



Influenza WG Considerations and Proposed Recommendations

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2017-18 ACIP Influenza Recommendations— Core Recommendation

- Re-iterates core recommendation that annual influenza vaccination is recommended for all persons aged 6 months and older who do not have contraindications.

2017-18 ACIP Influenza Recommendations— Vaccine Composition for 2017-18

- U.S. Influenza vaccine composition for 2017-18
 - Trivalent Vaccines
 - A/Michigan/45/2015 (H1N1)pdm09-like virus (updated)
 - A/Hong Kong/4801/2014 (H3N2)-like virus
 - B/Brisbane/60/2008-like virus (Victoria lineage)
 - Quadrivalent Vaccines
 - Above three, plus B/Phuket/3073/2013-like virus (Yamagata lineage)

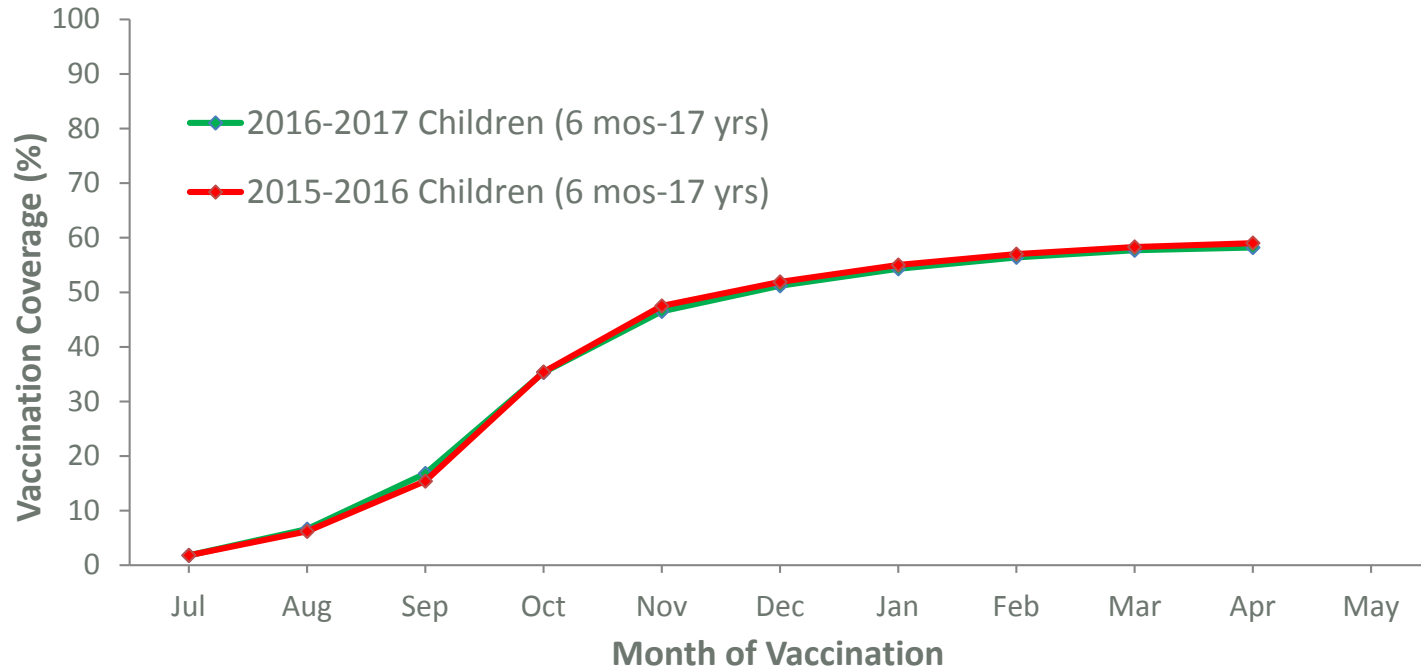
2017-18 ACIP Influenza Recommendations— New Products/Licensure Changes

- Discussion of products licensed and changes in existing approval since publication of last statement (information previously presented to ACIP):
 - Afluria Quadrivalent (IIV4, Seqirus), for persons aged ≥ 18 years
 - Flublok Quadrivalent (RIV4, Protein Sciences), for persons aged ≥ 18 years
 - FluLaval Quadrivalent (at 0.5cc dose) for children aged ≥ 6 months (previously licensed for ≥ 3 years)

2017-18 ACIP Influenza Recommendations— Flumist Quadrivalent (LAIV4)

- Extends the recommendation that LAIV not be used into the 2017-18 season.
- Awaiting further data (anticipated October 2017).

Preliminary Influenza Vaccination Coverage for the 2016-17 Season Compared with 2015-16 Final Season Estimates, Children, NIS-Flu, United States*



* Preliminary child results from NIS-Flu interviews conducted October through May for 2016-17 season, Final child results from NIS-Flu interviews conducted October through June for 2015-16 season.

Preliminary Influenza Vaccination Coverage for the 2016-17 Season Compared with 2015-16 Final Season Estimates by Age Group, Children, NIS-Flu, United States*

Age Group	2015-16 Season, Vaccinations received through April 2016 % (95% CI) [†]	2016-17 Season, Vaccinations received through April 2017 % (95% CI) [†]
All Children (6 months–17 years)	59.0 ± 0.8	58.2 ± 0.8
6 months–4 years	69.7 ± 1.3	69.4 ± 1.4
5–12 years	61.5 ± 1.2	59.2 ± 1.2 [§]
13–17 years	46.6 ± 1.3	47.7 ± 1.5

* Preliminary child results from NIS-Flu interviews conducted October through May for 2016-17 season, Final child results from NIS-Flu interviews conducted October through June for 2015-16 season.

[†] % - Kaplan-Meier coverage estimate; 95% CI - confidence interval half-width.

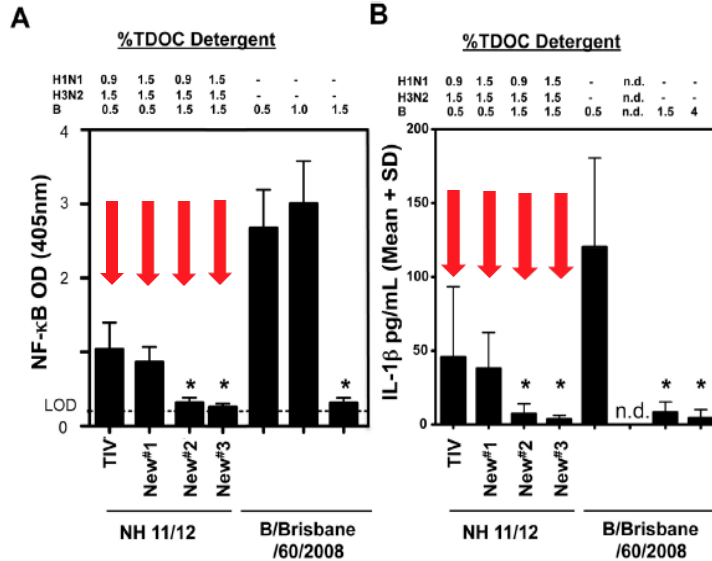
[§] Statistically significant decrease in preliminary 2016-17 coverage compared to 2015-16 final coverage.

2017-18 ACIP Influenza Recommendations— Proposed Recommendation for Afluria (IIV3) (1)

- Afluria is licensed by FDA for persons aged ≥ 5 years.
- Since 2010-11, ACIP has recommended Afluria for persons aged ≥ 9 years, following reports of febrile seizures and reactions in association with the 2010 Southern Hemisphere formulation
- February 2017: ACIP heard presentation from Seqirus summarizing investigation into root cause of reactions and manufacturing changes

Effect of Varying TDOC levels on Cytokine Signaling

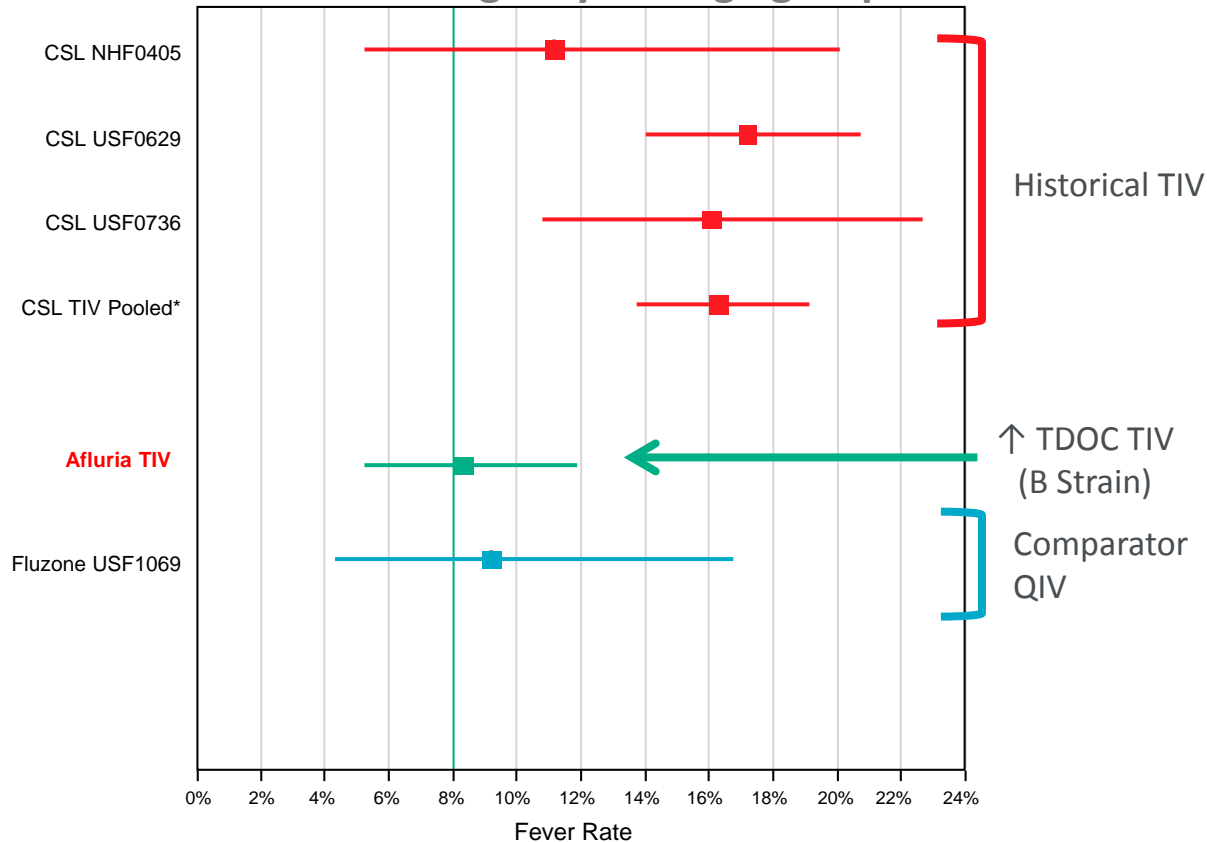
	%TDOC H1N1 A/California/07/2009		%TDOC H3N2 A/Victoria/210/2009		%TDOC B B/Brisbane/60/2008
Std TIV	0.9%		1.5%		0.5%
New #1	1.5% ↑		1.5% ↔		0.5% ↔
New #2	0.9% ↔		1.5% ↔		1.5% ↑
New #3	1.5% ↑		1.5% ↔		1.5% ↑



Increasing TDOC for both H1N1 /California/07/2009 and B/Brisbane/60/2008 resulted in the greatest attenuation of the inflammatory signal

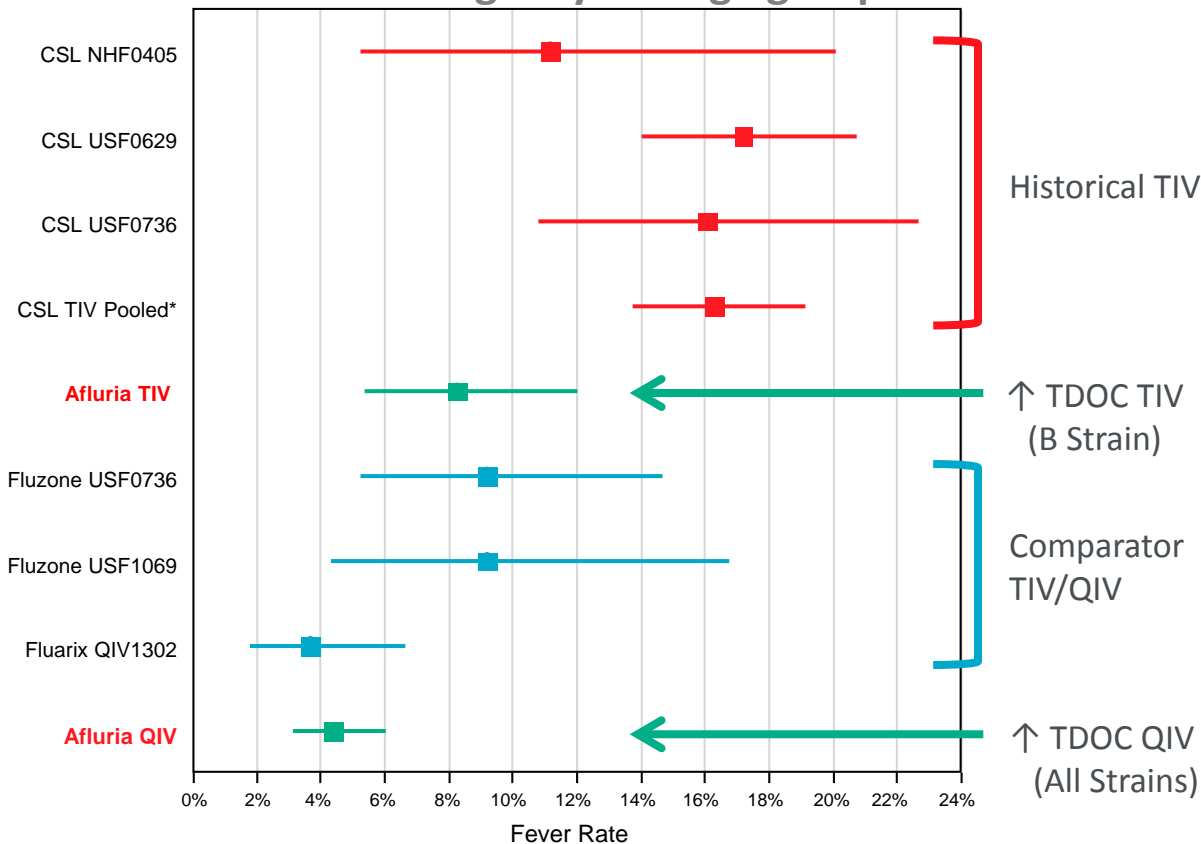
Comparison with Historical Fever Rates – Modified TIV

5 through 8 years age group



Comparison with Historical Fever Rates – Afluria QIV

5 through 8 years age group



Summary of Afluria (TIV & QIV) Safety in 5 -18 year olds

- Acceptable Safety Profile in TIV & QIV
 - Fever rates (5 to < 9 years) similar to comparator
 - Fever rates (5 to < 9 years) less than historical vaccines

- Both Afluria TIV & QIV will be offered in the U.S. during the 2017-2018 Influenza season

2017-18 ACIP Influenza Recommendations— Proposed Recommendation for Afluria (IIV3) (2)

- It is proposed that Table 1 be modified to indicate that Afluria is indicated for persons aged ≥ 5 years, and that the footnote stating that it is recommended by ACIP for persons aged ≥ 9 years be removed.

2017-18 ACIP Influenza Recommendations—

Proposed Recommendation for Vaccination of Pregnant Women

- Pregnant women with risk factors for severe influenza illness recommended to receive influenza vaccine since 1960s.
- Vaccination during 2nd and 3rd trimesters recommended during 1990s as later pregnancy noted to be a risk factor for severe illness, hospitalization.
- Influenza vaccination recommended by ACIP for women who will be pregnant during influenza season since 2004
 - Increased risk for severe influenza illness in pregnant women, particularly during second and third trimesters;
 - Adverse pregnancy outcomes in some studies
 - Association of some birth defects with maternal fever
- Current language states pregnant women should receive inactivated influenza vaccine (IIV)

2017-18 ACIP Influenza Recommendations—

Proposed Recommendation for Vaccination of Pregnant Women

- WG discussed information on pregnancy reports presented by Protein Sciences concerning Flublok (RIV)
- In addition, three Vaccine Adverse Event Reporting System (VAERS) reports since 2013 of pregnant women who received Flublok
 - In two reports no adverse event reported
 - In one report woman presented in clinic with vaginal bleeding and suspected spontaneous abortion

2017-18 ACIP Influenza Recommendations— Proposed Recommendation for Vaccination of Pregnant Women

WG considerations (continued)

- Few data concerning use of Flublok in pregnancy
- More experience with IIVs:
 - Evidence base, mostly observational studies and safety surveillance data, is reassuring
 - Longer clinical experience with IIVs than with RIV
 - However, data more limited for first trimester, and also for some newer inactivated vaccines (quadrivalents, cell based vaccines)

2017-18 ACIP Influenza Recommendations—

Proposed Recommendation for Vaccination of Pregnant Women

WG considerations (continued)

- General safety profile of Flublok in comparison to IIVs reassuring
 - Reactogenicity similar to that observed with IIVs in clinical studies
- Relatively few additives listed in RIV package insert (e.g., preservatives, antibiotics, gelatin, egg protein)
 - However, not all inactivated vaccines contain these agents
 - Does contain some residual insect cell and *Baculovirus* proteins/DNA
- On initial licensure, RIV3 designated Pregnancy Category B (similar to most IIVs)
 - Flublok Quadrivalent (RIV4) package insert includes new FDA Pregnancy and Lactation Labeling language

2017-18 ACIP Influenza Recommendations— Proposed Recommendation for Vaccination of Pregnant Women

2016-17:

“Because pregnant and postpartum women are at higher risk for severe illness and complications from influenza than women who are not pregnant, the ACIP recommends that all women who are pregnant or who might be pregnant in the upcoming influenza season receive **IIV**. Influenza vaccination can be administered at any time during pregnancy, before and during the influenza season.”

Proposed New:

“Because pregnant and postpartum women are at higher risk for severe illness and complications from influenza than women who are not pregnant, the ACIP recommends that all women who are pregnant or who might be pregnant in the upcoming influenza season receive **influenza vaccine. Any licensed, recommended, and age-appropriate, trivalent or quadrivalent IIV or RIV may be used.** Influenza vaccination can be administered at any time during pregnancy, before and during the influenza season”

For more information, contact CDC
1-800-CDC-INFO (232-4636)
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