



HPV Vaccine and Rapid Fire; CDC ACIP Immunization Update Discussion

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Outline

- Background
- Schedule and Recommendations
- Food and Drug Administration (FDA) vs Advisory Committee on Immunization Practices (ACIP) Guidelines
- Vaccine Safety
- The Role of Pharmacy
- Financing
- Addressing Parents' Concerns

Influenza

- Vaccination should be offered by the end of October; however, vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available.
- Children aged 6 months through 8 years who require 2 doses (see Figure) should receive their first dose as soon as possible after vaccine becomes available, and the second dose ≥ 4 weeks later.

Influenza

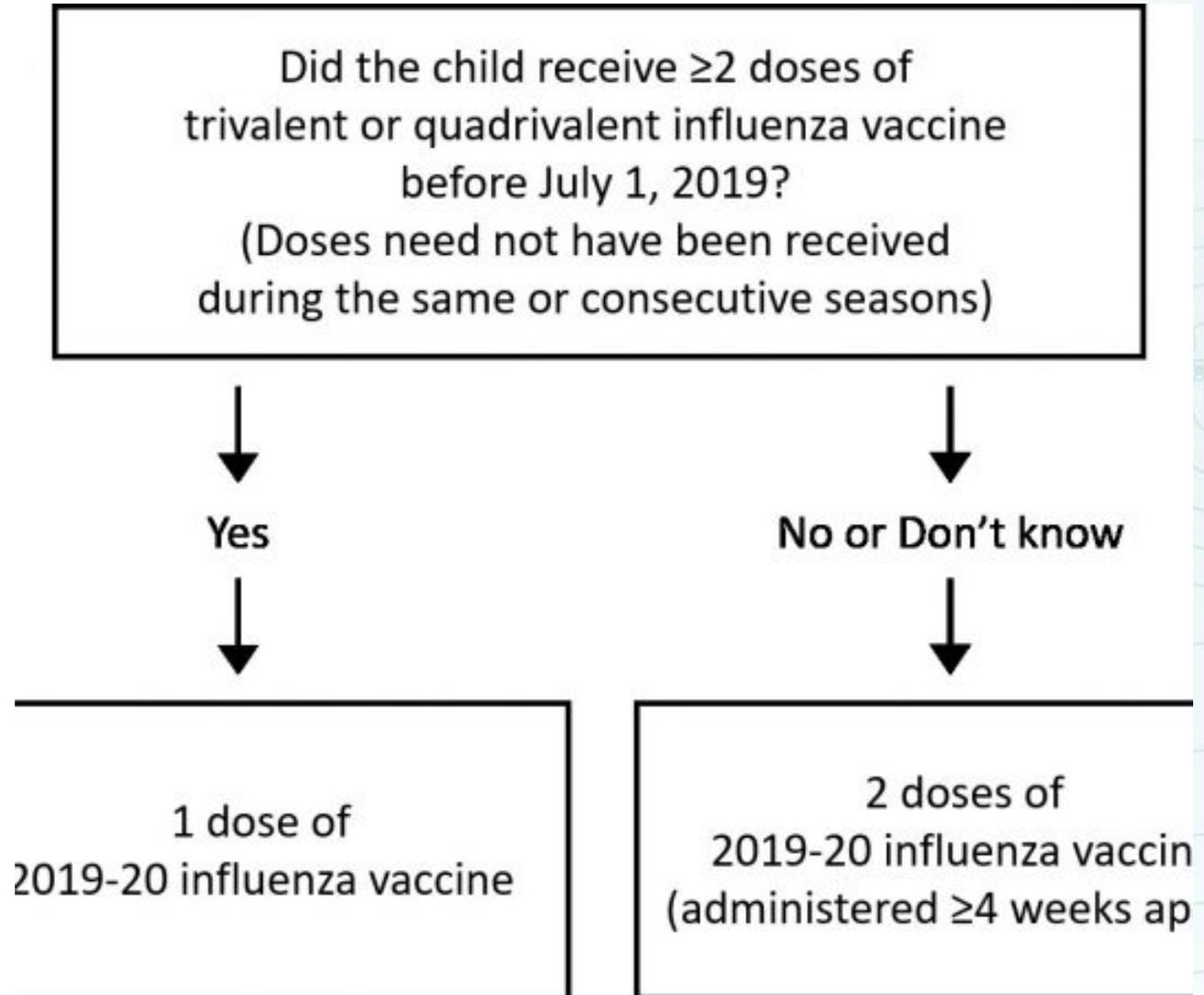
- <https://nmhealth.org/news/vaccine/2020/1/?view=825>
- How did the 2019-2020 vaccine do?
 - A/Brisbane/02/2018 (H1N1)pdm09-like virus (updated)
 - A/Kansas/14/2017 (H3N2)-like virus (updated)
 - B/Colorado/06/2017-like (Victoria lineage) virus
 - B/Phuket/3073/2013–like virus (Yamagata lineage)
- New Mexico:

Influenza Rapid Fire Question

- A 3 year old presents to your pharmacy and has had seasonal flu shots since 6 months, does the patient need to return in 4 weeks for a second dose?
- A 7 year old presents to your pharmacy and has never had a flu shot, does the patient need to return in 4 weeks for a second dose?
- An 8 year old patient, who is turning 9 years old in two weeks, presents to your pharmacy and has never had a seasonal flu shot, should the patient return in 4 weeks for a second dose?

Influenza Rapid Fire Answer

- A 3 year old presents to your pharmacy and has had seasonal flu shots since 6 months, does the patient need to return in 4 weeks for a second dose?
 - NO
- A 7 year old presents to your pharmacy and has never had a flu shot, does the patient need to return in 4 weeks for a second dose?
 - YES
- An 8 year old patient, who is turning 9 years old in two weeks, presents to your pharmacy and has never had a seasonal flu shot, should the patient return in 4 weeks for a second dose ?
 - YES, if a second dose is recommended even if the child turns age 9 years between dose 1 and dose 2, they should still return for dose 2.



Influenza Rapid Fire Question

- A 70 year old patient (or any patient age 65 or older), presents to your pharmacy wanting a flu shot, is the High-dose required or more effective?
- Is Fluvad the same as High-dose vaccine?

Influenza Rapid Fire Answer

- A 70 year old patient (or any patient age 65 or older), presents to your pharmacy wanting a flu shot, is the High-dose required or more effective per the CDC?
 - NO, not required
 - YES, more effective than trivalent, not studied in comparison with quadrivalent vaccine.
- Is Fluad the same as High-dose?
 - NO, FLUAD (for 65 years and older) is formulated with the adjuvant MF59 (an adjuvant is an ingredient added to a vaccine that helps create a stronger immune response to vaccination).
 - MF59 is an oil-in-water emulsion of squalene oil, naturally occurring substance found in humans, animals and plants, is highly purified for the vaccine manufacturing process.
- Persons aged ≥ 65 years **may** receive any age-appropriate IIV (standard- or high-dose, trivalent or quadrivalent) or recombinant vaccine.
- High-dose vaccine exhibited superior efficacy over a standard-dose IIV3 in a large randomized trial, & may provide better protection than standard dose IIV3 for this age group.
- Vaccination should not be delayed to find a particular product if an appropriate one is available.

Tdap

- Either Td or Tdap vaccine can be used in the following situations when previously only Td was recommended
 - 10 year booster dose: “To ensure continued protection against tetanus and diphtheria, booster doses of either Td or Tdap should be administered every 10 years throughout life.”
 - Tetanus prophylaxis for wound management: “For nonpregnant persons with documentation of previous vaccination with Tdap, either Td or Tdap should be used if a tetanus toxoid-containing vaccine is indicated.”

Tetanus Rapid Fire Question

- “I have never been vaccinated against tetanus”

Clean minor wounds	Dirty or puncture wounds
Immunization status unknown or less than 3 doses - Give DTaP	Immunization status unknown or less than 3 doses - Give DTaP plus TIG
Greater than 10 years since last dose - Give TDaP	Greater than 5 years since last dose - Give TDaP
Greater than 3 doses and less than 10 years since last shot - no prophylaxis needed.	Greater than 3 doses and less than 5 years since last shot - no prophylaxis needed.

Tetanus Rapid Fire Answer

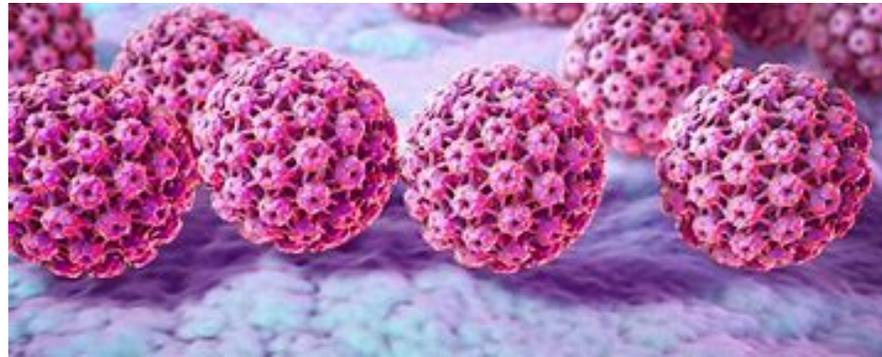
- “I have never been vaccinated against tetanus”
- GREAT!



- Persons aged (7–18 years and ≥ 19 years) who have never been vaccinated against pertussis, tetanus, or diphtheria should receive a series of three tetanus and diphtheria toxoid-containing vaccines, which includes *at least 1 dose* of Tdap. The preferred schedule is a dose of Tdap, followed by a dose of *either Td or Tdap* at least 4 weeks afterward and another dose of *either Td or Tdap* 6 to 12 months later.

HPV

- HPV Vaccine ACIP recommends catch-up vaccination for persons through age 26 years who are not adequately vaccinated
- ACIP recommends vaccination based on shared clinical decision making for individuals aged 27 through 45 years who are not adequately vaccinated
- *Note: HPV vaccines are not licensed for use in adults older than age 45 years



Pneumococcal

- Pneumococcal Vaccines ACIP recommends PCV13 based on shared clinical decision making for adults 65 years or older who do not have an immunocompromising condition and who have not previously received PCV13
- All adults 65 years or older should receive a dose of PPSV23
- PPSV23 contains 23 strains of the bacteria, but is not terribly effective at reducing a person's risk of developing community-acquired pneumonia
- It is much more effective at reducing a person's risk of developing bacteremia or meningitis caused by those 23 strains in healthy adults
- PCV13 was developed to improve the vaccine's ability to guard against community-acquired pneumonia caused by *S. pneumoniae*
- To date, however, no study has shown that PCV13 reduces the risk of getting pneumococcal pneumonia or invasive pneumococcal disease in adults

Pneumococcal Rapid Fire Question

- Do studies prove that PCV13 boosts immune responses to the 13 strains that are in both vaccines (PCV13 and PPSV23)?

- Prior doses count towards doses recommended below and do not need to be repeated.
- If PPSV23 was given previously: (1) Wait 1 year before giving PCV13; (2) For group B, wait at least 5 years before giving a second dose of PPSV23.
- No more than two doses of PPSV23 recommended before 65th birthday and one dose thereafter.
- DO NOT administer PCV13 and PPSV23 at the same visit.

A. Smoker, long-term care facility resident, or chronic conditions:

- Heart Disease (excluding hypertension)
- Lung Disease (including asthma)
- Liver Disease (including cirrhosis)
- Diabetes
- Alcoholism

PPSV
23

B. Immunocompromised:

- HIV Infection
- Chronic Renal Failure
- Nephrotic Syndrome
- Asplenia (including sickle cell)

PCV
13

8 Weeks

PPSV
23

5 Years

PPSV
23

C. CSF Leaks or Cochlear Implants

PCV
13

8 Weeks

PPSV
23

Pneumococcal Rapid Fire Answer

- Do studies prove that PCV13 boosts immune responses to the 13 strains that are in both vaccines (PCV13 and PPSV23)?
 - YES
 - Studies have shown is that PCV13 appears to boost immune responses to the 13 strains common to both vaccines better than PPSV23—a finding that suggests PCV13 will ultimately be shown to be the superior vaccine.

Pneumococcal Rapid Fire Question

- Why is PPSV23 recommended for smokers or diabetic patients but not PCV13?
- I have a patient on Humira for RA, does this meet the definition of immunosuppressed for PCV13?
- YES
- Humira is considered immunosuppressive because serious infections have been reported in people taking the drug

Pneumococcal Rapid Fire Answer

- Why is PPSV23 recommended for smokers or diabetic patients but not PCV13?
- The level of risk for pneumococcal disease in these population is not as high as immunocompromised, asplenic patients, HIV, hematological cancers, or cochlear implants
- This lower risk level suggests PPSV23 will be the most beneficial vaccine and for <65 years of age

Pneumococcal Rapid Fire Answer

- I have a patient on Humira for RA, does this meet the definition of immunosuppressed for PCV13?
- Humira is considered immunosuppressive because serious infections have been reported in people taking the drug

Hepatitis A

- Hepatitis A Vaccines ACIP recommends that all children and adolescents aged 2 through 18 years who have not previously received Hepatitis A vaccine be vaccinated routinely at any age (i.e., children and adolescents are recommended for catch-up vaccination)
- ACIP recommends all persons with HIV aged ≥ 1 year be routinely vaccinated with Hepatitis A vaccine
- The New Mexico Dept. of Health is investigating a current outbreak of hepatitis A

Meningococcal B

- ACIP recommends a MenB booster dose 1 year following completion of a MenB primary series followed by additional booster doses every 2-3 years thereafter, for as long as increased risk remains
- MenB is routinely recommended for:
 - People age 10 years and older with asplenia, immune deficiencies, on immune suppression therapy
 - Students on college campuses at risk of an outbreak caused by a vaccine serogroup
 - Microbiologists who work with meningococcus bacteria in a laboratory
 - Category B recommendation allows the clinician to make a MenB recommendation based on the risk and benefit for the individual patient
 - For adolescents and young adults, ACIP recommends that a MenB series may be administered to people 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years

MenB Rapid Fire Question

- So Should college students be vaccinated against MenB?

MenB Rapid Fire Answer

- Should college students be vaccinated against MenB?
 - YES
- Several small outbreaks of meningococcal serogroup B disease have occurred on college campuses since 2013, but the CDC notes that college students in general are not at higher risk of meningococcal serogroup B disease than persons of the same age who are not college students
- However, data derived from enhanced CDC meningococcal disease surveillance suggests that while the incidence of serogroup B meningococcal disease in college students is low, college students age 18–21 years are at increased risk compared to non-college students
- ACIP has not changed its recommendation that MenB vaccine is not routinely recommended for college students
 - However, college students may choose to receive MenB vaccine to reduce their risk of meningococcal serogroup B disease
 - *Note = consider giving both MenACWY and MenB vaccines to college students!

MenACWY vs MenB

- MenACWY vaccines provide no protection against serogroup B disease, and meningococcal serogroup B vaccines (MenB) provide no protection against serogroup A, C, W, or Y disease

3 serogroups cause most meningococcal disease:



2 vaccines provide protection:

MenACWY

MenB

Talk to a doctor about what vaccines are best for you or your child.



Rabies

- Status quo: 3-dose series, 3-4 week schedule [0,7, 21 or 28 days]
- Should a 2-dose, 1-week schedule [0,7 days] for rabies PrEP (pre-exposure prophylaxis) be recommended?
- Additional data needed for consideration of alternate PEP Schedule

What kind of animals get Rabies?

- The rabies virus can infect all **mammals**.
- **Mammals** are warm-blooded animals that have hair and mammary glands to produce milk for their babies.
- Animals like frogs, birds, and snakes do not get rabies.



Coronavirus

- <https://www.cnbc.com/2020/01/17/cdc-and-homeland-security-begins-screening-for-coronavirus-at-major-us-airports.html>
- The CDC and Homeland Security has started to screen travelers on direct and indirect flights from Wuhan, China to three U.S. airports: John F. Kennedy International Airport, San Francisco International Airport, and Los Angeles International airport
- Usually cause mild to moderate upper-respiratory tract illnesses, like the common cold
- Symptoms may include:
 - runny nose
 - headache
 - cough
 - sore throat
 - fever
 - a general feeling of being unwell

HPV vaccine linked to dramatic drop in cervical disease in Scotland

- Routine vaccination from 2008 to 2016 of 140,000 girls aged 12-13 years with the bivalent HPV vaccine led to a large reduction in pre-invasive cervical disease



Why is the HPV Vaccine Important?

- Human papillomavirus (HPV) is an extremely common disease that can be spread by sexual contact
- One out of four people in the United States are currently infected
- 9/10 people will clear the virus, but some will not and can lead to cancer
- Women can develop cervical, vaginal, and vulvar cancer
- Men can develop penile cancer
- Both sexes can develop anal and oropharyngeal cancer

HPV History

- Merck developed Gardasil, the first quadrivalent HPV vaccine in 2006 (HPV4)
- GlaxoSmithKline developed Cervarix, the 2 strain HPV vaccine in 2009
- Merck developed Gardasil 9, protecting against nine different strains, in 2014 (HPV9)
- Has been shown to prevent precancerous changes in both the cervix and anus.
- Both the HPV4 and HPV9 prevent warts.
- HPV9 has been the only HPV vaccine available in the US since 2016

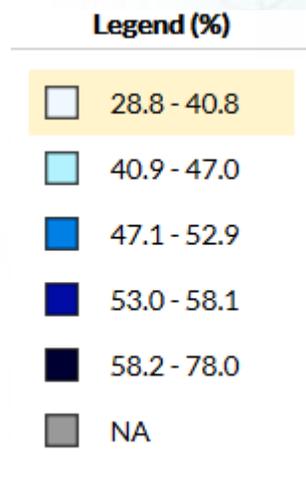
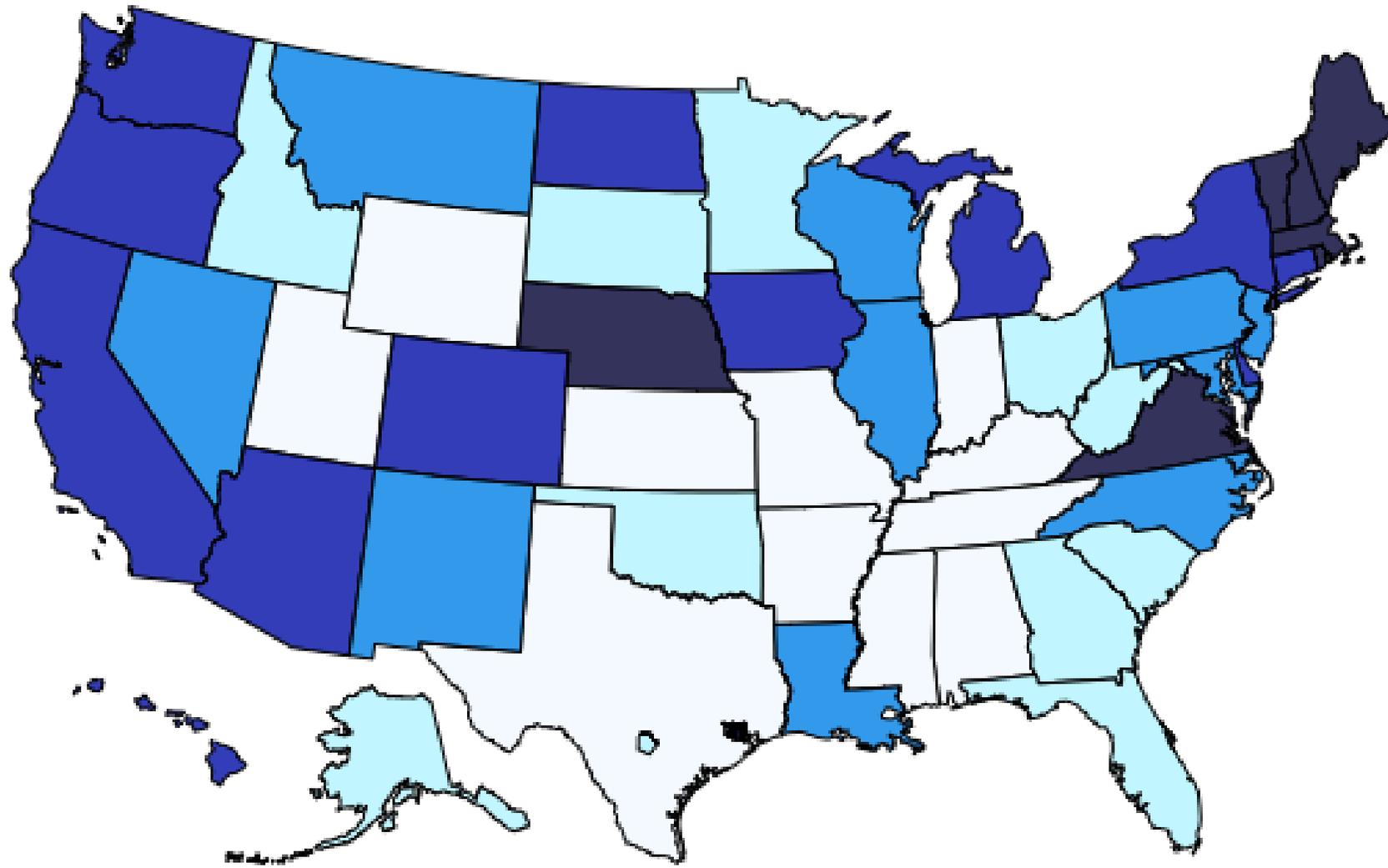
HPV Vaccines

Vaccine	HPV types	Manufacturer	Licensure ages
Bivalent (2vHPV)	16,18	GlaxoSmithKline	Females 9–25 yrs
Quadrivalent (4vHPV)	6,11,16,18	Merck & Co	Females and males 9–26 yrs
9-valent (9vHPV)	6,11,16,18, 31,33,45,52,58	Merck & Co	Females and males 9–45 yrs

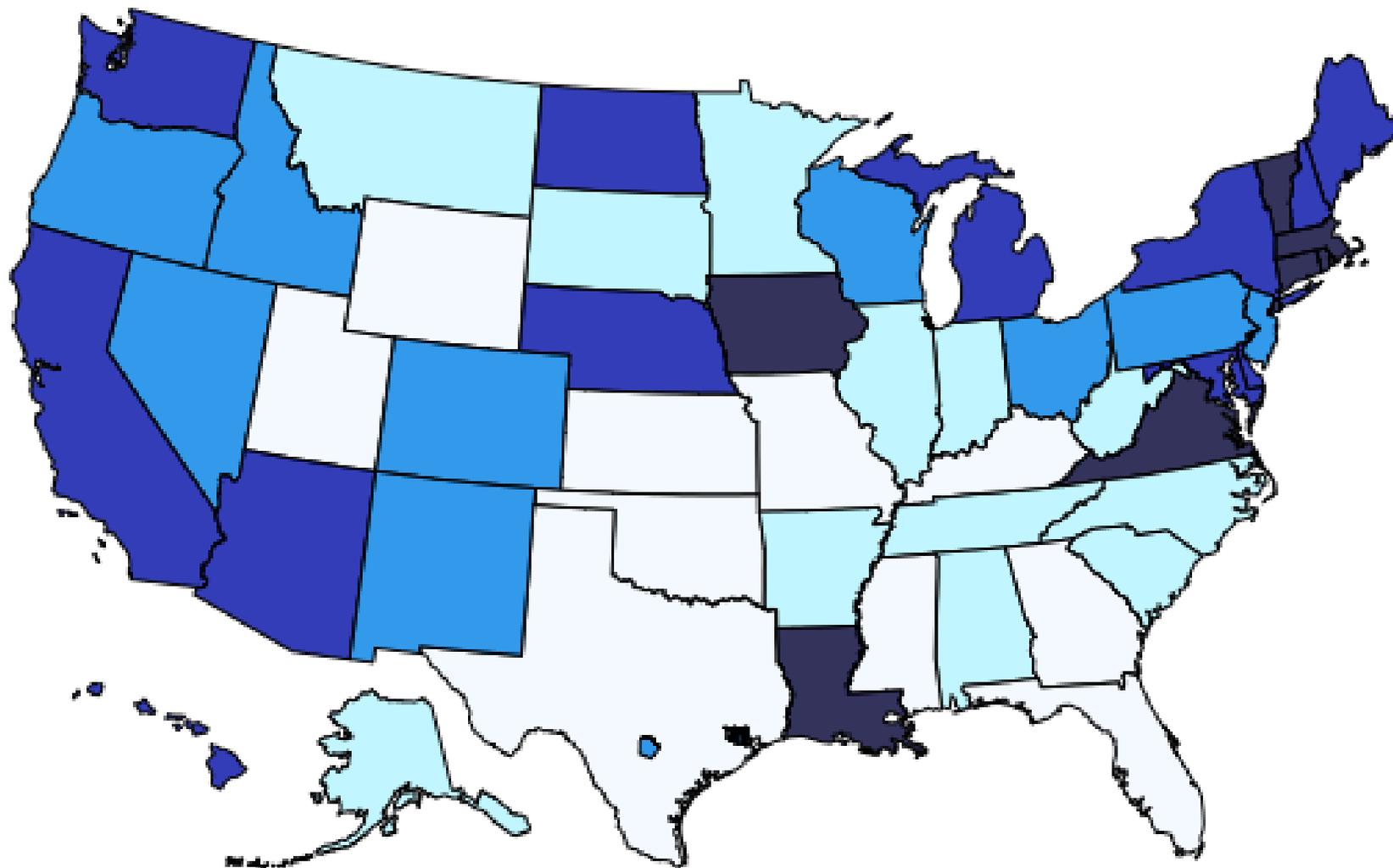
HPV Goals

- HPV vaccination is included on Healthy People 2020 goals.
- The target goal is 80% for children aged 13-15 having 2 to 3 doses.
- As of 2016, vaccination rates for children having >1 dose is 60.5%
 - Children aged 13-17 have a 42.9% rate

Currently Viewing: HPV Vaccination Up-To-Date, Males and Females >> Age >> 13-17
Years >> Coverage for 2017



Currently Viewing: HPV Vaccination Up-To-Date, Female >> Age >> 13-17 Years >>
Coverage for 2017



Legend (%)

□	28.8 - 40.8
□	40.9 - 47.0
□	47.1 - 52.9
□	53.0 - 58.1
□	58.2 - 78.0
□	NA

Schedules & Recommendations

	Flu Influenza	Tdap Tetanus, diphtheria, pertussis	HPV Human papillomavirus	Meningococcal	
				MenACWY	MenB
7-8 Years					
9-10 Years					
11-12 Years					
13-15 Years					
16-18 Years					
More Information:	Everyone 6 months and older should get a flu vaccine every year.	All 11- through 12-year-olds should get one shot of Tdap.	All 11- through 12- year olds should get a 2-shot series of HPV vaccine. A 3-shot series is needed for those with weakened immune systems and those who start the series at 15 years or older.	All 11- through 12- year olds should get one shot of meningococcal conjugate (MenACWY). A booster shot is recommended at age 16.	Teens 16-18 years old may be vaccinated with a serogroup B meningococcal (MenB) vaccine.

ACIP Recommendations for Children

- ACIP currently recommends all children ages 11-12 start the vaccination series
 - Can start as early as 9 years old
- 2 dose series 0, 6-12 months
 - If series started ages 9-14 years old
- 3 dose series 0, 1-2 months, 6-12 months
 - Aged 15-18 years old

ACIP Recommendations for Adults

- 2-3 doses depending on when the series was started
 - 2 doses if started before 15th birthday
 - Remember doses don't expire.
 - Only time a dose doesn't count is if it's too soon.
- Females ages 19-26
- Males aged 19-21
 - Some clinicians recommend 22-26

Duration of immunity of GARDASIL 9 has not been established

Special Situations

- Immunocompromising conditions (including HIV infection) through age 26
 - 3 dose series 0, 1-2 months, 6-12 months
- Men who have sex with men through age 26
 - 2 or 3 dose series depending on age at initial vaccination as above
- Transgender individuals through age 26
 - 2 or 3 dose series depending on age at initial vaccination as above
- Pregnancy through age 26
 - Not recommended
 - No intervention needed if vaccinated while pregnant
 - Pregnancy test not needed before vaccination
- Severe allergic reaction to yeast or a previous dose of Gardasil 9
 - Contraindicated

Special Situations

- Individuals who completed a 2 or 3 dose HPV vaccination series
 - No ACIP recommendation for 9vHPV after completing 4vHPV or 2vHPV
 - Available data show no serious safety concerns in persons who received the 9vHPV after completing three doses of 4vHPV
- Individuals who receive just one dose
 - Study showed that recipients who received one dose sustained an immune response against HPV 16 and 18, over a 4 year period, although it was less than the two or three dose recipients

Data supporting use of Gardasil 9 for expanded age ranges in women

- FUTURE 3, base study: 3,253 women 27 through 45 years of age, treated with a three dose regimen and followed for a median duration of 3.5 years after the 3rd dose
- 87.7% effective in preventing the combined incidence of:
 - HPV 6/11/16/18 related persistent infection
 - Genital warts
 - Vulval and vaginal intraepithelial neoplasia and cancer
 - Cervical dysplasia and cancer
 - Adenocarcinoma in-situ
- 95% effective in preventing the combined incidence of:
 - HPV 6/11/16/18 related genital warts or cervical dysplasia

Data supporting use of Gardasil 9 for expanded age ranges in women

- FUTURE 3: 600 women ages 27 through 45 were followed for 10 years
 - Sustained effectiveness for up to 10.1 years
 - No cases of HPV disease (HPV6/11/16/18 related CIN of any grade or genital warts) were observed in trial participants

Data supporting use of Gardasil 9 for expanded age ranges in women

- Long-Term Follow-up Observation of the Safety, Immunogenicity, and Effectiveness of Gardasil in Adult Women
 - 6 year post-vaccination analysis of women who were vaccinated at 24-45 years of age or 29-50 years of age
 - No cases of HPV 6/11/16/18-related CIN or EGL during the extended follow-up

Data supporting use of Gardasil 9 for expanded age ranges in men

- The MAM Study followed 150 men for four years who were vaccinated with Gardasil. Sera were collected and anti-HPV IgG levels were determined
 - Immune response to HPV vaccination in men ages 27 through 45 was comparable to that observed in younger men
 - 100% of men seroconverted
 - No serious adverse events were observed

What are the common side effects of Gardasil 9?

Percentages for Gardasil-9, after any dose

- Pain (~89%), redness (~34%), or swelling (~40-48%) at injection site
- Fever (~6%)
- Headache or feeling tired (~11-14%)
- Nausea (3.7%)
- Muscle or joint pain (0.7%)

Gardasil 9 Safety Profile

- 29 million doses were distributed between December 2014-December 2017
- 7,244 U.S. reports of adverse events
- Only 3% of those were classified as serious
- 4 confirmed reports of Guillain-Barre Syndrome
- 6 reports partially met diagnostic criteria of postural orthostatic tachycardia syndrome
- 2 reports of death, the evidence did not suggest a causal link between Gardasil 9 and the reported deaths
- 1 report of possible (incomplete information) chronic regional pain syndrome
- No reports of chronic fatigue syndrome
- There is no current evidence that HPV vaccines cause reproductive problems

Vaccination in Rural Communities

- In 2017, percentage of teens who received the first HPV vaccine dose was 11% lower in rural compared to urban areas
- What can rural clinicians do?
 - Recommend and administer all vaccines for teens in the same way and on the same day
 - Refer to a provider who can administer the vaccine if you don't have the vaccine in stock
 - Record all vaccines your patients receive on New Mexico State Immunization Information System (NMSIIS)
 - https://nmsiis.health.state.nm.us/webiznet_nm/Login.aspx

Vaccination in Rural Communities



Access to health care is a serious issue in New Mexico

32 of 33

New Mexico counties include areas designated as

“medically underserved”

The Role of Pharmacy

- The HPV vaccine is included in the protocol for pharmacist prescribing of vaccines in New Mexico
- Pharmacists follow the Center for Disease Control recommendations determined by the Advisory Committee on Immunization Practices (ACIP)
- Documentation of vaccination is recorded in NMSIIS

“Roughly 9 out of 10 Americans live within five miles of a community pharmacy, according to NACDS research”

Vaccine Financing

- 9-18 years old
 - Vaccine for Children Program pays for all vaccinations for all children with Medicaid
 - True Health New Mexico
 - Affordable Care Act
- ≥ 18 years old
 - New Mexico Health Connection
 - Presbyterian Centennial Care
 - True Health New Mexico
 - Affordable Care Act
 - Western Sky Medicaid
 - Blue Cross Blue Shield
 - Molina – not covered
- 19-20 years old
 - Early and Periodic Screening Diagnosis and Treatment program through Medicaid covers all ACIP-recommended vaccines

Vaccine Financing Links

- Vaccine for Children Program - <https://www.cdc.gov/vaccines/programs/vfc/parents/qa-detailed.html>
- Affordable Care Act - https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/HIM/2019/2019_NM_6T_HIM.pdf
- New Mexico Health Connection - https://www.mynmhc.org/uploads/FileLinks/199fc387297f49f2ba75f719e355510e/nmhc_formulary_0_copay_drug_list_010119_final_1.pdf
- Presbyterian Centennial Care - http://docs.phs.org/cs/groups/public/documents/communication/pel_00937013.pdf
- True Health New Mexico - https://www.truehealthnewmexico.com/uploads/FileLinks/45fef4e8f2c94a1f9445df9703a93c6f/thnm_aca_drug_list_0419.pdf
- Affordable Care Act - https://www.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/HIM/2019/2019_NM_6T_HIM.pdf
- Western Sky Medicaid - https://www.westernskycommunitycare.com/content/dam/centene/newmexico/Medicaid/PDFs/NM%20CNCNM001_20190227_Final%20PDF%20508C.PDF
- Molina - <https://www.molinahealthcare.com/members/wa/en-US/PDF/Medicaid/formulary.pdf>
- Early and Periodic Screening Diagnosis and Treatment program - <https://www.medicaid.gov/medicaid/quality-of-care/improvement-initiatives/vaccines/index.html>

Answering Parents' Questions

- “I’m worried my child will think that getting this vaccine makes it OK to have sex”
 - "Studies have shown that getting the vaccine doesn't make children have sex sooner. I made sure that I (or my child) got the vaccine. We can start the series today."
- “Is my child really at risk?”
 - "HPV is an extremely common virus that causes cancer in both males and females. Giving the vaccine can prevent these cancers."
- “Why do they need the vaccine so young?”
 - "It's best to give the vaccine before the children are ever exposed to the virus. Also, the younger children only need two shots and older children need three."

Thank you

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- Joslyn Gabaldon, PharmD Candidate
- Zoe Kasten, PharmD Candidate



HPV Vaccine

Thank you!

What questions do you have?

