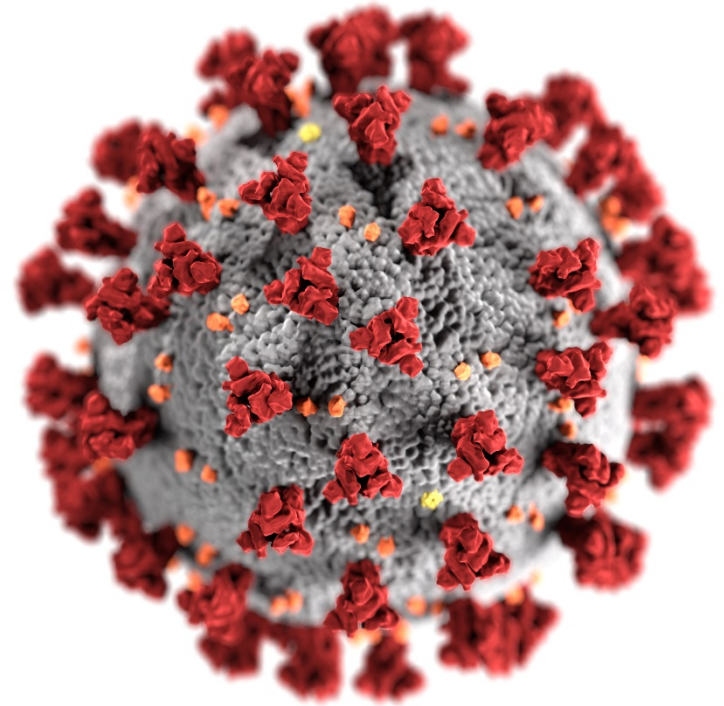


CDC and FDA updates

Temet McMichael, PhD
Epidemic Intelligence Service Officer
Public Health – Seattle & King County

Indian Country COVID-19 teleECHO
December 14, 2020



cdc.gov/coronavirus

FDA, COVID-19 page: <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

CDC, what's new: <https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>

WA DOH, literature reports:
<https://www.doh.wa.gov/Emergencies/COVID19/Resources>



FDA Authorizes First Direct-to-Consumer COVID-19 Test System

First direct to consumer non-prescription test system:

- LabCorp's Pixel COVID-19 test home collection kit
 - 18 or older
 - No rx needed
 - Self collected nasal swab
 - Mail based
 - PCR based test
 - For symptomatic, confirmed COVID-19 exposure, or testing recommended by: HCP, PH, or CT investigator
 - Positive or invalid test results are delivered to user by phone from HCP
 - Negative results delivered via email or online portal
 - Results within 1-2 days of sample arriving at lab; lab open 7 days a week



Accessed online, Pixel by LabCorp, 12/10/20: <https://www.pixel.labcorp.com/at-home-test-kits/covid-19-test-home-collection-kit>

FDA Authorizes First Direct-to-Consumer COVID-19 Test System



1. Complete a short eligibility* survey

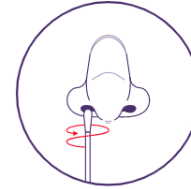
*Test requests are evaluated and, if appropriate, authorized by an independent physician.



2. Choose a billing option. We can bill your insurance, utilize federal funds to cover the cost of this test on your behalf if you're uninsured, or you can pay with a credit card. Learn more [here](#).



3. Receive your sample collection kit via FedEx



4. [Collect your sample](#) and send it back to our world-class lab for testing



5. Access your results online



FDA Authorizes First COVID-19 and Flu Combination Test for use with home-collected samples

Quest diagnostics RC COVID-19 +Flu RT-PCR test

- At home self collected nasal swab
- For those with symptoms of either virus
- For those 18 years and older
- Simultaneous detection of nucleic acids (PCR) from SARS-CoV-2 & influenza A and/or influenza B virus
- When HCP determines home collection is appropriate
 - Qualify patient
 - Submit order to Quest
 - Quest ships kit to patient
 - Patient ships back
- Results through MyQuest

Target 1 Influenza A	Target 2 SARS-CoV-2	Target 3 Pan-Sarbecovirus	Target 4 Influenza B	Interpretation
Negative	Negative	Negative	Negative	No target RNA Detected
Negative	Negative	Negative	Positive	Influenza B RNA Detected
Positive	Negative	Negative	Negative	Influenza A RNA Detected
Positive	Negative	Negative	Positive	Influenza A and Influenza B RNA Detected

Accessed online, FDA.gov, 12/10/20: <https://www.fda.gov/media/144177/download>



FDA Issues New Policy on Dry Heat for Reuse of Certain respirators

Guidance for Dry Heat Reuse of respirators

- Heat and time
- Filtering facepiece respirators (FFR); N95s
- Single user reuse by HCP when supplies are limited
- Reduced bio-burden, **not decontamination**
 - ≥ 3 - log reduction in non-enveloped viruses or vegetative bacteria
 - Respirator integrity maintained
- Use these recommendation with existing CDC recommendations for FFR reuse

Consistent temperature of 70 °C for 60 minutes or 75 °C for 30 minutes

Highly controlled heat transfer (lab oven, industrial convection oven, etc.)

NOT HOME OVEN

Updates from CDC

Updates:

- Cases and deaths update
- Social media toolkit
- Food Pantries and Food distribution sites
- Guidance for dental settings
- Ventilation

MMWR:

- COVID-19 Mortality Among AI/AN Persons – 14 states, January – June 2020
- Level COVID-19 Incidence in Counties With and Without a Mask Mandate – Kansas, June 1 – August 23, 2020
- Implementing Mitigation Strategies in Early Care and Educational Settings for Prevention of SARS-CoV-2 Transmission – Eight States, September – October 2020
- Trends in U.S. ED Visits Related to Suspected or Confirmed Child Abuse and Neglect Among Children and Adolescents Aged <18 Years Before and During the COVID-19 Pandemic — United States, January 2019–September 2020
- The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020





Coronavirus Disease 2019 (COVID-19)

CDC COVID Data Tracker

Maps, charts, and data provided by the CDC

Case Trends ▾

County View

Laboratory ▾

Global Cases and Deaths ▾

Community Impact ▾

Unique Populations ▾

COVID-19 Home

Cases and Deaths by State

[US and State Trends](#)

[Compare State Trends](#)

[Demographics](#)

[Trends by Population Factors](#)

[Forecasting](#)

[Trends in ED Visits](#)

United States COVID-19 Cases and Deaths by State

Reported to the CDC since January 21, 2020

TOTAL CASES

16,113,148

+181,032 New Cases

AVERAGE DAILY CASES PER 100K IN

LAST 7 DAYS

64.5

TOTAL DEATHS

298,266

+1,448 New Deaths

CDC | Updated: Dec 14 2020 12:16PM

🏠 More Resources

CDC in Action +

Global COVID-19 +

Science & Research +

Guidance Documents

Communication Resources -

COVID-19 One-Stop Shop Toolkits +

Social Media Toolkit -

Holidays

Donate Blood Plasma & Help Save Lives

Communities, Schools & Workplaces

Daily Life & Going Out

Stop the Spread

MORE RESOURCES

CDC Social Media Toolkit

Find social media ready COVID-19 content on a variety of topics to help you successfully communicate with your audiences.

Updated Dec. 10, 2020 [Español \(Spanish\)](#) [Print](#)



For more information on social media best practices, visit the [Social Media at CDC](#) webpage.

Please visit CDC at: <https://www.cdc.gov/coronavirus/2019-ncov/communication/social-media-toolkit.html>

CDC in Action +

Global COVID-19 +

Science & Research +

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Daily Life & Going Out

Stop the Spread

Graphics and Buttons

Print Resources

Social Media Toolkit: Holidays

Updated Nov. 19, 2020 [Print](#)



On This Page

[Planning Thanksgiving](#)

[Staying Home](#)

[Attending a Gathering](#)

[Healthy Habits](#)

[Hosting a Gathering](#)

[Other Activities](#)

Thanksgiving

Planning Thanksgiving

Twitter Sample Message

Planning for #Thanksgiving? Consider hosting a virtual meal with friends and family who don't live with you. Have people share recipes and show off their turkey, dressing, and other dishes:

<https://www.cdc.gov/coronavirus/2019-ncov/daily-life->



Please visit CDC at: <https://www.cdc.gov/coronavirus/2019-ncov/communication/holidays.html>

COVID-19 (Coronavirus Disease)

CASES ARE RISING.
ACT NOW!



WEAR A MASK



STAY 6 FEET APART



AVOID CROWDS

Your Health ▾

Community, Work & School ▾

Healthcare Workers & Labs ▾

Health Depts ▾

Cases & Data ▾

More ▾

Community, Work & School

Health Equity +

Community Mitigation Framework

Cleaning & Disinfecting +

Workplaces & Businesses +

Schools & Child Care +

Colleges & Universities +

COMMUNITY, WORK & SCHOOL

Considerations for Food Pantries and Food Distribution Sites

Updated Dec. 8, 2020 [Languages](#) ▾ [Print](#)



The COVID-19 pandemic has brought new challenges to food security across the U.S. Access to healthy food options and nutrition are important to overall physical and mental health and well-being. Food insecurity is expected to continue to increase for many households with more children not attending childcare and school in-person (a source of nutritious meals for many students) and with changes in employment status during the COVID-19 pandemic.

On This Page

[Operational Considerations](#)

[Cleaning and disinfection](#)



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Healthcare Workers & Labs ▾

Health Depts ▾

Cases & Data ▾

More ▾

🏠 Healthcare Workers

Resources for Community Health Workers

Testing +

Vaccination

Clinical Care +

Infection Control -

Infection Control Guidance

Using PPE

Hand Hygiene

Alternate Care Sites

HEALTHCARE WORKERS

Guidance for Dental Settings

Interim Infection Prevention and Control Guidance for Dental Settings During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated Dec. 4, 2020 [Print](#)



Key Points

- Recognize dental settings have unique characteristics that warrant specific infection control considerations.
- Prioritize the most critical dental services and provide care in a way that minimizes harm to patients from delaying care and harm to personnel and patients from potential exposure to SARS-CoV-2 infection.
- Proactively communicate to both personnel and patients the need for them to stay at home if sick.
- Know the steps to take if a patient with [COVID-19 symptoms](#) enters your facility.

Please visit CDC at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/dental-settings.html>

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Community Mitigation Framework

Cleaning & Disinfecting +

Workplaces & Businesses -

Guidance for Businesses & Employers

FAQs for Workplaces & Businesses

COMMUNITY, WORK & SCHOOL

Ventilation

Updated Dec. 8, 2020 [Languages](#) ▾ [Print](#)



CDC recommends a layered strategy to reduce exposures to SARS-CoV-2, the virus that causes COVID-19. This includes using multiple mitigation strategies with several layers of safeguards to reduce the spread of disease and lower the risk of exposure. While it may not be necessary to apply every consideration to be protective, implementing multiple mitigation strategies is recommended, if possible, to improve effectiveness. In addition to ventilation, the layered approach includes efforts to improve [social distancing](#), [wearing face masks](#), and [hand hygiene](#).

SARS-CoV-2 viral particles spread between people more readily indoors than outdoors. When outdoors, the concentration of viral particles rapidly reduces with the wind, even a very light wind. When indoors, ventilation mitigation strategies help to

Please visit CDC at: <https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html>

- No cost: opening windows; inspecting and maintaining local exhaust ventilation; disabling DCV controls; or repositioning outdoor air dampers
- Less than \$100: using fans to increase effectiveness of open windows; or repositioning supply/exhaust diffusers to create directional airflow
- \$500 (approximately): adding portable HEPA fan/filter systems
- \$1500 (approximately): adding upper room UVGI

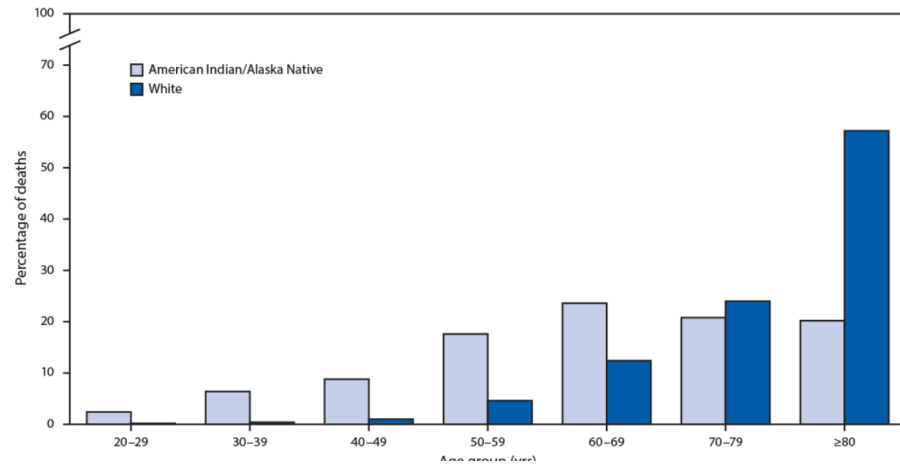


COVID-19 Mortality Among AI/AN Persons – 14 states, January – June 2020

Summary:

- COVID-19 workgroup to assess prevalence of COVID-19 deaths in AI/AN population
- States: AK, AZ, LA, MN, MS, NE, NM, NY, ND, OK, OR, SD, UT, and WA
- Age adjusted COVID-19 associated mortality among AI/AN was 1.8x compared to non-Hispanic Whites
- Among AI/ANs, mortality was higher among men vs. women
- Disparity in mortality compared with non-Hispanic Whites was highest among AI/AN aged 20–49 years

FIGURE. Percentage distribution of COVID-19–associated deaths among American Indian/Alaska Native* and non-Hispanic White persons aged ≥20 years, by age group[†] – 14 states,[§] January 1–June 30, 2020





Racial and Ethnic Differences in Parental Attitudes and Concerns About School Reopening During the COVID-19 Pandemic – United States, July 2020

Summary:

- Internet panel survey of parents of school aged children
- As compared to non-Hispanic White parents, racial and ethnic minority parents were more concerned about some aspects of school reopening
 - School mitigation measures
 - Safety
 - Their child contracting or bringing COVID-19 home
- Understanding these perceived differences could inform communication and mitigation strategies for school attendance during COVID-19 pandemic

TABLE 3. Parental attitudes and concerns about school reopening strategies and mask mandates, by race/ethnicity — ENGINE Insights, United States, 2020

Questions and responses	Racial/Ethnic group, % (95% CI)				
	Overall*	White, non-Hispanic*	Black, non-Hispanic *	Hispanic or Latino*	Other, ¹ non-Hispanic*
In light of the COVID-19 pandemic, how comfortable would you be with the following:					
Your children's school(s) reopening at full capacity in the fall					
Very comfortable/Somewhat comfortable	52.7 (48.9–56.4)	57.1 (52.4–61.8)	43.0 (32.0–53.9) [§]	53.3 (44.7–61.9)	32.5 (20.1–44.9) ^{§*}
Your children's school(s) reopening at 50% capacity in the fall, with the other 50% dedicated to virtual learning					
Very comfortable/Somewhat comfortable	66.2 (62.6–69.8)	67.9 (63.5–72.4)	58.2 (47.1–69.3)	67.1 (59.0–75.2)	64.8 (52.1–77.6)
Your children's school(s) reopening in the fall exclusively with virtual learning					
Very comfortable/Somewhat comfortable	69.7 (66.2–73.2)	69.1 (64.7–73.6)	73.3 (63.7–82.9)	69.8 (61.8–77.9)	66.7 (53.9–79.6)
When school resumes in the fall, do you believe wearing masks/facial coverings should be mandated for everyone (both students and staff)?					
Yes, at all times	68.3 (64.8–71.8)	62.5 (57.9–67.1)	73.1 (63.4–82.7)	79.5 (72.7–86.4) [§]	66.9 (54.2–79.5) [§]



Implementing Mitigation Strategies in Early Care and Educational Settings for Prevention of SARS-CoV-2 Transmission – Eight States, September – October 2020

Summary:

- Mixed methods study in head start programs from these states: AK, GA, ID, ME, MO, TX, WA, and WI
- Head Start and Early Head Start programs successfully implemented CDC recommended guidance
- Approaches documented to guide implementation of mitigation strategies in childcare settings
- Adherence to recommended mitigation strategies can reduce SARS-CoV-2 transmission in childcare settings
- Approaches could be applied to other in person early care and educational settings to reduce COVID-19 spread

Everyday prevention actions

- Reinforcement of hand hygiene behavior and respiratory etiquette
- Supervised handwashing and hand-sanitizing for children
- Intensified cleaning and disinfection efforts (e.g., with toys, frequently touched surfaces, and bedding)
- Required use of masks for staff members, visitors, and children aged >2 years
- Social distancing to the extent possible
- Daily health screening procedures on arrival for children and staff members
- Drop-off and pick-up procedures
- Monitoring for absenteeism
- Ability to monitor and restock supplies
- Steps to increase ventilation including installation of ion air purifiers
- Steps to decrease occupancy in areas without increased ventilation
- Use of outdoor space as much as possible
- Cohorting by classroom to minimize exposure between groups



Implementing Mitigation Strategies in Early Care and Educational Settings for Prevention of SARS-CoV-2 Transmission – Eight States, September – October 2020

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Actions when someone is ill

- COVID-19 point of contact identified
- Staff members trained in COVID-19 safety protocols
- Requiring ill children and staff members to stay at home
- Vigilance for symptoms
- Daily screening of staff members and children for signs and symptoms before facility entry
- Standard operating procedures for when a child or staff member experiences symptoms
- Identification of isolation room
- Plan to notify local health official of COVID-19 cases
- Plan to distribute instructions for primary care referral, testing, or both
- Plan to distribute instructions or guidance for home isolation
- Plan to require close contacts to wait 14 days before returning
- Flexible COVID-19 medical leave policies for staff members



Implementing Mitigation Strategies in Early Care and Educational Settings for Prevention of SARS-CoV-2 Transmission – Eight States, September – October 2020

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Communications and support

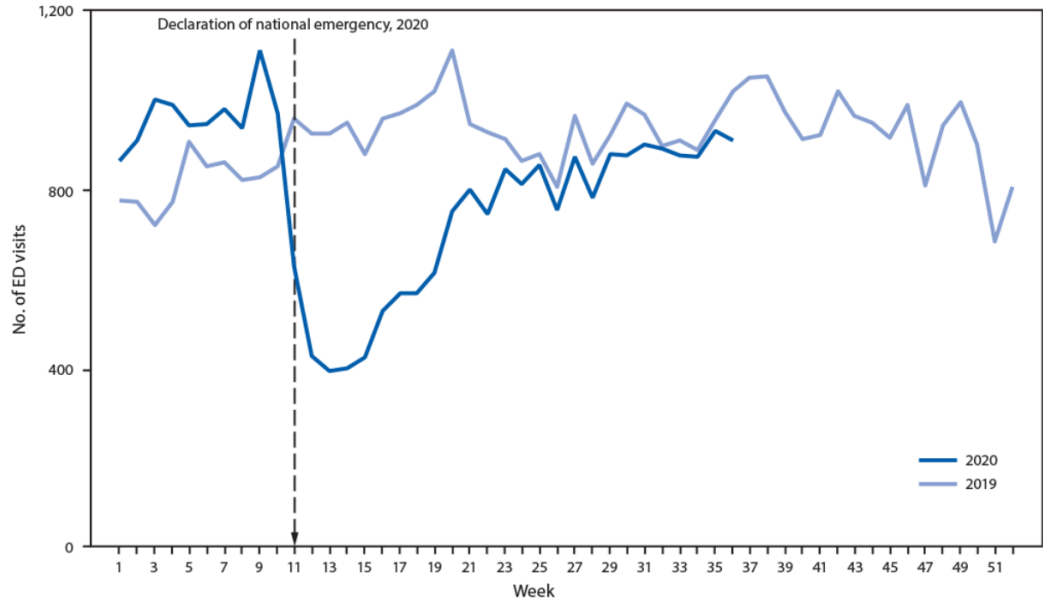
- Training and ongoing reinforcing of standard operating procedures and mitigation measures with caregivers, teachers, and other staff members
- Vigilance and training for the identification of COVID-19 related symptoms
- Masks and other personal protective equipment (e.g., face shields and gowns) provided to teachers and other staff members
- Incentives to adhere to mitigation strategies
- Flexible medical leave policies for staff members with emphasis on persons at higher risk for severe illness and those with caregiving responsibilities
- Flexible work hours and staggered shifts
- Telework options for staff members at higher risk for severe illness



Trends in U.S. ED Visits Related to Suspected or Confirmed Child Abuse and Neglect Among Children and Adolescents Aged <18 Years Before and During the COVID-19 Pandemic — United States, January 2019–September 2020

Summary:

- National Syndromic Surveillance Program (NSSP) data
- Tabulated weekly numbers of ED visits related to child abuse and neglect
 - Calculated proportion and percentage of ED visits/100,000
 - Percentage of confirmed or suspected ED visits related to child abuse and neglect ending in hospitalization
- During COVID-19 pandemic, total ED visits related to child abuse and neglect decreased, but percentage of these visits resulting in hospitalization increased (compared to 2019)
- Pandemic has affected health care–seeking patterns for child abuse and neglect raising concerns that victims might not have received care and that severity of injuries remained stable or worsened

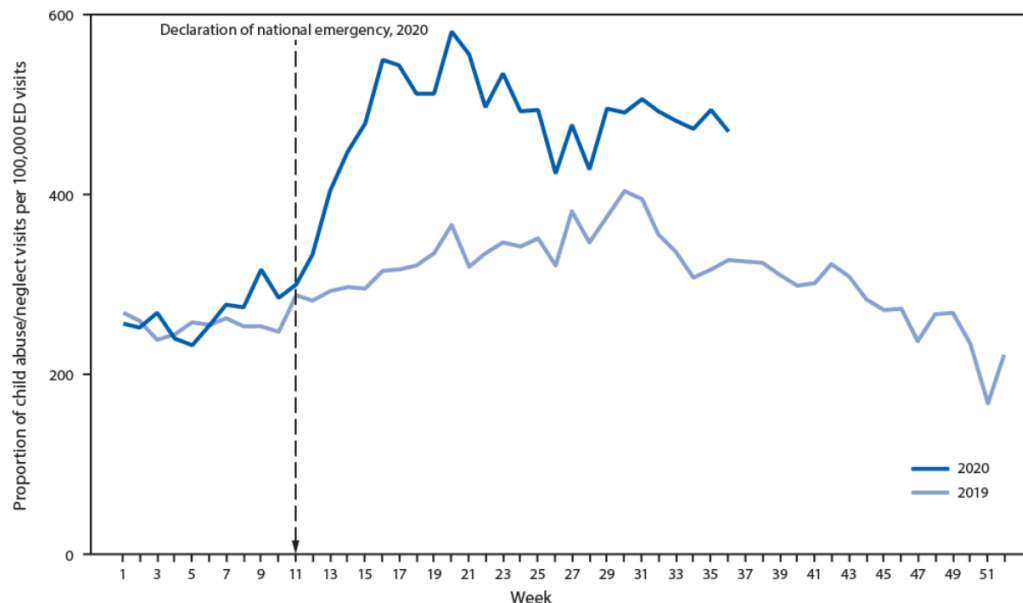




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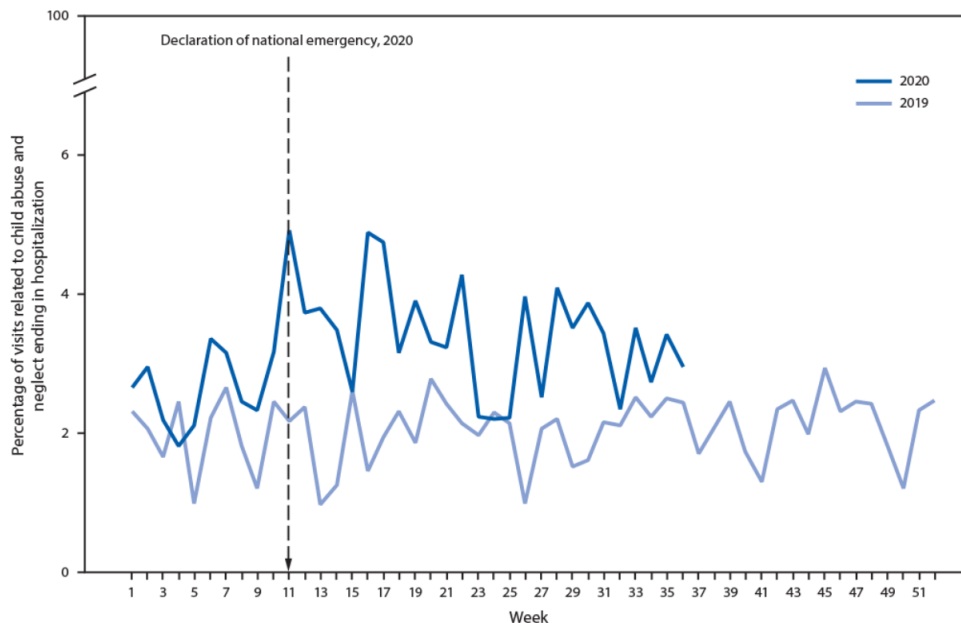




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The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Weekly / December 11, 2020 / 69(49);1857-1859

Summary

What is already known about this topic?

Demand is expected to exceed supply during the first months of the national COVID-19 vaccination program.

What is added by this report?

The Advisory Committee on Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel and 2) residents of long-term care facilities be offered COVID-19 vaccine in the initial phase of the vaccination program.

What are the implications for public health practice?

Federal, state, and local jurisdictions should use this guidance for COVID-19 vaccination program planning and implementation. ACIP will consider vaccine-specific recommendations and additional populations when a Food and Drug Administration–authorized vaccine is available.



COVID-19 (Coronavirus Disease)

CASES ARE RISING.
ACT NOW!



WEAR A MASK



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AVOID CROWDS

Your Health ▾

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Health Depts ▾

Cases & Data ▾

More ▾

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Health Equity +

Community Mitigation Framework

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COMMUNITY, WORK & SCHOOL

Recommendations for Tribal Ceremonies and Gatherings During the COVID-19 Outbreak

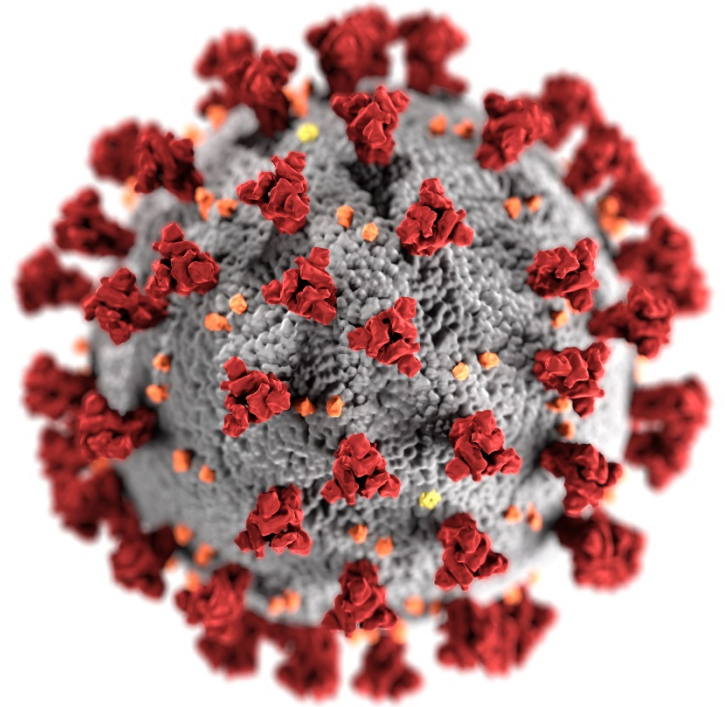
Updated Dec. 14, 2020

[Languages](#) ▾

[Print](#)



Tribal ceremonies such as *sweat lodge*, *social gatherings* and *seasonal ceremonies*, and larger gatherings such as *pow wows* and *rodeos*, are a vital part of cultural identity and common and traditional practices in tribal communities. CDC offers the following recommendations to help tribal communities, elders, and leaders decide how best to keep their communities safe and work to prevent the spread of COVID-19. These considerations are meant to support—not replace—tribal laws, rules, and regulations aimed at protecting the health of tribal communities.



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.

