# COVID-19 – Where We are and the Path Ahead for Staff and Patients



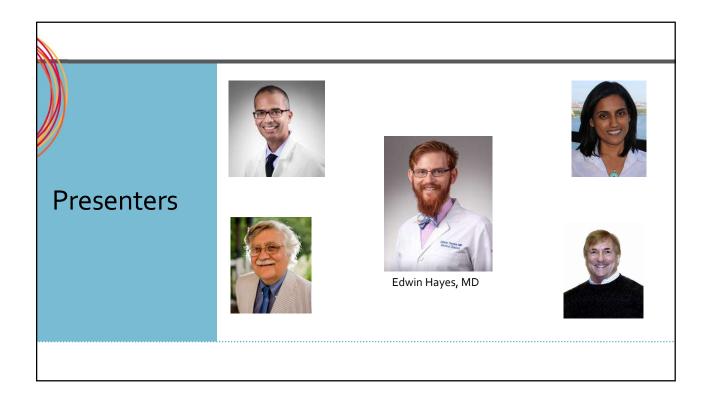


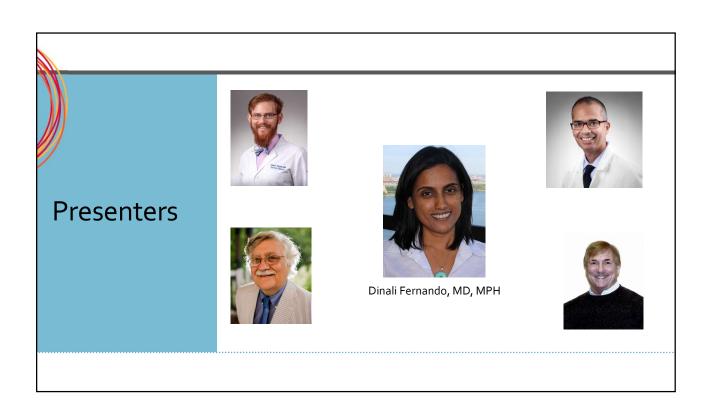
October 13, 2021

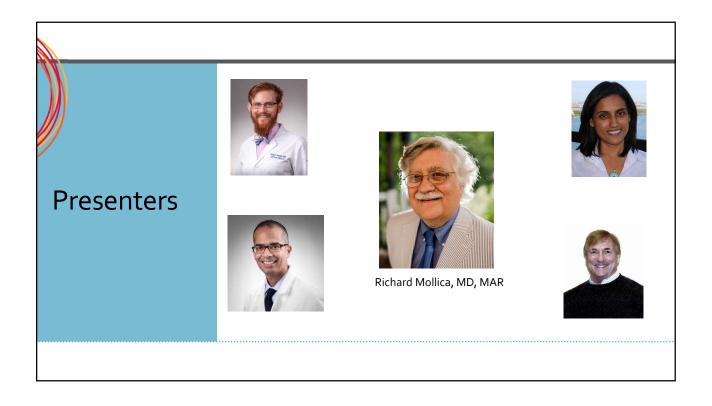
#### Objectives

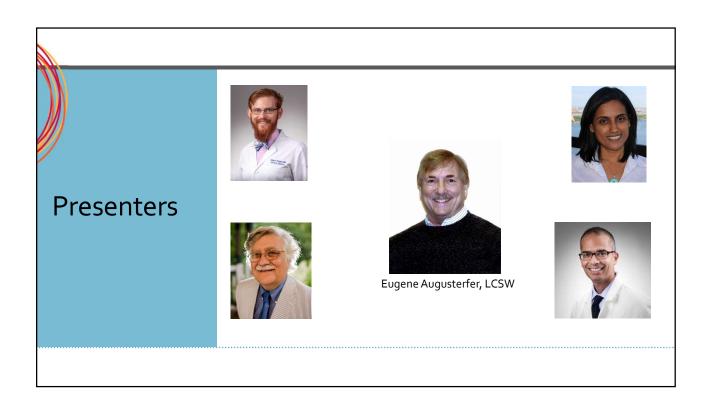
- Learn how the Delta Variant has affected SOT clinics and projects and thus, be able to plan for more in-person encounters with patients/clients in a safe manner.
- Gain a fuller understanding as to how the dynamics of the health care worker patient/client relationship shifted due to the lack of face-to-face encounters and how to best address this issue.
- Identify the importance of the principles of self-care.

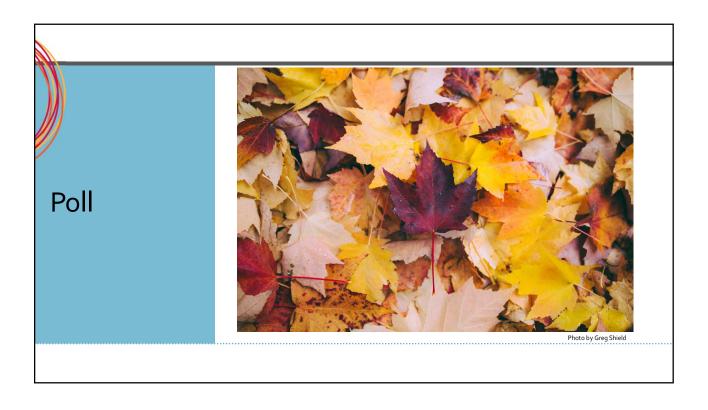












#### **COVID Pandemic**

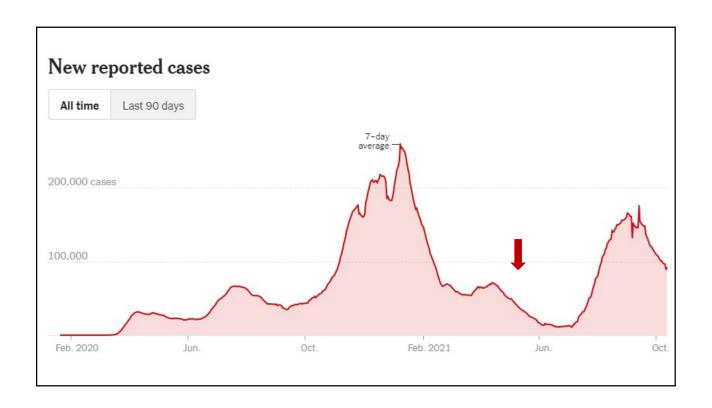
Where are we now?
Where are we headed?
Rajeev Bais and Edwin Hayes
10/13/2021

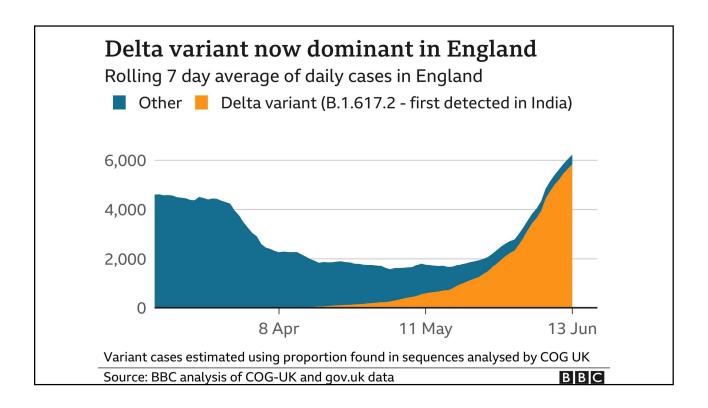
- Overview
- Who are the vulnerable groups?
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- What is new in terms of treatment?

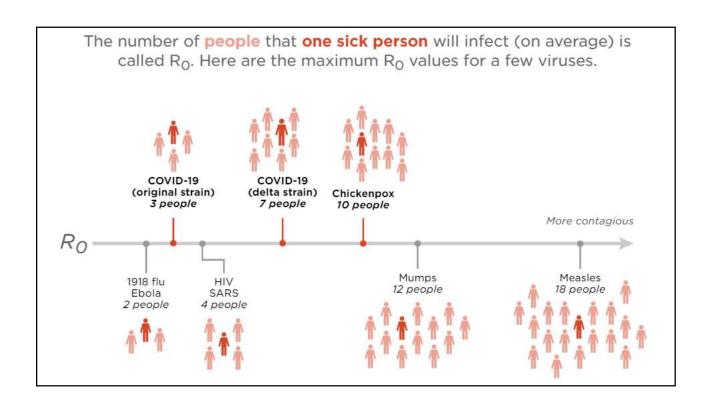
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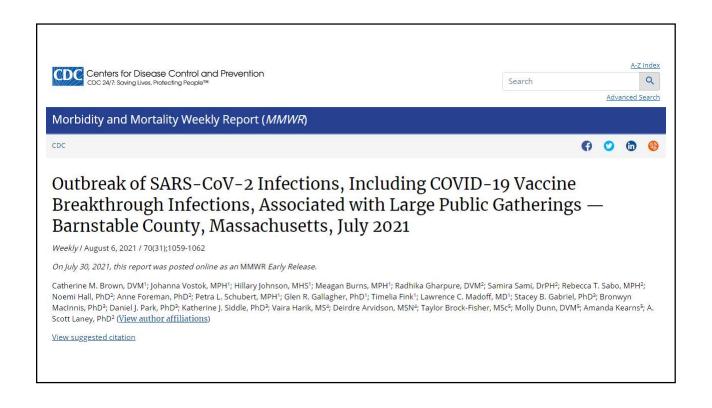


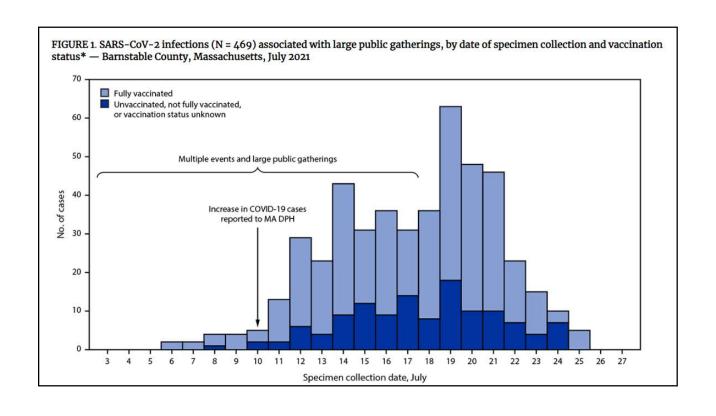


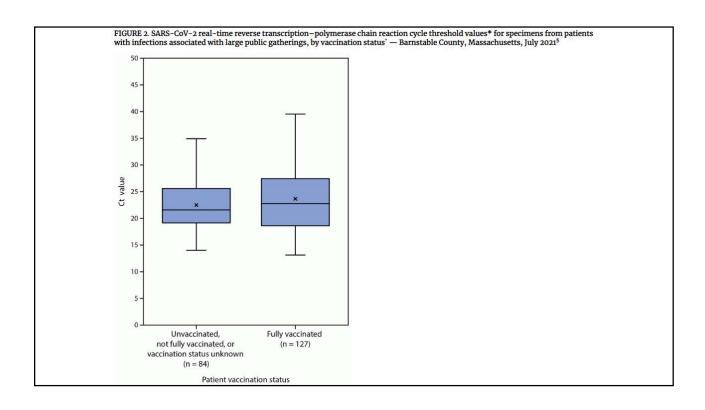


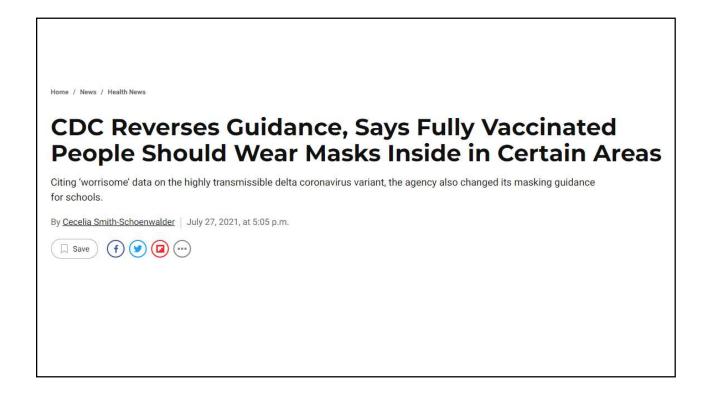








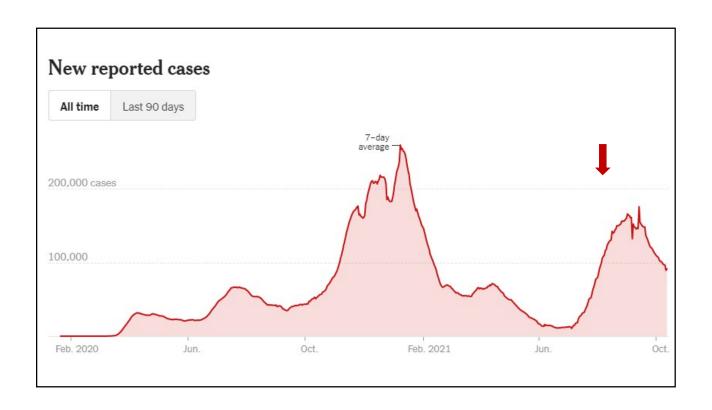




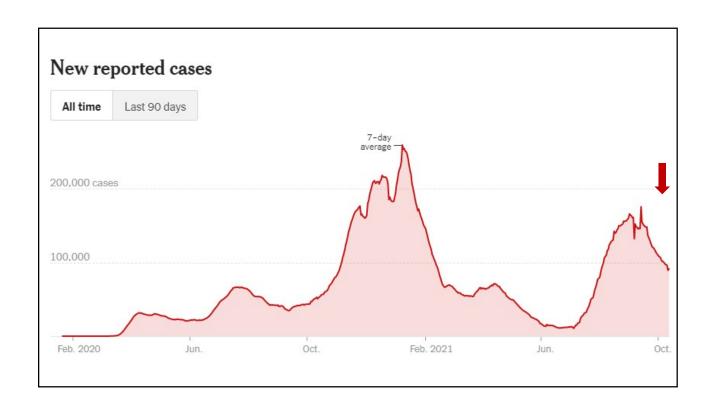






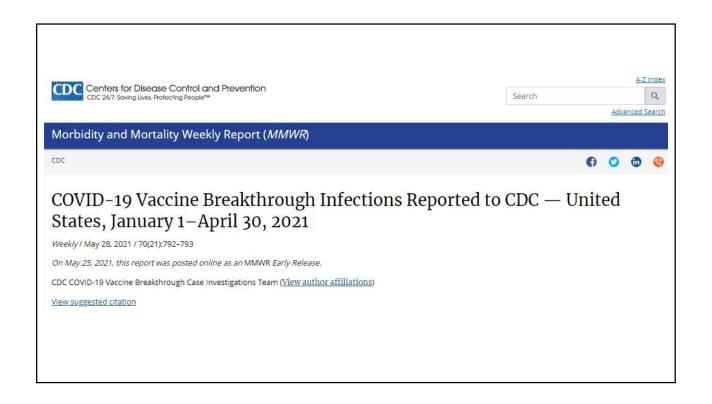


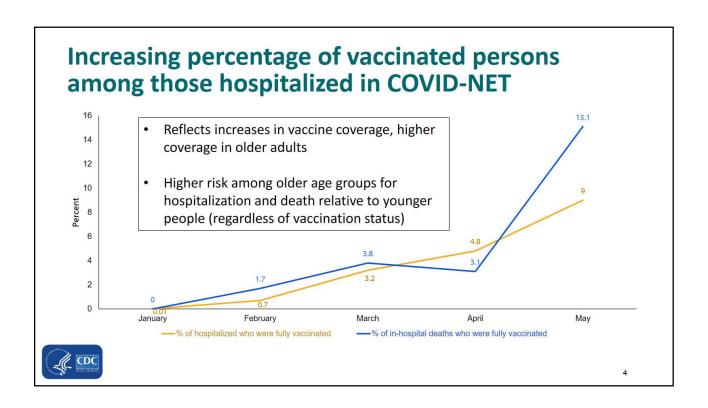




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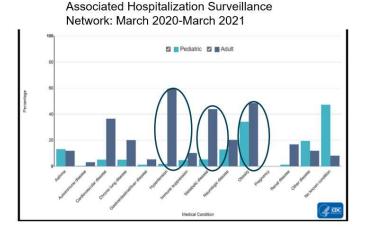


#### Common Comorbidities in hospitalized COVID-19 patients

#### Adults:

Obesity- 48.6% Diabetes-43.9% Cardiovascular disease-36.5%

Children: < 17 Obesity-34.2% Asthma-13.2%.



Coronavirus Disease 2019 (COVID-19)-

JAMA Pediatrics | Original Investigation

# Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection The INTERCOVID Multinational Cohort Study

José Villar, MD; Shabina Ariff, MD; Robert B. Gunier, PhD; Ramachandran Thiruvengadam, MD; Stephen Rauch, MPH; Alexey Kholin, MD; Paola Roggero, PhD; Federico Prefumo, PhD; Marynéa Silva do Vale, MD; Jorge Arturo Cardona-Perez, MD; Nerea Maiz, PhD; Irene Cetin, MD; Valeria Savasi, PhD; Philippe Deruelle, PhD; Sarah Rae Easter, MD; Joanna Sichitiu, MD; Constanza P. Soto Conti, MD; Ernawati Ernawati, PhD; Mohak Mhatre, MD; Jagjit Singh Teji, MD; Becky Liu, MBBS; Carola Capelli, MD; Manuela Oberto, MD; Laura Salazar, MD; Michael G. Gravett, MD; Paolo Ivo Cavoretto, PhD; Vincent Bizor Nachinab, MD; Hadiza Galadanci, MSc; Daniel Oros, PhD; Adejumoke Idowu Ayede, MD; Loïc Sentilhes, PhD; Babagana Bako, MD; Mónica Savorani, MD; Hellas Cena, PhD; Perla K. García-May, MD; Saturday Etuk, MD; Roberto Casale, MD; Sherief Abd-Elsalam, PhD; Satoru Ikenoue, PhD; Muhammad Baffah Aminu, MD; Carmen Vecciarelli, MD; Eduardo A. Duro, MD; Mustapha Ado Usman, MBBS; Yetunde John-Akinola, PhD; Ricardo Nieto, MD; Enrico Ferrazi, MD; Zulfiqar A. Bhutta, PhD; Ana Langer, MD; Stephen H. Kennedy, MD; Aris T. Papageorghiou, MD

JAMA Pediatrics | Original Investigation

# Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection The INTERCOVID Multinational Cohort Study

- Higher risk for
  - Preeclampsia/eclampsia (relative risk [RR], 1.76; 95% CI, 1.27-2.43)
  - Severe infections (RR, 3.38; 95% CI, 1.63-7.01)
  - Intensive care unit admission (RR, 5.04; 95% CI, 3.13-8.10)
  - Maternal mortality (RR, 22.3; 95% CI, 2.88-172)
  - Preterm birth (RR, 1.59; 95% CI, 1.30-1.94)
  - Medically indicated preterm birth (RR, 1.97; 95% CI, 1.56-2.51)
  - Severe neonatal morbidity index (RR, 2.66; 95% CI, 1.69-4.18)
  - Severe perinatal morbidity and mortality index (RR, 2.14; 95% CI, 1.66-2.75)



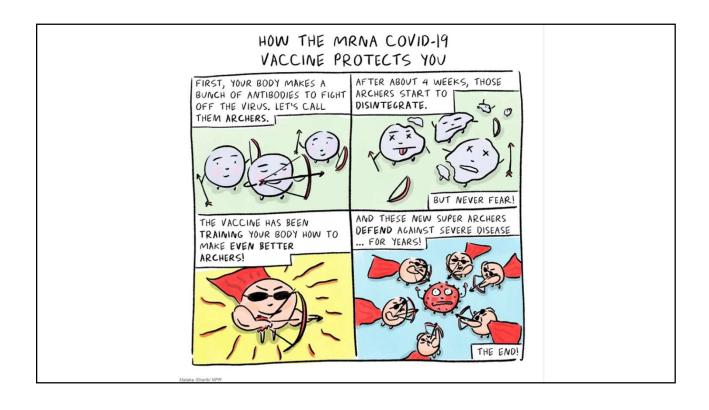
Immigrant, Refugee, and Migrant Health

#### COVID-19 in Newly Resettled Refugee Populations

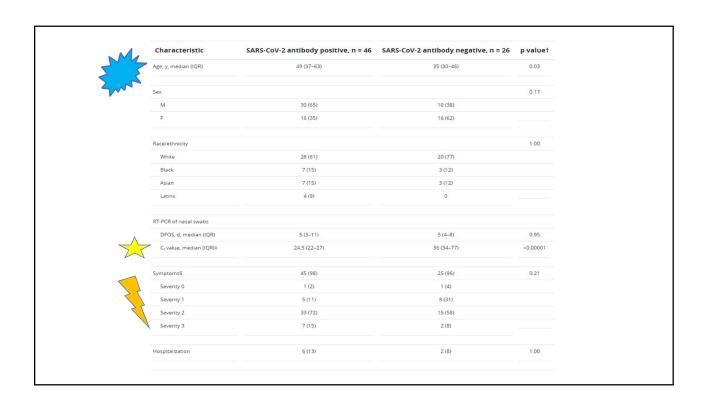
Español (Spanish)

 Refugees to the United States, especially those who are recently resettled, may experience living arrangements or working conditions that put them at greater risk of getting COVID-19.
 Some refugees also have limited access to health care, as well as certain underlying medical conditions that put them at increased risk of severe illness from COVID-19, compared to the rest of the U.S. population.

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# EMERGING INFECTIOUS DISEASES Predictors of Nonseroconversion after SARS-CoV-2 Infection Weimin Liu\*, Ronnie M. Russell\*, Frederic Bibolie-Ruche\*, Abhwin N. Skelly\*, Scott Sherrill-Mix\*, Drew A. Freeman\*, Regina Stoltz, Emily Lindemuth, Fang-Hua Lee, Sarah Sterrett, Karharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, Loyce Inc., Sarah Sterrett, Karharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, Loyce Inc., Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, Loyce Inc., Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, Loyce Inc., Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, Loyce Inc., Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E. Hensity, Thomas Kess, Albert Cupo, London, Sarah Sterrett, Raharine J. Bar, Nathaniel Erdmann. Signid Gourna, Scott E.

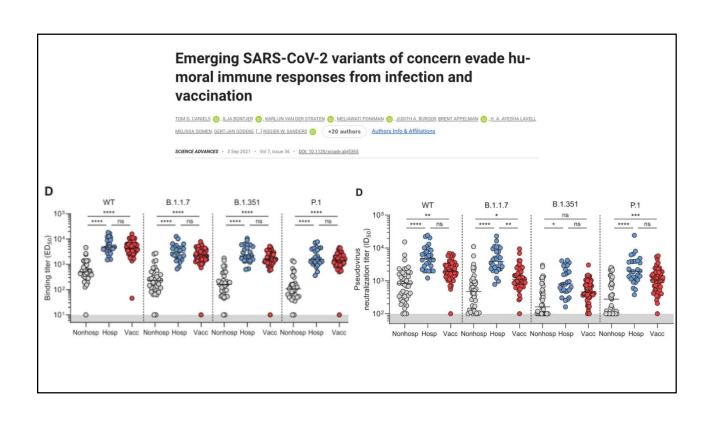


# Emerging SARS-CoV-2 variants of concern evade humoral immune responses from infection and vaccination

TOM G. CANELS . S. B. JA BONTJER . ARBLUN VAN DER STRATEN . MELIAWATI PONIMAN . S. JUDITH A BURGER BRENT APPELMAN . H. A AYESHA LAVELL
MELISSA OOMEN GERTJAN GODEKE [...] ROGIER W. SANDERS . +20 authors . Authors Info & Affiliations

SCIENCE ADVANCES - 3 Sep 2021 - Vol 7, Issue 36 - 100: 10.1126/jaciadv.ab/5365

- Mild Covid
- Severe Covid (hospitalized)
- Vaccinated
- examined serum effect on various SARAS-CoV2 variants
  - Spike protein binding
  - Neutralization Potential



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#### Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

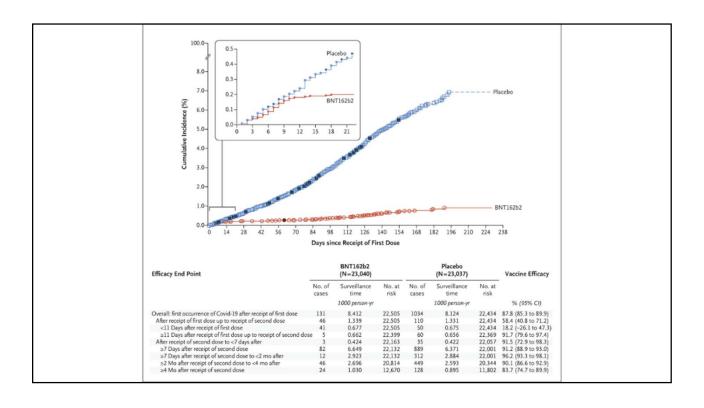
Stephen J. Thomas, M.D., Edson D. Moreira, Jr., M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Pérez Marc, M.D., Fernando P. Polack, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., et al., for the C4591001 Clinical Trial Group\*

Article Figures/Media

Metrics

September 15, 2021 DOI: 10.1056/NEJMoa2110345

- 44,165 > 16 yrs
- 2,264 12-15 yrs
- Overall vaccine efficacy at 6 mo was 91.3%
- Vaccine efficacy against severe disease was 96.7%
- gradual decline in efficacy over time
- Not powered to give assess efficacy according to subgroup, however VE was consistently high in all groups



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		NT162b2 N=23,040)		Placebo (Na=23,037)		
Efficacy Endpoint Subgroup	n1b	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	VE (%)	(95% CI°)
First severe COVID-19 occurrence after dose 1	1	8.439 (22,505)	30	8.288 (22,435)	96.7	(80.3, 99.9)
After dose 1 to before dose 2	0	1.351 (22,505)	6	1.360 (22,435)	100.0	(14.5, 100.0)
Dose 2 to 7 days after dose 2	0	0.425 (22,170)	1	0.423 (22,070)	100.0	(-3783.5, 100.0)
≥7 Days after dose 2	1	6.663 (22,142)	23	6.505 (22,048)	95.7	(73.9, 99.9)

Confirmed severe COVID-19 required confirmation of COVID-19 and the presence of  $\geq 1$  of the following: clinical signs at rest indicative of severe systemic illness (respiratory rate  $\geq 30$  breaths per minute, heart rate  $\geq 125$  beats per minute,  $SPO_{\perp} \geq 93\%$  on room air at sea level, or  $PaO_{2}/FiO_{2} < 300$  mmHg); respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation); evidence of shock (systolic blood pressure < 90 mmHg, diastolic blood pressure < 60 mmHg, or requiring vasopressors); significant acute renal, hepatic, or neurologic dysfunction; intensive care unit admission; and/or death

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#### Waning Immune Humoral Response to BNT162b2 Covid-19 Vaccine over 6 Months

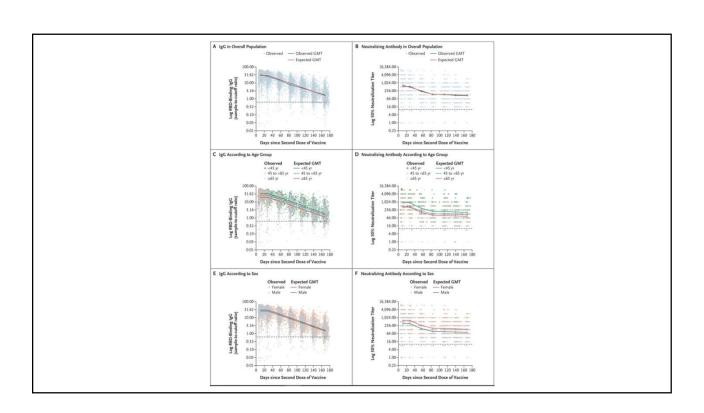
Einav G. Levin, M.D., Yaniv Lustig, Ph.D., Carmit Cohen, Ph.D., Ronen Fluss, M.Sc., Victoria Indenbaum, Ph.D., Sharon Amit, M.D., Ram Doolman, Ph.D., Keren Asraf, Ph.D., Ella Mendelson, Ph.D., Arnona Ziv, M.Sc., Carmit Rubin, M.Sc., Laurence Freedman, Ph.D., et al.

Article Figures/Media

Metrics

October 6, 2021 DOI: 10.1056/NEJMoa2114583

- 6 mo, prospective study on 4868 healthcare workers in Israel who were tested monthly for the presence of anti-spike IgG and neutralizing Ab
- Level of IgG decreased at a consistent rate
- Neutralizing ab decreased rapidly for the 1<sup>st</sup> 3 mo with a slow decrease after
- Neutralizing ab at 6mo was substantially lower in men, persons over 65yrs, and in those with immunosuppression



# Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar

Hiam Chemaitelly, M.Sc., Patrick Tang, M.D., Ph.D., Mohammad R. Hasan, Ph.D., Sawsan AlMukdad, M.Sc., Hadi M. Yassine, Ph.D., Fatiha M. Benslimane, Ph.D., Hebah A. Al Khatib, Ph.D., Peter Coyle, M.D., Houssein H. Ayoub, Ph.D., Zaina Al Kanaani, Ph.D., Einas Al Kuwari, M.D., Andrew Jeremijenko, M.D., et al.

Article Figures/Media

Metrics

October 6, 2021 DOI: 10.1056/NEJMoa2114114

- Dec 21,2020 Sept 5, 2021
- 947,035 received 1 dose; 907,763 received 2
- 18,746 breakthrough case; 10,543 with 2 doses
  - 35% received a dx of COVID-19 based on symptoms
- 377 (1 dose) and 106 (2 dose) hospitalizations
- 34 (1 dose) and 15 (2 dose) fatalities

#### ORIGINAL ARTICLE

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Article Figures/Media

Metrics

October 6, 2021 DOI: 10.1056/NEJMoa2114114

- Vaccine effectiveness against any SARS-CoV-2 infection
  - negligible for the 1st 2 weeks after the 1st dose
  - 36.8% in the 3rd week after the 1st dose
  - 77.5% in the 1st month after the 2nd dose
  - · effectiveness gradually declined afterward
  - patterns of decline effectiveness were similar in all strains

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- no significant difference between age groups above/below 60
- peak effectiveness against symptomatic disease was 81.5%
  - 73% against asymptomatic disease
- effectiveness against severe disease
  - negligible in 1st 2 weeks after 1st dose
  - 66% in 3rd weeks after 1st dose
  - >96% in 1st 2 months after 2nd dose

#### BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the Delta (B.1.617.2) variant in Qatar

- ② Patrick Tang, Mohammad R. Hasan, ③ Hiam Chemaitelly, ③ Hadi M. Yassine, ⑤ Fatiha M. Benslimane, Hebah A. Al Khatib, ③ Sawsan AlMukdad, ⑤ Peter Coyle, ⑥ Houssein H. Ayoub, ③ Zaina Al Kanaani, ③ Einas Al Kuwari, ⑤ Andrew Jeremijenko, ⑥ Anvar Hassan Kaleeckal, Ali Nizar Latif, ⑤ Riyazuddin Mohammad Shaik, ⑥ Hanan F. Abdul Rahim, ⑥ Gheyath K. Nasrallah, ⑥ Mohamed Ghaith Al Kuwari, ⑥ Hamad Eid Al Romaihi, ③ Adeel A. Butt, ③ Mohamed H. Al-Thani, Abdullatif Al Khal, ⑥ Roberto Bertollini, ⑥ Laith J. Abu-Raddad doi: https://doi.org/10.1101/2021.08.11.21261885
- Assessed 'real-world' effectiveness of mRNA vaccines against the delta variant
- Qatar: As of August 2021: 73.8% 2 doses, 87.8% 1 dose
- Pfizer: 906,078 (1 dose), 877,354 (2 doses)
- Moderna: 490,828 (1 dose), 409,041 (2 doses)
- Median date of second dose was May 7, 2021 (Pfizer) and May 12, 2021 (Moderna)
- Median age 31-32 yrs; co-morbidities not assessed

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- As of July 21, 2021
- Breakthrough Infections of the Delta Strain
  - Pfizer: 54 (1 doses) and 249 (2 dose)
  - Moderna: 27 (1 doses) and 26 (2 doses)
- Severe Infections (hospitalizations) from the Delta Strain
  - Pfizer: 3 (1 dose) and 4 (2 doses) [1 ICU admission]
  - Moderna: 3 (1 dose) and 0 (2 doses)
- Zero fatalities

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- Estimated Vaccine Effectiveness (+PCR regardless of reason for test)
  - >14 days after 1<sup>st</sup> dose: 64.2% (Pfizer), 79% (Moderna)
    - Severe dx effectiveness: 100% (Pfizer and Moderna)
  - >14 days after the 2<sup>nd</sup> dose: 53.5% (Pfizer), 84.8% (Moderna)
    - Severe dx effectiveness: 89.7% (Pfizer), 100% (Moderna)

#### Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings

Mark G. Thompson, Ph.D., Edward Stenehjem, M.D., Shaun Grannis, M.D., Sarah W. Ball, Sc.D., Allison L. Naleway, Ph.D., Toan C. Ong, Ph.D., Malini B. DeSilva, M.D., M.P.H., Karthik Natarajan, Ph.D., Catherine H. Bozio, Ph.D., M.P.H., Ned Lewis, M.P.H., Kristin Dascomb, M.D., Ph.D., Brian E. Dixon, M.P.A., Ph.D., et al.

- 21,544 ED or UC visits
- 41,552 hospitalizations
- Adults >50 yrs with COVID-like symptoms
- Jan-June 2021 (not yet delta)
- Tested for SARS-CoV-2
- Vaccination status determined
- Vaccine effectiveness estimated

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Vaccine	Vaccine Effectiveness	No. of Patients	% Positive for SARS-CoV-2
	(95% CI)	Unvaccinated	/fully vaccinated
BNT162b2	89% (85-91)	11,812/3,589	24.1/2.9
mRNA-1273	<b>92</b> % (89–94)	11,812/2,476	24.1/2.0
Ad26.COV2.S	<b>73</b> % (59–82)	8,461/456	26.0/6.4
		Hospitalization	
Vaccine	Vaccine Effectiveness	No. of Patients	% Positive for SARS-CoV-2
Yaccine	(95% CI)	Unvaccinated	/fully vaccinated
BNT162b2	(95% CI) 87% (85–90)	Unvaccinated 20,406/8,500	//fully vaccinated 18.1/1.9
	87%		

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- Vaccine effectiveness against hospitalization relating to:
  - African Americans 86%
  - Hispanics 90%
  - Patients > 85yrs 83%

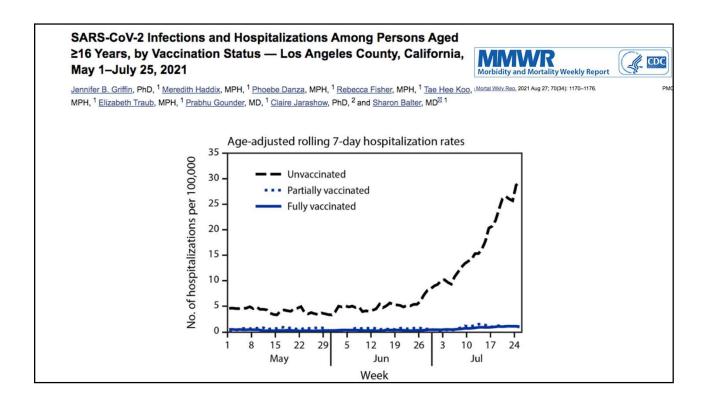
## SARS-CoV-2 Infections and Hospitalizations Among Persons Aged ≥16 Years, by Vaccination Status — Los Angeles County, California, May 1–July 25, 2021



Jennifer B. Griffin, PhD, <sup>1</sup> Meredith Haddix, MPH, <sup>1</sup> Phoebe Danza, MPH, <sup>1</sup> Rebecca Fisher, MPH, <sup>1</sup> Tae Hee Koo, Mertal Wely Rep. 2021 Aug 27; 70(34): 1170–1176. MPH, <sup>1</sup> Elizabeth Traub, MPH, <sup>1</sup> Prabhu Gounder, MD, <sup>1</sup> Claire Jarashow, PhD, <sup>2</sup> and Sharon Balter, MD<sup>M</sup> 1

• LACDPH/California Immunizations Registry 2 (CAIR2) data

- May1-July 25, 2021
- Delta predominant strain
- 43,127 reported COVID infections in people >16 years old
  - Fully Vaccinated:10,895 (25.3%)
  - Partially Vaccinated: 1,431 (3.3%)
  - Unvaccinated: 30,801 (71.4%)
- Fully Vaccinated: 3.2% hospitalized, 0.5% ICU, 0.2% mech vent
- Unvaccinated: 7.6% hospitalized, 1.5% ICU, 0.5% mech vent
- Unvaccinated had 4.9x the rate of infection and 29.2x the rate of hospitalization



#### Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel

Yair Goldberg, Micha Mandel, (2) Yinon M. Bar-On, Omri Bodenheimer, Laurence Freedman, Eric J. Haas, (2) Ron Milo, Sharon Alroy-Preis, Nachman Ash, Amit Huppert (3) Hotps://doi.org/10.1101/2021.08.24.21262423

- 60+ yr olds who received their vax in March 21 were 1.6x more protected against infection and 1.7x more protected against severe disease than those who received their vax in Jan 21
- Similar results were found in all age groups after 6 mo

#### Correlation of SARS-CoV-2 Breakthrough Infections to Time-fromvaccine; Preliminary Study

Barak Mizrahi, Roni Lotan, Nir Kalkstein, Asaf Peretz, Galit Perez, Amir Ben-Tov, Gabriel Chodick, Sivan Gazit, Tal Patalon

doi: https://doi.org/10.1101/2021.07.29.21261317

#### Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel

Yinon M. Bar-On, M.Sc., Yair Goldberg, Ph.D., Micha Mandel, Ph.D., Omri Bodenheimer, M.Sc., Laurence Freedman, Ph.D., Nir Kalkstein, B.Sc., Barak Mizrahi, M.Sc., Sharon Alroy-Preis, M.D., Nachman Ash, M.D., Ron Milo, Ph.D., and Amit Huppert, Ph.D.

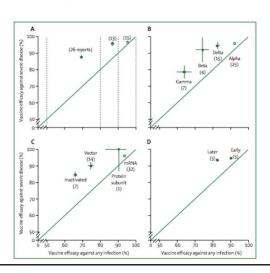
Article Figures/Media Metrics October 7, 2021

#### Table 2. Primary Outcomes of Confirmed Infection and Severe Illness.\*

Outcome	Nonbooster Group	Booster Group	Adjusted Rate Ratio (95% CI)†
Confirmed infection			11.3 (10.4–12.3)
No. of cases	4439	934	
No. of person-days at risk	5,193,825	10,603,410	
Severe illness			19.5 (12.9–29.5)
No. of cases	294	29	
No. of person-days at risk	4,574,439	6,265,361	

### Considerations in boosting COVID-19 vaccine immune responses

Philip R Krause, Thomas R Fleming, Richard Peto, Ira M Longini, J Peter Figueroa, Jonathan A C Sterne, Alejandro Cravioto, Helen Rees, Julian P T Higgins, Isabelle Boutron, Hongchao Pan, Marion F Gruber, Narendra Arora, Fatema Kazi, Rogerio Gaspar, Soumya Swaminathan, Michael J Ryan, Ana-Maria Henao-Restrepo



- Overview
- Who are the vulnerable groups?
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- How long does immunity from the vaccines last?
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- What is the current evidence for boosters?
- What is the status for children in terms of vaccination and infection?
- What is new in terms of treatment?

#### Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May-June 2021

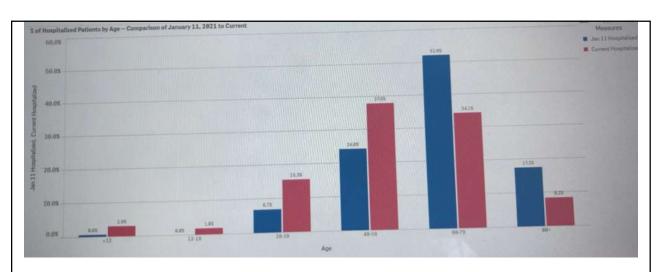
Weekly / August 13, 2021 / 70(32);1081-1083

On August 6, 2021, this report was posted online as an MMWR Early Release.

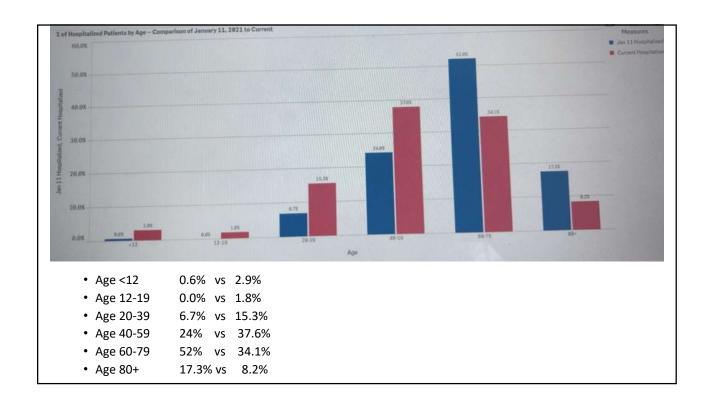
 $Alyson\ M.\ Cavanaugh,\ DPT,\ PhD^{1,2};\ Kevin\ B.\ Spicer,\ MD,\ PhD^{2,3};\ Douglas\ Thoroughman,\ PhD^{2,4};\ Connor\ Glick,\ MS^2;\ Kathleen\ Winter,\ PhD^{2,5}$ 

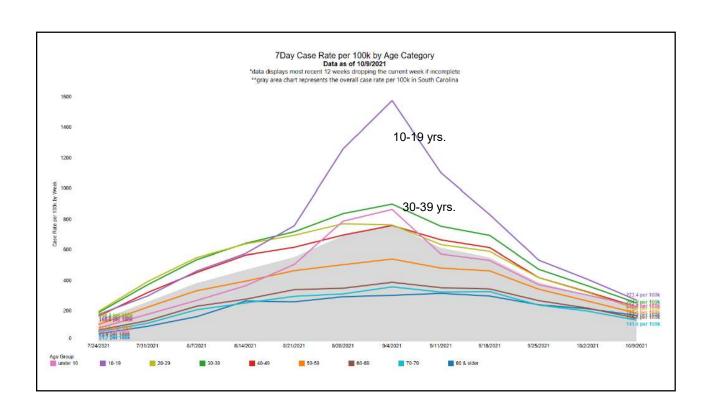
- case (1): control (2)
  - matched by age, sex, and date of initial + SARS-CoV-2 PCR test (March-December 2020)
  - 246 cases:492 controls
  - 60.6% female
  - Fully Vaccinated: 20.3% cases, 34.3% controls
  - Ky residents with previous infections who were unvaccinated had 2.34 times the odds of reinfection compared to those fully vaccinated

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- Comparing January to August 2021
- By age groups





					Mos	t Recen	ses (con t Comple	eted Wee	k Comp	ared to	2 Week	s Prior						
	und 7/24/21	er 10 10/9/21	7/24/21	- <b>19</b> 10/9/21	<b>20</b> 7/24/21	- <b>29</b> 10/9/21	<b>30</b> 7/24/21	- <b>39</b> 10/9/21	<b>40</b> -7/24/21		7/24/21	- <b>59</b> 10/9/21	7/24/21	- <b>69</b> 10/9/21	70 7/24/21	- <b>79</b> 10/9/21	80 & 7/24/21	older 10/9/21
Count Cases Suppressed	540	1,390	1,164	1,773	1,370	1,470	1,250	1,656	1,042	1,421	762	1,260	493	1,002	283	615	100	333
Case Rate by Age per 100k by Week	90.1	232.0	1795	273.4	200.3	214.9	192.4	254.9	168.4	229.7	113.3	187.4	76.0	154.5	65.1	141.6	51.7	172.2
% Change in Cases		157.4%		52.3%		7.3%		32.5%		36.4%		65.4%		103.2%		117.3%		233 09

				Cou				(confirm ed Week					ange					
		er 10 10/9/21	7/24/21	- <b>19</b> 10/9/21		- <b>29</b> 10/9/21		10/9/21		- <b>49</b> 10/9/21		10/9/21		- <b>69</b> 10/9/21		10/9/21	80 & 7/24/21	older 10/9/21
Count Hospitalizations Suppressed	<5	<5	<5	5	8	7	23	11	23	23	50	28	53	40	54	43	30	44
Hospitalization Rate by Age per 100k by Week	0.2	0.7	0.5	0.8	12	1.0	3.5	1.7	3.7	37	7.4	4.2	82	6.2	12.4	99	15.5	22.7
% Change in Hospitalization Rate by Age		300 0%		66.7%		-12.5%		-52.2%		0.0%		-44.0%		-24.5%		-20.4%		46.79

# Why are vaccination rates so low in 12-24? Myocarditis Fears

- VAERS data
- Kaiser Permanente Southern California analysis
- Incidence myocarditis post mRNA vaccine aged 18 and older
- Compared with myocarditis incidence in unvaccinated 12/14/2020-07/20/2021; and with vaccinated individuals during a 10-day period 1 year prior to vaccination



Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older

Anthony Simone, MD; John Herald, MD; Aiyu Chen, MPH; et al Research Letter | October 4, 2021

ONLINE FIRST

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/27848

Variable	Myocarditis cases, No.	No. of at-risk individuals	Follow-up time, person-days	Incidence over a 10-d observation period per 1 million individuals (95% CI)	Incidence rate ratio (95% CI)	P value
Compared with individuals who did not re	eceive the COVID-	19 mRNA vaccine				
Unexposed <sup>a</sup>	75 <sup>b</sup>	1577741	343 947 538	2.2 (1.7-2.7)		
0-10 d After dose 1	2	2 392 924	23 929 240	0.8 (0.2-3.3)	0.38 (0.05-1.40)	.15
0-10 d After dose 2	13	2 236 851	22 368 510	5.8 (3.4-10)	2.7 (1.4-4.8)	.004
Compared to the same cohort during a 10	0-d period 1 y pri	or to vaccination <sup>c</sup>				
During a 10-d observation period 1 y prior to dose 1	2	2 392 924	23 929 240	0.8 (0.2-3.3)		
0-10 d After dose 1	2	2 392 924	23 929 240	0.8 (0.2-3.3)	1.0 (0.1-13.8)	>.99
During a 10-d observation period 1 y prior to dose 2	4	2 236 851	22 368 510	1.8 (0.7-4.8)		
0-10 d After dose 2	13	2 236 851	22 368 510	5.8 (3.4-10)	3.3 (1.0-13.7)	.03

- 15 cases of myocarditis among the 2,392,924 Kaiser Permanente Southern California members who received at least 1 dose of the mRNA vaccines w/in 6 months of follow up
- 1 case per 172,414 fully vaccinated individuals
- Relative ratio of 2.7 compared with unvaccinated individuals

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/27848

Patient No.	Demographics <sup>b</sup>	Days to chest pain onset	ECG	Troponin I peak, ng/mL	Evaluation of CAD	LVEF on echo, %	LOS, d
1	18-25 y, White man	7	Diffuse ST elevation	8.10	No CT evidence of CAD	55-60	3
2	18-25 y, White man	5	Inferolateral T wave inversion	8.87 <sup>c</sup>	No CT evidence of CAD	55-60	2
3	18-25 y, White man	5	Sinus tachycardia, no ischemic changes	1.59 <sup>c</sup>	No CT evidence of CAD	60-65	3
4	26-40 y, White man	3	No ischemic changes	2.50	Normal coronaries on cardiac catheterization	60-65	3
5	26-40 y, Hispanic man	3	Diffuse ST elevation	1.53 <sup>c</sup>	Normal coronaries on cardiac catheterization	55-60	1
6	26-40 y, White man	3	Diffuse ST elevation	17.12 <sup>c</sup>	Normal coronaries on cardiac catheterization	45, Global hypokinesis	3
7	18-25 y, White man	4	Diffuse ST elevation	5.00	No cardiac catheterization or CT performed	60-65	2
8	18-25 y, Hispanic man	2	Diffuse ST elevation	11.79	No CT evidence of CAD, MRI with myopericarditis	50-55	3
9	18-25 y, White man	3	No ischemic changes	7.37	No CT evidence of CAD	55-50	5
10	26-40 y, Hispanic man	1	No ischemic changes	2.98	Normal coronaries on cardiac catheterization	60-65	3
11	26-40 y, man, unknown ethnicity	3	Diffuse ST elevation	32.30	No CT evidence of CAD	55-60	3
12	26-40 y, White man	1	Diffuse ST elevation	6.28	No cardiac catheterization or CT performed	55-60	1
13	18-25 y, Hispanic man	3	Diffuse ST elevation	16.9	No cardiac catheterization or CT performed	30-35, Global hypokinesis <sup>d</sup>	3
14	18-25 y, White man	1	Diffuse ST elevation	15.9 <sup>c</sup>	No cardiac catheterization or CT performed	50-55	3
15	26-40 v. Asian man	2	Diffuse ST elevation	0.49 <sup>c</sup>	No CT evidence of CAD	50-55	3

#### **Editorial**

ONLINE FIRST FREE

October 4, 2021

# COVID-19 Messenger RNA Vaccination and Myocarditis—A Rare and Mostly Mild Adverse Effect

Vinay Guduguntla, MD<sup>1,2</sup>; Mitchell H. Katz, MD<sup>3,4</sup>

» Author Affiliations | Article Information

JAMA Intern Med. Published online October 4, 2021. doi:10.1001/jamainternmed.2021.5634

All men aged <40 years, no prior cardiac history, discharged within 1-5 days (median 3) of conservative management

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2784801

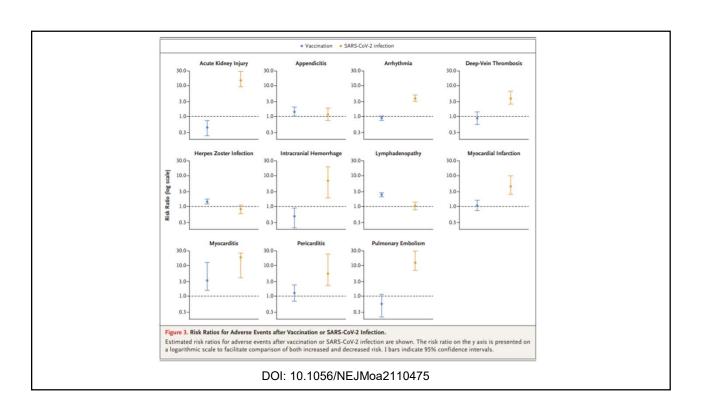
The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

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

- Vaccinated and control groups 884,828 persons
- Vaccination associated with an elevated risk of myocarditis (risk ratio, 3.24; 95% confidence interval [CI], 1.55 to 12.44)
- SARS-CoV-2 infection associated with substantially increased risk of myocarditis (risk ratio, 18.28; 95% CI, 3.95 to 25.12) and of additional serious adverse events, including deepvein thrombosis, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia

DOI: 10.1056/NEJMoa2110475



# Myocarditis: classic, MIS-C, and vaccine - associated

- Pre-print, retrospective cohort study, all patients hospitalized at Emory aged <21 years with classic viral myocarditis from 2015-2019, MIS-C myocarditis from 3/2020-2/2021 and COVID-19 vaccine-related myocarditis from 5/2021-6/2021</li>
- 201 total, 43 with classic myocarditis, 149 MIS-C myocarditis, and 9 COVID-19 vaccine-related myocarditis
- 93% (139/149) with MIS-C myocarditis and 100% of patients with COVID-19 vaccine-related myocarditis had normal LVEF at the time of discharge compared to 70% (30/43) of classic myocarditis group (p<0.001)

https://www.medrxiv.org/content/10.1101/2021.10.05.21264581v1

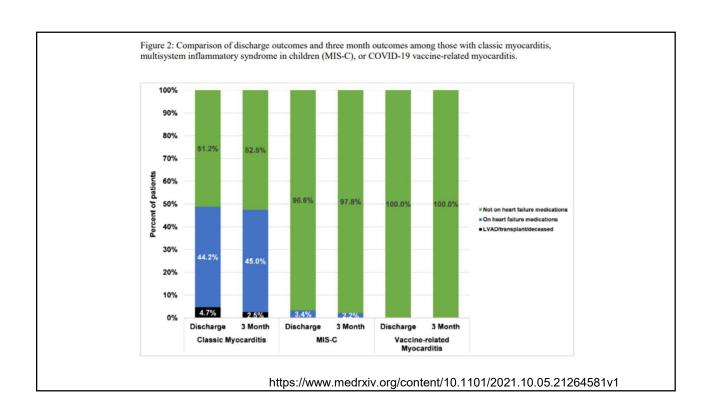
Multisystem
Inflammatory
Syndrome in
Children (MIS-C)

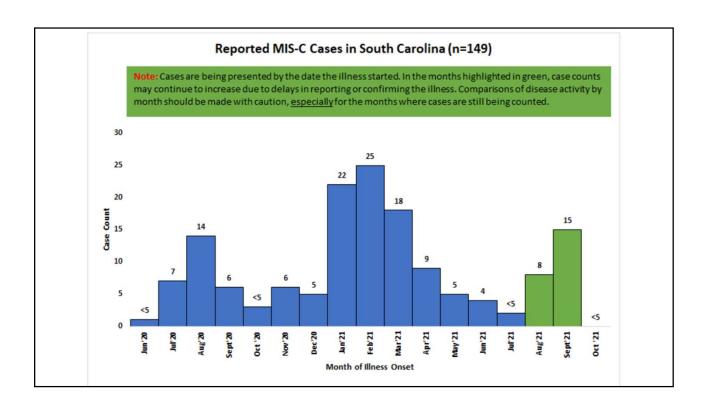




# Multisystem Inflammatory Syndrome in Children (MIS-C)

- An individual aged <21 years presenting with fever\*, laboratory evidence of inflammation\*\*, and evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; 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 the onset of symptoms.





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#### What is new in terms of treatment?

- Monoclonal antibodies
- Dexamethasone
- Remdesivir
- Tocilizumab/Baricitinib
- Molnupiravir

#### Molnupiravir

- Oral
- Ribonucleoside analog
- Inhibits the replication of SARS-CoV-2



#### Molnupiravir – MOVe-OUT

- Randomized, placebo-controlled, double-blind, multisite trial
- End points: Hospitalization and/or Death from time of enrollment through 29 days
- 775 pts, 18 yo or older
- Mild to moderate COVID
- Less than 5day of symptoms
- At least 1 risk factor associated with poor disease outcome
- Excluded HD/eGFR <30ml/min, HIV with VL>50 or AIDS defining illness w/in 6mo; hx of hep b/c with cirrhosis, ESLD, HCC, AST/ALT >3x ULN; plt<100K</li>

#### Molnupiravir – MOVe-OUT

- Compared 200mg; 400mg; 800mg of molnupiravir BID for 5 days to placebo
- Interim analysis: 775pts (Molnu:385, Placebo:377)
- Hospitalization/Death: 7.5% vs 14.1% (0 deaths vs 8 deaths)
- Delta, Gamma, Mu strains accounted for 80%
- Under FDA EUA evaluation

#### Costs



• Molnupiravir ~\$700 for 5-day course



 Monoclonal antibodies ~\$1,250-\$2,100 per infusion



• Vaccine ~\$20/dose

# COVID-19 hospitalizations October 8, 2021 49 Ventilated 3 Vaccinated (6%) 46 Unvaccinated (94%) 79 ICU 9 Vaccinated (11%) 70 Unvaccinated (89%) Combined data from all 11 Prisma Health hospitals treating COVID-19 patients in its Columbia and Greenville, S.C. markets. Percentages rounded. Get Vaccinated

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Thank you for attending this webinar!

# COVID-19 – Where We are and the Path Ahead for Staff and Patients October 13, 2021

The National Capacity Building Project is a project of the Center for Victims of Torture: <a href="www.cvt.org">www.cvt.org</a>

More resources are available at <u>www.healtorture.org</u>.

