

# Developing a mother-infant cohort in Sentinel's PRISM Program as a resource to monitor the safety of vaccine use during pregnancy

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# Disclosure

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- The views expressed in this presentation are those of the authors and are not intended to convey official U.S. Food and Drug Administration (FDA) policy or guidance
- No relationships to disclose

# Background

- Safety data on vaccine use during pregnancy for the mother and fetus are limited.
- Clinical trials do not typically include pregnant women.
- Limitations of passive surveillance systems and manufacturer-sponsored registries include lack of denominators or lack of formal comparators.

# Background

- The FDA-funded **Sentinel System** monitors the safety of FDA-approved medical products.
- Electronic claims and/or health record data from 17 partners.
- Strengths include **large population** (>500,000 deliveries) and ability to conduct formal epidemiologic assessment.

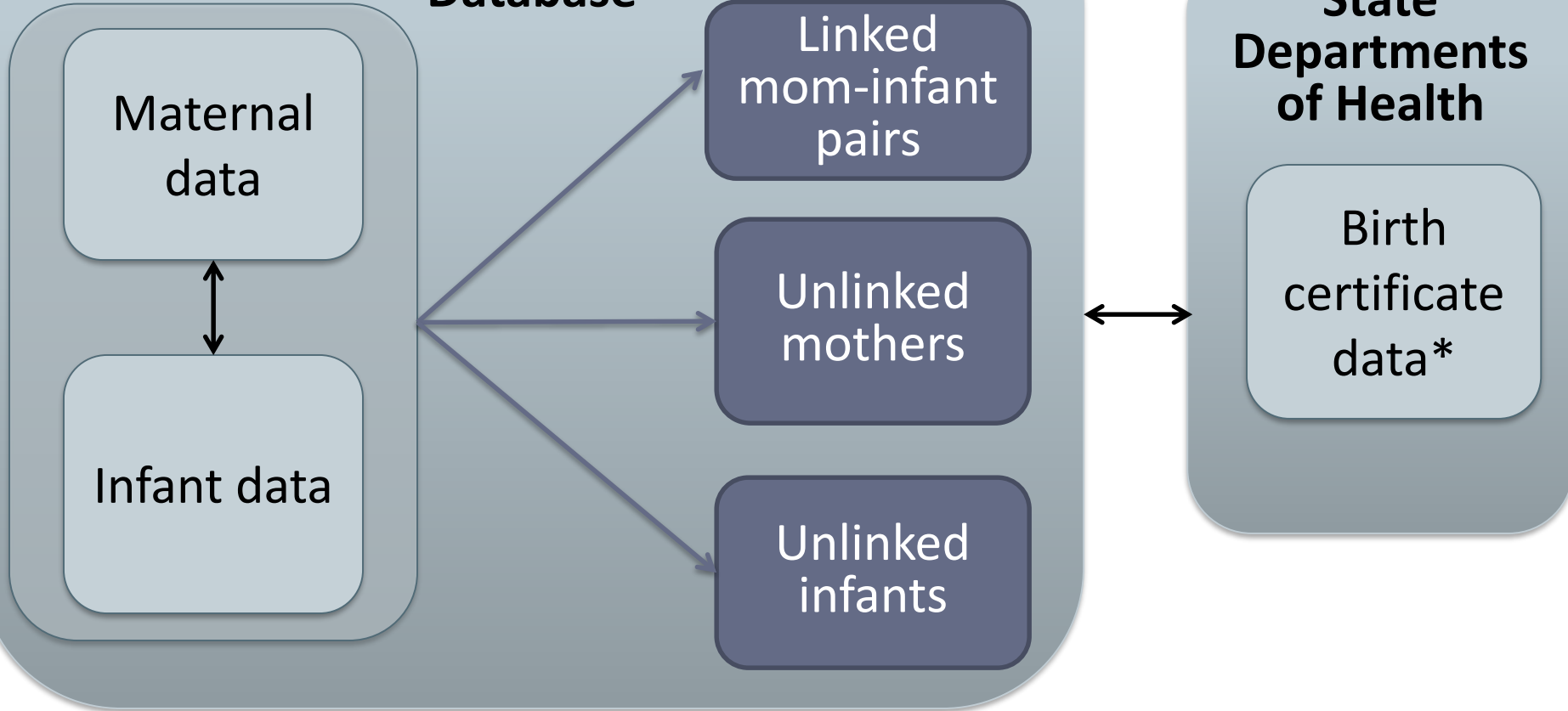
# Objective

- To develop capabilities to assess **infant outcomes** following **maternal vaccination** within Sentinel's vaccine safety system
  - Post-licensure Rapid Immunization Safety Monitoring Program (PRISM)
- To develop a **mother-infant cohort**
- To develop and validate a **claims-based gestational age algorithm** within the mother-infant cohort

# Study population

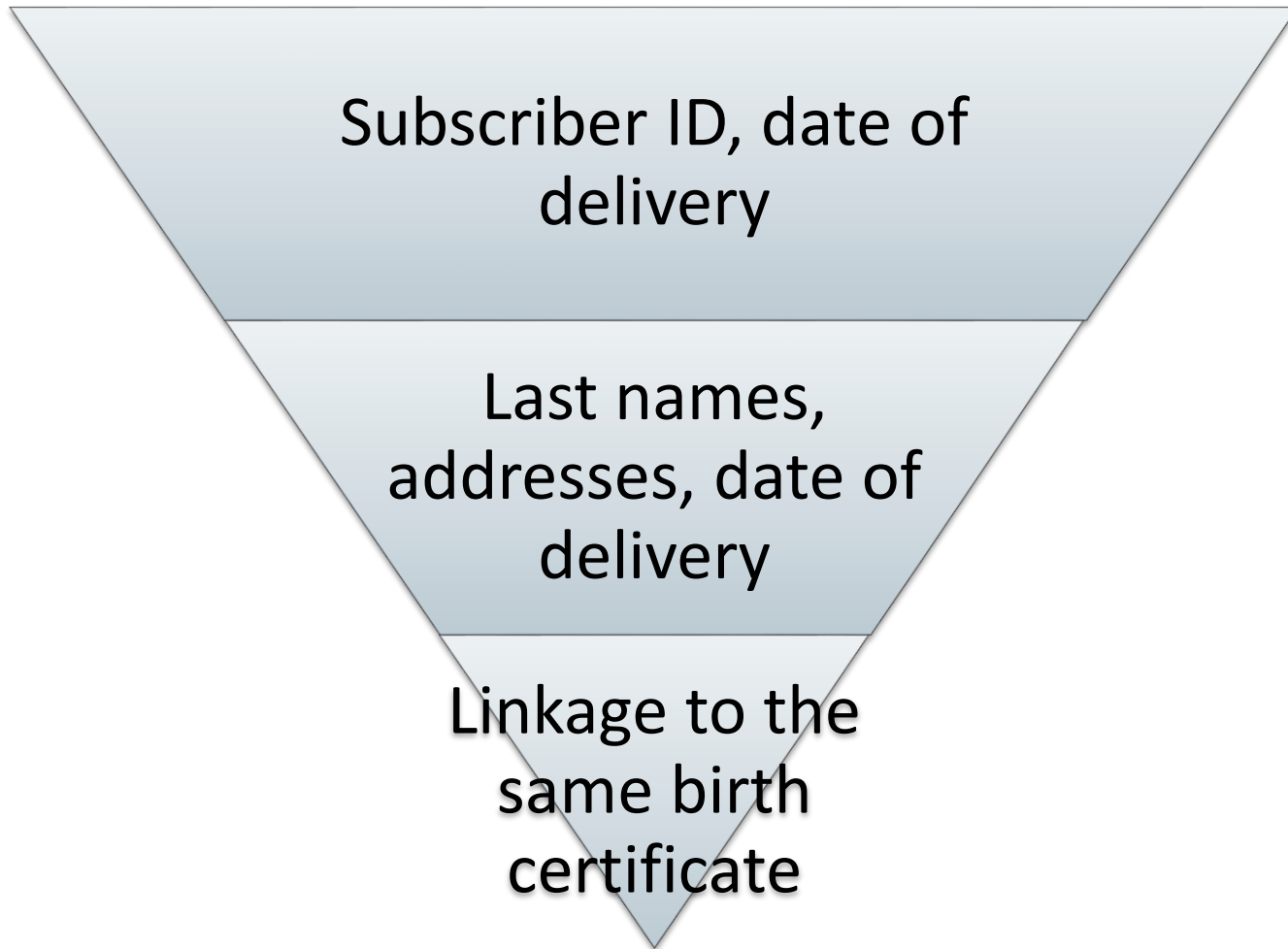
- 4 large Sentinel Data Partners: Aetna, HealthCore, Humana, Optum
  
- Women ages 10-54 with a diagnosis or procedure code for live birth delivery from 2004 through 2011
  - Continuous enrollment from 180 days before pregnancy start through 30 days after delivery
  
- Infants enrolled for at least one day

## Claims Data in Sentinel Distributed Database



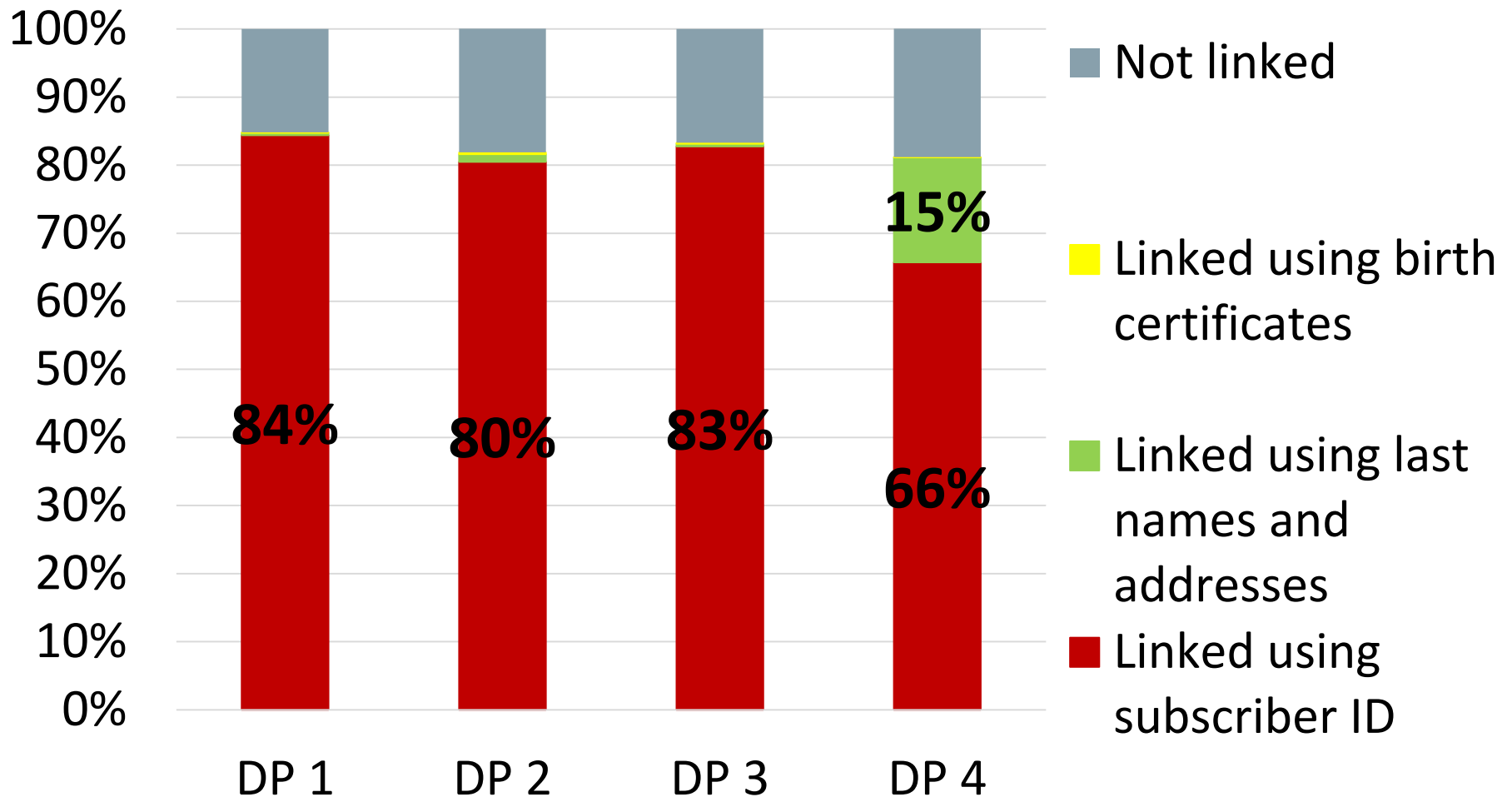
\*Birth certificates available for 9 states

# Methods to link deliveries to infants



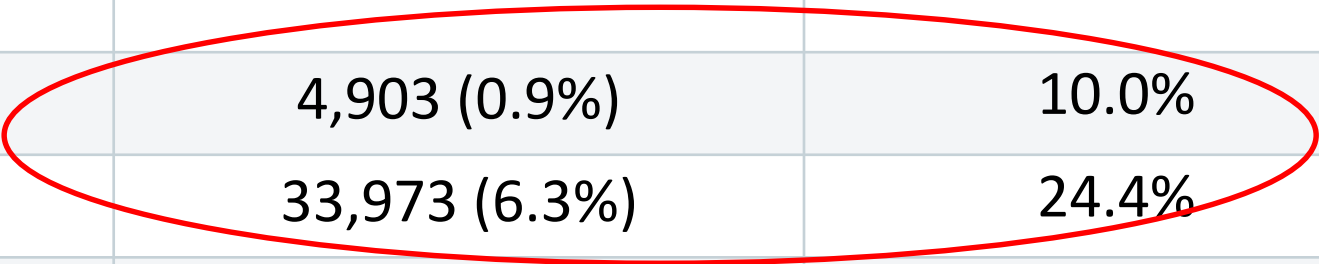


# Percent deliveries linked to infants (N=651,607)

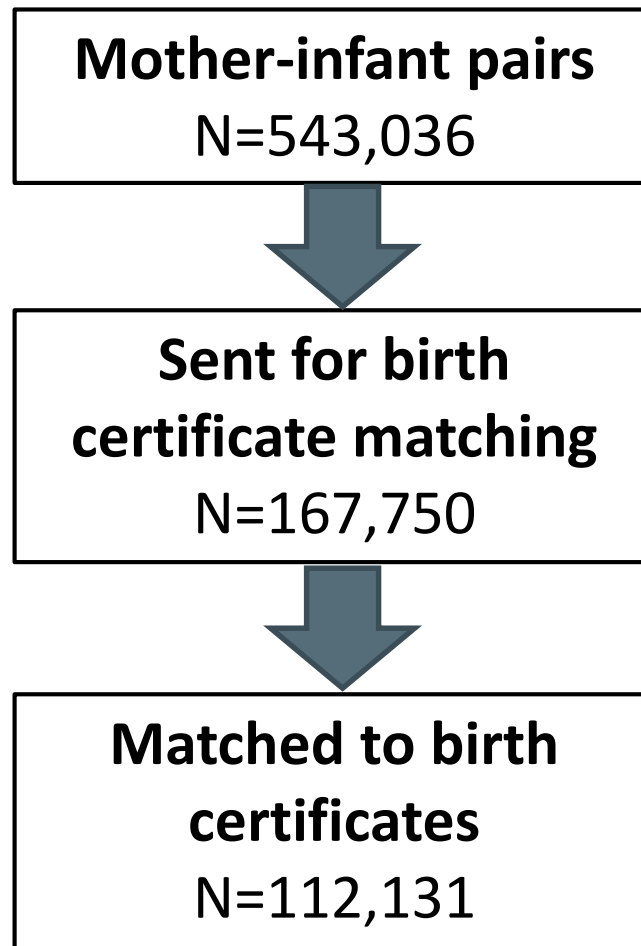


# Mother-infant cohort (N=543,036)

	PRISM (4 DPs)	2009 Birth Data from U.S. Vital Statistics
<b>Maternal age</b>		
<20	4,903 (0.9%)	10.0%
20 to 24	33,973 (6.3%)	24.4%
25 to 29	149,325 (27.5%)	28.2%
30 to 34	207,920 (38.3%)	23.1%
35 to 39	117,937 (21.7%)	11.5%
40 +	28,978 (5.3%)	2.8%
<b>Preterm birth</b>	56,130 (10.3%)	12.2%
<b>Multiple gestation</b>	24,666 (4.5%)	3.5%



# Percent mother-infant pairs linked to birth certificates



*Births from 9 states  
% of total: 31%*

*% mother-infant pairs  
linked to birth  
certificates: 67%*

## Claims algorithm for pregnancy start

- Identify date of delivery
- Identify maternal and infant ICD-9 codes specifying gestational age at delivery
  - Based on these codes assume gestational length
- Subtract assumed gestational length from date of delivery

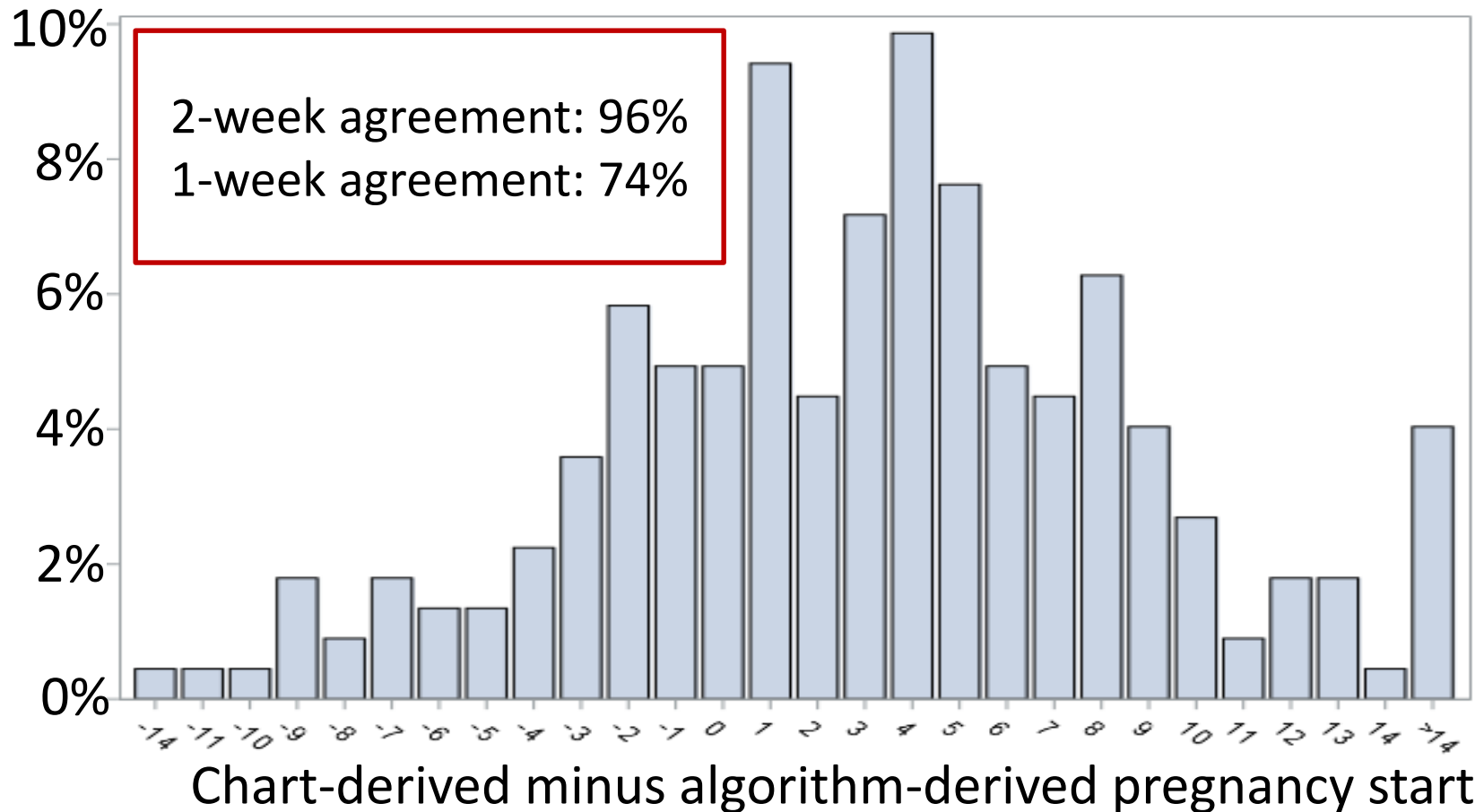
# Claims algorithm for pregnancy start

- ICD-9 codes for prolonged pregnancy (>42 weeks)
- ICD-9 codes for post-term pregnancy (>40-42 weeks)
- ICD-9 codes for preterm pregnancy
  - Not otherwise specified
  - <24 or 24 weeks
  - 25-26, 27-28,...35-36 weeks
- **None of the above:** Assume at-term (38 wks 4 d)

Li et al. *Pharmacoepidemiol Drug Saf* 2013;22(5):524-32

# Validation of pregnancy start algorithm\*

## N=223 mother-infant pairs



\*A total of 313 mother-infant pairs were chart-reviewed

# Conclusions

- Successfully linked mothers to infants in 4 large Sentinel Data Partners
- Demonstrated the validity of a claims-based algorithm for pregnancy start
  - Within 2-week agreement of claims and medical records in >90% mother-infant pairs
- Supports the feasibility of assessing infant outcomes following maternal vaccination exposures
- Further validation of electronic data elements is needed

# Acknowledgements

- We thank the following contributors:
  - Sentinel Operations Center Staff
  - Contributors in the FDA Centers for Biologics, Evaluation, and Research
  - Staff at Aetna, HealthCore, Humana, and Optum who provided data and expertise
  - State Departments of Health who participated in birth certificate matches



# Thank you!

- Questions?
- [Alison\\_Kawai@harvardpilgrim.org](mailto:Alison_Kawai@harvardpilgrim.org)

# Birth certificate matches

<b>Data Partner</b>	<b>States for birth certificate matching</b>
<b>Data Partner 1</b>	Colorado, Florida, Georgia, Pennsylvania, Virginia
<b>Data Partner 2</b>	California, Georgia, Missouri, Virginia
<b>Data Partner 3</b>	Colorado, Florida, Georgia, Louisiana, Utah
<b>Data Partner 4</b>	Colorado, Georgia

# Validation of pregnancy start algorithm

- Medical record review conducted on sample of 223 mother-infant pairs
  
- Prenatal, labor and delivery, and birth records retrieved
  
- If available, ultrasound and date of last menstrual period used to confirm pregnancy start
  - Otherwise, labor and delivery or birth record used

# Algorithm to match to birth certificates

- Child
  - First and last name
  - Date of birth
  - Sex
- Mother
  - First and last name
  - Social security number
  - Maiden name
  - Date of birth
  - Age at delivery