

ACIP Update, 2014: Summary of February, 2014 Meeting

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Meeting Topics

- ❑ **Influenza: vaccine effectiveness, LAIV vs IIV in children, new vaccine strains**
- ❑ **Meningococcal vaccine: MSM, HIV, and group B vaccine**
- ❑ **Pneumococcal conjugate vaccine schedule**
- ❑ **Yellow Fever booster dose**
- ❑ **General Recommendations: Storage and Handling**
- ❑ **Tdap vaccines' safety**
- ❑ **HPV: cancer attribution, HPV 9 vaccine**
- ❑ **Smallpox: ACAM 2000 vaccine for laboratory workers**

Influenza



❑ Interim VE:

- 61% - similar across age groups and influenza types
- http://www.cdc.gov/mmwr/preview/mmwrhtml/mm630/a1.htm?s_cid=mm630/a1_w

❑ LAIV vs IIV in children:

- modest increased benefit of LAIV in young children
- No safety concerns in those 2 years and older
- No preference expressed by Working Group

❑ **Vote taken on recommendations with few changes, including no strain changes, as recommended by WHO (and FDA's VRBPAC on Feb 28):**

- A/California/7/2009 (H1N1)
- A/Texas/50/2012 (H3N2)
- B/Massachusetts/2/2012
- B/Brisbane/60/2008.

Meningococcal Disease and Vaccines

❑ Meningococcal disease and

HIV infection

Modest increase in risk of disease

Lower risk than microbiologists

Low # of cases

No change in recommendations



Men who have sex with men (MSM)

Outbreaks since 2000 in Toronto, Chicago, NYC, LA

Small increased risk, low disease burden

No change in recommendations

Meningococcal group B outbreaks, Princeton U and UCSB

Vaccination with IND Novartis vaccine underway

More information at <http://www.cdc.gov/meningococcal/outbreaks/vaccine-serogroupB.html>

Pneumococcal Vaccine Schedule

- ❑ Reviewed GRADE evidence for immunogenicity, effectiveness, and safety of 3+1, 2+1, and 3+0 schedules
- ❑ Address perceptions
 - childhood schedule has become crowded, confusing
 - safety concerns about multiple injections
- ❑ ACIP Workgroup concluded
 - 3-dose schedules likely equivalent to 4-dose schedule
 - Implementation issues require more deliberation, e.g., recommendations for high-risk groups (AI/AN, other HR children)
 - Potential impact of non-adherence to be reviewed
 - No vote taken



Yellow Fever Vaccine Booster

- ❑ **WHO Strategic Advisory Group of Experts (SAGE) reviewed YF booster dose data and policy:**
 - No efficacy data; policy based in part on neutralizing antibody data
 - Current 10-yr booster recommendation based on limited data (80% of vaccinees have protective antibodies ≥ 10 yrs post-vaccination)
 - 99% of primary vaccinees develop protective antibody titers, and maintain them for decades, possibly lifetime
 - Few primary vaccine failures reported
- ❑ **SAGE recommended:**
 - “A single dose of YF vaccine is sufficient to confer sustained life-long protective immunity against YF disease; a booster dose is not necessary.”
- ❑ **CDC will review data, use GRADE process, and develop recommendations for YF booster doses in travelers, lab workers**

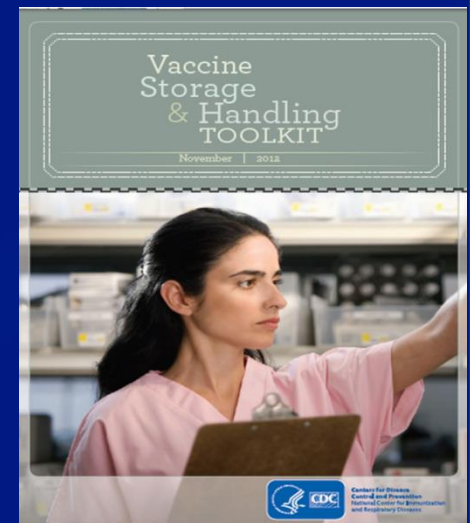


General Recommendations: Storage and Handling (S&H)

❑ 2016 Recommendations will address

- Storage temperature
- Response to out-of-range temperature reading
- Best practices (refer to CDC S&H Toolkit)
 - Equipment recommendations/requirements
 - Maintaining cold chain
 - Routine S&H practices
 - Inventory management
 - Emergency procedures to protect vaccines

❑ Next presentation will address persons with altered immunocompetence



Tdap in Pregnancy: Safety



□ VAERS

- Reviewed data from 10/11/2011 thru 01/13/2014
- Compared to period prior to current every pregnancy recommendation (Jan 2005-Jun 2010)
- Results
 - Increase in proportion of serious reports
 - Increase in proportion of some pregnancy-specific outcomes (e.g., stillbirths, preterm deliveries)
 - Increase in proportion of non-pregnancy specific outcomes (e.g., injection site reactions)
 - Most vaccinations now in 2nd and 3rd trimesters

□ VSD

- No adverse birth outcome associations
- Chorioamnionitis (CA) risk increased after Tdap – biological plausibility unclear, not controlled for other CA risk factors

HPV Update

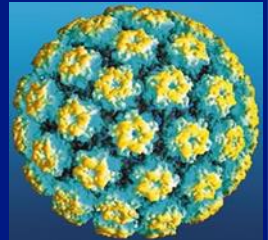
□ HPV Type Attribution in U.S. HPV-associated disease

■ CIN2+ lesions

- ~50% attributable to HPV types 16 and 18
- ~25% attributable to 5 additional types in investigational 9-valent vaccine
- Largest % ($\geq 41\%$) of lesions in all racial/ethnic groups studied attributable to types 16 and 18

■ HPV-associated cancers

- ~62% attributable to types 16 and 18
- ~11% attributable to other 5 types
- Largest % of lesions in all racial/ethnic groups attributable to types 16 and 18
 - No differences by race for cervical, vaginal, vulvar, penile, or anal cancers
 - Smaller % of oro-pharyngeal cancers attributable to HPV among non-Hispanic blacks; smaller % attributable to types 16 and 18



HPV Update – 2

□ 9-valent vaccine:

- Pivotal efficacy trial among females 16-26 years
 - Non-inferior to HPV-4 immunogenicity
 - 97% protection against new HPV types (31, 33, 45, 52, 58)-related disease
- Immunobridging studies in adolescents
 - Non-inferior immunogenicity in adolescents compared to adults
- Estimated Timeline:
 - BLA submitted to FDA, approval possible by end of 2014
ACIP vote February, 2015
 - Considerations will include routine adolescent vaccination, older adolescents and adults, and persons previously vaccinated with HPV-4

□ Considerations for 2-dose HPV vaccine schedule

Smallpox Vaccine for Laboratory Workers

- ❑ **Policy Question: Should new vaccine ACAM2000 be recommended routinely for persons at risk of orthopox disease?**

- ❑ **GRADE Evidence compared to Dryvax:**

- Cutaneous and neutralizing antibody responses:
non-inferior primary, inferior revaccination responses
- Critical Harms

- No difference in serious outcomes
- Myopericarditis no difference without sequelae; meaning of persistent ECG changes without symptoms unclear w ACAM2000

- ❑ **ACIP WG will update and revise recommendations for review and vote**



Thank you

Questions?