New and updated COVID-19 public health information

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Indian Country COVID-19 teleECHO

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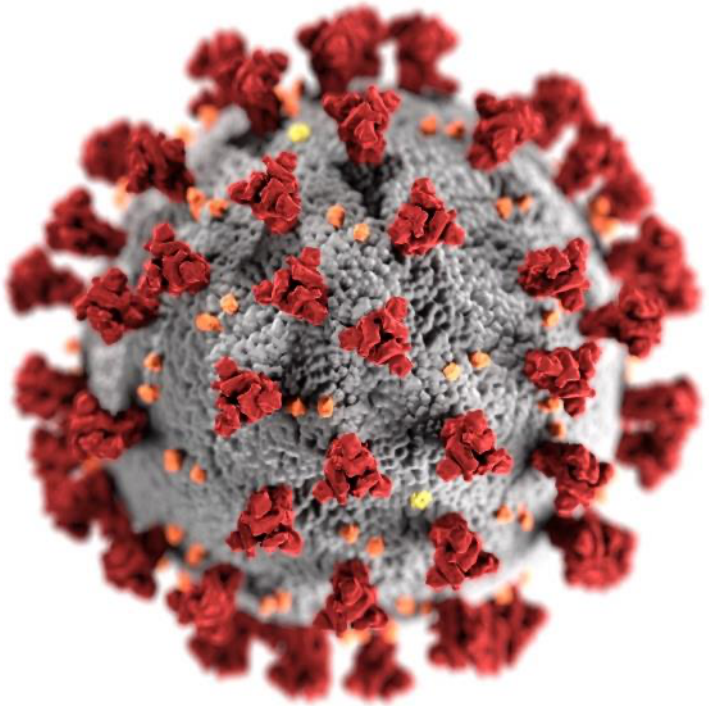


cdc.gov/coronavirus

Updates from FDA

- FDA allows more flexible storage and transportation conditions for Pfizer-BioNTech COVID-19 vaccine (2/25/2021)
- Preferred storage of undiluted frozen vials is in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F)
- New acceptable alternative for storage of undiluted frozen vials at conventional temperatures commonly found in pharmaceutical freezers (-25°C to -15°C [-13°F to 5°F]) for up to two weeks
- Change is based on data from Pfizer submitted to the FDA
  - Fact Sheet updated: https://www.fda.gov/media/144413/download
- Not applicable to storage of thawed vials before dilution (which can be held in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days). After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

Updates from FDA

- FDA issues Emergency Use Authorization (EUA) for Quidel QuickVue At-Home COVID-19 Test (3/1/2021)
- Rapid antigen test authorized for prescription home use for individuals suspected of COVID-19 by their healthcare provider within 6 days of symptom onset
  - Anterior nasal swab
  - Self-collected swab for individuals aged 14 years and older
  - Adult-collected swab for individuals aged 8 years and older
  - EUA: https://www.fda.gov/media/146309/download
- Clinical performance compared with RT-PCR in 161 symptomatic patients suspected of having COVID-19
  - Sensitivity 84.8%
  - Specificity 99.1%
  - Instructions for use: https://www.fda.gov/media/146312/download

Updates from FDA

- FDA Issues Authorization for First Molecular Non-Prescription, At-Home Test (3/5/2021)
- Nucleic acid amplification test authorized for non-prescription home use in persons with or without symptoms
- Anterior nasal swab
  - Self-collected swab for adults
  - Adult-collected swab for children aged 2 years and older
  - EUA: https://www.fda.gov/media/146467/download
- Clinical performance compared with a molecular comparator method in 273 subjects
  - Sensitivity 97.4%
  - Specificity 99.1%
  - Instructions for use: https://www.fda.gov/media/146470/download

Updates from NIH

- COVID-19 Treatment Guidelines Panel's statement on the EUA of the bamlanivimab plus etesevimab combination for the treatment of COVID-19 (2/23/2021)
  - https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-plus-etesevimab-eua/
- Panel recommends use of bamlanivimab 700 mg plus etesevimab 1,400 mg for treatment of **outpatients** with mild to moderate COVID-19 at high risk of clinical progression
  - BMI ≥35, chronic kidney disease, diabetes mellitus, immunocompromising condition or receiving immunosuppressive treatment, aged ≥65 years, or aged ≥55 years and have cardiovascular disease, hypertension, or COPD/other chronic respiratory disease
  - Treatment should start ASAP after positive SARS-CoV-2 test and within 10 days of symptom onset
- Panel recommends **against** the use of bamlanivimab + etesevimab for patients hospitalized because of COVID-19
- Bamlanivimab + etesevimab should not be withheld from a pregnant individual at high risk of progression to severe COVID-19
- Insufficient pediatric data to recommend either for or against the use of bamlanivimab + etesevimab or other monoclonal antibody products for children with COVID-19

Updates from HHS

- Biden Administration secures supply of new COVID-19 therapeutic treatment (2/26/2021)
  - https://www.phe.gov/Preparedness/news/Pages/COVID-etesevimab.aspx
- HHS and the Department of Defense collaborated to purchase 100,000 treatment courses of bamlanivimab + etesevimab
- HHS implemented a direct ordering system for healthcare facilities to order any of the available therapeutics, free of charge to receiving sites
  - C19 Therapies Direct Order Request: https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8

Updates from CDC

Guidance and Resources

- Vaccinate with confidence
- Updates to clinical considerations for use of COVID-19 vaccines

MMWR

- Recurrent COVID-19 infections at a skilled nursing facility
- Advisory Committee on Immunization Practices' interim recommendation for use of Janssen COVID-19 vaccine
- First case of variant P.1 in the United States
- Body mass index and risk for severe COVID-19

Vaccinate with Confidence

Protect communities. Empower families. Stop myths.

- CDC's Vaccinate with Confidence webpage provides information and resources for addressing vaccine hesitancy: https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html
- COVID-19 Vaccines Strategy: build trust, empower health care personnel, engage communities and individuals https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence/strategy.html
- Resources
  - How to Build Confidence in COVID-19 Vaccines: A Short Guide for Immunization Coordinators in Medical Centers and Clinics (PDF)
  - Communications and Confidence Readiness Checklist (PDF)
  - The COVID-19 Vaccine Confidence Conversation Starter (PDF)
  - COVID-19 Vaccination Communication Toolkit: posters, stickers, social medial messages, and more: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States - updated 3/3/2021

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

- Clinical considerations added for use of Janssen COVID-19 vaccine (Johnson & Johnson)
- People with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa
- For vaccinated people who subsequently experience COVID-19, prior receipt of a COVID-19 vaccine should not affect treatment decisions or timing of treatments
- If a person is fully vaccinated (i.e., ≥2 weeks after completion of a 2-dose mRNA series or single dose of Janssen COVID-19 vaccine) and tests positive for SARS-CoV-2, healthcare providers and local health departments are encouraged to request the specimen be held and to report the case to their state health department. Information about these cases should be reported to VAERS.
- Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination

Morbidity and Mortality Weekly Report (*MMWR*)

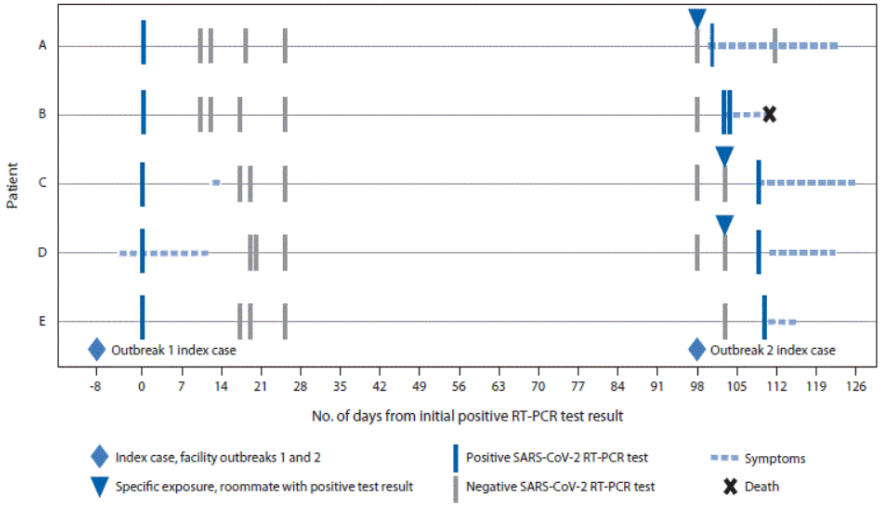
CDC

Suspected Recurrent SARS-CoV-2 Infections Among Residents of a Skilled Nursing Facility During a Second COVID-19 Outbreak — Kentucky, July–November 2020

Weekly / February 26, 2021 / 70(8);273–277

- 5 skilled nursing facility (SNF) residents received positive SARS-CoV-2 test results during facility outbreaks in Jul and Oct 2020, suggesting possible reinfection
  - All 5 residents had ≥ 4 negative test results between the two outbreaks
  - Disease severity worse during second outbreak
- SNFs should use strategies to reduce the risk for SARS-CoV-2 transmission among all residents, including those who have previously had COVID-19
- Vaccination of SNF residents and health care personnel is particularly important

Patient timelines



Morbidity and Mortality Weekly Report (*MMWR*)

CDC

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021

Early Release / March 2, 2021 / 70

- FDA issued an EUA for the Janssen (Johnson & Johnson) COVID-19 vaccine on Feb 27, 2021
  - Recombinant, replication-incompetent adenovirus vector vaccine that encodes the spike glycoprotein of SARS-CoV-2
  - Requires only a single dose and refrigerator temperatures (36°F–46°F [2°C–8°C]) for transportation and storage
- Advisory Committee on Immunization Practices (ACIP) recommends use of the Janssen COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19
- ACIP does not state a product preference; persons may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them

Morbidity and Mortality Weekly Report (*MMWR*)

CDC

First Identified Cases of SARS-CoV-2 Variant P.1 in the United States — Minnesota, January 2021

Early Release / March 3, 2021 / 70

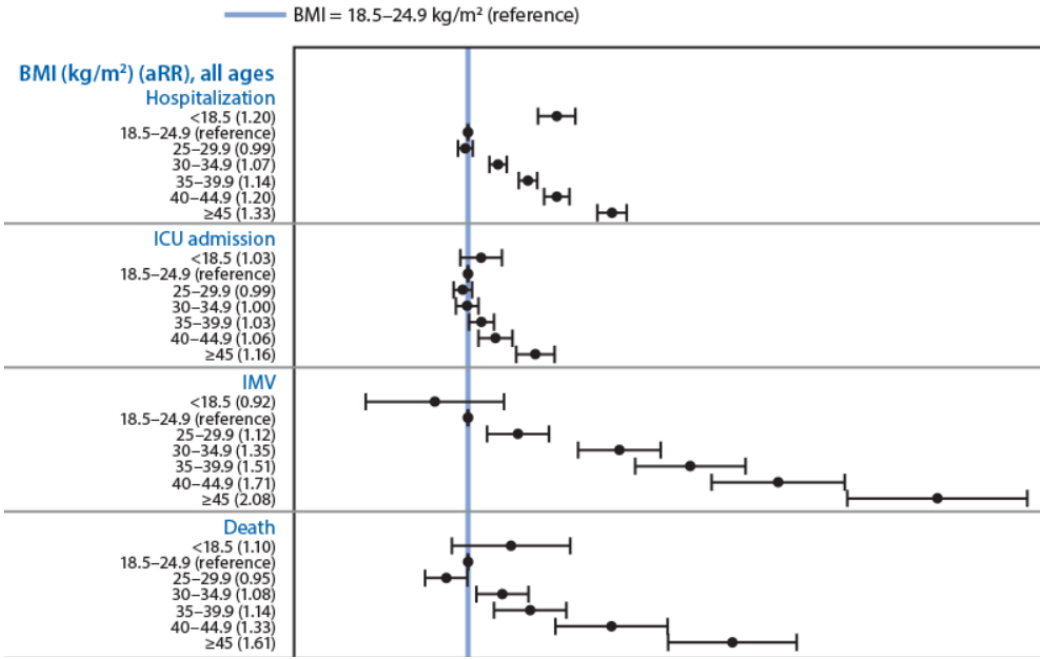
- Since Dec 2020, Minnesota Department of Health (MDH) has been sequencing 100 SARS-CoV-2 specimens a week for routine surveillance
- On Jan 25, 2021, MDH identified the first case of SARS-CoV-2 variant P.1 in the U.S.
  - P.1 was first detected in travelers from Brazil and is associated with increased transmissibility; changes in spike protein might disrupt vaccine-induced and natural immunity
  - 2 P.1 cases identified by MDH in a hospitalized patient who had recently traveled to Brazil and a household member
- As of Mar 15, 2021 15 cases of P.1 have been reported in the U.S. https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html
- Genomic surveillance of SARS-CoV-2 is an important public health tool
- Community prevention strategies to slow transmission of SARS-CoV-2 remain important

Body Mass Index and Risk for COVID-19–Related Hospitalization, Intensive Care Unit Admission, Invasive Mechanical Ventilation, and Death — United States, March–December 2020

Early Release / March 8, 2021 / 70

- Data from 148,494 adults who received a COVID-19 diagnosis at 238 U.S. hospitals during Mar–Dec 2020
- Overweight and obesity were risk factors for invasive mechanical ventilation; obesity was a risk factor for hospitalization and death, particularly among adults aged <65 years
- Findings highlight implications of higher BMIs, including the need for intensive management of COVID-19, vaccine prioritization and masking, and policies to support healthy behaviors

Association between BMI and severe COVID-19 illness



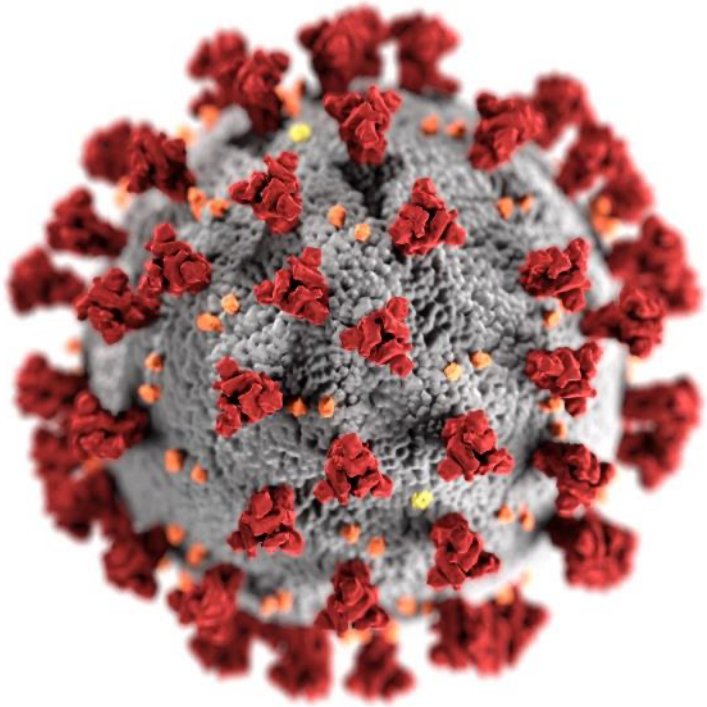
References

Updates (additional references)

- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer (FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine)
- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-authorization-quidel-quickvue-home-covid-19-test (FDA Issues Authorization for Quidel QuickVue At-Home COVID-19 Test)
- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-authorization-first-molecular-non-prescription-home-test (FDA Issues Authorization for Cue Non-prescription At-home COVID-19 Test)
- https://www.fda.gov/media/145801/download (EUA for bamlanivimab and etesevimab)

MMWRs

- Cavanaugh AM, et al. Suspected Recurrent SARS-CoV-2 Infections Among Residents of a Skilled Nursing Facility During a Second COVID-19 Outbreak — Kentucky, July–November 2020. MMWR Morb Mortal Wkly Rep 2021;70:273–277. DOI: http://dx.doi.org/10.15585/mmwr.mm7008a3
- Rinott E, et al. Reduction in COVID-19 Patients Requiring Mechanical Ventilation Following Implementation of a National COVID-19 Vaccination Program — Israel, December 2020–February 2021. MMWR Morb Mortal Wkly Rep. ePub: 26 February 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7009e3
- Oliver SE, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021. MMWR Morb Mortal Wkly Rep. ePub: 2 March 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7009e4
- Firestone MJ, et al. First Identified Cases of SARS-CoV-2 Variant P.1 in the United States — Minnesota, January 2021. MMWR Morb Mortal Wkly Rep. ePub: 3 March 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7010e1
- Kompaniyets L, et al. Body Mass Index and Risk for COVID-19–Related Hospitalization, Intensive Care Unit Admission, Invasive Mechanical Ventilation, and Death — United States, March–December 2020. MMWR Morb Mortal Wkly Rep. ePub: 8 March 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7010e4



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov