



From the Texas Department of State Health Services Immunization Branch

The goal of the Vaccine Advisory is to disseminate practical information related to vaccines, vaccine-preventable diseases, and the vaccine programs managed by the Immunization Branch.

The Immunization Branch welcomes readers' input to improve the contents of this document.

To view past issues, go to: www.dshs.state.tx.us/immunize/vacadvise/

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Updated Recommendations for Use of Serogroup B Meningococcal Vaccines

In June 2016, the Advisory Committee on Immunization Practices (ACIP) voted to uphold their existing recommendation regarding the use of all meningococcal B (MenB) vaccines despite changes to Food and Drug Administration (FDA) labeling for one of the vaccines. MenB vaccines are recommended for use in groups of persons aged 10 years and older who are at increased risk for serogroup B meningococcal disease. MenB vaccines can also be used in adolescents and young adults, with the preferred administration age of 16 – 18 years. This recommendation will be reevaluated by the ACIP in October 2016.

Full recommendations are in the October 23, 2015 CDC Morbidity and Mortality Weekly Report (MMWR) at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm>.

This advisory contains:

1. Background and Surveillance
2. Summary of New ACIP Recommendations
3. TVFC Program
4. Precautions and Contraindications
5. Meningococcal B Vaccine Safety
6. Should Meningococcal B Vaccine Replace Quadrivalent Meningococcal Vaccines?
7. Meningococcal Vaccination Requirements for School and College Entry
8. ImmTrac
9. Resources

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1) Background and Surveillance

Meningococcal disease is caused by the bacterium *Neisseria meningitidis*. Approximately one out of ten people have this type of bacteria in the back of their nose and throat with no signs or symptoms of disease; this is called being “a carrier.” Sometimes *Neisseria meningitidis* bacteria can invade the body causing certain illnesses which are known as meningococcal disease. There are five serogroups, or “strains,” of *Neisseria meningitidis* that cause the majority of meningococcal disease worldwide. The five most common strains are A, B, C, W, and Y. Three of these serogroups (B, C, and Y) cause most of the illness seen in the United States.

Meningococcal disease is spread from person to person. The bacteria are spread by exchanging respiratory and throat secretions (saliva or spit) during close or lengthy contact, especially if living in the same household. The bacteria are not spread by casual contact or by breathing.

Vaccination of adolescents and other high risk groups against strains A, C, W, and Y has been routinely recommended by the ACIP since 2005. Vaccines that provide protection against strains A, C, W, and Y include Menactra[®], Menomune[®], and Menveo[®]. None of these vaccines, however, protect against serogroup B. Currently, there are two vaccines approved by the Food and Drug Administration (FDA) for protection against serogroup B meningococcal disease. Trumenba[®] (MenB-FHbp) was approved in October 2014 and Bexsero[®] (MenB-4C) was approved in January 2015.

2) Summary of New ACIP Recommendations

ACIP recommends certain persons aged 10 years and older who are at increased risk for serogroup B meningococcal disease should be vaccinated to protect against serogroup B. This recommendation includes the following at risk groups:

- Persons with persistent complement component deficiencies
- Persons with anatomic or functional asplenia, including sickle cell disease
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
- Persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak

In June 2015, the ACIP expanded this recommendation to allow for individual clinical decision-making regarding the use of MenB vaccines. The ACIP voted to recommend that decisions to vaccinate adolescents and young adults, aged 16 through 23 years, against serogroup B meningococcal disease should be made by the provider. **The preferred age for MenB vaccination for persons not at high risk is 16 through 18 years of age.**

Both MenB vaccines are approved for use in persons aged 10 – 25 years. However, because there are no theoretical differences in safety for persons older than 25 years, the ACIP supports routine use of MenB vaccines in persons aged 10 years and older who are at increased risk for serogroup B meningococcal disease. The two MenB vaccines are not interchangeable; the same vaccine product must be used for all doses.

Bexsero[®] is approved as a two dose (0.5mL) series administered intramuscularly (IM) at least one month apart. Although the package insert for Trumenba[®] indicates an approval as a two or three dose series, the ACIP on recommends the use of a three dose (0.5mL) series administered IM on a 0-, 2-, and 6-month schedule. The series schedule for Trumenba will be reevaluated in October 2016.

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3) Texas Vaccines for Children (TVFC) Program

The TVFC Program supplies publicly purchased vaccine at no cost to enrolled providers. The TVFC Program aims to increase access and reduce barriers to vaccination services in Texas. MenB vaccines are available for order through the TVFC Program. MenB vaccines may be administered to eligible children and adolescents identified to be at high-risk, in addition to adolescents aged 16 – 18 years under the open recommendation. TVFC providers are expected to use all MenB vaccines as recommended by the ACIP; therefore, Trumenba[®] should only be administered as a three dose series until additional ACIP recommendations are available. For more information about the TVFC Program, please visit www.dshs.state.tx.us/immunize/tvfc/tvfc_about.shtm.

An updated resolution for the Federal Vaccines for Children (VFC) Program was released in June 2015 to allow for individual clinical decision-making regarding the use of MenB vaccines in children aged 16 – 18 years. For additional information regarding the VFC resolution, please visit www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2015-06-15-mening.pdf.

4) Precautions and Contraindications

Safety and effectiveness have not been established in children younger than 10 years of age. Persons who have had a life threatening reaction to a previous dose of MenB vaccine should not be vaccinated. There have been no studies evaluating the use of MenB vaccines during human pregnancy. MenB vaccines should be used during pregnancy only if clearly needed. It is not known whether MenB vaccines are excreted in human breast milk. Caution should be exercised when administering to a woman who is nursing. The tip caps of pre-filled syringes of Bexsero[®] contain natural rubber latex and caution should be used when administering to individuals with a latex allergy.

5) Meningococcal B Vaccine Safety

Seven pre-licensure clinical trials have been completed on Bexsero[®] before the vaccine was licensed by the FDA. The most common adverse reactions after administration of Bexsero[®] include pain at the injection site, myalgia, erythema, fatigue, headache, induration, nausea, and arthralgia.

Nine clinical trials have been completed on Trumenba[®] before the vaccine was licensed by the FDA. The most common adverse reactions after administration of Trumenba[®] include pain at the injection site, fatigue, headache, myalgia and chills.

On the basis of available data and expert opinion, MenB vaccines may be administered concomitantly with other vaccines indicated for this age but at a different anatomic site, if feasible. The safety of both Bexsero[®] and Trumenba[®] will be closely monitored by both the CDC and the FDA through three monitoring systems. These systems monitor adverse events already known to be caused by vaccines, as well as detect rare adverse events that were not identified during pre-licensure clinical trials. Please report all vaccine adverse events to the Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/index>.

6) Should Serogroup B Meningococcal Vaccines Replace Quadrivalent Meningococcal Vaccines?

Quadrivalent meningococcal vaccines provide protection against serogroups A, C W, and Y but not serogroup B. **Therefore, the ACIP does not recommend the routine use of MenB vaccines in place of quadrivalent meningococcal vaccination.**

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For best protection against meningococcal disease, the ACIP recommends that all 11 – 12 year olds be vaccinated with a quadrivalent meningococcal conjugate vaccine followed by a booster dose at age 16 years. For additional information regarding who needs to be vaccinated with meningococcal vaccines, please visit www.cdc.gov/vaccines/vpd-vac/mening/who-vaccinate.htm.

7) Meningococcal Vaccination Requirements for School and College Entry

The Texas Administrative Code is a compilation of all state agency rules in Texas. All immunizations required for school compliance can be found in Title 25, Part 1, Chapter 97, Subchapter B. Under Subchapter B, rule §97.63 requires that students aged 11 – 12 years or enrolling in 7th – 12th grades are required to have one dose of meningococcal vaccine.

In addition to meningococcal vaccination requirements for school entry, many entering college students are required to receive meningococcal vaccination as well. Title 3, Subtitle A, Chapter 51, Subchapter Z, Section 51.9192 of the Texas Education Code requires that an entering student at an institution of higher education be vaccinated against bacterial meningitis. Entering students must provide documentation of having received a meningococcal vaccination dose or booster during the five-year period preceding enrollment. The student must receive the required meningococcal vaccination no later than the 10th day before the first day of the semester or other term in which the student initially enrolls. For additional information on college vaccine requirements, please visit <http://collegevaccinerequirements.com/requirements.php>.

8) ImmTrac

ImmTrac, the Texas Immunization Registry, is a no-cost service offered by the Texas Department of State Health Services (DSHS). It is a secure and confidential registry available to all Texans. ImmTrac safely consolidates and stores immunization information from multiple sources electronically in one centralized system. The registry is a major component of the DSHS initiative to increase vaccine coverage across Texas.

ImmTrac users can report administration of MenB vaccinations using the below CPT codes. For more information about ImmTrac, please refer to www.ImmTrac.com.

- Bexsero[®] (MenB-4C): 90620
- Trumenba[®] (MenB-FHbp): 90621

9) Resources

- Know More About Your College Vaccine Requirements: <http://collegevaccinerequirements.com/requirements.php>
- Meningococcal Disease: www.cdc.gov/meningococcal/about/index.html
- Meningococcal: Who Needs to Be Vaccinated? www.cdc.gov/vaccines/vpd-vac/mening/who-vaccinate.htm
- Texas Administrative Code: [http://texreg.sos.state.tx.us/public/readtac\\$ext.viewtac](http://texreg.sos.state.tx.us/public/readtac$ext.viewtac)
- Texas Education Code: <http://www.statutes.legis.state.tx.us/Docs/ED/htm/ED.51.htm>
- Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm>

We encourage you to generously forward this advisory to others who may benefit from this information.