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/mm6307a1.htm?s_cid=mm6307a1_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6307a1.htm?s_cid=mm6307a1_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.
Menningococcal Disease and Vaccines

- Menningococcal 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
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.
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 % (>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?