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Name of Faculty or Presenter	Reported Financial Relationship
Paul G. Auwaerter, MD, MBA, FIDSA	JNJ: Ownership equity Scientific Consulting: Verily, EMD Serono, Shionogi DMSB: Humanigen

Dr. Auwaerter has indicated that may be referencing the unlabeled or unapproved use of agents currently being investigated in on-going studies and trials, including monoclonal antibodies, antivirals, and several vaccine platforms.

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#### **Learning Objectives**

 Describe current data pertaining to "rebound" infections after treatment with nirmatrelvir plus ritonavir.



This activity is supported by an educational grant from Gilead Sciences, Inc. and in-kind support by DKBmed LLC

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Please see **COVID19.DKBmed.com** for additional resources and educational activities



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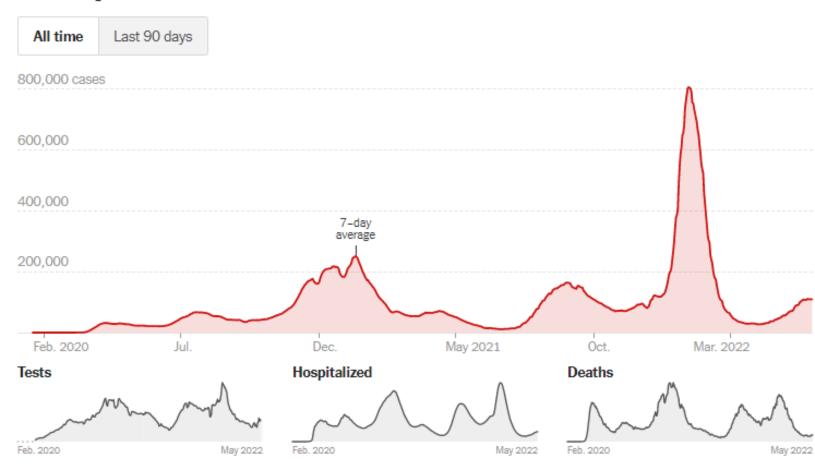
## **COVID-19 Pandemic**

Still with us, but more than ever, less of a handle



## **COVID-19: Recent Rise in REPORTED Cases Unclear True Extent of Current Infections**

#### New reported cases



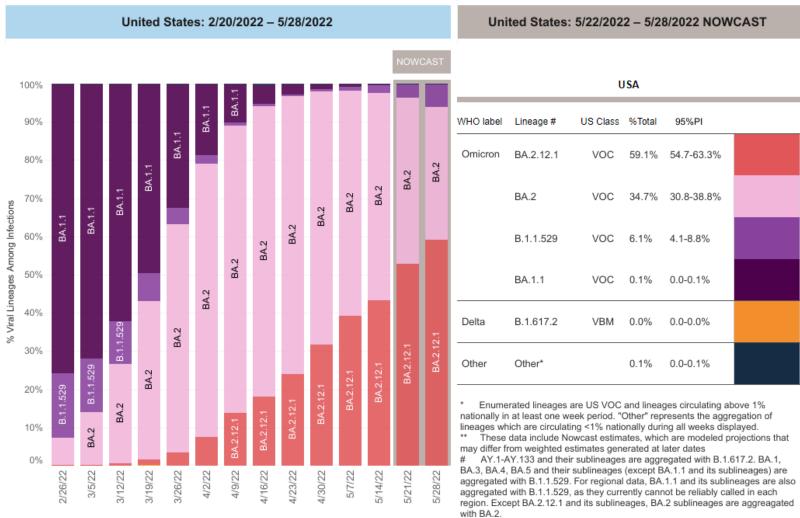
#### Vaccinations

	AT LEAST ONE DOSE	FULLY VACCINATED
All ages	78%	67%
5 and up	83%	71%
65 and up	95%	91%

CDC/NYT 5/31/22



### **Ongoing Changing Virological Landscape**



https://covid.cdc.gov/covid-data-tracker/#variant-proportions (accessed 5/31/22)



## **Treatment Update**

Not much has changed; however, are there nuances to prescribing nirmatrelvir/ritonavir?



#### **Rebound of the Virus**



## COVID-19 Rebound After Paxlovid Treatment

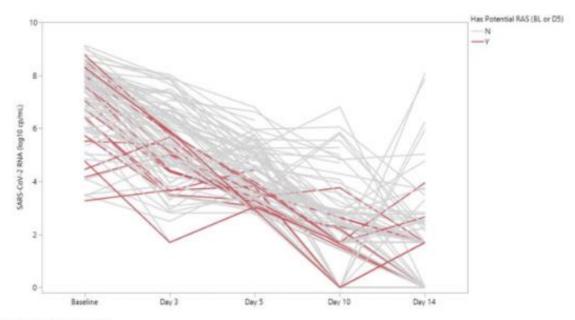




Distributed via the CDC Health Alert Network May 24, 2022, 9:00 AM ET

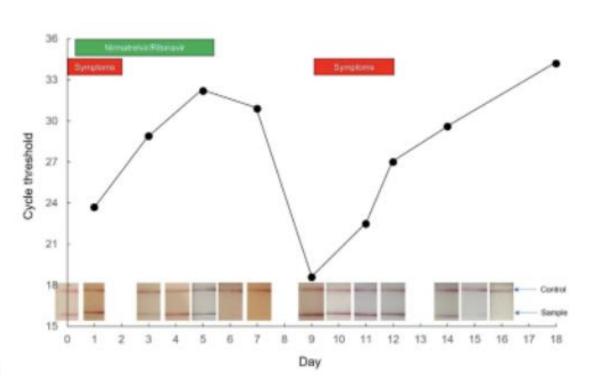


#### **Rebound of SARS-CoV-2**



Source: FDA analysis.

Figure 2. SARS-CoV-2 RNA levels in NP swabs among Paxlovid treated subjects with or without SARS-CoV-2 amino acid substitutions detected in Mpro or cleavage site positions potentially associated with resistance.



https://www.fda.gov/media/155194/download (12/21/21)

Gupta, https://assets.researchsquare.com/files/rs-1588371/v1/48342d2c-b3ea-4228-b600-168fca1fded7.pdf?c=1650977883



#### **CDC Health Advisory: Rebound Paxlovid**

#### Brief return of symptoms

- Occurs +/- treatment
- Regardless of vaccine status

#### Frequency w/ Rx, unclear

- Pfizer says 2%
- Mechanism unclear
- Transmission may occur (Boston VA)
  - Not due to mutational changes
  - 10 nonimmunocompromised pts (31-71 yrs) →

2 infected household members during relapse

#### Average 2-8 days post Rx

https://emergency.cdc.gov/han/2022/pdf/CDC\_HAN\_467.pdf (5/24/22) https://www.researchsquare.com/article/rs-1588371/v3 (5/23/22) Forms:

https://paxaes.pfizersafetyreporting.com/#/en

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

#### Remains "highly recommended"

- Reduction hospitalization/death
  - Trial in the unimmunized

No evidence for additional Rx

#### If rebound

Isolate additional 5d + 5d w/ mask (10d total)
 post rebound symptoms

#### Report cases

- Pfizer
- FDA MedWatch



#### **Paxlovid Indications**

#### **EUA**

- Within 5d symptom onset≥ 12 yrs, at least 40 kg
- High risk for progression
- Positive SARS-CoV-2 test
  - Outpatient (non-severe COVID-19)

#### **Potential Implications of Rx**

- Rebound of symptoms or antigen
   (+) post 5d course = need for return to isolation
- If with risk factors, and expected to respond well to vaccine w/ boosters
  - Consider no Rx
  - Avoid need for return to isolation.



## **COVID Aftermath**

Only beginning to understand the scope and the complexity



#### **Post-COVID Conditions**



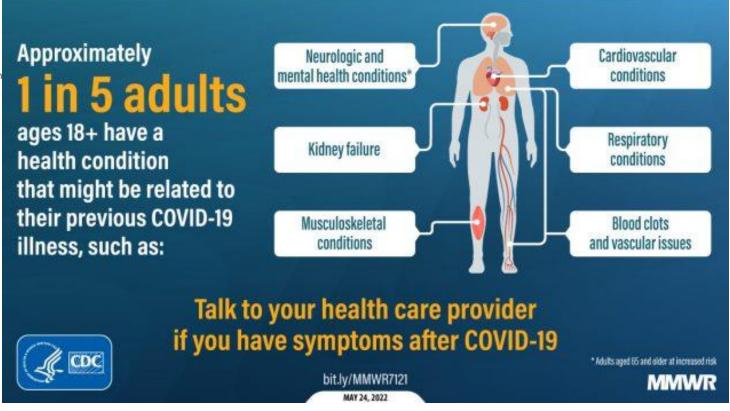
Post-COVID Conditions Among Adult COVID-19 Survivors Aged 18-64 and ≥65 Years — United States, March 2020-

November 2021

Weekly / May 27, 2022 / 71(21);713-717

On May 24, 2022, this report was posted online as an MMWR Early Release.

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Is there any value of fluvoxamine in treating outpatients with COVID-19?





The CDC still says that people with COVID can leave isolation after 5 days (if symptoms are improving). In your opinion, with rapid antigen tests readily available now, what do you think of the CDC guidance?



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