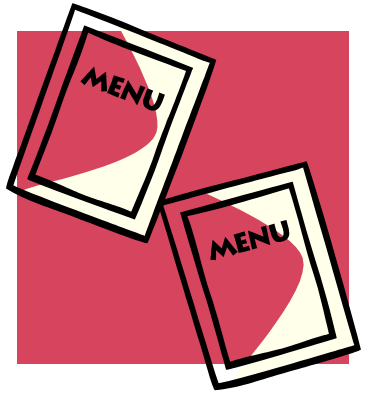

Combos and Specials: A Buffet of Vaccines and Recommendations

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MENU SELECTIONS

- ACIP
- Combination Vaccines
- Special Schedules
- Differences between vaccines for the same antigen
- New schedules/recommendations

Advisory Committee on Immunization Practices (ACIP)

- The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964 to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases.
  - In 1993, Congress gave ACIP unique statutory authority to determine recommendations for the routine administration of vaccines to children and adults in the civilian population; these recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications.
- The ACIP is the only entity in the federal government that makes such recommendations.
- The overall goals of the ACIP are to:
  - provide advice that will assist the Department of Health and Human Services and the nation in reducing the incidence of vaccine-preventable diseases;
  - increase the safe use of vaccines and related biological products.

ACIP CONTINUED

- The ACIP consists of 15 experts in fields associated with immunization and infectious diseases, including the chair. The Committee also includes eight nonvoting ex-officio members and several nonvoting liaison representatives from other health organizations. Major functions of the ACIP are as follows:
  - Develops technical recommendations on vaccine use and immunization practices;
  - Approves vaccines to be provided through the VFC program;
  - Recommends immunization schedules that are harmonized with recommendations of other advisory groups, such as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

- Final immunization recommendations are published in the *Morbidity and Mortality Weekly Report (MMWR)* when approved by the ACIP and the Director of CDC.

Combination Vaccines

- #1 Pediarix®
- #2 Pentacel®
- #3 Comvax®
- #4 TriHIBit®
- #5 ProQuad®
- #6 Kinrix®
- #7 Twinrix®

Rules to remember about combination vaccines

- The minimum interval and age of the combination vaccine is dependent on the antigen with the longest interval and/or the greatest minimum/maximum age.
- Only combination vaccines licensed by FDA should be used.
  - Vaccination providers should not combine separate vaccines into the same syringe to administer
  - Only two vaccines are licensed by the FDA which contain separate antigen components that require mixing by the user
    - Pentacel® (DTaP-IPV/Hib)
    - TriHIBit® (DTaP/Hib)

Extra doses of vaccine antigens

- Administering extra doses contained in combination vaccine should be avoided in most situations.

- Using combination vaccines containing certain antigens not indicated at the time of administration to the patient might be justified when:
  - The extra antigen is not contraindicated
  - Products that contain only the needed antigens are not readily available

Extra doses of vaccine antigens continued

- Potential benefits to the patient outweigh the potential risk for adverse events associated with the extra antigens
  - An extra dose of many live-virus vaccines and Hib or hepatitis B vaccine has not been found to be harmful.
  - However, the risk for an adverse event might increase when extra doses are administered at an earlier time than the recommended interval for certain vaccines (e.g., tetanus toxoid vaccines and PPSV)

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2011

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼ Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB			HepB						
Rotavirus[2]			RV	RV	RV[2]						
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP	*see footnote[3]*	DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	Hib[4]	Hib					
Pneumococcal[5]			PCV	PCV	PCV	PCV				PPSV	
Inactivated Poliovirus[6]			IPV	IPV	IPV						IPV
Influenza[7]					Influenza (Yearly)						
Measles, Mumps, Rubella[8]						MMR		see footnote[8]			MMR
Varicella[9]						Varicella		see footnote[9]			Varicella
Hepatitis A[10]						HepA (2 doses)				HepA Series	
Meningococcal[11]										MCV4	

Range of recommended ages for all children

Range of recommended ages for certain high-risk groups

Quiz – Question #1

Vaccine	Birth	2 Months	4 Months	6 Months	12 Months
Hep B	X				
Pediarix		X	X		
IPV				X	
DTaP				X	X

In this situation with these vaccines, is anything incomplete?

Quiz – Answer #1

Vaccine	Birth	2 Months	4 Months	6 Months	12 Months
Hep B	X			X	
Pediarix		X	X		
IPV				X	
DTaP				X	X

Combo #1 - Pediarix®

- Contains which vaccines?
  - DTaP
  - IPV
  - Hepatitis B
- What is the schedule?
  - 2, 4, and 6 months of age
  - Approved for primary series only
- Notes:
  - When hepatitis B is administered at birth, a dose needs to be administered at 24 weeks or greater to complete the series.

Combo #2 - Pentacel®

- Contains which vaccines?
  - DTaP
  - IPV
  - ActHIB®
- What is the schedule?
  - 2, 4, 6, and 15-18 months of age (first booster dose)
  - Not indicated for children 5 years of age or older or booster dose at 4-6 years.
- Notes:
  - Okay to administer four doses. A fifth dose of IPV will be needed at 4-6 years of age. Five doses of IPV is acceptable by ACIP.

Quiz – Question #2

Vaccine	Birth	2 Months	4 Months	6 Months	12 Months
Hep B	X				
Pediarix		X	X		
ActHIB		X	X		

If at 6 months you only have Pentacel, how do you finish the schedule for these vaccines?

Quiz – Answer #2

Vaccine	Birth	2 Months	4 Months	6 Months	12 Months
Hep B	X			X	
Pediarix		X	X		
ActHIB		X	X		
Pentacel				X	

Then at 15-18 months Pentacel can be administered to finish DTaP, Hib, and IPV.

Combo #3 - Comvax®

- Contains which vaccines?
  - Hepatitis B
  - PedvaxHIB®
- What is the schedule?
  - 2, 4, and 12-15 months of age
- Notes:
  - Hib follows PedvaxHIB® schedule of 2- dose primary series followed by a booster dose after 12 months
  - When hepatitis B is administered at birth, a dose needs to be administered at 24 weeks or greater to complete the series.

Combo #4 - TriHIBit®

- Contains which vaccines?
  - DTaP
  - Hib
- What is the schedule?
  - Only licensed for the fourth dose at age 15-18 months.
- This vaccine is not supplied by the Montana VFC Program.
- In 2011, Sanofi Pasteur will discontinue production of Tripedia® (DTaP) and TriHIBit® (DTaP-Hib). Supplies are expected to last through Q2 2011.

Quiz – Question #3

Vaccine	Birth	2 Months	4 Months	6 Months	12 Months
Hep B	X				
Comvax		X	X		
TriHIBit					X
DTaP		X	X	X	

In this situation with these vaccines, is anything incomplete?

Quiz – Answer #3

Vaccine	Birth	2 Months	4 Months	6 Months	12 Months
Hep B	X			X	
Comvax		X	X		
TriHIBit					X
DTaP		X	X	X	

Combo #5 - ProQuad®

- Contains which vaccines?
  - MMR
  - Varicella
- What is the schedule?
  - Approved for use 12 months through 12 years
    - The first dose of MMR and varicella is routinely recommended at 12-15 months
    - The second dose of these vaccines is routinely recommended at 4-6 years
    - For children 12 years of age and younger, varicella vaccine doses should be separated by at least 3 months. However, if the second dose was administered >28 days after the first dose, the second dose is considered valid and need not be repeated.

Notes: ProQuad®

- For the first dose of measles, mumps, rubella, and varicella vaccines at age 12–47 months, either MMR vaccine and varicella vaccine or MMRV vaccine may be used.
- Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers.
- Unless the parent or caregiver expresses a preference for MMRV vaccine, CDC recommends that MMR vaccine and varicella vaccine should be administered for the first dose in this age group.

Notes continued: ProQuad®

- For the second dose of measles, mumps, rubella, and varicella vaccines at any age (15 months–12 years) and for the first dose at age ≥48 months, use of MMRV vaccine generally is preferred over separate injections of its equivalent component vaccines (i.e., MMR vaccine and varicella vaccine).
- Considerations should include provider assessment, patient preference, and the potential for adverse events.

A personal or family (i.e., sibling or parent) history of seizures of any etiology is a precaution for MMRV vaccination. Children with a personal or family history of seizures of any etiology generally should be vaccinated with MMR vaccine and varicella vaccine.

Combo #6 - Kinrix®

- Contains which vaccines?
  - DTaP
  - IPV
- What is the schedule?
  - Is indicated for use as the fifth dose of DTaP and fourth dose of IPV in children aged 4 - 6 years
  - This vaccine should not be administered to children aged <4 years or ≥7 years;
- Notes:
  - If DTaP-IPV (Kinrix) is inadvertently administered for an earlier dose of the DTaP and/or IPV series, the dose should be counted as valid and does not need to be repeated provided minimum interval requirements have been met.

Combo #7 - Twinrix®

- Contains which vaccines?
  - Hepatitis A
  - Hepatitis B
- What is the schedule?
  - Approved for use in 18 years and older
  - 3 dose schedule
    - Administer dose 2 at least 4 weeks after dose 1
    - Administer dose 3 at least 6 months after dose 1
    - Doses 2 and 3 must be separated by at least 5 months
- Notes:
  - An alternative 4 dose schedule is approved - administered on days 0, 7, 21-30 followed by a booster dose at month 12.

Quiz – Question #4

What if one dose of Twinrix is administered and only single antigen is available at the next visits, how do you finish the series?

Quiz – Answer #4

Hepatitis B is the same schedule whether Twinrix or single-antigen hepatitis B vaccine is used.

Single-antigen hepatitis A vaccine may be used to complete a series begun with Twinrix and vice versa.

A person 19 years of age or older who receives one dose of Twinrix may complete the hepatitis A series with 2 doses of adult formulation hepatitis A vaccine separated by at least 5 months.

Quiz – Answer #4 continued

A person who receives two doses of Twinrix may complete the hepatitis A series with 1 dose of adult formulation hepatitis A vaccine or Twinrix 5 months after the second dose.

A person who begins the hepatitis A series with single-antigen hepatitis A vaccine may complete the series with 2 doses of Twinrix or one dose of adult formulation hepatitis A vaccine.

An 18-year-old should follow the same schedule using the pediatric formulation.

Special Schedules

- #1 Hepatitis B
- #2 Rotavirus
- #3 DTaP
- #4 PCV

Special #1 – Hepatitis B

- When does 1 + 2 = 4?

- The hepatitis B schedule
  - 1 month (4 weeks) between dose 1 and 2
  - 2 months (8 weeks) between dose 2 and 3
  - 4 months (16 weeks) between dose 1 and 3

  - **Don't forget the child must be at least 24 weeks of age to receive dose 3.**

Special #2 - Rotavirus

- Administer the first dose at age 6 through 14 weeks
  - 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
- The schedule is:
  - 2, 4, and 6 months of age
  - However, there are two different vaccines, RotaTeq® (3-dose schedule) and Rotarix® (2-dose schedule)
    - If Rotarix® is administered at ages 2 and 4 months, a dose at 6 months is not indicated.

Quiz – Question #5

Vaccine	Birth	2 Months	4 Months	6 Months
Rotarix		X		
RotaTeq			X	

Are any additional doses needed?

Quiz – Answer #5

Vaccine	Birth	2 Months	4 Months	6 Months
Rotarix		X		X or
RotaTeq			X	X

Yes, if the series is mixed between vaccines then three doses are needed.

Special #3 – DTaP #4

- The recommended age for DTaP #4 is 15-18 months.
- The minimum age for DTaP #4 is 12 months
- The minimum spacing between dose 3 and 4 of DTaP is 6 calendar months.
  - However, if a dose was accidentally administered at least 4 months after dose 3, then it does not need to be repeated.

Special #4 – Pneumococcal Conjugate Vaccine (PCV)

- Routinely administered at 2, 4, 6, and 12-15 months

- Administer 1 dose of 13-valent pneumococcal conjugate vaccine (PCV13) to all healthy children aged 24 through 59 months with any incomplete PCV schedule (PCV7 or PCV13) before 24 months.
  - For children 24-71 months with underlying medical conditions who received any incomplete schedule of <3 doses of PCV before 24 months, 2 doses of PCV 13 are recommended

A single supplemental dose of PCV13 given at least 8 weeks after the last dose of PCV7 is recommended for all children 14 through 59 months of age who have received 4 doses of PCV7.

- For children who have underlying medical conditions, a supplemental dose is recommended through 71 months of age.

PCV continued

- Healthy children aged 7-59 months who have not been vaccinated with PCV7 or PCV13 previously should receive 1-3 doses of PCV13, depending on when vaccination begins.
  - Infants 7-11 months – 3 doses
  - Children aged 12-23 months – 2 doses
  - Children 24 months and older
    - Unvaccinated healthy children – 1 dose
    - Unvaccinated children 24-71 months with underlying medical conditions – 2 doses

- References for PCV schedule:
  - Pink Book
  - Catch-up Immunization Schedule

General Vaccine Notes:

- Injectable or nasally administered live vaccines not administered on the same day should be administered at least four weeks apart.
  - The four day grace period does not apply to this minimum interval
- The series should not be restarted if the intervals are longer than recommended.

General Vaccine Notes continued:

- Vaccines should not be administered at intervals less than the minimum interval or at an age younger than the minimum age.
  - The repeat dose should be spaced after the invalid dose by the recommended minimum interval.
  - If the first dose in a series is administered before the minimum age, the dose should be repeated on or after the date when the child reaches at least the minimum age.
    - If the vaccine is a live vaccine, ensure that a minimum interval of 28 days has elapsed from the invalid dose.

Differences between vaccines for the same antigen

- Hib
- HPV

Haemophilus influenzae type b (Hib)

- Currently, there are three licensed single antigen Hib products in the market in the U.S.
  - ActHIB® (3 dose primary series + booster)
  - PedvaxHIB® (2 dose primary series + booster)
  - Hiberix® (booster dose only)

  - If PRP-OMP (PedvaxHIB or Comvax [HepB-Hib]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.

  - TriHIBit (DTaP/Hib) and Hiberix (PRP-T) should not be used for doses at ages 2, 4, or 6 months for the primary series but can be used as the final dose in children aged 12 months through 4 years.

Hib continued

- When children start the series late, the number of doses may change.

- References for Hib schedule:
  - Pink Book
  - Catch-up Immunization Schedule
  - Hib Vaccination Schedule for Children 12-59 Months of Age: http://www.dphhs.mt.gov/publichealth/immunization/vaccinesforchildren

Quiz – Question #6

If you use PedvaxHIB at 2 months and 4 months, which vaccine should be used for the booster dose?

Quiz – Answer #6

The booster dose can be any of the three licensed Hib products.

Human Papillomavirus (HPV)

- Currently, there are two licensed HPV products in the market in the U.S.
  - Cervarix® - Bivalent HPV vaccine (HPV2)
  - Gardasil® - Quadrivalent HPV vaccine (HPV4)
    - HPV4 may be administered in a 3-dose series to males aged 9 through 26 years to reduce their likelihood of genital warts.
- The schedule for both vaccines is:
  - Licensed for ages 9 through 26 years
  - Administer dose 2 at least 4 weeks after dose 1
  - Administer dose 3 at least 12 weeks after dose 2
  - Administer dose 3 at least 24 weeks after dose 1

New Schedules/Recommendations

- Tdap
- MCV4
- PPSV23

Tdap

- Timing of Tdap following Td
  - ACIP recommends that pertussis vaccination, when indicated, should not be delayed and that Tdap should be administered regardless of interval since the last tetanus or diphtheria toxoid-containing vaccine.
  - ACIP concluded that while longer intervals between Td and Tdap vaccination could decrease the occurrence of local reactions, the benefits of protection against pertussis outweigh the potential risk for adverse events.

Tdap continued

- Undervaccinated children aged 7 through 10 years
  - ACIP recommends a single dose for children aged 7 through 10 years who are not fully vaccinated* against pertussis and for whom no contraindication to pertussis vaccine exists.
  - If additional doses of tetanus and diphtheria toxoid--containing vaccines are needed, then children aged 7 through10 years should be vaccinated according to catch-up guidance, with Tdap preferred as the first dose.
  - Tdap is recommended in this age group because of its reduced antigen content compared with DTaP, resulting in reduced reactogenicity.
  - *Fully vaccinated is defined as 5 doses of DTaP or 4 doses if DTaP if the fourth dose was administered on or after the fourth birthday.

Tdap continued

- Adults aged 65 years and older
  - ACIP recommends that adults aged 65 years and older who have or who anticipate having close contact with an infant less than 12 months of age and have not previously received Tdap should receive a single dose of Tdap.
    - Grandparents
    - Child-care providers
    - Health-care practitioners
  - For other adults aged 65 years and older, a single dose of Tdap vaccine may be given instead of Td vaccine, in persons who have not received Tdap previously.

Meningococcal Conjugate Vaccine (MCV4)

- There are two licensed MCV4 products available.
  - Menactra®
  - Menveo®
- Menveo® vaccine does need to be reconstituted.
- Both are licensed for use in individuals 2 through 55 years.

Meningococcal Conjugate Vaccine (MCV4)

- **Adolescents 11-18 years of age**
  - Routinely recommended at 11-12 years
    - If vaccinated at 11-12 years, should receive a one-time booster dose at age 16 years
    - If vaccinated at 13-15 years, should receive a one-time booster dose at age 16 through 18 years
    - If vaccinated on or after 16 years, no booster is needed
  - There is no recommendation for a mass recall
  - If the primary dose was administered before the 16th birthday, a booster dose should be administered before enrollment in college. The booster dose can be administered anytime after the 16 birthday to ensure that the booster is provided.
  - The minimum interval between doses of meningococcal conjugate vaccine is 8 weeks.

MCV4 continued

- **HIV-infected individuals 11 through 18 years**
  - Primary Vaccination
    - 2 doses of MCV4, two months apart
  - Booster Dose
    - If vaccinated at 11-12 years, should receive a one-time booster dose at age 16 years
    - If vaccinated at 13-15 years, should receive a one-time booster dose at age 16 through 18 years
    - If vaccinated on or after 16 years, no booster is needed
- **Review ACIP Recommendations for guidance HIV-infected individuals in other age groups**

MCV4 continued

- **Persons aged 2 through 55 years with persistent complement component deficiency or functional or anatomical asplenia**
  - Primary Vaccination
    - 2 doses of MCV4, two months apart
  - Booster Dose
    - Should be repeated every five years thereafter
    - If only 1-dose was administered, then administer one dose and repeat every 5 years.

MCV4 continued

- **Persons aged 2 through 55 years with prolonged increased risk for exposure**
  - Travelers to or residents of countries in which meningococcal disease is hyperendemic or epidemic (the "meningitis belt" of Sub-Saharan Africa)
  - Microbiologists routinely exposed to isolates of *N. meningitides*

  - Primary Vaccination
    - Administer 1 initial dose

  - Booster Dose
    - If first dose received at ages 2 through 6 years and remain at increased risk for meningococcal disease, should receive an additional dose of MCV4 3 years after primary vaccination.

    - If person remains at increased risk, boosters should be repeated every five years thereafter.

MCV4 continued

- Booster Dose
  - If first dose received at age 7 or older and remain at increased risk for meningococcal disease, should receive an additional dose of MCV4 5 years after primary vaccination
  - If person remains at increased risk, boosters should be repeated every five years thereafter.

Meningococcal Conjugate Vaccine (MCV) Notes

- MCV4 administered before 10 years of age are not relevant or counted for the purpose of adolescent vaccination. Children should receive a dose at 11-12 and 16 years regardless of the number of doses they received before 10 years of age.

- MCV4 is preferred over meningococcal polysaccharide vaccine (MPSV4) for persons age 55 years and younger.

- Use **MPSV4 ONLY** if age 56 years or older or if there is a permanent contraindication/ precaution to MCV4.

Quiz – Question #7

What if you accidently do not reconstitute Menveo and administer a dose?

Quiz – Answer #7

If the individual is not traveling to the Hajj in Saudi Arabia, to an endemic area (including sub-Saharan Africa “meningitis belt”), or a microbiologist who routinely works with N. meningitides, the recommendation is that the dose does not need to be repeated.

Pneumococcal Polysaccharide Vaccine (PPSV23)

- PPSV23 should be administered to adults aged 19-64 years
  - with chronic or immunosuppressing medical conditions, including those who have asthma
  - who smoke cigarettes

- ACIP does not recommend routine revaccination for most persons for whom PPSV23 is indicated.

- However, a second dose of PPSV23 is recommended 5 years after the first dose for persons 19-64 years
  - for persons with functional or anatomic asplenia
  - for persons with immunocompromising conditions
  - ACIP does not recommend multiple revaccinations because of uncertainty regarding clinical benefit and safety.

PPSV23 continued

- Routine PPSV23 use is no longer recommended for Alaska Natives or American Indians aged less than 65 years, unless they have a medical indication for PPSV23.

- PPSV23 should be administered to all persons at age 65 years
  - If PPSV23 was received before age 65 years, another dose should be administered at age 65 years or later if at least 5 years have passed since previous dose.
  - If PPSV23 is received on or after 65 years, only one dose should be administered.
  - If two doses of PPSV23 were received prior to 65 years, then no further doses are recommended on or after 65 years.

Resources

- ACIP Childhood Schedule http://www.cdc.gov/vaccines/recs/schedules/downloads/child/0-6yrs-schedule-pr.pdf
- ACIP Adolescent Schedule http://www.cdc.gov/vaccines/recs/schedules/downloads/child/7-18yrs-schedule-pr.pdf
- ACIP Catch-up Schedule (4 mo-18 years) http://www.cdc.gov/vaccines/recs/schedules/downloads/child/catchup-schedule-pr.pdf
- ACIP Adult Schedule http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/adult-schedule.pdf
- Minimum ages and intervals table in the Pink Book http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm
- ACIP Recommendations: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm
- Morbidity and Mortality Weekly Report (MMWR) http://www.cdc.gov/mmwr/

Questions