

# IHS COVID-19 Vaccine Data Management Frequently Asked Questions

## General COVID-19 Vaccine Information can be found at:

- **CDC COVID-19 Vaccine Information**  
<https://www.cdc.gov/vaccines/covid-19/index.html>
- **CDC COVID-19 Vaccine FAQs for Healthcare Professionals**  
<https://www.cdc.gov/vaccines/covid-19/hcp/faq.html>
- **FDA COVID-19 Frequently Asked Questions**  
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions>

## General Frequently Asked Questions

1. How do I know what documentation I need to gather to report COVID-19 immunizations?
  - a. Approved vaccine documentation forms and checklists can be found at  
<https://www.ihs.gov/coronavirus/vaccine/ihs-tribal-health-program-and-urban-indian-organization-resources/>
2. Where can I find standardized vaccine questionnaires?
  - a. <https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>
3. Is there a vaccine standing order approved for IHS?
  - a. While IHS does not have an agency-approved standing order, the CDC has published standing orders for COVID-19 Vaccine that can be adopted by your facility utilizing your facility's standing order approval process. These documents can be found at:  
<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf>  
<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf>
4. Do vaccine recipients need to sign an informed consent to receive the COVID-19 vaccine?
  - a. No. Written or signed consent is not required by the FDA or CDC for COVID-19 vaccination. However, if a state law requires written consent for vaccinations, IHS-operated facilities should follow that law.
5. What is the requirement for providing a Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) Fact sheet to vaccine recipients?
  - a. Vaccines approved under an Emergency Use Authorization (EUA) will not have a Vaccine Information Statement (VIS) available.
  - b. In lieu of a VIS, vaccine recipients must receive a manufacturer-specific Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
  - c. The recipient or caregiver must have an opportunity to review the EUA Fact Sheet and the Healthcare Professional must respond to any questions or concerns the recipient or caregiver has prior to vaccine administration.
6. Where can I find COVID-19 vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients or Caregivers?
  - a. <https://www.cdc.gov/vaccines/covid-19/eua/index.html>

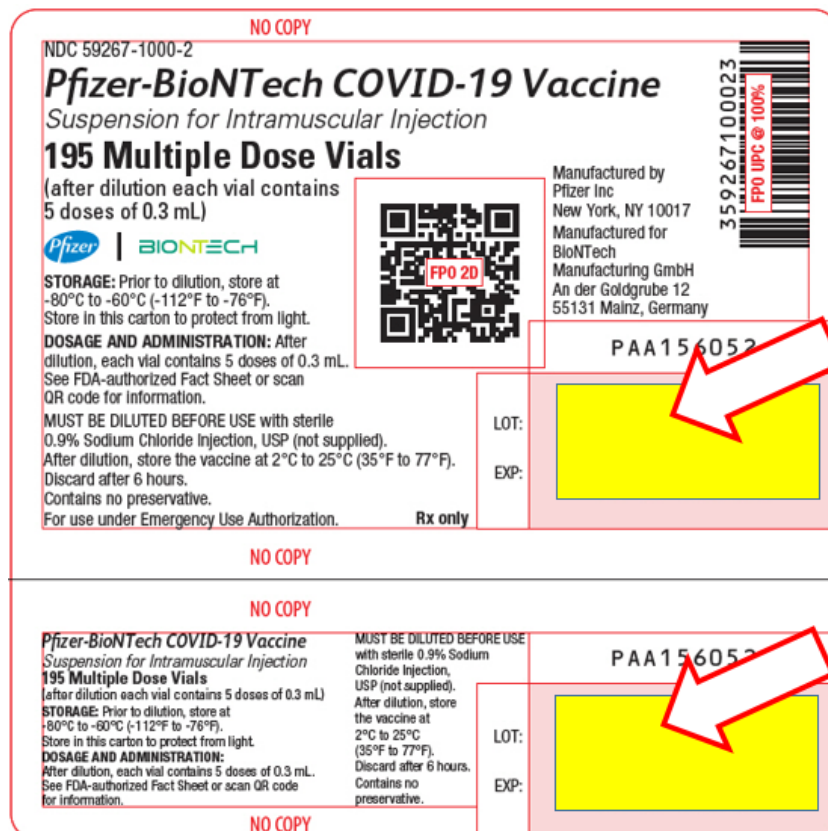
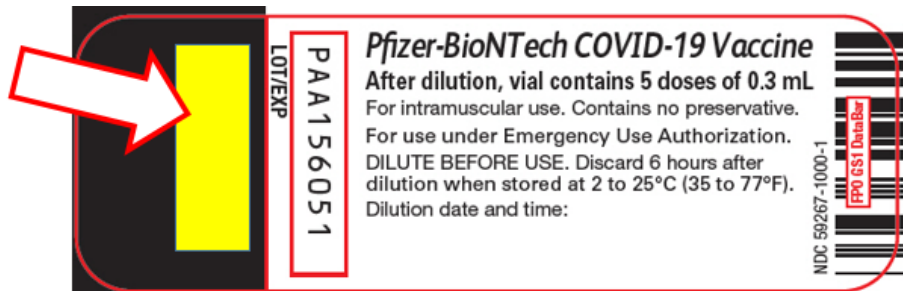
7. Is it appropriate for Tribal Health Programs to use the CDC's Vaccine Adverse Event Reporting System (VAERS) to report adverse vaccine events?
- a. Yes. VAERS is not specific to IHS, Tribal Health Programs, or Urban Indian Organizations. Anyone can report vaccine related adverse events in VAERS. VAERS is not specific to the COVID-19 vaccine but it a reporting tool for all vaccine related adverse events.
  - b. VAERS reporting is encouraged for anyone that learns about Adverse Events, but is mandatory for the following:
    - i. vaccine administration errors whether or not associated with any adverse event,
    - ii. serious adverse events\* (irrespective of attribution to vaccination)
      - \* *Serious adverse events are defined as:*
        - *Death;*
        - *A life-threatening adverse event;*
        - *Inpatient hospitalization or prolongation of existing hospitalization;*
        - *A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;*
        - *A congenital anomaly/birth defect; and*
        - *An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.*
    - iii. cases of Multi-symptom Inflammatory Response Syndrome (MIS) in adults or children, and
    - iv. cases of severe COVID-19 illness that result in hospitalization or death.
  - c. When entering an incident in VAERS, all facilities are encouraged to enter "IHS" into field #26 on the VAERS report.
  - d. More information can be found at:
    - [https://www.ihs.gov/sites/nptc/themes/responsive2017/display\\_objects/documents/pharmacovigilance/Reporting\\_Adverse\\_Vaccine\\_Events.pdf](https://www.ihs.gov/sites/nptc/themes/responsive2017/display_objects/documents/pharmacovigilance/Reporting_Adverse_Vaccine_Events.pdf)
    - [https://www.ihs.gov/sites/nptc/themes/responsive2017/display\\_objects/documents/pharmacovigilance/VAERSReportingPresentation.pdf](https://www.ihs.gov/sites/nptc/themes/responsive2017/display_objects/documents/pharmacovigilance/VAERSReportingPresentation.pdf)
    - <https://vaers.hhs.gov/reportevent.html>
8. I sometimes have one or two extra doses of vaccine in our vials. Can I use this vaccine? How do I account for this vaccine overage in Vaccine Administration Management System (VAMS)?
- a. Yes. The FDA has released guidance that overage in vaccine vials can be used for additional vaccine administrations. However, the vaccine should not be "pooled" from multiple vials to create full vaccine doses.
  - b. In VAMS, you may need to adjust your inventory by using the Manually Log Inventory and Manually Reduce Inventory options to "add" the overage doses to allow documentation of vaccine administration.
9. If I am an IHS-operated, a Tribal Health Program, or an Urban Indian Organization facility receiving COVID-19 vaccine through the IHS, do I need to report my COVID-19 immunization data directly to my State Immunization Information System (IIS)?
- a. No. The CDC agreements do not require reporting to State IIS.

## Vaccine Administration Management System Frequently Asked Questions

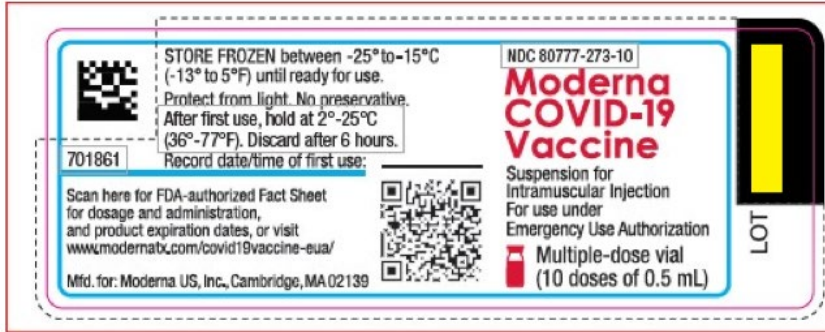
1. Who is my VAMS Point of Contact (POC)?
  - a. [https://www.ihs.gov/sites/coronavirus/themes/responsive2017/display\\_objects/documents/VAMS\\_Area\\_POCs.pdf](https://www.ihs.gov/sites/coronavirus/themes/responsive2017/display_objects/documents/VAMS_Area_POCs.pdf)
2. How do I get access to VAMS?
  - a. Each Area has designated one or more VAMS POCs. The Area VAMS POCs will add Clinics and Clinic POCs to VAMS. Clinic POCs can then add other users for their facility. VAMS is an online portal that is accessed through a web browser.
3. Who documents vaccinations in VAMS?
  - a. The healthcare professional, who administers the vaccine to the recipient, must be the individual who documents the vaccination in VAMS.
4. Does VAMS share vaccine information with my state IIS?
  - a. Not at this time.
5. Does the VAMS Inventory Manager communicate with RPMS?
  - a. No. It is recommended that facilities utilize an outside mechanism to track COVID-19 vaccine inventory and waste. Please contact your Area Vaccine Point of Contact (POC) or your VAMS POC for inventory tracking specifications.
6. What if recipients refuse to allow their immunizations to be documented in VAMS?
  - a. Reporting vaccinations to the CDC is a requirement for vaccine administration.
7. When the vaccine is administered is there a time limit to log the vaccine administration into VAMS?
  - a. It is recommended that you attempt to document the vaccination in VAMS the same day the vaccine is administered but no later than 24 hours after administration. VAMS does allow you to adjust the vaccine administration date so you can accurately report the date that the vaccine was administered.
8. If we have several clinic locations within our service unit, will each one need to be set up as a separate clinic in VAMS?
  - a. If you are administering vaccine at each facility, it is recommended that each clinic be added to VAMS. Consult your Area VAMS POC for further guidance.
9. When I was entering my inventory into VAMS, I accidentally input the number of doses instead of the number of vials. Now VAMS indicates I have 5 (or 10) times the number of doses that I actually have on hand. How do I fix this?
  - a. Notify your Area VAMS POC. You will need to use the “Manually reduce inventory” option in the Inventory Management tab in your clinic portal in VAMS. Your reason for inventory reduction will be “error in logging inventory”.
10. I made an error when logging a vaccine in VAMS (vaccine administration logged under wrong patient, duplicate vaccine entry, wrong manufacturer documented, recipient added to VAMS twice, etc). How do I fix this error?
  - a. At this time any errors in logging vaccine administration cannot be resolved in the clinic or jurisdiction portal. You would need to contact the VAMS helpdesk for support. Your Area VAMS POC can assist with initiating a helpdesk ticket. Please ensure you do not send any Patient Health Information (PHI) in e-mails to your POC or the VAMS helpdesk.

## COVID-19 Vaccine Lot Number and NDC Questions

- The Vaccine Administration Management System (VAMS) is asking me to log both a UoS (Unit of Shipment) lot number and UoU (Unit of Use) lot number when I am logging inventory. What is the difference between the UoS lot number and UoU lot number?
  - The UoS is the Unit of Shipment and is the lot number for the vaccine packaging.
  - The UoU is the Unit of Use and is the lot number for the vial.
  - Some vaccine manufacturers will have only one lot number.
  - In VAMS you will use the UoU lot number for both the UoS and UoU fields even if your vaccine has differing lot numbers for UoS and UoU.
- Do I use the UoS or the UoU lot number when logging the vaccine in RPMS or COTS system?
  - The Unit of Use (UoU) lot number is the correct lot number.
  - NOTE: lot numbers use the NUMBER zero, not the letter o.
- Where do I find the lot number on my vaccine vial or package?
  - Pfizer: the UoU lot number is located in the LOT/EXP field. Do NOT use the PAA number in the lot number field.



- b. Moderna: the UoU lot number can be found on the right side of the vial label or in the upper left of the back of the box. Do NOT use the GTIN number in the lot number field.



4. Where can I find the expiration date for the Moderna vaccine?
  - a. <https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup>
  - b. When using the Moderna COVID Vaccine expiration date finder, you will need to enter the lot number from your package.
  
5. I am logging Pfizer vaccine inventory in VAMS. The NDC on my vial is 59267-1000-01 but VAMS indicates the UoS NDC should end in "02". What is the correct NDC to enter?
  - a. The COVID-19 vaccine NDC numbers for the UoS NDC (outer packaging) and Unit of Use (UoU) NDC (vial) do differ. Code sets for the vaccines can be found at: <https://www.cdc.gov/vaccines/programs/iis/code-sets.html>.
  
6. I incorrectly documented the expiration date or lot number for my vaccine when adding inventory in VAMS. How do I edit my entry to reflect the correct expiration date or lot number?
  - a. At this time, the vaccine lot numbers and expiration dates cannot be edited in VAMS. You will need to submit a VAMS Helpdesk Support ticket. You can contact your Area VAMS POC for assistance with submitting this request.

### **RPMS EHR Configuration Frequently Asked Questions**

1. Where can we find COVID-19 vaccine Current Procedural Terminology (CPT) codes?
  - a. <https://www.ama-assn.org/press-center/press-releases/ama-announces-vaccine-specific-cpt-codes-coronavirus-immunizations>
  
2. Can the vaccine be entered in EHR as historical prior to upgrade or only after upgrade to the 2015 CHIT?
  - a. Only after upgrade and with new COVID-19 Immunization patch.