

The following FAQs are listed by topic in alphabetical order for reference. Topics include website links as information changes quickly. The date following each link refers to the CDC update used in this FAQ.

These FAQs can relate to a home health, hospice, private duty, infusion, palliative care or DMEPOS providers. Weekly updates made to topics or websites are noted in red to make it easier to see changes week to week.

If you have questions or comments, please send them to education@chapinc.org Thank you!!

<u>The Federal Public Health Emergency</u>: Former HHS Secretary extended the PHE effective January 21, 2021. The typical extension has been 90 days. Secretary Xavier Becerra has been confirmed and would make the decision to extend the PHE later in April. The Biden Administration did send a letter to the governors advising that 60-day notice will be given when the PHE will end. https://ccf.georgetown.edu/wp-content/uploads/2021/01/Public-Health-Emergency-Message-to-Governors.pdf Jan 22 2021

Α

Assisted and Independent Living Facility Access:

Check your state to determine if the governor or health department has mandated staff COVID-19 testing for ALFs. Home health and hospice staff are included in mandated testing as home care or hospice staff are a 'vendor'. Weekly or bi-weekly COVID 19 testing may be required.

<u>CMS addresses Home Health Agency (HHA) and Hospice access to assisted (ALF) and independent living</u> <u>facilities (ILF) and when Hospices should Discharge Patients if Restricted or No Access</u>

- ALFs and ILFs are not subject to federal regulation, rather state authority.
- Hospice and HHA personnel are expected to participate in any facility required screening.
- If access is restricted, hospices and HHAs should communicate with the facility administration about the nature of the restriction and gaining access to hospice or home care patients.
- HOSPICE DISCHARGE: If after reasonable attempts are made to access hospice patients in person and documented in the patient's record, the hospice is expected to discharge the patient as "outside of the hospice's service area" (Medicare Benefit Policy Manual, Chapter 9, 20.2.3):
 - Additionally, a hospice must forward to the patient's attending physician a copy of the hospice discharge summary and patient's clinical record if requested.

https://www.cms.gov/files/document/covid-faqs-non-long-term-care-facilities-

andintermediate-care-facilities-individuals-intellectual.pdf June 2020 Pages 9-13 • If an HHA is refused in-person access, document the situation in the patient's record and advise the patient's physician. <u>https://www.cms.gov/files/document/qso-20-18-hha-revised.pdf</u>

(March 10 Memo Revised April 23, 2020. Note the HHA reference to ALF/ILF access on page 6)



С

COVID-19:

Airborne Transmission or Spread of COVID 19:

Under certain conditions, people with COVID-19 can infect others who are more than 6 feet away. Scientists believe that in these situations' infectious smaller droplets and particles from the COVID-19 positive person are concentrated enough to spread the virus to other people in the same space during the same time or shortly after the person with COVID-19 left.

- This spread is "airborne transmission" and is the same as for TB, for example.
- Try to avoid crowded indoor spaces when providing care, <u>educate family and caregivers that well</u> <u>ventilated</u> spaces is the safest for everyone, bring in outdoor air as much as possible.

April 15: Variants of Concern:

- Viruses constantly change through mutation. CDC is closely monitoring variants of concern (VOC). These variants have virus mutations that cause the virus to act differently in ways that are significant to public health (e.g., causes more severe disease, spreads more easily between humans, requires different treatments, may changes the effectiveness of current vaccines).
- There are 3 levels: Variant of Interest, Variant of Concern, Variant of High Consequence
- Variants of Concern circulating in the US: UK (B.1.1.7); Brazil/Japan (P.1); B.1.351 (South Africa): B.1.427 and B.1.429 California. All have 20-50% increase in transmissibility.
- The UK variant is now in all states and is the predominant variant. 21,865 cases confirmed, primarily in order of number of cases FL, MI, MN, MA, <u>NEW CO</u>, <u>NEW GA</u>, CA, PA, NEW TN, and New CT. All 3 variants (UK, South Africa and Brazil) are in all of the preceding states except MI that has 2 variants reported. Estimated 27% of US new cases are from the UK virus.

https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variantinfo.html#Concern April 10, 2021

April 15: New COVID-19 Cases per Week

- Over the past 12 days cases have increased 2% compared to the previous 7 days (64,152).
- The US is well below the Jan 2021 high average of 250,446, and 7% below the second highest peak July 23, 2020 (67,337). Highest number of cases/100K in past 7 days MI, MN, NY, NJ, CT, and PA.
- CDC has concern over the next 4 weeks, the rate could double by the week ending April 17, 2021 due to the holidays and Spring Break. <u>https://www.cdc.gov/coronavirus/2019-ncov/cases-</u> updates/forecasts-cases.html April 14, 2021

Updated COVID-19 spreads through contact with contaminated surfaces-Updated information to share with patients, families, and staff providing homemaker services, as well as in offices:

It is possible for people to be infected through contact with contaminated surfaces or objects (fomites), but the risk is generally considered to be low. Research has confirmed that the COVID-19 virus can degrade quickly upon contact with surfaces. The risk for contamination is based on the following:



- The infection prevalence rate in the community
- The amount of virus that people known to be infected with COVID 19 expel for an example in a cough or sneeze.
- The accumulation of the expelled virus particles onto surfaces, which is affected by air flow and ventilation, and
- The efficiency of transferring those virus particles from the surfaces to the mucous membranes on the face (nose, mouth, eyes).

What Can Be Done to Reduce Risk of Transmission from Contaminated Surfaces:

- Ask unvaccinated visitors to wear masks.
- Isolate people who are sick with COVID-19
- Have everyone in the household, and staff (including those in the office) wash hands often, especially when returning from outside.
- Remind folks about cough and sneeze etiquette.
- Use the two-step process when cleaning:
 - 1) Clean visibly dirty surfaces with household cleaners containing soap or detergent.
 - 2) Then disinfecting if your disinfectant product does not have a cleaning agent (check the label to verify). Use a disinfectant that is known to be effective against COVID 19, see below.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/disinfecting-your-home.html April 5 2021

Disinfectants effective with COVID-19 – EPA website Made Easier to Use Table N

• Video and infographic on how to use EPA product Table N.

List N https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19

<u>Ventilation: The next element of protection from spreading the Virus: (Mask, 6 ft distancing, avoid</u> large gatherings and small spaces). The issue related to COVID spread in small spaces, and inside any building is ventilation. CDC has issued simplified guide to improve ventilation, including in homes and office buildings.

- For homes, better ventilation means primarily open windows and increase use of fans.
- CDC site noted below also includes specific technologies information including such items as ultraviolet germicidal irradiation (UVGI), otherwise known as germicidal ultraviolet (GUV). It is a disinfection tool used in many different settings, such as residential, commercial, educational, and healthcare settings and is effective with COVID-19. Issues is finding a reliable UVGI manufacturer.

https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html March 23, 2021

• **Poor ventilated space** is to be avoided as well as crowds even if fully vaccinated. <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html March 23 2021</u>

<u>CDC Clinician On-Call Center</u> is a hotline with trained CDC clinicians available to answer COVID-19 questions daily on a wide range of topics, such as diagnostic challenges, clinical management, and



infection prevention and control. To reach this service, call 800-CDC-INFO (800-232-4636) and ask for the Clinician On-Call Center.

Children -Pediatric Patients 17 yrs. old and Younger-Update:

- Jan 7, 2.9M cases in children (17yrs or younger) representing 12.5% of all COVID cases, -about 4% increase from Aug 2020.
- 0.2 to 3.1% of cases resulted in hospitalization; mortality 0-0.20% among reporting states, no change over reporting the past two quarters.
- Top 5 states in order where children are >15% of state's COVID cases: WY, AL; SC; TN; NM; ND Top 5states in order by Number of Children's COVID Cases: CA, IL, TN, FL, AZ,

https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20%20Children%20and%20COVID19%20State %20Data%20Report%201.7.21%20FINAL.pdf Jan 7 2020

Two diseases added to Conditions of who Children who are at increased risk for severe COVID 19

illness: obesity, medical complexity, severe genetic disorders, severe neurologic disorders, inherited metabolic disorders, **sickle cell disease, chronic kidney disease,** congenital (since birth) heart disease, diabetes, asthma and other chronic lung disease, and immunosuppression due to malignancy or immune-weakening medications. <u>https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-with-medicalconditions.html</u> December 29, 2020

MISC-C: Multisystem Inflammatory Syndrome in Children:

Multisystem inflammatory syndrome in children (MIS-C) is a rare, serious condition where different body parts become inflamed, including the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs. The cause of MIS-C is not known. Children with the disease test positive for COVID-19 or have been around someone with COVID-19.

Update: CDC information about MIS-C:

- CDC has received reports of **1288** confirmed cases of MIS-C and **28** deaths (2%)
- Reported in all states except West Virginia, Vermont, and Maine. Most cases reported in California, Texas, Louisiana, New York, and Florida.
- In 99% of cases (1269) the child tested positive for SARS CoV-2, the virus that causes COVID-19. The remaining 1% were around someone with COVID-19.
- Most children developed MIS-C 2-4 weeks after infection with SARS-CoV-2.
- The highest number of cases are among children aged 5-9, with the average age of 8.
- 76% of reported cases occurred in children who are Hispanic/Latino or Non-Hispanic Black
- 56% of reported cases are male. <u>https://www.cdc.gov/misc/cases/?deliveryName=USCDC_2067DM37553</u> Dec 7, 2020



Common Symptoms of MIS-C:

Fever	Neck Pain
Abdominal Pain	Rash
Vomiting	Bloodshot eyes
Diarrhea	Feeling extra tired

NOTE: Not all children have all the same symptoms.

Emergency care is needed for a child with any of the following signs or symptoms:

Trouble breathing	Inability to wake or stay awake
Pain or pressure in the chest that does not resolve	Bluish lips or face
New confusion	Severe abdominal pain

The latest MIS-C symptoms and information for parents can be found at:

https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/mis-c.html (May 20, 2020)

Updated Clinical Study Findings of US COVID 19 Patients:

- The incubation period continues to extend to 14 days, with a median time of 4-5 days from exposure to symptoms onset.
- The signs and symptoms of COVID-19 present at illness onset vary but over the course of the disease they include the following:

https://www.cdc.gov/coronavirus/2019ncov/symptomstesting/symptoms.html December 22, 2020

Fever or chills	Cough	Headache
Myalgia	Sore Throat	Shortness of Breath
Fatigue	Congestion or Runny Nose	Nauseas *
Diarrhea*	New loss of smell and taste **	Vomiting*

*People increasingly reporting GI symptoms such as nauseas, vomiting or diarrhea sometimes prior to having a fever and lower respiratory tract signs and symptoms.

** Lost of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation. <u>https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/endhomeisolation.html</u> *Dec 1, 2020*

COVID 19 Illness severity can range from mild to critical:

- Mild to moderate (mild symptoms up to mild pneumonia): 81%
- Severe (dyspnea, hypoxia, or more than 50% lung involvement on imaging): 14%



 Critical (respiratory failure, shock, or multiorgan system dysfunction): 5% <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html</u> Dec 8, 2020

<u>Study of Home Health COVID 19 Patients Risk for Rehospitalization</u>: Among patients with COVID-19 admitted to home health care, comorbid conditions associated with rehospitalization or death included heart failure, diabetes, chronic pain, and cognitive impairment.

Bowles et al. Surviving COVID-19 after hospital discharge: Symptom, functional, and adverse outcomes of home health recipients, Annals of Internal Medicine (November 24, 2020).

<u>Update and Addition of a Condition to COVID-19 VULNERABLE POPULATION by Condition Making Them</u> <u>Priority for Vaccine Access:</u>

Adults of any age with the following underlying medical conditions are at risk of severe illness from COVID -19:

Smoking	Down Syndrome
Type 2 Diabetes	Immune compromised from solid organ transplant
Heart conditions such as heart failure, CAD, cardiomyopathies	Sickle Cell Disease
COPD	Pregnancy
Chronic Kidney Disease	Severe Obesity (BMI <u>></u> 40kg/m
Cancer	Obesity: (BMI 30kg/m but < 40 kg/m)

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medicalconditions.html Dec 29 2020

COVID-19 VULNERABLE POPULATION by Age by Risk for Hospitalization and Death

Age Range	Hospitalization	Death
18-29 yrs.	Comparison Group	Comparison Group
30-39 yrs.	2X higher	4X -higher
40-49 yrs.	3X higher	10X higher
50-64 yrs.	4X higher	30X higher
65-74 yrs.	5X higher	90X higher
75-84 years	8X higher	220X higher
85+ years	13X higher	630X higher

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html Nov 27, 2020



COVID-19 Symptom List

- The list of symptoms of COVID-19 infection has been expanded. See CHAP document titled: "COVID-19: Updated Information Related to Symptoms and Protection" on education website at <u>https://education.chaplinq.org/</u>
- <u>New Guidance for Resident and Staff of Group Homes</u> -Including those with residents who leave to go to work or an on-site sheltered workshop. <u>https://www.cdc.gov/coronavirus/2019-ncov/community/group-homes.html</u> March 23, 2021
- <u>New CDC Guidance for Providers to Unsheltered Homeless -</u> Interim Guidance on Unsheltered Homelessness and Coronavirus Disease 2019 (COVID-19) for Homeless Service Providers and Local Officials <u>https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/unshelteredhomelessness.html</u> March 23, 2021

D

Disaster Shelters and COVID 19

<u>CDC Guidelines for Disaster Shelters During the Pandemic:</u> The CDC has released guidelines for state and county governments when opening shelters due to disasters (e.g., hurricanes, flooding, etc.).

- 50 or less people in a shelter to support social distancing.
- Daily symptom screening.
- The CDC preference is that vulnerable individuals *are not* moved to a shelter, but to remain at home.
- Medical support shelters and functional needs shelters may be available for the more vulnerable populations during disasters.

https://www.cdc.gov/disasters/disaster_resources.html (January 11, 2021)

If your patient will be evacuating and staying with another family, and so in closer quarters than usual see information for specific populations: <u>https://emergency.cdc.gov/groups.asp</u>



F

FDA Safety Communication Regarding Over-the Counter Pulse oximeters: February 19, 2021 The concern is about the grown number of purchases of over the counter (OTC) pulse oximeters during the pandemic. These products have serious limitations including inaccurate readings. OTC pulse oximeters do not undergo FDA approval, clinical testing and are not intended for medical purposes.

As a result, the FDA has issued a safety communication to pay close attention to all health symptoms, in relation to sighs of shortness of breath or low oxygen levels *rather than rely solely upon the readings of a pulse oximeter*. These symptoms include.

- Bluish coloring in the face, lips, or nails;
- Shortness of breath, difficulty breathing, or a worsening cough.
- Restlessness and discomfort
- Chest pain or tightness
- Fast or racing pulse rate.

CAUTION: Some patients with low oxygen levels may not show any of these symptoms.

- Patient education should include factors that may alter results such as:
 - o darker skin pigmentation
 - o poor circulation
 - Skin thickness
 - o Skin temperature
 - Current tobacco use
 - o Fingernail polish
- Education regarding appropriate use of pulse oximeters should include:
 - Follow the manufacturer's instructions for use.
 - Remove any fingernail polish.
 - Make sure your hand is warm when placing the oximeter on your finger.
 - Keep the hand relaxed and held below heart level.
 - Sit still and wait a few seconds until the reading stops changing and displays one steady number.
 - Write the oxygen level with the date and time of the reading for easy tracking of changes and trends.
 - It is often more meaningful to look at changes/trends over time than one single reading.

Flu versus COVID-19:

Symptom: Many symptoms of the Flu and COVID-19 are similar and may vary by degree of severity.

•	Fatigue - more common in flu	•	GI symptoms, nausea/vomiting/diarrhea -more common in children
•	Cough – More common in both	•	Headaches
•	Aches and pain – more common in flu	•	Shortness of breath



Runny or stuffy nose	Sore throat
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COVID-19 symptoms include new loss of taste and/or smell.

Symptom Onset

- COVID-19 Gradual Onset
- Flu Abrupt onset

Incubation Period

COVID-19 – 2-14 Days with contagious period 2 days prior to symptom onset and up to 10 days
 Flu – 1-4 days with contagious period 1 day prior to symptom onset and typically 3-4 days of illness but can be contagious as long as 7.

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<u>Reduce Risk of Infection COVID and the Flu</u>: Both are respiratory illnesses spread by person to person by close contact or through respiratory droplets when an infected person coughs, sneezes or talks. The preventive measures for the pandemic also help in decreasing the spread of flu:

- Social Distancing
- Mask
- Hand Hygiene

Flu vaccination and COVID Resource - https://www.cdc.gov/vaccines/pandemic-guidance/index.html

- <u>Individuals with a positive COVID test</u> but are asymptomatic defer the flu vaccination for 10 days from the positive test result date.
- Individuals who are symptomatic or with suspected/confirmed COVID-19, defer vaccination until:
 - $\circ~$ 10 days after symptom onset AND $\circ~$ 24 hours with no fever without the use of fever reducing medications AND $\circ~$ Improvement of COVID-19 symptoms AND
 - No longer moderately or severely ill.
- <u>Individuals with known COVID exposure</u> should not seek the flu vaccine until their 14-day quarantine period has ended.

<u>Flu Vaccination effectiveness</u>: Approximately two weeks after vaccination for protection against the flu. <u>COVID Vaccination effectiveness</u>: Approximately one-two weeks after all required doses.

Flu resources for patients and staff:

- 2020 Vaccine Storage and Handling Toolkit: <u>https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html</u>
- Vaccine Administration and storage and handling one page resource guide: <u>https://www.cdc.gov/vaccines/hcp/admin/downloads/vacc-admin-storage-guide.pdf</u>
- Take Three Actions to Fight Flu Infographic (English): <u>https://www.cdc.gov/flu/resourcecenter/freeresources/graphics/infographic-fight-flu.htm</u>
- Take Three Actions to Fight Flu Infographic (Spanish):



https://www.cdc.gov/flu/pdf/freeresources/graphics/take3-fight-flu-infographic-sp.pdf

• Flu fact sheet in multiple languages: https://www.cdc.gov/flu/resourcecenter/freeresources/multilanguage-factsheets.html

Ν

Nursing Home CMS Regulations for Testing – Including Hospice and Home Care Staff

CMS has authority over the Medicare Skilled Nursing beds (SNF) and Medicaid nursing facilities. August 26, 2020 CMS released federal testing regulations for SNFs and ICFs effective immediately.

Each facility must have one or more staff identified as an Infection Preventionist or IP who is responsible for the infection control program.

The federal regulations addressing testing scope and frequency are in addition to any state required testing and any facility-specific testing. CMS' June outreach to nursing homes regarding testing was recommendation, these regulations mandate testing.

https://www.cms.gov/files/document/qso-20-38-nh.pdf Aug 27, 2020

Workers who are not employees of the facility but provide direct care to the facility's residents, such as hospice workers, social workers, clergy etc., must be permitted to come into the facility if they are not subject to a work exclusion due to an exposure to COVID-19 or show signs or symptoms of COVID-19 after being screened. All staff must comply with COVID-19 testing requirements.

Nursing Home (ICF) and SNF Revised Visitation

CMS with the CDC have updated visitation guidance still emphasizing maintaining infection prevention practices, including maintaining at least 6 feet between people and wearing masks - noting the continued risk of COVID-19 transmission. Note: states may have their own guidance.

NOTE: Continued screening for temperature, signs or symptoms of COVID 19, or close contact with a person who is confirmed COVID 19 in the past 14 days is still recommended for all who enter regardless of the visitor's vaccination status.

- "Fully vaccinated" is defined by CDC as a person who is ≥2 weeks following receipt of the second dose in a 2- dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine.
- **Outdoor visitation is preferred** even if resident and others are *fully vaccinated*.
- Indoor visitation should be allowed at all times and for all residents -regardless of vaccination status.
 - If a resident is fully vaccinated, they can have close contact (including touch) with their visitor while wearing a well-fitting face mask and performing hand-hygiene before and after.
 - Compassionate care visits and visits required under federal disability rights law should be allowed at all times, for any resident -vaccinated or unvaccinated.



Exceptions to Indoor Visitation- an Outbreak which is a new onset of COVID-19. One new COVID-19 case among residents or staff and the facility should immediately begin outbreak testing and suspend all visitation (except that required under federal disability rights law), until at least one round of facility-wide testing is completed.

- Visitation can resume if residents in a particular area/unit of the facility have no cases of COVID 19 after the first round of testing.
- If the first round of outbreak testing reveals one or more new case of COVID-19 in other areas/units (e.g., new cases in two or more units), facilities should suspend visitation for all residents (vaccinated and unvaccinated), until the facility meets the criteria to discontinue outbreak testing.

Visitor Testing and Vaccination: CDC and CMS encourage (not require) facilities in medium (orange)- or high (red) positivity counties to *offer* visitor testing. Visitors should not be required to be tested or vaccinated (or show proof of such) as a condition of visitation.

- Facilities should prioritize visitors that visit regularly (e.g., weekly), although any visitor can be tested.
- Facilities may encourage visitors to be tested on their own prior to coming to the facility (e.g., within 2–3 days).
- CMS and CDC encourage visitors to become vaccinated.

https://www.cms.gov/files/document/qso-20-39-nh-revised.pdf Revised 3/10/2021 for the purpose state survey, effective April 10, 2021.

Nursing Homes Required to Advise Residents and Their Representative of COVID 19 Infection:

<u>https://www.cms.gov/files/document/nursing-home-reopening-recommendations-state-andlocalofficials.pdf</u> (May 18, 2020)

 Nursing homes must advise residents and their representatives within 12 hrs. of a single occurrence of a confirmed COVID-19 infection, or of 3 or more residents or staff who have new onset of respiratory symptoms within 72 hours. Updates to residents and their representatives must be provided weekly or each subsequent infection outbreak. Facilities must include information on action taken to prevent or reduce the risk of transmission, including if normal operations in the nursing home are altered. The information must be reported in accordance with existing privacy. regulations and statute.

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Operational Changes Under COVID-19:

<u>CDC Recommendations for Staff Diagnostic COVID-19 Testing</u>: NOTE the following recommendations were made by the CDC Updated December 14, 2020. The recommendations apply to Healthcare Personnel (HCP)

- *<u>Diagnostic testing</u>* is to be prioritized for:
 - 1. The staff member who has signs or symptoms consistent with COVID-19



a. Due to the extensive and close contact HCP have with vulnerable populations, even mild signs or symptoms (e.g., sore throat) of possible COVID-19 should prompt consideration for testing. Clinicians will need to utilize their judgement in making that determination.

2. Asymptomatic staff with high-risk exposures to SARS-CoV-2

- a. Higher risk exposures generally involve exposure of HCP's eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if these HCP were present in the room for an aerosol-generating procedure. The CDC recommendation would be that the exposed HCP be excluded from work for 14 days following the exposure.
- b. For HCP with higher risk exposures CDC recommends testing initially and if negative, again about 5-7 days post exposure to more quickly identify pre-symptomatic or asymptomatic HCP who could contribute to transmission in the community. Even if testing is not positive, those with higher exposures should be excluded from work for 14 days unless staffing shortages determine the need to shorten the quarantine period.
 - a. In situations of staffing shortages, the following options to shorten quarantine.
 - Quarantine can end after Day 10 without testing if no symptoms have been reported during daily monitoring (post quarantine transmission risk is estimated to be about 1% - 10%)
 - 2. When diagnostic testing resources are sufficient and available, then quarantine can end after day 7 if a diagnostic specimen tests negatives and no symptoms were reported during daily monitoring. The specimen may be collected and tested within 48 hours before the time of planned quarantine discontinuation, but quarantine cannot be discontinued any earlier than day 7. (post quarantine transmission risk is estimated to be 5-12%) <u>https://www.cdc.gov/coronavirus/2019ncov/more/scientific-briefoptions-to-reduce-quarantine.html</u>
- c. At risk exposure is contact for 15 minutes or more within 6 feet of the confirmed positive individual without the appropriate PPE. Any duration should be considered prolonged if the exposure occurred during performance of an aerosol generating procedure.
- d. 15 minutes exposure includes 15 minutes total over 24 hours.
- 3. For *lower risk exposures,* HCP may continue to work; however, CDC recommends screening for symptoms prior to starting work each day and using source control measures.

Handling Exposures Post Vaccination.

Vaccinated persons with an exposure to someone with suspected or confirmed COVID-<u>19 are NOT</u> required to quarantine if they meet all the following criteria:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
- Are within 3 months following receipt of the last dose in the series.
- Have remained asymptomatic since the current COVID-19 exposure.



Those who meet the above criteria and do not quarantine should monitor themselves for potential symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19.

Those who do not meet all the above criteria should continue to follow current quarantine guidance. <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#phrecs</u> Feb 10, 2021

Testing Timing: Testing only identifies the presence of virus at the time of the test. Repeat testing could be considered. Timing of symptoms can be 2-10 days after exposure.

Note: If you request that staff be tested when there is widespread SARS-CoV-2 transmission occurring in your community, positive tests among healthcare staff do not necessarily indicate transmission due to an exposure in the workplace.

CDC Identifies Two (2) Types of Testing:

- 1) <u>Diagnostic Testing</u> for SARS-CoV-2 intended to identify current acute infection in individuals (PT-PCR) tests that detect the virus's genetic material.
- 2) <u>Screening Testing</u> or POC (Point of Care) Testing: intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.

https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html#who-should-get-tested February 19, 2021

POC (Point of Care) Testing or Antigen Testing for SARS-CoV-2:

CDC General Guidance

<u>Antigen Tests Used at the point-of-care (POC)</u> detect the presence of a specific viral antigen, which implies current viral infection. The currently authorized devices return results in approximately 15 minutes. The reliability of the test and any limitations associated with the test (e.g., if a rapid antigen test known to have false positives and negatives) or the diagnostic test) in writing from the manufacturer and the FDA. Most often the interpretation of the results requires consideration of infection spread in

FDA Approved EUA Antigen Tests for use with a CLIA Waiver can be found at:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/vitro-diagnostics-euas#individual-antigen Feb 23, 2021(Scroll to Individual Antigen tests)

<u>State Requirements to Conduct Antigen Testing Must Also be Checked and Vary:</u> Contact your health department for interpretation of your organization's ability to conduct testing. List of state agencies: <u>https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf</u>



<u>POC Infection Control and Test Management</u>: Maintain six feet of separation from the person whose specimen was collected. CDC recommends using Standard Precautions. Follow the manufacturer's guidelines. <u>https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html</u> Oct 14 2020 Discontinuing Isolation and Quarantine can be a State Decision:

NOTE: State health departments may decide not to follow CDC recommendation and issue their orders that apply to a State or region or municipality.

Symptom Based Strategy to Discontinue Transmission Based Precautions and Isolation:

- Most persons with COVID-19, can end isolation and precautions 10 days after symptom onset¹ and resolution of fever for at least 24 hours, without using fever reducing medications, and with improvement of other symptoms.
- *Symptom onset* is defined as the date on which symptoms first began, including non-respiratory symptoms. the hospital "Course of Clinical Care Summary" has dates of clinical tests in the hospital more often than the H&P.
- Note: Some persons with severe illness may produce replication-competent virus beyond 10 days that warrants extending duration of isolation and precautions for up to 20 days after symptom onset; consider consultation with an infection control expert.

Ending Quarantine of Asymptomatic People Testing Positive for COVID 19, Options

- **CDC's recommendation remains 14 days quarantine,** as this option maximally reduces risk of post quarantine transmission risk and is the strategy with the greatest collective experience at present.
- The following science and research cited quarantine duration options are offered to reduce burden on individuals with asymptomatic illness.

End Quarantine After Day 10 Without Testing	End Quarantine After Day 7 – D <i>iagnostic Testing</i> <i>Required</i>
 No evidence of symptoms reported with daily monitoring from the start to day 10. Post-quarantine transmission risk ranges from 1% to 10% Symptom monitoring continues through day 14, any changes – self-isolate and be tested. Consistent mask use and social distancing, hand cough hygiene, environmental disinfecting, adequate ventilation, avoid crowds. 	 No evidence of symptoms reported with daily monitoring from the start to day 7. End only by negative Pt-PCR testing, specimen may be collected and tested 48 hrs. before day 7, but quarantine cannot be ended before day 7. Post-quarantine transmission risk is 5-12% Required consistent mask use and social distancing, hand cough hygiene, environmental disinfecting, adequate ventilation, avoid crowds.

Options to CDC 14-day Quarantine That Public Health Authorities May Put in Place:

https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html Dec 2, 2020

• For persons who develop new symptoms consistent with COVID-19 during the 3 months after the date of initial symptom onset, and an alternative etiology cannot be identified by a provider, the



CDC recommends consultation with an infectious disease or infection control expert and retesting may be indicated.

https://www.cdc.gov/coronavirus/2019-

ncov/hcp/durationisolation.html?deliveryName=USCDC_2067-DM35559# Aug 16, 2020

- Admitting COVID 19 Patients to home care: COVID 19 patients continue to be referred to home health, private duty, and hospice organizations across the country. If you accept COVID-19 patients for care or services, please consider the following questions shared by call participants:
 - **Ask staff who agrees to care for a COVID 19 patient**. Organizations report that not all staff will, and some staff have resigned rather than face the prospect.
 - How much PPE do you have and need (e.g., face shields, gloves, gowns, N95 masks)? CDC offers a PPE 'burn rate calculator: <u>https://www.cdc.gov/coronavirus/2019ncov/hcp/ppestrategy/burn-calculator.html</u> (April 7, 2020)
 - Will staff see only COVID 19 patients each day, or mixed with those who are not suspected or confirmed COVID 19? This decision impacts your PPE inventory. Organizations report two current practices: 1) leave the N95 mask, face shield and gown after use in the patient's home (if not soiled or possibly contaminated, and still 'sound'-not torn, and still fitting appropriately) and place these in a paper bag and the bag inside a box-with cautions for access by pets and children; or 2) staff removes PPE and places the N95 mask in a paper bag in a box in their trunk, and only uses when they see the next COVID 19 patient. In both instances, hand hygiene is performed per OPIM after removing PPE. (Shared practice not endorsed by the CDC).
- At referral request the COVID 19 status of each patient/client: CHAP recommends adding the question about each patient's COVID 19 status (confirmed, pending testing results, COVID symptoms) to your referral acceptance process it is critical to the health of the patient, their family, and your staff.
 - If the patient has confirmed or suspected COVID 19, remember to get orders for any specific symptom monitoring or intervention for the COVID 19 diagnosis, as well as care for other chronic illnesses.
 - Obtain information how long transmission-based precautions must be maintained or how you will know that the patient/client is no longer considered infectious. Meeting criteria for discontinuation of Transmission-Based Precautions is not a prerequisite for discharge.

Collection of COVID 19 Respiratory Specimens for Diagnostic Testing

 Nasopharyngeal swab is no longer the preferred method of specimen collection of Additional approved methods include oropharyngeal, nasal mid-turbinate. Anterior nares swab or nasopharyngeal wash/aspirate/nasal wash. The type of specimen collection is not as important as following proper collection guidelines. The following link provides detailed instruction in the collection guidelines of each method of specimen collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html (May 22, 2020)



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CDC Summary of Managing PPE Shortages at the CHAP Education Web Site:

PPE:

- Accessing PPE, the National Declaration of an Emergency distributes PPE via two (2) sources:
 - **the county and state health departments** access to the national supply stockpile is distributed from health departments on a governor's requests:
 - Contact your state or local health department to request supplies.
 - Also contact your state associations for information about accessing supplies –
 - When ordering N95 respirators have the model number of the masks fit-tested for your staff. If no model number, provide the manufacturer and year from a mask you have.
- <u>Update ASPR Regional Health Care Coalitions Areas and Contact Person for Resources</u>: Health care coalitions (HCC) are groups of health care and response organizations such as acute care hospitals, emergency medical service (EMS) providers, emergency management agencies, public health agencies, and more working in a defined geographic location to prepare for and respond to disasters and emergencies.

HCCs collaborate to ensure each member has what it needs to respond to emergencies and planned events, including medical equipment and supplies, real-time information, communication systems, and education. Website now allows identification of the coalition serving your area and a contact person.

o https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx February 2 2021

Maximizing PPE: – the CDC website offer specific recommendations to maximize the use of 5 categories of PPE used in the home. Note: information is often written with the inpatient setting in mind. Not all categories will apply to care in the home, but many do. Anticipate how to make these protections work in the home care setting.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html (July 20, 2020)

PPE Burn Rate Calculator: Excel Spreadsheets, instruction video and guidance for each type of PPE. https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html

Eye Protection: (NOTE CDC recognizes Face Shields AND Goggles as Eye Protection

• <u>Conventional Capacity: Your Organization's Usual practice with an adequate supply</u> (Goggles, Face Shield)

The purpose of eye protection is used to protect staff eyes from exposure to splashes, sprays, splatter, and respiratory secretions for all patient encounters when there is moderate to substantial community transmission of SARS-CoV-2).



CDC recommends shifting eye protection supplies to reusable devices (i.e., reusable face shields or goggles).

O Disposable eye protection (e.g., face shields and goggles, should be removed and discarded after use.

O Re-useable eye protection should be cleaned and disinfected after each patient encounter.

• <u>Contingency Capacity – expected temporary expected shortage, begin implementing extended use</u>. Extended use of eye protection is a staff member wearing the same eye protection for repeated close contact with several *different patients, without removing eye protection between patient encounters*.

O In an expected shortage, a disposable face shield or goggles should be dedicated to one staff member and cleaned and disinfected whenever visibly soiled or when removed and prior to putting it back on.

• Face shields or goggles should be discarded if damaged (e.g., face shield or goggles can no longer fasten securely to the provider, if staff cannot see clearly, and cleaning does not restore visibility).

- o If staff touch their eye protection or adjust it, they must immediately perform hand hygiene.
- o Staff should leave the patient care area if they need to remove their eye protection.
- <u>Crisis Capacity: Per CDC these practices do not meet US standards of care but are implemented</u> <u>during known periods of shortages of eye protection for staff.</u>

O Use the face shield or goggles beyond manufacturer shelf-life date (most often found on the label of either)

O Implement extended use for staff whose care activities require prolonged (more than 15 minutes) face-to-face or close contact with a *potentially infectious patient* for which eye protection is recommended.

O As an alternative, CDC advises to consider using safety glasses (e.g., trauma glasses) that have extensions to cover the side of the eyes. However, if these have gaps between glasses and the face, they likely do not protect eyes from all splashes and sprays.

O Exclude staff who are at risk for severe illness from COVID-19 infection from care of patients with *suspected or confirmed* infection.

Treat glasses and goggles like medical devices - Cleaning per manufacturer guidelines, use gloves to clean, and store in a clean or dirty area so staff know what is clean and what dirty for re-use. <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html</u> Dec 22, 2020

Gloves

• **Glove types:** There are two (2) primary types are used in health care, sterile surgical gloves and disposable medical gloves or patient examination gloves, referenced as "Examination" gloves most often.



- Home health, home care (private duty), palliation, hospice and home infusion use non-sterile disposable examination gloves. 'Specialty' examination gloves often are chemotherapy gloves, which have been tested with chemotherapy agents.
- <u>Glove product codes</u> represent the material used in manufacturing; the following is per the FDA:

Latex – (LYY)	Vinyl – (LYZ)	Synthetic Polymer – (LZA)
Nitrile – (LZA) Specialty – (LZC)		Finger Cot – (LZB)

Surgical gloves have a product code (NGO) to avoid ordering the wrong product when not needed. <u>https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-gloves-covid-19</u> (September 3, 2020)

• **Conventional Capacity: Your Organization's Usual practice with an adequate supply** Continued use of FDA-cleared disposable medical gloves following standard and transmissionbased and when indicated for other exposures such as handling cleaning chemicals.

- Reinforce indications and recommended practices for non-sterile disposable glove use, and how and where gloves are to be disposed.
- Remind staff about indications for gloves use, as well as common situations when gloves may *not* be needed. (conserve PPE)
- Prioritize medical gloves for handling chemotherapy agents (chemotherapy gloves) for staff handling chemotherapy and other hazardous drugs. Ensure staff and operations know which drugs meet this qualification to ensure adequate PPE.

• <u>Contingency Capacity – expected temporary expected shortage.</u>

Use gloves past their manufacturer-designated shelf life for training activities Non-sterile disposable gloves cleared by FDA are not required to have expiration date labeling; however, some manufacturers choose to designate a shelf life.

- If a manufactured date is noted, the FDA recommends not using the gloves if more than 5 years since that date.
- CDC advises using disposable medical gloves that are *like* FDA-cleared examination gloves and approved under other U.S. or international standards. Examples are shown in the Table at the following website. You would be looking for 'Examination' gloves.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/gloves.html (December 23, 2020)

• <u>Crisis Capacity: Per CDC these practices do not meet US standards of care but are implemented</u> <u>during known periods of gloves shortage. Implement extended use.</u>

- Use gloves past their manufacturer-designated shelf life.
- Prioritize non-sterile disposable gloves for use to protect hands from contact with potentially hazardous substances, including blood and body fluids (e.g., wound care, aerosol generating procedures).



- Extended use of disposable medical gloves by staff refers to the practice of wearing gloves without changing them between patients or tasks. Gloves can remain on but must be sanitized between patients.to prevent cross transmission from patient to patient.
- During a glove supply crisis gloves, can be used up to 4 hours continuously, but must be cleaned between patients to prevent cross transmission from patient to patient.

CDC offers two (2) means for re-use of disposable medical gloves in a time of inadequate supply.

- 1) Alcohol-based Hand Sanitizer (ABHS): If not visibly soiled, disposable latex and nitrile glove brands maintain their integrity when disinfected for up to six (6) applications of ABHS or until the gloves become otherwise contaminated or ineffective (wear, tears, etc.). Follow hand hygiene guidance for proper application of ABHS.
- 2) Soap and water can be used to clean donned, disposable medical gloves between tasks or patients. Long-cuffed surgical gloves are recommended as washing may be impractical for short, cuffed gloves where water may become trapped inside the worn gloves which then must be discarded. Disposable medical gloves <u>can be cleaned with soap and water up to 10 times</u> or until the gloves become otherwise contaminated or ineffective. Follow hand hygiene guidance for proper soap and water hand hygiene procedures.

Discard disposable medical or examination gloves always after:

- Visible soiling or contamination with blood, respiratory or nasal secretions, or other body fluids.
- Any signs of damage (e.g., holes, rips) or degradation are observed; and
- Maximum of four (4) hours of continuous use.
- Doffing previously removed gloves should not be re-donned as the risk of tearing and contamination increases. Disposable glove "re-use" should NOT be performed.
- After removing gloves for any reason, hand hygiene should be performed with alcohol-based hand sanitizer or soap and water.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/gloves.html (December 23, 2020)

N95 Masks - Particulate filtering facepiece respirators

- There are two types of respirators, standard N95 and surgical N95. When trying to access, you need only N95 or equivalent.
- Respirators are for healthcare staff who need protection from both:1) airborne droplets and 2) fluid as the close fit is to avoid permeation of both.

KN95 NIOSH (National Institute of Occupational Safety) Sampling identifies KN95 Masks that do not meet basic filtering standards, and in some cases are counterfeit.

- NIOSH developed tests to assess the filter efficiency and penetration (>95%) of a sample of respirators represented as certified by an international certification authority. NIOSH states that usual testing was not done previously due to the respirator shortage associated with COVID-19.
- NIOSH samples identified products that failed filtering tests.



- NIOSH has provided a table at the link below to identify the manufacturer and filtering test results. The table is regularly updated, even daily.
 - NIOSH warns of respirator masks with an ear loop design. NIOSH-approved N95s typically have head bands. Limited assessment of ear loop designs indicate difficulty achieving a proper fit.
 - NIOSH advises that while the manufacturer listed in the table at the link below is the manufacturer of record, NIOSH has been informed that some of these are counterfeit products. Some products with legitimate manufacturer names, showing poor filter penetration results (<95%), are counterfeit products.

Updated NIOSH website: <u>https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html</u> August 7, 2020

3M N95 Respirator Masks Fraud Remains Serious

The FBI, FDA and the 3M company continue to warn about large scale counterfeit 3M N95 masks. The counterfeit masks can be difficult to identify. 3M has taken the following action to reduce the fraud.

- Several 3M respirator masks are equipped with the 3M[™] Safe Guard[™] Product Authentication Process. This allows you to verify if the product you have is authentic.
 - Visit the 3M Safe Guard Authentication website(https://www.3m.com/3M/en_US/worker-health-safety-us/3m-safeguard/) for authentication instructions by model number.
- Basically, on the bottom of each authentic box of 3M respirators equipped with 3M Safe Guard are two codes a Secure Code and a Lot Code. Both are needed to authenticate the product. If your product is authentic, there is a green check mark message during the authentication check.
 - If any other mark appears, contact 3M anti-fraud hotline (1-800-426-8688 in the U.S.). The hotline is also available to answer any questions or concerns.

Conserving Inventory of Respirator Masks: Two (2) Ways to Approach

- Respirator Extended use: wearing the same respirator mask for repeated close contact encounters with patients, the maximum recommended extended use period is <u>6</u> hrs. https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergencyconsiderationsppe.html (May 5, 2020) https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergencyconsiderationsppe.html (May 5, 2020) https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergencyconsiderationsppe.html (May 5, 2020) https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergencyconsiderationsppe.html (May 5, 2020) https://www.db.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergencyconsiderationsppe.html (May 5, 2020) https://www.db.gov/coronavirus/2019-ncov/hcp/non-us-settings/emergencyconsiderationsppe.html (May 5, 2020) Respirators should be removed (doffed) and discarded before activities such as meals and restroom breaks.
- **Respirator Re-Use:** using the same respirator by one staff member for multiple encounters with different patients but removing it (i.e., doffing) after each encounter.
 - Data suggest limiting the number of reuses to no more than 5 uses per device to ensure an adequate safety margin. April 9, 2021 <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html</u>
 - One CDC example is to issue 5 respirators to each staff member. Each respirator is used on a day and stored in a breathable paper bag until the next week.



- This can result in each staff member requiring a minimum of five respirators if they put on, take off, care for them, and store them properly each day. The respirators may need to be stored in the staff's trunk vs. the home.
- The amount of time between uses should exceed the 72-hour expected survival time for COVID-19 virus.³ Healthcare staff should still treat the respirator as though it is still contaminated and follow the precautions.

Changes related to the use of N95 masks: <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-</u> strategy/index.html

Due to the significant increase in availability of N-95 respirator masks, the CDC has made updates to the use of these masks at the different capacity levels. The following is a summary of the changes noted at the above website. April 9, 2021

- <u>Exhalation Valves on Respirator Masks</u>
 - Study findings show that Filtering Facepiece Respirators with an exhalation valve provide respiratory protection to the wearer and can also reduce particle emissions to levels similar to or better than those provided by surgical masks, procedure masks, or cloth face coverings.

Conventional Capacity Strategy: N95

- Extended use of N95 respirators can be considered for source control while HCP are in the healthcare facility, to cover one's mouth and nose to prevent spread of respiratory secretions when they are talking, sneezing, or coughing. When used for this purpose, N95s may be used until they become soiled, damaged, or hard to breathe through. They should be immediately discarded after removal.
- Extended use strategy for N-95 being used as PPE should **NOT** be used when an organization is in conventional capacity mode.

Contingency Capacity Strategies for N-95

- Respirators are to be prioritized for Healthcare Personnel who are using them as PPE over those HCP who are using them for source control.
- Extended use strategy is permitted in contingency capacity, however, the N95 should be discarded immediately after being removed.

Crisis Capacity Strategies

- Healthcare staff should no longer utilize non-NIOSH approved respirators developed by manufacturers who are not NIOSH-approval holders.
- The number of re-uses of an N-95 should be limited to no more than 5 donnings per device by the same HCP. To ensure adequate respirator performance, HCP should always inspect the respirator and perform a seal check upon donning a re-used respirator. N-95 and other disposable respirators should not be shared by multiple HCP.



- Note that each re-use of N95 respirators requires 2 pair of gloves, a clean pair of gloves when donning or adjusting a previously worn N95 respirator. Then discarding these gloves and performing hand hygiene after the N95 respirator is donned or adjusted and using a new pair of gloves for care.
- Use of a cleanable face shield or facemask over the respirator can extend respirator use as it reduces/prevents contamination of the N95 respirator.
- Reuse can also be extended by putting a surgical mask on the patient.

Staff reuse of N95 Masks with presumptive or confirmed COVID-19 patients: Two sources of information on reuse:

- CDC: <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html</u> (April 22, 2020)
- NIOSH the National institutes of Occupational Safety <u>https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html</u> (March 27,2020)
- Inpatient staff recommendations are based on wearing the same staff wearing N-95 masks patientto-patient for several hours. Using inpatient criteria and applying it to the home, reuse is typically limited by.
 - hygienic concerns (the respirator is contaminated with blood, respiratory or nasal secretions, or other patient bodily fluids, or
 - the respirator is damaged or crushed and no longer meets fit test requirements.

Discard: N95 respirators if:

- contaminated with patient blood, respiratory or nasal secretions, or other bodily fluids.
 obviously damaged or becomes hard to breathe through; or
- inadvertent contact is made with the inside of respirator.
 - NOTE: Respiratory pathogens on the respirator surface can potentially be transferred by touch to the wearer's hands, increasing the risk of causing infection through subsequent touching of the mucous membranes of the face -

Face Masks

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/mask-fit-and-filtration.html CDC recommendations for "double masking" is based on the widespread COVID-19 variants some of which appear to spread more quickly and easily than the COVID-19 virus identified in early 2020.

- CDC recommendation are based on 4 factors:
 - \circ $\;$ How well a mask fits around the nose and below the eyes, and on the sides.
 - How well it filters air.
 - How many layers it has, and?
 - What mask to wear when, for example around people you do or do not know.



- Cloth Masks: What to look for:
 - Look for a cloth mask that is made of multiple layers of tightly woven, breathable fabric.
 - Make sure the cloth mask blocks light from coming through the fabric if held up to a bright light.
 - Does it have gaps around the sides of the face or nose? If so, it fits poorly and can allow respiratory droplets containing the virus to leak in and out around the mask.

What you can do: Layered a cloth mask on top of a medical procedure mask (forming a "<u>double mask</u>") for better fit and air filtration. Using a mask fitter or brace can also help to the improve fit of a cloth mask.

- Surgical Masks sold as "disposable face masks" for 1-time community use: What to Look For
 - Check the labels to ensure that they are made of *multi-layered,* non-woven material.
 - Look at the fit which is often poor fit as there are gaps around the nose and along the sides of the face, where respiratory droplets containing the virus can leak in and out.

What You Can Do: A medical procedure mask can be layered underneath a cloth mask (forming a "<u>double mask</u>") for better fit and air filtration. NOTE: a surgical mask <u>should not</u> be layered underneath a surgical mask. A mask fitter or brace can also help to improve fit around the face.

• KN95 Masks (also known as KN95 Respirators): What to Look For

KN95 masks are a type of filtering facepiece respirator that are commonly made and used in China. KN95 masks can be preferred mask to wear in situations that require prolonged <u>close contact</u> (less than 6 ft, for longer than 15 minutes) with people who do not live in the same household, or for people who are at increased risk for severe illness from COVID-19.

• NOTE: When fitting properly these masks filter up to 95% of particles. BUT!! many counterfeit (fake) KN95 masks are available, and sometimes it is hard to tell if they meet the right requirements just by looking at them. At least 60% of the KN95 masks evaluated by NIOSH did not meet the requirements that they claim to meet.

What You Can Do: use a KN95 mask identified on the FDA Emergency Use Authorization List https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks 2/9/21

• What Mask to Wear When: Some situations have higher risk of exposure to COVID-19 than others, so the how much protection you need can vary.

Cloth masks or surgical masks work well for community use. Examples might include:

- Talking with neighbors when you are outdoors and are <u>at least six feet</u> away.
- Going to a park, as long as you can stay <u>at least six feet</u> away from people who do not live with you.



When you will be in <u>close contact</u> (less than 6 ft) with people who do not live with you, a mask that gives you more protection (improved fit and/or improved filtration) such as double masking or KN95 is important.

Examples include:

- Going to the grocery store
- Visiting the doctor
- Working where you are exposed to people who do not live with you and you are not always able to maintain at least six feet of distance from others
- Riding on planes, buses, trains, or other forms of public transportation, especially when you are not able to maintain at least 6 feet of distance from other people who do not live with you
- Taking care of someone who is sick with COVID-19.

People who are older or have conditions that make them more likely at risk for severe COVID-19 illness should consider using KN95 masks or double masking when around people they do not live with.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/mask-fit-and-filtration.html Feb 10, 2021

Surgical Mask Use:

- **Conventional Capacity: Your Organization's Usual practice with an adequate supply** Facemasks are used by healthcare staff for 2 general purposes:
 - As PPE to protect their nose and mouth from exposure to splashes, sprays, splatter, and respiratory secretions. When used for this purpose, facemasks should be removed and discarded after each patient.
 - When used to cover one's mouth and nose to prevent spread of respiratory secretions when talking, sneezing, or coughing, facemasks may be used until they become soiled, damaged, or hard to breathe through. They should be immediately discarded after removal.

FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Facemasks that are not regulated by FDA, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

<u>Contingency Capacity – expected temporary expected shortage – implement extended use.</u>

Extended use of facemasks is the practice of staff wearing the same facemask during encounters with several different patients, without removing the facemask between.

- The facemask is discarded whenever it is removed, and always at the end of each workday.
- The facemask is removed and discarded if it is soiled, damaged, or hard to breathe through.
- Staff must take care not to touch their facemask. If they touch or adjust it, they must immediately perform hand hygiene.
- o HCP should leave the patient care area if they need to remove the facemask.



- Staff who wear a mask to cover one's mouth and nose to prevent spread of respiratory secretions when talking, sneezing, or coughing may use a cloth mask.
- Instead of providing a facemask to patients not already wearing their own cloth mask for source control, have them use tissues or other barriers to cover their mouth and nose.

<u>Crisis Capacity: Per CDC these practices do not meet US standards of care but are implemented during</u> <u>known periods of shortage. Implement limited re-use with extended use.</u>

- Pairing limited re-use of facemasks with extended use is one staff member using the same facemask for multiple patient contacts but removing it after several contacts and redonning it for further patient contacts.
- Ensure that staff do not touch outer surfaces of the mask during care, and that mask removal and replacement be done in a careful and deliberate manner.
- \circ $\;$ There is not a known maximum number of uses (donning) of the same facemask.
- The facemask should be removed and discarded if soiled, damaged, or hard to breathe through.
- Facemasks that fasten to the face by using ties may not be able to be undone without tearing and should be considered only for extended use, not re-re-use.
- Facemasks with elastic ear hooks may be the best for re-use.

Staff should leave patient care area if they need to remove the facemask. It should be carefully folded so that the outer surface is inward and against itself to reduce contact with the outer surface during storage. The folded mask can be stored between uses in a clean sealable paper bag or breathable container.

When no Facemasks are Available:

- Use a face shield that covers the entire front (that extends to the chin or below) and sides of the face with no facemask.
- If neither respirators nor facemasks are available, staff might use cloth masks as a last resort for care of patients with suspected or confirmed diagnosis for which facemask or respirator use is normally recommended. Caution should be exercised when considering this option. Cloth masks should ideally be used in combination with a face shield that covers the entire front (that extends to the chin or below) and sides of the face.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html November 23, 2020

FDA Surgical Face Masks:

The FDA issued an umbrella emergency use authorization (EUA) for certain disposable, single-use surgical masks that meet certain performance requirements for use in any healthcare settings when used by staff to provide a physical barrier to fluids and particulate materials to prevent exposure to respiratory droplets and large particles.

Surgical masks that have been confirmed by the FDA as meeting criteria under the EUA are included in Appendix A as authorized surgical masks and the list is updated regularly.

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/personal-protective-equipment-euas February 1, 2021



Gowns: CDC recommending Use of Disposable and Cloth Isolation Gowns

Gowns should be worn for aerosol-generating procedures such as suctioning, nebulizer treatments, and other care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of healthcare providers.

Conventional Capacity: Usual practice with anticipated adequate supply of gowns

The CDC encourages employers to consider several fluid-resistant and impermeable protective clothing options.

- Nonsterile *disposable patient <u>isolation gowns</u>* used for routine patient *care are appropriate for use by staff when caring for patients with suspected or confirmed COVID-19.*
- *Reusable (i.e., washable) gowns are also accepted for routine* use, and typically made of polyester or polyester-cotton fabrics. Gowns made of these fabrics can be safely laundered after each use according to routine procedures and reused.
 - Routinely inspect gowns for rips or being too thin.
 - Ensure clean gowns stored so clean gowns are easily identifiable.

Emergency Use Authorization for Isolation Gowns: Using ANSI/AAMI PB70 standard disposal gowns: Level 1 or 2 gowns (non-surgical isolation gowns) is recommended when there is low risk of contamination. <u>https://www.fda.gov/media/138326/download</u> May 20, 2020

Contingency Capacity – Temporary, expected shortage of gown, implement extended use.

Limit the use of isolation gowns:

- To patients with suspected or confirmed SARS-CoV-2 infections during aerosol generating procedures; and
- *during patient activities that involve close and prolonged contact with the patient or their immediate environment* (e.g., dressing, bathing/showering, transferring, providing hygiene, changing linens, changing briefs, or assisting with toileting, device care or use, and wound care).

NOTE: use of surgical gowns as isolation gowns requires changing gowns between patients and consideration of which surgical gown is used as they provide different levels of protection https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/

<u>Crisis Capacity: The practices are known not to meet US standards of care but are implemented in the care of patients during known periods of shortages</u>.

- Extend the use of isolation gowns (disposable or reusable) by having staff wear the same gown when interacting with more than one patient housed in the same location and known to be infected with the same infectious disease (e.g., all COVID 19 patients).
 - Re-use of the same gown with >1 patient can be considered **only** if there are no additional co-infectious diagnoses that can be transmitted by contact (such as Clostridioides difficile, Candida Auris).
 - A gown being used becomes visibly soiled, it must be removed and discarded or changed.



- Per the CDC, in situations of severely limited or no available isolation gowns, the following clothing
 can be considered <u>as a last resort for care of COVID-19 patients as single use</u>. None of these options
 can be considered PPE, since their capability to protect HCP is unknown. CDC recommends using this
 clothing if it has long sleeves and closures (snaps, buttons) that can be fastened and secured.
 - o Disposable laboratory coats
 - Reusable (washable) patient gowns
 - o Reusable (washable) laboratory coats
 - Disposable aprons
 - Combinations of pieces of clothing can be considered for activities that may involve high amounts of body fluids and when there are no gowns available.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/isolation-gowns.html_Jan 21, 2021

<u>Ongoing FDA Hand Sanitizer Alert: All alcohol-based hand sanitizers from Mexico on national import</u> <u>alert</u> - 84% of the samples analyzed by the FDA from April through December 2020 did not comply with the FDA's regulations and over half contained methanol and/or other toxic elements.

- The FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's <u>MedWatch Adverse Event</u> <u>Reporting</u> program.
- The FDA list to check if your hand sanitizer is a product you should use: <u>https://www.fda.gov/consumers/consumer-updates/your-hand-sanitizer-fdas-list-products-you-should-not-use</u>

Q

PHE Quality Reporting Exemptions on Public Reporting – Sept 2020

For Q1 2020 and Q2 2020, providers were excepted from data submissions. For this reason, CMS will hold the data constant (i.e., freeze the data) following the October 2020 refresh. The affected Compare site refreshes that were scheduled to contain CY 2020 COVID-19 data (Q1 2020, and Q2 2020) include:

- January 2021
- April 2021
- July 2021



October 2021 After the October 2021 refresh, CMS plans to resume public reporting. Figure 2 provides a summary.

Quarter Refresh	Home Health Compare OASIS – Assessment-Based Measures Claims-Based Measures	Home Health Compare CAHPS [®]
October 2020	Normal refresh (includes Q4 2019 data)	Normal refresh (includes Q4 2019 data)
January 2021	Freeze	Freeze
April 2021	Freeze	Freeze
July 2021	Freeze	Freeze
October 2021	Freeze	Freeze
January 2022	Public reporting resumes*	Public reporting resumes*
April 2022	Normal refresh	Normal refresh

*To account for missing PHE -excepted data (Q1 2020 and Q2 2020) when public reporting resumes, any potential change in measure calculation methodology will be subject to notice-and-comment rulemaking.

https://www.cms.gov/files/document/hhqrp-pr-tip-sheet081320final-cx-508.pdf

Home Health Flexibilities related to QRP due to the PHE.

CMS is delaying the release of the updated version of OASIS needed to support the Transfer of Health. (TOH) Information quality measures and new or revised Standardized Patient Assessment Data Elements (SPADES) to provide maximum flexibilities for providers of HHAs to respond to the COVID-19 PHE. The release of the updated version of the OASIS will be delayed until January 1 of the year that is at least 1 full calendar year after the end of the COVID-19 PHE.

CMS is providing relief to HHAs on the timeframes related to OASIS transmission through the following: (1) extending the 5-day completion requirement for the comprehensive assessment to 30 days; and (2) waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE. We are now allowing 30 days for the completion of the comprehensive assessment. HHAs must submit OASIS data prior to submitting their final claim to receive Medicare payment.

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Training.

Hospice Quality Reporting



Quarter Refresh	Hospice Compare HIS- Assessment Based Measures	Hospice Compare CAHPS [®]
November 2020	Normal refresh (includes Q4 2019 data)	Normal refresh (includes Q4 2019 data)
February 2021	Freeze	Freeze
May 2021	Freeze	Freeze
August 2021	Freeze	Freeze
November 2021	Freeze	Freeze
February 2022	Public reporting resumes*	Public reporting resumes*
May 2022	Normal refresh	Public reporting resumes*
August 2022	Normal refresh	Public reporting resumes*
November 2022	Normal refresh	Public reporting resumes*
February 2023	Normal refresh	Public reporting resumes*
May 2023	Normal refresh	Normal refresh

*To account for the PHE -excepted data (Q1 2020 and Q2 2020) when public reporting resumes, any potential change in measure calculation methodology will be subject to notice-and-comment rulemaking.

https://www.cms.gov/files/document/hqrp-pr-tip-sheet081320final-cx-508.pdf

Quality Reporting Pandemic Considerations:

Current care practices implemented for Home Health and Hospice agencies to minimize virus exposure have potential to impact patient responses related to the CAHPS survey and clinician responses related to the OASIS or HIS data.

Examples of these practices include the use of PPE, shortening the visit length to reduce exposure time, use of telecommunication for the provision of care, and staffing shortages.

Considerations: • PPE o use results in a barrier and the loss of "human touch" which facilitate relationship building o the loss of connection could impact patient answers to CAHPS questions such as: Were you listened to? Were you treated with respect? Did you receive confusing information?

Potential solutions:

 Consider methods of care delivery that facilitate relationship building. If a patient is stressed overuse of telecommunications, the ability to connect clinician to patient is hindered.



- Allowing a patient/caregiver to "see" the face of their clinician through a window or by a
 picture may facilitate the "human touch."
- Minimizing length of visits
 Shortening the length of visits requires alternate methods to
 provide the care of Using a combination of telecommunication and in-person visits to
 address patient needs will help ensure those needs are being met.
- Potential solutions include processes to increase the effectiveness of the shorter visit.
 - Possibly a checklist to stay on track.
 - Phone calls prior to or following the visit to obtain or verify information that does not require in-person contact.
 - Development of educational materials for patient review with the education conducted by telecommunication.
 - Use of Telecommunication for care delivery. Finding the optimum platform requires being able to validate the ability to conduct a comprehensive, effective visit that will meet the patient's needs. The same platform may not work for everyone.
- Coordination of care provided remotely, and care provided in-person is key to ensure quality care.
- Potential solutions
 - Standardized written instruction for participating in a remote visit.
 - Encourage patients to have ready items needed for the remote visit.
 - Examples include supplies to conduct blood glucose testing, any new or changed medications, any logs that are being maintained by the patient.
 - Needs identified during a remote visit require evaluation of whether an immediate in person visit is needed or not.
 - Communication is key if the agency is unable to maintain consistent care providers for the patient. Being able to reflect coordination of the patient's care will emphasize the "team" caring for the patient.

During this challenging time, it is necessary to amend processes to provide quality care within the confines of infection control safety, and to also evaluate how those alternate processes may impact the patient's quality of care, their perception of their care experience and your publicly reported quality measures. Evaluate your processes broadly and think out of the box but within the Conditions of Participation.

S

Schools: What we Know about COVID Safety in Schools

- Children can be infected with COVID-19 and spread the virus to others. However, children are less likely to develop severe illness or die from COVID-19.⁶/₂
- <10% of COVID-19 cases in the United States have been among children and adolescents aged 5–17 years old, about the same % as with other viruses.
 - Younger children (<10 years of age) may be less likely to be infected than adolescents.



- Studies identify those children and adolescents with highest risk for hospitalization:
 - Males, Hispanic ethnicity and black race, average age 8 yrs. old
 - Underlying medical conditions are also more commonly reported among children who are hospitalized or admitted to an ICU.¹⁶

<u>In-Person Learning Among Children is NOT associated with Causing Community Transmission of the COVID-</u> <u>19</u> now evident in studies of in-person schooling Europe and now the US.

- Outbreaks do occur in schools, but multiple studies show that transmission or spread of the COVID-19 virus within school settings is typically *lower than – or at least* similar to the levels of transmission or spread in your community - <u>when prevention strategies are in place in schools</u>.
- It's called "layered protection" in schools: masks, physical distancing, handwashing and respiratory etiquette (cough and sneezing), cleaning, ventilation and contact tracing. For example, if a report a parent ill and it is confirmed, the child quarantines for 14 days with the family.

3 Three Foot distancing? International and U.S. studies suggests layered protection even with physical distancing of less than 6ft is still effective is effective in reducing risk for spreading COVID 19.

• Recommendations from WHO⁶⁴ and the American Academy of Pediatrics state using a distance of at least 3 feet between students in classrooms could provide a reasonable definition of physical distancing so long as other prevention measures are maximized – the layered protection.

https://www.cdc.gov/coronavirus/2019-ncov/more/science-andresearch/transmission k 12 schools.html March 19

Staff Stress and Compassion Fatigue:

Providing care to others during the COVID-19 pandemic can lead to stress, anxiety, fear, and other strong emotions. How you and your team cope with these emotions can affect your well-being, the care you give to others while doing your job, and the well-being of the people you care about outside of work.

In a Pandemic the Mental Health Issue is Duration: Experiencing or witnessing life threatening events impacts everyone differently. People may experience clinically significant distress or impairment, such as acute stress disorder, PTSD, or <u>secondary traumatic stress</u> (also known as vicarious traumatization). Compassion fatigue may also result from chronic workplace stress and exposure to traumatic events during the COVID-19 pandemic. <u>https://www.cdc.gov/coronavirus/2019-ncov/daily-lifecoping/managing-stress-anxiety.html</u> July 1, 2020

What You Can Do - First Identify It: Recognize the symptoms of stress

- Feeling irritation, anger, or denial
- Fear and worry about your own health and the health of your loved ones, your financial situation or job, or loss of support services you rely on
- Feeling uncertain, nervous, or anxious



- Feeling helpless or powerless
- Lacking motivation
- Feeling tired, overwhelmed, or burned out.
- Feeling sad or depressed
- Having trouble sleeping
- Having trouble concentrating

Learning to Manage Your Reactions:

Focus on 4 Core Components for Self-Management:

- 1) adequate sleep and rest
- 2) good nutrition, eat healthy meals,
- 3) regular physical activity and
- 4) active relaxation spend time outdoors relaxing when you can.

Talk to Yourself!

- Remind yourself that you are not the only one in an unusual situation with limited resources.
- Identify and accept those things which you do not have control over.
- Recognize that you are performing a crucial role in fighting this pandemic and that you are doing the best you can with the resources available. you share a sisterhood and brotherhood with caregivers like yourself across the world.

Take Control of Aspects of Your Daily Life:

- Keep a consistent daily routine when possible as similar as you can to your schedule before the pandemic.
- Take breaks during your day to rest, stretch, or check in with *supportive* coworkers, friends, and family.
- Do things you enjoy during non-work hours the importance of taking time away from work.
- Take breaks from watching, reading, or listening to news stories, including social media. Hearing
 about the pandemic repeatedly can be upsetting and mentally exhausting, especially since you work
 with people directly affected by the virus.
- Practice good daily hygiene-how like or unlike your daily routine are you now? Hair, shave, dress?
- 'Wash Up' at the end of the day, to 'put away' your work.
- Create individual ceremonies or rituals that allow you to focus your thoughts on letting go of stress or honoring a memory of something positive; seek moments of 'joy'.
- Practice your spiritual beliefs, anyone can pray.
- Engage in mindfulness techniques, such as breathing exercises and meditation. (there are apps for this!)
- If you feel you or someone you know may be misusing alcohol or other drugs (including prescriptions), ask for help or offer help.



• If you are being treated for a mental health condition, continue with your treatment, and talk to your provider if you experience new or worsening symptoms.

If concerned that you or someone in your household or you work with may harm themselves or someone else here are additional resources. If you share these, you never know when someone may use it.

- National Suicide Prevention Lifeline Toll-free number 1-800-273-TALK (1-800-273-8255)
 - The online Lifeline Crisis Chat is free and confidential. You will be connected to a skilled, trained counselor in your area.
- <u>National Domestic Violence Hotline</u>
 Call 1-800-799-7233 and TTY 1-800-787-3224
- Disaster Distress Hotline (SAMSHA) (Created for those working during disasters.
 - Call 1-800-985-5990 or text TalkWithUs to 6674.

Other sources American Institute of Stress <u>https://www.stress.org</u> has additional resources.

Staff Anxiety: Leadership, Manager and Supervision -What you can do:

Expect staff to demonstrate increased anxiety as the PHE continues, if only as a natural reaction to a sustained period of no predictability that can or does impact all parts of our lives. As leaders you can take action to make a difference for your team! The following is excerpted studies of the impact of the pandemic on health care staff here in the US and the UK.

- 1) Your leadership goal reduce ambiguity for staff they just want to know.
 - a. Double down on communication
 - b. Make it open and honest their concern is financial security, physical safety, etc.
 c. Tell them where the company is at, you are going forward, will expect and accept COVID 19 patients- yes or no and only if you have the supplies to care for them and for your team. (recommended guideline You are expected to keep wearing PPE. Tell them that checking in with the symptom log is still expected, now it is critical to tracking.
 - d. Tell them what you learned from these seven months, reaffirm what worked and what will you do the same going forward. If something did not work, inform the staff group to address remember engaging folks offer hope which is based on taking action.
 - e. Clearly communicate the rationale behind changes you make going forward.
- 2) Acknowledge that you know that their job is stressful, and **they are** essential workers/heroes. Underscore the value of what they do -they let people stay at home-where we all want to be.
 - a. What can you do to empower them, give them control over elements of what they do?
 - b. Remind employees to take mental and physical breaks, exercise and participate in other non-work-related activities to <u>reduce anxiety</u>.
- 3) What roadblocks can you remove? They may have ideas.



- 4) Ensure that your team knows about mental health coverage as part of their benefits or access to these in the community (Noted at the end of the preceding information).
 - a. If you have a wellness program use it for self-care, self-help virtual sessions with experts. Your goal is to reduce the stigma for asking for help.
 - b. You may need to talk to some employees about seeking guidance.
- 5) So, what else is effective-in addition to clear communication about what is going on:
 - a. Show how you care about the individual employee.
 - b. Encourage supervisors and your management to check in with the team on about things other than work.
 - c. Find more way to express appreciation.
 - d. You are responsible to set a tone of respect.
 - e. Resolve conflicts quickly.

Folks need to know right now that someone cares about them and what they do.

<u>Staff Work Status and Antibody Testing</u>: The CDC advises that an antibody test should NOT be used to determine if someone can return to work:

https://www.cdc.gov/coronavirus/2019ncov/lab/resources/antibody-tests.html (May 28, 2020)

Staff COVID 19 Processes to Address the Following:

- Monitoring staff health status for symptoms of COVID 19 symptoms, https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html May 13, 2020
- Staff Feeling III go home and contact a doctor for care and/or testing. Per CDC.
- Designate who and how patients, families and other staff are notified that a staff member is ill, and what action they should take awaiting information is COVID 19 positive.
- Advise patients and caregivers how you monitor staff health status and ask their cooperation in telling you if any member of the household or visitor has confirmed COVID-19 or is awaiting results.

Staff Exposure: Restricting an Employee from Work

- CDC provided guidance for asymptomatic HCP who were exposed to individuals with confirmed COVID-19. Higher risk exposures involve exposure of HCP eyes, nose or mouth to material potentially containing SARS-Cov-2, especially if the interaction involved aerosol-generating procedures.
- HIGH RISK EXPOSURE HCP who had prolonged-(15 min or more or 15 minutes over a 24-hr. period), close contact (within 6ft) with a patient, visitor or HCP with confirmed COVID-19 AND did not wear appropriate PPE which would include respirator or face mask, eye protection, or HCP not wearing all recommended PPE while performing an aerosol-generating procedure. Exclude from work for 14 days. Advise HCP to self-monitor for fever or other symptoms of COVID-19 O Any HCP who develops symptoms should arrange for medical evaluation and testing.



- LOWER RISK EXPOSURE any HCP who had exposure without the high risk noted above

 No work restrictions. Continue wearing facemask for source control while at work. Do not report to work if ill.
 - Any HCP who develops symptoms consistent with COVID-19 should immediately self-isolate and arrange for medical evaluation and testing.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html#4 (May 29, 2020)

Staff Exposure post vaccination: Work Restriction?

Guidance related to when an individual has completed vaccination but been exposed to someone with suspected or confirmed COVID-19 may be applicable when considering work restrictions for fully vaccinated healthcare personnel with higher-risk exposures as a strategy to alleviate staffing shortages.

As of February 10th, 2021, an individual who has been fully vaccinated and had a subsequent exposure would not be required to quarantine if they meet all the following criteria:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
- Are within 3 months following receipt of the last dose in the series.
- Have remained asymptomatic since the current COVID-19 exposure.

Those who meet the above criteria and do not quarantine should monitor themselves for potential symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19.

Organizations who are experiencing staffing shortages, may use these criteria to determine if those with higher-risk exposures could continue to work.

Staff with lower-risk exposures are not expected to quarantine but must monitor symptoms and always continue source control measures of masking and social distancing.

Those who do not meet all the above criteria should continue to follow current quarantine guidance. <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#phrecs</u> Feb 10, 2021

Т

Telehealth:

Use of telehealth by Medicare Certified home health agencies.



- <u>A PRN telecommunication visit order</u> is permissible if it is accompanied by a description of the
 patient's medical signs and symptoms requiring the visit and a specific limit on the number of those
 visits to be made before an additional physician or allowed practitioner order is needed. Orders for
 care may indicate a specific range in frequency of visits to ensure that the most appropriate level of
 services is furnished. If a range of visits is ordered the upper limit of the range is considered the
 specific frequency.
- Comprehensive Assessments and Updates to the Comprehensive Assessment
 - Audio only or two-way audio-video telecommunication comprehensive assessment or an update to the assessment can be used if it is part of the patient's plan of care.
 Telecommunications cannot substitute for in-person visits as ordered on the plan of care.
- <u>Plan of care should be modified</u> as the type of visits change, noting which visits will be made in person and which visits will be conducted visa telecommunication technology.
- Expectations:
 - Education of patients as to the processes the agency has in place to protect patients as well as home care staff.
 - Not everything can be accomplished per telecommunication when skilled care is required.
 - The agency should work closely with the patient to determine what would reassure them that in-person visits with the agency staff are safe.

If the patient continues to refuse any in-person visits as per the plan of care, the agency will have to determine if the patient's medical, nursing, rehabilitation and social needs can be met in their place of residence. Per §484.60 <u>https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf</u> (page 57) Updated 6/2/2020

- <u>Hospice</u>: Hospice providers can provide services to a Medicare patient receiving routine home care through telecommunications technology (e.g., remote patient monitoring; telephone calls (audio only and TTY); and 2-way audio-video technology), if it is feasible and appropriate to do so. Only in person visits are to be recorded on the hospice claim.
- Face-to-face encounters for purposes of patient recertification for the Medicare hospice benefit can now be conducted via telehealth (i.e., 2-way audio-video telecommunications technology that allows for real-time interaction between the hospice physician/hospice nurse practitioner and the patient).

https://www.cms.gov/files/document/covid-hospices.pdf (5/15/2020)

Hospice FAQ Telehealth Answers and Expectations:

 $\circ\,$ Initial and Comprehensive Assessments



- Due to the role of the assessment as the foundation of the plan of care and crucial to establishing the hospice-patient relationship, the expectation is that in most situations, the initial and comprehensive assessments would be done in person. Especially for assessment of skin/wound care, uncontrolled pain/symptoms, effective teaching of patient/caregiver medication administration, etc.)
- It would be up to the clinical judgment of hospice as to whether such technology can meet the patient's/caregiver's/family's needs and the use of technology should be included on the plan of care for the patient and family.

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf Page 68 (Updated 6/2/2020)

- Medicaid and Private Insurance
 - The ability to bill for home health/hospice is dependent upon the state flexibilities and the program itself. Research should be conducted to determine when telehealth can be provided and if it is billable.
- Paid telehealth visits by licensed practitioners. As of March 6, 2020, Medicare pays for office, hospital visits or visits to a patient's home furnished via telehealth. These visits can be conducted by doctors, nurse practitioners, clinical psychologists, licensed clinical social workers, and other licensed practitioners.

https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-providerfactsheet (March 17, 2020)

Additionally, the HHS Office of Inspector General (OIG) is providing flexibility for these practitioners to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs.

Telehealth options:

- Types of telehealth communications:
 - Telehealth: refers to a broader scope of remote health care services than telemedicine as in addition to remote clinician services between a provider and patient/client, it also refers to remote non-clinical services such as clinician to clinician consults, patient education services, and interprofessional care team communications
 - Telemedicine: practice of delivering medicine using technology to deliver care at a distance. A physician/clinician in one location uses a telecommunications infrastructure to deliver care to a patient at a distant site. This is a subset of telehealth.
 - Remote patient monitoring refers to using technology to gather patient data outside of the traditional health care setting to monitor a patient's condition while they are at home. This is also a subset of telehealth and includes such devices as glucometers and digital scales.
 - mHealth: is abbreviated for mobile health and refers to the subset of telehealth that uses mobile technologies. Examples include apps and peripheral devices designed for use on smart phones and tablet. Can be used for videoconferencing, gathering patient data, or providing patient education.



Getting Started:

- What is the state requirement related to patient consent to use telehealth?
 - If verbal consent is obtained, a witness is appropriate, and the consent should be documented within the clinical record.
- Does the organization provide service under who may allow telehealth billing?
- How will telehealth be provided?
- Develop protocols for the delivery of telehealth visits
 O How will the type of interaction be
 determined?
 O How will education be provided to patients/family related to the visits?
 - $\,\circ\,$ Who is responsible for scheduling and does a link need to be sent?
 - How will the visit documentation be done? How will emergency/on call needs be addressed?

Virtual Visit Etiquette

- Start the visit by confirming the patient/family can see and hear. Make a clear verbal transition to the start of the clinical visit. Such as "How are you doing?"
- Let the patient/family know they can interrupt if they need to pause or adjust during the visit.
 Confirm that you will call them if sound, or video is lost during the visit
- For the 1st visit provide an overview of the visit.
 - The amount of visit time.
 - What is to be accomplished during the visit to Discuss any concerns or symptoms being experienced o Review of medications and need for refills. The plan for the next visit
- If responding from home, find a quiet location with a neutral background and good lighting.
- Always dress appropriately and wear plain clothes as patterns can cause nausea from the screen.
- Speak slowly and clearly and check every so often to ensure that you are being heard.
- Remember to look at the camera on your own device (not at the screen that has the patient's video)
- Call wrap up: Let the patient/family know when 5-10 minutes is left, and ask if there is information, they want to make sure to cover.
- End the visit by summarizing what you heard, what the plan is, reviewing medication needs. Inform the patient if the next visit will be a virtual or in-person visit.

Telehealth Resources:

- Northwest Regional Telehealth Resource Center https://www.nrtrc.org/covid-19-detail-117
 https://www.nrtrc.org/covid-19-detail-117
 https://www.nrtrc.org/covid-19-detail-117
- Health and Human Services <u>https://telehealth.hhs.gov/providers/getting-started/</u>



Mid Atlantic Telehealth Resource Center <u>https://www.matrc.org/matrc-telehealth-resources-for-covid-19/</u>

HIPAA and Telehealth: The HHS Office for Civil Rights (OCR) can waive penalties for HIPAA violations against health care providers serving patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the COVID-19 federal PHE. https://www.hhs.gov/hipaa/for-professionals/special-topics/emergencypreparedness/notificationenforcement-discretion-telehealth/index.html (March 23, 2020)

Tips for Success:

- Look for changes in care provision practices to evaluate any potential negative effects on patients.
- Ensure plans of care include telecommunications if staff are using.
- Ensure orders are obtained to reflect any changes in care including the use of telecommunications.
- If utilizing telecommunication, a checklist can aid the clinician to remember the needs of the visit as they provide care.

Travel:

The following tables provide direction related to domestic and international travel.

- The guidance explains differences in recommendations for those not vaccinated and those who are fully vaccinated.
- Fully vaccinated travelers are less likely to get and spread COVID-19.
 - Testing and self-quarantine is not needed if you are fully vaccinated OR have recovered from COVID-19 in the past 3 months.

Domestic Travel Recommendations and Requirements	Not Vaccinated	<u>Fully</u> Vaccinated
Get tested 1-3 days before travel	0	
Get tested 3-5 days after travel and self-quarantine for 7 days. Self- quarantine for 10 days if you don't get tested.	0	
Self-monitor for symptoms	0	0
Wear a mask and take other precautions during travel	0	0

https://www.cdc.gov/coronavirus/2019-ncov/travelers/infographic/infographic-quick-reference.html



CORONAVIRUS DISEASE 2019 (COVID-19)

International Travel Recommendations and requirements	Not Vaccinated	Fully Vaccinated	
Get tested 1-3 days before traveling out of the US	0		
Mandatory test required before flying to US	0	0	
Get tested 3-5 days after travel	0	0	
Self-quarantine after travel for 7 days with a negative test or 10 days without test	0		
Setf-monitor for symptoms	0	0	
Wear a mask and take other precautions during travel	0	0	
		cdc.gov/co	ronavi



https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html

V

Vaccine Communication Toolkits

- <u>Essential Worker Toolkit</u>: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/essential-</u> workers.html
- <u>Community-Based Organization Toolkit</u>: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/community-organization.html</u>

Toolkits can be used to educate essential workers and/or community members about COVID-19 vaccines, raise awareness about the benefits of vaccination and address common questions and concerns.

Tips for Effective COVID-19 Vaccine Conversation with Patients Can be Found at:

https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

Application of decreased restrictions for Fully Vaccinated Individuals only in non-healthcare settings!



- Visit with other fully vaccinated people indoors without wearing masks or physical distancing.
- Visit with unvaccinated people from a single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing.
- o Refrain from quarantine and testing following a known exposure if asymptomatic.

Preventative Measures to be continued by even those Fully Vaccinated:

- Take precautions in public like wearing a well-fitted mask and physical distancing.
- Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with unvaccinated people who are at increased risk for severe COVID-19 disease or who have an unvaccinated household member who is at increased risk for severe COVID-19 disease.
- Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households.
- Avoid medium- and large-sized in-person gatherings.
- Get tested if experiencing COVID-19 symptoms.
- Follow guidance issued by individual employers.
- Follow CDC and health department travel requirements and recommendations.

https://www.cdc.gov/coronavirus/2019-ncov/more/fully-vaccinated-people.html

Fully Vaccinated Health Care Personnel (HCP)

- Fully Vaccinated HCP with **higher-risk exposures** who are asymptomatic no longer need to be restricted from work for 14 days following their exposure. <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html</u>
- HCP who have recovered from SARS-CoV-2 infection in the prior 3 months of a **higher-risk exposure** are also no longer required to quarantine if they remain asymptomatic.
- NOTE: HCP who have underlying immunocompromising conditions (e.g., organ transplantation, cancer treatment) which may impact the level of protection provided by the COVID-19 vaccine should continue to implement work restrictions if they have incurred a higher risk exposure. <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html</u>
- Fully Vaccinated HCP who have traveled should continue to follow the same CDC recommendations as recommended for <u>any</u> traveler. This includes the following:
 - Get tested with a viral test 3-5 days after travel and stay home and self-quarantine for a full 7 days after travel.
 - Even if you test negative, stay home and self-quarantine for the full 7 days.
 - If you test positive, isolate yourself to protect others from getting infected.
 - If you do not get tested, stay home and self-quarantine for 10 days after travel.
 - \circ Avoid being around people who are at increased risk for severe illness for 14 days.
- Recommendations for testing of HCP remain unchanged, whether fully vaccinated or not.



- Four situations may require testing.
 - Testing of HCP with signs and symptoms consistent with COVID-19 is a priority.
 - Even a sore throat may be possible consideration for testing due to the extensive and close contact of HCP with vulnerable populations.
- Testing asymptomatic HCP with know high-risk exposure may be a priority also due to the contact with vulnerable populations. The CDC recommends HCP err on the conservative side.
- Testing of asymptomatic HCP without known or suspected exposure is primarily completed as part of expanded screening in skilled facilities.
- Testing of HCP may be done of those diagnosed with infection to determine that they are no longer infectious although a symptom-based method may result in less quarantine time due to the potential viral load causing continuing positive results. <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html</u>
- PPE usage remains unchanged for HCP who are fully vaccinated.

Vaccines What Do We Know and What Are We Still Learning

- We know that the 3 current COVID-19 vaccines in the US are effective at preventing COVID-19 disease, especially severe illness and death.
 - Per the FDA, the vaccines may not protect everyone. These vaccines are not FDA licensed vaccines only emergency use authorization (EUA).
- We know that other prevention steps such as masks and social distancing help stop the spread of COVID-19 even as vaccines are being distributed.
- We're still learning how well COVID-19 vaccines keep people from spreading the disease.
- April 15 : We're still learning how long immunity after vaccination will last, follow-up booster shots may be required in the winter months. Both Pfizer and Moderna began testing safety of boosters should a 3rd dose be needed.

"COVID-19 in 2021—Continuing Uncertaint<u>y"</u> Carlos del Rio, MD1; Preeti Malani, MD, MSJ2,3<u>JAMA</u>. 2021;325(14):1389-1390. doi:10.1001/jama.2021.3760 March 4, 2020

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html March 9, 2021

- We're still learning how effective the vaccines are against COVID 19 variants. Early data show the vaccines may work against some variants but could be less effective against others.
- We are still learning about variants:
 - How the disease caused by these new variants differs from the disease caused by other variants that are currently circulating
 - How these variants may affect existing therapies, vaccines, and tests

A one- page summary for use by your staff is **available on the CHAP education website**. Your team has great influence on people's choices to be vaccinated, especially patients as vulnerable individuals.



Designated COVID 19 Vaccinator Status as a Community-Based Organizations

- An HHA or hospice do not need to take any action to administer and bill for the COVID-19 vaccination, either through individual claims or roster bill, you are considered a mass immunizer. You will need to apply and be approved by your state or local health department to receive the vaccine. Contact the Immunization Program Manager now at your health department.
- Medicare payment for administering vaccinations: <u>https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment</u> and, <u>https://www.cms.gov/files/document/covid-home-health-agencies.pdf</u> (Nov 5 2020)
- How the vaccination is paid for: Vaccine doses purchased with U.S. taxpayer dollars are given at no cost. Vaccination providers can charge administration fees for giving the shot.

Pay rate increases for COVID-19 vaccines administered on or after March 15 may be raised to \$40 to administer each dose of a COVID-19 vaccine. The exact rate for administration of each dose depends on the type of entity provides the service and will be geographically adjusted based on where the service is furnished.

O This is an increase from approximately \$28 to \$40 for the administration of single-dose vaccines, and an increase from approximately \$45 to \$80 for the administration of COVID-19 vaccines requiring two doses.

• Expanded vaccinators-always remember to check state list: https://www.phe.gov/emergency/events/COVID19/COVIDvaccinators/Pages/default.aspx

Vaccination providers can get the administration fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the <u>Health Resources and Services</u> <u>Administration's Provider Relief Fund external icon</u>.

• <u>COVID 19 Vaccination Access Priority</u>:

State health departments, including local health departments, have the final determination of distribution and access to the vaccine.

Vaccinating Homebound Patients – CDC Recommendations:

3 Elements Key to Vaccinating Homebound Patients in home health, hospice and home care (private duty). **NOTE:** Organizations administering vaccine at home do assume additional responsibility, if you do not routinely do this, contact your liability insurer.

• Training:

CDC recommends that healthcare professionals become familiar with the COVID 19 vaccine that will be administered to ensure it is stored, handled, prepared, and administered correctly.



• Who Do You Train? Check who is licensed to administer vaccines in your state. Some states may have changed with the pandemic in mind, issuing state waivers to increase the availability of staff.

• Who needs to be trained:

- Experienced vaccinators as well as vaccinators who haven't administered vaccines in the past 12 months or longer.
- Support staff (not licensed to administer vaccines) who can assist with vaccine preparation and cold chain management such as data reporting, distribution of required materials to vaccine recipients, etc.
 CDC COVID 19 vaccination training and core competencies can be found at https://www.cdc.gov/vaccines/covid-19/training.html Jan 27, 2021

Pre-Plan for Home Vaccination-What is Involved?

Estimate the number of doses needed as closely as possible by:

- 1. Contacting patients or their caregivers in advance to determine who wishes to be vaccinated.
- 2. Planning to use all doses in a vial decide on a contingency plan to avoid vaccine waste.
- 3. Map out travel plans considering the time frames for vaccine use at different temperatures, factor in prevaccination preparation time, in-home time including post-vaccination observation.
- 4. Deciding how to maintain, monitor, and log the temperature of vaccine. Consider using a digital data logger.
- Identifying what is involved in transporting vaccine it differs for each vaccine. Understand how you can get access to and use of a "packout" container specific for vaccines. More important detail can be found at the following website including about using cars for transport: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf Feb 5, 2021
- 6. Deciding what paperwork that staff bring with them and if it needs to be in different languages? It needs to be specific to the vaccine you are administering.

Vaccine Administration – A Series of Actions You Need to Consider in Estimating Time in Home:

- 1. Assessing patient vaccination status and screening for contraindications and precautions, use the CDC pre-vaccination checklist -even for the second dose,
 - a. Observation of at least 15 minutes up to 30 minutes for persons with a history of an immediate allergic reaction (within 4 hours) of any severity to a vaccine or injectable therapy, and persons with a history of anaphylaxis due to any cause.
 - b. CDC recommends vaccination providers have at least 3 doses of epinephrine on hand.
- 2. Educating patients and caregivers,
- 3. Preparing and administering vaccines, and
- 4. Documenting the person's consent to receive the vaccine and the administration in your medical record within 24 hours of administration and reporting data to the relevant system (i.e., immunization information system) no later than 72 hours after administration.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html Feb 11, 2021

Information About COVID 19 Vaccines for Staff and for Patients:

CHAP COVID 19 Conference Calls April 15, 2021



COVID 19 – Authorized Vaccinations and Age Groups – Note Pfizer approval for 16 and older.

Under the FDA EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years
- Johnson and Johnson Janssen: age > 18 y

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

The U.S. vaccine approval system ensures that vaccines are as safe as possible. Each vaccine must demonstrate that the benefits outweigh the risks. Find out more about how vaccine safety is ensured at: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html</u> Feb 15 2021

CDC has developed <u>v-safe</u>, to increase the ability to rapidly detect safety issues with COVID-19 vaccines. V-safe is a smartphone-based, after-vaccination health checker for people who receive COVID19 vaccines. When you receive your vaccination, you find out how to register and you can report symptoms and be reminded of your next dose.



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html Dec 10, 2020

Time Between mRNA Vaccine Doses -Pfizer establishes how early 2nd Dose May Be Given

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 ml each): 3 weeks (21 days) apart
 - The second dose no more than 4 days earlier or 17 days after the first dose
- Moderna (100 μg, 0.5 ml): 1 month (28 days) apart
 - No specific recommendation for earlier dates

<u>CDC's updated guidance allows for second dose administration up to 6 weeks (42 days) after the first *if it is not feasible* to adhere to the recommended interval. CDC is not advocating for delaying the second dose, but the data from clinical trials support this range if access is an issue. <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u> Jan 21 2021</u>

mRNA Vaccine Second Dose If the Brand of the 1st mRNA Dose is Not Known

If the brand/product of the first dose of vaccine cannot be determined <u>or is no longer available</u>, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.



mRNA-COVID 19 Vaccination if the Person has had prior COVID-19 Infection.

Clinical trial data indicate that mRNA COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection. <u>This includes those with symptomatic or asymptomatic COVID infection</u> <u>before the any vaccination or after the first dose</u>. CDC recommends that vaccination be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

Important Medication Error Definitions and Action to Take for mRNA Vaccines:

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html Feb 10, 2021

April 15: What to Expect If You Receive the mRNA Vaccines (Pfizer, Moderna): You should receive a vaccination card or printout that says which COVID-19 vaccine you received, the date you received it, and where you received it. Also, each COVID-19 vaccine has its own fact sheet with information about side effects, and when your second shot is needed. You should receive this on paper or electronically when you receive you first shot.

April 15: Common Side Effects: Side effects are normal signs that your body is building protection and responding to the vaccine. These side effects should go away in a few days. Note that side effects most often occur the first day after the second mRNA dose. "Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines" Johanna Chapin-Bardales, PhD, MPH1; Julianne Gee, MPH1; Tanya Myers, PhD, MSc1 JAMA April 5, 2021 doi:10.1001/jama.2021.5374

Any Systemic Reactions	Pfizer BioNTech (64%)	Moderna (75%)
Fatigue	48%	60%
Headache	40%	53%
Myalgia	37%	51%
Chills	23%	40%
Fever	21%	37%
Joint Pain	20%	31%
Nausea	13%	20%
Vomiting	1%	2%
Diarrhea	6%	8%
Abdominal Pain	5%	7%



• **Important: Masking and Social Distancing Continues even after Vaccination** until more of the population is vaccinated. No current vaccine is 100% effective.

VAERS Side Effect Report from first 13.8M mRNA vaccinations:

March 25: Update Vaccine Side Effects (Note only mRNA vaccine information): Anaphylaxis after COVID-19 vaccination is **rare** and occurred in approximately 2 to 5 people per million vaccinated in the United States based on events reported to VAERS. This kind of allergic reaction almost always occurs within 30 minutes after vaccination. <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-</u> <u>events.html_</u>March 22, **2021**

- 91% of events reported to VAERS are non-serious: Most common headache (22.4%), fatigue (16.5%), and dizziness (16.5%).
- \circ $\;$ After the second dose, reactions more often reported for Pfizer vaccine.
- Expect transient local and systemic reactions. Injection site reactions may be 1-2 days.
- Note data includes a high proportion of LTCF residents as the first to be vaccinated.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm?s_cid=mm7008e3_w_February 19, 2021

Allergic Reactions to Vaccine

Severe Allergic Reaction - Anaphylaxis -after getting a COVID-19 vaccine.

- A severe allergic reaction results in an individual's needs to be treated with epinephrine or an EpiPen[©] or hospitalization.
- If an individual reports a severe allergic reaction to any ingredient in an mRNA COVID-19 vaccine,
 - they should not receive either of the currently available mRNA COVID-19 vaccines -do not try the other brand if a reaction has occurred to a mRNA COVID-19 vaccine.
 - <u>CDC recommends</u> that the individual should not get the second dose.

Immediate Allergic Reaction: to a COVID-19 vaccine

- Important definition: *immediate allergic reaction*: Within 4 hours of being vaccinated such as hives, swelling, and wheezing (respiratory distress).
- Anyone who has an immediate allergic reaction—even if it was not severe—to any ingredient in an mRNA COVID-19 vaccine, **the** CDC recommends that they should not get either of the currently available mRNA COVID-19 vaccines.
- An individual who had an immediate allergic reaction after the first dose of an mRNA COVID-19 vaccine, should not get the second dose. Their doctor may refer them to a specialist in allergies and immunology to provide more care or advice.

COVID 19 and Allergic Reactions to Other Types of Vaccines

If an individual has had an immediate allergic reaction—even if it was not severe—to a vaccine or injectable therapy for another disease, they should ask their doctor before getting a COVID-19 vaccine.

COVID 19 Vaccine and Allergies Not Related to Vaccines



- CDC recommends that people with a history of severe allergic reactions *not* related to vaccines or injectable medications—such as food, pet, venom, environmental, or latex allergies—get vaccinated.
- People with a history of allergies to oral medications or a family history of severe allergic reactions can also get vaccinated.

COVID 19 and previous allergic reaction to polyethylene glycol (PEG) or polysorbate

Polysorbate is not an ingredient in either mRNA COVID-19 vaccine but is closely related to PEG, which is in the vaccines. **People who are allergic to PEG or polysorbate should not get an mRNA COVID-19 vaccine.** <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html</u> Jan 22, 2021

mRNA Vaccines: Pfizer and Moderna

Pfizer and Moderna Vaccines use new technology: both are mRNA vaccines:

- Most vaccines use weakened or inactive parts of a virus to stimulate the body's immune response to create antibodies and kill the virus.
- The Pfizer and Moderna vaccines do not contain a live virus, and do not have the risk of causing the disease. These vaccines use what is called mRNA that triggers the process in our cells to build immunity to the virus that causes COVID-19. This approach has been studied for over a decade.

https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html November 24, 2020

Simple Presentation of How mRNA Vaccines Work:

- mRNA vaccines cannot give someone COVID-19 and do not use live virus.
- mRNA vaccines do not affect or interact with our DNA in any way.
 - o mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept.
 - \circ $\;$ The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-

vaccines/mRNA.html?ACSTrackingID=USCDC_2067-

DM47392&ACSTrackingLabel=Understanding%20mRNA%20COVID-19%20Vaccines%20%7C%20COVID-19&deliveryName=USCDC_2067-DM47392 Dec 18, 2020

Johnson & Johnson Janssen COVID 19 vaccine is a viral vector vaccine:

- Viral vector vaccines use a modified version of a different virus (the vector) to deliver instructions to our cells. For COVID-19 viral vector vaccines, the vector (**not** the virus that causes COVID-19, but a different, harmless virus) enters a cell in the body and then use the cell's machinery to produce **a harmless** piece of the virus that causes COVID-19 called a spike protein that is only found on the surface of the virus that causes COVID-19.
- The cell displays the spike protein on its surface, and our immune system recognizes it doesn't belong there. This triggers our immune system to begin producing antibodies and activating other immune cells to fight off what it thinks is an infection. As a result, our bodies protect us against future infection with the virus that causes COVID-19.
- Viral vectors cannot cause infection with COVID-19 or with the virus used as the vaccine vector.



- The genetic material delivered by the viral vector vaccine does not integrate into or affect a person's DNA.
- The J&J vaccine is 85% effective in preventing severe disease across all regions in the clinical trials and showed protection against COVID-19 related hospitalization and death, <u>beginning 28 days after</u> <u>vaccination</u>.
- Side effects of vaccination from the clinical trials: injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. Severe allergic reactions have occurred in clinical trials.

<u>https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf</u> (Fact sheet for healthcare providers administering Janssen COVID 19 Vaccine)

April 15: J&J Vaccination Pause -

<u>What Happened:</u> The use of the J&J COVID 19 vaccination has been paused by the CDC and the FDA in response to 6 reported cases of a severe and rare blood clot in women ages 18 to 48. Each woman reported symptoms 6 to 13 days after receiving the J&J vaccination, median 8 days. Over 7.2 million doses of J&J vaccine have been given nationwide.

<u>What Does a Pause Mean</u>: The CDC and FDA have stopped the use of the vaccine or "paused" it being used to give scientists a chance to review the data and decide if recommendations on who should get the vaccine need to change. They do not know enough yet to say if the vaccine is related to or causes this blood clot.

<u>What Should You Do if You Received a J&J Vaccination</u> seek medical care right away if you develop any of the following symptoms:

- severe headache (most common)
- backache,
- new neurologic symptoms (e.g. dizziness, slurred speech)
- severe abdominal pain,
- shortness of breath,
- leg swelling,
- tiny red spots on the skin (petechiae), or
- new or easy bruising

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html April 14

No reported CVST with thrombocytopenia in over 180M mRNA vaccinations administered through Apr 2021

Co-Vaccination

The COVID-19 vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. If benefits of co-administration outweigh the Potential unknown risks of vaccine coadministration (e.g., tetanus), the interval could be shorter period. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

TB testing and mRNA COVID-19 vaccination:



Not enough is yet known about the potential impact of mRNA vaccines on immune responses to know if the COVID-19 mRNA vaccine has a potential effect on TST or IGRA test results during the first 4 weeks after COVID-19 vaccination.

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry to facilities) at the same time they are to receive a COVID-19 mRNA vaccine, CDC recommends:

- Perform TB symptom screening on all healthcare personnel or patients.
- If using IGRA, draw blood prior to COVID-19 mRNA vaccination.
- If using TST, place prior to COVID-19 mRNA vaccination.
- If COVID-19 mRNA vaccination has already occurred, defer TST or IGRA until 4 weeks after completion of 2-dose COVID-19 mRNA vaccination.

https://www.cdc.gov/tb/publications/letters/covid19mrna.html#:~:text=For%20healthcare%20personnel%20or%20patients,to%20COV ID%2D19%20mRNA%20vaccination

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Waivers:

Types of 1135 waivers are issued during the Public Health Emergency (PHE). All waivers are effective March 1, 2020 and end effective when the federal Public Health Emergency ends.

- **Federal Blanket Waivers**: Publicly announced by CMS and applicable to all providers by Medicare benefit type. Examples include the home health and hospice waivers.
- State Medicaid waivers: States may request waivers of Medicaid regulations by contacting CMS. Over 48 states have requested waivers. To the following website, find your state, click on what is a letter to the state, scroll past the letter and you will find the details of the waiver. <u>https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federaldisasterresources/entry</u>

Please continue to join CHAP on our Weekly COVID 19 Conference Calls in 2021:

Thursdays 3 -4:00 PM ESDT Call in: 646-307-1479, or toll-free 877-304-9269 • Participant code: 246854#

Thank you for your dedication and be well!