

Appendix 1. Matched Case-Control Analysis of Stillbirths After Maternal Vaccination in the Prepregnancy* period

Peri-conception exposure	Vaccination rate in stillbirths (N = 795)	Vaccination rate in live births (N = 3180)	Crude Odds Ratio (95% CI)	Adjusted [†] Odds Ratio (95% CI)	P value
Any vaccination	69 (8.7%)	329 (10.4%)	0.82 (0.62-1.08)	0.85 (0.64-1.13)	0.26
Influenza vaccination[‡]	41 (5.2%)	213 (6.7%)	0.74 (0.52-1.06)	0.77 (0.53-1.11)	0.17
Tdap vaccination[§]	21 (2.6%)	90 (2.8%)	0.93 (0.57-1.51)	0.98 (0.59-1.61)	0.93
Non-routinely recommended vaccinations	20 (2.5%)	64 (2.0%)	1.26 (0.76-2.10)	1.30 (0.77-2.20)	0.32
Contraindicated vaccinations[¶]	2 (0.3%)	15 (0.5%)	0.53 (0.12-2.33)	0.48 (0.11-2.17)	0.34

Abbreviations: CI – confidence interval, Tdap – Tetanus, diphtheria, acellular pertussis

*120 days prior to pregnancy start – 30 days prior to pregnancy start

[†]adjusted for maternal age, smoking during pregnancy, obesity, nulliparity, history of stillbirth, Black non-Hispanic race, maternal comorbidities, pregnancy complications prior to vaccination or index date

[‡]Inactivated influenza vaccination with or without Tdap vaccine

[§]Tdap vaccine with or without inactivated influenza vaccination

^{||}Human papillomavirus, meningococcal, pneumococcal, inactivated polio, Japanese encephalitis, rabies, inactivated typhoid, yellow fever, hepatitis A, hepatitis B

[¶]Live attenuated influenza vaccination, measles, mumps, rubella, varicella, zoster

Panagiotakopoulos L, McCarthy NL, Tepper NK, Kharbanda EO, Lipkind HS, Vazquez-Benitez G, et al. Evaluating the association of stillbirths after maternal vaccination in the Vaccine Safety Datalink. *Obstet Gynecol* 2020;136.

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Appendix 2. Post-hoc Analysis: Selected Demographic Characteristics of Women With Pregnancies Ending in Stillbirths (N = 795) and Matched Live Births (N = 3,180)

Characteristic	Stillbirths, N (%)	Livebirths, N (%)	P value*
Age at delivery in years (mean, range)	30.6 (14 - 49)	31.0 (15-47)	0.98
Maternal age ≥ 35 years	218 (27.4)	930 (27.4)	1.00
Gestational age at prenatal care initiation in weeks (mean, range)	7.5 (5-30)	7.4 (5-37)	0.43
Maternal comorbidity[†]	108 (13.6)	132 (4.2)	<0.001
Pregnancy complication[‡]	365 (45.9)	227 (7.1)	<0.001
Gestational age at first vaccination in weeks (mean, range)	17.6 (2 - 39)	17.3 (2 - 38)	0.69
Tobacco smoking during pregnancy	57 (7.2)	260 (8.2)	0.005
Nulliparous	238 (29.9)	930 (29.3)	0.70
History of stillbirths	40 (5.0)	58 (1.8)	<0.001
Black non-Hispanic	107 (13.5)	408 (12.8)	0.63
Obesity	279 (35.1)	652 (20.5)	<0.001

*p-values calculated by chi-squared tests for categorical variables and Wilcoxon median 2-sample test for continuous models

[†]ICD-9 codes for maternal diabetes, systemic lupus erythematosus, thyroid disorders, hypertension, cardiovascular disease cholestasis, renal disease, and sickle cell disease in the 6 months prior to pregnancy through vaccination date or index date (stillbirth outcome date or reference date for matched control)

[‡]ICD-9 codes for maternal infections, placental complications, amniotic cavity or membrane problems, fetal growth restriction, maternal trauma and uterine rupture during current pregnancy and prior to vaccination date or index date

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Appendix 3. Post-hoc Analysis: Matched Case-Control Analysis of Stillbirths After Maternal Vaccination During Pregnancy*

Exposure during pregnancy	Vaccination rate in stillbirths (N = 795)	Vaccination rate in live births (N = 3180)	Crude Odds Ratio (95% CI)	Adjusted [†] Odds Ratio (95% CI)	P value
Any vaccination	411 (51.7%)	1670 (52.5%)	0.96 (0.80-1.15)	0.97 (0.80-1.17)	0.71
Influenza vaccination[‡]	343 (43.1%)	1396 (43.9%)	0.96 (0.80-1.15)	0.98 (0.81-1.17)	0.79
Tdap vaccination[§]	184 (23.1%)	734 (23.1%)	1.01 (0.78-1.30)	0.99 (0.77-1.29)	0.96
Non-routinely recommended vaccinations	9 (1.1%)	30 (0.9%)	1.21 (0.57-2.59)	1.36 (0.62-2.96)	0.44
Contraindicated vaccinations[¶]	0	2 (0.1%)	-	-	-

Abbreviations: CI – confidence interval, Tdap – Tetanus, diphtheria, acellular pertussis

*14 days after the last menstrual period through seven days prior to the index date (stillbirth outcome date or reference date for matched control)

[†]Adjusted for maternal age, smoking during pregnancy, obesity, nulliparity, history of stillbirth, Black non-Hispanic race, and maternal comorbidities and pregnancy complications occurring prior to vaccination

[‡]Inactivated influenza vaccination with or without Tdap vaccination

[§]Tdap vaccination with or without inactivated influenza vaccination

^{||}Human papillomavirus, meningococcal, pneumococcal, inactivated polio, Japanese encephalitis, rabies, inactivated typhoid, yellow fever, hepatitis A, hepatitis B

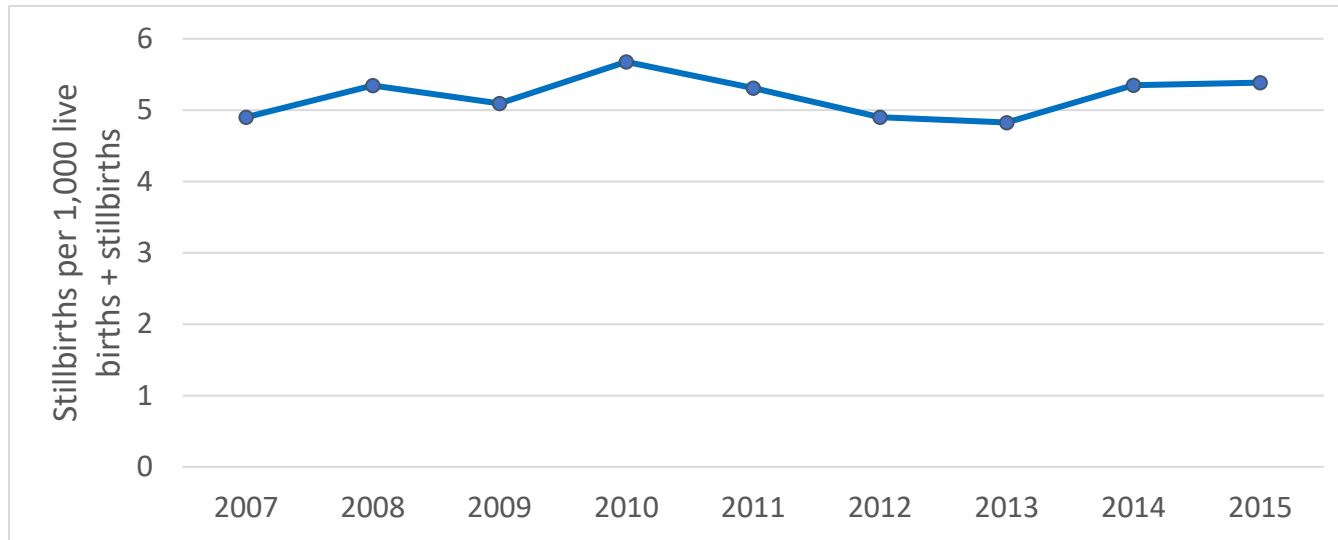
[¶]Live attenuated influenza vaccination, measles, mumps, rubella, varicella, zoster

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Appendix 4. Stillbirth rate by year in the Vaccine Safety Datalink in pregnancies ending between January 1, 2007, and December 31, 2015



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