

2024 Required VFC Education
Abbi Berg, MPH VFC QI Manager

NORTH Dakota | Health & Human Services
Be Legendary.

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Overview

- Enrollment Process
- Eligibility and Vaccines Covered
- Billing
- Borrow/Return
- VFC Agreement
- Storage and Handling
- NDIIS Update

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Acronyms/Terminology

- VFC – Vaccines for Children
- VFA – Vaccines for Adults
- 317 – Vaccine budget that allows for special vaccination programs
- CDC – Centers for Disease Control and Prevention
- NDIIS – North Dakota Immunization Information System
- NDHHS – North Dakota Department of Health and Human Services

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COVID-19 and Commercialization

- Once COVID-19 vaccine was commercialized it became a part of the VFC/VFA program
- All VFC/VFA program requirements apply to COVID-19 vaccine, there is no longer a separate COVID-19 program

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Enrollment Process

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VFC Enrollment process

- Vaccine Management Template, Borrow/Return forms and Vaccine Coverage Tables are always available on our website
- 2024 Vaccine Management Policy is in the process of being printed and will be mailed to each VFC enrolled facility by the end of the month.
 - After initial mailing additional copies will be available for order.
- Email with enrollment survey and VFC provider profile will be sent out early next week

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Enrollment process

- Education
 - Surprise – you are part of the way through the education requirement!
 - Lunch and Learn posttest satisfies education requirement
 - Posttest must be completed and passed by AT LEAST two people from each VFC enrolled facility
- Online survey: www.hhs.nd.gov/immunizations/providers
 - Update contact information
 - Storage and handling information
 - Medical Director signature (should be sent electronically to vaccine@nd.gov)
- **Due on or before Friday, March 8th**

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VFA Enrollment

- VFA enrollment will be sent out at the same time.
- Will require an additional shorter enrollment survey and a separate Medical Director's signature agreeing to the VFA program requirements
- Required for all facilities who will use NDHHS supplied vaccines for adults
 - Including those who do any NDHHS supplied adult influenza vaccine

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VFC Program Eligibility

- Individuals who are 18 years and younger who are:
 - Uninsured
 - Underinsured – has private health insurance but it does not cover vaccines.
 - American Indian
 - Medicaid enrolled/eligible
- Through 19th birthday
- Do not need to prove tribal membership

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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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COVID-19 and Underinsured Adults

- Un/Underinsured adults:
 - COVID-19 vaccine
 - These adults must not be charged an admin fee. Options for admin fees include:
 - NDHHS Immunization Unit Offset Program \$40 administration fee
 - For more information, please email vaccine@nd.gov

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317 Program Eligibility, cont.

- All infants born in a North Dakota birthing facility receive state-supplied hepatitis B vaccine, regardless of insurance status.
- Underinsured patients seen at private healthcare facilities
 - Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs) and deputized local public health units use VFC vaccine for underinsured patients.

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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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Patient Eligibility Screening


- Every patient must be screened at every immunization encounter.
- Patient insurance changes constantly and it is important for several reasons to make sure the clinic has the most up-to-date insurance information.
 - All demographic fields should also be verified at every immunization encounter
- Proof of screening will be reviewed at every VFC compliance site visit.
 - Example: If the patient’s eligibility is " Medicaid" the clinic will need to show proof of Medicaid number or card and that the screening information was checked on the date of the immunization encounter.

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NDIIS Reporting Requirements

- ND State Century code requires all pediatric doses and/or NDHHS supplied adult doses be entered into the NDIIS within four weeks of administration.
 - The majority of doses come in through the interoperability between the NDIIS and your facility’s EMR but if you are manually entering doses please take note of this timeframe.

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Billing for VFC Vaccine

- Never bill for the cost of the vaccine
 - Vaccine provided to clinics at no charge
- Cannot bill more than \$20.99 per dose
- Cannot turn over to collections or turn patient away due to the inability to pay for the administration fee
- Must accept Medicaid reimbursement rate

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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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Borrow and Return

- Any time a vaccine funding source (VFC/State vs. Private) is given to someone that doesn't match their eligibility a borrow is created in the NDIIS. If a balance already exists for that vaccine a return is created in NDIIS.
 - Example: Private vaccine given to uninsured child.
 - Example: VFC vaccine given to an insured child.
- All borrow and returns should be documented on a borrow and return form AND in NDIIS.
 - Borrow/Return form available here: www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/immunization-resources



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Follow all ACIP Recommendations

- Providers are required to follow immunization schedules, dosage and contraindications established by the ACIP unless:
 - In the provider's medical judgement, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
 - The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
 - Example: A provider office that is not offering hepatitis A vaccine to any of their patients would be in violation of the VFC program requirements.



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VFC Record Retention

- All records that pertain to the VFC program must be kept on hand for at least three years. These records include, but are not limited to:
 - Paper temperature logs
 - Electronic data logger temperature logs
 - Vaccine Packing Slips
 - VFC screening and eligibility documentation
- Immunization information in a patient's medical chart should be held at least as long as the VFC requirement (3 years) but may need to be kept longer according to the clinic's medical record retention rule.

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Vaccine Information Statements

- Federal law to give a VIS with each and every vaccination, regardless of age of patient or participation in the VFC program.
- Anytime there is an update to a VIS, all clinic contacts will receive the update via the immunization unit listserv.
- When in doubt consult the CDC [website](#).
- Immunize.org also provides [translated copies of the VISs](#)
- Providers are not required to keep large printed inventories of VISs on hand.
 - A paper free option: providers can have a binder of VISs in their office for parents to review prior to vaccination.
 - Parents and patients must be given the option to take home printed copies of the VISs.
 - Print directly from CDC website or EMR each time VIS is needed.
 - Both options save on printing and reduce wastage when updates to VISs are made.

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Immunization Information Statement

- When administering Nirsevimab, which is an antibody not a vaccine an immunization information statement (IIS) should be given to the patient's family in place of a VIS
 - [RSV Preventive Antibody Immunization Information Statement](#)

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Vaccine Adverse Event Reporting System

- VAERS is a database that is used to monitor the safety of all vaccines licensed in the United States.
- An "adverse event" is any health problem or "side effect" that happens after a vaccination.
- VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed.
- Anyone can report to VAERS. This includes health departments, healthcare providers, patients and vaccine manufacturers.
- Report all VAERS to their website: <https://vaers.hhs.gov>.
- Icon in NDIIS



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Vaccine Adverse Event Reporting System

- Healthcare providers are **required by law** to report to VAERS:
 - Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccinations
 - An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Healthcare providers are strongly **encouraged** to report to VAERS:
 - Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
 - Vaccine administration errors
- This also means that the same adverse event could be reported more than once or events that most would not deem related to a vaccine (car accident following immunization) can be reported as such.



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Reporting to MedWatch

- If an adverse event occurs following administration of Nirsevimab (a protective RSV antibody) the event should be reported to MedWatch
- MedWatch

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Offering All Routine and Non-Routine Vaccines

- All enrolled VFC facilities are required to carry ALL routinely recommended vaccines.
 - Certain exceptions can apply but must be approved by the NDHHS Immunization Unit.
- Non-routinely recommended (PPSV23 and Men B) vaccines must be made available to all VFC eligible patients who either request them or are recommended to receive them based on a high-risk condition.
 - VFC is an entitlement program, so therefore anyone who is eligible is entitled to that vaccine.
 - Providers are encouraged to keep both PPSV23 and Men B on hand at all times, however it would be acceptable to order at the time the dose is needed.
- Td, Abrysvo and PPSV23 are available for order in 1-dose increments.

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Offering all Routine Vaccines

- All VFC enrolled facilities will be required to stock Nirsevimab and COVID-19 vaccine in the near future.
 - Private and VFC Nirsevimab inventories will need to be in place by August 1st as long as supply constraints are not present.
 - Private and VFC COVID-19 inventories will need to be in place by March 31st.
 - If your facility does not currently have these immunizations in stock please begin or continue the planning process to meet these deadlines.

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ND – Vaccine Brand Choices

- ND has a brand choice law, meaning the Immunization Unit is required to offer all vaccines that are offered by the Federal Contract.
- As new vaccines are made available, they are added to the NDIS to allow for facility ordering.
- The NDHHS Immunization Unit will never express a brand preference and facilities are able to choose which vaccine brands and presentations they carry.

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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.
- NDHHS 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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Vaccine Loss Policy

- There are certain thresholds in which providers will be required to pay back VFC or state-supplied vaccines on a dose for dose basis.
- Exact situations found in the vaccine loss policy which is part of each year's Vaccine Management Policy.
- Common reasons for repayment:
 - More than 20 doses of a particular vaccine expire in a 30-day time period
 - Storage and handling mishaps that are deemed to be the provider's fault
 - Not taking appropriate actions when a temperature excursion happens

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Vaccine Storage and Handling



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Importance of Storage and Handling

- Storage and handling can be a time consuming and costly endeavor!
- However, if you think that one box of HPV9 vaccine purchased privately is over \$2,000 and most providers store on average between \$30,000 – \$40,000 worth of vaccine in their refrigerators at any given time.
- VFC providers in North Dakota receive anywhere up to \$800,000 per facility worth of VFC vaccine in any given year!
- Without good storage and handling, facilities can lose thousands of dollars, patients can receive sub optimal vaccines and may not be protected against very serious, even fatal disease.

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Vaccine Storage and Handling

- All vaccines, except varicella, MMR®II, and MMRV must be stored in the refrigerator at **36°F - 46°F (2 - 8°C)**.
 - Optimal refrigerator temperatures are **39°F - 42°F (4 - 6°C)**.
- MMRV and varicella vaccine must be stored in the freezer at **-58°F to 5°F (-50°C to -15°C)**.
 - Optimal freezer temperatures are **3°F or colder (≤ -17°C)**
- MMR®II can be stored in the refrigerator or freezer
 - Priorix® MMR vaccine **MUST** be stored in the refrigerator only.



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Data Loggers

- All storage units that contain VFC or state-supplied vaccine must use a continuous recording data logger.
- Back-up data loggers are also required in the event that the data logger would malfunction or quit working.
 - Required even if facility has a built-in temperature monitoring system.
- Vaccine orders will not be approved without a data logger temperature chart.
 - Any provider that does not submit monthly data logger temperature charts will be contacted by the Immunization Program and will not be able to order until they have been submitted.

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Data Logger Requirements

- The following are additional recommended characteristics for these devices that are required of all data loggers:
 - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol)
 - Alarm for out-of-range temperatures
 - Current, minimum, and maximum temperature indicator
 - Low-battery indicator
 - Accuracy of +/-0.5° C (+/-1°F)
 - Memory storage for at least 4,000 readings
 - Recommended maximum logging interval (or reading rate) of every 30 minutes that can be programmed by the user

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Updated Temperature Excursion Guidance

- If providers are able to reset their data logger, alarms triggers should be set at 30 minutes outside of the acceptable temperature range, whether it be warm or cold.
 - Email vaccine@nd.gov for assistance in resetting data loggers or to find out if your data logger can be reset.
- For those who are not able to reset their data loggers the updated excursion time frame will need to be in place by January 1, 2026 which should give providers enough time to replace data loggers as they expire.
 - In the meantime, previous excursion time frame will still be honored. Most brands of data loggers should be able to be reset.

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Temperature Charts

- Paper temperature logs may still be required to be used at clinics.
 - If a clinic's data logger can track date, time and staff initials of temperature checks, paper logs may be discontinued.
- Paper logs should be kept at clinic and will be reviewed at VFC compliance site visits.
 - Must be saved for three years. Can be discarded after that.
- Electronic data logger temperature charts should be emailed monthly (or sooner with temperature excursions) to dohtemplogs@nd.gov.

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Min/Max Temperature Requirement


- All providers are required to document minimum/ maximum temperatures once daily.
 - Preferably at the start of the clinic day.
 - Providers can continue to check temperatures twice daily and record if that is their preference.
 - Clinic staff should visually check temperatures each time a vaccine storage unit is entered to ensure that correct temperatures are being maintained throughout the day.

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Storage and temperature monitoring equipment

- To fully ensure the safety of vaccines, the following equipment is recommended:
 - Stand-alone refrigerator(s) with enough space to accommodate your maximum inventory without crowding.
 - Stand-alone freezers with enough space to accommodate your maximum inventory without crowding.
- Dormitory units must NEVER be used to store state-supplied or VFC vaccine.
 - Regardless of reason or duration.

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Vaccine storage and handling


- Out-of-range temperature: what do I do?
 - Vaccine manufacturers should be contacted first to determine vaccine viability.
 - Do NOT assume that vaccine is not viable
 - Do NOT discard any vaccine until the NDDoH has been notified
 - Label the vaccine as "DO NOT USE"
- All actions must be recorded and submitted monthly with temperature logs.
- Even one out-of-range temperature, especially on the cold side, may result in the need for revaccination!

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Do not disconnect signs

- Do not disconnect and circuit breaker signs are required for all outlets and circuit breakers connected to storage units with VFC or state-supplied vaccines.
- May seem obvious to clinical staff but in a healthcare facility many other staff involved with storage units, i.e., weekend maintenance or cleaning staff.



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Vaccine transport

- Vaccine transport is discouraged whenever possible.
- If providers must transport vaccine, data loggers must be used at all times.
 - Transport temperature charts must be submitted to the immunization program anytime VFC vaccine is transported.
 - Temperatures should be checked and documented every *HOUR* (2023 change to align with CDC recommendations).
- VFC or state-supplied vaccine must be transported in qualified coolers or packouts.
- Never leave vaccine unattended in a car for long periods of time, and never store in a trunk.
- All vaccines transfers (between providers) must be approved by the immunization program.
- All non-COVID Vaccine should never be stored in a transport cooler for more than 8 hours.
- Frozen vaccine must be transported in a frozen transport cooler, cannot use dry ice or transport refrigerator.

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Vaccine ordering

- We ask that providers only order once per calendar month.
 - Please contact the Immunization Unit (vaccine@nd.gov) prior to placing additional orders.
- Vaccine orders are submitted to the NDHHS Immunization Unit via NDIIS by providers for review and approval.
 - Order minimum – 1 month
 - Order maximum – 3 months

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Distribution System

- Non-frozen vaccine is shipped directly to your clinic from centralized distributor (McKesson).
 - Vaccines are generally shipped on Monday, Tuesday and Wednesdays.
 - Flu will be shipped separately and is generally overnighted.
- Varicella and MMRV vaccines are shipped directly from Merck.
 - Varicella and MMRV can ship any day Monday through Friday.
- It is incredibly important to keep the NDIIS up-to-date with accurate address, contact and business hour information each time a vaccine order is placed.

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Distribution System (cont.)

- **DO NOT** ship viable vaccine to McKesson.
- **DO NOT** ship viable or non-viable vaccine to the NDDoH.
- **DO NOT** contact UPS for vaccine returns or your facility may be charged!

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Returns Vs. Wastages

- Vaccine Return: nonviable vaccine that needs to be returned to McKesson because it was expired, was 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. Partially used MDVs must be documented as wasted vaccine.
 - Example: Expired vaccine, delivered non-viable etc.
- Vaccine 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.
 - Example: Open multi-dose vials, broken vials etc.

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Vaccine Returns and Wastages

- All vaccine returns and wastages must be entered into NDIIS and returned to McKesson within six months of becoming nonviable.
- Once the return has been submitted in the NDIIS, the primary contact will receive an email 1-2 business days later letting them know that their packing slip is ready to be printed.
- The provider should go back into the submitted return and print the packing slip.
- By submitting the return in NDIIS your pre-paid shipping label has been requested from McKesson and should be received in the mail 1-3 weeks later or via email within a few business days.
- If you do not receive your packing slip or shipping label, please contact a member of the immunization program.
 - Allow 2-3 business days before contacting.

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COVID Returns

- COVID-19 vaccine should follow the same rules for returns/wastages as all other NDHHS supplied vaccines.
 - Almost all non-viable doses of COVID-19 vaccine will be entered as a vaccine return and sent back to McKesson.
 - Each month we are having to re-enter MANY vaccine wastages as a return.

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IQIP

- Immunization Quality Improvement for Providers
- In-person or virtual visit where coordinators will bring clinic specific vaccination reports to assist providers in identifying strong vaccination areas as well as weaknesses.
 - Work together to identify quality improvement strategies for immunization services
 - Access to useful reports, one on one technical assistance and immunization resources
- Email vaccine@nd.gov if you'd like to schedule an IQIP visit for your location

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Post-Test

- Required VFC Education Survey: https://ndhealth.co1.qualtrics.com/jfe/form/SV_1vHsqDvutN70AxU
- Successfully complete the five-question post-test to receive your certificate for nursing credit and to complete the VFC enrollment requirement
 - Certificates will be an email from noreply@qemaiserver.com. If you don't receive your certificate within a few minutes of passing the posttest, please check your junk mail and check with IT.
 - If you still cannot retrieve the certificate, please email Miranda at mlbaumgartner@nd.gov
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations/providers

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Questions? vaccine@nd.gov

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