Influenza Vaccination: Safe and Proven to Help Protect Pregnant Women and Infants

Pregnant women are more at risk for severe outcomes from influenza infection[1-5]

Rising rates of maternal obesity, increasing age, and more chronic comorbid conditions may contribute to the risk of severe maternal morbidity due to influenza[4,5]

In a nationwide inpatient sample from 2000-2018, pregnant women with an influenza diagnosis at delivery were ***~2x*** as likely to experience severe maternal morbidity such as ***sepsis, shock, mechanical intubation, ARDS,*** and ***death***[2]

Pregnant women in their 3rd trimester were ***3-4X*** more likely to be ***hospitalized with cardiopulmonary illness*** during influenza season compared to post-partum women[3]

Pregnant women with comorbid conditions* were ***3x*** more likely to be ***hospitalized for respiratory illness*** during influenza season than women without these comorbid conditions[3]

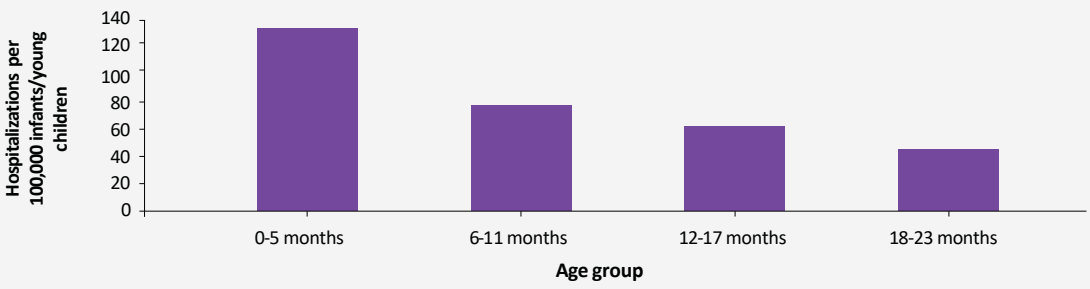
*chronic cardiac disease, chronic pulmonary disease, diabetes mellitus, chronic renal disease, malignancies, and immunosuppressive disorders

>2X

Pregnant women were more than ***2x*** as likely to be admitted to the hospital with ***influenza*** than non-pregnant women[4]

Infants/young children are also at increased risk from influenza infection[6]

Average number of influenza-associated hospitalizations per 100,000 children aged 0-23 months
Influenza Hospitalization Surveillance Network (FluSurv-NET), United States, 2010-11 through 2017-18 influenza seasons



- Annual influenza vaccination is recommended for persons ***≥6 months*** of age[1]
- Despite recommendations, vaccination coverage rate in pregnant persons has declined annually[7]

ACIP and ACOG recommend that persons who are pregnant or who might be pregnant or postpartum during the influenza season receive influenza vaccine[1,8]

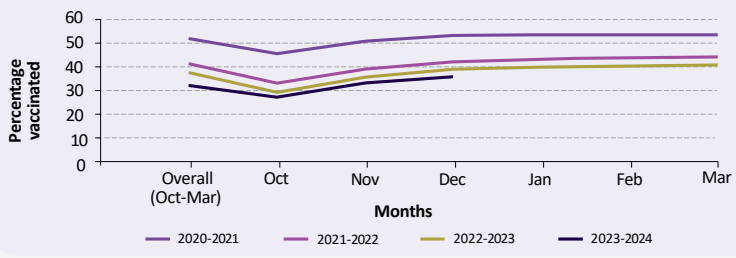
Any licensed recommended, and age appropriate IIV or RIV may be used

LAIV4 should not be used during pregnancy but can be used in eligible persons postpartum

Influenza vaccine can be administered at any time during pregnancy (i.e. during any trimester) before and during influenza season

Early vaccination (i.e. July and August) can be considered for persons who are in the 3rd trimester during these months

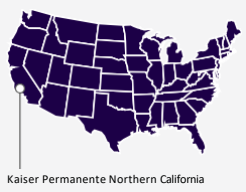
Declining vaccination coverage rate, influenza season (October-March) 2020-2024, pregnant women 18-49 years[7]



New data supports safety of recombinant influenza vaccine in pregnant women[9]

Background

- Large, observational safety surveillance study to assess safety of RIV4 during pregnancy
- All vaccinated pregnant women were a subset of a separate, cluster randomized effectiveness trial of ~1.6 million eligible Kaiser Permanente Northern California (KPNC) members
- Included ~48,000 routinely influenza-vaccinated pregnant women and their live born infants at KPNC during 2 influenza seasons (2018/19, 2019/20)



Primary objective

Evaluate the safety of quadrivalent recombinant influenza vaccine (RIV4) compared with quadrivalent inactivated influenza vaccine (SD-IIV4) in pregnant women and their offspring

Baseline characteristics

The demographics (age, race, ethnicity, comorbidity, trimester) of the pregnancy cohort were well balanced (**Table 1***)

*not all demographic results are provided

Table 1. Trimester demographics of pregnant women

Trimester of vaccination	RIV4 N=14,981; n (%)	SD-IIV4 N=33,800; n (%)
1st Trimester	5,092 (34.0)	10,787 (31.9)
2nd Trimester	4,851 (32.4)	11,470 (33.9)
3rd Trimester	4,288 (28.6)	10,176 (30.1)

Results

- Within a large population of pregnant women, there were ***no differences*** in pregnancy, birth, and neonatal/infant outcomes with RIV4 compared to SD-IIV4 for influenza vaccination (**Table 2**)
- ***No safety concerns*** were identified with RIV4 use in pregnancy

Table 2. Birth/infant outcomes

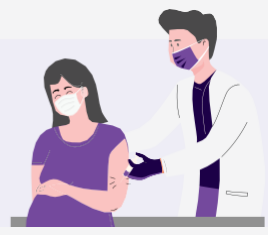
Outcome	RIV4 N=14,538; n (%)	SD-IIV4 N=32,856; n (%)	Adjusted OR (95% CI)*
Birth			
Preterm birth	1,061 (7.3)	2,450 (7.5)	0.98 (0.91, 1.05)
Low birth weight	852 (5.9)	1,918 (5.8)	1.00 (0.92, 1.09)
Small for gestational age	1,277 (8.8)	2,846 (8.7)	1.01 (0.94, 1.09)
Infant (up to 365 days)			
Infant death	27 (0.2)	59 (0.2)	1.05 (0.66, 1.65)
Congential anomalies	6,259 (43.1)	14,018 (42.7)	1.01 (0.97, 1.05)
• *Major congential anomalies*	*1,113 (7.7)*	*2,531 (7.7)*	*N/C*
• *Minor congential anomalies*	*5,698 (39.2)*	*12,762 (38.8)*	*N/C*
Failure to thrive	150 (1.0)	372 (1.1)	0.90 (0.75, 1.09)

*SD-IIV4 was the reference group for all analysis, logistic regresions adjusted for infant sex, infant race, infant ethnicity, maternal age group, and maternal trimester of influenza vaccine receipt. N/C; not conducted

Limitations

Imbalances in the quantity of RIV4 versus SD-IIV4 administered to pregnant women may have been attributed to provider preference once they knew an individual was pregnant, availability of either vaccine, or other factors affecting real-world studies

The results of this study in *48,781 pregnant women* support the current ACIP recommendation for the use of *inactivated/recombinant influenza vaccine* in this '*at risk*' population



Abbreviations:
ACOG, American College of Obstetricians and Gynecologists; ARDS, acute respiratory distress syndrome; ACIP, advisory committee on immunization practices; OR, odds ratio; CI, confidence interval; LAIV4, live attenuated quadrivalent influenza vaccine; IIV, inactivated influenza vaccine; IIV4, quadrivalent inactivated influenza vaccine; SD-IIV4, standard dose quadrivalent inactivated influenza vaccine; RIV, recombinant influenza vaccine; RIV4, quadrivalent recombinant influenza vaccine.

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