



Agenda

Quarterly Community Provider Network (CPN) Meeting

Contra Costa Health Plan

When: Time: 7:30 AM – 9:00 AM
Date: January 17, 2017

Where: West County Health Center
13601 San Pablo Ave, San Pablo, CA
Room A

Attention! Please enter by the side door (on San Pablo Ave.)

The agenda for the meeting is as follows:

I.	CALL TO ORDER and INTRODUCTIONS	Mary Berkery, RN
II.	REVIEW and APPROVAL of MINUTES from previous meeting	Mary Berkery, RN
III.	NEW BUSINESS	
	<ul style="list-style-type: none"> Communicable Disease Issues Update 	Louise Mc Nitt MD, CCHS Public Health
IV.	REGULAR REPORTS	
	<ul style="list-style-type: none"> CCHP Updates 	James Tysell, MD
VII.	ADJOURNMENT	

Our next scheduled meeting is:

April 18, 2017

CPN Quarterly Meeting

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CONTRA COSTA HEALTH PLAN
 West County
 Quarterly Community Provider Network (CPN)
Meeting Minutes – October 18, 2016

Attending:

CCHP Staff: Jose Yasul, MD, Mary Berkery, RN, Christine Gordon, RN, BSN, PHN; Maria Tesolin, Clerk

CPN Providers: D. Fernandes, MD; K. Kaminski, PA; P. Mack, MD; M. Ogawa, MD; K. O'Hearn, CPNP; P. Rene, PA; J. Mahony, MD; G. Aguilar, PA; K. Ceci, MD; O. Eaglin, PA; L. Trombla, PA; S. Bottomley, NP; K. Merchant, MD; M. Desai, MD; B. Olatunbosun, MD; A. Patridge, NP

Guests: Patricia Tanquary, CCHP CEO

Discussion	Action	Accountable
Meeting called to order at 7:45 A.M.		M. Berkery, RN
I. Agenda was approved with no revisions.		M. Berkery, RN
II. Review and Approval of Minutes from July 19, 2016: Minutes were approved as presented.		M. Berkery, RN
III. Announcements: Kaiser will conduct a 3 hour breastfeeding lecture on 11/7/16. Regular Reports: 1. <u>Quality</u> <ul style="list-style-type: none"> • HEDIS ethnicity disparity rates reviewed • Documentation method for persistent Asthma and medication refill • African American disparity in postpartum care is now gone 2. <u>Utilization Management</u> <ul style="list-style-type: none"> • Referral to Skilled Nursing Facilities (SNF) • Review of online provider directory to locate Skilled Nursing Facilities • Review of Epocrates formulary resource • Podiatrist on site at LifeLong • CCHP still recruiting for Podiatrists 3. <u>Palliative Care</u> <ul style="list-style-type: none"> • Offer muscular skeletal physical therapy prior to referral • Members taking high dose of medications continue Palliative Care • 3 months is the usual wait time for a referral to be processed 		J. Yasul, MD
IV. New Business: <u>Opioid Addiction</u> CCHP was awarded the Drug Medi-Cal Waiver Award. CCHP partners with AOD and community partners to offer alternative treatment for opioid addiction. Funding approved for Medi-Cal members to receive acupuncture therapy (twice a month in a year). Residential treatment is also available. <u>2016 Celebratory Year</u> This year California celebrates 50 years of Medi-Cal coverage in California. CCHP celebrated with George Miller, who helped pass the Affordable Care Act, which allowed Medicaid Expansion in the state which enabled financially eligible childless adults to receive Medi-Cal in California. <ul style="list-style-type: none"> • 13.5 million are enrolled in Medi-Cal in California 		P. Tanquary, CCHP CEO

<p><u>CCHP Statistics</u></p> <ul style="list-style-type: none"> • CCHP membership has doubled since 2014 (200,000 members) • Membership Demographics: <ul style="list-style-type: none"> 43% members are East County residents, 60% Adults, 40% children • 5500 Primary Care & Specialty Care Providers contracted with CCHP • 80,000 referrals a month sent to specialty care <p><u>Undocumented Children</u></p> <ul style="list-style-type: none"> • 1477 recorded undocumented children, 1279 (82%) have selected CCHP • 93% default to CCHP • Continuity of care assigned to: Kaiser, LifeLong, La Clinica and CCRMC • Letters sent to membership to inform of continuity of care • Outreach to Spanish speaking undocumented population is successful <p><u>Behavioral Health Access Line</u></p> <ul style="list-style-type: none"> • 24 hour access line available to membership 1-888-678-7277 <p><u>Autism Benefit</u></p> <ul style="list-style-type: none"> • Autism Benefit transferred to managed care • 125 ABA Providers contracted with CCHP <p><u>Non-Medical Transportation Benefit</u></p> <ul style="list-style-type: none"> • Medi-cal recipients will have Non-Medical Transportation Benefit in 2017 • CCHP extended benefit to: prenatal, cancer treatment, and dialysis therapy • A 800 number will be set up to contact transportation service • Uber will not be a source of transportation (drivers not vetted adequately) • Pro Transport is the first contracted transportation company <p><u>ER/Urgent Care</u></p> <ul style="list-style-type: none"> • LifeLong opened 2 Urgent Care Centers in West County • CCHP PCP's reminded not to refer members to Kaiser ER when possible • Kaiser to send a list of CCHP members repeatedly going to Kaiser ER • CCHP Advice Nurse line available to members 24/7 • 37% of member calls to Advice Nurse Unit resolved without further visits • Advice Nurse Unit has access to appointments at Urgent Care Centers <p><u>New! Drug Disposal Kiosks:</u></p> <ul style="list-style-type: none"> • Walgreens installed over 300 drug disposal kiosks nationwide • 19 located in the Bay Area (refer to page 6 of Care Matters Fall Bulletin) • Walgreens Walnut Creek location open 24 hours <p><u>Alta Bates Possible Closure in Future</u></p> <ul style="list-style-type: none"> • CCHP is working jointly with Kaiser <p><u>New! Palliative Care Out Patient Clinic</u></p> <ul style="list-style-type: none"> • Opened first Palliative Care Out Patient clinic in Martinez 		
<p>Adjournment: Meeting adjourned at 9:10 A.M.</p>		<p>M. Berkery, RN</p>

Next meeting January 17, 2017



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices

Weekly / December 16, 2016 / 65(49);1405–1408

Elissa Meites, MD¹; Allison Kempe, MD^{2,3}; Lauri E. Markowitz, MD¹ ([view author affiliations](#))

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Introduction

Vaccination against human papillomavirus (HPV) is recommended to prevent HPV infections and HPV-associated diseases, including cancers. Routine vaccination at age 11 or 12 years has been recommended by the Advisory Committee on Immunization Practices (ACIP) since 2006 for females and since 2011 for males (1,2). This report provides recommendations and guidance regarding use of HPV vaccines and updates ACIP HPV vaccination recommendations previously published in 2014 and 2015 (1,2). This report includes new recommendations for use of a 2-dose schedule for girls and boys who initiate the vaccination series at ages 9 through 14 years. Three doses remain recommended for persons who initiate the vaccination series at ages 15 through 26 years and for immunocompromised persons.

Background

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HPV infection causes cervical, vaginal, and vulvar cancers in women; penile cancers in men; and oropharyngeal and anal cancers as well as genital warts in both men and women (3). Three HPV vaccines are licensed for use in the United States. All are noninfectious. Quadrivalent and 9-valent HPV vaccines (4vHPV and 9vHPV, Gardasil and Gardasil 9, Merck and Co, Inc., Whitehouse Station, New Jersey) are licensed for use in females and males aged 9 through 26 years (1). Bivalent HPV vaccine (2vHPV, Cervarix, GlaxoSmithKline, Rixensart, Belgium) is licensed for use in females aged 9 through 25 years (1). As of late 2016, only 9vHPV is being distributed in the United States. The majority of all HPV-associated cancers are caused by HPV 16 or 18, types targeted by all three vaccines. In addition, 4vHPV targets HPV 6 and 11, types that cause genital warts. 9vHPV protects against these and five additional types: HPV 31, 33, 45, 52, and 58. All three vaccines have been approved for administration in a 3-dose series at intervals of 0, 1 or 2, and 6 months. In October 2016, after considering new

clinical trial results (4), the Food and Drug Administration (FDA) also approved 9vHPV for use in a 2-dose series for girls and boys aged 9 through 14 years (5). In October 2016, ACIP recommended a 2-dose schedule for adolescents initiating HPV vaccination in this age range. This report provides recommendations for use of 2-dose and 3-dose schedules for HPV vaccination.

Methods

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During November 2015–October 2016, the ACIP HPV Vaccines Work Group held monthly telephone conferences to 1) review and evaluate the quality of the evidence assessing immunogenicity, efficacy, and postlicensure effectiveness of a 2-dose schedule; 2) consider benefits and harms of a 2-dose schedule; 3) weigh the variability in the values and preferences of patients and providers for a 2-dose schedule; and 4) examine health economic analyses. During teleconferences, summaries of findings were presented for Work Group discussion.

A systematic review was conducted to identify studies involving human subjects* that reported primary data on any important or critical health outcomes related to HPV vaccination† after 2 doses of 9vHPV, 4vHPV, or 2vHPV, administered at an interval of 0 and ≥6 months (±4 weeks) to persons aged 9 through 14 years. The review focused on this age group given available 2-dose trial data for 9vHPV (4). Immunogenicity outcomes of interest were seroconversion, geometric mean titers (GMTs), or antibody avidity. Studies were excluded if they lacked a comparison group in which efficacy of 3 doses of HPV vaccine against clinical endpoints was demonstrated in clinical trials (e.g., females aged 15 through 26 years).[§] Evidence regarding a 3-dose schedule for HPV vaccine was reviewed previously (1,2).

Quality of evidence was evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Detailed methods and GRADE tables can be found online (4). Other studies from the search and from the broader literature informed additional expert guidance that extended beyond the research question addressed formally via GRADE analysis (7). Evidence was reviewed by the Work Group, summarized, and publicly presented at the February and June 2016 ACIP meetings. CDC vaccine recommendations are developed using the GRADE framework (8). Proposed recommendations were presented, and after a public comment period, were approved unanimously[¶] by the voting ACIP members at the October 2016 ACIP meeting.

Summary of Key Findings

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Immunogenicity. In the 9vHPV clinical trial that was the basis for FDA approval of a 2-dose series, participants were girls and boys aged 9 through 14 years, compared with young females aged 16 through 26 years (4). Among 1,377 participants, ≥97.9% seroconverted to all nine vaccine-preventable HPV types by 4 weeks after the last dose. For girls and boys who received 2 doses of 9vHPV 6 months apart (0, 6 month schedule) or 12 months apart (0, 12 month schedule), noninferiority criteria were met for seroconversion and GMTs. Furthermore, GMTs were significantly higher for all 9vHPV types among persons aged 9 through 14 years who received 2 doses compared with females aged 16–26 years who received 3 doses (0, 2, 6 month schedule). Six additional studies found similar results for 4vHPV and 2vHPV (4). Immunogenicity was found to be noninferior with 2 doses in persons aged 9 through 14 years compared with 3 doses in a group in which clinical efficacy was demonstrated (GRADE evidence type 3).

Efficacy and effectiveness. Although efficacy and postlicensure effectiveness studies were reviewed, none met the inclusion criteria detailed above. The prelicensure HPV vaccine efficacy trials were conducted with 3-dose series; post hoc analyses conducted with data from some of these trials found high efficacy against infection among vaccinees who received 2 doses and those who received 3 doses (9,10). A large study comparing 2 doses with 3 doses also suggested similar efficacy against infection (11). Postlicensure effectiveness studies have found lower effectiveness against various HPV-associated outcomes among vaccinees who received 2 doses compared with those who received 3 doses, but methodologic challenges with these studies limit interpretation of the findings.**

Duration of protection. Through 10 years of follow-up from clinical trials, no evidence of waning protection after a 3-dose series of HPV vaccine has been found (1). Because antibody kinetics are similar with 2-dose and 3-dose series, duration of protection is also expected to be long-lasting after a 2-dose series (12,13).

Health impact and cost-effectiveness modeling. Population-level effectiveness and cost-effectiveness of 2-dose and 3-dose schedules of 9vHPV in the United States have been modeled (14). Assuming both efficacy and duration of protection are similar with either schedule, a 2-dose series would be cost-saving and have similar population impact to a 3-dose series. Even if duration of protection is 20 years for a 2-dose series and lifelong for a 3-dose series, additional benefits of a 3-dose series would be relatively small, and a 2-dose series would be more cost-effective (14).

Rationale

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HPV vaccines are highly effective and safe, and a powerful prevention tool for reducing HPV infections and HPV-associated cancers (1,2). Based on the available immunogenicity evidence, a 2-dose schedule (0, 6–12 months) will have efficacy equivalent to a 3-dose schedule (0, 1–2, 6 months) if the HPV vaccination series is initiated before the 15th birthday (GRADE evidence type 3) (6). ACIP recommends a 2-dose schedule for HPV vaccination of girls and boys who initiate the vaccination series at ages 9 through 14 years (Category A recommendation).

Recommendations

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Routine and catch-up age groups. ACIP recommends routine HPV vaccination at age 11 or 12 years.

Vaccination can be given starting at age 9 years. ACIP also recommends vaccination for females through age 26 years and for males through age 21 years who were not adequately vaccinated previously. Males aged 22 through 26 years may be vaccinated. (See also: Special populations, Medical conditions)

Dosing schedules. For persons initiating vaccination before their 15th birthday, the recommended immunization schedule is 2 doses of HPV vaccine. The second dose should be administered 6–12 months after the first dose (0, 6–12 month schedule)^{††} (Table).

For persons initiating vaccination on or after their 15th birthday, the recommended immunization schedule is 3 doses of HPV vaccine. The second dose should be administered 1–2 months after the first dose, and the third dose should be administered 6 months after the first dose (0, 1–2, 6 month schedule)^{§§} (Table).

Persons vaccinated previously. Persons who initiated vaccination with 9vHPV, 4vHPV, or 2vHPV before their 15th birthday, and received 2 doses of any HPV vaccine at the recommended dosing schedule (0, 6–12 months), or 3 doses of any HPV vaccine at the recommended dosing schedule (0, 1–2, 6 months), are considered adequately vaccinated.

Persons who initiated vaccination with 9vHPV, 4vHPV, or 2vHPV on or after their 15th birthday, and received 3 doses of any HPV vaccine at the recommended dosing schedule, are considered adequately vaccinated.

9vHPV may be used to continue or complete a vaccination series started with 4vHPV or 2vHPV.

For persons who have been adequately vaccinated with 2vHPV or 4vHPV, there is no ACIP recommendation regarding additional vaccination with 9vHPV.

Interrupted schedules. If the vaccination schedule is interrupted, the series does not need to be restarted. The number of recommended doses is based on age at administration of the first dose.

Special populations. For children with a history of sexual abuse or assault, ACIP recommends routine HPV vaccination beginning at age 9 years.

For men who have sex with men,^{¶¶} ACIP recommends routine HPV vaccination as for all males, and vaccination through age 26 years for those who were not adequately vaccinated previously.

For transgender persons, ACIP recommends routine HPV vaccination as for all adolescents, and vaccination through age 26 years for those who were not adequately vaccinated previously.

Medical conditions. ACIP recommends vaccination with 3 doses of HPV vaccine (0, 1–2, 6 months) for females and males aged 9 through 26 years with primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity,^{***} such as B lymphocyte antibody deficiencies, T lymphocyte complete or partial defects, HIV infection, malignant neoplasms, transplantation, autoimmune disease, or immunosuppressive therapy, because immune response to vaccination might be attenuated (Table) (↗).

Contraindications and precautions. Contraindications and precautions, including those related to pregnancy, are unchanged from previous recommendations (1,2). Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (<https://vaers.hhs.gov> (<https://vaers.hhs.gov>)).

Acknowledgments

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Members of the Advisory Committee on Immunization Practices (ACIP) (member roster for July 2016–June 2017 is available online at <https://www.cdc.gov/vaccines/acip/committee/members-archive.html> (<https://www.cdc.gov/vaccines/acip/committee/members-archive.html>)); ACIP HPV Vaccines Work Group: Jorge E. Arana, MD, Atlanta, Georgia; Joseph Bocchini, MD, Shreveport, Louisiana; Harrell Chesson, PhD, Atlanta, Georgia; Tamera Coyne-Beasley, MD, Chapel Hill, North Carolina; C. Robinette Curtis, MD, Atlanta, Georgia; Carolyn D. Deal, PhD, Bethesda, Maryland; Shelley Deeks, MD, Toronto, Ontario, Canada; John Douglas, MD, Greenwood Village, Colorado; Linda Eckert, MD, Seattle, Washington; Sandra Adamson Fryhofer, MD, Atlanta, Georgia; Julianne Gee, MPH, Atlanta, Georgia; Bruce G. Gellin, MD, Washington, DC; Samuel Katz, MD, Durham, North Carolina; Alison Kempe, MD, Denver, Colorado (*Chair*); Aimée R. Kreimer, PhD, Bethesda, Maryland; Joohee Lee, MD, Silver Spring, Maryland; Lauri E. Markowitz, MD, Atlanta, Georgia (*CDC Lead*); Elissa Meites, MD, Atlanta, Georgia; Amy B. Middleman, MD, Oklahoma City, Oklahoma; Chris Nyquist, MD, Denver, Colorado; Sean O’Leary, MD, Aurora, Colorado; Sara E. Oliver, MD, Atlanta, Georgia; Cynthia Pellegrini, Washington, DC; Jeff Roberts, MD, Rockville, Maryland; José R. Romero, MD, Little Rock, Arkansas; Jeanne Santoli, MD, Atlanta, Georgia; Mona Saraiya, MD, Atlanta, Georgia; Debbie Saslow, PhD, Atlanta, Georgia;

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* No primary data on special populations or medical conditions, including immunocompromising conditions, [Top](#) were available for 2-dose intervals and age ranges specified.

† No primary data on other important and critical outcomes, including genital warts, precancers, oropharyngeal cancer, anal cancer, cervical cancer, vaginal/vulvar cancer, and penile cancer, were available for 2-dose intervals and age ranges specified.

[§] Studies were excluded when 2-dose interval was not ≥ 5 months.

[¶] Twelve votes to none, with one recusal.

** In studies conducted in the setting of a 3-dose HPV vaccine recommendation or policy, many 2-dose recipients received HPV vaccine doses at a 1–2 month interval; in addition, 2-dose recipients differed from 3-dose recipients in ways that suggested differences in HPV exposure.

†† In a 2-dose schedule of HPV vaccine, the minimum interval between the first and second doses is 5 months. If the second dose is administered after a shorter interval, a third dose should be administered a minimum of 12 weeks after the second dose and a minimum of 5 months after the first dose.

^{§§} In a 3-dose schedule of HPV vaccine, the minimum intervals are 4 weeks between the first and second doses, 12 weeks between the second and third doses, and 5 months between the first and third doses. If a vaccine dose is administered after a shorter interval, it should be readministered after another minimum interval has elapsed since the most recent dose.

^{¶¶} Including men who identify as gay or bisexual, or who intend to have sex with men.

*** The recommendation for a 3-dose schedule of HPV vaccine does not apply to children aged < 15 years with asplenia, asthma, chronic granulomatous disease, chronic liver disease, chronic lung disease, chronic renal disease, central nervous system anatomic barrier defects (e.g., cochlear implant), complement deficiency, diabetes, heart disease, or sickle cell disease.

References

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TABLE. Recommended number of doses and intervals for human papillomavirus (HPV) vaccine, by age at series initiation and medical conditions – United States, 2016

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Population	Recommended number of HPV vaccine doses	Recommended interval between doses
Persons initiating HPV vaccination at ages 9 through 14 years,* except immunocompromised persons†	2	0, 6–12 months [§]
Persons initiating HPV vaccination at ages 15 through 26 years [¶] and immunocompromised persons [†] initiating HPV vaccination at ages 9 through 26 years	3	0, 1–2, 6 months**

*ACIP recommends routine HPV vaccination for adolescents at age 11 or 12 years; vaccination may be given starting at age 9 years.

† Persons with primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity (see also: Medical conditions)

§ In a 2-dose schedule of HPV vaccine, the minimum interval between the first and second doses is 5 months.

¶ For persons who were not adequately vaccinated previously, ACIP recommends vaccination for females through age 26 years and for males through age 21 years; males ages 22 through 26 years may be vaccinated. Vaccination is recommended for some persons aged 22 through 26 years; see Medical conditions and Special populations.

** In a 3-dose schedule of HPV vaccine, the minimum intervals are 4 weeks between the first and second doses, 12 weeks between the second and third doses, and 5 months between the first and third doses.

Recommendations for use of vaccines in children, adolescents and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for use of vaccines in children and adolescents are

harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG). Recommendations for routine use of vaccines in adults are harmonized with recommendations of AAFP, ACOG, and the American College of Physicians (ACP). ACIP recommendations approved by the CDC Director become agency guidelines on the date published in the *Morbidity and Mortality Weekly Report (MMWR)*. Additional information about ACIP is available at <https://www.cdc.gov/vaccines/acip> (<https://www.cdc.gov/vaccines/acip>).

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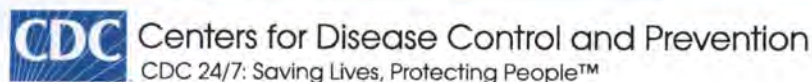
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Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons
 – Advisory Committee on Immunization Practices, 2016

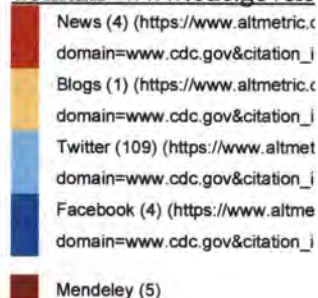
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At its
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meeting, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of meningococcal conjugate vaccine (serogroups A, C, W, and Y; including MenACWY-D [Menactra, Sanofi Pasteur] or MenACWY-CRM [Menveo, GlaxoSmithKline]) for persons aged ≥ 2 months with human immunodeficiency virus (HIV) infection. ACIP has previously recommended routine vaccination of persons aged ≥ 2 months who have certain medical conditions that increase risk for meningococcal disease (1), including persons who have persistent (e.g., genetic) deficiencies in the complement pathway (e.g., C3, properdin, Factor D, Factor H, or C5–C9); persons receiving eculizumab (Soliris, Alexion Pharmaceuticals) for treatment of atypical hemolytic uremic syndrome or paroxysmal nocturnal hemoglobinuria (because the drug binds C5 and inhibits the terminal complement pathway); and persons with functional or anatomic asplenia (including persons with sickle cell disease). Routine vaccination with meningococcal conjugate vaccine is also recommended for all healthy adolescents in the United States (2). This report summarizes the evidence considered by ACIP in recommending vaccination for HIV-infected persons, and provides recommendations and guidance for use of meningococcal conjugate vaccines (serogroups A, C, W, and Y) among HIV-infected persons aged ≥ 2 months; the majority of meningococcal disease among HIV-infected persons is caused by these four serogroups.

Summary

What is currently recommended?

The Advisory Committee on Immunization Practices (ACIP) currently recommends routine vaccination with meningococcal conjugate vaccine for all adolescents and for certain groups of persons at increased risk for meningococcal disease: persons who have persistent

Methods

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The ACIP Meningococcal Vaccines Work Group reviewed the immunogenicity and safety data from two studies of MenACWY-D in HIV-infected persons (2-4) during monthly teleconferences. No studies of immunogenicity or safety of MenACWY-CRM in HIV-infected persons are available. According to a nonsystematic literature search of PubMed using the search terms "meningococcal conjugate vaccine," "quadrivalent," and "HIV," and consultation with the manufacturers, these two studies represent all known evidence for the immunogenicity and safety of these vaccines in HIV-infected persons. The work group also evaluated the evidence and unpublished surveillance data regarding meningococcal disease epidemiology among HIV-infected persons in the United States and a cost-effectiveness analysis of routine vaccination of HIV-infected persons. The cost-effectiveness analysis of routine vaccination versus no vaccination of HIV-infected persons was conducted assuming an initial vaccine efficacy of 75% (range = 37%–91%) for persons with a high CD4 count and 37% (range = 24%–60%) for persons with a low CD4 count based on the immunogenicity data reported in the literature for MenACWY-D (2-4). A summary of the data reviewed and work group discussions was presented to ACIP; recommendations for use of meningococcal conjugate vaccines among HIV-infected persons aged ≥ 2 months were approved by ACIP at its June 22, 2016 meeting (detailed meeting minutes are available at <http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html> (<http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>)).

CDC vaccine recommendations are developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework (<http://www.cdc.gov/vaccines/acip/recs/grade/index.html> (<http://www.cdc.gov/vaccines/acip/recs/grade/index.html>)). The type and quality of available evidence supporting the use of meningococcal conjugate vaccines among HIV-infected persons aged ≥ 2 months were evaluated using GRADE. There is no available evidence for safety or effectiveness of these vaccines in HIV-infected persons aged < 2 years or ≥ 25 years.

Meningococcal Disease in HIV-Infected Persons

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Surveillance data for cases of meningococcal disease among HIV-infected persons in the United States are limited. The HIV status of patients with meningococcal disease is routinely captured in Active Bacterial Core surveillance (ABCs), an active population-based and laboratory-based surveillance system that operates in 10 sites, representing a population of approximately 43 million persons, or 14% of the U.S. population (5). However, the HIV status of patients with meningococcal disease is not reported through the National Notifiable Diseases Surveillance System (NNDSS), a passive surveillance system that operates in all U.S. states and territories. During 1995–2014, a total of 62 cases of meningococcal disease among HIV-infected persons were reported to ABCs; these cases represent 2% of the 3,951 meningococcal disease cases reported to ABCs during that period (CDC, unpublished

complement component deficiencies; persons who have anatomic or functional asplenia; microbiologists who routinely are exposed to isolates of *Neisseria meningitidis*; persons identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup A, C, W, or Y; military recruits; first-year college students living in residence halls; and persons who travel to or reside in areas in which meningococcal disease is hyperendemic or epidemic. In addition, ACIP recommends routine vaccination with serogroup B meningococcal (MenB) vaccine for persons who have persistent complement component deficiencies; persons who have anatomic

data, 2016). Thirteen (21%) cases were serogroup B, 23 (37%) were serogroup C, three (5%) were serogroup W, 17 (27%) were serogroup Y, and six (10%) were other/unknown serogroups (CDC, unpublished data, 2016). The majority (92%) of cases of meningococcal disease among HIV-infected persons occurred in adults aged 20 through 59 years.

Although surveillance data for cases of meningococcal disease among HIV-infected persons are limited in the United States, a growing body of evidence demonstrates an increased risk for meningococcal disease among HIV-infected persons. In studies from South Africa, the United States, and the United Kingdom, the incidence of meningococcal disease in HIV-infected persons ranged from 3.4 to 6.6 per 100,000 (relative risk = 5–13 compared with HIV-uninfected persons) (Table 1) (6–9). Among HIV-infected persons, a low CD4 count or high viral load were associated with an increased risk (7). Similar increased risk for meningococcal disease was observed for both males and females with HIV infection (7,9).

Data on the case-fatality ratio of meningococcal disease in HIV-infected persons vary: in the South Africa study, the case-fatality ratio among HIV-infected patients was 20%, compared with 11% among patients who did not have HIV infection (6). However, in the most recent studies from New York City and the United Kingdom, the meningococcal disease case fatality ratio observed among HIV-infected patients was lower than that among HIV-uninfected patients (7,8).

MenACWY-D Immunogenicity and Safety in HIV-Infected Persons [^ Top](#)

The immunogenicity and safety of MenACWY-D in 324 HIV-infected adolescents and young adults aged 11 through 24 years were evaluated in an open-label trial with a randomized second dose component (2,4). At study entry, participants received 1 dose of MenACWY-D. At 24 weeks, participants with CD4 percentage (the percentage of total lymphocytes that are CD4 cells) (CD4%) $\geq 15\%$ were randomized to receive or not receive a second dose of MenACWY-D; all participants with CD4% $< 15\%$ received a second dose. Vaccine effectiveness was inferred from serum bactericidal antibodies, measured using a serum bactericidal assay with a rabbit complement source (rSBA). Rates of seroresponse (proportion of subjects with a \geq fourfold rise in rSBA titer compared with the baseline titer) against each meningococcal serogroup (A, C, W, Y), geometric mean titers (GMT), and the percentage of subjects with rSBA at or above a predefined titer ($\geq 1:128$) were determined from sera obtained at study entry and at weeks 4, 24, 28, and 72. Adverse events (AEs) were assessed for 6 weeks after each MenACWY-D dose through active follow-up (2,4).

Among participants with CD4% $\geq 15\%$ who received 1 vaccine dose, the proportions of participants with rSBA titers $\geq 1:128$ at 4, 28, and 72 weeks were 65%, 31%, and 21%, respectively, against serogroup C, and 83%, 75%, 63%, respectively, against serogroup Y (2). Among participants with CD4% $\geq 15\%$ who received 2 doses (at 0, 24

or functional asplenia; microbiologists who routinely are exposed to isolates of *N. meningitidis*; and persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak.

Why are the recommendations being modified now?

A growing body of evidence supports an increased risk for meningococcal disease in human immunodeficiency virus (HIV)-infected persons. The evidence supporting the use of meningococcal conjugate vaccines in HIV-infected persons was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework.

What are the new recommendations?

All HIV-infected persons aged ≥ 2 months should

weeks), the proportions of participants with rSBA titers $\geq 1:128$ at 4, 28, and 72 weeks were 59%, 64%, and 35%, respectively, against serogroup C; and 73%, 83%, 71%, respectively, against serogroup Y (2). Among participants with CD4% $< 15\%$, all of whom received 2 doses (at 0, 24 weeks), the proportions of participants with rSBA titers $\geq 1:128$ at 4, 28, and 72 weeks were 22%, 22%, and 6%, respectively, against serogroup C, and 30%, 30%, 28%, respectively, against serogroup Y (2). A serious AE was experienced by 2.2%–6.5% of participants through 6 weeks post-vaccination*; one serious AE (ocular pain) was judged to be related to MenACWY-D. Serious AE rates were inversely related to entry CD4%. Two deaths were reported, but both were determined to be unrelated to the vaccine (2,4).

The immunogenicity and safety of MenACWY-D in 59 HIV-infected children aged 2 through 10 years with CD4% $\geq 25\%$ was evaluated in an open label trial (3). Participants received MenACWY-D at study entry and at week 24. Vaccine effectiveness was inferred from serum bactericidal antibodies, measured using a serum bactericidal assay with rSBA. Rates of seroresponse (proportion of subjects with a \geq fourfold rise in post-vaccination rSBA titer compared with the baseline titer) against each meningococcal serogroup (A, C, W, Y), GMTs, and the percentage of subjects with rSBA at or above a predefined titer ($\geq 1:128$) were determined from sera obtained at entry and weeks 4, 24, 28, and 72. Study participants were assessed for AEs 6 weeks after each MenACWY-D dose (3).

The proportion of participants with rSBA titers $\geq 1:128$ after 1 dose (week 4) and 2 doses (week 28) of MenACWY-D were 96% and 96%, respectively, for serogroup A, 49% and 80%, respectively, for serogroup C, 98% and 100%, respectively, for serogroup W, and 90% and 98%, respectively, for serogroup Y (3). At week 72 the proportions of participants with rSBA titers $\geq 1:128$ were 80% for serogroup A, 45% for serogroup C, 95% for serogroup W, and 91% for serogroup Y (3). Overall, 5% of participants reported a serious AE; no AE was judged to be related to MenACWY-D (3).

Evidence supporting the use of meningococcal conjugate vaccines in HIV-infected persons was evaluated using the GRADE framework and was determined to be type 3 (low level of evidence) (Table 2). The recommendation was designated as Category A (recommended for all persons in an age-based or risk factor-based group) because of the epidemiologic data supporting an increase in risk for meningococcal disease among HIV-infected persons.

From a lifetime perspective, it is estimated that, compared with no vaccination, approximately 122 (95% confidence interval [CI] = 116–129) cases and 23 (CI = 18–29) deaths could be prevented, and 385 (CI = 230–458) quality-adjusted life years (QALYs) could be saved, at a mean cost per QALY of \$732,000 (CI = \$337,000–\$1,218,000) with a meningococcal conjugate vaccination program that includes a

routinely receive meningococcal conjugate vaccine; children aged < 2 years should be vaccinated using a multidose schedule. Persons aged ≥ 2 years with HIV who have not been previously vaccinated should receive a 2-dose primary series of meningococcal conjugate vaccine. Persons with HIV who have been previously vaccinated with meningococcal conjugate vaccine should receive a booster dose at the earliest opportunity (at least 8 weeks after the previous dose) and then continue to receive boosters 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, a booster should be

primary vaccination series followed by lifelong booster doses until age 70 years, targeting all currently HIV-infected persons aged ≥ 2 months in the United States (CDC, unpublished data, 2016).[†]

administered 5 years later and every 5 years thereafter throughout life.

Recommendations

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HIV-infected persons aged ≥ 2 months should routinely receive meningococcal conjugate vaccine (Table 3). HIV-infected children aged < 2 years should receive the vaccine in accordance with the age-appropriate, licensed, multidose schedule (1, 10). Persons aged ≥ 2 years with HIV infection who have not been previously vaccinated should receive a 2-dose primary series of MenACWY conjugate vaccine. Persons aged ≥ 2 years with HIV infection who have been previously vaccinated with 1 dose of meningococcal conjugate vaccine should receive a booster dose at the earliest opportunity, provided at least 8 weeks have elapsed since the previous dose, and then continue to receive boosters at the appropriate interval throughout life.⁵ The recommendations for children aged 2 months through 2 years and persons aged ≥ 25 years are based on expert opinion; the vaccine was not studied in HIV-infected persons in these age groups. On the basis of available data and expert opinion, either MenACWY-CRM or MenACWY-D may be used in HIV-infected persons.

The same vaccine product should be used for all doses. However, if the product used for previous doses is unknown or unavailable, the vaccination series may be completed with any age- and formulation-appropriate meningococcal conjugate vaccine. Although no data on interchangeability of meningococcal conjugate vaccines in HIV-infected persons are available, limited data from a postlicensure study in healthy adolescents suggests safety and immunogenicity of MenACWY-CRM are not adversely affected by prior immunization with MenACWY-D (1, 11).

ACIP recommends that HIV-infected infants aged 2 through 23 months receive MenACWY-CRM. HIV-infected children should not receive MenACWY-D before age 2 years, similar to the recommendation for children with functional or anatomic asplenia. Previously, children with functional or anatomic asplenia were recommended to receive 13-valent pneumococcal conjugate vaccine (PCV13) according to the normal schedule but to delay MenACWY-D vaccination until age 2 years because of immune interference (1, 12). Because MenACWY-CRM does not demonstrate immune interference with 7-valent pneumococcal conjugate vaccine (PCV7) after the 12-month dose (13-15), MenACWY-CRM can be administered concomitantly with PCV13.

In addition, new data suggest the potential for immunologic interference in the meningococcal human complement serum bactericidal assay (hSBA) responses when MenACWY-D is administered 30 days after Daptacel (diphtheria and tetanus toxoids and acellular pertussis vaccine [DTaP], Sanofi Pasteur) (16). In one study among children aged 4 through 6 years, the hSBA responses to all four meningococcal serogroups failed to meet noninferiority criteria when MenACWY-D was administered 30 days after Daptacel. In contrast, co-administration of MenACWY-D and Daptacel was not associated with reduced hSBA responses to all four meningococcal serogroups. The study objectives did not include evaluation of the potential for interference that other DTaP containing vaccines might have on meningococcal seroresponse rates (16). If MenACWY-D is to be administered to a child at increased risk for meningococcal disease, including children who are HIV-infected, it is recommended that MenACWY-D be given either before or concomitantly with DTaP.

MenACWY is recommended for HIV-infected persons aged ≥ 56 years because of the need for revaccination (i.e., booster doses). Meningococcal polysaccharide vaccine (MPSV4, Menomune, Sanofi Pasteur) is the only licensed meningococcal vaccine for adults aged ≥ 56 years; however, no data are available on use of MPSV4 in HIV-infected adults. For healthy adults who have received MenACWY previously, limited data demonstrate a higher antibody response after a subsequent dose of MenACWY compared with a subsequent dose of MPSV4 (1).

To date, no randomized, controlled clinical trials have been conducted to evaluate use of MenACWY vaccines in pregnant or lactating women. Pregnancy should not preclude indicated vaccination with MenACWY.

Precautions and Contraindications

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Before administering meningococcal conjugate vaccines, health care providers should consult the package insert for precautions, warnings, and contraindications (13,16). Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (<https://vaers.hhs.gov> (<https://vaers.hhs.gov>)).

Acknowledgments

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ACIP members (the membership roster for July 2015–June 2016 is available at

<http://www.cdc.gov/vaccines/acip/committee/members.html>

(<http://www.cdc.gov/vaccines/acip/committee/members.html>)); ACIP Meningococcal Vaccine Work Group.

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* Serious adverse events (AEs) defined as Guillain-Barré syndrome, death, and new grade 3 or higher AE according to the December 2004 Division of AIDS AE Grading Table. [^ Top](#)

† Unpublished data, ACIP meeting June 2016. Key model assumptions were presented at the June 2016 ACIP meeting. Methods described in Shepard CW, Ortega-Sanchez IR, Scott RD 2nd, Rosenstein NE. Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States. *Pediatrics* 2005;115:1220–32.

[§] 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, a booster dose should be administered 5 years later.

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TABLE 1. Evidence of increased risk for meningococcal disease among HIV-infected persons compared with HIV-uninfected persons – seven study populations, 1996–2013

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Period	Study site	Age group	No. of cases*	Increase in meningococcal disease rate among HIV-infected compared with HIV-uninfected persons	Serogroups
1996–1999	Australia [†]	All ages	60	5-fold	B, C
1990–2000	London [§]	All ages	2,900	14-fold	B, C
1988–1993	Atlanta, Georgia [¶]	18–45 years	132	24-fold	B, C, Y
2003–2007	South Africa**	All ages	504	11-fold	A, B, C, W, Y
2000–2008	United States ABCs ^{††}	25–64 years	491	13-fold	B, C, W, Y
2000–2011	New York City ^{§§}	15–64 years	265	10-fold	C, Y
2011–2013	United Kingdom ^{¶¶}	All ages	2,353	5-fold	A, B, C, W, Y

Abbreviations: ABCs = Active Bacterial Core surveillance; HIV = human immunodeficiency virus.

* Total number of meningococcal disease cases reported during the study period regardless of HIV infection status

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^{**} Cohen C, Singh E, Wu HM, et al. Increased incidence of meningococcal disease in HIV-infected individuals associated with higher case-fatality ratios in South Africa. *AIDS* 2010;24:1351-60.

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^{§§} Miller L, Arakaki L, Ramautar A, et al. Elevated risk for invasive meningococcal disease among persons with HIV. *Ann Intern Med* 2014;160:30-7.

^{¶¶¶} Simmons RD, Kirwan P, Beebejaun K, et al. Risk of invasive meningococcal disease in children and adults with HIV in England: a population-based cohort study. *BMC Med* 2015;13:297.

TABLE 2. Summary of evidence for meningococcal conjugate vaccination of HIV-infected persons aged ≥2 months using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE)* framework – United States

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Outcome	Evidence type [†]
Benefits	
Short-term immunogenicity 4 weeks after 1 dose (week 4)	3
Short-term immunogenicity 4 weeks after 2 doses (week 28)	3
Persistence of immunogenicity 48 weeks after 2 doses (week 72)	3
Harms	
Serious adverse events (after any dose)	4

* <http://www.cdc.gov/vaccines/acip/recs/grade/index.html> (<http://www.cdc.gov/vaccines/acip/recs/grade/index.html>).

[†] Evidence type: 1 = highest level of evidence; 2 = high level of evidence; 3 = low level of evidence; 4 = lowest level of evidence.

TABLE 3. Recommended meningococcal conjugate vaccination schedule and intervals for HIV-infected persons – Advisory Committee on Immunization Practices, United States, 2016

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Age group	Recommended schedule and intervals
Primary vaccination	
<2 years	4 doses of MenACWY-CRM (Menveo) at ages 2, 4, 6, and 12–15 months*
	2 doses of MenACWY-D (Menactra) at age 9–23 months, 12 weeks apart ^{†,§,¶}

Age group	Recommended schedule and intervals
	2 doses of MenACWY-D or MenACWY-CRM, 8–12 weeks apart ^{†,‡}
Booster dose	
<7 years at previous dose	Additional dose of MenACWY-D or MenACWY-CRM 3 years after primary series; boosters should be repeated every 5 years thereafter**
≥7 years at previous dose	Additional dose of MenACWY-D or MenACWY-CRM 5 years after primary series; boosters should be repeated every 5 years thereafter

* MenACWY-CRM is licensed for use in persons aged 2 months through 55 years. Children aged 7 through 23 months who initiate vaccination with MenACWY-CRM should receive 2 doses 12 weeks apart, with the second dose administered after the first birthday. Source: Food and Drug Administration. Menveo U.S. package insert. <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf> (<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf>) .

† MenACWY-D is licensed for use in persons aged 9 months through 55 years. Source: Food and Drug Administration (FDA). Menactra U.S. package insert. <http://www.fda.gov/downloads/BiologicBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf> (<http://www.fda.gov/downloads/BiologicBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf>) .

‡ If MenACWY-D is used, it should be administered at least 4 weeks after completion of all pneumococcal conjugate vaccine doses.

¶ If MenACWY-D is to be administered to a child at increased risk for meningococcal disease, including children with HIV infection, it is recommended that MenACWY-D be given either before DTaP or concomitantly with DTaP.

** If the most recent dose was received before age 7 years, a booster dose should be administered 3 years later.

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

Suggested citation for this article: MacNeil JR, Rubin LG, Patton M, Ortega-Sanchez IR, Martin SW. Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons – Advisory Committee on Immunization Practices, 2016. MMWR Morb Mortal Wkly Rep 2016;65:1189–1194. DOI: <http://dx.doi.org/10.15585/mmwr.mm6543a3> (<http://dx.doi.org/10.15585/mmwr.mm6543a3>) .

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Page last reviewed: November 3, 2016

Page last updated: November 3, 2016

Content source: Centers for Disease Control and Prevention (<http://www.cdc.gov/>)



California Tuberculosis Risk Assessment Pediatrics



- Use this tool to identify asymptomatic **children** for latent TB infection (LTBI) testing.
- Re-testing should only be done in persons who previously tested negative, and have **new** risk factors since the last assessment.
If initial negative screening test occurred prior to 6 months of age, repeat testing should occur at age 6 months or older
- For children with TB symptoms or abnormal chest x-ray consistent with active TB disease → Evaluate for active TB disease
Evaluate for active TB disease with a chest x-ray, symptom screen, and if indicated, sputum AFB smears, cultures and nucleic acid amplification testing. A negative tuberculin skin test or interferon gamma release assay does not rule out active TB disease.

Check appropriate risk factor boxes below.

LTBI testing is recommended if any of the 4 boxes below are checked.

If LTBI test result is positive and active TB disease is ruled out, LTBI treatment is recommended.

Foreign-born person from a country with an elevated TB rate

- Includes any country other than the United States, Canada, Australia, New Zealand, or a country in western or northern Europe
- Interferon Gamma Release Assay is preferred over Tuberculin Skin Test for foreign-born persons ≥ 2 years old

Immunosuppression, current or planned

HIV infection, organ transplant recipient, treated with TNF-alpha antagonist (e.g., infliximab, etanercept, others), steroids (equivalent of prednisone ≥ 2 mg/kg/day, or ≥ 15 mg/day for ≥ 2 weeks) or other immunosuppressive medication

Close contact to someone with infectious TB disease at any time

Foreign travel or residence of ≥ 1 month consecutively in a country with an elevated TB rate

- Any country other than the United States, Canada, Australia, New Zealand, or a country in Western or Northern Europe

See the [Pediatric TB Risk Assessment User Guide](#) for more information about using this tool.

Provider: _____

Assessment Date: _____

Patient Name: _____

Date of Birth: _____

(Place sticker here if applicable)





California Pediatric TB Risk Assessment User Guide



Avoid testing persons at low risk

Routine testing of low risk populations is not recommended and may result in unnecessary evaluations and treatment because of falsely positive test results.

Local recommendations, mandated testing and other risk factors

Several risk factors for TB that have been used to select children for TB screening historically or in mandated programs are not included among the 5 components of this risk assessment. This is purposeful in order to focus testing on children at highest risk. However, certain populations may be mandated for testing by statute, regulation, or policy. This risk assessment does not supersede any mandated testing. Testing can also be considered in children with frequent exposure to adults at high risk of TB infection, such as those with extensive foreign travel in areas with high TB rates. Local recommendations should also be considered in testing decisions. Local TB control programs and clinics can customize this risk assessment according to local recommendations. **Providers should check with local TB control programs for local recommendations.**

Decision to test is a decision to treat

Because testing of persons at low risk of TB infection should not be done, persons that test positive for LTBI should generally be treated once active TB disease has been ruled out with a chest radiograph and, if indicated, sputum smears, cultures, and nucleic acid amplification (NAAT). However, clinicians should not be compelled to treat low risk persons with a positive test for LTBI.

When to repeat a risk assessment and testing

Risk assessments should be completed on new patients, patients thought to have new potential exposures to TB since last assessment, and during routine pediatric well-child visits. Repeat risk assessments should be based on the activities and risk factors specific to the child. High-risk children who volunteer or work in health care settings might require annual testing and should be considered separately. Re-testing should only be done in persons who previously tested negative and have new risk factors since the last assessment (unless they were <6 months of age at the time of testing). In general new risk factors would include new close contact with an infectious TB case or new immunosuppression, but could also include foreign travel.

Immunosuppression

The exact level of immunosuppression that predisposes to increased risk for TB progression is unknown. The threshold of steroid dose and duration used here are based on data in adults and in accordance with ACIP recommendations for live vaccines in children receiving immunosuppression.

Foreign travel or residence

Travel or residence in countries with an elevated TB rate may be a risk for TB exposure in certain circumstances (e.g., extended duration, likely contact with infectious TB cases, high TB prevalence of TB in travel location, non-tourist travel). The duration of at least 1 consecutive month to trigger testing is intended to identify travel most likely to involve TB exposure. TB screening tests can be falsely negative within the 8 weeks after exposure, so are best obtained 8 weeks after a child's return.

IGRA preference in foreign-born children ≥2 years old

Because IGRA has increased specificity for TB infection in children vaccinated with BCG, IGRA is preferred over the tuberculin skin test for foreign-born children ≥2 years of age. IGRAs can be used in children <2 years of age, however, there is an overall lack of data in this age group, which complicates interpretation of test results. In BCG vaccinated immunocompetent children with a positive TST, it may be appropriate to confirm a positive TST with an IGRA. If IGRA is not done the TST result should be considered the definitive result.

Negative test for LTBI does not rule out active TB

It is important to remember that a negative TST or IGRA result does not rule out active TB. A negative TST or IGRA in a patient with active TB can be a sign of extensive disease.

Emphasis on short course for treatment of LTBI

Shorter regimens for treating latent TB infection have been shown to be as effective as 9 months of isoniazid, and are more likely to be completed. Use of these shorter regimens is preferred in most patients, although the 12 week regimen is not recommended for children <2 years of age, children on antiretroviral medications, or pregnant adolescents. Drug-drug interactions and contact to drug resistant TB are other contraindications for shorter regimens.

Medication	Frequency	Duration
Rifampin	Daily	4 months
Isoniazid + rifapentine*	Weekly	12 weeks**

*The CDC currently recommends DOT for this regimen; however, preliminary data suggests that SAT is noninferior to DOT in the United States. Many clinicians are using SAT or modified DOT.

**11-12 doses in 16 weeks required for completion

CDPH 3HP Fact Sheet: available on the CDPH TBCB website: <http://www.cdph.ca.gov/programs/tb>

Refusal of recommended LTBI treatment

Refusal should be documented. Recommendations for treatment should be made at future encounters with medical services. If treatment is later accepted, TB disease should be excluded and CXR repeated if it has been more than 3 months from the initial evaluation.

Symptoms that should trigger evaluation for active TB

Patients with any of the following symptoms that are otherwise unexplained should be evaluated for active TB: cough for more than 2-3 weeks, fevers, night sweats, weight loss, hemoptysis or excessive fatigue.

ACIP= Advisory Committee on Immunization Practices; LTBI=latent TB infection; IGRA= Interferon gamma release assay (e.g., QuantiFERON-TB Gold, T-SPOT TB); BCG=Bacillus Calmette-Guérin; TST= tuberculin skin test; DOT=Directly observed therapy; CXR=chest x-ray



California Tuberculosis Risk Assessment Adults



- Use this tool to identify asymptomatic **adults** for latent TB infection (LTBI) testing.
- Re-testing should only be done in persons who previously tested negative, and have new risk factors since the last assessment.
- For TB symptoms or abnormal chest x-ray consistent with active TB disease → Evaluate for active TB disease
Evaluate for active TB disease with a chest x-ray, symptom screen, and if indicated, sputum AFB smears, cultures and nucleic acid amplification testing. A negative tuberculin skin test or interferon gamma release assay does not rule out active TB disease.

Check appropriate risk factor boxes below.

LTBI testing is recommended if any of the 3 boxes below are checked.

If LTBI test result is positive and active TB disease is ruled out, LTBI treatment is recommended.

Foreign-born person from a country with an elevated TB rate

- Includes any country other than the United States, Canada, Australia, New Zealand, or a country in western or northern Europe
- If resources require prioritization within this group, **prioritize** patients with at least one medical risk for progression (see User Guide for list)
- Interferon Gamma Release Assay is preferred over Tuberculin Skin Test for foreign-born persons

Immunosuppression, current or planned

HIV infection, organ transplant recipient, treated with TNF-alpha antagonist (e.g., infliximab, etanercept, others), steroids (equivalent of prednisone ≥ 15 mg/day for ≥ 1 month) or other immunosuppressive medication

Close contact to someone with infectious TB disease at any time

See the [California Adult Tuberculosis Risk Assessment User Guide](#) for more information about using this tool.

Provider: _____

Patient Name: _____

Assessment Date: _____

Date of Birth: _____

(Place sticker here if applicable)



To ensure you have the most current version, go to the PROVIDERS page at www.ctca.org

Oct 2016

California Adult TB Risk Assessment User Guide

Avoid testing persons at low risk

Routine testing of low risk populations is not recommended and may result in unnecessary evaluations and treatment because of falsely positive test results.

Prioritize persons with risks for progression

If health system resources do not allow for testing of all foreign-born persons from a country with an elevated TB rate, prioritize patients with at least one of the following medical risks for progression:

- diabetes mellitus
- smoker within past 1 year
- end stage renal disease
- leukemia or lymphoma
- silicosis
- cancer of head or neck
- intestinal bypass/gastrectomy
- chronic malabsorption
- body mass index ≤ 20
- history of chest x-ray findings suggestive of previous or inactive TB (no prior treatment). Includes fibrosis or non-calcified nodules, but does not include solitary calcified nodule or isolated pleural thickening. In addition to LTBI testing, evaluate for active TB disease.

United States Preventive Services Task Force

The USPSTF has recommended testing persons born-in or former residents of a country with an elevated tuberculosis rate and persons who live in or have lived in high-risk congregate settings such as homeless shelters and correctional facilities. Because the increased risk of exposure to TB in congregate settings varies substantially by facility and local health jurisdiction, clinicians are encouraged to follow local recommendations when considering testing among persons from these congregate settings. USPSTF did not review data supporting testing among close contacts to infectious TB nor among persons who are immunosuppressed because these persons are recommended to be screened by public health programs or by clinical standard of care.

Local recommendations

Local recommendations and mandates should also be considered in testing decisions. Local TB control programs can customize this risk assessment according to local recommendations. **Providers should check with local TB control programs for local recommendations.**

Directory of TB Control Programs:

http://www.ctca.org/index.cfm?fuseaction=page&page_id=5071

Mandated testing and other risk factors

Several risk factors for TB that have been used to select patients for TB screening historically or in mandated programs are not included among the 3 components of this risk assessment. This is purposeful in order to focus testing on patients at highest risk. However, certain populations may be mandated for testing by statute, regulation, or policy. This risk assessment does not supersede any mandated testing. Examples of these populations include: healthcare workers, residents or employees of correctional institutions, substance abuse treatment facilities, homeless shelters, and others.

Age as a factor

Age (among adults) is not considered in this risk assessment. However, younger adults have more years of expected life during which progression from latent infection to active TB disease could develop. Some programs or clinicians may additionally prioritize testing of younger foreign-born persons when all foreign-born are not tested. An upper age limit for testing has not been established but could be appropriate depending on individual patient TB risks, comorbidities, and life expectancy.

Children

This risk assessment tool is intended for adults. A risk assessment tool created for use in California for children is available here: <http://www.cdph.ca.gov/programs/tb/Documents/TBCB-CA-Pediatric-TB-Risk-Assessment.pdf>

Foreign travel

Travel to countries with an elevated TB rate may be a risk for TB exposure in certain circumstances (e.g., extended duration, likely contact with infectious TB cases, high TB prevalence of TB in travel location, non-tourist travel).



California Adult TB Risk Assessment User Guide — *continued*

When to repeat a test

Re-testing should only be done in persons who previously tested negative, and have new risk factors since the last assessment. In general, this would include new close contact with an infectious TB case or new immunosuppression, but could also include foreign travel in certain circumstances.

When to repeat a risk assessment

The risk assessment should be administered at least once. Persons can be screened for new risk factors at subsequent preventive health visits.

IGRA preference in BCG vaccinated

Because IGRA has increased specificity for TB infection in persons vaccinated with BCG, IGRA is preferred over the TST in these persons. Most persons born outside the United States have been vaccinated with BCG.

Previous or inactive tuberculosis

Chest radiograph findings consistent with previous or inactive TB include fibrosis or non-calcified nodules, but do not include a solitary calcified nodule or isolated pleural thickening. Persons with a previous chest radiograph showing findings consistent with previous or inactive TB should be tested for LTBI. In addition to LTBI testing, evaluate for active TB disease.

Negative test for LTBI does not rule out active TB disease

It is important to remember that a negative TST or IGRA result does not rule out active TB. In fact, a negative TST or IGRA in a patient with active TB can be a sign of extensive disease and poor outcome.

Symptoms that should trigger evaluation for active TB disease

Patients with any of the following symptoms that are otherwise unexplained should be evaluated for active TB disease: cough for more than 2-3 weeks, fevers, night sweats, weight loss, hemoptysis.

Decision to test is a decision to treat

Because testing of persons at low risk of LTBI should not be done, persons that test positive for LTBI should generally be treated once active TB disease has been ruled out with a chest radiograph and, if indicated, sputum smears, cultures, and nucleic acid amplification testing. However, clinicians should not be compelled to treat low risk persons with a positive test for LTBI.

Emphasis on short course for treatment of LTBI

Shorter regimens for treating LTBI have been shown to be more likely to be completed and the 3 month 12-dose regimen has been shown to be as effective as 9 months of isoniazid. Use of these shorter regimens is preferred in most patients. Drug-drug interactions and contact to drug resistant TB are frequent reasons these regimens cannot be used.

Shorter duration LTBI treatment regimens

Medication	Frequency	Duration
Rifampin	Daily	4 months
Isoniazid + rifapentine*	Weekly	12 weeks

*The CDC currently recommends DOT for this regimen, however, preliminary data suggests that SAT is noninferior to DOT in the United States. Many clinicians are using SAT or modified DOT.

CDPH 12-dose isoniazid + rifapentine regimen Fact Sheet:

<http://cdph.ca.gov/programs/tb/Documents/TBCB-INH-RIF-LTBI-fact-sheet.pdf>

DOT = Directly observed therapy; SAT = Self-administered therapy; IGRA = Interferon gamma release assay (e.g., QuantiFERON-TB Gold, T-SPOT.TB); BCG = Bacillus Calmette-Guérin; TST = tuberculin skin test; LTBI = latent TB infection

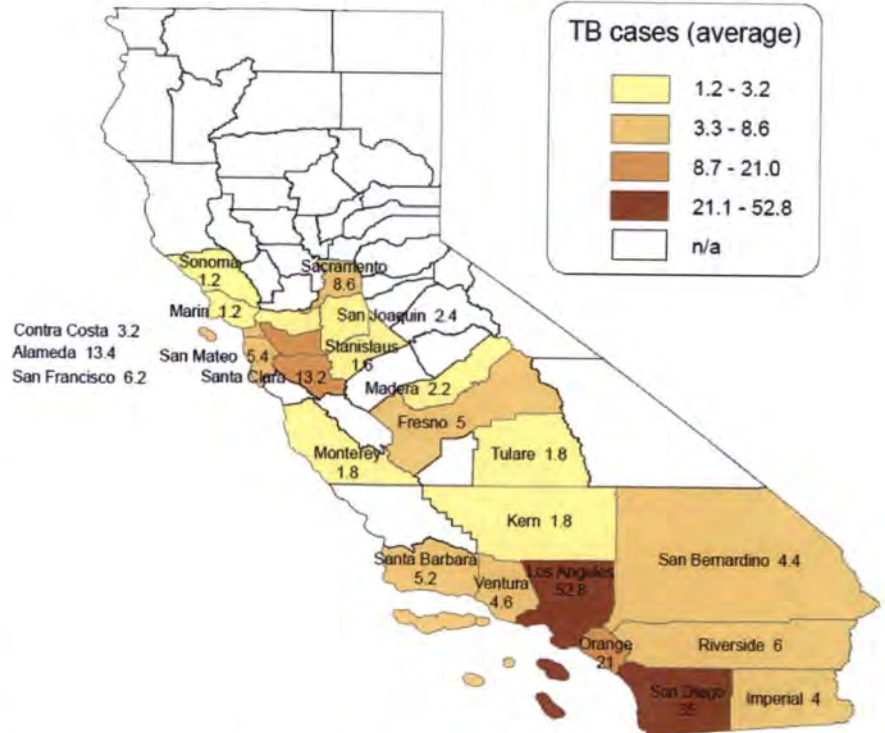
Prevent Tuberculosis in Teenagers and Young Adults in California

FACT SHEET

Average annual TB cases among persons 11-24 years old California 2010-2014

TB cases in Californian teens and young adults

- **244** TB cases in teens 11-17 years of age in 2010-2014
- **828** TB cases in young adults 18-24 years of age in 2010-2014
- Children and young adults of Hispanic ethnicity, Asian race, foreign birth and those with parents born outside of the U.S. are disproportionately affected by tuberculosis



Impact of TB on middle schools and high schools in California

Teens with TB infection

- In California approximately **33,000** teens 11-17 years and **95,000** young adults 18-24 have TB infection
- TB infection can be treated and prevented from turning into disease if identified

Public Health Actions

- Ensure risk-based TB testing for TB infection of adolescents as recommended by the American Academy of Pediatrics
- Interferon Gamma Release Assays are the preferred diagnostic test for foreign born individuals who have received BCG vaccination
- Treat all teens and young adults found to have latent tuberculosis infection and consider short course regimens such as 12 weekly doses of isoniazid and rifapentine or 4 months of daily rifampin
- Identify teens exposed to tuberculosis in schools and treat if infected

Average of 1 student per week with TB disease in a California high school or middle school

- Average of >100 exposed students for each TB case identified
- Resource intensive investigations
- Infection and disease requiring treatment