Strategic National Stockpile:

Point of Dispensing Training

MISSOURI DEPARTMENT OF HEALTH & SENIOR SERVICES

MISSOURI DEPT OF PUBLIC SAFETY SERVICE SAFETY SECURITY EMERGENCY MANAGEMENT

Handouts

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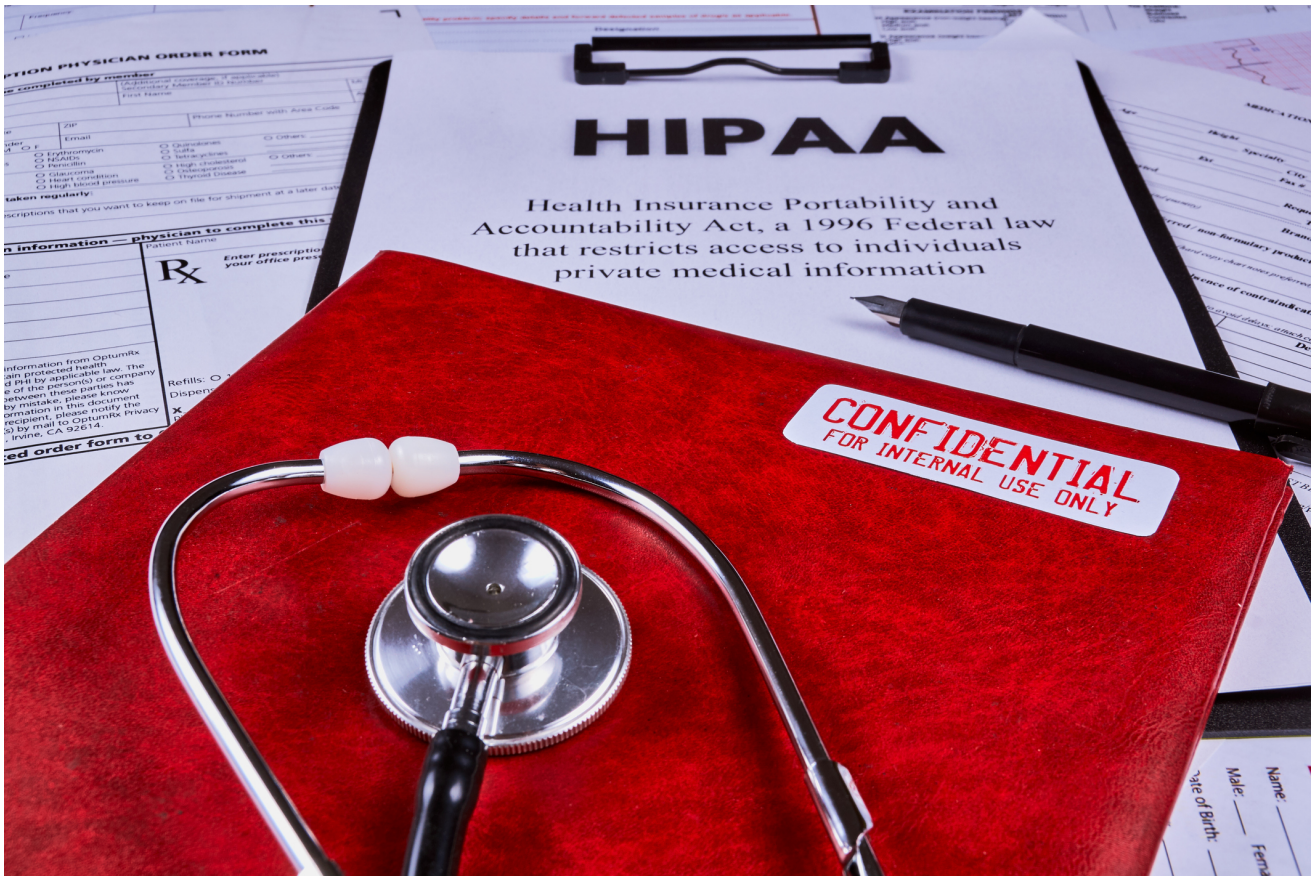
mln Fact Sheet

KNOWLEDGE • RESOURCES • TRAINING

HIPAA Basics for Providers: Privacy, Security, & Breach Notification Rules



What's Changed?

No substantive content updates

Health Insurance Portability & Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules protect the privacy and security of health information and give patients rights to their health information. HIPAA establishes standards to safeguard the protected health information (PHI) that you hold if you're one of these covered entities or their business associate:

- Health plan
- Health care clearinghouse
- Health care provider that conducts certain health care transactions electronically

Privacy Rule

The Privacy Rule protects your patients' PHI while letting you securely exchange information to coordinate your patients' care. The Privacy Rule also gives patients the right to:

- Examine and get a copy of their medical records, including an electronic copy of their medical records
- Request corrections
- Restrict their health plan's access to information about treatments they paid for in cash

Under the Privacy Rule, most health plans can't use or disclose genetic information for underwriting purposes. You're allowed to report child abuse or neglect to the authorities.

PHI

The Privacy Rule protects PHI that you hold or transmit in any form, including electronic, paper, or verbal. PHI includes information about:

- Common identifiers, such as name, address, birth date, and SSN
- The patient's past, present, or future physical or mental health condition
- Health care you provide to the patient
- The past, present, or future payment for health care you provide to the patient

Requirements

The Privacy Rule requires you to:

- Notify patients about their privacy rights and how you use their information
- Adopt privacy procedures and train employees to follow them
- Assign an individual to make sure you're adopting and following privacy procedures
- Secure patient records containing PHI so they aren't readily available to those who don't need to see them

Sharing Information with Other Health Care Professionals

To coordinate your patient's care with other providers, the Privacy Rule lets you:

- Share information with doctors, hospitals, and ambulances for treatment, payment, and health care operations, even without a signed consent form from the patient
- Share information about an incapacitated patient if you believe it's in your patient's best interest
- Use health information for research purposes
- Use email, phone, or fax machines to communicate with other health care professionals and with patients, as long as you use safeguards

Sharing Patient Information with Family Members & Others

Unless a patient objects, the Privacy Rule lets you:

- Give information to a patient's family, friends, or anyone else the patient identifies as involved in their care
- Give information about the patient's general condition or location to a patient's family member or anyone responsible for the patient's care
- Include basic information in a hospital directory, such as the patient's phone and room number
- Give information about a patient's religious affiliation to clergy members

Incidental Disclosures

The HIPAA Privacy Rule requires you to have policies that protect and limit how you use and disclose PHI, but you aren't expected to guarantee the privacy of PHI against all risks. Sometimes, you can't reasonably prevent limited disclosures, even when you're following HIPAA requirements.

For example, a hospital visitor may overhear a doctor's confidential conversation with a nurse or glimpse a patient's information on a sign-in sheet. These incidental disclosures aren't a HIPAA violation as long as you're following the required reasonable safeguards.

The Office for Civil Rights (OCR) offers guidance about how this applies to health care practices, including incidental uses and disclosures FAQs.

Visit HHS HIPAA Guidance Materials for information about:

- De-identifying PHI to meet HIPAA Privacy Rule requirements
- Patients' right to access health information
- Permitted uses and disclosures of PHI

Security Rule

The Security Rule includes security requirements to protect patients' electronic PHI (ePHI) confidentiality, integrity, and availability. The Security Rule requires you to:

- Develop reasonable and appropriate security policies
- Ensure the confidentiality, integrity, and availability of all ePHI you create, get, maintain, or transmit
- Identify and protect against threats to ePHI security or integrity
- Protect against impermissible uses or disclosures
- Analyze security risks in your environment and create appropriate solutions
- Review and modify security measures to continue protecting ePHI in a changing environment
- Ensure employee compliance

When developing compliant safety measures, consider:

- Size, complexity, and capabilities
- Technical, hardware, and software infrastructure
- The costs of security measures
- The likelihood and possible impact of risks to ePHI

Visit HHS Cyber Security Guidance Material for information about:

- Administrative, physical, and technical PHI safety measures
- Cybersecurity
- Remote and mobile use of ePHI

Breach Notification Rule

When you experience a PHI breach, the Breach Notification Rule requires you to notify affected patients, HHS, and, in some cases, the media. Generally, a breach is an unpermitted use or disclosure under the Privacy Rule that compromises the security or privacy of PHI. The unpermitted use or disclosure of PHI is a breach unless there's a low probability the PHI has been compromised, based on a risk assessment of:

- The nature and extent of the PHI involved, including types of identifiers and the likelihood of re-identification
- The unauthorized person who used the PHI or got the disclosed PHI
- Whether an individual acquired or viewed the PHI
- The extent to which you reduced the PHI risk

You must notify authorities of most breaches without reasonable delay and no later than 60 days after discovering the breach. Submit notifications of smaller breaches affecting fewer than 500 patients to HHS annually. The Breach Notification Rule also requires your business associates to notify you of breaches at or by the business associate.

Visit the HHS Breach Notification Rule for information about:

- Administrative requirements and burden of proof
- How to make unsecured PHI unusable, unreadable, or indecipherable to unauthorized individuals
- Reporting requirements

Who Must Comply with HIPAA Rules?

Covered entities and business associates must follow HIPAA rules. If you don't meet the definition of a covered entity or business associate, you don't have to comply with the HIPAA rules.

Learn more about covered entities and business associates, including fast facts for covered entities.

For definitions of covered entities and business associates, see 45 CFR 160.103.

Who Enforces HIPAA Rules?

The HHS OCR enforces the HIPAA Privacy, Security, and Breach Notification Rules. Violations may result in civil monetary penalties. In some cases, U.S. Department of Justice enforced criminal penalties may apply. Common violations include:

- Unpermitted PHI use and disclosure
- Use or disclosure of more than the minimum necessary PHI
- Lack of PHI safeguards
- Lack of administrative, technical, or physical ePHI safeguards
- Lack of patients' access to their PHI

Learn more about the HHS HIPAA Enforcement, including actual case examples.

Resources

- HIPAA FAQs for Professionals
- Model Notices of Privacy Practices
- Privacy, Security, and HIPAA
- Special Topics in Health Information Privacy
- Training Materials

Doxycycline for Post-Exposure Prophylaxis of Anthrax
Emergency Use Instructions for Healthcare Providers

This fact sheet provides instructions for the use of doxycycline for post-exposure prophylaxis (PEP) during an emergency involving anthrax (referred to as Emergency Use Instructions (EUI) fact sheet). Doxycycline is FDA-approved for PEP of inhalation anthrax – to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis (B. anthracis)*.[1] The Food and Drug Administration (FDA) has also issued an order permitting the emergency dispensing of oral formulations of doxycycline without a prescription during an anthrax emergency to individuals who may have been exposed to *B. anthracis*.[2]

What is inhalation anthrax?
Anthrax is a serious disease caused by the spore-forming bacterium *B. anthracis.* Inhalation anthrax is the most deadly form of the disease, with a historical mortality rate of approximately 90% for untreated cases. Inhalation anthrax occurs when an individual inhales aerosolized spores. It is not spread from person to person. Early symptoms include fever, chills, fatigue, cough or headache. Later symptoms include shortness of breath, chest pain, confusion or nausea. 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 (animal data show symptoms can occur more than 50 days after exposure).

Who should NOT take doxycycline?
Do not give doxycycline to anyone who is allergic to doxycycline or another antibiotic in the tetracycline class.

What is the usual dose of doxycycline for PEP of anthrax?
The full PEP regimen is 60 days. During an anthrax emergency, recipients may receive an initial 10-day supply to begin doxycycline therapy; public health officials will announce whether recipients need more doxycycline and how to get additional quantities of the drug.

- **Children weighing 76 lbs (35 kg) or more and Adults (≥ 18 years):** Take one tablet (100 mg) by mouth every 12 hours (one tablet in the morning and one tablet in the evening) each day with a full glass of water (with or without food or milk). For those who **cannot swallow tablets**, provide the crushing and mixing directions (which can also be found by searching "doxycycline crushing instructions" on www.cdc.gov). These instructions are appropriate **only** for 100 mg **tablets**.
- **Children weighing less than 76 lbs (35 kg):** Weight-based dosing (2.2 mg/kg) every 12 hours (one dose in the morning and one dose in the evening) each day. Provide the crushing and mixing instructions (which can also be found by searching "doxycycline crushing instructions" on www.cdc.gov). These instructions are appropriate **only** for 100 mg **tablets**.
- **Children weighing less than 30 lbs (14kg)**: Children weighing less than 30 lbs (14 kg) should receive priority for doxycycline oral suspension, dosed by weight every 12 hours (one dose in the morning and one dose in the evening) each day. For convenience, the table below provides dosing by weight-range based on 2.2 mg/kg derived calculation.[3] Doses in the table below are specific to **doxycycline powder for oral suspension** in the **25 mg/5 mL concentration only**.
  - Follow the instructions provided with the oral suspension to mix the doxycycline powder with water before dispensing the drug to the recipient. Write the dose on the bottle and mark the dose with a line on the oral syringe.
  - Tell the recipient to shake the oral suspension very well (15 seconds) before each use.

Weight in pounds (kilograms)	Dose in mL based on 25 mg/5 mL concentration (mg)	Number of 60-mL bottles (25 mg/5 mL concentration) needed for 10-day supply for one child
≤ 5 lbs (≤ 2 kg)	1 mL (5mg)	ONE (1) Bottle
6–10 lbs (3–4 kg)	2 mL (10 mg)	
11–15 lbs (5–7 kg)	3 mL (15 mg)	
16–20 lbs (8–9 kg)	4 mL (20 mg)	TWO (2) Bottles
21–25 lbs (10–11 kg)	5 mL (25 mg)	
26–30 lbs (12–14 kg)	6 mL (30 mg)	

What are common side effects of doxycycline?
Inform recipients that mild gastrointestinal side effects such as nausea, vomiting, and/or diarrhea, a mild sunburn or a vaginal yeast infection may be experienced but to continue taking doxycycline. If these side effects become severe, over-the-counter or prescription drugs can help to relieve the symptoms.

[1] See the FDA-approved package insert for doxycycline at www.dailymed.nlm.nih.gov and search for doxycycline.
[2] FDA's emergency dispensing order applies to all FDA-approved oral dosage forms of doxycycline products for the post-exposure prophylaxis of inhalation anthrax during an emergency involving *B. anthracis*. For details, see www.fda.gov.
[3] Weight-range dosing table is provided as exact dose calculation (based on 2.2 mg/kg) may not be feasible during an emergency.

What are possible serious side effects of doxycycline?

Tell recipients to **STOP** the doxycycline and get medical help immediately if they develop any of the following:

- Serious allergic/hypersensitivity reactions (anaphylactic and/or severe rashes)
- Severe stomach cramps with high fever or bloody diarrhea (antibiotic-associated diarrhea and pseudomembranous colitis)
- Liver problems (anorexia, jaundice, dark brown or tea-colored urine, pruritus or tender abdomen)
- Pain when swallowing (esophageal ulcers)
- Unusual bleeding or bruising
- Severe headaches, dizziness or double vision

What should recipients avoid while taking doxycycline?

- If a recipient is taking multivitamins, supplements or antacids that contain aluminum, calcium, magnesium, or iron, or drugs containing bismuth subsalicylate, instruct the recipient to take doxycycline at least 2 hours before or 2 hours after taking any of these products.
- Doxycycline can interact with certain drugs like blood thinners (increased blood thinning) or seizure drugs (decreased doxycycline concentration). If a recipient is taking these or other drugs with known interaction with doxycycline, consider changing the dose of these drugs or recommending alternative drugs. For more information on doxycycline drug interactions, please see package insert.

What additional information should be provided to recipients taking doxycycline?

- Tell recipients to take with food or milk if they have gastrointestinal upset with doxycycline. Co-administration of doxycycline with food or milk does not significantly reduce doxycycline absorption.
- Doxycycline is recommended as antimicrobial PEP for anthrax during pregnancy and while breastfeeding, but if taken during the last half of pregnancy or possibly when nursing, infants may have permanent tooth discoloration (yellow-gray-brown) and poor enamel formation. This may also occur in children under 8 years old who take doxycycline.
- Slowed bone growth may occur in children who take doxycycline.
- Doxycycline can cause sun sensitivity. Instruct recipients to use sunscreen and cover exposed skin.
- The effectiveness of birth control pills may be reduced with doxycycline use. Recommend a second form of birth control while taking doxycycline.
- Instruct recipients to keep doxycycline tablets dry and to store them at room temperature (between 68–77°F or 20–25°C).
- If you have been asked to dispense doxycycline with an expired date on the container, please note that FDA is allowing for the use of certain lots of doxycycline beyond the labeled expiration date during an anthrax emergency based on scientific review. For more information, go to the FDA website at www.fda.gov (search for “doxycycline expiration”).
- The Countermeasures Injury Compensation Program (CICP) is a federal program created to help pay for related costs of medical care and other specific expenses for eligible people seriously injured by the administration or use of certain medical countermeasures. Medical countermeasures may include vaccines, medications, devices or other items used to prevent, diagnose or treat the public during a public health emergency or security threat. For more information about CICP, visit www.hrsa.gov/cicp or call: 1-855-266-2427.

Risk-Benefit Statement

Although doxycycline has some potential and serious adverse events, the expected benefit of doxycycline to help prevent disease and death associated with anthrax exposure outweighs these risks.

Available Alternatives

During an anthrax emergency, you will be informed of any alternative antibiotics that are available, such as ciprofloxacin, levofloxacin or amoxicillin. The risks and benefits of available alternative antibiotics will be explained in their own fact sheets.

Reporting Adverse Event or Medication Errors

Report adverse events or medication errors to MedWatch (www.fda.gov/medwatch) by completing a MedWatch Form 3500 or by calling 1-800-FDA-1088.

Give recipients "Anthrax Emergency: How to Take Doxycycline to Prevent Anthrax" instructions.

Space Reserved for State/Local Public Health Information

Ciprofloxacin for Post-Exposure Prophylaxis of Anthrax
Emergency Use Instructions for Healthcare Providers

This fact sheet provides instructions for the use of ciprofloxacin for post-exposure prophylaxis (PEP) during an emergency involving anthrax (referred to as Emergency Use Instructions (EUI) fact sheet). Ciprofloxacin is FDA-approved for PEP of inhalation anthrax – to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis (B. anthracis)*.[1] The Food and Drug Administration (FDA) has also issued an order permitting the emergency dispensing of oral formulations of ciprofloxacin without a prescription during an anthrax emergency to individuals who may have been exposed to *B. anthracis*.[2]

What is inhalation anthrax?
Anthrax is a serious disease caused by the spore-forming bacterium *B. anthracis*. Inhalation anthrax is the most deadly form of the disease, with a historical mortality rate of approximately 90% for untreated cases. Inhalation anthrax occurs when an individual inhales aerosolized spores. It is not spread from person to person. Early symptoms include fever, chills, fatigue, cough or headache. Later symptoms include shortness of breath, chest pain, confusion or nausea. 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 (animal data show symptoms can occur more than 50 days after exposure).

Who should NOT take ciprofloxacin?
Do not give ciprofloxacin to anyone who is allergic to a quinolone antibiotic (including ciprofloxacin) or has a history of myasthenia gravis. Avoid concomitant administration of ciprofloxacin and Zanaflex (tizanidine) since ciprofloxacin can increase effects of tizanidine (e.g., bradycardia, hypotension); consider switching either ciprofloxacin or tizanidine to an alternative drug.

What is the usual dose of ciprofloxacin for PEP of anthrax?
The full PEP regimen is 60 days. During an anthrax emergency, recipients may receive an initial 10-day supply to begin ciprofloxacin therapy; public health officials will announce whether recipients need more ciprofloxacin and how to get additional quantities of the drug.

- **Children weighing 67 lbs (31 kg) or more and Adults (≥ 18 years):** Take one tablet (500 mg) by mouth every 12 hours (one tablet in the morning and one tablet in the evening) each day with a full glass of water (with or without food). For those who **cannot swallow tablets**, consider an oral suspension/liquid form (of ciprofloxacin or alternative drug) or a drug that can be mixed with food or liquid (such as doxycycline).
- **Children weighing less than 67 lbs (31 kg):** Weight-based dosing of ciprofloxacin oral suspension every 12 hours (one dose in the morning and one dose in the evening) each day. For convenience, the table below provides dosing by weight-range based on 15 mg/kg derived calculation.[3] Ciprofloxacin oral suspension comes in two concentrations **[5% (250 mg/5 mL) and 10% (500 mg/5 mL)]** and is supplied as ciprofloxacin microcapsules with diluent.
  - Follow the instructions provided with the oral suspension to mix the microcapsules in the diluent before dispensing the drug to the recipient. Write the dose on the bottle and mark the dose with a line on the graduated teaspoon or oral syringe.
  - Tell the recipient to shake the oral suspension very well (15 seconds) before each use.

Weight in pounds (kilograms)	Dose* in mL (mg)		Number of 100-mL bottles needed for 10-day supply for one child	
	250 mg/5 mL Concentration	500 mg/5 mL Concentration	250 mg/5 mL Concentration	500 mg/5 mL Concentration
≤ 7 lbs (≤ 3 kg)	1 mL (50 mg)	0.5 mL (50 mg)	ONE (1) Bottle	ONE (1) Bottle
8–14 lbs (4–6 kg)	2 mL (100 mg)	1 mL (100 mg)		
15–22 lbs (7–10 kg)	3 mL (150 mg)	1.5 mL (150 mg)		
23–29 lbs (11–13 kg)	4 mL (200 mg)	2 mL (200 mg)		
30–36 lbs (14–16 kg)	5 mL (250 mg)	2.5 mL (250 mg)		
37–44 lbs (17–20 kg)	6 mL (300 mg)	3 mL (300 mg)	TWO (2) Bottles	
45–51 lbs (21–23 kg)	7 mL (350 mg)	3.5 mL (350 mg)		
52–58 lbs (24–26 kg)	8 mL (400 mg)	4 mL (400 mg)		
59–66 lbs (27–30 kg)	9 mL (450 mg)	4.5 mL (450 mg)		
> 67 lbs (> 31 kg)	10 mL (500 mg)	5 mL (500 mg)		

*Dosage adjustment is needed for individuals with severe renal impairment (see package insert).[1]

What are common side effects of ciprofloxacin?
Inform recipients that mild gastrointestinal side effects such as nausea, vomiting, and/or diarrhea, a mild sunburn or a vaginal yeast infection may be experienced but to continue taking ciprofloxacin. If these side effects become severe, over-the-counter or prescription drugs can help to relieve the symptoms.

[1] See the FDA-approved package insert for ciprofloxacin at www.dailymed.nlm.nih.gov and search for ciprofloxacin.
[2] FDA's emergency dispensing order applies to all FDA-approved oral dosage forms of ciprofloxacin products for the post-exposure prophylaxis of inhalation anthrax during an emergency involving *B. anthracis*. For details, see www.fda.gov.
[3] Weight-range dosing table is provided as exact dose calculation (based on 15 mg/kg) may not feasible during an emergency.

What are possible side effects of ciprofloxacin?
Tell recipients to **STOP** the ciprofloxacin and get medical help immediately if they develop any of the following:

- Tendon rupture, tendinitis or joint problems
- Serious allergic/hypersensitivity reactions (anaphylactic and/or severe rashes)
- Liver problems (anorexia, jaundice, dark brown or tea-colored urine, pruritus or tender abdomen)
- Central nervous system effects (seizures, tremors, paranoia, anxiety)
- Serious heart rhythm changes (QT prolongation and torsade de pointes)
- Severe stomach cramps with high fever or bloody diarrhea (antibiotic-associated diarrhea and pseudomembranous colitis)
- Changes in sensation and possible nerve damage (peripheral neuropathy)

What should recipients avoid while taking ciprofloxacin?

- If a recipient is taking Carafate (sucralfate), Videx (didanosine), phosphate binders or multivitamins, supplements or antacids containing magnesium, calcium, aluminum, iron or zinc, instruct the recipient to take ciprofloxacin at least 2 hours before or 6 hours after taking any of these products.
- Ciprofloxacin can interact with certain drugs such as blood thinners (increased blood thinning), oral antidiabetic drugs (increased glucose-lowering effect), phenytoin (loss of seizure control), theophylline (increased theophylline concentration), or clozapine (irregular heartbeat). If a recipient is on these or other drugs with known interaction with ciprofloxacin, consider changing the dose of these drugs or recommending alternative drugs. For more information on ciprofloxacin drug interactions, please see package insert.

What additional information should be provided to recipients taking ciprofloxacin?

- Ciprofloxacin can exacerbate myasthenia gravis symptoms. It can also greatly potentiate effects of Zanaflex (tizanidine) (e.g., bradycardia, hypotension). Instruct those with a history of myasthenia gravis or taking tizanidine to avoid taking ciprofloxacin.
- Instruct recipients not to take ciprofloxacin with dairy products (like milk or yogurt) or calcium-fortified juices.
- Ciprofloxacin can cause sun sensitivity. Instruct recipients to use sunscreen and cover exposed skin.
- Ciprofloxacin, while not generally recommended for use in pregnancy, is recommended as antimicrobial PEP for anthrax during pregnancy and while breastfeeding due to the risks of anthrax. The very limited data available on ciprofloxacin use in pregnancy suggest the benefits of ciprofloxacin outweigh the risks.
- Recipients may wish to cut back on their caffeine intake, as the caffeine half-life may be prolonged.
- Instruct recipients to keep ciprofloxacin tablets dry and to store tablets and reconstituted oral suspension at room temperature (68–77°F or 20–25°C). Reconstituted oral suspension may be stored at room temperature up to 14 days.
- If you have been asked to dispense ciprofloxacin with an expired date on the container, please note that FDA is allowing for the use of certain lots of ciprofloxacin beyond the labeled expiration date during an anthrax emergency based on scientific review. For more information, go to the FDA website at www.fda.gov (search for "ciprofloxacin expiration").
- The Countermeasures Injury Compensation Program (CICP) is a federal program created to help pay for related costs of medical care and other specific expenses for eligible people seriously injured by the administration or use of certain medical countermeasures. Medical countermeasures may include vaccines, medications, devices or other items used to prevent, diagnose or treat the public during a public health emergency or security threat. For more information about CICP, visit www.hrsa.gov/cicp or call: 1-855-266-2427.

Risk-Benefit Statement
Although ciprofloxacin has some potential and serious adverse events, the expected benefit of ciprofloxacin to help prevent disease and death associated with anthrax exposure outweigh these risks.

Available Alternatives
During an anthrax emergency, you will be informed of any alternative antibiotics that are available, such as doxycycline, levofloxacin or amoxicillin. The risks and benefits of available alternative antibiotics will be explained in their own fact sheets.

Reporting Adverse Event or Medication Errors
Report adverse events or medication errors to MedWatch (www.fda.gov/medwatch) by completing a MedWatch Form 3500 or by calling 1-800-FDA-1088.

Give recipients "Anthrax Emergency: How to Take Ciprofloxacin to Prevent Anthrax" instructions.

Space Reserved for State/Local Public Health Information

Step 1 LIST ALL HOUSEHOLD MEMBERS FOR WHOM YOU ARE PICKING UP MEDICATIONS TODAY, INCLUDING YOURSELF		**Step 2** FOR **EACH** HOUSEHOLD MEMBER LISTED BELOW, ANSWER **ALL** QUESTIONS.				**FOR PUBLIC HEALTH WORKER'S USE ONLY** **Drug Assignment** **D, C, X** **D** for Doxycycline **C** for Ciprofloxacin **X** for Do Not Dispense	
		Question 1 • Is this person allergic to doxycycline or other "cycline" drugs? • Is this person pregnant?	**Question 2** • Does this person have difficulty swallowing pills? • Is this person both less than 90 pounds and less than 18 years of age?	**Question 3** • Is this person allergic to Ciprofloxacin or "floxacin" drugs? • Does this person have seizure disorder or epilepsy? • Is this person taking Tizanidine (Zanaflex)? • Does this person have renal (kidney) disease?	**Question 4** • Does this person have difficulty swallowing pills? • Is this person both less than 90 pounds and less than 18 years of age?		
Last name	**First name**	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	**D, C, X**	**Lot Number**

Step 3 Write in your address and telephone number to the right. If more than one, include all.	Telephone:	Address:

FOR PUBLIC HEALTH WORKER'S USE ONLY	Dispensing Site Name _____ Dispenser Signature _____ Date: _____

Instructions for Public Health Worker ***(follow the instructions to the right for each individual)***	**Q1** **NO:** Evaluate question ***2*** **YES:** Skip to question ***3***	**Q2** **NO:** Provide Doxycycline and **STOP** **YES:** Provide Doxycycline and Emergency Preparation Instructions & **STOP**	**Q3** **NO:** Evaluate question ***4*** **YES:** Advise person seek medical consult	**Q4** **NO:** Provide Ciprofloxacin **YES:** Advise person to seek medical consult	

GUIDANCE

What if someone has an incomplete form? Please refer them back to Intake for assistance. Intake will assess the situation and refer as needed. Please note that **Step 3** on this form is optional.

What do I do once the form is completed? Evaluate each household member for the distribution of antibiotics according to the instructions above. Record the appropriate letter and lot number for that household member's drug assignment. Once this has been completed, label each member's antibiotic with their name and give the present household member the correct handouts for the household. **If the present household member has further questions or concerns,** please refer him or her to the Medical Distribution Specialist. Place the completed form in your completed pile.

What do I do if someone is visually or hearing impaired? Please refer them back to Intake for assistance. Intake will assess the situation and refer as needed.

What is Tizanidine (Zanaflex)? This is a short-acting muscle relaxer used to treat muscle spasms caused by certain conditions such as multiple sclerosis and spinal cord injury. It should not be taken with Ciprofloxacin.

Question 1	Question 2	Question 3	Question 4	Antibiotic
No	No	X	X	Doxycycline (D)
No	Yes	X	X	Doxycycline (D) with Instructions
Yes	X	No	No	Ciprofloxacin (C)
Yes	X	Yes	X	Advise to seek medical consult (X)
Yes	X	No	Yes	Advise to seek medical consult (X)

START HERE

Medication Assessment Form

Missouri Medical Countermeasures/Strategic National Stockpile Program

Name:

Address:

City, State, Zip:

E-Mail:

Phone:

_____

Step 1. Place your own name in the first line below. List all household members for whom you are picking up medicine below your name.

Step 2. For each person listed, answer all 5 questions.

Step 3 Each person should take the medicine provided exactly as instructed.

Last Name, First Name	**Question 1 2 PARTS** **1.** Is this person smaller than 76 pounds? **2.** If YES, write in the weight in pounds. If NO, leave blank. **Weight if less than 76 pounds?**	**Question 2** Can this person swallow pills? **Yes, No, Don't Know?**	**Question 3 4 PARTS** **1.** Is this person allergic to **or** should not take *Cipro* (Ciprofloxacin), *Levaquin* (levofloxacin), or other floxacin antibiotic? **OR** **2.** Does this person take tizanidine (*Zanaflex*)? **OR** **3.** Does this person have a history of the muscle disease myasthenia gravis? **4.** If answer to any question is YES, answer Yes below. **Yes, No, Don't Know?**	**Question 4** Is this person allergic to **or** should not take doxycycline, tetracycline, or other "cycline" antibiotic? **Yes, No, Don't Know?**	**Question 5** Is this person pregnant? **Yes, No, Don't Know?**	**Mark the antibiotic provided; Affix label here**					
1.						Doxy Tabs	Cipro Tabs	Doxy Tabs Crush Ins	Doxy Susp	Cipro Susp	
2.						Doxy Tabs	Cipro Tabs	Doxy Tabs Crush Ins	Doxy Susp	Cipro Susp	
3.						Doxy Tabs	Cipro Tabs	Doxy Tabs Crush Ins	Doxy Susp	Cipro Susp	
4.						Doxy Tabs	Cipro Tabs	Doxy Tabs Crush Ins	Doxy Susp	Cipro Susp	
5.						Doxy Tabs	Cipro Tabs	Doxy Tabs Crush Ins	Doxy Susp	Cipro Susp	
August 2016	**Add totals under the columns** →										

Once you have received your medicine:

- Be sure to carefully read the fact sheet you have been given.
- Take the medicine exactly as prescribed unless your medical provider or a public health official tells you to stop. If you stop too soon, you could become sick.
- Take the medicine even if you feel well. If you do begin to feel sick with symptoms of the disease, it is important to get medical help right away.
- If you have questions, contact your medical provider or

_____.

STAFF USE ONLY

For persons who cannot take an adult dose or cannot swallow pills, use available options: Doxy **tab**lets with **Crush**ing **Ins**tructions, Doxy **Susp**ension, or Cipro **Susp**ension. Dose is based on person's weight.

Example of a Medication Dispensing Protocol to Accompany the Medication Assessment Form Developed by the Missouri Medical Countermeasures/Strategic National Stockpile Program

As part of the response to a bioterrorism attack utilizing certain types of bacterial agents, prophylactic antibiotics would be offered to potentially-exposed persons at point of dispensing (POD) sites. Persons who will receive prophylaxis at these sites will first provide to POD staff certain medically-relevant information so that the appropriate antibiotic accompanied by appropriate dosage instructions can be provided. One mechanism to collect this information is the medication assessment form developed by the Missouri Medical Countermeasures/Strategic National Stockpile Program. If this assessment form is used, there would need to be an accompanying medication dispensing protocol that POD staff could use to determine, based on the answers provided on the form, which antibiotic to provide, in what form (i.e., tablet, suspension, or tablet with crushing instructions), and in what dosage.

On the following page is an example of what a dispensing protocol might look like. It is very important to understand that the protocol shown here is meant to be an example, and it is based on a number of assumptions that might not be valid in an actual bioterrorism incident. Among these assumptions are the following:

- Both doxycycline and ciprofloxacin (the two antibiotics available at the PODs) would provide effective prophylaxis against the organism.*
- Doxycycline is the preferred drug for individuals of all ages, except in pregnant women where ciprofloxacin would be the preferred drug.
- Doxycycline suspension would be used in children less than 31 pounds; if doxycycline suspension was not available, ciprofloxacin suspension would be used in these individuals. If neither suspension was available, these children would receive doxycycline tablets with crushing and dosage instructions.
- Individuals 31-66 pounds who cannot take doxycycline, but can take ciprofloxacin, would receive ciprofloxacin suspension if it is available.

In an actual incident, some or all of these assumptions might be different. Also, local medical professionals (including the physician[s] who will be signing the Standing Orders for POD staff) might believe changes to the protocol need to be made. Consequently, the actual dispensing protocol that would be utilized in a real incident can only be finalized after the incident is recognized and incident-specific information and guidance become available. However, while a dispensing protocol cannot be completely finalized in advance, it is important for jurisdictions to decide beforehand the basic format for this document, and the protocol example shown below is intended to assist in this process (and it can also, of course, be utilized in exercises). It is emphasized that all decisions on these issues should be made in close collaboration with appropriate medical professionals, including the physician(s) who will sign the Standing Orders for POD staff.

*Also note that the dosages in the dispensing protocol example are based on guidance provided in the current Emergency Use Instructions (EUIs) for anthrax prophylaxis. The recommended dosages for other bacterial agents may be different.

January 2017

Doxycycline Preferred With Ciprofloxacin Alternate
(Ciprofloxacin Preferred for Pregnant Women)

1. Weight: 76+ pounds

2. Able to Swallow Pills: Yes

3. Cannot Take Cipro	4. Cannot Take Doxy	5. Pregnant?	Dispense
No/DK	No/DK	No/DK	Doxy 100 mg Tablets
No/DK	No/DK	Yes	Cipro 500 mg Tablets
Yes	No/DK	Any	Doxy 100 mg Tablets
No/DK	Yes	Any	Cipro 500 mg Tablets
Yes	Yes	Any	Refer

2. Able to Swallow Pills: No

3. Cannot Take Cipro	4. Cannot Take Doxy	5. Pregnant?	Dispense
No/DK	No/DK	No/DK	Doxy 100 mg Tablets + Crushing Instructions
No/DK	No/DK	Yes	Doxy 100 mg Tablets + Crushing Instructions
Yes	No/DK	Any	Doxy 100 mg Tablets + Crushing Instructions
No/DK	Yes	Any	Refer
Yes	Yes	Any	Refer

1. Weight: 67-75 pounds

2. Able to Swallow Pills: Yes

3. Cannot Take Cipro	4. Cannot Take Doxy	5. Pregnant?	Dispense
No/DK	No/DK	No/DK	Doxy 100 mg Tablets + Crushing Instructions
No/DK	No/DK	Yes	Cipro 500 mg Tablets
Yes	No/DK	Any	Doxy 100 mg Tablets + Crushing Instructions
No/DK	Yes	Any	Cipro 500 mg Tablets
Yes	Yes	Any	Refer

2. Able to Swallow Pills: No

3. Cannot Take Cipro	4. Cannot Take Doxy	5. Pregnant?	Dispense
No/DK	No/DK	No/DK	Doxy 100 mg Tablets + Crushing Instructions
No/DK	No/DK	Yes	Doxy 100 mg Tablets + Crushing Instructions
Yes	No/DK	Any	Doxy 100 mg Tablets + Crushing Instructions
No/DK	Yes	Any	Refer
Yes	Yes	Any	Refer

Note that in the tables, **Yes**, **No**, or **DK** (Don't Know) refer to the answers given to the questions on the Medication Assessment Form. For example, for "3. Cannot Take Cipro," a **No** answer means the person has indicated they do not have any of the reasons listed on the form for not taking ciprofloxacin, and thus they can be given this drug if indicated. On the other hand, a **Yes** answer means the person has indicated they do have one or more of the reasons listed on the form for not taking ciprofloxacin, and thus they should not be given this drug.

1. Weight: 31-66 pounds

2. Able to Swallow Pills: Any

3. Cannot Take Cipro	4. Cannot Take Doxy	5. Pregnant?	Dispense
No/DK	No/DK	NA	Doxy 100 mg Tablets + Crushing Instructions
Yes	No/DK	NA	Doxy 100 mg Tablets + Crushing Instructions
No/DK	Yes	NA	Cipro Suspension*
Yes	Yes	NA	Refer

1. Weight: 0-30 pounds

2. Able to Swallow Pills: Any

3. Cannot Take Cipro	4. Cannot Take Doxy	5. Pregnant?	Dispense
No/DK	No/DK	NA	Doxy Suspension**
Yes	No/DK	NA	Doxy Suspension**
No/DK	Yes	NA	Cipro Suspension*
Yes	Yes	NA	Refer

DK = Don't Know, **NA** = Not Applicable Note that the crushing instructions for doxycycline tablets contain a dosage chart based on weight.

*Provide Cipro Suspension according to the instructions in Table 1, below. Ensure the dose, based on Table 1, is written on the bottle AND marked with a line on the graduated teaspoon or oral syringe provided. If Cipro Suspension is not available, refer.

**Provide Doxy Suspension according to the instructions in Table 2, below. Ensure the dose, based on Table 2, is written on the bottle AND marked with a line on the graduated teaspoon or oral syringe provided. If Doxy Suspension is not available and the individual can take ciprofloxacin, then provide Cipro Suspension according to the instructions in Table 1, below. Ensure the dose of Cipro, based on Table 1, is written on the bottle AND marked with a line on the graduated teaspoon or oral syringe provided. If neither Doxy Suspension or Cipro Suspension is available and the individual can take doxycycline, then provide Doxy 100 mg Tablets + Crushing Instructions.

Table 1. Ciprofloxacin Oral Suspension

Weight in pounds (kilograms)	Dose* in milliliters (mL) 250 mg/5 mL strength	Dose* in milliliters (mL) 500 mg/5 mL strength	Number of 100 mL bottles needed for 10-day supply for one patient	
			250 mg/5 mL strength	500 mg/5 mL strength
0–7 lbs (0–3 kg)	1 mL (50 mg)	0.5 mL (50 mg)	ONE (1) Bottle	ONE (1) Bottle
8–14 lbs (4–6 kg)	2 mL (100 mg)	1 mL (100 mg)		
15–22 lbs (7–10 kg)	3 mL (150 mg)	1.5 mL (150 mg)		
23–29 lbs (11–13 kg)	4 mL (200 mg)	2 mL (200 mg)		
30–36 lbs (14–16 kg)	5 mL (250 mg)	2.5 mL (250 mg)		
37–44 lbs (17–20 kg)	6 mL (300 mg)	3 mL (300 mg)	TWO (2) Bottles	
45–51 lbs (21–23 kg)	7 mL (350 mg)	3.5 mL (350 mg)		
52–58 lbs (24–26 kg)	8 mL (400 mg)	4 mL (400 mg)		
59–66 lbs (27–30 kg)	9 mL (450 mg)	4.5 mL (450 mg)		
> 67 lbs (> 31 kg)	10 mL (500 mg)	5 mL (500 mg)		

Table 2. Doxycycline Oral Suspension

Weight in pounds (kilograms)	Dose in mL (based on 25 mg/5 mL concentration)	Number of 60 mL bottles (25 mg/5 mL concentration) needed for 10-day supply for one patient
0–5 lbs (0–2 kg)	1 mL (5mg)	ONE (1) Bottle
6–10 lbs (3–4 kg)	2 mL (10 mg)	
11–15 lbs (5–7 kg)	3 mL (15 mg)	
16–20 lbs (8–9 kg)	4 mL (20 mg)	TWO (2) Bottles
21–25 lbs (10–11 kg)	5 mL (25 mg)	
26–30 lbs (12–14 kg)	6 mL (30 mg)	

January 2017

Step 1 LIST ALL HOUSEHOLD MEMBERS FOR WHOM YOU ARE PICKING UP MEDICATIONS TODAY, INCLUDING YOURSELF		**Step 2** FOR **EACH** HOUSEHOLD MEMBER LISTED BELOW, ANSWER **ALL** QUESTIONS.				**FOR PUBLIC HEALTH WORKER'S USE ONLY** **Drug Assignment** D, C, X **D** for Doxycycline **C** for Ciprofloxacin **X** for Do Not Dispense	
		Question 1 • Is this person allergic to doxycycline or other "cycline" drugs? • Is this person pregnant?	**Question 2** • Does this person have difficulty swallowing pills? • Is this person both less than 90 pounds and less than 18 years of age?	**Question 3** • Is this person allergic to Ciprofloxacin or "floxacin" drugs? • Does this person have seizure disorder or epilepsy? • Is this person taking Tizanidine (Zanaflex)? • Does this person have renal (kidney) disease?	**Question 4** • Does this person have difficulty swallowing pills? • Is this person both less than 90 pounds and less than 18 years of age?		
Last name	**First name**	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	**D, C, X**	**Lot Number**
Soprano	Anthony						
Soprano	Carmella						
Soprano	Meadow						
Soprano	Anthony Jr.						
Baccalieri	Robert						

Step 3 Write in your address and telephone number to the right. If more than one, include all.	Telephone: 573-298-1191	Address: 14 Aspen Dr. Columbia, MO 65201

FOR PUBLIC HEALTH WORKER'S USE ONLY	Dispensing Site Name _____ Dispenser Signature _____ Date: _____

Step 1 LIST ALL HOUSEHOLD MEMBERS FOR WHOM YOU ARE PICKING UP MEDICATIONS TODAY, INCLUDING YOURSELF		**Step 2** FOR **EACH** HOUSEHOLD MEMBER LISTED BELOW, ANSWER **ALL** QUESTIONS.				**FOR PUBLIC HEALTH WORKER'S USE ONLY** **Drug Assignment** D, C, X D for Doxycycline C for Ciprofloxacin X for Do Not Dispense	
		Question 1 • Is this person allergic to doxycycline or other "cycline" drugs? • Is this person pregnant?	**Question 2** • Does this person have difficulty swallowing pills? • Is this person both less than 90 pounds and less than 18 years of age?	**Question 3** • Is this person allergic to Ciprofloxacin or "floxacin" drugs? • Does this person have seizure disorder or epilepsy? • Is this person taking Tizanidine (Zanaflex)? • Does this person have renal (kidney) disease?	**Question 4** • Does this person have difficulty swallowing pills? • Is this person both less than 90 pounds and less than 18 years of age?		
Last name	**First name**	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	If yes to **any**, write yes If no to **all**, write no	**D, C, X**	**Lot Number**
Soprano	Anthony	NO	NO				
Soprano	Carmella	Yes		NO	Yes		
Soprano	Meadow	NO	Yes				
Soprano	Anthony Jr.	Yes		Yes			
Baccalieri	Robert	Yes		NO	NO		

Step 3 Write in your address and telephone number to the right. If more than one, include all.	Telephone: 573-298-1191	Address: 14 Aspen Dr. Columbia, MO 65201

FOR PUBLIC HEALTH WORKER'S USE ONLY	Dispensing Site Name _____ Dispenser Signature _____ Date: _____

Instructions for Public Health Worker ***(follow the instructions to the right for each individual)***	**Q1** **NO:** Evaluate question ***2*** **YES:** Skip to question ***3***	**Q2** **NO:** Provide Doxycycline and **STOP** **YES:** Provide Doxycycline and Emergency Preparation Instructions & **STOP**	**Q3** **NO:** Evaluate question ***4*** **YES:** Advise person seek medical consult	**Q4** **NO:** Provide Ciprofloxacin **YES:** Advise person to seek medical consult

GUIDANCE

What if someone has an incomplete form? Please refer them back to Intake for assistance. Intake will assess the situation and refer as needed. Please note that **Step 3** on this form is optional.

What do I do once the form is completed? Evaluate each household member for the distribution of antibiotics according to the instructions above. Record the appropriate letter and lot number for that household member's drug assignment. Once this has been completed, label each member's antibiotic with their name and give the present household member the correct handouts for the household. **If the present household member has further questions or concerns,** please refer him or her to the Medical Distribution Specialist. Place the completed form in your completed pile.

What do I do if someone is visually or hearing impaired? Please refer them back to Intake for assistance. Intake will assess the situation and refer as needed.

What is Tizanidine (Zanaflex)? This is a short-acting muscle relaxer used to treat muscle spasms caused by certain conditions such as multiple sclerosis and spinal cord injury. It should not be taken with Ciprofloxacin.

Step 1

LIST ALL HOUSEHOLD MEMBERS FOR WHOM YOU ARE PICKING UP MEDICATIONS TODAY, INCLUDING YOURSELF

Step 2

FOR **EACH** HOUSEHOLD MEMBER LISTED BELOW, ANSWER **ALL** QUESTIONS.

Question 1
- Is this person allergic to doxycycline or other "cycline" drugs?
- Is this person pregnant?

Question 2
- Does this person have difficulty swallowing pills?
- Is this person both less than 90 pounds and less than 18 years of age?

Question 3
- Is this person allergic to Ciprofloxacin or "floxacin" drugs?
- Does this person have seizure disorder or epilepsy?
- Is this person taking Tizanidine (Zanaflex)?
- Does this person have renal (kidney) disease?

Question 4
- Does this person have difficulty swallowing pills?
- Is this person both less than 90 pounds and less than 18 years of age?

FOR PUBLIC HEALTH WORKER'S USE ONLY

Drug Assignment

D, C, X
D for Doxycycline
C for Ciprofloxacin
X for Do Not Dispense

Last name	First name	Q1: If yes to any, write yes If no to all, write no	Q2: If yes to any, write yes If no to all, write no	Q3: If yes to any, write yes If no to all, write no	Q4: If yes to any, write yes If no to all, write no	D, C, X	Lot Number
Soprano	Anthony	NO	NO			O	DOXYCYCLINE 100MG 20 TABLETS LOT# D1234 EXP: 12-22 RX# XXXXX SAMPLE
Soprano	Carmella	Yes		NO	Yes	X	
Soprano	Meadow	NO	Yes			D(I)	DOXYCYCLINE 100MG 20 TABLETS LOT# D1234 EXP: 12-22 NDC – 66336 – 449 – 20 SAMPLE
Soprano	Anthony Jr.	Yes		Yes		X	
Baccalieri	Robert	Yes		NO	NO	C	CIPROFLOXACIN HCl 500MG 20 TABLETS LOT# C1234 EXP: 12-22 NDC 66336 – 903 – 20 SAMPLE

Step 3

Write in your address and telephone number to the right. If more than one, include all.

Telephone: 573-298-1191

Address: 14 Aspen Dr. Columbia, MO 65201

FOR PUBLIC HEALTH WORKER'S USE ONLY

Dispensing Site Name KCHD

Dispenser Signature Sebastian Gely Date: 01/31/24

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

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.

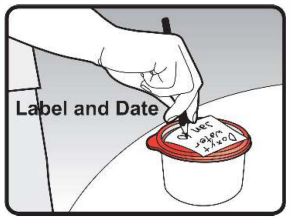
Space Reserved for State/Local Public Health Information

What should you do with any leftover doxycycline and water mixture remaining in the first bowl?

Throw it away if your child weighs 51 pounds or more (or is 6 years or older). You do NOT have enough left over to make another dose.

Keep it if your child weighs 50 pounds or less (or is 5 years or younger). You will have enough left over to make another dose.

- **Store** the **doxycycline and water mixture** in a covered bowl or cup at room temperature (between 68–77°F or 20–25°C) for up to 24 hours.
- **Write** the date, time and container contents on a label.
- **Keep** the mixture in a safe place, out of the reach of children or pets.
- **Throw away** any unused mixture after 24 hours and make a new doxycycline and water mixture for the next dose.



What should you know about side effects?

- Do not take doxycycline if you are allergic to an ingredient in doxycycline hyclate or any tetracycline antibiotics.
- Get emergency help if you have any signs of an allergic reaction, including hives, difficulty breathing or swelling of your face, lips, tongue or throat.
- Doxycycline may cause diarrhea, skin reaction to the sun, loss of appetite, nausea and vomiting. Refer to "Anthrax Emergency: How to Take Doxycycline to Prevent Anthrax" instructions for more information on possible side effects.
- Report any reaction to doxycycline to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

Accessible at: https://www.cdc.gov/anthrax/medical-care/doxy-crushing-instruction-pamphlet.html

In an Emergency: How to Prepare Doxycycline Hyclate for Children and Adults Who Cannot Swallow Pills

During a public health emergency, you might need to prepare emergency doses of doxycycline for children and adults who cannot swallow pills. This pamphlet shows you how to mix doxycycline hyclate 100 mg tablets with food or drink.

Follow the instructions below to prepare and give your child the **right amount** of medicine **every 12 hours** (once in the morning and once at night) **each day,** as long as directed. Use the same directions for adults who cannot swallow pills.

A Get the supplies you need.

You will need these items to make doses of doxycycline for children and adults who cannot swallow pills:

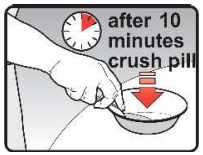
- 1 doxycycline hyclate **tablet** (100 mg)
- 1 metal teaspoon
- 1 oral syringe or medicine spoon (if available)
- 2 small bowls
- small amount of drinking water (4 teaspoons or 20 mL)
- 1 of these foods or drinks to make the crushed doxycycline taste better*:
  - milk, including breast milk and formula for infants
  - chocolate milk
  - chocolate pudding
  - apple juice mixed with 2 to 4 teaspoons of sugar

*Doxycycline works just as well whether you take it with or without food or milk.

A supplemental video of these instructions is available by searching "doxycycline crushing instructions" on www.cdc.gov

Doxycycline EUI Crushing Instructions (originally issued 03/28/2016; revised 08/18/2017)

B Soak the tablet in water and crush it.



1. Put 1 doxycycline hyclate tablet in a small bowl.
2. Add 4 teaspoons (20 mL) of water to the same bowl.
3. Let the tablet **soak** in the water for at least **10 minutes** to soften it.
4. **Crush** the tablet with the back of the metal spoon until you can't see any pieces of the tablet in the water.
5. Stir the tablet and water to mix it well.

You have now made the doxycycline and water mixture.

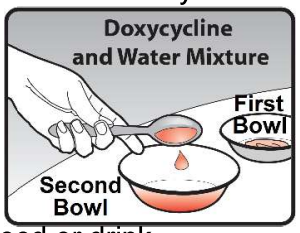
C Measure the right amount of doxycycline.

1. **Find your child's weight** on the chart below.
   *Weight is better, but if you don't know how much your child weighs, find your child's **age** on the chart.*
2. Follow the row of your child's weight or age across to the column "**Amount of Doxycycline & Water Mixture to Measure**."

Weight	Age	Amount of Doxycycline & Water Mixture to Measure*
12 pounds or less	Less than 1 month	½ teaspoon (2.5 mL)
13 to 25 pounds	1 to 11 months	1 teaspoon (5 mL)
26 to 50 pounds	1 to 5 years	2 teaspoons (10 mL)
51 to 75 pounds	6 to 8 years	3 teaspoons (15 mL)
76 pounds or more (Adult Dose)	9 years or older	4 teaspoons (20 mL)

*Weight-range dosing based on 2.2 mg/kg derived dose calculation.

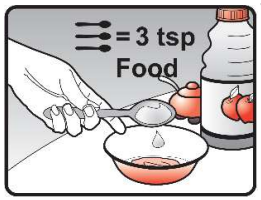
3. **Measure** the amount of doxycycline and water mixture for your child's weight or age from the first bowl.
   *For a ½ **teaspoon** dose, fill the teaspoon halfway or use an oral syringe (if available). It is better to give a little more of the medicine than not enough.*

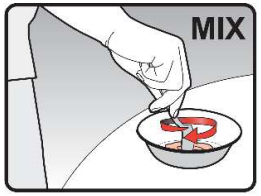


4. Place this amount into the **second bowl**. This is **one dose** that should be mixed with food or drink.

For children weighing 76 pounds or more and adults who cannot swallow pills, **use all** of the doxycycline and water mixture in the first bowl (4 teaspoons); the **entire contents of the first bowl** makes **one dose** that should be mixed with food or drink.

D Mix the dose with food or drink.





1. **Mix** the **dose** (measured amount of doxycycline and water mixture) in the second bowl with **3 teaspoons** of one of the following:
   - Milk, including breast milk and formula for infants
   - Chocolate milk
   - Chocolate pudding

   OR
   - Apple juice mixed with 2 to 4 teaspoons of sugar

You now have one dose, mixed with food or drink.

2. Stir well before giving it to your child.

E Give the dose.

1. Give your child **all** of the doxycycline, water and food mixture from the second bowl. Make sure your child swallows all of it. This is one dose.

2. Do this once **every 12 hours** (once in the morning AND once at night) **each day** for as long as directed.

Doxycycline EUI Crushing Instructions (originally issued 03/28/2016; revised 08/18/2017)

You Must Provide Patients with Vaccine Information Statements (VISs) – It's Federal Law!

What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act, NCIVA) requires a healthcare professional to provide a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox).

Where to get VISs

All available VISs can be downloaded from the websites of Immunize.org at www.immunize.org/vaccines/vis/about-vis/ or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 40 languages on the Immunize.org website at www.immunize.org/vaccines/vis-translations/spanish/.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vaccines/vis-translations/spanish/

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private healthcare setting.

Top 10 Facts About VISs

FACT 1 It's federal law! You must provide current* VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL ages** when administering these vaccines:

- DTaP
- Td and Tdap
- hepatitis A
- hepatitis B
- Hib
- HPV
- influenza (inactivated and live, intranasal)
- MMR and MMRV
- meningococcal (MenACWY, MenB)
- pneumococcal conjugate
- polio
- rotavirus
- varicella (chickenpox)

For the vaccines not covered under NCVIA (i.e., adenovirus, anthrax, COVID-10, dengue, ebola, Japanese encephalitis, pneumococcal polysaccharide, rabies, RSV, smallpox/monkeypox, tick-borne encephaliatis, typhoid, yellow fever, and zoster), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given. When administering a vaccine under conditions of an emergency use authorization (EUA), an EUA fact sheet must be used.

*Federal law allows up to 6 months for a new VIS to be used.

FACT 2 VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format

CONTINUED ON THE NEXT PAGE ▶

As of December 7, 2023, the most recent versions of the VISs are:

Adenovirus	1/8/20	**MMRV**	8/6/21
Anthrax	1/8/20	**Multi-vaccine**	7/24/23
COVID-19	10/19/23	**PCV**	5/12/23
Cholera	10/30/19	**PPSV23**	10/30/19
Dengue	12/17/21	**Polio**	8/6/21
DTaP	8/6/21	**Rabies**	6/2/22
Ebola	6/30/22	**RSV**	10/19/23
Hepatitis A	10/15/21	**Rotavirus**	10/15/21
Hepatitis B	5/12/23	**Smallpox/monkeypox**	11/14/22
Hib	8/6/21	**Td**	8/6/21
HPV	8/6/21	**Tdap**	8/6/21
Influenza	8/6/21	**Tick-borne encephalitis**	12/7/23
Japanese enceph	8/15/19	**Typhoid**	10/30/19
MenACWY	8/6/21	**Varicella**	8/6/21
MenB	8/6/21	**Yellow fever**	4/1/20
MMR	8/6/21	**Zoster**	2/4/22

Immunize.org

FOR PROFESSIONALS www.immunize.org / **FOR THE PUBLIC** www.vaccineinformation.org

www.immunize.org/catg.d/p2027.pdf
Item #P2027 (12/7/2023)

Scan for PDF

used, the goal is to provide a current VIS just prior to vaccination. (For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC's *VIS Frequently Asked Questions* at www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.

FACT 3 VISs are required in both public and private sector healthcare settings.

Federal law requires the use of VISs in both public and private sector settings, regardless of the source of payment for the vaccine.

FACT 4 You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.

FACT 5 You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

FACT 6 You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix, Vaxelis) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS.

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.

FACT 7 VISs should be given in a language / format that the recipient can understand, whenever possible.

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in more than 40 languages, visit the Immunize.org website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.

FACT 8 Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).

FACT 9 To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)

In addition, providers must record:

- The office address and name and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number

FACT 10 VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

Additional resources on VISs and their use are available from the following organizations:

Immunize.org

- *VIS general information and translations in more than 40 languages:* www.immunize.org/vaccines/vis/about-vis/
- *Current Dates of Vaccine Information Statements:* www.immunize.org/catg.d/p2029.pdf

Centers for Disease Control and Prevention

- *VIS website:* www.cdc.gov/vaccines/hcp/vis
- *VIS Facts:* www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
- *VIS FAQs:* www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html

Anthrax Vaccine:
What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Anthrax vaccine can prevent **anthrax**.

People can get anthrax disease from contact with infected animals or contaminated animal products such as wool, meat, or hides. The anthrax bacteria could also be used as a biological weapon.

Anthrax is not spread from person to person. It is spread in one of four ways, and signs and symptoms can vary depending on how anthrax enters the body:

- Through breaks in the skin. Cutaneous anthrax causes blisters or bumps on the skin, swelling around the sore, and a painless skin sore (ulcer) with a black center. The sore is usually on the face, neck, arms, or hands.
- From eating infected meat. Ingestion anthrax can cause fever and chills. It can affect the upper part of the gastrointestinal (GI) tract, the lower part of the GI tract, or both. When it affects the upper part, there is swelling of the neck or neck glands, sore throat, and painful swallowing or difficulty breathing. When it affects the lower GI tract, nausea and vomiting, stomach pain and swelling, and diarrhea may be present. The patient may also look flushed (red), have red eyes, or faint.
- From inhaling spores of the bacteria that causes anthrax. Inhalation anthrax can cause shortness of breath, cough, chest discomfort, confusion, nausea or vomiting, stomachache, sweats, and dizziness.
- From injecting heroin. Injection anthrax can result in swelling at the injection site, nausea and vomiting, and sweats.

All types of anthrax can cause fever, chills, fatigue, and headache. Anthrax can spread throughout the body and cause severe illness, including brain infections and even death, if left untreated.

2 Anthrax vaccine

Anthrax vaccine is approved by the Food and Drug Administration (FDA) and recommended for adults 18 through 65 years of age **who are at risk of exposure to anthrax bacteria**, including:

- Certain laboratory workers who work with *Bacillus anthracis*
- People who handle potentially infected animals or their carcasses
- Some military personnel (determined by the Department of Defense)
- Some emergency and other responders whose response activities might lead to exposure

These people should get 3 doses of anthrax vaccine, followed by booster doses for ongoing protection.

Anthrax vaccine is also recommended for **unvaccinated people of all ages who have been exposed to anthrax**. These people should get 3 doses of anthrax vaccine together with recommended antibiotic drugs.

Anthrax vaccine has not been studied or used in children less than 18 years of age. Because its use in exposed children is not approved by FDA, it must be used under an expanded access Investigational New Drug (IND) program and requires informed consent from a parent or legal guardian.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of anthrax vaccine**, or has any **severe, life-threatening allergies**.
- Is **pregnant** or thinks she might be pregnant.
- Has a **weakened immune system**.
- Has a **history of anthrax disease**.

In some cases, your health care provider may decide to postpone anthrax vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting anthrax vaccine.

If you are receiving the vaccine because you have been exposed to anthrax, tell your health care provider if you are not feeling well. You might need immediate medical care.

Your health care provider can give you more information.

4 Risks of a vaccine reaction

After getting a shot of anthrax vaccine, you may have:

- Tenderness, redness, itching, or a lump or bruise where the shot is given
- Muscle aches or short-term trouble moving your arm
- Headaches or fatigue

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines. If you have been injured by the anthrax vaccine, you can learn more about this Program by visiting the program's website at **www.hrsa.gov/cicp,** or calling **1-855-266-2427**.

7 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's anthrax website at **www.cdc.gov/anthrax**

Vaccine Information Statement
Anthrax Vaccine

Office use only

01/08/2020

Influenza (Flu) Vaccine (Live, Intranasal): *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Live, attenuated influenza vaccine

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

Live, attenuated influenza vaccine (called "LAIV") is a nasal spray vaccine that may be given to non-pregnant people 2 **through 49 years of age**.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Is **younger than 2 years or older than 49 years** of age
- Is **pregnant**. Live, attenuated influenza vaccine is not recommended for pregnant people
- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Is a **child or adolescent 2 through 17 years of age who is receiving aspirin or aspirin- or salicylate-containing products**
- Has a **weakened immune system**
- Is a **child 2 through 4 years old who has asthma or a history of wheezing** in the past 12 months
- Is **5 years or older and has asthma**
- Has **taken influenza antiviral medication** in the last 3 weeks
- **Cares for severely immunocompromised people** who require a protected environment
- Has other **underlying medical conditions** that can put people at higher risk of serious flu complications (such as **lung disease, heart disease, kidney disease**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

like diabetes, kidney or liver disorders, neurologic or neuromuscular or metabolic disorders)
- Does **not have a spleen**, or has a **non-functioning spleen**
- Has a **cochlear implant**
- Has a **cerebrospinal fluid leak** (a leak of the fluid that surrounds the brain to the nose, throat, ear, or some other location in the head)
- Has had **Guillain-Barré Syndrome** within 6 weeks after a previous dose of influenza vaccine

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

For some patients, a different type of influenza vaccine (inactivated or recombinant influenza vaccine) might be more appropriate than live, attenuated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Runny nose or nasal congestion, wheezing, and headache can happen after LAIV vaccination.
- Vomiting, muscle aches, fever, sore throat, and cough are other possible side effects.

If these problems occur, they usually begin soon after vaccination and are mild and short-lived.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/flu**.

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

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4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/flu**.

CHECKLIST of Best Practices FOR Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. These CDC guidelines and best practices are essential for patient safety and vaccine effectiveness. This checklist should be used in any non-traditional vaccination clinic settings, such as workplaces, community centers, schools, makeshift clinics in remote areas, and medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, walk-through, curbside, and drive-through clinics, and vaccination clinics held during pandemic preparedness exercises. **A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held**. To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

This document also contains sections, marked in red, that outline best practices for vaccination during the COVID-19 pandemic. For continued up-to-date guidance, please visit www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. This person will be responsible for completing the steps below and will be referred to as "you" in these instructions.
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. **Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: STOP. If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic. Follow your organization's protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed you can move forward with the clinic.**
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, whether patients' personal information was protected appropriately, or other responses that you have marked as "NO" in rows that do not have the STOP.
5. This checklist should be used in conjunction with CDC's *Vaccine Storage and Handling Toolkit*: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For information about specific vaccines, consult the vaccine manufacturer's package insert.
6. **This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures** (i.e., between 2–8° Celsius or 36–46° Fahrenheit).
7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). (*If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.*)
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor is overseeing different shifts) and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor: _____

Name of facility where clinic was held: _____

Address where clinic was held (street, city, state): _____

Time and date of vaccination clinic shift (the portion you oversaw): _____ (Time (AM/PM)) _____ (Date (MM/DD/YYYY))

Time and date when form was completed: _____ (Time (AM/PM)) _____ (Date (MM/DD/YYYY))

Signature of clinic coordinator/supervisor: _____

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This document was created by the Influenza Work Group of the National Adult and Influenza Immunization Summit.
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BEFORE THE CLINIC (Please complete each item before the clinic starts.)

VACCINE SHIPMENT

YES	NO	N.A.	
☐	☐		Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. (*Direct shipment is preferred for cold chain integrity.*)

VACCINE TRANSPORT (IF IT WAS NOT POSSIBLE TO SHIP VACCINES DIRECTLY TO THE FACILITY/CLINIC SITE)

YES	NO	N.A.	
☐	☐ STOP	☐	**Vaccines were transported using a portable vaccine refrigerator or qualified container and packout designed to transport vaccines** within the temperature range recommended by the manufacturers (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines). Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. *See CDC's* Vaccine Storage and Handling Toolkit *for information on qualified containers and packouts*: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
☐	☐ STOP	☐	The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. (*Your qualified container and packout should include packing instructions. If not, contact the company for instructions on proper packing procedures.*)
☐	☐	☐	The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).
☐	☐ STOP	☐	A digital data logger with a buffered probe and a current and valid Certificate of Calibration Testing was placed directly with the vaccines and used to monitor vaccine temperature during transport.
☐	☐	☐	The amount of vaccine transported was limited to the amount needed for the workday.

VACCINE STORAGE AND HANDLING (UPON ARRIVAL AT FACILITY/CLINIC)

YES	NO	N.A.	
☐	☐ STOP	☐	If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.
☐	☐ STOP	☐	If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion (i.e., out-of-range temperature) during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). *Note: CCMs are for one-time use and should be thrown away after being checked.*
☐	☐ STOP		Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and packout specifically designed and tested to maintain the manufacturer-recommended temperature range). *Follow the guidance for unpacking and storing vaccines specified in CDC's* Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
☐	☐ STOP		Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (*i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines*).
☐	☐		Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer's package insert) until ready for use at the vaccination clinic.
☐	☐ STOP		Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.

CLINIC PREPARATION AND SUPPLIES

YES	NO	N.A.	
☐	☐		A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.
☐	☐ STOP		An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.
☐	☐ STOP		All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in an emergency, and know the location of epinephrine and are trained in its indications and use.
☐	☐		There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).
☐	☐		Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene. If administering injectable vaccines, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles and syringes and a sharps container are provided.
☐	☐		Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.
☐	☐	☐	If using a standing order protocol, the protocol is current and available at the clinic/facility site.
☐	☐		A process for screening for contraindications and precautions is in place.
☐	☐ STOP		A sufficient number of vaccine information statements (VISs or Emergency Use Authorization [EUA]) forms, if required) for each vaccine being offered is available at the clinic/facility site.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
☐	☐		A designated clean area for vaccine preparation has been identified and set up prior to the clinic.
☐	☐		A qualified individual has been designated to oversee infection control at the clinic.

PREVENTING TRANSMISSION OF COVID-19 AT THE CLINIC

YES	NO	N.A.	
☐	☐		Sufficient supply of PPE for staff is available, including face masks, gloves, and, if appropriate, eye shields.
☐	☐		Sufficient supply of face coverings is available for visitors and patients who may not have one.
☐	☐		Sufficient hand sanitizer is available so that staff and patients can repeatedly practice hand hygiene.
☐	☐		Cleaning supplies are available so workspaces can be cleaned regularly (note the amount needed may be more than normally required). (See EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2 the virus that causes COVID-19.)
☐	☐		Additional controls, such as counters and plastic shields, are in place to minimize contact where patients and staff interact (e.g., registration or screening areas).
☐	☐		Signs, barriers, and floor markers to instruct patients to remain 6 feet apart from other patients and clinic staff have been set up before the clinic.
☐	☐		Sufficient supply of thermometers to check patient temperatures prior to entering the vaccination clinic and COVID symptom checklists.

DURING THE CLINIC (Please complete each item while the clinic is occurring and review at the end of your shift.)

VACCINE STORAGE AND HANDLING (AT FACILITY/CLINIC)

YES	NO	N.A.	
☐	☐ STOP		Vaccines are being kept in proper storage equipment that maintains the manufacturer-recommended temperature range (*i.e., a portable vaccine refrigerator or qualified container and packout specifically designed and tested to maintain correct temperatures when opened and closed during the clinic*).
☐	☐ STOP		Vaccine temperature is being monitored during the clinic using a digital data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing. *Follow the monitoring guidance specified in CDC's* Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
☐	☐ STOP	☐	If vaccines are being stored in a storage unit at the site, vaccine temperature data are being reviewed and documented a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures (*i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines*). *If you are a VFC provider, check with your state immunization program for specific requirements for vaccine temperature monitoring during mass vaccination clinics.*
☐	☐ STOP	☐	If vaccines cannot be stored in a storage unit at the site, they are being kept in the portable vaccine refrigerator or qualified packout with a temperature monitoring device (with a probe in a thermal buffer) placed as close as possible to the vaccines, and temperatures are being read and recorded at least once an hour. The container is being kept closed as much as possible.
☐	☐		Vaccines are being protected from light during the vaccination clinic per the manufacturer's package insert.

VACCINE PREPARATION

YES	NO	N.A.	
☐	☐ STOP		Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered. *(Note: If you are using multidose vials, be sure to review beyond use dates, along with expiration dates.)*
☐	☐		Vaccines are being prepared in a clean, designated medication area, away from any potentially contaminated items.
☐	☐ STOP	☐	If using reconstituted vaccines, they are being prepared according to the manufacturer's guidelines.
☐	☐	☐	Vaccines are being prepared at the time of administration.
☐	☐	☐	If vaccines are predrawn from a multidose vial, **only the contents of 1 multidose vial are being drawn up at one time by each staff member administering vaccines (the maximum number of doses per vial is described in the package insert).**
☐	☐	☐	If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine.
☐	☐ STOP		Once drawn up, vaccines are being kept in the recommended temperature range. (*Questions about specific time limits for being out of the recommended temperature range should be referred to the manufacturer.*)

VACCINE ADMINISTRATION

YES	NO	N.A.	
☐	☐ STOP		Vaccine information statements (VISs or Emergency Use Authorization [EUA] forms, if required) are being provided to every patient, parent, or guardian before vaccination (as required by federal law).
☐	☐ STOP		All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
☐	☐		Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled. www.cdc.gov/handhygiene/providers/index.html
☐	☐	☐	If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques between patients.
☐	☐		Staff is triple-checking labels, contents, and expiration dates or beyond use dates (as noted in the manufacturer's package insert, if applicable) before administering vaccine.
☐	☐ STOP		Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
☐	☐		Each staff member is administering only the vaccines they have prepared.
☐	☐	☐	If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.
☐	☐ STOP		Vaccines are being administered using aseptic technique.
☐	☐ STOP		Staff is administering vaccine to the correct patient (e.g., if a parent/guardian and child or two siblings are at the vaccination station at the same time, patient's name and date of birth are verified prior to vaccination).
☐	☐ STOP		Staff is administering vaccines using the correct route per manufacturer instructions.
☐	☐ STOP		Staff is administering the correct dosage (volume) of vaccine.
☐	☐ STOP		Staff has checked age indications for the vaccines and is administering vaccines to the correct age groups.
☐	☐ STOP	☐	For vaccines requiring more than 1 dose, staff is administering the current dose at the correct interval. *Follow the recommended guidelines in Table 3-1 of the* General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#t-01.
☐	☐ STOP	☐	If vaccine administration errors are observed, corrective action is being taken immediately.
☐	☐	☐	Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately and referred for additional medical care if needed.
☐	☐		Patients are being encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events. **This is especially critical at drive-through or curbside clinics where drivers are being vaccinated.**

ADMINISTRATION OF INJECTABLE VACCINES *(In this section, N.A. is ONLY an option if the clinic is EXCLUSIVELY using non-injectable vaccines, such as live, attenuated influenza vaccine.)*

YES	NO	N.A.	
☐	☐ STOP	☐	**A new needle and new syringe are being used for each injection. (Needles and syringes should never be used to administer vaccine to more than one person.)**
☐	☐ STOP	☐	Single-dose vials or manufacturer-filled syringes are being used for only one patient.
☐	☐ STOP	☐	Vaccines are being administered following safe injection practices.
☐	☐	☐	For walk-through clinics, seats are provided so staff and patients are at the same level for optimal positioning of anatomic site and injection angle to ensure correct vaccine administration.
☐	☐ STOP	☐	Staff is identifying injection site correctly. (For intramuscular route: deltoid muscle of arm [preferred] or vastus lateralis muscle of anterolateral thigh for adults, adolescents, and children aged ≥3 years; vastus lateralis muscle of anterolateral thigh [preferred] or deltoid muscle of arm for children aged 1–2 years; vastus lateralis muscle of anterolateral thigh for infants aged ≤12 months. For subcutaneous route: thigh for infants aged <12 months; upper outer triceps of arm for children aged ≥1 year and adults [can be used for infants if necessary].)
☐	☐	☐	Staff is inserting needles quickly at the appropriate angle: 90° for intramuscular injections (e.g., injectable influenza vaccines) or 45° for subcutaneous injections (e.g., measles, mumps, rubella vaccine).
YES	**NO**	**N.A.**	
☐	☐ STOP	☐	Multidose vials are being used only for the number of doses approved by the manufacturer.
☐	☐ STOP	☐	Vaccines are never being transferred from one syringe to another.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
☐	☐ STOP	☐	Used needles and syringes are being immediately placed in a sharps container following administration. (Needles are NOT being recapped.)

VACCINE DOCUMENTATION

YES	NO	N.A.	
☐	☐		Each vaccination is being fully documented with name of person vaccinated; vaccination date; vaccine type, lot number, manufacturer; patient receipt of vaccine information statement (VISs or Emergency Use Authorization [EUA] form), including edition date and date VIS was provided; injection site; vaccination route; dosage; and name, title, and office/company address of person who administered the vaccine.
☐	☐	☐	Your state's immunization information system (IIS) was used to document vaccinations administered. (*CDC recommends using your state's IIS to document vaccinations.*)
☐	☐		Patients are receiving documentation for their personal records and to share with their medical providers.

PREVENTING TRANSMISSION OF COVID-19 AT THE CLINIC

YES	NO	N.A.	
☐	☐		All staff and patients have their temperature checked before entering the clinic and are answering the COVID screening questions before entering the clinic.
☐	☐		All patients are wearing a face covering. Face masks should not be placed on children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
☐	☐		All staff is wearing recommended personal protective equipment (PPE), including face masks, gloves (optional for subcutaneous and intramuscular injections, required for intranasal and oral vaccinations), and eye protection (based on level of community transmission). See www.cdc.gov/vaccines/pandemic-guidance/index.html for current guidance.
☐	☐		Social distancing guidance is being followed, including signs, banners, and floor markers to instruct staff and patients where to stand, shields as appropriate when the 6-foot minimum distance cannot be observed, and one-way traffic flow.
			All areas are being wiped down and cleaned more frequently than normal cleaning that takes place during vaccine preparation and administration and between patients.

AFTER THE CLINIC (Please complete each item after the clinic is over.)

POST-CLINIC ACTIONS

YES	NO	N.A.	
☐	☐	☐	Temperature of remaining vaccine was checked and recorded at the end of clinic. If not still at manufacturer-recommended temperature (i.e., *between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines*), follow your organization's protocols and/or contact your state or local health department for guidance.
☐	☐	☐	Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded. *An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to the syringe). If absolutely necessary, a partially used multidose vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained, the vaccine is normal in appearance, and the maximum number of doses per vial indicated by the manufacturer has not already been withdrawn, or the beyond use date indicated by the manufacturer has not been met. However, a partially used vial cannot be transferred from one provider to another or across state lines or returned to the supplier for credit.*
☐	☐ STOP	☐	**Viable, unused vaccine was placed back in proper storage equipment that maintains the manufacturer-recommended temperature range at the end of the clinic day and was not stored in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.** (This includes vaccine transported for a multi-day clinic to a remote location where adequate storage at the site is not available.)
☐	☐	☐	Any needlestick injuries were recorded in a sharps injury log and reported to all appropriate entities (e.g., local health department and your organization).
☐	☐	☐	Any vaccine administration errors were reported to all appropriate entities.
☐	☐		All biohazardous material was disposed of properly.

POST-CLINIC DOCUMENTATION

YES	NO	N.A.	
☐	☐	☐	Vaccinations were recorded in the jurisdiction's immunization information system (IIS) where available.
☐	☐	☐	If not submitted to an IIS, vaccination information was sent to primary health care providers as directed by an established procedure based on state or jurisdiction regulations.
☐	☐	☐	Any adverse events were reported to the Vaccine Adverse Event Reporting System (VAERS): vaers.hhs.gov/index.
☐	☐ STOP		All patient medical information was placed in a secured storage location for privacy protection.
☐	☐		The staff sign-in sheet was attached to this document (with shift times, clinic location, and date).

N.A. means Not Applicable.

This checklist was adapted from materials created by the California Department of Public Health, the Centers for Disease Control and Prevention, and the Immunization Action Coalition.

If you check "NO" in ONE OR MORE answer boxes that contain a STOP, DO NOT move forward with the clinic.

» Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.

» Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

ADDITIONAL INFORMATION AND RESOURCES

If you are concerned that CDC guidelines were not followed during your vaccination clinic held at a satellite, temporary, or off-site location, contact your organization and/or state or local health department for further guidance.

COVID-19 information can be found at:

- www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html

» CDC's guidelines and resources for vaccine storage, handling, administration, and safety:
- Vaccine storage and handling: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- Vaccine administration:
  - www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
  - www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
  - www.cdc.gov/vaccines/hcp/admin/resource-library.html
- Injection safety: www.cdc.gov/injectionsafety/providers.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/
- Videos on preparing and administering vaccines. www.cdc.gov/vaccines/hcp/admin/resource-library.html (includes videos on intramuscular injections and administration of live, attenuated influenza vaccine)

» The Immunization Action Coalition has a skills checklist for staff administering vaccines: www.immunize.org/catg.d/p7010.pdf.

» The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:
- Screening tools: http://www.immunize.org/handouts/screening-vaccines.asp
- Vaccination after-care:
  - Children: www.immunize.org/catg.d/p4015.pdf
  - Adults: www.aimtoolkit.org/docs/vax.pdf

» The Immunization Action Coalition has information on the medical management of vaccine reactions:
- Children and adolescents: www.immunize.org/catg.d/p3082a.pdf
- Adults: www.immunize.org/catg.d/p3082.pdf

» Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: www.immunize.org/packageinserts/pi_influenza.asp

This checklist is a valuable resource for use in temporary mass vaccination clinics and other vaccination exercises, such as those conducted at vaccine points of dispensing (PODs) or vaccination and dispensing clinics (VDCs) as part of public health emergency preparedness (PHEP) program activities.

Medical waste disposal is regulated by state environmental agencies. Contact your state immunization program or state environmental agency to ensure that your disposal procedures comply with state and federal regulations.

States have laws on documentation of vaccinations, use of immunization information systems (IISs), and types of health care providers who can administer vaccines.

Frequently Asked Questions

about the National Adult and Influenza Immunization Summit "Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations" and Pledge for Implementing the Checklist

- *The questions in this document relate to the checklist and pledge found here:*

CHECKLIST: www.izsummitpartners.org/off-site-vaccination-clinic-checklist
PLEDGE: www.izsummitpartners.org/pledge-for-organizations-conducting-off-site-vaccination-clinics

Questions about the purpose of the checklist and pledge

1 **What is the purpose of the checklist? It seems long and complicated.**

Recently, reports have been published of major errors occurring at vaccination clinics held at satellite, temporary, or off-site locations related to the safe transport, storage, and administration of vaccines. These reports are likely the tip of the iceberg. To prevent future errors at clinics in these settings, we developed this checklist as a step-by-step guide to help clinic coordinators / supervisors overseeing vaccination clinics held at satellite, temporary, or off- site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness.

2 **What is the pledge, who is it for, and why should we sign up to be a pledging organization?**

This pledge is for any organization that conducts satellite, temporary, or off-site vaccination clinics to sign annually affirming that they will adhere to best practices by using the "Checklist of Best Practices" at every vaccination clinic they hold in these settings. Organizations that sign the pledge will be recognized on the Summit website for their commitment to provide safe and effective vaccine clinics. This can be a great way to promote your organization as one that conducts vaccination clinics using the highest standards. Additionally, companies seeking to hire an organization to conduct a vaccination clinic can check to see if that organization has signed the pledge and is recognized on the Summit website.

Questions related to the intended users of the checklist

1 **All of our staff have many years of experience and we do hundreds of vaccination clinics a year. Do we still need to use the checklist?**

Yes! For organizations like yours where running vaccination clinics is central to your mission, it is important to use the checklist because it allows you to DOCUMENT that you are using best practices. Your organization likely already has protocols in place that cover the topics in the checklist. Thus, checking off the boxes should take a few extra minutes since you are likely already doing all of the items in the rows anyway. Also, if your organization takes the pledge stating that it

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intends to have its clinic coordinators implement the vaccine checklist at each vaccination clinic, it can be recognized as a leader in the field and one that consistently follows best practices. It's a win-win.

2 **We have many new staff all over the country. The checklist seems too cumbersome to use in our situation. Do we need to use it?**

Yes! It is precisely in these situations that the checklist should be utilized so that you can ensure consistency and best practices from clinic to clinic. Part of the reason that the checklist is so long is because it is comprehensive. The checklist covers best practices during each stage of the vaccination clinic.

Questions about how to use the checklist

1 **If nurses in the field hit a stop sign, it would be a real burden / inconvenience to stop the clinic. For efficiency, do we still need to use the checklist in these situations?**

Yes! Even though it might be very inconvenient to stop the clinic when you encounter a "No" at a stop sign, clinics should never continue when the quality of the vaccine has been compromised, or when unsafe administration practices have been identified. Using the checklist is very important at every clinic, to ensure that the vaccine is being delivered safely.

2 **Is every staff member at the clinic supposed to fill out the checklist?**

No, only the clinic supervisor/coordinator needs to fill out the checklist. However, we encourage the clinic coordinator to print out the checklist and give copies to all personnel who are vaccinating at the clinic to ensure that all staff members are aware of best practices.

3 **What if our vaccination clinic does not have a clinic coordinator/supervisor?**

We ask that prior to the start of the clinic, you designate one of the team members to be the clinic coordinator/supervisor so that one person is responsible for filling out the checklist and returning it to an appropriate storage place upon completion of the clinic.

4 **Is it okay if we concentrate on one section of the checklist and only fill out that section at each clinic?**

Ideally, the best approach is to complete the entire checklist at every vaccination clinic. If you do not think your organization can follow each row of the checklist (for instance, if you have already purchased your supplies for the flu season, and you did not purchase appropriate qualified containers and pack-outs, but have confirmed correct temperatures were maintained throughout the clinic), we encourage you to try completing as much as you can on the checklist during your clinics this year, and make sure that you include resources to purchase appropriate materials for next flu season.

Technical questions

1 **The checklist states that CDC prefers direct shipment of vaccine, rather than transporting vaccine. However, when direct shipments are made to healthcare providers who participate in the "Vaccines for Children" program, there is a list of administrative requirements that they must check**

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off to ensure proper storage and handling of vaccines when they receive the direct shipment. Why is there nothing comparable for clinics in satellite, temporary, or off-site locations that will be receiving direct shipments?

Immunization programs may have additional requirements that are state-specific. Nonetheless, it is important for organizations that receive vaccines as direct shipments for satellite, temporary, or off-site vaccination clinics to follow guidelines outlined on p. 32 of the Vaccine Storage and Handling Toolkit ("Vaccine Deliveries"): www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For more detailed, state-specific requirements, please consult with your state immunization program.

2 **We use a thermometer that is not digital during transport, but there is a stop sign in that row of the checklist, implying that the thermometer must be digital. However, our thermometers are tested for accuracy and we trust their readings. How should we answer this section (especially since there is a stop sign)?**

The safest option for the vaccine is to use the digital data logger during transport. Although there might be situations where your non-digital thermometers are accurate, we have several concerns about utilizing these for maintaining the cold chain. The nature of one-time use indicators prevent device validation. Additionally, the interpretation of the "trip points" for these indicators only provide a range of potential exposure and not specific data. Due to these concerns, we feel the requirement for a digital data logger with a buffered probe is warranted and the clinic should not proceed. For specific storage and handling-related questions, please refer to CDC's Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

2 **Is every staff member at the clinic supposed to fill out the checklist?**

No, only the clinic supervisor/coordinator needs to fill out the checklist. However, we encourage the clinic coordinator to print out the checklist and give copies to all personnel who are vaccinating at the clinic to ensure that all staff members are aware of best practices.

3 **Manufacturers that ship directly to our site do not use digital data loggers. Yet, the checklist requires that we use digital data loggers when transporting. Why is this discrepancy allowed?**

Manufacturers have their product's specific stability data that they use in calculating their shipping processes. This makes it hard to compare what the manufacturer does during vaccine shipment to what we recommend for the public during vaccine transport.

4 **We obtain different temperature readings during transport based on where the probe is placed in the pack-out. It is all within the acceptable range, but it varies widely. Is there guidance on how to do this correctly for consistent temperature readings?**

As stated above, we recommend using a digital data logger for more accurate and consistent temperature readings. It is not uncommon to have different temperature readings within a transport unit or a vaccine storage unit. Passive transport containers might have more variability due to the design of the container. However, if they are qualified to maintain temperature between 2-8C and are maintaining temperature, there should not be an issue with the temperature variability. The probe should continue to be placed in the area of the pack-out with the vaccines to best monitor the temperature.

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5 What is meant by qualified container and pack-out?

Qualified containers and pack-outs are types of containers and supplies specifically designed for use when packing vaccines for transport. They are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time. We cannot endorse a specific brand, but if you type "qualified container and pack-out" into your internet search bar, you will find many acceptable options.

6 Are we allowed to use coolers purchased at big box stores/retail stores for transporting vaccine?

No. This is not an acceptable practice. Vaccine should be transported in qualified containers and pack-outs (see above).

7 In some of our off-site vaccination clinics, we give over 1,000 doses of vaccine per day. Our clinic wants to use qualified containers and pack-outs, but in order to hold this many doses, the qualified containers and pack-outs available are too heavy for our staff to lift.

There are several companies that make qualified containers and pack-outs that are lightweight (16–21 lbs, depending on the model). Some of these lighter weight options hold up to 100 pre-filled syringes. You could purchase several of these qualified containers and then make multiple trips to refill, as needed. Many State health departments follow the guide from the Oregon "Vaccines for Children" program that outlines the CDC requirements and recommendations for appropriate vaccine storage units: www.oregon.gov/oha/ph/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/VFCfridgefreezerguide.pdf.

8 In the "Vaccine Preparation" subsection of the checklist, it states that vaccines must be prepared in a clean, designated medication area. However, a few rows down, it states that vaccines should be prepared at the time of administration. What is the proper protocol?

Multi-dose vials (MDVs) that will be used for >1 patient should not be kept or accessed in the immediate patient treatment area. Thus, if the vaccine is coming from an MDV that will be used as a source of vaccine for multiple patients, doses should not be drawn up in the same space where the injections are being administered. This link provides guidance on MDVs that explains the logic: www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html. If the injection is being prepared from a single-dose vial (SDV), which should be used for only 1 patient, we wouldn't have the same concerns but would want to make sure that the vial is being handled aseptically in a clean area (e.g., any waste from the previous patient has been discarded).

9 In the "During the Clinic" section of the checklist, there is a row under the "Vaccine Documentation" subsection for patients to receive documentation of the vaccination for their personal records and to share with their medical providers. However, many of our clients decline this documentation and state, "I'll just lose it" or "you have it in your system". Do we have to offer documentation to all of our clients since it does not seem to be a priority for most of the people we serve?

Yes, it's a best practice to provide clients with their vaccination information that includes the vaccine given, the lot number, the date, and the signature of the person who gave the vaccination. Once the parent/client has been given the information, they can then decide if they want to keep the information. The provider can also offer the parent/client an opportunity to take a cell phone picture of the signed form. Then they own the information.

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Frequently Asked Questions *continued*

10 If my state has an Immunization Information System (IIS, or registry) do I still need to give the patient a vaccine record card?

Yes. Patient-held cards are an extremely important part of a person's medical history. The person may move to an area without a registry, and the personal record may be the only vaccination record available. In addition, even within a state, all healthcare providers may not participate in the registry, and the personal record card would be needed.

Do you have additional questions? Send us an email as shown below.

Questions about the Checklist: checklist@izsummitpartners.org

Questions about the Pledge: vaxclinicpledge@izsummitpartners.org

Ten Principles for Holding Safe Vaccination Clinics at Satellite, Temporary, or Off-Site Locations

During All Stages (Pre-Clinic, During the Clinic, and Post-Clinic)

1. **Keep vaccines at the correct temperature at all times** using proper procedures for vaccine transport, handling and storage. Document temperature monitoring at appropriate intervals during all stages. For further guidance: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Pre-Clinic

2. **Have vaccine shipped directly to the site.** If direct shipment is not possible, **transport vaccine using correct storage and handling guidelines**.
3. **Train staff to perform CPR and treat medical emergencies,** including anaphylaxis. Ensure supplies are on site, including an emergency medical kit and infection control supplies, as well as **enough Vaccine Information Statements (VISs)**.

During the Clinic

4. **Always check for medical contraindications and allergies** before vaccinating anyone. **Provide VISs for all patients or guardians.**
5. **Follow manufacturers' instructions and Advisory Committee on Immunization Practices guidelines for correct age and intervals** (for vaccines that require more than one dose).
6. **Follow manufacturers' instructions for injection dose, site, and route.**
7. **Only use vaccines that are not damaged, not expired, at the correct temperature, and prepared using aseptic technique.**
8. **Follow safe handling of needles and syringes**, including using a new needle and syringe for every injection. Dispose of all sharps in a sharps container.
9. **Document** every vaccination and give patients a copy.

Post-Clinic

10. Keep patient information **secure and private**. Record vaccinations in the Immunization Information System (IIS), if available.

For further guidance, refer to the full checklist:
www.izsummitpartners.org/off-site-vaccination-clinic-checklist

National Adult and Influenza Immunization Summit

▶ ***This document is NOT intended to replace use of the checklist.***

Version 3 (Updated January 25, 2019)

YOU CALL THE SHOTS

Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist

Below are supplies that may be needed to conduct a satellite, temporary, or off-site vaccination clinic. The list may not be comprehensive. Your state or local public health immunization program may also have a checklist.

For large-scale clinics held at large facilities, such as stadiums and arenas, or over multiple days, additional supplies will be needed. Contact your state or local public health preparedness program and work with the clinic medical director for additional guidance and assistance.

Quantity of supplies needed will vary significantly between smaller, one-day clinics held in schools, churches, or pharmacies and large-scale clinics held in arenas or held over multiple days.

VACCINES

Refrigerated vaccines

Select the vaccine(s) that will be offered at the clinic.

- ☐ Diphtheria, tetanus, and pertussis (DTaP)
- ☐ DTaP-HepB-IPV (Pediarix)
- ☐ DTaP-IPV/Hib* (Pentacel)
- ☐ DTaP-IPV (Kinrix, Quadracel)
- ☐ *Haemophilus influenzae* type b* (Hib)
- ☐ Hepatitis A (HepA)
- ☐ Hepatitis B (HepB)
- ☐ HepA-HepB (Twinrix)
- ☐ Human papillomavirus (9vHPV)
- ☐ Influenza, injectable (IIV) (in season)
- ☐ Influenza, live attenuated intranasal (LAIV) (in season)
- ☐ Measles, mumps, rubella* (MMR)
- ☐ Meningococcal ACWY* (MenACWY)
- ☐ Meningococcal B (MenB)
- ☐ Pneumococcal conjugate (PCV13)
- ☐ Pneumococcal polysaccharide (PPSV23)
- ☐ Polio, inactivated (IPV)
- ☐ Rotavirus* (RV)
- ☐ Tetanus-diphtheria, adult (Td)
- ☐ Tetanus, diphtheria, and pertussis (Tdap)
- ☐ Zoster, recombinant (RZV, Shingrix*)

Frozen vaccines

(Frozen vaccines may only be administered at satellite, temporary, and off-site clinics if they can be safely shipped to and monitored at the site. They should never be transported from one location to another.)

- ☐ Measles, mumps, rubella, varicella* (MMRV, ProQuad)
- ☐ Varicella*

*Diluent for ActHIB, Hiberix, Menveo, Pentacel, Rotarix, and Shingrix comes packaged in the same container as the lyophilized component. Diluent for MMR, MMRV, and varicella comes from the manufacturer packaged with the vaccine in separate containers.

CLINICAL SUPPLIES

Administration supplies

- ☐ Adhesive bandages
- ☐ Appropriate needles (length, guage) for the route of administration (Subcut, IM) and the expected patient population
- ☐ Sterile alcohol prep pads
- ☐ Syringes (1 or 3 cc)

Clinic supplies

- ☐ Alcohol-based hand sanitizer (at least 60% alcohol)
- ☐ Digital data logger for each storage unit/container
- ☐ Disposable table covers
- ☐ Gauze pads
- ☐ Medical gloves
- ☐ Partition screens
- ☐ Paper towels
- ☐ Sanitizing products for vaccination and preparation surfaces
- ☐ Sharps containers
- ☐ Table and chairs for patient and vaccination provider at each vaccination station
- ☐ Vaccine storage units (onsite) or portable refrigerators or packouts (for transport) that can maintain the appropriate vaccine cold chain
- ☐ Wastebaskets

Clinic documentation

- ☐ Billing forms, if needed
- ☐ Immunization record cards
- ☐ Immunization schedule for targeted audience(s)
- ☐ Internet access or hotspot
- ☐ Forms to record vaccine administration (this may be done by computer)
- ☐ Laptops, computers, tablets, or smartphones, as well as printers and 2D barcode readers (if using), including multiple plug outlet strips and extension cords
- ☐ Screening checklist for contraindications to vaccines for children, teens, and adults
- ☐ Vaccination standing orders and protocols, as necessary
- ☐ Vaccine information statements (VISs) for each vaccine being offered and in multiple languages as appropriate (in some instances, an emergency use authorization [EUA] form may be required)
- ☐ Vaccine storage temperature log(s)

Office supplies

- ☐ Clipboards
- ☐ Notepads
- ☐ Pens
- ☐ Printer paper
- ☐ Printers, if applicable
- ☐ Rope, cones, and/or tape as needed to direct traffic flow
- ☐ Signage for clinic hours, future clinics, clinic flow, and easels or other equipment for displaying
- ☐ Trash bags
- ☐ Walkie-talkies or similar devices, depending on size of the clinic

MEDICAL EMERGENCY SUPPLIES

If possible, it is preferable that emergency medical services (EMS) staff be available during the clinic. Clinical staff providing vaccine should be trained in CPR and able to respond to medical emergencies.

At a minimum, there should be:

- ☐ Antihistamines (diphenhydramine [Benadryl], hydroxyzine [Atarax, Vistaril], and syringes if needed)
- ☐ Cell phone or land line to call 911
- ☐ Epinephrine in prefilled autoinjector or prefilled syringe (various doses), prepackaged syringes, vials, or ampules (Epi-pens)
- ☐ First aid kit

Additional supplies may include:

- ☐ Blood pressure measuring device
- ☐ Light source to examine mouth and throat
- ☐ Oxygen
- ☐ Stethoscope
- ☐ Timing device for measuring pulse
- ☐ Tongue depressors
- ☐ Tourniquet

Additional supplies needed during the COVID-19 pandemic

During the COVID-19 pandemic, additional supplies are needed to protect both staff and patients, including:

- Additional hand sanitizer with at least 60% alcohol for hand hygiene
- Additional cleaning equipment for more frequent cleanings, using EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2
- Additional signage, tape, ropes, and cones to encourage physical distancing and provide one-way flow through the clinic
- Face coverings for patients who arrive without one
- Hand soap, as appropriate
- Personal protective equipment (PPE) for staff. Gloves should be worn by anyone administering intranasal or oral vaccine. Depending on level of community transmission, eye protection may also be recommended.
- Thermometers for checking patient temperature before entering the clinic, if required
- Tissues

Guide to Contraindications and Precautions to Commonly Used Vaccines for All Ages[1]

For information on contraindications and precautions when administering COVID-19 vaccine, see CDC's *COVID-19 Vaccine Quick Reference Guide for Healthcare Professionals* at www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf.

Vaccine	Contraindications or Not Recommended[2]	Precautions[3]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • No prior documented lab-confirmed dengue infection, such as DENV PCV test or detection of anti-DENV IgG	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate of severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria (DT)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • **For DTaP only:** encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of a DTP or DTaP	• Guillain-Barré Syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid-containing or tetanus- toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine • Moderate or severe acute illness with or without fever • **For DTaP only:** progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized
***Haemophilus influenzae* type b[4] (Hib)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • **For Hiberix, ActHib, and PedvaxHIB only:** history of severe allergic reaction to dry natural latex	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including yeast (except PreHevbrio, which does not contain yeast) • Pregnancy: Heplisav-B and PreHevbrio are not recommended during pregnancy due to a lack of safety data in pregnant women.	• Moderate or severe acute illness with or without fever
Hepatitis A – Hepatitis B (HepA-HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Pregnancy: HPV vaccination is not recommended until after pregnancy.[4]	• Moderate or severe acute illness with or without fever
Influenza, egg-based, inactivated injectable (IIV)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine of any type or valency. **Note:** See ccIIV and RIV precautions below for considerations for the use of these products following a severe allergic reaction to a previous dose of influenza vaccine. • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component (excluding egg)	• Guillain-Barré Syndrome (GBS) within 6 weeks after a previous dose of any influenza vaccine • People with egg allergy with symptoms other than hives (e.g., angioedema, respiratory distress) or required epinephrine or another emergency medical intervention: any influenza vaccine appropriate for age and health status may be administered. If using egg-based IIV or LAIV, administer in a medical setting under the supervision of a healthcare provider who can recognize and manage severe allergic conditions. • Moderate or severe acute illness with or without fever

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Vaccine	Contraindications or Not Recommended[2]	Precautions[3]
Influenza, cell culture-based inactivated injectable (ccIIV)	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component of ccIIV	• GBS within 6 weeks after a previous dose of any type of influenza vaccine • Providers can consider giving ccIIV to people with a history of severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV, LAIV, or RIV while in a medical setting under the supervision of a healthcare provider who can recognize and manage severe allergic reactions. Consider allergist consultation to determine vaccine component responsible for the reaction. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV)	• Severe allergic reaction (e.g., anaphylaxis) to RIV of any valency or any RIV component	• GBS within 6 weeks after a previous dose of any type of influenza vaccine • Providers can consider giving RIV4 to people with a history of severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV, LAIV, or ccIIV while in a medical setting under the supervision of a healthcare provider who can recognize and manage severe allergic reactions. Consider allergist consultation to determine vaccine component responsible for the reaction. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV)	• Severe allergic reaction (e.g., an anaphylaxis) to any component of the vaccine or to a previous dose of any IIV, LAIV, ccIIV, or RIV • Children younger than age 2 years and adults age 50 years or older • Children age 2 through 4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protective environment • Pregnancy[4] • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• GBS within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons age 5 years or older • People with a history of severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV or LAIV may receive ccIIV or RIV under certain circumstances: see ccIIV and RIV sections above. • People with egg allergy with symptoms other than hives (e.g., angioedema, respiratory distress) or required epinephrine or another emergency medical intervention: any influenza vaccine appropriate for age and health status may be administered. If using LAIV (which is egg based) or egg-based IIV, administer in a medical setting under the supervision of a healthcare provider who can recognize and manage severe allergic conditions. • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus) • Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with human immunodeficiency virus [HIV] infection who are severely immunocompromised) • Pregnancy[4] • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product; see Table 6 in www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • **For MenACWY-D (Menactra) and MenACWY-CRM (Menveo) only:** severe allergic reaction to a diphtheria toxoid- or CRM197-containing vaccine • **For MenACWY-TT (MenQuadfi) only:** severe allergic reaction to a tetanus toxoid-containing vaccine[3]	• Moderate or severe acute illness with or without fever

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Vaccine	Contraindications or Not Recommended[2]	Precautions[3]
Meningococcal B (MenB) (Men-4C [Bexsero], MenB-FHbp [Trumenba])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Pregnancy • **For MenB-4C (Bexsero) only:** latex sensitivity • Moderate or severe illness with or without fever
Pneumococcal conjugate[4] (PCV15, PCV20)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid-containing vaccine or to its vaccine component	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide[4] (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever
Poliovirus, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Pregnancy • Moderate or severe acute illness with or without fever
Rotavirus (RV, RV1 [Rotarix], RV5 [RotaTeq])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • **For RV1 (Rotarix) only:** Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, pertussis (Tdap) **Tetanus, diphtheria (Td)**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • **For Tdap only:** encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause within 7 days of administration of previous dose of a DTP, DTaP, or Tdap	• GBS within 6 weeks after a previous dose of tetanus toxoid-containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid-containing or tetanus- toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine • Moderate or severe acute illness with or without fever • **For Tdap only:** progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella (Var)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy[4] • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product; see Table 6 in www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf) • Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever
Zoster recombivant vaccine[4] (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Current herpes zoster infection

FOOTNOTES

1. This table is adapted from "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger – United States, 2022" *MMWR* Vol.71(7):234–237, available at www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7107a2-H.pdf and "Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older – United States, 2022" *MMWR* Vol.71(7):229–233, available at www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7107a1-H.pdf. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including vaccine components, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states
2. When a contraindication is present, a vaccine should not be administered (see www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html). In the absence of a contraindication, CDC may state that the use of certain vaccine products is not recommended in certain vaccine products in certain circumstances (e.g., during pregnancy) if available data are insufficient to inform assessment of vaccine-associated risks.
3. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction (see www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html).
4. CDC has no recommendations for vaccination during pregnancy for Hib, PCV15, PCV20, PPSV23, or RZV. For additional information on which vaccines should not be administered during pregnancy, see "Vaccinations Needed During Pregnancy" at www.immunize.org/catg.d/p4040.pdf.

Screening Checklist for Contraindications to Vaccines for Adults

YOUR NAME _____

DATE OF BIRTH _____/_____/_____
month day year

For patients: The following questions will help us determine which vaccines you may be given today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means we need to ask you more questions. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Are you sick today?	☐	☐	☐
2. Do you have allergies to medications, food, a vaccine component, or latex?	☐	☐	☐
3. Have you ever had a serious reaction after receiving a vaccine?	☐	☐	☐
4. Do you have any of the following: a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, a cochlear implant, or a spinal fluid leak? Are you on long-term aspirin therapy?	☐	☐	☐
5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?	☐	☐	☐
6. Do you have a parent, brother, or sister with an immune system problem?	☐	☐	☐
7. In the past 6 months, have you taken medications that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?	☐	☐	☐
8. Have you had a seizure or a brain or other nervous system problem?	☐	☐	☐
9. Have you ever been diagnosed with a heart condition (myocarditis or pericarditis) or have you had Multisystem Inflammatory Syndrome (MIS-A or MIS-C) after an infection with the virus that causes COVID-19?	☐	☐	☐
10. In the past year, have you received immune (gamma) globulin, blood/blood products, or an antiviral drug?	☐	☐	☐
11. Are you pregnant?	☐	☐	☐
12. Have you received any vaccinations in the past 4 weeks?	☐	☐	☐
13. Have you ever felt dizzy or faint before, during, or after a shot?	☐	☐	☐
14. Are you anxious about getting a shot today?	☐	☐	☐

FORM COMPLETED BY _____ DATE _____

FORM REVIEWED BY _____ DATE _____

Did you bring your immunization record card with you? **yes** ☐ **no** ☐

It is important to have a personal record of your vaccinations. If you don't have a personal record, ask your healthcare provider to give you one. Keep this record in a safe place and bring it with you every time you seek medical care. Make sure your healthcare provider records all your vaccinations on it.

Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines for Adults

Read the information below for help interpreting answers to the screening checklist. To learn even more, consult the references in ***Note*** *below.*

NOTE: For additional details, see CDC's "Adult Immunization Schedule" (www.cdc.gov/vaccines/schedules/hcp/imz/adult.html) and *General Best Practice Guidelines for Immunization* sections on "Contraindications and Precautions" (www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html) and "Altered Immunocompetence" (www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html). For more details on COVID-19 vaccines, see "Use of COVID-19 Vaccines in the United States: Interim Clinical Considerations" at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

1. **Are you sick today?** *[all vaccines]*

   There is no evidence that acute illness reduces vaccine efficacy or safety. However, as a precaution, all vaccines should be delayed until moderate or severe acute illness has improved. Mild illnesses with or without fever (e.g., otitis media, "colds," diarrhea) and antibiotic use are not contraindications to routine vaccination.

2. **Do you have allergies to medications, food, a vaccine ingredient, or latex?** *[all vaccines]*

   Gelatin: If a person has anaphylaxis after eating gelatin, do not give vaccines containing gelatin. **Latex:** An anaphylactic reaction to latex is a contraindication to vaccines with latex as part of the vaccine's packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). For details on latex in vaccine packaging, refer to the package insert (listed at www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states). **COVID-19 vaccine:** History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a COVID-19 vaccine component is a contraindication to use of the same vaccine type. People may receive the alternative COVID-19 vaccine type (either mRNA or protein subunit) if they have a contraindication or an allergy-related precaution to one COVID-19 vaccine type. Allergy-related precautions include history of 1) diagnosed non-severe allergy to a COVID-19 vaccine component; 2) non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one COVID-19 vaccine type (see **Note**). ***Not contraindications:*** **Eggs:** ACIP and CDC do not consider egg allergy of any severity to be a contraindication or precaution to any egg-based influenza vaccine. **Injection site reaction** (e.g., soreness, redness, delayed-type local-reaction) to a prior dose or vaccine component is not a contraindication to a subsequent dose or vaccine containing that component.

3. **Have you ever had a serious reaction after receiving a vaccine?** *[all vaccines]*
   - Anaphylaxis to a previous vaccine dose or vaccine component is a contraindication for subsequent doses of the vaccine or vaccine component. (See question 2.)
   - Usually, one defers vaccination when a precaution is present unless the benefit outweighs the risk (e.g., during an outbreak).

4. **Do you have any of the following: a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, a cochlear implant, or a spinal fluid leak? Are you on long-term aspirin therapy?** *[MMR, VAR, LAIV]*

   LAIV is not recommended for people with anatomic or functional asplenia, a cochlear implant, or cerebrospinal fluid (CSF) leak. Underlying health conditions that increase the risk of influenza complications such as heart, lung, kidney, or metabolic disease (e.g., diabetes) and asthma are precautions for LAIV. **MMR:** A history of thrombocytopenia or thrombocytopenic purpura is a precaution to MMR. **VAR:** Aspirin use is a precaution to VAR due to the association of aspirin use, wild type varicella infection, and Reye syndrome in children and adolescents.

5. **Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?** *[LAIV, MMR, VAR]*

   Live virus vaccines are usually contraindicated in immunocompromised people, with exceptions. For example, MMR vaccine is recommended and VAR may be considered for adults with CD4+ T-cell counts of greater than or equal to 200 cells/mcL. See **Note**.

6. **Do you have a parent, brother, or sister with an immune system problem?** *[MMR, VAR]*

   MMR or VAR should not be administered to a patient with congenital or hereditary immunodeficiency in a first-degree relative (e.g., parent, sibling) unless the patient's immune competence has been verified clinically or by a laboratory.

7. **In the past 6 months, have you taken medicines that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?** *[LAIV, MMR, VAR]*

   Live virus vaccines should be postponed until chemotherapy or long-term high-dose steroid therapy concludes. See **Note**. Some immune mediator and modulator drugs (especially anti-tumor necrosis factor [TNF] agents) may be immunosuppressive. Avoid live virus vaccines in people taking immunosuppressive drugs. A list of such drugs appears in CDCs Yellow Book at wwwwnc.cdc.gov/travel/yellowbook/2024/additional-considerations/immunocompromised-travelers.

8. **Have you had a seizure or a brain or other nervous system problem?** *[influenza, Td/Tdap]*

   Tdap: Tdap is contraindicated in people with a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to using Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, vaccinate as usual. **A history of Guillain-Barré syndrome (GBS):** 1) **Td/Tdap**: GBS within 6 weeks of a tetanus toxoid-containing vaccine is a precaution; if the decision is made to vaccinate, give Tdap instead of Td; 2) **all influenza vaccines**: GBS within 6 weeks of an influenza vaccine is a precaution; influenza vaccination should generally be avoided unless the benefits outweigh the risks (e.g., for those at high risk for influenza complications).

9. **Have you ever been diagnosed with a heart condition (myocarditis or pericarditis) or have you had Multisystem Inflammatory Syndrome (MIS-A or MIS-C) after an infection with the virus that causes COVID-19?**

   Precautions to COVID-19 vaccination include a history of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine or a history of Multisystem Inflammatory Syndrome (MIS-C or MIS-A). Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution: the patient should generally not receive additional COVID-19 vaccine. A person with a history of myocarditis or pericarditis unrelated to vaccination may receive a COVID-19 vaccine once the condition has completely resolved. A person with a history of MIS-C or MIS-A may be vaccinated if the condition has fully resolved and it has been at least 90 days since diagnosis. Refer to CDC COVID-19 vaccine guidance for additional considerations for myocarditis, pericarditis, and MIS (see **Note**).

10. **In the past year, have you received immune (gamma) globulin, blood/blood products or an antiviral drug?** *[MMR, VAR, LAIV]*

    See **Note** (schedule) for antiviral drug information (VAR, LAIV). See "Timing and Spacing of Immunobiologics" (www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#antibody) for intervals between MMR, VAR and certain blood/blood products, or immune globulin.

11. **Are you pregnant?** *[HPV, HepB, IPV, LAIV, MenB, MMR, VAR]*

    Live virus vaccines (e.g., LAIV, MMR, VAR) are contraindicated in pregnancy due to the theoretical risk of virus transmission to the fetus. People who could become pregnant and receive a live virus vaccine should be instructed to avoid pregnancy for 1 month after vaccination. **IPV and MenB** should not be given except to those with an elevated risk of exposure during pregnancy. **HepB:** Heplisav-B and PreHevbrio are not recommended during pregnancy, use Engerix-B or Recombivax-HB. **HPV** is not recommended during pregnancy.

12. **Have you received any vaccinations in the past 4 weeks?** *[LAIV, MMR, VAR, yellow fever]*

    People given live virus vaccines, such as those listed above, should wait 28 days before receiving another live virus vaccine (wait 30 days for yellow fever vaccine). Inactivated vaccines may be given at the same time or at any spacing interval.

13. **Have you ever felt dizzy or faint before, during, or after a shot?**

    Fainting (syncope) or dizziness is not a contraindication or precaution to vaccination; it may be an anxiety-related response to any injection. CDC recommends vaccine providers consider observing all patients for 15 minutes after vaccination. See Immunize.org's resource on vaccination and syncope at www.immunize.org/catg.d/p4260.pdf.

14. **Are you anxious about getting a shot today?**

    Anxiety can lead to vaccine avoidance. Simple steps can help a patient's anxiety about vaccination. Visit Immunize.org's "Addressing Vaccination Anxiety" clinical resources at www.immunize.org/handouts.

VACCINE ABBREVIATIONS

HepB = Hepatitis B vaccine
HPV = Human papillomavirus vaccine
IIV = Inactivated influenza vaccine
ccIIV = Cell culture inactivated influenza vaccine
IPV = Inactivated poliovirus vaccine
LAIV = Live attenuated influenza vaccine
MenB = Meningococcal B vaccine
MMR = Measles, mumps, and rubella vaccine
RIV = Recombinant influenza vaccine
Td/Tdap = Tetanus, diphtheria, (acellular pertussis) vaccine
VAR = Varicella vaccine

STATE OF MISSOURI
DEPARTMENT OF HEALTH AND SENIOR SERVICES

IMMUNIZATION CONSENT AND HISTORY

CLINIC IDENTIFICATION

LAST NAME	FIRST NAME	MI	DATE OF BIRTH	SEX
				☐ Male ☐ Female

STREET ADDRESS	CITY	STATE	ZIP CODE	TELEPHONE NO.

RACE (SELECT ALL THAT APPLY)

☐ Amer Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ Black or African American ☐ White

ETHNICITY

☐ Hispanic or Latino ☐ Not Hispanic or Latino

PARENT/GUARDIAN FULL NAME

I have been given copy and have read, or had explained to me, the information in the "Vaccine Information Statement(s)," where applicable, for the vaccine(s) indicated below. I have had a chance to ask questions and had them answered to my satisfaction. I understand the benefits and risks of the vaccine(s) requested and ask that the vaccine(s) currently due for which I have signed below be given to me or to the person named above for whom I am authorized pursuant to Section 431.058, RSMo to make this request.

VACCINE AND ROUTE (CIRCLE TYPE GIVEN WHERE APPLICABLE)	VISIT NO. & M/D/Y GIVEN	INJECTION SITE	VACCINE MANUFACTURER/ LOT NUMBER	VACCINE EXP. DATE	VIS REVISION DATE	DATE VIS GIVEN	SIGNATURE OF VACCINATOR
Hepatitis B							
Hep B IM							
Diphtheria, Tetanus, Pertussis							
DTap DTP DT IM							
Haemophilus influenzae type b							
Hib IM							
Polio							
Polio SQ IM							
Pneumococcal							
PCV 13 IM							

PATIENT OR PARENT/GUARDIAN CONSENT

VISIT #1 DATE

SIGNATURE

ELIGIBILITY STATUS
☐ Medicaid
☐ No health insurance
☐ Amer Indian/Alaska Native
☐ Underinsured (FQHC/RHC)
☐ **NOT VFC Eligible**

VISIT #2 DATE

SIGNATURE

ELIGIBILITY STATUS
☐ Medicaid
☐ No health insurance
☐ Amer Indian/Alaska Native
☐ Underinsured (FQHC/RHC)
☐ **NOT VFC Eligible**

VISIT #3 DATE

SIGNATURE

ELIGIBILITY STATUS
☐ Medicaid
☐ No health insurance
☐ Amer Indian/Alaska Native
☐ Underinsured (FQHC/RHC)
☐ **NOT VFC Eligible**

VISIT #4 DATE

SIGNATURE

ELIGIBILITY STATUS
☐ Medicaid
☐ No health insurance
☐ Amer Indian/Alaska Native
☐ Underinsured (FQHC/RHC)
☐ **NOT VFC Eligible**

COMMENTS

PATIENT NAME

IMMUNIZATION CONSENT AND HISTORY (CONTINUED)

VACCINE AND ROUTE (CIRCLE TYPE GIVEN WHERE APPLICABLE)	VISIT NO. & M/D/Y GIVEN	INJECTION SITE	VACCINE MANUFACTURER/ LOT NUMBER	VACCINE EXP. DATE	VIS REVISION DATE	DATE VIS GIVEN	SIGNATURE OF VACCINATOR	PATIENT OR PARENT/GUARDIAN CONSENT
Pneumococcal polysaccharide PPSV 23 SQ IM								**VISIT #5** DATE SIGNATURE
Measles, Mumps, Rubella MMR SQ								**ELIGIBILITY STATUS** ☐ Medicaid ☐ No health insurance ☐ Amer Indian/Alaska Native ☐ Underinsured (FQHC/RHC) ☐ **NOT VFC Eligible**
Varicella Varicella SQ								
Rotavirus RV1 Oral RV5 Oral								**VISIT #6** DATE SIGNATURE
Hepatitus A Hep A IM								**ELIGIBILITY STATUS** ☐ Medicaid ☐ No health insurance ☐ Amer Indian/Alaska Native ☐ Underinsured (FQHC/RHC) ☐ **NOT VFC Eligible**
Human papilloma-virus HPV IM								**VISIT #7** DATE SIGNATURE
Meningococcal MenACWY IM								**ELIGIBILITY STATUS** ☐ Medicaid ☐ No health insurance ☐ Amer Indian/Alaska Native ☐ Underinsured (FQHC/RHC) ☐ **NOT VFC Eligible**
Meningococcal B MenB IM								**VISIT #8** DATE SIGNATURE
Tetanus, Diphtheria, Pertussis (7 years old and above) Tdap IM Td IM								**ELIGIBILITY STATUS** ☐ Medicaid ☐ No health insurance ☐ Amer Indian/Alaska Native ☐ Underinsured (FQHC/RHC) ☐ **NOT VFC Eligible**
Influenza IIV (inactive) IM RIV (recombinant) IM LAIV (live attenuated intranasal) IN								**VISIT #9** DATE SIGNATURE **ELIGIBILITY STATUS** ☐ Medicaid ☐ No health insurance ☐ Amer Indian/Alaska Native ☐ Underinsured (FQHC/RHC) ☐ **NOT VFC Eligible**
Zoster (Shingles) RVZ (recombinant) IM ZVL (live) SQ								**VISIT #10** DATE SIGNATURE **ELIGIBILITY STATUS** ☐ Medicaid ☐ No health insurance ☐ Amer Indian/Alaska Native ☐ Underinsured (FQHC/RHC) ☐ **NOT VFC Eligible**
Other								
Other								

COMMENTS

Handouts and Resources

POD Train the Trainer

March 2024

Where Can I Find an Electronic Copy of the Handouts?

1. HIPAA Resource - https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/hipaaprivacyandsecurity.pdf
2. Anthrax Doxy EUI HC –
3. 3. Anthrax CIPRO EUI HC -
4. Dispense Assist – www.dispenseassist.net/Library/Paper%20Form%20-%20Antibiotic.pdf
5. Dispense Assist Cheat Sheet – N/A
6. Medication Assessment Form – N/A
7. Dispensing Protocol Example – N/A
8. Exercise Dispense Assist – N/A
9. Anthrax CIPRO EUI UP - hhttps://archive.cdc.gov/#/details?q=CIPRO%20EUI&start=0&rows=10&url=https://www.cdc.gov/anthrax/pdf/cipro-eui-recipients-H.pdf
10. Anthrax Doxy EUI - https://archive.cdc.gov/#/details?url=https://www.cdc.gov/anthrax/pdf/doxy-eui-recipients-H.pdf
11. Doxy Crushing EUI UP – https://www.cdc.gov/anthrax/pdf/doxy-crushing-instruction-H.pdf
12. Vaccine Information Statements - http://www.immunize.org/catg.d/p2027.pdf
13. Anthrax VIS – www.immunize.org/vaccines/vis/anthrax/
14. Flu Intranasal VIS – www.immunize.org/vaccines/vis/influenza-live/
15. Flu Recombinant VIS – www.immunize.org/vaccines/vis/influenza-inactivated/
16. Vaccine Satellite Site Checklist - https://www.izsummitpartners.org/content/uploads/2019/02/off-site-vaccination-clinic-checklist.pdf
17. FAQ Satellite Checklist - https://www.izsummitpartners.org/content/uploads/2019/02/faqs-for-checklist-and-pledge.pdf
18. Ten Principles Vaccine Clinic - https://www.izsummitpartners.org/content/uploads/2017/04/Ten-principles-for-safe-vac-clinics-1-pg-sum.pdf
19. Vaccine Satellite Site Supply List - https://archive.cdc.gov/#/details?q=vaccine%20satellite%20supply%20list&start=0&rows=10&url=https://www.cdc.gov/vaccines/hcp/admin/downloads/2020-vaccine-clinic-supply-checklist-508.pdf
20. Guide to Contraindications all ages - http://www.immunize.org/catg.d/p3072a.pdf
21. Adult Vaccine Contraindications - http://www.immunize.org/catg.d/p4065.pdf
22. DHSS Immunization Consent - Immunization Consent and History (mo.gov)

Additional Useful Resources

1. Skills Checklist for Vaccine Administration – www.immunize.org/wp-content/uploads/catg.d/p7010.pdf
2. CDC Vaccine Storage and Handling Toolkit
   Video - https://www.youtube.com/watch?v=ok8j-1qx8II
   PDF - https://www.cdc.gov/vaccines/hcp/downloads/storage-handling-toolkit.pdf
3. Vaccine Adverse Event Reporting System (VAERS):
   Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS) website at www.vaers.hhs.gov or by calling 1-800-822-7967
4. For medication adverse event program, FDA: 1-800-FDA-1088 - https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
5. CDC Pandemic Influenza Checklist for Workplace, K-12, Childcare and Event Planning https://www.cdc.gov/pandemic-flu/php/fed-gov-planning/community-mitigation.html#:~:text=Nonpharmaceutical%20interventions%20(NPIs)%20are%20readily,particularly%20important%20during%20a%20pandemic.
6. Vaccine Safety – https://www.cdc.gov/vaccine-safety/index.html
7. Vaccinating Adults: A Step-by-Step Guide – https://www.immunize.org/about/history/pub-archives/adult-guide/
8. Medical Management of Vaccine Reactions in Adults – https://www.immunize.org/wp-content/uploads/catg.d/p3082.pdf
9. Medical Management of Vaccine Reactions in Children and Teens - https://www.immunize.org/wp-content/uploads/catg.d/p3082a.pdf
10. Immunization techniques and review CDC's Vaccine Administration eLearn at - https://www.cdc.gov/vaccines/hcp/admin/resource-library.html
11. You Call the Shots: Web Based Training Course - https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/index.html
12. Live Attenuated Influenza Vaccine (LAIV) Nasal Administration - https://www.youtube.com/watch?v=FUaptzVvRmU