

What's New in Immunizations?

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Children's Minnesota

Washington Vaccine Update
10.27.17



National
Foundation for
Infectious
Diseases®

Disclosures

- No financial conflicts to disclose
- Some content from NFID, Clinical Vaccinology Course, used with permission. Thanks to Phyllis Arthur, William Schaffner
- Vaccine research phases from CDC.gov

Disclosures

This activity is coprovided by WithinReach and Cardea Services.

Successful completion of this continuing education activity includes the following:

- Attend the entire conference
- Complete an online evaluation at <http://www.surveygizmo.com/s3/3840875/WA-Vaccine-Update-Learner-Evaluation>
- Complete an online certificate request at the link above

If you have any questions about this CE activity, contact Margaret Stahl at seattle@cardeaservices.org or (206) 447-9538

Disclosures

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CARDEA

Training, Organizational Development and Research

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Richard Fischer, MD is a member of an Organon speaker's bureau.

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CARDEA

Training, Organizational Development and Research

Learning Objectives

By the end of this session, you should be able to:

1. Describe recent changes in HPV vaccine recommendations
2. List some expected changes in vaccine recommendations in the near future



CARDEA

Training, Organizational Development and Research

Topics

- Describe the journey of vaccines and learn how vaccines are approved
- Describe most recent ACIP recommendations for adult and childhood/adolescent immunization
- Review what is in the pipeline for vaccine research and development

About NFID

Non-profit 501(c)(3) organization dedicated to educating the public and healthcare professionals about causes, treatment, and prevention of infectious diseases across the lifespan

- Reaches consumers, health professionals, and media through:
 - Coalition-building activities
 - Public and professional educational program
 - Scientific meetings, research, and training
- Longstanding partnerships to facilitate rapid program initiation and increase programming impact
- Flexible and nimble organization



The Vaccine Journey

Research

Pre-Clinical Trials

Clinical Trials

Phase I: Animal testing

Phase II: Human Immune response

Phase III: Compares to other vaccines adverse events

Phase IV: Post-licensure tracking

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FDA Licensing

-product

-manufacturing site

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-product

-manufacturing site

ACIP

Makes recommendations
for practice implementation

~MMWR

~AAP

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FDA Licensing

-product

-manufacturing site

Ongoing Safety

-VSD

-VAERS

-CISA's

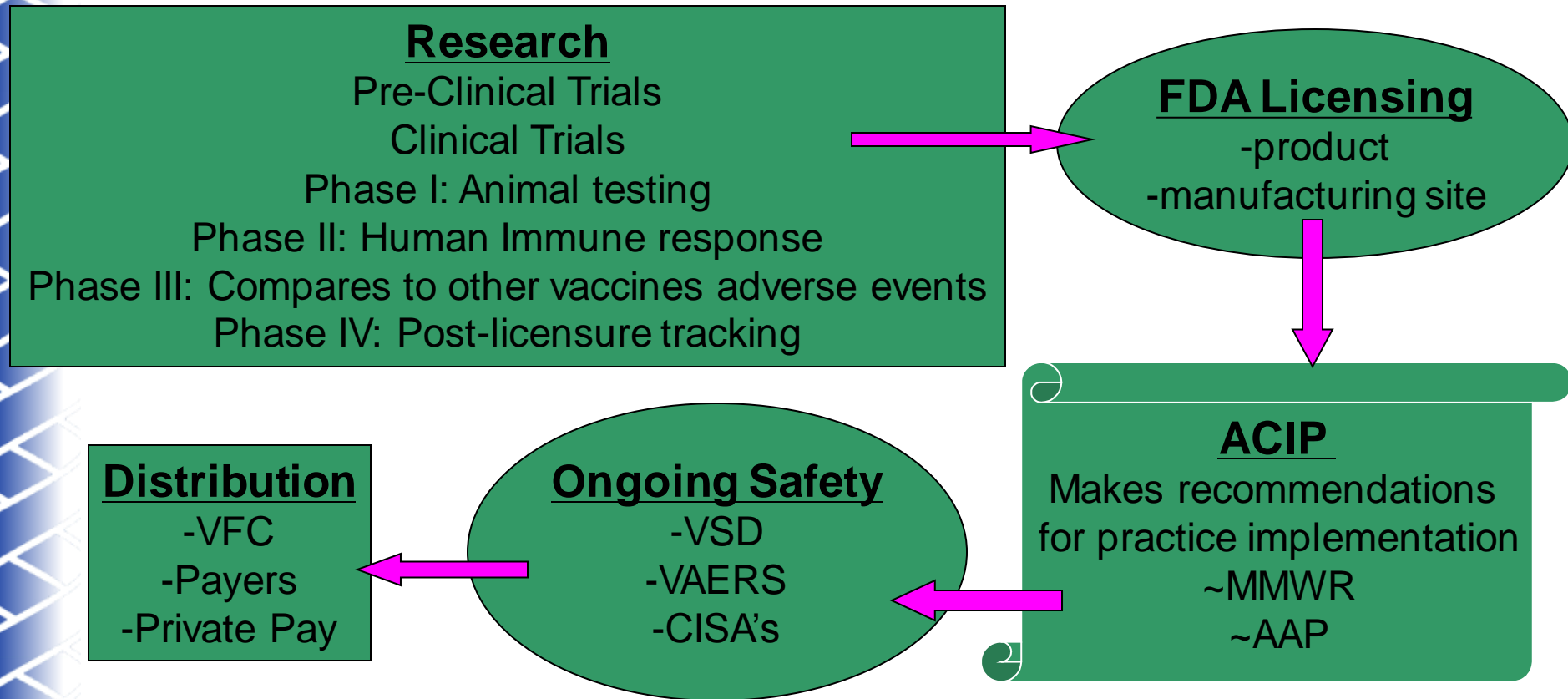
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Distribution

-VFC

-Payers

-Private Pay

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Storage and Handling

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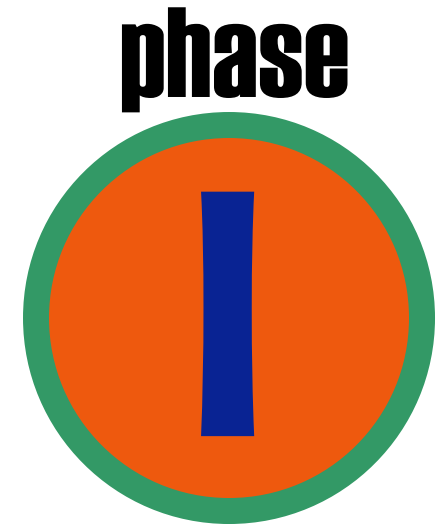
Administration

Follow-up

Four Phases Of Clinical Trials On People:

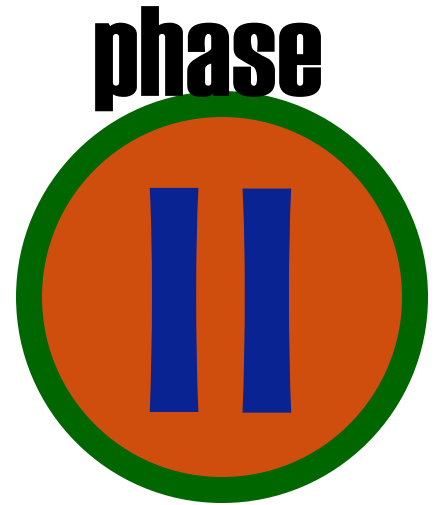
Phase I Involves Animal Testing

- After years of research, a vaccine that's been proven safe on animals goes through four phases of trials on people.
- In Phase I, anywhere from 20 to 100 volunteers receive the vaccine.
- The first phase is limited to just a few people, because scientists are triple-checking for safety, looking for serious side effects.



Phase II Trials Are Long And Complicated.

- Hundreds of volunteers take part in Phase II trials.
- These trials might take a few months, or they might last for years.
- Safety, safety, safety—that's still being studied in Phase II.
- Phase II tests also explore how the human immune system responds to the vaccine.



Phase II Also Finds The Precise Dose.

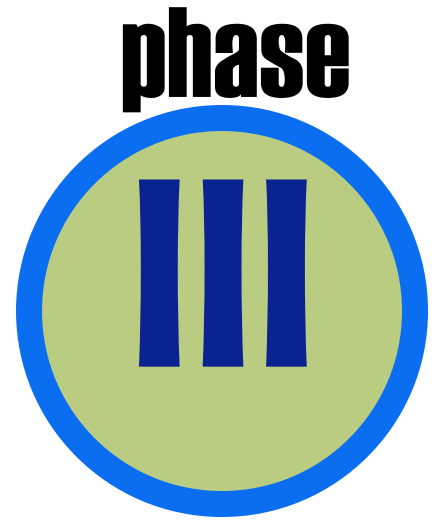
- Now the vaccine is fine-tuned. Phase II trials set (1) the most effective use of the vaccine, (2) the best dose for effectiveness and safety, and (3) the right number of doses.
- Adverse reactions are recorded. *Local reactions* include redness and swelling where the vaccine is given. General bodily reactions, such as fever or muscle aches, are also tracked.
- Some Phase II volunteers will get placebo or another already licensed vaccine to compare outcomes.



Phase III

(The Longest One Of All)

- Phase III trials may last several years. A few hundred to tens of thousands volunteers may be involved.
- Some volunteers receive another already-licensed vaccine instead of the vaccine under study.
- That way, researchers can compare one vaccine to another for adverse effects—anything from a sore arm to a serious reaction.
- If everything about the proposed vaccine checks out for safety and effectiveness in Phase III, the manufacturer applies for a license from the Food and Drug Administration (FDA).



One License Won't Do— There Have To Be Two.

- During the application phase, the FDA reviews everything: clinical trial results, product labeling, the manufacturing plant itself, and the manufacturing protocols.
- A biologic license is the license the FDA gives for the vaccine itself AND for the manufacturing plant where the vaccine is made.



Advisory Committee on Immunization Practices (ACIP)

- 15 members
- 3 meetings/year
- 36 liaison representatives from professional/academic societies
- 8 ex-officio members from federal agencies
- Media are present
- Public comment at each meeting
- Meeting agenda, transcripts, slides available at:
www.cdc.gov

Phase IV Tracks Vaccines After Licensing.

- A license can be recommended or refused. This decision is made after an FDA team of specialists (microbiologists, chemists, biostatisticians, and medical officers) assess the safety data from the vaccine trials.
- If a license is issued, post-licensure monitoring takes place.
- Monitoring is the continual tracking of tens of thousands of people who have been immunized with the vaccine under study.
- Post-licensure monitoring gives valuable information about the vaccine's long-term safety and effectiveness.



Vaccine Adverse Event Reporting System (VAERS)

- Sometimes, rare side effects and delayed reactions don't show up in clinical trials.
- So, once a vaccine is released to the public, data on effects and reactions are gathered continually.
- To make the gathering of information about potential side effects as complete as possible, the CDC and the FDA started a national system called the Vaccine Adverse Event Reporting System (VAERS) in 1990.



Frontiers of Vaccines Beyond Preventing Diseases in Children

New Populations



- Adults
- Pregnant women
- Pre-surgery prevention

New technologies



- Adjuvants
- Platforms using new cell lines and approaches
- Gene editing and sequencing

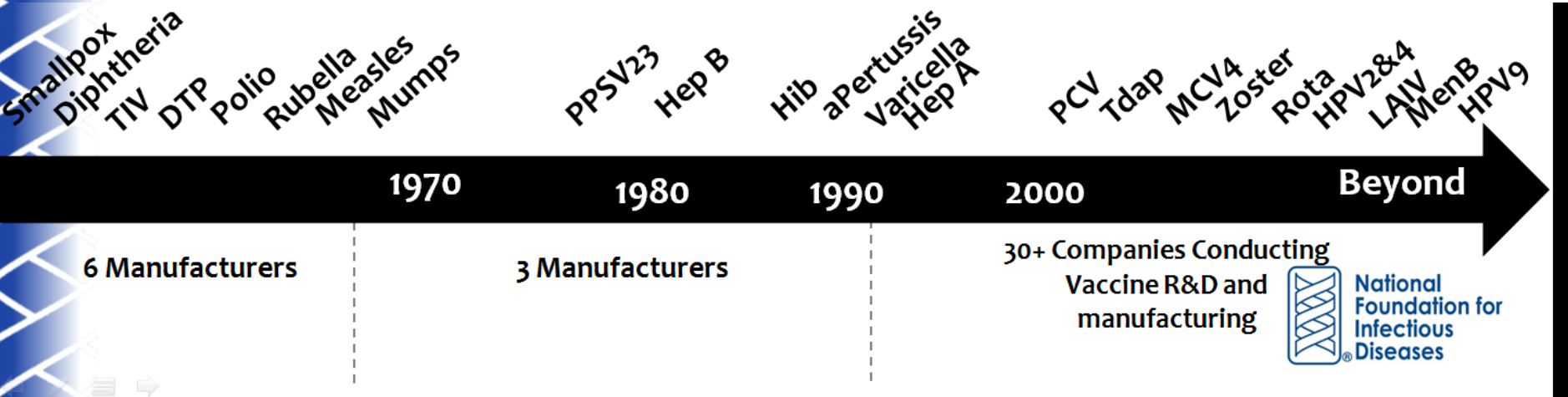
Emerging Diseases



- Ebola
- Zika
- Outbreak response



More Manufacturers than Ever



Zika Vaccine Landscape 9/12/16

Technology/ Platform

Recombinant or Subunit

Live Attenuated

Whole Inactivated

Nucleic Acid

Viral Vector

Other

Discovery and in vitro

Pre-clinical

Clinical



Dengue/Zika
Chimera



DNA-VRC



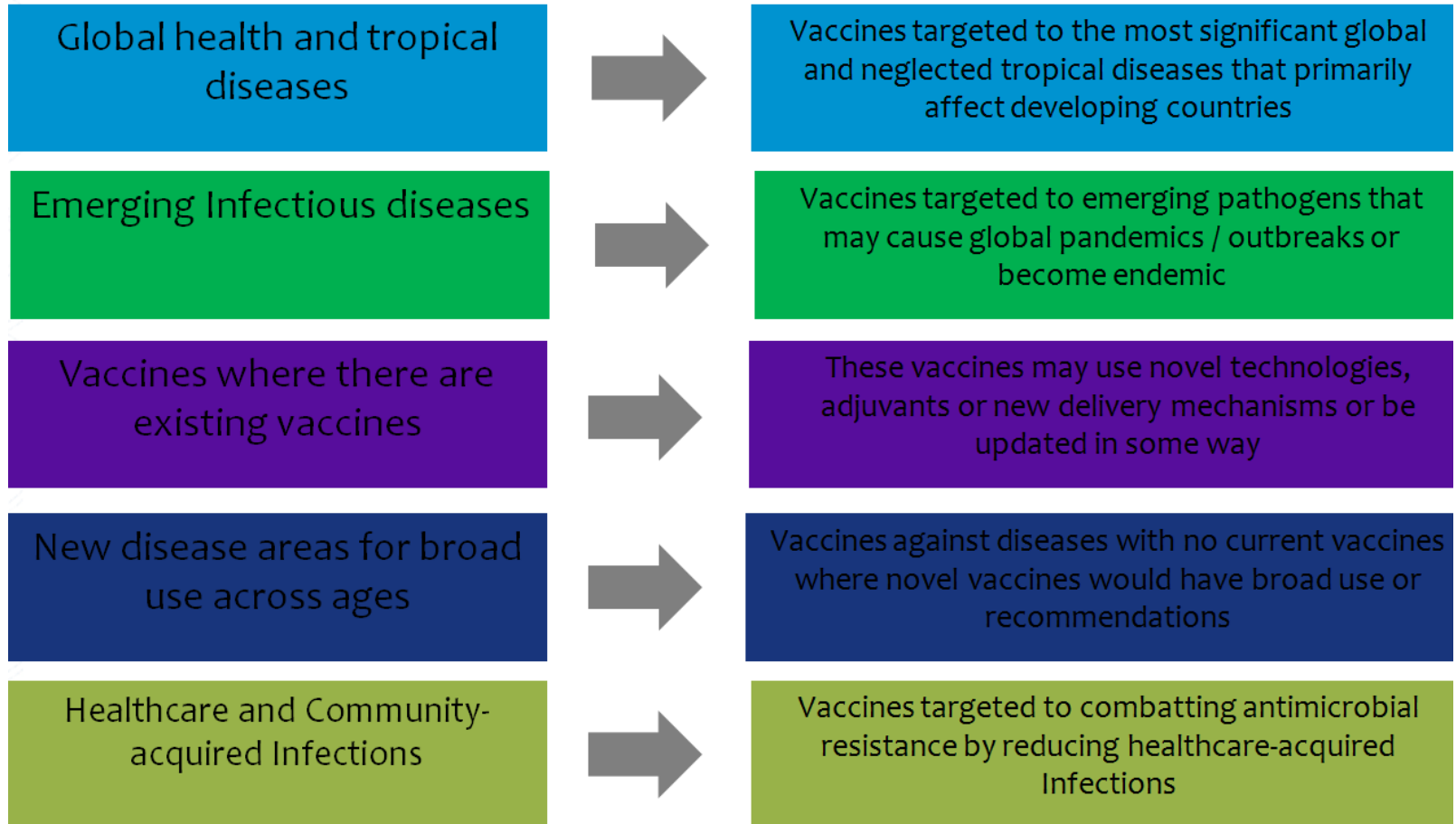
VSV with
Harvard



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Areas of New Vaccine Development



Vaccines on the Horizon

Data Sources: BioMedTracker, FDA website, clinicaltrials.gov, company websites through October 2016

Vaccine Areas of Research	Specific Vaccines in Development
Global & Tropical Diseases	HIV, TB, Malaria, Dengue, Yellow Fever, Typhoid Fever, Cholera, Leishmaniasis
Emerging Infectious Diseases	Ebola, Zika, MERS/SARS, West Nile, Marburg/Plague, Smallpox, Pan Flu, Chikungunya
New Vaccines where there are Existing	Flu, Herpes Zoster, Hib, Pneumococcal, Hepatitis B, Meningococcal, HPV, Pertussis
New Vaccines for diseases with none	RSV, CMV, E Coli, Hepatitis C, Group B Strep, Norovirus, Herpes Simplex Virus
New Vaccines against Antimicrobial Resistance	Staph Aureus, Candida, Strep Pneumo, E Coli, Salmonella, Shigella, Mycobacterium TB, C diff, Group B Strep, Pseudomonas Aeurigenosa

ACIP Recent Hot Topics

June 21-22, 2017 ACIP Agenda

One VOTE:

- Influenza vaccine. Recommendations the same—all persons 6 months of age or over receive injectable influenza vaccine. No LAIV approved.

February 22-23, 2017 ACIP Agenda

One VOTE:

- Hepatitis B vaccine in infants born to Hepatitis B positive mothers, updated recommendations and Vaccines for Children (VFC) vote

VOTE: Hepatitis B revaccination for infants born to HBV+ Mothers

- Language will allow lab testing after initial 3 dose series and if seropositive, no further vaccines
- If seronegative, may do one additional dose and retest
- Language remains that allows for choosing to just repeat the 3 dose series without lab testing after the first dose followed by lab testing after the 6th dose
- If Anti-HBs is ≥ 10 is protected, no further vaccination or testing.
- If Anti-HBs is ≤ 10 is a non-responder, no further vaccination or testing.

February and June 2017 ACIP

DISCUSSION ONLY TOPICS:

- Influenza
- Adult Immunization
- Herpes Zoster Vaccines
- Meningococcal Vaccines
- Global Immunization Update
 - Polio eradication
 - Dengue, Zika, Yellow Fever
- Vaccination Errors
- Mumps Disease and Vaccine

Herpes Zoster Vaccines

- Epidemiology of herpes zoster (HZ) reviewed (1 million cases in US annually, lifetime risk 1:3)
- Current vaccine (Zostavax®) efficacy 51% HZ, 67% post-herpetic neuralgia
- Uptake at ~28% adults 60 years and over
- 2 new vaccines for the prevention of HZ are being evaluated and not yet approved by FDA; both in phase 3 efficacy trials in persons 18 years and older:
 - HZ/su (GSK) glycoprotein E + adjuvant 2 dose series
 - V212 (Merck) inactivated formulation of Zostavax®

Zoster Vaccine(s)

Merck

Zostavax[®] (ZVL)

Attenuated Live chickenpox
(x14)
1 dose

Adults ≥ 60

Efficacy vs shingles 51%

Efficacy vs PHN 65%

Protection wanes over 7-10 yrs

GSK

Shingrix[™] (HZ/su)

Glycoprotein E + adjuvant
2 doses, a month apart
More local reactions

Adults ≥ 50

Efficacy vs shingles 92%

Protection maintained over 4 yrs

Herpes Zoster Vaccine Policy Questions

- Should ACIP recommend HZ/su immunocompetent adults? (Category A or B?)
- At what age should HZ/su recommendation start?
- Should ACIP recommend a preference for HZ/su over ZVL?
- Should ACIP recommend persons previously vaccinated with ZVL receive HZ/su?

Vaccination Errors

Vaccine Safety Office Tom Shimabukuro, MD, Beth Hibbs, RN

- Great presentation. Lots of committee comments, questions
- VAERS in 2000-2013 311,185 reports, 7% are error reports (21,843)
- Main error is inappropriate schedule (27%), storage and dispensing (23%) and wrong vaccine (15%) 2/3rds of errors
- Top 3 vaccines with errors are often sound alike Varivax/Zostavax, Dtap/Tdap, IIV age indication issues, Pneumo conjugate/pneumo poly, HepA/Hep B.
- 75% of vaccination errors reports to VAERS did not document adverse health events (AE)
- Of the 25% error reports that did have AE they were similar to non-error related reports. 92% are non serious reports
- Case studies: rotavirus injected, insulin instead of influenza, injecting diluent

Strategies for reducing vaccination errors

- Education and training on the schedule
- Training on administration techniques
- Monitor vaccine storage temps
- Pay attention to expiration dates
- Engineer differentiation between sound alike names/acronyms
- Screening for contraindications standardized
- Engineer interventions
- Bar coding for box and product to match

Mumps Epidemiology

- Mumps vaccine has reduced disease by 99%
- Mumps outbreaks persist 2006, 2010, 2016 (nearly 6000 cases)
- Most are in fully vaccinated college students
- If vaccine immunity is waning, no older vaccinated cases
- 2 dose schedule may be sufficient for general population
- 3 doses commonly used in outbreaks
- Benefit of 3rd dose in general population needs assessing

Mumps Disease and Vaccine

Questions for the Workgroup

- Why do we see mumps primarily in a tight age-range of teens and young adults? (19-23 years median in 16 outbreaks).
- When the outbreaks occur, they are largely on college campuses where there are close living situations, but we don't similarly see mumps outbreaks in military recruits. Why not?
- If we are seeing waning immunity of the vaccine how does that explain specific geographic outbreaks and no cases in older adults?
- Are certain populations at higher risk for mumps disease compared to others?
- Are there proper vaccine storage and handling concerns in certain areas?
- Has there been a shift in mumps genotypes in the US compared to what is in the vaccine?
- Should a third dose of mumps containing vaccine be used in an outbreak setting only or is there evidence to support a 3rd dose as a more broad routine recommendation.

Vaccine Adverse Event Reporting System (VAERS) 2.0

- ❑ VAERS 2.0 consists of two major initiatives
 - A new VAERS form with revised data elements
 - VAERS 2.0 reporting form
 - An updated processes for submitting VAERS reports
 - Option 1: updated online reporting tool
 - Option 2: writable PDF form combined with electronic document upload capability

Partial Screen Shot of VAERS 2.0 Online Reporting Tool (Direct Online Reporting)

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Completion Status | Report an Adverse Event - Patient Information | Instructions | en Español

☐ Patient Information
☐ Reporter Information
☐ Facility Information
☐ Vaccine Information
☐ Additional Information

Note: Fields marked with an * are essential and should be completed.

Item 1

Patient first name: Patient last name:

Street address:

City: State: County:

Zip code: Phone: Email:

Item 2

* Date of birth (mm/dd/yyyy) Sex: ☐ Male ☐ Female ☐ Unknown

Item 3

* Date of vaccination (mm/dd/yyyy) Time: AM ☐ PM

Item 4

* Date adverse event started (mm/dd/yyyy) Time: AM ☐ PM

Item 5

* Age at vaccination years months Today's date:

Item 6

Item 7

Item 8

[Click to preview VAERS form](#)

VAERS 2.0 Form (Writable, Savable, and Uploadable to VAERS Website)

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)

1. Patient name: (first) (last)
Street address:
City: State: County:
ZIP code: Phone: () Email:
2. Date of birth: (mm/dd/yyyy) 3. Sex: ☐ Male ☐ Female ☐ Unknown
4. Date and time of vaccination: (mm/dd/yyyy) Time: AM ☐ PM
5. Date and time adverse event started: (mm/dd/yyyy) Time: AM ☐ PM
6. Age at vaccination: Years Months 7. Today's date: (mm/dd/yyyy)
8. Is the report about vaccine(s) given to a pregnant woman? ☐ No ☐ Unknown ☐ Yes
If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18.

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to patient: ☐ Healthcare professional (staff) ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other:
Street address: Check if same as item 1.
City: State: ZIP code:
Phone: () Email:
14. Best doctor/healthcare professional to contact about the adverse event: Name: Phone: () Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
16. Type of facility: Check one:
☐ Doctor's office or hospital
☐ Pharmacy or drug store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School/student health clinic
☐ Other:
Street address: Check if same as item 13.
City: State: ZIP code:
Phone: ()

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4. (Route is HOW vaccine was given. Body site is WHERE vaccine was given. Use Continuation Page if needed.)

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

18. Describe the adverse event(s), treatment, and outcome(s), if any: (Symptoms, signs, time course, etc.)
21. Result or outcome of adverse event(s): Check all that apply:
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization: Number of days (if known)
Hospital name:
City: State:
☐ Prolongation of existing hospitalization (vacuum received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died: Date of death (mm/dd/yyyy)
☐ Congenital anomaly or birth defect
☐ None of the above

19. Medical tests and laboratory results related to the adverse event(s). Include date(s):
20. Has the patient recovered from the adverse event(s)? ☐ Yes ☐ No ☐ Unknown

ADDITIONAL INFORMATION (Use Continuation Page if needed)

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

23. Has the patient ever had an adverse event following any previous vaccine? If yes, describe adverse event, patient age at vaccination, vaccination date, vaccine type, and brand name.
☐ No ☐ Unknown ☐ Yes

24. Patient's race: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander
Check all that apply: ☐ White ☐ Unknown ☐ Other:

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown 26. Immune prog. report no.: (Health Dept use only)

COMPLETE ONLY FOR U.S. MILITARY (DEPARTMENT OF DEFENSE (DoD)) RELATED REPORTS

27. Status or vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other: 28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS-2.0 (017)

[SAVE](#)

- “Essential” items (high value data elements) are highlighted with asterisks in the online reporting tool and with yellow boxes in the writable PDF form

The Perfect Vaccine—We can dream!

- Single dose
- Oral
- Omnivalent
- Neonatal
- 100% effective
- No adverse events
- Lifelong immunity
- Loved by providers, nurses, parents and the media
- Easy to pronounce and talk about

