

Getting Medicine to Millions: New Strategies for Mass Distribution

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This article examines the feasibility of allowing private industries such as grocery stores, wholesale clubs, and community immunizers to partner with public health authorities for the mass distribution of vaccines or antibiotics. Retail grocery and wholesale stores already have experience with annual influenza vaccination and may be a resource in a public health emergency, including a bioterrorist attack. This analysis suggests that retail store executives are willing to work with public health authorities to plan for and respond to public health emergencies.

IN A HEALTH EMERGENCY, such as the aftermath of a bioterrorist attack or in the midst of a pandemic, extraordinary systems and planning will be needed to rapidly distribute medications to millions of people. We investigated one potential solution to this logistical and medical challenge: tapping private sector retail stores for assistance with the distribution of vaccines, antibiotics, or other medical resources during a public health emergency.

Many retail businesses have experience in organizing and operating large vaccination clinics for influenza every year, and they have resources that may be useful in a public health emergency. For example, many stores have the necessary outdoor parking as well as the indoor space to accommodate large numbers of people; they have electronic inventory systems and can receive and manage large volumes of goods. We explored the willingness of the private retail industry to work with public health officials for the mass distribution of medicines and vaccines. The results from this qualitative study indicate that the resources within the private sector could be essential in saving lives in a public health emergency; however, these resources may be left untapped if relationships between public health and the private sector are not explored and developed before the next emergency.

BACKGROUND

Many of the challenges of mass delivery of medicines in an emergency involve the receipt, breakdown, and distribution of the Strategic National Stockpile (SNS). The U.S. Centers for Disease Control and Prevention (CDC) is responsible for determining the composition of the SNS and for rotating materials within it to assure stocks are within shelf-life limits. The SNS includes vaccines, medications, and other medical supplies to be used in an emergency. It is positioned in 12 undisclosed locations throughout the country and can be delivered to any location in the U.S. within 12 hours.¹ Federal officials take responsibility for delivering the SNS to the affected area, but, once it arrives, local health officials are responsible for breaking down the SNS and distributing its contents.

The CDC requires that state and local public health agencies be prepared to receive, manage, and dispense the SNS under a cooperative agreement that provides funding to states and select cities for public health emergency preparedness. In spite of planning efforts by local, state, and federal officials, progress has been limited.² According to Trust for America's Health, only 7 states and 2 cities have met CDC's criteria for readiness to distribute SNS material in an emergency.² Secretary Leavitt

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has stressed the importance of local preparedness and stated that

the Federal government can deliver stockpiles of medication and supplies to a city in the U.S. in a matter of hours—but it is distribution at the State and local level that defines victory. In a moment of crisis, if we are not able to deliver pills to people over wide areas in short time frames, lives will be lost. We need to create a seamless preparedness network where we are all working together for the benefit of the American people.³

Thus far, the capacity to deliver medicines on this scale has not, for the most part, been developed.

Planning to receive and distribute the SNS is complicated and resource intensive. Currently, many public health strategies for the mass distribution of the SNS rely on the points of dispensing (POD) model.⁴ In an emergency, POD clinics are to be set up in schools, neighborhood centers, or other familiar locations in the community. Citizens would be referred to their local POD clinic to receive information and medicines. The POD model assumes that each community will customize their distribution model to accommodate local infrastructure and population needs. At a minimum, POD locations are advised to have the following:^{5,6}

- Ability to accommodate large numbers of people (with parking) in a facility that is convenient and trusted by community members;
- Secure storage for a stock of medicines and supplies at appropriate temperatures;
- Personnel in sufficient numbers trained to administer vaccines and medications and to document who receives which medication; and
- Support staff in sufficient numbers to run nonmedical aspects of the clinic.

In reality, many communities have not yet identified a sufficient number of POD locations necessary to meet the anticipated public demand.

Communities will need to leverage every available resource to meet the challenges of mass distribution of vaccines and medicines. To do this, public health officials must continue to work with traditional emergency planning partners, including first responders, emergency management, schools, and volunteers from local organizations such as the American Red Cross, the Medical Reserve Corps, and Citizen Corps. However, traditional resources will not be sufficient during a large-scale disease outbreak. Other community resources, including the private retail industry, should be considered to meet public health demands in an emergency.

Each fall, grocery stores, wholesale clubs, and chain pharmacies distribute influenza vaccine to millions of

customers nationally. Although some organizations manage yearly vaccination campaigns internally, many businesses enlist the expertise and logistical support of private community-based health service providers. Approximately 25 to 30 million doses, or a third of the nation's flu vaccine supply, are administered annually in retail stores and other community nonclinical settings.⁷⁻⁹ These retail stores have existing systems and relationships that enable them to deliver medicines in large quantities to the public. From warehouse space to electronic inventory systems and expert staffing, retail businesses have both the infrastructure for and experience with organizing and operating large clinics. As such, retail businesses could be a valuable partner for inclusion in existing community POD plans.

METHODS

Over a 12-week period between March and June 2005, we conducted semistructured qualitative interviews with 15 executives representing 11 different organizations. This represents a 75% response rate for the original sample recruited for the study. Of the executives that we were unable to engage for this study, only one executive declined an interview, and the rest were not reachable within the time constraints of the study. The research was completed in a short period of time in order to develop timely policy recommendations. Thus, interviewees represent a small sample of executives who are particularly interested in this topic, which may introduce a selection bias.

The executives interviewed in this study were senior-level decision makers from retail chain grocery stores, wholesale club pharmacies, and private community-based health service providers.* Respondents were recruited based on their organizational roles and their corporate or professional experience in planning and operating annual influenza vaccine clinics. In aggregate, respondents had oversight and decision-making responsibility for health service or pharmaceutical operations in retail stores located in 41 states and Washington, DC. Interviews were conducted in person or by telephone and on average ranged from 35–60 minutes in length. Re-

*For purposes of this study, a retail chain grocery store is defined as a grocery business with multiple locations; a wholesale club is defined as a warehouse retail store, and wholesale club pharmacies refer to the pharmacy services provided within a wholesale club; and private community-based health service providers are defined as organizations that provide medical staffing, wellness services, and often home health care. Chain pharmacies, defined as retail pharmacy stores with multiple locations, are not represented in this research.

spondents were told that no comment would be attributed to them or their organization directly. We inquired about the organizations' experiences with operating influenza vaccine clinics and asked whether the respondents thought their organizations would be interested in working with public health officials in planning for public health emergencies. The interview focused on key questions (Figure 1) about their prior experience in holding influenza vaccination clinics and their perspectives on public health emergency preparedness, which framed a more detailed discussion.

KEY FINDINGS

Retail Leaders Are Willing to Take on Responsibility for Mass Distribution

Retail pharmacies, or pharmacies located within chain wholesale clubs and chain grocery stores, appear interested in planning for and responding to public health emergencies. The executives interviewed were nearly unanimous in their positive responses. They recognized that their retail infrastructure (including physical space, staff, security, and technology), their experience in hosting influenza vaccination clinics, and the public's familiarity with their local stores are major assets for public health officials. Furthermore, they indicated that their companies have a social responsibility to provide this "community service" during an emergency.

Retail executives noted that their customers would *expect* them to have a role, particularly because many consumers already rely on local grocery stores and wholesale club pharmacies for routine medicines and annual flu vaccines. While executives were mindful of the need to maintain a profit, they identified a strong connection between assisting during an emergency and maintaining or improving their reputation within the community. Nearly all retail executives acknowledged that doing the "right thing" for the community and the nation would be the "right thing" for their business in the long run.

Respondents felt that one of the biggest advantages of involving retail stores is that the public knows and trusts them, a factor that will be critical to the success of a mass distribution effort.⁶ For instance, one grocery store pharmacy executive remarked:

Grocery stores should be partners [with public health officials]. It makes sense to use facilities and people that the public already knows and trusts. It's strategically better to have clinics where people can go in their neighborhood and lots of them—like at grocery stores, instead of trying to get hundreds of thousands of people funneled through a few areas.

Although executives were unanimous in saying that their organizations should be seen as partners in this effort, they differed in how their organizations could or should participate.

- Why did your company decide to start offering the influenza vaccine? What are the benefits and risks for your company?
- What kind of relationship, if any, did you develop with local public health agencies in order to do this?
- What liability issues needed to be considered and how were these resolved?
- Who decides whether to host a flu clinic each year, and where, within the organization, is that decision made?
- How is it decided which stores will offer influenza vaccines, and does geographic location influence this decision?
- What was your company's experience with the flu vaccine shortage in 2004?
- Has your company thought about their potential role in a public health emergency?
- In the event of a public health emergency, including a bioterrorist attack, do you think your company would be willing to distribute vaccines or antibiotics in support of a larger public health mass distribution effort?
 - What factors would influence the feasibility of your company doing this?
 - What are the liability issues that would need to be addressed?
 - What, if any, liability issues have you addressed so far?
 - What resources would you need?
 - What authority would you need to do this?

FIGURE 1. SAMPLE INTERVIEW QUESTIONS

Retail Stores Have Physical Space for Mass Distribution

Some of the retail executives interviewed felt that their strongest asset would be providing the physical space to host either mass distribution or mass immunization clinics. One executive commented:

In the event that there is a national emergency, then I think absolutely, the place to [hold clinics] is at retail. Nobody is better equipped to handle large volumes of people than [large warehouse clubs or retail locations] . . . with lots of parking spaces, lots of room, the ability to handle crowds effectively.

For example, according to one respondent, a leading wholesale club has an average size “between 70,000 and 110,000 square feet,” as well as “sufficient parking to accommodate customer and clinic flow.” According to the National Association of Chain Drug Stores, there are currently more than 16,000 chain grocery, wholesale, or drug store pharmacies across the country, many of which could be possible sites of distribution during an emergency (personal communication, Jill Jonassen, National Association of Chain Drug Stores, July 28, 2005). Additionally, there is a retail pharmacy within 5 miles of 95% of the population in the U.S.¹⁰ Some executives reported that although they may not be able to provide staff to run the clinics, they would consider providing facility space, as long as another organization, such as local public health or a third-party health service provider, organized and operated the clinic. Many of these executives had a preference for working with the third-party providers that have previously organized and run their annual influenza vaccination clinics.

Retail Stores Have Trained Pharmacy Staff for Dispensing Medicines and Vaccines

Some executives reported that they would be willing to provide trained staff from their pharmacies, including pharmacists and pharmacy technicians, to assist public health officials in mass distribution or vaccination clinics. These executives noted that many of their pharmacists were already trained and/or certified to provide injectable vaccinations, such as influenza and pneumococcal vaccines, and would be qualified to assist public health officials in dispensing antibiotics or administering vaccines during an emergency.

Respondents indicated that interest and willingness among pharmacists to assist during a public health emergency is generally high. One executive noted a study conducted by the state pharmacy board in a mid-Atlantic state, which found that more than 1,000 retail and nonretail pharmacists surveyed would be willing to volunteer during a disaster or public health emergency.

Retail Leaders Are Willing to Work with Public Health Agencies

Some executives indicated that given the dire nature of public health emergencies and the need to reach large numbers of people quickly, it would make sense for public health officials to work with their organizations in a joint planning effort. These respondents emphasized that retail partners have readily available resources to facilitate the distribution of medicines, both antibiotics and vaccines. As one respondent said:

It's only natural that pharmacists and pharmacies should be involved. The public knows us, trusts us. We have rapport and familiarity with them. We also have the infrastructure—nationwide computer systems that can track patients [and] the drugs or vaccines they are given; we can look up medical histories and drugs; and we can look for drug interactions.

Existing computer systems or databases currently are used to track patients' prescriptions and identify potential drug interactions. Perhaps these systems could be adapted for use for mass distribution of antibiotics or vaccines. Lessons derived from Hurricane Katrina indicate that these pharmacy databases may be very useful.¹¹ During the response to Katrina, the federal government and several private pharmacies worked together to compile a centralized database of patient pharmaceutical information. This information was published on a secure Internet portal so that healthcare providers around the country could access individuals' information and provide accurate care to patients whose medical records had been lost in the hurricane. Planning efforts prior to the next emergency should explore how to leverage these private sector resources during a public health emergency.

Private Community-Based Health Service Providers Should Be Involved

Many grocery stores and wholesale clubs contract with private third-party health service providers to run their annual influenza clinics. Respondents from these organizations expressed interest in working on public health emergency planning and viewed themselves as “natural” partners, given their routine experience in delivering health services in their communities and operating immunization clinics in retail and community settings. According to one respondent:

We absolutely need to be involved. Who else has experience doing mass distribution of vaccines? We do it every year. You need people who are already trained, who know their communities, who have the experience running clinics like this, and who have the infrastructure to do it. That's us.

Retailers Identify Obstacles to Participation

Although retailers indicated a desire to be included in public health preparedness planning, they also identified potential obstacles that should be addressed to better facilitate this public-private partnership.

Liability

Respondents identified two major liability concerns. First, they questioned whether appropriate liability coverage would be provided for nongovernment employees assisting with the distribution of medicines during a public health emergency. This concern was emphasized particularly with regard to the distribution or administration of an Investigational New Drug (IND).

Second, executives questioned the boundaries of the liability coverage. For example, they were concerned whether the company would be protected if a client were to be injured at their facility while visiting a distribution site.

Executives explained that, during annual vaccination clinics, liability is covered through either the third-party health service provider organization or the liability coverage provided to individual staff pharmacists. Although executives are satisfied with these options during routine clinics, they cautioned that in an emergency situation additional liability coverage would be needed. Whatever the solution, respondents overwhelmingly agreed that it is important to resolve the liability issues in advance of an emergency, whether it is handled locally or by the federal government.

Lack of Standardized Public Health Response Policies

Another challenge identified by many of the retail executives is the lack of standardization between public health department response plans and bureaucracies. Executives were concerned about the need to negotiate with multiple government agencies to engage in planning and response efforts, and they were concerned that differences between jurisdictions might inhibit their participation. For example, many of the retail chains represented in this study have regional divisions (spanning multiple cities and states) that determine policies and protocols for local operations. Executives indicated that improved standardization within and among states would facilitate their participation in public health emergency planning.

DISCUSSION AND RECOMMENDATIONS

Developing effective mass distribution systems for public health emergencies requires leveraging existing community expertise and infrastructure. This analysis suggests a number of ways retailers' experience and infrastructure can be used to deliver medications or vac-

cines in an emergency. There are several steps that should be taken to take advantage of these resources.

- ***Develop standardized policies, within and among states, to guide how retail businesses could and should be used during a local public health response.*** Variations in public health agency response plans, within and between states, may hinder corporate involvement. Differences in local public health structure, jurisdiction, and bureaucracy can be a barrier to fostering partnerships with private retailers. It is not in the best interest of private corporations to have to navigate a different bureaucracy in each region. The Department of Health and Human Services (HHS), the parent agency of CDC, should provide a standardized gateway of entry. This includes developing policies to guide how retail businesses may approach public health and developing templates for these partnerships and agreements. State and local public health agencies should be further encouraged by HHS, in the form of financial and advisory support, to develop these partnerships.

- ***Federal authorities should clarify potential liability issues that could arise in a public health emergency, explain new liability policies, and communicate these solutions to all parties that might be involved in the response.*** Since the conclusion of this research, the Public Readiness and Emergency Preparedness Act was signed into law as part of the Department of Defense Appropriations Act 2006. This legislation provides liability protection to "covered persons" for the administration of a "covered countermeasure" upon the issuance of a declaration by the Secretary of HHS determining that a public health emergency exists that requires the administration of countermeasures identified by the Secretary.¹² This is a step in the right direction, but the details of what is and is not covered need to be clarified and communicated to state and local public health officials and potential private industry partners.

- ***CDC public health emergency planning guidance to state and local health authorities should further recognize and support, with dedicated funding and detailed guidance, the inclusion of public and private organizations as partners with local and state health officials for emergency response.*** CDC guidance should provide suggestions on where existing private sector expertise may be useful, including the breakdown of SNS, delivery/transportation of SNS to dispensing sites, and the actual delivery of medications to the public. CDC experts should be available for consultation and provide regular feedback to states and locals on the progress of different jurisdictions in order to document lessons learned and promulgate existing successes.

- ***Partnerships and plans between public health agencies and private retailers should be communicated jointly to the local community as soon as possible.*** Each

customer interaction at the local grocery store or wholesale pharmacy is an opportunity to educate the consumer on what to expect and where to turn during an emergency. Executives interviewed emphasized the importance of the routine contact they have with their consumers. Since these potential partners interact with the community on a regular basis, they can be a valuable resource for sharing information about plans for mass distribution of medicines before and during the emergency (personal communication, Mitch Rothholz, American Pharmacists Association, July 8, 2005).

• *In order to increase capacity and efficiency for emergency distribution of medications, state authorities need to establish the appropriate legal authorization and regulatory guidelines to allow pharmacists in all states to vaccinate.* Currently pharmacists are not legally authorized to vaccinate in every state. To resolve this, first, states have to grant pharmacists the legal authority to immunize members of the population. Second, appropriate regulatory protocols, to direct pharmacists in immunization practice, must be devised. These are the responsibility of one or more state regulatory boards (i.e., state boards of pharmacy, nursing, or medicine). According to the American Pharmacists Association, pharmacists have legal authority to vaccinate in 44 states; however, not all of these states have established the necessary regulatory guidelines (personal communication, Gwen Norheim, American Pharmacists Association, July 12, 2005). To maximize the number of individuals within the U.S. who are trained and authorized to provide vaccinations (injectable and noninjectable), all states should be directed and supported financially to implement the necessary protocols, procedures, and training to provide pharmacists with this authority and responsibility.

CONCLUSION

As public health officials across the country plan for local responses to emergencies, public-private partnerships should be cultivated to expand the reach of public health measures and quicken response and recovery. Hurricane Katrina demonstrated that private sector assistance is likely to be essential to meet the needs of communities in the midst of a crisis.¹³ During a public health emergency, retail stores have resources and expertise that may ease the burden placed on municipalities. The resources they bring to the table may ultimately be essential for successful emergency response. Local, state, and federal health authorities should consider developing these partnerships and plans now in order to capitalize on the experience, expanded infrastructure, and existing community relationships of retail stores.

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REFERENCES

1. U.S. Centers for Disease Control and Prevention. *Strategic National Stockpile*. Atlanta: U.S. Centers for Disease Control and Prevention; April 14, 2005. Available at: <http://www.bt.cdc.gov/stockpile/> Accessed April 27, 2006.
2. Trust for America's Health. *Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism: 2005*. Washington, DC: Trust for America's Health; December 2005. Available at: <http://healthyamericans.org/reports/bioterror05/bioterror05Report.pdf> Accessed April 27, 2006.
3. *Hearings before the House Committee on Energy and Commerce, November 8, 2005* (testimony of Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services). Available at: <http://www.hhs.gov/asl/testify/t051108.html> Accessed April 27, 2006.
4. U.S. Centers for Disease Control and Prevention. *Mass Antibiotic Dispensing: Streamlining POD Design and Operations* [webcast]. Atlanta: U.S. Centers for Disease Control and Prevention; April 14, 2005. Available at: <http://www.phppo.cdc.gov/PHTN/webcast/antibiotic3/media.asp> Accessed April 27, 2006.
5. National Association of City and County Health Officials (NACCHO). *The Strategic National Stockpile (SNS): A Reference for Local Planners*. Washington, DC: National Association of City and County Health Officials; undated. Available at: <http://archive.naccho.org/documents/NACCHO-NPS-Guide.pdf>. Accessed April 27, 2006.
6. U.S. Centers for Disease Control and Prevention. *Smallpox Vaccination Clinic Guide*. Atlanta: U.S. Centers for Disease Control and Prevention; 2002. Available at: <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/sm-allpox-vax-clinic-guide.pdf> Accessed April 27, 2006.

7. *Hearings before the Senate Special Committee on Aging, September 28, 2004* (testimony of Janet Heinrich, Director, Health Care and Public Health Issues, Government Accountability Office). Available at: http://securities.stanford.edu/USDC_CAND/1032/CHIR04_01/2005527_r10x_04CV04293.pdf Accessed April 27, 2006.
8. Singleton JA, Poel AJ, Lu PJ, Nichol KL, Iwane MK. Where adults reported receiving influenza vaccination in the United States. *Am J Infect Control* 2005;33(10): 563–570.
9. U.S. Centers for Disease Control and Prevention. *Questions and Answers: Vaccine Supply and Prioritization Recommendations for the U.S. 2005–06 Influenza Season*. Atlanta: U.S. Centers for Disease Control and Prevention; February 3, 2006. Available at: <http://www.cdc.gov/flu/about/qa/0506supply.htm>. Accessed April 27, 2006.
10. *Hearings before the House Committee on Energy and Commerce Subcommittee on Health, Subcommittee on Oversight and Investigations, September 22, 2005* (testimony of Bob Dufour, Director, Pharmacy Professional Services and Government Relations, Walmart, Inc.). Available at: <http://energycommerce.house.gov/108/Hearings/09222005hearing1643/DuFour.pdf> Accessed April 27, 2006.
11. Krim J. Health records of evacuees go online. *Washington Post* September 14, 2005:A24. Available at: <http://www.washingtonpost.com/wpdyn/content/article/2005/09/13/AR2005091302128.html> Accessed April 27, 2006.
12. Cohen H. *Pandemic Flu and Medical Biodefense Countermeasure Liability Legislation: P.L. 109-148, Division C (2005)*. Washington, DC: Congressional Research Service; January 6, 2006.
13. Freedburg S Jr. Hurricane response shows gaps in public-private coordination. *GovExec.Com* December 22, 2005. Available at: http://www.govexec.com/story_page.cfm?articleid=33068&printerfriendlyVers=1 Accessed April 27, 2006.

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