



The Front Lines of the Fight Against COVID-19

A TOWN HALL CONVERSATION XII

We will begin at 10 a.m.



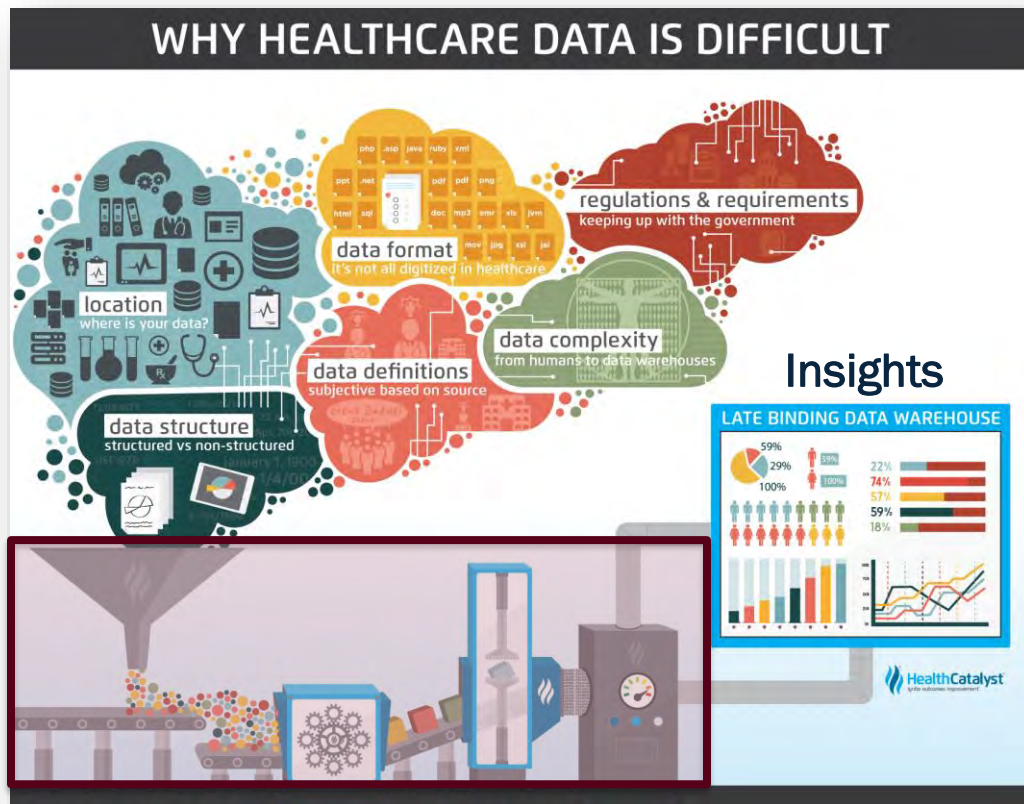
Houston Methodist COVID-19 Surveillance and Outcomes Registry : CURATOR

Farhaan S. Vahidy, PhD MBBS MPH FAHA

Associate Professor and Associate Director – Center for Outcomes Research

Digitization challenge of healthcare

- **Multiple siloed locations** (EMR, Imaging, Pharmacy, Lab, Billing)
- **Non uniform data structures** (Non-standardized data capture)
- **Data format** (free-text, binary large object – BLOB)
- **Inconsistent and variable data definitions** (administrative vs. clinical vs. research definitions)
- **Complex data streams** (wave form data, raw image reconstruction)
- **Confidentiality & regulatory requirements**



COVID-19 Data Demands for a Healthcare System



Clinical and
Research
Enterprise

HOUSTON
Methodist
LEADING MEDICINE

Houston Methodist and
Houston Methodist Academic Institute (HMAI)



1.3M
PATIENT
ENCOUNTERS



6,973
PHYSICIANS



681
FACULTY



1,960
CREDENTIALLED
RESEARCHERS



29,408
TRAINEES

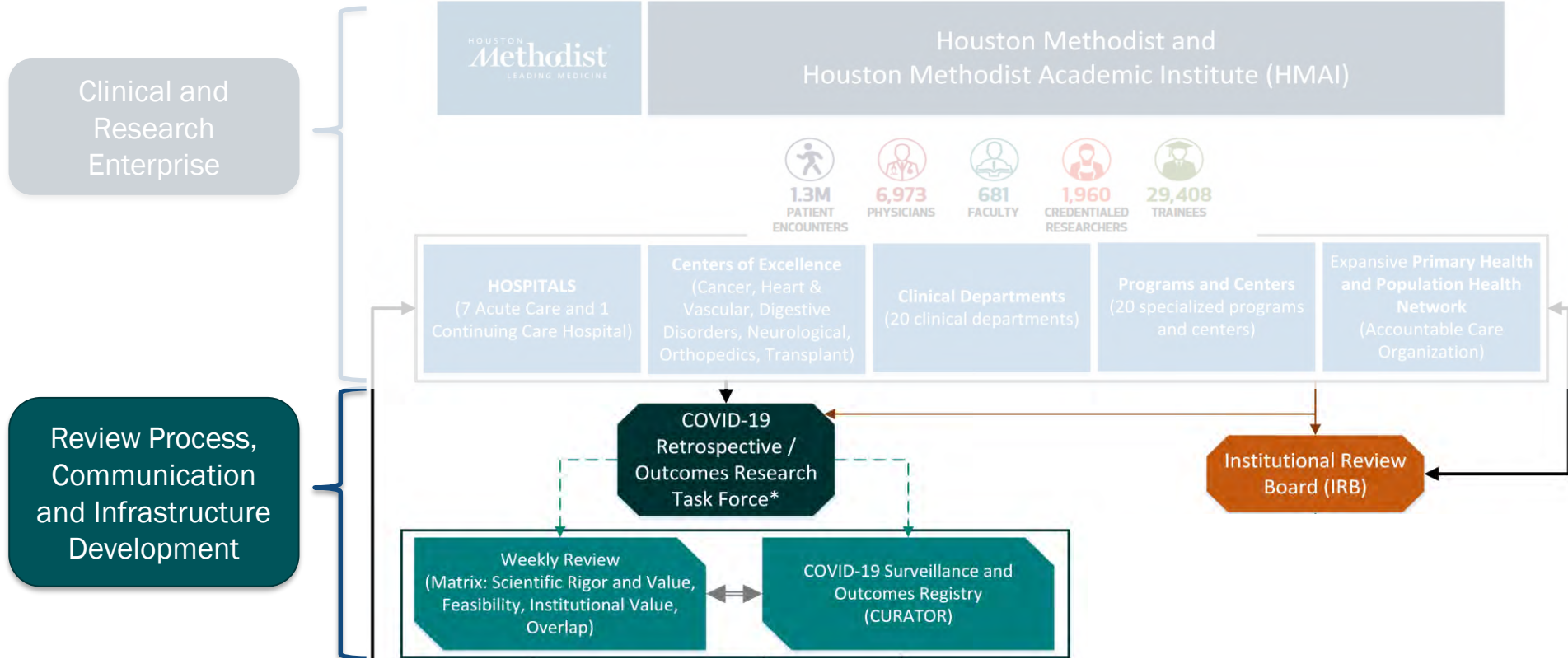
HOSPITALS
(7 Acute Care and 1
Continuing Care Hospital)

Centers of Excellence
(Cancer, Heart &
Vascular, Digestive
Disorders, Neurological,
Orthopedics, Transplant)

Clinical Departments
(20 clinical departments)

Programs and Centers
(20 specialized programs
and centers)

**Expansive Primary Health
and Population Health
Network**
(Accountable Care
Organization)



March 20, 2020 : RRTF Established

March 27, 2020 : RRTF First Meeting

April 11, 2020 : CURATOR Protocol Approved


Houston Methodist and Houston Methodist Academic Institute (HMAI)

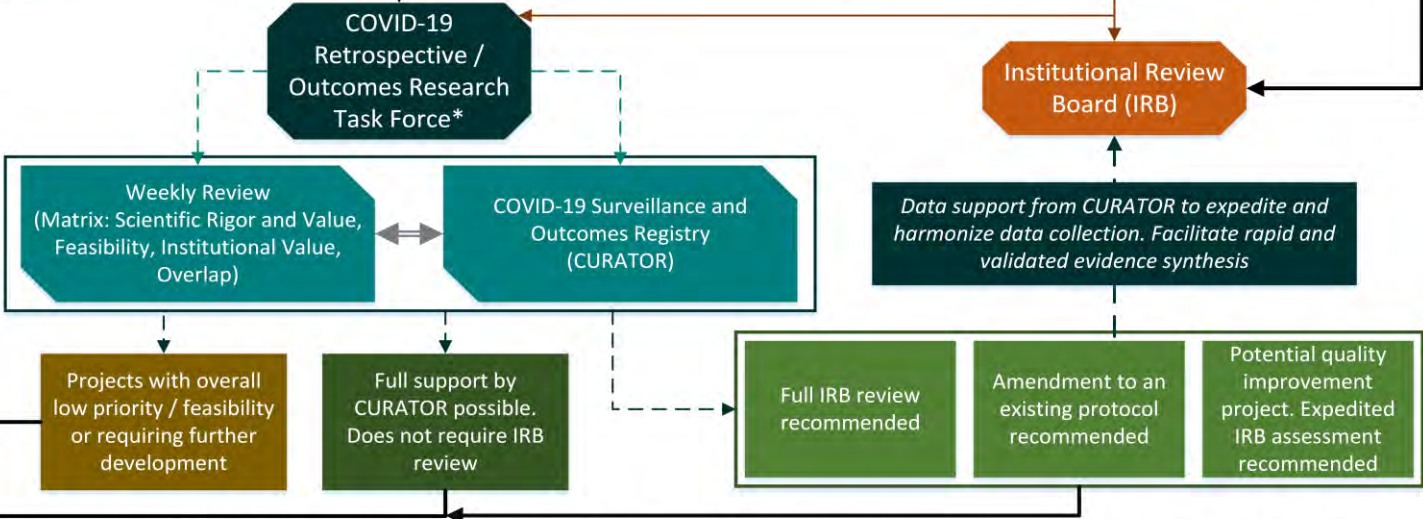
 **1.3M** PATIENT ENCOUNTERS
 **6,973** PHYSICIANS
 **681** FACULTY
 **1,960** CREDENTIALLED RESEARCHERS
 **29,408** TRAINEES



Clinical and Research Enterprise

Review Process, Communication and Infrastructure Development

Process Outcomes and Communication

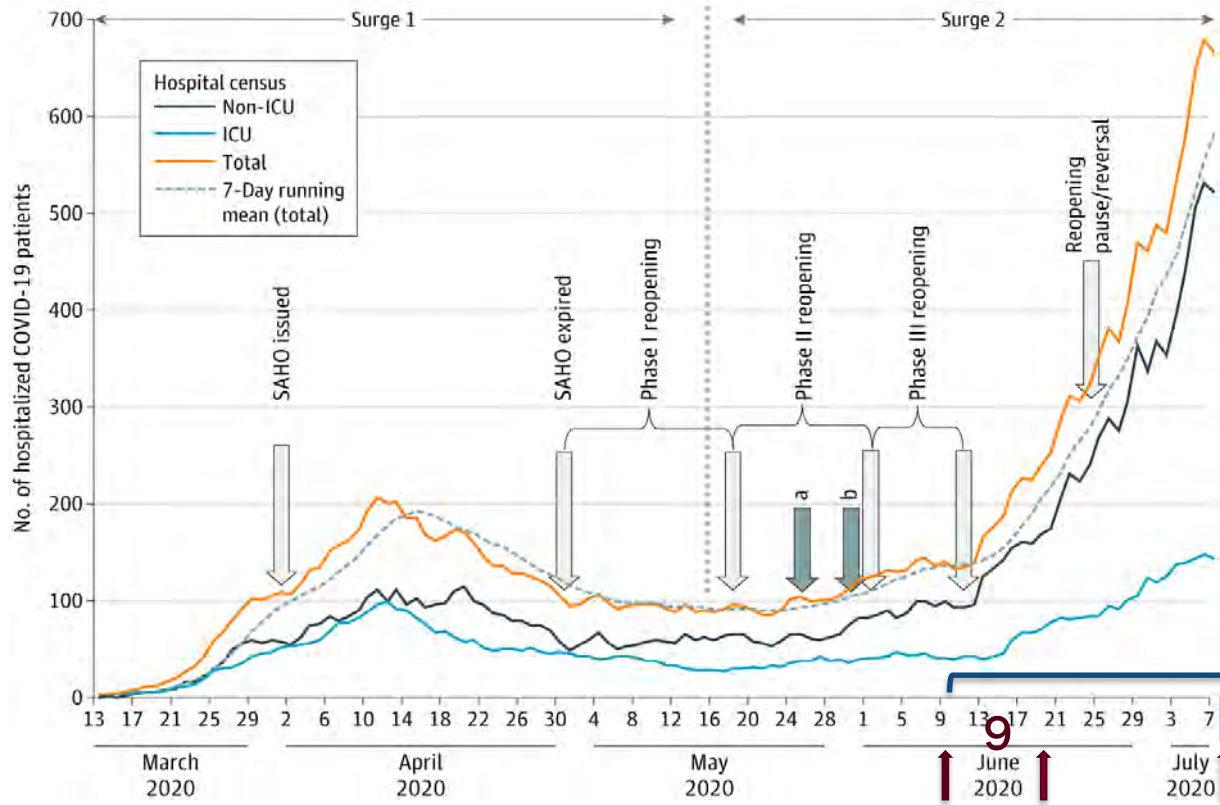


**Representation and expertise: Epidemiology, Health Policy and Management, Health Services Research, Physician Leadership / Clinical expertise, Research Design, Data Analytics, Data Science, Research Technology, IRB, HMAI Leadership, Administration, Project Management*



Characteristics and Outcomes of COVID-19 Patients During Initial Peak and Resurgence in the Houston Metropolitan Area

Vahidy, Drews, Masud, Schwartz, Askary, Boom, Phillips



222

About this Attention Score

In the **top 5%** of all research outputs scored by Altmetric

High Attention Score compared to outputs of the same age (98th percentile)

Timeline of research milestones:

- June 9: First (J1 / J2) Submission
- July 6: JAMA R1 Submission
- July 8 - 31: JAMA R2 Sub / Acceptance / Pub
- August 1 - 13: JAMA R2 Sub / Acceptance / Pub

16/64
(25%)

CURATOR Driven – COVID-19 Research Outputs

Public Health / Health Systems / Disparities



Research Letter | Infectious Diseases

Prevalence of SARS-CoV-2 Infection Among Asymptomatic Health Care Workers in the Greater Houston, Texas, Area

Farhaan S. Vahidy, PhD, MBBS, MPH, David W. Bernard, MD, PhD, Marc L. Boom, MD, MBA, Ashley L. Drews, MD, Paul Christensen, MD, Jeremy Finkelstein, MD, Roberta L. Schwartz, PhD



Adapting an outpatient psychiatric clinic to telehealth during COVID-19: A practice perspective

Farzan Sasangohar; Major R Bradshaw; Marianne Carlson; James N Flack; James C Fowler; Diana Freeland; John Head; Kate Marder; William Orme; Benjamin Weinstein; Jacob Kolman; Bitu Kash; Alok Madan;

PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Sex differences in susceptibility, severity, and outcomes of coronavirus disease 2019: Cross-sectional analysis from a diverse US metropolitan area

Farhaan S. Vahidy, Alan P. Pan, Hilda Ahnsjodt, Yashasvee Munshi, Hulmahn A. Choi, Yordanos Tiruneh, Khurram Nasir, Bitu A. Kash, Julia D. Andrieni, Louise D. McCullough

Published: January 13, 2021 • <https://doi.org/10.1371/journal.pone.0245558>

Open access

Original research

BMJ Open Racial and ethnic disparities in SARS-CoV-2 pandemic: analysis of a COVID-19 observational registry for a diverse US metropolitan population

Farhaan S Vahidy, Juan Carlos Nicolas, Jennifer R Meeks, Osman Khan, Alan Pan, Stephen L Jones, Faisal Masud, H Dirk Sostman, Robert Phillips, Julia D Andrieni, Bitu A Kash, Khurram Nasir

medRxiv

Disparities in COVID-19 Hospitalizations and Mortality among Black and Hispanic Patients: Cross-Sectional Analysis from the Greater Houston Metropolitan Area

Alan Pan, Osman Khan, Jennifer Meeks, Marc Boom, Faisal Masud, Julia Andrieni, Robert Phillips, Yordanos Tiruneh, Bitu Kash, Farhaan Vahidy

Neurology[®]

NEUROLOGY/2020/146712

Association of Prior Cognitive Impairment with SARS-CoV-2 Susceptibility and COVID-19 Mortality

Alan P. Pan, Jennifer Meeks, Thomas Potter, Osman Khan, Sudha Seshadri, Joseph C. Masdeu, and Farhaan S. Vahidy

ANESTHESIA & ANALGESIA



Provider Burnout and Fatigue During the COVID-19 Pandemic: Lessons Learned From a High-Volume Intensive Care Unit

Farzan Sasangohar, PhD, SM, MASc,[†] Stephen L. Jones, MD, MSHI,^{*} Faisal N. Masud, MD,[‡] Farhaan S. Vahidy, PhD, MBBS, MPH,^{*} and Bitra A. Kash, PhD, MBA, FACHE^{*§}

BMJ Quality & Safety

ORIGINAL RESEARCH

Use of telecritical care for family visitation to ICU during the COVID-19 pandemic: an interview study and sentiment analysis

Farzan Sasangohar ^{1,2} Atiya Dhala,³ Feibi Zheng ³
Nima Ahmadi ² Bitra Kash ^{2,4} Faisal Masud ⁵



Rapid Implementation and Innovative Applications of a Virtual ICU during the COVID-19 Pandemic: A Case Study








Atiya Dhala; Farzan Sasangohar; Bitra Kash; Nima Ahmadi; Faisal Masud;

CURATOR : Rationale and Design

Published on 23.2.2021 in Vol 9, No 2 (2021): February

Preprints (earlier versions) of this paper are available at <https://preprints.jmir.org/preprint/26773>, first published December 24, 2020.

Rapid Response to Drive COVID-19 Research in a Learning Health Care System: Rationale and Design of the Houston Methodist COVID-19 Surveillance and Outcomes Registry (CURATOR)

Farhaan Vahidy¹, PhD, MBBS, MPH ; Stephen L Jones¹, MD, MSHI ;
Mauricio E Tano¹, PhD ; Juan Carlos Nicolas¹, BS ; Osman A Khan¹, BS ;
Jennifer R Meeks¹, MS ; Alan P Pan¹, MPH ; Terri Menser¹, PhD ;
Farzan Sasangohar¹, PhD ; George Naufal¹, PhD ; Dirk Sostman¹, MD ;
Khurram Nasir¹, MD, MPH ; Bitra A Kash¹, PhD, MBA 

Citation

Please cite as:

Vahidy F, Jones SL, Tano ME, Nicolas JC, Khan OA, Meeks JR, Pan AP, Menser T, Sasangohar F, Naufal G, Sostman D, Nasir K, Kash BA

Rapid Response to Drive COVID-19 Research in a Learning Health Care System: Rationale and Design of the Houston Methodist COVID-19 Surveillance and Outcomes Registry (CURATOR)

JMIR Med Inform 2021;9(2):e26773

doi: [10.2196/26773](https://doi.org/10.2196/26773)

PMID: 33544692



CURATOR : Rationale and Design

Vahidy et al JMIR Medical Informatics Feb 2021

- **Big Data Platform**

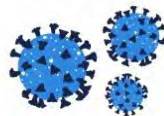
- Volume, Velocity, Variety, Veracity, Value

- **Design Features**

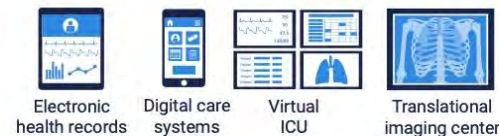
- Longitudinal
- Controls (all levels)
- Vaccinated cohort
- Integrated

Rapid Response to Drive COVID-19 Research in a Learning Health Care System: Rationale and Design of the Houston Methodist COVID-19 Surveillance and Outcomes Registry (CURATOR)

90 million COVID-19 cases worldwide
(as of December 31, 2020)



Increased demand for successful data digitization practices



A multimodal automated database that supports cross-institutional COVID-19 research



CURATOR current status

199,291 patients currently registered

- Demographics
- Lab & test results
- Imaging results
- Procedures
- Medications
- Outcome results

Actively supports 30 COVID-19 research projects

Summary: CURATOR provides a learning health care system-based approach for digitization of COVID-19-related information across a complex health organization to optimize evidence synthesis and decision-making.

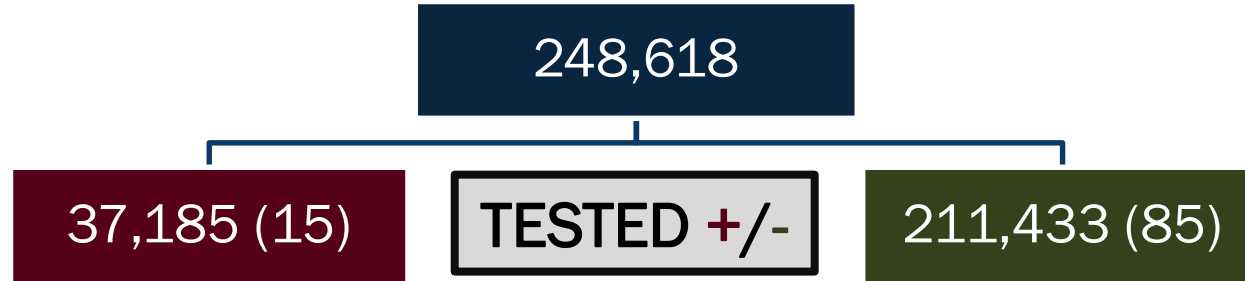
Vahidy et al JMIR Medical Inform 2021;9(2):e26773
<http://medinform.jmir.org/2021/2/e26773/>
DOI: 10.2196/26773



JMIR Publications
Advancing Digital Health & Open Science

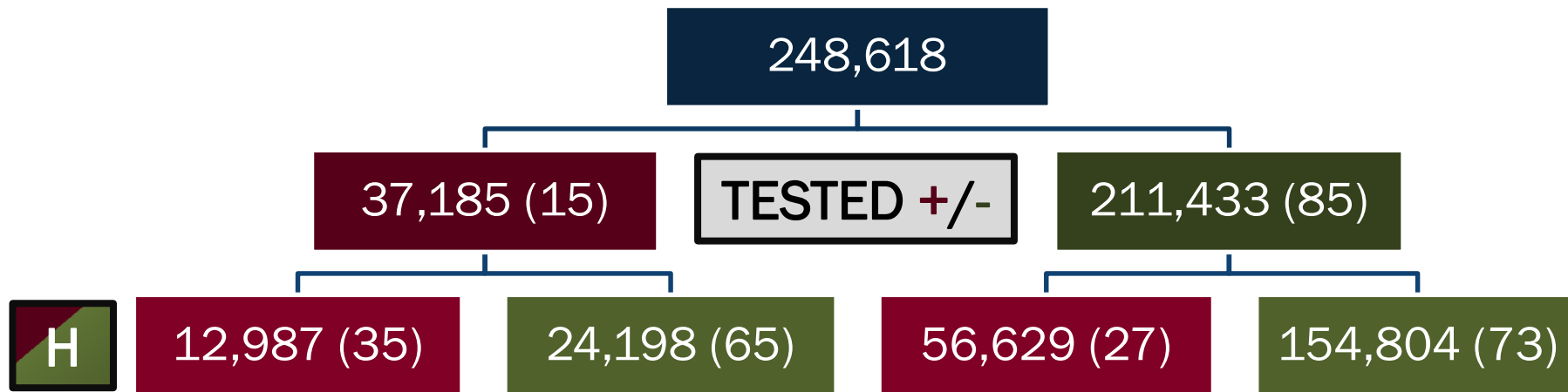
CURATOR : Current Metadata

Monday, March 1st, 2021



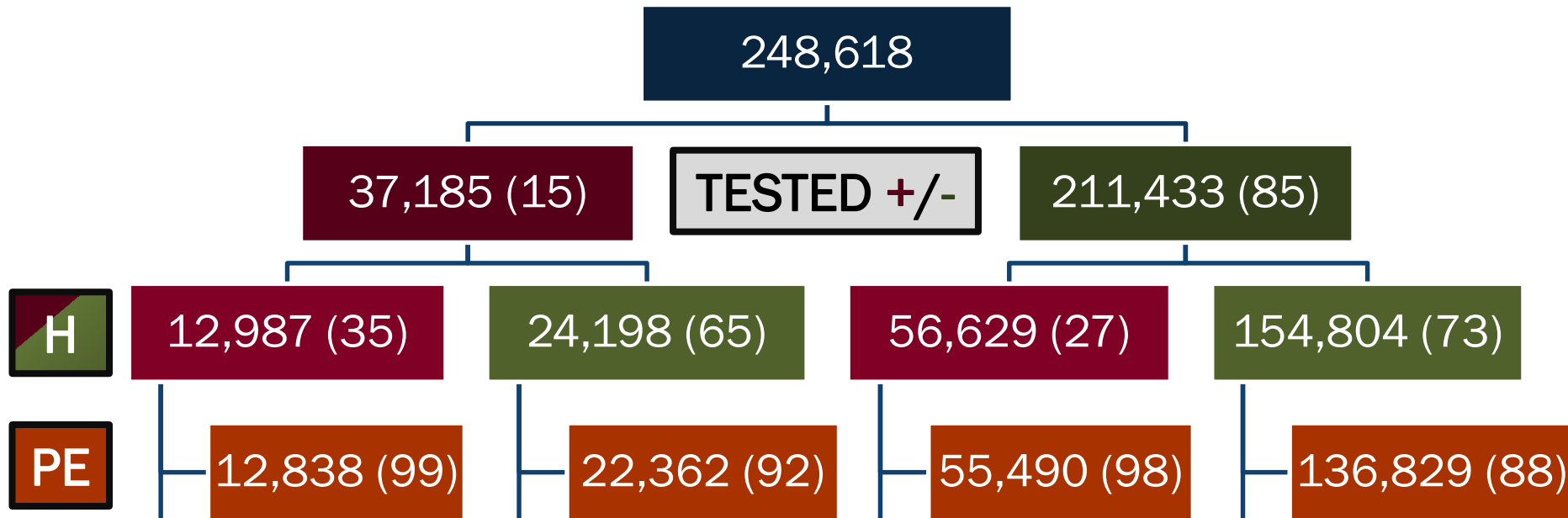
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Monday, March 1st, 2021



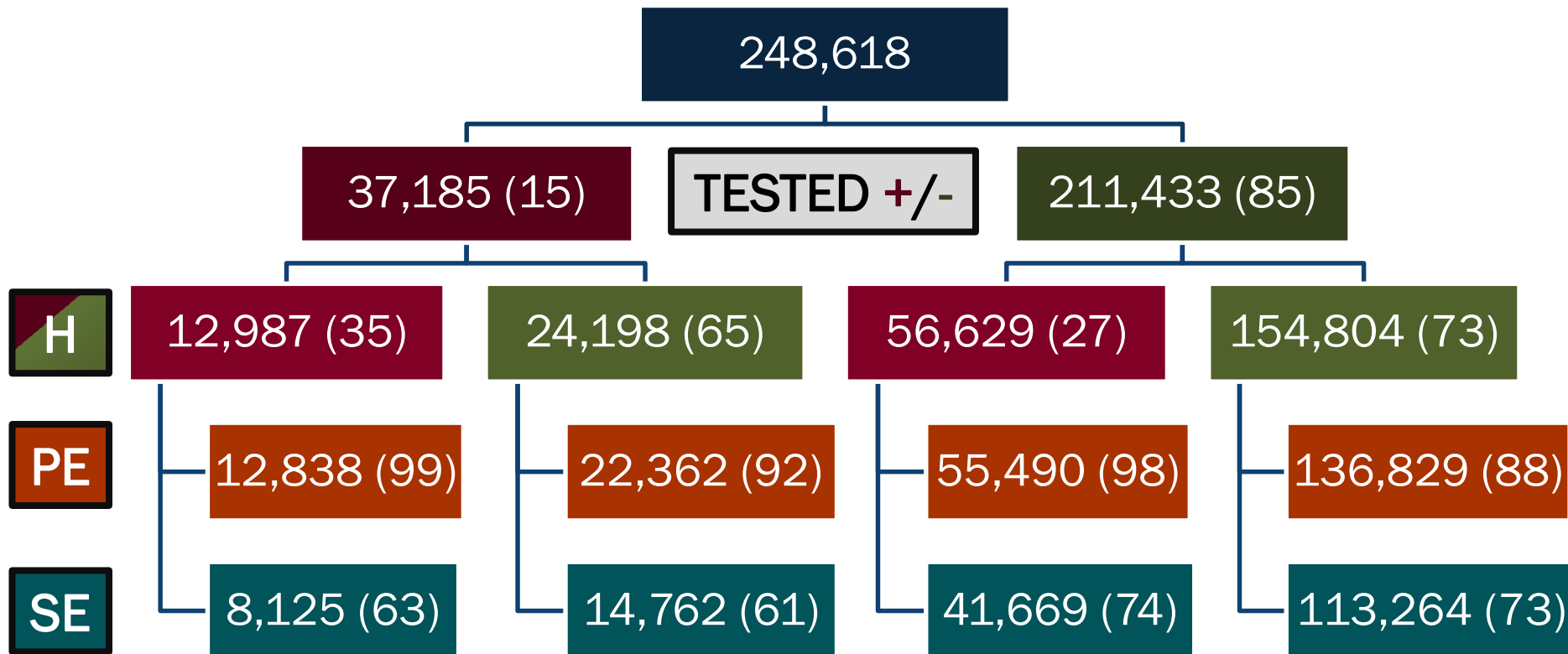
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Monday, March 1st, 2021



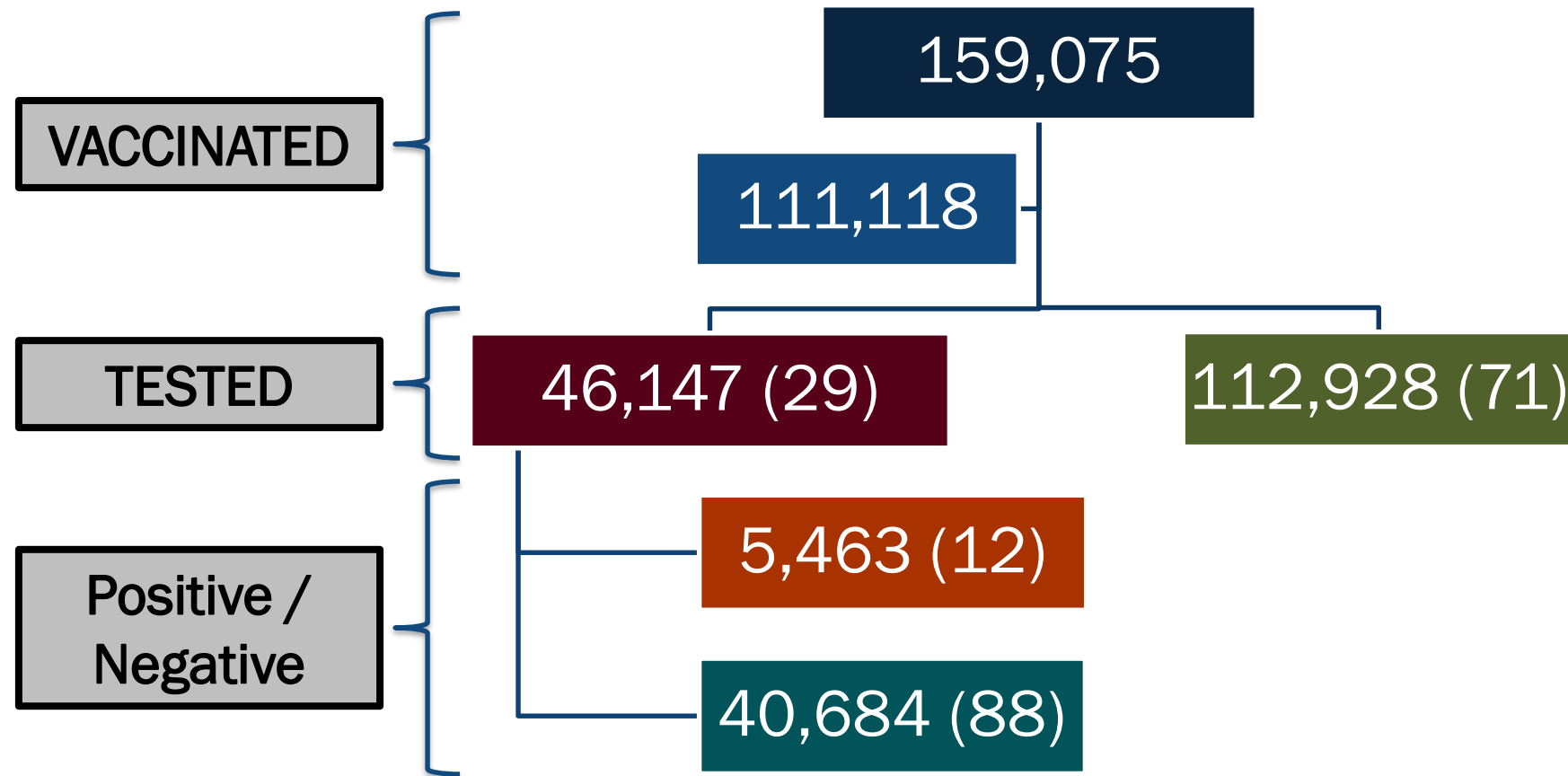
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Monday, March 1st, 2021



CURATOR : Current Metadata

Monday, March 1st, 2021



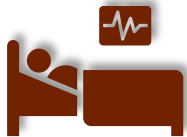
CURATOR : Supported Projects



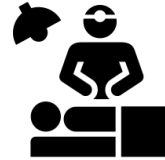
- Echocardiographic findings
- CV MRI findings myocardial damage
- Vasculopathy & COVID-19
- Predictors of myocardial damage
- Statins, lipid control and COVID-19



- Post-Stroke COVID-19 outcomes
- COVID-19 with pre-existing neurological diseases
- COVID-19 and cognitive disease



- Corticosteroid in COVID-19 critical illness
- COVID-19 treatment algorithms in the ICU and outcomes
- Proning and COVID-19 outcomes
- Tocilizumab in COVID-19 critical illness
- ICU ethics and COVID-19



- Emergency surgical volumes during COVID-19 pandemic
- Outcomes among transplant COVID-19 patients
- NSQUIP and COVID-19



- Race and ethnic disparities
- Sex differences
- Demographic transitions across the COVID-19 pandemic
- Physical therapy and COVID-19



- Evolution of symptomatology and complications of COVID-19
- Epidemiology and genetics of COVID-19

CURATOR : Data Democratization

curator@houstonmethodist.org

- Front-end Interface
- IRB regulated
- Governance Structure
- Digital template for BD / AI

CURATOR COVID-19 Surveillance and Outcomes Registry

HOME EXPLORE REQUEST CODEBOOK

Request Form

Name of Study

IRB Protocol # Study Type

Principal Investigator Principal Investigator Email

Requestor: TEST USER Requestor Email: testuser@houstonmethodist.org

Collaborator(s)

Study Description Inclusion / Exclusion Criteria

Requested Categories

Requested Identifiers

SUBMIT

My Requests

Hospitalization Breakdown

Discharged Alive

4700 (85.50%) 799 (14.50%)

Hospitalization Breakdown

Deaths

879 (8.71%) 9121 (91.29%)

CURATOR COVID-19 Surveillance and Outcomes Registry TEST USER

HOME EXPLORE REQUEST CODEBOOK

Maybe add some information on how encounters and testing data are determined/collected here.

Sociodemographic

Comorbidities

Vital Signs

Labs

In-Hospital Treatment

Medications

Outcomes

Clinical Trials

COR Leads and Institutional Partners

Center for Outcomes Research



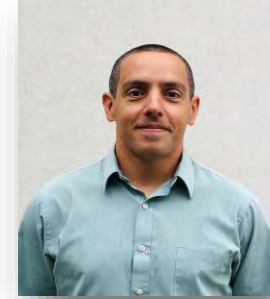
Bita Kash
Director



Khurram Nasir
Co-Director



Steve Jones
Informatics Chief

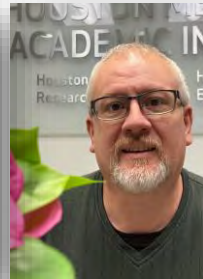


Charlie Nicolas
Infrastructure Architect

Academic Tech & Informatics



Ginny Torno
Director



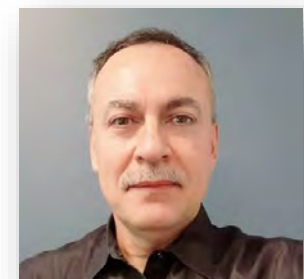
Jon Raines
App Team Lead

Healthcare Informatics & Analytics



Jay Kumar
Director

System Qual Ops & Analytics



Billy Askari
Director

HOUSTON
Methodist[®]
LEADING MEDICINE

METHODIST COVID RECOVERY CLINIC

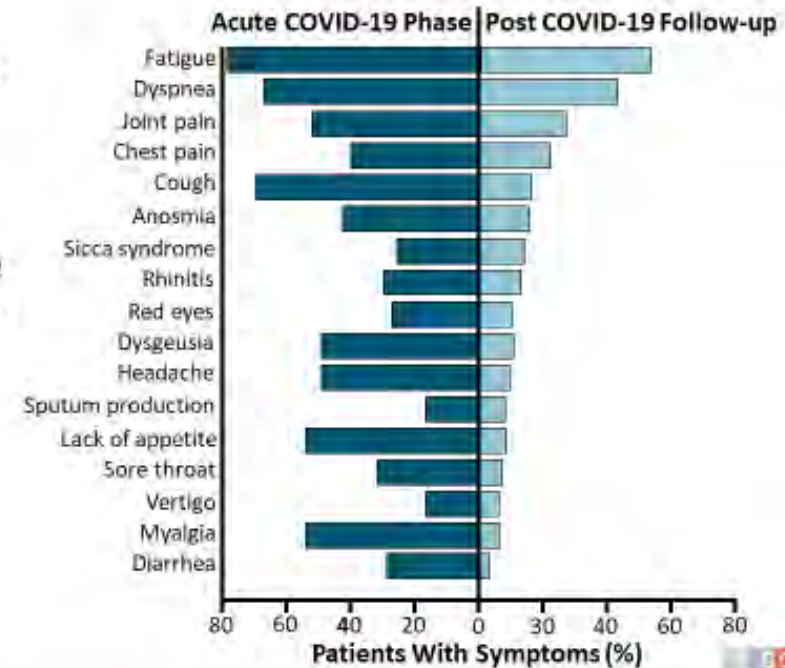
Sandeep Lahoti, MD MBA

Medical Director, Ambulatory Clinics, Department of Medicine
Associate Chief for Clinical Affairs, Division of Gastroenterology



COVID-19 Symptom Persistence: Experience From Italy

- Postacute outpatient service for patients who recovered from COVID-19 (N = 143)
 - Mean hospital stay: 13.5 days
- Assessed by standardized questionnaire at mean of 60.3 days after onset of first COVID-19–related symptom
 - 32% had 1-2 persistent symptoms
 - 55% had ≥ 3 persistent symptoms
 - None with fever, signs of acute illness
- 44% of patients reported lower QoL



Carfi, JAMA, 2020;324:693.

Slide credit: clinicaloptions.com

6-month consequences of COVID-19 in patients discharged from hospital: a cohort study

- Choi, et al. Lancet January 8, 2021
- 1733/2469 pts evaluated (median age 57, 52% men)
- Nearly 80% had at least one residual symptom 6 months after discharge – even in those with milder disease
- More than half had persistent lung abnormalities (more common with initially severe illness)
- Over 20% below normal 6 min walking test
- 13% with normal GFR at discharge reduced at 6 months

Table 2 Symptoms, exercise capacity, and health-related quality of life at follow-up according to severity scale

Symptoms	Total (n=1733)	Seven-category scale			OR or β (95% CI)	
		Scale 3: not requiring supplemental oxygen (n=439)	Scale 4: requiring supplemental oxygen (n=1172)	Scale 5–6: requiring HFNC, NIV or IMV (n=122)	Scale 4 vs 3	Scale 5–6 vs 3
Any one of the following symptoms	1265/1655 (76%)	344/424 (81%)	820/1114 (74%)	101/117 (86%)	OR 0.70 (0.52 to 0.96)*	OR 2.42 (1.15 to 5.08)*
Fatigue or muscle weakness	1038/1655 (63%)	281/424 (66%)	662/1114 (59%)	95/117 (81%)	OR 0.74 (0.58 to 0.96)*	OR 2.69 (1.46 to 4.96)*
Sleep difficulties	437/1655 (26%)	116/424 (27%)	290/1114 (26%)	31/117 (26%)	OR 0.92 (0.71 to 1.21)	OR 1.15 (0.68 to 1.94)
Hair loss	359/1655 (22%)	93/424 (22%)	238/1114 (21%)	28/117 (24%)	OR 0.99 (0.74 to 1.31)	OR 1.17 (0.67 to 2.04)
Smell disorder	176/1655 (11%)	55/424 (13%)	107/1114 (10%)	14/117 (12%)	OR 0.69 (0.48 to 1.00)	OR 0.90 (0.43 to 1.87)
Palpitations	154/1655 (9%)	45/424 (11%)	96/1114 (9%)	13/117 (11%)	OR 0.86 (0.58 to 1.28)	OR 1.31 (0.61 to 2.80)
Joint pain	154/1655 (9%)	51/424 (12%)	86/1114 (8%)	17/117 (15%)	OR 0.56 (0.38 to 0.83)*	OR 0.74 (0.36 to 1.50)
Decreased appetite	138/1655 (8%)	42/424 (10%)	85/1114 (8%)	11/117 (9%)	OR 0.84 (0.56 to 1.27)	OR 1.56 (0.71 to 3.43)
Taste disorder	120/1655 (7%)	37/424 (9%)	75/1114 (7%)	8/117 (7%)	OR 0.84 (0.54 to 1.30)	OR 0.80 (0.32 to 2.02)
Dizziness	101/1655 (6%)	32/424 (8%)	60/1114 (5%)	9/117 (8%)	OR 0.77 (0.48 to 1.22)	OR 0.95 (0.39 to 2.31)
Diarrhoea or vomiting	80/1655 (5%)	27/424 (6%)	48/1114 (4%)	5/117 (4%)	OR 0.71 (0.42 to 1.22)	OR 0.39 (0.11 to 1.42)
Chest pain	75/1655 (5%)	19/424 (4%)	46/1114 (4%)	10/117 (9%)	OR 0.94 (0.52 to 1.67)	OR 2.55 (0.99 to 6.62)
Sore throat or difficult to swallow	69/1655 (4%)	20/424 (5%)	44/1114 (4%)	5/117 (4%)	OR 0.91 (0.50 to 1.65)	OR 1.21 (0.40 to 3.73)
Skin rash	47/1655 (3%)	16/424 (4%)	27/1114 (2%)	4/117 (3%)	OR 0.64 (0.32 to 1.26)	OR 0.71 (0.18 to 2.87)
Myalgia	39/1655 (2%)	11/424 (3%)	24/1114 (2%)	4/117 (3%)	OR 0.80 (0.38 to 1.69)	OR 1.72 (0.47 to 6.27)
Headache	33/1655 (2%)	10/424 (2%)	20/1114 (2%)	3/117 (3%)	OR 0.76 (0.35 to 1.69)	OR 1.53 (0.36 to 6.52)
Low grade fever	2/1655 (<1%)	1/424 (<1%)	1/1114 (<1%)	0	NA	NA

Outpatients: Long-Term Follow-up

Sequelae in Adults at 6 months After COVID-19 Infection

Table. Demographic and Clinical Characteristics of the Study Cohort

Characteristic	No. (%)				
	Total recovered individuals (n = 177)	Inpatients (n = 16)	Outpatients (n = 150)	Asymptomatic individuals (n = 11)	Healthy controls (n = 21)
Age, mean (SD), y	48.0 (15.2)	54 (15.1)	46.3 (14.3)	63.8 (18.8)	50.8 (15.8)
Sex					
Women	101 (57.1)	8 (50.0)	87 (58.0)	6 (54.5)	11 (52.4)
Men	76 (42.9)	8 (50.0)	63 (42.0)	5 (45.5)	10 (47.6)
BMI, mean (SD)	27.1 (5.8)	28.7 (9.1)	26.4 (6.6)	26.3 (5.4)	25.2 (7.1)
Race/ethnicity					
Non-Hispanic/Latino					
White	135 (76.3)	6 (37.5)	121 (80.7)	8 (72.7)	16 (76.2)
Black	3 (1.7)	1 (6.2)	2 (1.3)	0	0
Other ^a	31 (17.5)	8 (50.0)	21 (14.0)	2 (18.2)	5 (23.8)
Hispanic/Latino	7 (4.0)	1 (6.2)	5 (3.3)	1 (9.1)	0
Missing	1 (0.6)	0	1 (0.7)	0	0
Influenza vaccination	130 (73.4)	12 (75.0)	109 (72.7)	9 (81.8)	18 (85.7)
Comorbidities					
Hypertension	23 (13.0)	3 (18.8)	18 (12.0)	2 (18.2)	0
Diabetes	9 (5.1)	4 (25.0)	4 (2.7)	1 (9.1)	1 (4.8)
Active smoking	8 (4.5)	0	7 (4.7)	1 (9.1)	1 (4.8)
Highest level of care accessed during acute illness					
None	107 (60.5)	0	96 (64.0)	11 (100)	21 (100)
Primary care	37 (20.9)	0	37 (24.7)	0	0
Urgent room or emergency department	17 (9.6)	0	17 (11.3)	0	0
Admitted to hospital or ICU	16 (9.0)	16 (100)	0	0	0
Post-COVID-19 follow-up characteristics					
Time after illness onset, median (SD), d ^b	169 (39.5)	179 (44.9)	169 (37.1)	139 (47.1)	87 (31.3)
Persistent symptoms ^c					
0	119 (67.2)	10 (62.5)	98 (65.3)	11 (100.0)	20 (95.2)
1-2	29 (16.4)	2 (12.5)	28 (18.7)	0	0
≥3	24 (13.6)	3 (18.8)	21 (14.0)	0	1 (4.8)
Missing	7 (4.0)	1 (6.3)	3 (2.0)	0	0
Worsened quality of life ^d	53 (29.9)	7 (43.8)	44 (29.3)	2 (18.2)	2 (1.4)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COVID-19, coronavirus disease 2019; ICU, intensive care unit.

^a Other race/ethnicity included American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, and more than 1 race.

^b Time since symptom onset in severe/mild cohorts, time since first positive test in asymptomatic individuals, time since enrollment in healthy controls.

^c Participants with COVID-19 were asked whether they experienced continued symptoms from their COVID-19 illness. Healthy patients in the control group were

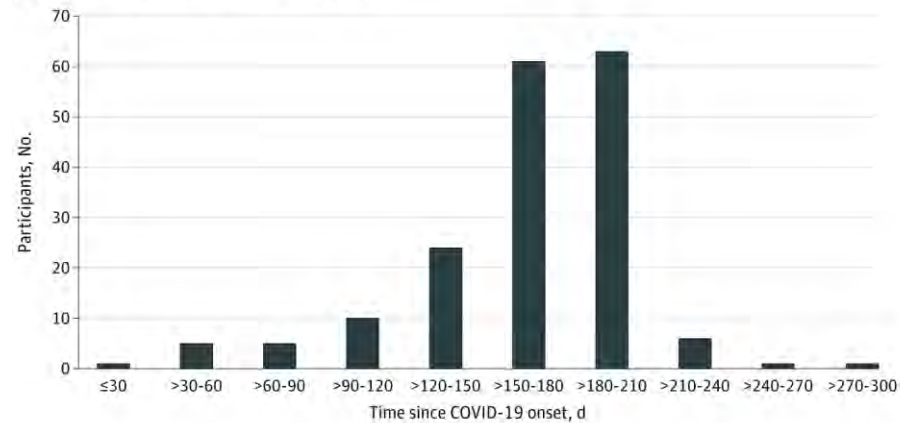
asked whether they experienced symptoms from an illness at the time of follow up survey completion.

^d Quality of life was assessed using a sliding scale ranging from 0 (worst imaginable health) to 100 (best imaginable health). Worsened quality of life was defined as a 10-point decrease in health status from before COVID-19 to the time of survey completion.

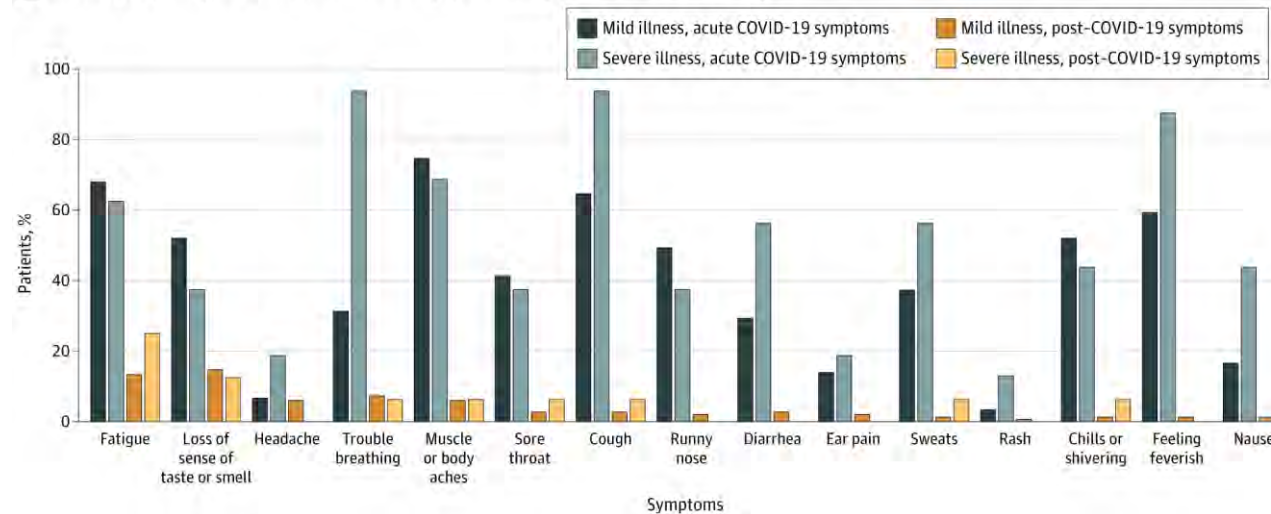
Outpatients: Long-Term Follow-up

Sequelae in Adults at 6 months After COVID-19 Infection

A Survey completion by days after illness onset



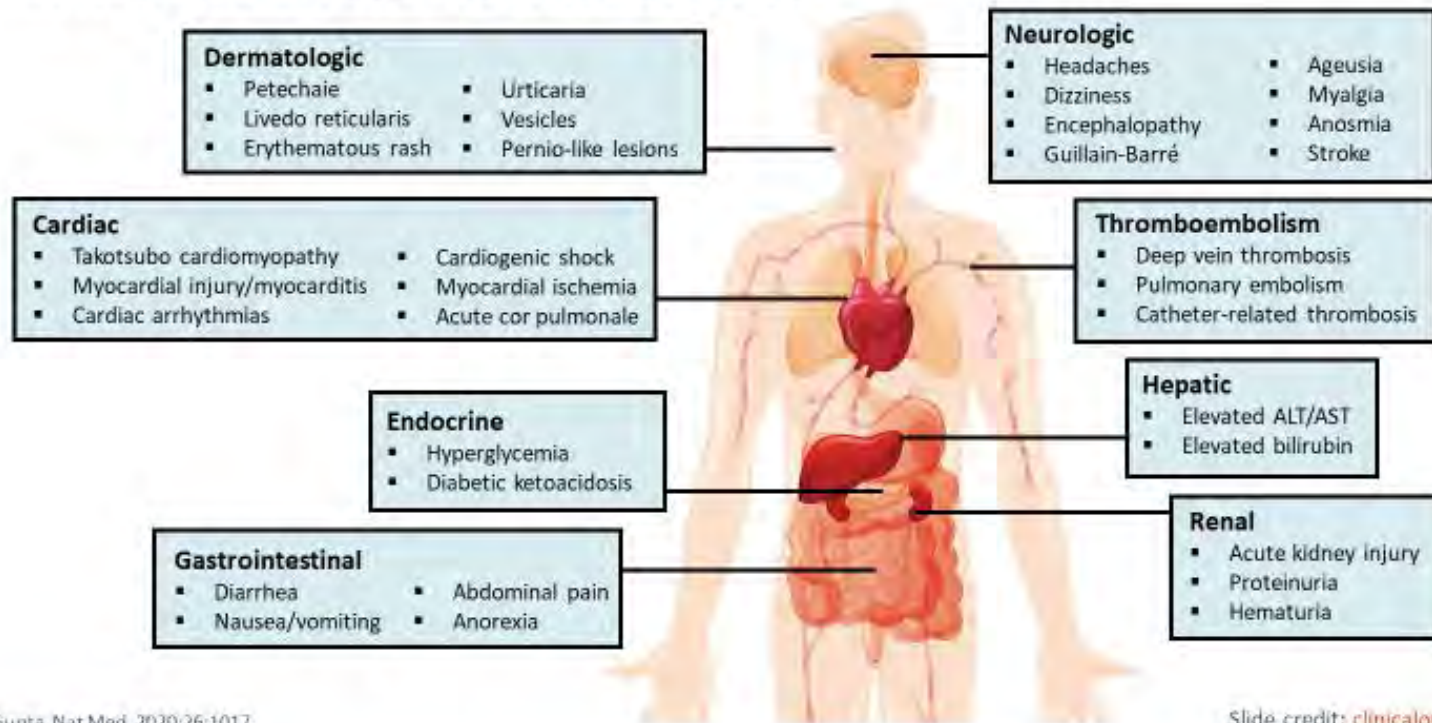
B Percentage of participants who reported COVID-19 symptoms during acute illness and at follow-up



Characterizing Long COVID in an International Cohort: 7 Months of Symptoms and Their Impact

- Survey results from 3762 individuals across 56 countries – predominantly white (79%), women (85%), between 30-60 years of age (89%), living in the United States (41%)
- 92% outpatient treatment (only 8% admitted)
- 257 questions, median time of 69.3 minutes to complete
- 2464 respondents had symptoms lasting 6 months or longer
 - Fatigue 78%, post-exertional malaise 72%, cognitive dysfunction 55%
- 45% required a reduced work schedule compared to pre-illness
- 22% were not working due to their health condition

Extrapulmonary Manifestations of COVID-19: Which of These Return or Last?



- Over 28 million cases of COVID-19 in the US
 - Substantial mortality: over 500K dead in the US alone
 - Less publicized is the significant morbidity associated with the infection
- “Second pandemic”
 - Long-haulers
 - Long COVID
 - Post-COVID syndrome
- Post-Acute Sequelae of SARS-CoV-2
 - No set definition / testing for diagnosis
- NIH launches new initiative to study “Long COVID” – \$1.15 billion over 4 years

- Multidisciplinary virtual clinic
 - Phase 1: patients discharged from HMH
 - Phase 2: incorporated referrals to specialists for both inpatients and outpatients
 - Phase 3: in process of hiring staffing for an intake clinic
 - Patients can be scheduled via phone (346-356-3320) or via Epic referral form
 - Web page being developed

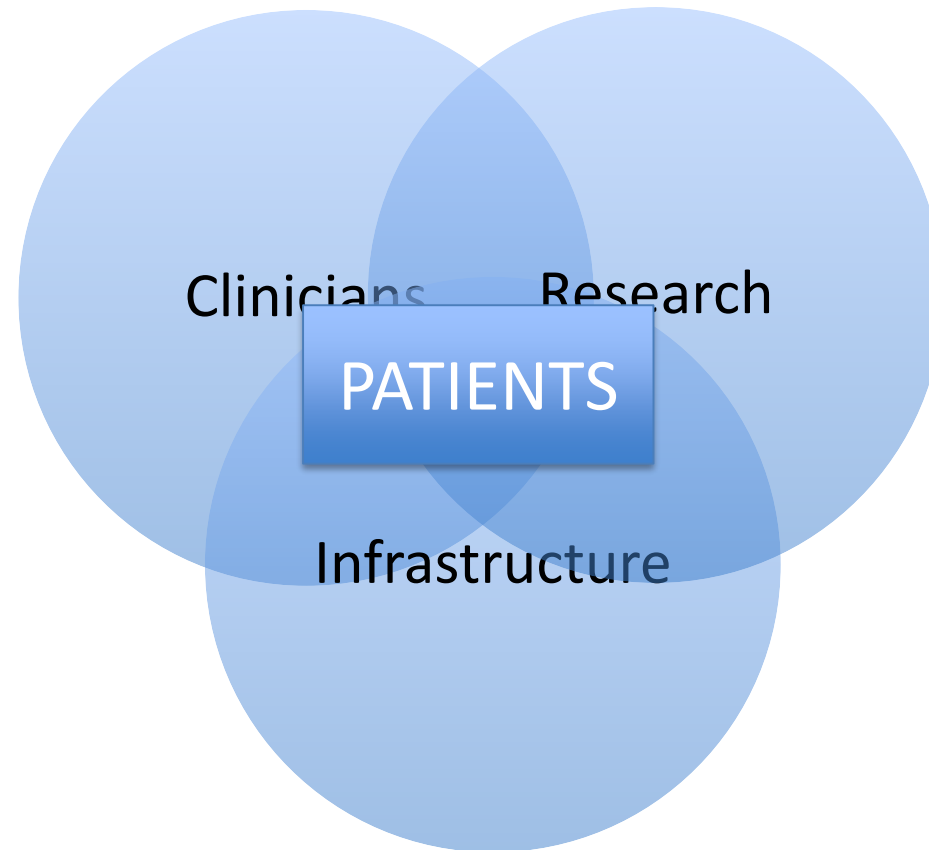
COVID Recovery Clinic

Participating Sub-Specialists

Physician	Specialty
Sean Hebert, MD	Nephrology
Abhishek Kansara, MD	Endocrinology
Bhargavi Patham, MD	Endocrinology
Archana Sadhu, MD	Endocrinology
Teresa Kaldis, MD	Physical Medicine & Rehabilitation
Khurram Nasir, MD	Cardiology
Mouaz Al-Mallah, MD	Cardiology
Maan Malahfji, MD	Cardiology
Jenny Petkova, MD	Hematology
Ashley Anderson, MD	Neurology
Bing Liao, MD	Neurology
Georges Youssef, MD	Pulmonology
Faisal Zahiruddin, DO	Pulmonology
Omar Ahmed, MD	Otolaryngology

****Currently negotiating for counseling services / recruiting for an APP to help support this initiative****

- Initial visit is a thorough assessment
 - Full spectrum of labs
 - Chest x-ray
 - Questionnaires (QOL, socioeconomic, cognitive)
 - Pulmonary function tests for pulmonary patients
- Further testing / referrals to other specialists as deemed necessary
- Pulmonary rehab in development (both physical and virtual)
- Symptomatic therapy



Research Initiatives (DOM)

COVID Drug Studies

Study	PI
Clazakizumab	Howard Huang, MD
iMAB	Deepa Gotur, MD
CARDEA	Mukhtar Al-Saadi, MD
EIDD	Daniela Moran, MD
MK-4482	Daniela Moran, MD
LAU-7b	Faisal Zahiruddin, DO
Regeneron Outpatient	Howard Huang, MD
PYAB BLAZE Outpatient	Howard Huang, MD
RLF-100 EAP	J. Georges Youssef, MD
RLF-100 RCT (concluded)	J. Georges Youssef, MD
Inhaled Nitric Oxide EAP (concluded)	J. Georges Youssef, MD
Inhaled Nitric Oxide RCT (concluded)	J. Georges Youssef, MD

- Best treatment is PREVENTION
 - Socially distance
 - Face masks
 - Get your vaccine
- Vaccines most likely reduce transmission (? is how much)
 - Lower chance of getting infected (in the 80 – 90 % range)
 - Two studies out of UK (one on HCW and the other on people over the age of 70) and one study out of Israel
 - Lower viral load if infected
 - One study out of Israel
 - Questions regarding duration of protection / effect of variants
 - Studies were observational studies not RCTs
 - Studies were preprints / press releases (not yet peer reviewed)

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COVID-19 Vaccine Update

March 4, 2021

H. Dirk Sostman, MD FACR

Ernest Cockrell Jr. Presidential Distinguished Chair

EVP & Chief Academic Officer












Approved or Near-Approved Vaccines

		Protection from Asymptomatic Infection	Protection from Symptomatic Illness	Protection from Severe Illness	Protection from Hospitalization or Death
	 Approved (US, UK, EU)	66% after 1 st dose (Preliminary) Yes in monkeys	94%	100%	100%
	 Approved (US, UK, EU)	90% after second dose Yes in monkeys	95%	90%	100%
	 Approved (US)	74% Yes in monkeys	72% (US) 68% (S. America) 64% (S. Africa)	82% - 88%	100%
	 Approved (UK, EU)	66% (Preliminary) No in monkeys	76% (UK) 10% (S. Africa)	100%	100%
	 Not yet approved	No data	89% (UK) 60% (S. Africa)		100%

The exact numbers you will see quoted for different vaccines will vary depending on efficacy, but also








- clinical trial or “real world evidence”
- 1 or 2 doses
- outcome criteria
- length of follow up
- which country
- what time period
- etc.

Approved or Near-Approved Vaccines

		Protection from Asymptomatic Infection	Protection from Symptomatic Illness	Protection from Severe Illness	Protection from Hospitalization or Death
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	 Approved (UK, EU)	66% (Preliminary) No in monkeys	76% (UK) 10% (S. Africa)	100%	100%
	 Not yet approved	No data	89% (UK) 60% (S. Africa)		100%

Accumulating preliminary evidence suggests vaccines will protect against asymptomatic infection – and thus transmission – with efficacy similar to their protection from symptomatic infection.










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	 Not yet approved	No data	89% (UK) 60% (S. Africa)		100%

All vaccines easily clear the FDA's 50% efficacy bar.






The S Africa variant might reduce the efficacy of vaccines, but this is not proven.

Approved or Near-Approved Vaccines

		Protection from Asymptomatic Infection	Protection from Symptomatic Illness	Protection from Severe Illness	Protection from Hospitalization or Death
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	 Not yet approved	No data	89% (UK) 60% (S. Africa)		100%

All the major vaccines provide good protection from severe illness.

Approved or Near-Approved Vaccines

		Protection from Asymptomatic Infection	Protection from Symptomatic Illness	Protection from Severe Illness	Protection from Hospitalization or Death
	 Approved (US, UK, EU)	66% after 1 st dose (Preliminary) Yes in monkeys	94%	100%	100%
	 Approved (US, UK, EU)	90% after second dose Yes in monkeys	95%	90%	100%
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	 Approved (UK, EU)	66% (Preliminary) No in monkeys	76% (UK) 10% (S. Africa)	100%	100%
	 Not yet approved	No data	89% (UK) 60% (S. Africa)		100%

All the major vaccines provide good protection from hospitalization and death.

J & J Vaccine

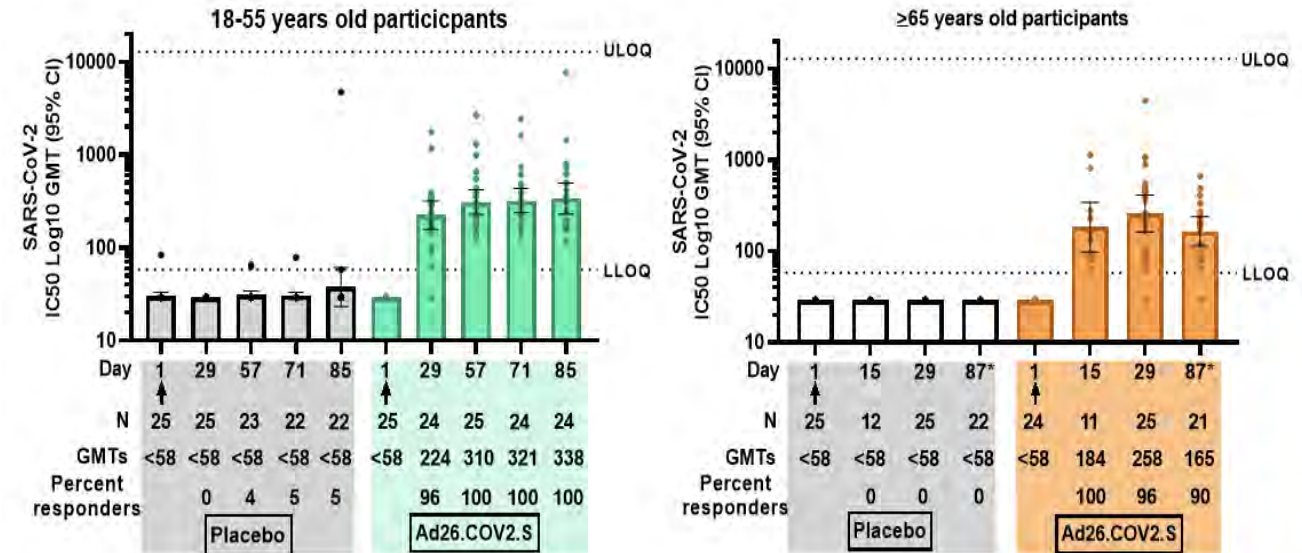
- Adenoviral vector vaccine (similar to AstraZeneca vaccine)
- Efficacy
 - 72% effective at preventing symptomatic COVID in US portion of trial (74% against asymptomatic)
 - 77% effective at preventing severe disease 14 days after administration, 85% after 28 days, 92% after 42 days
 - 100% effective at preventing hospitalization
 - 100% effective at preventing death

- Safety

- Reduced reactogenic effects
- Side effects (unclear relation to vaccine)
 - Tinnitus (6 cases in vaccine group, 0 in placebo)
 - 2 cases of anaphylaxis in S Africa study

- Under investigation

- Would a second shot improve efficacy?



- Real World Data on vaccinated groups
 - Israel – 96% protection from infection
 - Scotland – hospitalization reduced by 85% (Pfizer) and 94% (Astra Zeneca)
 - England – vaccine efficacy 73% (AstraZeneca) to 89% (Pfizer)
 - Houston Methodist – reduced employees' positive tests rate 95%

Vaccine Safety Overview

Phase 3 Clinical Trial

Adverse Effect (AE)	Vaccine Group	Placebo Group
Solicited inject site AE	73%	11%
Solicited systemic AE	70%	34%
Unsolicited non-serious AE	27%	13%
Serious AE	0.6%	0.5%
Withdrawal for AE	0.6%	0.5%
Allergic reaction	0.6%	0.5%
Death	2	4

Early Deployment Experience

- Only unexpected development was a small number of severe allergic reactions. Seen in all three approved vaccines.
- **2.5 to 4.7** cases per million vaccinations
 - flu vaccine = 1.3 per million
- **Treatment**
 - Antihistamines and Epi-Pen
 - Fatalities = 0
- **Precautions**
 - Allergy to vaccine components or to first dose → do not vaccinate
- **Risk Benefit**
 - Much more than 1,000 times safer than getting COVID-19

Vaccine Rollout & Population Immunity

- **Johnson & Johnson vaccine approved February 27**
 - AstraZeneca vaccine probably April – May
 - Novavax vaccine probably May – June
- **By summertime**
 - Vaccine supplies should be ample
 - Vaccination logistics improving continually
 - We can approach population immunity this summer
 - Population immunity means epidemic under control with normal life
 - Local outbreaks and sporadic cases will continue
- **If all goes well, by fall life will be relatively normal**
 - Kids in school
 - Indoor dining
 - Social gatherings

“If All Goes Well.....”
What Could Go Wrong?

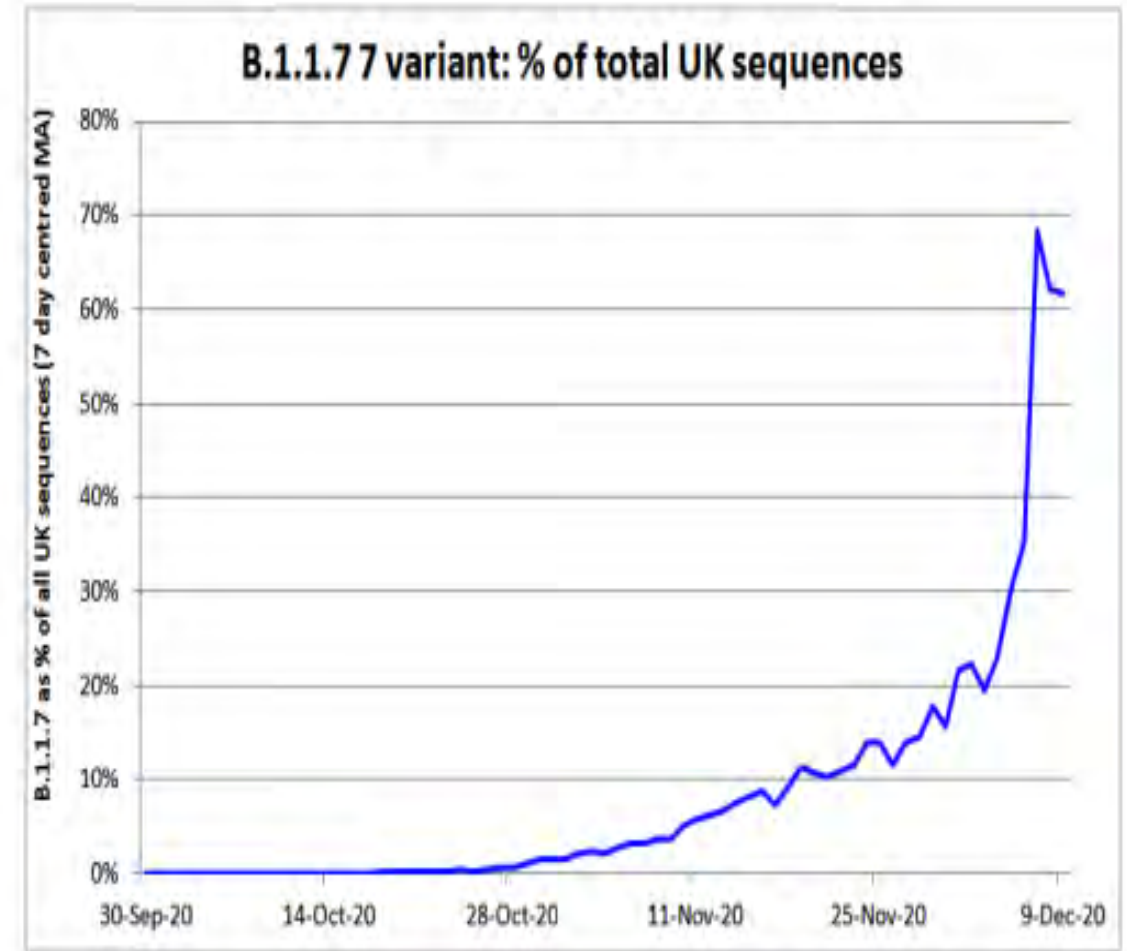
What Could Go Wrong?

- Vaccine production problem
- Vaccine delivery problem
- Vaccine refusers
- Premature re-opening of society leading to fourth wave
- Viral variants proliferate and “outrun” vaccination efforts

What Could Go Wrong?

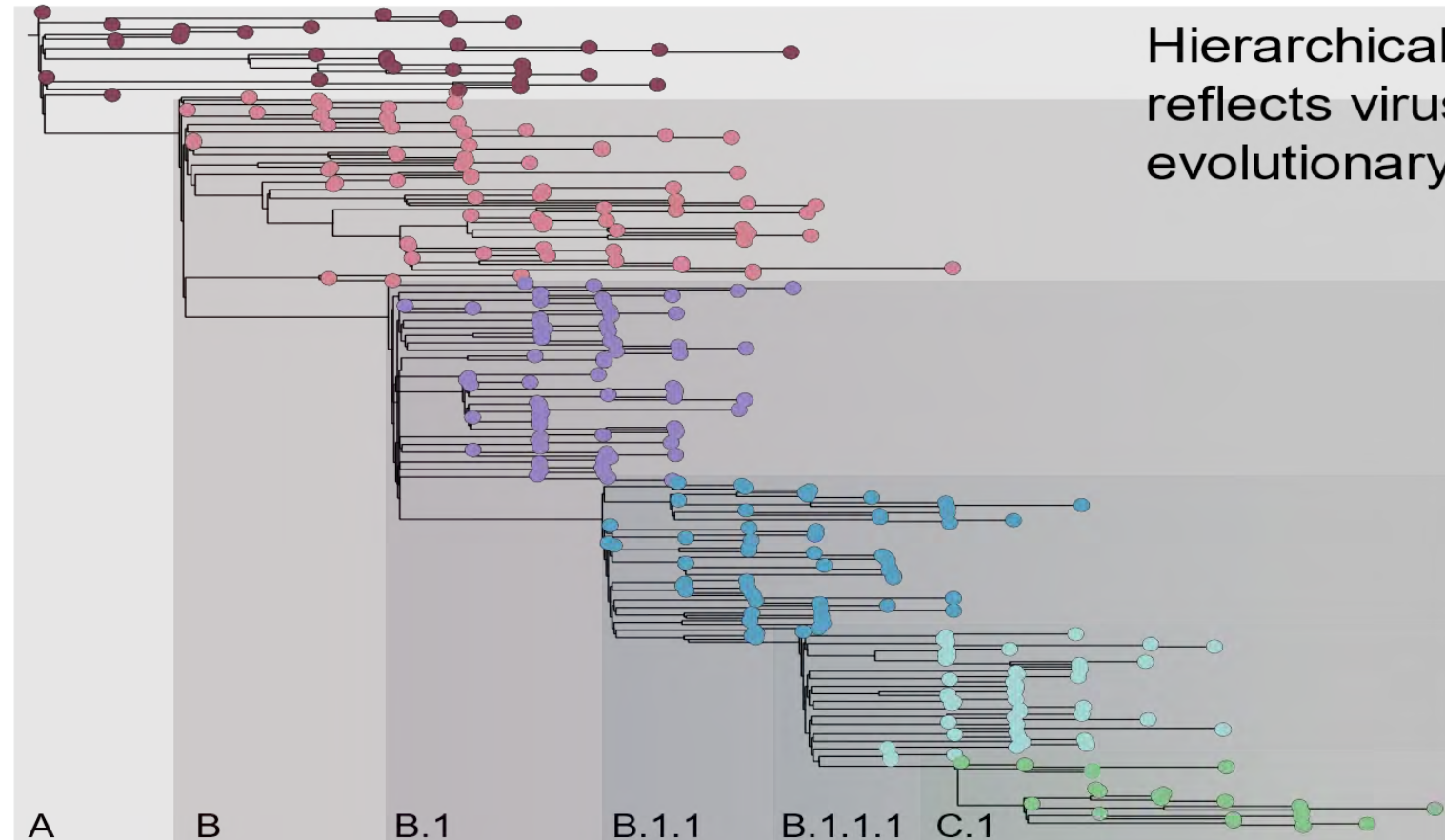
Viral Mutations

- All viruses mutate – and evolve with selective pressure
- Possible concerns
 - Resistance to antibodies
 - Vaccines
 - Monoclonals
 - Previous infection
 - Drug resistance
- Currently tracking
 - California B.1.427/429
 - New York B.1.526
 - United Kingdom B.1.1.7
 - Uganda A.23.1
 - South Africa B.1.351
 - Brazil variant P.1 (B.1.1.28.1)



Viral Taxonomy

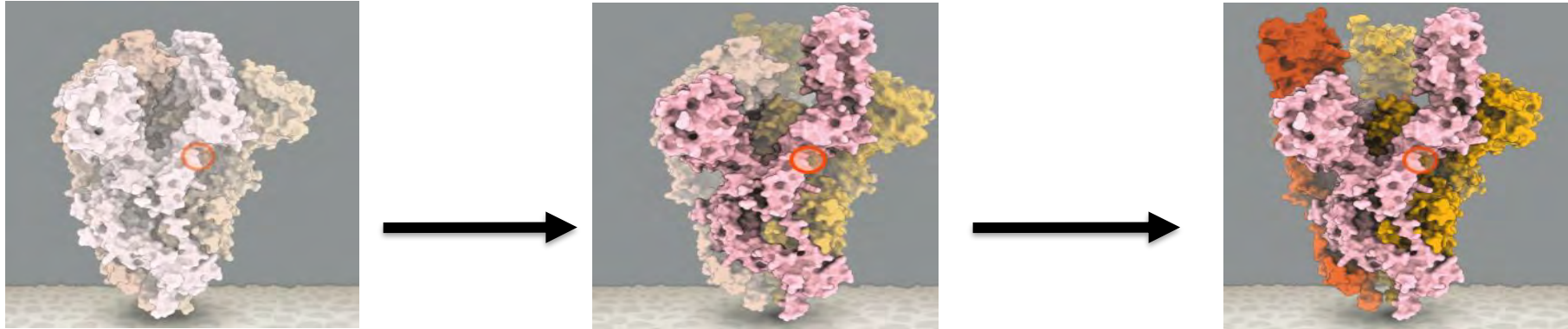
- After 5 levels, strain is given a new one letter label
- Brazil variant P.1 is B.1.1.28.1
- Concerning variants usually have many mutations



“I think all of us are becoming very confused by the different variant names,” said Maria Van Kerkhove, an infectious-disease epidemiologist and COVID-19 technical lead for the WHO.

What Could Go Wrong?

Antibodies May Not “Recognize” Spike Protein with Too Much Change



Vaccine Efficacy	UK – B.1.1.7	S Africa – B.1.351
Pfizer	1.4x reduction*	1.25 – 6x reduction*
Moderna	89%	4x -10x reduction*
Novavax	86%	60% (non HIV)
J&J	72% (USA data)	64%
AstraZeneca	76%	10%

*in the lab in model systems

What Does the Future Hold?

- Not yet clear how big a problem current variants pose to existing vaccines and immunity
- S protein mutations – over time – will likely require updated vaccines
 - Flu: new vaccine when new strain 8x less sensitive to old vaccine
 - Need for more surveillance of COVID mutations
 - mRNA technology well suited to respond to viral mutations
 - Science – several weeks
 - Regulatory – a few months
- Annual or biennial COVID booster likely to be needed for the next several years
- Advise masks during flu season
- Once first exposure to COVID is in childhood, it probably will become a mild endemic illness – many years from now
 - Great pandemic of 1889-1890 “Asiatic flu” killed 1 million people out of a world population of 1.5 billion
 - Probably due to coronavirus HCov-OC43 jumping cattle → humans, now one cause of the common cold

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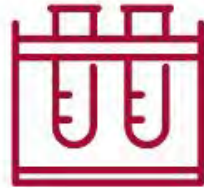
COVID-19 and Vaccine Update

Marc L. Boom, MD
March 4, 2021



Houston Methodist and COVID-19
BY THE NUMBERS

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37,454

Total number of patients tested positive



14,904

Hospitalized COVID-19 Patients



22,000 GALLONS
Hand Sanitizer

(This equals two full tanker trucks!)



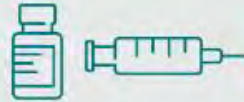
118 MILLION
Gloves



3,476
Monoclonal Antibody Treatments



28
COVID-19 Related Clinical Trials



293,387

Vaccines administered



365
Command Days



731
Peak number of patients



25,350
Media placements

Percentage of HM Employees Vaccinated



81% of employees have scheduled or have received at least one dose



Mask Mandate Lifted in Texas

DJIA 31451.09 0.19% ▲ S&P 500 3841.11 0.75% ▼ Nasdaq 13072.91 2.14% ▼ U.S. 10 Yr -28/32 Yield 1.468% ▼ Crude Oil 61.19 2.41% ▲ Euro 1.2072 0.15% ▼

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- TRACKING VACCINE DISTRIBUTION
- MASK UPGRADES
- STATE-BY-STATE VACCINE GUIDE
- COVID STORM SERIES


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Texas Governor Lifts Covid-19 Mask Mandate, Business Restrictions

Gov. Greg Abbott, announcing end of state mandates on March 10, cites availability of protective gear and testing and increase in vaccinations



Texas to End State Mask Mandate

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Texas and Mississippi to lift mask mandates and roll back Covid restrictions

Gov. Greg Abbott said Texas would be back open "100 percent" by March 10, and Mississippi Gov. Tate Reeves said his state's mask mandate would end Wednesday.



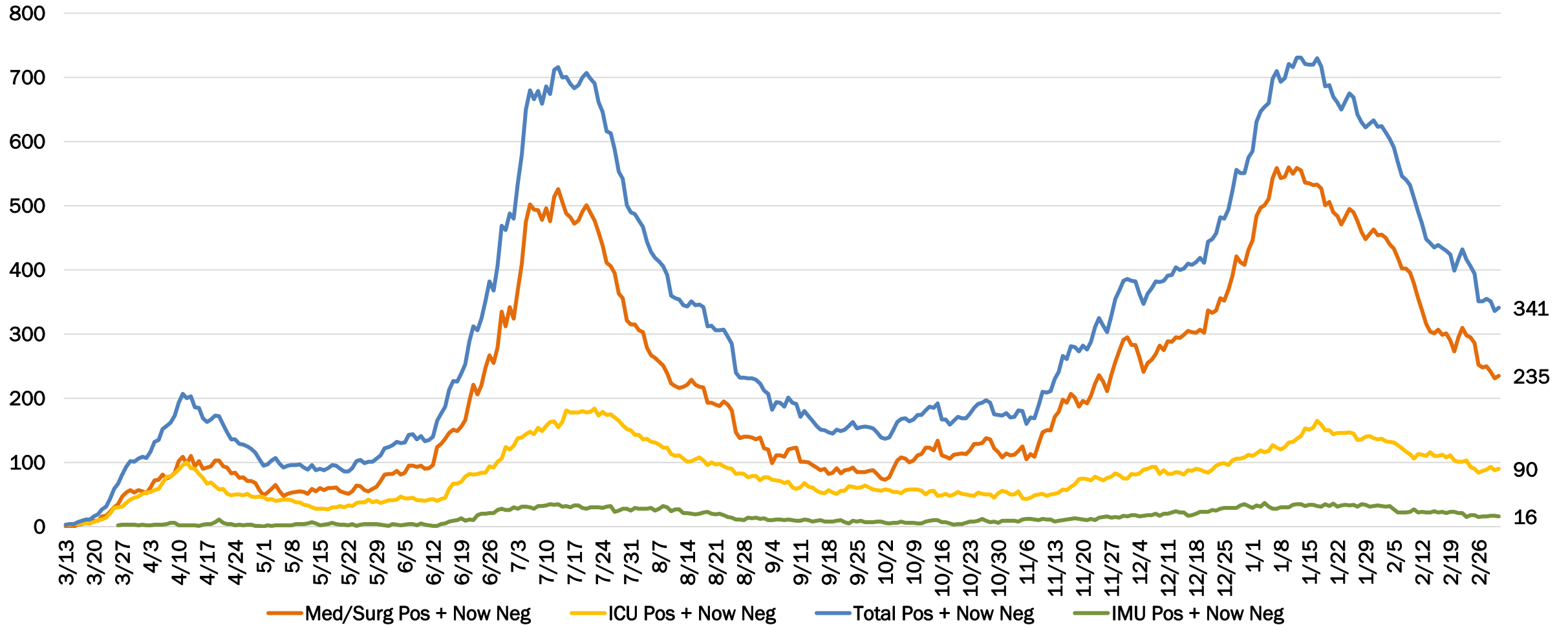
TAP TO UNMUTE

NBC NEWS NOW

Houston Methodist COVID-19 Cases by Day



Houston Methodist COVID-19 Patients by Day



Data as of March 2, 2021

The “Sacred AND”

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”

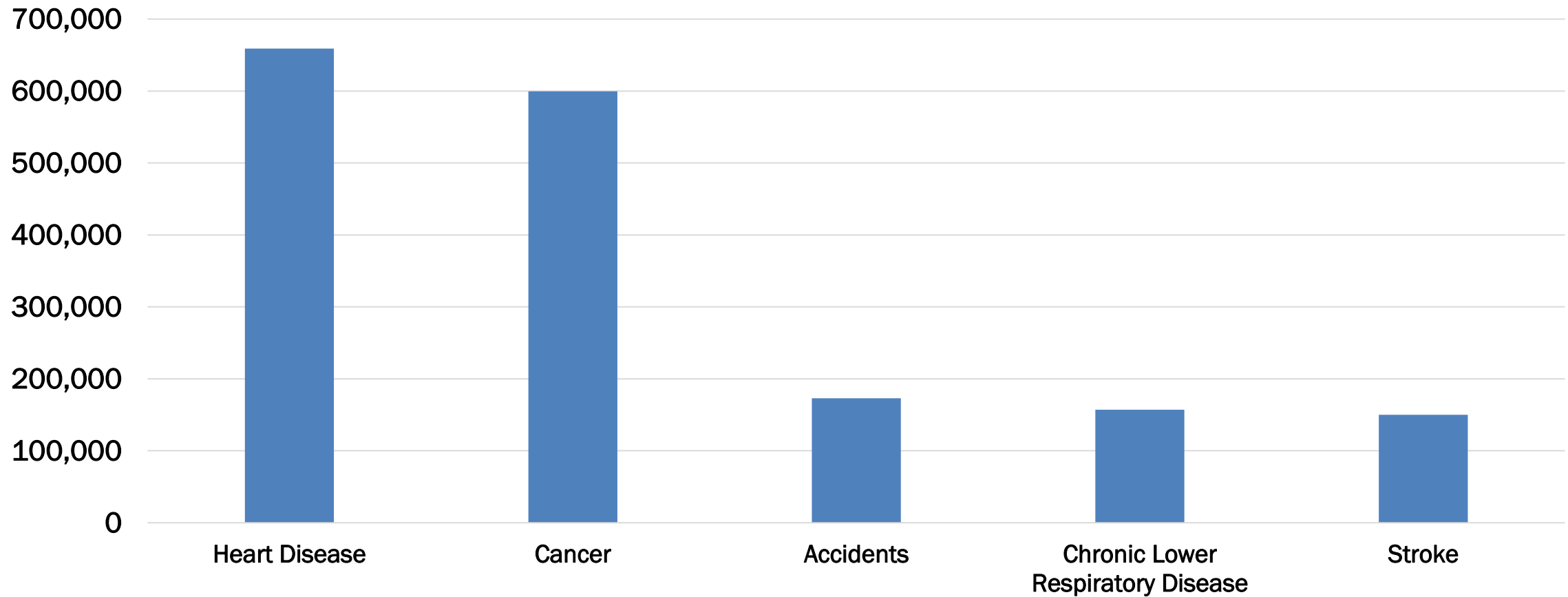
- *We have proven to be incapable of accepting this on our own*
- *Masks must be mandatory until the virus is in control*

MY KEY TAKE HOME MESSAGE TODAY:

GIVE US 90-120 DAYS!!

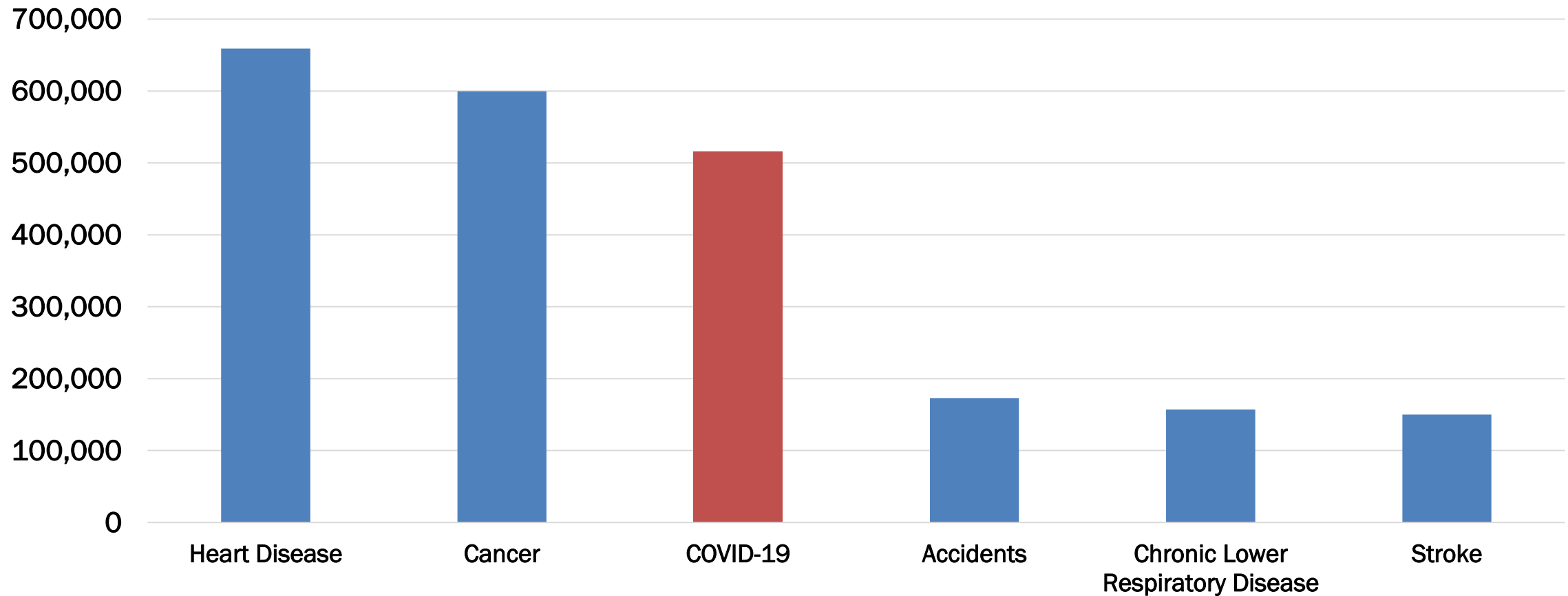
Leading Causes of Death

Leading Causes of Death in U.S.
(12 Month Period)



Leading Causes of Death

Leading Causes of Death in U.S.
(12 Month Period)



IHME Model: Daily Deaths in Texas

Texas

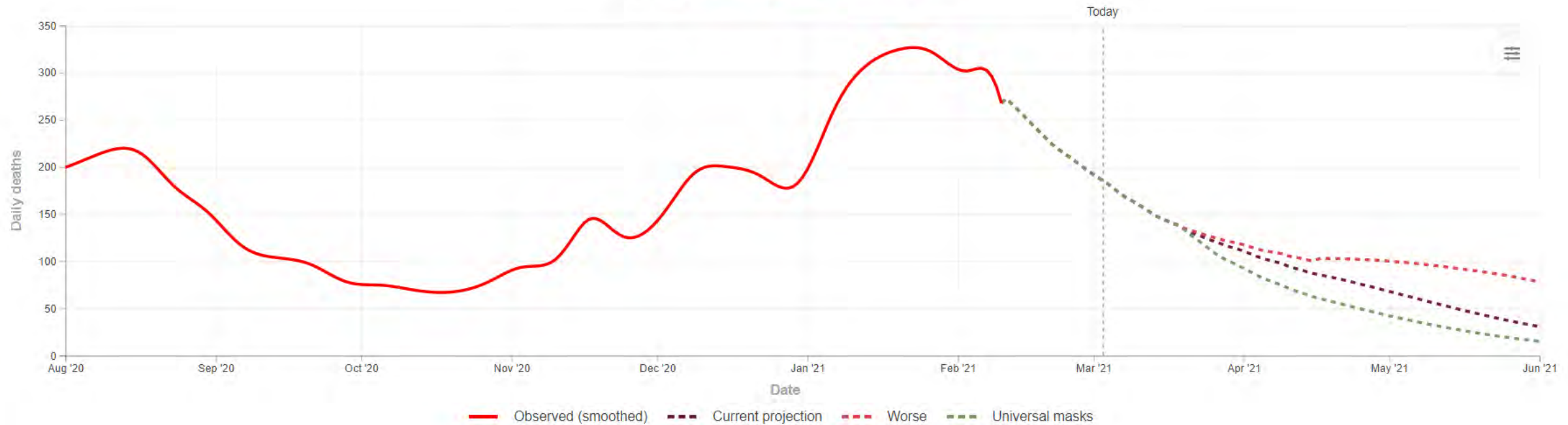
Total deaths Daily deaths Hospital resource use Infections and testing Mask use Social distancing

Daily deaths

Trend Compare Map

Daily deaths is the best indicator of the progression of the pandemic, although there is generally a 17-21 day lag between infection and deaths.

Scenario Projection Worse Masks



All deaths specific to COVID-19 patients.

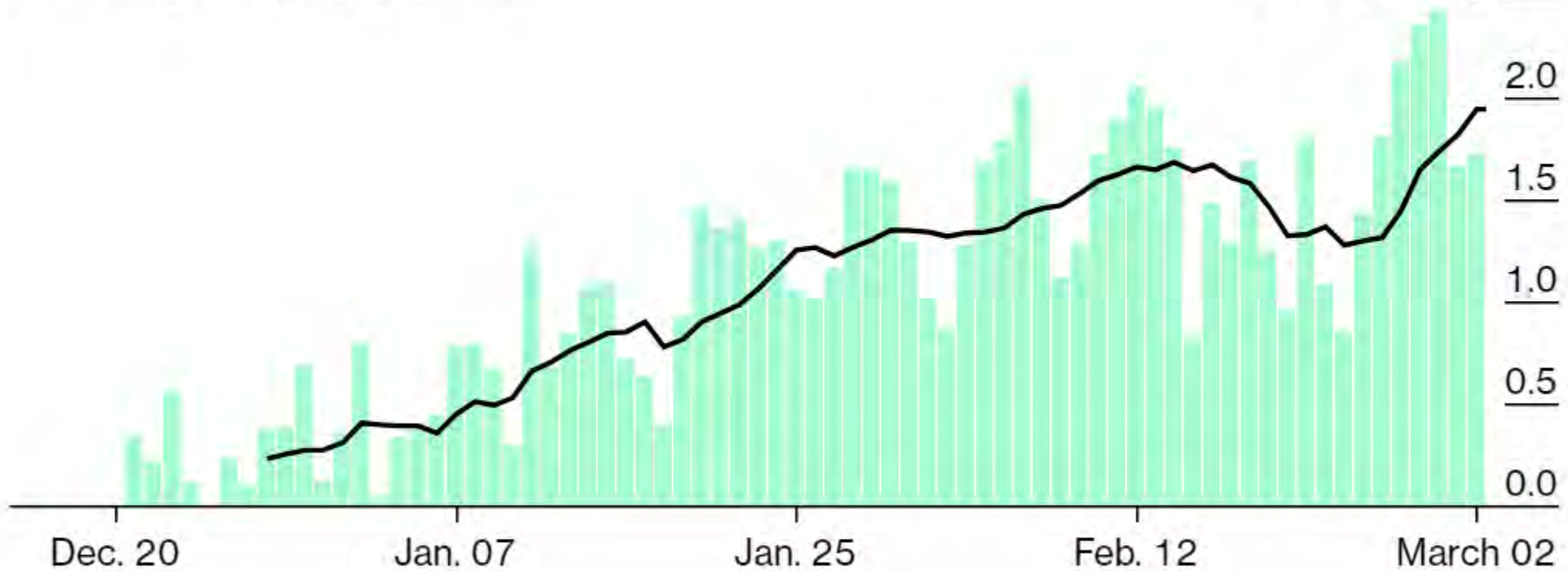
Daily COVID-19 Vaccinations in the U.S.

Daily Vaccinations in the U.S.

The vaccination rate is 1.94 million doses per day.

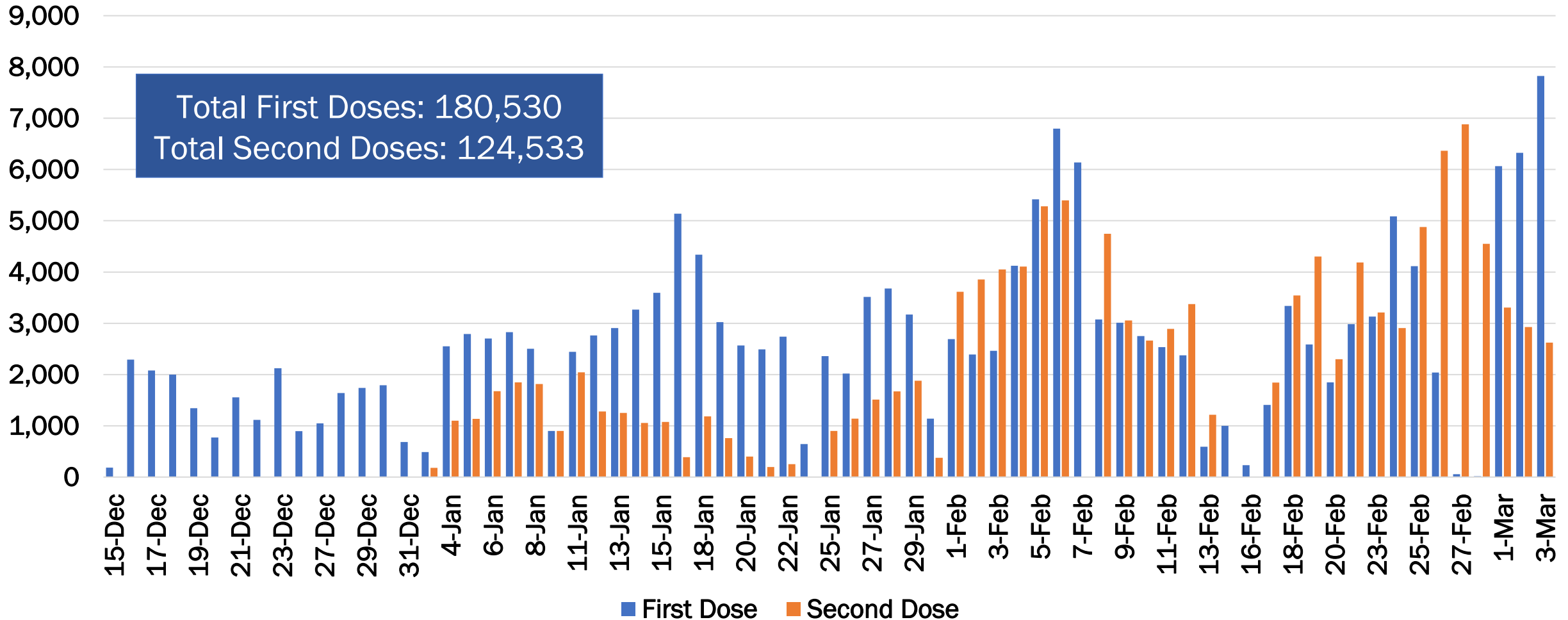
Average daily rate estimate

Doses per day: 2.5M

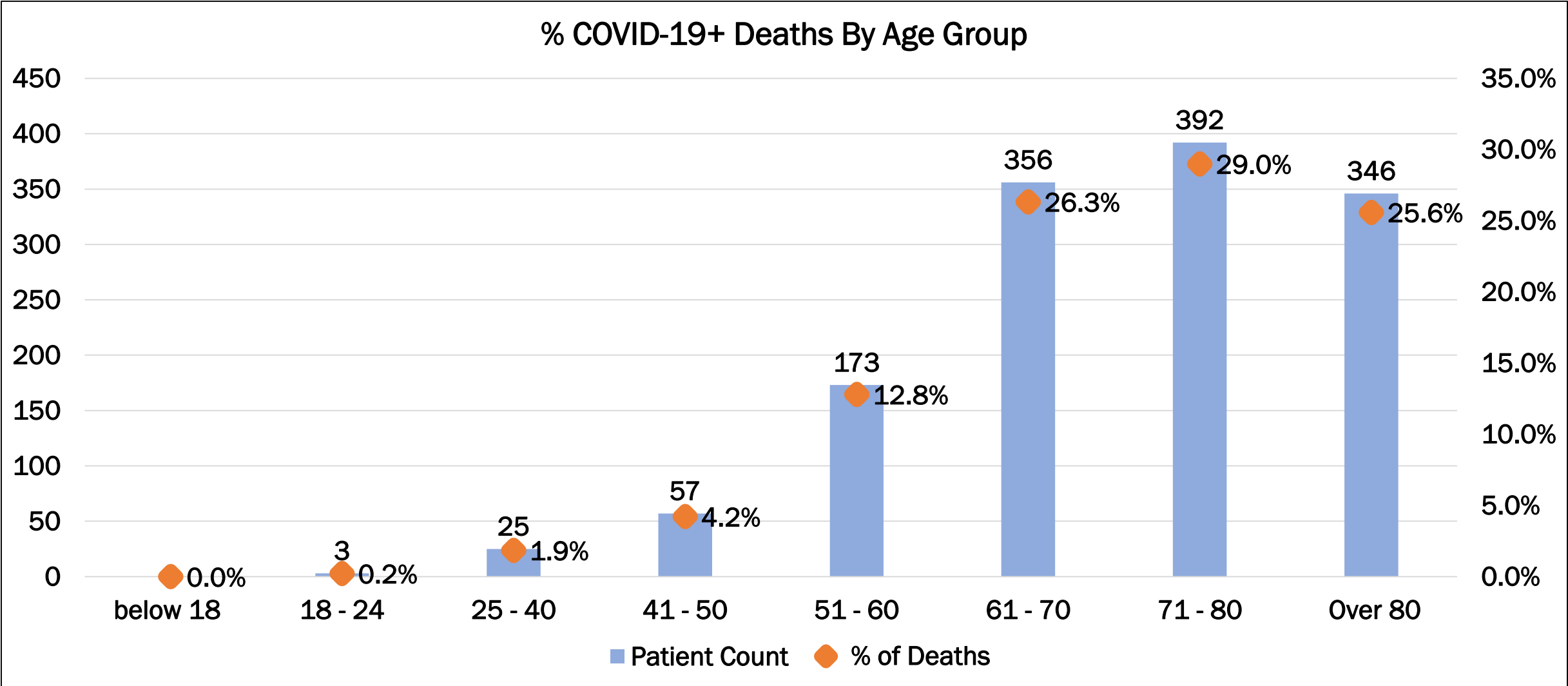


HM COVID-19 Vaccines Administered

Individuals Vaccinated at HM by Day



Houston Methodist COVID-19 Mortality by Age Group



Vaccine Distribution Plan at Houston Methodist

1A

- HM Employees
- Healthcare Workers
- First Responders (based on State criteria)

1B (Part One)

- Individuals 75+ being scheduled

Individuals invited to schedule now.

1B (Part Two)

- Individuals 65+ being scheduled

Individuals invited to schedule now.

1B (Part Three)

- Individuals 16+ with a medical condition

Individuals 50-64, with an underlying health condition, are currently being invited.

Additional invitations continue to be sent.

Healthy adults will be invited to schedule vaccine appointments once there is sufficient supply of vaccine and it is authorized by the State.

State Vaccine Criteria Update



**Texas Department of State
Health Services**

First and foremost, thank you for all you have done to administer COVID-19 vaccine across the State of Texas. Your efforts are greatly appreciated. As of today, you have administered nearly 6 million doses to your fellow Texans, and more than 2 million are now fully vaccinated.

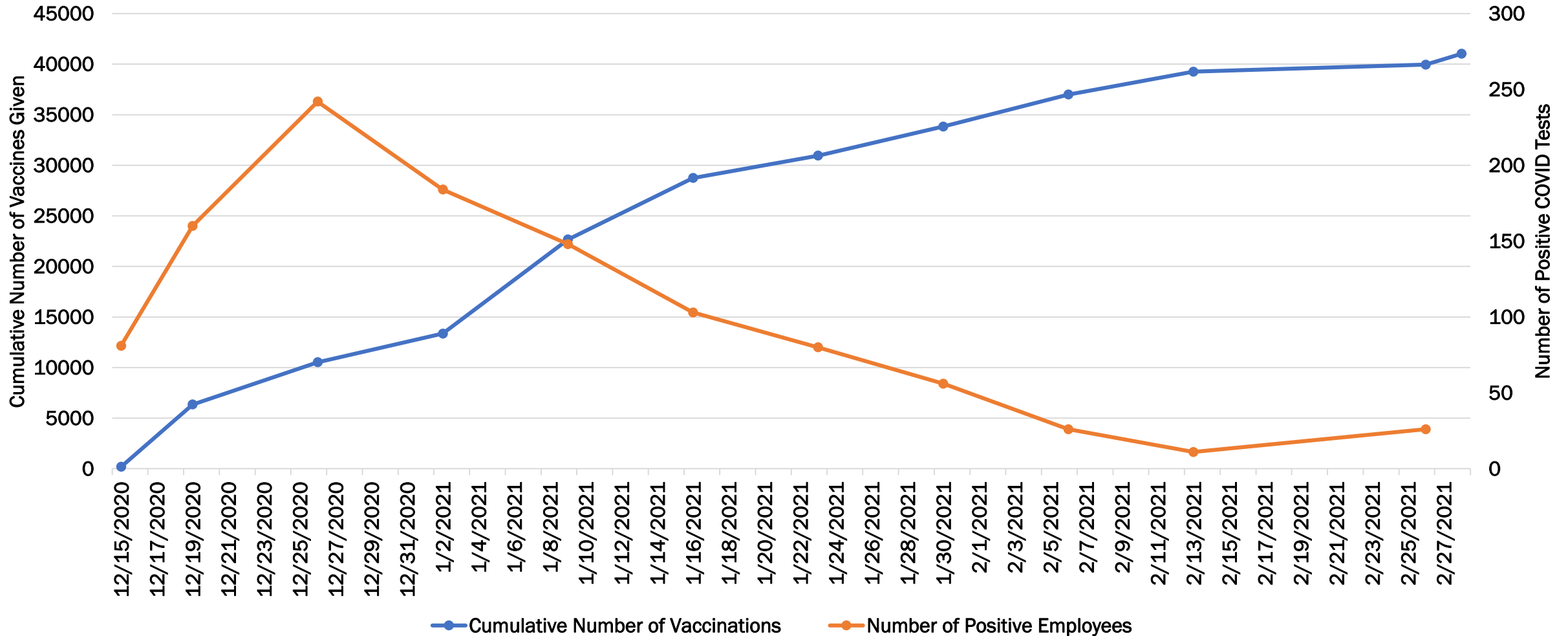
Yesterday, the U.S. Department of Health and Human Services directed states to expand vaccine eligibility to include people who work in school and child care operations. As stated in the attached federal directive, this includes:

“those who work in pre-primary, primary, and secondary schools, as well as Head Start and Early Head Start programs (including teachers, staff, and bus drivers) and those who work as or for licensed child care providers, including center-based and family care providers.”

In light of this federal directive, all vaccine providers in Texas should immediately include these personnel in vaccination administration and outreach to ensure they are able to be immunized. This action does not change the other groups prioritized for vaccination in Texas, and I encourage you to continue your efforts to vaccinate older adults since the burden of COVID-19 falls so severely on people ages 65 and older.

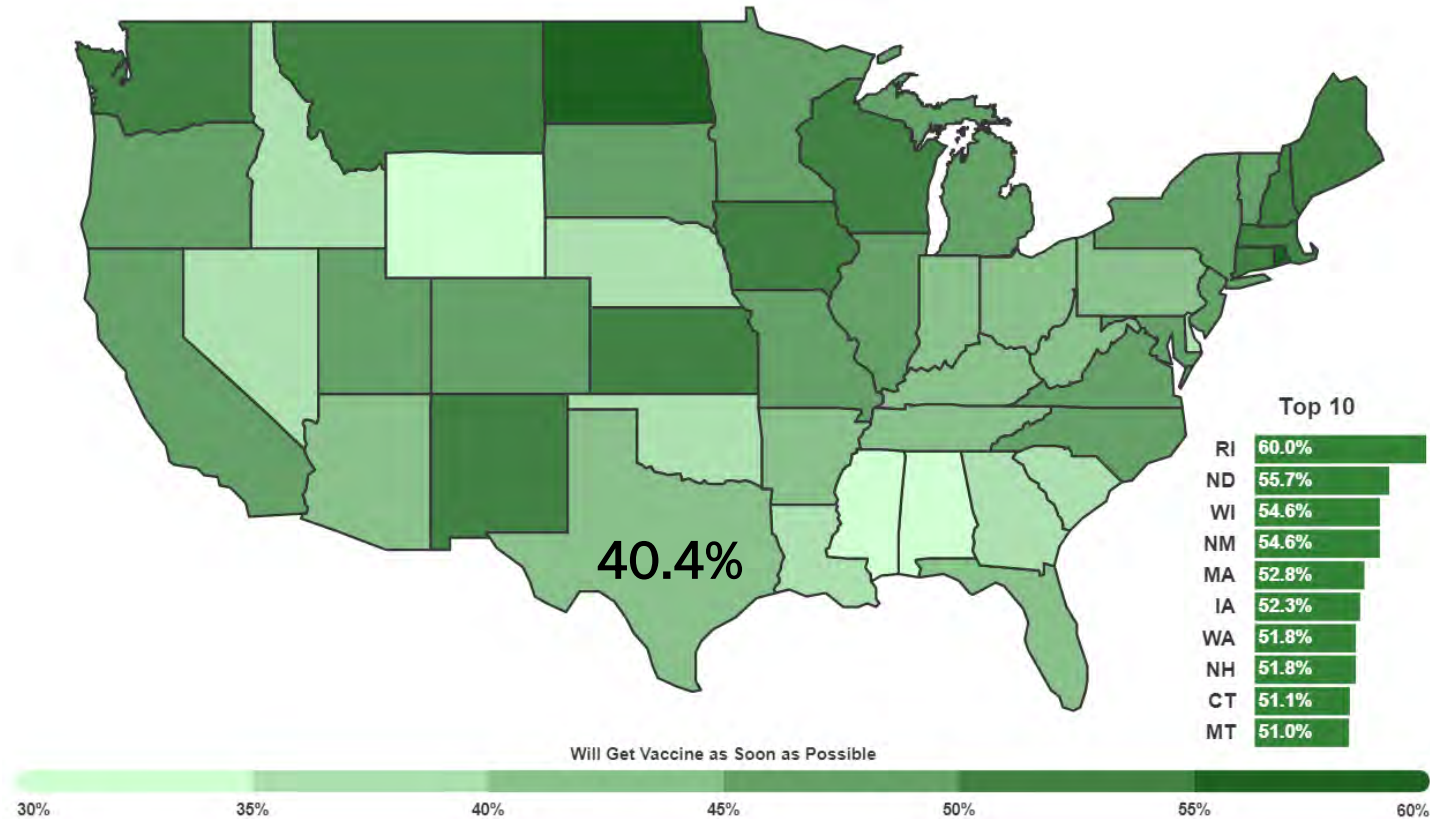
HM Employee Vaccination Rate vs. COVID-19 Infections

Vaccine and Positive COVID-19 Test Comparison 2.26.21



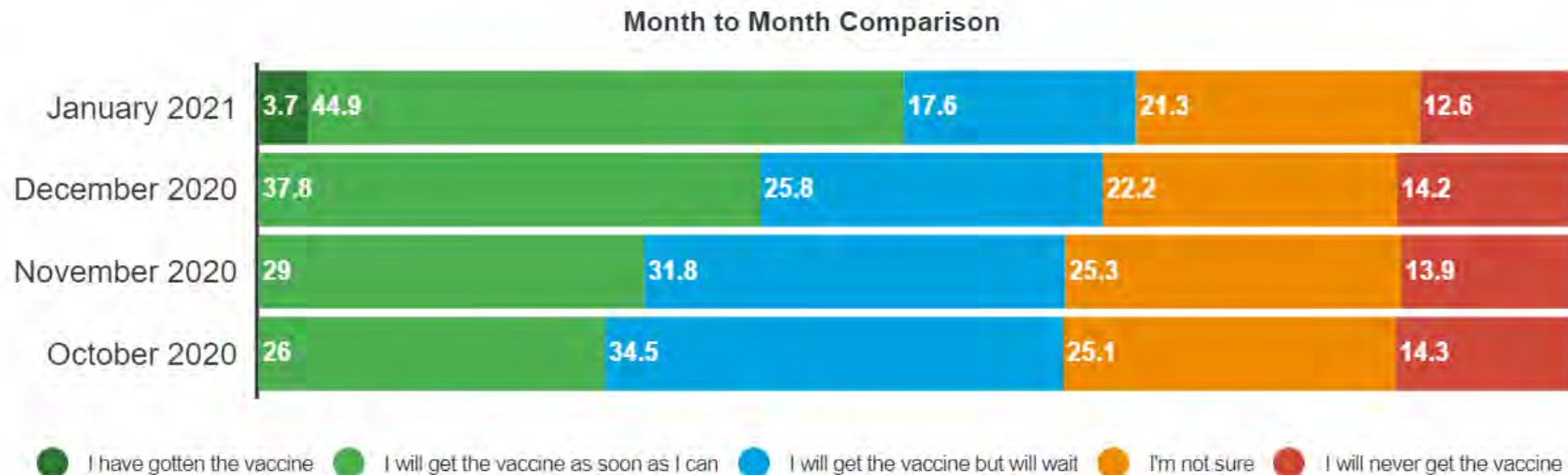
COVID-19 Vaccine Demand by State

How likely are you to get the COVID-19 vaccine when it becomes available to you?



COVID-19 Vaccine Demand Over Time

How likely are you to get the COVID-19 vaccine when it becomes available to you?



● I have gotten the vaccine
 ● I will get the vaccine as soon as I can
 ● I will get the vaccine but will wait
 ● I'm not sure
 ● I will never get the vaccine

COVID-19 Vaccine Demand by Demographics for Texas



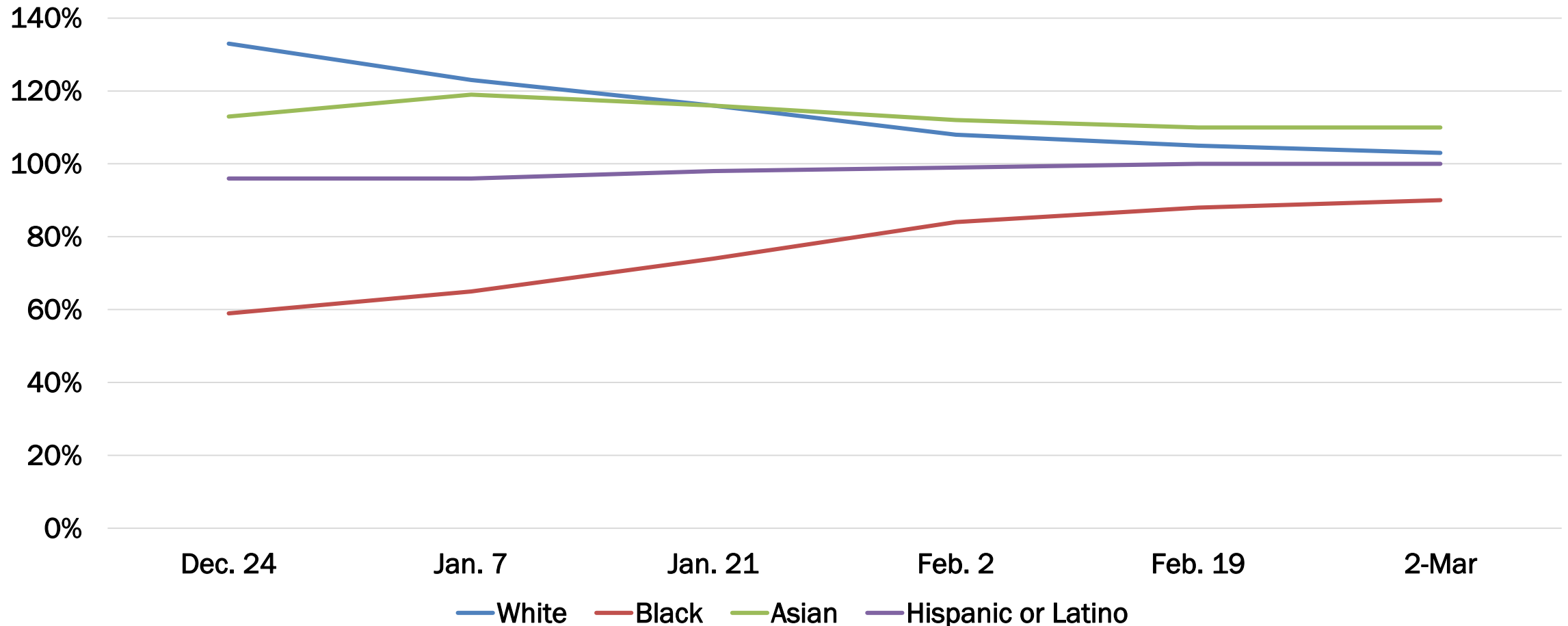
● I have gotten the vaccine
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 ● I will get the vaccine but will wait
 ● I'm not sure
 ● I will never get the vaccine



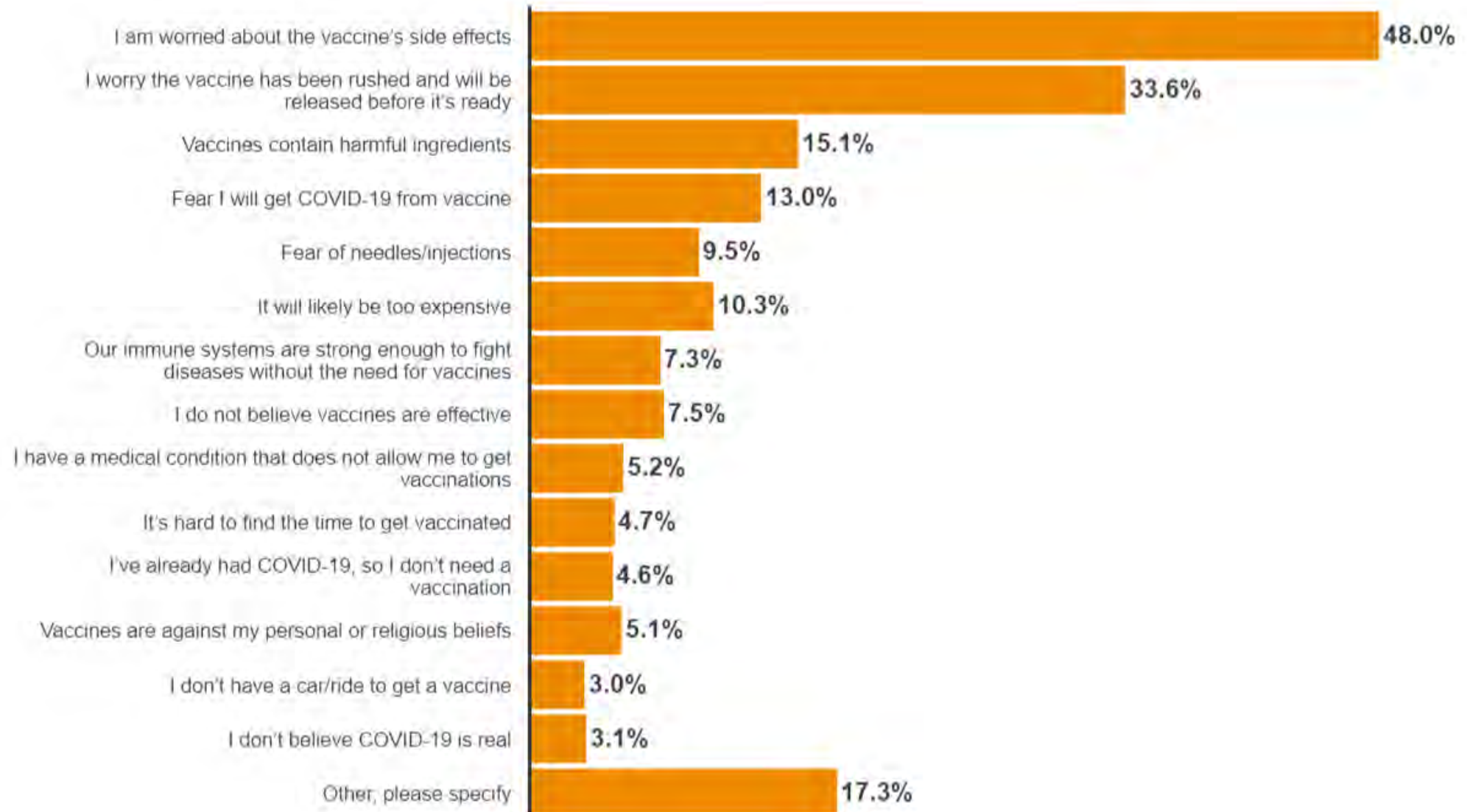
● I have gotten the vaccine
 ● I will get the vaccine as soon as I can
 ● I will get the vaccine but will wait
 ● I'm not sure
 ● I will never get the vaccine

Houston Methodist Employee Vaccination by Race/Ethnicity

Ratio of Percent of Employees by Race/Ethnicity to Receive First Dose vs. Percent of Overall Employees by Ethnicity

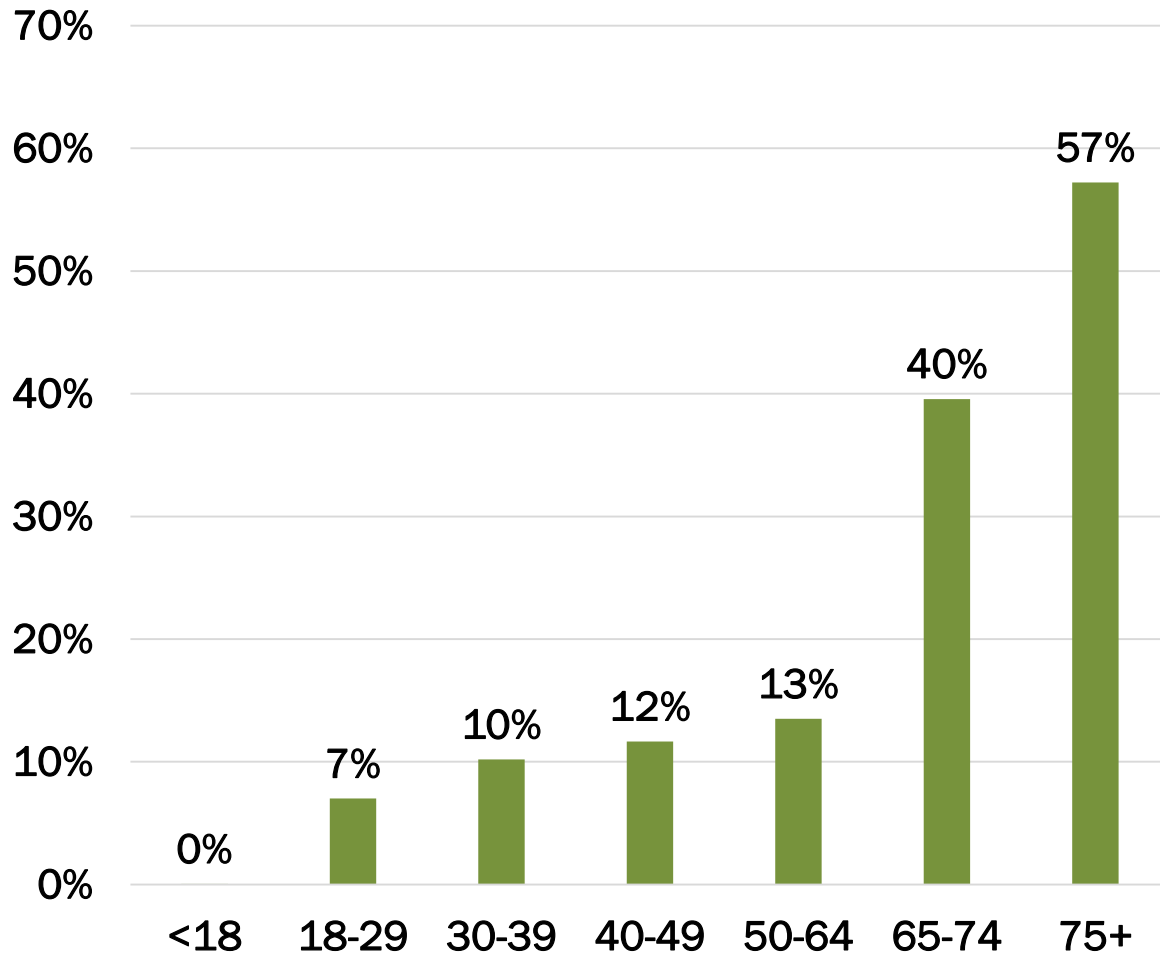


COVID-19 Vaccine Concerns

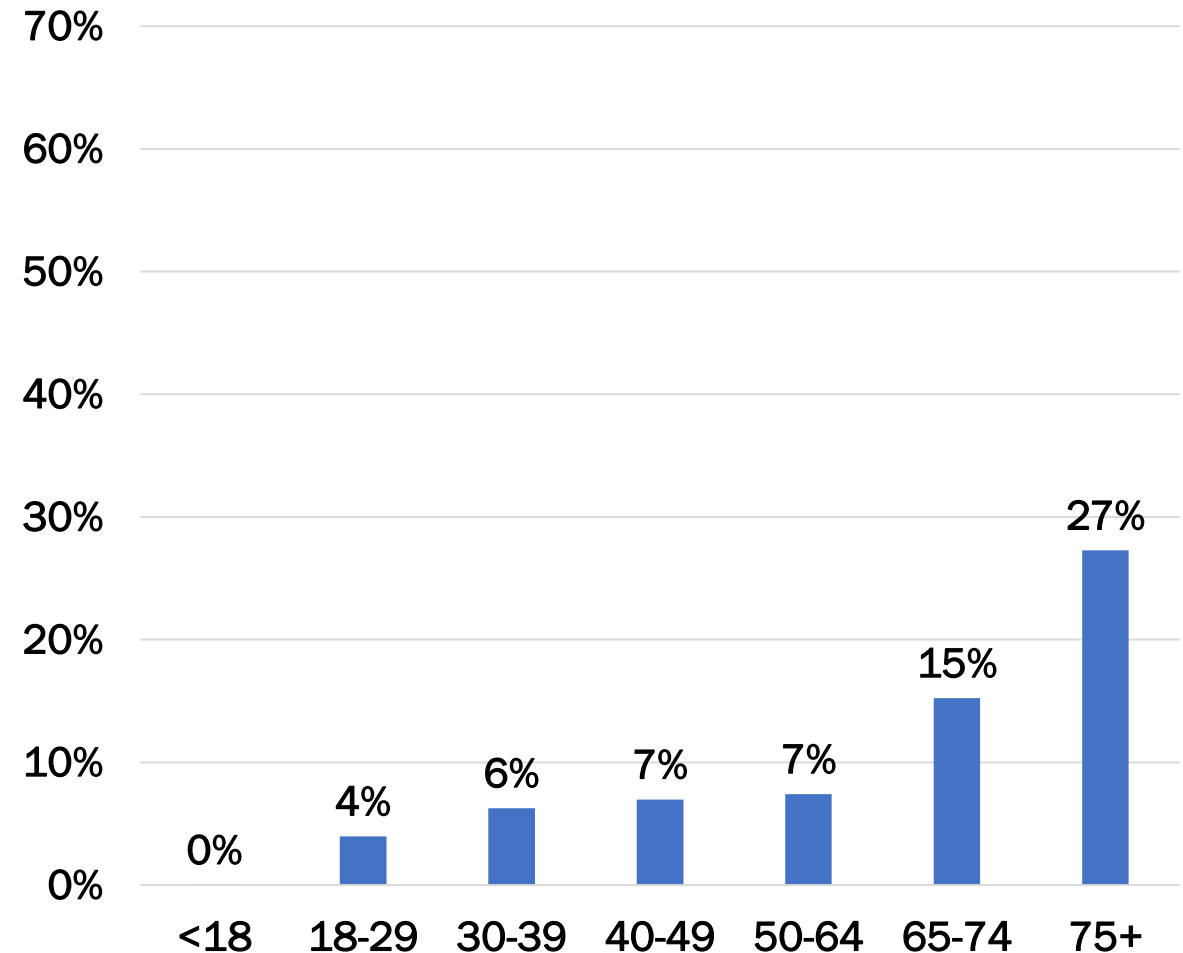


National Vaccination Rate by Age

Percent of Population Receiving 1 or More COVID-19 Vaccine By Age Group



Percent of Population Fully Vaccinated for COVID-19 By Age Group



Herd Immunity Threshold

Percent of Individuals Required to Be Immune at Various Herd Immunity Thresholds

R(0) or R(t)	HIT	95% Efficacy of Vaccine	70% Efficacy of Vaccine
1.5	33%	35%	47%
2	50%	53%	71%
2.5	60%	63%	86%
3	67%	70%	95%
3.5	71%	75%	102%
4	75%	79%	107%
4.5	78%	82%	111%
5	80%	84%	114%

Definitions:

- R(0) is baseline “spreadability” of virus
- R(t) is observed “spreadability” of virus as impacted by safeguards in the community at a given time
- HIT is the percentage immunity at which point epidemic conditions end; isolated outbreaks still occur, but widespread epidemic or even pandemic conditions end

Herd Immunity Threshold Summary

- Population of the U.S.: ~332M
- Eligible Adults (16+): ~261M
- 75% of Eligible Adults (16+): ~196M
- Until individuals under 16 are eligible to be vaccinated, we either need ~26% underlying immunity (previous infection) or need to convince more people to be vaccinated to get to 70% HIT
- For 80% HIT, need ~50% underlying immunity

70% HIT: 232M

80% HIT: 266M

Full herd immunity will not occur for months (either from more infections or when children can be vaccinated).
However, COVID-19 should be dramatically lower.

COVID-19 Vaccine Doses Distribution

COVID-19 Vaccine Distributed By End of Each Month

	Dec. - March	April	May	June	July
Pfizer	120M	40M	40M	50M	50M
Moderna	100M	50M	50M	50M	50M
Johnson & Johnson	20M	26.7M	26.7M	26.7M	–
Total Doses	240M	116.7M	116.7M	126.7M	100M
Total Individuals	130M	71.7M	71.7M	71.7M	50M
Cumulative Individuals	130M	201.7M	273.4M	350M	400M

COVID-19 Vaccine Herd Immunity Modeling

Realistic Timing After Distribution to Full Immunity for Vaccinated Individuals

	Feb.	March	April	May	June	July	Aug.	Sept.
Cumulative Total	~26M	51.8M	73.8M	161.3M	233M	305M	371.6M	400M
Percent of Overall Population	7.9%	15.6%	22.2%	48.5%	70.1%	92.5	111.8%	120.4%
Percent of Eligible Adults (16+)	10.0%	19.8%	28.2%	61.7%	89.1%	116.9%	142.2%	153%

COVID-19 Vaccine Herd Immunity Modeling

Realistic Timing After Distribution to Full Immunity for Vaccinated Individuals

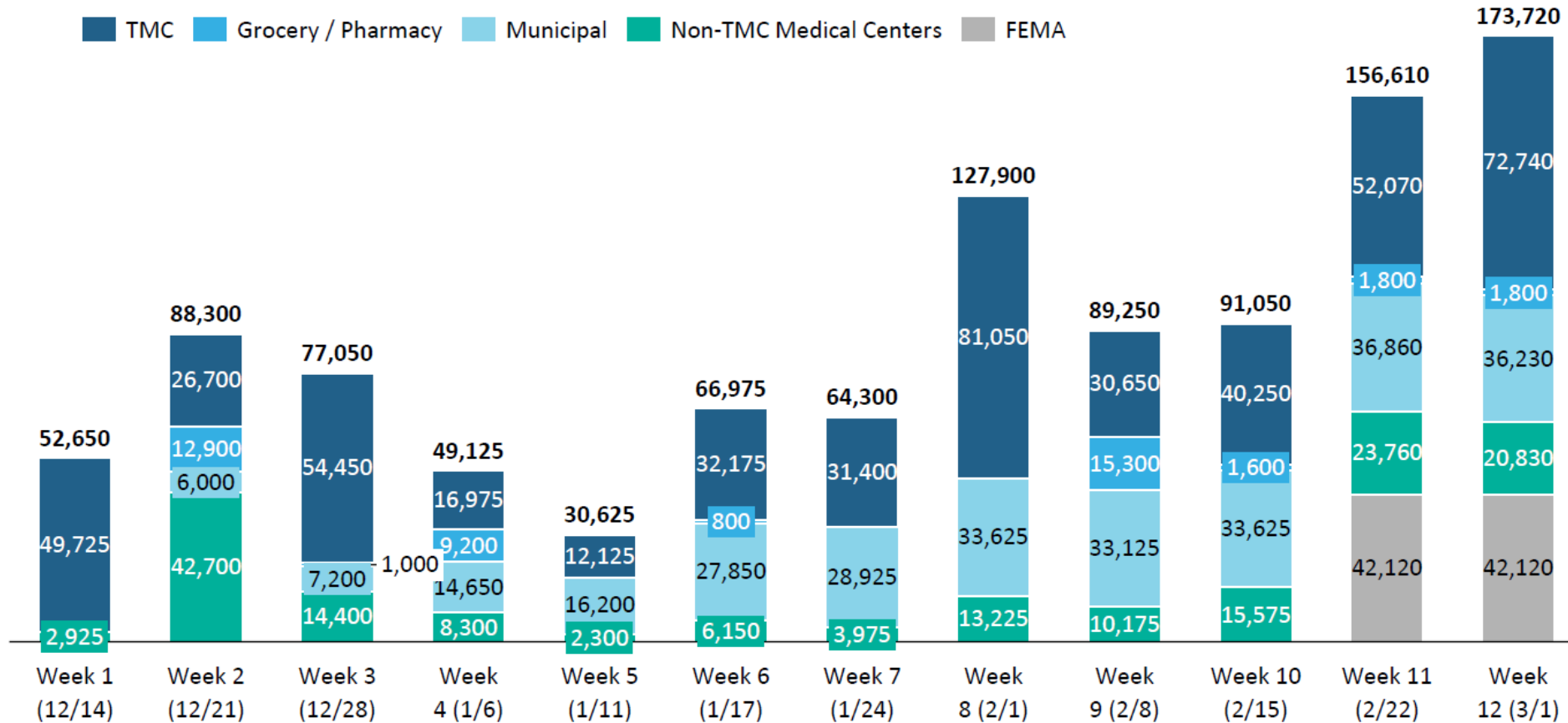
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Percent of Eligible Adults (16+)	10.0%	19.8%	28.2%	61.7%	89.1%	116.9%	142.2%	153%

Greater Houston First Dose Supply

COVID-19 VACCINE ALLOCATIONS FOR GREATER HOUSTON

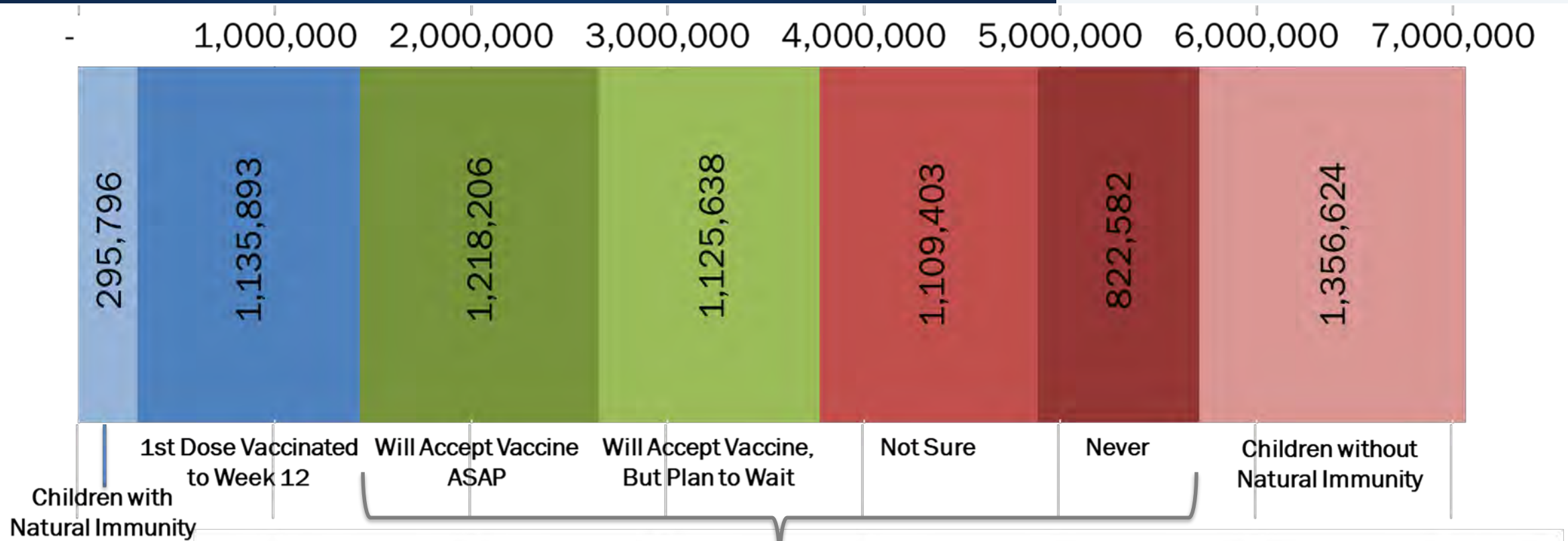
Weekly vaccine allocation for Greater Houston Area¹ (# doses)

TMC Grocery / Pharmacy Municipal Non-TMC Medical Centers FEMA



*Starting in week 11, the labels on Pfizer vaccine vials were updated to increase the number of doses per vial from 5 to 6 doses.

HIT Model: Current Status



2,203,337 Individuals with Some Immunity

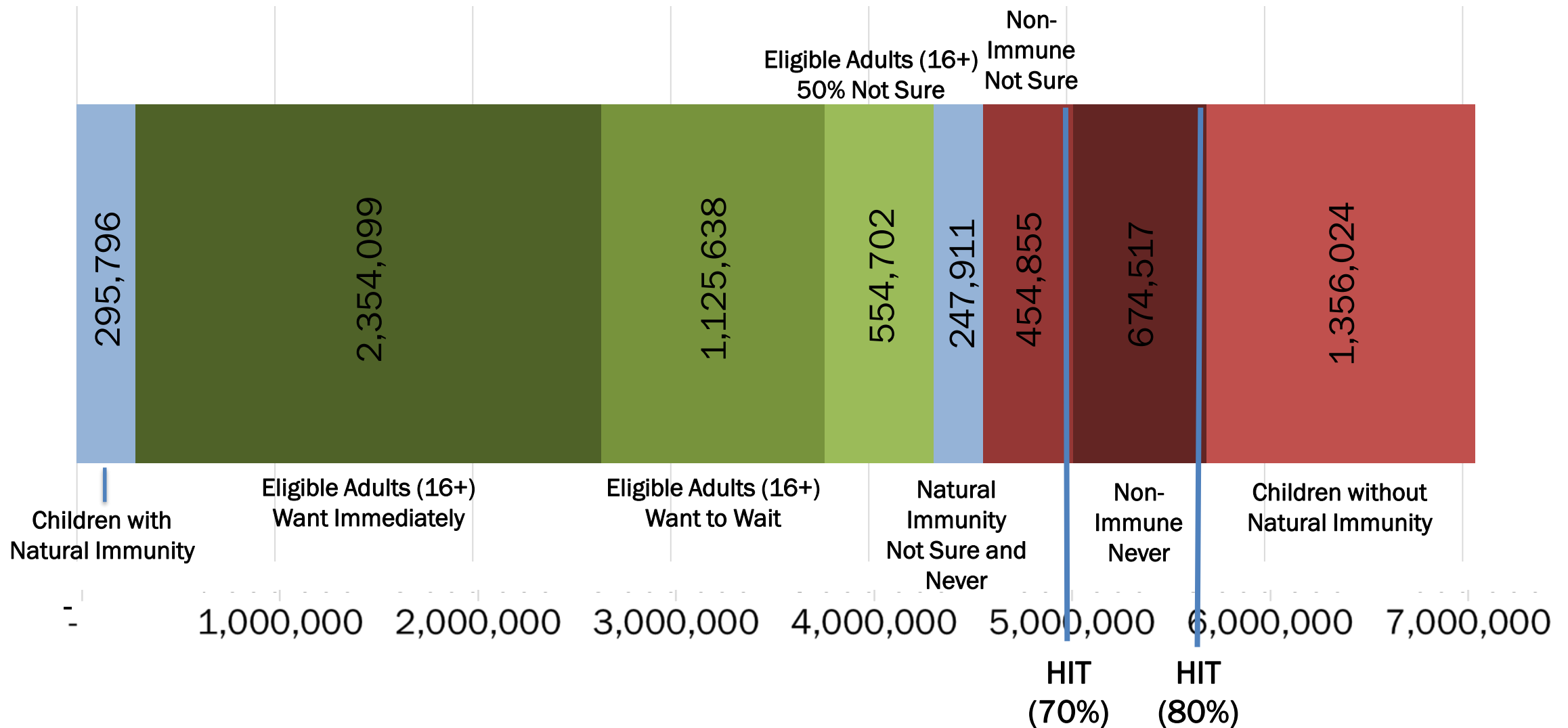
Up To 31% Immunity Present

**Unvaccinated Adults
3,509,179**

**769,649 with
Natural Immunity***

* Assumes 20% have natural immunity that is 90% effective

HIT Model: Vaccine Preference



* Assumes 20% have natural immunity that is 90% effective

Advice Around COVID-19 Vaccine

- The vaccines are safe and effective; get it immediately when it is your turn.
- Please be patient.
- The state creates the prioritization; please wait your turn.
- Recognize that side effects, while mild, are common; they are much better than getting COVID.
- Take the first vaccine you are offered anywhere, anytime.
- Even after vaccination, please continue wearing a mask and physical distancing.

It's a two-way street Masks protect you & me

When we all wear masks, we take care of each other



MY KEY TAKE HOME MESSAGE TODAY:

GIVE US 90-120 DAYS!!

HOUSTON
MethodistSM
LEADING MEDICINE

THANK YOU FOR ATTENDING OUR TOWN HALL CONVERSATION

If you would like more information about CURATOR, the COVID-19 Recovery Clinic, or The Society for Leading Medicine, please contact foundation@houstonmethodist.org

Take care and be well

