





The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XVII

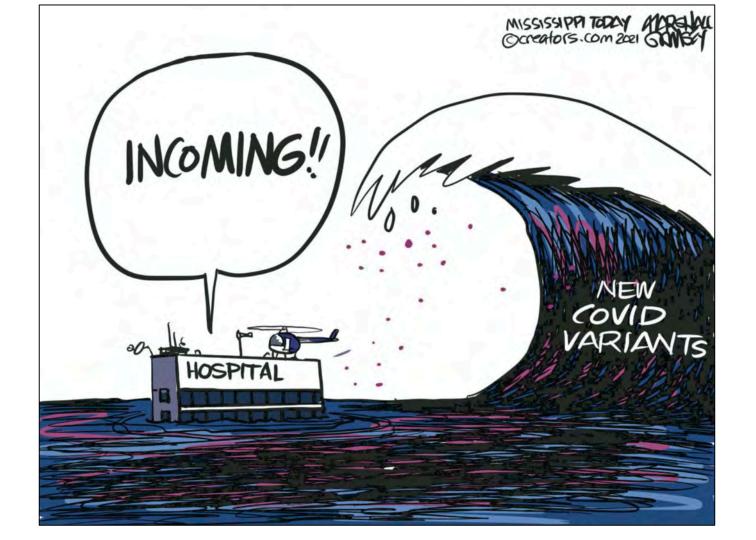
We will begin at 10 a.m.



COVID-19 and Vaccine Update

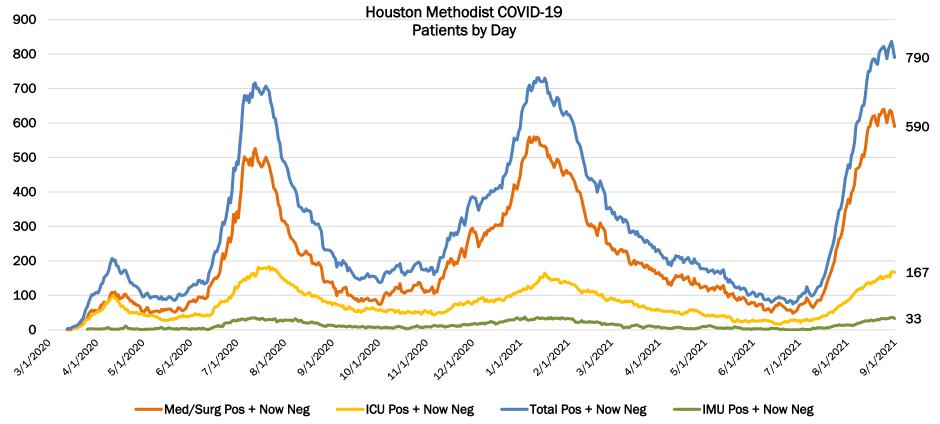
Marc L. Boom, MD September 2, 2021





Houston Methodist COVID-19 Cases by Day



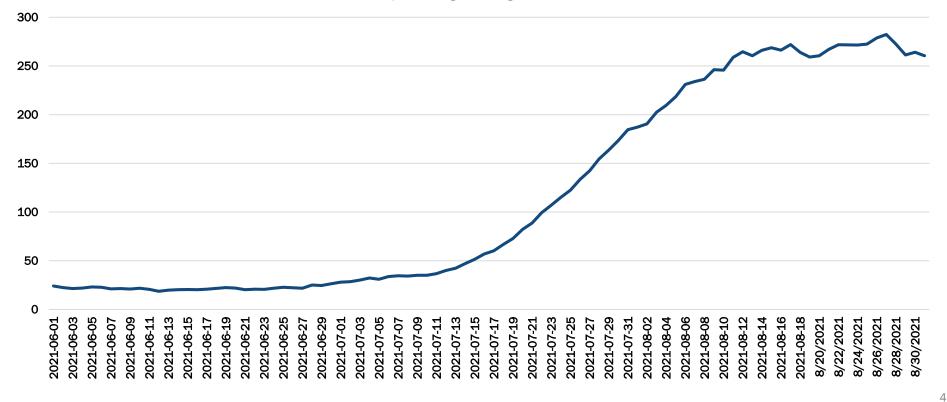


Data as of September 1, 2021

Houston Methodist COVID-19 7-Day Average Positive Tests



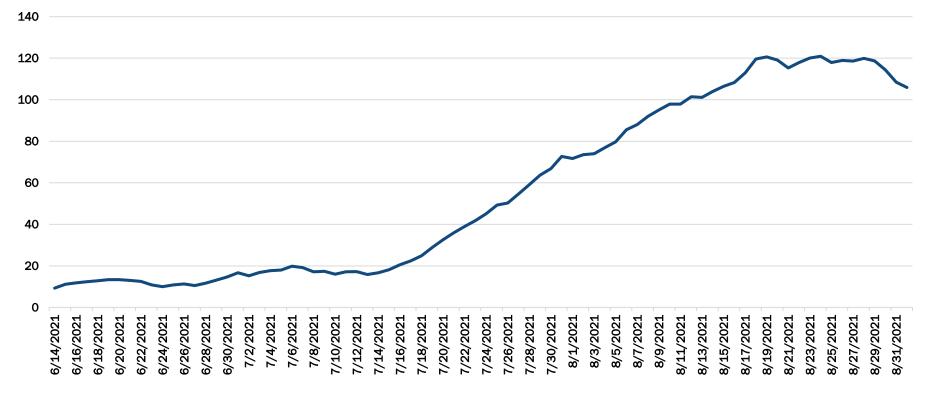
Seven Day Rolling Average Positive Tests



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



7 Day Average Admissions per Day



Houston Methodist COVID-19 Hospitalization Predictions





TMC Hospitals Release Letter to Community



TMC TEXAS MEDICAL MEDICAL MEDICAL MEDICAL MEDICAL Health Health Health Health Health

An Open Letter to the People of Houston,

As CEOs of large hospital systems serving the greater Houston region, we are constantly asked for advice regarding the return of our children to schools. Therefore, in the spirit of working together as a community to achieve a common goal of safely educating our children, we offer the following letter with scientifically and medically backed advice for schools, parents, and the broader Houston community.

In ordinary times, back-to-school season is a time of hopeful anticipation. Milestones are celebrated. New shoes and backpacks acquired. Children look forward to reconnecting with old friends and meeting new ones. The new school year is full of promise and possibilities.

These are not ordinary times.

In the second year of our great pandemic, for parents the start of this school year has become a disconcerting blend of guilt, anxiety, and apprehension. It is time to go back to school. Virtual options are less available than last year. The pandemic education experience to date has left many behind academically and has taken a social, emotional, and economic toll on children and families. This year, most families do not have the option of virtual learning. Parents cannot stay home from work to home school. They have little choice but to return their children to school, and in doing so are asking themselves: Am I putting my child's health at risk?

Even in the midst of the pandemic — and as the Delta variant surges — we have tools to provide a relatively safe school environment with an acceptable level of risk. However, creating safe schools will not occur by luck. It will require a thoughtful, unified collaboration between schools, parents, and our community. Each one of us has a role to play in ensuring a safe and healthy return to school for Houston students, even if you are not a parent, teacher, or student.

Let us start with the good news. We know children tend to have milder disease. We have experience across the country last year with safe school openings with appropriate safety protocols in place'. Over the course of the entire pandemic, there have been just over 400 documented deaths in the United States of children under eighteen. One death is too many, and statistics are of little comfort if it is your child, but out of 73 million children in the US, the absolute risk is still very low.

However, If COVID-19 has taught us anything, it should be humility related to what we do not know. We cannot be complacent. Most of our documented, epidemiologically validated data to date comes from before the emergence of the Delta variant. Delta is clearly more infectious. Pediatric cases are on the rise, and in some areas of the country they are beginning to strain hospital ICU capacity. Although the risk to the overall pediatric population remains statistically low, some children do become critically ill. The Delta variant is different than its predecessors and needs to be taken seriously.

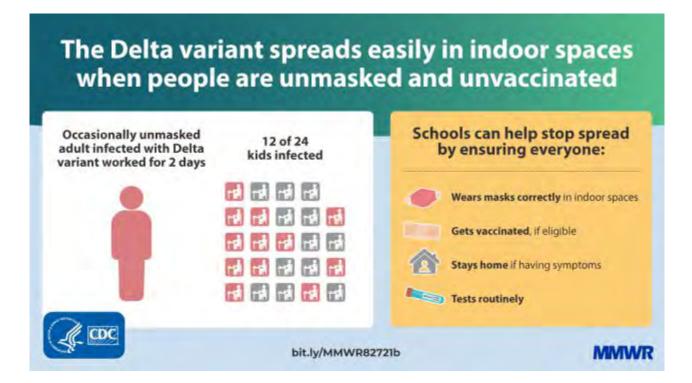
Another cause for caution. While the virus has changed, so have the schools. Where much of last school year was blended with lower than normal classroom density, there are less virtual options this year, and classroom density will almost certainly be higher, making effective distancing more difficult.

Guidelines for schools and school systems:

- Strongly encourage vaccination of your faculty and staff. Require vaccination if you can. At a minimum, strongly encourage vaccination. This is our single most powerful tool to protect ourselves, our community, and our children. Vaccines are safe, effective, free, and available.
- Implement masking for all people in school buildings faculty, staff, and students.
- Promote distancing. Maintain at least three feet of space between students, when possible, within the practical limits of your facilities.
- Limit or eliminate outside guests/visitors to school buildings.
- Do everything possible to discourage teachers and staff members from coming to work if they are sick (fever, cough, breathing difficulty, fatigue, body aches, sore throat, congestion, loss of taste or smell, diarrhea, headache), or if they test positive for COVID-19.

CDC Warns of COVID-19 Outbreaks in Elementary Schools





Five Difficult Lessons



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

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

 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

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 Our social lives must take a backseat to the "Sacred AND"

No bars

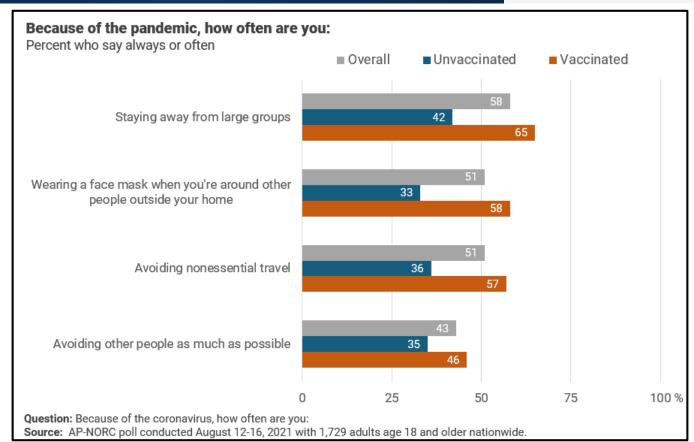
- No large gatherings, including sporting events
- Limited social gatherings

5. Masks are a means to accomplish the "Sacred AND"

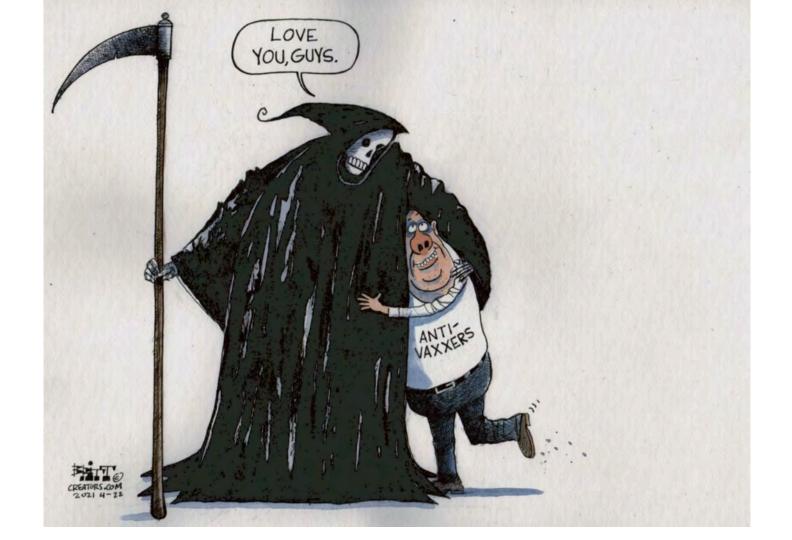
- We have proven to be incapable of accepting this on our own
- Masks must be mandatory until the virus is in control

Behaviors of Vaccinated vs. Unvaccinated



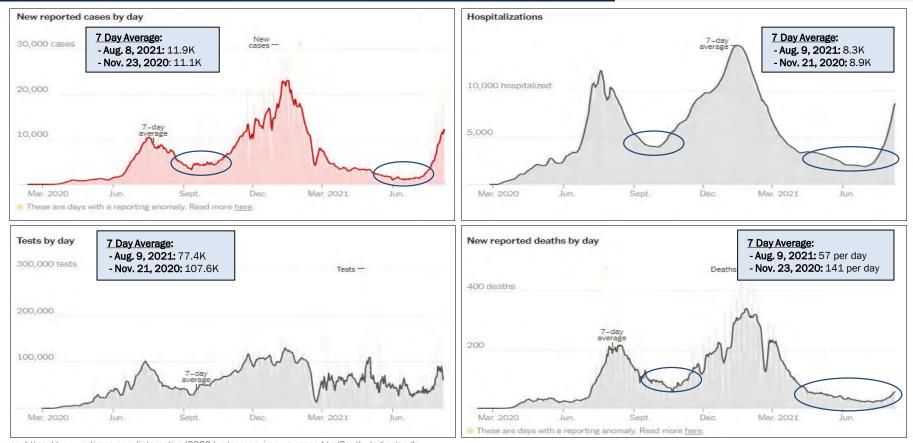






Texas COVID-19 Trends

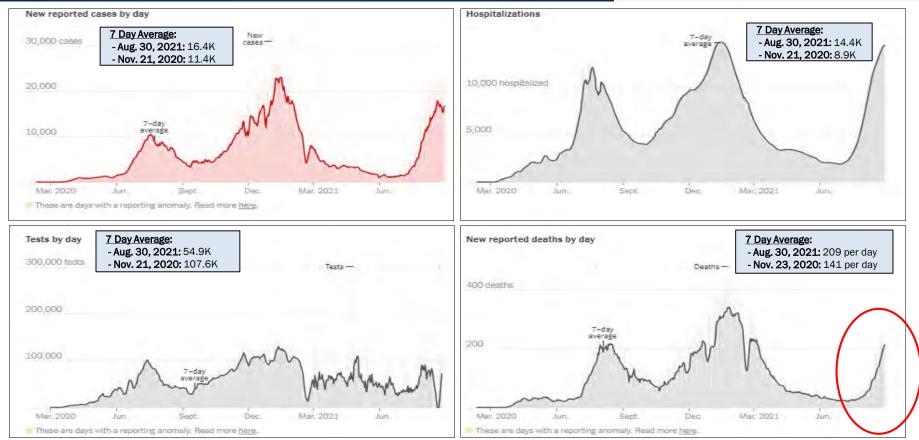




Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?auth=login-google

Texas COVID-19 Trends

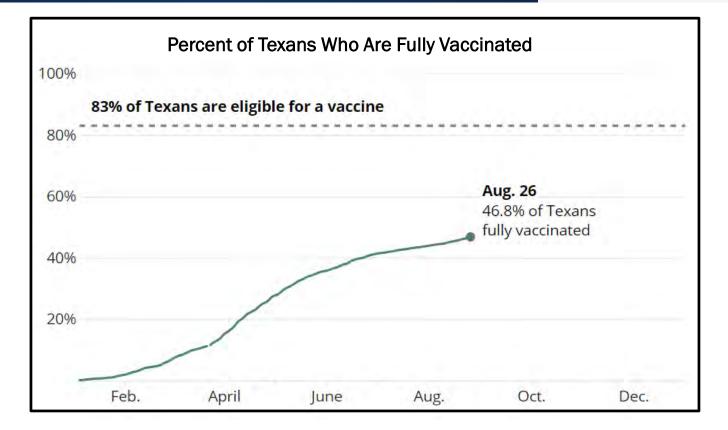




Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html?auth=login-google

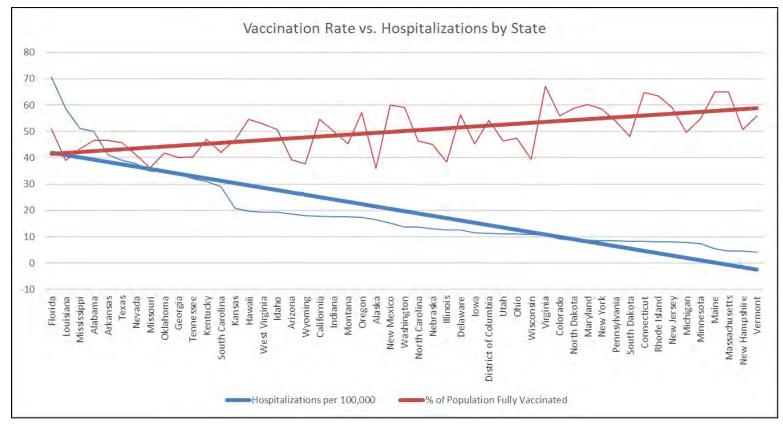
Rate of Fully Vaccinated Texans





Vaccination Rate vs. Hospitalizations by State





Top 50 Most Vaccinated Countries



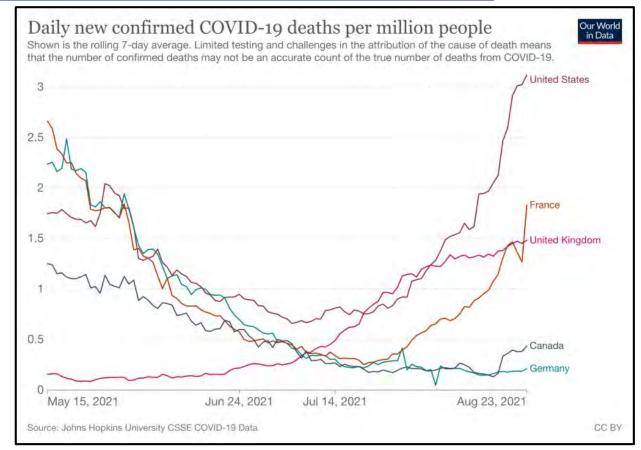
			% of Population	
Deals	0	Total Doses	Partially	% of Population
Rank	Country	Given per 100k		Fully Vaccinated
1	Malta	180,354	93.70%	
2	Singapore	151,718		
3	Qatar	157,284		
4	Portugal	143,046		
5	Iceland	145,981	77.30%	
6	Uruguay	161,405		
7	Denmark	147,353		
8	Chile	153,180	76.10%	72.10%
9	Seychelles	145,912	75.00%	70.90%
10	Belgium	141,046	73.30%	70.80%
11	Spain	139,502	77.40%	70.10%
12	Ireland	138,343	74.60%	68.40%
13	Canada	141,912	74.30%	67.60%
14	Mongolia	134,369	69.40%	64.90%
15	Britain	136,149	71.90%	64.20%
16	Bahrain	146,282	67.40%	64.00%
17	Bhutan	135,873	73.60%	62.30%
18	Netherlands	126,245	69.00%	61.70%
19	Italy	129,095	70.70%	60.80%
20	Germany	122,553	65.30%	60.70%
21	Israel	151,800	66.10%	60.60%
22	France	130,370	72.20%	59.70%
23	Austria	117,795	62.00%	58.60%
24	Greenland	129,104	70.90%	58.20%
25	Norway	130,013	72.30%	57.70%

		Total Doses	% of Population	
		Given per	Partially	% of Population
Rank	Country	100k	Vaccinated	Fully Vaccinated
26	Luxembourg	123,139	65.70%	57.40%
27	Monaco	122,888	66.50%	56.30%
28	Maldives	126,715	70.90%	55.80%
29	Mauritius	118,234	62.60%	55.70%
30	Sweden	122,493	67.00%	55.50%
31	Lithuania	113,654	59.50%	54.10%
32	Liechtenstein	113,467	60.30%	53.90%
33	Czechia	107,557	55.70%	53.70%
34	Greece	106,460	56.50%	53.50%
35	Andorra	118,820	66.20%	52.70%
36	U.S.	111,511	61.80%	52.40%
37	Switzerland	112,118	58.10%	51.90%
38	Cambodia	115,767	65.50%	51.70%
39	Finland	123,671	72.90%	50.80%
40	Poland	95,564	50.80%	49.50%
41	Ecuador	110,862	61.60%	49.30%
42	Malaysia	108,772	61.80%	47.00%
43	Japan	103,671	57.30%	46.30%
44	Turkey	112,871	57.90%	44.50%
45	Saudi Arabia	108,359	64.80%	43.50%
46	Dominican Republic	103,847	54.20%	43.40%
47	Cyprus	91,308	47.90%	43.40%
48	Slovenia	90,866	47.50%	43.30%
49	El Salvador	97,595	54.90%	42.70%
50	Morocco	92,460	51.30%	41.20%

Source: https://www.washingtonpost.com/graphics/2020/world/mapping-spread-new-coronavirus/

Daily COVID-19 Deaths Comparison Across Countries





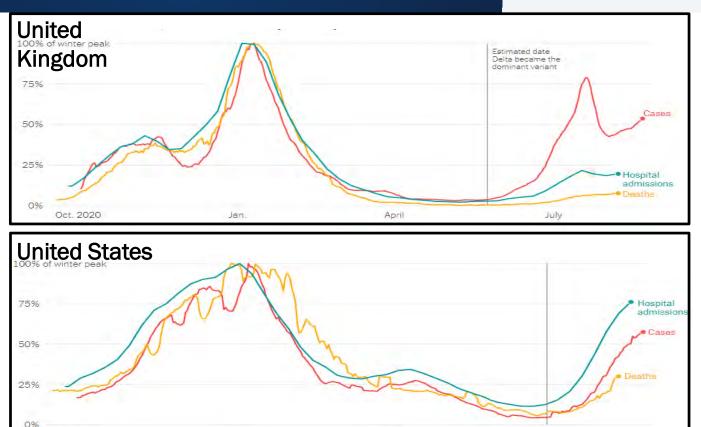
18



U.S. and U.K. Comparison of COVID-19 Cases, Hospitalizations, and Deaths



July

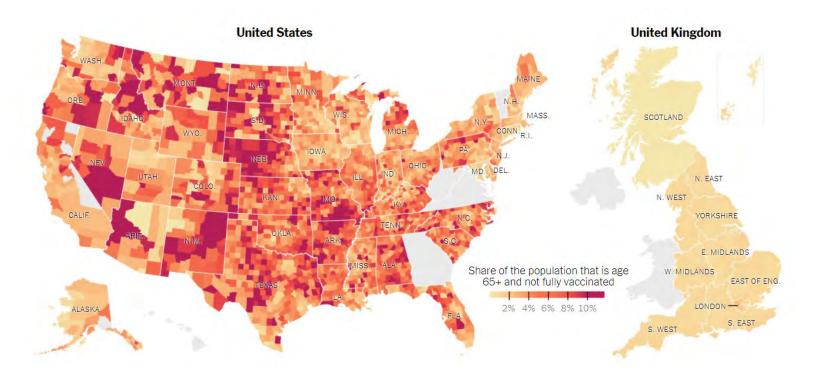


April

Jan.

U.S. and U.K. Comparison of Unvaccinated 65+





https://www.nytimes.com/interactive/2021/08/24/world/vaccines-seniors.html?ullocked_article_code=AAAAAAAAAAAAAAAACHPuonUyYiZ_tU1Gw5CRWySB4B991re1b-VnPsjgWX6IG-LQD1JzulYGM2b9kHMYrB4Us2JDRDPHvDIgSft0gh0l0k4qDAiuvpaek28Zijs47oviDj1sg8LAG000qmavMzfmdKJ1n-Gy-hvbYTbuCqaPg3Vyc134scwLSHcOnYCzqtAEu5zy4MiaghXsYmMG9GMCcavPDocWrBMcGGa3zf4zoxX0/ZXILDIILWauJAEz/VwWwHD4o6n086dhfJNocIK_GSh/resb6ir4VYXd6vatmonG09cYCK-MKOSdvhu0&snid=em-share





The 4.53 M dead around the world would stretch from the West Coast of the U.S. to London!





FDA Approves Pfizer COVID-19 Vaccine – August 23, 2021

THE WALL STREET JOURNAL Subscribe Sign In Home World U.S. Politics Economy Business Tech Markets Opinion Books&Arts Real Estate Life&Work WSJ. Magazine Sports Q BUSINESS | HEALTH CARE | HEALTH SHARE FDA Approves Pfizer-BioNTech Covid-19 Vaccine for G People 16 and Older Approval, based on six months of clinical data, comes less than four months after submission in 0 The New Hork Times The F.D.A. grants full approval to the Pfizer-BioNTech Covid-19 vaccine. Covid-19 Boosters Are Coming: Here's Wh to Know



FDA NEWS RELEASE FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

f Share 🔰 James 👔 Linkedin 🔤 Email 🖨 Print

For Immediate Release: August 23, 2021

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product," said Acting FDA Commissioner Janet Woodcock, M.D. "While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated. Today's milestone puts us one step closer to altering the course of this pandemic in the U.S."

Pfizer Vaccine Fully Approved

tion.

Holy cow. The lengths some

tion.





Now we all know. No more

And it's time for the private

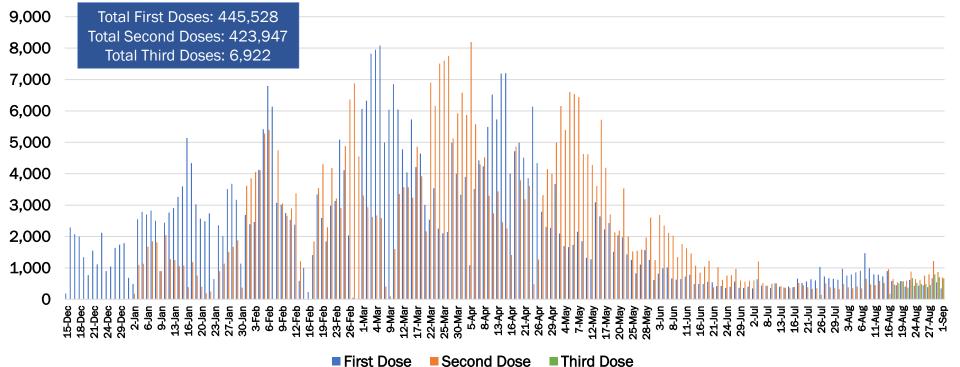
per day are getting their first dose

26

HM COVID-19 Vaccines Administered







Infections and Hospitalizations Among Unvaccinated in Los Angeles



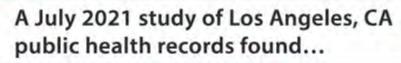




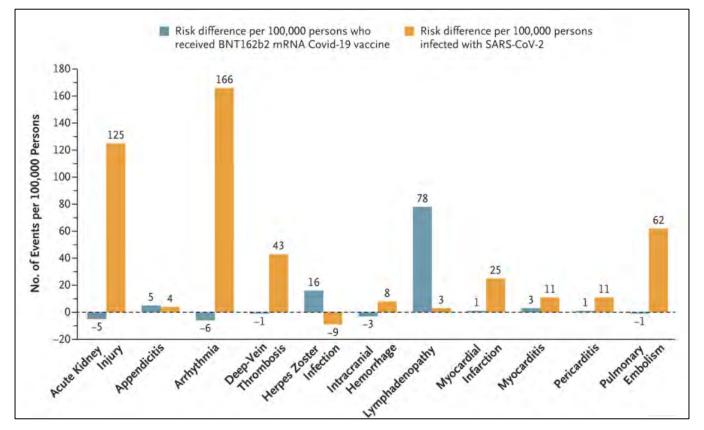


TABLE. Effectiveness of COVID-19 vaccines against any SARS-CoV-2 infection among frontline workers, by B.1.617.2 (Delta) variant predominance and time since full vaccination — eight U.S. locations, December 2020–August 2021

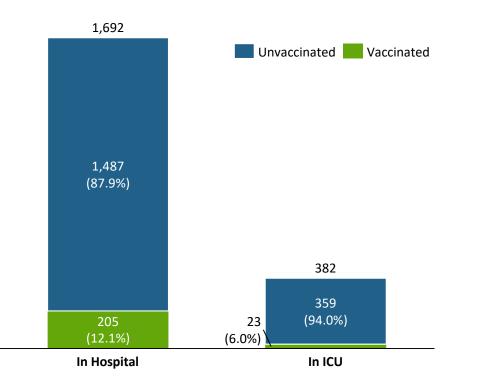
Period and vaccination status	No. of contributing participants*	Total no. of person-days	Median days (IQR)	No. of SARS-CoV-2 infections	Adjusted VE, [†] % (95% CI)
Full cohort to date					
Unvaccinated	4,136	181,357	20 (8-45)	194	N/A
Fully vaccinated [§]	2,976	454,832	177 (115-195)	34	80 (69-88)
14-119 days after full vaccination	2,923	284,617	106 (106-106)	13	85 (68-93)
120–149 days after full vaccination	2,369	66,006	30 (30-30)	3	81 (34-95)
≥150 days after full vaccination	2,129	104,174	52 (37-64)	18	73 (49-86)
Pre-Delta variant predominance					
Unvaccinated	4,137	156,626	19 (8-43)	175	N/A
Fully vaccinated	2,875	329,865	124 (95-149)	10	91 (81-96)
Delta variant predominance					
Unvaccinated	488	24,871	43 (37-69)	19	N/A
Fully vaccinated	2,352	119,218	49 (35-56)	24	66 (26-84)

NEJM: Absolute Excess Risk of Adverse Events after Vaccination or COVID-19 Infection





TMC TOTAL HOSPITALIZATIONS BY VACCINATION STATUS^{1,2}



1. Includes: Harris Health System, Houston Methodist, MDA Cancer Center, St. Luke's, Texas Children's Hospital, and UTMB.

2. Data is snapshot from 8/20/21 and will be updated daily as soon as daily reporting is finalized by all Institutions. This is in progress and should be completed week of September 1.

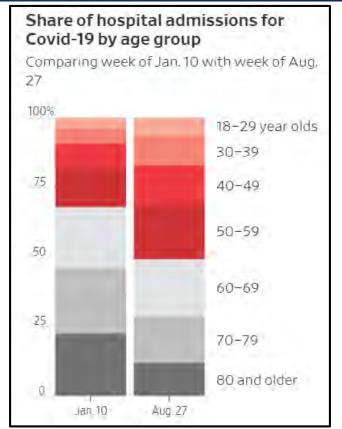
MC TEXAS MEDICAL CENTER

 A significant majority of TMC total hospitalized and ICU patients are unvaccinated.

This document is solely intended to share insights and best practices rather than specific recommendations. Individual institution data is shown as reported and has not been independently

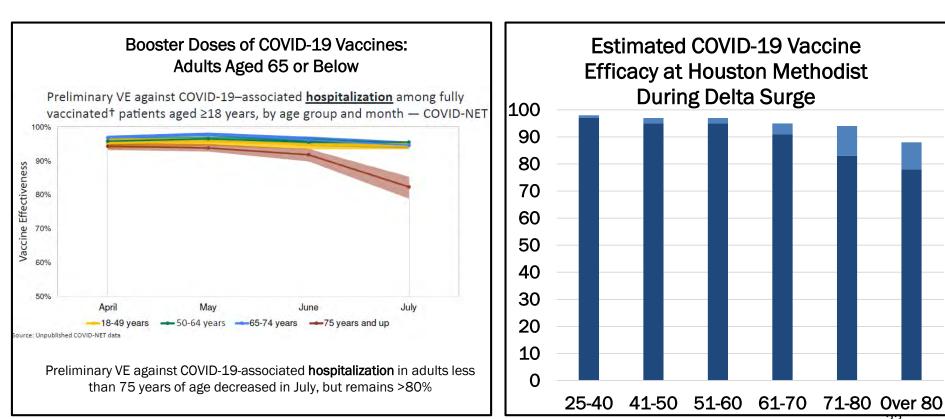
COVID-19 Hospitalizations by Age Group





CDC Estimate of Vaccine Efficacy During Delta Surge vs. "Back of the Envelope" Estimate





https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/09-COVID-0liver-508.pdf

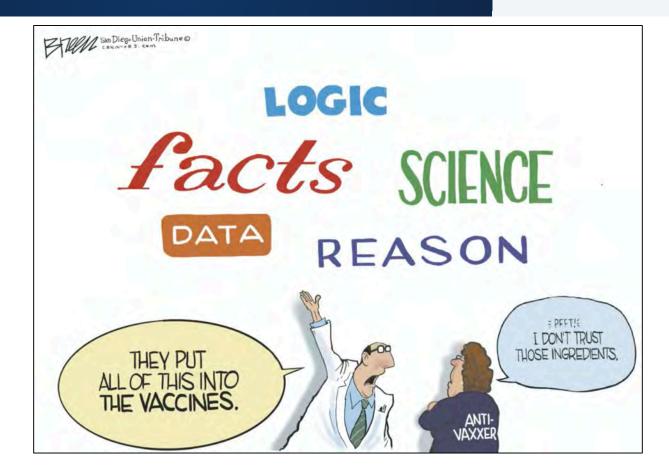
Employers' Central Role in Vaccinating the Population



- Ethical responsibility to protect customers
- Ethical responsibility to create a safe workplace
- Maintenance of operations
- Economic stability
- Financial cost of employees with COVID

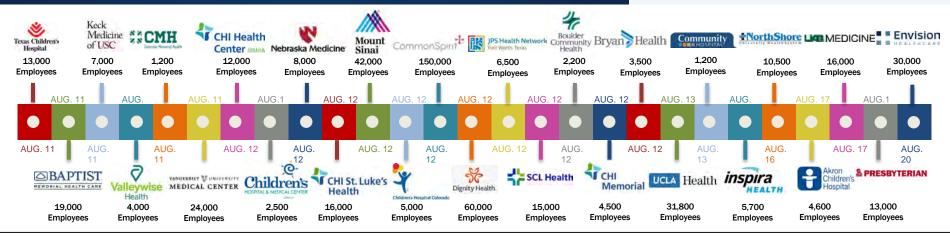
The Employers' Job is Not Easy!

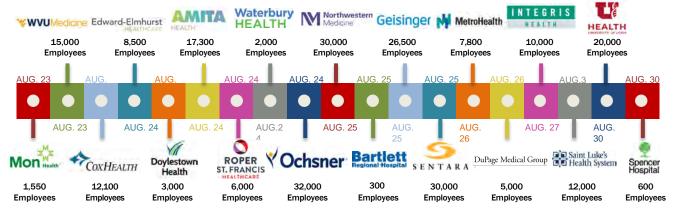




Hospitals Announcing COVID-19 Mandates Since Last Town Hall Conversation

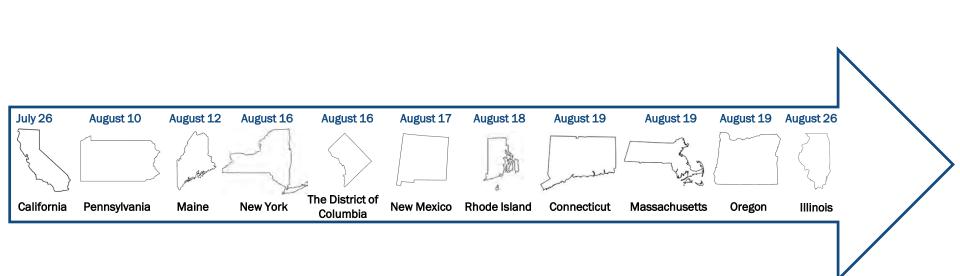






Multiple States Announce COVID-19 Vaccine Mandate for Healthcare Workers







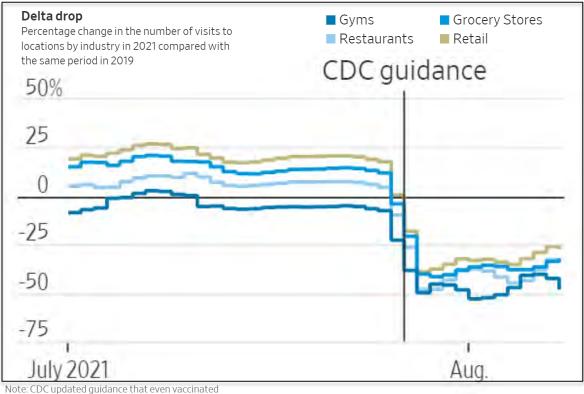


In the past month I've been writing one to three letters per week to families of employees who lost their life, all unvaccinated," he said. "And so, to me, once you view the world through that prism, it seemed like no choice. It's about saving lives.

> - Scott Kirby CEO of United Airlines

Delta Variant's Mark on Businesses

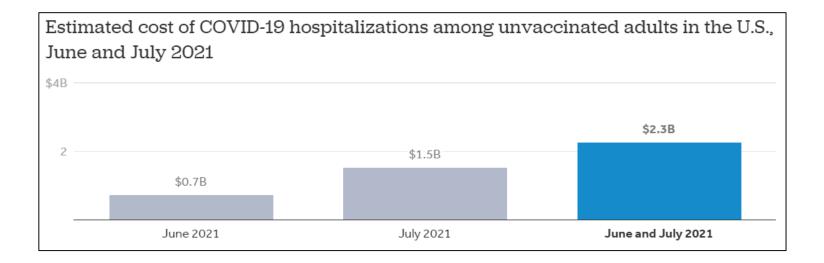




Americans should wear masks indoors where infection rates are high. Source: SafeGraph

Unvaccinated COVID-19 Hospitalization Cost to Society





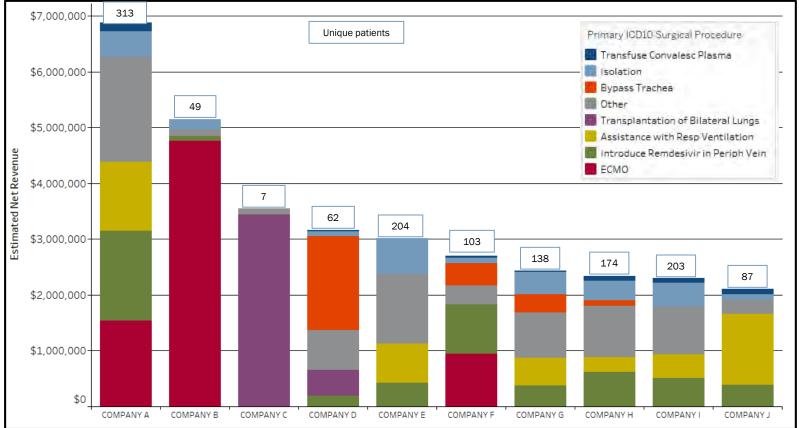
COVID-19 Cost Comparison Across Private Employers at Houston Methodist



	Non-COVID	COMPANY A	COMPANY B	COMPANY C	COMPANY D	COMPANY E	COMPANY F	COMPANY G	COMPANYH	COMPANY	COMPANY J
_	\$55,000,000-	88.9%			_						
	\$50,000,000-										
	\$45,000,000-	-									
le	\$40,000,000-	1									
Estimated Net Revenue	\$35,000,000										
ed Net	\$30,000,000	-			-	89.7%			92.9%	92.1%	
stimat	\$25,000,000-	•							-		
ш	\$20,000,000-						88.1%	87.5%			89.3%
	\$15,000,000	-			20.00						
	\$10,000,000-	11.1%	64.1%	1	76.3%						
	\$5,000,000- \$0_		35.9%	76,9%	23.7%	10.3%	11.9%	12.5%	7.1%	7.9%	10.7%

Private Employers with COVID-19 Costs >\$2 Million at Houston Methodist





Data From: Q2 2020 through Q2 2021 Source: EPSi

Delta CEO's Memo to Employees For COVID-19 Vaccination



he Washington Post

Delta Air Lines to require that employees be vaccinated or pay health insurance surcharge

The carrier is the latest major employer to push workers to get coronavirus shots, although the airline industry hasn't settled on a uniform approach

A Listen to article 4 min



Delta's robust actions to increase our vaccination rate:

- Effective immediately, unvaccinated employees are required to wear <u>masks</u> in all indoor Delta settings
- Starting Sept. 12, any U.S. employee who is not fully vaccinated will be required to take a <u>COVID</u> test each week
- Beginning Nov. 1, unvaccinated employees enrolled in Delta's account-based healthcare plan will be subject to a <u>\$200 monthly</u> <u>surcharge.</u>
 - The average hospital stay for COVID-19 has cost Delta \$50,000 per person. This surcharge will be necessary to address the financial risk the decision to not vaccinate is creating for our company.
- Effective **Sept. 30**, in compliance with state and local laws, COVID pay protection will <u>only</u> be provided to <u>fully vaccinated individuals</u> who are experiencing a breakthrough infection.

Gallup: Workers Have Strong Views on Vaccine Mandates



U.S. Employees' Views of Employer Vaccination Requirements

How would you feel about your employer requiring all employees (who do not have a medical exemption) to receive the coronavirus/COVID-19 vaccination?

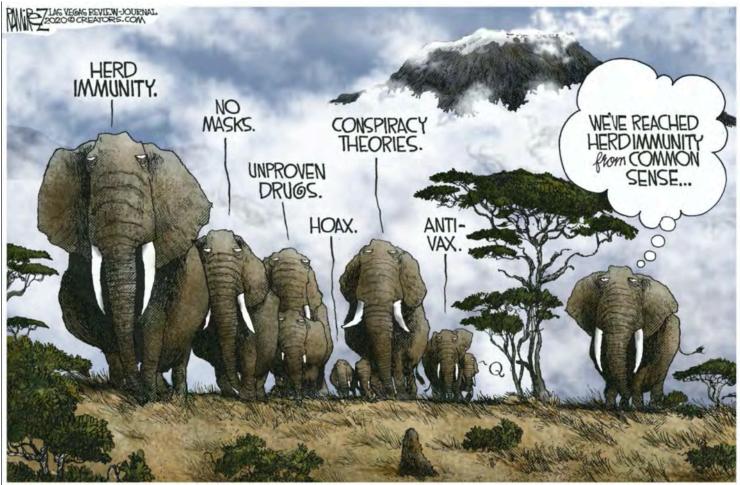


U.S. Employees' Reports of Employer Vaccination Policy

To the best of your knowledge, will your employer require or encourage employees to get vaccinated for coronavirus/COVID-19 in order to return to the workplace?



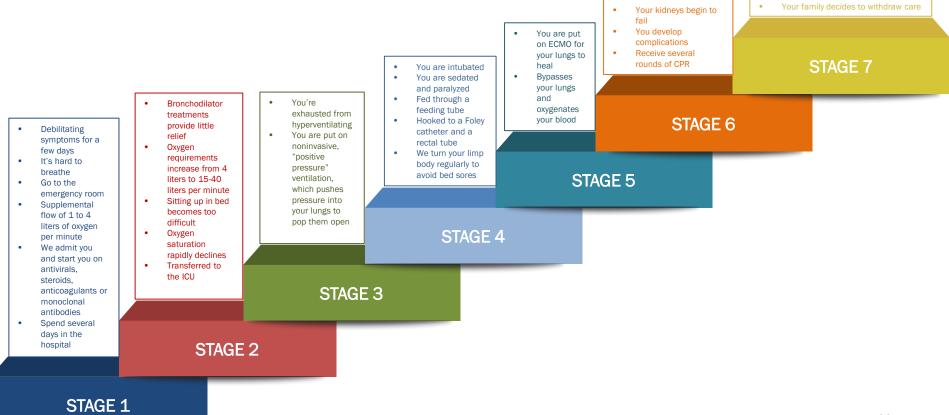
- 52% favor their employer requiring all employees to receive the COVID-19 vaccine
- 45% of individuals said that cash incentives and PTO would make them more likely to get the COVID-19 vaccine





michaelpramirez.com

On the Front Lines: One Respiratory Therapist's Methodist Perspective on the Seven Stages of Severe COVID-19 LEADING MEDICINE



Source: https://www.latimes.com/opinion/story/2021-08-26/pandemic-covid-19-stages-vaccination-intensive-care-respiratory-therapist

٠

Real Conversations Between a Houston Physician and Her COVID Patients

LEADING MEDICINE

"When will my breathing get better?"

"I don't know. Every person is different."

"When will I get to go home?"

"When your oxygen is better."

"When will my oxygen get better?"

"It's difficult to predict. A few days, a week, two or three weeks? Some patients have stayed for months."

"Am I getting better at all?"

"Well, you're not getting worse, so let's try to focus on that."

"Am I going to be OK?"

"We're doing everything we can to get you better."

"But really, do you think I'll be alright?"

"It's too early to say right now. We're doing everything we can. Time will tell."

"Can I get the vaccine now?"

"No, it's too late."

"How soon can I get it?"

"After you recover."

"When will that be?"

"Again, I don't know. COVID-19 takes time and is unpredictable."

"Doctor, am I going to die?"

"You are very sick and that is a real possibility, but we are doing everything we can to get you through this. We have to take this one day at a time."

"What if I get worse?"

"We'll have to consider putting you on a ventilator."

"How long would I be on a ventilator?"

"At least two to four weeks, maybe longer."

"What would be my chances of making it?"

"If you're sick enough to require a ventilator, the survival rate has been less than 20 percent."

"Can you check on my daughter? She's in the ER right now."

"Yes, I can."

Can you check on my husband? He's getting intubated in the ICU right now."

"Yes, I can do that."

"So, I urge everyone: If you trust us enough to rush to us when you're sick, which means you trust us enough to try to save your life, then trust us now. Help us save your life now, before it may be too late."
Nicole Zeisig, Hospitalist at Memorial Herman Sugar Land Hospital

COVID-19 Vaccine Myths



The COVID-19 vaccine can affect my fertility

Why it's false: There's no data to suggest that these vaccines pose a risk to someone who is pregnant or wants to become pregnant.



I don't need the vaccine because I've already had COVID-19

Why it's false: You may experience some level of immunity after having COVID-19, but it's unclear how long this protection might last.



The vaccine can affect my DNA

Why it's false: The genetic material in COVID-19 vaccines cannot interact with or change your DNA in any way.



I don't need the vaccine because I'm young and healthy

Why it's false: Even mild COVID-19 can cause uncomfortable and/or lingering symptoms. Plus, even those who are young and healthy must be vaccinated to achieve herd immunity.



A vaccine developed so quickly can't be safe

Why it's false: Available vaccines have undergone thorough testing and external review. These vaccines may seem new, but there's decades of research behind them.



I don't need to wear a mask after being vaccinated

Why it's false: Until herd immunity is reached, wearing a mask and social distancing continue to be important safety measures. МҮТН #3

The vaccine can give me COVID-19

Why it's false: The mild side effects associated with the vaccines are a sign that your body is building immunity to the virus. These vaccines cannot give you COVID-19.

Methodist LEADING MEDICINE It makes me wonder in these situations if the person(s) who refused to get vaccinated and spread it, do they feel guilt or remorse for being the catalyst for someone's life being cut short? Do they not understand that by not doing something, it can have a negative impact on someone else? The pandemic has brought out a lot of selfishness in people and it's completely disheartening. I became a nurse to help those in their time of need, but when will those same people realize that they need to help us (nurses, doctors, health care workers) in return?

> Nurse Practitioner at Houston Methodist

CVICU SPLATTER | UNLEASH | CREATE

CPAM Splatter Paint Tent

WHO: CVICU Staff

WHERE: CVICU Serenity Room

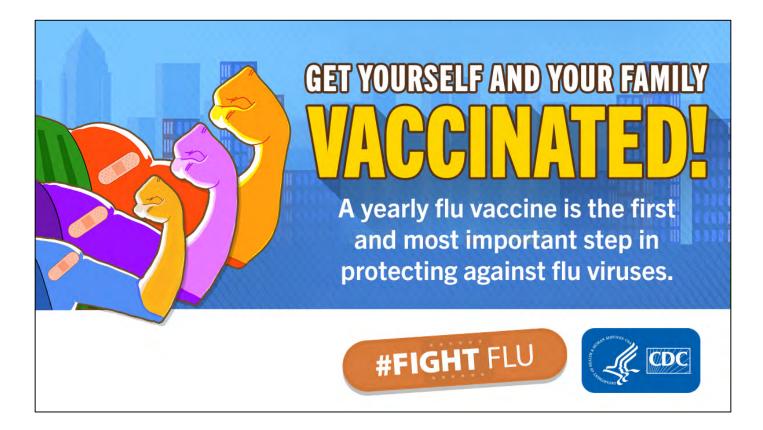
WHEN: September 9-16

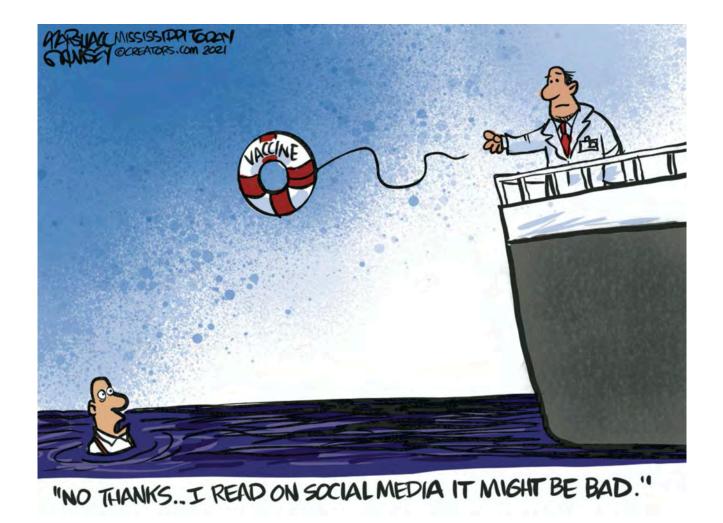
WHY: To creatively unleash stress, with a cathartic experience, and as a team create something beautiful!

CENTER FOR PERFORMING ARTS MEDICINE

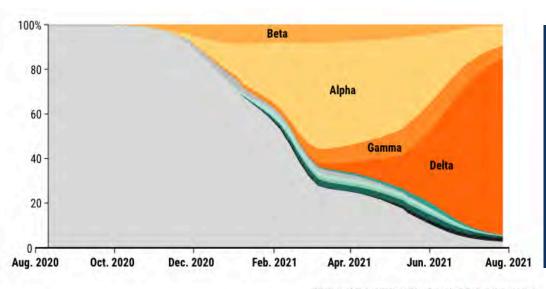
Get your flu shot!











(GRAPHIC) N. DESAI/SCIENCE; (DATA) NEXTSTRAIN; GISAID

Vaccines, Variants and the "Pandoomerang"

Town Hall, September 2, 2021

H. Dirk Sostman, MD FACR Ernest Cockrell, Jr. Presidential Distinguished Chair EVP & Chief Academic Officer





• FDA approved the Pfizer vaccine for prevention of COVID-19 in individuals 16 and older

- -Vaccine still available under EUA for
 - children 12-15 years old and
 - "third dose" in immunocompromised individuals
- -Vaccine will be marketed as Comirnaty (koe-mir'-na-tee) and can be prescribed by physicians now

FDA approval process

- -Submission of a Biologics License Application by the manufacturer
- BLA builds on the data and information that supported the EUA
 - preclinical and clinical trial data in (22,000 vaccinated people with 4-6 month follow-up)
 - long-term effects and potential for rare adverse events
 - how vaccine "efficacy" translates into real-world effectiveness
 - manufacturing quality control and consistency process review and site inspections

FDA Approves Pfizer Vaccine: FAQs August 23 2021



- Can physicians prescribe a booster shot now that the vaccine is fully approved?
 - -Yes. As with other FDA-approved medications, licensed health care providers can
 - prescribe the Pfizer vaccine as approved, or
 - use their judgement for off-label prescribing
- What is an example of off-label?
 - -A licensed provider prescribing a booster shot outside of the FDA's fully-approved uses
 - -Uses covered by EUA are not considered off-label prescription
- Will Houston Methodist vaccine clinics accept off-label prescriptions from a physician for vaccination of a patient who is outside of the FDA approval?
 - -Our vaccine clinics accept off-label prescriptions for patients 16 and older
- What is the Difference Between "Booster" and "Third Dose"?
 - "Third dose" is part of prime series for immune compromised people, given ~28 days after second dose
 - Booster is a third dose given to "top up" antibody levels, given ~6-8 months after second dose

Houston Methodist Vaccine Scientific Committee Advice

August 23 2021



- Should patients be tested for antibody titers prior to third dose?
 - -Evidence that antibody titers are correlated with protection from COVID-19 is strong
 - Data not yet precise enough to standardize clinical management of individual patients
 - The CDC ACIP specifically recommends against use of antibody titers for clinical decision making
 - -Accordingly, we do not require titers prior to a third dose
- If someone has been tested and knows that they have a high titer, is a third dose still recommended?
 - -Serology may be ordered by the patient's physician and interpreted in light of the patient's medical history
 - -Low titers have been used to justify the administration of additional vaccine doses
 - -Less data regarding correlation of higher titers with individual protection
 - -Therefore, we recommend a booster shot at 8 months even in the presence of high antibody titers
- Do we recommend only homologous third doses or are heterologous third doses acceptable?
 - Homologous (e.g., Pfizer Pfizer) third doses are recommended, but heterologous (e.g., Moderna Pfizer) third doses are acceptable

Houston Methodist Vaccine Scientific Committee Advice August 23 2021

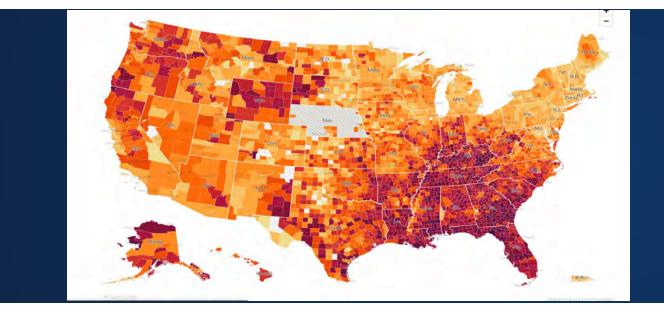


- If someone got a booster already, is another booster still recommended at 8 months?
 - A booster should be administered > 6 months (recommended, 8 months) after the last dose of mRNA vaccine
 - -Those who have already gotten a booster in that timeframe do not need an additional dose
- If < 8 months since completing the prime series, what is the recommendation now?
 - Eligible to receive a third dose as soon as 6 months since completing prime series
 - -Recommended at 8 months
- What about individuals who received one dose of J&J? Should they get a booster? If so, what kind? Also at 8 months?
 - Data is limited and recommendations more tentative
 - J&J can produce durable antibody and cellular responses up to 8 months (239 days) after vaccination
 - -So, it may be less important for individuals who received the J&J vaccine to have a booster now
 - -However, mRNA vaccines produce a more robust early antibody response with higher initial clinical efficacy
 - Accordingly, if an individual wishes to have a booster with an mRNA vaccine in the same time frame after initial vaccination with J&J vaccine, the committee is comfortable with this

Logistics of Third / Booster Doses at Houston Methodist



- As of now, we only have reached out to immunocompromised patients.
- We will continue to administer 3rd doses to those who are immunocompromised and attest to that via our consent process.
- In addition, we will administer 3rd dose boosters by provider order/prescription. If someone who is not immunocompromised wants a 3rd booster, they need a provider order/prescription.
- Until we get more clarity from CDC/ACIP on boosters later in September, we will not send proactive communications on 3rd dose boosters.
- Patients can self-schedule at any of our locations directly from our website for their 3rd dose.
- We will only be administering Pfizer at the vaccine clinics.
- We will update our processes as things develop.



The "Pandoomerang": What Happened?



Social Developments: 5 Steps to Renewed Crisis



- 1. Vaccinations stalled at ~60% of eligible
- 2. CDC announced that vaccinated people do not need masks indoors
 - -Correct based on short term data
 - -Announced without longer term data
 - -Utterly naïve about human behavior
- 3. The entire USA stopped wearing masks
 - Many people headed for the beach or the barAir travel and vacations took off
- 4. Some politicians forbade sensible public health measures
- 5. Delta variant got the opening it needed
 - -Infections disseminated widely

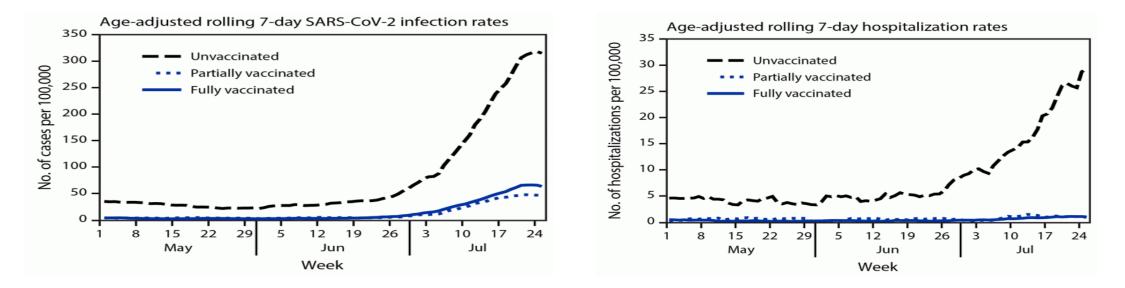


CDC: Vaccine Efficacy Versus Delta Variant

Reduced Effectiveness for Infection, Still Highly Effective Against Severe Disease



	USA – Nursing Homes (Pfizer) MMWR August 18 2021	USA – Nursing Homes (Moderna) MMWR August 18 2021	USA – Health Workers MMWR August 24 2021
Pre-Delta	74%	75%	91%
Delta	52%	51%	66%



MMWR August 24 2021

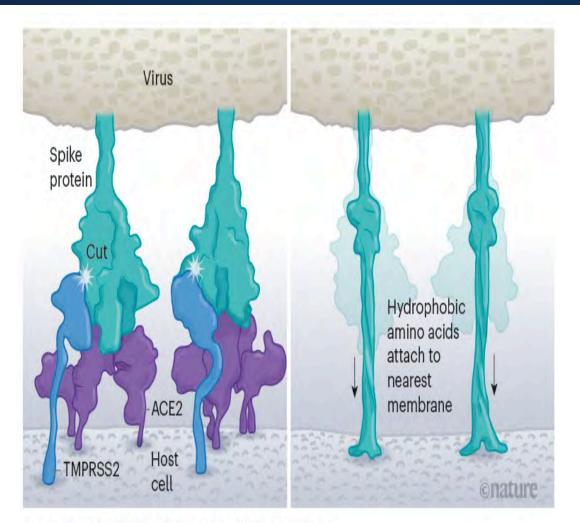


- Host factors
 - -Some people develop lower antibody response to immunization (vaccination or infection)
 - -All antibody levels decline with time after immunization
 - -Although immunized cells mount a rapid response to re-infection, it is not instantaneous
 - -People with breakthrough infections have only 10-35% neutralizing antibody levels as controls
- Virus factors
 - -Delta is 3x less sensitive to neutralization by antibodies against previous strains
 - -Delta 2x more infectious
 - present at high levels in nasopharynx \rightarrow gives high dose of virus
 - more efficient at infecting cells
- High dose of more infectious virus temporarily overwhelms immune defenses
 - -Decoupling between infection and severe disease likely due to immune response "catching up"
- Delta may be associated with more severe disease

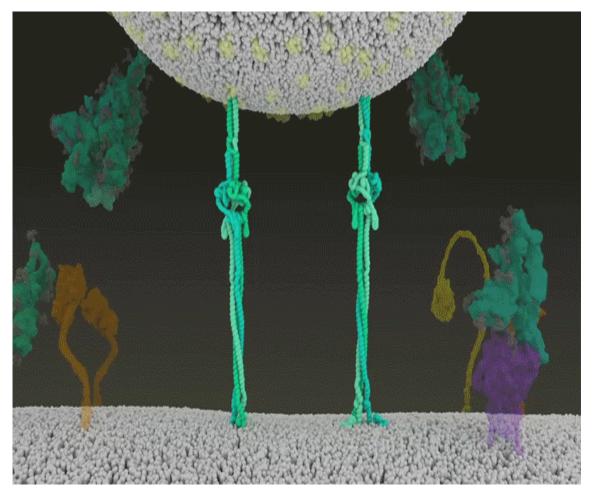
Why is Delta More Contagious?



Spike Protein Function Modification is One Reason



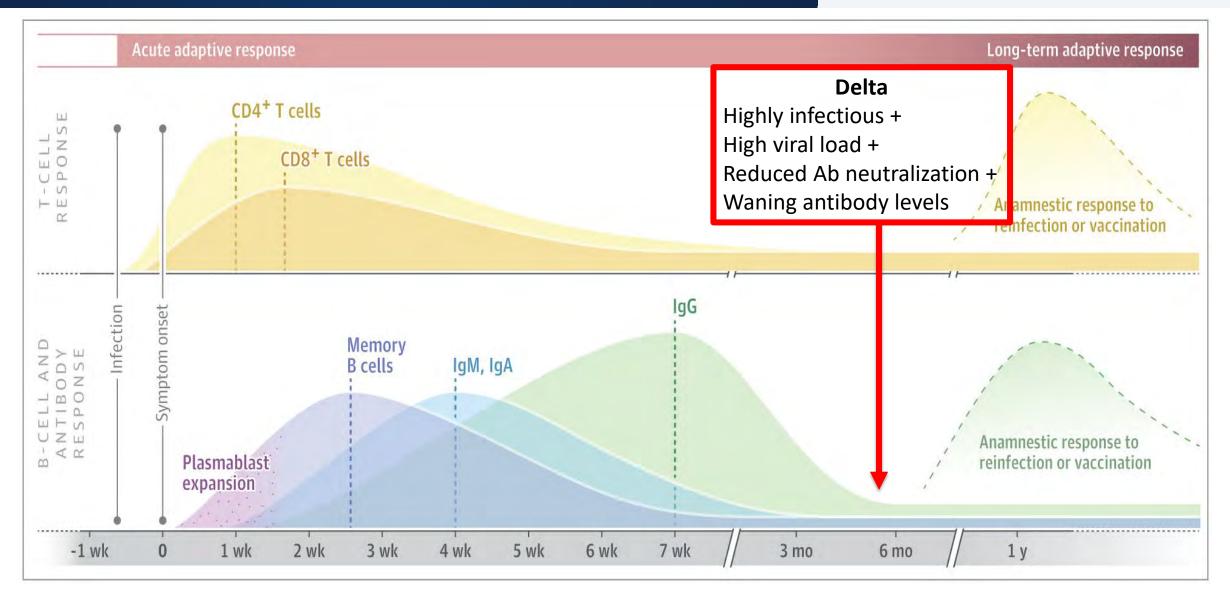
Source: Janet Iwasa, Univ. Utah; Graphic: Nik Spencer/Nature



An animation of the way SARS-CoV-2 fuses with cells. Credit: Janet Iwasa, University of Utah https://www.nature.com/articles/d41586-021-02039-y#ref-CR24

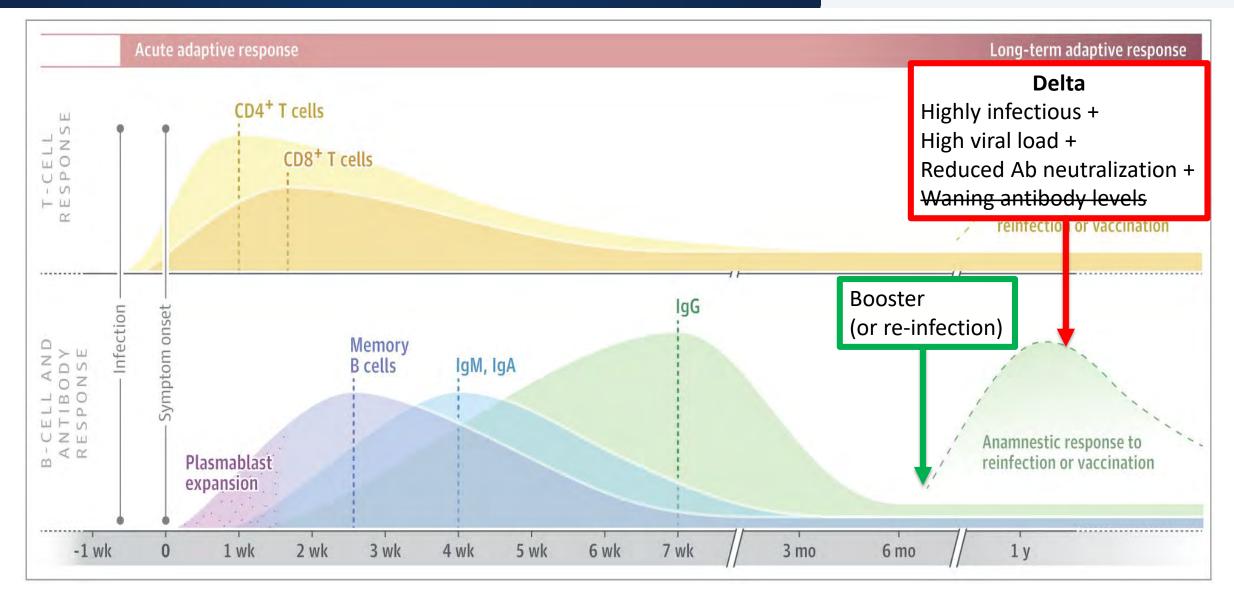
Delta Breakthrough Infections: Putting It All Together





Delta Breakthrough Infections: Rationale for Boosters





Booster Shots

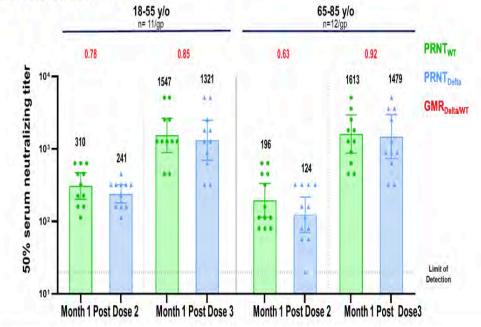
What do they do? Who needs them? How will we deliver them?



Booster Shot In Vitro Data



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

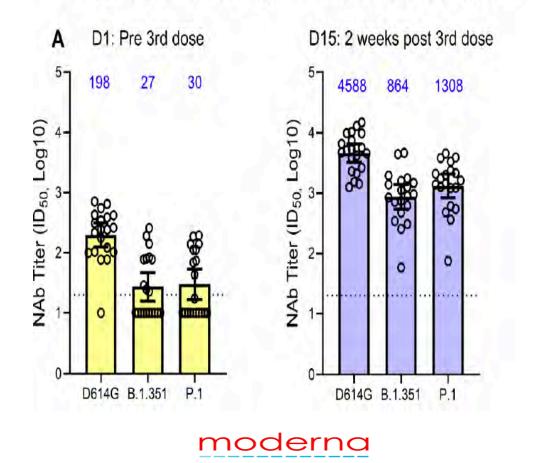
1. Initial data; 2. Samples were lested against each variant separately; PRNT: Plaque Reduction Neutralizing Test; Wt: Wild Type; GMR: Geometric Mean Ratio

27



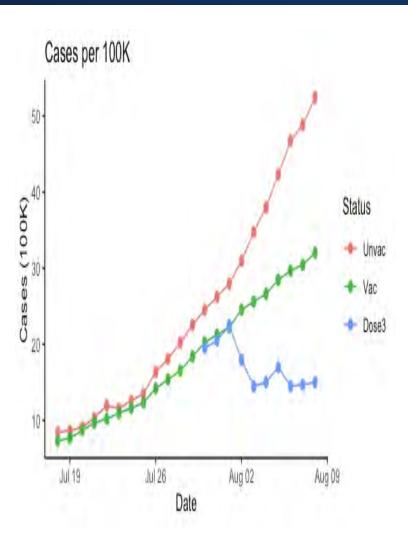
Data submitted for publication

Immunogenicity After Boosting with Booster Dose of 50 µg of mRNA-1273



Do Booster Shots Reduce Infections?

Country of Israel Data



Maccabi Health Services Data

824,774 over 60 yo

Booster \rightarrow

86% effective in preventing infection



Israeli Ministry of Health Data

1,144,690 over 60 yo

 $Booster \rightarrow$

11-fold decrease in rate of infection

10 fold decrease in rate of severe disease

Who Might Benefit from a COVID-19 Booster?



Biden administration aims to offer boosters starting September

- Older (> 65) age
 - -Antibody response lower and wanes faster in older people
 - -Older people have more comorbidities and higher risk of severe disease
- Health care workers and other essential frontline workers
- Immunocompromised people
 - -Multiple studies show reduced or absent antibody response to vaccination
 - -Response to third dose in a substantial minority
- Completed vaccine series longer ago
 - -Antibody titers from natural infection or vaccination decline with time
 - -Not everyone agrees with this use!
 - Vaccine protection against "any infection" will wane, but against severe infection may be durable
- CDC ACIP meeting (August 30) discouraged boosters without more data
 - -CDC will use risk-based criteria used for Prime Series

On the Other Hand: Boosters Around the World

CDC ACIP meeting (August 30) discourages boosters without more data



- Israel started given 3rd dose of Pfizer-BioNTech to persons over 60 who had completed their second dose 5 months ago or longer on 7/30/21; gradually expanded to include entire population.
- Hungary started offering 3rd dose to anyone who had completed full vaccination 4 months ago or longer beginning 8/1/2021. Physician choice on vaccine type.
- Germany has stated it will give boosters in September 2021 with Pfizer-BioNTech or Moderna to older people, residents of care homes and persons with compromised immune systems. Also offering mRNA boosters to persons previously vaccinated with AZ or Janssen.
- France has stated it will give third booster to "the elderly and vulnerable" starting in September 2021.
- UK plans to offer third booster to those at highest risk (elderly, clinically extremely vulnerable and frontline healthcare workers) starting in September 2021.

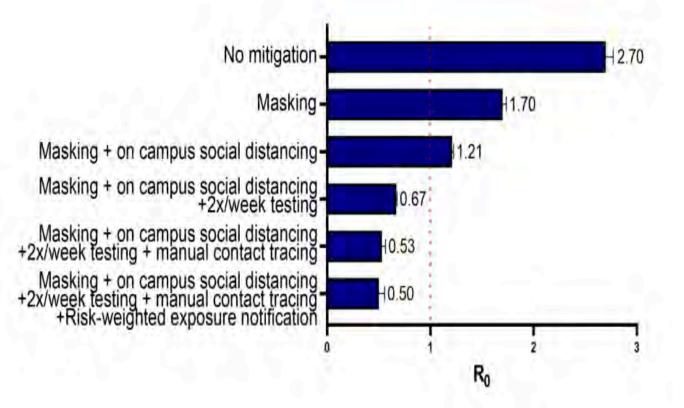
Beyond Boosters – Protect Yourself in Other Ways



Mitigation Works! Effects in School Settings



University of Illinois (Comparable results with similar programs at Cornell University and Northeastern University) medRxiv 2021.08.03.21261548



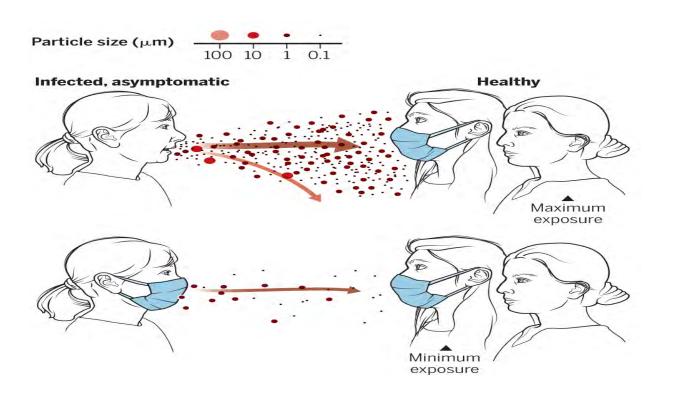
CDC Analyses of K-12 Schools (MMWR March 26, 2021)

- Springfield, MO
 - Masks, distancing, ventilation, contact tracing
 - Effective in reducing in-school transmission
 - Low in-school transmission despite high community transmission
- Salt Lake County, UT
 - Low in-school transmission despite high community transmission
 - High mask adherence but separation only ~3 feet

Mask Misconceptions



- Masks do not work
 - Masks protect healthy people from infected people!
 - Reduce egress/ingress of infected droplets and aerosols
- The virus is smaller than the pores in the mask
 - Droplets are larger than pores
 - Aerosols are trapped by other mechanisms
- Masks restrict oxygen supply
 - Measurements show no effect on oxygen or carbon dioxide
- Masks are not needed with social distancing
 - Wrong! Sneezes and coughs can travel 30 feet
- Masks are not needed outdoors
 - Risks much lower outdoors
 - But transmission still possible (e.g., crowds)
 - Use your judgement
- Masks not needed after vaccination
 - Vaccines not 100% protective
 - Reducing the dose of virus is important
 - Possibility of transmission to vulnerable people





Types of Masks That Work Best



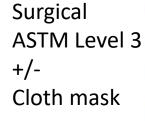


KF94 Face Mask **KN95** COVAFLU" KN93 KN95 24-0

https://www.who.int/emerge ncies/diseases/novelcoronavirus-2019/advice-forpublic/when-and-how-touse-masks

MADE IN USJ

DEMEMASK KIDS SURGICAL MASK ASTM LEVEL 3 SIZE: SMALL (BOX OF 50)



N95



https://www.fda.gov/medicaldevices/coronavirus-covid-19and-medical-devices/facemasks-including-surgicalmasks-and-respirators-covid-19

Should You Take Precautions? Common Sense Approach

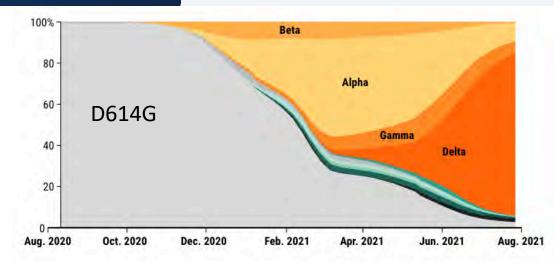


- How susceptible are you?
 - -Vaccinated?
 - -Risk factors for severe disease?
 - -Immune suppression?
- How prevalent is infection in the community?
 - -Prevalence of variants of concern
- What exposure are you envisioning?
 - -Vaccinated family gathering <u>vs.</u> movie theater, Costco, airport, etc.
 - -Indoors vs. outdoors
 - -Quiet (watching TV) <u>vs.</u> aerosol generating (choir practice)
 - -Brief <u>vs.</u> extended
- What's the downside of being cautious?

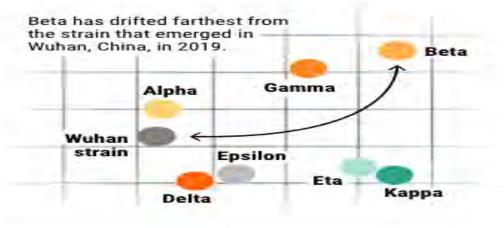
The Future

"We're better at explaining the past than at predicting the future" – Andrew Read, viral evolutionary biologist Metholist LEADING MEDICINE

- What could happen next?
 - Lesser, endemic surges if delta is at "optimum fitness" for the virus
 - possible, but not the way to bet
 - -Mutations
 - leading to increased or decreased severity of illness
 - leading to increased viral "fitness" for infection and/or transmission
 - gradual immune escape under selective pressure of population immunity
 - limited correlation between these effects
 - -Sudden immune escape due to viral recombination
 - very challenging scenario requiring emergency deployment of updated vaccines



(GRAPHIC) N. DESAI/SCIENCE; (DATA) NEXTSTRAIN; GISAID



(GRAPHIC) N. DESAI/SCIENCE, (DATA) DEREX SMITH/UNIVERSITY OF CAMBRIDGE, DAVID MONTEFIORI/DUKE UNIVERSITY

HOUSTON Methodist LEADING MEDICINE

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

