



Beware of B: Meningococcal B Toolkit

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Michael R. Pence Governor

Jerome M. Adams, MD, MPH State Health Commissioner

January 27, 2016

Addition of Serogroup B Meningococcal (MenB) Vaccine to the Indiana Vaccines for Children Program Formulary

Dear Indiana Vaccines for Children Program Provider,

This letter serves as a notification from the Indiana Immunization Division that the Indiana Vaccines for Children (VFC) Program has expanded its formulary to include Serogroup B Meningococcal (MenB) vaccine. All enrolled and active VFC providers are expected to order <u>and</u> administer MenB vaccine for your eligible patient population (aged 16 through 18 years) within the next 60 days.

Indiana VFC providers shall order and administer MenB vaccine to any VFC eligible adolescent 16 through 18 years of age unless contraindicated. MenB vaccines should be ordered through VTrckS with your regular vaccine order. The Indiana Adult Vaccine Program **does not** currently offer the MenB vaccine to young adults 19 through 23 years of age.

Indiana VFC providers who have patients aged 10 through 15 years of age who meet the high risk definition should order vaccine using the <u>vaccine special order request form</u>.

In June 2015, the Advisory Committee on Immunization Practices (ACIP) recommended use of MenB vaccines among certain groups of individuals aged ≥ 10 years who are at increased risk for serogroup B meningococcal disease, as well as adolescents and young adults 16 through 23 years of age based on an individual clinical decision. Please consult the published ACIP recommendation for more information (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm).

The MenB vaccine should be administered as either a 2-dose series of MenB-4C (Bexsero®) or a 3-dose series of MenB-FHbp (Trumenba®). The same vaccine series should always be used for all doses administered, as the two available vaccines are not interchangeable. Please note, the ACIP does not recommend the routine use of MenB vaccines in place of routine adolescent vaccination with quadrivalent meningococcal vaccines.

Thank you for your continued support of the Indiana VFC Program.

Sincerely,

Dave McCormick,
Director Immunization Division



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To promote and provide essential public health services.

STATE OF INDIANA

EXECUTIVE DEPARTMENT INDIANAPOLIS

Executive Order

PROCLAMATION

TO ALL TO WHOM THESE PRESENTS MAY COME, GREETINGS:

WHEREAS, meningococcal disease is any infection caused by the bacterium

Neisseria meningitidis, or meningococcus. Neisseria meningitidis bacteria can cause illness and spread through respiratory

secretion; and

WHEREAS, in the United States, there are approximately 1,000-1,200 cases

of meningococcal disease annually, and 10-15 percent of infected individuals will die, while 11-19 percent of those who live will suffer from serious morbidity, including loss of limbs

and impacts to the nervous system; and

WHEREAS, there have been several recent outbreaks of serogroup B

meningococcal disease on college campuses, with some cases

resulting in death; and

WHEREAS, the CDC recommends that decisions to vaccinate 16-23 year olds

against serogroup B meningococcal disease should be made at

the individual level; and

WHEREAS, it is critical that students, parents, educators, and health care

providers understand the dangers of meningitis B and are aware

that a vaccine is available to prevent disease; and

WHEREAS. Indiana takes all reasonable steps to urge all high schools,

colleges, and universities in Indiana to provide information to all

students and parents about meningococcal disease;

NOW, THEREFORE, I, Michael R. Pence, Governor of the State of Indiana, do hereby

proclaim August 22-28, 2016 as

MENINGOCOCCAL DISEASE AWARENESS WEEK

in the State of Indiana, and invite all citizens to duly note this occasion.

In Testimony Whereof, I hereto

set my hand and cause to be affixed the

Great Seal of State. Done at the

City of Indianapolis, this 4th

day of August in the year of our

Lord 2016 and of the Independence

of the United States 241.



BY THE GOVERNOR Quill P. Que

Bacterial Meningococcal Facts and Highlights

Remember, the health care provider's recommendation to vaccinate is the SINGLE MOST influential factor in determining whether a parent gets their child vaccinated.

Bacterial Meningitis Facts and Highlights

- Meningococcal disease is bacterial infection caused by Neisseria meningitids. Bacteria can invade the body, leading to severe swelling of the tissue surrounding the brain and spinal cord (meningitis) or bloodstream infection.
- Meningitis, caused by meningococcal disease, is a serious disease which can lead to lifelong complications and even death. Adolescents and young adults are at an increased risk for meningitis.
- Symptoms of meningitis are often mistaken for flu or less serious illnesses. Symptoms can progress quickly and include high fever, stiff neck, headache, confusion, nausea, vomiting, purplish rash, and exhaustion.

Meningococcal Vaccination

- Vaccination is the best protection against meningococcal disease. There are two types of vaccines available to help prevent it:
 - Meningococcal serogroup B (MenB) vaccination may be administered to adolescents and young adults age 16-23 years, with a preferred age of 16-18 years.
 - Meningococcal serogroup A, C, W, and Y (MCV4) vaccination is recommended for adolescents age 11- 12 years, with a booster dose at age 16 years.

Importance of Vaccination against Bacterial Meningitis

- Serogroup B is the most common cause of meningococcal disease in the US adolescents and young adults. It is also the cause of recent outbreaks of the disease on US college campuses.
- Since 2012, there have been 38 confirmed meningococcal disease cases in Indiana. Out of the 38 cases, 27 cases were meningococcal serogroup B.

http://www.nfid.org/idinfo/meningococcal/meningococcal-college-toolkit/meningococcal-disease-flyer.pdf





School Entry Immunization Requirements 2017-2018 School Year

Below are the number of doses and each vaccine required for school entry. Changes for this year include the Hepatitis A vaccine for grades K-3.

| Grade 12 | Grades 6 to 11 | Grades 4 to 5 | K-3rd grade | 3 to 5 years old |
|---|--|----------------------------------|---|---|
| 3 Hep B 5 DTaP 4 Polio 2 Hep A* | 3 Hep B 5 DTaP 4 Polio 2 Hep A* | 3 Hep B 5 DTaP 4 Polio | 3 Hep B 5 DTaP 4 Polio | 3 Hep B (Hepatitis B) 4 DTaP (Diphtheria, Tetanus & Pertussis) 3 Polio (Inactivated Polio) 1 MMR (Measles, Mumps & Rubella) 1 Varicella |
| 2 MMR 2 Varicella 1 Tdap (Tetanus & Pertussis) 2 MCV4 (Meningococcal) MenB (Meningococcal B)* | 2 MMR 2 Varicella 1 Tdap (Tetanus & Pertussis) 1 MCV4 (Meningococcal) | 2 MMR 2 Varicella 2 Hep A* | 2 MMR 2 Varicella 2 Hep A (Hepatitis A) | nus & Pertussis)) s & Rubella) |

Hep B The minimum age for the 3rd dose of Hepatitis B is 24 weeks of age.

DTaP Four doses of DTaP/DTP/DT are acceptable if 4th dose was administered on or after child's 4th birthday.

students in grades kindergarten through 5th grade, the final dose must be administered on or after the 4th birthday, and be administered at least 6 months after the previous dose. **Polio** Three doses of Polio are acceptable for all grade levels if the third dose was given on or after the 4th birthday and at least 6 months after the previous dose with only one type of vaccine used (all OPV or all IPV). For

children entering preschool through 7th grade. Parental report of disease history is acceptable for grades 8-12. **Varicella** Physician documentation of disease history, including month and year, is proof of immunity for

Hep A The minimum interval between 1^{st} and 2^{nd} dose is 6 calendar months. K-3 is required MCV4 Individuals who receive dose 1 after their 16th birthday only need 1 dose of MCV4.

Indiana State Department of Health, Immunization Division

(800) 701-0704

2018-2019 School Year (Proposed) School Entry Immunization Requirements

Below are the number of doses and each vaccine required for school entry. Changes for this year include Hepatitis A for grades K-4, 6 and 12th grade and Meningococcal Serogroup B vaccine for 12th grade.

| 3 to 5 years old 3 | 3 Polio (Inactivated Polio) 1 MMR (Measles, Mumps & Rubella) 1 Varicella | s & Rubella) |
|--------------------|--|--|
| K-4th grade 5 | 3 Hep B 5 DTaP | 2 MMR 2 Varicella |
| | 4 Polio | 2 Hep A (Hepatitis A) |
| 3 | 3 Нер В | 2 MMR |
| Grade 5 5 | 5 DTaP | 2 Varicella |
| | 4 Polio | 2 Hep A* |
| ω | 3 Нер В | 2 MMR |
| | 5 DTaP | 2 Varicella |
| Grade o 4 | 4 Polio | 1 Tdap (Tetanus & Pertussis) |
| 2 | 2 Нер А | 1 MCV4 (Meningococcal) |
| 3 | 3 Нер В | 2 MMR |
| | 5 DTaP | 2 Varicella |
| or dues / w 11 4 | 4 Polio | 1 Tdap (Tetanus & Pertussis) |
| 2 | 2 Hep A* | 1 MCV4 (Meningococcal) |
| Grade 12 5 2 | 3 Hep B 5 DTaP 4 Polio 2 Hep A | 2 MMR 2 Varicella 1 Tdap (Tetanus & Pertussis) 2 MCV4 (Meningococcal) 2 MCPB (Maging Coccal B) |

Hep B The minimum age for the 3rd dose of Hepatitis B is 24 weeks of age

DTaP Four doses of DTaP/DTP/DT are acceptable if 4th dose was administered on or after child's 4th

or all IPV). For students in grades kindergarten through 6th grade, the final dose must be the 4th birthday and at least 6 months after the previous dose with only one type of vaccine used (all OPV administered on or after the 4th birthday, and be administered **at least 6 months** after the previous Polio. Three doses of Polio are acceptable for all grade levels if the third dose was given on or after

MCV4 Individuals who receive dose 1 on or after their 16th birthday only need 1 dose of MCV4

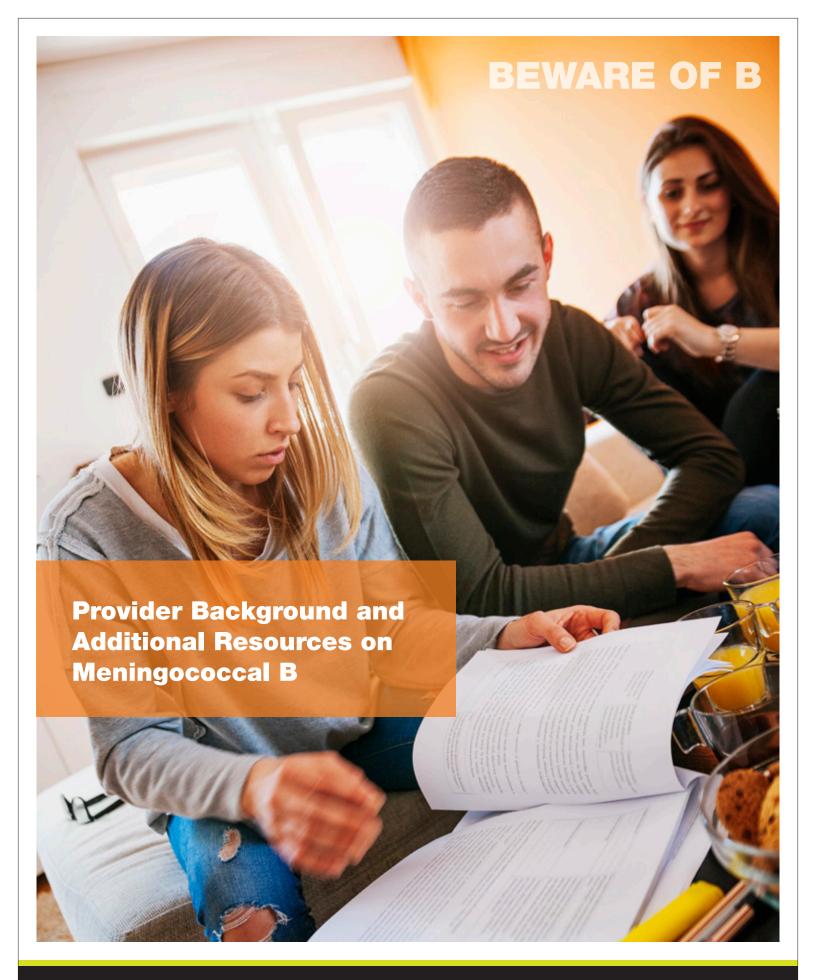
required for K-4, 6th and 12th grades and recommended for 5th grade and grades 7-11 **Hep A** The minimum interval between 1^{st} and 2^{nd} dose is 6 calendar months. Two doses of Hep A is

Indiana State Department of Health, Immunization Division (800) 701-0704

^{*}For grades 4-12, two doses of Hep A are recommended

MenB A complete series of Meningococcal Serogroup B vaccine

^{*}For grade 12,a complete series of MenB is recommended





Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015

Jessica R. MacNeil, MPH¹; Lorry Rubin, MD²; Temitope Folaranmi, MBChB^{1,3}; Ismael R. Ortega-Sanchez⁴; PhD; Manisha Patel, MD¹; Stacey W. Martin, MS¹

At its June 2015 meeting, the Advisory Committee on Immunization Practices (ACIP) recommended that adolescents and young adults aged 16-23 years may be vaccinated with a serogroup B meningococcal (MenB) vaccine to provide short-term protection against most strains of serogroup B meningococcal disease. This report summarizes the deliberations of ACIP, the rationale for its decision, and recommendations for use of MenB vaccines in adolescents and young adults. Two MenB vaccines have recently been licensed by the Food and Drug Administration (FDA) for use in the United States and approved for use in persons aged 10-25 years: MenB-FHbp (Trumenba, Wyeth Pharmaceuticals, Inc.) and MenB-4C (Bexsero, Novartis Vaccines). Both MenB vaccines were licensed based on statutory regulations for accelerated approval (1), which enabled FDA to approve the MenB vaccines for serious or life-threatening diseases based on safety and demonstration that vaccine effectiveness, as measured by bactericidal antibody responses with assays using several MenB test strains that were representative of prevalent strains in the United States, is reasonably likely to predict clinical benefit. As a requirement for accelerated approval, confirmatory studies in the postmarketing period will be conducted to verify and further describe the effectiveness of the vaccines against an

Recommendations for routine use of vaccines in children, adolescents, and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children and adolescents are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG). Recommendations for routine use of vaccines in adults are harmonized with recommendations of AAFP, ACOG, and the American College of Physicians (ACP). ACIP recommendations approved by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report (MMWR). Additional information is available at http:// www.cdc.gov/vaccines/acip.

extended number of MenB strains that represent a broader diversity of endemic disease. Additional postlicensure safety data are also needed and will be reviewed by ACIP as they become available.

Methods

The ACIP Meningococcal Vaccines Work Group reviewed the immunogenicity and safety data from seven clinical trials of MenB-FHbp (2-5) (Pfizer, unpublished data) and five clinical trials of MenB-4C (6-10) during monthly teleconferences. The work group evaluated the available published and unpublished data and evidence regarding meningococcal disease epidemiology in the United States, carriage, costeffectiveness, immunogenicity, and safety. Based on a literature search and consultation with the manufacturers, these studies represent all known clinical trials and evidence for these two vaccines. A summary of the data reviewed and Work Group discussions was presented to ACIP, and recommendations for use of MenB vaccines in adolescents and young adults were approved by ACIP at its June 24, 2015, meeting (meeting minutes are available at http://www.cdc.gov/vaccines/acip/ meetings/meetings-info.html).

The type and quality of evidence supporting the use of MenB vaccines in adolescents and young adults, including college students, was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework (11,12) (Table 1).

Epidemiology of Serogroup B Meningococcal Disease Among Adolescents and Young Adults, Including College Students

ACIP reviewed the burden of serogroup B meningococcal disease among adolescents, young adults, and college students. Meningococcal disease is a rare but serious illness and each case is life-threatening. The United States is currently experiencing a historic low in meningococcal disease incidence (0.18 per 100,000 among persons of all ages) (CDC, unpublished data, 2013), and the incidence of disease has declined for all meningococcal serogroups, including serogroup B, a serogroup not included in the quadrivalent (serogroups A, C, W, Y) meningococcal conjugate vaccines. The incidence of serogroup B meningococcal disease is stable and low in

adolescents and young adults aged 11-23 years, with approximately 50 to 60 cases and five to 10 deaths reported annually; the majority (>80%) of these cases occur in older adolescents and young adults aged 16–23 years (CDC, unpublished data). Seven outbreaks of serogroup B meningococcal disease have occurred on college campuses since 2009 (range = 2–13 cases), resulting in 41 cases and three deaths. Whereas several outbreaks of serogroup B meningococcal disease have occurred in recent years on college campuses, during 2009–2013, the estimated incidence of serogroup B meningococcal disease in college students aged 18–23 years (0.09 per 100,000) was similar to, or lower than, the incidence in all persons aged 18–23 years (0.14 per 100,000), and non-college students aged 18–23 years (0.21 per 100,000) (CDC, unpublished data).

It is estimated that approximately 15 to 29 cases and two to five deaths could be prevented annually with a routine adolescent MenB vaccination program administered at age 11, 16, or 18 years (Table 2). A recommendation for college students only is estimated to prevent approximately nine cases and one death annually (Table 2).

MenB Vaccine Immunogenicity and Safety

Evaluation of vaccine effectiveness against all serogroup B meningococcal strains is difficult because the strains are antigenically and genetically diverse. Efficacy studies designed to assess clinical disease outcomes would be the clearest demonstration of the benefit of MenB vaccines to prevent meningococcal B disease; however, such studies would be difficult to conduct because of the low prevalence and sporadic occurrence of disease in the United States. Vaccine effectiveness of MenB-FHbp and MenB-4C, for purposes of U.S. licensure, was inferred based on an immunologic marker of protection, serum bactericidal activity with human complement (hSBA) as measured by assays using selected meningococcal serogroup B strains. Immunogenicity was assessed as the proportion of subjects who achieved a fourfold or greater increase in hSBA titer for each of the serogroup B strains tested, and the proportion of subjects who achieved a titer greater than or equal to the lower limit of quantification of the assay for all strains

TABLE 1. Summary of evidence for MenB-FHbp and MenB-4C vaccination of healthy adolescents and young adults, including college students — United States

| | Evidence type* | | |
|--|----------------|---------|--|
| Outcome | MenB-FHbp | MenB-4C | |
| Benefits | | | |
| Short-term immunogenicity | 2 | 2 | |
| Persistence in immunogenicity | 4 | 3 | |
| MenB immunogenicity with concomitant vaccination | 2 | † | |
| Harms | | | |
| Serious adverse events | 2 | 2 | |
| Serious adverse events following concomitant vaccination | 2 | † | |

^{*} Evidence type: 2 = moderate level of evidence; 3 = low level of evidence; 4 = lowest level of evidence.

(composite response) (13). The lower limit of quantification was defined as the lowest amount of the antibody in a sample that can be reliably quantified.

Both MenB-FHbp and MenB-4C vaccines contain components that include factor H binding protein. In two animal models, antibodies measured after MenB-4C vaccination have been noted to be cross-reactive with human factor H (14,15). However, it is not known if auto-antibodies to factor H develop in humans after vaccination with MenB-FHbp or MenB-4C and, if auto-antibodies are generated postvaccination, whether they are of clinical significance. FDA reviewed safety data from six MenB-4C clinical trials and seven MenB-FHbp clinical trials, which included approximate totals of 3,100 and 4,500 vaccine recipients, respectively. For most participants who reported an autoimmune condition, the onset of symptoms consistent with the diagnosis existed before the first vaccination (16,17). Theoretically, onset of autoimmune-disease-related symptoms could be delayed well beyond vaccination and postlicensure safety surveillance will be important to detect any potential safety signals.

MenB-FHbp

MenB-FHbp consists of two purified recombinant lipidated factor H binding protein (FHbp) antigens. One antigen from

TABLE 2. Potential cases and deaths prevented and cost-effectiveness of different strategies for MenB vaccination of adolescents and young adults, including college students, by age — United States

| Age at MenB series | Cases prevented | Deaths prevented | NNV* to prevent case | NNV to prevent death | Cost per QALY (million \$) |
|--------------------|-----------------|------------------|----------------------|----------------------|----------------------------|
| 11 yrs | 15 | 2 | 203,000 | 1,512,000 | 8.7 |
| 16 yrs | 28 | 5 | 107,000 | 788,000 | 4.1 |
| 18 yrs | 29 | 5 | 102,000 | 638,000 | 3.7 |
| College student | 9 | 1 | 368,000 | 2,297,000 | 9.4 |

Abbreviations: MenB = meningococcal B vaccine; NNV = number needed to vaccinate; QALY = quality-adjusted life years.

Sources: Unpublished data, ACIP meeting June 2015. Key model assumptions were presented at the June 2015 ACIP meeting. Methods described in Shepard CW, Ortega-Sanchez IR, Scott RD 2nd, Rosenstein NE. Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States. Pediatrics 2005;115:1220–32.

[†] Not assessed because of lack of available data.

each FHbp subfamily (A and B) is included in the vaccine. MenB-FHbp is licensed as a 3-dose series, with the second and third doses administered 2 and 6 months, respectively, after the first dose.

The immunogenicity and safety of MenB-FHbp in adolescents and young adults were evaluated in seven clinical trials: five randomized controlled trials and two open-label studies (2–5,16,18) (Pfizer, unpublished data). In a multicenter trial conducted in the United States, persons aged 11–17 years were randomly assigned to one of three groups: group 1 received MenB-FHbp and quadrivalent human papillomavirus vaccine (4vHPV [Gardasil, Merck and Co.]); group 2 received MenB-FHbp and saline; and group 3 received 4vHPV and saline.

One month following the third dose, 81.0% (95% confidence interval [CI] = 78.0%–83.7%) of subjects in group 1 and 83.9% (CI = 81.1%–86.4%) of subjects in group 2 had a composite response to all four strains tested (2,18). One month following the second of 3 doses, approximately 50% of the subjects in each study group had a composite response to all four strains. In studies conducted in Europe among persons aged 11–18 years, the hSBA responses in subjects who received MenB-FHbp according to the same schedule were similar to hSBA antibody responses in subjects in the U.S. study (3,18).

Evaluation of concomitant administration of MenB-FHbp with vaccines routinely administered to adolescents in the United States or Europe occurred in three trials. Subjects received MenB-FHbp coadministered with 4vHPV, quadrivalent meningococcal conjugate vaccine (MenACWY [Menactra, Sanofi Pasteur]), tetanus-diphtheria-acellular pertussis vaccine (Tdap, [Adacel, Sanofi Pasteur]), or tetanusdiphtheria-acellular pertussis-inactivated polio (Tdap/IPV [Repevax, Sanofi Pasteur]) vaccines, depending on the study population in the trial. Except for the antibody response to HPV type 18, no immunogenic interference was observed for serogroup B or concomitant vaccine antigens (HPV types 6, 11, 16, MenACWY, tetanus, diphtheria, pertussis, and IPV antigens) when MenB-FHbp was administered concomitantly (4,5). For HPV type 18, noninferiority criteria (lower bound of the CI of the geometric mean titer ratio >0.67) were not met for the geometric mean titer ratio at 1 month after the third 4vHPV dose (lower bound of the CI for the geometric mean titer ratio was 0.62); however, for each HPV vaccine type, ≥99% of subjects achieved seroconversion.

Antibody persistence through 48 months after dose 3 for MenB-FHbp was evaluated in a clinical trial (Pfizer, unpublished data). The data demonstrate an initial rapid decline in antibodies after vaccination followed by a flattening out of the antibody curve at approximately 6 months after the third dose. At 48 months, >50% of vaccinated subjects continued to demonstrate hSBA titers greater than or equal to the lower

limit of quantification against three of the four strains tested (Pfizer, unpublished data).

In seven clinical trials (2–5) (Pfizer, unpublished data), a total of 9,808 subjects received at least 1 dose of MenB-FHbp; four subjects reported seven serious adverse events that were considered by the study investigator to be related (or possibly related) to the vaccine.* All vaccine-related serious adverse events resolved without sequelae. No increased risk for any specific serious adverse event considered to be clinically significant was identified in any of the studies. No deaths were considered to be related to MenB-FHbp. The most common solicited adverse reactions observed in the 7 days after receipt of MenB-FHbp in the clinical trials were pain at the injection site (\geq 85%), fatigue (\geq 40%), headache (\geq 35%), myalgia (\geq 30%), and chills (\geq 15%) (18).

MenB-4C

MenB-4C consists of three recombinant proteins (neisserial adhesion A [NadA], factor H binding protein [FHbp] fusion protein, and neisserial heparin binding antigen [NHBA] fusion protein) and outer membrane vesicles (OMVs) containing outer membrane protein PorA serosubtype P1.4. MenB-4C is licensed as a 2-dose series, with doses administered at least 1 month apart, although in some studies, MenB-4C doses were administered up to 6 months apart. No data are available following 3 doses of MenB-4C in a North American population.

The immunogenicity and safety of MenB-4C in adolescents and young adults were evaluated in five clinical trials; three randomized controlled trials, one randomized uncontrolled trial, and one immunogenicity extension study (6–10,17,19). In a randomized controlled trial conducted in Chile, persons aged 11–17 years received 2 doses of MenB-4C 1, 2, or 6 months apart. One month following the second dose, 90%–94% of subjects had a composite response to all three strains tested, depending on the vaccination schedule administered; 77%–94% of subjects had an hSBA titer of ≥1:4 against all three strains tested at 18–24 months after the second dose, depending on the vaccination schedule administered (9).

In a randomized controlled trial conducted in the United Kingdom, a subset of enrolled subjects (university students aged 18-24 years) received 2 doses of MenB-4C vaccine 1 month apart. One month following the second dose, 88% (CI = 82%-93%) of subjects had a composite response to all three strains tested; 66% (CI = 58%-72%) of the subjects had a composite response to all three strains tested at 11 months

^{*}The administration of the investigational vaccine and a serious adverse event were considered reasonably related in time and the serious adverse event could not be explained by causes other than exposure to the investigational vaccine. The reported serious adverse events included pyrexia (1), vomiting (1), vertigo (1), chills (1), headache (1), anaphylaxis (1), and neutropenia (1).

after the second dose (8). In a randomized uncontrolled trial conducted in Australia and Canada, persons aged 11-17 years received 2 doses of MenB-4C 1 month apart. One month following the second dose, 63% (CI = 57%-68%) of subjects had a composite response to all three strains tested (7,19).

In three clinical trials for which a control group was available, serious adverse events were assessed in 2,716 subjects who received at least 1 dose of MenB-4C and for whom safety data were collected through 6 months postvaccination (6,8,10). Five serious adverse events were considered by the study investigator to be related (or possibly related) to the vaccine. † Rates of serious adverse events were similar in the vaccine and the control groups. In addition, information about serious adverse events was collected during three vaccination campaigns in response to three outbreaks of serogroup B meningococcal disease (at two U.S. universities and in one region of Canada). A total of 59,091 participants in the vaccination campaigns received at least 1 dose of MenB-4C. Three serious adverse events were considered to be related (or possibly related) to the vaccine[§]; all resolved with no sequelae (CDC and Novartis, unpublished data). No deaths were considered to be related to MenB-4C in the clinical trials or campaigns. The most common solicited adverse reactions observed in the 7 days after receipt of MenB-4C in the clinical trials were pain at the injection site $(\geq 83\%)$, myalgia $(\geq 48\%)$, erythema $(\geq 45\%)$, fatigue $(\geq 35\%)$, headache (≥33%), induration (≥28%), nausea (≥18%), and arthralgia (≥13%) (19). Immunogenicity and safety data regarding MenB-4C when coadministered with vaccines routinely administered to U.S. adolescents are not available.

Summary of ACIP Deliberations and Rationale

The available data suggest that MenB vaccines might be an important step for controlling serogroup B meningococcal disease. Although current data suggest they will protect against the majority of currently circulating strains, these vaccines are not expected to provide protection against disease caused by all serogroup B strains circulating in the United States. Additional studies assessing breadth of strain coverage are ongoing, and ACIP will review results as they become available. Immune responses following MenB vaccination in the studies described were evaluated after completion of the primary

Summary

What is currently recommended?

The Advisory Committee on Immunization Practices recommends routine vaccination of all adolescents aged 11–18 years with a quadrivalent meningococcal conjugate vaccine (MenACWY). A single dose should be administered at age 11 or 12 years with a booster dose at age 16 years for persons who receive the first dose before age 16 years. Routine vaccination of certain persons at increased risk for meningococcal disease with MenACWY and serogroup B meningococcal (MenB) vaccine is also recommended.

Why are the recommendations being modified now?

Two serogroup B meningococcal vaccines were recently licensed by the Food and Drug Administration and approved for use in persons aged 10–25 years. The evidence supporting the use of MenB vaccines in adolescents and young adults was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation framework. The recommendation was designated as Category B (recommended for individual clinical decision making).

What are the new recommendations?

A MenB vaccine series may be administered to adolescents and young adults aged 16–23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16–18 years.

immunization series, but no data are available on vaccine effectiveness against clinical disease endpoints or duration of protection against clinical disease. On the basis of the limited available data, no concerning patterns of serious adverse events have been reported for MenB vaccines; additional safety data and postlicensure safety surveillance data are needed and will be reviewed by ACIP as they become available. In addition, the potential impact of MenB vaccines on nasopharyngeal carriage and herd protection is inconclusive, as is the potential impact vaccine introduction might have on the population of *Neisseria meningitidis*.

After reviewing the available data, ACIP supported consideration of vaccination of all adolescents rather than college students only, primarily because an important number of serogroup B meningococcal disease cases occurs in persons aged 18–23 years who are not attending college, and vaccinating college students only is estimated to prevent the fewest cases and deaths among all the options considered (Table 2). However, ACIP also acknowledges the impact that cases and outbreaks have on college campuses, both in terms of the cost for vaccination campaigns in response to these outbreaks as well as public concern. On the basis of the available antibody persistence data, ACIP concluded that a preference to administer the MenB series in later adolescence exists, preferably at

[†] The administration of the investigational vaccine and a serious adverse event were considered reasonably related in time and the serious adverse event could not be explained by causes other than exposure to the investigational vaccine. The reported serious adverse events included tremor (1), dyspnea (1), acute thyroiditis (1), and juvenile arthritis (2).

[§] The administration of the investigational vaccine and a serious adverse event were considered reasonably related in time and the serious adverse event could not be explained by causes other than exposure to the investigational vaccine. The reported serious adverse events included rhabdomyolysis (1), anaphylaxis (1), and fever (1).

age 16–18 years, to maximize the likelihood that protection would last into the highest age-related risk period.

The current low prevalence of disease, coupled with the fact that important data for making policy recommendations for MenB vaccines are not yet available, resulted in ACIP determining that insufficient evidence exists to make a routine public health recommendation that all adolescents be vaccinated with MenB vaccine. Given the seriousness of meningococcal disease and the availability of licensed vaccines, ACIP agreed that sufficient evidence exists to encourage individual clinical decision making.

Recommendations

A MenB vaccine series may be administered to adolescents and young adults aged 16–23 years to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16–18 years (recommendation Category B).

MenB vaccine should either be administered as a 3-dose series of MenB-FHbp or a 2-dose series of MenB-4C. The two MenB vaccines are not interchangeable; the same vaccine product must be used for all doses. On the basis of available data and expert opinion, MenB-FHbp or MenB-4C may be administered concomitantly with other vaccines indicated for this age, but at a different anatomic site, if feasible.

No randomized controlled clinical trials have been conducted to evaluate use of MenB vaccines in pregnant or lactating women. Vaccination should be deferred in pregnant and lactating women unless the woman is at increased risk (20), and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks.

Additional information for health care providers and parents can be found on the CDC website at http://www.cdc.gov/meningococcal.

In February 2015, ACIP recommended routine use (recommendation Category A)** of MenB vaccines in certain groups of persons at increased risk for serogroup B meningococcal disease, including during outbreaks of serogroup B meningococcal disease (20). College campuses that have recently experienced an outbreak of serogroup B meningococcal disease should continue to follow the recommendations for use of MenB vaccines in outbreak settings that recommend vaccination for persons aged ≥10 years.

Precautions and Contraindications

Before administering MenB vaccines, health care providers should consult the package insert for precautions, warnings,

and contraindications (18,19). Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov).

Acknowledgments

ACIP members (membership roster for July 2014–June 2015 available at http://www.cdc.gov/vaccines/acip); ACIP Meningococcal Vaccines Work Group.

¹Meningitis and Vaccine Preventable Diseases Branch, Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, CDC; ²Advisory Committee on Immunization Practices Meningococcal Vaccines Work Group, Steven and Alexandra Cohen Children's Medical Center of New York, New Hyde Park, New York and Hofstra North Shore-LIJ School of Medicine, Hempstead, New York; ³Epidemic Intelligence Service, CDC; ⁴Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, CDC.

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[¶] Category B recommendations are made for individual clinical decision making.
** Category A recommendations are made for all persons in an age- or risk-factor-based group.

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Resolution No. 10/16-3

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

VACCINES FOR CHILDREN PROGRAM

VACCINES TO PREVENT MENINGOCOCCAL DISEASE

The purpose of this revision is to update the recommended vaccination schedule and intervals for Trumenba®, one of the sergroup B vaccines covered by the resolution.

VFC resolution 6/16-1 is repealed and replaced by the following:

A. Meningococcal Conjugate Vaccines (MenACWY and HibMenCY)

Eligible groups

- Children aged 2 months through 10 years who are at increased risk for meningococcal disease attributable to serogroups A, C, W, and Y, including:
 - Children who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D or taking eculizumab [Soliris®])
 - Children who have anatomic or functional asplenia, including sickle cell disease
 - o Children infected with Human Immunodeficiency Virus (HIV)
 - Children traveling to or residing in countries in which meningococcal disease is hyperendemic or epidemic, particularly if contact with local population will be prolonged (MenACWY vaccines only)
 - o Children identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroups A, C, W, or Y.
- All children aged 11 through 18 years

Recommended Vaccination Schedule and Intervals

Recommended schedules and intervals for meningococcal conjugate vaccines can be found at the following links:

- www.cdc.gov/mmwr/pdf/rr/rr6202.pdf
- www.cdc.gov/mmwr/preview/mmwrhtml/mm6324a2.htm

Recommended dosage

Refer to product package inserts.

Contraindications and Precautions

Contraindications and Precautions can be found in the package inserts available at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833

B. Serogroup B Meningococcal Vaccines (MenB)

Eligible groups

- Children aged 10 through 18 years at increased risk for meningococcal disease attributable to serogroup B, including:
 - Children who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D or taking eculizumab [Soliris®])
 - Children who have anatomic or functional asplenia, including sickle cell disease
 - Children identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B
- Children aged 16 through 18 years without high risk conditions may also be vaccinated

Recommended Vaccination Schedule and Intervals

| Age Group | Vaccine ¹ | Dosing Schedule |
|----------------|--------------------------------|---|
| 10–18 years | MenB (Bexsero®, GSK) | Two doses, at least one month apart (0 and 1-6 month schedule) |
| 10–18 years | MenB (Trumenba®, Pfizer) | Persons at increased risk for meningococcal disease and for use during serogroup B outbreaks: Three doses (0, 1-2, and 6 month schedule) Healthy adolescents who are not at increased risk for meningococcal disease: Two doses (0, 6 months) ² |

Table Notes:

- 1. Use of brand names is not meant to preclude the use of other comparable US licensed vaccines
- 2. If the second dose is given at an interval of <6 months a third dose should be given at least 6 months after the first dose.

Recommended dosage

Refer to product package inserts.

Contraindications and Precautions

Contraindications and Precautions can be found in the package inserts available at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833

[If an ACIP recommendation or notice regarding meningococcal vaccination is published within 12 months following this resolution, the relevant language above (except in the eligible groups sections) will be replaced with the language in the recommendation and incorporated by reference to the publication URL.]

Adopted and Effective: October 19, 2016

This document can be found on the CDC website at: www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2016-10-3-mening.pdf

Additional Resources

National Foundation for Infectious Diseases:

www.nfid.org

Search for: Meningococcal Disease Toolkit

Centers for Disease Control and Prevention

www.cdc.gov

Search for: Meningococcal Disease

National Meningitis Association

www.nmaus.org

Search for: Serogroup B Meningococcal Disease

Immunization Action Coalition

www.immunize.org

Search for: Ask the Experts: Disease & Vaccines - Meningococcal Disease

Meningitis Research Foundation

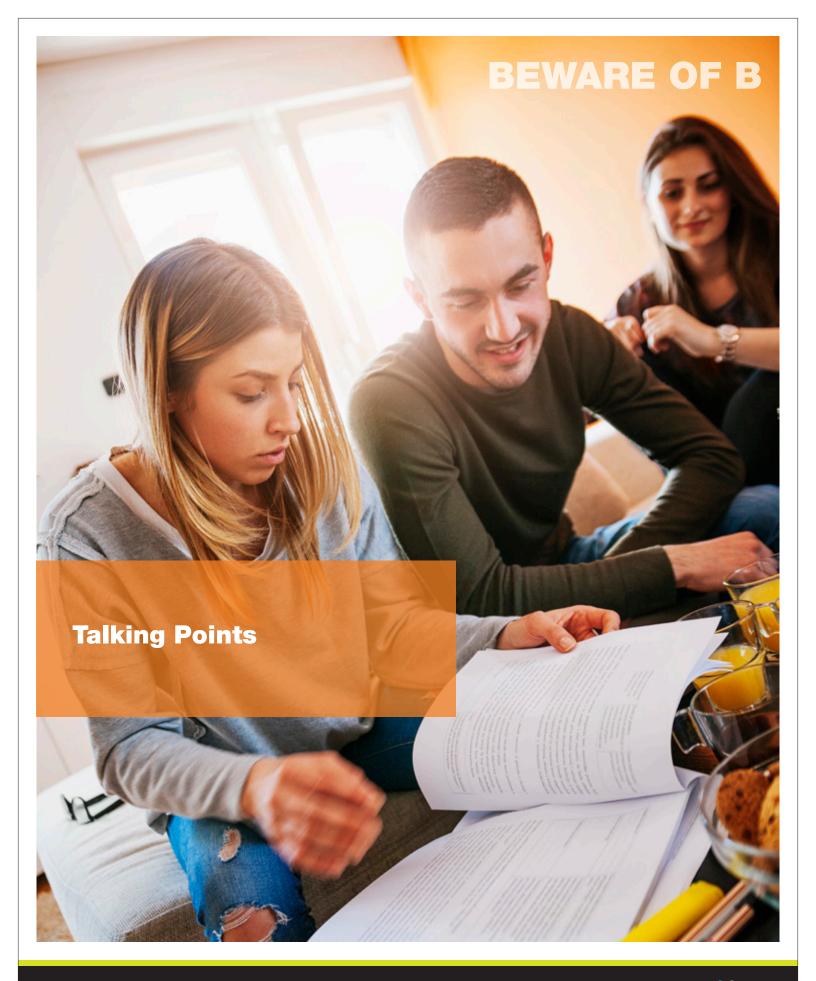
www.meningitis.org

Search for: MenB vaccine

Toolkit Updates check:

www.vaccinateindiana.org







Two Important Points to Communicate to Parents about Meningococcal Disease Prevention

- Adolescents and young adults have an increased risk of contracting meningococcal disease, also known as meningitis, a bacterial infection that can lead to lifelong complications and even death. However, the majority of cases are vaccine-preventable.
- There are two types of vaccines available to help protect against meningococcal disease.
 - Quadrivalent meningitis vaccine, MCV4, protects against four serogroups (A, C, W, and Y). It is recommended that adolescents are vaccinated at ages 11 to 12 years, with a booster dose at 16 years.
 - However, MCV4 does not protect against the most common cause of the disease, serogroup B. MenB continues to cause outbreaks on college campuses.
 In 2014, two vaccines became available in the United States to protect against serogroup B, Bexsero and Trumenba. MenB vaccines are recommended by healthcare providers for individuals age 16 to 23 years.

http://www.nfid.org/idinfo/meningococcal/meningococcal-college-toolkit/welcome-packet.pdf





Planning for Prevention: Tips to Manage Meningococcal Disease Outbreaks on Campus

Meningococcal disease (meningitis) is a rare but deadly bacterial infection. In addition to the serious medical impact, even one case on a college campus can cause social anxiety and fear among students and parents, often taking up a great deal of campus resources. Serogroup B is the most common cause of meningococcal disease in US adolescents and young adults. It is also the cause of recent college outbreaks of the disease.

Parents may think their college-age children are protected against meningococcal disease because they received the routinely recommended quadrivalent vaccine (ACWY) – but, that vaccine does not protect against serogroup B disease. Students may request the serogroup B vaccine from their healthcare professional. Vaccines to protect against serogroup B became available in the US in 2014. Yet, very few adolescents and young adults have received it.

The National Foundation for Infectious Diseases (NFID), a nonprofit organization dedicated to educating the public and healthcare professionals about the causes, prevention, and treatment of infectious diseases, offers the following tips to help increase and maintain a high level of awareness about meningococcal disease and prevention through vaccination:

- Encourage all incoming and returning students to get vaccinated according to CDC and state
 recommendations. Take every opportunity to inform students and their parents, including welcome
 packets, orientation, health center visits, website updates, and social media, about vaccines available
 to help protect against the disease.
- Educate students, prospective students, and parents with credible information. Use resources from
 reliable sources, such as NFID and CDC, for access to the latest information. Links to valuable
 resources are available at: www.nfid.org/meningitis-toolkit.
- Evaluate resources and discuss how you would respond to a meningococcal disease case on campus.
 - Meet with relevant department heads/administrators, student and community leaders, and healthcare professionals to discuss the level of knowledge about the disease, symptoms, potential impacts on campus, and college vaccine requirements/recommendations.
 - Establish relationships with local news media so that they understand the issue, can help
 promote information about the disease, and can help during a crisis. Provide easy access to
 information on all aspects of meningococcal disease, including diagnosis, treatment,
 transmission, and prevention to inform current and future media coverage.
- Establish a meningococcal disease response team, including representatives from health services, communications, administration, and the local community. Encourage team members to review the recommendations in the NFID report (http://www.nfid.org/meningococcal-b), based on real experiences with meningococcal disease serogroup B cases/outbreaks. Meet on a regular basis to discuss how your students can best be protected.

Dear Parents, Guardians and Students,

One type of meningitis is caused by a bacterium called Neisseria meningitidis. Infections caused by this bacterium are serious, and may lead to death. Symptoms of an infection with Neisseria meningitidis may include a high fever, headache, stiff neck, nausea, confusion and a rash. This disease can become severe very quickly and often leads to deafness, loss of arms or legs and even death. The bacteria are spread from close person to person contact through the exchange of nose and throat secretions, by activities such as kissing or sharing food or drinks. The bacteria are not spread by casual contact or by simply breathing the air where a person with meningitis has been.

There are 2 types of meningococcal vaccine available in the United States. Vaccines for meningococcal serogroups A, C, W and Y (MCV4) are composed of polysaccharide (sugar molecules) from the surface of the meningococcal bacteria. Vaccines for meningococcal serogroup B (MenB) are composed of proteins also found in the surface of the bacteria. Neither type of vaccine contains live meningococcal bacteria. MCV4 vaccines provide no protection against serogroup B disease and MenB vaccines provide no protection against serogroup A, C, W or Y disease. For protection against all 5 serogroups of meningococcus it is necessary to receive both vaccines, MCV4 and MenB.

The United States Centers for Disease Control and Prevention (CDC) recommends vaccination of children with MCV4 vaccine (Menactra and Menveo) at 11 or 12 years of age, with a booster dose of the vaccine at 16 years of age. The booster dose at age 16 provides ongoing protection from the disease after high school. The CDC also recommends that a MenB vaccine (Bexsero and Trumenba) may be administered to persons 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years. This permissive (Category B) recommendation allows the clinician to make a MenB vaccine recommendation based on the risk and benefit for the individual patient.

The state of Indiana requires all students in grades 6-12 to have the appropriate number of MCV4 vaccine doses. One dose of MCV4 vaccine is required for all students in 6th -11th grade. A second booster dose is required for students entering 12th grade. These vaccines are a legal requirement for school entry (Indiana Administrative Code 410 IAC 1-1-1) for the 2016-2017 school year. The MenB vaccine is not a legal requirement for school entry at this time, and cannot be used for the meningococcal vaccine requirement for school entry. However, to be fully protected against meningitis the CDC recommends that all students receive both MCV4 and MenB.

Information about meningococcal disease can be found at:

The Centers for Disease Control and Prevention (CDC) website:

http://www.cdc.gov/vaccines/vpdvac/mening/default.htm

IN State Department of Health website:

http://www.in.gov/isdh/25455.htm

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Frequently Asked Questions: Meningococcal Disease

What is meningococcal disease?

Meningococcal disease is any illness that is caused by *Neisseria meningitids*, a type of bacteria, also called meningococcus. These illnesses can be severe and include infections of the lining of the brain and spinal cord (meningitis) and bloodstream infections (bacteremia or septicemia).¹ Three different types of the bacteria, serogroups B, C, and Y, are the most prevalent in the United States.²

Why is meningococcal disease serious?

Since 2012, in Indiana, 27 out of the 38 confirmed cases of meningococcal disease were caused by serogroup B.³ Meningococcal disease is one of the most severe vaccine-preventable diseases. One out of every ten people who get the disease will die and two in ten will suffer serious and permanent problems including brain damage; amputation of arms, legs, fingers, or toes; hearing loss; and kidney damage.²

What are the symptoms of meningitis?

Early symptoms of meningitis are often mistaken for flu or less serious illnesses, which can cause a delay in diagnosis and treatment. Symptoms progress very quickly and may include: stiff neck, high fever, headache, nausea, vomiting, purplish rash, and exhaustion. Death can occur within as little as 24-48 hours.²

Students who experience these symptoms, especially if they are sudden, progressive or severe, should be seen by a medical profession **as soon as possible**.²

How does meningococcal disease spread?

Meningococcal disease is spread from person to person. Respiratory and throat secretions, such as saliva spit, can spread the bacteria during close contact, such as kissing or sharing drinks.²

How can meningococcal disease be prevented?

Vaccination is the best protection against disease. There are two types of vaccines available:

- MCV4 protects against serogroups A, C, W, and Y; vaccination is recommended for all adolescents age 11 to 12 years, with a booster dose at 16 years. Most teens receive the first dose of MCV4; however, only three in ten receive the booster dose.
- MenB protects against serogroup B, the most common meningococcal disease serogroup in the United States.
 Vaccination is recommended for anyone age 16 to 23 years, with a preferential recommendation for those 16 to 18 years.^{1,2}

Will insurance cover vaccines against serogroup B disease?

Yes. The Vaccines for Children (VFC) program provides serogroup B vaccines at no cost for eligible students (up to 18 years of age).² In Indiana, all VFC providers are required to stock meningococcal b vaccine. Private insurance also covers serogroup B vaccines; however, it is important to check with individual payers.

- 1. https://www.cdc.gov/meningococcal/about/symptoms.html
- 2. https://www.cdc.gov/meningococcal/about/causes-transmission.html
- 3. http://www.in.gov/isdh/20667.htm



Meningococcal B Vaccine:

CDC Answers Your Questions

Experts from the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention answer your questions about meningococcal serogroup B (MenB) vaccine.

Which meningococcal vaccines are available in the United States?

Since 2005, two types of meningococcal vaccines have been available in the United States that protect against meningococcal serogroups A, C, W, and Y: 1) meningococcal polysaccharide vaccine (MPSV4, Menomune, Sanofi Pasteur) which is made up of polysaccharide (sugar molecules) from the surface of the meningococcal bacteria; and 2) meningococcal conjugate vaccines (MenACWY, Menactra, Sanofi Pasteur; Menveo, GSK) in which the polysaccharide is chemically bonded ("conjugated") to a protein to produce better protection.

More recently, two vaccines have become available that offer protection from meningo-coccal serogroup B disease (MenB, Bexsero, GSK; Trumenba, Pfizer). These vaccines are composed of proteins also found on the surface of the bacteria. Both MenB vaccines are approved by the Food and Drug Administration for use in persons 10 through 25 years of age.

MPSV4 and MenACWY provide no protection against serogroup B disease and meningo-coccal serogroup B vaccines (MenB) provide no protection against serogroup A, C, W, or Y disease. For protection against all 5 serogroups of meningococcus, it is necessary to receive MenACWY or MPSV4 and MenB.

Which individuals in risk groups are recommended to be vaccinated against meningococcal serogroup B disease?

CDC's Advisory Committee on Immunization Practices (ACIP) recommends routine MenB vaccination of the following individuals in certain risk groups:

- People age 10 years and older who have functional or anatomic asplenia
- People age 10 years and older who have persistent complement component deficiency, including people taking eculizumab (Soliris)
- People age 10 years and older who are at risk during an outbreak caused by a vaccine serogroup, such as on a college campus
- Microbiologists who work with meningococcus bacteria in a laboratory

Administration of MenB vaccine in persons older than 25 years of age is an off-label use. Clinicians may choose to use vaccines off-label if they believe it would be of benefit to their patients.

Which individuals are recommended to be vaccinated against meningococcal serogroup B disease who are not in risk groups?

ACIP recommends that a MenB vaccine series may be administered to people 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years. This Category B recommendation gives clinicians an opportunity to discuss the value of MenB vaccination with their patients to make a decision together about the individual's need or desire for the vaccine based on risks, benefits, and wish for protection from the disease. Because it is a Category B recommendation, MenB vaccination is covered by the Vaccines for Children Program for anyone who is eligible. Under the Affordable Care Act, private insurance must also cover the costs of both Category A and B recommended vaccines.

What is the difference between a Category A and Category B recommendation?

A Category A recommendation is made for all persons in an age- or risk-factor-based group. The meningococcal conjugate vaccine recommendation for all preteens at 11–12 years of age is an example of a Category A recommendation. A Category B recommendation does not apply to everyone, but in

the context of a clinician-patient interaction, vaccination may be found to be appropriate for a person as noted above for MenB vaccination of healthy adolescents.

Does the Affordable Care Act (ACA) require health plans (non-grandfathered) to provide benefit coverage on Category B recommended vaccines?

Yes. ACA requires coverage of vaccines with both Category A and B recommendations. The Vaccines for Children Program also includes vaccines with a Category A and B recommendations.

Should college students be vaccinated against meningococcal B disease?

Although several small meningococcal serogroup B disease outbreaks have occurred on college campuses since 2013, college students in general are not at higher risk of meningococcal B disease than persons of the same age who are not college students. Consequently, ACIP does not routinely recommend MenB vaccination for college students. However, college students may choose to receive MenB vaccine to reduce their risk of serogroup B meningococcal disease.

Should international travelers receive both meningococcal conjugate vaccine and meningococcal serogroup B vaccine?

Travelers are not considered to be a group at increased risk for serogroup B meningo-coccal disease and are not recommended to receive serogroup B vaccine. Meningococcal conjugate vaccine (MenACWY) continues to be recommended for certain international travelers (residents of and travelers to sub-Saharan Africa and the Hajj in Saudi Arabia).

What is the schedule for administering MenB vaccine?

Bexsero is a 2-dose series with dose #2 given at least 1 month after dose #1. Trumenba is either a 2-dose series with doses adminis-

CONTINUED ON THE NEXT PAGE

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www.immunize.org/catg.d/p2040.pdf • Item #P2040 (11/16)

tered at least 6 months apart or a 3-dose series with dose #2 and dose #3 administered 2 and 6 months after dose #1. The ACIP recommends that persons at increased risk of meningococcal serogroup B disease (complement component deficiency, functional or anatomic asplenia, at risk during an outbreak of meningococcal B disease and microbiologists) receive either the 2-dose Bexsero series or the 3-dose Trumenba series. Persons not at increased risk (such as healthy adolescents and young adults) can receive either the 2-dose Bexsero series or the 2-dose Trumenba series.

What is the least amount of time allowable between doses (minimum intervals) when administering either of the MenB vaccines?

Neither ACIP nor the CDC meningococcal subject matter experts have addressed this issue. So we must assume that the routinely recommended intervals are also the minimum intervals (see previous question). It is important to use these intervals when scheduling doses. However, if these intervals are violated, CDC recommends that the dose can be counted and does not need to be repeated.

Can the MenB series be completed with a different MenB brand from the one the series was begun with?

No. You may not switch MenB vaccines in order to complete a series. The series must be started and completed with the same MenB brand.

I have a patient who was given Trumenba in August. Two months later she was given a dose of Bexsero. How should I proceed with her MenB vaccination series? We stock both vaccines.

Since the ACIP meningococcal serogroup B vaccine recommendations state that the same vaccine must be used for all doses in the MenB series, the clinician needs to complete a series with one or the other vaccine. If a non-high risk person has already received

1 dose of Bexsero and 1 of Trumenba, then pick a brand and finish a recommended schedule with that brand. Ignore the extra dose of the other product that was already administered. If you choose to use Bexsero, it should be separated from the previous dose of Bexsero by one month. If you choose to use Trumenba, it should be separated from the previous dose of Trumenba by 6 months.

We have a 1-year-old with congenital asplenia. He already received a series of meningococcal conjugate vaccine. Should we also give him MenB vaccine?

Use of either meningococcal serogroup B vaccine in persons younger than age 10 years is off-label in the U.S. There is currently no ACIP recommendation for use of this vaccine for this age group. However, Bexsero brand meningococcal B vaccine has been studied in children and is approved for children as young as 2 months of age by the European Medicines Agency (the European version of the U.S. Food and Drug Administration). It is routinely recommended for infants in the United Kingdom (see www.nhs.uk/ conditions/vaccinations/pages/meningitisb-vaccine.aspx for details). A clinician may choose to use a vaccine off-label if, in their opinion, the benefit of the vaccine exceeds the risk from the vaccine. Product information for Bexsero can be found on the European Medicines Agency website at www.ema.europa. eu/ema. These doses may not be covered by insurance.

Can meningococcal conjugate (MenACWY) and MenB vaccines be given at the same visit?

Yes. Meningococcal conjugate and MenB vaccines can be given at the same visit or at any time before or after the other.

Which groups of patients should receive a booster dose of MenB vaccine after completion of the series?

ACIP does not currently recommend booster doses of MenB vaccine for any group.

By what route should meningococcal B vaccines be administered?

MenB vaccines are given by the intramuscular route.

What are the contraindications and precautions to MenB vaccine?

As with all vaccines, a severe allergic reaction to a vaccine component or a reaction following a prior dose is a contraindication to subsequent doses. The tip caps of the Bexsero pre-filled syringes contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals. The only precaution for administering MenB vaccine is the presence of a moderate or severe acute illness. Vaccination should be deferred until the illness improves.

What adverse reactions have been reported after MenB vaccine?

For both MenB vaccines the most common adverse reactions observed in clinical trials were local reactions, including pain at the injection site (83%–85%), erythema and swelling.

How should MenB vaccines be stored?

MenB vaccines should be stored refrigerated at 36°F to 46°F (2°C to 8°C). Do not freeze the vaccines. Discard any vaccine that has been exposed to freezing temperature. Protect the vaccine from light.

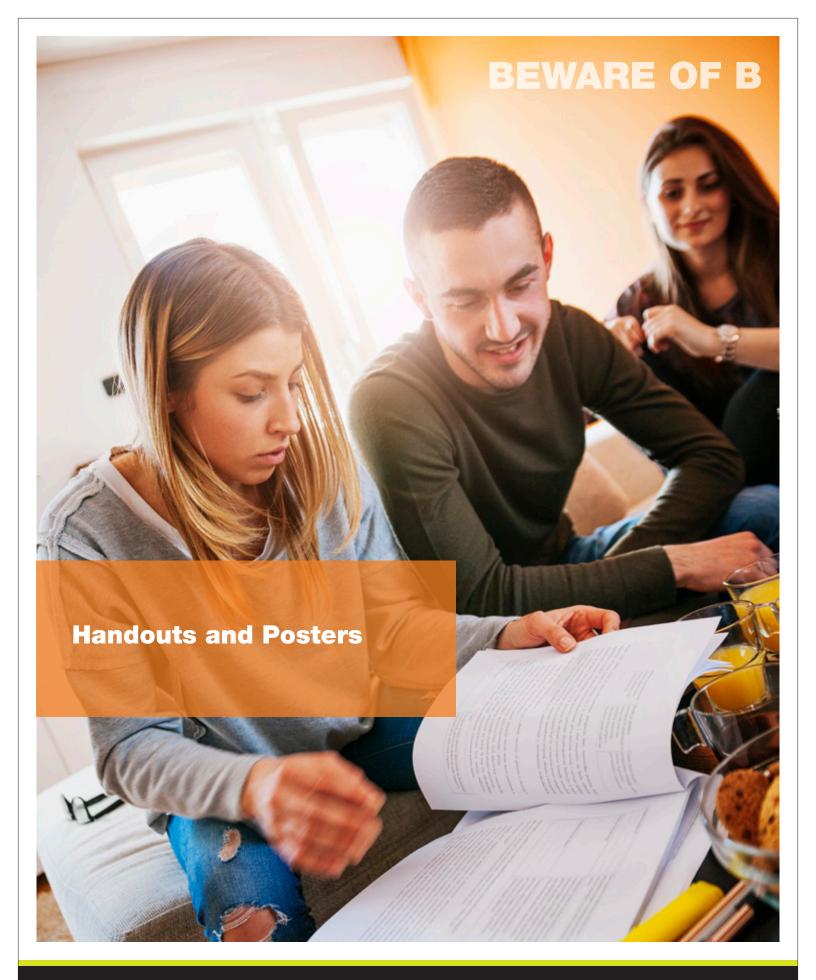
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CDC. Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR* 2016;64(No.22): 608-12.

CDC. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015. MMWR 2015;64(No.41):1171-6.

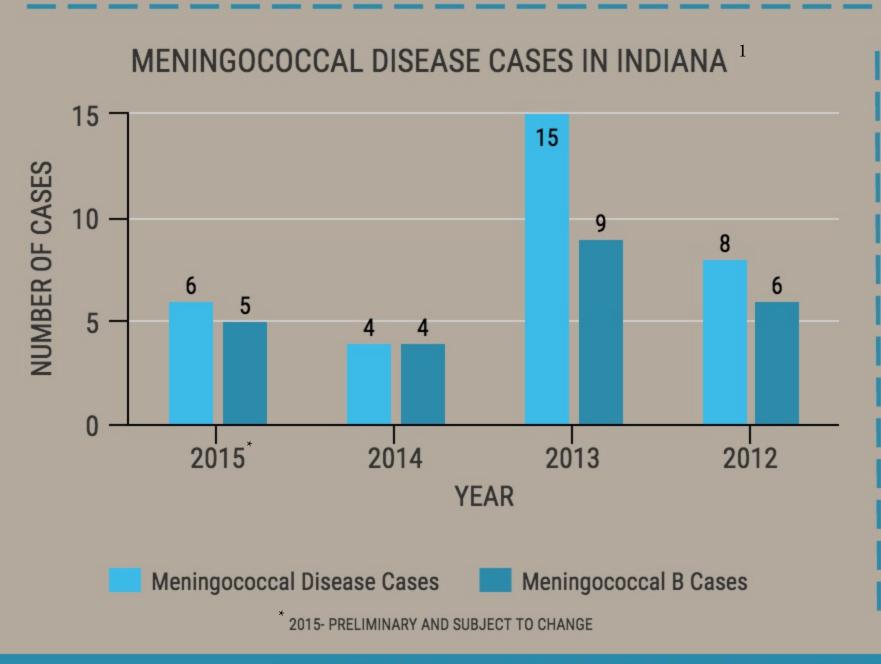
Immunization Action Coalition - Saint Paul, Minnesota - 651-647-9009 - www.immunize.org - www.vaccineinformation.org

www.immunize.org/catg.d/p2040.pdf - Item #P2040 (11/16)





PROTECTING AGAINST BACTERIAL MENINGITIS





MENINGOCOCCAL DISEASE CAN CAUSE BACTEREMIA, SEPTICEMIA OR BACTERIAL MENINGITIS, THE MOST SERIOUS OF MENINGITIS. 4

11%-19% OF SURVIVORS SUFFER PERMANENT

DEPILITATIONS INCLUDING:









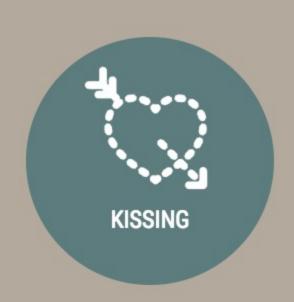
10%-14% OF CASES ARE FATAL

CAN HINDER TREATMENT

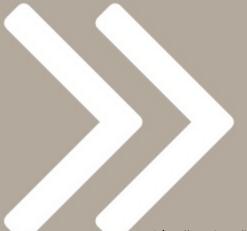


IT IS PASSED VIA CLOSE CONTACT. 5 THOSE WITH THE HIGHEST RISK ARE COLLEGE STUDENTS AND OTHER YOUNG ADULTS. 6









COLLEGE STUDENTS NEED TWO VACCINES FOR FULL PROTECTION 2



ONE FOR SEROGROUPS A, C, W AND Y, KNOWN AS THE MCV4 VACCINE



THE SECOND FOR B, THE MORE COMMON SEROGROUP IN THE US, KNOWN AS THE MENB VACCINE

 $1. \ http://www.in.gov/isdh/20667.htm; \ 2. \ http://www.cdc.gov/meningococcal/about/prevention.html; \ 3. \ http://www.cdc.gov/meningococcal/about/diagnosis-treatment.html; \ 4. \ http://www.cdc.gov/meningococcal/about/diagnosis-treatment.html$

In the past <u>three years</u>, more than <u>34 U.S. college campuses</u> were impacted by meningococcal disease.

Two kinds of vaccines <u>TOGETHER</u> offer the best protection against 5 major serogroups (or types) of meningococcal disease.

MenACWY Vaccine: one dose at age 11-12 years with a booster at age 16 years.



MenB Vaccine: two doses preferably at age 16 - 18 (or through 23 years).

Ask your healthcare provider to get vaccinated today.

For more information visit vaccinateindiana.org

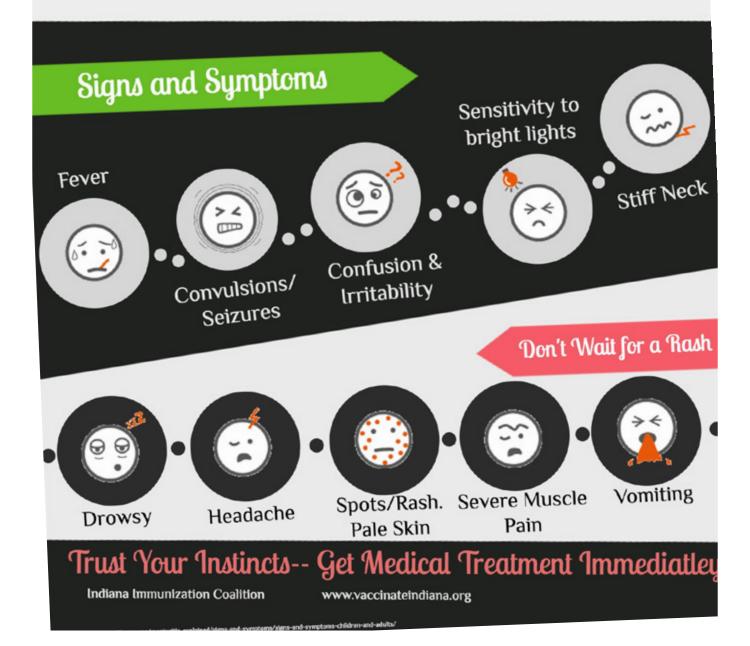


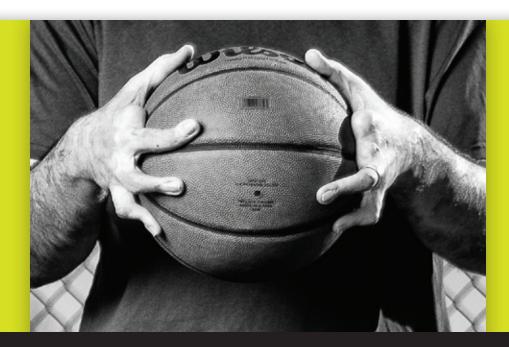
Meningitis Signs and Symptoms

Signs and Symptoms can appear in any order. Some may not appear at all.

Early symptoms include:

Fever, Headache, Muscle Pain, Vomiting, and Fever with Cold Hands and Feet





Is your child heading off to college?

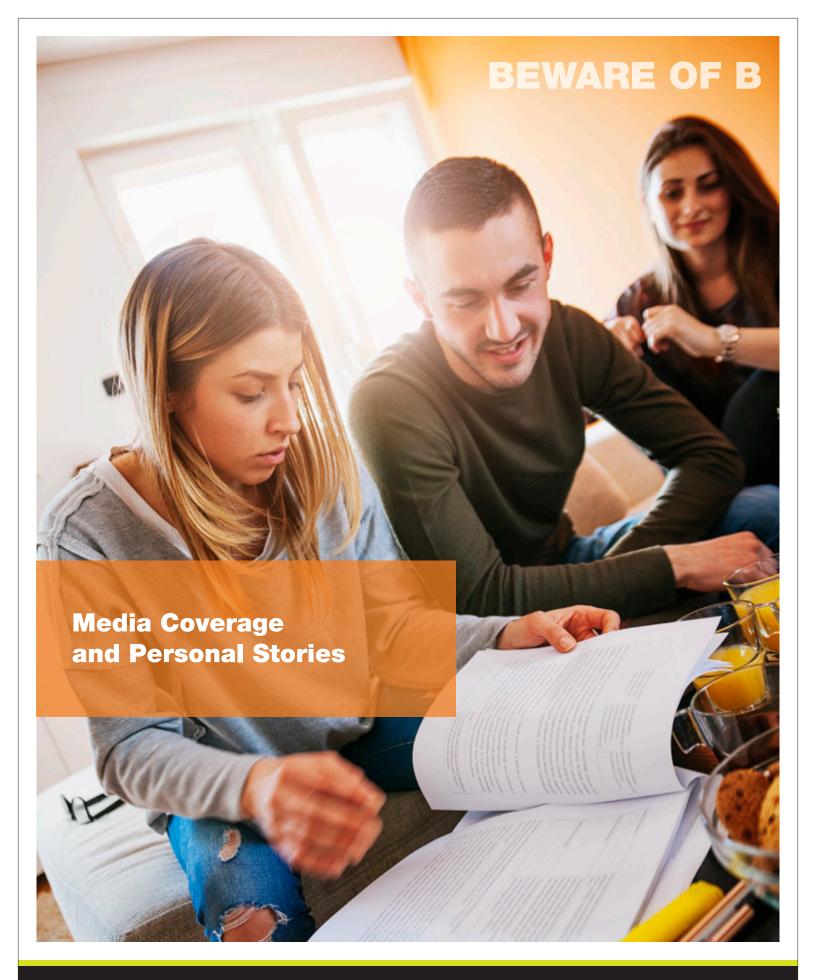
If so, **#BewareofB**

Students living in close quarters, like college dorms, are at highest risk for catching #MeningitisB. In fact, recent outbreaks have occurred on 5 major college campuses in the U.S. Know the risks and talk to your doctor about ways to protect your college student before sending them off to school.

vaccinateindiana.org/beware-of-b



These materials were created by the Indiana Immunization Coalition, Inc. and were funded by the Indiana State Department of Health through a grant from the Centers for Disease Control and Prevention (Award No: 5H23IP52252





Media Outlets

College students urged to get new vaccine to combat meningitis B

WXIN-TV (FOX)

6 p.m. newscast + 11 p.m. newscast (8.2) + 5 a.m. newscast (8.3)

August 2, 2016 + August 3, 2016

http://fox59.com/2016/08/03/college-students-urged-to-get-new-vaccine-to-combat-meningitis-b/

Doctors suggest college students get vaccine for meningitis B

WTTV-TV (CBS)

5 a.m. newscast + 6 a.m. newscast

August 3, 2016

http://cbs4indy.com/2016/08/03/doctors-suggest-college-students-get-vaccine-for-meningitis-b/

Beware of Meningitis B

WAWV-TV (ABC)

5 p.m. newscast + 6 a.m. newscast

August 4, 2016

http://www.mywabashvalley.com/news/beware-of-meningitis-b

Beware of B

WTWO-TV (NBC)

6 p.m. newscast + 11 p.m. newscast (8.4) + 6 a.m. newscast (8.5)

August 4, 2016 + August 5, 2016

Men-B Vaccine Recommended by CDC Prior to Starting College

WREB-FM

August 5, 2016

http://www.wrebfm.com/2016/08/05/men-b-vaccine-recommended-by-cdc-prior-to-startingcollege/

"Beware of B" launched to educate college students about Meningitis B

WOWO-FM

August 13, 2016

http://www.wowo.com/beware-b-launched-educate-college-students-meningitis-b/

Why students, parents should 'Beware of B'

Lafayette Journal and Courier

By Meghan Holden

August 17, 2016

http://www.jconline.com/story/news/college/2016/08/17/beware-of-b/88274274/



Media Outlets continued

Meningitis B vaccination vital, but often overlooked

Tribune Star

By Lisa Trigg

August 21, 2016

http://www.tribstar.com/news/local_news/meningitis-b-vaccination-vital-but-oftenoverlooked/article_d4069d34-66b5-52e0-9028-66a355de04e0.html

Regionally Speaking

WLPR-FM (NPR)

August 24, 2016

http://lakeshorepublicmedia.org/regionally-speaking-wednesday-august-24-2016/

Flashpoint: Meningitis B vaccination should never be overlooked

Tribune Star

By Dr. Karla Loken

August 28, 2016

http://www.tribstar.com/opinion/flashpoint/flashpoint-meningitis-b-vaccination-should-never-beoverlooked/article_27c8395f-380d-5b3d-935d-6b865f314228.html

Get vaccinated to prevent meningitis B

News-Sentinel

By Dr. Karla Loken

August 30, 2016

http://www.news-sentinel.com/opinion/letters/

Letter-to-the-editor--Get-vaccinated-to-preventmeningitis-B





College students urged to get new vaccine to combat meningitis B

Reporter: Tanae Howard

August 2, 2016 + August 3, 2016

WXIN-TV (FOX), 6:16 p.m. + 11:16 p.m. (8.2) + 5:36 a.m. (8.3) http://fox59.com/2016/08/03/college-students-urged-to-get-new-vaccine-to-combat-meningitis-b/

As college students prepare to head to the tight quarters of campus there's a new vaccine on the market to combat meningitis B.

This summer, the Indiana Immunization Coalition launched a campaign called 'Beware of B' to get the word out to young adults that this vaccine is now available.

A local doctor who serves on the coalition says this is a major development. Her family knows the deadly disease firsthand.

"On Saturday she was shopping for a tennis skirt getting ready for her junior year of high school and on Sunday evening she was dead of meningitis," said Dr. Karla Loken. Dr. Loken's older sister Laura was gone in a matter of hours.

"Just six hours later she was dead of cardiac arrest and internal organ failures because the bacteria had basically eaten her body alive that quickly," Dr. Loken said.

From that moment she has made it her mission to get the word out. Not only about the signs and symptoms of meningitis which include many flu symptoms like a fever, a stiff neck, nausea and vomiting.

But the goal is also about prevention through vaccinations. There's been a vaccine for other strains for many years. But this is the first year there's a vaccine for meningitis B.

"The reason it's been hard to get a vaccine for meningitis b is because the bacteria has a harder capsule and it was harder to develop the vaccine for it," Dr. Loken said.

The Indiana Immunization Coalition is urging young adults 16-23 years old and especially college students to get the vaccine. In 2015 in Indiana 5 of the 6 meningitis cases was the b strain. And just because this disease isn't common doesn't mean you shouldn't be mindful of how it's spread and take precaution.

"It's things like sharing chap sticks, drinking out of shared soda bottles and things like that because that's how

the bacteria gets transmitted," Dr. Loken said.

She says this is a moment in medicine her family has been waiting for.

"We can just take a deep breath and say finally there is a vaccine for that and another family doesn't have to go through what we went through, it can be prevented."

For more information on where to get the vaccine near local college campuses click here.

Audience Viewership: 28,116 individuals (TV Eyes)





Meningitis B vaccination vital, but often overlooked

By: Lisa Trigg August 21, 2016

http://www.tribstar.com/news/local_news/meningitis-b-vaccination-vital-but-oftenoverlooked/ article_ d4069d34-66b5-52e0-9028-66a355de04e0.html

Moving students into college has occupied the energy of many families this week, but do families make a medical

checklist for their young ones living away from home to go alone with the one for dorm-room furnishings?

They should. Many students, and people in general, may be overlooking an important precaution that could save lives: immunization against the meningitis B bacteria.

Terre Haute native Ashley Goeller urges everyone to be vaccinated against the disease that cost her both feet, three fingers and left her with scars and skin grafts on 40 percent of her body.

Goeller was a freshman at Indiana University in Bloomington in 2005 when she developed flulike symptoms that would later be diagnosed as meningitis.

"I had gone to my family doctor and gotten all of the college shots except meningitis because my doctor didn't have it available at the time," she said. "He said to go to campus and get it. I was 18, and I went off to school and forgot about it."

Two months later, Goeller was fighting for her life and given a 20 percent chance of survival.

"It is a wonder that I even survived this at all," Goeller said. "I'm laying there in the hospital thinking just 48 hours ago I was running around the dorm at IU. I was just 18. It was so surreal."

New environment

Living quarters that put people in close proximity to others, such as dorms and student apartments, are among the settings where the disease can spread rapidly.

That's one reason why the Indiana Immunization Coalition is urging students and families to review their vaccination records and get updates and additional shots that include HPV, influenza, pneumococcal, hepatitis and meningococcal vaccines.

There are five common groups of meningococcal disease. The first vaccine for the B strain was approved in 2014, and while not required as part of childhood immunizations, the Centers for Disease Control and Prevention does recommend it for anyone ages 11 to 23.

Indiana law requires that all colleges and university inform students about the risk of getting meningitis, but according to the Indiana Immunization Coalition, the information does not always include information about the B strain.

The meningitis B strain accounts for 50 percent of all cases in those ages 17 to 23 in the United States. Each year, about 1,000 people contract some form of meningitis. In Indiana, all of the meningitis cases in 2014 were caused by the meningitis B strain, and in 2015, five of six cases were meningitis B. Currently, an outbreak of



meningitis B is occurring on the campus of Rutgers University. A meningitis outbreak is also being tracked in Southern California.

At Saint Mary-of-the-Woods College, move in day for freshmen was Thursday. Registered nurse Crystal Junker said most students come to campus fully vaccinated according to state law, which actually applies only to Indiana's seven state educational institutions. Private institutions such as SMWC can voluntarily comply.

SMWC complies with that public law requiring vaccinations for diptheria, tetanus, and the trifecta of measles, mumps and rubella, Junker said.

"We are noticing that since most school districts require students to be vaccinated these days, the students are coming to us fully vaccinated," Junker said.

While the college does not have a health clinic, Junker said her health office does provide literature for students on recommended vaccinations, and she makes referrals to community physicians and clinics when requested.

According to the National Meningococcal Disease Awareness Survery, nearly four in five parents said they were unaware that their child was not fully immunized against the five common groups of meningococcal disease.

Of those who become infected, the CDC reports that 10 to 15 percent will die. Of those who survive, 20 percent will suffer from permanent disabilities such as brain damage, loss of limbs, hearing loss and other serious nervous system problems.

Goeller fought on

Goeller's reaction to being affected at such a young age was to fight back. After three months in the hospital, she learned to walk again, and was then determined to continue her education. She returned to Indiana University the following August and earned a degree in human biology. She graduated from IU in 2011, and became employed in pharmaceutical sales.

She now lives in McCordsville with her husband Scott. In December, they celebrated the birth of their son, Elijah.

"There have been bumps in the road," Goeller said of her experience since her illness. "People ask me, are you angry or mad, and I say no. Look at all it's led to. I have success in my work. I met my husband, and we have a beautiful baby. Life just works out that way sometimes."

Goeller has become a spokesperson for the National Meningitis Association, and she is an advocate for vaccinating against childhood and adult diseases, even when diseases such as the forms of meningitis are not specifically required by the CDC.

"You don't want what happened to me to happen to your child," Goeller said. "They probably won't live, and if they do, do you want them to go through what I did?"

For more information about the meningococcal vaccine and other immunizations, go online to the Indiana Immunization Coalition at www.VaccinateIndiana.org.



MENINGOCOCCAL MENINGITIS

Ashley Goeller

How Meningococcal Meningitis Changed My Life

I was 18 years old and a freshman at Indiana University. I went to the doctor because I had flu-like symptoms. About 12 hours later, a rash developed and I was transferred to Methodist Hospital in Indianapolis where I was given a medication called Xigris within 20 minutes of arrival.



My parents were told that I had Meningococcal Meningitis and that I had a 20% chance of survival and to prepare for the worst. I was in the hospital for 3 months fighting for my life. The doctors prescribed antibiotics to fight the infection, but the disease had progressed significantly already. I had kidney failure, my heart stopped twice, I had both feet amputated, over 20 surgeries, 3 fingers amputated, and 40 percent of my body has skin grafting and scars. Miraculously, I survived and I am a spokesperson for the National Meningitis Association, and I am able to educate others about Meningitis and the importance of receiving the vaccine to prevent this potentially fatal and dangerous infection.

Ashley is not alone. There are about 1500 cases of Meningococcal Meningitis in the US each year, and 1 out of 9 persons die. Adolescents and young adults are at a higher risk to contract the disease. Up to 20% of survivors have long-term, serious disabilities including brain damage, limb amputations, organ damage, and hearing loss.

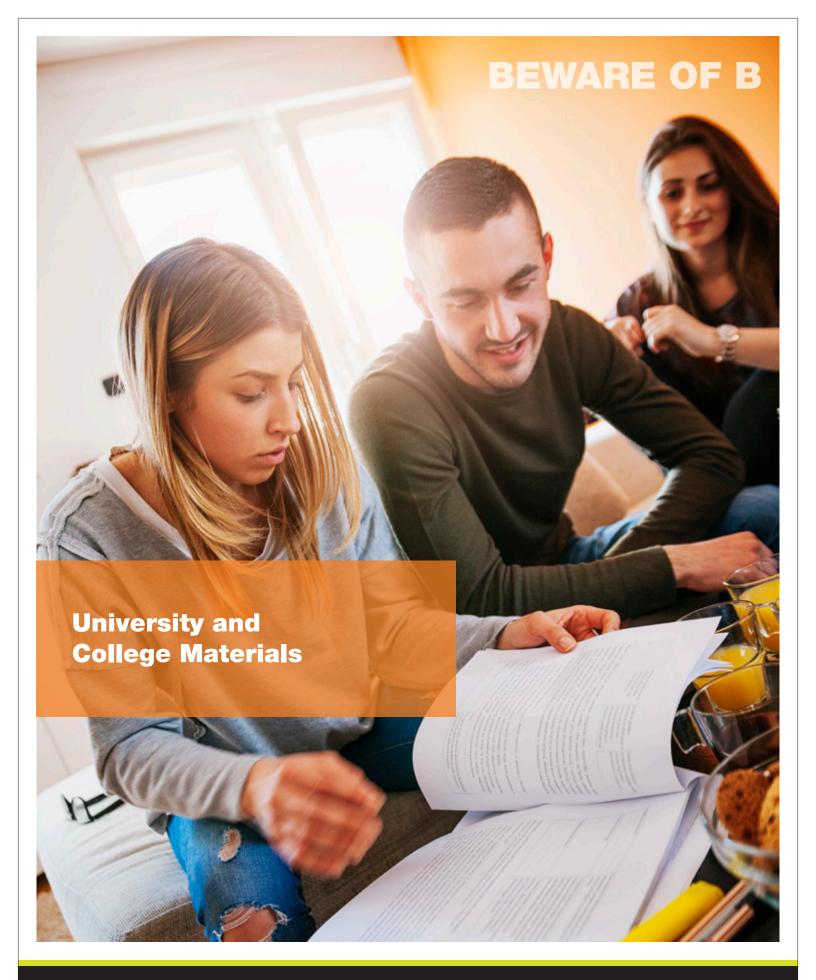
Meningococcal Meningitis is a rare, but deadly bacterial infection that is spread through respiratory droplets (coughing, sneezing, and kissing). It is hard to diagnose, and if left untreated, can progress rapidly.

Fortunately, most cases of meningitis that occur in the US can be prevented by receiving a safe and effective vaccine. The vaccine is recommended for all 11 and 12 year olds, with a booster dose at age 16. All young people should receive the vaccine before entering college. Others with high-risk conditions should also receive the vaccine.

Ask your doctor about the Meningococcal vaccine.

For more information, visit www.vaccinateindiana.org









Meningitis B | University Toolkit

Template Newsletter Insert / e-Newsletters to Students, Parents

'BEWARE OF B' AND GET VACCINATED

<INSERT UNIVERSITY> reminds (Parents / Students) that a newer vaccine is available to protect against meningitis B. The meningitis B bacteria – a strain that accounts for 50 percent of meningococcal disease cases – is especially dangerous for college students because the disease is easily spread. Dorm living, shared bathrooms, crowded events, sharing food and drinks are all catalysts for spreading the bacteria. Since the spring of 2013, meningitis B outbreaks have occurred on five major college campuses in the U.S.

Every year, approximately 1,000 Americans contract meningococcal disease, a rare but deadly disease. Around 10 to 15 percent of these cases prove fatal, according to the Centers for Disease Control and Prevention (CDC), and another 20 percent will suffer from permanent disabilities, such as brain damage, loss of limbs, hearing loss and/or other serious impacts to the nervous system. Many young people have been vaccinated for meningitis; the meningitis B vaccine just became available in 2014.

<INSERT UNIVERSITY> urges its students to get vaccinated specifically against meningitis B at one of the following locations on or close to the <INSERT UNIVERSITY> campus:

<INSERT LOCATION(S) ON OR AROUND CAMPUS WHERE VACCINE CAN BE ADMINISTERED>

You can protect yourself by:

- Not sharing items that have touch someone else's mouth... like cups, cigarettes, lip gloss, bottles, etc.
- Refraining from close contact, like kissing, coughing, and smoking with those who are ill with flu-like symptoms
- Getting vaccinated against meningitis B

For more information on the Beware of B campaign, please visit: http://vaccinateindiana.org/beware-of-b/





Meningitis B | University Toolkit Template News Release

<INSERT UNIVERSITY> URGES STUDENTS TO 'BEWARE OF B' AND GET VACCINATED

FOR IMMEDIATE RELEASE

<INSERT DATE>

<INSERT CITY> -- Each year, approximately 1,000 people contract meningococcal disease in the United States. The Centers for Disease Control (CDC) has found that among those who become infected, 10 to 15 percent will die. Of those who survive, 20 percent will suffer from permanent disabilities, such as brain damage, loss of limbs, hearing loss and/or other serious impacts to the nervous system.

This fall, <INSERT UNIVERSITY> is linking up with the 'Beware of B' campaign – a statewide effort to educate parents and students about the benefits of the meningitis B vaccination, and to make it easy to obtain the important protection needed while in college.

Most students have been vaccinated against several strains of meningitis, but not meningitis B – a strain that accounts for 50 percent of all cases in persons 17 to 23 years of age in the U.S. Until recently, there was no vaccine to combat the B strain of meningitis.

Indiana is not immune to the disease. All of Indiana's meningitis cases in 2014 were caused by the meningitis B strain and in 2015, 5 of the 6 cases were due to meningitis B.

The meningitis B vaccine is critically important for college students, those who are some of the most likely to contract the disease. Dorm living, shared bathrooms, crowded events, sharing food and drinks are all catalysts for spreading the bacteria. Since the spring of 2013, meningitis B outbreaks have occurred on five major college campuses in the U.S.

With college students potentially the most at risk, preventing meningitis is a top priority at <INSERT UNIVERSITY>.

<INSERT UNIVERSITY> urges its students to get vaccinated against meningitis B at one of the following locations close to the <INSERT UNIVERSITY> campus:

<INSERT LOCATION(S) ON OR AROUND CAMPUS WHERE VACCINE CAN BE ADMINISTERED>

For more information on the Beware of B campaign, please visit: http://vaccinateindiana.org/beware-of-b/





Meningitis B | University Toolkit Social Posts Template

Twitter:

#DYK: the meningitis vaccine doesn't protect you against #meningitisB? #BewareOfB and get vaccinated at our local Walgreens

<INSERTSCHOOLMASCOT/NICKNAMES>: the CDC recommends the #meningitisB vaccination for anyone ages 16 to 23. Have you been vaccinated? #BewareOfB

#DYK: #meningitisB is the most common strain of meningitis? Get your vaccination at the Walgreens at <INSERTLOCALADDRESS> #BewareOfB

<INSERTSCHOOLMASCOT/NICKNAMES>: kick off the school year with the #meningitisB vaccine #BewareOfB

Facebook:

Did you know the meningitis vaccination does not vaccinate you against #meningitisB? Meningitis B accounts for 50% of all cases in persons 17 to 23 years of age in the U.S. To protect yourself against meningitis B, get the vaccine at Valgreens at <INSERTLOCALADDRESS> #BewareofB

The CDC recommends that anyone ages 16 to 23 get the #meningitisB vaccine. Have you been vaccinated yet? <INSERTSCHOOLMASCOT > has! #BewareOfB (picture of mascot)

The most commonly recommended meningitis vaccine does not protect you against the most common strain amongst college students #meningitisB <INSERTSCHOOLMASCOT/NICKNAMES> #BewareOfB – make sure you are vaccinated.

Instagram:

Since Spring 2013, #meningitisB outbreaks occurred on 5 major college campuses. To get your meningitis b vaccine and keep <@INSERTSCHOOL> safe, visit Walgreens at <INSERTLOCALADDRESS> #BewareOfB

Did you know the most common strain of meningitis is #meningitisB and college students are among the most likely to contract it? #BewareOfB and get vaccinated like #INSERTSCHOOLMASCOT # did!

*Insert picture of mascot

Students are the most likely to attract #meningitsB – yet very few are vaccinated. Have you gotten your vaccine yet? #BewareOfB













Meningitis B | University Toolkit Example Oped – Dr. Karla Loken

On a Saturday afternoon in March of 1988 my sister Laura Lynn Loken – who was 16 at the time – had spent the day shopping and hanging out with friends. She suddenly developed a fever and headache. These common "flulike" symptoms quickly turned deadly, as the meningitis B bacteria took over Laura's body.

She died less than 24 hours later.

I always wanted to work in medicine, and the experience of losing my sister definitely solidified my path. It is a privilege now to be able to work with the Indiana Immunization Coalition to raise awareness about this deadly disease and the new vaccine for meningitis B. I practice as an obstetrician and gynecologist, and I am a parent myself. My entire family is thrilled that today parents can protect their children against meningitis B – an opportunity we did not have.

Shockingly, there is no requirement in the state of Indiana for vaccinations against meningococcal disease. Indiana State Law does, however, require all universities and colleges to inform students of the risks associated with meningococcal disease and the benefits of vaccination. However, this required information does not specifically address the B strain of the disease – a strain that accounts for 50 percent of all cases in persons 17 to 23 years of age in the U.S.

The first meningitis B vaccine was FDA approved in 2014 and is recommended by the Centers for Disease Control and Prevention (CDC) for anyone ages 11 to 23. The vaccine is especially important for those living in close quarters, like college dorms, where the disease can rapidly spread. Frighteningly, since spring of 2013, meningitis B outbreaks have occurred on five major college campuses in the U.S.

Despite these cases, since the vaccination is not required, it is so important that parents ASK their doctor or pharmacist to receive the vaccine. Fortunately, most insurance providers do cover the meningitis B vaccine.

I applaud the efforts of the Indiana Immunization Coalition and its Beware of B campaign to educate parents and college students about the dangers of meningitis B – and the need to be vaccinated.

I only wish this vaccine existed when my sister was 16. Our goal is that no more families have to experience this heartache. Don't think this cannot happen to your high school or college age student. Get vaccinated. To learn more about the Beware of B campaign, visit www.vaccinateindiana.org/beware-of-b/.

Dr. Karla Loken, D.O. OB/GYN





Meningitis B | University Toolkit Fact Sheet

What is meningococcal disease?

- Meningitis is bacterial or viral disease that results in the inflammation of the protective membranes that cover
 the brain and spinal cord. Symptoms include headache, fever, nausea, vomiting, increased sensitivity to light
 and confusion and can develop within three to seven days after exposure to the disease.
- In the United States, approximately 1,000 people contract meningococcal disease every year. While meningococcal diseases are relatively rare, 10 to 15 percent of those who contract the disease will die. Another nearly 20 percent will suffer from loss of limbs and/or other serious impacts to the nervous system, according for the Centers for Disease Control and Prevention (CDC).
- The bacteria that causes meningitis spreads through the exchange of respiratory secretions and salvia during close or lengthy personal contact. Students and young adults are among the most likely to contract the disease, especially in settings like college dorms where students are living in close proximity to each other. Since the spring of 2013, meningitis B outbreaks have occurred on five major college campuses in the U.S.

So, what is meningitis B?

- There are at least 12 types, or "serogroups," of meningococcal diseases. One is serogroup B a strain that accounts for 50 percent of all cases in the U.S.
- The most commonly recommended meningitis vaccine protects against four major serogroups (A, C, W, and Y) and is recommended for all individuals by age 11 or 12, with a booster at age 16. However, this vaccine does not protect against one of the most common disease strains: serogroup B.

The meningitis B Vaccine(s):

• In 2014, the Food and Drug Administration licensed a vaccine to protect against meningitis B, but very few people have received it. The CDC recommends the vaccination for anyone ages 16 to 23.

Specifics for Indiana:

- In Indiana, all of the meningitis cases in 2014 were caused by the meningitis B strain and in 2015, 5 of the 6 cases were meningitis B.
- Currently, in Indiana, colleges and universities are only required to inform students of the risk that accompany
 the meningococcal disease and the benefits of its vaccination. This legal requirement does not mandate
 schools to educate students on the difference between strains of meningitis or to specifically address the B
 strain of the disease.

The Beware of B Campaign:

- As college students head back to school, the Indiana Immunization Coalition
 is partnering with Walgreen's pharmacies across the state on a 'Beware of B'
 campaign to inform college students and their parents about the importance of
 the meningitis B vaccine, and to make it easy to get.
- To learn more, please visit http://vaccinateindiana.org/beware-of-b/







Meningitis B | University Toolkit Email Template – PARENTS

Dear < INSERT MASCOT > Parents,

We want to alert you to important health information for your college student concerning meningitis. Most of your sons or daughters have been vaccinated against several strains of meningitis, but a different strain – meningitis B – has become more prevalent on college campuses, and a new vaccine is available against it.

While the meningococcal disease is rare, it is extremely contagious, especially for those who live close together, like in college dorms. <INSERT UNIVERSITY> has almost <# OF UNDERGRAD STUDENTS> undergraduates on campus – with many living in close quarters, an environment that is friendly to the disease.

Until recently, there was no vaccine to combat the B strain of meningitis – a strain that accounts for 50 percent of all cases in persons 17 to 23 years of age in the U.S. In Indiana, all of the meningitis cases in 2014 were caused by the meningitis B strain and in 2015, 5 of the 6 cases were meningitis B.

Now there are two FDA-approved vaccines that can guard against contracting the B strain.

This fall, <INSERT UNIVERSITY> is linking with the 'Beware of B' campaign – a statewide effort to educate parents and students about the benefits of the meningitis B vaccination, and to make it easy to obtain the important protection needed. Now that students are back, please urge your son or daughter to get vaccinated against meningitis B at one of the following locations close to the <INSERT UNIVERSITY> campus:

<INSERT LOCATION(S) ON OR AROUND CAMPUS WHERE VACCINE CAN BE ADMINISTERED>

For more information on the Beware of B campaign, please visit:

http://vaccinateindiana.org/beware-of-b/

<INSERT SIGNATURE>

