

m1 DEPARTMENT OF HEALTH

60-Day Dispensing for Anthrax Prophylaxis


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- Introduction – Setting the Stage
- 11-60 Day Dispensing for Anthrax
- Anthrax Vaccine
- Demobilization
- Questions
- Conclusion

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Setting the Stage

- 10-day regimens of medication have been dispensed
- Law enforcement and epidemiological investigations ongoing
- Laboratory testing for effectiveness of amoxicillin underway
- Follow-on shipment of antibiotics and anthrax vaccine (AVA) arriving



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What's Different about Days 11-60 Dispensing?

Target population may be narrowed:

- More intelligence = better idea of who was actually exposed.
- Some may be able to stop taking antibiotics



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Acronym Intervention

IND	EUA	EUI
Non-emergency or emergency	Emergency or pre-event preparedness	Emergency or pre-event preparedness
Individual recipient or widespread use	Intended for mass-medical countermeasure (MCM) use	Intended for mass-MCM use
No emergency declaration required	Emergency/potential emergency determination <u>and</u> declaration by the Secretary required	Emergency/potential emergency determination by the Secretary required
MCM use for isolated incidents or mass events	MCM use for mass events	MCM use for mass events
Unapproved MCM or unapproved use of approved MCM	Unapproved MCM or unapproved use of approved MCM	Approved MCM concerning approved conditions of use
★ Institutional Review Board (IRB) review or approval required	No IRB review or approval required	No IRB review or approval required

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Post Exposure Prophylaxis for Inhalational Anthrax

Antibiotic/Vaccine	Tablet/Capsule/Suspension	Subcutaneous Injection (Adults)	Intramuscular Injection (Pediatrics)	Regulatory Status	Ship/Store Temperature
Amoxicillin	X			EUA	Controlled Room Temperature (CRT)
Ciprofloxacin	X			FDA approved; requires EUI	CRT
Doxycycline	X			FDA approved; requires EUI	CRT
Anthrax Vaccine Adsorbed (AVA) 3-dose series		X		FDA approved in 18-65 years	2° C-8° C
			X	EUA/EUI > 65 years IND < 18 years	2° C-8° C

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Who can receive the Anthrax Vaccine?

AVA is FDA approved for adults between the ages of 18 and 65

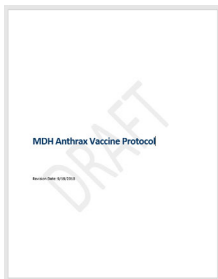
Adults over 65 can receive AVA under an Emergency Use Authorization (EUA)

Children 17 and under can receive AVA as an Investigational New Drug (IND)



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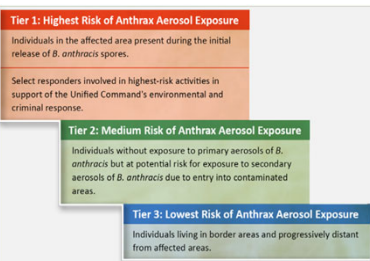
How Does the Anthrax Vaccine Fit In?



- MDH's Anthrax Vaccine (AVA) Protocol is still in draft.
- Post-exposure AVA series is 0, 2, & 4 weeks (3 shots).
- Anthrax vaccination record cards used to track dosage, dates, and other vaccination details are shipped with AVA.
- AVA is in MIIC.

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What if there isn't enough Anthrax Vaccine?



- CDC will tell MDH who is prioritized to receive vaccine.
- If supply is insufficient given the size of the event, supply may be reserved by priority tier.

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Anthrax Vaccine Considerations

Will oral dispensing and vaccine administration be located within the same POD?

> If not, how will you communicate separate locations to the public?

Will CPODs administer vaccine?

How will your POD flow be impacted by vaccine administration?

> Will you be able to keep families together?



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Anthrax Vaccine Considerations

There are different qualifications and skillsets for staff administering anthrax vaccine.

- Licensed to give injections
- Monitor and respond to anaphylaxis/adverse events
- Be able to enter data into MIIC

Additional supplies will be needed for vaccine administration.

- Vaccine storage and handling (i.e. refrigerators or freezers)
- Ancillary supplies
- Biohazardous waste disposal

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Public Messaging Challenges

- Importance of taking full regimen of medication
- Urgency of returning to POD for additional medication
 - Can clients be contacted directly?
- Why has the target population changed?
- Who is prioritized for vaccine and why?
- Disregarding medication expiration dates



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Responder Safety and Health


- Both physical and behavioral health considerations
- Staffing support/mutual aid
- Continuity of operations planning
- Collecting data to support long-term tracking



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Demobilization

- Sending back your stuff
- Data retention
- Hotwash and AAR-IP
- Long-term tracking of responders



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Resources

- CDC: Receiving 60-day Anthrax Medical Countermeasures from CDC's Strategic National Stockpile: Planning Considerations for State, Local, Tribal, and Territorial Partners
- NACCHO/ASTHO: Extended Medical Countermeasure Distribution and Dispensing Considerations for Anthrax Incidents
- MDH Mass Dispensing Guidelines
- MDH Anthrax Vaccine Protocol – *DRAFT*
- CDC Website – Anthrax information for Healthcare Providers
- Advisory Committee on Immunization Practices (ACIP)

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Questions

- What are your questions about 60-day dispensing?
- Questions about anthrax vaccine?
- About anything else MCM-related?



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Thank you!

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