

CDC Immunization Update 2020-Focus on the Schedule

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Disclosures

Dr. Mary Koslap-Petraco has nothing to disclose



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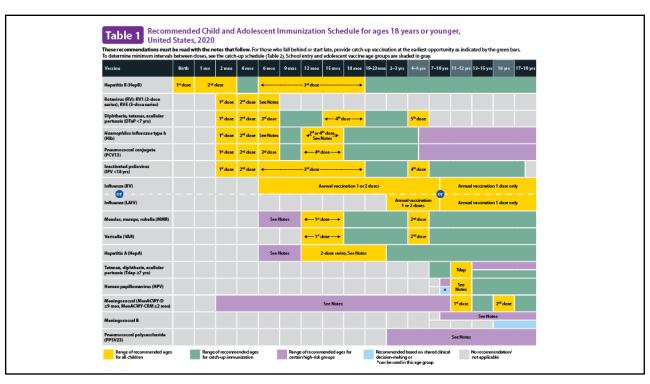
Learning Objectives

- At the end of this presentation the participant will analyze the changes in the 2020 ACIP schedule
- At the end of this presentation the participant will appraise the efficacy of meningitis b vaccine
- At the end of the presentation the participant will evaluate the safety of HPV vaccine
- At the end of the presentation the participant will interpret the changes in General Best Practices Guidelines for Immunizations
- At the end of the presentation the participant will examine shared decision making for vaccine administration



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Helpful Information on Cover Sheet

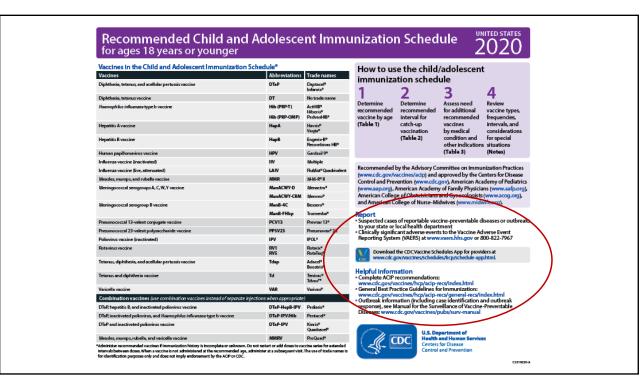
- Information for reporting vaccine preventable diseases
- Link to Vaccine Adverse Event Reporting System (VAERS)
- Link to complete ACIP recommendations
- Link to Best Practices
- Download the CDC Vaccine Schedules app





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Haemophilus Influenza b Vaccine

- The Hib note was revised
- Indicates that catch-up vaccination is not recommended for previously unvaccinated children 5 years (60 months) or older
 - Unless they are at high risk.





Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020

For vaccine recommendations for persons 19 years of age or older, see the Recommended Adult Immunization Schedule.

- older, see the Recommended Adult Immunication Schedule.

 Additional Information

 *Consult relevant ACIP statements for deallied recommendations
 at www.ccd_powlendershipschapet-schildeschmit.

 For information on contraindications and precaudions for the
 use of a vaccine consult for General Best Practice Guidelines for
 use of a vaccine consult for General Best Practice Guidelines for
 use of a vaccine consult for General Best Practice Guidelines for
 use/contraindications.html and relevant ACIP statements at
 www.ccd.gov/vaccines/fixplactp-ecs/indexclarin.

 For calculating internals between doses, 4 weeks = 28 days,
 intervals or 24 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as
- Information on travel vaccine requirements and recommendations is available at www.cdc.gov/tr

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

- For Kinnix or Quadracell)

 Routine vaccination

 * 5-dose series at 2, 4,6,15-18 months, 4-6 years.

 * 5-dose series at 2, 4,6,15-18 months, 4-6 years.

 * Frospectively Dose 4 mays be administered as early as age
 12 months if at least 6 months have elapsed since dose a.

 * Retrospectively * A** dose that was insulve tentify
 administered as early as 12 months may be counted if at least 4
 months have elapsed since dose

 * Cat Ch-4:pp vaccination

 * Cat Ch-4:pp vaccination

 * To roider and at least of months after dose 3.

 * For other catch-up guidance, see Table 2.

- Routine vaccination

 * Actilis, Hiberts, or Pentacet 4-dose series at 2, 4, 6, 12–
 15 months

 * Pedvanting: 3-dose series at 2, 4, 12–15 months

 * Pedvanting: 3-dose series at 2, 4, 12–15 months

 * Dose I at 7–11 months. Administer dose 2 at least 4 weeks later and dose 3 (final dose) at 12–15 months of weeks after dose 2 (whichever is later).

 **Dose I at 12–14 months: Administer dose 2 (final dose) at least

- who are not considered high risk do not require calch-up breakation.

 For other calch-up guitatice, see taske 2.

 Special situations

 * Chemotherapy or nadiation treatment
 12-59 months.

 * L'invaccinated or only 1 dose before age 12 months 2 doses, to weeks gain.

 * Univaccinated or only 1 dose before age 12 months 2 doses, and the previous objects and the previous objects and the previous objects and the previous objects and the previous dose.

 **Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.

- Hematopoletic stem cell transplant HSCT:

 -3-dose series 4 weeks apart starting 6 to 12 months after
 successful transplant, regardies of the Vacchation history

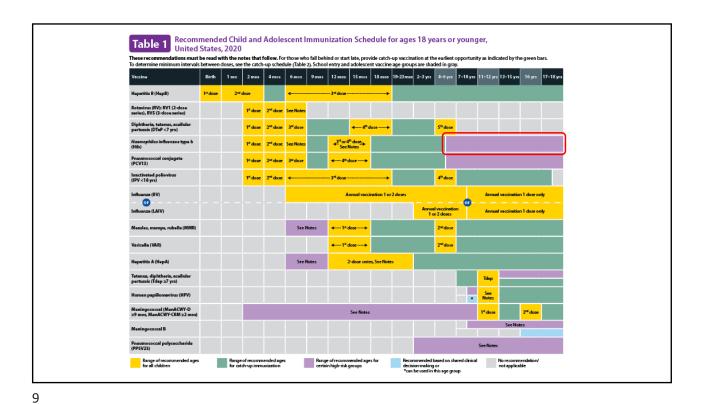
 Anatomic or functional asplenia (including sickle cell
 disease):

 12-59 months
 Unwaccinated or only 1 dose before age 12 months: 2 doses,
 80 weeks agart
 subsects agart
 after preducts disease before age 12 months: 1 dose at least 8 weeks
 after preducts conditionally after the subsection of the s

- do in these and the previous done the previous d

*Unvaccinated = Less than routine series (through 14 months)
OR no doses (15 months or older)

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Case Study

- A 5 year old child comes to your office and your review the shot record and you note the child only received one dose of Hib vaccine at age 6 months. What is your course of action for this child.
- A. Do not give any more doses of Hib vaccine. The child is up to date
- B. Give one more dose to complete the series
- C. Give 2 more doses to complete the series
- Answer A Catch up is not recommended for 5 year olds or older unless child is high risk



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Hepatitis A Vaccine

- The HepA note revised to recommend catch-up
- All children and adolescents 2 through 18 years of age who have not previously received hepatitis A vaccine
- Should complete a 2-dose series
 - Minimum interval between doses is 6 months





Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020

Hepatitis A vaccination (minimum age: 12 months for routine vaccination)

2-dose series trans-12 months arch-up vaccination

unch-up vaccination

Unwaccinate persons through 18 years should complete a
2-dois earlies (initiativum intervuls émonths).

Persons who previously received 10 dose at age 12 months or
obter should receive dose 2 at tess 6 months after dose 1.
Adolscients 18 years and obter may receive the contribued
Heph and Hepb vaccine, "Iviatinata", as a 3-dose series (0, 1, and
on othic) of 4-dose series (0, 7 and 21-30 days, follower layer
dose 10 months).

In a contribution of 4-dose series (0, 1 and 21-30 days, follower layer
dose 10 months).

- ternation Transasson working in countries with high or termschale endemic hepatitis. A dwww.cdc.gov/traws(t): infinants age 6-11 months: 1 dose betwee departure; reseccinate with 2 doses, separated by at least of months, between 12 and 23 months of age Unraccinated age 12 months and olden Administer dose 1 as soon as travel is considered.

Birth dose (monovalent HepB vaccine on ly)
Mother is HBsAg-negative: 1 dose within 24 hours of birth for all medically stable linfants 22,000 grams. Infants <2,000 grams: Administer 1 dose at chronological age 1 month or hospital

weight.

ants <2,000 grams, administer HBIG in addition to HepB

le (in separate limbs) within 12 hours of birth. Administer

lithout doses of vaccine (total of 4 doses) beginning at age

SOON as possess, but no seed than 7 ways or age.

*3-dose series at 0, 1–2, 6–18 months (use monovalent Hep8 vaccine for doses administered before age 6 weeks)

- Infants who did not receive a birth dose should begin the series as soon as exaktle (see Table 2).

 *Administration of Adoes is permitted when a contribution vaccine containing lepth is seed after the birth dose.

 *Minimum age for the final Ger of a 10 dose 2 A weeks

 *Minimum intervals: dose 1 to dose 2.6 veeks of dose 2 to dose 2 and a containing the containing Catch-up vaccination

 Univaccinated persons should complete a 3-dose series at 0, 1–2,

- 6 months.
 Adolescents age 11–15 years may use an atternative 2-dose schedule with at least 4 months between doses (adult formutation Recombinate Hill only).
 When the schedule of the schedu

- Revaccination may be revoluted including:
 Infants born to HBsAg-positive mothers
 Hemodialysis patients
 Other immunocompromised persons
 For detailed revaccination recommendations, see www.cdc.gov/ vaccines/hcp/aclp-ecc/vacc-specifix/hepa.html.

Human papillomavirus vaccination (minimum age: 9 years)

Routine and catch-up vaccination

- occusions y succinated 2- or 3-dose series depending on age at initial vaccination: Age 9 through 14 years at initial vaccination: 2-dose series at 0,6-12 months (minimum interval: 5 months; repeat dose if administered too soon)
- at 0,6-12 months (minimum intervals 5 months; repeat dose if administreed too soon)

 Age 15 years or older at initial vaccination; adoes series at 0,1-2 months, formoths (minimum intervals dose 1 to dose 2.4 weeks / dose 2 to dose 3.7 weeks / dose 1 to dose 3.5 months; repeat dose if administed too soon)

 If completed valid vaccination series with any HPV vaccine, no additional doses needed

- Immunocompromising conditions, including HIV infection:
 3-dose series as above
 History of sexual abuse or assault: Start at age 9 years.
 9 regnancy: HIV vaccination not recommended until after
 pregnancy: not reversible needed if vaccinated while pregnant,
 pregnancy; testing not needed before vaccination.

- Routine vaccination

 Use any influenza vaccine appropriate for age and health status
- Use any influenza vaccine appropriate for age and health status annually:

 2 dosses, sparated by at least 4 weeks, for children age 6 months—9 years who have received week than 2 influenza vaccine closes before July 1, 2019, or whose influenza vaccine tolstory is unknown fourthister for our 2 even if the child turns of between receipt of dose 1 and dose 2).

 1 dose for children age 6 months—9 wars who have received at least 2 influenza vaccine doses before July 1, 2019 = 1 dose for children age 6 months—of vaccine for 1 dose for children age 6 months—6 vaccine 1 dose for children age 6 months—6 vaccine 1 dose for children age 6 months—1 dose for children age 6 months—6 vaccine 1 dose for all person age 9 wars and older 6 for the 2020–21 sesson, see the 2020–21 ACIP influenza vaccine recommendation.

- recommendations.

 Special situations

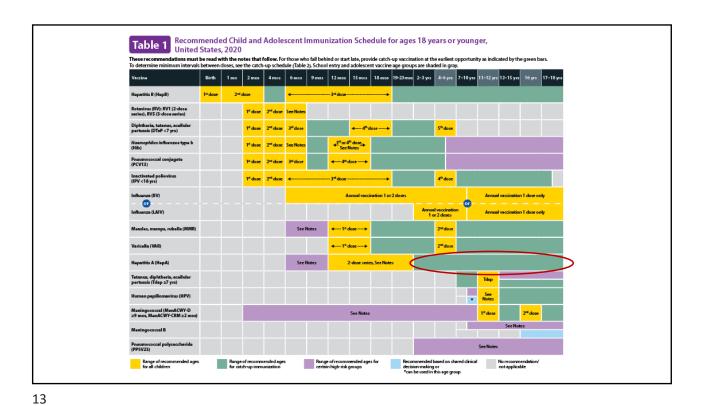
 * Egg allergy, hives only. Any influenza vaccine appropriate for age and health status annually.

 Egg allergy with symptoms other than hives (e.g., anguederra, respitatory disbers, need for emergen; medical services or oping-inner). Annualized a vaccine appropriate and the status of th

- LAUY should not be used in persons with the following conditions of statutions.

 -History of sever aeliergic reaction to a previous dose of any influenan vaccine of to any vaccine component (excluding egg, see details showe).

 -Receiving again or salicytate-containing medications are considered to the control of the con



Case Study

- You are caring for an 17 year old adolescent. You notice that the adolescent had one dose of Hepatitis A vaccine at age 11 years. What will you do for this adolescent.
- A. Give nothing. Adolescent is up to date
- B. Start the series again with a dose today
- C. Catch the adolescent up with the second and final dose in the series
- Answer C All children through age 18 should receive catch up Hep A vaccine



Practitioners Practice

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Hepatitis B Vaccine

- The "special situations" section of the **HepB** note contains information regarding:
 - Populations for whom revaccination may be recommended
 - Infants born to hepatitis b positive mothers
 - Hemodialysis patients
 - Other immunocompromised patients
- For detailed revaccination recommendations, please see the HepBMMWRpublications at https://www.cdc.gov/vaccines/hcp/aciprecs/vacc-specific/hepb.html



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Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020

Catch-up vaccination

- dose at 12 months).
 Intermation all travel
 Persons traveling to or working in countries with high or intermentate endemic hepatitis A (www.ccc.gov/travel/):
 Inflants age 6-11 months: 1 dose better departure; reroccinate with 12 coses; sparated by at least 6 months, between 12 and 22 months of age
 Unwaccinated age 12 months and older: Administer dose 1 as soon as travel is considered.

birth weight. For infants <2,000 grams, administer HBIG in addition to HepB vaccine (in separate limbs) within 12 hours of birth. Administer 3 additional closes of vaccine (total of 4 closes) beginning at age

SOON as possess, but no seed than 7 ways or age.

*3-dose series at 0, 1–2, 6–18 months (use monovalent Hep8 vaccine for doses administered before age 6 weeks)

· Unwaccialed persons should complete a 3-doze series a. w, 1-2, 6 months.

· Adolescents age 11-15 years may use an atternative 2-dose schedule with a fleast 4 months between doses (south formutation Recombinate Net only).

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**Adolescents 18 years and older may receive the committed Net) and Hepf Net) (April Net) (Apple Net) (Appl

or 4 does series (u.f., amus. months).

For other catch-up-guidance, see Table 2.

Special situations

Revacantation is not generally recommended for persons with a normal immune stable; selon were successed as infrants, children, adquiseems, of adults.

Revaccination rise to excess the including:
- Infants born to HBsAg-positive mothers
- Hemodialysis patients
- Other immunocompromised persons

Human papillomavirus vaccination (minimum age: 9 years) Routine and catch-up vaccination

at 0,6-12 months (minimum in letwals 5 months; repeat dose if administered too sons)

- Age 15 years or older at linital vaccination: 3-dose series at 0, 1-2 months, from this (minimum intervals dose 1 to dose 2: 4 weeks / dose 2 to dose 2: 12 weeks / dose 1 to dose 2: 5 months; repeat dose if administered to so sons of the older 1 to dose 3: 5 months; repeat dose if administered to so additional doses needed

• Immunocompromising conditions, including HIV Infection: 3-dose series as above History of sexual abuse or assault: Start at age 9 years. • Pregnancy: HIV vaccination not recommended until after pregnancy, not intervention needed if vaccinated while pregnant, pregnancy testing not needed before vaccination

Routine vaccination

• Use any influenza vaccine appropriate for age and health status

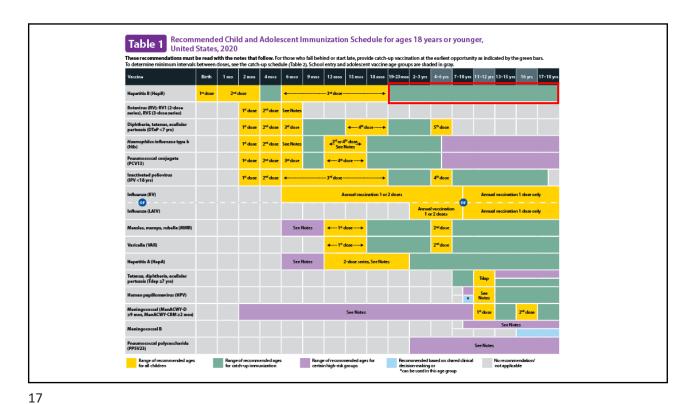
recommendations.

* Signal allergy, hives only. Any influenza vaccine appropriate for age and health stabus annually seed than hives (e.g., angivederrux, respitatory distens, need for amergency medical services or epilepa

see dedail skow)

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Age 2-4 years with history of a shima or wheezing
immunicompromised due to any cause (including medication
and HV hitection)
Anatomic or functional apperia
Anatomic of surfactional apperia
Cerebrogrand if fluid-onophasypoid communication
Citiose contacts or ecopyless of severe fluiminionauppressed
persons who require a protected environment.

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Case Study

- You are caring for a baby born of a Hepatitis b positive mom. The baby completed the 3 dose Hepatitis b series on time at age 6 months. The baby's titers were checked a month later and you note the baby is still showing positive for hepatitis b infection. What do you do regarding the baby's hepatitis b vaccine status?
- A. Do nothing the baby is fully vaccinated
- B. Repeat the Hepatitis b vaccine series by giving the first dose
- C. Give one dose of Hepatitis b vaccine
- Answer B Repeating the series is appropriate in special situations



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MenACWY Vaccine

- Guidance regarding adolescent vaccination for children who received MenACWY prior to age 10 years has been added to the MenACWY note.
- Conditions include
 - Complement component deficiency
 - Compliment inhibitor (i.e. eculizumab, ravulizumab)
 - HI\/
 - Asplenia
- Follow booster dose schedule
 - Most recent dose before age 7 years, administer the booster dose 3 years later
 - Most recent dose at age 7 years or older, administer the booster dose 5 years later
 - Administer boosters every 5 years thereafter throughout life;
 - As long as the person remains at increased risk for meningococcal disease
- https://www.cdc.gov/vaccines/vpd/mening/hcp/administering-vaccine.html



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MenACWY Vaccine Booster Doses

- Adolescent vaccination of children who received MenACWYprior to age 10 years:
- Children in whom boosters are not recommended due to an ongoing increased risk of meningococcal disease (e.g., a healthy child who traveled to a country where meningococcal disease is endemic)
 - Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years





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MenACYW Vaccine for High Risk Children

- DOSING SCHEDULES ARE DIFFERENT FOR MENVEO & MENACTRA
- Menveo Anatomic or functional asplenia(including sickle cell disease), HIV infection, persistent complement component deficiency, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab)
- Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
- Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after the 1st birthday)
- Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart



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MenACWY Vaccine for High Risk Children

- Menactra Persistent complement component deficiency or complement inhibitor
- Age 9–23 months: 2 doses at least 12 weeks apart
- Age 24 months or older: 2 doses at least 8 weeks apart
- Menactra Anatomic or functional asplenia, sickle cell disease, or HIV infection
- Age 9–23 months: Not recommended
- 24 months or older: 2 doses at least 8 weeks apart
- Menactra must be administered at least 4 weeks after completion of PCV13 series



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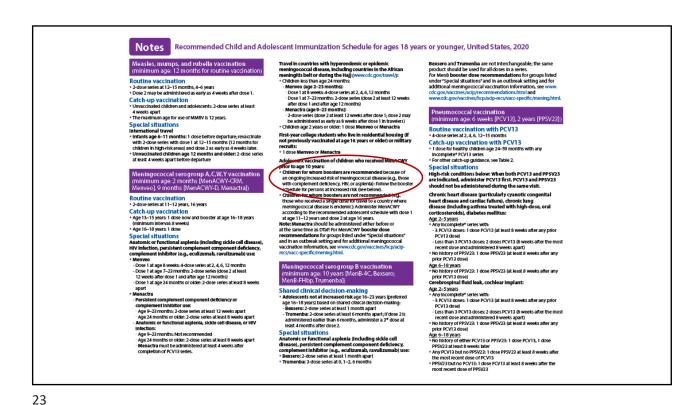


Table 1 Recommended United States, 2020 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, ndations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars. imum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray. Rirth 1 mo 2 mos 4 mos 6 mos 9 mos 12 mos 15 mos 18 mos 19-23 mos 2-3 yrs 4-6 yrs 7-10 yrs 11-12 yrs 13-15 yrs 16 yrs 17-18 yrs Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series) 1st dose 2nd dose See Notes Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs) 1st dose 2st dose 3st dose 4---- 4th dose ------5th dose 43rd or 4th dose_s See Notes 1st dose 2nd dose See Notes Pneumococcal conjugate (PCV13) Inactivated poliovirus (IPV <18 yrs) 1st dose 2^{sd} dose **←-----**Annual vaccination 1 or 2 doses Annual vaccination 1 dose only **a** za (LAIV) Annual vaccination 1 dose only epatitis A (HepA) 2-dose series, See Notes etanus, diphtheria, acellular ertussis (Tdap ≥7 yrs) Tdap Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos) Pneumococcal polysaccharide (PPSV23) Range of recommended ages for certain high-risk groups

Recommended based on shared clinical decision-making or certain high-risk groups

*can be used in this age group

*can be used in this age group Range of recommended ages for all children Range of recommended ages for catch-up immunization

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Case Study

- You are caring for a 9 year old with sickle cell disease. The child received MCV4 at age 7 years. What do you do regarding other doses of MCV4?
- A. Give another dose at age 12 years
- B. Give another dose now
- C. Give nothing. No further doses are necessary
- Answer A for children immunized at age 7 years or older and are high risk give dose 5 years after previous dose





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Meningitis b Vaccine

- Booster doses are now recommended for persons aged ≥10 years with the following:
 - Complement deficiency
 - Those who use complement inhibitors
 - · Persons with asplenia
 - Persons who are microbiologists
 - Persons determined by public health officials to be at increased risk during an outbreak
- First booster dose should be given 1 year after the primary series
- Repeat every 2–3 years as long as the increased risk is present
- Booster doses are not recommended for healthy adolescents routinely vaccinated with MenB vaccine

https://www.immunize.org/askexperts/experts meningococcal b.asp



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Meningitis b Vaccine

- The MenB note has been updated
 - Includes a link to the detailed recommendations For MenB booster dose recommendations for groups listed under "Special situations" and in an outbreak setting
 - For additional meningococcal vaccination information, see www.cdc.gov/vaccines/acip/recommendations.html and www.cdc.gov/vaccines/hcp/acip-recs/vaccspecific/mening.html OR
 - https://www.immunize.org/askexperts/experts meningococcal b.asp





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Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020 Bexsero and Trumenba are not interchangeable; the same product should be used for all closes in a series. For MenB booster dose recommendations for groups listed under "special situations" and in an outbreak setting and for advancemental proposocial vaccinition information; series of advancemental proposocial vaccinition information; series of a power of the proposocial vaccinition information; series of proposocial vaccinition information; series of proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinitions and proposocial vaccinitions are series of the proposocial vaccinities and proposocial vaccinitions are series of the proposocial vaccinities and proposocial vaccinities are series of the proposocial vaccinities and proposocial vaccinities are series of the proposocial vaccinities and proposocial vaccinities are series of the proposocial vaccinities and proposocial vaccinities are series of the proposocial vaccinities and proposocial vaccinities are series of the proposocial vaccinities are series and proposocial vaccinities are series and proposocial vaccinities are series are series and proposocial vaccinities are series are series ar Measles, mumps, and rubella vaccination (minimum age: 12 months for routine vaccination) Catch-up vaccination
• Univaccinated children and adolescents: 2-close series at least Unvaccinated children and adolescents: 2-dose : 4 weeks apart The maximum age for use of MMRV is 12 years. Pneumococcal vaccination (minimum age: 6 weeks [PCV13], 2 years [PPSV23]) *The maximum age for use of MMRV is 12 years.
Special situations
International travel
- Infants age 6-11 months: 1 dose before departure, revocchate
with 2-lose series with dose 1 at 12-15 month (2 months for
children in high-fixt aeral) and dose 2 as early as 4 weeks later.
- Unvascinated children age 12 months and older: 2-dose series
at local weeks gard before departure. Routine vaccination with PCV13

• 4-dose series at 2, 4, 6, 12–15 months NOUTION PACCINATION WITH PCV13

* 4-doise series at 2, 4, 8, 12–15 months

Catch-up vaccination with PCV13

1 doise for healthy childen age 24–59 months with any incompiete PCV13 series

For other activity pullation, see Table 2.

Special situations

High-risk conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PcV13 and PPSV23 are indicated, administered fouring the same visit.

Chronic heart disease particularly cyanotic congenital heart disease and cardiac failure, chronic kung disease (Including asthma treated with high-doise, oral corticosterolicial, diabetes melliter, chronic kung disease (Including asthma treated with high-doise, oral corticosterolicia, diabetes melliter, chronic kung disease (Including asthma treated with high-doise, oral corticosterolicia, diabetes melliter, chronic kung disease (Including asthma treated with high-doise, oral corticosterolicia, diabetes melliter, chronic kung disease (Including asthma treated with high-doise, oral corticosterolicia, diabetes melliter, chronic kung disease (Including asthma treated with high-doise, oral corticosterolicia) (Jabetes melliter). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia) (Jabetes melliter). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia). About 12 disease (Including asthma treated with high-doise, oral corticosterolicia). About 12 disease (Including asthma treated with high-doise). About 12 disease (Including asthma trea To lose Menveo or Menactra

Adolescent vaccination of Orlidern who received MenaCWY
prior to age 10 years on Children who received MenaCWY
prior to age 10 years on the control of the con Meningococcal serogroup A,C,W,Y vaccination (minimum age: 2 months [MenACWY-CRM, Menveo]. 9 months [MenACWY-D, Menactra]) ROUTINE VANCAUSE - 2-20es series at 11-12 years, 16 years

Catch-up vaccination
Age 13-15 years, 10 see now and booster at age 16-18 years
(minimum intervals 4 weeks)
Age 16-18 years, 10 doe

Special situations
Anatomic or functional applenia (including sickle ceil disease),
HIV Infection, persistent complement component deficiency,
complement himbitor (e.g., ecultamah, avaditumab) in the complement of th Menveo

- Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months

- Dose 1 at age 7-23 months: 2-dose series (dose 2 at least

12 weeks after dose 1 and after age 12 months)

- Dose 1 at age 24 months or older: 2-dose series at least 8 weeks PROF IX 13 SUGGE Agg 6-18 years

* No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Cerebrospinal fluid leak, cochlear implant: Core-brospital fluid leak, cochlear implant:
Age 2-Syeats
Any incomplete' series with:
- 3 PCV13 doses: 1 dose PCV13 fit least 8 weeks after any prior
PCV13 doses: 1 dose PCV13 fit least 8 weeks after the most
- Less time 1 a CV13 doses: 2 dose PCV13 fit weeks after the most
- Less time 1 a CV13 doses: 2 dose PCV13 fit weeks after the most
- No history or PSV22 in Jose PSV23 at least 8 weeks after any
prior PCV13 dose)
- Age 6-18 years
- No history or dether PCV13 at PSV22: 1 dose PCV13, 1 dose
- PSV23 at loast 8 weeks after
- The most recent dose of PCV13
- The pSV23 at least 8 weeks after
- The most recent dose of PCV13
- The pSV23 at least 8 weeks after
- The most recent dose of PCV13
- The pSV23 at least 8 weeks after
- The most recent dose of PSV23
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- The pSV23 at least 8 weeks after 1 weeks afte Shared clinical decision-making

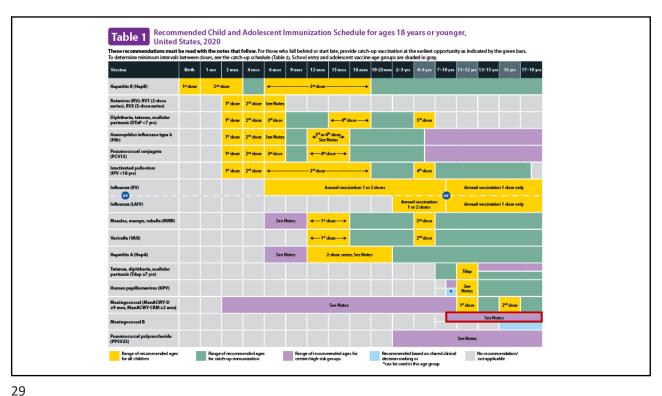
* Adolescents not at increased risk age 16-23 years (preferred age 16-18) years) based on shared clinical decision-making:

- Bessero: 2-does series at least 1 month agart

- Trumenba 2-does series at least 1 months agart; iff dose 2 is administered earlier than 6 months, administered 2 administered enactra versistent complement component deficiency or complement inhibitor use: Age 9-23 months: 2-dose series at least 12 weeks apart Age 24 months or older: 2-dose series at least 8 weeks apart knatomic or functional aspienia, sickie cell disease, or HIV Special situations
Anatomic or functional asplenia (including siddle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) u

- Bexsero: 2-dose series at least 1 month aport

- Trumenba: 3-dose series at 0, 1–2, 6 months



Case Study

- You are caring for a 13 year old with asplenia who received a two dose Men b vaccine series one year ago. What is your course of action for this adolescent?
- A. Give nothing. No more doses are indicated
- B. Give another 2 doses separated by 6 months
- C. Give a one dose booster now
- Answer C and give booster every 2-3 years since this is a high risk adolescent





Meningitis b Vaccine Efficacy

- Study published in *NEJM* evaluated the efficacy of vaccination with the multicomponent meningococcal group B (4CMenB) vaccine for actual versus expected incidence of the disease in young children
 - Results were positive
- Researchers compared the observed incidence of meningococcal group B disease with the expected incidence
 - Based on the incidence during the 4-year prevaccination period in equivalent cohorts
 - They also used disease trends from cohorts of children aged younger than 5 years who were ineligible to get the vaccine



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Meningitis B Vaccine Efficacy

- Incidence of meningococcal disease was significantly lower in the vaccine-eligible cohorts than the expected incidence
 - 63 observed cases compared with 253 expected cases
 - incidence rate ratio, 0.25
 - 95% confidence interval [CI], 0.19-0.36)
- Additionally, there was a 75% reduction of incidence of meningococcal disease in the age groups that were considered fully eligible to receive the vaccine
- Over the course of the 3 years studied, a total of 169 cases of meningococcal group B disease occurred in the vaccine-eligible cohorts and an estimated 277 cases (95% CI, 236-323) were prevented
- Ladhani SN, Andrews N, Parikh SR, et al. Vaccination of infants with meningococcal group B vaccine (4CMenB) in England. N Engl J Med. 2020;382(4):309-317



Meningitis b Efficacy

- Concluded that the 4CMenB vaccine had a positive effect against meningococcal group B disease
- Protection from the disease lasted at least 2 years after receiving 3 doses
- <u>Australian study</u> that examined whether the 4CMenB vaccine can build herd immunity in teenagers
 - Results indicated that the vaccine does not, making it even more imperative that children receive the vaccine when they are young.

Ladhani SN, Andrews N, Parikh SR, et al. Vaccination of infants with meningococcal group B vaccine (4CMenB) in England. N Engl J Med. 2020;382(4):309-317.

Marshall HS, McMillan M, Koehler AP, et al. Meningococcal B vaccine and meningococcal carriage in adolescents in Australia. N Engl J Med. 2020;382(4):318-327.



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Polio Vaccine Notes

- Detailed information has been added regarding which OPV doses may be counted toward the U.S. vaccination requirements
- Series containing oral polio vaccine (OPV), either mixed OPV-IPV or OPV-only series:
 - Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule
 - See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements
 - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign)
 - Doses of OPV administered on or after April 1, 2016, should not be counted
 - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w



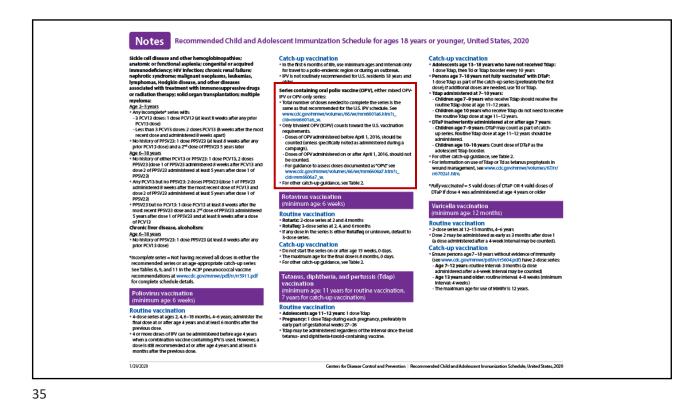


Table 1 Recommended United States, 2020 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, ndations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars. nimum intervals between doses, see the catch-up schedule (fable 2), School entry and adolescent vaccine age groups are shaded in gray. Rirth 1 mo 2 mos 4 mos 6 mos 9 mos 12 mos 15 mos 18 mos 19-23 mos 2-3 yrs 4-6 yrs 7-10 yrs 11-12 yrs 13-15 yrs 16 yrs 17-18 yrs Hepatitis B (HepB) Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series) 1st dose 2st dose See Notes Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs) 1st dose 2st dose 3st dose 4---- 4th dose ------5th dose 43rd or 4th dose_s See Notes 1st dose 2nd dose See Notes Pneumococcal conjugate (PCV13) 1st dose 2st dose 3st dose 4---- 4ⁿ dose -----> 1st dose 2^{sd} dose **◄-----**nactivated po IPV <18 yrs) nza (IIV) Annual vaccination 1 or 2 doses Annual vaccination 1 dose only za (LAIV) Annual vaccination 1 dose only epatitis A (HepA) 2-dose series, See Notes Tdap . Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos) 1st dose Pnoumococcal polysaccharido (PPSV23) Range of recommended ages for all children Recommended based on shared clinical decision-making or "can be used in this age group Range of recommended ages for catch-up immunization Range of recommended ages for certain high-risk groups No recommendation/ not applicable

Case Study

- You are caring for a 7 year old child who is from Pakistan. The child received 3 doses of OPV. The series was started in July 2016. The doses were administered at 0, 1, and 6 months. What will you do for this child at this visit?
- A. Give nothing since the series was completed
- B. Give IPV at this visit and make an appointment to give another dose in 4 weeks
- C. Give one booster dose at this visit
- Answer B This child will need 3rd dose in series 6 months after 2nd dose. Any OPV vaccine given after 4/1/16 outside US does not count toward US vaccine series



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Tdap Vaccine

- The <u>Tdap note</u> has been updated to allow either Td or Tdap
 - Option for decennial tetanus booster doses and catch-up series doses in persons who have previously received Tdap
- Additionally, the note has been edited to reflect recent updates to the clinical guidance for children 7 through 18 years of age who received doses of Tdap or DTaP at age 7 through 10 years
 - A dose of Tdap or DTaP administered at 10 years of age may now be counted as the adolescent Tdap booster
 - A dose of Tdap or DTaP administered at 7 through 9 years of age should **not** be counted as the adolescent dose and Tdap should be administered at 11–12 years of age
- The DTaP note has been updated to note that dose 5 is not necessary if dose 4 was administered at age 4 years or older AND at least 6 months after dose 3



Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020

sickle cell disease and other hemoglobinopathles; anatomic or functional asplenia; congenital or acquired immunodeficiency; HV infections chronic renal failure apphracite; syndrome; malignature acopiasmis, leukamias, lymphomas, Hodgkin disease, and other diseases, and other diseases are considered in the superior of the control of the constant of t

- prior PCV13 dobe jairo a Z = dobe of PV5V23 5 years later Agg. 6-18 years No history of either PCV13 or PP5V23: 1 dose PCV13, 2 doses PP5V23 (dose 1 of PF5V23 administered 8 weeks after PCV13 and dose 2 of PP5V23 administered at least 5 years after dose 1 of
- uose 2 of PPSV23 administered at least 5 years after dose for PPSV23; Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23)
 PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a 2nd dose of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13
 for PCV13
 for notic liver disease, alcoholism:
- Chronic liver disease, alcoholism: Age 6–18 years No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)
- "Incomplete series = Not having received all doses in either the recommended series or an age-appropriate catch-up series see Tables 8, 9, and 11 in the ACIP pneumococcal vaccine recommendations at www.cdc.gov/mmwr/pdf/rtr/rt5911.pdf for complete schedule details.

- Routine vaccination

 4-dose series at ages 2, 4,6–18 months, 4–6 years; administer the final dose at or after age 4 years and at least 6 months after the
- Ither Mos. 4 of all more previous dose.

 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended at or after age 4 years and at least 6 months after the previous dose.

- Catch-up vaccination
 In the first 6 months of life, use minimum ages and intervals only for travel to a potito-endemic region or during an outbreak.
 IPV is not routinely recommended for U.S. residents 18 years and older.
- Series containing oral pollo vaccine (OPV), either mixed OPV-IPV or OPV-only series:
 *Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/hrmw/volumes/i66/wr/mm/601a6.htmls_
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination
- offly unitaria.

 Dose of OPV administered before April 1, 2016, should be counted (united specifically noted as administered during a campaign).

 Doses of OPV administered on or after April 1, 2016, should not
- Doses of the automost and the becommended as "OPV," see For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_
- cid=mm6606a7_w. For other catch-up guidance, see Table 2.

Rotavirus vaccination (minimum age: 6 weeks)

- Routine vaccination

 Rotarix: 2-dose series at 2 and 4 months
- RotaTeq: 3-dose series at 2, 4, and 6 months
 If any dose in the series is either RotaTeq or unknown, default to 3-dose series.
- Catch-up vaccination

 Catch-up vaccination

 Do not start the series on or after age 15 weeks, 0 days.

 The maximum age for the final dose is 8 months, 0 days.

 For other catch-up guidance, see Table 2.
- Tetanus, diphtheria, and pertussis (Tdap) vaccination

vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

- Routline vaccination

 Adolescents age 11–12 years: I dose Tdap

 Adolescents age 11–12 years: I dose Tdap

 Pregnancy: I dose Tdap during each pregnancy, preferably in
 early part of gestational weeks 27–36

 Tdap may be administered regardless of the Interval since the last
 telanus- and ophtheria-t-woold-containing vaccine.

- Catch-up vaccination

 * Adolescents age 13–18 years who have not received Tdap:
 I door Elian, then Id or Tabo Doorder every 10 years
 **Persons age 7–18 years not fully wocknated with Drape:
 **Persons age 7–18 years not fully wocknated with Drape:
 **Order additional doors are needed, use Td or Tsign.
 **Children age 7–9 years who receive Tabp should receive the routine Tabp does at age 11–12 years.
 **Children age 10 years who receive Tsign plond or not need to receive the unufue Tsign does at age 11–12 years.
 **Ora P madere tently administrated at or after age 7 years.
 **Ora P madere tently administrated at or after age 10 catching series. Souther Estap does at age 11–12 years should be administred.
 **Children age 10–18 years Count Association of TSIP a years.
- Children age 10–18 years: Count close of DTaP as the adolescent Tdap booster.
- r or other catch op goldance, see Table 2.

 For information on use of Tdap or Tdas tetanus prophylaxis in wound management, see www.cdc.gov/mmwr/volumes/67/m/m6702a1.htm.
- *Fully vaccinated = 5 valid doses of DTaP OR 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

Varicella vaccination (minimum age: 12 months)

- Routine vaccination

 2-dose series at 12-15 months, 4-6 years

 Dose 2 may be administered as early as 3 months after dose 1
 (a dose administered after a 4-week interval may be counted).
- (a dose administered after a 4-week interval may be counted).

 Catch—up vaccination

 *Insure persons age?—I8 years without evidence of immunity

 (see www.cdc.gov/mmm/pdf/mm/5604.pdf) have 2-dose series

 Age?—12 years is cuttine interval: 2 months (a dose

 administered are 4-week interval army be counted)

 Age 13 years and olders routine interval: 4-8 weeks (minimu

 interval: 4-week)

 The maximum age for use of MMRV is 12 years.

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Centers for Disease Control and Prevention | Recon nended Child and Adolescent Immunization Schedule, United States, 2020

Notes Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020

For vaccine recommendations for persons 19 years of age or older, see the Recommended Adult Immunization Schedule.

- Additional Information

 * Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/ncp/acip-recs/index.html.
- a www.ccc.govyaccines/ncp/auprecs/miesznini.

 For information on contraindications and precautions for the use of a vaccine, consult the General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/actp-recs/general-recs/contraindications.html and relevant ACIP statements at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For calculating intervals between closes, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- umber range (e.g., 12–18), a dash (–) should be re
- Through! Nacon the season to should be resulted through! Nacon the obes administered as days before the minimum age or interval are considered valid. Does of any vaccine administered as days settler than the minimum age or minimum interval as days of the object of the object of a season through the object of the object of a season through the object of the object
- recommendations is valiable at www.doc.gov/eme/, For vaccidation of persons with immunicated relates, see for vaccidation of persons with immunicated relates, see the person of persons with the person of persons of persons time and persons of persons of persons of persons of persons recommendation at www.doc.gov/vaccine/hppcing-reck/general-reck/mmunicated/persons.phrs, and minimunication in Special Clinical Corumstances in himberlin DNR, Bardy MR, Jackson MA, Long SS, etc. And Book. 2018 Report of the committee on intertious persons of the perso
- For information regarding vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- uegat mierit.

 The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All ioutine child and adolescent vaccines are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information, see www.hrsa.gov/

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

- For Kintik of QuatroconRoutine vaccination
 5-dore series at 2,4,6,15–18 months, 4-6 years
 Prospectively: Dose 4 may be admiristered as early as age
 12 months if a teal of morniths have eligipsed since dose à
 administered as early as 12 months may be counted if at least 4
 months have engress size dose 2.
- **Constitution |

 **Dose 5 is not necessary if dose 4 was admini or older and at least 6 months after dose 3.

 **For other catch-up guidance, see Table 2.

Maemophilus influenzae type b vaccination

- Routine vaccination

 * ActHIB, Hiberix, or Pentace: 4-dose series at 2, 4, 6, 12–15 months
- ths HIB: 3-close series at 2, 4, 12–15 months
- Texturanties 2-0005 series at 2-4 (2-13 months)

 Catch—up watchnation

 Does 1 at 7-11 months. Administer close 2 at least 4 weeks later and close 3 (final close) at 12-15 months or 8 weeks after close 2 (whichever is later).

 Does 1 at 12-14 months: Administer close 2 (final close) at least 8 weeks after dose 1.

- S weeks after dose 1.

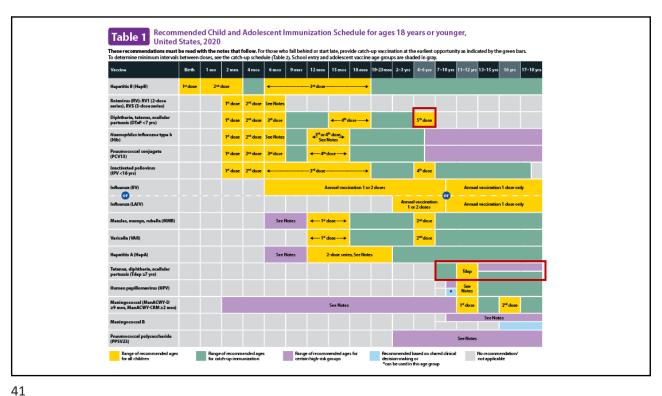
 Dose 1 before 12 months and dose 2 before 15 months:
 Administer dose 2 (mai dose) 8 weeks after dose 2.
 2 doses of Pedvas4IB before 12 months: Administer dose 3 (final dose) 8 at 12 doses of Pedvas4IB before 12 months: Administer dose 3 (final dose) 8 at 12-59 months and at least 8 weeks after dose 2.
 2 thruscathated at 15-59 months: 1 dose 0 months or older 1- Previously unvaccinated children age 60 months or older more are not considered high risk don't equire catch-up
- vaccination. For other catch-up guidance, see Table 2.

- Zu I must assess before age 12 months: 1 dose at least 8 weeks after previous dose Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.

- Hematopoletic stem cell transplant (HSCT):
 -3-dos estrie-4 weeks apart starting 6 to 12 months after
 successful transplant, regardies of the Yauchautlon history
 -4 nationic or functional asplenia (including sickle cell
 disease):
 12-59 montios
 13-90 montios
 13-90

- I dose
 Hective spienectomy:
 Unvaccinated* persons age 15 months or older
 I dose (preferably at least 14 days before procedure)
 HIV Infection:
 12-59 months
- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart 2 or more doses before age 12 months: 1 dose at least 8 weeks
- after previous dose Unvaccinated* persons age 5–18 years 1 dose
- 1 dose Immunogiobulin deficiency, early component complement deficiency: 12–59 months Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- o weeks apart 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

*Unvaccinated = Less than routine series (through 14 months) OR no doses (15 months or older)



Case Study

- You are seeing a 11 year old in your office. This adolescent received Tdap at age 10 years. What will you do for this child?
- A. Give another dose of Tdap
- B. Give nothing
- C. Give another dose when the child is 12 years old
- Answer B Child is up to date since Tdap given at age 10 or older is considered the booster dose



Influenza Preliminary Data as of 3/21/20

- 38 54 million flu illnesses
- 18 26 million flu medical visits
- 400,000 730,000 flu hospitalizations
- 24,000 62,000 flu deaths
- 155 Pediatric deaths
- Nationally, influenza A (H1N1) viruses are most common at this time. Previously, influenza B/Victoria viruses predominated nationally

https://www.cdc.gov/flu/weekly/?deliveryName=USCDC 7 3%20-%20DM10907&blm aid=6801426





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Quadrivalent Recombinant Influenza Vaccine

- Flublok Quadrivalent recombinant influenza vaccine
- First licensed by the FDA in the United States for use in adults 18 years and older in 2017
- An earlier trivalent version was licensed in 2013
- Quadrivalent version replaces trivalent presentation
- For use in people 18 years of age and older
- Use in people with severe egg allergy





New Influenza Vaccine NanoFlu

- Recombinant quadrivalent seasonal influenza vaccine candidate, adjuvanted with Matrix-M™, for adults 65 years of age and older
- Phase III clinical trial data showing recombinant quadrivalent seasonal influenza vaccine candidate, NanoFlu, met all primary endpoints in adults aged 65 and older against Sanofi's Fluzone Quadrivalent
- Improvement over egg-based vaccines, which frequently result in mismatch and poor effectiveness
- Does not require an egg-grown vaccine virus and does not use chicken eggs in the production process
- As a result of the successful data, the company will submit to US Food and Drug Administration (FDA) under the agency's accelerated approval pathway

 $\underline{\text{http://ir.novavax.com/news-release/news-release-details/novavax-granted-fast-track-designation-nanoflu-older-adults}$



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Benefits & Safety of Recombinant Influenza Vaccine

- Manufacturing process might be faster than that of egg-based vaccines
- Eggs not needed to grow virus so could be faster to produce vaccines
 - Especially in a pandemic
 - · Can contain vaccine viruses that cannot be grown in eggs
 - Avoids mutations when viruses are grown in eggs which can limit how well the finished vaccine works
- Safety comparable to that of other injectable influenza vaccines





Universal Influenza Vaccine

- New progress in the development of a universal influenza vaccine candidate, using a novel approach called chimeric hemagglutinin
- Interim results indicate that this is the first human trial able to generate antibodies
- Antibodies will target a different area of the hemagglutinin protein
- Protein binds the influenza virus to target cells different from traditional influenza vaccines
- Adjuvanted inactivated vaccine induced a substantial immunoglobulin G (IgG) antibody response after the prime immunization, with a 7-time increase in anti-H1 stalk titers on day 29
- Additional results rom the study will be available upon completion of the research at the conclusion of 2019

Bernstein, et al. (2019).



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Influenza Vaccine Composition 2020-21

- Influenza A (H1N1) component:
 - The egg-based H1N1 vaccine component was updated from an A/Brisbane/02/2018 (H1N1)pdm09-like virus to an A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus.
 - The cell- or recombinant-based H1N1 vaccine component was updated from an A/Brisbane/02/2018 (H1N1)pdm09-like virus to an A/Hawaii/70/2019 (H1N1)pdm09-like virus.
- Influenza A (H3N2) component:
 - The egg-based H3N2 vaccine component was updated from an A/Kansas/14/2017 (H3N2)-like virus to an A/Hong Kong/2671/2019 (H3N2)-like virus.
 - The cell- or recombinant-based H3N2 vaccine component was updated from an A/Kansas/14/2017 (H3N2)-like virus to an A/Hong Kong/45/2019 (H3N2)-like virus.
- Influenza B/Victoria component:
 - The B/Victoria lineage vaccine component was updated from a B/Colorado/06/2017 (B/Victoria lineage)-like virus to a B/Washington/02/2019 (B/Victoria lineage)-like virus.
- Influenza B/Yamagata component:
 - The influenza B/Yamagata lineage vaccine component was not updated. It remains a B/Phuket/3073/2013-like virus (Y3).



Xofluza

- Genentech is seeking approval of Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated influenza in otherwise healthy children aged one to less than 12 years of age who have been symptomatic for no more than 48 hours
- FDA has licensed Xofluza (baloxavir marboxil) as one-dose granules for oral suspension (2 mg/mL)
- More convenient option for children and those who have difficulty swallowing
- The FDA also accepted application for post-exposure prophylaxis of influenza in people one year of age and older for both the oral suspension and currentlyavailable tablet formulation
- FDA is expected to make a decision on these approvals by November 23, 2020
- Shortens course of influenza by 72 hours

 $\frac{\text{https://www.biospace.com/article/releases/fda-accepts-genentech-s-new-drug-application-for-xofluza-for-the-treatment-of-influenza-in-children-/}{}$



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Human Papilloma Vaccine Safety - AAP

- Two independent safety studies support safety of HPV vaccine
- VAERS received 7244 reports after 9vHPV
 - 31.2% among females
 - · 21.6% among males
 - 47.2%, sex was not reported
- Overall, 97.4% of reports were nonserious
- Dizziness, syncope, headache, and injection site reactions were most commonly reported
- Most commonly reported AEs were similar between females and males
- Two reports of death after 9vHPV were verified
 - No information in autopsy reports or death certificates suggested a causal relationship with vaccination
- Approximately 28 million 9vHPV doses were distributed during the study period

Shimabukuro, T., Su, J., Marquez, P.L., Mba-Jonas, A., Arana, J.E., & Cano, M. Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics* Dec 2019, 144 (6) e20191791; **DOI:** 10.1542/peds.2019-1791



Human Papilloma Vaccine Safety - AAP

- No new or unexpected safety concerns or reporting patterns of 9vHPV with clinically important AEs were detected
- Safety profile of 9vHPV is consistent with data from prelicensure trials and from postmarketing safety data of its predecessor, the quadrivalent human papillomavirus vaccine
- Second study near real-time vaccine safety surveillance for 24 months after the vaccine became available in the Vaccine Safety Datalink
- Prespecified adverse events included anaphylaxis, allergic reaction, appendicitis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, injection site reaction, pancreatitis, seizure, stroke, syncope, and venous thromboembolism
- Observed and expected numbers of events after 9vHPV were compared weekly by using sequential methods
- Both historical and concurrent comparison groups were used to identify statistical signals for adverse events
- Unexpected signals were investigated by medical record review and/or additional analyses.

Donahue, J. G., Kieke, B. A., Lewis, E. M., Weintraub, E. S., Hanson, K. E., Mcclure, D. L., ... Belongia, E. A. (2019). Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics*, 144(6). doi: 10.1542/peds.2019-1808



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Human Papilloma Vaccine Safety - AAP

- During 105 weeks of surveillance, 838 991 doses of 9vHPV were administered
- Identified unexpected statistical signals for 4 adverse events
 - Appendicitis among boys 9 to 17 years old after dose 3
 - Pancreatitis among men 18 to 26 years old
 - Allergic reactions among girls 9 to 17 years old and women 18 to 26 years old after dose 2
- On further evaluation, which included medical record review, temporal scan analysis, and additional epidemiological analysis no signals for any adverse events were confirmed
- Donahue, J. G., Kieke, B. A., Lewis, E. M., Weintraub, E. S., Hanson, K. E., Mcclure, D. L., ... Belongia, E. A. (2019). Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics*, 144(6). doi: 10.1542/peds.2019-1808



Human Papilloma Vaccine Safety - AAP

- After 2 years of near real-time surveillance of 9vHPV and several prespecified adverse events, no new safety concerns were identified
- · Both of these studies included very large number of subjects
 - 28 million and more than 830,000 respectively
- Such large studies should reassure parents that HPV vaccine is safe for their children



Donahue, J. G., Kieke, B. A., Lewis, E. M., Weintraub, E. S., Hanson, K. E., Mcclure, D. L., ... Belongia, E. A. (2019). Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine. *Pediatrics*, 144(6). doi: 10.1542/peds.2019-1808



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Shared Clinical Decision Making

- Difference between routine, catch-up, and risk-based recommendations and shared clinical decision-making recommendations
 - Default decision is to vaccinate
 - · Based on age group or other indication, unless contraindicated
- For shared clinical decision-making
 - No default
- Decision about whether or not to vaccinate
 - · May be informed by the best available evidence of who may benefit from vaccination
 - Individual's characteristics, values, and preferences
 - · Health care provider's clinical discretion
 - · Characteristics of the vaccine being considered
- There is no prescribed set of considerations or decision points in the decision-making process
- ACIP makes SCDM recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html#scdm



Shared Clinical Decision Making

- Some vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group
- Shared clinical decision-making recommendations are individually based
 - Informed by a decision process between the health care provider and the patient or parent/guardian
- ACIP recommends shared decision making for Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
 - For persons at increased risk of meningococcal b disease
 - Preferably at 16 through 18 years old
- Must get the same brand for all doses
 - MenB-4C (Bexsero) 2-dose series 0 and 1 month
 - MenB-FHbp (Trumenba) 0, 1–2, and 6 months and a 2-dose series (administered at 0 and 6 months)
- https://www.cdc.gov/vaccines/acip/acip-scdm-fags.html#scdm



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Shared Clinical Decision Making

- Those at increased risk for meningitis b include:
 - Persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5–C9, properdin, factor D, factor H
 - Taking eculizumab [Solaris]
 - Anatomic or functional asplenia (including sickle cell disease)
 - Microbiologists routinely exposed to isolates of Neisseria meningitidis
 - Persons identified as at increased risk because of a serogroup B meningococcal disease outbreak

Patton ME, Stephens D, Moore K, MacNeil JR. Updated Recommendations for Use of MenB-FHbp Serogroup B Meningococcal Vaccine — Advisory Committee on Immunization Practices, 2016. MMWR Morb Mortal Wkly Rep 2017;66:509–513. DOI: http://dx.doi.org/10.15585/mmwr.mm6619a6



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YES Vaccine Preventable Diseases ARE Still a Threat!

- As of 4/5/20 **TWELVE Measles** cases were reported to CDC
- According to GAVI measles is the number one worry
- World is preoccupied w COVID-19
- · Routine immunization is critical
- · Measles outbreak during pandemic will overwhelm already stressed health systems
- World is facing a resurgence of the once all-but-eradicated disease, which is a highly contagious, sometimes fatal viral infection
- Last year marked highest number of measles cases in single year in US since 1992
 - Total of 1,282 confirmed cases
 - · More than 73% of cases were linked to outbreaks in NY affecting under vaccinated communities
- Measles was declared eliminated in US in 2000
 - Sustained transmission of almost 12 months nearly led to loss of US elimination status

UN News. (2020, March 26) https://news.un.org/en/story/2020/03/1060402



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Measles Outbreak in NY 2018-2019

- What was learned after the outbreak
 - Vaccine hesitancy
 - Targeted anti-vaccine activity and misinformation
 - Multiple importations following large outbreak in Israel
 - Large gatherings
 - Close-knit communities
 - Large families
 - Underreporting and unidentified transmission
 - · Families did not always seek medical care
 - · Lab testing limitations
- Blima Marcus ANP lead Orthodox Nurses to combat misinformation
 - Parents Educating and Advocating for Children's Health, or PEACH (antivaxx) book vs. PIE (pro vaxx) Parents Informed and Educated book

 $\underline{\text{https://www.cdc.gov/grand-rounds/pp/2020/20200218-measles-elimination-vaccine.html}}$



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YES Vaccine Preventable Diseases ARE Still a Threat!

- A measles outbreak in the Congo led to more than twice as many deaths there than the ebola outbreaks that preceded it
- COVID-19 is forcing parents in vulnerable places across the world to <u>skip routine immunization</u>, and others are opting to wait to vaccinate their children for fear of the vaccine
 - The Polio Eradication Campaign has been shut down due to COVID-19
- **Hepatitis A** outbreaks are already <u>spreading</u> in places such a Georgia, USA, with nearly a quarter of the almost 90 cases there requiring hospitalization

https://www.cdc.gov/grand-rounds/pp/2020/20200218-measles-elimination-vaccine.html



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SARS-CoV-2 in Children

- Better known as COVID-19
- Some evidence of vertical transmission from study in Wuhan, China
- Neonate born to mother infected with SARS-CoV-2 had elevated levels of IgM and IgG antibodies and abnormal cytokine results 2 hours after birth
 - Suggests newborn was infected in utero
- Children at all ages appeared susceptible
 - · No significant gender difference
- Clinical manifestations of children's COVID-19 cases were generally less severe than those of adults' patients
- Young children, particularly infants, were most vulnerable
- Distribution of children's COVID-19 cases varied with time and space
 - Most of the cases concentrated in Hubei province and surrounding areas
- Study provides strong evidence for human-to-human transmission

Dong Y, Mo X, Hu Y, et al. Epidemiological characteristics of 2143 pediatric patients with 2019 coronavirus disease in China. Pediatrics. 2020; doi: 10.1542/peds.2020-0702



SARS-CoV-2 in Children

- Less severe illness may be attributed to
 - Less exposure or sensitivity to COVID-19
 - Different immune response mechanisms
 - Higher levels of antibodies to viruses than in adults due to broader exposures to respiratory infections in winter
- 6% of children were critical
 - Most had underlying medical conditions
 - Infection seems more severe in infants
- 1 child died according to published study results
- 2572 cases documented in children (>18 years) in US as of 4/2/20
- 73% had cough, fever, dyspnea
 - 93% of adults had same symptoms
- Children may be asymptomatic and spreading virus

Dong Y, Mo X, Hu Y, et al. Epidemiological characteristics of 2143 pediatric patients with 2019 coronavirus disease in China. Pediatrics. 2020; doi: 10.1542/peds.2020-0702



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SARS-CoV-2 in Children

- Children represent <2% of US cases
- Infants represent 15% of US cases but may be underrepresented
- Median age is 11 years
- Rhinorrhea is slightly more prevalent in children than adults
- Three US deaths in children reported
 - Review of cases is ongoing to confirm covid-19 as likely cause of death
- CDC stressed that children with mild symptoms or asymptomatic cases are likely playing a part in the spread of the virus

Coronavirus Disease 2019 in Children — United States, February 12–April 2, 2020. MMWR Morb Mortal Wkly Rep. ePub: 6 April 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6914e4



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Latest on COVID in Children

- U.K. is warning that the coronavirus could be linked to Kawasaki disease
- Kawasaki can develop after influenza or any viral infection
- A number of children diagnosed with COVID-19 died despite having no underlying health issues in U.K.
- Northern Italy reported "extraordinarily large numbers" of children under age 9 with severe cases of what looks to be Kawasaki
- Study not yet published peer review journals
 - Not all of the children studied who had Kawasaki were diagnosed with COVID-19
- COVID-19 can cause just about any symptom and attack any part of the body
 - Particularly the vasculature
 - It causes a lot of inflammation

https://www.cbsnews.com/news/coronavirus-kawasaki-rare-disease-children-pediatrician-dyan-hes/



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Latest on COVID in Children

- **64** suspected cased of **pediatric multisystem inflammatory syndrome** being investigated in NY as of 5/5/20
- Syndrome has features which overlap with Kawasaki Disease and Toxic Shock Syndrome.
- Inflammatory markers may be elevated
- Fever and abdominal symptoms may be prominent
- Rash also may be present
- Myocarditis and other cardiovascular changes may be seen
- Some patients have developed cardiogenic or vasogenic shock and required intensive
- This inflammatory syndrome may occur days to weeks after acute COVID-19 illness
- https://www.health.ny.gov/press/releases/2020/docs/2020-05-06 covid19 pediatric inflammatory syndrome.pdf



QUESTION

Which of the following is true of a potential corona virus vaccine

- A. It will be easy to manufacture because the US has the genome sequence
- B. It will have to be administered every year
- C. It will be a one time only vaccine
- D. It will be available in a year or less



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Which of the following is true of a potential corona virus vaccine

• ANSWER: C. It will probably be a one-time only vaccine because the virus does not mutate very much



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"Finding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority," said NIAID Director Anthony S. Fauci, M.D.



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Corona Virus Vaccine

- Only around four to ten genetic differences between the coronavirus strains that have infected Americans and those of the original virus in Wuhan
- 'That's a relatively small number of mutations for having passed through a large number of people,' according to Peter Thielen, a Johns Hopkins molecular geneticist
- The mutation rate of the virus would suggest that the vaccine developed for SARS-CoV-2 would be a single vaccine, rather than a new vaccine every year like the flu vaccine
- A potential coronavirus vaccine would act more like those for the measles or chickenpox, in which one shot grants immunity for a substantial amount of time

https://www.washingtonpost.com/health/the-coronavirus-isnt-mutating-quickly-suggesting-a-vaccine-would-offer-lasting-protection/2020/03/24/406522d6-6dfd-11ea-b148-e4ce3fbd85b5_story.html



Corona Virus Vaccine

- Dr. Paul Offit, vaccine expert who heads Vaccine Information Center at Children's Hospital of Philadelphia, cautions that a vaccine could be multiple years, not months away
- FDA looks to see that those in vaccinate group of clinical trial have less of targeted disease than those in control group
 - That the vaccine is safe
 - · Causes few and mild side effects
- Skepticism in order to temper layperson optimism is OK right now

https://mail.google.com/mail/u/0/#search/karen/FMfcgxwHMZTKShVcZZnlZXxNXgZWBjnG



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Candidate Vaccine in Development

- Phase 1 clinical trial evaluating an investigational vaccine designed to protect against coronavirus disease 2019 (COVID-19)
 - at Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle
- National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is funding the trial
- Open-label trial will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks
- The first participant has received the investigational vaccine
- First of multiple steps in the clinical trial process for evaluating the potential benefit of the vaccine

NIH clinical trial of investigational vaccine for COVID-19 begins. (2020, March 16). https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins Retrieved from the web April 28, 2020



Candidate Vaccine in Development

- Study is evaluating different doses of the experimental vaccine for safety and its ability to induce an immune response in participants
- Investigational vaccine was developed using a genetic platform called mRNA (messenger RNA)
- Investigational vaccine directs the body's cells to express a virus protein that it is hoped will elicit a robust immune response
- The mRNA-1273 vaccine has shown promise in animal models
- First trial to examine mRNA vaccine in humans

NIH clinical trial of investigational vaccine for COVID-19 begins. (2020, March 16). https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins Retrieved from the web April 28, 2020



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Other Vaccine in Development

- Old-fashioned formulation consisting of a chemically inactivated version of the virus in development in China
- Tried on an animal model which is first step in vaccine production
- Produced no obvious side effects
- · Human trials began on 16 April
- Limitations of the study
 - Number of animals was too small to yield statistically significant results
 - Also raised concerns about the way the stock of novel coronavirus was grown that was used to challenge the animals
 - It may have caused changes that make it less reflective of the virus that infect humans.
- Another concern is that animals do not develop the most severe symptoms that SARS-CoV-2 causes in humans
- · Currently 90 vaccine candidates are in development throughout the world

https://www.sciencemag.org/news/2020/04/covid-19-vaccine-protects-monkeys-new-coronavirus-chinese-biotech-reports



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Keep Immunizing in the Face of a Pandemic

- DO NOT FORGET to keep children up to date with routine child health vaccines
- See well children in the morning and sick children in the afternoon
 - · Less cross contamination
- Clean all touch surfaces after sick children leave
- Separating patients spatially, such as by placing patients with sick visits in different areas of the clinic or another location from patients with well visits
- Collaborating with providers in the community to identify separate locations for holding well visits for children
- Prioritize newborn care and vaccination of infants and young children (through 24 months of age) when
 possible
 - · Drive up appointments

Coronavirus Disease 2019 in Children — United States, February 12–April 2, 2020. MMWR Morb Mortal Wkly Rep. ePub: 6 April 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6914e4

https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html?deliveryName=USCDC 2070-DM25408



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COVID Hoax Conspiracy Theories

 Anti-vaxxers and other conspiracy theorists are promoting the idea that the pandemic is a hoax because they have <u>video proof</u> that hospitals are empty and not overrun right now

The facts:

<u>Most laypeople</u>, especially those who have had elective and non-emergent surgeries canceled, understand that none of this is part of a hoax or a conspiracy

 <u>Canceling non-essential procedures</u> frees up workers and hospital beds in preparation for a surge of critical COVID-19 patients.

In the meantime, <u>hospitals in hotspots</u> such as New York City are being overrun by the very real COVID-19

Voices for Vaccines. (April 4, 2020). This week in vaccine hesitancy. https://mail.google.com/mail/u/0/#search/karen/FMfcgxwHMZTKShVcZZnlZXxNXgZWBjnG Retrieved from the web April 4, 2020Information



General Best Practices Updates Published 2/21/20

PAGE 23 [38 pages]

Timing and Spacing of Immunobiologics

The recommendation was changed to allow providers to administer a dose of live, injectable vaccine even if the interval after an antibody-containing blood product is not complete. The dose should be invalidated and repeated. Serology is no longer recommended to ascertain whether the dose provided protection.

• PAGE 39 [38 pages] Timing and Spacing of Immunobiologics

Table 3-5 Footnotes

The specific source material for understanding antibody quantities in antibody products is now listed. Also listed is the process for determining how to calculate the interval between antibody product and live, injectable vaccine, based on the quantity of antibody in the product.

• https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/general-recs-errata.html



Practitioners Nurse

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General Best Practices Update Published 2/21/20

• <u>PAGE 55 [19 pages]</u> Contraindications and Precautions

Table 4-1

A footnote is placed after HPV vaccine to clarify that HPV vaccine is not recommended during pregnancy.

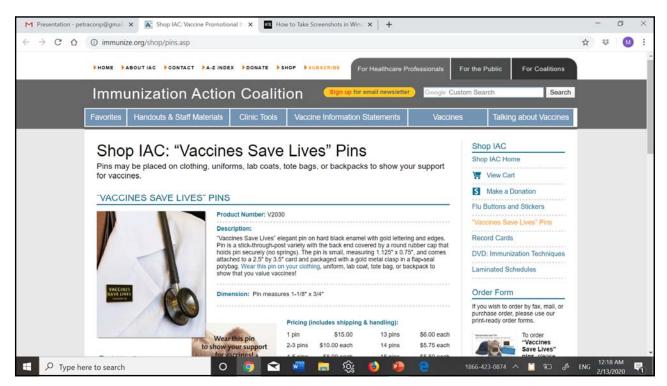
• PAGE 115 [6 pages]

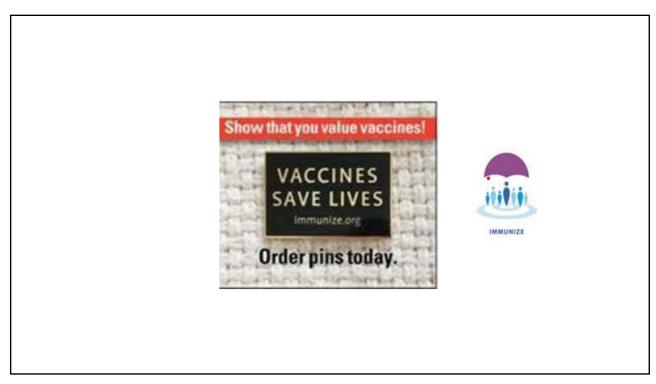
Storage and Handling of Immunobiologics

For response to out-of-range temperature readings, if a non-live vaccine is administered and then found out to have been stored at a deviated temperature, the dose should be repeated and does not need to wait an interval from the invalid dose. Shingrix is a non-live vaccine, this dose needs to be repeated and does need to wait 4 weeks after the invalid dose.

• https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/general-recs-errata.html











VYF Released its 2020 State of the ImmUnion

Report

CHILDHOOD VACCINES SAVE

LIVES AND MONEY

The vaccination of children born between 1994 and 2018 will prevent:

936,000 \$1,9

Flu and Hep A Outbreeks Outbreeks

Flu and Hep A Outbreeks

Outbreeks

STATE OF THE IMMUNION

ACCINATE OUR FAMILY STATE OF THE MUNION

TRILLION IN
TOTAL SOCIETAL COSTS:

81

You Can Find VYF Online and on Social Media



The Next Generation of Every Child By Two

Website: Vaccinateyourfamily.org
Blog: Shotofprevention.com
Facebook: Vaccinate Your Family
Twitter: @Vaxyourfam
Instagram: Vaccinate Your Family
YouTube: Vaccinate Your Family



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 Please stay safe everyone and thank you for all you do for the children and their families!!





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