

Proposed Recommendations 2015-16 Influenza Season

**Lisa Grohskopf, MD, MPH
Influenza Division, CDC**

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US Influenza Vaccine Efficacy
Network

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Lenee Blanton

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Updated Information for 2015-16

Discussed and Approved at February 2015 ACIP Meeting

- ❑ Reiteration of core guidance that routine annual influenza vaccination is recommended for all persons 6 months of age and older
- ❑ Revision of recommendations regarding use of LAIV for healthy children 2 through 8 years of age
 - No preference is expressed for LAIV or IIV for any person aged 2 through 49 years for whom either vaccine is appropriate.

Further Proposed Updates for 2015-16

- ❑ U.S. influenza vaccine composition for 2015-16
- ❑ Updated influenza vaccine product descriptions, reflecting new licensures, labeling information, and expected availability
- ❑ Revised algorithm for determining number of doses needed for children 6 months through 8 years of age

U.S. Influenza Vaccine Composition for 2015-16

FDA Vaccine and Related Biologic Products Advisory Committee (VRBPAC)—March 4, 2015:

- An A/California/7/2009 (H1N1)pdm09-like virus;
- An A/Switzerland/9715293/2013 (H3N2)-like virus
 - replaces A/Texas/50/2012 (H3N2)-like
- A B/Phuket/3073/2013-like virus (Yamagata lineage)
 - replaces B/Massachusetts/2/2012-like (Yamagata lineage)
- For quadrivalent vaccines, these viruses PLUS a B/Brisbane/60/2008-like virus (Victoria lineage)

Influenza Vaccine Product Updates for 2015-16

New licensures, labeling information, and expected presentations reflected in text and/or table:

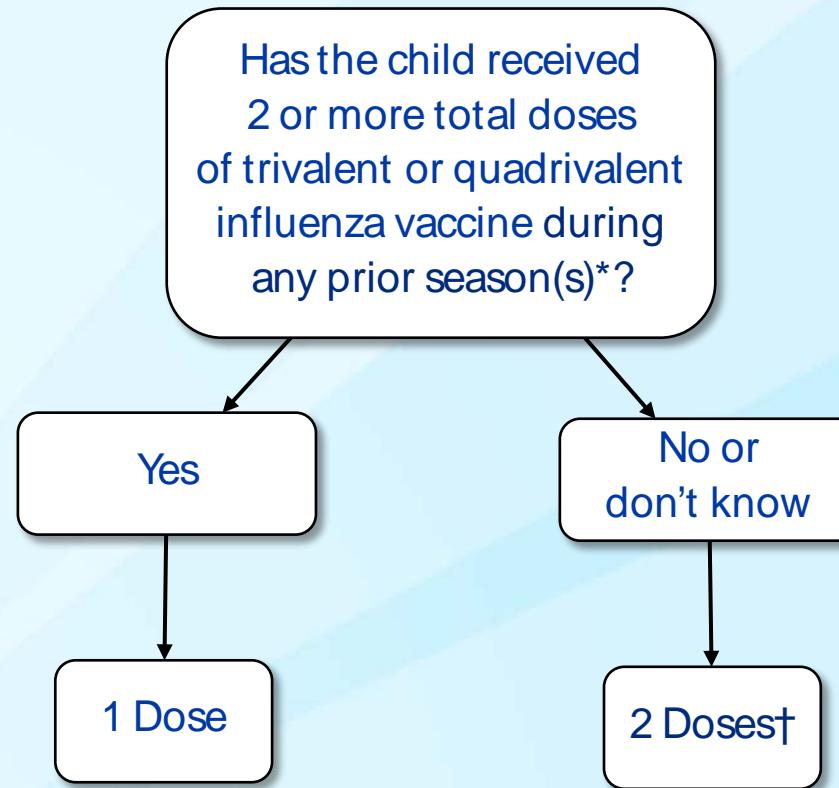
- FluZone® Intradermal Quadrivalent IIV
- Expanded age indication for Flublok® (now 18 and older)
 - Previously noted in online vaccine table and the ACIP Adult Schedule
- Approval of administration of Afluria® by Stratis® jet injector for persons 18 through 64 years of age
 - Previously noted in online vaccine table
- Any additional labeling changes arising prior to publication

Determination of Doses Needed for Children Months Through 8 Years of Age

- Since 2010-2011, algorithm for determining appropriate number of doses in this age group has considered vaccine doses containing A(H1N1)pdm09 separately
 - As a pandemic virus, considered relatively antigenically novel
 - Led to somewhat complicated algorithm(s)
- This virus has been represented by an A/California/7/2009(H1N1-like virus in trivalent and quadrivalent vaccines since 2010-2011
 - Likely a diminishing number of children each season who have not been exposed to this virus
- The WG proposes language that would eliminate separate counting of doses containing A(H1N1)pdm09-type virus
 - Single simplified algorithm

Determination of Doses Needed for Children Months Through 8 Years of Age

Proposed Approach for 2015-16 Season (ORIGINAL VERSION)

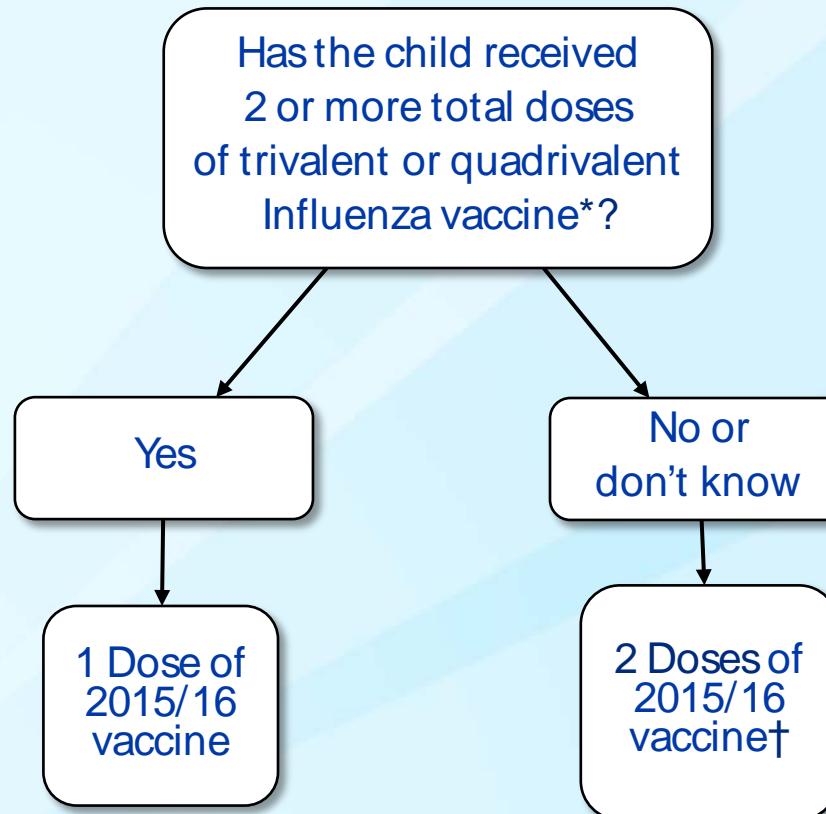


* The two doses need not have been received during the same season.

† Doses should be administered ≥ 4 weeks apart

Determination of Doses Needed for Children Months Through 8 Years of Age

Proposed Approach for 2015-16 Season (EDITED PER ACIP DISCUSSION)



* The two doses need not have been received during the same season or consecutive seasons.

† Doses should be administered ≥ 4 weeks apart

Thank You

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: www.cdc.gov