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webinar series

William Atkinson, MD, MPH*

Vaccine Update
A Summary of the Proceedings of the Advisory Committee on Immunization Practices (ACIP), June 25-26, 2014

July 17, 2014

immunization action coalition
IAC
immunize.org

***Representing the Immunization Action Coalition, Saint Paul, MN**

Disclosures

- William Atkinson has no financial conflict or interest with the manufacturer of any product named during this presentation
- The speaker will not discuss the use of any product in a manner not approved by the U.S. Food and Drug Administration (FDA)
- The speaker will not discuss vaccines not licensed by the FDA

Advisory Committee on Immunization Practices (ACIP)

- Composed of 15 experts in clinical medicine and public health who are not government employees
- Ex-officio (FDA, NIH, CMS, etc) and liaison (AAP, AAFP, ASTHO, Pharma, etc) members (non-voting)
- Provide guidance on the use of vaccines and other biologic products to the Department of Health and Human Resources, CDC, and the U.S. Public Health Service

www.cdc.gov/vaccines/acip/

Advisory Committee on Immunization Practices (ACIP)

- A Work Group (WG) is created as necessary for each vaccine or issue
  - permanent WGs: General Recommendations, Influenza, Adult and Childhood Schedules
- WGs meet as needed via conference call to discuss issues and create provisional recommendations
- WG recommendations presented to full ACIP at regular meetings for discussion and vote

Advisory Committee on Immunization Practices (ACIP)

- Recommendations are approved by a simple majority of voting ACIP members*
- Recommendations approved by ACIP are not "official" until they are
  - approved by the CDC Director and the U.S. Secretary of Health and Human Services, AND
  - published in *Morbidity and Mortality Weekly Report (MMWR)*

***ACIP members with real or potential financial conflicts of interest do not vote on issues related to the conflicted issue**

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ACIP Meeting, October 25, 2011

ACIP Meeting, Atlanta, Georgia

- Day 1 – June 25, 2014
  - General Recommendations (altered immunocompetence)
  - Childhood Schedule (catch-up schedule focus groups)
  - Yellow Fever vaccine
  - Influenza vaccines*
  - Human Papillomavirus (HPV) vaccines
  - Vaccine Safety (febrile seizures)
  - Adult Immunization (coverage)

***1 vote taken**

ACIP Meeting, Atlanta, Georgia

- Day 2 – June 26, 2014
  - Typhoid vaccines
  - PCV13 recommendations for adults
  - Measles update
  - Meningococcal outbreaks and vaccine use
  - Hepatitis vaccines
  - Pertussis

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 60 / No. 2
January 28, 2011

General Recommendations on Immunization

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html

U.S. Department of Health and Huma
Centers for Disease Control and Prevent

General Recommendations on Immunization

- Major sections
  - Timing and spacing (intervals, ages, etc)
  - Contraindications and precautions
  - Vaccine administration
  - Storage and handling
  - Altered immunocompetence
  - Special situations (pregnancy, breastfeeding, allergy, vaccination outside the U.S.
  - Vaccination records and IISs
  - Vaccination programs

Clinical Infectious Diseases Advance Access published December 4, 2013

IDSA GUIDELINES

2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

Lorry G. Rubin,[1] Myron J. Levin,[2] Per Ljungman,[3,4] E. Graham Davies,[5] Robin Avery,[6] Marcie Tomblyn,[7] Athos Bousvaros,[8] Shireesha Dhanireddy,[9] Lillian Sung,[10] Harry Keyserling,[11] and Insoo Kang[12]

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An international panel of experts prepared an evidenced-based guideline for vaccination of immunocompromised adults and children. These guidelines are intended for use by primary care and subspecialty providers who care for immunocompromised patients. Evidence was often limited. Areas that warrant future investigation are highlighted.

Keywords. vaccination; immunization; immunocompromised patients; immunosuppression; asplenic patients; immunodeficiency patients

General Recommendations on Immunization

- Scheduled to vote on the entire document at the October 2014 meeting
- Estimated publication in 2016 (?)

Child and Adolescent Immunization Schedules

- Information only
- Discussion topics
  - status of 2015 schedules
  - focus group testing of catch-up schedule
  - "Job Aids" for catch-up vaccination

FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States, 2014.

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Persons aged 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepatitis B[1]	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus[2]	6 weeks	4 weeks	4 weeks[2]		
Diphtheria, tetanus, & acellular pertussis[3]	6 weeks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[5]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12 through 14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[5] if current age is younger than 12 months and first dose administered at < 7 months old 8 weeks and age 12 months through 59 months (as final dose)[5] if current age is younger than 12 months and first dose administered between 7 through 11 months (regardless of Hib vaccine [PRP-T or PRP-OMP] used for first dose); OR if current age is 12 through 59 months and first dose administered at younger than age 12 months; OR first 2 doses were PRP-OMP and administered at younger than 12 months. No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 (PRP-T) doses before age 12 months and started the primary series before age 7 months	
Pneumococcal[6]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus[7]	6 weeks	4 weeks[7]	4 weeks[7]	6 months[7] minimum age 4 years for final dose	
Meningococcal[13]	6 weeks	8 weeks[13]	See footnote 13	See footnote 13	
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months			
Hepatitis A[11]	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, & acellular pertussis[4]	7 years[4]	4 weeks	4 weeks if first dose of DTaP/DT administered at younger than age 12 months 6 months if first dose of DTaP/DT administered at age 12 months or older and then no further doses needed for catch-up	6 months if first dose of DTaP/DT administered at younger than age 12 months	
Human papillomavirus[12]	9 years	Routine dosing intervals are recommended[12]			
Hepatitis A[11]	12 months	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks[7]	6 months[7]	
Meningococcal[13]	6 weeks	8 weeks[13]			
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

DTaP, Tdap, and Td Catch-up Vaccination Recommendations by Prior Vaccine History and Age

This table summarizes the recommendations of CDC's Advisory Committee on Immunization Practices for the use of DTaP and Tdap in children, adolescents, and adults who are unvaccinated or who have fallen behind.

For use in infants and children through age 6 years:
DTaP = Diphtheria and tetanus toxoids with acellular pertussis vaccine
DT (pediatric) = Diphtheria and tetanus toxoids (no pertussis)
For use in children age 7 years and older and adults:
Tdap = Tetanus and diphtheria toxoids with acellular pertussis vaccine
Td (adult) = Tetanus and diphtheria toxoids

Current Age of Child or Adult	Number of Prior Doses	Minimum Interval Between Doses of DTaP, Tdap, or Td Starting from the Most Recent Dose Given			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
4 weeks through 6 years	Unknown	4 weeks	4 weeks	6 months[1]	6 months[2]
	0	4 weeks	4 weeks	6 months[1]	6 months[2]
	1	4 weeks	4 weeks	6 months[1]	6 months[2]
	2		4 weeks	6 months[1]	6 months[2]
	3			6 months[1]	6 months[2]
	4				6 months[2]
7 through 18 years[3] *or* **Adults age 19 years and older[4]**	Unknown	4 weeks	4 weeks	6 months	
	0	4 weeks	4 weeks	6 months	
	1	4 weeks	4 weeks, if dose 1 given at younger than12 mos 6 months if dose 1 given at age 12 mos or older	6 months, if dose 1 given at younger than12 mos	
	2		4 weeks, if dose 1 given at younger than12 mos 6 months if dose 1 given at age 12 mos or older	6 months, if dose 1 given at younger than12 mos	
	3			6 months, if dose 1 given at younger than 12 mos	

- Children ages 2 months through 6 years should receive DTaP; the pediatric product, DT, should only be used in children with a valid contraindication to the pertussis component.
- The routine schedule for administering DTaP to children is a 3-dose series at age 2, 4, and 6 months, followed by boosters at age 15–18 months and 4–6 years. The first booster may be given at age 12–15 months as long as there is an interval of at least 6 months from the preceding dose.
- All adults should receive 1 dose of Tdap, if they haven't previously received Tdap as an adolescent.
- Pregnant women should receive Tdap during each pregnancy, preferably between 27 and 36 weeks' gestation. Women who have never received Tdap and fail to receive it during their pregnancy should receive it immediately postpartum.
- Tdap can be given with no minimum interval since the previous tetanus toxoid-containing product (e.g., DTaP, Td).

Yellow Fever Vaccine

- Current recommendation is for a booster dose every 10 years
  - 18 vaccine failures documented since 1940
  - 10 cases in U.S. and European travelers since 1970
- World Health Organization recommended 1 lifetime dose (no boosters) in April 2013
- Booster dose language will be removed from International Health Regulations in 2016

Yellow Fever Vaccine

- CDC yellow fever group wanted a vote to remove the booster dose recommendation for most travelers
- There was confusion among committee members about who did and did not need a booster dose
- Issue was tabled
- Will be revisited at the October 2014 meeting

Influenza Vaccine

Influenza Vaccine

- 1 vote taken
- Topics
  - novel influenza vaccine WG update
  - vaccine safety
  - proposed 2014-2015 recommendations

Influenza Vaccine

- Safety – no signals detected using either VAERS or VSD
- Study by CISA comparing fever rates among children younger than 5 years who received LAIV or IIV
  - no difference
- 2014-15 vaccine
  - components
  - minor wording changes in egg allergy and pediatric dosing

Influenza Vaccine Strains 2014-2015

- No change from last year's vaccine strains
- Trivalent vaccine will contain:
  - A/California/7/2009 (H1N1)pdm09-like virus
  - A/Texas/50/2012 (H3N2)-like virus
  - B/Massachusetts/2/2012-like virus
- Quadravalent vaccine contains the same three strains as in trivalent vaccine plus:
  - B/Brisbane/60/2008-like virus

Live Attenuated Influenza Vaccine (LAIV) for Children

- Two randomized studies have been conducted in young children that compare the benefits provided by the LAIV and IIV
  - one study was conducted in children 6 to 59 months of age and the other was conducted in children 6 to 71 months of age
- Both studies indicated that LAIV provided about 50% better protection than IIV in young children

Influenza Vaccine 2014-2015

- Vote:
  - *when available,* LAIV should be used for healthy children age 2 through 8 years who have no contraindications or precautions (approved)
- AAP guidance may say “should be considered” rather than “should be used”
  - these 3 words were debated at length

Live Attenuated Influenza Vaccine (LAIV) for Children

- The new ACIP recommendation is based on a review of available studies that suggests LAIV can provide better protection against laboratory-confirmed, medically attended influenza illness than inactivated influenza vaccine among children ages 2 through 8 years

Influenza Vaccine 2014-2015

- Text will make clear that both IIV and LAIV are safe and effective
- Vaccination should not be delayed if LAIV is not available
- 2014-15 recommendations will be published in MMWR as a “Policy Note” during the summer

Choice of Influenza Vaccine

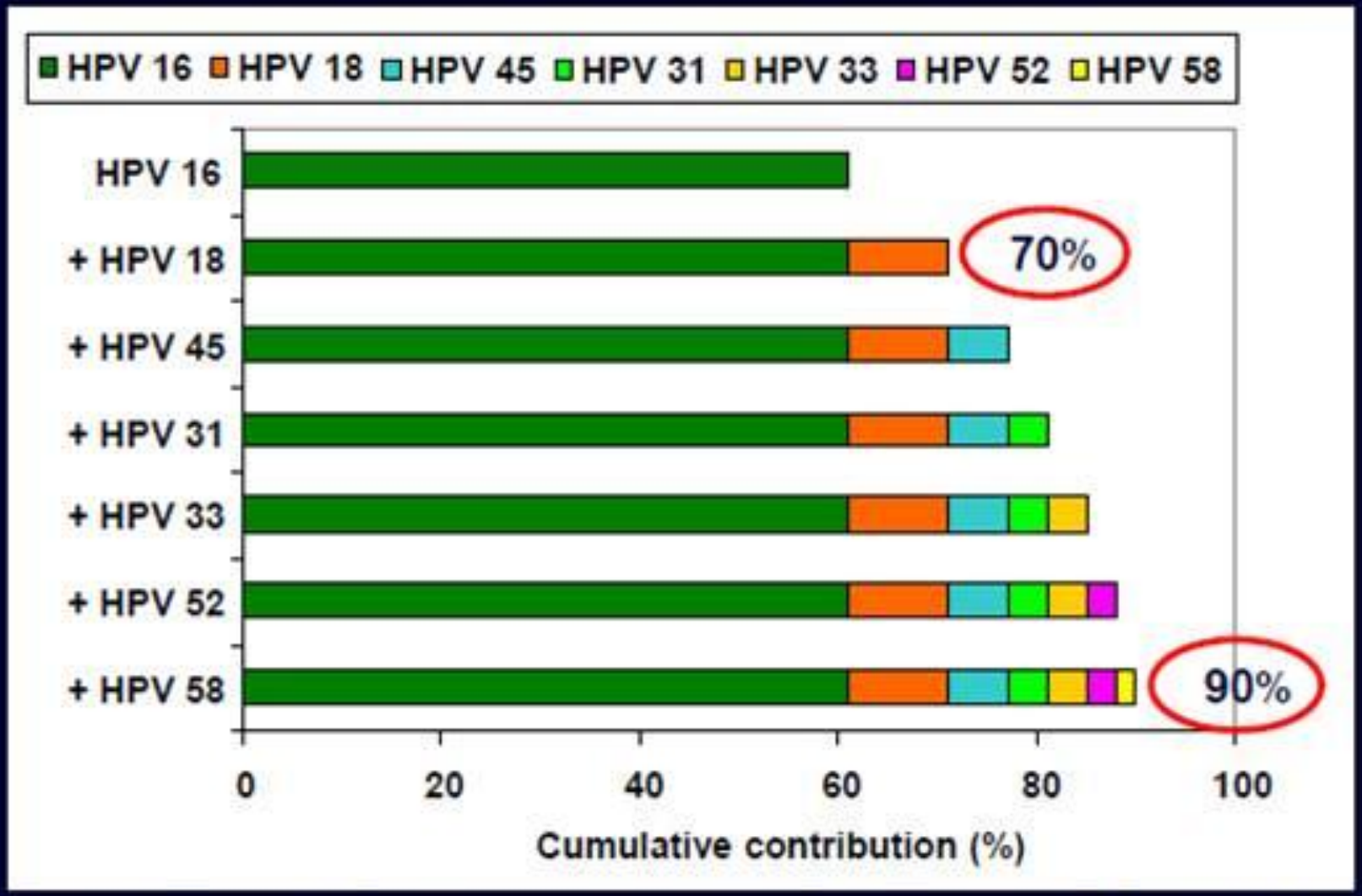
- Where more than one type of vaccine is appropriate and available, ACIP has no preferential recommendation for use of any influenza vaccine product over another
  - quadrivalent vs trivalent
  - high-dose vs standard dose
  - IIV vs LAIV except in children ages 2 through 8 years

www.cdc.gov/mmwr/pdf/rr/rr6207.pdf

Human Papillomavirus Vaccine

- Information only
- Topics
  - 9-valent vaccine clinical trial data
  - Policy considerations and approach to GRADE for 9-valent vaccine
  - 2 dose schedules for existing bivalent and quadrivalent vaccines

Relative Contribution of HPV Types in 9vHPV Vaccine to Cervical Cancers Worldwide



Among HPV-positive cervical cancers; based on de Sanjose et al. Lancet Oncol. 11:1048-56 (2010); Serrano et al. Infect Agent Cancer 7:38 (2012)

Efficacy Against HPV 31/33/45/52/58
(Cervical/Vulvar/Vaginal Disease, Persistent Infection)
Per Protocol Efficacy Population

Endpoint	9vHPV Vaccine No. of cases/n	qHPV Vaccine No. of cases/n	Efficacy (95% CI)
≥CIN2, VIN2/3, VaIN2/3	1 / 6016	30 / 6017	96.7% (80.9, 99.8)
All CIN, VIN, VaIN	3 / 6016	103 / 6017	97.1% (91.8, 99.2)
6-month persistent infection	35 / 5939	810 / 5953	96.0% (94.4, 97.2)

Merck data presented to ACIP, February 27, 2014

Protocol 001: Vaccine-Related Adverse Experience (AE) Summary

(Days 1 to 15 Following Any Vaccination)

Subjects	9vHPV Vaccine (N=7,071) n (%)	qHPV Vaccine (N=7,078) n (%)
All vaccine-related* AEs	**6,519 (92.2)**	**6,200 (87.6)**
Injection-site	6,422 (90.8)	6,023 (85.1)
Systemic	2,086 (29.5)	1,929 (27.3)
Discontinued** due to a vaccine-related AE	5 (0.1)	3 (0.0)
With serious vaccine-related* AEs	**2 (0.0)**	**1 (0.0)**
Discontinued** due to a serious vaccine-related AE	1 (0.0)	0 (0.0)
	0 (0.0)	0 (0.0)

**Determined by the investigator to be related to the vaccine **Study medication withdrawn*

Merck data presented to ACIP, February 27, 2014

HPV 2-dose Schedules

- Reasons to consider
  - cost
  - simplicity
- Limited data available
  - serologic response similar to 3 dose schedule
  - efficacy may be less
  - no data on long-term effectiveness
- HPV WG will continue to discuss

Vaccine Safety

- Information only
- Topics
  - Seizures following multiple vaccines (VSD study)
  - Febrile seizures after trivalent influenza vaccine

Febrile Seizures After Multiple Vaccines – VSD study

- The concomitant administration of IIV + PCV and IIV + DTaP-containing vaccines had higher risk of febrile seizure than when the vaccines were given separately
- The concomitant administration of IIV + PCV + DTaP-containing vaccines had the highest risk (rate ratios 2.9 – 6.6 depending on year)
- Analysis continuing
- No change in policy

Febrile Seizures after Inactivated Influenza Vaccine (PRISM study)

- Studies 2010-2011 influenza season
- Administering IIV and PCV13 on the same day did not significantly increase the risk of febrile seizure compared to separate day vaccination
- No change in policy

Adult Vaccination

- Information only
- National Health Interview Survey, 2012
  - coverage for adult vaccines remains far below HP2020 targets
  - some improvements from 2011 (modest increases in HPV and Tdap)
  - racial and ethnic disparities remain

Morbidity and Mortality Weekly Report

MMWR 2014;63(5):95-102 (Feb 7, 2014)

Noninfluenza Vaccination Coverage Among Adults — United States, 2012

Walter W. Williams, MD[1], Peng-Jun Lu, MD, PhD[1], Alissa O'Halloran, MSPH[1], Carolyn B. Bridges, MD[1], Tamara Pilishvili, MPH[2], Craig M. Hales[3], MD, Lauri E. Markowitz, MD[4] (Author affiliations at end of text)

Vaccinations are recommended throughout life to prevent vaccine-preventable diseases and their sequelae. Adult vaccination coverage, however, remains low for most routinely recommended vaccines (*1*) and well below *Healthy People 2020* targets.* In October 2013, the Advisory Committee on Immunization Practices (ACIP) approved the adult immunization schedule for 2014 (*2*). With the exception of influenza vaccination, which is recommended for all adults each year, vaccinations recommended for adults target different populations based on age, health conditions, behavioral risk factors (e.g., injection drug use), occupation, travel, and other indications (*2*). To assess vaccination coverage among adults aged ≥19 years for selected vaccines, CDC analyzed data from the 2012 National Health Interview Survey (NHIS). This report summarizes the results of that analysis for pneumococcal, tetanus toxoid–containing (tetanus and diphtheria vaccine [Td] or tetanus and diphtheria with acellular pertussis vaccine [Tdap]), hepatitis A, hepatitis B, herpes zoster (shingles), and human papillomavirus (HPV) vaccines by selected characteristics (age, race/ethnicity,† and U.S. Census Bureau for CDC's National Center for Health Statistics. Questions about receipt of recommended vaccinations for adults are asked of one randomly selected adult within each family in the household. The presence of high-risk conditions,§ as defined by ACIP for pneumococcal disease, was determined by responses to questions in the NHIS (*2*). Comprehensive information on all high-risk conditions for hepatitis B or A were not collected in the 2012 NHIS. Analyses were conducted to estimate Tdap vaccination of adults aged ≥65 years being collected in the NHIS for the first time starting in 2012. The final sample adult component response rate for the 2012 NHIS was 61.2%. Weighted data¶ were used to produce national vaccination coverage estimates. Point estimates and estimates of corresponding variances were calculated using statistical software to account for the complex sample design. Statistical significance was defined as $p<0.05$.

Pneumococcal Vaccination Coverage

Pneumococcal vaccination coverage (overall, for 23-valent

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

December 9, 1994 / Vol. 43 / No. RR-14

MMWR
Recommendations and Reports

MORBIDITY AND MORTALITY WEEKLY REPORT

Typhoid Immunization

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

13-Valent Pneumococcal Conjugate Vaccine (PCV13)

- Information only
- Topics
  - consideration for routine adult immunization with PCV13
  - discussion of CAPITA trial data
- Note: PCV13 was approved by FDA for the prevention of pneumonia and invasive disease caused by vaccine serotypes in persons age 50 years and older in December 2011

CAPITA trial

- Community-Acquired Pneumonia Immunization Trial in Adults
- Intended to determine if PCV13 was effective in reducing the risk of a first episode of CAP among persons 65 years and older
- Double-blind, placebo controlled
- ~85,000 persons 65 years or older in the Netherlands

CAPITA trial

- 46% efficacy against vaccine-type CAP
- 75% efficacy against vaccine-type invasive pneumococcal disease
- More effective in persons younger than age 75
- 35% of recipients reported local AE (mostly pain)

Pfizer data presented to ACIP, June 25, 2014

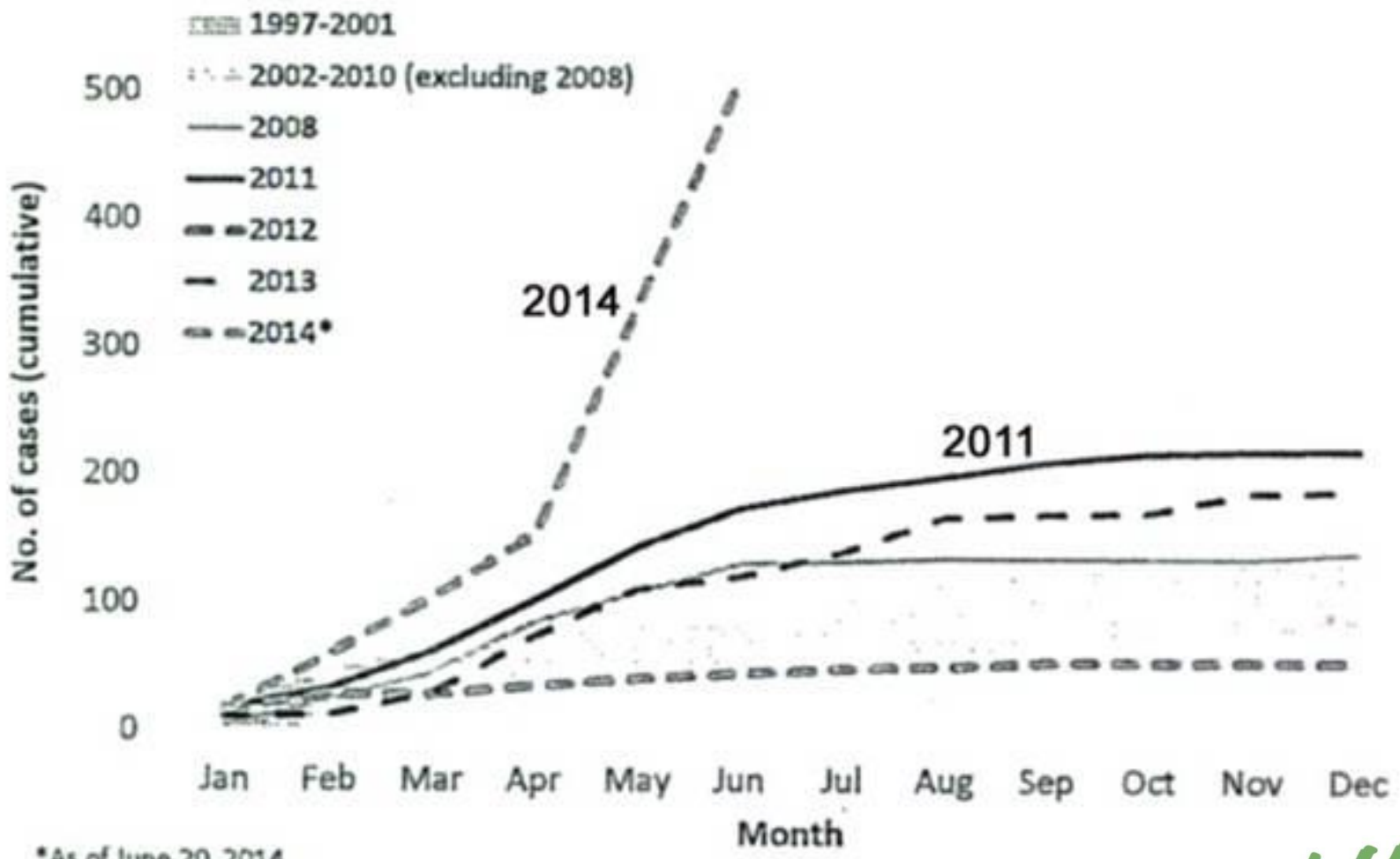
PCV13 Recommendations Being Considered by ACIP

- The Pneumococcal WG believes a recommendation for universal PCV13 vaccination of adults is warranted
- Options
  - ADD a dose of PCV13 at age 65 years or older to the currently recommended PPSV23 regimen
  - REPLACE a dose of PPSV23 at age 65 years with a dose of PCV13
- No vote was taken pending additional consideration by WG (schedules, intervals)

Measles

Measles, U.S., 1997-2014*

Cumulative Number by Month of Rash Onset



*As of June 20, 2014

Measles – United States, 2014*

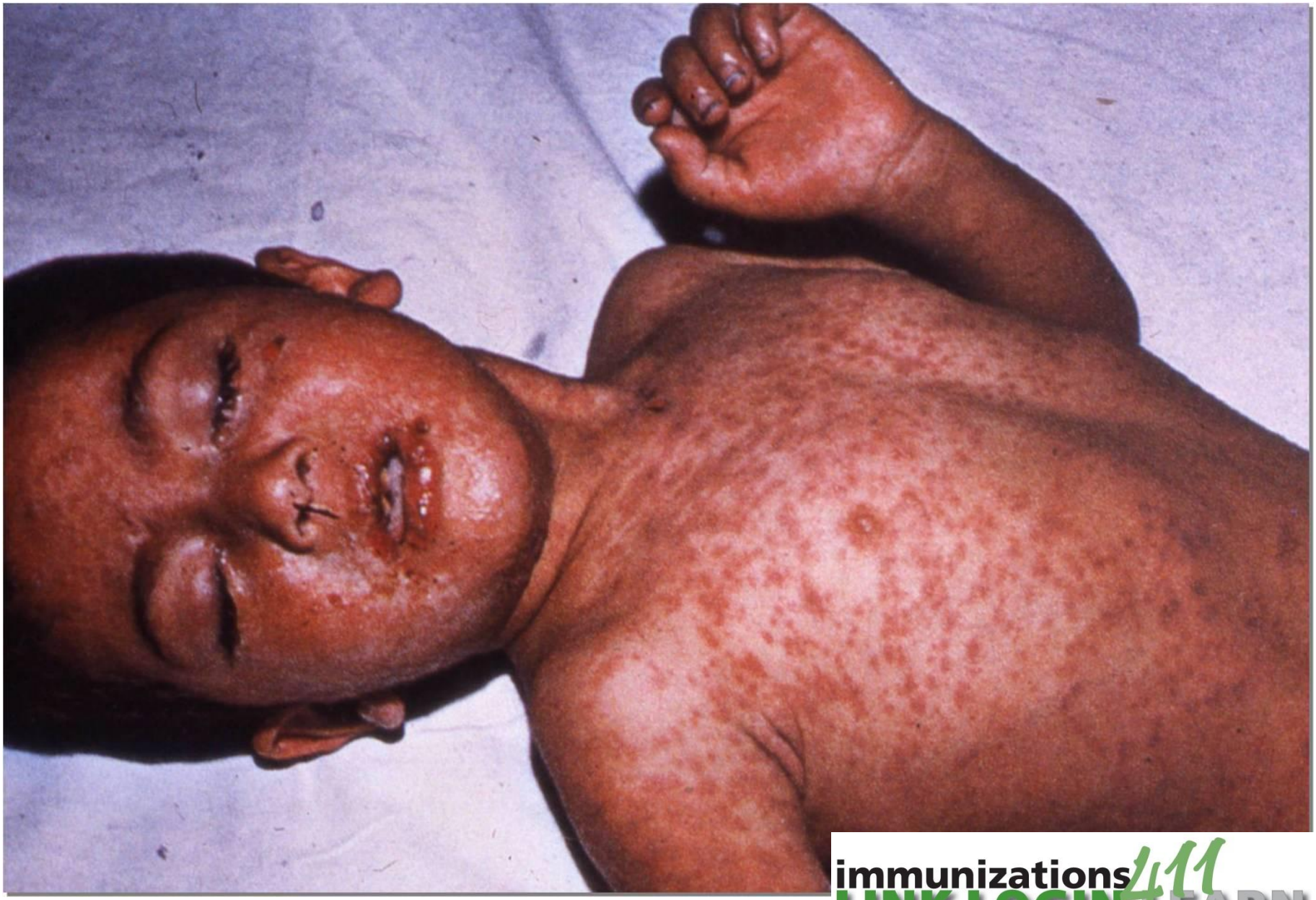
- 514 cases reported to CDC
  - 49 importations (23 from the Philippines)
- Cases among U.S. residents (N=506)
  - 7% vaccinated (including 5% with 2 or more doses)
  - 81% unvaccinated
    - 87% personal belief
    - 5% too young

***as of June 20. CDC data presented to ACIP, June 26, 2014**

Measles Outbreaks – United States, 2014*

- Knox County, OH
  - 340 cases (in progress)
  - source imported from Philippines
- New York City
  - 25 cases (transmission interrupted)
  - source imported
- Kansas City metro
  - 22 cases (in progress)
  - source imported

***as of June 20. CDC data presented to ACIP, June 26, 2014**



Measles
Keep Your Guard Up

- Any patient with fever and rash should be assumed to have measles until proven otherwise
  - immediate isolation
- Be highly suspect of patients with fever and coryza and/or conjunctivitis, particularly if unvaccinated or international travel
- Be certain of your measles immunity status

***MMWR* 2013;62(RR-4)**

Evidence of Measles Immunity for Healthcare Personnel

- Appropriate vaccination
  - 2 doses of measles-containing vaccine (preferably MMR), or
- Laboratory evidence of immunity, or
- Laboratory confirmation of disease
- Physician-diagnosed disease no longer recommended as evidence of measles (or mumps) immunity

***MMWR* 2013;62(RR-4)**

MMR Vaccine

- First dose at 12-15 month, second dose routinely at 4-6 years of age
- Minimum interval between doses is 4 weeks
- Infants as young as 6 months should receive MMR before international travel
- Adults born after 1956 with unknown or undocumented MMR vaccination history should receive 1 or 2 doses

***MMWR* 2013;62(RR-4)**

Meningococcal Vaccines

- Information only
- Topics
  - epidemiology of meningococcal disease outbreaks in the United States
  - interim guidance for the use of serogroup B meningococcal vaccines under a CDC-sponsored IND

Meningococcal Vaccines

- Serogroup B now predominant among adolescents
- Serogroup C outbreaks are less frequently reported since high coverage with MCV achieved
- 3 recent University-based serogroup B outbreaks
  - larger than past serogroup B outbreaks
  - longer intervals between cases

ACIP, June 25-26, 2014

- Hepatitis WG update
  - intend to revise both statements
- Vaccine Supply update
  - manufacturers project 153-159 million doses of influenza vaccine for 2014-2015 season
- Pertussis WG
  - deferred to October meeting
  - discussion of Tdap revaccination of HCP

Public Comment

Public Comment

- Kora Peters
  - requested ACIP recommend hepatitis A vaccine for "adult performers", as their "lifestyle choice" put them at increased risk for hepatitis A

ACIP Meeting Slides, Video and Minutes

- Slides and video usually available about 6 weeks after the meeting
- Minutes available about 2 months after the meeting
- ACIP website
  - www2a.cdc.gov/vaccines/acip/

Next ACIP Meeting

- October 29-30, 2014
- CDC Headquarters, Atlanta, Georgia
- You may attend in person or view via internet
- Register by October 13, 2014 (to attend in person)
- www2a.cdc.gov/vaccines/acip/

Thank You

Questions?

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hosted by the Missouri Department of Health and Senior Services' Bureau of Immunization Assessment and Assurance
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