

# SARS-CoV-2 Infection and COVID-19 Vaccination In Pregnancy

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## **MotherToBaby Pregnancy Studies**

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UC San Diego

***34<sup>th</sup> Annual Education Meeting for Organization of Teratology Information Specialists  
Members and MotherToBaby Affiliates  
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- NIH-NICHD/BARDA Grant 3P50 HD106463-01S1
- Pfizer-BioNTech
- NIH-NIDA Supplement

# Infection with SARS-CoV-2 In Pregnancy

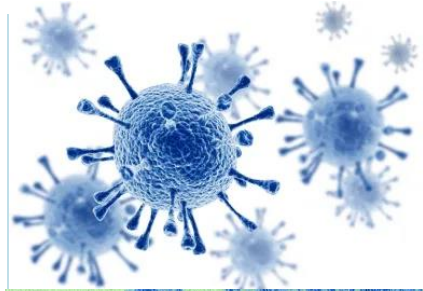


MotherToBaby  
Medications & More During Pregnancy & Breastfeeding  
Ask The Experts

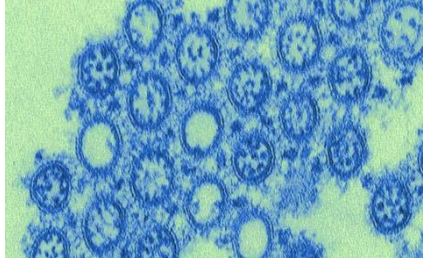
# Questions to be Answered with a Novel Virus

## Is there an increased risk for.....

- Severe maternal illness and death
- “Vertical transmission”
- Birth defects
- Spontaneous abortion or stillbirth
- Preterm delivery
- Growth deficiency
- Long-term neurodevelopmental deficits



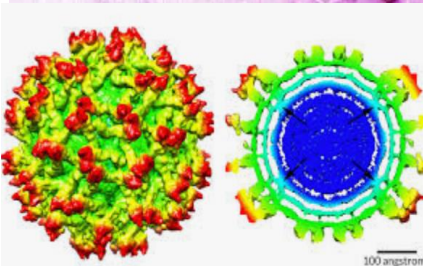
*HIV: 25% vertical transmission  
(without treatment)*



*H1N1: Increased maternal  
morbidity and mortality*



*Ebola: 72-90% maternal  
and fetal mortality*



*Zika: Up to 60% vertical  
transmission, fetal microcephaly,  
neurologic defects*

# Characteristics and Maternal and Birth Outcomes of Hospitalized Pregnant Women with Laboratory-Confirmed COVID-19 — COVID-NET, 13 States, March 1–August 22, 2020

Miranda J. Delahoy, PhD<sup>1,2</sup>; Michael Whitaker, MPH<sup>1,3</sup>; Alissa O'Halloran, MSPH<sup>1</sup>; Shua J. Chai, MD<sup>1,4</sup>; Pam Daily Kirley, MPH<sup>4</sup>; Nisha Alden, MPH<sup>5</sup>; Breanna Kawasaki, MPH<sup>5</sup>; James Meek, MPH<sup>6</sup>; Kimberly Yousey-Hindes, MPH<sup>6</sup>; Evan J. Anderson, MD<sup>7,8</sup>; Kyle P. Openo, DrPH<sup>7,8,9</sup>; Maya L. Monroe, MPH<sup>10</sup>; Patricia A. Ryan, MS<sup>10</sup>; Kimberly Fox, MPH<sup>11</sup>; Sue Kim, MPH<sup>11</sup>; Ruth Lynfield, MD<sup>12</sup>; Samantha Siebman, MPH<sup>12</sup>; Sarah Shrum Davis, MPH<sup>13</sup>; Daniel M. Sosin, MD<sup>14</sup>; Grant Barney, MPH<sup>15</sup>; Alison Muse, MPH<sup>15</sup>; Nancy M. Bennett, MD<sup>16</sup>; Christina B. Felsen, MPH<sup>16</sup>; Laurie M. Billing, MPH<sup>17</sup>; Jessica Shiltz, MPH<sup>17</sup>; Melissa Sutton, MD<sup>18</sup>; Nicole West, MPH<sup>18</sup>; William Schaffner, MD<sup>19</sup>; H. Keipp Talbot, MD<sup>19</sup>; Andrea George, MPH<sup>20</sup>; Melanie Spencer, MPH<sup>20</sup>; Sascha Ellington, PhD<sup>1</sup>; Romeo R. Galang, MD<sup>1</sup>; Suzanne M. Gilboa, PhD<sup>1</sup>; Van T. Tong, MPH<sup>1</sup>; Alexandra Piasecki, MPH<sup>1,21</sup>; Lynnette Brammer, MPH<sup>1</sup>; Alicia M. Fry, MD<sup>1</sup>; Aron J. Hall, DVM<sup>1</sup>; Jonathan M. Wortham, MD<sup>1</sup>; Lindsay Kim, MD<sup>1</sup>; Shikha Garg, MD<sup>1</sup>; COVID-NET Surveillance Team

**TABLE 2. Intensive care unit (ICU) admissions, receipt of invasive ventilation, receipt of extracorporeal membrane oxygenation (ECMO), and deaths among symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 (N = 409,462), by pregnancy status, age, race/ethnicity, and underlying health conditions — United States, January 22–October 3, 2020**

Outcome*/Characteristic	No. (per 1,000 cases) of symptomatic women		Risk ratio (95% CI)	
	Pregnant (n = 23,434)	Nonpregnant (n = 386,028)	Crude <sup>†</sup>	Adjusted <sup>†,§</sup>
<b>ICU admission<sup>¶</sup></b>				
All	245 (10.5)	1,492 (3.9)	2.7 (2.4–3.1)	3.0 (2.6–3.4)
<b>ECMO***</b>				
All	17 (0.7)	120 (0.3)	2.3 (1.4–3.9)	2.4 (1.5–4.0)
-				
<b>Death<sup>§§§</sup></b>				
All	34 (1.5)	447 (1.2)	1.3 (0.9–1.8)	1.7 (1.2–2.4)

Research Letter

FREE

January 15, 2021

# Clinical Characteristics and Outcomes of Hospitalized Women Giving Birth With and Without COVID-19

Karola S. Jering, MD<sup>1</sup>; Brian L. Claggett, PhD<sup>1</sup>; Jonathan W. Cunningham, MD<sup>1</sup>; [et al](#)

[» Author Affiliations](#) | [Article Information](#)

*JAMA Intern Med.* 2021;181(5):714-717. doi:10.1001/jamainternmed.2020.9241

**Table 2. In-Hospital Outcomes of Pregnant Women Giving Birth According to Coronavirus Disease 2019 (COVID-19) Status**

Outcome	No. (%)		P value	Unadjusted OR (95% CI)	Adjusted OR (95% CI) <sup>a</sup>
	Without COVID-19 (n = 400 066)	With COVID-19 (n = 6380)			
Cesarean delivery	109 865 (27.5)	1847 (28.9)	.01	1.08 (1.02-1.14)	1.07 (1.02-1.13)
Preterm labor	16 137 (4.0)	332 (5.2)	<.001	1.31 (1.17-1.46)	1.19 (1.06-1.33)
Preterm birth <sup>b</sup>	23 234 (5.8)	459 (7.2)	<.001	1.26 (1.14-1.38)	1.17 (1.06-1.29)
Stillbirth	1289 (0.3)	34 (0.5)	.003	1.66 (1.18-2.33)	1.23 (0.87-1.75)
Preeclampsia	27 078 (6.8)	564 (8.8)	<.001	1.36 (1.22-1.46)	1.21 (1.11-1.33)
Eclampsia	288 (0.1)	8 (0.1)	.12	1.74 (0.86-3.52)	1.56 (0.77-3.16)
HELLP syndrome	989 (0.2)	33 (0.5)	<.001	2.10 (1.48-2.97)	1.96 (1.36-2.81)
Myocardial infarction	18 (0.0)	8 (0.1)	<.001	27.90 (12.13-64.20)	30.89 (12.56-75.99)
Stroke	14 (0.0)	0	.64	NA	NA
VTE	268 (0.1)	15 (0.2)	<.001	3.52 (2.09-5.92)	3.43 (2.01-5.82)
Thrombotic event <sup>c</sup>	300 (0.1)	22 (0.3)	<.001	4.61 (2.99-7.11)	4.47 (2.87-6.96)
Intensive care	1747 (0.4)	212 (3.3)	<.001	7.84 (6.78-9.06)	6.47 (5.55-7.55)
Mechanical ventilation	212 (0.1)	86 (1.3)	<.001	25.77 (20.03-33.15)	23.70 (17.95-31.29)
Renal replacement therapy	238 (0.1)	12 (0.2)	<.001	NA	NA
Chest imaging <sup>d</sup>	4122 (1.0)	748 (11.7)	<.001	NA	NA
Discharge disposition					
Home	398 388 (99.6)	6309 (98.9)	<.001	NA	NA
Postacute care	197 (0.0)	13 (0.2)		NA	NA
Death	20 (0.0)	9 (0.1)		28.26 (12.86-62.08)	26.07 (11.26-60.38)
Hospice	74 (0.0)	1 (0.0)		NA	NA
Other	1387 (0.3)	48 (0.8)		NA	NA
Length of stay, mean, d	2.4 (2.5)	2.8 (3.4)	<.001	NA	NA
Length of stay, category, d					
≤2	267 177 (66.8)	4099 (64.3)	<.001	NA	NA
3	91 690 (22.9)	1387 (21.7)		NA	NA
>3	41 199 (10.3)	894 (14.0)		NA	NA



## OBSTETRICS

# **Maternal and perinatal outcomes of pregnant women with SARS-CoV-2 infection at the time of birth in England: national cohort study**

**Ipek Gurol-Urganci, PhD; Jennifer E. Jardine, MSc; Fran Carroll, PhD; Tim Draycott, FRCOG; George Dunn, BA; Alissa Fremeaux, MSc; Tina Harris, PhD; Jane Hawdon, PhD; Edward Morris, FRCOG; Patrick Muller, MSc; Lara Waite, MSc; Kirstin Webster, MSc; Jan van der Meulen, PhD; Asma Khalil, MRCOG, MD, MSc (Epi), DFRH, Dip (GUM)**

- All singleton births
- March 29, 2020, through Jan 31, 2021
- Total of 342,000 births
- 3,527 positive for infection

**TABLE 2**

**Comparison of study outcomes between pregnant women with and without laboratory-confirmed SARS-CoV-2 infection (International Classification of Diseases, tenth revision U07.1) at the time of birth**

	Pregnant women without SARS-CoV-2 infection		Pregnant women with laboratory-confirmed SARS-CoV-2 infection		Unadjusted OR (95% CI)	Pvalue	Adjusted OR <sup>a</sup> (95% CI)	Pvalue
	Cases/births	%	Cases/births	%				
<b>Maternal data</b>								
Fetal death	1140/338,553	0.34	30/3527	0.85	2.54 (1.81–3.56)	<.001	2.21 (1.58–3.11)	<.001
Preterm birth	18,572/322,494	5.8	369/3047	12.1	2.25 (2.03–2.50)	<.001	2.17 (1.96–2.42)	<.001
Small for gestational age	17,521/320,188	5.5	191/3009	6.4	1.17 (1.00–1.37)	.05	0.99 (0.84–1.16)	.87
Preeclampsia or eclampsia	8591/338,553	2.5	139/3527	3.9	1.58 (1.32–1.89)	<.001	1.55 (1.29–1.85)	<.001
Induction of labor	96,651/236,822	40.8	940/2382	39.5	0.95 (0.82–1.08)	.42	0.95 (0.83–1.08)	.40
Elective cesarean delivery	46,843/338,553	13.8	380/3527	10.8	0.75 (0.67–0.85)	<.001	0.81 (0.71–0.91)	<.001
Emergency cesarean delivery	62,479/338,553	18.5	975/3527	27.6	1.69 (1.56–1.83)	<.001	1.63 (1.51–1.76)	<.001

## Placental histopathology after SARS-CoV-2 infection in pregnancy: a systematic review and meta-analysis



Raffaella Di Girolamo, MD; Asma Khalil, MD, PhD; Sara Alameddine, MD; Emanuela D'Angelo, MD, PhD; Carmen Galliani, MD; Barbara Matarrelli, MD; Danilo Buca, MD; Marco Liberati, MD, PhD; Giuseppe Rizzo, MD, PhD; Francesco D'Antonio, MD, PhD

**S**ARS-CoV-2 infection started spreading toward the end of 2019 and is still a major issue of public health, with new cases of infection, hospitalization, admission to the intensive care unit, and death increasing daily, worldwide.<sup>1</sup> Pregnancy has been reported to be an independent risk factor for adverse outcomes in women with SARS-CoV-2 infection, especially if other comorbidities, such as diabetes mellitus or preeclampsia, coexist. The peculiar changes occurring in the

**OBJECTIVE:** This study aimed to report the spectrum of placental pathology findings in pregnancies complicated by SARS-CoV-2 infection.

**DATA SOURCES:** MEDLINE, Embase, Google Scholar, and the Web of Science databases were searched up to August 11, 2021.

**STUDY ELIGIBILITY CRITERIA:** Histopathologic anomalies included maternal vascular malperfusion, fetal vascular malperfusion, acute inflammatory pathology, chronic inflammatory pathology, increased perivillous fibrin, and intervillous thrombosis. Moreover, subanalyses of symptomatic women only and high-risk pregnancies were performed.

**METHODS:** Histopathologic analysis of the placenta included gross examination, histopathology on hematoxylin and eosin, immunohistochemistry, fluorescence in situ hybridization, quantitative reverse transcription-polymerase chain reaction on placental tissue, and transmission electron microscope. Random-effect meta-analyses were used to analyze the data.

**RESULTS:** A total of 56 studies (1008 pregnancies) were included. Maternal vascular malperfusion was reported in 30.7% of placentas (95% confidence interval, 20.3–42.1), whereas fetal vascular malperfusion was observed in 27.08% of cases (95% confidence interval, 19.2–35.6). Acute and chronic inflammatory pathologies were reported in 22.68% (95% confidence interval, 16.9–29.0) and 25.65% (95% confidence interval, 18.4–33.6) of cases, respectively. Increased perivillous fibrin was observed in 32.7% (95% confidence interval,

**Cite this article as:** Di Girolamo R, Khalil A, Alameddine S, et al. Placental histopathology after SARS-CoV-2 infection in pregnancy: a systematic review and meta-analysis. *Am J Obstet Gynecol MFM* 2021;3:100468.

### AJOG MFM at a Glance

#### Why was this study conducted?

This systematic review aimed to quantify the prevalence of placental histopathologic abnormalities in women with SARS-CoV-2 infection in pregnancy.

#### Key findings

A significant proportion of women with SARS-CoV-2 infection in pregnancy showed placental histopathologic abnormalities, suggesting placental hypoperfusion and inflammation. The findings from this study might explain the higher risk of stillbirth observed in women with SARS-CoV-2 infection in pregnancy.

#### What does this add to what is known?

The results from this systematic review showed a high rate of maternal and fetal vascular malperfusion associated with acute and chronic inflammatory pathologies, potentially linking the observed increased risk of stillbirth with placental anomalies.





## MotherToBaby Pregnancy Studies



Ongoing Studies: Providing Better Information on Medication Safety in Pregnancy



LIVE CHAT

# Infection with SARS-CoV-2 in pregnancy

- MotherToBaby Pregnancy Studies protocol was modified in March 2020, to capture COVID-19 symptoms, testing, treatment from all enrolled mothers, and to specifically recruit pregnant persons who might be infected
- As of June 2022, MotherToBaby Pregnancy Studies has enrolled 950 pregnant women across U.S. who met criteria
  - Tested positive
  - Symptomatic, not tested
  - Symptomatic, tested negative
  - High risk exposure, asymptomatic/not tested
- And ~459 pregnant women who did not report any of the above
- With NIDA supplemental funds, MotherToBaby began offering antibody testing to participants at enrollment and again in the 3<sup>rd</sup> trimester
- Completed a small pilot study on t-cell response and innate immunity in 8 women

# MotherToBaby Pregnancy Studies

- By maternal interview and medical records abstraction with follow-up to one year post-partum, is there an increased risk for
  - Major and/or minor birth defects, specifically a pattern
  - Spontaneous abortion, preterm delivery
  - SGA, postnatal growth, serious/opportunistic infections
  - Not meeting developmental milestones

# Infection with SARS-CoV-2 in pregnancy

Journal of Reproductive Immunology 149 (2022) 103464



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journal homepage: [www.elsevier.com/locate/jri](http://www.elsevier.com/locate/jri)

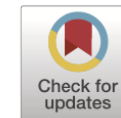


## SARS-CoV-2-specific T cell responses and immune regulation in infected pregnant women

Li-En Hsieh <sup>a</sup>, Alba Grifoni <sup>b</sup>, Hiral Dave <sup>a</sup>, Jasmine Wang <sup>a</sup>, Diana Johnson <sup>a</sup>, Jennifer Zellner <sup>a</sup>, John Sidney <sup>b</sup>, Christina Chambers <sup>a,1</sup>, Alessandra Franco <sup>a,\*,1</sup>

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<sup>b</sup> *La Jolla Institute for Immunology, Division of Vaccine Discovery, United States*



# Infection with SARS-CoV-2 in pregnancy

## A B S T R A C T

We studied the T cell response to SARS-CoV-2 spike and non-spike peptide epitopes in eight convalescent pregnant women together with the immune monitoring that included innate tolerogenic dendritic cell populations important to maintain the immunological mother/fetus interface to address a potential risk for the antiviral cellular response in the outcome of pregnancy. Four subjects had pre-existing chronic inflammatory conditions that could have potentially affected the SARS-CoV-2-specific T cell response. Seven of eight subjects responded to SARS-CoV-2 peptides with differences within CD4+ T helper (Th) and CD8+ cytotoxic T cells (CTL). SARS-CoV-2-specific inducible regulatory T cells (iTreg) were numerous in circulation. CD4+ T cell memory included central memory T cells ( $T_{CM}$ ) and effector memory ( $T_{EM}$ ). As far as the CD8+ memory repertoire,  $T_{CM}$  and  $T_{EM}$  were very low or absent in eight of eight subjects and only effector cells that revert to CD45RA+, defined as  $T_{EMRA}$  were measurable in circulation. T cells were in the normal range in all subjects regardless of pre-existing inflammatory conditions. The immune phenotype indicated the expansion and activation of tolerogenic myeloid dendritic cells including CD14+ cDC2 and CD4+ ILT-4+ tmDC. In summary, SARS-CoV-2 infection induced a physiological anti-viral T cell response in pregnant women that included SARS-CoV-2-specific iTreg with no negative effects on the tolerogenic innate dendritic cell repertoire relevant to the immune homeostasis of the maternal-fetal interface. All eight subjects studied delivered full-term, healthy infants.



# Symptoms At 1<sup>st</sup> Screen

	Test Positive %	Symptomatic Not Tested %	Test Negative %
Fever	33.7	47.8	40.5
Chills	52.0	50.0	54.1
Rigor	11.2	0	5.4
Body Ache	66.3	73.9	56.8
Headache	67.3	69.6	64.9
Runny nose	40.8	56.5	51.4
Sore throat	40.8	76.1	67.6
Cough	61.2	80.4	70.3
Wheezing	13.3	8.7	21.6
Short of breath	54.1	60.9	48.6
Chest pain	23.5	8.7	24.3
Nausea/vomiting	36.7	39.1	27.0
Abdominal pain	13.3	13.0	13.5
Diarrhea	33.7	52.2	29.7
Loss of taste	57.1	19.6	13.5
Loss of smell	68.4	19.6	18.9
Loss of appetite	50.0	23.9	27.0
Dermatologic	9.2	4.3	10.8

# Preliminary Findings

	Infection from 30 days prior LMP to 1 Day Before LMP	Infection LMP to End of 1 <sup>st</sup> Trimester	Infection 2 <sup>nd</sup> Trimester	Infection 3 <sup>rd</sup> Trimester	Pre-Pandemic Comparison
Number of Pregnancies with Outcome	18/310 (5.8%)	113/310 (36.5%)	133/310 (42.9%)	99/310 (31.9%)	933 (100%)

# SARS-COV-2 Infection in Pregnancy

	Infection from 30 days prior LMP to 1 Day Before LMP	Infection LMP to End of 1 <sup>st</sup> Trimester	Infection 2 <sup>nd</sup> Trimester	Infection 3 <sup>rd</sup> Trimester	Overall	Pre-Pandemic Comparison
Major Birth Defects in Pregnancies Ending in Live Birth - n/N (%)	0/17	1/110 (0.9%)	1/131 (0.8%)	2/98 (2.0%)	3/303 (1.0%)	51/796 (6.4%)
RR (95% CI)	---	0.14 (0.02, 1.02)	0.12 (0.02, 0.85)	0.32 (0.08, 1.29)	0.15 (0.05, 0.49)	Reference
Malformations		VSD	Cleft Lip/PFO*	VSD		

\*CL/PFO: maternal infection started in 2nd trimester and continued into 3<sup>rd</sup> trimester

Retrospective reports of limb reduction defect with 1<sup>st</sup> trimester exposure; Trisomy 21 with 1<sup>st</sup> trimester exposure ending in spontaneous abortion

# SARS-COV-2 Infection in Pregnancy

	Infection from 30 days prior LMP to 1 Day Before LMP	Infection LMP to End of 1 <sup>st</sup> Trimester	Infection 2 <sup>nd</sup> Trimester up to 20 Weeks	Overall	Pre-Pandemic Comparison
# Events Spontaneous Abortion in Enrolled (and Exposed) <20 Weeks	1/7	3/54	0/21	4/69	19/575
Left Truncation Accounted Rate (95% CI)	28.3% (2.1%, 99.4%)	35.2% (20.9%, 55.3%)	0	38.9% (20.6%, 65.0%)	12.4% (11.6%, 13.4%)
HR (95% CI)	9.82 (1.28, 75.33)	3.40 (0.99, 11.63)	--	4.34 (1.46, 12.94)	Reference

\*no stillbirths in infected group; 2 stillbirths in comparison group

# SARS-COV-2 Infection in Pregnancy

	Infection from 30 days prior LMP to 1 Day Before LMP	Infection LMP to End of 1 <sup>st</sup> Trimester	Infection 2 <sup>nd</sup> Trimester	Infection 3 <sup>rd</sup> Trimester Before 37 Weeks	Overall	Pre-Pandemic Comparison
# Events Preterm Birth in Singleton Pregnancies Enrolled (and Exposed) Before 37 Weeks	1/14	5/101	10/23	6/68	17/75	64/568
Left Truncation Accounted Rate (95% CI)	6.9% (0.9%, 44.4%)	5.4% (2.2%, 13.1%)	9.7% (5.0%, 18.4%)	12.0% (4.9%, 27.7%)	7.8% (4.7%, 12.8%)	8.7% (6.7%, 11.2%)
HR (95% CI)	0.99 (0.14, 7.12)	0.61 (0.25, 1.52)	1.14 (0.58, 2.21)	1.52 (0.66, 3.51)	0.91 (0.53, 1.56)	Reference

# SARS-COV-2 Infection in Pregnancy

	Infection from 30 days prior LMP to 1 Day Before LMP	Infection LMP to End of 1 <sup>st</sup> Trimester	Infection 2 <sup>nd</sup> Trimester	Infection 3 <sup>rd</sup> Trimester	Overall	Pre-Pandemic Comparison
SGA Weight Among Liveborn Singletons – n/N (%)	1/17 (5.9%)	11/98 (11.2%)	12/127 (9.4%)	7/96 (7.3%)	29/285 (10.2%)	65/761 (8.5%)
RR (95% CI)	0.69 (0.10, 4.68)	1.31 (0.72, 2.40)	1.11 (0.62, 1.99)	0.85 (0.40, 1.81)	1.19 (0.79, 1.81)	Reference
SGA Length Among Liveborn Singletons – n/N (%)	0/16 (0)	4/96 (4.2%)	3/121 (2.5%)	5/91 (5.5%)	12/273 (4.4%)	36/739 (4.9%)
RR (95% CI)	0	0.86 (0.31, 2.35)	0.51 (0.16, 1.63)	1.13 (0.45, 2.80)	0.90 (0.48, 1.71)	Reference

# Preliminary Conclusions

- No suggestion of an increased risk to date for malformations
- Slightly elevated, but not significantly so, risk for preterm delivery with third trimester exposure; magnitude of risk similar to previous reports
- Numbers too small to say anything yet about spontaneous abortion
- No evidence of an increased risk for SGA on weight or length at birth; consistent with previous reports

# COVID-19 Vaccination In Pregnancy

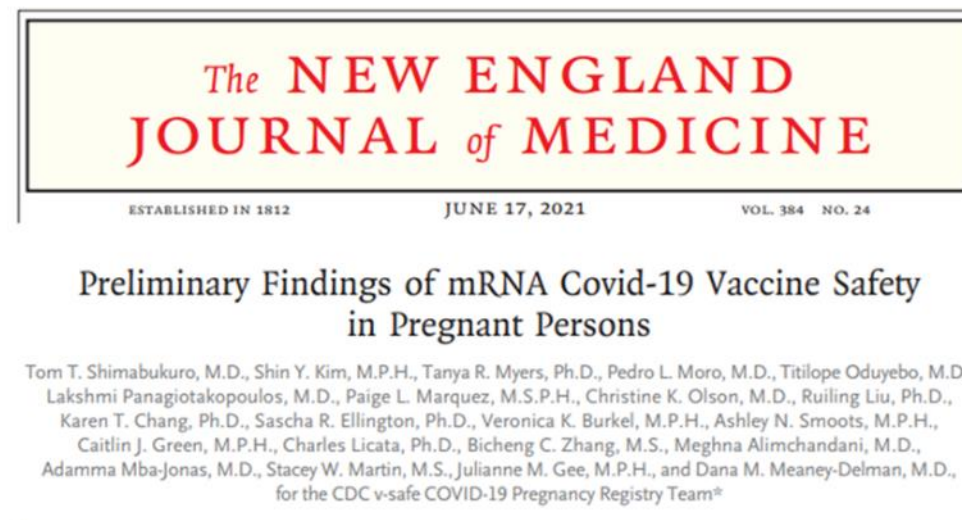




# V-Safe Pregnancy Registry

Dec 14, 2020-Feb 28, 2021:

- 827 completed pregnancies
- 724 live-born infants
  - 98% 3<sup>rd</sup> trimester vaccination



**Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.**

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	no./total no. (%)
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk <sup>15-17</sup>	10–26	104/827 (12.6)‡
▶ Stillbirth: ≥ 20 wk <sup>18-20</sup>	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
▶ Preterm birth: <37 wk <sup>21,22</sup>	8–15	60/636 (9.4)¶
▶ Small size for gestational age <sup>23,24</sup>	3.5	23/724 (3.2)
Congenital anomalies <sup>25**</sup>	3	16/724 (2.2)
▶ Neonatal death <sup>26††</sup>	<1	0/724

Stillbirth, preterm birth, SGA, neonatal deaths similar to published background incidences

Shimabakuro TT, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. N Engl J Med 2021; 384:2273-2282.

# V-Safe Pregnancy Registry

- Cumulative risk of SAB (6-19 weeks) in 2052 participants after receiving an mRNA COVID-19 vaccine was **14.1%**
- Age-standardized cumulative risk was **12.8%**
- Similar to previously published baseline estimates of SAB (11-16%)

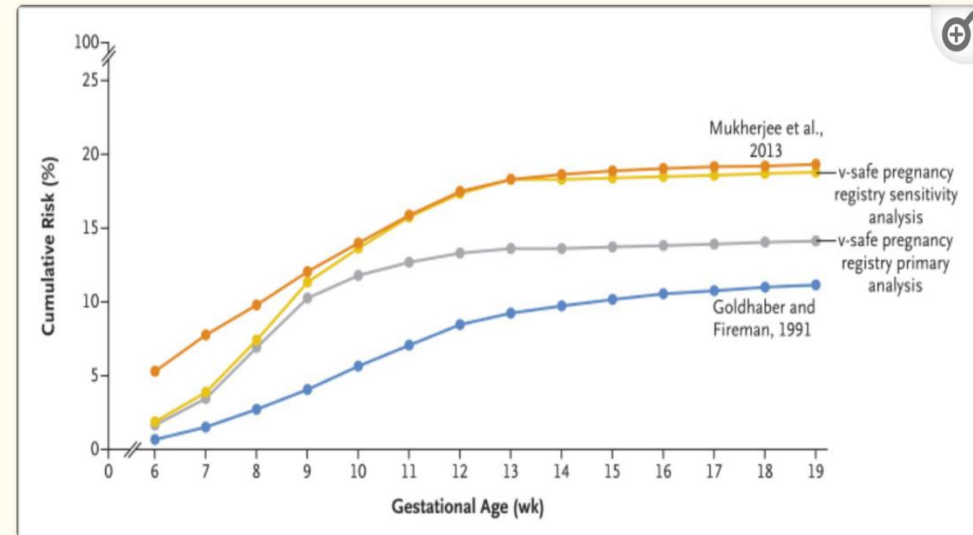


Figure 1

Cumulative Risk of Spontaneous Abortion in the v-safe Covid-19 Vaccine Pregnancy Registry and in Two Historical Cohorts.

Data from Mukherjee<sup>2</sup> were presented as race-specific rates and are provided here for White women to maximize comparability with the v-safe pregnancy registry.

Zauche LH, et al. Receipt of mRNA COVID-19 vaccines risk of spontaneous abortions. N Engl J Med, Correspondence, Sept 8, 2021.

# Vaccine Safety Datalink (VSD)

## COVID-19 vaccines received during pregnancy

(Dec 15, 2020 – Jun 28, 2021, for 105,446 unique pregnancies <20 weeks' gestation)

Seven surveillance periods (Dec 15, 2020 – Jun 28, 2021)	Ongoing Pregnancies N (%)	Spontaneous abortions N (%)
All included pregnancies	92,286	13,160
<b>Vaccine type</b>		
Janssen / J&J	480 (0.5)	48 (0.4)
Moderna	5638 (6.1)	675 (5.1)
Pfizer	7463 (8.1)	804 (6.1)

Adjusted Odds Ratios for receipt of COVID-19 vaccine in 28 days prior to SAB, Dec 15, 2020 – Jun 28, 2021

	aOR (95% CI)
<b>Full population</b>	1.02 (0.96–1.08)
<b>By gestational age strata</b>	
6–8 weeks	0.94 (0.86–1.03)
9–13 weeks	1.07 (0.99–1.17)
14–19 weeks	1.08 (0.89–1.29)
<b>By vaccine type</b>	
mRNA-1273, Moderna	1.03 (0.94–1.11)
BNT162b2, Pfizer-BioNTech	1.03 (0.95–1.11)

aOR = adjusted odds ratio; SAB= spontaneous abortion

GEE models adjusted for gestational age group, study month, site, maternal age group, number of antenatal visits, and race/ethnicity and accounted for repeated ongoing pregnancies

Women with SAB were no more likely to have received a COVID-19 vaccine in the prior 28 days than women with ongoing pregnancies

Kharbanda et al. Spontaneous abortion following COVID-19 vaccination during pregnancy. JAMA. 2021 Sep 8

# MotherToBaby Counseling Services



## COVID-19



Your Health

Vaccines

Cases & Data

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### 🏠 Vaccines

Getting Your Vaccine —

Find a Vaccine

Preparing for Your Vaccine +

Different Groups of People —

Pregnancy or Breastfeeding


## COVID-19 Vaccines While Pregnant or Breastfeeding

Updated June 29, 2021 [Languages](#) [Print](#)

Pregnant and recently pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. **If you are pregnant, you can receive a COVID-19 vaccine.** Getting a COVID-19 vaccine during pregnancy can protect you from severe illness from COVID-19. If you have questions about getting vaccinated, a conversation with your healthcare provider might help, but is not required for vaccination.

### If you are pregnant and have questions about COVID-19 vaccine

If you would like to speak to someone about COVID-19 vaccination during pregnancy, please contact MotherToBaby. MotherToBaby experts are available to answer questions in English or Spanish by phone or chat. The free and confidential service is available Monday-Friday 8am-5pm (local time). To reach MotherToBaby:

- Call 1-866-626-6847
- Chat live or send an email [MotherToBaby](#) 

# KFF COVID-19 Vaccine Monitor: Pregnancy Misinformation – May 2022

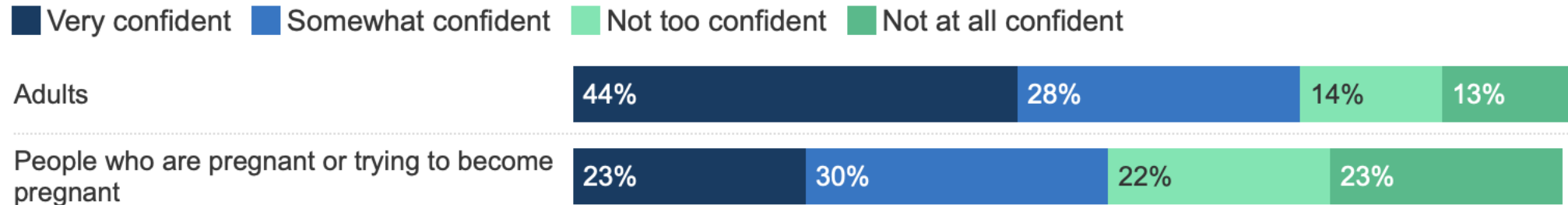
Grace Sparks  , Lunna Lopes , Alex Montero , Liz Hamel  , and Mollyann Brodie 

Published: May 27, 2022

Figure 5

## Seven In Ten Are Confident In The Safety Of COVID-19 Vaccines For Adults, With Fewer Confident In The Safety For Pregnant People

How confident, if at all, are you that the COVID-19 vaccines are safe for...?



NOTE: See topline for full question wording.

SOURCE: KFF COVID-19 Vaccine Monitor (May 10-19, 2022) • [PNG](#)

[KFF COVID-19  
Vaccine Monitor](#)

# COVID-19 Vaccination In Pregnancy Study

- MotherToBaby Pregnancy Studies protocol was modified in December 2020, to capture COVID-19 vaccine dates, maternal vaccine-related symptoms from all enrolled mothers, and to specifically recruit for exposure to the vaccine
- As of June 2022, MotherToBaby Pregnancy Studies has enrolled 2,123 pregnant women across U.S. who were vaccinated and/or boosted with any dose of Pfizer BioNTech, Moderna or J&J COVID-19 vaccines in the period from 30 days prior to LMP through the end of pregnancy
- As of June 2022, MotherToBaby Pregnancy Studies has enrolled 542 pregnant women who were not vaccinated with any COVID-19 vaccine in pregnancy but may have received Tdap or influenza vaccine





# Study Design

- With funding from NICHD/BARDA, the study under the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) umbrella, will continue to follow approximately 3,000 pregnancies to outcome and live born infants to at least one year of age with maternal interviews and medical records abstraction
- A subset of 180 pregnancies (60 per trimester) will be enrolled in a substudy to examine T-cell response and innate immunity following vaccination in pregnancy, as well as measure antibody status in mother and infant in the two months post-partum



# TO LEARN MORE



<https://mothertobaby.org/pregnancy-studies/>



<https://www.aaaai.org/about/strategic-relationships/vampss>



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**THANK YOU!**

