





The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XVI

We will begin at 10 a.m.



U.S. News & World Report Best Hospitals Rankings 2021 - 2022

Marc L. Boom, MD August 12, 2021



EXCELLENCE IN PATIENT CARE & SAFETY



U.S. News & World Report Summary



Ranked in 10 of 15 Specialties:

- Cancer (#23)
- Cardiology & Heart Surgery (#15)
- Diabetes & Endocrinology (#16)
- Gastroenterology & GI surgery (#10)
- Geriatrics (#22)
- Gynecology (#19)
- Neurology & Neurosurgery (#21)
- Orthopedics (#12)
- Pulmonology and Lung Surgery (#19)
- Urology (#29)



Benchmark Scorecard Scorecard								
	Honor Roll	CMS Star	Leapfrog	Vizient*				
Mayo Clinic	1	***	Α	****				
Cleveland Clinic	2	***	A	-				
UCLA Medical Center	3	***	В	_				
Johns Hopkins Hospital	4	***	Α	-				
Massachusetts General Hospital	5	***	Α	-				
Cedars-Sinai Medical Center	6	***	С	_				
New York-Presbyterian Hospital	7	***	С	_				
NYU Langone Hospitals	8	****	Α	****				
UCSF Medical Center	9	☆☆☆☆	Α	-				
Northwestern Memorial Hospital	10	☆☆☆☆	В	_				
University of Michigan Hospitals	11	☆☆☆☆	Α	_				
Stanford Health Care	12	***	Α	_				
Hospitals of the University of Pennsylvania	13	☆☆☆☆	Α	-				
Brigham and Women's Hospital	14	***	A	****				
Mayo Clinic-Phoenix	15	****	A	-				
Houston Methodist Hospital	16	***	A	****				
Barnes-Jewish Hospital	17	***	С	****				
Mount Sinai Hospital	17	***	В	_				
Rush University Medical Center	19	***	Α	_				
Vanderbilt University Medical Center	20	***	В	-				

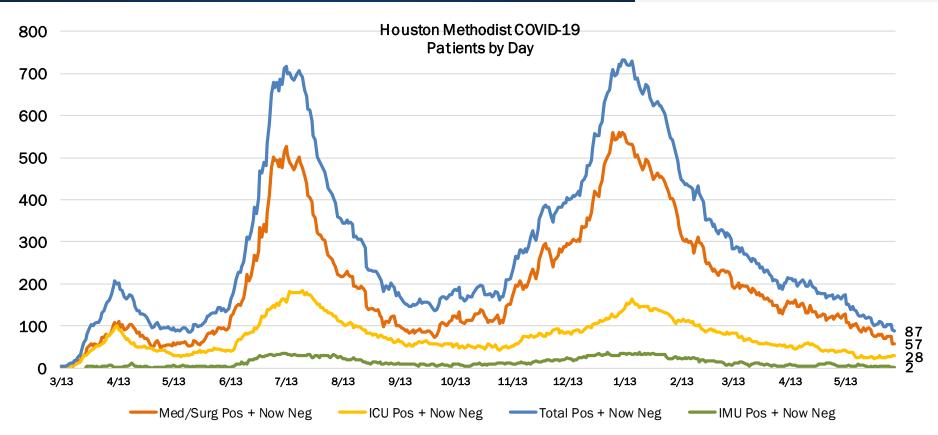
COVID-19 and Vaccine Update

Marc L. Boom, MD August 12, 2021



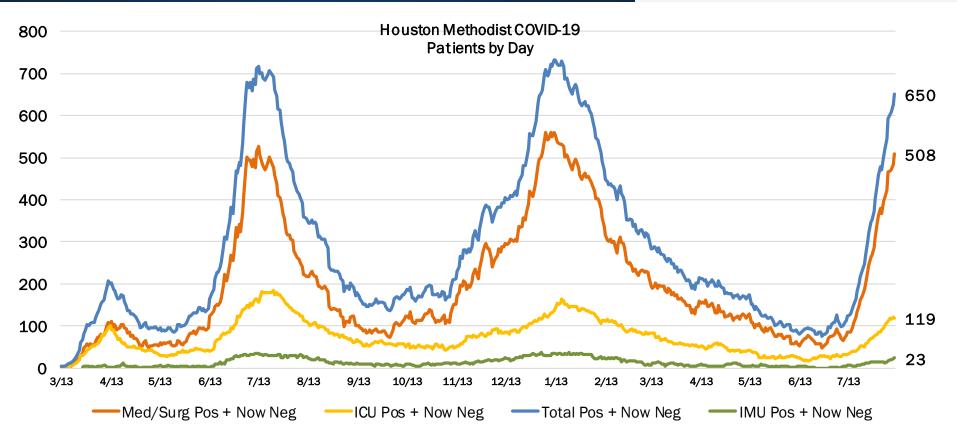
Houston Methodist COVID-19 Cases by Day – June 9





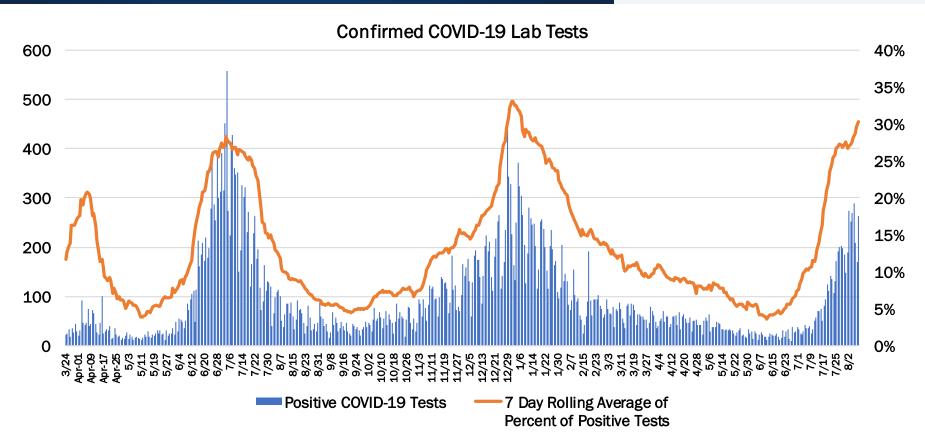
Houston Methodist COVID-19 Cases by Day – August 11





Houston Methodist Testing Trend





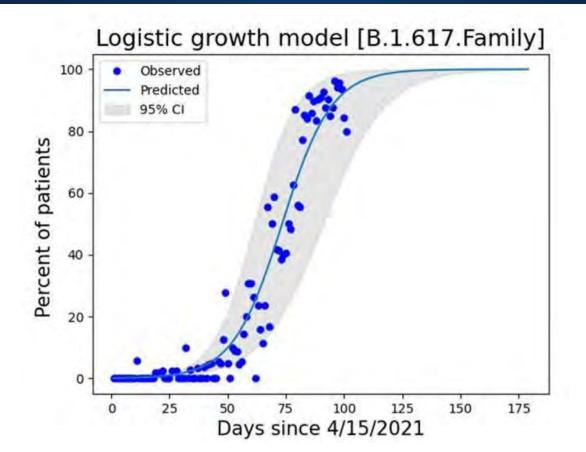
LIFE WAS ALMOST NORMAL.

WHAT THE @*#\$ HAPPENED?



Delta Variant Dominates





Why is this happening?

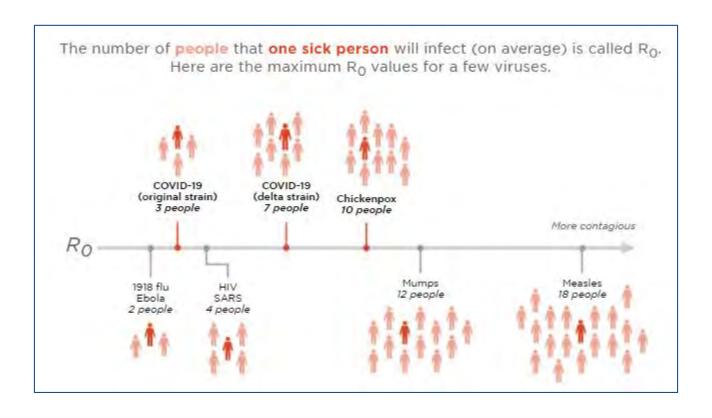
Delta Infectiousness

Low Vaccination Rates

Little To No Community Mitigation

How Infectious is the COVID-19 Delta Variant?

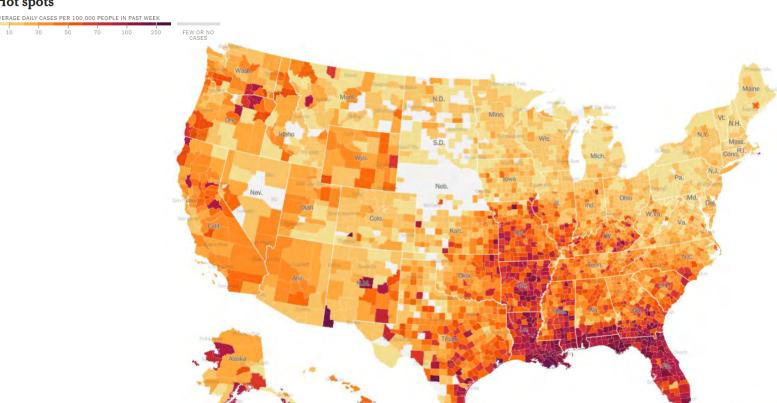




United States COVID-19 Hot Spots

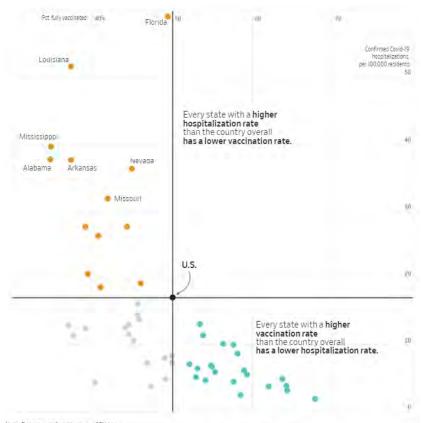


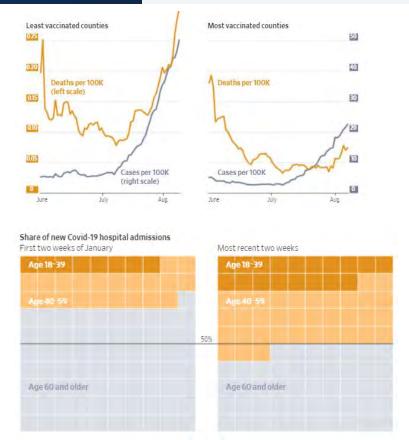
Hot spots



WSJ Analysis: "Highly Vaccinated States Keep Worst COVID-19 Outcomes in Check"







Note: Data are adult patients as of Friday.

Sources: Centers for Disease Control and Prevention (Vaccination rates); Dept. of Health and Human Services (hospitalizations).

Total Beds, COVID-19 Hospitalizations, and Vaccination Rate Across the U.S.



	Number of Total Beds	% COVID Occupancy	State Vaccination Rate		
Houston Methodist	2541	25.58%	44.60%		COVID-19 Occupancy and State Vaccination Rate
Alabama #1	1103	12.15%	34.90%		Comparison Across the U.S.
Arkansas #1	540	13.52%	37.70%		Companson Across the c.c.
California #1	495	4.04%	53.70%	80.00% -	
California #2	420	5.24%	53.70%		
California #3	600	2.33%	53.70%	70.00%	
California #4	1005	3.88%	53.70%	10.00%	
Connecticut #1	1554	2.19%	63.90%	60.00%	
Florida #1	491	14.87%	49.70%	60.00%	
Florida #2	1700	22.18%	49.70%	50.00 %	
Florida #3	1041	18.54%	49.70%	50.00%	
Georgia #1	2046	15.05%	39.10%		
Georgia #2	630	14.60%	39.10%	40.00% —	
Indiana #1	1750	9.26%	44.70%		
lowa#1	865	3.24%	50.00%	30.00%	
Kentucky #1	985	4.77%	46.30%		· ·
Maryland #1	2591	3.09%	59.50%	20.00%	
Massachusetts #1	3085	1.85%	64.40%	_0.00%	.ll Illi
Massachusetts #2	1050	2.00%	64.40%	10.00%	
Michigan #1	1000	2.00%	49.20%	10.00%	
Missouri #1	2544	10.42%	42.20%	0.00%	
Nebraska #1	520	7.12%	50.10%	0.00%	T
New York #1	3100	4.61%	57.80%	#	
New York #2	624	5.45%	57.80%	Ş	usetts utsetts utsetts and the provided with the
Pennsylvania #1	2940	1.94%	53.10%	Vermont	Massachusetts Connecticut Maryland New York New York Califomia Califomia Califomia Califomia Califomia Califomia Pennsylvania Pennsylvania Pennsylvania Pennsylvania Misconsin Nebraksa Nebraksa Pennsylvania Pennsylvania Pennsylvania Alabama Florida Florid
Pennsylvania #2	860	2.91%	53.10%	>	A A A A A A A A A A A A A A A A A A A
Texas #1	4400	18.34%	44.60%		Assaction of the control of the cont
Texas #2	715	23.22%	44.60%		ž ž Ŷ
Texas #3	371	17.25%	44.60%		
Vermont #1	505	1.58%	68.00%		% COVID Occupancy State Vaccination Rate
Wisconsin #1	721	6.93%	52.30%		

IS THIS REALLY A "PANDEMIC OF THE UNVACCINATED?" WHAT ABOUT BREAKTHROUGH INFECTIONS?

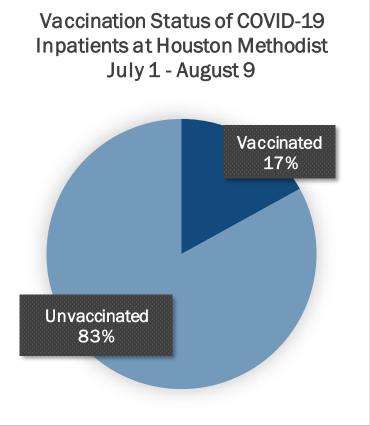
Inpatient Breakthrough of COVID-19 Infections





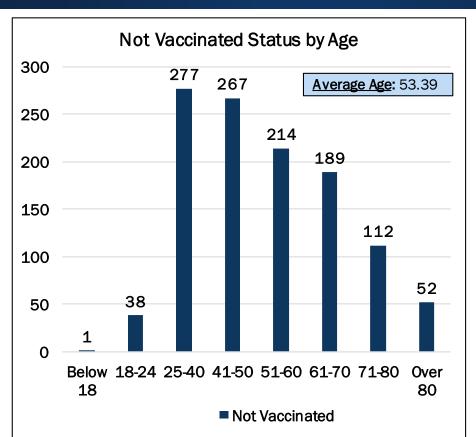
Data was received from 38 hospitals across the region.
A total of 1,554 inpatients with COVID were reported from the responding hospitals. A total of 1,410 of those patients were described as not vaccinated.

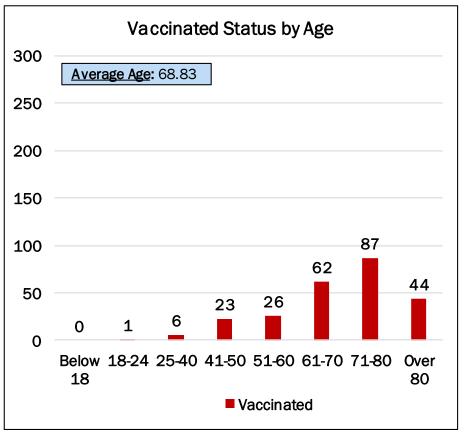
Overall, approximately <u>91%</u> of inpatients diagnosed with COVID were <u>unvaccinated</u> on August 5, 2021.



Houston Methodist COVID-19 Inpatient Vaccine Status

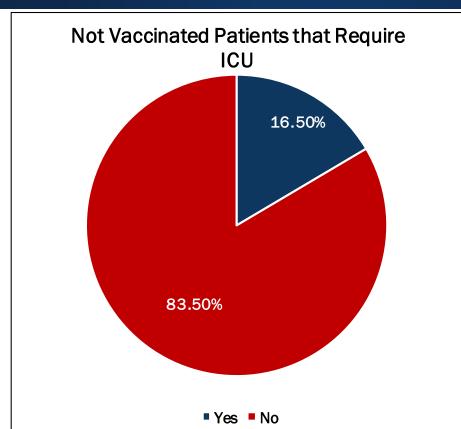


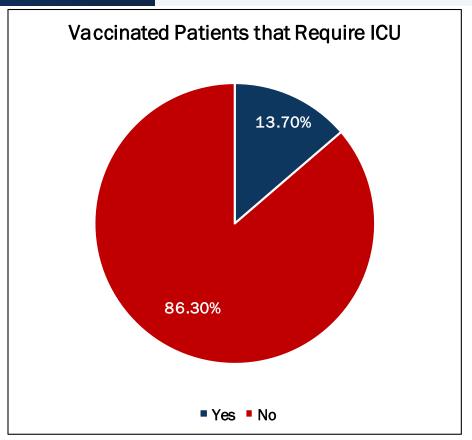




Houston Methodist COVID-19 Inpatient Vaccine Status







COVID-19 Vaccination Rate by Age



Percent of People Receiving COVID-19 Vaccine by Age and Date Reported to CDC, United States



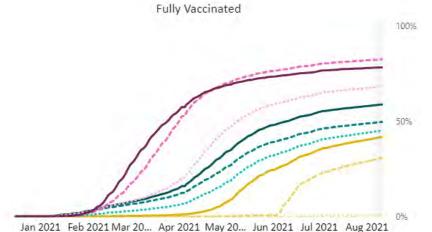
December 14, 2020 - August 11, 2021

<12 vrs	12-15 yrs	16-17 vrs	18-24 vrs	25-39 vrs	40-49 vrs	50-64 vrs	65-74 yrs	75+ yrs
		-				30000		
0.5%	43.0%	52.8%	55.5%	59.3%	68.9%	77.9%	92.6%	87.9%
0.3%	30.8%	41.7%	45.0%	49.6%	58.7%	68.1%	82.4%	78.2%
	0.5%	0.5% 43.0%	0.5% 43.0% 52.8%	0.5% 43.0% 52.8% 55.5%	0.5% 43.0% 52.8% 55.5% 59.3%	0.5% 43.0% 52.8% 55.5% 59.3% 68.9%	0.5% 43.0% 52.8% 55.5% 59.3% 68.9% 77.9%	0.5% 43.0% 52.8% 55.5% 59.3% 68.9% 77.9% 92.6%



At Least One Dose

Jan 2021 Feb 2021 Mar 2021 Apr 2021 May 2021 Jun 2021 Jul 2021 Aug 2021

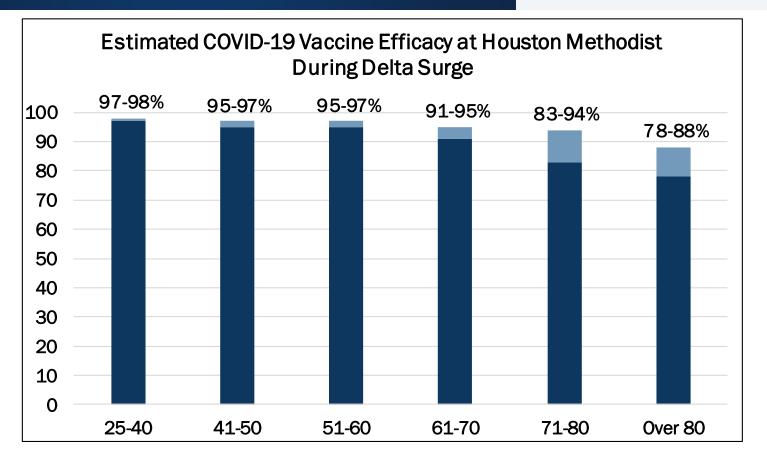


Age data were available for 99.0% of vaccinations

Percent Vaccinated

"Back of the Envelope" Estimate of Vaccine Efficacy During Delta Surge in HM Experience



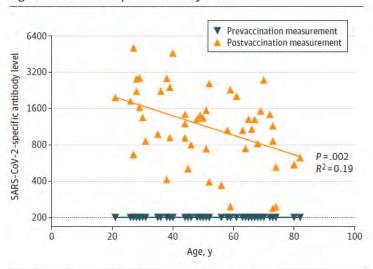


Age-Dependent Neutralization of SARS-CoV-2 and P.1 Variant by Vaccine Immune Serum Samples

JAMA Network

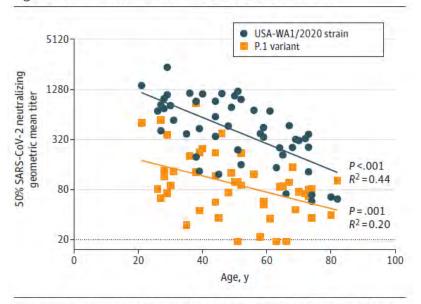


Figure 1. SARS-CoV-2-Specific Antibody Levels



Enzyme-linked immunosorbent assay measurement of SARS-CoV-2 spike receptor-binding domain-specific antibody levels and association with age at time of vaccination for 50 participants 14 days after receiving their second vaccine dose. Prevaccination samples for all participants were below the limit of detection, indicating no prior exposure. Postvaccination samples displayed a significant negative association with age. The dotted line indicates the lower limit of quantification.

Figure 2. Neutralization of Live SARS-CoV-2 Clinical Isolates

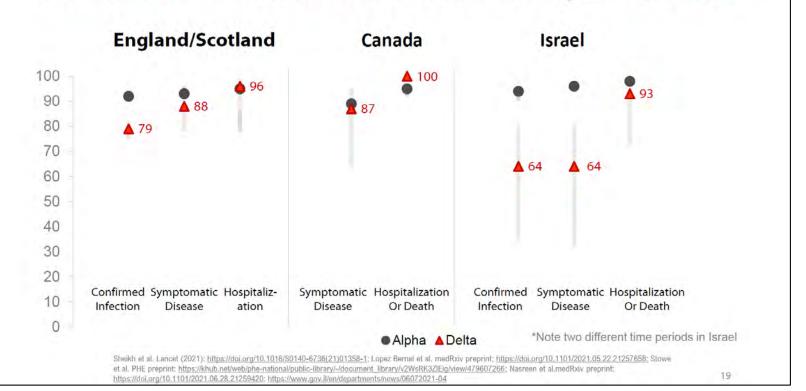


Live virus neutralization of participant serum samples collected 14 days after the second vaccine dose. Neutralization experiments were performed with the USA-WA1/2020 strain and P.1 variant. Both show a significant negative association with participant age. The dotted line indicates the lower limit of quantification.

COVID-19 Vaccine Effectiveness



Pfizer 2-Dose Vaccine Effectiveness for Alpha vs. Delta



Vaccine Effectiveness Associated With Delta Variant In England During May To July 2021

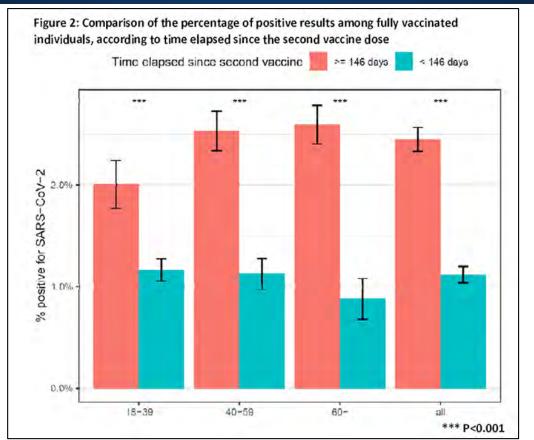


Table 5. Unadjusted and adjusted estimates of vaccine effectiveness against infection for self-reported vaccine status and linked vaccine status for rounds 12 and 13 of REACT-1 for participants aged 18 to 64 years.

Vaccination data source	Adjustment	Vaccine effectiveness (2 doses)											
(n)	Adjustment		ound 1		Round 13								
Self-report, All positives,	Age, Sex	61%	(2%		84%)	47%	(18%	,	65%)
18 to 64 years	Age, sex, IMD, region, ethnicity	64%	(11%	,	85%)	49%	(22%	,	67%)
Self-report, Symptomatic	Age, Sex	81%	(5%	,	96%)	56%	(19%	,	77%)
only, 18 to 64 years	Age, sex, IMD, region, ethnicity	83%	(19%	,	97%)	59%	(23%	,	78%)
Linked, All positives, 18	Age, Sex	75%	(33%	,	90%)	61%	(36%	,	76%)
to 64 years	Age, sex, IMD, region, ethnicity	75%	(35%	,	90%)	62%	(38%	,	77%)

Elapsed Time Since Vaccine and Risk of COVID-19 Infection





Limitations:

- Most of infections occurred in last two weeks of study.
- Study occurred during a time of rising prevalence.
- Study occurred during time of Delta's emergence.
- Study does not compare distribution of positive vs negative tests during the study period.

25

Countries That Are Administering Third Dose Boosters



Russia

Began offering boosters in July to those vaccinated six months ago or more

Hungary

Began offering boosters as of Aug. 1 to healthcare workers

Indonesia

Began offering boosters in July to healthcare workers

Israel

Began offering Campaign begins boosters in July to those aged 60 or older

Germany

Campaign begins Sept. for elderly and vulnerable

France

Campaign begins Sept. for elderly and vulnerable



Announced: Jul.1

Announced: **Jul.16**

Announced: Jul.27

Announced: Jul.29

Announced: Aug.1

United Kingdom

Sept. for all

Announced: Aug.2

Announced: Aug.4

FDA Poised to Authorize 3rd Vaccine Dose for Immune-Compromised People







FDA poised to authorize 3rd vaccine dose for immunecompromised people: Sources

In a statement, the FDA said it will share information in the near future.

The Food and Drug Administration is planning to authorize a third shot for the immune-compromised on Thursday, two sources familiar with the plans confirmed to ABC News.

If the FDA green-lights the additional shots -- first reported by NBC News -- it's up to the Advisory Committee on Immunization Practices, the Centers for Disease Control's expert advisory panel,

CDC Meeting on Immunization Practices



Draft - August 9, 2021

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention Atlanta, Georgia 30329 August 13, 2021

AG	ENDA ITEM	PRESIDER/PRESENTER(s)
Friday, Au	gust 13, 2021	
11:00	Welcome & Introductions	Dr. Grace Lee (ACIP Chair)
		Dr. Amanda Cohn (ACIP Executive Secretary, CDC)
11:15	Coronavirus Disease 2019 (COVID-19) Vaccines	
	Introduction	Dr. Matthew Daley (ACIP, WG Chair)
	Updates on additional doses in immunocompromised individuals	Dr. Kathleen Dooling (CDC/NCIRD)
	Break	
	Public Comment	
	COVID-19 epidemiology and vaccine impact	TBD
	Considerations for booster doses of COVID-19 vaccines	Dr. Sara Oliver (CDC/NCIRD)
1:30	Discussion	
2:00	Adjourn	

Some Individuals Are Opting For An Unauthorized Third Dose of the COVID-19 Vaccine



BECKER'S -

HOSPITAL REVIEW

1.1 million people got unauthorized COVID-19 booster shot, CDC estimates

Maia Anderson - 14 hours ago Print | Email







The CDC has estimated that 1.1 million people have received an unauthorized third dose of either Pfizer or Moderna's COVID-19 vaccine, according to an internal CDC document obtained by ABC News.

The publication reported Aug. 10 that the number is likely an undercount because it only included people who received Moderna or Pfizer's shot and got a booster, not those who received Johnson & Johnson's.

It's unclear if the people who got a booster shot did so under the direction of a physician. The FDA has not authorized booster shots, but there have been reports of some physicians encouraging severely immunocompromised people to get them, ABC reported.

The FDA has said it expects to establish a national strategy on booster shots by early September. But the World Health Organization on Aug. 4 called for a moratorium on booster shots until more low-income countries receive access to first doses.

Newsweek

One million people have opted for a third COVID booster shot, CDC estimates



The Centers for Disease Control and Prevention estimates that 1 million people have opted to get a vaccine booster shot for COVID-19. Above, a syringe is filled with a first dose of the Pfizer vaccine at the Weingart East Los Angeles YMCA on August 7. (Patrick T. Fallon/AFP/Getty Images)

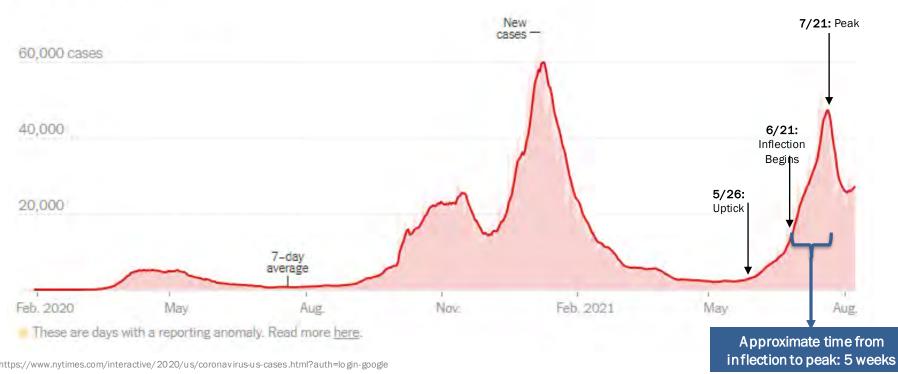
Chief White House medical adviser Anthony Fauci said this past Sunday on *Meet the Press* that booster shots will be needed "sooner or later."

How bad will this surge get?

New COVID-19 Cases Reported in the U.K. by Day



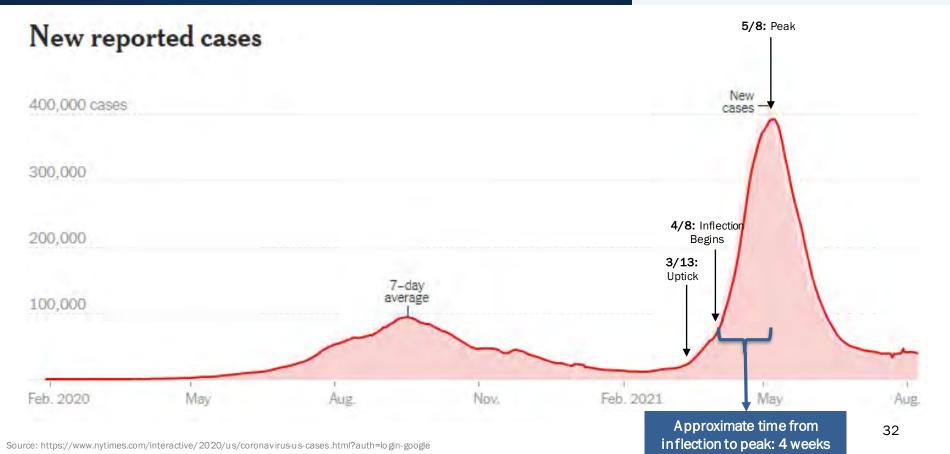
New reported cases



Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?auth=login-google

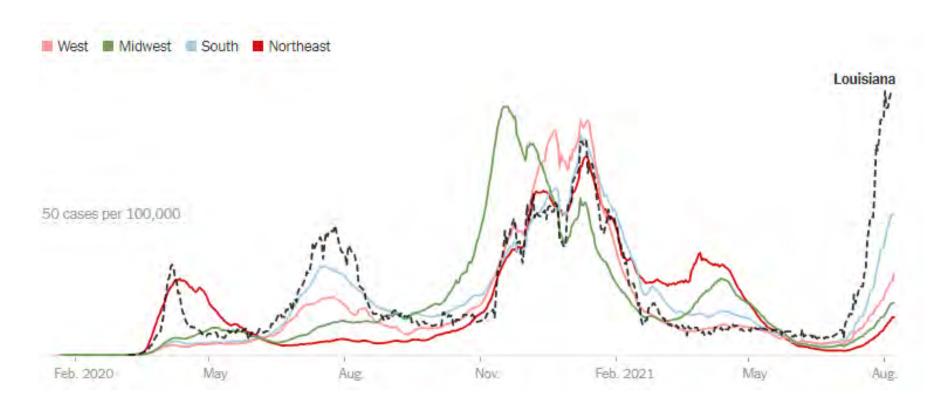
New COVID-19 Cases Reported in India by Day





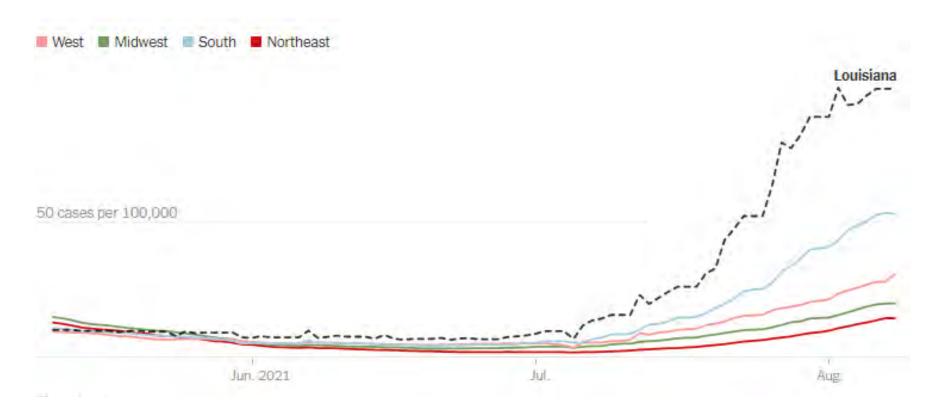
All COVID-19 Cases Reported by Region in the U.S.





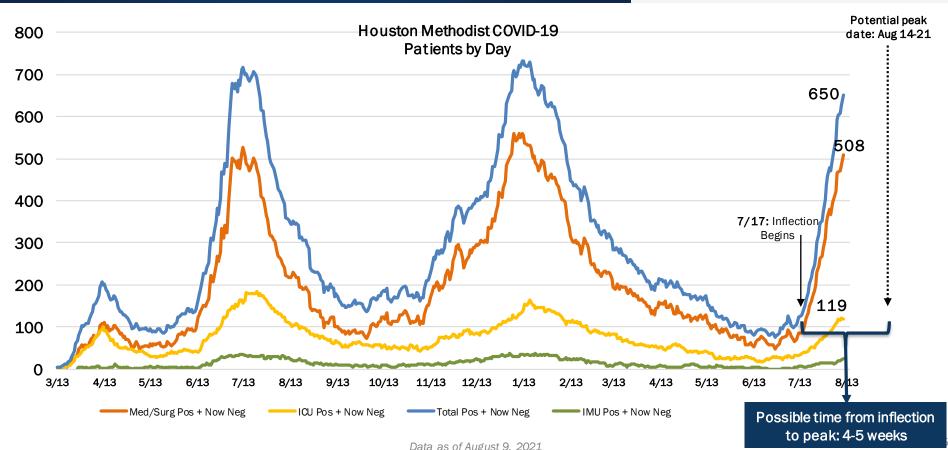
COVID-19 Cases Reported by Region in the U.S. in the Last 90 Days





Houston Methodist COVID-19 Cases by Day – Potential Peak





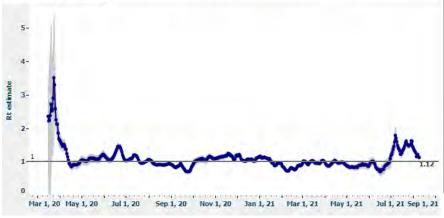
R(t) Shows Some Mitigation



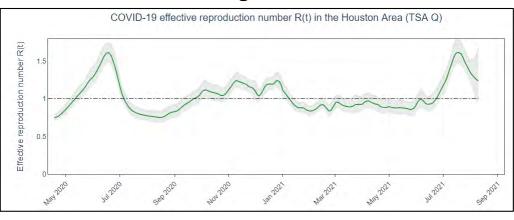
UT School of Public Health COVID-19 Dashboard

Rt estimate

This graph shows the R(t) over time. R(t) is a measure of contagiousness or how many people one COVID19 person infects. If R(t)>1, the epidemic is increasing. If R(t)< 1, the epidemic is declining. There is higher alert if the whole interval is above the horizontal line at 1. For $\bf Q$ - Houston, the rate of contagiousness is 1.12; the epidemic is increasing.



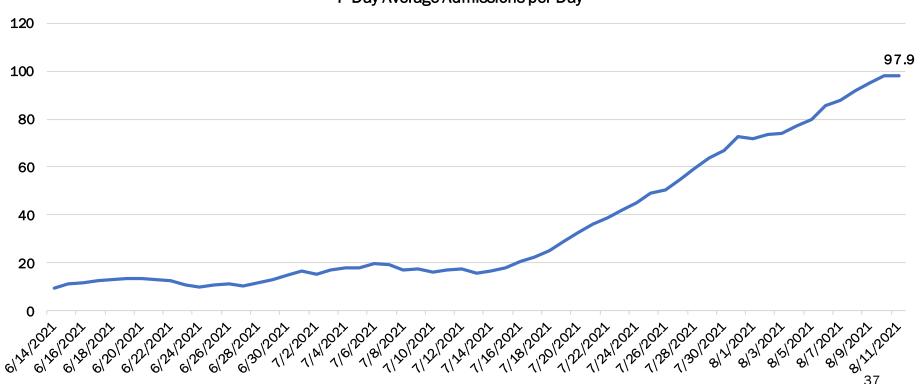
The University of Texas COVID-19 Modeling Consortium



Houston Methodist 7-Day Average COVID-19 Admissions Per Day

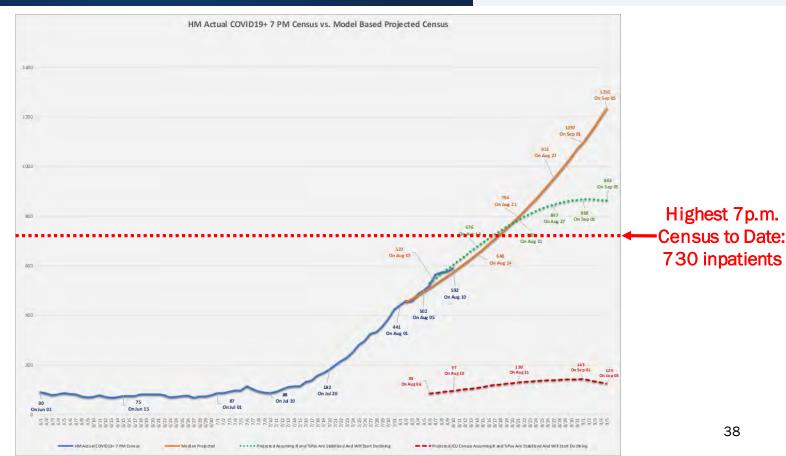






Houston Methodist COVID-19 Hospitalization Predictions





Hospitalization Predictions



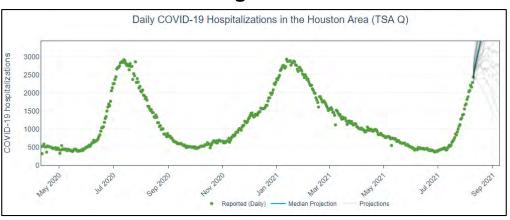
UT School of Public Health COVID-19 Dashboard

Prediction of number of new cases in the next 10 days with 95% confidence intervals

Predictions in ${\bf Q}$ - **Houston.** If the upper band for the predictions is approximately below the current number of new cases, cases are expected to decrease. If the lower band for the predictions is approximately above the current numbers of new cases, cases are expected to increase. Otherwise, they are not expected to increase or decrease significantly. For dates prior to the predictions, the 7-day moving average is shown.



The University of Texas COVID-19 Modeling Consortium

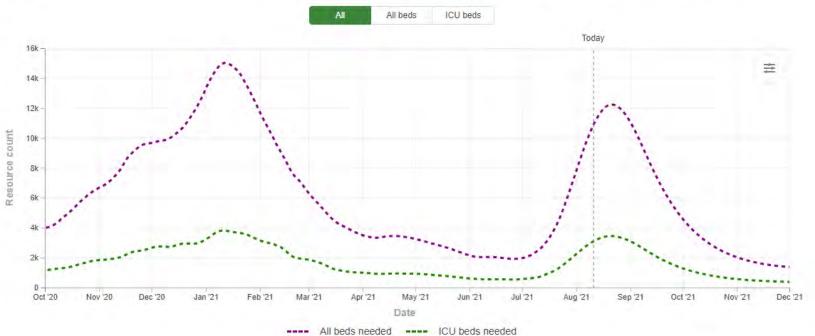


IHME: Projections for Texas



Hospital resource use ☑

Hospital resource use indicates how equipped a location is to treat COVID-19 patients for the **Current projection** scenario. Select **All beds** or **ICU beds** for descriptions of each measure.

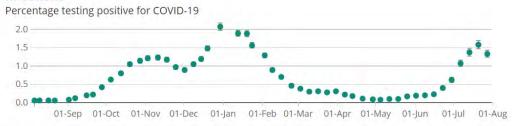


IS THIS SURGE LESS SEVERE IN TERMS OF DEATH RATES?

COVID-19 Infections and Hospital Admissions Increased In England

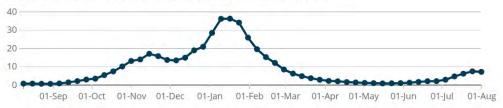


Infections



Hospital admissions





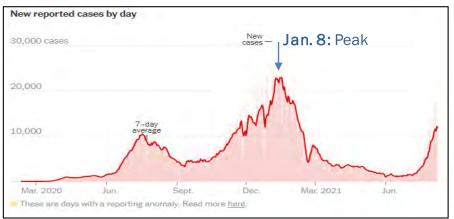
Deaths involving COVID-19

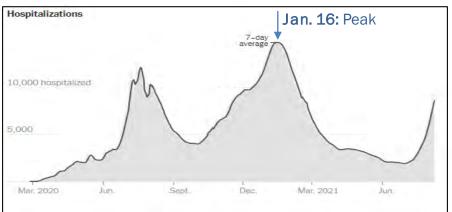
Number of deaths involving COVID-19 registered by week, England

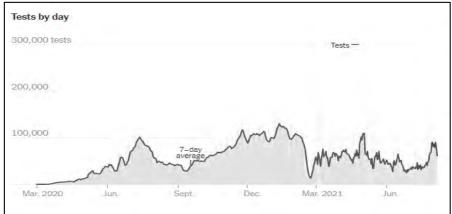


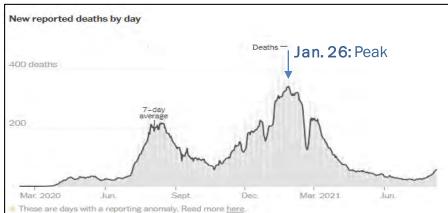
Texas COVID-19 Trends







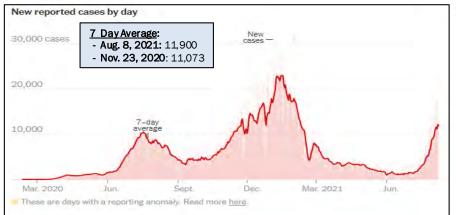




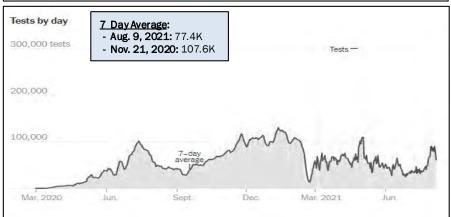
Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?auth=login-google

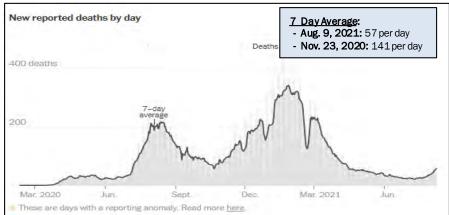
Texas COVID-19 Trends







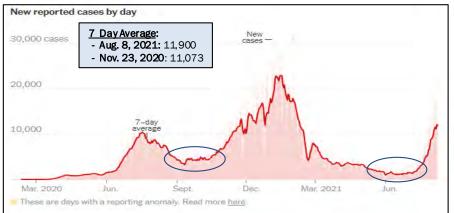


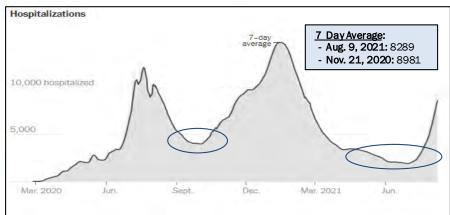


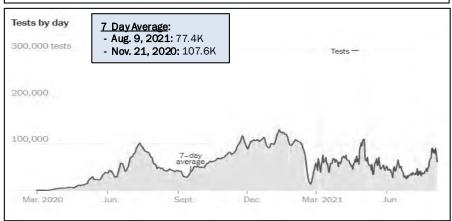
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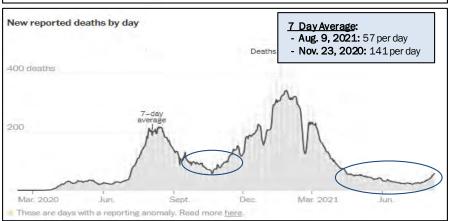
Texas COVID-19 Trends







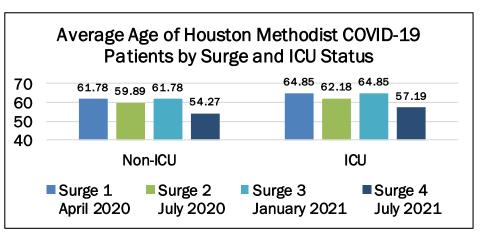


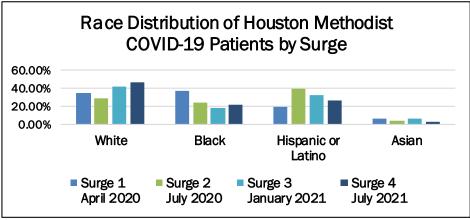


Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?auth=login-google

Houston Methodist COVID-19 Inpatient Demographics by Surge

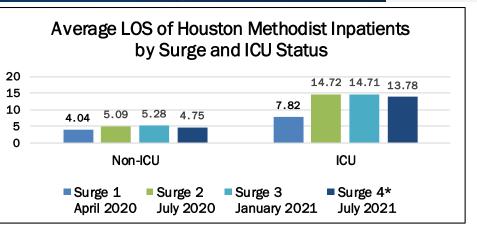




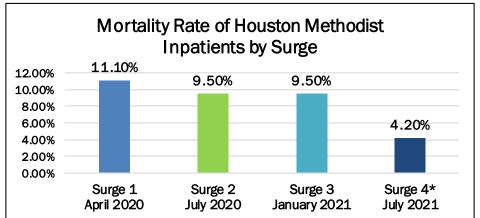


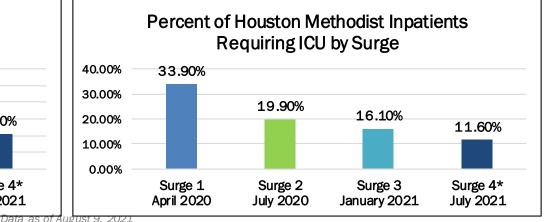
Houston Methodist COVID-19 Inpatient Outcomes by Surge





*Note: It is likely that
Surge 4 ICU utilization,
LOS and mortality will
increase as many
sicker patients'
ultimate outcomes are
yet to be determined.





How do we get out of this mess?

Five Difficult Lessons



1. Science, especially biological science, is messy in real time.

Science is also our only real hope to conquer COVID-19

2. Hospitals together must work on their "Sacred AND"

Care for COVID-19 patients

<u>AND</u> care for traditional patients <u>AND</u> protect our staff and physicians

3. Our political leaders must work together on society's "Sacred AND"

Control COVID-19 <u>AND</u>
protect the economy <u>AND</u>
educate our children

- 4. Our social lives must take a backseat to the "Sacred AND"
 - No bars
 - No large gatherings, including sporting events
 - Limited social gatherings

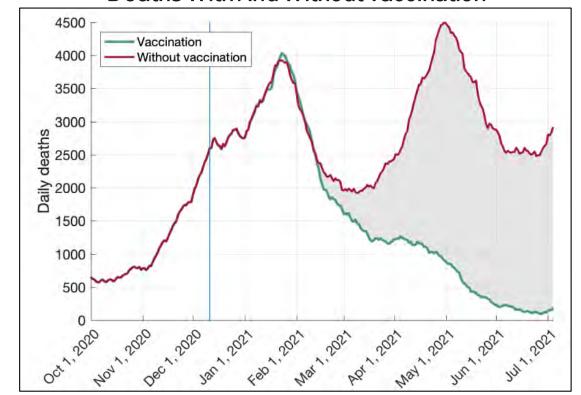
- 5. Masks are a means to accomplish the "Sacred AND"
- We have proven to be incapable of accepting this on our own
- Masks must be mandatory until the virus is in control

Impact of COVID-19 Vaccination Campaign on Deaths



"The U.S. COVID-19 vaccination campaign has significantly curbed the virus's spread and national death toll, saving an estimated 279,000 lives and averting up to 1.25 million hospitalizations."

Estimated U.S. Seven-day Rolling Average Of Daily Deaths With And Without Vaccination



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





Morbidity and Mortality Weekly Report

August 6, 202

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

Alyson M. Cavanaugh, DPT, PhD1-2; Kevin B. Spicer, MD, PhD2-3; Douglas Thoroughman, PhD2-5; Connor Glick, MS2; Kathleen Winter, PhD2-5

Although laboratory evidence suggests that antibody responses following COVID-19 vaccination provide better neutralization of some circulating variants than does natural infection (1,2), few real-world epidemiologic studies exist to support the benefit of vaccination for previously infected persons. This report details the findings of a case-control evaluation of the association between vaccination and SARS-CoV-2 reinfection in Kentucky during May-June 2021 among persons previously infected with SARS-CoV-2 in 2020. Kentucky residents who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated (odds ratio [OR] = 2.34: 95% confidence interval [CI] = 1.58-3.47). These findings suggest that among persons with previous SARS-CoV-2 infection, full vaccination provides additional protection against reinfection. To reduce their risk of infection, all eligible persons should be offered vaccination, even if they have been previously infected with SARS-CoV-2.*

Kentucky residents aged ≥18 years with SARS-CoV-2 infection confirmed by positive nucleic acid amplification test (NART) or antigen test results⁴ reported in Kentucky's National Electronic Disease Surveillance System (NEDSS) during March-December 2020 were eligible for inclusion. NEDSS data for all Kentucky COVID-19 cases were improrted into a REDCap database that contains laboratory test results and case investigation data, including dates of death for deceased patients reported to public health authorities (3). The REDCap database was queried to identify previously infected persons, excluding COVID-19 cases resulting in death before May 1, 2021. A case-patient was defined as a Kentucky resident.

hstps://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

with laboratory-confirmed SARS-CoV-2 infection in 2020 and a subsequent positive NAAT or antigen test result during May 1-lune 30, 2021. May and lune were selected because of vaccine supply and eligibility requirement considerations; this period was more likely to reflect resident choice to be vaccinated, rather than eligibility to receive vaccine. 5 Control participants were Kentucky residents with laboratoryconfirmed SARS-CoV-2 infection in 2020 who were not reinfected through June 30, 2021. Case-patients and controls were marched on a 1:2 ratio based on sex, age (within 3 years). and date of initial positive SARS-CoV-2 test (within 1 week). Date of initial positive test result refers to the specimen collection date, if available. The report date in NEDSS was used if specimen collection date was missing. Random matching was performed to select controls when multiple possible controls were available to match per case (4).

Vaccination status was determined using data from the kentucky Immunization Registry (KYIR), Case-patients and controls were matched to the KYIR database using first name, last name, and date of birth. Case-patients were considered fully vaccinated fils asingle doso of Jansent (Johnson) or a second dose of an mKNA vaccine (Pfizer-Bio/VTEch or Moderna) was exceived 214 days before the einforction date. For controls, the same definition was applied, using the reinfection date of the matched case-patient. Partial vaccination was defined as receipt of 21 dose of vaccine, but either the

Nay and June were selected for two primary reasons. First, whose succination applies see to so, one periodary infected persons were deferring vectoration for 90 days to allow meet-infected persons principly for available vaccine for 90 days to allow meet-infected persons priority for available vaccine for some finework. by May 201, deferral for 90 days was no longer areason for those infected in 2020 to remain unreactianted. Second, although vaccination fingularly was intuitly exercised used on age, connectifieties, up also eccupations, by April 5, 2021, all Kennicky residents aged 24 foyens became eligible for excitanted unlarged life-fix general general deplicated 1951 (2014) chariff-Alex Second general priority of the 2014 (2014) and the priority of the property of the priority of the



Summary

What is already known about this topic?

Reinfection with human coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, has been documented. Currently, limited evidence concerning the protection afforded by vaccination against reinfection with SARS-CoV-2 is available.

What is added by this report?

Among Kentucky residents infected with SARS-CoV-2 in 2020, vaccination status of those reinfected during May–June 2021 was compared with that of residents who were not reinfected. In this case-control study, being unvaccinated was associated with 2.34 times the odds of reinfection compared with being fully vaccinated.

What are the implications for public health practice?

To reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection.

^{*}Intps://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.

Cleveland Clinic: Necessity Of COVID-19 Vaccination In Previously Infected



Summary:

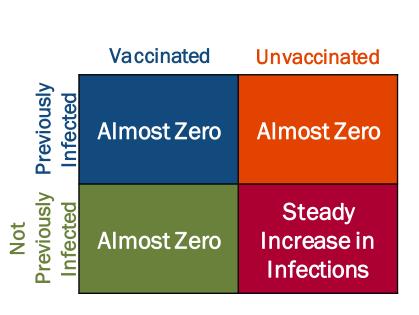
- Studied 52,238 employees
- Cumulative incidence of SARS-CoV-2 infection almost zero in previously infected unvaccinated, previously infected vaccinated, and previously uninfected vaccinated compared with a steady increase in previously uninfected subjects who remained unvaccinated
- Authors draw conclusion that prior infection is as protective as vaccination

Limitations:

- Preprint and not yet peer-reviewed
- No surveillance testing
- Only 5 months follow-up
- Occurred prior to Delta

Observations:

- Inconsistent with several antibody level studies
- Inconsistent with Houston Methodist experience



Cleveland Clinic: Necessity Of COVID-19 Vaccination In Previously Infected



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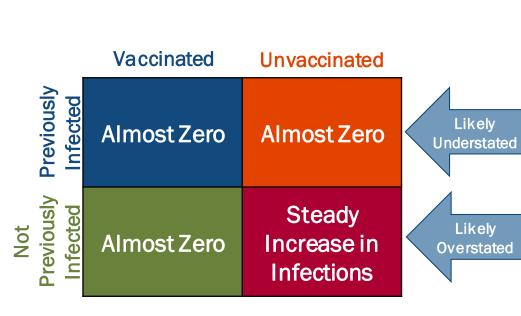
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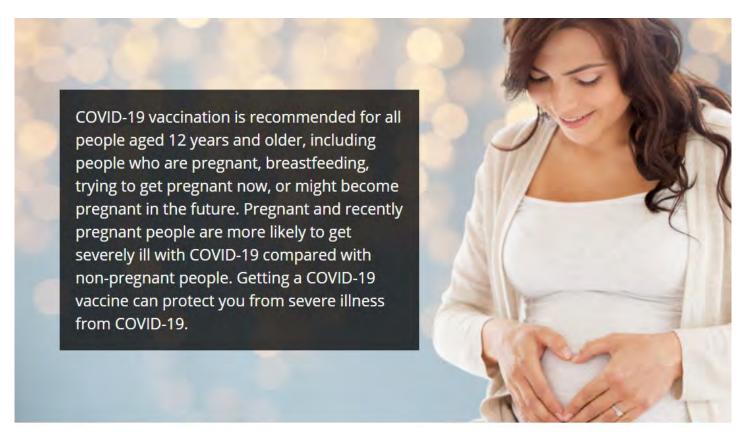
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- Inconsistent with Houston Methodist experience



CDC COVID-19 Vaccination Recommendation Now Includes Pregnant and Breastfeeding Women



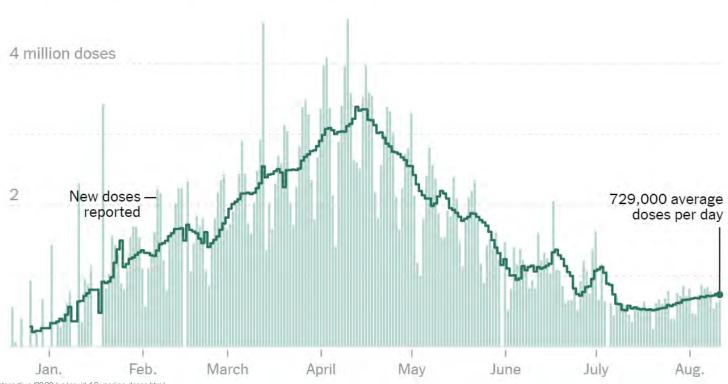




Number of Vaccine Doses Administered by Day in the U.S.



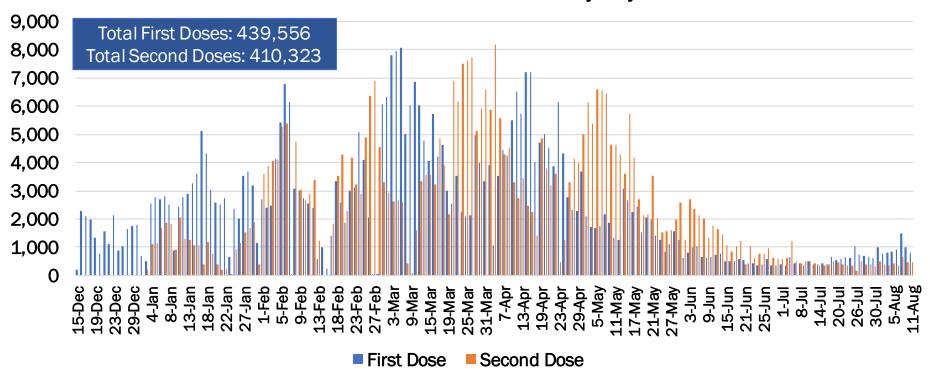
New reported doses administered by day



HM COVID-19 Vaccines Administered

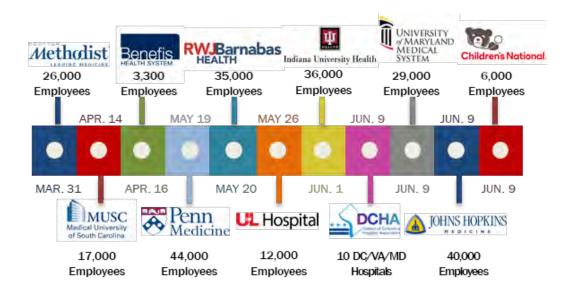


Individuals Vaccinated at HM by Day



Multiple Hospitals Announce COVID-19 Vaccine Mandate for Employees – As of June 9





Support for Mandatory COVID-19 Vaccination for Healthcare Workers





July 13, 2021



July 16, 2021



July 21, 2021



July 26, 2021





"American Academy of Pediatrics, American Medical Association, American Nursing Association, American Psychiatric Association and 53 other medical associations released a joint statement urging hospitals to require employees to get vaccinated."

"We call for all health care and long-term care employers to require their employees to be vaccinated against COVID-19," the statement read. "We stand with the growing number of experts and institutions that support the requirement for universal vaccination of health workers."

Multiple Hospitals Announce COVID-19 Vaccine Mandate for Employees

7.000

Employees

6.300

Employees

21.512

Employees

29.233

Employees

10.650

Employees

7.100

Employees

12.800

Employees



ChristianaCare

3.586

Employees

24.000

Employees



12.000

Employees

3.932

Employees

3.586

Employees

400

Employees

26.000

Employees

15.000

Employees

Multiple Hospitals Announce COVID-19 Vaccine Mandate for Employees





Healthcare Vaccine Mandates





Houston Methodist COVID-19 Employees In House



August 9, 2020

- 12 Hospitalized
- 9 in the ICU
 - 2 on ECMO
 - 2 Passed Away

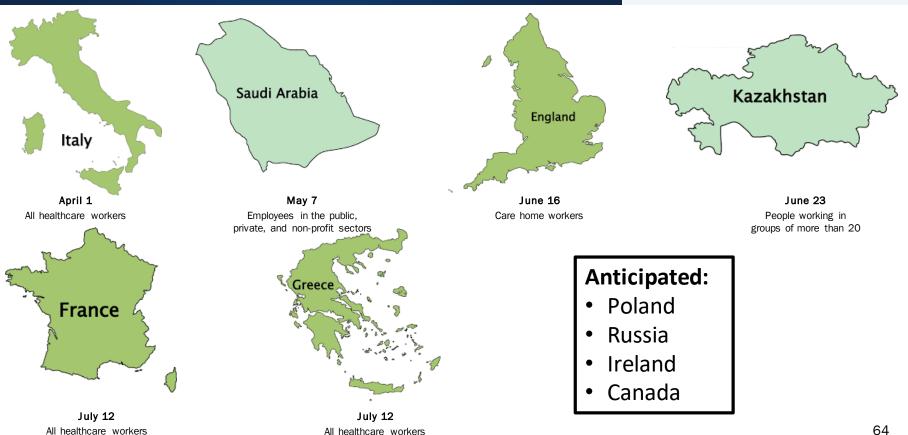
<u> August 9, 2021</u>

- 2 Hospitalized
 - Both unvaccinated with exemptions/deferrals
- 0 in the ICU

Our COVID-19 vaccine mandate protects patients, employees, and our employees' ability to serve the community during a surge.

Countries that have a COVID-19 Vaccine Mandate for Health Workers





GHP Urges Businesses to Play a More Active Role in Controlling the Pandemic



BUSINES

Greater Houston Partnership encourages companies to require vaccinations



Rebecca Carballo, Staff writer

Aug. 11, 2021 | Updated: Aug. 11, 2021 6:47 p.m.



(LtoR) Sadiq Wahid, Giovanna Garcia and Guilla Avoltini work in their office, Wednesday, Aug. 4, 2021, at ZT Corporate's Houston office. The company's CEO, Taseer Badar, is pushing to require 100% of his employees to be vaccinated. Mark Mulligan, Houston Chronicle / Staff photographer

"While the responsibility clearly rests with each of us individually as employers, the benefit of joint action will be profound."

A Letter to the Business Community from the Partnership and Local Business and Health Care Leaders:

- 1. Be a forceful champion for vaccination.
- Begin giving consideration, if you haven't already, to requiring vaccination of your staff (with appropriate religious and medical exceptions).
- 3. Temporarily require masks for all indoor workspaces other than individual workspaces.
- 4. Temporarily reconsider any additional steps planned for bringing people back to the office in the next few weeks.

Employee Vaccine Mandates



How to Develop a Covid-19 Employee Vaccination Policy

by Susan M. Miller, Robert A. Phillips, Roberta L. Schwartz, H. Dirk Sostman, Carole Hackett, and Marc L. Boom

July 01, 2021



Harvard Business Review

"Employers around the world are struggling with the question of whether they should mandate that their workers be vaccinated against Covid-19. Houston Methodist, an eight-hospital academic medical center, developed a seven-step process that can help all employers make this decision. It includes guidelines for allowing workers to be temporarily or permanently exempted from the mandate."

Employee Vaccine Mandates



How Employers Can Reduce Vaccine Hesitancy

by Jessica H. Jones, Jeff Levin-Scherz, and Julie Noblick

March 02, 2021



Boston Globe/Getty Images

Harvard Business Review

"Employers have a central role to play in the drive to persuade people to get vaccinated against Covid-19. This article offers 12 strategies that leverage the power of behavioral economics."

COVID-19 Vaccine Approval for Children Under 12



The New Hork Times

At the F.D.A.'s urging, Pfizer-BioNTech and Moderna are expanding their trials for children 5 to 11.



At the urging of federal regulators, two coronavirus vaccine makers are

SE NEWS

Covid vaccines for kids under 12 expected midwinter, FDA official says

After emergency use authorization, the agency hopes to move quickly to full approval.



A health care worker prepares a dose of the Pfizer-BioNTech Covid-19 vaccine at Boston Medical Center on June 17.

American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN®



see Park Blad

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AAP Washington Office 601 13th St NW, Suite 400N Washington, DC 20005

Phone 202/147-8600 E-mail: kidststill gap.org

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August 5, 2021

lanet Woodcock, MD Acting Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Dr. Woodcock:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children. adolescents, and young adults, I write to urge the Food and Drug Administration (FDA) to continue working aggressively towards authorizing safe and effective COVID-19 vaccines for children under age 12 as soon as possible.

Pediatricians and the families they care for have been anxiously awaiting a vaccine that can be used in children 11 years of age and younger, and especially so now given the rise of the hyper infectious Delta variant. The Delta variant is surging at extremely alarming rates in every region of America. This surge is seriously impacting all populations, including children. The AAP and the Children's Hospital Association have been tracking COVID cases in children since the start of the pandemic. Last week saw the largest week-over-week percentage increase in pediatric COVID-19 cases since the start of the pandemic. The data show 71,726 COVID cases in children reported last week, almost double the 38,654 reported in the previous week. Simply stated, the Delta variant has created a new and pressing risk to children and adolescents across this country, as it has also done for unvaccinated adults

As the numbers of children infected with the Delta variant have increased, not surprisingly the proportion of COVID-19 cases occurring in the United States among children is also increasing. in large part due the current ineligibility of children under 12 years of age to receive COVID vaccines. Since the pandemic began, children have represented 14.3% of total cumulated cases. However, for the week ending July 29, children were 19,0% of reported weekly COVID-19 cases. The higher proportion of cases in this population means this age group could be contributing in driving continued spread of COVID-19. Sadly, over 350 children have died of COVID since the start of pandemic and millions of children have been negatively impacted by missed schooling, social isolation, and in too many cases, the death of parents and other caregivers.

We understand that the FDA has recently worked with Pfizer and Moderna to double the number of children ages 5-11 years included in clinical trials of their COVID-19 vaccines. While we appreciate this prudent step to gather more safety data, we urge FDA to carefully consider the impact of this decision on the timeline for authorizing a vaccine for this age group. In our view, the rise of the Delta variant changes the risk-benefit analysis for authorizing vaccines in

Voice of the Employee





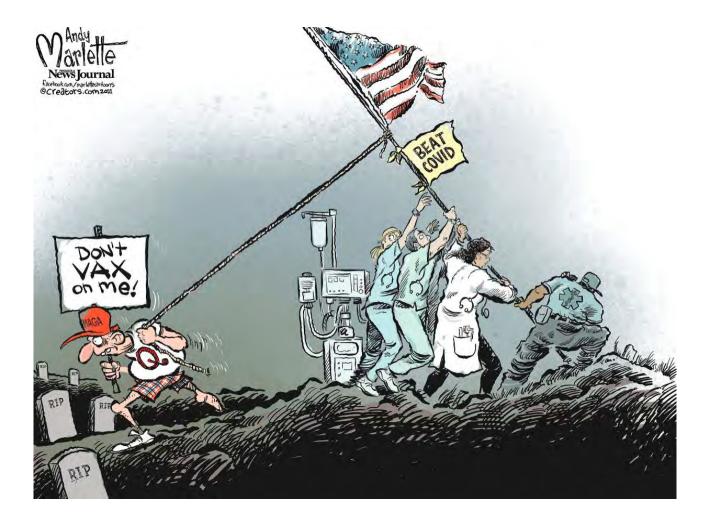














TOWN HALL CONVERSATION XVI

COVID-19 VACCINE AND VARIANT UPDATE

August 12, 2021

Ashley L. Drews, MD FACP HM System Epidemiologist



Delta Variant



- B.1.617.2 (Pango lineageexternal icon)^a
- Spike Protein Substitutions: T19R, (V70F*), T95I, G142D, E156-, F157-, R158G, (A222V*), (W258L*), (K417N*), L452R, T478K, D614G, P681R, D950N
- Name (Nextstrainexternal icon)b: 21A/S:478K
- WHO Label: Delta
- First Identified: India
- Attributes:
 - Increased transmissibility
 - -Potential reduction in neutralization by some EUA monoclonal antibody treatments
 - -Potential reduction in neutralization by post-vaccination sera
- May be TWICE as transmissible as D614G

Delta variant vaccine breakthrough cases may be as transmissible as unvaccinated cases



- Breakthrough cases reported to national passive surveillance have lower Ct values by 3 cycles (~10-fold increase in viral load) for Delta (Ct=18, n=19) compared with Alpha (Ct=21, n=207) and other lineages (Ct=21, n=251)
- Barnstable County, MA, outbreak: No difference in mean Ct values in vaccinated and unvaccinated cases [median among vaccinated (n=80): 21.9; unvaccinated (n=65): 21.5]

Delta variant may cause more severe disease than Alpha or ancestral strains: Published evidence



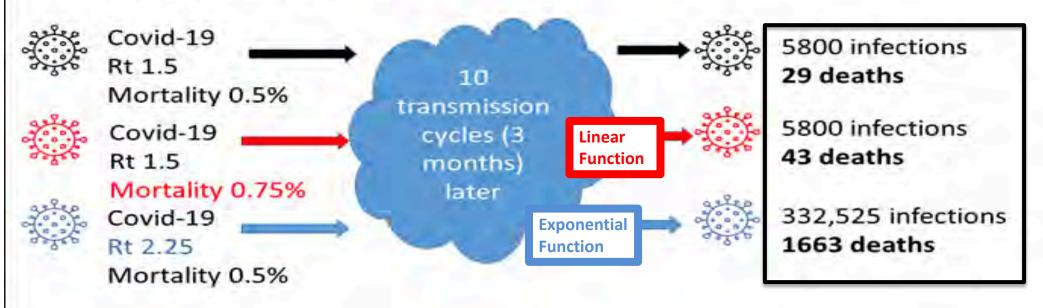
- Canada: Higher odds of hospitalization [aOR 2.20 (CI 1.93-2.53)], ICU admission [aOR 3.87 (CI 2.98-4.99)], and death [aOR 2.37 (CI 1.50-3.30)]¹
- Singapore: Higher odds of oxygen requirement, ICU admission, or death [aOR 4.90 (CI 1.43-30.78)] and pneumonia [aOR 1.88 (CI 0.95-3.76)]²
- Scotland: Higher odds of hospitalization [HR 1.85 (CI 1.39-2.47)]³

^{1.} Fisman and Tuite, <u>doi:10.1101/2021.07.05.21260050</u>; 2. Ong et al. <u>doi:10.2139/ssrn.3861566</u>; 3. Sheikh et al. <u>doi:10.1016/S0140-6736(21)01358-1</u>

Viral Variants: Transmission vs. Lethality



Which is worse? 50% more transmissible or 50% more lethal?



Courtesy of Perry Wilson MD Yale University

Viral Variants and Vaccines



Vaccine Efficacy	D614G	Alpha B.1.1.7	Beta - B.1.351	Delta B.1.617.2
Pfizer	95%	85% - 95%*	75% - 100%	39% - 88%
Moderna mRNA-1273	94%	89%*	Probably similar to Pfizer based on single dose data	Probably similar to Pfizer based on single dose data
1&1	72%	72%	57%	67%
Novavax	95%	89%	60% (HIV negative)	
AstraZeneca	70%	76%	10%	60%

B.1.617 is now 90+% of isolates in Houston

Pfizer Vaccine vs. Variants

Highly vaccinated countries



Country of Qatar

- B.1.1.7 = 44.5% of cases, B.1.351 = 50% of cases
- Prevention of infection
 - -B.1.1.7 89.5%
 - -B.1.351 75%
- Prevention of severe, critical or fatal disease
 - -Any form of SARS-CoV-2 97.4%
 - -B.1.1.7 or B.1.351 100%

Country of Israel

- B.1.1.7 predominant period
 - Prevention of
 - Asymptomatic infection 91.5%
 - Symptomatic infection 97.0%
 - Hospitalization 97.2%
 - Death 96.7%
- B.1.617 predominant period
 - Prevention of
 - Asymptomatic infection 39%
 - Symptomatic infection 41%
 - Hospitalization 88%
 - Severe illness 91%

-

Correlates of Immunity



Antibody

- -Antibodies to RBD of viral spike protein produced after natural infection or vaccination and are associated with neutralizing activity which is associated with protection against reinfection
- -Can measure COVID-19 Anti-spike IgG titer

T cell

- -SARS-CoV-2-specific CD4 and CD8 T cell responses are generated after infection and vaccination as well
- -Cannot measure these in clinical laboratories

Why Get Two Doses?

Patient Outcomes



Pfizer Vaccine Houston Methodist Jan – April 2021	One Dose	Two Doses
Prevention of Hospitalization	77%	96%
Prevention of Death	64%	99%

Public Health England Oct 2020 – May 2021	Pfizer Dose 1	Pfizer Dose 2	AZ Dose 1	AZ Dose 2
B.1.117 (alpha)	49%	94%	50%	75%
B.1.617.2 (delta)	31%	88%	33%	67%

Mixture of D.614.G and B.1.117

Bernal et al, NEJM July 2021

Is immunity from natural infection enough?

Does vaccine offer anything additional to persons previously infected with SARS-CoV-2?

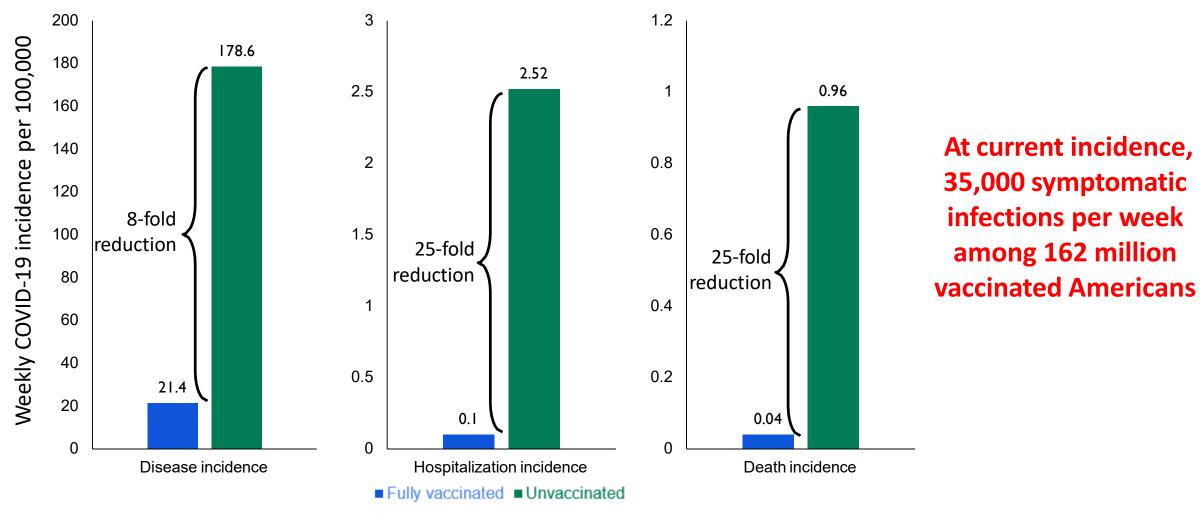


- Vaccination appears to further boost antibody levels in persons previously infected with SARS-CoV-2 and might improve the durability and breadth of protection
- Case-control study from Kentucky of persons previously infected with SARS-CoV-2
 - -246 cases that had documented infection with SARS-CoV-2 in 2020 and documented reinfection in May or June 2021
 - -492 controls matched by age, sex, date of initial infection in 2020
 - -20.3% of case patients vs 34.3% of controls were fully vaccinated
 - -Risk of reinfection 2.34x higher in unvaccinated than fully vaccinated (OR = 2.34; 95% CI = 1.58–3.47)
 - Partial vaccination was not significantly associated with reinfection (OR = 1.56; 95% CI = 0.81–3.01)

GET VACCINATED EVEN IF YOU HAVE HAD INFECTION WITH SARS-CoV-2!

Greater risk of disease, hospitalization and death among unvaccinated vs. vaccinated people: National estimates

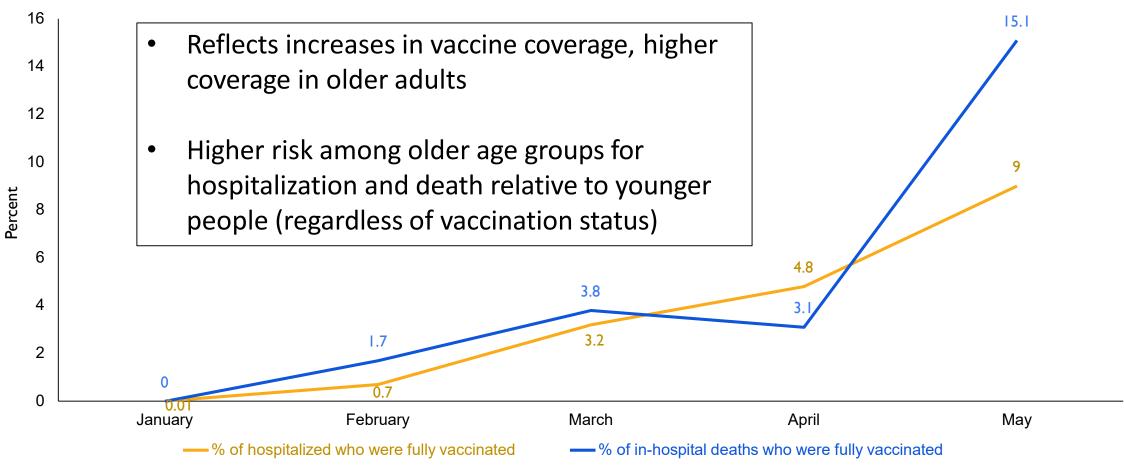




Data from COVID Tracker as of July 24, 2021. Average incidence 100 cases per 100,000 persons per week. Vaccine effectiveness against symptomatic illness = 88% (Lopez Bernal et al. <u>NEJM 2021</u>), where risk is [1 – VE] or 12%. Vaccine effectiveness hospitalization (or death) = 96% (Stowe et al. <u>PHE preprint</u>), where risk is [1 – VE] or 4%. Rate in unvaccinated = Community rate/((1-fully vaccinated coverage) + (1-VE)*fully vaccinated coverage proportions were from COVID Data Tracker as of July 24, 2021 (50% for US,).

Increasing percentage of vaccinated persons among those hospitalized in COVID-NET







The Good News



Hat Tip to Marc Thiessen, Washington Post

- According to the <u>CDC</u>, as of July 19, a total of 4,072 vaccinated Americans had been hospitalized with symptomatic breakthrough infections, out of 161 million who have been fully vaccinated – a breakthrough hospitalization rate of less than 0.003%.
- Of those hospitalized, only 849 have died of COVID-19 the death rate from those breakthrough infections is 0.0005%.
- Death rate from COVID-19 since 2020 = 1.8% (3540 times greater)
- Death rate from COVID-19 in USA last week = 0.4 % (800 times greater)
- The chance of dying <u>from a lightning strike</u> is .0007%, and the chance of dying <u>from a seasonal flu</u> is 0.1%. If you're vaccinated, you have a much greater chance of <u>dying from a hornet</u>, wasp or bee string, a dog attack, a car crash, drowning, sunstroke, or choking on food than you do of dying from COVID-19 infection.

Duration of immunity?

Do I need a booster? When?

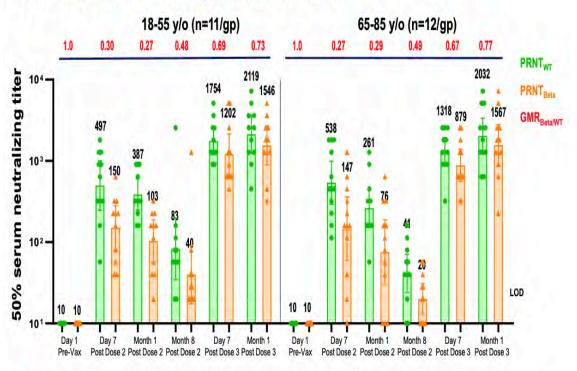


- VE of BNT162b2 through 6 months f/u
 - -91% (95% CI 89.0-93.2) against COVID-19
 - -97% (95% CI 80.3-99.9) against severe disease
 - -100% (95% CI 53.5, 100.0) in South Africa where variant of concern, B.1.351 (beta) was predominant
- VE of mRNA-1273 through 6 months f/u
 - -93% against COVID-19 (Moderna press release)

Pfizer Booster Shot Data



COVID-19 Vaccine: Neutralization Titers Much Higher Post 3rd Dose Than Post 2nd for Wild Type and Beta Variants^{1,2}

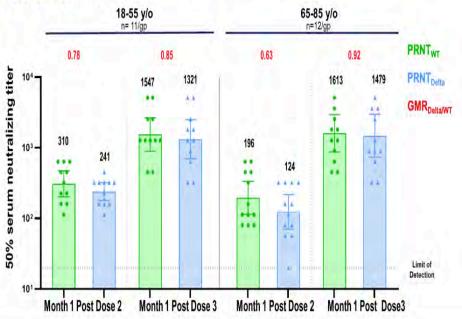


1. Initial data, Phase 1 sentinel subjects received dose 1 & 2 of 30mcg BNT162b2 21 days apart, subjects then came back and received BNT162b2 30 mcg as a 3rd booster dose;
2. Samples were tested against each variant separately; PRNT: Plaque Reduction Neutralizing Test; GMR: Geometric Mean Ratio; WT: Wild Type; LOD: Limit of Detection

Second Quarter 2021 Earnings

Data submitted for publication

COVID-19 Vaccine: 3rd Dose Strongly Boosts Neutralizing Titers Against Delta Strain^{1,2}



Post dose 3 titers vs. the Delta variant are >5-fold post dose 2 titers in 18-55 y/o & >11-fold post dose 2 titers in 65-85 y/o Estimated potential for up to 100-fold increase in Delta neutralization post-dose three compared to pre-dose three

1. Initial data; 2. Samples were tested against each variant separately; PRNT: Plaque Reduction Neutralizing Test; Wt: Wild Type; GMR: Geometric Mean Ratio



26

Second Quarter 2021 Earnings

ata submitted for publication

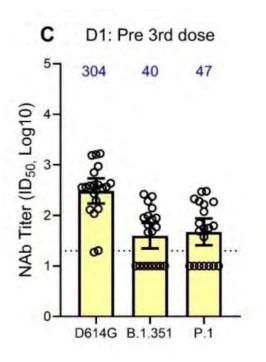
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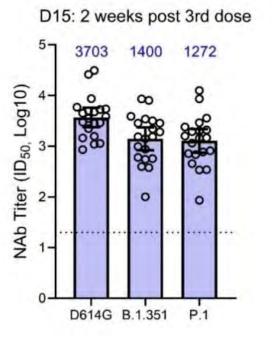
Moderna Booster Shot Data



Compared three options

- -Third shot of mRNA-1273
- -Booster of mRNA-1273.351 (optimized to SA variant)
- -50:50 mixture
- Before booster
 - —6-8 months after primary vaccination
 - -92.5% had titers against D614G
 - -Only 50% had titers against B.1.351 or P.1
- After booster versus B.1.351
 - -GMT = 1400 for mRNA-1273.351
 - -GMT = 864 for mRNA- 1273





Who could benefit from a COVID-19 vaccine booster?



- Elderly
 - —Antibody response lower and wanes faster in the elderly
 - –More comorbidities and at higher risk of progression to severe disease if infected with SARS-CoV-2
- Immunocompromised
 - -Multiple studies now show inadequate response to vaccination in many of these groups with risk of infection, severe disease and death despite full vaccination
- Those who completed their vaccine series longer ago
 - —Antibody titers wane with time from natural infection or vaccination

Lower estimates of VE for mRNA vaccines among immunocompromised populations: Published evidence



- 71% (CI 37-87%) against SARS-CoV-2 infection 7-27 days after 2nd dose of Pfizer-BioNTech vaccine among immunosuppressed* people vs. 90% (CI 83-96%) overall¹
- 80% against SARS-CoV-2 infection ≥7 days after 2nd dose of mRNA vaccine among people with IBD on immunosuppressive medication²
- 75% (CI 44-88%) against symptomatic COVID-19 7-27 days after 2nd dose of Pfizer-BioNTech vaccine among immunosuppressed* people vs. 94% (CI 87-97%) overall¹
- 59% against COVID-19 hospitalization among immunocompromised ≥14 days after
 2nd dose of mRNA vaccine³ vs. 91% (CI 86-95%) without immune compromise³

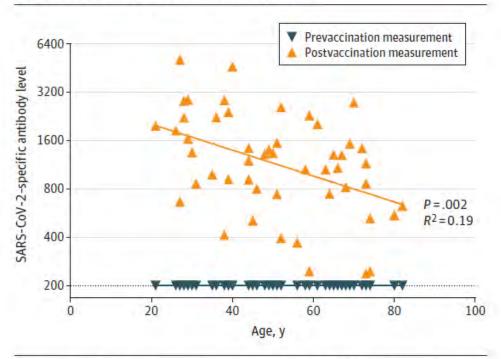
^{*}Immunocompromised conditions (e.g., recipients of hematopoietic cell or solid organs transplant, patients under immunosuppressive therapy, asplenia, and chronic renal failure: advanced kidney disease, dialysis, or nephrotic syndrome)

Age-Dependent Neutralization of SARS-CoV-2 and P.1 Variant by Vaccine Immune Serum Samples

JAMA Network

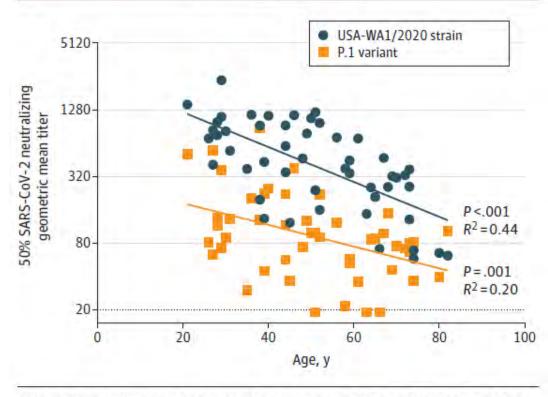






Enzyme-linked immunosorbent assay measurement of SARS-CoV-2 spike receptor-binding domain-specific antibody levels and association with age at time of vaccination for 50 participants 14 days after receiving their second vaccine dose. Prevaccination samples for all participants were below the limit of detection, indicating no prior exposure. Postvaccination samples displayed a significant negative association with age. The dotted line indicates the lower limit of quantification.

Figure 2. Neutralization of Live SARS-CoV-2 Clinical Isolates



Live virus neutralization of participant serum samples collected 14 days after the second vaccine dose. Neutralization experiments were performed with the USA-WA1/2020 strain and P.1 variant. Both show a significant negative association with participant age. The dotted line indicates the lower limit of quantification.

The booster debate in the U.S.



- Pfizer-BioNTech proposing third dose for those at highest risk particularly to augment protection against variants
- FDA and CDC said Americans don't need third doses yet
- WHO has called for a moratorium on booster shots in wealthy countries until the end of September to focus on getting vaccine supplies to help all countries vaccinate at least 10% of their populations
- Latest update is FDA expects to have a strategy by early September 2021 about who will get booster and when

COVID-19 Monoclonal Antibody Therapy Treatment



- Infuse monoclonal antibodies to non-hospitalized persons with confirmed SARS-CoV-2 infection and mild to moderate illness to reduce likelihood of hospitalization and severe disease
- Reduced risk of hospitalization and death vs placebo (1 vs 3.2%; 70% relative risk reduction)
 - —Need to treat within 10 days of symptom onset
 - –Need to have a +COVID test
 - Cannot be on supplemental oxygen for COVID
 - Need to have a risk factor for severe disease

• BMI \geq 25 -Pregnant

Chronic kidney disease
 Cardiovascular disease

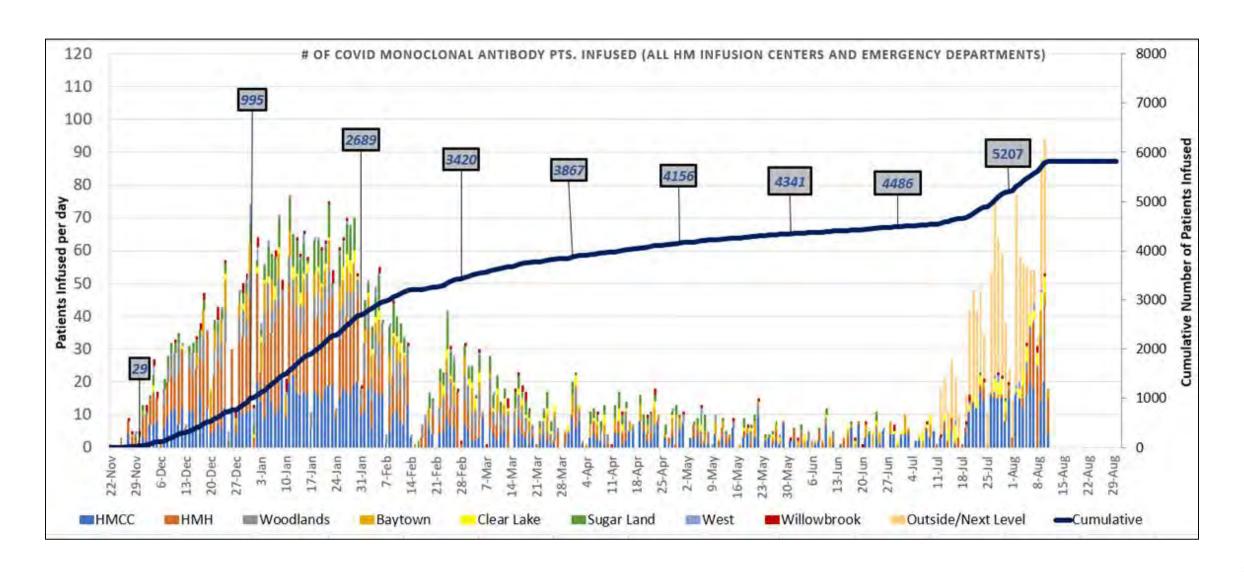
• DM -COPD/chronic respiratory disease

Immunosuppressive disease or rx
 -Sickle cell disease

• Age <u>></u> 65 -Other

Monoclonal Antibody Infusions at Houston Methodist





COVID-19 Monoclonal Antibody Therapy Prophylaxis



- Vaccination is the best strategy to prevent COVID-19
 - -Vaccination coverage is not 100%
 - —Some persons have poor response to vaccination and remain at risk despite full vaccination
- Monoclonal antibody casirivimab-imdevimab got EUA 7/30 for post-exposure prophylaxis for high-risk persons
 - -Patient has close exposure to a COVID+ person (>15 minutes in close contact)
 - —And person is either unvaccinated or unlikely to have responded to a vaccine (SOTR, immunosuppressed)
 - —And patient has a high-risk condition (list is the same as for treatment)



THANK YOU FOR ATTENDING OUR TOWN HALL CONVERSATION

If you'd like more information about the topics discussed today, or would like to support the COVID-19 Front-Line Heroes Appreciation Initiative, please contact us at foundation@houstonmethodist.org.

Take care and be well

