The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XVII

We will begin at 10 a.m.
INCOMING!!

NEW COVID VARIANTS
Houston Methodist COVID-19
Cases by Day

Houston Methodist COVID-19
Patients 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
Houston Methodist COVID-19 Hospitalization Predictions
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

The Delta variant spreads easily in indoor spaces when people are unmasked and unvaccinated

Occasionally unmasked adult infected with Delta variant worked for 2 days
12 of 24 kids infected

Schools can help stop spread by ensuring everyone:
- Wears masks correctly in indoor spaces
- Gets vaccinated, if eligible
- Stays home if having symptoms
- Tests routinely

bit.ly/MMWR82721b
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 AND care for traditional patients AND protect our staff and physicians

3. Our political leaders must work together on society’s “Sacred AND”

Control COVID-19 AND protect the economy AND 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
Behaviors of Vaccinated vs. Unvaccinated

Because of the pandemic, how often are you:
Percent who say always or often

- **Staying away from large groups**
  - Overall: 58
  - Unvaccinated: 42
  - Vaccinated: 65

- **Wearing a face mask when you’re around other people outside your home**
  - Overall: 51
  - Unvaccinated: 33
  - Vaccinated: 58

- **Avoiding nonessential travel**
  - Overall: 51
  - Unvaccinated: 36
  - Vaccinated: 57

- **Avoiding other people as much as possible**
  - Overall: 43
  - Unvaccinated: 35
  - Vaccinated: 46

**Question:** Because of the coronavirus, how often are you:

**Source:** AP-NORC poll conducted August 12-16, 2021 with 1,729 adults age 18 and older nationwide.
You don't have to wear a mask if you're vaccinated?

Of course I'm vaccinated.
Texas COVID-19 Trends

**New reported cases by day**
- **7 Day Average:**
  - Aug. 8, 2021: 11.9K
  - Nov. 23, 2020: 11.1K

**Hospitalizations**
- **7 Day Average:**
  - Aug. 9, 2021: 8.3K
  - Nov. 21, 2020: 8.9K

**Tests by day**
- **7 Day Average:**
  - Aug. 9, 2021: 77.4K
  - Nov. 21, 2020: 107.6K

**New reported deaths by day**
- **7 Day Average:**
  - Aug. 9, 2021: 57 per day
  - Nov. 23, 2020: 141 per day

Texas COVID-19 Trends

New reported cases by day

7 Day Average:
- Aug. 30, 2021: 16.4K
- Nov. 21, 2020: 11.4K

Percent of Texans Who Are Fully Vaccinated

83% of Texans are eligible for a vaccine

Aug. 26
46.8% of Texans fully vaccinated

Source: https://apps.texastribune.org/features/2020/texas-coronavirus-cases-map/
Vaccination Rate vs. Hospitalizations by State

Data Emailed on August 20, 2021 from Bill King
## Top 50 Most Vaccinated Countries

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Total Doses Given per 100k</th>
<th>% of Population Partially Vaccinated</th>
<th>% of Population Fully Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Malta</td>
<td>180,354</td>
<td>93.70%</td>
<td>93.40%</td>
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<td>2</td>
<td>Singapore</td>
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<td>Qatar</td>
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<td>82.00%</td>
<td>75.20%</td>
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<td>4</td>
<td>Portugal</td>
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<td>7</td>
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<tr>
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<td>Switzerland</td>
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<td>Cambodia</td>
<td>115,767</td>
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<td>51.70%</td>
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<td>Finland</td>
<td>123,671</td>
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<td>40</td>
<td>Poland</td>
<td>95,564</td>
<td>50.80%</td>
<td>49.50%</td>
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<td>41</td>
<td>Ecuador</td>
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<td>42</td>
<td>Malaysia</td>
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<td>Japan</td>
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<td>46.30%</td>
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<td>44</td>
<td>Turkey</td>
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<td>45</td>
<td>Saudi Arabia</td>
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<td>Dominican Republic</td>
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<td>47</td>
<td>Cyprus</td>
<td>91,308</td>
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<td>43.40%</td>
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<td>48</td>
<td>Slovenia</td>
<td>90,866</td>
<td>47.50%</td>
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<td>49</td>
<td>El Salvador</td>
<td>97,595</td>
<td>54.90%</td>
<td>42.70%</td>
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<tr>
<td>50</td>
<td>Morocco</td>
<td>92,460</td>
<td>51.30%</td>
<td>41.20%</td>
</tr>
</tbody>
</table>

Daily COVID-19 Deaths Comparison Across Countries

Daily new confirmed COVID-19 deaths per million people

Shown is the rolling 7-day average. Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.

Source: Johns Hopkins University CSSE COVID-19 Data

CC BY
WE'RE #1

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

United Kingdom

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

https://www.nytimes.com/interactive/2021/08/24/world/vaccines-seniors.html?unlocked_article_code=AAAAAAAAAAAAAAACEIPuoii7Y1_twU1Gw5CRWwyS84B991re1b-VnPsjgWXBiG-LQ0JzuYGM2b9kHMYrB4Idsk2QkQDpWwDlq7tq7ogoh0j0y4qaiuuppea3201js470vD117q8L4GQ0000mavzZdfmK11n-y-hvbYbuCqaPg3Vxy134scesLSnHe0n1YbqAEh5z4M-ia9n3YmMG9GMCqsPZoCoaF8BMcG9a3z4gooxQJ2XLDjLWauuJEaGjVwWwHD4e6nB86Dh1NocMk_6SfYnc8bt64vYx6vxtmpGQ9tCk-MKQ5dyhdxQ&smid=em-share
The 4.53 M dead around the world would stretch from the West Coast of the U.S. to London!
THE LIGHT AT THE END OF OUR TUNNEL
FDA Approves Pfizer COVID-19 Vaccine – August 23, 2021

The New York Times

The F.D.A. grants full approval to the Pfizer-BioNTech Covid-19 vaccine.

“"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.”
No excuses with full Pfizer approval

It’s a game-changer for all the holdouts whose hesitancy has nothing to do with politics.

There’s no good excuse now that the FDA granted full approval Monday to the Pfizer-BioNTech vaccine, a milestone expected to boost the immunization drive amid a renewed surge.

That no longer includes Pfizer. We want the leaders who so proudly extolled a COVID-19 vaccination wave after having been fully vaccinated, not to extend their order to fully approved vaccines. Instead, given his recent experience, he should be the boss challenger to get unvaccinated people to protect themselves from severe illness, hospitalization and death.

The Pentagon said Monday it will require service members to be vaccinated now that the vaccine is fully approved. California, CYS Health, Chevron, Delta and a growing list of other major companies are mandating vaccinations for employees.

The FDA’s announcement is not surprising but it is important. The vaccine has been shown to be highly effective and safe. It is also crucial for people to be vaccinated to prevent the spread of the virus and to protect those who cannot be vaccinated due to underlying health conditions.

There are several options available for people who are hesitant to get vaccinated, including discussing concerns with a healthcare provider. It is important for people to make informed decisions about whether to get vaccinated or not, based on their personal health status and lifestyle.
HM COVID-19 Vaccines Administered

Total First Doses: 445,528  
Total Second Doses: 423,947  
Total Third Doses: 6,922
Infections and Hospitalizations Among Unvaccinated in Los Angeles

A July 2021 study of Los Angeles, CA public health records found...

Unvaccinated have

5X

more COVID-19 infections than fully vaccinated

Unvaccinated have

29X

more COVID-19 hospitalizations than fully vaccinated

Get vaccinated to reduce spread and protect yourself

https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e5.htm\
Effectiveness of COVID-19 Vaccines

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

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

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7034e4-H.pdf
NEJM: Absolute Excess Risk of Adverse Events after Vaccination or COVID-19 Infection
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 verified.

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.

A significant majority of TMC total hospitalized and ICU patients are unvaccinated.
COVID-19 Hospitalizations by Age Group

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

Preliminary VE against COVID-19–associated hospitalization among fully vaccinated† patients aged ≥18 years, by age group and month — COVID-NET

Preliminary VE against COVID-19–associated hospitalization in adults less than 75 years of age decreased in July, but remains >80%

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!
<table>
<thead>
<tr>
<th>Hospital</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Texas Children's Hospital</td>
<td>13,000</td>
</tr>
<tr>
<td>Keck Medicine of USC</td>
<td>7,000</td>
</tr>
<tr>
<td>CMH</td>
<td>1,200</td>
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<tr>
<td>CHI Health Center</td>
<td>12,000</td>
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<tr>
<td>Nebraska Medicine</td>
<td>8,000</td>
</tr>
<tr>
<td>Mount Sinai</td>
<td>42,000</td>
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<tr>
<td>CommonSpirit</td>
<td>150,000</td>
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<td>JPS Health Network - East Wichita, KS</td>
<td>6,500</td>
</tr>
<tr>
<td>Boulder Community Health</td>
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<tr>
<td>Bryan Health</td>
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<tr>
<td>Community Health</td>
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<td>UMass Medical Center</td>
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<td>children’s Hospital Health Center</td>
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<td>Aiken Children Hospital</td>
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<td>Presbyterian</td>
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<td>WVU Medicine</td>
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<td>Edward-Elmhurst</td>
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<td>AMITA Health</td>
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<td>Waterbury Health</td>
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Multiple States Announce COVID-19 Vaccine Mandate for Healthcare Workers

July 26 - California, Pennsylvania, Maine, New York, The District of Columbia, New Mexico
August 10
August 12
August 16
August 16
August 17
August 18
August 19
August 19
August 19
August 26

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

Delta drop
Percentage change in the number of visits to locations by industry in 2021 compared with the same period in 2019

Note: CDC updated guidance that even vaccinated Americans should wear masks indoors where infection rates are high.
Source: SafeGraph
Unvaccinated COVID-19 Hospitalization Cost to Society

Estimated cost of COVID-19 hospitalizations among unvaccinated adults in the U.S., June and July 2021

- June 2021: $0.7B
- July 2021: $1.5B
- June and July 2021: $2.3B

COVID-19 Cost Comparison Across Private Employers at Houston Methodist

Data From: Q2 2020 through Q2 2021  Source: EPSi
Private Employers with COVID-19 Costs >$2 Million at Houston Methodist

Data From: Q2 2020 through Q2 2021  Source: EPSi

Unique patients

Data From: Q2 2020 through Q2 2021  Source: EPSi
Delta CEO’s Memo to Employees
For COVID-19 Vaccination

Delta’s robust actions to increase our vaccination rate:
• Effective immediately, unvaccinated employees are required to wear masks in all indoor Delta settings
• Starting Sept. 12, any U.S. employee who is not fully vaccinated will be required to take a COVID test each week
• Beginning Nov. 1, unvaccinated employees enrolled in Delta’s account-based healthcare plan will be subject to a $200 monthly surcharge.
  • 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 only be provided to fully vaccinated individuals who are experiencing a breakthrough infection.

Gallup: Workers Have Strong Views on Vaccine Mandates

• **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

On the Front Lines: One Respiratory Therapist’s Perspective on the Seven Stages of Severe COVID-19

STAGE 1

- Debilitating symptoms for a few days
- It’s hard to breathe
- Go to the emergency room
- Supplemental flow of 1 to 4 liters of oxygen per minute
- We admit you and start you on antivirals, steroids, anticoagulants or monoclonal antibodies
- Spend several days in the hospital

STAGE 2

- Bronchodilator treatments provide little relief
- Oxygen requirements increase from 4 liters to 15-40 liters per minute
- Sitting up in bed becomes too difficult
- Oxygen saturation rapidly declines
- Transferred to the ICU

STAGE 3

- You’re exhausted from hyperventilating
- You are put on noninvasive, “positive pressure” ventilation, which pushes pressure into your lungs to pop them open

STAGE 4

- You are intubated
- You are sedated and paralyzed
- Fed through a feeding tube
- Hooked to a Foley catheter and a rectal tube
- We turn your limp body regularly to avoid bed sores

STAGE 5

- You are put on ECMO for your lungs to heal
- Bypasses your lungs and oxygenates your blood

STAGE 6

- Your kidneys begin to fail
- You develop complications
- Receive several rounds of CPR

STAGE 7

- You’re exhausted from hyperventilating
- You are sedated and paralyzed
- Fed through a feeding tube
- Hooked to a Foley catheter and a rectal tube
- We turn your limp body regularly to avoid bed sores

Real Conversations Between a Houston Physician and Her COVID Patients

“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

**MYTH #1**
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.

**MYTH #2**
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.

**MYTH #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.

**MYTH #4**
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.

**MYTH #5**
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.

**COVID-19 POSITIVE**

**MYTH #6**
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.

**MYTH #7**
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.
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!

GET YOURSELF AND YOUR FAMILY VACCINATED!

A yearly flu vaccine is the first and most important step in protecting against flu viruses.

#FIGHT FLU
"NO THANKS... I READ ON SOCIAL MEDIA IT MIGHT BE BAD."
Vaccines, Variants and the “Pandoomerang”

Town Hall, September 2, 2021

H. Dirk Sostman, MD FACP
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
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
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
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
• 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 bar
   – Air 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

<table>
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<tr>
<th></th>
<th>USA – Nursing Homes (Pfizer)</th>
<th>USA – Nursing Homes (Moderna)</th>
<th>USA – Health Workers</th>
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<td>MMWR August 18 2021</td>
<td>MMWR August 18 2021</td>
<td>MMWR August 24 2021</td>
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<tr>
<td>Pre-Delta</td>
<td>74%</td>
<td>75%</td>
<td>91%</td>
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<tr>
<td>Delta</td>
<td>52%</td>
<td>51%</td>
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</table>

MMWR August 24 2021
Why is Delta So Hard to Control? And Why the Disconnect Between Infection and Severe Disease?

• 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 → 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

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
Highly infectious +
High viral load +
Reduced Ab neutralization +
Waning antibody levels
Delta Breakthrough Infections: Rationale for Boosters

Delta
 Highly infectious +
 High viral load +
 Reduced Ab neutralization +
 Waning antibody levels

Booster
(or re-infection)
Booster Shots

What do they do? Who needs them? How will we deliver them?
COVID-19 Vaccine: 3rd Dose Strongly Boosts Neutralizing Titers Against Delta Strain

Post dose 3 titers vs. the Delta variant are >8-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

Pfizer
Second Quarter 2021 Earnings

Do Booster Shots Reduce Infections?

**Country of Israel Data**

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<tr>
<th>Maccabi Health Services Data</th>
<th>Israeli Ministry of Health Data</th>
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<td>824,774 over 60 yo</td>
<td>1,144,690 over 60 yo</td>
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<tr>
<td>Booster →</td>
<td>Booster →</td>
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<tr>
<td>86% effective in preventing infection</td>
<td>11-fold decrease in rate of infection</td>
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<tr>
<td></td>
<td>10 fold decrease in rate of severe disease</td>
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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 giving 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

100 micron droplet settles in 5 sec
1 micron aerosol takes 12 hours
Types of Masks That Work Best

- **N95**
- **KF94**
- **KN95**
- **Surgical ASTM Level 3 +/- Cloth mask**

For more information:
- [When and how to use masks](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks)
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 vs. movie theater, Costco, airport, etc.
  – Indoors vs. outdoors
  – Quiet (watching TV) vs. aerosol generating (choir practice)
  – Brief vs. 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

• 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
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