New and updated COVID-19 public health information

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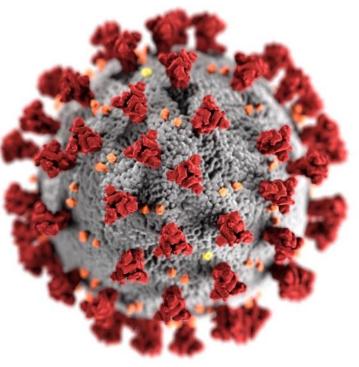
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Indian Country COVID-19 teleECHO

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cdc.gov/coronavirus

Updates from FDA

- FDA issues Emergency Use Authorization (EUA) for Adaptive Biotechnologies T-Detect COVID Test (3/5/2021)
- For identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or prior infection
- PCR + sequencing to identify T-cell receptor beta gene sequences specific for SARS-CoV2
 - Authorized for use in patients 15 days or more post symptom onset
 - EUA: <u>https://www.fda.gov/media/146481/download</u>
- Clinical performance evaluated using blood samples from 175 COVID-19 patients (≥ 15 days from onset) and 99 negative controls
 - Sensitivity 96.0%
 - Specificity 99%



Updates from FDA

- Why you should not use ivermectin to treat or prevent COVID-19 (3/5/2021)
- FDA has not approved ivermectin for use in treating or preventing COVID-19 in humans
- The FDA has received multiple reports of patients who required medical support and been hospitalized after self-medicating with ivermectin intended for horses
- Taking large doses of this drug is dangerous and can cause serious harm. Ivermectin preparations for animals are very different from those approved for humans.
- https://www.fda.gov/consumers/consumer-updates/why-you-should-not-useivermectin-treat-or-prevent-covid-19



www.fda.gov

Updates from CMS

- CLIA SARS-CoV-2 variant testing frequently asked questions (3/10/2021)
- Does a facility that performs surveillance testing to identify SARS- CoV-2 genetic variants need a CLIA certificate?
 - Sequencing to identify SARS-CoV-2 variants can be performed in a facility that is <u>NOT</u> CLIA certified, provided that patient-specific results are <u>not</u> reported to (1) the individual who was tested or (2) their health care provider
 - Results can be reported to Public Health Departments for public health purposes
 - CLIA-certified laboratories can report patient-specific results to authorized persons (e.g. individual who was tested, their health care provider, or a Public Health Department) for SARS-CoV-2 genetic variant testing
 - If a CLIA certified laboratory decides to report patient-specific results to an individual or their healthcare provider, the laboratory must establish performance specifications for their assay
- CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 genetic variant testing
- https://www.cms.gov/files/document/clia-sars-cov-2-variant.pdf

Updates from CMS

- Biden-Harris administration increases Medicare payment for life-saving COVID-19 vaccine (3/15/2021)
- Effective for COVID-19 vaccines administered on or after 3/15/2021, the average payment rate for physicians, hospitals, pharmacies and other immunizers will be \$40 to administer each dose of a COVID-19 vaccine
 - Increase from approximately \$28 to \$40 for the administration of single-dose vaccines, and an increase from approximately \$45 to \$80 for vaccines requiring two doses
- The exact payment rate will depend on the type of entity that furnishes the service and will be geographically adjusted based on where the service is furnished
- https://www.cms.gov/newsroom/press-releases/biden-harris-administration-increases-medicare-payment-lifesaving-covid-19-vaccine

Updates from HHS

- Biden administration to expand COVID-19 vaccine program to 950 community health centers (3/11/2021)
- An additional 700 Health Resources and Services Administration (HRSA)-supported health centers will be invited to join the Health Center COVID-19 Vaccine Program
- 700 health centers invited to participate in this program include those that:
 - Serve high proportions of low income and minority patients
 - Provide services to rural/frontier populations
 - Operate Tribal/Urban Indian Health Programs
 - Utilize mobile vans to deliver services
- List of participating and invited health centers: <u>https://www.hrsa.gov/coronavirus/health-center-program/participants</u>

Updates from CDC

Guidance and Resources

- Public health recommendations for fully vaccinated people
- Updated healthcare recommendations in response to COVID-19 vaccination MMWR
- Racial and ethnic disparities in COVID-19 incidence
- COVID-19 vaccine second dose completion
- Effectiveness of COVID-19 vaccine in skilled nursing facility outbreaks

Interim Public Health Recommendations for Fully Vaccinated People (3/8/2021)

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinatedguidance.html

Fully vaccinated people can:

- Gather indoors with other fully vaccinated people without wearing masks or physically distancing
- Gather indoors with unvaccinated people from one other household without masks, unless any of those people or anyone they live with has an increased risk for severe illness from COVID-19
- Refrain from quarantine and testing following a known exposure if asymptomatic

Fully vaccinated people should continue to:

- Take precautions in public (masks and distancing) and when visiting with people at increased risk for severe COVID-19
- Avoid medium or large gatherings





Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination - updated 3/11/2021

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

- Fully vaccinated health care personnel (HCP) who are asymptomatic do not need to be restricted from work for 14 days following a COVID-19 exposure
 - Work restrictions should still be considered for HCP who have underlying immunocompromising conditions, which might impact vaccination
- HCP who have traveled should continue to follow CDC travel recommendations and requirements, including restriction from work
- Fully vaccinated inpatients and residents in healthcare settings should continue to quarantine following close contact with someone with SARS-CoV-2 infection
 - Although not preferred, healthcare facilities could consider waiving quarantine for fully vaccinated patients and residents following close contact as a strategy to address critical issues (e.g., lack of space, staff, or PPE to safely care for exposed patients or residents) when other options are unsuccessful or unavailable

CDC

Racial and Ethnic Disparities in COVID-19 Incidence by Age, Sex, and Period Among Persons Aged <25 Years — 16 U.S. Jurisdictions, January 1– December 31, 2020

Early Release / March 10, 2021 / 70

- Data from 16 jurisdictions with ≥ 70% race and ethnicity data complete
- Incidence higher in females and lowest in younger children
- Largest persistent disparities in incidence involved American Indian or Alaska Native and Hispanic persons
- Ensuring equitable and timely access to preventive measures, including testing, safe work and education settings, and vaccination is important to address racial/ethnic disparities

Race/ethnicity (n)	No. of cases	Cases per 100,000 pop. (95% Cl)	Rate Ratio (95% CI)
AI/AN	536	163 (150–177)	4.6 (4.2–5.1)
Asian	498	54 (49–59)	1.5 (1.4–1.7)
Black	2,461	87 (83–90)	2.5 (2.3–2.6)
NH/PI	73	88 (70–111)	2.5 (2.0–3.1)
White	4,947	35 (34–36)	Ref
Hispanic/Latino	6,129	137 (133–140)	3.9 (3.7–4.0)
Multiple, non- Hispanic	424	38 (35–42)	1.1 (1.0–1.2)

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COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020-February 14, 2021 Race/ethnicity Completed No 2nd dose Overdu

Early Release / March 15, 2021 / 70

- Data from 12,496,258 persons who received a first COVID-19 vaccine dose with sufficient time to receive the 2nd dose
- 88.0% completed the series; 8.6% awaiting 2nd dose; 3.4% overdue for the 2nd dose
- Lowest series completion and highest proportion overdue for 2nd dose was among AI/AN persons
- Providers can help people get the 2nd dose on time
 - Schedule 2nd dose appointments at 1st dose visits
 - Send reminders

Race/ethnicity (n)* (n=6,764,604)	Completed series (%)	No 2 nd dose but within window	Overdue 2 nd dose
AI/AN (145,449)	83.7	11.2	5.1
Asian (365,379)	90.2	7.0	2.8
Black (366,379)	88.8	8.6	2.6
NH/PI (17,755)	90.3	6.8	2.9
White (4,138,164)	90.2	7.4	2.3
Hispanic/Latino (718,384)	87.0	9.5	3.5
Multiple/other, non-Hispanic (1,013, 031)	86.1	10.7	3.2

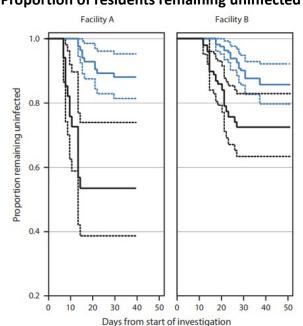
*reported from 54.1% of persons

CDC

Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020–February 2021 Proportion of residents remaining uninfected

Early Release / March 15, 2021 / 70

- Investigation of two skilled nursing facilities with COVID-19 outbreaks after each facility's first vaccination clinic
- Vaccine effectiveness (VE) estimated for partial vaccination (>day 14 after 1st dose through day 7 after 2nd dose)
- VE in preventing SARS-CoV-2 infection was 63% (33%–79%)
- While partial vaccination with Pfizer-BioNTech COVID-19 vaccine provided protection, high coverage with the complete 2-dose series is recommended to optimize vaccine impact among this population.



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Unvaccinated — Partially vaccinated ::: 95% confidence intervals

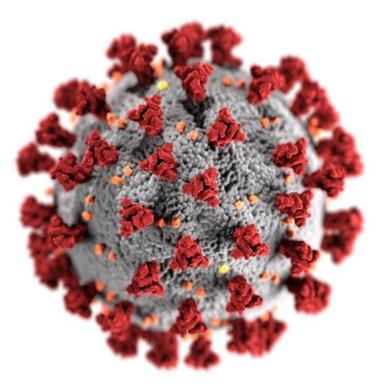
References

Updates (additional references)

- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-adaptivebiotechnologies-t-detect-covid-test (FDA Authorizes Adaptive Biotechnologies T-Detect COVID Test)
- <u>https://www.hhs.gov/about/news/2021/03/11/biden-administration-expand-covid-19-vaccine-program-950-community-health-centers.html</u> (Biden Administration to Expand COVID-19 Vaccine Program to 950 Community Health Centers)

MMWRs

- Van Dyke ME, et al. Racial and Ethnic Disparities in COVID-19 Incidence by Age, Sex, and Period Among Persons Aged
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- Kriss JL, Reynolds LE, Wang A, et al. COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020–February 14, 2021. MMWR Morb Mortal Wkly Rep. ePub: 15 March 2021. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7011e2</u>
- Britton A, et al. Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020–February 2021. MMWR Morb Mortal Wkly Rep. ePub: 15 March 2021. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7011e3</u>



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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

