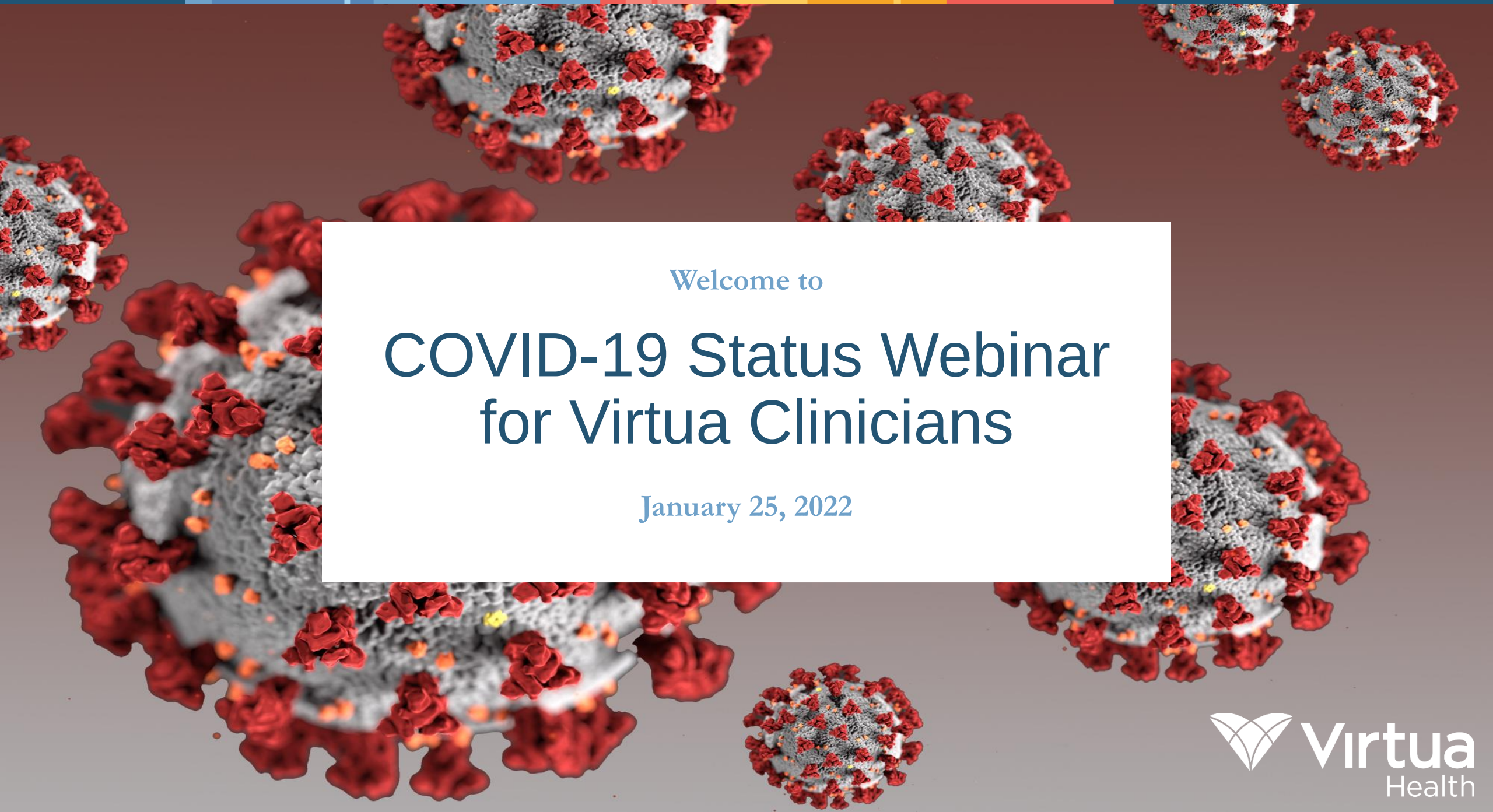


Welcome to

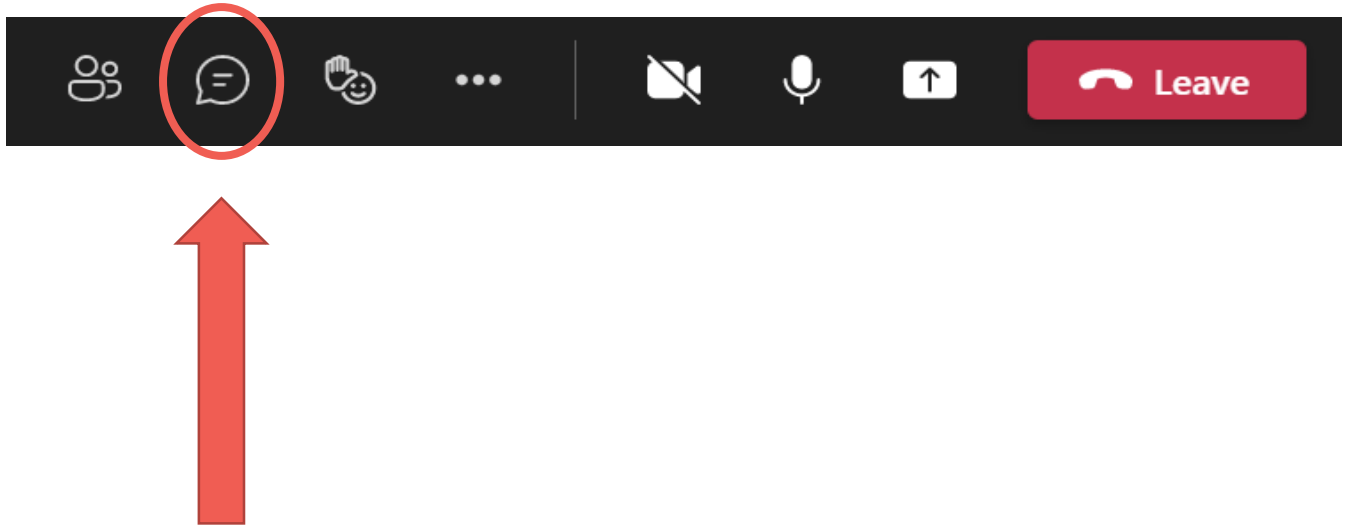
COVID-19 Status Webinar for Virtua Clinicians

January 25, 2022

Virtua Health

Housekeeping

- This program will be recorded
- All participants should have their microphones muted
- Please send questions for the presenters via the chat function



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Today's Agenda

Introduction
Reg Blaber, MD, MBA, FACC, Executive VP and Chief Clinical Officer

State of the House
Jennifer Khelil, DO, MBA, Senior VP and Chief Medical Officer

Epidemiology and Therapeutics
Marty Topiel, MD, FSHEA, Infection Control Officer

Surgical Practice Overview and Plans: Update for Proceduralists
Howard J. Winter, MD, VP Surgical Practice & Outcomes

Testing and Vaccination Site
Samuel Weiner, MD, VP, Clinical Operations

Q&A

Closing Remarks
Reg Blaber, MD, MBA, FACC, Executive VP and Chief Clinical Officer

Virtua Health

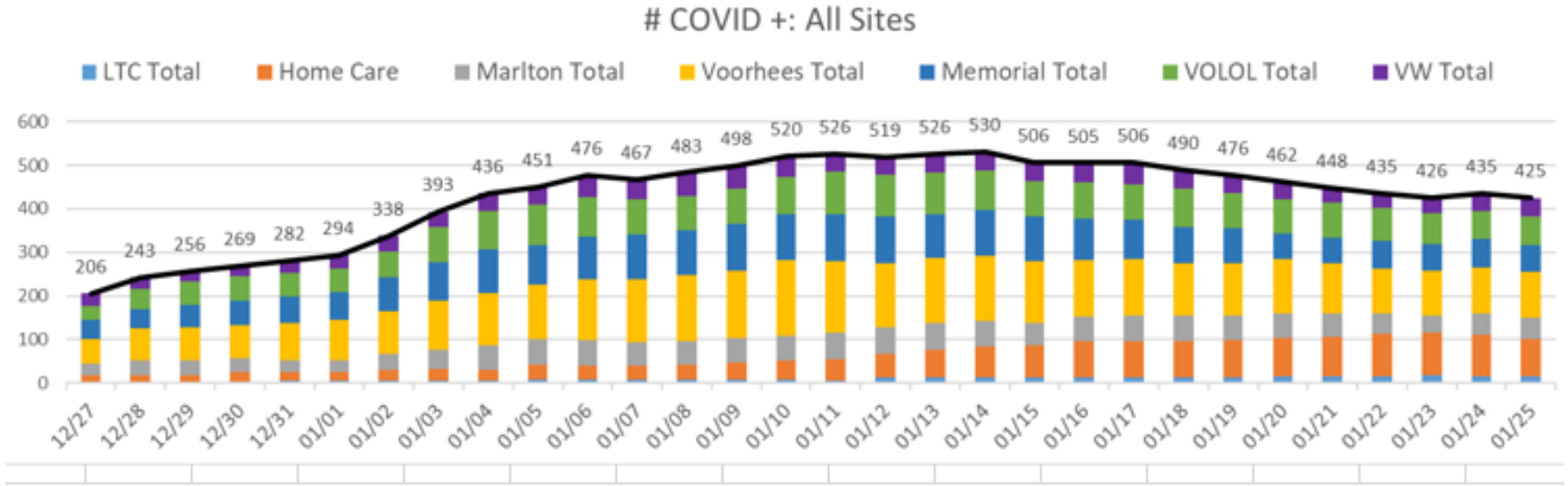
Introduction

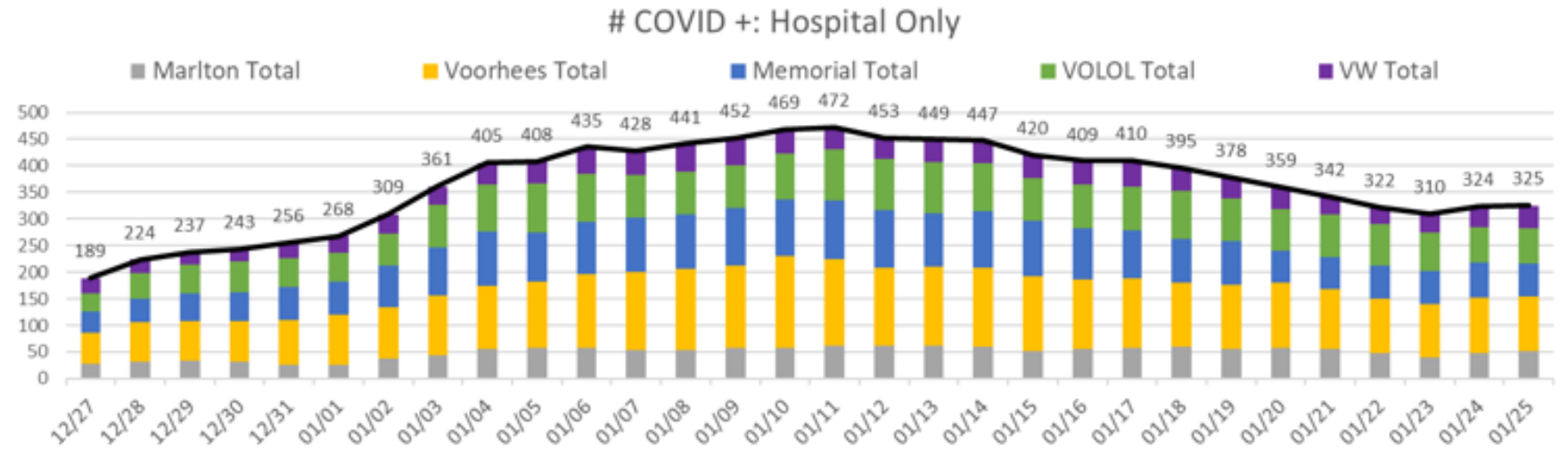
Reg Blaber, MD, MBA, FACC
Executive VP and Chief Clinical Officer

State of the House

Jennifer Khelil, DO, MBA
Senior VP and Chief Medical Officer

COVID Census





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Epidemiology and Therapeutics

Virtua Town Hall

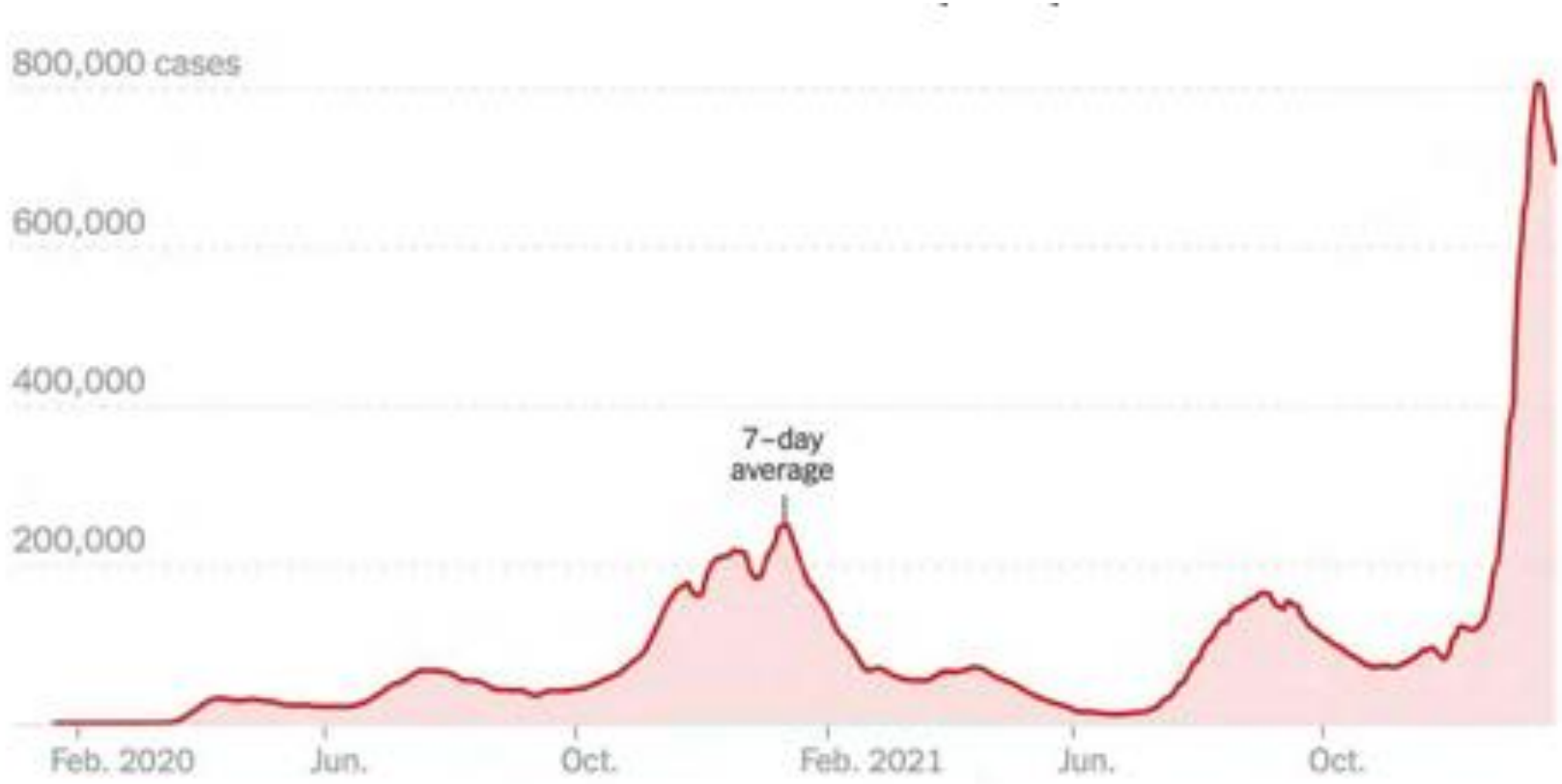
January 25, 2022

Martin Topiel MD, FSHEA

Virtua Infection Control Officer

REPORTED COVID-19 CASES IN THE UNITED STATES

Cumulative Cases – 70,466,160



Increased by 8 % from two weeks earlier

Source: New York Times 1-23-22

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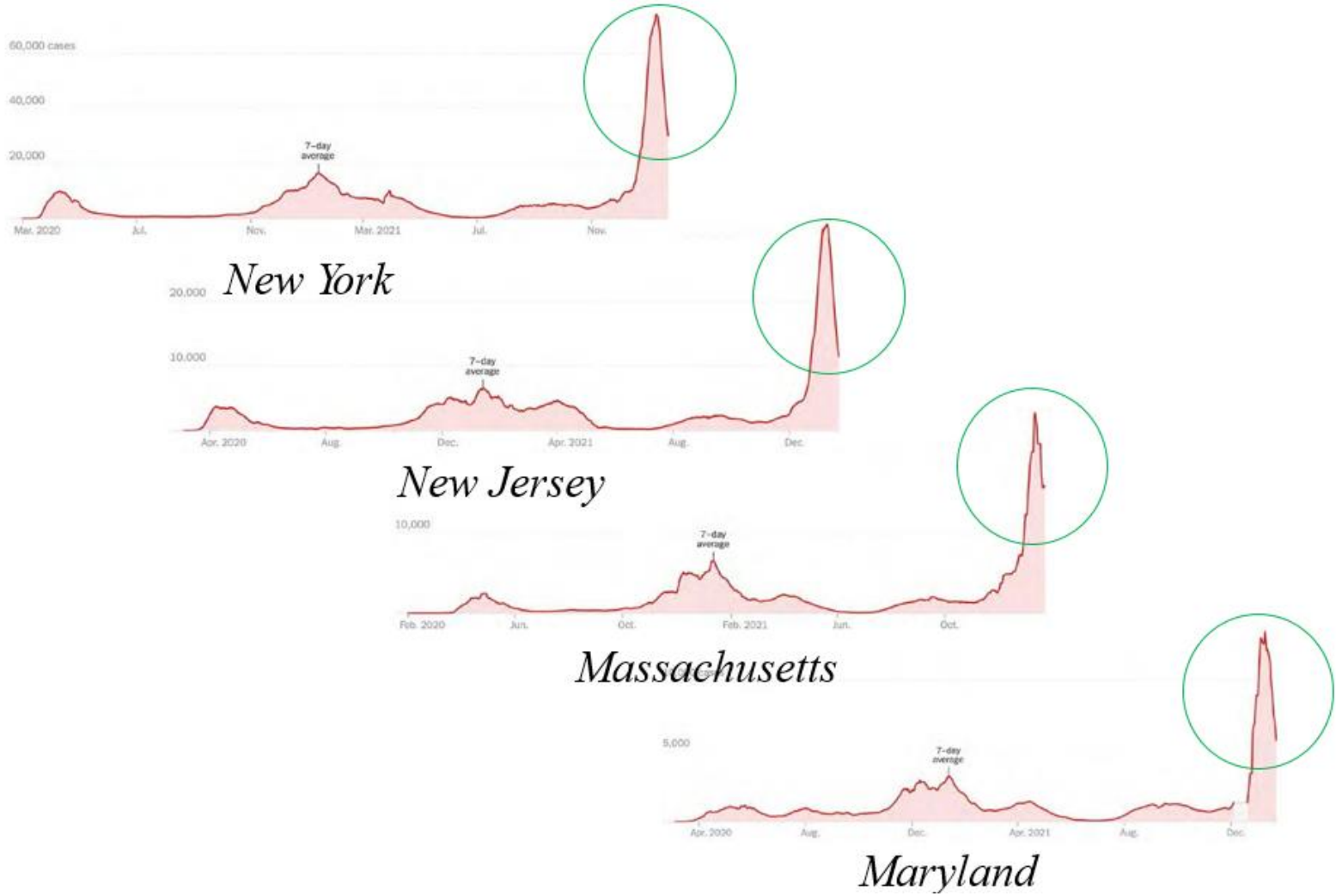
COVID-19 CASE ACCRUAL IN FOUR STATES



Source: New York Times 1.23.2022

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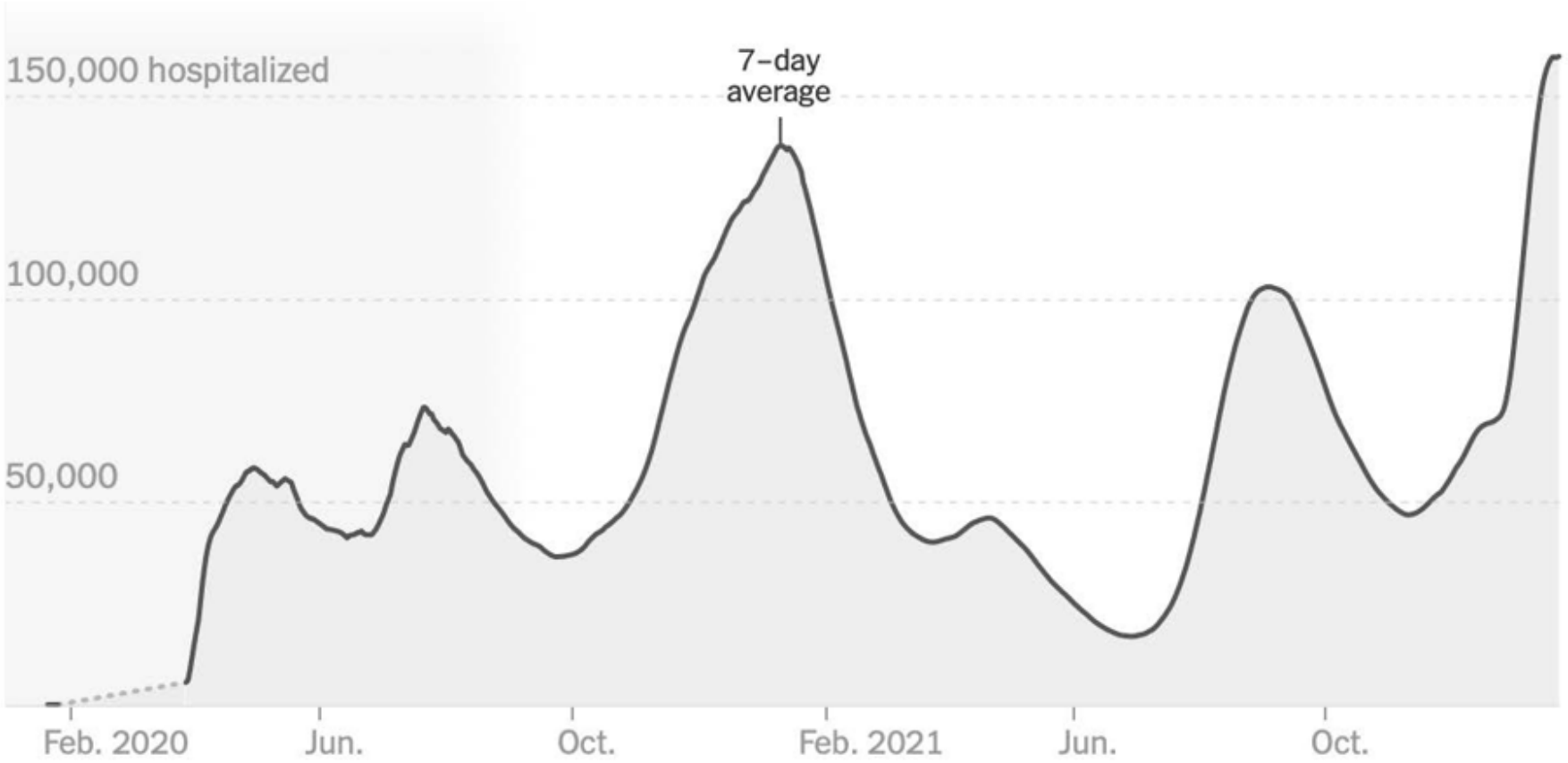
HOSPITALIZATIONS FOR COVID-19 IN THE UNITED STATES



Increased 24% from two weeks earlier

Source: New York Times 1-23-22

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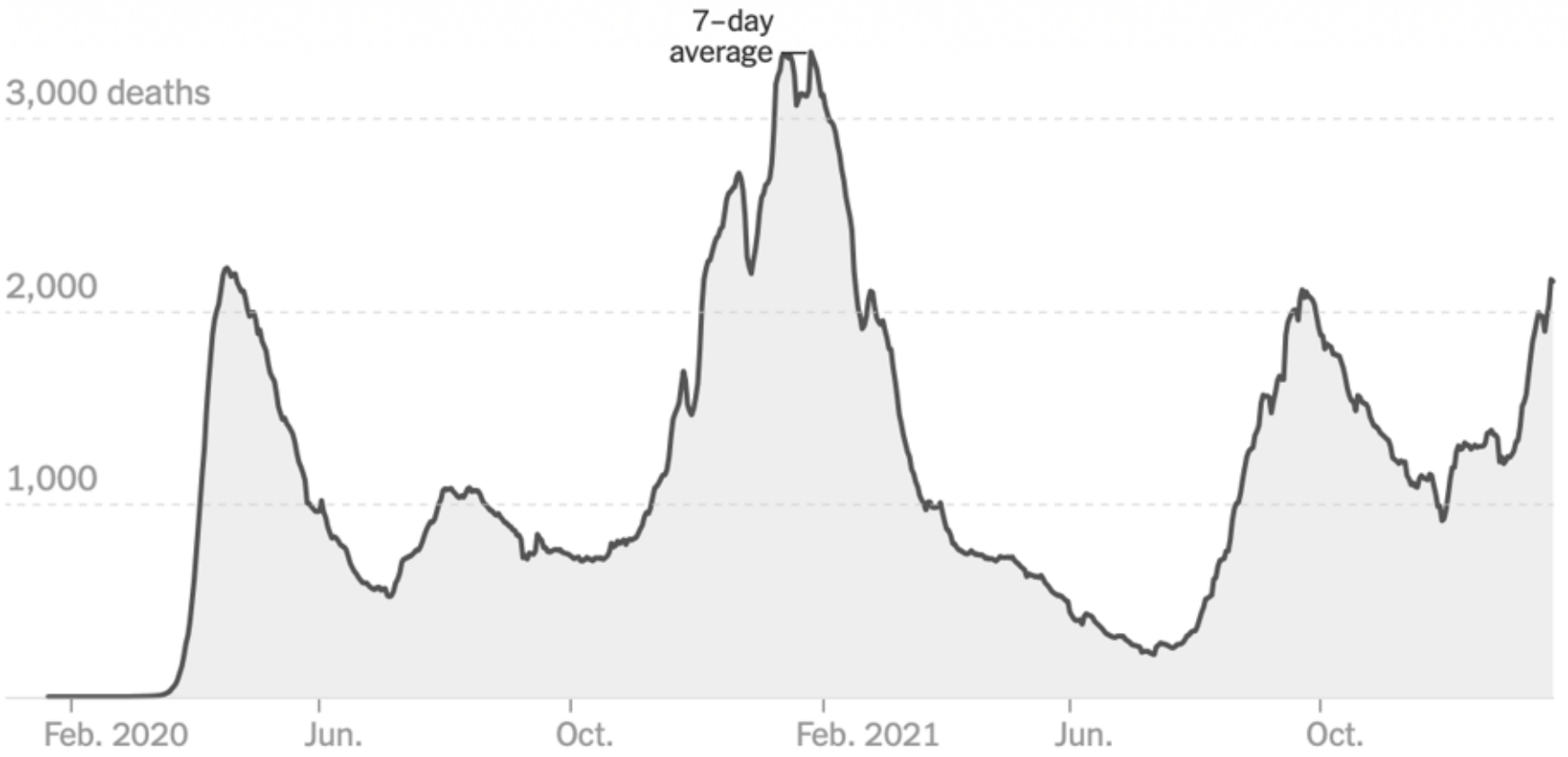
COVID-19 DEATHS IN THE UNITED STATES

Cumulative Deaths – 865,117



41% increase from two weeks earlier

Source: New York Times 1-23-22

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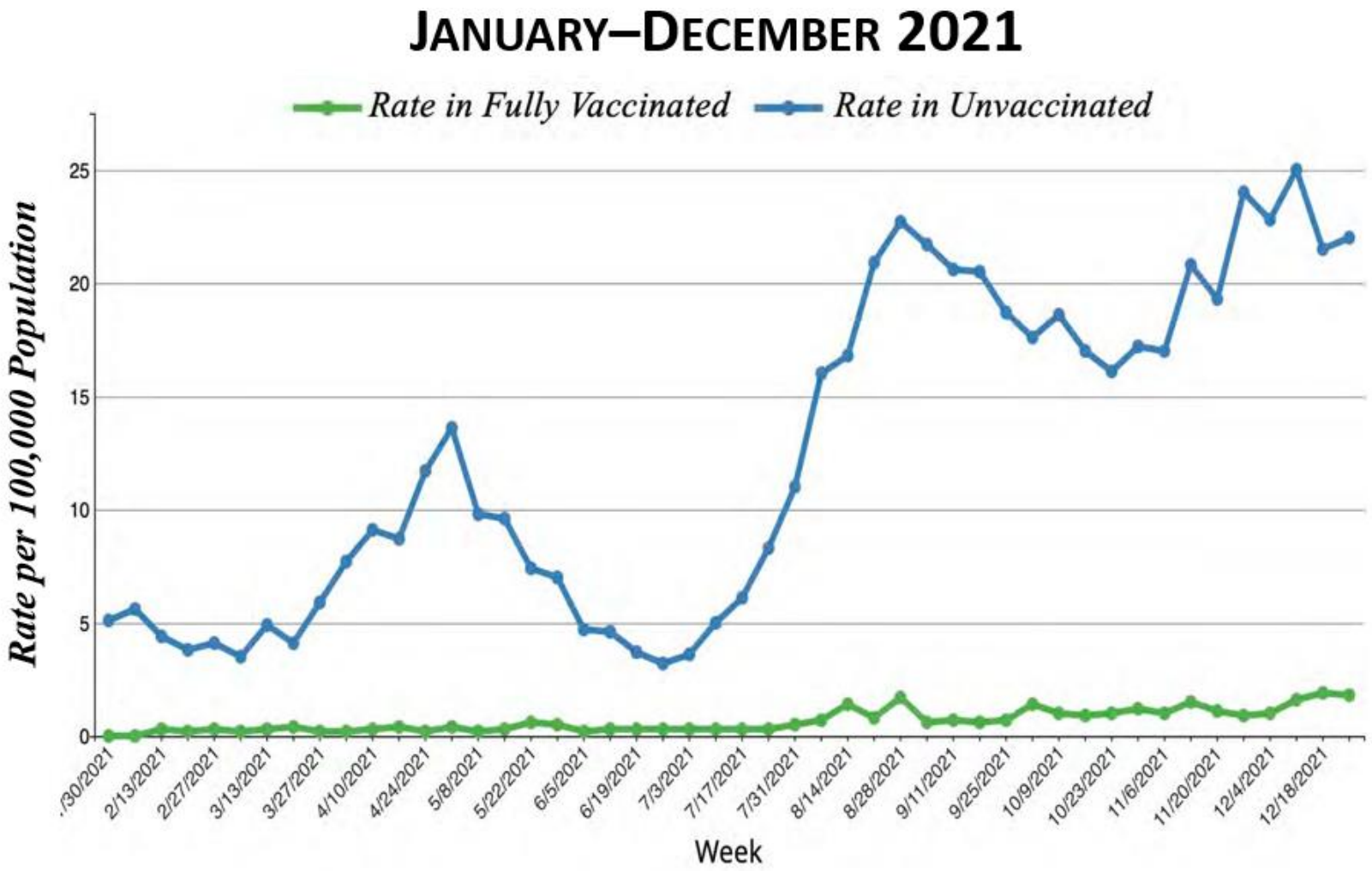
RATES OF COVID-19-ASSOCIATED HOSPITALIZATIONS BY VACCINATION STATUS IN ADULTS AGES 18–49 YEARS



Source: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

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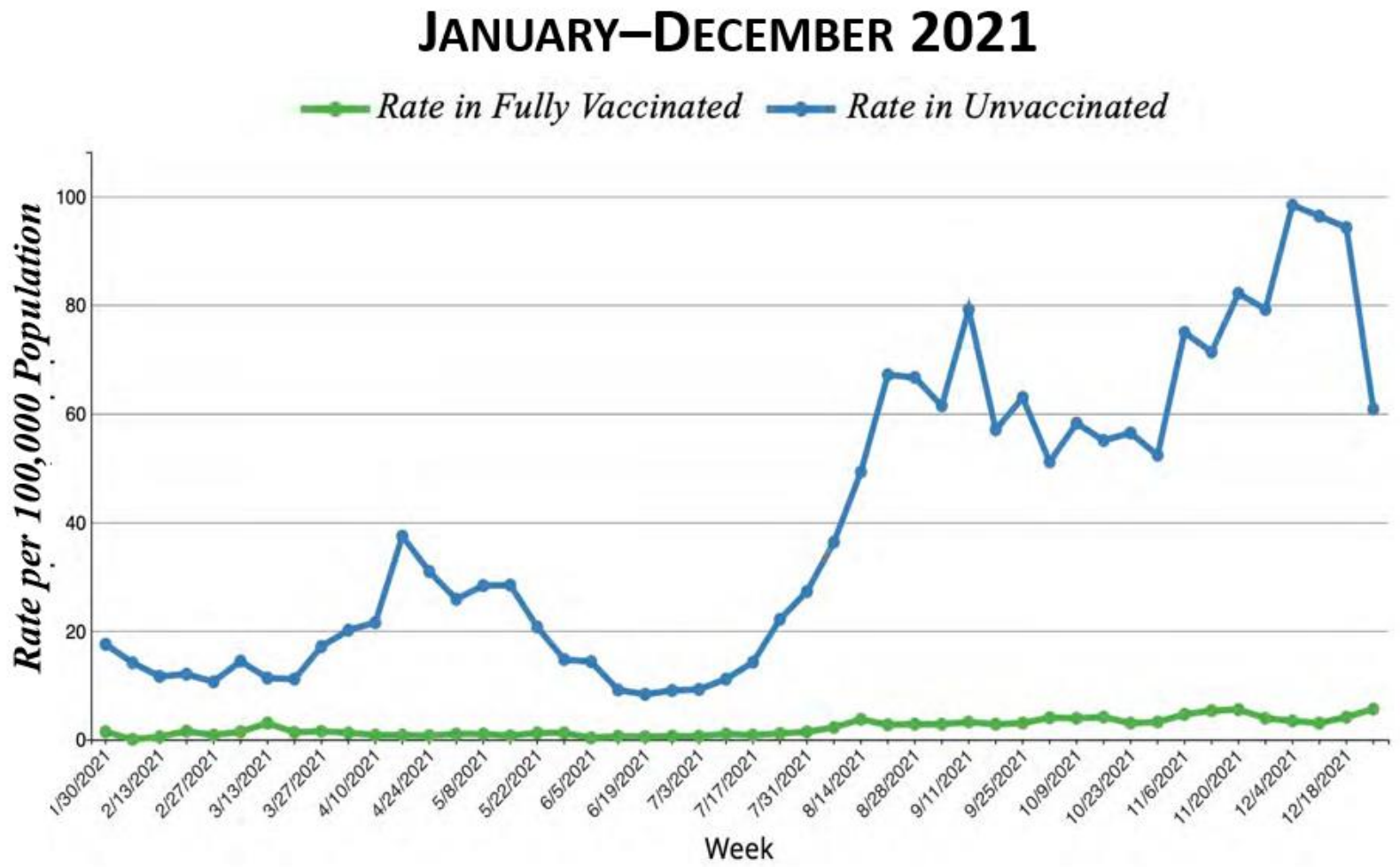
RATES OF COVID-19-ASSOCIATED HOSPITALIZATIONS BY VACCINATION STATUS IN ADULTS AGES 50–64 YEARS



Source: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

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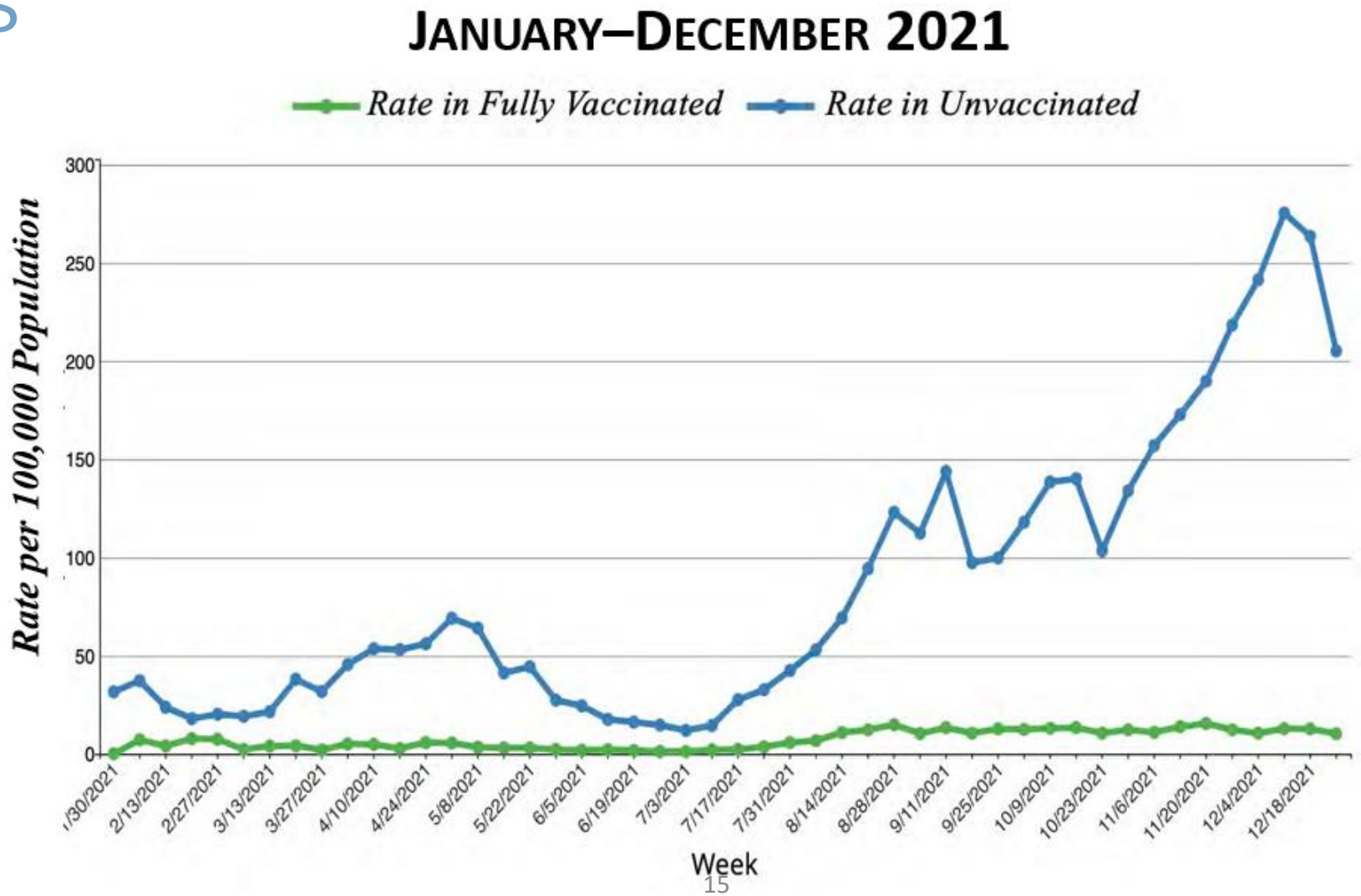
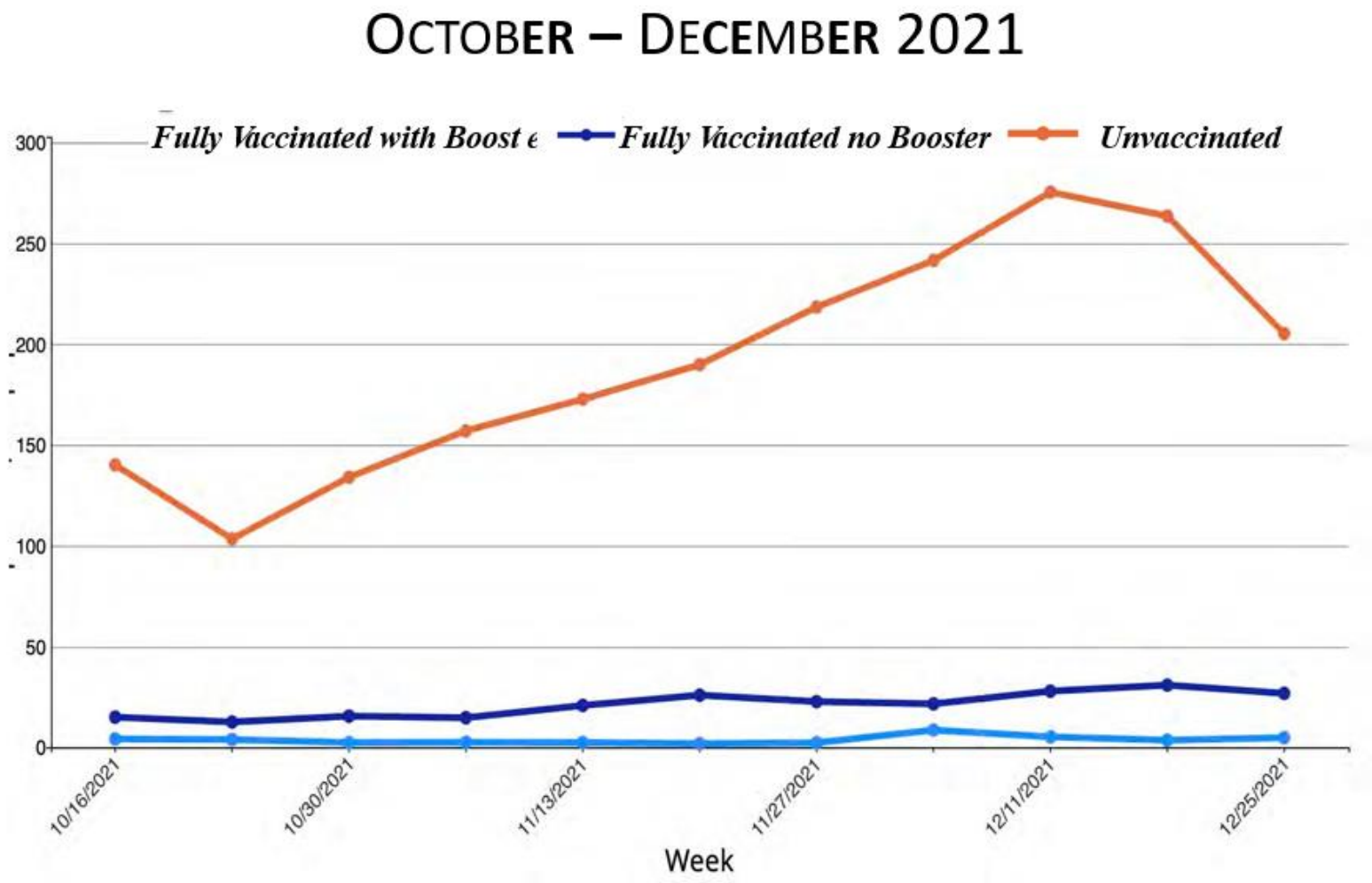
RATES OF COVID-19-ASSOCIATED HOSPITALIZATIONS BY VACCINATION STATUS IN ADULTS AGES > 65 YEARS



Virtua Health

RATES OF COVID-19-ASSOCIATED HOSPITALIZATIONS BY VACCINATION STATUS IN ADULT AGES > 65 YEARS



Source: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

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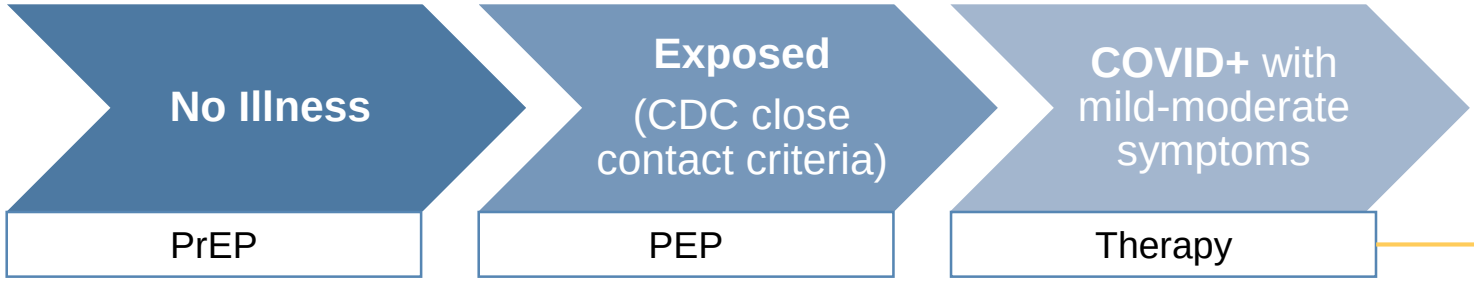
Outpatient COVID-19 Therapies



Vaccines

mAbs for PrEP
- Tixagevimab/ cilgavimab (Evusheld)

mAbs for PEP
- Casirivimab/ imdevimab*
- Bamlanivimab/ etesevimab*

mAbs for treatment
- Casirivimab/ imdevimab*
- Bamlanivimab/ etesevimab*
- Sotrovimab

Antivirals
- Nirmatrelvir + ritonavir (Paxlovid)
- Molnupiravir
- Remdesivir x 3d^

*Casirivimab/imdevimab and bamlanivimab/etesevimab are not recommend at this time due to poor activity versus Omicron variant

^Outpatient use of remdesivir is not able to be offered through Virtua health at this time

At this time, ALL outpatient therapies are indicated ONLY for patients at high risk of progression to severe disease

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Paxlovid Authorization for Treatment

- Nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use
- Nirmatrelvir is a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor

Authorization: for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid Clinical Considerations

- **Drug-drug interactions**
  - CONTRAINDICATIONS for co-administration with some drugs highly dependent on CYP3A for clearance and some potent CYP3A inducers
- **Renal impairment**
  - eGFR ≥30 to <60 mL/min: Dose reduction
  - eGFR <30mL/min: Not recommended
- **Severe hepatic impairment**
  - Child-Pugh Class C: Not recommended
- **Uncontrolled or undiagnosed HIV-1 infection:**
  - Consider risk of development of HIV-1 resistance to protease inhibitors

Health Care Provider Fact Sheet:
https://www.fda.gov/media/155050/download

Paxlovid (nirmatrevir + ritonavir) Interactions

Common CYP3A4-mediated drugs that will be significantly increased by ritonavir

Alpha-1 antagonist: afluzosin

Antianginal: ranolazine

Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine

Anti-gout: colchicine

Antipsychotics: clozapine

Antiplatelets: ticagrelor, clopidogrel

Anti-rejection: tacrolimus, sirolimus, cyclosporine

PDE5 inhibitors for PAH: sildenafil

Statins: lovastatin, simvastatin

Sedative/hypnotics: triazolam, midazolam

CYP3A4-inducing drugs that will reduce concentrations of nirmatrelvir

Anticonvulsants: carbamazepine, phenobarbital, phenytoin

Antibacterials: rifampin

Concomitant administration of Paxlovid with any of these drugs should be **avoided**

A free and comprehensive drug interaction database can be found at:
www.covid19-druginteractions.org

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Molnupiravir Clinical Considerations

- **Embryo-fetal toxicity**
  - Not recommended for use during pregnancy
  - Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose.
  - Breastfeeding is not recommended during treatment and for 4 days after the last dose.
  - Non-clinical studies to fully assess the potential to affect offspring of treated males have not been completed (if sexually active with individual of childbearing potential, contraception advised during treatment and for at least 3 months after the last dose).
- **Not authorized for pediatric use (< 18 y)**
  - Potential to affect bone and cartilage growth

Health Care Provider Fact Sheet:
https://www.fda.gov/media/155054/download

Oral Antivirals: Who is eligible?

	Paxlovid (nirmatrevir + ritonavir)	Lagevrio (molnupiravir)
Eligibility requirements	• Age ≥ 12 and ≥ 40 kg • Ambulatory patients with mild-moderate COVID-19 and high risk for progression to severe disease • Positive SARS-CoV-2 viral test • Within 5 days of symptom onset	• Age ≥ 18 • Ambulatory patients with COVID-19 and high risk for progression to severe disease ***AND for whom alternative options are not accessible or clinically appropriate*** (ex. monoclonal antibodies, Paxlovid, outpatient remdesivir) • Positive SARS-CoV-2 viral test • Within 5 days of symptom onset
Use NOT authorized	• Patients hospitalized due to COVID-19 • Pre- or post-exposure prophylaxis	

Note: These drugs are approved via Emergency Use Authorization by the FDA. Therefore, these medications are authorized ONLY for the criteria indicated. “Off-label” use is not allowed by the FDA at this time.

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Oral Antivirals: Clinical Comparisons

	Paxlovid (nirmatrevir + ritonavir)	Lagevrio (molnupiravir)
Dose	300 mg nirmatrelvir (two 150 mg tablets) + 100 mg ritonavir (one 100 mg tablet) BID	800 mg (four 200 mg capsules) BID
Renal Dose Adjustment	eGFR ≥30 to < 60 mL/min: 150 mg nirmatrelvir + 100 mg ritonavir BID eGFR < 30 mL/min: NOT RECOMMENDED	None
Duration	5 days	5 days
Adverse Reactions	Dysguesia, diarrhea, hypertension, myalgia	Diarrhea, nausea, dizziness
Contraindications	Severe hepatic impairment Severe renal impairment	Pregnancy
Drug Interactions	Due to co-formulation with ritonavir, **major drug interactions are anticipated** with some CYP3A4-mediated drugs	None identified during studies used to gain EUA approval

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Oral Antivirals: Clinical Trial Data

	Paxlovid (nirmatrevir + ritonavir)	Lagevrio (molnupiravir)
Trial Name	EPIC-HR Trial	MOVe-OUT Trial
Patient Population	High-risk non-hospitalized symptomatic adults with COVID19, N = 2,246	High-risk non-hospitalized adults with mild-moderate COVID19, N = 1,433
Outcomes	COVID-related hospitalization or all-cause death at day 28: • 0.8% Paxlovid vs. 6.3% placebo Mortality at day 28: • 0% Paxlovid vs. 1.1% placebo	COVID-related hospitalization or all-cause death at day 28: • 6.8% molnupiravir vs. 9.7% placebo Mortality at day 28: • 0.1% molnupiravir vs. 1.3% placebo
Relative Risk Reduction	**88%**	**30%**
NNT	**18**	**31**

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EUA Requirements for Oral Medications

Under Emergency Use Authorization (EUA), it is required to communicate information consistent with AND provide a copy of the **Fact Sheet for Patients, Parents, and Caregivers**

Counseling Points:

- What is an EUA?
- What is the drug and who is it for?
- How to take
- Potential side effects
- How to manage drug interactions

Paxlovid Fact Sheet:
https://www.fda.gov/media/155051/download

Molnupiravir Fact Sheet:
https://www.fda.gov/media/155055/download?ftag=MSF0951a18

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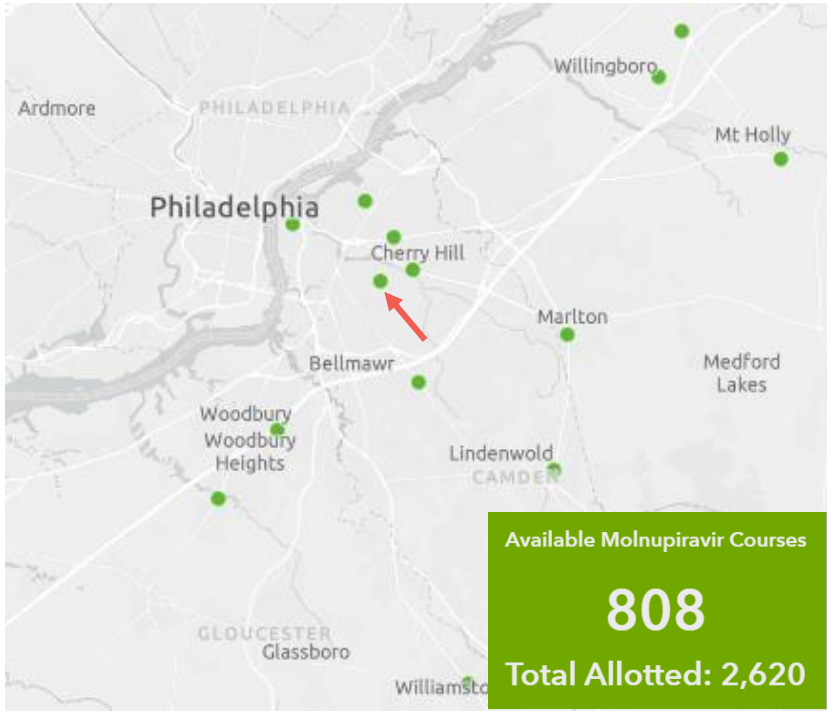
Where are these therapies available?

- Selected pharmacies in Camden and Burlington Counties, however, supply continues to be extremely limited

https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/



Walgreens Store #05984
8 HADDON AVE, HADDON TOWNSHIP, NJ 8108

Therapeutic: Paxlovid
Courses Available: 0
Total Courses Allotted: 60
Last Order Date: 12/28/2021 12:00:00 AM
Last Date Delivered: 12/30/2021 12:00:00 AM

Walgreens Store #05984
8 HADDON AVE, HADDON TOWNSHIP, NJ 8108

Therapeutic: Molnupiravir
Courses Available: 124
Total Courses Allotted: 140
Last Order Date: 12/27/2021 12:00:00 AM
Last Date Delivered: 12/31/2021 12:00:00 AM

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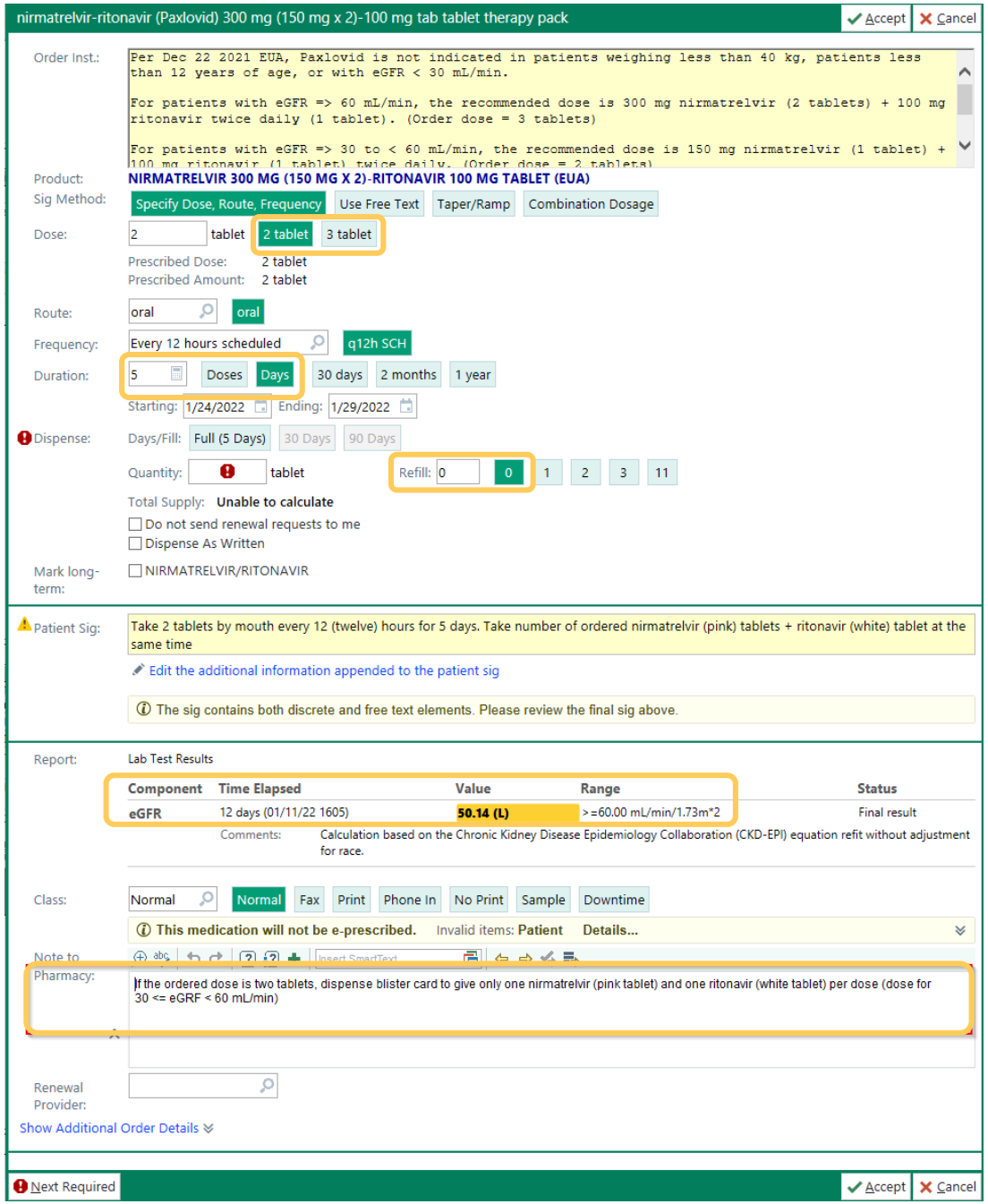

3 tablets

2 x nirmatrelvir 150 mg +
1 x ritonavir 100 mg

2 tablets

1 x nirmatrelvir 150 mg +
1 x ritonavir 100 mg

Potential drug interactions will appear in Epic, however, alternative resources may be more helpful for decision-making

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EVUSHELD Authorization for PrEP

- Tixagevimab co-packaged with cilgavimab, SARS-CoV-2 spike protein-directed attachment inhibitor.

Authorization: for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **OR**
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID19 vaccine component(s)

Eligible Conditions

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

Evusheld Drug Information

- 150 mg of tixagevimab and 150 mg of cilgavimab (mAbs) administered as two separate consecutive intramuscular injections
- NOT intended to replace vaccine, but instead supplement it
- Expected duration of activity of 6 months
  - Doses may be repeated if patient still immune suppressed
- Some reduction in activity against the Omicron variant, but still recommended at this time

Health Care Provider Fact Sheet:
https://www.fda.gov/media/154701/download

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Monoclonal Antibody Referral

- Hotline: 856-325-3150
- Patients may also call the main access center number, 1-888-VIRTUA3
- Epic entry
- EVUSHELD:

monoclonalantibodyinfusion@virtua.org

monoclonaltriage@virtua.org

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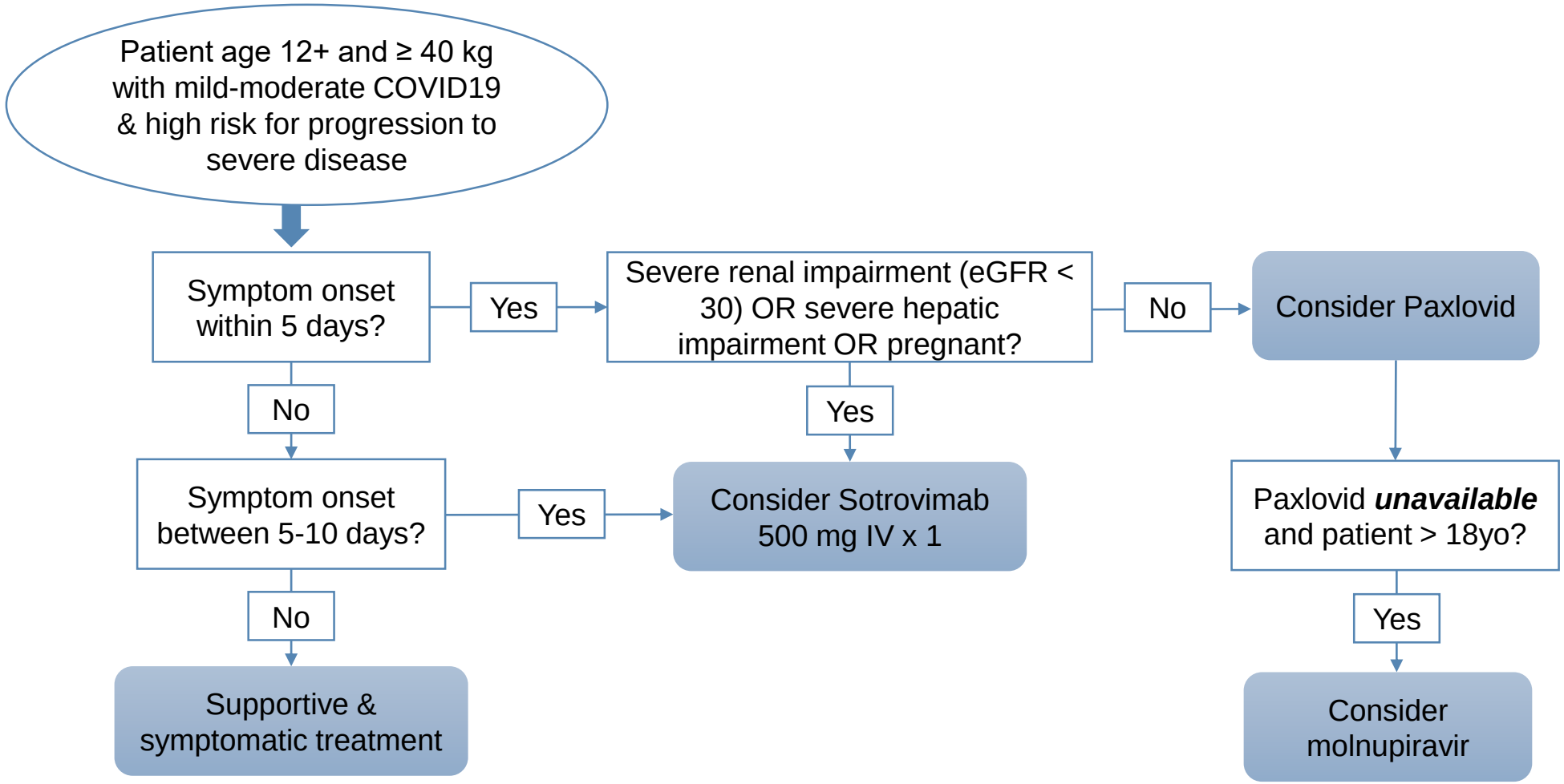
Treatment Decision Guide



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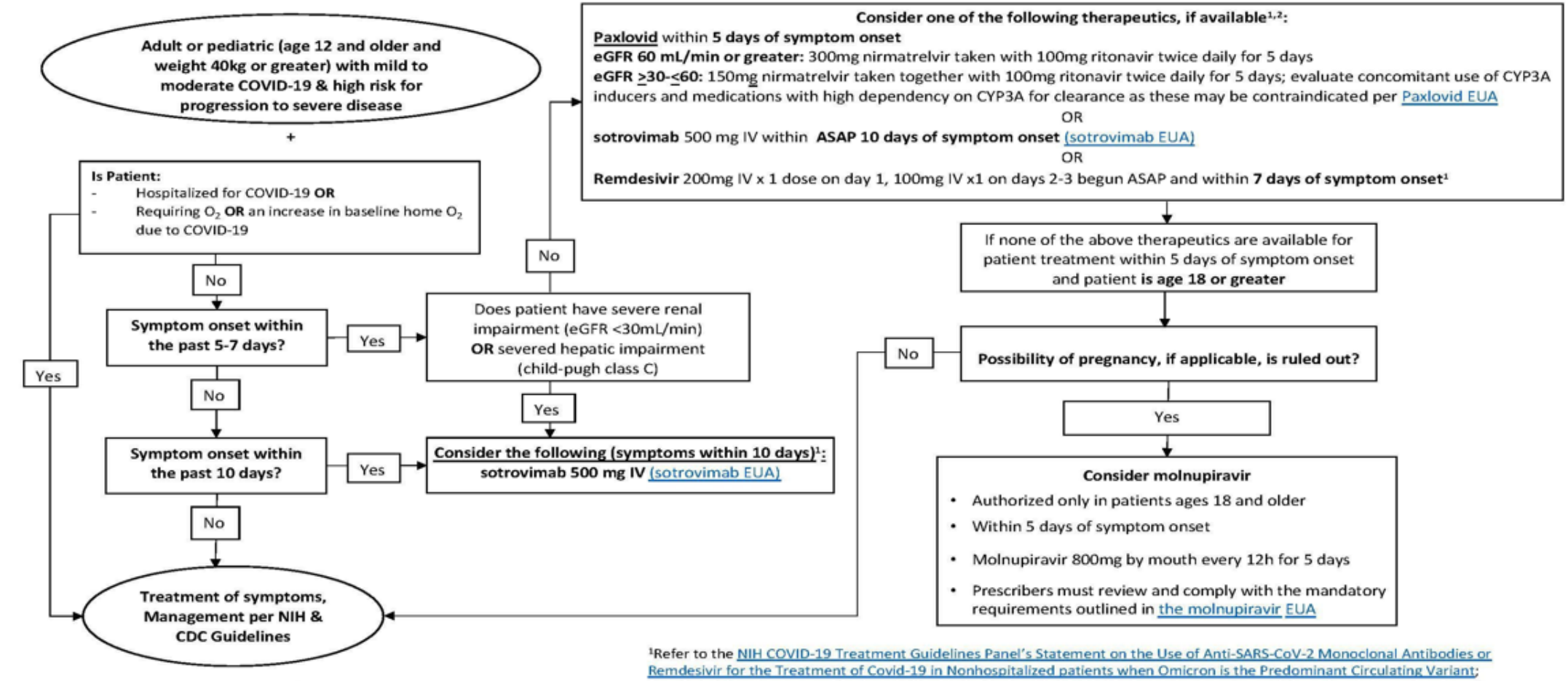
COVID-19 Outpatient Therapeutics Decision Guide



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

December 30, 2021

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2] COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)

Questions?

Thank you.

Surgical Practice Overview and Plans

Update for Proceduralists

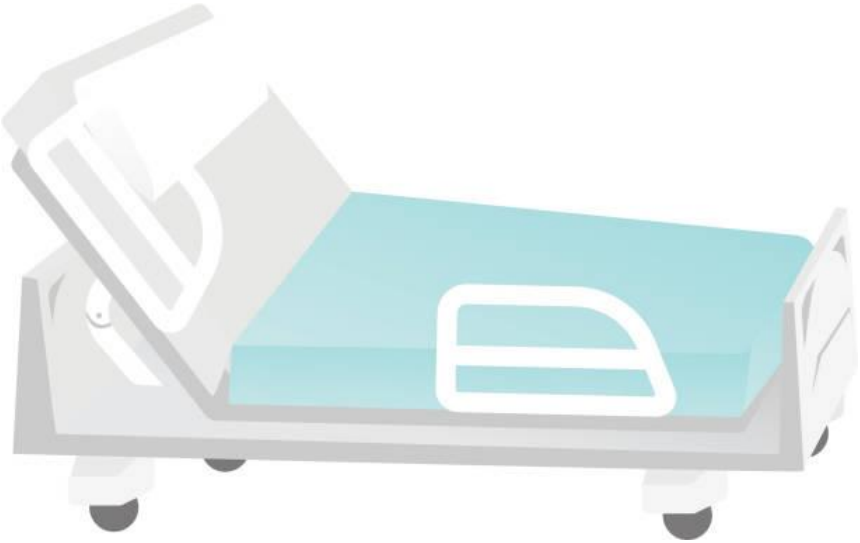
Howard Winter, M.D.

VP Surgical Practice & Outcomes

Jan. 25, 2022

The Issues: Omicron Surge

- Lack of beds…surge in both COVID and non-COVID patients
  - Preop and Recovery areas converted to hospital beds
- Lack of staff due to COVID infections
- Became critical by Jan. 5



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Measures Taken

- **Jan. 5**, and for the next 2 weeks:
  - Postponed invasive procedures: most outpatients and procedures needing inpatient stays at the 5 hospitals except for:
    - Emergencies
    - Urgent cases
      - Delay for 2 weeks would cause significant harm
      - Cancer cases

- By **Jan. 19**: began to allow most outpatients and limited hospital stays according to divisional resources

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As of now: Omicron peak has just passed, numbers improving slowly

- All outpatients being done
- Increasing inpatient cases every day
- Looking to resume “normal” OR schedules by the end of this week

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Current COVID Processes

- **Pre-Procedure Testing**
  - All patients staying at least overnight (SDA's & 23 hour stays)
  - All unvaccinated OP's
  - When?: 3 days preop
  - What is "fully vaccinated"?
    - 2 doses of Pfizer or Moderna, 1 dose of J&J
  - All unscheduled admissions, regardless of vaccination, get tested

- **Quarantine:** 4 days pre-op……Why?
- **Positive Test:** Postpone case unless deemed necessary. Contact OR medical director in that case

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Continued

- **When to reschedule postponed cases:**
  - Asymptomatic: after 14 days from positive test
  - Symptomatic: after 14 days if symptoms resolve
  - Immunocompromised: after 21 days
- **What is immunocompromised?**
  - Chemotherapy (cytotoxic, not hormonal)
  - Biological agents (such as: Remicade, Humira, etc)
  - Steroids: >20 mg/day prednisone or equivalent for >2 weeks
  - Autoimmune
  - Transplant
  - AIDS (CD4 <200)

Continued

PAT calls: Nurses will screen all patients.

- **Positive screen:** generally should be postponed at least 14 days unless case cannot wait….surgeon's decision
- **Day of Procedure:** Screened again
- **What is an exposure?**

  In the last 7 days spending >15 minutes within 6 feet of a + or strongly suspected person with either of you unmasked

Medical Therapies

- Refer patients to their primary care doctors.
- If no primary care, refer to VMG for an appointment.

Blood Shortage

- National, due to decreased donations secondary to COVID
- Just beginning to improve slightly
- Message from Blood Bank:
  - DONATE if you can
  - Postpone 2 weeks elective cases which you know will require >2-3 units, if possible
  - Alert Blood Bank in advance if you cannot postpone such cases so they can prepare

Thank You

- Dr. Howard Winter
- Email: hwinter@virtua.org
- Cell: 856-495-3841

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Testing and Vaccination Site

Sam Weiner, MD
VP, Clinical Operations, Virtua Medical Group

COVID-19 Vaccine
Burlington County Mega-Site

- Eastgate Square Shopping Center on Nixon Road, Mt. Laurel, NJ
- Hours: Tuesday, Wednesday and Saturday 9am-3:30pm
  Thursday and Friday 11am-5:30pm
- Tuesdays are Moderna days
- 1st, 2nd, 3rd, and Booster doses
- Children 5+ can receive the vaccine
- Can schedule through MyChart or CovidMegaSite@virtua.org
- Walk-ins accommodated, but appointments strongly encouraged

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Virtua COVID-19 Testing

Barry Brown Health Education Center (HEC) in Voorhees

- SYMPTOMATIC TESTING BY APPOINTMENT ONLY; PCR testing only - No Antigen Testing
- Hours of Operation: Now M-F, 8am – 12pm
- Patients with positive at-home/rapid test do not need PCR
- Drive-through self-swabbing
- Virtua colleague, VMG patient, and community testing available through self-scheduling at Virtua.org
- All patients must have MyChart
  - Adult results (positive and negative) through MyChart only
  - Parents/guardians of minors (<18 y.o.) will be called with positive results only; negative results will not be called
- No change to pre-op testing

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Virtua COVID-19 Testing

Virtua Urgent Care

- Symptomatic testing only
- Unless appointment scheduled by urgent care telehealth or triage team, full urgent care evaluation is necessary
- Point-of-care “rapid” testing and PCR testing available for Monoclonal Ab candidates; flu and strep point of care testing also available
- Virtua colleagues must call employee hotline, no “walk-ups”

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Q & A

Please submit your questions via the chat function

Concluding Remarks

Reg Blaber, MD, MBA, FACC Executive
VP and Chief Clinical Officer

Virtua
Health