

Dispensing Mass Prophylaxis – The Search for the Perfect Solution

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ABSTRACT

Biological agents can be highly contagious and fatal, requiring a timely response to avoid economic loss, loss of life and large-scale panic. Local mass prophylaxis plans are based on the concept of Points of Dispensing (POD). However, there are various challenges that the local health department (LHD) in large metropolitan areas may encounter. We examine the benefits and challenges of POD and proposed alternate modes of dispensing. Considering that resources will always be under pressure, LHD will need to conduct analyses to determine what are the best alternate modes of dispensing for their jurisdiction. As a starting point, each LHD should consider what aspects of their POD plan are most in need of supplementation – sites, security, staffing, throughput, locations, etc. – so that the relative importance of addressing the different criteria becomes clearer. Tools from the field of decision analysis can facilitate the analysis and subsequent discussion necessary to make a well-informed choice.

INTRODUCTION

In this paper we examine Points of Dispensing (POD) and proposed alternate modes of dispensing for oral prophylaxis from the perspective of a local health department (LHD) in a large metropolitan area. We include this geographic focus as the challenges LHD will encounter in rural or sparsely populated areas will most likely be different from those seen in large urban areas with a densely concentrated population. After presenting each mode of dispensing and its potential benefits and challenges, we summarize the choice facing the LHD and provide recommendations for enhanced planning. It is important for homeland security planning to consider the realistic

limitations of each of the potential modes of dispensing and to explore options to supplement this system. To choose among the options, it is necessary to evaluate the benefits that each has to offer in alleviating the need for resources that are scarce within the community.

Starting with President Clinton's Executive Order 12938 in 1994, the funding for bioterrorism initiatives has increased significantly.¹ Ten years later, in 2004, President George W. Bush signed Homeland Security Presidential Directive 10 to strengthen the nation's preparedness and defense against the use of biological and chemical weapons.² Effective on March 1, 2003, the National Pharmaceutical Stockpile became the Strategic National Stockpile (SNS) and serves as a national repository of antibiotics, chemical antidotes, antitoxins, vaccines, medical equipment, and supplies to combat "Category A" Threat Agents as defined by the Centers for Disease Control and Prevention (CDC).³ The mission of the SNS is to help state and local jurisdictions prepare a strategic and uniform response to a large-scale natural disaster or an act of terrorism.⁴ It is the responsibility of local health departments to dispense SNS assets within their jurisdiction – the SNS does not provide dispensing team personnel, facilities, or transportation support beyond the delivery of the supplies to a state-identified receiving site.⁵

Local mass prophylaxis plans are based on the concept of Points of Dispensing (POD) as a mechanism for dispensing medicine and medical supplies to the general population during a large-scale public health emergency.⁶ Although the POD-based model has shortcomings, the CDC and the Department of Health and Human Services (DHHS) still view POD as the cornerstone of dispensing during a bioterrorism event requiring oral prophylaxis.⁷ The CDC Division of the Strategic National Stockpile

(DSNS) requires project areas to complete three of seven DSNS drills; of these, four are directly related to POD activation, set-up, and throughput and complete one functional or full scale exercise for each Cities Readiness Initiative Metropolitan Statistical Area (MSA) that tests key components of mass prophylaxis plans.⁸ These tests must be completed within each Public Health Emergency Preparedness Grant year (typically August 10, 20XX – August 9, 20XX + 1). Failure to meet these benchmarks could result in withholding of funds or future funding under the Pandemic and All-Hazards Preparedness Act (PAHPA).⁹

The Cities Readiness Initiative (CRI), a part of the SNS, was established to enhance preparedness in the nation's largest cities. Through CRI, state and cities are required to develop plans in order to provide antibiotics to the entire population within their jurisdiction within forty-eight hours.¹⁰ This timeframe provides the optimum benefit of post-exposure prophylaxis among those people who have inhaled anthrax spores.¹¹

While there have been no incidents requiring mass prophylaxis using the medical emergency model, the recent set of vaccination efforts in response to the H1N1 influenza outbreaks indicated that there are serious gaps in public health personnel, personnel available to administer vaccines, locations for the administration of the intervention, and necessary medical supplies. A public health emergency requiring activation of POD for immediate life-saving interventions will operate under different rules and regulations but will probably encounter the same resourcing issues.

POINTS OF DISPENSING

The CDC recommends that POD be sites the community is familiar with such as sports arenas, convention centers, community centers, and, in some cases, schools. These facilities are usually located in areas with high population density and easy access, ample parking, and close to public transportation facilities.¹² Such facilities also provide secondary advantages such as a large space (with available floor plans that denote all rooms, entrances, and exits); familiarity of

local law enforcement with securing the facility; and climate control (especially important in areas with extreme weather conditions). POD are typically non-clinical sites to ensure that treatment centers would be able to continue treating their existing patients as well as anyone who is symptomatic or injured during the course of the emergency. Mass prophylaxis coordination requires advance planning and integration of staffing, security, traffic, and control plans to successfully respond to an incident.¹³

Response planning based on the traditional POD has many advantages. It is easily scalable so the number of POD opened can be commensurate with the actual incident. It is open to the entire population (i.e., there are no restrictions on who may obtain prophylaxis from a POD). Several exercises in the United States have tested POD models and many jurisdictions use exercise data to justify their POD efficiency, as required under the Pandemic and All Hazards Preparedness Act (PAHPA).¹⁴ Of all the alternate modes of dispensing, the traditional POD has undergone the most frequent and rigorous testing, even though criticisms have been leveled at the testing for failing to: include set-up times; include elements of uncertainty; include the interaction with security or law enforcement; use full security staffing; and test coordination between POD, the Receipt, Store, and Stage (RSS) Warehouse and the Command Center.¹⁵

One disadvantage of the POD approach is that special needs populations may not be able to wait in long lines for hours to receive their medications, a frequent feature of POD.¹⁶ No acceptable standard approach – such as an extra line for those with special needs or immediate priority service for special-needs individuals – has been found to resolve these issues. These alternative solutions will require extra staff (either additional staff or staff borrowed from current POD operations), as well as extra set-up for expedited processing, monitoring, security, and controls at the POD sites – all of which affect POD efficiency. In addition, there are the ethical considerations for both population groups (general and special

needs) in terms of waiting times, priority, and access.¹⁷

The Bioterrorism and Epidemic Outbreak Response Model (BERM) estimates that in an anthrax scenario, assuming twelve-hour work shifts (with a downtime of 15 percent) and a throughput of 1,200 people per minute, 348 POD would be required to process a population of 10 million in order to prophylax everyone in forty-eight hours.¹⁸ Due to local variations of POD design and patient flow plans, staff requirements differ between jurisdictional POD models. Using the staffing determined by the BERM model, if all 348 POD are activated, Los Angeles County Department of Public Health would require 8,352 clinical staff and 41,760 non-clinical staff.

In a large scale incident where the full population needs prophylactic services, site and staffing requirements reveal the disadvantages of the POD system. A first issue is whether or not there are sufficient adequate sites within the geographic boundaries of an LHD to serve as POD that have not been designated to serve other emergency needs such as a shelter or alternate medical care site. In addition to the sheer physical number of POD sites, memoranda of understanding need to be developed and signed with each site owner that address the site owner's concerns about liability, damage to the site, and potential future ramifications to the facility associated with its use during the bioterrorism event. Given the complex structures of government organizations and their relationships with the private sector, this will take time and a considerable amount of effort.

A second set of issues surrounds the staffing requirements needed for a large metropolitan area (e.g., the need for over 8,000 clinical staff and almost 42,000 non-clinical staff in Los Angeles County). These staffing requirements are not unique to Los Angeles. The CDC guidance for dispensing site operations suggests that metropolitan public health agencies may have to train thousands of people to meet the key dispensing site personnel needs,¹⁹ and that identifying and training these personnel in adequate numbers poses a problem.²⁰

Staffing to these levels will be dependent on volunteers.²¹ This implies that the LHD or

some other public agency must have a volunteer procurement arm dedicated to recruiting volunteers and setting up registries, prior to an emergency, that can pre-register, pre-credential clinical staff, and ideally pre-train non-clinical POD staff – a time-consuming and expensive process. This represents a serious additional workload at a time when most LHD are understaffed to run their daily functions and public agencies face serious budget cuts.²² Contacting, training, and transporting this number of volunteers to the POD sites is practically infeasible, especially as the CDC strongly recommends that all dispensing sites be opened simultaneously to avoid panic or the perception of preferential treatment.²³ The sheer number of volunteers poses difficulties in obtaining and maintaining up-to-date lists with current, accurate contact information. Beyond obtaining the volunteers, they must be dispatched to the various functioning POD sites.

Several exercises in Los Angeles County found that volunteers arriving spontaneously at POD sites without prior coordination would negatively influence POD operations as personnel are pulled from their primary tasks to handle the unexpected volunteers. In addition, if there is no pre-planned staging area for staff to gather, “flocking” at undesirable locations – such as POD, hospitals and other healthcare facilities – can occur,²⁴ resulting in compromised care, uncoordinated staffing efforts, and over- or under-staffing. The exercises concluded that coordination of volunteer personnel and a pre-designated staging area are essential and will need to be staffed by LHD personnel.²⁵ Given the need for large numbers of non-clinical staff, training will be done on a just-in-time basis. Numerous tools for this purpose have been made publicly available through the National Association of County and City Health Officials.²⁶ Training is vital. Volunteers need to be familiarized with the POD setup and operations; without a clear understanding of the POD flow and layout, POD efficiency will be negatively affected.²⁷ Administering this training will require time and manpower, a task that will likely also fall to the LHD. This implies that during an emergency, in addition to setting up the POD at their locations, LHD staff will need to

contact volunteers, provide just-in-time training, and coordinate volunteer distribution among POD.

Training has been found to be an essential step for all individuals associated with POD functioning. Breakdowns in communication and logistics, such as an inability to order supplies or report problems, can result in diminished POD efficiency.²⁸ The slower a POD works, the more POD will be needed to meet the prophylaxis mandates, increasing the need for sites and personnel. Additional training on the need and necessity of complying with personal protective equipment (PPE) guidelines will be required. Without training and fit-testing volunteers, POD staff is not likely to adhere to the guidelines.²⁹

Clinical staff pose additional challenges since many medical volunteers who would normally be willing and able to volunteer, such as hospital doctors and nurses, fire department personnel, EMT, and paramedics, may have other duties at their primary places of employment that take priority during a medical emergency. Many of these medical volunteers also participate in other community organizations such as Community Emergency Response Teams (CERT), Disaster Medical Assistance Teams (DMAT), California Medical Assistance Teams (CalMAT), etc. Another, almost opposite issue, has been documented as well. Several studies have found public health and medical professionals reluctant to participate in the response to a biological attack or a pandemic influenza outbreak.³⁰ The actual number of medical volunteers responding to an incident may be far less than planned.

Finally, the number of volunteers needed to maintain round-the-clock dispensing operations may be higher than estimated. The original estimates supplied by the BERM model are based on the assumption that workers would be willing to stay for twelve-hour shifts. As discussed in Trust for America's Health,³¹ there are many reasons why twelve-hour shifts may be unattainable – in which case the number of volunteers needed increases.

A third set of issues surround the ability to provide security for the POD – both the security at the site as well as traffic control issues. POD are large facilities that will

attract a large number of people; as such, they provide terrorists with an “optimal” combination of mass casualty and mass media exposure. They should therefore be considered a high-value, high-payoff target.³² Security is also needed for the transport of prophylactic materials and to direct and manage the flow of traffic at each of the sites.³³ Additional issues may arise when there are multiple law enforcement jurisdictions within a large metropolitan area. It is necessary to identify one central coordinator for all of the jurisdictions, who each of the agencies will accept – a task that has proven difficult.³⁴ While security is not within the purview of the LHD, the ability of a city or county to supply the requisite security personnel is frequently limited. Security personnel must be used to preserve the functioning of civil society during the emergency. Unfortunately, police forces have been cut in these times of budgetary difficulties and many jurisdictions are starting to rely on volunteers.³⁵ The LHD must take into account the security implications of its mass prophylaxis programs to ensure they will be feasible within the security constraints of its area.

Most large LHD concede they will not be able to set up and operate all POD at once and that POD would be opened based on availability of staffing and security resources. This implies that more POD would eventually need to open to be able to “make-up” the lost time and still be able to prophylax the entire population within the forty-eight-hour window.

ALTERNATE MODES OF DISPENSING

Alternate methods of dispensing are meant to complement POD as they reduce the number of people who need to be moved through POD.³⁶ The CDC recommends several alternate modes of dispensing shown to be best practices (there are several other alternate modes of dispensing that are regularly discussed on the SNS listserv hosted by the CDC). Some are based on the “open” model (anyone may receive prophylaxis) and others on the “closed” model (prophylaxis is only available to a

specific subpopulation). The CDC states that in order to create robust alternate modes of dispensing, the LHD needs to first identify the population that it would serve, research the availability of resources, and create a strong partnership with stakeholders such as local law enforcement, medical reserves corps, CERT networks, the Red Cross, and those organizations that would be partners in the alternate mode of dispensing (businesses, schools/universities, retail pharmacies, health maintenance organizations, other government agencies, etc.).³⁷ Not all of the alternatives will be feasible in every jurisdiction. Therefore, early assessment and analysis is critical to designing a plan to supplement the traditional POD system.

PRE-POSITIONING MEDICATIONS

Prepositioning can be used for first responders and/or for hospital and medical staff and/or for all government employees and their families. The CDC guidance is that these preferences (early treatment for first responders) need to have been discussed openly within the community.³⁸ Prophylactic drugs can be purchased using funding from the Urban Area Security Initiative (UASI) or Metropolitan Medical Response System (MMRS) to stockpile medications for first responders; funds from CDC can be used to purchase drugs for public health emergency response personnel; and funds from the Health Resource and Services Administration (HRSA) can be used for hospitals. The most important step in setting up a pre-positioning operation is to coordinate plans between LHD and other local government agencies and hospitals. The LHD would be responsible for writing and managing grants and ensuring that the drugs are rotated before they expire. In the case of an emergency, the partner agency would be responsible for picking up and dispensing the drugs. If the drugs were to be pre-deployed to the agencies themselves, then it would be the responsibility of the agency accepting the drugs to maintain their cache under strict supervision of the LHD. No agency would be allowed to distribute drugs without the consent of the Public Health Officer of the LHD. A signed memorandum of understanding (MOU) would be required

between agencies detailing the maintenance of the cache and the requirements and responsibilities of both agencies. The LHD would be responsible for ensuring compliance with the policies of the program and would therefore need to create a registry for all personnel working for each partner agency. The registry would include all locations of the drugs, the quantity of drugs, and contact information for the personnel responsible for dispensing at the partner agency.

An important advantage of prepositioning is that personnel required for mass prophylaxis and medical response would receive the required prophylaxis ahead of time, before the SNS arrives, which would ensure that once the SNS becomes available personnel are at work and ready to distribute it to the public. Additionally, the security requirements for pre-positioning are generally deemed as low; all that is needed is a locked, secure area with oversight by licensed personnel and a means to limit access to authorized personnel only. Another advantage is that these individuals and their immediate family members will not need to go to the POD.³⁹ If the drugs are stored at each agency, then during an emergency no LHD staff is required. If the drugs are stored at a central warehouse, then only warehouse staffing is required for dispensing prophylaxis.

The main disadvantage to pre-positioning is that the initial set-up can be time consuming, as it requires buy-in from the partner agencies (hospitals, other governmental departments, other government agencies).⁴⁰ The rights, responsibilities, and liabilities of these partners must be agreed upon – issues which become more complicated if the partners are provided with their own cache of medications. In addition, antibiotics have an expiration date and would have to be rotated, committing the various entities to a continuous maintenance program and requiring reapplication for grants to fund such operations.

DISPENSING AT BUSINESSES

Local health departments have forwarded the idea of dispensing at businesses, which has

the potential of benefitting both the business and the LHD. If large employers prophylax their own employees and employee families during a large health emergency that would require activation of POD, employees will be encouraged to come to work – a clear benefit to the private sector. In addition to protecting their own workforce, private industry has proven to be extremely helpful in disaster recovery efforts, not only because businesses are citizens of their own communities, but also because without continuity of community no business can be done.⁴¹ The much quoted statement from Stanley Weiss, one of the founders of Business Executives for National Security (BENS), is that “Being dead is bad for business.”⁴² From the LHD perspective, the option of dispensing at businesses becomes attractive if it can reduce the number of individuals who will need to use the POD system.⁴³ Target businesses include large companies (the Orange County Health Care Agency defines “large” as businesses that have 100 employees or more) and those that deal with critical infrastructure such as power, water, and communications.

The LHD in Orange County, Florida, has had great success working with local businesses and obtaining agreements with them to prophylax their own employees (in effect serving as a closed business POD) with their business POD. The challenge is to prophylax 1.6 million people in Orlando (the largest city within Orange County) within forty-eight hours. After establishing memoranda of agreement (MOA) with large employers and medical facilities to prophylax their own employees and their families, the department estimates that they can prophylax 40 percent of their population without recourse to their traditional POD system.⁴⁴

A business POD would require an MOU between the LHD and the private sector partner that specifies the roles and responsibilities of both agencies. It would be the responsibility of the LHD to notify business partners about the activation of the dispensing plan, separate and repackage medication that will be allotted to each business, and create and send forms, as well as notify a responsible party regarding the location (the distribution site) and pick-up

time for the prophylactic medications. The health department would also be responsible for training key personnel to provide just-in-time training to the business POD staff. Businesses would be responsible for picking up and dispensing drugs to their employees with proper medical oversight, distributing forms and information sheets to their employees, setting up and staffing a business POD, and returning all unused items (along with completed patient forms) to the department of health.⁴⁵

After an MOU is signed, the LHD would issue an authorization letter to the businesses, and the person responsible for picking up the medications would have to bring this letter and photo identification in order to gain access to the distribution site. Since the location(s) of the pick-up sites for businesses would not be publicly known nor publicized, the assumption is that this covert approach would negate the security threat. Large businesses typically have occupational health nurses on staff to oversee issues such as workers’ compensation and therefore provide medical oversight; they may in some cases choose to contract their employee health services from an outside agency such as an industrial health clinic or a medical consultant firm to come in during an emergency and provide for medical oversight of dispensing. Nevertheless, businesses may be unable to locate medical staff to provide proper dispensing oversight. In such cases, businesses would ask employees if they have any relative who has a medical license – such as a nurse, doctor, pharmacist or dentist – and would be willing to take responsibility for medical oversight during dispensing. While this may seem like an odd approach, it is one way of locating additional personnel who have medical licenses and are not already committed to serve in another capacity in a crisis. The goal is to locate all potential personnel who have, can maintain, or can reapply for the ability to handle medications. The MOU would not be signed unless this resource could be located. In the worst-case scenario, the LHD would provide medical staff for medical oversight. However, the goal of this alternate mode of dispensing is for the LHD *not* to deploy any medical personnel.

Advantages of this dispensing alternative include the ability to prophylax a large

number of individuals without using POD and the ability to preserve scarce clinical personnel resources. The disadvantages are the need to develop MOU, sorting through legal ramifications, training business staff, ensuring that the proper standards are met for dispensing prophylaxis, and staffing a warehouse distribution center. There is also the worry that businesses will need clinical staff volunteers if they are not able to locate their own resources in times of emergency. Most states have very strict laws limiting the dispensing of medications to clinical staff and pharmacists so non-clinical individual citizens are usually prohibited from dispensing medications, even under emergency situations.⁴⁶ If clinical staff (a very limited resource) needs to be provided by the LHD, then the advantages to using the private sector are greatly diminished.

DISPENSING TO SHELTERED-IN POPULATIONS

Sheltered-in Populations (SIP) are defined as those populations that cannot make it to a POD. As seen during Katrina, the sheltered-in population residing in nursing homes, group homes, and assisted living facilities can easily be victimized when staff abandons their facilities to care for themselves and their families.⁴⁷

The Oklahoma City/County Health Department developed a SIP plan that targeted jails, nursing homes, group homes, residential care, hospice, and home health care facilities. This plan required minimum staffing and security and could still serve a significant portion of this population. The program also developed relationships with meals-on-wheels programs to distribute prophylaxis. In 2006, there were 150 facilities in the registry providing prophylaxis to 250,000 people in Oklahoma County. During an exercise, 50,000 doses were given out in three hours using only nine dispensing staff members and minimal security.⁴⁸

An advantage of leveraging SIP facilities to serve as a mode of dispensing is that most of these facilities are required by law to have medically licensed staff on hand. Where this was not the case in Oklahoma City, the health department looked to family members of the resident or a family friend who had a medical

license and was willing to take responsibility for the given facility. While this may seem like an odd approach, it was highly successful in Oklahoma where they were able to find relatives of persons living in the sheltered-in facilities who were willing and able to take on the responsibilities of dispensing in each of these venues. It would be the responsibility of this representative to dispense the drugs to the resident population at their facility and in every case they found a representative.⁴⁹ Turning to relatives of SIP residents met one of the goals of the planning process: to locate local medical staff not committed to other response functions who can be used in a crisis situation.

The biggest challenge Oklahoma City encountered in setting up its SIP dispensing plan was the creation of a registry, because finding their target agencies was very challenging. The Oklahoma City/County Health Department worked closely with state agencies involved in licensing, other agencies that deal with the target populations, and even resorted to using the phone book. The registry included all locations of the target populations, the number of people living at each location, and the number of staff working there along with the members of their immediate households. The registry also identified a single primary and two secondary points of contact during an emergency to be notified of the location of the SIP site. These contacts were required to be licensed medical professionals.⁵⁰ The registry created another difficulty because it requires constant updating due to the high turnover rate at the targeted facilities.⁵¹ Another challenge was the development of the MOU. The higher-level personnel at each agency had to be actively involved in the mass prophylaxis discussion and many of them were reluctant because they were under the impression that their in-house physician could provide the drugs needed during an emergency.⁵²

DISPENSING AT COLLEGES/UNIVERSITIES

College and university health centers in the United States provide low-cost primary health care to many students nationwide. Nurse practitioners, registered nurses, or physicians' assistants usually staff these health centers and many campuses are

affiliated with medical schools.⁵³ Colleges and universities have the infrastructure (large open spaces for dispensing such as auditoriums or basketball courts), medical staff, and non-clinical staff in the form of teachers as well as the student body required to run a university-only POD serving students, faculty, and staff (and their families). It would be the responsibility of the university to set up, staff, and operate a POD with guidance available from the LHD.

An appropriate MOU must be developed between the LHD and the university, verifying location and set-up of the university POD, staffing for the POD, and security for the POD (which may be provided by campus security forces if available), as well as delineating the roles and responsibilities of each organization. Universities with an extremely large student body may require additional clinical staff from the LHD to prophylax within the forty-eight-hour timeframe. Since some colleges and universities are state-run, LHD must consult their state board of education as well as the university management during early stages of planning.

One advantage of this system is that, for certain colleges and universities, it would be possible to prophylax the entire campus population without recourse to any additional resources (other than the prophylactic medications) from either the LHD or local security forces. Additionally, since colleges and universities represent large social sub-populations that will need prophylaxis in an emergency, permitting on-campus prophylaxis means a large subpopulation will be served that no longer needs to access transportation services of any kind. Disadvantages are that the effort of developing the MOU, especially if the state board of education needs to become involved, may be too substantial given the number of individuals who would be prophylaxed.

DISPENSING AT MAJOR HOTEL CHAINS

Most major metropolitan areas such as Los Angeles, Las Vegas, and New York not only have large local populations but must also deal with a fluctuating population of tourist and business travelers. Local health departments must be able to prophylax this

additional population to meet the federal mandate. The Southern Nevada Health District (SNHD), which includes Las Vegas, has over 300,000 tourists on peak days and adopted a unique solution to deal with its fluctuating population.⁵⁴ The SNHD partnered with hotel and resort chains to set up closed POD to prophylax employees and their families as well as all guests. This partnership was successful and both parties were pleased with its design. The partnership decreases the potential for economic loss for the hotels and resorts by safeguarding their guests and staff, provides an incentive for staff to return to work (by providing them with prophylaxis), and ensures continuity of operations. At the same time, the partnership allows the LHD to prophylax the fluctuating and local population.⁵⁵

To make such a plan operational an MOU between the LHD and the hotel and resort chains would be required. It would be the responsibility of the LHD to provide the hotel chains with proper forms, medications, and training of key personnel involved in the dispensing process. It would be the responsibility of the hotel and resort chains to set up and run the POD and provide all medical and non-medical staff required for dispensing; they would also have to demonstrate the availability of space and staff before the MOU could be signed. Hotel and resort chains often have an occupational nurse on staff for issues such as workers comp or may choose to contract with an industrial health clinic, local nursing float pool, or a medical consultant firm. The non-medical staff would be taken from the existing hotel staff.

The advantage of this mode of dispensing is that it reaches a population that may otherwise have difficulties finding and traveling to a regular POD. In addition, no additional clinical or non-clinical staff would need to be provided by the LHD in an emergency. The primary disadvantage would be the amount of effort required to develop MOU with large hotel chains and settle liability issues within the MOU. While MOU are required in all dispensing options, some are more difficult and time-consuming to establish than others.

DISPENSING THROUGH LARGE HEALTH MAINTENANCE ORGANIZATIONS

Health maintenance organizations (HMO) are a type of a managed care organization that provides both health insurance and health services. In the Denver Metro Area a unique relationship has developed between the LHD and Kaiser Permanente, the largest health care provider in the area. Kaiser Permanente typically conducts a drive-thru flu clinic in the area and therefore has experience in mass prophylaxis. Kaiser Permanente also has the clinical and non-clinical staff to support mass prophylaxis as well as the location and partnerships to set up a drive-thru POD. The MOU between the LHD and Kaiser Permanente states that the LHD is responsible for providing Kaiser Permanente with prophylactic medications and forms. It would be the responsibility of Kaiser Permanente to dispense medications to their members and employees (and families of employees) only.

Advantages of this mode of dispensing are that it requires no clinical or non-clinical staff from the LHD, there is a potential that the HMO could also provide their own trucks and drivers for medication retrieval from the warehouse, and people are familiar with and trust their HMO for medical assistance. Also, health maintenance organizations are often sizable employers in addition to having large numbers of members, which can significantly lessen the number of individuals seeking care from the POD. The only disadvantage is the amount of effort required to set up an MOU that clearly delineates the responsibilities of each entity.

DOOR-TO-DOOR DISPENSING

The 2004 MOU between DHHS and the United States Postal Service (USPS), known as the postal plan, states that the USPS would suspend mail delivery during an emergency and bring medicine directly to homes.⁵⁶ This option would only be available to areas designated as Cities Readiness Initiative (CRI) areas based on population and geographic location.⁵⁷ As of 2006 there are seventy-two CRI areas in the United States.⁵⁸ The postal plan is subject to availability of

resources and funding and is entirely voluntary on part of the USPS.⁵⁹

In this mode of dispensing, postal employees would deliver a single bottle of doxycycline to each household, to provide individuals with the first dose and prevent initial surge at POD and giving LHD the time to gather resources. On November 11, 2006, postal employees delivered empty cardboard boxes and information flyers to residents in certain Seattle neighborhoods. During the nine-hour exercise, forty-one postal employees accompanied by armed police officers delivered medications to 38,000 households. Based on the average household size in Seattle, (2.05 people), the LHD could have initially kept 77,900 people (15 percent of the population) away from POD.⁶⁰

In non-CRI cities, other resources might be utilized. In Chesapeake, Virginia, the LHD partnered with school districts to accomplish the task of prophylaxing its population of 218,000. Using school buses, bus drivers, escort vehicles, and eight medical personnel, the LHD dispensed medication to 1,100 individuals in less than two hours driving door to door. The receipt was confirmed by a phone call into an automated system that kept track of the delivery via geographic information system (GIS). The Chesapeake Health Department now plans to prophylax their entire population using 200 school buses and with help from local Community Emergency Response Teams (CERT) and the Medical Reserve Corps (MRC).⁶¹ Similarly, LHD could choose to contract with UPS, FedEx or DHL to provide door-to-door delivery. All major delivery service providers have a logistic infrastructure that includes personnel, GIS tracking, and route planning software.

The main disadvantage to this mode of dispensing is the security requirements. However, the Presidential Executive Order signed by Barak Obama calls for supplementing local law enforcement personnel with local federal law enforcement officers as well as other appropriate personnel to escort postal workers delivering prophylactic drugs.⁶²

DRIVE-THRU POD

Drive-thru POD originally gained popularity as a mechanism to deliver influenza prophylaxis to the elderly. A review of the program in the post-9/11 era determined that the program could be used to provide personal protective equipment and prophylaxis to the population while maintaining some form of isolation. The drive-thru POD have a simple set up: patients drive to the site and, while in their car, receive informed consent, have a brief history taken (to prevent contraindications), and then receive immunization without leaving the vehicle.⁶³

Drive-thru POD should be located close to major roads, highways, or freeways in order to prevent traffic jams. It is strongly recommended that the ingress and egress points be large enough to allow multiple lanes of traffic. Similarly, the location should be large enough to accommodate multiple lanes for dispensing.⁶⁴

The Orlando Health Department plan calls for ten lanes of dispensing to ensure a high throughput and to prevent overflow of traffic onto neighboring streets.⁶⁵ They predict a reduction in the number of staff needed (compared to the traditional POD) and anticipate prophylaxing 60 percent of their population using this method.⁶⁶

The main advantage of drive-thru POD is that they are regularly used as flu vaccination clinics each year. Space requirements are much more dynamic and are not bound by the strict constraints of traditional POD. In terms of security, law enforcement agencies have stated that they find it much easier to control traffic at a drive-thru POD than at a traditional POD.⁶⁷ Another advantage to using drive-thru POD is that the environment within the car can be climate controlled, hence protecting the population from extreme heat or cold.

There are some disadvantages to using a drive-thru POD. The POD staff is exposed to the weather conditions and the LHD is still responsible for providing all POD staff. Drive-thru POD would be limited to daytime operations and the LHD must plan to remove cars that break down or run out of gas. There is also an increased risk of careless or

panicked drivers, road rage, and carbon monoxide/dioxide exposure.

DISPENSING THROUGH RETAIL PHARMACIES

Private sector pharmacies, located at retail stores, wholesale markets, and stand-alone buildings, could also be a potential partner for health departments during a public health emergency requiring mass prophylaxis. There is a retail pharmacy within five miles of 95 percent of the US population.⁶⁸ Every year, large retail stores with pharmacies and private pharmacy chains conduct influenza vaccination clinics at their facilities. Some of these conduct their vaccination campaigns internally, whereas others contract with private community-based health service providers to organize their campaign and provide the vaccination service.⁶⁹ Twenty-five to thirty million doses, accounting for one-third of the nation's flu vaccine, were administered by retail store/wholesale store pharmacies and private chain pharmacies.⁷⁰

Many private retail companies would be willing to work closely with the LHD during mass prophylaxis. Dr. Onora Lien interviewed executives from various grocery store retail pharmacies and pharmacies located within chain wholesale clubs and they were almost undivided in their endorsement and interest in planning for and responding to a public health emergency.⁷¹ Representatives from these businesses noted that although they were a "for-profit" business there was a "strong connection between assisting during an emergency and maintaining or improving their reputation within the community."⁷²

Advantages of this mode of dispensing are that no staff would be required from the LHD and many pharmacies have ample outdoor parking as well as the indoor space to accommodate a large number of people and maintain their normal operations. In addition, pharmacies have electronic inventory systems to receive and manage SNS inventory, a secure location to store drugs, medical staff to meet federal and state dispensing requirements, and non-medical staff who can serve essential functions during the dispensing process.⁷³

An MOU needs to be established with the pharmacy chain and potentially with each individual pharmacy. Due to a large number of pharmacies in any area, it is necessary to consider geospatial analysis and find optimal locations such as areas without POD, areas with low security concerns, and areas with a moderate population density.

CHOOSING AMONG THE ALTERNATIVE MODES OF DISPENSING

There are several alternate modes of dispensing available for local health departments. However, each alternative requires a substantial amount of effort to be able to implement it. This represents a

serious additional workload at a time when most LHD are understaffed to run their daily functions.⁷⁴ Most LHD will not be able to pursue all of these options. Therefore, it becomes necessary to choose among them. Table 1 summarizes the advantages and disadvantages of each alternate mode of dispensing.

The optimal choice for a LHD will be determined by a number of different variables depending on the relative importance of speed of dispensing, population reached, security, and staffing requirements. Additionally, the LHD must take into account the costs and political ramifications associated with the alternate modes of dispensing as well as the specific legal quandaries raised by the alternate modes of dispensing.

Alternate Mode of Dispensing	Type	Clinical Staff through LHD	Non-clinical staff through LHD	Security Needs	Numbers Reached	Other Considerations
Prepositioning of medications	Closed	No	No	Low	Low	Ensures staff for POD and hospitals is ready prior to mass prophylaxis
Dispensing at businesses	Closed	Maybe	No	Low	High	Businesses become involved in community
Dispensing to SIP	Closed	No	No	Medium	Low	Without special assistance this population may not otherwise be able to receive prophylaxis.
Dispensing at colleges / universities	Closed	Maybe	No	Medium	Medium	Implementation becomes easier if there is a campus environment
Dispensing at hotels	Closed	Maybe	No	Low	Medium	Effectively deals with the non-local population (business and tourist)
Dispensing at HMO	Closed	No	No	Low	High	Only provide prophylaxis to those having a particular health insurance
Door-to-door dispensing	Open	No	No	High	High	Voluntary program that currently requires a large security component
Drive-thru dispensing	Open	Yes	Yes	Medium	Medium	Savings in terms of staffing are small, speed of dispensing is slower
Dispensing at pharmacies	Open	No	No	Medium	Medium	Convenient locations and strong bond with community

Open – anyone may receive prophylaxis

Closed – prophylaxis is only available to a specific subpopulation

Table 1. Comparison of Alternate Modes of Dispensing

Costs associated with alternate modes of dispensing break down into two major subcategories: preplanning costs and implementation costs. Preplanning costs are those associated with setting up an option, whereas implementation costs those incurred when the option is implemented during an emergency. Both costs can be difficult to define, estimate, or measure and may include work-hours lost to the project, employee salary and benefits, contractor fees, and travel. Although cost of implementation may be overlooked during an emergency, it is very unlikely that public and private partners would ignore the need to estimate both types of costs during the preplanning phase.

By partnering with other agencies, LHD make the problem of mass prophylaxis a community-oriented problem and private partners may fill gaps that LHD cannot. However, especially when using closed models of dispensing, LHD may be accused of favoritism for exercising one option and not the other.

There are several legal issues, liability (tort and workers compensation) in particular, that may hinder the implementation of any mass prophylaxis plan. Chester Lee Smith, from the Georgia Division of Public Health, hosted several meetings with BENS members and their legal representatives between October 2003 and January 2007. During these meetings it emerged that the liability issue was of great concern to all potential partners in the private sector.⁷⁵ Private partners must also consider that insurance companies may refuse to cover claims resulting from injuries, as dispensing medications is not a part of their normal operations.⁷⁶

The government has made significant strides in alleviating some of these concerns by passing the Public Readiness and Emergency Preparedness (PREP) Act in 2005, which, when issued by the secretary of the Department of Health and Human Services, provides immunity from tort liability (except for willful misconduct) for both the administration and use of countermeasures.⁷⁷ The federal government as also instituted the Volunteer Protection Act of 1997,⁷⁸ but many feel that this act has too many loopholes to be effective and states have the ability to opt out of the act entirely.

This raises the issue that states do not have a uniform approach to the issues of liability. Most states have a range of legislation surrounding “Good Samaritan” laws, but the strength and coverage of these laws varies from state to state and is very confusing.⁷⁹ The BENS members at these meetings recommended new legislation or changes in current legislation such as the states’ “Good Samaritan” laws that would protect them from legal liability and litigation occurring from incidental injuries but not from willful negligence.⁸⁰

CONCLUSION

Many LHD may find it extremely difficult to prophylax their entire population within forty-eight hours using only their POD because of staffing, security, and site availability concerns. Local health departments could open more POD, but this would not resolve the issue because the number of POD is directly correlated to the requisite number of resources. The Trust for America’s Health determined that “ensuring the public can quickly and safely receive medications during a major health emergency is one of the most serious challenges facing public health officials” and that many states still do not have viable means of addressing volunteer staffing issues.⁸¹ Considering that resources will always be under pressure it becomes necessary for public health officials to consider alternate modes of dispensing.⁸² This implies that LHD will need to conduct analyses to determine the best alternate modes of dispensing for their jurisdictions. This is a difficult task since each mode of dispensing has a unique set of advantages and disadvantages.

As a starting point, each LHD needs to make a realistic assessment of how many traditional POD it will be able to make operational in a few hours time. This will allow the LHD to determine the amount of unmet need. Workshops or tabletop exercises designed specifically to evaluate total system response capacity and capacity resource requirements would be a good starting point to make this assessment. Traditional exercises such as those listed in the HSEEP

guidance are operationally focused either as functional exercises – such as running one or a couple of dispensing options for a short period of time – or simulating actual responses to a mock incident or conducting discussions (workshops, games, tabletops) with a similar focus.

While helpful, these exercises do not focus on the total response effort required, typically assuming perfect scalability. While the HSEEP evaluation methodology could still be used as a means of evaluating the workshops/tabletop exercises, the exercises themselves would need to be refocused to assess the total response effort required. Only by doing a complete systems analysis of all of the planned response elements within the health department's jurisdiction will a solid assessment of the degree to which the public's needs are met by the response plan become apparent. This analysis must also include the total response requirements for each entity involved in the plan (health department, security/law enforcement, government, transportation, community partners). For these efforts, it is critical to bring together LHD staff, health professionals, government officials, police and other law enforcement personnel, their response plans, and the assumptions that each agency makes about the actions, capability, and availability of the other agencies. The discussions will need to center around these assumptions and their realism as well as the total response effort needed to meet the federal mandates.

After such a workshop/tabletop exercise, a realistic picture of the constraints within the community should become apparent. Important questions include estimates of the number of sites required and the staffing needed to support all of these sites; the quantity of medical professionals that have been double counted; estimates on the number of law enforcement personnel who will be committed to tasks ensuring an orderly society (and not available to a dispensing operations); logistics of deploying large numbers of non-medical volunteers; logistics of on-the-spot credentialing of medical personnel who spontaneously volunteer; availability (and timeliness) of using assets from the National Guard, military bases, police academies, etc; and the

suitability and logistics of the POD sites that are not within the top ranked choices. Given this information, the LHD can consider what aspects of their POD plan are most in need of supplementation – sites, security, staffing, throughput, locations, etc. – so that the relative importance of addressing the different criteria becomes clearer.

Once the gap analyses have been completed, and resource needs and their relative importance/priority determined, the next question is how to best remedy these needs. The decision makers for each jurisdiction, potentially the local health department or other emergency response agencies or a consortia of response agencies, need to choose, in concert with their community partners, what combination of POD and alternate modes of dispensing best meet the needs of the population within their jurisdiction. Table 1, adapted and expanded to reflect the specific details of the jurisdiction is a good starting point for building an augmented system. If too many options are available in a given jurisdiction, or if the preferences and priorities vary widely between community partners, tools from the field of decision analysis, such as multi-criteria decision-making, can facilitate the analysis and subsequent discussion necessary to make well-informed choices. The Los Angeles County Department of Public Health conducted such an analysis for two types of dispensing situations.⁸³ This research provides a template for the analysis but the results will necessarily vary by jurisdiction and the specific needs and gaps identified in each case.

Areas of future research should include full systems analyses of a jurisdiction's response capability showing how an integrated approach could provide potential solutions to existing capability and staffing limitations. Ideally this would include analyses for jurisdictions of different sizes and geographical locations to see if there are any global best practices or combinations that appear to work best with certain types of localities or geographical features or population demographics.

There are many options for expanding mass prophylaxis dispensing, each with its own particular set of benefits and drawbacks. It is of utmost importance to have a realistic

sense of potential areas with resource constraints if the jurisdiction relies solely on the traditional POD system. The key is to evaluate the overall system from all response partners' perspectives to ensure that plans can be translated into reality in a full response situation. Only this type of holistic analysis will reveal limitations within the current policy. It is important for government agencies at various levels to realize that a "one size fits all" approach is likely to fall short given the incredible diversity in our cities and states. It is equally important for individual jurisdictions to thoughtfully assess their individual situations and decide, once the constraints in a particular jurisdiction are identified, which alternate modes of dispensing can be pursued to best supplement the system. Only once this is done can the local health departments be assured they are providing the best service possible to the public that relies on them.

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