PRACTICE REPORT

Guide for mass prophylaxis of hospital employees in preparation for a bioterrorist attack

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Purpose. The key elements required for the health-system pharmacist to prepare and implement a hospital-based mass prophylaxis distribution effort for hospital employees are described.

Summary. A bioterrorist attack may involve multiple jurisdictions which would necessitate a regional response. Pharmacists should collaborate not only with colleagues in their immediate areas, but also with pharmacists and emergency-management planners in neighboring counties and jurisdictions. Pharmacists must also develop antibiotic drug selection protocols and define the quantity needed to maintain hospital operations after a bioterrorist attack. Once the desired antibiotics have been selected and the number of employees has been determined, along with the length of prophylaxis therapy, it should be determined how much money will be needed to purchase and store enough medications to meet the need. Next, provisions must be made to acquire and store the antibiotic cache, with attention paid to cache rotation and packaging and repackaging recommendations. A detailed procedure for the deployment of an antibiotic cache must be developed. This procedure should include job descriptions and job action sheets for deployment team members and plans for receiving and dispensing antibiotics from the Strategic National Stockpile. Once the employee prophylaxis procedure is developed, staff must be educated about it, and exercises should be conducted to identify possible weaknesses in the procedure.

Conclusion. Health-system pharmacists should play an active role in designing and implementing an antibiotic prophylaxis plan for employees for a potential bioterrorist attack. Understanding and following procedures provided in the tool kit are critical to their successful readiness.

Index terms: Antiinfective agents; Biological warfare; Disaster planning; Drugs; Guidelines; Hospitals; Personnel; Pharmacists, hospital

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After the 2001 terrorist attacks on the World Trade Center and the anthrax mailings shortly thereafter, it became widely apparent that the need for timely access to prophylaxis medications is a significant logistical endeavor. The bioterrorist agents of most concern are referred to by the Centers for Disease Control and Prevention (CDC) as category A disease agents.[1] Certain diseases caused by some of these agents can be prevented with adequate antibiotic prophylaxis and include anthrax, tularemia, and plague.

When considering the potential release of an aerosolized agent, such as *Bacillus anthracis* spores, a region's response plan generally involves establishing multiple community point-of-dispensing (POD) units throughout the area. The goal of these POD units is to dispense prophylaxis medications to the affected population within 48 hours of the release. Unlike the nonaerosolized *B. anthracis* spores that were sent through the U.S. mail in 2001, an aerosolized category A agent could be distributed in a fashion that would expose thousands of individuals. Since the scope of exposure may not be known early in such a crisis, there may be a need to provide prophylaxis to a large segment of the community.

In addition to these community POD units, the affected region's health care systems must be prepared with an analogous prophylaxis response plan for their employees. The primary objective of any hospital-based prophylaxis strategy is to provide an alternative to the community POD

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units in order to keep employees at work and maintain hospital operations during and after a bioterrorism event. Employees and family members would receive prophylaxis only if they were considered to have possibly been exposed. The response plan should be activated as soon as possible after such an event and well in advance of the community POD being established. This strategy will encourage a hospital's workers to report to work rather than having to leave work to obtain medications for themselves and their families from community POD units.

Establishing a hospital-based POD involves drug acquisition, storage, and distribution. During such an event, pharmacists will undoubtedly be working in a high-stress and often chaotic environment. In order to be successful in this endeavor, a detailed and complete procedure must be developed and tested in advance. The role of the health-system pharmacist is vital to the success of such a plan. While hospitals generally have emergency-preparedness plans, those plans may not adequately address the details of a mass prophylaxis effort.

Pharmacists must supervise and dispense medications at a POD and ensure that a detailed mass prophylaxis procedure, which has been successfully tested, is in place. This article outlines the key elements required for the health-system pharmacist to prepare and implement a hospital-based mass prophylaxis distribution effort for hospital employee. For supplementary information, textbooks discussing pharmacy preparedness[1,2] and the ASHP public health resource center on emergency preparedness[3] are recommended.

Hospital Incident Command System

Before developing a mass prophylaxis procedure, the health-system pharmacist must be aware of the Hospital Incident Command System (HICS),[4,5] which helps hospitals comply with the larger National Incident Management System put forth by the Federal Emergency Management Agency.[6] The HICS uses a standardized hierarchical administrative structure similar to that utilized by emergency-response personnel (e.g., firefighters, police officers) during a disaster, creating a chain of command to organize emergency responders during a crisis to prevent the chaos that could result from lack of coordination. Many hospitals have adopted either the HICS or its predecessor (Hospital Emergency Incident Command System), and the pharmacist must be aware of how the HICS is implemented within his or her institution and to whom the pharmacist reports. Each person within the command structure has clearly defined duties.

Preparing the health system for a bioterrorist event

In addition to understanding the necessary steps for preparing a health system for a bioterrorist event, the health-system pharmacist may utilize the online tool kit, which is a comprehensive procedure for the deployment of an antibiotic drug cache.[7] The tool kit contains job action sheets for deployment personnel, drug protocols for antibiotic prophylaxis (including diagrams and pediatric dosing tables), a detailed description of the POD, detailed instructions for preparing and dispensing a 72-hour supply of antibiotics, and sample forms (including a medical screening form, dispensing log, disease fact sheets, prescription labels, and drug information sheets).

Step 1: Seek collaboration within your region. A bioterrorist attack may involve multiple jurisdictions, which would necessitate a regional response. Pharmacists should collaborate not only with colleagues in their immediate areas, but also with pharmacists and emergency-management planners in neighboring counties and jurisdictions. By doing so, shared needs can be identified and collaborative efforts on disaster preparedness may be facilitated. In many cases, pharmacists may already be actively working on plans that directly affect their hospital's and their overall region's state of disaster preparedness and would be willing to share information. This may prevent duplication of efforts and could benefit the regional health system directly.

Local county emergency medical services will often support a partnership with pharmacists in their jurisdiction who are willing to volunteer to assist during public health emergencies and offer resources and support during exercises and an actual event. Forming these relationships before an event is crucial. These pharmacists may be in a subcommittee of a local pharmacy association chapter or an independent core group that would be willing to orient and train other pharmacists eager to participate as volunteers during exercises and actual events.

Area hospitals within the local community can also work together to develop plans that would assist in maintaining disaster preparedness. Collaboration may include the funding, acquisition, and forward placement of stockpiled medications to include antibiotics, antivirals, and nerve agent antidotes. Pharmacists can also assist in the development of regional or local pharmaceutical caches, which may be used during a mass casualty event requiring postexposure prophylaxis or treatment.

By forming a health care disaster-preparedness council that meets periodically and includes all of the local area hospitals, an ongoing disaster-preparedness effort can be maintained. Membership should include the hospitals' safety officers and key medical personnel, including pharmacists. Additional members should be local government emergency-preparedness planners, law enforcement, fire officials, and military contacts, if appropriate. Depending on the magnitude of the event, many of these council members may be working together under the incident command system and would benefit

by forming these multijurisdictional partnerships well in advance.

Lastly, pharmacists should consider subscribing to the Strategic National Stockpile (SNS) e-mail listserver. This is a nationwide forum, administered by the SNS, to facilitate the sharing of information, ideas, and tools among emergency-management planners. To subscribe, pharmacists can e-mail a request to listserve@list.nih.gov.

All emergency-preparedness activities should be supported by the health system's administration and emergency-preparedness committee. The role of the health-system pharmacist in emergency preparedness has been well articulated by a position statement written by the American Society of Health-System Pharmacists,[8] and every pharmacy director should be familiar with its contents.

Step 2: Develop protocols for antibiotic drug selection. Postexposure prophylaxis for the agents that cause anthrax, plague, and tularemia is effective and cost-effective with doxycycline or a fluoroquinolone (e.g., ciprofloxacin).[9-16] A recent article by Brouillard et al.[9] discussed the susceptibility patterns and differences in cost, based on available data, of ciprofloxacin and doxycycline. Although the authors discussed the possibility that ciprofloxacin is more effective than doxycycline for the treatment of inhalation plague, this finding was based on one study conducted with mice whose lungs were directly inoculated with the bacilli. With human data lacking on inhalation plague, ciprofloxacin was not selected as the primary antibiotic cached in our region (San Diego). When doxycycline was compared with ciprofloxacin with respect to efficacy, adverse effects, and cost, doxycycline was determined to be the preferred antibiotic in the management of category A bioterrorism agents in our region. This recommendation is also consistent with other jurisdictions, including our neighboring Los Angeles County, as well as with CDC recommendations.[10]

Penicillins may be effective in the treatment of anthrax, but concerns exist regarding resistance.[10] Therefore, treatment of anthrax with amoxicillin should not commence until culture and sensitivity results are confirmed, contraindications to doxycycline and ciprofloxacin exist, and at least 14 days of therapy with either doxycycline or ciprofloxacin has been completed. Since the goal of this project is to provide initial prophylaxis of antibiotics until additional resources become available (i.e., 3–14 days), amoxicillin will be omitted from the cache.

The online tool kit contains a complete drug protocol.[7] In summary, individuals should receive either doxycycline or a fluoroquinolone. For cost purposes, we chose to limit the use of ciprofloxacin to those who are allergic to tetracyclines.

Once a protocol is developed, it should be approved by the appropriate entities within the health system (e.g., infectious disease division of the medical staff, pharmacy and therapeutics committee, emergency-preparedness committee, employee health department).

Step 3: Define the quantity needed to maintain hospital operations. When deciding the quantity of medications to stockpile, begin by obtaining the number of employees of various departments within the system. Similarly, a list of physicians with hospital privileges can be obtained from the medical staff office. Since funding sources are typically limited, planners may be faced with some difficult decisions as to who is considered critical to the operations of the hospital. Planners need to clearly identify in advance which employees and physicians will be eligible for prophylaxis through the hospital-based POD and which should be referred to public PODs. Once eligibility is determined, the goal length of prophylaxis should be determined. We chose three days, which we believed was enough to get through the initial event and allow SNS assets to arrive.

When determining the quantity of antibiotics to purchase, it is important to account for employees' family members as well. We recommend using a family household factor of 3–5. For example, a family household factor of 3 represents the employee plus two family members, whereas a family household factor of 5 represents the employee plus four family members. Each facility must clearly define the term "family member." We defined this as a family member (or a caregiver of a family member) or significant other residing in the same household.

Step 4: Obtain a funding source for the antibiotic cache. Once the desired antibiotics have been selected and the number of employees and length of prophylaxis therapy have been determined, the cost to purchase and store enough medications to meet the need for prophylaxis should be estimated. Funding sources may be federal or state grants or budgeted money by individual hospitals for disaster preparedness. In our case, monies were available for hospitals throughout San Diego County from the Health Resources and Services Administration (HRSA) National Bioterrorism Hospital Preparedness Program. Amounts for each hospital were determined based on the bed size of each hospital.

One must also determine how replenishing the cache will be funded. In our case, when the money for each hospital was determined, the amount allocated by HRSA to each hospital exceeded the amount required to purchase and stock a three-day supply for employees and their families (using the household factor of 3). In some cases, it exceeded the amount by two or three times. To best utilize the money, many hospitals worked closely with their wholesalers and were able to establish credit for remaining monies to be kept with the understanding that they would be used once the "first wave" of antibiotics expired. This strategy essentially extended the vi-

ability of the project for many years beyond what would have normally been had the money been spent in "one wave."

Step 5: Acquire and store the antibiotic cache. *Acquisition.* When purchasing the antibiotics, it is important to work closely with your wholesale supplier. Alternatively, if the quantities you intend to purchase are large enough, you might decide to work directly with a generic drug manufacturer or repackager. In our case, the quantities per hospital were not large enough to warrant this, and we worked with the wholesale supplier. An important aspect to consider is the shelf life of the various brands and dosage forms offered. For example, we found that doxycycline capsules, though a bit more expensive per unit, offer upward of a twofold shelf-life advantage (four years versus two years) over doxycycline tablets.

One helpful formula to use when analyzing and comparing different lots and prices of brands of an antibiotic is to divide the price per unit by the shelf life, which yields a unit price per day of shelf life (Table 1).

Storage considerations. Because of issues with accessibility, accountability, security, cost of goods, and stock rotation, pharmaceutical caches should be segregated from normal stock in an onsite locked area to ensure accessibility and availability when needed. Antibiotics should be stored in a secured, climate-controlled environment (59–86 °F). Medications should be routinely inspected for expiration and degradation.

Cache rotation. To avoid antibiotics from expiring unused and thus to avoid waste, the feasibility of antibiotic cache rotation was examined so that a perpetual inventory of stockpiled antibiotics can be rotated into the hospital supply when their expiration date is within six months. We compared the numbers of doses needed to be kept available for employees with the approximate annual use of ciprofloxacin or doxycycline and found that the amount represented only 2–3% of the total antibiotic cache. Given the relatively low cost of these drugs, the labor needed to do the rotation, and the relatively small amount of these medications for general use compared with what is needed to be cached, we decided that it was not feasible to rotate the cache.

Repackaging and packaging recommendations. To preserve the original expiration date established by the manufacturer, medications generally need to be repackaged from manufacturer bulk containers by a licensed repackager; however, doing so adds substantially to the cost, effectively reducing the number of available doses. Because our hospitals employ full-time pharmacists, we chose to purchase and store bulk bottles. In the event the decision is made to initiate prophylaxis, pharmacists and pharmacy technicians will repackage and dispense the medications while adhering to the appropriate record-keeping requirements. The online tool kit lists supplies needed to be kept with the cache for repackaging.[7]

Table 1.
Sample Calculation To Determine Optimal Choice Between Alternative Products

Drug	Quantity	Price	Price/Unit	Shelf Life (Days)	Unit Price per Day of Shelf Life[a]
A	500	$20	$0.04	500	$0.00008
B	500	$30	$0.06	1000	$0.00006

[a]If drug A is $20 for 500 capsules and expires in 500 days and drug B is $30 for 500 capsules and expires in 1000 days, this shows that drug B is most cost-effective.

Step 6: Develop procedure for deploying antibiotic cache. Developing a detailed procedure for deploying an antibiotic cache is crucial. Given the high expectations of accurately delivering medications to all hospital staff and their families within a 48-hour period, it is essential that all staff involved in the deployment have clear instructions, organized leadership, and the materials needed to perform the task. Since creating such an elaborate procedure can be very time-consuming, an example procedure is available in the online tool kit.[7]

Job descriptions and job action sheets for deployment team members. The pharmacy unit leader is the pharmacist responsible for coordinating the deployment of the antibiotic cache. The procedure must be very detailed for this person to be successful in this endeavor and should include the worst-case scenario. It should be assumed that the person writing the procedure will not be available during a real event. Any pharmacist must be able to use the procedure efficiently and effectively. The procedure should also contain detailed instructions for each member of the dispensing team.

Description of POD. The POD is the physical location where the prophylactic antibiotics will be dispensed. There is substantial literature available on the design and operations of a community-based POD,[17-27] but no publications focusing on the details of a hospital-based POD for employee prophylaxis are available to date. Table 2 describes the four basic physical areas into which we divided our POD units.

Instructions for the "pull" versus "push" dispensing techniques. The traditional method of setting up a dispensing area and having all employees flow through that area in order to receive their medication would be considered the "pull" approach. The "push" concept is a strategy to help alleviate congestion in the POD and to avoid having employees who are currently working from leaving their

Table 2.
Distinct Areas of Point of Dispensing (POD)[a]

Location	Personnel	Duties
Triage area	Registered nurses	Identify symptomatic employees and refer them to the emergency department, distribute medical screening form/dispensing log and disease fact sheet, guide employees to briefing area
Briefing area	Employee health nurse or physician, infection control nurse, any other qualified clinician	Brief groups of employees of the following: purpose of their visit, current information on who may have been exposed, disease information, purpose of antibiotic prophylaxis and why different antibiotics may be given, possibility of resupply by the Strategic National Stockpile, description of where employee goes next in POD
Interview area	Registered nurses	Verify that individual is an employee or physician, review medical screening form for completeness and accuracy, identify appropriate drug regimen for all individuals listed on medical screening form
Dispensing area	Pharmacists and pharmacy technicians	Technicians: package and label antibiotic prescriptions, separating them by medication and strength; pharmacists: confirm drug selection identified by interviewer, retrieve packaged prescriptions, fill out names on prescription labels, fill out doses of medications on prescription labels for pediatrics, dispense prescriptions and drug information sheets

[a]See reference 7 for detailed duties of all personnel.

posts. Instead of "pulling" employees into the POD, there should be consideration of "pushing" the medications to the employees, particularly those staff who are needed at the bedside or may be located in distant buildings. Once the POD is functional, unit leaders or managers from the various departments within the hospital go through it for their respective staff. After listening to the briefing, staff bring copies of the medical screening form or dispensing log to their departments. The manager or designee briefs his or her employees, who in turn fill out the form. The manager then brings the forms back to the POD. Medications are dispensed, and the manager brings the medications back to his or her department for distribution.

Plans for receiving or dispensing antibiotics from the SNS. Depending on the initial length of prophylaxis, at some point you will need to assess whether or not more prolonged prophylaxis will be required. When the POD first opens, the details of the exact nature of the exposure are often not available. It is not known exactly who is at risk, and county health officials appropriately decide to administer antibiotic prophylaxis to a very large group of people. As the details of the exposure are determined, the group of individuals at risk is usually narrowed considerably. If hospital employees are determined to be at high risk, then the POD unit may have to dispense the remainder of the duration of prophylaxis using antibiotics on hand or those supplied by the SNS.

Screening form/dispensing log and other forms. Many forms and handouts are needed for an antibiotic cache. The most important form is the screening form/dispensing log. This form is initially completed by the employee. The employee and each family member are listed on the form, along with answers to questions aimed at determining if any drug contraindications are present. The dispensing team completes the remainder of the form, documenting which drug regimen is dispensed to each person. The form expedites throughput in the POD and serves as the dispensing record. Many other forms and supplies will need to be stored with the antibiotic cache,[7] and these items must be prepared in advance of the event.

Step 7: Educate. Once the employee prophylaxis procedure is developed, staff must be educated about it. We chose to utilize live inservice education programs, Web-based training, and exercise participation. Other creative approaches are certainly encouraged. Regardless of the approach used, all pharmacy staff members must be aware of the procedure and their role in it. In addition, since this is something that will hopefully only be conducted during exercises, some type of education or reminder needs to be provided on a regular basis to prevent staff from forgetting the procedure. An example is the use of interactive computer screen savers to maintain awareness of an issue over the long-term.[28] We plan to incorporate a couple of questions about the procedure into our annual competency examinations.

Step 8: Conduct exercises. Exercises can vary in size and description.

In tabletop excercises, several team members from affected departments sit at a table, a scenario is described, and each team member discusses what he or she would do in that situation. Tabletop exercises are the easiest type of exercises to implement, but they provide the least value in helping to identify potential weaknesses in your procedures or in the effectiveness of your training.

Another type of exercise is a live, single-hospital exercise. Again, a mock scenario is played out, but team members go through the motions of performing their duties as if it were a real event. Candy may be used in place of medications. This type of exercise helps to identify potential areas of improvement in your procedures and engage and educate hospital staff.

A live, countywide or statewide exercise possesses the same advantages as the single-hospital exercise, but it also encourages regional collaboration and standardization, tests the interhospital communication systems and incident command structure, and raises the level of awareness and importance of emergency-preparedness planning. These exercises are certainly the most complicated to conduct, but they are coordinated by the local department of health.

Regardless of the type of exercise chosen, participants must establish the goals of the exercise before designing it and deciding at which level to participate. Pharmacists should participate in their hospital's emergency-preparedness committee. This committee is, among other things, responsible for selecting, conducting, and reviewing exercises within the hospital. Pharmacists should advocate for exercises that involve the deployment of pharmaceutical caches. With the assistance of the committee in planning, scheduling, and coordination, the pharmacist can focus on drug-dispensing activities.

Conclusion

Health-system pharmacists should play an active role in designing and implementing an employee antibiotic prophylaxis plan for a potential bioterrorist attack. Understanding and following procedures provided in the tool kit are critical to their successful readiness.

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