***REVISED MEETING AGENDA**	**Public Health and Pharmacy Formulary Advisory Committee Meeting** **February 21, 2024 9:00AM** The committee will meet virtually. **Public Attendance by Phone: (503) 446-4951 Phone Conference ID: 381 036 918 #** To sign up to provide public comment, email your request to pharmacy.formulary@bop.oregon.gov by 12:00PM on ***2/21/2024*** *If you need accommodations under the Americans with Disabilities Act (ADA), complete and submit the online OBOP Request for ADA Accommodations for Public Meetings form located on our website.*

Committee Members

- Lorinda Anderson, RPH
- Katherine Hammond, APRN
- Ellisha Lee, RPH
- Sarah Wickenhagen, APRN
- Andrew Gibler, RPH
- Sean Jones, MD
- Mark Meyers, MD

OBOP Agency Staff to Committee

- Jennifer Davis, RPH, Pharmacy Consultant
- Rachel Melvin, Operations Policy Analyst
- Brianne Efremoff, RPH, Compliance Director

Subject Matter Experts

- Ian Doyle, RPH Professor Emeritus, Pacific University School of Pharmacy
- Geoff L'Heureux, RPH Clinical Pharmacy Specialist, G Street Health
- Katie Yabut, RPH Clinical Pharmacy Manager, Legacy Health
- Eugenia Su, RPH PCMHI Clinical Pharmacy Specialist, Eugene VA Health Care Center
- Kiyomi Lehman, RPH Clinical Pharmacist, Mosaic Medical
- Elise Phelps, RPH Clinical Pharmacist, Virginia Garcia
- Amy Valdez, RPH Manager, Clinical Pharmacy Services, Kaiser
- Crystal Sharp, RPH Pharmacy Manager, Fred Meyer
- Nancy Pietroski, RPH Medical Editor, Shoreland Travax
- Asad Obaidi, RPH Medical Science Liaison, Dynavax

	Agenda Items
Welcome	❖ **OPEN SESSION – PUBLIC MAY ATTEND** ➢ Roll call ➢ Housekeeping & Meeting Etiquette ➢ Agenda review and approval *Action Necessary* ➢ 9/15/2023 PHPFAC Meeting Summary review & approval *Action Necessary*
Committee Business	❖ Reappointment Update ❖ Rules Update
	❖ Committee Protocol Development ➢ Concept #1: STI PEP **#A** ➢ Concept #2: Short-acting Opioid Antagonists **#A1** ❖ Formulary/Protocol Review ➢ Continuation of Therapy – Damaged Therapy **#B**

	➢ Tobacco Cessation **#B1** ➢ Vaccines **#B2** ▪ Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway ▪ Standard Protocol for All Vaccines: Managing Adverse Reactions ▪ Coronavirus 2019 ▪ Haemophilus Influenzae Type ▪ Inactivated Influenza ▪ Japanese Encephalitis ▪ Meningococcal Containing ▪ Pneumococcal ▪ Polio ▪ Respiratory Syncytial Virus ▪ Tetanus Diphtheria Containing ▪ Yellow Fever ➢ Travel Medications **#B3** ❖ Items to Explore ➢ Formulary- Continuous Glucose Monitors & Related Supplies **#C** ➢ Protocol- Mpox vaccine **#C1** ❖ Public Comment ❖ ADJOURN *Action Necessary*
Upcoming Meeting Schedule (*subject to change)*	❖ 2024 Virtual Meetings: ➢ May 2024 TBD, 8/21/2024, 11/20/2024

NOTE: The committee may rearrange its agenda to accommodate the committee or subject matter experts.

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

PREVENTATIVE CARE

POST-EXPOSURE PROPHYLAXIS FOR BACTERIAL SEXUALLY TRANSMITTED INFECTIONS (STI PEP)

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335 a pharmacist licensed and located in Oregon may prescribe post-exposure preventative treatment for chlamydia, gonorrhea, and syphilis (STI PEP).

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized STI PEP Patient Intake Form (pg. x)
- Utilize the standardized STI PEP Assessment and Treatment Care Pathway (pg. x)
- Utilize the standardized STI PEP Prescription Template *optional* (pg. x)
- Utilize the standardized STI PEP Provider Fax (pg. x)
- Utilize the standardized STI PEP Patient Informational Handout (pg. x)

PHARMACIST TRAINING/EDUCATION:

- No required training/education
- *Recommended*: Completion of an educational training program of at least 1 hour related to the prescribing of DoxyPEP or STD curriculum:
  - DoxyPEP: Who, When, and How. https://www.iasusa.org/events/webinar-2023-luetkemeyer/ International Antiviral Society–USA (IAS–USA); Program is Accreditation Council for Pharmacy Education (ACPE) accredited
  - National STD Curriculum (A free educational website from the University of Washington STD Prevention Training Center). https://www.std.uw.edu/

RESOURCES:

- Doxycycline for STI PEP Implementation Toolkit. National Coalition of STD Directors. https://www.ncsddc.org/wp-content/uploads/2023/07/Doxycycline-as-STI-PEP-Toolkit-July-2023.pdf (accessed 1/5/2024)

Commented [JD1]: Will hyperlink once available.

Commented [ID2]: For PHPFAC Consideration: Edu for trauma-informed care similar to HIV-PEP

Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)
Self-Screening Intake Form
(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other_____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

1.	Are you UNDER 13 years old?	□ Yes □ No
2.	Do you identify as gay, bisexual, or a man who has sex with men? Do you identify as a transgender woman?	□ Yes □ No □ Yes □ No
3.	a) Has a healthcare provider EVER tested or diagnosed you with a chlamydia OR gonorrhea OR syphilis infection? b) If yes, how recently? _____ What were the results? _____ _____ c) How many infections have you experienced within the last 12 months? _____	□ Yes □ No □ Not sure
4.	a) Have you ever experienced a difficult-to-treat chlamydia OR gonorrhea OR syphilis infection, or had the treatment not work? b) What treatments (if any) have you tried for past and/or current chlamydia OR gonorrhea OR syphilis infections? Please list them here: _____ _____	□ Yes □ No □ Not sure
5.	Symptom review: Do you currently have: - Abnormal discharge (color, smell, consistency, etc.) from penis - Burning sensation when peeing (urination) - Anal itching, discharge, or bleeding - One or multiple sores in, on, or around penis, anus, or rectum; or rash anywhere - Soreness in rectum, or painful bowel movements - Pain and swelling in one or both testicles - Other symptoms (describe): _____	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
6.	Have you used antibiotics in the last month?	□ Yes □ No □ Not sure
7.	a) Do you have oral, anal, or vaginal sexual contact WITHOUT a condom? If yes, how recently (date)? Did this activity happen more than once in the past 12 months? b) In the future, will you have oral, anal, or vaginal sexual contact WITHOUT a condom? c) Have you had multiple sex partners in the past 12 months? d) Do you (will you) engage in group sex or chem-sex? e) Do you (will you) participate in sexual activities during weekend events, cruises, festivals, or similar?	□ Yes □ No ___/___/___ □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
8.	Have you had an exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
9.	a) Are you currently taking HIV Pre-Exposure Prophylaxis (HIV PrEP) medications? b) Do you use HIV Post-Exposure (HIV PEP) medications?	□ Yes □ No □ Not sure □ Yes □ No □ Not sure
10.	Do you have a health condition involving your esophagus, intestines, or liver?	□ Yes □ No □ Not sure
11.	Do you have any other medical problems?	□ Yes □ No □ Not sure

Commented [ID1]: Did not ask about pregnancy as currently CDC recommendations to not apply to people able to conceive

Commented [ID2]: Baseline STI testing required before prescribing? CDC recommendation is "should" (or is a "Considerations for ancillary services"). ATCP is designed currently as "not required if no signs of infection". Screen in required every 3-6 months for continuing therapy (i.e., refills). Does PHPFAC agree that benefit outweighs risk for 1st prescription? If not, can change protocol to require BASELINE screening. Concern: do not want baseline screening to be barrier to to access to STI PEP.

Commented [ICD3]: Guideline for PEP: have had at least 1 infection in last 12 months

Commented [ICD4]: Attempting to capture symptoms of chlamydia, gonorrhea, and syphilis (stage 1 and 2). Active diseases may be asymptomatic.
If symptoms, need to refer.

Commented [ID5]: Using this Q as a cross-check for Q4 in case patient does not recognize associate STI "treatments" with "antibiotics". Can delete Q if that is recommendation of PFPHAC.

Commented [ID6]: For PHPFAC Consideration: use of Q similar to HIV-PEP?

Commented [ID7]: Opportunity to ensure patient can received optimized, comprehensive care

Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)
Self-Screening Intake Form
(CONFIDENTIAL-Protected Health Information)

	If yes, list them here: _____ _____	
12.	Are you currently taking any medications, supplements, and/or vitamins? If yes, list them here: _____ _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Standardized Assessment and Treatment Care Pathway
Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)

1) STI PEP patient population eligibility for enrollment in protocol (Form Q: #1-2)

a. Q1: If patient less than 13 years of age -> **REFER** to medical provider (doxycycline contraindicated if <8 years old)

b. Q2: If patient identifies as gay, bisexual, a man who has sex with men (GBMSM), or transgender woman (TGW) who has sex with men -> Continue algorithm (Step 2)

- If not -> **DEFER** prescribing STI PEP; advise to continue condom use. Refer to medical provider if non-protocol-eligible patient wants STI PEP. Studies do not support the use of STI PEP in other patient populations.

2) Bacterial Sexually Transmitted Infection (STI) Screen and Risk Assessment: chlamydia OR gonorrhea OR syphilis infection (Form Q: #3-7)

		Sexual Behavior or Activity	
		Q7a: Reports ***condomless*** anal, oral, or vaginal sexual contact with ≥ 1 cis-male or trans-female partner in the past 12 months	Q7a: **DOES NOT** report ***condomless*** anal, oral, or vaginal sexual contact with ≥ 1 cis-male or trans-female partner in the past 12 months
Infection History	Q3a-c: Has had one (1) or more chlamydia OR gonorrhea OR syphilis infections within 12 months	**Prescribe STI PEP**	Consider STI PEP Q7b: If expects to have ***condomless*** sex in future: -> prescribe STI PEP.
	Q3a-c: Has ***NOT*** had one (1) or more chlamydia OR gonorrhea OR syphilis infections within 12 months	Consider STI PEP If history of, or expectation for: Q7c: multiple sex partners, OR Q7d: group sex/ chem-sex, OR Q7e: participating in sexual activities that are known to increase likelihood of exposure to STIs, e.g., during weekend events, cruises, and festivals: -> prescribe STI PEP.	Consider STI PEP If history of, or expectation for: Q7c: multiple sex partners, OR Q7d: group sex/ chem-sex, OR Q7e: participating in sexual activities that are known to increase likelihood of exposure to STIs, e.g., during weekend events, cruises, and festivals: -> prescribe STI PEP.

a. **EXCEPTIONS**:

- Q4: If history of doxycycline-resistant chlamydia OR gonorrhea OR syphilis infection-> **REFER to medical provider**
- Q5: If experiencing symptoms consistent with current STI: Abnormal discharge (color, smell, consistency, etc.) from penis; Burning sensation when peeing (urination); Anal itching, discharge, or bleeding; One or multiple sores in, on, or around penis, anus, or rectum; or rash anywhere; Soreness in rectum, or painful bowel movements; Pain and swelling in one or both testicles.
  - If YES to any of these symptoms -> **REFER for diagnosis and active treatment of possible STI.**
- Q7: If condomless sexual contact reported:
  - < 72 hours ago: direct patient to take doxycycline immediately after receipt of prescription
  - > 72 hours ago: direct patient not to use doxycycline; **Refer** to medical provider for assessment. May continue to provide STI PEP for future sexual activity.

b. SCREENING: IF PATIENT MEETS CRITERIA FOR PRESCRIBING STI PEP:

Commented [ID1]: This exception is not addressed in CDC guidelines. I am making the presumption a complex presentation is outside the scope of community pharmacy.

Standardized Assessment and Treatment Care Pathway
Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)

- Q3a-b: Recommend to patient they undergo bacterial STI testing at anatomic sites of exposure at baseline before initiation of STI PEP
    - If patient had STI testing AND has not had sexual contact since test:
        - History of negative testing may serve as baseline (patient to provide records)
    - Provide lab order for BASELINE screen: nucleic acid amplification test for gonorrhea and chlamydia at anatomic sites of exposure, and serologic testing for syphilis.
    - Patient may decline BASELINE screen testing.
    - Pharmacy may prescribe STI PEP without baseline results.
    - If STI testing is positive for chlamydia OR gonorrhea OR syphilis -> **REFER for diagnosis and active treatment of possible STI.**

Commented [ID2]: See comments on Patient Intake Form about baseline screening

3) Comprehensive therapy assessment (Form Q: #7-9)

a. Q8: SEXUAL ASSAULT SURVIVOR? If the patient experienced a sexual assault, continue with the algorithm to prescribe STI PEP and then refer the patient to the emergency department for a sexual assault workup.
    - Oregon licensed pharmacists are mandatory reporters of child abuse (ORS Chapter 419B). Pharmacists should also report elder abuse and vulnerable adult abuse. Reports must be made to the Oregon Department of Human Services @ 1-855-503-SAFE (7233).

b. Q9: Assess for the need for HIV PEP and encourage the use of HIV PrEP
    - If not currently utilizing HIV PreP or HIV PEP, offer patient to complete respective Patient Intake Forms for these statewide protocols.

c. Q7a-e: Counsel on risk reduction strategies including:
    - Condom use for every instance of sexual contact
    - Consideration of reducing the number of partners

3) Medication and Disease State Screen (Form Q: #10-12)

a. Q10: History of gastrointestinal (GI) conditions (e.g., esophagitis, diarrhea, Crohn's, etc.) -> Use caution. Have the patient contact pharmacy or medical provider if experiencing exacerbation of condition.

b. Q11-12: Review medication history for duplicative therapy and/or drug-drug, drug-disease state interactions

4) Assess and Initiate Therapy:

All therapies are equally effective for STI PEP. Choice of therapy should be based on patient safety, preference, availability, and cost.

- Doxycycline hyclate delayed release 200 mg (1 tab) - OR - Doxycycline hyclate or monohydrate immediate release 100 mg (2 tabs/caps taken simultaneously)
    - Doxycycline 200 mg should be taken ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sexual contact
    - Doxycycline can be taken as often as every day, depending on frequency of sexual activity, but individuals should not take more than 200 mg within a 24 hour period
    - Suggested maximum initial quantity: #30 doses of 200 mg; NO Refills
        - Adjust quantity on individual assessment through shared decision making (sexual contact frequency)

5) Complete Patient Encounter

Advise:

- Take doxycycline exactly and prescribed and only for its intended purpose.
- Seek advice from a medical care provider if STI symptoms develop despite use of STI PEP.
    - If diagnosed with an STI while using STI PEP, patient should be treated according to standard CDC STI Treatment Guidelines
- Potential side effects (phototoxicity, esophagitis and esophageal discomfort, gastrointestinal intolerance) and methods to mitigate side effects.
- Potential for development of antimicrobial resistance in other pathogens and commensals.

- Importance of separating the doxycycline dose by at least 2 hours from antacids and supplements that contain calcium, iron, magnesium or sodium bicarbonate.
- Consider checking CBC and LFTs annually, particularly in individuals with a history of liver disease.
- Counsel on risk reduction strategies including:
    - Condom use for every instance of sexual contact
    - Consideration of reducing the number of partners

Encourage:

- Vaccines which protect against sexually transmitted or sexually associated infections according to current local eligibility and ACIP Guidance
    - MPX Vaccine (Jynneos)
    - Meningococcal Vaccine (MenACWY)
    - Hepatitis A/ Hepatitis B
    - HPV

Document: All required elements

6) Monitoring and Continuation of Therapy

a. Refills of STI PEP provided upon evidence of negative STI testing at every 3-month intervals (maximum 6-month interval)
    - Provide patient lab order for routine STI screening at 3-month intervals: nucleic acid amplification test for gonorrhea and chlamydia at anatomic sites of exposure, and serologic testing for syphilis.
    - Patient may instead receive STI screening labs via another medical provider and submit results to pharmacy
        i. It is recommended to screen for HIV in HIV-negative patients. See Step 3 above. It is possible that patients are having labs collectively complete under order of another provider.

b. If no STI is currently present, prescribe refill for STI PEP.

Standardized Assessment and Treatment Care Pathway
Post-Exposure Prophylaxis for Bacterial STIs (STI PEP)

Medication considerations:

- ***Doxycycline:***
    - *Dose and directions*: Take 200 mg by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 200 mg per 24 hours.
    - *Warnings/Precautions*: Potential patient harm is associated with known side effects of taking doxycycline. It is well tolerated but may cause symptoms such as diarrhea and yeast infections. More rare side effects may include:
        - Intracranial hypertension (monitor for vision changes)
        - Skin reactions: Monitor for rash development
    - *Contraindications for doxycycline use: (consider other therapy)*
        - Patient age less than 8 years; may cause teeth discoloration
        - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other tetracyclines

References:

- Doxycycline. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Accessed January 5, 2024. http://www.micromedexsolutions.com
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial STI Prevention. https://www.cdc.gov/std/treatment/guidelines-for-doxycycline.htm Division of STD Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (accessed 1/5/2024)
    - Molina JM, Charreau I, Chidiac C, et al. Post-exposure prophylaxis with doxycycline to prevent sexually transmitted infections in men who have sex with men: an open-label randomised substudy of the ANRS IPERGAY trial. Lancet Infect Dis. 2018 Mar;18(3):308-317.
    - Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure doxycycline to prevent bacterial sexually transmitted infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306. DoxyPEP Reference (Conference Data- needs to be updated when paper available)
    - Jean-Michel Molina, Beatrice Bercot, Lambert Assoumou, Algarte-Genin Michele, Emma Rubenstein, Gilles Pialoux, et al. ANRS 174 DOXYVAC: An Open-Label Randomized Trial to Prevent STIs in MSM on PrEP. CROI [Internet]. 2023 Feb 19;Seattle, Washington. Available from: https://www.croiconference.org/abstract/anrs-174-doxyvac-an-open-label-randomized-trial-to-prevent-stis-in-msm-on-prep/
    - Stewart J, Oware K, Donnell D, Violette L, Odoyo J, Simoni J, et al. Self-reported adherence to event-driven doxycycline postexposure prophylaxis for sexually transmitted infection prevention among cisgender women. STI and HIV 2023 World Congress, Chicago, IL. 2023 Jul 24; Seattle, Washington. Available from: https://www.croiconference.org/abstract/doxycycline-postexposure-prophylaxis-for-prevention-of-stis-among-cisgender-women/
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention. https://www.regulations.gov/document/CDC-2023-0080-0002 Centers for Disease Control and Prevention, Regulations.gov (accessed 1/5/2024)
- Guidelines for the Use of Doxycycline Post Exposure Prophylaxis for Bacterial STI Prevention. https://www.youtube.com/watch?v=2hYvrrK_W58 Centers for Disease Control and Prevention (accessed 1/5/2024)
- Guidelines for the Use of Doxycycline Post-Exposure Prophylaxis for Bacterial Sexually Transmitted Infection (STI) Prevention; Request for Comment and Informational Presentation. https://www.federalregister.gov/documents/2023/10/02/2023-21725/guidelines-for-the-use-of-doxycycline-post-exposure-prophylaxis-for-bacterial-sexually-transmitted Centers for Disease Control and Prevention, FederalRegister.gov (accessed 1/5/2024)

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Optional -May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

Rx

Doxycycline (hyclate or monohydrate) 100mg tablets or capsules

Sig: Take 2 tablets/ capsules by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 2 tablets/capsules per 24 hours.

Quantity: 60

Refills: 0

-or-

Doxycycline hyclate **delayed release** 200 mg tablets

Sig: Take 1 tablet by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 1 tablet per 24 hours.

Quantity: 30

Refills: 0

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

Provider Notification
Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed STI Post-Exposure Prophylaxis (STI PEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) for a _____ day supply and follow-up STI testing is recommended in approximately _____ months _____/_____/_____ (Date)

This regimen consists of the following (check one):

- ☐ Doxycycline (hyclate or monohydrate) 100mg tablets or capsules
  - Take 2 tabs/caps by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 2 tabs/caps per 24 hours.
- ☐ Doxycycline hyclate delayed release 200 mg tablets
  - Take 1 tab by mouth as soon as possible within 72 hours after condomless oral, anal, or vaginal sex. Max 1 tab per 24 hours.

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• Syphilis/Treponemal antibody:	____/____/_____	☐ *reactive* ☐ *indeterminate* ☐ non-reactive	☐ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		☐ *Yes*

Urinalysis result:	Pharyngeal test result:	Rectal test result:
☐ *reactive* ☐ *indeterminate*	☐ *reactive* ☐ *indeterminate*	☐ *reactive* ☐ *indeterminate*
☐ non-reactive	☐ non-reactive	☐ non-reactive

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about STI PEP.*

Provider Pearls for STI PEP:

- STI PEP is prescribed for up to a 30-dose or approximately 90-day supply for each prescription to align with appropriate lab monitoring guidelines.
- An NIH-funded study found that doxycycline as STI Post-Exposure Prophylaxis (PEP) reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals taking HIV PrEP (Pre-Exposure Prophylaxis). Doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57% in people living with HIV (PLWH) (Source: N Engl J Med 2023; 388:1296-1306). This current efficacy data only applies to gay and bisexual men and other men who have sex with men (GBMSM) and transgender women; studies among heterosexual cis-gender women are ongoing.
- Patients using doxycycline as STI PEP should still engage in regular sexual health testing, including being screened for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV) every three (to six) months. If a person utilizing doxycycline as STI PEP is diagnosed with an STI, they should be treated according to the 2021 CDC STI treatment guidelines.
- Consider monitoring CBC and LFTs annually.

Pharmacist Monitoring of STI PEP and Transition of Care:

- The pharmacist prescribing and dispensing STI PEP conducts and/or reviews results of STI screen and testing as part of their patient assessment.
- Patients who test reactive or indeterminate for gonorrhea/chlamydia, or syphilis will be referred to your office for evaluation, diagnosis, and treatment. ☐ Patient declined baseline STI testing.
- Your office may take over management of this patient's STI PEP from the pharmacy at any time.

This prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

If you have additional questions, please contact the prescribing pharmacy. For information about STI PEP, please visit the CDC website.

Commented [ID1]: Suggest to allow doxy prescribing without baseline results. CDC guideline is "should". my opinion: benefits outweigh risks.

Commented [JD2]: Will insert hyperlink once available

Patient Information

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

To help prevent certain sexually transmitted bacterial infections (STI) like chlamydia, gonorrhea, and syphilis, you have been prescribed doxycycline. Listed below is the medication you have been prescribed and some key points to remember about this medication.

Medications:

- Doxycycline

Key Points:

What is STI PEP?

- STI PEP means taking the antibiotic doxycycline after sex, to prevent getting an STI. It is like a morning-after pill, but for STIs.
- An NIH-funded study published by the New England Journal of Medicine in April 2023 found that using doxycycline as STI PEP reduced syphilis by 87%, chlamydia by 88%, and gonorrhea by 55% in individuals also taking HIV PrEP (Pre-Exposure Prophylaxis). For people living with HIV, doxycycline as STI PEP reduced syphilis by 77%, chlamydia by 74%, and gonorrhea by 57%. This current data is specific to gay and bisexual men, and other men who have sex with men, and transgender women; studies among heterosexual cis-gender women are ongoing.
- If you use doxycycline as STI PEP, it's important to continue regular sexual health testing every three to six months for gonorrhea, chlamydia, syphilis, and HIV (if not known to be living with HIV). If you are using doxycycline as STI PEP and are diagnosed with an STI, you will need to follow treatment directions for that STI, which may include different antibiotics.

When should I take STI PEP?

- Doxycycline 200 mg should be taken ideally within 24 hours but no later than 72 hours after condomless sex. Condomless sex means oral, anal or vaginal/front-hole sex where a condom isn't used for the entire time.

What about when I have sex again?

- If you have sex again within 24 hours of taking doxycycline, take another dose 24 hours after your last dose. You can take doxycycline as often as every day when you are having condomless sex but don't take more than 200 mg every 24 hours.

How should I take doxy-PEP?

- Take doxycycline with plenty of water or something else to drink so that it does not get stuck when you swallow. If your stomach is upset by doxycycline, taking it with food may help.
- Avoid calcium, antacids, or multivitamins 2 hours before after taking doxycycline.
- Please do not share your doxycycline with others.

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

What are the possible side effects of doxycycline (STI PEP)?

- Some people are more sensitive to the sun when they take doxycycline, so wear sunscreen.
- Irritation to your esophagus (swallowing tube). If it occurs, alert your pharmacist or healthcare provider.
- Diarrhea is possible (it depends on how many doses per week you take). If severe or lasting more than a couple days, consult your pharmacist or healthcare provider.
- Yeast infections: Report any of the following presentations to your healthcare provider:
    - Mouth: white-colored patches and soreness
    - Penile-inverted vagina (front hole) of transgender women: white-colored, possibly malodorous discharge, and/or itching
    - Skin (skinfolds) or in the navel: bright-red rash, sometimes with breakdown of skin and small pustules, and itching
    - Anus: raw, white or red, and itchy
- Report any vision changes... it might be a sign of high pressure inside the skull.
- Other types of skin rashes... follow up with a medical provider immediately if this appears.

Reminders

- Call us if you run out of doxycycline, if you are having any side effects, or if you think you may have an STI. We may need to refer you to a different healthcare provider.
- Please continue to get tested for STIs every 3 months AND whenever you have STI symptoms.
- STI PEP doesn't protect against other viral infections like monkeypox or HIV.

Follow-up and Next Steps

1 . Make plans with pharmacy or a different healthcare provider to get STI screening every 3 months.

Resources used to create this document:

https://www.ncsddc.org/wp-content/uploads/2023/08/Doxycycline-as-STI-PEP-Toolkit-August-2023.pdf
https://www.sfcityclinic.org/sites/default/files/2023-02/Doxy-PEP%20info%20sheet%2012.9.22.pdf
Luetkemeyer AF, Donnell D, Dombrowski JC, et al. Postexposure doxycycline to prevent bacterial sexually transmitted infections. N Engl J Med. 2023 Apr 6;388(14):1296-1306.

Patient Information

Post-Exposure Prophylaxis Treatment for Bacterial STIs (STI PEP)

Pharmacy Name: _____Pharmacist Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

PREVENTIVE CARE

SHORT-ACTING OPIOID ANTAGONIST (SAOA)- NALOXONE / NALMEFENE

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.800 and ORS 689.802, a pharmacist may prescribe, distribute and administer a short-acting opioid antagonist (SAOA) and the necessary medical supplies to administer the SAOA. Per ORS 689.689, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in OAR 855-115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe a SAOA and the necessary medical supplies to administer the SAOA.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized SAOA Patient Intake Form *optional* (pg. X-X)
- Utilize the standardized SAOA Assessment and Treatment Care Pathway (pg. X-X)
- Utilize the standardized SAOA Prescription Template *optional* (pg. X-X)
- Utilize the standardized SAOA Provider Fax *optional* (pg. X)
- Utilize the standardized Patient Information (pg. X-X)

PRESCRIBING PARAMETERS

- No limitations exist for quantity or refills

RESOURCES:

Naloxone: Opioid Overdose, Prevention, Recognition & Response – Oregon State College of Pharmacy - CE. Accessed February 4, 2024. https://oregon-state-pharmacy-ce.catalog.instructure.com/courses/naloxone

Prescribe to Prevent – Prescribe naloxone, save a life. Accessed February 4, 2024. https://prescribetoprevent.org/

Oregon Health Authority. Pharmacist Prescribing of Naloxone. Accessed February 4, 2024. https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/toolkit/RPh-info-sheet.pdf

Oregon Health Authority. Naloxone Poster for Pharmacies. Accessed February 4, 2024. https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/toolkit/Naloxone-Poster.pdf

Stay Safe Oregon: Prescription Opioid Safety, Treatment & Information. Stay Safe Oregon. Accessed February 4, 2024. http://staysafeoregon.com/

SAMSHA Behavioral Health Treatment Services Locator. Accessed February 4, 2024. https://findtreatment.samhsa.gov/

Oregon Health Authority. Reducing Opioid Overdose and Misuse. Accessed February 4, 2024. https://www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/index.aspx

Oregon Health Authority. Training on Lifesaving Treatment Protocols. Accessed February 4, 2024. https://www.oregon.gov/oha/ph/ProviderPartnerResources/EMSTraumaSystems/Pages/epi-protocol-training.aspx#opioidoverdose

Commented [JD1]: SMEs requested that this document be optional and potentially not included in protocol package.

Commented [JD2]: SMEs requested that this document be optional and potentially not included in protocol package.

Optional- May be used by pharmacy if desired

Self-Screening Patient Intake Form – Short-acting Opioid Antagonist (e.g., naloxone, nalfemene)

CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Have you experienced an opioid overdose are you likely to experience an opioid overdose?	□ Yes □ No
2.	Are you a family member, friend, caregiver, or other person in a position to administer an opioid overdose drug to a person at risk of experiencing an opioid overdose?	□ Yes □ No
3.	Would you like to receive a short-acting opioid antagonist kit (e.g., naloxone, nalfemene)? If yes, how many doses would you like? _____	□ Yes □ No

Medical History:

4.	If known, does the individual that will receive naloxone allergic to it or have any known serious side effects to naloxone or nalfemene or any of their ingredients?	□ Yes □ No □ Not sure

Signature_____ Date_____

Assessment and Treatment Care Pathway- Short Acting Opioid Antagonists (SAOAs) Naloxone / Nalmefene

(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

1. Is the person or entity's representative requesting an opioid antagonist?		Notes:
☐ No. Do not prescribe, consider giving more information regarding opioid antagonists and opioid overdoses.	☐ Yes. Proceed to Step 2.	
2. Choose a product based on their preference or your professional discretion. Counsel and train appropriately. If appropriate, provide patient information with how to administer naloxone / nalmefene.		Notes:

AVAILABLE TREATMENT OPTIONS	
Naloxone	• Prepackaged intranasal naloxone 4 mg (Narcan®) or 8 mg (Kloxxado™). Dispensed as 2 unit-dose nasal spray devices per box. • Intramuscular naloxone 0.4 mg/mL SDV. Inject the contents of one vial intramuscularly into outer thigh for signs of opioid overdose. Must be dispensed with a 3 mL syringe with a 21-25 G x 1-1 ½ inch needle. • Intramuscular naloxone 5 mg/0.5 mL ready to use prefilled single dose syringe (Zimhi™). Dispensed as 2 syringes per box. Inject the contents of 1 syringe intramuscularly into outer thigh for signs of opioid overdose. • Intramuscular naloxone auto-injector (Evzio®) • Intranasal naloxone 2 mg/2 mL prefilled luer-lock syringe. Instructions for use: Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril. Must be dispensed with a Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe.
Nalmefene	• Prepackaged intranasal nalmefene 2.7 mg (Opvee®). Dispensed as 2 unit-dose nasal spray devices per box.

PRESCRIBING CONSIDERATIONS

- **Patient Characteristics:** Consider the patient's medical history, allergies, and any contraindications to specific formulations or delivery methods. Consider the patient's ability to administer the medication. For example, some formulations may be more user-friendly for bystanders.
- **Ease of Administration:** Evaluate the ease of use for both the patient and potential bystanders. Nasal spray formulations like Narcan® and Kloxxado™ are designed for easy administration without the need for special training.
- **Training and Familiarity:** Consider the level of training required for proper administration. Some formulations, like auto-injectors (e.g., Evzio®), provide step-by-step instructions, making them suitable for individuals without extensive medical training.
- **Onset of Action:** Different formulations may have varying onset times. Intramuscular (IM) naloxone may have a faster onset compared to intranasal formulations. Consider the urgency of the situation and the desired speed of response.
- **Storage and Stability:** Assess the storage requirements for each formulation. Some naloxone products may have specific temperature or storage conditions that need to be considered.
- **Cost and Accessibility:** Evaluate the cost and accessibility of different naloxone formulations. Some formulations may be more cost-effective or more widely available, which can impact patient access.

Assessment and Treatment Care Pathway- Short Acting Opioid Antagonists (SAOAs) Naloxone / Nalmefene

(CONFIDENTIAL-Protected Health Information)

- **Local Guidelines and Protocols:** Familiarize yourself with local and state guidelines regarding SAOA use. Some areas may have specific recommendations or requirements for the use of certain formulations.
- **Patient Preference:** Consider the patient's preference and comfort level with a specific formulation. Involving the patient in the decision-making process can enhance adherence.
- **Repeat Dosing:** Some formulations may require repeat dosing if the initial response is not sufficient. Providers should be aware of the dosing requirements for each formulation.
- **Patient Education:** Ensure that patients and potential bystanders receive proper education on the chosen naloxone formulation. Provide training materials, demonstrations, and clear instructions for use.

COUNSELING POINTS

- **Addressing Stigma and Building Trust**:
  - Start with empathy and non-judgmental language. Avoid terms like "addict" or "overdose victim," and instead use phrases like "person at risk of overdose" or "someone experiencing an opioid overdose."
  - Normalize the conversation. Explain that opioid misuse and overdose can happen to anyone, regardless of background or circumstance.
  - Focus on harm reduction. Explain that SAOAs are a tool for saving lives, not a guarantee of addiction recovery.
- **Explaining SAOAs and their Use:**
  - Clearly explain how SAOAs work. Describe how it quickly reverses the effects of opioids, restoring breathing and consciousness.
  - Demonstrate administration methods. Show patients how to use the specific product they are receiving, practicing with the nasal spray or auto-injector if available.
  - Emphasize calling 911 immediately after administering a SAOA. Explain that even after SAOAs, medical attention is crucial.
- **Addressing Concerns and Answering Questions:**
  - Anticipate and address common concerns. These might include potential side effects, dependence on SAOAs, or legal issues. Offer accurate and reassuring information.
  - Be prepared to answer specific questions. Be familiar with local resources for addiction treatment and support and connect patients with relevant information.
  - Validate potential hesitation and encourage further discussion. Let patients know you are available to answer questions and provide support at any time.
- **Additional Points:**
  - Offer training materials and resources. Provide patients with written instructions, video demonstrations, and contact information for crisis hotlines or support groups.
  - Encourage SAOAs for bystanders. Explain that anyone can carry SAOAs and save a life, regardless of their relationship to the person at risk.
  - Follow up with patients. Check in with patients who receive naloxone to see if they have any questions or need additional support.

PRESCRIBING PARAMETERS

- No limitations

TREATMENT CARE PLAN

- No documented follow-up required

Pharmacist Signature_____Date____/____/_____

Prescription- Short Acting Opioid Antagonists (e.g., naloxone, nalmefene)

Optional-May be used by pharmacy if desired (labeling not required for intranasal sprays)

Patient (or Entity) Name:	Date of birth (if applicable):
Address:	
City/State/Zip Code:	Phone number:

Rx

☐ **Prepackaged intranasal naloxone ☐ 4 mg (Narcan®) or ☐ 8 mg (Kloxxado™)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1. #___ doses, ___ refills

☐ **Intramuscular naloxone ☐ 0.4 mg/mL single dose vial (SDV) or ☐ 5 mg/0.5mL (Zimhi™) ready to use prefilled single dose syringe (SDS)**
- Inject the contents of one vial or syringe intramuscularly into outer thigh for signs of opioid overdose. Call 911. May repeat x1. #____ SDV or SDS, ____ refills
- Supplemental devices to dispense for single dose vial:
  - 3ml Syringe with a 21-25G ×1-1 1/2 inch needle
    - Use as directed for naloxone administration, #____, ____ refills

☐ **Intramuscular naloxone auto-injector (Evzio®)**
- Administer the dose from one auto-injector for signs of opioid overdose. Call 911. May repeat ×1., #____ auto-injectors, ____ refills

☐ **Intranasal naloxone** 2 mg/2 ml prefilled luer-lock syringe
- Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril for signs of opioid overdose. Call 911. May repeat ×1., #____ pre-filled syringes, ____refills
- Supplemental devices to dispense:
  - Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe
    - Use as directed for naloxone administration, #____, ____ refills

☐ **Prepackaged intranasal nalmefene 2.7 mg (Opvee®)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1. #__ doses, ____ refills

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____

_____

Optional- May be used by pharmacy if desired

Provider Notification
Short-acting Opioid Antagonist (SAOA)- Naloxone / Nalmefene

Pharmacy Name:_____ Pharmacist Name: _____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Patient Name:_____ DOB: ____/_____/_____ Age:_____

Healthcare Provider:_____ Phone: (____)_____-_____ Fax: (____)_____-_____

Your patient was seen at our pharmacy on ____/____/____ requesting a short-acting opioid antagonist (SAOA). During this visit, we carefully reviewed the patient's medical history, prescription history, and lifestyle factors to ensure the safety of all medications prescribed. Upon review it was determined that the patient could benefit from obtaining a SAOA. The following prescription(s) were provided to your patient:

☐ **Prepackaged intranasal naloxone ☐ 4 mg (Narcan®) or ☐ 8 mg (Kloxxado™)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1. #___ doses, ___ refills

☐ **Intramuscular naloxone ☐ 0.4 mg/mL single dose vial (SDV) or ☐ 5 mg/0.5mL (Zimhi™) ready to use prefilled single dose syringe (SDS)**
- Inject the contents of one vial or syringe intramuscularly into outer thigh for signs of opioid overdose. Call 911. May repeat x1. #____ SDV or SDS, ___ refills
- Supplemental devices to dispense:
  - 3ml Syringe with a 21-25G ×1-1 1/2 inch needle
    - Use as directed for naloxone administration, #___, ___ refills

☐ **Intramuscular naloxone auto-injector (Evzio®)**
- Administer the dose from one auto-injector for signs of opioid overdose. Call 911. May repeat ×1., #____ auto-injectors, ___ refills

☐ **Intranasal naloxone** 2 mg/2 ml prefilled luer-lock syringe
- Attach atomizer to naloxone syringe then spray one-half of the contents of syringe into each nostril for signs of opioid overdose. Call 911. May repeat ×1., #____ pre-filled syringes, ___ refills
- Supplemental devices to dispense:
  - Mucosal Atomization Device (example MAD300) compatible with the prefilled syringe
    - Use as directed for naloxone administration, #____, 0 refills

☐ **Prepackaged intranasal nalmefene 2.7 mg (Opvee®)**
- Administer one spray into one nostril for signs of opioid overdose. Call 911. May repeat ×1, #___doses, ___ refills

Commented [DJ*B1]: This is a starting point. Edit away. https://opvee.com/wp-content/uploads/2023/07/Combined-USPI_Patient-Info_IFU_Clean_05July2023.pdf

Provider Pearls for SAOAs:

- SAOAs should be administered promptly in suspected opioid overdose cases, even if the exact opioid involved is unknown.
- Repeat dosing may be necessary, as the duration of action for some opioids can outlast that of a SAOA. Close monitoring is crucial, and additional doses may be administered as needed.
- SAOAs are generally safe and well-tolerated, but withdrawal symptoms, including agitation and nausea, may occur in individuals who are opioid-dependent.
- Individuals who have been administered SAOAs should seek immediate medical attention, as the effects of the SAOA are temporary, and further medical assessment is essential.

This prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

OREGON STATE PUBLIC HEALTH DIVISION
EMS & Trauma Systems
Kate Brown, Governor

800 NE Oregon Street, Suite 465
Portland, OR 97232
Phone: 971-673-0520
Fax: 971-673-0555

October 6, 2017

For more information, contact David Lehrfeld, MD,
Medical Director, EMS & Trauma Systems:
(971) 673-0520

Opiate Overdose Treatment: Naloxone Training Protocol

As of October 6, 2017, training oversight is not required, although it is recommended that a healthcare professional or pharmacist be involved as needed for basic education on naloxone and overdose. As required per rule, a pharmacist provides patient counseling prior to dispensing naloxone.

I. Signs and symptoms of opiate overdose

The signs and symptoms of opiate overdose include:

- Unresponsiveness to yelling or stimulation, like rubbing your knuckles up and down the person's sternum, or breast bone (also called a sternum rub) [This symptom effectively draws the line between overdosing and being really high but not overdosing.]
- Slow, shallow, or no breathing
- Pulse (heartbeat) is slow, erratic, or not there at all
- Turning pale, blue or gray (especially lips and fingernails)
- Snoring/gurgling/choking sounds
- Body very limp
- Vomiting

II. Opiate overdose treatment overview

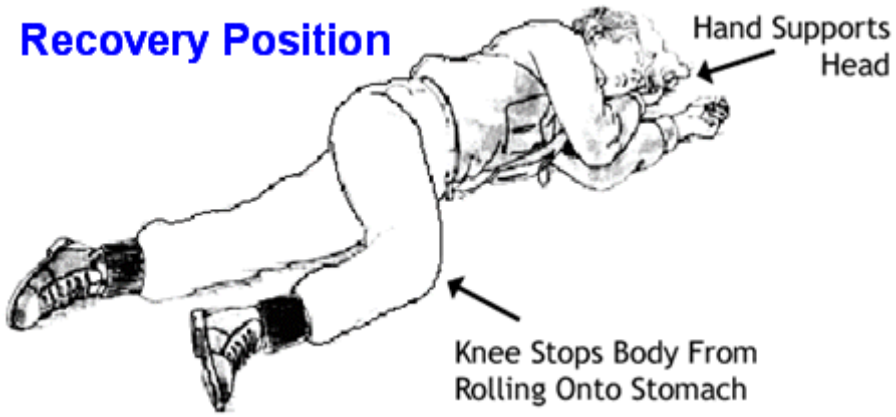
1. Check for a response.
2. Call 911.
3. Start chest compressions.
4. Administer naloxone.
5. Resume chest compressions with rescue breathing if the person has not yet started breathing.
6. Conduct follow-up – administer a second dose of naloxone if no response after 3 minutes and resume chest compressions with rescue breathing.
7. If naloxone is administered, provide details to emergency medical services.

III. Responding to an opiate overdose

1. **Check for responsiveness**.
   a. Yell.
   b. Give a sternum rub. Make a fist and rake your knuckles hard up and down the front of the person's sternum (breast bone). This is sometimes enough to wake the person up.
   c. Check for breathing. See if the person's chest rises and falls and put your ear near the person's face to listen and feel for breaths.
   d. If the person does not respond or is not breathing, proceed with the steps listed below.

2. **Call 911**. If you have to leave the person, put the person in the **recovery position.***
   a. State that someone is unconscious due to suspected overdose and indicate if the person is not breathing. (If you call police or 911 to get help for someone having a drug overdose, Oregon's Good Samaritan Law protects you from being arrested or prosecuted for drug-related charges or probation or parole violations based on information provided to emergency responders.)
   b. Give the address and location.
   c. Be aware that complications may arise in overdose cases. Naloxone only works on opiates, and the person may have overdosed on something else, e.g., alcohol or benzodiazepines. **Emergency medical services are critical.**

   ***Recovery position:**
      a. Roll the person over slightly on the person's side.
      b. Bend the top knee.
      c. Put the person's top hand under the person's head to support it.
      d. This position should keep the person from rolling onto his/her stomach or back, so the person does not choke if he/she vomits.



3. **(A) Start chest compressions with rescue breathing (CPR).**
   a. Place heel of one hand over center of person's chest.
   b. Place other hand on top of first hand, keeping elbows straight with shoulders directly above hands.
   c. Use body weight to push straight down, at least 2 inches, at rate of 100 compressions per minute.
   d. Give 2 breaths for every 30 compressions.
   e. CPR should be performed for 5 rounds (2 breaths for every 30 compressions), or for approximately 2 minutes, before reassessing.

Image courtesy of Nursing411.org

OR

(B) If overdose is witnessed, i.e., you see the person stop breathing, or you are sure it is overdose due to personal knowledge of the person or situation, you have the option to start rescue breathing. Be aware when you call 911 that they may instruct you to perform CPR as well.

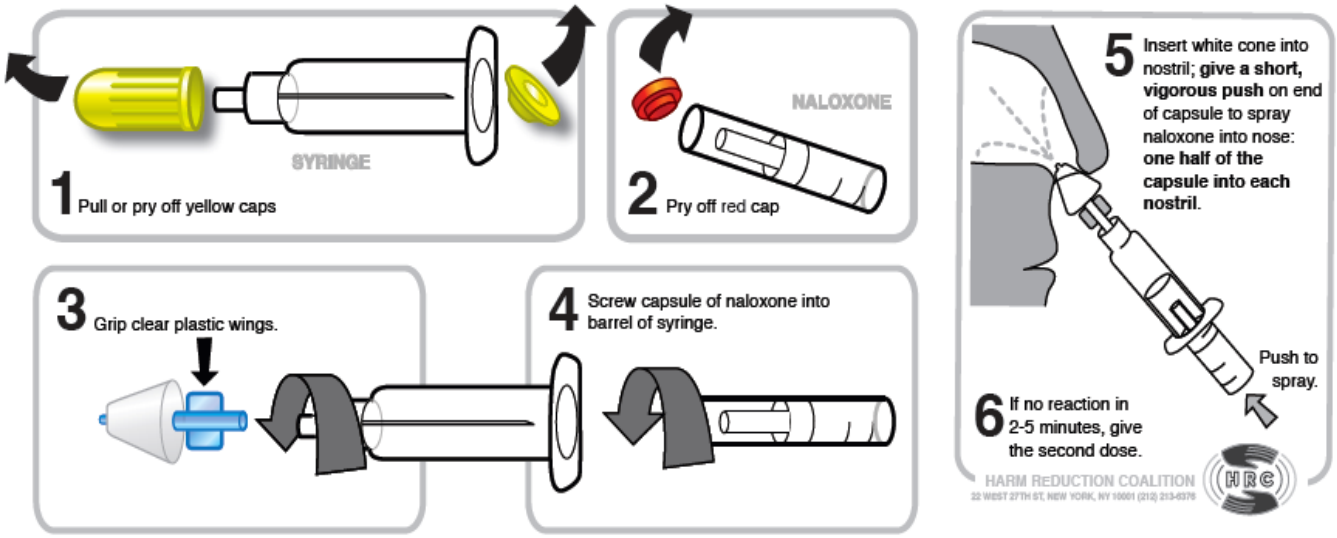
   a. Check the person's airway for obstructions and remove any obstructions that can be seen
   b. Tilt the person's forehead back and lift chin – see diagram below.
   c. Pinch the person's nose and give normal breaths – not quick and not overly powerful breaths.
   d. Give one breath every five seconds.
   e. Continue rescue breathing for approximately 30 seconds.

Image courtesy of Nursing411.org

4. **Administer naloxone**.
   If the patient has been receiving opioids, giving them naloxone may result in temporary withdrawal symptoms. This response can include abrupt waking up, vomiting, diarrhea, sweating, and agitated behavior. While these symptoms can be dramatic and unpleasant, they are not life threatening and will only last until the naloxone has worn off. See details about specific naloxone products below.

   a. **<u>If your naloxone kit is a syringe set up to be given as a nasal (nose) spray</u>**:

      1. Pull or pry off both top and bottom covers on the syringe.
      2. Pry off the cap of the naloxone capsule.
      3. Grip the clear plastic wings.
      4. Screw the naloxone cartridge into the barrel of syringe.
      5. Insert white cone into nostril; give a short vigorous push on the end of the naloxone cartridge to spray naloxone into the nose: one half of the cartridge goes into each nostril.
      6. If minimal or no response in 3 minutes, then give a second dose.



b. <u>If your naloxone kit is NARCAN® Nasal Spray</u>:

1. Peel back the package to remove the device
2. Hold the nozzle between two fingers as shown in image below.
3. Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.
4. Press the plunger firmly with thumb to release the dose into the patient's nose.
5. If minimal or no response in 3 minutes, then give a second dose.

NARCAN Nasal Spray: Peel back the package to remove the device

Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose

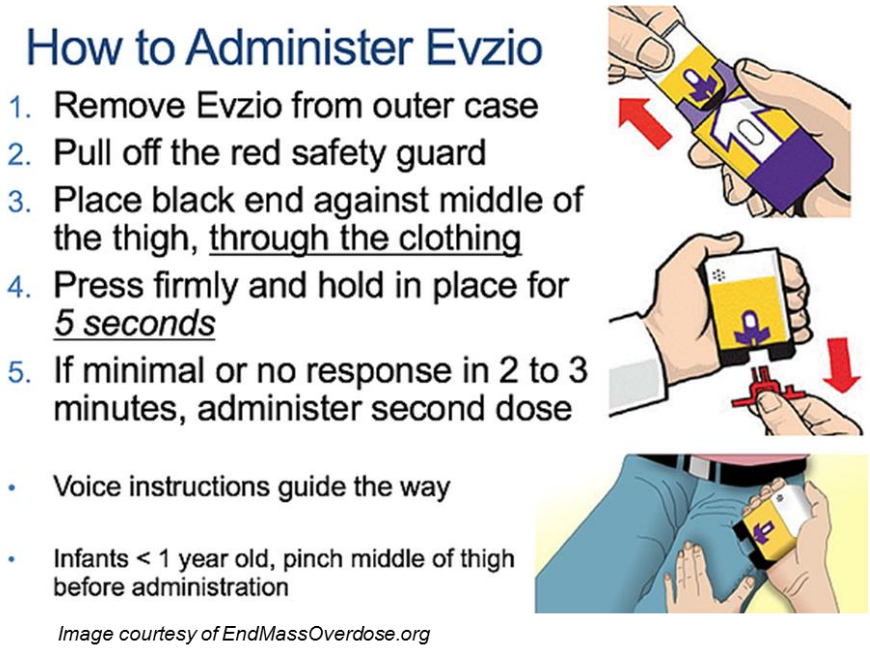
Press the plunger firmly to release the dose into the patient's nose

c. <u>If your naloxone kit is a syringe set up to be given as an injection into a muscle (intramuscular):</u>

1. Remove cap of the naloxone vial.
2. Draw up 1mL of naloxone into a syringe. (Ideally, the needle size for an injection into the muscle is 1 to 1.5-inches long and 25-gauge width)
3. If available, clean the area with an alcohol wipe before you inject.
4. Inject into muscle in the upper arm, thigh, or buttocks.
5. Insert the needle at a 90-degree angle to the skin and push in plunger.
6. If minimal or no response in 3 minutes, then give a second dose.

Image courtesy of the Chicago Recovery Alliance

d. <u>If your Naloxone kit is an Evzio® Injectable Device:</u>



5. **Resume chest compressions with rescue breathing (or chest compressions only) if the person has not yet started breathing.**
   Brain damage can occur after 3-5 minutes without oxygen. The naloxone may not kick in that quickly. You may have to perform CPR for the person until the naloxone takes effect or until emergency medical services arrive.

6. **Conduct follow-up**.
   a. Naloxone takes several minutes to kick in and wears off in 30-45 minutes. The person may go back into overdose after the naloxone wears off.
   b. It is recommended that you watch the person for at least an hour or until emergency medical services arrive, in case the person goes back into overdose.
   c. You may need to give the person more naloxone. Give a second dose if the person does not respond after 3 minutes.
   d. If an overdose victim revives, keep the person calm. Tell the person that drugs are still in his/her system and that the naloxone wears off in 30-45 minutes. Recommend that the person seek medical attention and assist him/her if necessary.
   e. Do not let the person use more opiates. The naloxone will block them and the person could overdose again after the naloxone wears off.

By signing this form, I acknowledge that I have read and understand the naloxone training protocol.

_____	_____	_____
Printed Name	Signature	Date

Name _____ Date _____
Address _____

℞

Refills _____ Pharmacist _____
Pharmacy Name / Address_____
_____

CONTINUATION OF THERAPY

Including Emergency Refills of Insulin

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Per ORS 689.696, a pharmacist may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies to a person who has evidence of a previous prescription from a licensed health care provider.

- Following all elements outlined in OAR 855-115-0345 ~~OAR 855-020-0110~~, a pharmacist licensed and located in Oregon may prescribe any non-controlled drug or device~~medication~~ to a person who has evidence of a previous prescription drug or device from a licensed health care provider in order to:
  - Replace a damaged* ~~-~~prescription ~~therapy~~ drug or device within the original duration of therapy; or
  - Extend a patient's current prescription ~~therapy~~ drug or device (same drug/device, dose and directions) to avoid interruption of treatment.

*The Pharmacist must use their reasonable professional judgment as defined by OAR 855-006-0005 to determine if the drug or device is damaged. This includes physical damage like broken containers or spills, chemical changes like discoloration or unusual odors, and damage from exposure to heat or moisture, which can affect the medication's effectiveness and safety.

Commented [JD1]: OAR 855-006-0005(46) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Continuation of Therapy Patient Intake Form (pg. 2)
- Utilize the standardized Continuation of Therapy Assessment and Treatment Care Pathway (pg. 3)
- Utilize the standardized Continuation of Therapy Prescription Template *optional* (pg. 4)
- Utilize the standardized Patient Informational Handout *optional* (pg. 5)
- Utilize the standardized Continuation of Therapy Provider Fax *optional* (pg. 6)

PRESCRIBING PARAMETERS

- **For Non-Insulin Medication, Medication Related Devices and Supplies:**
  - Quantity sufficient for the circumstances
  - Maximum quantity:
    - Damaged: May not exceed original duration of therapy
    - Extend: May not exceed a 60-day supply
  - Maximum frequency:
    - Damaged: No more than one replacement in a rolling 12-month period per medication
    - Extend: No more than two extensions in a rolling 12-month period per medication

- **For Insulin, Insulin Related Devices and Supplies (excluding pump devices):**
  - Quantity sufficient for the circumstances
  - Maximum quantity: Lesser of a 30-day supply or the smallest available package size
  - Maximum frequency: No more than three extensions in a calendar year (Jan 1- Dec 31)

PHARMACIST TRAINING/EDUCATION: None required.

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list: _____
Any allergies to foods (ex. menthol/soy)? Yes / No If yes, please list: _____
List of medicine(s) you take:_____
_____
_____

In addition to smoking, are you also currently using non-cigarette products (ie chewing tobacco, vaping, e-cigarettes, juul)? If yes, what products are you using and how much do you use in a day?
_____

Do you have a preferred tobacco cessation product you would like to use?_____
Have you tried quitting smoking in the past? If so, please describe: _____
What best describes how you have tried to stop smoking in the past?

- ☐ "Cold turkey"
- ☐ Tapering or slowly reducing the number of cigarettes you smoke a day
- ☐ Medicine
  - o Nicotine replacement (~~like~~ e.g. patches, gum, inhalers, lozenges, etc.)
  - o Prescription medications (e.g~~x~~. bupropion [Zyban®, Wellbutrin®], varenicline [Chantix®])
- ☐ Other_____

Health and History Screen – Background Information:

1.	Are you under 18 years old?	□ Yes □ No
2.	Are you pregnant, nursing, or planning on getting pregnant or nursing in the next 6 months?	□ Yes □ No □ Not sure
~~3.~~	~~Are you currently using and trying to quit non-cigarette products (ex. Chewing tobacco, vaping, e-cigarettes, Juul)?~~	~~□ Yes □ No~~

Commented [KLPBB1]: Removed to allow pharmacists to prescribe for dual users and added the question to the top section of the assessment.

Medical History:

34.	Have you ever had a heart attack, irregular heartbeat or angina, or chest pains in the past two weeks?	□ Yes □ No □ Not sure
45.	Do you have stomach ulcers?	□ Yes □ No □ Not sure
56.	Do you wear dentures or have TMJ (temporomandibular joint disease)?	□ Yes □ No □ Not sure
67.	Do you have a chronic nasal disorder (ex. nasal polyps, sinusitis, rhinitis)?	□ Yes □ No □ Not sure
~~8.~~	~~Do you have asthma or another chronic lung disorder (ex. COPD, emphysema, chronic bronchitis)?~~	~~□ Yes □ No □ Not sure~~

Commented [KLPBB2]: No longer relevant as NRT inhaler has been discontinued

Tobacco History:

79.	Do you smoke fewer than 10 cigarettes a day?	□ Yes □ No

Blood Pressure Reading _____/_____ mmHg (**Note: Must be taken by a pharmacist*)

STOP **Stop here if patient and pharmacist are considering nicotine replacement therapy or blood pressure is ≥ 160/100 mmHg.**

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

KEEP GOING

If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) and blood pressure is < 160/100mmHg continue to answer the questions below.

Medical History Continued:

8~~1~~	Have you ever had an eating disorder such as anorexia or bulimia?	□ Yes □ No □ Not sure
9~~1~~ ~~1.~~	Have you ever had a seizure, convulsion, significant head trauma, brain surgery, history of stroke, or a diagnosis of epilepsy?	□ Yes □ No □ Not sure
10.	Have you ever been diagnosed with chronic kidney disease?	□ Yes □ No □ Not sure
11.	Have you ever been diagnosed with liver disease?	□ Yes □ No □ Not sure
14 2.	Have you been diagnosed with or treated for a mental health illness in the past 2 years? (e.g~~x~~. depression, anxiety, bipolar disorder, schizophrenia)?	□ Yes □ No □ Not sure

Medication History:

15 3.	Do you take a monoamine oxidase inhibitor (MAOI) antidepressant? (e.g~~x~~. selegiline [Emsam®, Zelapar®], p~~P~~henelzine [Nardil®], i~~I~~socarboxazid [Marplan®], t~~T~~ranylcypromine [Parnate®], r~~R~~asagiline [Azilect®])	□ Yes □ No □ Not sure
14.	Do you take linezolid?	□ Yes □ No □ Not sure
15 ~~7~~.	Do you use alcohol or have you recently stopped taking sedatives? (e.g~~x~~. b~~B~~enzodiazepines)	□ Yes □ No □ Not sure

The Patient Health Questionnaire 2 (PHQ 2):

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3

Suicide Screening:

Over the last 2 weeks, how often have you had thoughts that you would be better off dead, or have you hurt yourself or had thoughts of hurting yourself in some way?	0	1	2	3

Patient Signature_____ Date_____

Tobacco Cessation Assessment & Treatment Care Pathway

STEP 1: Health and History Screen Part 1 Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	No = No Contraindicating Conditions (Continue to step 2)	Yes/Not sure = Contraindicating Conditions Refer	Refer to PCP and/or Oregon Quit Line 1-800-QUIT-NOW
~~**STEP 2: Health and History Screen Part 2**~~ ~~Review Tobacco Cessation Patient Questionnaire (Question 3)~~	~~Smoking Cigarettes.~~ ~~Continue to step 3~~	~~Yes to question 3~~ ~~Refer~~	~~Refer to Oregon Quit Line 1-800-QUIT-NOW to receive counseling and NRT~~
STEP 23: Blood Pressure Screen Take and document patient's current blood pressure. (nNote: RPh may choose to take a second reading if initial is high)	BP < 160/100 (Continue to step 4)	BP ≥ 160/100 Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW
STEP 34: Medical History Nicotine Replacement Therapy Questions (Questions 34-45)	No to question 4 and 5 (Continue to step 5)	Yes to question 4 and/or 5 Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW
STEP 45: Medical History Nicotine Replacement Therapy Questions (Questions 5-66-8) Question 56 = if Yes, avoid using nicotine gum Question 67 = if Yes, avoid using nicotine nasal spray ~~Question 8 = if Yes, avoid using nicotine inhaler~~	If patient wants NRT, prescribe NRT*	If patient wants bupropion or varenicline, continue to step 6	
Prescribing NRT*(pg.6): • Combination NRT is preferred (nNicotine patch + aAcute NRT) • Acute NRT = nNicotine gum, nNicotine lozenge, nNicotine nasal spray, ~~Nicotine inhaler~~	**Tobacco History (Question 9 on questionnaire)** If Yes to smoking ≤</=10 cigs/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If less than 20mg of nicotine per day), start with nicotine patch 14mg/day If No to smoking > 10 cigs/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If equal to or more than 20mg of nicotine per day) start with nicotine patch 21mg/day		
STEP 6: Medical History Bupropion and varenicline screening (Questions 8-12)~~10-14~~	Consider NRT* if yes to any question from 10-14 a) If yes to any question → avoid bupropion = If patient still wants bupropion, refer b) If yes to any questions from 12-14→ avoid varenicline - If patient still wants varenicline, refer If patient answered no to questions 10-~~,~~ 14, continue to step 7 If patient answered no to questions 12-14, but yes to question 10 and/or 11, AND wants varenicline (but not bupropion), skip to step 8	Refer Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW; NRT* can be considered
STEP 7: Medication History (Questions 13-15)~~15-17 on questionnaire.~~	If patient answered no to questions 15-17, review depression screening step 8	If patient answered yes to any question from 15-17 → aAvoid bupropion - Refer if patient still wants bupropion - If patient wants varenicline, continue to depression screening step 8 Refer	Refer to PCP if patient wants bupropion; NRT* can be considered
STEP 8: The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	If sScore < 3 on PHQ2. rReview Suicide Screening in step 9	~~Score~~ If score ≥ 3 on PHQ. aAvoid bupropion and varenicline and refer to PCP for treatment. NRT* can be offered. Refer	Refer to PCP; NRT* can be considered
STEP 9: Suicide Screening	If sScore of 0 on suicide screening, m May prescribe bupropion or varenicline	If sScore ≥ 1 on suicide screening, place **Immediate** referral to PCP Refer	Call PCP office to notify them of positive suicide screening and determine next steps. After hours, refer to suicide hotline 1-800-273-8255

Commented [KLPBB1]: Recommend removal of Step 2 which does not allow pharmacists to prescribe tobacco cessation for dual users

Commented [KLPBB2]: Removed as no longer available

Commented [KLPBB3]: Added in calculating total nicotine for dual users when prescribing NRT

Tobacco Cessation Assessment & Treatment Care Pathway

Prescribing Bupropion:	Prescribing Varenicline:
150mg SR daily for 3 days then 150mg SR twice daily for 8 weeks or longer. Quit day after day 7. Consider combining with n~~N~~icotine patch or n~~N~~icotine lozenge or n~~N~~icotine gum for increased efficacy.* For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.	0.5mg daily for 3 days then 0.5mg twice daily for 4 days then 1mg twice daily for 12 to 24 weeks. Quit day between days 8 and 35 after initiation of varenicline. ~~after day 7 or alternatively quit date up to 35 days after initiation of varenicline.~~ Generally not used in combination with other ~~smoking~~ tobacco cessation medications as first line therapy.

***Nicotine Replacement Dosing:**

	Dose
Long Acting NRT	
Nicotine Patches	• Patients smoking >10 cigarettes/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes, e-cigarettes, and chewing tobacco. If equal to or more than 20mg of nicotine per day ~~:~~ begin with 21mg/day for 6 weeks, followed by 14mg/day for 2 weeks, finish with 7mg/day for 2 weeks. • Patients smoking ≤ 10 cigarettes/day (if patient also uses e-cigarettes and/or chewing tobacco calculate patient's total daily nicotine including nicotine from cigarettes,e-cigarettes, and chewing tobacco. If less than 20mg of nicotine per day) ~~:~~ begin with 14mg/day for 6 weeks, followed by 7mg/day for 2 weeks. • **Note:** Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).
Acute NRT	
Nicotine Gum	• Chew 1 piece of gum when urge to smoke occurs. If strong or frequent cravings are present after 1 piece of gum, may use a second piece within the hour (do not continuously use one piece after the other). • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise, the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: Chew 1 piece of gum every 1 to 2 hours (maximum: 24 pieces/day); if using nicotine gum alone without nicotine patches, to increase chances of quitting, chew at least 9 pieces/day during the first 6 weeks o Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day) o Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day)
Nicotine Lozenges	• 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: 1 lozenge every 1 to 2 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day); if using nicotine lozenges alone without nicotine patches, to increase chances of quitting, use at least 9 lozenges/day during the first 6 weeks o Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) o Weeks 10 to 12: 1 lozenge every 4 to 8 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)
~~Nicotine Inhaler~~	~~• *Initial treatment*: 6 to 16 cartridges/day for up to 12 weeks; maximum: 16 cartridges/day~~ ~~• Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation.~~ ~~• *Discontinuation of therapy:* After initial treatment, gradually reduce daily dose over 6 to 12 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.~~
Nicotine Nasal Spray	• Initial: 1 to 2 doses/hour (each dose [2 sprays, one in each nostril] contains 1 mg of nicotine) • Adjust dose as needed based on patient response; do not exceed more than 5 doses (10 sprays) per hour [maximum: 40 mg/day (80 sprays)] or 3 months of treatment • If using nicotine nasal spray alone without nicotine patches, for best results, use at least the recommended minimum of 8 doses per day (less is likely to be effective). • Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation.

Commented [KLPBB4]: Changed the wording slightly to be more consistent with varenicline package insert.

Commented [KLPBB5]: Added in calculating total nicotine for dual users when prescribing NRT

Commented [KLPBB6]: Removed as inhaler has been discontinued

	• *Discontinuation of therapy:* Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.

Oregon licensed pharmacist must adhere to Prescribing Parameters, when issuing any prescription for tobacco cessation.

PRESCRIBING PARAMETERS:

- 1st prescription(s) up to 30 days
- Maximum duration = ~~12~~ 24 weeks
- Maximum frequency = 2x in a rolling 12-month period

TREATMENT CARE PLAN:

- Documented follow-up: within 7-21 days after patient starts tobacco cessation medication(s), phone consultation permitted

Medication Counseling Points

Long Acting NRT	
Nicotine Patches	• Local skin reactions (redness, rash, itching) • Sleep disturbances (abnormal dreams, insomnia)
Acute NRT	
Nicotine Gum	• Jaw soreness • Mouth and throat irritation • Hiccups • Nausea • Heart-burn • Lightheadedness/dizziness
Nicotine Lozenges	• Mouth and throat irritation • Hiccups • Nausea • Heart-burn • Lightheadedness/dizziness
Nicotine Nasal Spray	• Nasal or throat irritation (hot, peppery sensation) • Runny nose • Runny, itchy eyes • Sneezing • Cough • Headache
Other Agents	
Bupropion	• Insomnia • Dry mouth • Nausea • Anxiety • Constipation • Tremor • Rash
Varenicline	• Nausea • Sleep disturbances (abnormal dreams, insomnia) • Headache • Gas • Constipation • Altered taste

Managing Withdrawal from Tobacco Products

Commented [KLPBB7]: Should we recommend changing this from 12 weeks to 24 weeks as there is evidence for continuing both varenicline and bupropion beyond 12 weeks?

Commented [EP8R7]: Yes, seems like a great idea to me.

Commented [KLPBB9]: Added this to clarify the call to the patient is to be made after the patient starts the medication(s) as sometimes patient's don't start the medication right away.

Commented [EP10]: Added to serve as a quick reference for prescribing pharmacists

Commented [EP11]: Added to serve as a quick reference for prescribing pharmacists

Tobacco Cessation Assessment & Treatment Care Pathway

Anxiety	• Typically occurs within two days of last cigarette and lasts around two weeks • Take a walk or a hot bath • Limit caffeine • Use relaxation techniques (deep breathing, quiet time, etc.)
Depressed mood	• Can last weeks and usually resolves after a month • Engage in activities/hobbies that you enjoy • Spend time with family and friends
Hunger/weight gain	• Drink extra water or low-calorie beverages • Have low-calorie snacks available
Insomnia	• Variable and can last weeks to months • Limit caffeine • Use relaxation techniques (deep breathing, quiet time, etc.)
Irritability	• Generally peaks in the first week of stopping smoking and usually resolves in the first month • Take a walk or a hot bath • Limit caffeine • Use relaxation techniques (deep breathing, quiet time, etc.)
Nicotine cravings	• Can occur frequently for the first 2-3 days and last for months to years • Wait out the urge as able, it usually only lasts a few minutes • Avoid situation and activities that may trigger a craving • Increase activity • Do something to keep mind and hands busy (word search, crossword, some sort of craft, etc.) • Use relaxation techniques (deep breathing, quiet time, etc.)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Cover Page & Assessment and Treatment Care Pathway

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a Pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in ~~OAR 855-020-0110~~OAR 855-115-0330 and OAR 855-115-0335 a Pharmacist licensed and located in Oregon may prescribe and administer routine and travel vaccines in adherence with current CDC ACIP recommendations, CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases and CDC Yellow Book: Health Information for International Travel information.

Commented [JD1]: Will insert hyperlink once available.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized All Vaccines Assessment and Treatment Care Pathway (pg. 2)
- Utilize the Protocol for each specific vaccine to be administered
- Utilize the Protocol for Managing Adverse Reactions when applicable

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-019-0270.
- The Pharmacist maintains active CPR certification as outlined in OAR 855-019-0270.

RESOURCES:

CDC ACIP: Vaccine Recommendations and Guidelines- https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases- https://www.cdc.gov/vaccines/pubs/pinkbook/index.html

CDC Yellow Book 2024: Health Information for International Travel information- https://wwwnc.cdc.gov/travel/page/yellowbook-home~~https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020~~

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Adults- http://www.immunize.org/catg.d/p4065.pdf

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Children and Teens- http://www.immunize.org/catg.d/p4060.pdf

CDC Adult Immunization Schedule -https://www.cdc.gov/vaccines/schedules/hcp/adult.html

CDC Child and Adolescent immunization Schedule- https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

~~CDC Checklist for Determining Recommended Vaccines- http://www.cdc.gov/vaccines/hcp/adults/downloads/patient-intake-form.pdf DELETE THIS, REPLACE WITH IAC checklists above~~

Commented [NP2]: Delete this link and replace it with IAC checklists per this site: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
Prevaccination Screening Checklist
CDC is replacing the COVID-19 specific screening questionnaire these resources from Immunize.org that will help providers determine if a contraindication or precaution exists for all routinely recommended vaccines.

CDC Vaccine Information Statements - https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

Administering Vaccines to Adults: Dose, Route, Site, and Needle Size-https://www.immunize.org/catg.d/p3084.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

National Vaccine Errors Reporting Program (VERP)- https://www.ismp.org/form/verp-form

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Cover Page & Assessment and Treatment Care Pathway

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Gather information to screen for indications including age, health conditions, occupation, travel, and lifestyle
- Check the ALERT Immunization Information System (IIS). If ALERT is unavailable, use documentation and patient statement.
- Check patient health records and other records
- Gather information to screen for precautions and contraindications including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status

STEP 2: ASSESS

- Assess routine and travel vaccinations in adherence with current CDC ACIP recommendations, CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases and CDC Yellow Book: Health Information for International Travel information and each specific vaccine protocol
- Assess immunization needs based on age, health conditions, occupation, travel, and lifestyle indications
- Assess immunization history using IIS records, patient health records, and other sources of records to determine whether the patient needs this vaccine and any other vaccines
- Assess precautions and contraindications to needed vaccine(s) based on responses to screening questionnaire

STEP 3: PLAN

- Strongly recommend needed vaccine(s)
- Offer to administer vaccine or refer the patient to another immunizing health care provider

STEP 4: IMPLEMENT

- Provide current patient education and Vaccine Information Statements (VIS) and answer questions
- Prescribe and administer needed vaccine(s)
  - Verify needle length for injection.
  - To avoid injury related to vaccine administration, immunizer must recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.
- Provide documentation to patient and record all required data elements in the patient's permanent health record
- Report to ALERT Immunization Information System (IIS)

STEP 5: FOLLOW-UP

- Monitor patient for 15 minutes after administration of vaccine(s) for signs and symptoms of syncope, localized and/or generalized reactions
- Adverse Events Reporting
  - Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.
  - VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.
- Schedule follow-up for subsequent doses of multidose vaccine series
- Refer patient for other health, wellness, or follow-up services to their identified primary care provider or another provider (provide patient with documentation of referral)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110 a Pharmacist licensed and located in Oregon may prescribe and administer medications used in the management of adverse reactions following immunization in adherence with current CDC ACIP recommendations and Epidemiology, Prevention of Vaccine-Preventable Diseases (Pink Book), and CDC Yellow Book: Health Information for International Travel information.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Managing Adverse Events Assessment and Treatment Care Pathway (pg.2)
- Utilize Managing Adverse Events Protocol (pgs. 3-9)
- Utilize Adverse Event Record Tool (Appendix A) & Emergency Kit Medications & Equipment List (Appendix B)
- Refer to Recognizing & Responding to Anaphylaxis (Appendix C)

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-019-0270
- The Pharmacist maintains active CPR certification as outlined in OAR 855-019-0270

RESOURCES

CDC ACIP General Best Practice Guidelines: Preventing and Managing Adverse Reactions- https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book): Vaccine Administration- https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

Medical Management of Vaccine Reactions in Adults in a Community Setting- https://www.immunize.org/catg.d/p3082.pdf

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting- https://www.immunize.org/catg.d/p3082a.pdf

State of Oregon Trauma and EMS Systems. Treatment of severe allergic reaction; A Protocol for Training (2018). https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EMSTRAUMASYSTEMS/Documents/Training%20Material/Epinephrine-Training-Protocol.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Observe patient's signs and symptoms
- Obtain prepared Emergency Kit (E-Kit)

STEP 2: ASSESS

- Assess patient's blood pressure and vital signs
- Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips)
- Activate emergency response (Call 911) if signs and symptoms indicate progression towards anaphylaxis

STEP 3: PLAN

- Prepare treatment medications if indicated
- Prepare for CPR

STEP 4: IMPLEMENT

- Apply treatment plan and/or administer treatment medications per protocol
- If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately and apply AED if available

STEP 5: FOLLOW-UP

- Continue assessing vitals and monitor per protocol until Emergency Medical Services arrive
- Document actions using Adverse Event Record Tool
- Report anaphylaxis and vasovagal syncope to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.
- VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.

Event and Interval From Vaccination
A. Anaphylaxis or anaphylactic shock (7 days) B. Vasovagal syncope (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Any acute complication or sequelae (including death) of above events (interval – not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

1. What's New

A. N/A

2. Anaphylaxis Protocol (Generalized Symptoms)

A. If symptoms are generalized, call 9-1-1 immediately. This should be done by a second person if available, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Do not delay transport; DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.
B. Keep patient in recumbent position (flat on back) unless patient is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
C. Take and record the patients' blood pressure and vital signs (pulse, respirations) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any medication.
D. The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
E. Administer 1mg/mL epinephrine intramuscularly (IM) into the anterolateral thigh (all ages), through clothing if necessary, with the correct needle length for the patient's age and size according to the dosage chart in Table 1.
F. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
G. Complete the Adverse Event Record Tool.
H. If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately. Apply AED if available.
I. Monitor until Emergency Medical Services arrive.
J. Any patient who develops signs and symptoms of anaphylaxis MUST be transported via a fully equipped emergency vehicle to an emergency department. Any refusal of transport must be handled by EMS personnel.
K. Give report and list of medications given to emergency medical personnel upon arrival.
L. Medication Schedule: *See Table 1 on next page*

Table 1: Anaphylaxis

Inject EPINEPHRINE (1mg/mL): 0.01 mg/kg of body weight up to 0.5mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.
Give intramuscularly (IM) in the vastus lateralis muscle of the thigh, regardless of age, either by auto injector or by syringe and needle, through the clothing if necessary. [1]

Suggested dosing of Epinephrine for children[2] and adults: consider needle length				
Age Group	**Weight in lb[#]**	**Weight in kg[#]**	**Epinephrine injectable (1:1000 dilution); IM =(1mg/mL) [Minimum dose: 0.05mL]**	**Epinephrine auto–injector 0.1mg (7.5-14.5 kg), 0.15mg (15-29.5 kg) or 0.3 mg (≥30 kg)**
6 months (use only for dosing by weight)	9-16 lb	4-7 kg	0.05 mL (or mg)	Off-Label
	16.5-19 lb	7.5-8.5 kg		0.1mg/dose[*]
7-36 months (use only for dosing by weight)	20-32 lb	9-14.5 kg	0.1 mL (or mg)	0.1mg/dose[*]
37-59 months	33-39 lb	15-17.5 kg	0.15 mL (or mg)	0.15mg/dose
5-7 years	40–56 lb	18–25.5 kg	0.25 mL (or mg)	0.15mg/dose
8–10 years	57–76 lb	26–34.5 kg	0.3 mL† (or mg)	0.15 mg/dose or 0.3mg/dose
11–12 years	77–99 lb	35–45.5 kg	0.4 mL (or mg)	0.3mg/dose
≥13 years	100+ lb	46+ kg	0.5 mL‡ (or mg)	0.3mg/dose

[#]Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months. Round kg to nearest 0.5 kg.

[*] The 0.15mg epinephrine autoinjector can also be used for children 7.5 kg (16.5 lb) to 14.5 kg (32 lb) when other alternatives are not available.

†Maximum dose for children (prepubertal)[1]

‡Maximum dose for adolescents and adults[1]

3. Urticaria Protocol (Localized Symptoms)

A. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
B. Apply ice to the site where the vaccine was administered. If more than one site is involved, apply ice to the sites that appear to be red, warm, or swelling.
C. Administer diphenhydramine intramuscularly (IM) with the correct needle length for the patient's age and size according to the dosage chart in Table 2.
D. Administer hydroxyzine hydrochloride orally if diphenhydramine unavailable according to patient's age and size in the dosage chart in Table 3.
E. Complete the Adverse Event Record Tool.
F. Take and record the patient's blood pressure and vital signs at the initial assessment, and at minimum - every 10 minutes, and following the administration of any additional medication.

G. Continue to monitor for and treat signs and symptoms progressing towards anaphylaxis when indicated. If signs and symptoms present, immediately initiate anaphylaxis protocol.

H. Medication Schedule:

Table 2: Urticaria

First-Line Treatment for Urticaria: Give Diphenhydramine IM as follows:			
Suggested dosing of Diphenhydramine for children[2] and adults			
Age Group Dose	**Weight in lbs[#]**	**Weight in kg[#]**	**Injectable: 50mg/mL IM[†]**
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	5-10 mg (0.1 - 0.2 mL)
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	10-15 mg (0.2 - 0.3 mL)
37-59 months	33-39 lbs	15-17.5 kg	15-20 mg (0.3 - 0.4 mL)
5-7 years	40–56 lbs	18–25.5 kg	20–25 mg (0.4 - 0.5 mL)
8–12 years	57−99 lbs	26−45.5 kg	25–50 mg (0.5 - 1.0 mL)
≥13 years[‡]	100+ lbs	46+ kg	50 –100 mg (1 - 2 mL)[*]

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 1-2mg/kg

[‡] Maximum single dose is 100mg for persons ≥13 years[2-3]

[*] No more than 1 mL per injection site

Table 3: Optional Treatment: Hydroxyzine Hydrochloride

Hydroxyzine Hydrochloride for urticaria when Diphenhydramine is unavailable: Give PO as follows:			
Suggested dosing of Hydroxyzine Hydrochloride for children[2] and adults			
Age Group Dose	**Weight in lbs[#]**	**Weight in Kg[#]**	**Liquid: 10mg/5mL or 25mg/5mL[†]**
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	2.5-5 mg/dose
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	5-7.5 mg/dose
37-59 months	33-39 lbs	15-17.5 kg	7.5-10 mg/dose
5-7 years	40–56 lbs	18–25.5 kg	10-12.5 mg/dose
8–10 years	57−76 lbs	26−34.5 kg	12.5–15 mg/dose
11–12 years	77–99 lbs	35–45.5 kg	15–25 mg/dose
≥13 years	≥100 lbs	≥46 kg	25 mg/dose

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 0.5-1 mg/kg

[*] Maximum single dose is 25mg for persons ≥13 years[2-3]

4. Loss of Consciousness/Syncope Protocol

A. If the individual "feels faint", ammonia ampules should be used if available. Crush and wave near patient's nose.
B. Have patient lie flat with feet elevated or sit with their head down for several minutes.
C. If the patient loses consciousness, place flat on back, with feet elevated.
D. Unconsciousness from fainting should only last seconds. In a vasovagal response, the pulse should be slow. A weak, thready or rapid pulse may indicate anaphylaxis. Continue to monitor for signs and symptoms progressing towards anaphylaxis. If signs and symptoms present, immediately initiate anaphylaxis protocol.
E. Have patient rest in a quiet area for 10 minutes after regaining consciousness. Slowly have patient move to a sitting position and then standing, checking to make sure no symptoms recur.
F. Complete the Adverse Event Record Tool.

5. Contraindications

A. There are **no** contraindications for the use of epinephrine to treat anaphylaxis
B. Previous hypersensitivity is a contraindication for diphenhydramine and hydroxyzine.
C. Do not administer epinephrine auto-injector to children weighing less than 16.5 lbs.

6. Other Considerations

A. Required Documentation:
- Current Healthcare Provider CPR Card as required by OAR 855-019-0270
- Completed Adverse Event Record Tool for each event (Appendix A).

B. Required Medications & Equipment: See Emergency Kit Medications & Equipment List (Appendix B)

7. Storage and Handling

A. Store medications according to OAR 855-041-1036.

8. Adverse Events Reporting

A. Anaphylaxis and vasovagal syncope must be reported to the Vaccine Adverse Events Reporting System (VAERS) online at: https://vaers.hhs.gov/reportevent.html.
B. VAERS Table of Reportable Events Following Vaccination: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

9. References

1. CDC. Management of Anaphylaxis at a COVID-19 Vaccination Location. Last updated 11 February 2022. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html Accessed 23 August 2022.
2. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting. July 2019. Available at: https://www.immunize.org/catg.d/p3082a.pdf. Accessed 23 August 2022.
3. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Adults in a Community Setting. July 2019. Available at: https://www.immunize.org/catg.d/p3082.pdf. Accessed 23 August 2022.

10. Appendix

A. Adverse Event Record Tool
B. Emergency Kit Medications & Equipment
C. Recognizing & Responding to Anaphylaxis Reference

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

APPENDIX A: Adverse Event Record Tool

Patient Name: _____ Allergies: _____
Date of Birth: _____ Vaccine(s) Given: _____
Date: _____ Site(s):_____
Pharmacist: _____ Route(s): _____
Patient is displaying signs of: Anaphylaxis – Urticaria – Syncope (Circle One)

VITALS							
Time	**Pulse**	**Respirations**	**Blood Pressure**	**Medication**	**Dose**	**Site–Route**	**Initials**

Notes:

APPENDIX B: Emergency Kit Medications & Equipment List

Required Medications & Equipment	**Quantity/Type**	**Expiration Date**	**Optional Medications & Equipment**	**Quantity/ Type**	**Expiration Date**
Epinephrine solutions	**1** multi-dose vial (MDV) of 1mg/mL Epinephrine **OR** Epinephrine auto-injectors; **3** doses each of adult and pediatric size units		Hydroxyzine Hydrochloride for use when Diphenhydramine is unavailable	Liquid: 10 mg/5 mL or 25 mg/5 mL Tablets: 10 mg or 25 mg Capsules: 25 mg	
Diphenhydramine 50 mg/mL injectable	**1** multi-dose vial (MDV) **OR 2** single-dose vials (SDV) vials		Bottle of water for swallowing oral antihistamines		
Blood Pressure Monitor (regular adult and large adult cuff size required; ~~with~~ pediatric cuff if applicable)	Automated devices must show current calibration and replace batteries as needed		Sphygmomanometer and Stethoscope (regular adult and large adult cuff size required; ~~with~~ pediatric cuff if applicable)		
Syringes/Needles	For Epinephrine injection only: 1-cc syringes with 22–25g, 1-1½" needles For Diphenhydramine injection only: 1-3-cc syringes with 22-25g, 1–1½" needles		Ammonia Ampules	**1** Box	
Standard injection supplies	N/A				

Commented [CS1]: Introducing more clarity regarding cuff size. Regular and large adult required; pediatric cuff if applicable.

APPENDIX C:

Recognizing and Responding to Anaphylaxis

How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system.**

Respiratory:
- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough

Gastrointestinal:
- nausea
- vomiting
- diarrhea
- abdominal pain

Cardiovascular:
- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)

Skin/mucosal:
- generalized hives
- itching
- swelling of lips, face, or throat

Neurological:
- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

What to do if you suspect anaphylaxis

Assess airway, breathing, and circulation

Administer epinephrine

Call Emergency Medical Services (EMS)

Place in supine position

Detailed information can be found in the Interim Considerations:
Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination

www.cdc.gov/COVID19

CS322867-A | 03/1/21

Protocol for Coronavirus 19 Vaccines
(Pfizer-BioNTech, Moderna, Novavax)

1. What's New

A. There is a new formulation of COVID-19 Vaccine (Comirnaty by Pfizer) that comes in a pre-filled single dose glass syringe. The glass syringe is stored in the refrigerator and can not be frozen.

~~A.~~B. ACIP no longer categorizes Pfizer and Moderna as preferred Coronavirus 19 (COVID-19) vaccines for the 2023-2024 season. Individuals ages 12 years and older may receive either the 2023-2024 mRNA (Moderna of Pfizer) or the 2023-2024 adjuvanted (Novavax) vaccine, as appropriate.

2. Immunization Protocol

A. Administer a dose of updated 2023–2024 Pfizer, Moderna, or Novavax COVID-19 vaccine according to ACIP recommendations and the vaccine package insert. See section 3 for vaccine volume and spacing based on age and vaccine formulation.[1-5]

B. COVID-19 vaccine may be administered concomitantly with other vaccines. There is no need to separate COVID-19 vaccine from other vaccinations by 2 weeks.

3. Vaccine Schedule[1-3]

A. Any immunocompetent person 7-11 years of age who has received at least 1 dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine is currently up-to-date.[6]

B. Any immunocompetent person ≥12 years of age who has received at least 1 dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine OR who is previously vaccinated* and has received at least 1 dose of adjuvanted (Novavax) 2023-2024 COVID-19 vaccine is currently up-to-date.[5]

C. Any immunocompetent unvaccinated person 7-11 years of age may be brought up-to-date with a single dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine.[6]

D. Any Immunocompetent unvaccinated persons ≥12 years of age may be brought up-to-date with a single dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine OR a two dose series of updated adjuvanted (Novavax) 2023-2024 COVID-19 vaccine.[5,6]

E. The PREP Act currently allows pharmacists to administer COVID-19 vaccines to persons aged 3-18 years old through 12/31/24.[2] Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.

*Previously vaccinated indicates the individual has received 1 or more doses of any mRNA vaccine; 1 or more doses of Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses.

PFIZER[1,3]

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 3 mcg, IM (yellow cap and border). ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Unvaccinated children 3-4 years of age*		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	3-4 years of age (<5 years)	
2		3 weeks
3		8 weeks

*Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 vaccine, supplied in vials with yellow caps and borders.[1]

Children 3-4 years of age previously vaccinated with Pfizer vaccine, any formulation ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 dose	2 doses 2023-2024 Pfizer	3 weeks after last dose
2 or more doses	1 dose 2023-2024 Pfizer	8 weeks after last dose

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 10 mcg, IM (blue cap and border) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years of age	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Pfizer 2023-2024 mRNA vaccine (COMIRNATY®) Dose and Route – 0.3-mL, 30 mcg, IM (gray cap and border or pre-filled syringe)[3]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1*	≥ 12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

MODERNA[2,4]

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border)[2]		
Unvaccinated children 3-4 years of age ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	6 months-4 years (<5 years)	
2*		28 days

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Immunocompromised children may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

Children 3-4 years previously vaccinated with Moderna COVID-19 vaccine, any formulation[2] ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Spacing**
1 dose	1 dose 2023-2024 Moderna (0.25mL, dark blue cap and green border)	4 weeks after last dose*
2 or more doses	1 dose 2023-2024 Moderna (0.25 mL, dark blue cap, green border)	8 weeks after last dose*

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Unvaccinated children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years (<12 years)	

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children 5-11 years of age previously vaccinated with Moderna COVID-19 vaccine, any formulation ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Spacing**
1 or more doses	1 dose 2023-2024 Moderna* (0.25mL, dark blue cap and green border)	8 weeks after last dose

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 mRNA vaccine (SPIKEVAX®) Dose and Route – 0.5-mL, 50 mcg, IM (dark blue cap and border)[4]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1*	≥ 12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

* Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

NOVAVAX[5]

Novavax 2023-2024 adjuvanted vaccine Dose and Route –0.5-mL, 5 mcg, IM (dark blue cap, light blue on label)		
Unvaccinated children ≥ 12 and adults		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥12 years	
2		21 days

Children ≥ 12 and adults previously vaccinated with COVID-19 vaccine		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 or more doses (any original monovalent or bivalent COVID-19 vaccine)	1 dose 2023–24 Novavax*	8 weeks after last dose

*Immunocompromised persons may receive an additional dose of Novavax COVID-19 vaccine at least two months following the last dose of 2023-2024 COVID-19 vaccine. Additional doses of 2023-2024 Novavax COVID-19 vaccine may be administered sat the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Cap/Label Color**
Pfizer 2023-2024 formulation[1]	mRNA	0.9 mL, 3 dose vial 0.3 mL, single dose vial	3-4 years 5-11 years	Yellow Cap Blue Cap
Pfizer COMIRNATY®[3] 2023-2024 formulation	mRNA	0.3 mL, single dose vial 0.3 mL, prefilled syringe	≥ 12 years	Gray Cap
Moderna 2023-2024 formulation[2]	mRNA	0.25 mL, single dose vial	3-11 years	Blue Cap/Green Label
Moderna SPIKEVAX® 2023-2024 formulation[4]	mRNA	2.5 mL, 5 dose vial 0.5 mL, single dose vial 0.5 mL, prefilled syringe	≥ 12 years	Blue Cap/Blue Label
NVX-CoV2373[3] (NOVAVAX® 2023-2024 formulation)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years	Royal Blue Cap

5. Recommendations for Use[1-7]

A. An updated, 2023–2024 mRNA COVID-19 vaccine dose should be offered to all persons aged ≥ 7 years. For adults and children ≥12 years of age, a 2023-2024 protein subunit (Novavax) vaccine may be used.
B. For a primary series, COVID-19 vaccines are not routinely interchangeable. When multiple doses are indicated (i.e. in unvaccinated children), the same vaccine brand should be used. In exceptional situations in which an mRNA vaccine series was begun, but the particular product administered for previous doses is not available, the other mRNA COVID-19 vaccine may be administered to complete the primary vaccine series.
C. Doses for adults and immunocompromised persons ≥7 years of age may be any authorized product.
D. Children ≤11 years of age with immune compromise require a 3-dose primary series. All three doses should be the same vaccine brand. At least one dose should be of the 2023–24 COVID-19 vaccine.[1,2]
E. For all persons with immune compromise, additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.[7]
F. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.
G. Conditions causing moderate to severe immunodeficiency include:
    - Active treatment for solid tumor and hematologic malignancies
    - Receipt of solid-organ transplant and taking immunosuppressive therapy
    - Receipt of Chimeric antigen receptor (CAR)-T-cell or hematopoietic cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy
    - Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
    - Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
    - Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day)
    - Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-5]

Vaccine	Contains
Pfizer 2023-2024 formulation[1] (yellow cap and border)[1]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N itetradecylacetamide, 0.01 mg 1,2-distearoyl-snglycero-3-phosphocholine, and 0.02 mg cholesterol), 9.4 mg sucrose, 0.02 mg tromethamine, and 0.12 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.88 mg sodium chloride per dose.
Pfizer 2023-2024 formulation[1] (blue cap and border)	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-

	2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2- distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 31 mg sucrose, 0.06 mg tromethamine, and 0.4 mg tromethamine hydrochloride.
Pfizer COMIRNATY® 2023-2024 formulation[3] (gray cap and border)	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate),0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose
Moderna 2023-2024 formulation[2] (dark blue cap and green border)	Total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.
Moderna SPIKEVAX® 2023-2024 formulation[4] (dark blue cap and border)	Total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.
NVA-CoV2373 (NOVAVAX® 2023-2024 formulation)[5]	Cholesterol, phosphatidylcholine, potassium dihydrogen phosphate (3.85 µg), potassium chloride (2.25 µg), disodium hydrogen phosphate dihydrate (14.7 µg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.766 mg) and polysorbate 80 (0.050 mg). The vaccine contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus infected Sf9 (fall armyworm) insect cells and Matrix-M™ adjuvant is composed of Fraction-A (42.5 µg) and Fraction-C (7.5 µg) of saponin extracts from the soapbark tree, Quillaja saponaria Molina. The pH is adjusted with sodium hydroxide or hydrochloric acid.

7. Warnings and Precautions[7]

A. History of severe allergic reaction (e.g. anaphylaxis) to any other vaccine or injectable therapy (e.g. intravenous, intramuscular or subcutaneous).

B. Persons who have a contraindication to additional doses of mRNA COVID-19 vaccines are considered to have a precaution to the Novavax vaccine. A single dose may be given in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. This additional dose could be considered after a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. See Appendix A for additional information.

C. Moderate or severe acute illness.

8. Other Considerations[7]

A. Patients with known COVID-19 infection should wait until their symptoms have resolved and criteria have been met to discontinue isolation. Persons who have a history of COVID-19

disease should be vaccinated if otherwise indicated. If desired, persons with acute COVID-19 may wait up to 90 days to receive vaccination, as reinfection within 90 days is uncommon. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

B. Patients who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.
C. Patients with a known community or outpatient setting COVID-19 exposure should wait until the end of their quarantine period before seeking vaccination to avoid potentially exposing healthcare personnel.
D. Patients who have been exposed to COVID-19 living in congregate settings, including long-term care, homeless shelters, or correctional institutions, where exposure or transmission can occur repeatedly over a long period of time may be vaccinated without completing a quarantine period.
E. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Patients with a history of severe allergic reactions should be asked to remain for 30 minutes.
F. CDC recommends that vaccine for children aged 5–17 years of age with history of Multisystem Inflammatory Syndrome of Children (MIS-C) be delayed for 90 days after their diagnosis of MIS-C. Providers should inform patients that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.
G. COVID-19 vaccination is recommended for all people of childbearing age, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
H. Persons who are trying to become pregnant do not need to avoid pregnancy after receiving COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.
I. Persons with underlying medical conditions who have no contraindications may receive COVID-19 vaccine.
J. Children 3 years through 4 years of age should complete a multi-dose initial series (2 doses of Moderna vaccine or 3 doses of Pfizer vaccine) with at least one dose of the 2023–2024 COVID-19 mRNA vaccines. Doses for adults and immunocompromised persons ≥5 years of age may receive any age-appropriate authorized product.

9. Side Effects and Adverse Reactions

A. COVID-19 vaccines appear to be more reactogenic than most. Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12-24 hours.

Pfizer[1,3] and Moderna[2,4] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 93%
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Up to 16%
Lymphadenopathy*	Up to 20%

Serious adverse events	Uncommon, up to 1% (similar to placebo group)

Novavax[5] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 82%
Systemic events (fatigue, muscle pain, headache, nausea)	Very common, up to 62%
Fever	Uncommon, up to 6%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. For Pfizer vaccine only: thaw, if needed. The single dose pre-filled glass syringe (COMIRNATY) CAN NOT be frozen and stored in the refrigerator. The yellow cap formulation requires reconstitution; the blue and gray cap formulations are ready to administer.[1,3]

C. For Moderna vaccine only: thaw vaccine prior to administration.[2,4]

Vaccine	**Temp**	**Storage Issues**	**Notes**
Pfizer[1,3]	-90° to -60° C (-130° to -76° F)	Vaccine may be stored until the expiration date.	Do not freeze the single dose pre filled glass syringe (discard if frozen)
	2° to 8° C (36° to 46° F)	**Adolescent/adult 2023-2024~~bivalent~~ formulation (blue or gray cap vial OR single dose pre-filled plastic pre-filled syringe):** store in the refrigerator for up to 10 weeks	
		Pediatric formulation (yellow cap): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
		Adolescent/adult 2023-2024~~bivalent~~ formulation (single dose pre-filled glass syringe): Store in the refrigerator for up to 6 months	Do not freeze the single dose pre ~~filled glass~~filled glass syringe (discard if frozen)
	Ambient temperatures	**Adolescent/adult 2023-2024~~bivalent~~ formulation (blue or gray cap vial OR~~or~~ single dose pre-filled glass syringe OR single dose pre-filled plastic syringe):** vaccine may be held at room temperature for up to 12 hours	Any unused vaccine should be discarded.
		Pediatric 2023-2024~~bivalent~~ formulations (yellow cap): once mixed, vaccine may be held at	

		room temperature for up to 12 hours	
Moderna[2,4]	-50° to -15° C (-58° to 5° F)	Vaccine is viable until the expiration date.	For multi-dose vials, once stopper has been punctured, all doses must be used within 12 hours. Do not refreeze once thawed. Protect vaccine from light.
	2° to 8° C (36° to 46° F)	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vials of vaccine is viable for up to 24 hours at room temperature	
Novavax[5]	2°– 8°C (36° to 46° F)	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at www.novavaxcovidvaccine.com enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C (36° to 77° F) for use within 12 hours. Discard the vial 12 hours after first puncture. Do not freeze. Protect vaccine from light.

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12. Appendix

A. COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, September 2023: https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf

Protocol for Haemophilus influenzae type b Vaccines
(ActHIB®, HIBERIX®, PedvaxHIB®)

1. **What's New**
   A. Contraindications- Latex (Removed for ActHib® and PedvaxHIB®)[1,3]

Commented [CS1]: Removed latex allergy

2. **Immunization Protocol**
   A. Administer a 0.5-mL dose, IM, of Hib vaccine to persons ≥7 years of age according to high-risk group indication.
   B. Hib vaccines can be given with all other routinely recommended vaccines.

3. **Vaccine Schedule**
   A. Not routinely recommended. See recommendations for use for guidance for high-risk groups.

Hib Vaccine (ActHIB®, HIBERIX®, PedvaxHIB®)[1-3] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		28 days
3		28 days

4. **Licensed Vaccines**

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ActHIB®[1] (PRP-T)	Hib (tetanus toxoid conjugate)	0.5-mL lyophilized single-dose vials packaged with single-dose diluent	6 weeks – 5 years*	None
HIBERIX®[2] (PRP-T)	Hib (tetanus toxoid conjugate)		6 weeks – 4 years*	
PedvaxHIB®[3] (PRP-OMP)	Hib (meningococcal protein conjugate)	0.5-mL single-dose suspension	6 weeks – 5 years*	

*Any licensed product presentation may be used for Catch-Up for Persons at High Risk

5. **Recommendations for Use**
   A. **Routinely Recommended Use**- N/A
   B. **Catch-Up for Healthy Children**- N/A
   C. **Catch-Up for Persons at High-Risk[4]**

High-Risk Group	Vaccine Guidance
Patients aged ≥7 years undergoing elective splenectomy	If unimmunized, 1 dose at least 14 days prior to procedure
Asplenic patients ≥7 years	If unimmunized, 1 dose
HIV-infected children 7-18 years	If unimmunized, 1 dose
HIV-infected persons ≥19 years	Hib immunization is not recommended
Hematopoietic stem cell transplantation (HSCT) ≥7 years	3 doses (4-week intervals) beginning 6–12 months after HSCT regardless of prior Hib vaccine history

Protocol for Haemophilus influenzae type b Vaccines
(ActHIB®, HIBERIX®, PedvaxHIB®)

~~6. Contraindications[5]~~

~~A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (PedvaxHIB®[3]).~~

6. Contraindications

A. N/A

Vaccine	Contains
Hib (ActHIB®[1])	Sodium chloride, formaldehyde, sucrose
Hib (HIBERIX®[2])	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB®[3])	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride

7. Warnings and Precautions

A. N/A

8. Other Considerations [1-3]

A. In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever	Very common, up to 70%
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 49%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 6%
Severe pain, induration or swelling at injection site	Uncommon, up to 4%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
ActHIB®[1]	2°to 8°C (36° to 46°F) vaccine & diluent	Do not freeze.	
HIBERIX®[2]	2°to 8°C (36° to 46°F) vaccine 2°to 25°C (36° to 77°F) diluent	Protect from light. Do not freeze.	Discard if the diluent has been frozen.
PedvaxHIB®[3]	2°to 8°C (36° to 46°F) vaccine	Do not freeze.	

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12. Appendix

A. N/A

Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®),
Recombinant Influenza Vaccine (Flublok®),
Cell Cultured Influenza Vaccine (Flucelvax®),
Adjuvanted Inactivated Influenza Vaccine (Fluad®)

1. What's New

A. ACIP Recommended that all egg-based inactivated influenza vaccines for use in the 2023-2024 influenza season Northern Hemisphere[9] contain the following:
   a. A/Victoria/4897/2022 (H1N1) pdm09-like virus
   b. A/Darwin/9/2021 (H3N2)-like virus
   c. B/Austria/1359417/2021-like virus (B/Victoria lineage)
   d. B/Phuket/3073/2013-like virus (B/Yamagata lineage)

B. ACIP Recommended that all cell-culture-based inactivated or recombinant-based influenza vaccines for the 2023-2024 influenza season Northern Hemisphere[9] contain the following:
   a. A/Wisconsin/67/2022 (H1N1) pdm09-like virus
   b. A/Darwin/6/2021 (H3N2)-like virus
   c. B/Austria/1359417/2021-like virus (B/Victoria lineage)
   d. B/Phuket/3073/2013-like virus (B/Yamagata lineage)

C. ACIP recommends that adults aged ≥65 years preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).[10]

D. All persons ages ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.[11]

2. Immunization Protocol

A. Administer a 0.25-mL, 0.5-mL, or 0.7-mL dose, IM, of an appropriate influenza vaccine, to persons ≥ 6 months of age based on the patient's age and the formulation being used.

B. May be given with all ACIP-recommended child and adult vaccinations, including COVID-19 vaccines.

C. When co-administering COVID-19 vaccines and adjuvanted or high-dose influenza vaccines that might be more likely to cause a local reaction, different limbs should be used, if possible.[10]

3. Vaccine Schedule

Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2023–2024 Flu Season[1-8] Dose and Route – 0.25-mL or 0.5-mL (dose based on age and formulation), IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 6 months ~~– 35 months~~	

Commented [CS1]: Combined both tables into 1 and indicated dose is 0.25 mL or 0.5 mL based on age and indication. No rationale to have 2 separate tables as the dosing for the 6-35 month age group depends on the vaccine formulation (see table below)

2*	≥ 6 months – ~~35 months~~ <9 years of age	28 days, *see flowchart in recommendations for use for determining 1 or 2 doses

~~Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2023–2024 Flu Season[1,2] Dose and Route – 0.5 mL, IM~~		
~~Dose~~	~~Acceptable Age Range~~	~~Minimum Acceptable Spacing~~
~~1~~	~~≥ 36 months~~	
~~2*~~	~~36 months – 8 years of age~~	~~28 days, *see flowchart in recommendations for use for determining 1 or 2 doses~~

4. Licensed Vaccines

Product Name	Presentation	Hemagglutinin (IIV and RIV) for each vaccine virus (mcg/per dose)	FDA Age Range	Thimerosal (mcg Hg)
Afluria® Quadrivalent[1]	0.5 mL prefilled syringes‡	15 mcg/0.5 mL	≥ 3 years~~6 months~~	None
	5-mL multi-dose vial†	7.5 mcg/0.25 mL 15 mcg/0.5 mL	≥ 6 – 35 months ≥ 3 years	24.5
Fluad® Quadrivalent[8]	0.5 mL prefilled syringes	15 mcg/0.5 mL	≥ 65 years	None
Fluarix® Quadrivalent[2]	0.5 mL prefilled syringes‡	15 mcg/0.5 mL	≥ 6 months	None
Flublok® Quadrivalent[6]	0.5 mL prefilled syringes	45 mcg/0.5 mL	≥ 18 years	None
Flucelvax® Quadrivalent[7]	0.5 mL prefilled syringes‡	15 mcg/0.5 mL	≥ 6 months	None
	5-mL multi-dose vial	15 mcg/0.5 mL		25
FluLaval® Quadrivalent[3]	0.5 mL prefilled syringes‡	15 mcg/0.5 mL	≥ 6 months	None
Fluzone High Dose® Quadrivalent[4]	0.7 mL prefilled syringes	60 mcg/0.7 mL	≥ 65 years	None
Fluzone® Quadrivalent[5]	0.5 mL prefilled syringes‡~~‡~~	15 mcg/0.5 mL	≥ 6 months	None
	0.5 mL single dose vial‡	15 mcg/0.5 mL		None

	5 mL multi-dose vial‡	7.5 mcg/0.25 mL 15 mcg/0.5 mL		25

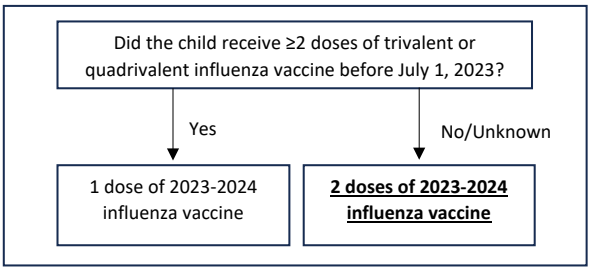
IIV4= inactivated influenza vaccine, RIV4= recombinant influenza vaccine

† The approved dose volume for Afluria® Quadrivalent is 0.25 mL for ages 6-35 months and 0.5 mL for ages ≥3 years. However, 0.25-mL prefilled syringes are no longer available. For ages 6-35 months, a 0.25-mL dose must be obtained from a multidose vial.~~FDA approved for ≥ 6 months; however, the approved dose is 0.25 mL for ages 6 months-35 months.~~

‡Fluzone® Quadrivalent is approved for children aged 6 – 35 months at either 0.25 mL or 0.5 mL per dose; however, 0.25-mL prefilled syringes are no longer available. If a prefilled syringe of Fluzone® Quadrivalent is used for a child in this age group, the dose volume will be 0.5 mL per dose.

5. Recommendations for Use

A. All persons ≥ 6 months of age that do not have contraindications. Children < 9 years of age receiving flu vaccine for the first time need 2 doses, separated by at least 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should receive the 2nd dose in the same season.[10]



B. Persons who are pregnant may be vaccinated with inactivated influenza vaccine during any trimester.[10]

C. Persons with history of egg allergy may receive any vaccine (egg-based or non-egg-based) that is otherwise appropriate for their age and health status. Beginning with the 2023-2024 season, additional safety measures are no longer recommended for flu vaccination of people who are allergic to eggs beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of allergic reactions are available, such as a pharmacy.[11]

D. For non-pregnant adults, vaccination in July or August should be avoided, even if vaccine is available, unless there is serious concern that later vaccination might not be possible.[10]

E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered as long as unexpired vaccine is

available.[10]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component. However, ACIP makes an exception for allergy to egg (see Persons with a History of Egg Allergy above).
   a. Most flu shots and the nasal spray flu vaccine are manufactured using egg-based technology. Because of this, they contain a small amount of egg proteins, such as ovalbumin. However, studies that have examined the use of both the nasal spray vaccine and flu shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in people with egg allergies are unlikely.[11]

Vaccine	Contains[14]
Afluria® Quadrivalent	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multidose vials)
Fluad® Quadrivalent	Squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Fluarix® Quadrivalent	Octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Flublok® Quadrivalent	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100
Flucelvax® Quadrivalent	Madin-Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and βpropiolactone, Thimerosal (multi-dose vials)
FluLaval® Quadrivalent	Ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution.
Fluzone High Dose® and Fluzone® Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

7. Warnings and Precautions

A. **Persons with a history of Guillain-Barré Syndrome (GBS)** within 6 weeks following influenza vaccination have a substantially greater likelihood of subsequently developing GBS than

persons without such a history. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Consult with an individual's health care provider and consider avoiding a subsequent influenza vaccination in persons known to have developed GBS within **6 weeks** of a previous influenza vaccination. Experts believe that the benefits of influenza vaccination justify yearly vaccination for most persons who have a history of GBS and who are at risk for severe complications from influenza.[10]

B. **History of severe allergic reaction to a previous dose of an egg-based influenza vaccine** is a precaution to both Flublok® and Flucelvax. ®[10]

8. Other Considerations

A. **Foreign travelers:** Travelers who want to reduce the risk for influenza infection should consider influenza vaccination, preferably at least 2 weeks before departure. In particular, persons who live in the United States and are at higher risk for complications of influenza and who were not vaccinated with influenza vaccine during the previous Northern Hemisphere fall or winter should consider receiving influenza vaccine before departure if they plan to travel to the tropics, with organized tourist groups or on cruise ships, or to the Southern Hemisphere during the Southern Hemisphere influenza season (April–September).[10]

B. **Lactation:** Inactivated and recombinant influenza vaccines are safe for breastfeeding mothers and their infants.[12]

C. **Immunocompromised:** Persons with immunocompromising conditions should receive an age appropriate IIV or RIV4. Immune response to influenza vaccines might be blunted in persons with some conditions, such as persons with congenital immune deficiencies, persons receiving cancer chemotherapy, and persons receiving immunosuppressive medications.[13]

D. **Novel adjuvants:** Because of the limited data on the safety of simultaneous administration of two or more vaccines containing novel adjuvants and the availability of nonadjuvanted influenza vaccine options, selection of a nonadjuvanted influenza vaccine may be considered in situations in which influenza vaccine and another vaccine containing a novel adjuvant are to be administered concomitantly. However, vaccination should not be delayed if a specific product is not available.

E. **Antiviral agents for influenza:** consult CDC's most recent recommendations for guidance on clinical management of influenza using antiviral agents. Available at: www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

F. **Hematopoietic Stem Cell Transplant (HSCT) recipients:** Influenza vaccine should be administered beginning at least 6 months after HSCT and annually thereafter for the life of the patient. A dose of vaccine can be given as soon as 4 months after the transplant, but a second dose should be considered in this situation. Do not use live influenza vaccine in this population.[13]

G. **Ocular and Respiratory Symptoms after Vaccination: Oculo-respiratory syndrome** (ORS) The cause of ORS has not been established; however, studies suggest that the reaction is not IgE-mediated. When assessing whether a patient who experienced ocular and respiratory symptoms should be revaccinated, providers should determine whether signs and symptoms concerning for IgE-mediated immediate hypersensitivity are present. Health care providers who are unsure whether symptoms reported represent an IgE-mediated hypersensitivity immune response should seek advice from an allergist/immunologist. See https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

9. Side Effects and Adverse Reactions [1-8]

Adverse Event	Frequency
Local reactions: soreness, erythema, induration at injection site	Up to 60%
Fever, malaise, chills	10% -15%
Severe allergic reactions	1 per 3 million doses

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Latex	Storage Issues	Notes
Afluria® Quadrivalent [1]	Store at 2° to 8°C (36° to 46°F)	No	Store in original package to protect from light. Store multi-dose vials in recommended conditions.	Discard opened multi-dose vials 28 days after opening.
Fluad® Quadrivalent[8]				Use opened multi-dose vials through the expiration date
Fluarix® Quadrivalent[2]				
Flublok® Quadrivalent[6]				
Flucelvax® Quadrivalent[7]				
FluLaval® Quadrivalent[3]				
Fluzone High Dose® and Fluzone® Quadrivalent[4,5]				

11. References

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Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®),
Recombinant Influenza Vaccine (Flublok®),
Cell Cultured Influenza Vaccine (Flucelvax®),
Adjuvanted Inactivated Influenza Vaccine (Fluad®)

12. Appendix

A. N/A

Protocol for Japanese Encephalitis Vaccine (IXIARO®)

1. What's New

A. ~~N/A~~Updated references to reflect the updated 2024 CDC Yellow Book.

2. Immunization Protocol

A. Administer a 0.5- mL dose, IM, of Japanese Encephalitis (JE) vaccine to persons ≥7 years of age according to age and schedule if indicated.

B. IXIARO® can be given with all other ACIP-recommended vaccines.

3. Vaccine Schedule

JE Vaccine (IXIARO®) [1] Dose and Route – 0.5-mL IM				
Age	**Dose in Series**	**Acceptable Age Range**	**Dose Volume**	**Booster**
7-17 years	2 doses at 0 and 28 days	≥ 7 years	0.5 mL	≥ 1 year after primary series†
18-64 years	2 doses at 0 and 7-28 days*			
≥ 65 years	2 doses at 0 and 28 days			

* This is the only age group for which an accelerated schedule is approved.

† If ongoing exposure or re-exposure to JE virus is expected.[2]

4. Licensed Vaccine[3]

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IXIARO®[1] (JE-VC)‡	6 antigen units purified, inactivated JEV proteins and 250 µg of aluminum hydroxide per 0.5-mL dose	0.5 mL suspension in a pre-filled single dose syringe	2 months – 65 years	None

‡JE-MB (JE-VAX) is no longer manufactured in the United States.

5. Recommendations for Use[2]

A. JE vaccination is recommended for the following:
   a. Persons moving to JE-endemic countries.
   b. Travelers who plan to spend a month or longer in endemic areas.
   c. Laboratory personnel who work with live, wild-type JE virus strains.[3]

B. Vaccine should also be considered for the following:
   a. Shorter-term travelers (e.g. less than 1 month) with an increased risk of exposure to JE based on planned travel duration, season, location, activities, and accommodations.[2]
   b. Travelers going to endemic areas, but who are uncertain of specific destinations, activities, or duration of travel.

C. Booster doses
   a. A booster dose should be given ≥1 year after completion of the primary JE-VC series if ongoing exposure or re-exposure to JE virus is expected.

b. The 2-dose primary series of JE-VC vaccine should be given to persons who received JE-MB (JE-VAX®) † and need a booster.
c. Vaccinated, at-risk laboratory personnel should receive appropriate booster doses of JE vaccine or be evaluated regularly for JE virus-specific neutralizing antibodies to assure adequate titers.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains
IXIARO® (JE-VC)	Protamine sulfate, aluminum hydroxide and phosphate buffered saline (sodium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate)[1]

7. Warnings and Precautions

A. Hypersensitivity to protamine sulfate[1]
B. Other vaccines: Studies of concomitant administration of JE vaccine with hepatitis A vaccine and JE vaccine with rabies vaccine have showed noninferiority compared to administering each vaccine alone. An additional study of concomitant administration of JE vaccine, rabies vaccine and meningococcal conjugate vaccine showed protective responses to all administered vaccines.[3]
C. Pregnancy: No studies of JE-VC in pregnant women have been conducted. Pregnancy is a precaution for use of JE-VC and in most instances, its administration to pregnant women should be deferred. However, pregnant women who must travel to an area where risk for JE virus infection is high should be vaccinated when the theoretical risk of immunization is outweighed by the risk of infection.[2]
D. Newborns: JE vaccine has not been tested in individuals ≤2 months of age.[3] Older adults: In a post-licensure study, seroprotection and gross mean titers were substantially lower among adults ≥65 years of age compared to younger persons. No data exists on the safety or immunogenicity of an additional dose or early booster dose of JE vaccine for adults ≥65 years of age. [3]

8. Other Considerations [1-3]

A. Although ≤1% of JEV infections results in clinical disease, JE is a devastating illness that has a case-fatality rate of 20%–30% and neurologic or psychiatric sequelae in 30%–50% of survivors. No specific treatment exists.[3]
B. In all instances, travelers are advised to take personal precautions to reduce exposure to mosquito bites.[2]
C. The decision to use JE-VC should balance the risks for exposure to the virus and for developing illness, the availability and acceptability of repellents and other alternative measures, and the side effects of vaccination.[2]
D. Risk assessments should be interpreted cautiously because risk can vary within areas and from year to year.[2]

E. Risk of JE for travelers to highly endemic areas during the transmission season can reach 5 to 50 cases per 100,000; the risk for most short-term travelers may be 1 per million or less.[2]
F. Adverse Events: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[4]
G. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. Immunosuppressive therapies may decrease the immune response to IXIARO®[1]
H. Lactation: Breastfeeding is not a contraindication or precaution to JE vaccine.[3]

9. Side Effects and Adverse Reactions[1]

Adverse Events	Frequency
Infants and Children	
Pain, itching, redness or swelling at the injection site	Up to 20%
Fever	Up to 10%
Allergic reactions	Rare
Adults	
Soreness, redness or itching at the injection site, headache, fatigue	Up to 30%
Vomiting, fever, chills, rash	Up to 5%
Allergic reactions	Rare

10. Storage and Handling

A. IXIARO® is a clear liquid with a white precipitate. Before administration, shake the syringe well to obtain a white, opaque, homogeneous suspension.
B. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
IXIARO®[1]	2°– 8°C (36˚F–46˚F)	Do not freeze. Store in original container. Protect from light.	No natural rubber latex. Do not use after manufacturer's expiration date on product label.

11. References

1. IXIARO® (2018) package insert, available at: www.fda.gov/media/75777/download. Accessed 12 April 2023.
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12. ~~References~~Appendix

A. N/A

Protocol for Meningococcal Containing Vaccines
MenQuadfi®, Menveo®, Bexsero®, and Trumenba®, Penbraya™

1. What's New

A. Meningococcal ABCWY vaccine, Penbraya™, was added as an alternative vaccine option for individuals 10-25 years of age who are intending to receive both the MenACWY and MenB vaccines at the same visit. Contraindications- Latex (Removed for Bexsero®[5])

A.

B. Menveo® dosage and administration updated for 1 and 2 vial presentations.[4]

C. Menactra® has been removed from the market, all guidance related to Menactra® removed from protocol.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of meningococcal vaccine according to age-appropriate schedules and high-risk conditions.

B. Meningococcal ACWY vaccines are interchangeable when more than one brand is age-appropriate.[1]

C. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.[1]

D. Meningococcal conjugate quadrivalentThe MenACWY vaccine and Meningococcal B vaccines may be given simultaneously at different sites if indicated.[1] Alternatively, patients intending to receive both MenACWY and MenB vaccines at the same visit may instead receive the MenABCWY vaccine.[7]

E. Meningococcal vaccines can be given with all other routinely recommended vaccines.[2]

3. Vaccine Schedule

3.

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	11-18 years	
Booster	16-18 years	8 weeks

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		8 weeks if 2 doses indicated
Boosters (if person remains at risk)	Aged <7 years at completion of primary series: Single dose at 3 years after primary vaccination and every 5 years thereafter Aged ≥7 years at completion of primary series: Single dose at 5 years after primary vaccination and every 5 years thereafter	

MenB Vaccines (Bexsero®, Trumenba®) Schedule for Healthy Persons*, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	16-23 years	
2		28 days for Bexsero®, 6 months for Trumenba®

*ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. See section 5 for guidance.

MenB Vaccines (Bexsero®, Trumenba®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥10 years	
2		28 days
3*		4 months after dose 2
Boosters (if person remains at risk)		Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter

*Dose 3 applies to Trumenba® only, not needed if dose 2 was administered at least 6 months after dose 1. If dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3.

MenABCWY Vaccines (Penbraya™) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	10-25 years	
2		6 months

*If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:

- Trumenba® for additional MenB dose(s) when MenACWY isn't indicated
- Any MenACWY vaccine when MenB isn't indicated

4. Licensed Vaccines

Meningococcal ACWY Conjugate Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenACWY-TT[3] (MenQuadfi®)	Neisseria meningitidis serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein	0.5-mL single-dose vials	≥2 years	None
MenACWY-CRM[4] (Menveo®)	Neisseria meningitidis serogroup A, C, Y, and W-135 oligosaccharides conjugated individually to Corynebacterium	Single-dose 2 vial presentation (gray and orange caps) that requires reconstitution. 0.5-mL dose once reconstituted	2 months-55 years	None

	diphtheriae CRM protein	0.5-mL single-dose 1 vial presentation (pink cap) that does **not** require reconstitution	10-55 years	None
Meningococcal B Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenB-4C (Bexsero®)[5]	Recombinant proteins Neisserial adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp)	0.5-mL prefilled syringes	10-25 years	None
MenB-fHbp (Trumenba®)[6]	Two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL prefilled syringes	10-25 years	None
Meningococcal ABCWY Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenABCWY (Penbraya™)[7]	Neisseria meningitidis serogroup A, C, W, and Y polysaccharides conjugated to tetatnus toxoid and two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	10-25 years	None

Meningococcal B Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenB-4C (Bexsero®)[5]	Recombinant proteins Neisserial adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp)	0.5-mL prefilled syringes	10-25 years	None
MenB-fHbp (Trumenba®)[6]	Two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL prefilled syringes	10-25 years	None

5. Recommendations for Use

A. Routine use of Meningococcal ACWY vaccine[1]
   a. All adolescents 11–18 years of age without contraindications. Preferred age for dose one is 11-12 years with a booster dose at age 16 years. Catch-up vaccination age for dose one is 13–15 years with a booster dose at age 16–18 years. If series started at age 16 or older, no booster dose is indicated.
      i. Children who received MenACWY at age 10 years do not need an additional dose at age 11–12 years but should receive the booster dose at age 16 years. Children who received MenACWY before age 10 years and with no ongoing risk for meningococcal disease for which boosters are recommended should still receive MenACWY according to the recommended adolescent schedule.
   b. Unvaccinated or under vaccinated first-year college students living in residence halls. One dose may be administered to persons 19-21 years who have not received a dose after their 16th birthday. Boosters are not routinely recommended unless there is another indication.
   c. Military recruits 19-21 years of age who have not received a dose after their 16th birthday. Administer one dose with booster every 5 years based on assignment. Vaccine recommendations for military personnel are made by the U.S. Department of Defense.
   d. Booster doses for previously vaccinated persons who become or remain at increased risk. At 3 or 5 years after primary vaccination depending on age at last dose and every 5 years thereafter.

B. Use of Meningococcal ACWY vaccine in high-risk persons[1]
   a. Persons with complement component deficiency or who are taking complement inhibitor medications, with anatomical or functional asplenia, or with HIV should receive 2 doses 8 weeks apart.

b. Microbiologists routinely exposed to isolates of Neisseria meningitidis, persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]), and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic, particularly the meningitis belt in sub-Saharan Africa, should receive 1 dose.
   i. Vaccination is required for entry for persons traveling to Saudi Arabia for the Hajj and Umrah pilgrimages.

C. Use of Meningococcal B vaccine in healthy persons[1]
   a. Vaccination of adolescents and young adults aged 16–23 years with a 2-dose MenB series on the basis of shared clinical decision-making. MenB vaccination is not routinely recommended for all adolescents. Instead, ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss MenB vaccination with persons aged 16-23 years who are most likely to benefit.
      i. Pharmacists are authorized to administer MenB vaccine if the following risk factor is present: College students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities

D. Use of Meningococcal B vaccine in high-risk persons[1]
   a. Persons with persistent complement component deficiencies or who are taking complement inhibitor medications, with anatomic or functional asplenia, and Microbiologists routinely exposed to isolates of *Neisseria meningitidis* should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
      i. A single booster dose for previously vaccinated persons who remain at increased risk should be given at 1 year after completion of primary vaccination and every 2-3 years thereafter.
   b. Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among MSM should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
      i. A single booster dose for previously vaccinated persons and identified at increased risk during an outbreak should be given if ≥1 year after completion of primary series (a ≥ 6-month interval might also be considered by public health).

~~i.~~ E. Use of Meningococcal ABCWY vaccine
   a. If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead.
      i. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:
         1. Trumenba® for additional MenB dose(s) when MenACWY isn't indicated
         2. Any MenACWY vaccine when MenB isn't indicated
      ii. The minimum interval between MenABCWY doses is 6 months.
   b. People with prolonged increased risk for serogroup A, C, W, or Y and B meningococcal disease need regular boosters. However, the recommended interval between doses varies by age and vaccine type. MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit.

Otherwise, MenACWY and MenB vaccines should be given separately as appropriate.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[3-7]

Vaccine	Contains
MenACWY-TT – MenQuadfi®	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid
MenACWY-CRM - Menveo®	formaldehyde, CRM197 protein
MenB-4C - Bexsero®	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB-FHbp - Trumenba®	polysorbate 80, aluminum phosphate, histidine buffered saline
MenABCWY- Penbrayra™	L-histidine, trometamol, sucrose, aluminum phosphate, sodium chloride, and polysorbate 80

7. Warnings and Precautions[3-6]

A. N/A

8. Other Considerations

A. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. [3-6]
B. Pregnant and lactating women should receive MenACWY vaccine if indicated. However, due to a lack of data, vaccination with MenB should be deferred unless the woman is at increased risk and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks. [1]
C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.[1]
D. MenACWY meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W meningococci. They are not protective against serogroup B meningococci.[5,6]
E. Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7years of age. [1]
F. Immunization with MenQuadfi® or Penbraya™ does not substitute for routine tetanus immunization.[3,7]

9. Side Effects and Adverse Reactions[3-7]

MenACWY Vaccines	
Adverse Event	**Frequency**
Low-grade fever, headache, redness at injection site, dizziness	Up to 40%
Grade 3 - fever, headache, redness at injection site, dizziness	Up to 3%
MenB Vaccines	
Adverse Event	**Frequency**
Headache, fatigue, redness at injection site	Up to 51%
Pain at injection site	Up to 26%
Chills, joint pain	Up to 20%
Fever	Up to 2.5%
MenABCWY Vaccines	
Adverse Event	**Frequency**
Pain at injection site	Up to 89%
Fatigue	Up to 52%
Headache	Up to 47%
Muscle pain	Up to 26%
Injection site redness	Up to 26%
Injection site swelling	Up to 25%
Joint pain	Up to 20%
Chills	Up to 20%

~~10.~~ 10. Storage and Handling

~~A. Menveo® two-vial presentation reconstitution[4]:~~

~~a. Use the MenCYW-135 liquid conjugate component (Vial 1, gray cap) to reconstitute the MenA lyophilized conjugate component (Vial 2, orange cap) to form Menveo®.~~

~~b. Invert Vial 2 and shake well until the lyophilized conjugate component is dissolved.~~

~~c. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine.~~

~~d. Administer Menveo® immediately or store between 36°F and 77°F (2°C and 25°C) for up to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.~~

~~B.~~A. Store medications according to OAR 855-041-1036.

~~C.~~ All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

B.

Vaccine	Temp	Storage Issues	Notes
MenQuadfi®[3]	Store at 2°to 8°C (36° to 46°F)	Protect from light. Do not use if vaccine has been frozen.	
Menveo®[4] and diluent			After reconstitution, administer Menveo® immediately or store between 2°C and 25°C (36°F and 77°F) for up to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours. ~~See directions for Menveo 2 vial presentation reconstitution above~~
Bexsero®[5] and Trumenba®[6]			
Penbraya™[7]		During storage, a white deposit and clear supernatant may be observed in the prefilled syringe containing the MenB Component. Store the	After reconstitution, administer PENBRAYA immediately or store between 2°C and 30°C (36°F and 86°F) and use within 4 hours. Do not freeze.

		carton horizontally to minimize the time necessary to resuspend the MenB Component. Do not freeze. Discard if the carton has been frozen	

11.10. References

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12.11. Appendix

A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Meningococcal B Vaccination in Adolescents and Adults: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-mening-b-shared-clinical-decision-making.pdf

Protocol for Pneumococcal Vaccines
PCV15 (VAXNEUVANCE™), PCV20 (Prevnar 20®)and
Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

1. What's New

~~A. N/A~~

A. The 13-valent pneumococcal conjugate vaccine (PCV13) has been deleted from all sections. Previous children and adolescent schedules containing PCV13 have been updated with new recommendations for use of PCV15, PCV20, and PPSV23.
B. All vaccine schedule tables have been updated to provide additional clarity on recommended subsequent doses, minimum vaccine spacing and the addition of shared clinical decision making, when applicable.
C. Additional information was provided to clarify what conditions should be considered for patients over the age of 65 to qualify for PCV20 via shared clinical decision making.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of pneumococcal conjugate vaccine (PCV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication **OR**
B. Administer a 0.5-mL dose, IM or SQ, of pneumococcal polysaccharide vaccine (PPSV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication.
C. PCV and PPSV should not be given at the same time. Either vaccine type may be given simultaneously with influenza and most other ACIP-recommended child and adult vaccinations.~~5~~4

3. Vaccine Schedule

A. Routine Schedule

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons ≥ 65 Years of Age Dose-0.5-mL, Route varies by product				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
≥ 65 years	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 1 year later‡
			PCV20 IM	Complete*
	Unvaccinated	1 dose (at any age)	PCV15 IM ≥ 1 year later **or**	Complete*
			PCV20 IM ≥ 1 year later	Complete*
	PCV13 only (at any age)	Unvaccinated	PCV20 IM ≥ 1 year later **or**	Complete*
			PPSV23 IM or SQ ≥ 1 year later‡	Complete*
	PCV13 (at any age)	1 dose (at < 65 years old)	PCV20 IM ≥ 5 years after last	Complete*

			pneumococcal dose **or**	
			PPSV23 IM or SQ ≥ 5 years after last pneumococcal dose‡	
	PCV13 (at any age)	1 dose (≥ 65 years old)	The patient and vaccine provider may consider administering PCV 20 via ***shared clinical decision making*** to patients who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 (See Section 5 for additional details).	
‡ For adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak, the minimum interval for PPSV23 is ≥ 8 weeks since last PCV13 dose and ≥ 5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥ 1 year since last PCV13 dose and ≥ 5 years since last PPSV23 dose.				

B. Special Conditions Schedule

Pneumococcal Vaccine (PCV15 or PCV20; PPSV23) for Persons 7-18 Years of Age with Immunocompromising Conditions* Dose-0.5-mL, Route varies by product				
Acceptable Age Range	**Previous PCV Vaccination History**	**Previous PPSV23 Vaccination History**	**Due Now/Route** (≥ 8 weeks since last pneumococcal vaccine)	**Due Next**
7-18 years of age with immune-compromising conditions	No previous history of PCV13, PCV15, or PCV20	Unvaccinated	PCV15 IM **or**	Administer PPSV23 in ≥8 weeks.
			PCV20 IM	Complete
		1 dose	PCV15 IM **or**	Revaccinate with PCV20 or PPSV23 in 5 years.
			PCV20 IM	Complete
	≥1 dose of PCV13 or PCV15 before age 6	Unvaccinated	PCV 20 IM **or**	Complete
			PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
	≥1 dose of PCV20 before age 6	Unvaccinated	Complete	
	≥1 dose of PCV13 at or after age 6	Unvaccinated	PCV20 IM **or**	Complete
			PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.

		1 dose	PCV20 **or**†	Complete
			PPSV23†	Complete

*Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies

†Vaccination must occur at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23

Pneumococcal Vaccine (PCV15 or PCV20; PPSV23) for Persons 7-18 Years of Age with Chronic Conditions Dose-0.5-mL, Route varies by product**

Acceptable Age Range	**Previous PCV Vaccination History**	**Previous PPSV23 Vaccination History**	**Due Now/Route** (≥ 8 weeks since last pneumococcal vaccine)	**Due Next**
7-18 years of age with chronic conditions	No previous history of PCV13, PCV15, or PCV20	Unvaccinated	PCV15 IM **or**	Administer PPSV23 in ≥8 weeks.
			PCV20 IM	Complete
		1 dose	PCV15 IM **or**	Complete
			PCV20 IM	Complete
	≥1 dose of PCV13 or PCV15 before age 6	Unvaccinated	PCV 20 IM **or**	Complete
			PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
	≥1 dose of PCV20 before age 6	Unvaccinated	Complete	
	≥1 dose of PCV13 at or after age 6	Unvaccinated	PCV20 IM **or**	Complete
			PPSV23 IM or SQ	Complete
		1 dose	Complete	

**Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Immunocompromising Conditions* Dose-0.5-mL, Route varies by product

Protocol for Pneumococcal Vaccines
PCV15 (VAXNEUVANCE™), PCV20 (Prevnar 20®)and
Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

Age	Previous PCV Vaccination History	Previous PPSV Vaccination History	Due Now/Route	Due Next
19-64 years with immune-compromising conditions	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 8 weeks later‡
			PCV20 IM	Complete¥
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PCV dose **or**	Complete¥
			PCV20 IM ≥ 1 year after last PCV dose	Complete¥
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose **or**	Complete¥
			PPSV23 IM or SQ ≥ 8 weeks later‡	Revaccinate with PPSV23 in 5 years.
	PCV13	1 dose	PCV20 IM ≥ 5 years after last PPSV23 dose **or**	Complete¥
			PPSV23 IM or SQ ≥ 5 years after last PPSV23 dose	PCV20 IM ≥ 5 years after last PPSV23 dose
	PCV13	2 doses	PCV20 IM ≥ 5 years after last PPSV23 dose	Complete¥

* Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.
‡May use minimum interval of 8 weeks for adults with an immunocompromising condition*, cochlear implant, or cerebrospinal fluid leak.
¥Review pneumococcal vaccine recommendations when patient turns 65 years old

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Chronic Conditions Dose-0.5-mL, Route varies by product**				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
19-64 years with chronic conditions	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 1 year later
			PCV20 IM	Complete
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PPSV dose **or**	Complete
			PCV20 IM ≥ 1 year after last PPSV dose	Complete

	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose **or**	Complete
			PPSV23 IM or SQ ≥ 1 year later	Complete¥
	PCV13	1 dose	Complete¥	
**Chronic conditions include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies. ¥Review pneumococcal vaccine recommendations when patient turns 65 years old				

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Cochlear Implant or Cerebrospinal Fluid Leak Dose-0.5-mL, Route varies by product				
Age	**Previous PCV Vaccination History**	**Previous PPSV Vaccination History**	**Due Now/Route**	**Due Next**
19-64 years	Unvaccinated	Unvaccinated	PCV15 IM **or**	PPSV23 IM or SQ ≥ 8 weeks later‡
			PCV20 IM	Complete
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PPSV dose **or**	Complete
			PCV20 IM ≥ 1 year after last PPSV dose	Complete
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose **or**	Complete
			PPSV23 IM or SQ ≥ 8 weeks later‡	Complete¥
	PCV13	1 dose	PCV20 IM ≥ 5 years after last pneumococcal dose **or**	Complete¥
‡May use minimum interval of 8 weeks for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak. ¥Review pneumococcal vaccine recommendations when patient turns 65 years old				

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
Pneumococcal Conjugate Vaccines				

Prevnar 20™ (PCV20) [1]	Sterile suspension of mixture of saccharides of the capsular antigens of S. pneumoniae, individually linked to non-toxic diphtheria CRM197 protein	0.5 mL prefilled syringes	≥ 6 weeks of age	None
VAXNEUVANCE™ (PCV15) [2]		0.5 mL prefilled syringes	≥ 2 months	
Pneumococcal Polysaccharide Vaccine				
Pneumovax 23® (PPSV23) [3]	Pneumococcal Vaccine Polyvalent is a sterile, liquid vaccine consisting of a mixture of purified capsular polysaccharides from Streptococcus pneumoniae	0.5 mL single dose vials	≥ 2 years	None
		0.5 mL prefilled syringes		

5. Recommendations for Use

A. Routine

1. Age 65 years or older:
   - b. Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose
     - i. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.
     - ii. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.
   - c. Previously received only PCV7: follow the recommendation above.
   - d. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
   - e. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
   - f. Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

~~a.~~g. Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older: Adults aged 65 or older have the option to receive PCV20 if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23. This includes one dose of PCV13 at any age and all recommended doses of PPSV23, including one dose at or after age 65. PCV20 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Instead, ACIP recommends a PCV20 vaccination for persons aged 65 or older who have received both PCV13 and PPSV23 on the basis of shared clinical decision-making.

Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss PCV20 vaccination with persons aged 65 or older who are most likely to benefit.

Pharmacists are authorized to administer PCV20 vaccine if one of the following risk factors is present AND at least 5 years has elapsed since last pneumococcal vaccination:

i. Individuals living in nursing homes or other long-term care facilities.
ii. Individuals living in areas with low pediatric pneumococcal conjugate vaccine uptake.
iii. Individuals with immunocompromising conditions, cochlear implant, cerebrospinal fluid leak, or more than one of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes.

~~5.~~**B.Special Conditions**

~~B.~~1. Age 7-18 years:

~~a.~~A. Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

~~i.~~a. Any incomplete series with PCV: no further PCV doses needed
~~ii.~~b. No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)

~~b.~~B. Cerebrospinal fluid leak, cochlear implant:

~~i.~~a. No history of either PCV or PPSV23: 1 dose PCV, 1 dose PPSV23 at least 8 weeks later
~~ii.~~b. Any PCV but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV
~~iii.~~c. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent dose of PPSV23

~~c.~~C. Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:

i.a. No history of either PCV or PPSV23: 1 dose PCV, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)

ii.b. Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)

iii.c. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent PPSV23 dose and a dose 2 of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV

D. Hematopoietic Stem Cell Transplant[6]: Children aged <19 years who are hematopoietic stem cell transplant (HSCT) recipients are recommended to receive 4 doses of PCV20, starting 3–6 months after HSCT. Administer 3 doses of PCV20, 4 weeks apart starting 3–6 months after HSCT. Administer a fourth PCV20 dose ≥6 months after the third dose of PCV20 or ≥12 months after HSCT, whichever is later.

a. If PCV20 is not available, 3 doses of PCV15 4 weeks apart, followed by a single dose of PPSV23 ≥1 year after HSCT, can be administered. For patients with chronic graft versus host disease (GVHD) who are receiving PCV15, a fourth dose of PCV15 can be administered in place of PPSV23 because these children are less likely to respond to
PPSV23.Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)

b. A patient's clinical team is best informed to determine the appropriate timing of vaccination.

C.2. Age 19–64 years:

a.A. Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV, Hodgkin disease, immunodeficiency, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplants, or sickle cell disease, or other hemoglobinopathies

i.c. Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose.

1.a) A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak

2.b) Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or

acquired asplenia, sickle cell disease, or other hemoglobinopathies

ii.d. Previously received only PCV7: follow the recommendation above

iii.e. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

iv.f. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23

v.g. Previously received both PCV13 and PPSV23 but have not completed the recommended series: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

D.1. Age 65 years or older:

a. Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose

i. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.

ii.i. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.

b.a. Previously received only PCV7: follow the recommendation above.

c.a. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

d.a. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.

e.a. Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

f. Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older: Adults aged 65 or older have the option to receive PCV20 if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23. This includes one dose of PCV13 at any age and all recommended doses of PPSV23, including one dose at or after age 65. PCV20 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Instead, ACIP

~~recommends a PCV20 vaccination for persons aged 65 or older who have received both PCV13 and PPSV23 on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision-making to discuss PCV20 vaccination with persons aged 65 or older who are most likely to benefit. Pharmacists are authorized to administer PCV20 vaccine if one of the following risk factors is present AND at least 5 years has elapsed since last pneumococcal vaccination:~~

~~i. Persons living in nursing homes or other long-term care facilities~~
~~ii. The presence of underlying medical conditions or other risk factors that increase the risk of developing severe disease (refer to Section 5.B.a. for list).~~

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. PCV20[1]~~,~~ or PCV15[2]~~, or PCV13[4]~~: Persons who experienced an anaphylactic reaction to a previous dose of any diphtheria toxoid-containing vaccine.
~~C. PCV13[4]: Allergy to soy peptones.~~

7. Warnings and Precautions

A. PPSV23: Care should be exercised when administering to patients with severely compromised cardiovascular or pulmonary function in whom a systemic reaction would pose a significant risk.[3]

8. Other Considerations

A. Adults with previous PPSV23 only: Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23. ~~[5]~~[4]
~~B. Adults with previous PCV13: The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series.[5] One dose of PCV20 may replace the PPSV23 if PPSV23 is not available.~~
~~C.~~B. Lactation: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing. [1-4]3
~~D.~~C. Pregnancy: Pneumococcal vaccine should be considered for persons at increased risk.~~[10]~~[9]
~~E.~~D. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See section 5, recommendations for use, for the necessary minimum interval between doses.[4],5~~,[7]~~
~~F.~~E. Splenectomy, immunocompromising therapy, or cochlear implant: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, age appropriate PCV vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If vaccine is not administered before surgery, it should be administered ≥2 weeks after surgery. If the patient is unlikely to return, vaccine can be administered in the immediate postoperative period.[9]7

~~G.~~F. Children who have experienced invasive pneumococcal disease should receive all recommended doses of a pneumococcal conjugate vaccine as appropriate for their age and underlying condition. The full series of scheduled doses should be completed even if the series is interrupted by an episode of invasive pneumococcal disease. ~~9~~7

~~H.~~G. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.[1-~~4~~3]

~~I.~~H. Recipients of Hematopoietic Cell Transplants (HCT): ACIP recommends that patients be revaccinated with three sequential doses of age appropriate PCV vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.~~10~~7

9. Side Effects and Adverse Reactions

PCV20[1], PCV15[2] Adverse Events	**Frequency**
Soreness at the injection site, fatigue	Up to 76%
Headache, muscle pain, joint pain, decreased appetite, local swelling, decreased arm movement	Up to 30%
Vomiting, fever, chills, rash	Up to 30%
Allergic reactions	Rare
PPSV23[3] Adverse Events	**Frequency**
Soreness, redness, swelling at the injection site	Up to 60%
Headache, muscle pain, fatigue	Up to 20%
Nausea, fever, chills	Rare, up to 2%
Allergic Reactions	Rare

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	**Temp**	**Storage Issues**	**Notes**
Prevnar 20™ [1]	Store at 2°– 8°C (36°- 46°F)	Store syringes horizontally to minimize re-suspension time; do not freeze	
VAXNEUVANCE™ [2]		Do not freeze. Protect from light.	
Pneumovax® 23[3]		None	

11. References

1. Prevnar 20™ (PCV20). [Package insert]. ~~June~~ April 2023. www.fda.gov/media/149987/download. Accessed ~~23 July 2023~~14 January 2024.
2. VAXNEUVANCE™ (PCV15~~),~~). [Package insert]. ~~July 2022~~May 2023. www.fda.gov/media/150819/download. Accessed ~~23 July 2023~~14 January 2024.

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~~6. Matanock A, Lee G, Gierke R, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2019;68(46);1069–75. Available at: . Accessed 23 July 2023.~~
~~7.~~5. Kobayashi M, Bennett NM, Gierke R, et al. Intervals between PCV13 and PPSV23 vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2015;64(34):944–7. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm Accessed ~~23 July 2023~~14 January 2024.
~~8.~~ ACIP Updates: Recommendations for Use of 20-Valent Pneumococcal Conjugate Vaccine in Children — United States, 2023. MMWR Morbidity Mortal Weekly Rep 2023;72:1072. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7239a5-H.pdf~~Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among children aged 6–18 years with immunocompromising conditions: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2013;62(25):521–4. Available at: . Accessed 23 July 2023.~~
~~9. Nuorti JP, Whitney CG. Prevention of pneumococcal disease among infants and children — use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010;59(RR11);1–18. Available at: . Accessed 24 Oct 2022.~~
6. . Accessed 14 January 2024.
~~10.~~7. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). 20 June 2023. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed ~~23 July 2023~~14 January 2024.

12. Appendix

A. Centers for Disease Control and Prevention (CDC). Pneumococcal Vaccine Timing. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
B. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Pneumococcal Conjugate Vaccine (PCV20) Vaccination in Adults Aged ~~19~~65 Years or Older: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human

Services, CDC; 2023. https://www.cdc.gov/vaccines/hcp/admin/downloads/job-aid-SCDM-PCV20-508.pdf

C. Centers for Disease Control and Prevention (CDC). Pneumococcal PneumoRecs VaxAdvisor Mobile App for Vaccine Providers. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

Protocol for Polio Vaccine
(IPOL®)

1. **What's New**
   A. ~~N/A~~Routine recommendations for adults who are known or suspected to be unvaccinated or incompletely vaccinated were updated to include completion of the 3-dose IPV primary series. The recommendation for adults who are at increased risk for exposure to poliovirus and have completed the primary series was also added.

2. **Immunization Protocol**
   A. Administer 0.5-mL dose, IM or SQ, of polio vaccines as recommended for age, vaccination status, and travel itinerary.
   B. May be given with all ACIP-recommended child and adult vaccinations.

3. **Vaccine Schedule**
   A. **Routine schedule for children <18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Recommended Spacing**
1	7-17 years~~≥ 7 years~~	
2		4-8 weeks from previous dose
3		6-12 months from previous dose
4		A 4th dose is not necessary if 3rd dose administered at age 4 or older and at least 6 months after the previous dose. A 4th dose is indicated if all previous doses were administered at <4 years or if the 3rd dose was administered <6 months after the second dose. The minimum interval between the 3rd and 4th dose is 6 months.

   B. **Accelerated schedule for children <18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	~~≥ 7 years~~7-17 years	
2		≥4 weeks after dose 1
3		≥6 months after dose 2

   C. **Unvaccinated, incompletely vaccinated, or unknown vaccine status for ~~travelers~~ ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Recommended Spacing**
1	≥18 years	
2		4-8 weeks after dose 1
3		6-12 months after dose 2

   D. **Accelerated schedule for unvaccinated, incompletely vaccinated, or unknown vaccine status for ~~travelers~~ ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**

1	≥18 years	
2		≥4 weeks after dose 1*
3		≥4 weeks after dose 2*

* If less than 8 weeks but more than 4 weeks is available before protection is needed, 2 doses of IPV should be administered at least 4 weeks apart. If less than 4 weeks is available before protection is needed, a single dose of IPV is recommended.[5]

E. **Fully vaccinated travelers ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	≥12 months after last dose

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
IPOL®[1]*	Inactivated polio virus (IPV) serotypes 1,2 and 3	5-mL multi-dose vials	≥ 6 weeks	None

*Combination vaccines including polio may also be used according to approved age indication

5. Recommendations for Use

~~A. IPV is considered routine for children <18 years of age but is not routinely recommended for unvaccinated adults ≥18 years.~~

A. Adults known or suspected to be unvaccinated or incompletely vaccinated known or suspected to be unvaccinated or incompletely vaccinated: administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series. Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

B. Adults who previously completed the full, routine polio vaccine series and are at increased risk of exposure to poliovirus~~are planning to travel to any country with circulating poliovirus~~, should receive a onetime booster dose of polio vaccine IPV. Adults working in health care settings, refugee camps or other humanitarian aid settings in countries bordering a country with circulating poliovirus should also receive a one-time booster dose of IPV.[5] Countries where a booster of IPV is recommended before travel can be found at: https://wwwnc.cdc.gov/travel/notices/alert/global-polio

~~B.~~C. Adults ~~and adolescents age 18 years~~ known or suspected to be unvaccinated or incompletely vaccinated known or suspected to be unvaccinated or incompletely vaccinated: administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series. Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

Commented [NP1]: 2024 recs
https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#child

Commented [NP2]: This is in 2024 recs, but I think it is captured in this bullet, so no change needed unless want clarification of complete primary series which is in next bullet (as new info)
https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#child

Adults at increased risk of exposure to poliovirus who completed primary series*: may administer one lifetime IPV booster
AND
Adolescents aged 18 years

Commented [NP3]: 2024 recs
https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#child

~~C.~~D. ~~Unvaccinated adults who are traveling to countries with increased risk of exposure to poliovirus should receive a three-dose series of IPV vaccine.~~ Adults who have received only one or two doses in the past should get the remaining doses of IPV vaccine administered at least 4 weeks apart.[3] If an adult cannot complete the series before travel departure, an accelerated schedule (doses administered at least 4 weeks apart) is recommended.[3]

~~D. Adults who continue to be at risk of exposure to poliovirus should complete the IPV 3-dose series when they return from travel.[3]~~

E. If a child cannot complete the accelerated schedule before departure, the remaining doses should be given in the visited country, or upon return home, at the intervals recommended in the accelerated schedule.[3]

F. Children completing the accelerated schedule should still receive a final dose of IPV at ≥4 years old, and at least 6 months after the previous dose.[3]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains[3]
IPOL®[1]	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium

7. Warnings and Precautions

A. Moderate or severe acute illness with or without fever.[4]

B. Although no causal relationship between IPOL® vaccine and Guillain-Barré Syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.[1]

8. Other Considerations

A. IPOL® can also be given by the subcutaneous route.[1]

B. Polio vaccine given outside the United States is valid if written documentation indicates that all doses were given after 6 weeks of age and the vaccine received was IPV or trivalent oral poliovirus vaccine (tOPV). Recipients receiving both tOPV and IPV require a total of 4 doses.[5]

~~C.~~ OPV given before April 1, 2016, can be assumed to be trivalent and valid.[5] OPV doses given in April of 2016, can only be counted as valid if the documentation indicates that it was trivalent.[5] OPV given after May 1, 2016 should not be counted as valid because it was a bivalent or monovalent vaccine.[5]

C.

~~D.~~ Persons <18 years of age with doses of OPV that do not count should receive IPV to complete the series.[5] Oral polio vaccine (OPV) has been unavailable in the United States since 1999.[5]

D.

~~E.~~ Travelers staying in a polio-infected country longer than 12 months may receive available poliovirus vaccine (IPV or OPV) in the infected country to meet the departure requirement.[3]

E.

~~F.~~ Immunodeficiency: IPV may be administered safely to immunocompromised travelers and their household contacts. Although a protective immune response cannot be ensured, IPV might confer some protection to the immunocompromised person.[4] People with certain primary immunodeficiency diseases should not be given live, attenuated OPV and should avoid contact with excreted OPV virus (such as exposure to a child vaccinated with OPV in the previous 6 weeks). Because OPV is no longer given in the United States, this situation would arise only if a child receives OPV overseas.[5] Revaccination with 3 doses of IPV is recommended 6–12 months after hematopoietic stem cell transplantation.

F.

~~G.~~ Mild Illness: IPV may be administered to people with diarrhea. Minor upper respiratory illnesses with or without fever, current antimicrobial therapy, and the convalescent phase of acute illness are not contraindications for vaccination.[6]

G.

~~H.~~ Pregnancy: If a pregnant woman is unvaccinated or incompletely vaccinated and requires immediate protection against polio because of planned travel to a country or area where polio cases are occurring, IPV can be administered as recommended for adults.[5]

H.

~~I.~~ Breastfeeding: Is not a contraindication to administration of polio vaccine to an infant or mother.[5] It is not known whether polio-containing vaccines are excreted in human milk. Use with caution in nursing mothers.[1]

I.

~~C.~~J. After an interval of 15–40 years, 25%–40% of survivors of paralytic poliomyelitis may experience muscle pain and exacerbation of existing weakness or develop new weakness or paralysis. This disease entity, referred to as post-polio syndrome, has been reported only in persons infected during the era of wild poliovirus circulation. This is not an infectious process.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any local reaction – pain, redness, induration or swelling at the injection site	Up to 75%
Redness ≥50 mm at injection site	Up to 18%
Severe pain, induration or swelling at the injection site	Up to 9%
Any systemic reaction – fever, malaise, aches, persistent crying, drowsiness	Up to 50%
Severe (grade 3) systemic reactions including fever above 102° F	Up to 3%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
IPOL®[1]	Store at 2°to 8°C (36°to 46°F)	Do not use if vaccine has been frozen. Protect from light.	

11. References

1. IPOL®. Package insert. Swiftwater, PA: Sanofi Pasteur SA; Updated May 1, 2022. https://www.fda.gov/media/75695/download. Accessed April 14, 2023.
2. Use of Inactivated Polio Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2023.~~Poliomyelitis prevention in the United States: updated recommendations of the Advisory Committee on Immunization Practices (ACIP) Advisory Committee on Immunization Practices.~~ MMWR ~~2000;49(RR-5)~~2023;72(49):1327-30. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7249a3.htm. ~~www.cdc.gov/mmwr/PDF/rr/rr4905.pdf~~ Accessed ~~14 Apr 2023~~17 January 2024.
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4. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf Accessed 14 Apr 2023.
5. Marin M, Patel M, Oberste S, Pallansch M. Guidance for assessment of poliovirus vaccination status and vaccination of children who have received poliovirus vaccine outside the United States. MMWR 2017; 66:23–5. Available at www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6601a6.pdf. Accessed 14 Apr 2023.

12. Appendix

A. N/A

Protocol for Respiratory Syncytial Virus Vaccine
(ABRYSVO™, AREXVY™)

1. **What's New**
   A. Added ~~indication for~~additional clarification regarding Abrysvo™ seasonal administration during the final trimester of pregnancy ~~between 32–36 weeks' gestation~~and additional guidance on subsequent vaccination for future pregnancies.

2. **Immunization Protocol**
   A. Administer a 0.5-mL dose, IM, of respiratory syncytial virus (RSV) vaccine to persons ≥ 60 years of age, using shared clinical decision making, as described in Section 5.
   B. May be given with all ACIP-recommended adult vaccinations.

3. **Vaccine Schedule**

RSV Vaccine (ABRYSVO™, AREXVY™) [1,2] Dose and Route – 0.5-mL IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥60 years	

RSV Vaccine (ABRYSVO™ only) [4] Dose and Route – 0.5-mL IM			
Dose	**Acceptable Age Range**	**Indication**	**Minimum Acceptable Spacing**
1	N/A	Pregnancy	Administer 32 weeks 0 days–36 weeks and 6 days of pregnanc during or just prior to the star of the RSV season*.

*Vaccine should be administered to pregnant persons during September–January in most of the continental United States, including Oregon, to target vaccine to pregnant persons whose infants will be in their first months of life during the RSV season. Administer RSV vaccine regardless of previous RSV infection. All other pregnant persons: RSV vaccine not recommended. There is currently no ACIP recommendation for RSV vaccination in subsequent pregnancies. No data is ~~are~~ available to inform whether additional doses are needed in later pregnancies.

4. **Licensed Vaccines**

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ABRYSVO™[1]	60 mcg RSV prefusion F A protein and 60 mcg RSV prefusion F B protein	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	≥60 years	No
AREXVY™[2]	120 mcg of the recombinant RSVPreF3 antigen, 25 mcg of MPL and 25 mcg of QS-21	0.5-mL single-dose vial of adjuvant suspension and single-dose vial of lyophilized antigen		

MPL: 3-O-desacyl-4'-monophosphoryl lipid A; QS-21: saponin purified from plant extract *Quillaja Saponaria* Molina

5. **Recommendations for Use**[3,4]
   A. Shared clinical decision making for patients 60 years of age and older: until additional evidence becomes available from post-marketing surveillance clarifying the potential risk (e.g. neurologic inflammatory events, atrial fibrillation), RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease. Pharmacists can

Commented [NP1]: 2024 recs also added this https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult
-Administer RSV vaccine regardless of previous RSV infection
-All other pregnant persons: RSV vaccine not recommended There is currently no ACIP recommendation for RSV vaccination in subsequent pregnancies. No data are available to inform whether additional doses are needed in later pregnancies.

Commented [CS2R1]: added

Commented [NP3]: 2024 recs just added this new info https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

Pregnant at 32 weeks 0 days through 36 weeks **and 6 days** gestation from September through January in most of the continental United States

Commented [CS4R3]: added

engage in shared clinical decision making to discuss RSV vaccination with persons aged 60 years or older who are most likely to benefit. Pharmacists are authorized to administer RSV vaccine if the patient provides information that one of the following risk factors is present:

Chronic underlying medical conditions
• Lung disease (such as chronic obstructive pulmonary disease and asthma) • Cardiovascular disease (such as congestive heart failure and coronary artery disease) • Moderate or severe immune compromise* • Diabetes mellitus • Neurologic or neuromuscular conditions • Kidney disorders • Liver disorders • Hematologic disorders • Other underlying conditions that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease
Other factors
• Frailty† • Advanced age‡ • Residence in a nursing home or other long-term care facility • Other underlying factors that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease

*A list of potentially immune compromising conditions is available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html

† Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 pounds or 4.5 kilograms in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity.

‡ Among adults aged ≥ 60 years, RSV incidence increases with advancing age. Although age may be considered in determining an older adult patient's risk for severe RSV-associated disease, there is no specific age threshold at which RSV vaccination is more strongly recommended within the age group of adults aged 60 years.

B. Pregnancy: Administer at 32–36 weeks' gestation during every pregnancy using seasonal administration (September–January in most of the continental United States, including Oregon) for prevention of RSV-associated LRTI in infants aged < 6 months.

6. Contraindications[1,2]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains
ABRYSVO™[1]	Tromethamine, tromethamine hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride, host cell protein and DNA
AREXVY™[2]	Trehalose, sodium chloride, potassium dihydrogen phosphate, dipotassium phosphate, polysorbate 80, disodium phosphate anhydrous, dioleoyl phosphatidylcholine (DOPC), host cell protein and DNA

7. Warnings and Precautions[1,2,4]

A. Individuals with acute, moderate, or severe illness with or without fever should delay immunization until symptoms have improved.

B. Individuals with an immunocompromising condition may experience a diminished immune response to the vaccine.

C. Potential risk of preterm birth. To avoid the potential risk of preterm birth (defined as birth before 37 weeks' gestation), administer Abrysvo™ as indicated only to pregnant individuals at 32 through 36 weeks' gestational age.

8. Other Considerations[1,2,4]

A. Coadministration with other vaccines: Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines is currently limited. Coadministration of RSV and influenza vaccines met noninferiority criteria for immunogenicity except for a lower antibody response to the influenza A Darwin H3N2 strain when ABREXVY™ was administered with an adjuvanted quadrivalent inactivated influenza vaccine. The clinical significance of this is unknown.

Administering RSV vaccines with one or more other adult vaccines during the same visit may increase local or systemic reactogenicity. When determining whether to coadminister other vaccines with the RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preference.

B. Pregnancy and Breastfeeding: RSV vaccines are not approved for individuals <60 years of age. It is unknown if RSV vaccines are excreted in human milk.

C. Nirsevimab administration: Providers who care for pregnant persons should discuss the relative advantages and disadvantages of maternal RSV vaccination and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab for prevention of RSV in the infant. Nirsevimab administration is recommended for infants aged < 8 months who are born during or are entering their first RSV season and whose mother did not receive a RSV vaccination or vaccination status is unknown; but administration of both products is not needed for most infants.

9. Side Effects and Adverse Reactions

Adverse Event	**Frequency**
ABRYSVO™[1]	
Fatigue	15.5%
Headache	12.8%
Injection site pain	10.5%
Myalgia	10.1%
Adults who are pregnant	
Preeclampsia	1.8% (95% CI 1.4, 2.3)
Gestational hypertension	1.1% (95% CI 0.8, 1.5)
AREXVY ™[2]	
Injection site pain	60.9%
Fatigue	33.6%

Myalgia	28.9%
Headache	27.2%
Arthralgia	18.1%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
ABRYSVO™[1]	Store at 2°– 8°C (36°- 46°F)	Store in original carton and protect from light. Do not freeze. Discard if carton has been frozen.	Reconstituted vaccine may **only** be stored at room temperature, 15°– 30°C (59°- 86°F). Discard reconstituted vaccine if not used within 4 hours.
AREXVY™[2]			Reconstituted vaccine may be stored in the refrigerator between 2°– 8°C (36°- 46°F) or at room temperature up to 25°C (77°F). Discard reconstituted vaccine if not used within 4 hours.

11. References

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4. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus-associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices— United States, 2023. MMWR ePub: 9 October 2023. Available at http://dx.doi.org/10.15585/mmwr.mm7241e1. Accessed 9 Oct 2023.

12. Appendix

A. Centers for Disease Control and Prevention. Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023. Available from: https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf

Protocol for Tetanus Diphtheria Containing Vaccines
(Adacel®, Boostrix®, TENIVAC®, and TDVAX™)

1. **What's New**
   A. Updated recommendations to reflect that if Tdap is administered inadvertently to children 10 years of age that the Tdap dose may be counted as the adolescent dose recommended at age 11-12 years. This previously was considered to be an invalid dose.
   ~~A. N/A~~

2. **Immunization Protocol**
   A. Administer a 0.5-mL dose, IM, of tetanus-containing vaccine, according to the age-appropriate schedule and vaccine history.
   B. May be given with all ACIP-recommended child and adult vaccinations.

3. **Vaccine Schedule**

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
For unvaccinated persons ≥ 7 years of age[1]*		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
2		4 weeks after dose 1
3		6 months after dose 2
The preferred schedule is 1 dose of Tdap, followed by either Td or Tdap for dose 2 & 3		
*See appendices for catch-up schedule for partially vaccinated children.		

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
Booster schedule for persons ≥ 10 years of age[2]		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
Adolescent booster	11-18 years	These persons should receive a single dose of Tdap, preferably at age 11–12 years. For persons aged 7–9 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap dose should be administered at age 11–12 years. If a Tdap dose is administered at age ≥10 years, the Tdap dose may count as the adolescent Tdap dose.
Routine booster	≥19 years	Regardless of the interval since their last tetanus or diphtheria toxoid–containing vaccine, persons aged ≥19 years who have never received a dose of Tdap should receive 1 dose of Tdap.
Additional boosters		To ensure continued protection against tetanus and diphtheria, 1 booster dose of either Td or Tdap should be administered every 10 years throughout life.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM
For Pregnant Persons[2]

Protocol for Tetanus Diphtheria Containing Vaccines
(Adacel®, Boostrix®, TENIVAC®, and TDVAX™)

Tdap should be administered during **every** pregnancy, at 27-36 weeks' gestation, preferably during the earlier part of the third trimester. Vaccination during the third trimester provides the highest concentration of maternal antibodies to be transferred closer to birth.
Tdap can be given at any time during pregnancy if needed for catch-up or wound management.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM For Wound Management[2]				
History of absorbed tetanus toxoid doses	**Clean, minor wounds**		**All other wounds***	
	Tdap or Td	**TIG#**	**Tdap or Td**	**TIG#**
Unknown or <3 doses	Yes	No	Yes	Yes
≥ 3 doses	Administer if ≥ 10 years since last dose	No	Administer if ≥ 5 years since last dose	No
*Wounds contaminated with dirt, feces, soil or saliva; puncture wounds; avulsions; or wounds from missiles, crushing, burns or frostbite. #Persons with HIV or severe immunodeficiency should receive Tetanus Immune Globulin (TIG), regardless of immunization history or wound severity.				

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range***	**Thimerosal**
Adacel®[3]	Tetanus, diphtheria, and acellular pertussis	Single-dose vials and prefilled syringes containing a 0.5- mL suspension for injection	10-64 years	None
Boostrix®[4]			≥10 years	
TENIVAC®[5]	Tetanus and diphtheria		≥7 years	
TDVAX™[6]		Single-dose vials containing a 0.5- mL suspension for injection		≤0.3 mcg (not as a preservative)
*Off-label use is approved by ACIP				

5. Recommendations for Use

A. Routine use: All persons ≥11 years of age who have not received a dose of Tdap should receive a single dose of Tdap at the first opportunity, regardless of when they last received a Td booster.[1]

B. Catch-up vaccination: Persons who do not have documentation of receiving a series of diphtheria/tetanus-containing vaccine in childhood need a single-dose of Tdap and two doses of either Td or Tdap vaccine.

C. Pregnant persons: No change has been made to the recommendations for routine Tdap immunization during pregnancy. Pregnant persons should receive 1 dose of Tdap during each pregnancy, irrespective of their history of receiving the vaccine. Tdap should be administered at 27–36 weeks' gestation, preferably during the earlier part of this period, although it may be administered at any time during pregnancy.

D. Wound management: Either Td or Tdap can be used for wound management. Tdap is preferred for persons who haven't previously received Tdap or whose history is unknown.[2]

6. Contraindications

A. Allergy: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (Adacel®, Boostrix®, Tenivac®)

Vaccine	Contains[7]
Adacel®	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde, tip caps of prefilled syringes may contain latex
Boostrix®	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80, tip caps of prefilled syringes may contain latex
Tenivac®	aluminum phosphate, formaldehyde, sodium chloride, tip caps of prefilled syringes may contain latex
TDVAX™	aluminum phosphate, formaldehyde, thimerosal

B. Encephalopathy: (Tdap) Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap. These persons should receive Td in place of Tdap.[5]

7. Warnings and Precautions

A. Neurological disorders: (Tdap) Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized; these precautions are for pertussis components.[1]
B. Guillain-Barré syndrome: Guillain-Barré syndrome <6 weeks after a previous dose of tetanus toxoid-containing vaccine.[1]
C. Arthus-type hypersensitivity: History of Arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid–containing vaccines; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid–containing vaccine.[1]

8. Other Considerations

A. Catch up schedules for 7 through 18 years of age:
   i. If patients' vaccination status is unknown or incomplete, guidance for catch-up schedules can be found at https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html
      1. For children 7-9 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-1.pdf
      2. For children and adolescents 10-18 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-2.pdf
B. History of disease:
   i. Persons who have a history of pertussis should receive a booster dose of Tdap according to the routine recommendation. While pertussis disease likely confers some natural immunity, duration of protection is not long-term.[5]
   ii. Tetanus or diphtheria disease does not confer immunity against re-infection. Persons who have a history of a primary series should receive a booster dose during convalescence. Persons without a history of vaccination should begin the 3-dose Tdap/Td series.[1]
C. Inadvertent administration of the incorrect formulation:[1]

i. DTaP is not indicated for persons aged ≥7 years. If DTaP is administered inadvertently to a fully vaccinated child aged 7–10 years, this dose should be counted as the adolescent Tdap dose.
ii. If DTaP is administered inadvertently to an under-vaccinated child aged 7– 10 years, this dose should count as the Tdap dose of the catch-up series, and the child should receive an adolescent booster dose of Tdap.
iii. If DTaP is administered inadvertently to a person aged ≥11 years, this dose should count as the Tdap dose, and the person should not receive an additional dose of Tdap.
iv. Children aged 7–9 years who are fully vaccinated. If Tdap is administered inadvertently, the Tdap dose should not be counted as valid. The adolescent Tdap dose should be administered as recommended when this child is aged 11–12 years.
v. Children aged 10 years who are fully vaccinated. If Tdap is administered inadvertently, the Tdap dose may be counted as the adolescent dose recommended at age 11-12 years.
~~iv.~~

Commented [NP1]: Look carefully at this 2024 recs https://www.cdc.gov/vaccines/schedules/hcp/schedule-changes.html#adult

Tdap administered at age 10 years may be counted as the adolescent dose recommended at age 11–12 years

9. Side Effects and Adverse Reactions

Tdap[3,4] Adverse Events	Frequency
Injection site pain	Very common, up to 78%
Other local reactions (redness, swelling)	Less Common, up to 21%
Fever >100. 4°F	Uncommon, up to 5%
Other systemic reactions (fatigue, headache, GI symptoms)	Common, up to 43%

Td[5,6] Adverse Events	Frequency
Injection site pain	Very common, up to 81%
Other local reactions (redness, swelling)	Less Common, up to 26%
Fever >100. 4°F	Uncommon, up to 2%
Other systemic reactions (fatigue, headache, GI symptoms)	Less Common, up to 25%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Adacel®[3] Boostrix®[4] Tenivac®[5]	Store at 2°– 8°C (36°- 46°F)	Do not freeze. Do not use if vaccine has been frozen.	
TDAVAX™[6]			No latex.

11. References

1. Liang, JL, Tiwari T, Moro P, et al. Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the ACIP. MMWR 2018; 67(2):1–48. Available at: www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf. Accessed 23 July 2023.

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12. Appendix

A. N/A

Protocol for Yellow Fever Vaccine
(YF-VAX®)

1. **What's New**
   A. ~~YF-VAX® (yellow fever vaccine) is now available in the United States. As of May 6, 2021, Stamaril® is no longer available. Providers with a current Oregon Yellow Fever Vaccination Stamp may now order YF-VAX® from the manufacturer.~~[2] Updated references to reflect the updated 2024 CDC Yellow Book.

2. **Immunization Protocol**
   A. Administer a 0.5-mL dose, SQ, of yellow fever vaccine to persons ≥7 years of age if indicated.
   B. YF-VAX®[3] may be given with all other ACIP-recommended vaccines.
   C. **You must be an Oregon-certified Yellow Fever (YF) vaccine provider to administer this vaccine**. More information on Oregon's yellow fever certification can be found at: https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/yellfev.aspx

3. **Vaccine Schedule**

Yellow Fever Vaccine (YF-VAX®)[3] Dose and Route – 0.5-mL SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
Booster[#]		10 years

[#]Not routinely recommended. See Recommendations for use.

4. **Licensed Vaccine**

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
YF-VAX®[1]	17D-204 strain of YF virus grown in chicken embryos with gelatin and sorbitol as a stabilizer	Vaccine vial, 1 Dose supplied in a package of 5 vials Diluent vial containing sodium chloride, 0.6 mL, supplied separately in a package of 5 vials Vaccine vial, 5 Dose supplied in a package of 1 vial Diluent vial, 3 mL supplied separately in a package of 1 vial	≥9 months	None

5. **Recommendations for Use**
   A. Due to the risk of serious adverse events that can occur following YF vaccine administration, providers should carefully observe the contraindications and consider the precautions to vaccination prior to administration; and vaccinate only persons who are at risk of exposure to YF virus or who require proof of vaccination for country entry.[2]
   B. YF vaccine is recommended for persons aged 7 years and older who are traveling to or living in areas at risk for yellow fever virus (YFV) transmission in Central and South America or Africa.[2]

C. Countries or areas with risk of yellow fever transmission are listed at: https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/yellow-fever-vaccine-malaria-prevention-by-country. ~~wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/yellow-fever-vaccine-and-malaria-prophylaxis-information-by-country.~~ Vaccination is also recommended for travel outside the urban areas of countries that do not officially report the disease but that lie in a yellow fever-endemic zone.[2]

D. Yellow fever vaccination may be required for international travel. Some countries in Africa require evidence of YF vaccination from all entering travelers and some countries may waive the requirements for travelers arriving from areas where there is no current evidence of significant risk for contracting yellow fever and will be staying less than 2 weeks. Some countries require an individual, even if only in transit, to have a valid International Certificate of Vaccination if the individual has been in countries either known or thought to harbor yellow fever virus. The certificate becomes valid 10 days after vaccination with YF vaccine.[2]

E. Laboratory personnel who might be exposed to virulent yellow fever virus or to concentrated preparations of the yellow fever vaccine strain by direct or indirect contact or by aerosols should be vaccinated.[3]

F. Simultaneous Administration of Other Vaccines or Drugs: No evidence exists that inactivated vaccines and YF vaccine interfere with the immune response to the vaccine. Therefore, inactivated vaccines can be administered either simultaneously or at any time before or after YF vaccination. YF vaccine should be administered either simultaneously or 28 days apart from other live viral vaccines because the immune response to one live virus vaccine might be impaired if administered within 28 days of another live-virus vaccine.[6]

G. Booster Dose recommendations: As of July 11, 2016, International Health Regulations NO LONGER require revaccination at intervals of 10 years: a completed International Certificate of Vaccination or Prophylaxis is now valid for the lifetime of the vaccinee. Vaccine administrators should check national requirements.[4]
   a. High-Risk Travel: Travelers who received their last dose of yellow fever vaccine at least 10 years previously and who will be in a higher-risk setting based on season, location, activities, and duration of their travel. This would include travelers who plan to spend a prolonged period in endemic areas or those traveling to highly endemic areas such as rural West Africa during peak transmission season or an area with an ongoing outbreak.
   b. Hematopoietic stem cell transplant recipients: Persons who received a hematopoietic stem cell transplant after receiving a dose of yellow fever vaccine and who are sufficiently immunocompetent to be safely vaccinated should be revaccinated before their next travel that puts them at risk for yellow fever virus infection.
   c. HIV Infection: Persons who were infected with human immunodeficiency virus when they received their last dose of yellow fever vaccine should receive a dose every 10 years if they continue to be at risk for yellow fever virus infection.
   d. Pregnancy: Persons who were pregnant when they received their initial dose of vaccine should receive 1 additional dose before they are next at risk for YF.
   e. Laboratory workers: Individuals who routinely handle wild-type yellow fever virus should have yellow fever virus-specific neutralizing antibody titers measured at least every 10 years to determine if they should receive additional doses of the vaccine. For laboratory workers who are unable to have neutralizing antibody titers measured, yellow fever vaccine should be given every 10 years as long as they remain at risk.

Protocol for Yellow Fever Vaccine
(YF-VAX®)

6. Contraindications[1]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. History of life-threatening allergic reaction to eating eggs or chicken.
C. History of thymus disorders associated with abnormal immune cell function, such as thymomas or myasthenia gravis.[3]
D. Symptomatic HIV infection.[3]
E. History of primary immunodeficiencies, malignant neoplasms, transplantation, immunosuppressive or immunomodulatory therapies. Persons receiving current or recent radiation therapy or immunosuppressive drugs.[1]
F. Postpone vaccination in case of an acute or febrile disease.[1]

Vaccine	Contains
YF-VAX®[1]	sorbitol, gelatin, sodium chloride, egg protein

7. Warnings and Precautions

WARNING

Yellow fever vaccine-associated viscerotropic disease (YEL–AVD)[1]
YEL-AVD is a severe illness similar to wild-type YF disease, with vaccine virus proliferating and disseminating throughout the host's tissues. To date, two specific risk factors for YEL-AVD have been identified: older age and a history of thymus disease or thymectomy. YEL-AVD has been reported to occur only after the first dose of YF vaccine.

Yellow fever vaccine-associated neurotropic disease (YEL–AND)[1]
YEL-AND is a serious but rarely fatal adverse event that occurs in first-time YF vaccine recipients. YEL-AND represents a conglomeration of clinical syndromes, including meningoencephalitis, Guillain-Barré syndrome, acute disseminated encephalomyelitis, and cranial nerve palsies.

Adults ≥60 years of age[1]
Age ≥60 years is a precaution to receiving YF vaccine, particularly a first-ever dose. The risks of YEL-AVD and YEL-AND are higher in this age group.

A. Avoid vaccinating breastfeeding women against YF. However, when travel of nursing mothers to YF–endemic areas cannot be avoided or postponed, these women should be vaccinated. Some experts recommend breastfeeding women who receive YF vaccine should temporarily suspend breastfeeding, pump, and discard pumped milk for at least 2 weeks after vaccination before resuming breastfeeding. Lactation is a precaution for vaccination, particularly if the breastfeeding infant is <9 months of age, because of the risk of encephalitis.[4]
B. Pregnancy is a precaution, and pregnant persons should avoid travel to a yellow fever-endemic area. If travel is unavoidable and the vaccination risks outweigh the risks of YFV exposure, pregnant persons should be excused and issued a medical waiver to fulfill health

regulations. Pregnant persons who must travel to areas where YFV exposure is likely should be vaccinated.[1]

C. Persons ≥60 years of age maybe at increased risk for serious adverse events after vaccination, compared with younger persons. The rate of serious adverse events following vaccination is 1.5 times higher than the average rate for persons 60–69 years of age and 3 times higher for persons 70 years or older.
If travel is unavoidable, the decision to vaccinate travelers aged ≥60 years needs to be weighed against their destination-specific risk for exposure to YFV. Particular caution should be considered for older travelers receiving YF vaccine for the first time.[1]

D. Asymptomatic HIV infection with moderate immune suppression, i.e., CD4+ T-lymphocyte values of 200 to 499/mm^3 for persons aged ≥6 years old.[4]

8. Other Considerations

A. ACIP recommends that a woman wait 4 weeks after receiving the yellow fever vaccine before conceiving.[3]

B. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.[5]

C. HIV-infected persons, because vaccination of asymptomatic HIV-infected persons might be less effective, measurement of their neutralizing antibody response to vaccination should be considered before travel. Contact CDC at 970-221-6400 to discuss serologic testing further.[6]

D. Allergic Reactions: less severe or localized manifestations of allergy to eggs or to feathers are not contraindications to vaccine administration and do not usually warrant vaccine skin testing.[1]

E. National YF vaccination requirements are mandatory and are primarily intended to prevent importation into and transmission of YF virus within a given country. Some countries require evidence of vaccination from all entering travelers. International Health Regulations stipulate that a Yellow Fever Stamp-Approved care provider may issue a waiver of yellow fever vaccination to a traveler, if the provider judges that yellow fever vaccination is medically contraindicated. The traveler also should be advised of the possibility that the medical waiver might not be accepted by the destination country. Failure to secure validations can cause a traveler to be quarantined, denied entry, or possibly revaccinated at the point of entry to a country.[4] Country requirements are subject to change at any time; therefore CDC encourages travelers to check with the appropriate embassy or consulate before departure. Because requirements may change, current information should be obtained from the CDC's Travelers' Health website: https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/yellow-fever-vaccine-malaria-prevention-by-country.~~https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/yellow-fever-vaccine-and-malaria-prophylaxis-information-by-country.~~

F. All travelers to yellow fever endemic countries should be advised of the risks of the disease and available methods to prevent it, including personal protective measures and vaccine. All travelers should take precautions to avoid mosquito bites to reduce the risk of YF and other vector-borne infectious diseases. These precautions include using insect repellent, wearing permethrin-impregnated clothing, and staying in screened or air conditioned-rooms.

Additional information on protection against mosquitoes and other arthropods can be found at: https://wwwnc.cdc.gov/travel/page/avoid-bug-bites

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Local injection site reactions like pain, redness, swelling, rash	Up to 71.9%
Systemic symptoms like fever, tiredness, headache, muscle pain	Up to 30%
Vaccinees over 60 years of age are at increased risk of systemic adverse events and at lower risk of local reactions.	
Yellow Fever Vaccine–Associated Neurologic Disease (YEL-AND) YEL-AND represents a conglomeration of clinical syndromes, including meningoencephalitis, Guillain-Barré syndrome, acute disseminated encephalomyelitis, and, rarely, cranial nerve palsies	0.8/100,000 doses **Age ≥ 60 years:** 2.2/100,000 doses
Yellow Fever Vaccine–Associated Viscerotropic Disease (YEL-AVD) YEL-AVD is a severe illness similar to wild-type YF disease, with vaccine virus proliferating in multiple organs and often leading to multiorgan dysfunction or failure and occasionally death	0.3/100,000 doses **Age ≥ 60 years:** 1.2/100,000 doses

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
YF-VAX®[1]	2° to 8°C (36˚F to 46˚F)	Do not use if vaccine has been frozen.	Use immediately. Reconstituted vaccine not used must be discarded after one hour. Discarded vaccine must be either sterilized or disposed in red hazardous waste containers.

11. References

1. YF-VAX® February 2019 package insert. Available at: https://www.fda.gov/media/76015/download Accessed 13 April 2023.
2. Yellow Fever. In: 2024 ~~CDC~~ Yellow Book ~~2020:~~ Health Information for International Travel. Gershman, M, Staples, JE. ~~Oxford University Press. June 2020. Chapter Four.~~ Available at: https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/yellow-fever. ~~https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/yellow-fever.~~ Accessed ~~13 April 2023~~17 January 2024.
3. Yellow fever vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010. 59(RR07); P 1–32. Available at: www.cdc.gov/mmwr/pdf/rr/rr5907.pdf. Accessed 13 April 2023.

4. CDC. Yellow fever vaccine booster doses: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015. MMWR 2015;64;647–50. Available at: https://www.cdc.gov/mmwr/pdf/wk/mm6423.pdf. Accessed 13 April 2023.
5. CDC. Notes from the field: Fatal yellow fever vaccine-associated viscerotropic disease–Oregon, September 2014. (2015). 64(10);279-81. Available at: https://www.cdc.gov/mmwr/pdf/wk/mm6410.pdf. Accessed 13 April 2023.
6. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html. Updated 7 Apr 2023. Accessed 13 April 2023.
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8. CDC. Transmission of yellow fever vaccine virus through breast-feeding— Brazil,2009. MMWR 2010;59(05);130-132. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm5905a2.htm. Accessed 21 March 2023.
9. World Health Organization. Vaccine-preventable diseases, Yellow Fever. Available at: https://www.who.int/news-room/fact-sheets/detail/yellow-fever. ~~https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/yellow-fever~~. Accessed ~~13 April 2023~~6 February 2024.

Commented [NP1]: The WHO d/c'd alot of their pages this is updated one: https://www.who.int/news-room/fact-sheets/detail/yellow-fever

Commented [JD2R1]: Updated

12. Appendix

A. N/A

PREVENTIVE CARE

TRAVEL MEDICATIONS

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE:

- Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.
- Following all elements outlined in ~~OAR 855-020-0110~~OAR 855-~~020-0110~~115-0330 and OAR 855-115-0335, a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
  - Malaria prophylaxis
  - Traveler's diarrhea
  - ~~Acute mountain sickness~~Altitude illness prophylaxis
  - Motion sickness

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Travel Medications Patient Intake Form (pg. 2-3)
- Utilize the standardized Travel Medications Assessment and Treatment Care Pathway (pg. 4-10)
- Utilize the standardized Travel Medication Prescription Template *optional* (pg. 11)
- Utilize the standardized Travel Medication Provider Notification (pg. 12-13)
- Utilize the standardized Travel Medication Patient Visit Summary (pg. 14)

PHARMACIST TRAINING/EDUCATION:

- APhA Pharmacy-Based Immunization Delivery certificate (or equivalent); and
- Minimum of 4 hour comprehensive training program related to pharmacy-based travel medicine services intended for the pharmacist (one-time requirement); and
- A minimum of 1 hour of travel medication continuing education (CE), every 24 months.

~~REFERENCES~~RESOURCES:

- CDC Yellow Book 2024: Health Information for International Travel. Oxford University Press; 2023. https://wwwnc.cdc.gov/travel/page/yellowbook-home.~~CDC Yellow Book 2024: Health Information for International Travel. Oxford University Press; 2023.~~Centers for Disease Control and Prevention. CDC Yellow Book 2020: Health Information for International Travel. Oxford University Press; 2019. https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020
- ~~https://wwwnc.cdc.gov/travel/page/yellowbook-home~~

RESOURCES:

- 2020 2024 Yellow Book Home | Travelers' Health | CDC. Accessed February 14, 2023.January 15, 2024. https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020
- Travelers' Health | CDC. Accessed February 14, 2023January 15, 2024. https://wwwnc.cdc.gov/travel/

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

PATIENT INFORMATION

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other_____

Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

~~Any allergies to medications, eggs, latex? Yes / No~~ ~~If yes, please list~~ _____

TRAVEL SPECIFICS

Purpose of Trip: _____

Activities: _____

Departure Date: _____ Return Date: _____

List Countries AND Cities to be Visited Chronologically (Include Layovers)	**Arrival Date**	**Departure Date**

Have you traveled outside the United States before? □ Yes □ No

If yes, where and when?

_____

_____

1.	Will you ~~-~~ONLY be using airplane as your mode of transportation If no, explain: _____	□ Yes □ No □ Not sure
2.	Will you ~~-~~ONLY be visiting major cities? If no, explain: _____	□ Yes □ No □ Not sure
3.	Will you ~~-~~ONLY be staying in hotels? If no, explain: _____	□ Yes □ No □ Not sure
4.	Will you be visiting friends and family?	□ Yes □ No □ Not sure
5.	Will you be ascending to high altitudes? (≥8000~~>~~ ~~7,000~~8,250 ft or 2,~~300~~ 45500 meters) in	□ Yes □ No □ Not sure
6.	Will you be working in the medical or dental field with exposure to blood or bodily fluids?	□ Yes □ No □ Not sure

Commented [CS1]: Other area down below to list

Commented [NP2]: WMS altitude illness guidelines 2024
were pulled temporarily off the wms.org site because of publishing issue, but we should reference these

Unacclimatized individuals are at risk of high altitude illness
when ascending to altitudes above 2500m.

Commented [CS3R2]: Not seeing this in yellow book. Likely will need to cite something that is currently accessible.

Commented [CS4R2]: Updated altitude to be aligned with YB

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

ALLERGIES

□ No known drug or vaccine allergies □ No known food allergies

Drug/Vaccine Allergies: (describe reaction, ie, rash, hives, anaphylaxis, etc)

_____

Food Allergies: (describe reaction, ie, rash, hives, anaphylaxis, etc) -

_____

VACCINE MEDICAL INFORMATION

Please complete the table below ***(please bring your vaccination record to the pre-travel consult)***

Vaccinations	~~Yes – *(Enter vaccination date below)*~~	No	Not Sure
Chikungunya			
Cholera			
COVID-19~~19~~ ~~(Manufacturer):~~	Dose 1: 2: Booster(s):		
Haemophilus Influenzae B (HIB)			
Hepatitis A	Dose 1: 2:		
Hepatitis B ~~B~~ (Manufacturer):_____	Dose 1: 2: 3:		
Hepatitis A/B Combo	Dose 1: 2: 3:		
Human Papillomavirus (HPV)			
Influenza			
Japanese Encephalitis	Dose 1: 2:		
Meningococcal B	Dose 1: 2:		
Meningococcal ACWY~~Meningitis~~	Dose 1: 2:		
~~MMR (~~Measles, Mumps, Rubella~~)~~ (MMR)	Dose 1: 2:		
Pneumonia ~~PPSV23: PCV20: PCV15:~~			
PPSV23			
PCV (Select: 13/15/20)			
Polio ~~(Adult Booster)~~			
Rabies	Dose 1: 2:		
Respiratory Syncytial Virus (RSV)			
Shingles	Dose 1: 2:		
Tetanus (Select: Tdap/Td/DTaP/DT)			
Tick-Borne Encephalitis	Dose 1: 2: 3: 4:		
Typhoid (Select: Oral / ~~Shot~~Injection)			
Varicella	Dose 1: 2:		
Yellow Fever			
Other:			
Other:			

MEDICAL HISTORY

List your current prescription medications and medical conditions treated (include birth control pills and anti-depressants):

Current Medical Conditions:_____

_____

Current Prescription Medications:_____

_____

Regularly used Non-Prescription Medications (over the counter, herbal, homeopathic, vitamins, and supplements including those purchased at health-food stores):_____

Commented [NP5]: so again - this assumes no pharmacists giving cholera, TBE, chik vaccines yet, but they are available
also - do pharmacists discuss routine vax not listed here just to make sure people are current or not enough time? Hib, HPV are on travel meds 5 form, why not here?

Commented [CS6R5]: Added

Travel Medication Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

~~7~~1.	Are you currently using steroids?	□ Yes □ No □ Not sure
2~~8~~.	Are you currently receiving radiation therapy?	□ Yes □ No □ Not sure
~~9~~3.	Are you currently receiving immunosuppressive therapy?	□ Yes □ No □ Not sure
4~~1~~	Are you pregnant or are you planning to become pregnant within the next year?	□ Yes □ No □ Not sure
5~~1~~	Are you currently breast-feeding?	□ Yes □ No □ Not sure

QUESTIONS/CONCERNS

Please list additional questions or concerns that you might have regarding your travel: _____

_____

Signature:_____Date:_____

Travel Medications - Assessment and Treatment Care Pathway

STEP 1: Assess routine and travel vaccinations.
STEP 2: Choose and issue prescription(s) for appropriate prophylaxis medication(s), in adherence to the CDC's 2024 Yellow Book: Health Information for International; https://wwwnc.cdc.gov/travel/page/yellowbook-home ~~CDC's 2020 Yellow Book: Health Information for International Travel (v. 06/11/2019)~~ and this protocol. Must also include documented screening for contraindications (see pgs. 6-7).
STEP 3: Prescribe medications and administer vaccinations.
STEP 4: Provide a written individualized care plan to each patient.

1. **Malaria Prophylaxis**
   a. **Patient assessment**
      i. Review detailed itinerary
      ii. Identify zones of resistance
      iii. Review recommendations by the CDC
      iv. Discuss planned activities
      v. Assess risk of acquiring malaria and body weight (kg)
   b. **Prophylaxis**
      i. Discuss insect precautions and review signs/symptoms of malaria with patient
      ii. Screen for contraindications
      iii. Assess travel areas for resistance:
         1. **Non-chloroquine resistant zone**
            a. *Chloroquine (Aralen®)*
            Adult dosing: Chloroquine 500 mg
            - Begin 1-2 weeks prior to ~~travel~~entering malarious area-1 tablet weekly
            - Take~~n~~ once weekly ~~during trip~~while in malarious area and for 4 weeks after leaving risk area

            Pediatric dosing:
            8.3 mg/kg (maximum is 500 mg)
            - Begin 1-2 weeks prior to ~~travel~~entering malarious area -1 dose weekly
            - Taken once weekly during trip and for 4 weeks after leaving ~~risk~~ malarious area

            OR

            b. *Hydroxychloroquine (Plaquenil®)*
            Adult Dosing: Hydroxychloroquine 400 mg
            - Begin 1-2 weeks prior to ~~travel~~entering malarious area -1 tablet weekly
            - Take~~n~~ once weekly during trip and for 4 weeks after leaving ~~risk~~ malarious area

            Pediatric Dosing:
            6.5 mg/kg (maximum is 400mg)
            - Begin 1-2 weeks prior to malarious area~~travel~~-1 dose weekly
            - Take~~n~~ once weekly during trip and for 4 weeks after leaving malarious~~risk~~ area

         2. **Chloroquine-resistant zone**
            a. Atovaquone/Proguanil (Malarone®)
            Adult Dosing: Atovaquone/Proguanil 250mg/100mg
            - Begin 1 tablet daily 1-2 days prior to ~~travel~~ entering malarious area
            - Take~~n~~ daily during trip and 7 days after leaving ~~risk~~ malarious area

            Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg
            5–8 kg: 1/2 pediatric tablet daily
            9–10 kg: 3/4 pediatric tablet daily
            11–20 kg: 1 pediatric tablet daily

Commented [NP1]: Would try a different approach - see CDC YB 2024 table at end of this doc

Commented [CS2R1]: Elect to remove. This is duplicative of b.ii.

Commented [NP3]: For all of these, it shouldn't be prior to travel because travel to malarious area may not happen right away

Commented [CS4R3]: Agreed

21–30 kg: 2 pediatric tablets daily
31–40 kg: 3 pediatric tablets daily
> 40 kg: 1 adult tablet daily

- Begin 1 dose daily 1-2 days prior to ~~travel~~ entering malarious area
- Take~~n~~ daily during trip and 7 days after leaving malarious~~risk~~ area

OR

b. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult Dosing: Doxycycline 100mg
- Begin 1 tablet or capsule daily 1-2 days prior to ~~travel~~ entering malarious area
- Take~~n~~ daily during trip and for 4 weeks after leaving ~~risk~~ malarious area

Pediatric Dosing:
≥8 years old: 2.2 mg/kg (maximum is 100 mg) daily

- Begin 1 dose daily 1-2 days prior to entering malarious area~~travel~~
- Take~~n~~ daily during trip and for 4 weeks after leaving malarious~~risk~~ area

OR

c. *Mefloquine (Lariam®)*
Adult Dosing: Mefloquine 250mg
- Begin ~~1 -~>2 weeks prior to entering malarious area ~~travel~~-1 tablet weekly
- Take~~n~~ once weekly during travel in malarious area and for 4 weeks after leaving ~~risk~~ malarious area

Pediatric Dosing:
≤9 kg: 5 mg/kg
10-19 kg: ¼ tablet weekly
20-30 kg: ½ tablet weekly
31-45 kg: ¾ tablet weekly
> 45 kg: 1 tablet weekly

- Begin 1-2 weeks prior to ~~travel~~entering malarious area-1 dose weekly
- Take~~n~~ once weekly during and for 4 weeks after leaving ~~risk~~ malarious area

3. Mefloquine-Resistant zone

a. *Doxycycline monohydrate (Monodox®) or hyclate (Vibramycin®) (≥8 years)*
Adult dosing: Doxycycline 100 mg
- Begin 1 tablet or capsule daily 1-2 days prior to ~~travel~~ entering malarious area
- Take~~n~~ daily during trip and 4 weeks after leaving marlarious area

Pediatric dosing:
≥8 years old: 2.2 mg/kg (maximum is 100 mg) daily

- Begin 1 dose daily 1-2 days prior to ~~travel~~ entering malarious area
- Take~~n~~ daily during trip and 4 weeks after leaving malarious area

OR

b. Atovaquone/Proguanil (Malarone®)
Adult dosing: Atovaquone/Proguanil 250mg/100mg
Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg
5–8 kg: 1/2 pediatric tablet daily
9–10 kg: 3/4 pediatric tablet daily
11–20 kg: 1 pediatric tablet daily
21–30 kg: 2 pediatric tablets daily
31–40 kg: 3 pediatric tablets daily

Commented [NP5]: Per CDC YB 2024 Table 5-28 https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/malaria#treatment

Commented [CS6R5]: agreed

> 40 kg: 1 adult tablet daily
- Begin 1 dose daily 1-2 days prior to entering malarious area ~~travel~~
- Take~~n~~ daily during trip and 7 days after leaving malarious area

2. Traveler's diarrhea (TD)

a. Patient assessment
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patient's risk of acquiring traveler's diarrhea and body weight (kg)
   iii. Screen for contraindications
   iv. Consult ~~CDC guidelines~~CDC Yellow Book for list of high-risk factors for TD

b. Prophylaxis education
   i. Discuss dietary counseling, avoidance of high-risk foods, food and beverage selection and sanitary practices, oral rehydration
   ii. Educate patient on how to recognize symptoms and severity of traveler's diarrhea
      1. **Mild:** diarrhea that is tolerable, not distressing, and does not interfere with planned activities
      2. **Moderate:** diarrhea that is distressing or interferes with planned activities
      3. **Severe:** dysentery (bloody stools) and diarrhea that is incapacitating or completely prevents planned activities
   iii. Pharmacotherapy prophylaxis
      Pepto-Bismol®: Two 262-mg tablets or 2 fluid oz (60 mL) QID for up to 3 weeks
      Note: Avoid in patients <12 years old, patients taking doxycycline for malaria prophylaxis, anticoagulants, allergic to aspirin, probenecid, methotrexate

c. Treatment *(Note: while the CDC Yellow Book includes ciprofloxacin, this protocol only permits azithromycin)*
   i. First line for mild TD and adjunctive treatment for moderate TD
      1. *Loperamide (OTC- Imodium® AD)*
      Adult Dosing: Loperamide 2 mg
      - Take 4 mg at onset of diarrhea, followed by additional 2 mg after each loose stool (Max of 16 mg per day)

      Pediatric Dosing:
      - 22 to 26 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 4 mg per day)
      - 27 to 43 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 6 mg per day)
   ii. Antibiotic treatment (for moderate or severe TD)
      1. Consult ~~CDC guidelines~~the CDC Yellow Book ~~for~~ resistance rates to antibiotics
      2. Empiric treatment for moderate TD and severe TD (age <18 requires a prescription from PCP) a
         a. *Azithromycin 500mg*
         • 1 tablet daily for ~~1~~ 3 days
         • 1 course/14 days, Max 2 courses for trips >14 days

Commented [NP7]: All in YB 2024 - see tables below

Travel Medications - Assessment and Treatment Care Pathway

3. ~~Acute Mountain~~Altitiude ~~Sickness~~Illness
    a. Patient assessment/Education
        i. Review detailed itinerary and identify travel areas of increased risk
        ii. Assess patients' risk of acquiring ~~Acute Mountain Sickness (AMS)~~altitude illness and body weight (kg)
        iii. Review signs/symptoms of altitude illness ~~AMS~~, discuss safe ascent rates and tips for acclimating to higher altitudes (alcohol abstinence, limited activity)
        iv. Screen for contraindications
            1. AcetaZOLAMIDE
                a. Hypersensitivity to acetazolamide or sulfonamides
    b. Prophylaxis
        i. Consult ~~CDC guidelines~~the CDC Yellow Book for list of risk factors for AMS. If risk factors are present and warrant prophylaxis:
            1. *AcetaZOLAMIDE (Diamox®)*

            Adult Dosing: Acetazolamide 125 mg; 250 mg if >100 kg

            - Take 1 dose twice daily starting 24 hours before ascent, continuing ~~during ascent, and 2-3 days after highest altitude achieved or upon return~~ the first 2 days at elevation, and longer if ascent continues

            Pediatric Dosing:

            2.5 mg/kg/dose every 12 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return~~.~~ (m~~M~~aximum of 125 mg/dose).

Commented [NP8]: YB 2024 https://wwwnc.cdc.gov/travel/yellowbook/2024/environmental-hazards-risks/high-elevation-travel-and-altitude-illness

Commented [CS9R8]: Changed to altitude illness

Travel Medications - Assessment and Treatment Care Pathway

4. Motion Sickness

a. Patient assessment
   i. Review detailed itinerary and identify travel areas of increased risk
   ii. Assess patients' risk of acquiring motion sickness and body weight (kg)
   iii. Review signs/symptoms of motion sickness, discuss tips for reducing motion sickness: being aware of triggers, reducing sensory input
   iv. Screen for contraindications

b. Prophylaxis
   i. Consult ~~CDC guidelines~~ the CDC Yellow Book ~~-~~for list of risk factors for m~~M~~otion sickness. If risk factors present and warrant pharmacologic prevention:
   ii. Adults
      1. **First-line**: *Scopolamine transdermal patches* (a~~A~~ge <18 r~~R~~equires prescription from PCP)
      • Apply 1 patch (1.5 mg) to hairless area behind ear at least 4 hours prior to exposure; replace every 3 days as needed

AND/OR

      2. **Second-line:**
         a. *Promethazine 25mg Tablets:* Take one tablet by mouth 30 – 60 minutes prior to exposure and then every 12 hours as needed
         b. *Promethazine 25mg Suppositories:* Unwrap and insert one suppository into the rectum 30-60 minutes prior to exposure and then every 12 hours as needed
         c. *Meclizine 12.5-25mg* (OTC/Rx):
         Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

   iii. Pediatrics
      1. **First-line**:
         a. 7-12 years old
            • *DimenhyDRINATE (OTC Dramamine®)* 1-1.5mg/kg/dose*:* Take one dose 1 hour before travel and every 6 hours during the trip ~~-~~ (m~~M~~aximum 25 per dose)
            • *DiphenhydrAMINE (OTC Benadryl®)* 0.5-1mg/kg/dose*:* Take one dose 1 hour before travel and every 6 hours during the trip~~-~~ (m~~M~~aximum 25 mg per dose)
         b. ≥ 12 years old
            • *Meclizine 12.5-25mg* (OTC/Rx): Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

Travel Medications - Assessment and Treatment Care Pathway

Screen for Protocol Contraindications:

Malaria Prophylaxis

1. Chloroquine
    c. Age < 7 years old
    d. Hypersensitivity to chloroquine, 4-aminoquinolone compounds, or any component of the formulation
    e. Presence of retinal or visual field changes of any etiology
2. Hydroxychloroquine
    a. Age < 7 years old
    b. Hypersensitivity to hydroxychloroquine, 4 aminoquinoline derivatives, or any component of the formulation
3. Atovaquone/proguanil
    a. Age < 7 years old
    b. Weight < 5 kg
    c. Hypersensitivity to atovaquone, proguanil or any component of the formulation
    d. Prophylactic use in severe renal impairment (CrCl < 30 mL/min)
    e. Cannot be used by women who are pregnant or breastfeeding a child that weighs < 5 kg.
4. Doxycycline
    a. Age < 8 years old
    b. Hypersensitivity to doxycycline, other tetracyclines
    ~~c. Pregnancy During second or third trimester of pregnancy~~
    ~~d. Breast feeding~~Breast-feeding
5. Mefloquine
    a. Age < 7 years old
    b. Hypersensitivity to mefloquine, related compounds (i.e. quinine and quinidine)
    c. Prophylactic use in patients with history of seizures or psychiatric disorder (including active or recent history of depression, generalized anxiety disorder, psychosis, schizophrenia, or other major psychiatric disorders)
    d. Not recommended for people with cardiac conduction abnormalities.

Traveler's Diarrhea

1. Loperamide
    a. Age < 7 years old
    b. Hypersensitivity to loperamide or any component of the formulation
    c. Abdominal pain without diarrhea
    d. Acute dysentery
    e. Acute ulcerative colitis
    f. Bacterial enterocolitis (caused by *Salmonella, Shigella, Campylobacter)*
    g. Pseudomembranous colitis associated with broad-spectrum antibiotic use
    h. OTC—do not use if stool is bloody or black
2. Azithromycin
    a. Age < 18 years old will require a prescription from a PCP
    b. Hypersensitivity to azithromycin, erythromycin or other macrolide antibiotics
    c. History of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

Acute Mountain Sickness

1. AcetaZOLAMIDE
    a. Age < 7 years old
    b. Marked hepatic disease or insufficiency
    c. Decreased sodium and/or potassium levels
    d. Adrenocortical insufficiency
    e. Cirrhosis

Commented [NP10]: Mention this? From PI: Hypersensitivity to acetazolamide or any excipients in the formulation. Since acetazolamide is a sulfonamide derivative, cross sensitivity between acetazolamide, sulfonamides and other sulfonamide derivatives is possible.

Commented [CS11R10]: Added

Commented [NP12]: same comment as above

f. Hyperchloremic acidosis
g. Severe renal dysfunction or disease
h. Long term use in congestive angle-closure glaucoma
~~h.~~i. Hypersensitivity to acetazolamide or any excipients in the formulation. Since acetazolamide is a sulfonamide derivative, cross sensitivity between acetazolamide, sulfonamides and other sulfonamide derivatives is possible.

Motion Sickness

1. Scopolamine
   a. Age < 18 years old will require a prescription from a PCP
   b. Hypersensitivity to scopolamine
   c. Glaucoma or predisposition to narrow-angle glaucoma
   d. Paralytic ileus
   e. Prostatic hypertrophy
   f. Pyloric obstruction
   g. Tachycardia secondary to cardiac insufficiency or thyrotoxicosis
2. Promethazine
   a. Age < 7 years old
   b. Hypersensitivity to promethazine or other phenothiazines (i.e. prochlorperazine, chlorproMAZINE, fluPHENAZine, perphenazine, etc)
   c. Treatment of lower respiratory ~~tract symptoms~~conditions (e.g., asthma)
   ~~d. Asthma~~
3. Meclizine
   a. Age < 12 years old
   b. Hypersensitivity to meclizine
4. DimenhyDRINATE
   a. Age < 7 years old
   b. Hypersensitivity to dimenhyDRINATE or any component of the formulation
   ~~c. Neonates~~
5. DiphenhydrAMINE
   a. Age < 7 years old
   b. Hypersensitivity to diphenhydrAMINE or other structurally related antihistamines or any component of the formulation
   ~~c. Neonates or premature infants~~
   ~~d.~~c. Breast-feeding

Travel Medications - Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:
Patient Weight (kg):	

Rx

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________

- Directions: ____
- Quantity: _______ + 0 refills

Commented [NP1]: Consider changing to "Altitude Illness" per 2024 WMS Guidelines

Commented [CS2R1]: Done

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________

- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________

- Directions: ____
- Quantity: _______ + 0 refills

Written Date: ______________________________

Prescriber Name:__________________________Prescriber Signature: ______________________

Pharmacy Address:______________________________Pharmacy Phone: __________________

Provider Notification
Travel Medications

Pharmacy Name:________________________ Pharmacist Name: ________________________________
Pharmacy Address:____
Pharmacy Phone:_______________________ Pharmacy Fax: ___________________________________

Patient Name:_______________________________________ DOB: ____/_____/_____ Age:_____

Healthcare Provider:_________________________________ Phone: (____)_____-________ Fax: (____)_____-________

Your patient was seen at our pharmacy on ____/____/____ for a professional travel consultation. During this visit, we carefully reviewed the patient's medical history, prescription history, and lifestyle factors to ensure the safety of all medications prescribed and vaccines administered. Upon review it was determined that the patient could benefit from prescription/~~immunization~~ vaccine therapy. The following prescription(s) and/or ~~immunization~~vaccine~~s~~ were provided to your patient:

☐ **Medications Prescribed**

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________
- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________
- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________
- Directions: ____
- Quantity: _______ + 0 refills

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness

☐ **Drug:** ___________________________________
- Directions: ____
- Quantity: _______ + 0 refills

☐ **~~Immunization~~Vaccine~~s~~Vaccines Administered**

~~Immunization~~Vaccine~~s~~Vaccines							
Recommended	Given	Declined	Dose #	Recommended	Given	Declined	Dose#
☐ Cholera	☐	☐		☐ Polio	☐	☐	
☐ COVID-19	☐	☐		☐ PPSV23	☐	☐	
☐ Hepatitis A/B	☐	☐		☐ Rabies	☐	☐	
☐ Hepatitis A	☐	☐		☐ RSV	☐	☐	
☐ Hepatitis B	☐	☐		☐ Shingles	☐	☐	
☐ Hib	☐	☐		☐ Td/Tdap	☐	☐	
☐ HPV	☐	☐		☐ Typhoid IM	☐	☐	
☐ Influenza	☐	☐		☐ Typhoid PO	☐	☐	
☐ Japanese Encephalitis	☐	☐		☐ Varicella	☐	☐	
☐ Meningococcal	☐	☐		☐ Yellow Fever	☐	☐	
☐ PCV 15/20	☐	☐		☐ Other: _____________	☐	☐	

Commented [NP1]: same comment - consider changing to Altitude Illness per YB 2024 and WMS 2024 Guidelines

Commented [NP2]: Discuss ones not here- cholera, TBE, PCV15, RSV, Chik

Commented [CS3R2]: Added cholera, PCV15/20 and RSV

☐ **Medications and/or ~~Immunization~~Vaccines NOT provided at our pharmacy, because:**

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine.

- ☐ **Drug/~~Immunization~~Vaccine:**
  _____
- ☐ **Reason for Referral:** _____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

- ☐ **Drug/~~Immunization~~Vaccine:**
  _____
- ☐ **Reason for Referral:** _____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

- ☐ **Drug/~~Immunization~~Vaccine:**
  _____
- ☐ **Reason for Referral:** _____

Please contact us if you have any questions about the care provided to your patient or if you would like to obtain additional information about our pharmacy's patient care services.

Pharmacist Signature:_____ Date:_____
Pharmacist Name (Print):_____

The prescription was issued pursuant to the Board of Pharmacy protocol authorized under OAR 855-115-0345.

Commented [JD4]: Will add hyperlink once available.

- **CDC Yellow Book 2024: Health Information for International Travel.** New York: Oxford University Press; 2023.Retrieved from https://wwwnc.cdc.gov/travel/page/yellowbook-home.

Patient Visit Summary

Travel Medications

Pharmacy Name:_______________________________ Pharmacist Name:_____________________________________

Pharmacy Address:____

Pharmacy Phone: ____________________________ Pharmacy Fax: ____________________________

Today, on ____/____/____ , you were seen by Pharmacist, _______________________________ for a professional travel consultation.

☐ **You were provided** the following travel medications and/or ~~immunization~~vaccines:

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

☐ **Drug/~~Immunization~~Vaccine:**

____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

☐ **Drug/~~Immunization~~Vaccine:**

____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

☐ **Drug/~~Immunization~~Vaccine:**

____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

☐ **Drug/~~Immunization~~Vaccine:**

____

~~Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Sickness Prophylaxis ☐ Motion Sickness ☐~~ ~~Immunization~~Vaccine

~~☐ **Drug/Immunization**~~**Vaccine~~:~~**

~~____~~

-- and/or --

☐ You were **not able to receive** the following travel medications and/or ~~immunization~~vaccines today, and *must consult with a primary care provider for additional evaluation* prior to receiving services, because:

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine.

☐ **Drug/~~Immunization~~Vaccine:**

____

☐ **Reason for Referral:**

____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

☐ **Drug/~~Immunization~~Vaccine:**

____

☐ **Reason for Referral:**

____

Commented [NP1]: Per YB 2024, "Altitude Illness"and WMS 2024 Guidelines, would be the more updated term - will get copy to you, not posted yet

Commented [CS2R1]: Updated

Patient Visit Summary

Travel Medications

Pharmacy Name:_____ Pharmacist Name:_____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

Indicated for: ☐ Malaria Prophylaxis ☐ Traveler's Diarrhea ☐ Altitude Illness~~Sickness~~ Prophylaxis ☐ Motion Sickness ☐ ~~Immunization~~Vaccine

- ☐ **Drug/~~Immunization~~Vaccine:**
  _____
- ☐ **Reason for Referral:**
  _____

From: oregon-gov-web-services@egov.com
To: PHARMACY FORMULARY * BOP
Subject: PHPFAC protocol feedback
Date: Monday, January 29, 2024 6:29:10 PM
Attachments: formsubmission.csv

First & Last Name	Crystal Sharp
Email Address	
Provide Feedback	Please add "continuous glucose monitors and related supplies" to current "Formulary: devices and supplies" as there is only "diabetic blood sugar testing supplies" which is not synonymous. Thanks!

From: PHARMACY FORMULARY * BOP
To: PHARMACY FORMULARY * BOP
Cc:
Subject: RE: PHPFAC protocol feedback
Date: Tuesday, February 6, 2024 2:30:48 PM

Eric,

We appreciate your feedback and will share it with the team of Pharmacists responsible for drafting vaccine protocols. These protocols are then reviewed by the Public Health and Pharmacy Formulary Committee. It's important to clarify that the Mpox protocol issued by the Oregon Health Authority (OHA) is specifically for use by public health departments, not by pharmacies. OHA never issued a Mpox protocol for pharmacy use.

Oregon Board of Pharmacy
pharmacy.formulary@bop.oregon.gov
(971) 673-0001 phone
(971) 673-0002 fax
www.oregon.gov/pharmacy

From: oregon-gov-web-services@egov.com <oregon-gov-web-services@egov.com>
Sent: Friday, February 2, 2024 4:31 PM
To: PHARMACY FORMULARY * BOP <pharmacy.formulary@bop.oregon.gov>
Subject: PHPFAC protocol feedback

First & Last Name	Eric Schettini
Email Address	_____
Provide	Hello, is there an immunization protocol for MPox like OHA used to

Feedback	have? Thank you.