ADVISORY COMMISSION ON CHILDHOOD VACCINES
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March 7, 2013

- **CDC MMWR,** "Infant Meningococcal Vaccination: Advisory Committee on Immunization Practices (ACIP) Recommendations and Rationale" 7.5

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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

DRAFT February 5, 2013

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

Teleconference Only

March 7, 2013
(10:00 am – 5:00 pm Eastern Daylight Time)
Dial: 1-800-369-3104
Passcode: ACCV

Thursday, March 7, 2013

Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Mr. David King, Chair
10:10 AM	Public Comment on Agenda Items	
10:15 AM	Approval of December 2012 Minutes	Mr. David King, Chair
10:20 AM	Report from the Division of Vaccine Injury Compensation	Dr. Vito Caserta Acting Director, DVIC
10:50 AM	Report from the Department of Justice	Mr. Vince Matanoski Deputy Director Torts Branch, DOJ
11:20 AM	Report from the Maternal Immunization Workgroup	Dr. Kristen Feemster ACCV Member
11:40 AM	Report from the Process Workgroup	Ms. Luisita dela Rosa ACCV Member
12:00 PM	Lunch	
1:00 PM	Review of Vaccine Information Statement's (VIS's)	Ms. Jennifer Hamborsky Mr. Skip Wolfe CDC
2:30 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimabukuro CDC
2:45 PM	Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH

Time	Agenda Item	Presenter
3:00 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	LT. Valerie Marshall CBER, FDA
3:15 PM	Update from the National Vaccine Program Office (NVPO)	Dr. Jody Sachs NVPO
3:30 PM	Public Comment (follows the preceding topic and may commencer earlier or later the 3:30 pm)	
3:45 PM	Future Agenda Items/New Business	Mr. David King, Chair
4:00 PM	Adjournment of the ACCV March Quarterly Meeting	Mr. David King, Chair

Charter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

42 U.S.C. 300aa-19, Section 2119 of the PHS Act. The Advisory Commission on Childhood Vaccines (hereinafter referred to as the "Commission") is governed by the provisions of Public Law 92-463 (5 U.S.C. App. 2), which sets forth standards for the formation of advisory committees.

Objectives and Scope of Activities

The Secretary of Health and Human Services is mandated under Section 2119 of the Public Health Service (PHS) Act to appoint an advisory commission to give advice regarding the National Vaccine Injury Compensation Program (the Program), which provides compensation for certain vaccine-related injuries or deaths.

Description of Duties

The Commission shall: (1) advise the Secretary on the implementation of the Program; (2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table; (3) advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; (4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of Section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; (5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program; and (6) consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act.

Agency or Official to Whom the Commission Reports

The Commission on Childhood Vaccines shall advise and make recommendations to the Secretary on matters related to the Program responsibilities.

Support

Management and support services shall be provided by the Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration.

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Commission, including compensation and travel expenses for members, but excluding staff support, is approximately $84,685. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $257,582.

Designated Federal Officer

HRSA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Commission meeting and ensure that all procedures are within applicable, statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, call all of the Commission or subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Commission reports. The DFO or his/her designee shall be present at all meetings of the full Commission and subcommittees.

Estimated Number and Frequency of Meetings

The Commission shall meet no less than 4 times per year and at the call of the DFO. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

Duration

Continuing.

Termination

Unless renewed by appropriate action prior to its expiration, this charter will expire two years from the date the charter is filed.

Membership and Designation

The Secretary shall select members of the Commission. The members of the Commission shall select a Chair and Vice Chair from among the members. Appointed members of the Commission shall be appointed for a term of office of 3 years. Members may serve after the expiration of their term until their successors have taken office.

The Commission shall be composed of the following:

(1) Nine members appointed by the Secretary as follows:

(A) three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians;

(B) three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and

(C) three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The nine members appointed by the Secretary shall serve as Special Government Employees. The ex officio members and the DFO shall be Regular Government Employees.

Subcommittees

Subcommittees may be established with the approval of the Secretary or designee. Subcommittee members may be members of the parent Commission. The subcommittee shall make recommendations to be deliberated by the parent Commission. The Department's Committee Management Officer will be notified upon the establishment of the each subcommittee and will be provided information on the subcommittee's name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the committee, formally and informally established subcommittees, or other subgroups of the committee, shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

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Filing Date
July 21, 2012

Approved:

July 17, 2012
Date

for Jennifer Rizzle
Wendy Ponton
Director, Office of Management

Roster

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2013 Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2013 MEETING DATES

March 7, 2013
June 6 & 7, 2013
September 5 & 6, 2013
December 5 & 6, 2013

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Advisory Commission on Childhood Vaccines

December 6, 2012

Teleconference Minutes

Members Present

David King, Chair
Charlene Douglas, Ph.D.
Kristen Feemster, M.D.
Edward Kraus, J.D.
Ann Linguiti Pron, MSN, CRNP, RN
Luisita dela Rosa
Jason Smith, J.D.
Sylvia Fernandez Villareal, M.D.
Michelle Williams, JD

Division of Vaccine Injury Compensation

Vito Caserta, MD., Acting Director, DVIC
Andrea Herzog, Staff Liaison

Department of Health and Human Services

Elizabeth Saindon, Office of the General Counsel

Welcome, Report of the Chair and Approval of Minutes
David King, ACCV Chair

Mr. King welcomed all on the teleconference and invited introductions. He commented that, although a meeting at which all could attend in one place might be preferable, budgetary constraints dictated a "virtual" meeting via telephone. He added that staff and HRSA would be investigating various options to make future meetings more effective and efficient. He invited public comment about the day's agenda and there were none.

Mr. King invited approval of the minutes of the September 6, 2012 meeting and, on motion duly made and seconded, those minutes, with minor typographical error corrections, were unanimously approved.

Report from the Division of Vaccine Injury Compensation,
Vito Caserta, Acting Director, DVIC

Dr. Caserta provided an overview of the agenda for the meeting. Turning to statistics, he noted that new filings related to autism and the Omnibus Autism Proceeding (OAP) had fallen dramatically to only a few during the last three years. However, non-autism filings have been steadily increasing and it appears that the projected filings for the fiscal year will be about 476, which would be a ten-year high. He added that the majority of claims filed are filed by adults, mainly associated with injuries alleged to have been caused by influenza vaccine.

With regard to adjudications, the upward trend is the same as for filings, but the dramatic increase in adjudications, from a few hundred between 2007 and 2010 to 2,683 in 2012 reflect the high number of OAP dismissals. In the first weeks of FY 2013, 19 of 115 adjudicated claims were

compensable; the rest were dismissed. Claims may be considered compensable or not, and in FY 2012 there were only 6 (4%) such cases conceded by DHHS, while 33 (12%) had to be resolved by a decision of the court; 210 (84%) were settled by the parties involved. A fair number of cases are deemed by the Court to be non-compensable, usually because there is insufficient evidence to proceed with the case or the alleged injury is not covered by the Injury Table.

Dr. Caserta showed a table of award amounts paid in those cases that were finally adjudicated and over the last few years the awards have ranged between about $163,000 and $216,000. However, attorney's fees have more than doubled in the same timeframe, from about $9,000 in 2010 to more than $23,000 in 2012.

The Trust Fund, which receives income from an excise tax on covered vaccines and interest on the principal of the Fund, stands at almost $3.5 billion, with interest income of $255 million in tax revenue and $320 million in interest earned in 2012.

Dr. Caserta noted that there was only one significant event that he attended as a representative of DVIC – the Advisory Committee on Immunization Practices (ACIP) on October 24-25 in Atlanta. At that meeting the Committee updated the recommendations for MMR vaccine, and revised the recommendation to administer DTAP to pregnant women, increasing the frequency from one immunization presumably during the first pregnancy, to an immunization during each pregnancy.

Contact information was passed on to those attending the teleconference: contact Andrea Herzog at DVIC, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 (phone 301-443-6643 – e-mail aherzog@hrsa.gov), or visit the web site at www. hrsa.gov/ vaccinecompensation.

Report from the Department of Justice
Vincent J. Matanoski, J.D.
Deputy Director, Torts Branch, Civil Division

Mr. Matanoski referenced the DOJ Power Point materials (DOJ PP), dated December 6, 2012, as part of his presentation.

Mr. Matanoski began with DOJ's statistical report for the time period of August 16, 2012 – November 15, 2012 (DOJ PP, pp. 2-4). During this reporting period, 149 new petitions were filed. The majority of these newly-filed cases were adult claims, and there were no autism claims. Referencing Dr. Caserta's earlier comments, Mr. Matanoski also saw an increase in the number of cases being filed. However, Mr. Matanoski could not detect any seasonal patterns or trends to the filings at this time although he would monitor this and report to the ACCV if he saw an emerging pattern. Mr. King asked if there would be an increase in DOJ resources to handle the greater number of claims, and whether or not a backlog would be created. Mr. Matanoski answered that it was premature to determine whether or not there would be a backlog. DOJ's resources are fixed, and until there is an increase in the budget, there are no additional resources such as personnel. Recalling past seasonal dips in case filings and fluctuations, Mr. Matanoski could not predict with any certainty what to expect for this year but assured the ACCV that DOJ would process cases as quickly as possible, and continue to monitor the number of cases being filed. Ms. Williams asked about DOJ's budget and the possibility of requesting additional funds, which Mr. Matanoski confirmed would be the next step. Mr. Kraus asked Mr. Matanoski to clarify the source of DOJ's budget, which Mr. Matanoski stated is from the Trust Fund, as is DVIC and court funding.

Mr. Matanoski reported that there were 361 cases adjudicated during this reporting period. (DOJ PP, p. 3). Of those, 88 were compensated and 273 were not compensated. Of the non-compensated cases, 50 did not involve autism and 233 were autism claims. The number of autism dismissals has decreased since the last meeting, which is a reflection of the Court's previous substantial efforts to process Omnibus Autism Proceeding (OAP) cases, resulting in fewer pending OAP cases. Of the 88 compensated cases, 4 were conceded cases, and 84 were not. Of the 84 non-conceded cases, 3 were

resolved with a proffer (an agreement between the parties as to what the evidence shows regarding damages) and 81 were resolved with a settlement. In past meetings, Commission members asked about the different processing times for conceded and non-conceded cases. Mr. Matanoski noted that there was not an appreciable difference in processing time for those two types of cases – both classes of cases took approximately two years to reach a final resolution. He cautioned that he was looking at a very small sample size, as there were only 4 conceded cases this reporting period. For this meeting, Mr. Matanoski also examined processing times for the 84 non-conceded cases. Cases resolved by proffers took much longer to process than cases resolved by settlement. This data was not surprising, because cases resolved with a proffer typically have a longer procedural history, which may include an entitlement hearing, before the parties agree to a proffer. There were 6 cases that were voluntarily withdrawn from the Program. (DOJ PP, p. 4). Of those, 4 were non-autism cases and 2 were autism cases. Voluntarily withdrawals are a seldom-used method for petitioners to exit the Program.

DOJ's presentation materials included the familiar glossary of terms (DOJ PP, pp. 5-7) and case processing diagrams (DOJ PP. 8-10). Mr. Matanoski offered to answer any questions about these slides, but no questions or comments were raised. Mr. Matanoski turned the discussion to recent appellate activity in the Program (DOJ PP, pp. 11-16). First, the Program has a case pending before the U.S. Supreme Court, *Sebelius v. Cloer.* (DOJ PP, 11). In *Cloer*, respondent sought certiorari following a decision issued by the U.S. Court of Appeals for the Federal Circuit (CAFC), which held that attorneys can be awarded fees for work in cases filed outside of the statute of limitations. The Supreme Court granted certiorari and briefing is underway. Argument is expected as early as March 2013. Two cases were recently appealed to the CAFC. (DOJ PP, p. 13). *Hrieche v. HHS,* involved a *pro se* petitioner and was part of the OAP. It was dismissed on May 31, 2012. After dismissal, there is a specific time period allotted for seeking review to the U.S. Court of Federal Claims (CFC), and petitioner did not seek review by that tribunal until after the time period expired. After the time period to appeal to the CFC expired, petitioner appealed to the CAFC. Respondent has moved to dismiss the appeal because it should have been appealed to the CFC, not the CAFC. *Shapiro v. HHS* was dismissed by the special master for lack of sufficient evidence. Petitioner appealed to the CFC, where the special master's decision was upheld. Petitioner has now sought review by the CAFC. Six new appeals were filed at the CFC (DOJ PP, p. 15). All six appeals were brought by petitioners. Five of these appeals involve factual matters, expert testimony, and whether the evidence was sufficient to establish entitlement to compensation. One appeal, *Wax v. HHS*, a predominately legal issue of statute of limitations. In *Wax*, petitioner's claim was time-barred by five years. Petitioners sought relief through equitable tolling claiming that they believed that Thimerosal, which they claimed was responsible for the injury alleged in the case, was an adulterant. Thus, they could not file the claim under the Vaccine Act, because the Vaccine Act does not permit cases involving adulterated vaccines. Petitioners filed a civil suit, which was dismissed, and then filed a claim under the Vaccine Act. The special master found that petitioners' confusion regarding court jurisdiction was not amenable to remedy through equitable tolling as a matter of law, or relief from the statute of limitations. The CFC affirmed.

Finally, Mr. Matanoski turned to DOJ's settlement chart for the current reporting period (DOJ PP, pp. 17-25). There were 81 settled cases. Of those, Mr. Matanoski illustrated five different categories of settlement as follows: 16 cases settled in less than one year; 30 cases were settled in less than two years; 25 cases were settled in less than three years; 7 cases were settled in less than four years; and 3 cases were settled after four years. Mr. Matanoski summarized that approximately twenty percent of the cases were settled in less than one year, with fifty-seven percent settled in less than two years. By three years, eighty-eighty percent of the cases settled were settled. Thus, the majority of cases being settled are done so in less than three years. Of those cases settled, the predominant vaccine involved has been influenza and the predominant injury involved has been Guillain-Barre Syndrome (GBS); Mr. Matanoski observed that this is consistent with past reporting periods.

Mr. Matanoski then answered two questions raised during the prior public comment period. The first question concerned a slide that reported on a case involving autism. The slide in question had not been provided by DOJ, and Mr. Matanoski declined to comment. The second question was about adjudicated settlements and whether the settlement amounts could be provided. Mr. Matanoski explained that DOJ was comfortable publicly reporting the information found in the DOJ PP, pp. 17-25, which

responds to the Commission's prior request for information about vaccine injury and vaccines involved and processing time. This information is sufficiently generic without identifying case-specific information that could compromise a petitioner's privacy protections afforded under the Vaccine Act, which Mr. Matanoski clarified could be found in 42 U.S.C. Section 300-aa 12(d)(2). Further clarifying, Mr. Matanoski stated that the report does not distinguish between flu / GBS cases involving adults or children but based on his experience, the settlements predominately involved adult cases. Turning to page 18 of DOJ's PP presentation, Dr. Villareal questioned using trade names in reporting the information. Mr. Matanoski indicated that for purposes of compiling this information for the ACCV, the information is abstracted directly from the petition and will endeavor to go through the list to provide generic names. Turning to page 11 of DOJ's PP presentation involving *Sebelius v. Cloer*, Mr. King posed a philosophical question of whether petitioners knew that their claim was untimely when they started or was there a question about that, noting that the CAFC decided 7-6 that attorneys' fees should have been awarded. Mr. King asked whether seeking to overturn that decision would harm petitioners by discouraging attorneys from filing vaccine claims because they could ultimately not be paid on an untimely claim. Mr. King asked for Mr. Matanoski's thoughts on seeking review by the Supreme Court. Mr. Matanoski explained that the *Cloer* case involved a legal question. According to Section 16 of the Vaccine Act, no petition may be filed where the time period is greater than 36 months between the time of the injury and the time that the claim is filed. This means that one cannot file a petition and therefore should not be in the Program at all because there is no authority to be there. Without a petition, one cannot seek an award of attorneys' fees. Noting that Congress used specific words and phrasing to access the Program in a timely manner, Mr. Matanoski observed that attorneys can review the cases before filing and screen cases accordingly. Mr. King remarked that timeliness issues are not always clear from the outset, and expressed concern that the spirit of the Vaccine Program could be jeopardized with the *Cloer* review. Mr. Matanoski commented that there were past discussions involving other sections of the Vaccine Act that could have read differently. He cited to an issue involving guardianship costs, which according to the statute, supports a view that those costs are not permissible. When a statute reads one way but a different result is desired, the "fix" is try and change the statute. Mr. Matanoski recalled that there has been support for extending the time limit for the statute of limitations from three years but that folks sitting on both sides of that debate have different ideas on where to draw the line. From Mr. Matanoski's perspective of processing cases, the important thing is to have a clear line. Acknowledging the philosophical nature of the discussion, Mr. Matanoski reiterated that for *Cloer*, the government is looking at the law as written. Mr. King stated that the Process Working Group is working on a number of issues and considering recommending changes to the Program. He asked if DOJ would be willing to co-recommend some of those changes proposed by the Commission. Mr. Matanoski replied that there is a process by which recommendations are received and considered by DOJ. Mr. Kraus commented that the position of attorney who represents vaccine-injured petitioners generally it is very difficult for counsel to agree to become involved in a case in which there is a question of whether the case has been brought within the 36-month statute of limitations period. In many instances, the only way to determine whether a case is timely is by undertaking a time-intensive review of the records, which could result in no compensation if the claim is found untimely. Mr. Kraus expressed disappointment in the government's decision to appeal *Cloer* to the Supreme Court, and stated that if *Cloer* were overturned, it would create a strong disincentive for attorneys who need to be paid for representing these types of clients and outlaying costs. Mr. Kraus expressed that a consequence of *Cloer* being overturned by the Supreme Court would be a negative for the Program. Mr. Kraus observed that if a an attorney brought a claim that was obviously untimely, even if *Cloer* was not overturned, DOJ could capably argue that attorneys' fees should not be awarded because there was no reasonable basis to bring the claim. Mr. Kraus noted that the cases at issue are not obviously untimely. Mr. Matanoski reiterated that CAFC's 7-6 decision *Cloer* permitting attorneys' fees in an untimely case, represented a departure from existing case law, which did not permit attorneys' fees for untimely cases. If the Supreme Court overturns the CAFC's decision *Cloer,* it would be a return to the Vaccine Act as it had previously been interpreted.

Dr. Shimabukuro asked if DOJ could specify in the settlement chart whether the influenza vaccine was a live or inactivated. Mr. Matanoski said that might be difficult given how DOJ abstracts the information [from a petition]. Mr. Matanoski offered that the majority of the influenza settlements were for adults older than 50, so most likely involved the inactivated, injected vaccine.

Report of the 2012 Judicial Conference
Jocelyn McIntosh, Office of the Special Master
Patricia Campbell-Smith, Chief Special Master

Chief Special Master Campbell-Smith commented that the 25th Judicial Conference, held on November 15th, was a highly successful meeting that included three sessions on vaccines. One session focused on the Injury Table revisions. The second session included a briefing from the Office of Special Masters, touching on practice; an announcement that two additional special masters will be added in December; a brief description of reorganization of the Court's web site; and a discussion of changes to the courts written decisions, including expansion of summary dismissal decisions. The third session looked at the Office of Special Masters proposed revisions to the vaccine program practice, intended to be a tool to help attorneys understand the expectations of the court in moving cases forward in the program. The guidelines should be published by February. Chief Special Master Campbell-Smith added that all of the sessions at the meeting were recorded and is available on the court's web site – www.uscsc.uscourts.gov.

During discussion, Chief Special Master Campbell-Smith explained that the two new special masters have actually been identified, and their appointments require a vote by the sitting judges at the Court of Federal Claims. Then assuming their responsibilities depends on the time it takes for them to wind down their other affairs and assume their duties as special masters.

Report from the Maternal Immunization Workgroup
Dr. Kristen Feemster, ACCV member

Dr. Feemster reported that the workgroup has continued to gather information in consideration of the current recommendations to immunize pregnant women against influenza, pertussis and tetanus and to contemplate future recommendations for vaccines now under development, including an RSV vaccine and a Group B streptococcus vaccine. The workgroup's charge is to develop recommendations for vaccines currently under development that may be recommended for administration to pregnant women, and to consider the pros and cons of including those vaccines in the vaccine compensation program. Secondly, the workgroup is considering compensation for injuries to a live-born infant who may have been exposed to a vaccine administered to the mother while the infant was in utero. Third, the workgroup will consider the current safety monitoring infrastructure with regard to vaccines specifically administered to pregnant women. Finally, the workgroup will look at the ACCV charter vis-a-vis changes in the VICP related to coverage of vaccines administered to women during pregnancy. The workgroup's objective is to develop a preliminary report that will be presented at the next ACCV meeting

Report from the Process Workgroup
Luisita dela Rosa, ACCV member

Ms. dela Rosa announced that the workgroup had met six times and early on decided to rely on two ACCV documents – the summary of recommendations to the Secretary in 2009 and the legislative proposal of 1998. As early as the September 6 meeting, the workgroup agreed that one set of recommendations would require statutory changes – extension of the statute of limitations for injury and death claims, and an increase in benefit caps for death, and pain and suffering. Another set of recommendations would involve decision of law – entitlement to injury and death benefits, allowing compensation for counseling and for expenses related to establishing and maintaining trusts, guardianships and conservatorships, and allowing payment of interim fees and costs for a claimant's attorney.

There was agreement on a final recommendation that the Secretary appoint to the Commission a person who was vaccine-injured as an adult (or his representative, such as a family member) who would occupy one of the three positions allocated to the general public. It was noted that the legislation defined the general public membership as two representatives of vaccine-injured children and one member whose qualification is not defined. Mr. Kraus observed that this could be accomplished without legislative change by waiting until the next vacancy occurs in the general public allocation. Dr. Douglas mentioned

that she represented the general public and her term would end in 2014. Dr. Feemster commented that it is appropriate to include members who represent or are vaccine-injured individuals, but one of the three should represent the general public, a person who is typically not involved with vaccine injury.

Ms. Williams commented that this provides an opportunity to look at a slight change in the focus of the Commission, to include adults who have been injured rather than only children. Mr. Kraus added that such a recommendation to the Secretary should include a discussion of the background of the proposal and a justification. He agreed to develop a draft of that statement for the recommendation. Dr. Villareal pointed out that the charter of the ACCV specifically states that it is a commission on childhood vaccines. Dr. Caserta observed for a vaccine to be covered by the program the vaccine must be recommended for routine use in children, regardless of whether the vaccine is also recommended for adults. And when a vaccine is covered by the program, it is covered for anyone who receives it, child or adult.

On motion duly made and seconded, the Commission unanimously approved a recommendation to the Secretary to consider appointing a Commission member who was vaccine-injured as an adult. That appointment could also be an individual to represent such an individual.

Update on the Immunization Safety Office (ISO)
Tom Shimabukuro, CDC

The Vaccine Safety Datalink (VSD) and the Clinical Immunization Safety Assessment (CISA) Project contracts were awarded in September 2012. The main change is that CDC now has task order contracts with VSD and CISA, whereas before there was a single prime contractor that then subcontracted to the VSD and CISA sites. Another project was awarded to the Brighton Collaboration to conduct an enhanced evaluation of narcolepsy associated with Pandemrix and Arepanrix. Pandemrix is a monovalent H1N1 vaccine that was used widely in Europe during the 2009 pandemic. Arepanrix was used in Canada and some other countries. Neither of the vaccines were licensed for use in the United States (adjuvanted influenza vaccines are not licensed in the United States)

Dr. Shimabukuro noted that at the October 2012 ACIP meeting there was a recommendation that passed for providers of prenatal care to implement a Tdap immunization program for all pregnant women. Pregnant women should receive Tdap during each pregnancy regardless of the patient's prior vaccination history. The change in the recommendation is for repeat administration of Tdap during each pregnancy, preferably between 27 and 37 weeks gestation. The timeframe is meant to optimize benefit to the infant through passive antibody transfer.

With regard to persons with perinatal HIV infection, whether or not MMR had been administered before effective antiretroviral treatment, they should receive two appropriately spaced MMR vaccines once the antiretroviral therapy has been established. The two doses are recommended for all persons age 12 months or older who do not have evidence of severe immunosuppression.

Dr. Shimabukuro mentioned that the ACIP recommendations may not be published in the MMWR for some time because there is a review period, but that interim recommendations would be posted in the meantime.

During the ACIP meeting there were routine votes to approve both the childhood and adult immunization schedules for 2013, and the Vaccine for Children Program, including a resolution to change terminology from trivalent inactivated influenza vaccine (TIV) to inactivated influenza vaccine (IIV) to allow inclusion of the quadrivalent inactivated influenza vaccines as they become licensed, approved and recomended. Of note, three manufacturers presented data on their quadrivalent influenza vaccine products.

Dr. Shimabukuro described paper by Tomljenovic and Shaw (Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceutical Regulatory Affairs: Open Access 2012,S12:001) of two deaths in young females after administration of

quadrivalent human papillomavirus vaccine. The authors concluded that the deaths were attributed to autoimmune cerebral vasculitis. CDC and the CISA addressed key deficits in the data, methodology and analysis and posted a technical report on the CDC website addressing the deficits.

Finally, Dr. Shimabukuro cited three articles of interest. Abedi et all reported on adverse events following a third dose of MMR vaccine given in response to an outbreak of mumps. The authors' conclusions were that a third dose of MMR vaccine administered in an outbreak setting is safe, with injection site reactions reported more frequently than systemic reactions. However, to assess risk for rare or serious adverse events after a third dose of MMR vaccine, longer term studies would be required. O'Leary et al. surveyed physicians about giving MMRV vaccine to healthy 12-15 month-old children. After receiving data regarding febrile seizure risk after MMRV, few physicians report they would recommend MMRV to a healthy 12--15-month-old child. The risk of febrile seizure is lower when MMR and varicella vaccine are administered separately. Finally, Moro et al analyzed the literature on seasonal influenza and the H1N1 2009 monovalent vaccine and concluded that data from surveillance systems and observational studies did not identify any pattern of adverse events of concern in vaccinated pregnant women or their infants.

Update on Vaccine Activities at the National Institute for Allergies and Infectious Diseases, Barbara Mulach, NIAID

Dr. Mulach commented that the NIH Director, Francis Collins, has established an active blog to pass on information about health-related events like effects of Hurricane Sandy, and NIAID has a new YouTube Internet presence at www.youtube.com/user/NIAID. There are short subjects such as understanding good and bad bacteria, and how influenza pandemics occur.

In September, NIAID awarded several contracts to expand pre-clinical services for researchers trying to bring new vaccines along. The support helps overcome hurdles such as assay development, toxicity studies, safety tests, clinical and nonclinical sample testing and so on. Finally, NIAID recently added to the NIH Guide a request for information from the pharmaceutical community on the availability of dry formulation technologies. This may elicit information about how the companies are developing formulations to increase stability and minimize the need for preservatives.

Update on the Center for Biologics, Evaluation and Research (CBER)
LT Valerie Marshall, FDA

LT. Marshall announced that on November 14, the Vaccine and Related Biological Products Advisory Committee (VRBPAC) held an open session to discuss the safety and immunogenicity of an influenza A H5N1 virus monovalent vaccine manufactured by GlaxoSmithKline. The committee voted that immunogenicity and safety data are sufficient to support use of the vaccine. On November 15, the VRBPAC looked at Dynavax's Heplisav, a hepatitis B vaccine, and voted 8 to 5 with one abstention that the available data do not support the safety of the vaccine in those 18 to 70 years of age, but voted (13 - 1) that immunogenicity data submitted in the BLA support the product's efficacy claims.

On November 20, 2012, CBER/OVRR approved Flucelvax, an influenza vaccine indicated for active immunization of persons 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. The vaccine is manufactured by Novartis Vaccines and Diagnostics and is the first seasonal influenza vaccine licensed in the United States produced using mammalian cells (MDCK cells), instead of fertilized chicken eggs. Cell culture technology is another manufacturing alternative to conventional egg-based influenza vaccine production.

Update from the National Vaccine Program Office (NVPO)
Jennifer Read, NVPO

Dr. Read stated that the Institute of Medicine report on health outcomes related to the recommended childhood immunization schedule, originally scheduled for release in the fall of 2012, is now expected to be released in January 2013.

Dr. Read commented that the National Vaccine Advisory Committee would meet on February 5-6, 2013 but its agenda has not been finalized. At its June 2012 meeting, the NVAC voted to create the Maternal Immunization Working Group, which has begun its work and plans to release a report in September 2013. Dr. Read added that she and Dr. Richard Beigi are members of both the NVAC and ACCV Maternal Immunization Working Groups, so there is a line of communication between the two groups.

Public Comment

Mr. King invited public comment, and Theresa Wrangham, representing the National Vaccine Information Center, clarified her request to the Department of Justice earlier in the meeting. She asked that the DOJ provide information about each vaccine and the alleged injuries or conditions that are part of the claims filed, and the amount of the compensation awarded.

Concerning the statute of limitations issue, she felt that the 36-month period is not supported by available science. Despite the law's requirement for the conduct of ongoing vaccine safety research, 85% of the most common adverse events have little or no causality science to support a decision concerning the statute of limitations. There is also a lack of awareness of the existence of the VICP. Ms. Wrangham expressed the opinion that the ACCV's efforts with regard to changes in the Injury Table were commendable, but there has been no evidence of publicity about that success. Finally, she endorsed the recommendation made during the meeting that a member of the Commission should represent the adult vaccine-injured population and that appointment of a member injured by vaccines while he or she was an adult would be appropriate.

Mr. Wayne Rohde, a parent of a vaccine-injured child, offered a plea that the ACCV focus more attention on public outreach. He stated there was growing distrust of vaccines, evidenced by the increased rate of vaccine exemptions for children. He suggested that perhaps as few as five percent of vaccine adverse events are even reported to VAERS. He added that research has indicated that those who did not file were unaware of the VICP or learned about it too late to file a claim. He urged the Commission to refocus on outreach, adding that it would be appropriate to accept written comments from the public and make them a part of the public record.

Future Agenda Items

Mr. King invited suggestions for future agenda items, or discussion of old or new business. Dr. Caserta offered an observation on the probable trend toward more meetings that are held relying on electronic communications, such as the teleconference. He suggested that throughout the Department, budget constraints will limit meetings for advisory groups such as the ACCV to perhaps as few as one per year.

There was a brief discussion among the Commission members about the ramifications of that constraint and there was a suggestion that the in-person meetings should include agenda items that require a high level of interactive discussion, or sessions that require person-to-person interaction, such as the new member orientation.

The final topic of discussion concerned making it easier for individuals to locate legal representation, a topic that was discussed at the last ACCV meeting. Ms. Herzog explained that there was a link on the ACCV website, "How to file a claim," that takes a visitor to another link to the Court of Federal Claims website, which does provide a list of attorneys. This allows access to attorneys without appearing to endorse specific attorneys. Mr. Kraus commented that he was less concerned with listing attorneys, since an individual who knows he wants to file a claim should be able to locate an attorney specializing in vaccine injuries – perhaps through a Google search. He stated he was more concerned

with making the public more aware of the existence of the program. Mr. King agreed, but maintained that the ACCV should make it easier to navigate through the claims process, which includes identification of attorneys who specialize in vaccine injury claims.

There being no other business, on motion duly made and seconded, the meeting was adjourned by consensus.

_____
David King, ACCV Chair

_____ _____
Vito Caserta, M.D. Date
Executive Secretary, ACCV

3

Vaccine Injury Compensation Trust Fund

Balance as of December 31, 2012

$3,489,648,655.08

Figures for October 1, 2011 – December 31, 2012

Excise Tax Revenue: $41,985,000
Interest on Investments: $15,602,397
Net Income: $57,587,397
Interest as a Percentage of Income: 27%

Source: U.S. Treasury, Bureau of Public Debt
February 11, 2013

4

4.1

National Vaccine Injury Compensation Program Statistics Report - March 4, 2013

I. Petitions Filed

Fiscal Year	Non-Autism	Autism	Total
FY 1988	24	0	24
FY 1989	148	0	148
FY 1990	1,492	0	1,492
FY 1991	2,718	0	2,718
FY 1992	189	0	189
FY 1993	140	0	140
FY 1994	107	0	107
FY 1995	180	0	180
FY 1996	84	0	84
FY 1997	104	0	104
FY 1998	120	0	120
FY 1999	410	1	411
FY 2000	162	1	163
FY 2001	193	23	216
FY 2002	184	773	957
FY 2003	156	2,436	2,592
FY 2004	127	1,087	1,214
FY 2005	147	588	735
FY 2006	156	169	325
FY 2007	238	172	410
FY 2008	163	254	417
FY 2009	288	109	397
FY 2010	433	16	449
FY 2011	382	4	386
FY 2012	399	1	400
FY 2013	170	0	170
Total	8,914	5,634	14,548

II. National Vaccine Injury Compensation Adjudications [1]

Fiscal Year	Non-Omnibus Autism Proceeding			Omnibus Autism Proceeding			Total
	Compensable	Dismissed	Sub-Total	Compensable*	Dismissed	Sub-Total	
FY 1989	9	12	21	0	0	0	21
FY 1990	100	33	133	0	0	0	133
FY 1991	141	447	588	0	0	0	588
FY 1992	166	487	653	0	0	0	653
FY 1993	125	588	713	0	0	0	713
FY 1994	162	446	608	0	0	0	608
FY 1995	160	575	735	0	0	0	735
FY 1996	162	408	570	0	0	0	570
FY 1997	189	198	387	0	0	0	387
FY 1998	144	181	325	0	0	0	325
FY 1999	98	139	237	0	0	0	237
FY 2000	125	104	229	0	0	0	229
FY 2001	86	87	173	0	0	0	173
FY 2002	104	99	203	0	4	4	207
FY 2003	56	78	134	0	21	21	155
FY 2004	62	122	184	0	111	111	295
FY 2005	60	70	130	0	51	51	181
FY 2006	69	82	151	0	109	109	260
FY 2007	83	86	169	0	34	34	203
FY 2008	147	80	227	0	55	55	282
FY 2009	134	44	178	0	187	187	365
FY 2010	179	79	258	1**	214	215	473
FY 2011	260	106	366	0	1,265	1,265	1,631
FY 2012	255	144	399	1**	2,292	2,293	2,692
FY 2013	123	43	166	0	284	284	450
Totals	**3,199**	**4,738**	**7,937**	**2**	**4,627**	**4,629**	**12,566**

*May include case(s) that were originally filed and processed as an OAP cases but in which the final adjudication does not include a finding of vaccine-related autism.

**HHS has never concluded in any case that autism was caused by vaccination.

III. National Vaccine Injury Compensation Awards Paid [2]

Fiscal Year	Compensated 3			Dismissed		Interim Fees		Total Outlays
	# of	Petitioners'	Attorneys' Fees/	# of Payments	Attorneys' Fees/	# of Payments	Attorneys' Fees/	
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,270,237.04	72	$2,432,847.05	2	$117,265.31	$83,536,901.46
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53
FY 2011	251	$216,323,760.31	$9,736,216.87	402	$5,425,243.19	28	$2,001,770.91	$233,486,991.28
FY 2012	248	$163,286,998.82	$9,106,720.30	1,017	$8,621,182.32	37	$5,420,257.99	$186,435,159.43
FY 2013	163	$103,235,896.43	$5,011,592.33	405	$3,512,163.89	29	$607,264.47	$112,366,897.12
Total	3186	$2,448,256,199.98	$97,111,067.04	4,075	$53,605,933.78	146	$14,336,725.11	$2,613,339,925.91

- Generally, petitions/claims are not adjudicated in the same fiscal year as filed. On average, it takes 2-3 years to adjudicate a petition/claim after it is filed.

[2] "Compensated" are claims that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/claims are determined compensable. "Dismissed" includes the the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the claim, whether or not the petition/claim is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

[3] Due to the populations receiving vaccines added to the VICP in recent years, the proportion of adults to children seeking compensation has changed. Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult claims related to that vaccine have been filed.

4.2

Claims Filed and Compensated or Dismissed by Vaccine [1] March 4, 2013
Vaccines Listed in Claims as Reported by Petitioners

Vaccine(s)	Filed			Compensated	Dismissed
	Injury	Death	Total		
DT (diphtheria-tetanus)	65	9	74	23	50
DTP	3,282	696	3,978	1,267	2,703
(diphtheria-tetanus-whole cell pertussis)					
DTP-HIB	16	8	24	4	19
DTaP	337	76	413	163	195
(diphtheria-tetanus-acellular pertussis)					
DTaP-Hep B-IPV	53	23	76	24	27
DTaP-HIB	6	1	7	4	3
DTaP-IPV-HIB	8	7	15	2	4
Td (tetanus-diphtheria)	172	3	175	91	64
Tdap	108	0	108	54	5
Tetanus	82	2	84	34	35
Hepatitis A (Hep A)	50	2	52	19	14
Hepatitis B (Hep B)	581	51	632	227	368
Hep A- Hep B	12	0	12	8	1
Hep B-HIB	8	0	8	3	3
HIB (Haemophilus influenzae type b)	23	3	26	11	13
HPV (human papillomarvirus)	190	9	199	48	58
Influenza (Trivalent)	999	59	1,058	516	114
IPV (Inactivated Polio)	262	14	276	7	267
OPV (Oral Polio)	280	28	308	158	150
Measles	143	19	162	55	107
Meningococcal	29	1	30	14	2
MMR (measles-mumps-rubella)	854	56	910	348	499
MMR-Varicella	22	1	23	10	5
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	5	3	8	2	6
Pneumococcal Conjugate	33	5	38	9	23
Rotavirus	54	1	55	32	16
Rubella	189	4	193	70	123
Varicella	67	6	73	42	21
Nonqualified2	76	9	85	0	82
Unspecified3	5,409	8	5,417	4	4,950
TOTAL	13,440	1,104	14,544	3,256	9,946

1 The number of claims filed by vaccine as reported by petitioners in claims since the VICP began on October 1, 1988, which have been compensated or dismissed by the U.S. Court of Federal Claims (Court). Claims can be compensated by a settlement between parties or a decision by the Court.

2 Claims filed for vaccines which are not covered under the VICP.

3 Insufficient information submitted to make a determination. The majority of these claims are part of the Omnibus Autism Proceedings.

5

5.1

Vaccine Information Statement

Influenza (Flu) Vaccine (Live, Intranasal): What you need to know
2013-14

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

Your doctor recommends that you get a dose of flu vaccine today.

1. Why get vaccinated?

Flu vaccine is the best way to protect yourself from flu and avoid spreading flu to others.

Influenza ("flu") is a contagious disease that spreads around the United States every winter, usually between October and May.

It is caused by the influenza virus, which can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but risk of infection is highest among children. Symptoms come on suddenly and last several days. They include:
• fever/chills • sore throat • muscle aches • fatigue • cough • headache
• runny or stuffy nose

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker.

Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

Each year thousands of people die from flu, and many more are hospitalized.

2. Live, attenuated flu vaccine – LAIV, Nasal Spray

There are two types of influenza vaccine:

You are getting a **live, attenuated** (weakened) influenza vaccine, which is sprayed into the nostrils.

There is also an **inactivated** (killed) vaccine, the "flu shot," which is given by injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Flu viruses are always changing. Flu vaccine is changed each year to match the strains of flu virus that are causing disease that year. Each year's LAIV contains 4 virus strains.

You should get a dose of flu vaccine every year to make sure you are protected from the latest virus strains. Some children 8 years old and younger should get two doses their first year.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts about a year.

Flu vaccination is especially important for people more likely to get a severe case of flu, such as young children, older people, and people with certain health problems. It is also important for anyone in close contact with these people.

Other illnesses can look like flu, and are often mistaken for flu. Flu vaccine will not prevent these illnesses.

It will also not prevent all cases of flu. But people who are vaccinated and still get the flu usually get a milder case than people who aren't vaccinated.

LAIV may be given to healthy people **2 through 49 years of age**, who are not pregnant. It may safely be given at the same time as other vaccines.

LAIV does not contain thimerosal or other preservatives.

3. Precautions

- If you ever had a life-threatening allergic reaction after a dose of flu vaccine, you should not another dose.
- If you have a severe allergy to any component of flu vaccine, you should not get it. *Tell your doctor if you have any severe allergies.*
- Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralyzing illness, also called GBS). Your doctor will help you decide if flu vaccine is recommended for you.
- Some people should get the flu shot instead of LAIV. These include:
  - Pregnant women.
  - Anyone with a weakened immune system.
  - People with certain long-term health problems.
  - Some children with asthma or wheezing problems.
  - Children or adolescents on long-term aspirin therapy.
  - Close contacts of people who need special care for an extremely weakened immune system.

  Your doctor can give you more information.
- Tell your doctor if you have gotten any other vaccines in the past 4 weeks.
- If you are sick, your doctor might suggest waiting to be vaccinated until you have recovered.

4. Risks

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Serious problems from flu vaccine are very rare. LAIV is made from weakened virus and **does not cause flu**.

Mild problems following LAIV:
Some children and adolescents 2-17 years of age have reported:
- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:
- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems following inactivated flu vaccine:

- A severe allergic reaction could occur after any vaccine (estimated less than 1 in a million doses).

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

5. What if there is a serious problem?

What should I look for?
- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?
- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7. How can I learn more?

- Ask your doctor or other healthcare professional.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC): Call 1-800-232-4636 or visit CDC's website at www.cdc.gov/flu

Vaccine Information Statement (Interim)
Live Attenuated Influenza Vaccine (date)
42 U.S.C. §300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention

5.2

Vaccine Information Statement

Influenza (Flu) Vaccine (Inactivated): What you need to know
2013-14

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Influenza ("flu") is a contagious disease that spreads around the United States every winter, usually between October and May.

It is caused by the influenza virus, which can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but risk of infection is highest among children. Symptoms come on suddenly and last several days. They include:
• fever/chills • sore throat • muscle aches • fatigue • cough • headache
• runny or stuffy nose

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker.

Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

Each year thousands of people die from flu, and many more are hospitalized.

2. Inactivated flu vaccine

There are two types of influenza vaccine:

You are getting an **inactivated** (killed) vaccine, the "flu shot," which is given by injection with a needle.

There is also a **live, attenuated** (weakened) influenza vaccine, which is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

Flu viruses are always changing. Flu vaccine is changed each year to match the strains of flu virus that are causing disease that year. Each year's flu shot contains 3 or 4 virus strains.

You should get a dose of flu vaccine every year to make sure you are protected from the latest virus strains. Some children 8 years old and younger should get two doses their first year.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts about a year.

Flu vaccination is especially important for people more likely to get a severe case of flu, such as young children, older people, and people with certain health problems. It is also important for anyone in close contact with these people.

Other illnesses can look like flu, and are often mistaken for flu. Flu vaccine will not prevent these illnesses.

It will also not prevent all cases of flu. But people who are vaccinated and still get the flu usually get a milder case than people who aren't vaccinated.

If you are 65 years of age or older, you can get an optional "high-dose" flu vaccine. Your doctor can tell you more about it.

Some inactivated flu vaccine contains a mercury-based preservative called thimerosal. Studies have shown that thimerosal in vaccines is not harmful, but thimerosal-free flu vaccine is available.

Flu vaccine may safely be given at the same time as other vaccines.

3. Precautions

- If you ever had a life-threatening allergic reaction after a dose of flu vaccine, you should not another dose.

- If you have a severe allergy to any component of flu vaccine, you should not get it. *Tell your doctor if you have any severe allergies.*

- Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralyzing illness, also called GBS). Your doctor will help you decide if flu vaccine is recommended for you.

- If you are sick, your doctor might suggest waiting to be vaccinated until you have recovered.

4. Risks

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Serious problems from flu vaccine are very rare. Inactivated flu vaccine is made from killed viruses, so **getting flu from the vaccine is not possible**.

Mild problems following inactivated flu vaccine:

• soreness, redness, or swelling where the shot was given
• hoarseness; sore, red or itchy eyes; cough
• fever • aches • headache • itching • fatigue
If these problems occur, they usually begin soon after the shot and last 1-2 days.

Moderate problems following inactivated flu vaccine:

Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.

Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Severe problems following inactivated flu vaccine:

- A **severe allergic reaction** could occur after any vaccine (estimated less than 1 in a million doses).

- In 1976, a type of flu (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, no flu vaccine has been clearly linked to GBS. Such a link can't be ruled out, but the risk would be no more than 1 or 2 cases per million. This is much lower than the risk of severe flu, which can be prevented by flu vaccine.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

5. What if there is a serious problem?

What should I look for?
- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?
- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

7. How can I learn more?

- Ask your doctor or other healthcare professional.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC): Call 1-800-232-4636 or visit CDC's website at www.cdc.gov/flu

Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (date)
42 U.S.C. §300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention

5.3

Vaccine Information Statement

Pneumococcal Conjugate Vaccine: What You Need to Know

Your doctor recommends that you, or your child, get a dose of PCV13 vaccine today.

1. Why get vaccinated?

Pneumococcal conjugate vaccine (PCV13) is recommended to protect infants and toddlers, and some adults with certain health conditions, from **pneumococcal disease**.

Pneumococcal disease is caused by infection with *Streptococcus pneumoniae* bacteria. These bacteria can spread from person to person through close contact.

Pneumococcal disease can lead to severe health problems, including pneumonia, blood infections, and meningitis.

Meningitis is an infection of the covering of the brain. Pneumococcal meningitis is fairly rare (less than 1 case per 100,000 people each year), but it leads to other health problems, including deafness and brain damage. In children, it is fatal in about 1 case out of 10.

Children younger than two are at higher risk for serious disease than older children.

Adults with certain medical conditions, people over age 65, and cigarette smokers are also at higher risk.

Before vaccine, pneumococcal infections caused many problems in children under 5 in the United States, including:
- over 700 cases of meningitis,
- 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths.

About 4,000 adults still die each year because of pneumococcal infections.

Pneumococcal infections can be hard to treat because some strains are resistant to drugs. This makes **prevention through vaccination** even more important.

2. PCV13 Vaccine

There are more than 90 types of pneumococcal bacteria. PCV13 vaccine protects against 13 of them. These 13 strains cause most severe infections in children and about half of infections in adults with damaged immune systems.

PCV13 is routinely given to children at 2, 4, 6, and 12 through 15 months of age. This is when they are at greatest risk for serious diseases caused by pneumococcal infection.

PCV13 vaccine may also be recommended for some older children or adults. Your doctor can give you details.

A second type of pneumococcal vaccine, called PPSV23, may also be given to some children and adults, including anyone over age 65. There is a separate Vaccine Information Statement for this vaccine.

3. Precautions

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. Tell your doctor if the person being vaccinated has any severe allergies.

If the person scheduled for vaccination is sick, your doctor might decide to reschedule the shot on another day.

Your doctor can give you more information about any of these precautions.

4. Risks

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Reported problems associated with PCV13 varied by dose and age, but generally:

- About half of children were drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F).
- Up to about 8 out of 10 became fussy or irritable.

Adults receiving the vaccine have reported redness, pain, and swelling where the shot was given. Also mild fever, fatigue, headache, chills, or muscle pain.

Life-threatening allergic reactions from any vaccine are very rare.

5. What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heart beat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, get the person to the nearest hospital or call 9-1-1. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

7. How can I learn more?

- Ask your doctor or other healthcare professional.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  -Call **1-800-232-4636 (1-800-CDC-INFO),** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

5.4

Rotavirus Vaccine: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite http://www.immunize.org/vis

Your doctor recommends that your child gets a dose of rotavirus vaccine today.

1. Why get vaccinated?

Rotavirus infection is one of the most common causes of severe diarrhea, mostly in babies and young children. It also causes vomiting and fever, and can lead to dehydration.

Before rotavirus vaccine, rotavirus infection was a serious health problem for children in the United States. Every year:

- more than 400,000 babies had to see a doctor for rotavirus infection,
- more than 200,000 had to go to the emergency room,
- 55,000 to 70,000 had to be hospitalized, and
- 20 to 60 died.

Almost all children in the U.S. had at least one rotavirus infection before their 5th birthday.

2. Rotavirus vaccine

Rotavirus vaccine has been used since 2006 in the United States. Thanks to the vaccine, rotavirus office visits, hospitalizations, and emergency visits have all dropped dramatically.

Two brands of rotavirus vaccine are available. Your baby will get either 2 or 3 doses, depending on which vaccine is used.

Doses of rotavirus vaccine are recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed)

Rotavirus vaccine is an oral (swallowed) vaccine, not a shot.

Rotavirus vaccine may safely be given at the same time as other vaccines.

Rotavirus vaccine is very good at preventing diarrhea and vomiting caused by rotavirus. Almost all babies who get rotavirus vaccine will be protected from **severe** rotavirus diarrhea. And most of these babies will not get rotavirus diarrhea at all. The vaccine will not prevent diarrhea or vomiting caused by other germs.

3. Precautions

- A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose.

  A baby who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine.

  Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.

- Babies with "severe combined immunodeficiency" (SCID) should not get rotavirus vaccine.

- Babies who have ever had a type of bowel blockage called "intussusception" should not get rotavirus vaccine.

- Babies who are mildly ill can probably get the vaccine today. Babies who are moderately or severely ill should probably wait until they recover. This includes babies with moderate or severe diarrhea or vomiting.

- Check with your doctor if your baby's immune system is weakened because of:

  - HIV/AIDS, or any other disease that affects the immune system

  - treatment with drugs such as long-term steroids

  - cancer, or cancer treatment with x-rays or drugs

4. Risks

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most babies who get rotavirus vaccine do not have any problems with it. But some problems have been associated with rotavirus vaccine:

Mild problems
Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.

Serious problems
Intussusception is a type of bowel blockage that is treated in a hospital, and could require surgery. Studies in Australia and Mexico have shown a slight risk of intussusception, usually within a week after the first dose of rotavirus vaccine. The risk is estimated at 1 to 3

intussusception cases per 100,000 babies. This increased risk has not been seen in the United States, but it cannot be ruled out.

5. What if there is a serious problem?

What should I look for?

- For about a week after the first dose of rotavirus vaccine, look for signs of stomach pain with severe crying (which may be brief). Your baby might also act weak or be very irritable, or could vomit or have blood in the stool.

- Look for anything else that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get your baby to the nearest hospital. Otherwise, call your doctor.

- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine may file a claim with VICP by calling **1-800-338-2382** or by visiting their web-site at **www.hrsa.gov/vaccinecompensation**.

7. How can I learn more?

- Ask your doctor or other healthcare professional.

- Call your local or state health department.

- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

6

112TH CONGRESS
2D SESSION

S. 3716

AN ACT

To amend the Internal Revenue Code of 1986 to include vaccines against seasonal influenza within the definition of taxable vaccines.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ADDITION OF VACCINES AGAINST SEASONAL INFLUENZA TO LIST OF TAXABLE VACCINES.

(a) IN GENERAL.—Subparagraph (N) of section 4132(a)(1) of the Internal Revenue Code of 1986 is amended by inserting "or any other vaccine against seasonal influenza" before the period.

(b) EFFECTIVE DATE.—

(1) SALES, ETC.—The amendment made by this section shall apply to sales and uses on or after the later of—

(A) the first day of the first month which begins more than 4 weeks after the date of the enactment of this Act, or

(B) the date on which the Secretary of Health and Human Services lists any vaccine against seasonal influenza (other than any vaccine against seasonal influenza listed by the Secretary prior to the date of the enactment of this Act) for purposes of compensation for any vaccine-related injury or death through the Vaccine Injury Compensation Trust Fund.

(2) DELIVERIES.—For purposes of paragraph (1) and section 4131 of the Internal Revenue Code of 1986, in the case of sales on or before the effective date described in such paragraph for which de-

livery is made after such date, the delivery date shall be considered the sale date.

Passed the Senate January 2, 2013.

Attest:

Secretary.

112TH CONGRESS
2D SESSION

S. 3716

AN ACT

To amend the Internal Revenue Code of 1986 to include vaccines against seasonal influenza within the definition of taxable vaccines.

7

7.1

Pertussis outbreak has state encouraging vaccinations for adults and children

Posted By Andrew Stein On December 20, 2012 @ 11:57 pm In Health | 5 Comments

Vermont is experiencing the most severe outbreak of pertussis, or whooping cough, in documented history. While state numbers show the vaccine's inefficacy in the Green Mountain State, top health officials say there's no better solution.

The 568 cases the state has so far recorded this year are double the previous high of 283 cases set in 1997. [1]

To address the situation, the Department of Health administered more than 3,200 TDaP — or tetanus, diphtheria and acellular pertussis — vaccinations for free on Wednesday, and the state is encouraging all Vermonters to get vaccinated. The outbreak has also rekindled a passionate debate over how to best address immunization and whether legislation mandating vaccines in school-aged children is necessary.

"The vaccination is the best way we have in public health to protect pertussis," said Patsy Kelso, state epidemiologist.

But the pertussis vaccination is also one of the least effective immunization regimens that are commonly prescribed. According to the CDC, the TDaP vaccination protects seven out of 10 people, and the DTaP — diphtheria, tetanus and acellular pertussis — vaccination used on children has an efficacy rate of 80 percent to 90 percent during and after the five-shot process. After five years, the CDC estimates the efficacy rate drops to 70 percent.

A New England Journal of Medicine study found that a child's chance of contracting pertussis increases 42 percent every year after the fifth dose [2]. The Journal of the American Medical Association conducted similar research [3] and came to the same conclusion: The DTaP vaccination wanes in efficacy.

In August, the state found that 90 percent of 178 Vermont kids between the ages of six months and 18 years who contracted pertussis had received at least one dose of the vaccination. About 80 percent of those children had received five or six doses [2].

Since then, the state has not recorded how many people who have contracted pertussis were vaccinated, and the state doesn't plan to use these numbers to make policy.

"We know that pertussis can occur in vaccinated people, and our efforts are focused on increasing vaccination rates and tracking cases," said Kelso. "Whether a case was vaccinated or not wouldn't change anything we're doing."

According to the U.S. Centers for Disease Control (CDC), roughly 93 percent of Vermont's kindergartners have received the DTaP vaccination [4]and about 90 percent of kids over the age of 10 have received the TDaP vaccination [5].

Commissioner of the Department of Health Harry Chen said that although the vaccination has a lower efficacy rate than others, it still provides a higher level of protection to communities and can help mitigate the effects of pertussis if contracted.

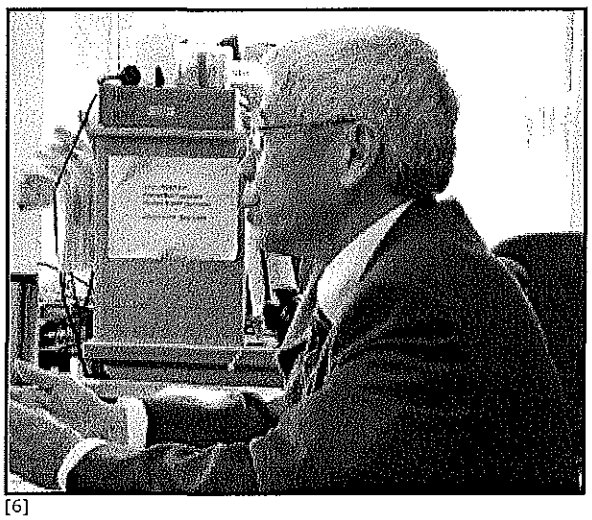
"There's no perfect vaccine, but it is the best thing we have to prevent pertussis," he said. "So, even if after nine or 10 years it's only (70 to) 80 percent effective, it's still the best we have. Certainly the CDC will look at new vaccines. But, until then, our best strategy is to get everyone vaccinated."

In an op-ed entitled "Whooping cough numbers show vaccine rates need to be higher [7]," Rutland Sen. Kevin Mullin, vice chair of the Senate Health and Welfare Committee, agreed with Chen.

"We are seeing firsthand what happens when parents don't immunize their children," he wrote. "It's a danger not only to the child, but also to the community at large."

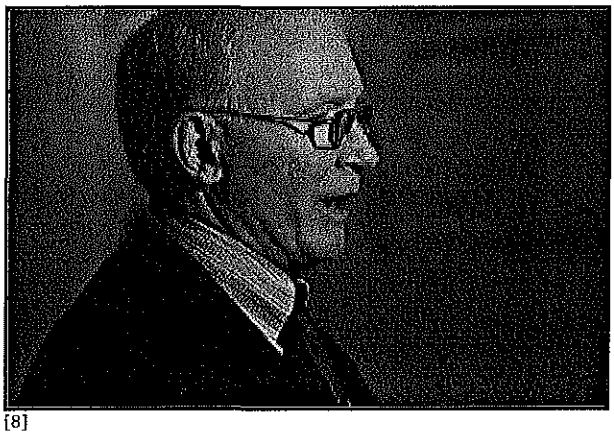
Last year, Mullin spearheaded legislation that called for mandatory child vaccinations in public schools with no philosophical exemptions. It passed in the Senate but failed to pass in the House.

Asked if he would take a stab at a similar bill this year, Mullin said only if the House would move on it.



[6]

Vermont Department of Health Commissioner Harry Chen. VTD File Photo/Alan Panebaker



[8]

Sen. Kevin Mullin, R-Rutland. VTD File Photo/Josh Larkin

That, however, is not likely to happen.

"I know his views on this, and I don't personally disagree,"said Rep. Michael Fisher, chair of the House Health Care Commttee, about Mullin's stance. "I don't think he and I are far apart in terms of policy. But my response is that we just addressed this area of law last year, and I believe we need to give it time to work before making further adjustments. It is not on my agenda to take up immunization bill issues this year."

Chen said he is in support of last year's bill, but isn't going to dwell on its disapproval in the House.

"While I absolutely agree with the policy around mandating vaccinations, I personally feel like we can improve more by concentrating our efforts on (people who) aren't quite up to date (on their vaccines) but want to get up to date and provide better education to parents," he said.

Chen is working with a task force to draw up a report due to legislators next month that will address ways of dealing with children who can't be vaccinated due to underlying diseases or have health issues that make them more vulnerable to contracting certain diseases. Two recommendations that could come out of that report, he said, are to put such children in classes or schools with higher immunization rates and to require teachers and staff to be fully vaccinated.

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[1] The 568 cases the state has so far recorded this year are double the previous high of 283 cases set in 1997.: **http://healthvermont.gov/prevent/pertussis/surveillance.aspx**
[2] A New England Journal of Medicine study found that a child's chance of contracting pertussis increases 42 percent every year after the fifth dose: **http://vtdigger.org/2012/10/08/90-percent-of-whooping-cough-cases-in-vermont-among-vaccinated-children/**
[3] Journal of the American Medical Association conducted similar research: **http://jama.jamanetwork.com/article.aspx?articleid=1456072**
[4] DTaP vaccination : **http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6133a2.htm?s_cid=mm6133a2_w**
[5] TDaP vaccination: **http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6134a3.htm?s_cid=mm6134a3_w**
[6] Image: **http://vtdigger.org/vtdNewsMachine/wp-content/uploads/2012/02/02172012HarryChenSlider.jpg**
[7] Whooping cough numbers show vaccine rates need to be higher: **http://vtdigger.org/2012/12/17/mullin-whooping-cough-numbers-show-vaccine-rates-need-to-be-higher/**
[8] Image: **http://vtdigger.org/vtdNewsMachine/wp-content/uploads/2011/05/20110503-leglistatureGallery.jpg**
[9] : **mailto:dmorso1@netzero.net**
[10] : **http://www.7dvt.com/2012immune-reason**
[11] : **http://healthvermont.gov/prevent/pertussis/Pertussis.aspx**

7.2

February 12, 2013
HUFFPOST HEALTHY LIVING

Whooping Cough: 2012 Was Worst Year For Pertussis Since 1955

By MIKE STOBBE 01/04/13 02:38 PM ET EST AP

The nation just suffered its worst year for whooping cough in nearly six decades, according to preliminary government figures.

Whooping cough ebbs and flows in multi-year cycles, and experts say 2012 appears to have reached a peak with 41,880 cases. Another factor: A vaccine used since the 90s doesn't last as long as the old one.

The vaccine problem may continue to cause higher than normal case counts in the future, said Dr. Tom Clark of the Centers for Disease Control and Prevention.

"I think the numbers are going to trend up," he said. The agency provided the latest figures on Friday.

Last year, cases were up in 48 states and outbreaks were particularly bad in Colorado, Minnesota, Washington state, Wisconsin and Vermont.

The good news: Despite the high number of illnesses, deaths didn't increase. Eighteen people died, including 15 infants younger than 1.

Officials aren't sure why there weren't more deaths, but think that the attention paid to bad outbreaks across the nation resulted in infected children getting diagnosed faster and treated with antibiotics.

Also, a push last year to vaccinate pregnant women – a measure designed to pass immunity to infants – may have had some small measure of success, Clark said.

The final tally will be higher but unlikely to surpass the nearly 63,000 illnesses in 1955, he said.

Whooping cough is a highly contagious disease that can strike people of any age but is most dangerous to children. Its name comes from the sound children make as they gasp for breath.

It used to be a common threat, with hundreds of thousands of cases annually. Cases gradually dropped after a vaccine was introduced in the 1940s.

For about 25 years, fewer than 5,000 cases were reported annually in the U.S. But case counts started to climb again in the 1990s although not every year. Numbers jumped to more than 27,000 in 2010, the year California saw an especially bad epidemic.

Experts looking for an explanation have increasingly looked at a new vaccine introduced in the 1990s, and concluded its protection is not as long-lasting as was previously thought.

Children are routinely vaccinated with five doses beginning at 2 months, and a booster shot is recommended at around 11 or 12. Health officials are considering recommending another booster shot, strengthening the vaccine or devising a brand new one.

Online:

Whooping cough: http://www.cdc.gov/features/pertussis/

7.3

JANUARY 28, 2013

Panel Pushes Vaccine for Pregnant Women

By JENNIFER CORBETT DOOREN

Pregnant women should be vaccinated against whooping cough during each pregnancy to protect their infants, as public-health officials warn of a steep rise in the disease, according to new recommendations from a federal advisory committee.

Associated Press/Republican-American

Susan Bojka, manager of the Family Birthing Center in Waterbury, Conn., prepares the pertussis vaccine for a new mother last fall.

Federal guidelines currently call for all adults, including pregnant women, to receive the whooping cough vaccination one time.

The Centers for Disease Control and Prevention said more than 41,000 cases of whooping cough were reported to the agency last year, the highest level in more than 50 years and more than double the 2011 total. The disease was linked to 18 deaths in 2012, with the majority of them babies younger than 3 months old.

The new recommendation for pregnant women is contained in the 2013 version of the U.S. adult immunization schedule, updated yearly by the CDC's vaccine advisory panel. It says women should receive a vaccine for tetanus, diphtheria and pertussis, together known as Tdap, toward the end of pregnancy, or between 27 and 36 weeks' gestation. The vaccination is intended to offer protection against pertussis, the bacteria that causes whooping cough, until babies are old enough to begin receiving their own vaccinations against the disease starting at 2 months of age.

Mothers who are vaccinated during pregnancy produce antibodies to pertussis and other bacteria that are passed on to babies before they are born, said Sandra A. Fryhofer, a liaison to the CDC's advisory committee on immunization practices and who represents the American College of Physicians.

"Clearly pertussis is back and we are in danger of losing control" of the disease, said H. Cody Meissner, a professor of pediatrics at Tufts University School of Medicine and a liaison to the CDC's vaccine advisory panel. "People forget how bad pertussis can be."

The advice is at odds with other federal regulations on the vaccine. The U.S. Food and Drug Administration has only approved it for one-time use, rather than multiple

uses. But doctors don't need FDA approval to administer the vaccine repeatedly, so the agency's stance won't necessarily hinder adherence to the new guidelines.

Whooping cough is highly contagious and spread through coughing and sneezing. The disease can cause persistent, violent and rapid coughing until the air is gone from the lungs and people are forced to inhale with a loud "whooping" sound. The cough can last for weeks.

The adult vaccination schedule was published online Monday in the Annals of Internal Medicine and will be available on the CDC's website. An updated 2013 immunization schedule for children and adolescents also recommends pregnant adolescents receive the Tdap vaccine.

The Tdap vaccine is sold as Boostrix by GlaxoSmithKline PLC and as Adacel by a unit of Sanofi SA. Boostrix has FDA approval for use in people 10 years old and above while Adacel is approved for in people ages 11 through 64.

Babies and children are vaccinated against pertussis, diphtheria and tetanus through a similar vaccine that's referred to as Dtap in a five-dose series during infancy and up to age 6. Additional vaccinations are recommended when children are 11-to-12 years old and for adults because it's believed that immunity to pertussis from childhood vaccines wanes over time.

The advisory panel voted to adopt the recommendation last October. The new immunization schedules have also been approved by medical groups that include the American College of Physicians and the American College of Obstetricians and Gynecologists.

The new guidelines also recommend people with mild egg allergies receive a flu shot rather than FluMist, a vaccination made by a unit of AstraZeneca PLC that is delivered through the nose. Prior recommendations had suggested that anyone with egg allergies not receive an influenza vaccine. Now, only people with severe egg allergies are advised not to get an influenza vaccine. Flu vaccines are recommended annually for people ages 6 months and older.

Write to Jennifer Corbett Dooren at jennifer.corbett-dooren@dowjones.com

Corrections & Amplifications

H. Cody Meissner is a professor of pediatrics at Tufts University School of Medicine and also works at Tufts Medical Center. An earlier version of this article incorrectly said he is a professor at Tufts University Medical Center.

A version of this article appeared Jan. 29, 2013, on page D2 in some U.S. editions of The Wall Street Journal, with the headline: Panel Pushes Vaccine for Pregnant Women.

7.4

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Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedules for Persons Aged 0 Through 18 Years and Adults Aged 19 Years and Older — United States, 2013

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Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedules for Persons Aged 0 Through 18 years and Adults Aged 19 Years and Older — United States, 2013

Introduction

Each year, recommendations for routine use of vaccines in children, adolescents, and adults in the United States are developed by the Advisory Committee on Immunization Practices (ACIP). This year, for the first time, recommended immunization schedules for persons aged 0 through 18 years and adults aged 19 years and older are being published together.

Placing These Schedules on Your Website

CDC's National Center for Immunization and Respiratory Diseases (NCIRD) maintains the most current immunization schedules on the Vaccines and Immunizations pages of CDC's website (http://www.cdc.gov/vaccines/schedules), including the schedules published in this supplement. If errors or omissions are discovered after publication of the schedules, CDC posts revised versions on the Vaccines and Immunizations Web pages.

CDC encourages organizations that have previously relied on copying and posting PDFs of the schedules to their websites to instead use a safer method to consistently display current schedules. This form of "content syndication" ensures that the most current and accurate immunization schedule information is on each organization's website. This one-time step assures that your website displays current yearly schedules as soon as they are published, or revised.

To place the schedules on a website, organizations simply include two lines of CDC-furnished computer code on their Web page. Each organization's Web developer places the code into their existing website; the code automatically loads the current CDC schedule and footnotes. The schedule is visible within the organization's Web page, and all other images and Web navigation display unchanged. Any CDC revisions or updates will automatically and immediately be reflected on the organization's Web page.

This form of content syndication also gives organizations the ability to offer a PDF of each schedule on their website. Staff members and Web visitors can print as well as view immunization schedules and be confident they have the most current versions. Instructions for copying and placing syndication code are available at http://www.cdc.gov/vaccines/schedules/hcp/syndicate.html.

CDC offers technical assistance for organizations implementing this form of content syndication. For assistance, readers can complete the e-mail form on the NCIRD Web support page (http://www.cdc.gov/vaccines/web-support.html), and a NCIRD Web team staff member will contact them and provide assistance.

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 Obstetrics and Gynecology (ACOG). Recommendations for routine use of vaccines in adults are reviewed and approved by the American College of Physicians (ACP), AAFP, ACOG, and the American College of Nurse-Midwives. ACIP recommendations adopted by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report (*MMWR*).

Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule for Persons Aged 0 Through 18 Years — United States, 2013

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Each year, the Advisory Committee on Immunization Practices (ACIP) reviews the current recommended immunization schedules for persons aged 0 through 18 years to ensure that the schedule reflects current recommendations for licensed vaccines. In October 2012, ACIP approved the recommended immunization schedules for persons aged 0 through 18 years for 2013, which includes several changes from 2012.

Health-care providers are advised to use both the recommended schedule and the catch-up schedule (Figures 1 and 2) in combination with their footnotes (pages 6–8) and not as stand-alones. For guidance on the use of all the vaccines in the schedules, including contraindications and precautions to use of a vaccine, providers are referred to the respective ACIP vaccine recommendations.

Printable versions of the regular and catch-up schedules are available at http://www.cdc.gov/vaccines/schedules in various formats, including landscape and pocket-sized, in regular paper or laminated versions. A "parent friendly" regular schedule is available at http://www.cdc.gov/vaccines/schedules/easy-to-read/child.html#print.

For 2013, several new references and links to additional information have been added, including one for travel vaccine requirements and recommendations (*1*). New references also are provided for vaccination of persons with primary and secondary immunodeficiencies. Changes to the previous schedules (*2*) include the following:

- Figure 1, "Recommended immunization schedule for persons aged 0 through 18 years" replaces "Recommended immunization schedule for persons aged 0 through 6 years" and "Recommended immunization schedule for persons aged 7 through 18 years."
  - Wording was added to bars to represent the respective vaccine dose numbers in the series.
  - The meningococcal conjugate vaccine (MCV4) purple bar was extended to age 6 weeks, to reflect licensure of Hib-MenCY vaccine.
  - The hepatitis A (HepA) vaccine yellow bar was extended to better reflect routine age recommendations for use of HepA vaccine. New green and purple bars were added to reflect hepatitis A vaccine recommendations for older children.
  - Abbreviations for influenza vaccine were updated with the anticipation of quadrivalent vaccine for the 2013–14 influenza season.
  - Pneumococcal polysaccharide vaccine (PPSV23) was added to Figure 1.
- Footnotes were combined and standardized formatting was used to provide recommendations for each vaccine related to routine vaccination, catch-up vaccination, and vaccination of persons with high-risk medical conditions or under special circumstances.
  - Meningococcal conjugate vaccine (MCV4) footnotes were updated to reflect recent recommendations (*3*).
  - Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine footnotes were updated to reflect recent recommendations (*4*).
  - Influenza vaccine footnotes were updated to provide dosing guidance for children aged 6 months through 8 years for the 2012–13 and 2013–14 influenza seasons (*5*).
- Meningococcal conjugate (MCV4) vaccine minimum ages and intervals were updated in Figure 2, "Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind—United States, 2013," to reflect licensure of Hib-MenCY vaccine.

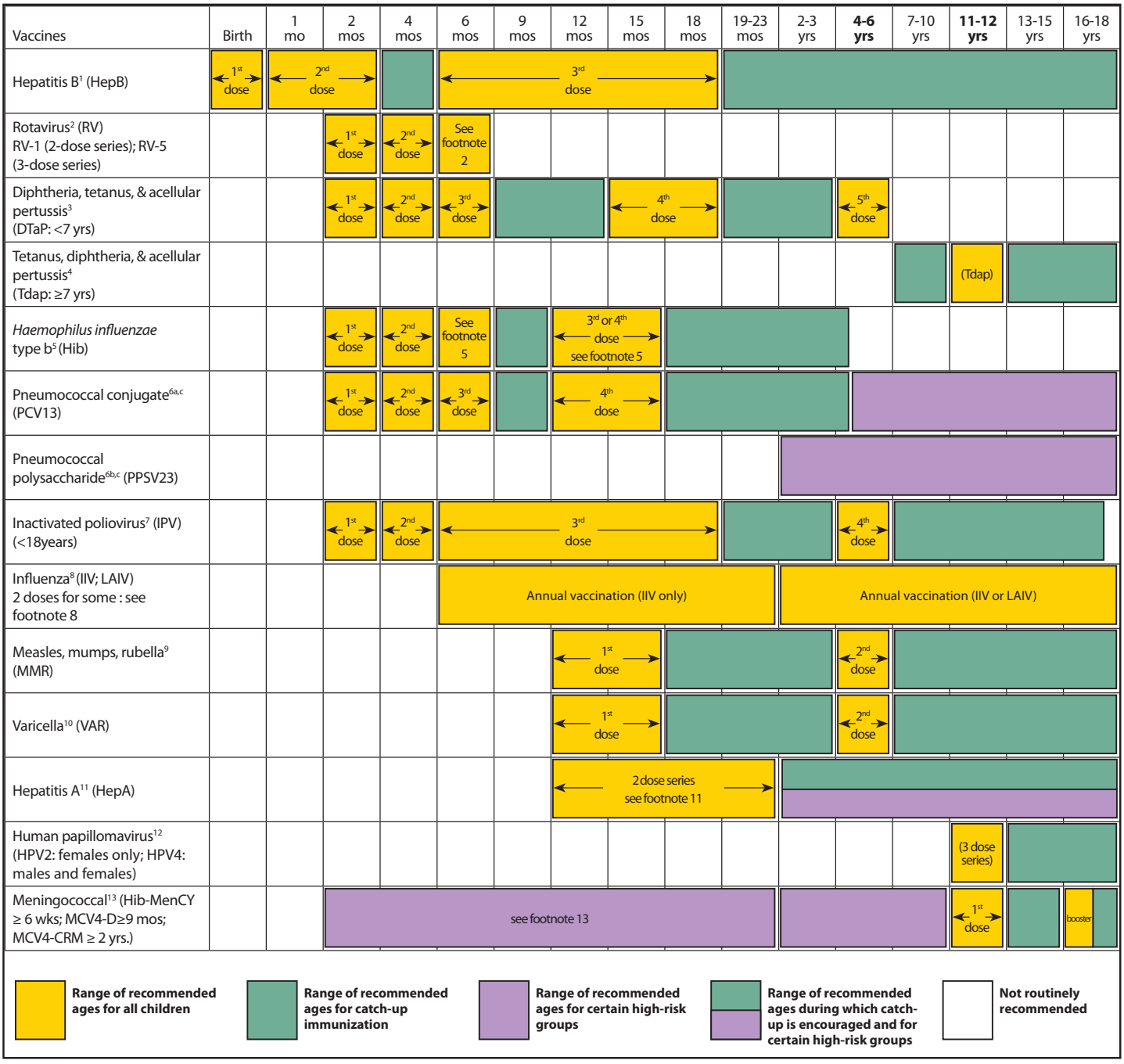
References

1. CDC. Traveler's health: vaccinations. Atlanta, GA: US Department of Health and Human Services, CDC; 2012. Available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
2. CDC. Recommended immunization schedules for persons aged 0–18 years—United States, 2012. MMWR 2012;61(5).
3. CDC, Advisory Committee on Immunization Practices. Resolution no. 10/12-2. Vaccines to prevent meningococcal disease. Atlanta, GA: US Department of Health and Human Services, CDC, Advisory Committee on Immunization Practices; 2012.
4. CDC. Update on use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine in pregnant women. Atlanta, GA: US Department of Health and Human Services, CDC.
5. CDC, Advisory Committee on Immunization Practices. Resolution no. 10/12-3. Vaccines to prevent influenza. Atlanta, GA: US Department of Health and Human Services, CDC, Advisory Committee on Immunization Practices; 2012. Available at http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/1012-3-flu.pdf.

ACIP Childhood/Adolescent Immunization Work Group

FIGURE 1. Recommended immunization schedule for persons aged 0 through 18 years —2013 (for those who fall behind or start late, see the catch-up schedule [Figure 2])

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.



This schedule includes recommendations in effect as of January 1, 2013. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes on pages 6–8.

FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind — United States, 2013

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Persons aged 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B[1]	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus[2]	6 weeks	4 weeks	4 weeks[2]		
Diphtheria, tetanus, pertussis[3]	6 weeks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[5]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[5] if current age is younger than 12 months 8 weeks (as final dose)[5] if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months	
Pneumococcal[6]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks	6 months[7] minimum age 4 years for final dose	
Meningococcal[13]	6 weeks	8 weeks[13]	see footnote 13	see footnote 13	
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months			
Hepatitis A[11]	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, pertussis[4]	7 years[4]	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human papillomavirus[12]	9 years	Routine dosing intervals are recommended[12]			
Hepatitis A[11]	12 months	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks[7]	6 months[7]	
Meningococcal[13]	6 weeks	8 weeks[13]			
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

NOTE: The above recommendations must be read along with the footnotes on pages 6–8.

Footnotes: Recommended Immunization Schedule for Persons Aged 0 Through 18 Years — United States, 2013

Additional guidance for use of the vaccines described in this publication is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm

1. **Hepatitis B (HepB) vaccine. (Minimum age: birth)**
   Routine vaccination:
   At birth
   - Administer monovalent HepB vaccine to all newborns before hospital discharge.
   - For infants born to hepatitis B surface antigen (HBsAg)–positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).

   Doses following the birth dose
   - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
   - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
   - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
   - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.

   Catch-up vaccination:
   - Unvaccinated persons should complete a 3-dose series.
   - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
   - For other catch-up issues, see Figure 2.
2. **Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [RotaTeq]).**
   Routine vaccination:
   - Administer a series of RV vaccine to all infants as follows:
     1. If RV-1 is used, administer a 2-dose series at 2 and 4 months of age.
     2. If RV-5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
     3. If any dose in series was RV-5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

   Catch-up vaccination:
   - The maximum age for the first dose in the series is 14 weeks, 6 days.
   - Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months, 0 days.
   - If RV-1 (Rotarix) is administered for the first and second doses, a third dose is not indicated.
   - For other catch-up issues, see Figure 2.
3. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.

   Catch-up vaccination:
   - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
   - For other catch-up issues, see Figure 2.
4. **Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for Boostrix, 11 years for Adacel).**
   Routine vaccination:
   - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
   - Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
   - Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.

   Catch-up vaccination:
   - Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine should not be given.
   - Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
   - An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
   - For other catch-up issues, see Figure 2.
5. ***Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a Hib vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (PedvaxHib or Comvax) is administered at 2 and 4 months of age, a dose at age 6 months is not indicated. One booster dose should be administered at age 12 through15 months.
   - Hiberix (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have received at least 1 dose of Hib.

   Catch-up vaccination:
   - If dose 1 was administered at ages 12-14 months, administer booster (as final dose) at least 8 weeks after dose 1.
   - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
   - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
   - For unvaccinated children aged 15 months or older, administer only 1 dose.
   - For other catch-up issues, see Figure 2.

   Vaccination of persons with high-risk conditions:
   - Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unvaccinated or partially vaccinated persons aged 5 years or older who have leukemia, malignant neoplasms, anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, or other immunocompromising conditions.

6a. **Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a series of PCV13 vaccine at ages 2, 4, 6 months with a booster at age 12 through 15 months.
   - For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

   Catch-up vaccination:
   - Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
   - For other catch-up issues, see Figure 2.

   Vaccination of persons with high-risk conditions:
   - For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 if 3 doses of PCV were received previously, or administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
   - A single dose of PCV13 may be administered to previously unvaccinated children aged 6 through 18 years who have anatomic or functional asplenia (including sickle cell disease), HIV infection or an immunocompromising condition, cochlear implant or cerebrospinal fluid leak. See MMWR 2010;59 (No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
   - Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

6b. Pneumococcal polysaccharide vaccine (PPSV23). (Minimum age: 2 years)
Vaccination of persons with high-risk conditions:
- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV should be administered after 5 years to children with anatomic or functional asplenia (including sickle cell disease) or an immunocompromising condition.

6c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older and for which use of PCV13 is indicated in children aged 24 through 71 months:
- Immunocompetent children with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus; cerebrospinal fluid leaks; or cochlear implant.
- Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction);
- Children with immunocompromising conditions: HIV infection, chronic renal failure and nephrotic syndrome, diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)
Routine vaccination:
- Administer a series of IPV at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:
- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up issues, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV]; 2 years for live, attenuated influenza vaccine [LAIV])
Routine vaccination:
- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) those with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) those who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV see MMWR 2010; 59 (No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.
- Administer 1 dose to persons aged 9 years and older.

For children aged 6 months through 8 years:
- For the 2012–13 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. For additional guidance, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations, MMWR 2012; 61: 613–618, available at http://www.cdc.gov/mmwr/pdf/wk/mm6132.pdf.
- For the 2013–14 season, follow dosing guidelines in the 2013 ACIP influenza vaccine recommendations.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)
Routine vaccination:
- Administer the first dose of MMR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older, before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:
- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)
Routine vaccination:
- Administer the first dose of VAR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:
- Ensure that all persons aged 7 through 18 years without evidence of immunity (see MMWR 2007;56 [No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2 doses of varicella vaccine. For children aged 7 through 12 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A vaccine (HepA). (Minimum age: 12 months)
Routine vaccination:
- Initiate the 2-dose HepA vaccine series for children aged 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months, should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:
- The minimum interval between the two doses is 6 months.

Special populations:
- Administer 2 doses of Hep A vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection.

12. Human papillomavirus (HPV) vaccines. (HPV4 [Gardasil] and HPV2 [Cervarix]). (Minimum age: 9 years)
Routine vaccination:
- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11-12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series can be started beginning at age 9 years.
- Administer the second dose 1 to 2 months after the **first** dose and the third dose 6 months after the **first** dose (at least 24 weeks after the first dose).

Catch-up vaccination:
- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines (MCV). (Minimum age: 6 weeks for Hib-MenCY, 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM]).
Routine vaccination:
- Administer MCV4 vaccine at age 11–12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, with at least 8 weeks between doses. See MMWR 2011; 60:1018–1019 available at: http://www.cdc.gov/mmwr/pdf/wk/mm6030.pdf.
- For children aged 9 months through 10 years with high-risk conditions, see below.

Catch-up vaccination:
- Administer MCV4 vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children younger than 19 months of age with anatomic or functional asplenia (including sickle cell disease), administer an infant series of Hib-MenCY at 2, 4, 6, and 12-15 months.
- For children aged 2 through 18 months with persistent complement component deficiency, administer either an infant series of Hib-MenCY at 2, 4, 6, and 12 through 15 months or a 2-dose primary series of MCV4-D starting at 9 months, with at least 8 weeks between doses. For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of MCV4-D at least 8 weeks apart.
- For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease), who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of either MCV4-D or MCV4-CRM. If MCV4-D (Menactra) is administered to a child with asplenia (including sickle cell disease), do not administer MCV4-D until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children aged 9 months and older who are residents of or travelers to countries in the African meningitis belt or to the Hajj, administer an age appropriate formulation and series of MCV4 for protection against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children who are present during outbreaks caused by a vaccine serogroup, administer or complete an age and formulation-appropriate series of Hib-MenCY or MCV4.
- For booster doses among persons with high-risk conditions refer to http://www.cdc.gov/vaccines/pubs/acip-list.htm#mening.

Additional Vaccine Information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
- For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Information on travel vaccine requirements and recommendations is available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in General Recommendations on Immunization (ACIP), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm; and American Academy of Pediatrics. Passive immunization. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. Red book: 2012 report of the Committee on Infectious Diseases. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedule for Adults Aged 19 Years and Older — United States, 2013

ACIP Adult Immunization Work Group
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Vaccines are recommended for adults on the basis of age, prior vaccinations, health conditions, lifestyle, occupation, and travel. Current levels of vaccination coverage among adults are low (*1*). Health-care providers should be aware of the importance of routinely assessing patients' vaccination histories and recommending and providing routinely recommended vaccines. A strong recommendation from a health-care provider is associated with increased uptake of vaccines (*2,3*). Other interventions shown to increase vaccine uptake, such as implementation of reminder/recall systems and standing orders, have been summarized by the Community Guide (*3*).

The Advisory Committee on Immunization Practices (ACIP) annually reviews and updates the adult immunization schedule, which is designed to provide vaccine providers with a summary of existing ACIP recommendations regarding the routine use of vaccines for adults (Figures 1 and 2). The adult schedule also includes a table summarizing the primary contraindications and precautions for routinely recommended vaccines (Table). In October 2012, ACIP approved the adult immunization schedule for 2013. This schedule also incorporates changes to vaccine recommendations voted on by ACIP at its October 24–25, 2012 meeting.

The primary updates include adding information for the first time on the use of 13-valent pneumococcal conjugate vaccine (PCV13) and the timing of administration of PCV13 relative to the 23-valent pneumococcal polysaccharide vaccine (PPSV23) in adults (*4*). PCV13 is recommended for adults aged 19 years and older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants. The schedule also clarifies which adults need 1 or 2 doses of PPSV23 before age 65 years. Other changes to the PPSV23 footnote include adding information regarding recommendations for vaccination when vaccination status is unknown.

For tetanus, diphtheria, and acellular pertussis (Tdap) vaccine, recommendations have been expanded to include routine vaccination of adults aged 65 years and older and for pregnant women to receive Tdap vaccine with each pregnancy. The ideal timing of Tdap vaccination during pregnancy is during 27–36 weeks' gestation. This recommendation was made to increase the likelihood of optimal protection for the pregnant woman and her infant during the first few months of the infant's life, when the child is too young for vaccination but at highest risk for severe illness and death from pertussis (*5,6*).

Manufacturers of the live, attenuated influenza vaccine (LAIV) have obtained Food and Drug Administration (FDA) approval for a quadrivalent influenza vaccine that contains one influenza A (H3N2), one influenza A (H1N1) and two influenza B vaccine virus strains, one from each lineage of circulating influenza B viruses. In approximately half of the recent influenza seasons, the trivalent influenza vaccine has included an influenza B vaccine virus from the lineage different from the predominant circulating influenza B strains (*7*). Inclusion of both lineages of influenza B virus is intended to increase the likelihood that the vaccine provides cross-reactive antibody against a higher proportion of circulating influenza B viruses. For LAIV, beginning with the 2013–14 season, it is expected that only the quadrivalent formulation will be available and manufacture of the trivalent formulation will cease. It is possible that quadrivalent inactivated influenza vaccine formulations might be available for the 2013–14 season as well. Because a mix of quadrivalent and trivalent influenza vaccines might be available in 2013–14, the abbreviation for inactivated influenza vaccine has been changed from trivalent inactivated influenza vaccine (TIV) to inactivated influenza vaccine (IIV). The abbreviation for LAIV remains unchanged.

Minor wording changes, clarifications, or simplifications have been made to footnotes for measles, mumps, rubella vaccine (MMR), human papillomavirus vaccine (HPV), zoster vaccine, and hepatitis A and hepatitis B vaccines. A correction has been made to Figure 1 for MMR vaccine: the bar that indicated the vaccine might be used in certain situations by persons born before 1957 has been removed. Persons born before 1957 are considered immune, and routine vaccination

is not recommended. Considerations for the possible use of MMR vaccine in outbreak situations are included in the 2011 *MMWR* publication on vaccination of health-care personnel (*8*). In addition, a correction was made to Figure 2 for PPSV23. This vaccine is indicated for men who have sex with men if they have another risk factor (e.g., age or underlying condition); the bar has been changed from yellow to purple to more accurately reflect the recommendation.

Vaccine providers are reminded to consult the full ACIP vaccine recommendations if they have questions and to bear in mind that additional updates might be made for specific vaccines during the year between updates to the adult schedule. Printable versions of the 2013 adult immunization schedule and other information is available at http://www.cdc.gov/vaccines/schedules/hcp/adult.html. Information about adult vaccination is available at http://www.cdc.gov/vaccines/default.htm. ACIP statements and information for specific vaccines is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Adverse events from vaccination should be reported at http://www.vaers.hhs.gov or by telephone, 800-822-7967. This schedule has been approved by the American Academy of Family Physicians, the American College of Physicians, the American College of Obstetrics and Gynecology, and the American College of Nurse-Midwives. The adult immunization schedule is published in the *Annals of Internal Medicine* at the same time that it is published in *MMWR*.

Changes for 2013

Footnotes

- Information was added to footnote #1 to direct readers to additional information regarding recommendations for vaccination when vaccination status is unknown.
- The influenza vaccination footnote (#2) now uses the abbreviation IIV for inactivated influenza vaccine and drops the abbreviation TIV for trivalent inactivated vaccine (TIV). For the 2013–14 influenza season, it is expected that the LAIV will be available only in a quadrivalent formulation; IIV might be available in both trivalent and quadrivalent formulations.
- The tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination footnote (#3) is updated to include the recommendation to vaccinate pregnant women with Tdap during each pregnancy, regardless of the interval since prior Td/Tdap vaccination and to include the recommendation for all other adults, including persons aged 65 years and older, to receive 1 dose of Tdap vaccine.
- The varicella (#4) and HPV (#5) footnotes were simplified; no changes in recommendations were made. Additional information was added to the HPV footnote regarding HPV vaccination and pregnancy.
- The zoster footnote (#6) was changed to clarify that ACIP recommends vaccination of persons beginning at age 60 years both for persons with and without underlying health conditions for whom the vaccine is not contraindicated.
- The measles, mumps, rubella (MMR) vaccine footnote (#7) was modified to reflect the new recommendation that a provider diagnosis of measles, mumps, or rubella is not considered acceptable evidence of immunity. Previously, a provider diagnosis of measles or mumps, but not rubella, was considered acceptable evidence of immunity.
- Information was added to the pneumococcal polysaccharide (PPSV23) vaccination footnote (#8) and PPSV23 revaccination footnote (#9) to clarify that persons with certain medical conditions are recommended to receive 2 doses of PPSV23 before age 65 years. In addition, even those who receive 2 doses of PPSV23 before age 65 years are recommended to receive PPSV23 at age 65 years, as long as it has been 5 years since the most recent dose. The PPSV23 footnote refers to footnote #10 for pneumococcal conjugate 13-valent vaccine (PCV13) regarding the timing of PCV13 vaccine relative to PPSV23 for those persons recommended to be vaccinated with both pneumococcal vaccines.
- A new footnote (#10) was added for PCV13 vaccine. This vaccine is recommended for adults aged 19 years and older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants. Those not previously vaccinated with PCV13 or PPSV23 should receive a single dose of PCV13, followed by a dose of PPSV23 at least 8 weeks later. Those previously vaccinated with PPSV23 should be vaccinated with PCV13 one year or more after PPSV23 vaccination (*4*).
- The hepatitis A vaccine footnote (#12) was updated to clarify that vaccination is recommended for persons with a history of either injection or noninjection illicit drug use.
- The hepatitis B vaccine footnote (#13) includes minor wording changes and adds information on the vaccine schedule for hepatitis B vaccine series for the Recombivax HB vaccine. The dosing schedules for other hepatitis B vaccines were included in prior years' schedules.

Figures

- For figure 1, the bar for Tdap/Td for persons aged 65 years and older has been changed to solid yellow because all adults, including those 65 years and older, are now recommended to receive one dose of Tdap vaccine (*5*).
- The bar for MMR vaccine for persons born before 1957 has been removed. MMR vaccine is not recommended routinely for persons born before 1957. Considerations for vaccination in measles or mumps outbreak settings are discussed in the ACIP recommendations for health-care personnel (*8*).
- A new row for PCV13 vaccine has been added.
- For Figure 2, the recommendation for Tdap vaccination with each pregnancy is included, with a single dose of Tdap recommended for all other groups (*6*).
- A correction was made to change the color for PPSV23 from yellow to purple for men who have sex with men (MSM). PPSV23 is recommended for MSM who have another risk factor such as age group or medical condition.
- A row for PCV13 was added (*4*).

Contraindications and Precautions Table

- The inactivated influenza vaccine precautions were updated to indicate that persons who experience only hives with exposure to eggs should receive IIV rather than LAIV.
- Pregnancy was removed as a precaution for hepatitis A vaccine. This is an inactivated vaccine, and similar to hepatitis B vaccines, is recommended if another high risk condition or other indication is present.
- Language was clarified regarding the precaution for use of antiviral medications and vaccination with varicella or zoster vaccines.

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ACIP Adult Immunization Work Group

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FIGURE 1. Recommended adult immunization schedule, by vaccine and age group[1]

These recommendations must be read with the footnotes that follow.

VACCINE ▼ AGE GROUP ▶	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza [2,*]	1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella [4,*]	2 doses					
Human papillomavirus (HPV) Female [5,*]	3 doses					
Human papillomavirus (HPV) Male [5,*]	3 doses					
Zoster [6]					1 dose	
Measles, mumps, rubella (MMR) [7,*]	1 or 2 doses					
Pneumococcal polysaccharide (PPSV23) [8,9]	1 or 2 doses					1 dose
Pneumococcal 13-valent conjugate (PCV13) [10]	1 dose					
Meningococcal [11,*]	1 or more doses					
Hepatitis A [12,*]	2 doses					
Hepatitis B [13,*]	3 doses					

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.
Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.
Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.
Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

FIGURE 2. Recommended vaccinations indicated for adults based on medical and other indications[1]

VACCINE ▼ INDICATION ▶	Pregnancy	Immuno-compromising conditions (excluding human immunodeficiency virus [HIV])[4,6,7,10,15]	HIV infection CD4+ T lymphocyte count[4,6,7,10,14,15] < 200 cells/μL	HIV infection CD4+ T lymphocyte count[4,6,7,10,14,15] ≥ 200 cells/μL	Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and persistent complement component deficiencies)[10,14]	Chronic liver disease	Kidney failure, end-stage renal disease, receipt of hemodialysis	Diabetes	Healthcare personnel
Influenza [2,*]	1 dose IIV annually				1 dose IIV or LAIV annually	1 dose IIV annually					1 dose IIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	1 dose Tdap each pregnancy	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs									
Varicella [4,*]	Contraindicated			2 doses							
Human papillomavirus (HPV) Female [5,*]		3 doses through age 26 yrs				3 doses through age 26 yrs					
Human papillomavirus (HPV) Male [5,*]		3 doses through age 26 yrs				3 doses through age 21 yrs					
Zoster [6]	Contraindicated				1 dose						
Measles, mumps, rubella (MMR) [7,*]	Contraindicated			1 or 2 doses							
Pneumococcal polysaccharide (PPSV23) [8,9]						1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13) [10]					1 dose						
Meningococcal [11,*]					1 or more doses						
Hepatitis A [12,*]						2 doses					
Hepatitis B [13,*]						3 doses					

*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

No recommendation

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2013. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Footnotes: Recommended Immunization Schedule for Adults Aged 19 Years and Older — United States, 2013

1. **Additional information**
   - Additional guidance for the use of the vaccines described in this supplement is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
   - Information on vaccination recommendations when vaccination status is unknown and other general immunization information can be found in the General Recommendations on Immunization at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.
   - Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) are available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
2. **Influenza vaccination**
   - Annual vaccination against influenza is recommended for all persons aged 6 months and older.
   - Persons aged 6 months and older, including pregnant women, can receive the inactivated influenza vaccine (IIV).
   - Healthy, nonpregnant persons aged 2–49 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist), or IIV. Health-care personnel who care for severely immunocompromised persons (i.e., those who require care in a protected environment) should receive IIV rather than LAIV.
   - The intramuscularly or intradermally administered IIV are options for adults aged 18–64 years.
   - Adults aged 65 years and older can receive the standard dose IIV or the high-dose IIV (Fluzone High-Dose).
3. **Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination**
   - Administer one dose of Tdap vaccine to pregnant women during each pregnancy (preferred during 27–36 weeks' gestation), regardless of number of years since prior Td or Tdap vaccination.
   - Administer Tdap to all other adults who have not previously received Tdap or for whom vaccine status is unknown. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-toxoid containing vaccine.
   - Adults with an unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series including a Tdap dose.
   - For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.
   - For incompletely vaccinated (i.e., less than 3 doses) adults, administer remaining doses.
   - Refer to the Advisory Committee on Immunization Practices (ACIP) statement for recommendations for administering Td/Tdap as prophylaxis in wound management (see footnote #1).
4. **Varicella vaccination**
   - All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
   - Special consideration for vaccination should be given to those who have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
   - Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
   - Evidence of immunity to varicella in adults includes any of the following:
     - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
     - U.S.-born before 1980 except health-care personnel and pregnant women;
     - history of varicella based on diagnosis or verification of varicella disease by a health-care provider;
     - history of herpes zoster based on diagnosis or verification of herpes zoster disease by a health-care provider; or
     - laboratory evidence of immunity or laboratory confirmation of disease.
5. **Human papillomavirus (HPV) vaccination**
   - Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).
   - For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years, and for those aged 13 through 26 years, if not previously vaccinated.
   - For males, HPV4 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years, and for those aged 13 through 21 years, if not previously vaccinated. Males aged 22 through 26 years may be vaccinated.
   - HPV4 is recommended for men who have sex with men (MSM) through age 26 years for those who did not get any or all doses when they were younger.
   - Vaccination is recommended for immunocompromised persons (including those with HIV infection) through age 26 years for those who did not get any or all doses when they were younger.
   - A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose (at least 24 weeks after the first dose).
   - HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. If a woman is found to be pregnant after initiating the vaccination series, no intervention is needed; the remainder of the 3-dose series should be delayed until completion of pregnancy.
   - Although HPV vaccination is not specifically recommended for health-care personnel (HCP) based on their occupation, HCP should receive the HPV vaccine as recommended (see above).
6. **Zoster vaccination**
   - A single dose of zoster vaccine is recommended for adults aged 60 years and older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons aged 50 years and older, ACIP recommends that vaccination begins at age 60 years.
   - Persons aged 60 years and older with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.
   - Although zoster vaccination is not specifically recommended for HCP, they should receive the vaccine if they are in the recommended age group.
7. **Measles, mumps, rubella (MMR) vaccination**
   - Adults born before 1957 generally are considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine, or laboratory evidence of immunity to each of the three diseases. Documentation of provider-diagnosed disease is not considered acceptable evidence of immunity for measles, mumps, or rubella.

   Measles component:
   - A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
     - are students in postsecondary educational institutions;
     - work in a health-care facility; or
     - plan to travel internationally.
   - Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type during 1963–1967 should be revaccinated with 2 doses of MMR vaccine.

   Mumps component:
   - A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
     - are students in a postsecondary educational institution;
     - work in a health-care facility; or
     - plan to travel internationally.
   - Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health-care facility) should be considered for revaccination with 2 doses of MMR vaccine.

   Rubella component:
   - For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

HCP born before 1957:

- For unvaccinated health-care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health-care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.

8. Pneumococcal polysaccharide (PPSV23) vaccination

- Vaccinate all persons with the following indications:
  - all adults aged 65 years and older;
  - adults younger than age 65 years with chronic lung disease (including chronic obstructive pulmonary disease, emphysema, and asthma); chronic cardiovascular diseases; diabetes mellitus; chronic renal failure; nephrotic syndrome; chronic liver disease (including cirrhosis); alcoholism; cochlear implants; cerebrospinal fluid leaks; immunocompromising conditions; and functional or anatomic asplenia (e.g., sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]);
  - residents of nursing homes or long-term care facilities; and
  - adults who smoke cigarettes.
- Persons with immunocompromising conditions and other selected conditions are recommended to receive PCV13 and PPSV23 vaccines. See footnote #10 for information on timing of PCV13 and PPSV23 vaccinations.
- Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis.
- When cancer chemotherapy or other immunosuppressive therapy is being considered, the interval between vaccination and initiation of immunosuppressive therapy should be at least 2 weeks. Vaccination during chemotherapy or radiation therapy should be avoided.
- Routine use of PPSV23 is not recommended for American Indians/Alaska Natives or other persons younger than age 65 years unless they have underlying medical conditions that are PPSV23 indications. However, public health authorities may consider recommending PPSV23 for American Indians/Alaska Natives who are living in areas where the risk for invasive pneumococcal disease is increased.
- When indicated, PPSV23 should be administered to patients who are uncertain of their vaccination status and there is no record of previous vaccination. When PCV13 is also indicated, a dose of PCV13 should be given first (see footnote #10).

9. Revaccination with PPSV23

- One-time revaccination 5 years after the first dose is recommended for persons aged 19 through 64 years with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions.
- Persons who received 1 or 2 doses of PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose.
- No further doses are needed for persons vaccinated with PPSV23 at or after age 65 years.

10. Pneumococcal conjugate 13-valent vaccination (PCV13)

- Adults aged 19 years or older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, CSF leaks or cochlear implants, and who have not previously received PCV13 or PPSV23 should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later.
- Adults aged 19 years or older with the aforementioned conditions who have previously received one or more doses of PPSV23 should receive a dose of PCV13 one or more years after the last PPSV23 dose was received. For those that require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years since the most recent dose of PPSV23.
- When indicated, PCV13 should be administered to patients who are uncertain of their vaccination status history and there is no record of previous vaccination.
- Although PCV13 is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons aged 50 years and older, ACIP recommends PCV13 for adults aged 19 years and older with the specific medical conditions noted above.

11. Meningococcal vaccination

- Administer 2 doses of meningococcal conjugate vaccine quadrivalent (MCV4) at least 2 months apart to adults with functional asplenia or persistent complement component deficiencies.
- HIV-infected persons who are vaccinated also should receive 2 doses.
- Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- First-year college students up through age 21 years who are living in residence halls should be vaccinated if they have not received a dose on or after their 16th birthday.
- MCV4 is preferred for adults with any of the preceding indications who are aged 55 years and younger; meningococcal polysaccharide vaccine (MPSV4) is preferred for adults aged 56 years and older.
- Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia or persistent complement component deficiencies).

12. Hepatitis A vaccination

- Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
  - men who have sex with men and persons who use injection or non-injection illicit drugs;
  - persons working with HAV-infected primates or with HAV in a research laboratory setting;
  - persons with chronic liver disease and persons who receive clotting factor concentrates;
  - persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A; and
  - unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. (See footnote #1 for more information on travel recommendations). The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
- Single-antigen vaccine formulations should be administered in a 2-dose schedule at either age 0 and 6–12 months (Havrix), or age 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21–30, followed by a booster dose at month 12.

13. Hepatitis B vaccination

- Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection:
  - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men;
  - health-care personnel and public-safety workers who are potentially exposed to blood or other infectious body fluids;
  - persons with diabetes younger than age 60 years as soon as feasible after diagnosis; persons with diabetes who are age 60 years or older at the discretion of the treating clinician based on increased need for assisted blood glucose monitoring in long-term care facilities, likelihood of acquiring hepatitis B infection, its complications or chronic sequelae, and likelihood of immune response to vaccination;
  - persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease;
  - household contacts and sex partners of hepatitis B surface antigen-positive persons; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection; and
  - all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.
- Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second

dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.

- Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 µg/mL (Recombivax HB) administered on a 3-dose schedule at 0, 1, and 6 months or 2 doses of 20 *µg*/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

14. Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used

- 1 dose of Hib vaccine should be considered for persons who have sickle cell disease, leukemia, or HIV infection, or who have anatomic or functional asplenia if they have not previously received Hib vaccine.

15. Immunocompromising conditions

- Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.

TABLE. Contraindications and precautions to commonly used vaccines in adults[1]*†

Vaccine	Contraindications	Precautions
Influenza, inactivated vaccine (IIV)	Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine or to a vaccine component, including egg protein.	Moderate or severe acute illness with or without fever. History of Guillain-Barré Syndrome (GBS) within 6 weeks of previous influenza vaccination. Persons who experience only hives with exposure to eggs should receive IIV with additional safety precautions.[2]
Influenza, live attenuated (LAIV)[3]	Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine or to a vaccine component, including egg protein. Conditions for which the Advisory Committee on Immunization Practices (ACIP) recommends against use, but which are not contraindications in vaccine package insert: immune suppression, certain chronic medical conditions such as asthma, diabetes, heart or kidney disease. and pregnancy.[4]	Moderate or severe acute illness with or without fever. History of GBS within 6 weeks of previous influenza vaccination. Receipt of specific antivirals (i.e., amantadine, rimantadine, zanamivir, or oseltamivir) 48 hours before vaccination. Avoid use of these antiviral drugs for 14 days after vaccination.
Tetanus, diphtheria, pertussis (Tdap); tetanus, diphtheria (Td)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component. For pertussis-containing vaccines: encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of Tdap or diphtheria and tetanus toxoids and pertussis (DTP) or diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine.	Moderate or severe acute illness with or without fever. GBS within 6 weeks after a previous dose of tetanus toxoid–containing vaccine. History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diptheria toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine. For pertussis-containing vaccines: progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.
Varicella[2]	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component. Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy[5] or patients with human immunodeficiency virus (HIV) infection who are severely immunocompromised). Pregnancy.	Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product).[6,7] Moderate or severe acute illness with or without fever. Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination.
Human papillomavirus (HPV)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.	Moderate or severe acute illness with or without fever. Pregnancy.
Zoster	Severe allergic reaction (e.g., anaphylaxis) to a vaccine component. Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, or long-term immunosuppressive therapy[5] or patients with HIV infection who are severely immunocompromised). Pregnancy.	Moderate or severe acute illness with or without fever. Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination.
Measles, mumps, rubella (MMR)[3]	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component. Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy[5] or patients with HIV infection who are severely immunocompromised). Pregnancy.	Moderate or severe acute illness with or without fever. Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product).[6,7] History of thrombocytopenia or thrombocytopenic purpura. Need for tuberculin skin testing.[8]

See footnotes on page 18.

TABLE. *(Continued)* Contraindications and precautions to commonly used vaccines in adults[1]*†

Vaccine	Contraindications	Precautions
Pneumococcal polysaccharide (PPSV)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.	Moderate or severe acute illness with or without fever.
Pneumococcal conjugate (PCV13)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including to any vaccine containing diphtheria toxoid.	Moderate or severe acute illness with or without fever.
Meningococcal, conjugate, (MCV4); meningococcal, polysaccharide (MPSV4)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.	Moderate or severe acute illness with or without fever.
Hepatitis A (HepA)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.	Moderate or severe acute illness with or without fever.
Hepatitis B (HepB)	Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.	Moderate or severe acute illness with or without fever.

1. Vaccine package inserts and the full ACIP recommendations for these vaccines should be consulted for additional information on vaccine-related contraindications and precautions and for more information on vaccine excipients. Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. A contraindication is a condition in a recipient that increases the chance of a serious adverse reaction. Therefore, a vaccine should not be administered when a contraindication is present.
2. CDC. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP) — United States, 2012–13 influenza season. MMWR 2012;61:613-8.
3. LAIV, MMR, and varicella vaccines can be administered on the same day. If not administered on the same day, these live vaccines should be separated by at least 28 days.
4. For a complete list of conditions that CDC considers to be reasons to avoid getting LAIV, see CDC. Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR 2010;59(No. RR-8). Available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
5. Immunosuppressive steroid dose is considered to be 2 or more weeks of daily receipt of 20 mg prednisone or the equivalent. Vaccination should be deferred for at least 1 month after discontinuation of such therapy. Providers should consult ACIP recommendations for complete information on the use of specific live vaccines among persons on immune-suppressing medications or with immune suppression because of other reasons.
6. Vaccine should be deferred for the appropriate interval if replacement immune globulin products are being administered.
7. See CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60(No. RR-2). Available at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
8. Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine may be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for at least 4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.

* Adapted from CDC. Table 6. Contraindications and precautions to commonly used vaccines. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices. MMWR 2011;60(No. RR-2):40–41 and from Atkinson W, Wolfe S, Hamborsky J, eds. Appendix A. Epidemiology and prevention of vaccine preventable diseases. 12th ed. Washington, DC: Public Health Foundation, 2011. Available at http://www.cdc.gov/vaccines/pubs/pinkbook/index.html.

† Regarding latex allergy. Consult the package insert for any vaccine administered.

Advisory Committee on Immunization Practices
Membership List, October 2012

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7.5

Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (MMWR)

Infant Meningococcal Vaccination: Advisory Committee on Immunization Practices (ACIP) Recommendations and Rationale

Weekly

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At its October 2012 meeting, the Advisory Committee on Immunization Practices (ACIP) voted to recommend vaccination against meningococcal serogroups C and Y for children aged 6 weeks through 18 months at increased risk for meningococcal disease. Meningococcal groups C and Y and *Haemophilus* b tetanus toxoid conjugate vaccine (Hib-MenCY-TT [MenHibrix, GlaxoSmithKline Biologicals]) is licensed for active immunization for prevention of invasive disease caused by *Haemophilus influenzae* type b (Hib) and meningococcal serogroups C and Y. Hib-MenCY-TT is not indicated for prevention of disease caused by meningococcal serogroup B, the most common serogroup causing disease in infants, or serogroups W135 or A, which are represented in quadrivalent meningococcal vaccines. Before licensure of Hib-MenCY-TT, no meningococcal conjugate vaccine was licensed for infants aged 2 through 8 months. MenACWY-D (Menactra, Sanofi Pasteur) is licensed as a 2-dose series for infants and toddlers aged 9 through 23 months, and MenACWY-D and MenACWY-CRM (Menveo, Novartis Vaccines) are licensed for persons aged 2 through 55 years as a single dose. These vaccines are recommended routinely for persons aged 11 through 18 years and persons aged 2 through 55 years at increased risk for meningococcal disease (and persons aged 9 months through 55 years for MenACWY-D) (*1*,*2*). This report summarizes the deliberations of ACIP, the rationale for its decision, and recommendations for use of Hib-MenCY-TT in infants at increased risk for meningococcal disease.

Methods

On June 14, 2012, the Food and Drug Administration licensed Hib-MenCY-TT for the prevention of invasive Hib and serogroups C and Y meningococcal disease in children aged 6 weeks through 18 months (*3*). In monthly teleconferences during 2009–2012 and annual in-person meetings, ACIP's Meningococcal Vaccines Work Group reviewed safety and immunogenicity data from phase 2 and phase 3 clinical trials as well as data on disease epidemiology and the infant vaccination schedule. The work group reviewed published peer-reviewed literature and unpublished data that were relevant to infant meningococcal vaccination. Summaries of the data that were reviewed and work group discussions were presented to ACIP before recommendations were proposed. Proposed infant meningococcal vaccination recommendations were presented at the October 2012 ACIP meeting and approved by ACIP.

Hib-MenCY-TT Safety and Immunogenicity

Hib-MenCY-TT is a combination of three discrete polysaccharide-protein conjugates. Each capsular polysaccharide is bound covalently to tetanus toxoid. The first dose may be given as early as age 6 weeks. The fourth dose may be given as late as age 18 months. Hib-MenCY-TT is supplied as a single-dose vial of lyophilized vaccine to be reconstituted with the accompanying vial of saline diluent (*3*). Hib-MenCY-TT effectiveness was inferred based on the following: 1) Hib antibody responses after Hib-MenCY-TT vaccination that were comparable to antibody responses after Hib-TT (first 3 doses) or Hib polyribosylribitol phosphate–meningococcal outer membrane protein (PRP-OMP) (PedvaxHIB, Merck and Co) (fourth dose) vaccination, and 2) the proportion of persons with measurable meningococcal serogroups C and Y serum bactericidal activity using human complement (hSBA) after Hib-MenCY-TT vaccination. Evaluation of hSBA responses in clinical studies could be used to infer protection because an association between serum bactericidal activity and clinical effectiveness already exists (*4*). In the United States, meningococcal clinical endpoint efficacy trials with Hib-MenCY-TT were not feasible, and no meningococcal vaccine is licensed and available for this age group to allow a comparative trial.

A single-blinded, controlled, multicenter study with two parallel randomized groups was conducted to evaluate safety and immunogenicity of Hib-MenCY-TT compared with U.S.-licensed Hib-TT (ActHIB, Sanofi Pasteur) in healthy infants at ages 2, 4, and 6 months (*5*). The proportions of children who, after dose 3, had hSBA titers ≥1:8 (the clinical threshold defined as protective) to serogroups C and Y were 99% and 96%, respectively (*5*). The proportion of children who had anti-HibPRP antibody concentrations ≥1.0 μg/mL (the accepted level indicative of long-term protection) after dose 3 was 96% in the Hib-MenCY-TT group and 91% in the Hib-TT group (*5*). Hib-MenCY-TT also was evaluated before and after the fourth dose given at age 12–15 months. HibPRP-OMP was used in the control vaccine group. The proportion of subjects with hSBA titers ≥1:8 was 99% for serogroups C and Y 1 month after the fourth dose. The Hib response after the fourth dose also was demonstrated to be noninferior to HibPRP-OMP (the percentage of subjects with anti-HibPRP antibody concentrations ≥1.0 μg/mL was 99.2% in both treatment groups).

Hib-MenCY-TT was co-administered with DTaP-HepB-IPV and 7-valent pneumococcal conjugate vaccine (PCV7) at ages 2, 4, and 6 months, and with measles-mumps-rubella, varicella, and PCV7 vaccines at age 12–15 months. In clinical trials, no decreased immunogenicity of coadministered vaccines was observed (*5,6*). A randomized, controlled, multicenter study evaluated the percentage of subjects with hSBA titers ≥1:8 at 2 months after the second dose was administered at age 4 months. In the group vaccinated with Hib-MenCY-TT, 94% and 83% of subjects achieved hSBA antibody titers ≥1:8 for meningococcal serogroups C and Y, respectively, after dose 2 (*7*). Rates of local and systemic adverse events observed after administration of Hib-MenCY-TT were comparable to rates observed after administration of Hib-TT. Thus, Hib-MenCY-TT was found to be safe and immunogenic for both Hib and meningococcal serogroups C and Y.

Summary of ACIP Deliberations and Rationale

Infants at increased risk for meningococcal disease. Infants with persistent complement component pathway deficiencies or functional or anatomical asplenia have an increased risk for meningococcal disease compared with healthy infants. Complement component deficiencies rarely are observed in

infancy, but infants might be identified because of family history. Certain infants with complex congenital heart disease have asplenia, and infants with sickle cell disease often are identified via newborn screening programs. Infants with sickle cell disease initially might have functioning spleens, but develop functional asplenia during early childhood. Infrequently, healthy infants also might be at increased risk because of a serogroups C or Y meningococcal disease outbreak for which vaccination is recommended. The number of U.S. infants in these high-risk groups is small (estimated at 3,000–5,000), making a targeted high-risk vaccination policy feasible and reasonable given the potential increased risk in these infants. Infants who are traveling with their families to the Hajj or to the "meningitis belt" of sub-Saharan Africa need protection against serogroups A and W135, which are not in Hib-MenCY-TT, and should receive a quadrivalent meningococcal conjugate vaccination licensed for children aged ≥9 months before travel (*8*).

Infants not at increased risk for meningococcal disease. ACIP reviewed the burden of meningococcal disease among infants and children aged 0–59 months. Meningococcal disease is a serious, but rare, infectious disease. Rates of meningococcal disease have declined in all age groups since 2000, and, in 2011, the overall rate of meningococcal disease was at a historic low of 0.21 per 100,000 population (CDC, unpublished data, 2011). In the United States, during 1993–2011, average annual rates of meningococcal disease were higher among children aged 0 through 59 months (1.74 per 100,000 population) than in adolescents aged 11 through 19 years (0.57 per 100,000) (CDC, unpublished data, 2011). However, approximately 60% of disease among children aged 0 through 59 months is caused by serogroup B meningococcal disease, which is not prevented by any meningococcal vaccine licensed in the United States. Additionally, the highest incidence in the first 5 years of life occurs in infants aged 0 through 6 months, most of whom are too young to have received the minimum 2 or 3 doses of vaccine that likely will be needed to provide protection. The case-fatality ratio of meningococcal disease caused by serogroups C and Y is lower among children aged <59 months (6%) compared with adolescents (11%) (*9,10*). During 2007–2009, approximately 77 cases and four to eight deaths from serogroups C and Y *Neisseria meningitidis* occurred annually in children aged <59 months. For the estimated 205 annual cases of meningococcal disease in children aged <59 months that occurred during 2007–2009, a universal infant meningococcal vaccination program would have prevented 40–50 cases (nearly 25% of cases in this age group) (CDC, unpublished data, 2012). The epidemiology of meningococcal disease is dynamic, and rates of disease could increase in the future, requiring a reassessment of immunization strategy.

Presentations, including 1) a cost-effectiveness analysis of vaccinating all U.S. infants, 2) programmatic aspects of adding meningococcal vaccination to the infant routine immunization schedule, and 3) results of a survey evaluating attitudes of pediatricians and family physicians toward vaccinating all infants with meningococcal vaccines, were made at the October 2011 ACIP meeting and summarized during the October 2012 ACIP meeting.* These considerations support the ACIP decision, but the current epidemiology of meningococcal disease is the primary rationale for the decision. In summary, the current low burden of disease, as well as the low proportion of meningococcal cases that are preventable with vaccines that do not protect against serogroup B disease, limit the potential impact of a routine meningococcal vaccination program in infants in the United States. Therefore, ACIP concluded

that a targeted approach to protect infants at increased risk for meningococcal disease was the optimal vaccination strategy at this time. At the October 2012 ACIP meeting, ACIP voted to recommend vaccination with Hib-MenCY-TT only for infants at increased risk for meningococcal disease.

ACIP Recommendations for Infants at Increased Risk for Meningococcal Disease

Infants at increased risk for meningococcal disease should be vaccinated with a 4-dose series of Hib-MenCY-TT. These include infants with recognized persistent complement pathway deficiencies and infants who have anatomic or functional asplenia including sickle cell disease. Additionally, Hib-MenCY-TT can be used in infants aged 6 weeks through 18 months who are in communities with serogroups C and Y meningococcal disease outbreaks, but Hib-MenCY-TT is not adequate for infants traveling to the Hajj or the "meningitis belt" of sub-Saharan Africa (a quadrivalent meningococcal vaccine that contains serogroups A and W135 is required for those infants and may be given starting at age 9 months).

If an infant at increased risk for meningococcal disease is behind on his or her Hib vaccine doses, Hib-MenCY-TT may be used following the same catch-up schedule used for Hib vaccine. However, if the first dose of Hib-MenCY-TT is given at or after 12 months of life, 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease. For infants at increased risk for meningococcal disease who have received or are going to receive a different Hib vaccine product, ACIP recommends a 2-dose series of MenACWY-D if they are aged 9 through 23 months or either of the two quadrivalent meningococcal vaccine products after age 23 months.

Hib-MenCY-TT may be co-administered with other routine infant vaccinations, including 13-valent pneumococcal conjugate vaccine. Hib-MenCY-TT should not be co-administered with other Hib-containing vaccines.

Guidance for Use of Hib-MenCY-TT

Based on an assessment of the potential public health impact, including the current low incidence of meningococcal disease in the United States, at this time ACIP does not recommend routine meningococcal vaccination for infants who are not at increased risk for meningococcal disease. Hib-MenCY-TT is safe and immunogenic against Hib and *N. meningitidis* serogroups C and Y. Hib-MenCY-TT may be used in any infant for routine vaccination against Hib and will offer some protection against serogroups C and Y meningococcal disease. Four doses of Hib-MenCY-TT fulfill the primary series and booster dose Hib immunization recommendations. If Hib-MenCY-TT vaccine is used to achieve protection against serogroups C and Y, Hib-MenCY-TT should be used for all 4 doses of Hib vaccine. Because the protection offered by meningococcal vaccines wanes over time, an infant series will be unlikely to provide persistent protection against meningococcal disease until age 11–12 years, the age of recommended adolescent vaccination. Infants and children who received Hib-MenCY-TT and are travelling to areas with high endemic rates of meningococcal disease such as the "meningitis belt" are not protected against serogroups A and W-135 and should receive a quadrivalent meningococcal conjugate vaccine licensed for children aged ≥9 months before travel.

ACIP will continue to reevaluate trends in epidemiology to determine whether meningococcal vaccines should be added to the routine infant schedule and what schedule should be implemented for

reimmunization. Vaccines that provide long-term protection against meningococcal disease early in life have the potential to reduce the burden of meningococcal disease, especially if they provide protection against serogroup B meningococcal disease. Health-care providers should be aware of the continued need for early recognition and treatment of meningococcal disease.†

Reported by

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* Additional information available at http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.

† Information available at http://www.cdc.gov/meningitis.