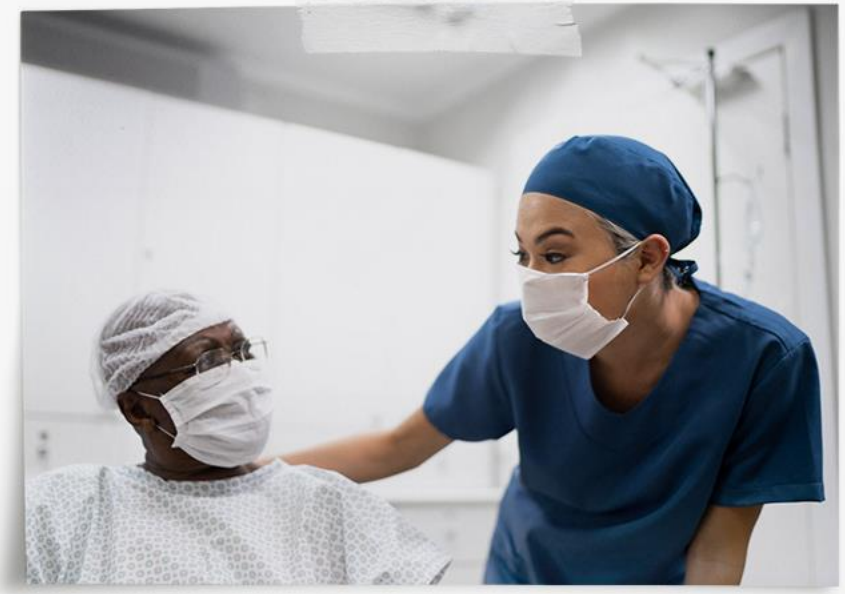

The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XV

We will begin at 10 a.m.

Hosted by the Houston Methodist Cancer Center Council and the Houston Methodist Urology Task Force

4

COVID-19 and Urologic Diseases

Brian J. Miles, M.D.
Centennial Chair in Urologic Oncology
Professor of Urology, Weill Cornell Medical College
Medical Director, Robotic Surgery
Vice Chair, Department of Urology
Houston Methodist Hospital

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COVID-19

As with all aspects of medical care, this virus changed all our worlds in dramatic fashion.

- Fewer clinic visits
- Fewer surgeries
- Isolation

COVID-19

- This was the experience in all areas of the country – some much more than others.
- I would like to share with you 3 slides from a report from the Association of Community Cancer Centers.

COVID-19

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Cancer program staff have been *tested*.

- The COVID-19 pandemic strained the resources of cancer programs. Patient volume and revenue dropped dramatically in the first COVID-19 wave. Workloads increased and provider and staff roles and responsibilities expanded.
- Mandatory physical distancing contributed to social and emotional isolation for many staff and patients. Providing support for staff became a full-time occupation for many leaders and managers.
- Information flow and exchange was severely disrupted in 2020. Cancer programs and practices spent more on resources to support COVID-related safety protocols and telehealth.

COVID-19

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COVID-19 *transformed* the dynamics of clinical and operational practices.

- The shift from being in the clinic to remote work was seismic. Financial navigators, oncology social workers, genetic counselors, administrators, and other staff worked remotely more than physicians and nurses, who often had to be in clinics and infusion centers. This shift reshaped communication between clinicians, staff, and their patients and colleagues.
- Cancer programs and practices identified new operational approaches to address disruptions.
- Telehealth became more prominent in 2020, often despite lack of infrastructure and multiple implementation barriers. Members are hopeful that relaxed regulations introduced in 2020 will remain and emphasized the potential for telehealth to improve health equity by removing transportation barriers, particularly for those in rural and underserved communities.
- Flexibilities established in clinical research have long-term potential to reshape the design and conduct of clinical trials and potentially address health inequities.

COVID-19

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Cancer program staff have shown remarkable *resilience*.

- Cancer care teams acutely felt the loss of in-person social connection and the disruption of everyday professional and personal life.
- COVID-19 reinforced the importance of face-to-face communication for clinical practice and financial navigation. Oncology staff found new ways to communicate and connect—with each other and with their patients.
- To bolster this resiliency, cancer programs and practices repurposed conference rooms and other areas as designated staff spaces; got innovative with staff recognition and perks, like hosting milkshake and ice cream bars; developed robust buddy systems; sent daily supportive messaging and shared positive stories and accomplishments; and reinforced a "speak up" culture, especially when issues and challenges arose.

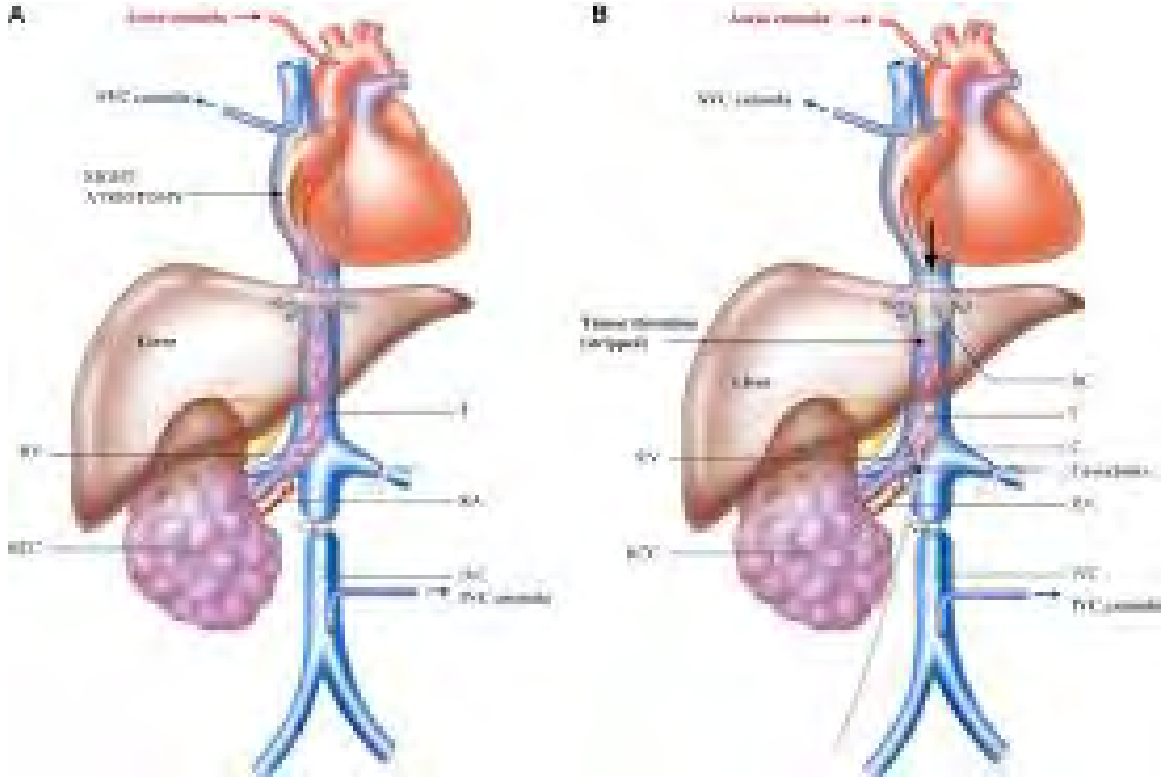
COVID-19

- In urology, cancer care did suffer mostly due to limitations of surgical prioritization and patient fears.
- Stone disease patients would not come to the office unless pain was so severe they couldn’t avoid it.
- Routine urologic care was greatly compromised.
- Andrology and low testosterone managed to hold its own regarding patient visits.
- International patient visits were down dramatically.

COVID-19

The most serious issues, however, involved patient fears of getting the virus and ignoring or minimizing signs and symptoms of possible significant health issues:

- Hematuria
- Flank pain
- Inability to urinate
- And, of course, others like coughing up blood, breast lumps, etc.


A
B

Conclusions

- COVID-19 has had significant impact on health care in our country.
- Unfortunately, fears of this virus created “collateral” damage.
- In the future we must educate our patient population about not only global disease issues, but also about the need not to ignore other important aspects of individual health.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Breast Cancer Updates

Polly Niravath, MD

June 10, 2021

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Objectives

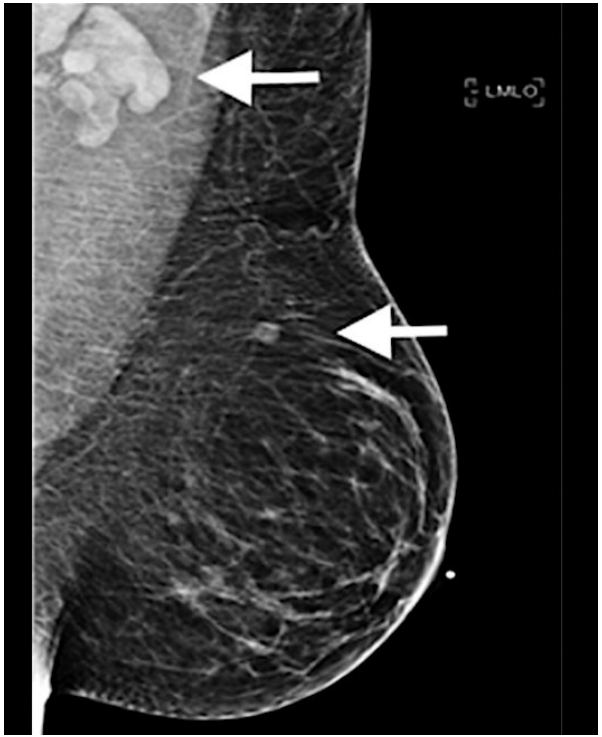
- To clarify the optimal timing from COVID vaccination to subsequent mammogram
- To describe the components of the Cancer Survivorship Program at Houston Methodist Hospital

Case History

Janice

- Janice is a 52 y/o woman with hypertension, diabetes, and family history of breast cancer
- Mother had breast cancer at age 49, and her maternal aunt had breast cancer at age 52
- She has been taking hormone replacement therapy with estrogen and progesterone for the past 6 years
- Janice now comes in for her annual mammogram

Janice’s Mammogram



Imaging Technology News, itnonline.com

Should we be concerned?

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- No, this is the body's normal, healthy immune response (also seen with other vaccines)
- May lead to unnecessary additional imaging or biopsies, anxiety
- Highest incidence of enlarged lymph nodes is usually 3-10 days after vaccination

Recommendations

- Axillary ultrasound is warranted for enlarged lymph nodes on mammogram
- If axillary lymphadenopathy is seen on the same side as recent COVID vaccination, and there are no breast abnormalities, you may repeat the imaging 6-12 weeks after final injection
- If there is clinical concern, may proceed with biopsy of the lymph node for confirmation, as a last resort

What happened to Janice?

- Breast ultrasound also showed a 6 mm right breast mass, and enlarged right axillary lymph nodes
- Due to her high risk features (family history, combined HRT, and breast abnormality on MMG), she was biopsied
- Breast biopsy and axillary lymph node biopsy were negative

What can we do?

- Ideally, wait 6-12 weeks after last vaccination
- If you have a breast concern, or have a history of breast cancer, don't delay your mammogram!
- If possible, choose the opposite arm, or the thigh can also be used as a vaccination site

Cancer Survivorship

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Who is a Cancer Survivor?

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A cancer survivor is anyone who has been diagnosed with cancer – from the time of diagnosis and for the balance of his or her life.

NCCN: National Coalition for Cancer Survivorship
http://www.canceradvocacy.org

Who cares?

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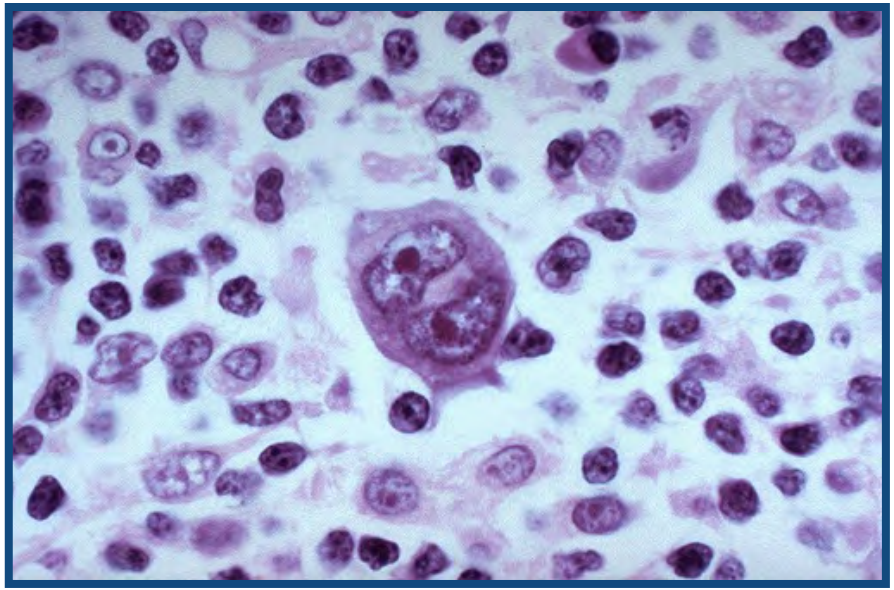
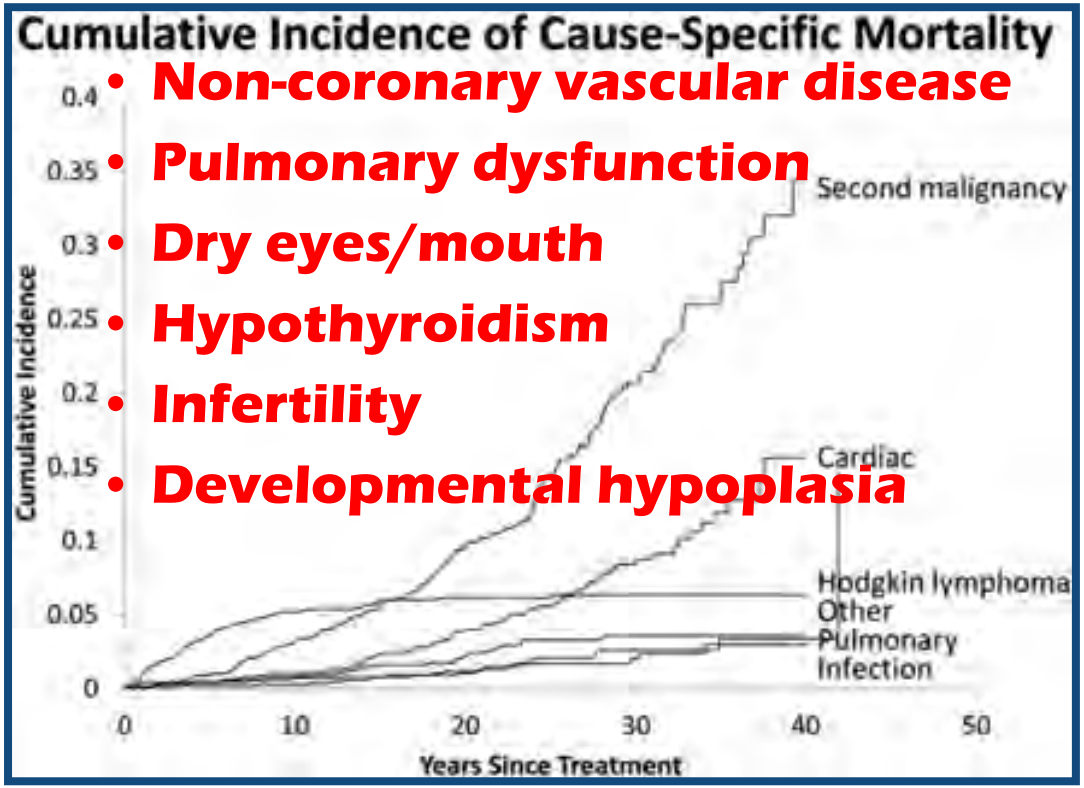


Hodgkin's Lymphoma



Ng, Blood 2014

Changing the Field

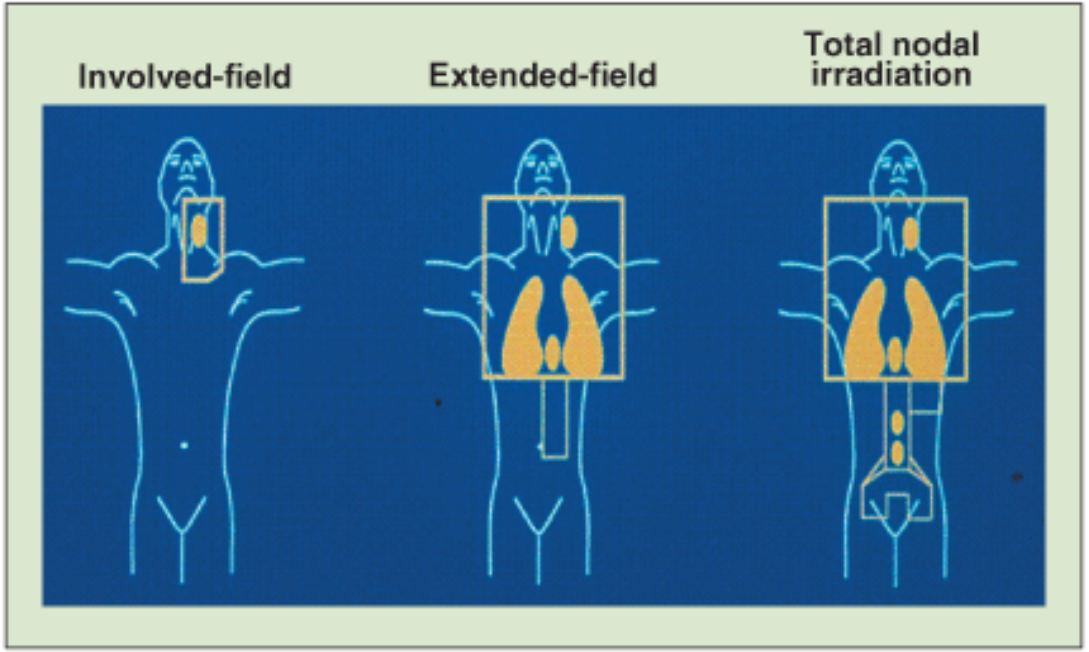
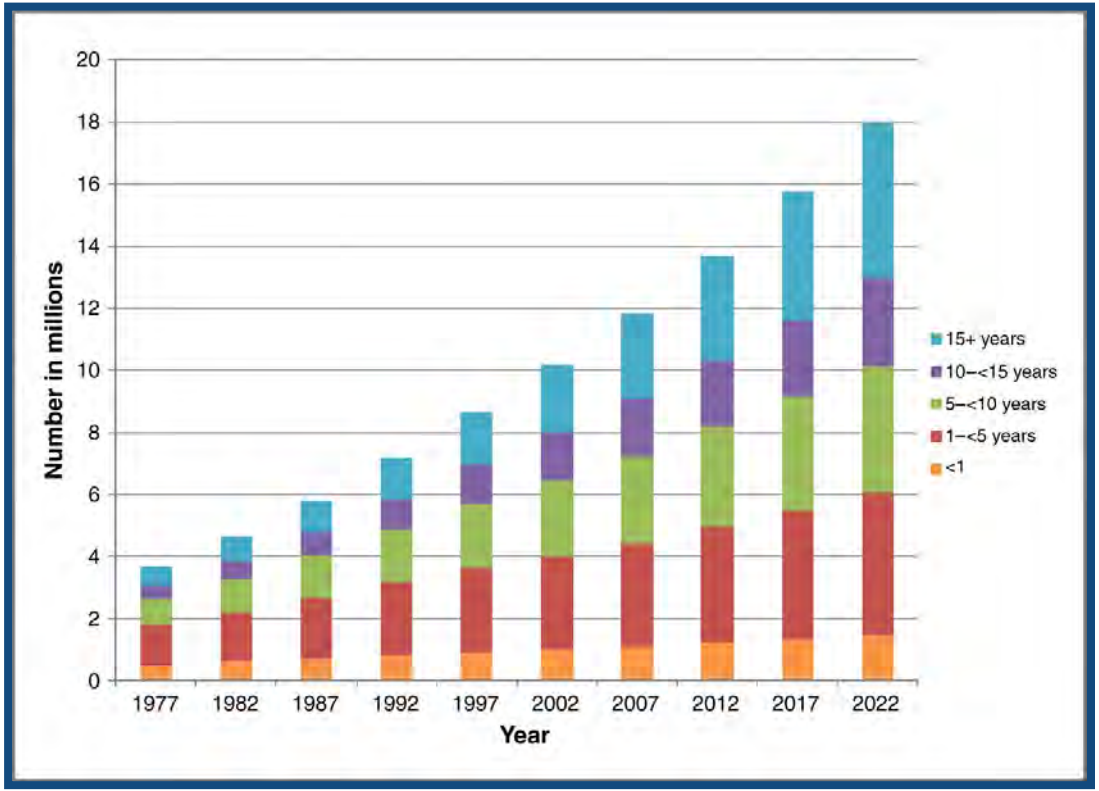


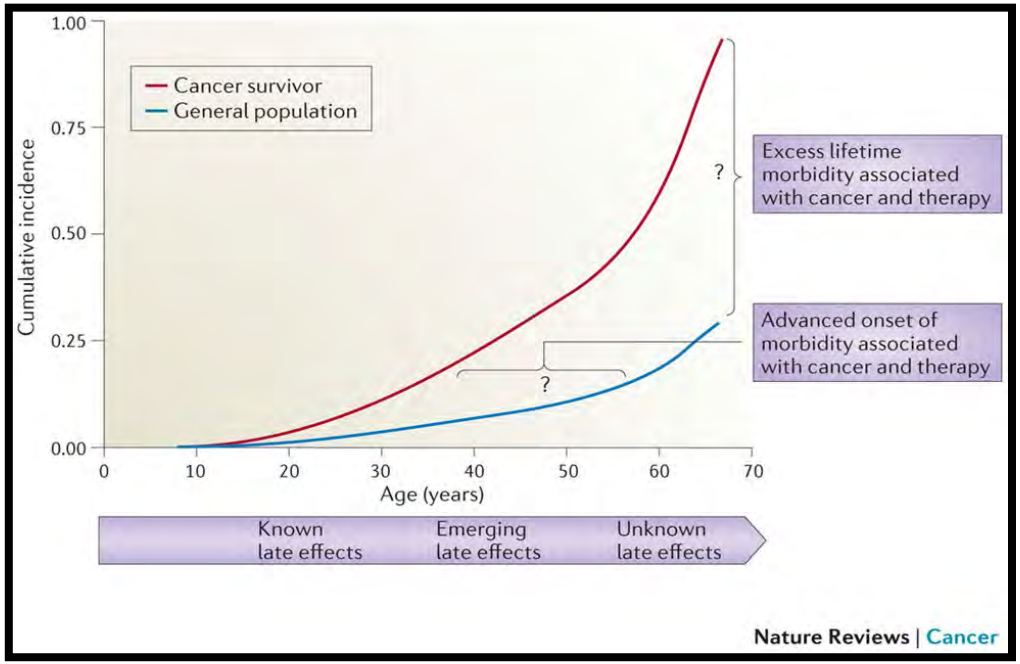
Figure 1: Radiotherapy Techniques and Fields—Involved-field, extended-field, and total nodal irradiation in a patient with left cervical involvement of Hodgkin's lymphoma (clinical stage I).

Projected US Cancer Survivors



de Moor, et. al. Cancer Epidemiol Biomarkers Prev 2013

Bridge the Gap



Nature Reviews Cancer 14, 61–70 (2014)

Case History

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Case History: Alma

- 47 y/o woman, works as a VP at an oil and gas company
- Married, with 2 kids, ages 15 and 12
- Enjoys long distance running, traveling, mentoring
- Diagnosed with breast cancer 1 year ago, now in remission
- Was treated with chemotherapy, mastectomy, and radiation

Year 1

- “Why do I feel like I have old lady joints?”
- “Why am I taking naps during the day?”
- “I can’t remember as much as I used to.”
- “I can barely run these days.”
- “I want to rip off all my clothes when I get these hot flashes!”
- “I have no sex drive anymore.”

REVIVE Clinical Trial

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- Post menopausal women who are taking an aromatase inhibitor (Arimidex, Femara, Aromasin) for breast cancer, and have vaginal dryness

- Randomized to vaginal estrogen versus Replens

REVIVE Clinical Trial

HOUSTON Methodist LEADING MEDICINE

- Early data shows that vaginal estrogen…
  - Causes minimal estrogen absorption in the blood
  - Decreases vaginal itching/discomfort
  - Improves pain with intercourse
  - Associated with improved libido
  - Normalizes vaginal pH

Benefits of Survivorship Care

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Key Goals of Survivorship Care

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- Prevent cancer recurrence and new cancers
- Assess medical and psychosocial late effects
- Manage late effects
- Multi-disciplinary approach
- Provide routine health promotion

Clinical Services

- Dietitian
  - Cooking Lessons
  - Group and Individual Lessons
- Physical Medicine & Rehabilitation/PT
  - Cancer Pre-hab
- Stoma Care
- Speech Therapy
- Neurology
- Cardiology
- Uro-gynecology
- Fertility Services

Psychological Services

- Counselor, Psycho-oncologist
  - Depression/Anxiety
  - Isolation
  - Altered Body Image
- Support Groups
- Music Therapy
- Sexual Therapy
- Chaplaincy

Social Services

- Unemployment
- Disability
- Advocacy
- Employment Rights
- Community Partnerships
  - ACS
  - Livestrong
  - Komen

Complementary Medicine

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- Acupuncture
- Massage
- Yoga
- Meditation
- Mindfulness
- Exercise Classes

Clinical Trials

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Clinical Trials

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- Chemo-induced cardiomyopathy
- Chemobrain
- Aromatase Inhibitor Induced Arthralgia
- Sexual Dysfunction
- Peripheral Neuropathy
- Cancer-Related Fatigue
- Acupuncture for Peripheral Neuropathy


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COVID-19 Vaccine & Treatment Update

Town Hall, June 10, 2021

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

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Real World Data on Vaccination

- Israel
  - 96% protection from infection
  - April 23 was first day in 7 months with 0 COVID deaths
- Scotland
  - hospitalization reduced by 85% (Pfizer) and 94% (AstraZeneca)
  - 30% reduction in household contact infections after one dose
- England
  - Public Health England – vaccine efficacy 73% (AstraZeneca) to 89% (Pfizer)
  - Cambridge Health – 75% reduction in asymptomatic infection
  - Public Health England – 45% reduction in household transmission
- USA – health care workers
  - Houston Methodist – reduced employees' positive test rate 95%
  - St. Jude – 94% reduction in asymptomatic, 100% in symptomatic (2 doses)
  - CDC study – single dose efficacy = 82%, two doses = 94% (https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm)

CDC Breakthrough Infection Data

	Unvaccinated 1/1/2020 – 12/31/2020	Vaccinated 1/1/2021 – 4/27/2021
Infections	92 / 1,000	0.97 / 1,000 27% of the infections were asymptomatic
Hospitalizations	900 / 1,000,000	8.7 / 1,000,000
Deaths	1,680 / 1,000,000	1.38 / 1,000,000

https://www.cdc.gov/vaccines/covid-19/health-departments/past-breakthrough-data.html

Why Get Two Doses?

Houston Methodist Patient Outcomes

- 91,134 patients
- January 1 – April 4, 2021
  - –70.2% not vaccinated
  - –4.5% had one dose of vaccine
  - –25.4% had two doses of vaccine
- 2,017 COVID hospitalization
- 225 COVID mortality

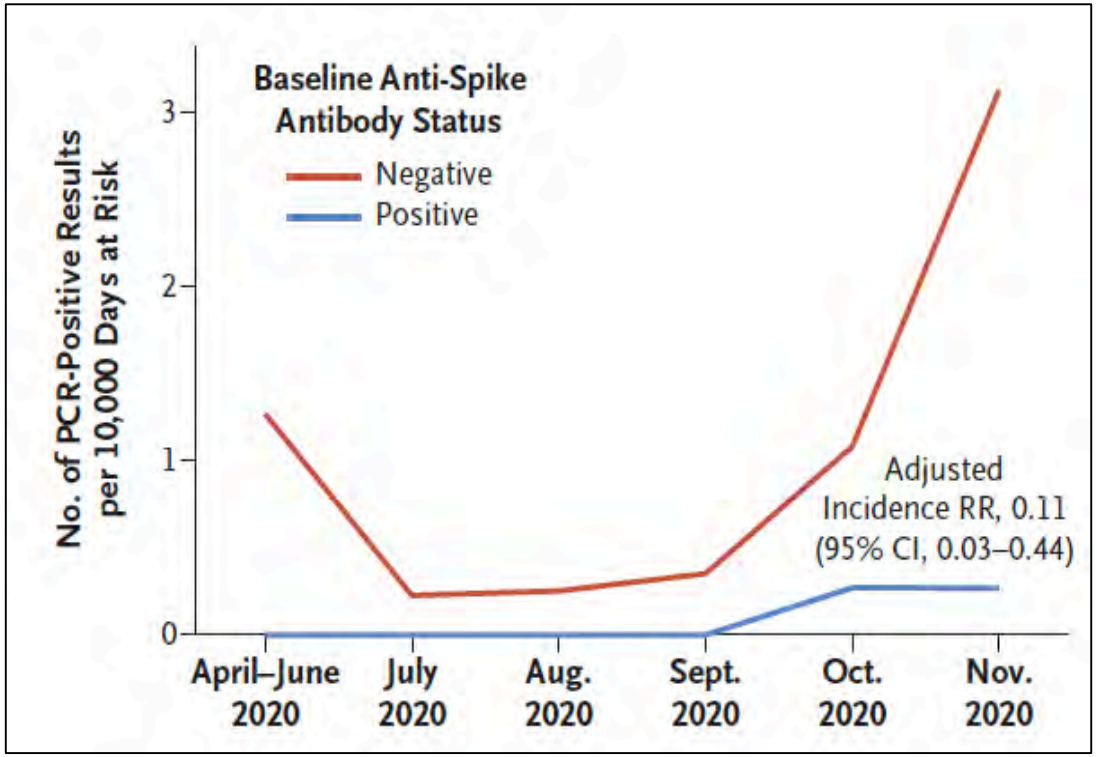
Pfizer Vaccine	One Dose	Two Doses
Prevention of Hospitalization	77%	96%
Prevention of Death	64%	99%

Recommended interval between doses:
Pfizer 3 weeks, Moderna 4 weeks – CDC allows 6 weeks

Maximum possible interval is not known

Protection by Prior Infection

Oxford study
12,000 health care workers followed for 6 months



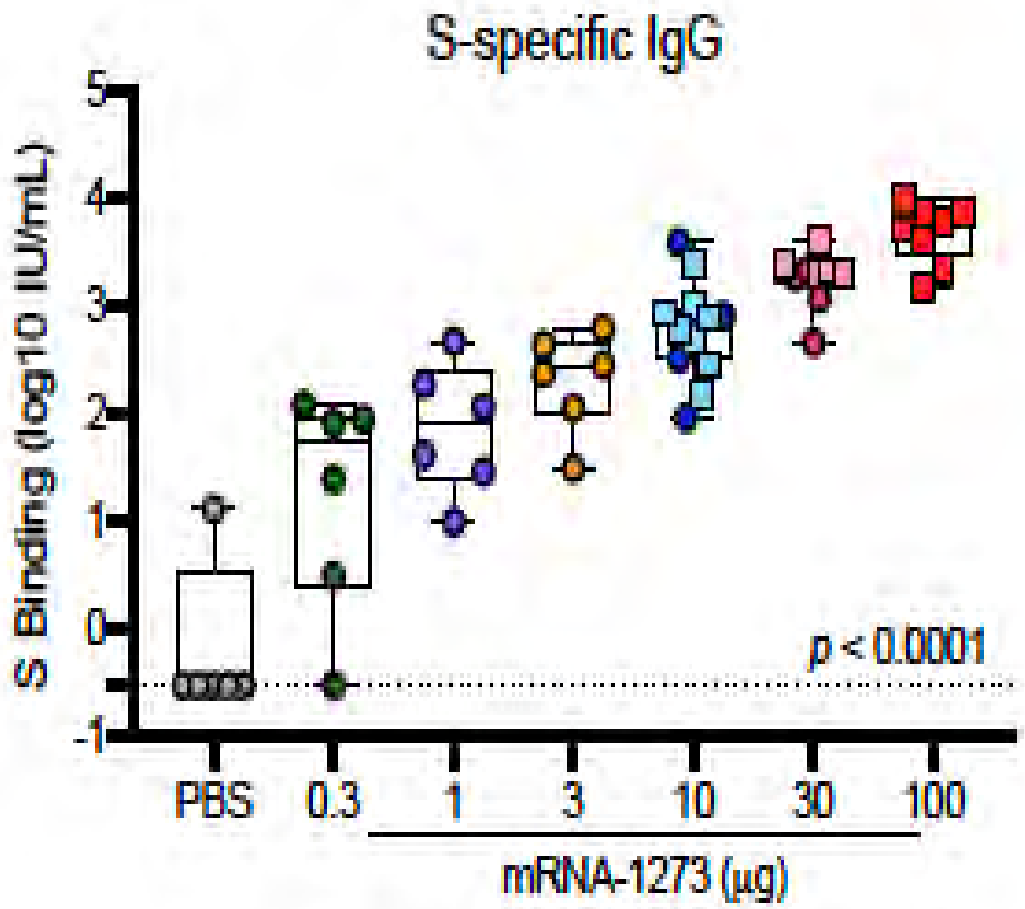
Public Health England SIREN Study

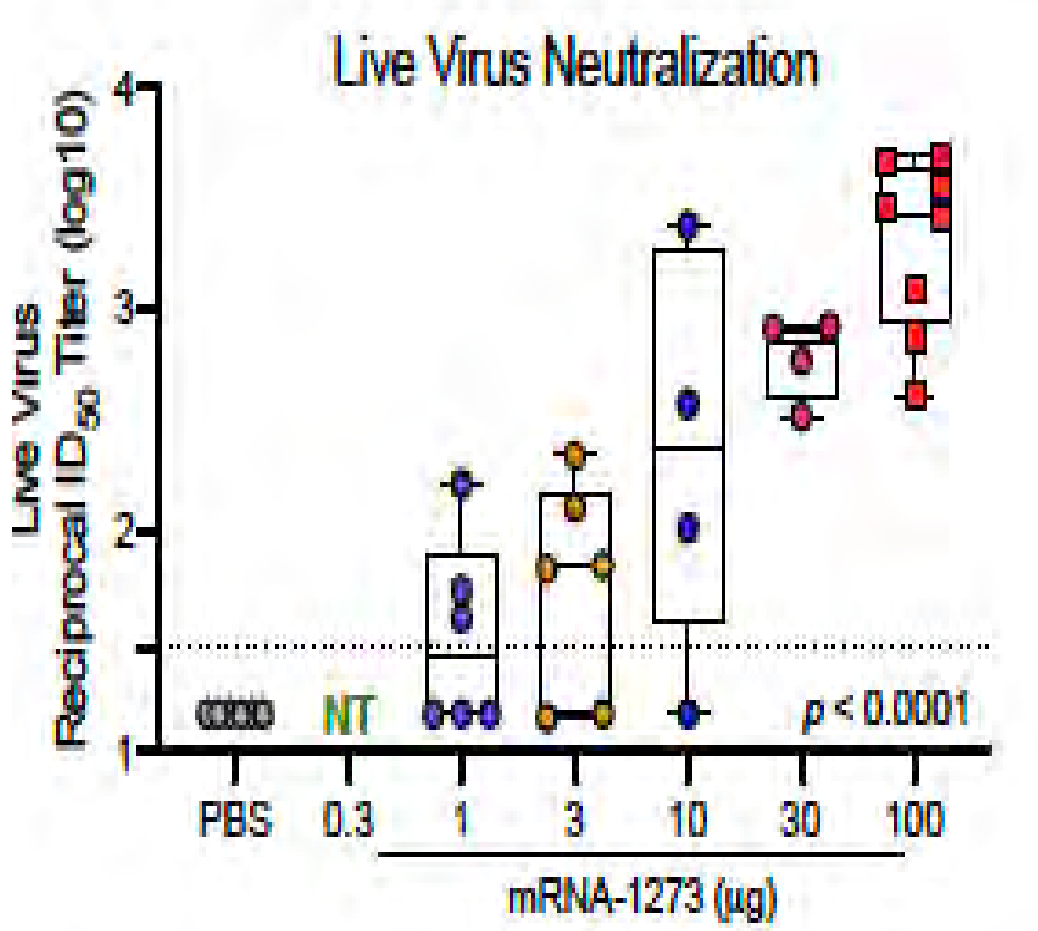
- Regular antibody and PCR testing of 20,000 HCWs
- Of those without antibodies at baseline
  - 409 were infected
  - 79% had symptoms
- Of those with antibodies
  - 44 were re-infected = **83% reduction in likelihood of infection**
  - only 12% had symptoms
- **But** even with antibodies, some had high levels of virus

Turner et al Nature May 2021

- Anti-Spike IgG declines rapidly for 4 mos, then slowly for 7 mos
- Still detectable at 11 mos
- Circulating memory B cells present
- Long lived bone marrow plasma cells present

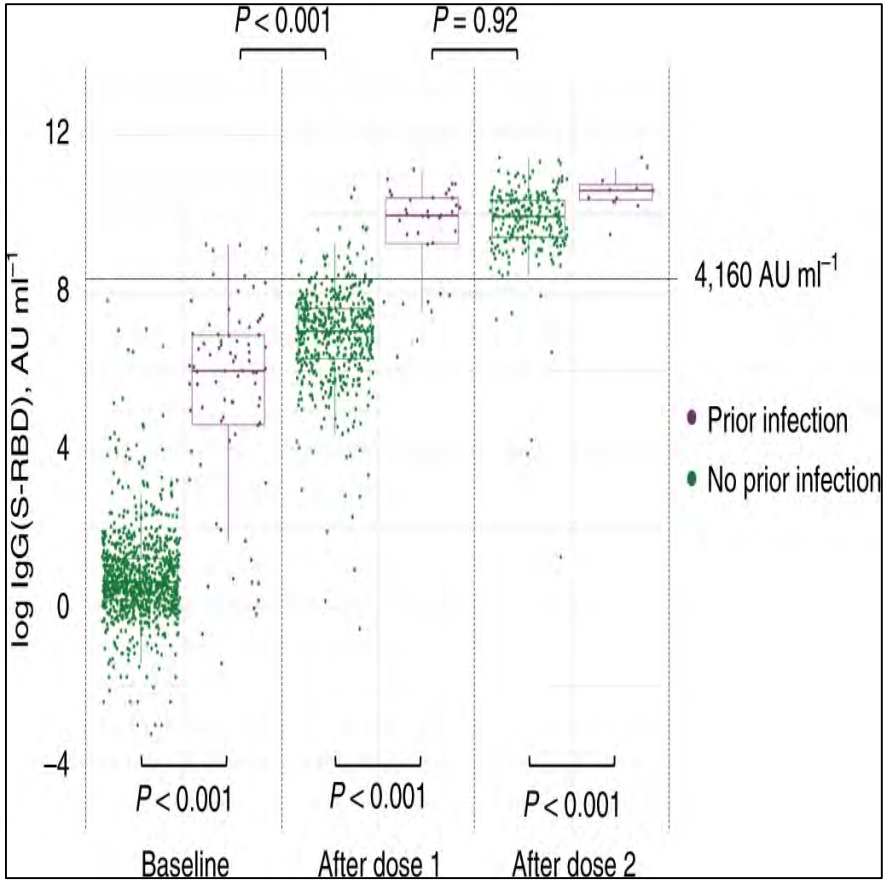
Correlates of Protection (Moderna)



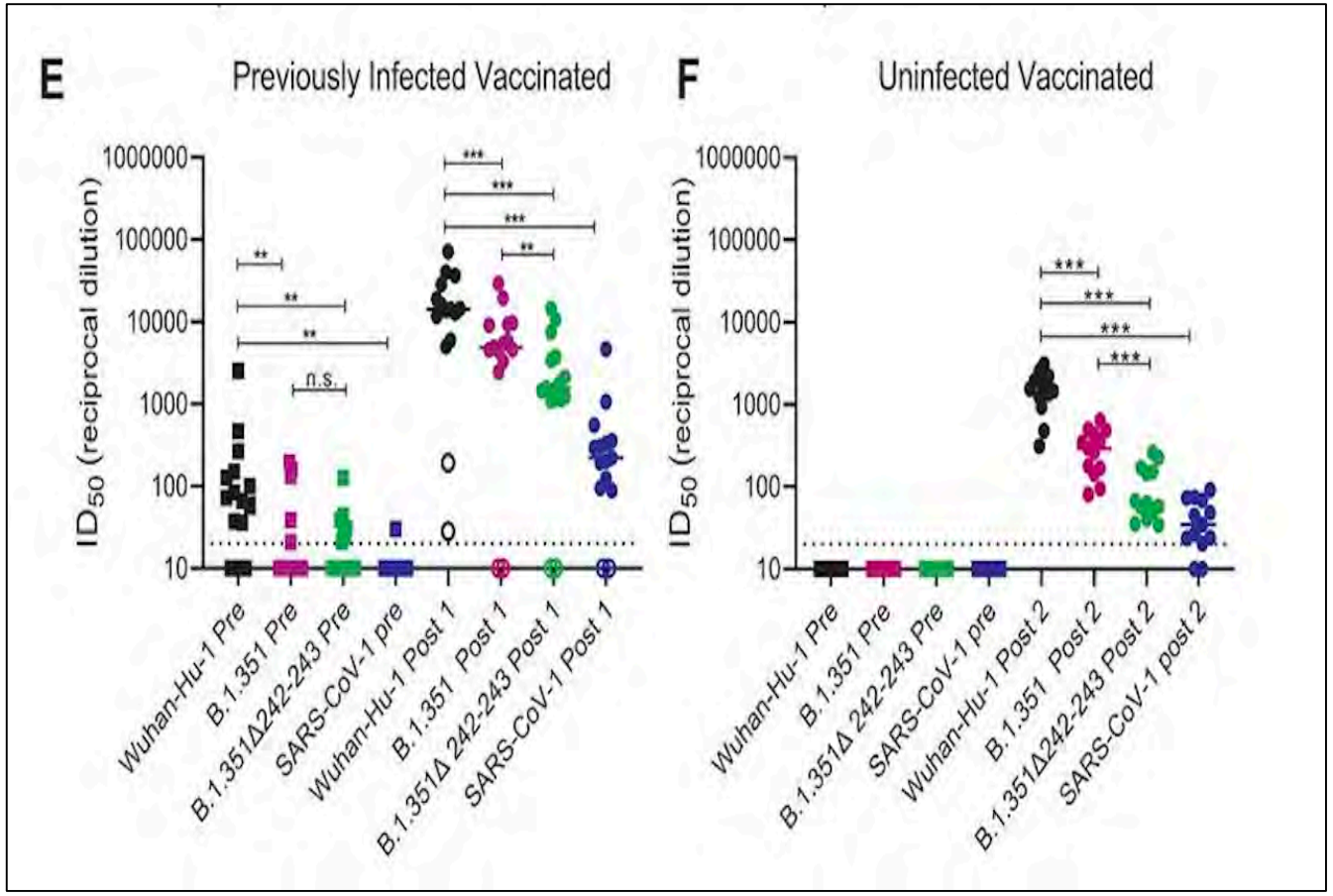


Protection by Prior Infection or Vaccination

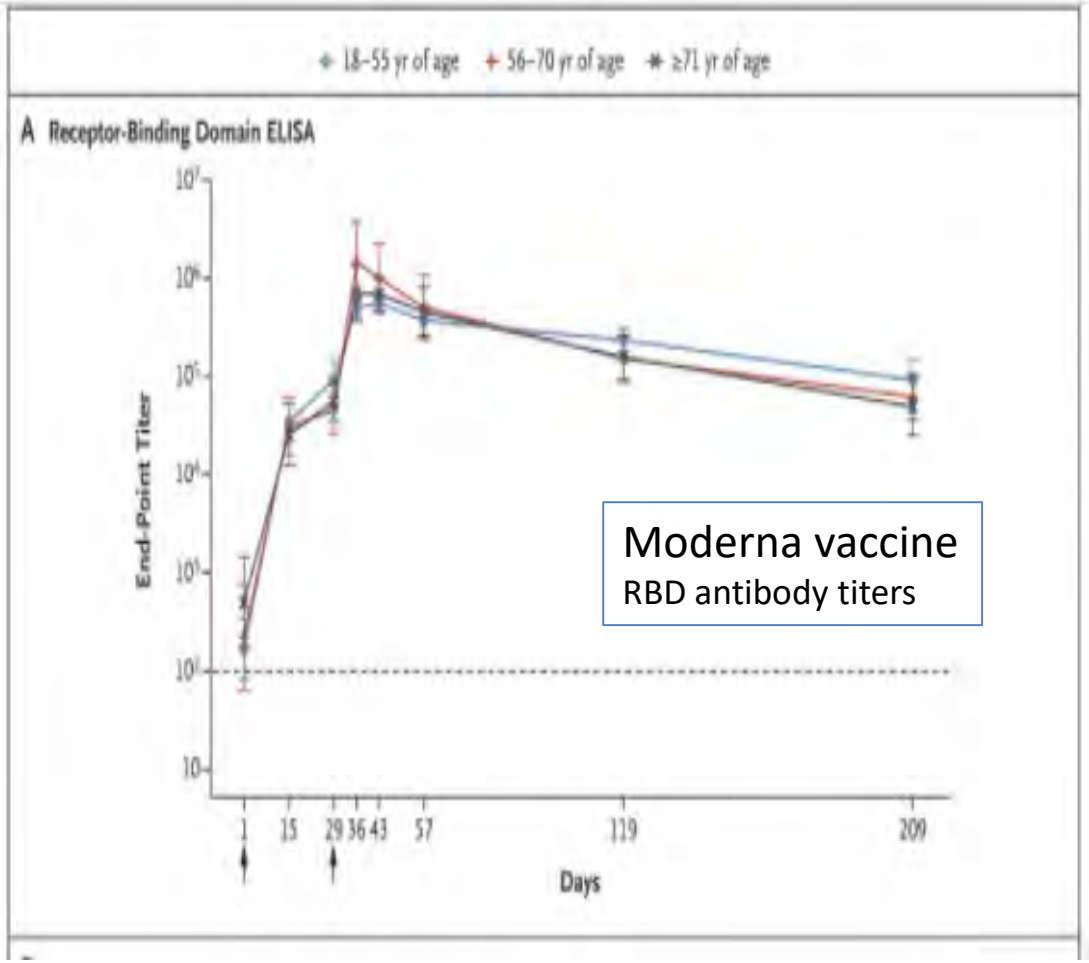
Ebinger et al Nature Medicine April 2021



Stamatatos et al Science March 2021



Durability of Response to Vaccination



- Pfizer vaccine 6 month follow up (N=46,307)
  - –91.3% effective against symptomatic infection
  - –95.3% effective against severe COVID-19 (FDA definition)
  - –100% effective against severe COVID-19 (CDC definition)
  - –100% effective preventing death from COVID-19

What Could Go Wrong?

Update on Viral Variants & Patients with Immune Suppression

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Viral Variants and Vaccines

Vaccine Efficacy	D614G	UK – B.1.1.7	S Africa – B.1.351	India B.1.617.2
Pfizer	95%	85% - 95%*	75% - 100%	88%
Moderna mRNA-1273	94%	89%*		
J&J	72%	72%	57%	
Novavax	95%	89%	60% (HIV negative)	
AstraZeneca	70%	76%	10%	60%

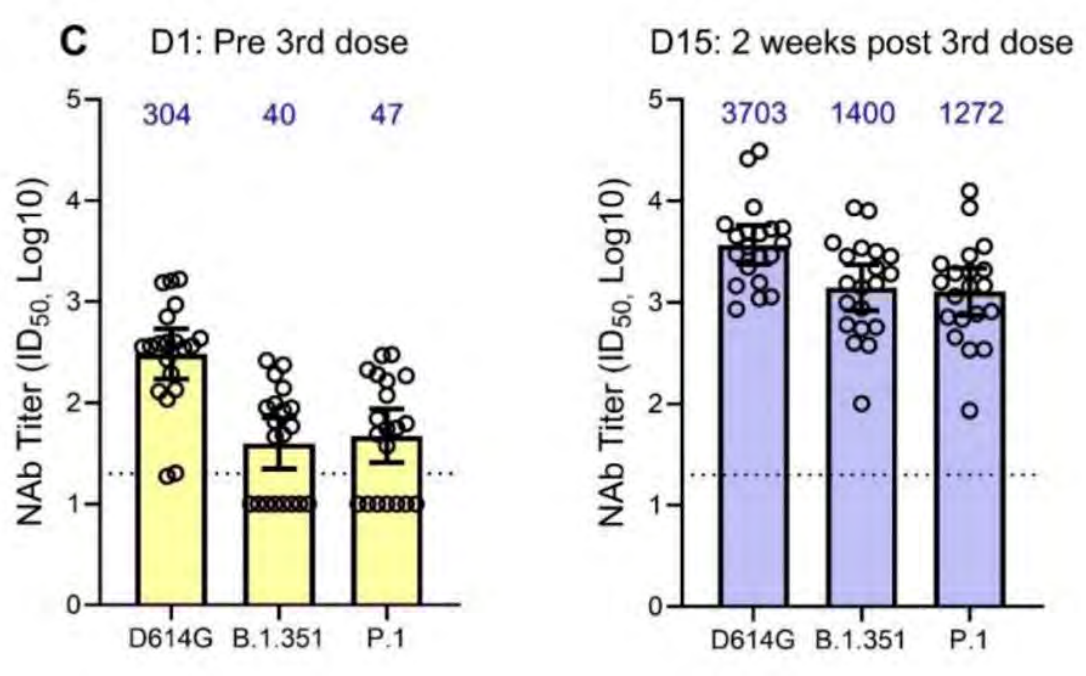
B.1.1.7 is still 85+% of isolates in Houston

*In vitro data

- similar slightly reduced potency against B.1.1.7, B.1.526, B.1.429 and P.1 variants
- all vaccines show much reduced potency against B.1.351 & B.1.617.2 in vitro

Moderna Booster Shot Data

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



Transplant Patients and Vaccination

- Consistent with other vaccines: ~50% antibody response rates
- Post-transplant adverse factors
  - Age > 65
  - Recent transplantation
  - Mycophenolate or mTOR inhibitors
  - Poor graft function
- If possible, vaccinate before transplantation
- Possible options
  - delay vaccination until 3 mos post transplant
  - higher vaccine dose
  - booster doses (including mixed booster)
  - intradermal injection
  - adjuvants (safety concern)

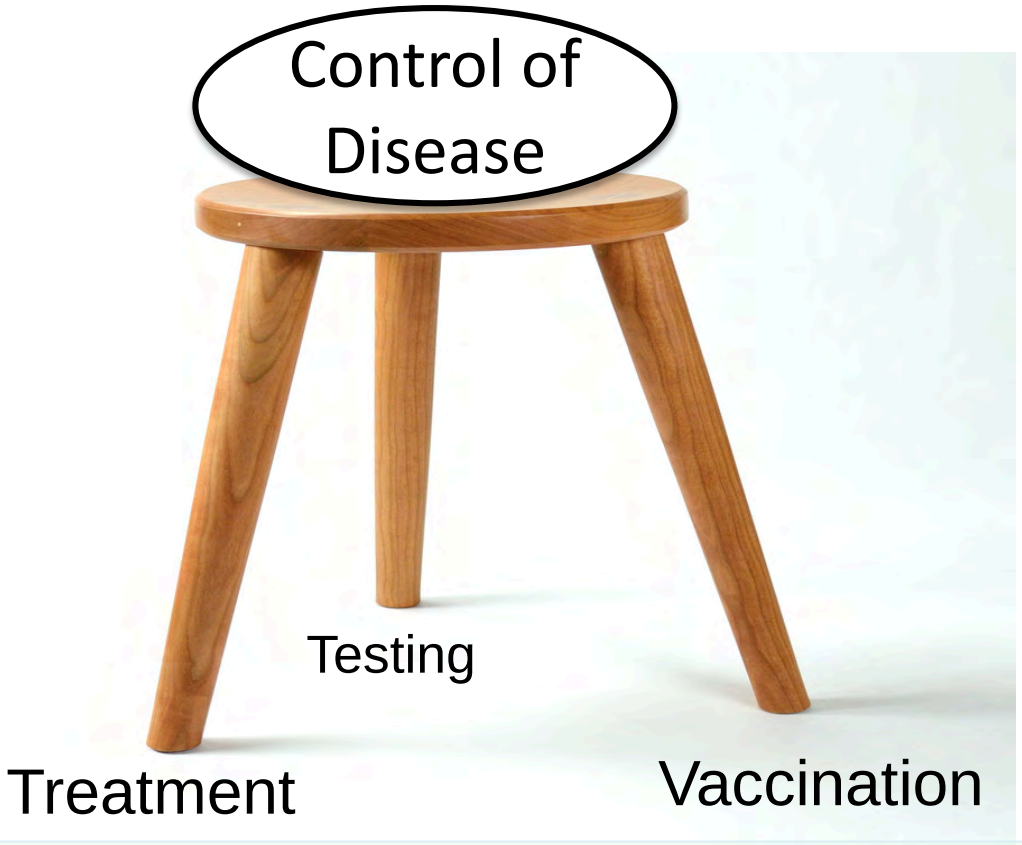
Recent Data on mAb Therapy for COVID

- 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 UK and SA variants
  - Recent data show sub-Q injection as effective as IV
  - **Prophylaxis for immune compromised a realistic idea but not yet EUA**

Controlling Infectious Diseases



Masks, Hand Hygiene & Other Precautions

What Else is Happening?

Drug Therapy for COVID-19

Masks & Precautions

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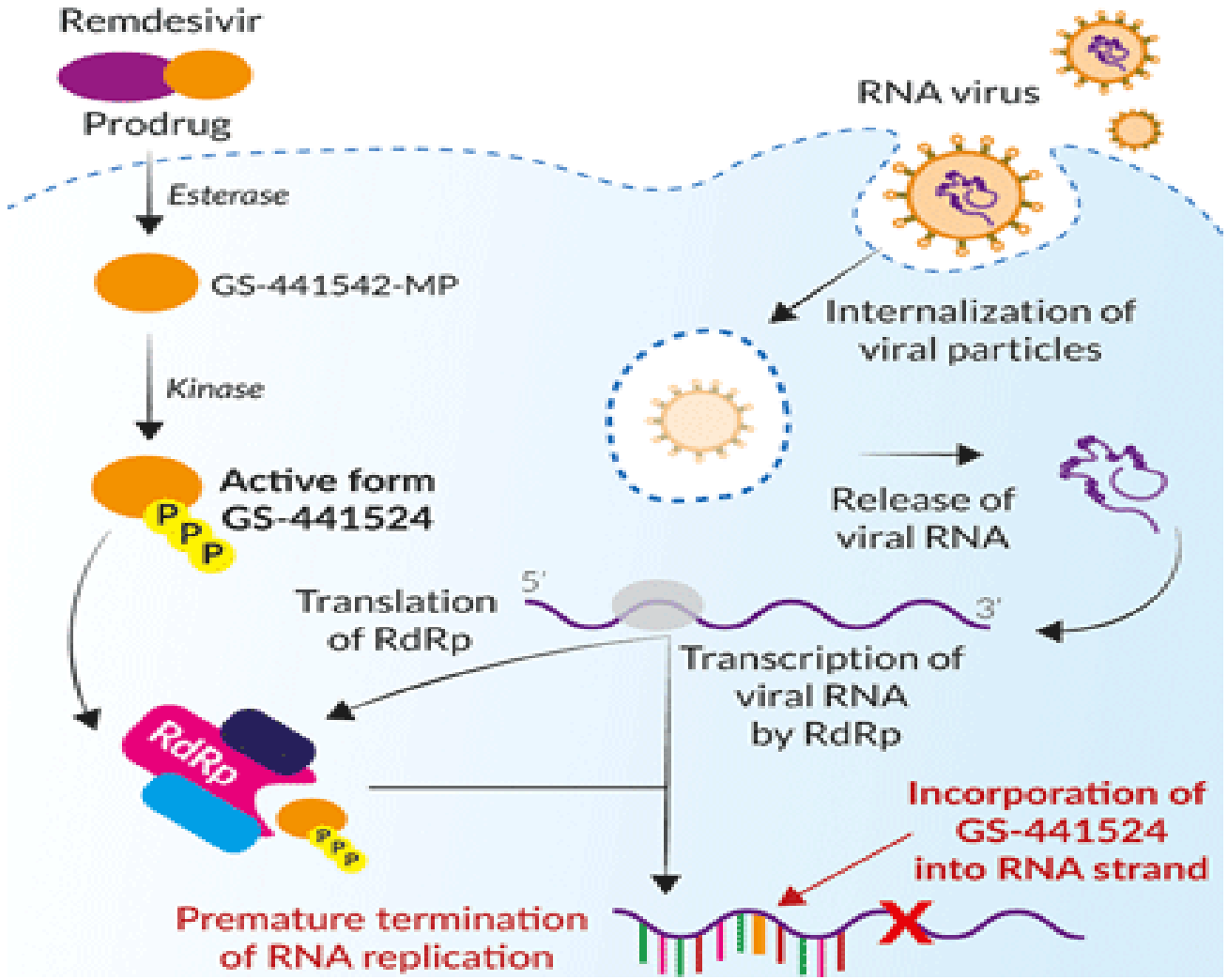
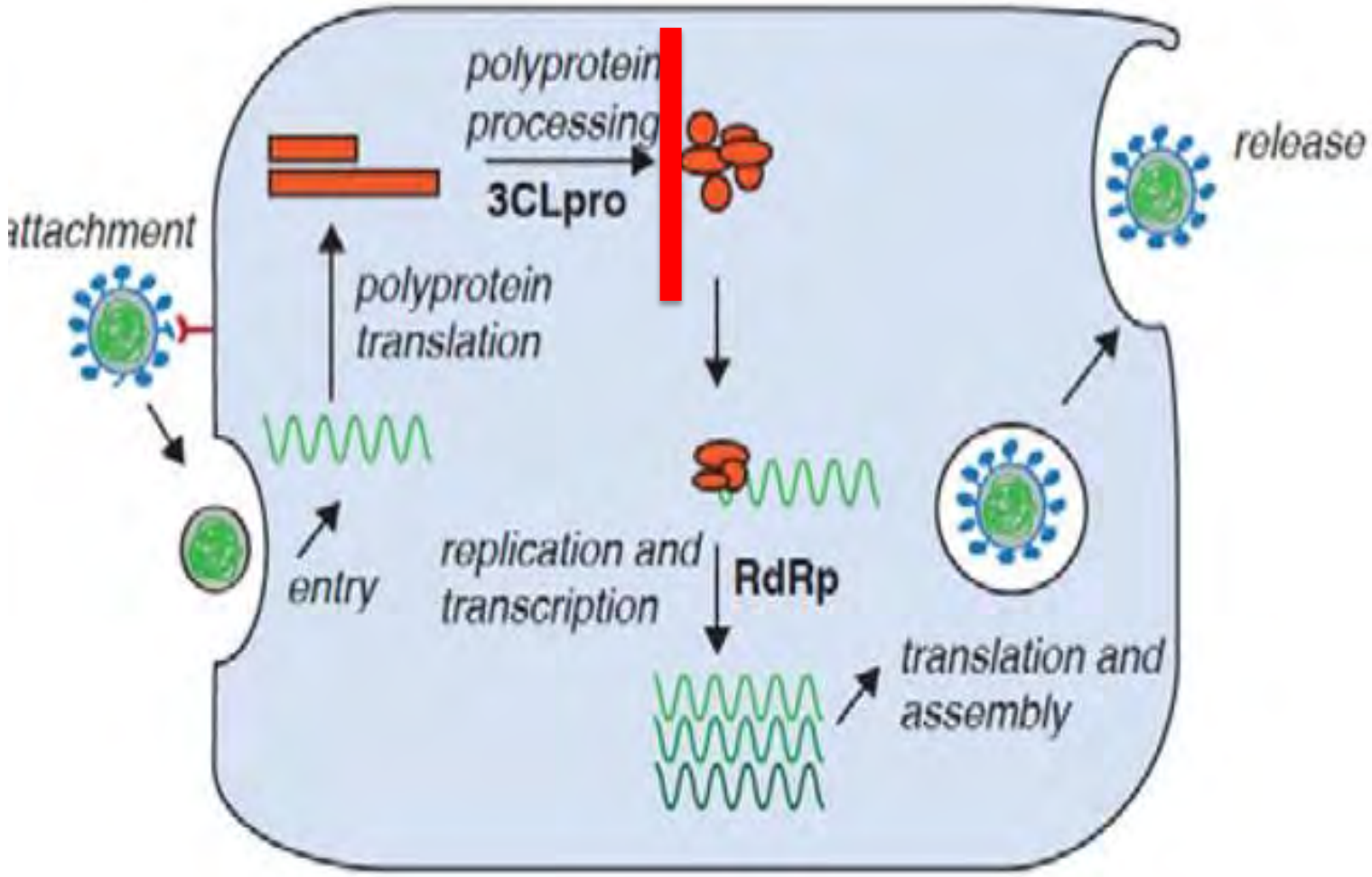
Drugs Under Active Investigation

- RNA polymerase inhibitors
  - –Favipiravir (Fuji)
  - –Molnupiravir (Merck)
- Combination therapy with protease inhibitors?



Drugs Under Active Investigation

- Protease inhibitors
  - PF-07304814 (intravenous)
  - PF-07321332 (oral)
- Combination therapy with polymerase inhibitors?



Repurposed Drugs in COVID-19

- Some shown to be “effective”
  - **Dexamethasone (and other corticosteroids)**
  - Remdesivir
  - Barcitinib
  - Tocilizumab
- Many proposed for outpatients with mild disease, none proven yet
  - Ivermectin
  - Budesonide
  - Statins
  - Fluvoxamine
- UK RECOVERY trial – hospitalized patients
- NIH ACTIV-6 Trial will start soon, evaluate outpatient treatments

Masks etc.?

Common Sense Approach

- How susceptible are you?
  - Vaccinated
  - Unvaccinated but otherwise healthy
  - Immune suppression
- How prevalent is infection in the community?
  - In general
  - In your local area
  - Prevalence of variants of concern (Beta, Delta, etc.)
- 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?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COVID-19 and Vaccine Update

Marc L. Boom, MD
June 10, 2021

HOUSTON Methodist
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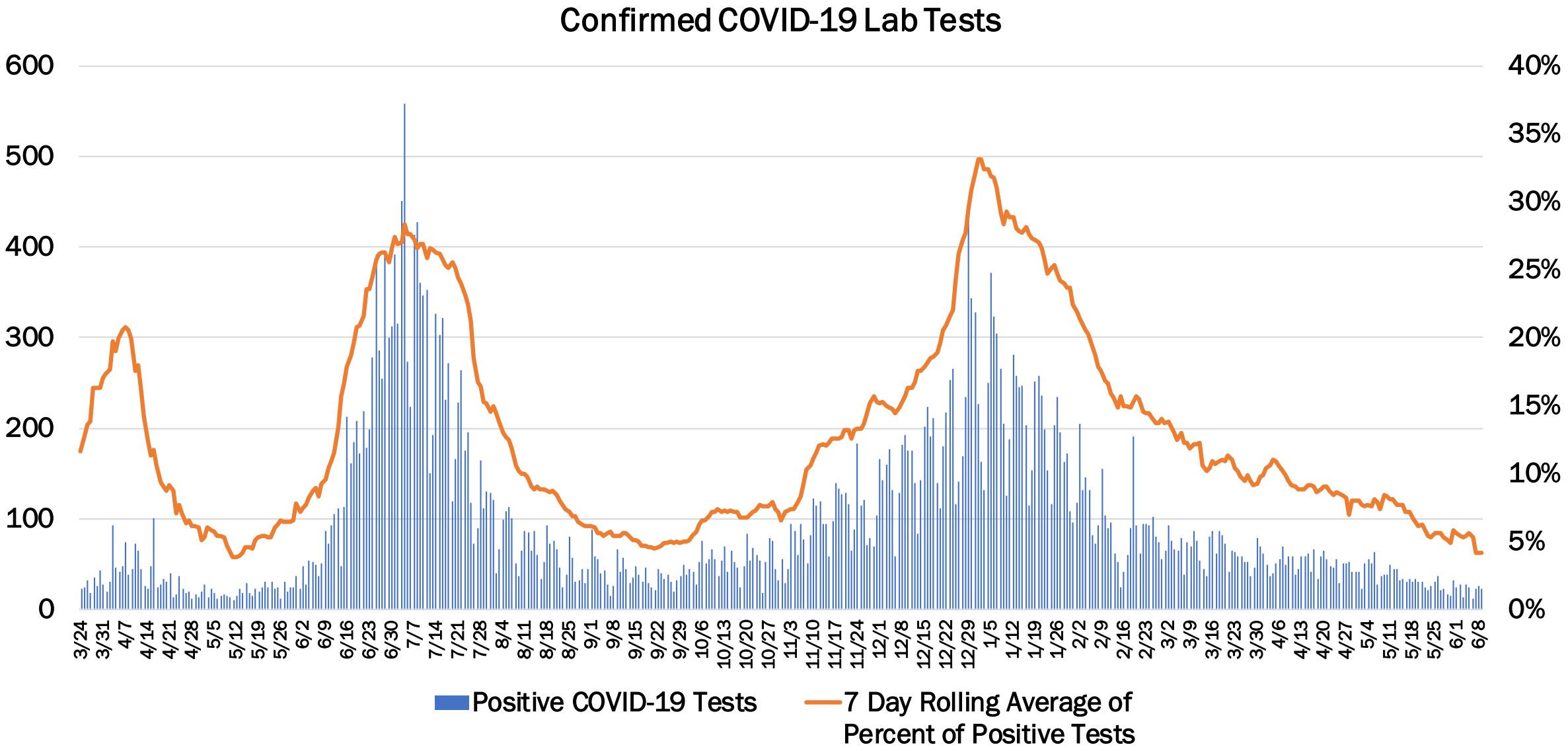
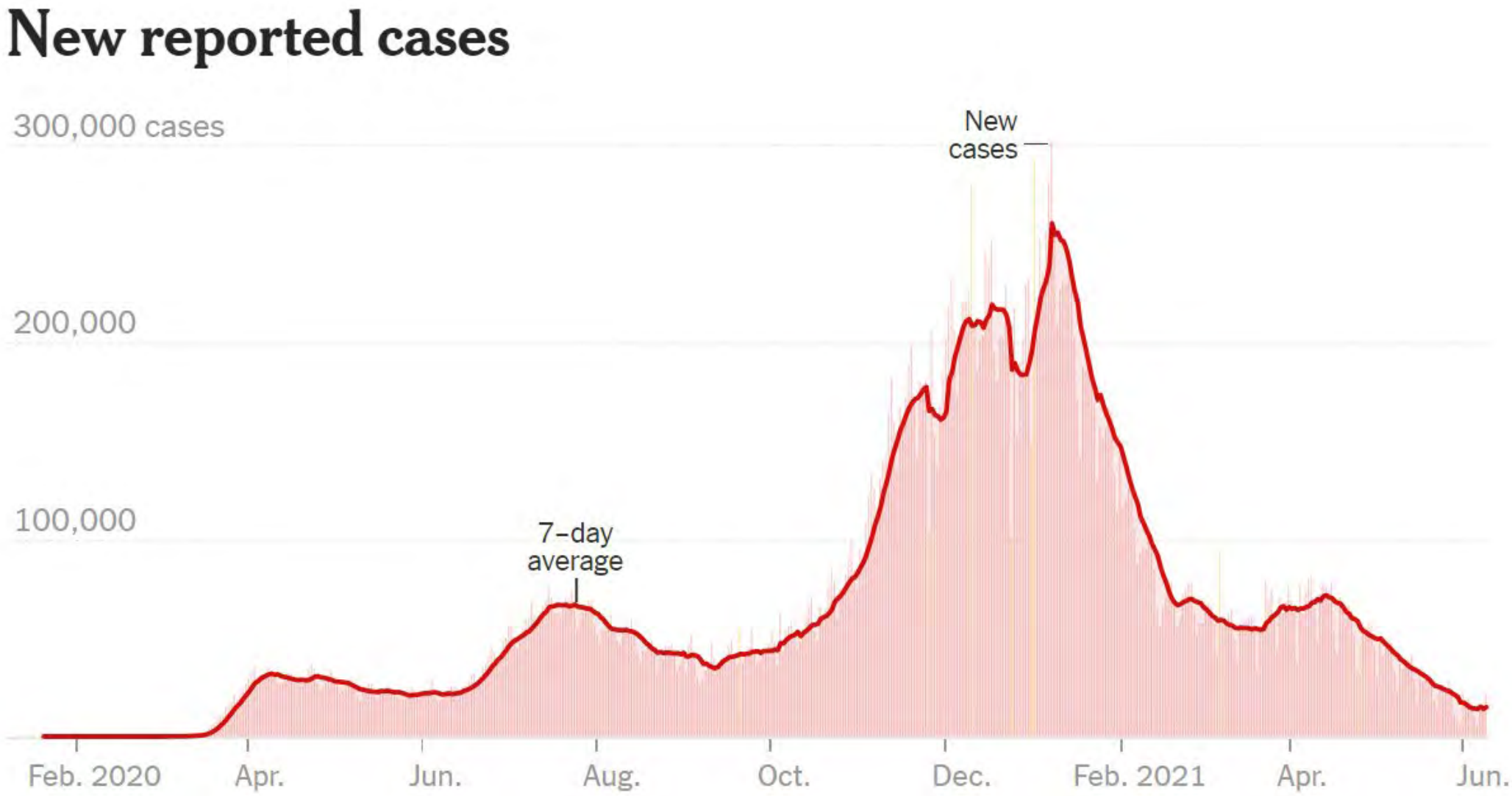
Houston Methodist Testing Trend

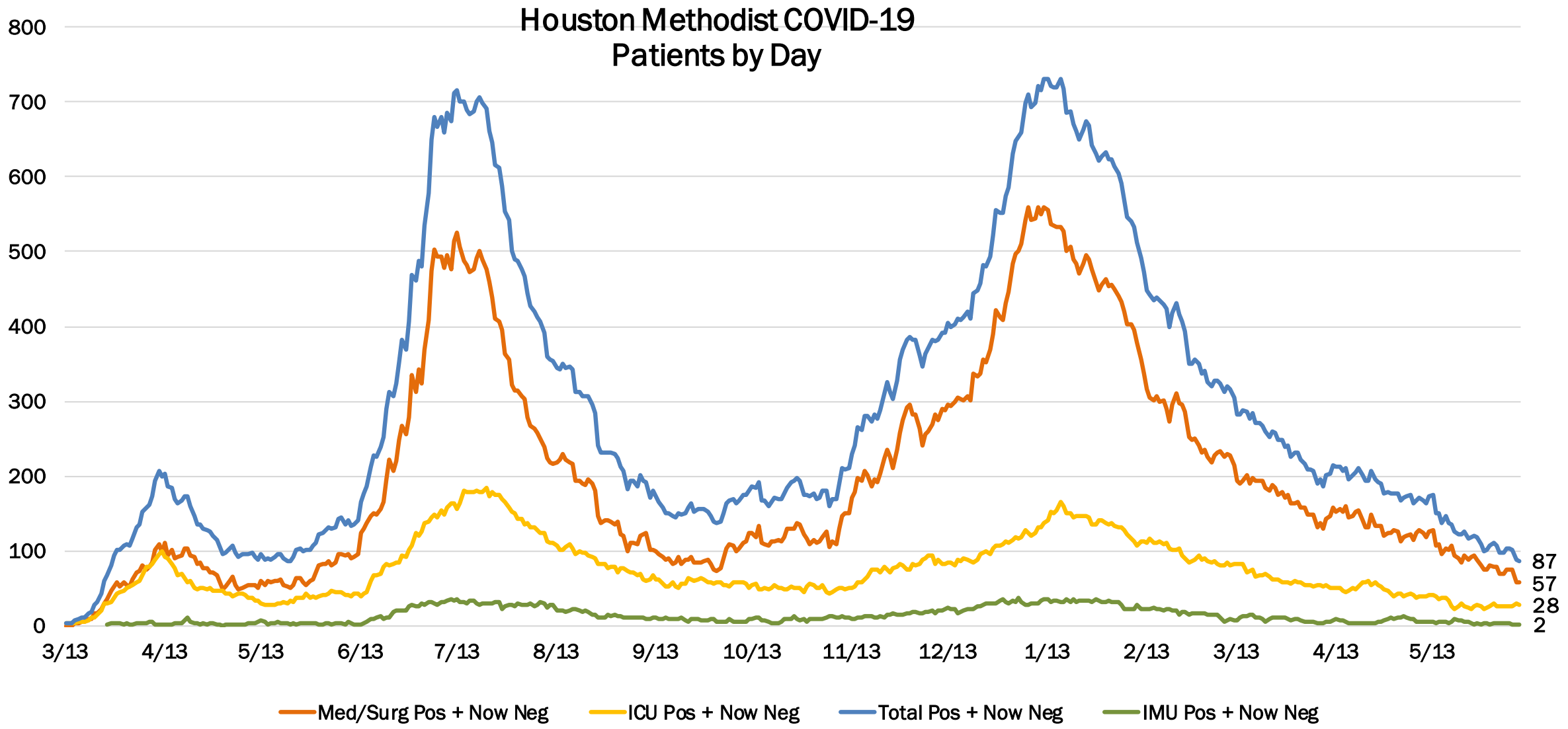


New COVID-19 Cases Reported in U.S. by Day



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

Houston Methodist COVID-19 Cases by Day



Data as of June 9, 2021

My key take home message today:

TRUST THE VACCINES!

National Distribution and Administration of COVID-19 Vaccine

HOUSTON Methodist LEADING MEDICINE

Total Vaccine Doses

Delivered	372,495,525
Administered	304,753,476

Learn more about the distribution of vaccines.

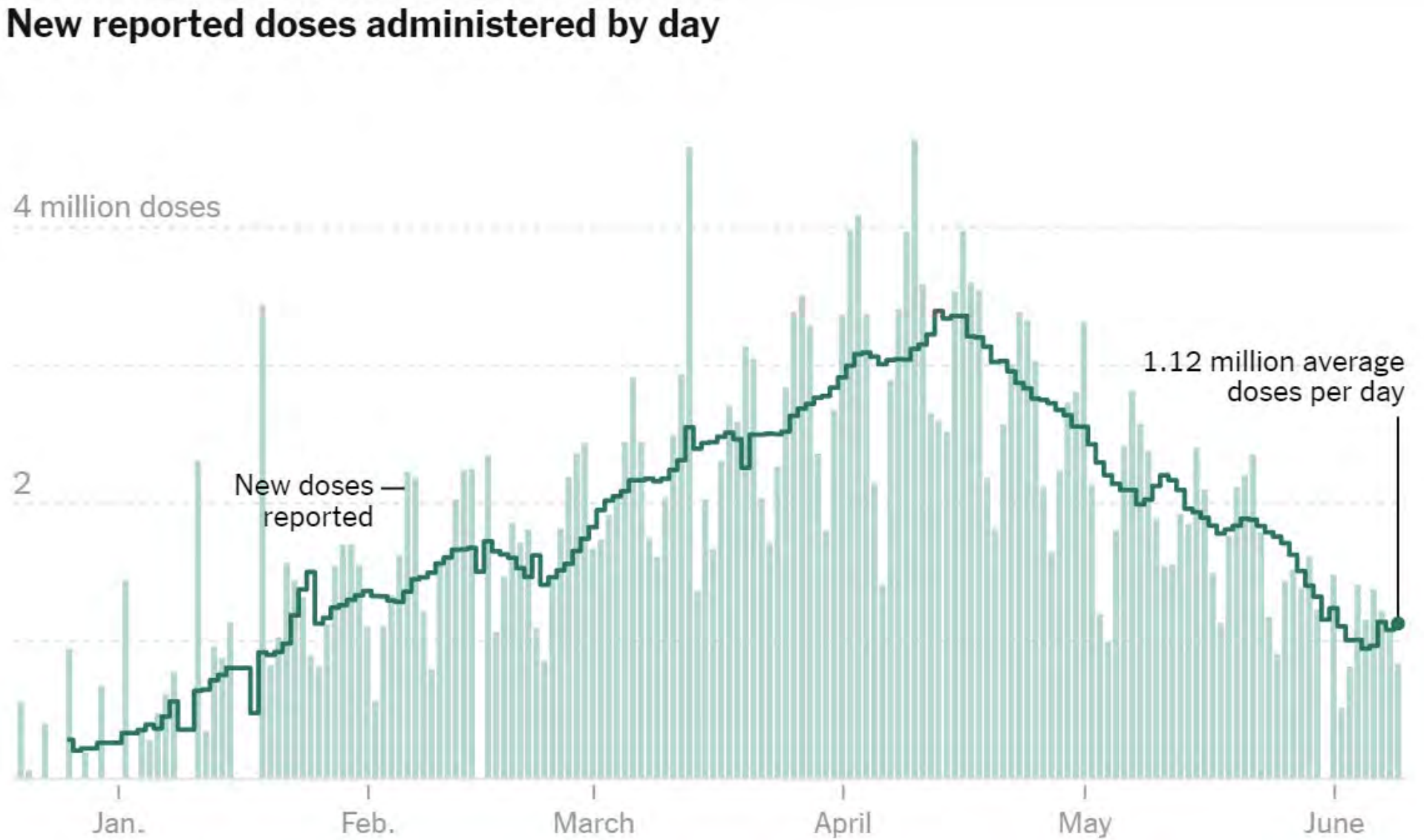
141.0M

People fully vaccinated

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	172,054,276	140,980,110
% of Total Population	51.8%	42.5%
Population ≥ 12 Years of Age	171,897,072	140,944,391
% of Population ≥ 12 Years of Age	61.3%	50.3%
Population ≥ 18 Years of Age	164,828,274	137,516,193
% of Population ≥ 18 Years of Age	63.9%	53.3%
Population ≥ 65 Years of Age	47,287,298	41,412,423
% of Population ≥ 65 Years of Age	86.5%	75.7%

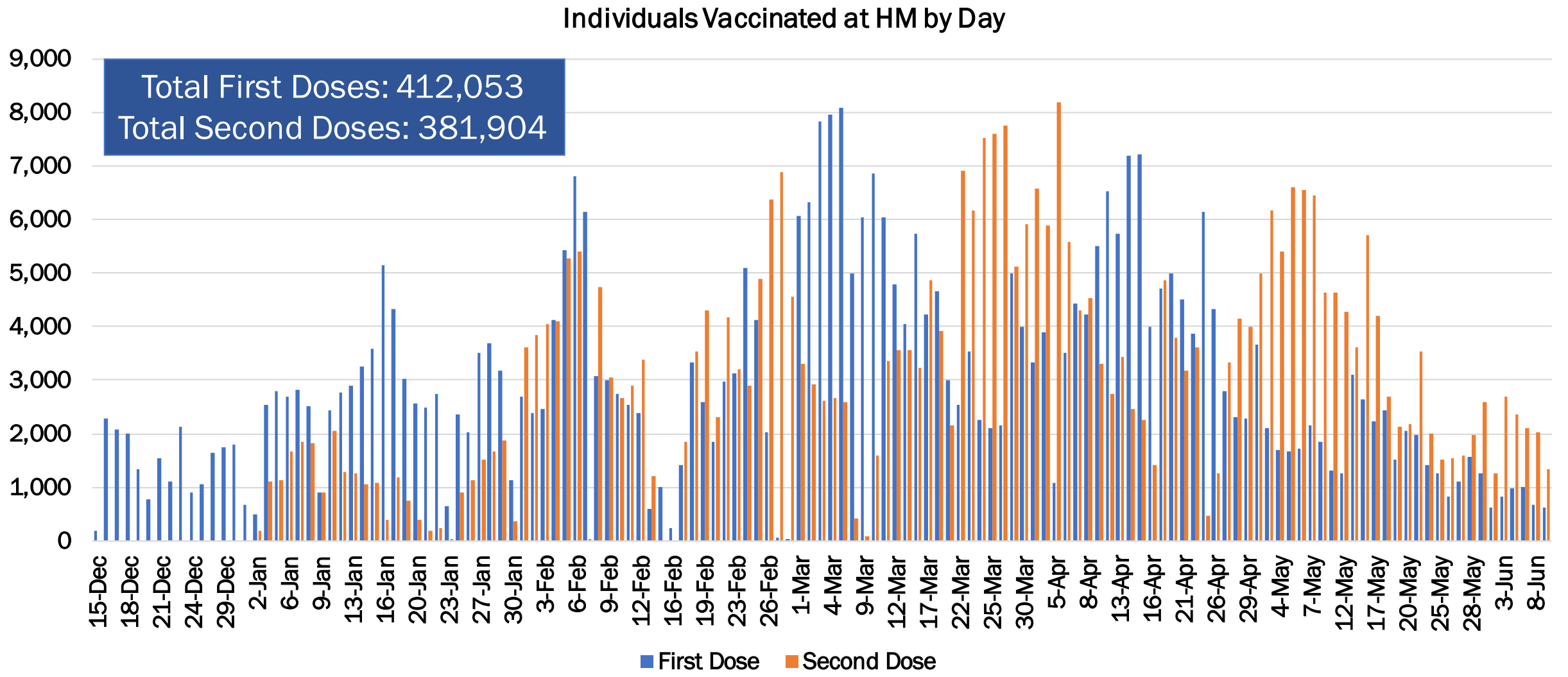
https://covid.cdc.gov/covid-data-tracker/#vaccinations

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

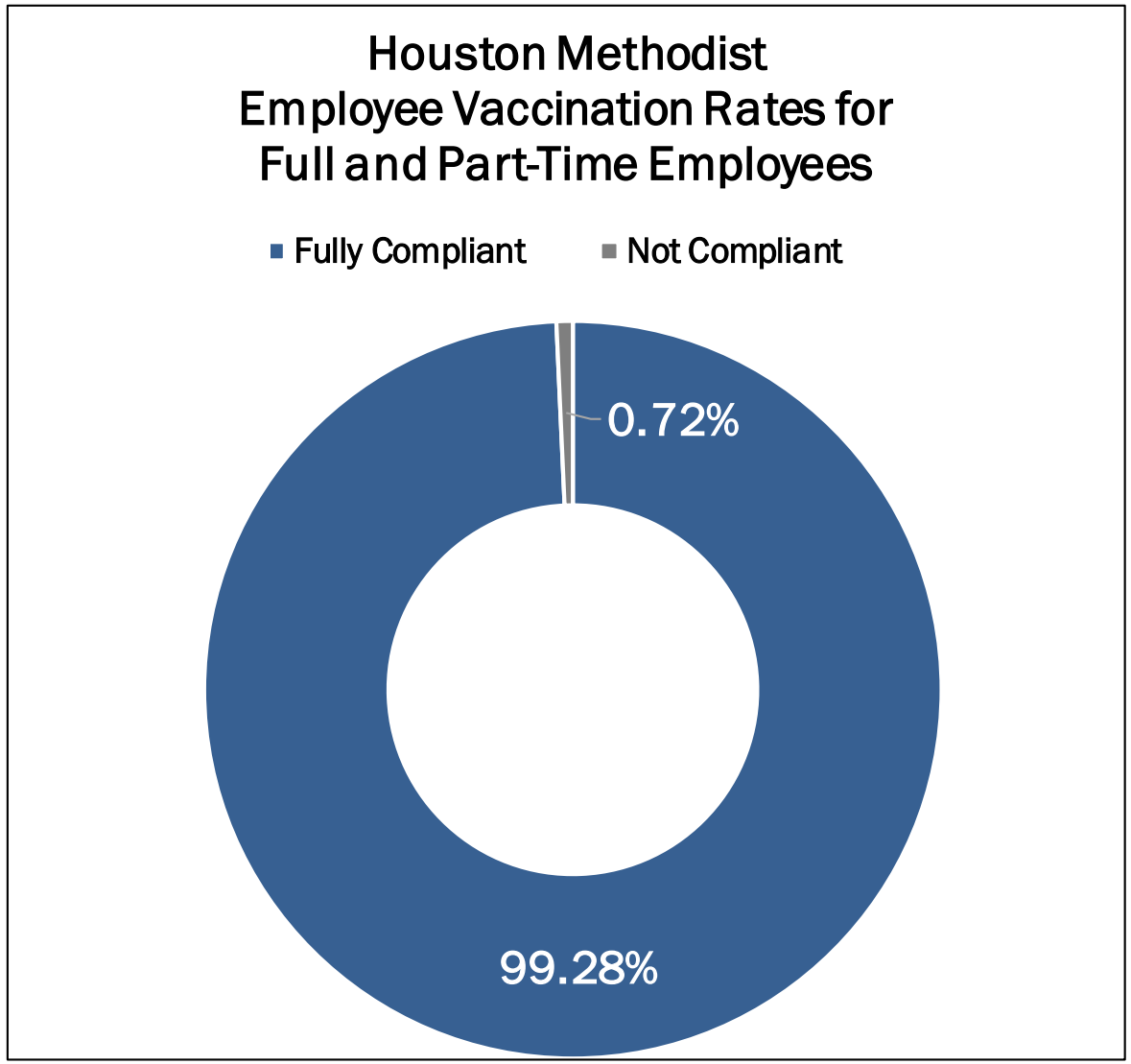


https://www.nytimes.com/2021/05/03/health/covid-herd-immunity-vaccine.html

HM COVID-19 Vaccines Administered



Vaccine Mandate for Houston Methodist Employees



Full and Part-Time Employees:

- Compliant: 23,590
- Vaccine Partially Done: 26
- Non-Compliant: 144

PRN Employees:

- Compliant: 1,981
- Vaccine Partially Done: 5
- Non-Compliant: 45

I wanted to tell you that Houston Methodist is an inspiration to us for carrying out the decision to require all of your employees to be vaccinated.

Houston Methodist just paved the way for other health systems to follow your lead and potentially save countless lives.

– **CEO of Large Hospital System in Northeast**

Multiple Hospitals Announce COVID-19 Vaccine Mandate for Employees

HOUSTON Methodist LEADING MEDICINE

UofL Health
May 26
12,000 Employees

JOHNS HOPKINS MEDICINE
June 9
40,000 Employees

UNIVERSITY of MARYLAND MEDICAL CENTER
June 9
29,000 Employees

HOUSTON Methodist LEADING MEDICINE
March 31
26,000 Employees

Penn Medicine
May 19
44,000 Employees

DCHA District of Columbia Hospital Association
June 9
10 DC/VA/MD Hospitals

March → April → May → June

Benefis HEALTH SYSTEM
April 16
3,300 Employees

RWJBarnabas HEALTH
May 20
35,000 Employees

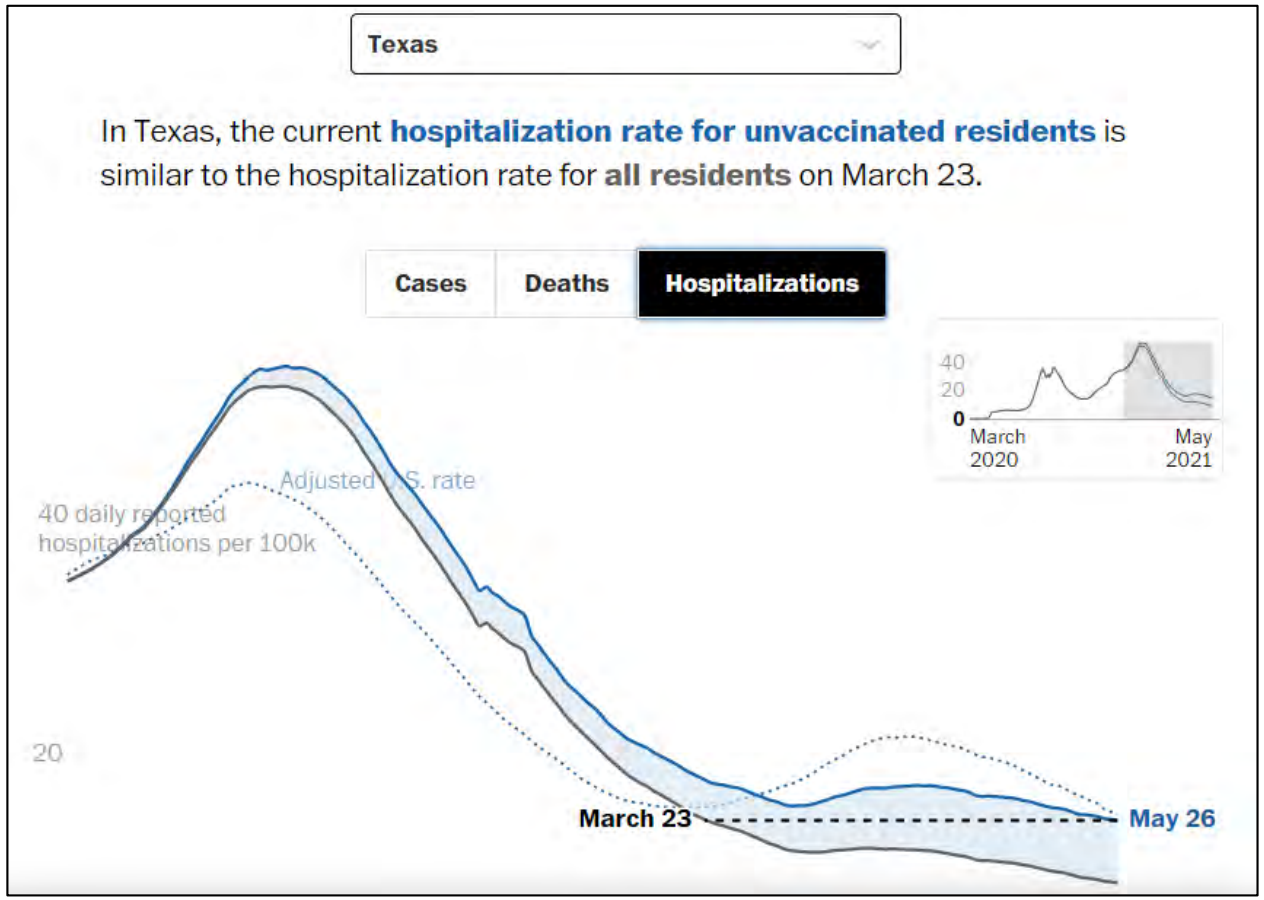
IU HEALTH
Indiana University Health
June 1
36,000 Employees

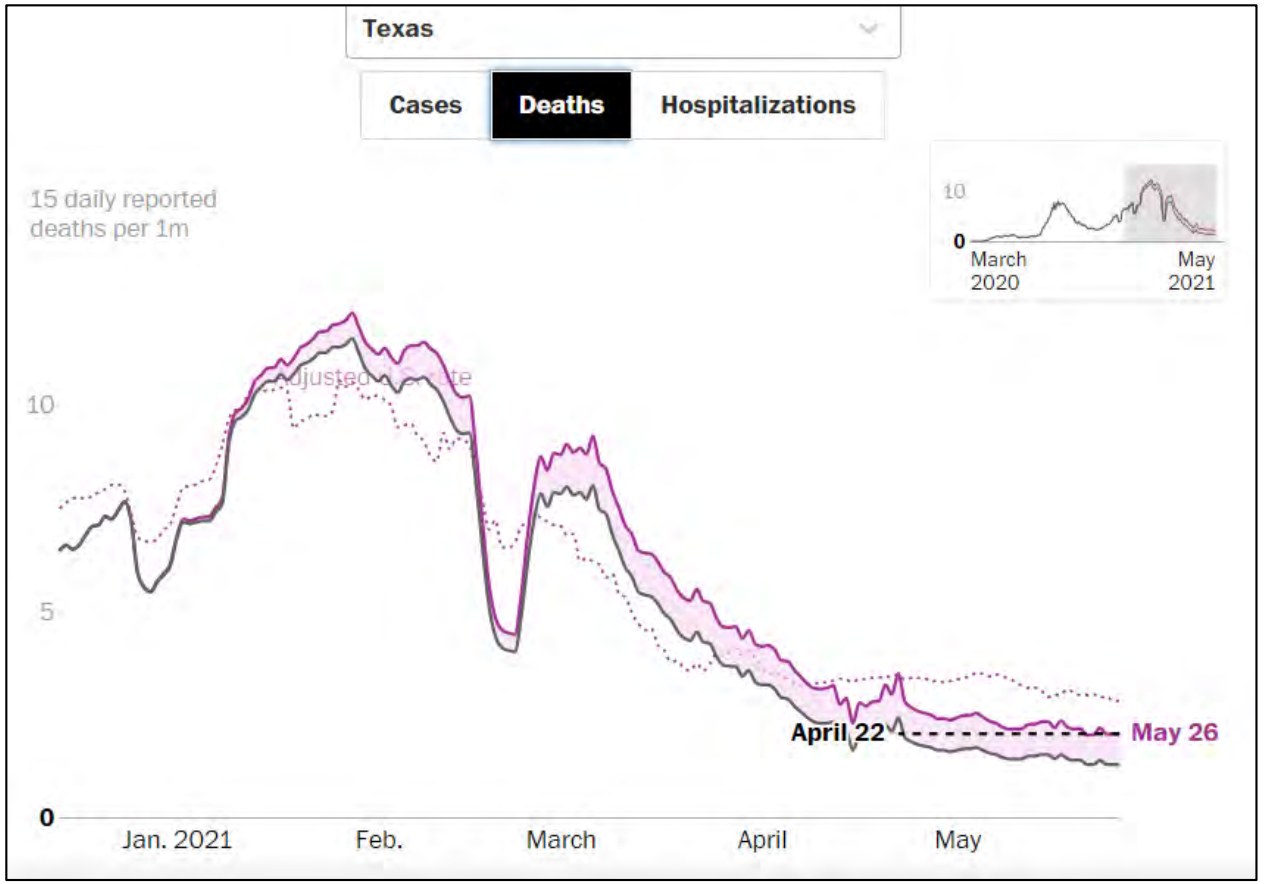
COVID-19 Significant Risk for Unvaccinated

HOUSTON Methodist LEADING MEDICINE

The Washington Post

The unseen covid-19 risk for unvaccinated people





https://www.washingtonpost.com/health/interactive/2021/covid-rates-unvaccinated-people/

THE VISION FOR THE SECOND CENTURY

Houston Methodist will set a new standard for leading academic medical centers through ***unparalleled safety, quality, service and innovation.***

HOUSTON Methodist℠
LEADING MEDICINE

4

Press Our Strategic Advantage

1. Focus on unparalleled safety, quality, service and innovation
2. Care for our people
3. Invest strategically and aggressively in academic programs
4. Optimize marketing and public relations for further differentiation
5. Continue strategic plans for expansions and recapitalization
6. Invest aggressively in innovation

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Summer of Rest and Recuperation

Astros Contest

Chick-Fil-A w/ CEO

HEB Contest

Lunch with Your Boss

Snacks and Balloons

Southwest Contest

Sunshine Boxes

Ice Cream Cart

Grand Prize


HOUSTON
Methodist
SM
LEADING MEDICINE

THANK YOU FOR ATTENDING OUR TOWN HALL CONVERSATION

If you'd like more information about men's health, our cancer survivorship program, or The Society for Leading Medicine, please contact us at foundation@houstonmethodist.org.

Take care and be well

HOUSTON Methodist LEADING MEDICINE