pandemic Vaccine Distribution

a. Financial Incentives

Publicly-funded vaccine assures manufacturers that a volume of vaccine will be purchased by a primary purchaser, which is the USG. USG legislation has invested in expanding production capacity and new technologies. These investments have served the supply side of vaccine administration and have been directed toward private sector production manufacturers. The USG should consider complimentary investments for the administration of vaccine to the distribution side and its supporting provider network. A similar recommendation was made to Congress (CRS, 2007) that payment for vaccine administration be considered. This could come in the form of direct payments to providers who administer vaccine during a PHE or through a mechanism with insurance carriers to cover the insured. Financial reimbursements frustrated the administration of H1N1 vaccine as the USG worked through the issues of whether or not providers could charge an administrative fee for vaccine administration. These issues should be reviewed and address in advance of a PHE.

An alternative financial incentive could be tax breaks for members of the provider network who participate in a PHE and administer vaccine. Congress has considered tax credits for certain vaccine research and distribution activities to effectively lower the cost to manufacturers (GAO 2006). Similar incentives should be considered for those providers who support a PHE.

Consider, for example, the H1N1 response and marginal participation by one target group's provider OB/GYN providers. OB/GYNs typically do not provide vaccination services. There were few incentives for them to gear up for H1N1 vaccinations, yet their clients, who viewed them as their medical home, had to find vaccination elsewhere. So how does government incentivize OB/GYNs to join the provider network for a PHE? As discussed previously, a provider-centered strategy would be to minimize administrative barriers by arranging reimbursement for the administrative fee or third-party reimbursement complimented with tax breaks during a PHE.

Finally, the policy should include coverage under the National Vaccine Injury Compensation Program (VICP), not unlike other vaccines used to protect children,

healthcare workers and DoD personnel. The smallpox vaccine was covered under the *Smallpox Vaccine Injury Compensation Program* established in 2003 (HRSA, 2006).

b. Improve Coordination

Congress has worked to improve coordination among vaccine industry representatives to advance vaccine research and development efforts. For example, this strategy was used in 2002 to avoid supply shortages intended for childhood vaccinations "among federal regulators, private manufacturers, government scientists, and purchasers" (GAO, 2006). Similar coordination efforts would expand the vaccinator corps by bringing together national and state health and medical associations, and state regulatory agencies. The desired outcome is to address restrictions to health professionals with the vaccination skill set but restricted by scope of practice.

c. Procurement Justification and Accountability Requirement Alternatives

The nation witnessed a record production time for H1N1 pandemic vaccine using several legislated mechanisms to expedite the production and approval process coordinated by BARDA. The survey described a number of administrative tasks that were slowed or delayed due to adherence to bureaucratic compliance requirements by both state and federal officials. These administrative requirements should be studied and identified. In addition, alternatives should be sought to expedite administrative bottlenecks that delay issues of readiness, response and capacity. Administrative means such as "fast-track mechanism" or "accelerated approval" should be considered to expedite the logistics support requirements for a PVD campaign.

D. BARRIERS TO IMPLEMENTATION

Three barriers to implementation of the proposed policy are discussed. Barriers include the labyrinth of statutory, regulatory and licensure issues, universal vaccination as a factor that supports development of an integrated vaccine distribution system and issues of trust that could obstruct public and private sectors working collaboratively toward a new model.

Some states acted on their own accord during H1N1 response and deputized dentists, pharmacists and paramedics (Smith, 2009). Other states required an executive order from the governor. Other state executives issued no declaration, and their state health professionals remained on the bench. But barriers remained even after executive intervention. The question is why, after years of pandemic plan exercises at national, state and local levels, were these issues not identified and corrective actions not taken? The simplistic response is because exercise scenarios most often dealt with issues of limited supply, mass vaccination clinics, isolation and quarantine protocols and related vaccine administration issues but rarely addressed issues of distribution.

Consider New York where dentists were not authorized to receive vaccine because they were not an authorized medical specialty, but Governor Patterson's executive order authorized them to vaccinate those eligible for H1N1 vaccination.

> Under current state law, some health care professionals are prohibited from delivering the vaccine because of limits on their professional duties. The governor's order waives any law that would prevent these people from giving vaccinations, according to Claire Pospisil from the New York state department of health. (Solomon & Shin, 2009, p. 1)

In addition, dentists who volunteered to administer vaccine "must do so at a New York state health department distribution center" (Solomon & Shin, 2009, p. 1). In effect, while the order taps dentists as manpower, the action reduces the number of vaccination venues and reinforces the traditional mass vaccination model directing clients to a centralized location. It also reinforces the hub and spoke system of vaccination rather than encouraging a point-to-point service that would characterize a client-centered strategy. This serves as a brief example of barriers and disincentives to recruit non-traditional vaccinators. H1N1 was declared a public emergency by HHS Secretary Sebelius, declared an emergency by President Obama, and yet neither declaration directed professionals with the vaccination skill set to vaccinate. States act on their own accord, and health professionals are licensed by a state. Issues of this nature must be worked at the state level and among those entities that represent the stakeholders. Dentistry is one medical specialty whose professionals could serve as vaccinators during

public health emergencies. They offer the nation an additional option to expand its vaccinator corps but scope of practice issues must be explored in advance of activation, deputizing and other executive order mechanisms (ASTHO, 2010).

Issues of medical control will be a limiting factor when the discussion turns to expanding the scope of practice for health and medical disciplines, which was an issue in the use of dentists in New York described above. Scope of practice among New York dentists was limited, and they were required to be supervised by a medical physician. Therefore, dentists authorized to administer vaccine did so under standing orders signed by a public health physician. Physicians are authorized by state statue to maintain quality control of patient care and therefore provide oversight or supervision of other disciplines that provide medical care. Patient care is controlled through medical orders, such as a prescription, which instructs the nature of patient care by another professional. Using the example of pharmacists, even though the profession has prepared pharmacists for vaccination duties, tending to patients still required a physician's order or prescription. As stated earlier, pharmacists that vaccinate were under a physician's standing order. Administration of a vaccine by a pharmacist required a medical order.

For example, the South Carolina General Assembly took up a resolution to change the scope of practice for pharmacists by permitting vaccination without a medical order. While it illustrates amending the scope of practice to permit pharmacists to vaccinate without a medical order, it shows the pharmacists scope of practice still limited to "adverse events."

> Section 40-43-190. (A)(1) The Board of Medical Examiners shall issue a written protocol for the administration of influenza vaccines by pharmacists without an order of a practitioner. The administration of influenza vaccines as authorized in this section must not be to persons under the age of eighteen years.
>
> (2) The written protocol must further authorize pharmacists to administer without an order of a practitioner those medications necessary in the treatment of adverse events. These medications must be used only in the treatment of adverse events and must be limited to those delineated within the written protocol. (South Carolina General Assembly. [SCGA], 2010, p. 1)

Paramedics are another group of professional who conduct needle sticks routinely but to vaccinate requires authorization by a medical control officer. Paramedics and patient care are supervised by physicians who define what specifically paramedics can do. Thus, a change to the scope of practice required modification of a paramedics' scope of practice. States manage this differently state by state, but physicians are deemed the medical control officer for emergency medical services. These examples describe issues of medical control and the actions of state general assemblies, state licensure boards and state associations, both medical and non-medical, to change scope of practice.

The strategy of a single integrated vaccine distribution system was introduced and Canada referenced as a nation that has implemented the concept. One key to its success is the publicly funded component of its universal vaccination program for the seasonal flu campaign. Although, PHAC (MOH, 2008) has conducted extensive studies that have demonstrated the cost effectiveness of the Ontario program, adoption in the U.S. would find legislators balking at such a proposal. The current economic and political climate and the recent passage of health care reform, all create circumstances in which government is not likely to implement a similar strategy in the near future. Other innovative solutions may need to be considered to adopt incentives that support the integration strategy.

Finally, the issue of trust was identified in the survey from various perspectives. The distrust of government by the citizenry was fueled when the USG promise of H1N1 vaccine for all in mid-October could not be met and then limited supply issues persisted through the holiday season (ASTHO, 2010). The public sector distrust of the private sector's motives persisted when traditional providers were apprehensive to support the mass vaccination campaign. To some extent the use of non-traditional providers by public health delayed readiness and response. These issues of trust will be present as the USG moves forward with a new strategy for pandemic vaccine distribution response. But these are the professions that have found common ground to form partnerships to address vaccine supply and vaccine administration. Consider the complexity of the CDC target

groups and tiers by population sector, which addressed a number of ethical issues yet found wide acceptance by both professionals and the general public. A similar spirit of cooperation should be embraced to address the issues of distribution.

E. CONCLUSION

This chapter presented a new model for pandemic vaccine distribution built around a comprehensive public private partnership. Six goals were delineated and accompanied by gaps that were identified from the analysis of two models of vaccine distribution. A policy strategy was recommended to establish a comprehensive public private partnership for pandemic vaccine distribution that achieves the HHS goal and facilitates a rapid response. A framework for development of a U.S. policy for pandemic vaccine distribution was outlined. The framework addressed the six goals of the new model and offered a context to differentiate three processes essential to pandemic preparedness. The GAO described these when it reiterated ongoing gaps for pandemic response and recovery "the availability of antivirals and vaccines could be inadequate to meet demand due to limited production, distribution, and administration capacity" (2009a, p. 16).

The premise of this thesis is that progress has been made toward vaccine production self-sufficiency, and it has argued that vaccine administration guidance is well documented. What has not progressed is the process of vaccine distribution for emergencies. U.S. pandemic response where vaccination is the mitigation strategy should be conceptualized to breakout these three distinctive processes as a triangular network,[27] each equal, but requiring a body of knowledge to support its execution. Figure 9 illustrates the equivalency of relationships among these three vaccination processes.

[27] Triangulated irregular networks (TIN) are referenced in geospatial information systems (GIS) and supported by data digital structures. Beyond the scope of this thesis, the concept of TIN offers a perspective to understand the dynamics of market relationships that drive mass vaccination.

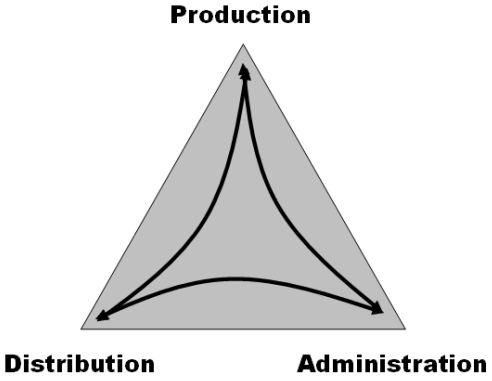

Figure 9. Vaccination: A Triangular Network of Interdependencies

Each process is distinctive. Each warrants a body of work essential for success but all three are interdependent to achieve herd immunity during a public health emergency. The public private partnership for pandemic vaccine distribution is a model for development of the distribution process. It becomes the building block that compliments the HHS pandemic plan and contributes to a mass vaccination model that is executable.

VIII. RECOMMENDATIONS AND CONCLUSION

This thesis has argued that the current public health infrastructure cannot adequately manage emergency vaccine distribution and that the distribution model defined by existing federal planning guidance is flawed. Public Health distributes and administers seven percent of seasonal influenza (flu) vaccine (HHS, 2005a), but in a public health emergency of national significance, it distributes 100 percent of the volume. Chapter IV survey results supported this argument by showing that the pandemic vaccine distribution model is not executable due to insufficient public health workforce capacity.

Even as the nation works toward vaccine production self-sufficiency (CBO, 2008), the issues of distribution remain unclear. In the midst of its first pandemic in 40 years, a July 2009 GAO described gaps in responsibility for distribution that persisted: "One of these was a lack of clarity regarding the roles and responsibilities of federal and state governments on issues such as state border closures and influenza pandemic vaccine distribution" (GAO, 2009, p. 7).

The current federal pandemic plan for distribution revealed its weaknesses as the nation responded to the 2009 H1N1 pandemic. Public Health did not have the infrastructure to support mass vaccination as expected in federal guidance to support the HHS goal. As a result, staffing limitations of state and local (DoH) were supplemented through the Public Health Emergency Response grants, and the private healthcare sector was recruited to assist with vaccination. This thesis proposed a new model for pandemic distribution that addressed problems inherent in the current model and implementation difficulties that came to light with the nation's response to the 2009 H1N1 pandemic.

A. RESEARCH QUESTIONS

Two research questions were poised at the beginning of this thesis:

- What criteria should be used to evaluate a model to support pandemic vaccine distribution and drive policy development?

- How could a model be designed to support pandemic vaccine distribution for a public health emergency of national significance?

The first research question developed model evaluation criteria that were used to evaluate two models of vaccine distribution. Chapter IV used two rounds of interviews with subject matter experts to identify, develop and validate the model evaluation criteria used in Chapters V and VI to evaluate the public health and private sector model. Six model evaluation criteria resulted from the survey executable, scalable, client-centered, provider-centered, integration and federal planning guidance (see Table 4). Evaluation criteria identified strengths and weaknesses of each model.

The second question sought to explore the development of a new model for pandemic vaccine distribution and used the results from the analysis in Chapters V and VI. Chapter VII proposed a new model for pandemic vaccine distribution and policy goals that should support a model for a public health emergency of national significance.

Three recommendations resulted from the analysis support development of a new hybrid model for PVD, which leverages the use of a public private partnership. The first recommendation targets the pre-pandemic period. Its aim is to extend the scope of practice among those disciplines whose professionals could serve as vaccinators during a public health emergency. The second recommendation is used during the inter-pandemic period and advocates for a single, integrated vaccination distribution system in which pandemic response is exercised through each seasonal flu campaign. The third recommendation targets pandemic response, using the nation's health and medical professionals to respond to a public health emergency when the mitigation strategy is a mass vaccination campaign.

B. RECOMMENDATIONS

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.

A staffing model is the critical path to accomplishing the goal of HHS to vaccinate 300 million citizens in six months. Neither states nor federal resources are sufficient to build a public health workforce capacity to accomplish the goal, but the nation has a corps of health and medical professionals with the skill set and desire to assist during emergency operations. This recommendation addresses the quagmire of legal, regulatory and licensure restrictions that limits health and medical professionals from serving as vaccinators and expands their scope of practice to include this skill set during 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 to upgrade state emergency health powers laws. The recommendation also supports states that deploy state pandemic preparedness plans and are challenged to adequately staff those plans.

To achieve this recommendation requires collaboration among state and federal government authorities as well as private sector national and state professional associations to address these issues. As discussed throughout this thesis, even when a discipline, such as pharmacy, worked through this process and readied its licensed professionals for vaccination, it took a crisis for recognition by other disciplines that a discipline is ready to serve in this capacity. This crisis worked to remove the remaining barriers and permit pharmacists to vaccinate. Collaboration must occur before a crisis and not in its midst.

The scope of this project scales the effort exerted to modernize public health statutes for states through the Model Emergency Health Powers Act (Center for Law and the Public's Health [CLHP], 2001). The result would be a readily available corps of vaccinators with an expanded scope of practice during emergencies. A study of scope of practice is a first step but must be accompanied by clarifying medical control issues for the emergency. Who manages and supervises vaccinators must be equally considered as well and therefore, calls for the collaborative effort among the various stakeholders. The effect of this action is to build workforce capacity in local communities that can respond to, not only pandemic threats, but also emerging infectious diseases such as SARS and acts of bioterrorism. It permits immediate response by local communities to biological

threats without the encumbrances that currently exist from state and federal statues and licensure restrictions. Three specific actions are proposed to support the recommendation:

- National health and medical specialty associations should conduct a gap analysis of its policies, scope of practice and those laws that block licensed professionals from serving as vaccinators.

- State health and medical specialty associations should conduct gap analysis of its policies, scope of practice and those laws that block licensed professionals from serving as vaccinators.

- State government, lead by the state public health authority in cooperation with regulatory counterparts should target those professions that could serve as non-traditional vaccinators and conduct a gap analysis of state statues that block scope of practice by those professionals.

National health and medical specialty associations exist to represent and protect the scope of practice defined through law and codified by licensure for their membership base. Likewise, regulatory agencies represent the public interest and must ensure the public is protected. As learned by the H1N1 response, association interests may not always serve community's best interests during public health emergencies. Health professionals watched while DoH, associations and advocates worked through these restrictions during the H1N1 incident.

The impetus must come from the federal government as a strategy to develop a robust vaccinator corps and make pandemic plans executable. But it is the associations themselves that must adopt this body of work and serve the philanthropic good for which their association was formed. It should serve the profession but the profession serves the public and the association should serve this greater good.

The USG should establish a pandemic implementation strategy that supports an integrated vaccine distribution infrastructure that works for both seasonal influenza and pandemic influenza.

A policy of vaccine production self-sufficiency is being pursued by the USG to protect the nation against biological threats. This thesis has argued that while much attention, resources and effort have been expended on the supply side, similar commitments are required to develop a distribution network, consisting of both venues

and vaccinators, to get vaccine out and into arms and/or noses. However, is it necessary to erect a second infrastructure whose sole mission is pandemic vaccine distribution and whose sustainment is unpredictable?

The strategy recommendation is to establish an integrated vaccine distribution infrastructure that works for both seasonal influenza and pandemic influenza. An integrated vaccine distribution infrastructure is a strategy that would be used each influenza season but equally is intended for use in a public health emergency that requires a mass vaccination strategy. Each flu season becomes an exercise for an infectious disease outbreak by using the seasonal campaign to test methods and procedures. It prepares all sectors to work together each season but prepares for an emergency when mass vaccination is the response strategy.

This strategy also offers dual-purpose application and could be used for other public health emergency distributions including medical countermeasures whether those are vaccine shortages, smallpox or other biologics.

> **The USG should adopt a policy strategy and 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 but incorporate distribution policy that supports the vaccine supply chain from production through distribution and into arms. A policy of vaccine distribution compliments the policy of vaccine production self-sufficiency. The limitations and barriers to deploy health and medical personnel in the aftermath of Hurricane Katrina revealed the legal, licensure and practice constraints (Santiago, 2006). Yet these issues were visited once again in an attempt to deploy vaccinators for the 2009 H1N1 pandemic.

A framework for development of a U.S. policy for pandemic vaccine distribution was outlined in Chapter VII. The framework addressed the six goals of the new model and offered a context to differentiate vaccine production from vaccine administration from vaccine distribution. U.S. pandemic response, when vaccination is the mitigation strategy, should be conceptualized as a triangular network and mapped to breakout these

three distinctive processes. Yet while all three processes are distinctive, they are essential and interdependent to achieve herd immunity during a public health emergency.

C. CONCLUSION

Public health seeks to administer social justice exemplified through vaccination target groups, and its tier-allocation scheme. It is a masterful work of targeting those at greatest risk, whether citizens represent a critical infrastructure sector or a population group predisposed to viral threats. Yet, while the tier system is based on the ethical principle of essential fairness, it falls short of equality in that most members of H1N1 high-risk groups did not get vaccinated and lower priority targets were only offered vaccination once the wave of infection had passed. Six months previously, the public had grown weary of repeated attempts to get vaccinated because government determined it could not do it all. By the time it arrived at this conclusion, it was too late to mobilize the necessary resources. In the aftermath of the 2009 H1N1 pandemic, the government discarded 40 million vaccine doses or 25 percent of production (United Press International, 2010). The University of Pittsburgh Medical Center's (UPMC) Center for Biosecurity, in a project of "why and how to catalyze the civic infrastructure for an extreme health event" (Schoch-Spana, Franco, Nuzzo, & Usenza, 2007, p. 1), called for community engagement in pandemic preparedness. The project presented examples of community engagement depicting a 1947 smallpox outbreak in New York City:

> During the 1947 smallpox outbreak, NYC health officials vaccinated more than 6.3 million people in 4 weeks (5 million alone in the first 2 weeks) using private physicians and volunteers from the Red Cross, teachers' groups, women's clubs, and civil defense groups; this partnership helped staff free clinics in 12 hospitals, 84 police precincts, and every public and parochial school. (Schoch-Spana, Franco, Nuzzo, & Usenza, 2007, p. 12)

The scenario reflects a remarkable capacity and resiliency to squelch a smallpox outbreak in record time. It describes an incident where community members mobilized a campaign to inoculate fellow citizens. This was a time when citizens felt responsible to respond without the burdens of statutory, regulatory or licensure restrictions.

Can a nation continue to support emergency vaccination campaigns whose premise is based on flawed assumptions and when billions have been invested without results? Justice is not served if vaccine is wasted, citizens go unprotected and a nation vulnerable to a threat it spent public funds to mitigate. The National Health Security Strategy (HHS, 2010) is built on the foundation of community resiliency demonstrated by New York City's ability to mobilize and respond with great urgency. This thesis recommended actions to empower communities to use its professional workforce and wage campaigns not unlike that of New York City in 1947. If communities are to achieve resiliency than those barriers that sideline the urgency for action, must be mitigated.

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APPENDIX A. SURVEY QUESTIONNAIRE ROUND ONE

Naval Postgraduate School
Strategic Policy for Pandemic Vaccine Distribution
Interview Questionnaire: Round 1

Review purpose of the research (refer to inject pg 4). Our focus is twofold:

1. Identification of desired outcomes from an flu vaccination campaign in the U.S.; and
2. Identification of criteria that can be used to compare, contrast and evaluate two vaccination models used in the United States.

For example, one desired outcome could be herd immunity. An alternative is individual immunity for high-risk group members or what we know as the CDC priority groups. But given the herd immunity goal, we would than wish to explore what must be incorporated into a vaccination campaign to ensure we achieve herd immunity.

Our interview is divided into three sections, some background information, than we'll explore your familiarity and involvement with seasonal influenza vaccination or what I'll refer to as the private sector model. Finally, we'll explore your involvement with pandemic influenza vaccination or what I'll refer to as the public sector model. For the purpose of this interview, we'll the Public Health Model as mass vaccination clinics at schools, community centers, etc pre H1N1.

First, tell me a little bit about your background as it relates to vaccination policy.

1. Briefly describe your day-to-day duties and how this relates to vaccination policy?
2. In your view, please describe the U.S. or federal policy
   a. For pandemic vaccination?
   b. For seasonal vaccination?

Let's explore what we know as seasonal influenza vaccination or the private sector model.

3. What has been your involvement (role) with seasonal influenza vaccine distribution?
4. What is your familiarity with the Private Sector Model (See definition pg 4)?

   Would you add anything to my brief description of the model?

   a. What does it accomplish?
   b. What does it not accomplish?
      i. Are there important outcomes that must be included in a policy?
      ii. Are there criteria in this model that should be re-evaluated?

Premise: Let us assume that cell-based vaccine production has begun in the U.S., several domestic facilities have come on line and the nation has progressed toward vaccine production self-sufficiency.

5. What is your familiarity with the Public Health Model for mass vaccination? Would you add anything to my brief description of the model?
   a. What does it accomplish?
   b. What does it not accomplish?

i. Are there important outcomes that must be included in a policy?
ii. Are there elements in this model that should be re-evaluated?

6. What has been your involvement (role) with pandemic vaccine distribution?
   a. Would you describe this as tactical?
   b. Would you describe this as strategic?

7. What do you see as the desired outcomes for the pandemic campaign?
   a. Why do you say A?
   b. Why do you say B?
   c. Why do you say C?

Finally and in general…

8. What ethical principles do you think are involved in these respective models?

Narrative Injects

Research Purpose	The purpose of this research is to evaluate two existing vaccine distribution models and synthesize a new, third model for pandemic vaccine distribution during a public health emergency. Policy analysis is selected to examine policy weakness in the current models, identify strengths (criteria) of the models, and develop a new model that will achieve the policy goal.
Criterion	Criteria or criterion as used in this study is defined as "a basis for comparison; a reference point against which other things can be evaluated."
Outcome	Outcome is the end result sought from a vaccination campaign. For example "herd immunity" is one such outcome.
Public Sector	The Public Sector Model is the federal policy and strategy for mass vaccination when a public health emergency is declared. It is documented by federal planning guidance that dates to the 1950's and 1960's when mass vaccination clinics were used to defeat childhood infectious diseases such as polio, smallpox, etc. but updated to address 21st century biological and emerging infectious disease threats.
Private Sector	The Private Sector model is represented by the seasonal influenza campaign and is a for-profit approach used annually. Vaccine is manufactured by the private sector, sold mostly to for-profit providers and distributed via the private sector. Its network is limited to the "for pay" sector, of which 74 percent includes physician practices. Public health distributes less than ten percent of seasonal flu vaccine in this model.

APPENDIX B. POLICY CONSIDERATION WORKSHEET

Policy Consideration Worksheet
(identified by subject matter experts in Round 1 interviews)

What was heard (The How)	Narrative Description	Policy Consideration (The What)	Relative[1] Importance	Rank[2] Order
Scaled vaccine production.	It was all or nothing with H1N1, need scalable plans but don't have enough criteria. H1N1 "caught us by surprise" and was approached as essential for biosecurity. Turned out to be of low severity but had no way to scale back. Need a way to scale response venues and vaccinators. Need for facilities like pharmacies, mobile units.	A Scalable Plan		
Robust vaccinator corps				
Mulitple venues. Not every town has an MD but every town has a pharmacy				
Seasonal flu should train for pandemic response	CDC introduced new technologies exclusively for H1N1 that proved to be inadequate and cumbersome. The lesson, systems should be introduced, trained and exercised prior to emergency deployment.	Integration		
One provider network, integrates a range of venues	Use one provider network that includes, public private health care components, workplace settings, etc for seasonal or pandemic. Distribution for pandemic should use same system as seasonal flu			
H1N1 "blended" model was an outgrowth from the VFC Program	Vaccine for Children (VFC) is federal policy and represents a third model used to vaccinate children under the age of 18. This delivery system is used for a full range of vaccine with a minor portion used for flu vaccine			
Transparency of vaccine production	The process of vaccine production should be transparent and communicated to the public and avoid the mis-information that accompanied H1N1. Insufficient education, messaging should especially target nurses.	Client Centered		
Lift barriers (administrative)	eliminating medical screening for public school children contributed to the success of this effort. To make further gains in vaccination rates, barriers should be lifted or minimized.			
Vaccination is convenient & accessibility, familiar & routine	Keeps patient in their medical home (H1N1). Public wants a fast food approach, convenience and accessibility which is why the public school vaccination campaign worked so well. Mobile RV vaccination units that deploy to a site or remote areas. Must reach underserved and uninsured			
Public funding, no cost to consumers	Should adopt a universal approach for emergencies. Funded vaccine…gets vaccine out quickly without encumbering administrative support requirements.			
Public health model accomplishments	Fills the gaps like the underserved population. Gets lots of vaccine out there quickly. Sends the media message…this is important!			

[1] What is the relative importance of this policy consideration in relation to other considerations (high, medum, low)?

[2] Rank order in relation to other considerations.

Page 1 of 2

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APPENDIX C. SURVEY QUESTIONNAIRE ROUND TWO

Naval Postgraduate School
Strategic Policy for Pandemic Vaccine Distribution
Interview Questionnaire: Round 2

Round 1 interviews are complete and the subject matter expert panel has identified xxx outcomes for Round 2. In Round 2, we will explore the evaluation criteria identified in the first round and discuss their relative importance to one another. I'm also curious to learn what your rationale for the importance you assign to the criteria. Relative importance will be assessed by low, medium and high.

I'll list the xxx criteria identified. As I go through the list, think through and assess each criterion, as low medium or high and what that assessment depends on

1. Why did you assign high to
   a. Criterion A
   b. Criterion B
   c. Criterion C
2. Why did you assign medium to
   a. Criterion D
   b. Criterion E
   c. Criterion F
3. Why did you assign low to
   a. Criterion G
   b. Criterion H
   c. Criterion I

We have explored your rationale for assigning L, M or H but let's look at their relative importance to each other.

4. What are the top three outcomes or policy considerations that should be considered in a pandemic vaccination distribution policy?
   a. Why A?
   b. Why B?
   c. Why C?

5. What are the next three outcomes or policy considerations that should be considered in a pandemic vaccination distribution policy?
   a. Why D?
   b. Why E?
   c. Why F?

6. Are there other outcomes that you feel strongly that should be included in a pandemic vaccine distribution policy that have not been included?

Page 3 of 3

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APPENDIX D. ANALYTICAL TOOLS TO SUPPORT PPP4PVD

William Blake wrote, “Execution is the chariot of genius.” This thesis described the current HHS pandemic influenza plan as non-executable, and it recommended a comprehensive policy strategy to establish a public private partnership for pandemic vaccine distribution (PPP4PVD) that achieves the HHS goal and facilitates a rapid response. But to accomplish this policy, a strategy will require complex organizations with the will to collaborate and develop innovative strategies that will accomplish the policy goal. It is this execution that would make William Blake proud that his statement applies equally to pandemic response.

How do complex organizations with missions, values and culture interact with complex organizations that are conservative, regulatory and cautious to innovation, collaborate in a way that they chart a new collective course? The ultimate objective and challenge is how to transform vaccination-avoidance behavior to vaccination-seeking behavior among citizens. Strategic innovation is inherent to American culture and the challenges described in this thesis deserve America’s best represented by both the public and private sector. But all will be for naught if we are unable to engage the consumer. The biosecurity we seek is dependent on consumer participation. The H1N1 pandemic response and vaccination campaign demonstrated the difficulties in this respect. While the USG was able to produce a record volume of vaccine in a relatively short period of time using 60-year old technology, success was still measured by sleeves rolled up.

To accomplish the policy goal this appendix explores three analytical tools to accompany the recommendations. These are 1) build execution into strategy, and 2) build trust relationships, and 3) build multi-disciplinary, multi-organizational structures.

A. EXECUTION INTO STRATEGY

This thesis has touched on innovation, but the policy goals proposed are significant “a huge lift” as described by one stakeholder and will require collaborations with a renewed spirit of cooperation. One concept that offers analytical tools that can graphically depict the concepts discussed in this thesis is Blue Ocean Strategy (BOS)

(Kim & Mauborgne, 2005). BOS is a strategic planning guide that describes how corporations are using innovation to create new consumer markets or "blue oceans" of opportunity. A few of the tools described in BOS are offered in this Appendix as a concept to display the relationship among strategies outlined in Chapter III through VII.

Eliminate	**Raise**
Non-executable Pan Flu Plan Offshore production dependence	Provider vaccination network Vaccination Rates Equity/Herd Immunity Plan Execution
Reduce	**Create**
Vaccine wastage Staffing limitations	Point-to-Point Service Single integrated system Federal planning guidance Public Private Partnership for pandemic vaccine distribution

Figure 10. PVD Four Actions Framework

The PVD Four Actions Framework in Figure 10 shows four actions of the PPP4PVD model and its' policy, eliminate, reduce, raise and create. The policy strategy works to eliminate a non-executable PVD plan and offshore vaccine production dependency in the broadest sense. It plans to reduce vaccine wastage and reduce staffing limitations by strategies and goals outline in Chapter VII. It will raise the provider network through the use of multiple venues staffed by both traditional and non-traditional providers that will provide the basis for an executable plan and achieve greater herd immunity. Finally, it will create a new model for distribution (PPP4PVD) that integrates pandemic vaccine distribution with the seasonal flu vaccine distribution system while establishing a point-to-point service for clients. As a result, these systems are documented in federal planning guidance to assist state and local planners.

Another analytical tool that builds from the PVD Four Action Framework is the Blue Ocean Strategy Canvas Map in Figure 11.

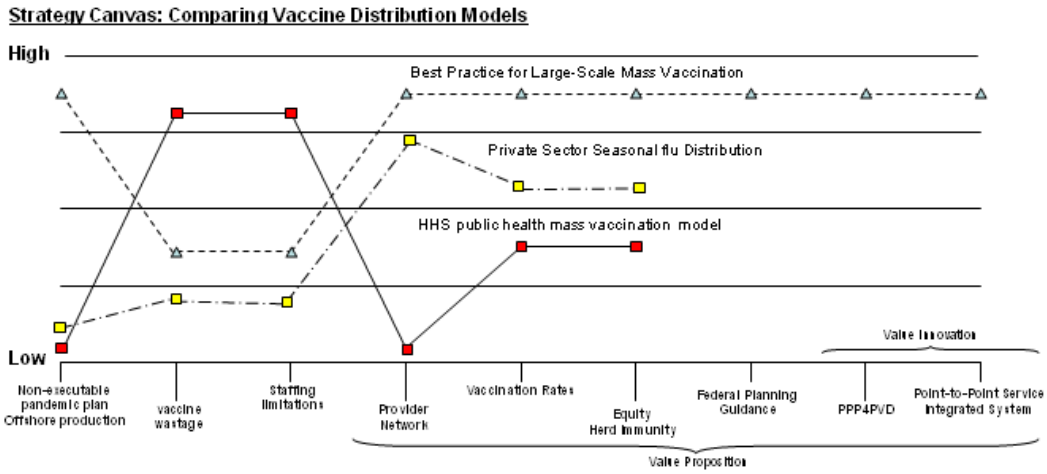

Figure 11. Strategy Canvas: Comparing Vaccine Distribution Models

Figure 11 illustrates the three models presented in Chapters V–VII and compares elements in the four actions framework (Figure 10) along a continuum (bottom) that underscores as value proposition and value innovation. On the left is the high to low axis. Value innovation results from the new strategies of the PPP4PVD model and the integration of point-to-point service and a single integrated vaccination system according to the BOS application. For example, look at vaccination rates along its vertical axis. The strategy canvas shows that the public health model (PHM) produces the least efficient vaccination rate followed by the private sector (PSM). The notion is that the new model given improvements will produce greater vaccination rates. Another example is the provider network. It depicts the PHM as the least staffed configuration, followed by the PSM, and shows that in an integrated model the nation should expect the greatest expansion to the provider network for public health emergencies.

Given the assumption of vaccine production self-sufficiency, the value innovation is to create a model staffing component by expanding the provider vaccination network and using client-centered strategies such as point-to-point service. This will be achieved through partnering with the private sector and using core competencies of both sectors for public health emergencies of national significance.

B. BUILD TRUST RELATIONSHIPS

Stakeholders referred to not only the pragmatics of pandemic vaccine distribution, but also discussed relationships, relationships with providers, relationships with patients, clients and consumers, relationships with the private sector, relationships with quasi-private state and national professional associations. The emphasis in these discussions was relationships that did not exist, should exist, or could be improved between government and its constituencies. It became apparent that these relationships must be established before the emergency. Not a surprise, "relationship building" is a tenet of NIMS and is achieved through the mantra of exercise and training. It was these discussions with stakeholders that served as the impetus for development of evaluation criteria, such as provider-centered and client-centered strategies to improve vaccine distribution. The result was a comprehensive policy for pandemic vaccine distribution that incorporated relationship building strategies for providers and clients based on their needs.

Establishing a policy that includes those strategies is step one, but how does an organization assess or measure "trust and relationship building" to ensure continued progress toward reaching the constituency, which is the target of the policy? Much work has been done over the past decade by media organizations. For example, the Institute for Public Relations published a series of guides for developing relationships. Its most recent targets trust "Guidelines for Measuring Trust in Organizations" to assist organizations build effective relationships. Take trust for example, referenced frequently throughout the interviews. Did the USG, or specifically the public health system, lose the public's trust when its promise to have 40 million H1N1 vaccine doses available for distribution by November 1, 2009 fell short? Paine (2003) describes six key components of relationships that can be measured, one of which is trust.

> There are three dimensions to trust: ***integrity:*** the belief that an organization is fair and just … ***dependability:*** the belief that an organization will do what it says it will do … and, ***competence:*** the belief that an organization has the ability to do what it says it will do.

The general belief is that the public health system has integrity as demonstrated by its priority vaccination scheme targeting high-risk groups. But when the other two dimensions are examined, dependability and competence, we may find the system falls short. The challenge is how to build a distribution system such that addresses these dimensions, but in such a way that its relationship with constituencies can be measured. Policy goals recommended strategies that target relationship building with constituents but how to measure progress? Relationship advocates recommend it is achieved by the numbers or by establishing performance measurements that target selected behaviors and then quantifying progress toward those performance measures.

An approach to measure "trust relationships" in a crisis has been proposed by Paine (2007, p. 137) and describes three measures, outputs, outtakes and outcomes.

- Measuring outputs and the effectiveness of the process: Pandemic or vaccination outputs refer to the monitoring of media to determine if messages are being communicated and to whom.
- Measuring outtakes and impact: Are pandemic/vaccination messages believed and do they sway public opinion.
- Measuring outcomes: the pandemic/vaccination outcome is herd immunity or assessing vaccination rates.

Vaccination outputs: Today's technology offers several methods to monitor the extent to which vaccination messages are published by media sources such as clipping services. This measure considers both volume and confirms message content reconciles with intended message and is straight forward. For example,

- Volume of print media articles (newspaper)
- Volume of broadcast messages (television)
- Volume of electronic messages (webpages)

Vaccination outtakes: Outtake measures whether messages are heard and found believable by the constituency. Whether an organization elects to conduct surveys using its resources or not, polling organizations typically poll major crisis events. Consider, for example, the H1N1 pandemic. Polls were conducted periodically by major polling

organizations throughout the event and offered insight into how the public perceived public health pandemic messages. For example, the Harvard Research Opinion Program (HORP) in a September 2009 survey reported that nearly 60 percent did not plan to get vaccinated and stated they would change their mind if "there were people in [their] community who were sick or dying from influenza A (H1N1)" Harvard Opinion Research Program [HORP], 2009, p. 1). Among those who stated that they would not get vaccinated, 87 percent believed H1N1 vaccine "very safe" or "somewhat safe."

- Overnight polling
    - Organizational based polling
    - Monitor the polling of national polling sources
- Trend analysis polling data

Another example of outtake is data gathered over several months or trend analysis. Public health authorities had the public's ear early in the pandemic as 67 percent reported hand washing or using hand sanitizer and 55 percent reported they would stay home if sick. (Steelfisher, 2010). But as the campaign geared up for vaccination in mid-October, interest waned. This table from HORP (2009, p. 2) shows trends from April through September 2009 in response to the question below. Note following events "very closely" the percentage declines modestly from 34 percent in April to 28 percent in September. Government authorities had the attention of the public, outtake data suggested this interest was waning and the vaccination campaign was about to commence. Yet government had thrown all the resources it had at its disposable to ready the nation for vaccination. All resources but private sector manpower and venues that would have overwhelmed the anticipated surge of vaccine which failed to show as expected. These relationships had yet to be established and state and local administrative protocol would delay their deployment until well into the campaign and after the virus attack had peaked.

> How closely are you following news about the recent outbreak of influenza A-H1N1? Are you following the news very closely, somewhat closely, not too closely, or not at all?

Table 14. Public Awareness of H1N1 Apr 2009–Sep 2009 (From HORP, 2009, p. 2)

	CLOSELY			NOT CLOSELY				
		Very	Somewhat	NET	Not too	Not at all	Don't know	Refused
9/20/09	73	28	45	26	18	8	*	*
6/28/09[i, ii]	72	27	44	28	23	6	*	*
5/6/09[iii]	76	31	46	23	17	7	*	*
4/29/09[iv]	77	34	43	22	15	7	*	*

Vaccination outcome: Vaccination outcome is measured by vaccination rates. Outcome data is a "post-mortem" assessment and measures behavior. It offers comparative norms from year to another or from one entity to another. For example, one stakeholder stated that only 22 percent of CDC workers were vaccinated with the H1N1 vaccine. In contrast, the U.S. H1N1 vaccination average was approximately 27 percent compared to 46 percent for Canada. Canada was reported to have the highest H1N1 vaccination rate in the world (K. Scott, personal interview, April 9, 2010).

C. BUILD MULTI-DISCIPLINARY, MULTI-ORGANIZATIONAL STRUCTURES

The H1N1 vaccination campaign revealed both a problem and the solution. The solution is the use of non-traditional providers which was incorporated into the execution strategy described in this thesis. The problem is the legal, regulatory and licensure process that protects one profession while preventing another profession from practicing parallel skill sets. A skill set, such as vaccination, is common across several professions and not unique to physicians and nurses. For example, in South Carolina (until recently) a pharmacist required a doctor's prescription to vaccinate. A pharmacist can distribute vaccine but cannot vaccinate without a physician's order. Large franchise pharmacy chains (e.g., CVS, Walgreen's) have standing orders that permit a pharmacist or contract nurse service to vaccinate in their retail outlets. A bill changed the scope of practice in "adverse events" recently by the South Carolina legislature and now permits pharmacists to vaccinate without a physician's prescription. This is one state, but the web of legal, regulatory and licensure limitations for many non-traditional providers that could be

recruited to vaccinate in an emergency must be solved such as dentists, vetenarians, EMTs, **phlebotomist** or numerous other allied health professionals including students. These barriers persist throughout several profession associations but what will it take to address and overcome these barriers?

The solution is the formation of collaborations or networks of associations at the federal, state and local levels of government, business (private sector healthcare providers) and professional associations. Each sector or community has issues and rationale for protecting its body of knowledge and it is the association that will protect those until its membership directs change. The discussion must be framed that in a declared public health emergency of national significance, than the professional scope of practice and standard of care rules change to protect the community. While the USG should incentivize the process, these initiatives can start locally or statewide but must also be initiated at the national level. For example, this work had begun at the local level in South Carolina and, grew to a statewide task force with the same mission. But the collaboration described must occur in fifty states and national associations and serves as one example of how the problem was addressed.

A task force was formed in South Carolina to look at the ethics of a pandemic influenza and the standard of care that must be altered in a pandemic (SCPETF, 2009, p. 4). The task force consisted of public health, state medical association, state hospital association, medical university, private sector physicians and legal council from the various bodies represented. It made three legal recommendations and demonstrates the effort that must occur to change the standard of care. Two are referenced here:

- The South Carolina Board of Medical Examiners under the Medical Practice Act should recommend and approve the South Carolina Pandemic Influenza Ethics Task Force Report as the clinical guidelines for implementation during a Pandemic Influenza Public Health Emergency.

- The South Carolina Board of Nursing under the Nurse Practice Act should recommend and approve the South Carolina Pandemic Influenza Ethics Task Force Report as the clinical and nursing guidelines for implementation during a Pandemic Influenza Public Health Emergency.

As described in the discourse of pandemics and ethics, the definition for “standard of care” must be altered to reflect the limited medical resources and provide essential guidance to medical professional for making difficult judgment regarding who gets first rights to available care. The current medical model of medicine is that the sickest patients get first claim on medical resources and system structures support this view such as legal, insurance and physician practice. Yet, in a pandemic the view shifts to patients with the best chance of recovery get first claim on limited medical resources. This same initiative must occur to modify the legal, licensure and credential barriers that prevent non-traditional providers from serving as vaccinations.

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