Frequently Asked Questions

Miranda Baumgartner, Vaccines for Children/QI Coordinator

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Be Legendary.

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A 7 year old comes to the clinic today who needs tetanus vaccine. What vaccine can they receive to be up-to-date?

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Be Legendary.

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What vaccine can they receive to be up-to-date?

- A) Administer a dose of DTaP since they are not old enough for a dose of Tdap and the series will be complete.
- B) Administer a dose of Tdap to complete the series.
- C) Wait until the child is 11 to administer a dose of Tdap.

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What vaccine can they receive to be up-to-date?

- A) Administer a dose of DTaP since they are not old enough for a dose of Tdap and the series will be complete.
- B) Administer a dose of Tdap to complete the series.
- C) Wait until the child is 11 to administer a dose of Tdap.

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Tdap

- Routinely recommended for adolescents at 11-12 years of age
  - Catch up is recommended for anyone not previously vaccinated
- There is no minimum interval…
  - Especially in situations where benefit outweighs risk such as a new baby, injury, exposures etc.
- If patient is receiving a tetanus catch up schedule, minimum intervals should be followed

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TDAP (CONT.)

- Children age 7–10 years who are not fully immunized against pertussis (i.e., did not complete a series of pertussis-containing vaccine before their seventh birthday) should receive a single dose of Tdap. If needed, they should complete their series with Td or Tdap. If a Tdap dose is administered at age 10 years or older, the Tdap dose may count as the adolescent Tdap dose.

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Tdap (cont.)

- Tdap catch up recommendations for children who were vaccinated at ages 7 – 9.
  - If a child receives DTaP or Tdap at ages 7 – 9, an additional dose of Tdap is needed at age 11.

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How long can a vial of IPV be used after the vial is opened/entered?

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Open IPV Expiration?

- A) Once the vial of IPV is open you have 28 days before the vial must be discarded.
- B) The open vial of IPV is good until the expiration date on the vial.
- C) The vial must be used within 2 months of opening.

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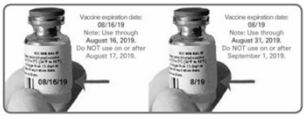
Open Multidose Vials

- Vaccines in multidose vials that do not require reconstitution can be used through the expiration date printed on the label as long as the vaccine is not contaminated unless indicated otherwise by the manufacturer.
  - IPV in a multidose vial can be used through the expiration date on the vial.



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Open Multidose Vials (CONT.)

- For some vaccines, the manufacturer specifies that once the multidose vial has been entered or the rubber stopper punctured, the vaccine must be used within a certain number of days.
- This is commonly referred to as the "beyond-use date" (BUD). Any vaccine not used within the BUD should be discarded. Specific information regarding the BUD can be found in the product information.

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Someone at your clinic administered a dose of varicella vaccine IM. Does this dose need to be repeated?

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Does this dose need to be repeated?

- A) Yes, MMR and varicella vaccine can only be administered SQ.
- B) No, but a VAERS report should be completed as that is an incorrect route.
- C) No, MMR and varicella can be administered either IM or SQ

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Does this dose need to be repeated?

- A) Yes, MMR and varicella vaccine can only be administered SQ.
- B) No, but a VAERS report should be completed as that is an incorrect route.
- C) No, MMR and varicella can be administered either IM or SQ.

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Vaccine Administration

- The U.S. Food and Drug Administration (FDA) has approved the addition of the intramuscular (IM) route of administration for Merck's MMRV family of vaccines: M-M-R®II, VARIVAX®, and ProQuad®. Priorix® which is GSK's MMR vaccine product is only licensed for IM administration.
- Links to the updated package inserts for these vaccines are shown below:
  - Package insert for MMR vaccine: Measles, Mumps and Rubella Virus Vaccine Live | FDA
  - Package insert for MMR-Varicella vaccine: PROQUAD | FDA
  - Package insert for Varicella vaccine: VARIVAX (refrigerated and frozen formulations) | FDA

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Vaccine Storage and Handling

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When you are recording your morning temperatures, you notice that your maximum is above the recommended temperature range. Do you need to be concerned?

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Do you need to be concerned?

- A. No, because you and the staff were not notified of an alarm.
- B. Yes, further investigation as to the duration of the high temperature should occur.
- C. No, because when you download the monthly report you can assess the temperature then.

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Do you need to be concerned?

- A. No, because you and the staff were not notified of an alarm.
- B. Yes, further investigation as to the duration of the high temperature should occur.
- C. No, because when you download the monthly report you can assess the temperature then.

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Temperature Monitoring and Excursions

- When reviewing daily minimum and maximum temperatures providers should be monitoring for those temperatures that are outside of the normal range of 2 to 8°C (36° to 46°F) or -50° to -15°C (-58° to +5°F).
- When these occur a provider should assess the length of time the unit was out-of-range and if an alarm occurred providers should take appropriate action for the temperature excursion.
- Providers should contact the manufacturers, as to determine the viability of the vaccine.
- Provider should also inform the Immunization Unit that an excursion has occurred. This can be done by email, phone, or online reporting form found here https://www.hhs.nd.gov/storage-and-handling.

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Temperature Excursion

- **IF YOU NOTICE A TEMPERATURE EXCURSION**:
  - Contact the primary or backup vaccine coordinator.
  - Document the current, minimum and maximum temperatures, duration of temperature excursion and the time when problem was discovered.
  - Label the vaccine "Do Not Use."
  - Store at the appropriate temperature. If your unit is not maintaining the appropriate temperature, transfer the vaccine to other storage units. Do not allow vaccines to remain in a unit while trying to fix it.
  - Contact the manufacturer for further guidance on use of the vaccine, Do not discard vaccine before contacting the manufacturer. If vaccine is wasted, report to the ND Immunization Unit.
  - Complete the online excursion tool to report the temperature excursion and any nonviable vaccine
  - Submit temperature logs to dohtemplogs@nd.gov
- https://www.hhs.nd.gov/storage-and-handling

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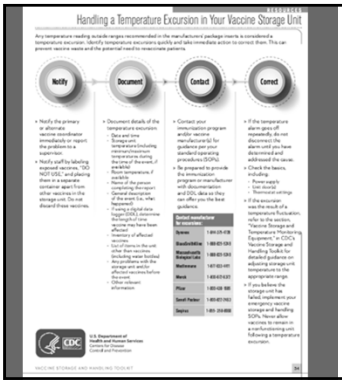

Handling a temperature excursion

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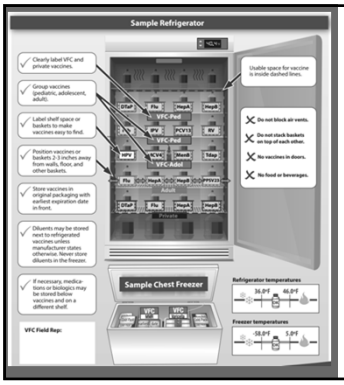

Vaccine Storage Best Practice

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Vaccine Deliveries

- Any issues with vaccine deliveries should be reported the day the shipment is received.
  - Vaccine issues not reported the same day will result in the vaccine not being replaced by McKesson and will result in vaccine loss.
- For viability concerns please reach out to McKesson using the phone number supplied with the vaccine shipment, if the shipment is received after McKesson's operational hours, please leave a voicemail.

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Vaccine Deliveries Cont.

- For any delivery issues, such as viability issues or missing product, please reach out to the Immunization Unit by phone or email **AFTER** McKesson has been contacted.
  - Phone: 701-328-2378 or 800-472-2180
  - Email: vaccine@nd.gov
  - Contacting the Immunization Unit does not replace the need to contact McKesson

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Merck Shipments

- Merck has implemented a new reporting process for CDC/VFC vaccine shipping or delivery issues for varicella and MMRV vaccines and diluent
- Providers need to report all shipping or delivery issues the day the shipment is received
- Providers no longer call Merck to report any issues, all issues need to be reported using the CDC/VFC Vaccine Inquiry Tool

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Merck Shipment Cont.

- The CDC/VFC Inquiry Tool can be accessed using https://cdcshipping.merck.com/
  - The reporting link can also be found https://www.hhs.nd.gov/storage-and-handling
- All direct ship orders from Merck are identifiable by the Purchase Order (PO) number. The PO number can be found on the vaccine packing slip or shipping label
- Once an issue is successfully reported, the reporting individual will receive an immediate confirmation email and then a follow-up communication from Merck within 5 business days

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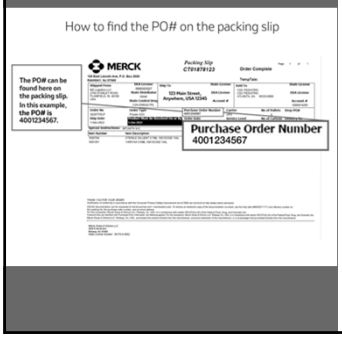

Merck Packing Slip

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Merck Shipping Label

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Your clinic has an open box of MMR that has expired. What should be done with this expired vaccine?

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What should be done with this vaccine?

- A) Dispose of the vaccine since the box is open and enter a wastage in the NDIIS.
- B) Enter a return in the NDIIS and send the vaccine back to McKesson.
- C) Nothing needs to be done since the vaccine is expired. It can just be discarded.

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What should be done with this vaccine?

- A) Dispose of the vaccine since the box is open and enter a wastage in the NDIIS.
- B) Enter a return in the NDIIS and send the vaccine back to McKesson.
- C) Nothing needs to be done since the vaccine is expired. It can just be discarded.

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Your clinic has one dose of Tdap and a vial of Pfizer COVID-19 vaccine that have expired. How should these doses be entered into NDIIS?

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How should these doses be entered into NDIIS?

- A) Both vaccines should be entered as a wastage in the NDIIS and the vaccine disposed of per your facility's policy.
- B) The Tdap should be entered as a return and sent back to McKesson and the Pfizer COVID-19 vaccine should be entered as a wastage and disposed of per your facility's policy.
- C) Both vaccines should be entered as a return and sent back to McKesson.
- D) Nothing needs to be done and the vaccine can be disposed of per your facility's policy.

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How should these doses be entered into NDIIS?

- A) Both vaccines should be entered as a wastage in the NDIIS and the vaccine disposed of per your facility's policy.
- B) The Tdap should be entered as a return and sent back to McKesson and the Pfizer COVID-19 vaccine should be entered as a wastage and disposed of per your facility's policy.
- C) Both vaccines should be entered as a return and sent back to McKesson.
- D) Nothing needs to be done and the vaccine can be disposed of per your facility's policy.

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Vaccine wastage vs return

- Wastage
  - Nonviable vaccine that is not able to be returned to McKesson. This includes broken vaccine vials or syringes, vaccine drawn into a syringe but not administered, lost or unaccounted for vaccine and partially used multi-dose vials
  - Vaccine being returned to McKesson must be entered as a vaccine return and should not be entered on this tab
- Return
  - Nonviable vaccine that needs to be returned to McKesson because it is expired, spoiled because of a temperature excursion or because of a vaccine recall. Multi-dose vials (MDV) can only be returned if no doses have been drawn from the vial

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Vaccine wastage vs return Continued

Return	Wastage
Any unopened MDV vaccine	Open IPV or MDV influenza
Partially used boxes of vaccine	Broken syringe/vial
Full unopened boxes of vaccine	Vaccine drawn up and not administered
	Pandemic vaccine (COVID19 and mpox)

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You have a 30 year old patient who has never had HPV vaccine and the forecaster is not forecasting doses. Is there an issue with the forecaster?

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Is there an issue with the forecaster?

- A) Since the HPV recommendation for those over age 27 is based on a shared clinical decision by the provider the NDIIS will not forecast the doses.
- B) The NDIIS forecaster has not been updated to include this age group but will in the future.
- C) Once a dose of HPV vaccine is administered and documented the NDIIS forecaster will then forecast the rest of the series.

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Is there an issue with the forecaster?

- A) Since the HPV recommendation for those over age 27 is based on a shared clinical decision by the provider the NDIIS will not forecast HPV vaccine after age 26.
- B) The NDIIS forecaster has not been updated to include this age group but will in the future.
- C) Once a dose of HPV vaccine is administered and documented the NDIIS forecaster will then forecast the rest of the series.

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HPV Vaccine for People Ages 27 - 45

- HPV vaccination for individuals aged 27 – 45 years old is based on shared clinical decision making.
- What this means is that HPV vaccine is not routinely recommended for everyone ages 27 – 45, but if a provider feels that a patient is at risk and should have it or if a patient requests the vaccine, then the provider can administer it.
  - This type of recommendation also ensures insurance coverage for HPV vaccine for people ages 27 – 45. Insurance companies should be covering HPV vaccine for this age group, but patients should always check with their insurance first.

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Your clinic has already placed their monthly vaccine order and you notice that you have vaccine that will expire within the next few weeks. Can you place another vaccine order now?

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Can you place another vaccine order now?

- A) Yes, providers can place a VFC vaccine order twice per month.
- B) Yes, but providers should contact the Immunization Unit before placing another VFC order.
- C) Yes, providers can place as many VFC vaccine orders in a month that they need to.
- D) Preferably providers are only able to place one VFC vaccine order per calendar month.
- E) Both B and D are correct

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Our clinic ordered Priorix® instead of M-M-R-II®. What can we do now?

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What can we do now?

- A) Enter the doses as a return in NDIIS and return the doses to McKesson.
- B) Use the doses and order the preferred vaccine the next time.
- C) Order the correct vaccine and keep the other doses on hand until they expire and can be sent back to McKesson.
- D) Find another provider that can use the doses and order the preferred vaccine once the doses have been transferred to that provider.
- E) Both B and D

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What can we do now?

- A) Enter the doses as a return in NDIIS and return the doses to McKesson.
- B) Use the doses and order the preferred vaccine the next time.
- C) Order the correct vaccine and keep the other doses on hand until they expire and can be sent back to McKesson.
- D) Find another provider that can use the doses and order the preferred vaccine once the doses have been transferred to that provider.
- E) Both B and D

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Vaccine Ordering

- VFC providers are able to place a vaccine order once per calendar month.
  - This does NOT apply to influenza or COVID-19 vaccine orders
- If providers are running out of vaccine and have already placed their monthly order please call or email (vaccine@nd.gov) the Immunization Unit prior to placing another vaccine order.
- Providers should allow up to 2 to 3 weeks for vaccine delivery.

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Vaccine ordering

- VFC-enrolled providers will order public vaccine using the Vaccine Ordering, Returns and Wastages module
- Providers must review their facility information and certify it is current before being able to place a vaccine order, return or wastage

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Vaccine Ordering

- All public vaccines available for a provider to order are listed in the ordering grid
- Providers must enter current inventory on hand when ordering vaccine
  - Inventory only needs to be completed for vaccines the provider is trying to order, it is not necessary for all vaccines on hand.
  - The ordering module will suggest an order minimum and maximum based on inventory on hand and doses administered
  - If ordering above the suggested maximum, a comment is required

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Vaccine Ordering

- The suggested order minimum is a one-month supply and the suggested order maximum is a three-month supply
- Submitting vaccine orders in NDIIS is a two-step process, providers must first save their vaccine order and then go back into the same order and click submit.

- The submit button will not appear until the vaccine order has been saved and reopened

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Vaccine Ordering

- Temperature logs for the provider's vaccine storage units must be submitted to the immunization program before vaccine orders will be processed
- Once a vaccine order is submitted, it is approved by the immunization unit and submitted to the Center's for Disease Control and Prevention's (CDC) VTrckS system
- After the vaccine is shipped, the provider order history grid will populate with the vaccine shipment tracking number

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Vaccine Ordering

- Once vaccine orders are submitted to CDC providers are unable to add to the vaccine order
- If providers have ordered a vaccine in error please contact the immunization unit at vaccines@nd.gov
  - Viable vaccine cannot be sent back to McKesson, if viable vaccine is returned to McKesson providers will need to replace the doses

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Vaccine Ordering

- If the incorrect vaccine was inadvertently ordered in NDIIS please reach out to the Immunization Unit prior to placing another vaccine order
- The vaccine that was ordered will either need to be transferred to a provider that can use the doses or ordered prior to placing another order for the preferred vaccine

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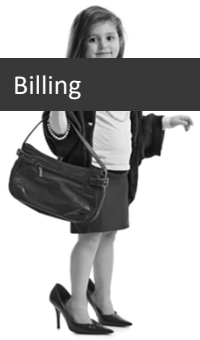
Billing



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A child was vaccinated at our office but insurance came back as denied because we are an out of network provider. Would this child be considered VFC eligible and we can therefore do a vaccine borrow?

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Would this child be considered VFC eligible and we can therefore do a vaccine borrow?

- A) Yes, the child is underinsured because their insurance denied the claim.
- B) No because the child's immunizations would have been covered at an in-network provider.
- C) They are not VFC eligible but a borrow can still be initiated to pay your stock back.

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Would this child be considered VFC eligible and we can therefore do a vaccine borrow?

- A) Yes, the child is underinsured because their insurance denied the claim.
- B) No because the child's immunizations would have been covered at an in-network provider.
- C) They are not VFC eligible but a borrow can still be initiated to pay your stock back.

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Common Eligibility Misconceptions

- Out of network
  - Not VFC eligible
- High deductible
  - Not VFC eligible
- Christian based cost sharing plan
  - VFC eligible – not considered insurance
  - Questionable insurance? – Insurance commissioner's office
- Out of state Medicaid
  - VFC Eligible but patient will have to pay out of pocket for VFC administration fee

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Billing

- Clinics must bill at the time of service or:
  - Bill within 90 days of service AND
  - Bill patient only once
  - Patient cannot be sent to collections for the administration fee (this is not new and has always been a part of the VFC program).
  - Unpaid administration fees must be waived by the clinic/health system.
  - Patients cannot be turned away or referred if they are unable to pay the administration fee.
- These billing requirements are only applicable for the vaccine administration fee, all other clinic/lab/hospital fees are outside of the scope of the VFC program.

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COVID and mpox vaccine

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You have a 75-year-old in clinic who has previously received 3 monovalent COVID-19 doses. How many doses do they need to be considered up-to-date?

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COVID-19 Vaccine Up-To-Date

A. One dose of Bivalent COVID-19 vaccine at least 8 weeks after any previous monovalent doses.
B. One dose of Bivalent COVID-19 vaccine at least 8 weeks after any previous monovalent doses followed by an additional bivalent dose 4 months after the first bivalent.
C. No additional doses.

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COVID-19 Vaccine Up-To-Date

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B. One dose of Bivalent COVID-19 vaccine at least 8 weeks after any previous monovalent doses followed by an additional bivalent dose 4 months after the first bivalent.
C. No additional doses.

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COVID-19 Vaccine Up-To-Date

- Everyone 6 years and older is considered up-to-date after they have received **1 bivalent dose** of Pfizer or Moderna COVID-19 vaccine.
- Recommendations for children aged 6 months – 5 years vary by brand the child has received.

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COVID-19 Vaccine Up-To-Date

- Adults 65+ years *may* receive another dose of bivalent COVID-19 vaccine at least **four** months after their previous bivalent dose.
- Immunocompromised people aged 6 years and older *may* receive another dose of bivalent COVID-19 vaccine at least **two** months after their previous bivalent dose.
- Neither of these recommendations for additional doses count towards the up-to-date status of an individual.

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Who needs additional bivalent doses?

Dr. Katelyn Jetelina (Your Local Epidemiologist) recommends basing the decision to get a "spring booster" on two criteria: Risk Factor and Time.

Risk Factor – Who is being hospitalized for and with COVID-19?

- People who haven't already received a dose of bivalent vaccine.
- Adults over 75 years
- Adults over the age of 65 years with a comorbidity
- Moderate or severely immunocompromised

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Who needs additional bivalent doses?

Time – When was your last infection or vaccine?

- 6+ months ago: Go get a spring booster today.
- 4-6 months: Schedule one, but you don't need to rush to the pharmacy.
- <4 months: Wait. But do not wait until past May/June, so that you enough runway time before the (anticipated) fall vaccine.

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I'm interested in providing Jynneos vaccine at community events. What route of administration do we use for that?

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Mpox vaccine administration

A. The vaccine should only be administered intradermally.
B. The vaccine should only be administered subcutaneously.
C. The vaccine can be administered both intradermally or subcutaneously depending on the age of the patient, preference of the patient and immunizer, and history of keloid scars.

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Mpox vaccine administration

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Mpox vaccine administration

- Earlier in the mpox response when vaccine was in short supply vaccine was administered intradermally outside of rare circumstances.
- Now that vaccine is more readily available providers are able to administer vaccine either intradermally or subcutaneously.
  - Patients with a history of keloid scars or who are under 18 should always receive vaccine subcutaneously.

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Mpox vaccine administration

- **CDC recommends vaccination against mpox if:**
  - You had known or suspected exposure to someone with mpox
  - You had a sex partner in the past 2 weeks who was diagnosed with mpox
  - You are a gay, bisexual, or other man who has sex with men or a transgender, nonbinary, or gender-diverse person who in the past 6 months has had any of the following:
    - A new diagnosis of one or more sexually transmitted diseases (e.g., chlamydia, gonorrhea, or syphilis)
    - More than one sex partner
  - You have had any of the following in the past 6 months:
    - Sex at a commercial sex venue (like a sex club or bathhouse)
    - Sex related to a large commercial event or in a geographic area (city or county for example) where mpox virus transmission is occurring
    - Sex in exchange for money or other items
  - You have a sex partner with any of the above risks
  - You anticipate experiencing any of the above scenarios
  - You have HIV or other causes of immune suppression and have had recent or anticipate future risk of mpox exposure from any of the above scenarios

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Mpox vaccine administration

- Jynneos vaccine ordering is available from NDHHS at Monkeypox Vaccine Providers | HHS (nd.gov).
- Please note that ordering is in vials, not doses. About 5 intradermal doses or 1 subcutaneous dose can be obtained from one vial.
- The ordering cadence for mpox vaccine mirrors the cadence for COVID-19 vaccine.

Orders Placed	Anticipated Warehouse Delivery
Thursday (after 12 pm CST) – Monday (until 12 pm CST)	Subsequent Friday

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What are the different types of visits completed by the VFC Program?

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What are the different types of visits completed by the VFC Program?

- A) IQIP
- B) Unannounced Storage and Handling
- C) VFC site visit
- D) A and C
- E) All of the above

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- D) A and C
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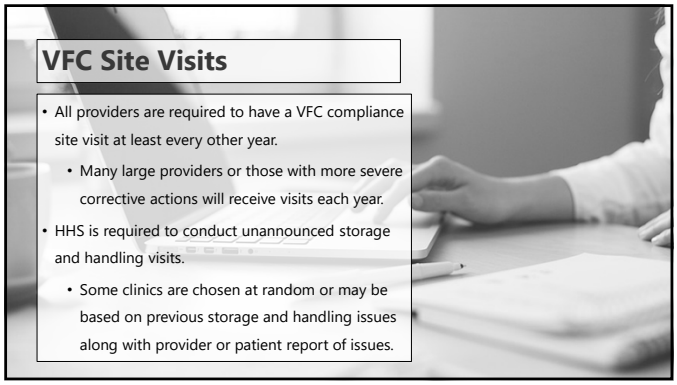

VFC Site Visits

- All providers are required to have a VFC compliance site visit at least every other year.
  - Many large providers or those with more severe corrective actions will receive visits each year.
- HHS is required to conduct unannounced storage and handling visits.
  - Some clinics are chosen at random or may be based on previous storage and handling issues along with provider or patient report of issues.

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VFC Site Visit Overview

- There are many areas that are covered during a VFC compliance site visit but some of the important and often incorrect areas include:
  - Borrow/return documentation
  - Doses owed to the state that have not yet been repaid
  - Correct storage and handling procedures
  - Review of temperature logs
  - Chart Audit
  - VIS publication dates
  - Current calibrated data loggers
  - Current calibrated back-up data loggers
  - Vaccine Management Template complete and up-to-date

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IQIP Site Visit

- IQIP is CDC's national, Vaccines for Children (VFC) provider-level immunization quality improvement (QI) program.
- IQIP promotes and supports implementation of provider-level strategies designed to help increase on-time vaccination of children and adolescents.
- Quality improvement (QI) programs, such as IQIP, analyze processes and use a systematic approach to improve performance. Like other QI programs, the IQIP program is based on these basic steps:
  - State the problem and desired result
  - Use data to understand the problem
  - Identify strategies for improvement
  - Implement strategies and refine as needed
  - Evaluate outcome

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Your clinic has an adult with Medicaid that is due for a Tdap. Should VFC vaccine be administered?

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Should VFC vaccine be administered?

- A) Yes, since the adult has Medicaid they would be VFC eligible.
- B) No, they should receive private vaccine and Medicaid should be billed. Adults with Medicaid coverage are not eligible for state-supplied vaccines.
- C) Eligibility depends on risk factors including pregnancy, infant at home etc.

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Should VFC vaccine be administered?

- A) Yes, since the adult has Medicaid they would be VFC eligible.
- B) No, they should receive private vaccine and Medicaid should be billed. Adults with Medicaid coverage are not eligible for state-supplied vaccines.
- C) Eligibility depends on risk factors including pregnancy, infant at home etc.

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317 Program Eligibility

- Un/underinsured adults:
  - Td/Tdap
  - MCV4
  - MMR
  - PPSV23
    - 19 – 64 year old with a high-risk condition
  - Pneumococcal Conjugate (PCV15 and PCV20)
    - 19 – 64 year old with a high-risk condition

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317 Program Eligibility, cont.

- Un/underinsured adults:
  - HPV
    - Medicaid adults should receive private vaccine (no longer an age gap in Medicaid coverage for adults)
    - 19 – 45 years of age (2022 change)
  - Influenza
    - Available for all providers to prebook and order

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317 Program Eligibility, cont.

- Un/underinsured adults:
  - Adult Hepatitis A and B
    - Not available to adults whose sole purpose of vaccination is for travel or employment.
    - Should be prioritized for those at risk of infection such as drug users and people experiencing homelessness.
      - For a complete list of risk factors please consult the vaccine coverage table at: www.hhs.nd.gov/immunizations/providers

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Mark your calendars!

Immunization Conference June 18-19th 2024 in Bismarck.

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Post-Test

- Post-test
  - Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_06v7o28Osda6ZmK
  - Successfully complete the five-question post-test to receive your certificate
  - Credit for this session will not expire until July 11, 2023.
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations

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