

**COVID-19
BRIEFING
SESSION 12:
IMPACT ON
WOMEN,
MOTHERS,
AND CHILDREN**

SEPTEMBER 29, 2021

7:00 PM - 8:00 PM EST



National Hispanic Medical Association

COVID-19 BRIEFING SESSION 12: IMPACT ON PREGNANT WOMEN, MOTHERS, AND CHILDREN

Moderator



Claudia Zamora
Founder and CEO
Zamora Consulting Group

Wednesday, September 29
at 7:00 p.m. ET

Registration:
bit.ly/NHMACOVIDBriefing

Speakers:

Luis Gomez MD, MScE

Maternal-Fetal Medicine Specialist
Perinatal Associates of Northern
Virginia, Inova Health System



Ana Lia Graciano MD, FAAP, FCCM

Professor of Pediatrics
Division of Pediatric Critical Care Medicine
University of Maryland School of Medicine



Sergio Rimola MD, FACOG

Attending Physician Ob/Gyn
Department
Inova Fairfax Hospital



WELCOME AND HOUSEKEEPING

CLAUDIA ZAMORA
FOUNDER AND CEO
ZAMORA CONSULTING GROUP



PRESENTATIONS TO BE
FOLLOWED BY Q&A
DISCUSSION AT THE END



TYPE QUESTIONS IN Q & A
BOX



PARTICIPANT
MICROPHONES AND VIDEO
ARE OFF AND MUTED



RECORDING AVAILABLE
NEXT WEEK ON
NHMAMD.ORG

COVID-19 AND PREGNANCY

Luis M. Gómez, MD, MScE

INOVA Health System

Division of Maternal-Fetal Medicine

September 29, 2021





LatinX

Celebrating Hispanic Heritage Month



Hispanic
Heritage Month
September 15 - October 15

DISCLOSURE

- No conflicts of interest
- I will be presenting data from the CDC, WHO, PAHO, IDSA, ACOG and SMFM

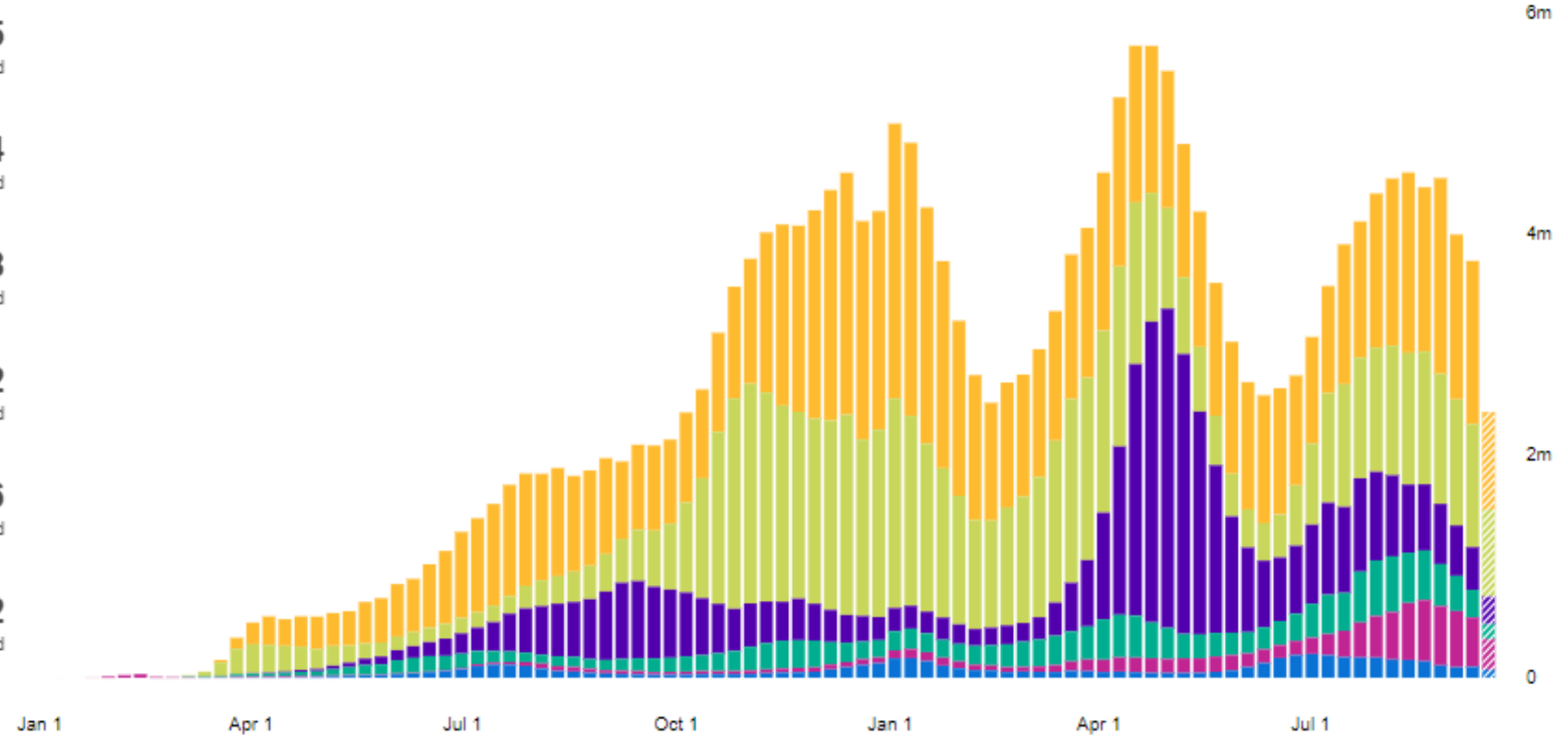
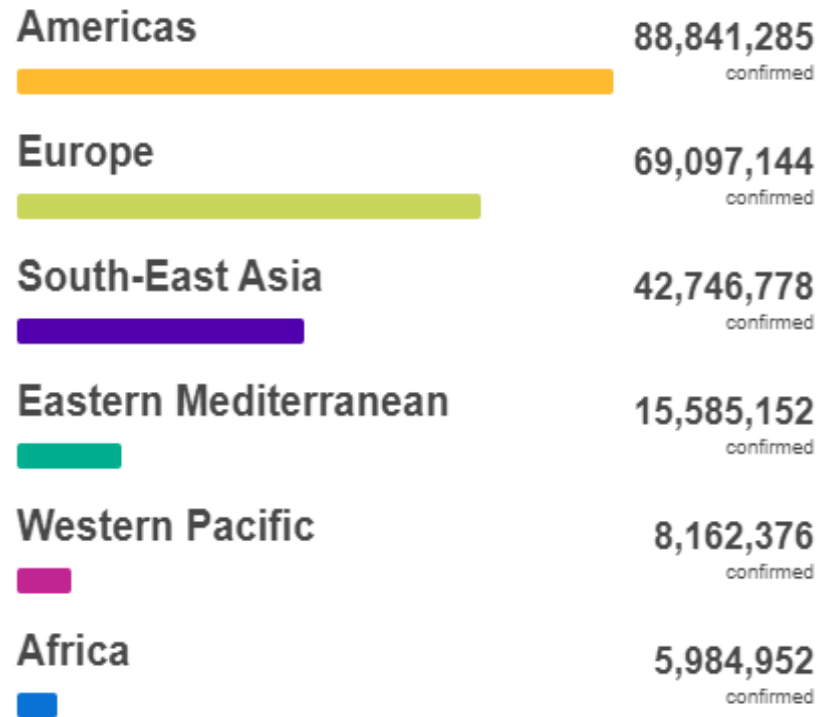
GOALS

- Define levels of COVID-19 severity (WHO guidelines)
- Understand pregnancy-associated morbidity and mortality
- Understand socio-demographic inequalities in morbidity and mortality
- Understand therapeutic interventions
- Share our INOVA Health System experience in COVID-19 & pregnancy

230'418,541 CASES

4'724,876 DEATHS

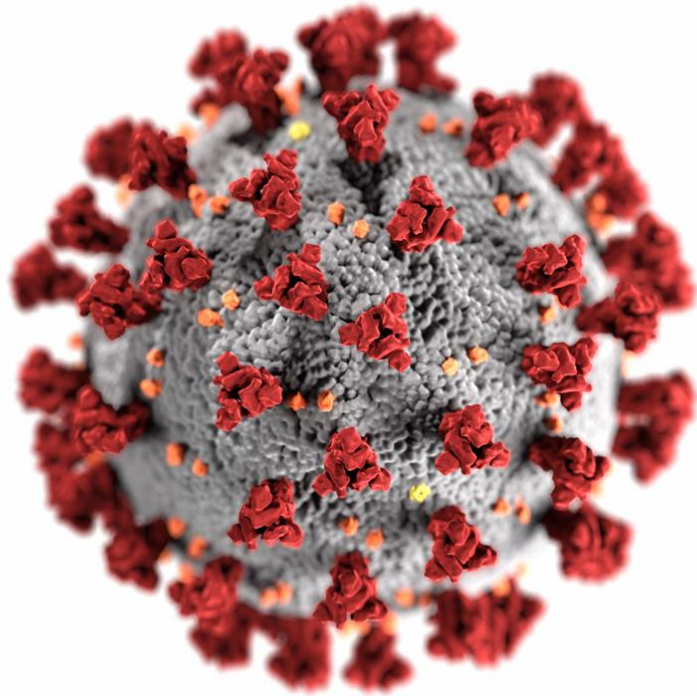
Situation by WHO Region



Source: World Health Organization
Data may be incomplete for the current day or week.

Source: WHO

WHY IS THIS TOPIC IMPORTANT?



COVID-19 PREGNANCY RISKS

CDC REPORT



4X

MORE LIKELY
TO REQUIRE
VENTILATION



2X

MORE LIKELY
TO DIE FROM
COVID-19

WHY IS THIS TOPIC IMPORTANT?

- Pregnancy is an independent risk factor for severe COVID-19 especially in patients with pre-existing comorbidities
- Compared with symptomatic non pregnant patients, infected pregnant individuals escalate faster to critical COVID-19 and have increased mortality
- Increased rate of adverse obstetric outcomes

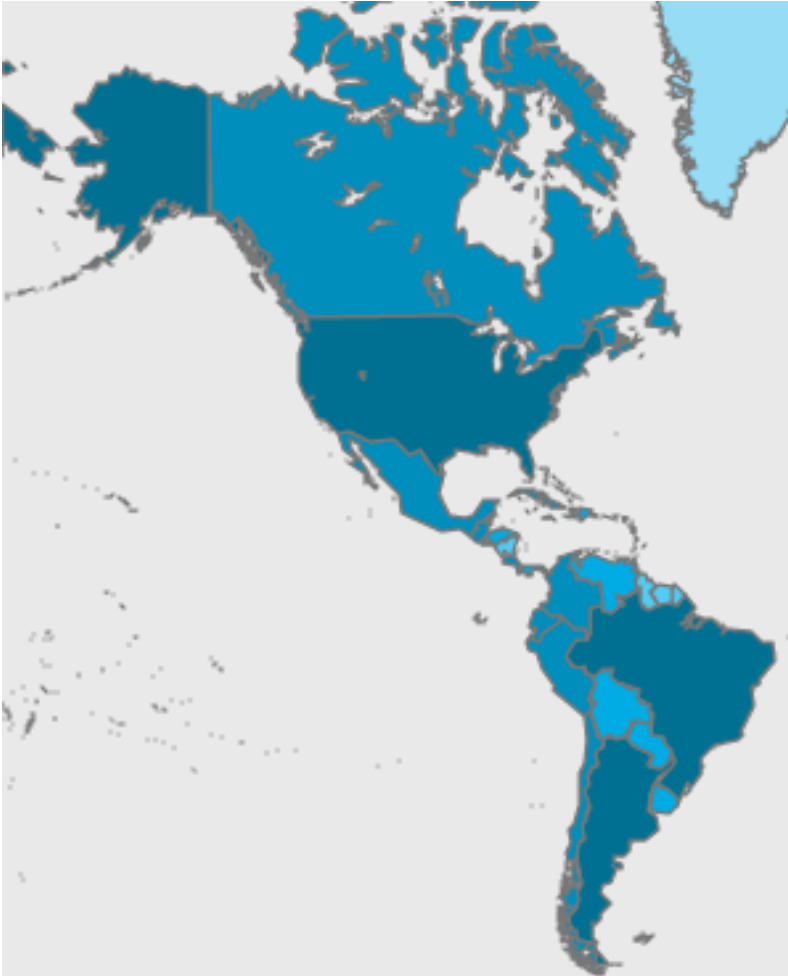
Source: SMFM

Pregnancy and perinatal outcomes

OUTCOMES	COVID-19 (%)	BACKGROUND (%)	V-SAFE PREGNANCY (%)
Miscarriage (<20 w)	(not increased)	26	15
Stillbirth (\geq 20 w)	1.2	0.6	<1
Gestational diabetes	20	7-14	10
Gestational hypertension / Preeclampsia	19.5-62.4	10-15	15
Fetal growth restriction	11-12	3-7	1
Preterm birth	18.5-43.3	10.1	10
Cesarean delivery	60	25-35	(not increased)
Venous thromboembolism	0.2-6	0.1-0.2	(<0.001)
Congenital anomalies	(not increased)	3-4	4
Small for gestational age	20-30	3-7	4
Neonatal death	0.8	0.38	0

Source: ACOG, SMFM

COVID-19 & Pregnancy in the Americas



- >270,000 pregnancies
- >2,600 maternal deaths
- Leading cause of maternal death in Mexico and Colombia
- Mexico, Argentina, and Brazil account for half of all COVID deaths among pregnant individuals in the region

Source: PAHO

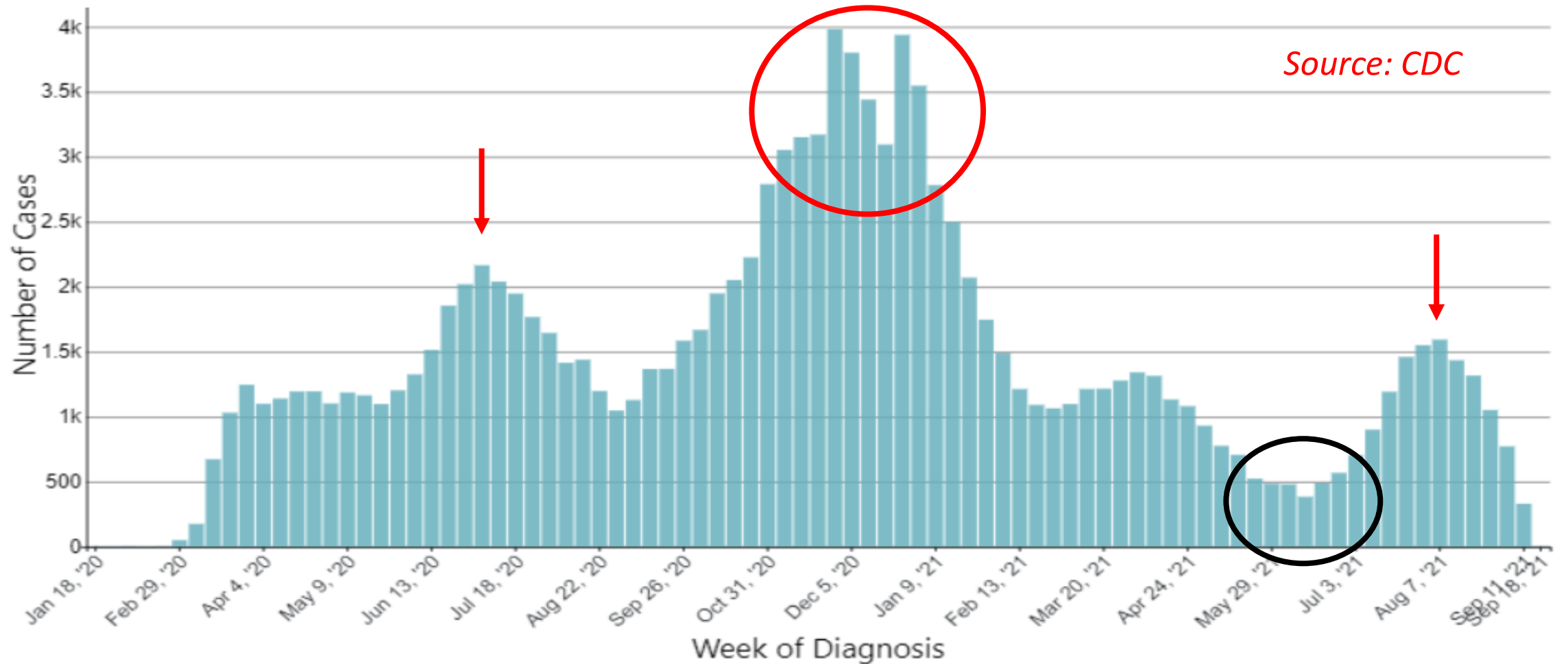
COVID-19 & Pregnancy in the USA

(Jan 2020 – Sep 2021)

21,823 HOSPITALIZED

123,633 CASES

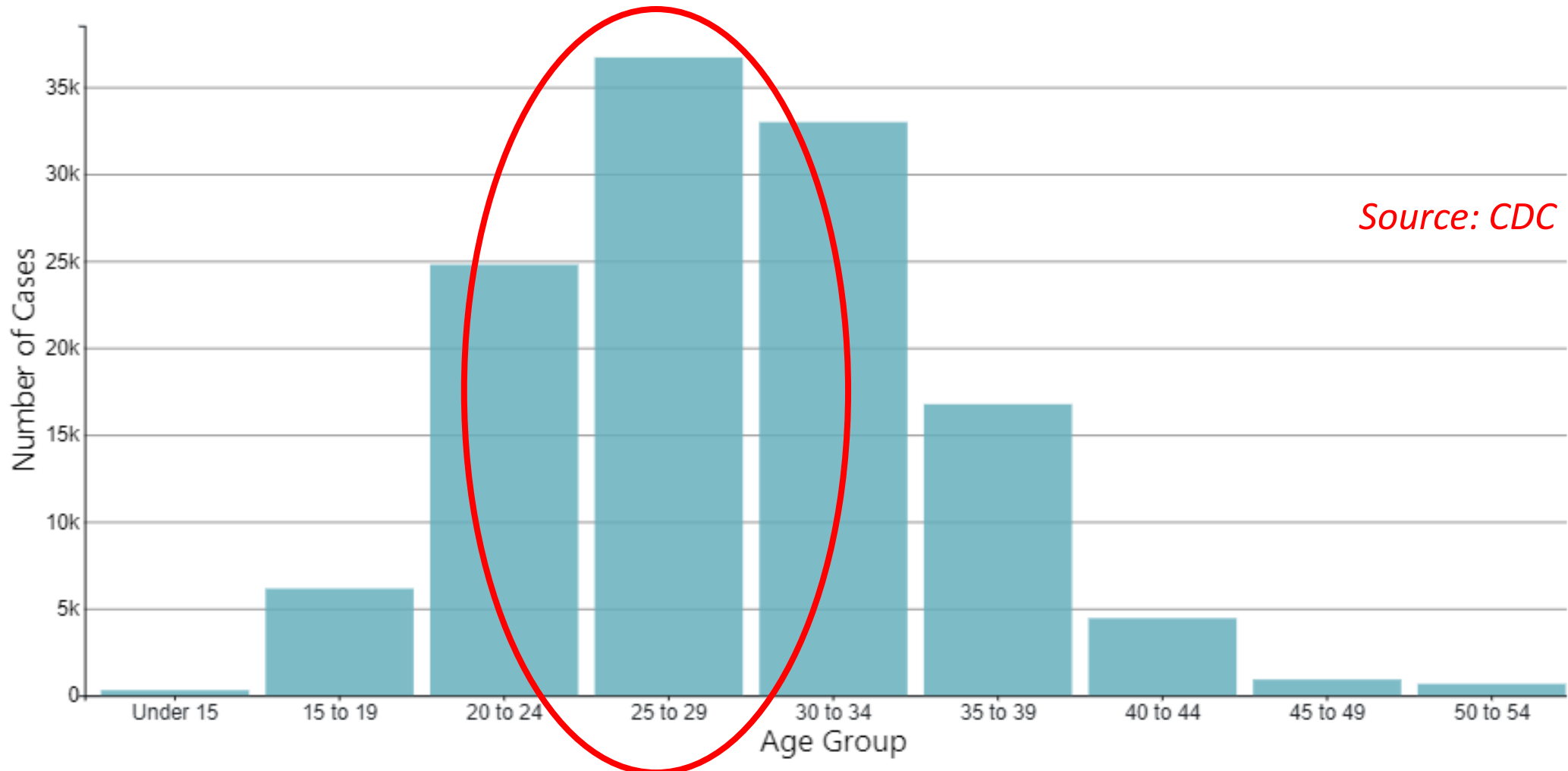
159 DEATHS



COVID-19 & Pregnancy in the USA by age group (Jan 2020 – Sep 2021)

123,633 CASES

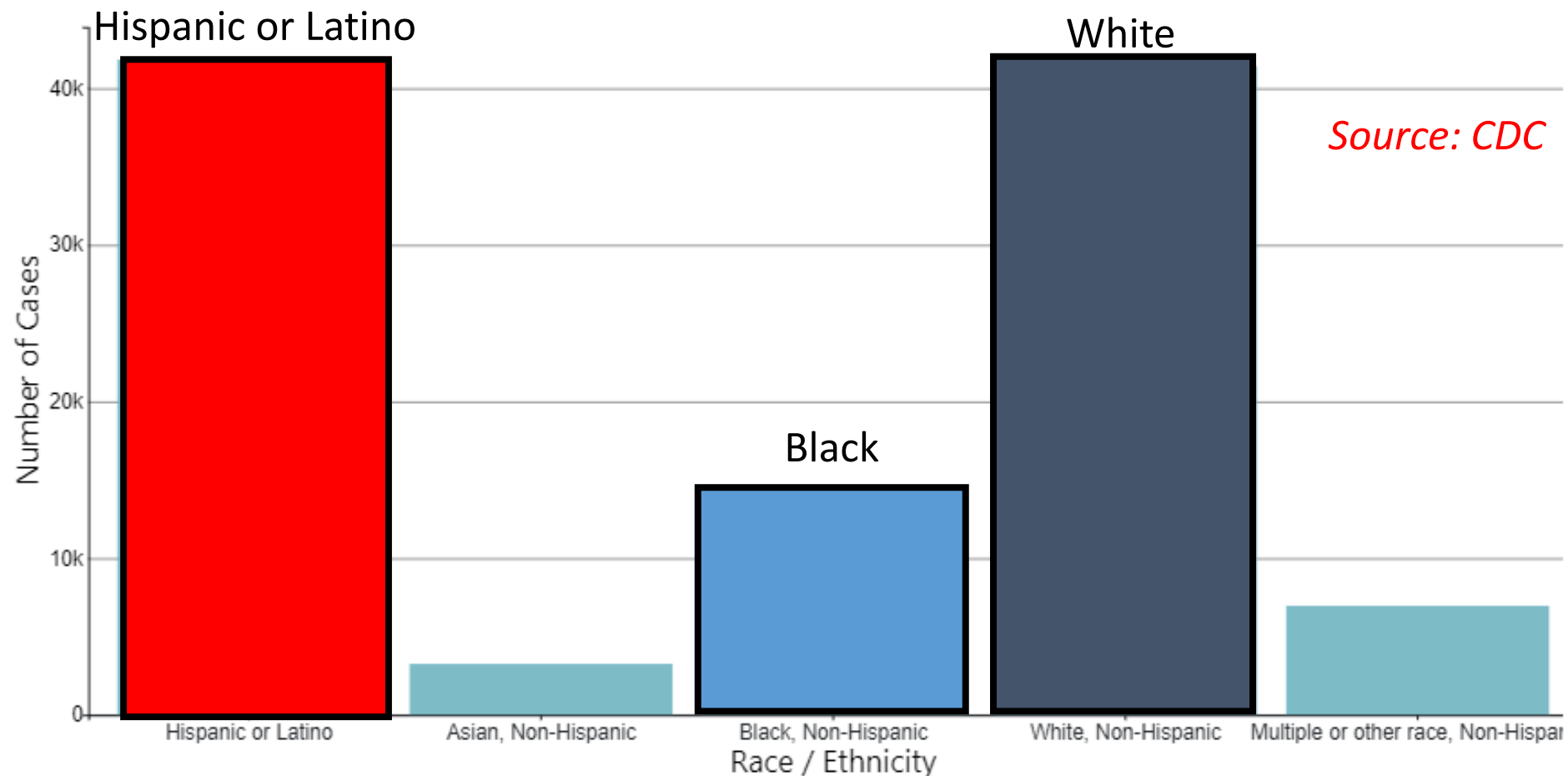
159 DEATHS



COVID-19 & Pregnancy in the USA by race / ethnicity (Jan 2020 – Sep 2021)

123,633 CASES

159 DEATHS





I'm pregnant. How can I protect myself against COVID-19?



Wash your hands frequently



Avoid touching your eyes, nose and mouth



Put space between yourself and others



Cough or sneeze into your bent elbow or a tissue

If you have fever, cough or difficulty breathing, seek care early. Call beforehand, and follow medical advice.



World Health Organization

#COVID19 #CORONAVIRUS

PREVENTION



EVALUATION MANAGEMENT THERAPEUTICS



IMMUNIZATION

COVID-19 Severity

MILD

('flu' like symptoms)

- Fever (responding to acetaminophen)
- Cough
- Myalgias
- Anosmia
- Ageusia

MODERATE

(lower respiratory tract disease)

- Refractory fever
- Dyspnea
- Tachypnea (RR \leq 30/min)
- SpO₂ \geq 94% (room air)
- Abnormal arterial blood gas
- Chest imaging: pneumonia

Source: SMFM, WHO

COVID-19 Severity

SEVERE (significant respiratory disease)

Prior symptoms PLUS:

- Tachypnea (RR >30/min)
- SpO₂ <94% (with supplemental O₂)
- PaO₂ / FiO₂ <300 *
- Chest imaging: >50% lung involvement

* *the lower PaO₂ / FiO₂, the greater the mortality risk (27-45%)*

CRITICAL

(multi-organ failure)

- Shock
- Need for high-flow nasal cannular or mechanical ventilation (intubation, ECMO)

Source: SMFM, WHO

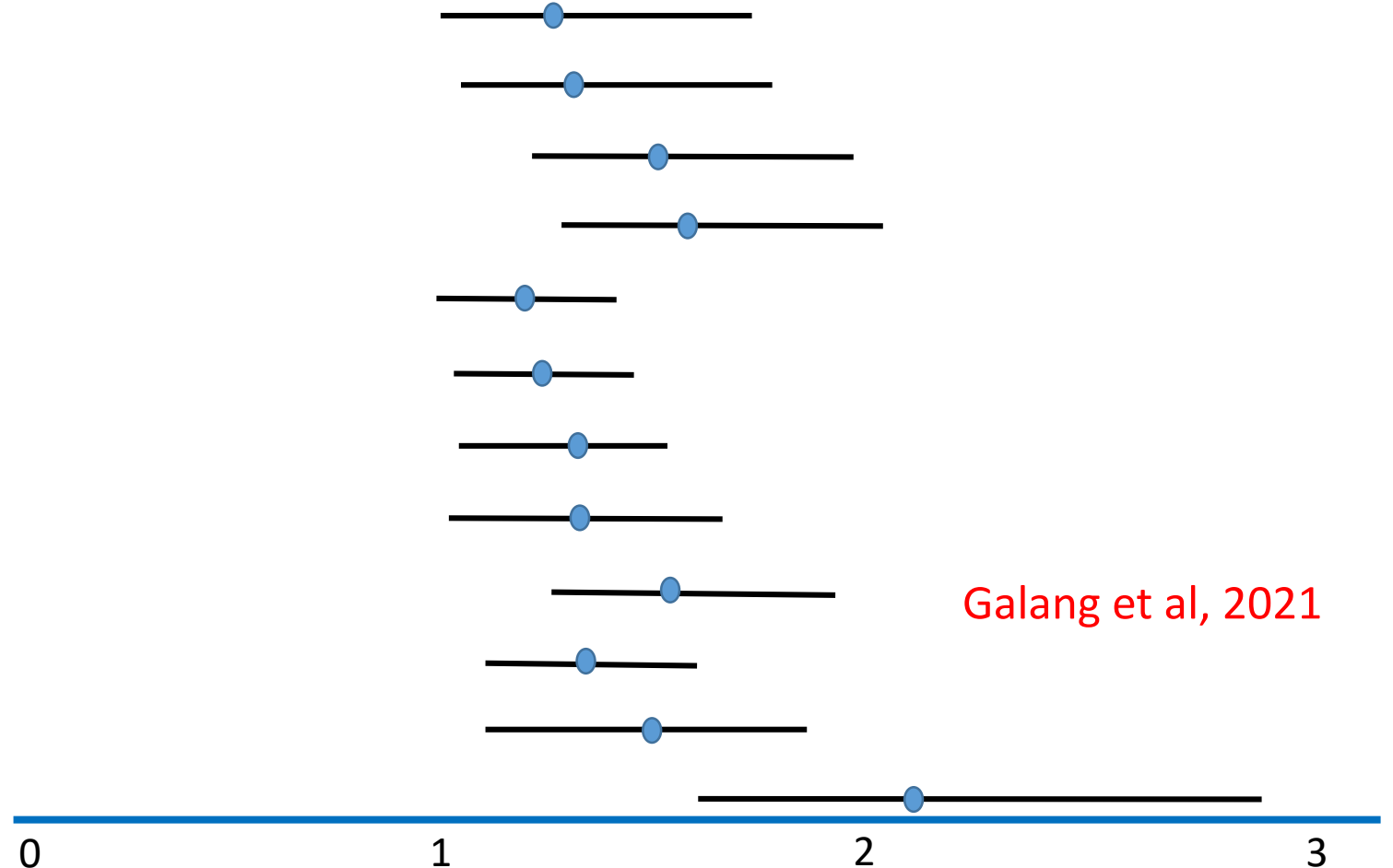
COVID-19 severity in pregnancy

- Compared to non pregnant people, pregnant patients are at increased risk of severe / critical illness and death
- Admission to the ICU OR 2.85 (95% CI 1.08-7.52)
- Preterm delivery OR 1.47 (95% CI 1.14-1.91)
- Maternal mortality OR 2.85 (95% CI 1.08-7.52)

Allote et al, 2021
Zambrano et al, 2020
CDC MMWR 2020

Risk Factors for Illness Severity Among Pregnant Women With Confirmed SARS-CoV-2 – CDC (March 2020 – March 2021)

CONDITION	Adjusted RR
AGE 25-29	1.32
AGE 30-34	1.43
AGE 35-39	1.53
AGE \geq 40	1.66
Healthcare worker	1.23
BMI \geq 30	1.33
Chronic lung disease	1.41
CHTN	1.40
Diabetes M	1.57
1 condition	1.41
2 conditions	1.51
\geq 3 conditions	2.11



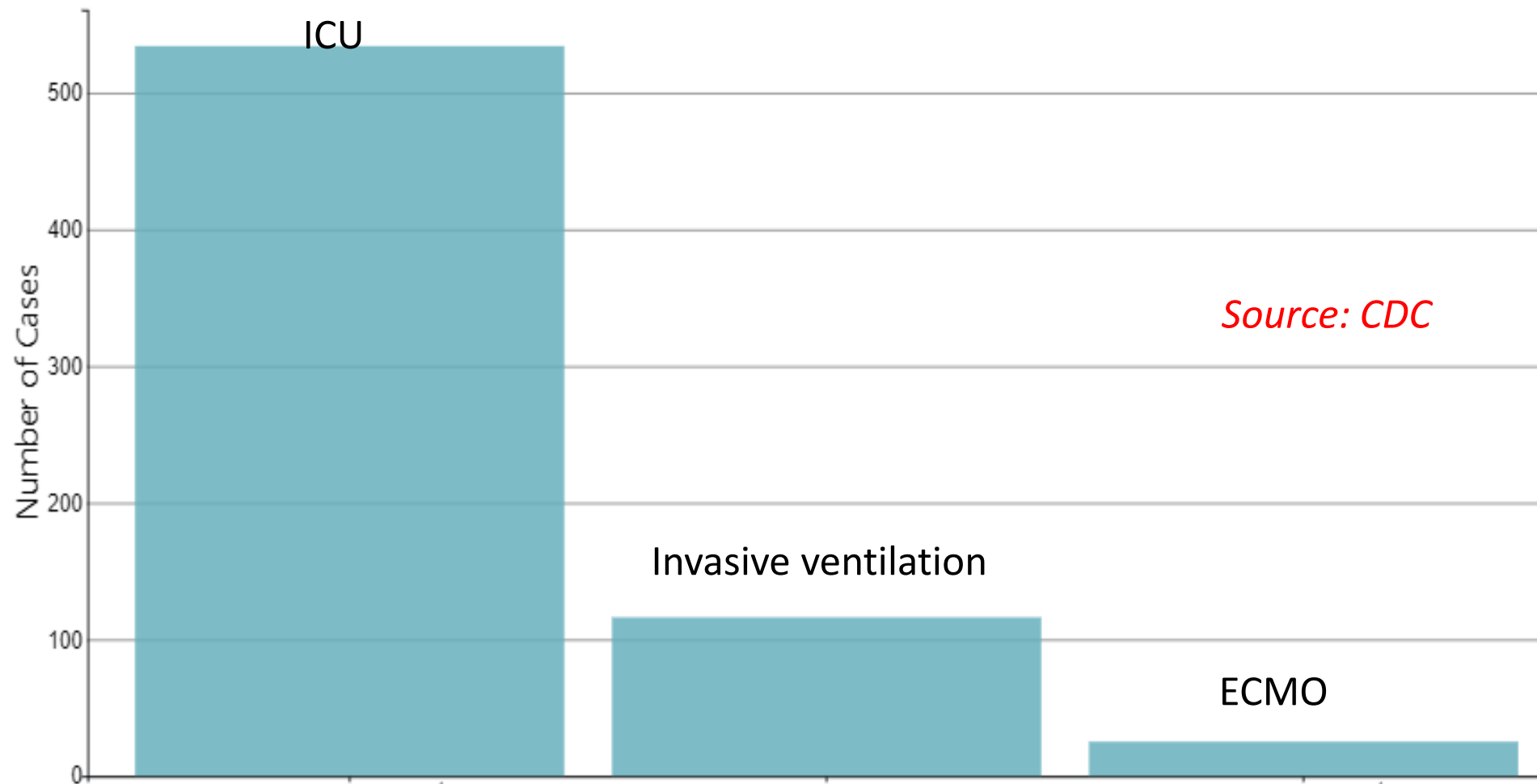
Distribution of COVID-19 severity in pregnancy

COVID-19 Severity	NICHD / MFM-U (n=1219) Mar-Jul 2020 *	INOVA HEALTH SYSTEM (n=717) Mar-Dec 2020 †
Asymptomatic	579 (47%)	425 (60.9%)
Mild	326 (27%)	232 (33.2%)
Moderate	173 (14%)	30 (4.3%)
Severe	98 (8%)	7 (1%)
Critical	43 (4%)	4 (0.6%)

* Metz et al, 2021

† Gomez et al, 2021

COVID-19 & Pregnancy in the USA: ICU admission, need for invasive ventilation or ECMO (Jan 2020 – Sep 2021) 123,633 CASES



Treatment of COVID-19

STAGE	Asymptomatic	Mild	Moderate	Severe	Critical
FEATURES	Positive test No symptoms	Fever, cough, changes in taste / smell	Dyspnea SpO2 \geq 94% Imaging: pneumonia	RR >30 SpO2 <94% Imaging: >50% lung infiltrates	Respiratory and multi organ failure Shock
PATHOGENESIS		Viral replication			
				Inflammation	
THERAPEUTIC		Ab cocktail		Dexamethasone	
		Monoclonal Ab		Monoclonal Ab	
				Remdesivir	
		Convalescent plasma		Enoxaparin	
				JAK inhibitors	

Source: IDSA

Oxygen saturation in pregnancy

- For non pregnant patients: $\geq 92\%$ or greater
- Recommended O₂ saturation in pregnancy is **$\geq 95\%$**

ADMISSION TO THE ICU

- **Inability to maintain O₂ saturation $\geq 95\%$** (pulse oximetry) with supplemental



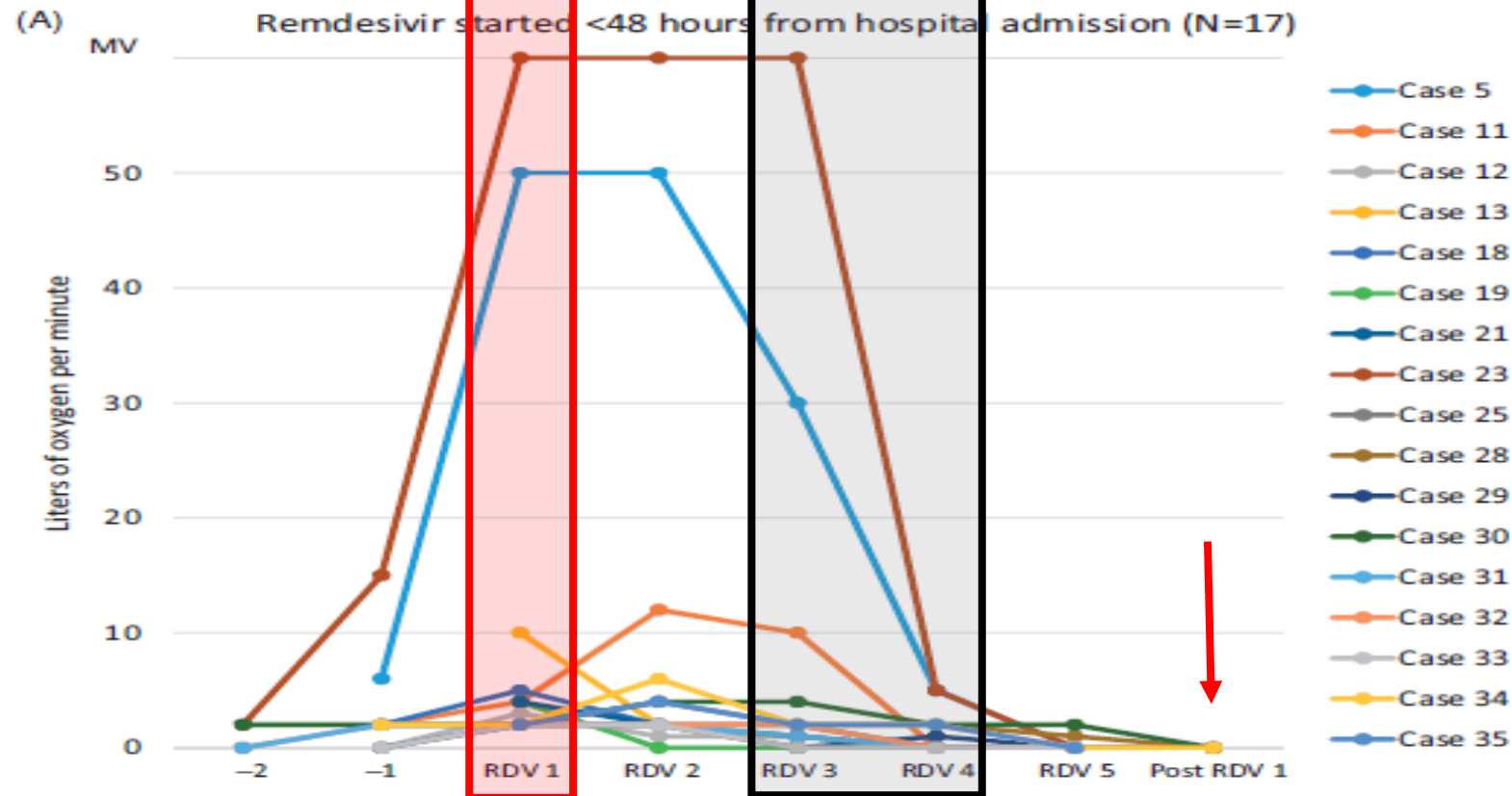
The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: (Print) (Online) Journal homepage: <https://www.tandfonline.com/loi/ijmf20>

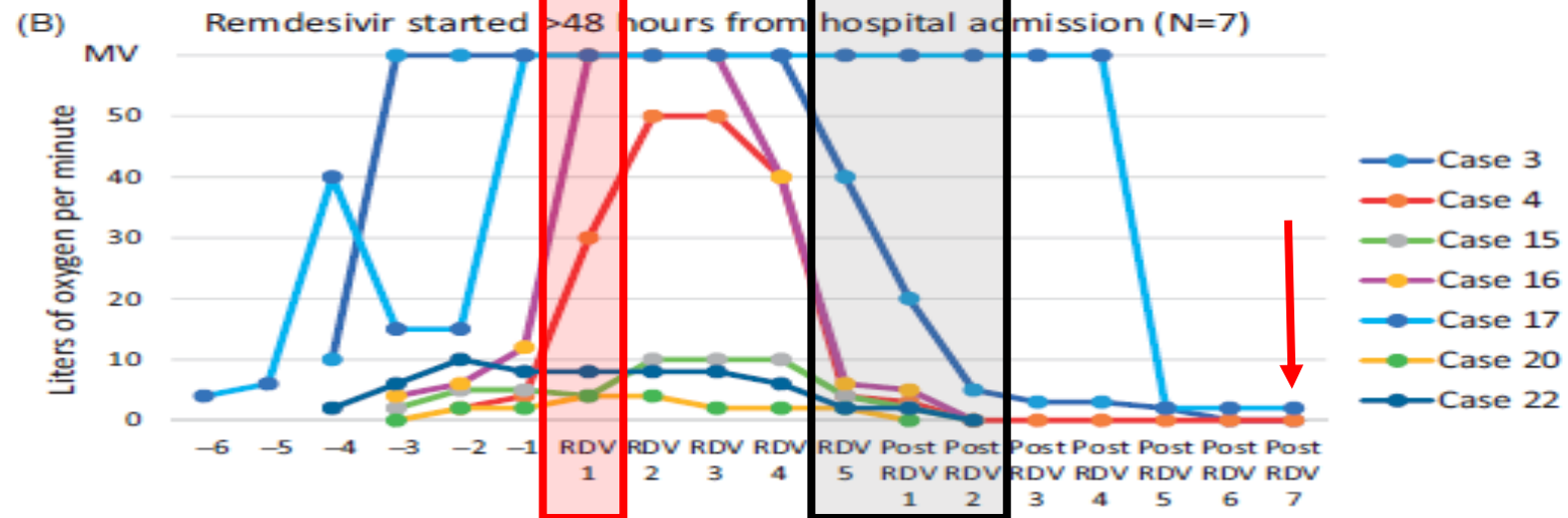
Pharmacological treatment in pregnant women with moderate symptoms of coronavirus disease 2019 (COVID-19) pneumonia

Sebastian Nasrallah, Anh Q. Nguyen, Laura Hitchings, Jenny Q. Wang, Sara Hamade, G. Larry Maxwell, Alfred Khoury & Luis M. Gomez

RDV
<48
hours

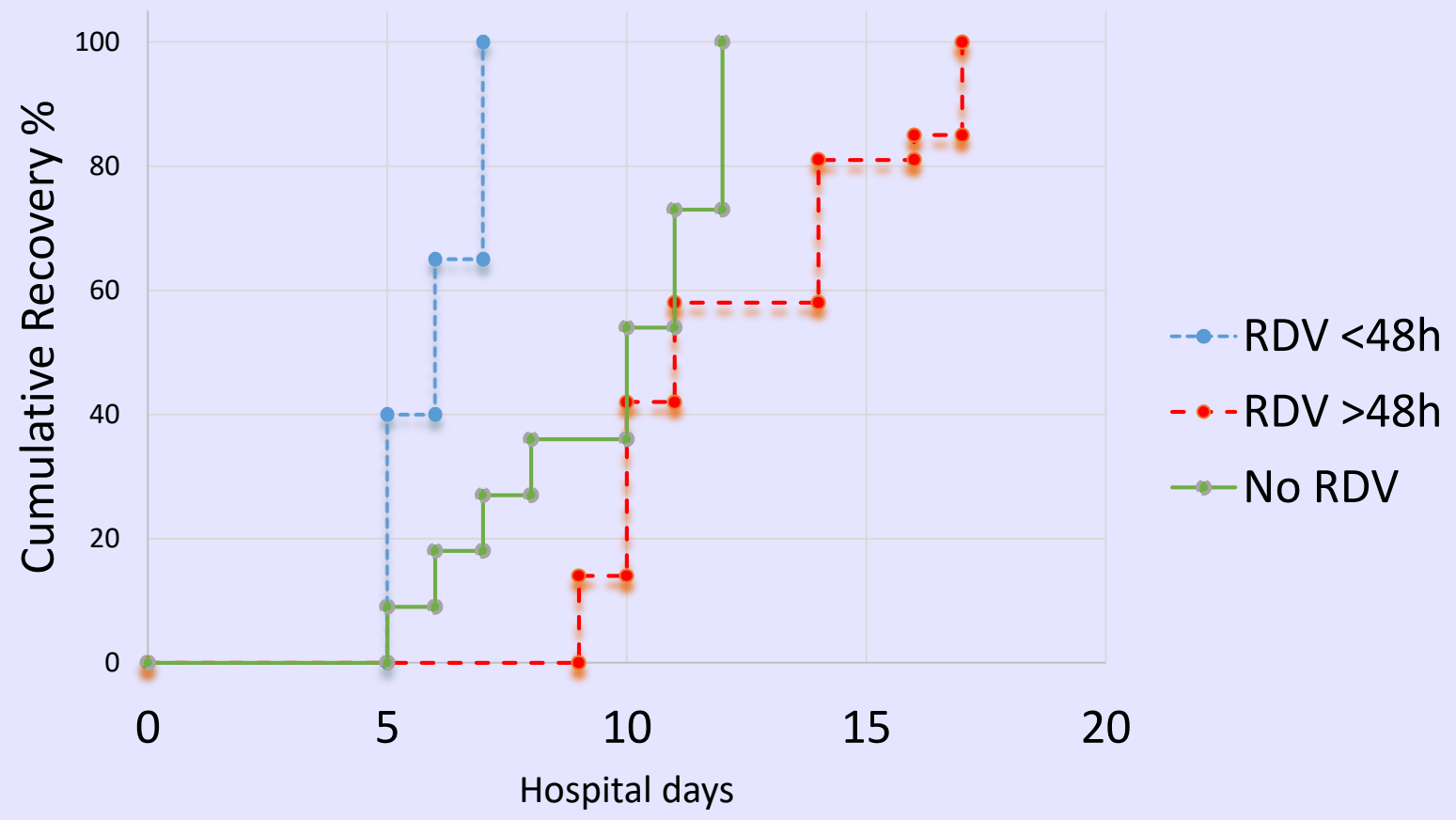


*Nasrallah et al,
2021*



RDV
>48
hours

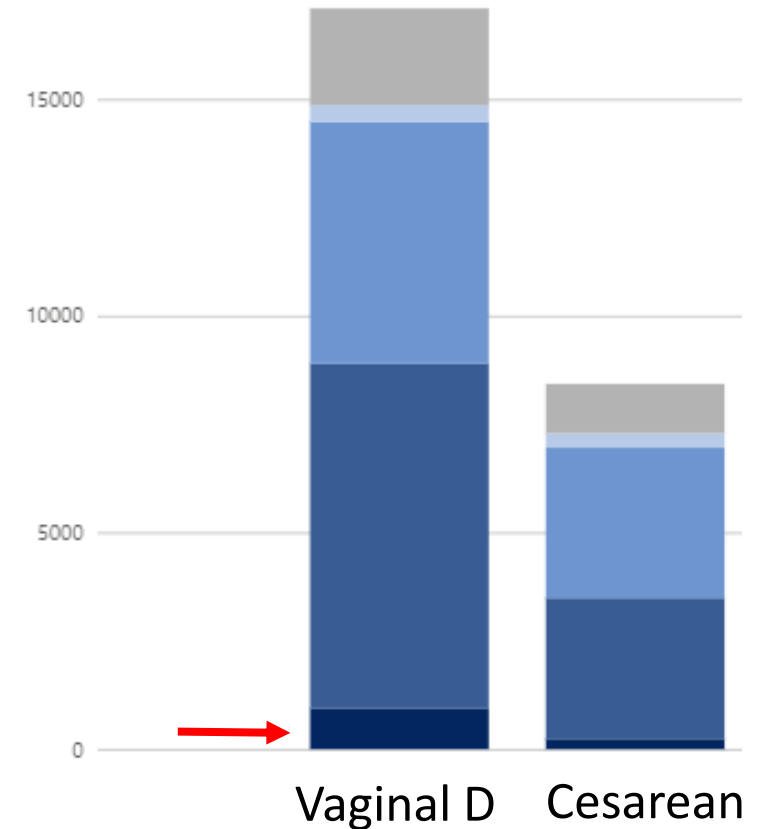
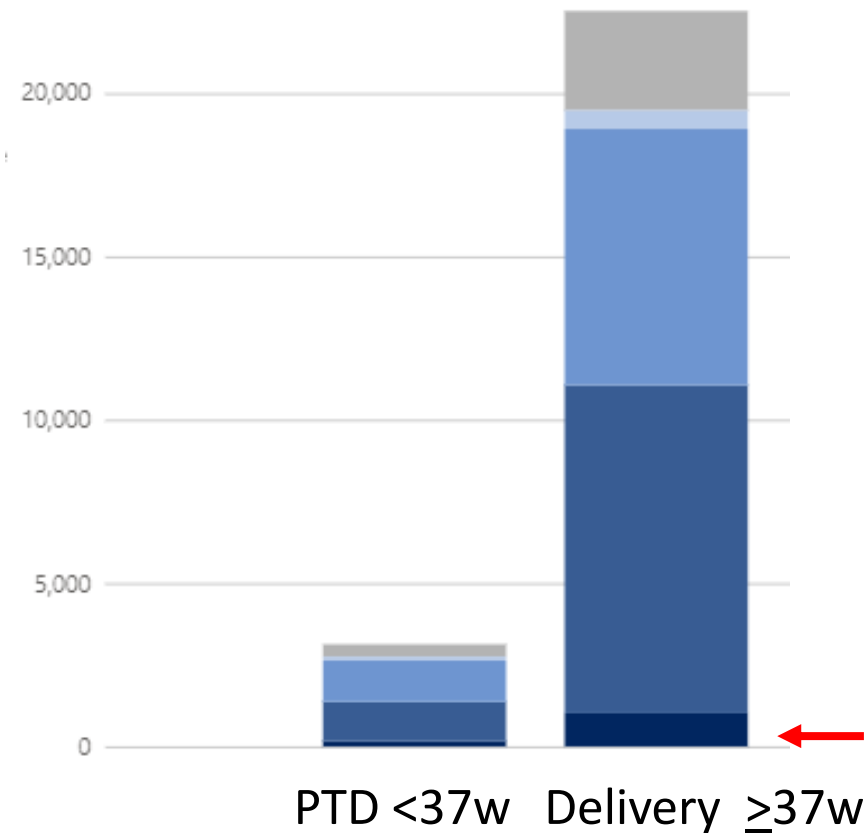
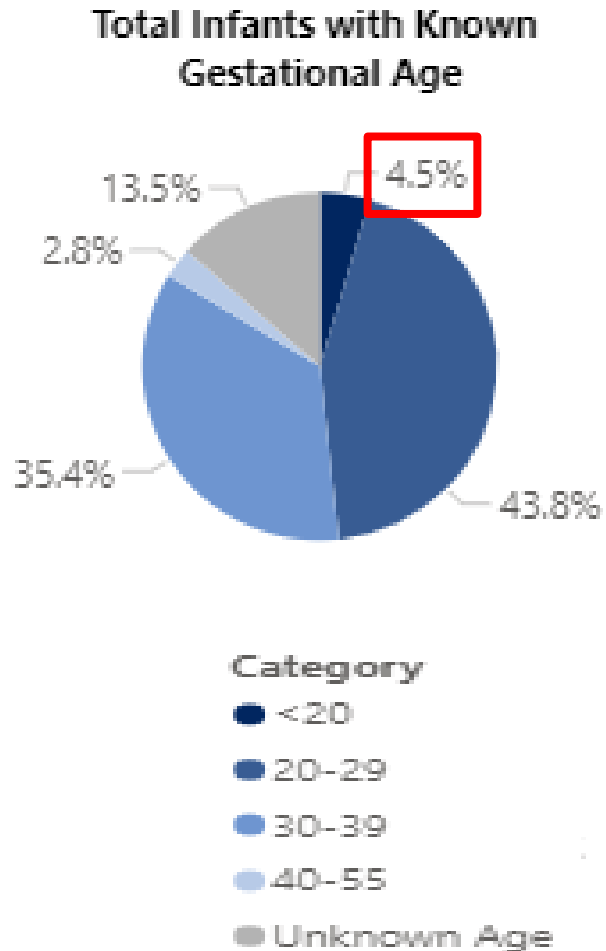
Time to clinical recovery in pregnant women with moderate COVID-19



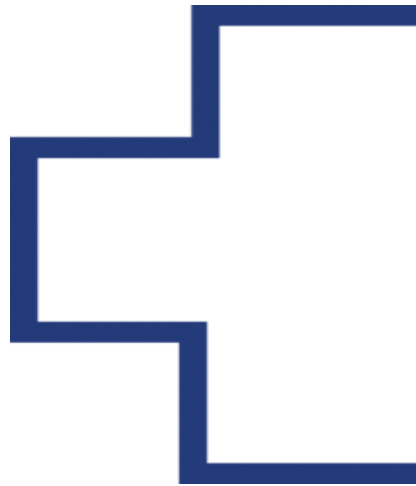
*Nasrallah et al,
2021*

COVID-19 & Teen Pregnancy in the USA – Year 2020

25,649 pregnancies 1,177 Adolescents (4.5%)



Source: CDC



Pregnancy outcomes in pregnant adolescent patients infected with SARS-CoV-2

Anh Q Nguyen, Ellen Murrin, Sebastian Nasrallah, Laura Hitchings, Jenny Wang, Luis M Gomez

COVID-19 in Pregnancy (INOVA): Adolescents vs. adults

TOTAL COVID-19 (N=743)	Adolescents (N=48) – 6.5%	Non adolescents (N=695) – 93.5%	P-value
Age, yo (mean, range)	18 (15-19)	27 (20-44)	<0.001
Ethnicity:			0.006
Hispanic/Latino	44 (91.7%)	518 (74.5%)	
Non-Hispanic:			
- Black	3 (6.3%)	64 (9.2%)	
- White	1 (2%)	35 (5.3%)	
- Asian	0	30 (4.3%)	
- Other	0	48 (6.9%)	
Medical insurance:			0.07
- Charity clinic	24 (50%)	436 (62.7%)	
- No Charity	24 (50%)	259 (37.3%)	
GA at dx (weeks-days, range)	34-5 (7-1 to 41-0)	31-4 (4-0 to 41-0)	0.015

Severity of COVID-19 in Pregnancy (INOVA): Adolescents vs. adults

Total (N=743)	Adolescents SARS-CoV-2-pos (N=48)	Non-adolescents SARS-CoV-2-pos (N=695)	P-value
Asymptomatic	38 (79.2%)	422 (60.7%)	0.01*
Symptomatic	10 (20.8%)	273 (39.3%)	
- Mild	6 (12.5)	232 (33.4%)	0.06
- Moderate	1 (2.1%)	30 (4.3%)	
- Severe	1 (2.1%)	7 (1%)	
- Critical	2 (4.2%)	4 (0.6%)	

* Adjusted p =0.03, adjusted OR 1.9, 95% CI 1.4-2.8

Nguyen et al, 2021

COVID-19 in Pregnancy (INOVA): Infected vs. non infected adolescents - Demographics

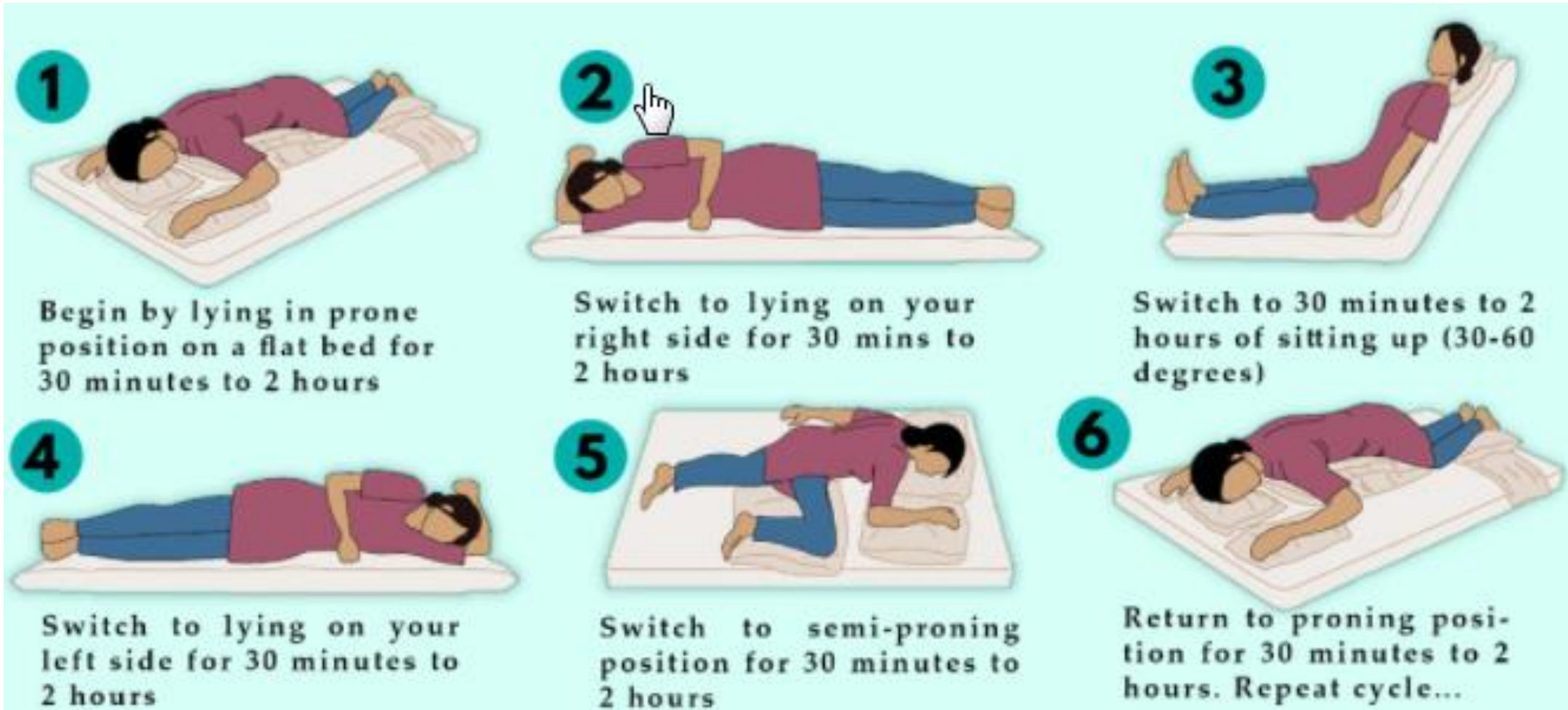
Nguyen et al, 2021

TOTAL (N=442)	Positive (N=48)	Negative (N=394)	P-value
Demographics			
Ethnicity:			
Hispanic/Latino	44 (91.7%)	48 (12.2%)	<0.001
Non-Hispanic:			
- Black	3 (6.3%)	41 (10.4%)	
- White	1 (2%)	52 (13.2%)	
- Asian	0	2 (0.5%)	
- Other	0	214 (54.3%)	
- Unavailable	0	37 (9.4%)	
Medical insurance:			
- None (Charity clinic)	24 (50%)	31 (7.9%)	<0.001
- Medicaid	21 (43.8%)	149 (37.8%)	
- Private	3 (6.2%)	204 (51.8%)	
- Self pay	0	10 (2.5%)	
Body mass index (mean)	29.5	29.3	NS

COVID-19 in Pregnancy (INOVA): Infected vs. non infected adolescents and pregnancy outcomes

	Teen SARS-CoV-2-pos (N=48)	Teen SARS-CoV-2-neg (N=394)	P-value
Gestational age at delivery (weeks-days, range)	39-1 (35-5 to 42-0)	38-4 (22-0 to 41-0)	0.002
Preterm delivery <37 weeks	2 (4.2%)	41 (10.4%)	NS
Cesarean delivery	12 (25%)	47 (11.9%)	0.03
Vaginal delivery, assisted	1 (2.1%)	22 (5.6%)	NS
Vaginal delivery, non assisted	35 (72.9%)	325 (82.5%)	
Birthweight, grams (range)	3,236 (2,150 to 3,990)	3,127 (310 to 5,440)	NS
Fetal growth restriction	2 (0.9%)	4 (1%)	NS
Apgar score at 5 minutes	8.8 (8-9)	8.7 (1-9)	NS
NICU admission	3 (6.3%)	62 (15.7%)	NS

Prone positioning is not contraindicated during pregnancy



How can COVID-19 affect the unborn or newborn baby? What about breastfeeding?

- Unknown if the virus can be passed to the fetus or baby during pregnancy or delivery.
- Unlikely that COVID-19 can pass through breast milk and cause infection in the baby.
- It seems safe to feed breast milk when positive for COVID-19.
- COVID-19 should not stop from breastfeeding
- Conflicting information on increased risk of stillbirth or neonatal death



Women with COVID-19 can **breastfeed** if they wish to do so. They should:



Practice respiratory
hygiene and wear a mask



Wash hands before and
after touching the baby



Routinely clean and
disinfect surfaces



World Health
Organization

#COVID19 #CORONAVIRUS

How to avoid passing COVID-19 to the newborn?

- Breastfeed safely, with good respiratory hygiene
- Wash your hands before and after touching the baby
- Wash your hands before touching any breast pump or bottle parts and clean all pump and bottle parts after use
- Keep all surfaces clean
- Wear a medical mask, during any contact with the baby including feeding
- Do not put a mask over the newborn's face
- Use of a support person



I'm pregnant. How can I protect myself against COVID-19?



Wash your hands
frequently



Avoid touching your
eyes, nose and mouth



Put space
between yourself
and others



Cough or sneeze into
your bent elbow or a
tissue

If you have fever, cough or difficulty breathing, seek care early.
Call beforehand, and follow medical advice.



World Health
Organization

#COVID19 #CORONAVIRUS



COVID-19 Information for the Community

Vaccines | Testing | FAQs | Visiting Hours | Cancellations

CDC COVID-19

[Inova COVID-19 Vaccinations](#)



[Inova COVID-19 Testing](#)



[Language Translations](#)



[Patient and Visitor Information](#)



PREGNANT INDIVIDUALS
**MAY BE AT INCREASED
RISK** FOR SEVERE
ILLNESS FROM COVID-19
COMPARED WITH THEIR
NON PREGNANT
COUNTERPARTS



PREGNANT
INDIVIDUALS AND
THEIR FAMILIES
SHOULD TAKE STEPS
TO **STAY HEALTHY**
AND **REDUCE THEIR
RISK** FOR GETTING
COVID-19



UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE

COVID Vaccination in Children: what we know and what we don't

Ana Lia Graciano, MD, FAAP, FCCM

Professor of Pediatrics

Medical Director PCICU

Division of Critical Care Medicine

University of Maryland Children's Hospital



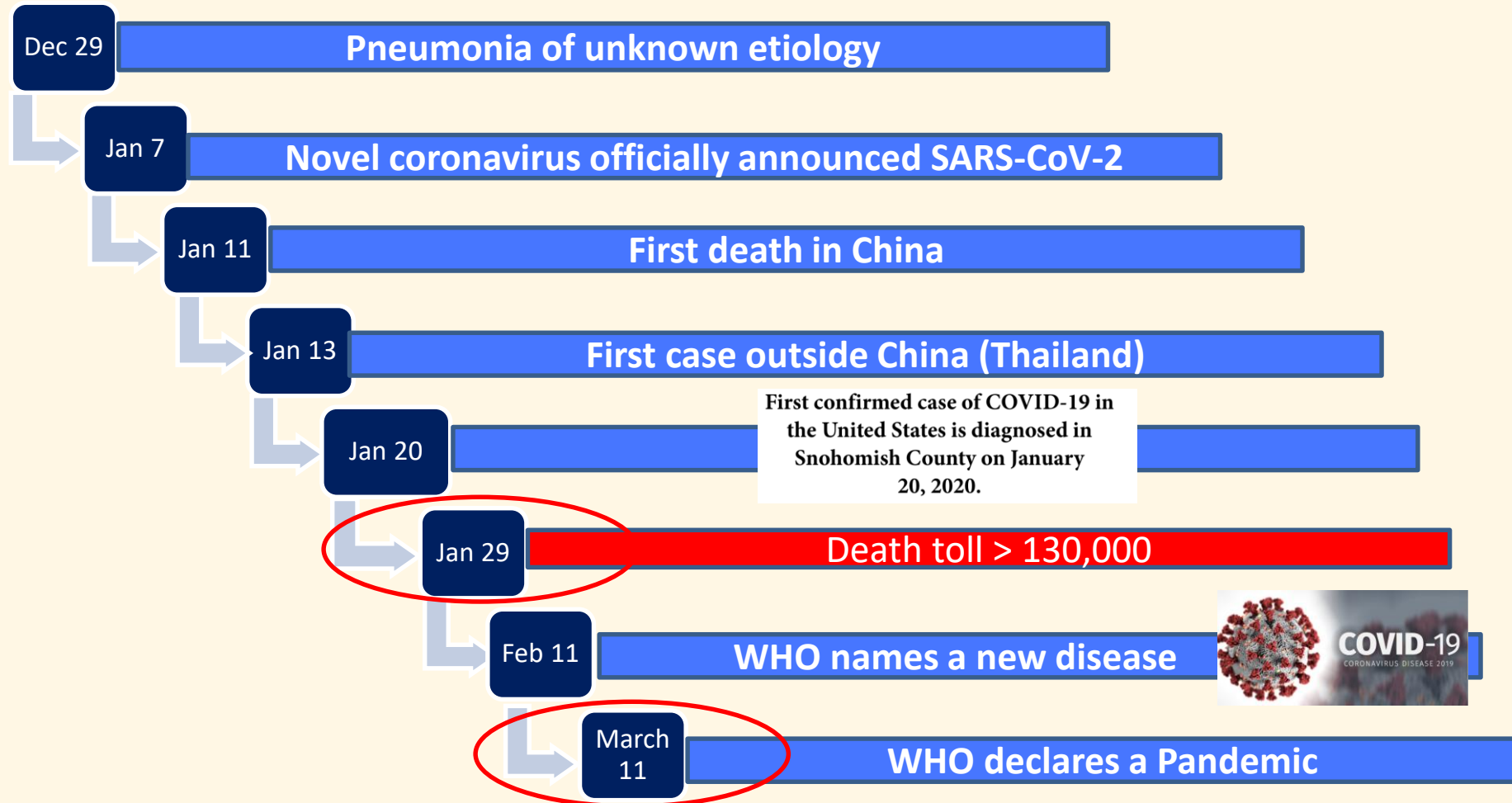
- No Disclosures



Objectives

- Describe the trajectory of COVID-19 in children since first reported
- Describe the characteristics of the Multisystem Inflammatory Syndrome in Children (MIS-C)
- Discuss current knowledge of FDA-approved COVID vaccine for children

From outbreak to pandemic



Received: 19 March 2020

Accepted: 20 March 2020

DOI: 10.1111/apa.15270

REVIEW ARTICLE

ACTA PÆDIATRICA
NURTURING THE CHILD

WILEY

Systematic review of COVID-19 in children shows milder cases and a better prognosis than adults

**MAYBE OR
MAY BE NOT**



An “unusual” illness

- Children admitted to ward or to intensive care units
 - Prolonged fever
 - Sore throat
 - Headache
 - Abdominal pain/Vomiting/Diarrhea
 - Skin rashes/conjunctivitis
 - Shock
 - Myocardial dysfunction
 - Kawasaki-like /Toxic Shock like
 - Elevated markers of inflammation
- The majority were SARS-CoV-2 PCR negative but had **positive antibodies**

Hyperinflammatory shock in children during COVID-19 pandemic

Shelley Riphagen¹, Xabier Gomez², Carmen Gonzalez-Martinez³, Nick Wilkinson³, Paraskevi Theocharis³

Lancet-May 6, 2020

- N=8
- Age 4-14 years
- Weight > 75th percentile
- Contact with COVID-19
- Fever (39-40C)
- Rash/Conjunctivitis
- Edema
- GI symptoms
- Vasoplegic shock

Laboratory

- Elevated DD, CRP, Troponin
- **SARS-CoV-2 PCR**
 - negative (n=6)
 - positive (n=2, 1 post-mortem)
- Echocardiogram: prominent coronaries

Treatment

- Intubated (n=7)- cardiogenic shock
- Vasopressors
- IVIG
- Ceftriaxone/Clindamycin
- Aspirin
- ECMO (n=1, death)

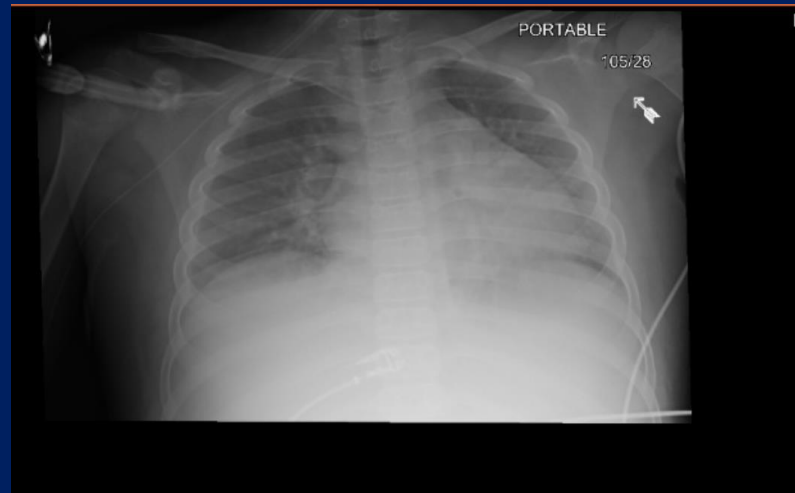
Multisystem Inflammatory Syndrome in Children (MIS-C)

CDC Case Definition

- < 21 years **AND**
- Fever + laboratory evidence of inflammation; **AND**
- Evidence of clinically severe illness requiring hospitalization; **AND**
- Multisystem (≥ 2) organ involvement (cardiac, renal, hematologic, gastrointestinal, dermatologic or neurological); **AND**
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; **OR** exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to onset of symptoms

Laboratory and Imaging in MIS-C

- Lymphopenia
- Neutrophilia
- Thrombocytopenia
- Elevated markers of inflammation
 - CRP
 - Sedimentation Rate
 - LDH
 - Fibrinogen
 - Ferritin
 - D-Dimers
 - Procalcitonin
 - Interleukin-6
- Elevated cardiac markers
 - Troponin
 - BNP or NT-proBNP
- Hypoalbuminemia
- Mildly elevated liver enzymes
- Echocardiogram
 - Depressed cardiac function
 - Pericardial effusion
 - Mitral regurgitation
 - Coronary abnormalities
- Chest-X ray
 - Normal
 - Consolidations (more common in acute COVID-19)
 - Pleural effusions
- Abdominal Imaging
 - Ascites
 - Bowel and mesenteric inflammation

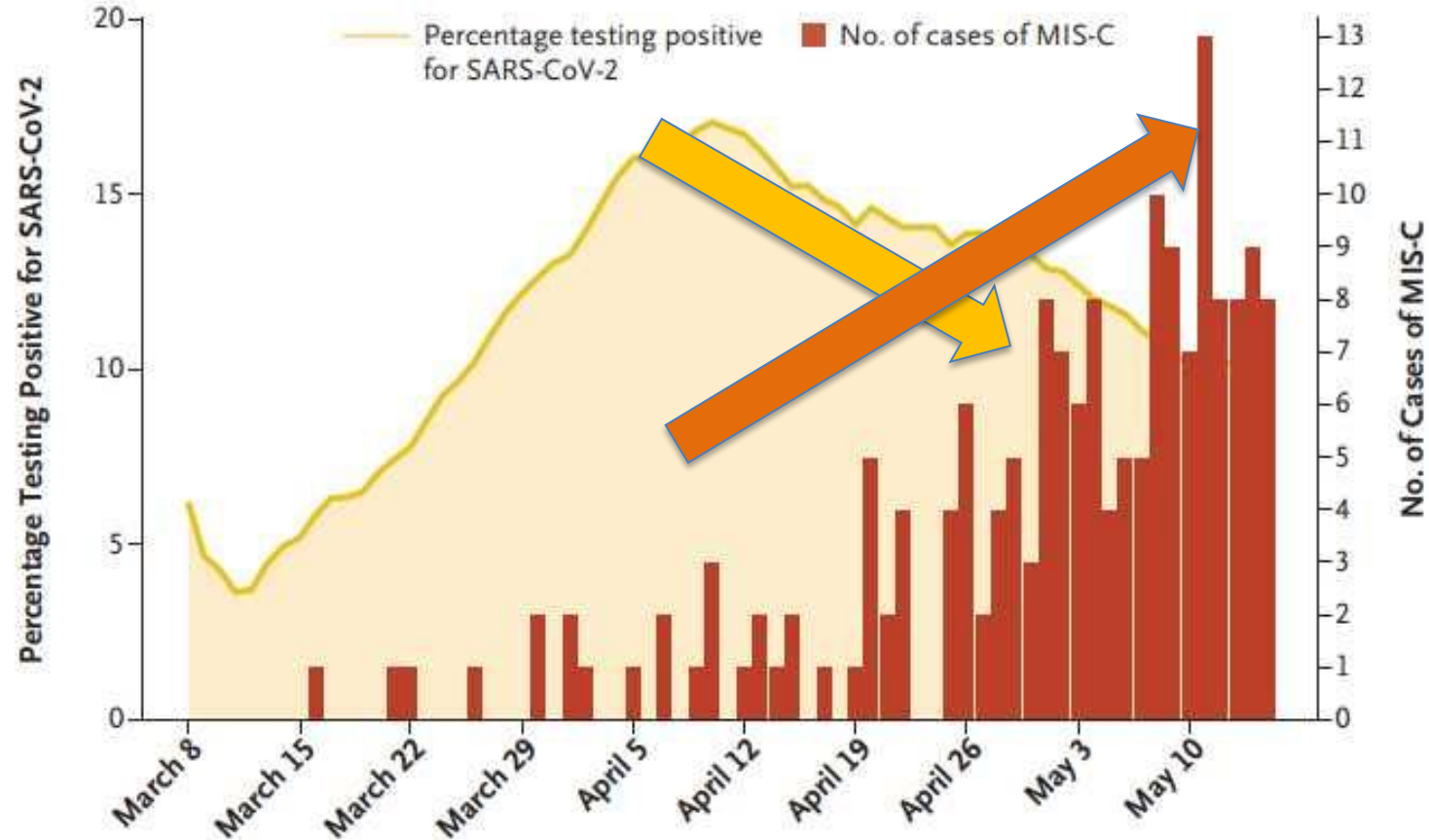


Multisystem Inflammatory Syndrome in U.S. Children and Adolescents

OVERCOMING COVID-19

N Engl J Med 2020;383:334-46.

B Temporal Relationship between MIS-C and Covid-19 Activity in Persons <21 Yr of Age

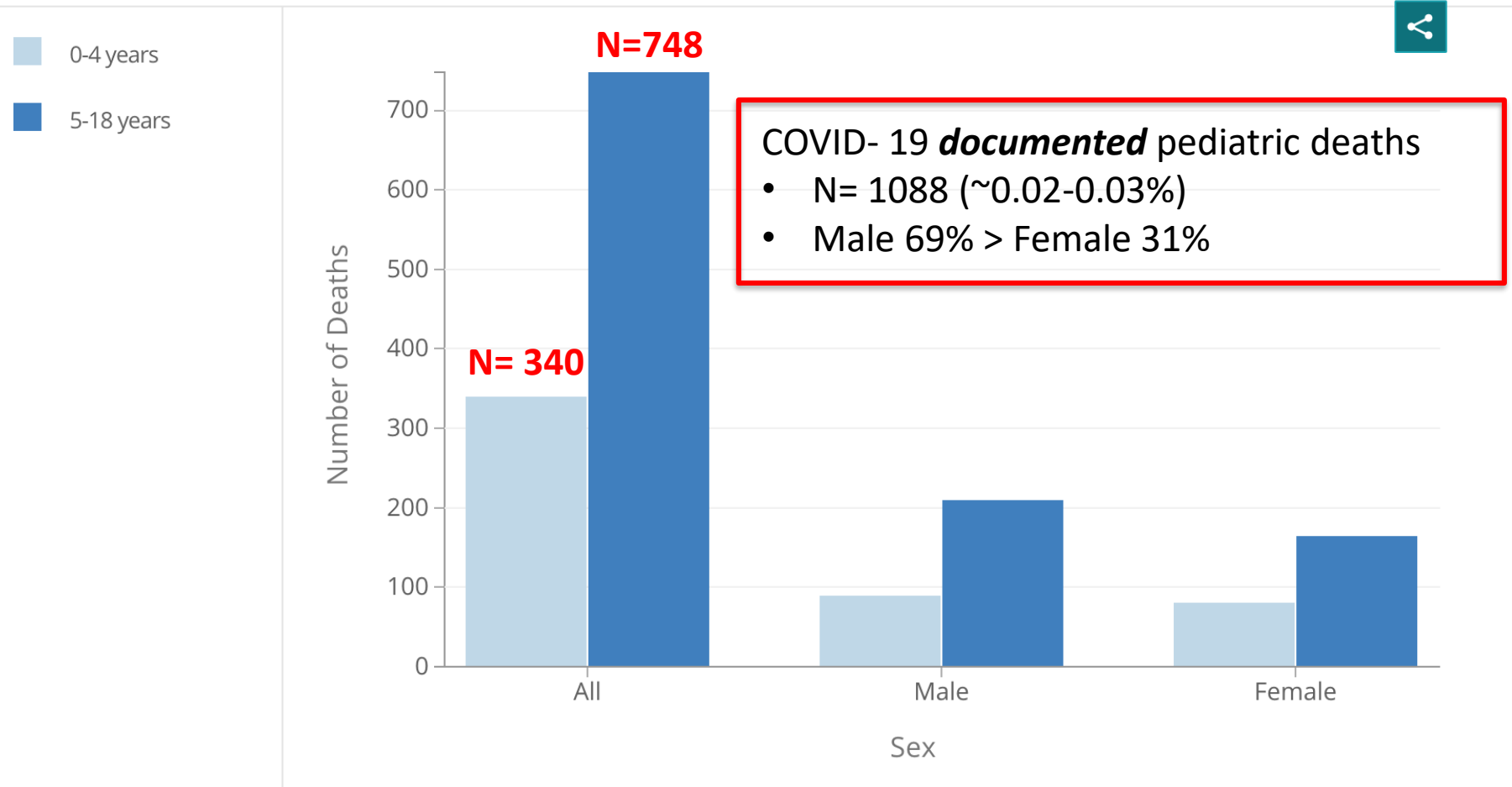


Burden of COVID-19 in Children

- All ages susceptible to SARS-CoV-2 infection
- Over 5 million pediatric cases reported in the US
- Previously healthy children are at risk
- Underlying medical conditions (obesity, asthma, chronic medical conditions) are risk factors for severity
- Children with severe COVID-19 may develop respiratory failure, myocarditis, shock, acute renal failure, coagulopathy, encephalopathy and multiorgan system failure
- There is a **high incidence of cardiovascular involvement** associated with Multisystem Inflammatory Syndrome in Children (MIS-C): myocarditis, arrhythmias, coronary anomalies
- *Hospitalizations rates in the US are **higher among Hispanic/Latino children and non-Hispanic Black** children compared with non-Hispanic White children.*
- *Mortality in children is much lower than in adults but nonetheless pediatric deaths are documented*

US COVID-19 Mortality in Children – CDC (9/22/21)

Figure 1. Provisional COVID-19 deaths by age group, by sex: United States



Vaccines approved for children in the US

- **Pfizer-BioNtech (BNT162b2)**
 - Approved for ≥ 16 years of age (August 2021)
 - EAU for ≥ 12 -15 years (May 2021)
 - 2 doses 3 weeks apart
 - Optimal protection occurs 7 days after second dose
 - 3rd dose can be given to immunocompromised children at least 28 days following the second dose
- **Moderna (mRNA1273)- not approved yet**
 - KidCOVE study (ongoing)
 - Not approved yet in the US
- **Both are mRNA vaccines**

<https://www.fda.gov/media/144413/download>

<https://www.cvdvaccine-us.com>

BioNtech Vaccine Common Side Effects

- Pain at injection site
- Fatigue, muscle pain
- Headache
- Fever, chills
- Joint pain
- Lymphadenopathy

➤ [JAMA Cardiol.](#) 2021 Jun 29;e212828. doi: 10.1001/jamacardio.2021.2828. Online ahead of print.

Patients With Acute Myocarditis Following mRNA COVID-19 Vaccination

Case Reports

➤ [Pediatrics.](#) 2021 Sep;148(3):e2021052478. doi: 10.1542/peds.2021-052478.

Epub 2021 Jun 4.

Symptomatic Acute Myocarditis in 7 Adolescents After Pfizer-BioNTech COVID-19 Vaccination

➤ [JAMA Cardiol.](#) 2021 Aug 10;e213471. doi: 10.1001/jamacardio.2021.3471. Online ahead of print.

Association of Myocarditis With BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children

Myocarditis and COVID-19 mRNA vaccine

- Post-marketing data demonstrate increased risks of myocarditis and pericarditis particularly within 7 days following the second dose
- Incidence: 12.6 cases per million doses of second dose
- Risk higher among young males (12-39 years of age)
- Clinical and laboratory presentation:
 - Chest pain, palpitations, shortness of breath
 - Elevated troponin
 - EKG- ST elevation
 - Cardiac MRI suggestive of myocarditis
- *Most individuals have resolution of symptoms with **conservative management***
- Information on potential long-term sequelae is not known

Acute Myocarditis and Acute Pericarditis- CDC Working Definitions

CDC Working Case Definitions

Acute Myocarditis

Probable Case

- Presence of ≥ 1 new or worsening of the following clinical symptoms
 - chest pain/ pressure/ discomfort
 - dyspnea/shortness of breath
 - palpitations
 - syncope
- AND ≥ 1 new finding of
 - elevated troponin above upper limit of normal
 - abnormal ECG or rhythm monitoring findings consistent with myocarditis*
 - abnormal cardiac function or wall motion abnormalities on echocardiogram
 - cardiac MRI findings consistent with myocarditis[†]
- AND no other identifiable cause of the symptoms and findings

Confirmed Case

- Presence of ≥ 1 new or worsening of the following clinical symptoms
 - chest pain/ pressure/ discomfort
 - dyspnea/shortness of breath
 - palpitations
 - syncope
- AND
 - histopathologic confirmation of myocarditis[‡]
 - OR
 - elevated troponin above upper limit of normal AND cardiac MRI findings consistent with myocarditis[†]
- AND no other identifiable cause of the symptoms and findings

Acute Pericarditis

Probable Case

- Presence of ≥ 2 new or worsening of the following clinical symptoms
 - acute chest pain (typically described as pain made worse by lying down, deep inspiration, cough, and relieved by sitting up or leaning forward, although other types of chest pain may occur)[§]
 - pericarditis rub on exam
 - new ST-elevation or PR-depression on ECG
 - new or worsening pericardial effusion on echocardiogram or MRI
- Autopsy cases may be classified as pericarditis on basis of meeting histopathologic criteria of the pericardium

Summary

- Fewer cases of COVID-19 have been reported in children compared with adults. But the number and rate of cases have been steadily increasing since March 2020
- Myocardial dysfunction and elevated cardiac markers are common in children with severe COVID and MIS-C
- Myocarditis temporally associated with mRNA vaccine has been reported in children and young adults (mostly men)
- Most cases reported after the second dose and within the first week after vaccination
- Most cases tend to be mild
- Suspected cases require a careful history, physical exam, laboratory work, EKG, echocardiogram and in some cases cardiac MRI
- No specific therapy is recommended at present time. Care is largely supportive.
- At this time patients with myocarditis/pericarditis after first dose of mRNA vaccination should defer a second dose

- *COVID-19 mRNA vaccination is recommended in all populations for which a benefit has been established as benefits of the vaccine outweighs the risks*
- Many questions remain :
 - Modifications to the vaccine schedule
 - Best management of postvaccine myocarditis
 - Frequency and type of follow up assessments
 - Recommendations on physical activities after vaccine related myocarditis
 - Long-term prognosis of vaccine related myocarditis is unknown
 - And many more....

THANK YOU

agraciono@som.umaryland.edu

Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting

Noam Barda, M.D., Noa Dagan, M.D., Yatir Ben-Shlomo, B.Sc., Eldad Kepten, Ph.D., Jacob Waxman, M.D., Reut Ohana, M.Sc., Miguel A. Hernán, M.D., Marc Lipsitch, D.Phil., Isaac Kohane, M.D., Doron Netzer, M.D., Ben Y. Reis, Ph.D., and Ran D. Balicer, M.D.

- Evaluated risk of adverse events among individuals ≥ 16 years of age who had received the Pfizer-BioNtech vaccine and risk of the same events after SARS-CoV-2 infection
- Used multiple data sets from the largest integrated payer provider health care organization in Israel in conjunction with data on SARS-CoV-2 PCRs and data on COVID-19 vaccine administration from the Israel Ministry of Health
- Matched eligible vaccinated individuals to unvaccinated controls



The NEW ENGLAND
JOURNAL of MEDICINE

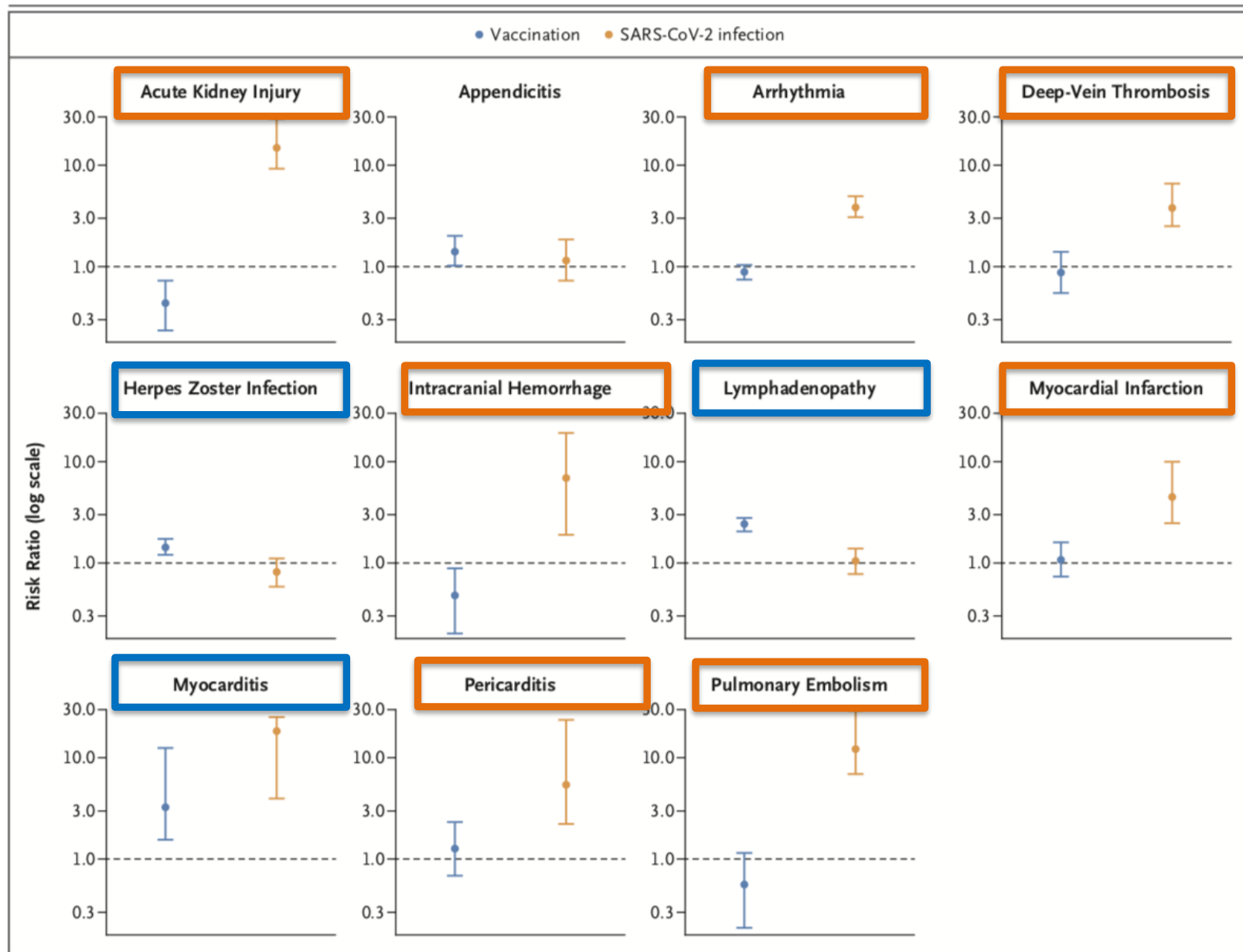
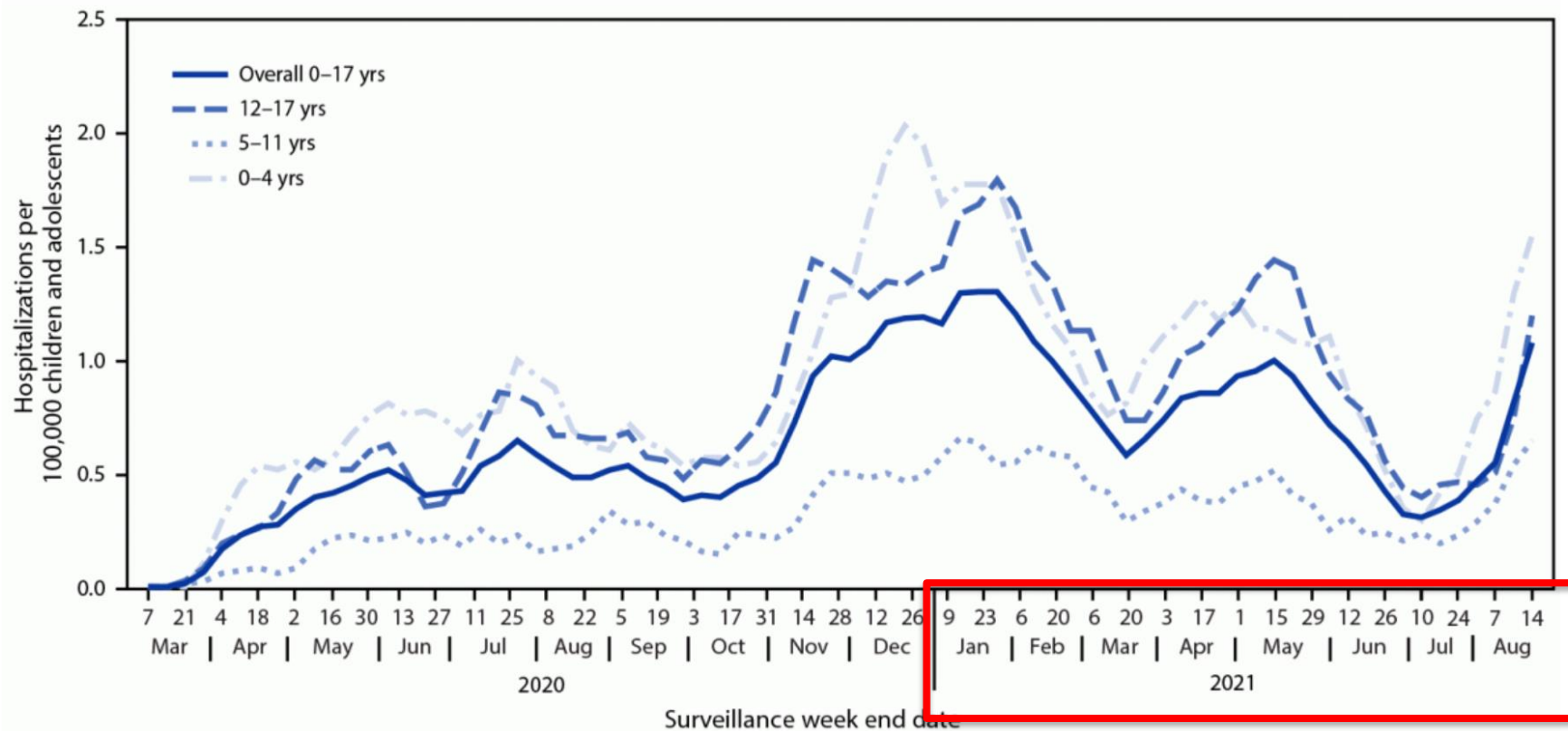


Figure 3. Risk Ratios for Adverse Events after Vaccination or SARS-CoV-2 Infection.

Estimated risk ratios for adverse events after vaccination or SARS-CoV-2 infection are shown. The risk ratio on the y axis is presented on a logarithmic scale to facilitate comparison of both increased and decreased risk. I bars indicate 95% confidence intervals.

Hospitalizations Associated with COVID-19 Among Children and Adolescents —
COVID-NET, 14 States, March 1, 2020–August 14, 2021

FIGURE 2. COVID-19–associated weekly hospitalizations per 100,000 children and adolescents,* by age group — COVID-NET, 14 states,† March 1, 2020–August 14, 2021 (3-week smoothed running averages)§



* Rates are subject to change as additional data are reported.

COVID-19 VACCINES DURING PREGNANCY

- ▶ SERGIO RIMOLA, MD FACOG
- ▶ NHMA DC METRO CHAIR
- ▶ INOVA HEALTH SYSTEM



COVID-19 VACCINES DURING PREGNANCY

The data indicate that pregnancy is an independent risk factor for severe COVID-19 disease.

Hispanic, Latinx, and black patients are disproportionately affected by severe maternal morbidity and mortality and have a disproportionately higher incidence of COVID-19 infection and death.

mRNA VACCINES

Currently three COVID-19 vaccines authorized for use in the United States.

mRNA vaccines (Pfizer-BioNTech BNT 162b2 and Moderna mRNA 1273 vaccines)

The Pfizer and Moderna contain mRNA, a genetic material that encodes the SARS-CoV-2 spike S protein that elicit neutralizing antibody responses to the S-protein and confer superior protective immunity compared with N-protein targeted antibodies.

No live vaccines, with rapid degradation by normal cellular processes.

No risk of genetic modification to people receiving the vaccine

JANSEEN BIOTECH (J&J VACCINE

- ▶ Uses an adenovirus to carry the gene for the coronavirus spike S protein into the host cell to produce for spike protein.
- ▶ Triggering both antibody and cell-mediated immune responses.
- ▶ The risk of genetic modification from adenovector vaccines is also low.
- ▶ Viral DNA carrying the gene encoding the coronavirus spike protein enters the host nucleus to be transcribed but is not integrated into the host's DNA.
- ▶ On April 13, 2021, the US FDA and CDC recommended a pause due to a rare, severe type of blood clot called cerebral venous thrombosis (CVST)
- ▶ Thrombosis with Thrombocytopenia syndrome (TTS) is a rare condition

EFICACY OF COVID-19 VACCINE

- ▶ **Data from clinical trials indicate that the efficacy of Pfizer vaccine after the second dose is 95% (95% CI, 90.3%-97.6%), and the efficacy of Moderna is 94.1% (95% CI, 89.3%-96.8)**
- ▶ **Both vaccines are highly effective in producing vaccine-antibody titers in pregnant and lactating women.**
- ▶ **Observational data demonstrate that the clinical effectiveness of mRNA vaccines in pregnant people is high.**
- ▶ **Delta variant: Pfizer 42-96%. Moderna 66-95%**
- ▶ **Data released on July 28 a booster dose of Pfizer strongly boosted protection against Delta variant.**

COVID-19 VACCINES IN PREGNANCY

- ▶ **The COVID-19 pandemic demonstrates the urgency of including pregnant individual in clinical research.**
- ▶ **Medical societies were unsuccessful in advocating for inclusion of pregnant individuals in the COVID-19 vaccine trials.**
- ▶ **Tendencies that contribute to exclusion of pregnant individuals include narrow focus on fetal risk rather than the health of the dyad.**
- ▶ **Exclusion of pregnant individuals from trials of COVID-19 vaccines has led to inconsistent policies.**

COVID-19 VACCINES IN PREGNANCY

- ▶ **During the initial roll out of COVID-19 vaccines on mid December 2020 there was not a clear guidance on recommendations during pregnancy and nursing.**
- ▶ **On March results from CDC's v-Safe voluntary after vaccination health check system showed that more than 30,000 women who received the Moderna and Pfizer-BioNTech vaccines have reported pregnancies, with no specific safety issues identified with similar side effects for pregnant and non-pregnant individuals.**
- ▶ **Birth outcomes of 827 completed pregnancies, rates of complications were not significantly different from those of unvaccinated pregnant women.**

COVID-19 VACCINES IN PREGNANCY

- ▶ **The CDC data indicated that it was safe for pregnant women to receive these vaccines, but without a strong formal recommendation.**
- ▶ **As a result The CDC, The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine strongly recommended that pregnant and lactating women have access to COVID-19 vaccines.**
- ▶ **Encouraging a conversation with health care providers about potential benefits and unknown risks regarding receipt of the vaccine.**
- ▶ **This conversation may be helpful but not required prior to vaccination.**

COVID-19 VACCINES IN PREGNANCY

- ▶ **The CDC Advisory Committee on Immunization Practices (ACIP) reports that preclinical studies have been reassuring.**
- ▶ **To date more than 139,000 pregnant people have self-reported within the CDC v-safe program, acute side effects do not appear to differ from those on the general population.**
- ▶ **More than 3,900 have been followed longitudinally in a registry for outcomes such as miscarriages, stillbirth, pregnancy complications, ICU admissions, adverse birth complications, neonatal death, infant hospitalizations and birth defects were similar.**

COVID-19 VACCINES IN PREGNANCY

- ▶ Available data from the Janssen Biotech (J&J) also include DART data and 8 pregnancies inadvertently enrolled in clinical trials.
- ▶ Previous vaccine trials using adenovirus vectors in pregnant patients, eg, Ebola vaccine, have not demonstrated adverse pregnancy outcomes.
- ▶ Safety monitoring in pregnant people is ongoing.
- ▶ Pfizer and Janssen are planning clinical trials in pregnant volunteers.

COVID 19 VACCINES IN PREGNANCY

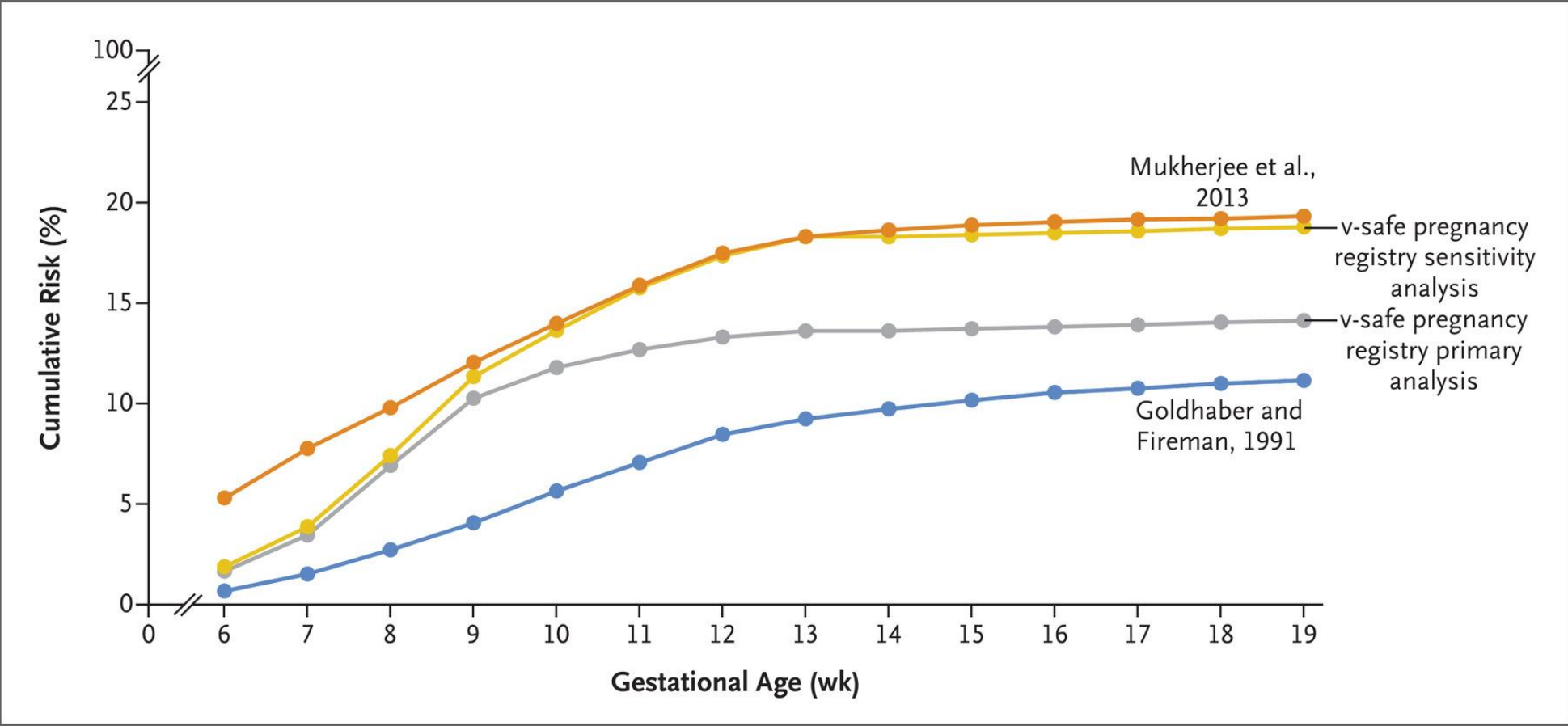
- ▶ **On 8/9/2021 20 leading organizations released a statement of strong medical consensus for vaccination of pregnant individuals against COVID-19**
- ▶ **Strongly urging all pregnant individuals, along with recently pregnant, planning to become pregnant, lactating and other eligible individuals to be vaccinated.**
- ▶ **Pregnant individuals are at increased risk of severe COVID-19 disease infection, including death particularly with increasing number of Delta variant.**
- ▶ **Vaccine is both safe and effective when administered during pregnancy.**

COVID-19 VACCINES IN PREGNANCY

- ▶ **8/11/21 New CDC Data: COVID-19 vaccination safe for pregnant people.**
- ▶ **CDC encourages all pregnant people or people who are thinking about becoming pregnant and those breastfeeding to get vaccinated to protect themselves from COVID-19. (Dr Rochelle Walensky)**
- ▶ **A new CDC analysis of current data from the v-safe pregnancy registry in early pregnancy did not find any increase of miscarriage among nearly 2,500 pregnant who received mRNA COVID-19 vaccine before 20 weeks, around 13%, 11-16% expected rate of miscarriage.**
- ▶ **Previously, data from three safety systems did not find any safety concerns for pregnant vaccinated late in the pregnancy or for their babies.**

Receipt of mRNA COVID-19 Vaccines and risk of spontaneous abortion

- ▶ **Study published on September 8 on NEJM group.**
- ▶ **Analyzed data from CDC v-Safe program to determine the cumulative risk of spontaneous abortion from 6 to less than 20 weeks of gestation.**
- ▶ **2,456 participants.**
- ▶ **The cumulative risks of spontaneous abortion were within the expected risk range.**
- ▶ **The findings add to the accumulating evidence about the safety of mRNA COVID-19 vaccination in pregnancy.**

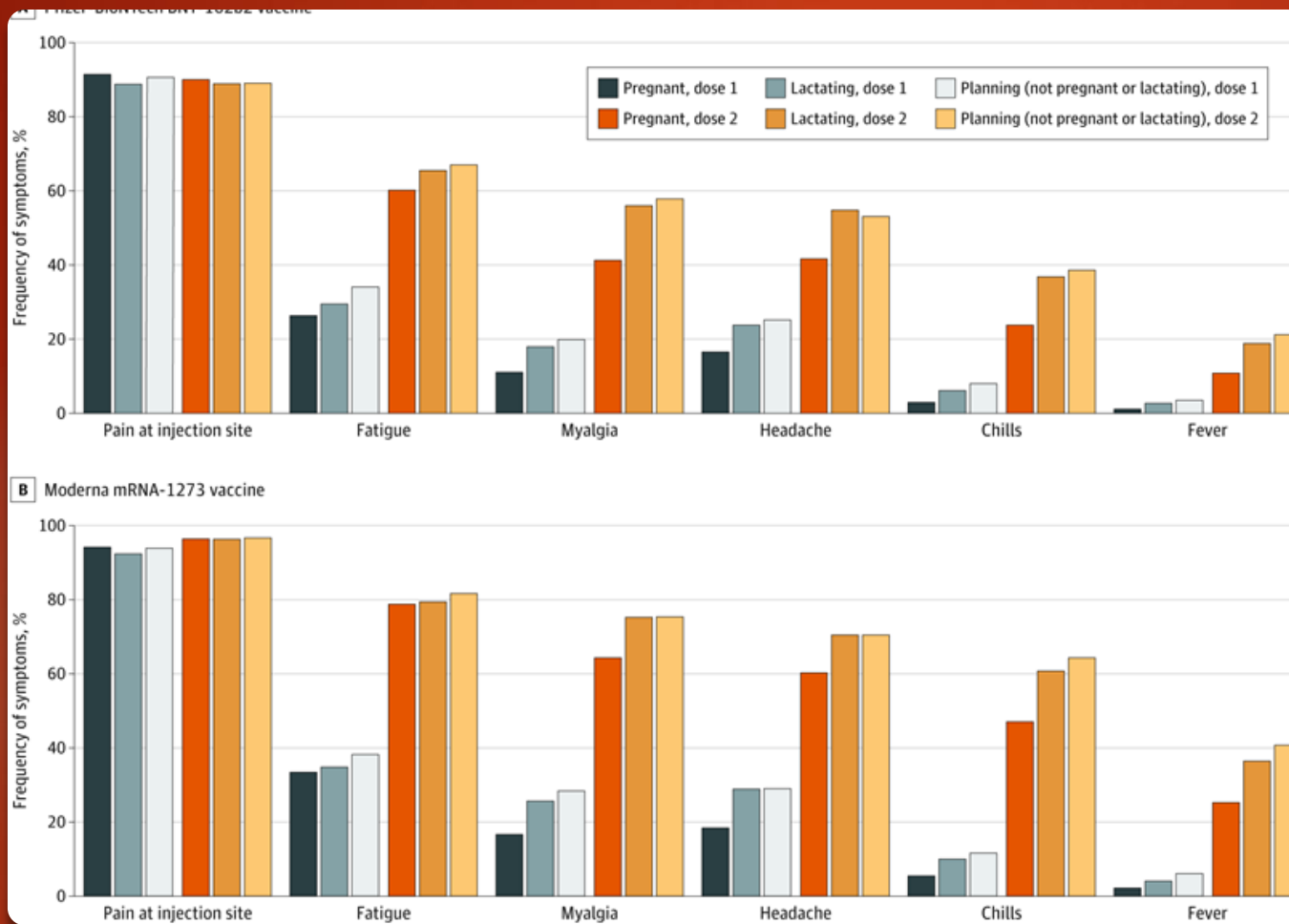


COVID-19 VACCINES IN PREGNANCY

- ▶ **8/23/21 ACOG statement on FDA approval of Pfizer-BioNTech's COVID-19 vaccine.**
- ▶ **“With today’s FDA licensure clinicians can feel more confident in recommending vaccination for their patients including pregnant patients.**
- ▶ **ACOG, The Society of Maternal-Fetal Medicine, The CDC and 18 organizations representing maternal care experts and public health professionals all recommending vaccination during pregnancy.**
- ▶ **Vaccination in pregnancy is safe and effective.**
- ▶ **The single best tool we have to protect us as individuals and fellow members of our communities against COVID-19**

SHORT-TERM REACTIONS AMONG PREGNANT AND LACTATING INDIVIDUALS IN THE FIRST WAVE OF THE COVID-19 VACCINE

- ▶ **January 2021 online prospective cohort study of adults primarily located in the USA who were pregnant, lactating, or planning pregnancy at the time of COVID-19 vaccine.**
- ▶ **17525 individuals Pfizer (10790) Moderna (6592) 17005 reported reaction after first dose. Pain at injection 91.4%, fatigue 31.3%. After second dose fatigue higher 69.2%.**
- ▶ **Odds of severe reactions were statistically significantly decreased among pregnant individuals.**
- ▶ **This large prospective cohort study found that COVID-19 vaccines were well-tolerated among individuals that were, pregnant, lactating of planing pregnancy.(Published 8/17/21 JAMA Network Open)**



VACCINE REACTIONS

COVID-19 IN PREGNANCY

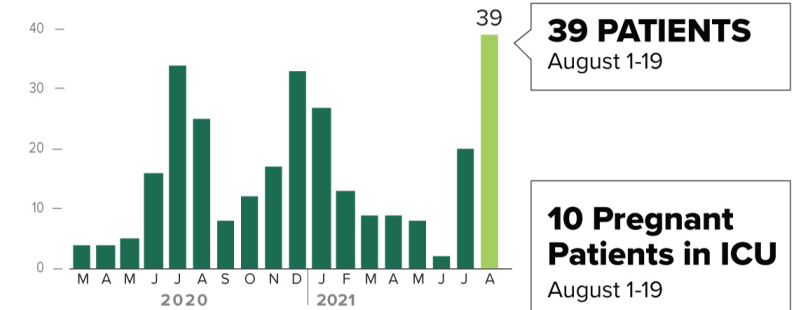
- ▶ UAB HOSPITAL ICU POPULATION INCLUDES 'ALARMING' NUMBER OF PREGNANT WOMEN
- ▶ 'A REAL TRAGEDY': IN COVID-19 PANDEMIC, RATES OF STILLBIRTHS DOUBLE IN MISSISSIPPI.

COVID affecting non-vaccinated pregnant women

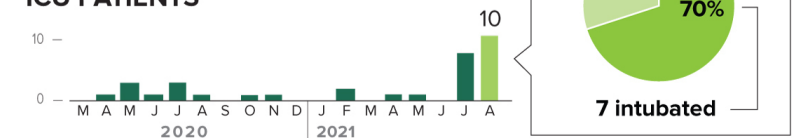
Hospitalizations of pregnant women with COVID at UAB Hospital has soared since March, including those needing ICU care.

UAB PREGNANT COVID-POSITIVE PATIENTS

ADMISSIONS



ICU PATIENTS



MATERNAL-NEONATAL TRANSFER OF SARS COV-2 IGG ANTIBODIES AFTER VACCINATION DURING PREGNANCY

- ▶ **Study publishes in AJOG September 18, 2021**
- ▶ **64 vaccinated parturient women and 11 parturient women who had COVID-19 during pregnancy.**
- ▶ **Significant higher SARS CoV-2 IgG levels in maternal serum and cord blood among vaccinated women ($p < 0.0001$)**
- ▶ **Study demonstrated efficient transfer of SARS CoV-2 IgG across the placenta from women vaccinated during pregnancy to their neonates.**
- ▶ **In addition to maternal protection against COVID-19, the vaccine may also provide neonatal humoral immunity.**

COVID-19 VACCINES IN PREGNANCY

- ▶ **DATA FROM CDC AS 9/4/21 VACCINATIONS IN PREGNANCY**
- ▶ **161,764 REPORTED PREGNANCY IN V-SAFE PROGRAM**
- ▶ **ALL RACES/ETHNICITY 25.2%**
- ▶ **HISPANIC/LATINO 21.4%**
- ▶ **WHITE 27.3%**
- ▶ **BLACK 13.8%**
- ▶ **ASIAN 35.7%**
- ▶ **OTHER 24.7%**

COVID-19 VACCINES IN PREGNANCY

- ▶ **Vaccine hesitancy**
- ▶ **Cultural and linguistical competent conversation**
- ▶ **Positive motivation**
- ▶ **Empathetic engagement to get to the roots of hesitancy**
- ▶ **Build trust**
- ▶ **Thank you!**



QUESTIONS

PLEASE SUBMIT YOUR QUESTIONS IN THE Q & A Box

THANK YOU

Contact us

- NMHA – NHMAmd.org
- NHHF- NHMAFoundation.org
- Questions: nhma@nhmamd.org
- Become a [Vaccinate4All Champion at nhmamd.org/vaccinate4all](http://nhmamd.org/vaccinate4all)

Don't miss!

- **NHMA 25th Annual Hispanic Health Conference** – March 24-27, 2022
- Join as an NHMA member or give tax-deductible donation to NHHF or Amazon Smile Today



National Hispanic Medical Association

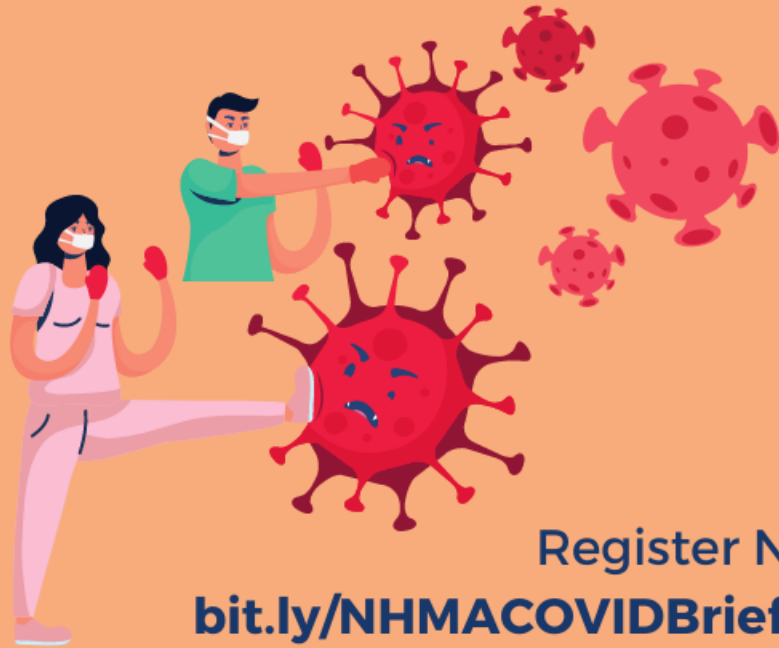


@NHMAMD

COVID-19 BRIEFING SESSION 13:

VaccinateForAll: How Medical Associations,
the Private Sector, and the Media are
Mobilizing Against COVID-19

October 27, 2021 • 7 p.m. ET



Register Now

bit.ly/NHMACOVIDBriefing

Panel 1

Moderator: Elena Rios, MD, MSPH, FACP
*President & CEO
NHMA*

Tracy Sun, MPH
*Community Engagement Manager at
the Asian & Pacific Islander American
Health Forum (APIAHF)*

Bobby Mukkamala, MD
AMA Chair, Board of Trustees

Rachel Villanueva, MD, FACOG
*President, National Medical
Association
Board Certified OB/GYN*

Panel 2

Moderator: Michelle Aquino, DO
*Hospitalist, Baptist Health
Medical Correspondent, Action News
NHMA VaccinateForAll Champion*

Yvette Calderon, MD, MS
*Professor of Emergency Medicine
Chair, Department of Emergency Medicine
Mount Sinai Beth Israel*

Hilton Perez, MD, MBA-
HA, BS, MT (ASCP)
*Chief Clinical Officer, Hoy
Health*

Panel 3

Moderator: Bertha Hidalgo, PhD, MPH
*Associate Professor
Department of Epidemiology*

Luis Rosero
*Vice President, Corporate and External Affairs
NBCUniversal Telemundo Enterprises*

Jorge Neri, Partner
*NERI Group
(Consultant, Ad Council)*

