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## ABSTRACT

**Background:** Since 2011, Centers for Disease Control and Prevention has recommended that women receive Tdap vaccination during pregnancy to minimize the significant burden of pertussis on infants. Prior to 2011, CDC recommended immediate postpartum Tdap vaccination. The Sentinel System's Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, established in response to the 2007 FDA Amendments Act to monitor the safety of FDA-regulated medical products, was used to estimate Tdap vaccination use among pregnant women.

**Objective:** To assess the Sentinel System's ability to identify Tdap vaccine exposures in pregnant women

**Methods:** We identified a cohort of pregnant women ages 10 to 55 years using electronic health plan data from six Sentinel Data Partners. Pregnancies ending in a live delivery from 2010 to 2015 were identified using a validated algorithm that incorporated diagnosis and procedure codes. Tdap vaccinations that occurred during pregnancy or immediately postpartum during the delivery visit were identified using procedure codes.

**Results:** We identified over 2.6 million live birth pregnancies, of which 15.5% (n=407,879) had a Tdap vaccination during pregnancy and 3.2% (n=84,172) had a Tdap vaccination during the delivery visit. The proportion of Tdap vaccination during pregnancy increased substantially overtime, from 0.8% for deliveries in 2010 to 38.8% for deliveries in 2015, with the largest increases from 2011 to 2012 and 2012 to 2013. By contrast, the proportion of Tdap vaccination during delivery visits remained low and relatively stable over time, with slight decreases from 2012 to 2015.

**Conclusions:** Trends of Tdap vaccination during pregnancy in the Sentinel population increased substantially in the years following the 2011 CDC recommendation, which is consistent with results from other studies of commercially insured women. This study demonstrated the feasibility of identifying vaccine exposures in pregnant women, which could facilitate vaccine safety or effectiveness surveillance using Sentinel's PRISM program. Mother-child linkages and characterization of other data elements would also be needed to conduct these vaccine surveillance activities.

## BACKGROUND

- In 2011, the Advisory Committee on Immunization Practices (ACIP) recommended that unvaccinated women receive Tetanus, Diphtheria, and Acellular Pertussis (Tdap) vaccination during pregnancy to protect infants from pertussis<sup>1</sup>
- In 2012, the recommendation was expanded to include all pregnant women
- The Sentinel System's Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program was established to monitor the safety of FDA-regulated medical products

## OBJECTIVE

- To assess the Sentinel PRISM program's ability to estimate Tdap vaccination use among pregnant women whose pregnancies resulted in a livebirth

## METHODS

## Data Source

- Insurance claims and administrative data from six Sentinel Data Partners in the Sentinel Distributed Database

## Study Population and Pregnancy Identification

- Women aged 10-55 years who delivered a liveborn infant between January, 2010 and September, 2015
- Pregnancy start and end dates were calculated using a validated algorithm that incorporated diagnosis and procedure codes
- The algorithm identified an inpatient delivery hospitalization and pre/post-term delivery codes to determine pregnancy duration
- In absence of pre/post-term codes, pregnancy duration was set to 273 days
- Pregnancies were included if women were continuously enrolled in the health plan for at least 294 days before the admit date for delivery

## Exposure of Interest

- Tdap vaccinations were identified using procedure codes
- Vaccinations that occurred (1) during pregnancy prior to the delivery hospitalization, and (2) during the delivery hospitalization were identified

## RESULTS

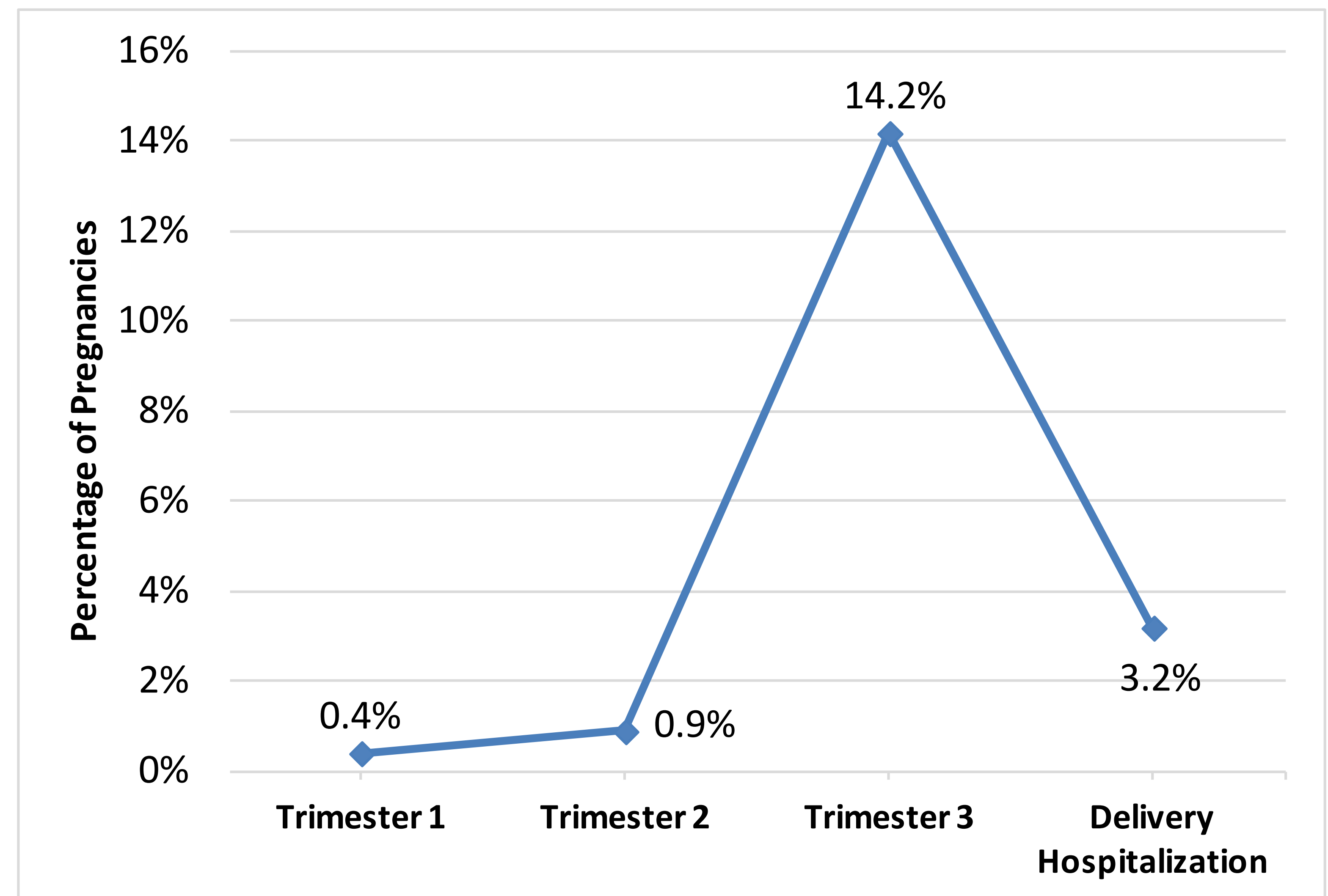
Table 1. Characteristics of Pregnancy Cohort

	Number of Pregnancies (%)
<b>Total Number of Pregnancies</b>	2,633,462 (100%)
<b>Maternal Age at Delivery (Years)</b>	
10-19	94,005 (3.6%)
20-29	1,015,266 (38.6%)
30-39	1,399,722 (53.2%)
40-49	120,567 (4.6%)
50-54	3,902 (0.1%)
<b>Calendar Year of Delivery</b>	
2010	450,830 (17.1%)
2011	464,332 (17.6%)
2012	466,295 (17.7%)
2013	470,585 (17.9%)
2014	457,745 (17.4%)
2015	323,675 (12.3%)
<b>Presence of Any Preterm Birth</b>	188,441 (7.2%)
<b>Presence of Any Post-term Birth</b>	367,248 (13.9%)

- The percentage of liveborn deliveries among females aged 10-19 years and the percentage of preterm liveborn deliveries are slightly lower than national averages (5.8% and 9.6% in 2015, respectively)<sup>2</sup>

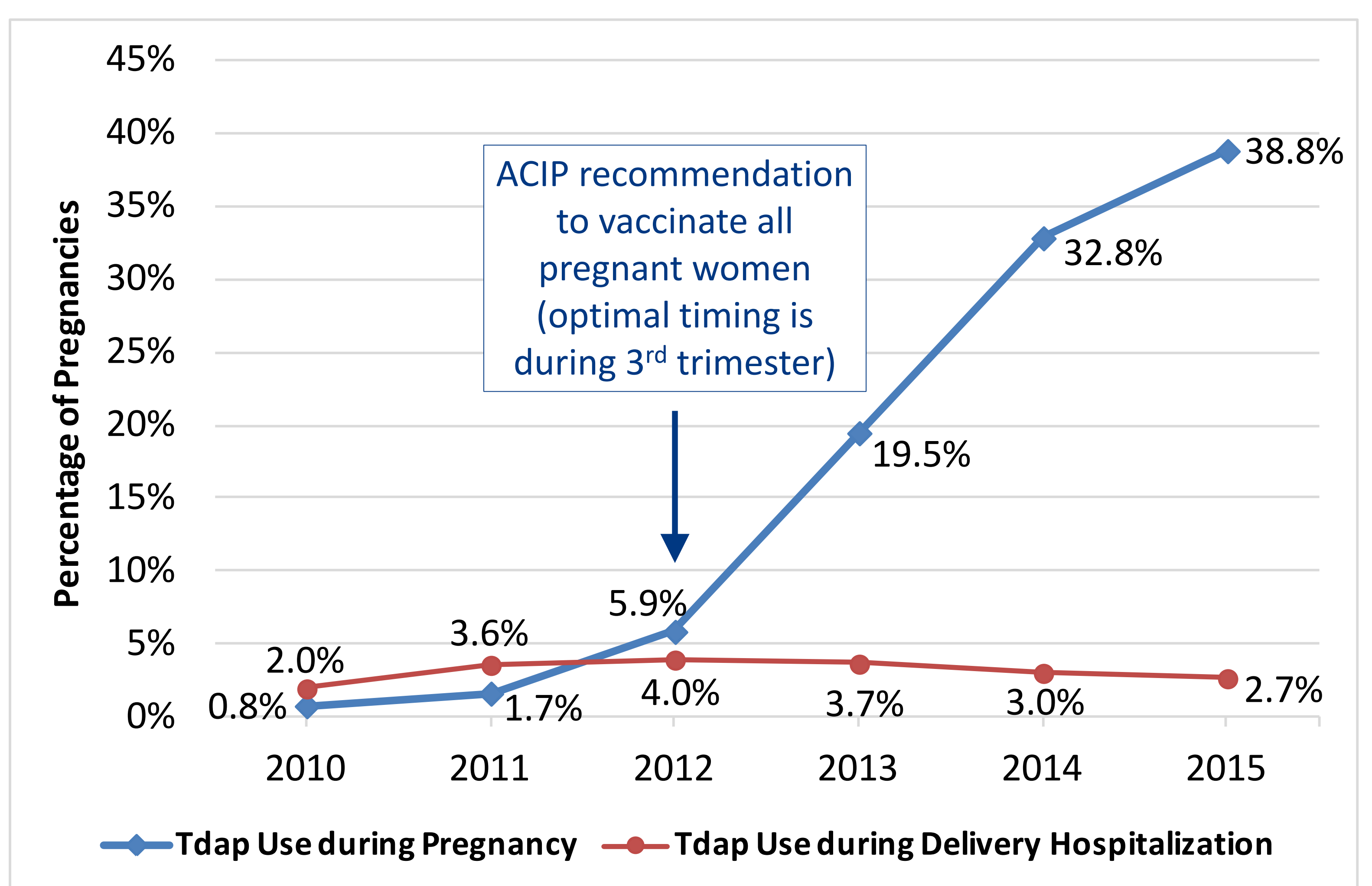
## RESULTS CONTINUED

Figure 1. Tdap Vaccinations during Pregnancy Trimester or Delivery



- Of the 2.6 million pregnancies identified, 15.5% (n=407,879) had a Tdap vaccination during pregnancy and 3.2% (n=84,172) had a Tdap vaccination during the delivery hospitalization

Figure 2. Tdap Vaccinations during Pregnancy or Delivery by Year



- The proportion of Tdap vaccination during pregnancy increased substantially overtime, from 0.8% for deliveries in 2010 to 38.8% for deliveries in 2015
- Tdap vaccination during pregnancy increased by 2.1% from 2010-11, 3.5% from 2011-12, 3.3% from 2012-13, 1.7% from 2013-14, and 1.2% from 2014-15
- By contrast, the proportion of Tdap vaccination during delivery hospitalizations remained low and stable over time, with slight decreases from 2012-2015

## CONCLUSIONS

- For the years analyzed, trends of Tdap vaccination during pregnancy in Sentinel's PRISM program are comparable to national estimates<sup>3</sup>
- This study demonstrated the feasibility of identifying vaccine exposures in pregnant women, which could facilitate vaccine safety or effectiveness surveillance using Sentinel's PRISM program
- Mother-child linkages and characterization of other data elements would also be needed to conduct vaccine surveillance activities

## DISCLOSURE

- This work was funded by U.S. Food and Drug Administration through the Department of Health and Human Services Contract # HHSF223201400030I
- The authors have no conflicts of interest to disclose
- Many thanks are due to Data Partners who provided data used in the analysis

<sup>1</sup> Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women — Advisory Committee on Immunization Practices (ACIP), 2012. *Weekly*, February 22, 2013 / 62(07);131-135.

<sup>2</sup> Hamilton BE, Martin JA, Osterman MJ. Births: preliminary data for 2015. National vital statistics report; vol 65 no 1. National Center for Health Statistics. [https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65\\_03.pdf](https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_03.pdf). June 6, 2017.

<sup>3</sup> Kahn KE, Black CL, Ding H, et al. Pregnant women and Tdap vaccination, internet panel survey, United States, April 2016. <https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/tdap-report-2016.html>. June 12, 2017.