



## OHIO DEPARTMENT OF HEALTH

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John R. Kasich/Governor

Richard Hodges/Director of Health

### In Re: Ohio Department of Health Standing Medical Order/Protocol for Ohio Local Health Departments: Prophylactic Use of Antibiotics and Vaccination

#### Director's Journal Entry

Recognizing the authority of the United States Food and Drug Administration (FDA) to promulgate an Emergency Use Authorization (EUA) as to the use of antibiotics and vaccine in the Strategic National Stockpile (SNS), in accordance with Ohio Revised Code 3701.13, this standing order for preventing the spread of contagious or infectious diseases is directed to the health officers of Ohio local health departments to establish mass clinics with approved protocols for the rapid and appropriate dispensing and administration of prophylactic antibiotics to persons with known or suspected exposure to *Bacillus anthracis* for the prevention of anthrax disease; *Yersinia pestis* for the prevention of plague; or *Francisella tularensis* for the prevention of tularemia; and for the rapid administration of vaccine to persons with known or suspected exposure to *Bacillus anthracis* for the prevention of anthrax disease.

This medical order does not cover treatment of persons with known or suspected disease from the bioterrorism agents *Bacillus anthracis*, *Yersinia pestis*, or *Francisella tularensis*. Such persons must be under the care of a physician and public health authorities. All persons with known or suspected disease must be reported immediately to the Ohio local health jurisdiction in which the person resides.


I order public health staff employed in or anyone volunteering for a nationally, state, or locally declared emergency involving the public's health as contemplated and set forth in this medically informed standing public health order to directly, or by delegation and supervision, dispense antibiotic medications herein prescribed by me, to individuals and members of their households, in order to protect against infection by the bioterrorism agents *Bacillus anthracis*, *Yersinia pestis*, or *Francisella tularensis*.

If the licensed anthrax vaccine adsorbed (AVA) is made available for use under an Emergency Use Authorization and the Centers for Disease Control and Prevention (CDC) releases the vaccine to Ohio for post-exposure prophylaxis, I order public health staff employed in or anyone volunteering for a nationally, state, or locally declared emergency involving the public's health as contemplated and set forth in this medically informed standing public health order to directly, or by delegation and supervision, vaccinate individuals in order to protect them against infection by the bioterrorism agent *Bacillus anthracis*. This part of my order is not in effect if the CDC does not release the vaccine for use in a mass vaccination setting or the AVA is released under an Investigational New Drug protocol.


All medications are prescribed, and must be dispensed in accordance with the national prophylactic treatment recommendations and within the stated restrictions and guidelines of the CDC's Division of Strategic National Stockpile (SNS) Program. When a mass dispensing site is activated and operational in Ohio in response to a public health event involving anthrax, plague or tularemia, one of the attached post-exposure prophylaxis dispensing orders/algorithms must be followed:

1. *Bacillus anthracis* Dispensing Orders and Vaccination Recommendations
2. *Yersinia pestis* Dispensing Orders
3. *Francisella tularensis* Dispensing Orders

Review of this order, and agency policies and procedures related to carrying out this order, will occur at least once a year with changes made as necessary.

  
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Mary DiOrio, MD, MPH  
Medical Director

2-16-16  
\_\_\_\_\_  
Date

  
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Richard Manges, MPA, Director  
Ohio Department of Health

2-18-16  
\_\_\_\_\_  
Date

**RECORD OF CHANGE AND REVIEW**

<b>DATE</b>	<b>CHANGE/REVIEW</b>	<b>BY</b>
3/7/2013	Annual Review Tularemia recommendations updated Record of change/review document added	Rebecca Sandholdt
6/30/14	Annual Review by Dr. Wapner Updated signatures	Viola Webber
3/20/15	Annual Review, Update to Peds	Viola Webber
2/11/16	Annual Review, Update to Pediatrics to specifically identify the maximum daily dose for the medications.	Viola Webber

**Bacillus anthracis Dispensing Orders and Vaccination Recommendations**

Recommended initial antimicrobial agent and anthrax vaccine adsorbed (AVA) dosages for post-exposure prophylaxis (PEP) after exposure to aerosolized *Bacillus anthracis* spores.

TABLE 1		
Population	Antimicrobials for 60-day* PEP	AVA dosage and route†,∞
<b>Adults (18-65 years)</b>	<p><b>One of the following for 60 days:</b>                      Ciprofloxacin,§ 500mg orally twice daily for 60 days                      or                      Doxycycline, 100mg orally twice daily for 60 days</p>	In conjunction with anti-microbial therapy. 3-dose subcutaneous (SC) series: first dose administered as soon as possible, second and third doses administered 2 and 4 weeks after the first dose.
<b>Children (&lt;18 years)††</b>	<p><b>One of the following for 60 days:</b>                      Doxycycline, ††. ¶¶ (maximum of 100 mg/dose)</p> <ul style="list-style-type: none"> <li>• &gt;8 years and &gt;45 kg: 100 mg every 12 hours for 60 days</li> <li>• &gt;8 years and ≤45 kg: 2.2 mg/kg every 12 hours for 60 days</li> <li>• ≤8 years: 2.2 mg/kg every 12 hours for 60 days</li> </ul> <p>or                      Ciprofloxacin,§. ††. §§ 15 mg/kg every 12 hours for 60 days (Not to exceed 500 mg/dose)</p> <p><b>If isolate is proved susceptible:</b>                      Amoxicillin ,** 75mg/kg/day, PO, divided every 8h (not to exceed 1 g/dose) for 60 days;</p>	Recommendations for use of AVA in children are made on an event-by-event basis
<b>Pregnant women¶, ***</b>	<p><b>One of the following for 60 days:</b>                      Ciprofloxacin, 500 mg orally twice daily for 60 days                      or                      Doxycycline, 100 mg orally twice daily for 60 days</p> <p><b>Alternate choice (if isolate is proved susceptible):</b>                      Amoxicillin, 1g orally every 8 hours for 60 days</p>	In conjunction with anti-microbial therapy. 3-dose SC series; first dose administered as soon as possible, second and third doses administered 2 and 4 weeks after the first dose

Table 1 was adapted from: Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009; *Morbidity and Mortality Weekly Report (MMWR)*, 59(RR6); July 23, 2010. **NOTE: Web version indicates the article is “archived” only because it was published in MMWR before January 2013. This IS a current recommendation.**, The American Academy of Pediatrics Red Book: 2012 Report of the Committee on Infectious Diseases, P 228 to 232, PEDIATRICS Volume 133, Number 5, May 2014, Pediatric Anthrax Clinical Management., CDC Emerging

Infectious Disease journal, Volume 20, Number 2- February 2014, Special Considerations for Prophylaxis for and Treatment of Anthrax in Pregnant and Postpartum Women.

- \* Antimicrobials should continue for 14 days after administration of the third dose of vaccine.
- † AVA used for PEP must be administered subcutaneously.
- ∞ Data on the safety of AVA are only available for persons aged 18-65 years; no information is available on the safety of this vaccine in children or older adults (>65 years).
- § Levofloxacin is a second-line antimicrobial agent for PEP for persons aged ≥6 months with medical issues (e.g. tolerance or resistance to ciprofloxacin) that indicate its use. *Children*: 16 mg/kg/day divided every 12 hours; each dose should not exceed 250 mg. *Adults*: 500 mg every 24 hours. Safety data on extended use of levofloxacin in any population for >28 days are limited; therefore, levofloxacin PEP should only be used when the benefit outweighs the risk.
- ¶ The antimicrobial of choice for initial prophylactic therapy among pregnant women is ciprofloxacin. Doxycycline should be used with caution in asymptomatic pregnant women and only when other appropriate antimicrobial drugs are contraindicated. Although tetracyclines are not recommended during pregnancy, their use might be indicated for life-threatening illness.
- \*\* If susceptibility testing demonstrates an amoxicillin MIC ≤0.125 µg/mL, oral amoxicillin should be used to complete therapy.
- †† Use of tetracyclines and fluoroquinolones in children can have adverse effects. These effects must be weighed carefully against the risk for developing life-threatening disease. If exposure to *B. anthracis* is confirmed, children may be treated initially with ciprofloxacin or doxycycline as prophylaxis. However, amoxicillin is preferred for antimicrobial PEP in children when susceptibility testing indicates that the *B. anthracis* isolate is susceptible to penicillins.
- §§ Each ciprofloxacin dose should not exceed 500 mg, or 1 g/day.
- ¶¶ In 1991, the American Academy of Pediatrics (AAP) amended the recommendation to allow treatment of young children with tetracyclines for serious infections such as Rocky Mountain spotted fever for which doxycycline might be indicated. Doxycycline is preferred for its twice daily dosage and low incidence of gastrointestinal side effects.
- \*\* Because of the lack of data on amoxicillin dosages for treating anthrax (and the associated high mortality rate), AAP recommends a higher dosage of 80 mg/kg/day, divided into 3 daily doses; each dose should not exceed 500 mg. If this higher dosage of amoxicillin is used, recipients should be carefully monitored for side effects from long-term treatment.
- \*\*\* Antimicrobial drug use in pregnant women in the setting of anthrax must be viewed in the context of the high mortality risk and the benefits of treatment for the mother and fetus, as well as possible effects on the fetus resulting from the infection or from administration of antimicrobial drugs to the mother. Although safety and pharmacokinetic data for pregnant women are limited, antimicrobial drugs used for anthrax post-exposure prophylaxis and treatment for pregnant/postpartum/ lactating women are generally the same as those for non-pregnant adults.

## Yersinia pestis Dispensing Orders

### Prescribed Post-exposure Prophylaxis for Pneumonic Plague<sup>¥</sup>

TABLE 2	
Patient Category	Recommended Therapy
Adults	<b>Preferred choices:</b> Doxycycline, 100 mg orally twice daily for seven days <b>IF adult is allergic to doxycycline, THEN</b> Ciprofloxacin, 500 mg orally twice daily for seven days €
Children	<b>Preferred choices:</b> Doxycycline <ul style="list-style-type: none"><li>• If child's weight is ≥45 kg, give adult dosage (100 mg orally twice daily) for seven days</li><li>• If child's weight is &lt;45 kg, give 2.2 mg/kg orally twice daily for seven days ( Not to exceed 100mg/ dose)</li></ul> <b>If child is allergic to doxycycline, THEN</b> Ciprofloxacin, 20 mg/kg orally twice daily for seven days €
Pregnant women and breastfeeding mothers	<b>Preferred choices:</b> Ciprofloxacin, 500 mg orally twice daily for seven days € <b>If individual is allergic to Ciprofloxacin THEN,</b> Doxycycline, 100 mg orally twice daily for seven days ‡

Table 2 adapted from: Inglesby TV, Dennis DT, Henderson DA, et al. Plague as a Biological Weapon: Medical and Public Health Management, *JAMA* 2000; 283:2281-90, (Page last reviewed: April 25, 2014).

- ¥ Recommendations were reached by consensus of the Working Group on Civilian Biodefense and may not necessarily be approved by the FDA.
- ‡ Although fetal toxicity may occur with doxycycline use and toxic effects on the liver in pregnancy have been noted with the tetracycline class, the Working Group on Civilian Biodefense recommend doxycycline or ciprofloxacin for post-exposure prophylaxis of pregnant women.
- € Other fluoroquinolones may be substituted at doses appropriate for age. Ofloxacin (and possibly other quinolones) may be acceptable alternatives to ciprofloxacin or levofloxacin; however, they are not approved for use in children. Each ciprofloxacin dose should not exceed 500 mg and maximum daily dosage for ciprofloxacin should not exceed 1 g.

## Francisella tularensis Dispensing Orders

### Prescribed Post-exposure Prophylaxis for Tularemia

Table 3	
Patient Category	Recommended Therapy ‡
Adults (including pregnant women)	<b>One of the following:</b> Ciprofloxacin, 500 mg orally twice daily for 14 days or Doxycycline, 100 mg orally twice daily for 14 days €
Children	<b>Preferred choices:</b> Doxycycline <ul style="list-style-type: none"><li>• If child's weight is <math>\geq 45</math> kg, give adult dosage (100 mg orally twice daily) for 14 days</li><li>• If child's weight is <math>&lt; 45</math> kg, give 2.2 mg/kg orally twice daily for 14 days ( Not to exceed 100mg/dose)</li></ul> <b>If child is allergic to doxycycline, THEN</b> Ciprofloxacin, 15 mg/kg orally twice daily for 14 days §

Table 3 adapted from the following reference for the recommended therapy information for adults: Dennis DT, Inglesby TV, Henderson DA, et al. Tularemia as a Biological Weapon: medical and public health management. *JAMA* 2001; 285(21): 2763-2773. Table 3 adapted from the following reference for the recommended therapy information for children: A National Consensus Conference for "Pediatric Preparedness for Disasters and Terrorism", March 2007, convened by the Mailman School of Public Health at Columbia University: <http://www.ncdp.mailman.columbia.edu/files/peds2.pdf>.

‡ Recommendations were reached by consensus of the Working Group on Civilian Biodefense and may not necessarily be approved by the United States Food and Drug Administration.

€ Although fetal toxicity may occur with doxycycline use, the Working Group on Civilian Biodefense recommended doxycycline or ciprofloxacin for post-exposure prophylaxis of pregnant women.

§ Other fluoroquinolones may be substituted at doses appropriate for age. Ofloxacin (and possibly other quinolones) may be acceptable alternatives to ciprofloxacin or levofloxacin; however, they are not approved for use in children. Each ciprofloxacin dose should not exceed 500 mg and maximum daily dosage for ciprofloxacin should not exceed 1 g.

**Contraindications and Precautions:**

Please refer to medication and vaccine package inserts for information regarding contraindications and precautions.

Persons taking other medications, including those sold over-the-counter, should check with their healthcare provider or pharmacist regarding possible medication interactions and whether any of the medications need dosage adjustments.