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NEEDLE TIPS

from the Immunization Action Coalition — www.immunize.org

What's In This Issue

ACIP Votes to Update Recommendations for HPV, Tdap, MenB, and HepB Vaccines

On October 19–20, CDC's Advisory Committee on Immunization Practices (ACIP) met in Atlanta and voted to update several of its existing vaccine recommendations. Some of the changes are described below.

Human Papillomavirus (HPV) Vaccine

ACIP voted to change the HPV vaccination schedule from a 3-dose to a 2-dose series for adolescents who begin the HPV series at 9 through 14 years of age, regardless of age at series completion. Those who start the series later, at 15 through 26 years of age, or who are immunocompromised, will continue to need 3 doses.

The 9vHPV vaccine (HPV9, Gardasil 9, Merck) will soon be the only HPV vaccine available in the U.S. As of October 2016, Merck is distributing only HPV9, and supplies of 2vHPV (Cervarix, GSK) in the U.S. are now depleted. HPV9 may be used to complete a series begun with 4vHPV (HPV4, Gardasil, Merck) or 2vHPV.

Meningococcal Serogroup B Vaccine

Bexero (MenB-4C, GSK) has previously been recommended by ACIP for use as a 2-dose series for high-risk individuals and in outbreak settings, and may also be administered to healthy individuals age 16 through 23 years. In April, FDA approved a label change giving MenB-FHbp (Trumenba, Pfizer) as either a 2-dose (0, 6 months) or 3-dose (0, 1–2, 6 months) series. ACIP voted to recommend that healthcare providers who use Trumenba continue to use the 3-dose series when vaccinating people at increased risk of meningococcal serogroup B disease (e.g., people with persistent complement component deficiencies or anatomical or functional asplenia) or during serogroup B outbreaks. The 2-dose series of Trumenba can be used for routine vaccination for healthy people age 16 through 23 years.

Tdap Vaccine

Previous ACIP recommendations called for prenatal care providers to vaccinate all pregnant women with Tdap vaccine during each pregnancy with optimal timing for this dose designated between 27 and 36 weeks gestation. In October, ACIP voted to recommend administering Tdap vaccination early in the 27- through 36-week "window" to maximize passive antibody transfer to the infant. The new recommendations also clarify that children age 7 through 10 years who receive Tdap as part of a catch-up series may be given an additional Tdap for the routinely recommended adolescent dose at 11–12 years of age.

Hepatitis B Vaccine

ACIP voted to approve a new guidance document that consolidates all previously published recommendations into a comprehensive statement. The committee reemphasized the importance of the HepB birth dose as a safety net against chronic HBV infection, now recommending that all newborns of HBsAg-negative (hepatitis B surface antigen-negative) mothers should be vaccinated with HepB vaccine within 24 hours of birth. ✦

Ask the Experts

The Immunization Action Coalition extends thanks to our experts, medical officer Andrew T. Kroger, MD, MPH, and nurse educator Donna L. Weaver, RN, MN, both with the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC).

HPV vaccine

What is the new HPV vaccine schedule recommendation?

In October 2016, the Advisory Committee on Immunization Practices (ACIP) voted to recommend a routine 2-dose HPV vaccine schedule for adolescents who start the vaccination series before the 15th birthday. The two doses should be separated by 6–12 months (the minimum interval between doses is 5 months). A 3-dose schedule continues to be recommended for people who start the series on or after the 15th birthday and for people with certain immunocompromising conditions (such as cancer, HIV infection, or taking immunosuppressive drugs). A revised ACIP statement is being prepared and is expected to be published in December 2016.

Has ACIP expressed a preference for the 2-dose over the 3-dose schedule for adolescents 9 through 14 years of age?

Yes. ACIP recommends the 2-dose schedule for people starting the HPV vaccination series before the 15th birthday, as long as they are immunocompetent.

Does the 2-dose HPV vaccine schedule need to be completed with the same vaccine, or can it include different vaccines (such as bivalent or quadrivalent vaccine)?

The 2-dose schedule can be completed with any combination of HPV vaccine brands as long as dose #1 was given before age 15 years. Dose #2 should be administered 6–12 months after dose #1.

If dose #1 of HPV vaccine was given before the 15th birthday and it has been more than a year since that dose was given, would the series be complete with just one additional dose?

Yes. Adolescents and adults who started the HPV vaccine series prior to the 15th birthday and who are not immunocompromised are considered to be

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Immunization questions?

- Email nipinfo@cdc.gov
- Call your state health department (phone numbers at www.immunize.org/coordinators)

Needle Tips

online at www.immunize.org/nt

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adequately vaccinated with just one additional dose of HPV vaccine.

We have adolescents in our practice who have received the first 2 doses of the HPV series 1 or 2 months apart according to the 3-dose schedule. Can we consider their HPV vaccine series to be complete or do we need to give these patients a third dose?

People who have received 2 doses of HPV vaccine separated by less than 5 months should receive a third dose 6–12 months after dose #1 and at least 12 weeks after dose #2.

Will the 2-dose recommendation be retroactive for children and teens vaccinated prior to 2016?

Yes. Any person who ever received 2 doses of any combination of HPV vaccines can be considered fully vaccinated if dose #1 was given before the 15th birthday and the 2 doses were separated by at least 5 months.

MenACWY vaccine

Please review the new recommendations for use of MenACWY vaccine in people with human immunodeficiency virus (HIV) infection.

A growing body of evidence supports an increased risk for meningococcal disease in HIV-infected people. The Advisory Committee on Immunization Practices (ACIP) recommends that all HIV-infected people 2 months of age and older should routinely receive an age-appropriate MenACWY vaccine (Menactra, Sanofi Pasteur; Menveo, GSK). Children younger than age 2 years should be vaccinated using a multidose schedule (see the IAC educational piece "Meningococcal Vaccine Recommendations by Age and Risk Factor for Serogroups A, C, W, or Y Protection" available at www.immunize.org/catg.d/p2018.pdf for details). People age 2 years and older with HIV infection who have not been previously vaccinated should receive a 2-dose primary series of MenACWY vaccine (doses separated by 8–12 weeks). People with HIV infection who have previously received one dose of MenACWY should receive a second dose at the earliest opportunity (at least 8 weeks after the previous dose) and then receive booster doses at the appropriate intervals. If the most recent dose was received before age 7 years, a booster dose should be administered 3 years later. If the most recent dose was received at age 7 years or older, a booster should be administered 5 years later and every 5 years thereafter throughout life.

I have an HIV-positive 64-year-old patient who received MenACWY vaccine last week. Was this the correct vaccine for this patient or should he have gotten meningococcal polysaccharide vaccine (MPSV4, Sanofi Pasteur) due to his age? Also, should this patient get another dose in 2 months?

MenACWY was the correct vaccine in this situation. The 2013 ACIP recommendations on MenACWY vaccination recommend the use of meningococcal conjugate vaccine in adults age 56 years and older who were vaccinated previously with MenACWY and now need revaccination, or are recommended to receive multiple doses. A person of this age with HIV infection should receive 2 doses of MenACWY separated by 8–12 weeks. Both MenACWY vaccines are licensed for use in people through age 55 years, which means that the use of these vaccines in people age 56 and older is off-label but recommended by ACIP.

I have a 24-month-old patient with HIV infection and I want to use Menactra (Sanofi Pasteur) because this is the only vaccine we have available in our clinic. However, this child received DTaP vaccine yesterday at another clinic. Can I administer Menactra today?

ACIP recommends that you wait 4 weeks from the dose of DTaP to administer the dose of Menactra. This is because data suggest a reduced response to the Menactra if given within a month after DTaP. If Menactra is to be administered to a child at increased risk for meningococcal disease, including children who have HIV infection, Menactra should be given either before or at the same visit as DTaP. Menveo brand MenACWY vaccine (GSK) can be given at any time before or after DTaP.

I have a 24-month-old patient with a complement component deficiency who received a dose of DTaP at 23 months of age and then received a dose of Menactra two weeks later. Do I need to repeat the dose of Menactra?

No. Even though ACIP recommends that Menactra should be given no less than 4 weeks after a dose of DTaP, there is no evidence to support repeating the dose of Menactra. A child with a complement component deficiency should still receive a second dose of MenACWY vaccine 8 weeks after the first dose.

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IAC's "Ask the Experts" team from the Centers for Disease Control and Prevention

Andrew T. Kroger, MD, MPH

Donna L. Weaver, RN, MN

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Does the recommendation about separation of DTaP and Menactra also apply to children with functional or anatomic asplenia?

Yes. The recommendation about spacing of DTaP and Menactra (described above) applies to children of any age with a high-risk condition for meningococcal disease, including travelers.

The ACIP MenACWY vaccine recommendations state that a routine second dose needs to be given at 16 years of age. Children with asplenia or other high-risk conditions should receive a booster dose every 5 years. If a child with a high-risk condition receives a dose of MenACWY at age 9 years (and a second primary dose 8 weeks later), should they receive a booster dose at age 14 years (5 years after the primary series), or should they receive a dose at age 16 years as recommended in the routine schedule?

The MenACWY booster dose should be given at 14 years (5 years after the primary series) and every 5 years thereafter. The every 5-year booster dose schedule for persons with high-risk conditions takes precedence over the routine second dose schedule.

MenB vaccine

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

Both MenB vaccines are licensed for use in people through age 25 years, which means that the use of these vaccines in people age 26 and older is off-label but recommended by ACIP.

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 (Bexero, MenB-4C, GSK; Trumenba, MenB-FHbp, Pfizer) 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 and 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 new schedule for Trumenba MenB vaccine?

The Food and Drug Administration approved a 2-dose schedule for Trumenba in April 2016. At its October 2016 meeting, ACIP voted to recommend a 2-dose schedule of Trumenba for people not at increased risk of MenB (for example, healthy adolescents). The two doses should be administered at least 6 months apart. ACIP recommends that people at increased risk of MenB disease (complement component deficiency, functional or anatomic asplenia, at risk during an outbreak of meningococcal B disease, and certain microbiologists) receive a 3-dose Trumenba series with dose #2 and dose #3 administered 2 and 6 months after dose #1.

The schedule for Bexsero has not changed. Bexsero is a 2-dose series with dose #2 given at least 1 month after dose #1.

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 then people of the same age who are not college students. Consequently,

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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.

ACIP recommendations for MenB vaccine say the vaccine will provide "short term protection." What does "short term protection" mean?
MenB vaccines were approved based on the serologic response to the vaccine. No data are available on vaccine effectiveness against clinical disease or duration of protection against clinical disease. Short term protection refers to the known duration of the antibody response. Available data indicate that a protective antibody level should persist in most recipients for 24–48 months after vaccination. This issue will continue to be monitored. For more information, see the ACIP recommendations at www.cdc.gov/mmwr/pdf/wk/mm6441.pdf, pages 1171–5.

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.

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.

To submit an "Ask the Experts" question…

You can email your questions about immunization to us at admin@immunize.org. IAC will respond to your inquiry. Because we receive hundreds of emails each month, we cannot guarantee that we will use your question in "Ask the Experts." IAC works with CDC to compile new Q&As for our publications based on commonly asked questions. Most of the questions are thus a composite of several inquiries.

Needle Tips correction policy

If you find an error, please notify us immediately by sending an email message to admin@immunize.org. We publish notification of significant errors in our email announcement service, ***IAC Express.*** Be sure you're signed up for this service. To subscribe, visit www.immunize.org/subscribe.

Influenza vaccine

Please provide details about the use of FluLaval influenza vaccine (GlaxoSmithKline) in children younger than 3 years.
On November 18, 2016, the Food and Drug Administration approved an extension of the age range of quadrivalent FluLaval (inactivated influenza vaccine, GSK) to include children 6 through 35 months of age. FluLaval was previously approved for people 3 years of age and older. The approval of the extended age range for FluLaval was based on a study showing an equivalent ("non-inferior") response compared to children who received Fluzone (Sanofi Pasteur) pediatric formulation. The vaccine will be supplied for this indication in manufacturer-filled syringes and multi-dose vials. The dosage approved for children 6 through 35 months of age is 0.5 mL – the same dosage as for people 3 years of age and older.

ACIP has not yet issued a recommendation regarding the use of FluLaval in children 6 through 35 months of age. However, clinicians are free to use this and other vaccines in a manner consistent with their labeling.

Can a child 6 through 35 months of age who needs 2 doses of influenza vaccine this season receive one each of Fluzone Pediatric and FluLaval vaccine?
Yes. Both Fluzone Pediatric (0.25 mL dose) and FluLaval (0.5 mL dose) are approved by the Food and Drug Administration for use in children 6 through 35 months of age.

A 2-year-old was inadvertently given a 0.25 mL dose of FluLaval rather than the recommended 0.5 mL dose. What should we do?
If the error is discovered while the child is still in the office you can administer the other "half" of the FluLaval dose. If the error is discovered later, then the child should be recalled to the office and given a full age-appropriate repeat dose, either a 0.5 ml dose of FluLaval or a 0.25 mL dose of Fluzone.

Can a clinic vaccinate children younger than age 3 years with influenza vaccine taken from a multidose vial of Fluzone or FluLaval? The multi-dose vials contain thimerosal as a preservative.
Yes. Multidose vials of Fluzone and FluLaval contain a small amount of thimerosal to prevent bacterial and fungal growth in the vial. Thimerosal-containing vaccines are safe to use in children. No scientific evidence indicates that thimerosal in vaccines causes adverse events unless the patient has a severe allergy to thimerosal. However, a few states have enacted legislation that restricts the use of thimerosal-containing vaccines in children. To find out if your state has such restrictions, check with your state immunization program (see www.immunize.org/coordinators for phone numbers). ✦

Vaccine Highlights

Recommendations, schedules, and more

Editor's note: The information in Vaccine Highlights *is current as of December 9, 2016.*

Next ACIP meetings

The Advisory Committee on Immunization Practices (ACIP) is comprised of 15 national experts who advise CDC on the appropriate use of vaccines.

ACIP meets three times a year in Atlanta; meetings are open to the public and viewable online via live webcast. The next meetings will be held on Feb. 22–23 and June 21–22, 2017. For more information, visit www.cdc.gov/vaccines/acip.

ACIP periodically issues recommendations on the use of vaccines; they are published and readily available in the *Morbidity and Mortality Weekly Report* (*MMWR*). Clinicians who vaccinate should have a current set for reference. Here are sources:

- Download from IAC's website: www.immunize.org/acip
- Download from CDC's website: www.cdc.gov/vaccines/hcp/acip-recs

In addition, extensive information on ACIP meetings is available at www.cdc.gov/vaccines/acip/meetings/index.html.

HPV vaccine news

On October 7, the Food and Drug Administration approved a 2-dose schedule for Gardasil 9 HPV vaccine (Merck) for people 9 through 14 years of age. The approval was based on a clinical trial that demonstrated a non-inferior response to 2 doses of Gardasil 9 among girls and boys 9 through 14 years of age compared to a 3-dose schedule among women 16 through 26 years of age. The revised package insert and Summary Basis for Regulatory Action is available on the FDA website at www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm426445.htm

On December 2, CDC released an updated human papillomavirus (HPV) vaccine VIS. It is similar to the previous 9-valent HPV vaccine VIS, except that it contains information about the recently approved 2-dose schedule. Providers are encouraged to begin using the new VIS now but may use up stocks of the previous version, especially for patients still using the 3-dose schedule.

The new VIS no longer has "Gardasil-9" in the title because the other two HPV vaccines (Cervarix and quadrivalent Gardasil) are no longer distributed in the U.S. The last doses of Cervarix have already expired, and the last doses of Gardasil will expire in May 2017. At that point Gardasil-9 will be the only HPV vaccine available in the U.S. and this will be the only VIS. The new VIS is available on the on the IAC VIS website at www.immunize.org/vis/vis_hpv_gardasil.asp. Translations of the HPV9 VIS are acceptable to use until new translations become available.

Influenza vaccine news

On November 18, the Food and Drug Administration approved an extension of the age range of quadrivalent FluLaval (inactivated influenza vaccine, GSK) to include children 6 through 35 months of age. FluLaval was previously approved for people 3 years of age and older. The dosage approved for children 6 through 35 months of age is 0.5 mL – the same dosage as for people 3 years of age and older. ACIP has not yet issued a recommendation regarding the use of FluLaval in children age 6 through 35 months. However, clinicians are free to use this and other vaccines in a manner consistent with their labeling. The revised package insert and Summary Basis for Regulatory Action is available on the FDA website at www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm112845.htm.

MenACWY vaccine news

On November 4, CDC published "Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons – ACIP, 2016" in *MMWR*. The document is available at www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6543.pdf, pages 1189–94. Routine meningococcal conjugate (MenACWY) vaccination is now recommended for all HIV-infected people age 2 months and older. Children 2 months and older should receive an age-appropriate series. People 2 years and older should receive 2 doses of MenACWY separated by 8 weeks. All HIV-infected people should receive booster doses of MenACWY throughout their life. ACIP previously recommended that children at increased risk of meningococcal disease not receive the Menactra brand of MenACWY until age 2 years. The new guidance clarifies that Menactra MenACWY may be given to children younger than age 2 years as long as it is given at least 4 weeks after completion of the PCV13 vaccine series. ACIP also clarified that Menactra MenACWY may be given before or at the same visit as DTaP but should not be given until at least 4 weeks after a dose of DTaP because of evidence of interference with the response to Menactra. The Menveo brand of MenACWY may be given any time before or after a dose of DTaP or PCV13.

Hepatitis B vaccine news

On October 19, ACIP voted to approve a single guidance document that consolidated previously published hepatitis B vaccination recommendations into a comprehensive statement. ACIP re-emphasized the importance of the hepatitis B birth dose as a safety net against chronic HBV infection by recommending that all infants of HBsAg-negative (hepatitis B surface antigen-negative) mothers should receive hepatitis B vaccine within 24 hours of birth. This removes previous policy language that allowed for a delay in administering the birth dose in certain rare circumstances and on a case-by-case basis. The new comprehensive hepatitis B ACIP statement is being prepared for publication. ✦

Current VIS dates

Check the dates on your supply of Vaccine Information Statements (VISs). If they are out of date, obtain the most up-to-date versions as well as VIS translations in more than 30 languages at www.immunize.org/vis.

Adenovirus	6/11/14	MMRV	5/21/10
Anthrax	3/10/10	Multi-vaccine	11/5/15
Chickenpox	3/13/08	PCV13	11/5/15
DTaP	5/17/07	PPSV	4/24/15
Hib	4/2/15	Polio	7/20/16
Hepatitis A	7/20/16	Rabies	10/6/09
Hepatitis B	7/20/16	Rotavirus	4/15/15
HPV	12/2/16	Shingles	10/6/09
Influenza	8/7/15	Td	2/24/15
Japanese enceph	1/24/14	Tdap	2/24/15
MCV4/MPSV4	3/31/16	Typhoid	5/29/12
MenB	8/9/16	Yellow fever	3/30/11
MMR	4/20/12		

For a ready-to-print version of this table for posting in your practice, go to www.immunize.org/catg.d/p2029.pdf.

Meningococcal B Vaccine: Q&A
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 meningococcal 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 meningococcal 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 meningococcal 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/meningitis-b-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.

REFERENCES

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.

Meningococcal Vaccine Recommendations by Age and Risk Factor for Serogroup B Protection

This document covers MenB vaccine. For information on vaccine that provides protection against meningococcal serogroup A, C, W, and Y disease, see www.immunize.org/catg.d/p2018.pdf.

Meningococcal serogroup type B vaccines:
- **Bexsero** (MenB-4C, GlaxoSmithKline)
- **Trumenba** (MenB-FHbp, Pfizer)

Routine Recommendations for Meningococcal Serogroup B Vaccination	
For teens and young adults ages 16 through 23 years who wish to be vaccinated. The preferred age is 16 through 18 years.	Give either 2 doses of Bexsero 4 weeks apart, or 2 doses of Trumenba on a 0- and 6-month schedule.

Risk-based Recommendations for Persons with Underlying Medical Conditions or Other Risk Factors	
For people ages 10 years or older with • persistent complement component deficiencies[1] • anatomic or functional asplenia, including sickle cell disease, For people ages 10 years or older who • are present during outbreaks caused by serogroup B,[2] or • have prolonged increased risk for exposure (e.g., microbiologists routinely working with *Neisseria meningitidis*)	Give either 2 doses of Bexsero 4 weeks apart, or 3 doses of Trumenba on a 0-, 2-, and 6-month schedule.

Note: The two brands of meningococcal B vaccine are not interchangeable. The series must be started and completed with the same brand of vaccine.

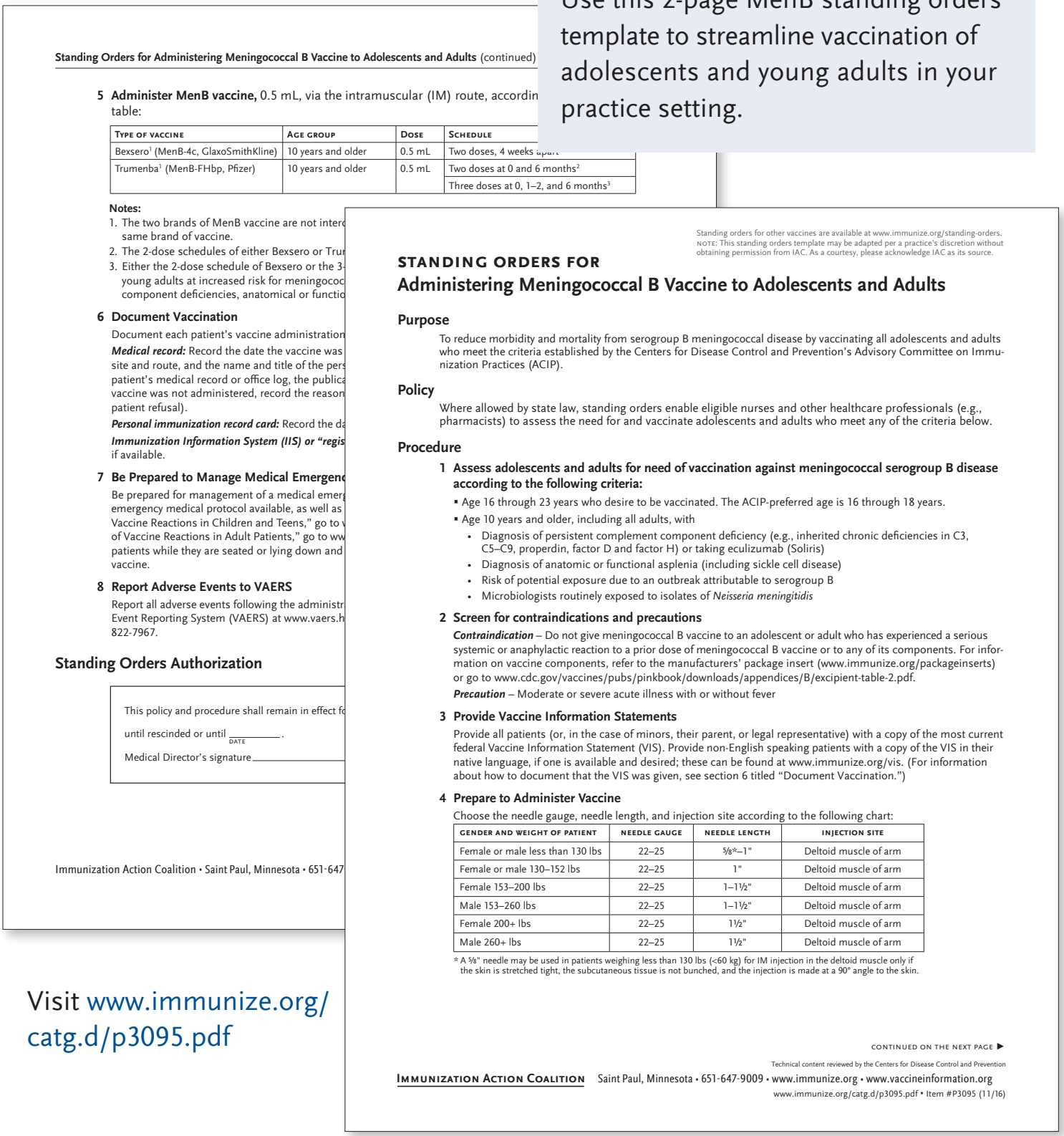
FOOTNOTES

1. Persistent complement component deficiencies (e.g., inherited or chronic deficiencies in C3, C5–C9, properdin, factor D, and factor H).
2. Seek advice of local public health authorities to determine if vaccination is recommended.

Technical content reviewed by the Centers for Disease Control and Prevention

Meningococcal B Vaccine Standing Orders Template Now Updated!

Use this 2-page MenB standing orders template to streamline vaccination of adolescents and young adults in your practice setting.



Standing Orders for Administering Meningococcal B Vaccine to Adolescents and Adults (continued)

5 Administer MenB vaccine, 0.5 mL, via the intramuscular (IM) route, accordin
table:

Type of vaccine	Age group	Dose	Schedule
Bexsero[1] (MenB-4c, GlaxoSmithKline)	10 years and older	0.5 mL	Two doses, 4 weeks apart
Trumenba[1] (MenB-FHbp, Pfizer)	10 years and older	0.5 mL	Two doses at 0 and 6 months[2]
			Three doses at 0, 1–2, and 6 months[3]

Notes:
1. The two brands of MenB vaccine are not interc
same brand of vaccine.
2. The 2-dose schedules of either Bexsero or Trur
3. Either the 2-dose schedule of Bexsero or the 3-
young adults at increased risk for meningococ
component deficiencies, anatomical or functio

6 Document Vaccination

Document each patient's vaccine administration

Medical record: Record the date the vaccine was
site and route, and the name and title of the pers
patient's medical record or office log, the publica
vaccine was not administered, record the reason
patient refusal).

Personal immunization record card: Record the da

Immunization Information System (IIS) or "regis
if available.

7 Be Prepared to Manage Medical Emergenc

Be prepared for management of a medical emerg
emergency medical protocol available, as well as
Vaccine Reactions in Children and Teens," go to v
of Vaccine Reactions in Adult Patients," go to ww
patients while they are seated or lying down and
vaccine.

8 Report Adverse Events to VAERS

Report all adverse events following the administr
Event Reporting System (VAERS) at www.vaers.h
822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect fo

until rescinded or until _____ .
DATE

Medical Director's signature _____

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Standing orders for other vaccines are available at www.immunize.org/standing-orders.
NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR
Administering Meningococcal B Vaccine to Adolescents and Adults

Purpose

To reduce morbidity and mortality from serogroup B meningococcal disease by vaccinating all adolescents and adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adolescents and adults who meet any of the criteria below.

Procedure

1 Assess adolescents and adults for need of vaccination against meningococcal serogroup B disease according to the following criteria:

- Age 16 through 23 years who desire to be vaccinated. The ACIP-preferred age is 16 through 18 years.
- Age 10 years and older, including all adults, with
  - Diagnosis of persistent complement component deficiency (e.g., inherited chronic deficiencies in C3, C5–C9, properdin, factor D and factor H) or taking eculizumab (Soliris)
  - Diagnosis of anatomic or functional asplenia (including sickle cell disease)
  - Risk of potential exposure due to an outbreak attributable to serogroup B
  - Microbiologists routinely exposed to isolates of *Neisseria meningitidis*

2 Screen for contraindications and precautions

Contraindication – Do not give meningococcal B vaccine to an adolescent or adult who has experienced a serious systemic or anaphylactic reaction to a prior dose of meningococcal B vaccine or to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precaution – Moderate or severe acute illness with or without fever

3 Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

Gender and weight of patient	Needle gauge	Needle length	Injection site
Female or male less than 130 lbs	22–25	⅝*–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* A ⅝" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

CONTINUED ON THE NEXT PAGE ▶

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www.immunize.org/catg.d/p3095.pdf • Item #P3095 (11/16)

Visit www.immunize.org/catg.d/p3095.pdf

Meningococcal Vaccine Recommendations by Age and Risk Factor for Serogroups A, C, W, or Y Protection

A separate vaccine is needed for protection against meningococcal serogroup B disease.

MenACWY = Menactra (Sanofi Pasteur) and Menveo (GlaxoSmithKline)
MenACWY-D = Menactra **Hib-MenCY** = MenHibrix (GlaxoSmithKline)
MenACWY-CRM = Menveo **MPSV** = Menomune (Sanofi Pasteur)

Routine Recommendations for Quadrivalent Meningococcal Conjugate Vaccine (MenACWY)

For preteens age 11 through 12 years	Give dose #1 of 2-dose MenACWY series. (Dose #2 is recommended at age 16 years.)
For teens age 13 through 15 years	Give catch-up dose #1 of 2-dose MenACWY series. (Dose #2 will be due at age 16 years.[1])
For teens at age 16 years	Give dose #2 of MenACWY.[1] (Separate from dose #1 by at least 8 weeks.)
Catch-up for teens age 17 through 18 years	If dose #2 not given at age 16 years, give dose #2 of MenACWY as catch-up.
Catch-up for teens age 16 through 18 years	If no history of prior vaccination with MenACWY, give 1 dose of MenACWY.
For first year college students, age 19 through 21 years, living in residence halls	If no history of prior vaccination with MenACWY, give 1 dose of MenACWY. If history of 1 dose of MenACWY given when younger than age 16 years, give dose #2 of MenACWY.

Risk-based Recommendations for Persons with Underlying Medical Conditions or Other Risk Factors

TARGETED GROUP BY AGE/OR RISK FACTOR	PRIMARY DOSE(S)	BOOSTER DOSE(S)
Travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic,[2] people present during outbreaks caused by a vaccine serogroup,[3] and other people with prolonged increased risk for exposure (e.g., microbiologists routinely working with *Neisseria meningitidis*)		
For age 2 through 6 months	Give 3 doses of MenACWY-CRM or Hib-MenCY,[4] 8 weeks apart, and a 4th dose at 12–15 months. If possible, vaccination should begin at age 2 months.	If risk continues, give initial booster after 3 years followed by boosters every 5 years.
For age 7 through 23 months who have not initiated a series of MenACWY-CRM	Give 2 doses of MenACWY-CRM[5] or HibMenCY[4,6] or, if 9–23 months, MenACWY-D.[7] Separate the 2 doses by at least 12 weeks.[8]	
For age 2 through 55 years	Give 1 dose of MenACWY.	Boost every 5 years with MenACWY.[9,10]
For age 56 years and older	If no previous MenACWY dose and either short-term travel or outbreak-related, give 1 dose of MPSV; all others, give 1 dose of MenACWY.	Boost every 5 years with MenACWY.[10]
People with persistent complement component deficiencies[11]		
For age 2 through 6 months	Give 3 doses of MenACWY-CRM or Hib-MenCY, 8 weeks apart, and a 4th dose at 12–15 months. If possible, vaccination should begin at age 2 months.	Give MenACWY booster after 3 years followed by boosters every 5 years thereafter.
For age 7 through 23 months who have not initiated a series of MenACWY-CRM	Give 2 doses of MenACWY-CRM[5] or Hib-MenCY[6] or, if age 9–23 months, MenACWY-D.[7] Separate the 2 doses by at least 12 weeks.	
For ages 2 through 55 years	Give 2 doses of MenACWY, 8 weeks apart.	Boost every 5 years with MenACWY.[9,12]
For age 56 years and older	Give 2 doses of MenACWY, 8 weeks apart.	Boost every 5 years with MenACWY.[12]
People with HIV infection or functional or anatomic asplenia (including sickle cell disease)		
For age 2 through 6 months	Give 3 doses of MenACWY-CRM or Hib-MenCY, 8 weeks apart, and a 4th dose at 12–15 months. If possible vaccination should begin at age 2 months.	Give MenACWY booster after 3 years followed by boosters every 5 years thereafter.[9]
For age 7 through 23 months who have not initiated a series of MenACWY-CRM	Give 2 doses of MenACWY-CRM[5] or Hib-MenCY.[6] Separate the 2 doses by at least 12 weeks. Or, if using MenACWY-D, give dose #1 at least 4 weeks following completion of pneumococcal conjugate vaccine series, and dose #2 at least 12 weeks after dose #1.[7]	
For ages 2 through 55 years	Give 2 doses of MenACWY, 8 weeks apart.	Boost every 5 years with MenACWY.[9,12]
For age 56 years and older	Give 2 doses of MenACWY, 8 weeks apart.	Boost every 5 years with MenACWY.[12]

FOOTNOTES

1. The minimum interval between doses of MenACWY is 8 weeks.
2. Prior receipt of Hib-MenCY is not sufficient for children traveling to the Hajj or African meningitis belt as it doesn't provide protection against serogroups A or W.
3. Seek advice of local public health authorities to determine if vaccination is recommended.
4. Children ages 2 through 18 months who are present during outbreaks caused by serogroups C or Y may be given an age-appropriate series of Hib-MenCY.
5. If initiating vaccination with MenACWY-CRM in a child age 7 through 23 months, dose 2 should be given no younger than age 12 months.
6. Hib-MenCY is not licensed for use in children age 18 months or older.
7. If MenACWY-D is to be administered to a child with increased risk for meningococcal disease, it should be given either before or concomitantly with DTaP.
8. If child age 7 through 23 months will enter an endemic area in less than 3 months, give doses as close as 2 months apart.
9. If most recent dose given when younger than age 7 years, give booster after 3 years; if given at or after age 7 years, give booster after 5 years; then boost every 5 years thereafter.
10. Booster doses are recommended if the person remains at increased risk.
11. Persistent complement component deficiencies include C3, C5–C9, properdin, factor D, factor H, or taking Soliris (eculizumab).
12. If the person has a history of only 1 dose, give dose 2 at least 8 weeks after dose 1, then boost every 5 years.

Technical content reviewed by the Centers for Disease Control and Prevention

Standing Orders Templates Updated for Administering MenACWY Vaccines to Children, Teens, and Adults

Standing orders for other vaccines are available at www.immunize.org/standing-orders. NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR

Administering Meningococcal ACWY Vaccine to Adults

Purpose

To reduce morbidity and mortality from meningococcal disease caused by serotypes A, C, W, or Y by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate adults who meet any of the criteria below.

Procedure

1 Assess adults for need of vaccination against meningococcal disease according to the following criteria:

Routine meningococcal ACWY vaccination

- First-year college students age 19 through 21 years living in a residence hall who were never vaccinated or who were last vaccinated when younger than age 16 years

Risk-based meningococcal ACWY vaccination

- Diagnosis of persistent complement component deficiency
- Diagnosis of anatomic or functional asplenia (including sic
- Diagnosis of human immunodeficiency virus (HIV) infectio
- Part of an outbreak attributable to a vaccine serogroup
- Anticipated travel to a country where meningococcal diseas the "meningitis belt" of sub-Saharan Africa), particularly if be prolonged
- Employment as a microbiologist with routine exposure to i

2 Screen for contraindications and precautions

Contraindications – Do not give MenACWY vaccine to an adult who anaphylactic reaction to a prior dose of the vaccine or to any of its c cine components, refer to the manufacturer's package insert (ww to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices

Precaution – Moderate or severe acute illness with or without feve

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine at www.immunize.org/vis. You must document in the patient's me tion date of the VIS and the date it was given to the patient. Provi a copy of the VIS in their native language, if one is available and de immunize.org/vis.

4 Review the vaccination schedule and criteria for MenACWY and

For schedule of vaccination of adults with risk factors as identifie gococcal Vaccination Recommendations by Age and Risk Factor f tion" found at www.immunize.org/catg.d/p2018.pdf.

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Download and use these standing orders templates "as they are," or modify them to suit your work setting.

Standing orders for other vaccines are available at www.immunize.org/standing-orders. NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR

Administering Meningococcal ACWY Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from meningococcal disease caused by serotypes A, C, W, or Y by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

1 Assess children and teens for need of vaccination against meningococcal disease according to the following criteria:

Routine meningococcal ACWY vaccination

- Age 11–12 years who have not received MenACWY at age 10 years or older
- As catch-up for ages 13–15 years who have not received MenACWY at age 10 years or older
- Age 16 years and in need of dose #2
- Ages 17 through 18 years and in need of dose #2 as catch-up
- As catch-up for all unvaccinated teens ages 16 through 18 years
- First-year college students age 19 through 21 years living in a residence hall who were never vaccinated or who were last vaccinated when younger than age 16 years

Risk-based meningococcal ACWY vaccination

- Age 2 months and older with diagnosis of persistent complement component deficiency (an immune system disorder, which may also be caused by the drug Soliris [eculizumab]), diagnosis of anatomic or functional asplenia (including sickle-cell disease), or diagnosis of infection with human immunodeficiency virus; children who are part of an outbreak attributable to a vaccine serogroup; or anticipated travel to a country where meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa), particularly if contact with the local population will be prolonged

2 Screen for contraindications and precautions

Contraindications – Do not give MenACWY vaccine to a child or teen who has a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component. For information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precaution – Moderate or severe acute illness with or without fever

3 Provide Vaccine Information Statements

Provide all patients (or, in the case of a minor, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS) available at www.immunize.org/vis. You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis.

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Adolescents (age 11–21 years)	22–25	5/8*–1"	Deltoid muscle of arm
Children (age 3–10 years)	22–25	5/8*–1"	Deltoid muscle of arm
Toddlers (age 1–2 years)	22–25	1–1¼"	Anterolateral thigh muscle
Infants (age 2–12 months)	22–25	1"	Anterolateral thigh muscle

* A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

(PAGE 1 OF 2)

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www.immunize.org/catg.d/p3081a.pdf • Item #P3081a (12/16)

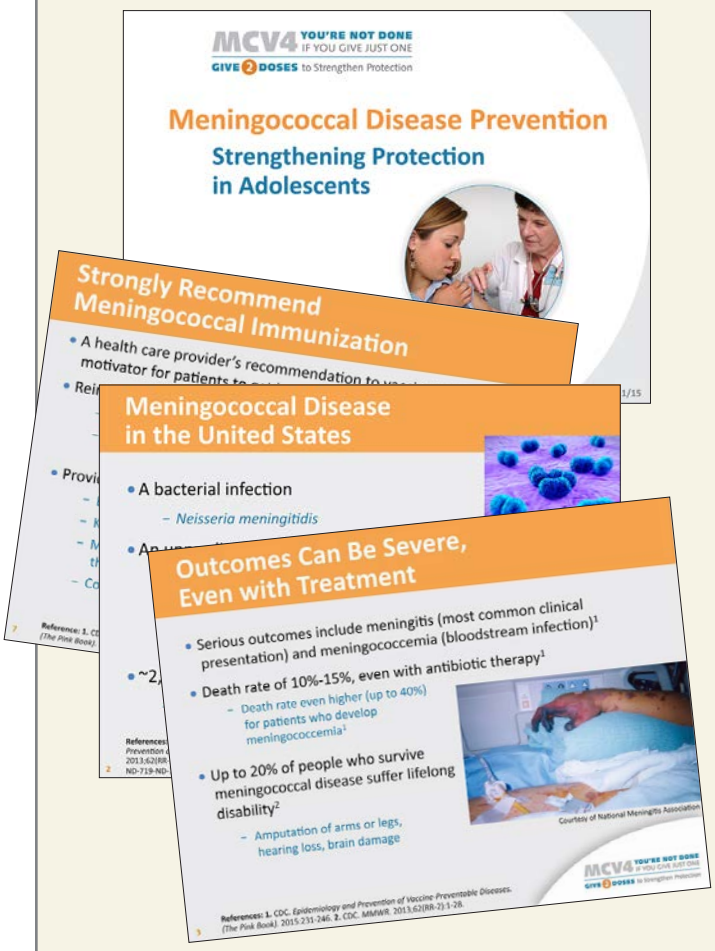
FOR ADULTS:
www.immunize.org/catg.d/p3081.pdf

FOR CHILDREN/TEENS:
www.immunize.org/catg.d/p3081a.pdf

Great Resources on www.Give2MCV4.org to Help Protect Preteens and Teens from Meningococcal A, C, W, Y Disease

- Meningococcal conjugate vaccine (MCV4) provides safe and effective protection against meningococcal disease caused by serogroups A, C, W, and Y.
- MCV4 is recommended at ages 11–12 followed by a second (booster) vaccination at age 16.
- According to CDC's 2015 National Immunization Survey–Teen, **only 33% of teens had received their recommended booster dose by 17 years of age**.

Valuable Resource! Downloadable **slide deck and speaker notes** for healthcare professionals



www.Give2MCV4.org

More Resources

Visit www.Give2MCV4.org to view the full collection of resources designed to help healthcare professionals improve rates for MCV4 and all recommended adolescent vaccines, including:

Recommending MCV4: What to Say and How to Say It
www.give2mcv4.org/wp-content/uploads/2015/07/Toolkit-Recommending-MCV4.pdf

Top 10 Ways to Improve Adolescent Immunization Rates
www.give2mcv4.org/wp-content/uploads/2015/07/Toolkit-Top-10-Ways.pdf

Screening Checklist for Contraindications to HPV, MCV4, MenB, and Tdap
www.immunize.org/catg.d/p4062.pdf

and much more!

"Dear Colleague" Letter: Call-to-Action from IAC, CDC, and professional societies emphasizing the importance of the second dose of MCV4
www.immunize.org/mcv4letter

MCV4 YOU'RE NOT DONE IF YOU GIVE JUST ONE
GIVE 2 DOSES to Strengthen Protection

Newly Updated Meningococcal Q&As: Download and Copy for Your Patients

Meningococcal: Questions and Answers

Q&A

INFORMATION ABOUT THE DISEASE AND VACCINES

What causes meningococcal disease?

Meningococcal disease is caused by the bacterium *Neisseria meningitidis*. This bacterium has at least 13 different subtypes (serogroups). Five of these serogroups, A, B, C, Y, and W, cause almost all invasive disease. The relative importance of these five serogroups depends on geographic location and other factors. In the United States almost all meningococcal disease is caused by serogroups B, C and Y. Each serogroup accounts for about one third of reported cases.

How does meningococcal disease spread?

The disease is spread person-to-person through the exchange of respiratory and throat secretions (e.g., by coughing, kissing, or sharing eating utensils). Meningococcal bacteria can't live for more than a few minutes outside the body, so the disease is not spread as easily as the common cold or influenza.

How long does it take to show signs of meningococcal disease after being exposed?

The incubation period of meningococcal disease is 3 to 4 days, with a range of 2 to 10 days. Meningococcal bacteria can make a person extremely ill by infecting the blood (septicemia) or by infecting the fluid of the spinal cord and around the brain (meningitis). Because this disease progresses quickly, it is important to be diagnosed and start treatment as soon as possible.

What are the symptoms of meningococcal disease?

The most common symptoms are high fever, chills, lethargy, and a rash. If meningitis is present, the symptoms will also include headache and neck stiffness (which may not be present in infants); seizures may also occur. In overwhelming meningococcal infections, shock, coma, and death can follow within several hours, even with appropriate medical treatment.

How serious is meningococcal disease?

Meningococcal disease caused by any serogroup is very serious. About 10 to 15% of people with meningococcal disease die even with appropriate antibiotic treatment. Of those who recover, up to 20% suffer from some serious after-effects, such as permanent hearing loss, limb loss, or brain damage.

How is meningococcal disease diagnosed?

The diagnosis is made by taking samples of blood and spinal fluid from a person who is sick. The spinal fluid is obtained by performing a lumbar puncture, where a needle is inserted into the lower back. Any bacteria found in the blood or spinal fluid is grown in a medical laboratory and identified.

Meningococcal disease is uncommon in the United States, and the symptoms can be mistaken for other illnesses, which unfortunately can lead to delayed diagnosis and treatment.

Can't meningitis be caused by a virus too?

Yes. The word "meningitis" refers to inflammation of the tissues covering the brain and spinal cord. This inflammation can be caused by viruses and fungi, as well as bacteria. Viral meningitis is the most common type; it has no specific treatment but is usually not as serious as meningitis caused by bacteria.

Is there a treatment for meningococcal disease?

Meningococcal disease can be treated with antibiotics. It is critical to start treatment early.

How common is meningococcal disease in the United States?

Fewer than 700 cases of meningococcal disease were reported each year since 2010 in the United States. An estimated average 80 deaths from meningococcal disease occurred each year in the United States since 2010.

The disease is most common in children younger than 5 years (particularly children younger than age 1 year), people age 16–21 years, and people age 65 years and older.

What people are at special risk for meningococcal disease?

For all meningococcal serogroups risk factors include age, having a damaged or missing spleen, persistent

CONTINUED ON THE NEXT PAGE ▶

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different serogroups
by other bacteria

children and adults (e.g., who are in the same school or church) aren't usually considered exposed unless they have had very close contact with the infected person (e.g., kissing or sharing a glass).

In addition to the antibiotic treatment, vaccination may be recommended for people 2 months of age and older if the person's infection is caused by meningococcus serogroup A, C, Y, or W-135, which are contained in 3 of the 5 meningococcal vaccines available in the United States.

What meningococcal vaccines are available in the United States?

There are 3 types of meningococcal vaccine available in the United States. Vaccines for meningococcal serogroups A, C, W and Y represent 2 of the 3 types. One is composed of polysaccharide (sugar molecules) from the surface of the meningococcal bacteria. The other meningococcal vaccines (MenACWY) are those in which the polysaccharide is chemically bonded ("conjugated") to a protein. These produce better protection and are more effective in young children than the original polysaccharide vaccine. A third type are vaccines for meningococcal serogroup B (MenB), which are composed of proteins also found in the surface of the bacteria. No type of vaccine contains live meningococcal bacteria.

Meningococcal polysaccharide or conjugate vaccines provide no protection against serogroup B disease and

Meningococcal Vaccines Licensed in U.S.

TRADE NAME	TYPE OF VACCINE	SEROGROUPS INCLUDED	YEAR LICENSED	APPROVED AGES
Menomune	Polysaccharide	A, C, W, Y	1981	2 years and older
Menactra	Conjugate	A, C, W, Y	2005	9 months–55 years*
Menveo	Conjugate	A, C, W, Y	2010	2 months–55 years*
Trumenba	Protein	B	2014	10–25 years†
Bexsero	Protein	B	2015	10–25 years†

*may be given to people age 56 years or older
†may be given to people age 26 years or older

to a person with
ted by being started
tely (ideally within
nosed). This is usu-
contacts and children
ersery school. Older

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 meningococcal conjugate or polysaccharide (that contain serogroup A, C, W, and Y) and a MenB vaccine.

CONTINUED ON THE NEXT PAGE ▶

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www.immunize.org/catg.d/p4210.pdf • Item #P4210 (11/16)

ed) page 3 of 4

PSV4) is
f the upper
MenACWY
or the deltoid
enB vaccines

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a as well as
ccal vaccine
Saudi Arabia,

- People working with meningococcus bacteria in laboratories

MenB is recommended for these groups:

- People age 10 years and older who have a damaged or missing spleen
- People age 10 years and older who have persistent complement component deficiency (an immune system disorder which may also be caused by the drug Soliris [eculizumab]), or are at risk during an outbreak caused by a vaccine serogroup
- People working with meningococcus bacteria in laboratories

MenB vaccines are not routinely recommended for all adolescents or college students. However, ACIP recommends that a MenB vaccine series 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.

Should college students be vaccinated against meningococcal disease?

The MenACWY vaccine is recommended for previously unvaccinated first-year college students, age younger than 22 years, who are or will be living in a residence hall. Some colleges and universities require incoming freshmen and others to be vaccinated with MenACWY; some may also require that a dose of MenACWY have been given since the age of 16 years. MenACWY may be available from the college health service.

Although several small meningococcal B disease outbreaks have occurred on college campuses since 2013, college students in general are not at higher risk of meningococcal B disease then 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 should a meningococcal B disease outbreak occur.

How many doses of meningococcal vaccine are needed?

For MenACWY vaccines the number of doses recommended depends on the age when the vaccine is given and the presence of certain medical conditions or risk factors. All adolescents should be vaccinated with one dose of MenACWY at ages 11 or 12 years and with a booster dose at age 16 years. All teens who were vaccinated with MenACWY at ages 13 through 15 years need a booster dose at age 16 through 18 years (at least 8 weeks after the first dose). First-year college students younger than 22 years who are or will be living in a residential hall should get a MenACWY booster dose if their previous dose was given before age 16 years. People ages 2 months and older who have certain risk factors such as no spleen or a damaged spleen, or persistent complement component deficiency (an immune system disorder which may also be caused by the drug Soliris [eculizumab]), may need more than one dose. In addition, vaccinated people who remain at risk, such as people without a spleen, people with HIV infection, microbiologists who work with meningococcus, or

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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. Booster doses of MenB vaccine following the initial series are currently not recommended, including for people with no spleen or persistent complement component deficiency.

How soon after their first MenACWY dose should people who remain at risk for meningococcal disease be vaccinated again?

The time between the primary (initial) doses(s) of MenACWY and the first booster varies. Children who received their primary MenACWY dose(s) before their seventh birthday should get their first booster 3 years after their primary dose(s). Children who received their primary MenACWY dose(s) at or after age 7 years and all adults should get MenACWY boosters 5 years after their primary dose(s).

What are the side effects of this vaccine?

Up to about half of people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given. These symptoms usually last for one or two days and are more common after MenACWY than after MPSV4. A small percentage of people who receive the vaccine develop a fever. Severe reactions, such as a serious allergic reaction, are very rare.

More than 60,000 persons have received MenB vaccines during clinical trials or for outbreak control on college campuses. The most common side effect was pain at the injection site, which was reported by about 80% of recipients. The Vaccine Adverse Event Reporting System (VAERS) and other vaccine safety systems will carefully monitor MenB vaccine safety as they do for other U.S.-licensed vaccines.

Who should not receive meningococcal vaccine?

These groups should not receive either type of meningococcal vaccine:

- People who have had a serious allergic reaction to a previous dose of either meningococcal vaccine or to one of the vaccine components. The packaging of some meningococcal vaccines may contain latex. Information on the contents of each vaccine is included with each vaccine.
- People who are moderately or severely ill.

Can a pregnant woman get meningococcal vaccine?

Studies of vaccination with MPSV4 during pregnancy have not documented adverse effects among either pregnant women or newborns. Post-licensure safety data suggest no concerns with the safety of MenACWY during pregnancy. Pregnancy is not considered to be a contraindication to either MPSV4 or MenACWY. Although experience with MenB vaccines is limited they have not been shown to be detrimental to a pregnant woman or fetus.

Can the vaccine cause meningococcal disease?

No. Only the *Neisseria meningitidis* bacterium can cause meningococcal disease. Meningococcal vaccines contain only the sugar capsule or capsule protein of the microbe.

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This 4-page handout for patients is ready for you to hand out in your medical setting.

Visit www.immunize.org/catg.d/p4210.pdf

▶ For IAC's ready-to-print Q&As about all vaccine-preventable diseases, visit www.immunize.org/handouts/vaccine-questions.asp

Here's More Meningococcal Vaccine Information for Your Patients

Two easy-to-read fact sheets – one about children, one for teens/adults.

Protect yourself from **meningococcal disease**…
Get vaccinated!

What is meningococcal disease?

Meningococcal disease can be a life-threatening illness. It is caused by bacteria that can infect the blood, brain, and spinal cord. People often call it meningitis.

How do you catch it?

Meningococcus bacteria are spread through upper respiratory droplets, like saliva (kissing, living in close quarters). You can catch meningitis from a person who looks healthy.

Is it serious?

Ask your healthcare provider if you need this vaccine!

Yes! Meningococcal disease may respond to antibiotics, but quick medical attention is extremely important. Even with proper treatment, 10–15% of people with meningococcal disease die. Of the people who survive, as many as 20% suffer from some serious c
such as loss of an arm or leg, brain damage, or pe
hearing loss.

Meningitis can cause shock, coma, and death with
the first symptom.

Am I at risk?

The disease most often strikes older teens and you
If you travel internationally or have certain medical
you may also be at risk.

How can I protect myself from meningitis?

Vaccination is the best way to prevent r

There are different types of meningococ
MenACWY conjugate and MenB (serog
MenACWY is given to preteens and teer
at age 11–12 years. A second dose is n
A MenB series can also be given to teer
adults starting at age 16.

People with certain medical conditions
vaccinated, and some should receive b
throughout life. Travelers to certain cou
should also get vaccinated.

▶ For more information, visit www.vaccineinform

For other vaccine handouts in this series, visit www.immunize.org/vaccine-summaries

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Download from IAC's website:

FOR CHILDREN
www.immunize.org/catg.d/p4316.pdf

FOR ADULTS
www.immunize.org/catg.d/p4410.pdf

Meningococcal disease is serious…
Make sure your child is protected!

What is meningococcal disease?

Meningococcal disease can be a life-threatening illness. It is caused by bacteria that can infect the blood, brain, and spinal cord. People often call it meningitis.

How do you catch it?

Meningococcus bacteria are spread through upper respiratory droplets, like saliva (kissing, living in close quarters). You can catch meningitis from a person who looks healthy.

Is meningococcal disease serious?

Ask your child's healthcare provider if your child is up to date for all vaccines!

Yes! Meningococcal disease may respond to antibiotics, but quick medical attention is extremely important. Even with proper treatment, 10–15% of people with meningococcal disease die. Of the people who survive, as many as 20% suffer from some serious complication, such as loss of an arm or leg, brain damage, or permanent hearing loss.

Meningitis can cause shock, coma, and death within hours of the first symptom.

Is my child at risk?

The disease most often strikes older teens and young adults. If your child travels internationally to certain countries or has certain medical conditions, he or she may also be at increased risk.

How can I protect my child from meningococcal disease?

Vaccination is the best way to prevent meningitis.

There are 2 meningococcal vaccines for children and teens: MenACWY and MenB. Preteens and teens need protection from meningitis. MenACWY is given to all preteens at age 11–12. A second dose is needed at 16. A MenB series can also be given to teens and young adults starting at age 16.

Children with certain medical conditions should also get vaccinated. Talk to your child's healthcare provider about these vaccines.

▶ For more information, visit www.vaccineinformation.org

For other vaccine handouts in this series, visit www.immunize.org/vaccine-summaries

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▶ For IAC's easy-to-read fact sheets about all vaccine-preventable diseases (including Spanish translations), visit www.immunize.org/handouts/vaccine-summaries.asp.

What If You Don't Vaccinate Your Child?

Your child is at risk for developing a vaccine-preventable disease

Vaccines were developed to protect people from dangerous and often fatal diseases. These diseases remain a threat. Vaccines are safe and effective protection.

Influenza or "flu" is a serious respiratory disease that can be deadly. Healthy babies and toddlers are especially vulnerable to complications from influenza. Every year children in the United States die from influenza.

Pertussis or "whooping cough" is an extremely dangerous disease for babies. It is not easily treated and can result in permanent brain damage or death. Since the 1980s, the number of cases of whooping cough has increased, especially among babies younger than 6 months of age and adolescents. Since 2010, several states have reported an increase in cases and outbreaks of whooping cough, including statewide epidemics in California and Washington. Whooping cough has killed many babies since 2010; most deaths were in those younger than 3 months of age.

Measles is a highly contagious disease that can lead to serious complications, including death. It remains common in many countries and has been brought into the United States by returning vacationers and foreign visitors. Vaccination caused measles to decline rapidly during the 1990s. Recently, vaccine hesitancy among parents in the United States and abroad has led to a growing number of children and teens who are not vaccinated and are unprotected from measles. This has led to outbreaks of measles in the United States, Canada, and other countries.

Chickenpox is very contagious. Before the development of a vaccine, chickenpox killed approximately 100 people every year in the United States. Most were previously healthy. Children infected with chickenpox must be kept out of day care or school for a week or more so they don't spread the disease to others.

Your child can infect others in the community

Children who are not vaccinated can transmit vaccine-preventable diseases at schools and in the community.

- Unvaccinated children can infect babies who are too young to be fully immunized.
- Unvaccinated children can infect people of any age who can't be immunized for medical reasons. This includes children and adults with leukemia and other cancers, immune system problems, and people of all ages receiving treatments or medications that suppress their immune systems.

Your child may have to be excluded from school or child care

During disease outbreaks, unvaccinated children may be excluded from school or child care to protect them and others. This can cause hardship for the child and parent.

Next steps…

We strongly encourage you to vaccinate your child. Please discuss any concerns you have with a trusted healthcare provider or call the immunization coordinator at your local or state health department. Your vaccination decision affects not only the health of your child, but also your family, your child's friends, their families, and your community.

▶ For more information about vaccines, visit these websites:

American Academy of Pediatrics
www.healthychildren.org

Centers for Disease Control and Prevention
www.cdc.gov/vaccines/parents

Every Child by Two
www.vaccinateyourfamily.org and www.ecbt.org

Immunization Action Coalition
www.immunize.org and www.vaccineinformation.org

Vaccine Education Center at the Children's Hospital of Philadelphia
www.vaccine.chop.edu

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www.immunize.org/catg.d/p4017.pdf • Item #P4017 (10/16)

NEWLY UPDATED!

Which Vaccines Do I Need Today?

This checklist helps you determine which vaccines your adult patients need.

Download and copy this screening questionnaire for your patients to fill out.

YOUR NAME _____ DATE OF BIRTH ____/____/____ TODAY'S DATE ____/____/____
(month / day / year)

☑ Which Vaccines Do I Need Today?

Vaccines are an important part of helping you stay healthy. Which of these recommended vaccines do you need? Check the boxes that apply to you, and then talk this over with your healthcare provider.

Influenza ("flu") vaccine

☐ I have not had my flu vaccine yet this season *(early fall through late spring)*.

Pneumococcal ("pneumonia") vaccines [Prevnar 13 [PCV13] and Pneumovax 23 [PPSV23]]

I am ***age 65 or older*** and:

☐ I have never received any pneumonia vaccine (or I don't remember if I have).

☐ I have received only 1 pneumonia vaccine since I turned 65.

☐ I received 1 or 2 doses of pneumonia vaccine before I turned 65, and it's now be since I received my last dose.

I am ***younger than age 65*** and:

☐ I have never received any pneumonia vaccine AND at least one of the following a

- I smoke cigarettes and I am age 19 years or older.
- I have a chronic disease of the heart, lung (including asthma, if I am age 19 y kidneys, or I have sickle cell disease.
- I have diabetes or alcoholism.
- I have a weakened immune system due to cancer, Hodgkin's disease, leukem myeloma, kidney failure, HIV/AIDS *or* receiving radiation therapy *or* taking a immune system.
- I live in a nursing home or other long-term care facility.

☐ I have had an organ or bone marrow transplant.

☐ I have had my spleen removed *or* have had a cochlear (inner ear) implant *or* have b provider that I have leaking spinal fluid.

Tetanus, diphtheria, and pertussis ("whooping cough")-containing vaccine (e.g., DT

☐ I have never received Tdap vaccine (or I don't remember if I have.)

☐ I have not received at least 3 tetanus- and diphtheria-containing shots.

☐ I have received at least 3 tetanus- and diphtheria-containing shots in my lifetime more than 10 years since I received the last one.

☐ I am pregnant (and I am in my late second or third trimester of my pregnancy) a of Tdap vaccine during this pregnancy.

Measles, mumps, rubella (MMR) vaccine

☐ I am a woman thinking about a future pregnancy and don't know if I'm immune

☐ I am a healthcare worker. I have received 1 MMR (or I don't remember if I have received mo I do not have a lab-confirmed report showing that I am immune to measles, mumps, and/o

I ***was born in 1957 or later*** and:

☐ I have never received MMR vaccine (or I don't remember if I have).

☐ I have received only 1 MMR and

- ☐ I am entering college or another type of school after high school.
- ☐ I am planning on traveling outside the U.S.[1]

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www.immunize.org/catg.d/p4036.pdf •

Human papillomavirus (HPV) vaccination

I ***have not completed a series*** of HPV shots and

☐ I am a woman age 26 or younger.

I am a man

- ☐ age 21 or younger.
- ☐ age 22 through 26 and at least one of the following applies to me:
  - I want to be protected from HPV.
  - I have a weakened immune system due to infection (including HIV), disease, or medications.
  - I have sex with men.
- ☐ I am now older than age 26 and have not completed the HPV vaccine series I began when I was age 26 or younger.

Hepatitis A vaccine

☐ I want to be vaccinated to avoid getting hepatitis A and spreading it to others.

☐ I might have been exposed to hepatitis A virus within the past 2 weeks.

☐ I received 1 dose of hepatitis A vaccine in the past, but I have not received the second dose (or I don't remember if I have).

☐ I have not received hepatitis A vaccine in the past (or I don't remember if I have) and at least one of the following applies to me:

- I travel (or plan to travel) in countries where hepatitis A is common.[1,2]
- I have (or will have) contact with a child within 60 days of the child's adoption from a country where hepatitis A is common.[2]
- I am a man who has sex with men.
- I use street drugs.
- I have chronic liver disease.
- I have a blood clotting factor disorder.
- I work with hepatitis A virus in a research laboratory or with primates infected with hepatitis A virus.

Hepatitis B vaccine

☐ I want to be vaccinated to avoid getting hepatitis B and spreading it to others.

☐ I am age 18 or younger and I have not begun or completed the series of hepatitis B shots (or I don't remember if I have).

☐ I have received at least one dose of hepatitis B in the past, but I have not completed the series of hepatitis B shots (or I don't remember if I have).

☐ I have not received or completed the series of hepatitis B shots (or I don't remember if I have) and at least

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Varicella ("chickenpox") vaccine

☐ I was born before 1980 *and* I am a healthcare worker or foreign-born and I don't remember if I've ever had chickenpox disease.

☐ I was born in 1980 or later *and* I have never had chickenpox disease or received the vaccine (or I don't remember if I have).

☐ I have received one dose of varicella vaccine, but I'm not sure if I have received more than one dose.

Meningococcal ("meningitis") type A, C, W, Y vaccine (MenACWY [MCV4])

☐ I am age 18 or younger and have never received any meningococcal vaccines (or I don't remember if I have).

☐ I am age 21 or younger *and*

- I have not had a meningococcal shot (MenACWY) since before my 16th birthday *and* I am (or will be) a college student living in a residence hall.
- I have not had a meningococcal shot (MenACWY) in the past 5 years and I am entering college.

☐ I have sickle cell disease.

☐ My spleen isn't working or has been removed.

☐ I have a persistent complement component deficiency.

☐ I have HIV infection.

☐ I have a risk of exposure due to an outbreak caused by serogroup A, C, W, or Y.

☐ I am a microbiologist who is routinely exposed to isolates of *Neisseria meningitidis*.

☐ I was vaccinated more than 5 years ago *and* I continue to be at risk due to travel, illness, or occupation.

Meningococcal ("meningitis") type B vaccine (MenB)

☐ I am age 16–23 with no specific risk factor and would like to be protected from this disease.

☐ I have a risk of exposure due to an outbreak caused by serogroup B.

☐ I have sickle cell disease.

☐ My spleen isn't working or has been removed.

☐ I have a persistent complement component deficiency.

Zoster ("shingles") vaccine

☐ I am age 60 or older and have never received a shingles vaccine (or I don't know if I have).

***Haemophilus influenzae* type b ("Hib") vaccine**

☐ My spleen has been removed, or I am scheduled to have it removed ("splenectomy").

☐ I have received a stem cell transplant.

Travel vaccines

☐ I am planning on traveling outside the U.S.[1,3] (Discuss this with your provider.)

FOOTNOTES

1. Call your local travel clinic to find out if additional vaccines are recommended.
2. Countries where hepatitis A is common include all countries other than the U.S., Western Europe, Canada, Japan, Australia, and New Zealand.
3. Areas with high rates of hepatitis B include Africa, China, Korea, Southeast Asia including Indonesia and the Philippines, South and Western Pacific Islands, interior Amazon Basin, certain parts of the Caribbean (i.e., Haiti and the Dominican Republic), and the Middle East except Israel. Areas with moderate rates include South Central and Southwest Asia, Israel, Japan, Eastern and Southern Europe, Russia, and most of Central and South America.
4. Most adults from moderate- or high-risk areas of the world do not know their hepatitis B status. All patients from these areas need hepatitis B blood tests to determine if they have been previously infected. The first hepatitis B shot can be given during the same visit as the blood tests but only after the blood is drawn.

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▶ Visit www.immunize.org/catg.d/p4036.pdf

IAC's Temperature Logs Updated for Your Use

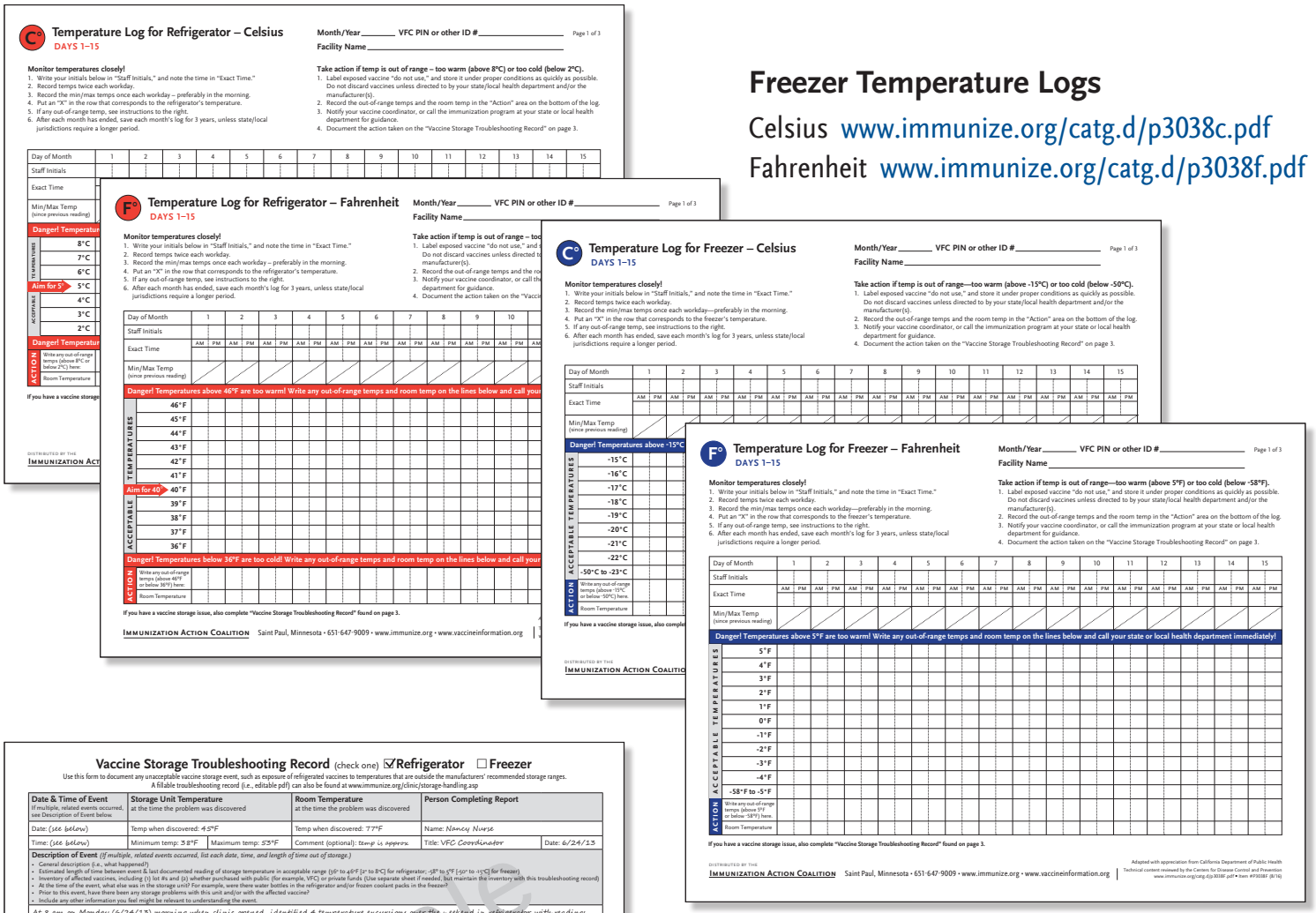
IAC has updated its Celsius and Fahrenheit temperature logs for refrigerators and freezers. They're ready for you to download, copy, and use. All are CDC reviewed.

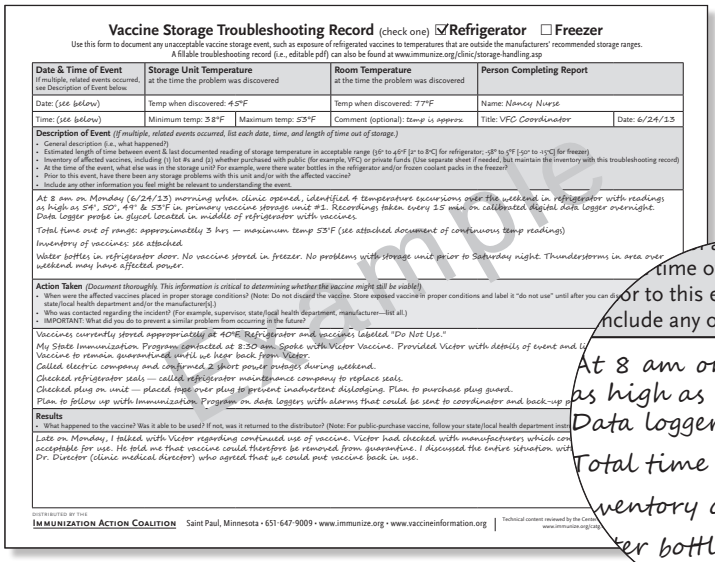
Refrigerator Temperature Logs

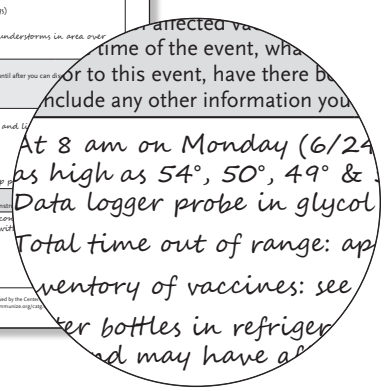
Celsius www.immunize.org/catg.d/p3037c.pdf
Fahrenheit www.immunize.org/catg.d/p3037f.pdf

Freezer Temperature Logs

Celsius www.immunize.org/catg.d/p3038c.pdf
Fahrenheit www.immunize.org/catg.d/p3038f.pdf





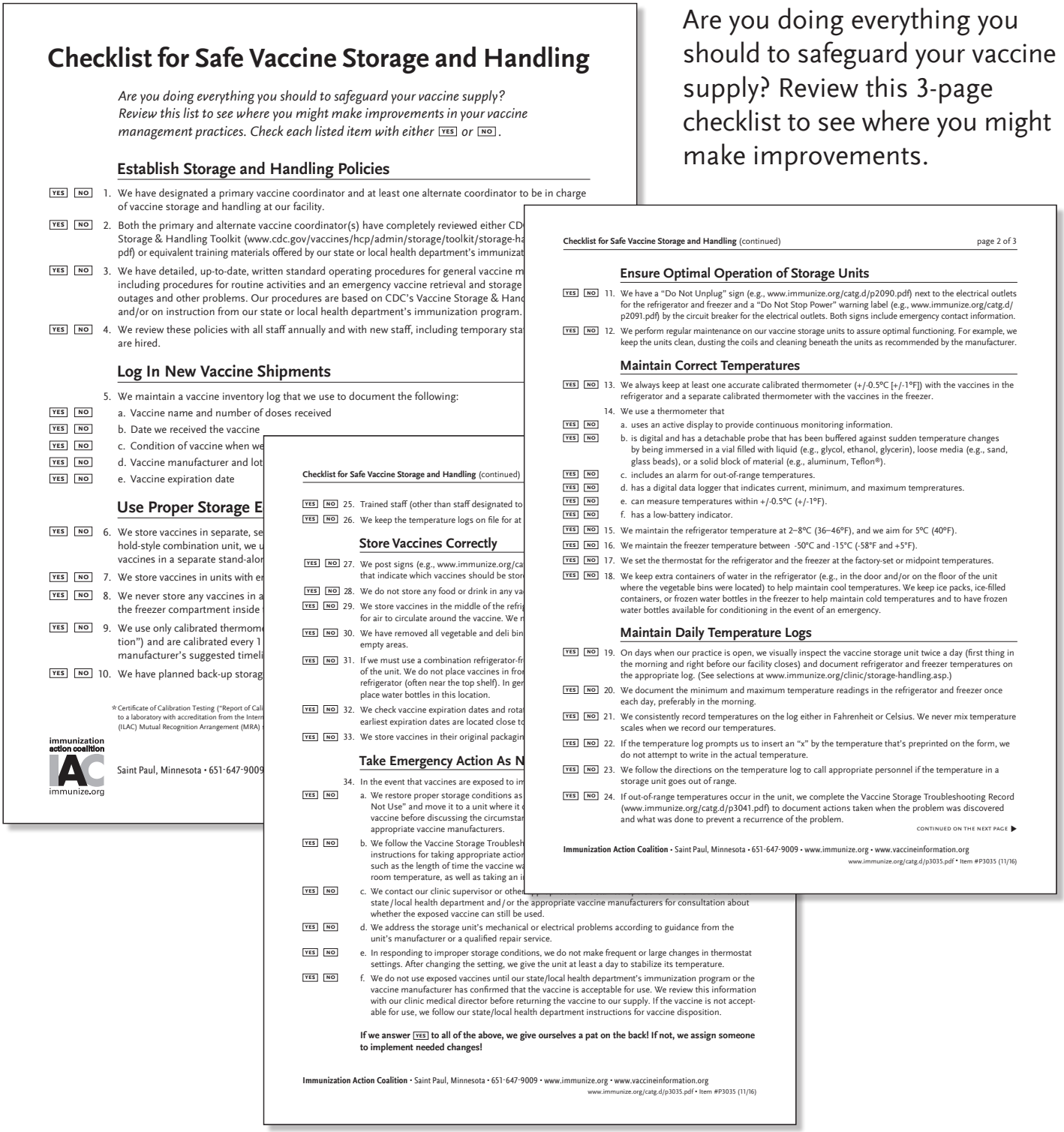


Additional Tool

Vaccine Storage Troubleshooting Record: www.immunize.org/catg.d/p3041.pdf

Use This Checklist to Maximize Protection of Your Valuable Vaccine Supply

Are you doing everything you should to safeguard your vaccine supply? Review this 3-page checklist to see where you might make improvements.



Checklist for Safe Vaccine Storage and Handling

Are you doing everything you should to safeguard your vaccine supply? Review this list to see where you might make improvements in your vaccine management practices. Check each listed item with either YES or NO.

Establish Storage and Handling Policies

YES NO 1. We have designated a primary vaccine coordinator and at least one alternate coordinator to be in charge of vaccine storage and handling at our facility.

YES NO 2. Both the primary and alternate vaccine coordinator(s) have completely reviewed either CD Storage & Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-ha pdf) or equivalent training materials offered by our state or local health department's immunizat

YES NO 3. We have detailed, up-to-date, written standard operating procedures for general vaccine m including procedures for routine activities and an emergency vaccine retrieval and storage outages and other problems. Our procedures are based on CDC's Vaccine Storage & Hand and/or on instruction from our state or local health department's immunization program.

YES NO 4. We review these policies with all staff annually and with new staff, including temporary sta are hired.

Log In New Vaccine Shipments

5. We maintain a vaccine inventory log that we use to document the following:

YES NO a. Vaccine name and number of doses received

YES NO b. Date we received the vaccine

YES NO c. Condition of vaccine when we

YES NO d. Vaccine manufacturer and lot

YES NO e. Vaccine expiration date

Use Proper Storage E

YES NO 6. We store vaccines in separate, se hold-style combination unit, we u vaccines in a separate stand-alor

YES NO 7. We store vaccines in units with er

YES NO 8. We never store any vaccines in a the freezer compartment inside

YES NO 9. We use only calibrated thermom tion") and are calibrated every 1 manufacturer's suggested timeli

YES NO 10. We have planned back-up storag

* Certificate of Calibration Testing ("Report of Cali to a laboratory with accreditation from the Intern (ILAC) Mutual Recognition Arrangement (MRA)

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Checklist for Safe Vaccine Storage and Handling (continued)

YES NO 25. Trained staff (other than staff designated to

YES NO 26. We keep the temperature logs on file for at

Store Vaccines Correctly

YES NO 27. We post signs (e.g., www.immunize.org/ca that indicate which vaccines should be stor

YES NO 28. We do not store any food or drink in any va

YES NO 29. We store vaccines in the middle of the refri for air to circulate around the vaccine. We r

YES NO 30. We have removed all vegetable and deli bin empty areas.

YES NO 31. If we must use a combination refrigerator-fr of the unit. We do not place vaccines in fro refrigerator (often near the top shelf). In ge place water bottles in this location.

YES NO 32. We check vaccine expiration dates and rota earliest expiration dates are located close to

YES NO 33. We store vaccines in their original packagin

Take Emergency Action As N

34. In the event that vaccines are exposed to im

YES NO a. We restore proper storage conditions as Not Use" and move it to a unit where it vaccine before discussing the circumstar appropriate vaccine manufacturers.

YES NO b. We follow the Vaccine Storage Troublesh instructions for taking appropriate actio such as the length of time the vaccine wa room temperature, as well as taking an i

YES NO c. We contact our clinic supervisor or other state/local health department and/or the appropriate vaccine manufacturers for consultation about whether the exposed vaccine can still be used.

YES NO d. We address the storage unit's mechanical or electrical problems according to guidance from the unit's manufacturer or a qualified repair service.

YES NO e. In responding to improper storage conditions, we do not make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.

YES NO f. We do not use exposed vaccines until our state/local health department's immunization program or the vaccine manufacturer has confirmed that the vaccine is acceptable for use. We review this information with our clinic medical director before returning the vaccine to our supply. If the vaccine is not acceptable for use, we follow our state/local health department instructions for vaccine disposition.

If we answer YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

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www.immunize.org/catg.d/p3035.pdf • Item #P3035 (11/16)

Checklist for Safe Vaccine Storage and Handling (continued) page 2 of 3

Ensure Optimal Operation of Storage Units

YES NO 11. We have a "Do Not Unplug" sign (e.g., www.immunize.org/catg.d/p2090.pdf) next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label (e.g., www.immunize.org/catg.d/p2091.pdf) by the circuit breaker for the electrical outlets. Both signs include emergency contact information.

YES NO 12. We perform regular maintenance on our vaccine storage units to assure optimal functioning. For example, we keep the units clean, dusting the coils and cleaning beneath the units as recommended by the manufacturer.

Maintain Correct Temperatures

YES NO 13. We always keep at least one accurate calibrated thermometer (+/-0.5ºC [+/-1ºF]) with the vaccines in the refrigerator and a separate calibrated thermometer with the vaccines in the freezer.

14. We use a thermometer that

YES NO a. uses an active display to provide continuous monitoring information.

YES NO b. is digital and has a detachable probe that has been buffered against sudden temperature changes by being immersed in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., aluminum, Teflon®).

YES NO c. includes an alarm for out-of-range temperatures.

YES NO d. has a digital data logger that indicates current, minimum, and maximum tempreratures.

YES NO e. can measure temperatures within +/-0.5ºC (+/-1ºF).

YES NO f. has a low-battery indicator.

YES NO 15. We maintain the refrigerator temperature at 2–8ºC (36–46ºF), and we aim for 5ºC (40ºF).

YES NO 16. We maintain the freezer temperature between -50ºC and -15ºC (-58ºF and +5ºF).

YES NO 17. We set the thermostat for the refrigerator and the freezer at the factory-set or midpoint temperatures.

YES NO 18. We keep extra containers of water in the refrigerator (e.g., in the door and/or on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures. We keep ice packs, ice-filled containers, or frozen water bottles in the freezer to help maintain cold temperatures and to have frozen water bottles available for conditioning in the event of an emergency.

Maintain Daily Temperature Logs

YES NO 19. On days when our practice is open, we visually inspect the vaccine storage unit twice a day (first thing in the morning and right before our facility closes) and document refrigerator and freezer temperatures on the appropriate log. (See selections at www.immunize.org/clinic/storage-handling.asp.)

YES NO 20. We document the minimum and maximum temperature readings in the refrigerator and freezer once each day, preferably in the morning.

YES NO 21. We consistently record temperatures on the log either in Fahrenheit or Celsius. We never mix temperature scales when we record our temperatures.

YES NO 22. If the temperature log prompts us to insert an "x" by the temperature that's preprinted on the form, we do not attempt to write in the actual temperature.

YES NO 23. We follow the directions on the temperature log to call appropriate personnel if the temperature in a storage unit goes out of range.

YES NO 24. If out-of-range temperatures occur in the unit, we complete the Vaccine Storage Troubleshooting Record (www.immunize.org/catg.d/p3041.pdf) to document actions taken when the problem was discovered and what was done to prevent a recurrence of the problem.

CONTINUED ON THE NEXT PAGE ▶

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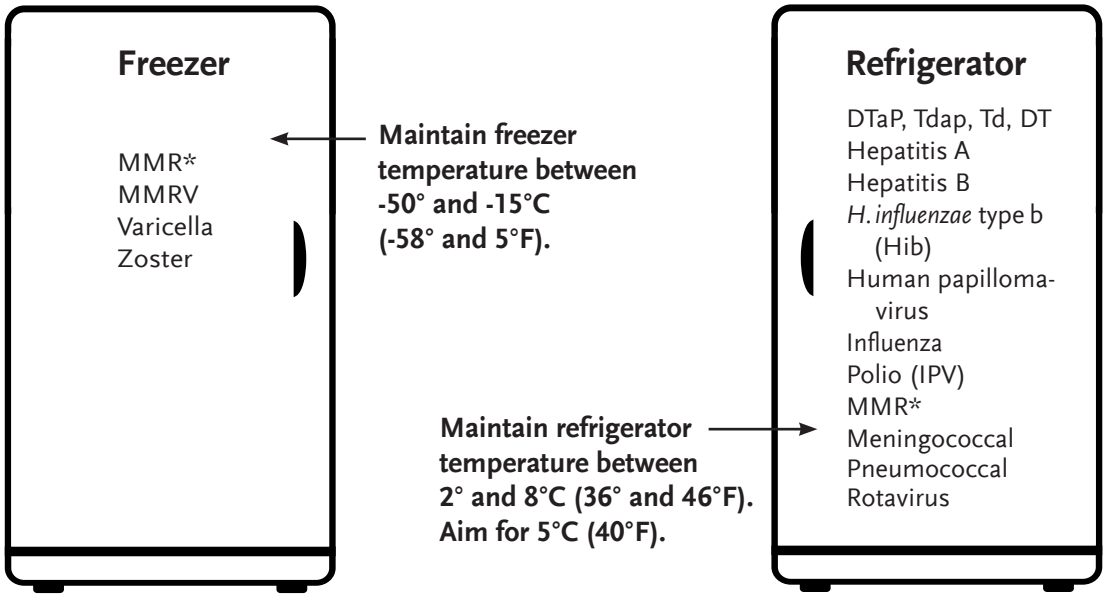
Vaccine Handling Tips

REMEMBER: Improperly stored or outdated vaccines won't protect your patients!



Manage vaccine inventories.

Inventory your vaccine supplies at least monthly and before placing an order. Expired vaccine must never be used and it becomes "cash in the trash!"

Always use the vaccine with the soonest expiration date first.

Move vaccine with the soonest expiration date to the front of the storage unit and mark it to be used first. These actions help ensure it will be picked up first by someone selecting vaccine from the unit.

Store vaccine appropriately.†

Place vaccines in refrigerator or freezer immediately upon receiving shipment. Keep vaccine vials in their original packaging. Place vaccine in clearly labeled wire baskets or other open containers with a 2–3" separation between baskets and 4" from wall of unit. Separate or clearly mark vaccines to distinguish those that were supplied from your state's Vaccines for Children program (or other state-funded source) from those that were privately purchased. Do not store vaccines in the door or on the floor of the unit.

Stabilize temperatures.

Store ice packs in the freezer and large jugs of water in the refrigerator along with the vaccines. This will help maintain a stable, cold temperature in case of a power failure or if the refrigerator or freezer doors are opened frequently or are accidentally left open. Because frequent opening of either the refrigerator or freezer door can lead to temperature variations that could affect vaccine efficacy, you should not store food or beverages in the refrigerator or freezer.

Safeguard the electrical supply to the refrigerator.

Make sure the refrigerator and freezer are plugged into outlets in a protected area where they cannot be disconnected accidentally. Label the refrigerator, freezer, electrical outlets, fuses, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps to be taken in case of interruption of power.‡ If your building has auxiliary power, use the outlet supplied by that system.

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*MMR may be stored in either the freezer or the refrigerator.

†Refer to package insert for specific instructions on the storage of each vaccine. If you have questions about the condition of the vaccine upon arrival, immediately place the vaccine in recommended storage, mark it "do not use," and then call your state health department or the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. For other questions, call the immunization program at your state or local health department.

‡For easy help with labeling units and power supplies, see IAC signs "Do Not Unplug Refrigerator or Freezer" (www.immunize.org/catg.d/p2090.pdf) and "Do Not Stop Power to Circuit Breaker" (www.immunize.org/catg.d/p2091.pdf). For guidance on steps to take during a power interruption, see IAC's "Emergency Response Worksheet" (www.immunize.org/catg.d/p3051.pdf).

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These products are available for purchase from the Immunization Action Coalition

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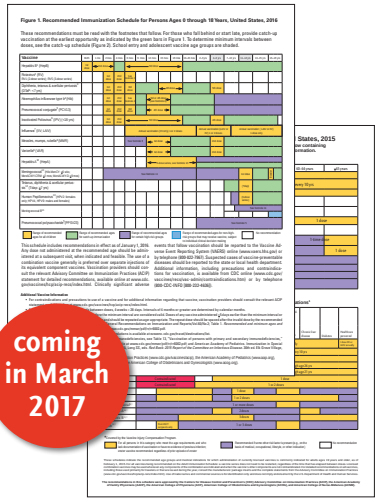

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DVD: $17 each
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Training Video: "Immunization Techniques — Best Practices with Infants, Children, and Adults"

The California Department of Public Health, Immunization Branch, updated its award-winning training video, "Immunization Techniques: Best Practices with Infants, Children, and Adults." The 25-minute DVD can be used to train new employees and to refresh the skills of experienced staff on administering injectable, oral, and nasal-spray vaccines to children, teens, and adults.

▶ To order, visit www.immunize.org/shop, or use the order form on page 22.

For healthcare settings in California, contact your local health department immunization program for a free copy.

The Vaccine Handbook: A Practical Guide for Clinicians ("The Purple Book") by Gary S. Marshall, MD

During my more than 25 years in the field of immunization education, I have not seen another book that is so brimming with state-of-the-science information. – Deborah L. Wexler, MD, Executive Director, IAC

Purchase *The Vaccine Handbook* (560 pages) from IAC at www.immunize.org/vaccine-handbook.

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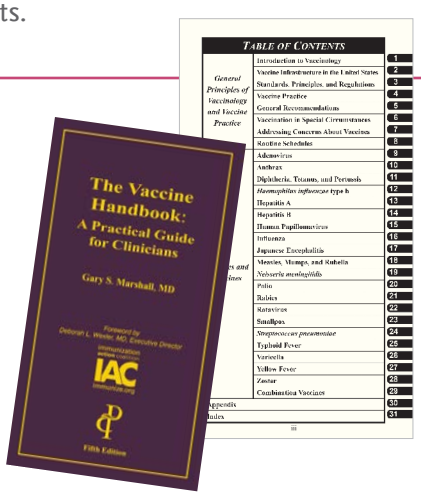

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