

# Adult Immunization Update: Are you Ready for your Vaccine Today?

David Glenn Weismiller, MD, ScM, FAAFP



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The logo for FMX, consisting of the letters 'FMX' in a bold, white, sans-serif font, set against a dark orange background with diagonal white stripes.

## David Glenn Weismiller, MD, ScM, FAAFP

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Dr. Weismiller is a graduate of Jefferson Medical College of Thomas Jefferson University in Philadelphia, Pennsylvania, and completed his residency at the University of Virginia Health Sciences Center in Charlottesville. Subsequently, he completed a fellowship in maternal-child health and earned a graduate degree in epidemiology at Brown University School of Medicine, Providence. A professor of family medicine at the new medical school of the University of Nevada, Las Vegas, he provides full-scope care that includes inpatient and maternity care. A proponent of “reflection in practice” and “learner-centered instruction,” he is recognized nationally for his work in continuing medical education and faculty development.

Having taught board review programs for the AAFP for more than 20 years, Dr. Weismiller is the founding and current chair of the AAFP Family Medicine Board Review Express™, as well as the AAFP's annual Family Medicine Update live course. He is a frequent presenter at AAFP Family Medicine Experience (FMX) and teaches American Board of Family Medicine (ABFM) Knowledge Self-Assessments throughout the country. He is the author of numerous publications on issues related to women's and children's health, and he is an advocate for empowering individuals to make sound health care choices.

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# Learning Objectives

1. Establish standardized adult immunization status screening during patient encounters.
2. Integrate current AAFP/ACIP adult immunization recommendations into current practice.
3. Develop standardized processes to address special populations and contraindications.
4. Counsel adult patients, using available patient education resources and motivational interviewing about vaccine safety and efficacy.

FMX

# Audience Engagement System



FMX

# Background

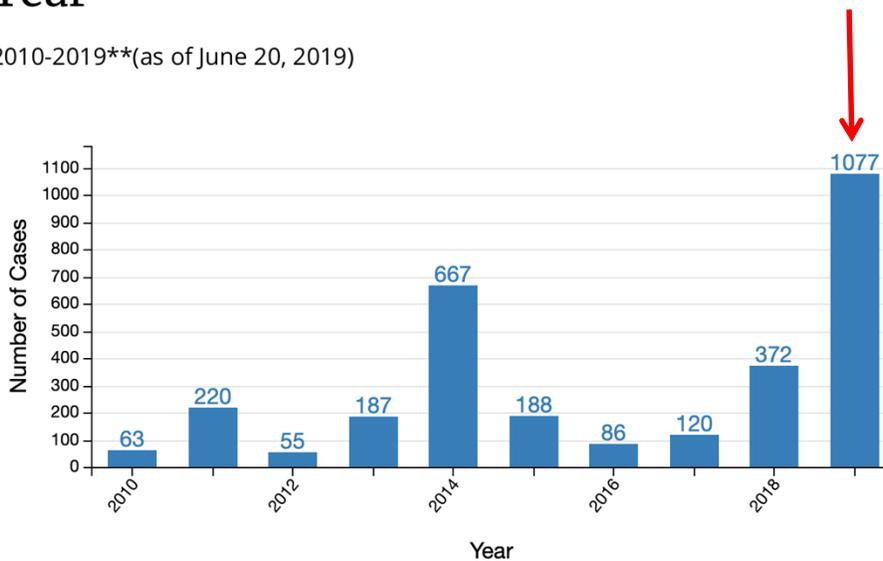
- Vaccines are considered one of the greatest public health achievements of the last century for their role in
  - Eradicating smallpox
  - Controlling polio, measles, mumps, rubella and other infectious diseases
- Despite their effectiveness in preventing and eradicating disease, substantial gaps in vaccine uptake persist
- WHO
  - One of the most cost-effective ways of avoiding disease
  - Prevents 2-3 million deaths per year
  - 1.5 million deaths could be avoided if global coverage of vaccinations improved

## Comparison of 20<sup>th</sup> Century Annual Morbidity and Current Morbidity: *Vaccine-Preventable Diseases*

Disease	20 <sup>th</sup> Century Annual Morbidity	2016 Reported Cases	Percent Decrease
Smallpox	29,005	0	100
Diphtheria	21,053	0	100
Measles	530,217	85	>99
Mumps	162,244	6,369	>96
Pertussis	200,752	19,972	90
Polio (paralytic)	16,316	0	100
Rubella	47,745	1	>99
Congenital rubella syndrome	152	2	98
Tetanus	580	34	94
Haemophilus influenzae	20,000	2,085	90

# Number of Measles Cases Reported by Year

2010-2019\*\*(as of June 20, 2019)



Measles Cases CDC - <https://www.cdc.gov/measles/cases-outbreaks.html>

## Leading the News



**AMA urges tech companies to stop spread of anti-vaccine misinformation**  
 Felicia S. Jansen, senior contributor Bruce Jansen reports the American Medical Association on Wednesday sent letters (PDF) to the CEOs of Amazon, Facebook, Google, Pinterest, Twitter and YouTube saying more needs to be done to combat vaccine misinformation on their platforms. The AMA said "vaccine-preventable diseases" like measles are increasing nationwide and threatening public health. The physician group is worried "that a parent or someone seeking quality health information" that "searches for information about a vaccine will instead be hit with anti-vaccination advertisements and content."

The Hill (3/13, Birnbaum) reports AMA CEO and Executive Vice President James L. Madara, M.D. wrote in the letters, "At a time when vaccine-preventable diseases, particularly measles, are resurging in the United States and threatening communities and public health, physicians across the country are troubled by reports of anti-vaccine related messages and advertisements targeting parents searching for vaccine information on your platforms." Facebook last week announced it is taking steps to curb the circulation of anti-vaccine content on its platform, while Amazon has been quietly taking down anti-vaccine documentaries and books, though it has not announced a larger plan to address the issue."

News > Medscape Medical News

## Senate Panel Tackles US Measles Outbreaks, Vaccine Exemptions

Kerry Dooley Young  
 March 06, 2019



Researchers on Tuesday offered a Senate panel suggestions for increasing use of vaccines, including addressing the worthiness of vaccine exemptions and paying physicians for time spent counseling parents on the benefits of these shots for their children and for society as a whole.

The Senate Health, Education, Labor and Pensions (HELP) Committee is looking for ways to help combat measles outbreaks, which have been linked to the refusal of some parents to have their children vaccinated.

At least 159 cases of measles have been confirmed this year in the United States. That marks an unwelcome resurgence of a viral infection that had been declared eliminated in 2000, said Senate HELP Committee Chairman Lamar Alexander (R-TN) at the hearing.

\*Charlatans and Internet fraudsters who claim that vaccines aren't safe are

**WHO – 30% global increase in cases of measles – a disease that had been nearly wiped out in some countries.**

-- 2019



**New York tackles 'largest measles outbreak' in state's recent history as cases spike globally**

# MMR Vaccine and Autism

- 1998 – Wakefield and colleagues
  - Ultimately retracted paper claimed there was direct connection
  - **Retraction**—Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*. 2010;375:445. [PMID: 20137807] doi:10.1016/S0140-6736(10)60175-4



## Mainstream Studies

*Consistently pointed toward a lack of association between MMR vaccine and autism*

- **Madsen KM, Hviid A, Vestergaard M, Schendel D, Wohlfahrt J, Thorsen P, et al.** A population-based study of measles, mumps, and rubella vaccination and autism. *N Engl J Med*. 2002;347:1477-82. [PMID: 12421889]
- **Jain A, Marshall J, Buikema A, Bancroft T, Kelly JP, Newschaffer CJ.** Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. *JAMA*. 2015;313:1534-40. [PMID: 25898051] doi:10.1001/jama.2015.3077
- **Hviid A, Hansen JV, Frisch M, Melbye M.** Measles, mumps, rubella vaccination and autism. A nationwide cohort study. *Ann Intern Med*. 2019. [Epub ahead of print]. doi:10.7326/M18-2101

# MMR Vaccine and Autism

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- March 2019\*
  - Nationwide Cohort Study, 657,461 children born in Denmark from 1999 through 31 December 2010, with follow-up from 1 year of age and through 31 August 2013
  - **Results**
    - During 5 025 754 person-years of follow-up, 6517 children were diagnosed with autism (incidence rate, 129.7 per 100 000 person-years).
    - Comparing MMR-vaccinated with MMR-unvaccinated children yielded a fully adjusted autism hazard ratio of 0.93 (95% CI, 0.85 to 1.02).
    - Similarly, no increased risk for autism after MMR vaccination was consistently observed in subgroups of children defined according to sibling history of autism, autism risk factors (based on a disease risk score) or other childhood vaccinations, or during specified time periods after vaccination.
  - **Conclusion**
    - Strongly supports that MMR vaccination **does not** increase the risk for autism, does not trigger autism in susceptible children, and is **not** associated with clustering of autism cases after vaccination.
    - It adds to previous studies through significant additional statistical power and by addressing hypotheses of susceptible subgroups and clustering of cases.

\* Hviid A, Hansen JV, Frisch M, Melbye M. Measles, Mumps, Rubella Vaccination and Autism: A Nationwide Cohort Study. *Ann Intern Med*. [Epub ahead of print] doi: 10.7326/M18-2101

The image shows two news articles. The top article is from CNN, titled "Superbugs and anti-vaxxers make WHO's list of 10 global health threats". The bottom article is from NBC News, titled "Recently vaccinated teen testifies before Congress about anti-vaccination". The NBC News article includes a quote: "For my mother, her love and affection and care as a parent was used to push an agenda to create a false distress," Eihan Lindenberg told a Senate committee. Below the quote is a video player showing a young man with glasses speaking at a hearing.

# Anti-Vaxers



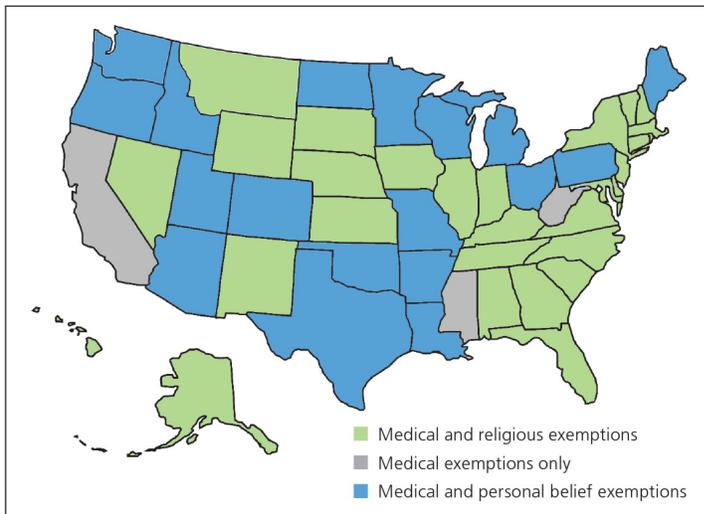
- Vaccines cause autism and other diseases
- Distrust of government and pharmaceutical companies
- Individual rights
- Religious freedoms
- CDC – No vaccination by age 2\*
  - Born in 2011 – 0.9%
  - Born in 2015 – 1.3%

*\*Olive JK, Hotez PJ, Damania A, Nolan MS (2018) The state of the antivaccine movement in the United States: A focused examination of nonmedical exemptions in states and counties. PLOS Medicine 15(6): e1002578. <https://doi.org/10.1371/journal.pmed.1002578>*

# Vaccine Refusal

- **AAFP**
  - Does NOT support immunization exemption policies except in cases of allergic and medical contraindication
  - Sign a refusal to vaccinate form, declination should be documented with provision of vaccine information statement
- **AAP**
  - Has developed form that can be used to document vaccine refusal
    - <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Pages/refusal-to-vaccinate.aspx>
- **Dismiss from practice?**
  - CDC recommends AGAINST dismissing the patient or family from the practice if they refuse vaccination
  - AAP now accepts this practice if done in a conscientious way

# School Vaccine Exemption Laws<sup>§</sup>



- Full vaccination of students enhances the safety of all, but states vary in regard to acceptable reasons for parental vaccination refusal.
- The choice of some parents not to immunize increases the infection risk for all children, **INCLUDING** those who are immunized.\*

\*Atwell JE, Van Otterloo J, Zipprich J, et al. Nonmedical vaccine exemptions and pertussis in California, 2010. *Pediatrics*. 2013;132(4):624–630.  
<sup>§</sup>From Johns Hopkins Bloomberg School of Public Health. School exemption laws by state. <http://www.vaccinesafetv.edu/cc-exem.htm>

## States that have introduced vaccination exemption bills

Lawmakers in 20 states have filed legislation this year to expand nonmedical exemptions for vaccinations or require doctors to provide more information on the risks of vaccines.



Source: American Academy of Pediatrics  
 Graphic: WB Hoag, CNN

## Leading the News

**Despite measles outbreaks, at least 20 states have introduced anti-vaccination bills**  
 CNN (3/6, Lou, Griggs) reports that despite the growing number of measles outbreaks across the U.S., "at least 20 states have introduced bills this year that would broaden the reasons why parents can exempt kids from getting vaccines even if there isn't a medical need," the American Academy of Pediatrics has indicated. The organization said, "The volume of legislative activity is greater than in past years... But adverse bills outnumbering supportive ones conforms with trends from prior years." The AAP explained to CNN, "While this advocacy by vaccine skeptic groups gets a lot of attention, it's rarely successful, which is good news for child health and wellness."

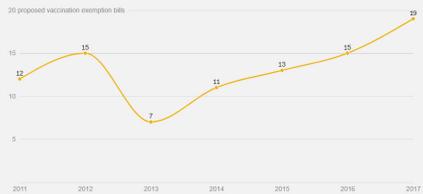
From the AMA

According to the American Academy of Pediatrics, at least 20 states have introduced bills this year that would –

- broaden the reasons why parents can exempt kids from getting vaccines even if there isn't a medical need
- require doctors to provide more information on the risks of vaccines

## Vaccination exemption bills have been on the rise in the US

Between 2011 and 2017, researchers identified 92 bills<sup>\*</sup> introduced across the country as legislation that would make it easier to get exemptions from vaccine requirements, according to a recent study published in the American Journal of Public Health.



\* Includes bills that were reintroduced in subsequent years  
 Source: American Journal of Public Health  
 Graphic: WB Hoag, CNN



Even with measles outbreaks across the US, at least 20 states have proposed anti-vaccination bills

By Michelle Lou and Brandon Griggs, CNN  
 Updated 4:36 PM ET, Wed March 6, 2019

# CDC Estimates

- Estimated that 50,000 adult lives could be saved per year if the ACIP immunization schedule was followed
- Among children born in the past 20 years
  - Prevent >21 million hospitalizations
  - Prevent 730,000 deaths

**Boeing 737 Max Hit Trouble Right Away, Pilot's Tense Radio Messages Show**  
The New York Times  
157 people killed  
March 10, 2019

**UNited Safety Card**  
R1  
B737-MAX9

**After a Lion Air 737 Max Crashed in October, Questions About the Plane Arise**  
The Washington Post  
189 people killed

**Trump: Boeing 737 Max 8 and 9 aircraft grounded**  
Newsroom  
President Donald Trump says new information about the crash of an Ethiopian Air Boeing 737 Max 8 led his administration to order the immediate grounding of all Max 8 and 9 aircraft in the US.  
Source: CNN  
March 13, 2019

# Unvaccinated Adults and the US Economy

- A toll on the US\$
  - \$7.1 billion in 2015
  - 80% of a total cost-of-illness burden of \$8.95 billion for vaccine-preventable diseases
- For every \$1 invested in vaccines in the U.S., \$10.20 is saved in direct medical costs

<sup>§</sup>Ozawa S, Portnoy A, Getaneh H, et al. Modeling the Economic Burden of Adult Vaccine-Preventable Diseases in the United States. Health Affairs. October 2016.

## Of this almost 9 Billion cost of Illness burden...

### *Greatest Cost\**

Disease	Amount of 2015 direct and indirect expenditures	Cases
Influenza	5.79 million	16.6 million
Pneumococcus	1.86 billion	283,000 cases
Herpes Zoster	782 million	1.1 million cases
HPV-linked conditions	333 million	447,000 cases

\*In- and Outpatient costs represented 95% of burden, and lost productivity 5%

<sup>§</sup>Ozawa S, Portnoy A, Getaneh H, et al. Modeling the Economic Burden of Adult Vaccine-Preventable Diseases in the United States. Health Affairs. October 2016

## AES Question 1

Which one of the following is the greatest influence on a patient's decision to undergo vaccination?

- A. Information from websites
- B. Recommendation from a pharmacist
- C. Recommendation from family and friends
- D. Recommendation from physician

## Who Most Influences Adults' Decisions to Get Immunized?

Who	Percentage
Personal physician	69%
Family member	19%
Celebrity physician, public figure, other	7%
None of the above	4%
No answer	1%

*Source: National Foundation for Infectious Diseases. 2009 National Adult Immunization Consumer Survey.  
In: Landers SJ. Physicians asked to persuade adults to get immunized. American Medical News. 2009.  
Available at: <http://amednews.com/article/20090803/profession/308039978/7/>.*

# Key Reasons for Low Vaccination Rates Among US Adults

## PHYSICIAN FACTORS

- Do not recommend to patient
- Recommend but without conviction
- Lack knowledge about current guidelines
- Unavailable in physicians' offices
- Do not use patient reminder systems
- Do not use EHR to identify patients who need vaccines



## PATIENT FACTORS

- Misconceptions about vaccines
  - Not effective
  - Not needed because the diseases they prevent no longer exist
  - Not needed by healthy individuals who live healthy lives
  - Are unsafe
  - Cause disease
  - Are expensive
- Lack of awareness about need for vaccines

# Addressing Concerns About Vaccination

## *Communication*

### Unhelpful

- *Directing style* – “*This is what you should do*”
  - Righting reflex – using information and persuasion to achieve change
  - Missing cues
  - Using jargon
  - Discrediting information source
  - Overstating vaccine safety
  - Confrontation

### Helpful

- *Guiding style* – “*May I help you?*”
  - Care with body language
  - Eliciting concerns
  - Asking permission to discuss
  - Acknowledging/listening/empathizing
  - Determining readiness to change
  - Informing about benefits *and* risks
  - Giving or signposting appropriate resources

# Barriers

## *What to do?*



- Successful dialogue
  - Take time to LISTEN
  - Solicit and welcome questions
  - Keep the language simple and uniform
  - Clear cohesive voice of vaccine safety
  - Keep the conversation going
- Every visit is an opportunity for primary prevention
- Trust develops when patients identify both competence and caring in their physician

## Current Immunization Schedules

- Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention – develops a vaccination schedule for adults that is approved annually by the AAFP and other professional organizations
- Information about these schedules is available at <http://cdc.gov/vaccines>
  - Frequently monitor CDC websites for the most current recommendations
- ACIP Immunization Advisory App (free for Apple devices)
  - [http://immunization.acponline.org/app\(immunization.acponline.org\)](http://immunization.acponline.org/app(immunization.acponline.org))
- CDC Immunization Advisory App (free for Android devices)
  - <http://www.cdc.gov/vaccines/schedules/hcp/schedule-app.html>

# Key Points to the 2019 Schedule

## (Adult)

- Any licensed influenza vaccine appropriate for a patient's age and health status may be now administered.
  - The recommendation supersedes those for the previous two seasons, in which the use of the intranasal live attenuated influenza vaccine (LAIV), such as *FluMist Quadrivalent* (AstraZeneca), was not recommended.
- Homeless individuals** are the latest addition to the list of those who should be routinely vaccinated against hepatitis A. They can receive a two-dose series of single-antigen hepatitis A vaccine (*Havrix*, GlaxoSmithKline; *Vaqta*, Merck) or a three-dose series of combination hepatitis A and B vaccine (*Twinrix*, GlaxoSmithKline).
  - The addition came after the CDC received reports of an outbreak of hepatitis A in multiple states in October 2018. There were 2500 cases and most occurred among people who were homeless, drug users, or both.
- For adults aged 19 years and older, ACIP recommends use of a new yeast-based single-antigen recombinant [hepatitis B vaccine](#) (*Heplisav-B*, Dynavax), which contains the novel cytosine-phosphate-guanine oligodeoxynucleotide 1018 adjuvant.
  - Approved by the US Food and Drug Administration in November 2017, the vaccine offers the advantage of a more rapid dosing schedule and a shorter time to protection. "It's effective with two doses given 1 month apart and can also be used as part of a series with older vaccines. It costs about twice as much as its older counterparts, however."
  - There is an absence of safety data on use during pregnancy, and pregnant women should not receive *Heplisav-B*.

Kim DK, Hunter P, on behalf of the Advisory Committee on Immunization Practices. Recommended Adult Immunization Schedule, United States, 2019\*. *Ann Intern Med.* 2019;170(3):182-92. doi: 10.7326/M18-3600

## Annals of Internal Medicine®

From: Recommended Adult Immunization Schedule, United States, 2019\*

*Ann Intern Med.* 2019;170(3):182-92. doi:10.7326/M18-3600

**Table 1** Recommended Adult Immunization Schedule by Age Group United States, 2019

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or Influenza recombinant (RIV)	1 dose annually				
Influenza live attenuated (LAIV)	1 dose annually				
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td booster every 10 yrs				
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)				
Varicella (VAR)	2 doses (if born in 1980 or later)				
Zoster recombinant (RZV) (preferred)	2 doses				
Zoster live (ZVL)	1 dose				
Human papillomavirus (HPV) Female	2 or 3 doses depending on age at initial vaccination				
Human papillomavirus (HPV) Male	2 or 3 doses depending on age at initial vaccination				
Pneumococcal conjugate (PCV13)	1 dose				
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication				
Hepatitis A (HepA)	2 or 3 doses depending on vaccine				
Hepatitis B (HepB)	2 or 3 doses depending on vaccine				
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication				
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication				

Recommended vaccination for adults who meet age requirement.
  Recommended vaccination for adults with an additional risk factor or another indication.
  No recommendation

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**Table 2** Recommended Adult Immunization Schedule by Medical Condition and Other Indications  
 United States, 2019

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count	Asplenia, complement deficiencies	End-stage renal disease, on hemodialysis	Heart or lung disease, alcoholism <sup>1</sup>	Chronic liver disease	Diabetes	Health care personnel <sup>2</sup>	Men who have sex with men
IIV or RIV or LAIV			<200							1 dose annually
			>200							1 dose annually
										1 dose annually
Tdap or Td	1 dose Tdap each pregnancy									1 dose Tdap, then Td booster every 10 yrs
MMR										1 or 2 doses depending on indication
VAR										2 doses
RZV (Shingrix)										2 doses at age ≥50 yrs
ZVL										1 dose at age ≥60 yrs
HPV Female										3 doses through age 26 yrs
HPV Male										2 or 3 doses through age 26 yrs
PCV13										1 dose
PPSV23										1, 2, or 3 doses depending on age and indication
HepA										2 or 3 doses depending on vaccine
HepB										2 or 3 doses depending on vaccine
MenACWY										1 or 2 doses depending on indication, then booster every 5 yrs if risk remains
MenB										2 or 3 doses depending on vaccine and indication
Hib										3 doses HSCT <sup>3</sup> recipients only
										1 dose

  Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection  
  Recommended vaccination for adults with an additional risk factor or another indication  
  Precaution—vaccine might be indicated if benefit of protection outweighs risk of adverse reaction  
  Delay vaccination until after pregnancy if vaccine is indicated  
  Contraindicated—vaccine should not be administered because of risk for serious adverse reaction  
  No recommendation

1. Precaution for LAIV does not apply to alcoholism. 2. See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. 3. Hematopoietic stem cell transplant.

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## Where are we with Adults in 2019?

- MMR
- Influenza
- Hepatitis B
- Prevnar 13
- Gardasil
- Shingrix



(Matthew Busch/For The Washington Post)

# MMR

<https://www.cdc.gov/vaccines/vpd/mmr/hcp/recommendations.html#risk-factors>

## Adults

- Should be up to date on MMR with either 1 or 2 doses depending on risk factors UNLESS they have presumptive evidence of immunity
- During measles outbreaks, health departments MAY provide additional recommendations to protect their communities.
- In healthcare facilities serving a measles out break area, two doses or MMR vaccine are recommended for health care personnel, regardless of birth year, who lack other presumptive evidence of measles immunity

## Presumptive Evidence of Immunity

*May be established in any of the following ways:*

- Written documentation of  $\geq 1$  doses of a measles-containing vaccine administered on or after the first birthday for preschool-age children and adults not considered high risk
- Written documentation of two doses of measles-containing vaccine for school-age children and adults at high risk, including students at post-high school secondary educational institutions, healthcare personnel, and international travelers
- Laboratory evidence of immunity
- Laboratory confirmation of disease
- Birth before 1957
  - Considered acceptable evidence of immunity, in routine circumstances, **healthcare facilities** should consider vaccinating healthcare personnel born before 1957 who lack laboratory evidence of immunity or laboratory confirmation of disease.

## High risk adults

*Certain adults are considered to be at high risk for either acquiring measles and/or transmitting disease to vulnerable persons*

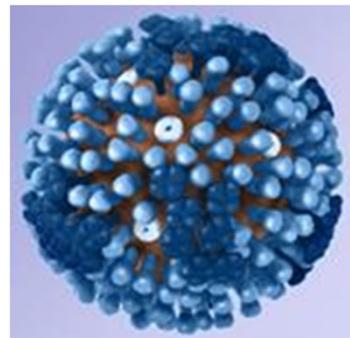
- High-risk adults need written documentation of two doses of MMR vaccine (each dose separated by at least 28 days), or other presumptive evidence of immunity
  - Students at post-high school educational institutions
  - Healthcare personnel
  - International travelers to any country outside the United States

<http://www.immunize.org/cdc/dear-provider-letter-adult-measles-vaccination.pdf>

# CDC - Measles Outbreak Toolkit for Health Care Providers

- <https://www.cdc.gov/measles/toolkit/healthcare-providers.html>
- Post-exposure Prophylaxis (PEP)
  - People exposed to measles who cannot readily show that they have evidence of immunity against measles should be offered PEP **or** be excluded from the setting (school, hospital, childcare).
  - To potentially provide protection or modify the clinical course of disease among susceptible persons, either administer MMR vaccine within **72 hours** of initial measles exposure, **or** immunoglobulin (IG) within **six days** of exposure.
  - Do **not** administer MMR vaccine and IG simultaneously, as this practice invalidates the vaccine.
  - If many measles cases are occurring among infants younger than 12 months of age, measles vaccination of infants as young as 6 months of age may be used as an outbreak control measure.
    - Note that children vaccinated before their first birthday should be revaccinated when they are 12 through 15 months old and again when they are 4 through 6 years of age.

Influenza



# Myths

- The influenza vaccine can cause influenza
- Healthy people don't need an influenza vaccine
- Influenza is just a "bad cold"
- The influenza vaccine isn't effective
- It's too late to get an influenza vaccine

# Influenza Vaccine Recommendations

**ACIP**

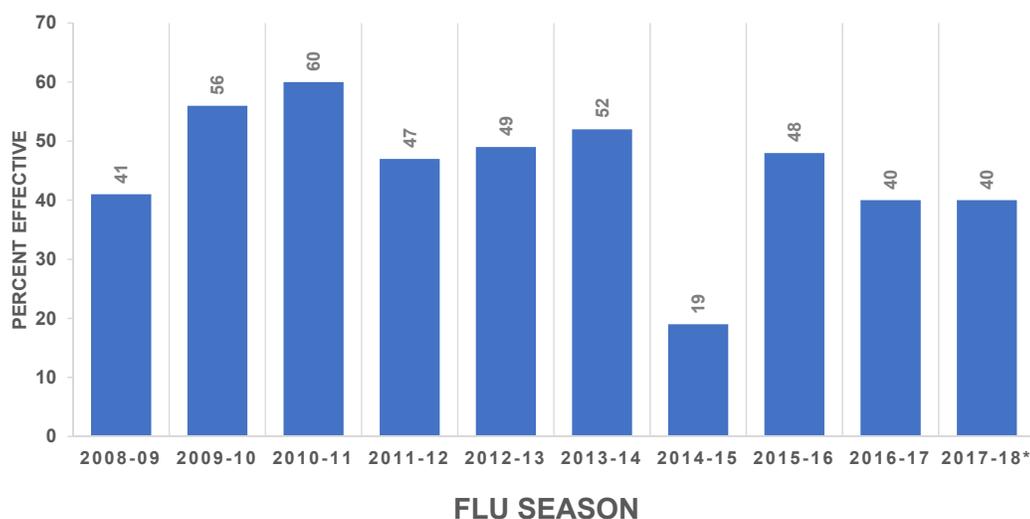
- In the Northern Hemisphere, all persons aged 6 months or older should receive influenza vaccine annually by the end of October, if possible.
  - Influenza vaccination should not be delayed to procure a specific vaccine preparation if an appropriate one is already available.
- Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine.
  - Inactivated influenza virus cell culture–based (ccIIV4; Flucelvax) or trivalent or quadrivalent recombinant influenza vaccine (RIV; Flublok) should be used
  - RIV may be used for persons aged 18 years or older who have no other contraindications
- **Regardless of allergy history, all vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available.**
- **Previous severe allergic reaction to influenza vaccine**, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine.

Grohskopf LA, Sokolow LZ, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2018–19 Influenza Season. *MMWR Recomm Rep*. 2018 Aug 24. 67 (3):1–20.

TABLE 1. Influenza vaccines — United States, 2018–19 influenza season\*

Trade name (Manufacturer)	Presentation	Age indication	HA (RVs and RV4) or virus count (LAIV) per dose (each vaccine virus)	Egg-grown virus, <sup>†</sup> cell culture-grown virus, or recombinant HA	Adjuvanted (Yes/No)	Latex (Yes/No)	Route	Thimerosal (Yes/No) ‡ Yes, mercury µg/0.5 mL
<b>Quadrivalent IVA (RV4)—Standard Dose—Contains inactivated virus</b>								
Afluria Quadrivalent (Seqirus)	0.5 mL PFS	≥5 yrs	15 µg/0.5 mL	Egg	No	No	IM <sup>§</sup>	No
	5.0 mL MDV	18 through 64 yrs (jet injector)						Yes (24.5)
Fluarix Quadrivalent (GSK/Sanofi)	0.5 mL PFS	≥6 mos	15 µg/0.5 mL	Egg	No	No	IM <sup>§</sup>	No
Flulaval Quadrivalent (ID Biomedical Corp of Quebec)	0.5 mL PFS	≥6 mos	15 µg/0.5 mL	Egg	No	No	IM <sup>§</sup>	No
	5.0 mL MDV							Yes (<25)
Fluzone Quadrivalent (Sanofi Pasteur)	0.25 mL PFS	6 through 35 mos	7.5 µg/0.25 mL 15 µg/0.5 mL	Egg	No	No	IM <sup>§</sup>	No
	0.5 mL PFS	≥3 yrs						No
	0.5 mL SDV	≥3 yrs						No
	5.0 mL MDV	≥6 mos						Yes (25)
Fluorix Quadrivalent (Seqirus)	0.5 mL PFS	≥4 yrs	15 µg/0.5 mL	Cell culture	No	No	IM <sup>§</sup>	No
	5.0 mL MDV							Yes (25)
<b>Trivalent IV (RV3)—Standard Dose—Contains inactivated virus</b>								
Afluria (Seqirus)	0.5 mL PFS	≥5 yrs	15 µg/0.5 mL	Egg	No	No	IM <sup>§</sup>	No
	5.0 mL MFV	≥5 yrs (needle/syringe) 18 through 64 yrs (jet injector)						Yes (24.5)
<b>Trivalent IV3—High-Dose—Contains inactivated virus</b>								
Fluzone High-Dose (Sanofi Pasteur)	0.5 mL PFS	≥65 yrs	40 µg/0.5 mL	Egg	No	No	IM <sup>§</sup>	No
<b>Trivalent IV3—Adjuvanted—Contains inactivated virus</b>								
Fluzel (Seqirus)	0.5 mL PFS	≥65 yrs	15 µg/0.5 mL	Egg	Yes (MF59)	No	IM <sup>§</sup>	No
<b>Quadrivalent RV (RV4)—Contains recombinant HA</b>								
Flublok Quadrivalent (Sanofi Pasteur)	0.5 mL PFS	≥18 yrs	45 µg/0.5 mL	Recombinant	No	No	IM <sup>§</sup>	No
<b>Quadrivalent LAIV (LAIV4)—Contains live, attenuated, cold-adapted virus</b>								
FluMist Quadrivalent (AstraZeneca)	0.2 mL prefilled single-use intranasal sprayer	2 through 49 yrs	10 <sup>6.5</sup> –7.5 fluorescent focus units/0.2 mL	Egg	No	No	NAS	No

## Effectiveness of Seasonal Flu Vaccines from the 2008 – 2018 Flu Seasons



Source: <https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm>

# Influenza Vaccine 2018-2019

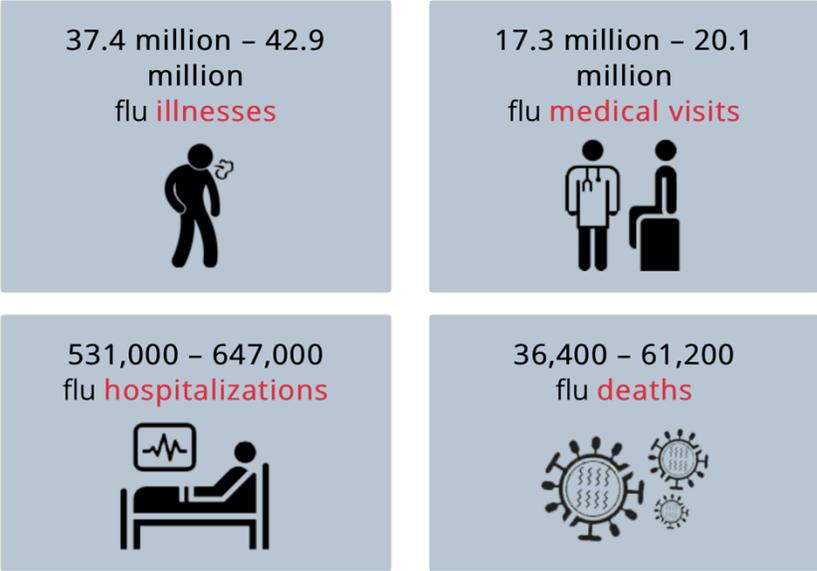


- Effectiveness\* (reducing a person’s risk of becoming sick enough to see a physician)
  - Adults 50%
  - Children 61%
    - Strain this season tended to affect children more than other age groups
  - Older Adults 8%
- Deaths 16,000
  - Relatively high for season considered to be “low severity.”
- When effectiveness is about 50% – see a large decrease in illness, hospitalizations, and death

*\*MMR, by comparison, is about 97% effective with two doses*

INFLUENZA 2018-2019)

CDC estimates that, from October 1, 2018, through May 4, 2019, there have been:



# Influenza

## *Treatment and Chemoprophylaxis*

- In the United States, prescription antiviral drugs approved for treatment and/or chemoprophylaxis of influenza and are active against recently circulating subtypes of influenza
  - Baloxavir marboxil (Xofluza)
    - 1 dose 40 mg (40-80 kg)
    - 1 dose 80 mg ( $\geq$ 80 kg)
  - Oseltamivir
  - Peramivir
  - Zanamivir

Grohskopf LA, Sokolow LZ, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices-United States, 2018-19 Influenza Season. *MMWR Recomm Rep.* 2018 Aug 24. 67 (3):1-20.

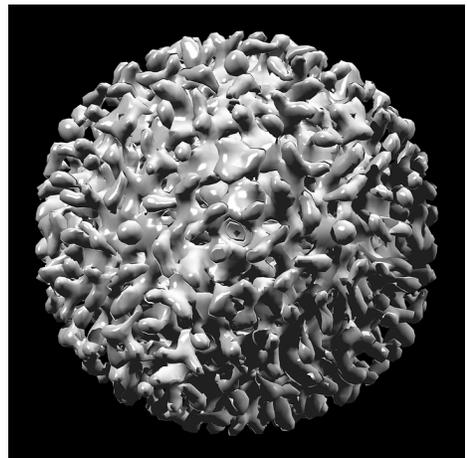
# Xofluxa

- Indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours.
  - In the primary endpoint in Trial 2, XOFLUZA reduced duration of flu symptoms to just 2.3 days compared with 3.3 days with placebo
  - In a secondary endpoint in Trial 2, in subjects aged 20-64 years, reduction of duration of flu symptoms was similar with XOFLUZA compared with oseltamivir

XOFLUZA [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; 2018.

# Baloxavir marboxil (Xofluza)

- Oral antiviral
- Indication:
  - Management of influenza >12yo and up if given within 48h of symptoms
- Dose:
  - 40-79kg use 40mg x 1 dose
  - ≥80kg use 80mg x 1 dose
- Efficacy:
  - Appears similar to a 5d course of oseltamivir
  - Possibly greater reduction in virus levels at 24h & a shorter duration of virus detection
  - CAPSTONE -2 trial focused on high risk and showed shorter duration of symptoms vs. placebo
  - Data lacking for oseltamivir-resistant influenza or transmission within households/outbreaks
- Safety:
  - Diarrhea, Possible increased viral resistance
  - Avoid cations like Calcium- decreases absorption
  - No dosage adjustment in CKD
- Cost:
  - \$90/dose vs \$100 for 5 days oseltamivir



# Hepatitis B

# Immunization

- **Who to vaccinate:** all medically stable infants weighing 2,000 g (4 lb, 6 oz) or more **within 24 hours of birth (ACIP 2018)**, unvaccinated infants and children, and unvaccinated adults requesting protection from hepatitis B or who are at increased risk of infection
- **Three-Dose Hepatitis B Vaccine Schedule of Administration**
  - Engerix-B (GlaxoSmithKline), Recombivax HB (Merck)
  - Three-dose series on a 0, 1, and 6-month schedule. The recommended doses depend on the vaccine brand and the person's age
- **Two-Dose Hepatitis B Vaccine Schedule of Administration (Adults Only)**
  - Heplisav-B (Dynavax)
  - Two-dose vaccine approved and recommended in the U.S. for use in adults aged 18 and older. The vaccine is administered as two doses given one month (at least 28 days) apart



*MMWR Recomm Rep. 2018; 67(1): 1-31.*

# Post-vaccination Testing?

- **Only recommended** in individuals who may not elicit a complete response to the vaccine based on risk factor assessment
  - Persons on hemodialysis
  - Persons who are immunocompromised
  - Sex partners of persons positive for HBsAg
  - Health care personnel
- Testing for anti-HBs should be performed **one to two months following the completion** of the vaccine series
- A responder is defined as a person with an anti-HBs level of 10 mIU per mL
- If the anti-HBs level is less than 10 mIU per mL after the initial vaccine series, revaccination is indicated



*MMWR Recomm Rep. 2013; 62(RR-10): 1-19.  
Best Pract Res Clin Gastroenterol. 2015; 29(6): 907-917.  
MMWR Morb Mortal Wkly Rep. 2018; 67(15): 455-458.*

# Revaccination

- (Method 1) Administer second complete hepatitis B vaccine series followed by anti-HBs testing one to two months later
- (Method 2) Administer a single hepatitis B vaccine dose followed by anti-HBs testing one to two months later
  - If anti-HBs <10 mIU per mL after a single dose, complete the series then test for anti-HBs one to two months after completing the series
  - A nonresponder is defined as a person with an anti-HBs level of less than 10 mIU per mL after six doses or more of the hepatitis B vaccine
- The CDC **does not** recommend administration of **more than two** complete hepatitis B vaccine series

MMWR Recomm Rep. 2013; 62(RR-10): 1-19.  
<https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm#D4>.



*Streptococcus pneumoniae*

# Prevnar 13

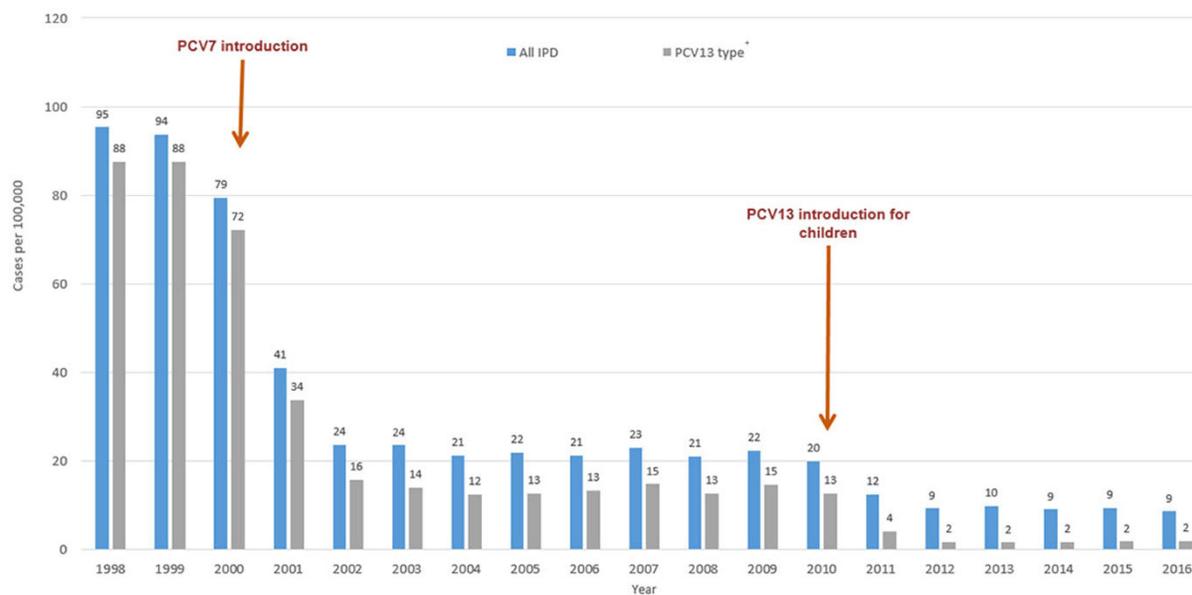
*ACIP June 26, 2019*

- **Reversal** of 2014 recommendation
- Do NOT recommend the 13-valent pneumococcal conjugate vaccine (Prevnar 13, Pfizer; PCV13) for ALL adults age 65 or older who have NOT previously received it
- Recommend decision based on shared decision making in adults  $\geq$  65 years who do not have an immunocompromising condition
- Recommendation follows continued reductions in PCV 13-type disease due to the indirect effects from Pediatric PCV13 use which ACIP foresaw as potentially limiting the 2014 recommendation

## Immunocompromising Conditions

- Congenital or acquired immunodeficiency (B or T lymphocyte deficiency, complement deficiencies, phagocytic disorders other than chronic granulomatous disease)
- HIV infection
- Generalized malignancy (e.g., metastatic disease, disease treated with chemotherapy)
- Hematologic malignancy (e.g., leukemia, Hodgkin lymphoma, non-Hodgkin lymphoma, multiple myeloma)
- Solid organ transplant
- Iatrogenic immunosuppression, including long-term systemic glucocorticoids or radiation
- Chronic renal failure (or Chronic kidney disease)
- Nephrotic syndrome

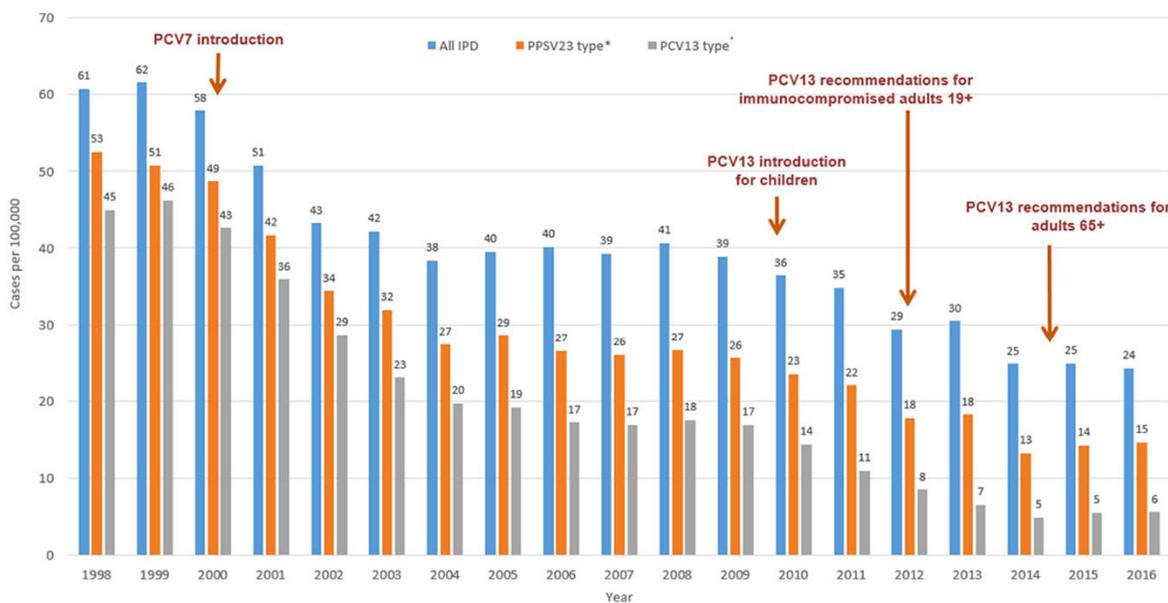
## Trends in invasive pneumococcal disease among children aged < 5 years old, 1998-2016



\*PCV13 serotype: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F

<https://www.cdc.gov/abcs/reports-findings/surveys/spneu-types.html> July 2018

## Trends in invasive pneumococcal disease among adults aged > 65 years old, 1998-2016



\*PPSV23 serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F

\*PCV13 serotype: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F

<https://www.cdc.gov/abcs/reports-findings/surveys/spneu-types.html>; July 2018

# HPV (Gardasil)

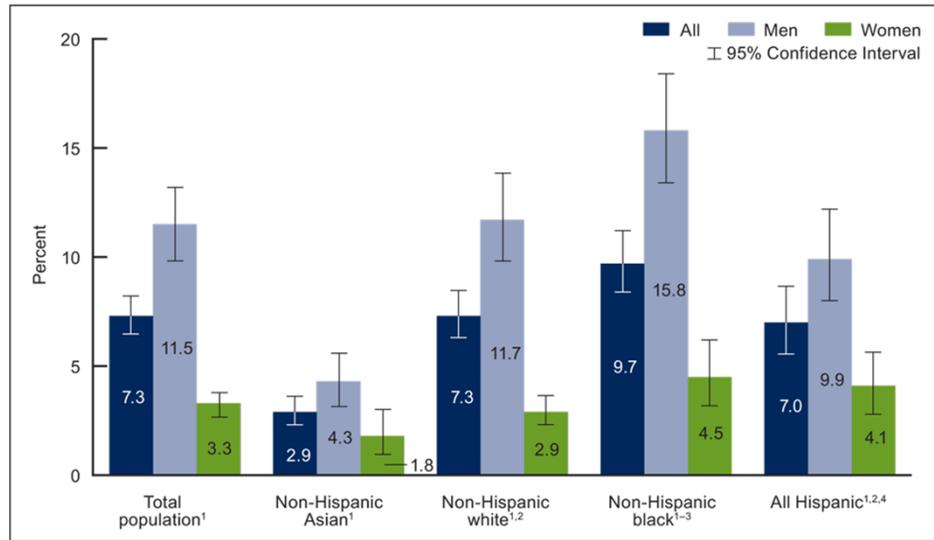
Seven of the 9 HPV types included in the vaccine are responsible for 90% of HPV related cancers

## Background to HPV

- More than 120 HPV types
  - Cutaneous epithelial cells: Common warts; majority
  - **Mucosal epithelial cells: genitals, mouth, throat; 40 types**
- Most HPV infections are asymptomatic; resolve spontaneously or become undetectable
- Persistent infections with high-risk (**oncogenic**) HPV types
  - **Cancers of the anus, cervix, penis, vulva, vagina; oropharynx**
  - Most common high risk types are 16 and 18

Cancer	Percentage
Cervical	Nearly all
Anal	>90%
Oral, throat, and neck	>70%
Penile	>60%

Figure 1. Prevalence of any oral HPV among adults aged 18–69, by race and Hispanic origin and sex: United States, 2011–2014

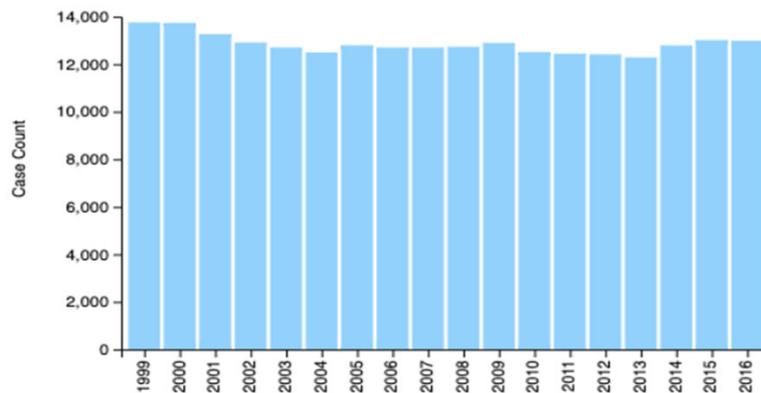


<sup>1</sup>Percentage for men is significantly different from women.  
<sup>2</sup>Percentage is significantly different from non-Hispanic Asian adults, all, men, and women.  
<sup>3</sup>Percentage is significantly different from non-Hispanic white adults, all and men.  
<sup>4</sup>Percentage is significantly different from non-Hispanic black adults, all and men.  
 NOTES: HPV is human papillomavirus. Any oral HPV means tested positive to one or more of the 37 HPV types from an oral rinse sample. Access data table for

McQuillan G, Kruszon-Moran D, Markowitz LE, Unger ER., Paulose-Ram R. Prevalence of HPV in adults aged 18–69: United States, 2011–2014. NCHS data brief, no 280. Hyattsville, MD: National Center for Health Statistics. 2017.

Annual Number of New Cancers, 1999-2016

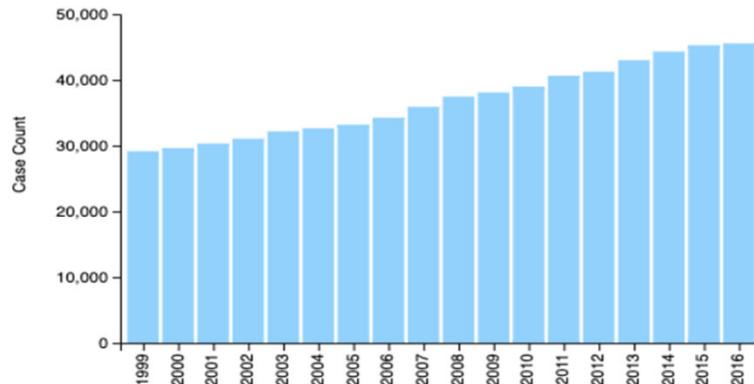
Cervix, United States



U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on November 2018 submission data (1999-2016): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; www.cdc.gov/cancer/dataviz, June 2019.

Annual Number of New Cancers, 1999-2016

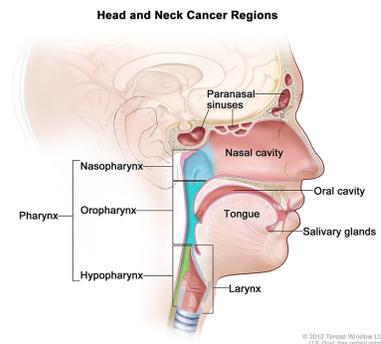
Oral Cavity and Pharynx, United States



U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on November 2018 submission data (1999-2016): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; [www.cdc.gov/cancer/dataviz](http://www.cdc.gov/cancer/dataviz), June 2019.

## Head and Neck Cancers

- Probably 70% caused by HPV, likely spread by oral sex
- Men may be up to six times more likely than women to develop an oral infection with the highest risk strain of HF
- Oropharyngeal cancer is now the most common HPV-associated cancer and is rising in males (*ACIP – February 2018*)



# Screening for Oropharyngeal Cancer

- No studies have shown that screening for oral cavity, pharyngeal, or laryngeal cancer would decrease the risk of dying from this disease
- > 50% of oral cancers have nodal or other areas of extension by the time they are found
- Look for lesions
  - Leukoplakia
  - Erythroplakia



## If You Find an Oral Lesion...

- **Toluidine blue stain:** lesions in the mouth are coated with a blue dye. Areas that stain darker are more likely to be cancer or become cancer.



- *A dark blue (royal or navy) stain is considered positive*
- *Light blue staining is considered doubtful*
- *No color absorbed by the lesion is a negative stain*

## If You Find an Oral Lesion...

- **Toluidine blue stain:** lesions in the mouth are coated with a blue dye. Areas that stain darker are more likely to be cancer or become cancer.
- **Fluorescence staining:** lesions in the mouth are viewed using a special light. After the patient uses a fluorescent mouth rinse, normal tissue looks different from abnormal tissue when seen under the light.
- **Exfoliative cytology:** collect cells from the oral cavity. A piece of cotton, a brush, or a small wooden stick is used to gently scrape cells from the lips, tongue, or mouth. The cells are viewed under a microscope to find out if they are abnormal.
- **Brush biopsy:** The removal of cells using a brush that is designed to collect cells from all layers of a lesion. The cells are viewed under a microscope to find out if they are abnormal.

## HPV Vaccine

- Begin series BEFORE age 15 (well known – antibody response STRONGER in young children)
  - Two dose vaccine series
  - Time zero and 6-12 months
- Routine vaccination at age 11-12
  - Can begin as young as age 9 REGARDLESS of whether they have a history of sexual assault or abuse (*Starting at a younger age helps take the question of sexual activity out of the discussions?*)
- To be considered immunized, 5 or more months MUST have passed between the first and second doses, otherwise third dose should be given at 6 months
- Immunocompromised persons (regardless of age) and ANYONE starting series AFTER age 15, 3 doses (Time 0, 1-2 months, six months)

Dobson SR, McNeil S, Dionne M, et. Al. Immunogenicity of 2 doses of HPV vaccine in younger adolescents vs 3 doses in young women: a randomized clinical trial. JAMA. 2013;309:1793-1802.

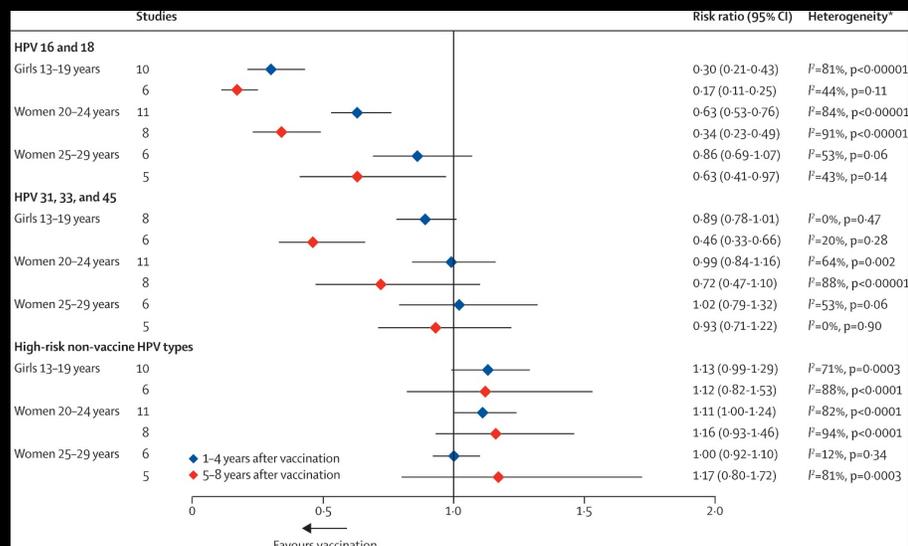
# Lancet – June 2019

## Efficacy of Vaccine (Meta-analysis)

- 65 studies in 14 high-income countries
- 13 years since the vaccine was approved, a “**substantial**” decrease in HPV infections, precancerous cervical lesions, and anogenital warts
  - Cases of HPV types 16 and 18 (cause 70% of cervical cancer) - decreased by 83% among girls ages 13-19 and by 66% among women 20-24
  - Dramatic decreases in cases of precancerous cervical lesions among screened teenage girls and young women
  - Decreases in anogenital warts across all age groups of men and women.
- Herd Immunity – as you vaccinate more and more people, the ability to spread disease also decreases

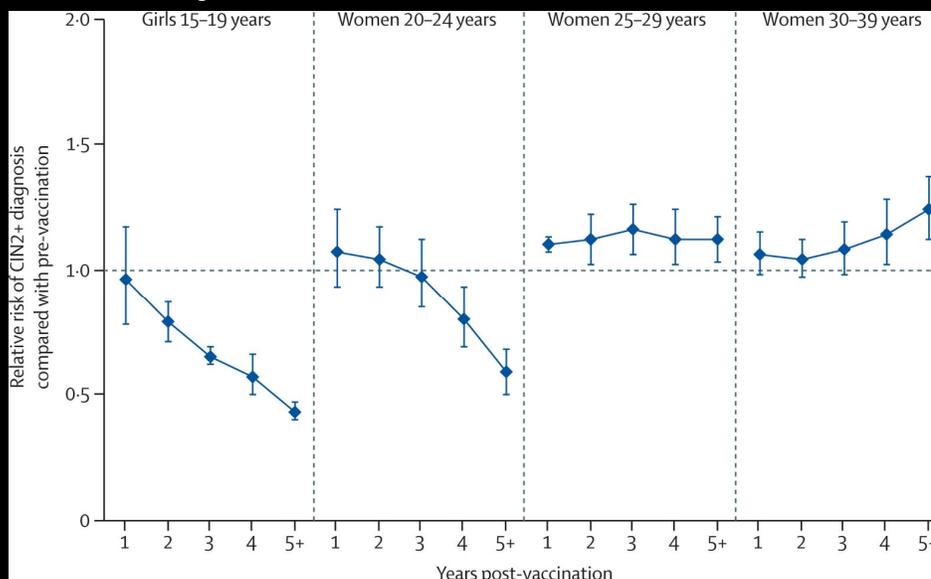
Drolet M, Benard E, Perez N, Brisson M, et. al. Population-level impact and herd effects Following the introduction of human papillomavirus vaccination programmes: updated Systematic review and meta-analysis. Published online June 26, 2019 [https://doi.org/10.1016/S0140-6736\(19\)30298-3](https://doi.org/10.1016/S0140-6736(19)30298-3)

### Changes in the prevalence of HPV infections between pre-vaccination and post-vaccination periods



The Lancet DOI: (10.1016/S0140-6736(19)30298-3)  
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*Changes in CIN2+ among screened girls and women during the first 7 years after the introduction of girls-only human papillomavirus vaccination, in countries with multi-cohort vaccination and high vaccination coverage*



The Lancet DOI: (10.1016/S0140-6736(19)30298-3)  
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## HPV Vaccine Safety Information

- Most common ( $\geq 10\%$ ) local and systemic adverse reactions in **females** were injection-site pain, swelling, erythema, and headache
- Most common ( $\geq 10\%$ ) local and systemic reactions in **males** were injection-site pain, swelling, and erythema
- Vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended
  - Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination.
  - When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion

# Gardasil 9 for Use in Women and Men Aged 27-45 Years

- **FDA**

- "...approval represents an important opportunity to help prevent HPV-related diseases and cancers in a broader age range" (*October 5, 2018*)

- **ACIP**

- **June 26, 2019**

- 10-to-4 vote, the advisory committee agreed to recommend HPV vaccination for women and men ages 27 to 45 who are not adequately vaccinated, through "shared clinical decision-making."

- **Effectiveness**

- Study: 3200 women aged between 27 and 45 years followed for an average of 3.5 years
- Gardasil was 88% effective in preventing the combined endpoint of persistent infection, genital warts, vulvar and vaginal precancerous lesions, cervical precancerous lesions, and cervical cancer related to HPV types covered by the vaccine

## Who needs it?

- Public health experts agree that for adults up to age 45, the decision should be based on each person's sexual experiences and expectations.

- **Example**

- A middle-aged person reentering the dating scene who had FEW previous sexual partners could become exposed to the virus for the first time and therefore might benefit from the vaccine.

# CDC

## *Epidemic Intelligence Service (April 2019)*

- National Health and Nutrition Examination Survey (4vHPV)-type
  - 4,674 females in the pre-vaccine (2003-2006) and vaccine (2013-2016) eras
- Very encouraging
  - Within 10 years (2006) of vaccine introduction, HPV prevalence decreased
    - 86% among females aged 14-19 years
      - Prevalence decreased from 11.5% to 1.8%
    - 71% in women aged 20-24
      - Prevalence decreased from 18.5% to 5.3%
- **Conclusion**
  - Vaccine prevents HPV infection and the POTENTIAL of HPV vaccination to reduce cervical cancers and other cancers caused by HPV in all women in the future.

*McClung NM, et al. Human papillomavirus prevalence among females in the United States, overall and by race/ethnicity, National Health and Nutrition Examination Survey, 2003–2006 and 2013–2016; Presented at: Epidemic Intelligence Service conference; April 29-May 2, 2019; Atlanta.*

# National Center for Health Statistics

*2017*

- **Cross-Sectional Study (*in the absence of clinical trials*)**
  - Data from the National Health and Nutrition Examination Survey (NHANES) collected from 2627 young adults aged 18 to 33 years during the period 2011-2014.
  - Study: Analyzed oral rinse samples collected by mobile health facilities.
    - Comparing individuals who had received the HPV vaccine (29.2% of women and 6.9% of men;  $P < .001$ ) to those who had not, the analysis found the prevalence of oral HPV infections covered by the vaccine (HPV-16, -18, -6, and -11) was significantly lower in the vaccinated group (0.11% vs. 1.61%;  $P = 0.008$ ).
    - The most significant reduction was seen in men. None of those whom had been vaccinated had an HPV infection of the types for which vaccinations were available, compared to 2.1% of unvaccinated men ( $P = 0.007$ ).

*Annual Meeting of the American Society of Clinical Oncology, 2017*

## *What Does This Mean?*

- Estimate – in an unvaccinated population about a million young adults would have oral HPV infection by types 16, 18, 6 or 11.
- Universal vaccination would prevent >900,000 of the infections

## Summary

- In the US, HPV vaccination rates have been rising, but at a much slower pace – and not fast enough to curb the rising rates of HPV related cancers
  - Inadequate access and education
  - Reluctance on the part of health care providers.
- CDC



## “Mixed Messages?”

- **Communication approach and agreement to same-day HPV vaccination**
  - Analysis of audio recordings – Pediatrician, 11- to 12-year old patient and caregiver
- **Acceptance**
  - 73% WITH presumptive language (HPV vaccine at the end of the list for which the child was “due”)
  - **Only** 22% when presumptive language was NOT used
- **Caregivers agreed to vaccinate**
  - 82% of time when delay was not mentioned
  - **Only** 6% when delay was offered or recommended
- **Conclusions**
  - Unambivalent recommendations could help to reduce mixed messages
  - Providing skills from motivational interviewing for talking with hesitant parents may be helpful

*Sturm et. Al., J Adolescent Health, 25 April 2017*

## Announcements versus Conversation

- Brewer et al. (2017)
  - Announcements, or statements that assumed parents were ready to vaccinate helped normalize HPV vaccination for parents
  - Address parents' questions and use their questions as an opportunity to discuss helping to prevent certain HPV-related cancers later in life
- *"Your child needs 3 vaccines today: one to help prevent meningitis, one that prevents certain HPV-related cancers, and a Tdap booster"*
  - This straightforward, matter-of-fact approach to recommending HPV vaccination can help improve vaccination rates in 11- and 12-year old patients

*Brewer NT, Hall ME, Malo TL, et al. Announcements versus conversations to improve HPV vaccination coverage: a randomized trial. Pediatrics. 2017;139(1):1–9. doi:10.1542/peds.2016–1764.*



## Herpes Zoster (Shingrix)

### **AES Question 3**

Which of the following statements is true regarding the Herpes Zoster Subunit Vaccine?

- A. It is a live recombinant subunit vaccine
- B. The efficacy for prevention of Zoster is 90%
- C. It is recommended in individuals  $\geq 60$  years of age
- D. Local and systemic side effects are exceedingly rare following administration

# Herpes Zoster Subunit Vaccine

- Shingrix Vaccine (Zoster Vaccine Recombinant Adjuvanted)
  - GlaxoSmithKline
  - FDA Approved **October 23, 2017** – Adults aged **50 years and older**
    - 1 million cases of shingles in US each year
  - Developed specifically to overcome the age-related decline in immune response
    - Combines an antigen, glycoprotein E, and an adjuvant system, AS01B, intended to generate a strong and long-lasting immune response that can help overcome the decline in immunity as people age
- **Non-live**, recombinant subunit vaccine
  - Given IM
  - Two doses (Time 0 and 2-6 months later)
- Efficacy across all age groups in prevention of shingles
  - **>90%**; over 4-year follow-up
  - Decreased overall incidence of postherpetic neuralgia

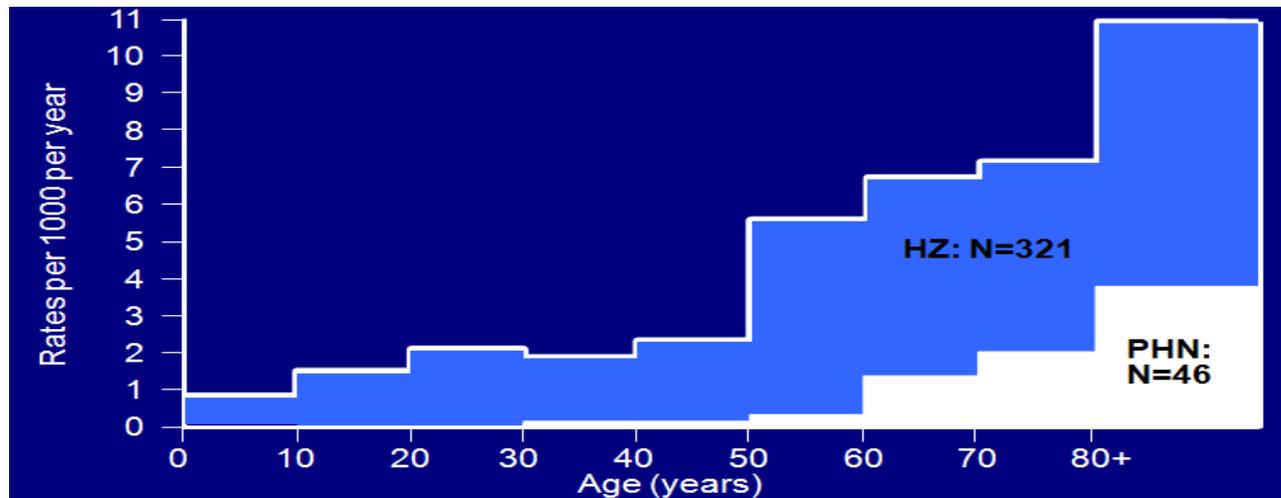
## Efficacy and Duration of Protection

### *Zostavax*

Study	Efficacy for prevention of Zoster	Efficacy for prevention of PHN
<i>Shingles prevention study</i> 38,546 subjects 4.9 year follow-up	<b>51%</b>	<b>67%</b>
<i>Short-term persistence substudy</i> 14,270 subjects 4-7 years follow-up	<b>40%</b>	<b>60%</b>
<i>Long-term persistence study</i> 6,687 subjects 7-10 years follow-up	<b>21%</b>	<b>35%</b>

***The effectiveness of HZ vaccine administered to patients >60 years for preventing zoster beyond 5 years remains uncertain.***

## Age-specific Incidence of Herpes Zoster and Postherpetic Neuralgia: U.K., 1947-1972



Hope-Simpson J R Coll Gen Pract 1975.

## Shingrix

- Unprecedented demand
  - October 2017 – June 2018: 3.2 million doses distributed
  - <https://www.cdc.gov/shingles/vaccination.html> (Patient Information)
- 99% of shingles vaccine market
- Local and systemic reactions to Shingrix are **quite common**
  - In trials, a reaction to the first dose DID NOT predict a reaction to the second dose

Lal H, Cunningham AL, Godeaux O, et al; ZOE-50 Study Group. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med.* 2015;372:2087-2096.  
Cunningham AL, Lal H, Kovac M, et al; ZOE-70 Study Group. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. *N Engl J Med.* 2016;375:1019-1032.

# Reactions

*(Most are self-limited and resolve in 2-3 days)*

- **Local**

- Administer IM; SubQ administration much more likely with injection site reaction – pain, redness, or swelling
- Eight clinical trials (>10,000 people)
  - 78% pain near injection site
  - 38% redness
  - 26% swelling

- **Systemic**

- 1 in 10 severe enough to limit activity
  - Myalgia
  - Fatigue
  - HA
  - Shivering
  - Fever
  - GI Illness

Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. *MMWR Morb Mortal Wkly Rep.* 2018;67:103-108.

## Summary



## Best Practice Recommendations

- Offer immunizations at every visit
- Use a *Guiding Style* of language
- *"Your child needs 3 vaccines today: one to help prevent meningitis, one that prevents certain HPV-related cancers, and a Tdap booster."*
  - *HPV vaccination provides safe, effective, and long-lasting protection against cancers caused by HPV*
- *"Are you ready for your [influenza] vaccine today?"*
- The recombinant zoster vaccine preferred to prevent shingles in adults age **50** and older
- PCV13 recommended based on shared decision making in adults  $\geq 65$  years who **do not** have an immunocompromising condition

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Thank you

# Questions



**FMX**