OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
MENINGOCOCCAL VACCINE

Revisions as of 05/08/2013 are based on ACIP recommendations in the 03/22/13 MMWR¹ regarding prevention and control of meningococcal disease.

1. Reference Only: Addition of Hib-MenCY (MenHibrix®) for infants 2–15 months of age who are at increased risk for meningococcal disease. See foot note, section III p. 4
2. Update to Recommendations² for Use, see table(s) section IV, p. 5-7

¹www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm
²ACIP Abbreviations for Vaccines http://www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.html

I. Order:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥11 years for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11—18 years of age.
4. Provide a current Vaccine Information Sheet (VIS) answering any questions.
5. Obtain a signed Vaccination Administration Record (VAR)
6. Give a single 0.5–mL intramuscular dose of quadrivalent meningococcal conjugate (MCV4-D) Menactra™ or (MCV-4) Menveo®; OR
7. Give a single 0.5-mL subcutaneous dose of quadrivalent meningococcal polysaccharide vaccine (MPSV4), Menomune® according to ACIP recommendations, age-appropriate schedules and high-risk conditions.
8. See recommendations for use for Menactra™, Menveo®, and MenHibrix® exceptions and concomitant use with other vaccines.

Immunizing Pharmacist Signature
Date
For multiple signatures see: 1.usa.gov/PharmacyImmunizationProtocols

Revised: 05-2013
Reviewed: 12-2013
Original: 06-2005
### II a. LICENSED QUADRIVALENT MENINGOCOCCAL CONJUGATE VACCINE (MCV4-CRM)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Acceptable Age Range</th>
<th>Thimerosal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Menveo</strong>&lt;sup&gt;1,2,3&lt;/sup&gt; (MCV4-CRM) (Novartis)</td>
<td>Quadrivalent meningococcal conjugate vaccine containing capsular polysaccharide from serogroups A, C, Y and W-135: 32.7 to 37.3 to 64.1 µg CRM&lt;sub&gt;197&lt;/sub&gt; protein&lt;sup&gt;3&lt;/sup&gt;</td>
<td>2–55 years</td>
<td>No (single-dose vials)</td>
</tr>
</tbody>
</table>

Menveo’s® MenA lyophilized conjugate component needs to be reconstituted only with the MenCYW-135 liquid conjugate component. It should be administered promptly after reconstituted or stored ≤77ºF (25ºC) and administered within 8 hours of reconstitution.

### II b. LICENSED QUADRIVALENT MENINGOCOCCAL CONJUGATE VACCINE (MCV4-D)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Acceptable Age Range</th>
<th>Thimerosal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Menactra</strong>&lt;sup&gt;TM 1,2,3,4&lt;/sup&gt; (MCV4-D) (Sanofi Pasteur)</td>
<td>Quadrivalent meningococcal conjugate vaccine containing capsular polysaccharide from serogroups A, C, Y and W-135 conjugated to 48 µg of diphtheria toxoid&lt;sup&gt;3&lt;/sup&gt;</td>
<td>9 months–55 years</td>
<td>No (single-dose vials)</td>
</tr>
</tbody>
</table>

### II c. LICENSED QUADRIVALENT MENINGOCOCCAL POLYSACCHARIDE VACCINE (MPSV4)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Acceptable Age Range</th>
<th>Thimerosal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Menomune</strong>&lt;sup&gt;2,3&lt;/sup&gt; (MPSV-4) (Sanofi Pasteur)</td>
<td>Quadrivalent meningococcal polysaccharide vaccine containing 50 µg of each of 4 purified bacterial capsular polysaccharides, A, C, Y, and W-135.</td>
<td>≥2 years</td>
<td>No (single-dose vials)</td>
</tr>
</tbody>
</table>

| | | | Yes (in diluent of multidoose vial), 0.01% |

A single-dose vial of MPSV4 vaccine should be administered within 30 minutes after reconstitution. MPSV4 should be administered as a single 0.5 ml injection by the SC route and should not be given at the same time as whole cell typhoid vaccine due to combined endotoxin content. (per package insert).
MCV4-CRM vaccines should be administered as a single 0.5-ml injection by the IM route.

If Menomune®, Menactra™ or Menevo® are administered to immunosuppressed persons, an adequate immunologic response may not be obtained. See recommendations for use for dosing and schedule, section V, p.8-10

Does not include meningococcal serogroup B.

Children with functional or anatomic asplenia should not be immunized with MenACWY-D (Menactra™) before age 2 years to avoid interference with the immune response to PCV-13 (Prevnar 13).

### III. LICENSED BI-VALENT MENINGOCOCCAL CONJUGATE VACCINE (Hib-MenCY-TT)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Acceptable Age Range</th>
<th>Thimerosal</th>
</tr>
</thead>
</table>
| MenHibrix®1,2,3,4 (Hib-MenCY-TT) GlaxoSmithKline | 1. Bivalent meningococcal conjugate vaccine containing 5mcg each of capsular polysaccharide from serogroups C and Y conjugated to 11.5mcg tetanus toxoid.  
2. 2.5mcg of Hib polysaccharide conjugated to 6.25mcg tetanus toxoid.  
3. 96.8mcg of Tris (trometamol)-HCL.  
5. ≤0.72mcg residual formaldehyde. | For high-risk7,8,9 individuals 6 weeks–15 months of age | None |

1If Menomune®, Menactra™, Menevo® or MenHibrix® are administered to immunosuppressed persons, an adequate immunologic response may not be obtained.

2MenHibrix® should be administered as a single 0.5-ml injection by the IM route.

3Does not include serogroup A, W135 or B.

4A single-dose vial should be used immediately after reconstitution.

5Immunization with MenHibrix® does not substitute for routine tetanus immunization.

6Urine antigen detection may not have a diagnostic value in suspected disease due to H. influenzae type b within 1 to 2 weeks after receipt of a H. influenzae type b-containing vaccine, including MENHIBRIX®.

7Infants with persistent complement component pathway deficiencies, functional or anatomical asplenia, complex congenital heart disease with asplenia and sickle cell disease and areas of disease outbreaks.

8Infants traveling with their families to the Hajj or to the “meningitis belt” of sub-Saharan Africa need protection against serogroups A and W-135, which are not in MenHibrix®, and should receive a quadrivalent meningococcal conjugate vaccination licensed for children ≥9 months of age before travel.

9May be given as early as 6 weeks and a late as 18 months of age for children in areas with C and Y outbreaks.
IV. RECOMMENDATIONS FOR USE

IV a. MCV4-D (MENACTRA™), MCV4-CRM (Menveo®) and MPSV-4 (Menomune®)

Routine vaccination is recommended for:

- Adolescents 11–18 years of age.
- Adolescents with HIV disease.
- These high-risk persons 2–55 years of age:
  1. College freshman living in dormitories
  2. Persons with terminal complement component deficiencies
  3. Persons with anatomic or functional asplenia
  4. Lab personnel who are routinely exposed to isolates of N. meningitidis
  5. Military recruits
  6. Travelers to or residents of sub-Saharan Africa’s “Meningitis Belt,” during December to June
  7. Visitors to Mecca in Saudi Arabia during annual Hajj; and
  8. Countries in which N. meningitidis is hyper-endemic or epidemic.
- To control outbreaks of meningococcal disease.

1 Revised Recommendations of ACIP to administer MCV4 at age 11–12 years followed by a booster dose at age 16 years (MMWR 2013; 62: 15–17).

2 MCV4 (Menactra™) is preferred among persons 9 months–55 years of age, or Menveo® is preferred for persons 2–55 years of age; Persons ≥56 years old should receive MPSV4 unless previously vaccinated with MenACWY. [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm) p. 15

3 Persons at prolonged increased risk for meningococcal disease should be revaccinated with MCV4 (ACIP revaccination schedule in Section IV, p.5).

4 See MenHibrix® recommendations for children 6 weeks through 18 months of age in section IVb, pg 6

5 May also be given to college students not living in dorms or to any adolescent upon request.

6 Contact a local travel clinic, health department, Centers for Disease Control and Prevention’s (CDC) travel line (877-394-8747) or [wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/meningococcal-disease.htm](http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/meningococcal-disease.htm) for the list of high-risk countries.

7 An Outbreak is defined as the occurrence of three or more confirmed or probable cases of meningococcal disease during a period of ≤3 months, with a resulting primary attack rate of ≥10 cases per 100,000 population (MMWR 2005; 54(RR-7): 14).
IV. RECOMMENDATIONS FOR USE Cont.

IV b. Hib-MenCY (MenHibrix®)

Vaccination is recommended for:

- High-risk individuals\(^1\) 2—15 months of age:
  1. Persons with persistent complement component pathway deficiencies
  2. Persons with anatomic or functional asplenia
  3. Complex congenital heart disease with asplenia
  4. Sickle cell disease
  5. Persons living in or traveling to countries\(^2-4\) in which *N. meningitidis* is hyperendemic or epidemic.
- To control outbreaks of meningococcal disease.

The first dose may be given as early as 6 weeks and the 4th dose as late as 18 months of age for children in areas with C and Y outbreaks.\(^5\)

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\(^1\) CDC. Infant meningococcal vaccination: Advisory Committee on Immunization Practices (ACIP) Recommendations and Rationale. MMWR 2013; 62(03): 52–54. Available at [www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a3.htm)

\(^2\) Infants traveling with their families to the Hajj or to the “meningitis belt” of sub-Saharan Africa need protection against serogroups A and W-135, which are not in MenHibrix®, and should receive a quadrivalent meningococcal conjugate vaccination licensed for children ≥9 months of age before travel.

\(^3\) Vaccination in the 3 years before the date of travel is **required by the government** of Saudi Arabia for all travelers to Mecca during the annual Hajj.

\(^4\) Contact a local travel clinic, health department, Centers for Disease Control and Prevention’s (CDC) travel line (877-394-8747) for the list of high-risk countries. Also found at [wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/meningococcal-disease.htm](http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/meningococcal-disease.htm)

\(^5\) An Outbreak is defined as the occurrence of three or more confirmed or probable cases of meningococcal disease during a period of ≤3 months, with a resulting primary attack rate of ≥10 cases per 100,000 population (MMWR 2005; 54(RR-7): 14).

\(^6\) Do not give MenHibrix with other Hib-containing vaccines at the same visit.
IV. RECOMMENDATIONS FOR USE Cont.

IV c MPSV4 (Menomune®)

Vaccination is recommended for:

1. Persons ≥56 years:
   a. Who are meningococcal vaccine-naïve
   b. who anticipate requiring a single dose\(^1\) of meningococcal vaccine

   A. Travelers\(^2\)

   B. Persons at risk as a result of a community outbreak

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\(^1\) For persons now aged ≥56 years who were vaccinated previously with MenACWY and are recommended for revaccination or for whom multiple doses are anticipated, MenACWY is preferred.

\(^2\) Those needing protection prior to travel can receive the 2nd dose as early as 2 months after the 1st dose.
### Va. VACCINE SCHEDULE\(^1\)

<table>
<thead>
<tr>
<th>Risk group</th>
<th>Primary series</th>
<th>Booster dose</th>
</tr>
</thead>
</table>
| Persons aged 11–18 years | 1 dose, preferably at age 11 or 12 years  
*See p. 3 for recommended vaccine | At age 16 years if primary dose at age 11 or 12 years  
3 years after primary dose, if primary dose given at age 13 through 15 years  
No booster needed if primary dose on or after age 16 years |
| Persons aged 11–18 years with HIV | 2 doses, 8 – 12 weeks apart  
*See p. 3 for recommended vaccine | At age 16 years if primary series not completed at age 11 or 12 years  
3 years after primary series, if primary series given at age 13 through 15 years  
No booster needed if primary series on or after age 16 years |
| 1\(^{st}\) year College Students ≤ 21 years old that are living in Residential housing | 1 dose  
*See p. 3 for recommended vaccine | None |
| College freshmen ≤ 21 years of age living in dorm who had received a single primary dose <16 years of age and ≥3 years earlier | N/A | 1 dose  
*See p. 2 for recommended vaccine |
| Persons aged 2–55 years with persistent complement component deficiency\(^2\) or functional or anatomical asplenia\(^3\) | 2 doses, 8 weeks apart  
*See p. 3 for recommended vaccine | Every 5 years if remain at risk |
| Persons aged 2–55 years with prolonged increased risk for exposure\(^4,5\) | 1 dose  
*See p. 3 for recommended vaccine | Persons aged 2–6 years:  
3 years after 1\(^{st}\) dose; then every 5 years if remain at risk  
Persons aged ≥7 years:  
5 years after 1\(^{st}\) dose; then every 5 years if remain at risk |
1. While MCV4 vaccine is the preferred vaccine for all risk groups, MPSV4 is acceptable.

2. Such as C5–C9, properidin, or factor D

3. Either conjugate vaccine is recommended 2 weeks before or ≥ 2 weeks after splenectomy. Persons aged ≥ 56 years old undergoing an elective splenectomy should receive MPSV4.

4. Children in this age group with HIV can be immunized with Menactra™ if another indication for vaccination exists.

5. Microbiologists routinely working with Neisseria meningitidis and travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic (e.g., “meningitis belt” of sub-Saharan Africa). Travelers to Mecca during the Hajj also should be vaccinated.

Note: Infants 9-23 months of age with complement component deficiencies, part of outbreaks, or travelers to meningococcal epidemic countries require 2 doses of MCV4-D, (Menactra™) 3 months apart with a booster dose 3 years after the primary series and then every 5 years thereafter if they remain at risk. See V b. footnote 9.
## V b. VACCINE SCHEDULE (MenHibrix®)

<table>
<thead>
<tr>
<th>Risk group¹</th>
<th>Primary series</th>
<th>Booster dose³,⁴,⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk persons 2–15 months of age</td>
<td>4 doses total at 2, 4, 6, and 12–15 months² of age</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>*See p. 3 for recommended vaccine</td>
<td></td>
</tr>
</tbody>
</table>

1. High-risk individuals 2–15 months of age:

   A. Persons with persistent complement component pathway deficiencies
   B. Persons with anatomic or functional asplenia
   C. Complex congenital heart disease with asplenia
   D. Sickle cell disease
   E. Countries³ in which *N. meningitidis* is hyper-endemic or epidemic.
   F. To control outbreaks of meningococcal disease.

2. The first dose may be given as early as 6 weeks and the 4th dose as late as 18 months of age for children in areas with C and Y outbreaks.

3. If an infant at increased risk for meningococcal disease is behind on his or her Hib vaccine doses, MenHibrix® may be used following the same catch-up schedule used for Hib vaccine.

4. If the first dose of MenHibrix® (Hib-MenCY) is given at or after 12 months of life, 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y.

5. For infants who have received or are going to receive a different Hib vaccine product, ACIP recommends a 2-dose series of MCV-4 (Menactra™) if they are aged 9 through 23 months or either of the two quadrivalent meningococcal vaccine products after age 23 months.
### VI. CONTRAINDICATIONS

1. A severe allergic (anaphylactic) reaction to thimerosal or any other vaccine component, including diphtheria toxoid (for **Menactra™**, Menveo® or tetanus toxoid (for **MenHibrix®**) or to dry natural rubber latex for **Menactra™** and **Menomune®**.

2. A severe allergic reaction following a prior dose of meningococcal vaccine

3. **Menveo®** should not be administered to persons with any bleeding disorder or persons receiving anticoagulant therapy, unless the potential benefit outweighs the risk.

4. Children with functional or anatomic asplenia should not be immunized with MenACWY-D (Menactra™) before age 2 years to avoid interference with the immune response to PCV-13 (Prevnar 13).

### VII. PRECAUTIONS

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

2. Pregnancy, breastfeeding and immunosuppression are **not** contraindications to vaccination.

3. Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including **MenHibrix®**, 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.
VIII. SIDE EFFECTS AND ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Local reactions for 1-2 days</th>
<th>Menactra</th>
<th>Menomune</th>
<th>Menveo</th>
<th>MenHibrix®¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>11%-59%</td>
<td>4%-48%</td>
<td>41%</td>
<td>15%-46%</td>
<td></td>
</tr>
<tr>
<td>Fever ≥100°F</td>
<td>5%</td>
<td>3%</td>
<td>0</td>
<td>11%-26%</td>
</tr>
<tr>
<td>Systemic reactions: headache, malaise, fatigue.</td>
<td>4%-62%</td>
<td>3%-60%</td>
<td>14%-29%</td>
<td>30%-71%</td>
</tr>
</tbody>
</table>

¹Irritability, drowsiness, loss of appetite.

¹Based on event and dose in schedule

IX. OTHER CONSIDERATIONS

1. MCV4-CRM, MCV4-D and MPSV4 meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W-135 meningococci. They are not protective against serogroup B meningococci, the most prevalent group in Oregon.

2. MenHibrix® vaccine stimulates protection only against infections caused by serogroups C and Y and is not protective against A, B, and W-135.

3. MCV4 is recommended 2 weeks before or ≥ 2 weeks after splenectomy surgery for persons ≥ 2 years. Source: American Academy of Pediatrics, “Red Book”, 2012, p. 89.

4. Revaccination is recommended at 5 year intervals for high risk persons receiving 1st dose at ≥ 7 years of age. [www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm p. 16](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)

5. In persons with HIV or persons receiving immunosuppressive therapy for dose schedule. See Recommendations for Use, Section IVa, p5 and Pg 8.

6. Any of the four meningococcal vaccines can be used for outbreak control of a specific serogroup; however, MCV4 is the preferred vaccine if the population targeted includes ages & serogroups for which they are licensed. Persons ≥ 56 years are recommended for MPSV4 for specific outbreak control unless they have received MCV4 previously.

Continued on next page
IX. OTHER CONSIDERATIONS cont.

7. Antimicrobial chemoprophylaxis: Antimicrobial post exposure chemoprophylaxis of close contacts of sporadic cases of meningococcal disease is the primary means for prevention of meningococcal disease in the United States. Close contacts include
   a) household members,
   b) daycare-center contacts, and
   c) anyone directly exposed to the patient’s oral secretions.

8. Contacts of cases should be referred to their primary healthcare provider and local health department for treatment and follow-up. See the Investigative Guideline for meningococcal disease for more details:

9. Protective levels of antibodies are usually achieved 7–10 days after vaccination.

10. For someone with a history of fainting with injections, a 15-minute observational period is recommended post immunization.

11. Immunization with MenHibrix® does not substitute for routine tetanus immunization.

12. Do not give MenHibrix® simultaneously with any other Hib-containing vaccine.

13. Children with functional or anatomic asplenia should not be immunized with MenACWY-D (Menactra™) before age 2 years to avoid interference with the immune response to PCV-13 (Prevnar 13).
X. ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: [www.vaers.hhs.gov](http://www.vaers.hhs.gov). In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4).

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 or 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

REFERENCES

1. CDC. Prevention and control of meningococcal disease: Advisory Committee on Immunization Practices (ACIP). MMWR 2013; 62(2) 1-28 Available at [www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)

2. CDC. Infant meningococcal vaccination: Advisory Committee on Immunization Practices (ACIP) recommendations and rationale. MMWR 2013; 62(03): 52–54). Available at [www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a3.htm)

3. CDC. ACIP Abbreviations for Vaccines. Available at [www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.html](http://www.cdc.gov/vaccines/acip/committee/guidance/vac-abbrev.html)


5. CDC. Updated Recommendations from the Advisory Committee on Immunization Practices (ACIP) for use of meningococcal conjugate vaccines. MMWR 2011; 60; 72–6. Available at [www.cdc.gov/mmwr/pdf/wk/mm6003.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6003.pdf)


9. Menveo® package insert at:
www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf

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Electronic copy of this protocol available at:
1.usa.gov/PharmacyImmunizationProtocols

APPENDIX:
Meningococcal Prevention Mandates for Elementary and Secondary Schools

November 2012

Current as of 04_03-2013

http://www.immunize.org/laws/