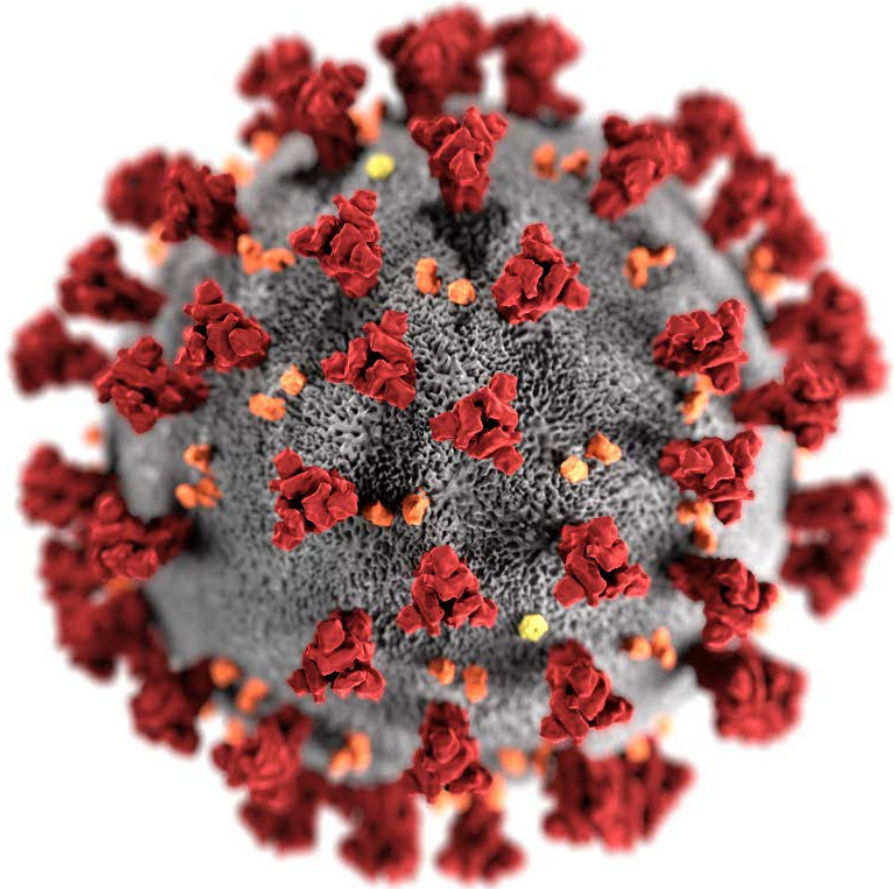
COVID-19 vaccine safety in pregnancy:

Updates from the v-safe COVID-19 vaccine pregnancy registry

Sep 22, 2021



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v-safe COVID-19 vaccine pregnancy registry
CDC COVID-19 Vaccine Task Force

For more information: **www.cdc.gov/COVID19**

Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC

V-safe pregnancy registry enrollment

Pregnancies reported to v-safe*

v-safe℠ after vaccination health checker

Individuals Reporting Pregnancy

Eligibility screeningŦŦ

Pregnant at Time of Vaccination

Vaccinated during Periconceptional Period

Eligible Individuals

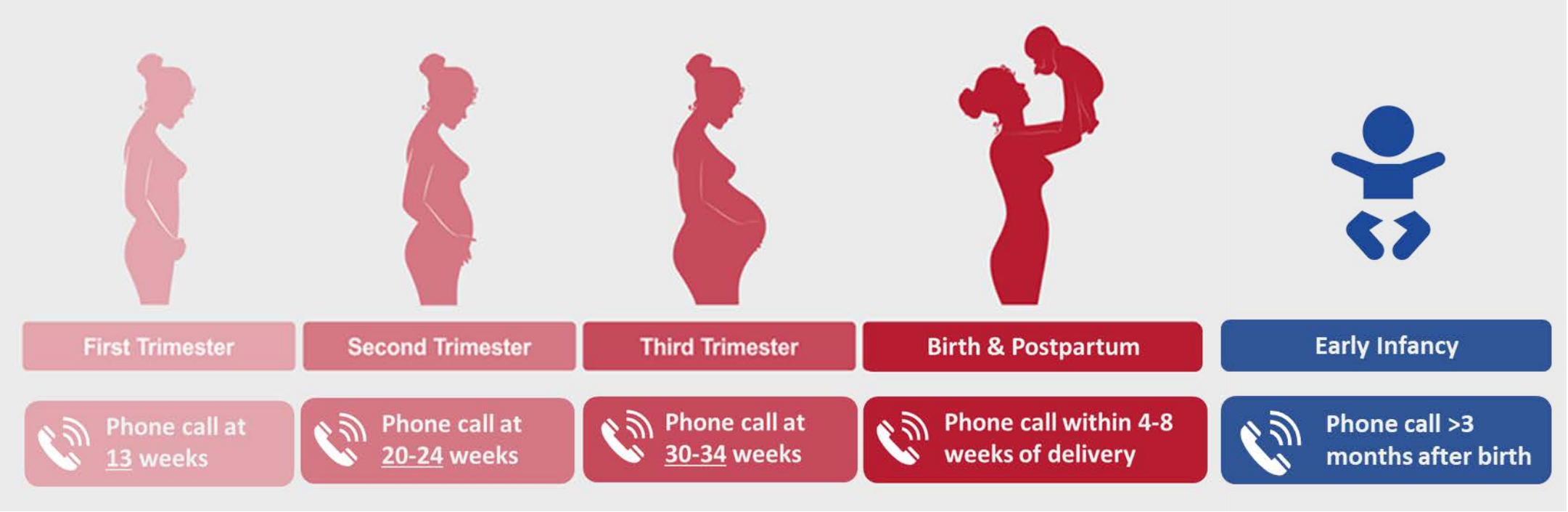
Consent for registry enrollment and follow-up

*Pregnancy questions in v-safe assessments on first survey after each dose and on post-vaccination days 21 and 42 and months 3, 6, and 12

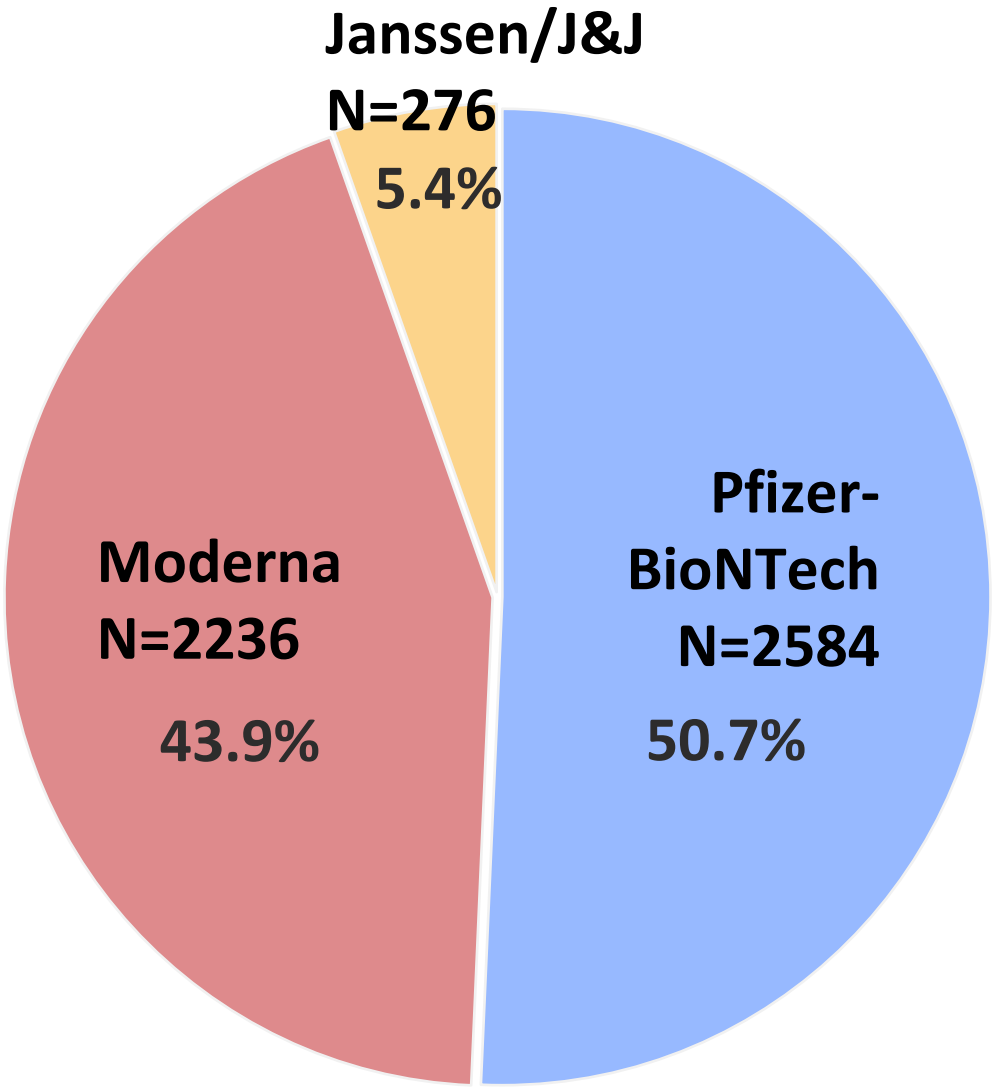
ŦEligibility determined from verbal interviews and responses to 3-question web-based v-safe follow-up survey received prior to May 31, 2021. Eligible individuals received COVID-19 vaccination during pregnancy or periconceptional period (≤ 30 days before the first day of the last menstrual period before pregnancy)

V-safe pregnancy registry active follow-up

- Participants interviewed during each trimester, postpartum, and during early infancy

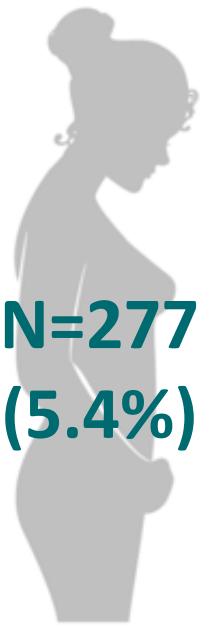


V-safe pregnancy registry participants, by vaccine manufacturer as of September 13, 2021, N=5096



Timing of first COVID-19 vaccination during periconception or pregnancy among v-safe pregnancy registry participants

Among 5093 participants*



N=277 (5.4%)

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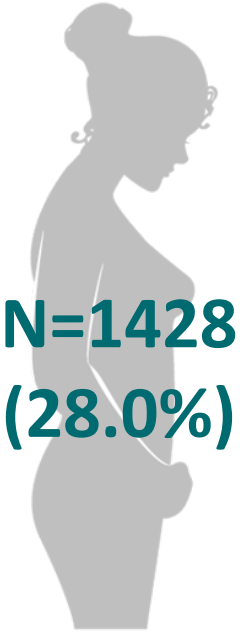
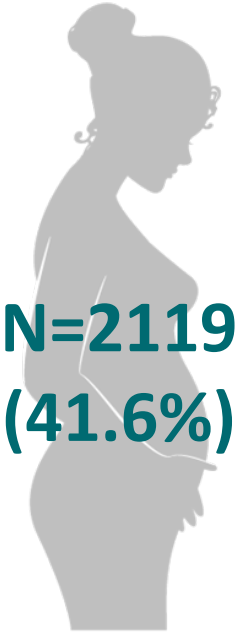


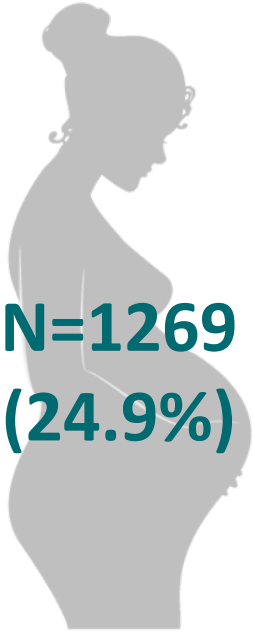
N=1428 (28.0%)

Trimester



N=2119 (41.6%)

Trimester



N=1269 (24.9%)

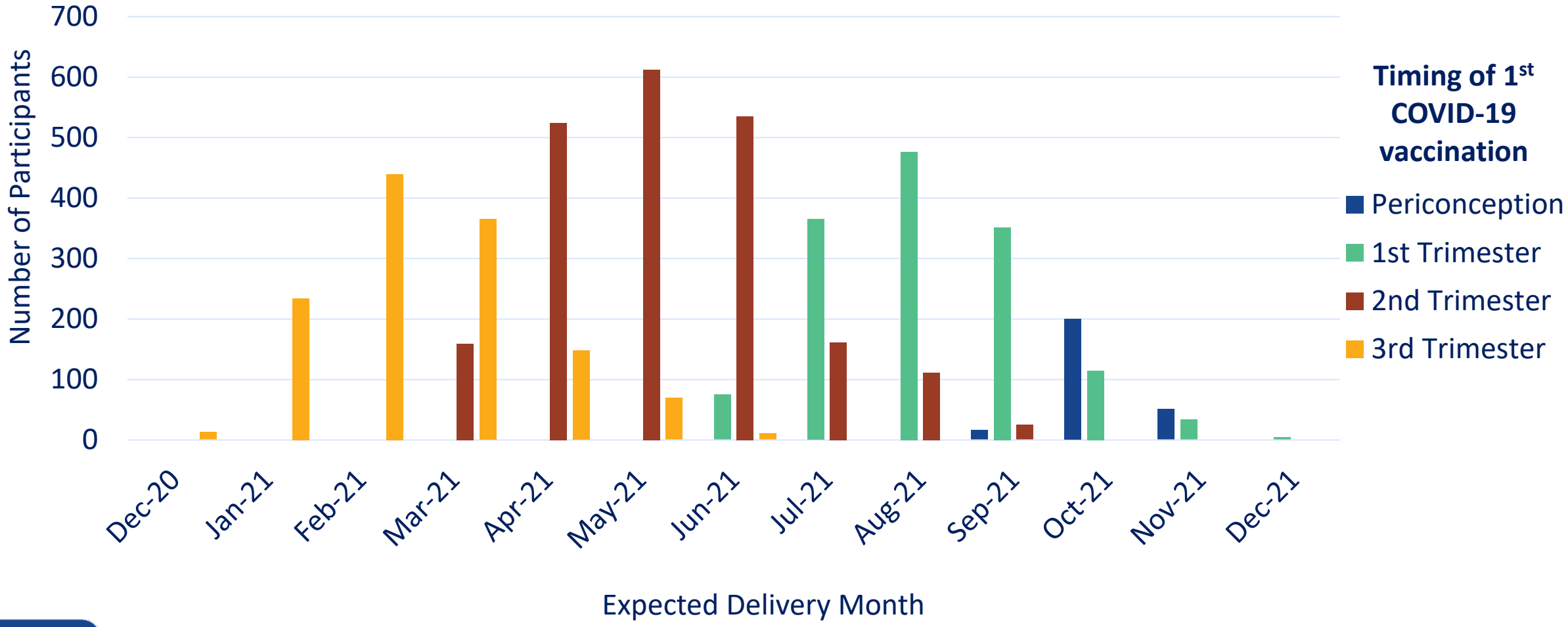
Trimester

*Eligibility dates missing for 3 participants

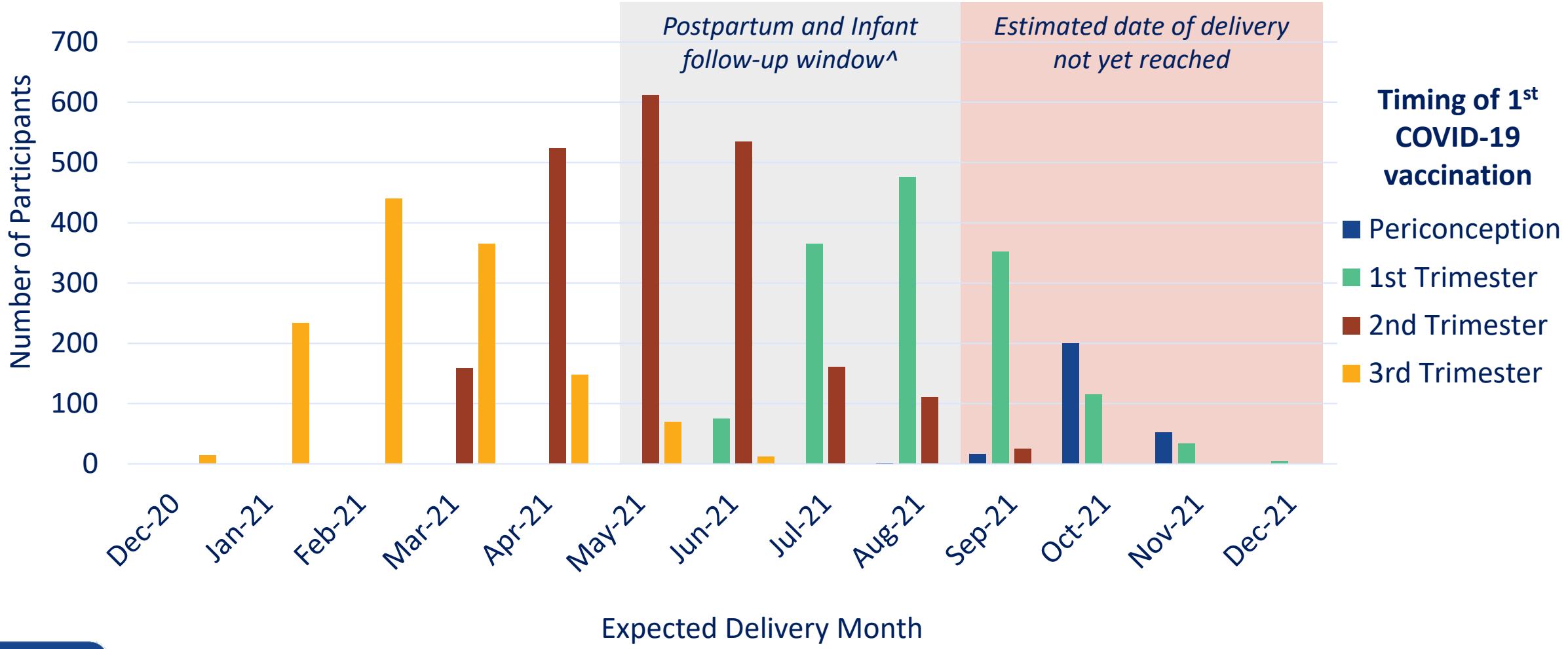
Definitions: Periconceptional: ≤30 days before the first day of the last menstrual period before pregnancy;
First trimester: 1st day of LMP to <14 weeks gestational age; Second trimester: 14-28 weeks; Third trimester: ≥28 weeks

Data as of September 13, 2021

Estimated month of delivery among enrolled participants, by timing of 1st COVID-19 vaccination received during periconception or pregnancy



Estimated month of delivery among enrolled participants, by timing of 1st COVID-19 vaccination during periconception or pregnancy



^Postpartum and infant follow-up interviews lag expected date of delivery by approximately 19 weeks

V-safe pregnancy registry participant characteristics (N=5096 enrolled)

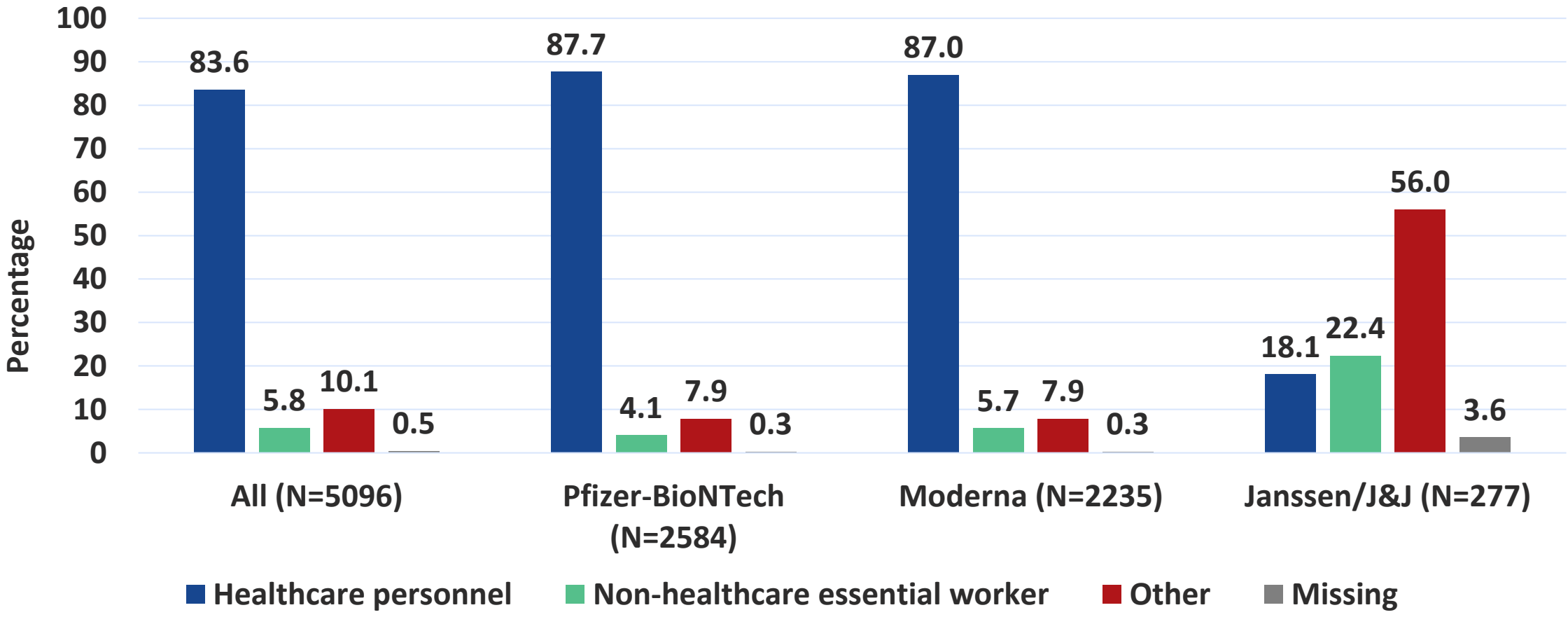
Age	Enrolled %
<20	0
20-24	1.1
25-34	65.3
35-44	33.3
>45	0.3

Race/Ethnicity*	Enrolled %
Non-Hispanic Black	1.4
Non-Hispanic White	79.4
Non-Hispanic Asian	8.4
Non-Hispanic Other	2.3
Hispanic	8.1

*Race/Ethnicity, Missing/Declined N=20 (of the 5096)

Data as of September 13, 2021

V-safe pregnancy registry participant occupation, as derived from vaccine priority group question



Data as of September 13, 2021

V-safe pregnancy registry analysis of early pregnancy loss

Receipt of mRNA COVID-19 vaccines and risk of spontaneous abortion (SAB)*

- **Objective**: Assess the cumulative risk of SAB after mRNA COVID-19 vaccination
- **Data source**: CDC's v-safe pregnancy registry, COVID-19 vaccination data 2020–21
- **Methods**:
  - Included 2456 pregnant people enrolled in v-safe pregnancy registry
    - Received at least one dose of an mRNA COVID-19 vaccine before pregnancy or prior to 20 weeks of pregnancy
    - Did not have a pregnancy loss before 6 weeks of gestation
  - Lifetable methods to examine cumulative risk

*Zauche et al. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion. N Engl J Med. 2021 Sep 8. doi: 10.1056/NEJMc2113891.

No increased risk of spontaneous abortion (SAB) after COVID-19 vaccination during pregnancy

- Unadjusted cumulative risk of SAB after mRNA COVID-19 vaccination 14.1%
- Age-standardized cumulative risk of SAB:

  12.8% (95% CI: 10.8%–14.8%)

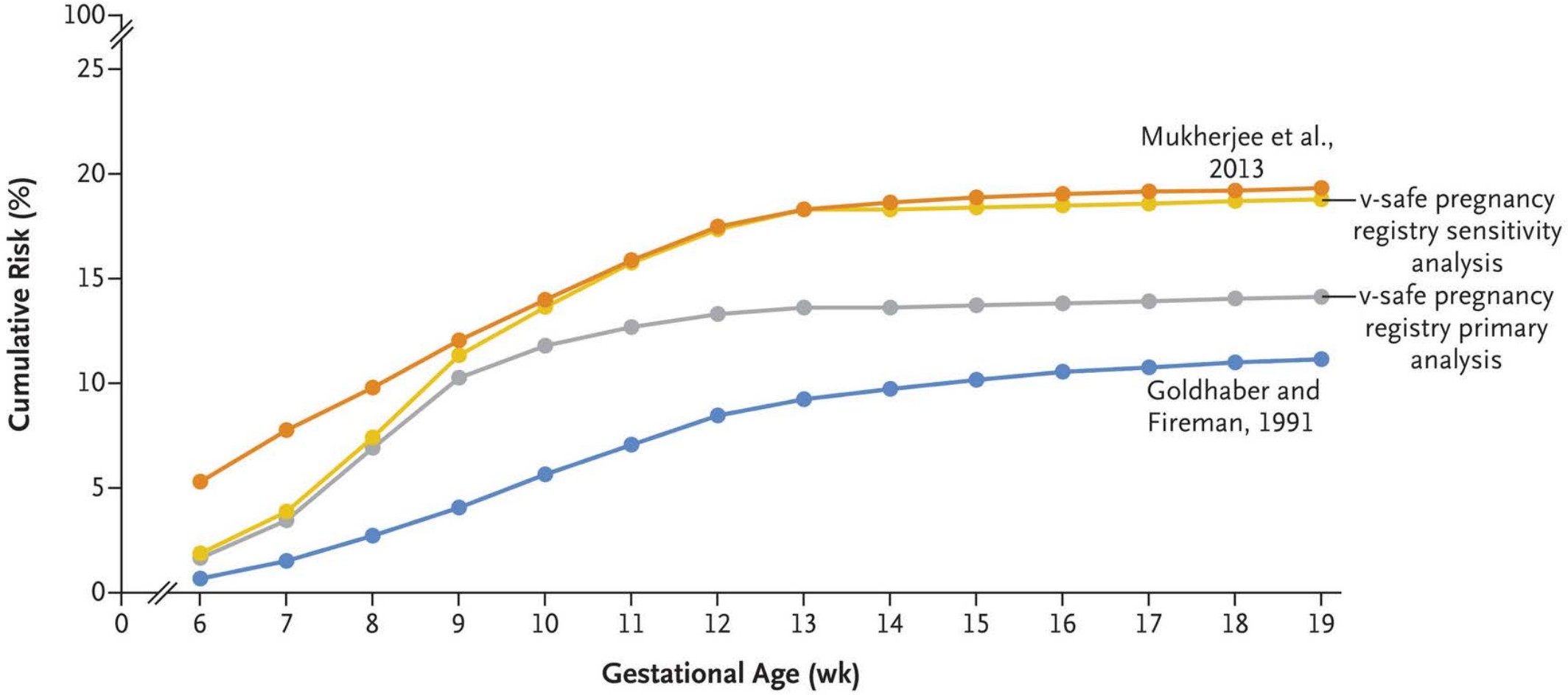
  - Similar to previously published baseline estimates of SAB (11%–22%)
- More evidence that mRNA COVID-19 vaccination during pregnancy is not associated with SAB

Table 1. Risk of Spontaneous Abortion among Participants in the v-safe Covid-19 Vaccine Pregnancy Registry, December 14, 2020, through July 19, 2021.

Gestational Age	Participants at Risk	Participants Who Reported Spontaneous Abortion	Week-Specific Risk	Cumulative Risk
	number of persons		*percent*	*percent (95% CI)*
6 to <7 weeks	904	15	1.7	1.7 (0.8–2.5)
7 to <8 weeks	982	18	1.8	3.5 (2.3–4.6)
8 to <9 weeks	1032	37	3.6	6.9 (5.4–8.5)
9 to <10 weeks	1087	39	3.6	10.3 (8.4–12.0)
10 to <11 weeks	1118	19	1.7	11.8 (9.9–13.7)
11 to <12 weeks	1184	12	1.0	12.7 (10.7–14.6)
12 to <13 weeks	1274	9	0.7	13.3 (11.3–15.2)
13 to <14 weeks	1394	5	0.4	13.6 (11.6–15.6)
14 to <15 weeks	1534	0	0	13.6 (11.6–15.6)
15 to <16 weeks	1632	2	0.1	13.7 (11.7–15.7)
16 to <17 weeks	1742	2	0.1	13.8 (11.8–15.8)
17 to <18 weeks	1848	2	0.1	13.9 (11.9–15.9)
18 to <19 weeks	1941	3	0.2	14.0 (12.0–16.0)
19 to <20 weeks	2052	2	0.1	14.1 (12.1–16.1)

Zauche et al. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion. N Engl J Med. 2021 Sep 8. doi: 10.1056/NEJMc2113891.

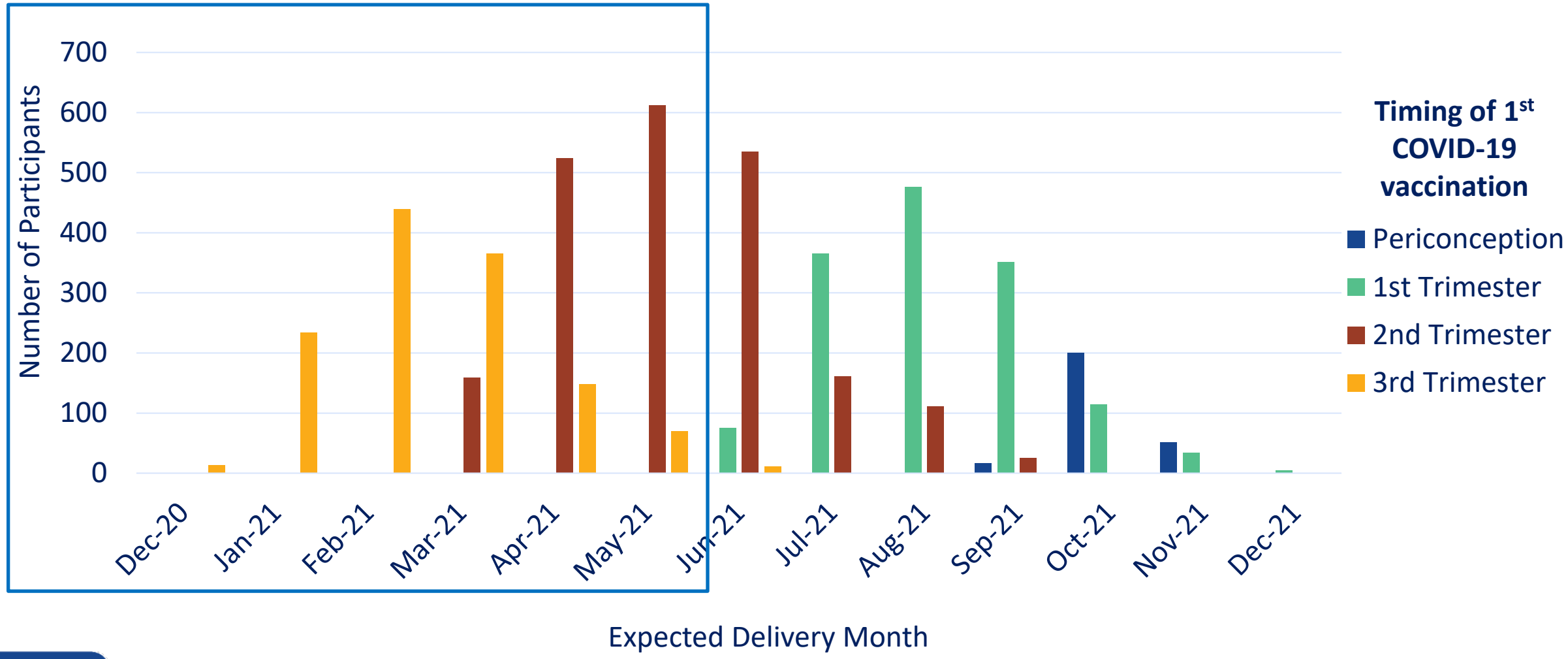
Cumulative risk of spontaneous abortion in the v-safe pregnancy registry and in two historical cohorts



Zauche et al. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion. N Engl J Med. 2021 Sep 8. doi: 10.1056/NEJMc2113891.

V-safe pregnancy registry infant outcomes at birth

Estimated month of delivery, among enrolled participants, by timing of 1st COVID-19 vaccination during periconception or pregnancy



Note: postpartum and infant follow-up interviews lag expected delivery date by approximately 19 weeks

V-safe pregnancy registry enrolled pregnancies included in maternal and infant outcomes cohort

5096 enrolled participants

- 2912 with EDD after May 15, 2021
- 7 withdrew

2177 estimated date of delivery (EDD) before May 15, 2021

- 501 pending follow-up
- 63 lost to follow-up

1613 pregnancies

1634* Live born infants

30 % 2nd trimester vaccination

70 % 3rd trimester vaccination

- **Participants enrolled in first trimester: 1427**
- **Pregnancies and follow-up ongoing; therefore, data are incomplete**
- **Will be included in future reports**

* Includes 42 infants from twin gestations

Data as of September 13, 2021

Infant outcomes among v-safe pregnancy registry enrolled participants* with pregnancies ending in live birth (N=1634 infants)

Live born infants	All infants N=1634 (%)	Background rate %†
Preterm [a]	99 (6.5)	8-15
Small for gestational age [b]	45 (2.8)	3.5
Admitted to NICU [c]	158 (9.7)	9.3
Neonatal or infant death [d]	0 (0)	<1

* Maternal and infant outcomes cohort defined as participants with completed follow-up and expected delivery dates prior to May 15, 2021, to account for the lag in ascertaining outcomes at infant 3-month follow-up.

† Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons in NEJM https://www.nejm.org/doi/full/10.1056/nejmoa2104983

[a] Preterm birth denominator is live births among mothers vaccinated before 37 weeks' gestation (n=1,514 infants)
[b] Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

[c] Among 2019 live births, National Vital Statistics Registry: https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-02-tables-508.pdf

[d] Among 2018 live births, National Vital Statistics Registry: https://www.cdc.gov/nchs/data/nvsr/nvsr69/NVSR-69-7-508.pdf

Preliminary birth defects data among live born infants of participants vaccinated in the 2nd or 3rd trimester

- Most birth defects arise in the first trimester; most pregnancies in the registry that were vaccinated in the first trimester are ongoing
- V-safe pregnancy registry participants report birth defects during the postpartum interview
  - Response to question “Was your baby diagnosed with a birth defect?”
- Reported birth defects were reviewed for inclusion and categorized by birth defect experts
- Birth defects were defined as a structural abnormality, chromosome anomaly, or genetic syndrome

Participant reports of birth defects among live born infants of participants vaccinated in the 2nd or 3rd trimester (N=1574)

Birth Defect Categories	Specific defects N=52*
Heart and circulatory system	**16**
Septal defects	*11*
Musculoskeletal system	**8**
Polydactyly and syndactyly	*4*
Genitalia	**7**
Hypospadias	*5*
Kidney and urinary system	**5**
Cleft lip +/- cleft palate	**4**
Chromosomal anomalies	**4**
Trisomy 21	*3*
Nervous system	**3**
Respiratory system	**2**
Other	**3**

Among the 45 infants with birth defects:

- Types of reported birth defects are consistent with data from birth defects surveillance in the United States
- No unusual types or clusters of birth defects noted
- The v-safe pregnancy registry has demonstrated its capability in identifying birth defect outcomes and their distinct types

*Among 45 infants who had one or more major birth defect; 6 infants had >1 birth defect; 1 infant was from a twin gestation

v-safe pregnancy registry

Data as of September 6, 2021

Closing thoughts on COVID-19 vaccination and pregnancy

Closing thoughts

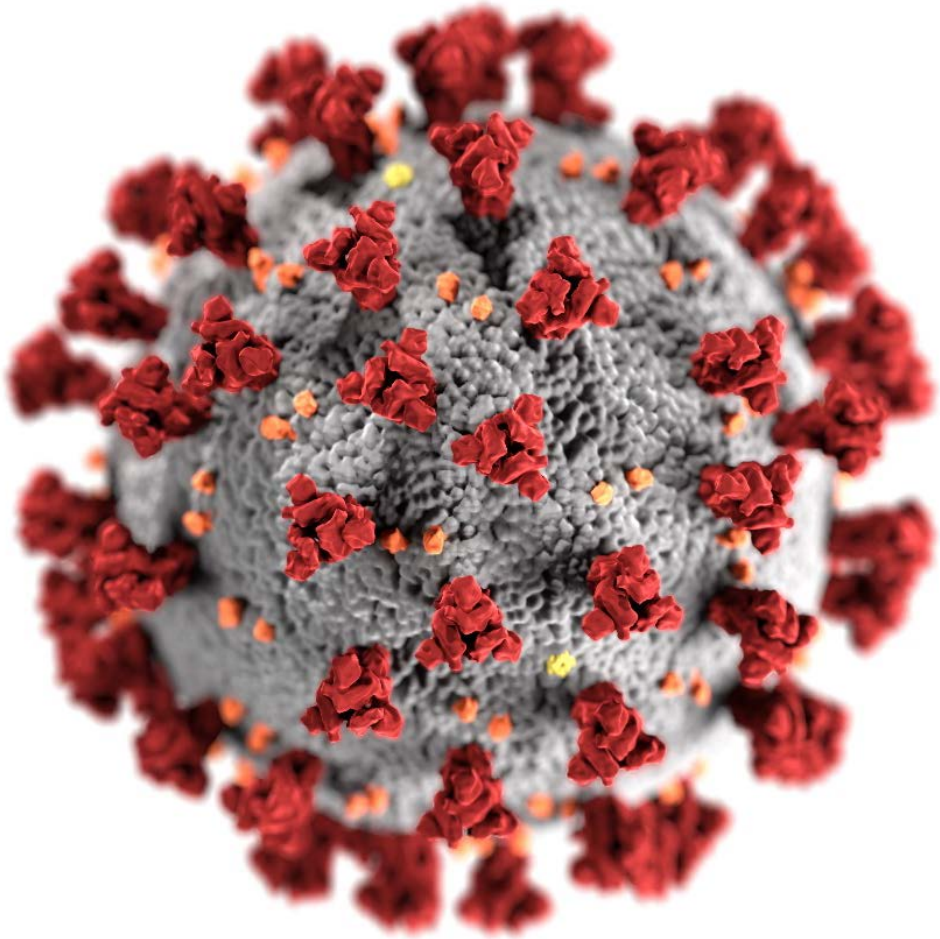
- Accumulating data on the safety of COVID-19 vaccination during pregnancy from the v-safe pregnancy registry adds to the growing body of evidence of the safety of COVID-19 vaccination during pregnancy
  - No evidence of any increase in spontaneous abortion rates
  - No evidence of any disproportionate infant outcomes
- CDC will continue to monitor the safety of COVID-19 vaccination during pregnancy

Acknowledgments

Thank you to the many people who continue to contribute to the vaccine safety monitoring work

- **V-safe After Vaccination Health Checker Team**
- **V-safe COVID-19 Pregnancy Registry Team**
- **Vaccine Safety Datalink Team**
- **VAERS Team**
- **Participants in all of the above vaccine safety monitoring systems**
- **CDC COVID-19 Vaccine Task Force**

Thank you!



For more information, contact CDC
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