

# ADVISORY COMMISSION ON CHILDHOOD VACCINES MATERNAL IMMUNIZATION WORKING GROUP DRAFT RECOMMENDATIONS

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# Outline



- Background
- Charge
- Recommendations
- Discussion

# Background

- The Advisory Commission on Immunization Practices (ACIP) currently recommends that:
  - ▣ all pregnant women with a gestational age of 20 weeks or more receive a tetanus-diphtheria-acellular pertussis (Tdap) immunization during each pregnancy
  - ▣ all pregnant women receive inactivated influenza vaccine
- New vaccines against respiratory syncytial virus (RSV) and Group B Streptococcus are currently under development and, if approved, would likely be exclusively recommended for pregnant women

# Impact of current (and potential) maternal immunization recommendations

- Address increased risk of morbidity and mortality associated with influenza in pregnant women
- Protect young infants by preventing transmission of pertussis, influenza, tetanus, RSV and Group B Streptococcus
  - ▣ At risk for poor outcomes associated with these diseases and are too young to be vaccinated.
- Decrease the risk of exposure by preventing disease in mothers
- Provide protection to the young infant through the passage of maternal antibodies.

# Safety and efficacy of maternal immunization

- Transplacental passage of maternal IgG antibodies substantially increases in the last 4 to 6 weeks of gestation
- Current studies show that maternal immunization benefits the mother and the infant, and have not identified any vaccine-related adverse events specific to vaccinated pregnant women and their infants<sup>1</sup>

<sup>1</sup> Refers to vaccines routinely recommended for the general population, exclusive of special situations such as bioterrorism, travel or pandemic settings

# Safety and efficacy of maternal immunization

- Key safety outcomes include potential for teratogenicity, growth or functional impairment, or impaired viability due to *in utero* exposure to a vaccine. Many of these outcomes occur at high rates in the general population:
  - ▣ Spontaneous abortion (10.4-22.4%)
  - ▣ Preterm birth (11.9%)
  - ▣ Small for gestational age (8-16%)
  - ▣ Birth defects (3%)
  
- No evidence that inactivated virus or bacterial vaccines or toxoids present a risk to the fetus for these or other outcomes

# Safety and efficacy of maternal immunization

- Theoretical risk that administration of live virus vaccines could result in transmission of vaccine virus to a fetus.
  - ▣ Live virus vaccines are contraindicated for administration to women 28 days before conception through pregnancy and no live virus vaccines are currently recommended for pregnant women.
- No evidence of fetal infection or malformation from pregnancy registries if live virus vaccines routinely recommended for the general population are inadvertently administered during pregnancy

# The Vaccine Injury Compensation Program and Maternal Immunization

- Successful implementation of recommendations for maternal immunization will require that women and health care providers trust the safety of vaccines during pregnancy.
  
- Important to ensure that:
  - ▣ current safety assessment and monitoring processes can effectively define, identify and respond to safety issues.
  - ▣ the VICP is available to mothers and their infants when vaccines are administered during pregnancy

# Background

- Convened in June 2012 to address the need for the Vaccine Injury Compensation Program to address evolving recommendations for vaccination during pregnancy
- In-person and conference call meetings every 1-2 months to discuss and develop recommendations for 4 charges
- Collaboration with the National Vaccine Advisory Committee Maternal Immunization Working Group
- Present draft recommendations at June 2013 ACCV meeting
- Final report coming soon

## Charge 1: Eligibility for compensation for injuries from vaccines not currently covered by the vaccine injury compensation program

- Provide information to ACCV regarding eligibility for compensation by the VICP for injuries from vaccines recommended for/sometimes given to pregnant women if the vaccines are not recommended for routine administration to children and are therefore not currently covered under the VICP
- Identify the pros and cons of covering such vaccines and providing compensation for such injuries under the VICP
- Develop a draft ACCV recommendation for the Secretary regarding covering such vaccines and providing compensation for such injuries under the VICP

**No currently recommended vaccines currently fit this condition, however, licensure of an RSV and Group B Streptococcus vaccine for exclusive administration to pregnant women is likely in the near future.**

Charge 2: Eligibility for compensation for injuries sustained by a live-born infant from covered vaccines received by the mother while the infant was in utero.

- Provide information to the ACCV regarding the eligibility for compensation by the VICP for injuries sustained by a live-born infant from covered vaccines received by the mother while the infant was in utero.
- Identify the pros and cons of providing compensation for such injuries under the VICP.
- Develop a draft ACCV recommendation for the Secretary regarding compensation for such injuries under the VICP.

**While the mother is ~~the~~ recipient of such vaccines, the group considered eligibility of the infant**

# Charges 3 and 4

- Charge 3: Provide information to the ACCV regarding current safety monitoring infrastructure of vaccines administered to pregnant women in light of expanding recommendations for maternal immunization.
- Review ACCV membership guidelines and consider inclusion of individuals who provide care to pregnant women to reflect changes in VICP

# What the working group reviewed

- available data about mechanisms of protection, efficacy and safety of vaccines administered during pregnancy
- available data from pre-licensure trials for RSV and Group B Streptococcus vaccines
- vaccine safety infrastructure
- activities of maternal immunization working group from NVAC
- current statute guiding program activities

# Draft Recommendations

Benefits and challenges of expanding coverage

Suggested Recommendation

Potential approaches to pursue recommendation

Benefits and challenges of each approach

# Charge 1: Compensability of In Utero Injuries from Vaccines Not Currently Covered

## □ **Benefits**

- match the evolution of VICP and the National Vaccine Program
- provide public reassurance that injuries from new vaccines recommended for pregnant women may be pursued under the VICP
- address barriers that the vaccine industry faces regarding liability to foster vaccine development and ensure an adequate supply of vaccines

## □ **Challenges**

- potential administrative cost to the VICP
  - additional excise tax on new vaccines and additional resources drawn from the Trust Fund for claims from expanded coverage
  - public perception that government is “pushing” more vaccines
- 
- Expanding coverage is not equivalent to recommending a new vaccine
  - Important to emphasize potential benefit to the public through the protection of pregnant women and young infants

# Charge 1: Compensability of In Utero Injuries from Vaccines Not Currently Covered

- The ACCV recommends that the Secretary work to expand coverage under the VICP to include vaccines that are recommended for categories other than children (such as pregnant women) and are not specifically recommended for routine administration in children. We recommend that the Secretary take whatever steps are necessary and within her legal authority to attain such expansion.

# Charge 1: Potential avenues

- Statutory amendment
  - ▣ the Secretary of Health and Human Services could propose legislation through the A19 process which explicitly includes language to expand coverage to vaccines that are recommended for categories other than children (i.e. pregnant women).
  
- Pros: definitive path
- Cons:
  - ▣ could take a significant amount of time
  - ▣ may not come to fruition
  - ▣ may have little control over the ultimate statutory change

# Charge 1: Potential Avenues

- Administrative rule-making to adopt a broader interpretation of the current statute
  - interpret “routine administration to children” to include administration of vaccines to pregnant women, because such a pregnant population may include individuals in the pediatric age range.
  - an infant could be considered the beneficiary of maternal immunization through receipt of the maternal antibodies
- Pros: expeditious and provides flexibility for VICP to adapt to changes in the immunization program
- Cons: set precedent for inclusion of other vaccines recommended for individuals other than children which could require significant changes in program operation and expenditure of resources.

**Important caveat: This approach requires that a broad interpretation by the Secretary is legally permissible and consistent with the Congressional intent of the statute**

## Charge 2: Compensability of In Utero Injuries from Covered Vaccines

- Benefits and challenges of expanding coverage similar to Charge 1
  
- Live-born infants as eligible individual
  - term clearly defines the infant as a separate individual from the mother and therefore, should be considered a separate injured individual
  - A fetus is dependent upon the mother and it is difficult to separate the injury from the mother
  - miscarriages and/or stillbirth do not present the same challenge or liability as injury claims since these can be pursued as the mother's claim

## Charge 2: Compensability of In Utero Injuries from Covered Vaccines

- The ACCV recommends that the Secretary should - support eligibility to pursue compensation for injuries sustained by a live-born infant whose mother receives a vaccine while the infant is in utero. In order to further her support, we recommend that the Secretary take whatever steps are necessary and within her legal authority. A few options that the Secretary may wish to consider are supporting a statutory amendment, pursuing administrative rulemaking, or supporting a litigation strategy.

# Charge 2: Potential Avenues

- Statutory amendment
  - ▣ the Secretary could propose legislation through the A19 process which explicitly includes language to specify eligibility of live born infants whose mother received a vaccine while the infant was in utero
- Pros: definitive path
- Cons:
  - ▣ could take a significant amount of time
  - ▣ may not come to fruition
  - ▣ may have little control over the ultimate statutory change

# Charge 2: Potential Avenues

- Administrative rule-making to adopt a broader interpretation of the current statute
  - ▣ Infants directly receive a product of maternal vaccination through passage of maternal antibodies
- Pros:
  - ▣ expeditious and provides flexibility for VICP to adapt to changes in the immunization program
  - ▣ issuing a rule is public and formal statement which may provide reassurance to the public, vaccine manufacturers and program administrators
- Cons:
  - ▣ non-binding, as the Court is the final adjudicator of claims

**Important caveat: Approach requires that the Secretary have the authority to issue such regulations**

# Charge 2: Potential Approach

## □ Litigation Strategies

- seek a binding decision in the U.S. Court of Appeals for the Federal Circuit by communicating position to the court on eligibility ~~of live born infants whose mother received a covered vaccine~~ on a case-by-case basis
  - the court makes ultimate determination of eligibility and if appealed up to the U.S. Court of Appeals, could yield a binding decision that sets precedent.
- allow petitioners to pursue in utero injury claims ~~without objection~~ and proceed to an adjudication of the merits (while not resulting in a binding Federal Circuit decision)

## □ Pros:

- First litigation approach would be binding
- Second approach would allow pursuit of claims in the current program and special masters would

## □ Cons:

- Binding decision would require a case and multiple appeals
- Special masters may find against eligibility

# Summary for Charges 1 and 2

- Recommend that the Secretary:
  - Work to expand coverage under the VICP to include vaccines that are recommended for categories other than children (such as pregnant women) and are not specifically recommended for routine administration in children.
  - Support eligibility to pursue compensation for injuries sustained by a live-born infant whose mother receives a vaccine while the infant is in utero.
  
- Secretary may take whatever steps are necessary and within her legal authority. Considerations include:
  - Supporting a statutory amendment
  - Pursuing administrative rulemaking
  - Supporting a litigation strategy.

**Each approach comes with unique benefits and challenges, we suggest recommending that the Secretary solicit input from the public, vaccine manufacturers and immunization program administrators.**

# Charge 3: Vaccine Safety Monitoring Infrastructure

- Monitoring for safety events during pregnancy takes places through:
  - Vaccine Adverse Event Reporting System (VAERS)
  - pregnancy registries maintained by vaccine manufacturers
  - Active surveillance through the Vaccine Safety Data Link
- Vaccines and Medications in Pregnancy Surveillance System (VAMPSS)
  - prospective and case-control surveillance to study safety of exposures to vaccines and medications during pregnancy (<http://www.pregnancystudies.org/what-is-vampss/>).
- Several recent studies and reviews explore the use of current vaccine safety monitoring tools for maternal immunization

# Charge 4: ACCV Membership

- As immunization program expands, must ensure that appropriate perspective and expertise is represented within ACCV membership

Suggest recommending that the Secretary consider having an obstetrician with maternal-fetal expertise as one of the health professionals under the current ACCV charter

# Charge 4: ACCV Membership

- Current ACCV charter states that the ACCV should be composed of 9 members including:
  - 3 members who are health professionals, who are not employees of the U.S., and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least 2 shall be pediatricians.

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