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Maryland Situation Update on Coronavirus Disease 2019 (COVID-19)

Maryland Department of Health

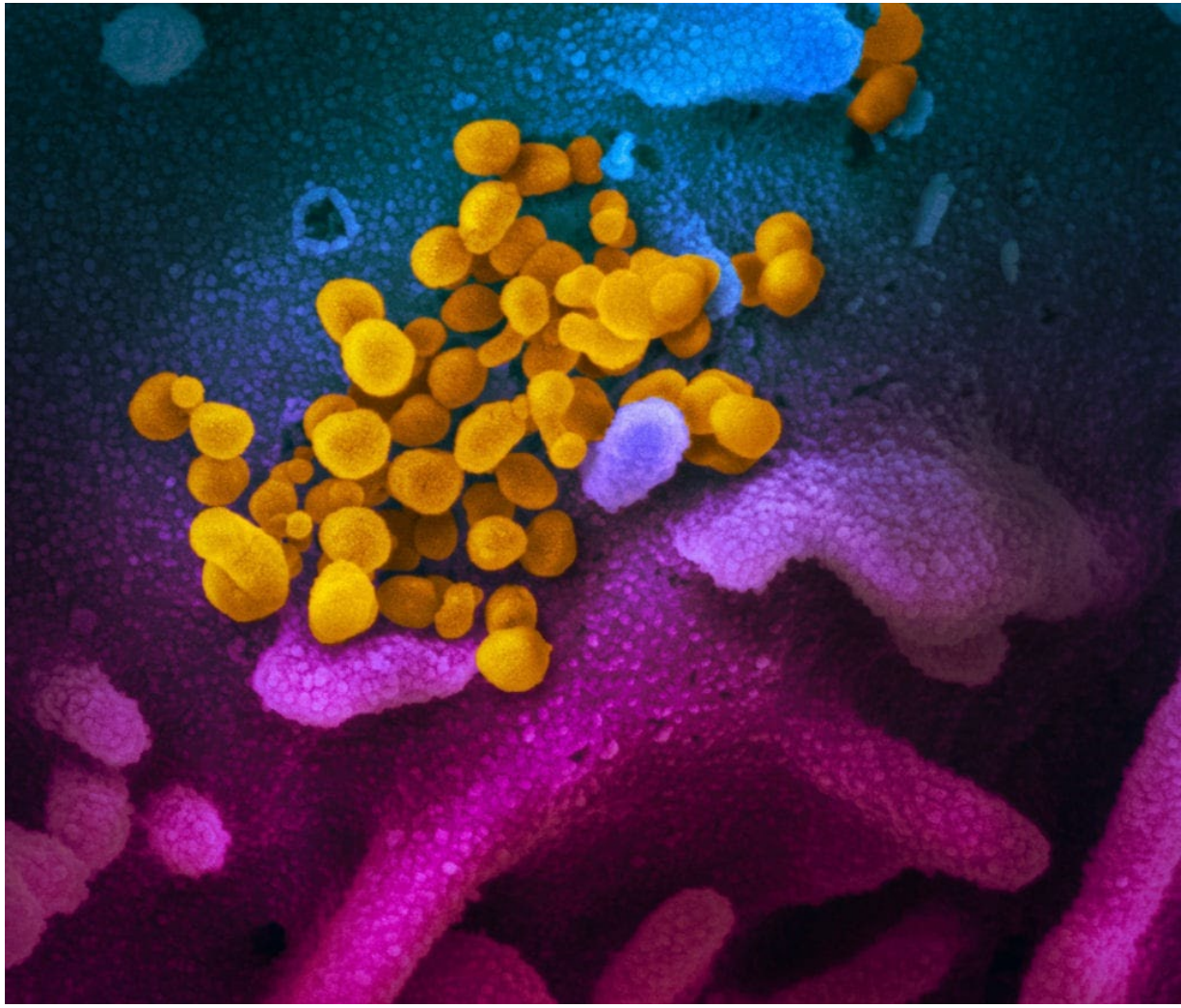
Infectious Disease Epidemiology and Outbreak Response Bureau

January 28, 2021

Call Agenda

- Maryland Epi Updates
- TAT Updates
- Out of Hospital COVID-19 Management: Less is More

Picture Courtesy of NIAID-RML



COVID-19 Epi Summary

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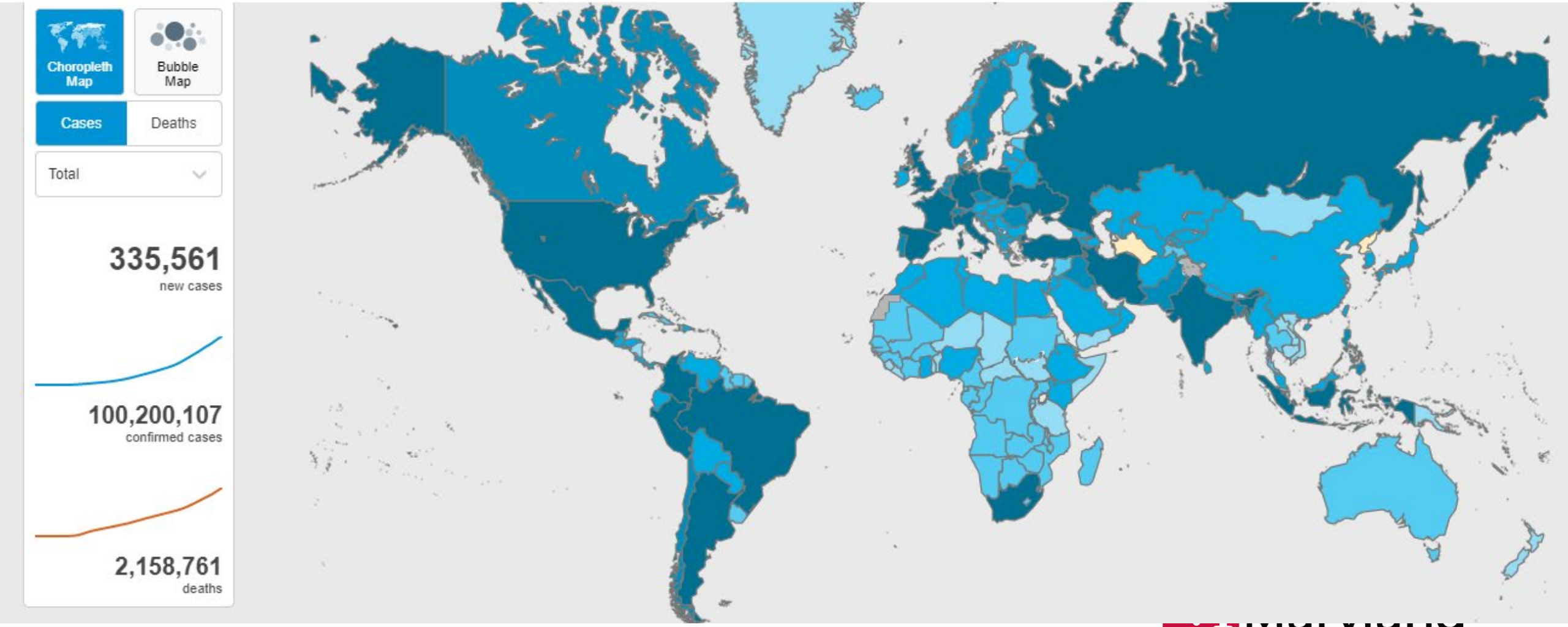
Worldwide: COVID-19



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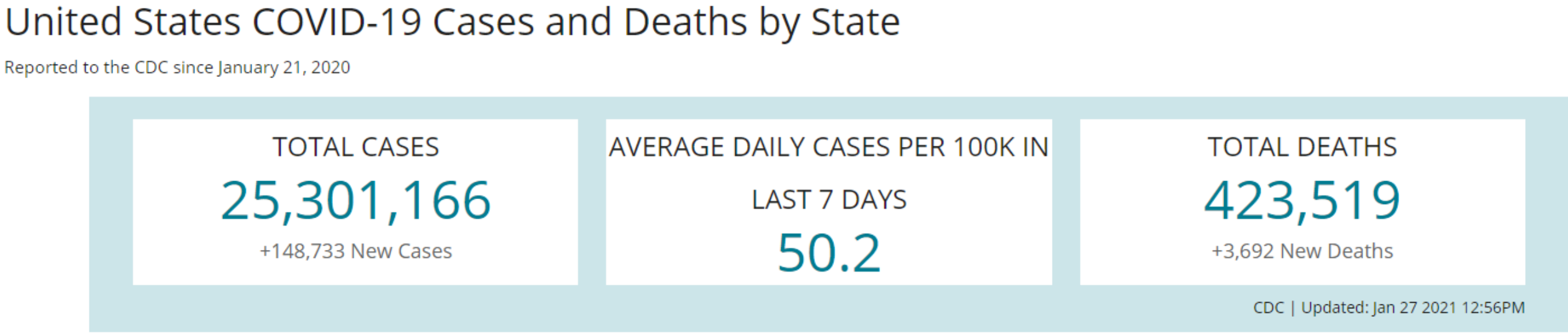
Source: https://covid19.who.int/ accessed January 28, 2021

U.S.: COVID-19



Source: CDC, https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days, accessed January 28, 2021

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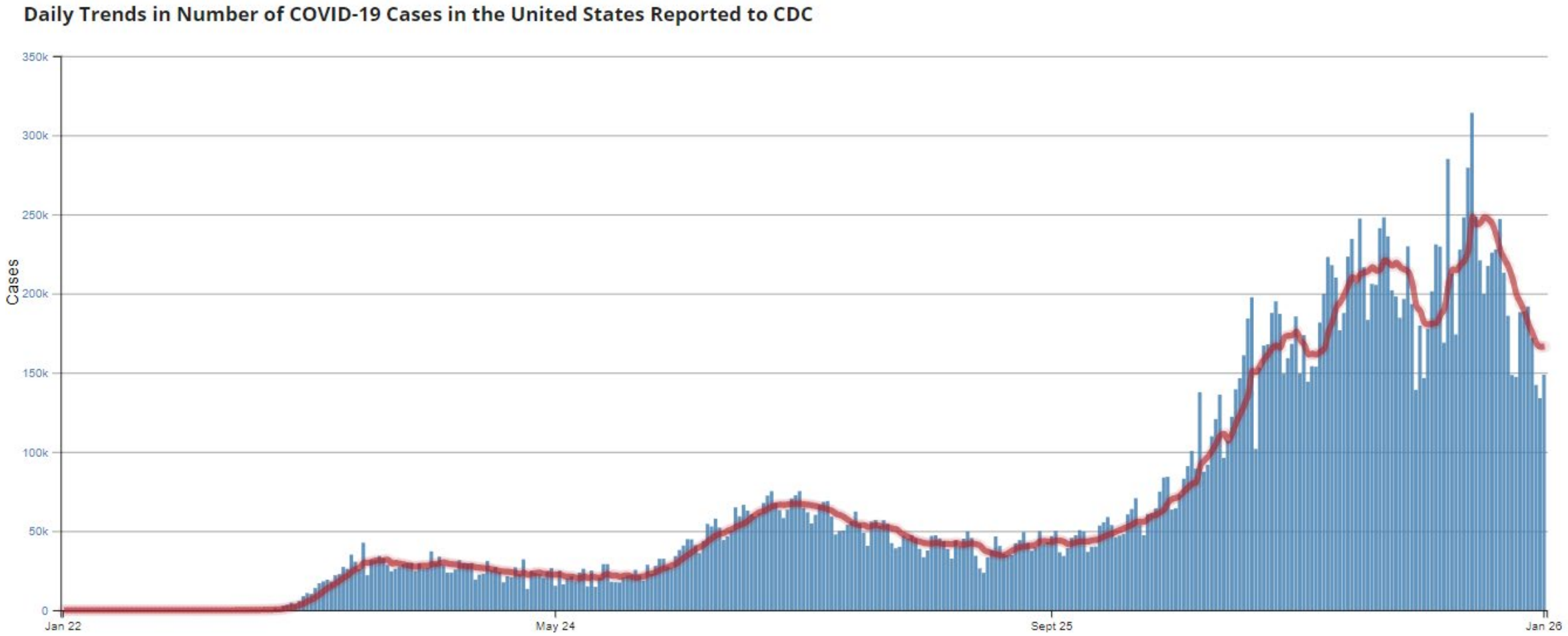
Daily US Trends in COVID-19 Cases



Source: CDC, https://www.cdc.gov/covid-data-tracker/index.html#trends, accessed January 28, 2021

US: COVID-19 Vaccinations

Overall US COVID-19 Vaccine Distribution and Administration

Total Doses Distributed	Total Doses Administered	Number of People Receiving 1 or More Doses	Number of People Receiving 2 Doses
47,230,950	24,652,634	20,687,970	3,801,053

CDC | Data as of: Jan 27 2021 6:00am ET | Posted: Jan 27 2021 12:56PM ET

Source: https://covid.cdc.gov/covid-data-tracker/#vaccinations accessed January 28, 2021

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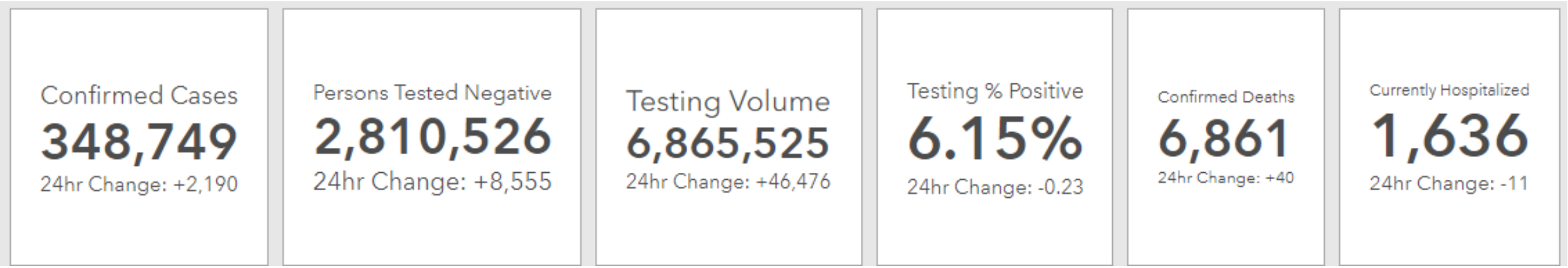
Maryland: COVID-19



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

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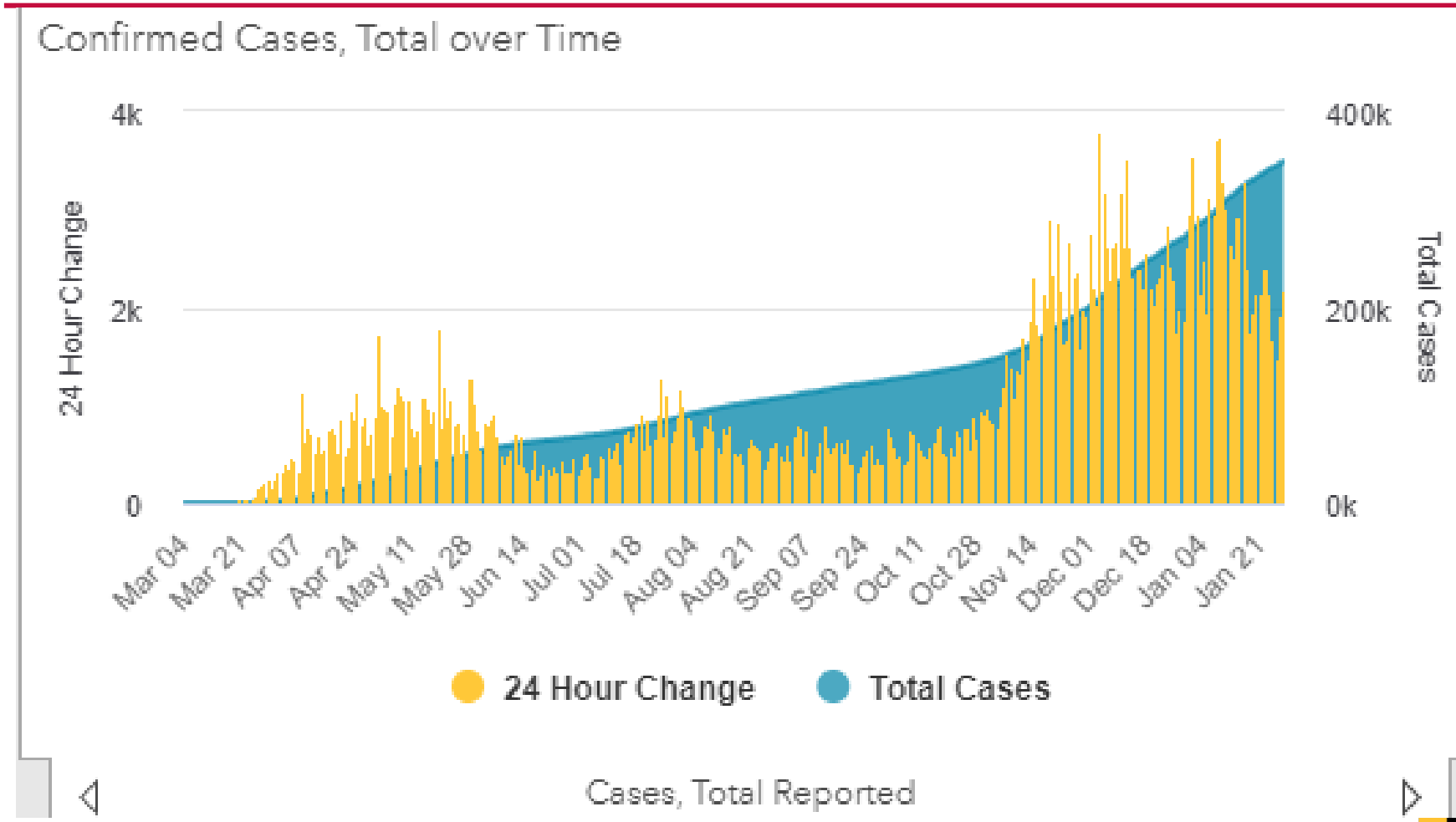
Maryland: COVID-19



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

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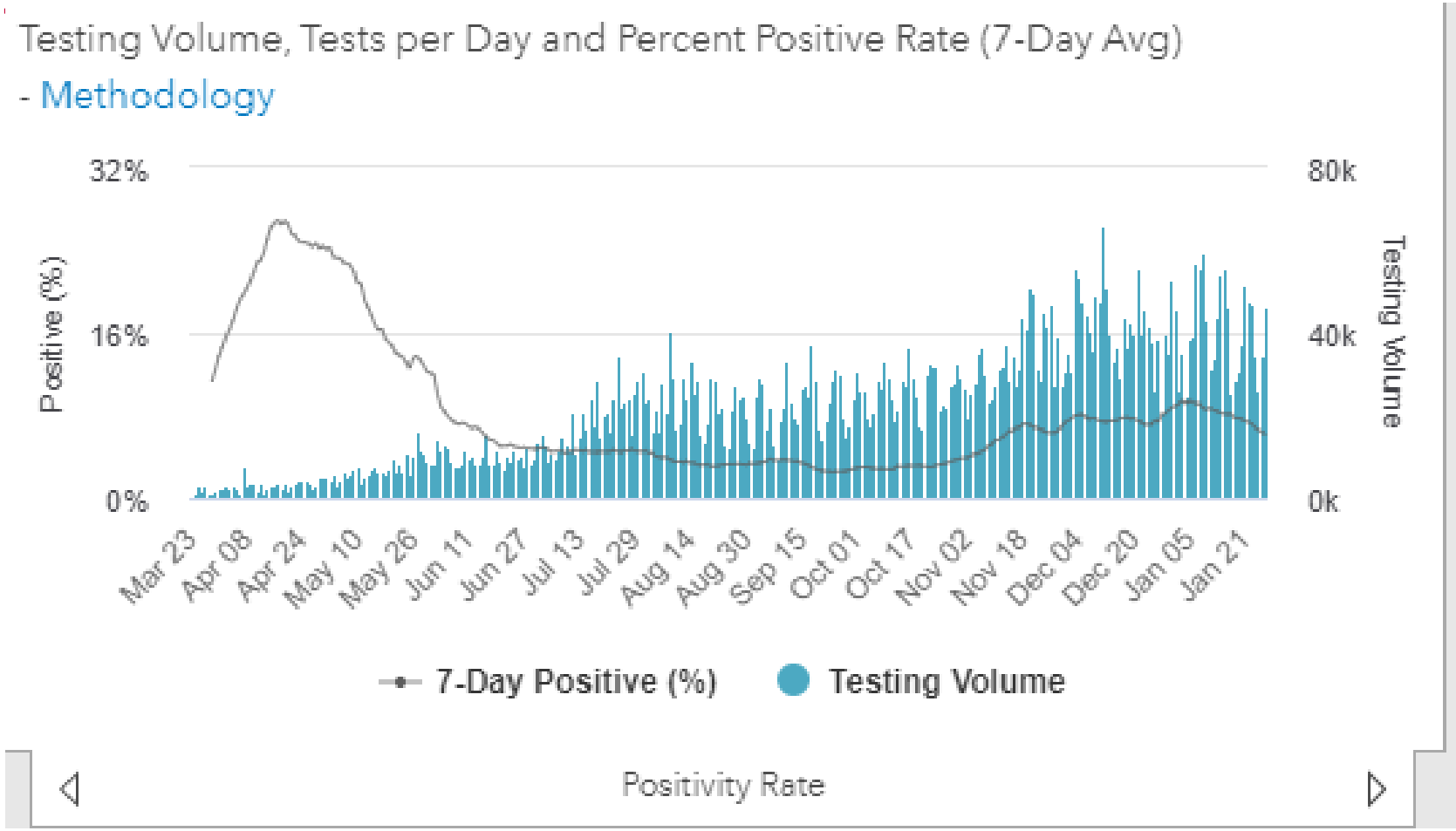
Maryland: COVID-19



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

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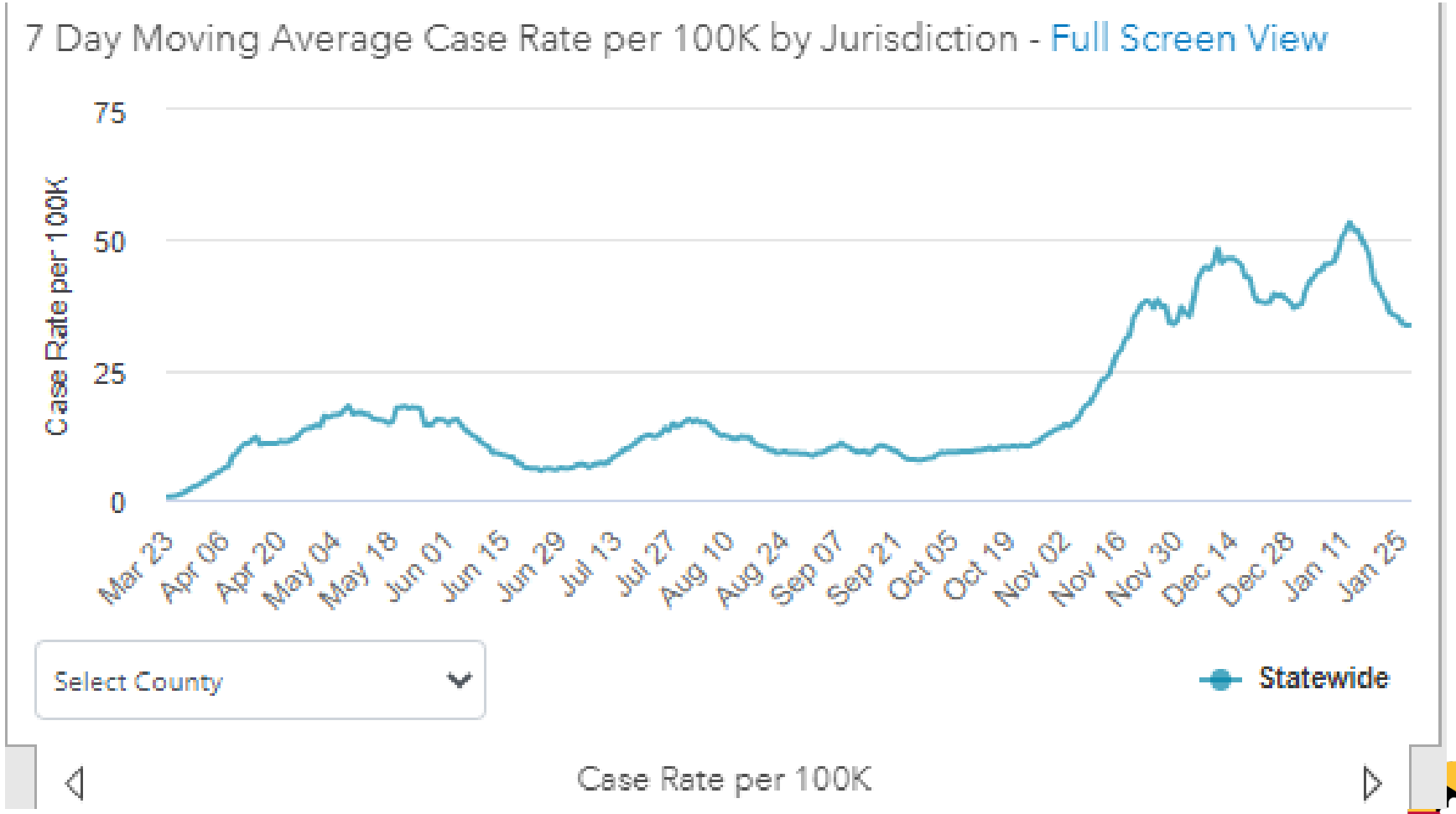
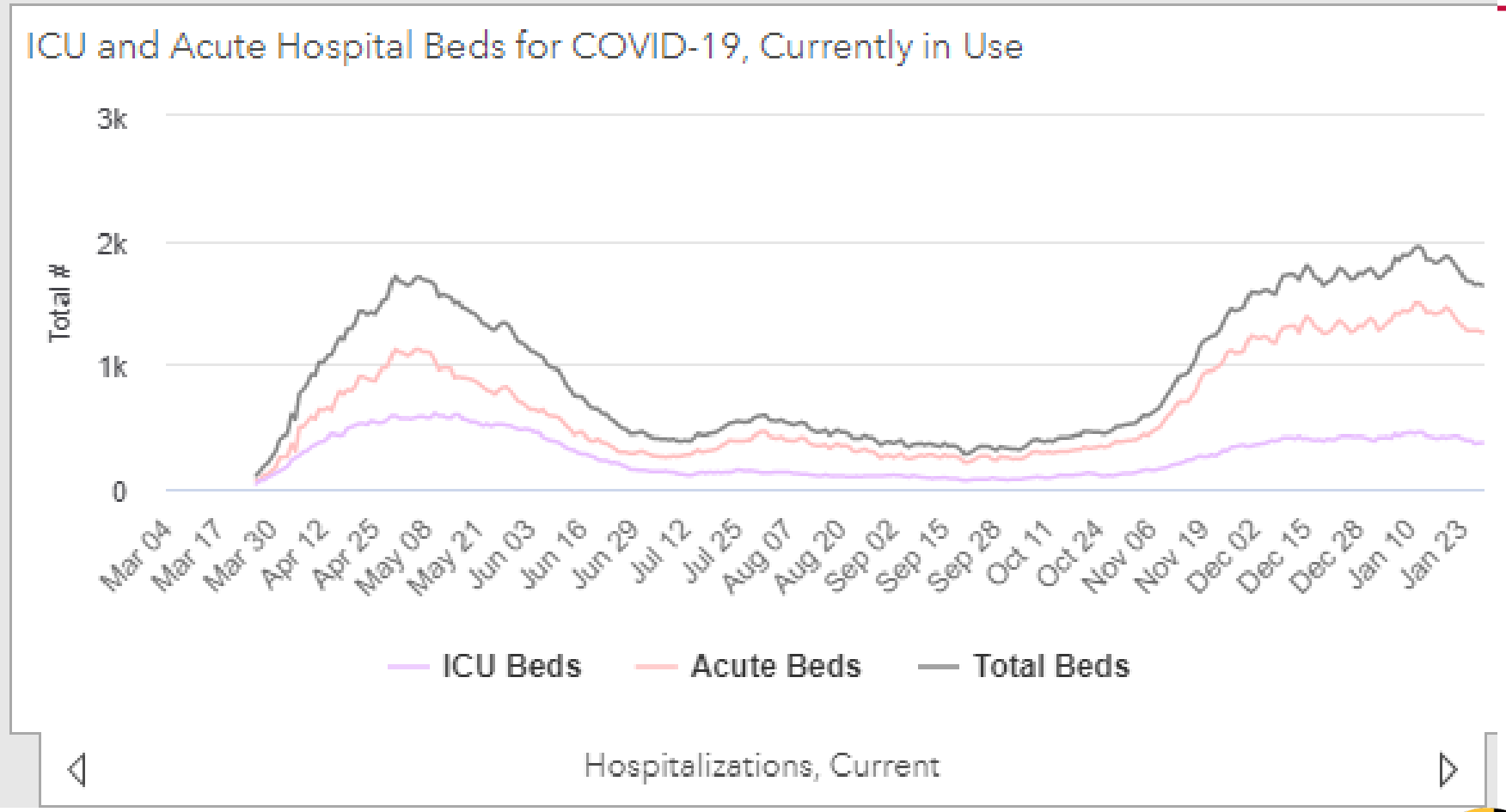
Maryland: COVID-19



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

Maryland: COVID-19



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

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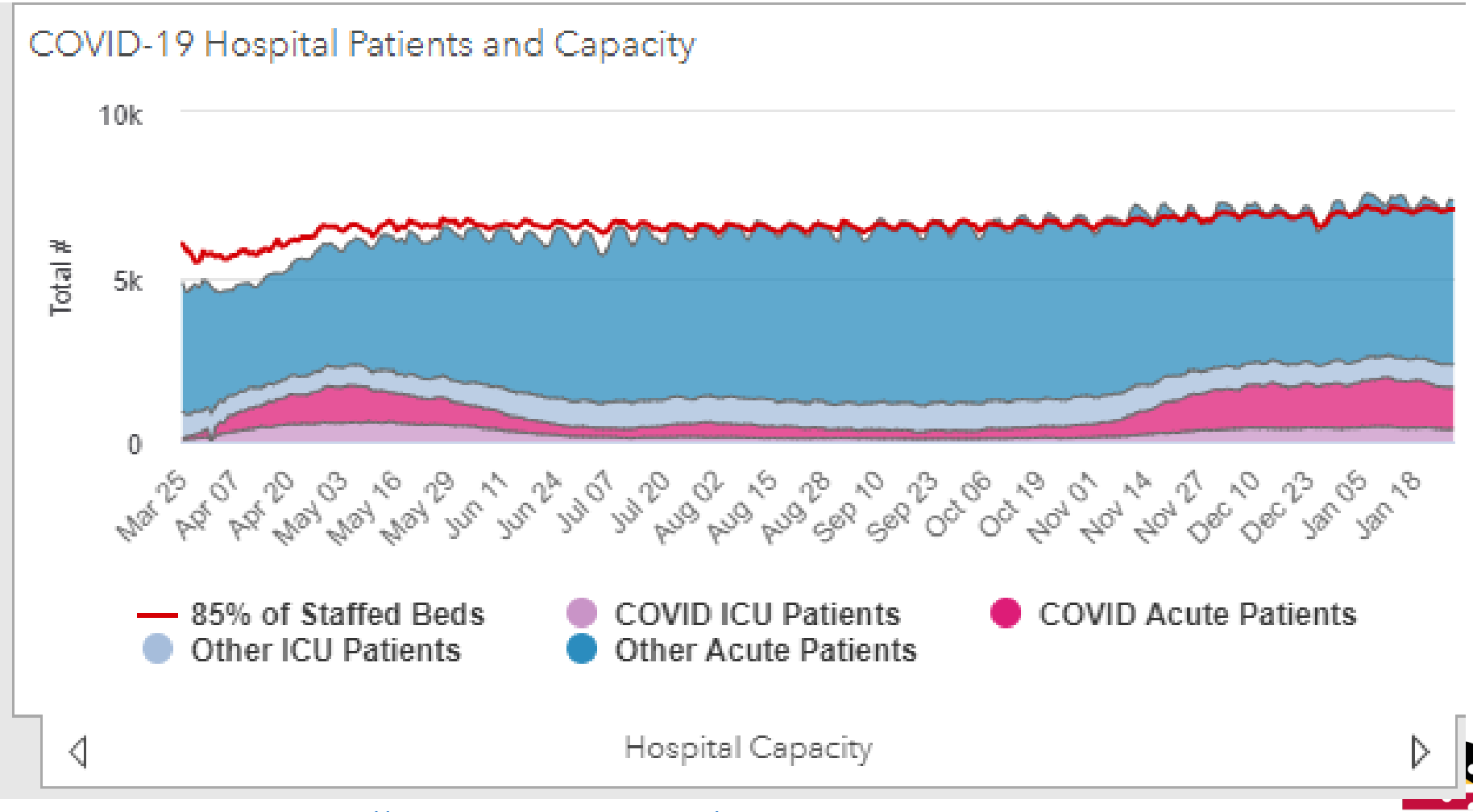
Maryland Hospital Capacity



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

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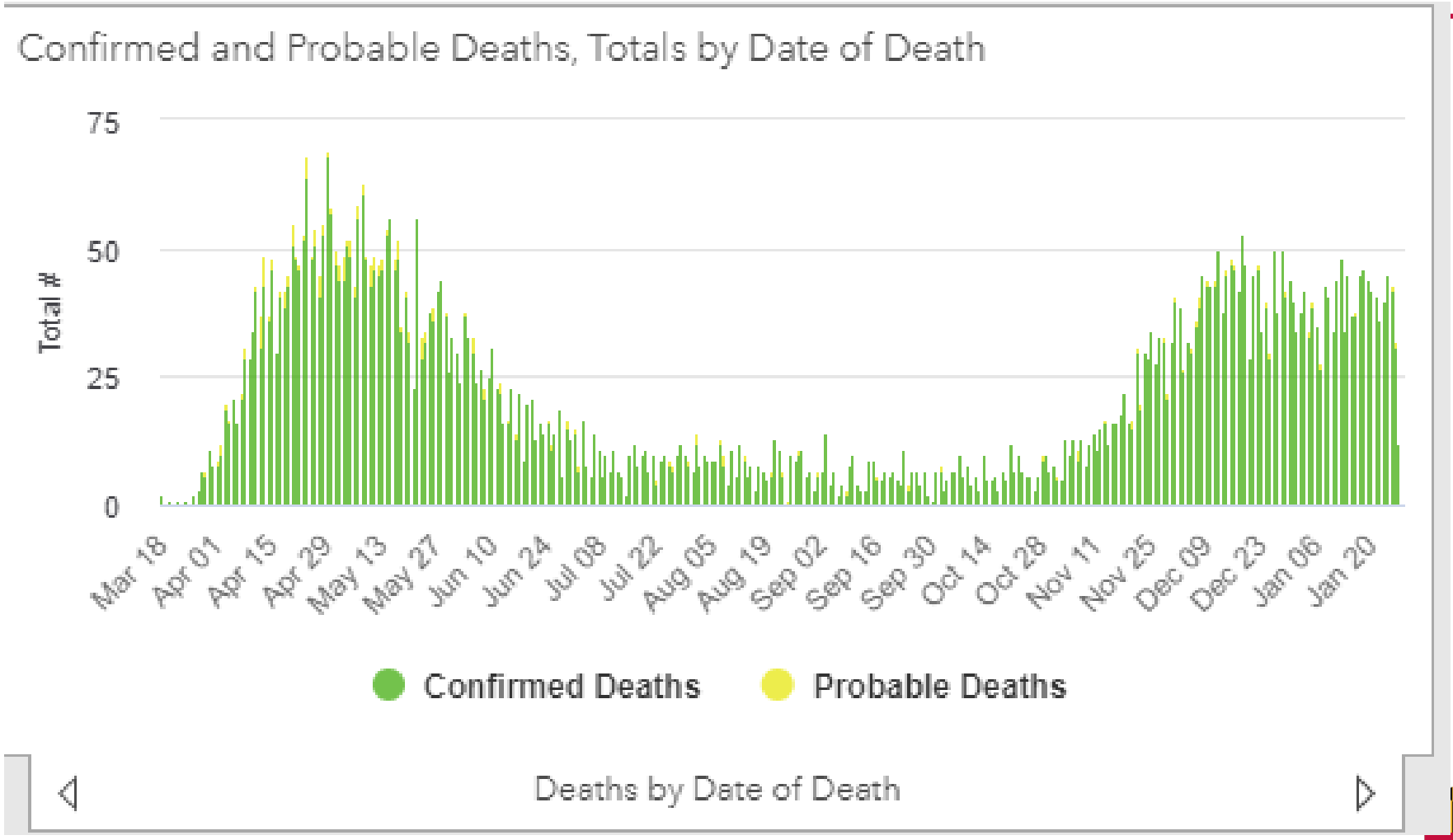
Maryland: COVID-19



Source: https://coronavirus.maryland.gov/, accessed January 28, 2021

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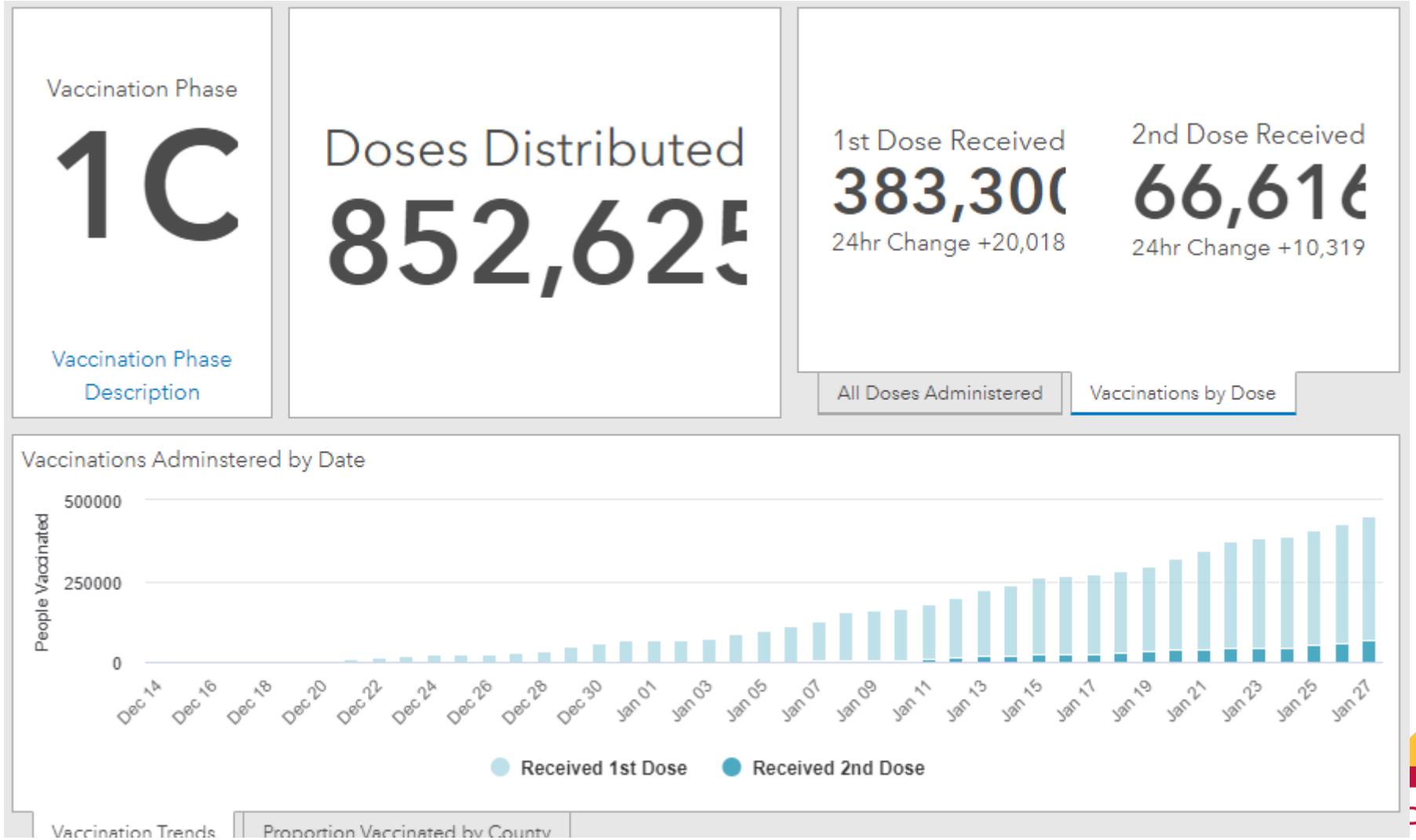
Maryland Vaccine Dashboard

https://coronavirus.maryland.gov/



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Maryland Influenza Epi Update

Week Ending January 15nd, 2021

Influenza-like illness (ILI) activity in Maryland was **minimal**

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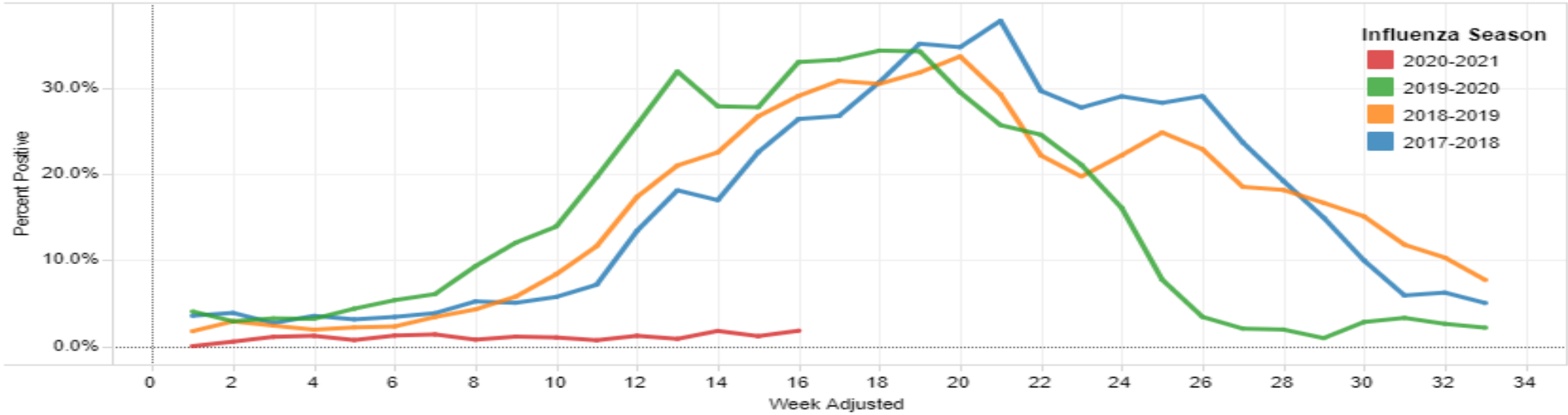
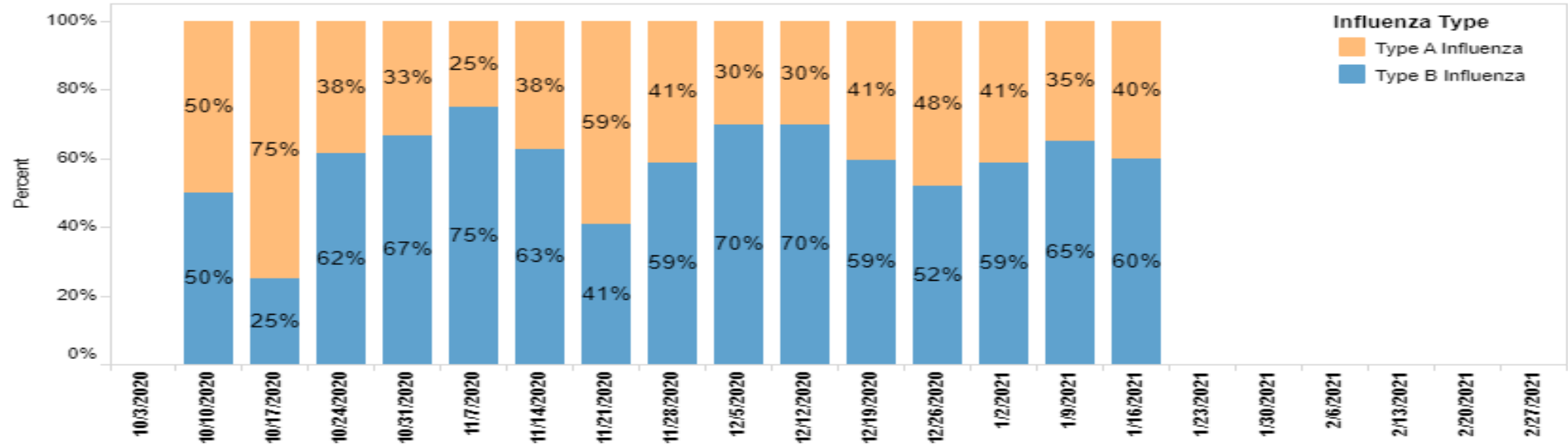
https://phpa.health.maryland.gov/influenza/Pages/flu-dashboard.aspx

Clinical Laboratory Influenza Testing



Proportion of Positive Influenza Tests Performed by Clinical Labs



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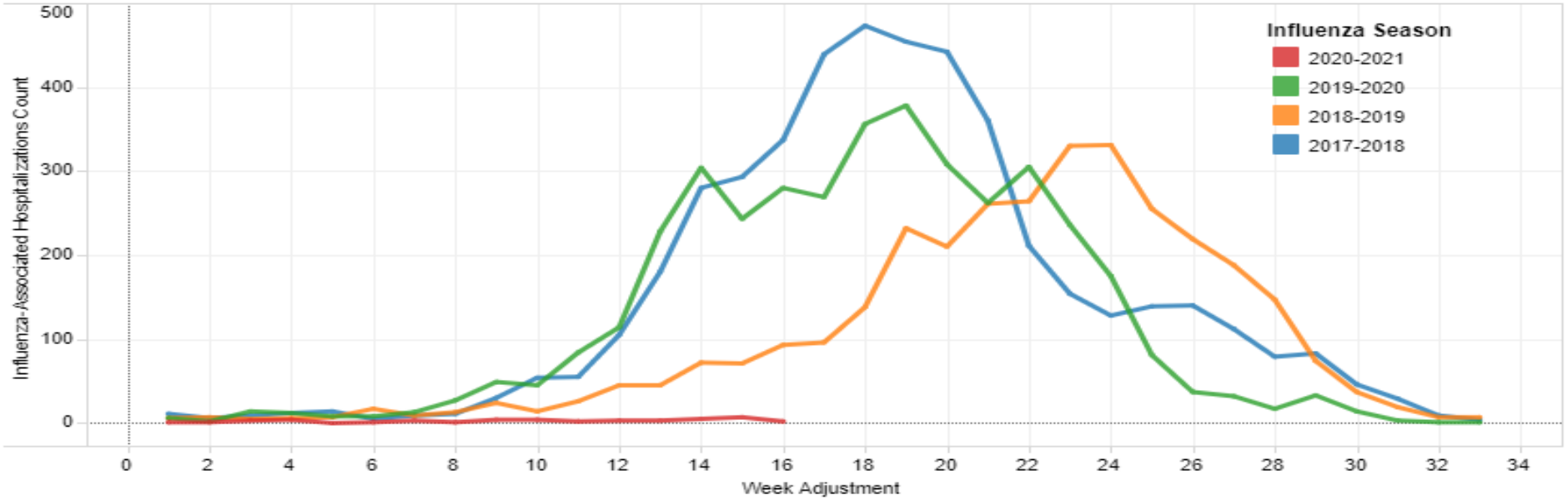
https://phpa.health.maryland.gov/influenza/Pages/flu-dashboard.aspx

Influenza-associated Hospitalizations



Influenza-Associated Hospitalization by Age Group

Age Group	This Week Number	This Week Percent	Last Week Number	Last Week Percent	This Season Number	This Season Percent
0-4	0	0%	0	0%	2	5%
5-24	0	0%	0	0%	2	5%
25-49	0	0%	2	29%	9	20%
50-64	2	100%	1	14%	7	16%
65+	0	0%	4	57%	24	55%
Grand Total	2	100%	7	100%	44	100%

Influenza-Associated Hospitalization by Gender

Gender	
Female	26
Male	18

Influenza-Associated Hospitalization by Race

Race	
African American or Black	20
White	22
Other	2

Influenza-Associated Hospitalization by Ethnicity

Ethnicity	
Hispanic or Latino	3
Non Hispanic or Latino	41

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TAT Updates

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- **24-hours TAT operation**:
-
- · There are two full 24-hours assistance teams that go out to facilities in each region daily. With exception to the Central region, who also sends out one regular TAT team daily due to the number of facilities in that region.
- · Facilities are selected based off of their risk score analysis and number of increased resident positive cases.
- · Both day and night teams consist of 3 RN/LPN and 2 GNA'S.
- · While in facilities teams cover monoclonal antibody education and assist with the process obtaining treatment for residents, TAT checklist, infection prevention, FIT testing, and PCR/POC testing assistance.
-

- **Fit Testing education / Assistance:**
- Must have own supplies
- Must have the OSHA health evaluation completed and signed by a provider
- Can request assistance by emailing me Melissa.Welch@Maryland.gov

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Out of Hospital COVID-19 Management: Less is More

Jacqueline Bork, MD, MS

Emily L. Heil, PharmD, MS

An 80-year-old male nursing home resident with mild dementia and congestive heart failure, was found to have a positive SARS-COV2 PCR test after another resident tested positive earlier. Vital signs are stable with O2 saturation of 95% on RA and febrile to 100.8 ºF.
You follow facility isolation procedures, prescribe symptom relief (antitussives, antipyretics etc.), order routine vital sign measurements with pulse oximetry, and…

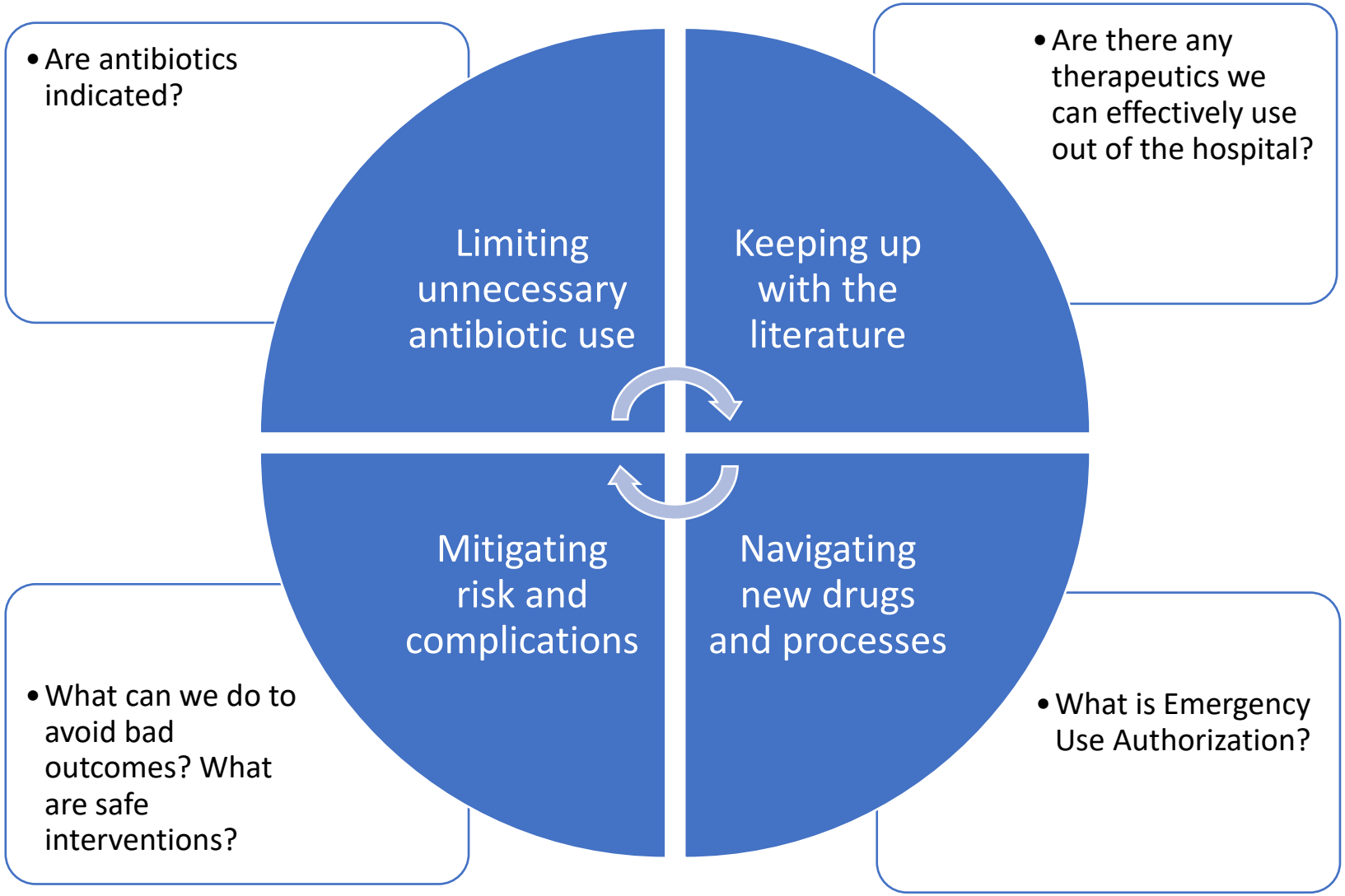
A. Prescribe Z-pak (Azithromycin)
B. Prescribe steroid of choice (prednisone, dexamethasone)
C. Prescribe hydroxychloroquine
D. Counsel patient/family on possible treatment with neutralizing monoclonal antibody
E. All of the above
F. None of the above (type other interventions)

Out of Hospital COVID

- Most adult patients infected with COVID managed out of the hospital (>80%)
  - Urgent Care
  - Primary Care
    - Telehealth
- Emergency Department highly utilized care location for COVID diagnosis and management
- Non-acute care facilities (e.g., long-term care facilities)

https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

What are the issues?

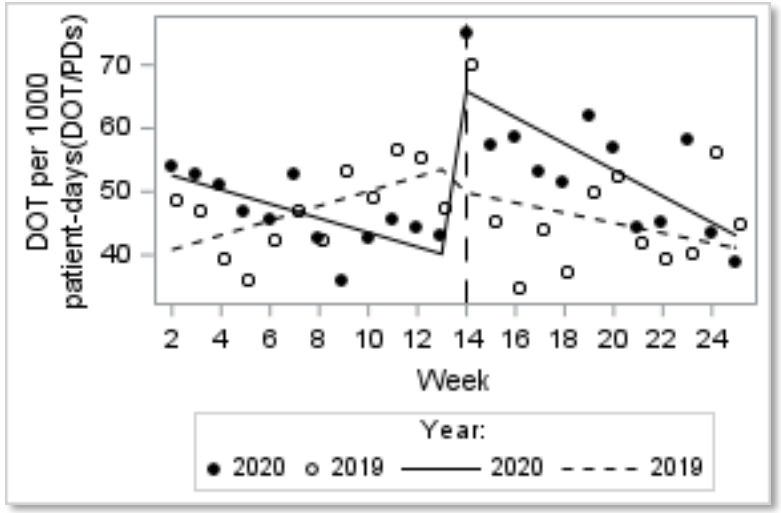


Local Experience – Diagnostic Uncertainty + Novel Disease State

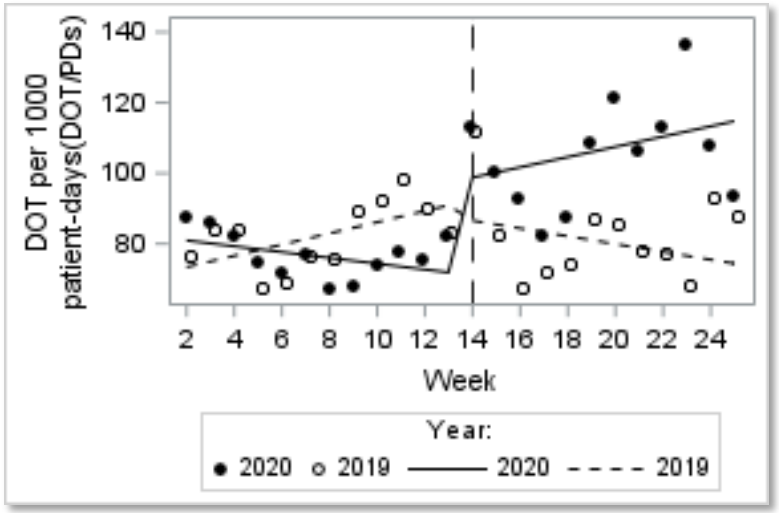
↑ Respiratory viral panels

↓ Sputum cultures, bronchoscopies

Antibiotics for Bacterial Pneumonia during 1st wave of Pandemic



Within 7d of admission



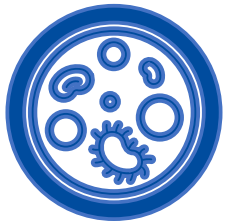
Total

Internal data, UMMC ASCOT

Antimicrobial Use (AU) during COVID-19

3.5%
Acute bacterial co-infection in COVID-19

14.3%
Secondary bacterial infection in COVID-19



72%
Patients received antibiotic therapy

74%
Antibiotics prescribed were fluoroquinolones & third-generation cephalosporins

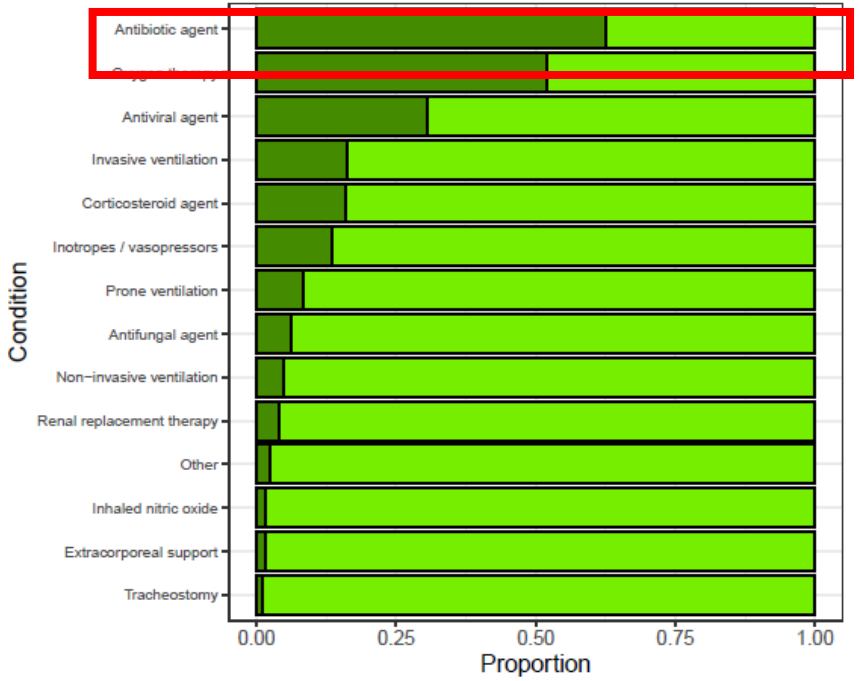
Langford BJ, et al. Clin Microbiol Infect 2020 (epub ahead of print); doi:10.1016/j.cmi.2020.07.016

Antimicrobial Use (AU) during COVID-19

- International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC) COVID-19 Report: 08 April 2020
  - 10,363 individuals from 240 sites across 25 countries
  - **62%** received antibiotics, **74.5%** among ICU patients

Treatment

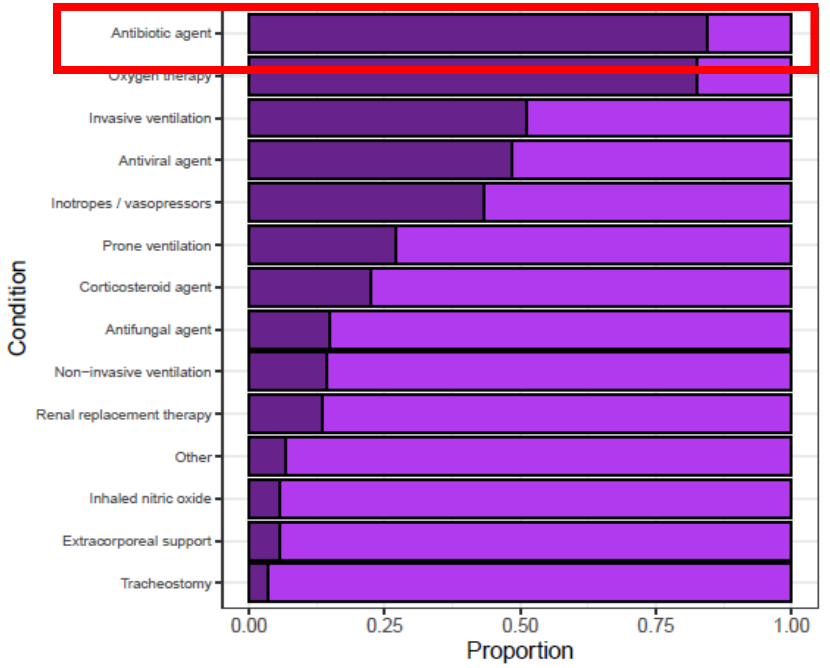
Figure 8: Treatments used. This only includes patients where this information was record



Intensive Care and High Dependency Unit Treatments

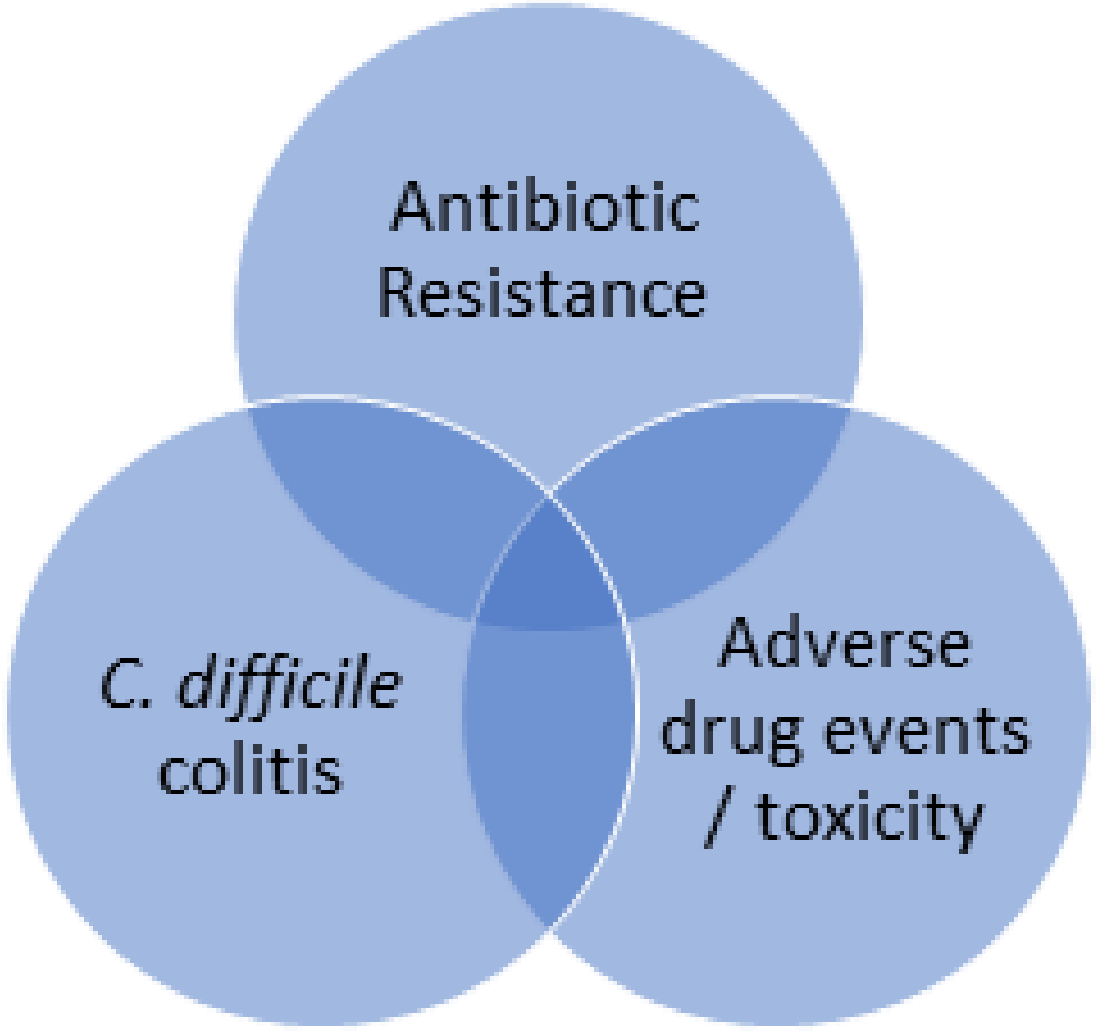
These figures include only the 212 ICU/HDU patients with complete details of treatments.

Figure 10: Treatments used.



International Severe Acute Respiratory and Emerging Infections Consortium. COVID-19 Report: 08 April 2020. Available at https://media.tghn.org/medialibrary/2020/04/ISARIC_Data_Platform_COVID-19_Report_8APR20.pdf Accessed Jul 20, 2020.

Why do we care??



Recommendations for Antibiotic Use in COVID-19

Guidelines	Antimicrobial Recommendations
National Institutes of Health	-In patients with COVID-19 and severe or critical illness, there are insufficient data to recommend empiric broad-spectrum antimicrobial therapy in the absence of another indication. (BIII) -If initiated they should be reassessed daily in order to minimize adverse consequences. (AIII)
World Health Organization	-Mild COVID-19: Recommend against antibiotics -Moderate COVID-19: Recommend against antibiotics, unless there is clinical suspicion of a bacterial infection -Severe COVID-19: Recommend empiric antimicrobials to treat all likely pathogens, should be targeted to host factors and local epidemiology, and assessed daily for de-escalation
Surviving Sepsis Campaign: Guidelines on the management of critically ill adults with COVID-19	In mechanically ventilated patients with resp. failure, suggest use of empiric antimicrobials/antibacterial agents, over no antimicrobials (weak rec., low-quality evidence) -Re-evaluate for de-escalation daily

1. https://www.covid19treatmentguidelines.nih.gov/ 2. 2. https://www.who.int/publications/i/item/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected. 3. Alhazzani W, et al. Intensive Care Med. 2020;46(5):854-887.

Repurposing drugs: What works ?

Hydroxychloroquine and Ivermectin..

Hydroxychloroquine

- Chloroquine has activity against SARS-CoV-2 in vitro
- **Data from multiple randomized controlled trials** of **hydroxychloroquine** demonstrated **no benefit** in the prevention or treatment of COVID-19.
- Additionally, the **inclusion of azithromycin to hydroxychloroquine has not been shown to be efficacious and is potentially dangerous** because of the interaction of QTc prolongation and possible severe, potentially lethal arrhythmias.
- **Neither hydroxychloroquine nor azithromycin should be prescribed for treatment or prevention of COVID-19.**

Ivermectin

- Ivermectin is an anthelmintic with in vitro activity against SARS-CoV-2, however the dosage needed in humans to display antiviral properties is not safely achievable
- Studies evaluating ivermectin for COVID-19 are limited by open label designs, different dosing regimens, differing clinical endpoints and publication bias
- Not currently recommended for use

Schmith VD. Clin Pharmacol Ther 2020

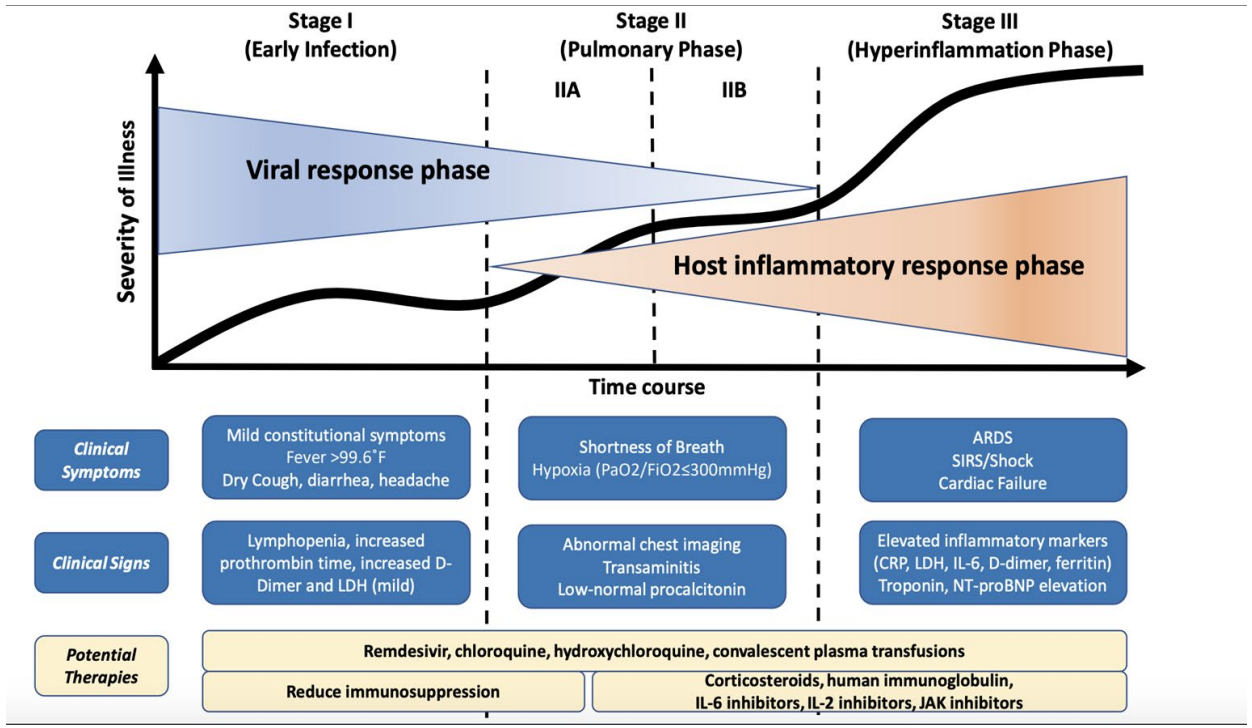
Corticosteroids

HISTORY

Corticosteroid use for SARS and MERS patients
- Higher plasma RNA levels at weeks 2-3 into illness (likely prolonged viremia)
- Increased 30-day mortality

Corticosteroid use for severe influenza pneumonia
- Higher rates of secondary bacterial infection and **mortality (OR 3.06, 95% CI 1.58-5.92)**

Danger Zone



Arabi YM et al. Corticosteroid therapy for critically ill patients with Middle East respiratory Syndrome. Am J Respir Crit Care Med. 2018;197:757-67.

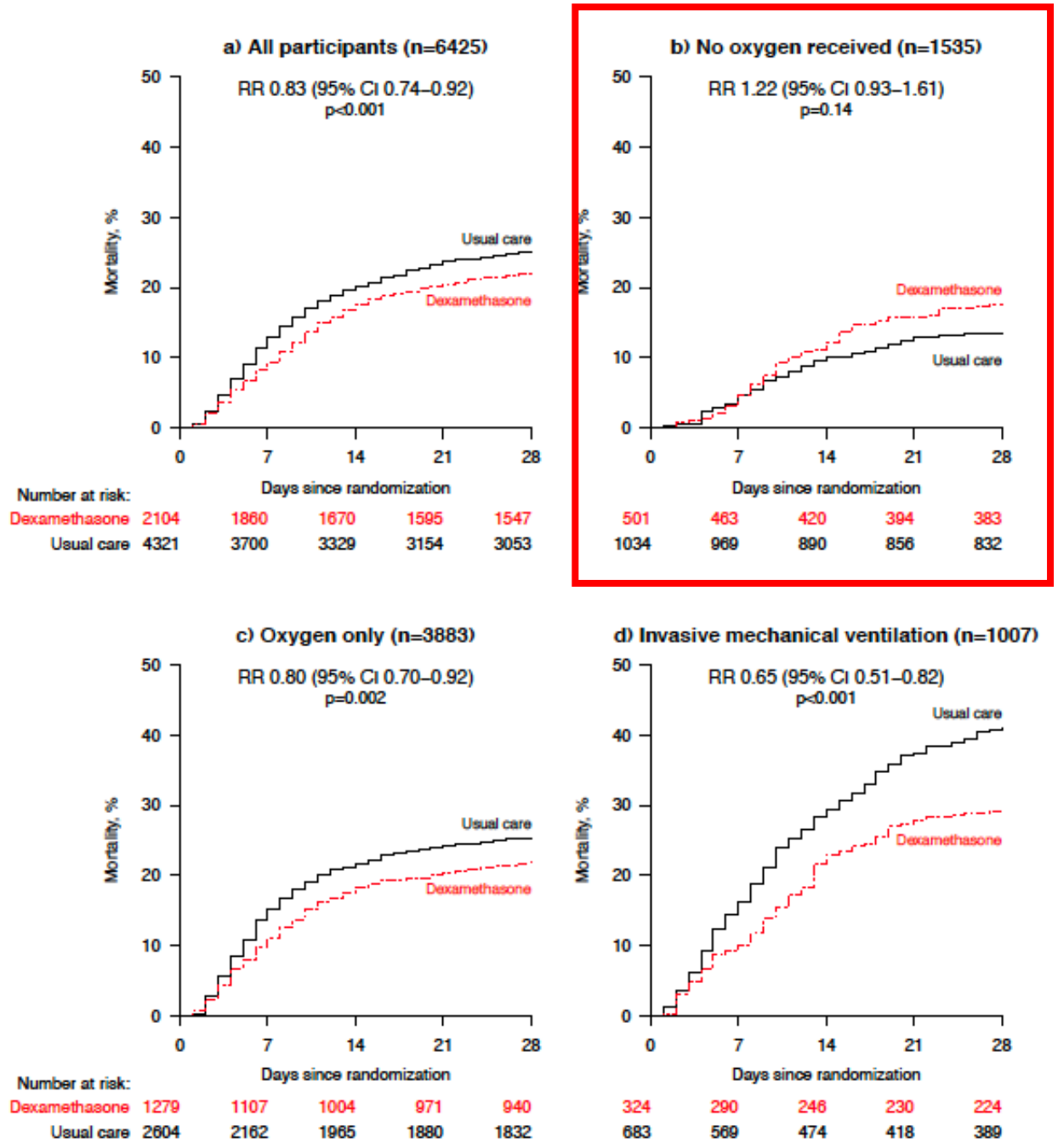
Rodrigo C, et al. Corticosteroids as adjunctive therapy in the treatment of influenza. Cochrane Review https://doi.org/10.1002/14651858.CD010406.pub2

RECOVERY

Randomised Evaluation of COVID-19 Therapy

- Randomized, open-label, adaptive, platform trial comparing multiple different treatments versus usual care in patients hospitalized with COVID-19 conducted across 176 National Health Service sites in the UK
- Inclusion: clinically suspected or lab confirmed SARS-CoV-2 and no medical history that might “in the opinion of the attending clinician put the patient at significant risk if they were to participate”
- Randomized 2:1 to either usual standard or care or usual standard of care plus dexamethasone (IV or PO) 6 mg once daily for up to 10 days (or until discharge if sooner)
- Primary outcome: 28 day all cause mortality
- 2014 randomized to dexamethasone and 4321 to usual care

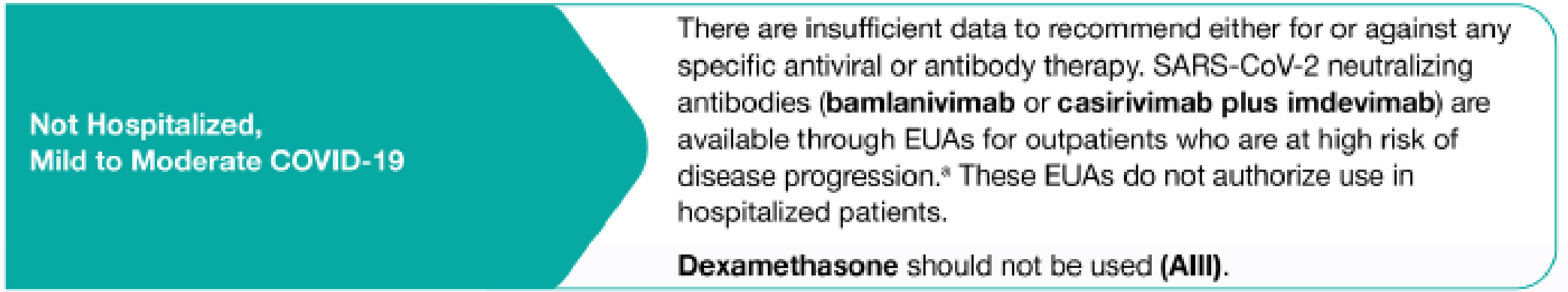
Horby PW, et al. Effect of dexamethasone in hospitalized patients with COVID-19. Preliminary report. https://doi.org/10.1101/2020.06.22.20137273



Dexamethasone was associated with decreased mortality in those with symptoms for more than 7 days but not among those with more recent symptom onset (p<0.001)

Horby PW, et al. Effect of dexamethasone in hospitalized patients with COVID-19. Preliminary report. https://doi.org/10.1101/2020.06.22.20137273

Guidelines for outpatient COVID



https://www.covid19treatmentguidelines.nih.gov/

Neutralizing COVID-19 Monoclonal Antibodies

- Bamlanivimab (Eli, BLAZE-1); n=467
  - Decrease in viral load marginally
  - Lower severity of symptoms
  - Decrease hospitalizations (1.6% vs 6.3%)
- Casirivimab plus imdevimab (Regeneron); n=269
  - Decrease in viral load marginally
  - Decrease in medically attended visits (3% vs 6%)

Neither demonstrated any safety signals

Chen NEJM 2020
Weinreich NEJM 2020

Neutralizing COVID-19 Monoclonal antibodies - who?

+SARS-COV2 direct testing, O2 > 94% and <10 days of symptoms with at least one of the following high-risk criteria:

- Age >= 65
- DM
- CKD
- BMI >=35
- Immunosuppressive tx
- Age >=55 and CV disease, HTN, or chronic respiratory disease

Emergency Use Authorization

- Mechanism for providing access to therapeutics (also diagnostics and vaccines) during emergency period, based on best available evidence
- NOT FDA approved
- Effective until emergency declaration ends
- Can be revoked by FDA at any time
- Need verbal informed consent (with appropriate documentation)
  - EUA fact sheet provided

What can the out of hospital provider do?

- Counseling, reassurance and symptom management
- Close monitoring
  - Pulse oximeter, routine vital signs
  - Referral to ED when indicated
    - Hypoxia <95% prompt early referral or new O2 requirement
    - Mental status changes may be prominent
- Early referral for neutralizing COVID-19 monoclonal antibody treatment when indicated

Monoclonal Antibody Referrals

Consider early – can provide EUA fact sheet and counsel patients in high-risk group before COVID-19 testing comes back

https://phpa.health.maryland.gov/Documents/Referring%20Patients%20to%20Monoclonal%20Antibody%20Infusions%20-%20FINAL.pdf

Process to refer your patients

1. Review patient eligibility criteria

for patients with mild-moderate symptoms. Full criteria listed by FDA (Bamlanivimab, Casirivimab and Imdevimab).

2. Perform a COVID-19 PCR or Point-of-Care Rapid Antigen Test

(POC Antigen Tests can be supplied by MDH: complete this form if interested).

3. Refer your positive patients to a partnering infusion site* ASAP

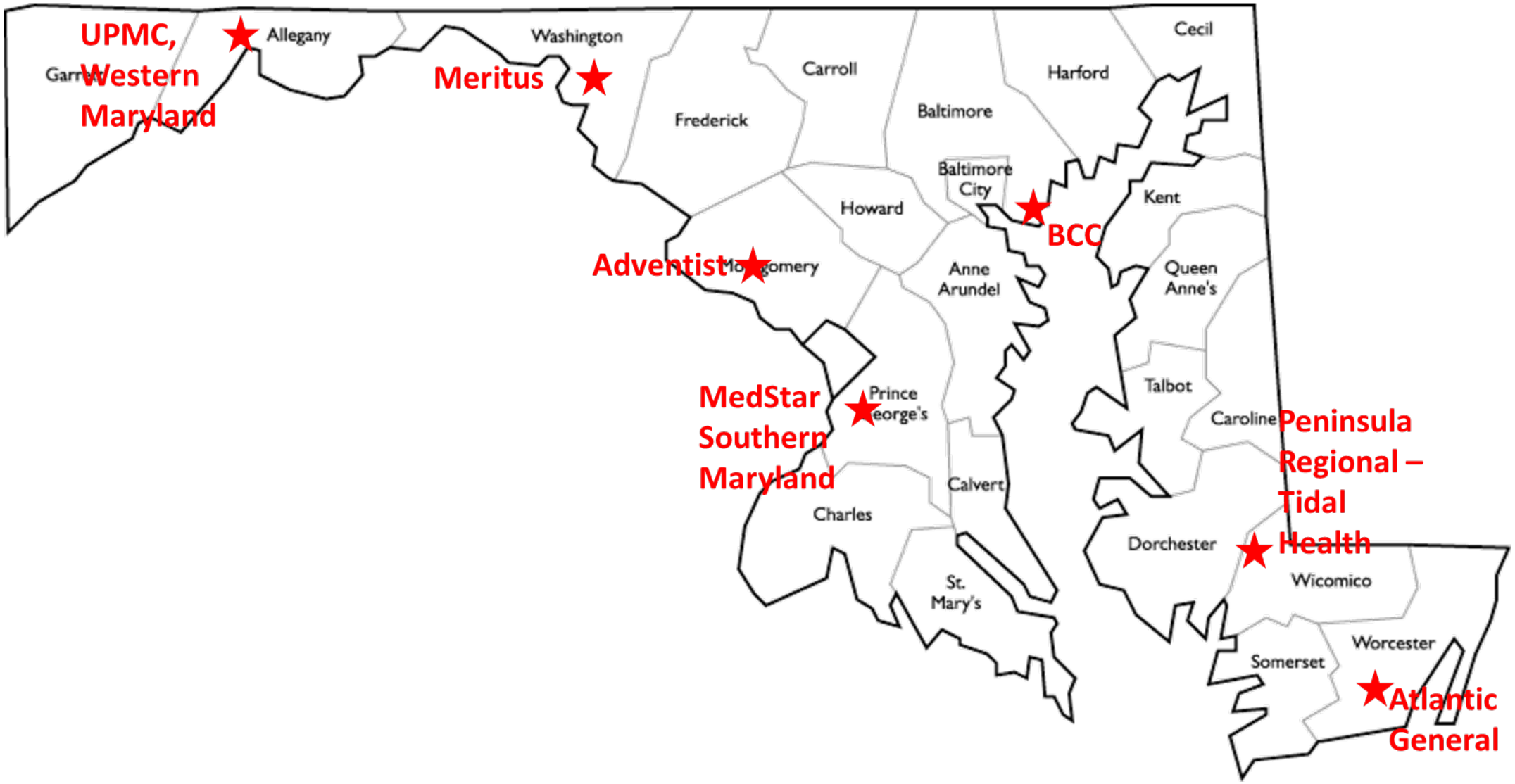
to start treatment within 10 days of onset of symptoms.

Option 1 **OR** **Option 2**

Send an e-Referral via the CRISP Unified Landing Page *(Starter guide: pp. 1-7, 24-34)*

Complete this referral form and submit directly to infusion site

Infusion sites



Hot off the press.. BLAZE-2

“Lilly's neutralizing antibody bamlanivimab (LY-CoV555) prevented COVID-19 at nursing homes in the BLAZE-2 trial, reducing risk by up to 80 percent for residents”

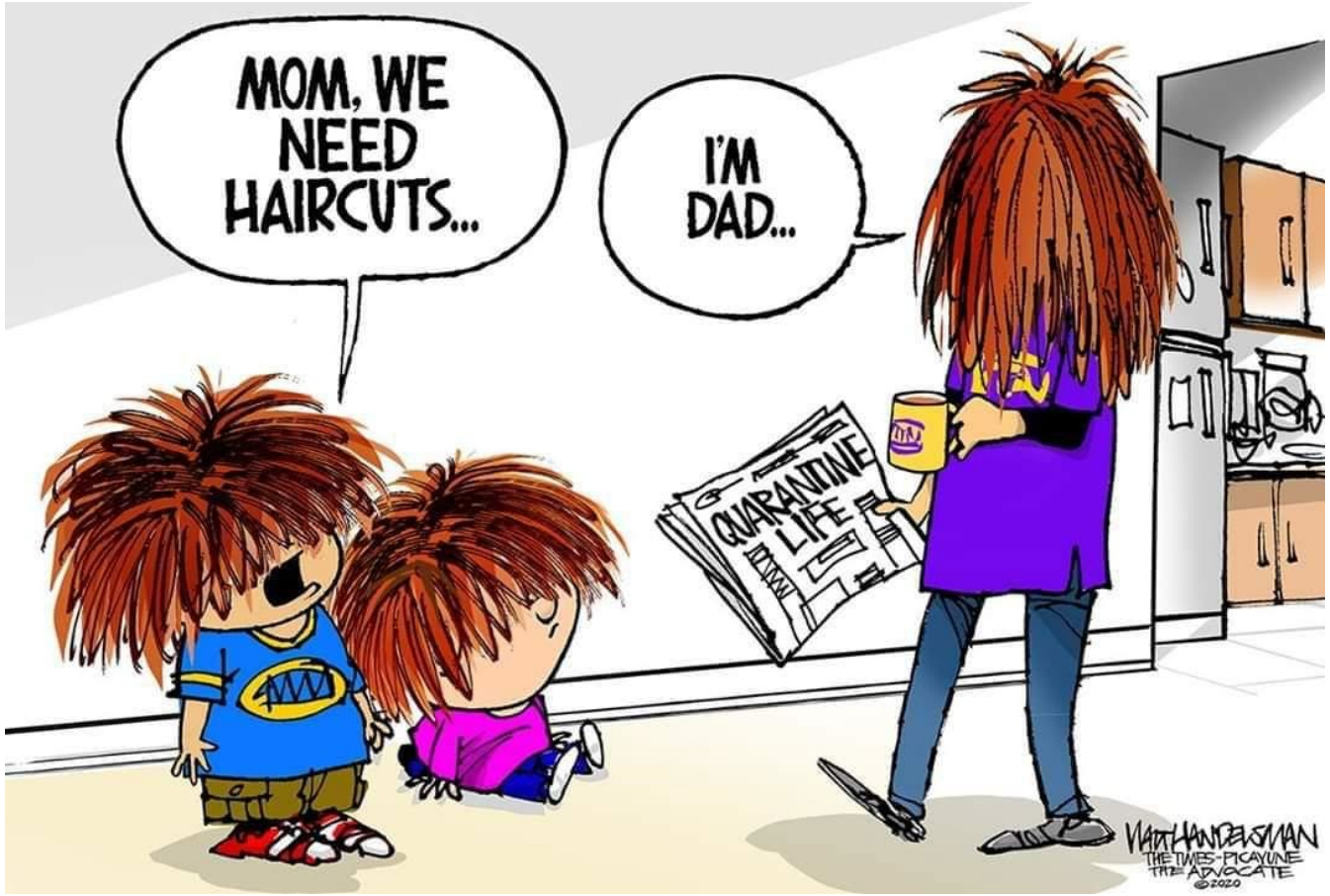
- 965 (299 residents and 666 staff) SARS-COV-2 neg
- 132 (41 residents and 91 staff) SARS-COV-2 pos
- Randomized bamlanivimab or placebo
- 8 week follow up, primary end point symptomatic COVID-19
- OR 0.43 (p=0.00021) for developing symptomatic COVID-19 in all
- No COVID related deaths in treatment arm (8 deaths in placebo)

https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-prevented

Out of Hospital COVID Management Takeaways

- Antibiotics and steroids - NOT indicated
  - May cause harm!
- Repurposed therapeutics such as hydroxychloroquine and ivermectin have NOT demonstrated efficacy
- Supportive care, reassurance, telehealth monitoring with pulse oximeter and thermometer
- Consider Monoclonal antibody referral early – may be logistically challenging at the moment, but data is promising

Thank you


MOM, WE NEED HAIRCUTS...
I'M DAD...
QUARANTINE LIFE
THE TIMES-PICAYUNE
THE ADVOCATE
©2020

Have a question?

Email MDH.IPCOVID@maryland.gov

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