
COVID19
Keeping Up with a Moving Target

CME Information

Jointly provided by Postgraduate Institute for Medicine, DKBmed, and the Institute for Johns Hopkins Nursing.

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The faculty reported the following financial relationships or relationships they or their spouse/life partner have with commercial interests related to the content of this continuing education activity:

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

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

All activity, content, and materials have been developed solely by the activity directors, planning committee members, and faculty presenters, and are free of influence from a commercial entity.

CME Information

To attest for CME/CE/AAPA credit, please visit

COVID19.dkbmed.com

Learning Objectives

- Discuss the various treatment options currently available for outpatients at risk of severe COVID-19

Thank You

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

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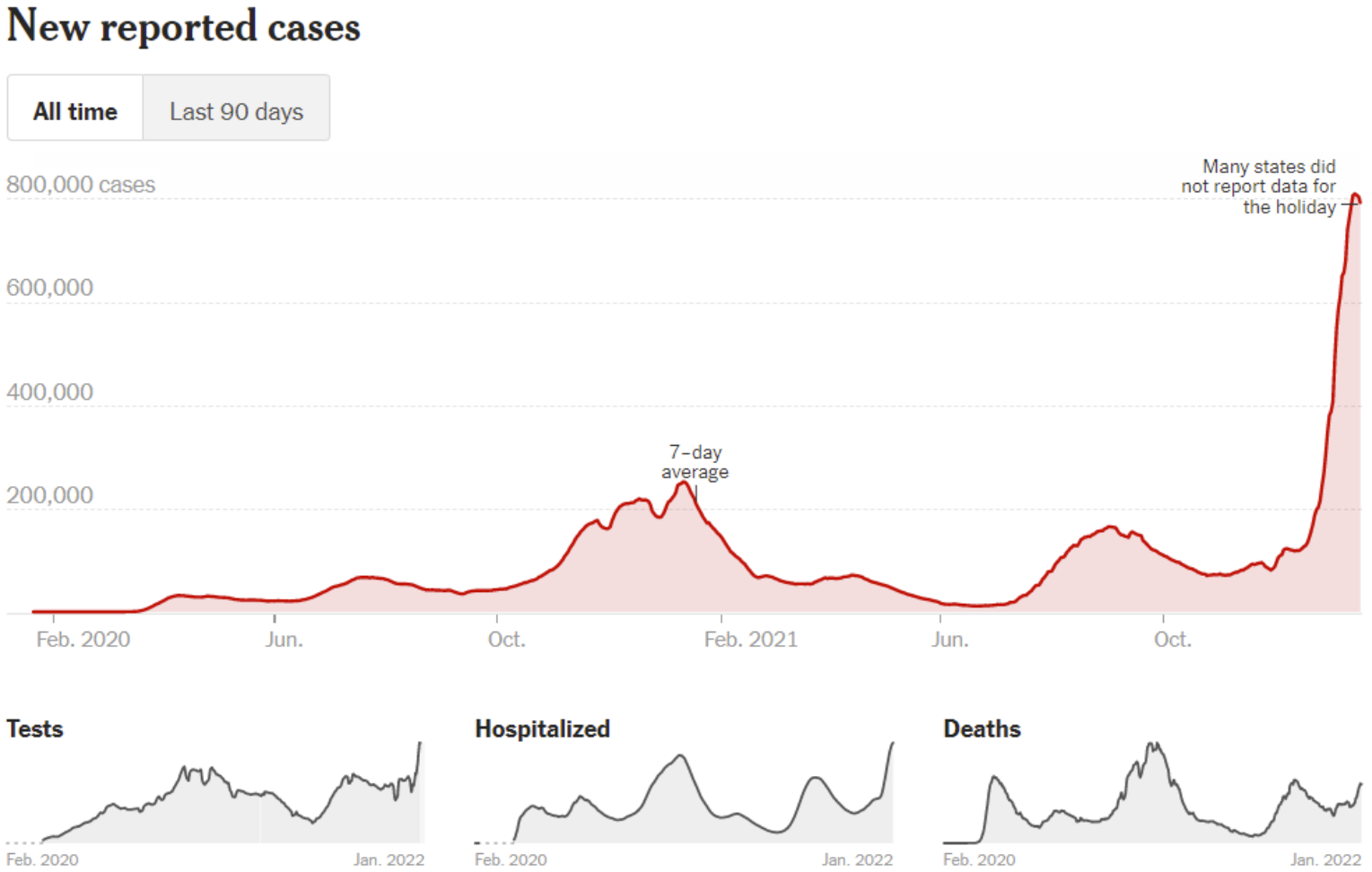
Please see **COVID19.DKBmed.com** for additional resources and educational activities

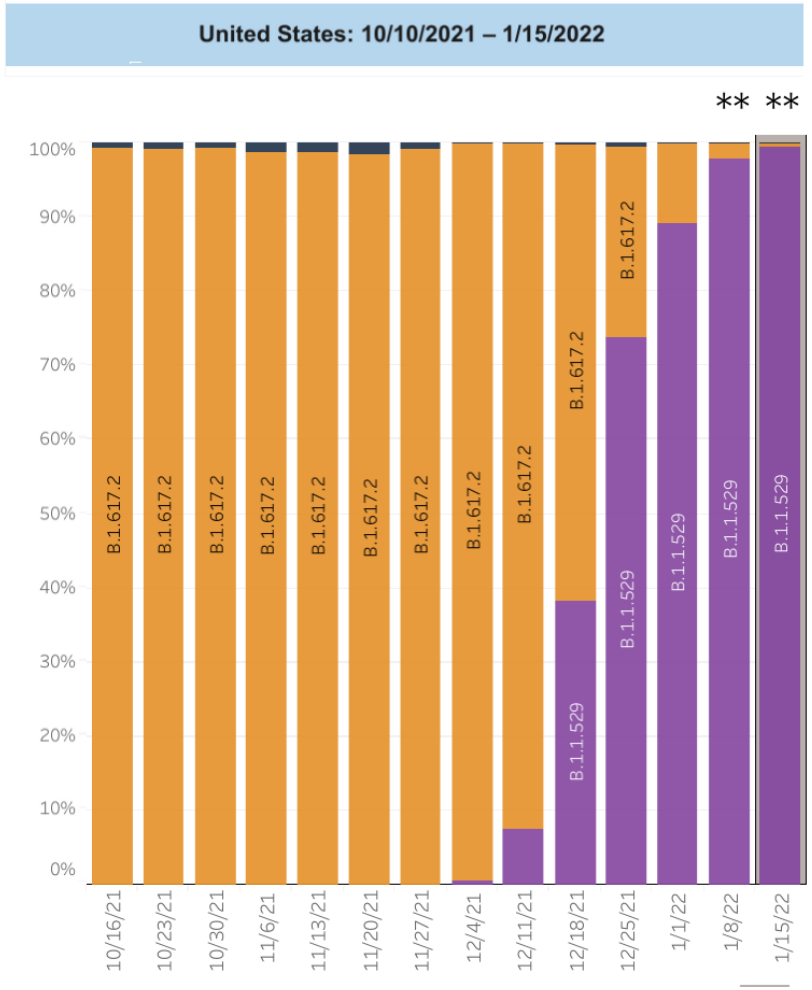
Paul Auwaerter, MD, MBA, FIDSA
Clinical Director, Division of Infectious Diseases
Sherrilyn and Ken Fisher Professor of Medicine
Fisher Center for Environmental Infectious Diseases
Johns Hopkins University School of Medicine

Impact of the Omicron Variant, US Data



CDC/NYT 1/18/22

The Success of the Omicron Variant



United States: 1/9/2022 – 1/15/2022 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	B.1.1.529	VOC	99.5%	99.3-99.7%
Delta	B.1.617.2	VOC	0.5%	0.3-0.7%
Other	Other*		0.0%	0.0-0.0%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# AY.1-AY.127 and their sublineages are aggregated with B.1.617.2. BA.1, BA.2 and BA.3 are aggregated with B.1.1.529.

Testing for SARS-CoV-2 Omicron variant

Antigen Binax Now reported for symptomatic illness

- Sensitivity ranging 50-90%
- Specificity >99%

Analysis Binax Now antigen, Omicron

- PCR positive swabs collected
- If > 100,000 copies/swab antigen = PCR (both delta & omicron)
- Antigen limited of detection = 20,000-70,000 viral copies/swab
  - Best in class limit of detection RT-PCR = 100 viral copies/swab

Detection of the omicron variant virus with the Abbott BinaxNow SARS-CoV-2 Rapid Antigen Assay | medRxiv (12/27/21)

Mild-Moderate COVID-19 Therapies for Ambulatory Patients at High Risk of Severe COVID-19, avoiding 28/29 day Hospitalization or Death

Drug/Study	Placebo	Experimental	Risk difference	NNT	Comments
Paxlovid/Pfizer w/i 5d sx, mITT	66/1049 (6.3%)	8/1039 (0.8%)	88% (95% CI: 75-94%)	18.2	9 vs. 0 deaths Drug interactions!
Molnupiravir	68/699 (9.7%)	48/708 (6.8%)	30% (95% CI: 1-51%)	34.5	9 vs. 1 deaths
Remdesivir (3d)	15/283 (5.3%)	2/279 (0.7%)	87% HR 0.13 (95% CI 0.03-0.59)	21.7	No deaths
Sotrovimab	21/292 (7%)	3/291 (1%)	85% 97.24% CI 44-96%	16.7	Interim analysis
Convalescent Plasma (high-titer)	37/589 (6.3%)	17/592 (2.9%)	54% RR 0.46, p = 0.004	29.4	Median transfusion sx 6d Pre-omicron

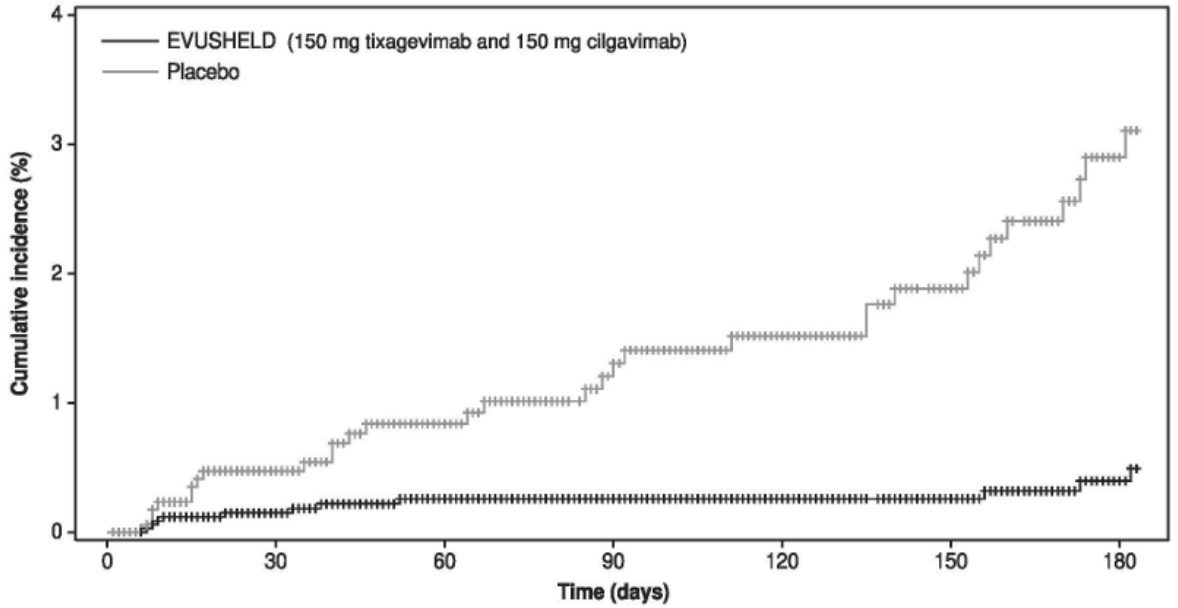
Paxlovid Healthcare Provider Fact Sheet (Dec 2021)
Molnupiravir Healthcare Provider Fact Sheet (Dec 2021)
Gottlieb NEJM 12/22/21
Gupta NEJM 11/18/21
Sullivan https://www.medrxiv.org/content/10.1101/2021.12.10.21267485v1 (12/21/21)

Evusheld for PrEP SARS-CoV-2
tixagevimab + cilgavimab

PROVENT trial

- Evusheld (n = 3,441) v. placebo (n = 1,731)
  - 1° endpoint: (+) SARS-CoV-2 RT-PCR over 183 d
  - 8 (0.2%) v. 17 (1.0%) in the placebo; 77% reduction (95% CI, 46-90%; *P* < 0.001)
- Appears safe

Figure 1 Kaplan Meier: Cumulative Incidence of Symptomatic COVID-19* (PROVENT)



Number of participants at risk

EVUSHELD	3441	2957	2393	2054	1815	1667	1044
Placebo	1731	1483	1177	991	856	774	472

* Subjects who do not experience a primary endpoint event (and had not discontinued) are censored at Day 183. Subjects who were unblinded/vaccinated prior to an event are also censored at the earlier time of unblinding/vaccination.

https://www.fda.gov/media/154701/download

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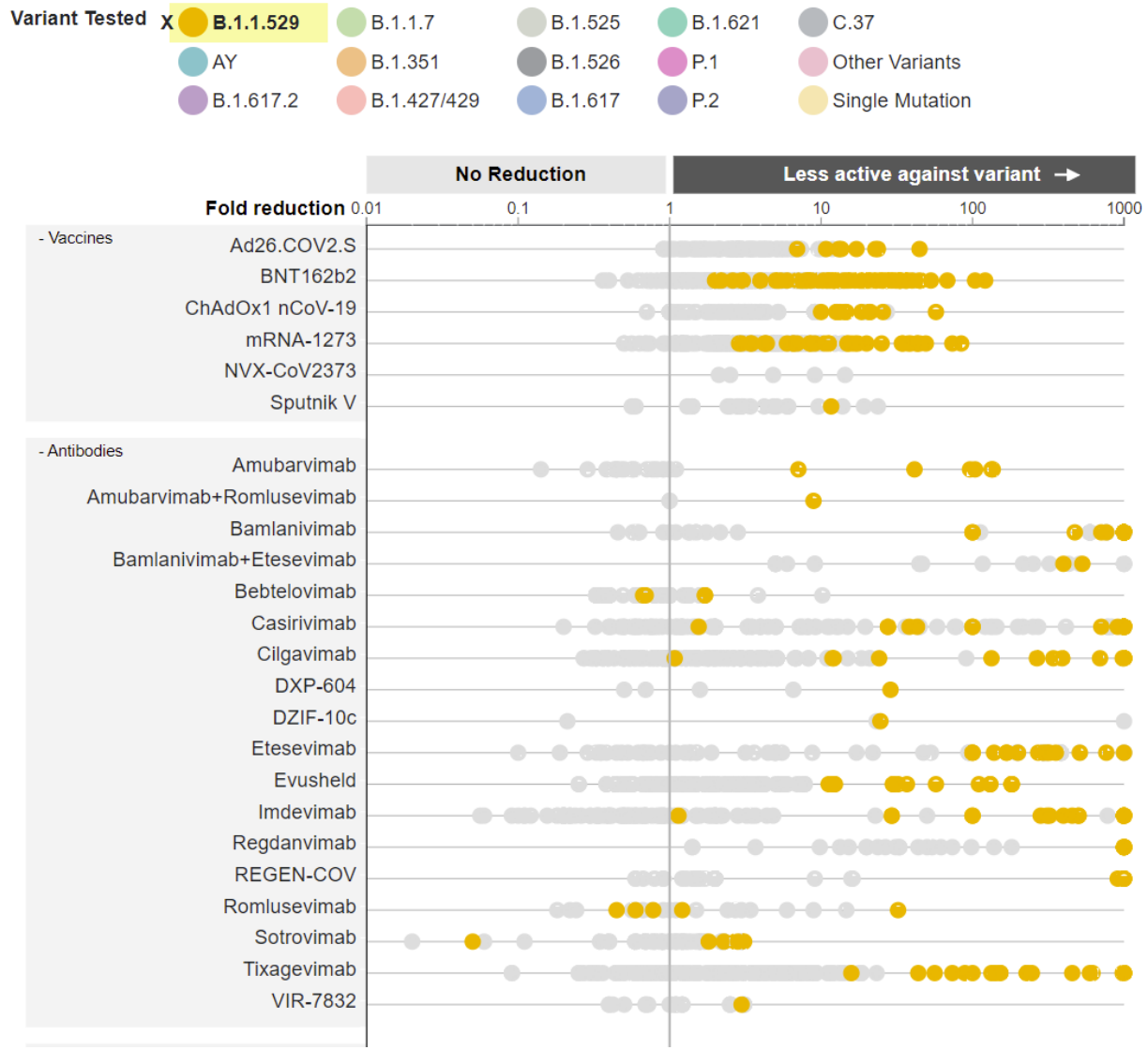
PROVENT trial caveats

- Two IM injections
  - No protection first two weeks
- PrEP had few immunosuppressed patients
- Data is only 83d of follow-up
- Some also immunized
- Study done w/ earlier variants
  - No data regarding efficacy w/ Omicron

https://www.fda.gov/media/154701/download

Omicron Effects

- In vitro studies
- Little or no significant activity
  - Bamlanivimab/etesevimab
  - Casiriviamb/imdevimab
- Sotrivmab retains activity
- Evusheld 10-100x reduced activity



https://opendata.ncats.nih.gov/variant/activity (accessed 1/18/22)

With limited supply of the drugs for outpatients, how are patients at high risk for severe disease being treated now?

Is throat or saliva swabbing more effective than nasal swabs for detection of omicron?

Thank You!

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Upon registering and successfully completing the activity evaluation, you will have immediate access to your certificate.

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- QA@dkbmed.com