

Development of a Pharmacy Point-of-Dispensing Toolkit for an Anthrax Exposure in Allegheny County Postal Workers

by

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University of Pittsburgh, 2022

Abstract

Background

The Center for Disease Control and Prevention (CDC) and the United States Postal Service (USPS) consider anthrax to be a potential threat to U.S. Postal workers. Allegheny County Health Department (ACHD) Pharmacy supports local USPS response in the event of an exposure. The ACHD Pharmacy team identified the need to review and update their response plan due to: updated clinical guidelines from the CDC, CDC Health Care Points-of-Dispensing planning resources, and lessons learned from the previous mass anthrax exposure incident in 2001.

Objectives

To develop a Pharmacy Point of Dispensing (POD) Toolkit that could be used for initial antibiotic mass dispensing operations in the event of an Anthrax exposure. 2) To describe the pharmacist's role in POD medical countermeasure planning.

Methods

The Public Health Emergency Preparedness and Response Planning Model guided the Toolkit development. The planning model consists of three phases.

- Phase 1 involved a needs assessment conducted by a series of stakeholder meetings from January 2022 to February 2022, a review of the current ACHD anthrax response plan, and past anthrax responses in 2001. Stakeholders identified were the ACHD Emergency Response team, ACHD Clinical teams, and ACHD's USPS contacts.

- Phase 2 involved developing strategies to address the needs identified in Phase 1 by reviewing other state health departments' anthrax response strategies as well as collaborating with stakeholders identified in Phase 1.
- Phase 3 involved the development of the first draft of the Pharmacy Point-of-Dispensing Toolkit. The Toolkit contents were then shared with the Advisory Stakeholder Board for feedback.

Results

Several revisions have been made based on feedback. However, some feedback discussed will require future meetings and discussions with specific ACHD teams and personnel.

Discussion/Implications

Development of this Toolkit and response plan highlights pharmacist involvement in medical countermeasures planning and increased overall ACHD Pharmacy involvement in the planning and implementation of the public health response. The Toolkit was created with adaptability in mind. The content of this Toolkit can easily be adopted and revised for mass antibiotic dispensing due to Anthrax or other Category A bioterrorism agents such as Plague (*Yersinia pestis*) or Tularemia.

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1.0 Introduction

As part of the United States Postal Service (USPS) mail processing operations, a Biohazard Detection System (BDS) is used to detect harmful biological agents. The U.S. Post Office located on California Avenue is a sorting facility, meaning large volumes of mail are sorted and pass-through this location daily. The BDS automated system collects an air sample from the mail handling equipment for one hour and concentrates airborne particles in sterile water to produce a liquid sample. Polymerase chain reaction (PCR) technology is then used on the liquid sample to amplify its genetic material, which is then compared to the genetic profile of a biological agent. (Allegheny County Health Department Emergency Preparedness and Response, 2014)

A positive BDS result would suggest that the genetic material in the sample matched the genetic profile of a biological agent, indicating that Postal Service employees may have been exposed. This would trigger the activation of the response plan. The BDS sample would then be forwarded to a Laboratory Response Network (LRN) lab for testing to confirm the positive result. In the event of a positive BDS result, the Allegheny County Health Department (ACHD) would provide the initial ten days of antibiotic medications to USPS employees while awaiting confirmation of the exposure. (Allegheny County Health Department Emergency Preparedness and Response, 2014)

This essay aims to describe the process of developing a Point-of-Dispensing (POD) Toolkit to be used in the event of a mass anthrax exposure at the United States Post Office located at 1001 California Avenue in Pittsburgh, Pennsylvania. A secondary aim is to describe the pharmacist's involvement in medical countermeasures planning for anthrax exposure.

1.1 Pathogenesis

Anthrax disease is caused by *Bacillus anthracis*, a sporulating gram-positive, rod-shaped bacteria normally found in soil. ("What is Anthrax?", 2022) There are four main routes by which spores enter the body: ingestion, transcutaneous inoculation, inhalation, and direct parenteral injection, such as in the case of contaminated heroin. Gastrointestinal anthrax infections most commonly occur in nature when contaminated plants are ingested by animals. *Bacillus anthracis* can also enter through the skin resulting in a cutaneous anthrax infection. This is often associated with edema and tissue necrosis. Inhalation anthrax is most commonly known due to past bioterrorism events. Once the spores are inhaled and reach the alveoli, they are transported to the mediastinal lymph nodes. Since the spores must be deposited in the alveoli, only spores 5 microns or less can travel to the lymph nodes and induce hemorrhagic mediastinitis. Inhaled spores can also cause nasal, pharyngeal, or laryngeal disease, although this is less common. (Wilson, 2020)

Inhalation anthrax is the most deadly of all the types of anthrax infections, with a case-fatality rate as high as 80%. The mortality and morbidity of anthrax disease, in general, are largely related to the production of exotoxins. These toxins enable the bacteria to evade the immune response allowing for the progression of the disease. Clinical presentation of inhalation anthrax also contributes to its poor survival. Often initial signs and symptoms such as fever, cough, myalgia, and fatigue are missed and incorrectly diagnosed for other respiratory illnesses such as influenza and pneumonia. Fatal complications such as meningitis can occur from any type of anthrax infection but have been observed in up to half of people diagnosed with inhalation anthrax. (Centers for Disease Control and Prevention, 2015)

1.2 Previous USPS Anthrax Exposure

A week after the terrorist attacks of September 11, 2001, four anonymous letters laced with deadly anthrax spores and a threatening message were sent to media companies and congressional offices. During the following months, five people died from inhaling anthrax, and 17 others became infected after exposure. Among those who died were two USPS workers. ("Timeline: How the Anthrax Terror Unfolded", 2022) The Brentwood Postal Facility, located in Washington, DC, and the Trenton Postal Distribution Center, located in Trenton, NJ, were impacted the most and consequently remained closed for years for decontamination.

The U.S. Postal Inspection Service teamed up with the Federal Bureau of Investigation Special Agents to form the Amerithrax Task Force. Its investigation spanned nine years and involved a variety of experts in the fields of microbiology and chemistry as well as bioweapons specialists from government, university, and commercial laboratories. (United States Postal Inspection Service, 2021)

At the time, it was not understood how spores spread through the postal facilities and how they escaped sealed envelopes. After a thorough epidemiological investigation, investigative teams determined the sealed envelopes containing *B. anthracis* were the source of the infection at the postal facilities. Prior to this investigation, it was thought spores could not escape a sealed envelope. However, this was disproven after the confirmation of many cutaneous and inhalation anthrax cases among postal workers. Investigators concluded that this aerosolization was most likely due to the use of high-speed mail sorters and air-blowers used for routine cleaning. ("Timeline: How the Anthrax Terror Unfolded", 2022) (United States Postal Inspection Service, 2021)

As a result of this investigation, a variety of initiatives were developed by the US Postal Inspection Service, including enhancements in mail screening to support USPS operations, improvements in intelligence gathering capabilities, and increased training for Postal Inspectors. In addition, investigative protocols and strategies were developed, and a Biohazard Detection System was placed in every mail processing facility in the U.S. ("Timeline: How the Anthrax Terror Unfolded", 2022)

2.0 Review of Relevant Literature

2.1 Lessons from the 2001 Anthrax Mass Exposure Incident

Some of the most common lessons learned from the previous USPS anthrax exposure dealt with poor communication and antibiotic adherence.

Blanchard et al. (2005) conducted a qualitative study evaluating the perceptions of workers at the US Postal Service Brentwood Processing and Distribution Center and U.S. Senate employees and U.S. Senate employees regarding the public health response to the 2001 anthrax exposure incident. They then used that feedback to generate recommendations for improving responses to bioterrorism based on the perceptions of those affected. Several of the concerns expressed in the focus groups were due to poor communication from public health officials. Participants in the focus groups reported inconsistent communication and declining trust in public health agencies as the most common complaints about the public health response. The perceived unfairness of treatment based on race and socioeconomic status was a source of lack of trust commonly reported by Brentwood participants. The lack of information about medications, such as side effects and drug interactions, was also commonly noted among focus group participants.

The results of another qualitative study by Williams et al. (2002) involving 100 randomly selected postal workers at a regional mail facility in Connecticut found many postal workers reported nonadherence or refused antibiotics, citing reasons of disbelief regarding anthrax exposure, problems with adverse events, and poor communication with regard to cultures. Thus, communication about the risks of acquiring anthrax, education about adverse events, and careful management of adverse events are essential elements to increasing adherence.

One study by Shepard et al. (2002) investigated both antimicrobial adherence and reported adverse reactions from six different U.S. sites where *Bacillus anthracis* exposures occurred. Less than half of the participants (44%) reported taking antimicrobial prophylaxis for the full 60 days. Among 2631 individuals who took at least one dose of antimicrobial prophylaxis but stopped before 60 days, 43% reported adverse events as the main reason for discontinuing prophylaxis, 25% perceived low risk for anthrax, and 7% feared long-term adverse effects of antimicrobial prophylaxis. Among the 172 individuals who failed to obtain their anthrax prophylaxis, 54% reported that they perceived their personal risk as low as the primary factor that prevented them from obtaining the recommended antimicrobial agent.

Following the poor antimicrobial prophylaxis adherence rates during the first phase of the bioterrorism-related outbreak of inhalational anthrax, strategies to improve adherence among more than 2,000 Washington, D.C., Processing and Distribution Center (DCPDC) workers were rapidly implemented by a designated CDC task force. Interventions were then evaluated for effectiveness and examined for influencing factors on adherence to assist with future mass prophylaxis distribution campaigns. (Jefferds et al., 2002)

To assess factors affecting adherence, a quantitative survey was administered to a sample of workers. Among 245 workers, 40% reported full compliance with prophylaxis, and 18% had discontinued it. Anxiety and reported adverse effects from antibiotics were the most significant risk factors for discontinuing therapy. Regular public health staff visits helped promote adherence. Workers continuously cited that the opportunity to ask questions and the distribution of patient education materials supported their prophylaxis adherence. Employees stated that this information helped reduce their stress and encouraged them to continue prophylaxis. Workers also recalled

receiving very little information at the POD, and many had forgotten or misunderstood the information that was given. (Jefferds et al., 2002)

The interventions that proved to be successful were repeated visits, allowing enough time for workers to ask questions, medication counseling, incorporating pill-taking into daily routines, and providing workers with as much information as possible about anthrax and antimicrobial therapy. CDC taskforce members' recommendations following this study for successful adherence promotion efforts include incorporating continual follow-ups with affected persons, providing consistent and clear patient education, and including interventions that help persons incorporate pill-taking into daily routines and manage known adverse effects. (Jefferds et al., 2002)

The major findings of these studies demonstrate the need to address antibiotic adherence when planning for future mass dispensing of antimicrobial prophylaxis, as well as the importance of clear and consistent public health communication.

2.2 Medical Countermeasure Planning and Response

Following the events of September 11, 2001, The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was passed by Congress and signed into law by President George W. Bush in 2002. The Bioterrorism Act addressed the accelerated approval of priority Medical Countermeasures (MCM) and the development of a final rule on animal models when human studies are not feasible or ethical. Additionally, it established the Strategic National Stockpile (SNS). ("MCM-Related Counterterrorism Legislation", 2022) (Public health security and bioterrorism preparedness and response act of 2002, 2002)

The SNS Program was created to support state and community response to public health emergencies by ensuring the availability of essential medications, antidotes, and medical supplies to combat biological diseases and chemical nerve agents. The CDC oversees the SNS and provides guidance on dispensing operations. The SNS Program is able to deploy and arrive at any location across the country within twelve hours to supplement medical resources. Despite its rapid response, it is not within the responsibilities of the SNS program support staff to be utilized as a stand-alone first response team. Additionally, HHS has established the National Disaster Medical System (NDMS) for rapid response to medical disasters, but both of these programs are not meant to replace planning and operations at the state and local levels. Rather, these national resources should be used to support the local response capabilities for mass prophylaxis. As a result, local and state health departments across the country are responsible for developing and maintaining the initial and ongoing capacity to dispense mass antibiotics and conduct vaccination campaigns tailored to their population's specific needs. (Hupert, Cuomo, Callahan, Mushlin, and Morse, 2004)

In 2011, the CDC published the Public Health Preparedness Capabilities: National Standards for State and Local Planning. It is comprised of 15 capability standards designed to improve the state and local health departments' emergency preparedness and response. It serves as a resource for state and local public health agencies to assess, plan and improve emergency preparedness and response capacity by helping guide program improvement initiatives that address gaps in preparedness and response planning.

The Public Health Emergency Preparedness and Response Planning Model outline a process that public health agencies should follow to identify public health program development priorities for emergency preparedness and response. The planning model recommends a three-

phase approach to identify needs and implement an emergency preparedness planning and response strategy.

- Phase 1: Assess the Current State. This consists of assessing roles and responsibilities within the organization as well as within community-based partners. It is important to understand everyone's roles ahead of time and determine what each organization or department will be tasked with during an emergency response effort. The first phase also consists of assessing resource elements and performance to better determine the extent of the availability of resources, who is responsible for providing specific resources, and how to learn and improve from previous response efforts.
- Phase 2: Determining Strategies and Activities by reviewing current and prior emergency response plans and using those to identify issues and gaps in response planning.
- Phase 3: Develop the Plan. A good plan should be sustainable, have short-term and long-term goals, and be regularly evaluated. (The Centers for Disease Control and Prevention, 2022)

Another CDC Health Care Points-of-Dispensing recommended planning resource is a planning guide for public health preparedness created by Weill Medical College of Cornell University faculty in the Department of Public Health. This guide focused on community-based mass prophylaxis planning and was created for the Agency for Healthcare Research and Quality under HHS. This planning tool outlines the five components of a mass prophylaxis response to epidemic outbreaks and focuses on planning and conducting dispensing operations from Points of Dispensing sites (PODs). POD planning is initiated by a series of questions that prompt organizers to think about who are the key stakeholders, what resources are required, as well as where, when,

and how mass antibiotic dispensing will work. The guide also includes sample patient flow plans. (Hupert, Cuomo, Callahan, Mushlin, and Morse, 2004)

2.3 Current Guidelines and Recommendations

In February of 2014, the Centers for Disease Control and Prevention (CDC) expert panel met to discuss the prevention and treatment of anthrax in adults. The following recommendations were made:

2.3.1 Initiation of antibiotic post-exposure prophylaxis (PEP)

Anthrax antibiotic PEP is recommended for all individuals who have been exposed to aerosolized bacteria anthracis. Ideally, antibiotics should be administered within 48 hours of exposure since their effectiveness declines with time. (Wilson, Anthrax Prevention 2020) (Hendricks et al., 2014)

2.3.2 Recommended Regimen

All individuals should receive both 42 to 60 days of either Ciprofloxacin 500mg every 12 hours or Doxycycline 100mg every 12 hours. Pregnant and nursing individuals should preferability receive a Ciprofloxacin regimen to eliminate potential harm to the fetus or infant. The Food and Drug Administration (FDA) approved three oral antimicrobial agents for anthrax post-exposure prophylaxis: Ciprofloxacin, Doxycycline, and levofloxacin. Doxycycline and Ciprofloxacin are

recommended first-line options based on proven efficacy in primate studies and are stockpiled by the United States for this purpose. (Wilson, Anthrax Prevention 2020)

2.3.3 Duration of Regimen

The duration of antibiotic therapy depends on age, immune status, pregnancy status, and vaccination status. For individuals who had not received pre-exposure vaccination, antimicrobial duration ranges from 42 to 60 days. The prolonged duration of therapy is due to the individual's presumed risk of developing inhalation anthrax from ungerminated spores that remain in the lung tissue. The individual is at risk until the immune response from the vaccine becomes protective. Prior to ACIP updated vaccination recommendations in 2019, all individuals were advised to receive 60 days of antibiotic therapy. However, recent immunogenicity data demonstrated high levels of protection two weeks after the last dose of the vaccine. (Hendricks et al., 2014) (Bower et al., 2019)

For this reason, it is recommended that nonpregnant, immunocompetent adults aged 18 to 65 years who completed the post-exposure vaccination regimen on schedule should continue antibiotic therapy for 42 days after the initiation of the vaccine series. Individuals younger than 18 and older than 65, Adults with immunocompromising conditions or receiving immunosuppressive therapy, individuals who are pregnant or breastfeeding, or any individual who was unable to complete the post-exposure vaccination regimen are recommended to receive antibiotics for 60 days. (Bower et al., 2019)

2.3.4 Vaccination Regimen

In the United States, the only FDA-approved anthrax vaccine licensed for human use is the anthrax vaccine adsorbed (AVA) or commercially known as BioThrax. It is recommended by the CDC as part of the PEP regimen for inhalation anthrax exposure, in addition to antibiotics. AVA for anthrax PEP can only be obtained through the CDC or state and local health departments. (Wilson, Anthrax Prevention 2020) It is recommended that vaccination begins within ten days of exposure. Under normal circumstances, one injection (0.5 mL) given subcutaneously at day 0, 2 weeks, and four weeks postexposure is preferred for PEP due to higher antibody concentrations and a higher four-week survival rate. (Bower et al., 2019)

2.3.5 Mass anthrax exposure and response

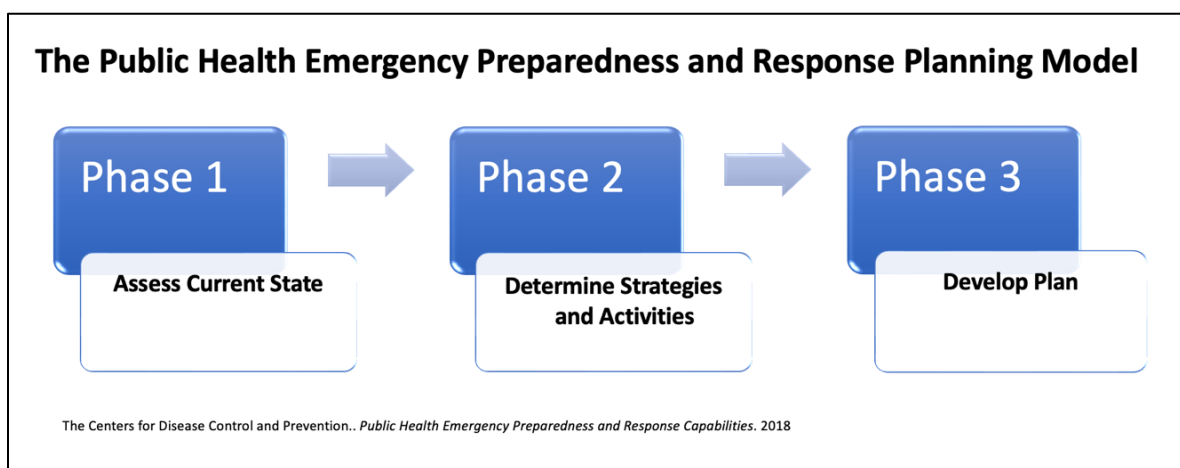
As a result of a large-scale inhalational exposure, ACIP has allowed for adjustments in the recommendations for post-exposure prophylaxis (PEP) to account for implementation challenges or to manage drug or vaccine shortages. ACIP stated AVA may be administered intramuscularly instead of subcutaneously if subcutaneous administration would lead to delays or other challenges. In immunogenicity studies, the subcutaneous route resulted in higher antibody concentrations in the first few weeks compared with the intramuscular route; however, the differences were not statistically significant after week 9. A dose-sparing regimen of AVA can be used if the vaccine supply is not sufficient to allow a standard three-dose vaccination series for all exposed individuals. These options would include: Two doses of full-dose vaccine – 0.5 mL administered

at zero and two to four weeks or Three doses of half-dose vaccine – 0.25 mL administered at zero, two, and four weeks. (Bower et al., 2019)

3.0 Methods

A three-phase planning model from “*Public Health Preparedness Capabilities: National Standards for State and Local Planning*” was used to guide the development of the Toolkit (see Figure 1). The process was conducted from January 2022 to March 2022. All phases were led by a Pharmacist Project Lead (S.S.) in collaboration with the ACHD Pharmacy Team (n = 7 pharmacists). This project was designated as non-human subjects research by the University’s IRB.

Figure 1: Planning Model



3.1 Phase 1: Assess Current State

A needs assessment was conducted utilizing a series of stakeholder meetings from January 2022 to February 2022, a review of the current ACHD anthrax response plan, and past anthrax

responses in 2001. Since the Pittsburgh postal processing facility was not one of the facilities affected by the exposure, the national response was reviewed instead.

3.1.1 Stakeholders Meetings for Toolkit Development

The roles and responsibilities of both ACHD response teams and USPS were determined through initial fact-finding meetings with the ACHD Emergency Preparedness and Response Manager and USPS contacts. Resources and needs were also assessed and discussed in this series of meetings (Table 1). An initial draft of the Toolkit was shared electronically with a Stakeholder Advisory Board consisting of ACHD employee stakeholders on March 9, 2022. Written feedback on the documents was requested by the end of the day on March 22. Advisory board members were encouraged to utilize the review/track changes function on each Word Document to provide their written feedback. This enabled feedback to be tracked more easily and allowed members to view each other's comments. On March 24, 2022, the Advisory Stakeholder Board convened to provide feedback on an initial draft of the Toolkit. This meeting was recorded on Microsoft Teams, and two pharmacy team members took handwritten notes. Stakeholder feedback from this meeting can be found in Table 3.

3.1.2 Review of Current ACHD Anthrax Response Plan

The current ACHD USPS anthrax response plan was reviewed by the project lead (S.S.) and the ACHD Pharmacy team. The current response plan consists of an ACHD-led POD for antibiotic dispensing that provides patients with an initial 10-day supply of medications. This

process allowed the team to identify the need to further discuss the following with the Stakeholder Advisory Board: 1) the incorporation of vaccinations into the POD workflow; 2) clarify ACHD's role in extended dispensing activities; and; 3) determine how best to facilitate patient-provider follow-up for long-term monitoring. Since this initial POD is only to dispense the first ten days of antibiotics, a plan to provide patients with the remaining antibiotics (pending laboratory confirmation) is essential. Additionally, an updated version of the current standing order for antibiotics and an easy-to-follow dispensing algorithm to be used at the POD was needed.

3.1.3 Review of National Anthrax Response

The most common lesson learned from the previous response was to emphasize patient communication and antibiotic adherence. Several studies mentioned above highlighted the importance of adherence promotion and adverse event management. The CDC adherence task force members recommended incorporating continual follow-ups with affected persons, allowing enough time for patient questions, providing consistent and clear patient education and medication counseling, and including interventions that help patients incorporate pill-taking into daily routines and manage known adverse effects. (Jefferds et al., 2002) These findings promote strategies to improve medication adherence and patient understanding which became a priority in the development of the Toolkit.

3.2 Phase 2: Determine Strategies and Activities

The development of strategies to address the needs identified in Phase 1 involved reviewing other state health departments' anthrax response strategies as well as collaborating with fourteen identified stakeholders. (See Table 1)

3.2.1 Review of Other State Health Departments' Anthrax Response Strategies

In 2011, the Missouri Department of Health and Senior Services published the following: Mass Dispensing of Prophylactic Antibiotic Medication Following a Bioterrorism Attack. This document included adaptations for mass exposures to *Bacillus anthracis* (anthrax), *Yersinia pestis* (Plague), and *Francisella tularensis* (Tularemia). The standing order for mass antibiotic prophylaxis following exposure to anthrax was utilized to revise the current ACHD standing order. The Missouri standing order included an easy-to-understand chart with antibiotic PEP recommendations. This was used as a template and then updated based on 2019 ACIP recommendations pertaining to the duration of therapy. A new ACHD POD intake form was also developed using a template found in this document. An easy-to-follow antibiotic dispensing algorithm was designed to assist ACHD response personnel with choosing the most appropriate antibiotic based on clinical recommendations and individual patient factors. (Missouri Department of Health and Senior Services, 2011)

In 2012 Oregon Public Health Division revised and published their Standardized Mass Prophylaxis for Point of Dispensing. The purpose of this document was to guide planning efforts for both mass prophylactic antibiotic dispensing and vaccination in a community setting. There are two types of PODs discussed: medical model PODs, where patients are screened for drug

allergies, drug interactions, and health conditions that may influence which medication is prescribed; and non-medical models, where patients self-screen to determine whether they are a candidate for medication prophylaxis. For the purpose of the development of this POD toolkit, the medical model POD planning documents were used as a guide to develop a POD Flow Chart. The Oregon POD documents were also used in the development of an anthrax POD pharmacy supply list. (Oregon Public Health Division, 2012)

3.3 Phase 3: Develop Plan

The development of the first draft of the Pharmacy Point-of-Dispensing Toolkit was centered around patient care and experience. On the reverse side of the Patient Intake/Consent form is a simplified pharmacy dispensing algorithm to ensure each patient receives the appropriate antibiotic. This form was also designed in this manner to support POD efficiency. In the event that wireless internet would not be available at the POD location, two drug interaction cheat sheets were incorporated into the Toolkit to ensure patient safety. All medication information provided to the patient by the pharmacist is recorded on the Medication-Related Action Plan (MAP). The MAP is a patient-focused document containing a list of actions for the patient to take regarding their medications. The patient and the pharmacist work together to complete the MAP. In addition to promoting a sense of empowerment in the patient, the MAP is designed to motivate the patient to actively participate in medication adherence.

A Provider Letter was also developed to help facilitate patient follow-up with their primary care provider. This letter briefly explains to the provider which antibiotic was dispensed, the quantity received, the date they received the antibiotics and anthrax vaccine, and when the patient

is due for subsequent vaccine doses. The letter also explains the recommended duration of antibiotic therapy, allowing the provider to prescribe the remaining quantity of antibiotics if the patient cannot get to an extended dispensing POD or if there is a small number of exposed individuals, which would not warrant another mass dispensing operation. The patient's provider is also expected to assist with managing potential concomitant medication interactions and dose adjustments. Recommendations for dose adjustments or increased monitoring by the pharmacist will be documented on both the provider letter and MAP to ensure patient safety.

Table 1: Summary of Stakeholder Meetings

Meeting Date	Attendees	Purpose and Agenda	Needs Identified
Jan-21-2022	ACHD Emergency Preparedness and Response Manager, ACHD Pharmacy Manager, ACHD Lead Pharmacist, Community Pharmacy Practice Development & Research Fellow	Initial Fact-Finding meeting: <ul style="list-style-type: none"> • Determine pharmacy's role in anthrax response • Identify additional stakeholders • Next steps for Toolkit development 	<ul style="list-style-type: none"> • Further investigation of pharmacy response • meeting with USPS contacts
Feb-14-2022	ACHD Emergency Preparedness and Response Manager, USPS Occupational Health Nurse Administrator PA 1 District, Division of Emergency Preparedness Specialist-Atlantic Area, ACHD Pharmacy Manager, ACHD Lead Pharmacist, Community Pharmacy Practice Development & Research Fellow	Second Fact-Finding meeting: <ul style="list-style-type: none"> • Verify ACHD response team roles with regard to dispensing of antibiotics • determine the current USPS response plan • determine who's responsible for patient follow-up and extended dispensing operations 	<ul style="list-style-type: none"> • POD patient intake form • Determine if ACHD has a current antibiotic standing order in place • Further investigation on vaccine procurement • Facilitate patient-provider follow up and determine a procedure for patients who do not have a provider
Feb-18-2022	ACHD Emergency Preparedness and Response Manager, ACHD Pharmacy Manager, ACHD Lead Pharmacist, Community Pharmacy Practice Development & Research Fellow	<ul style="list-style-type: none"> • Share early drafts of Toolkit Documents for feedback • Determine more specifics about USPS location • Number of postal workers who may be affected 	<ul style="list-style-type: none"> • Pharmacy dispensing record • Pharmacy supply list • Updated ACHD call list • Updated POD Policy and Procedure • Provider Letter
Feb-24-2022	Advisory Stakeholder Board: Deputy Director of Clinical Services, ACHD Emergency Preparedness and Response Manager, ACHD Pharmacy	<ul style="list-style-type: none"> • Introduce Anthrax POD Toolkit development project • Request involvement from members 	

	Manager, ACHD Lead Pharmacist, Community Pharmacy Practice Development & Research Fellow, 2 ACHD Pharmacists, 3 Public Health Nurse Supervisors	<ul style="list-style-type: none"> Outline expectations for the Advisory Stakeholder Board 	
Mar-24-2022	Advisory Stakeholder Board: Deputy Director of Clinical Services, ACHD Emergency Preparedness and Response Manager, ACHD Pharmacy Manager, ACHD Lead Pharmacist, Community Pharmacy Practice Development & Research Fellow, 2 ACHD Pharmacists, 3 Public Health Nurse Supervisors, a medical resident	<ul style="list-style-type: none"> Discuss feedback provided and the next steps for the Toolkit 	<ul style="list-style-type: none"> Develop vaccine standing order and intake form Incorporate vaccine into POD workflow Develop extended dispensing procedure

4.0 Results

Five stakeholder meetings were held between January 2022 and March 2022. A total of 14 stakeholders were engaged at these meetings to provide feedback for all three phases of the POD planning. Thirteen people attended the large Stakeholder Advisory Board meeting on March 24, 2022, including all members of the Advisory Stakeholder Board and one medical resident on clinical rotation (Table 1). A list of Anthrax POD Toolkit Content that was developed is provided in Table 2, and feedback from the meeting is provided in Table 3.

Table 2: Anthrax Pharmacy Point-of-Dispensing Toolkit Content

Toolkit Item	Description
1. Anthrax PEP POD Policy and Procedures	Describes dispensing operations at the point of dispensing site (POD) in response to a <i>Bacillus anthracis</i> post-exposure prophylaxis (PEP) for United States Postal Workers (USPS)
2. Antibiotic Standing Order	Prewritten medication order for Doxycycline and Ciprofloxacin with a specific prescribing protocol. The scope is limited to anthrax PEP mass dispensing event and must be signed ACHD Director
3. Patient Intake/ Consent Form	Patient form collecting medical/ medication history, allergies, and current medications. Includes antibiotic dispensing algorithm and patient consent for receiving medication
4. Pharmacy Dispensing Record	Internal pharmacy record of medication dispensed, quantity, lot number, expiration, and patient who received medication
5. Ciprofloxacin Drug-Drug Interaction Cheat Sheet	Quick reference for pharmacist or nurse of the most common or significant drug-drug interactions with Ciprofloxacin
6. Doxycycline Drug-Drug Interaction Cheat Sheet	Quick reference for pharmacist or nurse of the most common or significant drug-drug interactions with Doxycycline
7. Provider Letter	Letter explaining to provider which antibiotic was dispensed, the quantity received, the date they received the antibiotics and anthrax vaccine, and when the patient is due for subsequent vaccine doses.
8. Medication-Related Action Plan	Patient-focused document containing a list of actions for the patient to take regarding their medications
9. POD Flow Plan	Patient general flow through POD
10. Antibiotic Dispensing Flow Chart	Clinical antibiotic dispensing algorithm
11. POD Pharmacy Supply List	List of required supplies for pharmacy dispensing activities
12. ACHD Response POD Call List	ACHD anthrax POD responders contact list

13. CDC Patient Anthrax Fact Sheet: Ciprofloxacin	Patient education handout created by CDC on anthrax and use of Ciprofloxacin for PEP
14. CDC Patient Anthrax Fact Sheet: Doxycycline	Patient education handout created by CDC on anthrax and use of Doxycycline for PEP

Revisions were made from the feedback received; however, there was feedback discussed that will require ongoing meetings and discussions with specific ACHD teams and personnel. Many of these revisions were not within the original scope of the project, which was to develop a POD Toolkit for the initial pharmacy antibiotic dispensing response following an anthrax exposure in USPS workers. The ACHD Pharmacy Team will continue to collaborate with stakeholders to develop and revise future versions of the Anthrax POD Toolkit. (see Table 3)

Table 3: Toolkit Feedback and Revisions

Toolkit Item	Revisions made based on stakeholder feedback
Policy and Procedure	<ul style="list-style-type: none"> • Wording changes were suggested • Adapt dispensing procedure for patients who have contraindications to both Doxycycline and Ciprofloxacin
Patient Intake/ Consent Form	<ul style="list-style-type: none"> • Revised dispensing algorithm on intake form to make it easier to follow and more consistent with Antibiotic Dispensing Flow Chart
Provider Letter	<ul style="list-style-type: none"> • Separate Medication-Related Action Plan from Provider Letter
Revisions Requiring additional Stakeholder meetings:	
Collaborations with Immunization Team	<ul style="list-style-type: none"> • Determine how vaccination will be incorporated into the POD workflow • Dependent on how quickly the anthrax vaccine would be received from SNS • Develop Anthrax Vaccine Standing Order • Develop Anthrax Vaccine Patient Intake/ Consent Form

<p>Collaboration with Deputy Director of Clinical Services and Emergency Response Team</p>	<p>Develop Extended Dispensing Operations Procedure:</p> <ul style="list-style-type: none"> • Determine whom the patient will follow up with for long-term antibiotic therapy (ACHD or primary care provider (PCP)) • Depending on how many people are exposed, another large POD may be required, or having the patient follow up individually with ACHD or PCP may be sufficient. • Determine a protocol for patients who do not have a PCP <p>Develop an alternative version of the Provider Letter:</p> <ul style="list-style-type: none"> • In a mass exposure incident, the remaining antibiotic will most likely be supplied from the SNS and not from the patient's provider. Another version of the provider letter needs to be drafted to account for this scenario. • Pending approval of letters, appropriate signatures need to be added.
<p>Collaboration with ACHD Pharmacy Team</p>	<ul style="list-style-type: none"> • Pharmacy POD Supply List Revisions

5.0 Discussion

5.1 Next Steps for the Toolkit

Once all current and future documents have been revised, the Toolkit will be shared with the ACHD Emergency Preparedness and Response team for feedback. The final Toolkit document must be reviewed and approved by ACHD leadership. An electronic copy of the document will be created and stored in an agreed-upon location. Annually, the pharmacy team will re-evaluate the document and propose any needed revisions to the Stakeholder Advisory Board. All revisions will require the approval of the Stakeholder Advisory Board and ACHD Leadership. All Standing Orders will also be updated and signed by the current ACHD leadership. The final revised copy of the Toolkit will be shared electronically with all emergency response team members as well as anyone who would be responding to an anthrax exposure incident at the U.S. Postal Facility.

The development of this ACHD Pharmacy POD Toolkit highlights pharmacists' expertise in preparing for mass points of antibiotic dispensing. Pharmacists, by training, are experts at evaluating the safety and severity of medication-related interactions, determining the most appropriate drug therapy based on individual patient factors, and supporting medication adherence through patient education and drug therapy monitoring. This toolkit was thoughtfully designed by pharmacists with patient safety and medication adherence in mind. Through the use of documents contained in the Toolkit, the ACHD Pharmacy Team members will be able to effectively collaborate with the patient's health care provider on multiple aspects of patient care, including prevention and monitoring of adverse drug events, recommendations for existing drug therapy to

prevent potential drug-drug interactions, and educating other healthcare providers on potential alternative prophylactic antibiotics for patients who are unable to tolerate first-line therapy. The Toolkit was designed to be adaptable. Content of the Toolkit can easily be adapted and revised for mass antibiotic dispensing due to other Category A bioterrorism agents such as Plague (*Yersinia pestis*) or Tularemia.

5.2 The Need for Pharmacist involvement in Emergency Response Planning

The pharmacist's role has evolved beyond the traditional responsibilities of dispensing medications to expand to include more patient-oriented, administrative, and public health functions. In 2006 the American Public Health Association (APHA) published a policy statement entitled "The Role of the Pharmacist in Public Health" which went on to identify and promote pharmacists' current and future roles in public health, and to describe the framework for optimizing these roles. One area identified for increased pharmacist involvement was public health preparedness. In recent years, several events have called attention to the role pharmacists can play in public health planning and emergency preparedness. During a public health disaster, safe and efficient distribution of medications is essential. Pharmacists are also often consulted by other health care providers to recommend alternatives to care and solutions when resources are in short supply. For these reasons, many local health departments have included pharmacists in emergency response plans and planning activities. ("The Role of the Pharmacist in Public Health", 2006)

The 2001 anthrax mass exposure incident also highlighted the importance of including pharmacists in emergency response and preparedness operations by demonstrating their ability to promptly develop and oversee an anthrax prophylaxis clinic. Many U.S. Public Health Service

pharmacists published their own accounts of how they established and operated these clinics, which included the development of a document in the clinic to help pharmacists rapidly select the most appropriate antibiotic and determine patient counseling objectives. Patients were also able to speak to a pharmacist and ask questions about anthrax and the treatments available. Pharmacists were involved in all aspects of developing and operating this clinic, including dispensing medications, patient counseling, screening patients, and providing logistic support. (Setlak, 2004)

In recent years, the ACHD Pharmacy Team's role in emergency preparedness and response has been limited to the storage of medications from the SNS. However, the current pandemic has prompted the expansion of pharmacists' scope in emergency response. Following the FDA's Emergency Use Authorization of two mRNA COVID-19 vaccines, multiple point of dispensing (POD) sites were organized. Pharmacist POD involvement included, but was not limited to: 1) enrolling pharmacists and student pharmacists in the local Medical Reserve Corps to assist with surge capacity staffing at PODs; 2) developing and compiling clinical training materials for POD volunteer clinical staff; 4) training clinical volunteer staff; 5) working alongside local community organizations and Schools of Pharmacy for pop-up PODs in underserved neighborhoods; 6) dispensing and administering vaccines to patients, and 7) providing patient and staff education. This experience at the PODs demonstrated pharmacists' skills and abilities to assist in emergency response and reaffirmed the need for more pharmacist participation in emergency preparedness and response planning at the local level.

The ACHD Pharmacy POD Toolkit developed in the present project highlights pharmacists' medication expertise. It was developed by pharmacists in collaboration with the rest of the emergency response team with patient safety and medication adherence in mind. This process included the development of resources to facilitate collaboration between pharmacists and

other members of the healthcare team. During the initial fact-finding and needs assessment phase of the project, the pharmacist team identified several important medication-related patient care needs that may arise during a POD that pharmacists are the most experienced and qualified to prevent or solve. This Toolkit development emphasizes the importance of involving pharmacists in emergency preparedness and response planning at the Allegheny County Health Department and beyond.

5.3 Recommendations for expanding pharmacist involvement in ACHD emergency preparedness and response

Community pharmacists can also play a critical role during pandemics and other public health emergencies, serving as surge capacity for PODs. Many states, including the Pennsylvania Department of Health, have partnered with community pharmacies through established memoranda of understanding (MOU) for extended dispensing operations, administering vaccinations, distributing supplies, and providing patient education. (Bacci, Odegard, Arnold & Stergachis, 2021, Mercer 2022, Gessler 2021)

Both Duquesne University School of Pharmacy and the University of Pittsburgh School of Pharmacy have assisted with various aspects of the COVID-19 response in the community. Throughout the current COVID-19 pandemic, student pharmacists have been heavily relied on to assist with vaccination efforts and provide patient education. Through their achievements in this response, they have proven themselves to be valuable resources in emergency preparedness and response (Coley 2020)

5.3.1 Recommendations

1. ACHD should consider exploring partnerships with community pharmacies through the use of additional MOUs. The MOU could include targeted responsibilities such as administering vaccinations, dispensing medications, answering drug-related questions, or providing general information and resources to patients regarding a public health emergency.
2. Expand current partnerships with local pharmacy schools to include student pharmacists in Emergency Response. A potential role for student pharmacist involvement in the response to a mass bioterrorism attack such as anthrax could be providing patient medication counseling and answering patient questions through university-established drug information centers. Student pharmacists could also assist with patient follow-up calls to identify individual patient barriers to medication adherence and identify potential adverse drug events.

Both of these potential collaborations could result in increased patient access to information by providing another route for patients to ask important medication and public health-related questions to a qualified medical professional, therefore supporting overall patient medication adherence.

6.0 Conclusion

The Pharmacy Point-of-Dispensing Toolkit, created by pharmacists, is centered around patient care and illustrates the importance of pharmacist involvement in medical countermeasures planning. Pharmacists can use their medication expertise and experience with patient education to design a response plan focused on increasing patient safety and medication adherence. The success of this project should be used to further advocate for increased pharmacist involvement in emergency response planning.

Appendices : Pharmacy Point-of-Dispensing Toolkit

Allegheny County Health Department Pharmacy

Pharmacy Point-of-Dispensing Toolkit:

Anthrax Exposure in United States Postal Workers

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Allegheny County Health Department

	Policy Name	Anthrax USPS Points-of-Dispensing
	Policy Number	
	Effective Date	March 2022
	Responsible for Content	

I. Description

- a. The purpose of this document is to describe dispensing operations at the point of dispensing site (POD) in response to a *Bacillus anthracis* post-exposure prophylaxis (PEP) for United States Postal Workers (USPS).
- b. This document will define the roles and responsibilities of the clinical response team; provide an operational template and algorithm for dispensing medications to USPS employees; process for maintaining inventory of medication dispensed, tracking of recipients, and documentation procedures for medical evaluation and dispensing.

II. Overview and Rationale

- a. The US Postal Service (USPS) uses a Biohazard Detection System (BDS) to monitor for biological agents in the mail processing operation in the facility located at 1001 California Avenue, Pittsburgh PA 15290. The BDS is an automated system that draws a 1-hour sample of air from the mail handling equipment and concentrates airborne particles in sterile water to create a liquid sample. The liquid sample undergoes a 30-minute testing process that uses polymerase chain reaction (PCR) technology to amplify genetic material in the sample, which is then compared to the genetic profile of a biological agent.
- b. A positive result from the BDS would indicate that genetic material from the sample matched the genetic profile of a biological agent, and that there is a possibility that Postal Service employees had been exposed to that biological agent, requiring activation of response plans to protect the health of those employees. To confirm the positive result, the BDS sample would be sent to a Laboratory Response Network (LRN) lab for confirmatory testing.
- c. The Allegheny County Health Department (ACHD) will support the USPS response by dispensing antibiotic medications and providing health information to USPS employees, first responders, and other individuals who may have been affected. ACHD will begin the dispensing of antibiotics to the affected individuals while awaiting the results of the confirmatory testing to avoid delaying in care.
- d. The USPS stockpile of antibiotics is located in the ACHD pharmacy (425 First Avenue, Lower Level Pittsburgh PA 15219). This quantity of antibiotics

sufficient to provide a 10-day regimen for up to 800 individuals. If confirmatory testing warrants additional antibiotics for a longer regimen, they will be obtained from Strategic National Stockpile by ACHD.

III. Policy and Procedures

a. POD Staff Roles and Responsibilities:

i. Pharmacist

1. Definition:

- a. A Pennsylvania-licensed pharmacist who has been identified as qualified to dispense PEP antibiotic therapy

2. Responsibilities:

- a. Review all patient information provided on the intake and evaluate for potential drug interactions
- b. Follow and comply with the dispensing algorithm developed from CDC recommendations for Anthrax PEP
- c. Collaborate with medical supervisor (see below for definition) to determine appropriate antibiotic regimen
- d. Educate the patient on the appropriate therapy and provide patient with correct CDC patient education handout
- e. Refer the patient to their primary care provider by providing them with physician letter
- f. Complete the medication action plan with the patient
- g. Ensure all required documentation is complete and accurate

ii. Nurse

1. Definition:

- a. A Pennsylvania-registered nurse who has been identified as qualified to assist with medication dispensing operations

2. Responsibilities

- a. Conduct initial review of intake form and evaluates for contraindications
- b. Assist pharmacist with dispensing appropriate medication
- c. Educate the patient on the appropriate therapy and provide patient with correct CDC patient education handout
- d. Obtain patient consent for treatment
- e. Refer the patient to their primary care provider by providing them with physician letter.
- f. Complete the medication action plan with the patient

iii. Supervising Physician:

1. Definition:

- a. A licensed medical provider who has been identified by the health department as qualified to oversee medical operations of the POD

2. Responsibilities

- a. Oversees all POD staff including pharmacists, nurses, line staff/ dispensing technician

- b. Provide clinical decision-making, including screening, evaluation, management, and medication dispensing.
 - iv. Line Staff/Dispensing Technician:
 - 1. Definition
 - a. Volunteer, may be medical or nonmedical
 - 2. Responsibilities
 - a. Directs patients through the POD stations
 - b. Distributes intake forms and assists patients with completing the form
 - c. Ensure all intake forms are completed before moving to the next station
 - v. POD Lead
 - 1. Definition: still needs discription
 - 2. Responsibilities:
- b. Preparations – Stockpile Inventory, Standing Orders, and Supplies:
 - i. The ACHD Pharmacy is the repository for the USPS antibiotics. The ACHD Pharmacy will properly store and prepare labels for the antibiotics for dispensing on short notice. The ratio of the antibiotics consists of 27.5% ciprofloxacin / 72.5% doxycycline.
 - ii. The USPS will supply the antibiotic inventory, attending to the issue of expiration dates on the medication by using the Food and Drug Administration (FDA) Shelf Life Extension Program (SLEP) in determining when the product should be replaced.
 - iii. The ACHD pharmacy team will obtain a standing order from the ACHD Director authorizing medication dispensing in the event of a BDS alarm activation. (See Appendix A: 3 and 4)
 - iv. The ACHD pharmacy team will have printed patient intake forms, which include patient consent and medical and medication history, to be pre-staged at the USPS facility for distribution and use in the event of a BDS alarm activation. (See Appendix B:1)
- c. Alerting ACHD Response Teams
 - i. ACHD can receive emergency calls by phone at 412-687-ACHD (2243) on a 24-hour basis. Upon notification of a BDS alarm activation, the call will be directed to the appropriate ACHD Deputy or Program Manager to initiate a response and notify the ACHD Director.
 - ii. In consultation with USPS medical personnel, the ACHD Director or other designated ACHD physician will determine the appropriate course of action, including if and when to begin medical prophylaxis of USPS personnel.
 - iii. Upon determining that medical prophylaxis is appropriate, the ACHD Director or designee will notify the following: Deputy Director for Clinical Services, Chief Epidemiologist, and Emergency Preparedness & Response Manager.

- iv. The ACHD Director and/or the Emergency Preparedness and Response Manager, or designee will report to the USPS Emergency Operations Center to coordinate the ACHD involvement in the incident response.

d. Activation of POD Team

- i. The ACHD Deputy Director for Clinical Services will notify and mobilize the primary clinical response team and will alert the second team to be on standby status. The primary response team will report to the designated USPS facility to establish a POD to dispense medication.
 - 1. The ACHD Deputy Director for Clinical Services will identify two teams of response personnel, each containing a minimum of six ACHD clinical staff members (nursing, pharmacy), and 6 non-clinical staff (emergency preparedness team, administrative staff) with one team designated to staff a POD, and one team to serve in a logistics/administrative role. The ACHD Clinical Services Bureau Director and/or Emergency Preparedness and Response Manager will utilize a telephone call-down system to notify the team members of a BDS alarm activation. (Appendix A:1)
- ii. A designated ACHD Pharmacist will retrieve the antibiotics from the ACHD Pharmacy and will report to the designated USPS facility to supply and staff the POD.
- iii. The ACHD response team will receive from the USPS a listing of individuals who were in the USPS facility and may have been exposed during the 90 minute window of time that the positive BDS sample was collected and analyzed.
- iv. In addition, the ACHD will receive from the USPS a copy of USPS Form 8047, "Critical Event/Individual Status Report," that will include identity and contact information for each listed individual.

e. Medication Dispensing Operations

- i. The ACHD intake/consent form will be distributed to each listed individual. The ACHD patient information form will be used along with USPS Form 8047 to develop a case file on each individual.
- ii. Once the individual has completed the decontamination procedure and has received their first dose of BioThrax, the FDA licensed anthrax vaccine, they will proceed to the medication dispensing station
- iii. Pharmacist/nurse will review the patient intake form and use the patient information provided along with the dispensing algorithm to determine the most appropriate antibiotic for each individual. (See Appendix B:1)

- iv. After evaluating for potential contraindications and drug-drug interactions, the pharmacist/nurse will counsel the patient on the chosen antibiotic. All risks and benefits of therapy will be explained to the patient including the risks of discontinuing therapy prematurely.
- v. Pharmacist/nurse consults with supervising physician as needed for treatment recommendations according to Antibiotic Dispensing Flow Chart (see Appendix B:5)
- vi. After the patient has received either handout from the CDC (Anthrax Emergency: How to Take Doxycycline to Prevent Anthrax or Anthrax Emergency: How to Take Ciprofloxacin to Prevent Anthrax) and has been counseled by the pharmacist/ nurse, they **must** sign after the statement of consent at the bottom of the intake form for receive antibiotics. (See Appendix C: 3 and 4)
- vii. Pharmacist/ nurse will dispense medications pursuant to the standing order of the ACHD Director.
 - i. Pre-labeled and pre-packed ciprofloxacin and doxycycline will then be given to the patient along with a standard letter for their primary care physician explaining their exposure and the next course of action. (See Appendix C: 1)
 - ii.) MAP
- viii. The ACHD POD will continue until all of the listed individuals have received their initial 10-day supply of medication.

f. Extended Medication Dispensing Operations

IV.Original Policy Date Approval and Revisions:

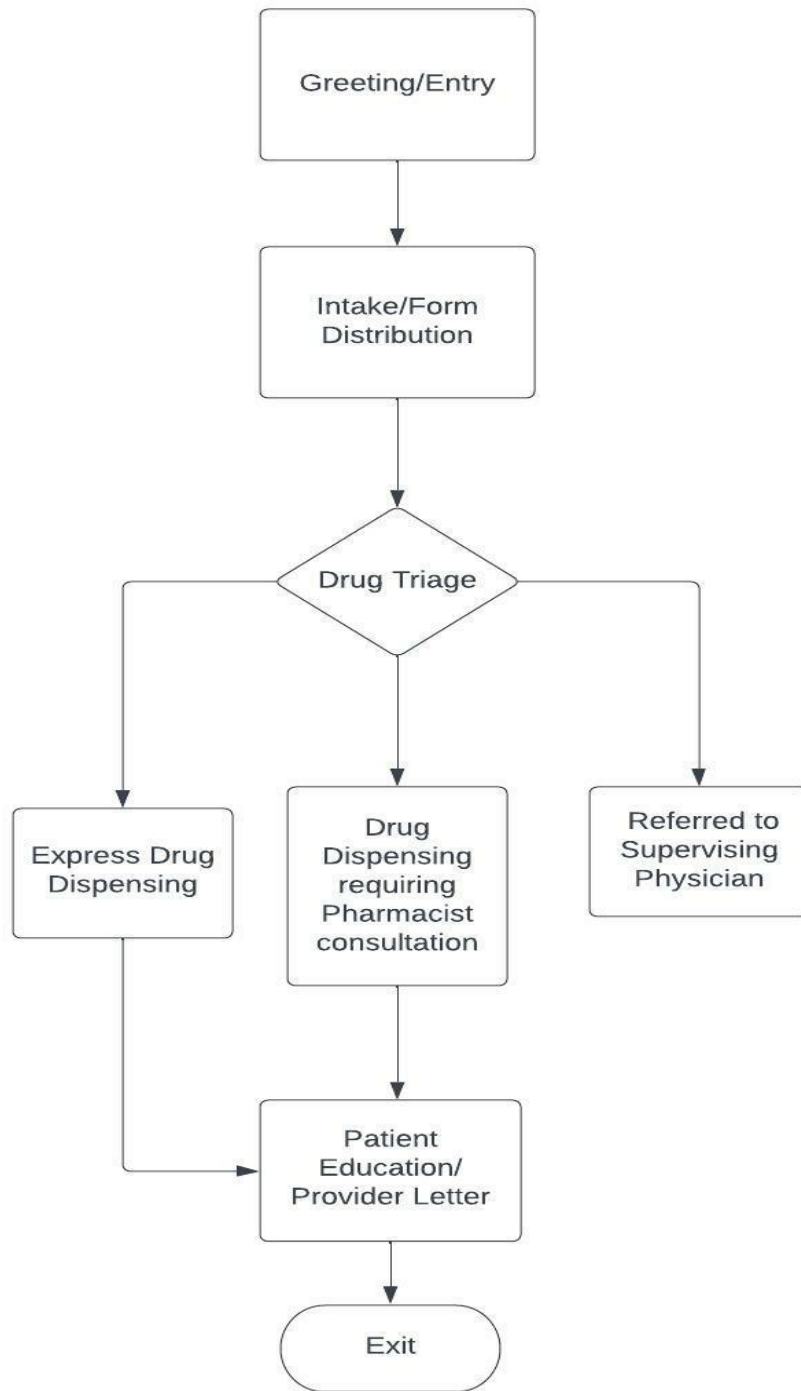
Revision #	Date
Original	2014
1	February 2022
2	March 2022
3	
4	
5	

Appendix A: POD Operations

1.ACHD Response POD Call list

ACHD Postal BDS Staff Call Down List			(List incomplete, for review, updates, and corrections only)			
Name	Title	Program	Cell Phone/SMS Text	Work Phone	Alternate Phone	Email
Dr. Debra Bogen	Director	ACHD	412-894-5961	412-578-8008	412-977-3996	debra.bogen@alleghenycounty.us
Patrick Dowd	Chief Operating Officer	ACHD	412-680-8007	412-578-8035		patrick.dowd@alleghenycounty.us
Dr. Barbara Nightingale	Deputy Director	Bureau of Clinical Services	412-451-3162	412-578-8063		barbara.nightingale@alleghenycounty.us
Tom Mangan	Emergency Preparedness & Response Manager	Emergency Preparedness and Response	412-475-2765	412-578-8352	412-916-8621	tom.mangan@alleghenycounty.us
Stacey Randolph	PH Administrator II	Emergency Preparedness and Response	412-452-7172	412-578-8064	412-657-4420	stacey.randolph@alleghenycounty.us
LuAnn Brink	Chief Epidemiologist	Bureau of Data, Reporting, and Disease Control	724-422-3202	412-578-8354		luann.brink@alleghenycounty.us
Dr. Kristen Mertz	Medical Epidemiologist	Bureau of Data, Reporting, and Disease Control	412-390-7625	412-578-8323	412-670-9350	kristen.mertz@alleghenycounty.us
Jen Fiddner	ERA Supervisor	Bureau of Data, Reporting, and Disease Control	352-342-2538	412-578-8002		jennifer.fiddner@alleghenycounty.us
Joni Carroll	Pharmacist	Pharmacy	814-449-6890			joni.carroll@pitt.edu
Amanda Rice	Pharmacy Manager	Pharmacy	412-951-9537	412-422-6080		Amanda.Rice@AlleghenyCounty.us
Kelsey Hake	Pharmacist	Pharmacy	724-255-8560			Kelsey.Hake@AlleghenyCounty.us
L. Renee Miller	PH Nurse Supervisor	Immunization Clinic	412-515-4112	412-578-8310		l.renee.miller@alleghenycounty.us
Lauren Brungo	PH Nurse Supervisor	TB Clinic	734-657-4208	412-578-7901		lauren.bruno@alleghenycounty.us
Diana Fox	PH Nurse Supervisor	Bureau of Data, Reporting, and Disease Control		412-578-8309	724-600-5422	diana.fox@alleghenycounty.us

2. POD flow plan



3. Antibiotic Standing order

Allegheny County Health Department Standing Order for Antibiotic Prophylaxis Point of Dispensing Site Following a Bioterrorism Attack with Bacillus anthracis (Anthrax)

The Director of the Allegheny County Health Department (ACHD) has declared a Public Health Emergency for Allegheny County effective _____.

Pharmacists, Registered Nurses (RN's) and Physicians employed by, or serving as volunteers for, the Allegheny County Health Department and working within Allegheny County are directed to dispense medications to individuals presenting to ACHD approved Points of Dispensing (PODs) for prevention of anthrax.

This order is effective on _____ and expires _____.

Pharmacists, nurses and physicians dispensing medications under this order are restricted to prepackaged and labeled medications provided by the ACHD and dispensed using the guidelines established by the Centers for Disease Control and Prevention (CDC).

Recommended Therapy for Inhalation Anthrax Infection Post-Exposure Prophylaxis

Category	Initial Oral Therapy	Total Duration of Therapy
Adults	<u>Ciprofloxacin 500mg</u> by mouth every 12 hours OR <u>Doxycycline 100mg</u> by mouth every 12 hours	42 to 60 days** For nonpregnant, immunocompetent adults aged 18 to 65 years who completed the post-exposure vaccination regimen on schedule, antimicrobial prophylaxis is continued for <u>42 days after initiation of the vaccine series</u>
Pregnant Women	<u>Ciprofloxacin 500mg</u> by mouth every 12 hours for 10 days	**Individuals younger than 18 and older than 65 , Adults with immunocompromising conditions or receiving immunosuppressive therapy , individuals who are pregnant or breastfeeding , or any individual who was unable to complete the post exposure vaccination regimen should receive antibiotics for <u>60 days</u>
Children	<u>Doxycycline</u> : <input type="checkbox"/> <45 kg: 4.4 mg/kg per day divided every 12 hours, not to exceed 100 mg per dose <input type="checkbox"/> ≥45 kg: 100 mg every 12 hours OR <u>Ciprofloxacin</u> 30 mg/kg per day divided every 12 hours, not to exceed 500 mg per dose	
References: 1. Bower WA, Schiffer J, Atmar RL, et al. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2019. MMWR Recomm Rep 2019; 68:1. 2. Hendricks KA, Wright ME, Shadomy SV, et al. Centers for disease control and prevention expert panel meetings on prevention and treatment of anthrax in adults. Emerg Infect Dis 2014; 20.		

ACHD Director

Date

ACHD Deputy Director of Clinical Services

Date

Appendix B: Pharmacy operations

1. Patient Intake/ Consent Form

ANTHRAX POST-EXPOSURE PROPHYLAXIS INTAKE AND CONSENT

Name:		
Date of Birth:		Sex:
Address:		
	City:	Zip code:
Phone #:		
Email:		
Primary Care Physician (PCP):		
PCP Phone:		

Medication Allergies (and reaction):	
Medical Conditions:	
Current Medications (including over-the-counter medicines, herbal supplements):	
Are you pregnant, breastfeeding or could be pregnant?	YES NO

For Clinic Use Only

Patient Consent:

I received the following handout from the Center for Disease Control and Prevention (CDC) on Anthrax exposure and the CDC's recommendations for post-exposure prophylaxis:

- ☐ Anthrax Emergency: How to Take Doxycycline to Prevent Anthrax
- ☐ Anthrax Emergency: How to Take Ciprofloxacin to Prevent Anthrax

I disclosed all known medication allergies and informed the health care team of all medications and supplements I am currently taking. I understand that I may have been exposed to Anthrax. I understand the benefits and risks of receiving Ciprofloxacin/Doxycycline. I request that I receive the medication.

Patient Signature

Date

ANTHRAX POST-EXPOSURE PROPHYLAXIS INTAKE AND CONSENT

For Health Care Team:

STEP 1:

All patients without any of the below contraindications will receive Doxycycline 100mg twice a day for 10 days and continue for 42 days after initiation of vaccine series

STEP 2: Does the patient have any contraindications to Doxycycline?

Allergy to Doxycycline or any other tetracycline	RECOMMENDED: If No, Dispense Doxycycline If yes to any... Proceed to Step 3
Pregnant, may become pregnant, breastfeeding	
Currently taking Isotretinoin	

STEP 3: Does the patient have any contraindications to Ciprofloxacin?

Allergy to Ciprofloxacin or any other fluoroquinolone	RECOMMENDED: If No, Dispense Ciprofloxacin If yes to any... Consult supervising physician
Poor Kidney Function (Stage 4)	
Increased risk of QT changes (Age >65 AND history of MI, CHF or drug-induced QT changes, ≥ 2 medications that prolong QT interval)	
Increased risk of tendon rupture (Risk Factors: Age >60 years <u>AND</u> one of the following corticosteroid therapy, rheumatoid arthritis, solid organ transplant recipients, diabetes)	
Currently taking Tizanidine	

Duration: 42 to 60 days**

For nonpregnant, immunocompetent adults aged 18 to 65 years who completed the post-exposure vaccination regimen on schedule, antimicrobial prophylaxis is continued for 42 days after initiation of the vaccine series

****Individuals younger than 18 and older than 65, Adults with immunocompromising conditions or receiving immunosuppressive therapy, individuals who are pregnant or breastfeeding, or any individual who was unable to complete the post exposure vaccination regimen should receive antibiotics for 60 days**

This patient will receive 10 days of:

Doxycycline 100mg

Ciprofloxacin 500mg

Recommended Total Duration of therapy (Pending Laboratory Confirmation):

42 days

60 days

Manufacturer:

Lot:

Expiration:

Quantity dispensed: **20**

Day Supply: **10**

Instructions: Take 1 tablet by mouth every 12 hours

Dispensing Pharmacist/Nurse

Date

2. Pharmacy dispensing record

PHARMACY DISPENSING RECORD

Patient Name	DOB	Medication	Quantity	LOT	Expiration date

3. Ciprofloxacin Drug-Drug Interaction Cheat Sheet

Ciprofloxacin: Significant Drug-Drug Interaction

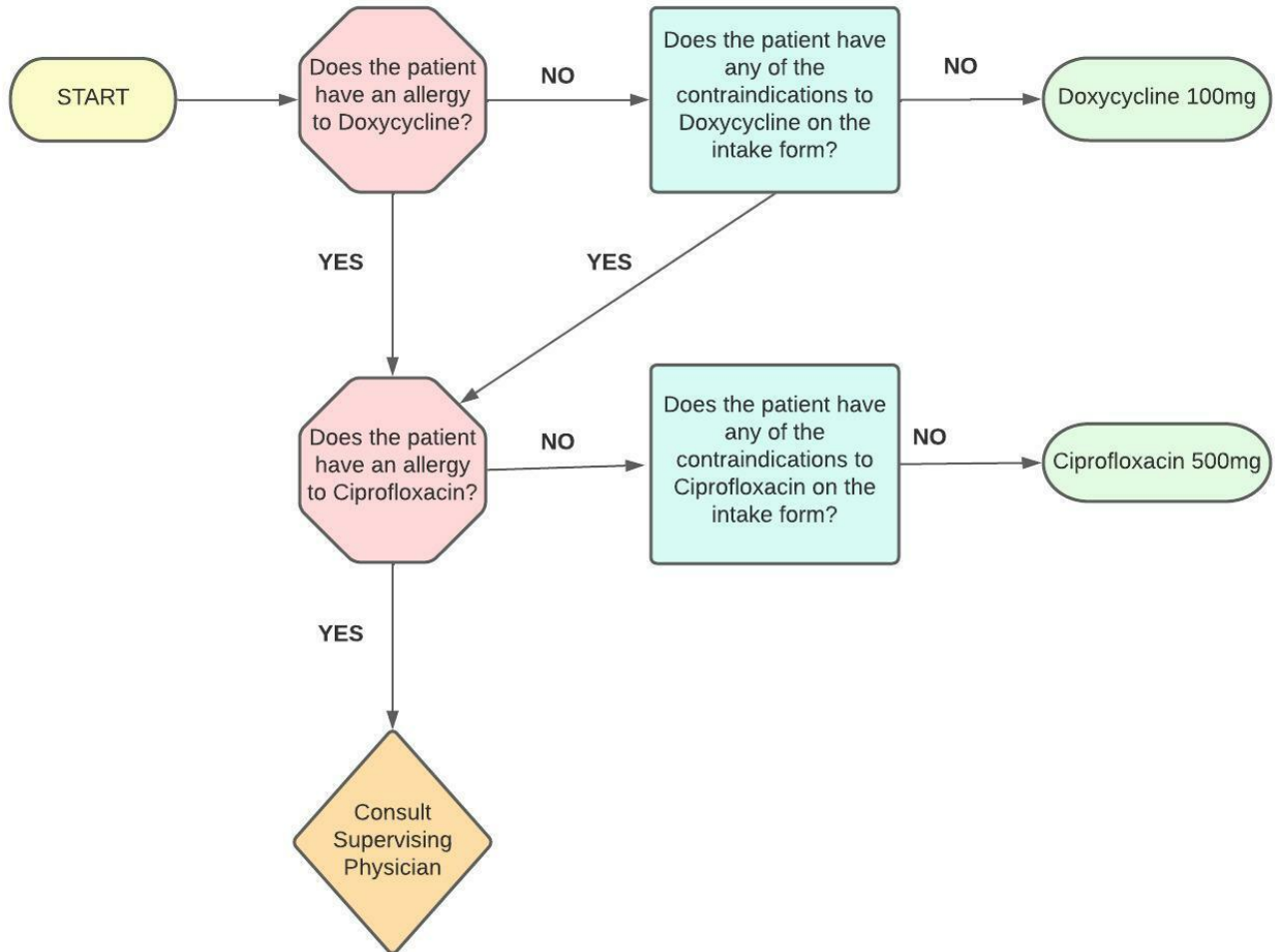
Category X (AVOID combination)	<input type="checkbox"/> Agomelatine <input type="checkbox"/> Aminolevulinic Acid <input type="checkbox"/> Lomitapide <input type="checkbox"/> Meptazinol <input type="checkbox"/> Nadifloxacin <input type="checkbox"/> Pimozide <input type="checkbox"/> Strontium Ranelate <input type="checkbox"/> TiZANidine	
Category D (Consider Modification)	Alosetron	Avoid concomitant use when possible. If combined use is necessary, monitor for increased alosetron effects/toxicities.
	Antacids	May decrease the absorption Cipro, take cipro at least 2hrs before or 6 hrs after antacid
	CloZAPine	may enhance the QTc-prolonging effect; may increase the serum concentration of CloZAPine. Reduce the clozapine dose to one-third of the original dose when adding ciprofloxacin and monitor closely for evidence of excessive QTc prolongation and clozapine toxicity.
	Didanosine	Administer oral quinolones at least 2 hours before or 6 hours after didanosine.
	Fexinidazole	May increase serum concentration of cipro, monitor for toxicities
	Lanthanum	May decrease serum concentrations of cipro, administer antibiotics at least one hour before or four hours after lanthanum
	Magnesium Salts	Decrease serum concentrations of cipro, administer cipro at least 6 hours before mag salts
	Patiromer	May decrease serum concentration of cipro, administer oral ciprofloxacin at least 3 hours before or 3 hours after patiromer
	Pirfenidone	may increase serum concentration of pirfenidone, if cipro dose is over 1500 mg/day, reduce pirfenidone dose to 1,602 mg/day
	Pomalidomide	May increase serum concentration of pomalidomide, consider reducing the pomalidomide dose to 2 mg
	Sucralfate	May decrease serum concentrations of cipro, administer at least 2 hours before or 6 hours after sucralfate
	Zolpidem	May increase concentrations of zolpidem, monitor for toxicity
Category C (Monitor therapy)	Agents with Blood Glucose Lowering Effects	may enhance the hypoglycemic effect
	Alprazolam	may increase the serum concentration of Alprazolam
	Corticosteroids (Systemic)	May enhance the adverse/toxic effect of Quinolones. Specifically, the risk of tendonitis and tendon rupture may be increased
	Dofetilide	may increase the serum concentration of Dofetilide
	Fosphenytoin	May decrease the serum concentration of Fosphenytoin; may enhance the QTc-prolonging effect
	Haloperidol	May enhance the QTc-prolonging effect
	Hydroxychloroquine	May enhance the QTc-prolonging effect
	Methotrexate	May increase serum concentration of MTX
	Methylphenidate	May enhance the cardiotoxic effect of Quinolones
	Phenytoin	may decrease the serum concentration of Phenytoin
	Propranolol	may increase the serum concentration of Propranolol
	Simvastatin	may enhance the myopathic (rhabdomyolysis)
	Thyroid Products	may decrease the serum concentration of Thyroid Products
	Warfarin	may enhance the anticoagulant effect of Vitamin K Antagonists

4. Doxycycline Drug-Drug Interaction Cheat Sheet

Doxycycline: Significant Drug-Drug Interaction

Category X (AVOID combination)	<input type="checkbox"/> Aminolevulinic Acid <input type="checkbox"/> Mecamylamine <input type="checkbox"/> Methoxyflurane <input type="checkbox"/> Retinoic Acid Derivatives - ISOtretinoin (Accutane), Tretinoin (systemic), topical products are okay	
Category D (Consider Modification)	Antacids	May decrease the absorption of Doxy, take Doxy at least 2hrs before or 6 hrs after antacid
	Bismuth Subsalicylate	May decrease the absorption of Doxy, take Doxy at least 2hrs before or 6 hrs after antacid
	Calcium Salts	May decrease the absorption of Doxy, take Doxy at least 2hrs before or 6 hrs after antacid
	Carbamazepine	decreases serum doxy, consider increase dose of doxy
	Fosphenytoin	decrease serum Doxy, Consider increase dose of doxy
	Iron Preparations	Decreased serum tetracycline and iron, if both are needed, iron should be given 3 hours before or 2 hours after doxycycline
	Lanthanum	Decreased absorption of doxy, separate administration by 2 hours
	Sucralfate	May decrease the absorption of Doxy, take Doxy at least 2hrs before or 6 hrs after antacid
Category C (Monitor therapy)	Bile Acid Sequestrants	Decreased absorption of doxy
	PPIs	Decreased absorption of doxy
	Phenytoin	May decrease the serum concentration of Doxycycline.
	Quinapril	May decrease the serum concentration of Tetracyclines.
	Neuromuscular-Blocking Agents	may enhance neuromuscular-blocking effect
	Rifampin	May decrease the serum concentration of Doxycycline.
	Sulfonylureas	may enhance the hypoglycemic effect
	Warfarin	may enhance the anticoagulant effect

5. Antibiotic Dispensing Flow chart



6. Pharmacy Supply list

Supplies	Quantity Requested
Printed intake forms	
Printed patient education handouts	
Printed MD letter	
Prelabeled/ packaged medications	
Pens, highlighters, clipboards, folders	
Wifi hot spot	
Laptop	

Appendix C: Patient Documents

1. Provider letter

ALLEGHENY COUNTY HEALTH DEPARTMENT

542 Fourth Ave □ Pittsburgh, PA 15219 □ 412-687-2243

Date:

To Whom It May Concern:

This letter is to inform you that your patient recently had a potential exposure to *Bacillus anthracis* (Anthrax). Inhalation anthrax occurs when an individual inhales aerosolized spores. Untreated, inhalation anthrax has an approximate mortality rate of 90%. **IT IS NOT SPREAD FROM PERSON-TO-PERSON.** Symptoms usually occur within 7 days of inhaling anthrax spores but can occur as soon as 24 hours after exposure or may take up to 6 to 7 weeks to appear.

Per the CDC recommendations for anthrax post-exposure prophylaxis, your patient has **received their first dose of BioThrax**, the FDA licensed anthrax vaccine on (Date) _____ and a **10-day supply of the following antibiotic on (Date)** _____

Circle one: CIPROFLOXACIN 500MG TWICE A DAY #20 DOXYCYCLINE 100MG TWICE A DAY #20

The patient has been informed that **PENDING LABORATORY CONFIRMATION** of the exposure, they are to follow up with their primary care provider to receive the remainder of the antibiotic therapy. They will receive the second and third dose of BioThrax from the ACHD immunization clinic at 2 weeks and 4 weeks.

The duration of antibiotic is based on completion of the vaccine series and other patient factors:

- ☐ For **non-pregnant, immunocompetent adults aged 18 to 65 years who completed the post-exposure vaccination regimen on schedule**, antimicrobial prophylaxis is continued for 42 days after initiation of the vaccine series.
- ☐ Individuals **younger than 18 and older than 65**, adults with **immunocompromising conditions** or receiving **immunosuppressive therapy**, individuals who are **pregnant or breastfeeding**, or **any individual who was unable to complete the post-exposure vaccination regimen** should receive antibiotics for 60 days.

Our Recommendations:

- ☐ We recommend the following monitoring parameters for long term antibiotic therapy: CBC, renal and hepatic function. For Ciprofloxacin also monitor for: glucose, altered mental status, signs and symptoms of tendinopathy, or peripheral neuropathy.
- ☐ We recommend that prescribers continue to identify and monitor potential drug-drug interactions in combination with these antibiotics.

2. Medication-Related Action Plan

MY MEDICATION-RELATED ACTION PLAN

Patient:	
Doctor (Phone):	
Pharmacy/Pharmacist (Phone):	
Date Prepared:	

The list below has important Action Steps to help you get the most from your medications.
Follow the checklist to help you work with your pharmacist and doctor to manage your medications
AND make notes of your actions next to each item on your list.

Action Steps ➡ What I need to do...	Notes ➡ What I did and when I did it...
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	
<input type="checkbox"/>	

3. CDC Patient Anthrax Fact Sheet: Ciprofloxacin

Accessible at: <https://www.cdc.gov/anthrax/public-health/cipro-eui-recipients.html>

Anthrax Emergency: How to Take Ciprofloxacin to Prevent Anthrax **Emergency Use Instructions for Recipients**

During an anthrax emergency, you will be given a medicine called **ciprofloxacin** (sip-roe-FLOX-a-sin) because you **may** have breathed in anthrax germs. These germs can be **deadly**. Taking this medicine reduces your chance of getting sick and dying. Until officials know for sure who breathed in the germs, it is important to start taking this medicine as soon as possible after the emergency starts. Public health officials will provide information on who should get the medicine. If you have questions, talk to a doctor or healthcare provider about taking ciprofloxacin.

People who may have breathed in anthrax germs should take this medicine twice a day for 60 days.
Most people will be given a 10-day supply to start. Public health officials will tell you whether you need more and how to get it. To reduce your chance of getting sick, take the medicine as long as you are directed and avoid stopping early.

What is anthrax?

Anthrax is a serious disease that can be deadly. You can get sick if you breathe in the anthrax germs. **You cannot get anthrax from another person who has anthrax.**

- ☐ Early on, you could have any of the following symptoms: fever, chills, tiredness, cough or headache.
 - ☐ Later, you could develop shortness of breath, chest discomfort, confusion or nausea. Symptoms usually start within 7 days of breathing in anthrax germs, but can start within 24 hours or take up to 6 to 7 weeks to appear.
- See a doctor right away if you have symptoms. **If you take ciprofloxacin as directed and begin to feel sick anyway or show any of the symptoms mentioned above, get medical care right away.**

What is ciprofloxacin?

Ciprofloxacin is a prescription antibiotic approved by the Food and Drug Administration (FDA) to prevent anthrax. FDA is allowing certain uses of ciprofloxacin, including its use without a prescription, during an anthrax emergency. If you were given ciprofloxacin with an expired date on the container, please note that FDA is allowing the use of certain lots of ciprofloxacin beyond the expiration date on the container based on FDA's scientific review. For more information, go to the FDA website at www.fda.gov (search for "ciprofloxacin expiration").

Who should NOT take ciprofloxacin?

Do not take ciprofloxacin if you have had a severe allergic reaction to ciprofloxacin or similar medicines known as quinolones. A severe reaction may include closing of the throat, trouble breathing, or swelling of the lips, tongue or face. **Avoid** taking ciprofloxacin if you have a history of myasthenia gravis or are taking Zanaflex (tizanidine). Talk to your doctor or public health official about other medicines available to prevent anthrax.

How do I take ciprofloxacin?

For children who weigh 67 pounds (31 kg) or more and adults aged 18 years or older:

- Take 1 pill (500 mg) in the **morning** with a full glass of water (with or without food) **and**
 - Take 1 pill (500 mg) in the **evening** with a full glass of water (with or without food)
- The morning and evening doses should be taken 12 hours apart each day for as long as directed. If you have trouble swallowing pills, please talk to your doctor for advice or an alternative medicine.

Children weighing less than 67 pounds (31 kg), the dose is determined based on weight

- Follow instructions provided on the liquid ciprofloxacin label.
 - Take the same amount in the morning and in the evening (12 hours apart) each day as long as directed. Shake the liquid very well for about 15 seconds before each use.
- ☐ Do not skip doses. However, if you miss a dose, **do NOT take 2 doses at once**. Take the next dose as scheduled.
 - ☐ If you have severe kidney disease, you may need a dose change. Talk to a doctor.
 - ☐ Do not split, crush or chew the pills.
 - ☐ Do not take ciprofloxacin with milk, yogurt or calcium-fortified juices.
 - ☐ Keep the pills dry. Store ciprofloxacin pills and liquid at room temperature (between 68–77°F or 20–25°C). The liquid can be stored for up to 14 days at room temperature.
 - ☐ Keep ciprofloxacin away from children and pets. Call the poison control center if children or pets ingest the medicine by accident (1-800-222-1222).



What are common side effects of ciprofloxacin?

KEEP taking ciprofloxacin if you have mild nausea, vomiting and/or diarrhea, a mild sunburn or a vaginal yeast infection. If these symptoms become severe, talk to your doctor.

What are possible serious side effects of ciprofloxacin?

Serious side effects from ciprofloxacin are rare. **STOP** taking ciprofloxacin and get medical care right away (go to the emergency room or call 911) if you have:

- Closing of the throat or trouble breathing
- Swelling of the lips, tongue or face
- Severe itching or rash, especially hives or wheals (red, swollen bumps on the skin)
- Pain, swelling or inflammation of joints or tendons
- Seizures, dizziness, tremors or serious mood changes
- Very fast or irregular heart beat
- Severe stomach cramps with fever or bloody or watery diarrhea
- Pain, burning, tingling, numbness or weakness of your arms, hands, legs or feet
- Yellowing of eyes or skin or dark brown or tea-colored urine
- Unusual bleeding or bruising

What if I am taking other medicines?

- If you take **Zanaflex (tizanidine)**, a medicine for muscle spasms, it is important to talk with your doctor right away. A change in medicine for muscle spasms or medicine to prevent anthrax would be necessary since tizanidine and ciprofloxacin should not be used together.
- Talk to your doctor if you take any of the following medicines: a blood thinner like warfarin, an anti-diabetic medicine like glyburide, phenytoin for seizures, theophylline for asthma or clozapine for schizophrenia. Ciprofloxacin may affect how much of these medicines you need.
- Ciprofloxacin might not work as well when taken with some medicines. Take it at least 2 hours before or 6 hours after taking:
 - Antacids
 - Carafate (sucralfate)
 - Videx (didanosine)
 - Multivitamins or supplements with magnesium, calcium, aluminum, iron or zinc
 - Phosphate binders

What else do I need to know about ciprofloxacin?

- It can worsen muscle weakness or breathing problems in myasthenia gravis. Talk to your doctor if you have a history of myasthenia gravis disorder.
- It can cause your skin to be more sensitive to the sun. Use sunscreen and cover exposed skin.
- It can make you feel jittery if you drink coffee, caffeinated sodas or energy drinks. Drink less caffeine if this occurs.
- Tell your doctor if you are or become pregnant or are breastfeeding.
- On rare occasions, ciprofloxacin can cause serious problems. A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. If you have been injured by ciprofloxacin used to prevent anthrax, you can learn more about this Program by visiting www.hrsa.gov/cicp or by calling 1-855-266-2427 (toll-free).

What other antibiotics can I take instead of ciprofloxacin?

Public health officials will tell you if other antibiotics (such as doxycycline, levofloxacin or amoxicillin) are available. The risks and benefits of other available antibiotics will be explained in separate instructions.

Risk-Benefit Statement

Although ciprofloxacin has some potential and serious side effects, the expected benefit of ciprofloxacin in helping to prevent disease and death associated with anthrax exposure outweighs these risks.

How do I report side effects or medication errors?

Tell your doctor or healthcare provider right away and report side effects or medication errors to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

Space Reserved for State/Local Public Health Information

4. CDC Patient Anthrax Fact Sheet: Doxycycline

Accessible at: <https://www.cdc.gov/anthrax/public-health/doxy-eui-recipients.html>

Anthrax Emergency: How to Take Doxycycline to Prevent Anthrax **Emergency Use Instructions for Recipients**

During an anthrax emergency, you will be given a medicine called **doxycycline** (DOX-i-SYE-kleen) because you **may** have breathed in anthrax germs. These germs can be **deadly**. Taking this medicine reduces your chance of getting sick and dying. Until officials know for sure who breathed in the germs, it is important to start taking this medicine as soon as possible after the emergency starts. Public health officials will provide information on who should get the medicine. If you have questions, talk to a doctor or healthcare provider about taking doxycycline.

People who may have breathed in anthrax germs should take the medicine twice a day for 60 days.
Most people will be given a 10-day supply to start. Public health officials will tell you whether you need more and how to get it. To reduce your chance of getting sick, take the medicine as long as you are directed and avoid stopping early.

What is anthrax?

Anthrax is a serious disease that can be deadly. You can get sick if you breathe in the anthrax germs. **You cannot get anthrax from another person who has anthrax.**

- ☐ Early on, you could have any of the following symptoms: fever, chills, tiredness, cough or headache.
- ☐ Later, you could develop shortness of breath, chest discomfort, confusion or nausea. Symptoms usually start within 7 days of breathing in anthrax germs, but can start within 24 hours or take up to 6 to 7 weeks to appear. See a doctor right away if you have symptoms. **If you take doxycycline as directed and begin to feel sick anyway or show any of the symptoms mentioned above, get medical care right away.**

What is doxycycline?

Doxycycline is a prescription antibiotic approved by the Food and Drug Administration (FDA) to prevent anthrax. FDA is allowing certain uses of doxycycline, including its use without a prescription, during an anthrax emergency. If you were given doxycycline that has an expired date on the container, please note that FDA is allowing the use of certain lots of doxycycline beyond the expiration date on the container based on FDA's scientific review. For more information, go to the FDA website at www.fda.gov (search for "doxycycline expiration").

Who should NOT take doxycycline?

Do not take doxycycline if you have had a severe allergic reaction to doxycycline or similar medicines known as tetracyclines. A severe reaction may include closing of the throat, trouble breathing, or swelling of the lips, tongue or face. Talk to your doctor or public health official about other medicines available to prevent anthrax.

How do I take doxycycline?

For children weighing 76 pounds (35 kg) or more and adults aged 18 years or older:

- Take 1 pill (100 mg) in the **morning** with a full glass of water (with or without food or milk) **and**
- Take 1 pill (100 mg) in the **evening** with a full glass of water (with or without food or milk).

The morning and evening doses should be taken 12 hours apart each day for as long as directed. Doxycycline works just as well whether you take it with or without food or milk.

If you **cannot swallow pills**, follow the doxycycline tablet [crushing and mixing directions](#) (which can also be found by searching "doxycycline crushing instructions" on www.cdc.gov).

For children weighing less than 76 pounds (35 kg), the dose is determined based on weight:

- Follow instructions provided on the liquid doxycycline label or doxycycline tablet [crushing and mixing directions](#) (which can also be found by searching "doxycycline crushing instructions" on www.cdc.gov).
- Take the same amount in the morning and evening (12 hours apart) each day for as long as directed.

- ☐ Do not skip doses. However, if you miss a dose, **do NOT take 2 doses at once**. Take the next dose as scheduled.
- ☐ Keep the pills dry. Store doxycycline pills and liquid at room temperature (between 68–77°F or 20–25°C).
- ☐ If you get an upset stomach when you take the medicine, take it with food.
- ☐ Keep doxycycline away from children and pets. Call the poison control center if children or pets ingest the medicine by accident (1-800-222-1222).



What are common side effects of doxycycline?

KEEP taking doxycycline if you have mild nausea, vomiting and/or diarrhea, a mild sunburn or a vaginal yeast infection. If these symptoms become severe, talk to your doctor.

What are possible serious side effects of doxycycline?

Serious side effects from doxycycline are rare. **STOP** taking doxycycline and get medical care right away (go to the emergency room or call 911) if you have:

- Closing of the throat or trouble breathing
- Swelling of the lips, tongue or face
- Severe itching or rash, especially hives and wheals (red, swollen bumps on the skin)
- Severe stomach cramps with fever or bloody or watery diarrhea
- Yellowing of the eyes or skin or dark brown or tea-colored urine
- Pain when swallowing (esophageal ulcers)
- Unusual bleeding or bruising
- Severe headaches, dizziness or double vision

What if I am taking other medicines?

- Talk to your doctor if you are on a blood thinner like warfarin or seizure medicine like phenytoin. Doxycycline may affect how much of these medicines you need.
- Doxycycline might not work as well when taken with some medicines. Take doxycycline at least 2 hours before or 2 hours after taking:
 - Multivitamins, supplements or antacids with aluminum, calcium, iron or magnesium
 - Helidac, Kaopectate, Pepto-Bismol or other products with bismuth subsalicylate used for indigestion, nausea or diarrhea

What else do I need to know about doxycycline?

- It can cause your skin to be more sensitive to the sun. Use sunscreen and cover exposed skin.
- It can slow bone growth in children.
- It can make birth control pills less effective. Use a second form of birth control until you finish taking all of your doxycycline.
- Long-term use can cause discolored teeth or poor tooth enamel in children younger than 8 years and in infants whose mothers took doxycycline during the last half of pregnancy or while nursing.
- Tell your doctor if you are or become pregnant or are breastfeeding.
- On rare occasions, doxycycline can cause serious problems. A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. If you have been injured by doxycycline used to prevent anthrax, you can learn more about this Program by visiting www.hrsa.gov/cicp or by calling 1-855-266-2427 (toll-free).

What other antibiotics can I take instead of doxycycline?

Public health officials will tell you if other antibiotics (such as ciprofloxacin, levofloxacin or amoxicillin) are available. The risks and benefits of other available antibiotics will be explained in separate instructions.

Risk-Benefit Statement

Although doxycycline has some potential and serious side effects, the expected benefit of doxycycline in helping to prevent disease and death associated with anthrax exposure outweighs these risks.

How do I report side effects or medication errors?

Tell your doctor or healthcare provider right away and report side effects or medication errors to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

Space Reserved for State/Local Public Health Information

Bibliography

1. Allegheny County Health Department Emergency Preparedness and Response (2014) *Plan to Support the US Postal Service in Response to Biohazard Detection System (BDS) Alarm Activation*
2. Bacci, J., Odegard, P., Arnold, J., & Stergachis, A. (2021). Strengthening pandemic preparedness through pharmacy and public health collaborations: Findings from a facilitated discussion exercise. *Journal Of The American Pharmacists Association*, 61(3), e99-e106. doi: 10.1016/j.japh.2020.12.024
3. Blanchard, J. C., Haywood, Y., Stein, B. D., Tanielian, T. L., Stoto, M., & Lurie, N. (2005). In their own words: lessons learned from those exposed to anthrax. *American journal of public health*, 95(3), 489–495. <https://doi.org/10.2105/AJPH.2004.038349>
4. Bower, W., Schiffer, J., Atmar, R., Keitel, W., Friedlander, A., & Liu, L. et al. (2019). Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2019. *MMWR. Recommendations And Reports*, 68(4), 1-14. doi: 10.15585/mmwr.rr6804a1
5. Centers for Disease Control and Prevention. (2015). *Clinical Framework and Medical Countermeasure Use During an Anthrax Mass-Casualty Incident*. Morbidity and Mortality Weekly Report.
6. Gessler, C. A., Richardson, R. M., Hall, D. L., & Coley, K. C. (2021). Operationalizing Pandemic Vaccinations at a Regional Supermarket Chain Pharmacy. *Disaster medicine and public health preparedness*, 1–6. Advance online publication. <https://doi.org/10.1017/dmp.2021.43>
7. Hendricks, K., Wright, M., Shadomy, S., Bradley, J., Morrow, M., & Pavia, A. et al. (2014). Centers for Disease Control and Prevention Expert Panel Meetings on Prevention and Treatment of Anthrax in Adults. *Emerging Infectious Diseases*, 20(2). doi: 10.3201/eid2002.130687
8. Hupert N, Cuomo J, Callahan MA, Mushlin AI, Morse SS. Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness. Prepared by Weill Medical College of Cornell University, Department of Public Health under Contract No. 290-02-0013-3. AHRQ Pub No. 04-0044. Rockville, MD: Agency for Healthcare Research and Quality. August 2004.
9. Jefferds, M., Laserson, K., Fry, A., Roy, S., Hayslett, J., & Grummer-Strawn, L. et al. (2002). Adherence to Antimicrobial Inhalational Anthrax Prophylaxis among Postal

Workers, Washington, D.C., 2001. *Emerging Infectious Diseases*, 8(10), 1138-1144. doi: 10.3201/eid0810.020331

10. Mercer, J., Liang, A., Yoon, J., Nguyen, J., Carroll, J. C., & Coley, K. C. (2022). COVID-19 pandemic vaccination preparedness strategies for independent community pharmacies. *Journal of the American Pharmacists Association : JAPhA*, S1544-3191(22)00003-6. Advance online publication. <https://doi.org/10.1016/j.japh.2022.01.003>
11. MCM-Related Counterterrorism Legislation. (2022). Retrieved from <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#bioterrorism>
12. Missouri Department of Health and Senior Services (2011) *Mass Dispensing of Prophylactic Antibiotic Medication a Bioterrorism Attack*
13. Oregon Public Health Division (2012) *Mass Prophylaxis Point of Dispensing (POD) Field Operations Guide (FOG)*
14. Public health security and bioterrorism preparedness and response act of 2002 (2002).
15. Setlak, P. (2004). Bioterrorism preparedness and response: Emerging role for health-system pharmacists. *American Journal Of Health-System Pharmacy*, 61(11), 1167-1175. doi: 10.1093/ajhp/61.11.1167
16. Shepard, C., Soriano-Gabarro, M., Zell, E., Hayslett, J., Lukacs, S., & Goldstein, S. et al. (2002). Antimicrobial Postexposure Prophylaxis for Anthrax: Adverse Events and Adherence. *Emerging Infectious Diseases*, 8(10), 1124-1132. doi: 10.3201/eid0810.020349
17. The Centers Disease Control and Prevention. (2011). *Public Health Emergency Response Guide for State, Local, and Tribal Public Health Directors Version 2.0*. Department of Health and Human Services.
18. The Centers for Disease Control and Prevention. (2022). *Public Health Emergency Preparedness and Response Capabilities*. 2018.
19. The Role of the Pharmacist in Public Health. (2006). Retrieved from <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/07/13/05/the-role-of-the-pharmacist-in-public-health>
20. Timeline: How the Anthrax Terror Unfolded. (2022). Retrieved from <https://www.npr.org/2011/02/15/93170200/timeline-how-the-anthrax-terror-unfolded>

21. United States Postal Inspection Service (2021, November 4) *The U.S. Postal Inspection Service Looks Back At the 20th Anniversary of Anthrax Mailings* [Press Release]. <https://www.uspis.gov/press-release-anthrax-mailing-20th-anniversary>
22. What is Anthrax?. (2022). Retrieved from <https://www.cdc.gov/anthrax/basics/index.html>
23. Wilson, K., MD (2020) Anthrax Prevention March 8, 2022 from <https://www.uptodate.com/contents/prevention-of-anthrax>
24. Wilson, K., MD (2020) Microbiology, Pathogenesis and Epidemiology of anthrax. *UpToDate*. Retrieved March 5, 2022 from <https://www.uptodate.com/contents/microbiology-pathogenesis-and-epidemiology-of-anthrax>
25. Williams, J. L., Noviello, S. S., Griffith, K. S., Wurtzel, H., Hamborsky, J., Perz, J. F., Williams, I. T., Hadler, J. L., Swerdlow, D. L., & Ridzon, R. (2002). Anthrax postexposure prophylaxis in postal workers, Connecticut, 2001. *Emerging infectious diseases*, 8(10), 1133–1137. <https://doi.org/10.3201/eid0810.020346>