# **ORIGINAL RESEARCH**

# Evaluating the Impact of Pharmacies on Pandemic Influenza Vaccine Administration

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### ABSTRACT

**Objectives:** The objective of this study was to quantify the potential retail pharmacy vaccine administration capacity and its possible impact on pandemic influenza vaccine uptake.

**Methods:** We developed a discrete event simulation model by use of ExtendSim software (Imagine That Inc, San Jose, CA) to forecast the potential effect of retail pharmacy vaccine administration on total weekly vaccine administration and the time needed to reach 80% vaccination coverage with a single dose of vaccine per person.

**Results:** Results showed that weekly national vaccine administration capacity increased to 25 million doses per week when retail pharmacist vaccination capacity was included in the model. In addition, the time to achieve 80% vaccination coverage nationally was reduced by 7 weeks, assuming high public demand for vaccination. The results for individual states varied considerably, but in 48 states the inclusion of pharmacies improved time to 80% coverage.

**Conclusions:** Pharmacists can increase the numbers of pandemic influenza vaccine doses administered and reduce the time to achieve 80% single-dose coverage. These results support efforts to ensure pharmacist vaccinators are integrated into pandemic vaccine response planning. (*Disaster Med Public Health Preparedness*. 2017;11:587-593)

Key Words: influenza, pandemic vaccine administration, pharmacies

nfluenza infection results in substantial morbidity and mortality during seasonal epidemics and occa-L sional pandemics.<sup>1</sup> The most effective medical intervention for influenza infection and its associated complications is vaccination.<sup>2</sup> Although annual seasonal influenza vaccination for all persons 6 months of age and older has been recommended since the 2010-2011 season, estimates of vaccination coverage for the 2015-2016 season were only 41.7% for adults and 59.3% for children (aged 6 months through 17 years).<sup>3</sup> During the 2014–2015 season, a season with a relatively high burden of severe disease, surveillance data indicated a hospitalization rate per 100,000 population of 322.8 for adults aged  $\geq$ 65 years, 54.8 for adults aged 50 to 64 years, 18.9 for adults aged 18 to 49 years, 16.5 for children aged 5 to 17 years, and 57.2 for children aged 6 months through 4 years.<sup>4</sup> Even with the relatively low vaccination rate, the Centers for Disease Control and Prevention (CDC) estimated that influenza vaccination averted approximately 67,000 influenza-associated hospitalizations during that season, the vast majority of whom (~58,000) were adults  $\geq 65$ years of age.<sup>5</sup> Increasing influenza vaccination coverage may further reduce influenza-associated hospitalizations.

Traditionally, vaccine providers have been located in hospitals, doctors' offices, clinics, health departments,

workplaces, and schools. Although many states did include vaccination as part of pharmacists' scope of practice, the proportion of influenza vaccinations delivered by pharmacists in the United States began to increase substantially in 2009 in response to the 2009 H1N1 pandemic.<sup>6</sup> By 2009, all states allowed vaccination-trained pharmacists to administer influenza vaccine. As of November 2015, approximately 1 in 4 adults who receive annual seasonal influenza vaccination are vaccinated in pharmacies or other retail settings, up from 1 in 20 in the 1998-1999 season.<sup>7</sup> When a novel influenza virus with pandemic potential emerges, its antigenic differences from seasonal viruses necessitate the production of a new vaccine. Timely and efficient vaccine delivery and administration of available pandemic vaccine, as soon as it becomes available for distribution, are critical to reducing the health and economic consequences of an influenza pandemic. Partnership between public health and the private sector will be essential to maximizing rapid access to pandemic vaccination during a severe pandemic. As such, initiatives to expand the number of and early involvement of pharmacist vaccinators may augment pandemic vaccine administration capacity. Retail pharmacies offer a number of advantages for vaccine administration that may prove particularly useful during a pandemic.

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Their benefits include proximity and convenience for the vast majority of the population, expanded hours of service, existing systems for vaccine distribution and distribution tracking, existing staff trained to administer influenza vaccine, and the ability to coordinate between stores within states.

However, the total administration capacity of both nonpharmacy vaccinators and retail pharmacy vaccinators is currently unknown, making it difficult to accurately predict and plan for the potential contribution of retail pharmacy vaccinators to pandemic vaccine administration. Therefore, we developed a discrete event computer simulation model for influenza vaccination to forecast the potential impact of community pharmacy vaccinators. Using this model, we developed estimates of the number of adults who could be vaccinated each week during a variety of administration scenarios. We also modeled the time required to achieve targeted pandemic coverage (vaccination of 80% of the population with one dose) in each state, with and without community pharmacy vaccinators.

### METHODS

#### Modeling Process

We constructed a discrete event simulation model using ExtendSim software (Imagine That Inc, San Jose, CA), a commercially available software package. We created a process map depicting influenza vaccine administration illustrating vaccine distribution and administration, model inputs, process rules, and outputs (Figure 1). From this map, we constructed an ExtendSim simulation model, assigned input values as detailed below, and ran the model to simulate a 26-week pandemic response to a severe influenza pandemic where vaccination demand was assumed to be high. The model simulates an administration scenario with a weekly production of 30 million vaccine doses. The current federal strategy for pandemic vaccine shipment utilizes the vaccine distributor currently contracted by the Vaccines for Children (VFC) program.<sup>8</sup> Doses are allocated to each state by the Centers for Disease Control and Prevention (CDC) proportional to population. We assumed that in each state 75% of doses would be allocated to adults and 25% to children. If the allocation for one age group was depleted, the model allowed that group's vaccine providers to receive vaccine, if available, from the other group's allocation within the same state. In the model, pharmacy providers vaccinated only adults because pharmacists' authority to vaccinate children of different ages varies by state.<sup>9</sup> The model assumed that vaccine providers administer vaccine daily and place weekly vaccine orders with their state health department based on their inventory levels. As orders are approved, they are forwarded to the vaccine distributor where they are filled on a first-come, first-serve basis. If inventory is depleted, orders are not filled. We analyzed model results to evaluate 2 major outcomes: state and national weekly vaccine administration, and time required for 80% single-dose coverage for adults.

#### Weekly Vaccine Delivery

We initially set weekly vaccine production to 30 million doses and allocated vaccine to each state according to state population. Based on 2010 US Census data estimating that 25% of the population is 18 years or younger,<sup>10</sup> the model assumed that 75% and 25% of weekly vaccine was allocated to adults and children, respectively, within each state. We assigned each state an ordering lead time based on historical data from the 2009 novel A (H1N1) pandemic.<sup>11</sup> Lead time was defined as the average historical delay between vaccine allocation and shipment to requester. The average lead times for states ranged from 2.1 days to 12.5 days. The model was also programmed to ramp up to peak vaccine administration capacity 5 weeks after the initial vaccine shipment based on input from the Influenza Vaccine Task Force, a working group comprising more than 20 CDC vaccination experts.

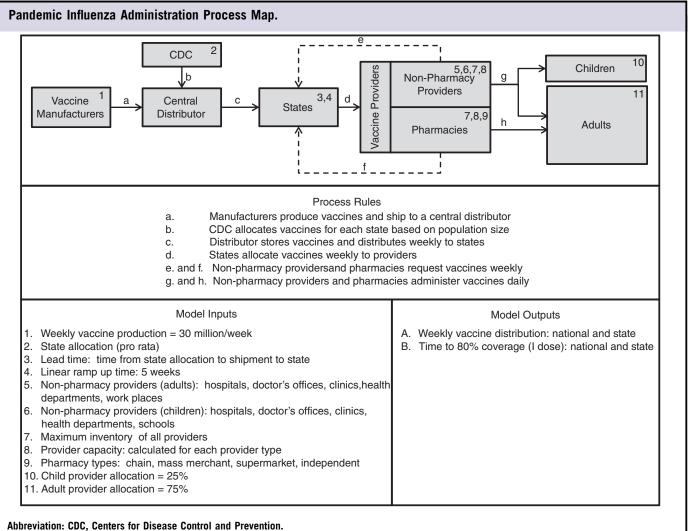
#### **Provider Types**

Nonpharmacy adult vaccine provider sites in the model included health departments, doctor's offices, clinics, hospitals, and workplaces (Figure 1). Doctor's offices, hospitals, health departments, and schools comprised the model's child provider types. Pharmacy providers included chain pharmacies, mass merchant pharmacies, supermarket pharmacies, and independent pharmacies. For simplicity, pharmacies were categorized as adult-only providers. We did not include temporary mass vaccination clinics (eg, mass vaccination clinics at public health-staffed Points of Dispensing, or PODs) as a separate vaccination setting outside of public health departments and hospitals, assuming that these public health staff would already be included in our calculations for capacities for the public health department or hospital. The model was designed to assess vaccination capacities of existing vaccination infrastructure and routine workforce, not additional temporary clinics without clear vaccination staffing in place.

#### **Provider Numbers**

We estimated each state's total number of adult provider sites by using its number of hospitals and Behavioral Risk Factor Surveillance System data on the place of influenza vaccination reported by US adults.<sup>6</sup> The District of Columbia was also included in our analysis. We assumed, for purposes of the model, that the percentage of individuals vaccinated at each location type would equal the percentage of that location within the state. From the total number of hospitals in each state obtained from the American Hospital Directory and the percentage of vaccination locations within each state, we deduced the number of provider sites in each of the specific categories. The number of child provider sites was determined by using VFC program records, the National H1N1 Flu Survey, and the National Immunization Survey for the 2009-2010 through 2011-2012 influenza seasons (unpublished data, available upon request). The National Association of Chain Drug Stores Economics Department provided numbers of pharmacies in each state based on July 1, 2012,

## **FIGURE** 1



National Council for Prescription Drug Program Pharmacy Provider File.

#### **Administration Capacities**

We assigned minimum, maximum, and typical administration capacities to each nonpharmacy provider type based on published literature<sup>12-16</sup> and expert opinion from the CDC Influenza Vaccine Task Force. To determine pharmacy capacities, we conducted a survey of pharmacists representing the 4 pharmacy types and averaged data for each pharmacy type to determine its maximum (surge), minimum, and typical influenza immunization capacities (unpublished data). The survey was distributed by e-mail to members of the National Community Pharmacist Association, and 25 pharmacy groups responded; one response was excluded because the pharmacy type was not indicated. The survey was reviewed by the institutional review board of the CDC. It was conducted in compliance with all applicable US federal regulations governing the protection of human subjects.

#### Weekly Total of Administration Capacities

To determine the total weekly maximum vaccine dose administration capacity in each state, we multiplied the number of provider sites, number of operating hours per day, number of operating days per week, and the hourly vaccination capacity per site, which was determined by triangular distribution of the minimum, maximum, and typical capacities. A target inventory was assigned to each provider site. For nonpharmacy providers, this target was based on their calculated maximum capacity. For pharmacies, the target inventory was assigned based on the surge capacity pharmacies had reported in the survey mentioned above.

#### **Vaccine Demand**

The model simulated a severe influenza pandemic where the demand for vaccine would be high. A weekly vaccine order for each provider was assigned to reflect weekly inventory replenishment. Orders equaled the difference between the site's maximum capacity and the number of vaccines the provider had administered that week. If there was insufficient vaccine inventory, the remaining demand would not be filled and would remain as part of the unvaccinated population that the providers would continue to vaccinate as vaccines became available.

#### **Model Validation**

We observed the model's animation throughout the 26-week model run period, noting flow and bottlenecks, to verify that vaccines were being transported and utilized according to our conceptual framework. We also ran the model, inputting both reasonable and extreme values and observing subsequent results at each process step, to verify that resultant outputs were logical and reasonable based on expert opinions. Monitoring vaccine quantities through specific model entities also assured us that the model logic was correct and accurate. Internal validity was established through 32 runs of the model, resulting in consistent outputs; across all states, the average standard deviation for the time to 80% coverage was 0.5 days. Model results are representative of multiple model runs.

#### **Modeling Assumptions**

(1) Public demand for vaccination would match or exceed supply. (2) The percentage of provider types in each state correlated directly to the percentage of people receiving vaccines from that particular provider type. (3) The total number of VFC providers equaled the total number of child vaccine providers for each state. (4) Hourly capacities per vaccinator were based on published studies<sup>12-18</sup> (Table 1). (5) Pharmacy vaccination capacity from survey results (not published) of a small subset of pharmacy providers accurately reflected all pharmacy providers in the same category (Table 1). (6) The percentage of pharmacies enrolling as vaccine providers was based on professional judgment of the authors. (7) The average number of vaccinators working at each site was based on professional judgment of the Influenza Vaccine Task Force working group at CDC. (8) The number of hours per day and the number of days per week of vaccine administration remained consistent throughout the model duration. (9) Vaccination that might occur at temporary mass distribution clinics or PODs would be part of the public health departments' capacities instead of a separate provider category.

#### RESULTS

Figure 2 illustrates weekly vaccine administration for children and adults. Weekly administration peaked at nearly 8 million doses for children (A), and remained near that level until 80% national coverage with a single dose of vaccine was achieved in 10 weeks (B). Since we assumed pharmacies would not vaccinate children, there was negligible impact of pharmacies on childhood vaccination. Maximum weekly vaccine administration for adults of nearly 25 million influenza vaccine doses occurred when both nonpharmacy and pharmacy providers were utilized (C) and 80% adult vaccination coverage was achieved in 11 weeks (D). Weekly administration using only nonpharmacy providers peaked at approximately 15 million doses (C) and required 18 weeks to achieve 80% coverage (D).

The predicted time required for each state to achieve 80% adult coverage is illustrated in Figure 3. Without pharmacies some states required more than 25 weeks to achieve 80% coverage, whereas no state required more than 15 weeks to achieve 80% coverage when pharmacy vaccinators were utilized. The time to coverage for the states varied considerably without the use of pharmacy vaccinators, but was fairly consistent with the inclusion of pharmacy vaccinators. Three states achieved 80% coverage in the same number of weeks with and without pharmacy participation. These were all states achieving coverage relatively quickly (10 or 11 weeks). For the remainder of states, however, coverage was achieved more rapidly with pharmacy participation. Differences ranged from 1 week to 15 weeks.

#### DISCUSSION

Our experience with a simulation model depicting vaccine administration revealed a substantial increase in coverage using community pharmacy vaccinators. This model provides important insight into the quantitative impact pharmacies have on pandemic influenza vaccine administration capacity and sheds light on overall vaccine administration capacity in comparison with estimated vaccine production capacity of 30 million doses per week. The model demonstrated a powerful effect of pharmacies on both the volume and timing of national vaccine administration. An average of 18 weeks was required to attain 80% national single-dose vaccination coverage without pharmacists compared with 11 weeks with pharmacists.

The impact of pharmacy vaccine administration is particularly notable when considering the pharmacist vaccinator role is relatively new in some states.<sup>19,20</sup> As in the 2009 H1N1 pandemic, pharmacy-based vaccinators may extend the reach of the health department, particularly to at-risk and vulnerable persons without a medical home or personal physician.<sup>21</sup> For example, state-level vaccination coverage for adults at high risk for influenza complications was positively associated with states shipping vaccine to locations that increased general access, including pharmacy and retail locations, during the 2009 H1N1 pandemic.<sup>11</sup>

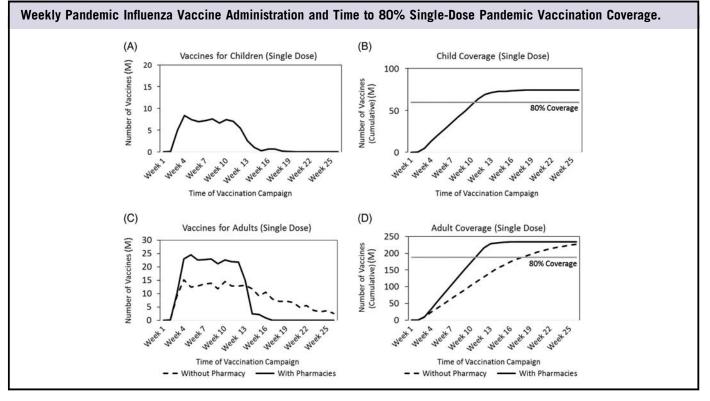
Pharmacist vaccinators provide improved access to vaccinations. For example, of the 43% of the US population residing in medically underserved areas, 41% are served by one of a major pharmacy chain's 2838 stores. Of the 4.5 million seasonal influenza vaccinations administered by this major retail chain during the 2009–2010 influenza season, more than one-third were administered at stores in medically underserved areas.<sup>22</sup>

## TABLE 1

#### Estimated Number of Enrolled Pandemic Vaccine Providers and Vaccination Capacity, by Provider Type

		Hourly Capacity Per Site			
Provider Type	Estimated Number of Enrolled Providers	Minimum	Maximum	Typical	Source
Physician office	29,920	8	12	10	(12–14)
Hospital	5723	20	30	25	(12–14)
Public health department	2204	15	20	17	(15)
School setting	10,720	15	30	23	(13, 16)
Work setting	14,496	5	25	15	Unpublished interview
Chain pharmacies	18,769	3	23	7	Unpublished survey of 10 pharmacies
Supermarket pharmacies	6755	1	15	6	Unpublished Survey of 2 pharmacies
Mass market pharmacies	5922	1	15	6	Unpublished survey of 2 pharmacies
Independent pharmacies	11,028	1	14	6	Unpublished survey of 10 pharmacies

### **FIGURE 2**

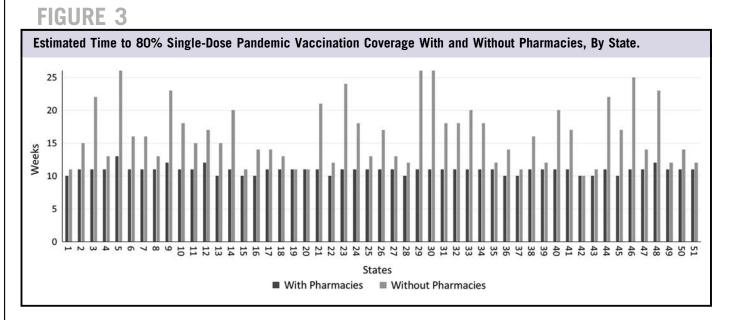


Pharmacies also offer vaccination during days and times when nonpharmacy providers are not typically available.<sup>23-25</sup>

An additional advantage of community pharmacists is the trust consumers have in the pharmacy profession.<sup>24,26</sup> Even when clients are initially hesitant to receive vaccine from a pharmacist, they may be amenable to education.<sup>27</sup> Health care professionals as well have been shown to support patients' access to influenza vaccine at pharmacies with 79% of physicians surveyed being willing to refer certain patients to other community vaccinators such as public clinics or pharmacies.<sup>28,29</sup>

Our model revealed the potential effect of pharmacy providers on administration capacity; however, it did not assess additional potential impacts of more rapid vaccination, such as reduced burden of illness as a result of influenza illness prevention.

Despite the advantages of pharmacy-based vaccination, barriers to pharmacist vaccination persist. A report published following a 2011 meeting of the American Pharmacists Association and the Academy of Managed Care Pharmacy noted "variability in state practice acts, reimbursement and compensation processes and systems, and mechanisms for documentation of vaccine services create substantial differences in how



pharmacist-provided immunizations are delivered throughout the United States."<sup>30</sup> Additionally, public health programs report that they plan to allocate relatively less pandemic vaccine to pharmacies compared to more traditional public health settings and providers,<sup>31</sup> suggesting that public health programs may be unaware of the potential vaccination capacity of pharmacies, as outlined in our article.

Additional coordination between public health programs and pharmacies is needed now to fully leverage vaccination capacity and the strength of pharmacies and to maximize early public access to pandemic vaccinations.<sup>32</sup> A national workgroup formed in collaboration between public health programs and pharmacy representatives and led by the Association of State and Territorial Health Officials has developed a model template Memorandum of Understanding (MOU) for coordination between public health programs and pharmacies on pandemic influenza vaccine program planning and response. The template MOU, also supported by National Association of Chain Drug Stores and the American Pharmacists Association, outlines ideal approaches and proposed best practices for coordinating pandemic influenza vaccine program planning, vaccination response, vaccine ordering, vaccine distribution, and data tracking between public health programs and pharmacies. The template MOU provides a proposed standardized approach across states to facilitate broader participation of national pharmacy chains in pandemic vaccine program planning across multiple states but allows for some flexibility given differences between jurisdictions.<sup>33,34</sup>

#### CONCLUSIONS

We used a discrete event model to explore the effects of different provider types on influenza vaccine administration in the adult population. The time required for 80% adult coverage, using nonpharmacist and pharmacist vaccinators

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was 7 weeks less than when only nonpharmacy providers were considered. Even though our analysis focused on adult vaccination, we expect the inclusion of pharmacies to have a positive impact on children as well.

The model results indicate the need for increased collaboration and planning between pharmacies and public health programs now, before the next pandemic, to fully realize the true vaccine administration capacity of both nonpharmacy vaccine providers and vaccinating pharmacists. This effort may be most important for reaching adult populations without existing access to vaccination services. We are currently developing a modeling tool that will allow individual public health planners to define and change their inputs according to the specific pandemic plans and organization of their vaccination programs.

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