

**ACCEPTABILITY OF PHARMACIES SERVING AS PRIMARY DISPENSERS OF  
ANTIVIRAL DRUGS DURING AN INFLUENZA PANDEMIC: PERSPECTIVES OF  
PHARMACY EXECUTIVES**

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## **ABSTRACT**

LISA M. KOONIN: Acceptability of Pharmacies Serving as Primary Dispensers of Antiviral Drugs During an Influenza Pandemic: Perspectives of Pharmacy Executives  
(Under the direction of Dr. Sandra Greene)

During a future severe influenza pandemic, as much as 30% of the United States (U.S.) population could become ill and may need prompt treatment with antiviral medicines. Because antivirals are infrequently used for seasonal influenza and are not available in large amounts in supply chains, the federal government has stockpiled caches of antivirals in the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile for use during a pandemic.

During the 2009 H1N1 pandemic, numerous antiviral distribution and dispensing challenges arose for state and local public health officials. In May 2011, the CDC launched an effort to explore a new method of antiviral distribution and dispensing during a future pandemic, based on U.S. pharmacies serving as primary dispensers of antiviral drugs. Key informant interviews with pharmacy executives from traditional chain stores, independent pharmacies, as well as pharmacies located in mass merchants and grocery stores were conducted, and the resulting transcripts were analyzed. The purpose of the study was to understand the executives' opinions and views about their pharmacies serving as primary dispensers of antiviral drugs during a future pandemic. Participants were asked

about their insights on the relative advantages, risks, compatibility with usual pharmacy processes, and support that might be needed to execute this function successfully.

Overall, every interviewed executive expressed support for this new antiviral distribution method, and most considered their pharmacies as key community stakeholders. Collectively, these executives proposed that if a new way of dispensing antivirals approximates existing pharmacy processes and procedures, it will meet patients' needs and add minimal complexity to pharmacy operations. The informants also identified a number of potential risks but mentioned few "showstoppers" that would cause their pharmacies to not participate with this new method of antiviral distribution and dispensing. Findings from this study can help CDC design a new way of distributing and dispensing antivirals (and potentially other medical countermeasures) in the United States for a future influenza pandemic. By leveraging the skills, systems, and willingness of pharmacies to collaborate in a pandemic response effort, public health officials may realize improved emergency response capability and better population health outcomes.

**To my husband, Sam:**

For always believing in me --- and for your unconditional love, unwavering support, many sacrifices, encouragement, and patience.

**To my children – Sarah, Mark, and Jay:**

You are my best teachers.

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## PREFACE

***“Perseverance Furthers”<sup>1</sup>***

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<sup>1</sup>Source: Wilhelm, R., & Baynes, C. F. (1967). *The I Ching; or, Book of Changes* (3rd ed.). Princeton, NJ: Princeton University Press.

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## **LIST OF ABBREVIATIONS**

APHA	American Public Health Association
ASTHO	Association of State and Territorial Officials
CDC	Centers for Disease Control and Prevention
CIDRAP	Center for Infectious Disease Research and Policy
DHHS	Department of Health and Human Services
DOD	Department of Defense
FEMA	Federal Emergency Management Agency
FOUO	“For Official Use Only”
HSEEP	Homeland Security Exercise and Evaluation Programs
HHS	Department of Health and Human Services
LHDs	Local health departments
LLIS	Lessons learned information sharing
NACCHO	National Association of County and City Health Officials
NACDS	National Association of Chain Drug Stores
NCPA	National Community Pharmacists Association
PPE	Personal protective equipment
RPCs	Retail pharmacy chains
RSS	Receipt, store, and stage
Rx	Prescription
SNS	Strategic National Stockpile
TFAH	Trust for America’s Health

U.S.	United States
VA	Department of Veterans Affairs
WHO	World Health Organization

## **CHAPTER 1: INTRODUCTION**

During a future severe influenza pandemic, as much as 30% of the United States (U.S.) population could become ill and will need prompt treatment (Reed et al., 2013). With current technologies, it will take about four to six months, after a pandemic is recognized, to produce a well-matched vaccine to protect the population. In the meantime, (and even after pandemic vaccine is available) public health officials will rely on antiviral influenza medicines to treat ill persons. The Centers for Disease Control and Prevention (CDC) recommends two neuraminidase inhibitor antiviral drugs (oseltamivir and zanamivir) for use during an influenza pandemic (CDC, 2009a). Oseltamivir is the most commonly used influenza antiviral drug used in the United States (Borders-Hemphill & Mosholder, 2012). When used as indicated for treatment during typical influenza seasons, these antiviral drugs can reduce the severity of influenza symptoms and shorten the time of illness by approximately one or two days. Also, although questioned by one set of researchers, others have found that treatment of hospitalized patients with antiviral drugs may reduce the time spent in the hospital, intensive care unit (ICU) admissions, and the development of pneumonia and, in high-risk populations, death (Jefferson et al., 2012; Muthuri, Myles, Venkatesan, Leonardi-Bee, & Nguyen-Van-Tam, 2013). For treatment, influenza antiviral drugs work best when started within two days after a person becomes ill (Bramley et al., 2012) but have shown

effectiveness when used after this time period (Louie et al., 2012; CDC, 2011d).

Antiviral drugs can also be effective in reducing transmission of disease from ill to well persons and can be used for prophylaxis (Pebody et al., 2011).

Because these antiviral medicines are seldom used during the regular influenza season, large quantities of these drugs are not routinely available in pharmaceutical supply chains or in pharmacies (approximately 1 to 2 million five-day regimens are prescribed for treatment of seasonal influenza each year in the United States; IMS Health, 2013). Therefore, since about 2006, the federal government, many state health departments, and some local health departments have stockpiled caches of antivirals to use during a pandemic, when it is expected that the commercial supply chain will be quickly exhausted and will not have sufficient stocks to meet the demand for a large number of ill persons.

The Strategic National Stockpile (SNS) was created in 1999 by the U.S. Congress to store caches of medications, antidotes, supplies, and equipment that can be deployed quickly to state health departments in response to a biological or chemical attack, or some other public health emergency, once the Secretary of Health and Human Services authorizes release of these items. The SNS is housed at the CDC, part of the Department of Health and Human Services (DHHS). Although the primary function of the SNS is to “shore up” state responses to terrorist attacks, starting in 2006, the SNS is responsible for procuring, storing, and distributing millions of antivirals for use during a pandemic. State health departments have also stockpiled additional supplies of these medicines (largely achieved through federal subsidies) and have been funded by CDC to create plans



to “administer antiviral drugs for treatment to priority groups when treatment of illness is indicated” (U.S. Government, 2008).

In 2005, a national goal was set by the HHS Pandemic Influenza Plan (U.S. Department of Health and Human Services, 2005) to ensure sufficient antiviral medication to treat 25% of the U.S. population by establishing a national stockpile of 81 million regimens of antiviral drugs for use during an influenza pandemic—6 million for containment of initial cases and 75 million for treatment of symptomatic patients (U.S. Homeland Security Council, 2006). Of the total 81 million regimens, 31 million were targeted for procurement by the Public Health Emergency Preparedness Project Areas (PHER grantees)—which include 50 states, 4 major metropolitan areas,<sup>2</sup> and 8 U.S. territories and jurisdictions<sup>3</sup>—through DHHS-subsidized contracts, and 50 million were procured and managed by the CDC’s SNS. As of February 2013, the SNS contained over 68 million regimens of oseltamivir and zanamivir in both adult and pediatric formulations. HHS, in collaboration with CDC/SNS is currently evaluating the amount of antivirals that may be needed for future procurement. Separately, state and local health departments collectively hold approximately 26.5 million usable regimens.<sup>4</sup> Although the expiry dates have been extended for some of these state-held antivirals, it is highly unlikely that additional federal funding will be made available to states for purchase of antivirals to replenish these stockpiles.

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<sup>2</sup>Washington, D.C.; Chicago; Los Angeles County; and New York City

<sup>3</sup>Puerto Rico, the Virgin Islands, American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Republic of the Marshall Islands, Republic of Palau, and the Federated States of Micronesia

<sup>4</sup>A. Patel (personal communication, April 12, 2013)

Currently, the federal plan for antiviral distribution and dispensing relies on the SNS to send these drugs to state health departments<sup>5</sup> after a pandemic emerges and the need for these drugs arises. Federal planning envisions that state and local health departments would serve as primary distributors and, at times, dispensers of antivirals during a pandemic. Each state is responsible for distribution and dispensing plans and protocols to ensure that stockpiled antiviral drugs reach its population. Deployment of SNS stockpiles of antiviral drugs is meant to supplement commercial availability of these medicines once commercial supplies are dwindling or exhausted. The SNS endeavors to ensure that these materials reach state public health officials rapidly, so the medicines can reach the public as quickly as possible. State health departments, in turn, have plans to distribute these drugs to local health departments, hospitals, pharmacies, and other entities in the state according to their pandemic plan. The current federal scheme relies heavily on health departments to distribute these medicines and also set up and staff clinics and sites to dispense antivirals to the public as specified by the National Strategy for Pandemic Influenza Implementation:

HHS, in coordination with DOD [Department of Defense], VA [Department of Veterans Affairs], and in collaboration with State, local, and tribal governments and private sector partners, shall assist in the development of distribution plans for medical countermeasure stockpiles to ensure that delivery and distribution algorithms have been planned for each locality for antiviral distribution. Goal is to be able to distribute antiviral medications to infected patients within 48 hours of the onset of symptoms. Measure of performance: distribution plans developed. (U.S. Homeland Security Council, 2006, p. 122, item 6.1.13.4)

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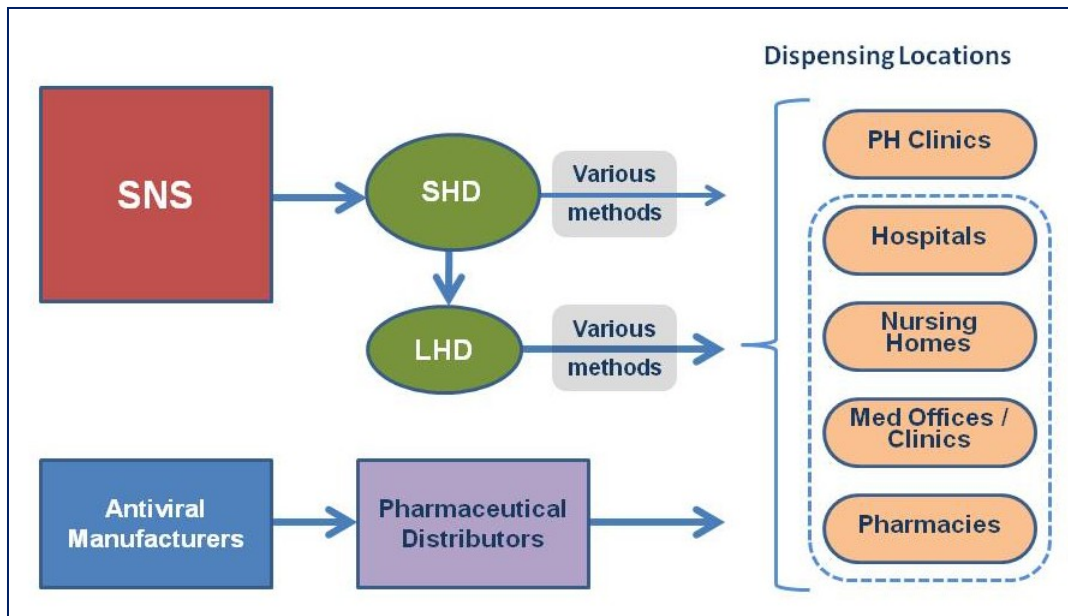
<sup>5</sup>For simplicity, these PHER grantees will be henceforth referred to as “states.”

Additionally, CDC has set as one of its key public health emergency capabilities that state health departments must have “the ability to provide medical countermeasures (including vaccines, antiviral drugs, antibiotics, antitoxin, etc.) in support of treatment or prophylaxis ... to the identified population in accordance with public health guidelines and/or recommendations” (CDC, 2011c, p. 12).

### **Background and Context: 2009 H1N1 Influenza Pandemic—A Real-Life Case Study in Distribution of the Stockpile**

On April 25, 2009, the World Health Organization (WHO) recognized the potential threat of the emerging and novel H1N1 influenza virus and declared a public health emergency of international concern. The next day, HHS issued a nationwide public health emergency to mobilize against an influenza pandemic. On that same day, the SNS began releasing 25% of the stockpiled antiviral supplies (~12 million regimens) to state health departments for further redistribution to local health departments and health care facilities in each state (Figure 1; CDC, 2010b). Local health departments were then tasked with sending antivirals to key health care facilities (and pharmacies in some states). Because of the relatively mild-to-moderate nature of the 2009 H1N1 influenza outbreak (Shrestha et al., 2011), and CDC guidance that recommended antiviral use primarily for those at high risk for complications (CDC, 2009a), few public health entities actually opened clinics and directly dispensed antivirals to ill persons (ASTHO & NACCHO, 2013).

In addition, pharmaceutical distributors and pharmacies had some (unspecified) amount of antivirals in their supply chains and in pharmacies, and most state health departments had stockpiled antivirals for use during a pandemic.



**Figure 1.** Distribution and dispensing of antiviral drugs by the SNS to state health departments during the 2009 H1N1 pandemic. SHD = state health department; LHD = local health department.

CDC recommended prompt antiviral treatment for patients who had confirmed or suspected 2009 H1N1 influenza and who were at increased risk for serious morbidity and mortality; had severe, complicated, or progressive illness; or were hospitalized (CDC, 2009a). Rapid treatment was especially important for pregnant women and young children who had become ill, and persons who were hospitalized with complications of influenza. Treatment has been shown to be most effective when started in the first 48 hours of illness. The effectiveness of timely treatment has been extensively studied, and a body of published literature from the 2009 H1N1 pandemic showed significant decreases in morbidity and mortality for ill persons who were promptly treated (Bogie, Grant, Hallford, & Anderson, 2011; Falagas et al., 2010; Jain et al., 2009; Lee et al., 2010; Louie et al., 2009; Louie et al., 2012; Siston et al., 2010; CDC, 2011b).

Although it is impossible to predict when the next influenza pandemic will arise, maintaining readiness to respond to a pandemic is a national priority. The National Strategy for Pandemic Influenza Implementation issued in 2006 called for detailed antiviral distribution and dispensing plans for all local areas; the 2009 H1N1 influenza pandemic was the first time that state and local health departments had to implement those plans for an actual public health emergency. There were anecdotal reports shared with CDC of difficulties in distributing and dispensing these medications in some communities, and spot shortages occurred, delaying treatment of some persons. Given the relatively mild-to-moderate morbidity and mortality associated with the 2009 pandemic, these problems, for the most part, did not have severe consequences (Shrestha et al., 2011). However, if the severity and the communicability of the influenza virus is greater in a future pandemic, a much larger number of people would become ill and need rapid access to these potentially life-saving drugs. In addition, delayed treatment may lead to an increased number of hospitalizations and deaths.

There were two waves of pandemic activity during 2009 (the spring wave was April – May, 2009, and the fall wave was August 2009 – March 2010), with significant heterogeneity in the timing and impact of disease occurrence by community. Some communities had profound outbreaks affecting thousands of people at the same time, while other communities had a milder event. Some localities were hardly affected by the disease during the spring wave, while other communities were particularly hard-hit. In areas with marked outbreaks of 2009 H1N1 influenza, state and local public health officials had to rapidly distribute SNS

(and perhaps, state-stockpiled) antivirals to hospitals, pharmacies, and other medical facilities for dispensing. Some of these jurisdictions could not keep up with the demand for antivirals during the peak of community outbreaks. In contrast, because a commercial supply of antivirals (specifically adult formulations) was already available in many pharmacies and in pharmaceutical supply chains, some health departments did not have to distribute and dispense antivirals from their stockpiles or from antivirals received from the SNS.

Three important realities have changed since 2006 when the SNS began stockpiling antivirals and state and local health departments began planning for their distribution. First, when the National Strategy for Pandemic Influenza Implementation Plan was released in 2006, there was limited antiviral production capacity worldwide (there were and are only two U.S.-approved antiviral manufacturers), and all of the manufacturing facilities were located outside of the United States (U.S. Homeland Security Council, 2006). However, by 2009, one of the major antiviral manufacturers had built a domestic facility and started to produce larger amounts of the drug. Therefore, the supply uncertainty related to offshore production was reduced.

Second, marked budget cuts in federal, state, and local public health programs since 2009 have reduced staffing levels and have further deepened the ongoing nationwide shortage of public health workers (Willard, 2010). The Trust for America's Health (TFAH), in their 2010 report, *Ready or Not? Protecting the Public's Health From Diseases, Disasters, and Bioterrorism*, found that "the H1N1 pandemic flu demonstrated ongoing budget and funds distribution challenges for emergency

health preparedness” (p. 37) and more specifically, “the public health workforce is in crisis. There are not enough professionals, particularly trained experts, to adequately protect Americans during health emergencies.” (TFAH, 2010, p. 38). In the 2011 report from this same organization, the authors warned that although significant progress in emergency preparedness had been realized over the past 10 years, “...local, state and federal cuts to public health budgets and staff are starting to erode a decade’s worth of progress. Health departments are increasingly spread thin and programs and core capabilities are being cut” (TFAH, 2011b, p. 3). The executive director of TFAH warned

We're seeing a decade's worth of progress eroding in front of our eyes... Preparedness had been on an upward trajectory, but now some of the most elementary capabilities—including the ability to identify and contain outbreaks, provide vaccines and medications during emergencies, and treat people during mass traumas—are experiencing cuts in every state across the country (TFAH, 2011a, para. 3).

This organization’s most recent report adds more bad news about cuts in state-level resources for preparedness as twenty-nine states have cut funding for public health from fiscal years (FY) 2010–11 to 2011–12, with 23 of these states cutting funds for a second year in a row and 14 for three consecutive years (TFAH, 2012).

Third, the 2009 H1N1 pandemic has given an opportunity, for the first time, to execute pandemic plans and evaluate the current system of antiviral distribution and dispensing (ASTHO & NACCHO, 2013). Anecdotal descriptions of problems arising with dispensing of antiviral medicines during the 2009 H1N1 pandemic were reported to CDC. Looking forward and in light of this limited experience during the 2009 H1N1 pandemic, some state plans for distributing and dispensing antiviral

medicines through state and local health departments in time of a severe pandemic may not be adequate to ensure timely access to these medicines.

Several researchers have examined antiviral distribution strategies to suggest ways to optimize and speed up this process, especially given that different communities were impacted differently. Dimitrov, Goll, Hupert, Pourbohloul, and Meyers (2011) conducted mathematical modeling to examine the number of stockpiled antivirals that should be released from the SNS and whether antivirals should be distributed on the basis of population (“pro rata,” which is the current method) or by using epidemiologic information to target the most affected areas. These authors concluded that for an influenza pandemic that is more transmissible than the 2009 H1N1 pandemic, “outcomes of antiviral use are more heavily impacted by choice of distribution intervals, quantities per shipment, and timing of shipments in relation to pandemic spread” (p. e16094). However, these investigators did not suggest how additional staff could be identified and trained, nor did they examine other alternatives for dispensing if staffing was not adequate as one of their parameters for optimizing this process. Because of anecdotal reports of challenges with antiviral dispensing during the 2009 H1N1 pandemic, and a need to improve emergency response efforts, a careful analysis is needed of what worked well and the challenges faced during the 2009 H1N1 pandemic. Based on findings from that exploration, new solutions can be formulated to improve antiviral distribution and dispensing.



## **Overarching and Concomitant Efforts That Will Inform Approach / Research Design and Methods**

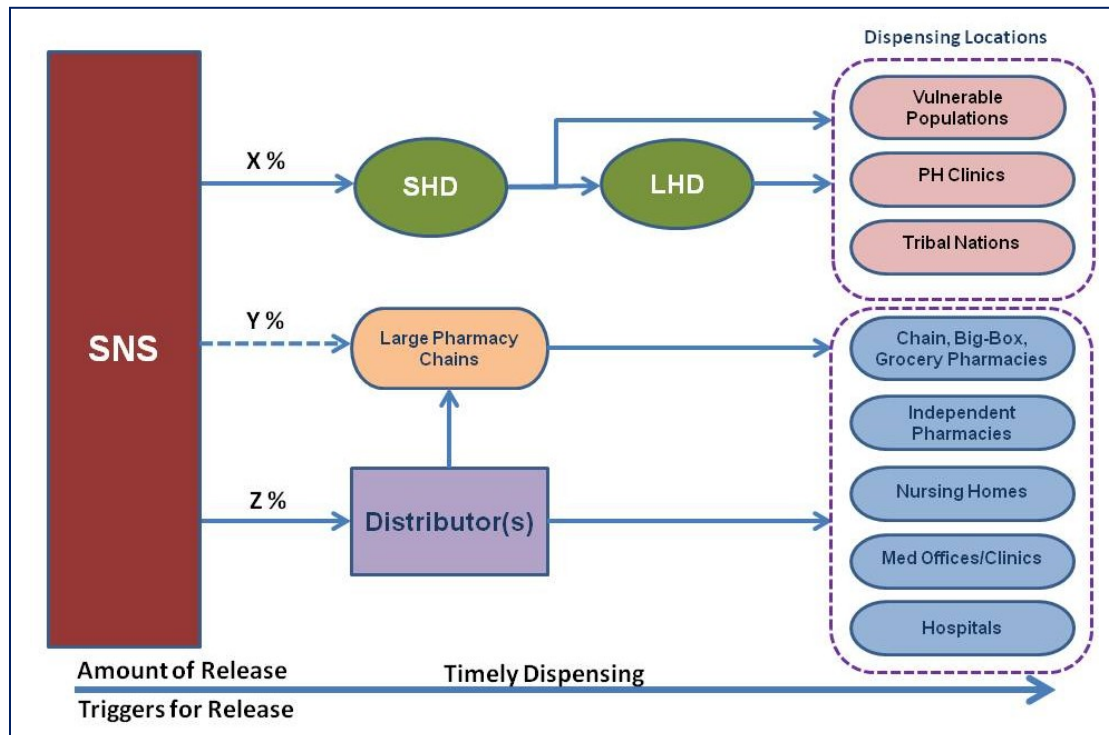
This dissertation research is linked to a larger CDC exploration that was launched in May 2011 to develop new methods of antiviral distribution and dispensing for the United States, based on the inherent strengths and capabilities of existing systems (Appendix A). A literature review of the 2009 H1N1 pandemic experience was conducted (see Chapter 2), and the findings were used to initiate and inform the CDC project. This CDC exploration is being conducted in close collaboration with key public health partners, the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO). The goal of the project is to explore the acceptability and feasibility of pharmaceutical distributors and pharmacies serving as the key distributors and dispensers of antivirals during a future pandemic. The researcher of this dissertation is directing this work as part of her day-to-day responsibilities as CDC's lead for the Pandemic Medical Care and Countermeasures Task Force.

Specifically, the CDC project is exploring whether a large proportion of SNS stockpiles could be sent to pharmaceutical distributors (and/or other commercial entities) rather than to state and local health departments, as called for in the current plan. The distributors would, in turn, send the antivirals to their existing customers who are chain, supermarket, mass-merchant, and independent pharmacies, as well as hospitals, clinics, and other medical facilities. Because these entities are already established customers of pharmaceutical distributors, the new method would leverage a fully functioning system during the time of a pandemic emergency (see Figure 1). This new method would provide antivirals to pharmacies (Figure 2), where

ill persons could obtain the drug with a valid prescription. (CDC assumes that antivirals would remain a prescription drug in the United States during a future pandemic, although other countries have reclassified oseltamivir “off-prescription”; Gauld, Jennings, Frampton, & Huang, 2012.) In the concept under exploration, state health departments would still receive an allotment of antivirals for use in public health clinics and for distribution to certain entities, but largely the public health role would be one of assuring that underserved and vulnerable populations have access to antivirals as well as monitoring and evaluation, with hopes that this shift could reduce a burden on public health during a pandemic emergency.

Because this medicine has already been purchased by the federal government, the concept assumes that there will be no charge for the product to pharmaceutical distributors and pharmacies, and contractually, they will not be able to charge patients for it. However, pharmacies could charge a dispensing fee (that will be capped at a benchmark rate). If patients have insurance or other third party coverage, then the dispensing fee will be billed to that entity. Although it is anticipated that the implementation of the Affordable Care Act in 2014 will reduce the number of people that do not have insurance, it is unknown at this time how much of the population will remain without coverage for medications (Congressional Budget Office, 2012). Therefore, ongoing work by CDC is exploring how to cover dispensing fee costs for those who are uninsured (or do not have pharmacy coverage) so the dispensing fee does not serve as a barrier to accessing antivirals. New methods of distribution of SNS antivirals through commercial entities to clinics,

hospitals, and nursing homes will be explored in a separate CDC effort and were not included in this dissertation research.



**Figure 2.** Proposed method of pandemic antiviral distribution and dispensing under investigation by CDC.

For this new method of antiviral distribution and dispensing to be considered, it must be judged as feasible and acceptable. During 2011–2012, CDC conducted feasibility assessments through (a) mathematical modeling of potential supply and demand factors, (b) two full-day simulations conducted at two pharmacies (one was an urban location of a chain pharmacy and the other was an independent pharmacy in a semi-rural location) to measure throughput and capabilities when faced with a surge of patients, and (c) exploration of system capabilities in pharmaceutical distribution systems.

Acceptability is also a key component for evaluation. First, distributors must be willing to perform this function during a pandemic emergency. CDC has explored their initial willingness to receive SNS-stockpiled antivirals and distribute them during a pandemic through their networks, and will engage them again in the future.

Acceptability to public health officials is a high priority in this project and is being explored in depth with project collaborators ASTHO and NACCHO. If the new methods are adopted, there will be a major shift in specific planning parameters and response duties expected by CDC of state and local public health entities during a pandemic. Although state (and therefore local) health departments will still receive some antiviral drugs for distribution to entities that the distributor cannot reach (e.g., public health clinics, tribal health clinics/hospitals, prisons, and homeless clinics), the need for public health authorities to further distribute and dispense antivirals will be markedly reduced (Hunter, Rodriguez, & Aragon, 2012).

Pharmacies and pharmacists will also play a central role in this new method of antiviral distribution and dispensing and must be willing to perform this function. The acceptability of frontline pharmacists as primary antiviral dispensers was assessed by a nationally representative poll of over 1,000 pharmacists that was conducted from February to April, 2012, by researchers from the Harvard School of Public Health (HSPH), who are collaborating with CDC on this effort (Appendix B). It is critical to understand what frontline pharmacists think of this new approach, and also to understand what they think may be hurdles or challenges to their participation in this new approach to dispensing antivirals during a pandemic.

Whereas pharmacists did dispense some antivirals during the 2009 H1N1 pandemic, few of them had to fill a large number of prescriptions within a short interval, because the H1N1 pandemic was mild to moderate in severity and antivirals were recommended only for those at highest risk for complications from the illness. During seasonal influenza, individual pharmacists typically dispense only a small number of prescriptions for antivirals, as this medicine is not commonly prescribed. Most pharmacies keep only a few packages of antivirals on their shelves at a given time. In contrast, during a severe future pandemic, approximately one third of the population could become ill, and CDC would likely recommend that almost all ill persons be treated, leading to a potentially much higher burden on pharmacists to maintain their usual pharmacy functions and dispense antivirals to a large number of patients at the same time. In addition, CDC would likely recommend empiric treatment (as it did in 2009), meaning that persons ill with ILI would be treated without a confirmatory laboratory test (Greene et al., 2012), which could lead to a large number of symptomatic persons seeking this medicine. The results from this HSPH poll informed the development of the key informant instrument used in this research.

The decision-makers at retail pharmacy companies (traditional chain pharmacies, independent pharmacies, as well as mass-merchant and supermarket pharmacies) will also have to deem this new method of antiviral distribution and dispensing as acceptable, as their pharmacies will serve in a primary role for dispensing antivirals. This dissertation research focused on how pharmacy executives (decision-makers) view this new method and whether they think this new

method of antiviral distribution and dispensing might be acceptable and feasible.

Pharmacy executives will decide ultimately if their pharmacies will participate, and their staff pharmacists will be the final link to patients who need antiviral medications during a pandemic.

## **CHAPTER 2: LITERATURE REVIEW**

A comprehensive and systematic review of the literature for studies and reports that examine federal, state, and local public health antiviral drug (oseltamivir and zanamivir) distribution and dispensing activities during the 2009 H1N1 influenza pandemic (April 2009 through April 2010; CDC, 2010b) was conducted to identify strengths and weaknesses of methods used by public health entities:

**What were the strengths and weaknesses of federal, state, and local public health antiviral distribution and dispensing programs during the 2009 H1N1 influenza pandemic in the United States?**

The literature review objectives were (a) determine the strengths and successes in antiviral distribution and dispensing by federal, state, and local public health during the 2009 H1N1 pandemic, and (b) determine the difficulties and challenges of federal, state, and local public health antiviral distribution and dispensing efforts during the 2009 H1N1 pandemic.

In particular, the literature was searched to identify the key challenges and barriers that state and local health departments faced in dispensing antivirals. Staffing, structural, funding, policy, and procedural barriers were examined to see if the current system seems adequate, or if improvement is needed.

## **Selection of Literature**

This literature review aimed to comprehensively compile and analyze reports and articles published from April 1, 2009, through January 31, 2013, to assess the performance of federal, state, and local public health entities regarding antiviral distribution and dispensing during the 2009 H1N1 influenza pandemic. Because it was unlikely that clinical trials or controlled studies were conducted to evaluate antiviral dispensing efforts during the 2009 H1N1 pandemic, this literature review included published descriptive analyses, performance evaluation reports, and “after-action” reports describing federal, state, and local dispensing efforts from credible governmental, nongovernmental, and academic sources.

First, studies were identified from the peer-reviewed literature that described antiviral shortages and/or addressed public health dispensing activities for antivirals during the 2009 H1N1 pandemic for the treatment of ill persons. A search was made for studies (both controlled and descriptive) that assessed or described antiviral dispensing activities by federal, state, and local public health entities. Second, the same inclusion/exclusion criteria were applied for screening governmental, government-advisory committee, nongovernmental, and academic reports of performance evaluation, as well as state-published after-action reports about antiviral dispensing activities by public health entities during the 2009 H1N1 pandemic. These reports were available through governmental and nongovernmental websites and other sources.



## Sources

A systematic search was performed using PubMed (which accesses MEDLINE) and two other databases: ISI Web of Knowledge, and Google Scholar (using the same search terms for all). Because relevant key words are sometimes not included in key articles, and because there is often a time lag in posting the latest month's journal issue to PubMed, the table of contents of four journals—*Emerging Infectious Diseases*, *Journal of Public Health Management & Practice*, *Clinical Infectious Diseases*, and *Disaster Medicine and Public Health Preparedness*—were hand searched for each month from October 2012 to January 2013 to ensure abstracts from the latest months' journal issues were included. Bibliographies of relevant articles and reports were also searched to identify additional applicable studies.

In addition to the databases and hand-searching methods listed above, selected governmental, nongovernmental, and academic websites were also searched for reports of “promising practices” performance evaluations, and for after-action reports of federal, state, and local public health antiviral-dispensing activities. In particular, searches were conducted on the Department of Homeland Security's Federal Emergency Management Agency's (FEMA) Lessons Learned Information Sharing (LLIS) website (FEMA, n.d.-b), where state and local public health are encouraged, as part of the Homeland Security Exercise and Evaluation Program (HSEEP), to post after-action reports and synopses of “best practices” using a standard format (FEMA, n.d.-a). Additional state after-action reports that were not found on LLIS and were obtained by CDC for programmatic use were also included.

All after-action and other reports that were published by state health departments and that addressed strengths and weaknesses in their antiviral distribution and dispensing activities during the 2009 H1N1 pandemic were carefully reviewed for relevant content. Relevant reports or studies on the following government websites were examined: HHS [www.flu.gov](http://www.flu.gov), CDC [www.cdc.gov](http://www.cdc.gov), and the U.S. Government Accountability Office (GAO) <http://www.gao.gov/>. Finally, nongovernmental websites were reviewed for relevant articles or reports: Association of State and Territorial Health Officials (ASTHO) <http://www.astho.org/Programs/Preparedness/>, National Association of County and City Health Officials (NACCHO) <http://www.naccho.org/topics/emergency/>, and the American Public Health Association (APHA) [http://www.getreadyforflu.org/preparedness/influenza\\_main.htm](http://www.getreadyforflu.org/preparedness/influenza_main.htm); and academic websites that focus on emergency preparedness were searched, including

- Columbia University <http://www.ncdp.mailman.columbia.edu/>,
- Johns Hopkins University <http://www.jhsph.edu/preparedness/>,
- Harvard School of Public Health <http://www.hsph.harvard.edu/policy-translation-leadership/emergency-preparedness-and-response/h-perlc-preparedness-and-emergency-response-learning-center/>,
- University of Pittsburgh <http://www.prepare.pitt.edu/>,
- University of North Carolina (Chapel Hill) <http://cphp.sph.unc.edu/>, and
- Center for Infectious Disease Research & Policy (CIDRAP; University of Minnesota) <http://www.cidrap.umn.edu/cidrap/index.html>

Only articles and reports for which a full-text version could be obtained were included in the review. A summary of the literature search strategy used in this analysis is included in Appendix C.

### **Inclusion/Exclusion Criteria Including Quality Assessment**

Seven inclusion criteria were used for this review. First, the article or report must be published in the English language. Second, the article must describe the use of antivirals used for humans (not animals). Third, the antiviral dispensing activities in the article should be those conducted during the 2009 H1N1 influenza pandemic (spanning April 2009 through April 2010). Fourth, the article or report should be published between April 2009 and January 2013. Fifth, the report or study must describe only antiviral dispensing activities that occurred in the United States and not in any other country. Sixth, the report or study must focus on antivirals used for treatment (not prophylaxis) of 2009 H1N1 influenza. Finally, seventh, the report or study must focus on antivirals used to treat influenza and not any other disease. See Table 1 for definitions used in this literature search.

Studies that focused only on federal distribution of antivirals from the SNS (and did not address state and local dispensing activities) were excluded from the search. Also excluded were reports that addressed pandemic planning activities rather than actual response during the 2009 H1N1 pandemic, those that were mathematical modeling or simulation studies, and studies and reports that only described antiviral policies but did not include an evaluation of how they were implemented during the 2009 H1N1 pandemic.

The title and abstract of each paper identified through the electronic, web, and hand searches were first screened for relevance to inclusion/exclusion criteria. If the article was in electronic format, an electronic search for the words *antiviral* or *oseltamivir* or *Tamiflu* or *zanamivir* or *Relenza*, as well as any mention of antiviral shortage or dispensing was used to screen further. Finally, if the abstract and article met the screening criteria, then the full text of the article was examined.

To ensure a consistent approach, definitions for search terms were developed and adhered to throughout the literature review process (Table 1).

**Table 1.** Definitions Used for Literature Search

Term	Definition
2009 H1N1 Influenza Pandemic	A worldwide epidemic caused by the emergence of a new influenza strain (2009 H1N1) to which humans had little or no immunity and which developed the ability to infect and be transmitted efficiently and between humans for a sustained period of time in the community. This virus was recognized as having pandemic potential in April 2009. On April 25, 2009, the World Health Organization (WHO) declared a public health emergency of international concern, and on April 26, the U.S. Department of Health and Human Services issued a nationwide public health emergency to mobilize against an influenza pandemic. The WHO announced the beginning of a pandemic on June 11, 2009. WHO Director-General Margaret Chan announced that the H1N1 influenza virus moved into the postpandemic period on August 10, 2010 (U.S. Government, 2008).
Influenza antivirals	Prescription medications used to treat influenza. The two types of influenza antiviral medications used during the 2009 H1N1 pandemic were oseltamivir (Tamiflu) and zanamivir (Relenza).
Distributing/distribution	The activity associated with the delivery of federal SNS assets from their original location to the state receiving, staging, and storing (RSS) warehouses, as well as from the RSS warehouses to local health departments, dispensing sites, alternate care facilities, and regional distribution sites/nodes.
Public health	Governmental agencies that routinely provide population health services at federal, state, or local levels.
Shortage	Lack of availability of antivirals when needed for treatment of ill persons during the 2009 H1N1 pandemic; may also include temporary or “spot” shortages of these medications.
Timely receipt of antivirals	Antiviral treatment started within the first 48 hours (2 days) of illness.
Delayed treatment	Antiviral treatment started later than 48 hours (2 days) after influenza signs and symptoms began.

## **Design for Literature Review**

Descriptive and observational studies as well as program evaluations, descriptive analyses, governmental committee reports, and after-action reports about public health activities conducted in the United States, written in English, and published between April 2009 and January 2013 were included.

### **Types of Participants**

Federal, state, or local public health personnel or agencies that distributed and dispensed antivirals in any setting for treatment of ill persons during the 2009 H1N1 pandemic were included.

### **Quality Criteria**

Studies were analyzed and assessed for quality on the basis of the following two criteria (maximum score could be 10):

#### **1. Published in peer-reviewed journal or by a credible source**

5: Yes

3: No, but credible government report or other source

1: No, only a single person's opinion or editorial or not published by a credible source

0: score was not assigned

#### **2. Objective evaluation of dispensing of antivirals during H1N1**

5: Yes, evidence of objective review

3: Difficult to assess objectivity

1: No, not objective analysis, opinion or conjecture

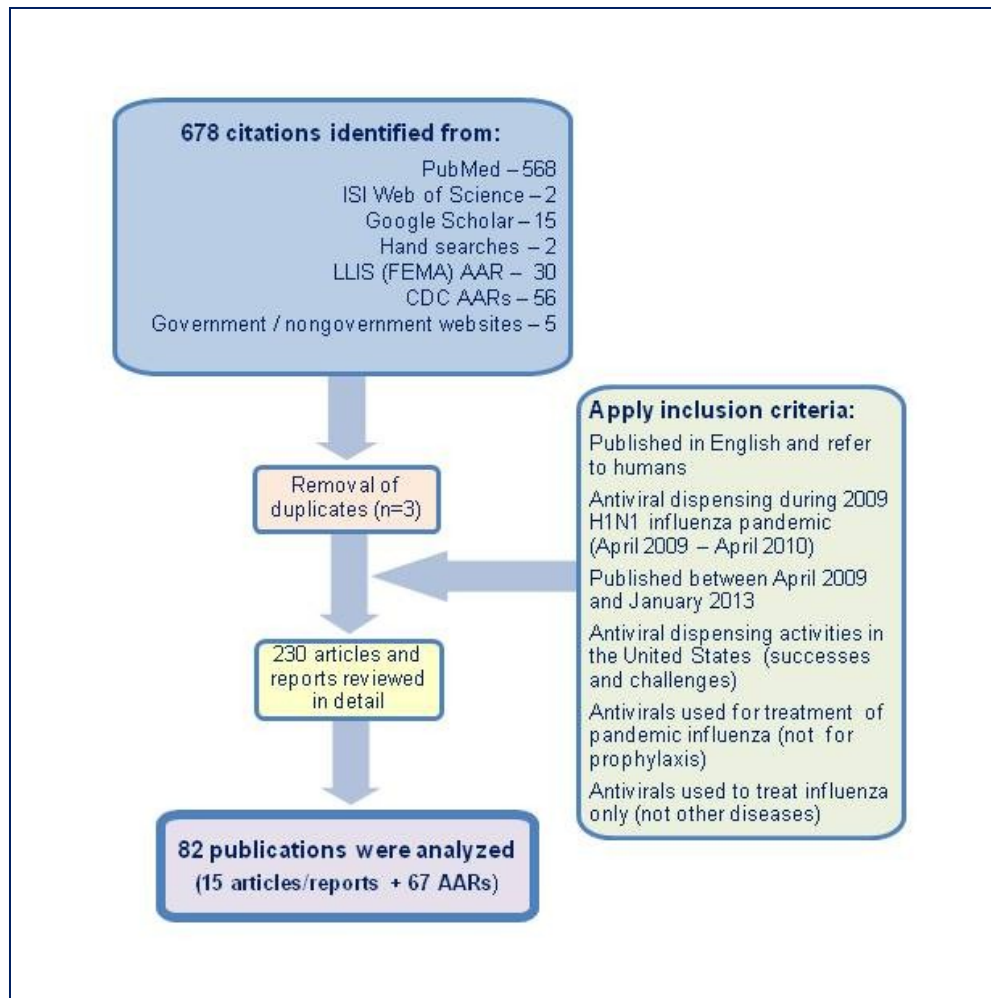
0: score was not assigned.

## **Process for Reviewing Literature**

Descriptions of the strengths, key challenges, and barriers that state and local health departments faced in distributing and dispensing antivirals during the 2009 H1N1 pandemic were identified. The researcher searched for mentions of antiviral shortages to see if shortages correlated with public health dispensing activities. Descriptions of staffing, structural, funding, policy, and procedural barriers were also sought to see if the current system seemed adequate, or if improvement was needed. Themes summarized below were derived directly from this review. All relevant articles and reports were noted on a summary sheet.

## **Literature Review Results**

Initially, 568 articles and reports from PubMed were identified for review. An additional two studies were identified from ISI Web of Science, and 15 from Google Scholar. Hand searches of specific journals yielded two more articles. A query of the FEMA, Department of Homeland Security's registered website (LLIS; FEMA, n.d.-b) produced 30 after-action reports that met the search criteria. Further, 54 after-action reports submitted directly to CDC (for other programmatic purposes) but not posted on LLIS were identified that met the search criteria. Two additional after-action reports were found through Internet searches, but were later found to be duplicates of two submitted to CDC. From all sources, after-action reports were found for all 50 states and the District of Columbia; 30 states had published more than one 2009 H1N1 after-action report, usually from differing time periods during the pandemic. Finally, scans of six other governmental and nongovernmental websites produced five reports for analysis (Figure 3).



**Figure 3.** Literature search results for antiviral dispensing successes and challenges during the 2009 H1N1 influenza pandemic.

After applying the inclusion criteria, full copies of 230 articles, reports, and after-action reports were reviewed in detail and determined eligible for analysis (see flowchart in Figure 3). After review, 19 of the state after-action reports (out of 86 posted on LLIS or available through CDC) did not meet the inclusion criteria. Overall, 82 articles, reports, and after-action reports met the inclusion criteria for this literature review (15 published articles or reports and 67 state after-action reports).



## **Quality of Studies Included in This Review**

All studies and reports were examined for quality using the previously described criteria. The majority of the information used in this comprehensive review was from state after-action reports filed on the Department of Homeland Security's FEMA secure website Lessons Learned Information Sharing (LLIS) (FEMA, n.d.-b) or submitted directly to CDC. LLIS is a national website that posts reports and summaries of disaster responses, exercises, and other efforts for public health, emergency response, and homeland security use. A limited number of peer-reviewed published reports were also used for this review. A ranking of quality assessment was performed for included studies and reports. Only studies that were from a credible source with objective findings were included (minimum score of 3/5). The state-published after-action reports were hard to rank for quality. Although they were produced by reliable state governments, objectivity in the findings was hard to assess. Therefore, quality scores were assigned only to the published studies. Characteristics of each published article or report (not including after-action reports) and quality scores are summarized in Table 2.

**Table 2.** Quality Scores of Published Studies Included in Literature Review

<b>Author</b>	<b>Type of article, journal</b>	<b>Quality score (credible source/objective evaluation)</b>
CDC (2010c)	Article: CDC's <i>Morbidity and Mortality Weekly Report</i>	5/5
GAO Report (2009)	Report	5/3
GAO Report (2011)	Report	5/3
Hanfling (2009)	Commentary: <i>Disaster Medicine and Public Health Preparedness</i>	5/1
Horton ( <i>Beyond readiness</i> , 2009)	Congressional Testimony	3/1
Hunter (2012)	Article: <i>BMC Public Health</i>	5/5
Jain (2009)	Article: <i>Journal of the American Medical Association</i>	5/5
Kumar (2009)	Article: <i>Viruses</i>	5/3
Lautenbach (2010)	Article: <i>Clinical Infectious Diseases</i>	5/5
Lee (2010)	Article: <i>Clinical Infectious Diseases</i>	5/5
Louie (2009)	Article: <i>Journal of the American Medical Association</i>	5/5
NACCHO Think Tank Report (2010)	Report	3/3
National Biodefense Science Board (2010)	Report	3/3
Siston (2010)	Article: <i>Journal of the American Medical Association</i>	5/5
Skarbinski (2011)	Article: <i>Clinical Infectious Diseases</i>	5/5
Sugerman (2011)	Article: <i>Clinical Infectious Diseases</i>	5/5

After reviewing all of the published articles, no studies that were randomized controlled trials or that employed any other experimental design were identified. However, six peer-reviewed journal articles described hospitalized patients ill with 2009 H1N1 influenza and mentioned delays in antiviral treatment (but with no reason given for the delay). The most relevant data for this review were obtained from state 2009 H1N1 pandemic after-action reports; they were the only source that included a description of antiviral successes and challenges during 2009 H1N1. About 35% (n=30/86) of the after-action reports were filed on the FEMA secure website (LLIS; FEMA, n.d.-b). This website is open for viewing only by government staff. The remainder of the after-action reports were submitted by states directly to CDC for program review purposes (n=54), and two after-action reports submitted to CDC were also posted on the Internet. Of the 86 after-action reports identified, 19 did not mention any success, challenge, or description of their antiviral distribution and/or dispensing activities. Therefore, 67 after-action reports were included in the analysis.

Almost all of the after-action reports submitted to CDC or found on LLIS (83%, n=71) were listed as “classified as For Official Use Only (FOUO).”<sup>6</sup> Although the researcher is authorized to access this website because of the investigator’s official CDC duties, the FOUO designation prevents her from citing individual reports in a way that the key themes could be linked to a specific state’s after-action report. Therefore, a summary of the successes and challenges that emerged following a

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<sup>6</sup>FEMA defines FOUO as follows: “The term ‘For Official Use Only’ applies only to unclassified information which is privileged, sensitive, and requires protection from disclosure to the general public, and for which a significant reason, statutory requirement, or regulatory instruction exists to preclude general circulation” (FEMA, 2000)

review of all of the journal articles and reports, as well as an aggregated summary of findings from the after-action reports, is presented in Tables 3 and 4.

### **Successes With Antiviral Dispensing**

This comprehensive literature review revealed three areas where state and local health departments reported successes with antiviral distribution and dispensing during the 2009 H1N1 pandemic (Table 3).

Thirty-seven percent of the states' after-action reports (n=25) noted that antiviral distribution and dispensing “worked well” in regard to timely distribution from the state to local health departments. However, this reference was almost always related to the warehouse (RSS) functions, and to transportation and distribution of antivirals to other entities (such as hospitals and clinics); very few states reported that they directly dispensed the antivirals to ill persons in public health settings. The following two excerpts are representative of the reports in this category:

*Distribution worked overall, solid A-.*

*Receipt, Store, and Stage (RSS) site staffs were able to successfully receive, repackage, stage, and distribute SNS assets within 27 hours. RSS staffs were able to successfully adapt and develop a “just-in-time” electronic warehouse inventory management system.*

**Table 3.** Summary of Successes With Antiviral Dispensing During the 2009 H1N1 Pandemic From Literature Review

No.	Successes	Number of articles or reports that cited this issue (n=15)	Number of state AARs that cited this issue (n=67)
1	Antiviral distribution and dispensing processes “worked well.”	0 (0%)	25 (37%)
2	Collaboration with pharmacies for antiviral distribution and dispensing worked well and was “successful.”	2 (13%)	18 (27%)
3	Pre-pandemic investments made by the federal government for state and local pandemic planning, staffing and exercises enabled a successful response.	1 (6%)	14 (21%)

Fourteen after-action reports (21%) mentioned that pre-pandemic investments made by the federal government for state and local pandemic planning enabled a successful response. In particular, some states commented that receiving previous CDC funding allowed them to focus on pandemic planning, train staff, and have a plan available to use during the response. A large number of states mentioned that previous efforts to exercise their plans proved to be beneficial in the 2009 H1N1 response, as it enabled them to have “worked the plan” before the pandemic arrived:

*Strategic National Stockpile (SNS) and Cities Readiness Initiative planning paid off as the RSS Warehouse performed extremely well. Recent training facilitated the building of partnerships with community stakeholders and with LHDs [local health departments] throughout the state.*

*[The state] had existing response plans that could be utilized immediately and served as a starting point for the response. While elements of this plan were field adapted during the duration of the response, without the plan to work*

*from as the response began, the initial response would have likely been less organized and less effective.*

*It was obvious that routine training and exercises and previous activation of the RSS to support major coastal hurricanes had allowed the staff to understand their roles and to implement mission requirements in a professional manner. Additionally, the warehouse and RSS contractor cooperated to facilitate a very successful operation.*

Multiple-year investments by the federal government in federal and state antiviral stockpiling, as well as federal funding and guidance to state and local health departments for pandemic planning, had created infrastructure that facilitated the response. CDC has provided significant funding to states to support pandemic planning. A total of \$325 million in cooperative agreement emergency supplemental funds was given prior to the 2009 H1N1 pandemic to enable state and local health departments to hire personnel, and to bolster the development of state and local pandemic influenza preparedness plans (U.S. Department of Health and Human Services, n.d.).

Eighteen after-action reports (27%) reported that pharmacies assisted the state health department in managing antiviral stocks and provided the public with access to antivirals. These states mentioned that they had developed partnerships and memoranda of understanding (MOUs) that enabled them to send antivirals to pharmacies for dispensing during the pandemic. To ensure access to antivirals for uninsured patients, some state and local health departments distributed cached antivirals to pharmacies and made special efforts to communicate to the public and providers that patients could receive antiviral medications at local pharmacies at no cost (Santa Clara Public Health Department, 2009, October 5; State of Louisiana Department of Health and Hospitals, 2009, October 7). Eighteen states reported that

collaborations with pharmacies and pharmacy boards worked well for antiviral distribution and dispensing and were “successful.” Specifically, states mentioned the inherent capabilities that pharmacies had for dispensing antivirals:

*A big hats off to State Bureau of Pharmacy in pushing out the Tamiflu® in an orderly fashion.*

*The retail pharmacy chains are new partners to Public Health and have the existing infrastructure in place in [state name redacted] to order, distribute, administer and report required data to the state in an efficient, timely, and consumer-oriented manner. Overall, the RPCs experiences were positive.*

*[The state health department] collaborated with the [state] Pharmacy Association to effectively distribute antiviral medications to locations throughout the state. ... This strong partnership allowed for total state coverage of all counties in [state] and completely alleviated the burden of providing antivirals through the local health departments.*

*[The state reported] doses of antiviral medications [were] delivered to retail pharmacies and Federally Qualified Health Centers (FQHCs) ... The program represented a very unique partnership between public health and private industry, and clearly identified a valuable resource for emergency response. This model could be duplicated for response to a variety of public health emergencies.*

During the pandemic, the Association of State and Territorial Health Officials (ASTHO) also actively sought to include pharmacies as a venue for administering the 2009 H1N1 vaccine (ASTHO, 2009).

### **Challenges With Antiviral Dispensing**

During an influenza pandemic, immediate access to antivirals for treatment of ill persons is critical to minimize morbidity and mortality, particularly if the pandemic is severe. However, even during a mild- to moderate-level severity pandemic like the 2009 H1N1 outbreak, almost all state after-action reports, some of the journal articles, and one report, mentioned that problems arose with distribution and dispensing of antivirals and/or with shortages of all types of antivirals in some

geographic locations, at some time during the pandemic (Table 4). No correlation between difficulty in distributing antivirals and community size were noted.

There were three sources of antivirals during the 2009 H1N1 pandemic: commercially available antivirals that were already in pharmacies or supply chains when the pandemic started; stockpiled antivirals that the federal government (SNS) released to state health departments (on a pro rata basis) during the early weeks of the pandemic; and antivirals that some states (and other jurisdictions) had purchased and stockpiled themselves, before the pandemic. Pre-pandemic planning parameters had never included scenarios that envisioned any available commercial supplies during a pandemic; thus the concomitant availability of commercial supplies of antivirals made the distribution and dispensing efforts confusing to state and local health departments.



**Table 4.** Summary of Challenges With Antiviral Dispensing During the 2009 H1N1 Pandemic From Literature Review

No.	Challenges	Number of articles or reports that cited this issue (n=15)	Number of state AARs that cited this issue (n=67)
1	Problems with tracking of antivirals (both stockpiled antivirals and commercial supplies)	2 (13%)	38 (57%)
2	Problems with ability to store and dispense antivirals at the state or local level (includes staffing issues)	2 (13%)	35 (52%)
3	Previous pandemic planning scenarios did not match the needs during the H1N1 response	2 (13%)	28 (42%)
4	Lack of clear communication between local and state HDs and some dispensing partners	1 (6%)	18 (27%)
5	Unclear or changing federal guidance about use of antivirals	3 (20%)	18 (27%)
6	Shortage of some types of antivirals and shortages in some locations	8 (53%)	9 (13%)
7	Communications between state and local health departments about delivery of stockpiles and use of medication	2 (13%)	6 (9%)
8	Delays in treatment of ill persons (treatment given more than 48 hours after symptoms arise)	6 (40%)	4 (6%)
9	Lack of visibility of commercial supply chain	2 (13%)	3 (4%)
10	Other (e.g., four states that required local health departments to get distributor licenses to transport antivirals, two states that had concerns/legal issues that slowed distribution to pharmacies)	0 (0%)	10 (15%)

Over one half of the state after-action reports (57%) mentioned problems with tracking and “visibility” of both state and SNS antivirals during the 2009 H1N1 response. Although a robust federal tracking system was used for H1N1 vaccine distribution during the response (Tropper et al., 2009), a uniform federal tracking system was never developed for antiviral distribution and dispensing, and most state health departments had also not developed any tracking system as part of pandemic planning. As one state commented in their after-action report,

*... an efficient and automated system to track antiviral medication utilization was not available.*

Because no standardized way existed for states to track antivirals, this placed an extra burden on health department staff to develop their own methods. Several state health departments created their own tracking systems during the response, but reported issues with these improvised systems:

*Due to the increased workload on providers and hospitals, many who had access to [state developed electronic tracking system] preferred to fill out the paper form regarding administration and inventory of antiviral and vaccines rather than taking the time to enter the data into [the state’s electronic system]. Those who weren’t registered and trained on the [system] sent in the paper forms as well. This created a tremendous backlog of work at the [state health department] in order to clarify ambiguities on forms and enter all of the data into [the electronic system]. The [state health department] hired temporary employees using H1N1 funds received from CDC but still could not keep up with workload.*

*The arrival of the State Cache Antivirals presented a novel problem for the [state] ... [the state] was forced to quickly devise an in-house strategy for tracking these antivirals. As such, although a protocol for reporting usage and a database for tracking were developed in a timely fashion; such systems only provide a week-old snapshot of antiviral usage in those who actually faxed in usage reports.*

There were other problems associated with lack of tracking of antivirals during the pandemic. State and local health departments had limited, only periodic, or no

visibility on the available commercial supply chain in their jurisdiction and thus could not judiciously deploy stockpiles to fill shortages or gaps (ASTHO, 2010). Also there was no way to track and monitor antivirals (Ringel, Moore, Zambrano, & Lurie, 2009) after they were distributed to local public health, hospitals, clinics, providers, etc.:

*Although a protocol for reporting antiviral usage at the sites and a database for tracking usage were developed, such systems lacked the ability to provide situational awareness and relied upon the sites to fax usage [to the state health department]. As such, problems with sites misreporting and/or not reporting were prevalent and compiling the reports that were received was time-consuming.*

Because many state and local health departments did not have information on the number of antivirals dispensed, some could not substantiate shortages, as they did not have data to support sending more antivirals to locations around the state or further SNS requests for a resupply of antivirals:

*During the spring 2009 event, the [state health department] did not have an accurate procedure to evaluate antiviral and PPE stockpile levels at hospitals, clinics and public health offices. It therefore was required to estimate these levels when evaluating where to push the SNS supplies from the RSS Site to dispensing sites.*

*There was insufficient data to support resupply requests from the SNS based on current Centers for Disease Control and Prevention (CDC) criteria.*

Importantly, most state and local health departments did not have information on utilization of distributed antivirals in their state/locality and could not assess uptake and use, nor account for their disposition. Little information was available to ensure that vulnerable or high risk populations received antivirals. Additionally, the absence of antiviral tracking precluded timely efforts to resupply communities that had high illness rates and were in need of more supplies. And last, state public

health officials reported that they needed more federal guidance to define key data elements to track and to identify systems to use for tracking.

Over half of the state after-action reports (52%) mentioned problems with storage, handling, and dispensing antivirals. The issues may have been linked to four problems: (a) lack of adequate local public health staffing to manage distribution and dispensing, (b) lack of detail in pre-pandemic antiviral dispensing plans, (c) lack of plans for lengthy storage of antivirals because pre-pandemic planning scenarios envisioned that storage at the local level would not be needed, and (d) a possible lack of expertise in pharmaceutical distribution and dispensing. After antivirals from the federal SNS arrived at state health departments, most were then sent to local health departments for dispensing.

Lack of public health staff to manage distribution and dispensing of antivirals was clearly an issue for local public health departments in several states. One state commented that local health department staff in their state

*... were busy with epidemiological investigations, outbreak control, and other duties related to the response and were not able to dispense medications.*

Public health workforce shortages have been a persistent problem over time (Perlino, 2006). The Trust for America's Health (2009) reported that during the 2009 H1N1 pandemic "public health departments did not have enough resources to carry out plans" (p. 3). In particular, this report urged that "stopping layoffs at state and local health departments and recruiting the next generation of public health professionals" (p. 2) were critical elements in being able to respond to a public health threat like the 2009 H1N1 pandemic. The National Association of County and City Health Officials reported that over a two-year period (January 2008 through

December 2009), 23,000 local health department (LHD) jobs were lost, representing approximately 15% of the national LHD workforce. During the last six months of 2009 (during the 2009 H1N1 response), about 46% of LHDs lost jobs to layoffs or attrition (Willard, Leep, & Shah, 2010). The Association of State and Territorial Health Officials reported that over one third of states (36%) expected to lose staff through layoffs or attrition in FY11 (ASTHO, 2011). Finally, TFAH (2011b) reported that during 2011, “40 states and Washington, D.C. have cut funds to public health, 30 states cut their budgets for the second year in a row and 15 of those have cut their budget three years in a row” (p. 3).

Some state and local health departments also lacked expertise in pharmaceutical distribution. One state mentioned that it had evenly divided the stockpiled antivirals and sent them to a large number of sites in the state, but were unable to redistribute those antivirals and resupply some areas of the state when needed. A number of local public health departments returned unused antivirals to the state or distributed them to hospitals because they had no way of dispensing them to ill people (Dorian, Rottman, Shoaf, & Tharian, 2009). Two states reported (in their after-action reports) that their legal counsel unexpectedly required that pharmaceutical distributor licenses be obtained by local public health agencies in the state because they were transporting medications for the pandemic response.

Antiviral shortages were mentioned by over half (53%) of the published articles/reports and 13% of the after-action reports. Although the 2009 H1N1 pandemic was milder than expected, shortages occurred, in some part because it was difficult for state and local health departments to know which commercial

antivirals were available in the supply chain and when to release stockpiled antivirals to fill gaps (more on this later in the discussion of tracking antivirals). Additionally, lack of public health expertise in supply chain management was inferred from several comments made in the state after-action reports.

In particular, the after-action reports and published articles noted shortages of pediatric formulations of antivirals in most states. Patel and Gorman (2009) noted in a paper published during the pandemic (September 2009) that the federal SNS likely needed additional pediatric antiviral formulations. The prescribing information for oseltamivir capsules currently includes instructions for pharmacists for emergency compounding of an oral suspension that can be used for children (Roche USA, 2011). In addition, CDC (2010a) included messages to parents and providers that pharmacies could extemporaneously compound adult oseltamivir capsules into a suspension for treatment of ill infants and children. However, the flavored syrup used by pharmacists in compounding adult formulations for pediatric use was also in short supply during the pandemic (U.S. Food and Drug Administration [FDA], 2009).

CDC released Tamiflu (oseltamivir) oral suspension from the CDC Strategic National Stockpile in November 2009 to enhance availability at state and local levels. However, some of the lots of suspension had an expired date on the label. CDC told providers and pharmacists that under the emergency use authorization for Tamiflu, FDA had authorized the use of certain lots of expired Tamiflu (FDA, 2010). In several after-action reports, states reported that this CDC advice to use expired product was confusing and unclear to public health officials and the public.

Pediatric antiviral shortages during a pandemic could have been resolved by increasing the available amount of pediatric antiviral suspension in stockpiles, improving the distribution method of these medications so they were available to those who needed them, and/or by increasing extemporaneous pediatric formulations by compounding the capsules into an oral suspension. However, manufacturers produce only a relatively small quantity of pediatric suspension, and its shelf life is limited. Resolution of shortages also may have been accomplished by utilizing supply distribution expertise, such as pharmaceutical distributors, which during an emergency may be able to leverage their logistics expertise to rapidly deliver scarce medical supplies to pharmacies where the medication is most needed (Healthcare Distribution Management Association, 2009). In addition, pharmacists are specially qualified to compound adult formulations of medicines into suspensions for children. Therefore, the increased involvement of pharmacies in a pandemic response may improve the availability of compounded formulations through pharmacies. It is imperative that solutions be developed to prevent shortages of pediatric antivirals in a future pandemic, as children were and will be one of the most vulnerable segments of the population when a novel influenza virus emerges.

Delays in treatment of hospitalized ill persons (treatment given more than 48 hours after symptoms arise) were mentioned in 40% of the journal articles and reports. Guidelines issued by CDC called for rapid treatment of ill persons whose illness required hospitalization or who were at high risk for complications, preferably within 48 hours after they became ill (CDC, 2009a). No explanation for the delays in treatments were given in the literature, but these delays may have resulted from a

shortage of antivirals, delay in seeking health care after onset of illness, delayed diagnosis of influenza while waiting for test results, delay in prescribing antivirals, and/or delay in receipt or administration of antivirals after a prescription was written (Fiore et al., 2011).

Forty-two percent of state after-action reports mentioned a “mismatch” between pre-2009 planning parameters and the severity of the 2009 H1N1 pandemic. Most states (and the federal government) had planned for a severe pandemic, where commercial antivirals would likely be unavailable, and where stockpiled antivirals would be the only source of the medication. Because the 2009 H1N1 pandemic was less severe than those planning parameters, there was some availability of antivirals through commercial supply chains (although precise amounts and locations were not known), which was confusing to state and local responders in determining how to optimally deploy the various antiviral stocks. Especially confusing was the determination of who received commercial supplies of antivirals and who received government-stockpiled medication. Additionally, pre-pandemic planning called for antivirals to be used for treatment as well as for prevention (prophylaxis). Although state health departments had planned for a mass prophylaxis dispensing model, this type of antiviral dispensing was not appropriate for the 2009 H1N1 response (U.S. Government, 2008).

Finally, three communication issues were included in the state after-action reports. Communication between state and local health departments was frequently mentioned as a barrier. Often local health departments had very short or no notice for receiving antiviral shipments from the state, or the time set by the state for



delivery of antivirals did not match the actual delivery time, which hampered planning and response. Longstanding communication issues between state and local health departments continue to need resolution to remove this barrier, particularly during an emergency response. Clear communication was also lacking between state and local health departments and between those health departments and providers (e.g., physicians, hospitals, clinics) about the appropriate use of antivirals (specifically concerning which populations should receive antivirals for treatment, which persons were eligible for government-supplied antivirals versus commercially supplied antivirals, and whether to use antivirals for treatment only or for prophylaxis too). States reported that the federal government needed to do a better job communicating to public health agencies and clinicians about when SNS shipments would arrive at the state depot, and when and how to use antiviral medications, including a clear statement about use of antivirals for prophylaxis during the 2009 H1N1 response (ASTHO, 2010; National Biodefense Science Board, 2010).

### **Strengths and Limitations of Literature**

None of the journal articles included in this review described formal program evaluations of how state health departments dispensed antivirals during the 2009 H1N1 pandemic. Therefore, the primary source of information for this review was from state after-action reports that summarized the strengths and weaknesses of their 2009 H1N1 response. Fewer than half of the states (n=24/50) filed an after-action report with the FEMA LLIS website; the remainder were submitted directly to CDC for program use. Although these reports were a rich source of self-reported

and anecdotal data, and are assumed to be credible as they are authored by state government officials, it is difficult to verify or validate their findings, understand them in quantitative ways, or assess their representativeness for other states. Some states could have overreported successes and/or underreported problems or challenges that were associated with lack of planning or difficulties with capability for response. State health departments may not want reports of emergency response system weaknesses to be shared with others or CDC because they worry that these findings may impact future federal funding or compromise their ability to make improvements. Moreover, state authorities may see release of this information as jeopardizing their ability to protect the public. No reports included external validation of the findings presented. Finally, because the majority of the after-action reports were designated “For Official Use Only (FOUO),” they are available to only a limited number of government researchers to assess validity of these conclusions.

Although the after-action reports from all 50 states and the District of Columbia have been reviewed, this literature review may be incomplete, and key publications may have not been identified.

### **Gaps in the Literature and Considerations for Future Research**

A systematic review of the literature allowed this researcher to answer the research question “What were the strengths and weaknesses of federal, state, and local public health antiviral distribution and dispensing programs during the 2009 H1N1 influenza pandemic in the United States?” A number of key challenges and successes were identified from the review. Although infrastructure investments in pandemic planning for antiviral distribution and dispensing and partnerships with

pharmacies were noted as areas of success during the pandemic, multiple problems with the implementation of antiviral dispensing and insufficient personnel to handle these operations served as barriers.

The literature review identified only the problems encountered, but did not identify solutions or any new models for testing. The problems encountered by state and local health departments may have had far greater impact if the 2009 H1N1 pandemic had been more severe and the consequences of untimely receipt of antiviral treatment more profound. Could a new method of antiviral dispensing resolve some of the problems faced? State health departments mentioned that their collaborations with pharmacies were successful in dispensing antivirals during the pandemic. Could pharmacies be utilized to dispense antivirals in a future outbreak? An exploration should be conducted that focuses on pharmacies and the pharmaceutical distribution systems that supply pharmacies as a possible alternative method of dispensing antivirals. In addition, it will be important to qualitatively assess private sector entities' perceptions of acceptability and feasibility of any new dispensing strategy. A careful assessment of feasibility and acceptability may yield information to inform the development of a new and more efficient way of dispensing lifesaving antiviral medications during a future pandemic.

## **CHAPTER 3: METHODS**

### **Background and Context to Support Methods**

Eighteen state after-action reports mentioned that working with pharmacies improved the distribution and dispensing of antivirals in their state. Because the severity of the 2009 H1N1 pandemic was mild to moderate, few state or local health departments actually dispensed antivirals to ill persons themselves. Instead they distributed these medicines to hospitals, clinics, and pharmacies to dispense per their usual methods. When considering the antiviral dispensing problems faced by public health during the 2009 pandemic, the question “Who can do this well?” comes to mind. Moreover, who performs this task every day and has become expert at pharmaceutical distribution and dispensing? The answer is pharmaceutical distributors and pharmacies.

Almost all U.S. pharmacies receive pharmaceutical products shipped by licensed distributors at least several times a week. Most pharmacies (especially in urban areas) receive a shipment each day. There are three major pharmaceutical distributors in the United States: Cardinal Health Inc., McKesson Corporation, and AmerisourceBergen Corporation. These companies are experts at distributing medications and manage approximately 90%–95% of the products (and market value) of the wholesale drug market. It is estimated that four out of every five

prescriptions dispensed in the nation have been handled by one of these top three distributors. Each day, these major pharmaceutical distributors deliver more than nine million prescription medicines and health care products to more than 164,000 pharmacies, hospitals, nursing homes, clinics, government facilities, and other providers in all 50 states (Healthcare Distribution Management Association, 2009). In addition to these three large distributors, approximately 5,500 other pharmaceutical distributors operate nationally or regionally, or specialize in distributing some types of pharmaceutical products or distributing to specialized pharmacies or institutions (Britt, 2007).

Is it possible that during a future pandemic these pharmaceutical distributors may be able to leverage their logistics expertise to rapidly deliver antivirals to pharmacies? Could pharmaceutical distributors receive SNS stockpiled antivirals from CDC and distribute them through their established networks to pharmacies all over the country during a pandemic? In alignment with usual practice, ill persons would get a prescription for this medicine from a licensed health care provider, and then they (or their family members) would go to a pharmacy to pick up the medicine.

Although government-held antivirals in the SNS have never been distributed through a private-sector entity, a study found that pharmaceutical distributors can provide next-day, same-day, or emergency delivery to reallocate scarce inventory during crises (Booz Allen Hamilton, 2007). Pharmaceutical distributors have expertise in forecasting, ordering, inventory management, stock rotation, tracking, and distribution derived from daily practical experience, to efficiently provide order fill rates of 95% and sustain the inventory of pharmaceuticals in drugstores and other

pharmacies. Pharmaceutical distributors also have expertise in electronic inventory-management systems (e.g., bar coding, stickers, electronic order entry) that may provide solutions to tracking antivirals after they have left SNS inventory controls (Healthcare Distribution Management Association, 2009).

At the public level, Americans rely on pharmacies and pharmacists every day to obtain needed prescription medications. Pharmacies offer expertise, familiarity, convenience, accessibility, extended hours of operation, and can be integrated as key community partners in a public health response. Pharmacists are highly trusted health care professionals with a unique degree of access to the public (Gallup, 2012). There are about 61,000 community pharmacies in the United States (National Association of Chain Drug Stores [NACDS], 2011), including:

- chain drugstores (37% of all pharmacies),
- independently owned drugstores (34%),
- supermarket pharmacies (15%), and
- mass merchants (large stores such as Target and Wal-Mart that have an in-store pharmacy; 14%).

Ninety-three percent of Americans currently live within 5 miles of a community pharmacy (NACDS, 2011). Drugstores are also familiar places to shop and are located in most communities. According to *Growth from Knowledge Mediamark Research & Intelligence*, in 2010, approximately 11% to 20% of adults aged 18 years and older had shopped at a drugstore at least one time in the past month (Growth from Knowledge, 2011). Studies have shown that in general, people consistently use the same pharmacy in their community and select that pharmacy

primarily because the pharmacy accepts their insurance, the pharmacy is convenient, the pharmacist is able to answer questions and concerns, and because of their perceptions/relationships with the pharmacy staff (NACDS, 2012b).

The share of prescriptions dispensed in 2010 by the community channel includes

- traditional chain drugstores, 48%;
- independent drugstores, 20%;
- supermarket pharmacies, 13%;
- pharmacies in mass merchandisers, 12%; and
- mail order, 7% (NACDS, 2011).

Although there are almost as many independent pharmacies as there are chain drugstores in the country, the traditional chain drugstores dispense 2.4 times as many prescriptions as independent pharmacies, on average. The NACDS (2012a) reports that currently, these chains "... fill over 2.7 billion prescriptions annually, which is more than 72% of annual prescriptions in the United States" (para. 5).

Even though independent pharmacies dispense fewer prescriptions overall than chain drugstores, they are important providers of pharmaceutical services, particularly in some areas of the country (NACDS, 2011). In North Dakota, for example, supermarket and mass merchant pharmacies are not allowed to conduct business because only pharmacies with a North Dakota resident as majority owner may operate a pharmacy in that state (Haarsager, 2010). Therefore, independent pharmacies provide 75% of all dispensing in North Dakota. In several other states

(Arkansas, South Dakota, Mississippi, Montana, and Oklahoma), about one half of pharmacies are independents (NACDS, 2011). According to the National Community Pharmacists Association (NCPA), independent pharmacies dispense about 1.5 billion prescriptions annually (NCPA, 2011b).

A relatively small number of corporations operate the majority of pharmacies in the United States (Table 5).



**Table 5.** Top Pharmacy Companies by Type of Pharmacy, Number of Pharmacies, Percentage of All Community Pharmacy Locations, Percentage of Prescription Share, and Pharmacy Sales, United States, 2010

Name of pharmacy company	Type of pharmacy	No. of pharmacies (rank)	% of all U.S. community pharmacy locations	% of U.S. prescription share (rank)	Pharmacy sales, millions of dollars (rank)
Walgreens	Chain	7,709 (1)	12.6%	21.3% (1)	43,823 (1)
CVS Caremark	Chain	7,108 (2)	11.6%	16.8% (2)	38,994 (2)
Rite Aid	Chain	4,714 (3)	7.7%	8.1% (3)	17,086 (3)
Wal-Mart Stores	Mass-Merchant	3,800 (4)	6.2%	6.1% (4)	15,616 (4)
The Kroger Co.	Grocery	1,969 (5)	3.2%	4.0% (5)	7,886 (5)
Target Corporation	Mass-Merchant	1,584 (6)	2.6%	1.8% (6)	3,033 (8)
Safeway	Grocery	1,362 (7)	2.2%	1.3% (9)	3,695 (6)
Sears Holding Co. (K-Mart)	Mass-Merchant	981 (8)	1.6%	1.1% (11)	2,495 (9)
SUPERVALU	Grocery	805 (9)	1.3%	1.2% (10)	2,313 (10)
Publix Supermarkets	Grocery	805 (10)	1.3%	1.1% (12)	1,558 (12)
Royal Ahold (Stop & Shop)	Grocery	665 (11)	1.1%	1.4% (7)	3,465 (7)
Medicine Shoppe Intl	Independent	657 (12)	1.1%	1.3% (8)	1,436 (14)
Sam's Club	Mass-Merchant	519 (14)	0.9%	0.7% (14)	1,781 (11)
Costco Wholesale Corp.	Mass-Merchant	465 (15)	0.8%	0.9% (13)	1,449 (13)
H-E-B	Grocery	188 (23)	0.3%	0.6% (15)	1,223 (15)

*Note.* In 2010, there were 60,134 community pharmacies (includes all four types of pharmacies) in the 50 states. Sam's Club is owned and operated by Wal-Mart Stores. Adapted from *NACDS 2011–2012 Chain Pharmacy Industry Profile* by the National Association of Chain Drug Stores, 2011, pp. 26–27.

However, it is not known if utilizing pharmaceutical distributors and pharmacies is a possible solution for improving antiviral distribution and dispensing during a future pandemic. Research should be conducted to explore the feasibility, practicality, and acceptability of this new method. Is this new method of government-to-private sector asset distribution workable? Will it work to improve antiviral dispensing? How will state and local public health officials view a change in the way antivirals are distributed and dispensed? By using pharmaceutical distributors, can we minimize antiviral shortages and delays in treatment, and improve tracking in the next pandemic? Will pharmacy companies, pharmacists, and pharmaceutical distributors be interested and, most importantly, willing to perform this function? Will this new method of dispensing antivirals resolve many or some of the problems encountered during the 2009 H1N1 pandemic? Will a new method of antiviral distribution and dispensing create new challenges? What will pharmacy companies think about a new method that includes their pharmacies serving as primary dispensers of antivirals?

### **Dissertation Research Question**

As the questions listed above imply, the viability of a new way of distributing and dispensing antiviral drugs during an influenza pandemic relies on feasibility and its acceptability by key stakeholders. In particular, understanding the opinions of corporate-level pharmacy company leaders (decision-makers) regarding conditions of acceptability of this new antiviral distribution and dispensing approach is a key factor in successful implementation of this new approach. These executives (and other pharmacy executives in similar roles) will likely be the leaders in their

companies who will determine if their pharmacies will or will not participate in this effort during a pandemic. It is therefore vital to understand their views as this new method of antiviral dispensing is being explored. Even if state and local public health officials, pharmaceutical distributors, and frontline pharmacists identify this new antiviral method as acceptable, it will not be feasible unless the decision-makers in the pharmacy companies also find it acceptable. Although these executives will be able to identify key factors that could make this new approach acceptable, and although it may or may not be possible to satisfy these conditions, it will be important to know their views in this early stage of planning, to enable future action.

Therefore, the research design and analysis undertaken for this study were intended to address the study's research question:

**What factors do pharmacy executives consider critical if pharmacies are to serve as the primary dispensers of antiviral drugs during an influenza pandemic?**

### **Data Collection: Planning**

Acceptability of this proposed new method of large-scale antiviral distribution and dispensing will rely heavily on its acceptability by pharmacies and pharmacists. Pharmacy executives have the power to approve or disapprove their company's participation in this new method of antiviral distribution and dispensing, so their outlooks about any barriers, risks, and relative advantages of this method must be clearly understood. A qualitative approach was employed to derive these views, issues, and meanings from pharmacy executives (Creswell, 2007).

Although this research did not use a mixed methods approach, findings from the poll conducted by the Harvard School of Public Health (HSPH) (described earlier) from February 24, 2012, to April 23, 2012, among a nationally representative sample of 1,076 pharmacists were used to inform an open ended qualitative approach (see Appendix B for a summary of findings from this poll; SteelFisher, Blendon, & Brule, 2012). These results about pharmacists' perceptions of possible advantages or risks of this new approach shed light on planning the key informant interview questions and indicated possible categories of issues that may also arise during interviews with pharmacy executives (Figure 4). In addition, data gathered from the HSPH poll included information on the participants' pharmacy surge capacity for staffing, capability of handling a large number of customers at one time, availability of home delivery and drive-through windows, and availability of other accommodations that could align with infection control practices during an influenza pandemic (by keeping sick people away from well people to reduce the chance of disease transmission).



**Figure 4.** Pharmacist's poll results informed key informant interviews.

## Conceptual Model

This proposed new way of distributing and dispensing antivirals during a future pandemic, namely using the capability of the commercial system of distributors and pharmacies, represents a radical departure for state and public health functions during an emergency (because of many years of previous plans that identified public health as shouldering the primary responsibility for this function). There is a possibility that, for the most part, this new method of antiviral distribution and dispensing may not be perceived as a radically new innovation for pharmacies, as the proposed model closely aligns with current pharmacy practices.

However, this new method is still a departure from “normal” for pharmacies and would probably be seen as something new and would require approval and acceptance by pharmacy company executives (as stated above, acceptance will also be needed from public health, pharmaceutical distributors, and others). Pharmacy company leadership will have to determine if this new method is an appropriate “fit” for their company. An adapted conceptual framework was applied to the design and conduct of this qualitative research. A conceptual model of diffusion of innovation developed by Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou (2004) informed this effort to improve antiviral distribution and dispensing during a pandemic and informed the conduct of the key informant interviews (Appendix D).

Greenhalgh et al. (2004) define innovation in service delivery and in an organization as

*a novel set of behaviors, routines, and ways of working that are directed at improving health outcomes, administrative efficiency, cost effectiveness, or users’ experience and that are implemented by planned and coordinated actions.* (p. 582)

The notion of dissemination (active and planned efforts to influence target groups to adopt a novel way of doing something) and the need for “innovation-system fit,” which is the relationship between the proposed innovation and the context or appropriateness for a given organization, are key concepts from Greenhalgh’s model that were extracted to guide the formulation of this dissertation research (Greenhalgh et al., 2004). Further, research conducted with physicians to identify why some decisions are easily adopted and which elements cause leaders to reject innovation found that innovation adoption was linked to perceptions of low cost, simplicity, and compatibility (Shafrin, 2011, September 20). Similarly, Greenhalgh’s model focuses on how innovation in health services organizations is spread and sustained, and includes the concepts of relative advantage, compatibility, low complexity, potential risks, and needed support (Greenhalgh et al., 2004). These selected concepts are particularly relevant to this dissertation research and served as the conceptual framework to inform construction of the interview questions that were used with participants. Although the researcher could not predict in advance if pharmacy executives would mention any of these factors or consider them relevant in their decision whether to adopt this new role, the conceptual framework served as a planning starting point that allowed the researcher to draft an approach and interview questions.

Greenhalgh et al. (2004) elaborates on the concept of relative advantage by stating “innovations that have a clear, unambiguous advantage in either effectiveness or cost-effectiveness are more easily adopted or implemented” (p. 594). Relative advantage is a likely factor that may influence the participants’ view

of acceptability of this new way of distributing and dispensing antivirals during a future pandemic. If the pharmacy executives see no advantage for their organizations in taking on this task, it is highly unlikely that there will be acceptance of this new method. Therefore, this concept is an important one to explore in depth with interview participants. Relative advantages to the new method of antiviral distribution and dispensing may include increased store traffic, financial gain, better serving customers (by being able to dispense a needed medicine during an emergency), and alignment with a company's concept of community stakeholder responsibility. However, relative advantage alone will probably not determine whether this new way of antiviral distribution and dispensing will be acceptable to pharmacy executives. They will have to understand the relative advantages in context with other dimensions to determine how any relative advantages might influence acceptability.

It was also critical to assess what the pharmacy executives identified as possible risks related to this new approach. Greenhalgh et al. (2004) state that if the innovation has a high degree of probability of an outcome that the individual perceives as adverse, then it is less likely to be adopted. Possible risks may include disruption in the pharmacy, security risks, financial loss, and staff exposure to disease. The interviews were designed to allow plenty of time for any perceptions pharmacy executives have of risks to surface. Probes were used to elicit strategies they may mention to mitigate those risks. Reduction of risk may be a shared component of actions taken by local government, public health agencies, and the participants' companies. If participants perceive formidable risks leading to adverse

outcomes associated with this new method, they may find it to be unacceptable unless certain risks are reduced. The participants may weigh the relative advantages against possible risks as they formulate their opinions about acceptability of this new approach.

Other concepts from the Greenhalgh model that affect the diffusion of innovation, such as compatibility, low complexity, and any support that will be needed, were also included in the interview questions. Greenhalgh et al. (2004) propose that “innovations that are compatible with the intended adopters’ values, norms, and perceived needs are more readily adopted” (p. 596). Compatibility with existing pharmacy functions has been a key planning notion for this effort. The design of this new system is heavily reliant on leveraging the existing capabilities, tasks, and functions of pharmaceutical distributors and pharmacies. This new method of antiviral distribution and dispensing is likely to be compatible with routine, everyday pharmacy functions (managing inventory, receiving prescriptions, dispensing medicine, counseling patients, etc.). A working assumption is that by aligning with current practices, the chance for system disruption is minimized, and the probability of a successful outcome during an emergency is enhanced.

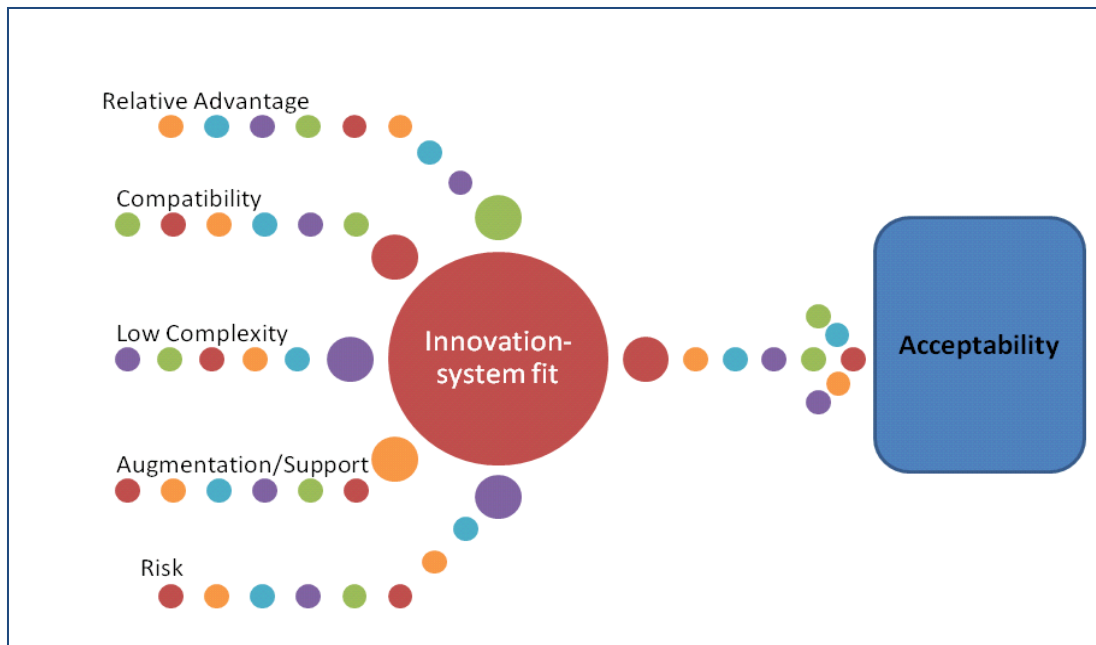
Low complexity is also an important component of successful diffusion of innovation. Greenhalgh et al. (2004) assert that “innovations that are perceived by key players as simple to use are more easily adopted” (p. 596). The new method of antiviral distribution and dispensing is expected to closely align with current pharmacy practices and functions and thus not create a significant number of new processes for pharmacists and pharmacies to handle. The CDC planning team



assumes that those new processes that are created will be, for the most part, low in complexity for pharmacy staff to manage.

Finally, Greenhalgh et al. (2004) assert that “successful adoption is more likely if the intended adopters have continuing access to information about what the innovation does and to sufficient training and support on task issues (i.e., about fitting the innovation to daily work)” (p. 600). Participants were asked about the kind of help or support they might need from state and local government, public health, and the federal government. Support may also be needed from corporate offices to individual pharmacies to implement this new method of antiviral distribution and dispensing. CDC may need to convene training, communication, and support networks for pharmacies, comprising state boards of pharmacy, public health, and not-for-profit chain pharmacy and independent pharmacy associations.

Therefore, these five conceptual categories were incorporated into a model that served as a starting point for this research (Figure 5).



**Figure 5.** Conceptual model of issues that may influence acceptability for pharmacy executives of a new method of antiviral distribution and dispensing during an influenza pandemic. Adapted from “Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations,” by T. Greenhalgh, G. Robert, F. Macfarlane, P. Bate, and O. Kyriakidou, 2004, *Milbank Quarterly*, 82(4), pp. 594–598.

## Using a Qualitative Approach

To learn about the views and opinions of pharmacy executives, key informant interviews were employed using a qualitative approach to data collection and analysis. Because pharmacy executives’ opinions about this new antiviral approach were not available from previous studies nor easily elicited using quantitative survey methods, interviews were a critical method to learn the key factors affecting these executives’ views (Saldaña, 2009). Using a qualitative approach enabled the researcher to hear each interviewee’s “voice” and opinions about the study issues, probe the beliefs that these executives held about the proposed new way of

distributing and dispensing antivirals during a pandemic, and better understand underlying and associated concerns and issues (Creswell, 2009).

### **Institutional Review Board Approval and Protection of Human Subjects**

Approval was sought and received from the CDC Institutional Review Board (IRB) for this research, and an exemption was granted by the CDC IRB on February 8, 2012 (Appendix E). Approval for this research was received from the researcher's dissertation committee (March 6, 2012), and from the University of North Carolina (UNC) IRB committee (March 27, 2012) before conducting the research (Appendix E). The researcher also received approval from CITI training to conduct research as part of her doctoral studies at UNC Chapel Hill (Appendix F).

Although IRB approval was imperative to conduct the research, the researcher also took precautions to protect the privacy of study participants. First, the researcher (and subsequently the IRB committees) concluded that there was not substantial or potentially harmful risks associated with participation in this research. The primary risk to subjects who participated in this study was breach of confidentiality. Because all study materials were held securely and all audio recordings of the interviews have been destroyed, this breach is highly unlikely. However, if information concerning the participants and their statements are somehow inadvertently released, no embarrassing, legal, or reputational threats were anticipated.

## **Selection of Study Participants**

To ensure that the data gathered for this research included a variety of perspectives, executives were interviewed from each of the four major types of pharmacies in the United States (i.e., traditional chain drugstores, independent pharmacies, pharmacies in grocery stores, and pharmacies in mass merchant stores). Table 6 describes the key informants and the dates they were interviewed.

### **Delimitations: Defining Eligible Pharmacy Executive Participants**

This qualitative research focused on the views of executives of some of the largest (and smallest) pharmacy companies in the United States. To learn about the key conditions for participation in a new method of antiviral distribution and dispensing during a pandemic emergency, the participants must have had substantial decision-making responsibilities for U.S. pharmacy retail operations in their companies. Therefore, the research excluded both pharmacy executives in companies that primarily dispense medicines in inpatient settings or outside of the community-pharmacy sector (e.g., hospitals, nursing homes, ambulatory clinics), and pharmacy executives who did not have key authority (or significant input) for determining their companies' decisions to adopt new pharmacy programs.

**Table 6.** Pharmacy Executive Participants in Key Informant Interviews

<b>Participant</b>	<b>Type of pharmacy</b>	<b>Participated in company response during the 2009 H1N1 influenza pandemic?</b>	<b>Senior leader (decision-maker) in company?</b>	<b>Date interviewed</b>
1	Traditional chain drugstore	Yes	Yes	April 5, 2012
2	Traditional chain drugstore	Yes	Yes	June 14, 2012
3	Traditional chain drugstore	Yes	Yes	April 13, 2012
4	Grocery store	Yes	Yes	May 1, 2012
5	Grocery store	Yes	Yes	April 27, 2012
6	Mass merchant	Yes	Yes	April 20, 2012
7	Mass merchant	Yes	Yes	May 7, 2012
8	Independent pharmacy (not affiliated with any other company, located in a semi-rural area)	Yes	Yes Owns pharmacy (pharmacist)	May 10, 2012
9	Independent pharmacy (affiliated with a large chain of independent pharmacies, located in a large city)	Yes	Yes Co-owns pharmacy (not a pharmacist)	May 1, 2012

## **Interview Methods**

Procedures and written information provided to the potential participants were approved by both the CDC and the UNC IRB. Key informants were recruited by e-mail that included an explanation of the research study. Prospective participants were asked if they would be willing to participate in a telephone interview to discuss issues around a new approach to distributing and dispensing antivirals during a pandemic (Appendix G). A copy of the Fact Sheet/Consent Form (Appendix H) was included with the invitation. This form included a description of the study, the project's potential benefits and risks, and methods that the researcher would use to ensure their privacy, and asked for their voluntary participation and informed consent. For those who did not respond within a week, a follow-up e-mail was sent, and for one participant, a phone call was made, to ask for their participation. All of the companies contacted agreed to participate. Seven of the nine executives contacted agreed to participate. For two companies, the person originally contacted referred the investigator to another senior colleague in their company who had responsibility for pharmacy operations, and they in turn agreed to participate. After participants agreed to be interviewed for the study, appointments were scheduled for the telephone interview, usually within two weeks of the initial contact. Each participant was informed that this research was for the researcher's dissertation (as part of doctoral studies at the UNC Gillings School of Global Public Health) and also was a key part of the researcher's work at CDC in this area.

Interviews were conducted by telephone with each participant between April 5, 2012, and June 14, 2012. After introductions were made and the purpose of the

study explained, verbal informed consent was requested over the telephone at the start of the interview, prior to data collection (Appendix I); all consented to be interviewed and participate in the study.

The interviews began with an explanation of the purpose of the study. The executives were informed that their participation in the study was completely voluntary, and the researcher explained to them that they could stop the interview at any time or opt to not answer any of the questions asked. All participants had received a written description of the study prior to the key informant interviews and had an opportunity to ask questions and/or express concerns prior to scheduling the initial interview as well as at the start of the interview.

The provisions for confidentiality were then described, and participants were assured that their name and their company name would not be associated with specific comments or answers, nor would their name or company name be included in any report or presentation of the findings. Participants were asked for their permission to audio record the discussion; all consented to have the interview recorded.

The researcher explained that quotations from their interview may be used in the dissertation, but no quotations would be attributed to participants by name or company name. Rather, the quotation would be noted as one given by a “pharmacy executive.” The researcher also explained that answers to interview questions would be grouped together in any report or presentation, and the aggregated information would be used in the researcher’s dissertation and by CDC to determine

how to better plan for a future pandemic. Other procedures for assurance of privacy included the following:

- At the time of the interview, participants were asked for permission to record the interview for transcription. All interviews were recorded, and a written transcript was made and stored securely. Each transcript was assigned a code, and all mentions of the participant, their company, or their geographic location were removed from the transcript. All interview recordings have since been destroyed after each transcript was validated against its recording.
- The principal investigator was the only person who had access to information that linked individual participants to the responses from their interviews, and the hard copy of the code sheet was kept in a secure, locked cabinet.
- Transcripts from each interview were stored electronically in protected files. Electronic copies of interview notes and other data were stored on a password-protected laptop kept in a secure location. All notes and transcripts will be destroyed upon completion of the study and after the dissertation is approved by the researcher's dissertation committee.

There were no offers of a monetary or nonmonetary incentive to the participants in this study, other than the offer to provide a copy of a completed summary of this research after committee approval. In addition, there were no costs to be borne by subjects, other than their time.



Participants were informed that there were no “right answers” to the researcher’s questions; the purpose of the interview was to learn as much detail as possible about their views and opinions. The researcher also let them know that although she was leading this exploratory effort at CDC, it was not yet known if this approach would be feasible or acceptable by CDC, and she did not know if it would be implemented.

Each interview was started by asking participants about their position in the company to confirm that they met the study inclusion definition of a “pharmacy executive decision-maker.” For context, each participant was asked to explain his or her role during the 2009 H1N1 pandemic. A scenario was then read that described a future pandemic and the proposed new method of antiviral distribution and dispensing by engaging pharmaceutical distributors and pharmacies. A semistructured approach was used by leading the interview with specific questions, but allowing the interviewee to talk about whatever they wanted in response to the question. Using the conceptual model developed for this research as a guide (Figure 5), a series of questions were asked to understand their views on each element of the model. The questions were posed to each participant in the same order, except when replies from participants warranted rearrangement of the question sequence.

In alignment with the study conceptual framework, the specific questions asked directly related to each of the study’s conceptual framework’s concepts (relative advantages, compatibility with usual pharmacy processes, level of complexity, support needed for implementation, and any risks or disadvantages to

the approach). After each initial question was posed, the researcher used open-ended probes to encourage clarification and gather more detail about each issue that was raised. Participants were encouraged to explain their ideas in detail and to elaborate on what they had said, as needed to get clarity on their views. Finally, the researcher repeated back to them what was heard regarding any major concepts or areas that they emphasized to ensure that their beliefs and views were understood.

## **Data Analysis**

Each interview was recorded, transcribed, and printed for analysis. To ensure the transcripts were accurate and reflected the exact wording of the participants, each transcript was verified by listening to the recording and simultaneously checking the transcript. The transcripts were then reviewed and manually coded. Manual coding techniques were used (rather than employing coding software) because the number of interviews conducted was felt to be manageable for manual coding, and the researcher determined that using a manual technique would allow the investigator “to communicate and connect with the data” (Basil, 2003, p. 152). Data codes derived from the study’s conceptual framework served as a starting point for codes, but other codes were used on the basis of information provided by the participants. After coding each transcript, common patterns, categories, and themes were identified from the conceptual model, which includes key factors that influence adopting innovation (Creswell, 2009). After all transcripts were coded, the codes that were mentioned consistently across participants were clustered and identified as themes. Frequency of mention and the importance of the issue as stated by the participants were two factors in the

identification of themes. A color-coded notation method was used to provided a consistent approach to coding and clustering codes as key themes (MacQueen, McLellan, Kay, & Milstein, 1998; Ryan & Bernard, 2003).

## **CHAPTER 4: RESULTS**

The primary purpose of this study was to identify the opinions and views of key pharmacy executive informants about use of a new antiviral method during a future influenza pandemic that would rely primarily on pharmaceutical distributors and pharmacies to distribute and dispense antivirals. Although this new method will increase the pharmacy's and pharmacist's roles as compared with the current response plans, these pharmacy executives had a favorable reaction to this idea and believed that it would closely align with everyday pharmacy processes. Numerous participants' direct quotations<sup>7</sup> are used in this chapter as they best illustrate these findings.

### **Key Findings and Major Themes**

Study responses from pharmacy executives representing traditional chain stores, mass merchants, and grocery stores (collectively referred to as "large pharmacy companies" henceforth) were very similar to one another. In contrast, for a few topics, there were differences in findings between the views of executives from large pharmacy companies and those from independent pharmacies. Therefore study results are presented separately for these two groups when differences in responses occurred.

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<sup>7</sup>Each set of quotations includes remarks made by different participants to illustrate the variety of comments on a certain topic.

## Overall Reaction

The first question asked of the executives after providing them with a short scenario and explanation of the new antiviral methods was designed to elicit their overall reaction:

**What do you think about this proposed method of having pharmacies serving as the primary dispensers of antivirals during a future pandemic?<sup>8</sup>**

Overall, each interviewed executive expressed consistent support for this new method of dispensing antiviral medications during a pandemic. Some were enthusiastic in their response even before they heard the details of this proposed plan:

***"I think it's a great idea."***

***"So as far as I'm concerned it's a fantastic plan."***

***"I think the proposed process you have is a huge step in the right direction of solving a pandemic problem."***

***"... so I'm a firm supporter of what you're trying to accomplish with getting the medication to the pharmacies, then getting it out to the public from there."***

***"I applaud the proactive interactive approach to it"***

Several pharmacy executives contrasted the method used for antiviral distribution during the 2009 H1N1 pandemic with the proposed method under study. Many of these pharmacy companies operated pharmacies that received antivirals from state and local health departments during the pandemic and mentioned that the various and heterogeneous state reporting requirements and methods for distributing antivirals to pharmacies were not aligned with usual pharmacy processes

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<sup>8</sup>See Figure 2 for a depiction of the new model of antiviral distribution and dispensing that was described to the participants and Appendix I for an explanation of the new method given to participants during the key informant interviews.

and added complexity for their companies. Several executives stated that the proposed method likely would improve efficiency:

*“Well, certainly I think it sounds like it would be an improvement from a logistics perspective of trying to get pandemic product to patients as opposed to going individually through the states. Certainly, the challenges that we faced at the time which was a very narrow window of trying to respond very rapidly to patients, and the challenges of trying to do that on a 50-state individual protocol individual requirement is nearly impossible to do. So I think from the perspective of saying that [previous method] is not an effective method to manage, then it’s certainly worthy of discussion on what are the alternatives.”*

*“I think this provides the opportunity to do the pull model to where if a store needs more, they don’t have to pick up the phone and have 18 different people say please send out more dosages to this store; they can actually just order it as they would order a normal product.”*

*“So it seemed like it was kind of cumbersome when it was coming through the health department where you called the health department and then you have to send somebody to go get it and all that.”*

*“Again, I do think that it—I do believe that the county health departments and the city health departments and the varying state health departments are excellent in what they do, but this process in essence kind of removes the middle man and can actually, ... I think this can probably cut out 24-48 hours of that supply chain process getting it into the ultimate consumer.”*

*“Well, certainly I think it sounds like it would be an improvement from a logistics perspective of trying to get pandemic product to patients as opposed to going individually through the states.”*

Two executives mentioned that if pharmacies were largely responsible for antiviral dispensing during a pandemic, they could reduce the burden on public health and extend the public health’s “reach” to the community. Another executive reinforced this point by mentioning that public health officials have different expertise than pharmaceutical distributors and that it would work best to utilize the expertise inherent in the pharmaceutical distributors:

*“... [public health is] good at the ‘let’s figure out how we want to do things,’ but when it comes down to how do we actually do it, that’s where you need the operators, and if you think through the wholesalers, this is what they’re built to do, if you think through the retail industry, that’s what they’re built to do. The ability of what they actually bring to the table is very tremendous not only from the record keeping, not only from the speed to get product moved throughout the country, but also from the speed of communication alone.*

*“... So I think that you’re really letting the people that are experts in the logistics operations take over that part of it so I think it’s the right thing to do. I think it’s fantastic.”*

To gauge overall reaction to this proposed method of antiviral distribution and dispensing, executives were asked about the key factors that would influence their decisions or their companies' leaders' decisions to participate with the proposed method of antiviral distribution and dispensing. Several executives (from both large and independent pharmacy companies) responded:

***"I could say if this type of solution was available right now we would certainly want to sign up."***

***"I mean I'd sign the dotted line right now that I'd do it."***

***"... right now if you're saying do you want to participate in being able to distribute medicines, yes, the answer is yes."***

***"Oh, absolutely just no issues at all. Just fantastic."***

### **Major Themes Identified from Interviews of Pharmacy Executives**

Many issues were raised, and numerous advantages and risks related to the new method were discussed during these interviews. However, five major themes emerged from the interviews that describe the factors that pharmacy executives considered critical if pharmacies are to serve as the primary dispensers of antiviral drugs during an influenza pandemic (Table 7). Each theme will be discussed separately, and examples of the comments made by the executives are provided to illustrate the key findings for each topic.

**Table 7.** Major Themes Identified From Key Informant Interviews of Pharmacy Executives if Pharmacies are to Serve as the Primary Dispensers of Antiviral Drugs During an Influenza Pandemic

Theme No.	Major Theme
1	The new way of dispensing antivirals during a pandemic is largely compatible with existing pharmacy processes and procedures and will add minimal complexity if aligned with usual distributor and pharmacy systems.
2	Each pharmacy executive believes that pharmacies are critical community stakeholders and his or her company has a commitment to participate in a community emergency response.
3	Pharmacy executives believe that the new way of dispensing antivirals during a pandemic will likely meet patient needs.
4	There are a number of potential risks, but few “showstoppers” that would cause pharmacies to not participate with this new method of antiviral distribution and dispensing.
5	Timely information, training, and collaborative planning are needed to ensure this new method operates optimally.

### **THEME 1: Compatibility With Existing Practices**

**The new way of dispensing antivirals during a pandemic is largely compatible with existing pharmacy processes and procedures and will add minimal complexity if aligned with usual distributor and pharmacy systems.**

One of the major reasons the executives voiced their support for this proposed method of antiviral dispensing was the similarity of the proposed method of antiviral distribution and dispensing with established current pharmacy practices. Several executives mentioned that this new method of antiviral distribution aligned



with the methods efficiently used every day by their pharmacies. The executives had numerous comments about this alignment:

***“I think that it leverages the capacity of the pharmacies to different communities and it would be a fast and efficient way of reacting to such a pandemic and being able to provide medication at the right time.”***

***“I think it’s very reflective of how medications are distributed for other reasons throughout the nation anyway so I like the proposed model a lot.”***

***“There’s distribution models that are out there today that are designed to handle just this very problem and logistics are already put into place so you might as well use them.”***

***“I see it as among the most ‘stablest’ ways to get the product to the health care providers [referring to pharmacists] that in my opinion should probably be the ones dispensing it anyway. I see it as a very, very simple solution.”***

***“I think it’s very important to use what we currently have out in the communities, to use the current processes that are out there.”***

***“We really need to utilize the current delivery methods that we have in place because one, they’re efficient and we know that they operate well.”***

***“I would say significant from my standpoint is that it fits within our normal process and we don’t have to create something new. The pharmacists don’t have to think of a new procedure to be able to get the product. It just folds into how operations work day-to-day.”***

***“Yes, it’s totally compatible... It’s compatible because it’s really the service model that we currently have and where we bring in the product from wholesalers or wholesale distributors and do the dispensing for the patient, so that it’s like the service model that we utilize.”***

***“It would not be complex at all. It’s really the way that we conduct business now.”***

***“I’m a strong supporter of having pharmacies serve as the distributor of the antivirals to the public. This is what we do on a daily basis for our patients, so you’re actually putting the responsibility into the right ownership in my opinion.”***

***“I like the fact that it’s coming from [the] normal distribution system, that works well.”***

Every executive mentioned that the new method would work best if it remained consistent with routine, everyday pharmacy functions as much as possible (e.g., receiving medications from their usual distributors, reordering through existing computer systems, filling prescriptions, billing patients the usual way, and counseling patients). By staying consistent with everyday practices, these executives believed that the new method of antiviral distribution would add little complexity to their

operations. The participants emphasized the importance of utilizing and leveraging existing processes:

***“I think it’s very important to use what we currently have out in the communities, to use the current processes that are out there.”***

***“So I see it being something that will fit in the workflow without, you know, hardly any modification at all ... I think this fits in nicely and exactly with ... the role and responsibilities of a pharmacy.”***

***“It’s within normal distribution models so it’s not something that [staff] have to learn.”***

***“Certainly [this method is compatible], just kind of at the fundamental level of receiving our medications from one of the large national wholesalers. We receive daily orders of medications you know, every day before we open so how we would receive [these] medications is consistent with our operations.”***

***“Honestly, truly, it is our normal process ... The great part of putting it through a wholesaler then into a pharmacy is you already have a very well documented process that’s there, plus you have tremendous abilities of record keeping.”***

Several participants mentioned that inventory control, tracking, and reordering would be simplified if current systems were used for this new method:

***“One hundred percent of the drugs that we get into our pharmacy is ordered through [a single large pharmaceutical distributor], you know, one of these large distributors out there and they have order numbers set up, our computer system is constantly monitoring on-hand inventory in the store and as soon as the inventory gets down to a certain level it places an order automatically and the next day in comes the order with the products that the pharmacy needs.”***

***“The pharmacists don’t have to think of a new procedure to be able to get the product. It just folds into how operations work day-to-day.”***

Executives also mentioned that because their companies have an existing infrastructure for dispensing medications, their pharmacies could adapt to an emerging pandemic emergency and ramp up quickly to serve the public.

***“We have the ability to scale up quickly to react to a pandemic like we did for H1N1.”***

***“... the infrastructure [of pharmacies] is better than it is anywhere else in the whole system to support the volume of patients.”***

***“The most significant really is the already-built framework for being in the community. So it really is the fact that we have so many sites, we’re able to process so many people for our buildings. That infrastructure is already stood up. We can react much faster than trying to figure out how to stand something up.”***

In particular, one executive from an independent pharmacy emphasized that smaller, independent pharmacies may be especially nimble during emergencies:

***“And I think our pharmacy would be a good choice and we’d do a good job because we’re accustomed to handling things that are different. We’re able to make policy at the store level. We don’t have to go through any huge rigmarole to adapt and adopt a plan to go with something that happens maybe suddenly and where we have to change our workflow or make adaptations with more help or do something differently. We’re able to do that and our employees are used to taking up a charge and going with something new.”***

The executives mentioned that the new method of antiviral distribution and dispensing (as currently envisioned) is not expected to create a significant number of new processes for pharmacies to handle. These interviewees stated repeatedly that if the new method of antiviral distribution and dispensing aligns with the way their stores usually receive, manage, and dispense medications, their staff would probably not have to learn and adapt to multiple new processes during an emergency, and it shouldn’t add too much complexity:

***“This is why I think this is such a smart move. So I think it removes the complexity, it uses the current processes that are out there in place today to make the most of that.”***

***“It really doesn’t sound complex at all. As I see it, you have the issue of your supply which is coming from your wholesaler which is normal. You have people coming into your pharmacy to fill a prescription which is normal.”***

***“I think it takes a lot of the complexity out of it. I think this is probably the most streamlined approach you could take.”***

## THEME 2: Pharmacies as Critical Community Stakeholders

**Pharmacy executives believe that pharmacies are critical community stakeholders and their company has a commitment to participate in a community emergency response.**

One of the most important findings from this study was the participants' consistent mention of the role of their pharmacies as integral stakeholders in the communities where they are located. Almost every executive stated that his or her company's participation in this new method of antiviral distribution and dispensing during a future influenza pandemic would be a very important role because of the company's established commitment to the community. Note that this response was unsolicited by the principal investigator. Each executive who mentioned this role emphasized its importance. These remarks provided insights into the executives' beliefs that pharmacies are an integral part of the communities where they are located. A few comments from large pharmacy companies emphasize that notion:

*"[We would participate because of our commitment to] the community or the better good, the need. You know, our role in helping solve the problem."*

*"I would tell you our company, first and foremost, has the strong connection to making sure the public is taken care of. We have a very long reputation of being first responders when it comes to emergency response or disaster recovery."*

*"[Our] pharmacies have a relationship with the community. They are members of the community and they already have a relationship with many of the patients, [we are] constituents of that community."*

*"... certainly the biggest advantage I think would be able to service the community, so you can participate in helping the community in a pandemic situation, being able to take care of those patients."*

*"... the store [is a] part of that community, being a resource within that community."*

*"... probably the most important [advantage of participating] ... is the fact that we want to be a good community citizen and a good community partner ... I want us to be a community leader and a good community partner so I think that's probably the biggest win."*

In particular, the executives from independent pharmacies also expressed these views and emphasized their pharmacies' community stakeholder roles:

***"A pharmacy isn't a business that just operates in the community, but it's a business that's part of the community."***

***"I feel that we are morally and ethically bound to assist during a pandemic like this and I think that it would be of benefit to our community if we were to participate."***

These remarks convey an underlying feeling of community responsibility and community connectedness that the executives felt was important to emphasize during the interviews, and that feeling was a strong driver of the acceptability of this proposed antiviral distribution method.

One executive summed up this strong belief of pharmacies as community citizens:

***"So I think it's just what pharmacists are supposed to do is help their neighbors."***

### **THEME 3: Meeting Patient Needs**

**Pharmacy executives believe that the new way of dispensing antivirals during a pandemic will likely meet patient needs.**

Almost all of the pharmacy executives commented about how the new method of antiviral distribution and dispensing would meet their patients'<sup>9</sup> expectations and needs. In particular, several executives believed that this new method would resonate with their company's mission to serve their patients:

***"[This new method would allow us to] serve our current patients in the time of their need. They depend on us and we're there for them."***

***"It fits squarely in our strategy to be a neighborhood health care provider."***

***"And it falls consistent with the company mission, to be able to help people move along the path to a better life. So it's consistent with everything that we do in the business of pharmacy."***

***"I see the advantages in being able to provide services that our constituents require."***

The executives from large pharmacy companies emphasized that they could efficiently serve many people during a pandemic because they have multiple pharmacies located in many communities across the country and already are integrated into those communities:

***“There’s 50,000 plus community pharmacies in the U.S. and they’re in basically every community in America, so you get deep penetration across a broad area very, very quickly.”***

***“Well, the fact that we have so many locations and these pharmacies have a relationship with the community. They are members of the community and they already have a relationship with many of the patients, constituents of that community.”***

***“We have [thousands] of pharmacies and [hundreds] of clinics, so we can reach a lot of people.”***

***“We are in [thousands of] pharmacy locations in [more than half of] states.”***

Several of the executives from large pharmacy companies also stated that in addition to multiple geographic locations in communities of all sizes, their companies also have colocated walk-in medical clinics staffed by nurse practitioners (or physician’s assistants) that could assist in providing access to prescription antiviral medicines in some locations.

Many participants discussed that continuity with current patients would be important during a pandemic emergency and that they would like to be able to serve their existing patients to meet their expectations. One executive explained the point as follows:

***“It’s important that if a patient already has a relationship [with a pharmacy], they need to be able to at least be allowed that opportunity to go get their medicine wherever they’re getting it today.”***

Most executives mentioned that pharmacies would also be convenient for patients and would speed up the process of obtaining antivirals during a pandemic:

***“We could ramp our stores to be open 24 by 7. We have safe, lighted parking, we’re in convenient areas and bus lines and (subway) lines, we are well-known in the community as a safe place to go, and we have the ability to scale up quickly to react to a pandemic like we did for H1N1.”***

***“I think that it leverages the capacity of the pharmacies to different communities, and it would be a fast and efficient way of reacting to such a pandemic and being able to provide medication at the right time.”***

***“I think it provides the broadest, quickest access in the pandemic that could possibly be given.”***

***“... it’s so much more convenient to know that I need to get this antiviral ... and I know that I can just walk into the pharmacy when it’s convenient for me and get the antiviral that I need.”***

***“I think this can probably cut out 24–48 hours of that supply chain process getting it into the ultimate consumer.”***

***“[This method] will actually deliver the medicine to the patient quicker in the event that an outbreak occurs.”***

Pharmacy executives from mass merchant and grocery store companies also mentioned the potential for convenience for their patients because their stores afford “one-stop shopping” during a pandemic:

***“... it’s also a huge benefit that people can get other items, not just for antivirals so they’re not necessarily being forced to go from one site to another site to another site to pick up items. That’s one of the big advantages you get from having retailers involved is you can pick up additional supplies, whether it’s water, food, other medical supplies, clothing. So we have the ability of reaching out much more broadly than just a distribution site of antivirals.”***

All of the executives emphasized that pharmacies are the right place for the public to obtain medications, as pharmacies are designed to expertly perform that function every day, have the trained staff and systems to ensure medication safety, and align with the public’s expectation and experience of getting medications at pharmacies.

Many of the executives emphasized that pharmacies and pharmacists are trusted and recognized by the public, and in particular, pharmacists are known as medication experts. These executives believed that their pharmacies and

pharmacists currently serve as important community health care providers and that their pharmacists should serve in this role of antiviral dispensers during a future pandemic. Several of the executives mentioned that if pharmacies and pharmacists could serve their patients and communities during a pandemic emergency, it would meet their patients' needs and benefit their pharmacies by reinforcing their role as community health care providers:

***"I think pharmacists are the most underutilized health care professional. I think that they would be a great source for assistance in any type of event like that."***

***"But we're certainly in a position to provide health care, we're the most accessible at providing health care ..."***

***"I think what it does for our company is it reinforces with our consumers, our patients each day, that we are a health care provider with them or our profession extends the view of the pharmacist as a primary place to go to receive these services particularly in critical time of need."***

***"I think that we are always looking to have our pharmacists be seen in the light of health care professionals that can provide solutions and we are the medication experts. So putting those in the hands of the pharmacists and our pharmacy teams can expand that professional view and image."***

***"I think it really may help shift the mindset of some consumers that you know, pharmacies and pharmacists just put pills in bottles, whereas under a pandemic, they're actually visiting pharmacies and pharmacists for health care to save their lives."***

A few of the pharmacy executives also mentioned the unique role that pharmacists could play in providing additional access to antivirals for patients during a pandemic, by not requiring them to see a physician for an antiviral prescription. This method, they explained, allows a pharmacist, working under specific written protocols from a physician, to provide patient access to certain prescription medications if the patients' conditions meet the criteria of an authorized protocol. The executives who mentioned this strategy offered it as an added advantage of pharmacists dispensing antivirals during a pandemic, especially if doctors' offices



and emergency rooms are very crowded and people are experiencing delays in seeing a health care provider:

***“I would offer though in the case of a pandemic, I think a process like this should be under protocol so if a patient presents with certain things, there's a protocol where the pharmacist just could dispense to them and we don't need to chase a piece of paper or wait for an electronic something to come. It's going to be a crazy time so we should empower our health care professionals on the frontline to make good decisions and take care of people quickly.”***

***“So in a time of a pandemic or an emergency it's gonna be hard for the patient to actually go see a doctor to get the antiviral. So the question I think we might want to explore is can we do it from a standing order or something like that.”***

#### **THEME 4: Potential Risks**

**There are a number of potential risks, but few “showstoppers” that would cause pharmacies to not participate with this new method of antiviral distribution and dispensing.**

In addition to the possible advantages that may be associated with the new method of antiviral distribution and dispensing, the interviewees identified multiple risks that may result. However, few “showstoppers” were mentioned that would cause these pharmacies to not participate with this method of antiviral distribution and dispensing. Each of these potential risks are summarized in Table 8 and discussed separately below.

**Table 8.** Key Informants’ Views of Potential Risks, Adverse Consequences, or Disadvantages of New Antiviral Distribution and Dispensing Method

Most frequently mentioned	
<ul style="list-style-type: none"> <li>• Adds complexity/risks if markedly deviates from usual pharmacy processes</li> <li>• Uneven/unfair distribution of product among pharmacies</li> <li>• Financial risk /complex billing issues</li> <li>• Potential for disruption in stores / crowd control</li> <li>• Risk of illness for staff/disease transmission</li> </ul>	
Occasionally mentioned	Rarely mentioned
<ul style="list-style-type: none"> <li>• Problems if new method too complex or bureaucratic</li> <li>• Confusion about commercial and government product (same NDC)</li> </ul>	<ul style="list-style-type: none"> <li>• Legal risks</li> <li>• Proposed method deviates from usual processes in a few ways</li> </ul>
“Showstoppers” <sup>a</sup>	
No showstoppers (mentioned by most of the participants)	Likely showstoppers (rarely mentioned)
<ul style="list-style-type: none"> <li>• No issues that would prevent participation</li> </ul>	<ul style="list-style-type: none"> <li>• Unresolved legal risks</li> <li>• No medication available</li> </ul>

<sup>a</sup> The issues that were categorized as “showstoppers” were mentioned as critical issues, that if unresolved, may influence a company to not participate in the new antiviral method during a future pandemic

### Added complexity/risks if new method differs from usual processes

The risk of participating in this new method of antiviral distribution and dispensing that was mentioned most often by all of the executives (from both large and independent pharmacies) was the possibility that the new method of antiviral distribution and dispensing might deviate too much from their usual pharmacy

processes. This was the converse of the issues discussed as part of the description of Theme 1, and has already been described in that section.

Specifically, several executives cautioned that if the new method was too bureaucratic or if pharmacists had to learn to conduct business in a very different way, then it would create problems for the dispensing pharmacist:

***“Our frontline pharmacists [would say] I have a patient in front of me, I need to take care of him, so do whatever you have to do but I need to take care of this patient. They care very much and should care very much and it’s their profession about taking care of the patient. So they don’t want barriers, they don’t want red tape, they don’t want to not hear that they can’t take care of that patient.”***

Several executives from large pharmacy companies noted that the new method as described deviated somewhat from their current operations. A few of these large pharmacies serve as their own distributor—their company purchases (some or many) medications directly from manufacturers and distributes them to their stores using their own logistics and systems. One executive explained the concern:

***“I think the only concern that I’ve got is that large drugstore-only companies don’t really exclusively use these commercially available distributors. They’ll use them as a backup but they warehouse themselves so they have their own warehouses and their own distribution method and system that goes out to all their stores. So I think that would just need to be addressed as a way so that they have equal access to it. But you’re only talking a few chains.”***

An executive from one large pharmacy company that serves as its own distributor for almost all of its medications, questioned if the new method would be efficient for them:

***“So in fact what you’re proposing to us would seem slower than what we could produce if it were just sent to us directly, and in the time of pandemic I would say that would be our preferred way to support such an activity.”***

This executive was concerned that the proposed process may add too many steps and may make it cumbersome for their company because their company does not usually engage with a pharmaceutical distributor. Although the new method did not align with their usual processes, this pharmacy executive mentioned that they could shift to using a distributor for antivirals during a pandemic emergency. This executive and all of the other large pharmacy company executives reported their companies currently have business relationships with one or more large pharmaceutical distributors, so no new business relationships would be needed to participate.

### **Inequity in antiviral distribution among U.S. pharmacies**

Another risk mentioned by almost all interviewees was related to a possible inequity or maldistribution of the antivirals among pharmacy companies. Most participants mentioned that it would be important for all of the pharmacies in the United States to get their “fair share”:

***“So we want our fair share ... How do you make sure that you have equal distribution of a limited distribution product? Undoubtedly there will be shortages and somebody has to make some tough decisions about who gets what and how much they get.”***

***“Things that come to my mind pretty quickly would be fair share distribution. So one of the challenges I think we’re gonna face is when you’re talking about the total retail population, making sure that companies are going to be able to get the right amount of antivirals that they’re going to be able to serve the public for.”***

Executives were especially concerned about the impact that would have on their brand and image if antivirals were not made available to their pharmacy (but were available to their competitor). They were concerned about the potential for an unfair business advantage if not all pharmacies are able to participate. Executives also expressed concerns that relationships with existing patients would be

jeopardized if they were unable to fill a prescription because of uneven availability of supplies.

***“Well, a disruption of supplies would be a risk because patients would be depending on us, not from the government for the medications and that would be a liability to our image.”***

***“The most significant [risk] would be unfair advantages. To us, it would be unfair advantages for competitors because it would harm our image and relationship with our patients.”***

Almost all of the executives also discussed the potential negative impact of a possible antiviral shortage during a future, severe pandemic. However, several executives said that their reputation would be harmed less if there was equitable distribution of antivirals, even if every pharmacy had fewer regimens than they needed because of an overall short supply of the drug. They asked for messaging from the government to explain to the public about any medication shortages so patients would not perceive that it was the “fault” of a pharmacy that did not have sufficient supplies of antivirals. Several executives also mentioned that public messaging would be helpful if the pharmacy had to follow CDC guidelines to provide antivirals only to high risk persons during a shortage:

***“If it were in short supply, I would like to be able to say, these are the guidelines and we have to go by the guidelines. I’d like to have something that was medically sound and based on CDC protocol.”***

Several of the large pharmacy executives were concerned that independent pharmacies may not receive their “fair share”:

***“So making sure that whether it’s an independent pharmacy, whether it’s a big retailer such as XXXX that has [thousands of] stores, so we get the right amount of product going to the right locations. I think that’s going to be one of the biggest challenges that we face.”***

***“[We need to make sure that] none of the different layers that are in the market have the advantage, so that we’re all in the same level playing field with the rest of the pharmacies that provide services to the community, both the large and independent chains ... so that all of them receive products at the same time and that there is sufficient quantities to be able to take care of their needs.”***

Moreover, the independent pharmacy executives were especially concerned that smaller pharmacies that are not part of a chain or other large pharmacy distributor networks might be “left out.” Executives from the independent pharmacies often have different distributors than the larger pharmacies. These executives also had particular concerns about rural pharmacies being able to access antivirals:

***“... It’s a smaller more independent distributor and that’s something that concerns me, you know, if they do this through normal supply chains, are they going to focus on the big [distributors] ... our primary supplier is a small wholesaler. So my concern there would be, would they make sure that entities like that are included in the plan so that [pharmacies like ours] would still be able to have access and be a part of that ... ” I***

***“One of the bigger concerns is not that it would be from participating but it would be from being shut out from participating almost; that we wouldn’t have the opportunity because we have a smaller wholesaler.”***

***“Two thirds of our state is rural; I think that the primary concern about how a wholesaler allocates inventory is among the only real concerns I really had.”***

### **Financial risks / concerns about billing**

Almost all of the interviewed executives expressed some concern about possible financial and billing issues. Although one model of this new method assumes there would be no product costs to pharmacies (because the government has already purchased the product and it would likely be provided free to distributors and then to pharmacies), pharmacies would be allowed to bill a fee for dispensing

the medication as is typical for other prescription medicines (NCPA, 2011a). Some executives mentioned concerns about a financial burden or how they would collect the dispensing fee from patients:

***“It would make it not acceptable if we have to incur [a large amount of] costs that are not a part of our normal structure but I don’t foresee this as having that.”***

***“I mean if [the antiviral] cost us, if we were paying \$100 you can’t [just give it away to everyone] but if what we’re out is our time and effort, sometimes you just have to say that was my good deed for the day. But if that goes on a hundred times a day, then you can’t afford to do it.”***

Patients with third party coverage would probably have some or the entire dispensing fee paid by insurance, while other solutions are still needed (unresolved to date) for those who are uninsured, those who are insured but do not have prescription medication coverage, or those whose pharmacy coverage would be insufficient. Specific financial concerns expressed by a few of the interviewees included a need for clarity on third party billing procedures:

***“We just need to make sure that we get the third party billing piece spelled out.”***

***“... if there’s something in Medicare or Medicaid or some other third party contract that causes an issue with how we would bill for this particular medication, that would be problematic ... particularly if something could [be] a violation of some of our contract as it relates to Medicaid or Medicare.”***

One pharmacy executive recognized these financial issues may be expected and cautioned that his or her company would be willing to “write-off” uncompensated expenses but needed to estimate how large this burden would be:

***“I think there’s going to be just the regular risk of compensation. That has to be there. So while you want to make sure you’re there to help the general public, you have to be able to understand the size of the write-off if there’s going to be a write-off. So if there’s a way of being compensated, making sure that’s ironed out, making sure that we understand it, and making sure that you’re not just overrun with giving away product.”***

Another executive mentioned additional financial concerns about how pharmacies were to account for the government-supplied antiviral drug inventory in their possession:

***“But how does a pharmacy, you know, because we actually all have to adjust the dollar value of our pharmacy like inventory for taxes and things ... And then also in the event of a fire or just any kind of natural disaster or robbery, we also have to properly insure our inventory in case, you know, we use that insurance policy ... how would I make sure my insurance policy covers these drugs that I did not buy?”***

Several executives said that during the 2009 H1N1 pandemic, the concomitant commercial supply of antivirals and SNS/state-provided antivirals in pharmacies caused a great deal of confusion for pharmacists, e.g., which patients should receive the billable commercial product and which patients should be offered the free government-provided product?

***“But if you have inventory coming from one group and inventory coming from a different location from another group, now you’re putting the pharmacist in the middle of a difficult situation with that interaction that happens at store level, and we do not want to do that.”***

***“... how do you determine free goods versus I’m paying for it with a third party insurance, and how do you deal with patients that say, well I heard you had it but you actually don’t, as it relates to product that someone wants to pay for insurance, and how do you handle that patient that comes in with that scenario. In other words, I come in, I have Blue Cross & Blue Shield and I heard you had this medicine but I only have the free product. How do you handle that interaction? I think that’s a risk.”***

A few executives also commented that having both types of antivirals in their pharmacies (that were marked with the same NDC code<sup>10</sup>) in a future pandemic would add complexity for the pharmacy staff as they tracked inventory on both almost-identical products.

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<sup>10</sup>The National Drug Code (NDC) is a unique numeric code that is assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug, and Cosmetic Act. The segments identify the labeler or vendor, the product (within the scope of the labeler), and the trade package of the product (FDA, 2013).



### **Safety risks for pharmacy staff: Crowd control**

Executives expressed concern that there may be safety risks for their pharmacy staff related to two issues: (a) the potential for disruption in stores/crowd control and managing surge of large numbers of patients, and (b) the risk of illness for staff. Almost all of the participants mentioned one of these issues as a potential risk.

A few executives mentioned that large crowds would need to be managed, but the risk of surge is not a new issue to many of the large pharmacy executives; their pharmacies have familiarity with periodic large crowds:

*“... you realize you’re gonna have a certain amount of disruption because you are in operation in an emergency. But for us we have a lot of already built-in processes and plans for how to handle those situations. One of the best examples would be if you take Black Friday. That’s a yearly ongoing basis. ... we have those types of best practices in place already so that we can keep the public safe and out of harm’s way.”*

One pharmacy executive mentioned physical safety concerns if patients become physically threatening to staff if there is a drug shortage:

*“I guess one negative thing about being one of these maybe partner sites for the CDC is if people perceive that we have these items on hand but that for whatever reason we’re not providing it to them.”*

### **Safety risks for pharmacy staff: Risks of illness**

Concerns about protecting the health of the staff and infection control practices that might be needed in pharmacies during a severe pandemic was mentioned as a risk by most of the participants. One executive mentioned that his or her company’s stores may become a gathering place for sick people, which could expose the staff to disease and could also be perceived by the public as a place that they do not want to go:

***“Something to always be considered is you have a general population that you’re now introducing a sick population into so to speak, that antivirals are to prevent, so hopefully we’re on the preventative side, but the truth of the matter is you’re now becoming a destination for essentially sick people walking in your building.”***

***“... people having the perception that you now have the illness or the problem inside your location. So there’s going to be a percentage of the population that will avoid those locations.”***

Several mentioned that they recognized new strategies would be needed to protect their workforce, and they would take measures to protect staff:

***“We still have to maintain a workforce so that’s a challenge to the general workforce inside the company when they think that they’re now introducing a disease inside the building, yet they have to come in and work there. ... it’s the motivation of making sure that our population of team members is still feeling comfortable enough that they can work and being able to give them the adequate reassurances whether it comes in supplies of masks or gloves or things like that that they can still perform their job duties.”***

However, unlike the safety concern of store crowding described above, many of the executives who mentioned this risk stated that they did not currently have a plan to mitigate these risks and would be dependent on CDC and public health to advise them how to reduce these types of risks.

Several executives also mentioned ways to minimize the risk of illness in their stores: ask well family members to pick up prescriptions for ill patients, encourage use of drive-through windows, and provide home delivery, if feasible.

A few executives also mentioned that they were committed to keeping their pharmacy staff protected during a future pandemic. A few voiced concerns about staff not reporting to work if they felt unsafe at the workplace because of exposure to disease during a pandemic. Although the risk of illness in pharmacies was possible during the 2009 H1N1 pandemic, one executive indicated that his or her pharmacy staff stayed on the job:

*“During the 2009 pandemic, we [were concerned that we] may not have staff that wants to come to work because they’re afraid of acquiring the virus or whatever it might be. And overwhelmingly, and again I think this probably speaks a little bit to the type of people that work in health care, we had very few if—I mean I don’t remember hardly any incidents where our pharmacists said, I’m not gonna dispense these products or I’m not gonna—I’m gonna get the blue flu, I’m not gonna come into work until this passes because I’m afraid of getting sick myself. Again, it may have been the fact that H1N1 was milder than future pandemics might be but that would be a concern as well making sure that we had the staff and the resources to accommodate that.”*

## Legal risks

Only a few executives voiced concerns about possible legal risks related to the new method. A particular remark was made about possible product liability risks related to new antivirals that might be used in a future pandemic:

*“... that’s always gonna be one of the concerns, especially if [the drug is] new and don’t have experience and people get kind of nervous, what happens if a whole bunch of people get sick and what if we get sued because we were the providers of that service or that product. So I think it’s always gonna be around that legal liability side of things is where most of the concerns would come from.”*

Although a number of risks were mentioned (see Table 8), few true “showstoppers” were stated by the pharmacy executives. After a discussion of potential risks was concluded, each executive was asked the following question:

**Are any of these risks (you mentioned) “showstoppers”—meaning that if this risk could not be reduced, then your company would not likely participate?**

Most of the executives stated that they could not identify any major issues that would prevent their participation:

***“No, I don’t see any of these as showstoppers. I think that our company has a pretty realistic approach to what’s there and that is one of the better parts of being in retail is we’re used to dealing with adversity on a daily basis and making plans on the fly and counteracting those adversities. So I don’t see any showstoppers to this.”***

***“Not at all. I think what you’re proposing is a great strategic shift in how these items are distributed and actually, I think, really where it should have always been.”***

***“No, I really can’t think of anything that would stop me from participating. All other things being equal I can’t think of anything that would stop us from participating. That sounds like—I don’t see the downside.”***

***“I don’t believe that it would be critical so that we would back off of participating. I think that it would be workable.”***

***“[Even if there were risks] I mean I think we would [participate]—our mission would pull us to participate with those because it’s the right thing to do.”***

One executive cautioned that specific “showstoppers” could not be identified until more details are known about how the new method would work; this executive said his or her company could determine if there was an issue that would prevent their participation once the details are known:

***“I think the best way to do that is to say, lay that out [details of the program] and then come back with here are our questions and concerns around things that would have to be worked through or issues and concerns and be able to answer that. From there, there may be something I would say this would be a make or break and can you solve it or not. I imagine anything can be solved.”***

Although concern with unspecified risks was identified, this pharmacy executive also mentioned support for the new method:

***“Listen, I think at the end what I’m hearing is a very good intent and a very noble intent to try and improve upon something that we’ve found was challenging and needed to have it improved if we are faced with this type of situation. So I’m with you from the perspective of what we did before and saying, boy everyone wanted to do the right thing and there were a lot of barriers in trying to do the right thing.”***

One executive stated definitively that an unresolved legal risk or liability could prevent their participation:

***“... I think that [the showstopper] would be the legal concerns, that if we couldn’t get comfortable with protection against legal concerns, that would be a showstopper.”***

However, this interviewee also offered that legal risks for his or her company could be reduced if there was a plan to “make sure that providers aren’t going to be liable for damages.”

Another executive mentioned that a shortage of medication could be a showstopper:

***“Hold on. Actually, there is a showstopper. If the manufacturer can’t produce to meet the demand.”***

When asked for clarification (Investigator: *So if there’s not enough medications, that’s a showstopper?*), this executive replied:

***“Well, it is. I mean because we really need to think that thing through because sometimes they’re [the manufacturer] just not able to produce it. So really good analysis on the front side about the predictability of the event and being able to kind of help them through that process and almost overdo it with the support and guarantees and the funding to back it up.”***

## **THEME 5: Information, Training, and Planning**

**Timely information, training, and collaborative planning are needed to ensure this new method operates optimally.**

The final theme identified from these executives was about the kind of help or support their pharmacies might need from their company as well as from government (state and/or local public health and the federal government) to plan for and implement this new method of antiviral distribution and dispensing. The executives outlined three areas in which they would need support and information: (a) pre-event training, (b) just-in-time training tools and information for their staff, and (c) a method of receiving timely and accurate information from their local and state health departments and CDC during the event.

Pre-event engagement, mentioned by several executives, focused on their desire to receive pre-event plans and optimally, collaborate with government to plan for this new antiviral distribution method. One executive also mentioned the need to conduct exercises or drills to test the plan:

***“We like to be very well documented and very well planned out. [We want] as much up-front planning information, practice drills, things like that. We like to put our teams through the course of action so that when the time to jump into action is that they’re not really reading it and trying to understand it; this is part of their daily operations. So we’d like to get proactive plans to share, you know, here’s what we do in the event of this emergency, and we do a couple of in-house practices, but it would be great to see some national practices as well.”***

## **Connected and Interrelated Themes**

After reviewing and visually arraying all of the major themes that emerged from this research, it became apparent that several thematic areas overlapped and were related to one another. Figure 6 depicts each of the themes identified, sub-themes, and areas of overlap. In particular, this array depicts the importance that the fewer new processes introduced to current pharmacy processes and practices by a new antiviral distribution and dispensing method, the less the complexity and risk. Conversely, the more the new method deviates from everyday pharmacy processes, the greater the challenges that will arise.



**Figure 6.** Connecting and interrelated themes

## Additional Results

To ascertain the applicability of this potential method of antiviral distribution and dispensing to other public health emergencies, all of the executives were also asked one more question:

**What do you think about pharmacies serving as the primary dispensers of other medical countermeasures (for example, antibiotics) for mass prophylaxis during other types of emergencies, such as an anthrax attack?**

Almost all of the pharmacy executives replied that they would be willing to consider this role for their pharmacies. Several restated that medication dispensing fits squarely in their pharmacies' expertise; their pharmacies are critical parts of a

community emergency response; pharmacists play an important role as health care providers during emergencies; and serving the needs of their patients is a priority:

***“I think we’re a great first choice because, again, we’re in the communities, we’re accessible, we have convenient places for people to go, we can scale, we’ve got locations, again, 24 by 7, it makes a lot of sense, they’re everywhere and everybody knows how to find them. So I would leverage [pharmacies] for whatever first responder program you have because I think we can deliver for you.”***

***“I think from an access perspective I think the pharmacies certainly are a critical point in the distribution channel and they’re the best equipped to handle large volumes, so patients in large volumes of product transactions. So it certainly makes more sense from a health care perspective to utilize the channel that’s out there and that does that today, and the retail channel being a part of that. From a distribution outlet it makes sense. So I think that’s a very logical thing to do.”***

***“Absolutely. I think when it comes to any of those kind of rapid distribution of pharmaceuticals it’s the natural place to go.”***

***“I think pharmacists are the most underutilized health care professional. I think that they would be a great source for assistance in any type of event like that.”***

However, risks similar to those identified for antiviral dispensing (e.g., maldistribution of the medication, drug shortages, crowd control, safety for pharmacy staff, and disruption in stores) were also mentioned. Several executives believed that the urgency related to providing countermeasures during an anthrax attack and increased community-level anxiety would result in more challenges for pharmacies than would be expected during a pandemic:



*"All the responses and things I [said to you before] would be exactly the same. But I only say that because of my experience in 2001 with ... and again, we were clearly not as close to things as people on the East Coast but we certainly experienced some behavior exhibited by groups with respect to kind of the shift in mindset with respect to all of a sudden that drug Cipro did not just become a tool to help people stay well, but it became like some type of like insurance against illness and death, and people's mindset really shifted with respect to that drug. And so, again, the safety related concerns might go up a little bit for pharmacy staff, but beyond that the same types of roles and responsibilities, the same positives and negatives from my perspective, those responses would all be the same."*

*"... the thing that really concerns me a little bit with that, and it's not as much as H1N1 but the level of angst that you can create in a community; there are other issues at play when you have something along those lines, meaning what kind of hysteria may be going on, and what kind of environment you would be ... going on inside of a retail location."*

*"So for instance, you had an anthrax attack in Springfield, Missouri, and you say, well, you can go get "X" at your local pharmacy, CVS, Walgreens, Wal-Mart, Target, whatever. If you really don't have the product flowing in, it can create a situation where you have a lot of—a crowd develop pretty quickly in front of your pharmacy and then you start having your pharmacy, store staff, etc.—kind of putting them in a bad situation."*

*"I believe when you're working with countermeasures because I think it's more time critical, I think you run into more possibilities of security crowd control, traffic control, getting those other groups involved, but then again, legal too. I mean would you have access to city police officers or highway patrol or county sheriffs, how does that all work, because I think that the urgency is a little bit different in some of those circumstances, don't you think?"*

In conclusion, all of the pharmacy executives reacted positively to the new method of antivirals distribution and dispensing and believed that dispensing antivirals during a future pandemic would be a natural fit for their pharmacies. Nonetheless, the participants very clearly pointed out multiple potential risks. Most of the participants offered suggestions to reduce those risks. This pharmacy executive summed it up very well:

*"I think it makes the most logical sense. People go to pharmacies for medication and that part has been happening for decades. So I think when it comes time to react whether it's anthrax, whether it's potassium iodide, whether it's a pandemic, I think the best spot to always tell people to go is the pharmacy. You have an expert back there [pharmacist] in terms of medical knowledge or medicine knowledge, drug knowledge, and this is what they do on a day-in and day-out basis; they dispense products to people to help them in their time of need. So it doesn't really matter to me what the situation is, I'm always a proponent that our pharmacies should be the ones that are dispensing medications."*

## **CHAPTER 5: DISCUSSION AND CONCLUSIONS**

The interviews with pharmacy executives identified five predominant themes that must be considered and/or addressed if pharmacies are to serve as the primary dispensers of antiviral drugs during an influenza pandemic. Overall, the participants were very supportive of this new method of antiviral distribution and dispensing, primarily because the new method was likely to be compatible with day-to-day pharmacy operations and methods and align with the mission of pharmacies.

### **Compatibility With Existing Pharmacy Practices**

The participants identified several advantages to this new method of antiviral distribution and dispensing and repeatedly stated their companies' commitment to serving their patients every day as well as during a public health emergency. Almost all of the executives believed that this new method would improve the way antivirals could be distributed and dispensed (compared with the methods used during the 2009 H1N1 pandemic); provide convenient access to the medication; meet patient needs and expectations (going to a pharmacy to pick up a prescription); afford access to electronic systems that can track and report antivirals dispensed to public health officials; and allow everyday systems to efficiently manage inventories and reorder medication.

Pharmacy executives mentioned that by performing this function during a pandemic, their pharmacies would be able to “lessen the burden on public health.” The literature review conducted for this dissertation research (Chapter 2) identified a number of problems that state public health officials encountered distributing and dispensing antivirals during the 2009 H1N1 pandemic. Several of the state “after-action” reports (AARs) identified a “structural mismatch” between the inherent capabilities of public health and the task of antiviral distribution and dispensing. Some AARs stated that their public health agency did not have the expertise to perform this task.

Moreover, public health departments have experienced state and federal budget cuts and reductions in staff since 2009 and have fewer resources to manage the next pandemic. The profound federal (and state) government economic challenges of 2013 continue to threaten resources available to states for pandemic planning (Schnirring, 2013, January 2).

Public health officials are expert at emergency response functions such as surveillance, epidemiology, command and control, preparedness planning and training, and communications to the public. Those functions are unique to state and local government during a public health emergency and cannot be transferred to a private sector entity for execution. However, pharmacies manage and distribute pharmaceuticals every day and are proficient in this function. There is a possibility, on the basis of findings from this research, that pharmacy companies may be willing to serve as primary dispensers of antivirals during a future pandemic and that the inherent strengths of pharmacies, such as their widespread locations, familiarity and

trust of pharmacists and pharmacies with communities, and expertise with ordering, managing, and dispensing medications, can be leveraged to improve a pandemic response.

### **Pharmacies as Key Community Stakeholders**

One of the most important findings from this research is the strong belief expressed by pharmacy executives regarding the role of pharmacies as community stakeholders. The principal investigator was not surprised, but very gratified, to learn that all participants in the study emphasized (without prompting from the researcher) the role of their pharmacies as key community stakeholders, especially during an emergency response.

Pharmacists have been involved in public health efforts for many years. In addition, pharmacists and pharmacies have previously been integrated into community emergency responses (Hogue, Hogue, Lander, Avent, & Fleenor, 2009), including significant roles assisting communities in natural disasters (Woodard, Bray, Williams, & Terriff, 2010) and providing vaccinations during the 2009 H1N1 pandemic (Koonin et al., 2011; Rosenfeld, Etkind, Grasso, Adams, & Rothholz, 2011). Corporate citizenship benefits both communities and corporations (Center for Corporate Citizenship, 2012).

Although these research findings may not be generalizable to other pharmacy companies, the participants' companies constitute almost one half (approximately 46%) of all U.S. pharmacies. Therefore, these findings may be pivotal for public health officials to know as planning for this new method proceeds. If public health officials can envision an alignment of their agency's emergency response mission to

serve the public with that of pharmacies in their community, then collaboration needed to implement this new method of antiviral distribution and dispensing may be enhanced.

### **Alternative Method of Antiviral Distribution and Dispensing Likely to Meet Patient Needs: Expanding Roles of Pharmacists and Pharmacies**

Almost all of the executives said this new method reinforces the role of the pharmacist as a health care provider and pharmacies' role as an essential part of a community emergency response. A recent report from the Office of the Chief Pharmacist, U.S. Public Health Service, to the U.S. Surgeon General stated that pharmacists are "remarkably underutilized in the U.S. health care delivery system given their level of education, training, and access to the community" (Giberson, Yoder, & Lee, 2011, p. 10).

Over the past decade or more, pharmacists' roles have been expanding to include prevention activities (such as immunizations), laboratory testing, chronic disease medication management, and selected primary care services under protocols and supervision from physicians (Chisholm-Burns et al., 2010; Hogue, Grabenstein, Foster, & Rothholz, 2006; Ross, 2011; Smith, 2012). Pharmacies are becoming an accepted place for people to get vaccinations for influenza; during the 2010–2011 influenza season, approximately 18% of adults of all ages and approximately 24% of adults older than 65 years were vaccinated at a pharmacy (Kennedy et al., 2011). Expanding pharmacists' scope of practice is also being currently discussed in light of national health care reform (Landro, 2012, November 19).

Several executives interviewed for this dissertation research suggested that during a future pandemic, CDC should encourage public health officials to engage with community pharmacists for providing access to prescription medication under written protocol with a physician. The Chief Pharmacist's report mentioned previously reinforces this view by stating that "Pharmacists' formal education appropriately prepares them to successfully perform clinical services related to the prevention and control of disease through medications" (Giberson et al., 2011, p. 12). This practice, known as a collaborative practice agreement (CPA) or a collaborative drug therapy agreement (CDTA), is an "agreement between pharmacists and authorized prescribers (e.g., doctors, physician assistants, nurse practitioners) that allows pharmacists to prescribe, modify, or discontinue medication therapy for a patient, without the patient having to be seen by a physician" (Public Health Practices, 2011, para. 2).

Use of CPA/CDTA strategies suggested by pharmacy executives could be used to improve access to antivirals during a severe pandemic, especially if doctors' offices and clinics are flooded with patients resulting in long waits to see a provider. During the 2009 H1N1 pandemic, a few jurisdictions focused on these approaches to improve antiviral dispensing in case the pandemic severity increased. In particular, Seattle-King County Public Health Department created partnerships with the Northwest Center for Public Health Practice, the Washington State Pharmacy Association, and the Washington State Board of Pharmacy to formulate a CDTA with a number of community pharmacists. They also produced a toolkit that other local health departments can use to develop their own agreements between pharmacists

and physicians (Advanced Practice Centers, 2010; Northwest Center for Public Health Practice, 2013). Currently 44 states have some written mention in their state pharmacy laws and regulations of collaborative practice and/or protocols between physicians and pharmacists (National Association of Boards of Pharmacy, 2010). In 2012, the Institute of Medicine asked members of the public in three communities about how they would react to pharmacists as “prescribers” and found that these participants favored this approach, as they were already familiar with pharmacists performing other clinical tasks, such as administering flu vaccines (Fain, Viswanathan, & Altevogt, 2012).

Pharmacies have other resources that could be leveraged to significantly serve ill persons during a pandemic. Several executives mentioned that their pharmacy companies also have primary care clinics colocated in their pharmacies that could serve ill persons. Many national drugstore chains and several mass-merchant pharmacies have opened their own “walk-in” or “convenient care” clinics, staffed by nurse practitioners or physician’s assistants, that are designed to diagnose and treat minor ailments, offer vaccinations, and prescribe and dispense some medications. As of 2012, there were approximately 1,400 retail clinics in 39 states in the United States, most of them affiliated with pharmacies (Cassell, 2012; Mehrotra & Lave, 2012; Merchant Medicine, 2013). These clinics have experienced rapid growth over the past five years and continue to increase in number. However, new protocols may be needed for these clinics to serve ill persons during a pandemic, including procedures for infection control to protect others in the store setting.

## **Risks Identified by Pharmacy Executives Must be Addressed**

In addition to the potential advantages, pharmacy executives identified multiple, potential risks that may be associated with this new method of antiviral distribution and dispensing. However, few “showstoppers” were mentioned that would cause these pharmacies to not participate with this method of antiviral distribution and dispensing. The risk of participating in this new method of antiviral distribution and dispensing that was mentioned most often by all of the executives was the possibility that the new method might deviate too much from their usual pharmacy processes. If pharmacists and pharmacy companies have to change their usual practices and systems in ways that are very different from usual and add complexity or increased bureaucracy, then delays in execution, difficulty in training staff, and a chance of increased errors can result. This issue closely aligns with the key principles of compatibility and low complexity as enablers for innovation system-fit from the conceptual framework for this research adapted from Greenhalgh, et al. (2004). CDC needs to strongly consider issues of compatibility and complexity with existing pharmacy processes when planning a new method of antiviral distribution and dispensing, even though a pandemic emergency may, unavoidably, present the need for some modification in systems or procedures.

Another risk mentioned by almost all interviewees was the possibility of uneven distribution of antivirals to pharmacy companies. Unequal distribution of a scarce and valued countermeasure during a severe pandemic creates both access problems for sick persons who need to take the drug soon after becoming ill, and risks to the pharmacies and pharmacy companies because they cannot serve their



patients. The executives were more concerned with maldistribution related to CDC selecting only a subset of distributors and pharmacies to receive this drug rather than with an overall drug shortage (where all entities would be affected).

Maldistribution of antivirals in a community (if some pharmacies have the medicine and others do not) may jeopardize the pharmacy's image and brand if they cannot provide the medicine when a patient needs it. Aside from an unavoidable national shortage (where every pharmacy has little of the medication), CDC planners need to develop strategies to maximize widespread and equitable distribution of antivirals to pharmacies if this new method is adopted. Strategies to accomplish this goal may include the Strategic National Stockpile providing antivirals as high up in the distribution chain as possible so that most pharmacies will have access to the drug through their usual customer relationships with manufacturers and distributors.

Almost all of the interviewed executives expressed some concern about possible financial and billing issues. If billing methods are very different from standard practices, this may pose a barrier to implementation. Even though these pharmacy executives had strong allegiance to their communities, some of them expressed limits to the financial burden that their companies would accept. Clearly these issues can present challenges for both pharmacies and patients. Patients with health insurance that includes pharmacy coverage would theoretically have some or all of pharmacy fees offset by their coverage. However, patients who are uninsured may not have another means to pay for the dispensing fees. Dispensing fees vary in the United States; the average co-pay for patients for 75% of all prescriptions was \$10 or less in 2011 but can be as high as \$40 on average for some name-branded

drugs covered by some health plans (IMS Institute for Healthcare Informatics, 2012).

One set of researchers found a link between low socioeconomic status and increased severity of illness during the 2009 H1N1 pandemic, possibly related to delayed care-seeking because of financial barriers (Levy, Nguyen, Westheimer, & Layton, 2013). CDC needs to work with HHS and others to develop a method to reduce financial barriers for patients and pharmacies in any new antiviral distribution method so that the pharmacy dispensing fee is not an impediment to timely receipt of medication for patients.

Key informants identified the risk of illness for staff as a concern if pharmacies serve as primary dispensers of antivirals. This finding was similar to that found when pharmacists were polled regarding a new method, except pharmacists also identified the risk of bringing disease home to family members as a key concern (Appendix B). The executives mentioned that they are confident methods could be devised to protect their staff from getting ill, but stated no specific methods for protecting them. Instead they said they would rely on CDC and public health authorities for infection control recommendations.

Pharmacy executives explained that they could visualize a large number of ill persons congregating in their stores. Several participants stated their concern that ill people may congregate in their stores. During a pandemic, CDC's likely guidance to the public will be that sick people "should stay home and avoid contact with other people except to get medical care," if at all possible (CDC, 2009b, para. 2). Public health officials in the United Kingdom advised, during the 2009 H1N1 pandemic, that ill persons identify a well "flu buddy" (who had the patient's identification details) to

pick up their antivirals at the pharmacy (Boseley, 2009, January 8). The practice of having someone else pick up prescription medicine for a sick person (for most types of medicine) is an established practice in the United States (Privacy of Individually Identifiable Health Information, 2002). However, some ill people will not be able to identify another person to perform this task, and there will likely be ill persons in pharmacies during a pandemic. Several executives mentioned that they had drive-through and walk-up windows in some of their stores that could be used to dispense antivirals to ill persons without the need to enter the pharmacy. Some pharmacies may be able to define separate waiting areas for those who are symptomatic. CDC will need to distribute clear and detailed guidance to pharmacies about specific infection control practices that they may need to use during a severe pandemic to minimize disease transmission.

Despite the risk of disease, several executives mentioned that their pharmacy staff would likely be willing to come to work during a future pandemic. In one study that surveyed health care workers, researchers found that 93% of pharmacists reported that they would be willing and able to come to work during a future pandemic (Stern et al., 2011). An interesting finding was that the most frequently cited strategy that would encourage clinicians (from all disciplines) to report to work was the availability of antiviral drugs for prophylaxis. Pharmacy executives interviewed for this dissertation research did not mention the use of antivirals for prophylaxis of pharmacy staff. However, when pharmacists were asked in the recent Harvard poll “How likely is it that you would come to work for your regular hours for all 12 WEEKS of the outbreak? (Assuming you are not sick

yourself),” 91% responded “very likely” (SteelFisher et al., 2012, slide 48; see also Appendix B). In that same poll, however, many pharmacists were worried about their own exposure to the influenza virus (59%), and almost three quarters (71%) of pharmacists were concerned about the risk of carrying the influenza virus back to their families. CDC should consider what it would recommend to protect pharmacists and pharmacy staff if this new method of antiviral distribution and dispensing is used.

Pharmacy executives also identified potential legal issues that might place their pharmacies at risk. Fortunately, the Public Readiness Emergency Preparedness (PREP) Act affords protection to reduce liability and legal risks to dispensing pharmacies. A PREP Act declaration is issued by the Secretary of the U.S. Department of Health and Human Services in response to a public health emergency like an influenza pandemic. This Act provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures.<sup>11</sup> For both planning and responding to a future pandemic, it will be important that HHS communicate the availability of protection through the PREP Act to private sector entities that engage in antiviral distribution and dispensing.

### **Research Findings Indicate That Some Challenges Experienced During the 2009 H1N1 Pandemic Could be Reduced**

On the basis of the findings from pharmacy executive interviews, a new method of antiviral distribution and dispensing may be able to resolve a number of

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<sup>11</sup>See section 319F-3 of the Public Health Service Act (42 U.S.C. § 247d-6d)

the problems encountered during the 2009 H1N1 pandemic (Table 9).

Improvements such as faster drug distribution, reducing burden on public health, improving visibility and tracking antivirals, minimization of medication shortages, and reduction of other challenges could lead to an improved emergency response.

**Table 9.** Potential for New Method of Antiviral (AV) Distribution and Dispensing to Solve or Reduce Key Antiviral Distribution and Dispensing Problems Encountered During the 2009 H1N1 Pandemic

<b>Key AV dispensing problems faced during the 2009 H1N1 pandemic<sup>a</sup></b>	<b>On the basis of key informant interviews, could the new method of AV distribution and dispensing solve or reduce the problem?</b>
Tracking AVs	<b>Yes.</b> The system used today by pharmaceutical distributors and pharmacies will be likely able to capture almost real-time data about inventory and antivirals regimens dispensed. Receipt of this information could be negotiated with manufacturers and distributors as part of the new method of distribution and dispensing to assure that federal, state and local public health authorities can monitor antiviral inventories and dispensing.
State & local health department storage/dispensing issues and state & local health department staffing problems to manage antivirals	<b>Yes.</b> This new method minimizes the burden on public health for antiviral distribution and dispensing and will reduce the number of antivirals that state and local health departments have to manage. Also, fewer public health staff will be needed to manage antivirals for this new method.
Lack of visibility of commercial supply chain	<b>Yes.</b> The system used today by pharmaceutical distributors and pharmacies will be able to provide data regarding inventory of commercial supplies of antivirals. This reporting could be negotiated with distributors as part of the new method of distribution and dispensing.
Legal concerns about transporting antivirals and providing antivirals from state health departments to pharmacies <sup>b</sup>	<b>Likely.</b> States will not be tasked with distributing antivirals to pharmacies. Under the new system, pharmacies will receive antivirals as they usually do, from distributors and/or through their company warehouses.

<b>Key AV dispensing problems faced during the 2009 H1N1 pandemic<sup>a</sup></b>	<b>On the basis of key informant interviews, could the new method of AV distribution and dispensing solve or reduce the problem?</b>
Pandemic scenario used for planning did not match that experienced during actual 2009 H1N1 response	<b>Uncertain.</b> Current planning needs to be flexible for a variety of future pandemic scenarios.
Shortage of some types of AVs and “spot” shortages in some locations	<b>Uncertain.</b> The new system is likely to minimize shortages as it will run on a reliable supply/demand model that has been used for years by pharmacies and distributors. However, this new method cannot prevent shortages of antivirals from government stockpiles.
Communications between state and local health departments about logistics of antiviral stockpile delivery and distribution plans	<b>Uncertain.</b> Clear communication about antiviral deliveries between different levels of public health may not be affected by a new method of distribution and dispensing, but this new method minimizes the load on public health for antiviral distribution and dispensing and may reduce the number of antivirals that state and local health departments have to manage.
Delays in treatment of ill persons related to availability of medication	<b>Uncertain.</b> This method may improve availability of antivirals but delays in treatment due to unavailability of the medication could arise.
Lack of clear communication between state and local health departments and between public health and dispensing partners about protocols for antiviral use	<b>No.</b> Clear communication about antiviral use between different levels of public health may not be affected by a new method of distribution and dispensing.
Unclear/changing federal guidance about use of AVs	<b>No.</b> Changing Federal guidance is likely in the next pandemic as key information will not be known when decisions for deploying antivirals need to be made.

*Note.* AV = antiviral

<sup>a</sup>These are the challenges that emerged from the literature review conducted for this dissertation; please see Chapter 2, Table 4. <sup>b</sup>Four states required local health departments to obtain distributor licenses to transport antivirals during the 2009 H1N1 pandemic, and two states had concerns or potential legal issues that slowed distribution to pharmacies.

## **Limitations of Methods and Findings**

There are potential limitations related to the methods employed and the findings derived from this research. Experts in qualitative research caution that the methods used for ensuring validity and reliability for quantitative research do not apply to qualitative research (Creswell, 2009). In alignment with the principles of qualitative research, participants for this study were purposefully selected from a list of the largest U.S. pharmacy companies and from a list of independent pharmacies (Creswell, 2009). These executives were intentionally invited to participate because their views were judged to be the best in addressing the research question.

Qualitative research is not designed to be representative of a larger population, and generalizability is not typically a goal of qualitative research, as every case is thought to be unique. The unique views of these particular executives from large companies were sought for this research because participation of their pharmacies would likely be needed to implement this new method. Experts advise that interviewees should have “a variety of perspectives” and “should be experienced and knowledgeable” in the interview content area (Rubin & Rubin, 2005, pp. 67, 64). However, the reader will appreciate that the views of these participants may differ from those of other pharmacy executives in other companies.

Additionally, the number of participants for this study was small (n=9). The data collected from the participants nevertheless reached “saturation” on all areas of inquiry (e.g., no further new concepts or ideas were emerging), and there were few differences between the perspectives of pharmacy executives from large companies and those of independent pharmacies (Creswell, 2007). As previously mentioned,

the participants' companies constitute almost one half (approximately 46%) of all U.S. pharmacies.

The principal researcher took several steps to ensure that consistent interviewing, data collection, and analytic approaches were used. First, the investigator printed out an interview guide to use for each interview and was consistent in the wording for each question posed to the participants. After the data were collected, the researcher created notes for each interview. Both Gibbs (2007) and Yin (2003) describe procedures to enhance "qualitative reliability," including (a) reviewing transcripts for errors (this was accomplished after listening to the audio recording of each interview and ensuring that the written transcript documented the interview verbatim), and (b) ensuring consistency in coding each transcript (this was accomplished by developing and adhering to a colored text coding scheme and by iteratively comparing coded data for all transcripts on each key issue to ensure consistency). To assure the reader that the researcher interpreted the findings correctly (and to add richness to the summary of findings), numerous direct quotations were used in the Results section of this dissertation to provide the reader with the participants' actual responses.

Credibility ("believability") of the findings was enhanced by triangulation (Creswell, 2009; Rubin & Rubin, 2005); that is, the information given by the interviewees was assumed to be truthful because the findings of this research closely aligned with the findings of similar work (with different participants) on the same topic (SteelFisher et al., 2012, unpublished findings from the HSPH pharmacist's poll). Angen (2000) describes validation of qualitative findings as a



“judgment of the trustworthiness” (p. 387) of the research, meaning the veracity of the findings can be enhanced by careful consideration and articulation of the research question, by carrying out inquiry in a respectful manner, and by having a dialogue of the findings with participants. The principal researcher often repeated statements the participants made and summarized key findings provided by each participant to make sure that what was heard by the researcher was what was meant by the participant. Finally, the researcher understood that qualitative research relies on the researcher’s ability to listen carefully to the participant’s perspectives—to be able to capture their views, feelings, and perceptions—rather than “...imposing the researcher’s views that might distort the ideas of the participants” (Holloway & Wheeler, 2010, p. 6).

Other authors describe the importance of “self-reflection” as a key method of qualitative research validation (Creswell, 2007, 2009; Rubin & Rubin, 2005; Saldaña, 2009). In qualitative research, the meaning that results from interaction with participants is derived through the lens of the researcher; therefore, explication of researcher bias concerning how interpretation of findings may influence the results is needed.

Admittedly, the principal researcher has a vested interest in the outcome of this study, as it is part of her work portfolio at CDC. In addition, the investigator had met and previously worked with five of the nine participants (all of these were from large pharmacy companies). Therefore, most of the participants knew the researcher, and this familiarity could have affected their responses. The researcher took precautions to curb her feelings and interests during the interviews, specifically

telling participants that she did not know if this new method would be acceptable or eventually implemented, and she diligently let participants talk without “coaching” their answers. The researcher reported the research findings honestly (without consciously inserting the researcher’s opinion) to minimize bias. However, there is always a possibility that the investigator subconsciously inserted findings that were not expressed, misinterpreted what the executives said, and/or used incorrect coding to analyze and interpret the data.

In defense of using a qualitative approach, one of the most important findings from this research (i.e., the overwhelming view of pharmacies as community stakeholders) could not have been predicted in advance of these interviews and may not have emerged if a quantitative design had been employed. Qualitative research is founded on the “emic perspective,” that is, a focus on learning about a participant’s perspectives in how they see the world and the notion that participants can best describe their perceptions, attitudes, and beliefs in their own words (Harris, 1976). Through use of a qualitative approach, the “voice” of these influential pharmacy executives was heard and their views recorded so that their concerns can be meaningfully considered as the research findings inform future planning and implementation of a new method of antiviral distribution and dispensing.

There may also be limitations regarding the data collected from the participants. First, the executives may not have been candid about their opinions. They may have said what they thought the researcher wanted to hear instead of their true feelings. Although the participants could not see the researcher’s facial expressions and body language in these telephone interviews, the researcher

carefully modulated her tone of voice and reactions to the executives' statements to encourage the participants to fully share their perspectives. Second, the participants may have not fully disclosed their views of the possible risks with this new method of antiviral distribution and dispensing, leaving out critical information that would be needed by planners. Third, there may be a difference between what the executives say they will do in the interview and future actions they may take. Finally, the views of these executives may not accurately reflect decisions that other leaders in their companies may take during a future pandemic, and therefore, may not reflect the ultimate decisions that their companies will make for participation in this new method of antiviral distribution and dispensing during a pandemic.

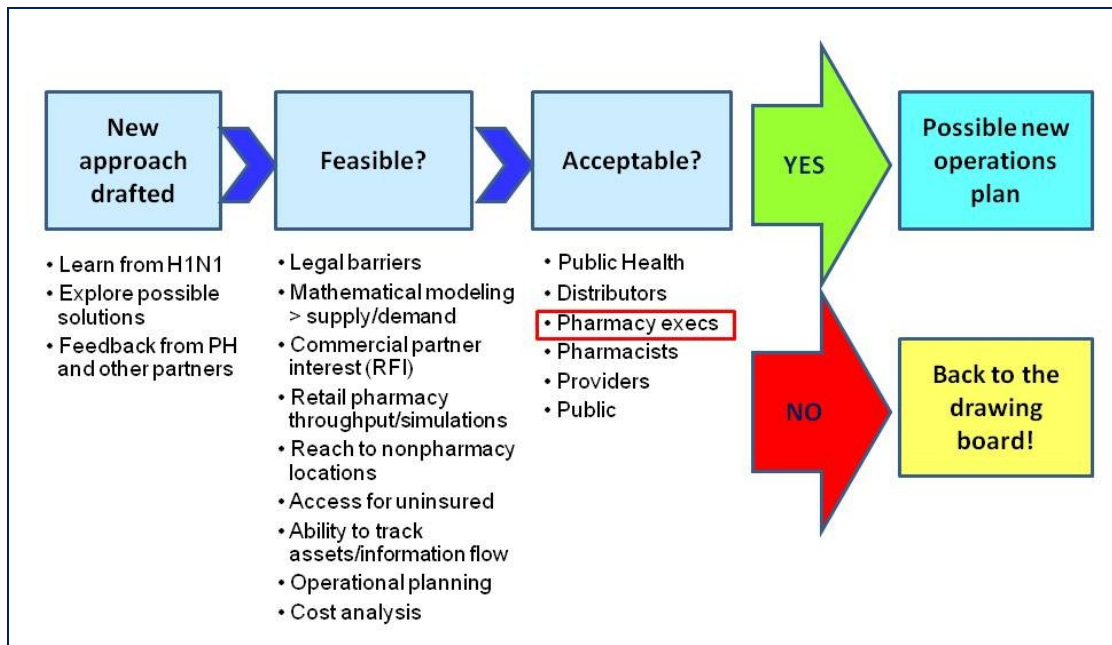
## **CHAPTER 6: IMPLICATIONS OF FINDINGS AND PLAN FOR CHANGE**

No one can predict when the next influenza pandemic will occur. However, a future pandemic, particularly a severe one, would likely affect most populations in the United States and around the world, and many people could become ill and die. Fortunately, there is no influenza pandemic anywhere in the world at the time of the writing of this dissertation. As federal emergency planners, CDC and HHS have the opportunity and obligation now to look back to the 2009 H1N1 pandemic, identify problems and issues with the response, develop solutions to improve future responses, and take actions to do so. Rapid and efficient distribution and dispensing of antiviral drugs to ill people will be a critical component of a future pandemic response. According to a recently published report by HHS, “challenges associated with antiviral drug utilization, allocation, and dispensing” (DHHS, 2012, p. 19) were noted during the 2009 H1N1 pandemic, as well as the inability to monitor the distribution, inventory, and utilization of these drugs. Therefore, HHS has identified improving the distribution and dispensing of antiviral drugs as a priority for CDC action (DHHS, 2012).<sup>12</sup>

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<sup>12</sup>The broad concept for an improved antiviral distribution and dispensing model met the December 2012 timeframe included in the HHS document for this task. However, HHS has extended the deadline for the overall project to June 2013 to allow for development of an operational plan.

This dissertation research is part of a larger effort started by CDC in 2011 to assess the acceptability and feasibility of a new antiviral distribution and dispensing approach (see Appendix A for a timeline and list of project activities). As part of her job responsibilities at CDC, the researcher initiated this project and serves as the co-lead for this effort. CDC and HHS leaders are aware of this dissertation research, and the findings will be used to inform operational planning that will begin in early 2013. The needs and priorities articulated by the pharmacy executives will be carefully considered; at the same time, the needs and priorities articulated by state and local public health authorities, pharmacists, and the public (ascertained through separate investigations) will also be incorporated into an action plan. This chapter describes the next steps toward the development of an operations plan. If that proposed antiviral distribution and dispensing plan is found to be acceptable and feasible by CDC/HHS leaders, then it will be vetted for adoption in summer /early fall, 2013 (Figure 7).



**Figure 7.** Change in pandemic antiviral distribution and dispensing operations will be dependent on acceptability and feasibility of this new approach.

## Potential Impact of Research Findings

The findings from this research have immediate potential utility to influence U.S. government pandemic preparedness operations (and perhaps changes in policy) in three ways:

First, these dissertation findings will influence a redesign of the method of SNS antiviral distribution and dispensing for the nation during a future pandemic. The new method will include a larger role for pharmacies as primary dispensers of antivirals. Some SNS antivirals will also be sent to state health departments during a future pandemic, but it is probable that far fewer antiviral regimens will be sent to public health locations compared to distributors and pharmacies.

Second, a redesign of the way antivirals are distributed and dispensed may reduce the burden on public health and reduce some of the challenges faced by public health officials during the 2009 H1N1 pandemic (see Table 9). It is likely that ongoing state and local budget cuts and ongoing economic challenges will continue to constrain public health department resources and staff. If pharmacies can serve as primary dispensers of antivirals, state and local public health may have less strain on their resources during a pandemic response, and this method may be more effective in ensuring that the population has timely access to these medicines.

Third, this new method of antiviral distribution and dispensing may inform models for countermeasure distribution and dispensing for other public health emergencies (e.g., an anthrax attack). If this new approach is deemed to be acceptable and feasible, then it could be considered by CDC as a model for other public health emergencies that require the targeted treatment of ill persons. However, further research and exploration would be needed to assess if this method would be suitable for other public health emergencies that require mass prophylaxis of a large proportion of a community.

### **Next Steps: Plan for Change**

A number of steps must be undertaken to create a new method of antiviral distribution and dispensing, incorporating this dissertation's research findings into the process. First, several information gaps need to be filled. Second, several options for the new model will be developed. These options will be carefully evaluated for feasibility and acceptability, and the pros and cons of each approach will be identified. Ongoing discussions with state and local health departments need

to continue as options are explored. Each model will also be examined for needed policy changes, if that model is adopted. Finally, an operational plan will be developed by a CDC cross-functional team for stakeholder vetting and CDC/HHS leadership approval. Leadership principles and strategies for change will be employed to optimize the work of this team toward bringing about an acceptable and feasible operational plan and stakeholder engagement plan.

### **Filling Information Gaps**

Findings from this dissertation research suggest at least three areas for further study that will be needed (within a short period of time) to inform development of an operational plan. First, to ensure that the voices of independent pharmacies are well understood; further discussions with executives of these less-networked and/or smaller pharmacies may be warranted. Although the views of executives from large and independent pharmacy companies gathered in this dissertation research were closely aligned, other executives from independent pharmacies in other parts of the country may have different views of a new method. Because independent pharmacies represent a substantial proportion of U.S. community pharmacies and in some states, are the predominant type of pharmacy, their voices need to be heard to inform planning (NCPA, 2012). This can be accomplished by communicating with key executives (and members) of organizations that represent independent pharmacies.

Second, more information is needed from pharmaceutical distributors and antiviral manufacturers regarding their views of potential new methods of antiviral distribution and dispensing. Although CDC released a Request for Information (RFI)



to pharmaceutical distributors in summer of 2011 to gather their feedback on this idea (CDC, 2011a), and several positive responses were received, no further discussions with pharmaceutical distributors have taken place since that time. Moreover, CDC has not yet engaged with antiviral manufacturers about potential models for a new method and would benefit from their views.

Finally, a cost analysis should be conducted to compare the government's costs related to the current plans for pandemic antiviral distribution and dispensing with any new method. The direct and indirect costs and any potential cost-savings and efficiencies gained from a new model will likely influence decisions made about adopting a new process in this era of governmental cost constraints.

All three of these further investigations to fill information gaps will be incorporated into an action plan going forward (Table 10, p. 134).

### **Exploring Options for a New Method of Antiviral Dispensing and Distribution**

Before an operational plan can be developed, decisions must be made and approved by CDC leadership regarding which model to pursue. Two concepts have emerged for a new antiviral distribution and dispensing method. Information given to the participants during the interviews included that there would be no costs to the pharmacy for antivirals, based on the working concept of the new method at the time of the interviews (April – June, 2012). To summarize this method, SNS-stockpiled antivirals would be provided to a selected number of distributors (the method for determining which distributors has not been developed), who would then distribute to their usual pharmacy customers by their usual methods (see Figure 2). If this model is used, there is a risk that smaller, independent pharmacies may not be included in

the distribution scheme. Since over half of independent pharmacies are located in rural areas, these communities may be underserved if only distributors that serve large pharmacies are selected for inclusion (NCPA, 2012). Because the antivirals have already been purchased by the federal government, there would be no charge for the product to pharmaceutical distributors, and they could not charge pharmacies for the medicine. Likewise, pharmacies would not charge patients who had a prescription for the drug. However, pharmacies could charge a usual dispensing fee (that will probably be capped at some benchmark level). If patients have insurance or other third party coverage for prescription drugs, then the dispensing fee could be (theoretically) billed to that entity.

However, after data from the pharmacy executives were collected, in November 2012, another concept was proposed for exploration. This model includes SNS providing antivirals directly to the antiviral manufacturers, similar to the way the U.S. government's Strategic Petroleum Reserve (SPR) operates (DOE, 2012). As background, the SPR was established in the aftermath of the 1973–1974 Arab oil embargo and serves as an emergency response tool for the U.S. government to ensure the availability of oil and gas in the United States in the event of disruptions in commercial petroleum supplies. During a shortfall in commercial petroleum supplies, the U.S. president or the secretary of the Department of Energy can authorize "loans" from the SPR to commercial firms experiencing shortages. After the event that created the shortfall has resolved, these companies repay SPR for the loan by providing replacement petroleum that is of a similar quality to that

which was loaned, along with additional barrels of oil (paid in lieu of interest), within a specified time.

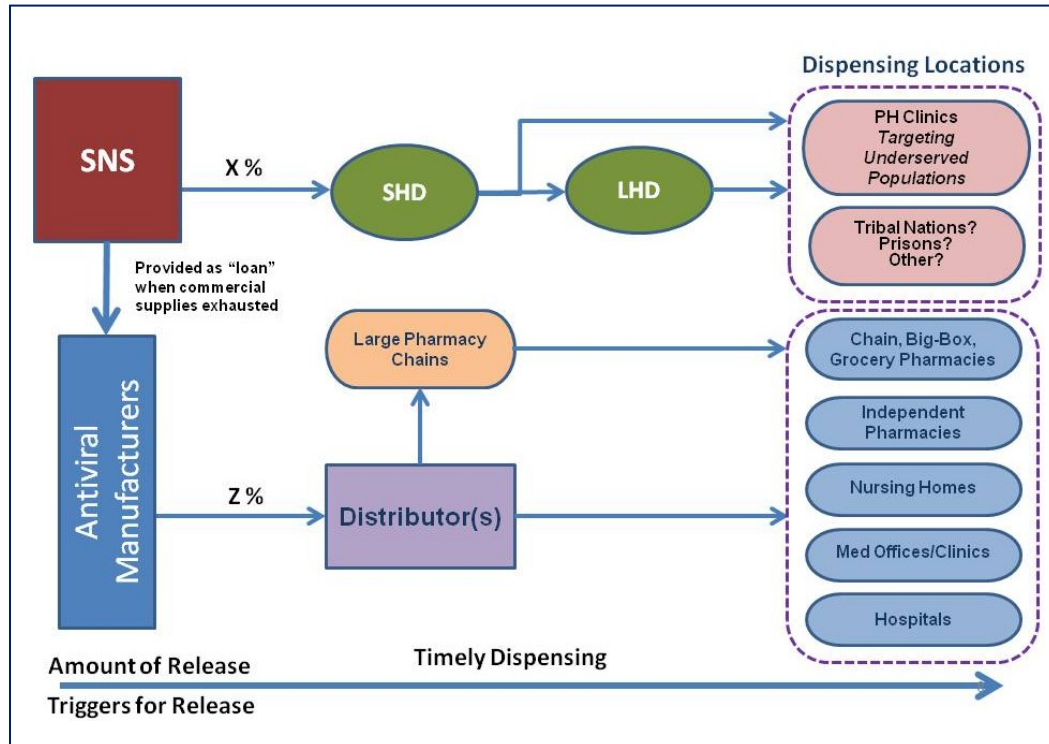
As previously stated, antiviral medicines are seldom used during the regular influenza seasons; hence, large quantities of these drugs are not routinely available in pharmaceutical supply chains or in pharmacies. During the 2009 H1N1 pandemic, commercial supplies of adult dosage antivirals remained available throughout the year-long outbreak and were never exhausted. However, during a future pandemic that is more severe than the 2009 pandemic (as severe as the 1957 pandemic, or worse), it is probable that the commercial supply of antivirals would be exhausted very quickly, and that stockpiled antivirals would be needed to treat ill persons.

Analogous to the way the SPR operates, under a pandemic scenario, SNS antivirals would be “loaned” to manufacturers (whose supplies of antivirals are exhausted or are likely to be depleted within a short period of time) who in turn, would sell those antivirals to distributors that are their usual customers (and perhaps to new distributor customers as well).<sup>13</sup> These distributors would in turn, sell the antivirals to their usual pharmacy customers, and patients would purchase the medication at pharmacies the same way that they obtain other prescription medicines. Patients would then pay a product cost as well as a dispensing fee to the pharmacy. Patients with health insurance that includes pharmacy coverage would theoretically have some or all of these fees offset by third party coverage.

Figure 8 illustrates how this “strategic stockpile” concept might work.

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<sup>13</sup>Theoretically the antiviral manufacturers would then replace the “loaned” antivirals back to the SNS at some future point in time along with an additional quantity of antivirals that would serve as interest.



**Figure 8.** Strategic Petroleum Reserve concept applied to SNS-stockpiled antivirals for a new method of antiviral distribution and dispensing during an influenza pandemic.

This alternative concept merits further exploration for feasibility and acceptability for CDC and affected stakeholders, particularly with state and local public health. It replicates the usual way that pharmaceutical products are distributed and dispensed every day in the United States. Therefore, this new concept may resonate with pharmacy executives, as it could resolve the three top risks identified by interviewees. The process (a) would not add complexity, as it won't deviate from usual pharmacy processes; (b) would not limit the number of pharmacies that receive antivirals (and thus may minimize the potential for uneven/unfair distribution of product among pharmacies); and (c) would involve no

new billing processes, as patient billing would be identical to that of everyday pharmacy practice. It will be important to engage pharmacy executives to learn their views about this model if it is considered for a new method of antiviral distribution and dispensing,

Notwithstanding the alignment of the SPR model with usual pharmacy practices and the possible reduction of risks for pharmacy companies, it has the potential for creating a significant risk for patients. This model would entail charging patients both a fee for the antiviral<sup>14</sup> and a pharmacy dispensing fee, which could create a barrier for some ill or indigent persons. Although more people will be covered under some form of health insurance in the near future through the implementation of the Affordable Care Act in 2014, it is unknown at this time how much of the population will remain without insurance for medications (Congressional Budget Office, 2012). In conformity with ethical guidelines specifically developed for a pandemic influenza response by CDC's Ethics Subcommittee of the Advisory Committee to the Director (Kinlaw, Barrett, & Levine, 2009), the distribution of goods during a pandemic should be conducted in a way that is fair, refrains from harming or injuring people and communities, and ensures equal opportunity to access the resources (within specified at-risk groups if needed). Distribution should *not* follow the principle "to each according to purchasing power" (Kinlaw et al., 2009, p. S189). It will be crucial to discuss these concepts with state and local public health colleagues to solicit their input, suggestions and concerns. Ongoing work by CDC, informed by its partners and stakeholders, is needed to define the best model and to

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<sup>14</sup>In 2013, the retail costs for oseltamivir are over \$100 per regimen, and the retail costs for zanamivir range from \$60 to \$70 per inhaler. Source: <http://www.goodrx.com/>

explore how to minimize cost barriers for those who are uninsured or underinsured. The findings from this dissertation research will inform the assessment of these models.

### **Potential Implications for Policy Change**

Although a new method of antiviral distribution and dispensing (if adopted) would be a change in operations for CDC and state/local public health officials, it is still uncertain if it will create the need for a change in HHS/CDC's pandemic preparedness and response policies. Policy changes that may be needed include approval to utilize SNS stockpiled antivirals as a "strategic reserve" for manufacturers during a pandemic, as the SNS product would be bought and sold on the marketplace. Currently, CDC states on its website that "the medicine in the SNS is FREE for everyone" (CDC, 2012, para. 2). It is unknown if this type of policy change would be acceptable and feasible. In addition, the statute that authorizes SNS must be examined to see if this method would be allowable (Federal-State Cooperation, 2009).

Another policy change could be required if this new method necessitates a different way of antiviral allocation to the states. At this time, SNS assets are simultaneously allocated to states on the basis of population size (i.e., pro rata). It is unknown if a new method of antiviral distribution and dispensing would require a different allocation model. Policy changes of these types would require senior level CDC, HHS, and interagency approval.

## **Plan for Change: Developing an Operational Plan**

To establish a new method of antiviral distribution and dispensing during a future pandemic, a detailed operational plan is needed. After that plan is developed, it will go through an approval process by CDC and HHS leadership. After a final model is approved, a number of strategies must be brought to bear to make a change in national, state, and local antiviral distribution and dispensing pandemic plans. CDC leaders are aware that the process of change must be carefully planned and deliberately executed to optimize the chances for success.

### **Leadership Principles**

A number of leadership principles must be employed for the successful development and implementation of an operational plan for a new method of antiviral distribution and dispensing. The National Public Health Leadership Network's "Public Health Leadership Competency Framework" (Wright et al., 2000) outlines several competencies that will be needed by CDC leaders as they endeavor to promulgate a new method of antiviral distribution and dispensing (including skills in team leadership, negotiation, marketing and education, and the use of ethical influence to bring about change).

The immediate next step in this effort is to assemble a cross-functional CDC project team to take these dissertation research findings (and the results of other project exploratory efforts) and create a path forward. The team will comprise representatives from several offices at CDC and will be tasked with creating an operational plan for a new method of pandemic antiviral distribution and dispensing. This cross-functional project team will be assembled for a specific, time-limited

purpose (Cohen & Bailey, 1997) and will “require the efforts of multiple leaders” (Yukl, 2010, p. 345). Although the researcher will co-lead this team, she will not have direct line authority over the members. Therefore, the team members’ usual leaders will also need to be engaged to reinforce the process of the team. In addition, the researcher will “...seek to influence and activate change well above and beyond established lines of [her formal role in] decision-making and control” (Marcus, Ashkenazi, Dorn, & Henderson, 2007, p. 3) and use principles of “meta-leadership” to ensure team functionality and productivity (Marcus et al., 2007; Marcus, Dorn, Ashkenazi, Henderson, & McNulty, 2012). Because altering the way that the SNS operates regarding the distribution and dispensing of antivirals is a pivotal change, the principles of “transformational leadership” will also be needed to accomplish this goal. As Bass and Avolio (1994) explain, a transformational leader offers followers something more than just working for self gain; he or she provides followers with an inspiring mission and vision, encourages them to see their work from a new perspective, and motivates followers to look beyond their self-interests and focus on the goals and priorities of the group. This theory is applicable, as the CDC team that will develop the operational plan will be selected from several offices at CDC, each with its own priorities and work style.

Finally, several leadership strategies for optimizing cross-functional teams as articulated by Barry (1991) and Yukl (2010) will need to be employed, namely envisioning, organizing, social integrating, and external spanning.

**Envisioning** entails articulating a vision for the team’s work that will inspire team members’ commitment. Most of the team members are aware of the problems



encountered during the 2009 H1N1 pandemic and have some “skin in the game” (as part of their ongoing job duties) to improving the process. The researcher and the team co-lead (who is the direct supervisor of several team members) will need to engage team members in a participatory goal-setting process and create an environment to allow “safe” discussion of assumptions and mental models, and promote brainstorming and dialogue so that innovative ideas can emerge (Sagie, 1996). In particular, details of the two models under exploration need to be fleshed out and presented to CDC leadership for approval before an operational plan can be developed.

**Organizing** the team’s schedule and function will need to occur in rapid fashion. Because of the short time frame for producing an operational plan, the leaders should use a highly directive team leadership style and incorporate a participative-focused approach to maximize team productivity and minimize conflicts between team member values (Klein, Knight, Ziegert, Lim, & Saltz, 2011).

The team leaders will use a facilitating approach to ensure that team members are **socially integrated**. The co-leads for this team will need to encourage mutual trust, open communication, and team cohesion. As the “personality” of the group emerges, the leaders may need to use a flexible approach and shift leadership behavior to align accordingly (Barry, 1991).

Finally, an **external spanning approach** will be critical to ensure that the team’s decisions and processes are compatible with that of external stakeholders. Although CDC (with concurrence from HHS) has both the legitimate power and authority (Yukl, 2010) to make these changes in SNS operations and pandemic

policy, it would be unwise to unilaterally change the method of antiviral distribution and dispensing without incorporating the feedback and participation from key stakeholders.

### **Stakeholder Engagement**

The principles of stakeholder engagement serve as a critical underpinning for this dissertation research. Identifying and including participation from “key players, power brokers, and stakeholders” will be essential to the successful implementation of a new antiviral distribution and dispensing process (Kotter, 1995; Wright et al., 2000). Establishing public/private partnerships at all levels (local, state, and national) will likely enhance a future pandemic response (Paige et al., 2010). Stakeholders’ beliefs, values, perceptions, needs, trust of the change agent, and motivation for action will meaningfully influence the outcome of a change process that directly affects them (Straker, 2010). In alignment with these leadership and change theory principles, CDC planners have engaged multiple stakeholders from the beginning of this exploratory effort to ensure widespread support, particularly with state and local public health organizations and their members (Kotter, 1995). Because the new method envisions pharmacies serving as the predominant frontline dispensers of antivirals during a pandemic, this dissertation research focused on the views of pharmacy executives. However, additional stakeholder feedback and buy-in are also critical for success. Public health officials and key public health organizations such as ASTHO and NACCHO play pivotal roles in pandemic response, and they and their members (state and local public health authorities) will be affected by a change in the method of distributing and dispensing antivirals.

Therefore, they have been involved as collaborators with CDC in the exploration of this new method from the beginning of the effort and have provided ongoing input and feedback on the pros and cons of new approaches. Pharmacist and pharmacy company support for a new method are paramount to the success of this effort. Discussions with state boards of pharmacy will be needed as part of planning as well. These and other stakeholders will be affected by a change in the way that antivirals are distributed and dispensed during a pandemic, and their overlapping and sometimes conflicting needs must be considered as a change in operations is evaluated.

### **Principles of Change**

Although Kotter's work (1995) refers largely to organizational change, his advice that change is a "process" and not a singular outcome, is relevant to changes in important multi-stakeholder operations. Leadership principles must be used along with change strategies, as Kotter advises "change, by definition, requires creating a new system, which in turn always demands leadership" (p. 60). The next steps for this process are outlined in Table 10 and are guided by applicable principles from leadership theories, (primarily from the Public Health Leadership Competency Framework developed by the National Public Health Leadership Network [Wright et al., 2000]) and change strategies (primarily from Kotter, 1995).

**Table 10.** Developing a New Method of Antiviral Distribution and Dispensing During an Influenza Pandemic: Plan for Change and Action Steps Informed by Selected Leadership Principles and Kotter's Steps for Leading Change

Kotter's <sup>a</sup> steps for leading change	Applicable principles from leadership theories	Action steps for proposed change in pandemic antiviral distribution and dispensing	Timeframe for action
<b>Establish a sense of urgency</b>	<p>Literature review findings of problems during 2009 H1N1 pandemic</p> <p>HHS 2009 H1N1 Influenza Improvement Plan.</p> <p>Interorganizational collaborating mechanisms (Wright et al., 2000)</p>	<ul style="list-style-type: none"> <li>• Engage senior leaders at CDC as project champions to share the urgency of creating a new antiviral distribution and dispensing model (per HHS tasking).</li> <li>• Ensure that key CDC leaders in operational divisions are committed to exploring a new method of antiviral distribution and dispensing.</li> <li>• Provide multiple opportunities for external stakeholder engagement in identification of the problem and need for solutions.</li> <li>• Conduct multiple activities to explore the feasibility and acceptability of using pharmacies as primary dispensers of antivirals during a pandemic (including this dissertation research).</li> </ul>	<b>DONE (April 2011 to present)</b>
<b>Form a powerful guiding coalition</b>	<p>Network Theory (Granovetter, 1973)</p> <p>Empower "central connectors" that can provide support to key concepts of planning with critical internal stakeholders (Cross &amp; Prusak, 2002)</p>	<ul style="list-style-type: none"> <li>• Rapidly establish a multidisciplinary CDC operational development team.</li> <li>• Select team members with content expertise, experience with formulating and executing operational plans, who have connections to plan influencers, and who will directly be responsible for execution of the plan.</li> </ul>	<p><b>1st Quarter, 2013</b></p> <p>CDC team will be identified, assembled, and will explore the feasibility, acceptability, and pros and cons of potential new models.</p>

Kotter's <sup>a</sup> steps for leading change	Applicable principles from leadership theories	Action steps for proposed change in pandemic antiviral distribution and dispensing	Timeframe for action
	<p>Team building competencies (Wright et al., 2000)</p> <p>Yukl's principles of leading a functional team (2010)</p> <p>Meta-leadership principle of "extending one's influence and accomplishment beyond one's formal bounds of authority to create productive connectivity." (Marcus et al., 2007)</p>	<ul style="list-style-type: none"> <li>• Ensure responsive, connected, and proactive team leadership.</li> <li>• Establish defined team goals, processes, and milestones.</li> <li>• Immediately explore the pros and cons of potential new antiviral distribution and dispensing models.</li> <li>• CDC leaders will delegate authority to team to work across the organization.</li> <li>• In collaboration with ASTHO and NACCHO, continue to discuss key issues with public health officials and provide periodic input and feedback to team outputs.</li> <li>• Continue to engage other key stakeholders.</li> <li>• Provide updates of team accomplishments and milestones to CDC leadership</li> </ul>	<p>CDC will engage stakeholders that have not yet provided extensive input in a discussion of operational plan options to assess feasibility of execution (e.g., state boards of pharmacy, pharmacy distributors, and antiviral manufacturers).</p> <p>CDC will engage pharmacy partners in discussions of feasibility of various options under consideration.</p> <p>CDC will discuss team progress and key findings with ASTHO and NACCHO.</p>
<b>Creating a vision (creating a strategy)</b>	<p>Sense of mission (Wright et al., 2000)</p> <p>Visionary leadership (Wright et al., 2000)</p>	<ul style="list-style-type: none"> <li>• Alternative models/options for a new method of antiviral dispensing and distribution will be identified.</li> <li>• Models developed for consideration going forward will balance the needs of key stakeholders.</li> <li>• CDC leadership will determine best model for which to build an operational plan.</li> <li>• Operational plan development aligns with the vision and goals set for the process.</li> </ul>	<p><b>2nd Quarter, 2013</b></p> <p>CDC team will explore the advantages, risks, and barriers of models under investigation; ascertain resources needed for implementation of each method; complete a cost analysis; identify any relevant policy changes that may be associated with each model; and share the findings with CDC leaders.</p>

Kotter's <sup>a</sup> steps for leading change	Applicable principles from leadership theories	Action steps for proposed change in pandemic antiviral distribution and dispensing	Timeframe for action
<b>Communicating the vision</b>	Effective change agent (Wright et al., 2000)	<ul style="list-style-type: none"> <li>Continued stakeholder engagement.</li> <li>Provide updates of team accomplishments and milestones to CDC leadership.</li> </ul>	<p>CDC team will make its recommendation to CDC leaders regarding the best approach for a new method of antiviral distribution and dispensing, and a decision about which model to pursue will be made.</p>
	Communicate effectively to translate mission and vision into action (Wright et al., 2000)	<ul style="list-style-type: none"> <li>Continued and iterative stakeholder engagement will enable CDC to “tell the story” and articulate rationale for new approach including a thorough discussion of the pros and cons.</li> <li>Use multiple strategies to “get the word out”.</li> <li>Key clinical influencers (such as ASTHO, NACCHO, and pharmacy organizations) will be briefed and will be asked to communicate their endorsement of this strategy to their members.</li> </ul>	<p><b>3rd Quarter, 2013</b></p> <p>CDC will brief other HHS and interagency leaders to engender their support for this new approach.</p> <p>CDC will brief ASTHO, NACCHO, and pharmacy organization partners and their members about new model of antiviral dispensing and distribution through the use of face-to-face meetings, webinars, conference calls, and conference presentations.</p>
Leading cross-agency connectivity/meta-leadership principle of strategically and intentionally devising cross-silo linkages (Marcus et al., 2007)			

Kotter's <sup>a</sup> steps for leading change	Applicable principles from leadership theories	Action steps for proposed change in pandemic antiviral distribution and dispensing	Timeframe for action
<b>Empowering others to act on the vision</b>	<p>Use principles of social marketing and incentives (Wright et al., 2000)</p> <p>Encourage nontraditional ideas, activities, and actions for implementation (Kotter, 1995)</p>	<ul style="list-style-type: none"> <li>• CDC leaders will attempt to reduce obstacles for change including identifying perverse or unintended outcomes that may result from this new antiviral distribution and dispensing strategy.</li> <li>• Stakeholders will be encouraged to contribute “best practices” in developing pandemic plans that incorporate this new approach.</li> </ul>	<p><b>3rd Quarter, 2013</b></p> <p>CDC will develop new recommendations for state and local public health departments as they adapt their pandemic plans to the new approach.</p> <p>ASTHO, NACCHO, and pharmacy organizations will communicate with members their support for this approach and provide tools for use in adopting this new model.</p>
<b>Plan for and create short-term wins</b>	<p>Understanding of organizational dynamics (Wright et al., 2000)</p> <p>Recognize and reward actions towards implementation (Kotter, 1995)</p>	<ul style="list-style-type: none"> <li>• CDC leaders will develop relevant incentives to encourage uptake for this new strategy.</li> <li>• CDC leaders will be open to midcourse corrections if needed.</li> <li>• CDC, in collaboration with ASTHO and NACCHO, will provide templates for tabletop exercises using the new approach.</li> </ul>	<p><b>4th Quarter, 2013</b></p> <p>CDC will develop incentives for state and local public health agencies to develop tabletop exercises that incorporate this new approach.</p> <p>CDC will work with ASTHO and NACCHO as they develop “just-in-time” training modules for the new approach.</p>

Kotter's <sup>a</sup> steps for leading change	Applicable principles from leadership theories	Action steps for proposed change in pandemic antiviral distribution and dispensing	Timeframe for action
<b>Consolidate improvements and produce more change</b>	Sustaining change (Goodfellow, 1985)	<ul style="list-style-type: none"> <li>• CDC leaders will continue to engage stakeholders and use change strategies to reinforce this new approach and ensure its adoption at all levels.</li> <li>• CDC leaders will plan for resistance and develop strategies to overcome resistance</li> <li>• CDC leaders will fully incorporate this new approach in CDC pandemic preparedness plans</li> </ul>	<p><b>1st Quarter, 2014</b></p> <p>CDC will incorporate this new approach in CDC's pandemic "operational plan" and include this method in its internal full-scale pandemic exercises to be held in March 2014.</p>
<b>Institutionalize new approaches</b>	Articulating connections between new approach and planning going forward (Kotter, 1995)	<ul style="list-style-type: none"> <li>• CDC will expect that this new antiviral approach will be incorporated into state pandemic plans.</li> </ul>	<p><b>2nd Quarter, 2014</b></p> <p>CDC will fully institute this new method of antivirals distribution and dispensing into guidance to state and local public health agencies and will monitor the uptake in this strategy.</p>

<sup>a</sup> Kotter's steps for leading change are found in "Leading Change: Why Transformation Efforts Fail," by J. P. Kotter, 1995, Harvard Business Review Onpoint, pp. 1–10.



## **Resources Needed**

Certainly personnel, and probably financial resources, will be needed to both develop and execute a new method of antiviral distribution and dispensing. CDC staff time will be needed to develop an operational plan, vet it with stakeholders, and present it to CDC leadership for decision-making. Once decisions have been made for the model to pursue, a dedicated workforce in several offices at CDC will need to work together to integrate the new plan into CDC's and state and local public health pandemic planning. It is uncertain if any monetary resources will be needed in the short-term to support engagement with commercial partners. Discussions with pharmaceutical distributors and antiviral manufacturers can explore how much, if any, additional financial resources would be needed at the time of a pandemic to facilitate the operations of this new method. In addition, just-in-time funds may be needed during a future pandemic to support this effort and should be incorporated into ongoing planning.

## **Evaluation of the Plan for Change**

As part of the development of the operational plan for a new method of antiviral distribution and dispensing, an evaluation plan will be created that can measure whether milestones have been reached in the development process of the operational plan. Acceptability and feasibility remain as key components for evaluation. This may be accomplished by reengaging stakeholders, conducting exercises or simulations to test plans, executing contractual arrangements with commercial entities, and resolving key outstanding issues, such as methods of

financing the new method and assuring that financial barriers to the public are reduced.

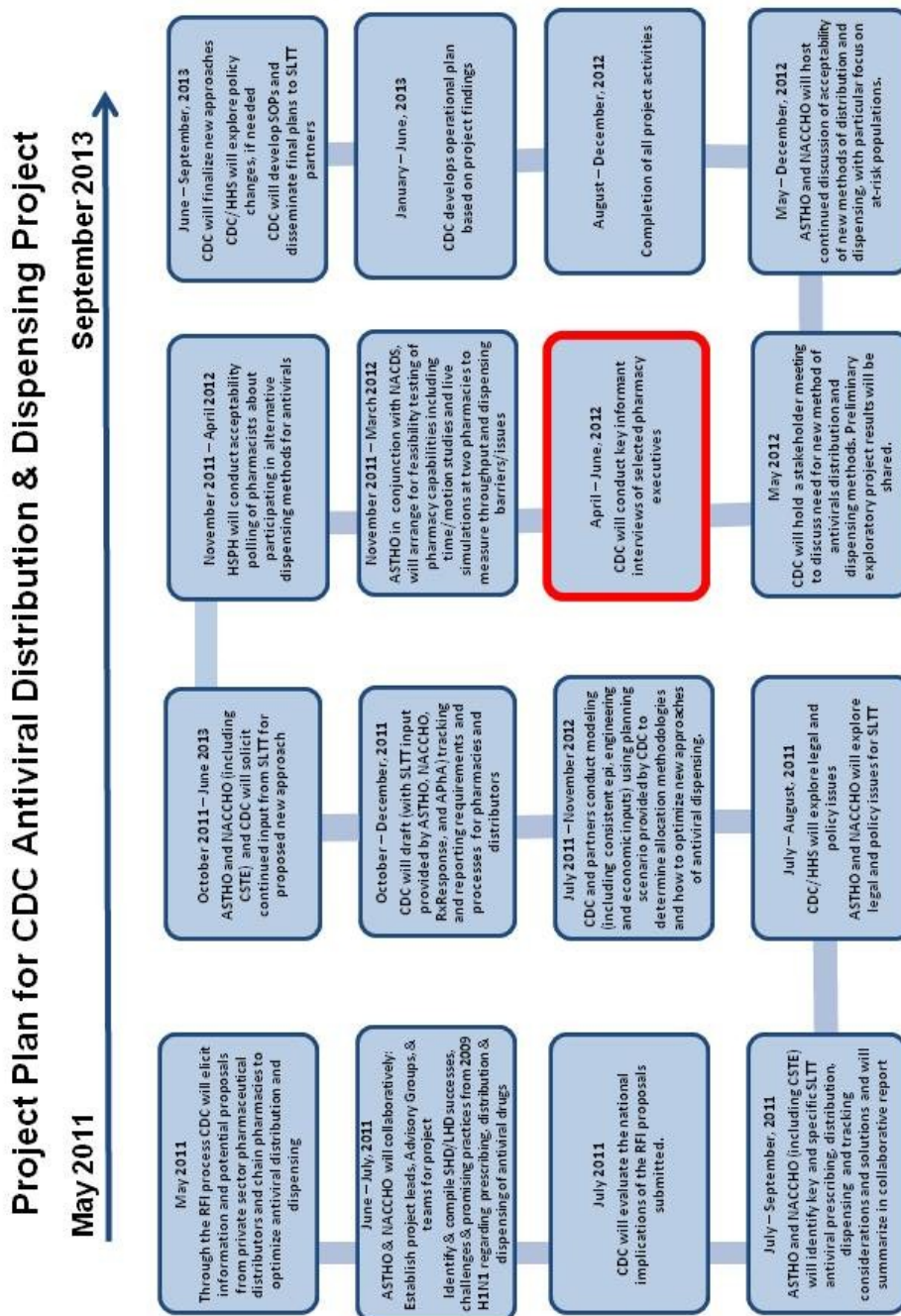
Ultimately, a plan will need to be developed to measure the effectiveness of this model during a future pandemic. The list of challenges experienced during the 2009 H1N1 pandemic can serve as a basis for this evaluation plan, e.g., does the new method reduce these challenges? An evaluation of any potential negative impacts and/or unintended consequences should also be undertaken.

## **Final Thoughts**

A future severe influenza pandemic will present challenges to public health officials in many ways. One priority will be to ensure that ill people receive needed antiviral medicines in a timely fashion. The favorable reactions to and key information about the advantages and risks of using pharmacies as the primary dispensers of antivirals from pharmacy executives in this dissertation research are promising and can inform national pandemic planning efforts going forward.

To ensure that the views and discoveries from this research will inform planning for a new method of antiviral distribution and dispensing, the findings of this study must be shared and understood by all the relevant stakeholders. Therefore, in addition to co-leading the CDC team that will develop a plan of action, the researcher will endeavor to work closely with key stakeholders to engage them in continued discussions about a new method of antiviral distribution and dispensing. By leveraging the skills, systems, and willingness of pharmacies to collaborate in a pandemic response effort, public health may realize improved emergency response capability and better population health outcomes.

# APPENDIX A: CDC Antiviral Distribution and Dispensing Project



# **APPENDIX B: Harvard School of Public Health Pharmacists Poll Results**

## **THE VOICE OF PHARMACISTS: A POLL ABOUT ALTERNATIVE METHODS FOR ANTIVIRAL DISTRIBUTION DURING A PANDEMIC INFLUENZA**

Gillian K. SteelFisher, Robert J. Blendon and Amanda S. Brulé  
Harvard Opinion Research Program, Harvard School of Public Health

### **Executive Summary**

#### ***Background and Methods***

The aim of this study was to assess acceptability among pharmacists in regard to an alternative method for antiviral distribution during a pandemic influenza. In this alternative method, the government would distribute a sizable share of stockpile antivirals to pharmaceutical distributors in order that retail pharmacies could dispense them to the public. In the description of this alternative method, pharmacists were told that the antivirals would be in unit-of-dose packaging and pharmacies would be able to charge a dispensing fee, though the medication itself would be free to the public. Pharmacists were also assured that “depending on the severity of the pandemic, measures will be recommended to protect you and pharmacy staff from the virus that will reduce the chance you will get ill and thereby reduce the chance you will infect others.” The poll addressed three areas of acceptability including: 1) pharmacists’ overall assessment of the idea, 2) their predictions about participation, and 3) possible barriers to and facilitators of participation based on their own perceptions and experience as well as on the characteristics of the pharmacies in which they work.

Through a cooperative agreement with the National Public Health Information Coalition (NPHIC) and the Centers for Disease Control and Prevention (CDC), researchers at the Harvard School of Public Health conducted the poll among a nationally-representative sample of 1,076 community pharmacists between February 24 and April 23, 2012. All of the participating pharmacists currently dispense medications directly to customers in at least one pharmacy, and work in a traditional chain drug store, a supermarket-based pharmacy, a mass-merchandise or large “big-box” store-based pharmacy or an independent pharmacy (stand-alone or chain). The margin of error for total respondents is +/- 3.00% at the 95% confidence level. This poll was conducted for the Harvard School of Public Health using an online and mail approach (mailed to home addresses) by SSRS/ICR, an independent research company.

## **Key Take-Aways**

Among community pharmacists, there is widespread appeal of the idea of the alternative delivery system as described and a willingness to participate in the case of a pandemic. These factors are supported by pharmacists' high predictions of their pharmacies' participation; their own experience with aspects of the process, such as compounding medications; and their comfort with challenging aspects of the process, like focusing dispensing on high-risk populations during antiviral shortages.

Nonetheless, pharmacists did have worries about the alternative delivery mechanism that could pose challenges for operations. These include worries about antiviral shortages or bringing the virus back to their family. Further, pharmacists have concerns about their pharmacies' abilities to dispense prescriptions at the levels needed in a pandemic, and they note structural limits to their pharmacies' abilities to provide for features like home delivery. Finally, relatively few pharmacists had experience with the administrative and operational structures that might facilitate the alternative delivery system, such as collaborative practice agreements and recent contact with state or local public health agencies.

## **Key Findings**

*Overall receptivity.* Overall, pharmacists were highly receptive to this alternative mode of antiviral distribution as described. The vast majority thought it was a good idea generally (85%) and a good thing for the pharmacist profession (84%). Nearly all agreed it would strengthen the role of pharmacists during a pandemic (96%) and their relationships with patients (93%). More than three-quarters agreed it would strengthen relationships with their local public health department, their state public health department and physicians (84%, 78% and 76% respectively).

*Participation predictions.* Predictions about participation were also high. Most pharmacists predicted that they would personally participate in the effort if their own pharmacy were involved (81%), and 91% thought they would come to work for all 12 weeks of an outbreak, as long as they weren't sick themselves. Nearly three-quarters (79%) thought it would be likely that they would come for additional shifts at routine pay in order to help address the likely increase in prescription volume. That fraction rose to 91% if those who initially declined were offered higher wages or comp time for those shifts.

*Possible personal facilitators.* Most pharmacists (79%) were comfortable with what might be considered a more challenging aspect of dispensing in an outbreak - distributing antivirals to high-risk groups (as defined by the CDC) in the case of a shortage, though only 39% were "very comfortable". Further, many had compounding experiences in the last 5 years that might support the idea of their participation; more than three-quarters (78%) had compounded medications for children or adults with swallowing problems or special dosing needs.

*Possible pharmacy facilitators.* Pharmacists' predictions about their own participation were supported by relatively high predictions about their pharmacies' reactions. Most (82%) thought

their own pharmacy would participate in such an effort, though 16% did not know whether they would.

*Possible personal barriers.* Despite overall support for the idea, sizable shares of pharmacists said they had worries about the alternative delivery mechanism. More than three-quarters said they were worried about a shortage of the antiviral (81%) and the risk of carrying the influenza virus back to their family (71%). Most were worried about their own exposure to the influenza virus (59%), managing their usual patients under these circumstances (59%), keeping order in the pharmacy (58%), and their personal legal liability (57%).

Further, relatively few pharmacists had recent experience with the administrative and operational structures that might facilitate the alternative delivery system. For example, about a third (37%) had experience with a collaborative practice agreement and a quarter had any contact with their local or state health department in the past year.

*Possible pharmacy barriers.* Pharmacists did have some concerns about the pharmacies' abilities to meet the need for higher dispensing volumes. More than a quarter (27%) thought their own pharmacy could not handle a prescription increase of 20% for 12 weeks, while much greater fractions did not think their pharmacies could handle a 50% or 100% surge for 2 weeks (53% and 72% respectively).

A sizable share of pharmacists identified structural limitations at the pharmacy level that could pose challenges for operations in a pandemic flu if they were not addressed up front. For example, only 35% of pharmacists have full access to the Internet while they work, which could impinge on their access to needed government-based websites, though this feature might be able to be changed relatively easily at the pharmacies of an additional 31% who have restricted access to the Internet. Further, only a third (34%) thought the pharmacy would be able to deliver prescriptions to people's homes, including 8% who said their pharmacy does not normally do this but would be willing to in a pandemic.

## APPENDIX C: Literature Search Strategy

Search topic	Search terms
<i>All searches were limited to English language, publication dates of 04/01/2009 through 1/31/2013, antiviral distribution and dispensing activities in the United States only, and the following:</i>	
Antiviral medicines	Antiviral OR antivirals, OR oseltamivir (MeSH term) OR zanamivir (MeSH term) OR Tamiflu OR Relenza
	AND
Federal, state, or local health	public Public health [MeSH term] OR local public health OR state public health OR federal public health
	AND
2009 H1N1 pandemic	H1N1 OR pandemic (MeSH term)
<i>Other search terms used with above</i>	
Dispensing	Dispense OR dispensing (all fields) OR distribution
Delay in treatment	Delay in treatment OR treatment delay
Program evaluation	Program evaluation OR ("program"[all fields] AND "evaluation"[all fields]) OR "program evaluation"[all fields] OR evaluation OR performance evaluation
Shortage of antivirals	Shortage OR "inadequate supply"
After-action report	"After action" report
Antiviral treatment	Treatment
Disaster planning	Disaster planning/methods
Strategic National Stockpile	Strategic national stockpile OR SNS

## APPENDIX D: Conceptual Model Adapted From Greenhalgh et al., With Relevant Section Highlighted

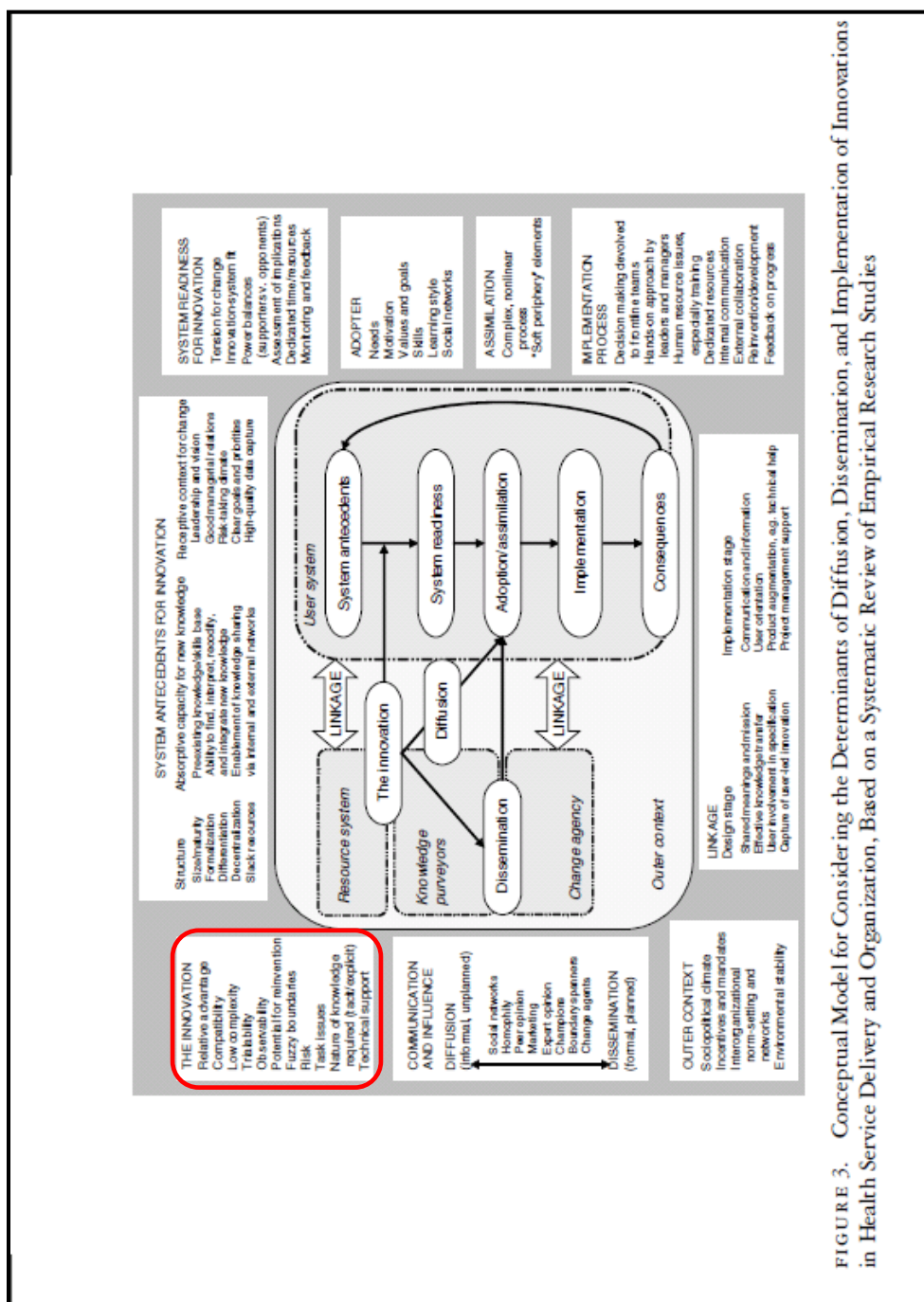


FIGURE 3. Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organization, Based on a Systematic Review of Empirical Research Studies

From "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations," by T. Greenhalgh, G. Robert, F. Macfarlane, P. Bate, & O. Kyriakidou, 2004, *The Milbank Quarterly*, 82(4), p. 595. Copyright 2004 by Wiley-Blackwell. Reprinted with permission.



## APPENDIX E: IRB Exemptions

CDC approves IRB exemption February 8, 2012



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Centers for Disease Control  
and Prevention (CDC)

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### Memorandum

**Date** February 8, 2012

**From** Barbara R. DeCausey, MPH, MBA  
Chief, Human Research Protection Office

**Subject** HRPO Exemption Determination for Protocol #6258.0, "Acceptability of Pharmacies Serving as Primary Dispensers of Antiviral Drugs during a Pandemic: Pharmacy Executives' Perspectives"

**To** Lisa M. Koonin, MN, MPH  
OID/ICU

On behalf of the CDC Human Research Protection Office (HRPO), I have reviewed the request to exempt protocol #6258.0, "Acceptability of Pharmacies Serving as Primary Dispensers of Antiviral Drugs during a Pandemic: Pharmacy Executives' Perspectives" and find that this research activity is exempt under 45 CFR 46.101(b)(2). This determination is valid for a period of three years through **02/07/2015**. However, we strongly encourage investigators to close out exempt protocols as soon as CDC staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

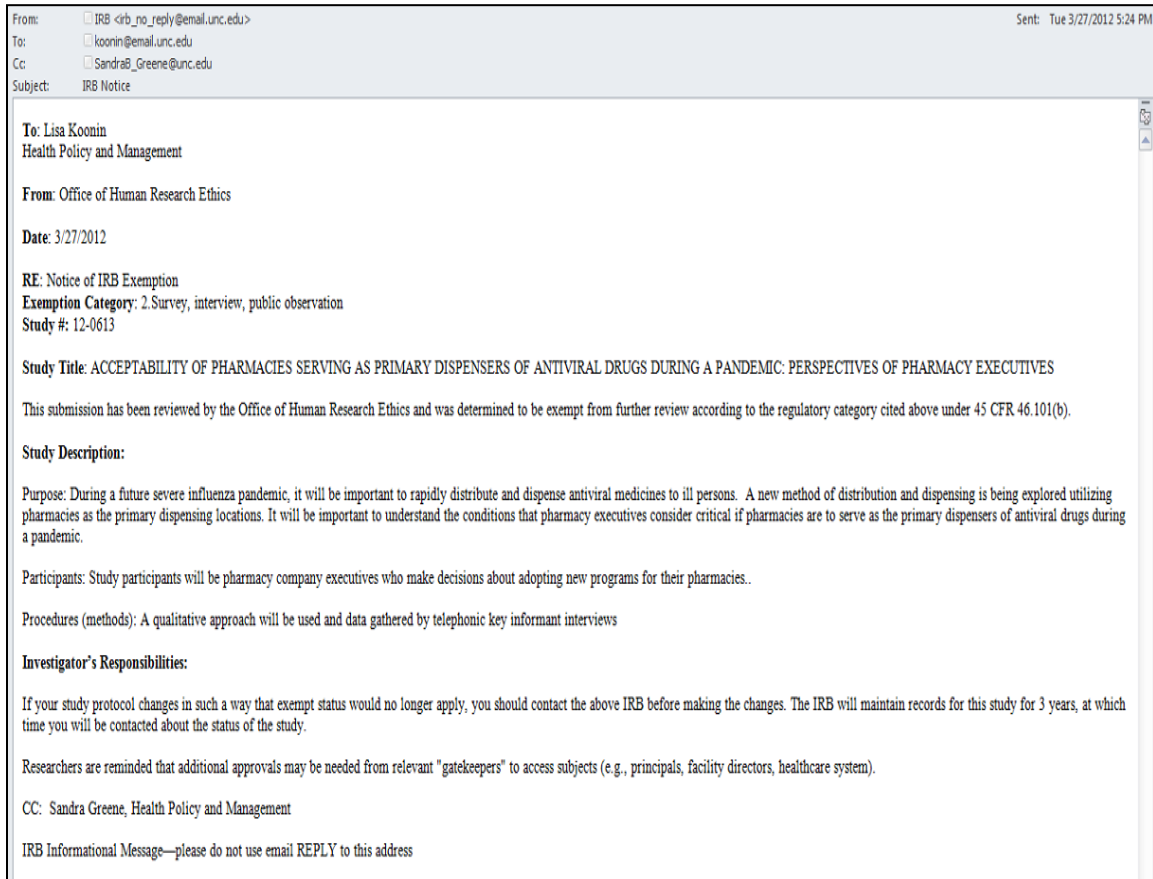
Please be aware that changes to this protocol may not be implemented until they are reviewed by HRPO and determined to be consistent with the exemption categories. You will be reminded in three years (if the study has not been completed and closed) to submit another request for continuation and to confirm that no changes have been made to the protocol or the related science that would affect the ethical appropriateness of the research or this exemption determination.

Please also be advised that investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact your Division Associate Director for Science, your National Center Human Subjects Contact, or HRPO at [huma@cdc.gov](mailto:huma@cdc.gov), or by telephone at 404-639-7570.

cc:  
Sonja Rasmussen

## UNC approves IRB exemption March 27, 2012



## APPENDIX F: Confirmation of CITI Training



THE UNIVERSITY  
of NORTH CAROLINA  
at CHAPEL HILL

104 Airport Drive Suite 2200, CB 1350  
Chapel Hill, NC 27599-1350  
Phone: (919) 966-3411  
Fax: (919) 962-5011 or (919) 962-3352

October 9, 2011

To Whom It May Concern:

In accordance with the National Institutes of Health (NIH) notices OD-00-039 of August 25, 2000 and OD-01-061 of September 5, 2001, The University of North Carolina at Chapel Hill submits the following information concerning the education in the protection of human research participants undertaken by the key personnel involved with this project. The following persons have been trained in the ethical and regulatory requirements for protection of human research participants in compliance with NIH requirements and The University of North Carolina at Chapel Hill "Policy on Education and Certification of Investigators Involved in Human Subjects Research." <http://ohre.unc.edu/irbtraining/>

Name	Dept	Training
Lisa Koonin	School Of Public Health	CITI Group 3: Data and Specimens ONLY

Should any additional persons come to work on this project and meet the definition of key personnel, they will be trained similarly; their names and certification of their training in the protection of human research participants will be forwarded.

Sincerely,

A handwritten signature in blue ink that reads "Sherrie E. Settle".

Sherrie Settle  
Director, Pre Award Services  
Office of Sponsored Research

## **APPENDIX G: Participant Recruitment Letter and E-mail**

Dear [insert participant's name],

Greetings! I am Lisa Koonin, a doctoral student (DrPH) at the University of North Carolina at Chapel Hill in the Gillings School of Global Public Health. I am requesting your participation in a doctoral research study I am conducting on a new way that the Federal government might distribute and dispense antiviral medicines during a future influenza pandemic. I also work at the Centers for Disease Control and Prevention (CDC), and as part of my CDC duties, I coordinate efforts to improve national emergency response efforts during a future pandemic.

I would like to talk with you via telephone for about 45-60 minutes at a time convenient to you. Your voluntary participation would involve discussing your opinions about the advantages and disadvantages of this new antiviral distribution and dispensing method that could be used during a pandemic.

Background: During the next severe influenza pandemic, as many people as 30% of the United States (US) population are likely to become ill and need rapid treatment with antiviral medicines. If given promptly after influenza symptoms appear, antiviral drugs can reduce the severity of symptoms, shorten the time of illness, reduce the need for hospitalization, and reduce the chance of death. The Centers for Disease Control and Prevention (CDC) has stockpiled caches of antivirals for pandemic use in the Strategic National Stockpile (SNS).

During the 2009 H1N1 pandemic, numerous challenges arose in antiviral dispensing. There is concern, based on this experience, that some state plans might not be adequate to ensure timely access to these medicines during a future pandemic. In May 2011, the CDC launched an effort to explore a new method of antiviral distribution and dispensing for the US.

Request for Your Opinions: To learn how your company might view this proposed dispensing method, I am interviewing key pharmacy executives like yourself. If you choose to participate, I am the only person who will have access to your individual responses. Your name and your company's name will not be disclosed and will not be used in any report or summary that results from this project. I would like to record the interview, so that I can analyze your opinions in detail. All records and notes will be safeguarded, as described in the enclosed study description.

Thank you for considering my request to discuss your opinions about a new way to distribute and dispense antiviral medicines during a pandemic. If you have any questions, please contact me at [koonin@live.unc.edu](mailto:koonin@live.unc.edu) or [lmk1@cdc.gov](mailto:lmk1@cdc.gov) or 404 921-7955. I will follow-up with a call to schedule an interview in the next week or so. I know that you are very busy, and I greatly appreciate your time and help with this effort.

Sincerely,

Lisa M. Koonin, MN, MPH

UNC DrPH Doctoral Student

and

Senior Advisor and Lead, Pandemic Medical Care and Countermeasures

Influenza Coordination Unit/ Office of Infectious Diseases

Centers for Disease Control and Prevention

Enclosure: Fact Sheet

## **APPENDIX H: Fact Sheet for Adult Participants in a Research Study and Consent to Participate in a Research Study**

**University of North Carolina–Chapel Hill**

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**Title of Study:** Acceptability of Pharmacies Serving as Primary Dispensers of Antiviral Drugs during a Pandemic: Perspectives of Pharmacy Executives

**Principal Investigator:** Lisa M. Koonin, MN. MPH

**UNC-Chapel Hill Department:** School of Public Health, Department of Health Policy and Management

**Faculty Advisor:** Sandra B. Greene, DrPH

**Study Contact telephone number:** 404-921-7955

**Study Contact email:** [koonin@live.unc.edu](mailto:koonin@live.unc.edu)

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### **What are some general things you should know about research studies?**

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future during an influenza pandemic. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named

above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**

The purpose of this research study is to learn about the views and opinions of pharmacy company executives about a proposed Centers for Disease Control and Prevention (CDC) plan to distribute antiviral medicine from Federal stockpiles to pharmaceutical distributors and then to pharmacies. Under this proposed plan, pharmacies would serve as the primary dispensers. You are being asked to be in the study because you have professional responsibilities related to decision-making and implementation of new protocols within your company. Currently, no decisions have been made whether to adopt or not adopt this plan.

**How many people will be interviewed for this study?**

If you decide to be interviewed for this study, you will be one of approximately 9 people interviewed for this research study.

**How long will your part in this study last?**

If you decide to be interviewed for this study, you will be asked to meet by telephone for a 45-60 minute interview. If you agree, you may also be contacted by e-mail or telephone by me to address follow up questions or clarifications if needed.

**What will happen if you take part in the study?**

Participation in interviews for this study will involve the following steps:

- Read this fact sheet and letter of invitation to determine your interest in participating in this study
- Contact the researcher listed on the first page of this form with any questions or concerns regarding your participation
- Schedule a time to participate in a 45-60 minute interview (interviews will be conducted over the telephone)
- Provide your consent for participation in this study over the phone.

- Participate in a interview over the telephone
- Address follow up questions or clarifications if needed after the interview

**What are the possible benefits from being in this study?**

Your participation will benefit by assisting public health planning for a new way to distribute and dispense antiviral medicines during an influenza pandemic. This research is designed to benefit society by gaining new knowledge, however, you may not benefit personally from being in this research study.

**What are the possible risks or discomforts involved from being in this study?**

There are no known or expected risks to participating in this study.

**How will your privacy be protected?**

The researcher listed on the first page of this form is the only person who will have access to information that links individual participants to the responses from their interviews. The names of the participants and their company will not be shared with anyone.

- Participants will not be identified in any report or publication about this study.
- Records of the interview will be stored electronically in password-protected files.
- At the time of the interview, participants will be asked for permission to audio-record the interview for transcription. If an interview is recorded, a transcript will be made and the audiotape will then be destroyed. Transcripts will be destroyed after the project is completed.
- Any hardcopy information linked to an individual's responses to interview questions will be stored in a locked file cabinet.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your



information in this research study could be reviewed by representatives of the University or government agencies for purposes such as quality control or safety.

**Will you receive anything for being in this study?**

You will not receive anything for taking part in this study, but your opinions will be valuable to assess a new way of distributing and dispensing antiviral medicine during a pandemic.

**Will it cost you anything to be in this study?**

Other than your time, there will be no costs for participating in the study.

**What if you have questions about this study?**

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researcher listed on the first page of this form.

**What if you have questions about your rights as a research participant?**

All research with human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the Institutional Review Board at 919/966-3113 or by email to [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu) .

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**Title of Study:** Acceptability of Pharmacies Serving as Primary Dispensers of Antiviral  
Drugs during a Pandemic: Perspectives of Pharmacy Executives

**Principal Investigator:** Lisa M. Koonin, MN. MPH

**Participant's Agreement:**

I have read the information provided above. I have asked all the questions I have at this  
time. I voluntarily agree to participate in this research study.

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Signature of Research Participant

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Date

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Printed Name of Research Participant

## **APPENDIX I: Key Informant Interview Guide – Questions for Pharmacy Executives**

### **Hello (Participant)**

I am Lisa Koonin, a doctoral student in the University of North Carolina's Gillings School of Global Public Health. I also work at the U.S. Centers for Disease Control and Prevention in the area of pandemic preparedness. Thank you for agreeing to participate in this interview to discuss your opinions about a proposed new way to distribute and dispense antiviral medicines during a future influenza pandemic. As I indicated in the introductory letter, the information I collect as a part of this study is for my dissertation research and is also related to my work at CDC

For this new method, the Federal government would send antiviral drugs from Federal stockpiles to pharmaceutical distributors and then they would be sent to pharmacies. Pharmacies would then serve as the primary dispensers of antiviral drugs during a future influenza pandemic. Antiviral medicines would still need to be authorized by prescription from a licensed health care provider.

Although I am leading this effort, I do not yet know if this new way of distributing or dispensing antivirals is feasible or acceptable. I want to interview you to learn about your perspectives. I attached a form explaining this research with the letter of invitation. I would like to review a few key issues about your participation in this research study. First of all, to participate in the study is voluntary. You may

refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

I will not share any details about you as a participant in this interview or associate your answers from this interview with your name or company name with colleagues at CDC or with any other organization. I will be interviewing about 9 pharmacy executives for this study. When I finish with all the interviews, I will group all the answers together in any report or presentation. I will not include your name or company name in any oral presentation or written report. The aggregated information will be used in my dissertation. The aggregated findings will also be used by CDC to determine how to better plan for a future pandemic.

In order to fully capture your responses today, I would like to record our conversation. Please know that, if you wish, I can turn the audio recording off at anytime. I will destroy the recording after I incorporate the information into the larger study.

And finally, please know as we go through the questions in this interview, that there is no “right answers” to the questions, rather I want to learn in as much detail as possible about your views and opinions. Also, please know that you don’t have to answer any question that you choose not to answer. We will just skip that question and go on to the next one.

Do you have any questions?

If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu)

Do I have your permission to record our conversation?

Do I have your permission to begin asking you questions?

### **Interview Questions**

1. Please describe your role/position in your company.
  - a. How many years have you had this role?
2. Do you make or inform decisions about whether the pharmacies in your company adopt new large scale policies or procedures? [IF NO—  
DISCONTINUE INTERVIEW]

I am going to read you a scenario now that will serve as a frame of reference for our discussion.

**Scenario:** During a future severe, influenza pandemic, it will be important to rapidly distribute and dispense antiviral medicines to ill persons.

*Please note; I do not have any current information about an impending pandemic, I am just using this as a scenario so we can discuss a new method of distribution and dispensing that is being explored by CDC.*

This new method includes utilizing pharmacies as the primary dispensing locations for antivirals. The proposed plan includes sending antiviral medicines that are stockpiled by the Federal Strategic National Stockpile (SNS) to pharmaceutical distributors during a future influenza pandemic. These distributors will in turn, distribute the antivirals to pharmacies in their networks. Because this medicine would still only be available by prescription, patients will bring a prescription in, or it will be transmitted electronically or by telephone to pharmacies. The antiviral products themselves will be provided to pharmacies for free from the government, but your pharmacies might choose to charge patients a dispensing fee. In order to ensure reimbursement to pharmacies from those without insurance, the government is exploring a way to allow pharmacies to be reimbursed even if a patient does not have insurance.

An influenza pandemic is likely to last a long time, as outbreaks occur in different parts of the country over the course of a year or more. In a given community, however, it is likely that an outbreak could last anywhere from 8 to 12 weeks. During this time, pharmacies will probably have more patients than usual, some of them would be existing patients, but there could also be a large number of new patients who are seeking this medicine.

Now I would like to ask you a few questions about your view of how you and your company would react to this proposed new method of antiviral distribution and dispensing.

Is it okay for me to proceed?

3. What do you think about this proposed method of having pharmacies serving as the primary dispensers of antivirals during a future pandemic? PROBE:  
Do you see any advantages of your company's participation with this new method of antiviral distribution and dispensing? (PROBE: how about increased store traffic, serving customers, community stakeholder in emergency response?)
  - a. Which of the advantages that you mentioned would you say is most significant?
4. Are any parts of this new method of antiviral distribution/dispensing compatible with your company's normal processes and mission? In what way?
5. What do you think about this proposed approach in terms of complexity?
6. What are the key factors that would influence you and your company's decision to participate in this kind of antiviral dispensing during a pandemic?
  - a. What do you think your company's top leadership will think about this new method of antiviral distribution and dispensing?
7. What conditions would make this new approach unacceptable?

PROBE:

- a. Are there any risks or adverse outcomes that you think might arise?

(PROBE: disruptions, increased complexity, security risk, financial loss, risk of disease transmission in the store and threat to health of employees?)

- b. Which of the risks or adverse outcomes that you mentioned would you say is most significant?

- c. Are any of these risks “show-stoppers”? Meaning if this risk could not be reduced, then your company would not likely participate in this new method of antiviral distribution and dispensing.

- d. Are there things that can be done to reduce these risks or make some of these risks more acceptable? If so, what would they be?

(EXAMPLE---PROBE: if concerned about increased disease transmission in the pharmacy is there a way to serve customers by home delivery or drive thru window? Asking friends and family to pick up medicines for sick persons?) (EXAMPLE--PROBE: If concerned about security risk, is there a way that private security firms or local government can help?)

- 8. What effect would decisions about participation made by others have on your company's decision to participate? For example:

- a. Competitors
- b. Front-line pharmacists in the company
- c. Others?



9. What type of information, training, or support would your company and your pharmacies need to be able to perform this role during a pandemic?
10. What else is important to you if pharmacies serve as primary dispensers of antivirals during a pandemic?
- a. What else would you like to tell me about this issue?
11. What do you think about pharmacies serving as the primary dispensers of other medical countermeasures during other types of emergencies, such as an anthrax attack?
12. May I contact you again with follow up questions or for clarifications? What is the best way to contact you, if needed?

**Conclusion:** **Thank you** for your time today to discuss a new way to distribute and dispense antivirals during an influenza pandemic. The opinions and insights that you shared will be valuable to my study and for national planning for a future pandemic. I really appreciate your time and interest in this emergency preparedness topic. Please feel free to contact me if you think of anything else that could inform this exploration.

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