

# **ACIP Working Group on Vaccines during Pregnancy and Breastfeeding**

**Carol J. Baker, MD – Chair**

**Stephanie Schrag, PhD - CDC Lead**

*ACIP Public Meeting*

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*Atlanta, GA*

# Terms of Reference: January 2007

1. Review current recommendations on use of vaccines during pregnancy and breastfeeding
2. Establish “guiding principles” for developing recommendations
3. Facilitate consistency in recommendations issued by ACIP
4. Promote harmonization across professional organizations

# Workgroup Membership

- Carol J. Baker – Chair
- Tracy Lieu – ACIP
- Kathy Neuzil- ACIP
- Doug Campos-Outcalt – AAFP
- Stanley Gall – ACOG
- Kevin Ault – ACOG
- Marion Gruber – FDA
- David Kimberlin – AAP
- Stephanie Schrag – CDC lead
- George Carlone – Tdap
- Jan Cragan – Birth defects
- Tony Fiore – Influenza
- Julianne Gee – Vaccine safety
- Diane Hoffman – Health Law
- Megan Lindley – Evidence-based workgroup
- Lauri Markowitz – HPV
- Nancy Rosenstein Messonnier – Tdap
- Gina Mootrey – Adult schedule
- Susan Reef – Rubella
- Fran Rubin - NIAID
- Judy Schmidt - CDC
- Barbara Slade – Vaccine safety
- Tami Skoff – CDC
- Sandy Steiner – CDC
- Susan Wang – Hepatitis B

# Workgroup Charge 1

- Reviewed existing recommendations
  - ACIP recommendations (March '07)
  - FDA vaccination indications and vaccine labeling language (April '07)
  - Recommendations of key professional organizations: AAP, ACOG, and AAFP (May '07)
- Presented findings at June '07 ACIP
  - Wide variation within ACIP statements: language, format and rationale/process
  - Many differences between ACIP and FDA
  - A few examples of lack of harmonization with AAP or ACOG

# Central Conclusion

- Not enough evidence to make general recommendations for vaccination during pregnancy or breastfeeding
  - for all vaccines
  - for specific subclasses of vaccines

Thus, each product requires a vaccine-specific statement....

# **WG Charge 2: Develop Guiding Principles for Future Recommendations**

## **– Target audience**

- Anyone drafting an ACIP statement on a vaccine for use in adolescent or adult women

## **– Product**

- Internal document for ACIP workgroups, website
- Short, user-friendly

## **– Status**

- A draft has been circulated to workgroup, Dale Morse, Larry Pickering, Jean Smith and Beth Bell
- A revised version will be circulated to full ACIP for comment directly after February meeting

# Guiding Principles: *Sneak Preview*

1. Guidance on structure and language of pregnancy and breastfeeding components of ACIP vaccine-specific statements
2. Guidance on process for formulating recommendations

***Key challenge: lack of evidence***

3. Appendix: Review of key issues regarding vaccination during pregnancy and breastfeeding

# Guidance on Structure: An Example

- All statements should have a background subsection on pregnancy and breastfeeding
- Topics to address
  - Disease burden
    - Pregnant women, fetus, newborns and young infants
  - Vaccination during pregnancy
    - Objective and Rationale
    - Immunogenicity and Efficacy
    - Safety and Timing
  - Vaccination during breastfeeding
    - Same subcategories as above
  - Cost-effectiveness
    - If pregnancy/breastfeeding issues are unique
  - Alternatives or adjuncts to vaccination
  - Logistics
  - Areas for future research



# Guidance on Language

- Primary focus: Recommendations section
- Guidance includes standard language templates
  - Four recommendation templates\*
    - Contraindication (eg, MMR, varicella)
    - Precaution (the vast majority fall here)
    - Neither (eg, Td)
    - Pregnancy is an indication for vaccination (eg, Inactivated influenza)
  - Several timing templates

\* The examples in this slide focus on pregnancy; similar categories are presented for breastfeeding

# Sample Language Templates

- Vaccination recommendation
  - “Pregnancy is a precaution and under normal circumstances vaccination should be deferred; vaccine should only be given when benefits outweigh risks”
- Timing
  - “Vaccine may be administered at any time postpartum for all women, whether or not they intend to breastfeed”

# Guidance on Process: Policy Decisions

- Review unpublished/pre-licensure data
- Assess whether there will be more data soon
- Assess safety monitoring: could adverse events be detected if they occurred?
- Review decisions of other respected organizations
- Consider ACIP “precedents”
  - Pregnancy
    - Live vaccines pose most theoretical concern
    - Vaccination during pregnancy most favored when provides direct protection to mom
    - More comfort with 2<sup>nd</sup> or 3<sup>rd</sup> trimester vaccination
  - Breastfeeding
    - Vaccination of breastfeeding women generally viewed as safe
    - Smallpox is only contraindicated vaccine for breastfeeding women

# Process: Decision-making in the Absence of Adequate Data

- Suggested areas of expertise to include in deliberations
- Suggested strategies for obtaining unbiased input
- What to do when expert opinion does not reach consensus

# Guiding Principles: Next Steps

- Circulate guiding principles to full ACIP for comment (first 3 weeks of March)
- Revise, finalize and clear document
- Post on ACIP website, circulate to WG chairs, issue MMWR notice to readers (?)
- *Review upcoming ACIP statements to assess whether they implement the guiding principles (?)*

# WG Charge 3: Facilitate Consistency in ACIP Recommendations

- Vaccine-specific workgroups must resolve inconsistencies
  - our WG is not charged with making vaccine-specific recommendations
- Guiding principles document provides the necessary facilitation
- CDC ACIP staff will ensure that the guidance is followed
- Inconsistencies in existing statements will be addressed as they come due for routine updates

# WG Charge 4: Promote Harmonization Across Professional Organizations

- *Aspirational* charge
- Where data are lacking, differences in expert opinion may lead to lack of harmonization

# Anticipated Concerns

- **“Teeth”**: How will the ACIP process ensure the guiding principles are used?
- **Narrow Scope**: Why can't ACIP do more, push the envelope?
- **Workgroup Load**: Do vaccine-specific workgroups have the time to do justice to a complicated issue like pregnancy?  
Breastfeeding?
- **Disappointment**: No way to prevent lack of harmonization across organizations (eg, Tdap)?