

Welcome to the Front Lines
of the Fight Against COVID-19

A TOWN HALL CONVERSATION

We will begin at 10 a.m.

HOUSTON
Methodist[®]
LEADING MEDICINE



Houston Methodist J.C. Walter Jr. Transplant Center
Sherrie and Alan Conover Center for Liver Disease and
Transplantation

Review of Questions

- **How are our transplant patients doing? Organ dependent?**
- **Are transplant patients impacted more or less than non-transplant? Outcomes? Is the hospital seeing more transplant patients?**
- Can COVID survivors (recovered) be organ donors?
- Will “at risk” populations such as transplant patients have early access to the COVID vaccine once approved?

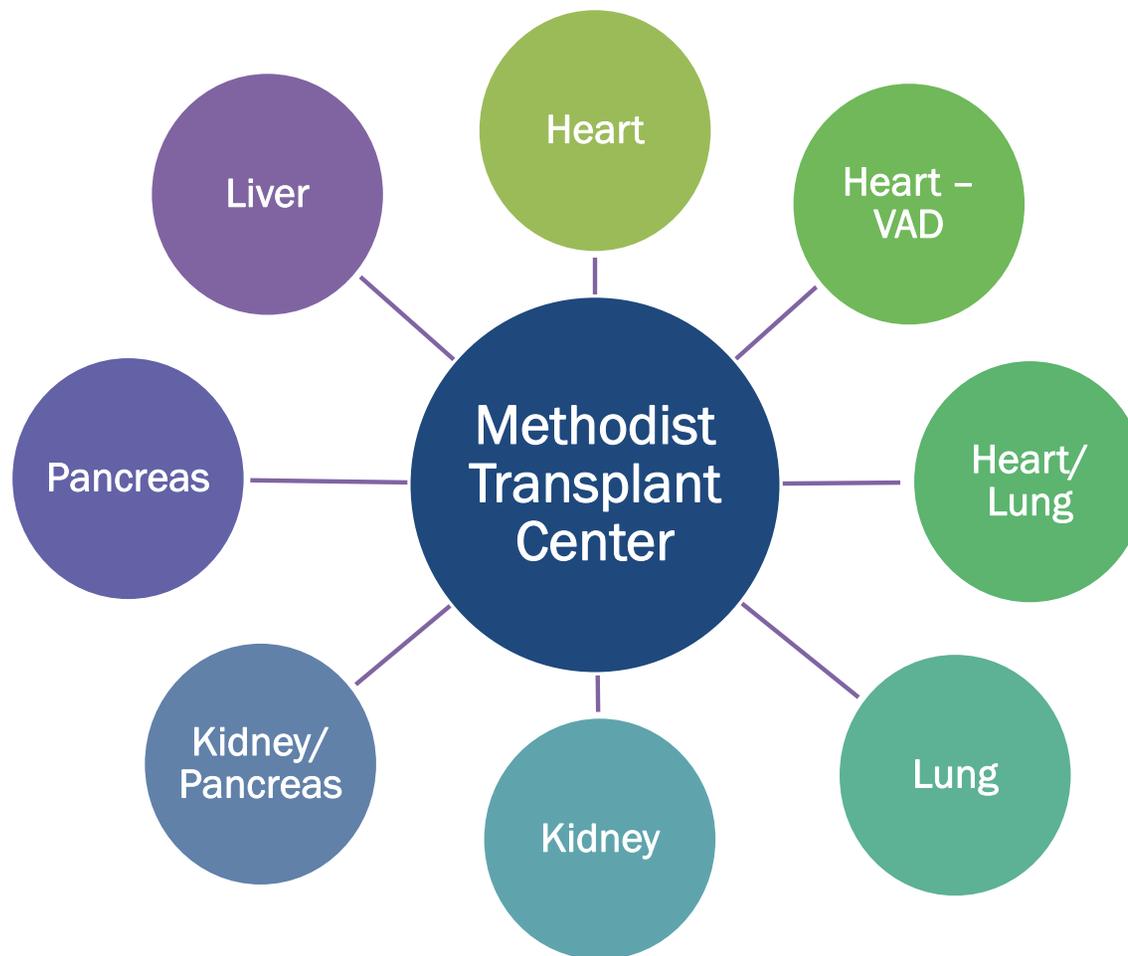
J.C. Walter Jr. Transplant Center

HOUSTON
Methodist[™]
J.C. WALTER JR.
TRANSPLANT CENTER



MTC Overview

Organ Programs

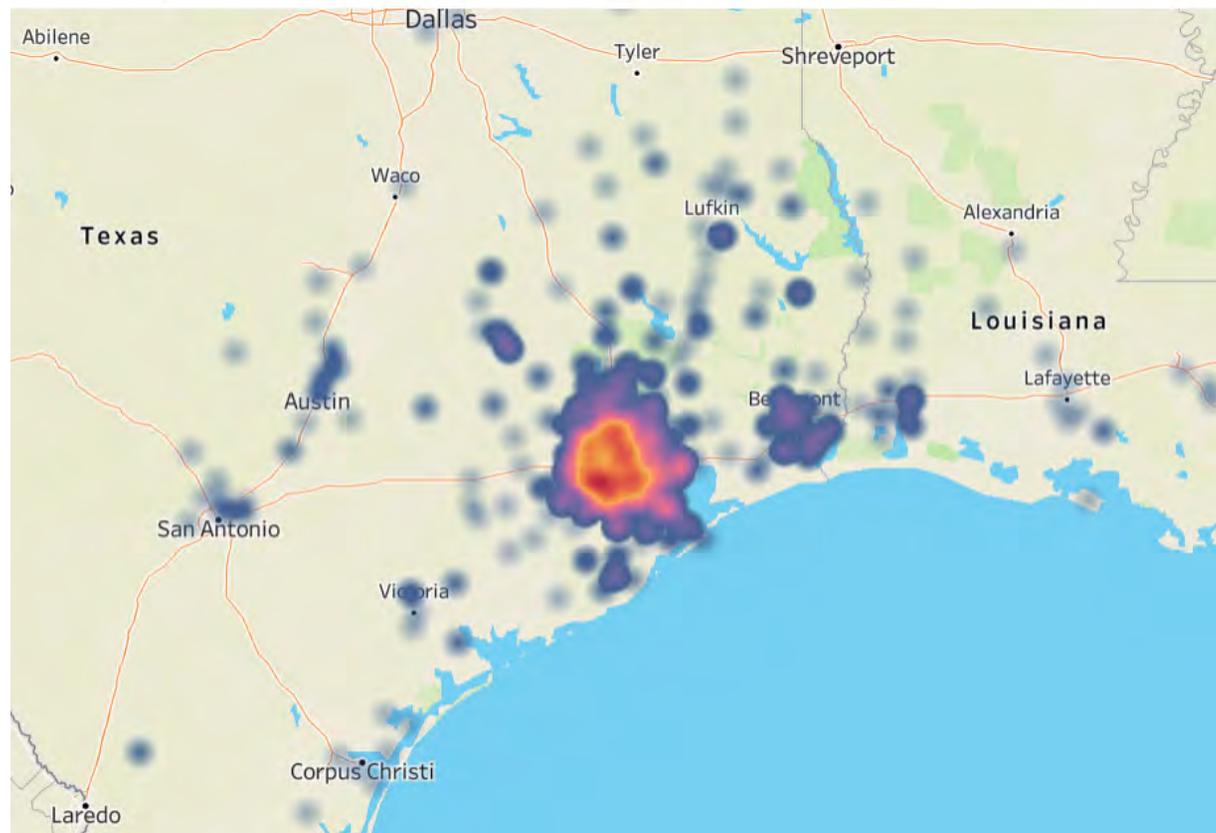


Transplant Waitlist Heatmap

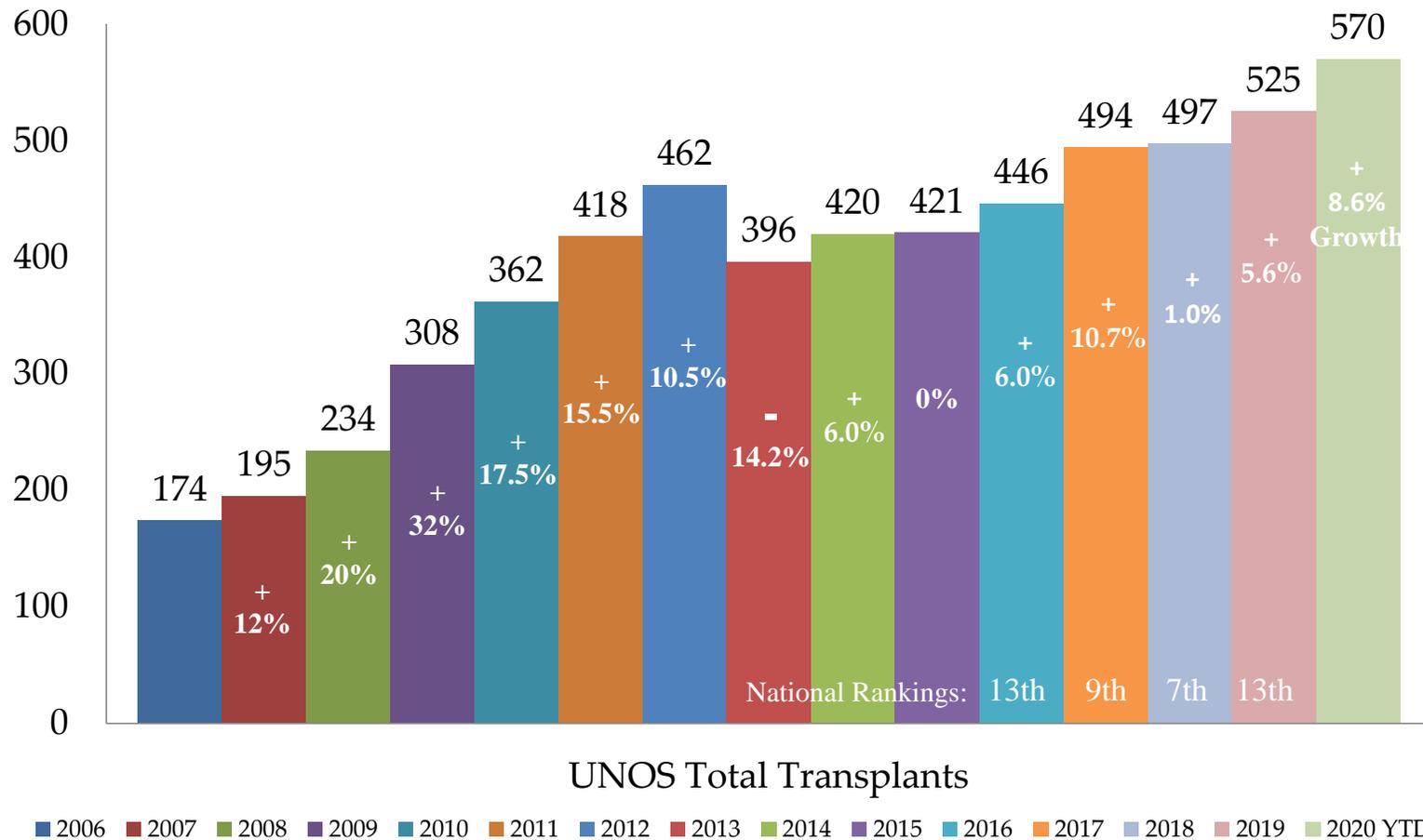
All Organs – 1/1/2016 to 8/2020

Organ (All)

Pre-Transplant



Total Transplant Volume



National Rankings

In 2019, only 4 centers landed in top 25 volumes for the 4 key organ programs.

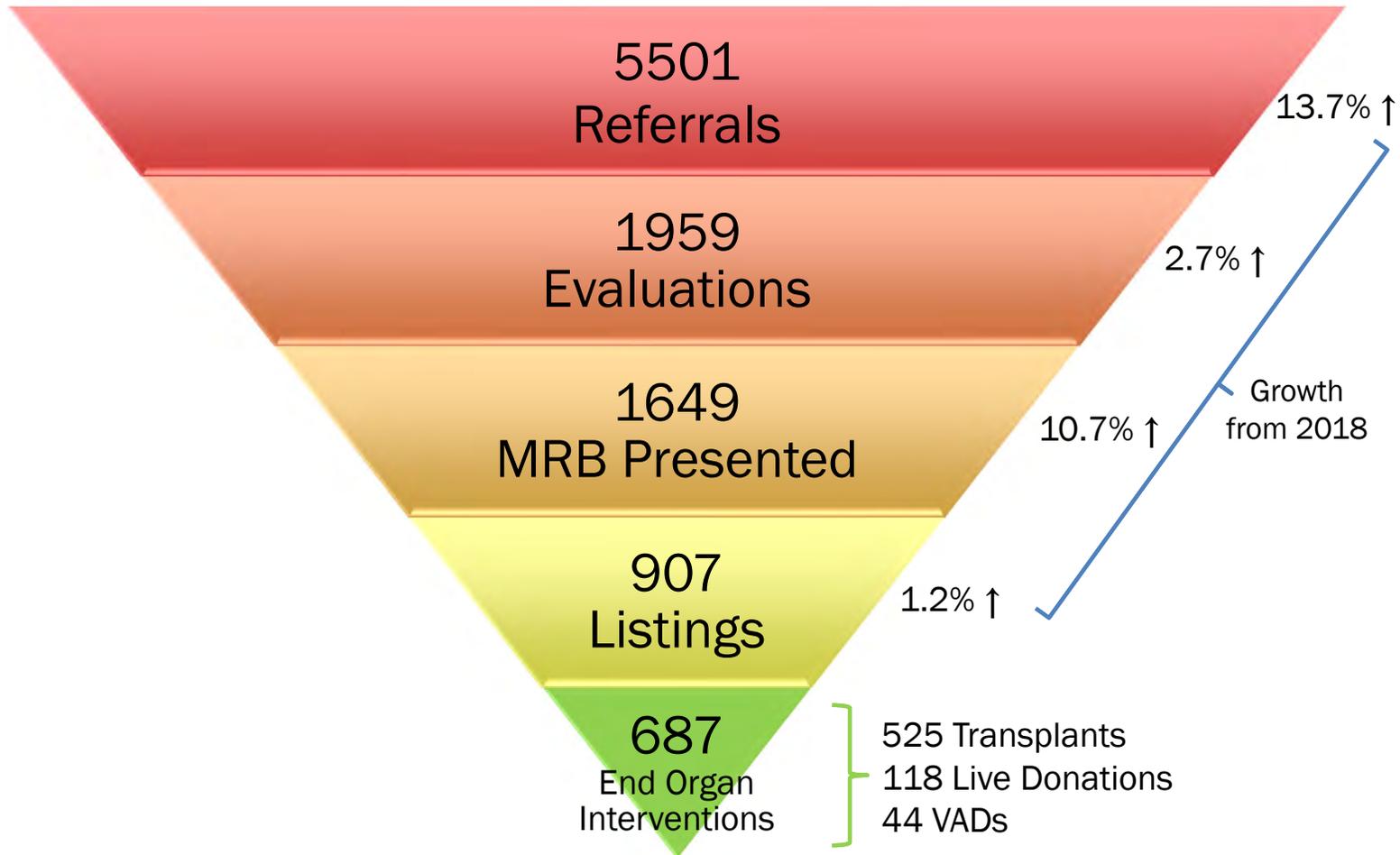
Hospital System	Kidney	Liver	Heart	Lung	Other	Total
UCLA	408	168	58	91	5	730
University of Pennsylvania	241	135	57	80	22	535
Houston Methodist Hospital	252	151	41	61	20	525
University of Colorado	284	134	43	44	10	515

Ranked #1 for Transplant volumes in 2019

	Kidney	Liver	Heart	Lung	Other	Total
Jackson Memorial	502	155	24	22	44	747

- Did not land in top 25 for lung or heart
- Kidney made up 67% of volumes (HM, 48%)

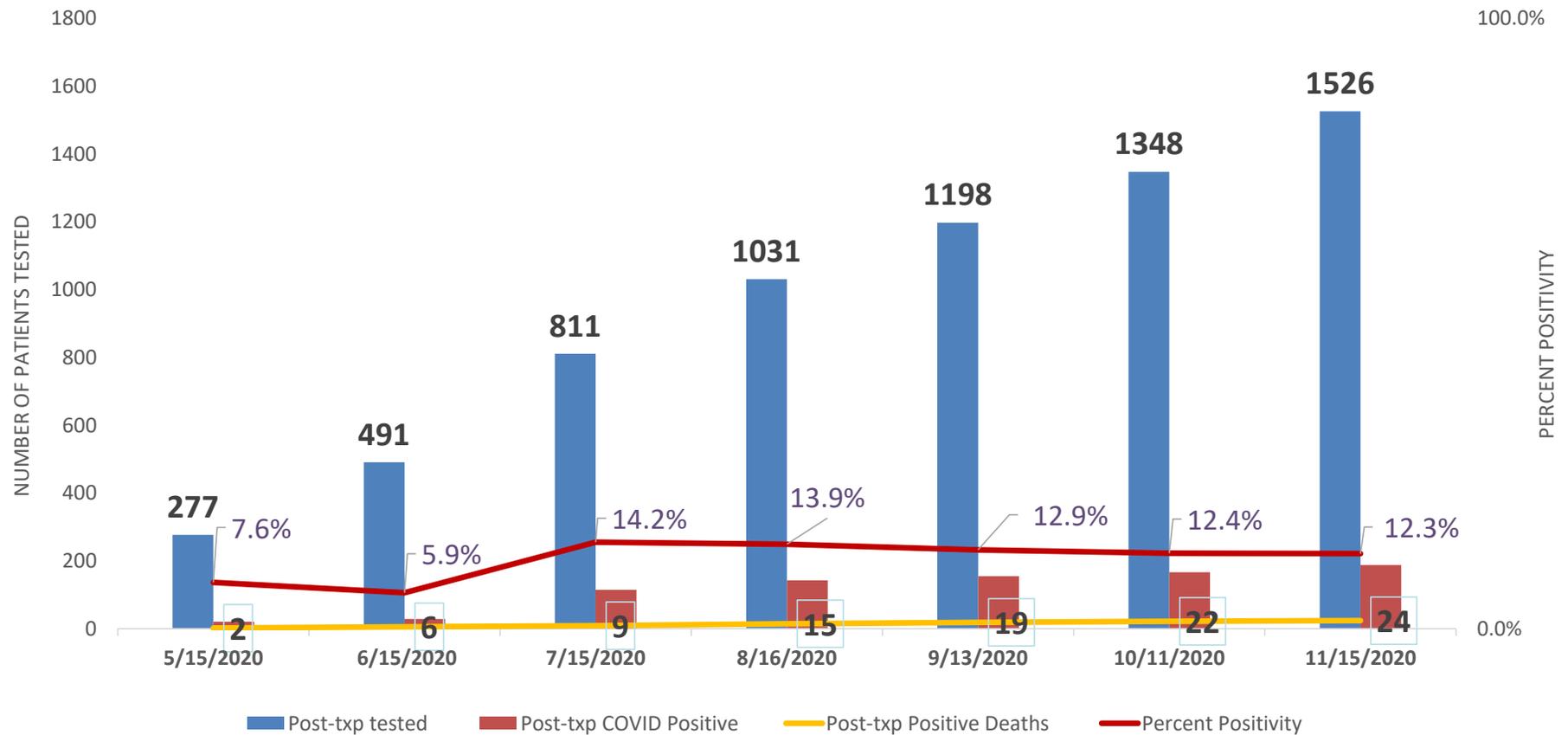
2019 Transplant Activity Funnel



COVID and Transplantation

- COVID transplant task force
- Follow CMS guidelines
- Increased transplantation rate after a brief slow period
- Implementation of strict guidelines for the transplant population
- COVID clinic

Post Transplant COVID – Cumulative



Post Transplant COVID – Cumulative

Trending	Post Transplant Percent Positivity	< 1 Yr Post Txp (death)	1-3 Yr Post Txp (death)	>3 Ys Post Txp (death)	Post Txp COVID Positive Deaths	Case Fatality Rate (CFR)
7/19/2020	120/843 (14.2%)	20 (2)	32 (3)	68 (5)	10	8.3%
7/26/2020	130/894 (14.5%)	20 (2)	34 (3)	76 (7)	12	9.2%
8/02/2020	136/932 (14.6%)	23 (2)	35 (4)	78 (7)	13	9.6%
8/09/2020	137/982 (14.0%)	23 (3)	37 (4)	78 (8)	15	11.0%
8/16/2020	143/1031 (13.9%)	25 (3)	37 (4)	81 (8)	15	10.5%
8/23/2020	147/1087 (13.4%)	25 (3)	38 (4)	84 (9)	16	10.9%
8/30/2020	150/1126 (13.3%)	25 (4)	38 (4)	87 (9)	17	11.3%
9/7/2020	153/1167 (13.1%)	26 (5)	38 (4)	89 (10)	19	12.4%
9/13/2020	155/1198 (12.9%)	27 (5)	38 (4)	90 (10)	19	12.2%
9/20/2020	158/1231 (12.8%)	27 (6)	38 (4)	93 (10)	20	12.7%
9/27/2020	159/1259 (12.6%)	28 (6)	38 (4)	93 (11)	21	13.2%
10/04/2020	161/1301 (12.4%)	28 (6)	39 (4)	94 (11)	21	13.0%
10/11/2020	167/1348 (12.4%)	31 (7)	41 (4)	95 (11)	22	13.2%
10/18/2020	169/1388 (12.2%)	31 (7)	41 (4)	97 (11)	22	13.0%
10/25/2020	173/1430 (12.1%)	31 (8)	42 (4)	100 (11)	23	13.3%
11/01/2020	176/1462 (12.0%)	32 (8)	43 (4)	101 (11)	23	13.0%
11/08/2020	180/1496 (12.0%)	32 (8)	44 (4)	104 (11)	23	12.8%
11/15/2020	188/1526 (12.3%)*	34 (8)	44 (4)	110 (12)	24/188	12.8%**

Post Transplant COVID – Cumulative

COVID-19 Positive Tests by Organ:

Kidney (94), Liver (27), Lung (19), Heart (18),
Kidney/Pancreas (9), Liver/Kidney (8), Heart/Kidney (4),
Heart/Liver (1), Heart/Lung (1), Pancreas (1), PAK (2),
Multi-Organ Other (4)

COVID-19 Positive Deaths by Organ:

Kidney (12), Liver (4), Lung (5), Heart (1),
Kidney/Pancreas (1), Heart/Kidney (1)

Post Transplant COVID – Cumulative

	Cases	Deaths	Percent
U.S.	11,439,011	248,462	2.2%
Transplant	188	24	12.3%

Review of Questions

- **Can COVID survivors (recovered) be organ donors?**
Not sure, long-term effects not clear
- **Will “at risk” populations such as transplant patients have early access to the COVID vaccine once approved?**
Hope so

Houston Methodist

Jenny Chang, MD



Articles

Clinical characteristics and risk factors associated with COVID-19 disease severity in patients with cancer in Wuhan, China: a multicentre, retrospective, cohort study

Jianbo Tian*, Xianglin Yuan*, Jun Xiao*, Qiang Zhong*, Chuanguang Yang*, Bo Liu*, Yimin Cai*, Zequn Lu*, Jing Wang, Yanan Wang, Shuanglin Liu, Biao Cheng, Jin Wang, Ming Zhang, Lu Wang, Siyuan Niu, Zhi Yao, Xiongbo Deng, Fan Zhou, Weiwei, Qinglin Li, Xin Chi, Wengiang Chen, Qin Yang, Shiji Wu, Jiquan Fan, Bo Shu, Zhiquan Hu, Shaogang Wang, Xiang-Ping Yang, Wenhua Liu, Xiaoping Miao†, Zhihua Wang†



Articles

Clinical impact of COVID-19 on patients with cancer (CCC19): a cohort study

Nicole M Kuderer*, Tariq K Chauhan*, Dimple P Shah*, Yu Shyr*, Samuel M Rubinstein, Donna R Rivera, Sanjay Shete, Chih-Yuan Hsu, Aakash Desai, Gilberto de Lima Lopes Jr, Petros Grivas, Corrie A Painter, Solange Peters, Michael A Thompson, Ziad Bakouny, Gerald Battist, Tarios Bekari-Saali, Mehmet A Bilen, Nathaniel Bouganim, Mateo Bover-Lamy, Daniel Castellana, Salvatore A Del Prete, Deborah B Doroshow, Pamela C Egan, Ariddle Elkrief, Dimitrios Farmakiotis, Daniel Flora, Matthew D Galsky, Michael J Glover, Elizabeth A Griffiths, Anthony P Gulati, Shilpa Gupta, Navid Hafez, Thorvardur R Halfdanarson, Jessica E Hawley, Emily Hsu, Anup Kasi, Ali R Khaki, Christopher A Lemmon, Colleen Lewis, Barbara Logan, Tyler Masters, Rana R McKay, Ruben A Mesa, Alicia K Morgans, Mary F Mulcahy, Orestis A Panagiotou, Prakash Peddi, Nathan A Pennell, Kerry Reynolds, Lane R Rosen, Rachel Rosovsky, Mary Salazar, Andrew Schmidt, Sumit A Shah, Justin A Shaya, John Steinhilber, Keith E Stoker-Goldstein, Suki Subbiah, Donald C Vinh, Firas H Wehbe, Lisa B Weissmann, Julie Tsu-Yu Wu, Elizabeth Wolff-Burckhardt, Zhuoer Xie, Albert Yeh, Peter PYu, Alice Y Zhou, Leyre Zubiri, Sanjay Mishra, Gary H Lyman*, Brian I Rini*, Jeremy L Warner*, on behalf of the COVID-19 and Cancer Consortium

Clinical impact of COVID-19 on patients with cancer (CCC19): a cohort study



Nicole M Kudener*, Toni K Chauhan*, Dimple P Shah*, Yu Shyr*, Samuel M Rubinstein, Donna R Rivera, Sanjay Shete, Chih-Yuan Hsu, Akash Desai, Gilberto de Lima Lopes Jr, Petros Grivas, Corie A Painter, Solange Peters, Michael A Thompson, Ziad Bakouny, Gerald Bolint, Tarios Bekali-Saali, Mehmet A Bilir, Nathaniel Bouganim, Mateo Bover-Lanzetta, Daniel Castellano, Salvatore A Del Prete, Deborah B Doroshov, Pamela C Egan, Arielle E Nrief, Dimitrios Farmakiotis, Daniel Flora, Matthew D Galsky, Michael J Glover, Elizabeth A Griffiths, Anthony P Gulati, Shilpa Gupta, Navid Hafez, Thorvardur R Halfdanarson, Jessica E Hawley, Emily Hsu, Anup Kasi, Ali R Khaki, Christopher A Lemmon, Colleen Lewis, Barbara Logan, Tyler Masters, Rana R McKay, Ruben A Mesa, Alicia K Morgans, Mary F Mulcahy, Drestis A Panagiotou, Prakash Peddi, Nathan A Perndl, Kory Reynolds, Lane R Rosen, Rachel Rosovsky, Mary Salazar, Andrew Schmidt, Sumit A Shah, Justin A Shaya, John Steinhafer, Keith E Stockert-Goldstein, Suki Subbiah, Donald C Vinh, Finas H Wiehbe, Lisa B Weissmann, Julie Tsu-Yu Wu, Elizabeth Wolff-Burchfield, Zhaoer Xie, Albert Yeh, Peter P Yu, Alice Y Zhou, Leyre Zubiri, Sanjay Mishra, Gary H Lyman*, Brian I Rini*, Jeremy L Warner*, on behalf of the COVID-19 and Cancer Consortium

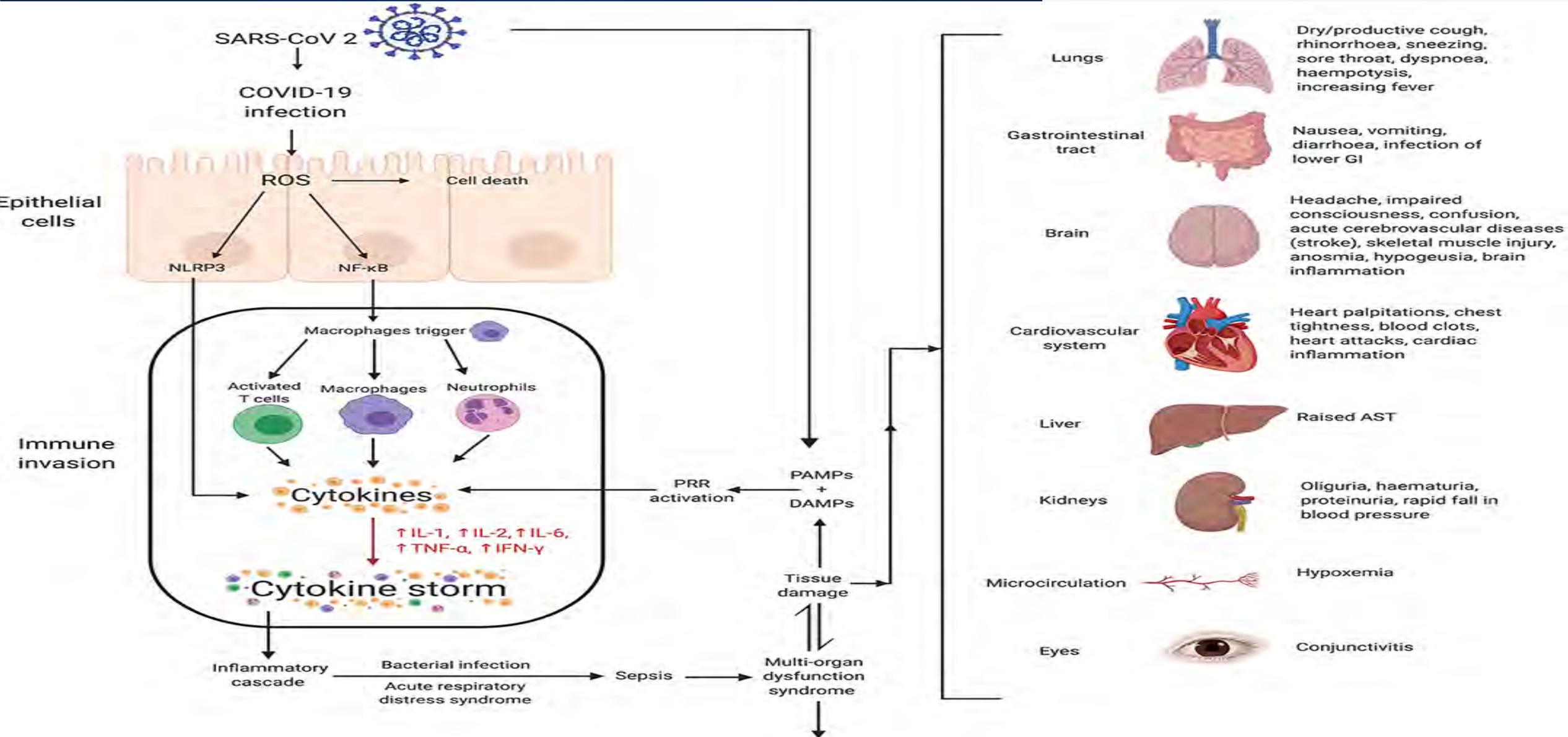
- To identify potential prognostic factors for mortality and severe illness in cancer patients with COVID-19
- COVID-19 and Cancer Consortium (CCC19) – USA, Canada, Spain
- 1035 patients included
- Most common cancers were breast (21%) and prostate (16%)

- **Age** (odds ratio 1.84, 95% CI 1.53-2.21)
- **Male sex** (odds ratio 1.63, 95% CI 1.07-2.48)
- **Smoking status** (odds ratio 1.60, 95% CI 1.03-2.47)

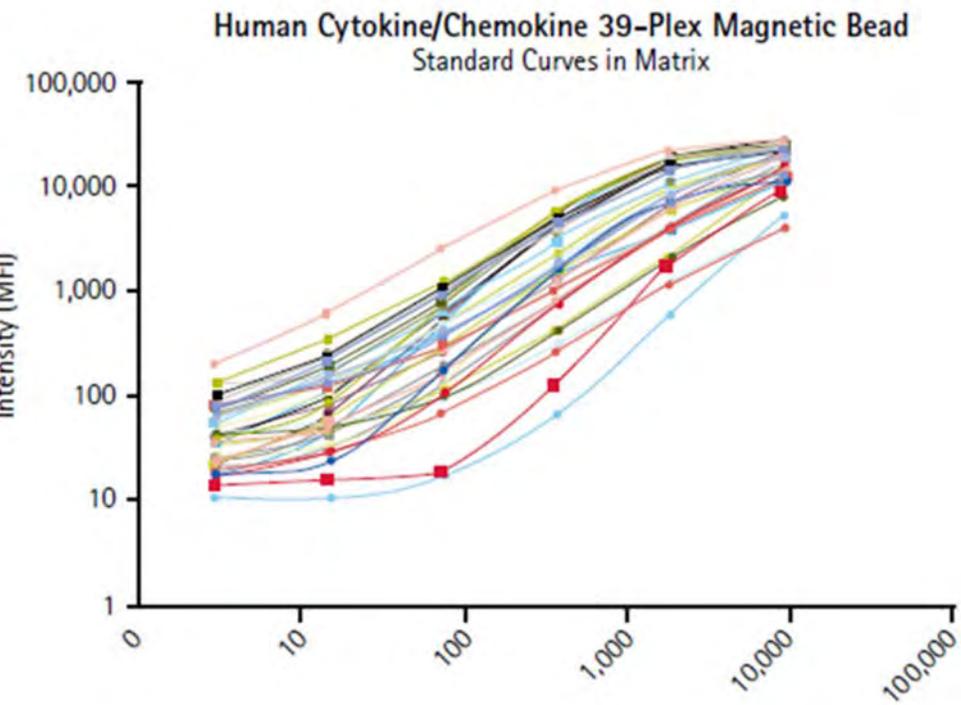
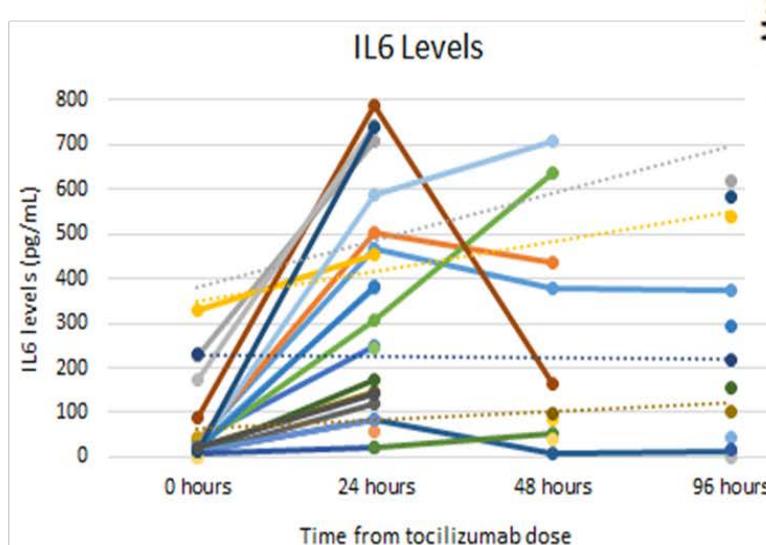
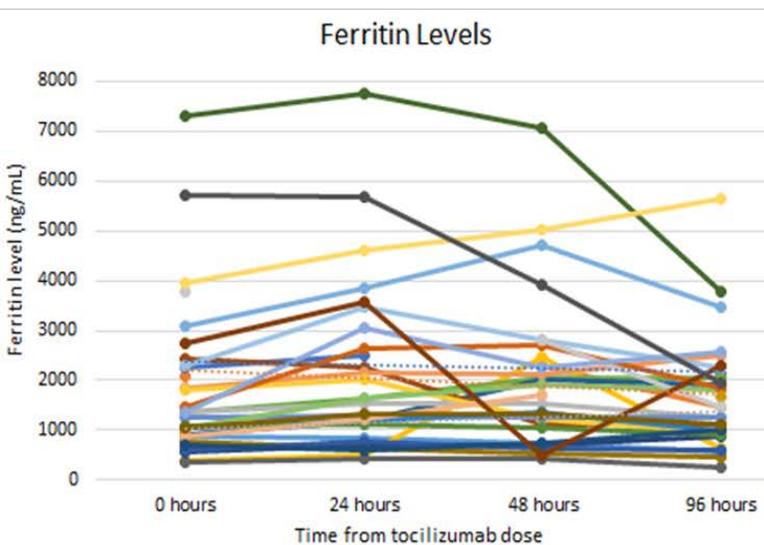
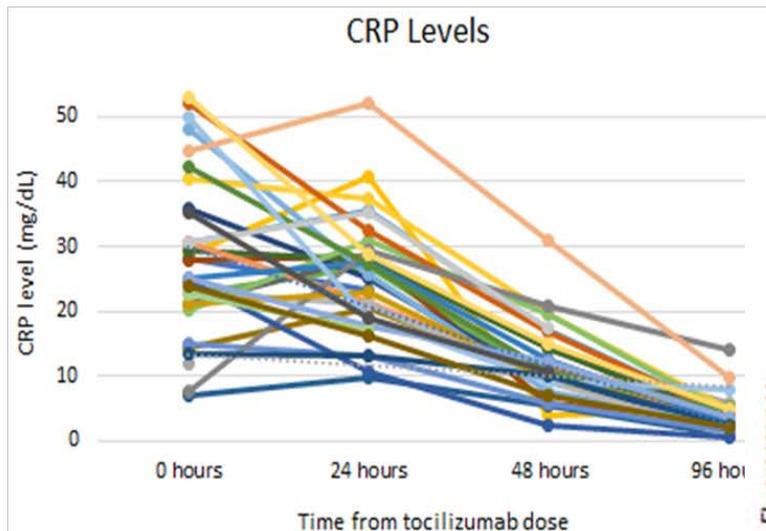
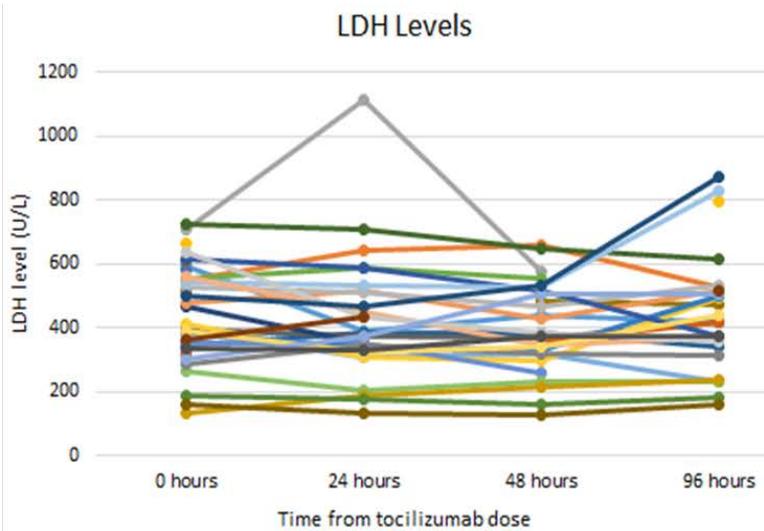
- Number of **co-morbidities** (odds ratio 4.50)
- **Poor Performance ECOG** (odds ratio 3.89)

- **Active cancer** (odds ratio 5.20)

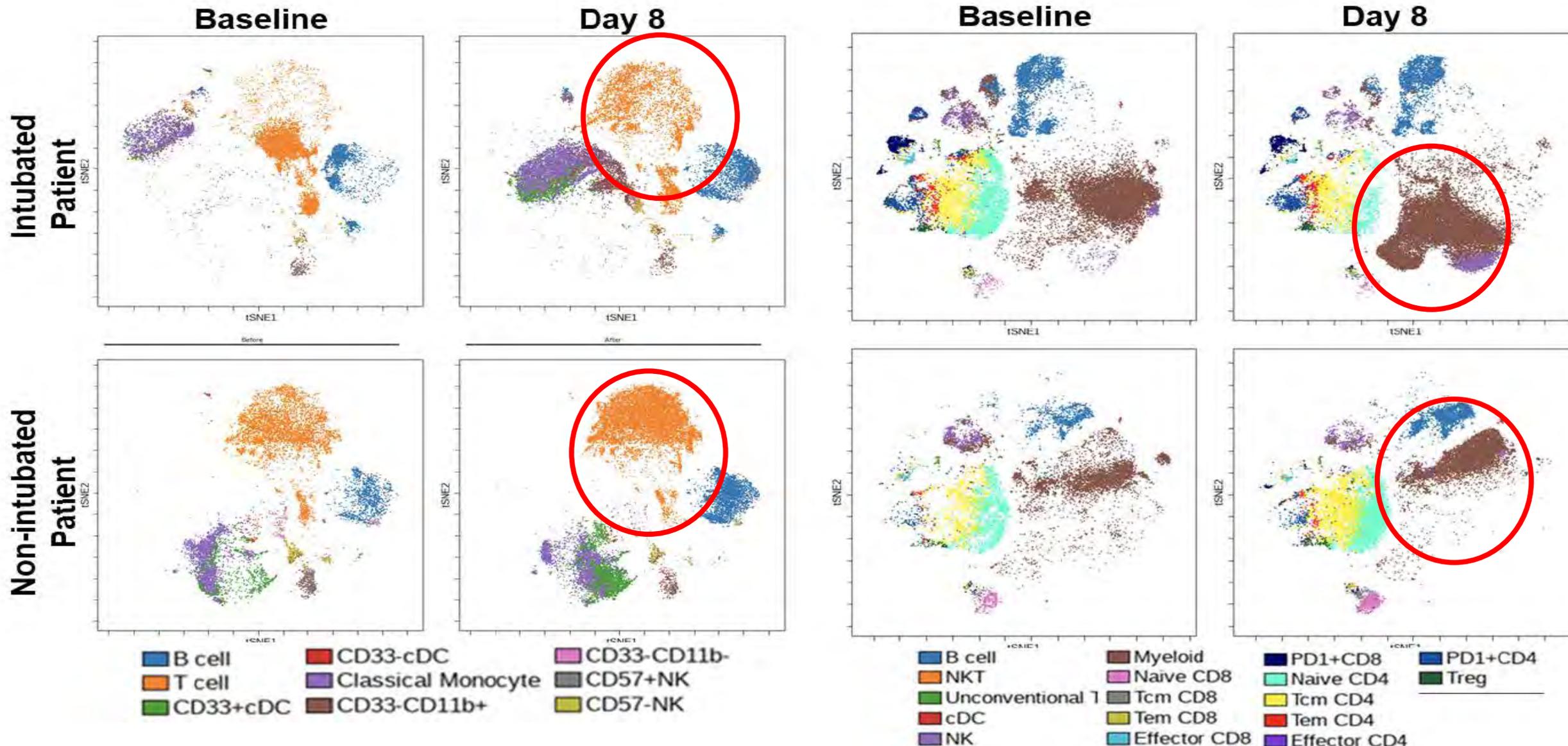
CYTOKINE STORM: CYTOKINE RELEASE SYNDROME



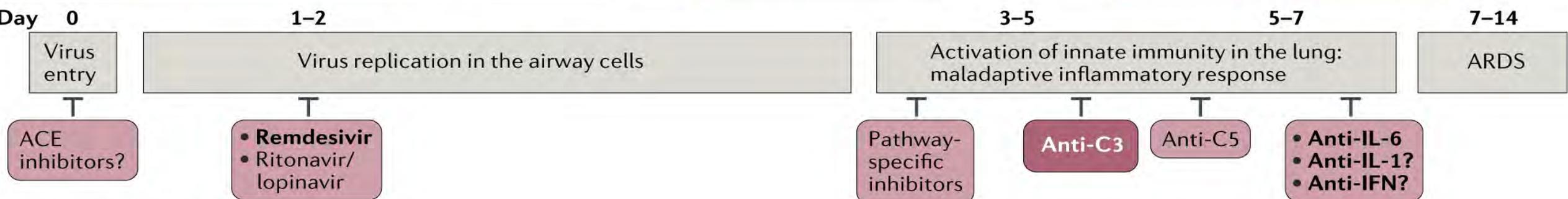
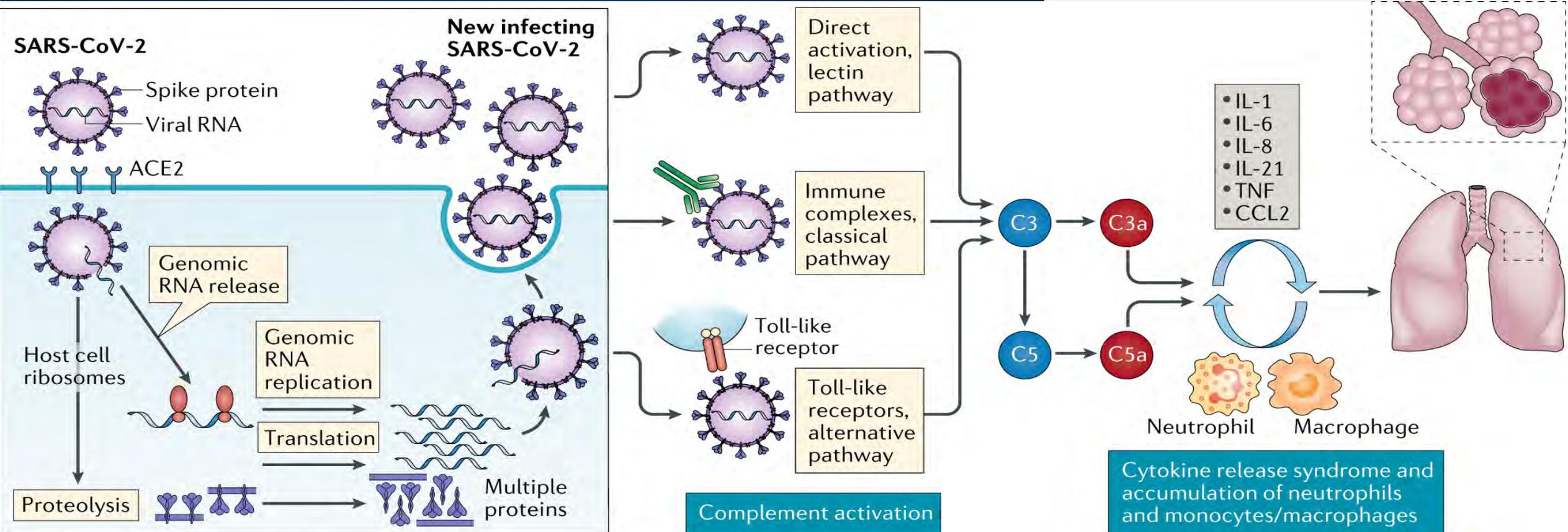
CHANGES IN BLOOD INFLAMMATORY MARKERS



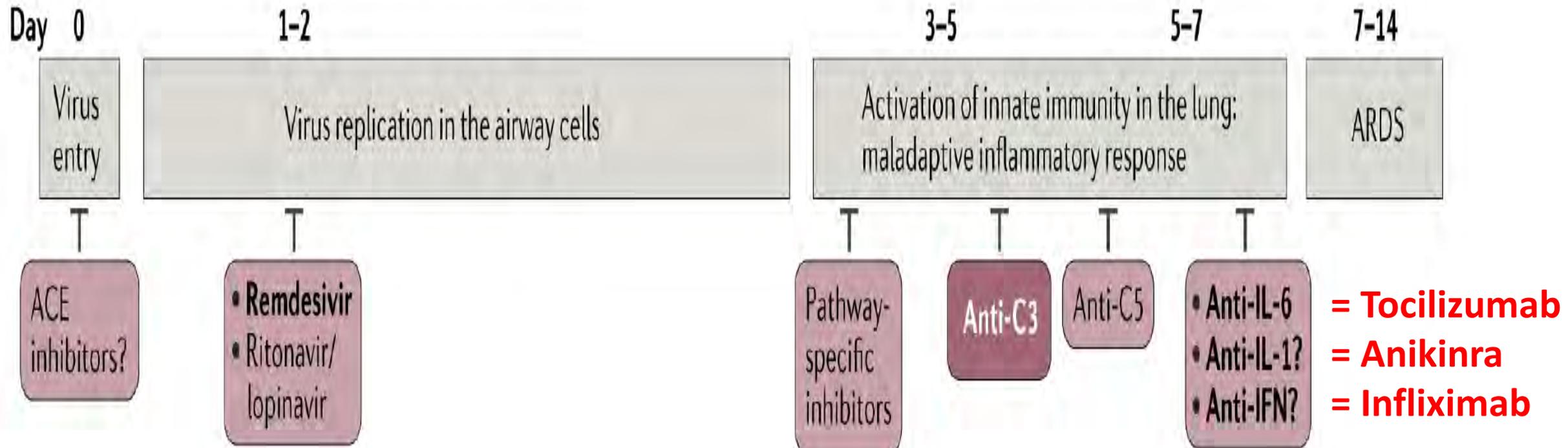
CYTOF ANALYSIS



MULTIPLE INFLAMMATORY PATHWAYS

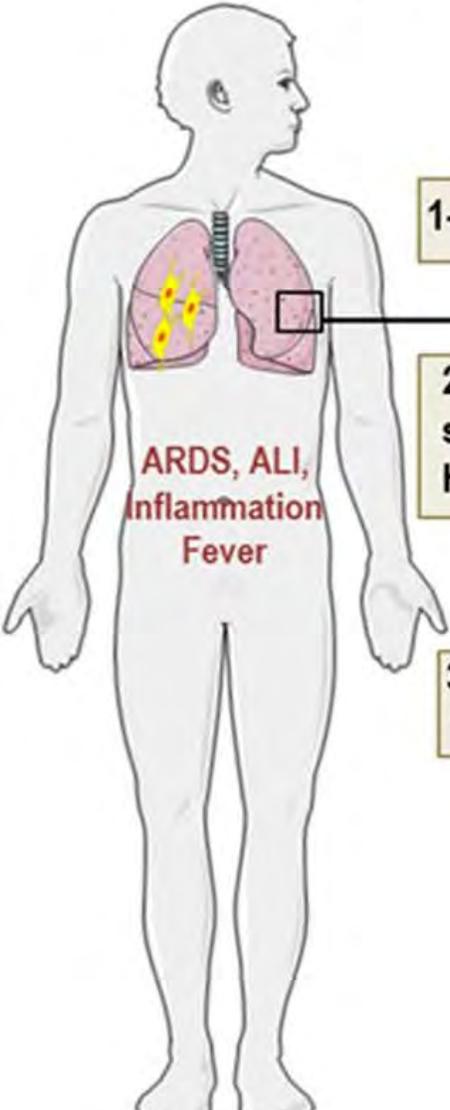


MULTIPRONG APPROACH



MULTIPRONG APPROACH

COVID-19 Subject

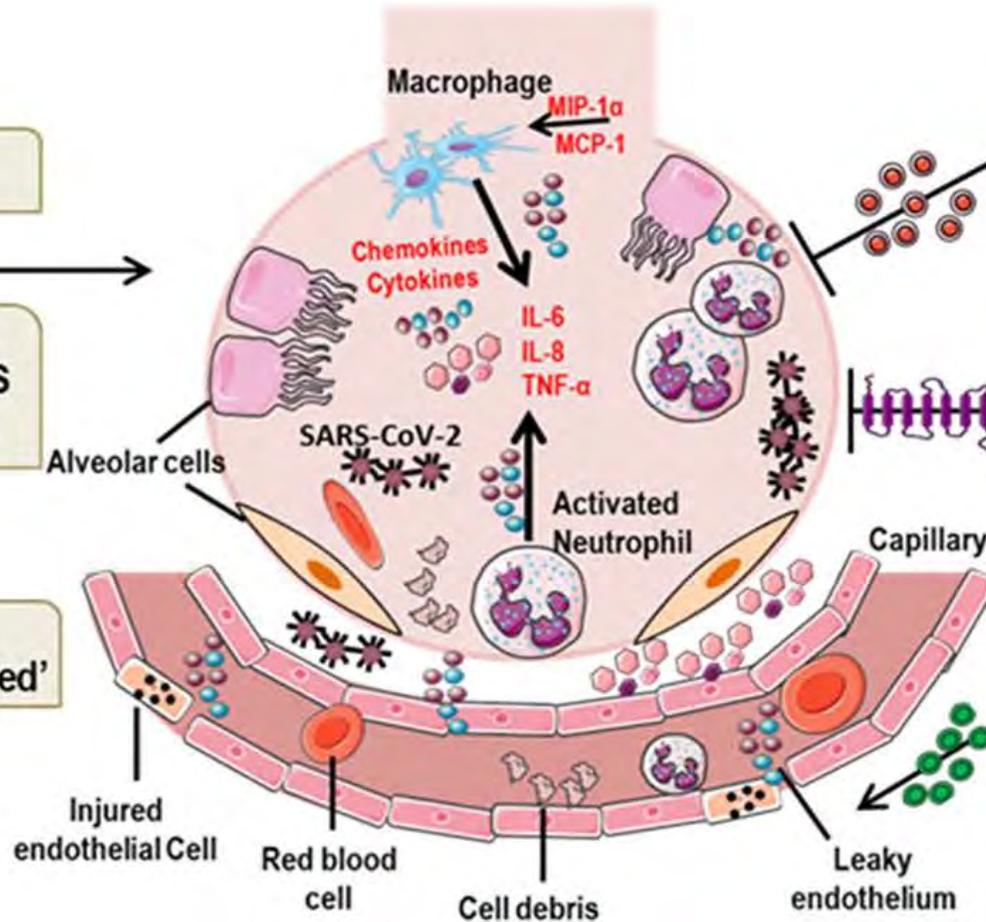


1- MSCs are safe

2- When delivered systemically, MSCs home to the lungs

3- MSCs are 'immune privileged'

ARDS

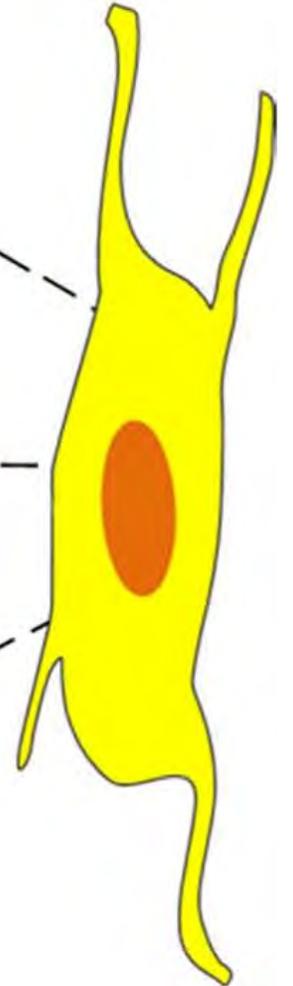


4- Immunomodulation:
via IL-10, TGF β , IDO, PGE2

5- Antimicrobial:
via LL-37, MicroRNAs

6- Regeneration
via VEGF, KGF, EGF

MSC



CARE DELIVERY

Analysis of the Implementation of Telehealth Visits for Care of Patients With Cancer in Houston During the COVID-19 Pandemic



Jorge G. Darcourt, MD, MHCMS^{1,2}; Kalia Aparicio, MSc¹; Phillip M. Dorsey, MHA¹; Joe E. Ensor, PhD¹; Eva M. Zsigmond, PhD¹; Stephen T. Wong, PhD^{1,2}; Chika F. Ezeana, MD^{1,2}; Mamta Puppala, MSc^{1,2}; Kirk E. Heyne, MD¹; Charles E. Geyer, MD¹; Robert A. Phillips, MD, PhD¹; Roberta L. Schwartz, PhD¹; and Jenny C. Chang, MD^{1,2}

Table 1. Patient Characteristics and Associations with Utilization of MyChart Video Visits

Demographics	No. of Patients (%) or Mean	No. of Patients Accepted (%) or Mean	No. of Patients Declined (%) or Mean	P (accepted vs. declined)
	N=1762	N=1477	N=285	
Mean age, years	61.4 (17-98)	60.2 (17-98)	67.7 (27-96)	<0.0001
Median income (in \$1k)	71.45 (8.5-154)	72.32 (8.5-154)	66.86 (2.15-141.9)	0.0021
Sex				
Male	585 (33.2)	476 (32.2)	109 (38.2)	0.0482
Female	1177 (66.8)	1001 (67.8)	176 (61.8)	
Ethnicity/race	N=1744	N=1464	N=280	0.3493
White	1061 (60.8)	877 (59.9)	184 (65.7)	
Black	312 (17.9)	270 (18.4)	42 (15.0)	
Hispanic	227 (13)	192 (13.1)	35 (12.5)	
Asian	103 (5.9)	91 (6.2)	12 (4.3)	
Other	41 (2.3)	34 (2.3)	7 (2.5)	
Insurance Type	N=1747	N=1464	N=283	<0.0001
Commercial				
Insurance	1087 (62.4)	926 (63.3)	111 (39.2)	
Medicare/Medicaid	543 (31.1)	489 (33.4)	154 (54.4)	
Other (Tricare, VA, self-pay)	67 (3.8)	49 (3.3)	18 (6.4)	

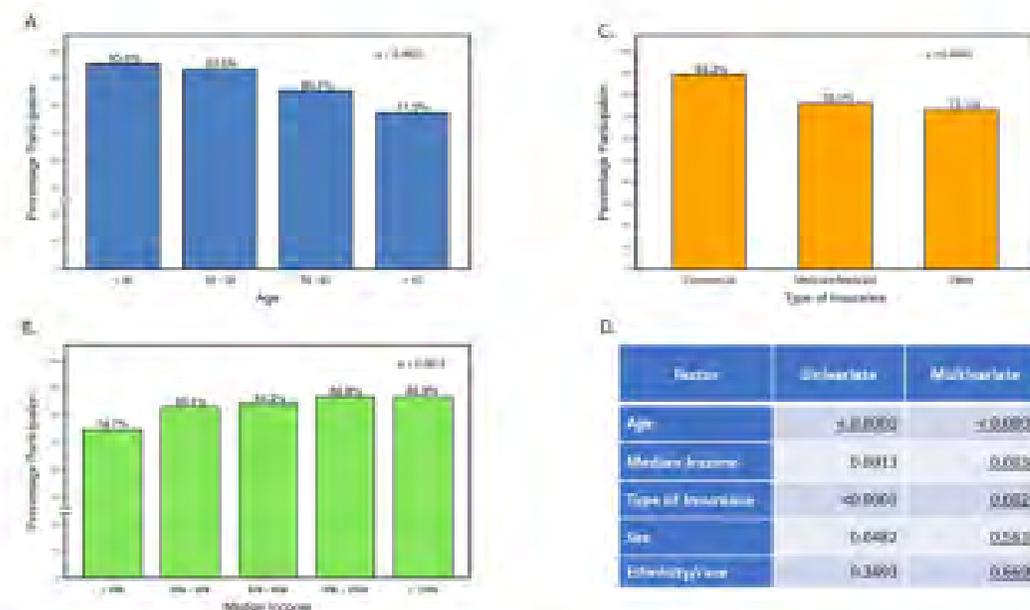


Figure 1. Univariate and multivariate analysis. A lower age (A, B), a higher median income (B, D) and having commercial insurance (C, D) are associated with participation with telemedicine video visits. Univariate analysis found sex is associated with participation but this association is not statistically significant in multivariate analysis (D). Age and median income are depicted as continuous variables and type of insurance as categorical.

COVID-19 CANCER CONSORTIUM

ccc19.org



The COVID-19 & Cancer Consortium

HOME FAQs COLLABORATORS COVID19NCANCER PUBLICATIONS RESOURCES OTHER EFFORTS



THE COVID-19 AND CANCER CONSORTIUM

Please click the button below to report on a cancer patient with COVID-19. See below for eligibility.

[ACCESS THE SURVEY](#)

THANKS



Katherine Perez
Deepa Gotur
Susan Miller
William Musick
Faisal Masud

Asma Zainab
Prakruthi Voore

Jasleen Randhawa
S Ravi Pingali
Shilpan Shah
Malcom Brenner
Helen Heslop
Tejaswini Reddy
Liliana Guzman
Jessica Bronstad
Stephen Wong
Akshjot Puri
Eric Bernicker
Jorge Darcourt

All our frontline
physicians, nurses, care
providers

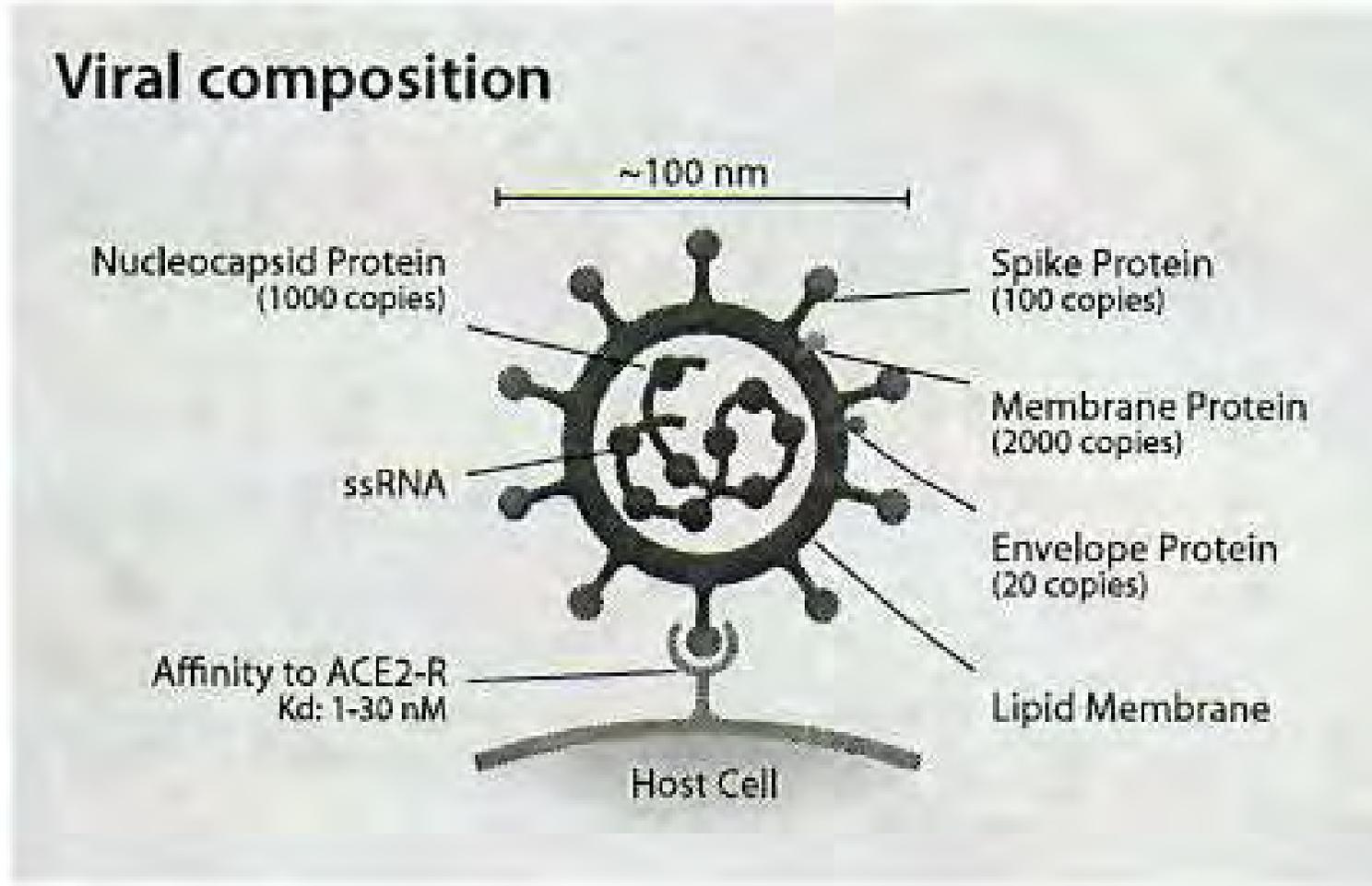
To and for our patients

COVID-19 Testing

Houston Methodist Town Hall

11/19/2020





Testing for COVID-19

- Viral RNA
- Proteins (Antigen)
- Immune response
 - Antibody
 - T-cell

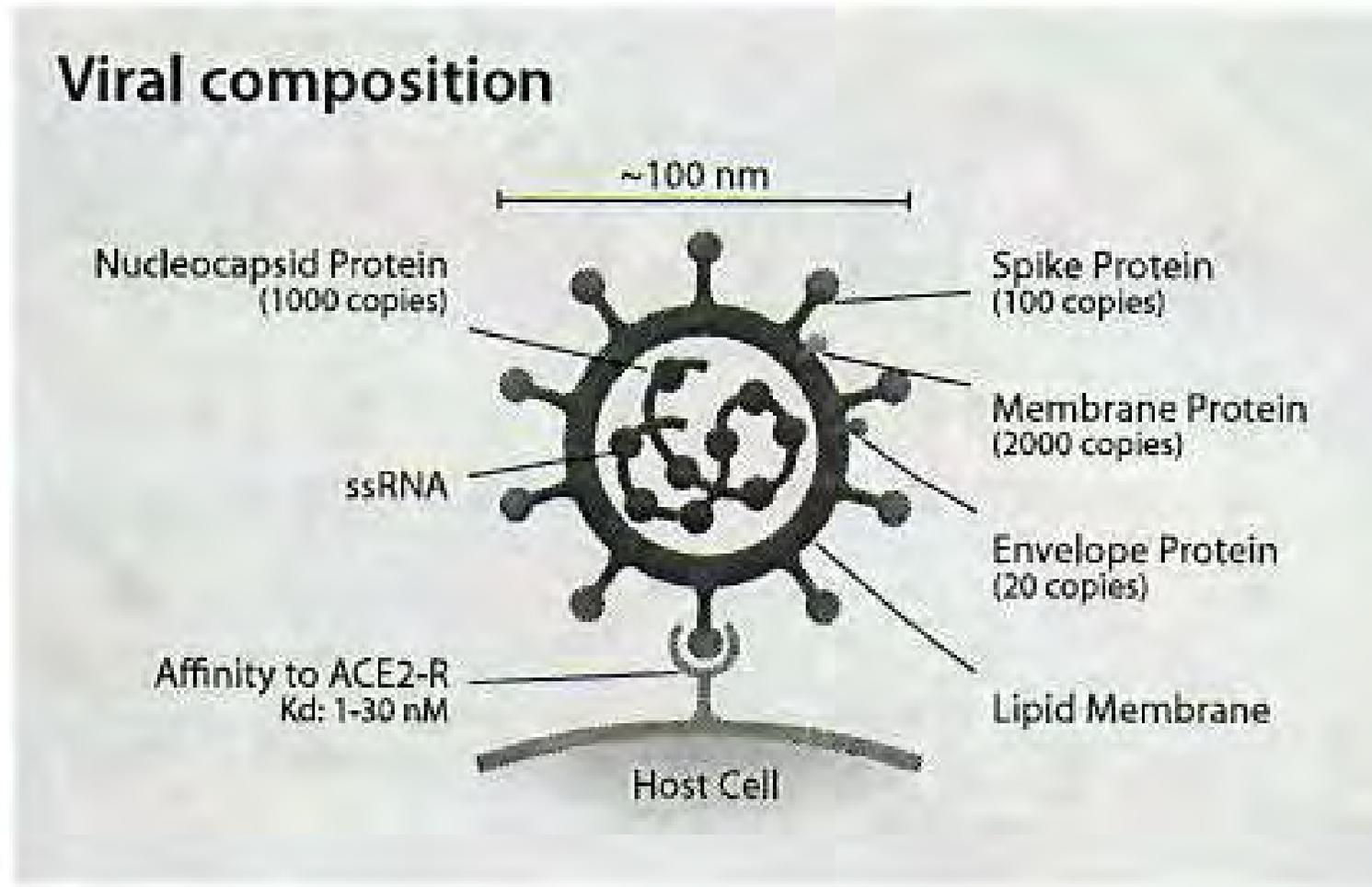
Laboratory Testing for COVID-19

- Sample
 - “Go to where the money is”
- Infects epithelia and other cells

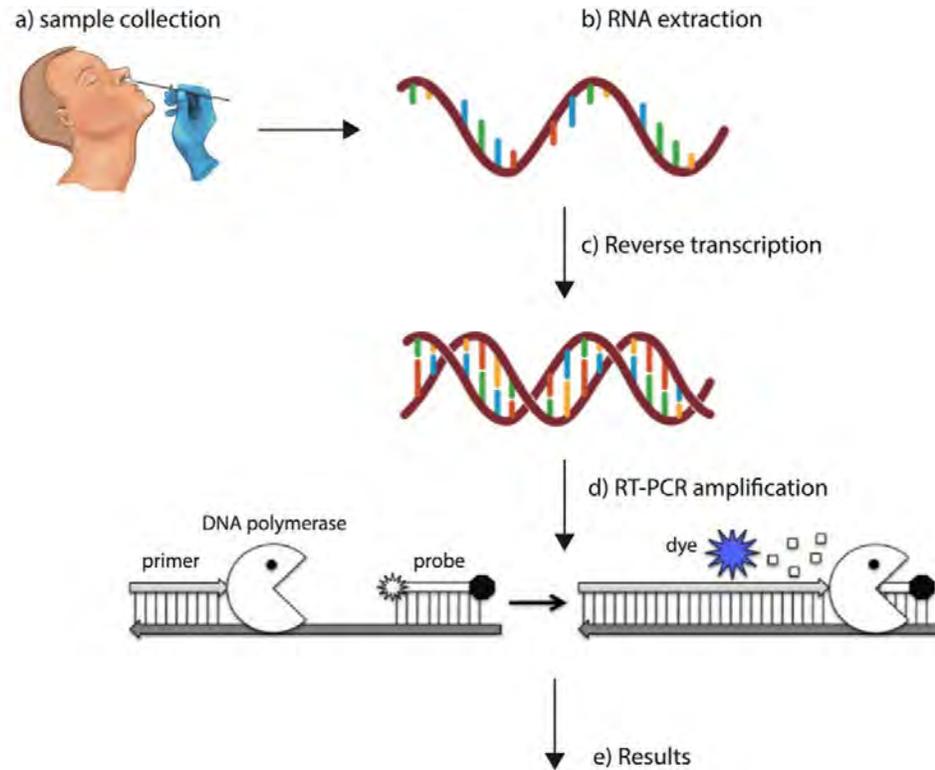
- Nasopharyngeal*
- Nasal*
- Oropharyngeal
- Sputum
- Bronchoalveolar Lavage
- Tracheal aspirates
- Saliva

- Discrepancies
 - Viral concentrations

- There are no FDA approved tests
- Two avenues for tests to be available for clinical use
 - Laboratory developed test
 - Only one lab, not marketed
 - Emergency Use Authorization from FDA
 - Expedited review of validation data by FDA
 - Can be marketed
 - Houston Methodist uses EUA assays



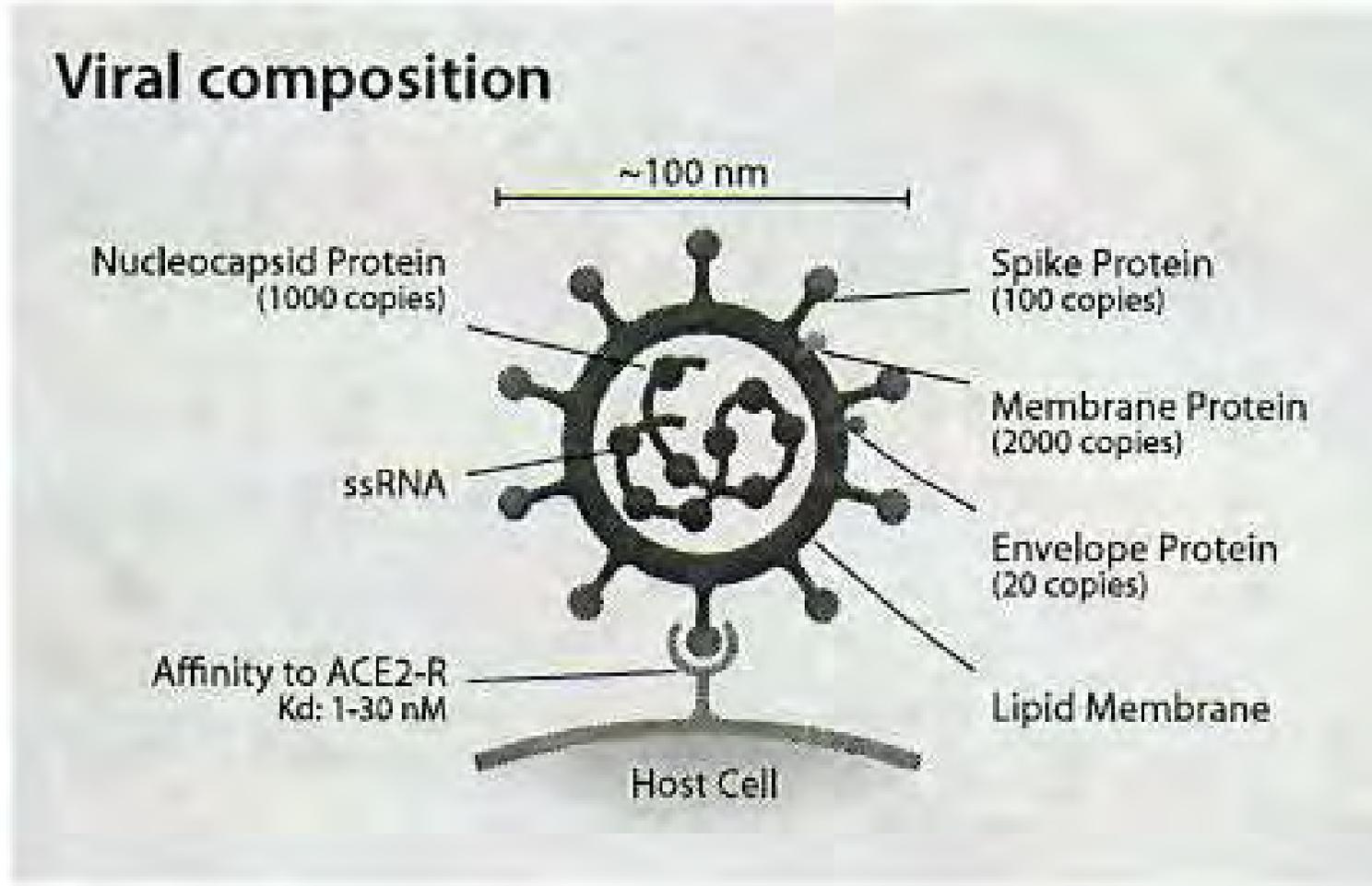
COVID-19 Nucleic Acid Amplification Tests



- Nucleic acid amplification tests
 - Reverse Transcriptase Real Time-PCR (RT-PCR)
- Multiple platforms (all concordant)
 - Fastest turnaround time is Cepheid with on-board time of 75 minutes
 - Reagents very limited by vendor allocation
 - Reserved for STAT situations
 - Average turnaround time (all platforms aggregated) in past 7 days is 5.4 hours from receipt in laboratory
 - Specimens: NP, OP, NS, BAL, sputum and Tracheal aspirations

- Statistics 262,741 tests
 - 27,985 positive
 - 10.07% cumulative positive
 - 2.5% of TX positives have been diagnosed at HM
 - Maximum throughput over 7,500 per day

– as of 11/16/2020



- Seven antigen assays
 - All but one detect nucleocapsid protein
 - Sampinute detects Receptor Binding Domains of Spike protein
 - Instrument read except BinaxNow and CareStart (visual)
- Sofia 2 SARS Antigen FIA (Quidel)
- BD Veritor System SARS-CoV-2
- LumiraDx SARS-CoV-2 Ag Test
- BinaxNOW COVID-19 Ag Card
- Sofia 2 Flu + SARS Antigen FIA
- CareStart COVID-19 Antigen test
- Sampinute™ COVID-19 Antigen MIA
- Note: BinaxNOW is totally under government control and not available from the vendor

- FDA indicates that each antigen test is unique
- All have decreased sensitivity relative to NAAT
- Negative test result:
 - BD and CareStart – all negative results are presumptive
 - Sofia (Quidel), LumiraDx and Sampinute – presumptive after certain time from symptom onset or exposure
- Positive test result:
 - Treat as positive
 - However, false positives (FP) do occur
 - Different algorithms are suggested for identification of FP and their resolution

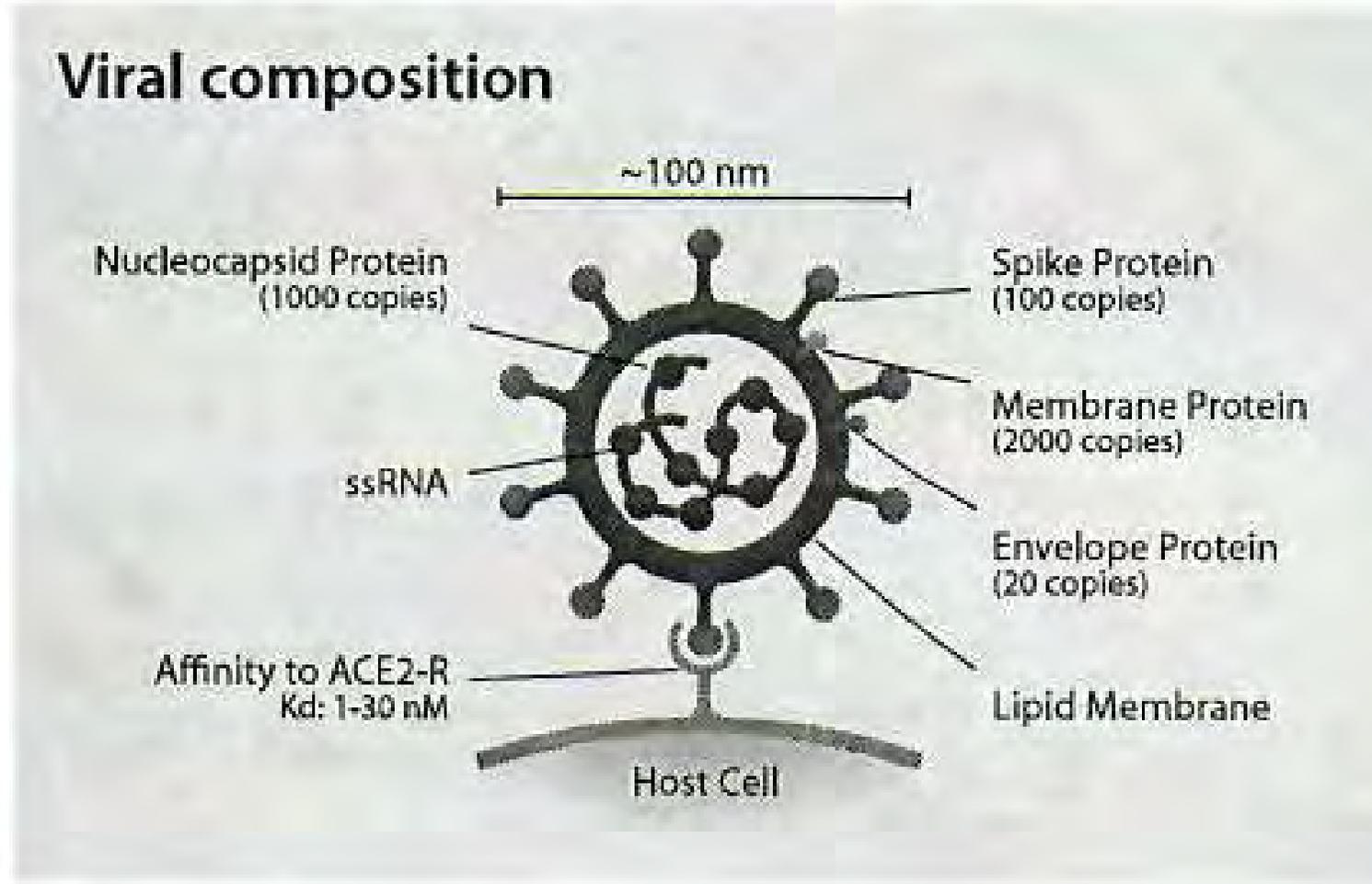
- FDA issued warning letter 11/03/2020
<https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory>
 - False positives occur
 - Highlighted areas of concern
 - Must adhere to manufacturer's instructions
 - Correlate with clinical symptoms especially in long-term care facilities

- We evaluated several other SARS-CoV-2 tests
 - Collected NP sample and tested by HM current method
 - Collected specimen for other test and/or also tested NP on candidate system per manufacturer's directions

Our Test Evaluations: Results

- Of 100 patients positive by **NP Swab by an HMH RT-PCR**:
 - 63 will be positive by nasal swab via RT-PCR
 - 47 will be positive on Abbott ID Now
 - 40 will be positive on Sofia (Quidel) Antigen test
- All patients negative on HMH RT-PCR were negative by other tests and/or with other specimen type
- Others ongoing

- Minimal Influenza in Southern Hemisphere in 2020 world-wide
- At Houston Methodist, there have been a total of 18 cases of Influenza A/Influenza B since September 15, 2020
- (<https://flu.houstonmethodist.org/>)
- COVID-19 plus Influenza tests are available



COVID-19 Antibody Development

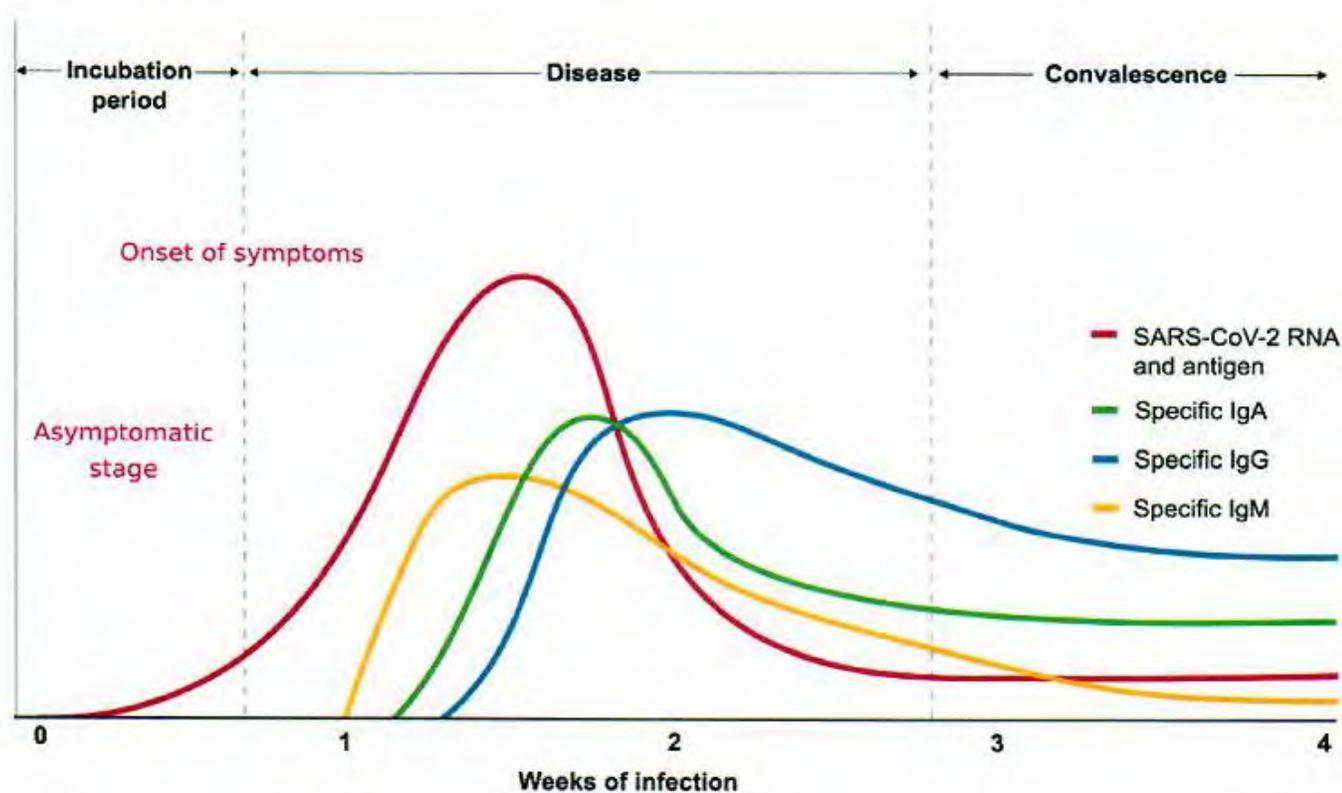


Figure 6

<https://www.globalbiotechinsights.com/articles/20247/the-worldwide-test-for-covid-19>

- Not for acute diagnosis
- Can demonstrate previous exposure/infection
- Immune status
 - Post-vaccination
- Convalescent plasma
 - Ortho Vitros assay is used to qualify convalescent plasma

- Post-vaccination Antibodies
 - Quantitative antibody levels tested at some frequency
 - Quantitative assay will be available at Houston Methodist
- T-cell Immunity
 - For those without post-vaccination antibody response
 - Methods are not easy or scalable
 - Active area of research

THANKS

- Dr. Musser, Chairman
- Molecular team
 - Drs. Olsen, Thomas, Li
- Microbiology team
 - Drs. Long and Olsen
- Serology team
 - Drs. Eagar and Yi
- Dr. Boom
 - Drs. Roberta Schwartz, Sostman and Phillips
- Many lab techs, staff, collectors, admin, etc.

COVID-19 Update

November 19, 2020

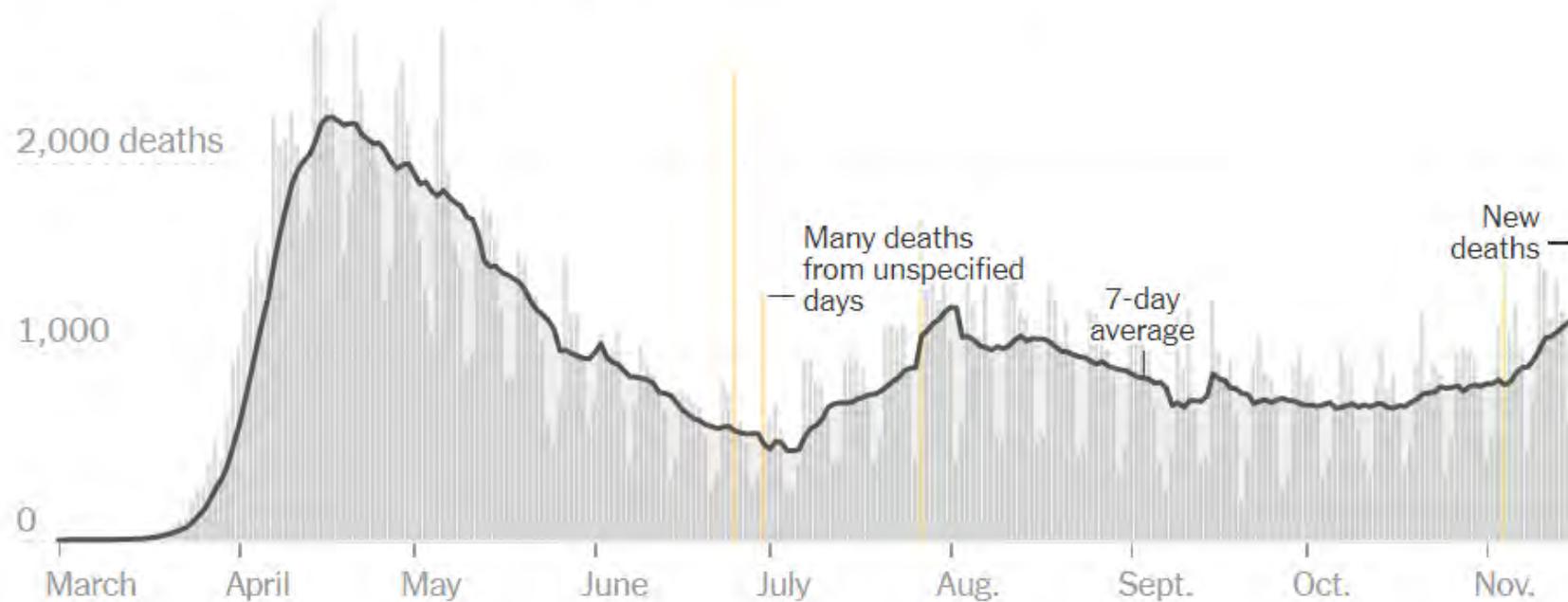


National COVID-19 Stats

New reported cases by day in the United States

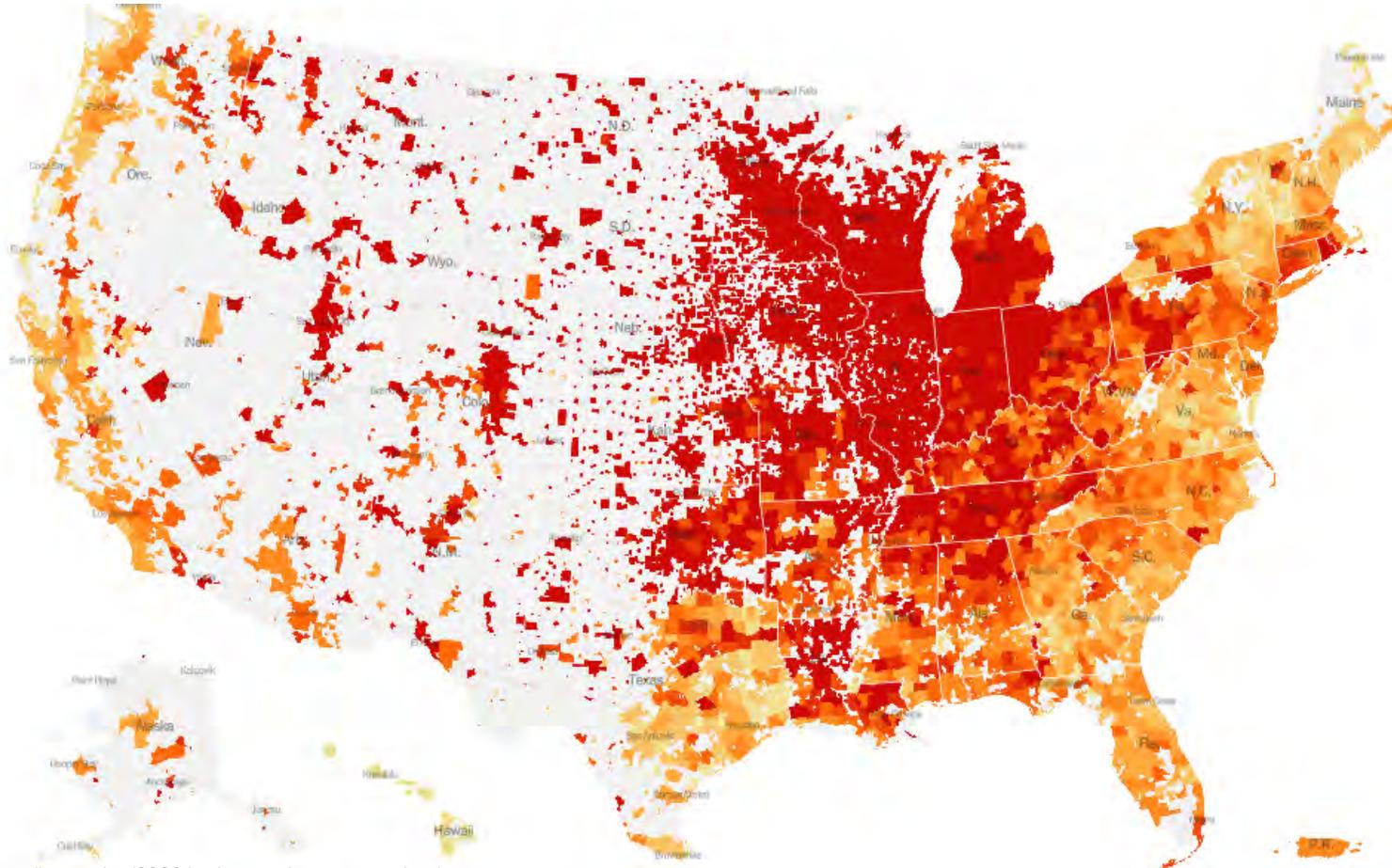
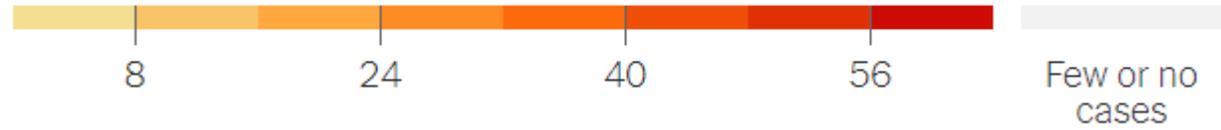


New reported deaths by day in the United States



National Hotspot Map

Average daily cases per 100,000 people in past week

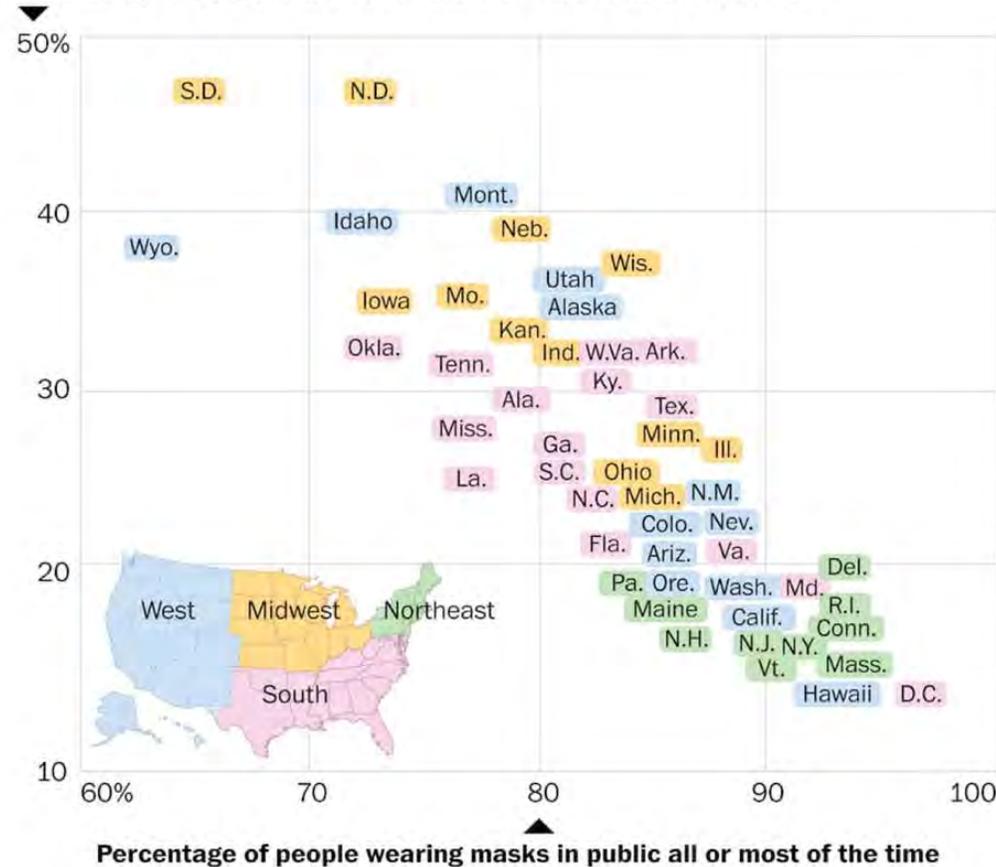


Trend of COVID-19 Compared to Mask Usage by State

Masking up

Fewer covid-19 symptoms reported in states with higher rates of mask use.

Percentage of people who know someone with covid-19 symptoms



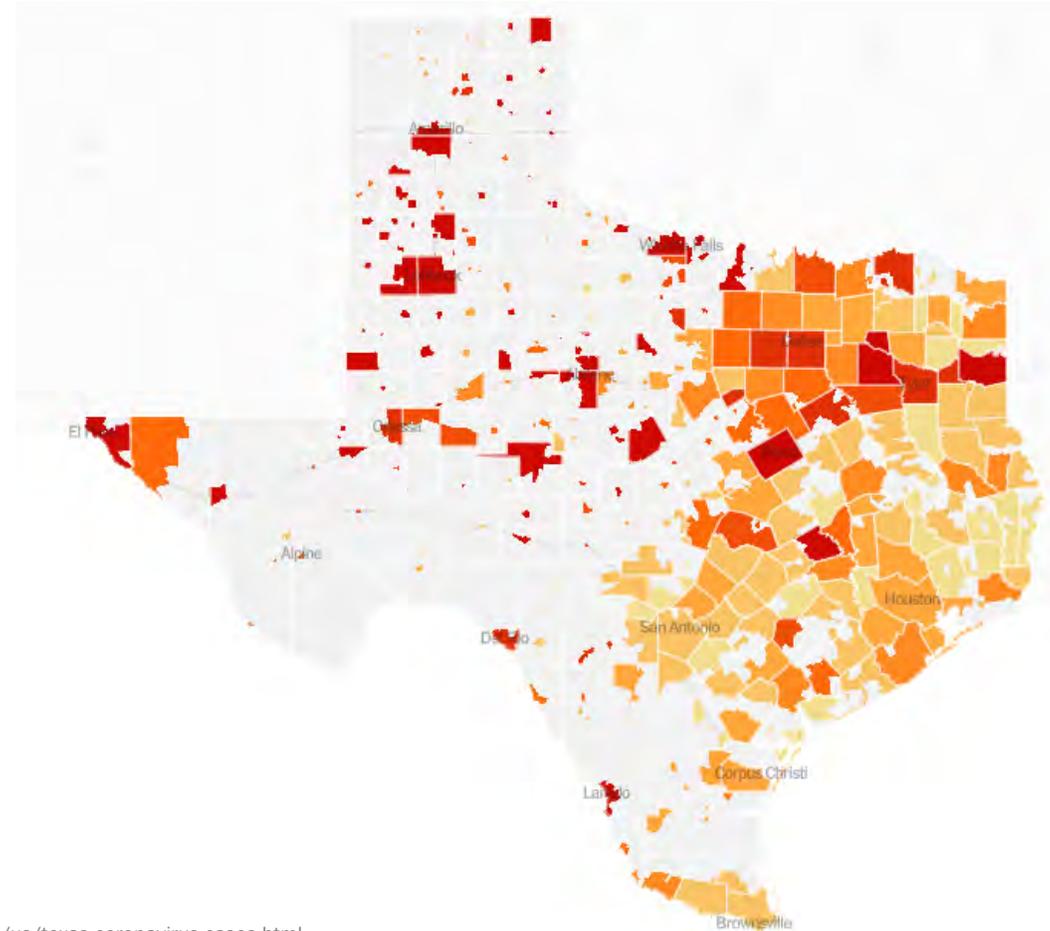
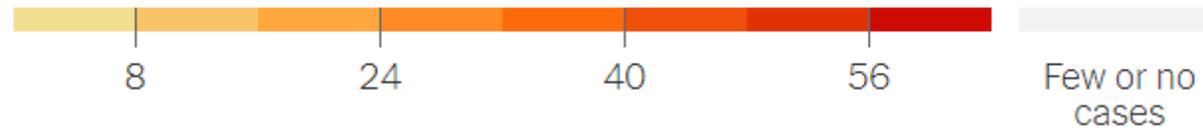
Data as of Oct. 19

Source: Delphi CovidCast, Carnegie Mellon University

THE WASHINGTON POST

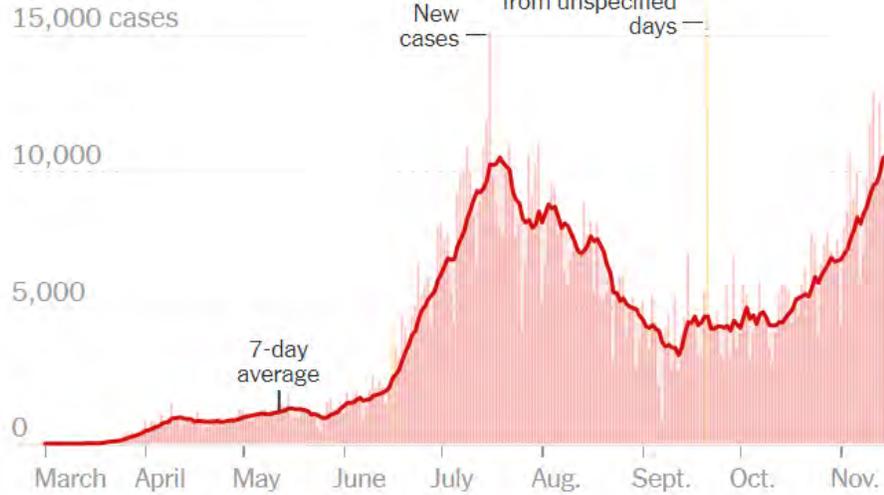
Texas Hotspot Map

Average daily cases per 100,000 people in past week

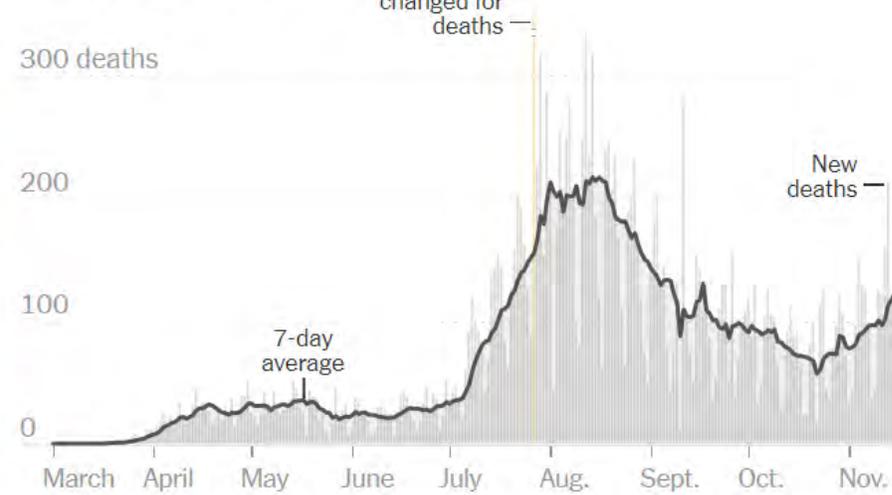


Texas COVID-19 Stats

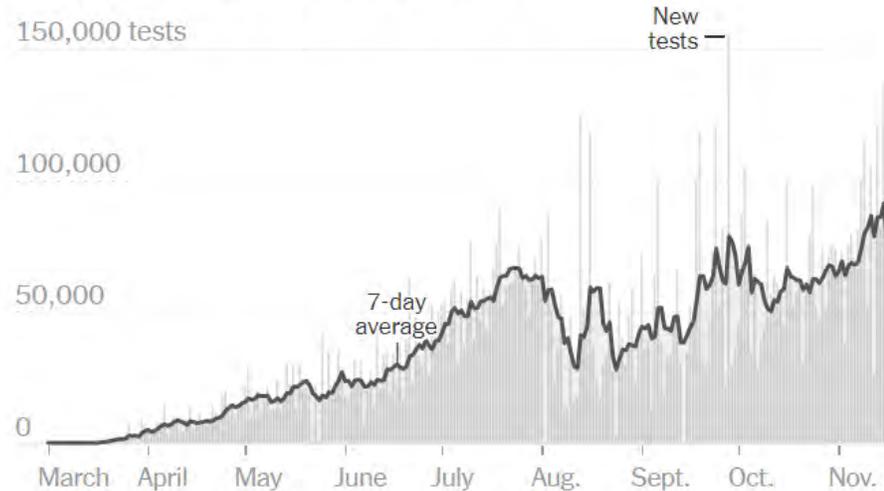
Daily reported new cases



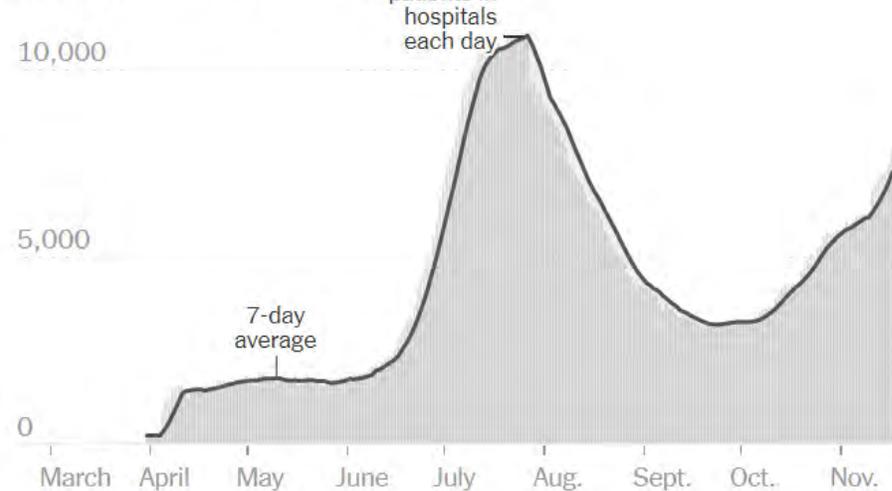
Daily reported deaths



Daily reported specimens tested



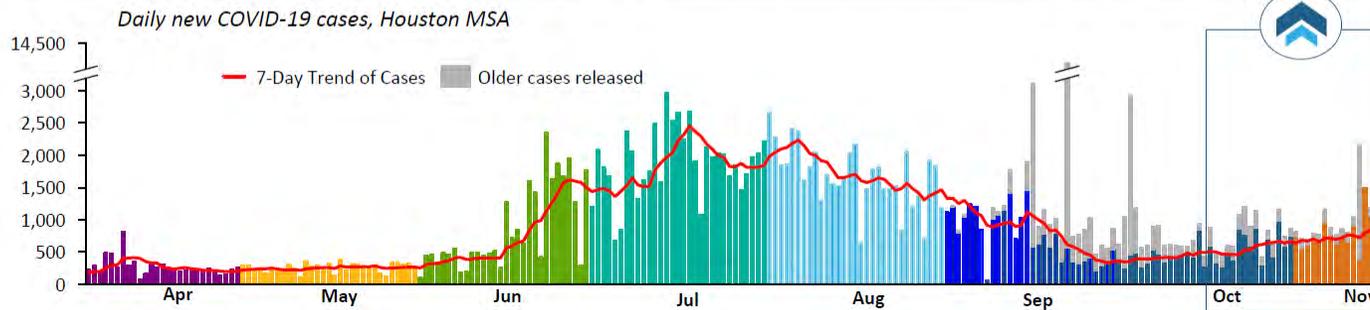
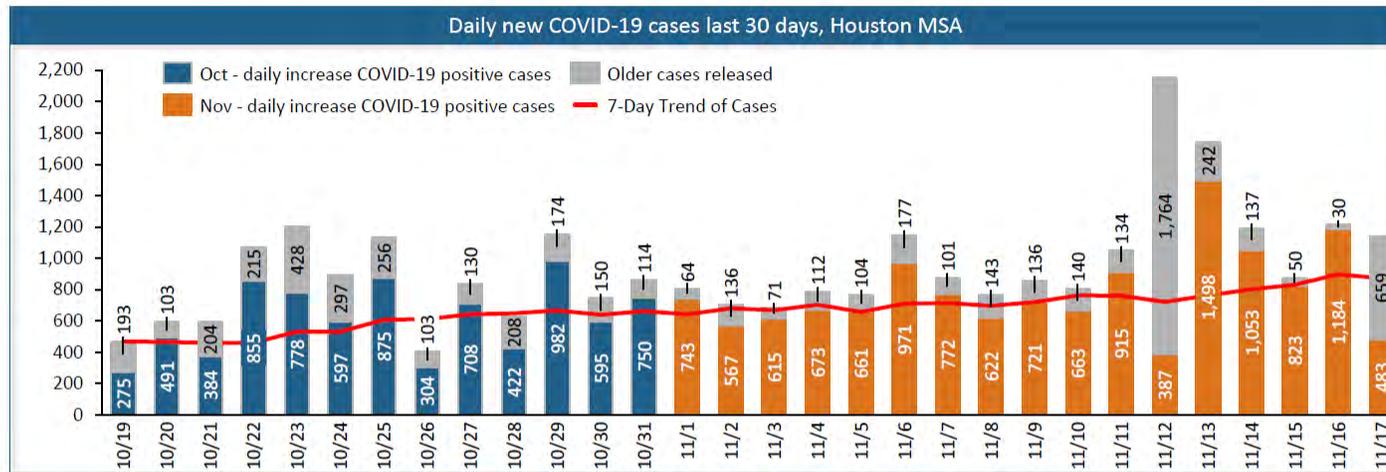
Hospitalizations



3 COVID-19 CASE TRENDS

DAILY NEW COVID-19 POSITIVE CASES

Greater Houston Area¹



TMC TEXAS MEDICAL CENTER

"TMC" refers to the group of systems that make up Texas Medical Center

1. Austin, Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery and Waller
 Source: TX Health and Human Services (<https://www.dshs.texas.gov/coronavirus/>)

November 17, 2020

Monitoring threshold:

Threshold is exceeded by the occurrence of a positive daily growth rate (averaged over 7 days) in the new daily case trend

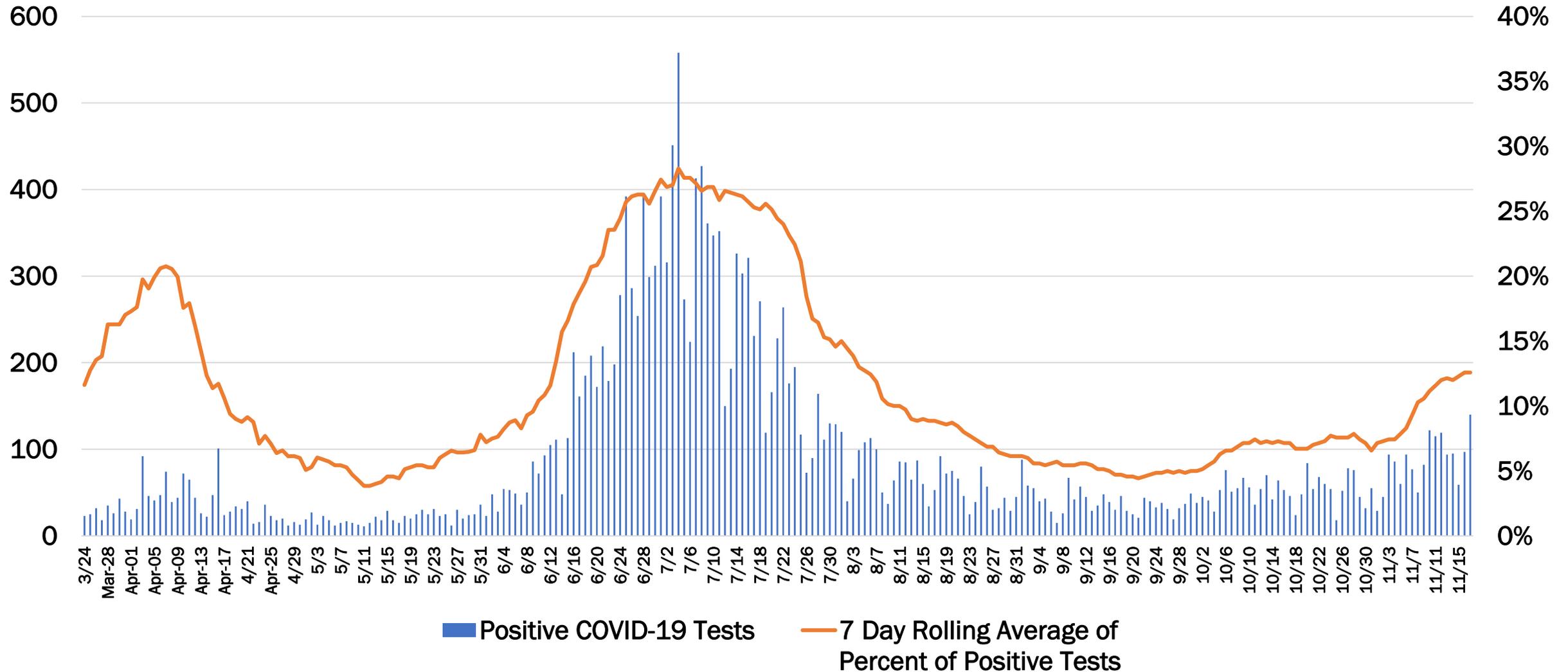
Current status:

12 days of positive daily growth rate (averaged over 7 days) in the new daily case trend

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

Houston Methodist Testing Trend

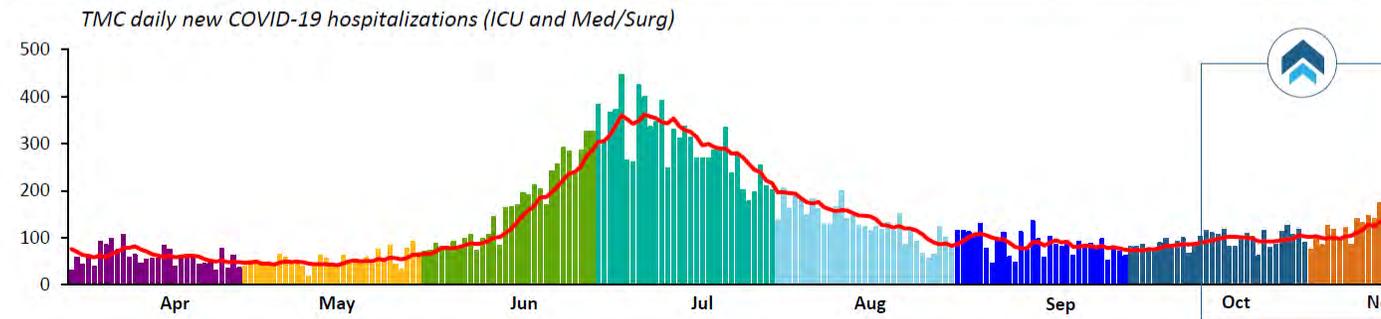
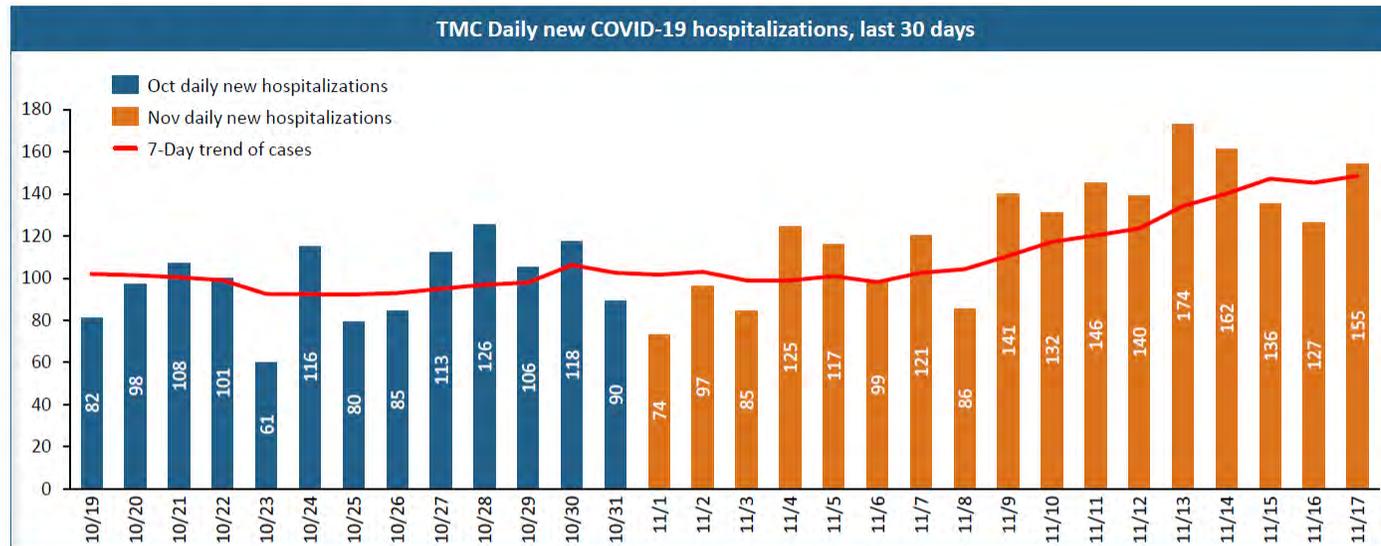
Confirmed COVID-19 Lab Tests



4

COVID-19 TMC HOSPITALIZATION TRENDS

TMC DAILY NEW COVID-19 HOSPITALIZATIONS



TMC TEXAS MEDICAL CENTER Source: TMC institution clinical census
 "TMC" refers to the group of systems that make up Texas Medical Center

November 17, 2020

Monitoring threshold:

Threshold is exceeded by the occurrence of a positive daily growth rate, averaged over 7 days

Current status: 0.8% daily growth rate (averaged over 7 days) in the COVID-19 daily hospital admissions trend

Notes:

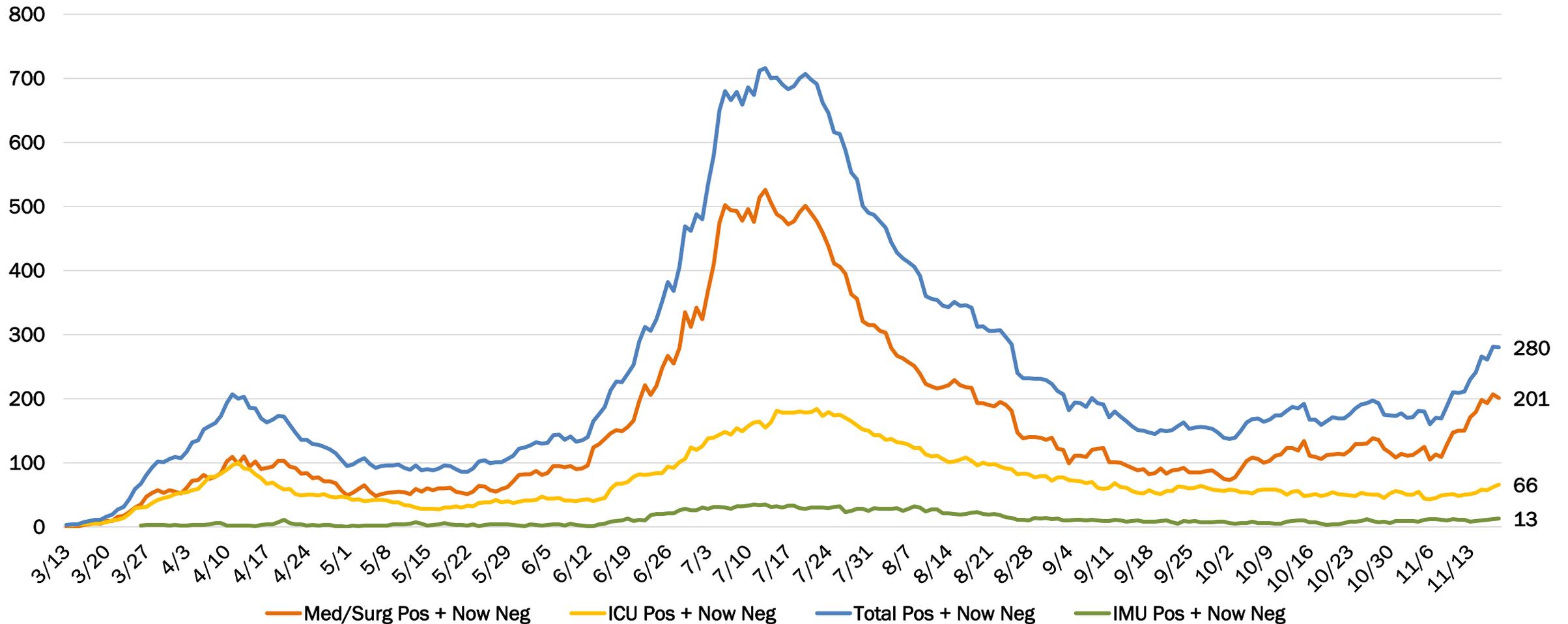
While new daily cases may fluctuate for a variety of reasons (e.g., testing), the daily hospitalization trend shows an objective view of how COVID-19 impacts hospital systems

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

Houston Methodist COVID-19 Cases by Day

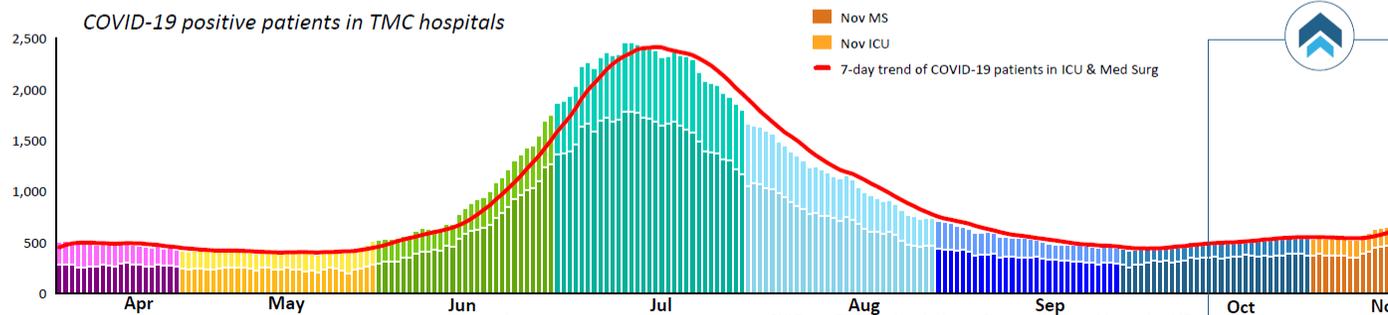
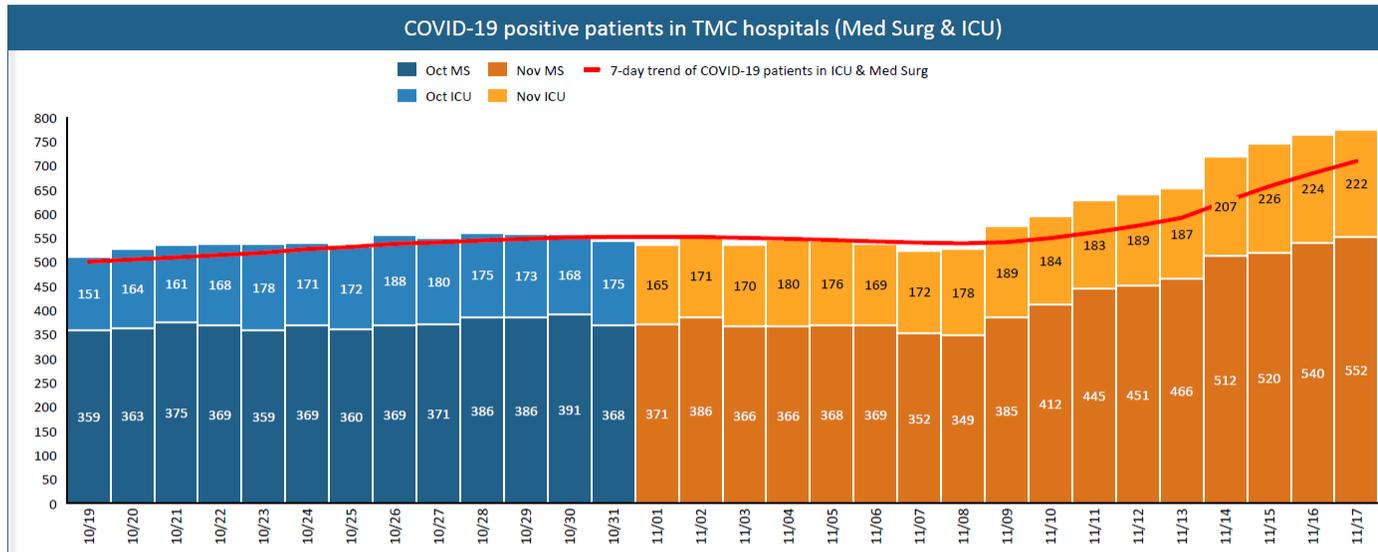


Houston Methodist COVID-19
Patients by Day



4 COVID-19 TMC HOSPITALIZATION

TOTAL TMC COVID-19 POSITIVE PATIENTS IN HOSPITAL



TMC TEXAS MEDICAL CENTER

Source: Internal data collected from the systems CHI Texas Division, Harris Health System, Houston Methodist, MD Anderson Cancer Center, Memorial Hermann, Texas Children's Hospital, UTMB
 "TMC" refers to the group of systems that make up Texas Medical Center
 All guidelines should be in accordance with CDC guidelines

November 17, 2020

Current status:

4.0% total daily growth rate
 (averaged over 7 days) in COVID-19 patients TMC hospitals

- **2.6% ICU daily growth rate**
- **4.6% Med Surg daily growth rate**

Notes:

While new daily cases may fluctuate for a variety of reasons (e.g., testing), the number of COVID-19 positive patients being treated in med surg and ICU shows an objective view of how COVID-19 impacts hospital systems

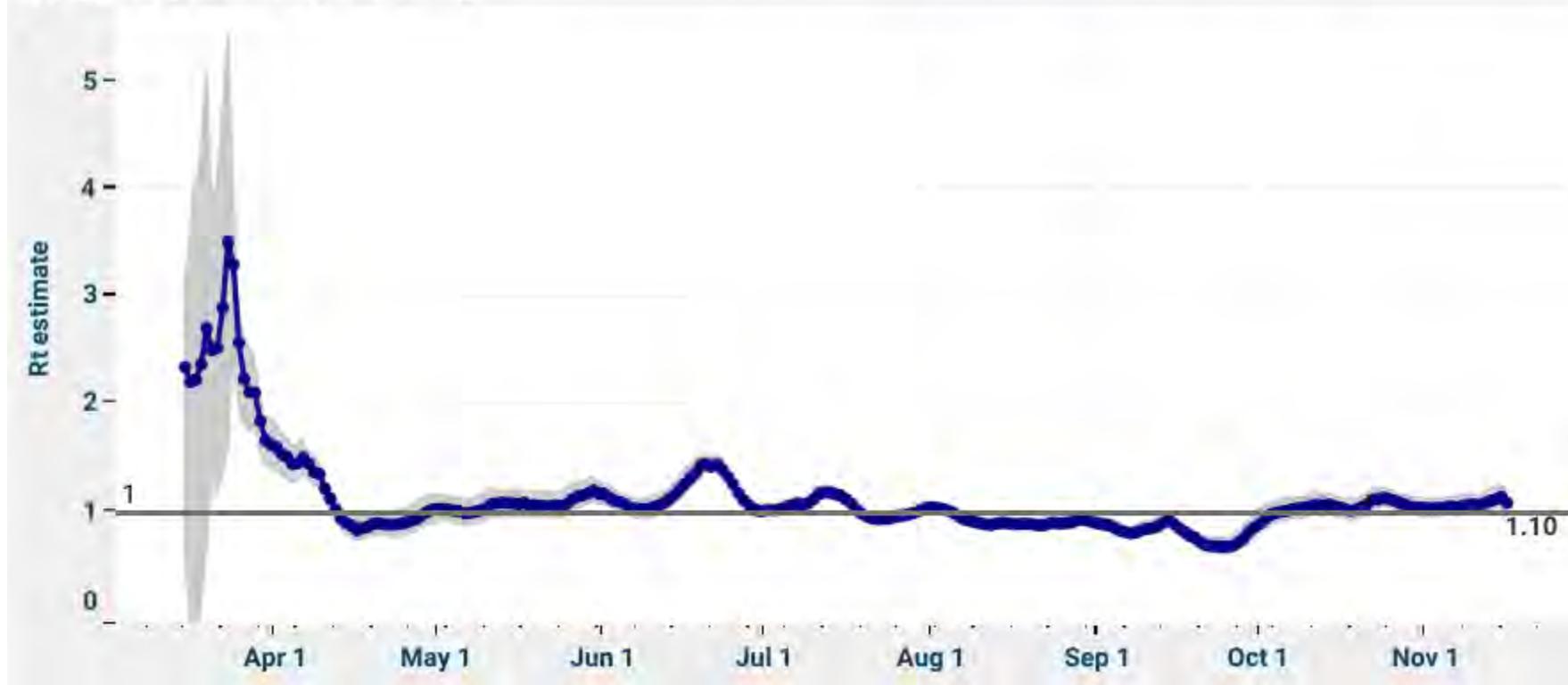
This document is solely intended to share insights and best practices rather than specific recommendations. Individual institution data is shown as reported and has not been independently verified.

HOW DO YOU ACCOUNT FOR THE $R(t)$ 'S CONTINUING TO HOVER A LITTLE ABOVE 1, BUT THE CASE COUNT AND POSITIVITY RATE KEEP INCREASING?

Houston Area Rt Estimate Trend

Rt estimate

This graph shows the $R(t)$ over time. $R(t)$ is a measure of contagiousness or how many people one COVID19 person infects. If $R(t) > 1$, the epidemic is increasing. If $R(t) < 1$, the epidemic is declining. There is higher alert if the whole interval is above the horizontal line at 1. For **Q - Houston**, the rate of contagiousness is **1.10**; the epidemic is **increasing**.



WHAT IS THE BEST WAY TO APPROACH FAMILY GATHERINGS
AT THE HOLIDAYS? ADVICE FOR FLYING?

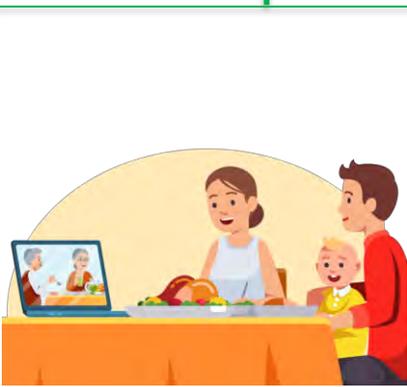
1. Science, especially biological science, is messy in real time.
2. Hospitals together must work on their “Sacred AND”
3. Our political leaders must work together on society’s “Sacred AND”
4. Our social lives must take a backseat to the “Sacred AND”
5. Masks are a means to accomplish the “Sacred AND”

COVID-19 Precautions – Holiday Safety

“The safest way to celebrate Thanksgiving this year is to celebrate with people in your household. If you do plan to spend Thanksgiving with people outside your household, take steps to make your celebration safer.”

Safest Options

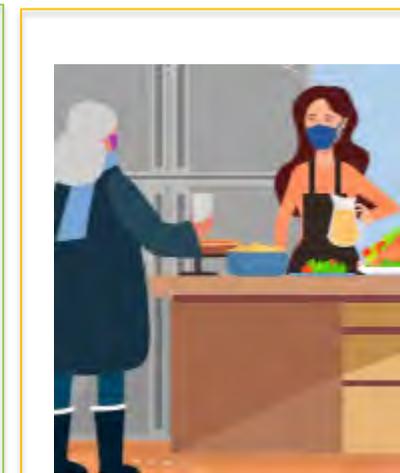
Least Safe Options



- Gather only with those in your household
- Host a virtual celebration



- Create a “holiday bubble” using social distancing and testing
- Bubble is only as strong as the weakest link



- Gather with individuals outside your “bubble”
- At a minimum, follow CDC recommendations

Hosting a Thanksgiving Gathering



If having guests to your home, be sure that people follow the steps that everyone can take to make Thanksgiving safer. Other steps you can take include:

- Have a small outdoor meal with family and friends who live in your community.
- Limit the number of guests.
- Have conversations with guests ahead of time to set expectations for celebrating together.
- Clean and disinfect frequently touched surfaces and items between use.
- If celebrating indoors, make sure to open windows.
- Limit the number of people in food preparation areas.
- Have guests bring their own food and drink.
- If sharing food, have one person serve food and use single-use options, like plastic utensils.

Thanksgiving Travel

Travel increases your chance of getting and spreading COVID-19. Staying home is the best way to protect yourself and others.

If you do travel

- Check travel restrictions before you go.
- Get your flu shot before you travel.
- Always wear a mask in public settings and on public transportation.
- Stay at least 6 feet apart from anyone who is not in your household.
- Wash your hands often or use hand sanitizer.
- Avoid touching your mask, eyes, nose, and mouth.
- Bring extra supplies, such as masks and hand sanitizer.



WHAT ARE THE MOST PROMISING TREATMENTS?

METHODIST HAS ONE OF THE LOWER DEATH RATES OF ANY HOSPITAL. DOES METHODIST HAVE A 'COVID BEST PRACTICES' THAT THEY SHARE WITH OTHER HOSPITALS? IF A LOVED ONE WERE TO GET SICK AT ANOTHER HOSPITAL, IS THERE A PARTICULAR 'FORMULA' TO THE TREATMENT OF PATIENTS THAT HAS BEEN SHARED?

HM Treatment Protocols

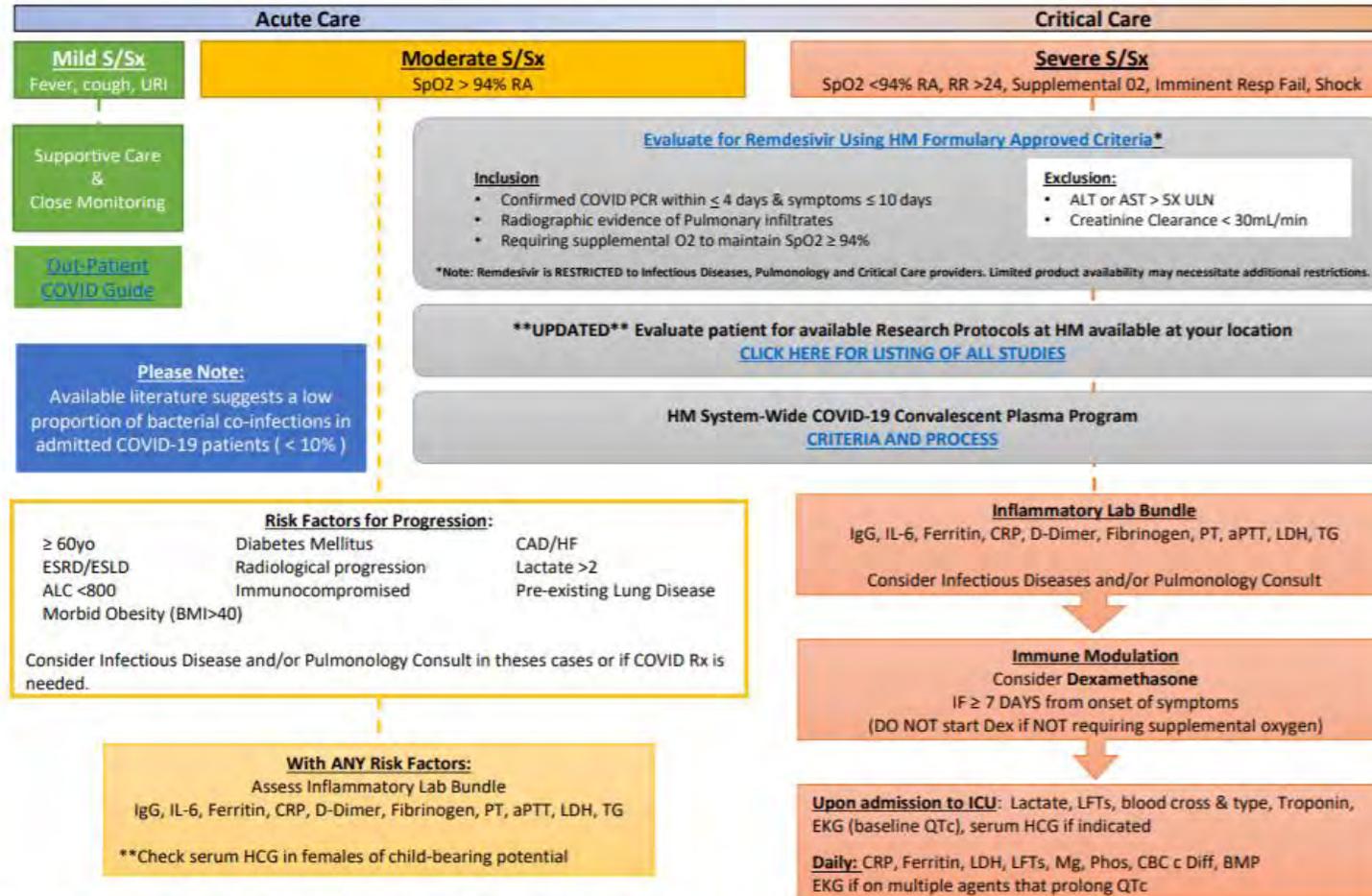
v. 15-Sept-2020
Next review:
17-Aug-
wlm

HM SARS-CoV-2 / COVID-19 TREATMENT ALGORITHM

This is a guidance document only and is not a replacement for clinical judgement in a multidisciplinary collaborative.

Confirmed POSITIVE SARS-CoV-2(COVID-19) PCR

All COVID-19 patients should receive chemical VTE prophylaxis unless contraindicated - [HM COVID Anticoagulation Guide](#)



→ Contact William Musick, PharmD (832-474-4749, wmusick@houstonmethodist.org) with questions and/or updates.

- Regeneron (Press release)
 - Dual mAb “cocktail” in 275 outpatients
 - Greater effect with poor native antibody response, high viral load
 - Reduced medical visits (4.9% low dose / 7.7% high dose vs. 15.2% placebo)
 - Infusion reactions: 2 in placebo group, 1 in antibody group
 - Inpatient trial
 - Pause for “unfavorable risk / benefit”
 - No details yet

Monoclonal Antibody Results

- Lilly
 - Single mAb in 452 outpatients (NEJM October 2020)
 - Hospitalization / ER visits: 1.7% treated vs. 6% placebo (RR = .28)
 - 8% resistant mutants in treated group vs. 6% in placebo
 - EUA November 2020 for high-risk outpatients
 - Dual mAb “cocktail” in 268 outpatients (Press release)
 - Hospitalization / ER visits: 0.9% treated vs. 5.8% placebo (RR = .15)
 - No resistant mutants in treated group
 - Inpatient trial halted for futility (Press release)
 - No details yet

U.S. reaches deal with Eli Lilly for experimental SARS-CoV-2 antibody treatment

[Reuters](#) (10/28) reports the U.S. “will pay as much as \$1.19 billion to Eli Lilly and Co to secure nearly 1 million doses of its experimental [SARS-CoV-2] antibody treatment.” The company “will start delivering 300,000 doses of the treatment, for which it is being paid \$375 million, within two months of receiving an emergency use authorization.” According to HHS, the federal government then “has an option to buy an additional 650,000 vials for \$812.5 million.”

Initial allocation for Texas = 5,780 vials / week

WILL YOU TAKE THE VACCINE? IS THE VACCINE SAFE?

THERE HAVE BEEN CONCERNS ABOUT SAFETY AND EFFICACY OF NEW VACCINES DUE TO REPORTS OF SAFETY SHORTCUTS AND REDUCED TESTING STANDARDS. PLEASE SHARE YOUR THOUGHTS ON PFIZER, ITS MANUFACTURING PROCESSES AND TESTING WITH REGARD TO SAFETY AND CLINICAL TRIALS.

Is COVID-19 HERE TO STAY? HOW LIKELY IS IT THAT THE (EVENTUAL) VACCINE WILL BECOME PART OF NORMAL CHILDHOOD/ADULT INOCULATIONS?

Vaccine Progress

Vaccine	Antibody Response	T Cell Response	Species	N of Doses	Protection (Monkeys)	EUA Target
Moderna	100% (2x – 8x CP)	100%	Human	2	Infection	December 2020
Pfizer / BioNTech	100% (5x – 30x CP)	94%	Human	2		November 2020
J & J	100%	82%	Human	1	Infection	Q1 2021
Oxford / Astra Zeneca	100% (= CP)	100%	Human	2	Disease	December 2020
Novavax	100% (2x CP)	100% (subgroup)	Human	2		Q1 2021

CP = convalescent plasma

- Pfizer
 - 43,538 enrolled and randomized to vaccine or placebo
 - 170 infections so far / 95% protection with vaccination
 - 10 severe cases, 9 in placebo group
 - Appears to be effective in all ages and ethnicities
 - Unknowns
 - Infection vs. disease
 - Duration of protection
 - Safety profile appears very good (2-4% headache / fatigue)
 - Logistics: Two doses & extreme cold chain needed
 - mRNA technology appears to work
 - Phase 1 & pre-clinical data suggest other vaccines will also be effective

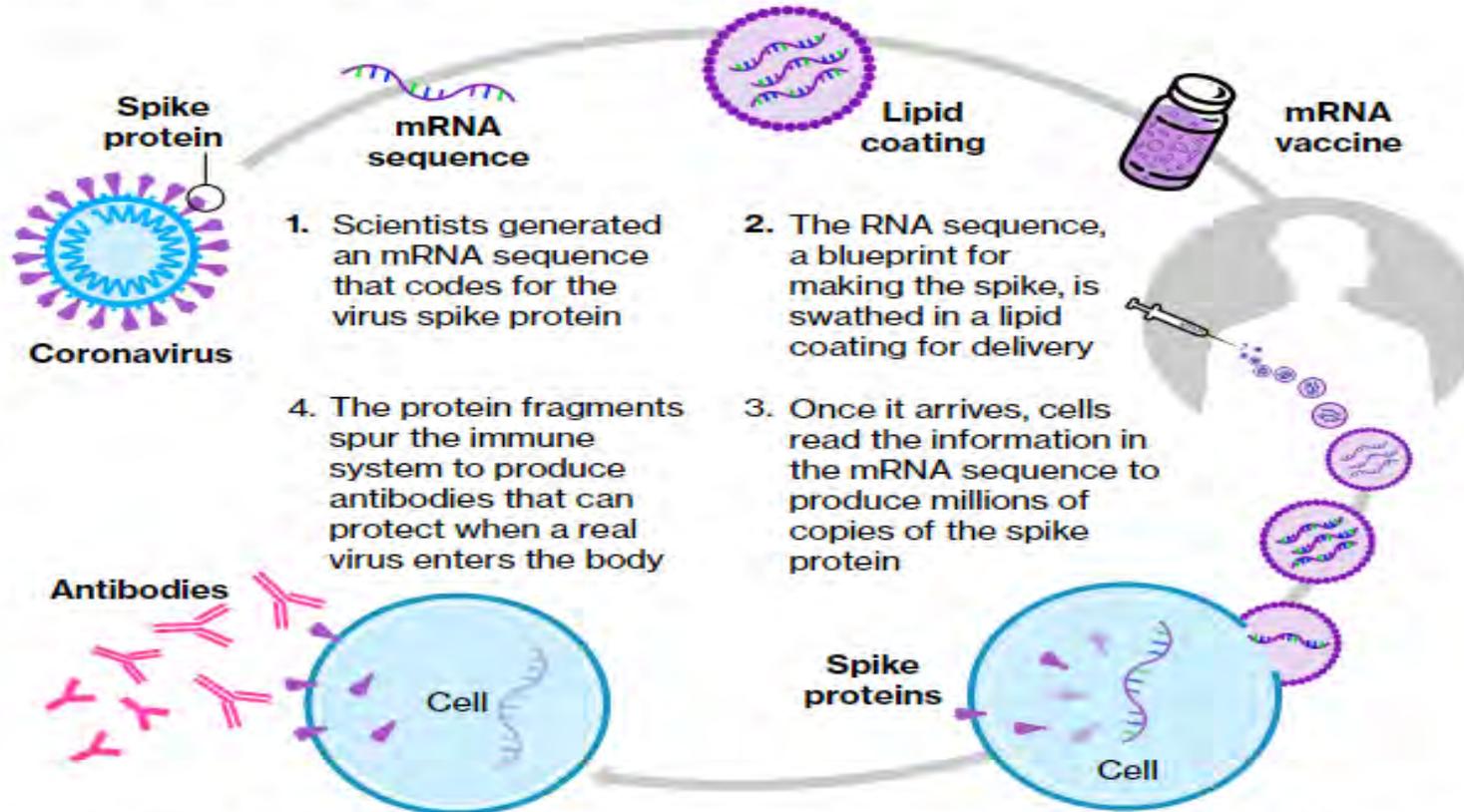


- Moderna
 - > 30,000 enrolled and randomized to vaccine or placebo
 - 95 infections so far / 95% protection with vaccination
 - 11 severe cases – all in placebo group
 - Similar efficacy in all subgroups (preliminary review)
 - Unknowns
 - Infection vs. disease
 - Duration of protection
 - Safety profile appears very good
 - Logistics: Two doses & cold chain needed
 - Phase 1 & pre-clinical data suggest other vaccines will also be effective



How mRNA Vaccines Work

The vaccine spurs healthy cells to produce viral proteins that stimulate a potent immune response



Sources: Pfizer, Bloomberg research

Bloomberg

How Did They Get to 90-95%?

- Hypotheses
 - Coronavirus is an easy target
 - Cross reactivity from other HCoV – is every dose a booster?
 - mRNA technology may just be that good
 - note the Ab responses for Pfizer and Moderna compared with viral vector (AstraZeneca)

- J & J
 - Trial re-started
- AstraZeneca
 - Trial re-started
 - Analysis of phase 1-2 data shows good immunogenicity > 55 yo
 - Reactogenicity was lower in > 55 yo
 - 1 death in Brazil – placebo group

Obstacles?

- Reluctance to accept vaccination
 - Political issues
 - Concerns about potential side effects
- Logistics Challenges
 - Supplies (borosilicate glass vials, needles, syringes, etc.)
 - Cold chain of refrigeration
 - Air freight capacity (8,000 jumbo jets)
 - Paperwork, customs, health regulations, etc.
 - Organizing administration sites, records, personnel
 - Monitoring safety, side effects

THANK YOU FOR ATTENDING OUR TOWN HALL CONVERSATION

If you would like more information about Transplant, Cancer, Testing, or The Society for Leading Medicine, please contact foundation@houstonmethodist.org

Take care and be well

