Strategies to Improve Maternal COVID-19 Vaccine Uptake While Pregnant and Breastfeeding

DECEMBER 9TH, 2021
12 PM EST

Presenters -

- Dr. Karen Puopolo M.D., Ph.D.
- Dr. Meg Kawan MD, MPH, IBCLC
- Sarah Mann J.D., and a national parent advocate

Let's TALK

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- All participants will remain muted during the session
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Objectives

At the end of this session, participants will be able to:

- Recognize the current data on pregnancy and post-pregnancy COVID-19 vaccine uptake
- Understand the COVID-19 vaccine placental antibody transfer among vaccinated pregnant people
- Understand the COVID-19 vaccine breastfeeding transfer of antibodies among vaccinated pregnant people
- Utilize strategies to improve and encourage vaccine uptake as a vaccine champion with parents pre- and post-birth

TODAY'S PRESENTERS

Karen M. Puopolo, M.D., Ph.D

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Let's Talk Series
December 9, 2021

Pregnancy, COVID-19 and Vaccines

Karen M. Puopolo MD, PhD

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Conflicts of Interest

- **Karen M. Puopolo, M.D., Ph.D. has documented no financial relationships to disclose or Conflicts of Interest to resolve**
- **This presentation will discuss the use of vaccines currently being administered under FDA Emergency Use Authorization**
- ***Funding***: **Work discussed today was supported in part by institutional funds from the University of Pennsylvania; NIH grants AI082630 (to E. Wherry) and UL1TR001878 (to D. Rader); CHOP Foerderer Grant (to K. Puopolo); Parker Institute for Cancer Immunotherapy (to E. Wherry); and charitable contributions.**

Current COVID-19 Data

WHO data 12/7/2021	CDC U.S. data 12/6/2021
265,713,467 cases	49,198,746 cases
5,260,888 deaths	787,064 deaths
7,952,750,402 vaccine doses	234,000,000 ≥1 vaccine dose
	75.7% of all persons ≥5 years

Pregnant Persons

CDC U.S. data 12/6/2021

150,036 cases → 248 deaths

25,402 hospitalized for COVID → 30 deaths

35% of all pregnant persons are fully vaccinated

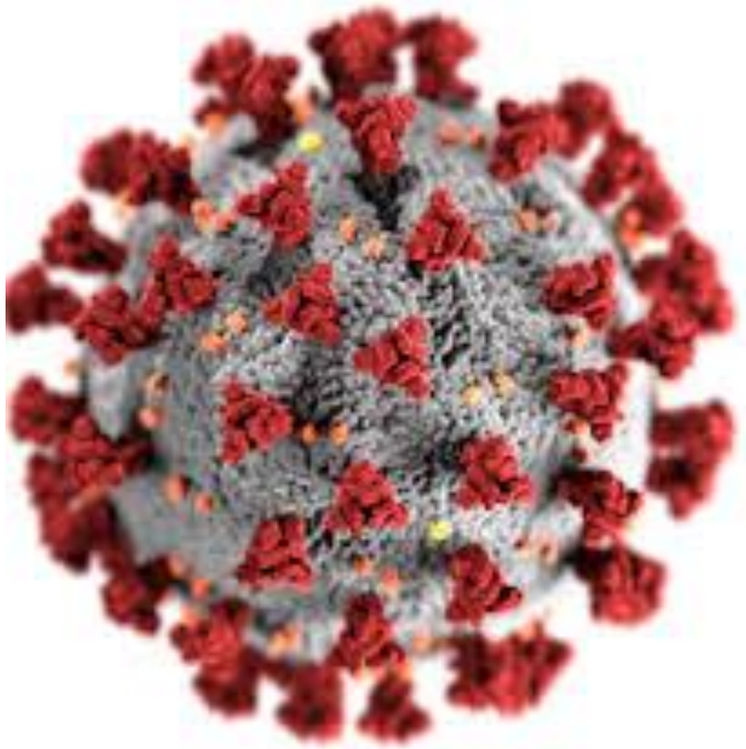
Outline for Today

- Impact of COVID-19 on pregnant persons
- Safety data on COVID-19 vaccination during pregnancy
- Current data on pregnancy and post-pregnancy COVID-19 vaccine uptake
- Placental antibody transfer among vaccinated pregnant people

IMPACT OF SARS-COV-2 INFECTION ON PREGNANT WOMEN

Seroepidemiology Among Pregnant Women in Philadelphia Region

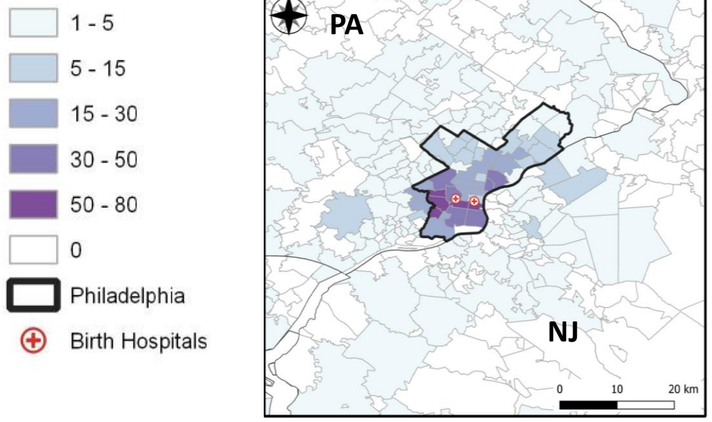
- Seroprevalence studies are an important component of the public health response to COVID-19
  - Viral testing data may underestimate mild/asymptomatic cases
  - Assuming all exposures result in immune response, may be a more complete reflection of community exposure

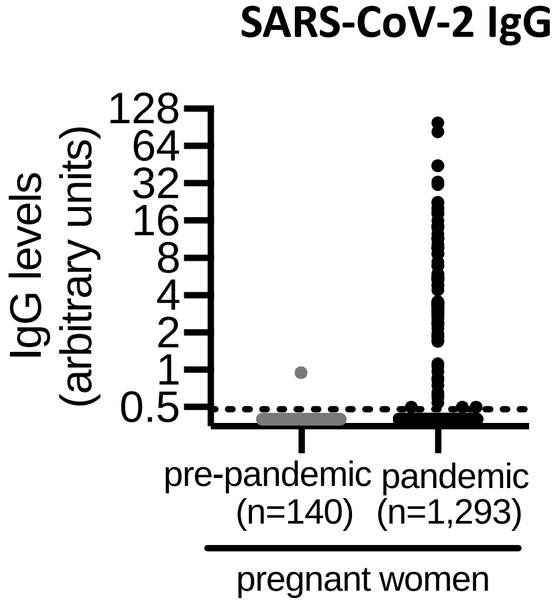


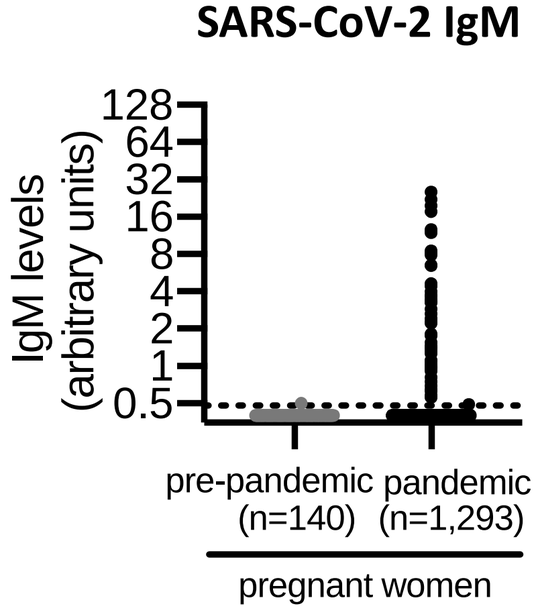
Study Procedures

- Residual sera collected for clinical purposes and scheduled for discard after maternal birth hospital discharge was collected, de-identified and transferred to research laboratory
- Sera tested by enzyme-linked immunosorbent assay (ELISA) for SARS-CoV-2 IgG and IgM antibodies to the spike protein receptor binding domain (RBD) antigen
- Limited data collection from review of electronic medical records

SARS-CoV-2 Seroprevalence Among Parturient Women Delivering in Philadelphia



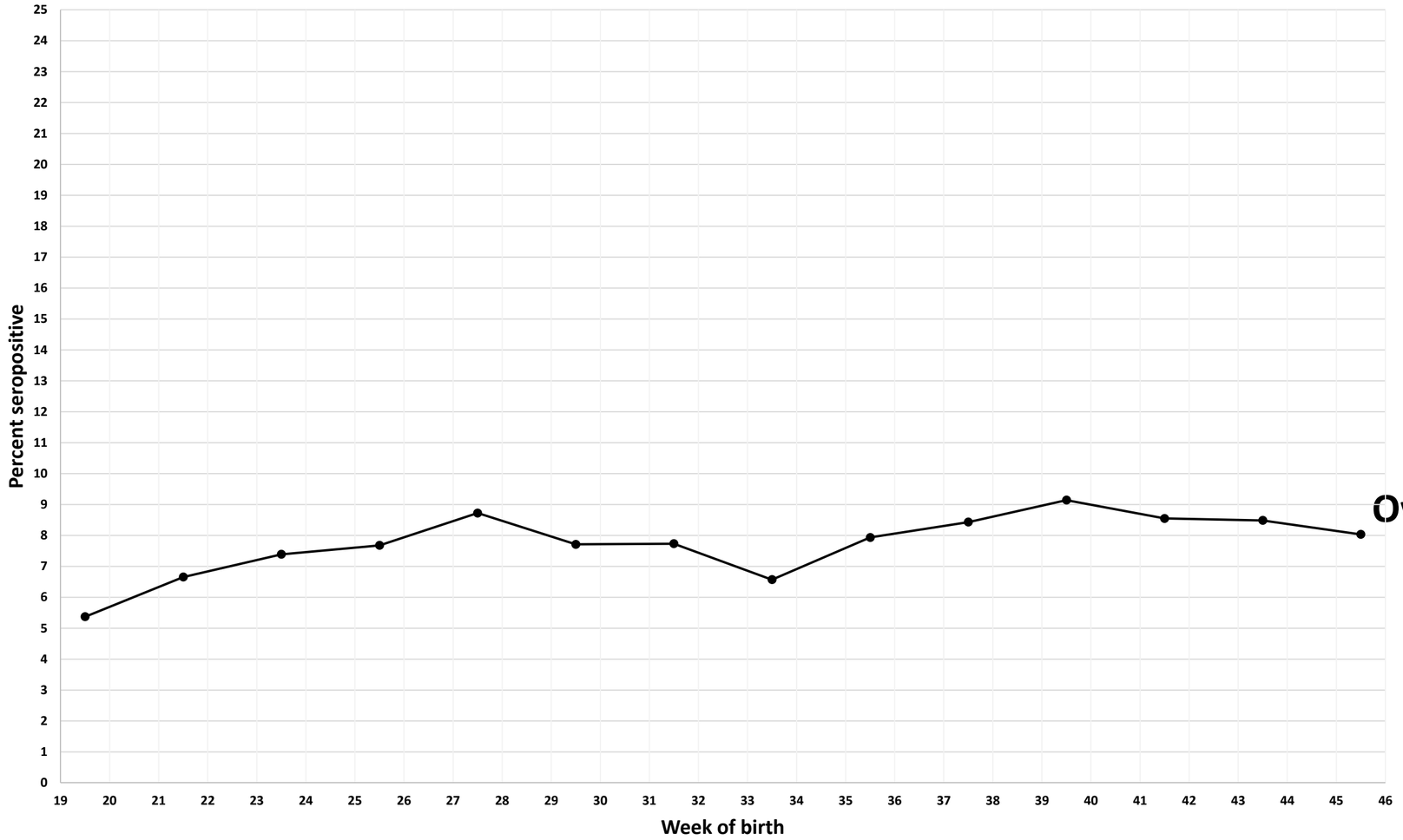




- **1293 women delivering April 4 – June 3, 2020**
- ***6.2% of parturient women with IgG and/or IgM at time of delivery***
- **At the same time, reported cases in the region based on viral testing suggested an infection rate of 1.4%, more than 4-fold lower**

Flannery, et al. *Sci Immunol* 2020

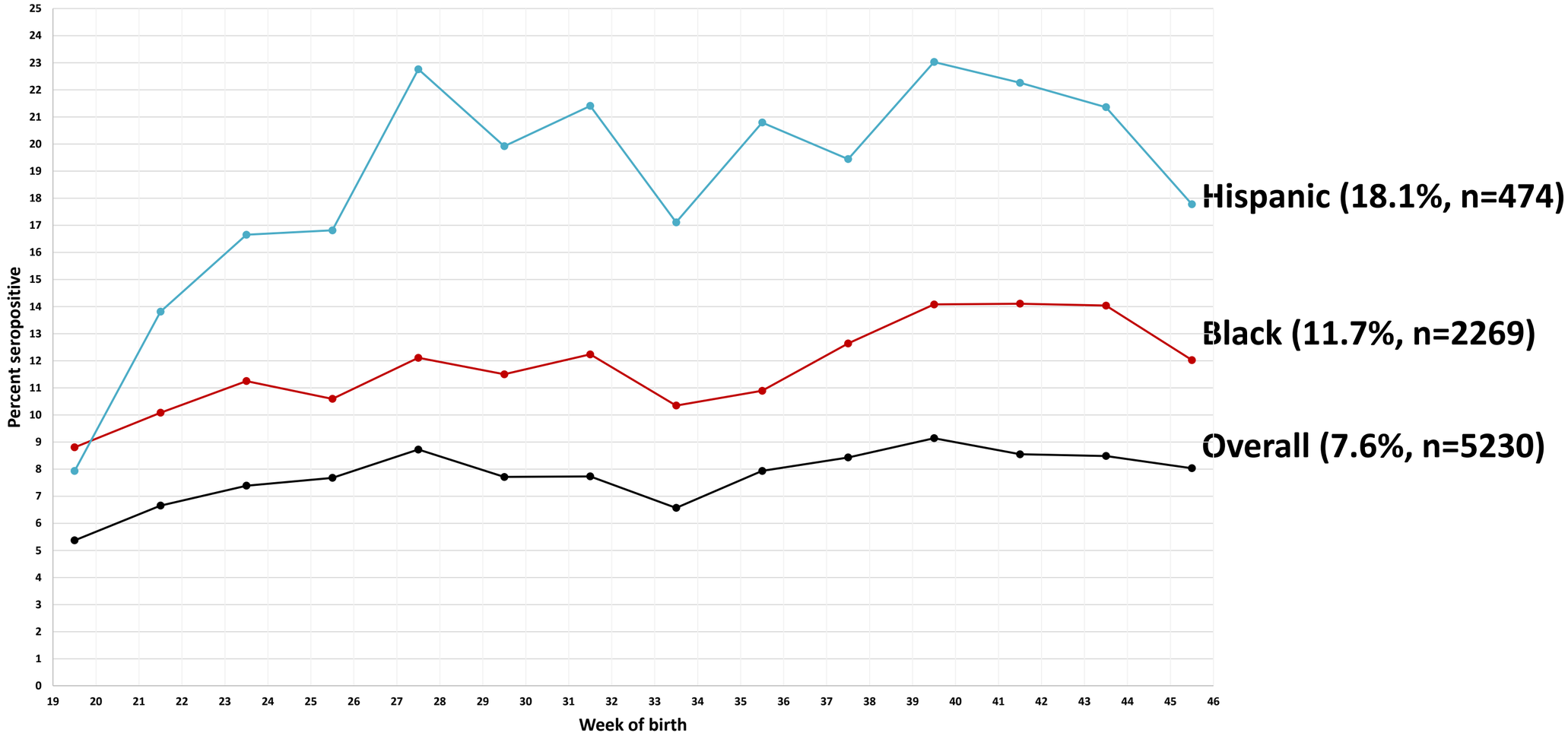
Seroprevalence: Two-Week Moving Average (4/8 – 11/17/2020)



Overall (7.6%, n=5230)

Puopolo and Hensley, unpublished data

Seroprevalence: Two-Week Moving Average (4/8 – 11/17/2020)



Puopolo and Hensley, unpublished data

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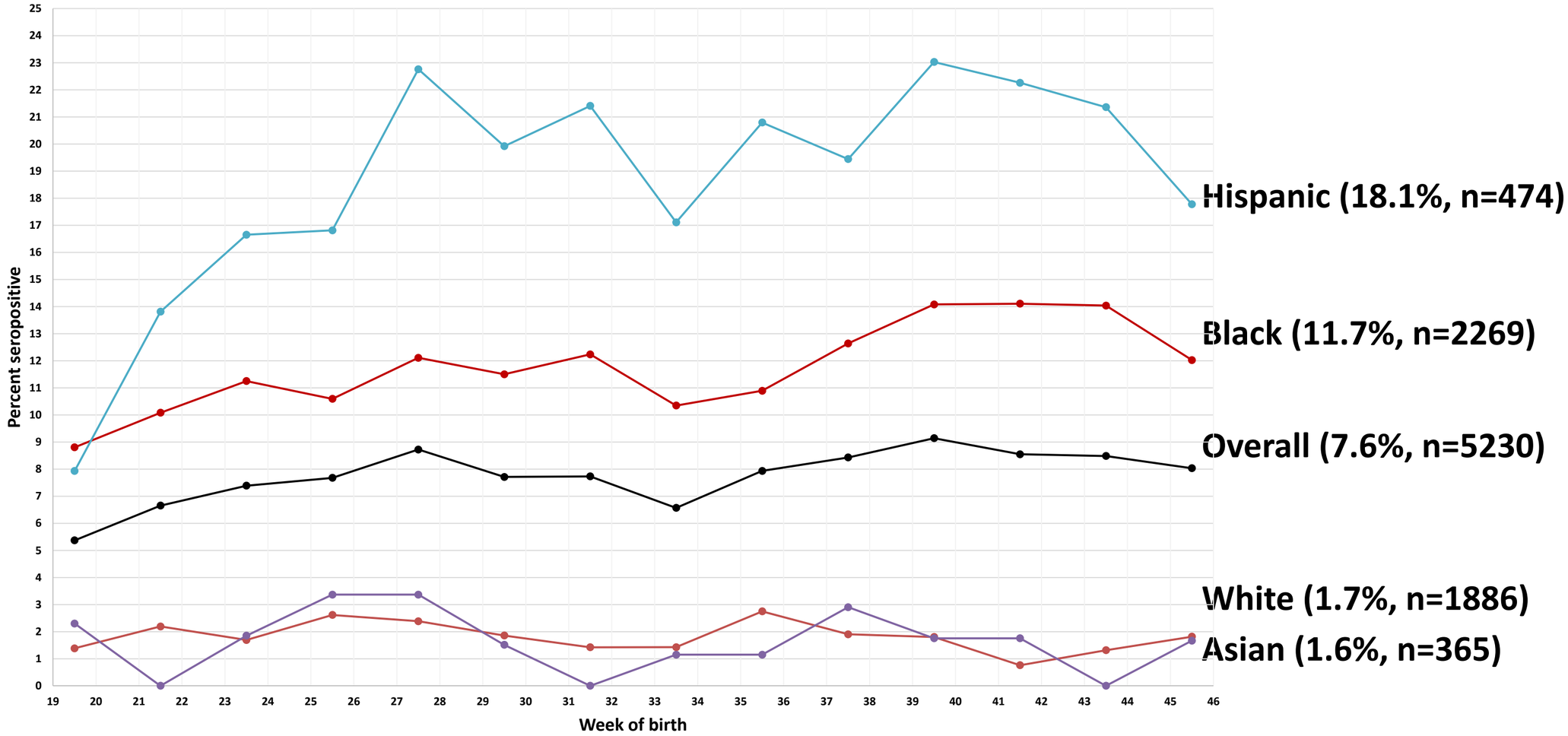
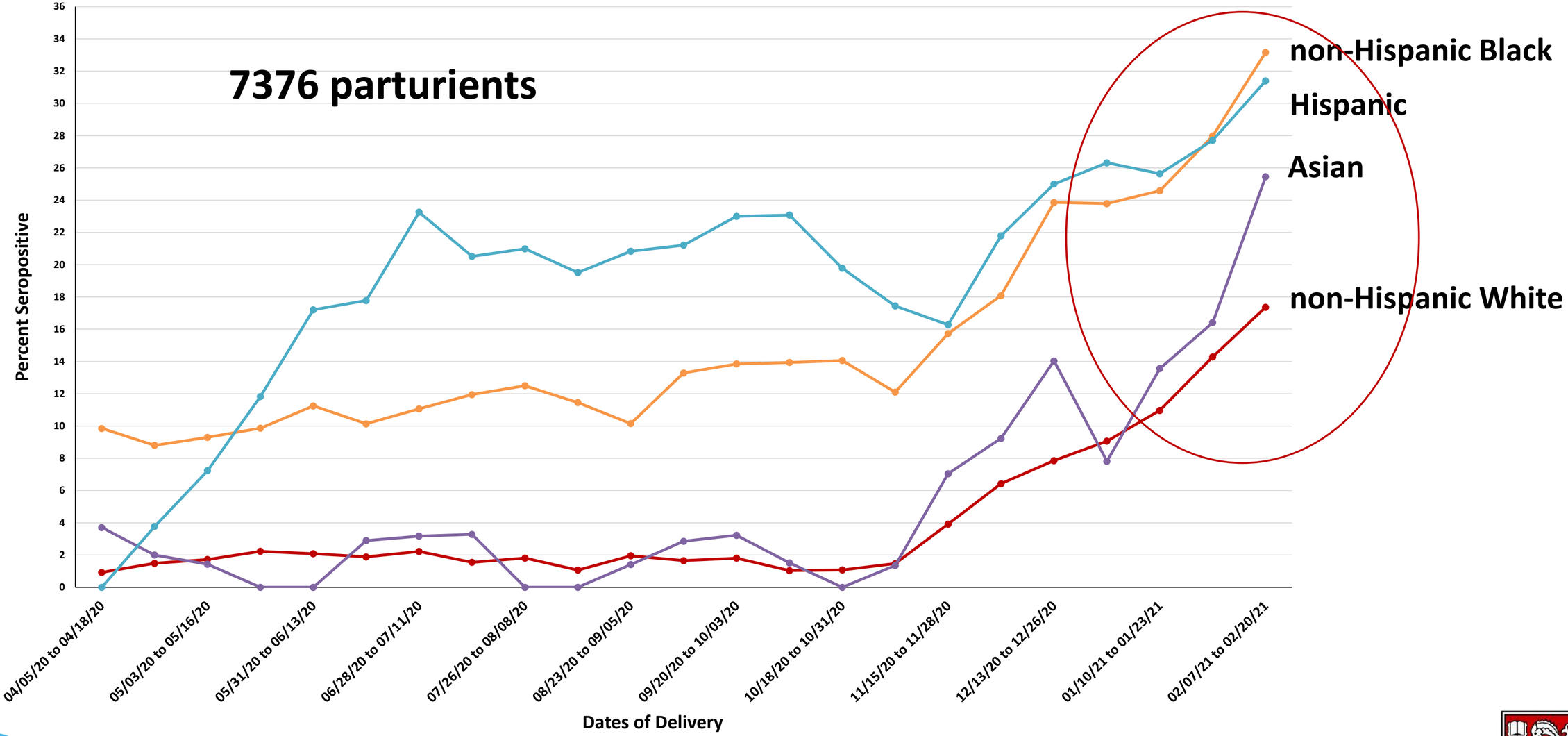


*Race/ethnicity unknown or other for 236 (4.5%)

Puopolo and Hensley, unpublished data

Maternal Seroprevalence April 2020 - February 2021



*Race/ethnicity unknown or other for 316 (4.3%)

Puopolo and Hensley, unpublished data

CDC Surveillance COVID-19 Outcomes

	MMWR 6/26/2020 Vol. 69 / No. 25	MMWR 11/6/2020 Vol. 69 / No. 44
Date	1/22/2020 – 6/7/2020	1/22/2020– 10/3/2020
Population	Females age 15-44 years Symptomatic with laboratory-confirmed infection	
Not pregnant, n	83,205	386,028
Confirmed pregnant, n	8207	23,434
Admission to ICU for COVID, aRR (95% CI)	1.5 (1.2–1.8)	3.0 (2.6–3.4)
Mechanical ventilation, aRR (95% CI)	1.7 (1.2-2.4)	2.9 (2.2–3.8)
Death, aRR (95% CI)	0.9 (0.5-1.5)	1.7 (1.2–2.4)

For pregnant persons with COVID-19, *absolute risks per 1000*:

- **10.5 admit ICU**
- **2.9 intubated**
- **0.7 ECMO**
- **1.5 die**

Note: US maternal mortality 0.2/1000

Adjusted for age, race/ethnicity and underlying conditions

Delta Variant May be Worse

- CDC surveillance in Mississippi, 3/1/2020 – 10/6/2021
- 1637 SARS-CoV-2 infections during pregnancy; 15 deaths
  - –Pre-Delta variant: deaths 5/1000 (95% CI, 1.7-10.3)
  - –Delta variant: deaths 25/1000 (95% CI, 11.3-46.8)
- 14/15 unvaccinated; 1 person partially vaccinated
- 14/15 had underlying conditions [obesity (10), HTN (8), diabetes (4), cancer (2), HIV (1)]
- 12 live births; 3 fetal deaths

Kasehagen, et al. MMWR 11/26/2021:70, No. 47

AAP Perinatal COVID Registry

- From 4/6/2020–3/19/2021, data for 7570 pregnant persons and 7647 live births submitted from 252 U.S. centers
- 2.2% of newborns tested positive for SARS-CoV-2 at 24-72 hours of age
- 15.6% infants born <37 weeks' gestation
  - –Higher than overall rate ~10% in 2019
- 18 maternal deaths during birth hospitalization
  - –Higher than expected 1-2 deaths

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Hudak and Puopolo, unpublished data

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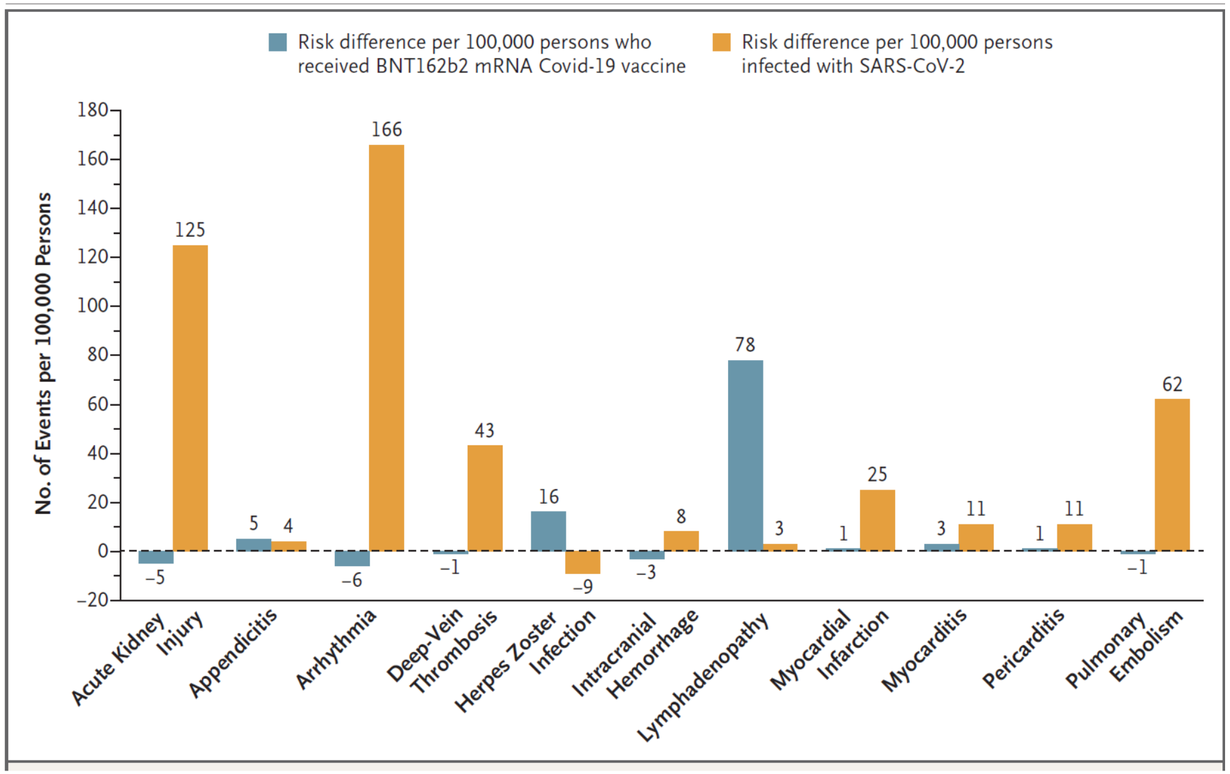
CHOP/PENN PERINATAL INFECTIOUS DISEASES

SAFETY OF COVID-19 VACCINES GIVEN DURING PREGNANCY

National Surveillance in Israel

- **Database including ~50% of all citizens**
- **Matched 884,828 vaccinated to 884,823 unvaccinated persons**
  - **Demographic factors and risk factors for COVID-19**
  - **12,164 pregnant persons**
- **Comparison group: 173,106 infected to 173,106 uninfected with SARS-Cov-2**
  - **9918 pregnant persons**



Barda, et al. *New Engl J Med* 2021

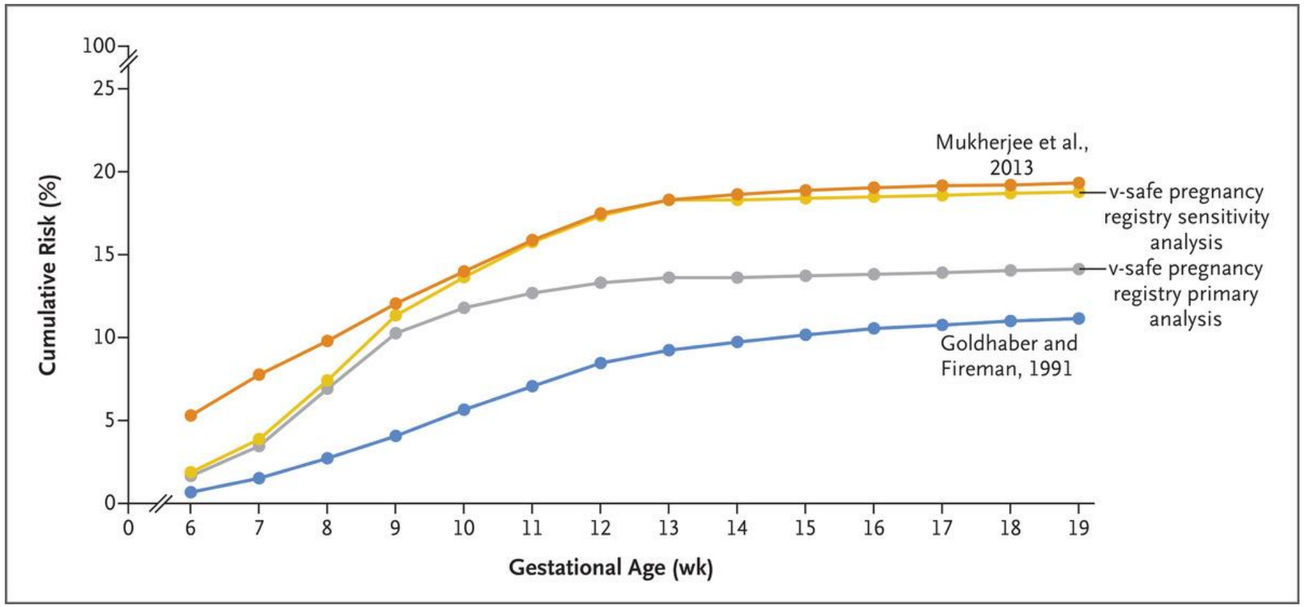
Norwegian Case-Control Study

- February – August 2021
- Matched
  - 13,956 women with ongoing pregnancies (5.5% were vaccinated)
  - 4521 women with miscarriages (5.1% were vaccinated)
- Estimated odds ratios with for COVID-19 vaccination within 5-week and 3-week windows before a miscarriage or ongoing pregnancy, adjusting for demographic factors and risk factors for COVID-19
- Among those with miscarriage:
  - Vaccination in prior 3 weeks: OR 0.91 (95% CI, 0.75 to 1.10)
  - Vaccination in prior 5 weeks: OR 0.81 (95% CI, 0.69 to 0.95)

Magnus, et al. *New Engl J Med* 2021

CDC V-Safe Surveillance and Miscarriage

- Smartphone-based, voluntary post-vaccine registry
- Participants with a singleton pregnancy
- ≥1 dose of mRNA vaccine before conception or before 20 weeks' gestation *and* no pregnancy loss before 6 weeks of gestation



- Overall rate 14.1% (95% CI, 12.1 to 16.1)
- Age-adjusted rate 12.8% (95% CI, 10.8 to 14.8)
- 65 participants could not be reached; sensitivity analysis with assumption all had miscarriage
- Comparable to historical cohorts

Zauche, et al. *New Engl J Med* 2021

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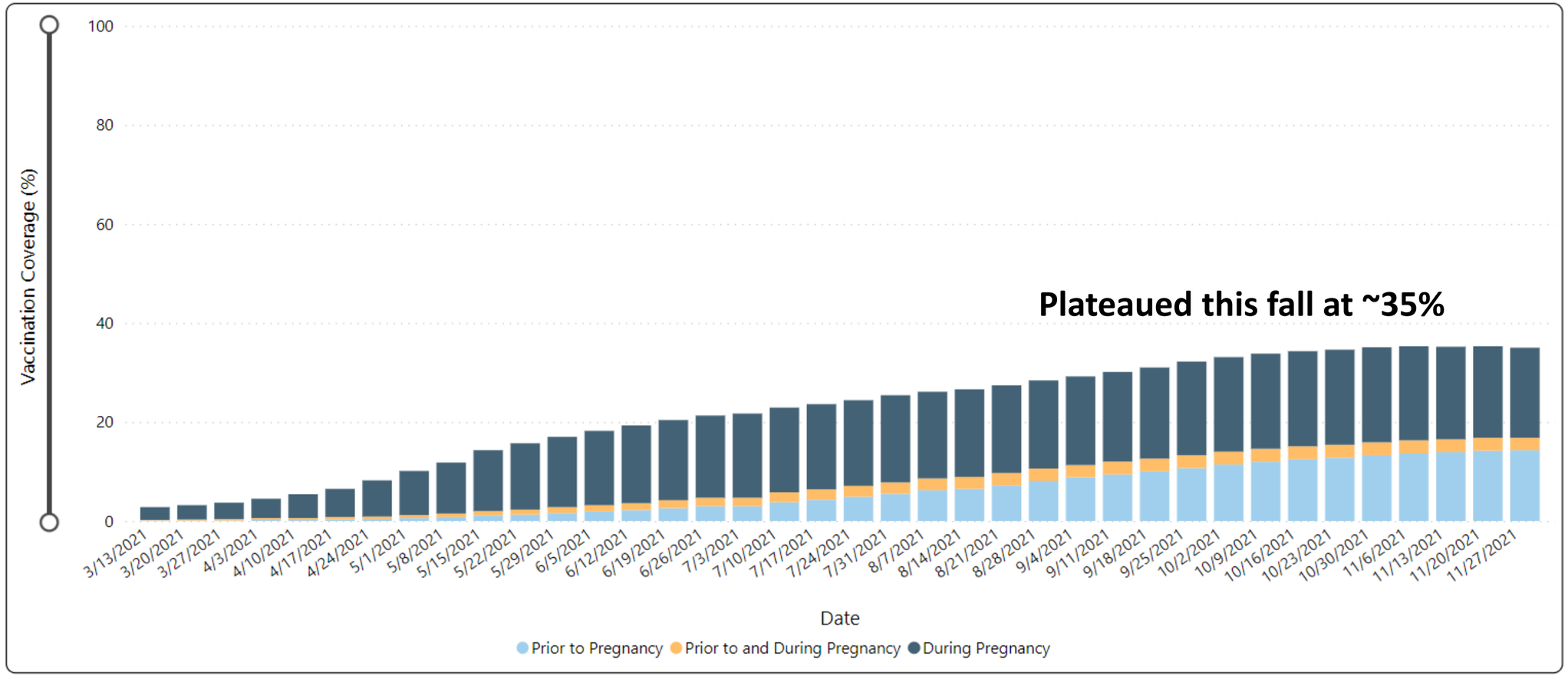
ACCEPTANCE OF COVID-19 VACCINES DURING PREGNANCY

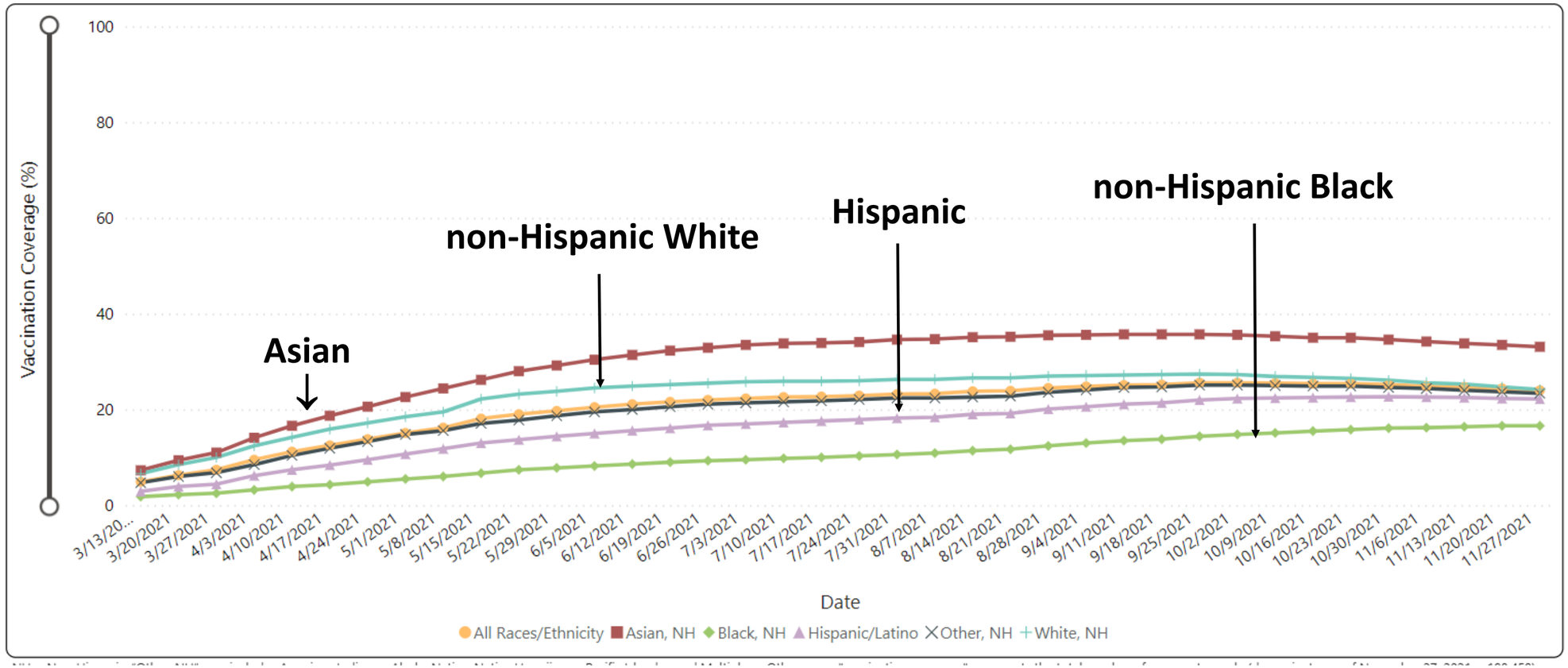
Percent of Pregnant People Vaccinated Before; Before and During; or During Pregnancy



- **Persons ages 18-49**
- **3/13/2021 – 11/27/2021**

Source: https://covid.cdc.gov/covid-data-tracker/#vaccinations-pregnant-women

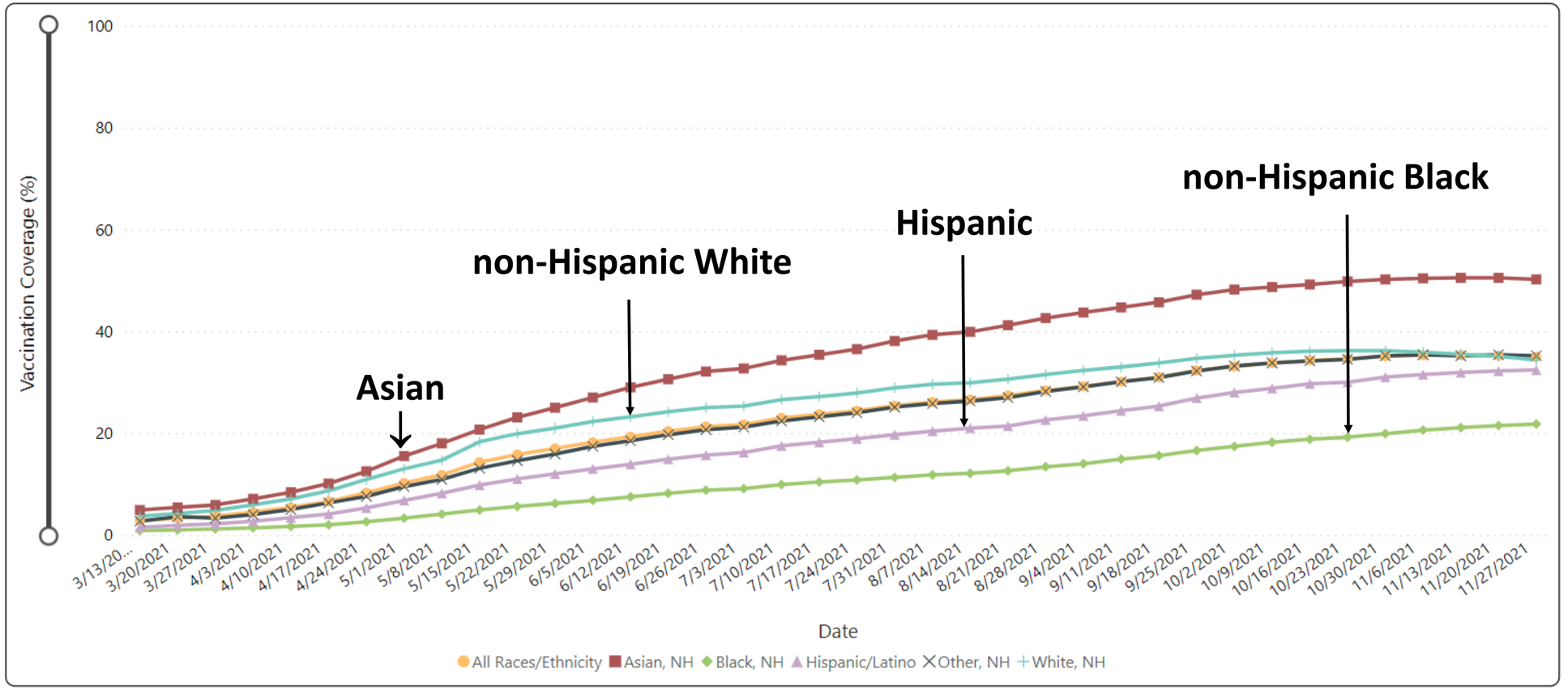
Percent of Pregnant People Receiving Vaccine During Pregnancy by Race/Ethnicity



- Persons ages 18-49 who received at least one dose
- 3/13/2021 – 11/27/2021

Source: https://covid.cdc.gov/covid-data-tracker/#vaccinations-pregnant-women

Percent of Pregnant People Fully Vaccinated Before or During Pregnancy by Race/Ethnicity



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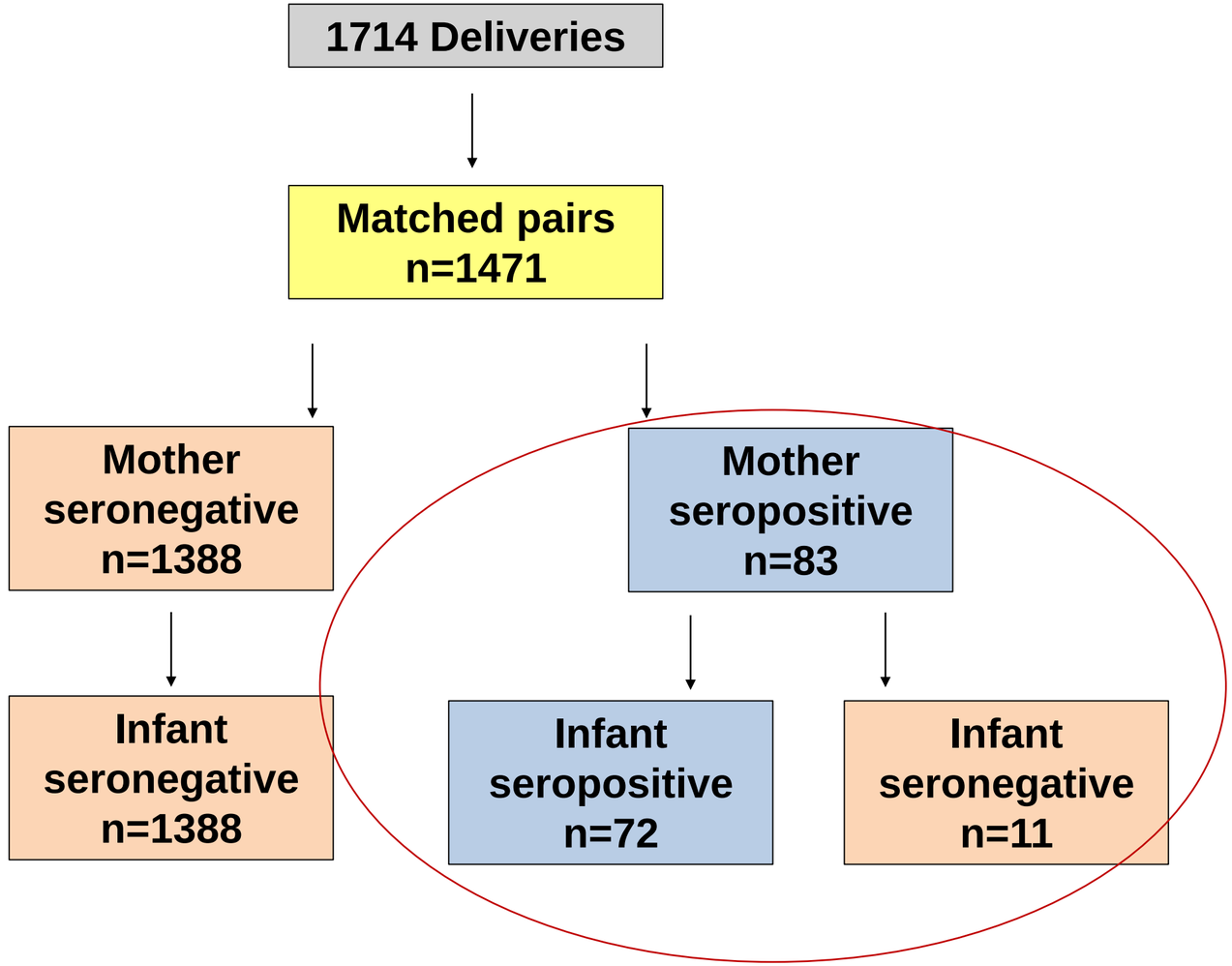
TRANSPLACENTAL TRANSFER OF INFECTION-INDUCED AND VACCINE-INDUCED ANTIBODY

Can Maternal Immunity Protect the Newborn?

- **Newborn immunity derives from**
  - **Innate immune responses**
  - **Maternally-derived, transplacentally-acquired antibody**
  - **Breast milk-acquired immunity/protection**
- **Most perinatal guidance around infectious diseases is centered on how maternally-derived immunity protects newborn**
  - **Maternal infections at birth (e.g., varicella)**
  - **ACOG recommendations for maternal influenza and TdaP vaccine**

Transplacental Antibody Study

- **Scavenged maternal and cord blood sera after clinical use when scheduled for discard**
  - **April 9 –August 8, 2020**
  - **Pennsylvania Hospital**



Flannery, et al. *JAMA Pediatr* 2021

Antibody Levels and Transfer Similar Over Spectrum of Maternal Illness

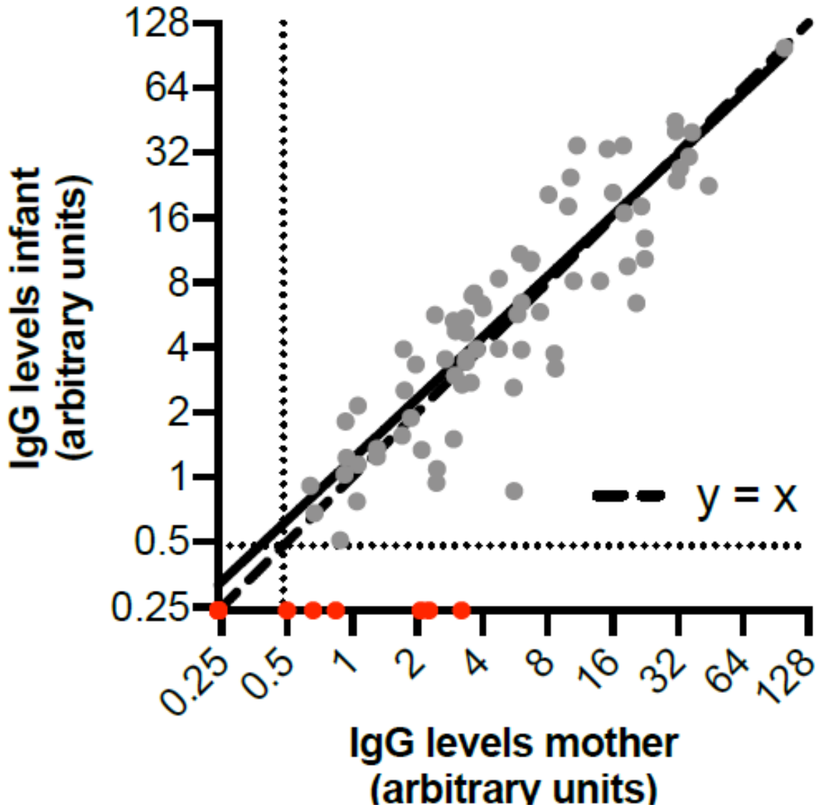
	Asymptomatic n = 50	Mild disease n = 25	Moderate to critical n = 8	*P* value
Maternal IgG level, geometric mean (95% CI)	3.92 (2.82–5.46)	4.44 (2.67–7.38)	15.27 (5.82–40.09)	0.91
Cord IgG level, geometric mean (95% CI)	4.01 (2.77–5.83)	3.09 (1.59–6.01)	14.58 (4.26–49.84)	0.44
Transfer ratio (%), geometric mean (95% CI)	1.02 (0.85–1.23)	0.70 (0.48–1.01)	0.95 (0.45–2.01)	0.34

No differences by maternal age, race/ethnicity, pre-pregnancy BMI, gestational HTN, diabetes, asthma

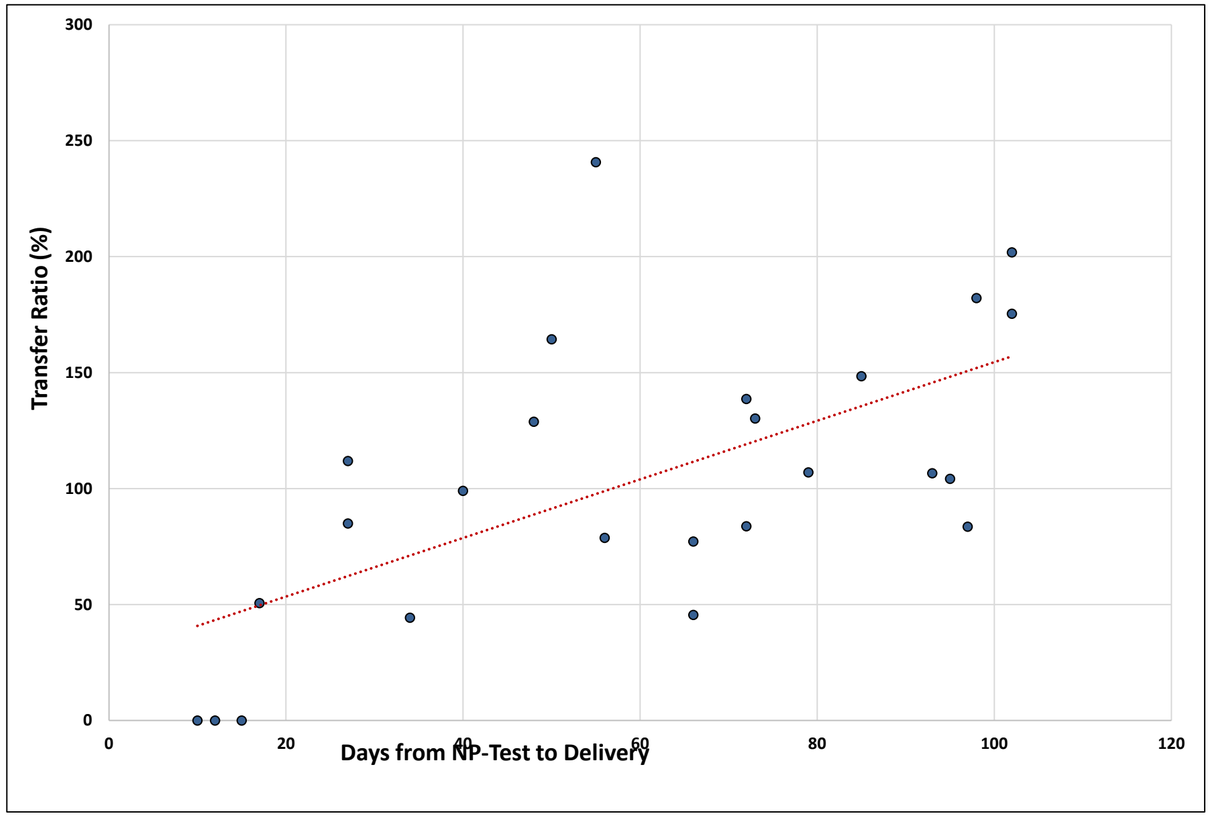
Transfer detectable to 31 weeks' gestation at birth

Maternal Antibody Level Correlates with Transfer

- **SARS-CoV-2 IgM antibodies were not detectable in any of the 72 seropositive infants**
- ***Positive correlation between SARS-CoV-2 IgG levels in cord and maternal sera***
- **Among 11 cases of seropositive mother and seronegative infant**
  - **In 5 cases, mother was seropositive only by IgM (without IgG)**
  - **In 6 cases, maternal geometric mean IgG levels were very low (p=0.005)**



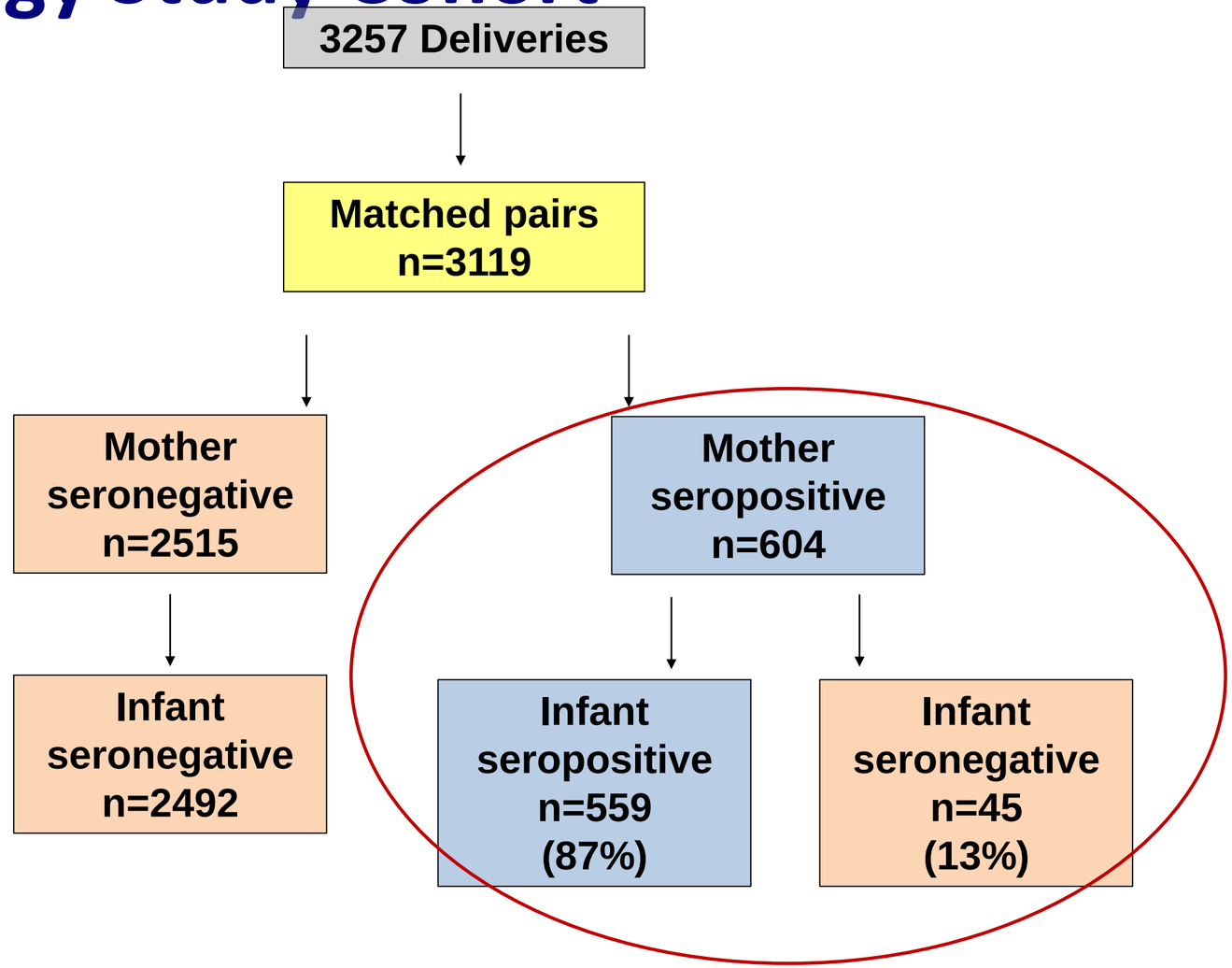
Transfer Ratio Dependent on Time from Maternal Infection



- **Among mothers with well-dated onset of illness and NP-testing**
  - ***Cord IgG present in all cases if the onset of maternal illness was >17 days before birth***
  - **Transfer ratio increases with increasing time from illness to delivery**

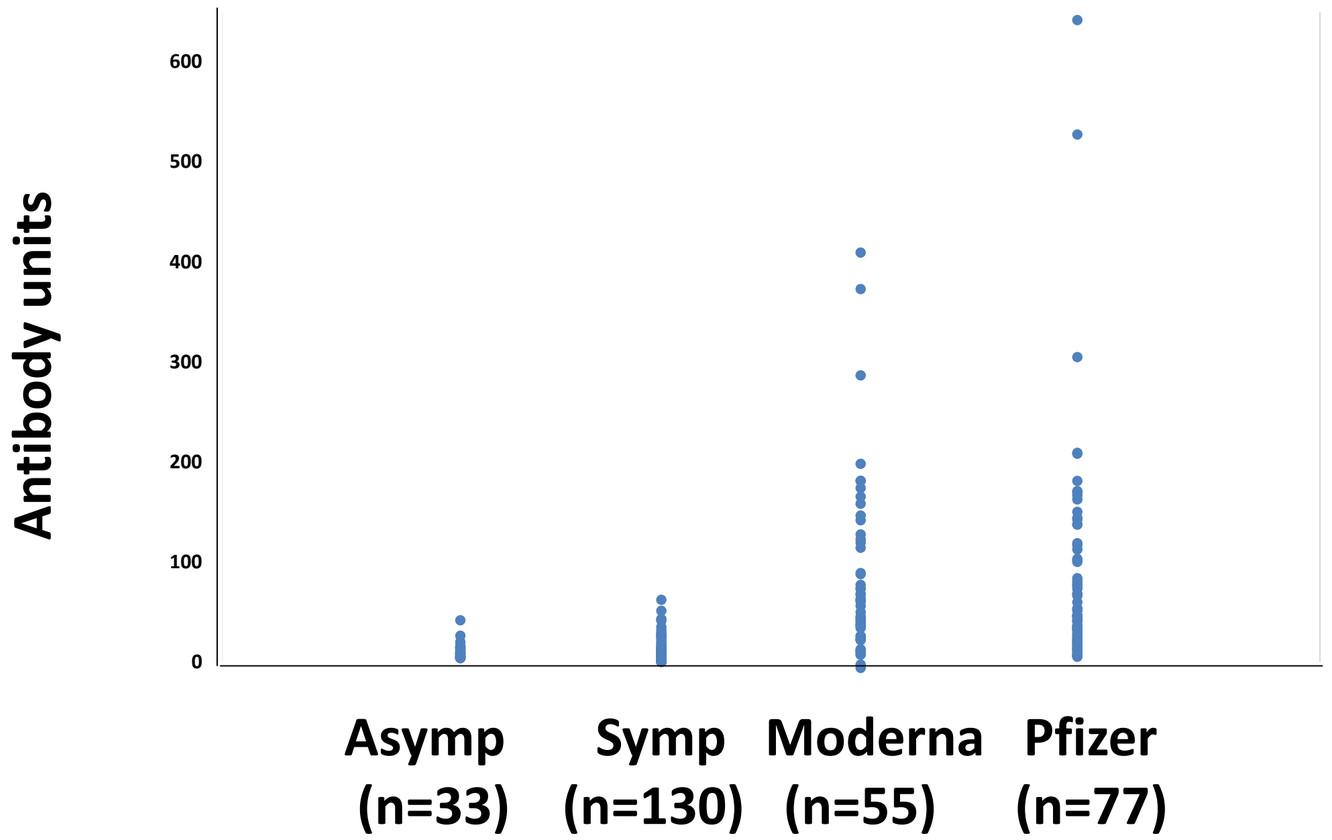
Vaccine Serology Study Cohort

- **Scavenged maternal and cord blood sera after clinical use when scheduled for discard**
  - **August 12, 2020 - April 25, 2021**
  - **Pennsylvania Hospital**



Puopolo, unpublished data

Relative Maternal Antibody Response



Puopolo, unpublished data

SARS-CoV-2 Antibody Due to Infection

	All N=407	Asymptomatic Infection		Symptomatic Infection N=142	P-value[a]
		PCR test positive N=38	PCR test negative or N/D N=227		
Maternal IgG concentration, geometric mean (95% CI)	2.8 (2.5-3.1)	3.4 (2.3-4.9)	2.3 (2.0-2.6)	3.7 (3.0-4.5)	<0.001
Cord IgG >0.48 U/mL, n (%)	381 (93.6)	33 (86.8)	215 (94.7)	133 (93.7)	0.98
Cord IgG concentration, geometric mean (95% CI)	3.0 (2.6-3.3)	2.4 (1.5-3.9)	2.6 (2.2-3.0)	3.9 (3.2-4.8)	0.001
Transfer ratio, geometric mean (95% CI)	1.1 (1.0-1.2)	0.7 (0.5-1.0)	1.1 (1.0-1.3)	1.1 (0.9-1.2)	0.94

Puopolo, unpublished data

SARS-CoV-2 Antibody After Vaccine

	All* N=171	Vaccine administered			P-value
		BNT162b2 N=98	mRNA-1273 N=60	JNJ-78436735 N=2	
Days from 1st vaccine dose to delivery, median (Q1, Q3)	43 (26, 63)	41 (25, 61)	43 (30, 65)	26 (23, 28)	0.30
Maternal IgG concentration, geometric mean (95% CI)	33.8 (27.7-41.4)	25.6 (19.3-33.9)	53.7 (40.5-71.3)	7.0 (0.2-283)	<0.001
Cord IgG >0.48 U/mL, n (%)	169 (98.8)	97 (99.0)	59 (98.3)	2 (100.0)	0.72
Cord IgG concentration, geometric mean (95% CI)	27.2 (21.2-34.8)	21.7 (15.3-30.8)	37.8 (26.0-54.8)	2.9 (0.0-6116)	0.04
Transfer ratio[e], geometric mean (95% CI)	0.8 (0.7-0.9)	0.9 (0.7-1.0)	0.7 (0.6-0.9)	0.4 (0.0-21.6)	0.15

*Vaccine type unknown in 11 cases

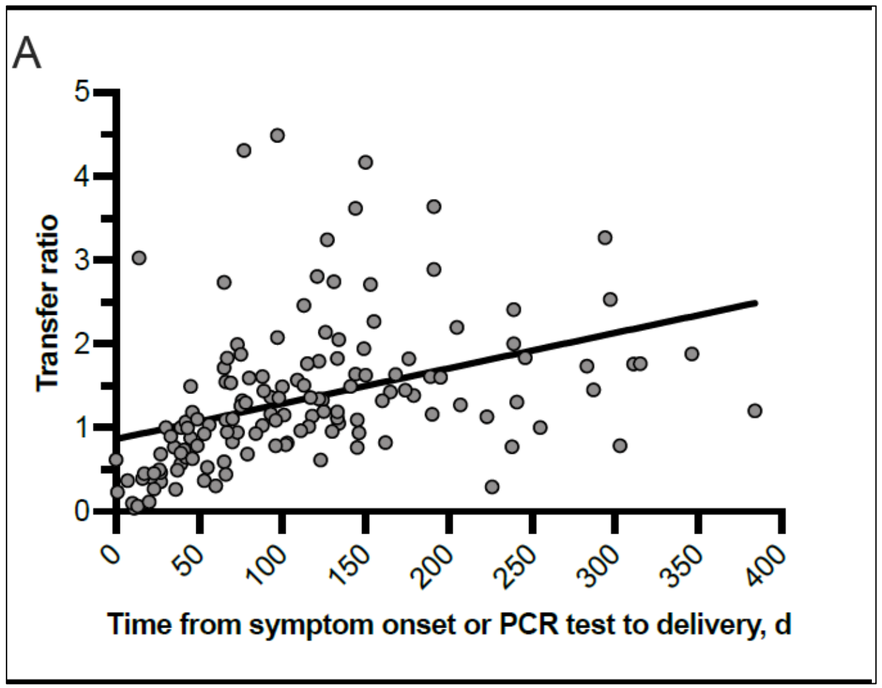
Puopolo, unpublished data

Placental Antibody Transfer Infection vs. Vaccination

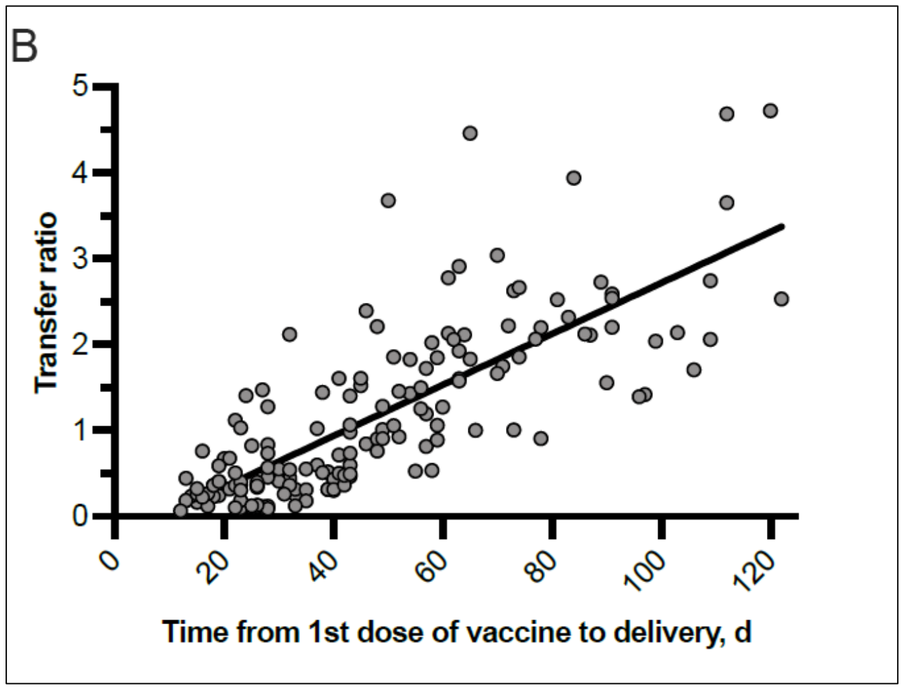
	Infection N=407	Vaccine N=171	P-value
Maternal IgG concentration, geometric mean (95% CI)	2.8 (2.5-3.1)	33.8 (27.7-41.4)	<0.001
Cord IgG concentration, geometric mean (95% CI)	3.0 (2.6-3.3)	27.2 (21.2-34.8)	<0.001
Transfer ratio, geometric mean (95% CI)	1.1 (1.0-1.15)	0.80 (0.7-0.9)	0.55

Puopolo, unpublished data

Transfer Ratio and Time



Days from positive PCR or onset of infection and birth



Days from first vaccine dose and infant birth

Puopolo, unpublished data

Conclusions

- SARS-CoV-2 infection can cause more severe disease in pregnant women compared to age-matched, non-pregnant women
- Women giving birth at Philadelphia Penn hospitals have significant levels of exposure to SARS-CoV-2 with differences by race/ethnicity
- mRNA vaccines appear safe for pregnant women
- Vaccines induce higher antibody response to spike protein than infection
- Efficient transplacental antibody transfer seen with antibody due to infection and after vaccination

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Breast/Chest feeding and the COVID-19 Vaccine

Meg Kawan, MD, MPH, IBCLC
Children's Hospital of Philadelphia
PA Chapter American Academy of Pediatrics
December 9, 2021

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Gender Neutral Language

- “Breast/chest feeding” has become more commonly used term
- Language surrounding pregnancy, birth and lactation have previously been heteronormative and female-gendered
- Important to recognize that this language is not inclusive of many individuals and affirm importance of using appropriate terms

Background

- COVID-19 vaccine approval: EUA for Pfizer and Moderna December 2020
- Lactating individuals excluded from clinical trials – no clinical data on safety of vaccine in nursing parents
- Challenging as many lactating individuals were frontline health care workers and essential workers

Initial Considerations – Dec. 2020

- Emphasis on shared decision making
- Based on mechanism, consensus of experts within ACIP, CDC, ACOG, AAP, and other organizations emphasized minimal risk and emphasized potential benefits to lactating child
- Academy of Breastfeeding Medicine issued guidance, “while there is little plausible risk to the child, there is a biologically plausible benefit.”
- Website: https://www.bfmed.org/abm-statement-considerations-for-covid-19-vaccination-in-lactation

UK experience

- UK initially withheld vaccine to lactating individuals for first month due to safety concerns
- Public outcry

"This data gap is not an anomaly. It is the result of a system of researching and licensing drugs that routinely discriminates against women, excludes them from the evidence base, and denies them the right to make informed choices about their own health. We implore researchers, industry leaders, and the MHRA to remember that pregnant and breastfeeding women are essential patient populations, not merely women who can wait."

Opinion; BMJ: Why Were Breastfeeding Women in the UK Denied the COVID vaccine. *BMJ* 2021;372:n4

Acceptance of vaccination in lactation

- Limited data
- One study of 1012 respondents found vaccine acceptance of 55.2% compared with 76.2% of non-pregnant respondents and 44.3% of pregnant respondents

Initial Questions

- Is vaccine safe for lactating parent and breastfeeding infant?
- Any unusual side effects for parent? Breastfeeding infant?
- Should lactating individuals who choose to receive the vaccine stop breastfeeding?
- Is there a need to “pump and dump” after vaccination?
- Does this vaccine offer protection to breastfeeding infant? For how long?

Breastfeeding infant - considerations

- Initial small study of six lactating parents milk samples demonstrated no evidence of vaccine mRNA in breast milk samples in first 48 hours after vaccination
- Multiple studies have now shown vaccine-stimulated Immunoglobulin A passes through breast milk

Breastfeeding infant - immunity

- Prospective, observational study from University of Florida evaluated milk and plasma samples from 22 vaccinated HCW with no known history of COVID-19 infection
- Plasma and human milk samples were collected at 3 time points, pre-vaccination, post first dose and post second dose

SARS- CoV2 Specific Antibodies in Human Milk Post vaccination

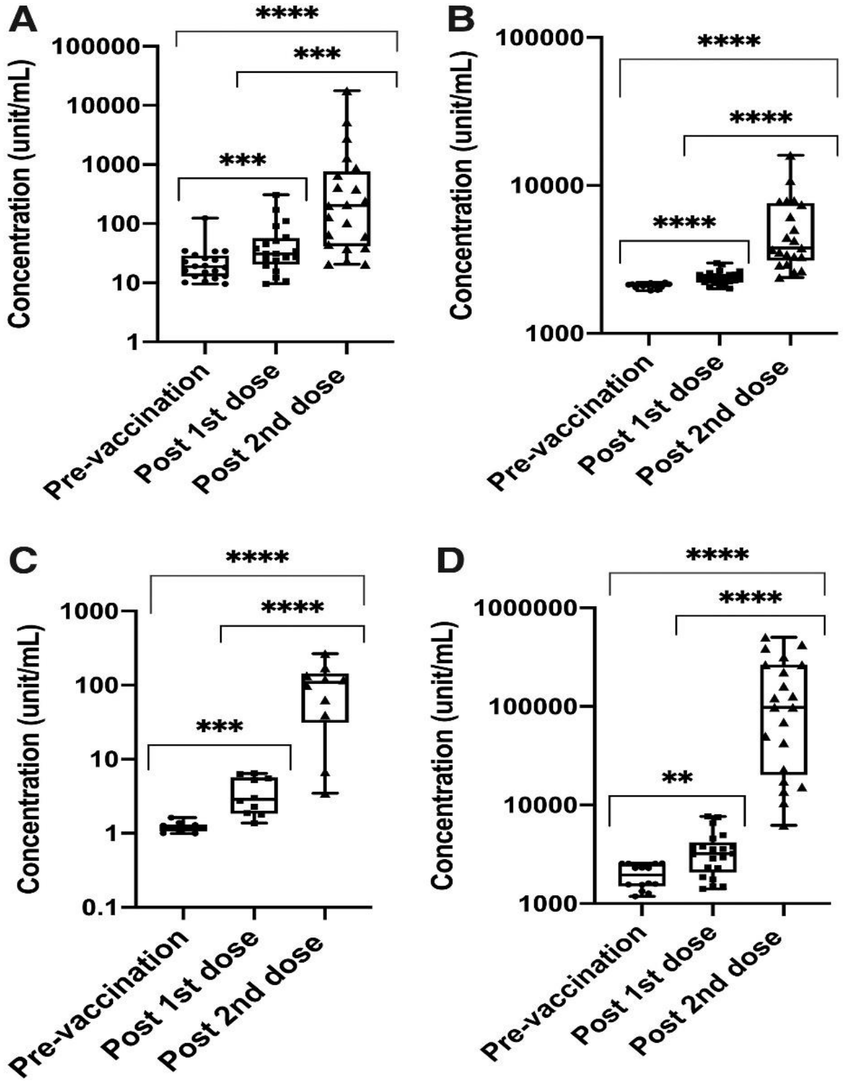
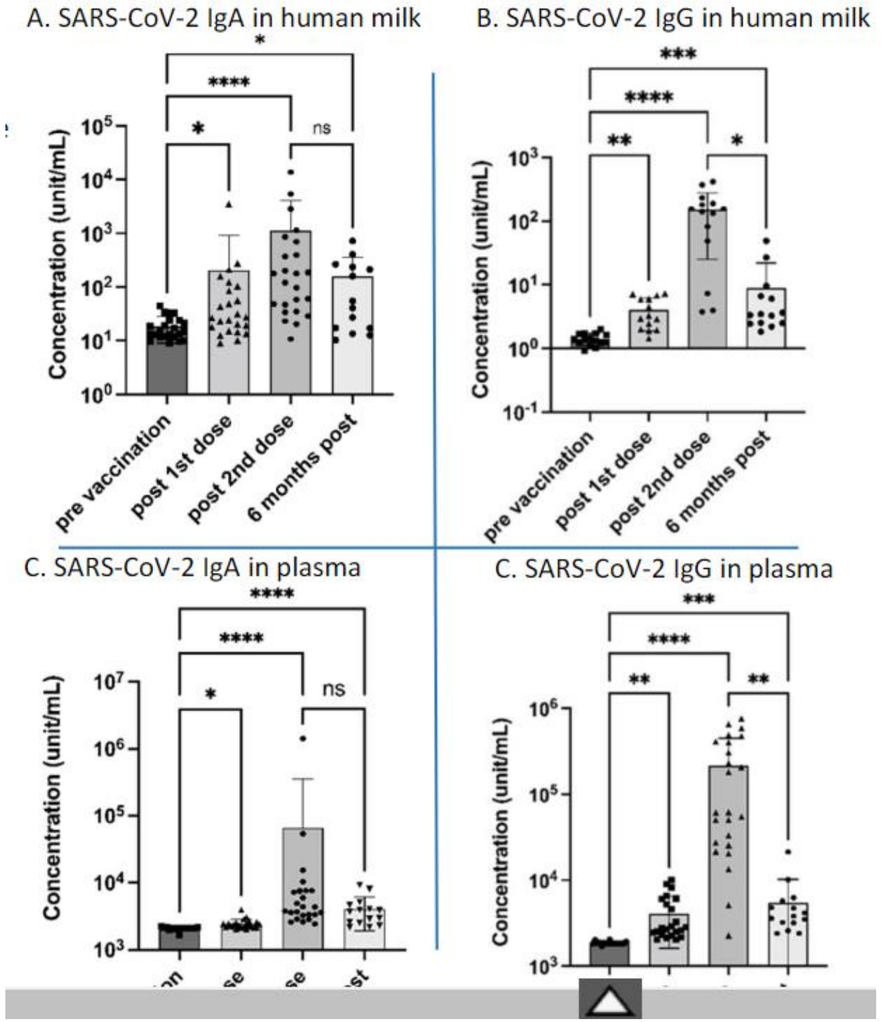


FIG. 1. Box and whisker plots of SARS-CoV-2-specific antibodies (IgA and IgG) in human milk and plasma pre-vaccination, post-first dose of vaccine, and post-second dose of vaccine measured as unit/mL (A) IgA in human milk, (B) IgA in plasma, (C) IgG in human milk, and (D) IgG in plasma

Vivian Valcarce, Lauren Stewart Stafford, Josef Neu, Nicole Cacho, Leslie Parker, Martina Mueller, David J. Burchfield, Nan Li, and Joseph Larkin III.Breastfeeding Medicine.ahead of print.
http://doi.org/10.1089/bfm.2021.0122

Six month update



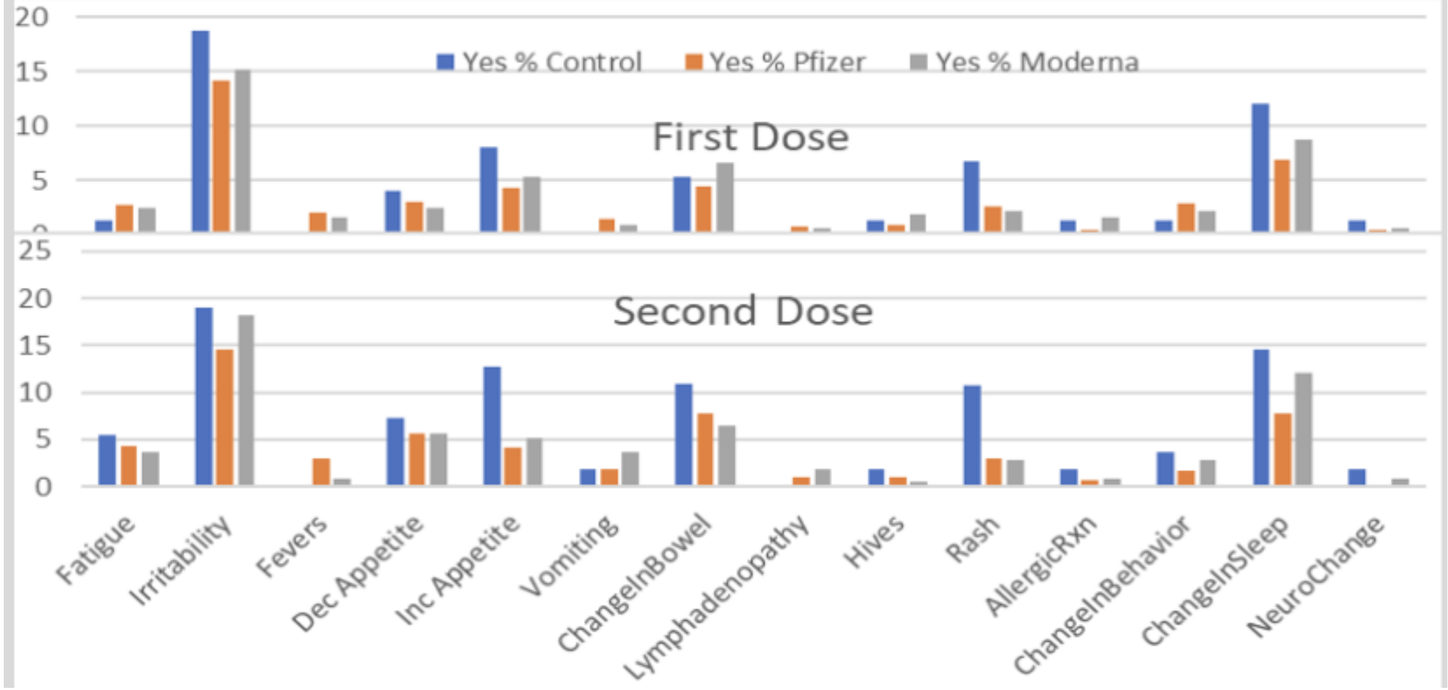
Breastfed infant- considerations

- Observational, non-blinded, prospective cohort study design was utilized to analyze COVID-19 mRNA vaccine potential effects on breastfed infants
- 1st dose: 1,154 participants Control N=73, Pfizer N=770, Moderna N=311
- For the second dose: 722 participants, Control N=56, Pfizer N=464,Moderna N=202.

Breastfed infant-Effects of vaccination

Results

Figure 1: Adverse Effects Reported After Each Dose, By Per Cent Reporting



Castillo A, Lavin E. Effects of Maternal COVID-19 vaccination on breastfed children. Poster presentation, Academy of Breastfeeding Medicine International Meeting, November 2021

Lactating parent - considerations

- Lymphadenopathy, engorgement and breast pain – common side effects after both doses, compared with controls, more notable on side of vaccination
- Milk supply- transient drop in milk supply noted after second Pfizer vaccine,
- Increased risk of mastitis, although not statistically significant

Evaluating parent and child outcomes

- Survey of 180 lactating parents who received both doses of mRNA vaccine (71.1% Pfizer, 28.9% Moderna)
- Child age of enrollment averaged 7.47 months
- 8.0% of parents receiving Pfizer and 23.4% of parents receiving Moderna reported transient drop in milk supply, resolved by 72 hours
- 3 women reported change in milk color (blue green)
- Few child events reported: fussiness/irritability (10%), poor sleep (8%)

Larger study – Dr. Hale and colleagues

- Cross-sectional survey of 4,455 mothers
- Post-vaccination symptoms more common after second dose
- Only 1.7% of respondents reported negative effect on lactation
- 89.4% of respondents reported that they “strongly agreed” they would make same choice to receive vaccination again, only 0.2% reported they disagreed.

Dr. Hale and colleagues, infant effects

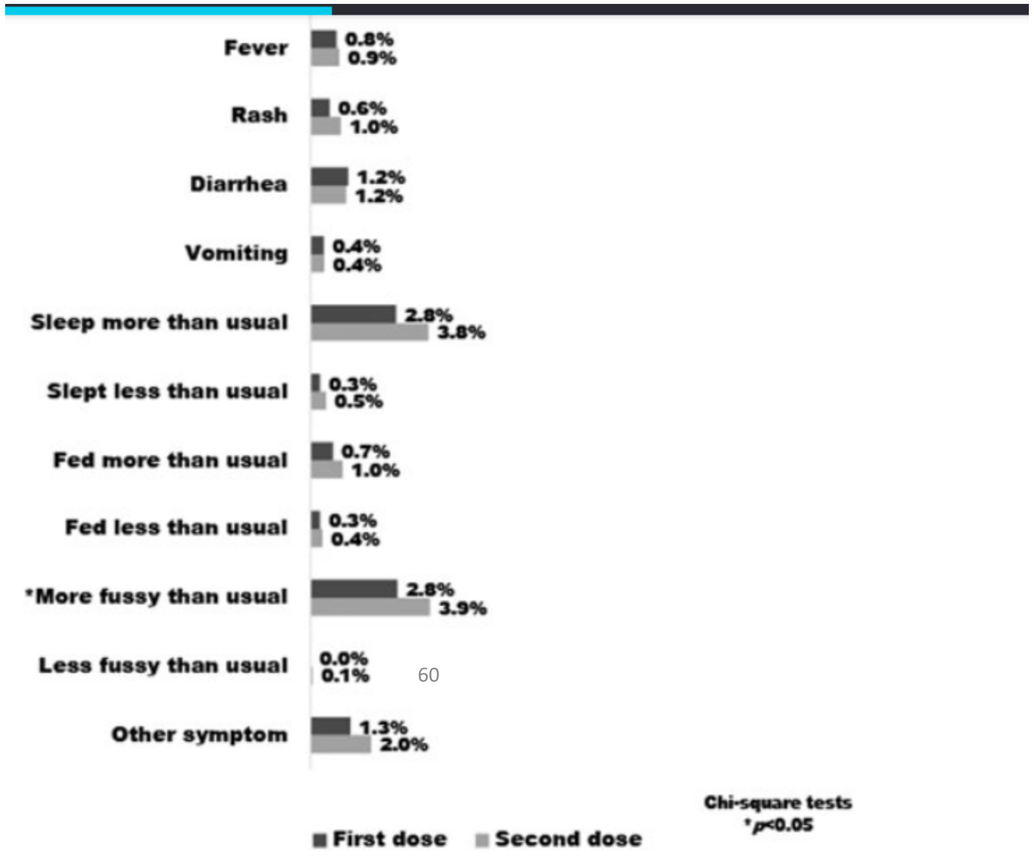


FIG. 3. Percentage of mothers reporting symptoms in their breastfed children following COVID-19 vaccination. Total number of mothers was 2,627 (one dose) and 1,828

Breastmilk Antibodies –Neutralizing effect

- Observational cohort study of milk samples of 47 lactating parents post COVID infection and 30 lactating parents post-vaccination
- Antibody response after infection was IgA dominant and highly variable, vs antibody response after vaccination was more robust, IgG dominant.
- Milk antibodies isolated from both groups showed neutralizing activity against live SARS-Cov2 virus

Duration of vaccination effect?

- Immune protection provided through human milk is passive immunity
- When eligible – breastfed infants/toddlers should receive vaccination
- Anecdotally, more parents breastfeeding for longer duration


Los Angeles Times

Breastfeeding and vaxxed: Parents delay weaning children to pass on COVID-19 antibodies

Conclusions

- COVID-19 vaccination is safe and well-tolerated in lactating parents.
- Adverse effects are minimal and transient in both lactating parent and breastfed infant
- There is no role for “pumping and dumping” after vaccination
- Breastfed infant receives immune protection after vaccination through SARS-CoV-2 specific IgA and IgG antibodies.
- Adverse effects to lactating parent may include lymphadenopathy, transient decrease to milk supply
- Adverse effects to breastfed infant are minimal, may include fussiness/irritability, small % of infants may develop fever related to vaccination.

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Thank you!

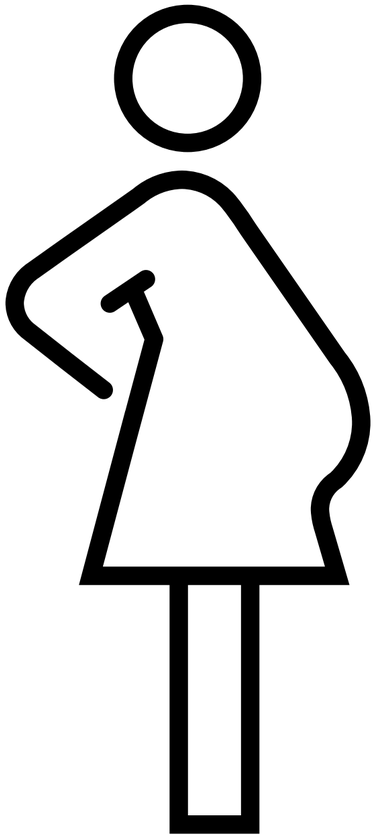
Photo credit: Dr. Michele Pena,
Division of Neonatology

Our Vaccine Story

Sarah & Baby Lauren

Be Patient With Your Patients

- Pregnancy Nerves
- Constant Caution
- Information Overload
- Need For Control



Nurses, Doctors, Teachers & Military Are Most Respected Jobs

Which of the following professions do you respect the most?
(Top 8 Responses)

Total	MALE	FEM	GOP	SWING	DEM	
49%	34%	62%	49%	53%	47%	Nurses/Doctors
47%	42%	52%	45%	46%	49%	Teachers
45%	42%	47%	71%	44%	36%	Military/soldiers
34%	32%	35%	10%	34%	42%	Scientists
26%	29%	24%	11%	25%	33%	Technology innovators
21%	18%	23%	45%	21%	10%	Police officers
21%	20%	21%	17%	22%	21%	Entrepreneurs/Small business owners
12%	14%	11%	18%	15%	7%	Ministers/priests/rabbis

Encouraging Vaccines

- Remind Patients of Your Mission
- Empathy & Understanding
- Share Stories
- Make Education Easy
- Prepare Advocates
- Ask & Answer Questions

Q&A Session

Sarah Mann, a national parent advocate

Dr. Meg Kawan MD, MPH, IBCLC

Dr. Karen Puopolo M.D., Ph.D.

Pennsylvania Chapter

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