Model Immunization Protocol

Meningococcal ACWY Vaccine (Menactra®, MenQuadfi®, Menveo®) and Meningococcal B Vaccine (Bexsero®, Trumenba®)	
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1. What's new

Addition of newly licensed MenACWY vaccine, MenQuadfi®.

New recommendation: People with ongoing high-risk conditions need booster doses of Meningococcal B vaccine as long as their risk continues.

2. Oregon model immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Screen clients for contraindications.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for IM injection.

F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.

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

H. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.[8]

I. Meningococcal conjugate quadrivalent vaccine and Meningococcal B vaccine may be given simultaneously at different sites if indicated.[9]

J. MenACWY-D (Menactra®) should not be given at the same time as PCV13 vaccine.[10]

K. MenACWY-D (Menactra®) should be administered either before or at the same time as DTaP. If it cannot be given before or simultaneously, it should be administered 6 months after DTaP. It may be given at any time in relation to Tdap.[5]

L. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

M. This order does **not** cover Advisory Committee on Immunization Practices (ACIP) recommendations that involve shared clinical decision making. Shared clinical decision making means the decision to vaccinate should be based on a discussion of benefits and risks between the patient and the clinician, after which the clinician may then prescribe the vaccine.

Health Officer Signature Date

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3. Vaccine schedule for meningococcal vaccines

Vaccine Schedule: Meningococcal ACWY-D (Menactra®), Meningococcal ACWY-CRM (Menveo®) and Meningococcal ACWY-TT (MenQuadfi®).			
Age Group	**Dose**	**No. of Doses**	**Route**
≥2 months	0.5 mL	Varies by age	Intramuscular
11–15 years		2	
16 years		1 or 2*	
Vaccine Schedule: Meningococcal B-4C (Bexsero®) and Meningococcal B-FHbp (Trumenba®)			
Age	**Dose**	**No. of Doses**	**Route**
≥10 years	0.5 mL	2 or 3	Intramuscular

* See high-risk schedule.

4. Licensed meningococcal vaccines

Meningococcal ACWY Conjugate Vaccines		
Trade Name	**Presentation**	**Acceptable Age Range**
Menveo® (MenACWY-CRM[1])	0.5-mL single-dose vials	≥2 months
Menactra® (MenACWY-D[2])	0.5-mL single-dose vials	≥9 months
MenQuadfi® (MenACWY-TT[14])	0.5-mL single-dose vials	≥2 years

Meningococcal B Vaccines		
Trade Name	**Presentation**	**Acceptable Age Range**
Bexsero® (MenB-4C[3])	0.5-mL prefilled syringes	≥10 years
Trumenba® (MenB-FHbp[4])	0.5-mL prefilled syringes	≥10 years

5. Recommendations for use of meningococcal vaccines

A. Routine use of **Meningococcal ACWY** vaccine[5]

- All adolescents 11–18 years of age without contraindications.
- First-year college students living in dorms should receive 1 dose of quadrivalent meningococcal vaccine within the five years before college entry.
- May be administered to adults 19–21 years of age if required for attendance at institution of higher education.

B. Use of **Meningococcal ACWY** vaccine in high-risk persons

- Persons aged ≥2 months with anatomical or functional asplenia, HIV or complement component deficiency or who are taking complement inhibitor medications.[5,7]
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*.[5]
- Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]).
- Persons aged ≥9 months traveling to Saudi Arabia for the Hajj and Umrah or to the meningitis belt in sub-Saharan Africa.[5]

C. Schedule for **Meningococcal B** vaccine in high-risk persons[9]

- Persons with persistent complement component deficiencies or who are taking complement inhibitor medications.
- Persons with anatomic or functional asplenia.
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*.

MenACWY Vaccine Routine Schedule[5]			
Dose	**Preferred Age**	**Minimum Acceptable Age**	**Minimum Acceptable Spacing**
1	11 years	10 years	
Booster	16 years		8 weeks*

* Per prescribing information for MenQuadfi®, minimum acceptable spacing is 4 years.

MenACWY Vaccine Schedule for High-Risk Persons[10]				
Age at Initial Dose	**Vaccine**	**Doses in Series**	**Schedule**	**Booster**
2 – 6 months	MenACWY-CRM (Menveo®)	4	2, 4, 6, 12 months	≤7 years of age at last dose, 1st booster at 3 years, then every 5 years. ≥7 years of age at last dose, boosters every 5 years.
7–8 months		2	12 weeks apart, 2nd dose ≥12 months of age	
9-23 months	MenACWY-D* (Menactra®)	2	12 weeks apart. For travel, dose 2 may be given 8 weeks after dose 1	
≥2 years	Menveo®, Menactra® or MenQuadfi®	2	8–12 weeks apart	

*For children with functional or anatomic asplenia or who are HIV+, do not use before 2 years of age, due to potential interference with PCV13.

Meningococcal B Vaccine for Healthy* Persons[6,8]				
Vaccine	**Dose**	**Recommended Spacing**	**Minimum Spacing**	**Recommended Age**
MenB-4C (Bexsero®)	1			16–23 years[5]
	2	1 month	28 days	
MenB-FHbp (Trumenba®)	1			
	2	6 months	6 months	

*Shared clinical decision making, not included in this order.

Meningococcal B Vaccine for High-Risk Persons[9]					
Vaccine	**Dose**	**Recommended Spacing**	**Minimum Spacing**	**Recommended Age**	**Booster Doses**
MenB-4C (Bexsero®)	1			≥10 years	1 year after completion of the series, then every 2-3 years as long as risk factors remain.
	2	1 month	28 days		
MenB-FHbp (Trumenba®)	1				
	2	1 month	28 days		
	3	5 months after dose 2 and 6 months after dose 1	4 months after dose 2		

6. Contraindications[1-4]

A. Severe allergic reaction to a previous dose or to a vaccine component, including latex[3] (Bexsero®).

Vaccine	Vaccine Excipient Summary[12, 14]
MenACWY-D (Menactra®)	sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, diphtheria toxoid
MenACWYTT (MenQuadfi®)	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid[14]
MenACWYCRM (Menveo®)	formaldehyde, CRM197 protein
MenB-4C (Bexsero®)	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenBFHbp (Trumenba®)	polysorbate 80, aluminum phosphate, histidine buffered saline

7. Warnings and precautions[1-4]

A. Immunization should be deferred during the course of moderate or severe acute illness.

B. Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including Menveo®, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination.

8. Other considerations

A. 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.[11]

B. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses.[1-4, 14]

C. 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.[5]

Bexsero®[3] pregnancy registry: 1–877–683–4732.10 • Menveo®[1] pregnancy registry: 1–877–311–8972.4 • Menactra®[2] pregnancy registry: 1–800–822–2463 • MenQuadfi®[14] pregnancy registry: 1-800-822-2463.

D. Lactation: It is not known whether meningococcal vaccines are excreted in

human milk. Use with caution in nursing mothers.[5]

E. 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.[1,2]

F. E.Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥2 years of age.[13]

9. Side effects and adverse reactions

MenACWY[1,2,14]	
Minor – low-grade fever, headache, redness at injection site, dizziness	Common, up to 40%
Grade 3 - fever, headache, redness at injection site, dizziness	Uncommon, up to 3%
MenB[3,4]	
Headache, fatigue, redness at injection site	Very common, up to 51%
Pain at injection site	Common, up to 26%
Chills, joint pain	Common, up to 20%
Fever	Uncommon, up to 2.5%

10. Storage and handling[1-4]

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
Menactra® and MenQuadfi®	Store at 2°–8°C 36°– 46°F	Protect from light. Do not use if vaccine has been frozen.	
Menveo® and diluent			Reconstitute only with the MenACWY liquid conjugate component. It should be administered promptly after reconstituted; or stored at ≤77ºF (25ºC) and administered within 8 hours of reconstitution
Bexsero® and Trumenba®			

11. 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

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (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).

12. References

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2. Menactra® package insert. Available at: www.fda.gov/media/75619/download. Accessed 28 Aug 2020.
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4. Trumenba® package insert. Available at: www.fda.gov/media/download. Accessed 28 Aug 2020.
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14. MenQuadfi® package insert. Available at www.fda.gov/media/137306/download. Accessed 28 Aug 2020.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: immunization protocols

13. Appendix

Not applicable