

Increasing Your Knowledge of Immunization Policies Through AAFP Vaccine Science Fellows

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This CME session is supported in part by an educational grant from GlaxoSmithKline.



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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.

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Dr. Epling earned his medical degree from Tufts University School of Medicine in Boston, Massachusetts. He completed an internship at the U.S. naval hospital in Charleston, South Carolina, and a family medicine residency at the Medical University of South Carolina in Charleston. He also completed a faculty development fellowship in evidence-based practice, policy, and education at State University of New York (SUNY) Upstate Medical University in Syracuse and a vaccine science fellowship with the AAFP. Dr. Epling maintains an active clinical family medicine practice and has taught family medicine, evidence-based medicine, and clinical prevention to all levels of learners throughout his career. His principal research interests include evidence-based medicine; translation of research into practice; quality improvement and human performance technology; and technology integration in medical education and practice. His clinical research areas of focus include clinical preventive services (i.e., screening, vaccination, preventive medication, behavioral risk counseling) and intimate partner violence. He has participated in several vaccination-related work groups on the state and national levels, and he joined the USPSTF in January 2016.

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Learning Objectives

1. Briefly explain the vaccine development, and identify the FDA as the regulatory agency responsible for vaccine licensing.
2. Describe the function and make-up of the Advisory Committee on Immunization Practice (ACIP) at CDC.
3. Identify two main ways that vaccine safety is continuously monitored after licensing and ACIP approval.
4. Understand AAFP policies/recommendations regarding immunization.

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Audience Engagement System



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Why understand vaccine policy?

- Know sources of clinical guidelines
- Combat vaccine hesitancy
- Counsel patients on vaccine safety infrastructure
- Help spread correct information in an era of misinformation

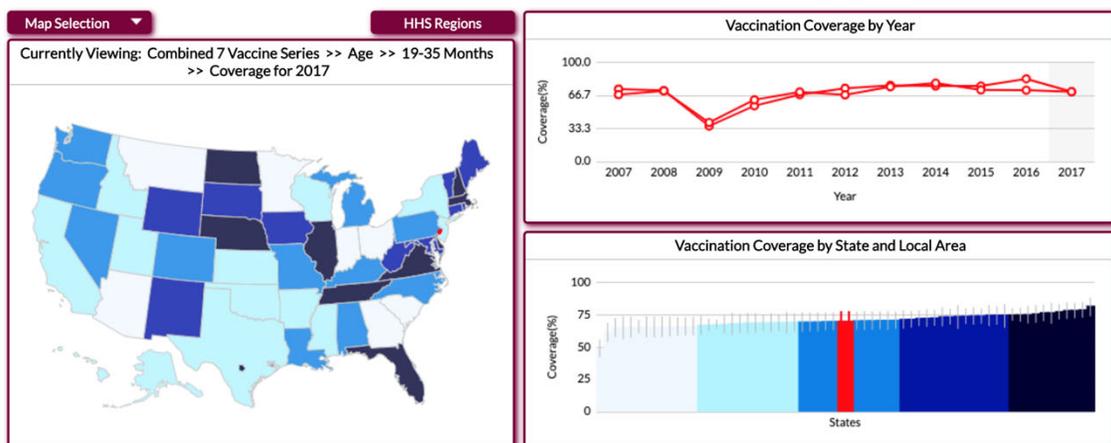
Family Physicians and Vaccines

- Prevention, especially primary prevention, is integral to family medicine
- Help patients establish healthy habits across the lifespan

Vaccine Coverage Data

- National Immunization Survey
 - Children through 35 months
 - Adolescents
- School Vaccination Assessment Reports
- Behavioral Risk Factor Surveillance System

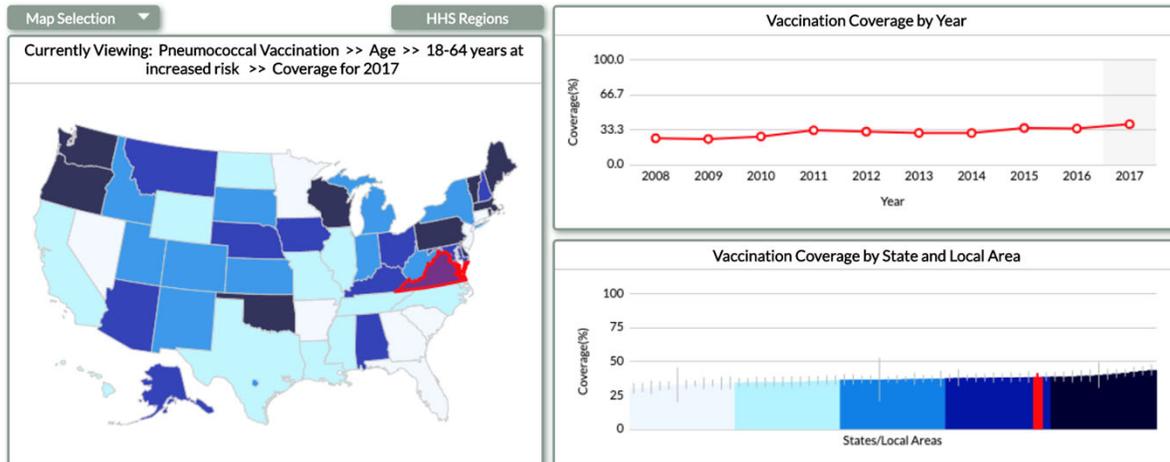
Combined 7-vaccine Series coverage among children 19-35 months by State, HHS Region, and the United States, National Immunization Survey-Child (NIS-Child), 2002 through 2017



<https://www.cdc.gov/vaccines/imz-managers/coverage/childvaxview/data-reports/7-series/trend/index.html>

Adults: Pneumo, Td(ap), Zoster

BRFSS data



<https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/data-reports/general-population/trend/index.html>

Poll Question 1

What is one source of data used by CDC to track immunization coverage in the US?

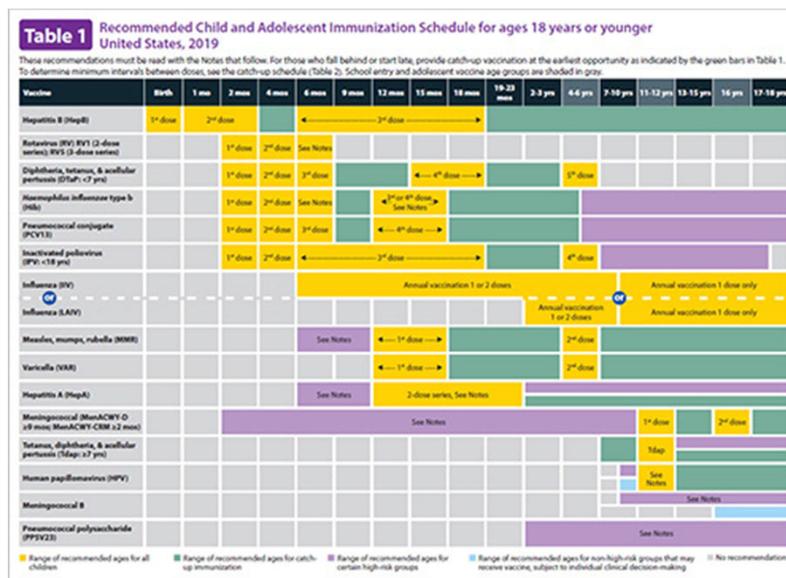
- A. Pharmaceutical company tracking
- B. The EHRs actually all communicate well with each other
- C. Medical Expenditure Panel Survey
- D. School Vaccination Assessment Reports

2010 – National Prevention Strategy

- Develop new and improved vaccines
- Enhance understanding of the safety of vaccines and vaccination practices
- Support informed vaccine decision-making
- Improve access to and better use of recommended vaccines.

National Prevention Council. *National Prevention Strategy: America's Plan For Better Health and Wellness*. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2011:125.

ACIP Child Immunization Schedule



ACIP Adult Immunization Schedule

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

Age-based

| Vaccine | 19–21 years | 22–26 years | 27–49 years | 50–64 years | ≥65 years |
|---|--|-------------|-------------|-------------|------------------------------|
| Influenza inactivated (IIV) or Influenza recombinant (RIV) ^{or} 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) ^{or} Zoster live (ZVL) | | | | | 2 doses ^{or} 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 | | | | 1 dose |
| 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, lack documentation of vaccination, or lack evidence of past infection
 Recommended vaccination for adults with an additional risk factor or another indication
 No recommendation

ACIP Adult Immunization Schedule

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

Condition-based

| Vaccine | Pregnancy | Immuno-compromised (excluding HIV infection) | HIV infection CD4 count <200 ≥200 | Asplenia, complement deficiencies | End-stage renal disease, on hemodialysis | Heart or lung disease, alcoholism ¹ | Chronic liver disease | Diabetes | Health care personnel ² | Men who have sex with men |
|-----------------------------------|--|--|-----------------------------------|-----------------------------------|--|--|-----------------------|----------|------------------------------------|---------------------------------|
| IIV or RIV ^{or} LAIV | 1 dose annually | | | | | | | | | |
| Tdap or Td | 1 dose Tdap each pregnancy | 1 dose Tdap, then Td booster every 10 yrs | | | | | | | | |
| MMR | CONTRAINDICATED | | | | | | | | | |
| VAR | CONTRAINDICATED | | | | | | | | | |
| RZV (preferred) ^{or} ZVL | DELAY | 2 doses at age ≥50 yrs ^{or} 1 dose at age ≥60 yrs | | | | | | | | |
| HPV Female | DELAY | 3 doses through age 26 yrs | | 2 or 3 doses through age 26 yrs | | | | | | 2 or 3 doses through age 26 yrs |
| HPV Male | 3 doses through age 26 yrs | | 2 or 3 doses through age 21 yrs | | | | | | | 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 | PRECAUTION | 2 or 3 doses depending on vaccine and indication | | | | | | | | |
| Hib | 3 doses HSCT ³ 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
 Contra-indicated—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.

Who recommends vaccines?

- FDA licensure
 - Center for Biologics Evaluation and Research (CBER)
 - Based on clinical studies
 - Phase 1 – immunogenicity and safety – tens
 - Phase 2 – dose-ranging – hundreds
 - Phase 3 – effectiveness and safety – thousands

Who recommends vaccines?

- FDA licensure (continued)
 - Vaccines and Related Biological Products Advisory Committee
 - Phase 4 - safety monitoring – hundreds of thousands

Who recommends vaccines?

- Advisory Committee on Immunization Practices
 - Commissioned/supported by CDC
 - Federal Advisory Committee – Advise to director of CDC
 - Experts in medicine and public health
 - Evaluates use of new vaccines upon licensure

Who recommends vaccines?

- ACIP Membership
 - 15 voting members (including 1 consumer)
 - 8 ex-officio members
 - 30 liaisons
- Evolution of ACIP recommendations
 - Consensus/expert-based to evidence-based
 - GRADE framework → “Evidence to Recommendations” (EtR) framework

Example – HPV age extension



ACIP Meeting June 2019

- Universal recommendation 9-26
 - Both sexes
- Shared decision making 27-45
 - Both sexes

Example – New PCV 13 Recommendations

- Prevention is complicated sometimes.
- ACIP: planned re-evaluation of PCV13 after 2014 recommendation
- PCV 13 after 65 only after shared decision-making process (if not immune compromise)

Poll Question 2

Which entity is responsible for changing the PCV13 vaccine recommendation, after we finally got the hang of it?

- A. ACIP
- B. FDA
- C. OMB
- D. NASA

How to keep up with ACIP

- AAFP news outlets (Liaison: Dr. Pam Rockwell)
- New schedule made yearly (February)
- CDC/ACIP website (takes a while for new info after meetings)
 - <https://www.cdc.gov/vaccines/acip/>

Vaccine Safety

- Rates
- FDA licensure
- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD)

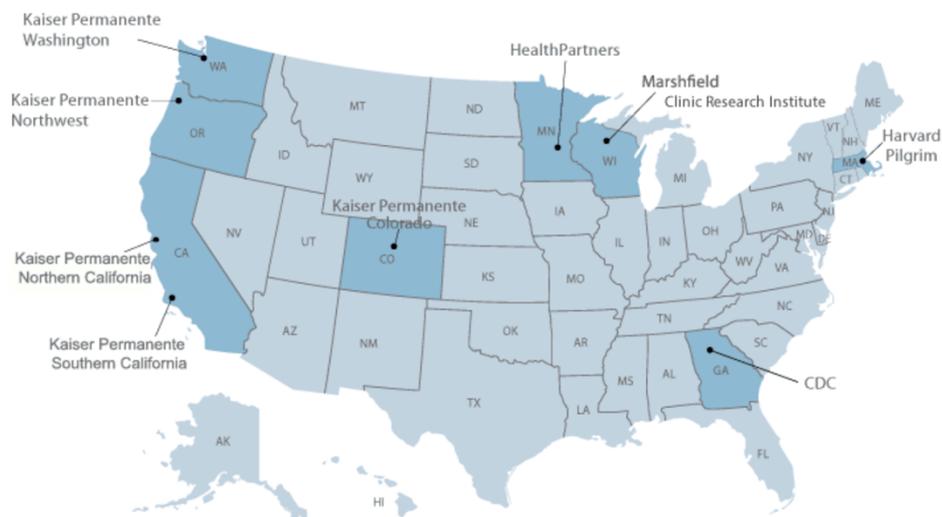
VAERS

- Adverse event vs. side effect
- All reports – related or not
- Anyone can report
- Output signals to be followed up

VSD

- 9 large managed care organizations connected electronically (9.8 mil people)
- Capability for studies of vaccine-related events – new methodologies invented
- Rapid cycle analysis – near real-time monitoring

Participating VSD Healthcare Organizations



<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/>

AAFP Immunization Policies

- Vaccine Coding
- AAFP Immunization Schedule
- AAFP Immunization Policies

Vaccine Coding

- Z23 – for all vaccines
- Well child
 - Z00.120, Z00.129 PLUS Z23
- Other CPT/administration codes
 - <https://www.aafp.org/practice-management/payment/coding/admin.html>

Vaccine Coding - Medicare

- Part B
 - Only influenza, pneumococcal, Hep B*
 - Injury-related (tetanus, rabies, etc.)
- Part D (depending on health plan)
 - Tdap, RZV (regardless of ACIP recs)

* Deductible and co-pay apply

AAFP Immunization Schedule

- AAFP immunization schedule?
- Harmonization – AAFP, AAP, ACP
 - Started in 1995

Vaccine History Timeline:
<http://www.immunize.org/timeline/>

AAFP Policies

- Access – for all
- Cost – lower risk of vaccine inventory
- Coverage – universal, first-dollar
- Medical Home – information flow
- Payment – for vaccine and admin
- Supply – ensure supply to primary care

Poll Question 3

Which of the following is NOT an AAFP immunization policy?

- A. Universal access
- B. First-dollar coverage
- C. No vaccines given at pharmacies
- D. Ensuring a supply to primary care

Other Vaccine Policy Things

- National Vaccine Program - HHS
- National Vaccine Advisory Committee
- National Vaccine Injury Compensation Program

National Vaccine Program

- Under Asst Secretary for Health
- Strategy for Vaccination
 - Research and development
 - Licensure, production, distribution
 - Safety, effectiveness, adverse events
- National Vaccine Plan

National Vaccine Advisory Committee

- (under National Vaccine Program)
- Ensures adequate supply of safe and effective vaccination products
- Research priorities for Director of the National Vaccine Program to enhance the safety and efficacy of vaccines.
- Advises the Director of the Program in implementation of sections 2102 and 2103 of the Public Health Service Act.
- Ensures government agency cooperation in implementing sections 2012/3

National Vaccine Injury Compensation Program

- "No-fault" hearing process for people suffering injury thought to be due to vaccines
- Created for market stabilization
- Funded by excise tax on vaccines
- HHS medical reviewer -> opinion to DOJ
- ~6600 people compensated (20K filed)

NVICP details

- 2006 to 2017 - 3.4 billion doses of covered vaccines were distributed in the U.S.
- 6,314 petitions adjudicated - 4,328 compensated
- 1 individual compensated per 1 million doses
- Since 1988
 - 20,728 petitions have been filed
 - 17,923 petitions have been adjudicated
 - 6,597 of those determined to be compensable
 - 11,326 were dismissed.
- Total compensation over the life of the program is approximately \$4.1 billion.

Beware...

Searching:
“AAFP” and
“Vaccination”

The screenshot shows the AAFP website with a search bar at the top right containing the text "Search CatVets.com". The main navigation menu includes "About AAFP", "Members", "Cat Friendly Practice®", "Education", "Practice Guidelines", and "Client Resources". The search results page displays the "Feline Vaccination Advisory Panel Report" with a sub-header "2013 AAFP Feline Vaccination Advisory Panel Report". Below this, there are links for "Download - Feline Vaccination Guidelines" and "Download - Client Brochure". A section titled "Disease Information Fact Sheets:" lists 10 items:

1. [Feline herpesvirus 1](#)
2. [Feline calicivirus](#)
3. [Feline panleukopenia](#)
4. [Rabies](#)
5. [Feline leukemia virus](#)
6. [Feline immunodeficiency virus](#)
7. [Feline infectious peritonitis](#)
8. [Chlamydophila felis](#)
9. [Bordetella bronchiseptica](#)
10. [Review of the immune response to vaccination](#)

Online Vaccination Resources

- <https://www.aafp.org/patient-care/public-health/immunizations.html>
- <https://www.cdc.gov/vaccines/>
- <http://www.nfid.org/about-vaccines>
- <http://www.immunize.org/>

AAFP Vaccine Science Fellowship

- Develop a cadre of family physicians interested in and knowledgeable about vaccines - ultimate goal of increasing immunization rates.
- 10th anniversary in 2019!
- ~20 family physicians completed
- Work in local, state and national positions



Practice Recommendations

- Read over the ACIP schedules each February for new vaccine information
- Do one VAERS report in the next year for an adverse reaction from vaccine
- Review your coding/billing practices to get compensated for vaccinating!

Contact Information

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Questions



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