

CDC/IDSA Clinician Call

Ending of the COVID-19 Public Health Emergency & Other Related Changes: What Clinicians Need to Know

June 6, 2023

Q&A

This is the Q&A transcript from the Zoom webinar held on May 4, 2023. The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

- 1. Are we allowed to break up Paxlovid boxes for inpatient unit dose pre-packaging and administration? How should it work when a patient is doing transition of care and goes from a hospital to home and has a few days left, will pharmacies be able to split boxes so patients don't get excess drug? Are we to assign a box to a patient and that box sticks with them throughout their care regardless of care setting? Any guidance on requirements or flexibility commentary around this are appreciated.**

Dr. John Farley: Good question as there are patients with mild-mod COVID who end up hospitalized. For those patients, treatment has been authorized under the EUA for a long time. Can't answer the pharmacy practice question and that likely is based on facility policies.

- 2. Your 5 ACH suggestion can be difficult and energy-expensive to achieve mechanically. What is CDC currently saying about upper-room germicidal UV light? It can easily achieve 10+ microbially-equivalent ACH.**

Dr. Brendan Jackson: Excellent point. I should have been clearer the recommendation is for equivalent ACH, which can include not just outdoor air but also filtration and UV light treatment, both of which can be less energy intensive.

- 3. Some countries such as Australia have Rapid Test reporting both + and - while the UK, has the Zoe symptoms app, both are helpful for the public to use as an early indicator and make decisions to stay safe. Why is the USA not doing one or the other? Where are the results of the NIH, makemytestcount.org posted with region breakdown?**

Dr. Brendan Jackson: NIH has supported a platform to report home tests called makemytestcount.org. Check it out; it's very easy to use. It yields similar results to other surveillance platforms. It's something we're very interested in at CDC and eager to see it progress.

- 4. Is it true that hospital onset COVID cases are /will no longer being reported/ tracked? If so, why? Mortality for HO COVID has been 11.2% for July 22-Mar 23 in Victoria, Australia (omicron era, high primary vaccination coverage and use of antivirals).**

Dr. Alex Kallen: Hi Marion. HO COVID will be optional due to new reporting requirements following end of PHE. It was never a great measure because it was cumulative measure of COVID after 14 days of admission. So, it was not at the person level (i.e., long admission for one person might skew things).

- 5. @Dr Pennini can you discuss the following questions about the new bivalent scheduled for the Fall of 2023 (1) It was purchased by USG and is free? (2) It will contain two Omicron variants.**

Dr. Meghan Pennini: Going forward, we will transition back to normal market channels for vaccines. The USG does not intend to purchase additional product for the expected fall campaign. We are working across HHS to develop programs to ensure continued access for all individuals. I cannot speak to the strain composition, there is a VRBPAC meeting scheduled for June 15th that will discuss the composition of the fall vaccine. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-15-2023-meeting-announcement>

- 6. How will HHS/ASPR address underinsured, not uninsured, re: vaccines and treatment?**

Dr. Brendan Jackson: The HHS Bridge Access Program is also intended to address the underinsured. More details to come. <https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-announces-hhs-bridge-access-program-covid-19-vaccines-treatments-maintain-access-covid-19-care-uninsured.html>

- 7. What public service announcements in the media will be initiated or continued to support the public's perception of the science of COVID and immunization?**

Dr. Brendan Jackson: The Assistant Secretary for Public Affairs in HHS is responsible for public service announcements around COVID-19 vaccines: <https://wecandothis.hhs.gov/>

- 8. Is there a funding/economic reason for why new monoclonals/monoclonal antibodies are not being developed and tested for new variants? I meant monoclonal antibodies/monoclonal antibody cocktails.**

Dr. Brendan Jackson: Not my area, but since you asked about COVID funding: <https://www.npr.org/2023/05/31/1178996725/debt-ceiling-deal-unspent-covid-relief-money-democrats-republicans>

Dr. Meghan Pennini: There is continued investment in R&D for next generation products through Project NextGen and other mechanisms. HHS continues to test the existing antibody treatments against the newer variants to determine if any become effective again.

Attendee Response: AstraZeneca are working on "Supernova" clinical trials, ie Evusheld 2.0.

Attendee Response: Thank you....just looked it up, very good data <https://www.astrazeneca-us.com/media/statements/2022/first-participant-dosed-in-supernova-phase-I-III-trial-evaluating-azd5156-a-next-generation-long-acting-antibody-combination-for-prevention-of-covid-19.html>

9. In Los Angeles there is no access to IV Remdesivir--no home health company will give it and hospitals require admission. What can be done to correct this?

Dr. Meghan Pennini: A quick glance on the locator tool shows about 5 providers in that area. <https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/> Though we appreciate it is not as accessible as some of the other products.

10. Is outpatient remdesivir fairly widely available?

Dr. Meghan Pennini: Due to the operational constraints associated with outpatient remdesivir administration, it is not widely available. We continue to encourage providers to offer this product whenever possible. Providers are also encouraged to sign up to be represented on our locator tool so that providers and patients are better able to find access points. <https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/>

11. What is the current diagnostic sensitivity for Rapid Antigen Home tests?

Dr. Brendan Jackson: FDA has some helpful material on this issue: <https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety>

Pointing to this study: <https://www.medrxiv.org/content/10.1101/2022.08.04.22278274v1>

There's no indication that recent variants have different impacts on these tests.

12. Is there a planned or approximate date for when US government will stop supplying COVID vaccine? Also, is there a new COVID vaccine (updated version) planned for Fall/Winter 2023?

Meghan Pennini: We expect this transition sometime in the fall. The FDA is holding a VRBPAC meeting on June 15th to discuss a potential new COVID-19 vaccine composition for the Fall/Winter. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-15-2023-meeting-announcement>

13. Can someone drop the telehealth link here?

Dr. William Harris: Here's the one I was referring to (on Medicaid), but let me know if you need a different one: <https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf>

14. For Medicare patients, a provider must request the test? Walk up testing sites will require a provider's order to be covered?

Dr. William Harris: For Medicare coverage, a lab-performed test needs to be ordered by an appropriate clinician. More info is available at: <https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf>

15. Any monoclonal antibodies available?

Meghan Pennini: There are currently no monoclonal antibodies authorized for use in the U.S. due to current circulating variants. The oral antivirals are widely available.

16. Is remdesivir covered 100% on commercial now?

William Harris: If you mean commercial insurance (private insurance), coverage levels may vary by plan.