



The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XVIII

We will begin at 10 a.m.



Town Hall Conversation XVIII

Influenza Update

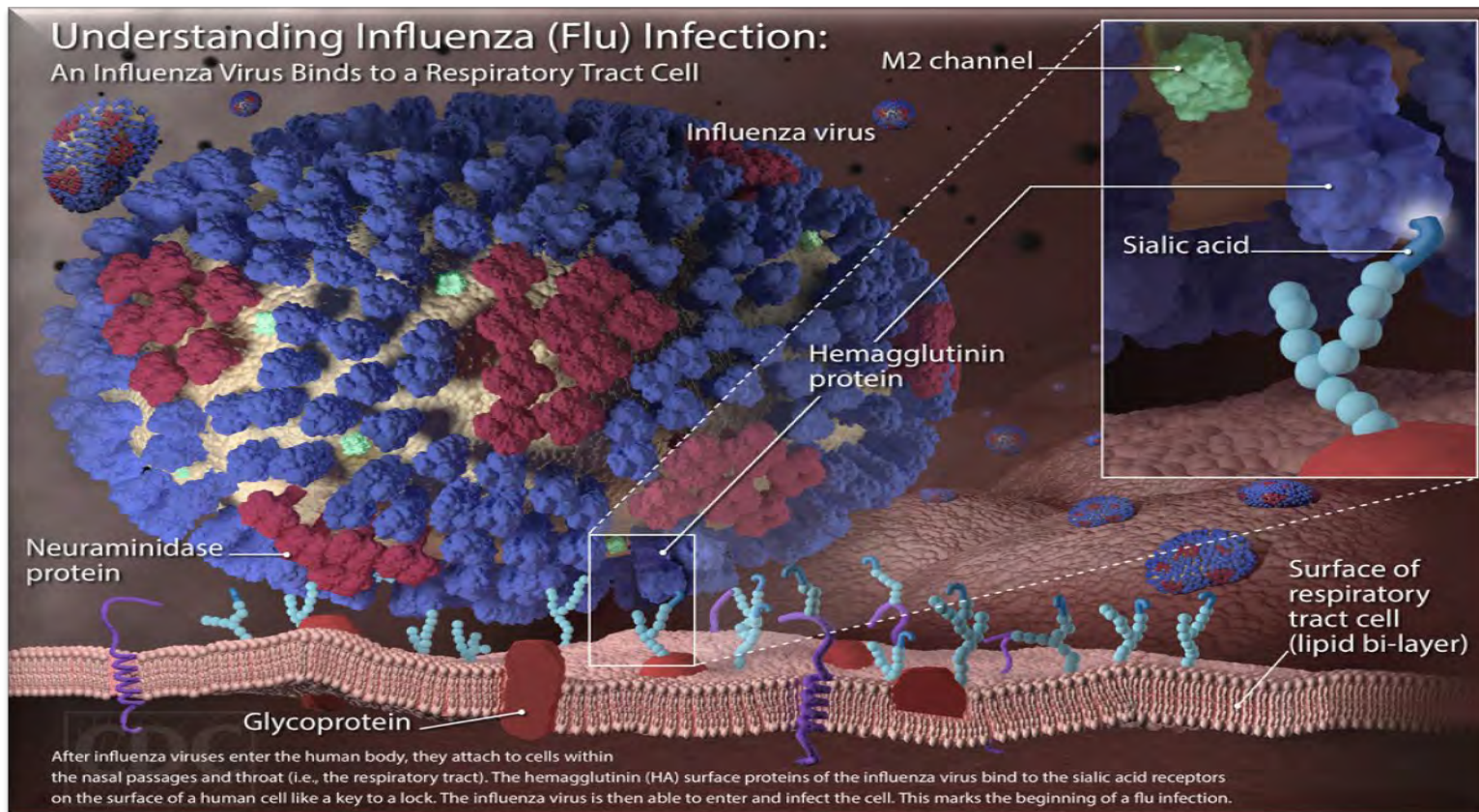
Ashley L. Drews, MD, FACP
HM System Epidemiologist

October 19, 2021

- Single-strand RNA virus in *Orthomyxovirus* family
- Respiratory transmission
 - Incubation period: 2 days
 - Viral shedding: 5-10 days
- Illness can range from mild to severe
- Complications
 - Secondary bacterial pneumonia
 - Otitis media
 - Exacerbation of underlying respiratory conditions

Influenza

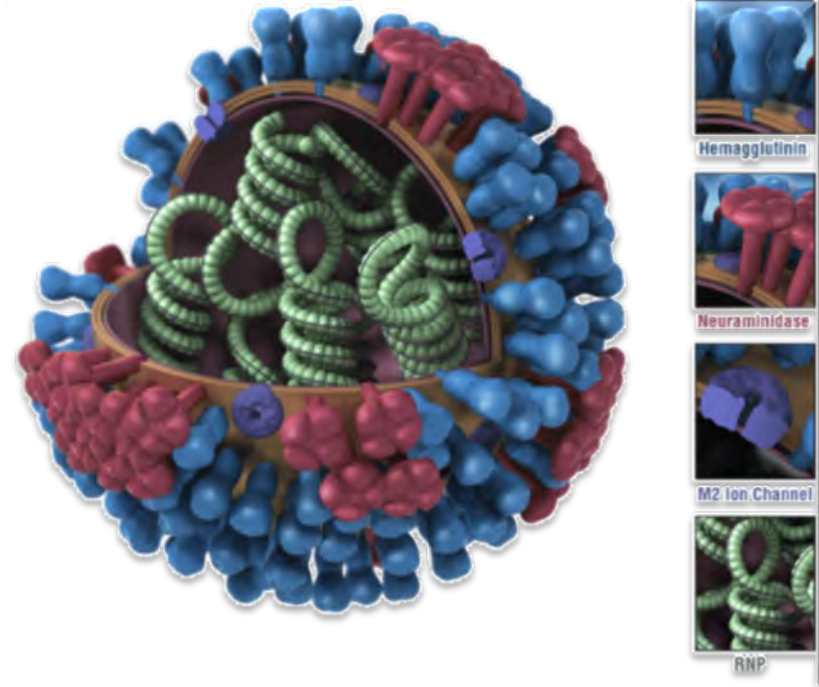
Background



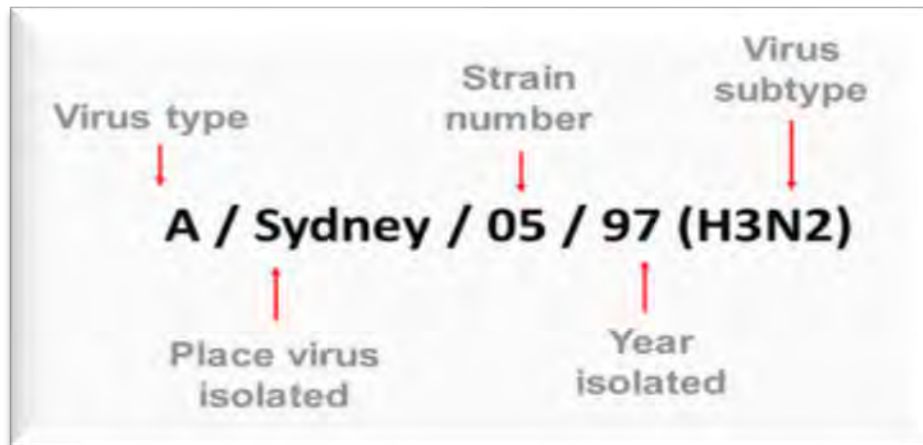
Influenza

Background

- Four types of influenza virus (A, B, C, and D)
 - Types A and B cause seasonal epidemics
- Influenza A viruses are subtyped based on two proteins on the viral surface
 - Hemagglutinin (H)
 - Neuraminidase (N)
- Antigenic drift accounts for seasonal recurrence
- Antigenic shift causes epidemics and pandemics



- Seasonal flu vaccines include four strains that are most likely to cause endemic illness each year
 - Based on biannual research done by the WHO from each hemisphere ahead of their upcoming flu season
 - It takes at least six months to manufacture large quantities of the flu vaccine



- Three main types of flu vaccine
- All contain four flu strains so they are considered *quadrivalent*

Inactivated Influenza Vaccine (IIV)

- Quadrivalent
- Egg vs cell-culture based
- IM

Recombinant Influenza Vaccine (RIV)

- Quadrivalent
- IM

Live Attenuated Influenza Vaccine (LAIV)

- Quadrivalent
- Egg based
- Nasal

IM = intramuscular

- Whole virus is chemically inactivated, then grown and replicated in a non-human medium
 - Egg based mediums are the most common given relatively low production cost & safety profile
 - Cell-culture based mediums can also be used but they are more costly & have a lower viral yield
- Provides antigen to the immune system without causing active infection

Influenza Vaccines

Recombinant Influenza Vaccine (RIV)

- Specific antigens from the viral strain of interest are genetically inserted on a non-pathogenic vector
- Provides antigen delivery to the immune system without causing active infection
 - Immune response is not quite as robust as with IIV

Yamayoshi, S., Kawaoka, Y. Current and future influenza vaccines. *Nat Med.* 2019;25:212–220.

Cox MM, Patriarca PA, Treanor J. FluBlok, a recombinant hemagglutinin influenza vaccine. *Influenza Other Respir Viruses.* 2008;2(6):211-219.

Influenza Vaccines

Live Attenuated Influenza Vaccine (LAIV)

- Live virus is attenuated via cold-adaptation to make it weaker
- Virus is still propagated in egg based medium
- Provides antigen to the immune system via replicating virus
 - Very robust immune response as this closely mimics natural infection
 - Not suitable for certain populations whose immune system is too weak to control attenuated virus

Influenza Vaccine

2021-2022 Season

Trade Name	Product	Indicated Age	Route
IIV – egg based			
Afluria Quadrivalent	0.25 mL PFS	6 to 35 mo	IM
	0.5 mL PFS	≥3 years	IM
	5 mL MDV	≥ 6 mo (needle/syringe) 18 to 64 years (jet injector)	IM
Fluarix Quadrivalent	0.5 mL PFS	≥ 6 mo	IM
FluLaval Quadrivalent	0.5 mL PFS	≥ 6 mo	IM
Fluzone Quadrivalent	0.5 mL PFS	≥ 6 mo	IM
	0.5 mL SDV		
	5 mL MDV		
Fluzone High-Dose Quadrivalent	0.7 mL PFS	≥ 65 years	IM
Fluad Quadrivalent (with MF59 adjuvant)	0.5 mL PFS	≥ 65 years	IM
IIV – cell culture based			
Flucelvax Quadrivalent	0.5 mL PFS 5 mL MDV	≥ 2 years	IM

PFS = pre-filled syringe; MDV = multi-dose vial; SDV = single-dose vial; IM = intramuscular

Influenza Vaccine

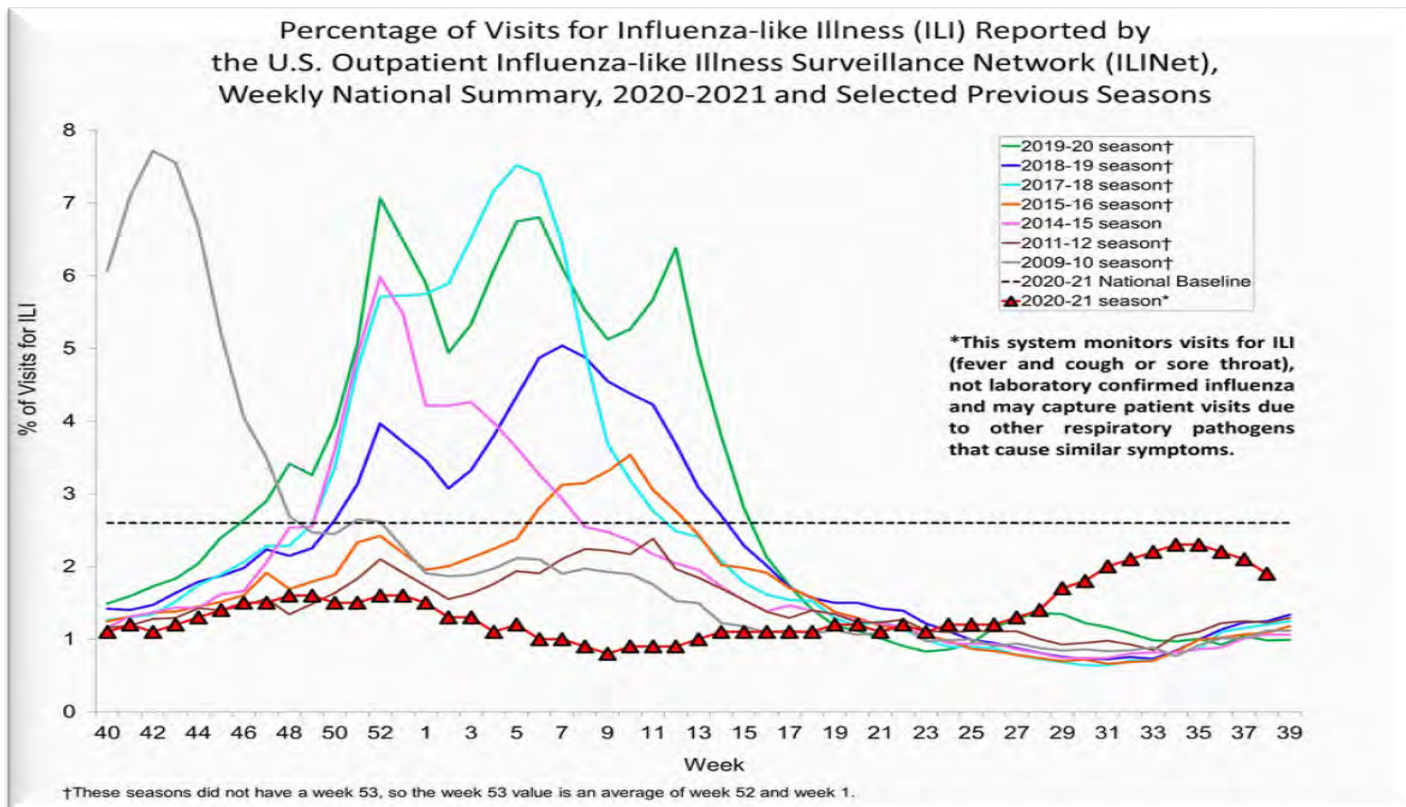
2021-2022 Season (cont)

Trade Name	Product	Indicated Age	Route
RIV			
Flublok Quadrivalent	0.5 mL PFS	≥18 years	IM
LAIV – egg based			
FluMist Quadrivalent	0.2 mL PFS via intranasal sprayer	2 to 49 years	Intranasal

PFS = pre-filled syringe; MDV = multi-dose vial; SDV = single-dose vial; IM = intramuscular

- Egg allergy
 - Egg-free vaccines: cell-culture based IIV or RIV
 - Persons who can eat scrambled eggs without issue are unlikely to be allergic to egg based vaccines
- High-dose vaccines should be given to persons ≥ 65 years of age
 - Additionally, immunocompromised patients may benefit from high-dose formulations
- Flu and COVID vaccines can be administered at the same visit
 - Patients with suspected or confirmed COVID can be vaccinated after criteria for ending isolation precautions are met

Influenza Reporting



- Influenza is an endemic infectious disease that has pandemic potential
- Prevention of active infection via vaccination is the best way to curb viral mutation and spread
- Several influenza vaccines are currently available to meet the needs of patients

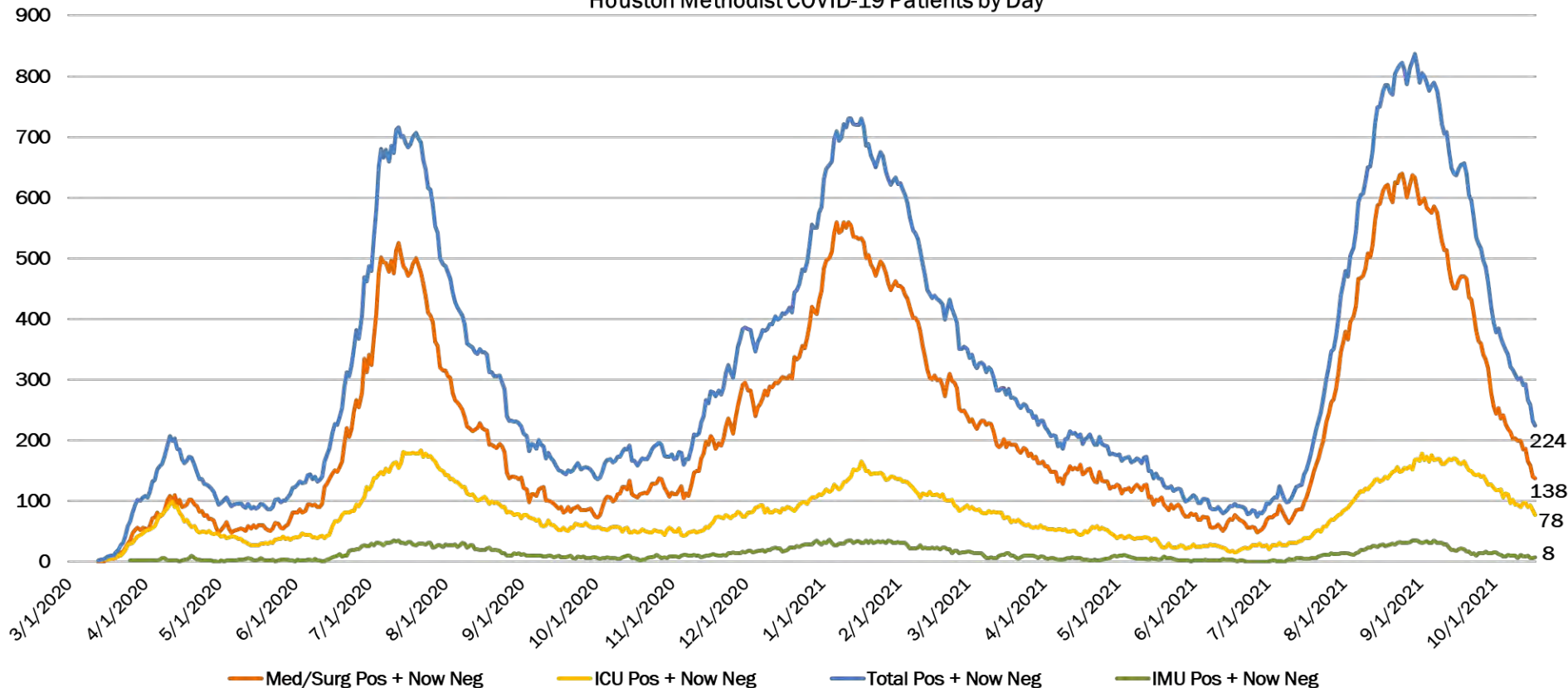
HOUSTON
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LEADING MEDICINE

COVID-19 and Vaccine Update

Marc L. Boom, MD
October 19, 2021

Houston Methodist COVID-19 Cases By Day

Houston Methodist COVID-19 Patients by Day



Data as of October 18, 2021

Houston Methodist Hospital Recognition of Service

Recognition of our
service to the
State of Texas as
a major
vaccination hub

COVID-19 VACCINE TRACKER

944,349

Vaccines Administered*

453,210

Vaccinations Dose 1*

433,795

Vaccinations Dose 2*

57,344

Vaccinations Dose 3*

*At Houston Methodist as of end of day 10/17/2021



STATE OF TEXAS
OFFICE OF THE GOVERNOR

*To all to whom these presents shall come, Greetings:
Know ye that this official certificate is presented to:*

Houston Methodist Hospital

As Governor of Texas, I am honored to thank you for your service to the state of Texas as a major vaccination hub. Your hard work has helped to mitigate the spread of COVID-19 in our communities while also safeguarding crucial state resources and ensuring the protection of our most vulnerable Texans.

I often say it is not our challenges that define us, but rather how we rise above them. You have demonstrated this ideal through your tireless efforts to serve your fellow Texans, and on behalf of the entire state, I thank you. You truly exemplify the very best of the Lone Star State.

First Lady Cecilia Abbott joins me in sending our deepest appreciation for your commitment to the people of Texas.

Under the laws of the State of Texas, with all rights, privileges, and emoluments appertaining to said office, I grant this official recognition. In testimony whereof, I have signed my name and caused the Seal of the State to be affixed at the City of Austin, this the 29th day of September, 2021.

Greg Abbott
Governor of Texas

Multiple Hospitals Announce COVID-19 Vaccine Mandate for Employees

April – Mid July

Late July – Early August



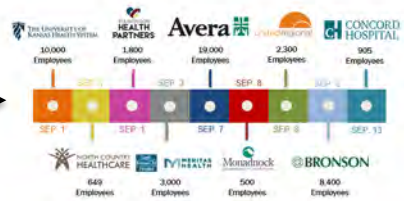
March 31, 2021
First Health System to Mandate the Vaccine



August

September

Now



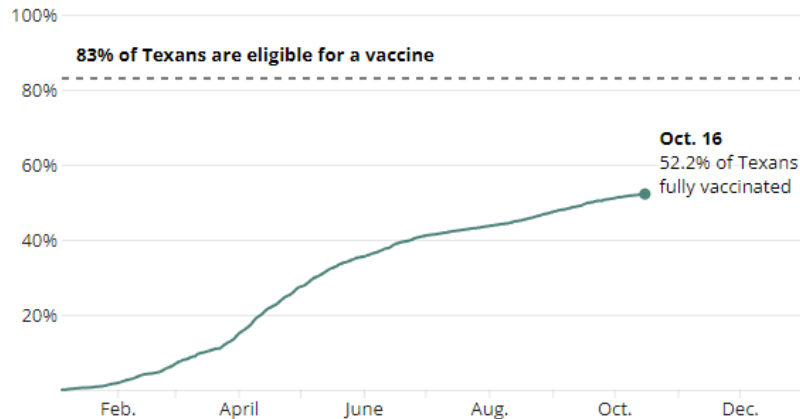
Over 2,500+ Hospitals and Health Systems



Texas Vaccination Stats

Percent of Texans who are fully vaccinated

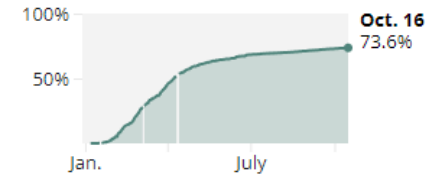
As of **Oct. 16**, about **52.2%** of Texas' 29.1 million people have been fully vaccinated. According to the Census Bureau's 2019 Vintage population estimates, 83% of Texans are age 12 and older and thus eligible for a vaccine.



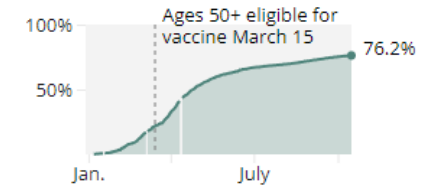
Percent of Texans fully vaccinated by age group

The percentage of residents vaccinated by age shows which age groups have been vaccinated at higher rates. Among the first groups eligible for vaccines in late December 2020 were Texans age 65 and older. Texas' population skews younger — about 17% are under 12.

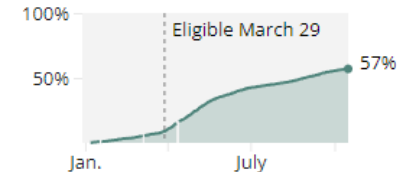
829,857 Texans are **80 years or older**



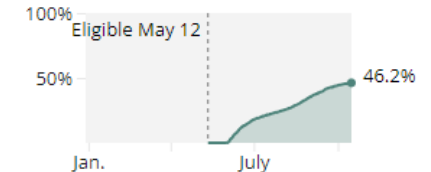
7.9 million Texans are **50 to 79 years old**

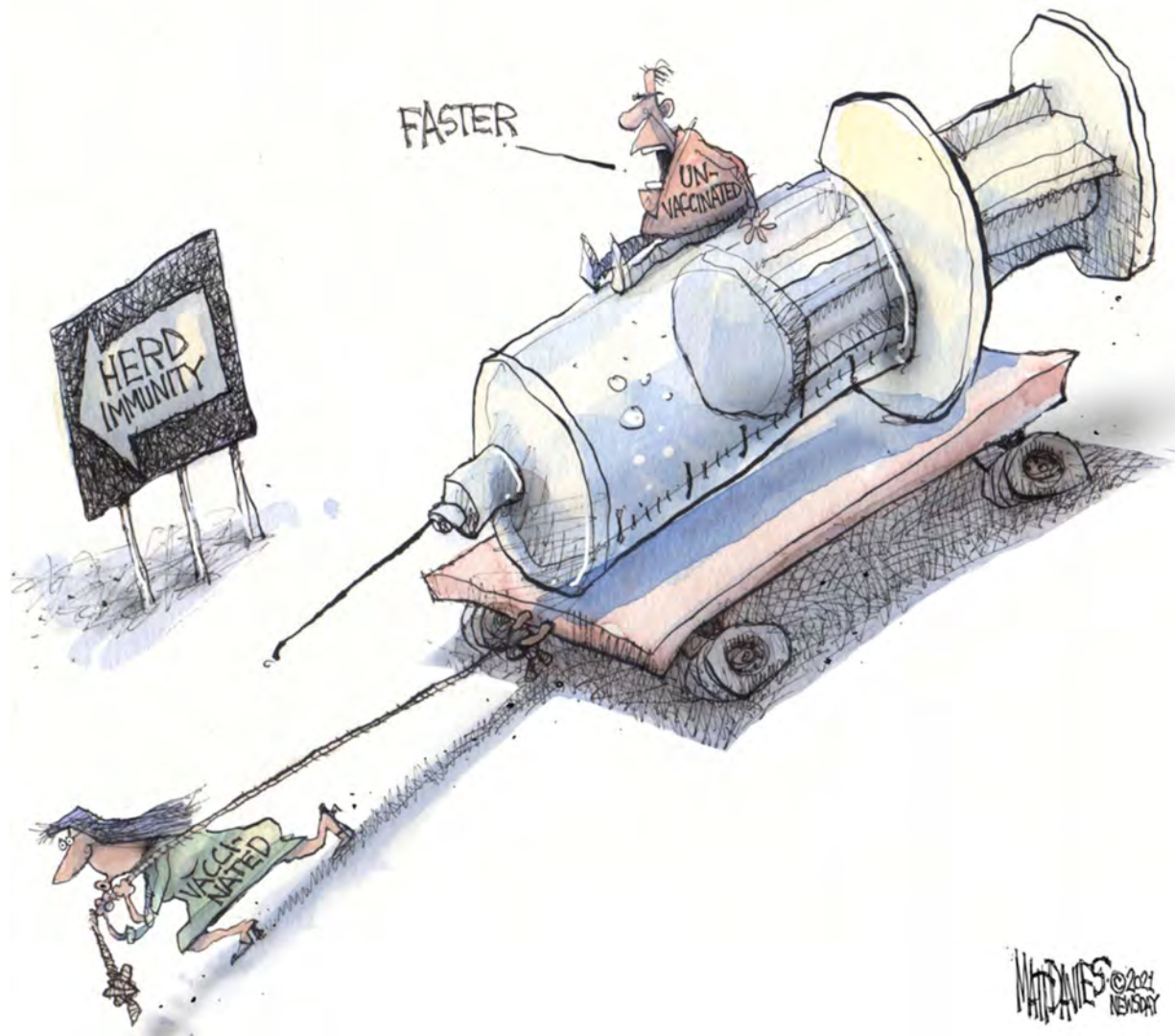


13.7 million Texans are **16 to 49 years old**



1.7 million Texans are **12 to 15 years old**





Whodunnit
© 2011
10/10/11

New Vaccination/Testing Requirements: Private Employers & Federal Contractors

PATH OUT OF THE PANDEMIC

PRESIDENT BIDEN'S COVID-19 ACTION PLAN



Vaccinating the
Unvaccinated



Further Protecting
the Vaccinated



Keeping Schools
Safely Open



Increasing Testing &
Requiring Masking



Protecting Our
Economic Recovery



Improving Care for
those with COVID-19

Key Requirements



Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly



Calling on Large Entertainment Venues to Require Proof of Vaccination or Testing for Entry



Requiring Vaccinations for all Federal Workers and for Millions of Contractors that Do Business with the Federal Government



Requiring Employers to Provide Paid Time Off to Get Vaccinated



Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings

Texas Executive Order Prohibiting Vaccine Mandates



STATE OF TEXAS
OFFICE OF THE GOVERNOR

MESSAGE

TO THE SENATE AND HOUSE OF REPRESENTATIVES OF THE EIGHTY-SEVENTH TEXAS LEGISLATURE, THIRD CALLED SESSION:

I, GREG ABBOTT, Governor of the State of Texas, by the authority vested in me by Article III, Section 40, and Article IV, Section 8, of the Texas Constitution, do hereby present the following additional subject to the 87th Texas Legislature, Third Called Session, for consideration:

Legislation establishing that no entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19.

Respectfully submitted,

GREG ABBOTT
Governor

Austin, Texas
October 11, 2021



GOVERNOR GREG ABBOTT

October 11, 2021

FILED IN THE OFFICE OF THE
SECRETARY OF STATE
4:30 PM CLOCK

OCT 11 2021

Secretary of State

Mr. Joe A. Esparza
Deputy Secretary of State
State Capitol Room 1E.8
Austin, Texas 78701

Dear Deputy Secretary Esparza:

Pursuant to his powers as Governor of the State of Texas, Greg Abbott has issued the following:

Executive Order No. GA-40 relating to prohibiting vaccine mandates, subject to legislative action.

The original executive order is attached to this letter of transmittal.

Respectfully submitted,

Gregory S. Davidson
Executive Clerk to the Governor

GSD/gsd

Attachment

COVID-19 Deaths Trend Younger

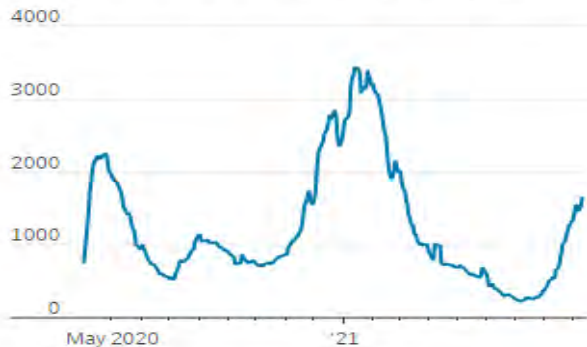
Covid-19 Deaths in Delta Surge Trend Younger in U.S.

Vaccines have shielded older people from the worst outcomes, leaving younger people who haven't gotten shots at risk

U.S. Covid-19 Death Toll

After falling this spring, the Covid-19 death toll is rising due to the spread of the Delta variant.

Daily death toll (7-day moving average)



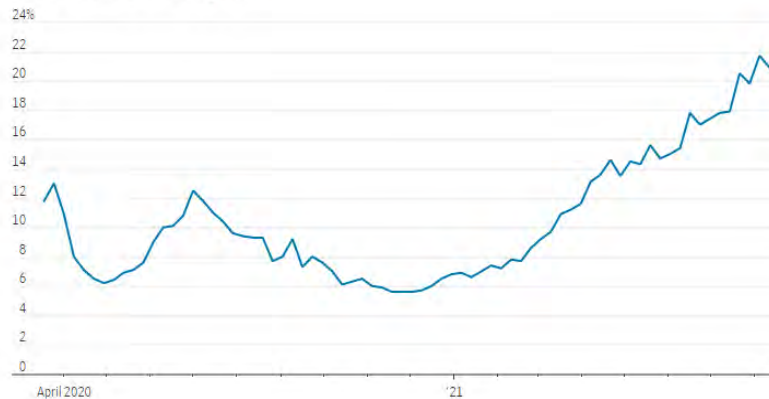
Source: Johns Hopkins University

- Deaths have been concentrated among the unvaccinated, federal data show. The CDC released studies on Friday showing that unvaccinated Americans were **4.6 times** as likely to be infected, **10 times** as likely to be hospitalized and **11 times** as likely to die.

Generational Shift

As most older people in the U.S. have gotten vaccinated, a growing share of the deaths are occurring among the young and middle-aged.

Share of Covid-19 deaths, ages 0-54



Source: CDC

- Younger age groups have represented a growing share of deaths since vaccines became available, a trend that has continued into the summer's Delta surge.
- Age is a major risk factor for people with Covid-19. **People in their 30s are four times as likely to die from infections as people ages 18 to 29**, according to the CDC. For people ages 75 to 84, the risk of death is 220 times as high.

Houston Methodist Mortality: Vaccinated vs. Unvaccinated

Age Group	Not Vaccinated			Vaccinated		
	Count Discharged Encounters	Mortality Count	Mortality Rate	Count Discharged Encounters	Mortality Count	Mortality Rate
below 18	4	0	0.0%	-	-	-
18 - 24	142	0	0.0%	11	0	0.0%
25 - 40	1,041	38	3.7%	98	2	2.0%
41 - 50	965	69	7.2%	163	9	5.5%
51 - 60	892	66	7.4%	200	8	4.0%
61 - 70	744	66	8.9%	364	23	6.3%
71 - 80	479	40	8.4%	384	22	5.7%
Over 80	232	26	11.2%	299	20	6.7%
Overall	4,499	305	6.8%	1,519	84	5.5%

Estimated Effectiveness against Hospitalizations:

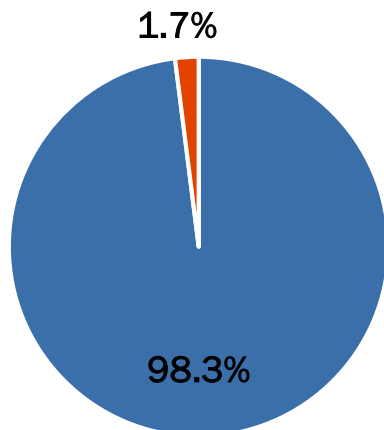
- Under 60: 90 – 93%
- 60 – 80: 86 – 88%
- Over 80: 77%

Estimated Effectiveness against Death:

- Under 60: 95 – 96%
- 60 – 80: 90 – 91%
- Over 80: 86%

Preventing Employee Hospitalizations

Employee Vaccination Status



■ Vaccinated ■ Unvaccinated
(Exempt or Deferred)

Employees Hospitalized (Current Surge)

	Vaccinated	Unvaccinated
<i>Total Employees</i>	26,124	454
<i>Employees Hospitalized</i>	8	6
<i>% Employees Hospitalized</i>	0.03%	1.32%

Unvaccinated employees are **44**
times more likely to be hospitalized

Vaccine Effectiveness at Preventing Employee Hospitalizations



Combating Misinformation in the Community

Examples of Opinions based on Misinformation:

"THE VAX IS A DEATH SENTENCE TO MANY – 80,000 people have thus far died from the Vax, 200,000 have been injured, many permanently (this is stats from the whistleblower)"

"I know people with serious illnesses that would rather die at home in peace than be put through the **torture this vax brings** to far too many. No one wants to play Russian Roulette."

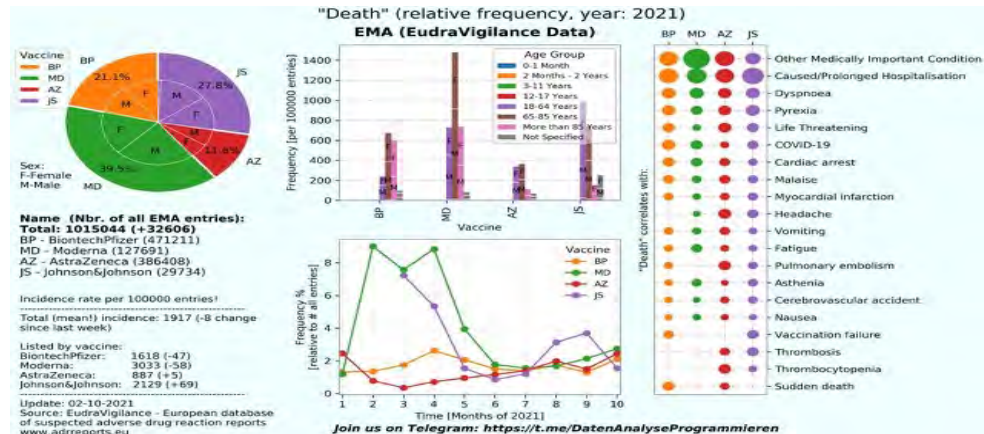
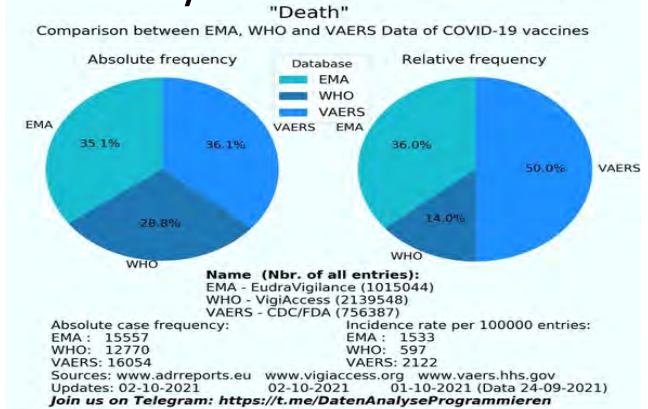
"Many doctors now are very interested in **de-population.**"

"They do **not** report deaths that occur for 14 days after the vax when many people die."

"This is against the **Nuremberg Code.**"

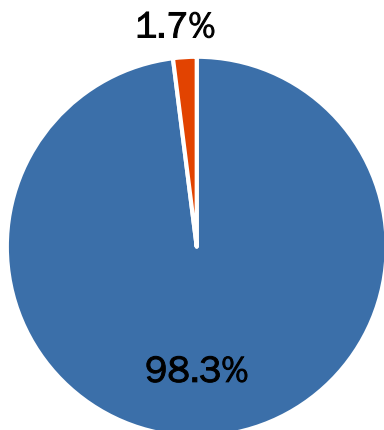
"Sincerely, A Concerned Citizen
Completely Against **Doctors Murdering People** For Their Political Overlords"

Examples of Misinformed Data:



Preventing Employee Hospitalizations

Employee Vaccination Status



■ Vaccinated ■ Unvaccinated
(Exempt or Deferred)

Employees Hospitalized (Current Surge)










	Vaccinated	Unvaccinated
<i>Total Employees</i>	26,124	454
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Unvaccinated employees are **44**
times more likely to be hospitalized

Vaccine Effectiveness at Preventing Employee Hospitalizations



Who can get a Pfizer booster?

Criteria	Self Schedule	CDC Recommendation
Received Pfizer <u>more than</u> six months ago		
65 years and older		Should
Residents in long-term care settings		Should
50-64 years of age with <i>underlying medical conditions</i>		Should
18-49 years of age with <i>underlying medical conditions</i>		May
18-64 years of age who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting		May
18-64 years of age who do not meet any of the criteria above		Discuss with your physician
Received Pfizer <u>less than</u> six months ago		
12+ years of age who are immunocompromised		Should
All individuals		Discuss with your physician
Received any other vaccine besides Pfizer		
All individuals		Discuss with your physician

Symbol Key:



Yes – please schedule your booster



You need a physician's order to schedule

Pfizer is available at all Houston Methodist locations

Houston Methodist COVID-19 Vaccine Scheduling Options

COVID-19 Vaccine Scheduling Options

Everyone **12 and older** can receive a COVID-19 vaccine in Texas. Before scheduling your appointment, please make sure you meet the criteria for each dose as described in the boxes below.

Schedule Your Pfizer COVID-19 Vaccine



First Dose

You are 12 or older and this is the first time you will be receiving the Pfizer COVID-19 vaccine. Your second Pfizer dose will be scheduled during your appointment.

[Schedule Your Vaccine](#)



Second Dose

You received your first dose of the Pfizer vaccine somewhere else, but would like to schedule your second Pfizer dose at Houston Methodist. You must schedule this second dose at least 3 weeks after your first dose.

[Schedule Your Vaccine](#)



Third Dose

If it has been 6 months after your initial **Pfizer** series, anyone 65+, any long-term care resident and anyone 18-64 with underlying medical conditions or increased risk to COVID-19 exposure, including job and institutional settings, can schedule a third dose.

In addition, immunocompromised 12+ can schedule a third dose 28 days after the second dose of the Pfizer (or Moderna*) vaccine.

[Schedule Your Vaccine](#)

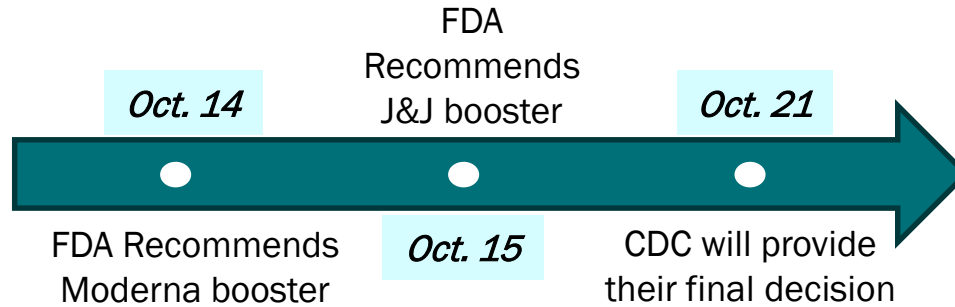


Doctor-Prescribed Dose

This Pfizer dose has been prescribed for you outside of FDA criteria and/or timelines. You must have a physician's order with you or in Houston Methodist's Electronic Medical Record (EMR) to receive this Pfizer dose.

[Schedule Your Vaccine](#)

Who can get a Moderna or J&J booster?



If approved by the CDC...

- A **Moderna** booster will be available to the same approved groups as Pfizer; however, it will not be available for those who need a physician's order until it receives full FDA approval
- A **J&J** booster will be available to everyone 18+, two months after their initial dose

Pfizer Vaccine Approval for Children Aged 5-11

The New York Times

The Coronavirus Pandemic > | **LIVE** Covid-19 Updates | Coronavirus Map and Cases | World Vaccination Tracker | Vaccine FAQ

Pfizer Asks F.D.A. to Authorize Its Covid-19 Vaccine for Children 5 to 11

The agency has promised to move quickly on the request and tentatively plans to meet on Oct. 26 to consider it. A decision could come soon after Halloween.

Food and Drug Administration meeting is scheduled for Oct. 26

Centers for Disease Control and Prevention is scheduled for Nov. 2 and 3

Six Rules That Will Define Our Second Pandemic Winter

1. The role of vaccines has changed (again)

Vaccines work more like dimmer switches than on/off buttons, and as their protection fades out, there are three thresholds that we care about: protection against infection, against symptoms, and against severe disease.

2. The proportion of vaccinated people matters, but who they are and how they cluster also matters

The difference between the U.K. and the U.S. isn't just that fewer Americans are vaccinated. It's that fewer of the most vulnerable Americans are vaccinated, and they tend to cluster together.

3. The people at greatest risk from the virus will keep changing

Relative risk will keep shifting, even if the virus somehow stops mutating and becomes a static threat.

4. As vaccination increases, a higher proportion of cases will appear in vaccinated people—and that's what should happen

The denominators in these calculations also change, dragging the numerators higher along with them. As surges grow, so too will the number of infected people.

5. Rare events are common at scale

The assessment for both how relatively common they are and how much they cost each affected individual will change as the pandemic waxes and wanes, and as the virus itself continues to mutate.

6. There is no single “worst” version of the coronavirus

All variants will have some common weakness: they can be stopped through the combined measures of vaccines, masks, distancing, and other measures that cut the conduits they need to travel.


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



HOUSTON
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LEADING MEDICINE

Controlling the Pandemic

Town Hall, October 19, 2021

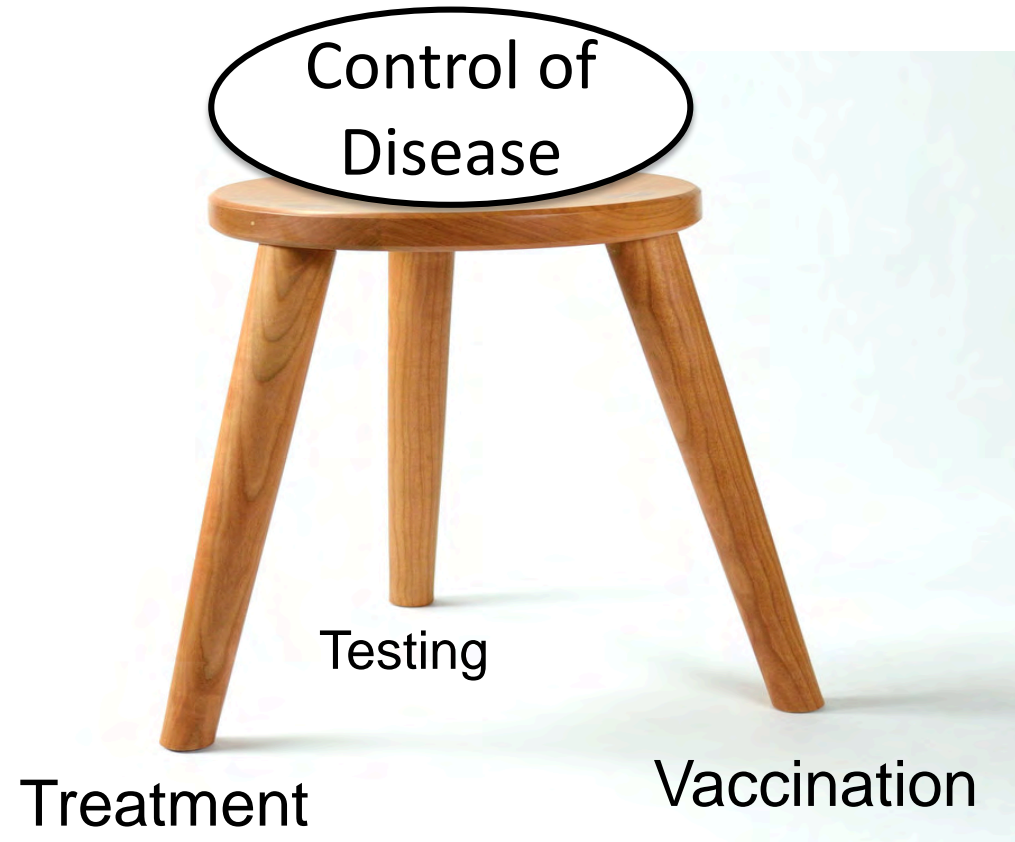
H. Dirk Sostman, MD FACR
Ernest Cockrell, Jr. Presidential Distinguished Chair
EVP & Chief Academic Officer



The Big Picture: Controlling Infectious Diseases

**We Now Have All of These
Measures Available to Fight
COVID-19
and
They Will Continue to Improve**

Controlling Infection →



Preventing infection →

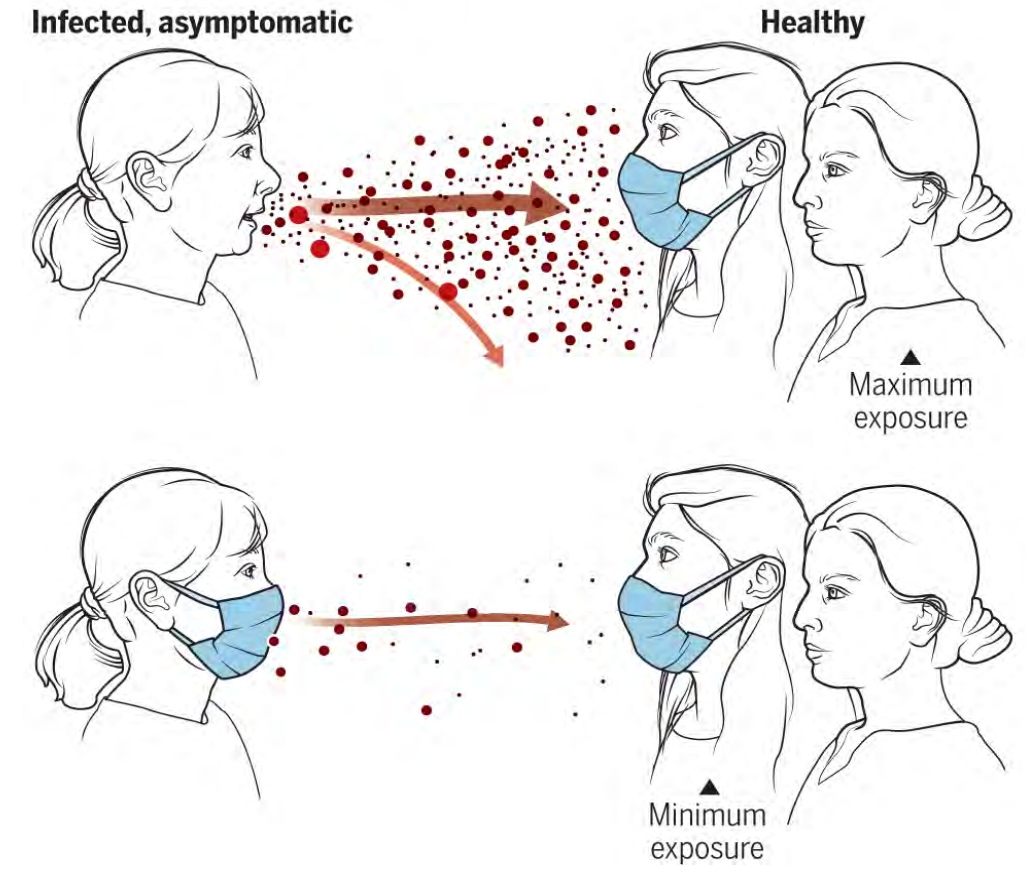
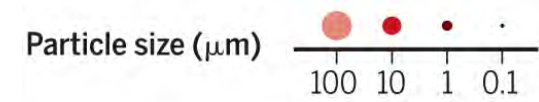
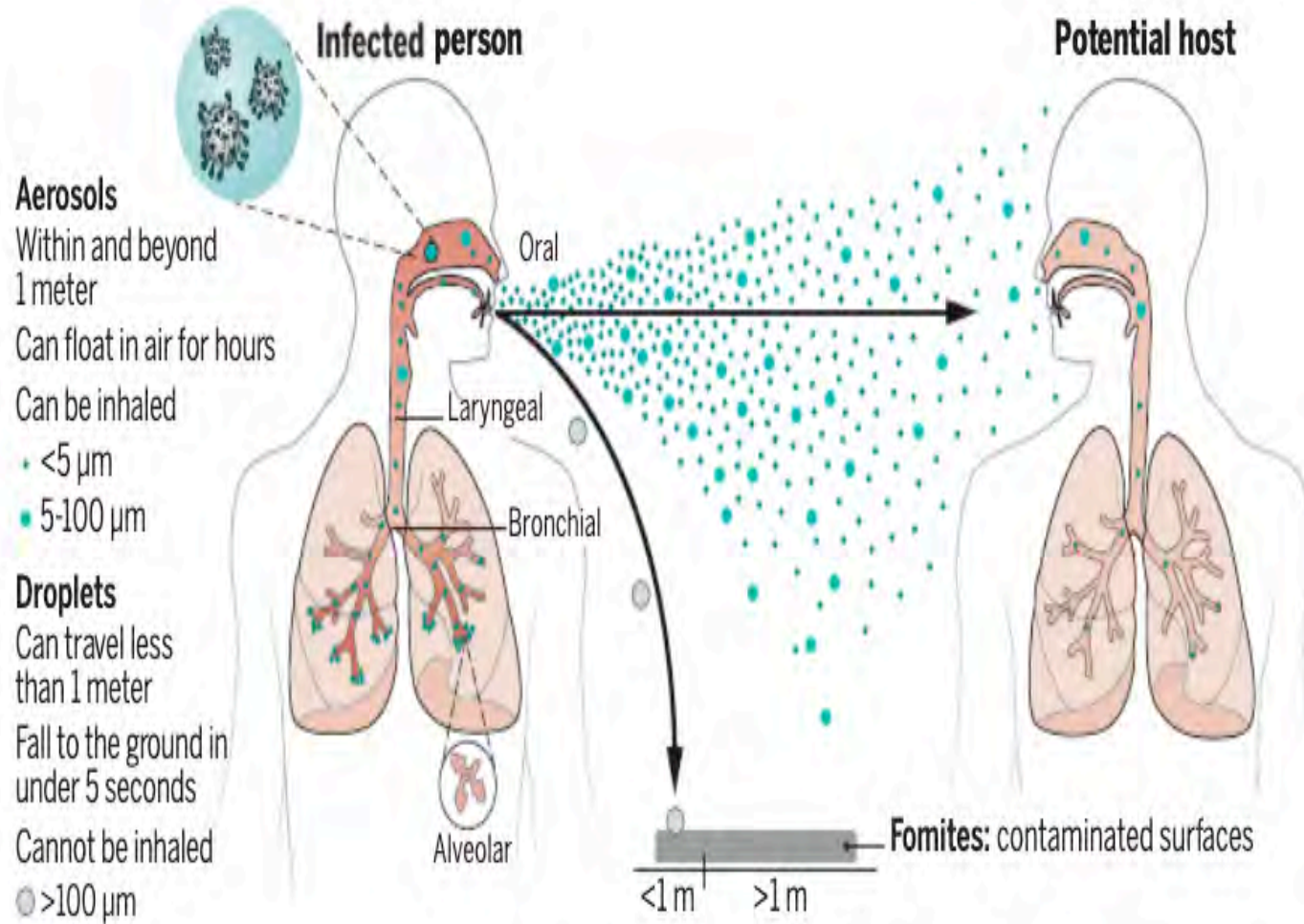
Masks, Hand Hygiene & Other Precautions

Preventing Infection

Hand Hygiene Remains Important

But We Now Know That Airborne and Droplet Transmission Are The Dominant Modes

Masks!



Studies Showing Mask Effectiveness

Brooks & Butler, JAMA March 2021

Table. Studies of the Effect of Mask Wearing on SARS-CoV-2 Infection Risk^a

Source	Location	Population studied	Intervention	Outcome
Hendrix et al	Hair salon in Springfield, Missouri	139 Patrons at a salon with 2 infected and symptomatic stylists	Universal mask wearing in salon (by local ordinance and company policy)	No COVID-19 infections among 67 patrons who were available for follow-up
Payne et al	USS Theodore Roosevelt, Guam	382 US Navy service members	Self-reported mask wearing	Mask wearing reduced risk of infection by 70% (unadjusted odds ratio, 0.30 [95% CI, 0.17-0.52])
Wang Y et al	Households in Beijing, China	124 Households of diagnosed cases comprising 335 people	Self-reported mask wearing by index cases or ≥1 household member prior to index case's diagnosis	Mask wearing reduced risk of secondary infection by 79% (adjusted odds ratio, 0.21 [95% CI, 0.06-0.79])
Doung-ngern et al	Bangkok, Thailand	839 Close contacts of 211 index cases	Self-reported mask wearing by contact at time of high-risk exposure to case	Always having used a mask reduced infection risk by 77% (adjusted odds ratio, 0.23 [95% CI, 0.09-0.60])
Gallaway et al	Arizona	State population	Mandatory mask wearing in public	Temporal association between institution of mask wearing policy and subsequent decline in new diagnoses
Rader et al	US	374 021 Persons who completed web-based surveys	Self-reported mask wearing in grocery stores and in the homes of family or friends	A 10% increase in mask wearing tripled the likelihood of stopping community transmission (adjusted odds ratio, 3.53 [95% CI, 2.03-6.43])
Wang X et al	Boston, Massachusetts	9850 Health care workers (HCWs)	Universal masking of HCWs and patients in the Mass General Brigham health care system	Estimated weekly decline in new diagnoses among HCWs of 3.4% after full implementation of the mask wearing policy
Mitze et al	Jena (Thuringia), Germany	City population aged ≥15 y	Mandatory mask wearing in public spaces (eg, public transport, shops)	Estimated daily decline in new diagnoses of 1.32% after implementation of the mask mandate
Van Dyke et al	Kansas	State population	Mandatory mask wearing in public spaces	Estimated case rate per 100 000 persons decreased by 0.08 in counties with mask mandates but increased by 0.11 in those without
Lyu and Wehby	15 US states and Washington, DC	State populations	Mandatory mask wearing in public	Estimated overall initial daily decline in new diagnoses of 0.9% grew to 2.0% at 21 days following mandates
Karaivanov et al	Canada	Country population	Mandatory mask wearing indoors	Estimated weekly 25%-40% decline in new diagnoses following mask mandates

^a See the Supplement for the complete table.

Use a Good Mask: Types That Work Best

Filtration + Fit Both Matter a Lot



N95



KF94

Recommended Mask Info

<https://www.bloomberg.com/graphics/2021-opinion-how-to-wear-face-mask-tactically-best-covid-protection/?sref=iiTFWQLU>



Surgical
ASTM Level 3
+/-
Cloth mask

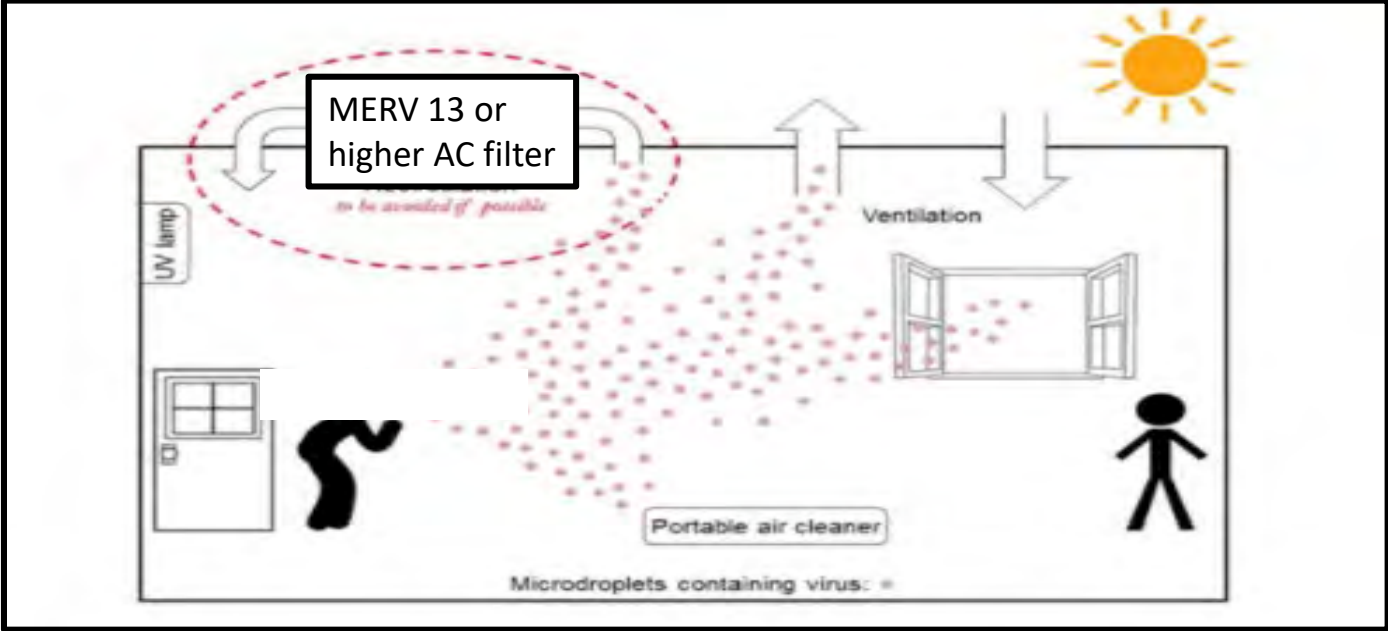
DEMEMASK KIDS SURGICAL
MASK ASTM LEVEL 3 SIZE:
SMALL (BOX OF 50)



KN95

Air Filters & Ventilation

<https://tinyurl.com/FAQ-aerosols>



Portable air cleaner with HEPA filter

ivp integrated viral protection™

Travel Mobile Unit Room Mobile Unit Venue Mobile Unit

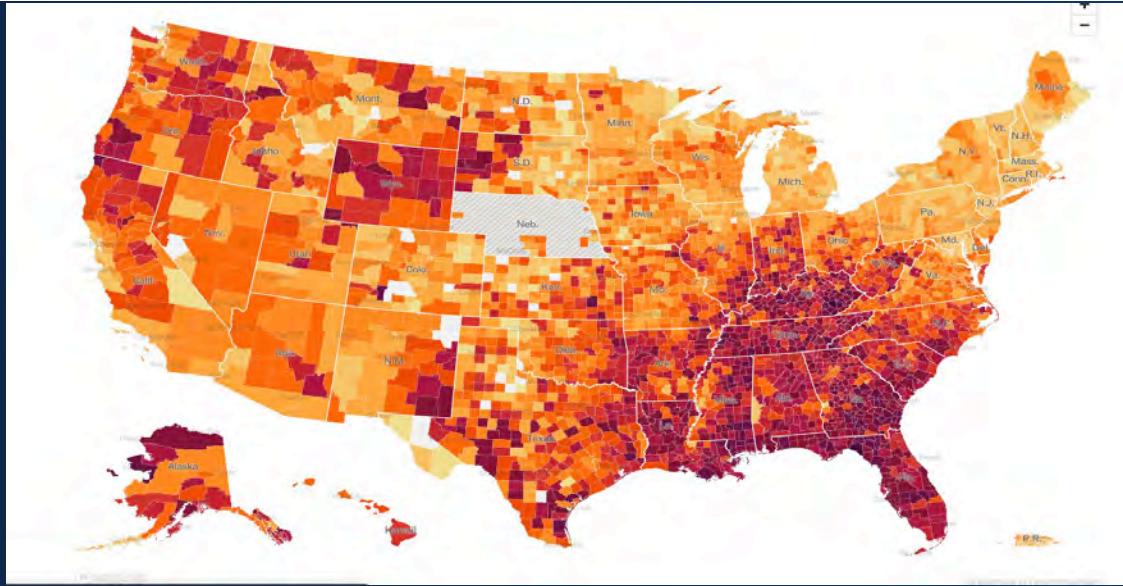
HVAC System Retrofit

Should You Take Precautions?

Common Sense Approach

- How susceptible are you?
 - 😊 Vaccinated?
 - 🙅 Risk factors for severe disease?
- How prevalent is infection in the community?
- What kind of exposure will you encounter?
 - 😊 Vaccinated small gathering
 - 🙅 Restaurant
 - 😞 Indoors
 - 😊 Outdoors
 - 😊 Quiet (watching TV)
 - 🙅 Aerosol generating (choir practice)
 - 😊 Brief
 - 😞 Extended
- What's the downside?
 - 🙅 Infection vs. inconvenience

Vaccines



Summary: What's Happening with Vaccines?

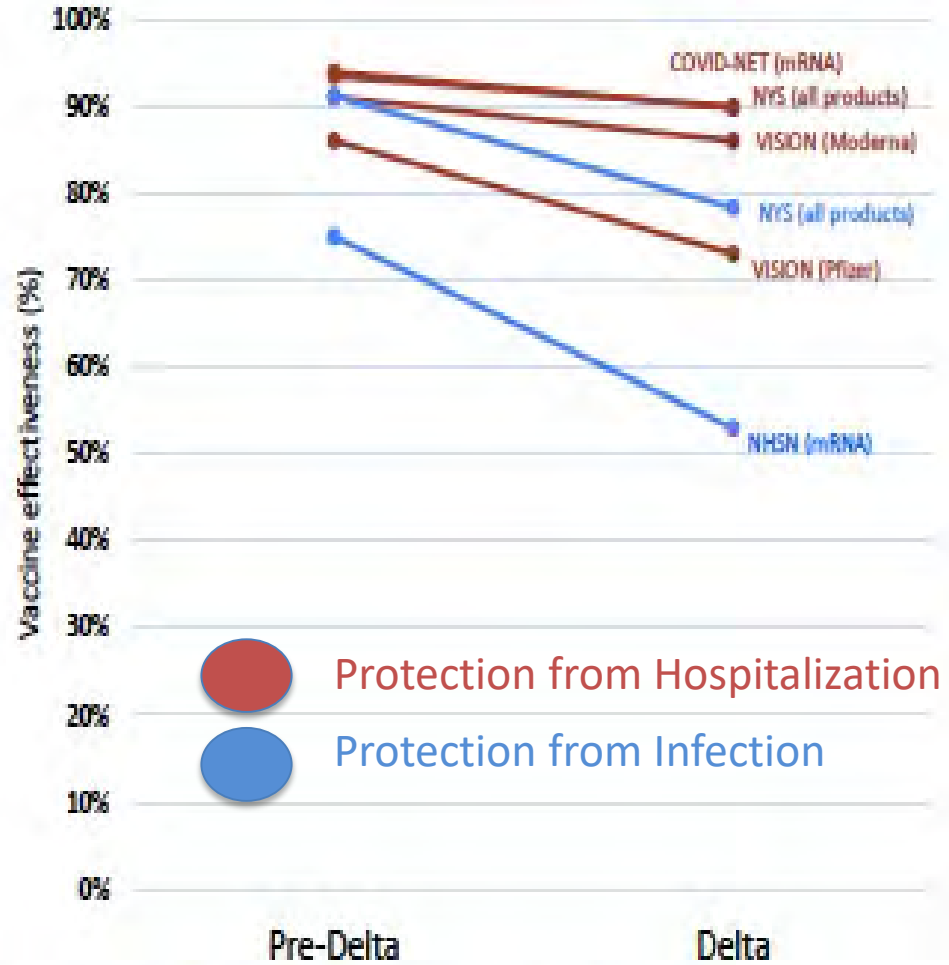
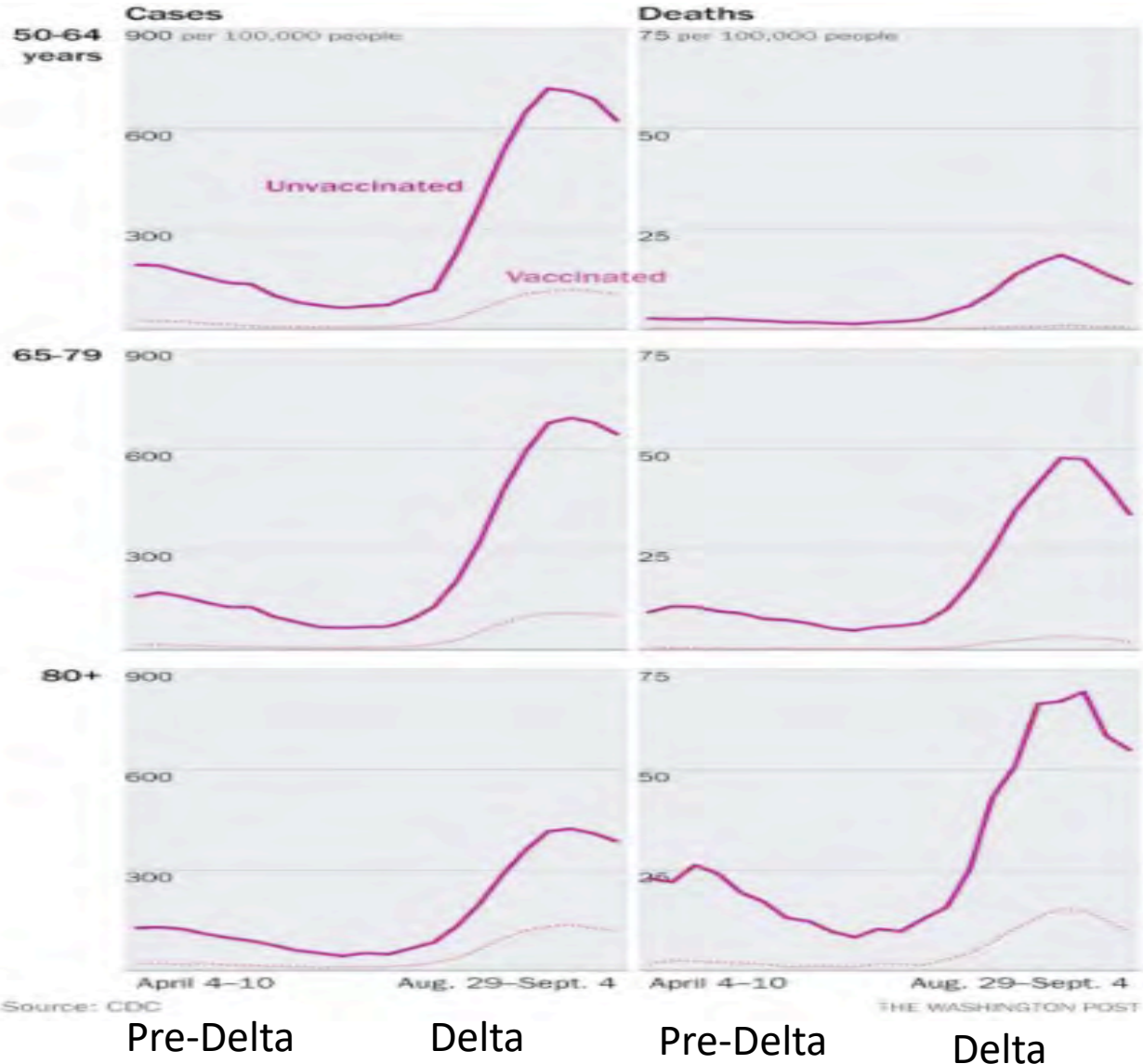
- As time passes, vaccines offer less immediate protection against infection
 - Related to lower levels of circulating antibodies
 - May also have other causes (vulnerable groups vaccinated first, community surges, etc.)
 - mRNA more potent initially, less durable than viral vector vaccines
- Protection against severe disease seems to be more durable
 - Likely related to cellular immunity
 - Big question: will this continue? Time will tell
- Moderna vaccine holding up better than Pfizer so far
 - Higher dose, longer interval between doses, other factors?
 - Will it continue? Probably not

Question: Is the Purpose of Vaccines Only to Reduce Severe Disease?
Or Also to Reduce Infection?

Summary: What's Happening with Vaccines?

- Vaccines remain effective against variants
 - Delta variant less sensitive to vaccines than wild type but still well covered
 - Beta variant least well covered by vaccines, but dying out worldwide
- What we know about boosters
 - They restore antibodies and protection against infection
 - Side effects from boosters same or less than primary series
 - Previous infection equivalent to one dose of vaccine (maybe better)
- Open questions about boosters
 - Role for mixed prime-boost series? (“Mix & Match”)
 - How long will renewed protection from infection last?
 - Who should get boosters and when?

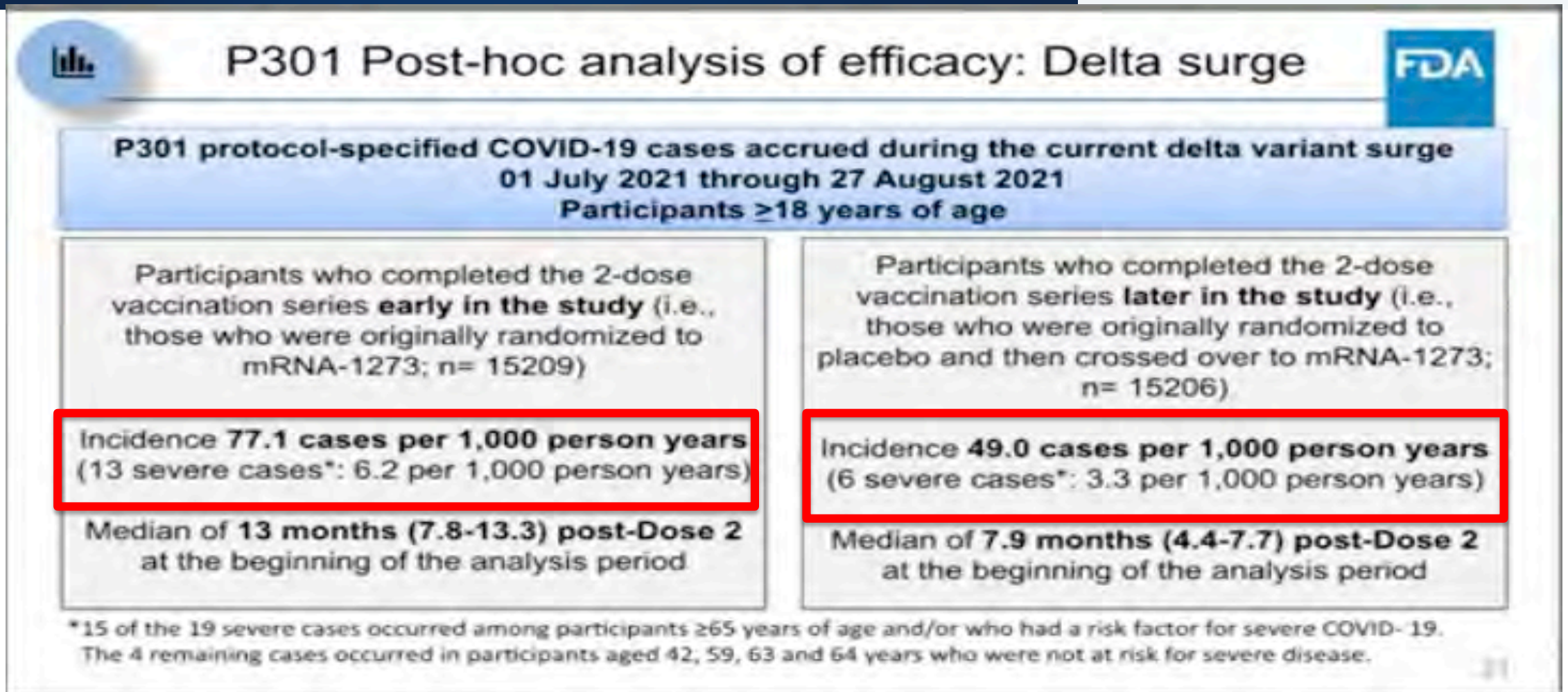
Vaccine Effectiveness: Age, Delta, Infection vs. Hospitalization



NHSN: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm>
 COVID-NET: CDC unpublished VISION: CDC unpublished

Moderna Vaccine Follow-up

FDA VRBPAC Meeting, October 14, 2021



**Infections 157% higher and severe disease 188% higher in those vaccinated 13 months vs 8 months ago.
They are still very uncommon but it's a worrisome data point.**

Booster Shots

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

FDA / CDC Booster Authorization Summary

As of October 15, 2021

- mRNA Vaccines (CDC pending for Moderna)
- people >65 years and residents in long-term care settings **should** receive a booster shot at least 6 months after their primary series,
- people 50–64 years with [underlying medical conditions](#) **should** receive a booster shot vaccine at least 6 months after their primary series,
- people 18–49 years with [underlying medical conditions](#) **may receive** a booster shot at least 6 months after their primary series, based on their individual benefits and risks, and
- people 18–64 years with increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may receive** a booster shot at least 6 months after their primary series, based on their individual benefits and risks.

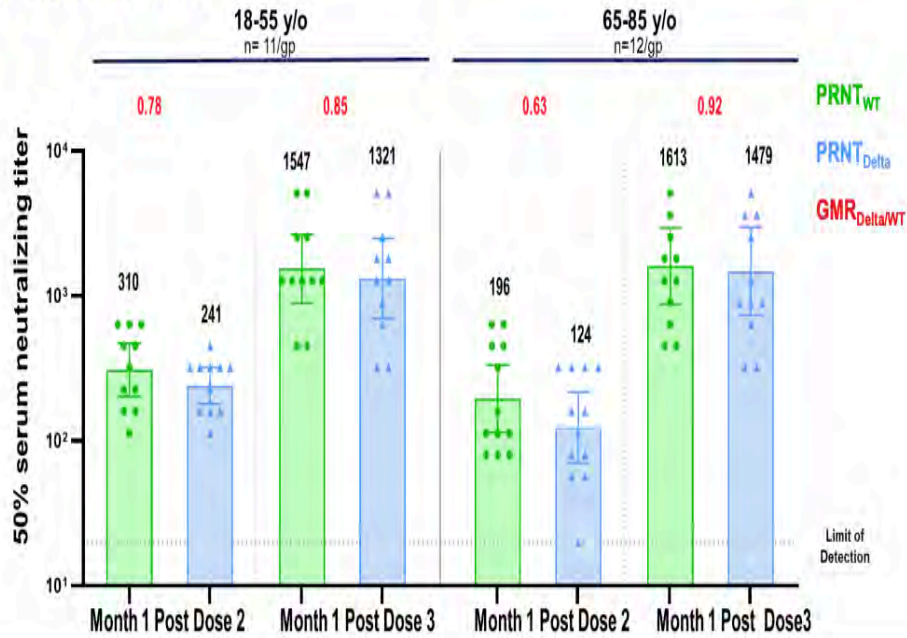
- J&J vaccine was authorized for all people 18 and older who received J&J first doses at least two months ago
- FDA analysis:
 - a second, booster dose of the J&J vaccine yielded a 94% efficacy against moderate-to-severe COVID-19
 - the first dose's efficacy is 70%
- FDA committee discussion really thought of the J&J vaccine as now being a two-dose vaccine
 - had to call the second dose a booster because J&J is authorized as a one dose vaccine
- CDC Pending

CDC ACIP committee meets October 21

- Disagreement about goal of vaccine – Prevent all disease? Or only severe disease?
- Myocarditis risk with 3rd dose in young males?
- Data that vaccinated front line workers are at risk?
- Focusing on vaccinating the unvaccinated would have greater effect
- Allowing people “at risk” from exposure would “throw the doors wide open”
- How long would protection last? Repeated boosters needed?
- Booster programs will overtax public health departments
- If only Pfizer boosters, what do we do about Moderna / J&J recipients?
- Increase inequity if only educated and wealthy could gain access to the system?
- Are we messaging to the public that the vaccines don’t work?

Booster Shot In Vitro Data

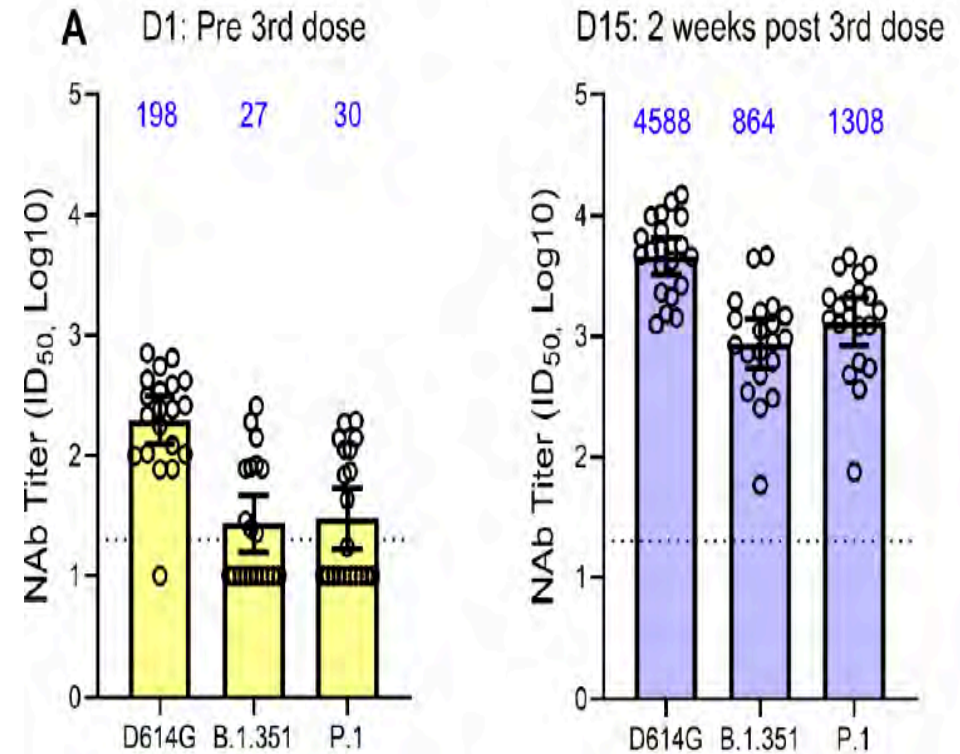
COVID-19 Vaccine: 3rd Dose Strongly Boosts Neutralizing Titers Against Delta Strain^{1,2}



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 tested against each variant separately; PRNT: Plaque Reduction Neutralizing Test; Wt: Wild Type; GMR: Geometric Mean Ratio

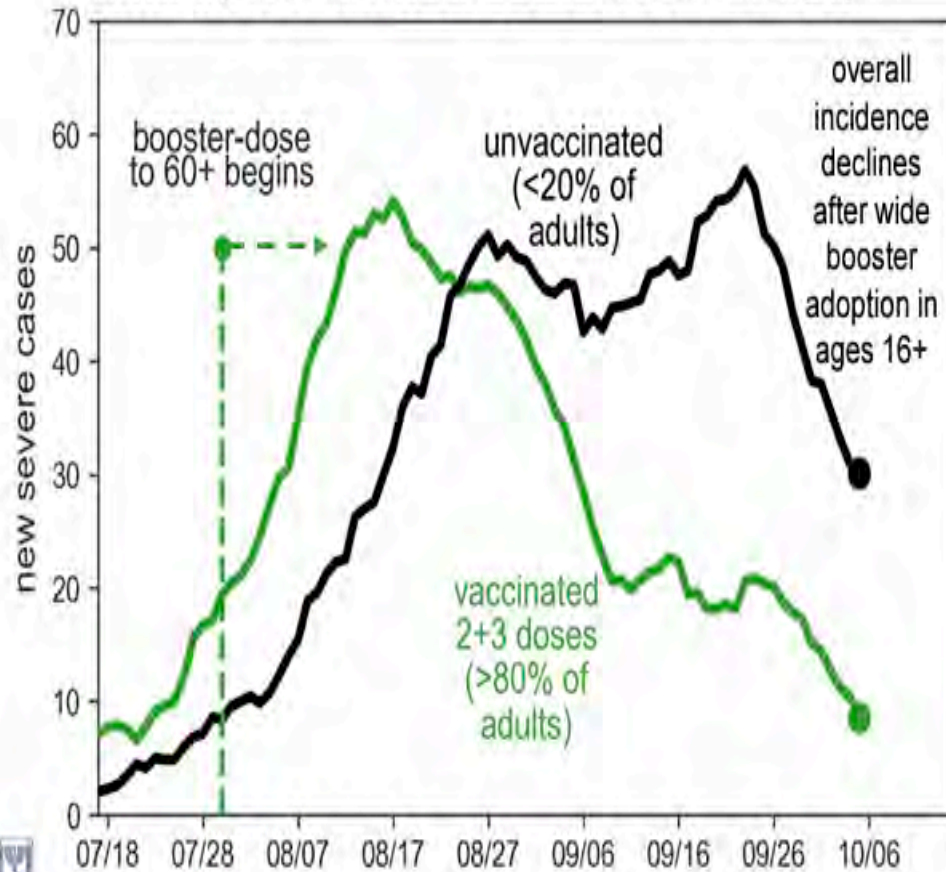
Immunogenicity After Boosting with Booster Dose of 50 µg of mRNA-1273



Pfizer Booster and Severe Cases

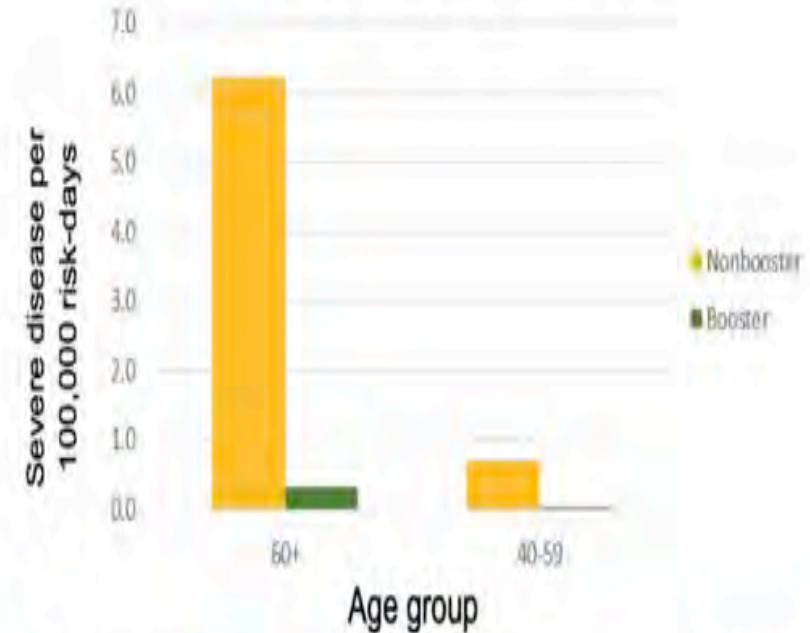
Presentation by Israel MOH to FDA, October 14, 2021

Following the third dose, severe cases among vaccinated decreased sharply



Absolute rates of **severe disease** per 100,000 risk-days

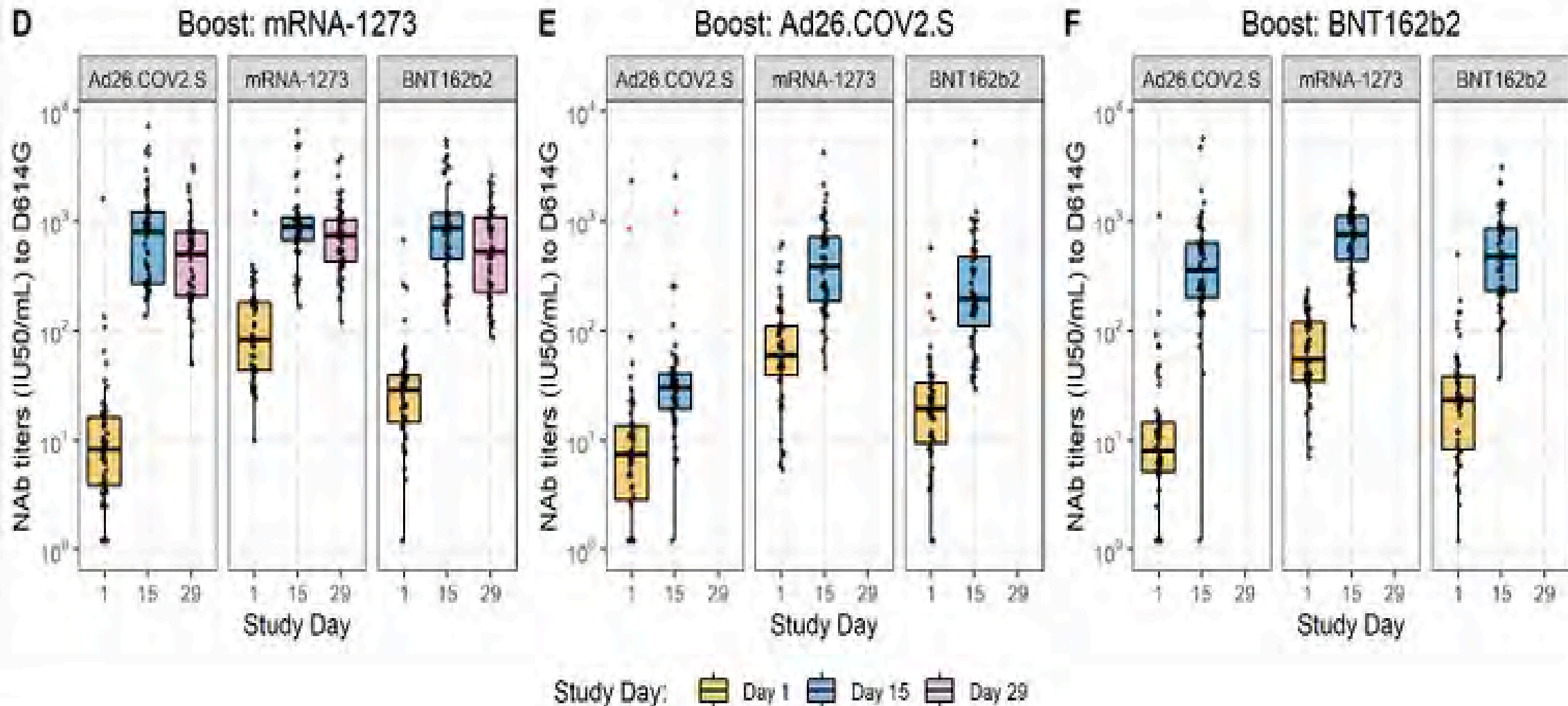
12+ days following booster versus 2nd dose only.
Based on data eligibility in age group until 9/29



*Severe disease (NIH definition):
resting respiratory rate
>30 breaths per minute,
or O2 saturation <94%,
or PaO2/FiO2 <300

Heterologous Prime Series (“Mix & Match”)

Atmar et al, medRxiv October 13, 2021



Testing

Testing

Per Dr. Bernard 10/6/21

THE BIOFIRE RESPIRATORY 2.1 PANEL MENU

Overall 97.1% sensitivity and 99.3% specificity (prospective specimens)³

SARS-CoV-2 98.4% PPA and 98.9% NPA⁴

Sample Type: Nasopharyngeal swab in transport media or saline

VIRUSES:

- Adenovirus
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus 229E
- Coronavirus OC43
- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A
- Influenza A/H1
- Influenza A/H3
- Influenza A/H1-2009
- Influenza B
- Parainfluenza Virus 1
- Parainfluenza Virus 2
- Parainfluenza Virus 3
- Parainfluenza Virus 4
- Respiratory Syncytial Virus

BACTERIA:

- *Bordetella parapertussis*
- *Bordetella pertussis*
- *Chlamydia pneumoniae*
- *Mycoplasma pneumoniae*



- Currently available
 - BioFire Respiratory Pathogen Panel plus COVID-19 (RPPC) in the HMM Microbiology lab. Sample transported in from all sites.
 - Flu A/B and RSV antigens available on-site at all hospital labs and ECC's.
 - COVID-19 PCR – on-site at all hospitals (Cepheid) and ECC's (Roche Liat). Reagents limited and on allocation.
- In process
 - PCG Same day clinics – Cepheid waived COVID-19, Flu A/B and RSV PCR.

At Home Testing

FDA EUA as of 10/4/21

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s) ¹	Authorization Documents ²
10/04/2021	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)
04/12/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card Home Test 12/16/2020	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)
06/04/2021	OraSure Technologies, Inc.	IntelliSwab COVID-19 Rapid Test Rx 06/04/2021	Lateral Flow, Visual Read, Prescription Home Testing	Home, H, M, W	HCP, IFU, IFU (Home Test)
02/11/2021	Ellume Limited	Ellume COVID-19 Home Test 12/15/2020	Lateral Flow, Fluorescence, Instrument Read, Over the Counter (OTC) Home Testing, Screening	Home, H, M, W	HCP, IFU, IFU (Home Test), FAQ
08/24/2021	Becton, Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test 8/24/2021	Lateral Flow, Digital Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s) ¹	Authorization Documents ²
08/23/2021	Access Bio, Inc.	CareStart COVID-19 Antigen Home Test 08/02/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
08/10/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Antigen Self Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
06/04/2021	OraSure Technologies, Inc.	IntelliSwab COVID-19 Rapid Test 06/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
03/31/2021	Abbott Diagnostics Scarborough, Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)
03/31/2021	Quidel Corporation	QuickVue At-Home OTC COVID-19 Test 03/31/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Serial Screening	Home, H, M, W	HCP, Individuals, IFU, IFU (Home Test)

Less accurate but useful because they are convenient, can be repeated often and best suited for high viral loads (transmissibility)

Outpatient Treatments

Early treatment of high risk outpatients is critical need

- Lilly Long Term Care Prevention Study

- 80% reduction in symptomatic infection in 299 Nursing Home residents who tested negative at study initiation
- In 41 who tested positive at study start, 0/21 in treatment group died, 4/20 in placebo

- Regeneron Household Contacts Prevention

- 100% prevention of symptomatic infection in people with household exposure to COVID
- Reduction in asymptomatic infection (5.4% in mAB group versus 6.7% in placebo group)
- Lower viral load and shorter duration of viral shedding

- Lilly Early Treatment Study (mAb “cocktail”)

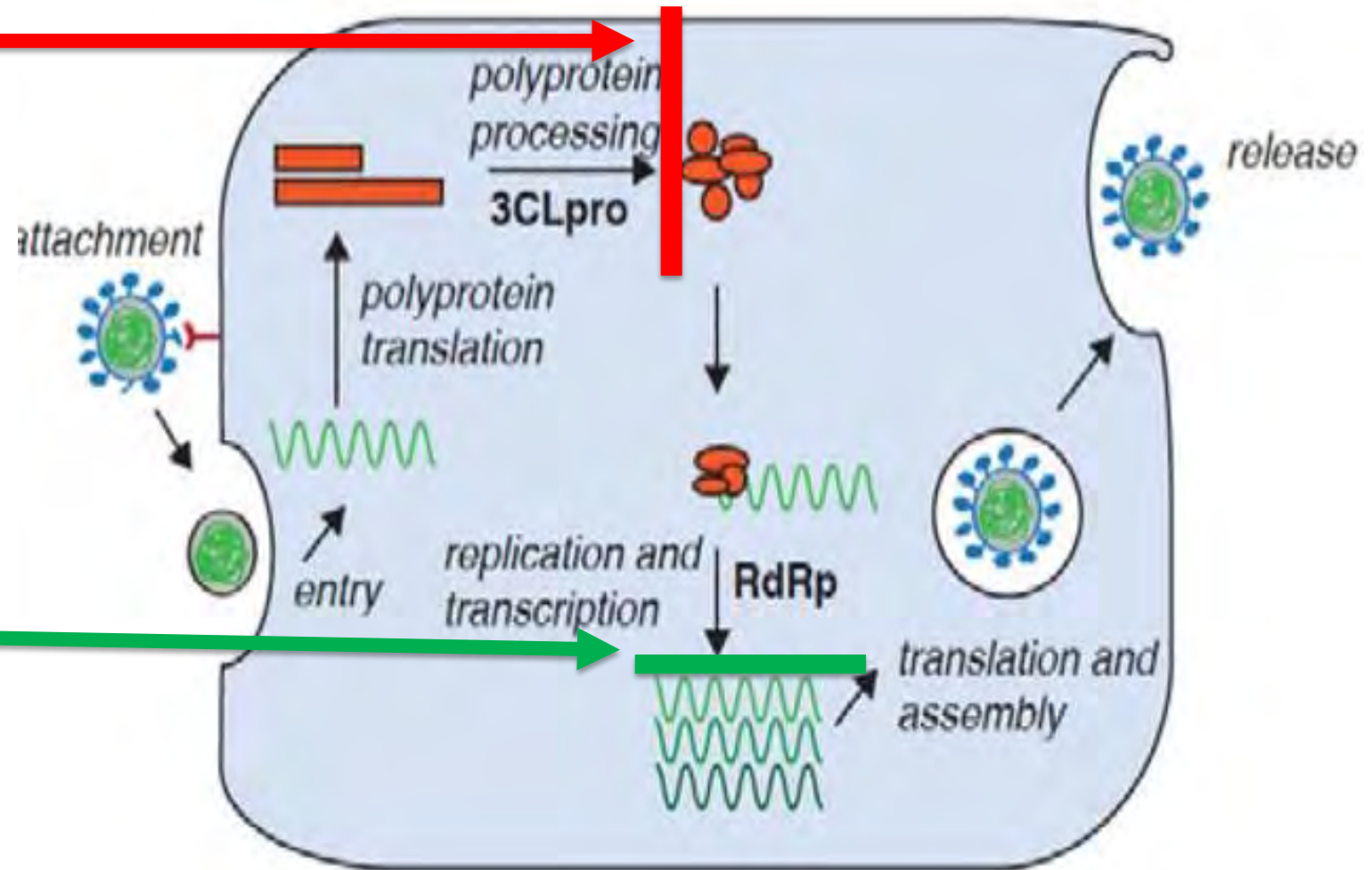
- 1,035 high risk patients with COVID
- mAb group – 2.1% events, placebo group 7%
- mAb group – 0 deaths, placebo – 10 deaths

- Action versus viral variants

- Dual mAb cocktail is **active** against all variants
- Recent data show sub-Q injection as effective as IV
- Prophylaxis for immune compromised a realistic idea but not yet EUA; Regeneron starting trial

Drugs Under Active Investigation

- RNA polymerase inhibitors
 - Remdesivir (intravenous)
 - Favipiravir (oral)
 - Molnupiravir (oral)
 - AT-527 (oral)
- Protease inhibitors
 - PF-07304814 (intravenous)
 - PF-07321332 (oral)
- Combination therapy could be advantageous



Molnupiravir Clinical Trial

Press release and ISDA conference presentation

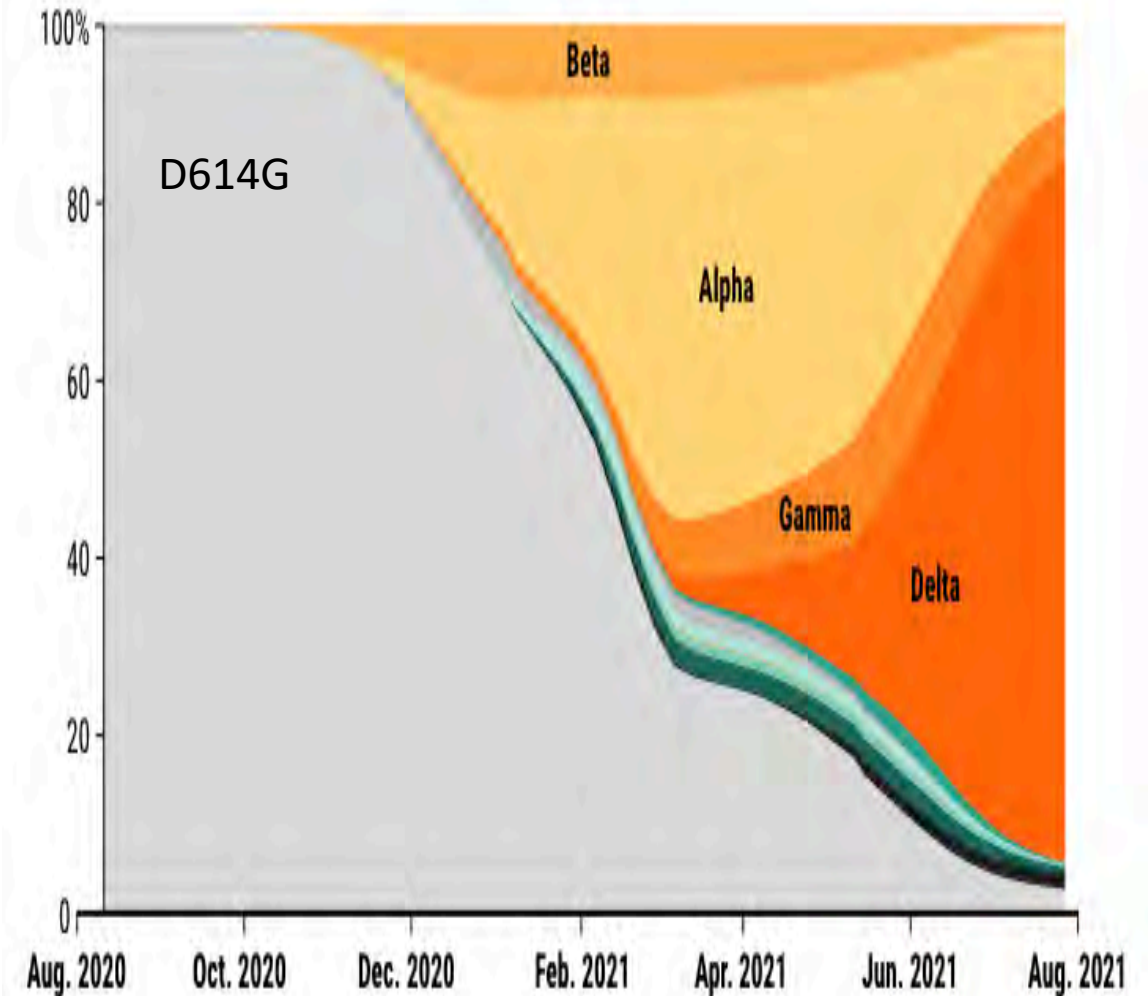
- 775 people with mild / moderate COVID
 - +At least one risk factor for progression
 - +Within five days of symptom onset
- Consistent efficacy across viral variants
- No safety signals
- Could be combined with other therapy
 - Protease inhibitor
 - mAb

Outcomes	Treated	Placebo
Hospitalized	7.3%	14.1%
Death	0	2.1%

What Could Happen Next?

“We’re better at explaining the past than at predicting the future.”
– Andrew Read, viral evolutionary biologist

- Delta has crushed other variants but has not yet infected every susceptible person
 - therefore, lesser, endemic surges are likely
 - if delta is “optimum fitness” this could be the last big surge
 - possible, but not the way to bet
 - eventually COVID → common cold
 - “eventually” is a long way away
- Effects of ongoing mutations – mostly uncorrelated
 - increased or decreased severity of illness
 - increased viral “fitness” for infection / transmission
 - gradual immune escape under new selective pressure of population immunity
- Sudden immune escape due to viral recombination
 - requires same cells infected with different variants – rare
 - crisis scenario requiring deployment of updated vaccines, mAbs, lockdowns, etc.



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

What Could Happen Next?

“The curve is shaped by public awareness. We’re sort of lurching between crisis and complacency.” Jennifer Nuzzo, epidemiologist

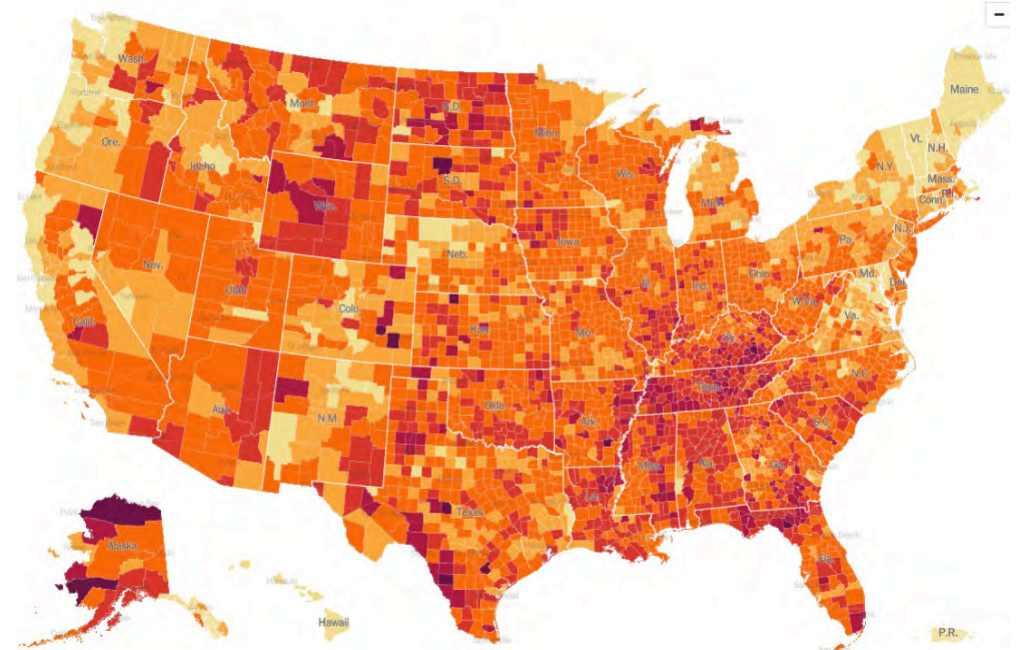
- Human behavior continues to be a “wild card” variable
 - Social behavior
 - Vaccine uptake
 - Social media misinformation / disinformation
 - Irresponsible political stunts

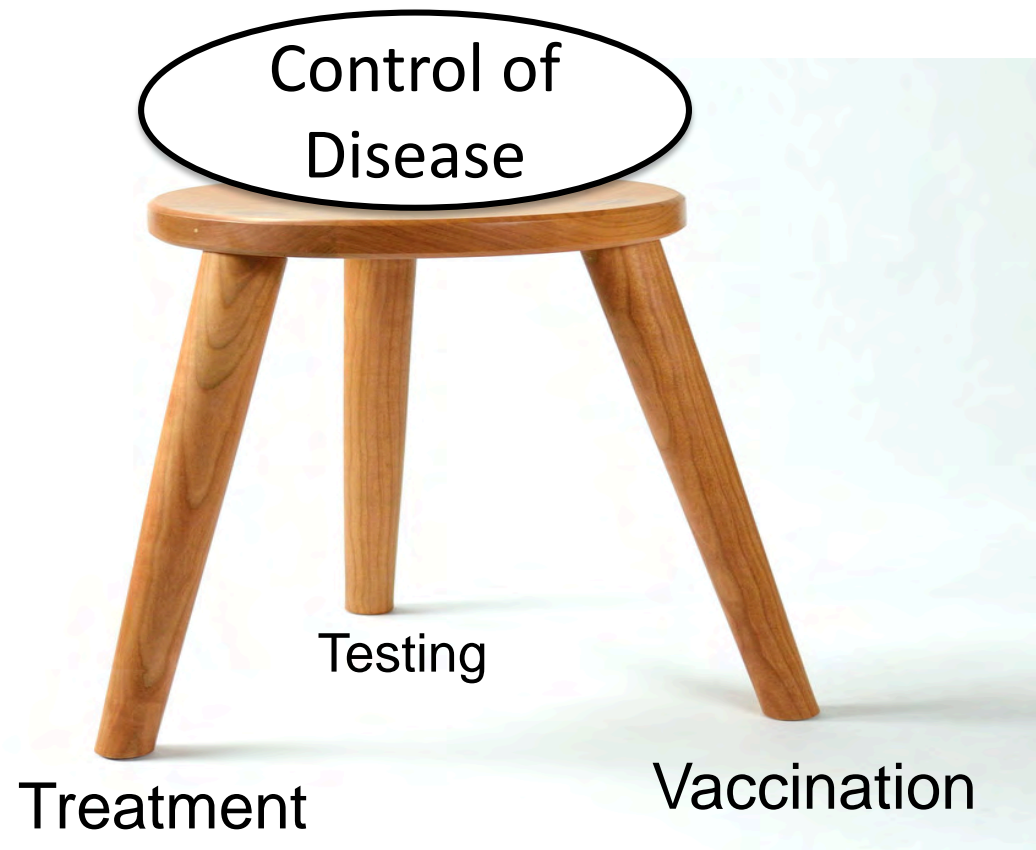


Facebook Takes Down Anti-Vax Hoax Network 'Primarily Conducted From Russia'



Facebook says that a marketing group was using its influence to push anti-vax messages targeting audiences in India, Latin America, and the United States. (file photo)





Masks, Hand Hygiene & Other Precautions

The tools to control the pandemic exist now. They will continue improving. We can stop the pandemic by using them with determination and consistency.

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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

