



MONKEYPOX INTRADERMAL VACCINE ADMINISTRATION AND INVENTORY MANAGEMENT

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Presenters

- Kathy Bay
- Heidi Kelly
- Jenny Arnold
- Elle Cooper, Anne Tu, and Brittany Jolivette
- Janel Jorgenson

Today's topics

- JYNNEOS vaccine general info: Kathy
- Intradermal vaccine administration, tips and tricks, lessons from the field: Heidi/Jenny/Tacoma Pierce County Health Department nurses
- Errors and deviations and VAERS: Kathy
- WAIIS vaccine inventory management: Janel
- Q&A

Vaccine Guidance

JYNNEOS Vaccine Preparation

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dos
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

FDA <u>emergency use authorization (EUA)</u> allows intradermal injection for people 18 years of age and older allows subcutaneous injection for most people under the age of 18

Vaccine Updates

- Utilizes dendritic cells in the skin to help produce a better immune response
- Site reaction:
 - More redness, firmness, itching and swelling at site
 - Less pain at site
- Previous study has confirmed non-inferior immune response
- Intradermal (ID) dose of 0.1 mL dose for adults
 - Not recommended for those with risk of keloid scars
 - Utilize 26 or 27 gauge TB syringe, ¼ to ½ inch short beveled needle
 - Volar aspect forearm
- Under 18 years should receive 0.5 mL subcutaneous dose

How to administer a JYNNEOS vaccine intradermally - YouTube

Intradermal Vaccine Updates

- Low dead volume syringes and/or needles can be used to extract 5 doses (0.1 mL each) for intradermal injection from a single vial
- If standard syringes and needles are used, there may not be sufficient volume to extract 5 doses from a single vial
- Must give full 0.1 mL dose, cannot pool vials for dosing
- Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture
- Use of sterile, single-use disposable needs and syringe for each injection is essential for prevention of cross contamination
- One and Only Campaign | Injection Safety | CDC

Infection Control

- Critical to use aseptic technique to prevent cross contamination of vial
- Vial must be used within 8 hours of first access
- Time and date vial when opened to allow for verification
- Do not pool vaccine from multiple vials to get extra doses
- Use of sterile, single-use disposable needs and syringe for each injection is essential for prevention of cross contamination

JYNNEOS Vaccine Admin Errors/Deviations

- Spacing
- Dosage
- Intervals
- Storage and handling

Intradermal Route

Dosage	If the incorrect dosage is administered, resulting in a lower- than-authorized dose (e.g., recipient pulled away, leaked out of a syringe, 0.1 mL administered subcutaneously).	Repeat dose immediately (no minimum interval). However, if a half-volume dose of vaccine is administered to a patient instead of the intended full volume, another half-volume dose can be administered on the same clinic day, and the 2 halves can count as 1 full dose.
Route	Incorrect route resulting in lower- than-authorized dose administered (e.g., inadvertent subcutaneous administration of 0.1 mL, when intradermal route was intended).	Repeat dose immediately via intended route (no minimum interval).

Source: Vaccine Administration Errors and Deviations | Monkeypox | Poxvirus | CDC

RESOURCES

Immunization Information System (IIS)

You will be directed to the page listing vaccines available for the clinic. Select the vaccine product on the far left, it will become highlighted with a blue check mark. To completely document the vaccination, use the scroll bar at the bottom of this section and scroll right for the remaining two fields "volume administered," and "unit of measure." Complete each field.







Important Note: To adjust the number by decimal points, it must be typed in. The default adjustment for the up/down arrows in PrepMod "volume administered" column is in whole numbers. Please use keyboard entry for dosage information. Wishington State Department of Health

IMMUNIZATION

Washington State Immunization Information System Monkeypox Vaccine Management in the WAIIS

The JYNNEOS monkeypox vaccine is coming to WA state through non-traditional ordering methods. A limited number of organizations will initially receive monkeypox vaccines. Organizations that receive vaccine allotment directly should manually add their facility's monkeypox vaccine inventory into the Washington State Immunization Information System (WAIIS). After adding the vaccine into the WAIIS, the monkeypox vaccine product can be electronically transferred to other providers that participate in the WAIS.

When transferring vaccine inventory to another provider, an official transfer request should be created in the WAIIS. Once the electronic transfer request is approved by the Department of Health, the physical transfer can occur. When the recipient physically receives the transferred vaccine, the provider should accept the official transfer in the WAIIS.

JYNNEOS monkeypox vaccine, CVX 206, can be administered as either an intradermal injection of 0.1mL or a subcutaneous injection of 0.5mL Both are a two-dose series with a 28-day interval between doses. Because the same product is being used for both types of injections, careful inventory management, frequent reconciliation, and meticulous record keeping are necessary.

How do I manually add monkeypox vaccines to my facility's WAIIS inventory?

 Log in to your organization and facility in the WAIIS. Click the blue Lot Numbers menu tab on the left of the page. Choose Search/Add.



PrepMod: Washington State's Mass Vaccination System | Washington State Department of Health

<u>348-903-</u> <u>MonkeypoxVaccineManagementWAIIS.pdf</u>

Resources

- Monkeypox (MPV) Provider FAQs and Resources | Washington State Department of Health
- <u>Alert: Monkeypox Vaccination Changes (govdelivery.com)</u>
- <u>Clinical Guidance | Monkeypox | Poxvirus | CDC</u>
- Infection Control: Healthcare Settings | Monkeypox | Poxvirus | CDC
- Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-Replicating) for Prevention of Monkeypox Disease in Individuals Determined to be at High Risk for Monkeypox Infection (fda.gov)
- Monkeypox Vaccination Program Provider Agreement | Monkeypox | Poxvirus | CDC
- Vaccine Administration Errors and Deviations | Monkeypox | Poxvirus | CDC

JYNNEOS Intradermal Administration

How to administer a JYNNEOS vaccine intradermally



STEP 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.



www.cdc.gov/monkeypox

How to administer a JYNNEOS vaccine intradermally



STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.



www.cdc.gov/monkeypox

How to administer a JYNNEOS vaccine intradermally



STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.



www.cdc.gov/monkeypox

How to administer a JYNNEOS vaccine intradermally



STEP 3

Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).



MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



www.cdc.gov/monkeypox

STEP 4

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.



Sites of Intradermal Administration

- Volar aspect of forearm (preferred)
- Alternate site based on patient preference include:
 - Upper back under shoulder blade (scapular region)



Adverse Reactions - Intradermal Administration

Source: Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization

Clinical study of smallpox vaccine-naïve subjects, sponsored by the National Institutes of Health (NIH):

- Frequencies of systemic and local adverse reactions reported in greater than 10% of subjects within 15 days of vaccination
- Erythema at the injection site was reported by 81.4% and 99.5% of participants in the SC and ID (intradermal) groups
- 44% of those who had ID administration still had erythema at the end of 14 days
- Reactions lasted longer in the ID subjects: at day 180, more than a third of subjects continued to have minimal induration or erythema
- A few subjects developed small nodules or discoloration at the injection site lasting 6 months or longer

Adverse Reactions - Intradermal Administration

Source: Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization

Reactogenicity event	SC (%)	ID (%)
	N=166	N=190
Feeling Tired	49.7	51.3
Muscle Aches	41.3	30.4
Headache	43.1	41.4
Nausea	21.6	23.0
Change in Appetite	15.0	20.4
Chills	12.6	14.7
Joint Pain	9.0	17.8
Pain at injection site	91.0	65.4
Erythema at injection site	81.4	99.5
Induration at injection site	69.5	99.5
Itchiness	48.5	89.0
Underarm pain	18.0	20.9
Underarm swelling	6.0	10.5

Table 2. Adverse reactions reported in >10% of individuals within 15 days following any dose

The vaccinating provider is required to report adverse reactions to <u>Vaccine Adverse Event Reporting System</u> (VAERS)

Clinical consults - Clinicians or Health Departments

- For urgent clinical consults, please contact CDC's Emergency Operations Center (770-488-7100)
- For non-urgent clinical consults, please email the clinical team at: eocevent482@cdc.gov

ID Administration Resources

- <u>How to administer a JYNNEOS vaccine intradermally YouTube</u>
- How to administer subcutaneous vaccine YouTube
- <u>JYNNEOS Preparation and Administration Summary (Intradermal</u> route)
- JYNNEOS Preparation and Administration Summary (Subcutaneous)
- JYNNEOS Interim Clinical Considerations



Inventory Management



MPV Vaccine Management in the IIS

Once Monkeypox vaccines are delivered to your clinic via transfer or direct order, the first step to managing inventory in the IIS is to add or receive the vaccine into your facility's inventory.



Washington State Immunization Information System

WASHINGTON STATE

Monkeypox Vaccine Management in the WAIIS

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348-903-MonkeypoxVaccineManagementWAIIS.pdf

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How to Manually add MPV to WAIIS

1. Log in to your organization and facility in the WAIIS. Click the blue **Lot Numbers** menu tab on the left of the page. Choose **Search/Add**.



NOTE: WAIIS users that do not have access to the blue **Lot Numbers** or **Orders/Transfers** menu tab can contact the IIS Help Desk at 1-800-325-5599 or WAIISHelpDesk@doh.wa.gov.

2. The Lot Number Maintenance screen will appear. Conduct a search before adding a product. Below the Search Results, click the Add button on the right.

Manufacturer			elect-					~					
Lot Number													
Facility:		AM	AC TE	ST FAC									
Inactive		All						~					
Inactive Reason	;	9	elect-					~					
Search Resul	ts												
how 100 v en	tries									Search:			
Facility		Manufacturer	\$	Lot Number	\$	Vaccine		Funding Source	٠	Exp. Date	+	Inactive	
					No c	tata available ir	a tabl	e					

How to Manually add MPV to WAIIS

- 3. The Lot Number Maintenance [Add] screen will appear. Enter data for all required fields. Regarding Reason for Change, use the most appropriate selection based on how you acquired the vaccine product. Once this form is complete, click the Add button on the bottom right.
 - The monkeypox vaccine product currently being used in Washington state is JYNNEOS by Bavarian Nordic A/S. The description in the WAIIS for this product is "Vaccinia, smallpox monkeypox vaccine live, PF".

Lot Number Maintenance [Add]			
Manufacturer:	BAVARIAN NORDIC A	VS-BN 🗸	
Vaccine:	Vaccinia, smallpox mor	keypox vaccine live, PF	
Lot Number:	testlot123		
Facility:	AMAC TEST FAC		
Expiration Date:	07/04/2022		
Funding Source:	PUB	~]
Reason Categories:	All Categories	~]
Reason for Change:	Order Received	~	
Date of Transaction:	07/18/2022		_
Number of Doses Added:	400		n
Product:	JYNNEOS	~	
Vaccine Settings Mapping:	Not Mapped	Map Vaccine Setting	
NDC Number:	50632-0001-02	~	
VFC PIN of other party (if applicable):			V
			Cancel Add

 Click the blue Lot Numbers menu tab on the left of the page. Choose Reconciliation. Your facility's Reconcile Inventory page will appear, and you should see the newly added monkeypox vaccine product.



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MPV Transfers



Complete MPV Vaccine Transfer Request

Transferring Facility

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Creates a vaccine transfer in the Immunization Information System (IIS):

- 1. Log into the Washington State Immunization Information System (IIS).
- 2. Ensure the correct facility displays at the top of the screen under: Organization/Facility.
- 3. Go to the Orders/Transfers menu in the left menu, select Create/View Orders and then Create Transfer.

▲ Orders/Transfers Alerts Create/View Orders Search History Modify Order Set Vaccine Advertiseme		rder/Transfer List Orders					
Cold Storage	Select	Order N	umber	PIN	Submit Date	Approval Date	Status
Provider Agreement	Backorde Select	red Orders Orde	er Number	PIN	Submit Date	Back	order Date
	Denied Or Selec	rders t O	rder Number	PIN	Submit Date	•	Denial Date
	Inbound T Select	Transfers Transfer Numb	er PIN	Submit Date	Sending	Organization/Facility	Status
	Outbound Select	l Transfers Transfer Numbe	er PIN	Submit Date	Receiving	g Organization/Facility	Status
	Rejected Select	Transfers Transfer Number f	PIN Submit Date	Receivi	ing Organization/Facility	Reject Date	Rejected By Status
						ม	

Complete MPV Vaccine Transfer Request

- 4. On the **Create Transfer** screen for the transferring facility:
 - a. Select the Receiving Organization from the drop-down menu and the Receiving Facility
 - b. Enter the Transfer Quantity (amount of CVP vaccine that will be transferred)
 - c. Enter Transfer Reason

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d. Select Create Transfer

Create Transfer	
Sending Organization	BECKY'S TEST ORGANIZATION
Sending Facility	BECKY'S TEST FACILITY TWO
Submitter	NICOLE PENDER (NPENDER)
Receiving Organization	BECKY'S TEST ORGANIZATION (10012)
Receiving Facility	BECKY'S TEST FACILITY THREE 🗸

Transfer Details						
Transfer Quantity	Vaccine	Funding Source	Lot Number	Quantity Available	Expiration Date	Transfer Reason
	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose (Pfizer)	PUB	1637642	100	02/25/2022	
19	DTaP-Hep B-IPV (Pediarix)	PUB	TEST234	19	08/31/2021	Soon to expire
	DTaP-Hib-IPV (Pentacel)	PUB	TEST456	14	12/30/2022	
					_	Create Transfer

Complete MPV Vaccine Transfer Request

- 5. Once **Create Transfer** is selected you will be directed back to the **Create/View Orders** page.
- 6. Under the Create/View Orders page you will be able to view your Outbound Transfers.

Current Ord Inbound Or	der/Transfer rders	List						
Select		Order Nun	nber	PIN	Submit Date	Approval	Date	Status
Backordere	ed Orders							
Select		Order I	Number	PIN	Submit Date		Backorder	Date
Denied Ord	lers							
Select		Ord	er Number	PIN	Submit Da	ite	Den	ial Date
Inbound Tra	ansfers							
Select	Transfe	r Number	PIN	Submit Date	Sendir	ng Organization/Fa	acility	Status
Outbound 1	Transfers							
Select Tran	sfer Number	PIN	Submit Date		Receiving Organization	/Facility		Status
>	38673	159999	12/16/2020	BECKY'S TES	T ORGANIZATION / BECK	Y'S TEST FACILITY	' TWO	In Manual Review
Rejected Tr	ransfers							
Select	Transfer Numb	er Pli	Submit Date	Receiv	ing Organization/Facility	Reject Da	ate Rejec	ted By Status
						Create Order 0	Create Transfe	r Vaccine Return

7. Once a transfer is approved by the state, the status will change from In Manual Review to Approved on the Outbound Transfers page and the coordinator will receive an email approval.

Outbou	nd Transfers						
Select	Transfer Number	PIN	Submit Date	Receiving Organia	zation/Facility		Status
>	38673	159999	12/16/2020	BECKY'S TEST ORGANIZATION /	BECKY'S TEST F	ACILITY TWO	Approved
Rejecte	d Transfers						
Select	Transfer Number	PIN	Submit Date	Receiving Organization/Facility	Reject	Date Rejecte	ed By Status
					Create Order	Create Transfer	Vaccine Return

Receiving Facility

1. Once the **Transferring Facility's** request is approved by the state, the transfer will then appear on the **Receiving Facility's Inbound Transfers** list.

Current	Order/Transfer I	List					
Sele	ct (Order Numb	er	PIN	Submit Date	Approval Date	Status
Backor	dered Orders						
Sel	ect	Order Nu	imber	PIN	Submit Date	Bac	ckorder Date
Denied	Orders						
Se	lect	Order	Number	PIN	I Submit Da	ite	Denial Date
Inboun	d Transfers						
Select	Transfer Number	PIN	Submit Date		Sending Organiz	ation/Facility	Status
>	38673	193999	12/16/2020	BECK	Y'S TEST ORGANIZATION /	BECKY'S TEST FACILITY	Y ONE Approved
Outbou	nd Transfers						
Select	Transfer	r Number	PIN	Submit Date	Receivi	ng Organization/Facility	Status
Rejecte	d Transfers						
Select	Transfer Numb	er PIN	Submit Date	Recei	iving Organization/Facility	Reject Date	Rejected By Status
						Create Order Create	Transfer Vaccine Return

- 2. The Receiving Facility will enter in the Receipt Quantity and select Receive.
 - a. Two things will happen once the transfer is received in the IIS:
 - i. The vaccine will subtract from the **Transferring Facility's** reconciliation (inventory) page
 - ii. The vaccine will be added to the Receiving Facility's reconciliation page

Shipped Quantity	Receipt Quantity	Rejected Quantity	Vaccine	Funding Source	Manufacturer	Lot Number	Expiration Date	Reason	Inventory Action	Reason for R	ejecting
19	19		DTaP-Hep B-IPV	PUB	SKB	TEST234	12/30/2022		Merging with Existing Lot	select	~
											Receive



If Receiving Facility does not have a PIN

Please send email to <u>WAAdultVaccines@doh.wa.gov</u>. We will create a PIN and set the provider's IIS access to allow for vaccine transfers



Reconciling Inventory



How to manage inventory in the IIS for JYNNEOS

- Report **inventory as vials** in the IIS and reconcile daily.
 - This will help the state monitor usage and progress toward meeting the 85% threshold required for obtaining additional supply.
- Regardless of the volume or route of administration given to the patient, administered doses will decrement from your inventory in IIS as a dose.
- If the provider is administering vaccine using the ID route and drawing multiple doses from a vial, the quantity on hand may show a negative number. Additional vials should be added through manual reconciliation.
- **Daily inventory reconciliation required** (working days only)

Inventory Guidelines

Requirement: You must count, reconcile and save your inventory <u>daily</u>.

Reconciling: Making sure your inventory in the IIS matches the number of vials your clinic has in your physical inventory.

IIS Quantity on Hand

How many vials the IIS thinks you have

Reconcile Inventory								
Vaccine	Lot Number	Exp Date	Quantity on Hand	Physical Inventory				
DTaP (Daptacel,Infanrix,Tripedia)	C5774BA	09/18/2022	9					
DTaP-Hep B-IPV (Pediarix)	7P2Y3	04/08/2023	10					
DTaP-Hib-IPV (Pentacel)	UJ466AAA	05/21/2022	3					

Physical Inventory

How many vials you have in your storage units.



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Counting Your Physical Inventory

• Select Lot Numbers and then Reconciliation in the left menu to view your IIS inventory.

▲ Lot Numbers Doses Administered Reconciliation

- Click the **Print** button at the bottom of the screen to print a reconciliation worksheet
- Count your **Physical Inventory** of MPV vaccine vials
 and note on the worksheet

Vaccine	Lot Number	Exp Date	Quantity on Hand	Physical Inventory	Adjustment	Reason	Funding Source	Inactive
DTaP (Daptacel,Infanrix,Tripedia)	C5774BA	09/18/2022	9				PUB	
DTaP-Hep B-IPV (Pediarix)	7P2Y3	04/08/2023	10				PUB	
DTaP-Hib-IPV (Pentacel)	UJ466AAA	05/21/2022	3				PUB	



Inventory Adjustments

It will be necessary to make adjustments to capture the number of vials vs doses in the IIS

- Entering the actual number of vials on hand in the **Physical Inventory** field.
- Select Category "Order Received" & Reason "Dose Count Variance Multi-dose Vial" for each lot number that needs to be adjusted.
- If you need to make multiple adjustments to the same lot number, click the + button to add another line.

Vaccinia, smallpox monkeypox vaccine live, PF (JYNNEOS)	FDP00009	05/31/2024	1,860	2000	140.0	Order Received	Dose Count Variance Multi-dose Vial	~	PUB	+
Vaccinia, smallpox monkeypox vaccine live, PF (JYNNEOS)	FDP00014	09/30/2024	1,105		0.0	No Category Required 🗸	No Reason Required	~	PUB	+

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Tools and Resources

MPV Vaccine Management in the IIS

- MPV Provider FAQs and Resources Webpage
- MPV Storage and Handling Summary
- <u>CDC Vaccine Transport Guidelines</u>

MPV Inventory Questions:

WAAdultVaccines@doh.wa.gov



To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email <u>civil.rights@doh</u>.