## mpox 2022 VACCINE TOOLKIT:

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mpox Medical Countermeasures Jynneos Request Process –Adults & Pediatrics			
Request Stage	Action Tracker	Notes	
Need for MCMs	<ul> <li>Agency identifies need for MCM request for mpox vaccine:</li> <li>People who have been in close physical contact with someone diagnosed with mpox in the last 14 days (PEP)</li> <li>Men who have sex with men, or transgender women, who report any of the following in the last 90 days:         <ul> <li>Having multiple or anonymous sex partners</li> <li>Being diagnosed with a sexually transmitted infection</li> <li>Receiving HIV pre-exposure prophylaxis (PrEP)</li> </ul> </li> <li>Certain Health care workers and public health response team members designated by public health</li> </ul>	Time-sensitive or clinical support needs after-hours need to use the Epi On-Call number at 919-733-3419	
Enrollment/Capacity Survey  MCM Request	All vaccine requestors should submit Enrollment/Capacity Survey. Sites not already enrolled and approved for vaccine storage and NCIR documentation will be contacted by the Immunization Branch to complete the necessary NCIR enrollment and training.  Complete mpox MCM Request Form	SNS Inbox will be monitored M-F, 8 am to 5 pm	
Survey			
Review Process	<ul> <li>mpox Response Team vets the request and makes 1 of 2 decisions:</li> <li>Approved- forward request to vaccine hub for fulfillment</li> <li>Denied- requesting agency will be provided with a justification for denial of fulfillment (vaccine supply with be limited in certain hub locations based on facility need)</li> </ul>	Available quantities to transfer will be dependent upon doses available for transfer as determined by vaccine hub needs/appointments scheduled.	
State fulfillment thru Hub locations	<ul> <li>mpox Response Team will identify the closest vaccine hub in North Carolina.</li> <li>mpox Response Team will email the requestor and vaccine hub location point of contact to connect the two locations</li> <li>Logistics should be coordinated between the two locations</li> </ul>	<ul> <li>Vaccine hub counties: Buncombe, Cumberland, Guilford, Mecklenburg, Pitt, Forsyth, Durham, Wake and New Hanover.</li> <li>Available quantities to transfer will be dependent upon the hub need to fulfill vaccine appointments scheduled.</li> <li>Alternative Transport plans can be arranged if the receiving site doesn't have the resources to physically pick up vaccine from vaccine hub location.</li> </ul>	

Name	Indication	Request Criteria/ Considerations for Vaccination /Treatment	Availability	Packaging/ Storage and Handling	Resources
<u>Jynneos</u> Vaccine	FDA Approved for prevention of smallpox & mpox  Individuals <18 can be treated under Jynneos EUA	<ul> <li>Post exposure prophylaxis (PEP) for individuals between 4-14 days after exposure</li> <li>Expanded post exposure prophylaxis (PEP++) for individuals with certain risk factors who are more likely to have been recently exposed to mpox</li> <li>Pre-exposure prophylaxis (PrEP) for individuals at high risk of exposure to mpox</li> </ul>	SNS request  OR –  Push product within NC county jurisdictions  Ancillary supplies not included	20 – Single dose vials of 0.5ml dose  Keep frozen at -25°C to -15°C (- 13°F to +5°F).  Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks (Updated Storage Info)	CDC mpox Vaccine Guidance  Jynneos Vaccine Information Sheet  Jynneos Package Insert
ACAM2000 Vaccine	FDA Approved for Smallpox prevention in adults and peds > 1 yo Expanded access IND for mpox	■ PEP, PEP++ or PrEP when Jynneos is contraindicated or unavailable. Risk-benefit discussions and review of current medical conditions that could increase risk for serious adverse events should be completed prior to administration. Use should be determined between patient and provider while considering medical history, individual/household profiles and ability to manage vaccine site lesion to prevent further transmission.	SNS Request Only Ancillary supplies included in shipment from SNS	3 ml MDV requiring reconstitution  Prior to reconstitution, <b>store frozen</b> at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months.  Diluent stored at room temperature of 15°C to 30°C (59°F to 86°F).	ACAM2000 Medication Guide – CDC  ACAM2000 Package Insert
Tecovirimat (Tpoxx) Antiviral medication	FDA approved for treatment of smallpox in adults and pediatric patients weighing at least 3 kg  Expanded access IND for mpox	<ul> <li>Individuals with severe disease (i.e. hemorrhagic disease, sepsis, encephalitis or others requiring hospitalization)</li> <li>High risk of severe disease:         <ul> <li>immunocompromising conditions such as HIV/AIDs</li> <li>pediatrics &lt;8 years old,</li> <li>pregnant/breastfeeding women</li> <li>history of atopic dermatitis</li> <li>≥1 complication of active infection</li> </ul> </li> <li>Aberrant infections involving anatomic areas of mpox virus infection that may create hazard (i.e., eyes, mouth, genitals, anus)</li> </ul>	SNS Request only	200mg capsules in bottles of 42 capsules; stored at room temperature  IV – requires refrigeration (shipping & storage)	CDC Guidance for Tecovirimat Use Tecovirimat Package Insert Tpoxx Fact Sheet

## NC Standing Order Template #1 JYNNEOS Vaccine Administration 2022/Pavised December 9, 2022/Corrected 12

Update: August 11, 2022/Revised December 9, 2022/Corrected 12/14/22

This is a template for a standing order:

**Purpose**: To reduce morbidity and mortality from Orthopoxvirus (Mpox, Smallpox) by vaccinating individuals with JYNNEOS (SMALLPOX AND MPOX VACCINE, LIVE, NON-REPLICATING) vaccine who are at high risk for exposure or as part of pre and post-exposure prophylaxis.

**Policy**: In addition to the approved standard subcutaneous regimen, on August 9, 2022, the FDA granted Emergency Use Authorization of JYNNEOS intradermal administration as an alternative to the subcutaneous route, as well as subcutaneous administration in those under 18 years of age.

As of 8/29/22, NC DHHS, in alignment with CDC guidance, requests that all providers administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. The only unique contraindication for intradermal injection is history/or presence of keloid scaring. If this contraindication does exist, then administer subcutaneously.

On 9/28/22, CDC release updated guidelines for the intradermal administration of JYNNEOS in adults and young children necessitating the revision of this standing order template.

On 10/12/22, NC DHHS expanded JYNNEOS eligibility criteria for pre-exposure vaccination in coordination with the CDC.

On 10/21/22, CDC revised their recommendation to providers re: seeking consultation with jurisdictional health department for administration of JYNNEOS from children 18 or less to children than 6 months of age.

On 12/9/22, NC DHHS rescinded their previous request to administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. This decision was made considering the decreasing incidence of cases, adequate supply statewide of vaccine and to reduce all barriers to care, in alignment with CDC guidance. As of 12/9/22, Public Health Jurisdictions and health care providers should decide whether to offer the intradermal or subcutaneous regimen based on balancing optimal vaccination use and acceptance, feasibility of administration and available vaccine supply. Additionally, in response to the WHO and CDC request to refer to monkeypox as "mpox" in order to reduce any stigma associated with the virus, NC DHHS has revised this standing order template to refer to monkeypox as "mpox".

Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Note: There is no change in product formulation. Dosage differs based on age of individual and vaccine administration route. Vials are preservative free. Unused vaccine will still need to be discarded 8 hours after the vial is first accessed. A 2<sup>nd</sup> dose is still required to be completely immunized. Please review (alternative regimen): Fact Sheet For Healthcare Providers Administering Vaccine:

Emergency Use Authorization Of JYNNEOS (Smallpox And mpox Vaccine, Live, Non-Replicating) For Prevention Of Mpox Disease In Individuals Determined To Be At High Risk For mpox Infection and the package insert for JYNNEOS (Smallpox and mpox Vaccine, Live, Non-replicating) suspension for subcutaneous injection (standard regimen) prior to implementing this standing order.

#### Condition or Situation

Condition or Situation in Which the SO Will Be Used JYNNEOS is a vaccine indicated for prevention of smallpox and mpox disease in highrisk individuals. <u>Based on patient preference the Standard Regimen or Alternative Regimen</u> <u>may be administered to patients 18 years of age or older</u>. **NO options are allowed for patients less than 18 years of age.** 

Patients who present requesting vaccination with JYNNEOS will receive:

## Primary Series STANDARD REGIMEN 18 years and older of age

• 2 subcutaneous injections (SQ) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time.

**NOTE**: Two doses are required to be considered completely immunized.

## **Primary Series LESS THAN 18 YEARS OF AGE**

• 2 subcutaneous injections (SQ) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time.

## **NOTE:**

- For individuals less than 6 months of age in need of JYNNEOS, please contact the Communicable Disease Branch's Epi On-Call Line at 919-733-3419 for consultation prior to administration.
- Two doses are required to be considered completely immunized.

## Primary Series - ALTERNATIVE REGIMEN 18 years of age and older:

• 2 intradermal injections (ID) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time.

## Recommended 2<sup>nd</sup> dose minimum and maximum intervals

See CDC interim clinical considerations for more information

• Minimum interval: The vaccine manufacturer advises against giving the second dose before the minimum interval of 28 days. However, based on ACIP's general best practices, a dose may be administered up to 4 days before the minimum

- interval of 28 days (known as the "grace period"), which would be a minimum of 24 days after the first dose.
- The second dose of JYNNEOS vaccine should be given 28 days after the first dose but may be given up to 7 days later than the minimum interval (i.e., up to 35 days after the first dose).
- If the second dose is inadvertently administered before the minimum interval, the dose may not need to be repeated. Please refer to <a href="Table 7">Table 7</a>. Vaccine Administration Errors and Deviations.
- If 1<sup>st</sup> dose was administered subcutaneously, provide ID injection as 2<sup>nd</sup> dose, unless otherwise contraindicated.

#### NOTE:

- Persons with a history of keloid scarring should not receive this vaccine intradermally. Vaccinate subcutaneously following the instructions for subcutaneous vaccination below.
- Two doses are required to be considered completely immunized

Standard and Alternative Dosing Regimens			
Age	Route		Dosing
			Interval*
≥ 18 Standard Regimen	Subcutaneous	0.5 mL	28 days
<18 Alternative Regimen	Subcutaneous	0.5 mL	28 days
People of any age who have a	Subcutaneous	0.5 mL	28 days
history of developing keloid scars			
≥ 18 Alternative Regimen	Intradermal**	0.1 mL	28 days

<sup>\*</sup>Recommended minimum interval to 2<sup>nd</sup> dose is 28 days and a maximum interval 7 days later than the minimum interval (i.e., up to 35 days). There is no need to restart or add doses to the series if there is an extended interval between doses.

## Pre and Post-Exposure Prophylaxis

Administer JYNNEOS to persons who present requesting vaccination and self-attest to being in a high-risk category:

## JYNNEOS Eligibility Criteria

- 1. Anyone who had close contact in the past two weeks with someone who has been diagnosed with mpox (see CDC Exposure risk assessment); or
- 2. Gay, bisexual, or other men who have sex with men, or transgender individuals, who are sexually active; or
- 3. People who have had sexual contact with gay, bisexual, or other men who have sex with men, or transgender individuals in the past 90 days: or

<sup>\*\*</sup> Requires use of a tuberculin syringe of 1/4 to 1/2 in in length and a 26- or 27-gauge needle.

- 4. People living with HIV, or taking medication to prevent HIV (PrEP), or who were diagnosed with syphilis in the past 90 days.
- 5. People who have had any of the following in the past 6 months:
  - a. Sex at a commercial sex venue
  - b. Sex in association with a large public event
- 6. Sexual partners of people with the above risks
- 7. People who anticipate experiencing the above risks
- 8. Health care workers who were in the same room with or within 6 feet of a patient suspected or confirmed to have mpox during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection.

mpox vaccines are recommended for people whose jobs expose them to mpox or related viruses. However, pre-exposure vaccination is not recommended at this time for most clinicians in the United States or for laboratorians not performing the orthopox virus generic test to diagnose orthopox viruses, including mpox virus. More information is available at CDC mpox and Smallpox Guidance

Health care workers meeting any of the following criteria are considered eligible to receive mpox vaccine as Pre-Exposure Prophylaxis (PrEP). Health care workers exposed to mpox virus who have not received the smallpox vaccine within the last 3 years should consider getting re-vaccinated.:

- 9. Clinical laboratory personnel who perform testing to diagnose orthopox viruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopox viruses, including mpox virus
- 10. Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopox viruses that infect humans, including mpox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains
- 11. Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes
- 12. People who can get PrEP if they want to receive it include healthcare personnel who administer ACAM2000 or anticipate caring for many patients with mpox.

#### Assessment

Assessment Criteria Patients determined to be at high risk for exposure shall be vaccinated with JYNNEOS. Patients who have experienced a high-risk exposure should ideally be vaccinated with JYNNEOS within 14 days of the date of exposure. Vaccination is most effective when

given within 4 days of the date of the exposure. Vaccine given between 4–14 days after the date of exposure may reduce symptoms of disease but may not prevent the disease.
Subjective
<ol> <li>Client presents requesting smallpox vaccine (JYNNEOS) and meets criteria above.</li> <li>Client presents requesting 2<sup>nd</sup> dose of JYNNEOS         <ul> <li>a) 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 any dose of JYNNEOS.</li> <li>b) Persons recommended to receive JYNNEOS due to an exposure to mpox virus should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.</li> </ul> </li> </ol>

	Objective
	<ol> <li>Immunization record reveals client has not previously completed a smallpox vaccine series with either ACAM2000 (smallpox) or JYNNEOS vaccine within the last two years for pre-exposure prophylaxis or within the last three years for post-exposure prophylaxis.</li> <li>Immunization record indicates receipt of 1 dose of JYNNEOS at least 4 weeks ago, and patient is presenting for second dose of the primary series.</li> </ol>
Nursing Plan of Car	

#### Nursing Plan of Care

Contraindications and Precautions

Screen all individuals for contraindications and precautions to JYNNEOS vaccine. Note that **pregnancy and breastfeeding are not contraindications.** Because JYNNEOS is non-replicating, it can be administered regardless of timing to previous live virus vaccine administration (e.g., MMR, Varicella). JYNNEOS is also safe for administration to people with HIV and atopic dermatitis.

Consult with medical staff if the following contraindications or precautions are present. These contraindications apply to use of STANDARD OR ALTERNATIVE REGIMEN.

TABLE 3: CONTRAINDICATIONS AND PRECAUTIONS FOR USE OF JYNNEOS VACCINE
(Note: JYNNEOS is formulated without preservatives. The vial stoppers are not made with natural rubber latex). More information on JYNNEOS cell line <a href="here">here</a>.

Contraindications:

• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine.

 ALTERNATIVE REGIMEN ONLY: People of any age who have a history of developing keloid scars

#### **Precautions:**

- Moderate to severe acute illness, with or without fever.
- History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin or
- History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products
  - After discussing risks and benefits with the patient, persons falling within these 3 categories of allergies may be vaccinated with a 30-minute observation period or vaccination may be delayed until consultation with an allergist-immunologist for persons in the last 2 categories after considering the impact of delay vaccine.
  - Specific Groups/Situations:
    - Pregnancy and breast feeding are not contraindications to vaccination.
    - Pediatric and Geriatric populations: there have not been adequate studies to determine safety and efficacy in those under 18\* or over the age of 65. (\*JYNNEOS is not licensed for administration to individuals under the age of 18; however, it has been authorized under EUA for use in individuals less than 18.). Due to an unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after receipt of vaccination before receiving an mRNA COVID-19 vaccine. If post-exposure prophylaxis is recommended, vaccination with JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine.
    - Coadministration with tuberculin skin test: Currently, there is no data on administering JYNNEOS vaccine at the same time as the tuberculin skin test (TST). If a delay in the TST will cause substantial burden, then the TST should not be delayed. The TST can be performed at the same time as JYNNEOS vaccination, using different forearms, one on the left and one on the right. The location of each injection site should be recorded in order to read the TST from the correct forearm. If delays in the TST will not cause substantial burden, a delay of at least 4 weeks after JYNNEOS vaccination is preferred. For patients with symptoms or signs of active tuberculosis (TB), all tests and examinations for TB should be pursued without delay, regardless of JYNNEOS vaccination.

**Nursing Actions** 

Implement the following vaccine regimen if above eligibility and assessment criteria are met and no precautions or contraindications are identified:

Prior to vaccination provide patient with a copy of <u>Fact Sheet for Recipients and Caregivers About JYNNEOS</u>. <u>Smallpox/mpox Vaccine (JYNNEOS<sup>TM</sup>)- English</u> and <u>Smallpox/mpox Vaccine (JYNNEOS<sup>TM</sup>)-Spanish</u> may be provided to augment EUA.

- Per NC Statute 90-21.5, written consent is required for JYNNEOS administration of JYNNEOS in persons less than 18 years old.
- Inform patient/caregiver of possible side effects and reactions. Injection site redness is common. Persons with a history of immunocompromising conditions should be counseled on the possibility of a reduced response to the vaccine.
- Counsel patients that it is not known if JYNNEOS will fully protect against
  mpox virus infection in this outbreak. Individuals wanting to minimize their
  risk of infection should take additional <u>preventive measures</u> and immediately
  self-isolate should symptoms occur, such as a rash.
- Health care personnel should follow routine infection control procedures when administering vaccines. Follow strict aseptic medication preparation practices. Perform hand hygiene before preparing vaccines. Use a designated, clean medication area that is not adjacent to areas where potentially contaminated items are placed. Avoid distractions. Some facilities have a nointerruption zone, where health care professionals can prepare medications without interruptions. Prepare medications for one patient at a time. Always follow the vaccine manufacturer's directions, located in the package inserts.
- Allow the vaccine to thaw and reach room temperature before use.
- Swirl the vial gently before use for at least 30 seconds.
- For individuals 18 years of age and older utilizing the **ALTERNATIVE REGIMEN** administer vaccine intradermally. Withdraw a dose of 0.1 mL into a sterile syringe.
- Select and cleanse vaccination site 2-4 inches below the antecubital fossa (elbow) on the volar aspect of the forearm. If the volar aspect of the forearm is not an option (e.g., strong patient preference), administer vaccine intradermally at the upper back below the scapula, or at the deltoid based on patient choice.
- Administer JYNNEOS intradermally into the volar surface of the forearm or other site location mentioned above.
- While pulling the skin taut, position the needle bevel facing up and insert the needle at a 5-to 15-degree angle into the dermis. Slowly inject 0.1mL intradermally. A noticeable pale elevation of the skin (wheal) is desirable but not required.
- If a lower-than-authorized dose is administered intradermally (e.g., patient pulled away, or leakage out of the syringe), repeat intradermal dose immediately (no minimum interval) at least 2 inches away from the site of vaccine leakage. If vaccine leakage occurs with two intradermal vaccinations on the same day, administer 0.5 mL subcutaneously.
- A bandage may be placed over the injection site as needed.
- NOTE: For persons who present for their second JYNNEOS vaccine dose and who are still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) administer second dose intradermally in the volar aspect of the contralateral forearm. If the volar aspect of

the contralateral forearm is not an option (e.g., strong patient preference), administer vaccine intradermally based on patient choice of either the upper back below the scapula, or at the deltoid.

- For persons with tattoos, avoid vaccination in the area where there is a recent (<1 month) tattoo. If tattoos cover both arms, choose a space that doesn't have pigment (i.e., Ink). However, if the tattoo cannot be avoided, the vaccine can still be administered through the tattoo.
- For individuals utilizing the **STANDARD REGIMEN** >12 months of age:
  - o Administer 0.5 ml JYNNEOS subcutaneously by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle.
  - o Use a 23-25g, 5/8" needle.
- For individuals utilizing the **STANDARD REGIMEN** with infants <12 months of age:
  - o Administer 0.5ml JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle.
  - o Use a 23-25g, 5/8" needle.
- Observe Patients after Vaccination for 15 minutes unless patient meets criteria listed above under "Precautions". Monitor all patients after vaccination for the occurrence of immediate adverse reactions, including syncope.
- Counsel the patient to return in 28 days (4 weeks) for the second dose if the dose administered is the first dose.
  - Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture. After thawing, the total time stored at +2°C to +8°C (+36°F to +46°F) should not exceed 8 weeks.
  - Document each patient's vaccine administration information and follow up in the following locations: Electronic medical record/North Carolina Immunization Registry (NCIR)- record the date the vaccine was administered, manufacturer and lot number, the vaccination site and route, the name and title of the person administering the vaccine. Race, ethnicity, and gender and are now required fields in NCIR and should be reviewed and updated to ensure accurate documentation for the JYNNEOS recipient. For tracking purposes, ensure doses are documented from live inventory in NCIR (do not enter historically).
  - If the vaccine was not administered, record reason (s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - Inform patient/caregiver to go to the Emergency Department of the nearest hospital if an adverse reaction occurs.

Follow-up	<ul> <li>Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov.</li> <li>Instruct patient to call clinic, or their health care provider with any questions and/or problems.</li> <li>Inform vaccine recipient of the importance of completing the two dose vaccination series (at least 28 days apart) for first time vaccine recipients.</li> <li>Vaccines inadvertently administered intramuscularly (IM) can be considered valid doses and do not need to be repeated. IM doses need to be reported to the manufacturer at drug.safety@bavarian-nordic.com.</li> <li>VAERS Reporting: Healthcare providers are required to report to VAERS adverse events found in the Reportable Events Table (RET). For events not included in the RET, healthcare providers are encouraged to report any additional clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event.</li> <li>Anaphylaxis Management: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis.</li> <li>Syncope: Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.</li> </ul>
	Criteria for Notifying the physician/APP
Criteria for Notifying the physician/APP	<ol> <li>Allergic reaction: Call 911, implement medical protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.</li> <li>Consult with physician/ advanced practice provider if the patient reports any contraindications or precautions to the vaccine prior to administration.</li> </ol>

Approved by:		Date approved	(or last reviewed):	
-	(Signature of physician/APP)			

# NC Standing Order Template #2 JYNNEOS Vaccine Administration Update: August 11, 2022/Revised December 9, 2022/Corrected 12/14/22

This is a template for a standing order:

**Purpose**: To reduce morbidity and mortality from Orthopoxvirus (Mpox, Smallpox) by vaccinating individuals with JYNNEOS (SMALLPOX AND MPOX VACCINE, LIVE, NON-REPLICATING) vaccine who are at high risk for exposure or as part of pre and post-exposure prophylaxis.

**Policy**: In addition to the approved standard subcutaneous regimen, on August 9, 2022, the FDA granted Emergency Use Authorization of JYNNEOS intradermal administration as an alternative to the subcutaneous route, as well as subcutaneous administration in those under 18 years of age.

As of 8/29/22, NC DHHS, in alignment with CDC guidance, requests that all providers administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. The only unique contraindication for intradermal injection is history/or presence of keloid scaring. If this contraindication does exist, then administer subcutaneously.

On 9/28/22, CDC release updated guidelines for the intradermal administration of JYNNEOS in adults and young children necessitating the revision of this standing order template.

On 10/12/22, NC DHHS expanded JYNNEOS eligibility criteria for pre-exposure vaccination in coordination with the CDC.

On 10/21/22, CDC revised their recommendation to providers re: seeking consultation with jurisdictional health department for administration of JYNNEOS from children 18 or less to children than 6 months of age.

On 12/9/22, NC DHHS rescinded their previous request to administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. This decision was made considering the decreasing incidence of cases, adequate supply statewide of vaccine and to reduce all barriers to care, in alignment with CDC guidance. As of 12/9/22, Public Health Jurisdictions and health care providers should decide whether to offer the intradermal or subcutaneous regimen based on balancing optimal vaccination use and acceptance, feasibility of administration and available vaccine supply. Additionally, in response to the WHO and CDC request to refer to monkeypox as "mpox" in order to reduce any stigma associated with the virus, NC DHHS has revised this standing order template to refer to monkeypox as "mpox".

Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Note: There is no change in product formulation. Dosage differs based on age of individual and vaccine administration route. Vials are preservative free. Unused vaccine will still need to be discarded 8 hours after the vial is first accessed. A 2<sup>nd</sup> dose is still required to be completely immunized. Please review (alternative regimen): Fact Sheet For Healthcare Providers Administering Vaccine:

Emergency Use Authorization Of JYNNEOS (Smallpox And mpox Vaccine, Live, Non-Replicating) For Prevention Of Mpox Disease In Individuals Determined To Be At High Risk For mpox Infection and the package insert for JYNNEOS (Smallpox and mpox Vaccine, Live, Non-replicating) suspension for subcutaneous injection (standard regimen) prior to implementing this standing order.

#### Condition or Situation

Condition or Situation in Which the SO Will Be Used JYNNEOS is a vaccine indicated for prevention of smallpox and mpox disease in highrisk individuals. <u>Based on agency directive on the day the patient presents the Standard</u> <u>Regimen or Alternative Regimen may be administered to patients 18 years of age or</u> <u>older.</u> Patients less than 18 years of age shall ONLY receive the Standard Regimen. Patients who present requesting vaccination with JYNNEOS will receive:

## Primary Series STANDARD REGIMEN 18 years and older of age

• 2 subcutaneous injections (SQ) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time.

NOTE: Two doses are required to be considered completely immunized.

## **Primary Series LESS THAN 18 YEARS OF AGE**

• 2 subcutaneous injections (SQ) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time.

#### NOTE:

- For individuals less than 6 months of age in need of JYNNEOS, please contact the Communicable Disease Branch's Epi On-Call Line at 919-733-3419 for consultation prior to administration.
- Two doses are required to be considered completely immunized.

## Primary Series - ALTERNATIVE REGIMEN 18 years of age and older:

• 2 intradermal injections (ID) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time.

## Recommended 2<sup>nd</sup> dose minimum and maximum intervals

See CDC interim clinical considerations for more information

• Minimum interval: The vaccine manufacturer advises against giving the second dose before the minimum interval of 28 days. However, based on ACIP's general best practices, a dose may be administered up to 4 days before the minimum

- interval of 28 days (known as the "grace period"), which would be a minimum of 24 days after the first dose.
- The second dose of JYNNEOS vaccine should be given 28 days after the first dose but may be given up to 7 days later than the minimum interval (i.e., up to 35 days after the first dose).
- If the second dose is inadvertently administered before the minimum interval, the dose may not need to be repeated. Please refer to <a href="Table 7">Table 7</a>. Vaccine Administration Errors and Deviations.
- If 1<sup>st</sup> dose was administered subcutaneously, provide ID injection as 2<sup>nd</sup> dose, unless otherwise contraindicated.

#### NOTE:

- Persons with a history of keloid scarring should not receive this vaccine intradermally. Vaccinate subcutaneously following the instructions for subcutaneous vaccination below.
- Two doses are required to be considered completely immunized

Standard and Alternative Dosing Regimens			
Age	Route	Dose	Dosing
			Interval*
≥ 18 Standard Regimen	Subcutaneous	0.5 mL	28 days
<18 Alternative Regimen	Subcutaneous	0.5 mL	28 days
People of any age who have a	Subcutaneous	0.5 mL	28 days
history of developing keloid scars			
≥ 18 Alternative Regimen	Intradermal**	0.1 mL	28 days

<sup>\*</sup>Recommended minimum interval to 2<sup>nd</sup> dose is 28 days and a maximum interval 7 days later than the minimum interval (i.e., up to 35 days). There is no need to restart or add doses to the series if there is an extended interval between doses.

## Pre and Post-Exposure Prophylaxis

Administer JYNNEOS to persons who present requesting vaccination and self-attest to being in a high-risk category:

## JYNNEOS Eligibility Criteria

- 13. Anyone who had close contact in the past two weeks with someone who has been diagnosed with mpox (see CDC <a href="Exposure risk assessment">Exposure risk assessment</a>); or
- 14. Gay, bisexual, or other men who have sex with men, or transgender individuals, who are sexually active; or
- 15. People who have had sexual contact with gay, bisexual, or other men who have sex with men, or transgender individuals in the past 90 days: or

<sup>\*\*</sup> Requires use of a tuberculin syringe of 1/4 to 1/2 in in length and a 26- or 27-gauge needle.

- 16. People living with HIV, or taking medication to prevent HIV (PrEP), or who were diagnosed with syphilis in the past 90 days.
- 17. People who have had any of the following in the past 6 months:
  - a. Sex at a commercial sex venue
  - b. Sex in association with a large public event
- 18. Sexual partners of people with the above risks
- 19. People who anticipate experiencing the above risks
- 20. Health care workers who were in the same room with or within 6 feet of a patient suspected or confirmed to have mpox during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection.

mpox vaccines are recommended for people whose jobs expose them to mpox or related viruses. However, pre-exposure vaccination is not recommended at this time for most clinicians in the United States or for laboratorians not performing the orthopox virus generic test to diagnose orthopox viruses, including mpox virus. More information is available at CDC mpox and Smallpox Guidance

Health care workers meeting any of the following criteria are considered eligible to receive mpox vaccine as Pre-Exposure Prophylaxis (PrEP). Health care workers exposed to mpox virus who have not received the smallpox vaccine within the last 3 years should consider getting re-vaccinated.:

- 21. Clinical laboratory personnel who perform testing to diagnose orthopox viruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopox viruses, including mpox virus
- 22. Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopox viruses that infect humans, including mpox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains
- 23. Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes
- 24. People who can get PrEP if they want to receive it include healthcare personnel who administer ACAM2000 or anticipate caring for many patients with mpox.

#### Assessment

Assessment Criteria Patients determined to be at high risk for exposure shall be vaccinated with JYNNEOS. Patients who have experienced a high-risk exposure should ideally be vaccinated with JYNNEOS within 14 days of the date of exposure. Vaccination is most effective when

given within 4 days of the date of the exposure. Vaccine given between 4–14 days after the date of exposure may reduce symptoms of disease but may not prevent the disease.
Subjective
<ul> <li>3. Client presents requesting smallpox vaccine (JYNNEOS) and meets criteria above.</li> <li>4. Client presents requesting 2<sup>nd</sup> dose of JYNNEOS <ul> <li>c) 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 any dose of JYNNEOS.</li> <li>d) Persons recommended to receive JYNNEOS due to an exposure to mpox virus should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.</li> </ul> </li> </ul>

	Objective
	<ol> <li>Immunization record reveals client has not previously completed a smallpox vaccine series with either ACAM2000 (smallpox) or JYNNEOS vaccine within the last two years for pre-exposure prophylaxis or within the last three years for post-exposure prophylaxis.</li> <li>Immunization record indicates receipt of 1 dose of JYNNEOS at least 4 weeks ago, and patient is presenting for second dose of the primary series.</li> </ol>
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#### Nursing Plan of Care

Contraindications and Precautions

Screen all individuals for contraindications and precautions to JYNNEOS vaccine. Note that **pregnancy and breastfeeding are not contraindications.** Because JYNNEOS is non-replicating, it can be administered regardless of timing to previous live virus vaccine administration (e.g., MMR, Varicella). JYNNEOS is also safe for administration to people with HIV and atopic dermatitis.

Consult with medical staff if the following contraindications or precautions are present. These contraindications apply to use of STANDARD OR ALTERNATIVE REGIMEN.

TABLE 3: CONTRAINDICATIONS AND PRECAUTIONS FOR USE OF JYNNEOS VACCINE (Note: JYNNEOS is formulated without preservatives. The vial stoppers are not made with natural rubber latex). More information on JYNNEOS cell line <a href="here">here</a>.

**Contraindications:** 

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine.

 ALTERNATIVE REGIMEN ONLY: People of any age who have a history of developing keloid scars

#### **Precautions:**

- Moderate to severe acute illness, with or without fever.
- History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin or
- History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products
  - After discussing risks and benefits with the patient, persons falling within these 3 categories of allergies may be vaccinated with a 30-minute observation period or vaccination may be delayed until consultation with an allergist-immunologist for persons in the last 2 categories after considering the impact of delay vaccine.
  - Specific Groups/Situations:
    - Pregnancy and breast feeding are not contraindications to vaccination.
    - Pediatric and Geriatric populations: there have not been adequate studies to determine safety and efficacy in those under 18\* or over the age of 65. (\*JYNNEOS is not licensed for administration to individuals under the age of 18; however, it has been authorized under EUA for use in individuals less than 18.). Due to an unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after receipt of vaccination before receiving an mRNA COVID-19 vaccine. If post-exposure prophylaxis is recommended, vaccination with JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine.
    - Coadministration with tuberculin skin test: Currently, there is no data on administering JYNNEOS vaccine at the same time as the tuberculin skin test (TST). If a delay in the TST will cause substantial burden, then the TST should not be delayed. The TST can be performed at the same time as JYNNEOS vaccination, using different forearms, one on the left and one on the right. The location of each injection site should be recorded in order to read the TST from the correct forearm. If delays in the TST will not cause substantial burden, a delay of at least 4 weeks after JYNNEOS vaccination is preferred. For patients with symptoms or signs of active tuberculosis (TB), all tests and examinations for TB should be pursued without delay, regardless of JYNNEOS vaccination.

**Nursing Actions** 

Implement the following vaccine regimen if above eligibility and assessment criteria are met and no precautions or contraindications are identified:

Prior to vaccination provide patient with a copy of <u>Fact Sheet for Recipients and Caregivers About JYNNEOS</u>. <u>Smallpox/mpox Vaccine (JYNNEOS<sup>TM</sup>)- English</u> and <u>Smallpox/mpox Vaccine (JYNNEOS<sup>TM</sup>)-Spanish</u> may be provided to augment EUA.

- Per NC Statute 90-21.5, written consent is required for JYNNEOS administration of JYNNEOS in persons less than 18 years old.
- Inform patient/caregiver of possible side effects and reactions. Injection site redness is common. Persons with a history of immunocompromising conditions should be counseled on the possibility of a reduced response to the vaccine.
- Counsel patients that it is not known if JYNNEOS will fully protect against
  mpox virus infection in this outbreak. Individuals wanting to minimize their
  risk of infection should take additional <u>preventive measures</u> and immediately
  self-isolate should symptoms occur, such as a rash.
- Health care personnel should follow routine infection control procedures when administering vaccines. Follow strict aseptic medication preparation practices. Perform hand hygiene before preparing vaccines. Use a designated, clean medication area that is not adjacent to areas where potentially contaminated items are placed. Avoid distractions. Some facilities have a nointerruption zone, where health care professionals can prepare medications without interruptions. Prepare medications for one patient at a time. Always follow the vaccine manufacturer's directions, located in the package inserts.
- Allow the vaccine to thaw and reach room temperature before use.
- Swirl the vial gently before use for at least 30 seconds.
- For individuals 18 years of age and older utilizing the **ALTERNATIVE REGIMEN** administer vaccine intradermally. Withdraw a dose of 0.1 mL into a sterile syringe.
- Select and cleanse vaccination site 2-4 inches below the antecubital fossa (elbow) on the volar aspect of the forearm. If the volar aspect of the forearm is not an option (e.g., strong patient preference), administer vaccine intradermally at the upper back below the scapula, or at the deltoid based on patient choice.
- Administer JYNNEOS intradermally into the volar surface of the forearm or other site location mentioned above.
- While pulling the skin taut, position the needle bevel facing up and insert the needle at a 5-to 15-degree angle into the dermis. Slowly inject 0.1mL intradermally. A noticeable pale elevation of the skin (wheal) is desirable but not required.
- If a lower-than-authorized dose is administered intradermally (e.g., patient pulled away, or leakage out of the syringe), repeat intradermal dose immediately (no minimum interval) at least 2 inches away from the site of vaccine leakage. If vaccine leakage occurs with two intradermal vaccinations on the same day, administer 0.5 mL subcutaneously.
- A bandage may be placed over the injection site as needed.
- NOTE: For persons who present for their second JYNNEOS vaccine dose and who are still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) administer second dose intradermally in the volar aspect of the contralateral forearm. If the volar aspect of

the contralateral forearm is not an option (e.g., strong patient preference), administer vaccine intradermally based on patient choice of either the upper back below the scapula, or at the deltoid.

- For persons with tattoos, avoid vaccination in the area where there is a recent (<1 month) tattoo. If tattoos cover both arms, choose a space that doesn't have pigment (i.e., Ink). However, if the tattoo cannot be avoided, the vaccine can still be administered through the tattoo.
- For individuals utilizing the **STANDARD REGIMEN** >12 months of age:
  - o Administer 0.5 ml JYNNEOS subcutaneously by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle.
  - o Use a 23-25g, 5/8" needle.
- For individuals utilizing the **STANDARD REGIMEN** with infants <12 months of age:
  - o Administer 0.5ml JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle.
  - o Use a 23-25g, 5/8" needle.
- Observe Patients after Vaccination for 15 minutes unless patient meets criteria listed above under "Precautions". Monitor all patients after vaccination for the occurrence of immediate adverse reactions, including syncope.
- Counsel the patient to return in 28 days (4 weeks) for the second dose if the dose administered is the first dose.
  - Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture. After thawing, the total time stored at +2°C to +8°C (+36°F to +46°F) should not exceed 8 weeks.
  - Document each patient's vaccine administration information and follow up in the following locations: Electronic medical record/North Carolina Immunization Registry (NCIR)- record the date the vaccine was administered, manufacturer and lot number, the vaccination site and route, the name and title of the person administering the vaccine. Race, ethnicity, and gender and are now required fields in NCIR and should be reviewed and updated to ensure accurate documentation for the JYNNEOS recipient. For tracking purposes, ensure doses are documented from live inventory in NCIR (do not enter historically).
  - If the vaccine was not administered, record reason (s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - Inform patient/caregiver to go to the Emergency Department of the nearest hospital if an adverse reaction occurs.

Follow-up	<ul> <li>Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov.</li> <li>Instruct patient to call clinic, or their health care provider with any questions and/or problems.</li> <li>Inform vaccine recipient of the importance of completing the two dose vaccination series (a least 28 days apart) for first time vaccine recipients.</li> <li>Vaccines inadvertently administered intramuscularly (IM) can be considered valid doses an do not need to be repeated. IM doses need to be reported to the manufacturer at drug.safety@bavarian-nordic.com.</li> <li>VAERS Reporting: Healthcare providers are required to report to VAERS adverse events found in the Reportable Events Table (RET). For events not included in the RET healthcare providers are encouraged to report any additional clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event.</li> <li>Anaphylaxis Management: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine diphenhydramine) where vaccines are provided to respond to severe allergic reactions anaphylaxis.</li> <li>Syncope: Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be place to avoid injury from fainting.</li> <li>Criteria for Notifying the physician/APP</li> <li>Allergic reaction: Call 911, implement medical protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.</li> </ul>	
Criteria for Notifying the physician/APP	<ul> <li>3. Allergic reaction: Call 911, implement medical protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.</li> <li>4. Consult with physician/ advanced practice provider if the patient reports any contraindications or precautions to the vaccine prior to administration.</li> </ul>	

Approved by:		Date approved	(or last reviewed):	
	(Signature of physician/APP)			

JYNNEOS Standing Order Template/ Update August 11, 2022/last revised December 14, 2022

## mpox Vaccination - Eligibility - Phase IV

JYNNEOS is a safe and effective vaccine that can prevent Mpox in people who have been exposed to the virus if given within 4 days of exposure and reduce the risk of severe illness if given within 14 days of exposure. Effective Wednesday, September 7<sup>th</sup>, vaccine is currently available to be given to people mpox that meet the following criteria:

- 1. Anyone who had close contact in the past two weeks with someone who has been diagnosed with Mpox; or
- 2. Gay, bisexual, or other men who have sex with men, or transgender individuals, who are sexually active; or
- 3. People who have had sexual contact with gay, bisexual, or other men who have sex with men, or transgender individuals in the past 90 days: or
- 4. People living with HIV, or taking medication to prevent HIV (PrEP), or who were diagnosed with syphilis in the past 90 days.

09/01/2022

## North Carolina Immunization Program Transportation Guidance for Vaccines

Transportation of vaccines should be rare and expected length of transport should be less than 30 minutes. If conducting an off-site clinic, the total time for transport and workday should be a maximum of 8 hours. A digital data logger with a current and valid certificate of calibration must be used for temperature monitoring during transport. For accountability tracking purposes, transfers must be documented via the North Carolina Immunization Registry (NCIR) when vaccine is transferred from one provider to another. If portable units purpose-built for vaccine transport are not available, the following methods can be used as an acceptable alternative.

## **Transporting Frozen Vaccines**

## Guidelines for vaccine transport in emergency situations

## Assemble packing supplies and documents

- 1. Hard-sided cooler
- **2. Frozen cold packs** Keep enough frozen cold packs in your freezer to make 2 layers in the transport cooler. NEVER USE DRY ICE.
- 3. Digital Data Logger (pre-conditioned to frozen temperatures)
- **4.** Packing Materials (bubble wrap, packing foam, or Styrofoam™) to prevent contents from shifting during transport.
- 5. Temperature Log Record the time and temperature of the vaccine in the cooler before departure, each time the cooler is opened, and upon arrival to the destination. Sample Transport Log: https://www.cdc.gov/vaccines/covid-19/downloads/transport-temperature-log.pdf

## Pack vaccines and prepare for transport

#### Prepare for Transport

- Verify that the destination site has enough room for your vaccine and that someone will be there when the vaccine
  arrives.
- Verify that you have all the packing supplies on the above list.

#### **Pack Vaccines**



Spread a layer of frozen ice packs to cover the bottom of the cooler.



Stack layers of vaccine boxes directly on top of the frozen ice packs.



Place the digital data logger probe with the top layer of the vaccine.



Spread another layer of frozen ice packs to cover the vaccine.



Fill the cooler to the top with insulation material (bubble wrap).



Close the cooler lid and place the digital data logger's display on top of the lid with a temperature log. Transport the vaccine.

## **Transporting Refrigerated Vaccines**

## Packing Vaccines for Transport during Emergencies

## Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine. In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

## Gather the Supplies



## Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



## Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- · Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



#### Insulating material — You will need two of each layer

- Insulating cushioning material Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- Corrugated cardboard Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

## Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.



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

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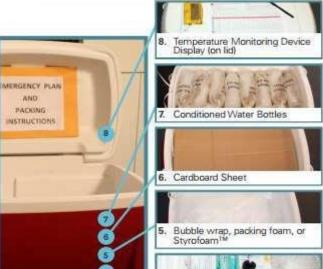
Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

## Packing Vaccines for Transport during Emergencies

## Pack for Transport

## Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



Close lid - Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles - Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material - Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material - Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines, Diluents, and Temperature Monitoring Device Probe

1. Conditioned Water Bottles

Vaccines - Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device - When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines - Stack boxes of vaccines and diluents on top of insulating material.

Insulating material - Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Bubble wrap, packing foam, or Styrofoam<sup>11</sup>

Insulating material - Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Cardboard Sheet

Conditioned frozen water bottles - Line bottom of the cooler with a single layer of conditioned water bottles.

## Arrive at Destination

Before opening cooler - Record date, time, temperature, and your initials on vaccine temperature log. Storage - Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting - If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

## NOTE:

This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

Updated 07/01/2022

## JYNNEOS Storage and Handling Guidance

## **Key Points**

- JYNNEOS is shipped at -20°C and can be used through the labeled expiration date when stored between -15°C and -25°C
- The NDC printed on the carton will differ than the NDC printed on the vial
- Expiration dates are printed on the carton, but not the vial
- Expiration dates, along with the corresponding lot and NDC numbers can be found at: <a href="https://aspr.hhs.gov/SNS/Pages/Mpox.aspx">https://aspr.hhs.gov/SNS/Pages/Mpox.aspx</a>
- When stored at refrigerated temperatures (2°C to 8°C), unopened vials can be used for up to 8 weeks (this differs from the package insert)
- Store the vaccine in the original package to protect from light
- Do not re-freeze a vial once it has been thawed

## **Temperatures During Transport**

- ➤ If temperatures **reach above -15°C** during transport (but not warmer than 8°C), place unopened vaccine in a refrigerated unit to be used for up to 8 weeks
- ➤ If temperatures are **maintained between -15°C and -25°C**, place unopened vials in a frozen storage unit to be used up to the printed expiration date
- ▶ If temperatures reach above 8°C, mark the carton "DO NOT USE", place the unopened vaccine in a refrigerated unit and contact the vaccine manufacturer, Bavarian Nordic Medical Services at 844-422-8274, for a viability assessment. DO NOT USE vaccine that has been exposed to out-of-range temperatures. Document actions taken. Sample Troubleshooting Log: <a href="https://www.immunize.org/catg.d/p3041.pdf">https://www.immunize.org/catg.d/p3041.pdf</a>

Updated 07/21/2022

**Coding Guidance for mpox** 

The following has been identified to use when providing specimen collection and vaccination for mpox. As more information is provided from the Centers for Disease Control (CDC) this guidance

will be updated.

May not be reimbursed by third party payors. Can be used in your electronic health record for

reporting purposes and billing once payment methods have been established.

**Specimen collection:** 

ICD-10: B04- Mpox

A viral disease infecting primates and rodents. Its clinical presentation in humans is similar to smallpox including fever; headache; cough; and a painful rash. It is caused by Mpox virus and is usually transmitted to humans through bites or via contact with an animal's blood.

Interhuman transmission is relatively low (significantly less than smallpox).

**CPT: 87798** 

Infectious agent detection by nucleic acid (DNA or RNA) not otherwise specified

Vaccination with Orthopox approved vaccine;

ICD 10: Z23

Immunization encounter

CPT: 90749

Immunization Vaccine Toxoid

\*Note: If applicable, encounter for immunization safety counseling, enter CPT: Z71.85

LTAT

Mpox guidance 07/05/2022 JB

7/05/22

# Screening Checklist for Contraindications

patient name		
-		

# for Contraindications to Vaccines for Adults

date of birth	/	<b>'</b>	/
	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 additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
I. 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 vaccination?			
<b>4.</b> Do you have a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, 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 3 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?			
<b>9.</b> During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?			
10. For women: Are you pregnant or is there a chance you could become pregnant during the next month?			
II. Have you received any vaccinations in the past 4 weeks?			
form completed by form reviewed by	date_ date_		
Did you bring your immunization record card with you? yes □  It is important for you to have a personal record of your vaccinations. If you don't	no □ t have a pers	sonal r	ecord,

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.



Saint Paul, Minnesota  $\cdot$  651-647-9009  $\cdot$  www.immunize.org  $\cdot$  www.vaccineinformation.org

www.immunize.org/catg.d/p4065.pdf - Item #P4065 (10/20)

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

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references in **Notes** below.

note: For supporting documentation on the answers given below, go to the specific ACIP vaccine recommendation found at the following website: www.cdc.gov/vaccines/hcp/acip-recs/index.html

note: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

#### I. Are you sick today? [all vaccines]

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

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

An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information or vaccines supplied in vials or syringes containing latex, see www.cdc.gov/vaccines-pubs/pinkbook/downloads/appendices/B/latex-table.pdf; for an extensive list of vaccine components, see www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

People with egg allergy of any severity can receive any IIV, RIV, or LAIV that is otherwise appropriate for the patient's age and health status. With the exception of ccIIV and RIV (which do not contain egg antigen), people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema, respiratory distress), or who required epinephrine or another emergency medical intervention, the vaccine should be administered in a medical setting, such as a clinic, health department, or physician office; vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

Have you ever had a serious reaction after receiving a vaccination? [all vaccines]

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

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

A history of thrombocytopenia or thrombocytopenic purpura is a precaution to MMR vaccine. LAIV is not recommended for people with anatomic or functional asplenia, complement component deficiency, a cochlear implant, or CSF leak. Underlying health conditions of the heart, lung, kidney, or metabolic disease (e..g., diabetes) and asthma are considered precautions for the use of LAIV. Aspirin use is a precaution to VAR.

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

Live virus vaccines (e.g., LAIV, MMR, VAR) are usually contraindicated in immunocompromised people. However, there are exceptions. For example, MMR vaccine is recommended and VAR vaccine may be considered for adults with CD4+T-lymphocyte counts of greater than or equal to 200 cells/µL. Immuno-suppressed people should not receive LAIV.

6. Do you have a parent, brother, or sister with an immune system problem? [MMR, VAR] 7. In the past 3 months, have you taken medications that affect your immune system, such as cortisone, 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 (e.g., LAIV, MMR, VAR) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, see references in **Notes** above. Some immune mediator and immune modulator drugs (especially the anti-tumor necrosis factor agents adalimumab, infliximab, etanercept, golimumab, and certolizumab pegol) may be immunosuppressive. A comprehensive list of immunosuppressive immune modulators is available in CDC Health Information for International Travel (the "Yellow Book") available at wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers. The use of live virus vaccines should be avoided in persons taking these drugs. To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see references in **Notes** above.

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

Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanustoxoid vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (IIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccination should generally be avoided unless the benefits outweigh the risks (for those at higher risk for complications from influenza).

9. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? [MMR, LAIV, VAR]

Certain live virus vaccines (e.g., MMR, LAIV, VAR) may need to be deferred, depending on several variables. Consult General Best Practice Guidelines for Immunization (referenced in **Notes** above) for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.

10. For women: Are you pregnant or is there a chance you could become pregnant during the next month? [HPV, IPV, MenB, MMR, LAIV, VAR]

Live virus vaccines (e.g., MMR, VAR, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to avoid pregnancy for one month following receipt of the vaccine. On theoretical grounds, IPV and MenB should not be given during pregnancy; however, it may be given if there is a risk of exposure. IIV and Tdap are both recommended during pregnancy. HPV vaccine is not recommended during pregnancy.

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

People who were given either LAIV or an injectable live virus vaccine (e.g., MMR, VAR, yellow fever) should wait 28 days before receiving another vaccination of this type (30 days for yellow fever). Inactivated vaccines may be given at any spacing interval if they are not administered simultaneously.

vaccine abbreviations

MMR or VAR vaccines should not be administered to persons who have a family history of congenital or be redited vine minimum ficiency in first of the potential vaccine

recipient has been substantiated clinically or verified by a laboratory.

LAIV = Live attenuated influenza vaccine HPV = Human papillomavirus vaccine IIV = Inactivated influenza vaccine

ccIIV = Cell culture inactivated influenza vaccine IPV = Inactivated poliovirus vaccine

MMR = Measles, mumps, and rubella vaccine RIV = Recombinant influenza vaccine Td/Tdap = Tetanus, diphtheria, (acellular

pertussis) vaccine VAR = Varicella vaccine

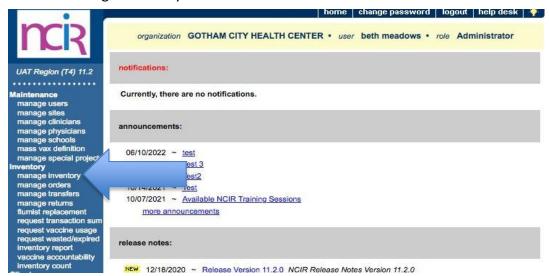
Immunization Action Coalition · Saint Paul, Minnesota · 651-647-9009 · www.immunize.org · www.vaccineinformation.org

www.immunize.org/catg.d/p4065.pdf · Item #P4065 - page 2 (10/20)

## **Entering JYNNEOS in NCIR**

Inventory must currently be manually added as private (as opposed to accepting a vaccine transfer). Please follow the steps below to ensure inventory is added correctly prior to vaccine administration.

1. Click on Manage Inventory



2. Click on Show Inventory



3. Click on Add Inventory

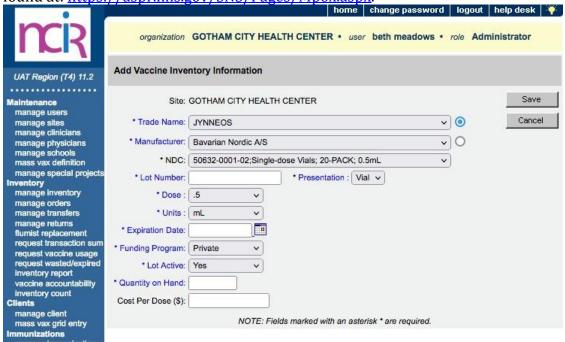


7/05/22

4. Locate and select the Trade Name JYNNEOS (the manufacturer will auto-populate). Select the NDC, add the correct lot number and expiration date from the vaccine box\*. Leave the funding program code as "private" and enter the number of doses received.

\*The NDC printed on the carton will differ than the NDC printed on the vial. Expiration dates are printed on the carton, but not the vial. Expiration dates, along with the corresponding lot and NDC numbers can be

found at: https://aspr.hhs.gov/SNS/Pages/Mpox.aspx.



5. Document the administered doses as usual.

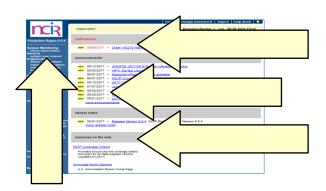
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## NORTH CAROLINA IMMUNIZATION REGISTRY (NCIR) QUICK REFERENCE GUIDE









#### **BOOKMARKING THE NCIR WEBSITE**

- Open a new browser window and type in <a href="https://ncir.dhhs.state.nc.us">https://ncir.dhhs.state.nc.us</a> in the address bar and then bookmark the site (it will bookmark the NCID website).
- Edit the bookmark by right-clicking on the bookmark itself, left-clicking on **Properties** and retyping the NCIR web address into the **URL** blank.

#### **USER ID AND PASSWORD**

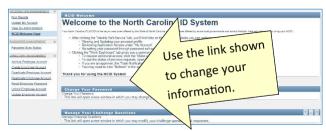
- UserID is not case sensitive, but password is.
- Do not share userID and passwords.
- For added security, close the browser window after logging out of NCIR.

If you forget your userID or password use the links provided.

Use this link if your username is locked.

## UPDATING YOUR USER PROFILE INFORMATION

Change your e-mail address or password by typing in the <a href="https://ncid.nc.gov">https://ncid.nc.gov</a> web address.



#### HOW TO OBTAIN A NCIR USER ID

1. Open a new browser window and type <a href="https://ncir.dhhs.state.nc.us">https://ncir.dhhs.state.nc.us</a> in the address bar.

3. Click the

**Business** 

button.

4. Complete the required personal information, including choosing your own *UserID* and *password*.

Password requirements are listed on the page and will remain **red** until your choice of password meets all requirements. The strength of your password will be assessed, and you will be required to type it twice to ensure correctness.

- 6. Click Continue.
- An e-mail from ncid.notifications@nc.gov will be sent to the provided e-mail address. Clicking the supplied link will verify your new UserID. You will be re-routed back to the NCID website, or you can copy the 6-digit code and paste it into the "Code" field.
- 8. Click Check Code.
- 9. Click Continue.

Ε

At this point, an NCIR Administrator in your organization must add your userID (instructions on page 7). You must share your UserID, but NOT your password. Once you have been added, return to https://ncir.dhhs.state.nc.us to log in.

- 9. The first time you log in, you will be required to select and answer *5 challenge questions* to verify your identity if your password is ever lost.
- Once completing your challenge questions, you will be forwarded to NCIR.

#### NCIR HOMEPAGE

**Inventory Notifications** 

M Program Announcements

#### **SEARCHING FOR A CLIENT**

Many clients are already in NCIR—and those who move into NC are easy to add!

 Using the navigation menu on the left, click Manage Client.

**NOTE:** In general, Gender is unnecessary when searching for a client and could limit results unnecessarily.

2. Click Find.

(continue to next page)

#### 4 Ways to Search—only choose one:

- Search by client (Last Name, First Name, and Date of Birth)
- Search by Chart Number (This must be assigned & entered by your organization)
- \* Search by Mother's Maiden Name (Mother's Maiden Name, Mother's First Name, Client's Date of Birth)
- Search by NCIR ID (allows for secure and confidential sharing of client information by NCIR Administrators)

If the client has a compound last name, try entering only one portion of the last name (i.e. Johnson-Smith—enter "Johnson").

2. Click the "Register!" link in bottom right corner of the blue box.

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Updates and Resources

U

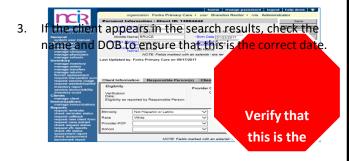
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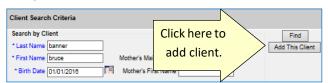
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4. If the property of the prop

	Last Name	First Name	Middle Name	Birth Date	Chart#	Mother's Maiden Last Il see the	Gender	City
5	No clients were	terjiget phy	nasapat	atound,	you wi	II see the	mes	sage
	belov	٧.						

Click the Add This Client button to create a new client in NCIR.



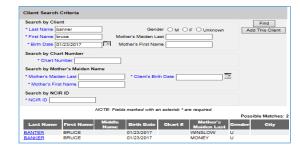
7. The information that you entered on the search screen will all be retained on the "enter new client" screen.

#### **DUPLICATE CLIENT RECORDS**

 If you locate a duplicate client record, contact the NC Vaccines Help Desk, at https:// ncgov.servicenowservices.com/csm\_vaccine.  Please note the NCIR ID number for both client records, and if possible, indicate which record is most accurate.

**DO NOT** e-mail client names or dates of birth! **DO USE** the Client ID (or NCIR ID) which appears in the gray bar at the top of each client screen.

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#### ADDING A NEW CLIENT

- Enter all of the required information (noted by a blue asterisk): Last Name, First Name, DOB, and County of Residence.
- 2. Mother's Maiden Name, Mother's First Name, and gender assist with deduplication of clients.
- Chart number is optional (organization specific). Please enter the correct Ethnicity/Race. Status defaults to "Active."
- Click SAVE.
- If a client already exists in NCIR with exact or similar information to the client that you are creating, you may see the screen shown below.

## If you are sure this is not the same client, click the "Create New Client" button.

- 6. If you think this may be the same client, click the last name of the existing client in blue.
- 7. If no match is found, click "Create New Client" button.
- 8. Click on Responsible Persons
  - Complete as much information as possible for each individual (minimum requirements: name, relationship, address and phone number)
  - Notices should be checked unless it is specified that that the responsible person does not want to receive immunization reminders.
  - Default for language is always "English" unless you select otherwise.
  - Be sure that a "Primary" person is designated.
  - To add more than one person, click on Next.
  - Scroll to the top of the screen and click Save.

#### **VIEWING HISTORY / RECOMMEND**

From the edit client screen, click **History / Recommend** to view the client record and recommendations.

The screen has 4 sections: Client Information, History, Current Age, and Vaccines Recommend by Tracking Schedule.

The history section lists vaccines the client has already re-ceived.

**Vaccine Group:** vaccine group for each immunization en-tered

Date Administered: day the client was given the vaccine

**Series:** sequence number within the immunization series **Trade Name:** trade name of the vaccine received

Dose: magnitude (amount administered—e.g. full, half, etc.)

**Owned?:** whether or not this shot was administered or entered by your organization (*blank* indicates "yes")

**Reaction:** any reactions the client had after receiving the vaccine

**Hist?:** whether the recorded immunization was historical or not

**Edit:** will allow you to edit the recorded immunization (see **EDITING A DOSE OF VACCINE** for specifics)

The **client's age** displays in a solid blue field between the immunization history and before the recommendations. **Note:** Age is calculated by DOB and today's date.

Vaccines Recommended by Selected Tracking Schedule are based on: Current ACIP Recommendations, Age of the client, History *entered* into NCIR, and Any client comments and/or contraindications.

Vaccines Recommended by Selected Tracking Schedule Add Se							
Select	Vaccine Group	Earliest Date	Recommended Date	Overdue Date	Latest Date		
	DTP/aP		Maximum Age Exc	eeded			
$\checkmark$	HepA	08/28/2005	08/28/2005	02/25/2006			
$\checkmark$	HepB	08/25/2004	08/25/2004	08/25/2005			
	Hb		Maximum Age Exc	eeded			
	HPV		Complete				
	Influenza		Contraindicat	ed			
$\checkmark$	Meningo	02/25/2020	02/26/2020	02/25/2022	02/24/2026		
abla	MMR	03/28/2005	02/25/2008	02/25/2010			
$\checkmark$	Polio	02/25/2008	02/25/2008	03/25/2011			
	Rotavirus		Complete				
	<u>Td</u>	02/26/2020	02/26/2025	04/26/2025			
	Tdap/Pertussis		Complete				
$\checkmark$	Varicella	05/28/2005	02/25/2008	02/25/2010			
Categor	Category B* Recommendation						
Select	Vaccine Group	Earliest Date	Recommended Date	Overdue Date	Latest Date		
$\checkmark$	<u>MeningB</u>	02/25/2020	02/25/2020	02/25/2022	02/24/2028		

**Select:** check boxes which can be used to pre-select any of the tracking schedule's immunizations (for entering doses given from inventory)

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History New Immunization Entry Historical Immunization Edit Client Reports Print Print Confidential

Current Age: 11 years, 2 months, 2 days

Vaccine Group: recommended vaccine group name

**Earliest Date:** dates which note the earliest date the selected client could receive the corresponding immunization

**Recommended Date:** the date that the selected client is recommended to have the corresponding immunization

**Overdue Date:** notes the date that the client is past due for corresponding immunization

**Latest Date:** the date after which the client should not receive the corresponding immunization

**Category B Recommendations** require individual clinical decision-making based on a clinician-patient discussion of risks and benefits.

#### **ENTERING HISTORICAL IMMUNIZATIONS**

Historical immunizations are immunizations that are not given from inventory (i.e. records from another office).

- 1. Search for the client using manage client or manage immunizations.
- 2. Click on **History / Recommend** button if using the manage client option.
- Compare the client's current immunization record with the doses listed in the NCIR and update as necessary. If doses are missing from the NCIR, click on Historical Immunization (located in the gray History bar below "Client Information").
- 4. Key in the provider organization next to the vaccine trade name details section. If all shots that you are entering were given at the same place, click in the blank box for provider organization it will automatically fill-in as needed. There is a drop-down menu at the bottom of the list for vaccines that you do not see.



5. Click on the calendar icon to the right for the Date Ad-

**ministered** and select date or key in the date MM/DD/YYYY.

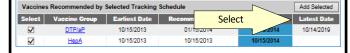
6. To enter the **Trade Name** and **Lot Number** click on the



**Trade Name Details** button (make sure provider organiza- tion and date are filled in first), then verify date, select

trade name and key in lot number, click SAVE.

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**NOTE**: for certain vaccines (e.g. combination vaccines, Hib, etc.) trade name is necessary to apply the correct vaccine schedule information.

#### ENTERING NEW IMMUNIZATIONS

New immunizations are immunizations given from your inventory.

- Search for the client using manage client.
- Click on the History / Recommend button. Review comments under "Client Information" at the top of the page and the "Current Age" in the blue bar about 2/3 of the way down the page.
- Review the Vaccine Recommended by Selected Track- ing Schedule below the age. The recommendations are based on the ACIP schedule, the child's age, client com- ments and contraindications, and vaccination history.
- The select column contains check boxes which can be used to pre-select any of the tracking schedule's immunizations when adding immunizations to the client.
- The check box will be disabled if the tracking schedule's recommended vaccination is contraindicated or if all required immunizations for that vaccine group have been received.
- The box is automatically selected for any vaccines that are recommended or overdue.
- To deselect any of the recommended vaccines, click the checkmark to remove it.
- Any vaccines that are not recommended or overdue, but still may be applied to the series (as noted by earli- est date) may be added by clicking in the box next to the vaccine name to add a checkmark.
- If you administer a vaccine that does not appear in the schedule, you will be able to add it on the next screen.

After making your vaccine choices, click Add Selected.
 Another entry screen will be displayed. The vaccines that you selected will have a checkmark in the New column.

NOTE: If you administered any vaccine that does not have a

check next to it in the **New** box, click on that box to add a checkmark.

**NOTE:** Only vaccine that you have available in inventory can be selected.

- 6. Under **Defaults for New Immunizations** verify or complete the following:
- **Organization Site:** for those organizations with multiple sites.
- Ordering Authority: the doctor who issues the order for vaccines to be administered
- Administered By: the clinician who administered the vaccine
- Date Administered: will default to today's date on the next screen if left blank
- 7. Click OK.
- 8. Choose an Eligibility.
- Choose the Trade Name/Lot Number, the Body Site, and enter/verify the Route for each vaccine selected.
   NOTE: As you select the trade name and lot number the most current date for each VIS will display on the bottom of the page.

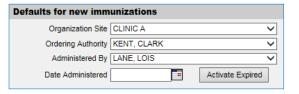
#### VIS Date

#### 10. Click **OK**.

## EDITING A DOSE OF VACCINE

To edit a dose of vaccine (including adding a vaccine reac-tion), click the **Edit** button next to the appropriate vaccine date on the History / Recommend screen.

Any person, at any organization, may delete or update a historical immunization. You may update any of the follow- ing fields for historical immunizations: trade name, lot num- ber, date provided, provider organization, or any reactions associated with vaccine administration







You may only delete or update a dose of vaccine from inventory, if it was administered by your organization. You may update any of the following fields for doses from your inventory: dosage from inventory, whether the dose was adequate, date provided, eligibility, ordering authority, administered by, body site, route of administration, VIS date (on the date of administration only), or any reactions associated with vaccine administration.



**NOTE:** If an incorrect lot number was entered for a new immunization the dose must first be deleted and then reentered with the correct lot number.

If the vaccine was given from another organization's inventory (as noted by **No** in the **Owned?** Column) click on the link to view which organization administered the shot as well as the contact information.



#### HOW TO ADD A CLIENT COMMENT

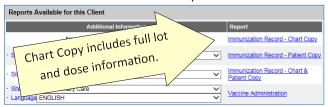
Client comments allow you to add HIPAA-safe information to an immunization record including contraindications, health conditions, refusals, and exemptions.

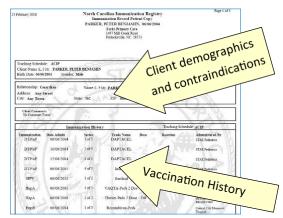
- On the Edit Client screen, select the Client Comment tab.
- Select the appropriate Client Comment from the dropdown menu.
- Enter an Applies To Date and, if appropriate, an End Date.
- 4. Click **Next** to add the Client Comment to the client's list



of comments.

The Client Comment will appear at the top of the immunization record and the recommendation page will reflect contraindicated or completed vaccine series.

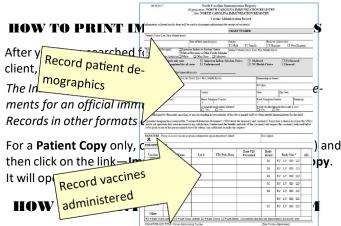




the client and/or doses administered in to the NCIR at a later time.

- From the left hand menu bar, click on Request New Client Form, under Reports.
- 2. Choose a site from the site drop-down menu (this is the site information that is printed at the top of the report) and click **Generate**.
- 3. The report should open in a new window as an Adobe .pdf file.

It is a good idea to keep several copies of these blank forms on hand in case of an outage.



The New Client Form should be used as a contingency plan in case of an NCIR outage or a loss of Internet access. The New Client Form contains all information necessary to enter

In the event that the NCIR is unavailable and you do not have any forms on hand, they are also available on the NC Immunization Branch website in both English and Spanish at <a href="http://immunize.nc.gov/providers/ncir.htm">http://immunize.nc.gov/providers/ncir.htm</a>.

### HOW TO ADD PRIVATE INVENTORY TO THE NCIR

You should use this procedure to add your private supply of vaccine. For state inventory see: ACCEPTING YOUR STATE SUPPLIED VACCINE ORDER.

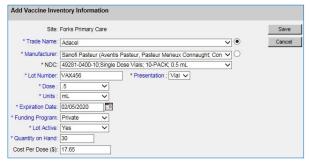
If the vaccine lot number is **NOT already in your inventory:** 

- 1. Click Manage Inventory.
- 2. Click **Show Inventory**.
- 3. Click Add Inventory.
- 4. Choose the **Trade Name**, the *Manufacturer* will automatically populate.
- 5. **HIGHLY RECOMMENDED!** Enter the **NDC** (noted on the <u>outside</u> of the vaccine box).
- 6. Enter the **Lot Number** (use the number on the vaccine box, NOT the vial).
- 7. Verify the **Dose** size from the drop-down menu.

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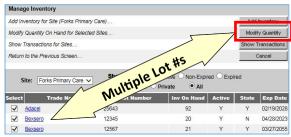


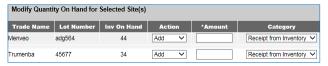
- Verify the Units (will always be mL unless you are administering a vaccine in capsule form). NOTE: Tubes are not considered capsules.
- Enter the Expiration Date. NOTE: Vaccines with only a month and year should be entered as the last day of the month of expiration.
- 10. Verify the **Funding Program** (should always be *Private*).
- 11. Lot Active drop-down must be set to Yes to be saved.

  ("Yes" will make the Lot number appear in the drop-down menu under the Lot Number/Trade Name when documenting administration of a dose of vaccine. If you do not want the lot number to appear in the drop-down menu, change the active indicator to "No" after saving the initial information.)
- 12. Enter the **Quantity on Hand** (the number of <u>doses</u>, not boxes or vials).
- 13. Cost Per Dose is optional.
- 14. Click Save.

*If the lot number ALREADY EXISTS in your inventory.* 

- 1. Click Manage Inventory.
- 2. Click Show Inventory.
- To get to the modify quantity on hand screen, place a checkmark in the select box and click Modify Quantity.





5. Click Save.

## HOW TO COMPLETE AN INVENTORY COUNT

All providers should complete a manual inventory count weekly to identify errors, identify shortages, and review expiration dates.

- Click Inventory Report, under Inventory.
- 2. Select **Funding Source** from the drop-down menu.
- 3. Click **Generate Report**. A report will open as an Adobe .pdf file.
- Print the document and use this to do your inventory count.



5. Document your physical count in the right-hand column and store for your convenience.

#### HOW TO SUBMIT AN

#### INVENTORY COUNT

Prior to placing an order, providers must submit a physical inventory count of state vaccine.

- Prior to submitting an inventory count, providers MUST REMOVE EXPIRED VACCINE from inventory. See page 6 for instructions.
- 2. Click Inventory Count, under Inventory.
- 3. Click Enter New Count.
- 4. Enter the amount of vaccine physically on hand in the "Physical Count" column.

#### **HOW TO PLACE A VACCINE ORDER**

#### **COVID-19 VACCINE, SEE SUPPLEMENT!**

Before placing an order, make sure that all doses administered have been keyed into NCIR, complete and submit and inventory count (see previous sections).

1. Click Manage Order.

#### NOTE: You will be unable to create an order if:

- Your organization has any unaccepted inbound transfers (including orders).
- An order has been placed within the past 14 days.
- An existing order is in "Pending" status.
- Your organization has expired vaccine (older than 31 days) in inventory.
- A required Inventory Count has not been submitted within the past 24 hours.
- Site-visit follow-up has not been completed by the required deadline.
- The Suggested order quantity is calculated from your doses administered (Tier Usage) and your inventory on hand. Review the Suggested Order Quantity to assist with placing your order.
- 4. Enter the amount, IN DOSES, of each vaccine you're requesting in the corresponding boxes. You may order vials, syringes, or a combination of the two based on availability. Make sure that you place the order for ALL

Vaccine	Vaccines from State						
Prev. Month Usage	Prev. Tier Usage	NCIR Inv. On Hand	Vaccine Tradename Packaging Description	Sugg. Order	PackSize/ Minimum Quantity	Doses Req.	
			DTP/aP Family				
0	0 0 DT-Peds						
1	DT / Single Dose Vials; 1-PACK; 0.5 mL			- 1			
1	2	17	DTaP	0			
	INFANRIX / Prefilled Syringes; 10-PACK; 0.5 mL				10		
	INFAN		INFANRIX / Single Dose Vials; 10-PACK; 0.5 mL	10			
0	0 0 21 DTaP/Polio/Hep B		0				
	PEDIARIX / Prefilled Syringes; 10-PACK; 0.5 mL		PEDIARIX / Prefilled Syringes; 10-PACK; 0.5 mL		10		
0	0	0	DTaP,5 pertussis antigens	0			
27	Suggested Order				5		
5	9	9	DTaP-IPV	2			
	KINRIX / Prefilled Syringes; 10-PACK; 0.5 mL				10		
			KINRIX / Single Dose Vials; 10-PACK; 0.5 mL		10		
			QUADRACEL / Single dose Vials; 10-PACK; 0.5mL		10		

4. Under the modify quantity on hand section, make sure the action is **Add**, enter the number of doses that you are adding, choose **Receipt from Inventory**.

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- 5. Click **Save & Submit**. You will be able to review the current Discrepancy Percentage in the lower right corner.
- 6. An order may be placed in the next 24 hours.

- 5. Scroll to the bottom of the page to verify your shipping information.
  - If all the shipping information is correct, click the button next to **No Changes to Site Information**.
  - If any information, including name, address, and delivery hours, need to be changed.

(continue to next page)

5



- Click Submit Order.
- 7. You will be redirected to the Manage Order page where your order shows up as "Pending" (An order in Pending status may be edited or update).

#### ACCEPTING YOUR STATE-SUPPLIED **VACCINE ORDER**

(OR AN INCOMING TRANSFER FROM ANOTHER ORGANZATION)

- 1. When you receive your vaccine, verify that the vaccine type, lot number, expiration date and quantity of the vaccines in the shipping container match what is listed on the packing list.
- Log in to the NCIR and click Manage Transfers.
- Under Inbound Transfer you should see your order from the Vaccine Distribution organization as shown below.



- Click on the date under Create Date.
- Verify that the order in the NCIR (amount, lot number,

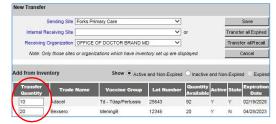
and trade name) matches your packing list. If the packing list does not match the NCIR, please call the Help Desk at 877-873-6247 before moving on to Step #6.

- If everything matches, click Accept Transfer.
- 7. Click **OK**. The vaccine should now be active in your inventory.

NOTE: An incoming transfer from another organization will display that organization's name in the "Sending Org: Site"

**Organization** . *Internal Receiving Sites* are other sites within your organization. Receiving Organizations are other NCIR Providers.

4. Enter the number of doses that you are transferring in the Transfer Quantity box next to the Trade Name.



- Click **Save**. You should see a message saying "Saved Successfully."
- You must generate and view either a Packing List or **Label** in order to complete the transfer.
- 7. Click Ship.
- 8. Enter a Ship Date.
- Click **Ship** again to complete the transfer.
- 10. You will see a message saying "Transfer Successfully Shipped," and it should show up in your outbound transfer list with a Ship Date.
- 11. The transfer is ready for the receiving organization to accept into their inventory.

#### **HOW TO REPORT AND RETURN** EXPIRED STATE-SUPPLIED VACCINE

- Click Manage Transfers.
- Click New Transfer.
- Click Transfer All Expired.

**COVID-19 VACCINE. SEE** SUPPLEMENT!

box.

#### TRANSFERRING VACCINE TO ANOTHER NCIR PROVIDER

**COVID-19 VACCINE, SEE SUPPLEMENT!** 

1. Click Manage Transfers.



5. Select the appropriate **Preventative Action** from the drop-down menu.

**NOTE:** If the physical count for a lot of vaccine is zero, enter a "0" in the physical count box and "None of These Apply To Me" and type "No vaccine on hand" in the text box.

- 6. Click Submit.
- 7. Verify that expired vaccine has been removed from your refrigeration unit.
- 8. Verify the correct e-mail address for mailing labels. If the e-mail address is incorrect, change the address immediately under "Manage Sites"

A pre-paid UPS shipping label will be sent to the e-mail address verified above and a "Return Packing List for VTrckS **Return ID**" will be generated for your return. Once the Packing List is complete, it will be visible under Notifications on the NCIR Home Page. This document MUST be printed and placed in the package with your expired vaccine.

#### HOW TO REMOVE PRIVATE **EXPIRED VACCINE**

- Click Manage Inventory.
- Click **Show Inventory**.
- Select the **Expired** and **Private** (as below).



Put a check in the select column beside each vaccine lot to be removed and click Modify Quantity.

Select	Trade Name	Lot Number	Inv On Hand	Active	State	Exp Date
<b>✓</b>	Afluria IIV4	123874	7	N	N	12/30/2016
	Fluzone Intradermal IIV4 Pres- Free	12548	0	N	N	08/12/2015

- 5. On the Modify Quantity screen choose "Remove—
- 4. Verify the **Physical Count.** If the number of doses being returned is incorrect, enter the number of doses being returned even if it does not match NCIR's estimate.

NOTE: The difference in physical and digital inventory is recorded as unaccounted vaccine.

Expired Private" from the Category drop-down menu.

- 6. All other fields will populate automatically.
- 7. Click Save.
- 8. Expired Inventory will be removed.

#### **HOW TO REPORT WASTED**

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#### **VACCINE**

#### **COVID-19 VACCINE, SEE SUPPLEMENT!**

Before wasting any vaccine due to out-of-range or inappropriate temperatures, providers MUST contact the NC Immunization Branch Storage & Handling line at 877-873-

6247, option 5. Branch Staff will determine the viability of

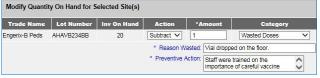
 Trade Name
 Lot Number
 Inv On Hand
 Action
 \*Amount
 Category

 Alluria IIV4
 123874
 7
 Subtract ✓
 7
 Remove - Expired Private ✓

vaccine. Damaged vials may be removed using the following instructions. In all other cases, viability **MUST** be determined by the NC Immunization Branch.

1. Click **Manage Inventory**. *(continue to next page)* 

- 2. Click Show Inventory.
- 3. Put a check in the select column beside each vaccine lot that you are removing.
- 4. Click Modify Quantity.
- 5. On the Modify Quantity screen, choose **Subtract** from the *ACTION* drop-down menu.
- Enter the number of doses that were wasted.
- Choose Wasted Doses from the Category drop-down menu.
- Type in the Reason Wasted (what caused the vaccine to become non-viable) and Preventative Action for future vaccine handling.



9. Click Save.

**NOTE:** Any open vials or syringes of vaccine should be discarded on site in your sharps container.

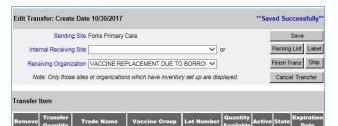
#### DOCUMENTING THE REPLACEMENT OF A BORROWED VACCINE DOSE

The VFC program allows for some borrowing between state and private vaccine inventories (see <a href="http://immunize.nc.gov/providers/ncip/pdf/borrowing">http://immunize.nc.gov/providers/ncip/pdf/borrowing</a> form.pdf).

After transferring a physical dose in your refrigerator, follow these steps to transfer the dose in NCIR.

**NOTE:** Before beginning this process, be sure that all inventory contains an NDC number. See **HOW TO ADD PRIVATE INVENTORY TO THE NCIR** on page 4.

- 1. Click Manage Transfers.
- 2. Click New Transfer.
- In the Receiving Organization drop-down menu, select "VACCINE REPLACEMENT DUE TO BORROWING."
- 4. In the **Transfer Quantity** column, enter the number of doses of each lot being replaced.



- Click Save. You should see a message saying "Saved Successfully."
- You must generate either a Packing List or Label in order to complete the transfer.
- 7. Click Ship.
- 8. Enter a Ship Date.
- Click Ship again to complete the transfer.
- 10. You will see a message saying "Transfer Successfully Shipped," and it should show up in your outbound transfer list with a *Date*.
- 11. The doses shipped to "VACCINE REPLACEMENT DUE TO BORROWING" are shipped back to the provider with the funding source reversed.



At that point, refer to the directions for **ACCEPTING YOUR STATE-SUPPLIED INVENTORY** (page 4) to accept the vaccine into your inventory.

All vaccine borrowing and replacement must be documented using a Borrowing and Replacement Form which must be faxed to the Immunization Branch (1-800-544-3058) and kept on site for review by Branch Staff upon request. See link at the top of this section.

#### HOW TO VIEW NCIR TRANSACTIONS

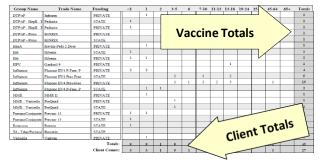
Viewing a list of your organization's transactions may help you review use of NCIR by staff and identify doses that were not properly recorded.

- 1. Click Manage Inventory.
- Click the Show Transactions button.
- Select the dates within which you would like to review transactions.
- 4. You may narrow your search using a number of factors, including *funding source*, *vaccine types*, *trade names*, *lot numbers*, etc.



#### HOW TO VIEW VACCINE USAGE

- Under the Inventory section, click Request Vaccine Usage.
- 2. Enter a date in the **From** and **To** text boxes.
- 3. Click Generate Report.
- A report will be generated, allowing you to review your offices use of each private and public vaccine and the number of clients that you have vaccinated.



#### HOW TO ADD NEW USERS TO THE NCIR

Before a user may be added to the NCIR, they must have completed NCID registration (instructions on Page 1).

- 1. Click Manage Users.
- 2. Click Add User.
- 3. Type the *userID* into the box provided.
- 4. Click Verify.
- 5. Confirm that the personal information retrieved is correct for the user that you are adding.
- Choose the Role for the user by clicking on the dropdown menu.
- 7. Click Save. You should see the message "User has been successfully saved."

**NOTE:** HIPAA-compliance requires that you *ALWAYS* inactivate users when they are no longer at your practice.

#### HOW TO ADD A CLINICIAN TO THE NCIR

- 1. Click Manage Clinicians.
- 2. Click Add Clinician.



CURRENT: 10/29/2021	5. Click <b>View</b> . Transactions will be displayed with a summary at the bottom of the page.	3. Choose the Role first:  Clinician: anyone who administers vaccines.  Ordering Authority: MD, DO, PA, or NP that signs orders for vaccines to be administered  (continue to next page) 7

- 4. Enter the Last and First Name.
- 5. Choose **Credentials** from the drop-down menu.
- Under the Complete Site Listing box click the name of the appropriate site and click Add to move it to the Selected Site box.
- 7. Address, phone, and e-mail are optional.
- 8. Click **Save**. You should see the message "Inserted clinician: Name."

**NOTE:** Please remember to inactivate clinicians when they are no longer at your practice.

#### HOW TO USE THE BENCHMARK REPORT

NCIR's Benchmark Report allows you to identify and contact patients who are not not up-to-date and completely protected from disease.

- 1. Under Reports, click Benchmark Report.
- "Clients Associated with" and "Clients who did NOT meet the benchmark" are pre-selected.
- 3. Select the **Age or Birth Date Range** that you would like to review (e.g. 24-35 months or 13 to 18 years).
- 4. **Standard Assessment** is pre-selected.
- 5. Enter the current date as the **Evaluation Date**.
- Select Benchmark by clicking on the age range that matches your selected age range (i.e. for 13-18 years, pick Adolescent Complete or for 24-36 months, pick @24 months).



- 7. Click **Generate**. You will be forwarded to the "Benchmark Report Status" page.
- Click Refresh.
- 9. Benchmark Report will be displayed showing any patients who are missing the requested vaccines.

#### **REVIEWING BENCHMARK RESULTS**



Any client who did not meet all of the Benchmarks, will appear on the report. Each vaccine column is split into two. The **first column** shows whether the client met the benchmark with a Y or a N. The **second column** shows how many doses the client has completed within the series. Zero doses show as blank. "C" means that the client received all doses after the benchmark age.

#### HOW TO USE THE REMINDER / RECALL REPORT

NCIR's Reminder/Recall Report allows you to generate letters for patients who are due or over due for vaccines. It can also be used to find eligible patients when your office has short-dated vaccine.

- 1. Under Reports, click Request Reminder.
- 2. Under "Indicate the Tracking Schedule ..." select **Use Tracking Schedule Associated with Each Client.**
- Under "Select the Vaccine Group(s) ..." select the vaccine groups you wish to review by adding vaccines from the left column to the right or removing unneeded vaccines.
- 4. Selecting a School & Primary Care Provider or Additional Demographic Criteria are generally not needed.
- 5. Under "Enter the Date Criteria" enter your chosen **Birth Date Range**. Other options are available here to adjust report results.
- 6. Click Generate.
- 7. At the Reminder Request Status page, click **Refresh** to check the status of the report.
- 8. Once the report is complete, click the blue link in the **Started** column. A summary of the report results will be displayed.
- 9. Proceed to the **Reminder Report Output Options**.

Output	Description		Additional Input
Client Query Listing	A list of clients eligible for reminder based on the report criteria (in .pdf format). Excludes omitted clients.	Report Name	
Reminder Letter	Standard Reminder Letter.	Report Name	
		Free Text	
		Phone #	
Reminder Card	Standard Reminder Card (4x5).	Report Name	
		Free Text	
		Phone #	
Mailing Labels	Avery Mailing Labels.	Report Name	
Client Extract	A .bd file of clients eligible for reminder based on the report criteria. Includes omitted clients.	Report Name	

#### ADDITIONAL RESOURCES

The NC Immunization Branch maintains a webpage with NCIR training resources for new and experienced staff at: http://immunize.nc.gov/providers/ncireducation.htm

NCIR Help Desk: 1-877-USE-NCIR (873-6247)

Each county has a **Regional Immunization Consultant** ready to assist with questions both simple and complex via phone, e-mail, and on-site training. You can find your Regional Immunization Consultant at the following website: <a href="http://immunize.nc.gov/contacts.htm">http://immunize.nc.gov/contacts.htm</a>

A full NCIR User Manual is available at any time by clicking **System User Manual** in the upper left-hand column.

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- 10. Selecting **Reminder Letter** will generate a pdf file of letters addressed to parents encouraging them to return for needed vaccinations. Additional messages can be added in the **Free Text** box.
- 11. For more detailed client information, including a summarized immunization record and responsible person information, click the **Client Query Listing**.







2

## NCIR QUICK REFERENCE GUIDE: DATA EXCHANGE SUPPLEMENT





NOTE: Electronic health record (EHR) products vary. The North Carolina Immunization Branch is able to provide instructions for the use of the North Carolina Immunization Registry (NCIR), however in some cases, corrections must be made through your EHR. For such assistance, providers may need to contact their vendors directly.

#### REVIEWING IMMUNIZATION TRANSACTIONS

Providers utilizing a data exchange between their EHR and NCIR should regularly review their NCIR transactions to ensure that immunizations are being transmitted correctly.

- 1. Click Manage Inventory.
- 2. Click the **Show Transactions** button.
- Select the date range within which you would like to review transactions.

4.	You	may
	nar-	row

5. Click **View**. Transactions will be displayed with a summary at the bottom of the page.

The transaction report will look very similar to those generated prior to use of a data exchange system, except that the "User Name" column will say "DATA EXCHANGE" because no NCIR user is logged in when the vaccine is recorded. Seeing "DATA EXCHANGE" is a sign that data is coming over correctly, but providers should closely review the information to ensure that it is correct and that no vaccines are missing.

## REVIEWING OWNED-NOT DEDUCTED (OND) DOSES

Owned Non-Deducted Doses—When NCIR receives vaccine details that do not match those in NCIR inventory the vaccine is noted on the patient record as having been given by your office (owned), but it does not deduct from inventory. These doses are designated as "Owned Non-

- Click dx imm transaction list.
- Select the Immunization Created Dates or Immunization Administered Dates to determine the timeframe for review.
- Select whether to review Owned Non-Deduct doses or Historical doses.

#### ERROR REASON EXPLANATIONS

**Lot Number Is Invalid:** The most common reason for EHR details not matching NCIR Inventory are incorrect lot number, incorrect manufacturer, or incorrect funding source being selected. For most EHR systems, this can be corrected in the EHR, but some cases may require the user to log into NCIR, delete the error and log the correct dose directly into NCIR.

Quantity on hand for vaccine lot not sufficient to support deduction: Inventory in NCIR was at zero before submission of the dose, most likely due to a vaccine lot incorrectly recorded on a patient record or wasted in error. Once the error is corrected and the dose is returned to inventory resubmit the dose for correct deduction.

**RXA Errors:** Most RXA errors are the result of some required information being left out of the transaction. Most must be evaluated and corrected by the provider's EHR vendor.

## REVIEWING PATIENT RECORDS IN NCIR

Data sent to a patient record can be reviewed in NCIR as needed.

- Look up client history using Manage Immunizations.
- 2. Click on the "Edit" button for the shot you wish to review (the icon looks like a pencil and paper).

NOTE: If the shot did not deduct from inventory "Owned Non-Deduct Immunization" will appear in red on the Edit Immunization Screen.

5. Clicking on the "Job ID" number will allow you to review

the data sent to NCIR via data exchange.

#### HOW TO ADD A CLINICIAN TO THE NCIR

It is critical that the names of your clinical staff in the NCIR Clinician List match the names of the same individuals in your EHR. If names are missing or are not a correct match, this field will remain blank in the NCIR vaccination record, in violation of North Carolina's immunization rules. This information must be checked every three months by providers utilizing the Data Exchange.

**NOTE:** Clinicians are not the same as users. A clinician may be entered without being a user.

1. Click Manage Clinicians.

Role:	O Clinician	Ordering Authority	Ordering Authority / Clinician	Save
Prefix:				Delete
* Last Name:				Cancel
First Name:				
Middle Name:				
Suffix:	*	Credentials:	~	
Complete site listir Forks Primary Ca		Add > Add All >>  Remove << Remove All	* Selected sites	

3. Choose the Role first:

Clinician: anyone who administers vaccines.

<u>Ordering Authority:</u> MD, DO, PA, or NP that signs orders for vaccines to be administered

- Enter the Last and First Name.
- 5. Choose **Credentials** from the drop-down menu.
- Under the Complete Site Listing box click the name of the appropriate site and click Add to move it to the Selected Site box.
- 7. Address, phone, and e-mail are optional.
- Click Save. You should see the message "Inserted clinician: Name."

**NOTE:** Please remember to inactivate clinicians when they are no longer at your practice.

Deducted" or OND. Such doses will cause inventory counts to be incorrect. NCIR allows providers to review OND doses at any time.

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- 3. Ensure that all information has populated correctly.
- 4. Click the "View Update History" button.









### MOVING COVID-19 VACCINE FROM CVMS

- When a provider opts to use NCIR for COVID-19 data entry, they will receive an e-mail with a "close of business" deadline for all CVMS entry.
- 2. All doses must be recorded for patients prior to that deadline and all inventory must be reconciled.
- 3. Following that deadline, all inventory in CVMS will be inactivated for that provider and transferred into that provider's active NCIR inventory.
- 4. Offices may resume use of COVID-19 vaccine, recording doses in NCIR at 8am the following morning.

#### **ORDERING COVID-19 VACCINE**

All COVID-19 vaccine is currently ordered outside of NCIR. Providers need to submit requests via the Allocation Request Form, available here: <a href="https://surveymax.dhhs.state.nc.us/TakeSurvey.aspx?">https://surveyID-98MI76m3#</a>

- Requests must be received by <u>Thursday at 10am</u> to be considered for shipment the following week.
- 2. NCDHHS will review all requests to ensure requests are in line with guidelines below.
- 3. Orders are confirmed on Friday.
- 4. Orders are delivered the following Tuesday or Wednesday.

**NOTE:** In most cases, denied requests will be due to insufficient administration history and/or forecasted booster dose demand at your site. Please only request direct allocation if you can administer the Minimum Order Quantity (MOQ) within 3 months of receipt.

If you believe your vaccine request was denied in error, please review the ordering guidelines below and resubmit with sufficient justification for how you will administer all doses within 3 months of receipt.

You can review our most current ordering guidance including minimum orders for the various brands of COVID-19 vaccine and allocation timelines here:

https://covid19.ncdhhs.gov/media/3323/open

#### TRANSFERRING COVID-19 DOSES TO AN OFFICE USING CVMS

**NOTE:** Transfers of COVID-19 vaccine between users using two different systems (CVMS and NCIR) is strongly discouraged. Offices who cannot use the minimum order quantity, and cannot find a user on the same system that can transfer doses to you should call the NC Vaccines Help Desk at 1-877-873-6247, option #1.

If there is no other solution, the NCIR provider sending vaccine must submit a Vaccine Transfer Form to

https://ncgov.servicenowservices.com/csm vaccine

or 1-800-544-3058 (fax) and receive approval prior to sending any vaccine to a non-NCIR provider:

https://immunize.nc.gov/providers/ncip/pdf/vaccine\_transfer\_form.pdf.

Guidance will then be provided via the Help Desk.

#### RECEIVING COVID-19 DOSES FROM AN OFFICE USING CVMS

**NOTE:** Transfers of COVID-19 vaccine between users using two different systems (CVMS and NCIR) is strongly discouraged. Offices who cannot use the minimum order quantity, and cannot find a user on the same system that can transfer doses to you should call the NC Vaccines Help Desk at 1-877-873-6247, option #1.

If there is no other solution, the CVMS provider sending vaccine must submit a Transfer Request within CVMS and receive approval before sending any COVID-19 doses.

Guidance will then be provided via the Help Desk.

## REPORTING WASTED, SPOILED, OR EXPIRED COVID-19 VACCINE

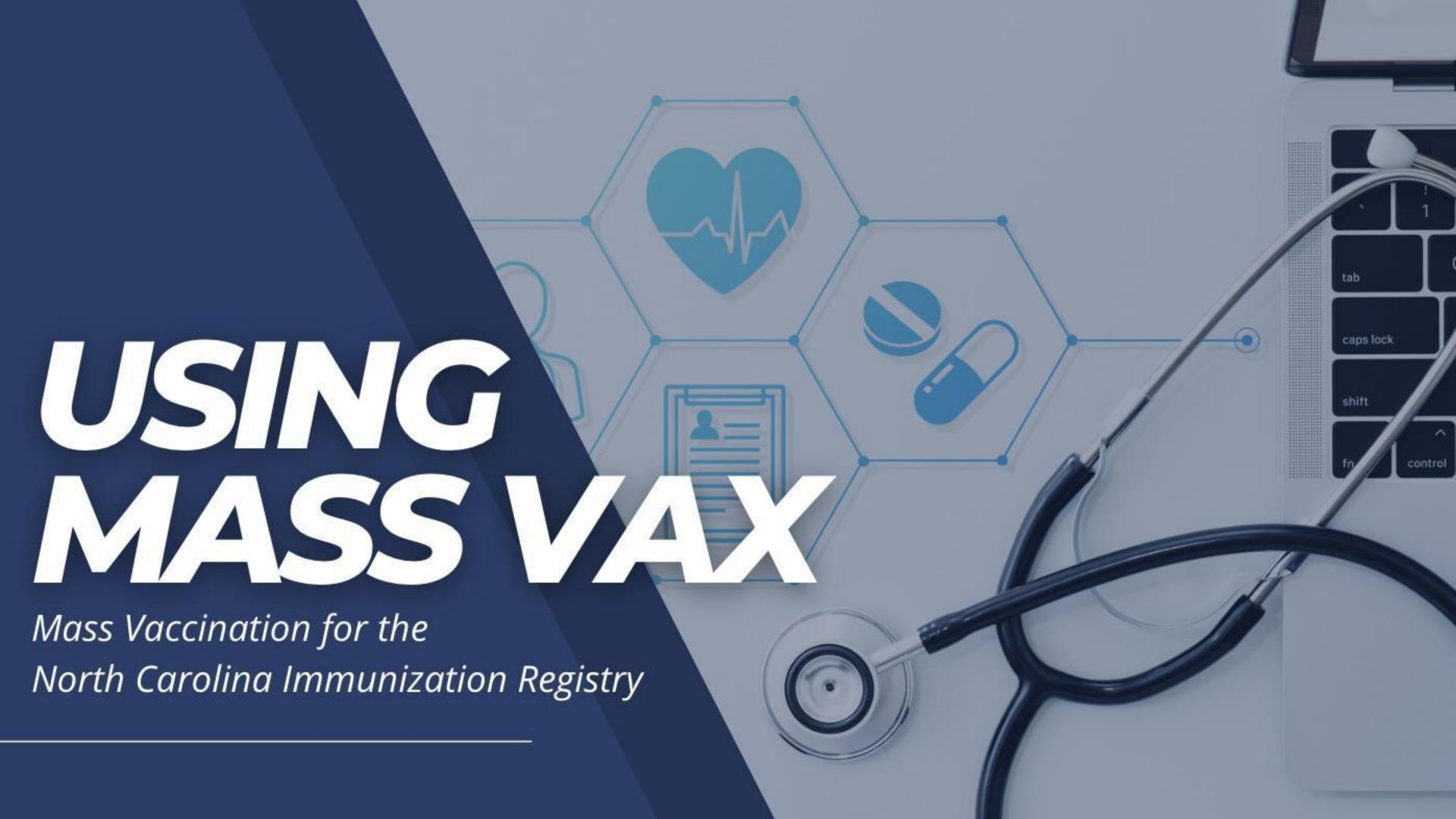
Instructions for wasting COVID-19 vaccines do not differ from other, routine vaccines. However, providers should dispose of all COVID-19 vaccine on site and **SHOULD NOT** attempt to send any COVID-19 vaccine back to McKesson Specialty, Pfizer, the State of North Carolina, or the Centers for Disease Control and Prevention.

The following reasons may be recorded in the provided text box when using "Wasted Doses" in the Modify Quantity function to waste COVID-19 vaccine.

- Broken Vial/Syringe
- Expired Vaccine
- Failure to store properly upon receipt
- Lost or unaccounted for vaccine
- Mechanical failure Natural disaster/Power outage
- Open vial but all doses not administered
- Recall
- Storage Unit too cold
- Storage Unit too warm
- Vaccine drawn into syringe but not administered
- Vaccine spoiled in transit (Freezer/Warm)
- Insufficient Quantity Pfizer (5 doses)
- Insufficient Quantity Janssen (4 doses)
- Insufficient Quantity Moderna (13 doses)

No other reasons should be recorded, and all non-COVID-19 vaccine must be subject to a viability study by Immunization Branch Storage and Handling Staff prior to destruction, wastage, and/or return.

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1

## **SETTING UP MASS VAX DEFINITIONS**

Maintenance

manage users
manage sites
manage clinicians
manage physicians
manage schedules
manage schools
mass vax definition

Administrators are responsible for adding the Mass Vax Definitions. See the Tips Section for more.

Start by clicking mass vax definition

**IMPORTANT NOTE:** Race and

ethnicity cannot be reviewed/updated using the Mass Vax entry form. Please ensure these fields are updated accordingly in NCIR for each vaccine recipient as this information is important for equity tracking purposes.

To add a new definition click **Add Definition**. This will allow you to enter the information you need for each definition

**Manage Mass Vaccination Definitions** 

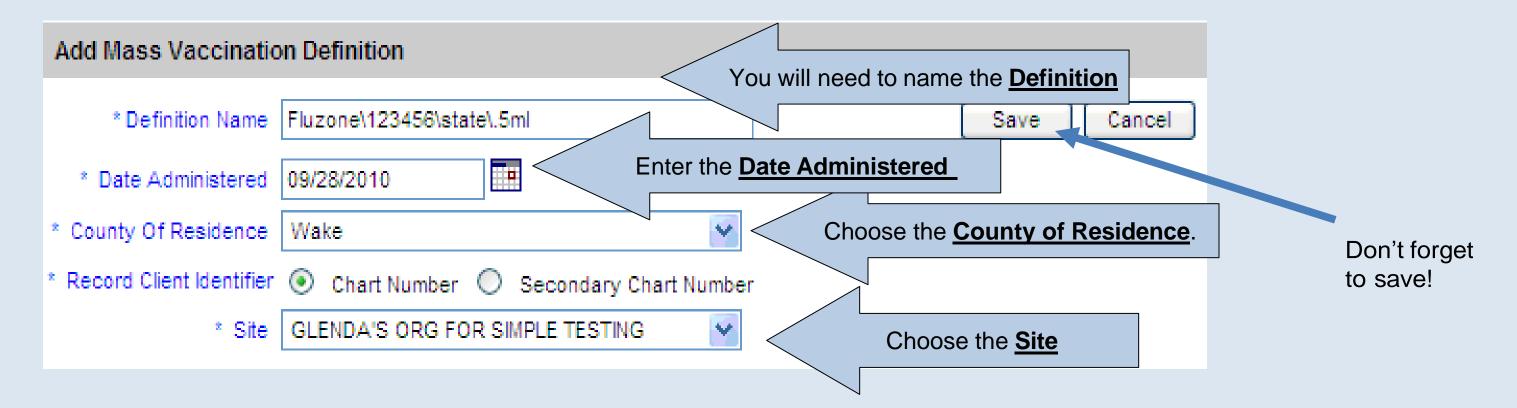
Add Definition

Select an existing mass vaccination definition to update information.

Site Name	Definition Name	Admin Date
GLENDA'S ORG FOR SIMPLE TESTING	Updating Mass Vax	09/28/2010



When adding definitions you can add as many as you need, but please remember when you run out of that lot number to delete the definition.

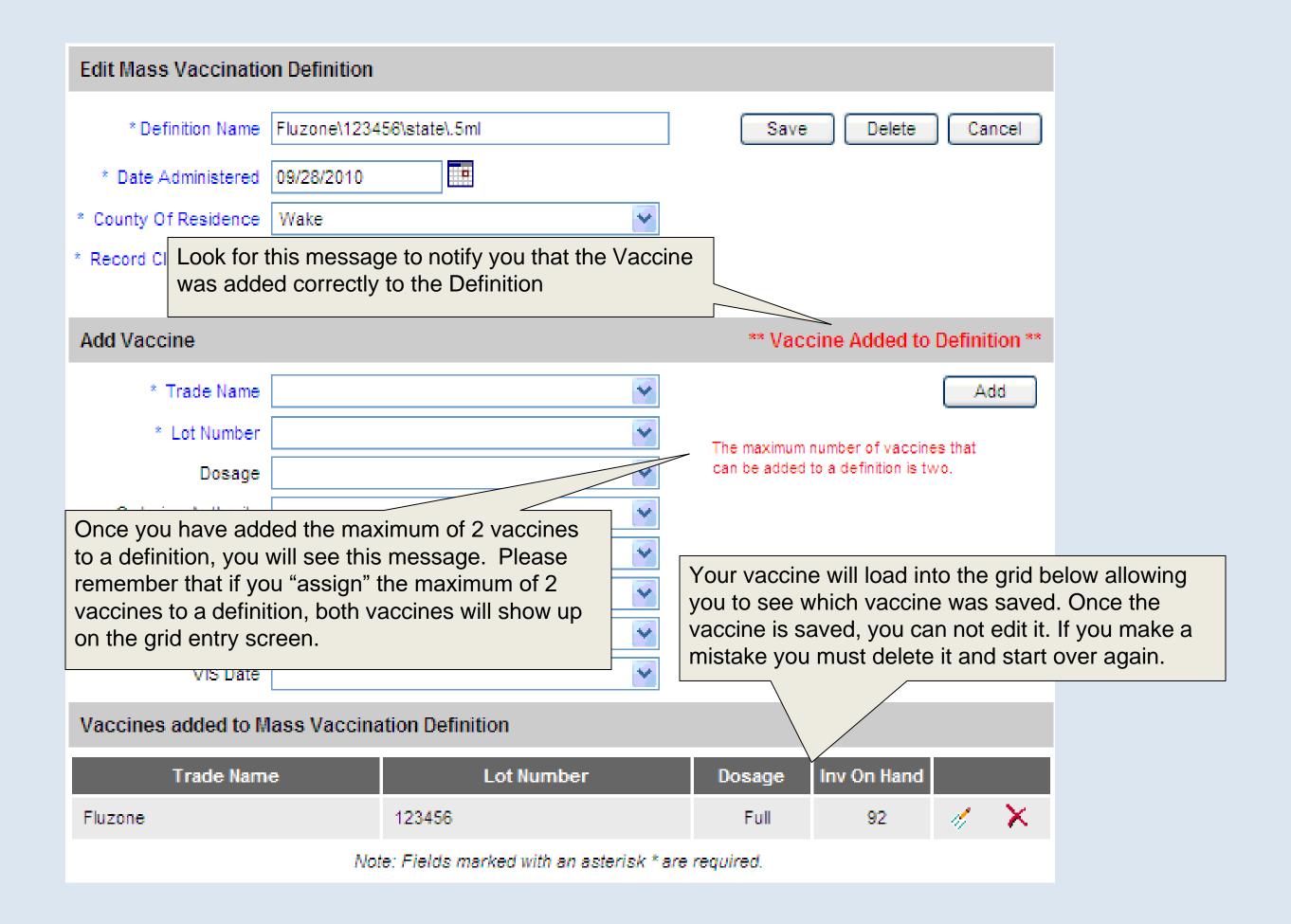


## Tips when naming a definition:

- 1. Remember that this definition will appear in the drop-down box on the entry screen.
- 2. You will be able to assign a maximum of 2 vaccines to each definition.
- 3. The example shown above indicates: name of vaccine, Lot Number, State (vs. private vaccine), dosage
- 4. You could also include who is going to administer the vaccine, body site of administration (right thigh, left arm...), the clinic "side" that it was administered (for example, if you give vaccine on the "blue side" of the office you can type that in the definition), etc.

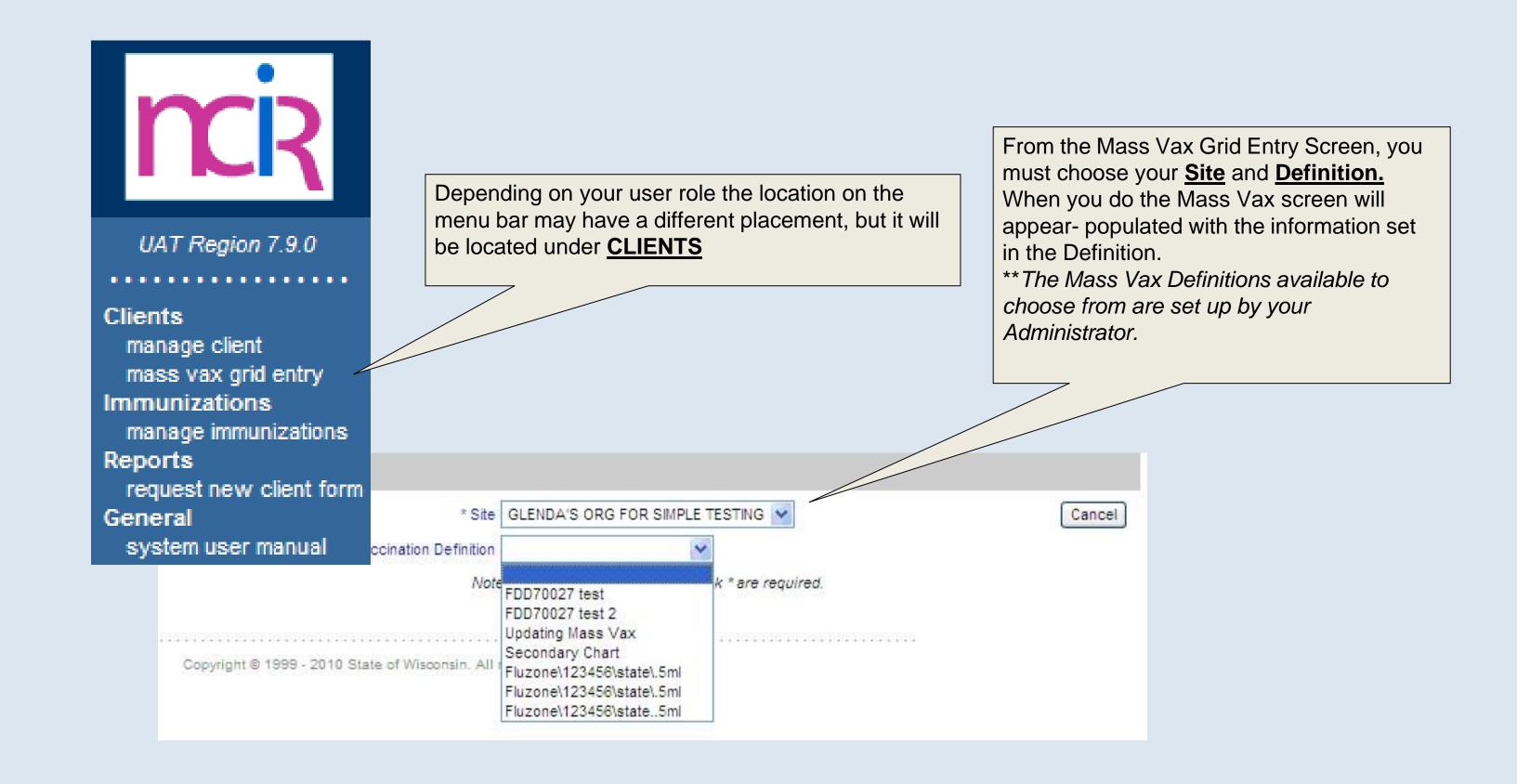
Look for this messa added correctly.			e to verify th	ne Definition was	3	** Mass V	accination Def	inition Added **	
* Definition Name		Fluzor		ve to complete		Sav	re Dele	te Cancel	
Note: Only Trade Name and Lot Number are REQUIRED, however, the more drop-downs added on this screen, the more information that will pre-populate in the Mass Vax Grid  Add Vaccine You can add 2 vaccines per Definition									
* Tr	rade Name	Fluzone		,	V			Add	
* L	ot Number	123456\state	A.5mL		~				
	Dosage	Full			<b>~</b>				
Ordering	Authority	Doctor, Ima			Y				
Admin	istered By	Ratchett, Nur	se		Y				
	Body Site	LEFT ARM			Y				
	Route	INTRAMUSCI	JLAR		Y				
	VIS Date	08/10/2010			<b>Y</b>	The n	nost recent	VIS Date will au	utomatically populate
Vaccines added to Mass Vaccination Definition									
Т	rade Nam	е		Lot Number		Dosage	Inv On Ha	ınd	
No Vaccines Added									



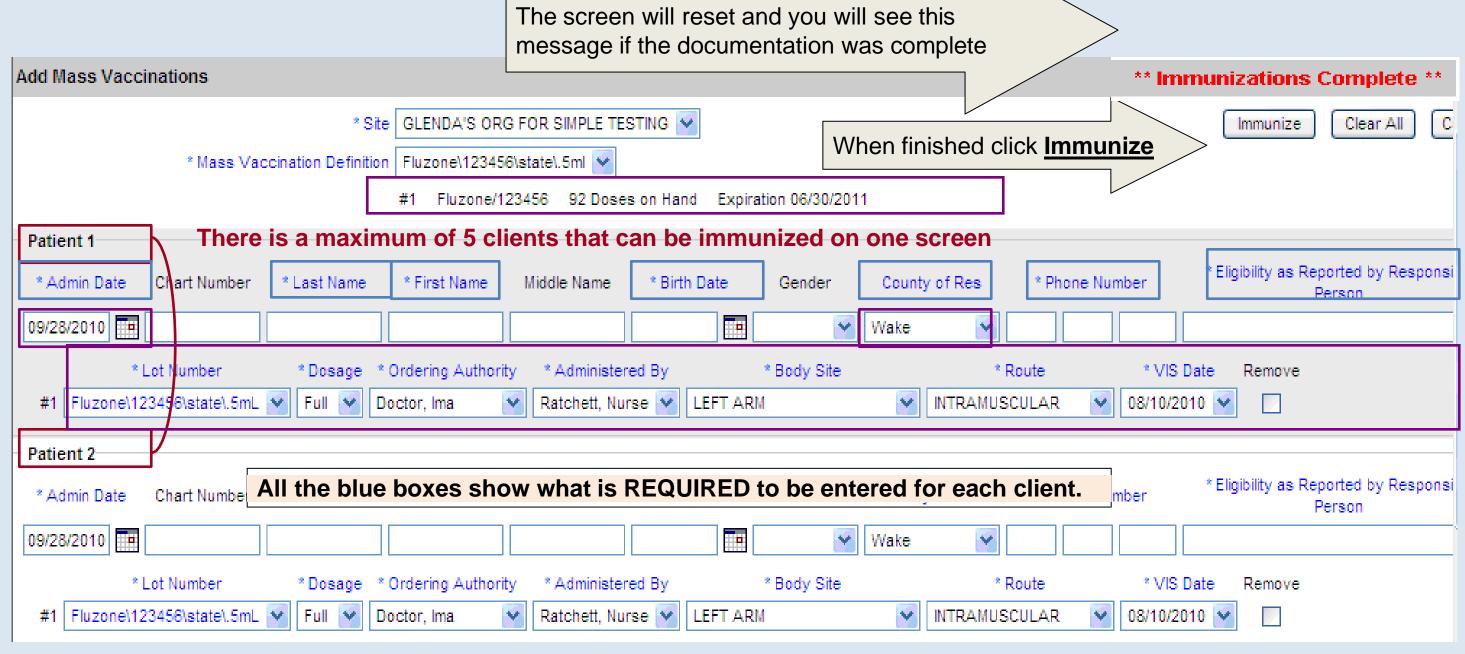


- > Once you have saved your definition, this is what will be used on the Mass Vax Grid Entry.
- > The Mass Vax Grid Entry will be available for Administrators, Inventory Control and Typical Users

## **DOCUMENTING MASS VACCINATIONS**







All the purple boxes denote information that was entered into the Definition previously. Every time you <u>Immunize</u> you will see the <u>Doses on Hand</u> (from inventory) at the top of the page adjust to the correct number on hand. Once you get below 10 doses it will appear in red.

## FREQUNTLY ASKED QUESTIONS



Why isn't there a default on the grid entry screen for a particular field (i.e. "body site")

It was not set up as part of the definition

Why can't I see the Mass Vax Grid?

The NCIR Administrator for your facility has not set up a definition to be displayed.

What happens if the client information entered is not an exact match for an existing client?

If the client information entered is not exact, it will create a new client with a responsible person equal to self and the corresponding phone number

How many vaccines can be included per definition?

2 vaccines per definiation



## The Mass Vax screens should only be used for mass vaccination and not for entering everyday vaccination information.

- · When setting up your Definitions, we recommend using a standardized way to name your definitions.
  - For Example: Name of Vaccine / State or Private / Lot Number
- If you run out of a vaccine then you should delete the definition in order to prevent users from selecting the wrong definition.
- Remember although you are using a Mass Vax definition to pre-populate fields on the mass vax grid entry screen, you will still be able to change the pre-selected drop downs (e.g. lot number, body site, administered by, etc.)
- The Dosage sizes available are half and full. The definition of what is half and what is full depends on how you have those doses set up in your inventory.
- When you have less than 10 doses on hand, the lot number definition will appear in red at the top of the mass vax grid entry screen.
- If you will be administering Seasonal Flu and an additional vaccine in the same clinic, you can set both of those vaccines to one definition. The system will document both vaccines at the same time.
  - For example: If you assign both the seasonal flu vaccine and pneumococcal vaccine to the same definition as you

can have 2 vaccines per definition - when you pull up the mass vax grid entry screen, it will display each client (although unnamed as of yet) as receiving both vaccines.



# If the NCIR stays inactive for an 30 minutes, it will time out and your unsaved information could be lost. When entering patient information, please save after 5 clients are entered, or after each grouping of clients, so that their information will not be lost.

- You may click the **Immunize** button prior to entering 5 clients
- If you have 2 vaccines set up in a definition, but if a patient does not receive both, instead of having to enter separately, you may click the remove button beside the vaccine not administered
- If your organization has several clinicians administering vaccines, it may be better to leave the **Administered By** dropdown blank when completing the definition (so that field is not pre-populated).
- If your organization does not have many clinicians administering vaccines, it may be better to set up a separate definition for each clinician by their name
- When choosing the County of Residence to set the definition, use the county where the clinic you are administering from is located.
- If you have more than 1 definition set up then you can switch between those definitions without having to leave the mass vax grid entry screen.