Alaska Native Medical Center

Protocol for Seasonal Flu Vaccine Administration During Mass Clinics: Flu Season 2020-21

1. Purpose

To reduce morbidity and mortality from influenza by vaccinating children and adults who meet the criteria established by the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP).

2. Scope

Eligible healthcare personnel practicing at the Alaska Native Medical Center (ANMC), Southcentral Foundation Anchorage Native Primary Care Center and its associated Southcentral Foundation clinics, Southcentral Foundation Benteh Nuutah Valley Native Primary Care Center, Southcentral Foundation Rural Clinics and licensed professional volunteers from the Centers for Disease Control (CDC) Arctic Investigations Program.

3. Policy

Where allowed by state law, this protocol enables eligible nurses and other healthcare professionals to assess the need for vaccination and to vaccinate children and adults who meet any of the criteria below.

4. Procedure

4.1. Assess for Need of Vaccination Against Influenza

4.1.1. All persons 6 months or older are recommended to receive influenza vaccination each year if they do not have a contraindication.

4.1.2. A second dose of influenza vaccine is recommended 4 weeks or more after the first dose for children age 6 months through 8 years if they have not or don't know if they have received 2 doses in prior years (not necessarily in the same season).

4.1.3. Women who are or will be pregnant during the influenza season. Administer any recommended, age-appropriate inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV) to pregnant women in any trimester. Do NOT administer live attenuated influenza vaccine (LAIV, Flumist®) to a pregnant woman.

4.1.4. Utilize the Alaska Immunization Information System VacTrAK to determine the vaccination status of the child or adult.

4.1.4.1. The child or adult may need to be vaccinated if their VacTrAK record indicates "Due Now" or "Past Due" for influenza vaccine.

4.1.4.2. Ask the patient (or, in the case of minors, their parents or legal representative) if influenza vaccine was received during the current influenza season.

4.1.4.3. People who have not or do not recall whether they received influenza vaccine during the current influenza season should be vaccinated.

4.2. Screen for Contraindications and Precautions

4.2.1. Contraindications for use of all influenza vaccines

4.2.1.1. Do not give influenza vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of any influenza vaccine or to any of its components (except egg). For a list of vaccine components, refer to the manufacturer's package insert (www.immunze.org/fda) or go to https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

4.2.2. Contraindications for use of live attenuated influenza vaccine (LAIV, Flumist®) only

4.2.2.1. Do not give live attenuated influenza vaccine (LAIV, Flumist®) to a person who:

4.2.2.1.1. Is pregnant.
4.2.2.1.2. Is under 2 years of age.
4.2.2.1.3. Is age 50 years or older.
4.2.2.1.4. Is age 2 through 4 years who has received a diagnosis of asthma or who has experienced wheezing or asthma within the past 12 months, based on a healthcare provider's statement or medical record.
4.2.2.1.5. Is immunocompromised due to any cause (including immunosuppression caused by medications or HIV infection) or no spleen (functional or anatomic asplenia).
4.2.2.1.6. Is age 6 months through 17 years and is receiving aspirin or salicylate containing medicine.
4.2.2.1.7. Has active cerebrospinal fluid (CSF) leak.
4.2.2.1.8. Has cochlear implants.
4.2.2.1.9. Received influenza antivirals within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and 17 days for baloxavir
4.2.2.1.10. Is a close contact of or who provides care for a severely immunosuppressed person who requires a protective environment (eg. an isolation room of a bone marrow transplant unit).

4.2.3. Precautions for use of all influenza vaccines

4.2.3.1. Moderate or severe acute illness with or without fever.
4.2.3.2. History of Guillain-Barre' syndrome within 6 weeks of a previous influenza vaccination.

4.2.4. Precautions for use of live attenuated influenza vaccine (LAIV, Flumist®) only

4.2.4.1. Age 5 years and older with asthma.
4.2.4.2. Other chronic medical conditions that might predispose the person to complications of influenza infection (eg. other chronic pulmonary, cardiovascular [excluding isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]).

4.2.5. NOTE REGARDING PATIENTS WITH EGG ALLERGY

4.2.5.1. History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of most IIVs and LAIV4. However, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria or hives (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices) supervised by a health care

provider who is able to recognize and manage severe allergic reactions, if a vaccine other than ccIIV4 (Flucelvax®) or RIV4 (Flublok®) is used.

4.2.5.2. Healthcare personnel will consult a medical provider if patient reports history of egg allergy before administering vaccines or refer the patient to their regular provider.

4.2.6. Screening checklists for contraindications are found online at Immunization Action Coalition (https://www.immunize.org/handouts/contraindications.asp) and are posted in Cerner under 'Adhoc' in the banner across the top of the display screen.

4.2.7. If any doubt regarding a contraindication or precaution, the patient will not be vaccinated during the mass clinic and referred to regular medical provider.

4.3. Screen for Vaccine Eligibility

4.3.1. Screen patient for eligibility to receive State-supplied vaccines before administering vaccines.

4.3.1.1. All children 18 years of age and under are eligible to receive State-supplied influenza vaccines.

4.3.1.2. All adults 19 years and older (regardless of IHS beneficiary status) are eligible to receive State-supplied influenza vaccines except adults insured with:

4.3.1.2.1. Medicare (as either the main or primary insurance).
4.3.1.2.2. Medicaid (as either the main or primary insurance).
4.3.1.2.3. Insurance that does not cover vaccine.
4.3.1.2.4. AlaskaCare Retiree Plans (as only insurance).
4.3.1.2.5. Veterans Affairs (as only insurance).

4.3.2. Administer State-supplied vaccines only to eligible patients. Administer private-supplied vaccine to patients who are not eligible to receive State-supplied vaccine.

4.3.2.1. NOTE: For the 2020-21 influenza season, State-supplied flu vaccine may be offered universally. This means adults who are not normally eligible may receive State-supplied flu vaccine; in this situation, administer State-supplied flu vaccine and document the eligibility status as 'Ineligible (Private)' for these particular patients.

4.3.3. Accurate documentation of vaccine eligibility is required.

4.4. Provide Vaccine Information Statements

4.4.1. Provide all patients (or, in the case of minors, their parents, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS) for each vaccine needed.

4.4.2. VIS are found online at CDC (https://www.cdc.gov/vaccines/hcp/vis/current-vis.html).

4.5. Prepare to Administer Vaccine

4.5.1. Prior to administering a vaccine, follow the ANMC Medication Administration Procedure 500-19C at http://share.home.anthc.org/cbss/ecs/SitePages/ANMC%20Polices%20and%20Procedures.aspx

4.5.2. Select an available influenza vaccine* that is appropriate for the age and health status of the patient:

Manufacturer	Brand Name	Type	Route	How Supplied	Age Range
GlaxoSmithKline	Fluarix	IIV4	IM	**0.5 mL** (single-dose syringe)	**6 months & older**
Sanofi Pasteur	Fluzone	IIV4	IM	**0.5 mL** (single-dose syringe or vial)	**6 months & older**
			IM	5 mL (multi-dose vial)-**draw 0.5 mL**	**6 months & older**
	Fluzone High Dose	HD-IIV4	IM	**0.7 ml** (single-dose syringe)	65 years & older
AstraZeneca	FluMist	LAIV4	NAS	0.2 mL (single-dose nasal sprayer)	2 yrs through 49 years
GlaxoSmithKline	FluLaval	IIV4	IM	**0.5 mL** (single-dose syringe)	**6 months & older**
Sanofi Pasteur	Flublok	RIV4	IM	0.5 mL (single-dose syringe)	18 years & older
Seqirus	Afluria	IIV4	IM	0.25 mL (single-dose syringe)	6 through 35 months
			IM	0.5 mL (single-dose syringe)	36 months & older
			IM	5 mL (multi-dose vial)-draw 0.25 mL	6 through 35 months
			IM	5 mL (multi-dose vial)-draw 0.5 mL	36 months & older
	Fluad	aIIV3	IM	0.5 mL (single-dose syringe)	65 years & older
		aIIV4	IM	0.5 mL (single-dose syringe)	65 years & older
	Flucelvax	ccIIV4	IM	0.5 mL (single-dose syringe)	4 years & older
			IM	5 mL (multi-dose vial)-draw 0.5 mL	4 years & older
* The flu vaccine products highlighted in grey may not be stocked for this season.					

4.5.3. Check vaccine name and expiration date.

4.5.3.1. Wash hands and draw up each vaccine separately using aseptic technique.

4.5.3.2. Label each syringe according to the ANMC Medication Administration Procedure 500-19C at http://share.home.anthc.org/cbss/ecs/SitePages/ANMC%20Polices%20and%20Procedures.aspx

4.5.4. For IIV or RIV influenza vaccine that are administered intramuscularly (IM), prepare the vaccine by choosing the needle gauge, needle length, and injection site according to the following chart:

Patient		Needle gauge	Needle length	Injection site
Infants age 6 months through 11 months		22-25	1”	Anterolateral thigh muscle
Age 1 year through 2 years		22-25	1-1 ¼”	Anterolateral thigh muscle
Age 3 years through 10 years		22-25	1”	Deltoid muscle of arm*
			1-1 ¼”	Anterolateral thigh muscle
Age 11 years through 18 years		22-25	1”	Deltoid muscle of arm*
			1-1 ½”	Anterolateral thigh muscle
Adults 19 years and older				
Gender & weight:	Less than 130 lbs.	22-25	1”	Deltoid muscle of arm
	130-152 lbs.	22-25	1”	Deltoid muscle of arm
	Female 153-200 lbs.	22-25	1-1 ½”	Deltoid muscle of arm
	Male 153-260 lbs.	22-25	1-1 ½”	Deltoid muscle of arm
	Female 200+ lbs.	22-25	1 ½”	Deltoid muscle of arm
	Male 260+ lbs.	22-25	1 ½”	Deltoid muscle of arm
*Preferred site.				

4.5.5. For live attenuated influenza vaccine (LAIV, Flumist®) that is administered intranasal (NAS), prepare the vaccine according to directions in the manufacturer’s package insert (www.immunize.org/fda).

4.5.6. Vaccines should continue to be stored at recommended temperatures until use.

4.5.6.1. Failure to adhere to recommended specifications for storage and handling of vaccines can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient.

4.5.7. NOTE REGARDING PRE-DRAWN SYRINGES

4.5.7.1. ACIP discourages the routine practice of personnel prefilling syringes for several reasons.

4.5.7.1.1. Because the majority of vaccines have a similar appearance after being drawn into a syringe, prefilling might result in administration errors.
4.5.7.1.2. Because unused prefilled syringes must be discarded if not used, vaccine wastage might occur. Unused prefilled syringes must be discarded after one hour.
4.5.7.1.3. The FDA does not license administration syringes for vaccine storage.

4.5.7.2. In certain circumstances in which a single vaccine type is being used (e.g., a community influenza vaccination campaign), filling a small number (10 or fewer) of syringes may be considered.

4.5.7.2.1. The doses should be administered as soon as possible after filling, by the same person who filled the syringes.
4.5.7.2.2. Unused syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed or needle attached) should be discarded after one hour.

4.6. Administer Influenza Vaccine

4.6.1. Utilize the 8 rights of medication administration:

4.6.1.1. Right person (name and DOB)
4.6.1.2. Right reason
4.6.1.3. Right medication
4.6.1.4. Right dose
4.6.1.5. Right route
4.6.1.6. Right time
4.6.1.7. Right documentation
4.6.1.8. Right response

4.6.2. Administer vaccine according to the age of the patient and appropriate route of vaccination (refer to above section 4.5. to verify appropriate vaccine selection, preparation, route and administration site).

4.6.2.1. Administer intramuscular (IM) injection at a 90 degree angle into the appropriate muscle.
4.6.2.2. Administer intranasal (NAS) 0.2 mL spray (0.1 mL into each nostril) according to directions in the manufacturer's package insert (www.immunize.org/fda).

4.6.3. Have the parent or legal representative hold the infant or toddler in a comforting manner that secures the limb for injection according to CDC guidance (https://www.cdc.gov/vaccines/parents/visit/holds-factsheet.html). Have older children, teens and adults sit or lie down for vaccination.

4.6.4. Never inject vaccine in the buttock.

4.6.5. Separate injection sites by 1 inch if injecting two or more vaccines in a single limb.

4.6.6. Immediately discard used needles, syringes and nasal sprayer in labeled puncture-proof containers.

4.6.7. The vaccine recipient should remain in clinic for 15 minutes after injection to monitor for adverse reaction. Have vaccine recipient remain seated to reduce the risk of syncope (fainting).

4.6.8. NOTE REGARDING NON-STANDARD ADMINISTRATION

4.6.8.1. ACIP discourages variations from the recommended route, site, volume, or number of doses of any vaccine.

4.6.8.1.1. Any vaccination using less than the standard dose should not be counted, and the person should be revaccinated according to age unless serologic testing indicates that an adequate response has developed.

4.6.8.1.2. If less than a full recommended dose of a vaccine is administered because of syringe, applicator, or needle leakage, the dose should be repeated.

4.6.8.2. Regarding live attenuated influenza vaccine (LAIV, Flumist®) given intranasal, if the person coughs or sneezes immediately after administration or the dose is expelled any other way, the vaccine dose need not be repeated.

4.7. Document Vaccination

4.7.1. Documentation Process (On-Site Pharmacist Clinics)

4.7.1.1. Patient completes the screening form and receives the appropriate Vaccine Information Statement (VIS). If contraindications are revealed or if there is doubt whether a contraindication exists, the patient will not be vaccinated during the mass clinic and referred to their regular medical provider.

4.7.1.2. In Cerner, pharmacists who received documentation training will document the immunization using 'Adhoc' located in Cerner's 'Immunization Schedule' utilizing an appropriate job aide.

4.7.2. Documentation Process (AFN Clinic)

4.7.2.1. Patient completes the screening and intake form and receives the appropriate Vaccine Information Statement (VIS). If contraindications are revealed or if there is doubt whether a contraindication exists, the patient will not be vaccinated during the clinic and referred to their regular medical provider.

4.7.2.2. The healthcare personnel administering vaccine will document the immunization on the patient's intake form. The intake form is collected and maintained by the mass clinic coordinator.

4.7.2.3. In VacTrAK, the immunization will be documented during or after the clinic utilizing the intake form and an appropriate job aide.

4.7.3. Documentation Process (On-Site Campus and Off-Site Clinics)

4.7.3.1. Patient completes the screening form and receives the appropriate Vaccine Information Statement (VIS). If contraindications are revealed or if there is doubt whether a contraindication exists, the patient will not be vaccinated during the mass clinic and referred to their regular medical provider.

4.7.3.2. Documentation will be completed per the expectations of the mass clinic coordinator utilizing an appropriate job aid.

4.7.4. Documentation is completed for each vaccine. Record the date of vaccine administration; the vaccine name, manufacturer, lot number and expiration date; the vaccination site and route; the Vaccine Information Statement (VIS) publication date; and vaccine funding source and eligibility.

4.7.5. The State of Alaska requires vaccine funding source and eligibility documentation on all administered vaccine doses. Document vaccine funding source and eligibility correctly.

4.7.5.1. When using Cerner, select the appropriate menu option in the 'Vaccines For Children' field to document vaccine eligibility and the 'Funding Source' field to document vaccine funding source. Both fields are located in the powerform used to document vaccines in Cerner.

4.7.5.2. When using VacTrAK, select the appropriate menu option in the 'Update VFC Eligibility' field to document vaccine eligibility and select the lot number associated with the appropriate vaccine funding source.

4.7.5.3. Vaccine eligibility and funding source must be documented for all administered vaccines given to children, teens and adults.

4.7.6. Per State of Alaska, healthcare organizations are required to report all administered immunizations to VacTrAK within 14 days of vaccine administration (7 AAC 27.650).

4.7.6.1. Vaccines documented in Cerner will transfer to VacTrAK electronically in real time.

4.7.7. The Cerner Registry Import offers healthcare personnel the capacity to import immunizations from VacTrAK into the Cerner patient medical record to complete the Cerner immunization record.

4.7.8. If vaccines are not administered (i.e. contraindicated or refused), the medical provider is notified. The medical provider documents in the Cerner 'Provider Notes' and the nurse or other healthcare personnel documents in the Cerner 'Immunization Schedule' or 'MAR'.

4.8. Be Prepared to Manage Medical Emergencies

4.8.1. An adverse event is an untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccination process. These events range from common, minor, local reactions to rare, severe, allergic reactions (e.g., anaphylaxis).

4.8.2. Be prepared for management of a medical emergency related to the administration of vaccine by activating the medical emergency processes specific to the department when indicated.

4.9. Report Adverse Events to VAERS

4.9.1. If an adverse event occurs, notify a medical provider and complete an incident report.

4.9.2. The medical provider or pharmacy will file a report to the federal Vaccine Adverse Event Reporting System (VAERS), if indicated. To submit a VAERS report, go to https://vaers.hhs.gov/.

5. Vaccine Transport and Itinerant Clinic Storage

5.1. Vaccines are transported off site and/or stored during the mass clinic using State approved vaccine transport and itinerant storage methods. The State Off-Site Clinic Forms are submitted when State-provided vaccine is administered during a mass clinic, these forms are found under the heading 'Vaccine Storage and Temperature Monitoring' here: (http://dhss.alaska.gov/dph/Epi/iz/Pages/vaxpacket/default.aspx).

6. Protocol Authorization

Alaska Native Medical Center

Protocol for Seasonal Flu Vaccine Administration During Mass Clinics: Flu Season 2020-21

This protocol, authorized by the signatures below, serves as a pre-authorization order for eligible healthcare personal who have demonstrated competency to administer vaccines according to the protocol criteria.

Attachments:

1. Protocol for Seasonal Flu Vaccine Administration During Mass Clinics WORKFLOW

References:

1. ANMC Medication Administration Procedure 500-19C: http://share.home.anthc.org/cbss/ecs/SitePages/ANMC%20Polices%20and%20Procedures.aspx
2. MMWR Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) -United States, 2020-21 Influenza Season, found here: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6908a1-H.pdf
    a. Summary of Recommendations: https://www.cdc.gov/flu/pdf/professionals/acip/acip-2020-21-summary-of-recommendations.pdf
3. ACIP General Best Practice Guidelines for Immunization, found here: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
4. CDC Pink Book, found here: https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
5. IAC Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination, found here: https://www.immunize.org/handouts/contraindications.asp
6. IAC Screening Checklist for Contraindications to Live Attenuated Intranasal Influenza Vaccination, found here: https://www.immunize.org/handouts/contraindications.asp
7. State of Alaska State-Supplied Vaccine Eligibility for Children and Adults, found here: http://dhss.alaska.gov/dph/Epi/iz/Pages/vaxpacket/default.aspx
8. IAC Standing Orders for Administering Influenza Vaccine to Children and Teens, found here: https://www.immunize.org/standing-orders/
9. IAC Standing Orders for Administering Influenza Vaccine to Adults, found here: https://www.immunize.org/standing-orders/

Signatures

These protocols shall remain in effect for all patients of influenza vaccination mass clinics coordinated by the Alaska Native Medical Center (ANMC), Southcentral Foundation Anchorage Native Primary Care Center, Southcentral Foundation Benteh Nuutah Valley Native Primary Care Center and Southcentral Foundation Rural Clinics effective upon signatures below until rescinded or until **June 30, 2021**.

ANMC President Medical Staff	Name: _____	Signature: _____	Date: _____
ANMC Chief Nursing Officer	Name: _____	Signature: _____	Date: _____
ANMC Director of Pharmacy	Name: _____	Signature: _____	Date: _____
SCF Medical Director	Name: _____	Signature: _____	Date: _____
SCF Nursing Director	Name: _____	Signature: _____	Date: _____