Immunization Update

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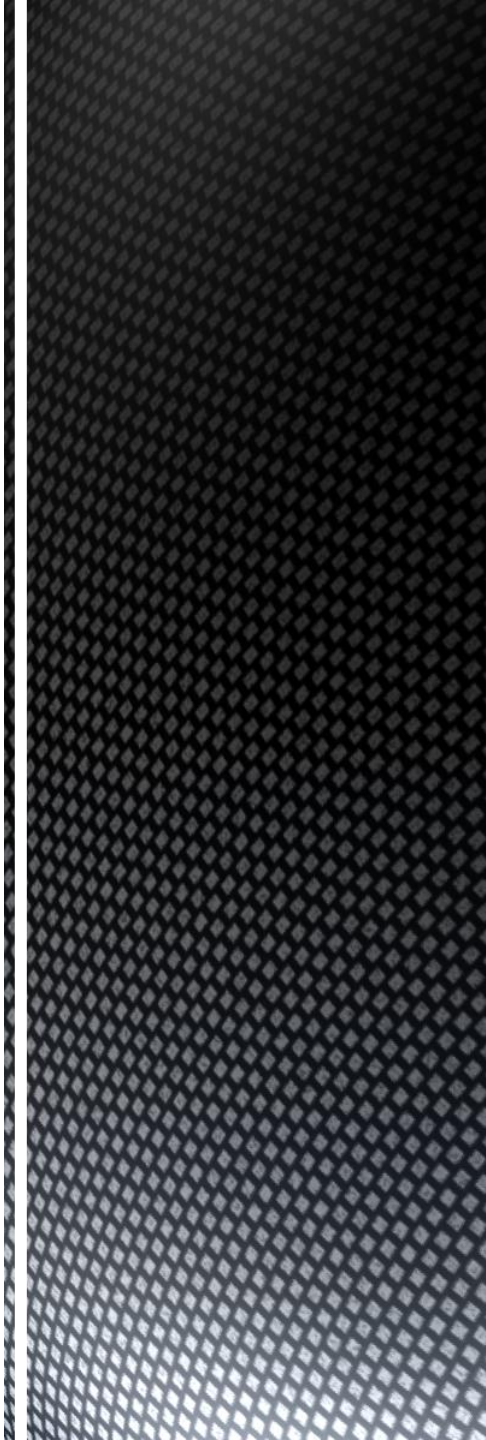


- ACIP August 2014 Mtg
- Voted 13-2 for the following recommendations

Prevnar 13

CAPITA trial

- Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA), the landmark study of approximately 85,000 subjects evaluating the efficacy of Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) in adults 65 years of age and older, achieved its primary clinical objective and both secondary clinical objectives. CAPiTA is the largest double-blind, randomized, placebo-controlled vaccine efficacy trial ever conducted in adults. The CAPITA trial results were presented at the June ACIP meeting.
- Recent data demonstrated **a 75% reduction in vaccine-type invasive pneumococcal disease (IPD) and 45% reduction in vaccine-type nonbacteremic pneumonia (NBP).** Disease is estimated at 2,600 PCV13-type IPD cases and more than 50,000 PCV13-type inpatient community acquired pneumonia (CAP). The workgroup also estimated a vaccine efficacy of 45% for PPSV23 against NBP. Based upon this new analysis, the impact of adding PCV13 to PPSV23 was estimated to reduce outpatient NBP by 2,261 cases, IPD deaths by 33, and deaths due to NBP by 104.
- The available data on the interval between vaccination of PCV13 and PPSV23 were discussed during the ACIP meeting, with the recommendation for PCV13 use in immunocompromised patients.
- The indirect effects (herd effects) of PCV13 on children since its introduction in 2010 are decreasing IPD caused by vaccine-type serotypes and will decrease the need for PCV13 in the near future. **The working group estimated there would be a decrease of CAP by 2019 by 86% due to this effect.** They suggest that this recommendation should be re-evaluated in 2018.

PCV 13

- Adults aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23.
- A dose of PPSV23 should be given 6 to 12 months following a dose of PCV13.
- If PPSV23 cannot be given during this time window, a dose of PPSV23 should be given during the next visit.
- The two vaccines should not be co-administered.
- Adults aged 65 years and older who have not previously received PCV13 and who have previously received one or more doses of PPSV23 should receive a dose of PCV13 at least 12 months following the PCV23.

PCV 13

- CMS would not likely be able to cover two pneumococcal vaccines during this upcoming season. It takes about 1 year to make a policy change based upon legal requirements, including public comment. Two vaccines would not be paid for by CMS, if given this year, because only one pneumococcal vaccine (type not specified) is already covered.

Procedure	Description	Charge Amount	Medicare	PBS	IBC Medicare	Aetna
90670	Pneumococcal Conjugate 13 Valent	185.00	145.10	174.31	158.02	161.65

Courtesy Dr Spencer

Zoster

- ACIP voted to make no change to VZV vaccine age recommendations

(> 60 yrs of age)-2014

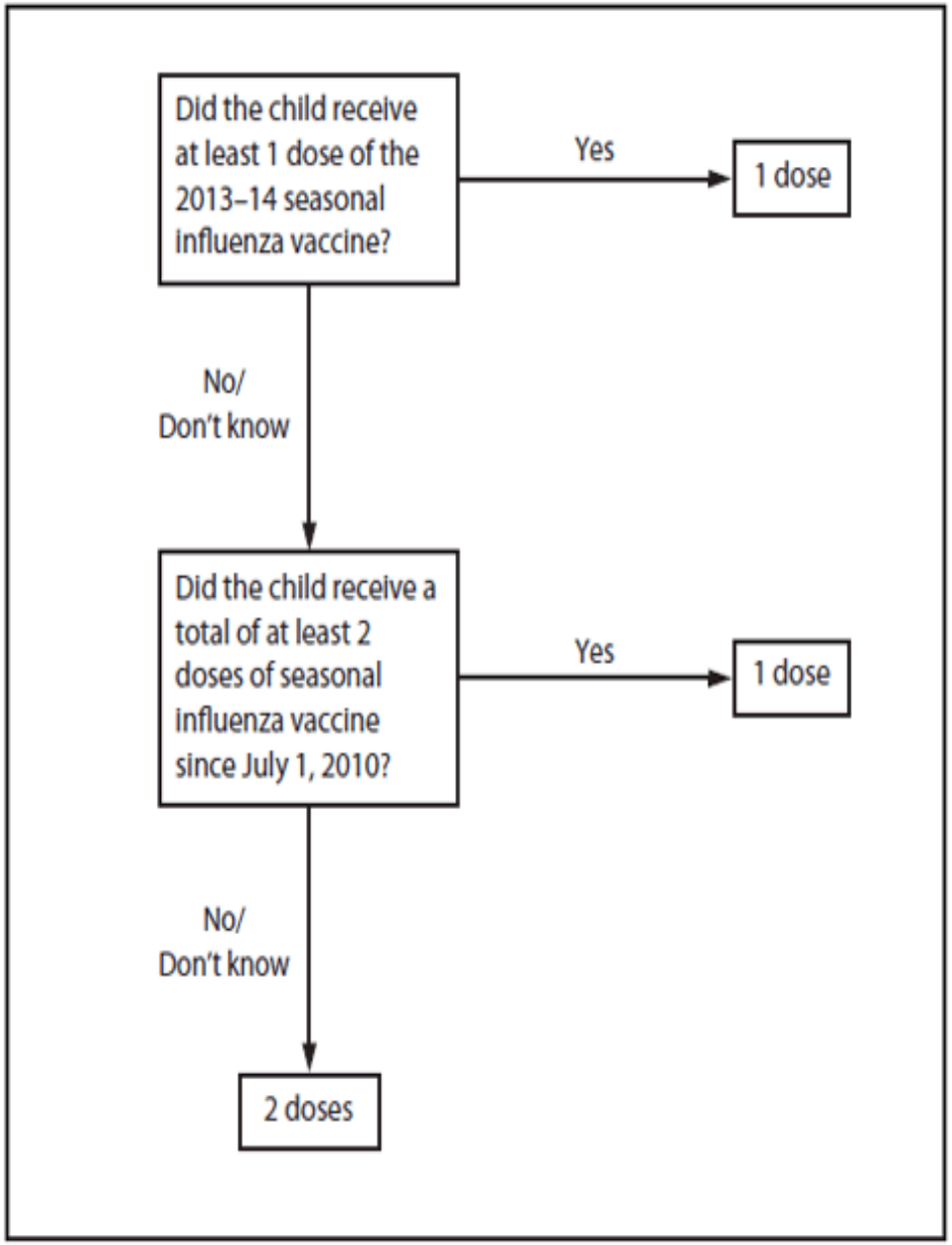
Influenza Vaccine Composition for the 2014–15 Season

- For 2014–15, U.S.-licensed influenza vaccines will contain the same vaccine virus strains as those in the 2013–14 vaccine. Trivalent influenza vaccines will contain hemagglutinin (HA) derived from an A/California/7/2009 (H1N1)-like virus, an A/Texas/50/2012 (H3N2)-like virus, and a B/Massachusetts/2/2012-like (Yamagata lineage) virus. Quadrivalent influenza vaccines will contain these antigens, and also a B/Brisbane/60/2008-like (Victoria lineage) virus

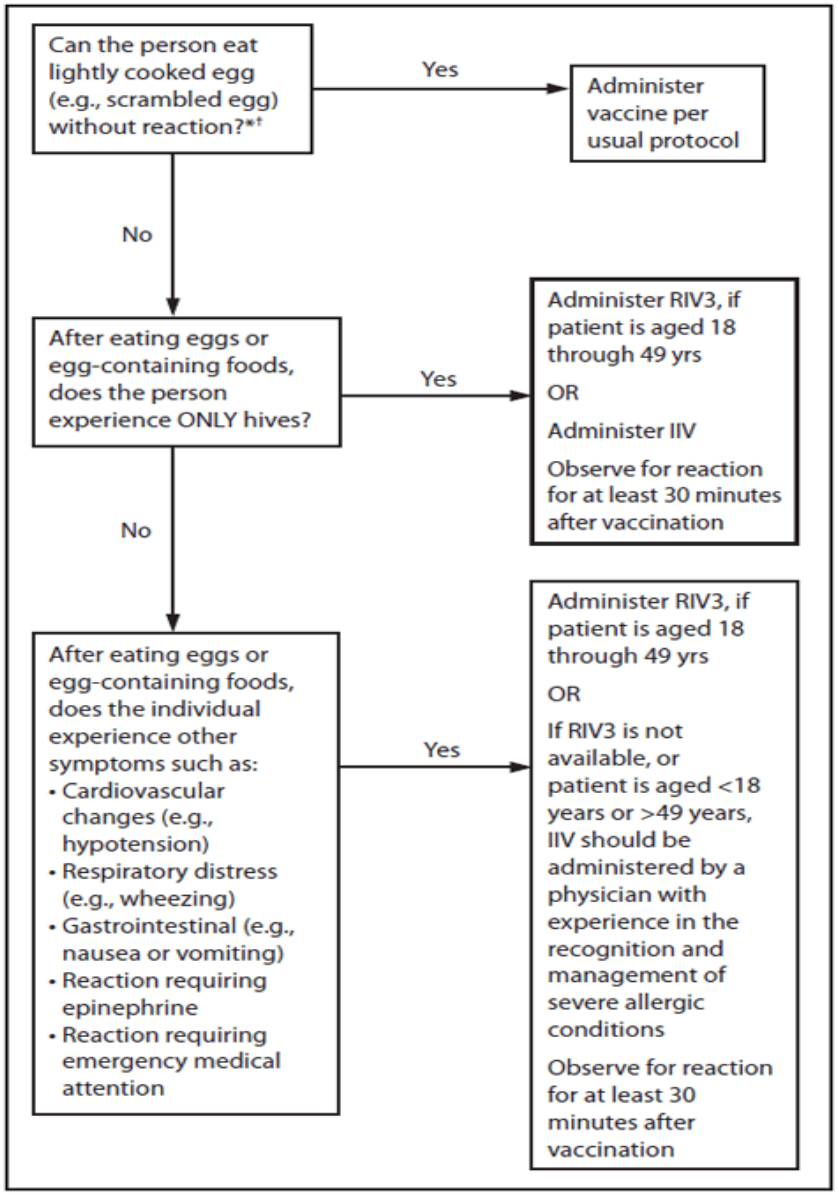
Influenza

- For 2014–15, ACIP recommends the following:

1. All persons aged ≥6 months should receive influenza vaccine annually. Influenza vaccination should not be delayed to procure a specific vaccine preparation if an appropriate one is already available.
2. When immediately available, **LAIV should be used for healthy children aged 2 through 8 years** who have no contraindications or precautions **(Category A**). If LAIV is not immediately available, IIV should be used. Vaccination should not be delayed to procure LAIV. The age of 8 years is selected as the upper age limit for this recommendation based on demonstration of superior efficacy of LAIV (ages 2 to 6 years), and for programmatic consistency (8 years is the upper age limit for receipt of 2 doses of influenza vaccine in a previously unvaccinated child). This recommendation should be implemented for the 2014–15 season as feasible, but not later than the 2015–16 season.



Influenza Vaccine in Children 6 months-8 years



Influenza and Egg Allergy

Hi Dose Flu Vaccine

- The high-dose, trivalent, inactivated influenza vaccine (IIV3-HD) contains four times as much hemagglutinin (HA) as is contained in standard-dose vaccines.

Hi Dose Flu

Efficacy of High-Dose Vaccine Relative to Standard-Dose Vaccine against Confirmed Influenza Caused by Any Viral Type or Subtype.

Table 2. Efficacy of High-Dose Vaccine Relative to Standard-Dose Vaccine against Confirmed Influenza Caused by Any Viral Type or Subtype.*

Variable	Laboratory-Confirmed Influenza†			Culture-Confirmed Influenza		
	IIV3-HD (N=15,990)	IIV3-SD (N=15,993)	Relative Efficacy (95% CI)	IIV3-HD (N=15,990)	IIV3-SD (N=15,993)	Relative Efficacy (95% CI)
	no. (%)		%	*no. (%)*		%
Protocol-defined influenza-like illness	228 (1.4)	301 (1.9)	24.2 (9.7 to 36.5)‡	206 (1.3)	268 (1.7)	23.1 (7.5 to 36.2)
Influenza A	190 (1.2)	250 (1.6)	24.0 (7.8 to 37.4)	170 (1.1)	222 (1.4)	23.4 (6.0 to 37.6)
A/H1N1	8 (<0.1)	9 (0.1)	11.1 (−159.6 to 70.2)	7 (<0.1)	9 (0.1)	22.2 (−134.7 to 75.4)
A/H3N2	171 (1.1)	223 (1.4)	23.3 (6.0 to 37.5)	156 (1.0)	199 (1.2)	21.6 (2.8 to 36.8)
Influenza B	38 (0.2)	51 (0.3)	25.5 (−15.7 to 52.4)	36 (0.2)	46 (0.3)	21.7 (−23.8 to 50.8)
Modified CDC-defined influenza-like illness	96 (0.6)	121 (0.8)	20.6 (−4.6 to 39.9)	84 (0.5)	110 (0.7)	23.6 (−2.4 to 43.2)
Influenza A	86 (0.5)	104 (0.7)	17.3 (−11.1 to 38.6)	75 (0.5)	94 (0.6)	20.2 (−9.3 to 41.9)
A/H1N1	3 (<0.1)	2 (<0.1)	−50.0 (−1696.0 to 82.8)	2 (<0.1)	2 (<0.1)	0.0 (−1280.0 to 92.8)
A/H3N2	77 (0.5)	95 (0.6)	18.9 (−10.7 to 40.8)	69 (0.4)	85 (0.5)	18.8 (−12.9 to 41.8)
Influenza B	10 (0.1)	17 (0.1)	41.2 (−36.0 to 75.9)	9 (0.1)	16 (0.1)	43.7 (−35.2 to 78.1)
Respiratory illness	316 (2.0)	387 (2.4)	18.3 (5.0 to 29.8)	277 (1.7)	339 (2.1)	18.3 (3.9 to 30.5)
Influenza A	262 (1.6)	313 (2.0)	16.3 (1.0 to 29.2)	227 (1.4)	272 (1.7)	16.5 (0.1 to 30.3)
A/H1N1	14 (0.1)	10 (0.1)	−40.0 (−252.4 to 42.2)	13 (0.1)	10 (0.1)	−30.0 (−231.3 to 47.33)
A/H3N2	231 (1.4)	281 (1.8)	17.8 (1.8 to 31.2)	205 (1.3)	246 (1.5)	16.6 (−0.7 to 31.1)
Influenza B	54 (0.3)	74 (0.5)	27.0 (−5.1 to 49.6)	50 (0.3)	67 (0.4)	25.4 (−9.3 to 49.3)

* CDC denotes Centers for Disease Control and Prevention.
† Laboratory confirmation of influenza was accomplished by a positive result on culture of a nasopharyngeal swab, a positive polymerase-chain-reaction assay, or both.
‡ The primary end point of the study was the occurrence, at least 14 days after vaccination, of laboratory-confirmed influenza caused by any influenza viral types or subtypes, in association with a protocol-defined influenza-like illness.

DiazGranados CA et al. N Engl J Med 2014;371:635-645.

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Efficacy of High-Dose Vaccine Relative to Standard-Dose Vaccine against Confirmed Influenza Caused by Strains Similar to the Vaccine Components.

Table 3. Efficacy of High-Dose Vaccine Relative to Standard-Dose Vaccine against Confirmed Influenza Caused by Strains Similar to the Vaccine Components.

Variable	Laboratory-Confirmed Influenza*			Culture-Confirmed Influenza†		
	IIV3-HD (N=15,990)	IIV3-SD (N=15,993)	Relative Efficacy (95% CI)	IIV3-HD (N=15,990)	IIV3-SD (N=15,993)	Relative Efficacy (95% CI)
	no. (%)		%	*no. (%)*		%
Protocol-defined influenza-like illness	73 (0.5)	113 (0.7)	35.4 (12.5 to 52.5)	63 (0.4)	92 (0.6)	31.5 (4.6 to 51.1)
Influenza A	56 (0.4)	82 (0.5)	31.7 (2.9 to 52.3)	46 (0.3)	63 (0.4)	27.0 (–8.5 to 51.2)
A/H1N1	7 (<0.1)	8 (0.1)	12.5 (–176.2 to 73.0)	3 (<0.1)	3 (<0.1)	0.0 (–646.8 to 86.6)
A/H3N2	49 (0.3)	74 (0.5)	33.8 (3.7 to 54.8)	43 (0.3)	60 (0.4)	28.3 (–7.8 to 52.7)
Influenza B	17 (0.1)	31 (0.2)	45.2 (–2.2 to 71.5)	17 (0.1)	29 (0.2)	41.4 (–10.3 to 69.8)
Modified CDC-defined influenza-like illness	26 (0.2)	51 (0.3)	49.0 (16.7 to 69.5)	22 (0.1)	45 (0.3)	51.1 (16.8 to 72.0)
Influenza A	21 (0.1)	36 (0.2)	41.7 (–2.7 to 67.6)	17 (0.1)	31 (0.2)	45.2 (–2.2 to 71.5)
A/H1N1	2 (<0.1)	2 (<0.1)	0.0 (–1280.0 to 92.8)	0	1 (<0.1)	100.0 (–3801.0 to 100.0)
A/H3N2	19 (0.1)	34 (0.2)	44.1 (–0.8 to 69.9)	17 (0.1)	30 (0.2)	43.3 (–6.1 to 70.7)
Influenza B	5 (<0.1)	15 (0.1)	66.7 (3.5 to 90.5)	5 (<0.1)	14 (0.1)	64.3 (–5.0 to 89.9)
Respiratory illness	106 (0.7)	146 (0.9)	27.4 (6.1 to 44.0)	85 (0.5)	118 (0.7)	28.0 (4.0 to 46.1)
Influenza A	82 (0.5)	101 (0.6)	18.8 (–9.8 to 40.1)	61 (0.4)	75 (0.5)	18.6 (–15.6 to 43.0)
A/H1N1	12 (0.1)	9 (0.1)	–33.4 (–258.4 to 48.4)	5 (<0.1)	3 (<0.1)	–66.7 (–973.5 to 67.6)
A/H3N2	70 (0.4)	92 (0.6)	23.9 (–5.0 to 45.0)	56 (0.4)	72 (0.5)	22.2 (–11.9 to 46.1)
Influenza B	24 (0.2)	45 (0.3)	46.7 (10.6 to 68.9)	24 (0.2)	43 (0.3)	44.2 (5.9 to 67.6)

* Laboratory confirmation of influenza was determined by a positive result on culture of a nasopharyngeal swab, a positive polymerase-chain-reaction assay, or both. For laboratory-confirmed influenza assessments, similarity was determined by ferret antigenicity testing complemented by genetic sequencing.
† For culture-confirmed influenza assessments, similarity was determined solely by the ferret antigenicity testing method.

DiazGranados CA et al. N Engl J Med 2014;371:635-645.

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