

# DoD COVID-19 PRACTICE MANAGEMENT GUIDE

Clinical Management of COVID-19

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*This Practice Management Guide does not supersede DoD Policy.*

*It is based upon the best information available at the time of publication. It is designed to provide information and assist decision making. It is not intended to define a standard of care and should not be construed as one. Neither should it be interpreted as prescribing an exclusive course of management. It was developed by experts in this field. Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of this guideline is responsible for evaluating the appropriateness of applying it in the setting of any particular clinical situation. The Practice Management Guide is not intended to represent TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within this guide does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at [www.tricare.mil](http://www.tricare.mil) or by contacting your regional TRICARE Managed Care Support Contractor. No federal endorsement is intended with respect to any references to non-federal documents, links, or other materials.*

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## **DoD COVID-19 Practice Management Guide v.8 Summary of Changes**

**Updated throughout with new literature, studies, and society guidelines across disciplines**

**Major Updates and Changes listed by Section (only sections listed have major changes):**

**Background & Epidemiology, Clinical Presentation:** Added and updated information on epidemiology, transmission risk, reinfection, mortality and hospitalization rates, including information on vaccinations, MIS-C, and the Omicron variant.

**Planning & Preparation:** Added new figures from references related to managing adult or pediatric ICU surges using pediatric or adult intensivists and nurses, respectively.

**Infection Prevention & Control:** Updated PPE to reflect current requirements to include the OSHA ETS OSHA Emergency Temporary Standard and removal of EUA reuse of N95

**Laboratory Diagnosis:** Significant updates to this section, including utilization of rapid testing. Currently available rapid antigen tests continue to be able to detect Omicron variant infection when used in the clinical setting. However, as newer variants emerge, the US FDA will continue to update their website with guidance on accuracy of rapid testing.

**Outpatient Management:** Updated treatment options and recommendations including new section on antivirals (nirmatrelvir/ritonavir, remdesivir, molnupiravir). Updated monoclonal antibodies section to include information on newer agents and on use in pre-exposure and post-exposure prophylaxis.

**Management of Critical COVID-19: Oxygen and ARDS:** Added algorithm for ARDS, including ECMO.

**Prevention of Complications:** Updated entire section, including figure and Appendix K related to Cardiopulmonary Return to Exercise and Physical Activity Recommendations. New figures and tables related to myocarditis and pericarditis after vaccination.

**Septic Shock & Cardiac Arrest:** Included updated guidelines and algorithms in Appendix O.

**Imaging of COVID-19:** Updates regarding lymphadenopathy on cross-sectional and breast imaging following vaccination. Recommendations regarding scheduling of imaging exams around vaccination as well as reporting and follow-up recommendations for incidentally discovered new lymphadenopathy.

**Therapeutic Management & Adjunctive Therapies:** Updated entire section, including updating the IDSA Treatment Guidelines in Appendix P.

**Longterm Implications of COVID-19:** New section added about post-COVID conditions.

**Special Populations:** Updated all sections, including epidemiology and recommendations for pregnant people, neonates, and children (including MIS-C)..

**Surgical & Invasive Procedures:** Minimal updates, except for updates to recommended timing of elective surgery in Appendix S.


**Operational Considerations:** Updates to recommendations.

**Behavioral Health:** Updated known information about how patients with a Behavioral Health diagnosis are affected by COVID-19 and treatment recommendations.

**Emergency Medical Services:** Small updates.

**Vaccinations to Prevent COVID-19:** New chapter added to reflect the current vaccines approved or authorized for use of prevention of COVID-19 in the United States.

**DoD COVID-19 Vaccine Implementation:** Changed the title of the chapter to reflect the implementation plan for vaccination within the DoD. Updated content to reflect current vaccine requirements for Uniformed Service Members, federal employees and federal contractors.

DoD COVID-19 PRACTICE MANAGEMENT GUIDE		
	<b>Clinical Management of COVID-19</b> To consolidate resources and optimize the management for patients requiring clinical care during the global COVID-19 pandemic.	
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## BACKGROUND

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Coronavirus disease 2019 (COVID-19) is a respiratory illness caused by a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 was first described in Wuhan, China in December 2019 and remains a global pandemic with 300 million confirmed cases and nearly 5.5 million deaths reported worldwide. In the United States, the number of deaths has exceeded 832,000 and surpassed that of deaths attributed to the 1918 H1N1 influenza pandemic. Most (80%) of those affected have milder illness, 15% will be severely ill (most often some degree of hypoxemic respiratory failure), and 5% will require critical care interventions, e.g., mechanical ventilation.(14, 15) Of those who are critically ill, most require mechanical ventilation. Other complications include septic shock and multi-organ failure, including acute kidney injury and cardiac injury, in the setting of an inflammatory and pro-thrombotic state.(16) Older age and certain comorbid conditions, including hypertension, diabetes, coronary artery disease, and chronic lung disease increase the risk of death.(17-19) The virus is highly contagious and spread via respiratory droplets, direct contact, and if aerosolized, airborne routes. As of March 2021, three vaccines to reduce the risk of SARS-CoV-2 infection have been authorized for emergency use in the United States. As of August 2021, one vaccine (COMIRNATY) has received full FDA approval for individuals  $\geq 16$  years of age.

The intent of this publication is to provide clinicians and military medical treatment facilities (MTFs) with leading practices based on the latest evidence to optimize the DoD's response to the current COVID-19 pandemic. Current knowledge about SARS-CoV-2 transmission, detection, treatment and long-term effects continues to rapidly evolve. Accordingly, the information in this document may or may not be correct based on current surveillance and science, but was included as it reflects the most up-to-date material at the time of inclusion.

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## EPIDEMIOLOGY, CLINICAL PRESENTATION & CLINICAL COURSE

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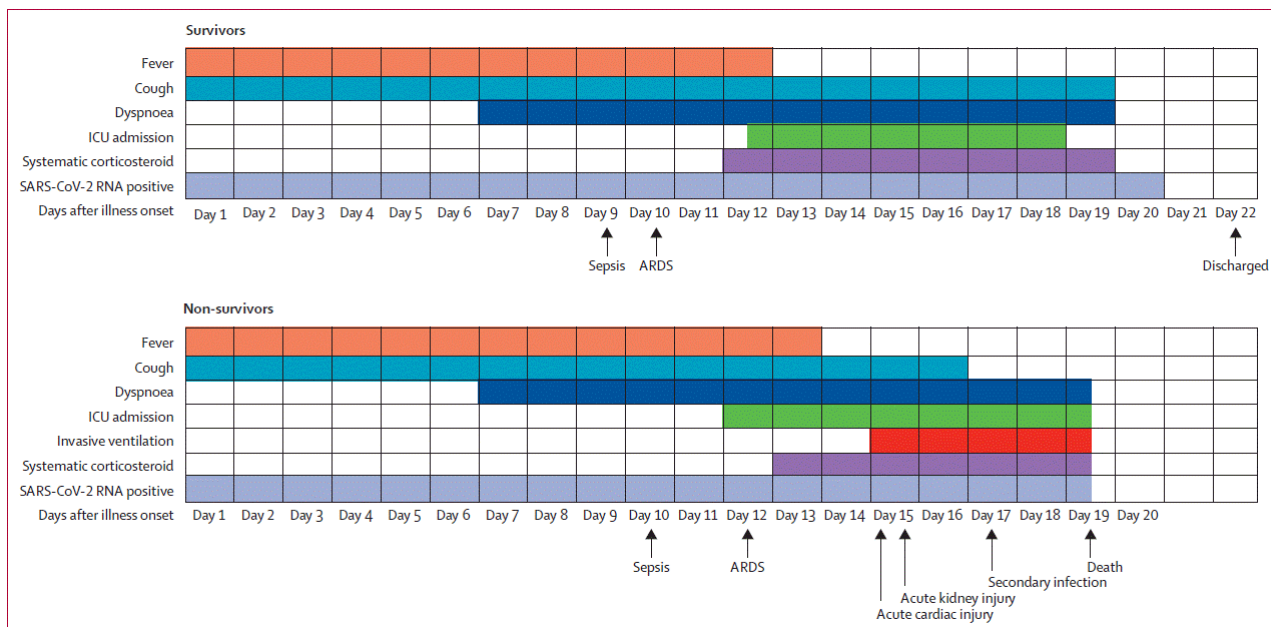
1. **Epidemiology:** According to the Centers for Disease Control and Prevention (CDC), the estimated burden of COVID-19 is significantly higher than the reported infections and deaths. Based on data and estimates for the US burden from February 2020 to September 2021: 1 in 4.0 (95% Uncertainty Interval [UI] 3.4-4.7) infections were reported; and 1 in 1.32 (95% UI 1.29-1.34) deaths were reported.(20, 21) According to these estimations, the calculated and likely actual infections and deaths that occurred from February 2020 to September 2021 are 146.6 million and 921,000, respectively. While approximately half (51%) of infections occurred in persons aged 18-49 years, over three-fourths (76%) of the deaths were among those aged 65 years and older. Applying the same ratios to reported infections (57.2 million) and deaths (827,879) per CDC's data as of January 6, 2022, the estimated number of actual infections and deaths that have likely occurred in the United States are 229 million and 1.1 million, respectively.
2. The largest single report of cases in the United States was published in a Morbidity and Mortality Weekly Report (MMWR) for data from 1,761,503 aggregate cases, of which 1,320,488 cases were analyzed. The median age was 48 years; incidence 403.6 cases per 100,000 population, highest among those aged  $\geq 80$  years (902.0) and lowest in children aged  $\leq 9$  years (51.1). For the 599,636 (45%) cases where information on both race and ethnicity were available, 33% were Hispanic (18% of the US population), 22% were black (13% of the US population), 4% were Asian, 1.3% were AI/AN (0.7% of the US population), <1% were non-Hispanic Native Hawaiian or other Pacific Islander, and 36% were white. The percent affected in the Hispanic, Black and AI/AN populations relative to their representation in the general population suggests they are disproportionately affected by the current pandemic.(22) Details on pediatric cases and ethnicity/race are included in Section 11 below. All estimates underestimate the true prevalence and burden of disease since the above only reflect reported cases and not those who were positive/infected, but not tested.
3. **Incubation period:** Approximately 4-5 days for previous dominant strains; more recent and early data from the Omicron variant (B.1.1.529) has suggested a shorter median incubation period of 3 days.(23-26) Some studies have estimated a wider range for the incubation period, up to 14 days. Data for human infection with other coronaviruses (e.g. MERS-CoV, SARS-CoV) suggest that the incubation period may range from 2-

14 days; a study of 181 COVID-19 patients supported these initial estimates and found that 97.5% of symptomatic patients develop symptoms within 11.5 days of infection, while a subsequent study of 1,084 COVID-19 patients suggested a longer incubation period – median of 7.76 days and up to an estimated 5-10% with incubation periods  $\geq 14$  days. A recent systematic review and meta-analysis reported a mean incubation period of 5.6-6.7 days, with the 95th percentile of 12.5 days when the mean age of patients was 60 years, increasing 1 day for every 10 years of age.(25, 27, 28) Additionally, the CDC reported that, of 616,541 infected persons for whom symptom status was reported, 22,007 (4%) were asymptomatic.(22)

4. **Transmission risk and infectiousness:** As reflected in CDC's guidance on quarantine and isolation, data on transmission risk suggest that risk is affected by multiple factors including type of exposure (e.g., close and within 6 ft, direct contact with respiratory secretions), duration of exposure (e.g., greater than 15 minutes), use of preventive measures (e.g., masks including type), and other factors (e.g., viral load, immunocompromised). Although the exact time period of infectiousness has yet to be firmly established, studies reflect that transmission occurs even when infected persons do not manifest symptoms, either before they become symptomatic or as they remain asymptomatic. Still, the period of greatest infectiousness appears to be around the time of symptom onset, approximately 1-2 days before through 1 day after, and with transmission unlikely after 7 to 10 days for previous dominant strains and shorter for Omicron. A study of 100 Taiwanese COVID-19 laboratory-confirmed cases and their 2761 close contacts found highest transmission rates when exposure to index cases occurred within 5 days of symptom onset vs. later (attack rate 1.0% vs 0%, respectively). Also reported were the attack rates for those with exposure exclusively during the presymptomatic period (0.7%) and among household (4.6%) and non-household (5.3%) family contacts.(29) A decision analytical model by the CDC estimates that transmission from asymptomatic individuals accounts for more than half (59%) of all transmissions.(30)
5. **Prolonged detection of SARS-CoV-2 RNA:** has been reported and appears to be related to severity of illness; in respiratory specimens (up to 6 weeks) and stool specimens (>30 days), and, though not clearly or significantly associated with or implicated in active and ongoing transmission, data continue to evolve. In a systematic review evaluating potential for fecal-oral transmission, across 91 studies, 51.8% (weighted pooled) of stool samples or anal swabs from COVID-19 patients tested positive for viral RNA; and 49/54 (91%) studies with serial SARS-CoV-2 RNA test results for both respiratory and GI specimens reported persistently positive GI specimens after respiratory specimens had become negative. However, only five studies (17 patients) evaluated for presence of viable virus, with live active virus found in 6 patients. (31-34)
6. **Reinfection:** has been reported, though risk of reinfection within the 6-7 months immediately after infection appears to be low (<1% for previous dominant strains; early data on Omicron suggests lower protection from infection with other strains and therefore higher risk for and rates of "reinfection" with SARS-CoV-2); additionally, older age appears to be associated with higher risk for reinfection.(35, 36)
7. **Variants:** Mutations in the viral genome can result in lower or ineffectiveness of vaccines and/or treatments such as monoclonal antibodies as well as limited protection from reinfection after primary infection with wild-type virus. Although in the late summer and fall of 2021, the Delta variant (B.1.617.2) was the predominant strain in the United States, with 99% of sequenced specimens being identified as Delta. In December 2021, there was a shift such that as of January 1, 2022, the Omicron variant (B.1.1.529) represents 95% of the sequenced specimens (<https://covid.cdc.gov/covid-data-tracker/>).. Other variants that are either no longer detected or are circulating at very low levels in the United States include: Alpha (B.1.1.7), first detected in the United Kingdom; Beta (B.1.351), first detected in South Africa; Gamma (P.1), first detected in Japan/Brazil; Iota (B.1.526), first detected in the United States-New York; Eta (B.1.525), first detected in the United Kingdom/Nigeria; Kappa (B.1.617.1) and B.1.617.3, first detected in India. These variants have mutations that alter the receptor binding domain of the spike protein and have variable impact on vaccine effectiveness (notably the E484K/Q mutation in Beta, Gamma, Eta, Iota, Kappa, and B.1.617.3; the N501Y mutation occurring in Alpha, Beta, and Gamma; the E417T/N mutations in Beta and Gamma; and the L452R mutation in Delta, Kappa and B.1.617.3).(37)
8. **Symptoms:** Frequently reported **symptoms** of patients admitted to the hospital: .
  - Fever (77–99%)

- Cough (46%–82%)
- Myalgia or fatigue (11–70%)
- Shortness of breath (SOB) or dyspnea (3-31%)
- GI symptoms, e.g., anorexia, diarrhea, nausea (pooled prevalence 17.6% in meta-analysis of 60 studies, may precede respiratory symptoms)
- Anosmia/hyposmia or ageusia/dysgeusia (8-87%) Common symptoms of Omicron variant also include rhinorrhea/ nasal congestion, sore throat, headache, and sneezing

Although fever is ultimately reported in the majority of patients during the course of illness, a lower proportion (20-44%) of patients are febrile on presentation. Among 1,099 hospitalized COVID-19 patients in China, fever was present in 44% at hospital admission, though developed in 89% during hospitalization.(24) In older patients, atypical presentations such as reports of falls or decline in mental status or cognition have been reported. Figure 1 illustrates a timeline of the clinical course of major symptoms. **Dermatologic findings** including maculopapular, urticarial and vesicular lesions (“COVID toes”) and livedo reticularis have



**Figure 1. Clinical Courses of Major Symptoms and Outcomes and Duration of Viral Shedding [from Zhou, et al.; Lancet (2020)].**(1) Figure shows median duration of symptoms and onset of complications and outcomes. ICU, intensive care unit; ARDS, acute respiratory distress syndrome.

been reported in association with illness, although a clear association has not yet been established.

- Risk for adverse outcomes:** Factors associated with increased adverse outcomes include advanced age, certain comorbidities (e.g., cardiovascular disease, diabetes, hypertension, chronic lung and/or kidney disease, obesity, cancer and immune system disorders), male gender, certain ethnicities (e.g., Black, Hispanic and South Asian descent), and specific laboratory abnormalities such as those associated with thrombotic and inflammatory dysregulation.(38) In patients with underlying conditions, hospitalizations were six times higher (45.4%), and deaths were 12 times higher (19.5%) than in those without underlying conditions (7.6% and 1.6%, respectively). Independent of other comorbid risk factors, obesity appears to place individuals at significantly higher risk for infection (OR = 1.46) and adverse outcomes including hospitalization (OR = 2.13), ICU admission (OR = 1.74) and mortality (OR = 1.48). One study proposed an underlying mechanism by which SARS-CoV-2 directly facilitates infection and a pathogenic inflammatory response in adipose tissue.(17, 22, 39-41)
- Pregnant women:** Pregnant women are at increased risk for severe illness, including hospitalization, ICU admission, mechanical ventilation, extracorporeal support, and death. Studies from the United States also suggest that pregnant women may be at higher risk of atypical presentation with severe disease and caesarean delivery. Women who develop pneumonia appear to have increased risk of preterm labor. Additionally, more recent analysis reflected a significantly increased risk for stillbirth to mothers with

documented COVID-19 at delivery (adjusted relative risk 1.90; 1.26% occurrence among deliveries to women with COVID-19 vs 0.64% without COVID-19).(42-48)

11. **Children:** Information continues to evolve and become available on the clinical presentation, clinical course, and risk factors for severe COVID-19 in children with approximately 5-6% presenting with severe illness. Although at this time, it appears that severe illness due to COVID-19 is uncommon among children, more data is needed, especially related to new variants and longer-term impacts of the pandemic on children, including long-term physical and emotional health effects. Since the onset of the pandemic, children represent 17.4% of total cumulated cases tracked by 49 states, New York City, the District of Columbia, Puerto Rico, and Guam. Nearly 7.9 million children have tested positive for COVID-19, representing over 1 in 10 US children. However, this case count is rapidly increasing with the week ending December 30, 2021 totaling over 325,000 child COVID-19 cases reported (a 64% increase over the previous week). Additionally, children (under age 18) made up 17.7% of the week's reported cases, while they make up 22.2% of the US population. Pediatric hospitalizations range from 1.7-4.1% of the total cumulative hospitalizations in the 24 states reporting data, with mortality remaining rare.(49) A systematic review of cases earlier in the pandemic reported a weighted mean age of 7.6 years, mostly mild disease (42.5%) with 2% ICU admissions and most commonly described symptoms of fever (51.6%) and cough (47.3%).(50) Along with the typical symptoms described, emesis and diarrhea appear to be prominent with the virus found in stool samples suggesting fecal-oral transmission. Critically ill children have presented with ARDS, septic shock, encephalopathy and myocarditis. Co-infections with other respiratory viruses or bacteria are common. A previous MMWR study reported that hospitalized children were more commonly <1 year and had underlying conditions, e.g., asthma. A MMWR publication analyzed data on 2,871,828 laboratory-confirmed cases of COVID-19 in children, adolescents and young adults aged 0-24 years in the US from March 1-December 12, 2020. Less than half (1,222,023 or 42.6%) of those cases were reported among those under 18 years old (16.3% in 14-17 years, 7.9% in 11-13 years, 10.9% in 5-10 years and 7.4% in 0-4 years). Cases were equally (50%) distributed across the sexes. Median age was reported to be 9 years.(51)
12. **Diabetes screening in children and adolescents:** Recent MMWR reported data suggest an increased risk (166% (IQVIA data), 31% (HealthVerity data)) for diabetes among children and adolescents with COVID; non-SARS-CoV-2 respiratory infection was not associated with diabetes. The exact mechanism is still unclear though the observed association may be attributed to effects of SARS-CoV-2 infection on organ systems; e.g., through direct attack of pancreatic cells expressing angiotensin converting enzyme 2 receptors, through stress hyperglycemia resulting from the "cytokine storm" and alterations in glucose metabolism. These findings are consistent with observations in adults.(52)
13. **Health disparities in children:** Although the proportion of cases among Hispanic persons decreased with increasing age, Hispanic children still comprised almost one-third (31%) of all persons aged under 18 years and over one-third (34.4%) of children aged under 5 years. The same trend of decreasing proportion of cases with increasing age was observed in Black children and adolescents; overall 12.3% of the cases were in Black persons though as high as 14.6% in those aged 0-4 years. Asian/Pacific Islander persons comprised 3.3% of cases in those aged 0-17 years, and AI/AN comprised 2.0%. A previous MMWR on COVID-19 deaths in children reported >80% of the 121 deaths in persons aged <21 years occurred in Hispanic, Black and AI/AN persons though these minority groups comprise approximately 40% of the US population aged <21 years. According to the CDC's public dashboard, currently, over half of the deaths reported in children occurred in persons of ethnic minority descent (in those aged 0-4 years: 33.3% Hispanic, 17.5% Black, 1.6% AI/AN; in those aged 5-17 years: 25.3% Hispanic, 16.3% Black, 2.4% AI/AN, 2.4% Asian, 0.6% NH/Other Pacific Islander) indicating that minority children are disproportionately affected by the pandemic.(23, 31, 32, 51, 53-60)
14. **Clinical course in children:** Though these data are limited and were available for only 41.9% of hospitalizations, 8.9% of ICU admissions and 49.1% of deaths, reports on children and adolescents in the US reflect that most (97.7%) experienced mild disease and are not hospitalized, few (0.8%) required ICU admission and even fewer (<0.1%) died, compared with proportions of 16.6%, 8.6% and 5.0%, respectively, in adults aged ≥25 years. In the same report, data indicated that less than a third (30.3%) of children were reported to have at least one underlying condition compared with 60.4% among adults aged ≥25 years. This



is consistent with data suggesting the greatest risk factors for severe disease and poorer outcomes are increasing age and underlying comorbidities.(51) Although hospitalizations in children remain less common than in adults, the number of children admitted to hospitals who are infected with COVID-19 is rapidly rising. More than 4 in 100,000 children aged 4 years or younger admitted to hospitals as of January 1, 2022 were infected with COVID-19, which is roughly 3 times the rate a year prior. Meanwhile, hospitalizations among 5-11 year olds remains low and unchanged.(61)

15. **MIS-C in Children:** While most children experience mild disease, there are continued reports of a severe post-infectious hyperinflammatory condition termed multisystem inflammatory syndrome in children (MIS-C), a syndrome similar to Kawasaki Disease or toxic shock. MIS-C can occur 2–6 weeks (most occur by the fourth week) after mild or asymptomatic infection with SARS-CoV-2, and evolving data suggest vaccination is highly effective against development of MIS-C. A recent MMWR reported that mRNA COVID vaccination (Pfizer-BioNTech) is associated with lower MIS-C incidence among adolescents. Comparing 102 children with MIS-C (95% unvaccinated) and 181 controls, estimated effectiveness of 2 doses of the mRNA vaccine against MIS-C was 91% (95% CI = 78%–97%). All MIS-C patients requiring life support were unvaccinated. Median age was 14.5 years, and 58% had at least one underlying condition (including obesity). Of the 102 children with MIS-C, 91 (89%) had cardiovascular involvement, 84 (82%) had gastrointestinal involvement and 68 (67%) had hematologic involvement; 62 (61%) were admitted to the ICU; and 38 (37%) received life support during hospitalization (invasive mechanical ventilation, vasoactive infusions or ECMO); hospital length of stay was similar among vaccinated and unvaccinated MIS-C patients (median = 5 days); no deaths were reported.(62)
16. **Clinical Course of Severe COVID-19 in Adults:** Clinical presentation among cases of COVID-19 varies in severity from asymptomatic to fatal illness. Several reports suggest clinical deterioration can occur during the 2nd week of illness (range: 5 – 13 days). Acute hypoxemic respiratory failure developed in 17–29% of hospitalized patients. Mortality is high in those requiring mechanical ventilation and ranges from 48% in younger patients ≤40 years to 84% in older patients > 80 years.(63) Secondary infection developed in 10%, with a median time from symptom onset to of respiratory failure of 8 days. Approximately 20-30% of hospitalized patients with COVID-19 and pneumonia have required critical care. Compared to patients not admitted to an intensive care unit (ICU), critically ill patients were older (median age 66 years vs. 51 years), and were more likely to have underlying co-morbid conditions (72% vs 37%). Additionally, one study found that post-discharge (mean 110.9 days after hospitalization), individuals reported persistent symptoms of fatigue (55%), dyspnea (42%), memory loss (34%) and sleep disorders (30.8%); no statistically significant difference between those admitted to the ward vs ICU.(64) Among critically ill patients admitted to an ICU, 11–64% received high-flow oxygen therapy and 47-71% received mechanical ventilation. A small proportion (3-12% of ICU patients) were supported with extracorporeal membrane oxygenation (ECMO).(40, 65, 66)
17. **Extra-pulmonary:** Other reported complications include cardiac injury, sudden cardiac death, arrhythmia, pericarditis, septic shock, liver dysfunction, acute kidney injury, acute pancreatitis, venous and arterial thrombosis despite chemoprophylaxis, and multi-organ failure. Viral RNA has been isolated in non-lung tissue, including in skin, heart, colon, small intestine, liver, spleen, and brain tissue. COVID-19 is associated with a hypercoagulable state. A Dutch review of COVID-19 positive patients admitted to an ICU with pneumonia revealed 31% experienced a thrombotic complication with the majority of these being pulmonary emboli. Viral inclusion bodies have been seen in endothelium of kidneys, small bowel, and heart suggesting that endotheliopathy could be contributing to thrombotic complications. The prevalence of arterial thrombosis such as stroke is not as well described as the significantly increased risk of venous thromboembolism. A retrospective analysis of 4,389 patients evaluating for association of anticoagulation with mortality and intubation found that patients who received anticoagulation, either therapeutic (T) or prophylactic (P) dosing, had lower in-hospital mortality [adjusted hazard ratio, aHR 0.53 (T) and 0.50 (P)] and intubation [aHR 0.69 (T) and 0.72 (P)], though, of 26 autopsies, 11 (42%) had thromboembolic disease not clinically suspected and 3/11 (27%) were on therapeutic anticoagulation.
18. **Mucormycosis:** Increasing reports of COVID-associated mucormycosis (CAM) noted; in India (>40,000 cases reported); typically diagnosed approx. 2 weeks after COVID diagnosis; can occur following non-severe

COVID; data still evolving though risk factors and proposed mechanisms include diabetes, corticosteroid use and may be related to COVID-19–induced immune dysregulation and/or medical treatments. In recent MMWRs, cases in Arkansas increased from approx. 9 cases/year to 10 cases in <3 month investigation timeframe and coinciding with Delta variant surge; 57% male, median age 57 years; majority receiving steroids (86%), comorbidity of diabetes (76%); most (90%) unvaccinated; 67% died; similar data from cases in Honduras.(67-70)

19. **Hospitalizations:** In the US, as of 25 December 2021, the overall cumulative hospitalization rate is 794.6 per 100,000. Rates continue to reflect hospitalization associated with increased age, with highest rates in people ≥65 yr (2195 per 100,000) and 50-64 yr (1173 per 100,000), lowest in children 5-17 yr (61.9 per 100,000). Early (though limited) data on the Omicron variant suggest decreased proportion of hospitalized patients requiring oxygen therapy (17.6% vs 74%) and critical care (18.5% vs 29.9%).(71) However, the surge in cases in January 2022 has resulted in a new peak of 5.18 per 100,000 new admissions of patient with confirmed COVID-19 for the first week of January 2022, again overwhelming many inpatient healthcare facilities.(61)
20. **Mortality:** Case fatality rates (CFR) appear to vary by location and to be related to demographics, e.g., median age, of the population. In the early wave of the pandemic, high mortality rates among hospitalized patients was observed; e.g., in the UK, 26% died (32% of those requiring ICU level care).(72) Mortality rates have declined significantly since the wide availability of vaccines. A recent MMWR reported a higher CFR (9 vs. 2.5 deaths per 1000 infections) in pregnant patients, although of note, none of the pregnant women who died were fully vaccinated.(73) It is important to note that CFR only reflects the rate of mortality in diagnosed and reported cases, and therefore is highly dependent on the accuracy and completeness of testing and reporting, and would not include home testing results. Since the extent of testing and reporting can vary by country (e.g., some widely test inclusive of asymptomatic persons), caution is advised in comparing CFRs reported by and for different countries.
21. **Racial disparities:** Rates continue to reflect disproportionately affected populations, with highest rates in AI/AN (1615 per 100,000), Black (1152 per 100,000), and Hispanic/Latino (935 per 100,000) persons; and lowest in white (626 per 100,000) and Asian/Pacific Islander (385 per 100,000) persons. The rate of hospitalizations in A/PI is now lower than that of white persons.(61)
22. **Vaccines:** In December 2020, two mRNA vaccines were authorized to be administered in the US with one (Pfizer-BioNTech's COMIRNATY) receiving full FDA approval for individuals 16 years of age and older in August 2021, with subsequent authorization under EUA for children 5 years of age and older. A third vaccine, a replication-incompetent human adenovirus vector vaccine, was approved for emergency use in late February 2021. The US began vaccinating persons on December 14, 2020. As of January 7, 2022, over 516 million vaccine doses have been administered to over 246 million people (74.1% of the US population), with over 207 million people being fully vaccinated (62.4%), and 73.8 million people (35.6%) having received a booster dose.(61)

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## PLANNING AND PREPARATION

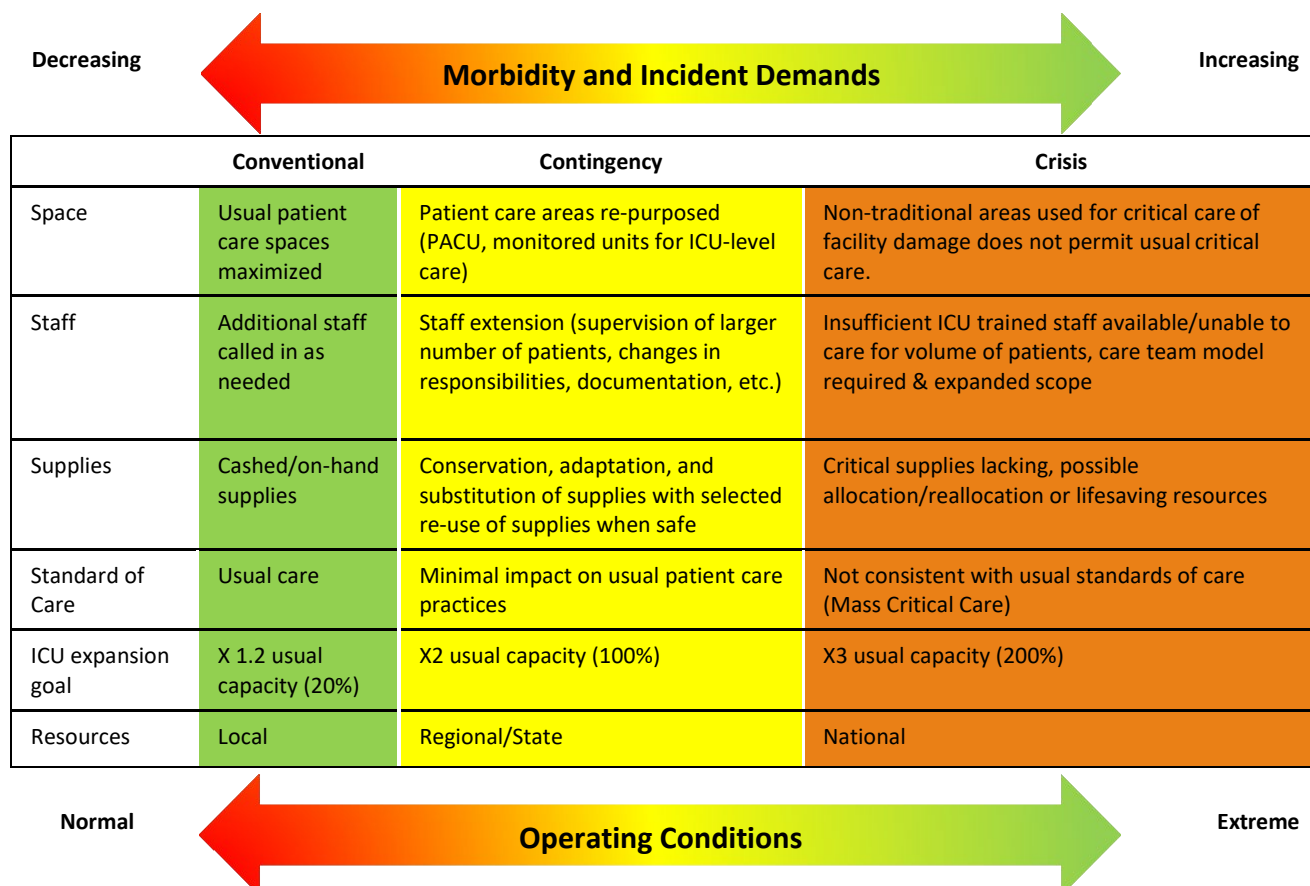
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### Facility Incident Command and Systems

1. A local emergency response command structure with clearly defined roles and lines of communication should be defined. These structures should have the ability to coordinate expansion or restriction of resources in conjunction with unit medical directors, help coordinate “just in time” training as well as regional expert consultation (i.e. tele-consultation with critical care, infectious disease, or other specialists), facilitate the flow of staff, critical equipment and patients, and coordinate Contingency and Crisis Standard of Care (CSC) changes on both a local and regional level. Additionally, the local Incident Command Center (ICC) should liaise and coordinate with the community if resource triage is needed depending on regional, not just local, healthcare utilization.
2. Establish and Manage Crisis/Contingency Standards of Care.
  - a. **Crisis Standards of Care (CSC)** are “a substantial change in usual healthcare operations and the level of

care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster.” This is the peak alteration in care starting at conventional (<120% typical capacity), moving to contingency (120-200% typical capacity), then Crisis (>200% typical capacity).

- b. The establishment of CSC should enable specific legal and regulatory protections for health care providers. For reference, DODI 6200.03 allows for establishment of a CSC within the DoD.
- c. Design and implementation of these standards for each agency should remain flexible based on each situation, should be tiered (i.e. normal operations, contingency, crisis) and have specific triggers to engage and de-escalate. In general Contingency when >120% typical capacity and Crisis when >200%.
- d. **Contingency Care** is more similar to typical care standards with most staff working in their usual environments but with expanded clinical responsibilities and carries only a mild increase in relative risk of mortality and morbidity over conventional care.
- e. CSC, if invoked, triggers significantly altered staffing models as described below with incumbent increased relative risk of morbidity and mortality above conventional care. The goal of CSC is to assist in resourcing for the best possible population outcomes recognizing it may impact individual outcomes. CSC should be developed by multi-disciplinary groups and collated by the Incident Command Center (ICC), individualized to a facility and consistent with the region. Topics that should be included:
  - i. Authority and triggers for enacting escalating from usual to Contingency then Crisis.
  - ii. “Just-in-time” training & scope of practice changes as CSC escalate (nursing, physician, etc.).
  - iii. Alterations in practice allowed (limiting documentation, changes in work hours and locations, changes in location of patient care and monitoring requirements).(5)
  - iv. Alterations from normal should be limited as much as possible to mitigate patient safety risks.
  - v. Process by which escalation through care phases is coordinated with regional facilities and balanced with national security needs.



**Figure 2.** A framework for critical surge capacity outlining the conventional, contingency, and crisis surge responses. PACU: post-anesthesia care unit. [adapted from Christian, et al.; Chest (2014) and Dichter, et al; Chest (2021)].(5, 74, 75)



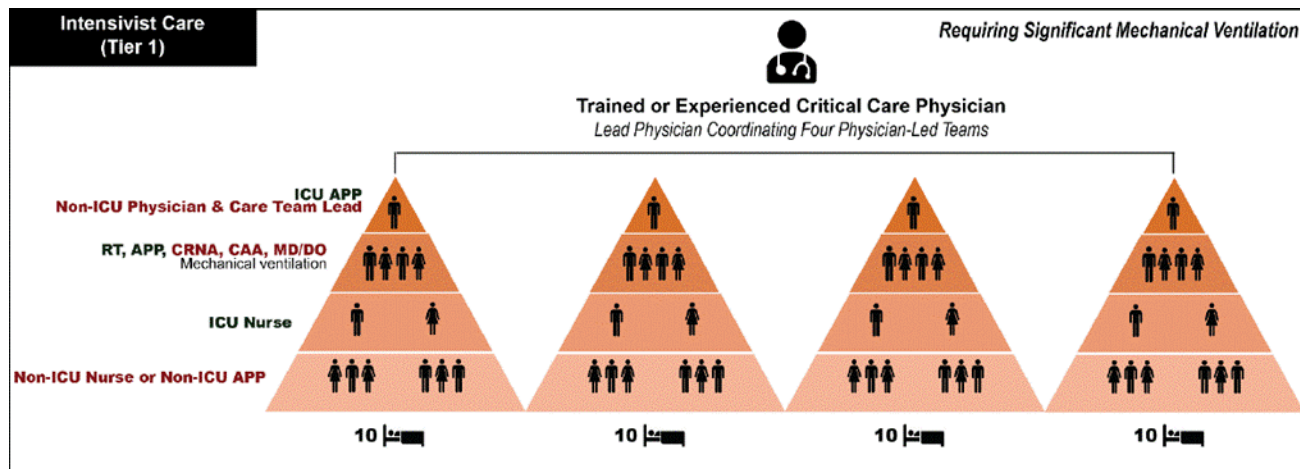
3. Establish clear lines of communication (LOC) to ensure:
  - a. The authority to trigger expansion of capabilities should be established. It is recommended that for the transition from conventional to contingency this be managed at the Unit/Service Medical Director level with rough framework provided by the ICC. Consider reserving Crisis Care transition decision to the authority of the ICC/Command as this carries significant additional risk and must be consistent with regional standards at the time of initiation.
  - b. The ability to communicate updated processes and protocols and rapidly respond to feedback from frontline health care workers.
  - c. The ability to transfer clinical information with patients through the system.
  - d. That communication be consistent, from designated sources, and information be trusted by staff.
4. Operationally define critical resources:
  - a. Definitions of critical resources should be standardized to ensure clear communications as the availability and level of risk associated with utilization of certain resources may change based on contingency vs crisis care with some examples below:
    - i. *Space*: XX Critical Care Beds (# of Beds in ICU spaces, with typical ICU equipment, with typical ICU staff but potentially altered care ratios) vs XX Crisis Critical Care Beds (# of maximally supported beds with non-ICU staff, staff or space, caring for ICU level patients).
    - ii. *Ventilators*: Consider classifying as “XX Conventional Ventilators” (i.e. # ventilators typically used in the intensive care unit) and “XX Crisis Ventilators” (i.e. # ventilators not typically used for critically ill patients but that would confer functionality in the setting of Crisis Care with additional morbidity and mortality risk).
    - iii. *Staff*: Consider dividing status into those available for conventional or contingency and those available for crisis care. Example: “XX Critical Care Nurses” (i.e., trained and experienced ICU nurses who typically work in an ICU environment) with “XX Crisis Critical Care Nursing augmentees” (i.e., RN, LPN, etc., who are able to assist in crisis with minimal training, but who will be practicing outside their usual environment).
5. Establish Patient Tracking and Re-unification systems: Plan and coordinate a system for patient tracking, identification, and the ability to communicate with next of kin who may be restricted from visitation.(76)
6. Establish security, access points, and “Hot zones” with access restricted for known COVID care:
  - a. Security should be included in the planning process given increased community stress and security risks during the COVID-19 pandemic.
  - b. Establish single or controlled points of entry for every facility and initiate screening procedures for possibly infected patients at entrances.(77)
7. Coordination of re-prioritization of clinical duties:
  - a. Focus on urgent care and readiness functions, but ensure a process for providing necessary routine care when unsafe to defer.
  - b. Depending on local epidemiology, care should be primarily virtual unless a face-to-face visit is necessary as determined by the care team.
  - c. Closely track access and demand and consider expanding or contracting services based on local epidemiology and need.
  - d. Coordinate re-allocation of assets off loaded by limitations to areas of need (Critical Care, Inpatient care, Initial triage, and Urgent/Emergency Care).(78)
  - e. Limit administrative, educational and academic duties to those needed to directly support patient care.
  - f. Frequently message patients and staff any changes in services, clinic hours, entry procedures, etc. to manage their expectations.
8. Develop recall roster for all assets (nursing, physician, housekeeping, dietary, security, admin, etc.) and triggers for re-calling those who may be needed from remote work.
9. Consider logistic/ancillary support needs when determining “Essential Personnel” for tasks including:
  - a. Disposal of personal protective equipment (PPE) and cleaning both “dirty” rooms and shared spaces. These tasks should be prioritized and will be in very high demand.(79)

- b. Allocation of adequate space for safe, respectful care of the deceased.(80)
- c. Designating locations and facilities to shelter and feed families of ill patients, staff members, and even families of staff members to augment and limit absenteeism (up to 40-50% or higher) that can be anticipated with illness, school/childcare closure, and fear.(77, 78)

### **Preparing Critical Care Resources & Teams**

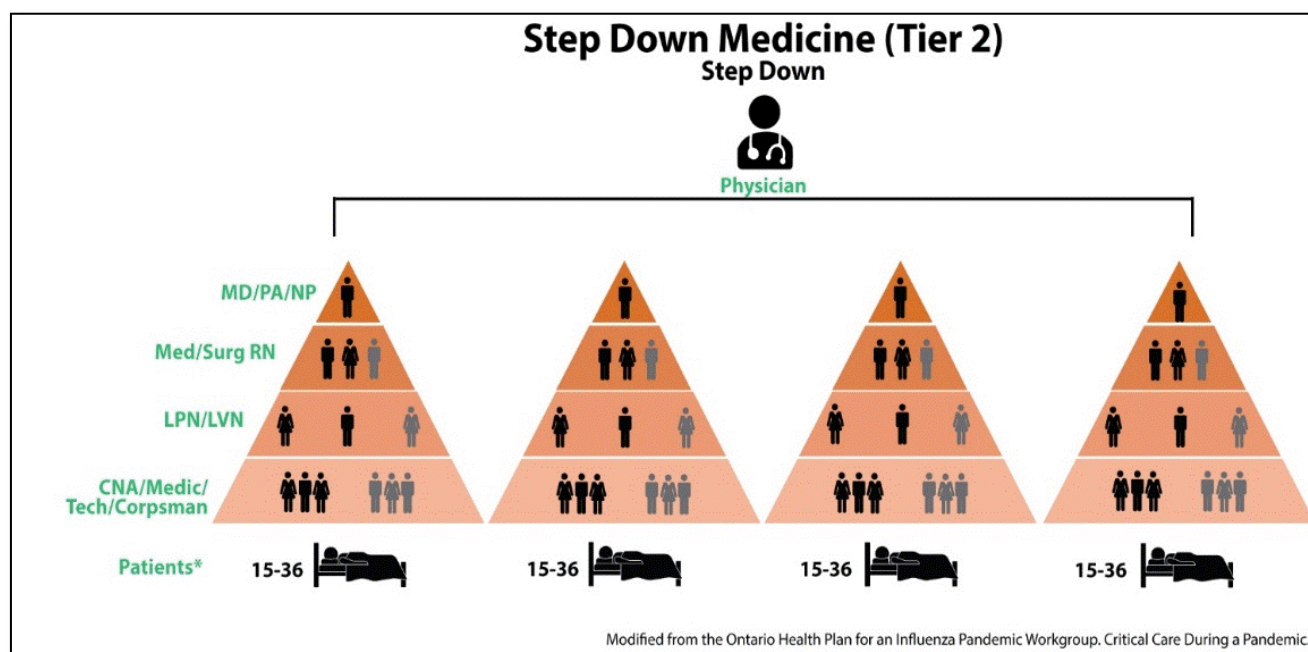
1. Understand the following steps provide a framework and are not the “correct” way to manage bed or staffing expansion. Exact staffing models, ratios, logistic and system support models should reflect the needs of the community and resources available at local centers. Transitioning to Crisis Care models carries with it significant increases in both morbidity and mortality above that seen in standard care models. It should be undertaken only when absolutely necessary, with careful consideration, and in an iterative way assessing for increased volume paradoxically leading to excessively increased morbidity and mortality. The American College of Chest Physicians recently published a preliminary consensus statement from their Committee on Emergency Mass Critical Care with 10 suggestions and operational strategies when dealing with surge care during the COVID-19 pandemic: 4 on staffing, 4 on load balancing, 1 on communication and 1 on use of technology.(5)
2. **Staffing:** In a global pandemic causing a surge of emergency room and admitted patients, additional staffing models should be considered. Although telehealth resources should be optimized, there may still be significant deficits in critical care trained healthcare workers.
  - a. Staff shortages:
    - i. Illness, fatigue, fear, and care giver duties, particularly with school/daycare closure, limit staff availability.
    - ii. Augmenting staffing initially with increased “mandated overtime” should be avoided as long as possible to avoid early staff burn out.
    - iii. Facility based alteration of staffing ratios (i.e. less provider staff in the inpatient setting overnight, moving to ratio-based rather than acuity-based nurse staffing) may help reduce staff burden while maintaining reasonable coverage in keeping with typical hospital processes.
    - iv. Strategies listed above may mitigate (facility based childcare, cohort care teams, etc.) but planning should consider at least a 25-40% reduction in staff availability. Additional recommendations to augment staff availability include:
      - A PPE officer (can be trained non-clinical staff) to train and monitor PPE and staff exposure on each ward
      - Mental health support or “resiliency teams” with focus on staff wellness and support
      - Team “Safety officers” to monitor/ensure breaks, hydration, toileting and nutrition
      - Procedural teams for intubation, central lines, proning, and other labor-intensive procedures.
    - v. **Critical care:** The Society of Critical Care Medicine (SCCM) recommends staffing models to support expanded critical care bed capacity in the event of a global pandemic, which includes use of multiple non-ICU trained healthcare workers. The CHEST statement offers as slightly different model based on increasing experience level allowing responsibility for more patients (from 12-24 patients/ICU Provider).(5) **Figure 3** provides a DHA-supported staffing model. At a minimum, the first four staff positions noted below should be ICU trained and experienced:
      - Critical Care Physician
      - Respiratory Therapist
      - Advanced Practice Providers (APP)
      - Critical Care Nurse (CCRN or experienced active RN working in critical care)
      - In facilities without intensivists, critical care teams may be directed by anesthesiologists, pulmonologists, hospitalists, or others with experience caring for critically ill patients.
      - Staffing for the other roles could include but are not limited to those with some previous critical care training or experience who currently work as:
        - Non-ICU physician: anesthesiologists, hospitalists, general surgeons or others with

- experience caring for critically ill patients
- CRNAs: May be utilized as advanced care providers because of their training, experience, and expertise in anesthesiology.(81)
- CAA, MD/DO: Residents from medical or surgical specialties (with appropriate supervision and graduated responsibility) or other medical or surgical staff preferably with experience in inpatient medicine
- Non-ICU nurse tiered from best to least suited:(82)
  1. RN currently working in progressive care units (telemetry or step down units)
  2. Ambulatory care setting with previous ICU experience (preferably within 3 years)
  3. Paramedics, EMTs or RNs and medical assistants/LPN that work in urgent care

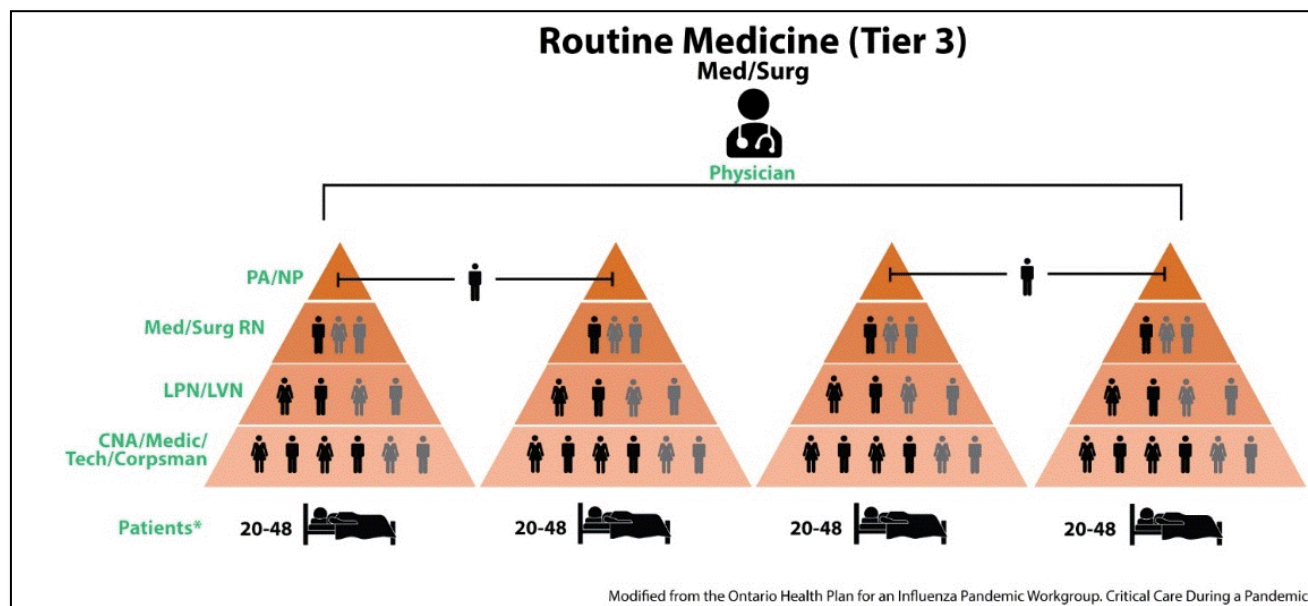


**Figure 3.** SCCM Tiered Critical Care Staffing Strategy for Pandemic. APP: advanced practice provider; RT: respiratory therapist; CRNA: certified registered nurse anesthetist; MD/DO: physician [modified from SCCM link above].(4)

- vi. **Step-down Care/Intermediate Care Ward (ICW):** **Figure 4** provides a framework staffing model for patients requiring more intensive support but not mechanical ventilation/vasopressor support, or those at imminent risk of requiring mechanical ventilation/vasopressor support, such as could be managed in a step-down unit. Ideally, this team would be led by an experienced hospitalist who oversees the care of physician-led teams. These staffing models would be supported by a minimum of two teams working no longer than 12-hour shifts. In the setting of COVID-19, these are likely patients that would be hospitalized in fixed facilities not in ICUs.
- vii. **Routine Inpatient/Ward Care:** **Figure 5** provides a framework staffing model for inpatient routine medicine care, with the team led by an experienced hospitalist or physician with hospital experience. In the setting of COVID-19 crisis care, these would likely be patients housed in “off-site” facilities with limited resources (e.g., tents, gyms, convention centers, etc.).
- viii. **Pediatric Care**
  - For MTFs that have a large footprint of pediatric providers (pediatric residents, pediatric intensivists, pediatricians, pediatric nursing), there should be consideration during crisis care to have pediatric providers care for adult patients with appropriate consultative support to offload adult services. Patient complexity and co-morbid status should be weighed more heavily than younger age when selecting appropriate patients.(83, 84) This will leverage appropriate expertise, as it is common for pediatric providers in the military to care for active duty personnel in the operational setting. If regional surge is significant, consider diverting critically ill pediatric patients to regional children’s hospitals to allow more space for adult care at the MTF utilizing pediatric assets. **Figure 6** provides an example framework.(5)



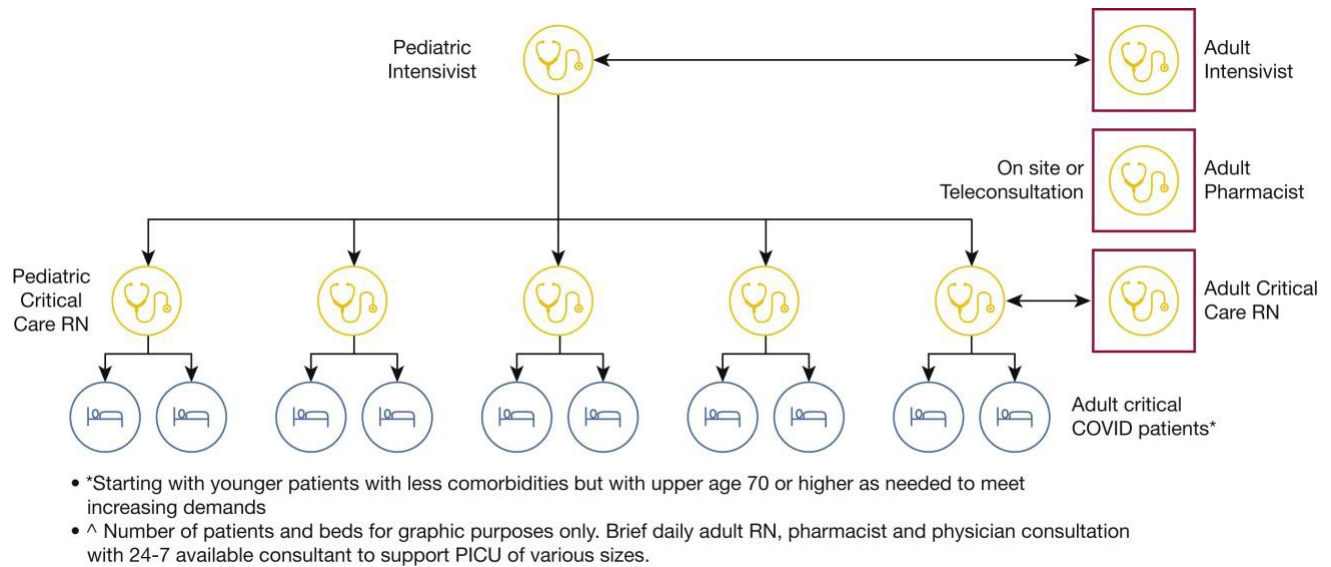
**Figure 4.** Tier 2 Staffing Strategy for Step-down Level Care during a Pandemic. \*Assumptions/Considerations for both Tiers 2 and 3: 1. Critical care/ICU staffed per DoD COVID Management Guideline; staff/patient ratio subject to local leadership judgment and may require modification for conditions based situations, according to availability of numbers, skill types, and competencies of licensed and unlicensed personnel and patient acuity and adjusted accordingly; necessity may require personnel to 'step up,' 'step over,' or 'step down' their practice in this team based nursing care model; 2. Staffing (ST 1-5) are available; 3. Patient 'pod' size adjusted to align with DoD 60% reduction ICU pod as base but provide a range dependent on patient population and resources accordingly; 4. Medical equipment is available; 5. This is a guideline until resumption of normal operations.(13)



**Figure 5.** Tier 3 Staffing Strategy for Routine Ward Level Care during a Pandemic. \*For assumptions, please see Figure 4 caption.

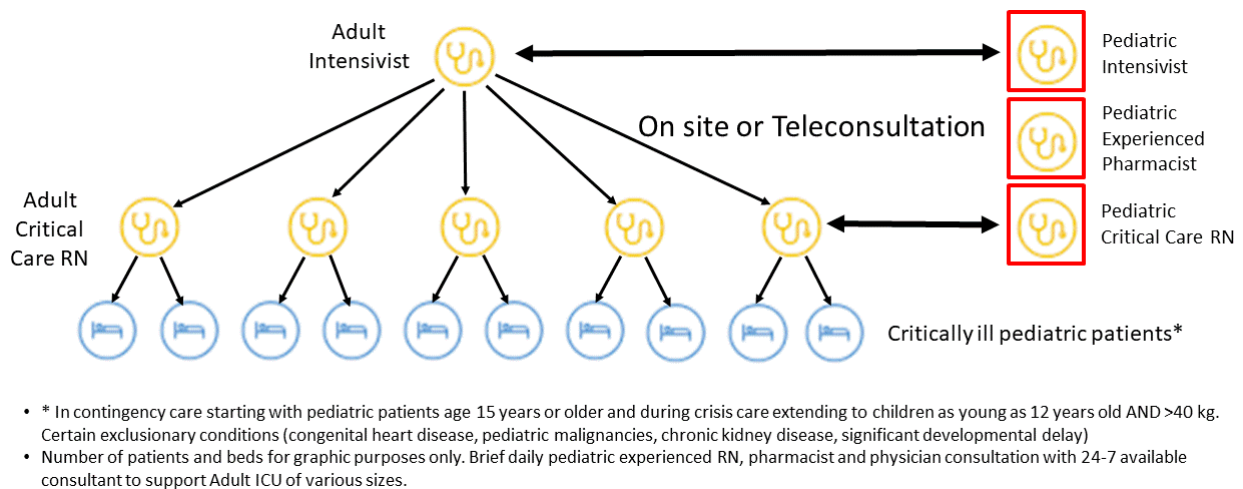
- For smaller MTFs that have minimal pediatric beds, minimal pediatricians (i.e., Family Practice caring for children), consider diverting inpatient pediatric patients to dedicated children's hospitals. This decision should be made based on available community capacity and there should be communication with local facilities to strategically plan for patient distributions. MTFs must still maintain dedicated non-COVID-19 medical missions, and should not sacrifice care in other areas (e.g., use NICU beds/ventilators for adult patients if needed in the NICU).





**Figure 6.** Diagram showing model for staffing and support of PICUs embedded in facilities that routinely care for adult patients to support adult surge. PICU: pediatric ICU; RN: registered nurse.(5)

- With the most recent surge of COVID-19 in January 2022, there has been an increase in pediatric infections and hospitalizations, which has impacted capacity at some pediatric hospitals. While in the first waves of the pandemic, pediatric providers were able to assist and offload adult critical care patients, it may now be necessary for adult providers to help offload pediatric patients. King, et al. (2022) provided a framework for adult intensivists and critical care nurses to help identify pediatric patients for whom they may be able to safely provide care.(12) **Figure 7** provides this example framework.



**Figure 7.** Diagram showing model for staffing and support of adult ICU staff to help care for pediatric critical care surge. RN: registered nurse.(12)

- Privileging options:** In accordance with national standards for accreditation, local leadership may cross-level providers to provide patient care, tr701542
- Treatment and services necessary as a life-saving or harm reducing measures, provided the care, treatment, and services are within the scope of the individual's license without modification of existing

privileges. During emergencies, providers undergoing “just in time” training for work outside their normal areas may work within the scope of their individual licensure and do not require privilege modification, addition or supervision. Privileging authorities may award disaster privileges on activation of their emergency management plans consistent with provisions established in DHA PM 6025.13, Volume 4.

**3. Staff training:**

- a. ICU “Just in time” training for augmentees are available at <https://www.sccm.org/covid19>, <https://www.chestnet.org/Guidelines-and-Resources/COVID-19/On-Demand-e-Learning>, <https://www.chestnet.org/Guidelines-and-Resources/COVID-19/Resource-Center>, <https://www.sccm.org/disaster>, and <https://covid19toolbox.com>.
- b. Training and augmentation platforms.
  - If local expertise is not available, utilization of existing DHA teleconsultation platforms (PATH, ADVISOR) may augment capabilities.
  - Places with ICU care should develop brief local ICU orientation models focusing on safety practices, unit hierarchy, protocols, and consultative relationships (brief, max 4-8 hours).
  - Training platforms for provider and nursing augmentees should focus on remote learning resources to provide baseline didactic training such as those above or those locally developed.
- c. Critical care considerations for pregnant women online training is available at: <https://www.smfm.org/critical-care/cases/new-2019>.
- d. DHA Clinical RN Refresher Training Packet was released with the intent of helping to refresh inpatient nursing experience. (<https://info.health.mil/edu/Pages/COVID.aspx>)
- e. PPE; Donning and doffing officers, which can be personnel pulled from non-clinical roles (administrators, support staff, etc.) should be assigned to train and monitor compliance with PPE protocols. Training video: <https://www.youtube.com/watch?v=bG6zISnenPg> (85)

**4. Equipment and consumables:** Daily assessment of ventilators, ventilator circuits, PPE, fluids, sedating and other critical medication and supplies should be tracked with equipment burn rates estimated and updated as information is available.

- a. Consider creating intubation/procedure packs with all necessary equipment and supplies to avoid going in and out of the room repeatedly.
- b. Consider alternative options to reduce and re-use critical items such as PPE and ventilator circuits. Encourage sharing local policies and solutions as they become available.
- c. Consider utilization of anesthesia ventilators during expansion, but ensure some remain in reserve based on facility needs for acute, non-COVID-19 emergencies.
- d. Inventory management.
  - Develop a list of key inventory to include PPE, ventilators and supporting equipment, fluids, key medications, fluids, nutrition, IV and other vascular access supplies, etc.
  - Assign personnel to develop a tracking system and publish regularly to ICC. Utilize models to predict inventory burn rate. A sample PPE utilization calculator available at: <https://www.chestnet.org/Guidelines-and-Resources/Resources/Essential-Institutional-Supply-Chain-Management-in-the-Setting-of-COVID-19-Pandemic>

**5. Space:**

- a. **ICU Contingency Units:** Many modern ICUs have rooms capable of expanding to hold two patients. These spaces need to be assessed to house appropriate ventilators, suction, and monitoring, but if so equipped, should be utilized first. Co-locating COVID-19 patients as much as possible will increase the efficiency of staff and supply use. If these spaces are exhausted, other monitored, ventilator capable areas may be available to use as alternative ICU rooms (OR, PACU, etc).
- b. **Ward cohorting:** Consideration should be given to establishing COVID-19 wards. Clean barriers on open units similar to chemical “hot lines” can be used. This includes cohorting staff to “COVID-positive” or “COVID-negative” teams based on which cohort they are caring for to reduce transmission. If possible, COVID-19 inpatient care should be limited to specific areas of the hospital with designated travel routes

reserved for flow of COVID-19 positive patients.

#### **Establishment of a DoD Case Registry for Clinical Performance Improvement**

1. Systematic collection and iterative analysis of key clinical data is essential to optimize delivery of care.
2. The COVID-19 case registry functions to support performance improvement in the setting of a learning health system.
3. Standardized electronic health record (EHR) templates have been developed to increase harmonization and completeness of important data elements needed for the registry.

#### **Returning to the “New Normal”**

The decision to de-escalate from contingency and crisis care should be governed by similar principles with ICC coordination, triggers for phased de-escalation, and clear communication. The risk of prolonged delay in routine care or altered practice models creating urgent or emergent care needs and increasing morbidity and mortality should be considered as the decision of when/how to transition back to more normal care models. Additionally, institutions should recognize and plan for a prolonged period (months or longer) with low level COVID-19 care needs requiring cohorted outpatient, emergency, and inpatient services as much as possible to avoid Healthcare associated spread. Plans should be in place with clear triggers to re-escalate to contingency or crisis care with the relaxing of social distancing.

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### **SCREENING AND TRIAGE: EARLY RECOGNITION OF PATIENTS WITH COVID-19**

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1. **Screening:** Screen and isolate all patients with suspected COVID-19 at the first point of contact with the health care system (ER/clinic/drive-through screening/labor and delivery). Establish processes for how to handle people screening positive at entrances. Processes should be clear and easy to follow and be standardized across facilities within the Local Command. It is also recommended to direct low-risk patients to drive-through screening facilities as available to reduce exposure and conserve PPE in MTFs.
2. **Initial clinical assessment:** Evaluate patients using standardized assessment tools and initiate the appropriate disposition decision depending on the clinical setting. Ensure standardized assessment protocols are established at the institutional level. Triage should be conducted telephonically or in a designated outdoor or dirty area when possible. Staff evaluating patients face-to-face should be pre-identified and outfitted and trained on appropriate PPE. Patients can pre-screen themselves using available self-checkers from the CDC and other organizations.
  - a. A potentially useful tool for initial categorization of clinical severity and aiding in triage is the National Early Warning Score (NEWS), **Figure 8**. This clinically derived score is easily measured in a triage area, clinic, emergency department or other initial assessment environment and consists of parameters listed below.
  - b. The score ranges from 0-21 and higher scores have been demonstrated to correlate with worsened mortality. A score above 5 increases the likelihood of eventual ICU level of care, while greater than 7 provides more specificity.
  - c. NEWS in COVID-19 has distinct advantages over qSOFA which can underestimate the severity of presentation if confusion, and hypotension are absent as they often are in COVID-19 patients.
  - d. An alternate version of the NEWS has been developed in China incorporating age >65 as a risk factor in the scoring. The development of this alternate score is based on an entirely different scoring system retrospectively created on patient data from the 2013 Avian Influenza epidemic,(86) although this score has not been prospectively validated/evaluated.(87) There have been 2 retrospective evaluations of this “NEWS+AGE” in the Adaptive COVID Treatment Trial (ACTT) and a DOD natural history study (EPICC) which showed a reasonable performance of either score, with a slight improvement in NEWS+AGE.(88, 89)
  - e. Early small observational studies in during the pandemic Scandinavian, Korea and Italy have confirmed the utility of NEWS over qSOFA in COVID19 demonstrated the utility of predicting severe illness/need for critical care admission with an initial score >7, showing a specificity of 80-90%.(90-93)

PHYSIOLOGICAL PARAMETERS	3	2	1	0	1	2	3
Respiration Rate	≤8		9 - 11	12 - 20		21 - 24	≥25
Oxygen Saturations	≤91	92 - 93	94 - 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35.0		35.1 - 36.0	36.1 - 38.0	38.1 - 39.0	≥39.1	
Systolic BP	≤90	91 - 100	101 - 110	111 - 219			≥220
Heart Rate	≤40		41 - 50	51 - 90	91 - 110	111 - 130	≥131
Level of Consciousness				A			V, P, or U

Figure 8. National Early Warning Score (NEWS).(59)

3. **Initial treatment of hospitalized inpatients** consists of optimized supportive and symptomatic care in the ward or intensive care unit. Patients with increased risk of severe disease and mortality include: (94)
  - Age >60
  - Cancer
  - Chronic kidney disease
  - COPD (chronic obstructive pulmonary disease)
  - Down syndrome (trisomy 21)
  - Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
  - Immunocompromised state (weakened immune system) from solid organ transplant
  - Obesity (body mass index [BMI] of 30 kg/m<sup>2</sup> or higher but < 40 kg/m<sup>2</sup>)
  - Severe Obesity (BMI ≥ 40 kg/m<sup>2</sup>)
  - Pregnancy
  - Sickle cell disease
  - Smoking
  - Type 2 diabetes mellitus
4. Patients may present with mild symptoms but have high risk of deterioration and should be admitted to a designated unit for close monitoring.
  - a. Additional consideration should be given to a patient's resource level in their residence (e.g., barrack dwellers), and ability to quarantine and self-monitor when deciding to admit or discharge a mildly symptomatic patient.
5. **Mild illness:** For mild illness, hospitalization may not be required unless concern about rapid deterioration. Isolation to contain/mitigate virus transmission should be prioritized. Safe home care can be performed according to CDC guidance (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>). Emerging evidence suggests that optimal vitamin D levels may prevent severe COVID-19 complications. In addition, zinc has been shown in vitro to inhibit viral replication.
6. **ICU admission criteria:** ICU admission and exclusion criteria may be a fluid decision based on the facility. Given that allocation of dedicated ICU beds and surge capabilities amongst individual hospitals are variable, each hospital should provide a specific plan regarding ICU admission/exclusion criteria. This could be based



on the percentage of resources utilized (e.g., beds, ventilators). **Figure 9** provides an example plan. Individual triage decisions could be made on the basis of a composite of factors including likelihood of recovery, pre-existing functional status, and severity of illness. An example triage schema is shown in **Appendix A**.

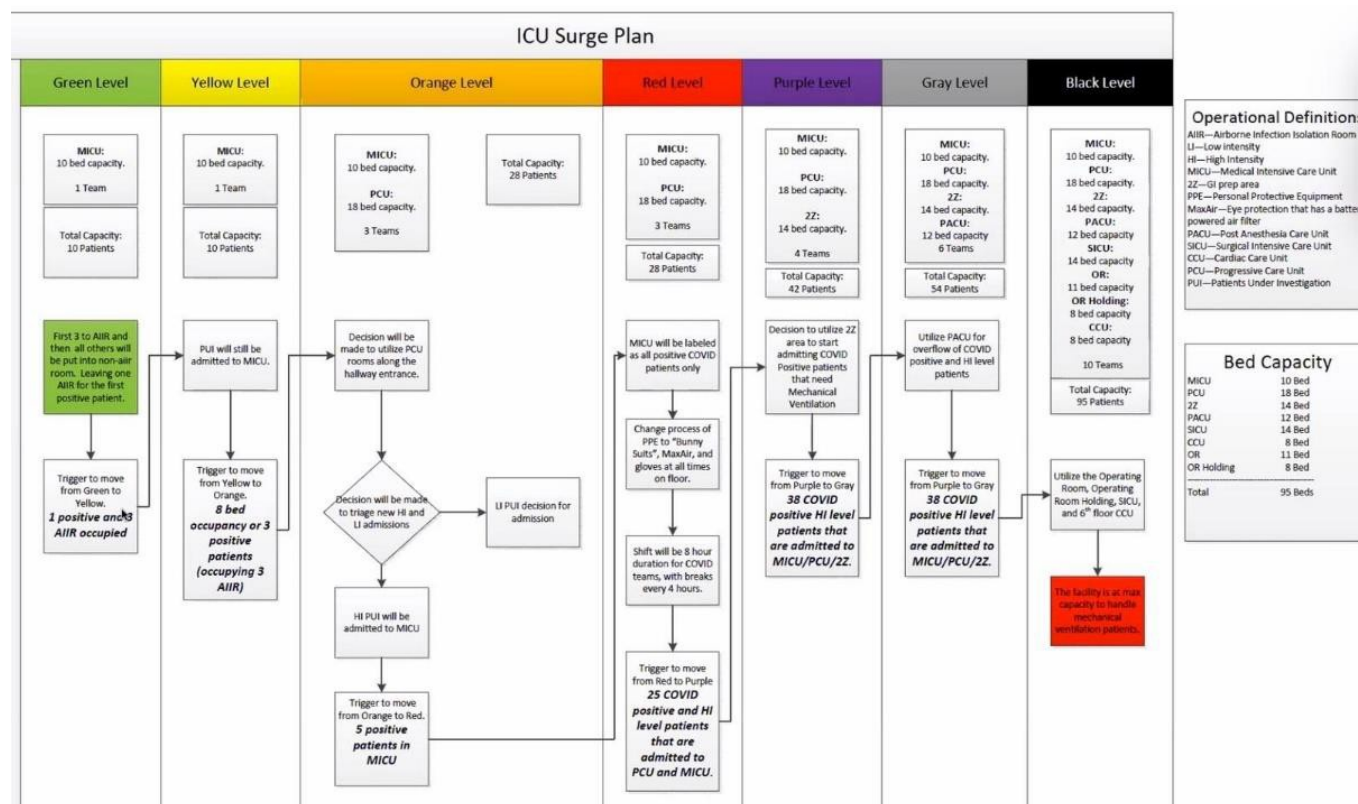


Figure 9. Example of an ICU Surge Plan (from the San Antonio Veteran's Affairs Hospital)

7. Development and deployment of Triage Planning Committees and Triage Teams to support contingency/crisis operations.
  - a. The above section on initial clinical assessment and disposition assumes normal operations (i.e. no resource limitation in effect) and that clinical disposition is not effected by contingency or crisis operation conditions. In the event of contingency or crisis operations, it is reasonable to consider a Triage Team to assist in disposition following the initial clinical assessment.
  - b. See **Appendix B** for potential compositions and roles for Triage Planning Committees and Triage Teams.
  - c. Triage Planning Committees should be established to have ultimate oversight of scarce medical resource allocation decisions. Triage Planning Committees should be charged with establishing pre-defined triage SOPs for conventional capacity, contingency capacity, and crisis capacity. Ensure SOPs are established in cooperation with Infectious Disease and Public Health are clear and easy for staff to follow. Try to keep protocols aligned with national (CDC) and local (state or municipal) guidance and update regularly as new guidance emerges.
  - d. Clinical treatment teams should not be responsible for making triage decisions. Instead, each MTF should develop Triage Teams prior to the onset of resource scarcity.
  - e. Triage Teams, at a minimum, should be comprised of a Triage Officer, a nurse with acute care experience, and an administrative staff member. If available and feasible, teams should also include a member of the ethics team, a representative from pastoral care, and a representative member of the community.
  - f. Responsibilities of the Triage Team should include implementation of a triage tool (see below for potential tool), matching priority score to available resources, and communicating this information back

to the clinical treatment teams.

8. Triage Teams should only receive clinically essential information from the clinical treatment team without specific patient identifiers. The Triage Team should be apprised of the patient's clinical condition and other medical information relevant to prognostication.

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## PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR PATIENT VISITS DURING COVID-19

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1. See **Appendix C** for additional guidance related to infection prevention and control.
2. Appropriate use of PPE plays an important role in the prevention of disease transmission, however ensuring appropriate work practice and environmental controls are in place is critical. In addition to implementing the PPE guidelines, MTFs should adhere to the following essential practices:
  - a. Screen all visitors and healthcare workers before entry into the MTF (i.e., inside as they enter) IAW with OSHA Emergency Temporary Standard 1910.502(d)(2) (ETS) for COVID-19 (27 Dec 2021).
  - b. Practice social distancing.
  - c. Adhere to frequent hand hygiene and wear a surgical at all times (includes visitors).
  - d. Surgical masks, at a minimum, are required for source control (FDA approved for healthcare use).
  - e. As of October 2021, reprocessing of PPE is not permitted. In the event that DHA MEDLOG issues a statement of a shortage then revert to CDC crisis capacity guidance: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html#crisis>
3. **PPE visual:** The following visuals from the CDC are available as printable PDFs: [https://www.cdc.gov/coronavirus/2019-ncov/downloads/A\\_FS\\_HCP\\_COVID19\\_PPE.pdf](https://www.cdc.gov/coronavirus/2019-ncov/downloads/A_FS_HCP_COVID19_PPE.pdf) and there is also a video at: [https://www.nejm.org/doi/full/10.1056/NEJMvcm2014809?query=featured\\_home](https://www.nejm.org/doi/full/10.1056/NEJMvcm2014809?query=featured_home).

### Implement Universal Use of Personal Protective Equipment for HCP

1. If SARS-CoV-2 infection is not suspected in a patient presenting for care (based on symptom and exposure history), HCP working in facilities located in areas with substantial or high transmission should also use PPE as described below:
  - a. NIOSH-approved N95 or equivalent or higher-level respirators should be used for:
    - i. All aerosol-generating procedures
    - ii. All surgical procedures that might pose higher risk for transmission if the patient has COVID-19 (e.g., that generate potentially infectious aerosols or involving anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, respiratory tract)
  - b. Facilities could consider use of NIOSH-approved N95 or equivalent or higher-level respirators for HCP working in other situations where multiple risk factors for transmission are present. One example might be if the patient is unvaccinated, unable to use source control, and the area is poorly ventilated.
  - c. Eye protection (i.e., goggles or a face shield that covers the front and sides of the face) should be worn during all patient care encounters.(95)
  - d. The US FDA Revokes Emergency Use Authorizations for Non-NIOSH-Approved Disposable Respirators and Decontamination Systems as Access to FDA-authorized and NIOSH-approved N95s Increases Nationwide in April 2021.(96)
2. Questions related to IPC can be sent to: [dha.ncr.clinic-support.list.ipc-group@mail.mil](mailto:dha.ncr.clinic-support.list.ipc-group@mail.mil)

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## LABORATORY DIAGNOSIS OF COVID-19

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1. **Introduction:** Testing capabilities, methodologies, and platforms for SARS-CoV-2 underwent a rapid development and evolution early in the pandemic. Since the first case was reported in the United States in January of 2020, testing methodologies and access have vastly improved. However, with each wave or new variant of the pandemic, questions are raised with respect to diagnostics. The FDA has a regularly updated webpage which documents any issues with SARS-CoV-2 mutations and impact on testing.(97) Pre-symptomatic, asymptomatic and "clinically positive" (patients with negative nasopharyngeal swabs but high

suspicion of COVID-19 due to clinical and/or epidemiologic risk) remain challenging clinical scenarios. A summary of the evidence regarding various testing modalities employed in the diagnosis of COVID-19 follows. The reader is directed to the Infectious Disease Society of America guideline homepage for further reading on all of the topics covered in this section.

2. **Molecular testing [polymerase chain reaction (PCR) and other nucleic acid amplification tests (NAAT)]:** Molecular testing by PCR or NAAT for SARS-CoV-2 is the current gold standard for making the diagnosis of COVID-19. Commercially available PCR based platforms (e.g., Cepheid, Biofire, Hologic, etc.) have supplanted the CDC assay and EUA waived “in-house” assays for daily use. Clinicians should be aware that there are some differences in these platforms (largely turnaround time, number of specimens that may be processed at one time). Of note, the IDSA December 2020 update to diagnostic recommendations had a consensus recommendation that isothermal NAAT testing (e.g. Abbott ID Now rapid platform) should only be used if either a rapid PCR or standard laboratory NAAT was not available due to issues with sensitivity. Negative NAAT testing does not necessarily rule out COVID-19. Re-testing can be considered if clinical suspicion for SARS-CoV-2 infection remains high, although in situations with limited availability of NAAT testing this may be impractical. NAAT based testing typically performs well although sensitivity can be affected by timing of specimen collection in the disease course, quality of sampling, type of sample, and sample transport. Due to the inherent variability in sample collection, cycle thresholds should not be used as a surrogate marker for “how positive” or “how negative” a single test might be.
3. **Specimen collection for NAAT:** Specimen collection has largely been via nasopharyngeal (NP) samples which should be collected via synthetic fiber swabs (“flocked swabs”). The DHA offers **Appendix D** as a standardized protocol for nasopharyngeal specimen collection. Other specimen types like saliva, sputum, endotracheal tube aspirates, bronchoalveolar lavage (BAL), blood and stool may be utilized, depending on the disease process. Nasal washing may lead to increased risk of aerosolization and could increase the risk of infection to HCPs. If unable to collect from the URT, specimens from the lower respiratory tract (LRT) using expectorated sputum or endotracheal aspirate may be indicated in hospitalized patients with lower respiratory tract infection. Bronchoalveolar lavage (BAL) may be required for sampling, but this methodology increases the risk to healthcare providers due to aerosolization of virus. Testing for other viral infections such as influenza should be obtained if indicated, depending on local epidemiology of respiratory viruses as well as pre-test probability for disease in the specific host. The Infectious Diseases Society of America (IDSA) issued guidelines for recommended specimen types in symptomatic and asymptomatic patients, to include recommendations for self-collection of nasal and mid-turbinate swabs by symptomatic patients, and saliva testing.(98) Ultimately, samples that should provide high sensitivity (>90%) testing substrates include nasopharyngeal swab, mid-turbinate swabs, anterior nasal swab, or saliva (with saliva in the setting of coughing being more sensitive). Oropharyngeal swab specimens (sensitivity 76%) alone should be avoided if possible. The Omicron variant has been reported to have more upper respiratory symptoms, and some have postulated that oropharyngeal specimens might be more effective at diagnosis.(99) This hypothesis requires further investigation.
4. **Antigen testing:** Antigen testing is designed to detect SARS-CoV-2 proteins in a rapid format, without the complexity of a molecular test. Although less sensitive than NAAT, antigen testing is rapid and specific – producing high positive predictive values (PPV), but low negative predictive values (NPV). This allows for the rapid detection of SARS-CoV-2 antigen in upper respiratory samples, but at the cost of more false negatives (depending of course on disease prevalence). The first antigen test received FDA authorization May 8, 2020. Patients with suspected COVID-19 who test positive with these assays, should be considered to have confirmed infection. Those who test negative should be retested with a molecular test before the diagnosis is excluded. Clinical scenarios where these are likely to be most helpful include in those with patients with a known exposure and early in their own symptom course, as well as in outbreak investigations in congregate settings where rapid identification and isolation are important. The BinaxNow™ rapid antigen test is currently predicted to still be diagnostic in the appropriate clinical setting for the Omicron variant.(100)
5. **Serologic testing:** Serologic assays include both point-of-care tests, (which use lateral-flow technology that are typically less sensitive), or laboratory tests, which use ELISA (Enzyme-Linked Immunosorbent Assay that

are generally more sensitive) or CIA (chemiluminescent immunoassay). Previously the Infectious Diseases Society of America (IDSA) had advised against using serologic testing due to challenges with sensitivity and specificity but as testing has improved, most experts agree on three main roles of serology: epidemiologic surveys, diagnostic testing when NAAT is either negative or not performed, and assessment of multisystem inflammatory syndrome in children. The type of serologic assay and the type of antibody are important when assessing the utility of serologic testing. For example, ELISA and CIA are more accurate than LFA, and detection of IgG is both more sensitive and specific than IgM. With the widespread availability of SARS-CoV-2 vaccines questions regarding antibody positivity and its significance for those vaccinated are likely to be raised. In patients who have received vaccines whose antigenic component is the S protein (e.g. Pfizer, Moderna), it is reasonable to expect that they could have a positive antibody test; however, because of the lack of data on the durability of antibody response, as well as the general lack of data to answer this specific question clinicians should interpret any antibody testing in the clinical context in which they were obtained.

6. **Retesting persons with SARS-CoV-2 infection:** Retesting persons with confirmed SARS-CoV-2 infection in general is not recommended as an infection prevention and control strategy. Published data has documented persons testing positive by molecular methods (using upper respiratory specimens) for up to 8 weeks. However, most viral culture data studies support a much shorter course of shedding viable virus (7-9 days). Most experts recommend to avoid retesting a patient with confirmed SARS-CoV-2 infection and subsequent clinical recovery in the 3 months after symptom onset. Some data suggests that immunocompromised hosts may shed culturable virus much longer than previously thought (two months in one small series of patients) but this needs further work to describe how often and what the impact will be on infection control.
7. **Personal Protective Equipment (PPE) during specimen acquisition:** Use appropriate PPE for specimen collection (droplet, contact, face shield precautions for URT specimens; contact, face shield, airborne precautions for LRT specimens).
8. **Pre-operative/pre-procedural testing:** assessing active COVID-19 infection to identify potential subclinical infection in patients who require invasive or non-invasive ventilation for surgical or other procedures should generally be limited to NAAT-based assays. Use of serologic assays to determine risk of infectivity to HCPs or to consider reduction of PPE is not recommended. The IDSA guidelines on diagnosis of COVID-19 provide additional guidance on preoperative and pre-procedural testing.
9. **Co-infections and multiplex assays:** Co-infections with SARS-CoV-2 and other respiratory viruses are infrequent but well described. Given that the clinical presentation of COVID-19 and influenza has a significant overlap, as resources allow diagnostic strategies that allow for identification of both pathogens is warranted for surveillance, infection prevention, and clinical management purposes. As relevant technologies become available, and resources allow, implementing either PCR based or rapid antigen assays during the flu season is recommended, particularly for groups at increased risk of complications from either influenza or COVID-19. Of note, influenza case rates had been at a historic low, however as masking guidance and adherence changes, these rates as well as rates of other upper respiratory viruses have increased.

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## MANAGEMENT OF COVID-19 BASED ON ILLNESS CATEGORY

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Per National Institutes of Health (NIH) COVID-19 Treatment Guidelines, in general, patients with COVID-19 can be grouped into the following illness categories:

- **Asymptomatic or Pre-symptomatic Infection:** Individuals who test positive for SARS-CoV-2 but have no symptoms.
- **Mild Illness:** Individuals who have any of various signs and symptoms (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal imaging.
- **Moderate Illness:** Individuals who have evidence of lower respiratory disease by clinical assessment or imaging and a saturation of oxygen (SaO<sub>2</sub>) >93% on room air at sea level.
- **Severe Illness:** Individuals who have respiratory frequency >30 breaths per minute, SaO<sub>2</sub> ≤93% on room air

at sea level, ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO<sub>2</sub>/FiO<sub>2</sub>) <300, or lung infiltrates >50%.

- **Critical Illness:** Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

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## OUTPATIENT MANAGEMENT OF COVID-19: TREATMENT AND MONITORING

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1. **Overall management:** The mainstay of treatment for mild cases of COVID-19 is supportive care. Specific outpatient management strategies found in **Appendix E** provide recommendations for personal lifestyle and nutrition recommendations associated with the prevention of severe disease and should be discussed with anyone who tests positive for SARS-CoV-2. These strategies are supported by evidence related to underlying health conditions and biological mechanisms (e.g., inflammation, oxidative stress, endothelial dysfunction) that increase the risk of morbidity and mortality from COVID-19. Additional patient information from the Consortium for Military Health and Performance (CHAMP) can be found at: <https://www.hprc-online.org/total-force-fitness/tff-strategies/personal-protective-nutrition-and-personal-protective-lifestyle>.
2. **Disposition:** Those with mild or moderate disease may be managed as an outpatient. Moderate cases should be considered for admission for close observation due to the risk of rapid pulmonary disease progression. The determination of outpatient vs inpatient care should be individualized based on consideration of symptom severity, risks for adverse outcomes (e.g., underlying illness and age), and the patient's social context:
  - a. Their access to resources such as food and other necessities for daily living
  - b. Their access to appropriate caregivers or ability to engage in self-care
  - c. Their ability to engage in symptom and public-health monitoring
  - d. The transmission risk within the home (e.g., the availability of a separate bedroom to minimize sharing of immediate living spaces; their access to PPE such as gloves and a facemask; their ability to adhere to home isolation, respiratory and hand hygiene, and environmental cleaning; and household members at increased risk for COVID-19 complications).
3. **Monitoring for symptomatic progression:** Monitoring for the evolution of symptoms may be conducted by clinical staff or public-health personnel, depending on local policy.
  - a. Although 81% of patients in a Chinese case series had mild symptoms, those who progressed to more severe disease were hospitalized a median of 7-11 days after the onset of illness. Therefore, close monitoring for symptomatic progression through the second week of illness is important for non-hospitalized patients.
  - b. Close monitoring should be emphasized in any patient who is identified as being at higher risk for severe illness per CDC guidelines at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html>. Monitoring via telehealth may be an option for these patients.
4. **Home care guidance:** Healthcare providers may provide patients and caregivers with available CDC guidance on home care:
  - a. What to Do If You Are Sick (<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>)
  - b. Caring for Someone at Home (<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/care-for-someone.html>)
  - c. Caring for Yourself at Home (<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>)
5. **Targeted therapy:** While the majority of clinical trials are focused on hospitalized patients, there are a number of clinical trials targeting mild to moderate outpatient cases and investigating the use of antiviral, immune-based, and adjunctive therapies. Antivirals nirmatrelvir (ritonavir-boosted) and remdesivir as well as monoclonal antibodies (see below) have been shown to reduce hospitalization rates when administered within the first few days of infection and should be administered as soon as possible after symptom onset. Supply and access to these agents are often limited and should be factors considered when deciding which to use. Molnupiravir, also an antiviral, is available but has not been shown to be as effective and may be limited in use due to potential teratogenicity. Further information and updates can be found at <https://www.clinicaltrials.gov> <https://www.clinicaltrials.gov>.



- a. The NIH COVID-19 Treatment Guidelines provide updated recommendations and supporting evidence for these therapies: <https://covid19treatmentguidelines.nih.gov/introduction/>.<sup>(8)</sup> Specifically, the NIH guidelines recommend (in order of preference):
    - i. **Paxlovid x 5 days** (nirmatrelvir 300 mg + ritonavir 100 mg orally twice daily); use caution with significant drug-drug interactions
    - ii. **Sotrovimab as a single IV infusion** (500 mg)
    - iii. **Remdesivir x 3 days** (200 mg IV on Day 1 then 100 mg IV on Days 2 and 3)
    - iv. **Molnupiravir x 5 days** (800 mg orally twice daily)
  - b. Additionally, the guidelines recommend against the routine use of corticosteroids in outpatients in mild cases not requiring supplemental oxygen therapy and against the use of colchicine.
6. **Antivirals:**
- a. **Nirmatrelvir** co-packaged with ritonavir (PAXLOVID) is an oral protease inhibitor available under FDA EUA for the treatment of adult and pediatric patients (12 years of age and older weighing at least 40 kg). Ritonavir, an HIV protease inhibitor, is used to increase nirmatrelvir plasma concentrations. Clinical trials have shown that ritonavir-boosted nirmatrelvir (nirmatrelvir/ritonavir) reduced the risk of COVID-19 related hospitalization or death by 89% compared to placebo in individuals with mild-to-moderate COVID-19 when given within five days of symptom onset; it should be administered as soon as possible. It is critical to perform a detailed and careful evaluation of the individual's current medications and possible drug-drug interactions. The dose of nirmatrelvir/ritonavir is 300 mg of nirmatrelvir with 100 mg of ritonavir twice daily for five days. Refer to the EUA (<https://www.fda.gov/media/155050/download>) for further details on appropriate use criteria. Note that nirmatrelvir/ritonavir is not authorized for treatment in patients requiring hospitalization due to COVID-19, pre-exposure or post-exposure prophylaxis or for use longer than five consecutive days.
  - b. **Remdesivir** is an antiviral with broad activity against RNA viruses which is approved for treatment of COVID-19 in hospitalized patients. It is administered via the IV route. According to a recent report of an RCT, a 3-day course of remdesivir resulted in an 87% lower risk of hospitalization or death.<sup>(101)</sup>
  - c. **Molnupiravir** is an oral nucleoside analog available under FDA EUA for the treatment of mild-to-moderate COVID-19 in patients  $\geq 18$  years old and was shown in clinical trials to reduce severe disease by 30% compared to placebo when given within 5 days of symptom onset. The dose of molnupiravir is 800 mg (four 200 mg capsules) twice daily for five days. Note that molnupiravir is not authorized for treatment in patients  $< 18$  year of age, patients who require hospitalization due to COVID-19, as pre-exposure or post-exposure prophylaxis or for use longer than five consecutive days. Additionally, due to potential teratogenicity, the use of molnupiravir is not recommended during pregnancy; women of childbearing potential should be advised to use effective contraception for the duration of treatment and for four days after the last dose. Similarly, breastfeeding is not recommended during treatment and for four days after the last dose; lactating persons may consider interrupting breastfeeding (by pumping and discarding breast milk) during treatment and for four days after the last dose.
7. **Monoclonal antibodies (mAb):** have shown a decreased risk of severe disease from COVID-19 between 70% and 85% in clinical trials.
- a. Three mAb preparations (**sotrovimab**, **bamlanivimab/etesevimab**, and **casirivimab/imdevimab**) have been granted FDA EUA for the treatment of outpatient adults and pediatric patients ( $\geq 12$  years old, weighing  $\geq 40$  kg) with confirmed mild-to-moderate COVID-19 who are at high risk for progression to severe disease/hospitalization.
  - b. Bamlanivimab/etesevimab and casirivimab/imdevimab are authorized for **post-exposure prophylaxis (PEP)**, while **tixagevimab/cilgavimab** is authorized for **pre-exposure prophylaxis (PrEP)** of COVID-19 in adults and pediatric individuals (12 years of age and older weight at least 40 kg) who are immunocompromised or who are not recommended to receive vaccination due to history of severe adverse reaction (refer to EUA for full details including immunocompromising conditions).
    - i. As with treatment, bamlanivimab/etesevimab and casirivimab/imdevimab should not be used for PEP in areas where the Omicron variant is the dominant circulating strain, while

- tixagevimab/cilgavimab confers protection against the Omicron variant and should be used where the Omicron variant is dominant.
- ii. For PrEP, the authorized dose of tixagevimab/cilgavimab is 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate intramuscular injections, ideally in the gluteal or vastus lateralis muscle.
  - c. Currently, supply of mAbs remains extremely constrained. Note that, consistent with federal guidance and due to the increasing proportions of/ infections with the Omicron variant and their reduced activity against it, bamlanivimab/etesevimab and casirivimab/imdevimab should not be used when the strain is unknown or is known to be Omicron. Data and evidence regarding effectiveness of specific mAbs against dominant circulating strains should be regularly reviewed and updated to reflect possible decreased susceptibility of variants.
  - d. Details regarding patient selection (e.g., definition of high risk and other inclusion/exclusion criteria), dosing, preparation, administration, and storage of these single-dose intravenous infusions can be found in the respective EUAs:
    - i. Sotrivimab: <https://www.fda.gov/media/149534/download>
    - ii. Bamlanivimab/etesevimab: <https://www.fda.gov/media/143603/download>
    - iii. Casirivimab/imdevimab: <https://www.fda.gov/media/143892/download>
    - iv. Tixagevimab/cilgavimab: <https://www.fda.gov/media/154701/download>
  - e. Please see the “Adjunctive Therapies for COVID-19” section of this Practice Management Guide for further discussion of the evidence behind these mAbs and the rationale behind these recommendations.
  - f. The implementation of mAb therapy in the outpatient setting presents significant challenges, to include:
    - i. The limited supply compared to the high incidence of infection among patients at high risk for progression to severe disease
    - ii. The short interval between symptom onset and dosing for which there is safety and efficacy data (median trial symptom duration, 3-4 days at randomization)
    - iii. The fact that an infusion requires patients at the peak of their contagiousness to present to a healthcare environment for dosing and the associated implications for nosocomial spread
    - iv. The infection-control incompatibility of dosing in established infusion centers serving immunocompromised hosts
    - v. Infrastructure/space limitations (e.g., emergency department, outpatient infusion on the ward, dedicated clinic)
    - vi. The time for preparation, infusion, and monitoring (approximately 3 hours/patient)
    - vii. Complicated preparation and limited stability
    - viii. Staffing and personal protective equipment limitations
    - ix. The risk for serious side effects
    - x. Unknown/ evolving data on efficacy against different variants/strains.
  - g. Each facility will need to balance these universal challenges within their unique context of physical and personnel infrastructure, resources, and patient population.
8. **Concomitant medications:** The NIH Guidelines provide recommendations and supporting evidence regarding the role of concomitant medications such as angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), HMG-CoA reductase inhibitors (statins), and non-steroidal anti-inflammatory drugs (NSAIDs).
9. **Discontinuation of home isolation:** As information continues to rapidly evolve around transmissibility and infectiousness of various strains and effectiveness of interventions, clinicians should contact local military public health and/or local/state health departments regarding criteria for discontinuation of home isolation and establish clear and easy-to-follow protocols to guide staff, patients, and commands on return to work/duty criteria. The CDC recommends symptom-based discontinuation strategies in lieu of test-based. Test-based strategies should only be considered in severely immunocompromised patients or when considering discontinuation of transmission-based precautions earlier than if the symptom-based strategy were used. Clinicians should be aware that states and local school districts may have additional

requirements for return to school for ill children that include: confirmation of condition other than COVID-19, confirmation of recovery from COVID-19, and / or a negative SARS-CoV-2 test result. Military bases or units may have administrative requirements for service members to be able to return to work/duty independent of clinical standards. Examples of such protocols can be found in **Appendix F**. The CDC guidelines for discontinuing isolation can be found at <https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html> for the general public and at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html> for healthcare personnel. Additionally, updated, clear and easy-to-follow algorithms for quarantine and isolation can be found in the DHA ASP mobile app: <https://mobile.health.mil/asp/#/covid-19/quarantine-vs-isolation>.

10. **Cardiopulmonary return to exercise:** Patients recovering from COVID-19 infection should follow the guidelines set forth in **Appendix K** for evaluation of cardiovascular risk and return to exercise.

## DIAGNOSIS AND TREATMENT OF CO-INFECTIONS

1. Clinical judgment and patient severity will dictate provider decision on early antibiotic therapy.
2. Procalcitonin levels have been low in COVID-19 mono-infection, with infrequent bacterial co-infections reported except in pediatric patients where >80% are reported to be elevated.(102)
3. Multiple series have raised concern for *Aspergillus* pulmonary superinfections in critically-ill patients. This is well-described in severe influenza as well. The optimum diagnostic strategy remains to be determined, but a syndrome of worsening fever, hypoxemia, and airspace opacification in a previously-improving patient may suggest secondary aspergillosis. Diagnostic options include serum 1,3-beta-D-glucan and galactomannan assays and (potentially) galactomannan measurement in bronchoalveolar lavage (BAL) fluid, although bronchoscopy should be performed only if no less-invasive option is available and only in airborne infection isolation rooms (AIIRs) with appropriate personal protective equipment (PPE). The culture of *Aspergillus* from tracheal aspirates or BAL is suggestive but not diagnostic.
4. Recommend empiric antimicrobials for intubated patients with COVID-19. The recommended empiric antibiotic therapy is as per the 2019 ATS/IDSA Community Acquired Pneumonia (CAP) guidelines or as per critical care or infectious disease consultation. **Table 1** can be used as a starting point upon intubation until consultation is available. Further information on recommendations and local susceptibilities can be found using the DHA Antimicrobial Stewardship web and mobile application: <https://mobile.health.mil/asp>.
5. Recommend obtaining blood cultures and tracheal aspirate prior to initiation of antibiotics if feasible.

**Table 1.** Empiric Antimicrobial Considerations for Intubated COVID-19 Patients (or PUI)

	Starting Antibiotic Regimen
No comorbidities or immunosuppression or risk factors for MRSA or <i>Pseudomonas aeruginosa</i> *	<ul style="list-style-type: none"> <li>• Ceftriaxone† 2 g once daily, <i>and</i></li> <li>• Azithromycin† 500 mg once daily</li> </ul>
With comorbidities‡	<ul style="list-style-type: none"> <li>• Cefepime 2 g every 8 hours, and Azithromycin† 500 mg once daily</li> <li>OR</li> <li>• Piperacillin-Tazobactam 4.5 g every 6 hours (or every 8 hours by extended infusion), and Azithromycin† 500 mg once daily</li> </ul>

MRSA, methicillin-resistant *Staphylococcus aureus*; \*Risk factors include prior respiratory isolation of MRSA or *P. aeruginosa* or recent hospitalization AND receipt of parenteral antibiotics (in the last 90 d). If concern for MRSA, add **vancomycin** 15-20 mg/kg q 8-12 hours; †If ceftriaxone is not available, replace with **ampicillin/sulbactam** 3 g q6h; If azithromycin is not available or contraindicated, replace with **doxycycline** 100 mg q12h; ‡Comorbidities include chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancy; immunodeficiency/asplenia. These are general recommendations: Please refer to local antibiogram for alternative empiric choices.

6. As noted in diagnostic testing section, co-detection of other respiratory pathogens has been observed with SARS-CoV-2. Rates of co-infection detection have been variable (as low as 3% in series from New York to as high as 50% in non-survivors in China).(18, 103) It is important to note that detection of another respiratory



pathogen does not exclude SARS-CoV-2 infection in a patient with an appropriate clinical syndrome.

### **COVID-19 and Influenza**

1. A small factor of the COVID-19 pandemic has been an unusually low incidence of influenza in most regions of the world during the 2020-2021 season, likely due to both high influenza vaccination rates and the impact of non-pharmacologic interventions for COVID-19 prevention.(104) During the influenza season, many clinicians will face the diagnostic dilemma of whether or not their patient has COVID-19, Influenza or both. Clearly the pre-test probabilities of these infections will be affected by local transmission rates; however there are a few important points to consider when approaching diagnosis:
  - a. Symptom overlap between influenza and COVID-19 make distinguishing the two very challenging – even for what seem like well described and specific symptoms to COVID-19, like loss of taste and smell, in a Cochrane Review did not meet a pre-specified positive predictive value that would be beneficial to clinicians.
  - b. Depending on the severity of the influenza season for 2021-2022 there could potentially be a worsening of testing supplies which would hinder the ability to diagnose and appropriately manage both treatment and infection control practices.
  - c. Differences in testing characteristics (e.g. highly specific rapid antigen tests versus more sensitive multiplex PCR testing) will affect the physician's ability to achieve an accurate diagnosis. Additionally, clinicians should regularly review data on effects of varying circulating strains on sensitivity and specificity of tests. Currently, data suggests the available tests are able to detect Omicron infections.
2. Rates of co-infection with other respiratory pathogens are still an area of active research, however some of the reports that have been published have argued that there are less frequent:
  - a. One study from two academic hospital ER's had in San Diego with 51 SARS-CoV-2 infections, only one patient had coinfection with influenza.(105)
  - b. A hospital in Singapore with 431 SARS-CoV-2 infections had a rate of 1.7% coinfection with influenza and no effect on morbidity or mortality.
  - c. Summer circulation of influenza in the United States is at an all-time low (0.2% of tests positive compared with 2-3.3% historically).
  - d. Recent data published suggests (even after allowing for variations in focus on SARS-COV-2 testing) that Influenza circulation in Chile, Australia and South Africa was very low during their influenza season months.
  - e. While this does not prove causality, it does reach biologic plausibility and argue strongly in favor of continued emphasis on fundamentals of pandemic mitigation (e.g. masking).
3. We suggest testing for both Influenza and SARS-CoV-2 for patients that have influenza-like illness. Multiple commercial platforms, including but not limited to Biofire and Cepheid Xpert systems, now have incorporated SARS-CoV-2 testing into multiplex panels that also include influenza A/B, RSV, and sometimes other relevant respiratory pathogens. Depending on laboratory resources, it may be reasonable to use a graded approach to choice of testing during the influenza season: rapid antigen testing (for both Flu A/B and SARS-CoV-2) is typically thought to be highly specific (although there can be some issues with Influenza testing) and if positive could avoid the need to use multiplex PCR testing. If these are negative and clinical suspicion remains, proceeding to a multiplex PCR (which should include both Influenza A/B, SARS-CoV-2) testing platform which is more sensitive would be appropriate. Whereas in previous years, PCR multiplex testing was not always performed during influenza season if the management strategy for a patient was unaffected by results, during the COVID-19 pandemic, testing will be key to inform pandemic response strategies. **Figure 11** offers a suggested algorithm for managing testing for COVID-19 during Influenza season.

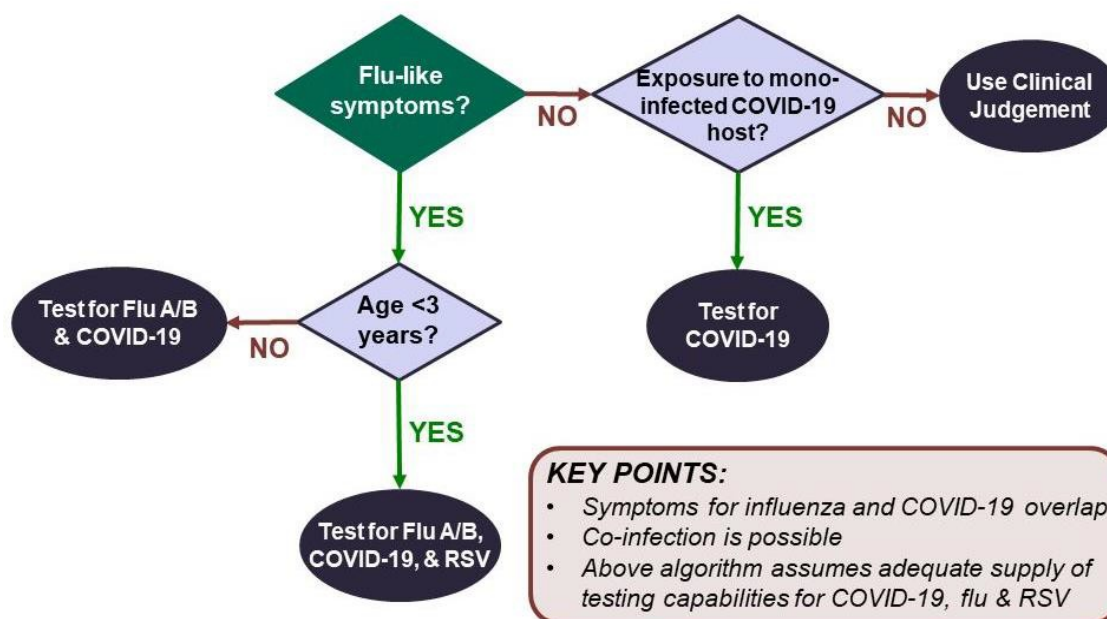
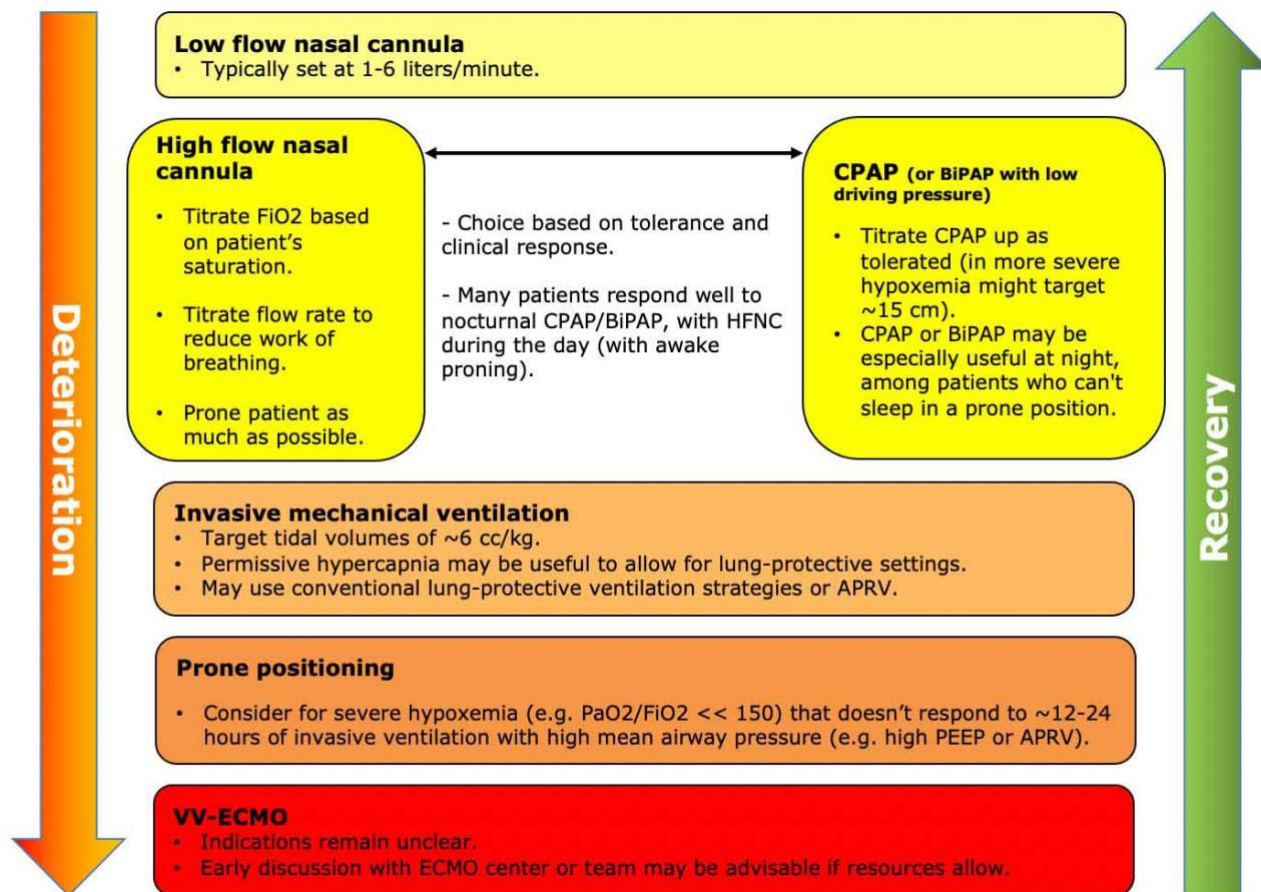


Figure 11. COVID-19 Testing during Influenza Season; RSV, respiratory syncytial virus

## MANAGEMENT OF CRITICAL COVID-19: OXYGEN & ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

1. Give supplemental oxygen therapy immediately to patients with respiratory distress, hypoxemia, or shock and target SpO<sub>2</sub> 92-96%. (106, 107) Hyperoxia (PaO<sub>2</sub> >225mmHg) should be avoided and is associated with worse outcomes. (108)
2. Begin with low flow nasal cannula (1-6 L/min) followed by high flow nasal cannula (**Figure 12**).
3. **High-flow nasal cannula (HFNC)**. Although once an area of controversy, current expert opinion favors HFNC over other NIV modalities because it appears to be well tolerated and less aerosolizing. There is presently no definitive evidence that HFNC augments transmission of virus, but HFNC will disperse air farther the higher the flow is set, (but not as far as CPAP). (109) A surgical mask should be placed over the HFNC in an effort to minimize aerosolization risk, especially in patients who are not in an airborne infection isolation room (AIIR). Consider a trial of non-invasive ventilation (NIV) to improve atelectasis if the patient is increasingly hypoxic despite high (>80%) FiO<sub>2</sub>. (110)
4. **Non-invasive ventilation (NIV)**. While previously there were recommendations to avoid NIV out of fear of aerosolization, current guidance is that NIV, with a good tight fitting seal, can be considered in order to treat the atelectasis component of COVID lung disease. Ideally, observe the patients response in the first few hours. Those with progressive hypoxia and/or increased work of breathing despite NIV should be considered for intubation. (110, 111)
5. **Awake proning**. Awake proning has been shown to decrease the incidence of intubation or death in patients on HFNC with acute hypoxemic respiratory failure due to Covid-19 pneumonia in a large meta-analysis and should be considered in all patients on HFNC. See **Appendix G** for full protocol for prone positioning of non-intubated patients. (163)(112, 113)
6. **Aggressive fluid resuscitation may worsen oxygenation** and outcomes in both children and adults, so in the absence of shock, fluid boluses should be minimized. Consider no more than 30 ml/kg ideal body weight (IBW) of isotonic crystalloid for adult patients, assuming no ongoing active fluid losses (e.g., from diarrhea).
7. **Admission studies and labs**: Consider the following diagnostic studies in **Table 2** for diagnosis, prognosis and risk stratification (and/or safety of agents) for all hospitalized patients with confirmed COVID-19 and for PUIs.

## General schema for respiratory support in patients with COVID-19



The optimal strategy for respiratory support in COVID-19 remains unknown. Patients with more complex respiratory disease (e.g. COPD plus COVID) might benefit more from BiPAP. Choice of CPAP vs. HFNC may vary depending to resources and patient preference. COVID appears to cause progressive micro-atelectasis, which responds well to CPAP.

-The Internet Book of Critical Care

**Figure 12.** General Schema for Respiratory Support in Patients with COVID-19 (<https://i1.wp.com/emcrit.org/wp-content/uploads/2020/03/respsup.jpg?resize=713%2C600&ssl=1>).

**Table 2.** Laboratory and Study Considerations for Hospitalized Patients with COVID-19 (or PUI), <https://emcrit.org/pulmcrit/nlr/>

#### Recommended Daily Labs:

- Complete Blood Count (CBC) with differential (trend neutrophil-lymphocyte ratio, NLR)\*
- Complete metabolic panel (CMP)
- C-reactive protein
- D-dimer

#### Recommend on Admission (may repeat q2-3 days if abnormal or with clinical deterioration)

- PT/PTT, Fibrinogen
- Ferritin
- LDH
- SARS-CoV-2 RT-PCR testing (e.g., CDC EUA assay, Biofire COVID-19 panel, Hologic, etc.)
- Electrocardiogram (ECG) (consider utilization of telemetry with severe infection; ECG if changes on telemetry)
- Portable CXR

#### If Clinically Indicated

- Blood cultures
- Troponin and BNP (if suspect acute coronary syndrome or heart failure)
- Tracheal aspirates for intubated patients
- Viral serologies if LFTs are elevated if clinically indicated (HBV sAb/cAb/sAg, HCV Ab, HIV q/2 Ab/Ag)
- For acute kidney injury (i.e. serum creatinine >0.3 above baseline), send urinalysis and spot urine protein: creatinine)
- Procalcitonin

### Endotracheal Intubation

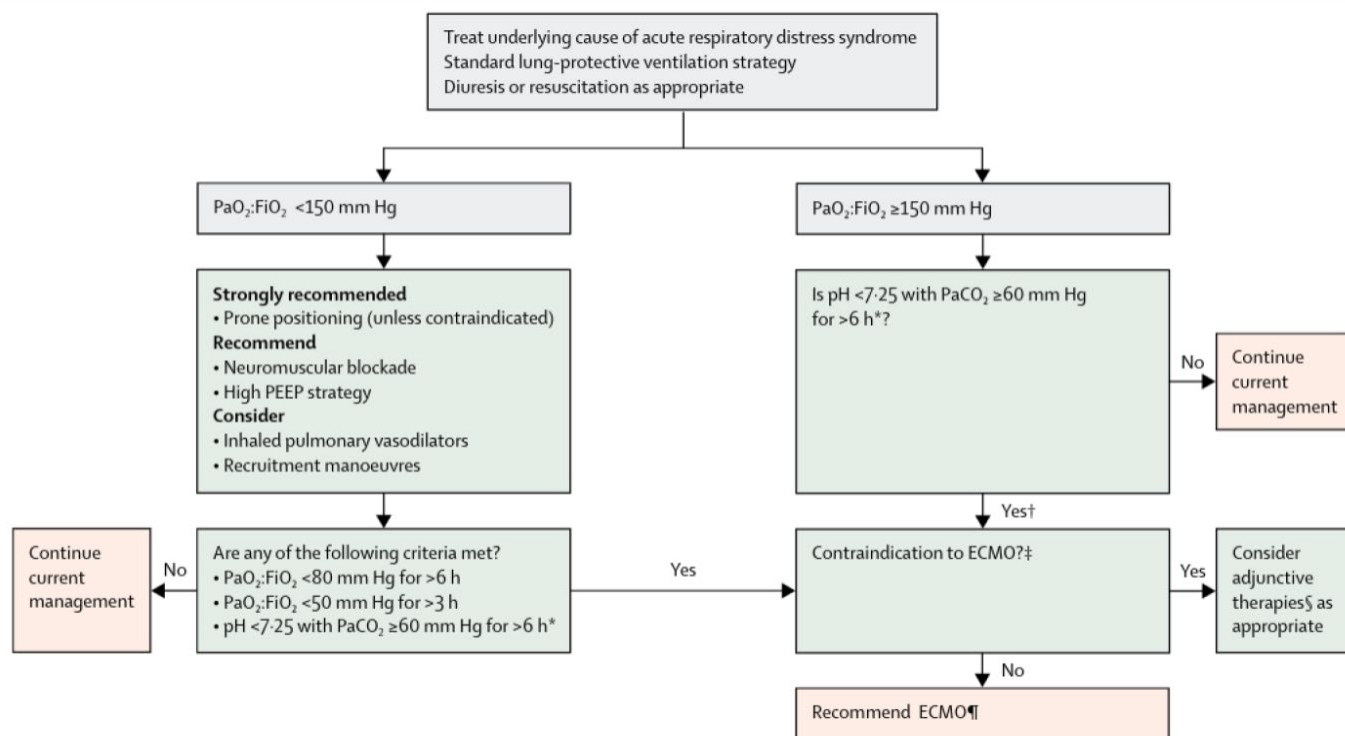
1. **Decision to intubate:** Neither a practice of ‘early intubation’ (reflexive decisions to intubate once a patient requires more than 5-6 L/m of oxygen), nor ‘permissive hypoxemia/happy-hypoxemic’ (allowing patients to persist with an oxygen saturation of lower than 88% for prolonged duration in order to avoid harms of intubation and mechanical ventilation) are NOT evidence based and should not be used. Clinical decisions to intubate should be based on existing evidence-based guidelines balanced with evolving knowledge regarding COVID-19 and preserving healthcare staff safety.
2. **Clear indications to intubate include progressive hypoxemia, hypercarbia or decreasing mental status, and progressive dyspnea.**
3. Intubation has the highest risk of aerosolization and exposure to COVID-19 of all procedures, and the person performing intubation is most at risk.(114) A PAPR may be used however, standard droplet and airborne precautions including gown, N95 mask, gloves, eye protection, and hair net are required when intubating known or suspected COVID-19 patients.
4. A pre-intubation checklist is encouraged, which should include supplies to be brought inside the room by specific team members and others that should remain outside the room. **Appendix H** provides an example intubation checklist (adapted from University of Washington). *Note: a disposable stethoscope should be used to avoid viral transfer and staff should touch as little as possible in the room to avoid fomites.*
5. For patients with a normal airway assessment, awake intubation should be avoided and modified RSI with sufficient muscle relaxation is strongly encouraged. For patients with difficult airways, good preparation of airway devices and detailed intubation plans should be made in advance.(115)
6. **Appendix H** also provides a framework for intubation with medications and doses, although this is not a substitute for clinical judgement. Example cognitive aids are also located in this Appendix.
7. **Extubation:** While the risks of aerosolization of COVID-19 during intubation have been well described, there has been less attention paid to extubation. During intubation, particularly with RSI, paralytics limit coughing and patient movement. During extubation, coughing can be pronounced and difficult to control. A protective algorithm similar to intubation should be used for extubation. **Appendix I** provides an example protocol, which was adapted from University Medical Center in Las Vegas, NV.

### Management of ARDS after Intubation

1. **Mechanical Ventilation:** It has been reported that many patients with COVID-19 pneumonia are initially characterized by a low elastance and high compliance despite severe hypoxemia, which is generally not observed in typical ARDS.(116) Despite this difference, the best available data demonstrates that a low tidal volume approach with appropriate PEEP as described below is the most effective treatment strategy for ARDS.(107, 117)
  - a. Target an *ARDSnet lung-protective strategy (4-8 mL/kg ideal body weight)*, and lower inspiratory pressures (**plateau pressure <30 cm H<sub>2</sub>O**).
    - i. Start with 6 mL/kg ideal body weight tidal volume and titrate to as high as 8 mL/kg as long as the lungs are compliant.
    - ii. In patients with moderate to severe ARDS, suggest titrating to a higher PEEP as tolerated. PEEP tables are available to guide titration: <http://www.ardsnet.org/tools.shtml>
  - b. *Permissive hypercapnia* ensuring adequate hemodynamics and a pH >7.15 may be tolerated.
  - c. Humidification will likely be needed to manage thick secretions. However, keep in mind the risk of aerosolization associated with breaking the circuit to change heat and moisture exchangers (HME) if this is all that is available. Ventilators with heated humidifiers do not require breaking the circuit to humidify the inspiratory limb and are preferred. Consider clamping the ETT during any circuit breaks.
2. **Proning:** Evidence has shown that patients who are unable to adequately ventilate in the supine position benefit from being placed in the prone position to improve oxygen saturation (PaO<sub>2</sub>), pulmonary mechanics, and arterial blood gases (ABGs).(118-122)
  - a. Prone positioning requires proper sedation/pain medications and paralytic agents if necessary.
  - b. Length of pronation cycle should be a minimum of 16 hours in the prone position with a return to supine positioning at least once a day.



- c. Prone positioning should be performed as clinically indicated within the first 24 hours of the diagnosis of severe hypoxemia.
  - d. Recommend use of a manual proning protocol with coordination if mechanical beds are not available. **Appendix G** provides an example protocol, which was adapted from University Medical Center in Las Vegas, NV. Additional protocols (including videos) are available.
  - e. Pregnancy is *not* a contraindication for proning or neuromuscular blockade.(123)
  - f. Consider the facility and staff safety and capacity for proning. Proning requires significant PPE and personnel resources (occupy staff in patient room for prolonged period of time). Circuit disconnection and loss of vascular access are among potential risks. The loss of manpower during proning and repositioning may be a contraindication in resource limited environments.
3. **Neuromuscular blockade:** In patients with moderate-severe ARDS ( $\text{PaO}_2/\text{FiO}_2 < 150$ ), neuromuscular blockade by continuous infusion should **not** be routinely used, but may be considered in the setting of worsening hypoxia or hypercapnia and in situations where the patient's respiratory drive cannot be managed with sedation alone resulting in ventilator dyssynchrony and lung decruitment.
  4. **Airway suctioning:** Use in-line catheters for airway suctioning and clamp endotracheal tube when disconnection is required (for example, transfer to a transport ventilator). Avoid disconnecting the patient from the ventilator, which results in loss of PEEP and atelectasis.
  5. **Bronchoscopy:** Routine diagnostic bronchoscopy (including nasal endoscopy or any instrumentation of this area) is **not** recommended. It is not necessary for the diagnosis of viral pneumonia and should be avoided to minimize aerosolization. Tracheal aspirate samples for diagnosis of COVID-19 are usually sufficient. If bronchoscopy is required for another reason, it should be performed with the same level of PPE as recommended for intubation.
  6. **Inhaled nitric oxide and prostacyclin:** There is no evidence demonstrating improved outcomes for patients receiving either prostacyclin analogues, such as epoprostenol, or NO.(124) However it is reasonable to initiate this therapy for refractory hypoxemia.
  7. **Extracorporeal membrane oxygenation (ECMO):** Consider early discussion with an ECMO center for patients with refractory hypoxemia despite lung protective settings. Referral centers will have specific criteria to identify potential ECMO candidates. **Figure 13** provides further information on ARDS management and consideration of ECMO For more information: <https://www.elso.org/COVID-19>.



**Figure 13.** Algorithm for management of acute respiratory distress syndrome, including indications for ECMO. (4)

\*With respiratory rate increased to 35 breaths per minute and mechanical ventilation settings adjusted to keep a plateau airway pressure of <32 cm H<sub>2</sub>O. †Consider neuromuscular blockade. ‡There are no absolute contraindications that are agreed upon except end-stage respiratory failure when lung transplantation will not be considered; exclusion used in the EOLIA trial (7) can be taken as a conservative approach to ECMO contraindications. §For example, neuromuscular blockade, high PEEP strategy, inhaled pulmonary vasodilators, recruitment maneuvers, and high-frequency oscillatory ventilation. ¶Recommend early ECMO as per EOLIA trial criteria; salvage ECMO, which involves deferral of ECMO initiation until further decompensation (as in the crossovers to ECMO in the EOLIA control group), is not supported by the evidence but might be preferable to not initiating ECMO at all in such patients. Credit: Abrams et al.(11). ECMO, extracorporeal membrane oxygenation; EOLIA, Extracorporeal Membrane Oxygenation to Rescue Lung Injury in Severe Acute Respiratory Distress Syndrome; PaCO<sub>2</sub>, partial pressure of carbon dioxide in arterial blood; PaO<sub>2</sub>:FiO<sub>2</sub>, ratio of partial pressure of oxygen in arterial blood to the fractional concentration of oxygen in inspired air; PEEP, positive end-expiratory pressure.

### Oxygen Delivery and Mechanical Ventilation in Settings with Resource Limitations

1. As the COVID-19 pandemic places additional strain on available resources, the supplies of available ventilators may not meet clinical demand of patients in respiratory failure in need of invasive positive pressure ventilation (IPPV). Facilities should assess respiratory support operational status as needed to account for equipment including ventilators, medications (induction agents, anxiolytics, sedatives, analgesics and paralytics), and staffing (respiratory therapists, providers and nurses).
2. Facilities must be prepared with alternate methods to support patients requiring IPPV in the event the number of patients with respiratory failure exceeds the number of ventilators. Alternate strategies in a crisis resource-limited clinical environment include the following:(125-128)
  - a. Deliver manual breaths via a manual resuscitator (“self-inflating bag”).
  - b. Transport mechanical ventilators may be used for prolonged ventilation of stable patients in the MTF (e.g. Impact 754 and 731 transport ventilators, see **Appendix J**), but need to be used with a viral filter.
  - c. Ventilators in storage (Home Station Medical Response materiel, War Reserve Material, and national stockpiles)
  - d. Anesthesia gas machines capable of providing controlled ventilation or assisted ventilation outside of the traditional use for anesthetic indication.

- e. Some non-invasive ventilators (e.g., for CPAP or BiPAP) can be used for invasive mechanical ventilation, but should only be used if the standard ventilator supply is exhausted and it is confirmed with the manufacturer (e.g V60) that they are invasive capable and can deliver prescribed breaths. In this case, a HEPA filter should be inserted into the expiratory limb to prevent aerosolization.
3. Conserve accessories used with ventilators, but use viral filters if available. Consider extending the duration of use of breathing circuit supplies and in-line heat and moisture exchangers for treating individual patients.
4. In accordance with professional society consensus statements, U.S. Public Health Service, and FDA guidance:
  - a. Use FDA-cleared conventional/standard full-featured ventilators to support patients with respiratory failure.
  - b. Use one ventilator per patient, matching ventilator settings with the patient's individual respiratory requirements.
  - c. While ventilators may have mechanical capacity to split circuits to support multiple patients, it is excessively difficult to safely implement. There is insufficient body of evidence to support consistent application of this practice. Neither research using animals and test lungs nor case reports of crisis or contingency application of this technique establish clinical safety.

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## MANAGEMENT OF CRITICAL ILLNESS AND COVID-19: PREVENTION OF COMPLICATIONS

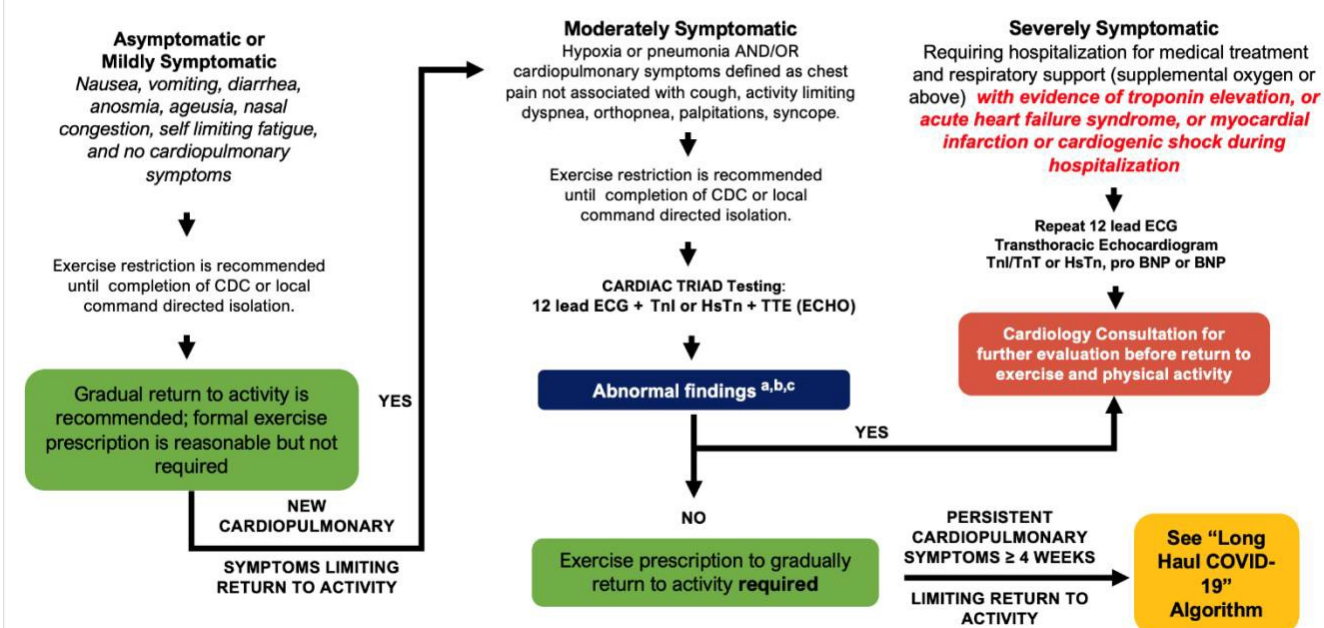
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### Cardiovascular Disease (CVD)

Cardiovascular comorbidities and the presence of CVD are common in patients with COVID-19 infections.

1. **Cardiovascular disease and acute SARS-CoV2 infection:**
  - a. **Underlying Cardiac Risk Factors and outcome in COVID-19:** Multiple reports have consistently demonstrated that cardiovascular risk factors (hypertension, diabetes, obesity, and smoking) are significant risk factors for increased disease severity and mortality. Age has been found to be the strongest predictor for severe disease and mortality,(129) with increased BMI being another strong predictor for severe disease and mortality.(130)
  - b. **Myocardial Injury in COVID 19:** Myocardial injury (as defined by the 4<sup>th</sup> Universal Definition of Myocardial infarction) is common in hospitalized patients with COVID-19 and is a strong predictor of mortality. Mortality rates have a linear relationship with degree of myocardial injury with mortality rates up to 65% in those with troponin levels 10x the upper limits of normal.(131-133) Most recent data suggest that acute, nonischemic myocardial injury is the predominant mechanism, driven by underlying etiologies such as stress cardiomyopathy, acute heart failure, pulmonary embolism, critical illness, sepsis, and myocarditis.(130)
  - c. **Acute Heart Failure in COVID-19:** Acute heart failure syndrome is suggestive of cardiac involvement in patients infected with SARS-CoV2, with reported rates of acute heart failure in up to 33% of hospitalized patients.(130, 132) Recent studies have demonstrated an increase in rates of right sided heart failure associated with an increased mortality risk among hospitalized COVID-19 patients.(134-136)
  - d. **Arrhythmias in COVID-19:** Arrhythmias are a common complication among COVID-19 patients. It is estimated that up to 18% of cases experience an abnormal rhythm during their course of disease with atrial fibrillation/flutter being the most common and 4-6% of hospitalized patients experience ventricular tachycardia/fibrillation.(137) Both outside hospital and in hospital cardiac arrest is common among critically ill COVID-19 patients and is a strong predictor of 30-day mortality.(138)
2. **Return to Exercise and Physical Activity following SARS-CoV2 Infection:** At the beginning of the pandemic, concerns existed for the potential risk surrounding COVID-19-myocarditis. Recent studies suggest that myocarditis is not as prevalent as initially thought and is particularly rare in athletic cohorts and cohorts with few comorbidities.(139, 140) Most recent evidence recommends a stepwise approach that uses the combination of moderate or severe cardiovascular symptoms with abnormal screening tests (electrocardiogram, echocardiogram, and cardiac biomarkers) to trigger further evaluation with cardiac MRI (CMR).(140) **Figure 14** illustrates a recommended flow diagram for return to exercise following infection.

## Return to Exercise and Physical Activity following COVID-19 Infection



**Figure 14.** Return to Exercise and Physical Activity Recommendations following COVID-19 infection. Patients with no symptoms or mildly symptomatic infection do not require further evaluation and can return to physical activity without an exercise prescription. Moderate to severely symptomatic patients require further evaluation prior to returning to duty. (ECG, electrocardiogram; Tnl, Troponin I; HsTn, high sensitivity troponin; TTE, transthoracic echocardiogram; BNP, B-type natriuretic peptide). See **Appendix K**.

**a: Abnormal ECG findings:** pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions, intraventricular conduction delays (BBB), AV nodal conduction delays (high grade AV block) that are outside of the normal parameters in athletes (<https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.01.015>)

**b: Abnormal Troponin:** >99<sup>th</sup> percent upper limit of normal levels for Tnl/TnT or High Sensitivity Troponin I/T.

**c: Abnormal TTE (ECHO):** regional wall motion abnormalities, dilated ventricles, abnormal right or left ventricular systolic function with a reduced EF <45%, moderate pericardial effusion, severe valvular disease, or pulmonary hypertension.

### 3. Post- Acute Sequelae of SARS-CoV-2 Infection (PACS) and the Cardiovascular System:

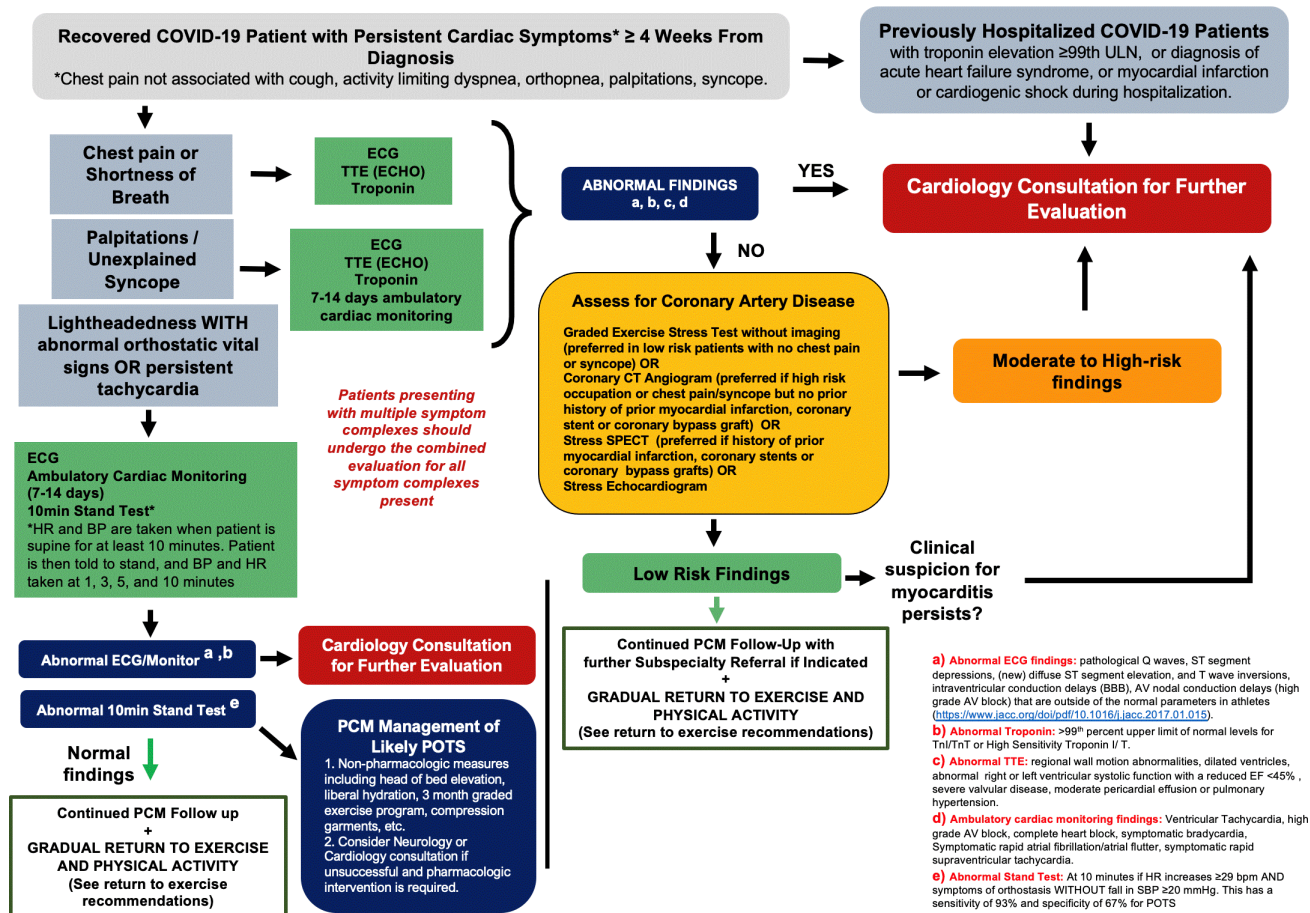
- a. **Definition:** A substantial minority of patients with a prior COVID-19 infection do not completely recover in the months following hospitalization or diagnosis and continue to experience cardiovascular symptoms such as dyspnea, chest pain, palpitations, thromboembolic events, and impaired quality of life.(141) We define cardiovascular symptoms from Post- Acute Sequelae of SARS-CoV-2 Infection (PACS) as persistent cardiovascular symptoms beyond four weeks from the onset of symptoms, with two sub categories:(142)
  - i. **Subacute** (ongoing symptomatic COVID-19) – symptoms or abnormalities present from 4-12 weeks from COVID-19 diagnosis.
  - ii. **Chronic-** symptoms or abnormalities not attributed to alternative diagnoses beyond 12 weeks from COVID-19 diagnosis.
- b. The most common cardiovascular symptoms reported are:(130, 141-143)
  - i. Shortness of breath at rest or with exertion
  - ii. Chest pain
  - iii. Palpitations / Arrhythmias or Tachycardia with autonomic dysfunction - inappropriate sinus tachycardia (IST) and postural orthostatic tachycardia syndrome (POTS)
- c. **Potential mechanism:** The potential mechanism of injury in the cardiovascular system remains poorly understood. It is suspected to be attributed to endothelial damage, myocardial injury (ischemic and acute non-ischemic), myocardial fibrosis, or scarring leading to cardiac remodeling and heart failure.



Proarrhythmic conditions from a heightened catecholaminergic state (direct cardiotropic effects from the infection or its hyperinflammatory response leading to adrenergic modulation following viral illness) are also a potential mechanism for cardiac arrhythmias among COVID-19 patients.(142, 143)

- d. **Evaluation of symptoms:** The challenge in evaluating cardiac symptoms is determining whether symptoms are due to PACS or underlying cardiovascular disease. Evaluation in the presence of PACS requires a multi-disciplinary approach. The provided algorithm in **Figure 15** aims to evaluate potential CV diagnoses as the etiology of symptoms with the evidence for each summarized below:

### Cardiac Evaluation for “Long Haul COVID-19” or Post-Acute Sequelae of SARS-CoV-2 Infection (PACS)



**Figure 15.** Cardiac Evaluation for Long Haul COVID 19 or PACS in patients with persistent symptoms. Patients with multiple symptom complexes should undergo the combined evaluation for all symptom complexes present.

- i. **Myocardial injury, heart failure during hospitalization, or cardiogenic shock:** Myocardial injury in COVID 19 patients is associated with an up to a 3x higher likelihood of major adverse cardiac events at five months post discharge.(133, 143) Adverse RV remodeling with associated right ventricular systolic dysfunction is associated with increased mortality risk among hospitalized patients 16,17. Given this increased risk of mortality and adverse events, hospitalized patients with evidence of myocardial injury, acute heart failure, myocardial infarction, or cardiogenic shock during hospitalization benefit from further cardiology evaluation and follow-up care.
- ii. **Chest pain and shortness of breath:** Nearly 40% of patients recovering from COVID-19 experience persistent shortness of breath, while 20% experience persistent chest pain at a 60-day follow up.(141, 142) The etiology of chest pain or dyspnea can be due to potential underlying coronary artery disease or underlying non-ischemic myocardial injury. Studies have shown that patients with COVID-19 often have cardiovascular risk factors such as hypertension, diabetes, obesity,

hyperlipidemia, or known coronary artery disease (CAD).(144) Patients experiencing chest pain or dyspnea with risk factors for CAD (with initial findings not suggestive of myocarditis) need further evaluation for underlying coronary artery disease.

- iii. **Palpitations or Unexplained Syncope:** Arrhythmias are a common complication in patients hospitalized with COVID-19. Palpitations occur in nearly 10% of patients recovering from COVID-19.(141) Recent data from the VA system suggests an almost two-fold higher incidence of arrhythmias at six months following COVID-19 infection.(145) Patients experiencing persistent palpitations or unexplained syncope need further evaluation for underlying arrhythmias.
- iv. **Lightheadedness with orthostatic vital signs or persistent tachycardia:** Case series have also reported a possible correlation between orthostatic intolerance and non-hospitalized patients recovering from COVID-19.(146-148) Characteristics of postural orthostatic tachycardia syndrome (POTS) include symptoms that occur with standing and result in an inappropriate rise in HR (>30 bpm, or >40 bpm if 12-19 years old) without associated fall in systolic blood pressure by more than 20 mmHg. This condition may be responsible for complaints of palpitations, chest pain, and dizziness in some patients.(147-149)
- e. **Management and Recommendations:**
  - i. Urgent evaluation is recommended for patients presenting with symptoms concerning for acute coronary syndrome, aborted sudden cardiac arrest, or other high-risk cardiac conditions.
  - ii. Cardiology should manage cardiovascular conditions (myocarditis, myopericarditis, obstructive coronary artery disease, congestive heart failure, severe valvular disease, and high-risk arrhythmias) in coordination with primary care clinicians with individualized treatment plans based on published established clinical guidelines. Patients with persistent palpitations with no evidence of underlying structural heart disease or other abnormal cardiac findings may require more prolonged event monitoring if 7–14 days ambulatory cardiac monitoring is unable to obtain a symptom-rhythm correlation. If in doubt, cardiology can assist with the decision to pursue more prolonged monitoring.
  - iii. In patients with symptoms of autonomic dysfunction in the absence of underlying cardiac abnormalities, further evaluation with neurology is strongly encouraged. In patients with symptoms of dyspnea or dyspnea disproportionate to the degree of cardiac disease, further evaluation with pulmonology is strongly encouraged.

#### 4. **SARS-CoV-2 Vaccination and Myocarditis:**

##### a. **Clinical presentation:**

- i. Myocarditis occurring after administration of COVID-19 mRNA vaccines (Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273) was noted by the US military in early 2021.(150) Cases with similar presentations have been documented in the US non-military population and international communities.(151-154)
- ii. The classic clinical presentation of COVID-19 vaccine-related myocarditis is acute chest pain, with average time of onset 3 days (range 1-28 days) after vaccination. Pericarditis most often occurs in conjunction with myocarditis, but when observed in isolation, the onset of chest pain may be somewhat later, with an average of 5 days (range 1-28 days) after vaccination.(153, 155)

##### b. **Incidence:**

- i. The incidence of myocarditis as an adverse event following COVID-19 vaccination is highly dependent on the sex and age of the patient, as well as vaccine dose and type. As a vaccine-related safety signal, myocarditis has been most firmly established in younger (under age 25 years) male patients after receiving their 2<sup>nd</sup> dose of mRNA (Pfizer-BioNTech or Moderna) vaccine. Although increased rates of myocarditis are also suggested in female patients, rates of myocarditis in younger female patients after the 2<sup>nd</sup> dose of mRNA vaccine are much lower than rates in male patients.
- ii. A safety signal for myocarditis has not been clearly established after non-mRNA vaccines (e.g., Janssen), after first dose of vaccine, or in patients over age 40 years.(156)

- iii. It is important to note that the background rate of myocarditis in the general population is estimated as 1-10 cases per 100,000 persons per year.(157) This background suggests an expected rate of 0.2 to 1.9 cases per million vaccine doses in the seven days following vaccination. Observed rates (including 95% confidence limits) are only clearly higher than expected rates among younger male patients after the 2<sup>nd</sup> dose of Pfizer or Moderna vaccine. The COVID-19 associated myocarditis is both more frequent and more severe than vaccine associated myocarditis.
- iv. The U.S. military has observed more than 50 cases of this AEFI in service members and beneficiaries (as of Aug 1, 2021). The military experience (**Table 3a**) is very consistent with the overall US experience (stratified by age and sex), as reported by CDC (**Table 3b**).

**Table 3a.** Incidence of myocarditis after COVID-19 vaccination per million doses, as reported by DoD

Males					Females			
Age (years)	Pfizer dose #1	Pfizer dose #2	Moderna dose #1	Moderna dose #2	Pfizer dose #1	Pfizer dose #2	Moderna dose #1	Moderna dose #2
12-17	0.0 (0.0-34.0)	<b>124.1</b> (15.3-232.9)	N/A	N/A	0.0 (0.0-34.1)	24.6 (0.0-72.8)	N/A	N/A
18-24	11.3 (0.0-26.9)	<b>54.7</b> (16.8-92.6)	16.3 (0.0-39.0)	<b>118.4</b> (48.4-188.3)	0.0 (0.0-27.2)	17.9 (0.0-53.0)	0.0 (0.0-41.2)	29.1 (0.0-86.3)
25-29	3.2 (0.0-9.4)	14.9 (0.3-29.5)	0.0 (0.0-6.8)	<b>23.1</b> (2.8-43.3)	6.3 (0.0-18.7)	0.0 (0.0-14.2)	8.2 (0.0-24.2)	10.2 (0.0-30.1)
40+	0.0 (0.0-6.3)	15.5 (0.3-30.7)	0.0 (0.0-7.4)	9.8 (0.0-23.3)	0.0 (0.0-7.9)	0.0 (0.0-9.0)	0.0 (0.0-11.1)	7.0 (0.0-20.8)

Source: DHA Immunization Healthcare Division data, rates (with 95% confidence limits), presented to the COVID-19 Vaccine Safety Technical (VaST) Subgroup, Sep 27, 2021.

**Table 3b.** Incidence of myocarditis after COVID-19 vaccination per million doses, as reported by the CDC

Males					Females			
Age (years)	Pfizer dose #1	Pfizer dose #2	Moderna dose #1	Moderna dose #2	Pfizer dose #1	Pfizer dose #2	Moderna dose #1	Moderna dose #2
12-15	<b>4.2</b>	<b>39.9</b>	N/A	N/A	0.4	<b>3.9</b>	N/A	N/A
16-17	<b>5.7</b>	<b>69.1</b>	N/A	N/A	0.0	<b>7.9</b>	N/A	N/A
18-24	2.3	<b>36.8</b>	<b>6.1</b>	<b>38.5</b>	0.2	2.5	0.6	<b>5.3</b>
25-29	1.3	<b>10.8</b>	<b>3.4</b>	<b>17.2</b>	0.2	1.2	0.4	<b>5.7</b>
30-39	0.5	<b>5.2</b>	2.3	<b>6.7</b>	0.6	0.7	0.5	0.4
40-49	0.3	2.0	0.2	2.9	0.1	1.1	0.2	1.4
50-64	0.2	0.3	0.5	0.6	0.3	0.5	0.5	0.4
65+	0.2	0.1	0.1	0.3	0.1	0.3	0.0	0.3

Source: US Vaccines Adverse Event Reporting System (VAERS) data presented by Dr. John Su, on behalf of the CDC COVID-19 Vaccine Task Force to the Advisory Committee on Immunization Practices (ACIP), October 21, 2021.

- v. Additional published incidence rate estimates of myocarditis as an AEFI,(152, 154, 158) are summarized in **Table 4**. Because the safety signal for myocarditis has only been identified in younger patients, estimating the incidence of myocarditis as an AEFI in the general population of vaccine recipients may obscure the signal. Comparing the incidence of myocarditis between different populations may only be done appropriately by stratifying or adjusting for age and sex.
- c. **Risk/Benefit of COVID-19 Vaccination:**
  - i. Using estimates of current risk for SARS-CoV-2 virus transmission, the benefits of vaccination
  - ii. substantially outweigh the risks of vaccination.(151, 156, 159)



**Table 4.** Incidence of myocarditis after COVID-19 vaccination as reported in largest published cohorts

COVID 19 Vaccine Related Myocarditis Incidence Rates and Cases				
Database Cohort	Vaccination Doses	Incidence Rate	Age Group	Myocarditis Cases Observed
<b>Kaiser Permanent Southern California</b>	2,392,924 patients who received at least 1 dose of COVID mRNA vaccine (50% Moderna, 50% Pfizer)	0.8 per million individuals after 1 <sup>st</sup> dose 5.8 per million individuals after 2 <sup>nd</sup> dose	49 years median age (IQR 34-64 years)	15 Cases: 2 after first dose, 13 after second dose. All men with a median age of 25 years All mild cases with conservative management
<b>Clalit Health Services (Israel)</b>	2,558,421 patients who received at least 1 dose of COVID mRNA vaccine (100% Pfizer)	21.1 cases per million individuals vaccinated.	44 years median age (IQR 30-63 years)	54 Cases: 69% of cases after second dose. 94% men 6% female median age of 27 years 41 mild cases, 12 intermediate cases, 1 fulminant myocarditis case. 65% discharged without ongoing medical treatment.
<b>Israel Ministry of Health Database</b>	9,289,765 patients who received at least dose of COVID mRNA vaccine (100% Pfizer)	30.46 per million individuals vaccinated	Not provided	283 cases: 83% of cases after second dose. 91% males, 76% under the age of 30 years 5% deemed moderate to severe. 1 fulminant myocarditis case subsequently died.

- iii. The CDC estimates that even among the groups at highest risk for myocarditis as an AEFI, many more SARS-CoV-2 hospitalizations, ICU admissions, and deaths are prevented from vaccination, relative to possible cases of vaccine-related myocarditis as presented in **Table 5**.

**Table 5.** Estimated COVID-19 outcomes prevented during 120 days after 2-dose mRNA COVID-19 vaccination by sex and age group – United States 2021\*

Age Groups (yrs)	Benefits: SARS-COVID-19 Outcomes Prevented Pfizer or Moderna Covid 19- Vaccine <sup>tb</sup>				Harms: Adverse Events <sup>†</sup>
	Cases	Hospitalizations	ICU admissions	Deaths	Myocarditis
<b>Females</b>					
18-29	12,800	750	50	5	3-4
30-49	14,600	950	140	20	1-2
50-64	17,500	1700	375	125	1
≥65	32,000	6200	1300	900	<1
<b>Males</b>					
18-29	9,600	300	60	3	22-27
30-29	11,000	700	160	25	5-6
50-69	14,700	1900	500	150	1
≥65	52,700	12500	3500	2400	1

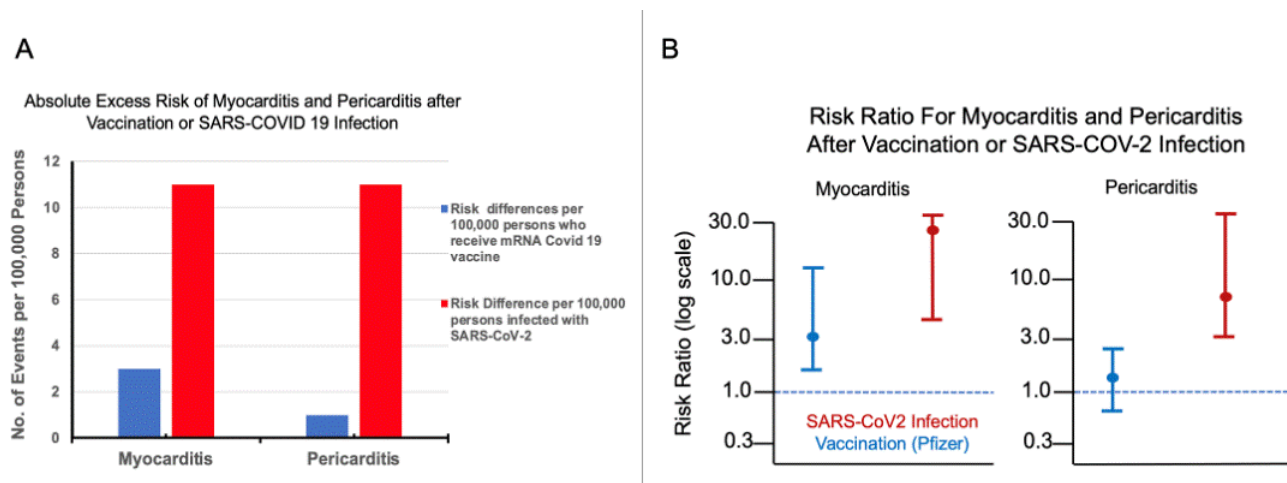
Adapted from Rosenblum et al. MMWR Morb Mortal Wkly Rep. 2021;70(32):1094-1099.

<sup>†</sup> Estimates based on an estimated risk of cases per million doses administered with a +/- 10% range.

<sup>tb</sup> Benefits and harms are calculated per million second doses of mRNA (Pfizer and Moderna) vaccine administered.

\* Benefits and harm calculated using incidence of hospitalization data for the week ending June 19, 2021. For harms using cases through June 30 projected for a 120-day period.

- iv. When comparing the risk of myocarditis and pericarditis following SARS-CoV-2 infection to the risks following COVID-19 vaccination, the benefits of immunization favor administration of the vaccine as outlined in **Figure 16**.



**Figure 16. A)** Point estimates of the risk differences for myocarditis and pericarditis. Risk differences are per 100,000 persons. Increased risks are positive values on the Y-axis. **B)** Estimated risk ratios for myocarditis and pericarditis after vaccination or SARS CoV2 infection. I bars indicate 95% confidence intervals.

**d. Areas of Clinical Uncertainty:**

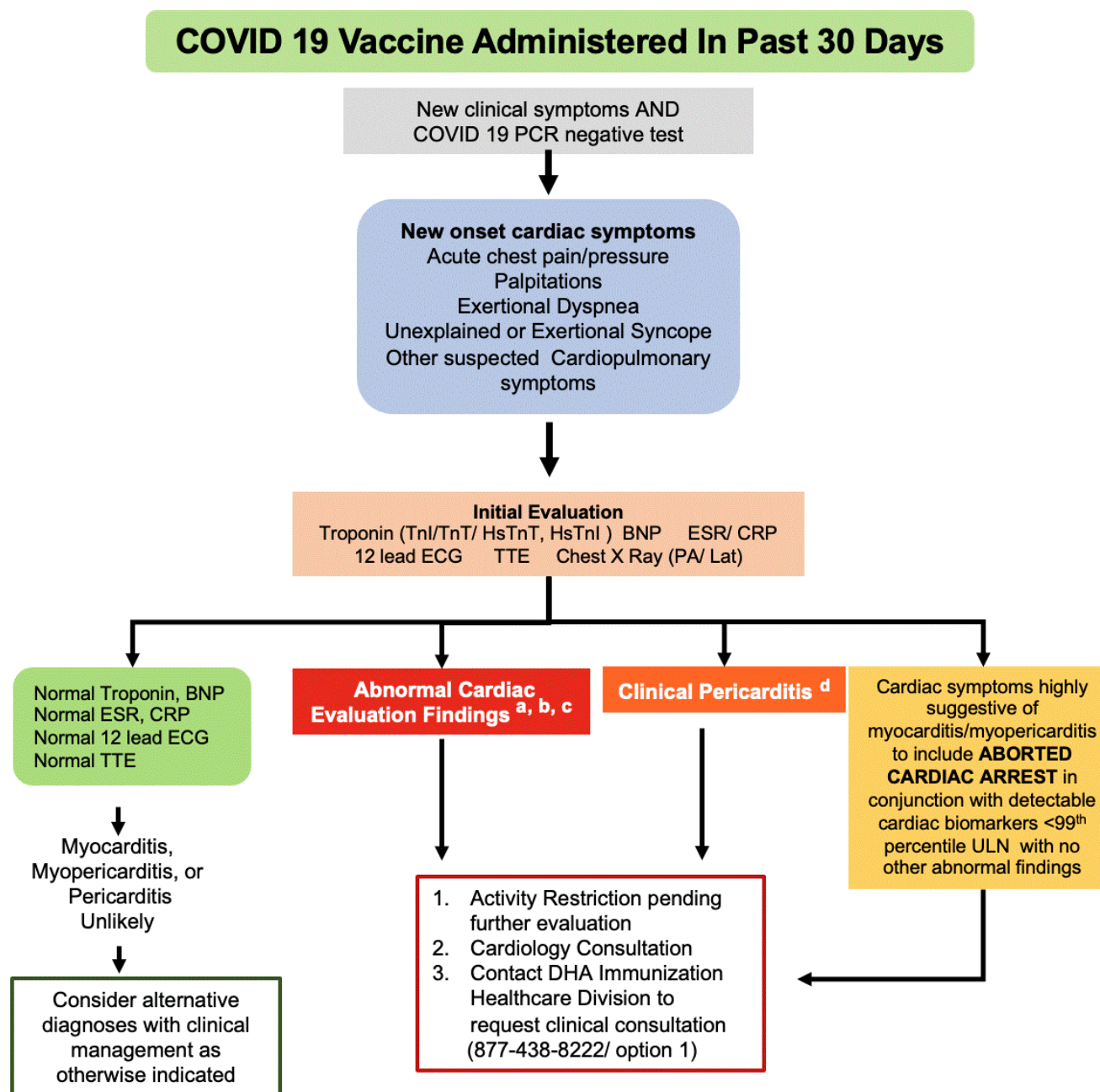
- i. Rates of myocarditis and pericarditis after booster doses of COVID-19 vaccine are uncertain, as booster vaccination was FDA-authorized in Sep 2021 (for Pfizer vaccine) and Oct 2021 (for Moderna and Janssen vaccines). Similarly, risk has not been defined after vaccination with a mixed series of COVID-19 vaccine products.
- ii. The risk of myocarditis and pericarditis in patients under age 12 years is not well defined, since clinical trials in this age group were not statistically powered to identify this safety signal. The FDA authorized a lower-dose Pfizer vaccine for children ages 5-11 years in Oct 2021, and the CDC subsequently recommended vaccination based on overall risk-benefit evaluations. In the ensuing 3 months, there has been no reported safety signal of concern.
- iii. Additionally, there is no robust study to date examining the risk of COVID-19 vaccination in patients who previously experienced myocarditis or pericarditis after either infection or vaccination.

**e. Diagnosis of Vaccine-Related Myocarditis:**

- i. We provide an updated algorithm in **Figure 17** to assist in evaluating suspected myocarditis following vaccination with important considerations discussed below.
- ii. Important considerations to remember as part of the evaluation:
  - **Time of Onset:** The classic clinical presentation of COVID-19 vaccine-related myocarditis is acute chest pain, with average time of onset 3 days (range 1-28 days) after vaccination. Pericarditis most often occurs in conjunction with myocarditis, but when observed in isolation, the onset of chest pain may be somewhat later, with an average of 5 days (range 1-28 days) after vaccination.(153, 155)
  - **Cardiac MRI:** Cardiac MRI is not a screening study in asymptomatic patients outside of an approved research protocol. More recent CMR studies comparing athletes recovering from COVID-19 to healthy athletic controls have noted indistinguishable rates of patterns of late gadolinium enhancement between groups (22% focal LGE at the RV insertion in COVID-19 positive athletes compared to 24% in healthy athletic controls), suggesting that cardiac changes attributed to athletic conditioning may be misinterpreted as evidence of myocarditis.(160) If resources allow, we recommend cardiac MRIs in active duty service members be performed by



DHA cardiac imaging specialists or at an academic center experienced in advanced cardiac imaging to ensure high-quality diagnostic studies. Cardiac MRI referrals to local civilian centers inexperienced in this evaluation are strongly discouraged.



- Abnormal ECG findings:** pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions, intraventricular conduction delays (BBB), AV nodal conduction delays (high grade AV block) that are outside of the normal parameters in athletes (<https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.01.015>)
- Abnormal Troponin:** >99<sup>th</sup> percent upper limit of normal levels for TnI/TnT or High Sensitivity Troponin I/ T.
- Abnormal TTE:** regional wall motion abnormalities, dilated ventricles, abnormal right or left ventricular systolic function with a reduced EF <45%, moderate pericardial effusion, severe valvular disease, or pulmonary hypertension.
- Acute Pericarditis definition and diagnostic criteria:** Pericarditic chest pain, pericardial rubs, new widespread ST-elevation or PR depression on ECG, pericardial effusion (new or worsening). Additional supporting findings: Elevated CRP, ESR, WBC

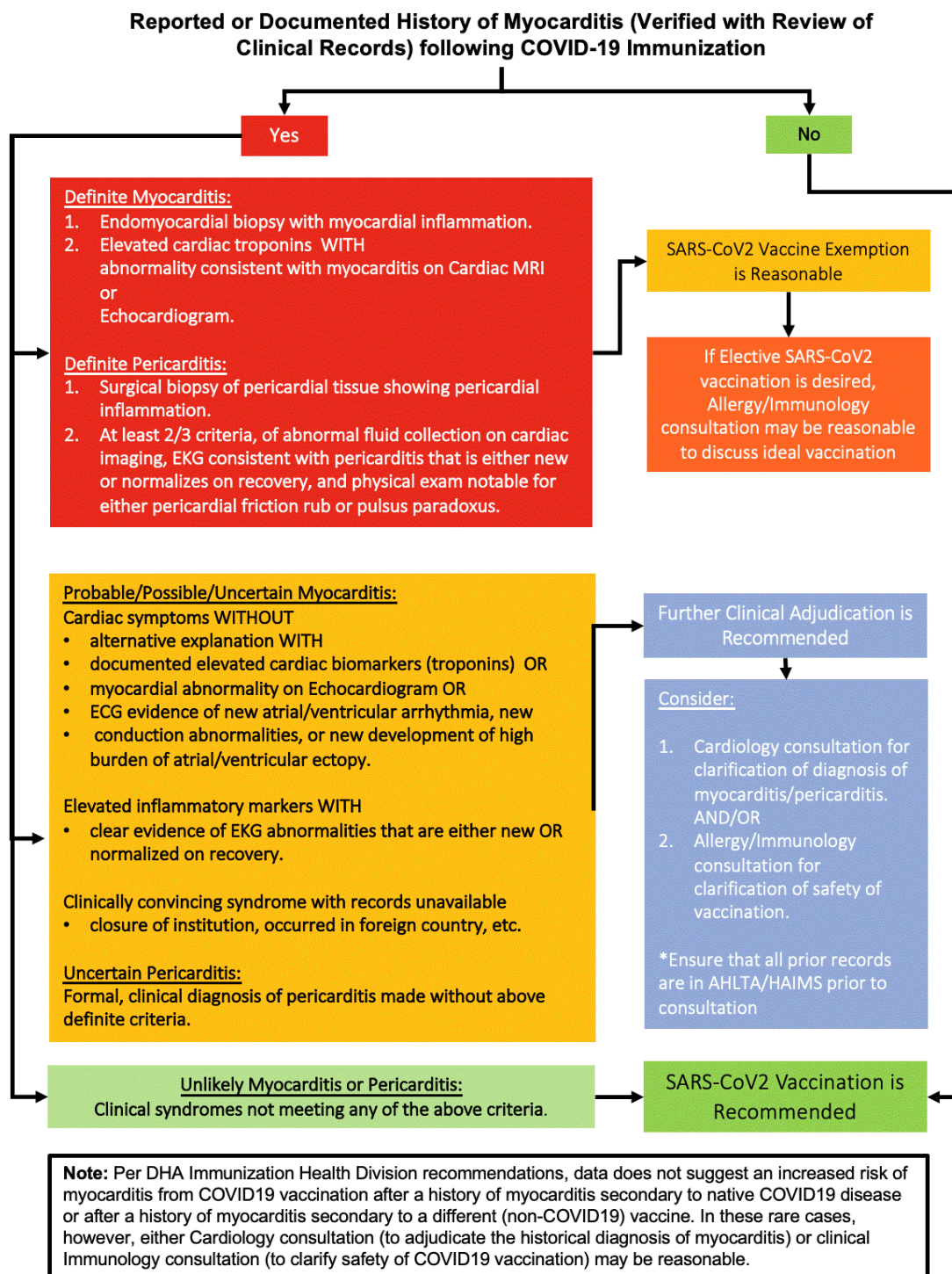
Figure 17. Recommended evaluation for suspected acute myocarditis occurring after a dose of SARS-CoV2 vaccine..

- **Cardiac Troponin as a screening biomarker:** By necessity, cardiac troponin serves as the primary marker of myocardial injury and, therefore, a key discriminator for myocarditis in an appropriate clinical context. One historical study using early-generation cardiac troponin assays, suggested sensitivity as low as 34% compared to an endomyocardial biopsy gold standard. That said, it should be noted that a relatively high (3.1ng/mL) cutoff was used, and 55% of patients with <1 month of symptoms had an elevated TnI during this earlier period of acute myocyte necrosis compared to 8% of patients with >1 month of symptoms.(161) More recent studies using increasingly sensitive assays and lower cutoffs have suggested improved performance with reported negative predictive values of 100% and 98.2% using cTnT and hsTnT, respectively.(162, 163) It should be noted that elevations in cardiac troponin are not specific for myocarditis as the differential diagnosis for myocardial injury in COVID-19 is broad,(164) an upper limit of normal is poorly defined in young athletes, and elevations of uncertain significance have been noted in numerous clinical syndromes including high intensity exercise.(165, 166) In the limited context of a symptomatic patient with suspected post-vaccination or viral myocarditis, a normal 4th-generation cardiac troponin or (preferably) 5th-generation/high sensitivity cardiac troponin offers an acceptable negative predictive value, thus lowering the pre-test probability of myocarditis. If not locally available, high sensitivity troponin assays are available through most commonly used contract laboratories.
- f. **Clinical Course:** The clinical course in myocarditis observed after COVID-19 vaccination is consistent with the well-established clinical course after smallpox vaccine-related myocarditis, and much milder than COVID-19 infection-related cardiac injury.(167) In the military, many patients report resolution of chest pain within days of presentation and two-thirds of cases experience resolution of all symptoms within six weeks. Among patients who continue to report symptoms after six weeks, primary concerns include fatigue or loss of stamina, episodic twinging chest pain, or episodic palpitations. Rare complications have been reported in the medical literature, particularly in patients with underlying medical conditions.(152, 168-170) To date, no cases of significant arrhythmia or fulminant heart failure have been identified in military service members following COVID-19 vaccine-related myocarditis
- g. **Case Mortality:** When counseling patients on the risk of post-vaccination myocarditis, we recommend against referencing the traditionally cited “20% mortality”. Historical case definitions of myocarditis were either based on an endomyocardial biopsy gold standard, which is limited by sampling only a small area, or relied upon less sensitive imaging studies and cardiac biomarkers than currently available.(171) Consequently, only much more significant cases of myocarditis were included in historical studies. Mortality in post-mRNA vaccination myocarditis is still being explored, with recently published cohorts reporting only one death from fulminant myocarditis, with an additional case of death from fulminant myocarditis in a small case series.(150, 152, 154, 156, 158, 159, 170)
- h. **Management:**
  - i. All cases of post-COVID19 or post-vaccination myocarditis should be referred to cardiology for evaluation and management. An exhaustive review of management is beyond the scope of this document. That said, it is cautioned that all service members believed to have active myocarditis should be placed on a restrictive profile for at least 3-6 months and not returned to duty until cleared by cardiology. DoD healthcare providers may be required to evaluate patients following suspected myocarditis, to confirm or exclude suspected prior cases requesting exceptions to the DoD COVID19 vaccination mandate. Refer to [DHA-IHD Vaccine-Associated Myopericarditis Diagnostic & Treatment Algorithm](#) for guidance in diagnosis and management of suspected post-vaccination Myopericarditis..
  - ii. Asynchronous telehealth for non-urgent cardiology consults is available through the Global Teleconsultant Portal (GTP), at: <https://help.nmcp.med.navy.mil/path/user/ViewLogin.action> or <https://path.tamc.amedd.army.mil/path/user/ViewLogin.action>.
  - iii. Any medical provider may request expert consultation by an immunizations specialist, submitted to the “COVID-19 Medical Contraindications Consult” group, in the Global Teleconsultant Portal (GTP)



at: <https://help.nmcp.med.navy.mil/path/user/ViewLogin.action> or  
<https://path.tamc.amedd.army.mil/path/user/ViewLogin.action>.

- i. **Adjudication of Prior History of Vaccine-Associated Myocarditis:** We recommended that the Brighton Collaboration Myocarditis Case Definitions be applied to suspected cases of post-vaccination myocarditis with the recommendations outlined in **Figure 18**.(172)



**Figure 18.** Adjudication of historical episodes of myocarditis or pericarditis to guide decision making in vaccine eligibility.

j. **Recommendations for COVID-19 Vaccination in Individuals with a history of myocarditis:**

Recommendations are discussed in full detail in the DHA Immunization Health Division Information Paper on options for COVID-19 Vaccination Following Myopericarditis, released 20 Oct 2021. This source document should be referenced for complex medicolegal questions. Their recommendations are summarized here:

- i. Individuals with a history of myocarditis that is NOT associated with the receipt of an mRNA COVID-19 vaccine may receive any COVID-19 vaccine as long as their myocarditis has fully resolved, including normalization of labs/imaging studies and return to baseline exercise tolerance.
- ii. Individuals with history of myocarditis or pericarditis that IS associated with the receipt of an mRNA COVID-19 vaccine should defer receiving subsequent doses of COVID-19 vaccine unless they are at high risk from future COVID-19 infection. If the patient does not desire further vaccination, a permanent medical exception is reasonable.
- iii. Individuals with a history of myocarditis or pericarditis that IS associated with the receipt of an mRNA COVID-19 vaccine but who ARE at increased risk of exposure or increased risk from future infection may ELECT to receive subsequent mRNA vaccine or non-mRNA (Janssen) vaccine. This may be best approached in consultation with clinical immunology consultants as close follow-up is required.

**Acute Kidney Injury (AKI)**

1. When defined by the Kidney Disease: Improving Global Outcomes Guidelines (KDIGO) criteria,(173) AKI occurs in 61-68% of critically ill patients with COVID-19.(174, 175) Among patients with AKI in the ICU setting, a significant proportion (31-55%) require renal replacement therapy.(174, 175)
2. The etiology of AKI in COVID-19 is predominantly acute tubular necrosis in the setting of multi-organ failure and shock.(175) However, there have been unpublished reports of SARS-CoV-2 being isolated from urine and observed on kidney pathology. In conjunction with evidence that hematuria and proteinuria are common findings in COVID-19, this suggests that direct viral injury to the kidney may also play a role.(176)
3. The standard of care for critically ill patients with severe AKI is continuous RRT (CRRT). The dose of CRRT is the same as that recommended for other critically ill patients: 25mL/kg/hr.
4. If a MTF admits a large number of patients, it is likely that there will be a shortage of CRRT supplies. If this occurs, slow low efficiency dialysis (SLED) should be considered. SLED is a hybrid therapy that utilizes standard dialysis machines.
5. Regardless of the modality of RRT used, special attention should be paid to volume status and ultrafiltration, consistent with the goals of a restrictive fluid strategy.
6. The preferred location of a dialysis catheter is the right jugular vein, followed by a femoral vein, followed by the left jugular vein.(173) The subclavian vein should be avoided.
7. Patients with COVID-19 are hypercoagulable and will likely require anticoagulants to maintain filter patency. Regional anticoagulation with citrate is preferred, however this should only be done by centers already familiar with the technique given the risks of hypocalcemia and citrate toxicity. Second line anti-coagulation is heparin. This topic is reviewed in [Kidney Disease: Improving Global Outcomes Guidelines on AKI](#) (Section 5.3). Other methods to improve filter patency are to increase blood flow (up to 400 mL/min), periodic 100mL flushes of the circuit, and pre-filter replacement fluid (if doing continuous veno-venous hemofiltration).

**Hematology**

1. Important pathophysiologic considerations concerning vasculature and blood in COVID-19:(177-180)
  - a. Patients with Covid-19 infection are at increased risk for VTE, although the extent of that risk has varied between studies.(181)
  - b. Endothelial cells abundantly express ACE2, the principal ligand for the SARS-CoV-2 Spike protein.
  - c. SARS-CoV-2 infects and damages endothelium. The endotheliopathy caused by SARS-CoV-2 is characterized by viral inclusions in endothelial cells, endothelial apoptosis and lymphocytic infiltration.
  - d. Damaged endothelium is incapable of maintaining an anticoagulant surface; microvascular and large

vessel thrombosis is common in severe SARS-CoV-2 infection.

- e. In severe SARS-CoV-2 infections, macrophage hyper-activation can occur and hemophagocytosis has been observed in spleen and lung. These findings are associated with elevated levels of IL-1B and IL-6, a so-called “cytokine storm.” Elevated inflammatory cytokine levels drive expression of other acute phase reactants including fibrinogen.
  - f. ARDS in general is associated with elevated levels of plasminogen activator inhibitors (PAI-1) and decreased fibrinolysis in lung tissue..
2. Key Hematologic Lab findings that may be associated with worsened prognosis in hospitalized patients:
- a. Lymphopenia (60% of hospitalized patients with ALC<1000; severe depletion of CD4+ lymphocytes associated with worse prognosis; lymphocyte recovery associated with viral clearance and improving clinical course)
  - b. Thrombocytopenia (most patients between 100-150; lower counts with severe disease)
  - c. Elevated D-dimers
  - d. Elevated fibrinogen (typically around 500 mg/dl)
  - e. Prolonged prothrombin time (generally mild, 1-2 seconds beyond normal range)
  - f. Hypercoagulability as measured by TEG or ROTEM (shorter K or CFT, elevated MA or MCF)
  - g. Hyperferritinemia (400-1500 ng/ml)
  - h. Elevated IL-6
3. Patient Management:
- a. Hematology laboratory testing to consider for known or suspected COVID-19 cases:(182)
    - i. CBC with differential (track lymphocyte count)
    - ii. Ferritin
    - iii. Type and Screen (needed if considering convalescent plasma treatment)
    - iv. D-dimer
    - v. TEG
    - vi. PT, aPTT
    - vii. Fibrinogen
    - viii. Anti-Xa activity
  - b. Anticoagulation considerations: (adapted from Washington University – St. Louis)
    - i. All admitted patients should receive at a minimum VTE chemoprophylaxis (enoxaparin 40 mg sc daily). If possible, check anti-Xa daily 4hrs after third dose with goal 0.3-0.5. If at goal, no need to re-check; if not, adjust dose and monitor until at goal.
    - ii. In patients at higher risk of VTE or with more severe COVID-19 disease (evidence of coagulopathy with elevated D-dimers, prolonged PT, elevated fibrinogen, TEG hypercoagulability; intubated, prone and persistently hypoxic; MOF; requiring CVVH), it is reasonable to consider therapeutic anticoagulation. Results with higher dose prophylaxis (e.g., enoxaparin 30 mg sc q12 hrs – “trauma dose” -- or enoxaparin 40 mg sc q12 hrs for patients with BMI>40) have been disappointing.(183, 184) Results of using up-front therapeutic anticoagulation instead of prophylaxis have varied across RCTs, but suggest that earlier use (prior to ICU admission) may prevent organ damage and improve outcomes.(185) For pregnant patients hospitalized for severe COVID-19, prophylactic dose anticoagulation is recommended if there are no contraindications to its use. Ref. NIH COVID treatment guidelines: <https://www.covid19treatmentguidelines.nih.gov/whats-new/https://www.covid19treatmentguidelines.nih.gov/whats-new/>.
    - iii. Persistent hypoxia should prompt evaluation for PE.
    - iv. VTE treatment (therapeutic anticoagulation) with enoxaparin should target anti-Xa of 0.6-1.0. Anticoagulation with unfractionated heparin should target anti-Xa of 0.3-0.7 (see dosing table).
    - v. Consider discharge thromboprophylaxis for patients with moderate to severe COVID-19 not diagnosed with VTE during hospitalization but at higher risk due to older age, cardiovascular disease, CKD, ICU stay (e.g., Apixaban 2.5 mg po q12 hrs for 30 days or Rivaroxaban 10mg PO q24 hours 30 days or Enoxaparin 40 mg sc daily).(186)



- vi. In patients with VTE and/or persistent hypoxia (P/F < 150) despite maximum ventilator interventions (suggesting microvascular thrombosis), elevated fibrinogen (>500 mg/dl) and elevated d-dimer (> 6x ULN), consider fibrinolytic therapy as a salvage regimen (tPA 50 mg bolus over 2 hours delivered with UFH full anticoagulation for 7 days with target aPTT of 60-80 sec; re-bolus tPA 50 mg if no/transient improvement in P/F) (187).
- c. **Appendix L** is a Weight-based Heparin Dosing Algorithm for venous thromboembolism.

## **Nutrition**

1. Nutrition care decisions are based on the patients' clinical presentation and the need to limit healthcare provider's exposure to patients, minimize contamination of equipment, and avoid transport.
2. Oral and enteral routes of nutrition are preferred. See **Appendix M** for Enteral Nutrition Pathway.
3. Ensure patients deficient in Vitamin D and Zinc are properly supplemented.
4. Ensure patients get adequate amount of Vitamin A and Vitamin C either in their diet or other route of nutritional support.
5. There is emerging research that high levels of biotin (a B vitamin), can interfere with the Elecsys Anti-SARS-CoV-2 test. If patients are taking a dietary supplement with high levels of biotin, they should discontinue use 72-hours prior to their antibody test. Clinicians should screen all patients for dietary supplement use, especially multi-vitamins advertised for "Hair, Skin, and Nails".
6. Enteral Nutrition (EN) for COVID-19 patients:
  - a. Consult a Registered Dietitian locally or via virtual health
  - b. Give early enteral nutrition (ideally within the first 24-36 hours of admission or within 12 hours of intubation), including patients on ECMO
  - c. Prefer gastric feeding for ease of placement and potential to use an existing NGT or OGT
  - d. Initial energy supply should target 15-20 kcal/kg actual body weight (ABW) for patients with body mass index (BMI) 18-29; target protein content is 1.2-2.0 g/kg daily. For patients with BMI 30-50, goal is 11-14 kcal/kg ABW/day and 22-25 kcal/kg ABW/day for patients with BMI >50.
  - e. Choose an nutrition formula based on facility availability and patient's medical presentation:  
[https://www.nutritioncare.org/Guidelines\\_and\\_Clinical\\_Resources/EN\\_Formula\\_Guide/EN\\_Adult\\_Formulas/](https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/EN_Formula_Guide/EN_Adult_Formulas/)
  - f. Note: A standard high-protein (>20% protein) polymeric isosmotic enteral formula is recommended pending no renal insufficiency and normal GI function
  - g. Assess for risk of malnutrition/refeeding syndrome; if present, start at 25% of caloric goal (monitor serum phosphate, magnesium & potassium). Highest risk occurs during the first 72 hours of feeding.
  - h. Continuous infusion is recommended; start nutrition at a slow rate (10ml-20ml/hr) and advance to goal as tolerated (ideally within 3-7 days of initiation)
  - i. If patient is to be placed in the prone position, raise head of bed 10-25 degrees to decrease the risk of aspiration. Patients in prone position generally tolerate gastric feedings
  - j. Monitor fluid intake closely
  - k. Consider medications that provide calories and adjust tube feeding rate as needed: Propofol (1.1kcal/ml); Dextrose (3.4kcal/ml).
  - l. Labs: monitor electrolytes and glucose closely and triglycerides if patient is on propofol.
  - m. See The American Society for Parenteral and Enteral Nutrition's (ASPEN) Resources for Clinicians Caring for Patients with Coronavirus:(175)  
[https://www.nutritioncare.org/Guidelines\\_and\\_Clinical\\_Resources/Resources\\_for\\_Clinicians\\_Caring\\_for\\_Patients\\_with\\_Coronavirus/](https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Resources_for_Clinicians_Caring_for_Patients_with_Coronavirus/)
7. If unable to initiate EN due to failed EN trial with appropriate gastric tube placement, use of prokinetic agent, and/or post-pyloric tube placement, or EN is contraindicated (ileus, SBO, Mesenteric ischemia, high pressure respiratory pressure etc.), consult Registered Dietitian locally or via virtual health immediately for possible parenteral nutrition (PN) initiation. For patients with COVID-19, the threshold to utilize PN may be lower than other critically ill patients.

## Other

1. Implement the following interventions in Table 3 below to prevent complications associated with critical illness. These interventions are limited to feasible recommendations and are based on Surviving Sepsis or other guidelines and have been adapted from the WHO guidelines for COVID-19.

**Table 6. Prevention of Complications**

Anticipated outcome	Interventions
Reduce days of invasive mechanical ventilation	<ul style="list-style-type: none"> <li>• Use weaning protocols that include daily assessment for readiness to breathe spontaneously</li> <li>• Minimize continuous or intermittent sedation, targeting specific titration endpoints (light sedation unless contraindicated) or with daily interruption of continuous sedative infusions</li> </ul>
Reduce incidence of ventilator-associated pneumonia	<ul style="list-style-type: none"> <li>• Oral intubation is preferable to nasal intubation in adolescents and adults</li> <li>• Keep patient in semi-recumbent position (head of bed elevation 30–45°)</li> <li>• Use a closed suctioning system; periodically drain and discard condensate in tubing</li> <li>• Use a new ventilator circuit for each patient; once patient is ventilated, change circuit if it is soiled or damaged, but not routinely</li> <li>• Change heat moisture exchanger when it malfunctions, when soiled, or every 5–7 days</li> </ul>
Reduce incidence of venous thromboembolism	<ul style="list-style-type: none"> <li>• Use pharmacological prophylaxis (low molecular-weight heparin [preferred if available] or heparin 5000 units subcutaneously BID or TID) in adolescents and adults without contraindications. For those with contraindications, use mechanical prophylaxis (intermittent pneumatic compression devices)</li> </ul>
Reduce incidence of catheter-related bloodstream infection	<ul style="list-style-type: none"> <li>• Use a checklist with completion verified by a real-time observer as reminder of each step needed for sterile insertion and as a daily reminder to remove catheter if no longer needed</li> </ul>
Reduce incidence of pressure ulcers	<ul style="list-style-type: none"> <li>• Turn patient every 2 hours</li> </ul>
Reduce incidence of stress ulcers and gastrointestinal (GI) bleeding	<ul style="list-style-type: none"> <li>• Give early enteral nutrition (within 24–48 hours of admission)</li> <li>• Administer histamine-2 receptor blockers or proton-pump inhibitors in patients with risk factors for GI bleeding. Risk factors for GI bleeding include mechanical ventilation for ≥ 48 hours, coagulopathy, renal replacement therapy, liver disease, multiple comorbidities, and higher organ failure score</li> </ul>
Reduce incidence of ICU-related weakness	<ul style="list-style-type: none"> <li>• Actively mobilize the patient early in the course of illness when safe to do so</li> </ul>

## MANAGEMENT OF CRITICAL ILLNESS AND COVID-19: SEPTIC SHOCK & CARDIAC ARREST

### Recognition of Septic Shock

1. Recognize septic shock in adults when infection is suspected or confirmed AND vasopressors are needed to maintain mean arterial pressure (MAP) 60–65 mmHg despite adequate fluid resuscitation.
2. Recognize septic shock in children with any hypotension (systolic blood pressure [SBP] < 5<sup>th</sup> percentile or > 2 SD below normal for age) or two or more of the following: altered mental state; bradycardia or tachycardia (HR < 90 bpm or > 160 bpm in infants and HR < 70 bpm or > 150 bpm in children); prolonged capillary refill (> 2 sec) or feeble pulses; tachypnea; mottled or cold skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia.
3. Standard care includes early recognition and the following treatments within 1 hour of recognition: antimicrobial therapy, and initiation of fluid bolus and vasopressors for hypotension (Surviving Sepsis Guidelines). The use of central venous and arterial catheters should be based on resource availability and individual patient needs. Detailed guidelines from the Surviving Sepsis Campaign and WHO are available for the management of septic shock in adults and children.
4. Due to physiologic changes in pregnancy, standard risk scoring systems are less predictive for sepsis in pregnancy, although the Modified Early Obstetric Warning Score (MEOWS) has a sensitivity of 89% and a specificity of 79% in predicting morbidity in the obstetric population.

### Septic Shock Resuscitation

1. For septic shock in adults: give 250–500 mL crystalloid fluid as rapid bolus in first 15–30 minutes and reassess for signs of fluid overload after each bolus.
2. For septic shock in children, give 10–20 mL/kg crystalloid fluid as a bolus as quickly as possible using a

manual push and reassess for signs of fluid response after each bolus.

3. **Avoid Excessive Fluid Resuscitation.** The cause of death from COVID-19 is most often ARDS and subsequent complications, which may be exacerbated by fluid administration. (16) Patients usually present with normal lactate and blood pressure, but some patients do suffer from superimposed bacterial septic shock. Conservative fluid therapy consistent with FACTT trial should be considered for patients with evidence of hypoperfusion and a without a history suggestive of hypovolemia (e.g. prolonged vomiting and diarrhea).(188) Consider use of POCUS to guide fluid resuscitation and prevent volume overload. If there is no response to fluid loading or signs of volume overload appear (e.g. jugular venous distension, crackles on lung auscultation, pulmonary edema on imaging, or hepatomegaly in children), then reduce or discontinue fluid administration. Clinical trials conducted in resource-limited studies comparing aggressive versus conservative fluid regimens suggest higher mortality in patients treated with aggressive fluid regimens.
4. Resuscitation endpoints include perfusion targets (e.g., MAP 60-65 mmHg in adults; urine output > 0.5 mL/kg/hr in adults or 1 mL/kg/hr in children; normalization of capillary refill; improved level of consciousness; and clearance of lactate).
5. In **pregnant women**, (>18 weeks gestation or when the uterus reaches the umbilicus) compression of the inferior vena cava can cause a decrease in venous return and cardiac preload and may result in hypotension and hypoperfusion. For this reason, pregnant women with sepsis and or septic shock should be placed in the left lateral decubitus position at 30 degrees to off-load the inferior vena cava. Respiratory failure and sepsis are managed similarly to non-pregnant adults.
6. Do **not** use hypotonic crystalloids, starches, or gelatins for resuscitation.
7. Vasopressors should be administered when shock persists during or after fluid resuscitation to maintain MAP goal 60-65 mmHg.
8. If central venous catheters are not available, vasopressors can be given through a peripheral IV, but use a large vein and closely monitor for signs of extravasation and local tissue necrosis. If extravasation occurs, stop infusion, aspirate as much as possible, and consider subcutaneous phentolamine. Vasopressors can also be administered through intraosseous needles.
9. If signs of poor perfusion and cardiac dysfunction persist despite achieving MAP target with fluids and vasopressors, consider an inotrope such as dobutamine.
10. Norepinephrine is considered first-line treatment in adult patients; epinephrine or vasopressin can be added to achieve the MAP target. Vasopressors are safe in pregnancy and MAP goal is >65 mmHg.
11. Intravenous hydrocortisone (200-300 mg total daily dose, administered in divided doses every 6-8 hours or as a continuous infusion after a 50-100 mg loading dose) is recommended for patients with persistent hypotension despite the use of two or more vasopressor agents.
12. Angiotensin II (Giapreza) is a vasopressor that may provide benefit in vasodilatory refractory shock as a third-line or fourth-line agent.
13. In children, epinephrine is considered the first-line vasopressor, while norepinephrine can be added if shock persists despite optimal dose of epinephrine.

#### **Rapid Response Team (RRT) and In-Hospital Cardiac Arrest (189)**

1. In-hospital cardiac arrest (IHCA) is common in critically ill patients who are hospitalized with COVID-19, ranging from 4.6% to 14% prevalence with mixed populations of ward and ICU-level patients.(190, 191) Multiple studies have demonstrated poor survival to discharge with intact neurologic status in this patient population, ranging from 0% in a single-center study to 7% survival at a multi-center study; however, survival chances differ by age.(190, 191) Due to the aerosol generation of certain components of cardiopulmonary resuscitations like closed chest massage (chest compressions) and bag-valve mask (BVM) ventilation, the goal of resuscitation protocols and processes is to incorporate management practices that treat the patient while reducing the risk of viral transmission to participating healthcare workers. Appendix N provides example protocols developed and used at Brooke Army Medical Center (BAMC).
2. The American Heart Association (AHA), in collaboration with multiple medical specialty societies, released interim guidance that was published in Circulation in April 2020 to help rescuers treat victims of cardiac arrest with suspected or confirmed COVID-19.(189) New cardiopulmonary resuscitation guidelines were

published in October 2020.(192) However, in October 2021, additional algorithms were developed to guide resuscitation in patients with suspected or confirmed COVID-19 infection.(6) The standard 2020 CPR algorithms and recommendations for resuscitation should apply to those patients who are known to be COVID-19 negative.

3. The 2021 Interim Guidance provides updated principles, specific strategies, and rationales for algorithm changes based on the consensus of multiple professional societies and summarizes the most up to date literature at the time of publication. **Appendix O** includes the six most recent BLS and cardiac arrest algorithms for adult and pediatric patients with suspected or confirmed COVID-19 infection.
4. Protecting healthcare personnel (HCP) is a major priority in medical emergencies for suspected or confirmed COVID-19 patients. Although medical emergencies are time-sensitive situations, donning the appropriate PPE is extremely important as unintentional HCP exposure can result in detrimental effects to the workforce. Central strategies to protect HCPs during a medical emergency include efficient placement of appropriate PPE outside a patient's room, minimizing personnel in the room, and regular training.
5. Regular training should focus on the expectations, roles, and responsibilities for the individual participants in these medical emergency events, as outlined in **Appendix N**. Mock simulated scenarios should be regularly used to practice these clinical situations.
6. For a RRT or Code Blue on a suspected or confirmed COVID-19 patient, the following are important considerations and recommendations:
  - a. Donning of enhanced PPE in an expeditious fashion should be performed with a PPE Buddy to confirm the appropriate infection control procedures.
  - b. Consider having PPE readily available for rescuers, such as having a "go bag" or have it positioned on each ward or in the immediate vicinity of the crash cart.
  - c. Entry to a patient's room during a RRT or Code Blue should be minimized to HCP that are essential for delivery of appropriate patient care.
  - d. Close the door, when possible, to reduce the risk of airborne contamination of adjacent indoor space.
  - e. The patient should be assessed by the most senior medical staff available to determine appropriate management and disposition, unless deferred by the responsible staff.
  - f. If a patient starts to decompensate or is found unresponsive, the initial responder should prioritize the placement of a closely available surgical mask on the patient.
  - g. Chest compressions during cardiopulmonary resuscitation (CPR) is aerosol generating. Before commencing CPR, all medical personnel should wear airborne PPE, including PAPR if able. If available, an automated compressor device should be used to minimize personnel and exposure.
  - h. Appropriate equipment and supplies (viral filter, video laryngoscope, etc) should be prepositioned in the vicinity of the crash cart on COVID-19 ICUs and/or wards. Depending on local availability of resources, consider modifying the protocol for bringing the entire crash cart into the room. Due to the high risk of aerosol generation that occur during these clinical events, attempts should be made to minimize the degree and amount of door opening that occurs.
  - i. If not intubated, a non-rebreather mask should immediately be placed on the patient for passive oxygenation, covered by a surgical mask. SAFETY NOTE: ensure continuous oxygen delivery is temporarily removed for defibrillation to avoid airway fire. Depending on local protocol, a bag-valve mask (BVM) with a high efficiency particulate air (HEPA) filter may be considered if using a two-person technique to ensure a tight seal.
  - j. Minimize the likelihood of failed intubation attempts. Pause chest compressions for intubation, and ideally time the pause with a pulse and rhythm check. Consider video laryngoscopy as it may reduce intubator exposure to aerosolized particles; however, the intubator should use the technique with which she/he is most likely to have first-pass success.
  - k. If the patient is connected to a ventilator, minimize disconnections of the closed-circuit to reduce the potential for aerosolization. If a circuit disconnection must occur to switch to BVM with HEPA filter, recommend clamping the endotracheal tube to reduce aerosolization. If the patient is already mechanically ventilated with an advanced airway, consider maintaining a closed-circuit connection to

reduce aerosolization. \*\*\*SAFETY NOTE: Use best clinical judgment and appropriate expertise for management of a patient already on mechanical ventilation at the time of cardiac arrest. Patients MUST be assessed for ventilator malfunction or airway obstruction as causative or contributing factor to cardiac arrest\*\*\*. Recommendations regarding the appropriate settings adjustments to allow for asynchronous ventilation, which replicates the bag-valve mask delivery of oxygen include:

- i. Increase FiO<sub>2</sub> to 100% (1.0).
  - ii. Change mode to Pressure Control Ventilation mode that limits the amount to pressure to target a tidal volume of 6 ml/kg of ideal body weight.
  - iii. Adjust the trigger to “Off” to prevent the ventilator from auto-triggering with chest compressions and possibly prevent hyperventilation and air trapping.
  - iv. Adjust the set respiratory rate to 10 breaths per minute.
  - v. Assess the need and tolerance for adjusting PEEP to ensure appropriate oxygenation.
  - vi. Adjust alarms, and ensure that the endotracheal tube and ventilator circuit are secured appropriate to avoid unplanned repositioning, dislodgement, or full extubation.
  - vii. Ensure that a clamp and BVM with HEPA filter are readily available to allow an immediate switch to BVM with HEPA filter, if needed. If so, then clamp, disconnect from the ventilator circuit, connect the BVM with HEPA filter, and unclamp.
  - viii. SAFETY REMINDER: preplan and practice these adjustments with local expertise and HCP (i.e. Critical Care Physicians, Critical Care Nurses, Respiratory Therapists) to ensure appropriate understanding and avoid confusion during the actual resuscitation.
  - l. Focus on potentially reversible conditions (H’s and T’s). For sudden hypoxia, use the mnemonic DOPE (Displacement of breathing tube, Obstruction, Pneumothorax, Equipment failure). Consider use of an available portable ultrasound. If a blood gas is obtained, utilize a portable analyzer or ensure appropriate infection control precautions if run outside of the room.
  - m. Avoid prolonged codes in patients with cardiac arrest. Discuss discontinuation at least after 20 minutes of a high-quality resuscitation attempt, taking into account the patient’s age, comorbidities, medical condition leading up to the event, and potential for reversal.
7. Refer to the resuscitation algorithms for further discussion of specific considerations, including: pediatric, maternal, neonatal, prone positioning at time of arrest, out-of-hospital cardiac arrest, and modified algorithms in **Appendix O**. A summary of the adjustments to the CPR algorithms for patients with suspected or confirmed COVID-19 is in **Figure 19.(6)**



<p><u>Reduce provider risk</u></p> <p>Healthcare providers can significantly reduce their risk of infection by receiving the vaccine and approved boosters (if applicable) against the SARS-CoV2 virus <sup>13, 14, 15</sup></p>
<p><u>Reduce provider exposure and provide timely care</u> (1-3)</p> <ul style="list-style-type: none"> <li>• Rapidly provide chest compressions, without delay or interruption</li> <li>• Do not delay chest compressions for provider PPE or to place a face covering on the patient</li> <li>• Relieve initial resuscitation personnel with providers wearing appropriate PPE for AGPs as soon as possible</li> <li>• Don appropriate PPE for AGPs (N95 masks with eye protection or positive-airway pressure respirators, gloves and gowns) prior to confirmed AGPs including bag-mask ventilation, intubation and positive pressure ventilation</li> <li>• Limit unprotected rescuers from exposure of AGPs</li> <li>• Consider using mechanical CPR devices <i>if available and personnel are already trained</i></li> <li>• Communicate COVID-19 status of the patient to any new providers and clearly communicate expectations of appropriate risk-matched PPE</li> </ul>
<p><u>Specific additional resuscitation strategies</u></p> <p>Pediatric and adult cardiac arrest</p> <ul style="list-style-type: none"> <li>• Defibrillate as soon as possible when indicated; do not delay defibrillation for application of masks or other PPE.</li> <li>• For agonal breathing, consider passive oxygenation until HEPA filtered ventilation can be provided</li> <li>• Securely attach a HEPA filter to any ventilation device</li> <li>• Ventilate with a bag-mask-HEPA filter with tight seal until a supraglottic or endotracheal airway is placed</li> <li>• Engage the intubator with the highest chance of first pass success</li> <li>• Consider use of video laryngoscopy, if available and personnel are already trained</li> <li>• Maximize chest compression fraction, pausing to intubate only if needed</li> <li>• Minimize endotracheal administration of medications to avoid aerosol generation</li> <li>• Minimize closed ventilation circuit disconnections</li> <li>• Commit to ethical and evidence-based termination of resuscitation policies</li> </ul> <p>Out-of-hospital cardiac arrest</p> <ul style="list-style-type: none"> <li>• For adults, prioritize chest compressions and defibrillate when indicated; compressors should apply their own masks if immediately available and retrieval does not delay treatment</li> <li>• For pediatrics, prioritize oxygenation and HEPA filtered ventilation with chest compressions; compressors should apply their own masks when available</li> </ul> <p>Maternal and neonatal cardiac arrest</p> <ul style="list-style-type: none"> <li>• Newborn babies are unlikely to be a source of SARS-CoV2 transmission</li> <li>• For newborns, bag-mask or T-piece / mask ventilation with appropriate risk-matched PPE is safe</li> <li>• Maternal respiratory secretions and fluids may be potential sources of SARS-CoV2 transmission for the neonatal team and newborn</li> </ul>

**Figure 19.** Summary of adjustments to cardiopulmonary resuscitation (CPR) algorithms in patients with suspected or confirmed coronavirus disease 2019 (COVID-19). (1-3) AGP indicates aerosol generating procedure; HEPA, high efficiency particulate air; PPE, personal protective equipment; and SARS-CoV-2, severe acute respiratory syndrome coronavirus 2. Figure from Hsu, et al (2021). (6)

8. **Table 7** includes frequently asked questions related to resuscitation during the COVID-19 pandemic.(6)

**Table 7.** Frequently asked questions related to resuscitation of patients with suspected or confirmed COVID-19 infection.

Is masking of the patient during the initial compressions necessary?	Chest compressions without ventilation results in tidal volumes far less than that of normal breathing. The airway of cardiac arrest patients is typically obstructed by the tongue, which further reduces the risk of aerosol transmission. In the unlikely event that an unmasked patient with suspected or confirmed COVID-19 suffers an unanticipated cardiac arrest, <i>do not delay compressions</i> . If within immediate reach, the concerned compressor may apply a surgical mask or layered cloth over the mouth and nose of the patient, but should not delay compressions.
Do first responders need to don masks for their safety?	There are no reports yet of chest compressions alone on COVID-19 positive patients resulting in transmission of the virus. It is reasonable for an unvaccinated first responder to don a mask immediately if within reach, but <i>initiation of chest compressions should not be delayed</i> . The risk of infection from vaccinated first responders performing compressions without a mask for a short duration is likely negligible. Ventilations, which are a priority in pediatric and neonatal arrests, are suspected to be an AGP and an N95 wearing provider should replace an unmasked first responder as soon as possible.
Are ‘intubation boxes’ useful in controlling aerosolization?	Evidence regarding using a protective barrier enclosure around the patient’s head and neck for intubations is still developing. In cardiac arrest resuscitations, logistical considerations affecting chest compressions and other critical care may limit the use of an intubation box.
Do mechanical compression devices help during resuscitation?	For institutions that have a system in place, timely implementation of mechanical compression devices can reduce the number of personnel required for chest compressions and maintain quality compressions, but are not superior to manual compressions in survival to discharge with intact neurologic function.

Adapted from Hsu, et al (2021). (6); AGP indicates aerosol generating procedure; and COVID-19, coronavirus disease 2019

### Patient Transport

1. Surgical masks should be used for ALL patients irrespective of COVID-19 status during the COVID-19 pandemic.
2. The movement of patients with COVID-19 should be limited with all efforts made to ensure the patient is initially admitted to the appropriate location.
3. If patient transport is necessary:
  - a. Non-intubated patients should be transferred wearing a surgical mask over their oxygen delivery device which may include nasal prongs or a non-rebreather mask up to 15 L/min.
  - b. Staff should wear airborne PPE.
  - c. Once a patient is admitted to the ICU, transport outside of the ICU should be limited. If transport is required, then coordination should occur to ensure safety standards are maintained.
  - d. Hallways must be cleared where possible and only essential staff should accompany the patient. Staff not involved in the transfer should not come within 6 feet of the patient.
  - e. Intubated patients should have closed circuits, a HEPA filter in situ, and appropriate cuff pressure to reduce the aerosolization risks.

### DoD Autopsies in Patients with COVID-19

1. To help researchers and clinicians understand COVID-19 and develop improved ways to treat severely affected COVID-19 patients with septic shock, Acute Respiratory Distress Syndrome (ARDS), myocardial dysfunction, and renal failure, Military Health System pathologists can provide critical support by performing autopsies, conducting diagnostic laboratory testing for the virus, performing critical clinical laboratory testing, and clearing blood products that facilitate safe patient care.
2. CDC recommendations for COVID-19 autopsies outline how to safely perform a postmortem examination with trained staff and appropriate safety precautions in place, along with the appropriate consent from the decedent’s legally authorized representative.
3. When seeking consent from the decedent’s legally authorized representative, the clinical care team should include a pathologist (preferably the pathologist performing the autopsy) in the discussion. Among other

things, the pathologist can explain the process, answer questions, and describe the contributions to scientific knowledge of this novel disease the autopsy would bring.

4. When conducting autopsies, pathologists need to follow CDC recommendations (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html>). This includes the use of eye protection (goggles or face shields), techniques that minimize aerosols, environmental controls, and PPE. Consistent with CAP guidance, and with the concurrence of the Residency Program Director, pathologists should/may include pathologists-in-training.
5. The decision regarding whether to conduct an autopsy is at the discretion of the MTF Director in conjunction with guidance from the Chief of Pathology.

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## **IMAGING OF COVID-19: RADIOLOGY DEPARTMENT GUIDANCE & IMAGING FINDINGS**

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Imaging findings have been widely reported in the context of COVID-19 and following initial guidance for non-urgent and elective procedures to be rescheduled, most institutions have now resumed non-urgent, screening or elective imaging exams. Local policies for when and how to resume imaging are variable and must take into consideration many site-specific, regional and organizational factors. The American College of Radiology (ACR) has consolidated generalizable guidance for imaging department workflow, pandemic practice management, COVID-19 imaging findings and standardized reporting on its “ACR COVID-19 Clinical Resources for Radiologists” page which is updated regularly.

### **Radiology Department Guidance Workflow**

1. A recent article by Davenport et al. addresses many considerations for radiology departments to safely resume routine care in the following categories: (193)
  - a. Safety measures
  - b. Respect local pandemic statistics
  - c. Risk-benefit decision making
  - d. Developing tiered plan for non-urgent exams
  - e. Accreditation and regulatory deferrals to avoid lapses
  - f. Address backlog of previously deferred exams
  - g. Manage fear
  - h. Develop local policies specific to academic practice environments

### **Use of Imaging for COVID-19**

2. Whether to image a patient under investigation (PUI) for COVID-19 or previously diagnosed with COVID-19 depends on multiple factors including clinical symptoms, pre-test probability, potential for imaging results to alter management, and local resource availability. Various guidelines on imaging indications continue to be published regularly.
  - a. The ACR, Society for Thoracic Radiology (STR) and the American Society of Emergency Radiology (ASER) recommend that CT should not be used to screen or as a first-line test to diagnose COVID-19.
  - b. Imaging should be reserved for cases where it will impact management or in order to evaluate for urgent/emergent alternative diagnoses.
  - c. Multinational consensus statement from the Fleischner Society on the role of chest imaging (CXR and CT) for COVID-19 was published 7 April 2020 and provides specific imaging recommendations based on three clinical scenarios: 1) patients with mild features of COVID-19, 2) moderate-severe features of COVID-19 and 3) moderate-severe features of COVID-19 in a resource constrained environment.
3. The reported sensitivity of Chest CT for COVID-19 ranges from 80-90% and the reported specificity ranges from 60-70%.
  - a. A normal chest CT does not mean a patient does not have COVID-19; a normal imaging study should not keep a patient from being quarantined if they meet other clinical criteria.
  - b. An abnormal CT is not specific for COVID-19 and it does not obviate the need for confirmatory

laboratory testing. (194)

4. There is accumulating evidence of thromboembolic complications of COVID-19. In the event of acute clinical deterioration with suspected pulmonary embolism and/or rising D-dimer levels, CT pulmonary angiography should be considered. The National Institute for Public Health of the Netherlands published recommendations for imaging for pulmonary embolism or deep venous thrombosis (DVT) in COVID-19 patients.
5. ACR recommends minimizing magnetic resonance imaging (MRI) use except where absolutely necessary. (ACR guidance on COVID-19 and MR use, <https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety/COVID-19-and-MR-Use>)
6. **Infection control and PPE:** When imaging is performed of patients who are positive or suspected positive for COVID-19, consider implementing the following infection control precautions.
  - a. Portable imaging is preferred when possible, preferably using a portable x-ray machine dedicated for imaging COVID-19 suspected/positive patients. When possible, similar designation of other radiology equipment (e.g. ultrasound, CT and MRI) specifically for imaging COVID-19 suspected/positive patients should be made to limit cross contamination.
  - b. Imaging should be performed nearest to the patient location to minimize exposure
  - c. Droplet precautions should be employed for all patients who are positive or suspected positive for COVID-19. Patients should be masked throughout the imaging exam and deep cleaning of all surfaces should be performed afterward by someone wearing proper PPE.
  - d. Airborne precautions are reserved for patients undergoing AGPs (e.g., bronchoscopy, transesophageal echocardiography, intubation, nebulization, or open suction).
  - e. Healthcare providers (technologist, nurse, etc.) should wear appropriate PPE (gloves, mask, eye-shield and possibly gown depending on the possibility of close or direct contact with the patient)
  - f. Record a census of other patients and staff present at the time of the patient visit, should the patient later test positive for COVID-19
7. When performing image-guided procedures on patients who are positive or suspected positive for COVID-19, consider implementing the following infection control precautions:
  - a. Store all PPE in secure locations with limited access, implement inventory controls, and clearly define PPE to be used based on patient status.
  - b. Identify a dedicated room to perform procedures on PUIs and COVID-19-positive patients. An air-negative room is strongly recommended if available.
  - c. Empty rooms designated for procedures on COVID-19-suspected/confirmed patients of all non-essential equipment and supplies to avoid contamination.
  - d. Create a staffing plan designed to preserve physician and staff availability if individuals become exposed and sick. Consider backup teams.
  - e. Minimize staff in the procedure room.
  - f. Develop clear plans for removing and disposing contaminated PPE.
  - g. Have a clear exit plan for COVID-19-suspected/confirmed patients to minimize staff exposure.
  - h. Ensure staff scrubs are changed and lead aprons are cleaned with EPA-approved disinfectants.

#### **Thoracic Imaging Findings of COVID-19 on Chest Radiographs (CXR)**

1. If imaging is part of a pre-hospital assessment of COVID-19 positive or PUI for COVID-19, portable x-ray is preferred (preferably using a dedicated portable x-ray machine to limit cross contamination).
2. In one study of 64 patients, baseline CXR had a sensitivity of 69%. (195)
3. Bilateral consolidation and ground glass opacities were the most common findings (59% and 41%, respectively) in a peripheral and lower lung distribution (51% and 63% respectively).
4. Severity of CXR findings peak at 10-12 days from date of symptom onset. (195)

#### **Thoracic Imaging Findings of COVID-19 on Chest Computed Tomography (CT)**

1. CT findings of COVID-19 overlap with findings of other viral pneumonias.
2. CT findings of COVID-19:



- a. Extent - bilateral, multi-lobar
- b. Distribution – peripheral and basilar or random
- c. Characterization – rounded or peripheral ground glass opacities (GGO) without or with septal thickening (“crazy paving” pattern), consolidation, central low attenuation (reverse halo sign of organizing pneumonia)
3. Lymphadenopathy, pleural effusions and a nodular pattern are not common.
4. CT finding severity peak from 6-11 days after symptom onset.
5. Standardized reporting guidelines were developed and endorsed by the Radiological Society of North America (RSNA), the Society of Thoracic Radiology and the American College of Radiology. (196)
  - a. Consultation with clinical colleagues at each institution is suggested to establish a mutual approach.
  - b. If features of COVID-19 are discovered incidentally on exams performed for other indications, contact referring providers to discuss the possibility of viral infection and consider using the more general term “viral pneumonia” in the differential diagnosis. However, if after discussion COVID-19 is felt to be likely, then the authors suggest using one of the four structured reporting categories listed below.
6. Structured reporting categories for COVID-19 on chest CT.
  - a. Typical appearance
    - i. Findings: Peripheral, bilateral GGO with or without consolidation or visible septal lines (“crazy paving”); multifocal rounded GGO; reverse halo sign or other signs of organizing pneumonia (later in disease).
    - ii. Suggested reporting language: “Commonly reported imaging features of COVID-19 pneumonia are present. Other processes such as influenza pneumonia and organizing pneumonia, as can be seen with drug toxicity and connective tissue disease, can cause a similar imaging pattern.”
  - b. Indeterminate appearance
    - i. Findings: Absent typical features AND multifocal, diffuse, peri-hilar or unilateral GGO with or without consolidation lacking a specific distribution; lacking a rounded or peripheral characterization; few very small GGO non-rounded and non-peripheral.
    - ii. Suggested reporting language: “Imaging features can be seen with COVID-19 pneumonia, though are nonspecific and can occur with a variety of infectious and noninfectious processes.”
  - c. Atypical appearance
    - i. Findings: Absent typical or indeterminate features AND isolated lobar or segmental consolidation without GGO, discrete small nodules (centrilobular or “tree-in-bud”), lung cavitation, smooth interlobular septal thickening with pleural effusion.
    - ii. Suggested reporting language: “Imaging features atypical or uncommonly reported for COVID-19 pneumonia. Alternative diagnoses should be considered.”
  - d. Negative for pneumonia
    - i. Findings: No CT features to suggest pneumonia.
    - ii. Suggested reporting language: “No CT findings present to indicate pneumonia. (Note: CT may be negative in the early stages of COVID-19.)”

### **Cardiac Imaging Findings of COVID-19**

1. In a study of 138 hospitalized patients positive for COVID-19, 16.7% of patients developed arrhythmia and 7.2% experienced an acute cardiac event. Transthoracic and transesophageal echocardiography, typical first line imaging tools for the heart, require close contact with the patient and necessitate the use of high-level PPE. Please refer to the Cardiology Section in Prevention of Complications above for use of TTE/TEE.
2. To evaluate exclusion of left atrial appendage thrombus prior to cardioversion, please reference the Cardiology Section in the Prevention of Complications Section above.
3. The Society for Cardiovascular CT (SCCT) has released guidelines for the performance of coronary CT angiography based on elective indications, semi-urgent indications and urgent indications delineated on a dedicated website: [SCCT.org/page/COVID-19](https://www.scct.org/page/COVID-19)
4. Patients with minimal COVID-19 symptoms at presentation may have cardiac dysfunction on imaging several months after recovery. Cardiac inflammation detected on CMR is common in the convalescent phase of



COVID infection, even in patients who were minimally symptomatic during the acute phase. CMR imaging findings support ongoing cardiac inflammation after COVID-19 infection in a subset of patients, including LGE. Although the long-term CV effects of the CMR findings is not yet determined in COVID-19 patients, several of the CMR findings (e.g., abnormalities in T1, T2 and LGE) were previously related to adverse outcomes in other inflammatory cardiomyopathies.

### **Neuroimaging Findings of COVID-19**

1. While the initial focus has been on the respiratory symptoms of coronavirus disease 2019 as drivers of morbidity and transmission, neuropsychiatric manifestations have been described as well. Perhaps most well-known is anosmia or ageusia, which occurs in the absence of nasal congestion or conductive pathology, and which has been attributed to neurotropic extension of SARS-CoV-2 along olfactory nerves, i.e. both neuroepithelial and endothelial tissue express ACE2 receptors. More nonspecific manifestations of neuro-COVID have included headache, paresthesias, and delirium (reported in 20-65% of SARS-CoV-2 patients). The underlying pathophysiology may be primary (direct viral invasion of CNS) and/or secondary (indirect effects of hypoxia or inflammatory cytokines) in nature, similar to HIV encephalopathy (197). A recent postmortem histopathological study including magnetic resonance microscopy (sub-mm resolution at 11.7-Tesla) found a pattern of multifocal microvascular injury in the brain and olfactory bulbs of deceased patients with COVID-19, without evidence of viral infection by RNA PCR or immunostaining.
2. One of the earliest reports of a neuroimaging manifestation was a middle-aged airline worker with acute (hemorrhagic) necrotizing encephalopathy, which demonstrated symmetrical thalamic signal abnormalities on MRI. Later case series identified diffuse confluent symmetrical white matter T2/DWI hyperintensities with microhemorrhages reminiscent of delayed posthypoxic leukoencephalopathy and cortical gray matter with subcortical white matter signal abnormalities suspicious for autoimmune encephalitis in COVID-19 patients with negative CSF RT-PCR. Other autoimmune patterns have also been reported on neuroimaging of COVID-19, e.g. acute disseminated encephalomyelitis (ADEM) and Guillain-Barré syndrome (including Miller Fisher variant).
3. Although these case reports or series have called attention to the less common and more unusual neuroimaging findings of COVID-19, it should be noted that routine cerebrovascular diseases such as acute ischemic strokes, intracranial hemorrhage, and cerebral venous thrombosis are the most common neurological manifestations in hospitalized patients. These cerebrovascular events reflect a combination of baseline risk factors plus endothelial injury with hypercoagulability in COVID-19 and require the usual stroke imaging evaluation (e.g. CTA) for guidance of treatment (e.g. thrombectomy for large vessel occlusion). A retrospective study of 2054 patients with COVID-19 from 2 hospitals at epicenter New York City in March-April 2020 found that 278 patients underwent brain CT/MRI, of whom 21% demonstrated acute or subacute findings, most commonly cerebral infarctions (11%) and less commonly parenchymal hematomas (3.6%), cranial nerve abnormalities (2.2%), posterior reversible encephalopathy syndrome (1.1%), or critical illness-associated microbleeds (1.1%).

### **Abdominal Imaging Findings of COVID-19**

1. In a recent single center, retrospective study of 412 inpatients with COVID-19, approximately one third had gastrointestinal symptoms. Of the patients who underwent abdominal imaging, bowel wall findings were common including bowel wall thickening, pneumatosis and portal venous gas. Possible etiologies include direct viral infection, small vessel thrombosis or nonocclusive mesenteric ischemia. Of patients who underwent ultrasound of the right upper quadrant, many had gallbladder sludge and distention, nonspecific evidence of cholestasis. (198)

### **Imaging Findings following COVID-19 Vaccination**

1. Adenopathy following vaccination has been reported in up to 1.1% of vaccinated patients, however, this is likely an underestimation of the true incidence. Axillary swelling was reported in up to 16% of patients following the second vaccine dose. This has the potential to confound diagnostic and surveillance imaging in cancer patients. Current recommendations are to perform imaging before vaccination when possible or at least 6 weeks following the final vaccine dose. Imaging should not be delayed for urgent or emergent clinical

- indications. Likewise, vaccination should not be delayed to accommodate previously scheduled imaging.
2. When reporting new lymphadenopathy on cross sectional imaging following confirmed recent vaccination, the authors suggested the following template: “New [right/left] [axillary/supraclavicular] adenopathy in the setting of recent ipsilateral COVID-19 vaccination, probably reactive. If clinically warranted, consider follow-up ultrasound for further evaluation.”(199)
  3. More specifically, the Society for Breast Imaging (SBI) released recommendations (updated as of 9 March 2021) for the management of axillary adenopathy after recent COVID-19 vaccination: 1) Unilateral axillary adenopathy on screening mammograms warrants a BI-RADS category 0, 2) Following appropriate work-up for unilateral adenopathy in patients who have received a COVID-19 vaccination dose within the preceding 4 weeks, consider short term follow up imaging in 4-12 weeks (BI-RADS category 3), and 3) If adenopathy persists after short term follow up, then consider lymph node sampling.

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## THERAPEUTIC MANAGEMENT AND ADJUNCTIVE THERAPIES FOR COVID-19

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**NIH COVID-19 Treatment Guidelines** are available at: <https://www.covid19treatmentguidelines.nih.gov/whats-new/>. **Figure 20** contains the NIH Recommendations for Therapeutic Management of Nonhospitalized Adults with COVID-19 and **Figure 21** contains the NIH Recommendations for Therapeutic Management of Hospitalized Adults with COVID-19 Based on Disease Severity Hospitalized.(8)

These evidence-based recommendations are complementary to the NIH guidelines and are intended to be updated regularly in response to rapidly emerging data.

From NIH Treatment Guidelines: Two main processes are thought to drive the pathogenesis of COVID-19. Early in the course of the infection, the disease is primarily driven by replication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Later in the course of infection, the disease is driven by an exaggerated immune/inflammatory response to the virus that leads to tissue damage. Based on this understanding, it is anticipated that antiviral therapies would have the greatest effect early in the course of disease, while immunosuppressive/anti-inflammatory therapies are likely to be more beneficial in the later stages of COVID-19.

The guidelines often discuss recommendations based on clinical presentation of patients according to hospitalization requirements and illness severity. In general, adults with SARS-CoV-2 infection can be grouped into the following severity of illness categories. However, the criteria for each category may overlap or vary across clinical guidelines and clinical trials, and a patient’s clinical status may change over time.

- **Asymptomatic or presymptomatic infection:** Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test or an antigen test) but who have no symptoms that are consistent with COVID-19.
- **Mild illness:** Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.
- **Moderate illness:** Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen (SpO<sub>2</sub>) ≥94% while breathing ambient air at sea level.
- **Severe illness:** Individuals who have evidence of lower respiratory tract disease with SpO<sub>2</sub> <94% on ambient air at sea level.
- **Critical illness:** Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

Recommendations on select specific agents based on disease severity are summarized in **Figure 20** and **Figure 21**.

- For **non-hospitalized** patients in order of preference (refer to previous PMG section “**Outpatient Management**” for details as well as **Figure 20**):

- Paxlovid x 5 days
- Sotrovimab as a single IV infusion (due to dominance of Omicron variant)
- Remdesivir x 3 days
- Molnupiravir x 5 days

PATIENT DISPOSITION	PANEL'S RECOMMENDATIONS
<p>Not Requiring Hospitalization or Supplemental Oxygen, As Determined by a Health Care Provider During an ED, In-Person, or Telehealth Visit</p>	<p>Provide symptomatic management for patients who are not at high risk of disease progression.</p> <p>For patients who are at high risk of progressing to severe COVID-19 (treatments are listed in order of preference, based on efficacy and convenience of use):</p> <ul style="list-style-type: none"> <li>• <b>Ritonavir-boosted nirmatrelvir (Paxlovid); or</b></li> <li>• <b>Sotrovimab; or</b></li> <li>• <b>Remdesivir; or</b></li> <li>• <b>Molnupiravir</b></li> </ul> <p>The Panel <b>recommends against</b> the use of <b>dexamethasone</b> or <b>other systemic glucocorticoids</b> in the absence of another indication (AIII).<sup>a</sup></p>
<p>Discharged From Hospital Inpatient Setting in Stable Condition and Does Not Require Supplemental Oxygen</p>	<p>The Panel <b>recommends against</b> continuing the use of <b>remdesivir (Alla)</b>, <b>dexamethasone (Alla)</b>, or <b>baricitinib (Alla)</b> after hospital discharge.</p>
<p>Discharged From Hospital Inpatient Setting and Requires Supplemental Oxygen</p> <p><i>For those who are stable enough for discharge but who still require oxygen<sup>b</sup></i></p>	<p>There is insufficient evidence to recommend either for or against the continued use of remdesivir, dexamethasone, and/or baricitinib. Review the text below when considering the use of any of these agents after hospital discharge.</p>
<p>Discharged From ED Despite New or Increasing Need for Supplemental Oxygen</p> <p><i>When hospital resources are limited, inpatient admission is not possible, and close follow-up is ensured<sup>c</sup></i></p>	<p>The Panel recommends using <b>dexamethasone</b> 6 mg PO once daily for the duration of supplemental oxygen (dexamethasone use <b>should not</b> exceed 10 days) with careful monitoring for AEs (BIII).</p> <p>There is insufficient evidence to recommend either for or against the use of remdesivir. When considering the use of remdesivir, review the text below for more information.</p> <p>The Panel <b>recommends against</b> the use of <b>baricitinib</b> in this setting, except in a clinical trial (AIII).</p>
<p><b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional</p> <p><b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>	

<sup>a</sup> There is currently a lack of safety and efficacy data on the use of these agents in outpatients with COVID-19; using systemic glucocorticoids in this setting may cause harm.

<sup>b</sup> These individuals should receive oximetry monitoring and close follow-up through telehealth, visiting nurse services, or in-person clinic visits.

<sup>c</sup> In cases where resources (e.g., inpatient beds, staff members) are scarce, it may be necessary to discharge an adult patient and provide an advanced level of home care, including supplemental oxygen (whether patients are receiving oxygen at home for the first time or are increasing their baseline oxygen requirements), pulse oximetry, and close follow-up through visiting nurse services, telehealth, or in-person clinic visits.

**Key:** AE = adverse event; ED = emergency department; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally

Figure 20. NIH Therapeutic Management of Nonhospitalized Adults with COVID-19. (8)

- For **hospitalized** patients, NIH guidelines recommend the use of **remdesivir and/or dexamethasone** as well as possibly a **second immunomodulatory** as stratified in **Figure 21**.



DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
<b>Hospitalized but Does Not Require Supplemental Oxygen</b>	<p>The Panel <b>recommends against</b> the use of <b>dexamethasone (AIIa)</b> or <b>other corticosteroids (AIII)</b>.<sup>a</sup></p> <p>There is insufficient evidence to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, remdesivir may be appropriate.</p>
<b>Hospitalized and Requires Supplemental Oxygen</b>	<p>Use 1 of the following options:</p> <ul style="list-style-type: none"> <li>• <b>Remdesivir<sup>b,c</sup></b> (e.g., for patients who require minimal supplemental oxygen) <b>(BIIa)</b></li> <li>• <b>Dexamethasone plus remdesivir<sup>b,c</sup></b> <b>(BIIb)</b></li> <li>• <b>Dexamethasone (BI)</b></li> </ul> <p>For patients on dexamethasone with rapidly increasing oxygen needs and systemic inflammation, add a second immunomodulatory drug<sup>d</sup> (e.g., baricitinib<sup>e</sup> or tocilizumab<sup>e</sup>) <b>(CIIa)</b>.</p>
<b>Hospitalized and Requires Oxygen Through a High-Flow Device or NIV</b>	<p>Use 1 of the following options:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone (AI)</b></li> <li>• <b>Dexamethasone plus remdesivir<sup>b</sup></b> <b>(BIII)</b></li> </ul> <p>For patients with rapidly increasing oxygen needs and systemic inflammation, add either <b>baricitinib<sup>e</sup></b> <b>(BIIa)</b> or <b>IV tocilizumab<sup>e</sup></b> <b>(BIIa)</b> to 1 of the 2 options above.<sup>d,f</sup></p>
<b>Hospitalized and Requires MV or ECMO</b>	<ul style="list-style-type: none"> <li>• <b>Dexamethasone (AI)<sup>g</sup></b></li> </ul> <p>For patients who are within 24 hours of admission to the ICU:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone plus IV tocilizumab (BIIa)</b></li> </ul> <p>If IV tocilizumab is not available or not feasible to use, IV <b>sarilumab</b> can be used <b>(BIIa)</b>.</p>
<p><b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional</p> <p><b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>	

<sup>a</sup> Corticosteroids prescribed for an underlying condition should be continued.

<sup>b</sup> If the patient progresses to requiring high-flow oxygen, NIV, MV, or ECMO, complete the full course of remdesivir (refer to Table A).

<sup>c</sup> Evidence suggests that the benefit of remdesivir is greatest when the drug is given early in the course of COVID-19 (e.g., within 10 days of symptom onset). Clinical trials have not demonstrated a mortality benefit for remdesivir, but a large placebo-controlled trial showed that remdesivir reduced time to clinical recovery in hospitalized patients. See Rationale for the Use of Remdesivir below.

<sup>d</sup> Drugs are listed alphabetically. There are no studies directly comparing baricitinib and tocilizumab, and there is insufficient evidence to recommend 1 drug or 1 class of drug (i.e., JAK inhibitors, anti-IL-6 receptor mAbs) over the other. Treatment decisions should be based on local guidance, drug availability, and patient comorbidities.

<sup>e</sup> If baricitinib and IV tocilizumab are not available or not feasible to use, **tofacitinib** can be used instead of baricitinib **(BIIa)** and **IV sarilumab** can be used instead of IV tocilizumab **(BIIa)**.

<sup>f</sup> The Panel **recommends against** the use of **baricitinib** in combination with **tocilizumab** for the treatment of COVID-19, except in a clinical trial **(AIII)**. Because both baricitinib and tocilizumab are potent immunosuppressants, there is the potential for an additive risk of infection.

<sup>g</sup> The combination of **dexamethasone plus remdesivir** may be considered for patients who have recently been intubated **(CIII)**. The Panel **recommends against** the use of **remdesivir** monotherapy in these patients **(AIIa)**.

**Key:** ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IL = interleukin; IV = intravenous; JAK = Janus kinase; mAb = monoclonal antibody; MV = mechanical ventilation; NIV = noninvasive ventilation; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally

**Figure 21.** NIH Therapeutic Management of Hospitalized Adults with COVID-19 Based on Disease Severity. (8)

There are insufficient data to recommend for or against the routine use of convalescent plasma for the treatment of early (i.e., <7 days from symptom onset) mild and moderate COVID-19.



Unless in the context of a clinical trial, we recommend against the use of the following agents in treatment of COVID-19: chloroquine/hydroxychloroquine, hydroxychloroquine + azithromycin, ivermectin, HIV protease inhibitors (except when used to “boost” plasma levels of other protease inhibitors), or other immunomodulators alone.

*Note:* All therapies except remdesivir remain investigational and the literature continues to evolve rapidly. No FDA unapproved medications should be routinely recommended for use outside of a clinical trial. The American Society of Health-System Pharmacists (ASHP) website has a number of regularly updated resources at:

<https://www.ashp.org/Pharmacy-Practice/Resource-Centers/Coronavirus>.

**Ethics of clinical research during a pandemic:** There is genuine uncertainty in the expert medical community over whether proposed off-label and investigational treatments are beneficial. Randomized, placebo-controlled trials (RCT) are the gold standard for determining if an experimental treatment can benefit patients. Some may question whether it is ethical to deprive patients of an agent that could potentially prevent or treat COVID-19, given the high mortality rate among critically ill patients and lack of known and available treatment options. A Committee of National Academies of Science, Engineering, and Medicine reviewed and conducted an analysis of the clinical trials conducted during the 2014–2015 Ebola virus disease outbreak in West Africa and found that the RCT was an ethical and appropriate design to use, even in the context of the Ebola epidemic. The position of “equipoise”—genuine uncertainty in the expert medical community over whether a treatment will be beneficial—“is the ethical basis for assigning only some participants to receive the agent. If the relative risks and benefits of an agent are unknown, participants who receive the experimental agent may receive a benefit or may be made worse off. Providing the experimental agent to all would expose all participants to potentially harmful effects.” (200)

### **Remdesivir**

1. On October 22, 2020, the FDA approved remdesivir for use in adult and pediatric patients ≥12 years of age and weighing ≥ 40 kg for the treatment of COVID-19 requiring hospitalization.
2. Remdesivir (Veklury) is the first medication to receive FDA approval for the treatment of COVID-19. It is an intravenous drug with broad activity against RNA viruses that inhibits replication through premature termination of RNA transcription. Remdesivir has in vitro activity against SARS-CoV-2 and in vitro and in vivo activity against related beta-coronaviruses. It has demonstrated in vitro activity against SARS-CoV-2. Remdesivir is also available through a FDA EUA for the treatment of COVID-19 in hospitalized pediatric patients weighing 3.5 kg to <40 kg or aged <12 years and weighing ≥3.5 kg. Remdesivir should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.(201-204) Of note, based on evolving data, remdesivir is now also recommended for outpatients (refer to “Outpatient Management” for more details on the recommended 3-day course).
3. The Adaptive COVID-19 Treatment Trial (ACTT-1) led by the National Institute of Allergy and Infectious Diseases (NIAID) was a randomized, placebo-controlled, double-blinded trial in 1,062 hospitalized subjects with mild, moderate and severe COVID-19 who received remdesivir (n=541) or placebo (n=521), plus standard of care. The primary goal of the ACTT-1 trial was to look at the time to recovery of hospitalized patients. Recovery was defined as either being discharged from the hospital or being hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care. The median time to recovery from COVID-19 was 10 days for the remdesivir group compared to 15 days for the placebo group, a difference that was highly statistically significant. The odds of clinical improvement at Day 15 were also statistically significantly higher in the remdesivir group when compared to the placebo group. The overall 29-day mortality was 11% for the remdesivir group vs 15% for the placebo group; this difference was not statistically significant.(204-207) The SOLIDARITY trial showed no mortality benefit to remdesivir in hospitalized patients, but despite its large sample size, its pragmatic design had significant methodological limitations.(208)
4. GS-US-540-5774 was a randomized, open-label multi-center clinical trial of hospitalized adult subjects with

moderate COVID-19 that compared treatment with remdesivir for five days (n=191) and treatment with remdesivir for 10 days (n=193) with standard of care (n=200). Researchers evaluated the clinical status of subjects on Day 11. Overall, the odds of a subject's COVID-19 symptoms improving were statistically significantly higher in the five-day remdesivir group at Day 11 when compared to those receiving only standard of care. The odds of improvement with the 10-day treatment group when compared to those receiving only standard of care were numerically favorable, but not statistically significantly different.(209)

5. GS-US-540-5773 was a randomized, open-label multi-center clinical trial of hospitalized adult subjects with severe COVID-19 that compared treatment with remdesivir for five days (n= 200) and treatment with remdesivir for 10 days (n= 197). Researchers evaluated the clinical status of subjects on Day 14. Overall, the odds of a subject's COVID-19 symptoms improving were similar for those in the five-day remdesivir group as those in the 10-day remdesivir group, and there were no statistically significant differences in recovery rates or mortality rates between the two groups.(206)

### **Glucocorticoids**

1. Although initially controversial, dexamethasone (a glucocorticoid), has been found to improve survival in hospitalized patients who require supplemental oxygen, with the greatest effect observed in patients who require mechanical ventilation. Therefore, the use of dexamethasone is strongly recommended in this setting. The RECOVERY trial and subsequent research now support the use of glucocorticoids in the treatment of hypoxemic patients with severe COVID-19.(205, 207, 210, 211)
2. NIH and IDSA guidelines both recommend dexamethasone 6 mg daily (IV or PO) for up to 10 days or until hospital discharge in patients with COVID-19 who are hospitalized with severe critical illness. The NIH and IDSA both recommend against using dexamethasone to treat patients with COVID-19 who do not require supplemental oxygen. When dexamethasone is unavailable, IDSA indicates that an equivalent glucocorticoid dose may be substituted (e.g., prednisone 40 mg PO daily, methylprednisolone 32 mg IV daily).
3. Following the publication of the RECOVERY trial, multiple additional randomized trials have demonstrated evidence of benefit for glucocorticoids for COVID-19. A meta-analysis of seven RCTs by the WHO's REACT working group was published in September 2020 in JAMA and reported an overall lower mortality rate for critically ill patients with COVID-19 who received systemic glucocorticoids.
4. Although dexamethasone 6 mg daily is the most widely-recommended drug and dose, similar benefits have been seen with methylprednisolone and hydrocortisone; it is likely this is a class effect, so other glucocorticoids may be considered if dexamethasone is unavailable or if there is a compelling consideration to use a different agent (e.g., hydrocortisone for vasopressor-resistant shock).

### **Anti-SARS-CoV-2 Monoclonal Antibodies**

1. Refer to previous section on monoclonal antibodies in Outpatient Management for additional and more detailed information on specific mAbs.
2. In the earliest stages of infection and before the host has mounted an effective immune response, anti-SARS-CoV-2 antibody-based therapies may have their greatest potential benefit. Data suggest that outpatients at risk for progressing to severe disease benefit from receiving anti-SARS-CoV-2 monoclonal antibodies early in the course of infection. The anti-SARS-CoV-2 monoclonal antibodies bamlanivimab, bamlanivimab plus etesevimab, and casirivimab plus imdevimab are available through EUAs for outpatients who are at high risk for disease progression; however, their use has been limited by decreased activity against the currently dominant Omicron strain.(212, 213) In general, use of monoclonal antibodies in hospitalized patients outside of a clinical trial has not been as widely studied and currently is not authorized in an EUA or outside of clinical trials. Of note, there are now data supporting use of higher doses of casirivimab/imdevimab (4,000 mg each) in hospitalized patients who are seronegative for the anti-spike protein antibody. In the RECOVERY study, while there was no statistically significant difference in 28-day all-cause mortality between hospitalized patients with COVID-19 receiving standard of care alone vs standard of care plus casirivimab/imdevimab, in subgroup analysis, there was a significant reduction in 28-day all-cause mortality in those who were seronegative for the anti-spike protein: casirivimab plus imdevimab arm (396 of 1,633 casirivimab plus imdevimab recipients [24%] died vs. 451 of 1,520 standard of care recipients [30%];

rate ratio 0.80; 95% CI, 0.70–0.91;  $P = 0.001$ ).<sup>20</sup> Factors to consider in using casirivimab/imdevimab which may limit its use include that the higher dose is not available through the current EUA; it is only currently authorized for use in nonhospitalized patients with COVID-19; rapid serology testing to identify seronegative individuals in real time is currently not widely available; and it has decreased efficacy against the currently dominant circulating Omicron/B.1.1.529 strain.

3. Bamlanivimab (also known as LY-CoV555 and LY3819253) is a neutralizing monoclonal antibody that targets the receptor-binding domain of the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Because this drug may block SARS-CoV-2 entry into host cells, it is being evaluated for the treatment of COVID-19. On November 9, 2020, the FDA issued EUA to make bamlanivimab available for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. The issuance of EUA does not constitute FDA approval of a product. The COVID-19 Treatment Guidelines Panel (the Panel) reviewed the available evidence from the published data on bamlanivimab for the treatment for COVID-19 and the FDA fact sheet that supported the EUA (available at link in “Outpatient Management” section).
4. The Blocking Viral Attachment and Cell Entry with SARS-CoV-2 Neutralizing Antibodies (BLAZE-1) trial is a randomized, double-blind, placebo-controlled, Phase 2/3 trial conducted at 49 centers in the United States to evaluate the safety and efficacy of bamlanivimab with or without the combination of etesivimab for the treatment of mild to moderate COVID-19 in an outpatient setting.(214, 215) An approximately 4-log decline in SARS-CoV-2 viral load was observed in monoclonal antibody recipients at day 11, with the highest decrease seen in those who received combination therapy, although the clinical significance of this is unknown. However, 5.8% of placebo recipients progressed to hospitalization in the trial, compared with 0.9–2.0% percent of monoclonal antibody recipients.
5. The FDA EUA allows for the use of bamlanivimab monotherapy as well as in combination with etesivimab for the treatment of nonhospitalized adults and children aged  $\geq 12$  years and weighing  $\geq 40$  kg who have a high risk for progressing to severe COVID-19 or hospitalization (available at link in “Outpatient Management” section).
6. Casirivimab (previously REGN10933) and imdevimab (previously REGN10987) are two recombinant human monoclonal antibodies that bind to non-overlapping epitopes of the spike protein receptor-binding domain (RBD) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The casirivimab plus imdevimab combination blocks the binding of the RBD to the host cell and is being evaluated for the treatment of COVID-19. On November 21, 2020, the FDA issued EUA to make the casirivimab plus imdevimab combination available for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization. The issuance of EUA does not constitute FDA approval of a product.
7. R10933-10987-COV-2067 is a Phase 1 and 2, randomized, double-blind, placebo-controlled trial conducted at 96 centers in the United States to evaluate the safety and efficacy of casirivimab plus imdevimab (REGN-COV2) for the treatment of mild to moderate COVID-19 in an outpatient setting. Participants received a single intravenous infusion of the casirivimab plus imdevimab combination within 3 days of having a positive SARS-CoV-2 virologic test result. Participants who were hospitalized because of COVID-19 before or at randomization were excluded from the study. According to the EUA, 799 participants were randomized to receive one of two doses of the casirivimab plus imdevimab combination, either the 2,400 mg dose (casirivimab 1,200 mg and imdevimab 1,200 mg) ( $n = 266$ ) or the 8,000 mg dose (casirivimab 4,000 mg and imdevimab 4,000 mg) ( $n = 267$ ), or placebo ( $n = 266$ ). The median time to symptom improvement was 5 days for participants who received casirivimab plus imdevimab and 6 days for those who received placebo. The analysis of the R10933-10987-COV-2067 study suggests a potential clinical benefit of casirivimab plus imdevimab for outpatients with mild to moderate COVID-19. However, the relatively small number of participants in this early phase trial and the low number of hospitalizations or emergency department visits make it difficult to draw definitive conclusions about the clinical benefit of casirivimab plus imdevimab.(216, 217)
8. The FDA EUA allows for the use of casirivimab plus imdevimab for the treatment of COVID-19 in

nonhospitalized adults and children aged  $\geq 12$  years and weighing  $\geq 40$  kg who are at high risk for progressing to severe COVID-19 and/or hospitalization (see link in “Outpatient Management” section).

9. To order either EUA product, sites must contact [cpoc@dla.mil](mailto:cpoc@dla.mil) with site name, DoDAAC/UIC, site address, Amerisource Bergen account number, shipment point of contact with phone number and email at the receiving site, the product requested, and the quantity requested. At the time of publication of this guideline, the minimum order quantity for Sotrovimab is 6 vials with a maximum quantity of 36 vials per order, and orders should be placed in multiples of 6 vials. Paxlovid orders are in multiples of 20 patient treatment courses with a minimum and maximum order of 20. Molnupiravir is also ordered in multiples of 20 treatment courses with a minimum order of 20 and no maximum order. EVUSHELD is still accepting pre-orders with no minimum/maximum at the time of publication. Non-overseas MTFs will receive product from Amerisource Bergen upon submitting a request to DLA Troop Support's Customer Pharmacy Operations Center (CPOC) at [cpoc@dla.mil](mailto:cpoc@dla.mil). Overseas MTFs will receive product from USAMMDA Force Health Protection Division either directly or via USAAMC-E or USAAMC-K upon submitting a request to CPOC. Note: For Navy Fleetships/Subs, do not use FPO/APO addresses because they are not serviceable through FEDEX. FPO/APO addresses need a port/dock/warehouse address they can physically pick up the product. Outpatient infusions operating procedures for patients with COVID-19 should be in place prior to ordering product.

### **Janus kinase (JAK) inhibitors**

1. JAK inhibitors have broad immunosuppressive effects, but their usefulness for COVID-19 remains investigational. Ongoing clinical trials should help clarify their role in the treatment of COVID-19.
2. Baricitinib is an oral Janus kinase (JAK) inhibitor that is selective for JAK1 and JAK2. It is being evaluated for the treatment of COVID-19 because it may prevent cellular immune activation and inflammation. Baricitinib is approved by the FDA to treat moderate to severe rheumatoid arthritis. On November 19, 2020, the FDA issued EUA for the use of baricitinib in combination with remdesivir in hospitalized adults and children aged  $\geq 2$  years with COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).(218)
3. ACTT-2, a multinational, randomized, placebo-controlled trial included 1,033 hospitalized patients with COVID-19 and evidence of pneumonia. Participants were randomized 1:1 to receive baricitinib 4 mg orally or placebo for up to 14 days (or until hospital discharge); both groups of participants also received intravenous remdesivir for 10 days (or until hospital discharge). The primary endpoint was time to recovery, which was defined as reaching category 1, 2, or 3 on an 8-point ordinal scale during the first 28 days. Patients were excluded from the trial if they were receiving any medications that were used off-label for the treatment of COVID-19, including corticosteroids. During the study, 10.9% of patients in the baricitinib plus remdesivir group and 12.9% of those in the placebo plus remdesivir group received corticosteroids. The median time to recovery was shorter in the baricitinib plus remdesivir group (7 days) than in the placebo plus remdesivir group (8 days) in the overall cohort (rate ratio 1.16; 95% CI, 1.01–1.32;  $p = 0.03$ ). There was no statistically significant difference in mortality by Day 28 between the baricitinib and placebo arms (OR 0.65; 95% CI, 0.39–1.09). Serious adverse events were less frequent in the baricitinib arm than in the placebo arm (16.0% vs. 21.0%; between-group difference of -5.0 percentage points, 95% CI, -9.8 to -0.3;  $p = 0.03$ ). New infections also occurred less frequently in the baricitinib arm (5.9% vs. 11.2%; between-group difference of -5.3 percentage points, 95% CI, -8.7 to -1.9;  $p = 0.003$ ). (219)
4. The NIH guidelines currently recommend for the use of baricitinib only in combination with remdesivir, in hospitalized, non-intubated patients in those infrequent situations where glucocorticoids cannot be used. Baricitinib is not recommended to be used in combination with dexamethasone. The use of other Janus kinase (JAK) inhibitors, (e.g, tofacitinib), is not recommended for the treatment of COVID-19 unless baricitinib is not available or except in a clinical trial.(220)

### **Chloroquine (CQ) / hydroxychloroquine (HCQ) and/or Azithromycin.**

1. RECOMMENDATION: NIH Guidelines **recommend against** the use of CQ/HCQ and/or azithromycin for the treatment of COVID-19 in either hospitalized or non-hospitalized patients.



2. Previously available for use based on small reports from France that treatment with HCQ alone and HCQ plus azithromycin were associated with marked reduction in time to clearance of SARS-CoV-2 RNA, although these findings have not been substantiated in a subsequent report.(221, 222)
3. Based on these reported findings and other anecdotes, FDA issued an Emergency Use Authorization (EUA) for use of HCQ and CQ in COVID-19 patients on 28 Mar 2020, but later revoked the EUA on 15 Jun 2021 (<https://www.fda.gov/media/138945/download>).
4. Clinical data do not support the efficacy of CQ or HCQ for either treatment nor for post-exposure prophylaxis. Potential toxicities include QTc prolongation, risk for arrhythmias, retinal pigmentation, and vision loss.

#### **Lopinavir/ritonavir**

1. RECOMMENDATION: NIH guidelines **recommend against** the use of lopinavir/ritonavir and other HIV protease inhibitors for the treatment of COVID-19 in hospitalized patients. However, it is important to note that ritonavir is used to “boost” or increase plasma levels of the protease inhibitor nirmatrelvir.
2. Coronavirus cellular infectivity and replication are dependent on virally-encoded and cellular protease activity. Clinically used protease inhibitors effective for HIV and HCV infection have been examined for potential utility in treatment of SARS, MERS, and COVID-19, but are currently not recommended.
3. On 18 March 2020, RCT results were reported that found no benefit in patients who received lopinavir/ritonavir compared to standard care for treatment of severe disease.
4. The use of lopinavir/ritonavir, or other antiretroviral agents intended for the treatment of HIV infection, should not be used for the specific therapy of COVID-19. Patients currently receiving these drugs for the treatment of HIV infection should have their medication list reviewed for possible interactions with COVID-19 therapies (e.g., interactions with/ boosting of other medications by ritonavir) and should be continued on their HIV therapy whenever possible.

Host-directed anti-inflammatory strategies. ARDS and sepsis, life-threatening downstream complications of COVID-19, and many other infectious and non-infectious conditions, remain significant unmet therapeutic gaps. Historically, numerous anti-inflammatory and anti-cytokine agents, as well as many other drug candidates, have been tested and failed to meaningfully affect morbidity and mortality in ARDS, sepsis and/or septic shock.

#### **IL-6 antagonists**

1. Per NIH Guidelines: In hospitalized patients who require supplemental oxygen and are receiving dexamethasone and have rapidly increasing oxygen needs and systemic inflammation, consider adding a second immunomodulatory drug (e.g., tocilizumab or baricitinib). Baricitinib or tocilizumab should only be given in combination with dexamethasone or another corticosteroid. Some clinicians may assess a patient’s clinical response to dexamethasone before deciding whether adding baricitinib or tocilizumab as a second immunomodulatory drug is necessary.
2. A variety of therapies are being administered to severely ill patients in China and elsewhere. One that is receiving substantial attention currently is an anti-IL6 receptor humanized monoclonal antibody, tocilizumab (Actemra®), which was added to the treatment guidelines published by China’s National Health Commission (4 Mar 20) to treat serious coronavirus patients with lung damage.
3. TocilizumabThe IL-6 antagonists tocilizumab and sarilumab are licensed in US for treatment of giant cell arteritis, rheumatoid arthritis, and cytokine release syndrome following CAR-T therapy. They carry a black box warning for risk of severe, potentially fatal, infections.
4. No high-quality evidence currently exists to support sole use.
5. Manufacturer-supported US randomized controlled trials of tocilizumab and sarilumab early in the pandemic were terminated due to lack of efficacy in critically ill patients. More recent trials have had contradictory results. Smaller double-blinded, placebo-controlled trials have generally shown no significant benefit with the addition of tocilizumab to therapy for patients with severe or critical COVID-19.(223-226) Conversely, two large open-label, pragmatic adaptive trials have recently reported evidence for a mortality benefit with the use of IL-6 antagonists (mainly tocilizumab) in severe and critical patients. Potential confounding

features include the use of glucocorticoids, which may either have a synergistic effect with IL-6 antagonists or could alternatively be responsible for most of the apparent benefit seen in these large platform trials.(227-229)

6. NIH guidelines recommend **against** use of IL-6 mAb therapy, e.g., siltuximab, for treatment, except in clinical trials. Additionally, caution advised for use of tocilizumab and sarilumab in patients who have not been adequately represented in clinical trials; e.g., immunosuppressed/ recently received other biologic immunomodulating drugs; ALT >5 times ULN; high risk for GI perforation; uncontrolled serious bacterial, fungal, or non-SARS-CoV-2 viral infection; ANC <500 cells/ $\mu$ L; thrombocytopenia <50,000 cells/ $\mu$ L; tocilizumab and sarilumab should only be given in combination with dexamethasone / corticosteroid
7. Of note, severe/disseminated strongyloidiasis cases have been reported during treatment with tocilizumab and corticosteroids, hence NIH recommends considering initiation of empiric treatment (e.g., ivermectin) with or without serologic testing in patients who are from areas where Strongyloides is endemic (i.e., tropical, subtropical, or warm temperate areas).

### **COVID-19 convalescent plasma**

1. RECOMMENDATION: NIH guidelines recommend **against** use of CCP for treatment of hospitalized patients without impaired humoral immunity.
2. Additionally, there is insufficient evidence to recommend for or against its use in nonhospitalized patients (with or without impaired humoral immunity) and hospitalized patients with impaired humoral immunity..
3. Convalescent plasma from patients who have recovered from SARS CoV-2 infection has been proposed as a potential therapy for patients with severe COVID-19.(230) An uncontrolled convalescent plasma expanded access program sponsored by Mayo Clinic, Johns Hopkins University and the FDA has reported a serious adverse event rate of <1% attributable to plasma transfusion and a 7-day mortality rate of 14.9% in over 5,000 severely ill COVID-19 patients.(231)
4. On 23 August 2020, the FDA issued EUA for the use of convalescent plasma to treat “serious or life threatening” COVID-19 disease based in part on the publication of retrospective, observational data from 20,000 hospitalized patients treated under the Mayo Clinic’s expanded access program which reported decreased observed mortality in patients who received convalescent plasma with higher anti-SARS-CoV-2 antibody titers and those treated earlier.
5. Multicenter trials of convalescent plasma in hospitalized patients with hypoxemia have generally shown no benefit;(232, 233) as such, **the use of convalescent plasma is not recommended in hospitalized patients.** It is possible that there is a clinical benefit when administered early to non-hypoxemic ambulatory patients early in disease, similar to anti-SARS-CoV-2 monoclonal antibodies.
6. A DOD Expanded Access IND protocol for convalescent plasma sponsored by Army OTSG and executed through USAMMDA FHP Division was approved on 20 May 2020. Patients, regardless of age or pregnancy status or beneficiary status, admitted to DoD facilities with confirmed COVID-19 and respiratory compromise (e.g., dyspnea, supplemental O<sub>2</sub> requirement) were eligible for treatment with convalescent plasma. This protocol is now closed to enrollment.

### **Antithrombotic Therapy**

1. A number of studies have reported varying incidences of venous thromboembolism (VTE) in patients with COVID-19. A meta-analysis of studies in hospitalized patients with COVID-19 found an overall VTE prevalence of 14.1% (95% CI, 11.6–16.9).<sup>5</sup> The VTE prevalence was higher in studies that used ultrasound screening (40.3%; 95% CI, 27.0–54.3) than in studies that did not (9.5%; 95% CI, 7.5–11.7). In randomized controlled trials conducted prior to the COVID-19 pandemic, the incidence of VTE in non-COVID-19 hospitalized patients who received VTE prophylaxis ranged from 0.3% to 1% for symptomatic VTE and from 2.8% to 5.6% for VTE overall.(234-236)
2. More recently, preliminary results (released by press release) from three harmonized trials (ACTIV-4a, ATTACC, and REMAP-CAP) reported futility with the empiric use of full therapeutic anticoagulation in critically-ill patients with COVID-19 and respiratory failure. Somewhat paradoxically, however, the same studies also reported a mortality benefit in patients with severe COVID-19 and hypoxemia requiring

- supplemental oxygen who were not critically-ill.(237)
3. Patients who are receiving anticoagulant or antiplatelet therapies for underlying conditions should continue these medications if they receive a diagnosis of COVID-19.(238)
  4. For non-hospitalized patients with COVID-19, anticoagulants and antiplatelet therapy should not be initiated for the prevention of venous thromboembolism (VTE) or arterial thrombosis unless the patient has other indications for the therapy or is participating in a clinical trial.(238)
  5. Hospitalized non-pregnant adults with COVID-19 should receive prophylactic dose. Anticoagulant or antiplatelet therapy should not be used to prevent arterial thrombosis outside of the usual standard of care for patients without COVID-19.(238)
  6. There are currently insufficient data to recommend either for or against the use of thrombolytics or higher than the prophylactic dose of anticoagulation for VTE prophylaxis in hospitalized COVID-19 patients outside of a clinical trial.(238) However, it may be reasonable to consider therapeutic anticoagulation prior to escalating to critical care in higher risk patients.
  7. Hospitalized patients with COVID-19 should not routinely be discharged from the hospital while on VTE prophylaxis. Continuing anticoagulation with a FDA-approved regimen for extended VTE prophylaxis after hospital discharge can be considered in patients who are at low risk for bleeding and high risk for VTE, as per the protocols for patients without COVID-19.(238)
  8. There are currently insufficient data to recommend either for or against routine deep vein thrombosis screening in COVID-19 patients without signs or symptoms of VTE, regardless of the status of their coagulation markers.(238)
  9. For hospitalized COVID-19 patients who experience rapid deterioration of pulmonary, cardiac, or neurological function, or of sudden, localized loss of peripheral perfusion, the possibility of thromboembolic disease should be evaluated.(238)
  10. For hospitalized children with COVID-19, indications for VTE prophylaxis should be the same as those for children without COVID-19.(238)
  11. When diagnostic imaging is not possible, patients with COVID-19 who experience an incident thromboembolic event or who are highly suspected to have thromboembolic disease should be managed with therapeutic doses of anticoagulant therapy.(238)
  12. Patients with COVID-19 who require extracorporeal membrane oxygenation or continuous renal replacement therapy or who have thrombosis of catheters or extracorporeal filters should be treated with antithrombotic therapy as per the standard institutional protocols for those without COVID-19.(238).

Several additional agents are under investigation and information is expected to emerge rapidly. Discernment of benefits and harms from novel therapies will require diligent attention to quality of evidence reported.

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## **LONGTERM IMPLICATIONS OF COVID-19 (POST-COVID CONDITIONS)**

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### **Background**

1. After acute infection with SARS-CoV-2, some patients have a prolonged recovery with persistent symptoms even after the period of active viral replication has resolved. The CDC has offered “post-COVID” as an umbrella term for symptoms persisting for four or more weeks after acute SARS-CoV-2 infection (other common names in literature are “long COVID,” “long-haul COVID,” and “post-acute-COVID-19 syndrome”).
2. There is further subdivision, suggested by some authors, between those who suffer symptoms from four weeks up to twelve weeks (“Ongoing symptomatic COVID-19”) versus those who continue to have symptoms beyond the 12-week mark (“Post-COVID-19 syndrome”); at this point it is unclear if this reflects a true difference in underlying pathophysiology.
3. The prevalence of long-term symptoms varies widely, but studies have suggested that lingering symptoms in recovering adults may be present in over 70% of adults six months after infection, and while the risk of “Long Covid” is more likely with severe disease, even patients with mild disease may experience prolonged

symptoms.(239-241)

### **Presentation**

1. Fatigue, muscle weakness, shortness of breath, and cognitive dysfunction are the most frequently reported symptoms, but symptomology may vary widely and is dependent on the specific organ system impacted.(18, 142, 240, 242-244)
2. Of note, over 20% of patients will experience prolonged anxiety and poor sleep. Symptoms may impact daily function, and they can persist or have a relapsing remitting course over time.(142)
3. Multisystem residual effects may be observed in every organ system, especially in more severe cases.(18, 243) Though cardiopulmonary symptoms are not uncommon, severe chest pain or dyspnea could suggest more acute post-COVID complications such as multi-system-inflammatory-syndrome (MIS) or thromboembolic complications such as pulmonary embolism.

### **Evaluation**

1. For patients hospitalized with COVID-19, outpatient follow up should occur within 1-2 weeks of discharge and again at 6 weeks unless completely asymptomatic at initial follow up.
2. In addition to medication reconciliation and a comprehensive physical exam, additional investigation is on a case-by-case basis depending on the clinical course of the acute infection and may include evaluation for impaired renal function, critical illness myopathy or neuropathy, residual cardiac or pulmonary sequelae, and neuropsychiatric disease.(142)
3. Postural Orthostatic Tachycardia Syndrome has been associated with post-COVID, so tilt-table testing and an orthostatic heart rate assessment may be considered. Patients with new or concerning symptoms including chest pain, palpitations or persistent oxygen requirement should be appropriately evaluated.(142)
4. Laboratory and imaging studies may be non-diagnostic and should be tailored for each patient, especially for those with symptoms extending beyond 12 weeks. Basic laboratory testing may include CBC, electrolytes, renal function, liver function, CRP and ESR, ferritin, thyroid function, vitamin D testing, and B-type natriuretic peptide.

### **Diagnosis**

1. The diagnosis remains clinical. The diagnosis presumes previous infection with COVID-19 but lack of laboratory proof should not exclude this diagnosis in a patient with a compatible history. No specific symptoms are pathognomonic and no single lab or combination of labs is confirmatory.
2. According to the CDC (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-index.html>), in the setting of an illness compatible with COVID-19, a patient with lingering symptoms for four or more weeks can be considered to have post-COVID in the absence of any alternative diagnoses.
3. Recently, the World Health Organization established a global standard clinical case definition: “Post COVID-19 condition occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis” (<https://apps.who.int/iris/bitstream/handle/10665/345824/WHO-2019-nCoV-Post-COVID-19-condition-Clinical-case-definition-2021.1-eng.pdf>).

### **Management**

1. The treatment of the acute illness can impact likelihood of full recovery. For patients with sustained symptoms, regular follow up to care should be provided (ideally one month after the initial visit and extended as needed). Many patients can be adequately managed by their primary care provider with subspecialty referrals only as needed to evaluate suspected specific organ injury or system dysfunction. A structured multidisciplinary approach is recommended as available. Specific assessment tools for cognitive function, functional status, and psychiatric conditions may be found in the CDC guidelines (see above).
2. Primary care providers should establish partnerships with relevant subspecialty care, including mental health and rehabilitation providers. Medical management should focus on optimization of function, helping patients to set achievable goals, and improvement in quality of life. Specified graded rehabilitation goals with progress logs may prove beneficial in conjunction with exercise prescriptions as appropriate.



Specific measurable rehab goals can help reassure patients that though symptoms are persistent, if they are improving and not worsening, then further specialist evaluation is not likely to be indicated. If measured home exercises show deterioration, then the PCM may want to consider further evaluation.

3. Depending on the relationship with subspecialty partners, some directed testing may occur prior to referral. For pulmonary referrals, pulmonary function testing, computerized tomography of the chest, and a 6-minute walk distance may be obtained at the same time the referral is made. In general, outside of FDA-approved vitamin or electrolyte supplements, pharmacologic interventions should be avoided. Antiviral medications are expected to have no benefit given that the period of active viral replication has resolved by the time a patient meets criteria for diagnosis of post-COVID and should therefore not be used in an attempt to alleviate persistent symptoms. The CDC offers several general suggestions for approaches to longitudinal care; no formal guidelines have been published in the US but there is a clinical guideline available from the UK (<https://www.nice.org.uk/guidance/ng188>). (245)
4. History of COVID-19 illness can be a deployment or duty limiting condition. PCMs should seek service-specific guidance regarding Limited Duty or profile and return to work. Additionally, service members who were moderately to severely ill may require an additional cardiac work-up, functional assessment and potentially a medical waiver prior to deployment depending on location.

### **Prognosis**

1. The natural history of post-COVID condition remains unclear. During two other coronavirus epidemics (SARS-CoV and MERS-CoV) and the 1918 influenza pandemic, some survivors reported persistent symptoms including fatigue, dyspnea and mental health problems resulting in functional disability for up to 18 months. (246)
2. Severity of the acute illness may be correlated with length and severity of post-COVID symptoms, but post-COVID can be associated with mild disease as well.
3. Symptoms may wax and wane and may be exacerbated by various stressors. Studies have suggested that 30% of adults are readmitted within 6 months of infection for a variety of reasons. (247) Up to a quarter of patients have persistent pulmonary radiographic abnormalities and diffusion capacity impairment one year after acute infection. (248) Several large cohort studies are ongoing to elucidate this question.

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## **CARING FOR SPECIAL POPULATIONS: Pregnancy and Lactation, Infants, Children, and the Elderly**

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### **Overview**

- Pregnant, postpartum and lactating people and those considering pregnancy should receive the COVID-19 vaccination. Vaccination is the best method to reduce maternal and fetal complications of SARS-CoV-2 infection.
- Recent data from the Centers for Disease Control and Prevention COVID-19 surveillance suggest that pregnancy is an independent risk factor for severe COVID disease. In patients with COVID-19, pregnant people appear to be at increased risk for certain manifestations of severe illness compared to non-pregnant people, including ICU admission, mechanical ventilation, extracorporeal support, and death.
- Healthcare providers should be aware of the physiologic changes associated with pregnancy. Pregnant people have changes in their bodies that may increase their risk of some infections.
- Healthcare providers treating pregnant people should be aware of the most current guidance on Pregnancy/ Lactation guidance as prescribed by the Centers for Disease Control and Prevention (CDC), American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal-Fetal Medicine (SMFM), among others.
- Visitors are limited to one (healthy) support person during the entire admission, this may be modified by HPCON conditions and local infection rates.
- Cross-collaboration with surgical services healthcare providers and communities and pediatric and neonatal healthcare providers and communities is essential to ensuring positive outcomes.
- Separation of infant and mother dyads with confirmed maternal COVID-19 is no longer recommended.

- ACOG and SMFM have developed an algorithm to aid practitioners in assessing and managing pregnant women with suspected or confirmed COVID-19, which is included in **Appendix Q**.

### **Caring for Pregnant Women during the COVID-19 Pandemic**

1. With the evolution of the COVID-19 pandemic, obstetric providers must manage pregnant patients with limited experience and lack of rigorous data on which to base practice and protocols. For the most up to date pregnancy specific information, please refer to the Society for Maternal-Fetal Medicine (SMFM) webpage.(9)
2. **Epidemiology:** Based on recent data from the CDC COVID-19 surveillance, pregnant people with COVID-19 appear to be at increased risk for more severe illness compared to non-pregnant people. This data also indicates an increased risk for ICU admission and mechanical ventilation, extracorporeal support, and death.(249) It is also important to emphasize that although this report suggests an increase in risk of severe outcomes in pregnant people with SARS-CoV-2 infection, the absolute risk for severe COVID-19 is low.(42-45) Similar to the general population, obesity and gestational diabetes were associated with hospitalization and worsening respiratory status, and Black and Hispanic pregnant people had disproportionate rates of SARS CoV-2 infection and death.(250) Clinical findings in reported cases were similar in cases of non-pregnant adults. Pregnant people experience immunologic and physiologic changes that make them more susceptible to viral respiratory infections.(44) Pregnant people are at greater risk for severe illness, morbidity, and mortality compared with the general population, as is observed with other related coronavirus infections.(44, 45) Pregnant people should receive the same care as those not pregnant in regards to screening, radiology studies, laboratory evaluations, vaccinations and critical care.
3. **Pregnancy Complications:** Pregnancy in the setting of a COVID-19 infection is associated with higher rates of miscarriage (39.1%), preterm birth less than 37 weeks (24.3%), preeclampsia (16.2%), cesarean delivery (84%), increased incidence of neonatal admission (57.2%) and perinatal death (11.1%) Some cases of preterm birth were iatrogenic and not due to spontaneous preterm labor.(43-45)
4. Pregnancy care should be considered non-elective during the COVID-19 pandemic.
5. Providers are encouraged to encourage patient enrollment of pregnant patients confirmed with COVID-19 in the Pregnancy Coronavirus Outcomes Registry (PRIORITY) (<https://priority.ucsf.edu/>).
6. Health care providers should be familiar with the physiologic changes of pregnancy that make pregnant women more susceptible to some respiratory infections.
  - a. Immune modulation of pregnancy
  - b. Pregnant women are more susceptible to respiratory failure and can decompensate quickly (especially in the third trimester) due to 20% decrease in functional residual capacity.
  - c. Respiratory changes: Pregnancy is a metabolically compensated respiratory alkalosis
    - i. Normal pregnancy ABG pH 7.4-7.47
    - ii. Normal pregnancy PaO<sub>2</sub> 75-106 mm Hg (PaO<sub>2</sub> increases by 30 mm Hg)
    - iii. Normal pregnancy PaCO<sub>2</sub> 26-32 mm Hg (PaCO<sub>2</sub> decreases by 30 mmHg)
    - iv. Normal pregnancy HCO<sub>3</sub> 18-21
  - d. A PaCO<sub>2</sub> of 35 to 45 is ABNORMAL in pregnancy, and signifies impaired ventilation and impending respiratory compromise.
  - e. Critical care considerations for pregnant women; online training available at <https://www.smfm.org/education/criticalcare>
7. **Screening guidelines:** ACOG and SMFM algorithm for outpatient assessment and management of pregnant women with suspected or confirmed COVID-19: <https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/clinical-guidance/practice-advisory/COVID-19-algorithm.pdf?la=en&hash=2D9E7F62C97F8231561616FFDCA3B1A6>
  - a. Pregnant people admitted with suspected COVID-19 or who develop symptoms consistent with COVID-19 during admission should be prioritized for testing. Testing of asymptomatic pregnant people is at the discretion of the healthcare provider and facility. Facilities may consider universal testing, especially in high prevalence areas, due to risk of asymptomatic patients presenting to labor and delivery units.
8. A system should be in place for pregnant people who are tested for COVID-19 to be reported to their OB

Providers. This will allow OB providers to make critical delivery, care planning recommendations and decisions related to PPE recommendations, as all obstetric patients will require inpatient admission for delivery and initial postpartum period (1-4 days).

9. **Risk of Vertical Transmission:** Although cases of vertical transmission of SARS-CoV-2 have been reported, available data suggest that vertical transmission is uncommon.(251) When maternal infection occurs within 14 days before delivery, there is a theoretical risk of intrauterine transmission, since the virus has been detected in amniotic fluid, umbilical cord blood, and the nasopharynx in the first 24 hours of life. SARS-CoV-2 receptors are minimally expressed within the human placenta, indicating that SARS-CoV-2 is unlikely to infect the placenta through these established mechanisms and that in-utero transmission maybe less likely.
10. **Changes to Routine OB Care during COVID-19 Pandemic:** To decrease opportunities of exposure to coronavirus, OB providers should be taking steps to reduce patient encounters and optimize telehealth visits and home blood pressure monitoring. Guidance for practice has been published and we recommend developing plans at each MTF to standardize changes in Prenatal Care.(252)
11. **Inpatient OB staffing:** To ensure the availability of healthy providers and nurses to support ongoing needs of necessary care, consider workplace segregation, which will ensure service continuity and social distancing of healthcare workers, infection control and facilitate contact tracing. This is especially important for obstetric and newborn service lines which must continue to provide necessary prenatal, intrapartum and neonatal/postpartum care.
12. **Care for the Pregnant Patient with PUI or COVID-19:**
  - a. **Admission:** Patients with suspected or confirmed COVID-19 should be admitted to a unit capable of caring for the respiratory needs of the patient as well as provide appropriate fetal monitoring as clinically indicated. Patient should be in isolation per hospital and CDC guidance. Patients with known COVID-19 or suspected of having COVID-19 should be cared for in a single patient room with a closed door. Patients undergoing AGPs should be cared for in Airborne Infection Isolation Rooms.(253)
    - i. Outpatient monitoring with a 14 day self-quarantine can be considered for pregnant patients with COVID-19 who have mild symptoms or are asymptomatic.
      1. Patients should be monitored closely by their health care provider for worsening symptoms. Patients should perform daily self-assessments and educations of symptoms for worsening condition.
        - Worsening shortness of breath
        - Tachypnea
        - Unremitting fever despite acetaminophen
        - Inability to tolerate oral hydration or needed medication
        - Oxygen saturation <95% at rest or with exertion (if home pulse oximetry is available)
        - Persistent pleuritic chest pain
        - New onset confusion or lethargy
        - Cyanotic lips, face, or fingertips
        - Obstetrical complaints such as preterm contractions, vaginal bleeding or decreased fetal movement.
    - ii. Inpatient monitoring may be needed for the following categories of patients.
      1. Pregnant COVID-19 patients with moderate to severe signs and symptoms or oxygen saturation less than 95%
      2. Pregnant COVID-19 patients with comorbid conditions: uncontrolled HTN, inadequately controlled gestational or pre-gestational diabetes, chronic renal disease, chronic cardiopulmonary disease, concurrent pulmonary disease or immunosuppressive state (intrinsic or medication related)
      3. Pregnant COVID-19 patients with fevers >39° Celsius despite acetaminophen, raising concern for secondary hemato-phagocytic lymphohistiocytosis (sHLH)
      4. Pregnant COVID-19 patient with significant dehydration
      5. Pregnant COVID-19 patient with concurrent obstetric concerns. (See Society for Maternal-

Fetal Medicine Management reference).(9)

- b. COVID-19 may be associated with a transaminitis and thrombocytopenia, this is an important consideration when assessing women with a hypertensive disorder to determine if she has features of preeclampsia or HELLP syndrome (hemolysis elevated liver enzymes low platelet count).
- c. **Guidance for treatment:** Any patient warranting pharmacologic treatment should be considered for inpatient monitoring. At this time all pharmacologic agents are considered investigational and drug efficacy in COVID-19 remains unclear. Supportive therapy should be administered. Aggressive infection control, testing for COVID-19, testing for co-infection, oxygen therapy as needed, avoidance of fluid overload, empiric antibiotics (due to risk of superimposed bacterial risk), fetal and uterine contraction monitoring for viable pregnancies, early mechanical ventilation for progressive respiratory failure, individualized delivery planning, Maternal Fetal Medicine (MFM) consultation, Pulmonology, Critical Care and Infectious disease involvement as indicated. Team based management is recommended. Consider early transfer to higher level facility if unable to provide services at MTF.(254)
  - i. Ongoing clinical trials are investigating several pharmacologic treatment strategies in non-pregnant populations. Pregnancy remains an exclusion criteria for clinical trials of many therapies. Obstetric providers can advocate for compassionate use protocols and inclusion at their institutions.
  - ii. Remdesivir has not been studied in pregnancy and no human or animal data could be found.(255) However, remdesivir should be offered to pregnant patients with COVID-19 who meet criteria for use, as there is no known fetal toxicity associated with remdesivir.(256, 257)
  - iii. Dexamethasone (6 mg PO or IV daily for up to 10 days while hospitalized) may be used in patients with an oxygen requirement or who require intubation. If glucocorticoids are indicated for fetal lung maturity, dexamethasone 6 mg IM every 12 hours for 48 hours (4 doses) followed by up to 10 days of 6 mg dexamethasone PO/IV daily. If glucocorticoids are not indicated for fetal lung maturity, 6 mg dexamethasone daily (PO/IV) for up to 10 days should be utilized.
  - iv. Monoclonal antibodies (mAb) have not been tested in pregnancy, and more data are necessary to make broad recommendations for this population. mAb treatments are available under emergency use authorization (EUA),, and these treatments should not be considered the standard of care. These treatments should be reserved for patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease or hospitalization. High risk has been defined as BMI  $\geq$  35, chronic kidney disease, diabetes, and immunosuppressive treatment. However, these treatments should not be withheld from pregnant patients who have a high risk of progression to severe COVID-19 if the clinician thinks the potential benefit of the drug outweighs potential risk. Examples include, but are not limited to pregnant patients with solid organ transplantation or advanced vascular disease or other comorbidities such as type 1 diabetes mellitus. There is no absolute contraindication to their use in appropriate pregnant patients.(9, 250)
    - 1. Bamlanivimab (Ly-CoV555) and a cocktail of bamlanivimab plus etesevimab are mAbs used in clinical trials to treat COVID-19. These medications have not shown a benefit for patients who already require oxygenation or are hospitalized.
    - 2. Casirivimab (REGN10933) and imdevimab (REGN10987) are also authorized by the FDA for emergency use and consist of polyclonal “cocktails” of antibodies for treatment of mild to moderate COVID-19. Exclusion criteria include supplemental oxygen requirement, hospitalization, or severe disease.
- 13. **Imaging:** Necessary radiographic studies should not be withheld from a pregnant patient. Fetal risk of anomalies, growth restriction or abortion have not been reported with radiation exposure of less than 50 mGy, a level above the range of exposure for most diagnostic procedures.
- 14. **Antenatal surveillance:** Gestational age appropriate fetal monitoring should be part of the initial assessment of any women with respiratory symptoms. Continuous fetal monitoring in the setting of severe illness should be considered only when delivery would not compromise maternal health, or as another noninvasive measure of maternal status. For women who recover from an acute infection, antepartum testing later in the pregnancy is not needed.



15. **Ultrasound:** Consider a detailed level 2 anatomic survey for women following recovery from a first trimester infection and a fetal growth assessment in the third trimester for women who recover from an infection later in pregnancy (later second trimester and third trimester infections). Healthcare providers should be aware of the AIUM Official Statement Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as well as Safe Handling and Use of Ultrasound Coupling Gel (<https://www.aium.org/officialStatements/57>).
16. **Delivery planning for the COVID-19 patient:** Timing of delivery, in most cases, should not be dictated by maternal COVID-19 infection. For women infected early in pregnancy who recover, no alteration to the usual timing of delivery is necessary. For women infected in the third trimester who recover, it is reasonable to attempt to postpone delivery (if no other medical indications arise) either until a negative COVID-19 testing result is obtained or quarantine status is lifted in an attempt to avoid transmission to the neonate. In general, COVID-19 infection itself is not an indication for delivery. Recommend health care team wear appropriate PPE during delivery and delivery should occur in a negative pressure room. Skin to skin care following delivery is not recommended. In cases of severe maternal infection with a term infant, care teams may consider avoiding delayed cord clamping to minimize the risk of transmission to the neonate.
17. **Timing of delivery for pregnant patients with refractory hypoxemia:** In patients at  $\geq 32$  weeks with refractory hypoxemia, delivery may be considered if it will allow for further optimization of care. The severity of maternal illness may dictate an earlier delivery. At 32 weeks, neonatal mortality is 0.2% and remains at this level or lower for each week thereafter. Major morbidity occurs infrequently at these gestational ages: 8.7% at 32 weeks, 4.2% at 33, 4.4% at 34, 2.8% at 35 and 1.8% at 36 weeks of gestation, respectively. There may be a benefit to reducing the physiological demands of pregnancy in certain patients, such as those with COVID myocarditis, refractory hypoxemia, or prolonged recovery. The logistical and other potential clinical benefits of a controlled delivery may also facilitate optimization of care, and possible avoidance of perimortem delivery if further decline continues. Planning and decision-making surrounding delivery should include a multidisciplinary team and all involved decision-makers (including family/surrogates for the patient).(9)
18. **Protocols for inpatient care of the COVID-19 pregnant patient:**
  - a. Vital sign assessment: depends on the severity of the illness. For patients with mild symptoms requiring inpatient management, vital signs every 4-8 hours and as needed. For patient with severe disease vital signs every 2-4 hours is appropriate. For patients with critical illness continuous pulse oximetry and telemetry should be utilized. Noninvasive and invasive cardiovascular monitoring as indicated and vital signs and respiratory support as needed and at least every 1-2 hours.
  - b. **Fetal monitoring:** at  $>24$  weeks, electronic fetal monitoring for antenatal surveillance at least daily. Recommend additional fetal monitoring with any change in the maternal status if a cesarean at bedside is feasible. The fetus can be a sixth vital sign reflecting early deterioration in maternal status.
  - c. Recommend maintaining maternal  $O_2$  saturations at  $> 95\%$ .
  - d. **Early warning signs of worsening condition:** increased sensation of dyspnea or work of breathing; inability to maintain adequate oxygen saturation; persistent/more frequent fevers; worsening myalgias.
  - e. **ICU admission criteria:** The SMFM provides **Figure 22** as an algorithm for ICU admission, but the presence of any of the following should prompt admission to the ICU:
    - i. Inability to maintain oxygen saturation  $> 95\%$  with supplemental oxygen or rapidly escalating supplemental oxygen requirement
    - ii. Hypotension (MAP  $<65$ ) despite appropriate fluid resuscitation (500-1000 mL bolus of crystalloid).
    - iii. Evidence of new end organ dysfunction (altered mental status, renal insufficiency, hepatic insufficiency, cardiac dysfunction, etc.)
  - f. Pregnancy has a **natural respiratory alkalosis** with a normal  $PCO_2$  of 28-32.
  - g. **Therapy for ARDS** involves low tidal volumes and permissive hypercapnia ( $PCO_2 > 60$ ). Data on permissive hypercapnia in pregnancy are limited, but there do not appear to be adverse fetal effects.
  - h. It may be necessary to increase tidal volume and/or PEEP to meet goal  $PaCO_2$  and oxygenation targets while remaining mindful not to allow alveolar plateau pressures to exceed 35 cm H<sub>2</sub>O.

- i. **Prone ventilation** has been found to improve oxygenation in the setting of ARDS. If the patient would benefit from prone ventilation it should be performed and is safe.
- j. In the third trimester, **increased PEEP** may be required for pregnant moms on mechanical ventilation.
- k. **Neuromuscular blockade** (paralytics) have shown a benefit in the management of moderate-severe ARDS, especially if intubated early. Timing and duration of neuromuscular blockade for pregnant patients should follow institutional protocols.(9)

Figure 1. Algorithm for Intensive Care Unit Admission

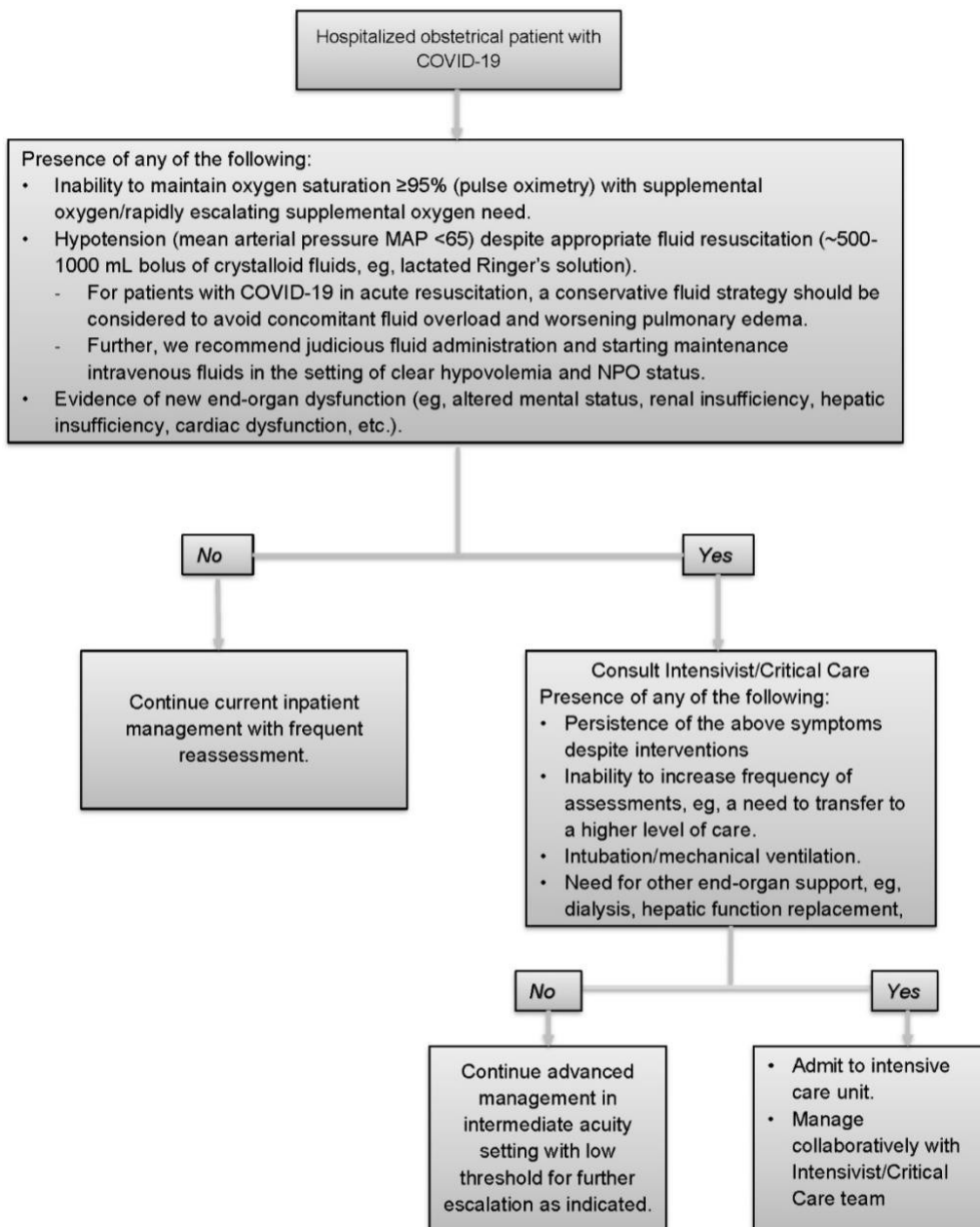


Figure 22. Algorithm for Intensive Care Unit Admission for Hospitalized Obstetrical Patients with COVID-19.(9)

- l. **Pulmonary vasodilators** may be useful with evolving, refractory hypoxemia in the parturient patient.

Although improved oxygenation is transient, it may allow for the initiation of other interventions such as transfer to a higher level of care, use of other modes of rescue ventilator strategies, mechanical circulation and/or delivery if greater than 32 weeks. Pulmonary vasodilators are not contraindicated in pregnancy, and use can be considered in the setting of refractory maternal hypoxemia. Fetal monitoring to determine delivery timing in viable neonates is not required, but should be discussed with the multidisciplinary team.(9)

- m. **Inhaled nitric oxide (NO)** and other inhaled vasodilators, such as prostacyclin, are not standard management for ARDS, but may be used as salvage therapy with refractory hypoxemia by dilating well-perfused ventilated lungs and leading to decreased V/Q mismatch and pulmonary shunting. Typically, the acute increase in oxygenation with inhaled NO is transient with no decrease in ventilator-free days or mortality. Additionally, there is some concern for renal impairment and methemoglobinemia, and methemoglobin levels should be assessed daily. Though the data on inhaled NO in pregnancy are limited, it has been used in pregnancy in cases of arterial hypertension and/or Eisenmenger syndrome. Because it is instantly metabolized, inhaled NO is thought to avoid placental metabolism and is not contraindicated in pregnancy.(9)
- n. **Veno-venous ECMO** is a proven life-saving salvage therapy for severe reversible respiratory failure, and its benefit among critically ill pregnant women has been reported. Pregnancy is not a contraindication to the use of ECMO, however there are special considerations related to adequate catheter placement, circuit flow, unit and/or institutional challenges, and overall care planning. ECMO should not be withheld from pregnant patients for whom it may potentially benefit if the patient is otherwise a candidate. An indication for or current use of ECMO is not necessarily an indication for delivery, and delivery timing should be a multidisciplinary decision. ECMO cannulation may prompt consideration of a timed delivery with consideration of risks and benefits of all available options for the pregnant mother and the fetus, and ECMO should not be delayed to effect delivery if no immediate life-threatening maternal or fetal indications exist. Indications for ECMO for obstetrical patients are similar to those for non-pregnant patients, although it is important to note that the definition of maternal refractory hypoxemia can be expanded to include the inability to maintain PaO<sub>2</sub> >70 mmHg with maximal FiO<sub>2</sub> despite efforts to optimize ventilation, which differs from the threshold of 60 mmHg in non-pregnant patients. The SMFM provides the algorithm below (**Figure 23**) for management of refractory hypoxemia in pregnancy.(9)
- o. Goal BP should be < 160/110.
- p. Patient should be positioned with left lateral tilt (if no other position is mandated for their treatment, for example, prone position) to relieve pressure from the gravid uterus on venous return.
- q. **Therapeutic anticoagulation** in critically ill pregnant patients: antepartum and postpartum
  - i. Prophylactic heparin or low-molecular weight heparin if there are no contraindications to use should be considered.(258)
  - ii. There is limited data on the use of therapeutic anticoagulation for severe COVID-19 disease.
  - iii. For therapeutic anticoagulation without confirmed thrombosis in a critically ill pregnant patient, unfractionated heparin should be considered due to its short half-life and reversibility with protamine sulfate. Unfractionated heparin should be considered for prophylaxis in patients at high risk for preterm birth due to its potential reversibility.
  - iv. For pregnant patients hospitalized for severe COVID-19, prophylactic anticoagulation is recommended if there are no contraindications to its use.(259)
  - v. Anticoagulation (UFH/LMWH) after discharge remains controversial, and routine VTE prophylaxis is not recommended after hospital discharge, however it is reasonable to consider additional patient-level risks such as obesity, pregnancy, immobility, and inherited thrombophilias when considering VTE prophylaxis after discharge.(9)
- r. **Antibiotics:** If co-infection is suspected cultures should be obtained when possible and appropriate antibiotics should be started as soon as possible after diagnosis. Ceftriaxone plus azithromycin or ceftriaxone alone are commonly used and are not contraindicated in pregnancy.

- i. For patients with severe disease or who have risk factors for hospital acquired, ventilator acquired or drug resistant types of pneumonia, broad spectrum agents should be employed such as cefepime, meropenem, piperacillin-tazobactam, linezolid, and vancomycin all are acceptable for use in pregnancy.

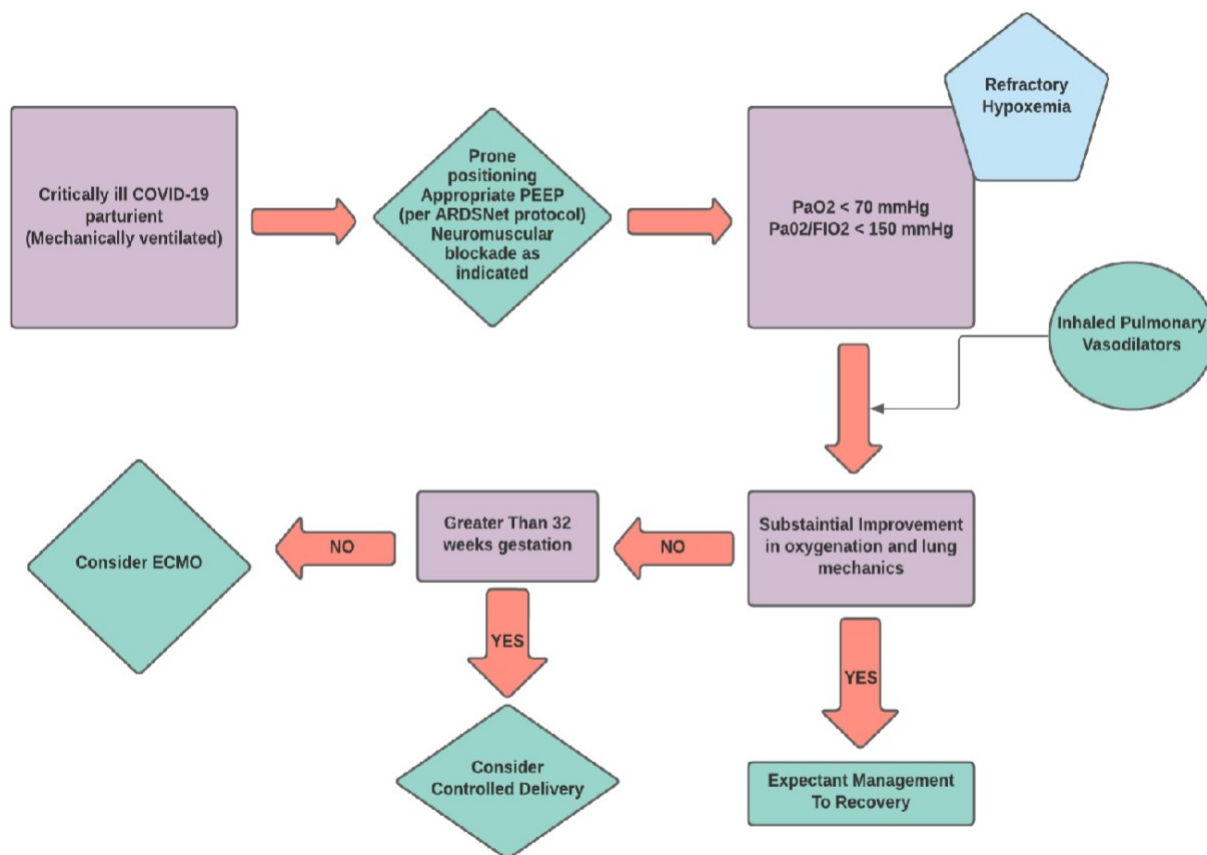


Figure 23. Algorithm for Refractory Hypoxemia for Critically Ill Obstetrical Patients with COVID-19.(9)

#### 19. Delivery planning in ICU:

- a. If pregnancy is complicated by critical illness, the patient should ideally be cared for at a Level III or IV hospital with obstetric services and an adult ICU. COVID-19 status by itself is not necessarily a reason to transfer a non-critically ill pregnant woman with suspected or confirmed COVID-19, but care location planning should be based on the levels of maternal and neonatal care.(260, 261)
- b. Equipment for emergency cesarean delivery should be at bedside, with neonatal resuscitative equipment including warmer.
- c. Hemorrhage Code Purple cart stocked with medications and devices should be in the ICU. Medications should readily available include methergine, hemabate, Tranexamic acid (TXA) and misoprostol.
- d. Use of terbutaline should be reviewed with critical care team, depending on patient's clinical status due to the risk of tachycardia.
- e. Establish effective means of communication with Nursing, ICU, anesthesia, neonatal, and obstetrical teams.
- f. If emergent delivery is planned, this may be performed at bedside in the ICU, or in a main operating room.
- g. Timing – consideration should be given to delivery > 32-34 weeks for critically ill maternal patient. Delivery consideration should be weighed carefully the risks and benefits. Decision for delivery requires close communication between the maternal fetal medicine and critical care team.
  - i. In the third trimester, the pressure of the uterus can decrease expiratory reserve volume,



inspiratory reserve volume, and functional residual capacity, which can increase the risk of severe hypoxemia in pregnant patients, especially those who are critically ill.(262)

20. Intrapartum care if a pregnant patient at term in critical condition goes into labor, precautions as above should be initiated. Assisted second stage (OB forceps/Vacuum) is likely to be necessary.
21. A dedicated obstetrician should be present at the time of delivery, and infant placed in isolation after delivery given the unknown risks of transmission.
22. Prevention of postpartum hemorrhage as detailed above.
23. Breast pumping encouraged after review of maternal medications.
24. Obstetric medications
  - a. Indomethacin – in the setting of indications for tocolysis, nifedipine may be considered as an alternative, given the uncertainty regarding NSAID impact on COVID-19.
  - b. Betamethasone/Dexamethasone for fetal maturation – given the unclear association between steroids and outcomes in pregnant women with COVID-19, recommend multi-disciplinary discussion on risks vs. benefits of steroids for fetal maturation. AVOID late preterm steroids 34-46 weeks for fetal maturation in COVID-19+/PUI patients.
  - c. Magnesium sulfate is recommended for fetal neuroprotection for anticipated preterm delivery <32 weeks or for seizure prophylaxis for Preeclampsia with severe features. Given potential respiratory complications, use judiciously in the setting of severe respiratory symptoms. Magnesium sulfate may be used in patients with mild-moderate symptoms, may consider single 4 gm bolus.
25. For pregnant people who are asymptomatic, mildly symptomatic, or moderately symptomatic who require analgesic medication beyond acetaminophen, nonsteroid anti-inflammatory drugs (NSAID) should be used if there are no other contraindications because systemic opioids likely pose more clinical risks.

**Table 8. Use of Common Obstetric Medications**

Gestational Age	< 32 weeks		32-34 weeks		34-36 weeks
Respiratory Sx	Mild-Mod	Severe	Mild-Mod	Severe	Any
Steroids for fetal maturation / rescue steroids	Use	Discuss risks/benefits with multi-D team (ID, Critical care, Neonatology)	Consider	Consider	Avoid
Indomethacin	May consider	Use nifedipine instead	Use nifedipine instead	Use nifedipine instead	Consider nifedipine instead
Magnesium sulfate neuroprotection	Use	Discuss risks/benefits with multi-D team (ID, Critical care, Neonatology)			

26. **Cardiac arrest:** in pregnancy should be managed similar to cardiac arrest in non-pregnant adults. If pregnancy is ≥ 20 weeks (uterus at or above the umbilicus), significant aortocaval compression exists. Left uterine displacement is recommended during high-quality CPR, with resuscitative cesarean delivery (perimortem cesarean delivery) if ROSC not achieved by 4-5 minutes. Resuscitative cesarean delivery should be performed at the bedside (do not move to the OR). See **Appendix O**.(6, 263)
27. **Intrapartum care during the COVID-19 pandemic:**
  - a. Screen all patients and support person(s) according to ACOG SMFM algorithm upon presentation to L&D.
  - b. We also suggest asking all patients and support person(s) about exposures (close contact) to COVID positive patients and if they themselves have been tested in the past 14 days for COVID-19.
  - c. Recommend a designated staff member at the front of the unit to verbally screen for URI symptoms, diagnosis of COVID-19 or PUI within the past 2 weeks.
  - d. Any patient with fever, cough, or respiratory symptoms (+/- fever) should put on a surgical mask and be evaluated by a nurse or provider (and put in a room).
  - e. If a patient screens positive to any of the above prior to a scheduled delivery (IOL or CD), evaluate to

- determine if re-scheduling in 2-3 days is feasible to allow for results of COVID-19 testing.
- f. For COVID-19 positive patients with mild or moderate symptoms not requiring immediate care, it is important to recognize that the severity of disease peaks in the second week, so planning delivery prior to that time is optimal.
  - g. Risk of vertical transmission – Although there are cases of reported vertical transmission of SARS-CoV-2, the data are reassuring that vertical transmission appears to be uncommon.
  - h. Avoid oxygen for fetal resuscitation (this intervention has not been shown to be beneficial and may increase the risk of aerosolization).
  - i. If a birth partner (support person) has a fever, cough, or respiratory symptoms (+/- fever) (or confirmed COVID-19 positive or PUI), they should not come to L&D, and will not be admitted to L&D as a support person.
  - j. Routine preoperative labs for scheduled cases should be drawn the day of procedure to minimize trips to the hospital.
  - k. **Intrapartum fever** – should be evaluated in the usual fashion with consideration for both obstetric and non-obstetric causes. Recommend empiric treatment for the clinically suspected cause (e.g. chorioamnionitis), with increased vigilance and consideration of rapid COVID-19 testing. Early experience has shown the possibility of asymptomatic pregnant patients to develop symptoms postpartum.
  - l. **Cesarean section:** As for all patients, cesarean section should be reserved for maternal and fetal indications. Consider conversions of operating rooms to negative pressure rooms (conversion to negative pressure ante-rooms or neutral pressure ORs are alternatives) for COVID positive or PUI. Such conversions may not be possible in all facilities, and with proper PPE and patient transfer protocols, cesarean deliveries can still be safely performed in a positive-flow OR. In general, negative pressure ORs should not have open surgical equipment (as is often done for designated emergent cesarean delivery rooms). Teams should coordinate with local infection control teams to inform these decisions. Consider universal airborne PPE use (including N95 masks) for all surgical procedures for COVID+/PUI patients during labor and delivery due to high risk for aerosolizing procedures (intubation).
28. **Support person:** If a birth partner (support person) has a fever, cough, or respiratory symptoms (+/- fever) (or confirmed COVID-19+ or PUI), they should not come to L&D or be admitted as a support person.
- a. Visitors are limited to one (healthy) support person during the entire admission. (252)
  - b. Support persons of a COVID-19 positive or PUI mother should wear a mask without exhalation vents during their hospital stay, and are restricted to the patient room (should not visit hospital areas outside patient room). They should use the bathroom in the patient room, and should have all meals brought to the room.
29. **Inductions of labor:**
- a. Induction of labor with medical indications in asymptomatic pregnant people should NOT be postponed or rescheduled. This includes 39-week inductions after patient counseling. However, in cases of extreme healthcare burden, it may be appropriate to consider postponing or rescheduling inductions. For example, in a region early in a COVID-19 emergency, it may be prudent to get patients delivered prior to high COVID-19 burden in the hospital.
  - b. Consider outpatient cervical ripening with Foley in low-risk women to limit hospital time.
  - c. Management of the first stage of labor is not generally altered. Oral restriction of fluid and solid food in the first stage of labor is not recommended, oral water and clear fluids can be encouraged as tolerated in labor. If oral restriction, IVF at 250 mL/hr. containing dextrose, with upright positions in the first stage of labor for women without epidural. If walking, must stay in the room. Oxytocin augmentation is recommended to shorten time in labor if slowed progress, with early amniotomy.
  - d. Intrapartum oxygen therapy has no fetal benefit and may cause harm, **recommend NOT utilizing oxygen therapy for fetal resuscitation.** Given the high rate of asymptomatic carriers, this principle applies to all patients on L&D regardless of the patient's COVID-19 status. Supplemental oxygen may be administered for maternal indications, cover nasal cannula with a surgical mask.

30. **Second stage (Pushing to delivery):** Pushing should not be delayed for any delivery as it prolongs time to delivery and increases chorioamnionitis and postpartum hemorrhage.
31. **Third stage (Delivery of baby to delivery of placenta):** There are concerns about limited blood resources during the COVID-19 pandemic. The below recommendations apply to all deliveries to further minimize use of blood products at delivery.
  - a. Recommend optimizing antenatal hemoglobin prior to delivery to minimize the need for blood transfusion at delivery.
  - b. Consider 400 mcg misoprostol buccally with delivery (to decrease risk of PPH).
32. **PPE considerations during COVID-19 pandemic for pregnancy:**
  - a. Screen positive patients (symptoms or prior COVID-19 diagnosis) or PUI:
    - i. PPE during admission: Surgical mask for all patients with symptoms or COVID-19+/PUI. Airborne precautions: N95 masks and droplet PPE (Gown, gloves, mask/face shield) for all HCP.
  - b. Screen negative patients (no symptoms or prior COVID-19 diagnosis):
    - i. PPE during delivery: Surgical mask and droplet PPE (Gown, gloves, mask/face shield) should be used during all patients in the second stage. N95 Mask could be considered for the surgical team for any cesarean section as there is the potential risk of requiring intubation during the surgery. Provider discretion and individual MTF PPE availability can be considered.(252)
  - c. Women who are COVID-19+ or PUI should wear a surgical mask at all times as clinically able.
  - d. Women who are COVID-19+ or PUI should be placed in an isolation/private room. Airborne infection isolation rooms (negative pressure rooms), if available, can be used if performance of aerosolizing procedures is anticipated. In general, isolation rooms with droplet precautions are recommended.
  - e. Staff PPE:
    - i. Proper donning and doffing of PPE takes time. Training in the use of PPE should emphasize safety of healthcare workers, recognizing that clinical response times may be slowed by these precautions.
    - ii. Proper donning and doffing procedures should be reviewed and practiced frequently; Recommend simulated patient transfers (e.g. from L&D to OR).
    - iii. Recommend posting diagrams and checklists in areas where donning and doffing will occur.
    - iv. For HCP that do not fit N95 masks, PAPR should be used. For staff in the operating the OR, the PAPR with shroud must be used, followed by sterile gown over the shroud. This ensures proper venting of the PAPR out the bottom of the surgical mask to ensure sterility of the field.
    - v. Have an observer witness donning/doffing when possible.
  - f. Anticipate emergencies as best as possible; plan ahead and proactively intervene for situations that could result in emergent cesarean delivery (e.g. Category II FHR), early pediatric notification. For COVID-19 positive patients undergoing procedures with high risk for intubation, full PPE with N95 mask or PAPR should be considered.(264)
  - g. Collaborate closely with Surgical Services to support additional operating room/staffing capabilities.
  - h. Define patient OR plan on admission (COVID-19 or not).
  - i. Coordination with Pediatrics and Neonatology upon admission for any mother COVID-19+ or PUI.

**Table 9. Suggested PPE During Obstetric Care (252)**

Care situation	Surgical mask*	Droplet PPE (gown, gloves, surgical mask/ face shield)	N-95 mask or PAPR
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<i>Patient (cloth mask acceptable if no resp sx)</i>	<i>X</i>	
<i>Provider during routine encounters</i>	<i>X</i>	
<i>Provider during patient encounters with URI sx</i>	<i>X</i>	
<i>Provider during patient encounters with suspected or confirmed COVID-19</i>	<i>X</i>	<i>X</i>

\* HCP working in areas with moderate to substantial community transmission are more likely to encounter asymptomatic or pre-symptomatic patients and should also wear eye protection to ensure protection from respiratory secretions during patient encounters. Personal eyeglasses and contact lenses are not considered adequate eye protection.

**33. Considerations for support person/visitors to L&D and antepartum/postpartum units:**

- One designated (healthy) support person during the entire admission, easily identifiable by L&D staff. Consider a colored wrist band for identification. Support person should be screened as above, wear a mask, and remain restricted to the patient room for mothers that are COVID-19 positive or PUI.
- No children < 16 years permitted.
- Additional visitors for end-of life situations or bereavement (e.g. IUFD) may be considered/evaluated on a case-by-case basis.
- All efforts should be made to limit the movement of COVID-19 positive/PUI women from one care area to another. Consider postpartum care in the same room as delivery if possible.
- If increased prevalence of disease and community transmission is present, individual MTFs could consider a no visitation policy to minimize potential exposure of staff and patients.

**34. Anesthesia considerations for intrapartum care (Refer to Implications for Surgical Care Section):**

- Recommend early epidural to minimize need for general anesthesia in the event of an emergent cesarean.
- COVID-19 is not a contraindication to neuraxial anesthesia.
- Anticipate emergencies as best as possible; plan ahead and proactively intervene for situations that could result in emergent cesarean delivery (e.g. Category II FHR tracing).
- Recommend limiting exposure of trainees to COVID+/PUI, with experienced staff providing care.
- Suspend nitrous oxide programs on L&D due to possible aerosolization.(265)

**35. Postpartum care:**

- In most centers, discharge prior to usual practice with the intent to reduce risk of COVID-19 infection provides no advantage to the newborn or family. The decision to early discharge should be a joint decision between OB, Pediatrics and the family, and eligibility for early discharge should remain consistent with the facility's pre-COVID practices.
- All postpartum visits, including wound checks, should be via telehealth. Can optimize by uploading photos through EMR/patient portals.

- 36. Pregnant patient work restrictions:** Delivery is a unique scenario in the COVID-19 pandemic. Hospital admissions for delivery are anticipated around the patient's due-date. In anticipation of hospital admission for delivery, if feasible and mission permitting, consider having pregnant people work from home at 37 weeks (2 weeks prior to 39 weeks or 2 weeks prior to anticipated delivery), and practice strict social isolation during this time.(252) Strict social isolation is encouraged for the entire family unit. The goal is to limit risk of exposure around the time of delivery. Depending on mission requirements and increasing disease burdens, such accommodations may not be possible but should be considered. Pregnant women may continue to work until they give birth or go on social isolation (as above). ACOG recommends that:(250)
- Pregnant individuals who continue to work should be provided the ability to occupy roles in which there is reduced risk of exposure to COVID-19 if they so choose.
  - Employers should follow current CDC guidance and direction from local and state health departments (CDC).
  - Employers assess the hazards to which their workers may be exposed; evaluate the risk of exposure; and select, implement, and ensure workers use controls to prevent exposure (Department of Labor).



- d. Prevention practices, including physical distancing, hand hygiene, surface decontamination, and wearing a cloth face covering or facemask (for source control), should be applied to all individuals given the potential for asymptomatic SARS-CoV-2 transmission.
  - e. Accommodations related to the work environment specific to non-pregnant employees with comorbidities should be applied to pregnant employees with similar comorbidities. This is because pregnant individuals with comorbidities continue to be at increased risk of severe illness consistent with the general population with similar comorbidities.
  - f. If a pregnant individual requests a letter to support a COVID-19-specific work accommodation, maternal health care professionals can respond to the request in the context of the risk to the pregnant individual considering the particular patient's circumstances. Further, maternal health care professionals should advocate for every possible protection from exposure to COVID-19 (e.g., masks, gloves, remote working, proper ventilation, etc.) for pregnant women in the work place.
37. **Pregnant health care workers:** Facilities consider limiting exposure of pregnant HCP to patients with confirmed or suspected COVID-19 infection, especially during higher-risk procedures such as aerosol generating procedures (AGP) [intubation, extubation, BiPAP, high flow nasal cannula, nebulized medications] if feasible based on staffing availability. With ongoing stresses in the MHS and increasing disease burdens, such accommodations may not be possible. All healthcare personnel, including pregnant women, should be provided and appropriately use recommended PPE, including facemasks, and follow public health guidance to avoid nosocomial or community acquisition of COVID-19. When all recommended PPE is not available, pregnant health care personnel should avoid exposure to high-risk procedures in patients with suspected or confirmed COVID-19. Health care personnel are not ethically obligated to provide care to high-risk patients without adequate protections in place. Pregnant individuals may continue to work in patient-facing roles until they give birth if they so desire and if all recommended PPE is available. Pregnant individuals with comorbidities, such as obesity, are likely at increased risk for severe illness consistent with the general population. Thus, any recommendations related to the work environment specific to health care personnel with comorbidities should be applied to pregnant health care personnel with similar comorbidities.(250)

### **COVID-19 Vaccination Considerations During Pregnancy and Lactation**

1. The Centers for Disease Control and Prevention, American College of Obstetricians and Gynecologists (ACOG), the American Society for Reproductive Medicine (ASRM) and the Society for Maternal Fetal Medicine (SMFM) recommend that pregnant, postpartum, and lactating people and those considering pregnancy receive the COVID-19 vaccination, and the vaccine should be offered independent of trimester. Emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health. ACOG also recommends that pregnant and recently pregnant people up to 6 weeks postpartum, including pregnant and recently pregnant health care workers, receive a booster dose of COVID-19 vaccine following the completion of their initial COVID-19 vaccine or vaccine series. Vaccination is the best approach to reduce maternal and fetal complications of SARS-CoV-2 infection.(266, 267)
2. Data indicate that pregnancy is an independent risk factor for severe COVID-19 disease. Pregnancy is independently associated with a 3-fold increased risk for ICU admission, a 2.4-fold increased risk for needing extracorporeal membrane oxygenation (ECMO), and a 1.7-fold increased risk of death due to COVID-19 compared to symptomatic non-pregnant patients. Pregnant patients with comorbidities (body mass index greater than 35 kg/m<sup>2</sup>, diabetes, heart disorders, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised from organ transplantation, sickle cell disease and smoking) and those older than age 35 also appear to have an increased risk of adverse maternal outcomes. Data also indicate increased risk of adverse obstetric outcomes, including cesarean delivery, preterm birth and possibly stillbirth in pregnant patients with symptomatic SARS-CoV-2 infection.
3. It is recommended that all pregnant individuals receive a COVID-19 vaccine, and they should be counseled by health care personnel in alignment with the CDC, ACOG, the ASRM, and the SMFM recommendations for vaccination. Counseling to support the recommendation for vaccination should include data on vaccine efficacy and vaccine safety during pregnancy and lactation. Provider counseling has been shown to have a significant positive impact on patient vaccination.

4. All currently available COVID-19 vaccines have demonstrated high efficacy among their clinical trial endpoints, and mounting evidence indicates that fully vaccinated people are less likely to have asymptomatic infection or transmit SARS-CoV-2 to others. Current safety data on COVID-19 vaccines in pregnancy is reassuring and does not indicate safety concerns. No safety signals (including miscarriage) were found in over 35 thousand pregnant persons studied, who received the COVID-19 vaccines, regardless of timing of vaccination. The mRNA vaccines contain mRNA, a genetic material that encodes the SARS-CoV-2 spike S protein, the predominant immunomodulatory target associated with severe effects. They are not live vaccines and preclinical data suggest rapid degradation (approximately 10-20 days) by normal cellular processes. There is no risk for insertional mutagenesis, as the mRNA does not enter the cell's nucleus. In other words, there is no risk of genetic modification to people receiving the vaccine. Data from Developmental and Reproductive Toxicity (DART) studies for the Pfizer-BioNTech COVID-19 vaccine have been reported in Europe with animal studies indicating that there are no direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or postnatal development. A combined developmental and perinatal/postnatal reproductive toxicity (DART) study of Moderna's mRNA-1273 in rats, showed that mRNA1273 given prior to mating and during gestation at a dose of 100 µg did not have adverse effects on female reproduction, fetal/embryonal development, or postnatal development except for skeletal variations, which are common and typically resolve postnatally without intervention.
5. Concerns that COVID-19 vaccines adversely affect fertility are unfounded. None of the currently available COVID-19 vaccines reach or cross the placenta. Because COVID-19 mRNA vaccines are not composed of live virus, they do not cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies. The mechanism of action of mRNA vaccines and existing safety data provide reassurance regarding the safety of COVID-19 mRNA vaccines during pregnancy.
6. However, protective antibodies to COVID-19 have been shown to cross the placenta and provide protection to the baby after delivery. Similarly, the COVID-19 vaccine is safe during lactation, and protective antibodies to COVID-19 are passed through the breastmilk for at least six weeks post-vaccination, providing additional protection to the nursing child.
7. The FDA has a warning about the possibility of thrombosis with thrombocytopenia syndrome (TTS) to the Janssen COVID-19 vaccine EUA fact sheet. Most cases of TTS reported following the receipt of the Janssen COVID-19 vaccine have occurred in women of reproductive age, however none of these individuals were pregnant. While TTS is a serious condition, it is rare, occurring in 8.9 out of every million doses of Janssen COVID-19 vaccine administered to females ages 18-49 years. Given the low incidence of TTS and the high risk of serious illness from COVID-19 infection, women under 50, including pregnant people can receive any FDA-authorized COVID-19 vaccine available to them. However, they should be aware of the rare risk of TTS after the Janssen COVID-19 vaccine, and that other FDA-authorized COVID-19 vaccines are available (i.e. mRNA vaccines). Patients who chose not to receive the Janssen COVID-19 vaccine should be strongly encouraged to receive one of the other COVID-19 vaccines available under EUA. Although the overall general risk of thrombosis is increased during pregnancy and postpartum, and with estrogen containing hormonal contraceptives, experts do not believe that these factors make people more susceptible to TTS after receiving the Janssen COVID-19 vaccine. There is no recommendation to discontinue or change hormonal contraception in patients who received or plan to receive the Janssen COVID-19 vaccine. People who take aspirin or anticoagulants as part of their routine medications, including during pregnancy, do not need to stop or alter the dose of these medications prior to receipt of the Janssen COVID-19 Vaccine.
8. COVID-19 vaccines may be administered simultaneously with other vaccines, including within 14 days of receipt of another vaccine. This includes vaccines routinely administered during pregnancy such as influenza and Tdap.
9. Dosing recommendations for the vaccine(s) are the same as for non-pregnant individuals). Pregnant women experiencing fever following vaccination should be counseled to take acetaminophen.
10. Patients who conceive in the window between the first and second dose of the vaccine should be offered the second dose of the vaccine at the appropriate interval.(268)

**Caring for Infants and Mothers with COVID-19: IPC and Breastfeeding**

1. Current evidence is inconclusive about in utero transmission of SARS-CoV-2 from mothers with COVID-19 to their newborns; however, data from the National Perinatal COVID-19 Registry, which includes over 4,300 maternal-infant dyads, suggests that symptomatic vertical transmission is rare.(269) Transmission of SARS-CoV-2 can occur after birth via contact with infectious respiratory secretions, and can lead to hospitalizations requiring respiratory support.(269) Data suggests that infants may be at higher risk for severe illness compared with older children.(269-272)
2. The risk of infection to the newborn during birth hospitalization is low and not greater when mother and infants room in together compared to when they are separated as long as precautions are taken. Separation can lead to delayed maternal-child bonding and impaired breastfeeding. Newborns should be allowed to room-in in accordance with usual practice. If choosing to room together, mothers should wear a facemask and practice hand hygiene during contact with the infant. When not in contact with the infant, the mother should be 6 feet from the mother or placed in an incubator.(271)

**Lactation: Breastfeeding, Pumping, or Expressed Breast Milk (273)**

1. Breast milk is the best source of nutrition for most infants. It is unknown if mothers with COVID-19 can transmit the virus via breast milk as several studies have detected SARS-CoV-2 nucleic acid in breast milk, but viable virus has not been detected.(274) Mothers with COVID-19 or PUI who are direct breastfeeding should perform hand hygiene and wear a mask.(269)
2. Postpartum patients with COVID-19 who are pumping should be provided with a dedicated breast pump while inpatient and follow CDC guidelines on equipment use and feeding. Mothers should wash hands and breasts before pumping and wear a mask.
3. Recommended procedure to follow while pumping milk:
  - a. Wipe the surface where syringes/bottles will be placed after collection with a germicidal disposable wipe, and cover surface with clean paper towel or cloth.
  - b. Mother collects breast milk by hand or by pump into clean syringes or bottles then ensures syringe/bottle cap is secured. The outside of the container will be wiped with a germicidal disposable wipe. A label is then placed to identify date, time, and patient.
  - c. Transport and storage of breast milk from mother's room to common refrigerated storage area should follow strict infection control procedures per hospital policy.
4. Current evidence suggests that human milk is not likely a source of SARS-CoV-2 infection, and pasteurization for use as donor milk further inactivates the virus.(275)

**Infants**

1. Infants born to mothers with suspected or confirmed COVID-19 should be considered PUIs.
2. Resuscitation for infants born to mothers with suspected or confirmed COVID-19 should utilize airborne PPE due to potential for aerosolization during the 2<sup>nd</sup> stage of labor and the potential need for aerosol-generating procedures (e.g., intubation, PPV, CPAP) of the infant. The infant should be bathed as soon as clinical condition allows.
3. The CDC recommends testing for all neonates born to women with confirmed or suspected COVID-19. Infants should be tested at ~24 hours. If initial test results are negative, testing should be repeated at 48 hours. If infant is asymptomatic and expected to be discharged at <48 hours, a single test performed when the infant is >24 hours is acceptable.(270) If testing is limited, infants with symptoms of COVID-19 and infants with exposure to COVID-19 and require escalation of care/suspected prolonged hospital course should be prioritized.(271)
4. While most elective procedures should be deferred while an infant is a PUI, the AAP recommends that well newborns, defined as negative molecular testing and asymptomatic, can receive a circumcision. Newborns who are PUIs are not eligible for elective circumcision.
5. If hearing tests can be performed outpatient, it is acceptable to defer until COVID-19 testing is negative, but best practices are to be done by 1 month of age.(276) If it is not easily available outpatient, ensure proper disinfection measures are used when cleaning equipment.

**Neonatal Intensive Care Unit (269, 277)**

1. Recommend any infant who has symptoms that meet criteria for NICU admission be assessed by the NICU team and admitted to a COVID-19 cohort pod or other segregated section of the unit.
2. Healthcare workers should wear full PPE including N95 (or PAPR), eye shields, gown, hair cover, and gloves should be worn when caring for the PUI or COVID-19 positive infant.
  - a. In situations where there is limited PPE available, N95 (or PAPR) use should be prioritized for use in the care of infants requiring CPAP, SiPAP, high-flow nasal cannula with flow rate >2LPM, or undergoing aerosolizing procedures such as intubation.
3. For newborns who have been separated from an infected mother shortly after birth and admitted directly to the NICU, infection control precautions should be used until the infant has negative testing at approximately 24 and 48-72 hours of age. This testing addresses the risk that the infant has acquired the virus by vertical transmission.(276)
4. For newborns who have been rooming-in with an infected, presumed or known contagious mother who subsequently require admission to the NICU, infection control precautions should be used until 10 days have passed since the last maternal-infant contact. Centers may determine testing based on their local resources; however, testing on admission to the NICU, and at 5-7 days after last maternal contact is recommended. This testing addresses the risk that the infant has acquired the virus by horizontal transmission.

**Newborn Visitation (271)**

1. No visitors experiencing cough, fever, or shortness of breath should be allowed in any care setting.
2. All visitors should wear a facemask and adhere to local infection control policies.
3. For NICU: Visitation should be limited to the mother and one support person. Mothers and partners who are fully vaccinated who have an exposure to COVID-19 should not be excluded from the NICU unless they develop symptoms consistent with SARS-CoV-2 infection. Mothers and partners with confirmed COVID-19 should not visit the NICU until they meet the following requirements:
  - a. At least 10 days have passed since symptoms first appeared (up to 20 days if they have more severe to critical illness or are severely immunocompromised); AND
  - b. They are afebrile for 24 hours without use of antipyretics; AND
  - c. Their other symptoms have improved.
  - d. For mothers who never develop symptoms, isolation and other precautions can be discontinued 10 days after the date of her first positive test.
  - e. Entrance to other family support personnel should be determined on a case by case basis.
4. For Labor and Delivery, Post-partum / Newborn Nursery: each COVID-19 positive or PUI postpartum mother may be allowed to have one support person with her who must remain with her throughout the admission. This support person should be isolated to the post-partum room and not traveling elsewhere in the hospital.
  - a. If the mother chooses to co-locate with the infant, the support person should help with infant care.
  - b. If the mother chooses to be separated from her infant, the support person may help with the infant's care when they are brought to the room.

**Newborn Discharge (269, 271)**

1. Early discharge does not provide benefit to reduce the risk of COVID-19 and may cause increased stress or burden on families and the healthcare system for outpatient follow up.
2. After hospital discharge, a mother with COVID-19 is advised to maintain a distance of at least 6 feet from the newborn, and when in closer proximity, to use a mask and hand-hygiene for newborn care until:
  - a. She is afebrile for 24 hours without use of antipyretics; **AND**
  - b. At least 10 days have passed since her symptoms first appeared (or, in the case of asymptomatic women identified only by obstetric screening tests, at least 10 days have passed since the positive test), **AND**
  - c. Symptoms have improved.
3. A mother with COVID-19 whose newborn requires ongoing hospital care should maintain separation until:
  - a. She is afebrile for 424 hours without use of antipyretics, **AND**
  - b. At least 10 days have passed since her symptoms first appeared (or, in the case of asymptomatic women



- identified only by obstetric screening tests, at least 10 days have passed since the positive test), **AND**
- c. Symptoms have improved.
  4. Breastfed infants by a PUI or confirmed COVID-19 should be considered as a close contact of a person with COVID-19, and should be quarantined for the duration of both the lactating parent's recommended period of home isolation **AND** during their own quarantine thereafter.

CDC Guidance: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-newborns.html>;

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/care-for-breastfeeding-women.html>

AAP Guidance: <https://services.aap.org/en/pages/2019-novel-coronavirus-COVID-19-infections/faqs-management-of-infants-born-to-COVID-19-mothers/>; <https://services.aap.org/en/pages/2019-novel-coronavirus-covidCOVID-19-infections/clinical-guidance/guidance-on-newborn-screening-during-covidCOVID-19/>

### **Caring for Children with COVID-19**

1. Children (<18 years) currently make up 16.4% of all the laboratory-confirmed COVID-19 cases in the United States with nearly 9.5 million pediatric cases as of January 15, 2022. To put this into perspective, consider that children make up approximately 22% of the US population. There has been a dramatic spike of COVID-19 cases among school-age and pre-school age children during the late summer 2021 and extending through the winter with SARS-CoV-2, associated both with the appearance of the Delta variant and, in many places, weak application of public health measures. More recently, there have been nearly 1 million cases reported for the week ending 13 January 2022, which is a 69% increase over the 580,000 added cases the week prior and four times the rate of the peak of last winter's surge.(49, 61, 278)
2. Both infected asymptomatic and symptomatic children have replicating virus present within nasopharyngeal space and the ability to transmit disease. Studies of child to adult and child to child transmission, regardless of setting, are limited by an overall lack of testing data in asymptomatic children, even when exposed.
  - a. A study of Arizona school districts, showed a strong association between the risk of school based outbreaks and the use of masks in schools, with a risk 3.5 times higher in schools without mask requirements as compared to those with a mask requirement early in the school year (OR = 3.5; 95% CI= 1.8–6.9).(279)
  - b. A study of 11 North Carolina school districts (K-12) with over 90,000 students and staff members with in-person learning for 9 weeks found only 32 cases of school-transmission of which there were 0 student-to-teacher cases. This study suggests strict adherence to masks and social distancing was effective in minimizing transmission while safely allowing in-person school attendance.(280)
  - c. A recent meta-analysis found the adult index cases had a secondary attack rate of 28.3% while pediatric index cases had a secondary attack rate of only 16.8%, suggesting less risk of transmission from children when compared to adults, but the reason for this observation is not fully understood and has the potential for observational biases. It also does not account for novel strains of the virus for which there is evidence of increased transmission.
  - d. In a study from the UK, for adults >65 years of age, living with children 0-11 years old was associated with an increased risk of COVID-19 infection, 1.06 (1.05 to 1.08). However, living with children >12-18 years old had a higher risk of COVID-19 infection (Hazard Ratio 1.0822, 95% CI 1.20-1.24) and no effects on the risk of hospital admission.(281) This study was conducted before the surge in pediatric cases that occurred associated with the Delta and Omicron variants and additional studies are required.
3. While pediatric cases are rising, mortality remains low at <0.1% for acute COVID-19 in children <18years old.(49, 51)
  - a. 1,131 COVID-19 related-deaths have been reported in children 0-17 years old as of Jan 2022.(61)
  - b. One study reported higher mortality rates for COVID-19 pediatric patients as compared to influenza and other respiratory viruses; this occurred despite similar invasive mechanical ventilation rates.(282)
4. Hospitalization rates in the US are higher for children 0-4 years-old as compared to 5-17 years-old, but both are still markedly below that of adults.
  - a. Almost half of all pediatric hospitalizations did not have a previously known medical condition. The top co-morbidities were reported were as follows: obesity (38.5%), other (17.9%), neurologic disease

- (12.8%), asthma (10.9%), and chronic lung disease (5%). Surprisingly, immunosuppression was only accounted for in 5.2% of hospitalizations.(283)
- b. 80% of pediatric patients requiring PICU-level care had significant long-term underlying medical condition. The top three were medically complex (40%), immunosuppressed or malignancy (23%), and obesity (15%).(284)
  5. Respiratory virus co-infections and secondary bacterial infections are possible. One study found 20.7% of COVID+ patients were also infected with one or more respiratory pathogens and results did not differ significantly in age (child vs. adult). The most common co-infections were rhinovirus/enterovirus (6.8%), RSV (5.2%) and non-SARS-CoV-2 coronaviridae (4.3%).(285)
  6. Pediatric symptoms, if present, are similar to common viral upper respiratory infections, which differs from adults, who tend to have lower respiratory symptoms as most prominent. A meta-analysis reported headache, fever, and/or cough were the most common pediatric symptoms followed by myalgias, congestion and sore throat. The common age-specific presentations are as following:
    - a. Neonates: temperature instability, lethargy, poor feeding, shortness of breath
    - b. Infants: fever, rhinorrhea, congestion, cough (similar to viral pneumonia or bronchiolitis)
    - c. Children: +/- fever, URI symptoms (congestion, sore throat), GI symptoms (abdominal pain, diarrhea)
    - d. Adolescents: +/- fever, myalgias, sore throat, cough
  7. Recent reports have identified children presenting with symptoms of a multisystem inflammatory syndrome with features overlapping Kawasaki disease, toxic shock syndromes and myocarditis (see below for details).
  8. Most laboratory results are normal. Acute inflammatory markers, such as CRP, ferritin, and procalcitonin may be elevated. White blood cell count varies, often seen with lymphopenia if moderate-severe.(286)
  9. When imaging is abnormal in children with COVID-19, CXR reveals non-specific increased lung markings or patchy infiltrates, and chest CT reveals glass opacities and halo signs.(102)
  10. Pediatric patients can be considered mild or moderate disease if there is no new supplemental oxygen requirement or no increased requirement for patients who require supplemental oxygen at baseline. A majority of these patients will self-resolve without intervention.
  11. Those who require hospitalization should receive supportive care to include critical care interventions as required.

**e. Respiratory Support**

- i. There is no current evidence to alter treatment of severe respiratory failure from standard pediatric ARDSNet guidelines (2005), including indications for intubation and use of non-invasive respiratory support although increased use of prone positioning is recommended if tolerated.
- ii. Use of viral filters on circuits are necessary including for side sampling ETCO<sub>2</sub>; consider effects on flow dynamics of added resistance for smaller patients.
- iii. Judicious sedation and/or neuromuscular blockade for intubated patients should be considered given risk of rapid decompensation and self-extubation with delayed provider response time while donning PPE.
- iv. Similar CT findings as in adults are expected for severe cases although often unhelpful to guide clinical practice.
- v. For mild/moderate patients requiring nasal cannula/mask, goal is to target SpO<sub>2</sub> >94% during resuscitation, and >90% once stable. For flows over 3 L/min use of a heated/humidified circuit (HHFNC) or non-invasive positive pressure ventilation (CPAP or BiPAP) are well tolerated, but its use will increase aerosolization.

**f. Shock**

- i. Recognize the multisystem inflammatory syndrome in children (MIS-C). Note this may also occur in young adults. Further discussion is below.
- ii. Recognize septic shock in children with any hypotension (systolic blood pressure [SBP] < 5th percentile or > 2 SD below normal for age) or two or more of the following: altered mental state; bradycardia or tachycardia (HR < 90 bpm or > 160 bpm in infants and HR < 70 bpm or > 150 bpm in children); prolonged capillary refill (> 2 sec) or weak pulses; tachypnea; mottled or cold skin or

- petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia. Mental status is often preserved in older children and adolescents.
- iii. For septic shock in children, give 10–20 mL/kg crystalloid fluid as a bolus as quickly as possible using a manual push and reassess for signs of fluid after each bolus. Evaluate for cardiogenic shock in unresponsive/worsening patients and use of vasoactive medications with the development of hepatomegaly, pulmonary edema or elevated CVP.(287)
  - iv. Resuscitation endpoints include perfusion targets (e.g. urine output > 1 mL/kg/hr in children, improved level of consciousness and perfusion, resolving lactate or improvements in clinical indicators (as measured by advanced monitoring: CVP, cvSaO<sub>2</sub>, cardiac index etc.).
  - v. In children, consider epinephrine for first-line treatment, while norepinephrine can be added if shock persists or primarily ‘warm’ shock. Milrinone is appropriate for use in diagnosed impaired cardiac contractility, if patient is no longer hypotensive.(287)
- g. **Adjunctive Therapies** – for severe patients only (see Therapeutic Management and Adjunctive Therapies section for more information)
- i. Enrollment in clinical trials or compassionate use of experimental therapies to include antivirals, should be considered for children with severe disease on a case-by-case basis with appropriate monitoring and in consultation with Pediatric Infectious Disease when possible.(288)
  - ii. **Remdesivir** is available at DoD sites, now FDA approved for use in children 12 years and older who weigh >40 kg, while it remains under the EUA for children <12 years of age. It should only be used on hospitalized children who require supplemental oxygen or an increase from baseline. Recent changes extended use to outpatient for non-hospitalized children who are at high risk for severe disease; however, the logistics for the once daily infusions for 3 days may be difficult without an establishing protocol.(289) Prescribing of remdesivir in children should only be done in consultation with a pediatric intensivist or pediatric infectious disease physician, which can be done telephonically. Lyophilized powder formulation should be used in patients <40 kg. USAMMDA FHP received lyophilized Remdesivir that will only be available for pediatric population weighing between 3.5-40 kg. Due to the limited quantity, the lyophilized remdesivir has been pre-positioned in limited quantity at MTF locations that have the ability to care for inpatient critically ill children, or at those OCONUS locations where prolonged stabilization of a critically ill child while awaiting transport could occur. Please email USARMY Ft Detrick MEDCOM USAMMDA Mailbox Force Health Protection [usarmy.detrick.medcom-usammda.mbx.force-health-protection@mail.mil](mailto:usarmy.detrick.medcom-usammda.mbx.force-health-protection@mail.mil) or call 24/7 hotline 1-301-401-2768 for shipment or resupply request.
    - Baseline LFTs should be obtained prior to administration and then every 2-3 days
    - Dosing recommendations from Pediatric Infectious Disease Society (verify with manufacturer)
      - <40kg: 5mg/kg IV loading dose on day 1; followed by 2.5mg/kg IV Q24hr
      - >40kg: 200mg IV loading dose on day 1; followed by 100mg IV Q24hr
    - Recommended duration:
      - Hospitalized patients: up to 10 days with 5-day duration favored for fast responders
      - Non-hospitalized patients: 3 days
    - One 5-week infant with COVID-19 induced severe ARDS improved after 5 days of remdesivir.(253)
  - iii. **Paxlovid** (Nirmatrelvir + Ritonavir) is a combination antiviral medication with EUA for patient who have mild-to-moderate COVID-19 and are at high risk to progress to severe COVID-19, including hospitalization and death. Limitations of use include those with liver impairment, renal impairment, and certain medications (due to interaction). The patient must meet the following criteria: (290)
    - Children 12-17 years of age (for 18+ refer to adult indications)
    - Weight >40kg
    - SARS-CoV-2 PCR positive and within first 5 days

- Mild to moderate disease, NOT hospitalized
  - At high risk for progression to severe disease (refer to CDC website for updated list)
  - eGFR >60mL/minute
  - Contraindications include:
    - Liver impairment (Child-Pugh Class C)
    - Renal impairment with eGFR <30 mL/minute
    - History of significant hypersensitivity reactions (TEN, SJS) to the active ingredients or other components of the product
    - Co-administration with medications that are highly dependent on CYP3A for clearance, for which elevated concentration as associated with serious and/or life-threatening reactions
    - Co-administration with medications that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with potential for loss of virologic response and possible resistance.
  - Dosing is 300mg Nirmatrelvir + 100mg Ritonavir taken PO twice daily for 5 days
    - Decrease dose to 150mg Nirmatrelvir + 100mg Ritonavir if eGFR 30-60mL/min
- iv. **Monoclonal Antibodies:** Bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab are monoclonal antibodies currently under EUA for high-risk patients to prevent severe COVID-19. They are indicated for use early in illness to prevent hospitalization. Prescribing of these monoclonal antibodies in children should only be done in consultation with a pediatric infectious disease physician, which can be done telephonically. The patient must meet ALL the following criteria:
- Children 12-17 years of age (for 18+ refer to adult indications)
  - Weight >40kg
  - SARS-CoV-2 PCR positive and within first 10 days of illness (ideally given <7 days symptom onset)
  - Mild to moderate disease, NOT hospitalized
  - BMI ≥85th percentile for their age and gender based on CDC growth charts, OR sickle cell disease, OR congenital or acquired heart disease, OR neurodevelopmental disorders, for example, cerebral palsy, OR a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
- v. Ivermectin is not recommended to treat or prevent COVID-19 in children.
- vi. Hydroxychloroquine is not recommended for treatment or post-exposure prophylaxis of COVID-19. Studies have shown no clinical benefit AND risk of cardiac adverse effects. Therefore, it is NOT recommended for use in patients with COVID-19.
13. There is no evidence to suggest that prophylaxis is necessary or effective for the majority of children.
14. Given the prolonged duration of shedding of respiratory viruses in children, during periods of substantial or high community transmission of SARS-CoV-2, it may be prudent to assume symptomatic children are infected, unless proven otherwise from an infection control standpoint - an issue particularly relevant to caregivers from vulnerable risk populations. For both epidemiological and patient management reasons, expanded access to multiplex testing either by PCR or in rapid antigen assays, for influenza and SARS-CoV-2, and possibly also RSV, will be important during the traditional respiratory virus season, particularly with schools being open.
15. Clinicians should be aware that states and local school districts may have additional requirements for return to school for ill children that include: confirmation of condition other than COVID-19, confirmation of recovery from COVID-19, and/or a negative SARS-CoV-2 test result. CDC guidance on ending isolation for those confirmed or suspected of having COVID-19 are available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>.



16. In terms of return to sports, athletes diagnosed with COVID-19 should be evaluated by their physician prior to returning to play or exercise, with special emphasis on cardiac symptoms, and consideration for further evaluation recommendations stratified by symptom severity. The American Academy of Pediatrics (AAP) has provided COVID-19 updated guidance (as of December 1, 2021) on return to play screening at: <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-interim-guidance-return-to-sports/>.

### **Family Presence During Pediatric Inpatient Admissions**

When an admitted pediatric patient is symptomatic or has tested positive for SARS-CoV-2, the American Academy of Pediatrics (AAP) recommends a limit of one family member/caregiver to be preserved when possible. Exceptions to limited family presence policies, however, should be considered for end-of-life situations to allow additional family members to be present. Exceptions should also be considered for children, adolescents, and young adults with disabilities and to ensure reasonable accommodation is provided in alignment with the Americans with Disabilities Act. Further recommendations for different family presence scenarios with pediatric admissions, to include family presence policies for admissions not related to COVID, and guidance for supporting family and patient-centered care during the pandemic can be referenced on the AAP COVID-19 website.(291)

### **Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19**

1. MIS-C is a novel syndrome that appears temporally associated with COVID-19, although rare (2 in 100,000 children), the true incidence is not yet defined. It consists of fevers and high inflammatory markers with no known source and a variety of clinical findings similar to incomplete/atypical Kawasaki in younger children and post-infectious myocarditis in adolescents. Only 40% are PCR positive for SARS-CoV-2, but more than 80% have positive serology for SARS-CoV-2 and in up to 30% of severe cases neither are positive. The peak incidence of this syndrome occurs 4-8 weeks after peak COVID disease in local community, suggesting a post-infectious etiology. The majority of patients have some cardiac involvement requiring ICU-level care. Due to severity of disease, it is of utmost importance for early recognition and transfer to tertiary care center. Awareness and communication of the risk of this disease in child and young adult populations. See **Appendix R** for DHA summary communication regarding MIS-C.
2. CDC case definition for MIS-C:
  - a. An individual aged < 21 years (editors note: older patients have been reported) presenting with all the following:
    - i. Fever 38°C for >24hrs or report of subjective fever lasting >24hrs **AND**
    - ii. Laboratory evidence of inflammation\* **AND\*** including, but not limited to one or more of the following: elevated CRP, ESR, fibrinogen, procalcitonin, d-dimer, ferritin, LDH, IL-6, elevated neutrophils, reduced lymphocytes and low albumin
    - iii. Evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological) **AND**
    - iv. No alternative plausible diagnoses **AND**
    - v. Positive current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or COVID-19 exposure within the 4 weeks prior to the onset of symptoms
3. The spectrum of illness in MIS-C is emerging. A typical patient has high persistent fevers, GI predominant symptoms (some with surgical abdomen) and cardiac dysfunction in severe cases. Respiratory symptoms are typically related to cardiac failure rather than primary respiratory disease. Consider evaluation in any pediatric patient with persistent fevers without known source. Clinical presentation can include:(292-297)
  - a. Fever (100%)
  - b. Hypotension (50-100%)
  - c. Diarrhea (60-100%)
  - d. Conjunctivitis (20-76%)
  - e. Mucosal changes such as pharyngeal erythema, fissured/cracked lips (40-54%)
  - f. Rash (50-57%)

- g. Neuro symptoms such as headache, irritability, stiff neck, vision changes (43-58%)
  - h. Swelling of hands/feet (35-50%)
  - i. Other: lymphadenopathy, myalgias, fatigue, cough, dyspnea
4. The management approach of MIS-C is outlined based on expert consensus in several practice recommendations, to include that from the Infectious Disease Society of America, the American College of Rheumatology, and other academic children's hospitals.(298-300) Patients with signs and symptoms compatible with MIS-C, should be evaluated for admission in an emergency department setting. Initial evaluation should include:
- a. Stabilization using PALS algorithms to optimize hemodynamics and respiratory support
    - i. Judicious fluid management due to potential cardiac involvement
    - ii. Attention to COVID infection prevention & control measures.
  - b. EKG, chest x-ray, and bedside cardiac ultrasound to evaluate function (if available)
  - c. **Tier 1 Labs:** Initial Labs (performed at initial point of care), See **Figure 24**.
    - i. CBC with manual differential
    - ii. CMP, Magnesium, Phosphorus
    - iii. CRP, ESR
    - iv. SARS-CoV-2 RT-PCR (NP specimen preferred)
    - v. Respiratory pathogen PCR (e.g. Biofire filmarray)
    - vi. Rapid strep and throat culture if signs or symptoms of pharyngitis
    - vii. Blood culture
    - viii. Urinalysis with urine culture
  - d. Transfer child to a military or civilian tertiary medical center with PICU and peds specialists (including rheumatology, immunology, cardiology, infectious disease and heme/onc) if any of the following:
    - i. Child is ill-appearing or has PEWS score >4
    - ii. Respiratory distress, hypoxia or shock present
    - iii. Abnormal EKG or point of care echo
    - iv. Age >5yo and Ferritin>1400 (80% sensitive for progression to severe disease)(301)
    - v. Neurologic deficits or changes in mental status
    - vi. Evidence of renal or hepatic injury
    - vii. Clinical Concern for Kawasaki disease or MIS-C
    - viii. Tier 1 labs return with the following:
      - 1. ESR > 40 and/or CRP > 5mg/dL AND at least one of the following:
      - 2. Absolute lymphocyte count (ALC) <1,000
      - 3. Platelet count <150,000
      - 4. Na < 135 mmol/L
      - 5. Neutrophilia > 75%
      - 6. Hypoalbuminemia
  - e. Once at a tertiary medical center w/ pediatric subspecialists and concern for MIS-C, obtain echocardiogram and **Tier 2 Labs:**
    - i. SARS-CoV-2 serology (if PCR is negative)
    - ii. Troponin (high sensitivity), Pro-B Natriuretic Peptide (pro-BNP), CK,
    - iii. Ferritin
    - iv. Procalcitonin
    - v. Coagulation panel to include D-dimer and fibrinogen
    - vi. Triglyceride, LDH
    - vii. Cytokine panel (if available, typically a send out laboratory)
    - viii. CSF studies if signs/symptoms of meningitis
    - ix. Rickettsial serologies if exposure to endemic regions
    - x. Save 5-7mL blood in EDTA tube and 5mL serum prior to any immune modulating treatment such as IVIG for future diagnostic studies.

- f. Initial treatment decisions should be made with a multidisciplinary approach as the most effective standard of care has not yet been determined and there is clinical overlap with other infectious and inflammatory conditions.
  - i. General
    - 1. Judicious fluid management due to potential cardiac dysfunction
    - 2. Close hemodynamic and electrolyte monitoring.
      - To prevent dysrhythmia, goal Mag  $\geq 2$ , Phos  $\geq 4$
  - ii. Empiric antibiotics – early discontinuation if no evidence of bacterial infection
    - 1. Clindamycin and Ceftriaxone for Toxic Shock Syndrome
    - 2. +/- Vancomycin if concerns about MRSA
    - 3. +/- Doxycycline if concerns for *Rickettsia*
  - iii. Anti-Inflammatory – based on input from Peds Cardiology, Rheumatology, Immunology
    - 1. IVIG 2g/kg over 8-12hrs; ideally within 7-10 days of fever onset
    - 2. Methylprednisolone should be utilized, in combination with IVIG, in all patients with severe manifestations (fluid refractory shock, ventricular dysfunction, or other severe organ dysfunction) and for all cases of refractory to IVIG in which steroids have not already been started.(302)
    - 3. High-dose aspirin (20mg/kg Q6hr) with Kawasaki Disease presentation or coronary artery findings
    - 4. If failure of initial IVIG course, consider additional immune blockade with agents such as:
      - a. An additional course of IVIG may be considered if the clinical presentation strongly favors Kawasaki disease over MIS-C and the patient can hemodynamically tolerate the added volume
      - b. Biopharmaceuticals in severe cases with expert consultation
        - i. IL-1R Antagonist (Anakinra) – Immunologic studies have shown elevated IL-1 (303)
        - ii. IL-6R Antagonist (Tocilizumab)
        - iii. TNF- $\alpha$  Antagonist (Infliximab)
  - iv. Anticoagulation
    - 1. Enoxaparin (Lovenox) with Peds Heme/Onc or Critical Care consultation
  - v. Follow-up
    - 1. Report suspected and confirmed cases of MIS-C to your local health department. The case report form available on CDC website. Strongly recommend tracking of confirmed and suspected cases given unknown sequela
    - 2. Trend troponins, ECG and Echocardiograms
    - 3. Discharge on ASA 5mg/kg/day unless contraindicated. Precautions for Influenza exposure
  - vi. Outpatient follow-up
    - 1. Cardiology follow-up starting 2-3 weeks after discharge (even if no cardiac involvement during hospitalization).
    - 2. Patients with myocarditis should have cardiology direction restriction and/or release for vigorous activities

## MIS-C Algorithm

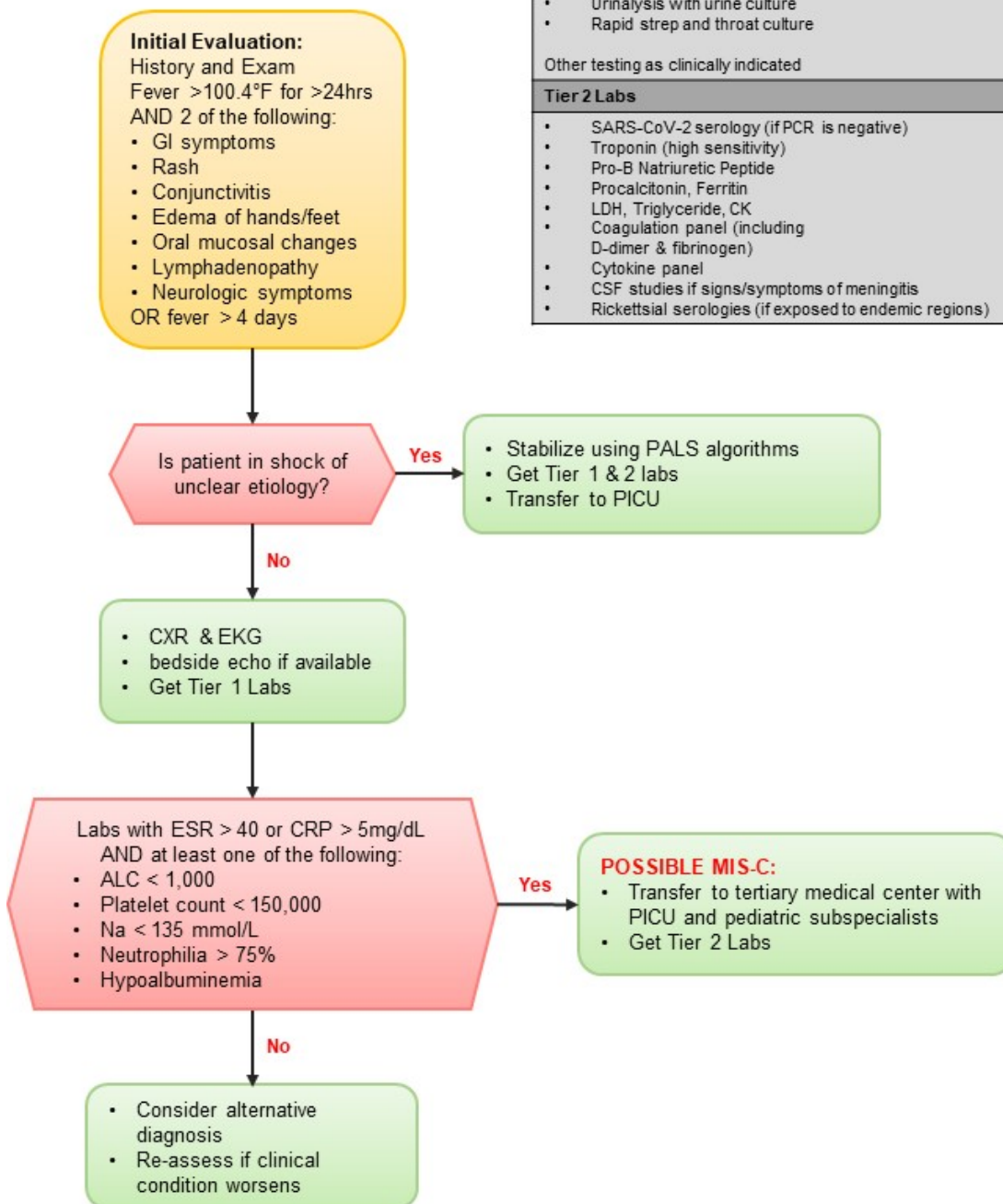


Figure 24. Multi-inflammatory Syndrome in Children (MIS-C) Algorithm

### Sustaining Pediatric Preventive Medicine Services During the Pandemic

The CDC and the American Academy of Pediatrics (AAP) both strongly support the sustenance of well child and preventive health care during the pandemic (citations: AAP COVID-19 website; CDC Information for Pediatric Healthcare Providers website). Of highest priority are the prevention of secondary outbreaks of vaccine-preventable illnesses, newborn follow-ups, and developmental surveillance.



### **COVID-19 Guidance for Promoting Safe Schools**

The CDC and AAP have provided guidance for promoting safe schools: <https://services.aap.org/en/pages/2019-novel-coronavirus-COVID-19-infections/clinical-guidance/COVID-19-planning-considerations-return-to-in-person-education-in-schools/>. The AAP recommends that school policies be guided by supporting the overall health and well-being, to include mental health needs, of all students and their families along with their communities, and should also provide for safe working environments for the school staff. The CDC has provided detailed public health guidance for schools, available at: <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html>.

### **Caring for Older Persons with COVID-19**

1. COVID-19 can result in severe disease and death among older adults. In the United States, 8 out of 10 deaths have been in adults above age 65.
2. Older adults, especially those that are frail and have multiple comorbidities, may not present with the typical syndrome of fever, fatigue, or cough. Atypical presentation of disease includes tachypnea, delirium, malaise, myalgias, and diarrhea early in the disease course; fever was not as prominent in several cases.
3. Have a high index of suspicion for COVID-19 in those patients not at their baseline, especially those residing in long term care facilities who present with respiratory difficulties, changes in vital signs other than temperature or other signs of infection or sepsis.
4. Ensure that care for the older adult and severely ill is in keeping with their goals of care, advance directives and patient and family wishes.
5. Conversations regarding goals of care should continue to be part of routine care.
6. Patients should be informed about their condition and their prognosis (if desired), in a way easy to understand.
7. If the patient is unable to communicate meaningfully, ensure that a surrogate decision maker or health care agent has been identified in accordance with state law based on facility location.
8. All providers should provide basic symptom management, perform routine discussions about goals of care and code status in seriously ill patients. If complex symptom management or difficult discussions surrounding goals of care or code status arise, consult a palliative medicine subspecialist if available at your institution.
9. Symptom management: Aggressive control of symptoms such as pain, dyspnea, or other symptoms relieves unnecessary suffering, which is crucial for all patients regardless of age, function, comorbidities and prognosis.
  - a. Pain

Acetaminophen should be used first, typically 500mg every 6 hours as needed.

If acetaminophen is insufficient, and other modalities such as topical agents are ineffective, start an opioid for moderate to severe pain (drug, dose, route, and frequency should be individualized and based on symptom severity, kidney/liver function and prior opioid exposure: See Table 7). Consider local supply in drug selection to mitigate risk of drug shortage.

Start a stimulant laxative, such as Senna 8.6mg PO daily, if prescribing an opioid to prevent constipation. Titrate to effect. Escalate bowel regimen as needed, with a goal of one soft bowel movement at minimum every other day.
  - b. Dyspnea

If providing supportive care and supplemental oxygen is ineffective for management of severe dyspnea, a low-dose opioid may be used to help alleviate symptoms.
10. Communication challenges may be exacerbated by the use of PPE. In patients with sensory impairments it is important to remember to eliminate or minimize background noise, state information slowly, and avoid yelling. It may be helpful to display information in writing. Hearing aids/glasses should be worn if available.
11. Older adults, especially those with cognitive impairment, when ill, hospitalized, or placed in a new environment may become anxious, agitated or less interactive. Delirium, a diagnosis not exclusive to older

adults, manifests as acute onset inattention, disorganized thinking and an altered level of consciousness. Delirium may be seen any patient, especially those with severe infection, and those requiring mechanical ventilation. Hyperactive delirium (delirium with agitation) may make management and risk mitigation challenging in those diagnosed with COVID-19.

- a. Early recognition and management of delirium is important. Regular delirium screening should occur using validated methods such as the Confusion Assessment Method, bCAM, or the 4AT ([www.the4AT.com](http://www.the4AT.com)).
- b. Risk factors for delirium include older age, sensory impairment (vision and hearing), history of dementia, patients admitted from long-term care units, and those with serious infection.
- c. Delirium is prevalent in patients diagnosed with COVID-19, and is associated with increase in-hospital mortality.
- d. Management of Delirium: (304, 305)

Prevention of delirium is the best strategy. Strategies include maintaining normal circadian rhythms, exposure to natural light, regular reorientation, mobilization, treating pain, fever, and nausea, maintaining oxygenation, avoiding constipation and urinary retention, and performing medication reconciliation to minimize potentially inappropriate medications. Ensure basic needs are met for food and water.

Standard non-pharmacological approaches such as frequent reorientation, family at bedside, hospital environmental manipulation (maintenance of day/night cycle, appropriate use of TV and lights), calming music, calls from family, and professional sitters should be employed but may not be feasible in an isolation setting.

In patients with hyperactive delirium, try nonpharmacological techniques first.

Current evidence does not support routine use of antipsychotics in management of delirium.

If severe agitation occurs, and nonpharmacological approaches have not been effective or more rapid control is needed for the safety of the patient or others, antipsychotics may be used but are off-label. When using an antipsychotic, use the lowest effective dose for the shortest amount of time. Of note, all antipsychotics carry a FDA Black Box warning due to an increase in mortality when used in patients with dementia. The patient should be monitored closely for side effects such as QTc prolongation and over sedation.

Some examples of antipsychotics are Quetiapine 25mg - 50mg PO, Olanzapine 2.5mg - 5mg PO/IM, and Haldol 0.25mg -1mg IV.

- e. Cautious use of antipsychotic medication is needed especially in patients with movement disorders such as Parkinson's disease and Lewy Body Dementia as this class of medication may exacerbate extrapyramidal symptoms. Quetiapine is preferred if antipsychotic medications are needed in patients with movement disorders given its lower risk of extrapyramidal symptoms. Any patient is at risk for acute dystonic reaction to antipsychotic medications.
12. Many older adults will recover from their illness, and it is important to not forget other complications such as hospital-associated deconditioning, falls and wounds. Standard of care should be provided for these other common complications alongside supportive care for COVID-19. Prompt mobilization and therapy should be started, when able, in accordance with infection control practices. Focusing on other treatable conditions should continue alongside supportive care for COVID-19.

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## **PALLIATIVE MEDICINE DURING THE COVID-19 PANDEMIC**

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Palliative medicine can assist at all stages of contingency/crisis planning. Prepare for increased use of symptom management resources including opioids (morphine IV and PO, hydromorphone IV and PO, oxycodone PO, fentanyl IV and transdermal), and benzodiazepines. Consider dedicated space for end-of-life care beds. Where possible, symptom management resources should be de-conflicted with highly utilized intensive care medications use to prevent and adapt to shortages.

## Goals of Care Discussions

(Adapted from vitaltalk.org COVID-19 Open Source Resources. [www.vitaltalk.org](http://www.vitaltalk.org))

1. Eliciting a patient's goals of care is integral to providing the best and most appropriate medical care and can improve resource allocation during a time of scarcity. Engage patients proactively in goals of care discussions informed by personal values and clinical context.
2. Treat patients and their families with respect and compassion. Quickly and effectively elicit a patient's concerns, values, and preferences with a few key statements. **Table 10** offers suggestions and examples to help guide your conversations.

**Table 10. Difficult Conversations and Scripts for Communicating with Patients and Families**

<i>What the patient/family says</i>	<i>What you may say</i>
<b>Admitting a Patient</b>	
How bad is this?	<ul style="list-style-type: none"> <li>From the information I have now and from my exam, your situation is serious enough that you should be in the hospital. <b>We will know more in the coming hours to days</b>, and we will update you. Who else should know about your/their situation and how will they know?</li> </ul>
Is my grandfather going to make it?	<ul style="list-style-type: none"> <li>I imagine you are scared. Here's what I can say: because he is 90, and is already dealing with other illnesses, I worry that he is at risk of dying if this worsens in the hospital. While it is too soon to say for certain, what worries you most about that?</li> </ul>
Are you saying that no one can visit me?	<ul style="list-style-type: none"> <li>I know it is hard to not have visitors. The risk of spreading the virus to other vulnerable people is so high that they and those they contact will be in more danger if they come into the hospital. I wish things were different.</li> </ul>
How can you not let me in for a visit?	<ul style="list-style-type: none"> <li>The risk of spreading the virus is so high that I am sorry to say we cannot allow visitors. We can help you be in contact electronically. <b>I wish I could let you visit, because I know it's important, but it is not possible now.</b></li> </ul>
<b>When things aren't going well, goals of care discussion, code status discussions</b>	
I want everything possible. I want to live.	<ul style="list-style-type: none"> <li>We are doing everything we can. This is a tough and scary situation for many of us. Could we step back for a moment so I can learn more about you? <b>What do I need to know about you to do a better job taking care of you?</b></li> </ul>
I don't think my grandfather would have wanted this.	<ul style="list-style-type: none"> <li>Well, let's pause and talk about your concern. Can you tell me what we should know to take the best care of him?</li> </ul>
I don't want to end up being a vegetable or on a machine.	<ul style="list-style-type: none"> <li>Thank you, it is very important for me to know that. <b>Can you say more about what you mean?</b></li> </ul>
I am not sure what my grandfather wanted – we never spoke about it.	<ul style="list-style-type: none"> <li>You know, many people find themselves in the same boat. This is a hard situation. To be honest, given his overall condition now, I worry that further treatments may not be successful in preventing him from dying. <b>In a situation like that, I have recommended that we allow a natural death. That could be hard to hear. What do you think?</b></li> </ul>
<b>When coping needs to be boosted, or emotions are running high</b>	
I'm scared.	<ul style="list-style-type: none"> <li>This is such a tough situation. I think anyone would be scared. Could you share more with me?</li> </ul>
I need some hope.	<ul style="list-style-type: none"> <li>Tell me about the things you are hoping for? <b>I want to understand more.</b></li> </ul>
You people are incompetent!	<ul style="list-style-type: none"> <li>I can see you are not happy with things. <b>I am willing to do what is in my power to improve things for you.</b> What could I do that would help?</li> </ul>
I want to talk to your boss.	<ul style="list-style-type: none"> <li>I can see you are frustrated. I will ask my boss to come by as soon as they can. Please realize that they are juggling many things right now.</li> </ul>
Do I need to say my goodbyes?	<ul style="list-style-type: none"> <li>I'm hoping that's not the case and I worry time could indeed be short. <b>What is most pressing on your mind?</b></li> </ul>

## Symptom Management Guidelines

(Adapted from BC Centre for Palliative Care COVID-19 Resources and Information, [bc-cpc.ca/cpc](http://bc-cpc.ca/cpc))

1. Patients with COVID-19 infections experience many of the same symptoms as other patients: dyspnea, oral secretions, anxiety and pain. Symptom management should be individualized based on clinical status.
  - a. **Dyspnea:** *dyspnea can present as anxiety – treat the dyspnea!*
    - i. Non-pharmacologic management for shortness of breath:
      1. Positioning, cool room temperatures, removing restrictive clothing
      2. Avoid bedside fan for patients with COVID-19. Consider bronchodilator therapy, fluid overload therapies, and heart rate control if >120 BPM.

- 3. Opioids are the mainstay of comfort care in severe dyspnea. When dosed effectively to control dyspnea, they do not contribute to a hastened death.
  - 4. Treat and reassess. IV opioids work within 10-15 min, oral opioids within 30-45 min.
  - ii. Goals for treatment: respiratory rate <25, minimal use of accessory muscles, resolution of pursed lip breathing, nasal flaring, and retractions or subjective dyspnea. Patient comfort is the goal.
  - iii. See Table 8 for recommended opioid dosing. If the dose does not work, increase it!
- b. Respiratory secretions/congestion near end of life:**
- i. Discuss congestion and secretions with family and bedside staff. Pharyngeal secretions are normal at end of life and rarely require treatment. A productive cough may benefit from mucolytics or opioids (**Table 11**). Limit oropharyngeal suction. Reduce or stop saline infusions.
  - ii. Medications may include:
    - 1. **Glycopyrrolate** 0.4 mg SQ/IV q4H PRN
  - iii. If severe and refractory to above medications, consider:
    - 1. **Furosemide** 20 mg SQ/IV q2h PRN with close monitoring of response.

**Table 11.** Opioid Dosing to Relieve Dyspnea and Pain in Adults

<b><i>Intermittent Dosing</i></b>		
<b>Dosing for Opioid Naïve Patient (patient not on opioid therapy) (<i>For frail, elderly patients, begin at low end of any range</i>)</b>		
Morphine	•	15 mg tablet ½ to 1 tab PO q 3 hours prn OR 5 mg SQ/IV q1H PRN shortness of breath (SQ/IV can be given as frequently as q30min PRN)
Hydromorphone	•	2 mg tablet ½ to 1 tab PO q 3 hours prn OR 0.4-0.8 mg SQ/IV q1H PRN shortness of breath (SQ/IV can be given as frequently as q30min PRN)
	•	If more than 6 PRN doses of opioid in 24 hours:
	•	Consider a basal opioid such as MSContin 15 mg PO BID. If patient unable to make needs known, consider SCHEDULED dosing of the immediate release opioid (q4H or 6H for frail elderly) AND continue PRN dose.
	•	TITRATE UP AS NEEDED for relief of dyspnea and/or pain
<b>Dosing for Patients ALREADY Taking Opioids</b>		
Applies to any opioid	•	Continue previous opioid, consider increasing dose by 25%
	•	To manage breakthrough symptoms: Start PRN opioid at 10% of total daily (24 hour) opioid dose.
	•	PRN q1H for PO and q30mins for SQ/IV
<b>PCA Infusion Dosing: For alert patients who need IV opioids (unable to take PO or with severe symptoms)</b>		
<b>PCA Infusion Pump Dosing for Opioid Naïve Patient NOT Already Taking Opioids</b>		
Opioid	Bolus Dose	Basal Rate (if severe symptoms)
MORPHINE	1.5 mg q10mins	1-2 mg/hour
HYDROMORPHONE	0.2 mg q10mins	0.1 – 0.3 mg/hour
FENTANYL	20 micrograms q10mins	10-25 micrograms/hr
Titrate the basal rate and bolus dose to effect. If using more than 1 rescue dose/hour, increase the basal rate for improved symptom control.		
<b>PCA Infusion Pump Strategy for Patient ALREADY Taking Opioids</b>		
•	For patients on chronic opioid therapy, rotate their long acting medication into the basal rate of your PCA. Titrate to effect.	
•	Bolus doses may be given q10 to 15min PRN; if the patient is NOT able to use the button, add a nurse administered bolus order of 5 mg IV q 2 hour prn for morphine PCAs and 0.8 mg IV q 2 hour prn for hydromorphone PCAs.	
•	Example titration: You start a morphine PCA at 1 mg/hr basal rate with 1 mg q 15 minutes rescue. The patient presses the button every 15 minutes and says he “feels nothing” and continues to be short of breath. Increase the rescue dose to 2 mg and reassess.	
•	Adjust bolus doses to 50-100% of new continuous infusion rate (e.g. Bolus dose of 2-4 mg q15min PRN for new rate of 4mg/h).	
•	New rate can be reassessed for adjustment again in 3-4 hours.	

- c. Anxiety:**
- i. Patients with dyspnea have associated fear and anxiety-- opioids are the first line oftreatment. The following adjuncts may be helpful in refractory anxiety:
    - 1. **Lorazepam** 0.5 – 1 mg PO/IV q1-4H PRN, consider scheduling Q4H if goals are for comfort-directed care and the patient is requiring frequent PRN dosing.



2. **Midazolam** 1 – 4 mg SQ/IV q30min PRN, consider scheduling Q4H if goals are for comfort-directed care and the patient is requiring frequent PRN dosing. *(for severe anxiety or SOB in ICU)*
- d. Delirium:**
- i. Delirium, either hypoactive or agitation, is common in hospitalized patients and can be distressing. Avoid benzos. Treat underlying causes of delirium if possible.
    1. **Haloperidol** 0.5mg PO OR 0.5 – 1 mg IV q4H PRN. Consider scheduling the medication Q4H if requiring frequent PRN dosing. Titrate dose in 0.5mg increments.
    2. **Olanzapine** 2.5 – 5 mg PO qHS and q8 hr PRN. This comes as a regular or oral dissolving tablet and can be titrated.
- e. Constipation:**
- i. Use of opioids will cause constipation. If the patient has more than 24 hours to live:
    1. Start a stimulant laxative, such as Senna 8.6mg PO daily if they are tolerating PO.
    2. PRN enema if unable to take PO and patient uncomfortable from distention.
    3. Escalate bowel regimen as needed, with a goal of one soft bowel movement at minimum every other day.

### **Palliative Ventilator De-Escalation**

(Adapted from “Palliative Ventilator De-escalation Recommendations for COVID-19 Positive or PUI. Developed by Bartlett, Christi for The University of Kansas Health System)

The following protocol is assumed to take place after appropriate goals of care discussions with family and/or surrogate decision makers. The endotracheal tube will remain in place and the ventilator circuit will remain intact to reduce the risk of COVID-19 exposure.

#### **Pre-procedure:**

1. Prepare family that prognosis can be as short as a few minutes but as long as a few days.
2. Deactivate defibrillators first. A magnet can also be placed over the device if needed to deactivate.
3. Ensure no paralytic medications are on board.
4. Code status should be DNR/ comfort measures only for patients at the end of life.
5. Discontinue tube feeds and remove unnecessary equipment from the room.

#### **Procedure:**

1. Turn off alarms and change room monitor to comfort care setting or turn off if family is present.
2. If a continuous opioid infusion is in place, continue THE SAME medication. All opioids contribute to relief of pain/dyspnea.
3. If the patient is already on a continuous opioid infusion, double current drip rate and order bolus doses of 100-200% of drip rate to be given q10min PRN. Use bedside infusion to provide boluses whenever possible.
4. If the patient is opioid naïve and not on a continuous infusion, begin with morphine 5mg IV or hydromorphone 0.5 – 1 mg IV q10min PRN. If possible, bring at least four doses into patient room for ventilator de-escalation.
5. Order midazolam 2-4 mg q10min PRN or lorazepam 2 mg q30min PRN for anxiety/breathlessness. If patient is already on a midazolam continuous infusion, double current rate and give boluses of 100-200% of drip rate available q10min PRN. Use bedside infusion to provide boluses PRN.
6. Pre-medicate with an opioid bolus as above (100% of drip rate) 10 minutes prior to de-escalation.
7. Pre-medicate with 2 – 4 mg of midazolam 10-15 min or 1 – 2 mg of IV lorazepam or prior to de-escalation.
8. Recommend glycopyrrolate 0.4 mg IV q4H PRN for secretions.
9. If patient requires sedative medication (propofol, precedex, etc) for comfort, continue as ventilator is weaned.
10. Stop vasopressors prior to weaning ventilator.
11. Ensure that patient appears comfortable prior to reducing ventilator settings. Titrate to comfort to palliate signs of discomfort: grimacing, agitations, or labored respirations.
12. For agitation/delirium management, consider Haloperidol 0.5 – 1 mg IV q30mins PRN.
13. If patient is obtunded and expected to die abruptly after ventilator is weaned, recommend immediate

reduction in ventilator settings to pressure support 5/5 and room air. Bolus opioid and benzodiazepine aggressively as needed to ensure comfort.

14. If the patient is alert, consider a gradual reduction in ventilator settings. Decrease FiO<sub>2</sub> to 40%, PEEP to 10, RR to 16. Recheck patient comfort and re-bolus opioids prn to achieve comfort. Reduce PEEP to 5, FiO<sub>2</sub> to 0.21.
15. Once the ventilator is set at PS 5/5 and FiO<sub>2</sub> of 21%, leave endotracheal tube in place and leave the ventilator circuit intact for the end of life.
16. Continue to re-bolus opioids, benzodiazepines and sedation as needed to ensure comfort.

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## IMPLICATIONS FOR SURGICAL AND INVASIVE PROCEDURES

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### Priorities for Surgical Resources

**Force Protection:** Protection of personnel and patients from disease transmission

**Mission Capability:** Maintaining capability to provide safe and effective surgical care

**Mission Support:** Support of the healthcare community response to COVID-19 through preservation of critical resources and re-deployment of personnel

### Triage and Decision-making

The ability to provide surgical care should be determined by health protection conditions, local and regional healthcare capability and capacity with consideration of logistic constraints.

1. During sustained or widespread community transmission, surgical care should be restricted to reduce risks of transmission between patients and healthcare personnel. To the extent possible, clinical encounters should be accomplished through virtual means and surgical treatment options deferred or delayed.(306)
2. MTFs should establish a review process to triage and prioritize medically necessary and time-sensitive surgical care.(307) This process should include multidisciplinary representation and be led by a senior surgeon, preferably the Department/Service Chief.(308)
  - a. This review should consider medical necessity, time sensitivity, risk and impact of viral transmission to either the patient or medical personnel, suitability of alternative treatment options, resource utilization, impact of delay of treatment, as well as readiness and mission impact.
  - b. Consider using an acuity scale or scoring system to assist in decision making.(309)
  - c. The surgical decision making and triage process should consider the availability and capabilities of ambulatory surgical suites & centers and incorporate these resources into plans to perform medically necessary, time sensitive, and mission critical surgical care.
3. Preoperative COVID-19 testing is recommended to assist in decision-making for all surgical patients including symptomatic and asymptomatic. In the event of a positive test, the surgical treatment plan can be reconsidered to reduce patient risk of morbidity and mortality and to reduce the risk of transmission to medical personnel and the community. Surgical teams and their patients should have access to preoperative testing to ensure adequate information is available to determine the best treatment strategy.
  - a. Treatment facility preoperative testing strategies should consider local prevalence of disease and the availability and performance of testing capability. Testing is expected to be most beneficial if performed within 48 hours of the surgical procedure. Recommendations for prioritization of testing are as follows:
    - i. All patients with symptoms suggestive of COVID-19.
    - ii. High-risk procedures such as head & neck, thoracic, and upper gastrointestinal surgery.
    - iii. Surgical procedures/patients with anticipated requirement for intensive care and/or prolonged hospitalization.
    - iv. Surgical procedures requiring inpatient postoperative care.
    - v. Outpatient procedures on patients whose age or comorbid conditions suggests a high-risk of morbidity or mortality from COVID-19.
    - vi. Routine outpatient procedures.
  - b. MTF policies and procedures regarding preoperative testing must balance the desire to support safe,

high-quality surgical care with efficient operations. Preoperative testing policies should not adversely impact capability to provide emergent and urgent surgical care.

4. In areas with low incidence or sustained reduction in the rate of new COVID-19 cases, expansion of surgical services should be considered.(310) Surgical services must adapt traditional and contingency operations into a new normal of patient care in the setting of ongoing COVID-19 risk. The surgical review and triage process should continue to prioritize surgical care as outlined in 2a above but can apply a progressively lower threshold to proceed with surgical care and utilization of healthcare resources.
  - a. Surgical resources including virtual care platforms, ambulatory surgical centers, and inpatient surgical care centers must each be optimally utilized to maintain the safety of patients and medical personnel while limiting the impacts of COVID-19 related delays in the provision of surgical care.
  - b. DoD Ambulatory Surgery Centers are primarily limited to COVID-19 negative and active duty care.
5. Prior to resumption of elective surgery, the following should be established:
  - a. Local Objective Triggers: Transition of MTF medical activities should be guided by local HealthProtection Condition (HPCON) level, local and/or state governments, Uniformed Military Department installation commander, and DHA recommendations based on coordination in key healthcare-sustaining areas discussed below. Triggers at the local level are:
    - i. Symptoms: Downward trajectory of influenza-like illnesses (ILI) reported within a 14-day period; and a downward trajectory of COVID-like cases reported within a 4-day period.
    - ii. Cases: Downward trajectory of documented cases within a 14-day period or a downward trajectory of positive tests as a percent of total tests within a 14-day period (flat or increasing volume of tests).
    - iii. Hospitals: Treat all patients without crisis care; and robust testing program in place for at-risk HCP.
  - b. Sufficient resources are available across phases of care, including PPE, healthy workforce, facilities, supplies, testing capacity, and post-acute care.(311)
    - i. Performance of elective surgery must not negatively impact capability to provide medically necessary and time sensitive surgical care.
    - ii. Surge capacity should be preserved.
  - c. Policies and process are established for perioperative screening and testing of surgical patients.
  - d. Evidence-based infection prevention policies and procedures are established to ensure a safe environment in which elective surgery can occur. (i.e., access control, workflow and distancing)
  - e. Non-COVID Care areas should be established to reduce risk of COVID-19 exposure and transmission; preferably these areas should be separate from other facilities to the extent possible (i.e., separate building, or designated rooms or floor with a separate entrance and minimal crossover with COVID-19 areas).
  - f. Establish policies, process and content for patient education on COVID related care risks and the risk mitigation strategies employed to ensure their safety.(312)
  - g. Following COVID-19 infection: determined on a case-by-case basis balancing the potential for increased pulmonary complications and mortality with risk of delay of surgical treatment. **Appendix S** provides an example of Surgical Care Timing for COVID-19 positive patients from Brooke Army Medical Center.
  - h. The American Society of Anesthesiologists and the Anesthesia Patient Safety Foundation provided updated guidance on Perioperative Testing for the COVID-19 Virus.(313)

### **Phases of Surgical Care Recommendations**

#### **Preoperative Care**

1. Virtual and telehealth should be utilized to accomplish preoperative administrative tasks, education, and assessments that do not require face to face interaction.
2. Post-operative care needs should be assessed and resource availability confirmed.
3. Patients planned for surgical care should be screened for symptoms or exposure history. Those patients that screen positive should undergo testing and their surgical treatment plan should be reconsidered.
4. Consider use of a Facility Readiness Checklist and/or Patient Information Sheet.

5. When available, preoperative COVID testing should be performed to identify asymptomatic patients whose surgical care plan can be altered in the event of a positive test result. Timing of the test should balance considerations regarding the availability and turnaround time of test against the risk of patient exposure and infection in the interval between testing and the scheduled procedure.
6. Patients who test positive in the pre-procedure phase of care require re-evaluation through the surgical decision-making and triage process. Furthermore, the surgical review committee, with emphasis on including ID service, should advise on the development of institutional policy regarding isolation, repeat testing, and PPE utilization for those patients who have tested positive.

### **Immediate Preoperative Care**

1. Recommend establishing Intubation/Extubation Airway Teams consisting of providers with a high degree of comfort with PPE and airway skills. Teams should bring their own PPE, medications, and airway equipment to avoid delays while limited or unfamiliar PPE is made available. During the pandemic, any emergency airway should be treated as potentially COVID-19 positive and full PPE worn.
2. For purposes of perioperative care, patients should be treated as presumed COVID-19 positive if they have symptoms/exposure history that warrants testing. PUIs at MTFs without an urgent indication for surgery preferably are tested for COVID-19 before any operative intervention (provided testing availability).
3. Optimally, an OR or pod of ORs should be predesignated with a distinct anteroom to maintain separation from non-COVID-19 patients. Negative pressure is not recommended for operating rooms. Consider reducing positive pressure and using a HEPA filtration system. Consult with facilities to ensure air handling is routed through the HEPA filter (i.e., air scrubber). An air scrubber is a portable filtration system that removes particles, gasses, and/or chemicals from the air within a given area. These machines draw air in from the surrounding environment and pass it through a series of filters to remove contaminants.
4. All patient interaction with COVID-19 positive or PUI patients will be performed with airborne and contact precautions, including eye protection:
  - a. N95 mask with surgical mask over the N95 mask, consider PAPR for AGPs.
  - b. Eye protection consisting of goggles, full face shield/mask worn over N95, or plastic disposable wrap-around glasses. Eyeglasses alone are not adequate.
  - c. Gown, double gloves, hair cover, shoe covers
  - d. Remove PPE except N95 mask before exiting the room. Surgical scrubs should be changed after each case.
5. The anesthesia service provider should attempt to remove all necessary medications and equipment from the carts prior to bringing the patient into the room. Avoiding contamination of the carts/machine should be prioritized over wasting consumable supplies.
6. Anesthesia service providers should not expect routine breaks during the case. Consider leaving cell phones, smart watches, and other personal devices out of the OR. Ensure there's a way to communicate/call for assistance organic to the OR. Recommend additional support staff immediately available outside the OR to assist with providing requested medications and supplies to the operating room team.
7. Patients on the ward should be transported directly to the OR by the anesthesia service team. If assistance is needed with transport, every attempt should be made to enroll a member from the care team (nurse, surgeon, and technician) to minimize staff exposure.

### **Intraoperative Care (314, 315)**

1. Surgeons and non-essential staff should not be present in the OR for either intubation or extubation unless necessary for patient safety. Exposure risks after these airway procedures is affected by risk mitigation strategies and engineering controls (airflow and filtration); therefore OR workflow and staff entry after airway manipulation should be adjusted based on a thorough understanding of these factors.
2. Only essential staff should be present in the OR during surgery. Enhanced droplet PPE protection should be worn for all AGPs.
3. Airway procedures should be performed in accordance with Anesthesia Patient Safety Foundation (APSF) guidelines.(316)

4. Use of a negative pressure Ante-rooms known as Airborne Infection Isolation Rooms, when available, and then Positive pressure operative room is recommended to reduce surgical site infection risk.
5. Place a HME/HEPA filter between the Y-piece of the breathing circuit and the patient's mask, endotracheal tube or laryngeal mask airway. The gas sampling line must exit the circuit proximal (closer to the machine) than the filter. The ASA/APSF recommends adding a second HME/HEPA filter on the expiratory limb before entering the anesthesia machine.
6. For sedation cases, a procedural/OR mask should be placed on the patient over the oxygen source. If a gas sampling line is used to monitor end tidal CO<sub>2</sub>, ensure a filter is used prior to gases entering the machine. The filter found in most epidural kits may be placed in-line and provide adequate machine protection. For sedation procedures that instrument the esophagus and generate high volume aerosolized secretions, intubation of the airway may be the best way to limit room exposure. Alternately, a Procedural Oxygen Mask may limit room exposure where intubation is contraindicated.
7. For pediatric patients or patients in whom the additional dead space or weight of the filter may be problematic, the HEPA filter can be placed on the expiratory end of the corrugated breathing circuit before expired gas enters the anesthesia machine. Again, ensure the gas sampling line is protected from contaminating the anesthesia machine.
8. Use disposable covers whenever possible (e.g., plastic sheets for surfaces, long ultrasound probe sheath covers) to reduce droplet and contact contamination of equipment and other environmental surfaces.

### **Postoperative Care**

1. Non-ICU patients should recover in a PACU negative pressure room. If a suitable recovery room isn't available, the OR may substitute until ready for Phase II of recovery from anesthesia.
2. Remove all PPE (except N95 mask) before exiting the OR. Avoid touching hair or face & perform hand hygiene.
3. Surgical scrubs should be changed immediately at the conclusion of each case.
4. Cloth surgical caps should not be worn in PUI cases.
5. The room should be cleaned in accordance with the designated processes for terminally cleaning rooms.
6. Consider air exchange rates for the treatment area and ensure an adequate interval of time between the completion of a procedure and entry of environmental services or other staff for cleaning or initiation of further patient care in that treatment area.
7. When transporting a ventilated patient, ensure a HEPA filter is placed between the ETT and the bag valve mask. Connect the bag valve mask to the ETT prior to opening the door in the negative pressure room. Ensure the door is closed when returning the patient before switching to the ventilator. The same filter may also be used on the exhalation loop of the anesthesia machine.
8. When transporting patients between the OR, a "clean" person who does not contact the patient should accompany the team to safely interact with the environment (e.g. open doors or elevators).

### **Post-discharge Care**

1. Post-discharge care needs should be assessed and resource availability confirmed.
2. Discharge care plans should consider the risks of exposure from extended healthcare stay (nursing home or other inpatient care facility) and face to face follow-up.
3. Virtual and telehealth should be utilized to accomplish postoperative assessments that do not require face to face interaction.

### **Special Considerations**

#### **Aerosol-Generating Procedures (AGP)**

Viral concentration in the aerodigestive tract and respiratory system and aerosol generation during surgical care present additional risks to surgical personnel.

1. The performance of high-risk procedures should be limited and risk mitigated through refinement of technique and/or utilization of adjunctive technology and protections. High risk activities include:
  - a. Endotracheal intubation



- b. Oral surgery
  - c. Tracheostomy and endotracheal tube manipulation/care
  - d. Upper aerodigestive endoscopy (including nasal endoscopy, laryngoscopy, bronchoscopy, and esophago-gastro-duodenoscopy)
  - e. Surgery involving the airway/upper aerodigestive tract, lower airways, or the potential to enter into the upper aerodigestive tract or lower airway.
2. Aerosol generation during surgical procedures can also be limited through the following:
  - a. Electrocautery should be set to the lowest effective setting and a smoke evacuator used if available.
  - b. Chest tubes and surgical drains are all potential sources of aerosolized droplets, and enhanced precautions should be taken during placement, manipulation, or removal.
3. Laparoscopy: Aerosol generation during laparoscopy can be minimized through scrupulous management of access sites, pneumoperitoneum, and through ultrafiltration of aerosolized particles in released CO<sub>2</sub>.
  - a. CO<sub>2</sub> insufflation should be set to the lowest effective pressure, and a filtration device should be used for CO<sub>2</sub> release if available.
  - b. Release all pneumoperitoneum via filtration device (if available) or contained suction device prior to specimen removal, port removal, or converting to open surgery.
  - c. Avoid venting insufflation from the ports during surgery.

### **Endoscopy Procedures**

Aerosol generation during endoscopy procedures may be difficult to control, therefore performance of these procedures should be carefully considered and engineering controls and PPE optimized to reduce the risk of personnel exposure.

1. In COVID-19 positive patients or PUIs:
  - a. Endoscopy should be performed only for emergent or urgent indications (i.e., cholangitis or gastrointestinal bleeding refractory to medical management).
  - b. Procedures should be performed in negative pressure rooms using PPE as described above in Clinical Management of COVID-19 using endotracheal intubation or a procedural oxygen mask (or similar device) for upper endoscopies, as described above in Intraoperative Care. Of note, negative pressure rooms for endoscopy differ from operative room recommendation for positive pressure rooms due to the risk of surgical site infection for the later.
  - c. Due to the presence of SARS-CoV-2 RNA in the stool, colonoscopies should be treated as AGPs and a surgical mask should be placed on the patient over the oxygen source.
2. After endoscopic procedures in COVID-19 positive patients or PUIs, sufficient time for enough air changes to remove potentially infectious particles should occur before terminal cleaning of the room. The time required for airborne contaminant removal depends on the number of air changes per hour in the room.
3. Endoscopes used in COVID-19 positive patients or PUIs may be reprocessed following standard guidelines for manual cleaning followed by high level disinfection.
4. Consider standard PPE, engineering controls, and room turnover only when the following criteria are met: (317, 318)
  - a. Low incidence or sustained reduction in the number of new COVID-19 cases
  - b. Patients at low risk for COVID-19 (i.e., no concerning symptoms or recent COVID-19 exposure)
  - c. Negative pre-procedure COVID-19 testing (see Surgical Triage and Decision-making, above)

### **Trauma and Emergency Care (319)**

1. All trauma/injured patients should be presumed positive/PUI until they can be ruled out (by testing or risk factor assessment). All patients undergoing evaluation and resuscitation for traumatic injury require screening and risk-factor assessment to determine the optimal treatment and isolation strategies and potential value of timing of COVID testing.
  - a. Trauma team members should all wear appropriate PPE, including airway and eye protection.
  - b. Unnecessary individuals in the trauma bay should be minimized.
  - c. Individuals should remove all PPE (except N95 mask) prior to exiting the resuscitation area.

- d. Any clothing worn in the resuscitation bay/ATLS area should be removed after PUI patient contact.
  - e. Commanders should modify uniform requirements as necessary to allow for multiple rapid clothing changes to avoid cross contamination.
  - f. All equipment in the resuscitation bay and ATLS area (i.e. x-ray, ultrasound, instrument packs, etc.) must be terminally cleaned after every PUI encounter.
  - g. Radiology: Maintain the segregation of PUI/COVID positive patients.
    - i. PUI/COVID positive patients are brought to main radiology to keep the ER/CT scanner COVID-free
    - ii. All staff should ensure donning/doffing of proper PPE is paramount AND maintaining integrity of the CT imaging control area.
  - h. Non-intubated patients should have a surgical mask applied during transport between the resuscitation bay and CT scanner and during any transit within the facility. Patients requiring oxygen should have a non-rebreather mask applied instead of a simple face mask.
  - i. All PUIs either requiring admission or transferred to the emergency department should be kept in isolation rooms (if available) until ruled out or ready for discharge (to quarantine facilities).
2. Staffing risk reduction
    - a. AGPs should have only necessary staff members present in the room (i.e. intubation, chest tube placement, etc.), and all staff must wear enhanced droplet precaution PPE. Following intubation, manual ventilation with a bag valve should be avoided. Intubation should be followed by immediate connection to a ventilator with HME/HEPA filter. ETCO<sub>2</sub> monitoring should be used rather than a detachable colorimetric device.
    - b. Each facility should consider options to minimize staff members entering the resuscitation area. This could include the use of runners or pass-through windows for deliveries from pharmacy, lab, etc.
    - c. All visitors should be restricted during the initial phase of resuscitation, and based on risk, may be restricted throughout the entire hospitalization at the discretion of the Commander.
  3. Consultations and therapies should be performed as needed and not delayed solely because a casualty is pending COVID-19 results. This includes specialty and subspecialty consultations, routine nursing care (i.e. pressure injury reduction, oral care, etc.), radiology, lab analyses, and physical/occupational/speech therapy.

#### Key References

1. Clinical Issues and Guidance From the American College of Surgeons 2020 [Available: <https://www.facs.org/COVID-19/clinical-guidance>].
2. The ACS, ASA, AORN and Joint Statement: Roadmap for Maintaining Essential Surgery during COVID-19 Pandemic updated November 23, 2020 [Available from: <https://www.facs.org/COVID-19/clinical-guidance/roadmap-maintain-essential-surgery> and <https://www.aorn.org/guidelines/aorn-support/roadmap-for-resuming-elective-surgery-after-COVID-19>].
3. APSF Guidelines. Perioperative Considerations for the 2019 Novel Coronavirus (COVID-19) 2020 [Available from: <https://www.apsf.org/news-updates/perioperative-considerations-for-the-2019-novel-coronavirus-COVID-19/>] and Elective Surgery and Anesthesia for Patients after COVID-19 Infection [Available from: <https://www.apsf.org/news-updates/asa-and-apsf-joint-statement-on-elective-surgery-and-anesthesia-for-patients-after-covid-19-infection/>].
4. JTS Management of COVID-19 in Austere Operational Environments v2.0 Clinical Practice Guideline 2020 [Available: [https://jts.amedd.army.mil/index.cfm/PI\\_CPGs/cpgs](https://jts.amedd.army.mil/index.cfm/PI_CPGs/cpgs)].

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## OPERATIONAL CONSIDERATIONS FOR COVID-19: PLANNING AND PREPARATION

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Providing safe and effective care in the deployed setting during an infectious disease pandemic is particularly challenging given limited resources, close living conditions, and delays in test results and supply arrival. The DOD GCP PI & ID 3551-13 provide a wealth of information, guidelines, and mitigation strategies for a pandemic, but are not tailored to the specific nuances of COVID-19. This section focuses on the unique aspects of dealing with the

COVID-19 pandemic in the deployed environment. Collaboration between base commanders and medical teams is an essential component of pandemic response. Additionally, coordination with TRANSCOM is essential as aeromedical evacuation may be limited to only critically ill COVID-19 patients requiring supplemental oxygen.

### **Division of Labor for Quarantine and Isolation**

1. **Close contact quarantine:** This is a *medically-supported command function* to separate high risk individuals who have been identified by medical personnel as a close contact to a known COVID-19 positive individual. Commanders are responsible for establishing and maintaining quarantine facilities within their area of responsibility (AOR). *Note: Close Contact Quarantine should not be confused with Restriction of Movement (ROM), which is a type of Travel Quarantine used prior to movement into an operational area that is typically 14 days in length.* As testing capability has increased, additional travel quarantine upon arrival to an operational area might be required if preflight COVID testing is >4% based on local medical standard operating procedures.
2. **Isolation:** This is a *command-supported medical function* to care for those with infection. These patients are confirmed COVID-19 positive identified by symptoms (i.e. fever, cough, dyspnea, diarrhea, etc.) or identified upon testing of known close contacts. The duration of isolation is 10 days from positive COVID-19 test and are released from isolation based on a time-out strategy due to limited testing capability and limited resupply. Since service members are not deployed with a family, even mildly symptomatic patients, who would typically be returned to the care of their family in the garrison setting, become the responsibility of the medical team, requiring medical isolation facility to include meal delivery.

### **Physical Requirements and Logistics of Quarantine and Isolation**

1. **Quarantine:** Quarters must be provided for persons suspected of having exposure to COVID-19 in an effort to prevent spread of disease to other service members (SM) and civilians on base. These quarters must be separate from the general population and must have their own dedicated toilet and shower facilities. Meals must be provided to quarantined individuals, and they must be checked regularly (i.e. via telephone or in person) to ensure they remain asymptomatic. If symptoms develop, medical personnel should be notified to arrange evaluation and potential transfer into inpatient medical isolation. Quarantined individuals should remain in their designated quarters; however, quarantined individuals should be allowed to go outside and exercise in wide open areas to promote mental and physical wellbeing. Personnel should be designated to do laundry for quarantined individuals. Dirty laundry should be placed in a sealed disposable plastic bag by the quarantined member and then handled with gloves by laundry personnel. Laundry should be placed in the washing machine without handling the clothes, and the bag discarded in an appropriate receptacle. Persons in quarantine often remain in quarantine for the allotted 14 days, however local standard operating procedures may allow for a test out of close contact quarantine at 10 days based on CDC guidance in the setting of asymptomatic patients. The 14-day quarantine only resets if large open bay living quarters (e.g., tents) are being used for close contact quarantine when any member of the quarantine group develops symptoms or has a positive PCR test result. To avoid excessively prolonged quarantines, every effort should be made to keep quarantined individuals in the smallest possible groups; individual quarters are the ideal quarantine environment. Any personnel interacting with or evaluating quarantined individuals must wear appropriate PPE.
2. **Isolation:** Patients who are symptomatic or test positive should become the primary responsibility of the medical team in isolation. Medical teams will need to plan for patient monitoring, treatment, housing, meal, and hygiene facilities. Based on the demand and the size of the medical treatment team, commanders may need to consider assigning additional non-medical personnel to assist with these tasks. Isolated patients should be classified by symptoms as asymptomatic, mild, moderate, or severe, which will determine the required level of care. Any personnel interacting or evaluating patients in isolation must wear appropriate PPE.
  - a. **Asymptomatic/Mild symptoms:** In CONUS locations these patients may be sent home for self-care and outpatient follow-up. In the deployed setting family support is absent and self-isolation is not feasible, so medical teams should coordinate with commanders to establish appropriate isolation housing with

routine medical oversight. Symptom progression should result in prompt medical reassessment. There must be a clear and universally-accessible communication plan to notify the medical team of any change in patient condition. This communication plan may need to include providing reliable WiFi to the living area for the isolated patients to use their cell phone or may need to be medical unit supplied radios or phones.

- b. **Moderate symptoms:** These patients require hospital ward admission. These facilities may be located within the MTF or established separately near the MTF. Although frequently unavailable, if available, negative pressure facilities should be reserved for aerosol producing procedures. A COVID-19 positive patient should not share a room with a non-COVID-19 patient.
- c. **Severe symptoms:** These patients require ICU admission for hemodynamic monitoring/treatment and management of severe respiratory symptoms. ICU care should be performed where the greatest medical capability exists, but these patient should not be placed in the same facility used for other non-COVID-19 patients (such as trauma patients). Negative pressure facilities should be used (if available) . If negative pressure facilities are not available then a well-ventilated tent or building can be used if it has an air handling separate from all other inpatient and clinic areas. Oxygen generating capability will need to be established along with continuous patient monitoring and nursing care. This level of care can be resource intensive and medical teams will need to work with TRANSCOM on patient transfer if they do not have adequate resources.
- d. **Discharge:** Patient placed in isolation should be classified as patients under investigation (PUI) while awaiting their test results. They will need to remain in isolation as a PUI until 2 separate RT=PCR tests at least 48 hours apart are negative and an alternative diagnosis is likely. If this criteria is not met, the patient will remain in isolation for 10 days before being released without retesting if they remain asymptomatic in the last 24 hours of their scheduled isolation (refer to CENTCOM/local guidance for updates). If they are symptomatic, they must also have improvement in their symptoms and be afebrile for at least 24 hours without fever-reducing medications prior to being released from isolation.

#### **Unique Limitations in the Austere Environment**

The military has faced particularly unique challenges as they have been forced to deal with a worldwide pandemic while in austere environments. Issues include limited medical supplies and oxygen, limited capacity, competing missions, the potential impact of COVID-19 on the primary mission, unforgiving temperatures, threat of indirect and direct fire, issues with resupply, limitations in personnel, travel restrictions, challenges with quarantine, difficult decisions regarding patient transfer to higher levels of care, and return to duty. In regards to the treatment modalities mentioned below, use what you have when clinically appropriate. Also, please consider leveraging tele-critical assets (JTCCN, ADVISOR, etc) when managing critically ill COVID-19 patients when local Critical Care consultation is not readily available.

1. **Oxygen:** The limitation of a continuous oxygen supply and generation has a direct impact on management of ARDS. Oxygen generation through the portable oxygen generation system (POGS) and expeditionary deployable oxygen concentration system (EDOCS) is significantly affected by the environment to include severe temperatures that often exceed 120 °F in austere environments. Most austere environments have no capability for high flow nasal cannula.
2. **Ventilator:** In the deployed setting, the only option for positive air pressure is through the Zoll® Impact 731 portable ventilator which has no preset non-invasive mode. There has been success using a full face mask and the ventilator's pressure support mode with a set positive end expiratory pressure (PEEP) without additional pressure support to simulate Continuous Positive Airway Pressure (CPAP) setting which has provided adequate mean airway pressure. This has led to alveolar recruitment and enhanced airway clearance which ultimately may prevent endotracheal intubations. Mechanical ventilation in the austere environment focuses on conservation of oxygen. This is achieved by obtaining the lowest level of supplemental oxygen as well as low tidal volume ventilation targeting tidal volumes of 6 ml/kg predicted body weight (PBW) with aggressive self and manual proning following the ARMA trials and PROSEVA trial. A high PEEP strategy is used to increase mean airway pressure by utilizing bedside drive pressure to regulate the degree of alveolar recruitability with goal to achieve lowest FiO2 requirements to preserve oxygen.

3. **Medications:** Dexamethasone, convalescent plasma, and remdesivir have been used to treat hypoxemic COVID-19 patients requiring supplemental oxygen in the forward deployed setting. There is ongoing research regarding the efficacy of remdesivir and other medications to treat COVID-19 with promising, but conflicting without clear mortality benefit. However, studies have demonstrated quicker resolution in symptoms and a reduction in the use of medical resources, such as oxygen, with use of these individual medications. This reduction in resource utilization alone is enormously beneficial in the deployed environment even in the absence of a mortality benefit. Other medications that have been used in the setting of treating hospitalized patients include IL-6 pathway inhibitors (e.g. tocilizumab) and the Janus kinase (JAK) inhibitor baricitinib.(219, 320) Deployed providers may not have access to compassionate use or trial medications, and should be familiar with the supportive care measures described elsewhere in this document. Additionally, the Society of Critical Care Medicine, ARDSNet, IDSA, NIH, and other professional societies provide continuously updated guidelines on their websites. Providers should work closely with pharmacy and logistics leadership to ensure adequate stocks of all commonly required medications, including antimicrobials, sedation, and paralytics.
4. **Prolonged Field Care:** Without the ability for routine renal replacement therapy (RRT) or on-site extracorporeal membrane oxygenation (ECMO) at many austere environments, it may be necessary to utilize conservative fluid management strategies (e.g., albumin and loop diuretics) to achieve a negative fluid balance. Additionally, initial pH-guided fluid resuscitation with a bicarbonate drip is often employed to facilitate management of hyperkalemia, which can be seen with COVID-19 related microthrombi induced acute kidney injury. There also remains some debate about the benefit versus risk of initial full anticoagulation when there is an elevated d-dimer greater than 1000 ng/ml to prevent worsening microthrombi induced kidney dysfunction.
5. **PPE:** Supply chain challenges have led to PPE shortages worldwide. Fortunately most units are deployed with CBRNE equipment that can be used for staff protection. Staff must be proficient at proper donning, doffing, and cleaning techniques. Local SOPs should be developed in the event that PPE needs to be conserved.
6. **Hygiene:** The austere environment lends itself to rapid spread of infectious disease. Commanders should emphasize the importance of handwashing/sanitizing, cleaning quarters, and appropriate social distancing.
7. **Testing:** Limited laboratory capability precludes performance of culture and sensitives as a part of the infectious workup. Some austere facilities do have a BioFire® FilmArray® 2.0 system that allows for point of care PCR testing of COVID-19 and other respiratory infectious pathogens, but resupply of test cartridges continues to be a limiting factor. The inability to perform antibiotic drug peaks and troughs limits the spectrum of antimicrobials that can be safely administered and monitored, which combine with the limited laboratory capabilities has modified the delivery of medical care.
8. **Transportation:** Units must coordinate with PMC to ensure safe and efficient movement of patients and/or testing samples around theater. Patients can be treated in place unless their clinical condition necessitates a higher level of care based on escalating oxygen requirements or multi-organ dysfunction. Unnecessary patient movement should be avoided to minimize personnel and resource exposure and transmission risk.
9. **Housekeeping and Cleaning Services:** Cleaning protocols must be established to ensure adequate sanitization occurs in quarantine, isolation, and medical facilities, as well as workspaces and quarters of those moved to quarantine/isolation status. PPE should be worn by cleaning personnel and disposed of in a manner that avoids the potential for cross-contamination.
10. **Mortuary Affairs and Casualty Liaison Teams:** While the COVID-19 mortality rate is expected to be low in the deployed military population, Mortuary Affairs teams should be prepared for increased demands and requirements. Casualty Liaison teams should be ready to work with commanders, medical teams and families on accurately reporting patient status.

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## BEHAVIORAL HEALTH AND WELLNESS IN COVID-19 CLINICAL MANAGEMENT

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### Delirium

1. Delirium is a common complication in patients with COVID-19., seen in up to 70% of patients with severe



respiratory failure and over 50% of patients admitted to the ICU. days. Traditional methods of diagnosis and non-pharmacologic management may be difficult given isolation precautions.(321) For instance, delirium may be due to alcohol withdrawal. Occult alcohol withdrawal should be considered and possibly ruled out as part of the differential in new onset delirium in people with less than 96 hours in the hospital before onset of symptoms. In addition to the CAM-ICU, the Stanford Proxy Test for Delirium (S-PTD) is a validated tool that relies on nursing report of their interactions with patients over their full shift to confirm diagnosis of delirium and would be useful in this setting.(322, 323) The following options may be considered for pharmacological management of delirium in COVID-19 positive patients (in addition to processes such as the Society for Critical Care Medicine's ABCDEF bundle):(324)

- a. Melatonin 10-15mg enteric at night for anti-inflammatory effects, agitation management, and regulation of sleep-wake cycle; first line due to being well tolerated and with minimal effects on respiratory function.(325)
  - b. Suvorexant 5-20mg enteric at night for sleep-wake cycle regulation
  - c. Alpha-2 agonists to mitigate cytokine and adrenergic storm
  - d. Dexmedetomidine IV 0.1-2.4 mcg/kg/hr to manage acute agitation and cycling
  - e. Guanfacine 0.5mg BID – 1mg TID enteric to taper off sedative drips
  - f. Antipsychotics to downregulate excess dopamine inherent to delirium (Haloperidol IV 0.5mg-30mg per 24 hours) *\*must monitor QTc prolongation*
  - g. Valproic Acid in hyperactive and/or mixed delirium due to potential anti-inflammatory and anti-oxidant effects. Might also decrease transcription of interleukin-6 (enteric or IV, 250-500mg BID and titrate to 500mg qAM, 500mg q afternoon, and 1000mg qHS) *\*monitor LFTs, platelets, ammonia levels*
2. Consider avoiding/ minimizing use of benzodiazepines, opioids, and medications with strong anticholinergic properties as they can be deliriogenic, though there are clinical circumstances where these are appropriate. Some medications can exacerbate discomfort or other side effects if abruptly discontinued. Any patient on benzodiazepines or antipsychotics should be removed from those medications slowly and/or with caution.

### Psychopharmacology

1. COVID-19 can invade the CNS and has been known to cause psychiatric illness and cognitive complaints. COVID-19 has been connected to both new onset as well as exacerbation of previous existing psychiatric illness to include depressive disorders, manic episodes, and acute psychosis. Sometimes psychiatric symptoms due to COVID-19 infection present without any other accompanying symptoms. Generally, patients are responsive to traditional treatment methods for their presenting symptoms though treatment choices should be mindful of side effects such as sedation, CNS depression, QTC prolongation, etc.
2. In patients WITHOUT known psychiatric history, it is important to review all medications as well as substance use history to delineate new onset primary psychiatric symptoms versus medication side effects or symptoms directly attributable to COVID-19 infection. In patients WITH known psychiatric history, it is important to maintain a broad differential, to include medication side effects (especially if recently changed), discontinuation syndromes, serotonin syndrome, neuroleptic malignant syndrome, and/or anticholinergic toxicity. Some medications, such as lithium or clozapine, may require dose adjustment to maintain therapeutic serum levels in patients with more severe illness. Patients who abruptly stop tobacco use due to illness or hospitalization will have decreased clearance of medications that are substrates of CYP1A2, which could lead to increased side effects
3. Due to the multi-organ system effects of COVID-19, consideration for use and need for monitoring of psychotropics must be tailored to the patient's specific situation. This list is not meant to be wholly inclusive – but use caution when the following symptoms are of clinical concern:
  - a. Leukopenia, neutropenia, agranulocytosis: Carbamazepine, clozapine, and all first and second generation antipsychotics *\*Clinicians who have patients on clozapine should consider cutting the dose by half if the patient develops fever and/or other signs of infection*
  - b. Platelet dysfunction and increased bleeding risk: Medications that inhibit serotonin reuptake (SSRIs, SNRIs, TCAs) and valproic acid
  - c. QTc prolongation and concern for exacerbation with some COVID-19 treatment options: some

- antipsychotics, tricyclic antidepressants, citalopram
- d. Drug-induced liver injury: chlorpromazine, carbamazepine, valproate, duloxetine, and nefazodone
- e. Impaired renal excretion: Lithium, gabapentin, topiramate, pregabalin, paliperidone, duloxetine
- f. Lowered seizure threshold: most antipsychotics, bupropion, tricyclic antidepressants (326)
- 4. There are multiple neuropsychiatric side effects associated with current medications used for treatment of COVID-19, to include psychosis, depression, sleep disruption, and anxiety/agitation. It is recommended these symptoms be treated as clinically appropriate, with cautious monitoring if there are concerns for additional complications (i.e., benzodiazepine use for severe anxiety symptoms). Specific medications with neuropsychiatric side effects include:
  - a. Remdesivir: None noted
  - b. Favipiravir: No published information
  - c. Monoclonal antibodies (Bamlanivimab +/- Etesevimab, Casirivimab + Imdevimab, Regdanvimab, or Sotrovimab): None noted in initial clinical trials(327)
  - d. Tocilizumab: Exacerbation of depression, anxiety, pain, and sleep disruption
  - e. Corticosteroids: depression, mania, agitation, mood lability, anxiety, insomnia, catatonia, depersonalization, delirium, psychosis
  - f. Interferon-Alpha: boxed warning for “life threatening or fatal neuropsychiatric disorders” – fatigue, mood disorders, suicidality, anxiety disorders, irritability, lability, apathy, sleep disturbance, cognitive deficits (326)

#### **Patients with Behavioral Health Diagnoses**

1. Since the beginning of the pandemic, studies have consistently shown an increase in depression, anxiety, PTSD, insomnia, and substance use across the general public. Risk increases with the level of disruption the pandemic has caused to their life overall. Patients who have existing behavioral health diagnoses are at risk of symptom exacerbation as a result of the pandemic, regardless of if they develop COVID-19 infection.
2. Patients with pre-existing mood disorders should be considered an ‘at-risk’ patient population. While there was no association with mood disorders and susceptibility to acquiring COVID-19 infection, there are significantly higher odds of being hospitalized and death if infection does develop.

#### **General BH Care for Patients with known or suspected COVID-19**

1. In accordance with HPCON, use telehealth and virtualization tools as much as possible for BH assessments and ongoing care of isolated patients. Promptly identify all COVID-19 patients with known mental illness and consult BH to assist with ongoing care.
2. There is an increased incidence in new psychiatric disorders in the first 3 months after COVID-19 diagnosis. Patients with persistent cognitive complaints after illness are at increased risk of anxiety and depression post infection.(328)
3. Recognize isolation as a barrier to communication. Keeping patients informed as to what is happening, what is likely to happen, and next steps in their care may provide a sense of control in the midst of a stressful and confusing situation. Expand virtual approaches to care and provide regular updates to patients and families.
4. Attend to negative impacts of isolation by facilitating virtual connection with providers, family, and loved ones as much as possible. This could include providing patients with dedicated mobile devices/tablets.
5. Anticipate patient concerns and misconceptions. Concerns that may be present include fears related to transmission to family members, fears related to hospital bed or equipment availability, duration and impact of isolation, or external stressors such as impact on job, housing, and finances.
6. Healthcare systems should establish easily accessible pathways for BH referrals for family members of patients admitted for COVID-19.
7. Resources to help in caring for Patients and Families can be found at: <https://www.cstsonline.org/COVID-19/caring-for-patients-and-families>.

#### **For Defense Health Agency COVID-19 Related Behavioral Health (BH) Resources**

1. **DoD CAC Enabled only:** <https://info.health.mil/army/bhsl/Covid19/Forms/AllItems.aspx>
2. Pandemic conditions require medical staff to be sensitive and responsive to patient, family, provider, and

leader needs. Common pandemic responses include a predictable range of distress reactions (e.g. insomnia, fear, grief), health risk behaviors (e.g. increased use of alcohol/other substances, work/life imbalance), and may also result in BH disorders (e.g. PTSD, depression, and anxiety). In response to multiple stressors, associated with quarantine or in support of critical care operations, common responses may also include anger, irritability, detachment, avoidance, impaired function, and burnout. Addressing stress responses early can mitigate enduring impacts.

### **General Considerations for Frontline Workers, First Responders, and Support Staff**

1. Prioritize basic needs. Proper sleep, nutrition and hydration, regular exercise, regular breaks, and appreciation/gratitude can sustain performance and enhance decision-making. Good sleep is perhaps the most critical of these to optimize immune function.
2. Social distancing, infection control, and isolation present a significant barrier to our usual approach to care, requiring innovative approaches, such as staff wearing photos of themselves unmasked.
3. Communication – words matter now more than ever. Clear and consistent messaging from leadership, between team members, and to patients and family is vital during crisis situations.
4. Anticipate fears of returning to work and provide thoughtful, transparent information.
5. Resources for leaders in support of Healthcare Workers can be found at: <https://www.cstsonline.org/COVID-19/supporting-healthcare-workers>

### **For Medical Staff**

1. Self-care, especially good sleep, is important for providers, patients, and families.
2. Connect to a sense of unified purpose; foster hope, fortitude, and tolerance in self and others.
3. Amplify positive stories and stories about competent efforts by self and colleagues. Encourage perceptions of competence among staff, especially junior and/or less experienced colleagues.
4. Recognize and attend to signs of stress reactions or burnout in self and others (e.g. out of character sadness, frustration, irritability, isolation/disconnectedness, substance use, and lack of self-care). Usually these can be addressed with simple measures, including normalization, peer-support, and rest with expectation of rapid return to full functioning.
5. Focus on what can be controlled – checklists, routines, self-care; and accept what cannot be controlled.
6. Promote a climate where it is acceptable for team members to talk about difficult events (e.g., death, triage, errors), as avoidance and fear of such thoughts are associated with greater long-term mental health problems.
7. Establish a routine of regular team meetings as an opportunity to pass relevant information, but also as an opportunity to check in with each other and rotate duties as needed. Maintain a climate where it is okay to not be okay and offer peer support when needed.
8. Resources for Healthcare Worker Self Care can be found at: <https://www.cstsonline.org/COVID-19/healthcare-worker-self-care>

### **For BH Providers**

1. Provide proactive support to frontline workers where possible, and at times of peak stress, ideally, in the form of BH outreach teams with established relationships to frontline and medical staff points of contact. Consider BH team outreach routinely (e.g. during daily rounds, at shift changes).
2. Be careful not to overlook other at risk groups such as janitorial, transport, food service, and other staff who make the medical system run and may also be at risk of exposure and are likely to experience distress.
3. Behavioral health care teams can provide both non-clinical support to frontline staff as well as be available to facilitate referral for additional BH care when needed.
4. Tailor resources and support as much as is feasible – and plan on changing/adapting resources with the unfolding realities of the medical mission. Flexibility is important.
5. Supportive care of healthcare workers is different from usual clinical care, and includes:
  - a. Check in with the physicians, nurses, technicians, and support staff, and get to know their mission and challenges in a non-intrusive manner.
  - b. Link with support services, such as Red Cross, Salvation Army, USO, etc., to provide food and beverages.

- c. Provide information on normal stress reactions and adaptive responses.
- d. Promote positive peer support and facilitate connections.
- e. Make connections during a calm time. Do not interrupt urgent patient care or sign-out.
- f. Offer combinations of simple supportive non-clinical strategies, as well as clinical triage when appropriate (e.g. find a quiet space to talk when things are chaotic).
- g. Ensure individuals have access to safe spaces and emotional/spiritual support.
6. Help units/hospitals develop a standard protocol for responding to a team member's death so that the organization can efficiently respond to every death the same way. Protocol may include things such as a live-streamed memorial service; grief support resources for staff; a temporary tribute area with photos, memorials, and a book in which colleagues can leave memories and kind words; a post on Social Media that would allow others to leave comments, etc.
7. Unique issues to consider when supporting frontline workers:
  - a. Be aware of the potential for distress related to ethical issues in providers who are making difficult and potentially life or death triage and management decisions.
  - b. Be aware of potential concerns of individual front line workers, including single parents, dual healthcare worker families, families with serious medical issues, workers living separate from their families, and individuals facing the community stigma of being "infected"
8. Resources for Patients can be found at: <https://www.cstsonline.org/COVID-19/mental-health-support>.

**For additional COVID-19 Related Behavioral Health (BH) Resources**

<https://www.cstsonline.org>

<https://asprtracie.hhs.gov/COVID-19>

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## **REHABILITATION CONCERNS FOR PERSONS WITH COVID-19**

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### **Rehabilitation of COVID-19 Patients and PUIs**

#### **Overview**

1. This document is intended to provide guidance and planning considerations for the provision of acute and critical care rehabilitation for hospitalized patients by practicing acute care Physical Therapy (PT) and Occupational Therapy (OT) providers and augmented staff dedicated to support the COVID-19 response.
2. The goal of acute care inpatient rehabilitation is to improve activity and mobility in order to reduce mortality, decrease hospital length of stay (LOS), decrease ICU and ventilator days, streamline patient throughput, and decrease the burden of acute rehabilitation after discharge.
3. Early rehabilitation involvement in the facility's COVID-19 planning team is recommended to anticipate rehabilitation needs.
4. Rehabilitation personnel should be dedicated to either COVID-19 patients or non-COVID-19 patients to minimize potential exposure whenever possible.
5. Pool staff resources as able and maximize distancing. Maintaining appropriate work/rest cycles by use of liberal leave policy when the census is low. For larger facilities, split rehab staff into clean and dirty teams.
6. Screening tools should be used to quantitatively determine a patient's need for therapy intervention.

#### **ICU / Critical Care Staffing ratio recommendations when respiratory rehabilitation is a primary intervention**

1. ICU recommendations: 4 therapy providers for the first 22 COVID ICU beds. One FTE for each 4-bed increase.
2. Acute Care Recommendations: 1 therapy provider FTE for the first 11 beds and a potential increase of 2 per additional 11 beds.
3. Subacute and Acute Inpatient Rehabilitation Unit (if present): 2.5 FTEs per 11 beds.
4. Staffing ratios may be lower when rehabilitation interventions are the primary focus rather than on respiratory rehabilitation.

#### **Personal Protective Equipment**

1. Prior to working with patients with COVID-19, therapy staff should be N95 fit tested, have comprehensive

training on the use of PPE to include donning and doffing

### **Treatment Guidelines**

1. Positioning: Rehabilitation staff may be involved in prone positioning with COVID-19 patients due to their expertise in safely and optimally performing this task.
2. Rehabilitation should progress to active movement as soon as possible.
3. Provide patient specific exercise programs and handouts. Provide the COVID-19 Patient and Caregiver Guide.
4. Partner with nursing for patient active participation in care and exercise.
5. Interactions with COVID-19 patients will be limited to a contained environment where airborne precautions can be maintained.
6. Therapy staff must have advanced understanding of medical implications of COVID-19.
7. Emphasize treatment of non-COVID-19 patients for quick discharge to decrease risk of exposure.
8. Attend to the well-being of the whole patient by promoting orientation and communication with patient during therapy sessions. Support patient's use of technology for communication with care providers and family members.

### **Discharge Planning**

1. Goal should be safe patient discharge to home from the acute hospital setting whenever possible.
2. Therapists should participate in multidisciplinary rounding/discharge planning to ensure necessary patient supports are in place for discharge.
3. Electronic communication with spouses and other care providers should be completed to promote patient and family confidence in the discharge plan.

More information on Rehabilitation Guidelines can be found in the DHA COVID-19 Patient and Caregiver Guide as well as the following sites: Allied Health Folder in <https://www.milsuite.mil/book/groups/COVID-19-clinical-operations-group> or <https://www.milsuite.mil/book/groups/acute-and-critical-care-physical-therapy>.

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## **TELEMEDICINE SUPPORT DURING THE COVID-19 PANDEMIC**

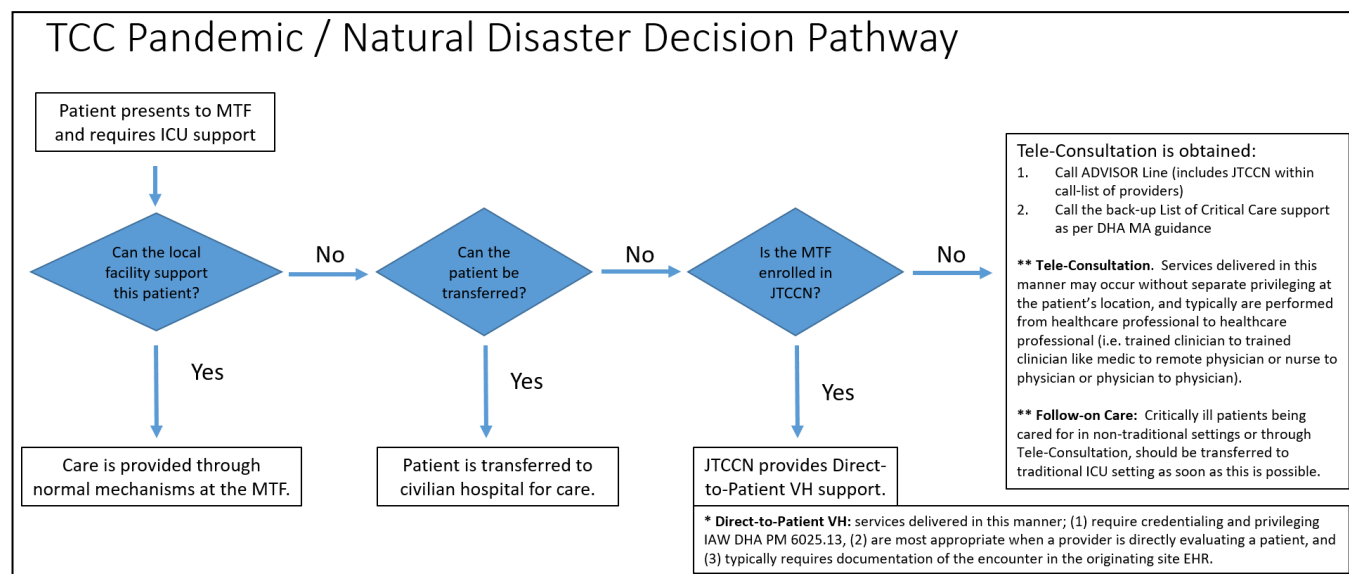
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1. Telemedicine, also referred to as virtual health (VH), encompasses a set of tools that leverage information and communication technologies to most commonly extend medical care across geographic distances and boundaries. These same tools have a significant and unique potential to support care delivery during an infectious pandemic in order to decrease healthcare worker exposure to contagion (i.e. "clinical distancing"), reduce the usage of consumable PPE, while also enabling continued medical care delivery for non-infected patients while in their home. Accordingly, the CDC now recommends the liberal use of telehealth during the COVID19 Pandemic (<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html>).
2. Telemedicine can be delivered through two primary manners
  - a. Direct-to-patient VH. Services delivered in this manner require credentialing and privileging IAW DHA PM 6025.13 using the centralized privileging by proxy for telemedicine (TPbP) through the Virtual Medical Center. A provider or a patient can be in the home for a telemedicine visit. Direct-to-Patient VH is most appropriate when a provider is directly evaluating a patient, and requires documentation of the encounter in the electronic health record (EHR).
  - b. Tele-Consultation. Services delivered in this manner may occur without separate privileging at the patient's location, and typically are performed from healthcare professional to healthcare professional (i.e. trained clinician to trained clinician like medic to remote physician or nurse to physician or physician to physician).
3. Telemedicine technology:
  - a. Phone calls can be used for a majority of patient encounters during the COVID Pandemic. The need for clinical video versus telephone and/or secure messaging will be based upon the provider's individual judgement, and will take into consideration the specific patient complaint evaluated.



- b. Clinicians engaging in telemedicine (especially forums that utilize video with the patient) must appreciate the burden it places upon valuable network resources. The solution that achieves clinical needs and uses the minimal network resources should be utilized when possible.
- 4. All care provided through telemedicine should be documented in the appropriate EHR. If the provider is delivering care from outside of the MTF, the DHA Application Virtualization Hosting Environment (AVHE) can be utilized to access the EHR.
  - a. AVHE can be accessed from a computer with a CAC-card reader through the following URL: <https://avhe.health.mil>.
  - b. Make sure to select your email certificate.
- 5. There are several use-cases for telemedicine during the COVID-19 Pandemic. Each require planning and practice to be successful.
- 6. Use cases for which currently available MHS approved solutions exist include:
  - a. Screening and Initial Evaluation (e.g. Virtual Clinics)
    - i. Phone calls can be used for a majority of patient encounters during the CoVID Pandemic. The need for clinical video versus telephone and/or secure messaging will be based upon the provider's individual judgement, and will take into consideration the specific patient complaint that is being evaluated.
    - ii. Web-portal based screening tools suggest need for patients to engage with their healthcare system (reduces overall burden on the system if patients are screened as low risk). Some examples of online tools are listed below, although none are created or owned by the DOD:
      - 1. <https://c19check.com/start>. Site hosted by Emory University Medical Center, which provides likelihood of CoVID infection based on answering series of online questions.
      - 2. <https://penn-chime.phl.io/> Site hosted by Penn State Medical Center, Predictive Healthcare Team, which provides patient volume projections during the pandemic.
    - iii. Asynchronous solutions including web-portal based messaging (e.g. Federal Secure aMessaging and MHS GENESIS patient portal) and e-mail allow engagement with the healthcare system with minimal network resource use.
    - iv. Where available, portable telemedicine units can be employed by triage and Emergency Department personnel to evaluate patients to reduce clinician exposure to potentially sick patients; Telehealth in a Bag (THIAB), Transportable Exam Station (TES), and Video Teleconferencing (VTC) Carts with/without virtual exam equipment.
    - v. These systems can connect a patient (within an isolation setting) to a provider (within a "clean" setting) by use of either portable data networks (PDN's), WiFi routers, cellular service, or hospital WiFi networks.
    - vi. Synchronous video to the patient's location can be accomplished through several mechanisms. The preferred and supported solutions are Adobe Connect and Cisco Meeting Server (more below).
  - b. Inpatient Wards (non-ICU)
    - i. Where available, portable telemedicine units can be employed by triage and Emergency Department personnel to evaluate patients; Telehealth in a Bag (THIAB), Transportable Exam Station (TES), and Video Teleconferencing (VTC) Carts.
    - ii. These systems can connect a patient (within an isolation setting) to a provider (within a "clean" setting) by use of either portable data networks (PDN's), WiFi routers, cellular service, or hospital WiFi networks.
  - c. Tele-Critical Care
    - i. Sites that are currently enrolled in the Joint Tele-Critical Care Network, should use this existing resource to support care of critically ill patients with or without suspected / confirmed COVID-19.
    - ii. Sites that are not currently enrolled in JTCCN, should attempt triage and management of patients as outlined in this document and per usual standards of care. For hospitals that typically do not care for critically ill patients, this may involve transfer of the patient to a local civilian hospital.
    - iii. MTFs that are not enrolled in the JTCCN that (1) do not have sufficient critical care expertise, and

- (2) cannot transfer critically ill patients, may be forced to care for these patients. In this situation, tele-consultation is available to support clinicians.
- d. Tele-consultation (outside of JTCCN):
- i. Advanced Virtual Support for Operational Forces (ADVISOR) Program. 1-833-ADVSRLN (238-7756) or DSN 312-429-9089
    1. The ADVISOR program was originally designed for operational VH support.
    2. Due to COVID-19 garrison support has been expanded to include:
      - Critical Care (Non-JTCCN MTFs)
      - Infectious Disease
      - Pediatric Infectious Disease
      - Palliative Care
    3. Phone calls will be routed by live ADVISOR Care coordinator(s) 24/7/365.
    4. The caller needs to identify that they are requesting support for critically ill patients located in a MTF.
    5. The care coordinator routes the call to a geographically located MTF with the available specialty.
    6. ADVISOR is only available for MHS providers.
    7. Information on the program can be found at: <https://info.health.mil/army/VMC/Pages/Home.aspx>
    8. Additional questions or information on ADVISOR can be obtained by emailing [dod.advisor\\_office@mail.mil](mailto:dod.advisor_office@mail.mil) or scanning the QR code (shown to the right):
- 
- e. Virtual Health to Patient Location (e.g. home)
- i. The CDC recommends providing outpatient care where/when possible through telemedicine to minimize infectious exposure in MTFs for at risk patients and staff.
    1. Virtual health to patient location can be established through several mechanisms.
      - a) Secure Messaging (e.g. Federal Secure Messaging, MHS GENESIS Patient Portal).
      - b) Establishing a clinic cell phone with texting services and publishing the number
      - c) Using phone calls to discuss patient problems/symptoms as indicated.
      - d) Conducting Synchronous Video Visits can be performed through either Adobe Connect or Cisco Meeting Server (preferred solutions), or through several non-public facing communication platforms.
        - Adobe Connect accounts can be requested from the VMC Front Office at: <https://info.health.mil/army/VMC/Pages/Home.aspx>
        - Online VH training should be completed prior to Adobe Connect account creation, but there are exceptions during the pandemic to get accounts deployed rapidly. The DHA Virtual Health Provider Training (US444) can be found on the JKO training website: <https://jkodirect.jten.mil>.
        - Additional guidance will be forthcoming IRT the Cisco Meeting Server capability. The capability being established by DHA J6 will have several interconnected servers spread across the enterprise.
        - The following non-public facing administrative communication tools are temporarily authorized for provider-patient medical interactions during the pandemic, however these technologies are not supported by the DHA or DOD for clinical care.
          - Apple FaceTime
          - Google Duo
          - Microsoft Skype for business
          - Commercial Virtual Remote/Microsoft Teams
- f. OCONUS MTFs may utilize existing asynchronous virtual health platforms (PATH for INDOPACOM, HELP for EUCOM, AFRICOM, and CENTCOM) to obtain teleconsultation subspecialty consultation.



**Figure 25.** Telecritical Care Pandemic/Natural Disaster Decision Pathway

## 7. Documentation, Billing, and Coding (See **Appendix T**)

- When direct-to-patient telemedicine is performed, encounters should be documented in the appropriate electronic medical record (AHTLA/Genesis for outpatients, Essentrisr/Genesis for inpatients).
- If the MTF is open and conducting normal clinical operations, no change in coding is necessary.
- Up to date virtual health coding references can be found at: <https://info.health.mil/army/VMC/Pages/COVID-19/CodingGuidance.aspx>
- If the MTF is open, but is restricting access for patients who can be treated virtually, the processes are:
  - By telephone only:
    - Document as normal for the appropriate encounter type (not in t-con module) to include history, any counseling, assessment and plan, and disposition. Include time spent during the encounter, if required, by service performed.
    - Assign the diagnoses, as appropriate.
    - Assign G2012 in the procedure (Healthcare Common Procedure Coding System [HCPCS]) code section.
    - Assign E/M 99499 or leave blank.
  - By synchronous visual and audio telecommunications:
    - Document as normal for the appropriate encounter type to include history, exam if done, any counseling, assessment and plan, and disposition. Include time spent during encounter if required by service performed.
    - Assign the diagnoses, as appropriate.
    - Assign any procedures performed and documented (e.g., psychotherapy, PHQ-9, etc.)
    - Assign appropriate Evaluation and Management (E/M) service, if performed; otherwise assign 99499 or leave blank.
    - Apply virtual encounter modifier to encounter (GT=MTF to MTF or 95=provider to patient location other than an MTF).

## 8. Other Considerations:

- Always be conscious of the need to maintain patient privacy and data security and clearly delineate risks to the patient or healthcare professionals using the system.
- Do NOT use photos, video, geospatial positions when you are in an operationally sensitive area: ALWAYS CONSIDER OPSEC!

- c. Before pursuing a new application of telehealth, CLEARLY DEFINE YOUR USE CASE, then consider technology resources (hardware, software, and network combinations) that can be used for your use case. Most importantly, consider HOW you will use the technology and practice this workflow before implementing it broadly at your location. Consider the following:
    - i. Who will use your solution?
    - ii. Why would they use your solution?
    - iii. When would they use this solution?
    - iv. Where will they use the solution (in a patient room, at a nursing station, from a home/office, to a home/office, etc.)?
    - v. What combination of hardware, software, and network will be used?
    - vi. How will they use it (training, how-to guides, etc.)
      - 1. How will they document care?
      - 2. How will you maintain patient regulation (admission/discharge/transfer)?
      - 3. How will you maintain team-based care as necessary?
  - d. PRACTICE your solution on a small scale before deploying more broadly.
  - e. Establish routine communication with leadership regarding current capabilities and your telehealth solution's potential to off-load aspects of bedside care to telemedicine support. Use telemedicine to triage bedside clinician time and activities. Necessary to do this is good communication and trust between the bedside clinical team and the remote clinical team. One way to facilitate this is to rotate teams from bedside duties to telemedicine duties or to shift infected caregivers toward telemedicine and recovered caregivers towards the bedside. Importantly, asking/having all clinicians participate in telemedicine increases their awareness and understanding of telemedicine capabilities and limitations.
9. Questions regarding MTF and Market telemedicine capabilities should be directed to MTF and Market virtual health leads. Questions that cannot be answered by the MTF/Market VH lead, or questions pertains to an enterprise VH service, should be directed to the regional VMC hub site.
- a. CONUS: VMC-C located in San Antonio (1-844-VMEDCEN)
  - b. INDOPACOM: VMC-IP located in San Diego, CA
  - c. EUROPE: VMC-E located in Landstuhl, Germany

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## **EMERGENCY MEDICAL SERVICES (EMS) AND GROUND TRANSPORT OF PERSONS WITH COVID-19**

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### **911 Public Safety Answering Points (PSAPs) and Dispatch Screening for COVID-19**

- 1. Persons assigned to EMS and first responder dispatch function should complete key question interrogation and dispatch resources accordingly. Dispatchers should reference the EMS COVID-19 questionnaire when obtaining information from 911 callers (Table 9). EMS systems may become strained due to an influx of 911 calls regarding known or suspected COVID-19 transmission or infection. In areas where EMS resources are overwhelmed by 911 call volumes, the following should be considered:
  - a. EMS and/or Fire Dispatch should triage 911 calls and prioritize responses accordingly (e.g. if a patient calls reporting signs and symptoms consistent with COVID-19, but denies respiratory distress and other complaints suggestive of a life-threatening condition (i.e. chest pain, etc.), ambulance services should be prioritized to an alternative, higher-acuity call.
  - b. If EMS arrives on scene and determines that a patient does not have a life-threatening or potentially hospitalization-requiring condition relating to the potential exposure to, or signs and symptoms of, COVID-19, EMS crews should contact On-line Medical Control to discuss non-transport and/or alternative transport destinations. If non-transport is approved, EMS Dispatch should direct the EMS crew to a higher-acuity 911 call. Refusal of Transport /Treat and Release should be coordinated with local On-line Medical Control
  - c. Callers using the 911 system for questions or concerns regarding COVID-19 testing (e.g. sites, locations, and decisions regarding testing criteria) should be diverted to established local, county, or state COVID-19 call centers. Installations and facilities should consult with their local EMS Medical Directors regarding

protocols and policies pertaining to call diversion for information-only requests from 911 callers.

- Additional guidance for PSAPs: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html>

### Pre-Arrival Screening or Initial Patient Assessment of Suspected COV-19 Patients

(For utilization by EMS/Fire Department Dispatch OR Responding Crews)

- EMS personnel should wear a mask (N95 if any respiratory/viral attributable complaint reported from dispatch or immediately on patient report) and gloves on entry to location of 911 call. Limit evaluation to one EMS provider with support personnel remaining six feet from patient whenever possible. With widespread COVID-19, all patients should wear a surgical-type mask (best) [or alternatives as available, e.g., cloth (better)].
- If the patient's condition allows, to minimize the risk of exposure, one individual should approach the patient, place a surgical-type mask on him/her, and complete the COVID-19 screening questionnaire/ initial assessment. Additional EMS/Fire personnel should be contacted for support only as required.
- If EMS personnel are first on-scene, and it is determined that the patient has symptoms of a respiratory illness (Box 1) and risk factors for COVID-19 (Box 2), Dispatch should be contacted to minimize response by additional units (Fire and Law Enforcement) to reduce the risk of exposure unless otherwise required.

**Table 12. Emergency Medical System/First Responder Pre-Arrival Screening for COVID-19**

Does the patient have:		
<b>BOX 1</b> <ul style="list-style-type: none"> <li>Fever (or are they hot to the touch)</li> <li>Cough</li> <li>Shortness of Breathing or Difficulty Breathing</li> <li>Other flu-like symptoms (sore throat, runny nose, body aches, chills, nausea, vomiting, diarrhea)</li> </ul>	AND	<b>BOX 2</b> <ul style="list-style-type: none"> <li>Are they currently under investigation or isolation for COVID-19 by public health or other medical professionals?</li> <li>Have they been in close contact with an individual who is known to be sick with, or under public health/medical professional investigation/isolation for COVID-19?</li> </ul>
<b>If the patient meets at least one criteria item from Box 1 and Box 2, see below:</b> <ul style="list-style-type: none"> <li>Instruct the individual to isolate him/herself from close contact with others until EMS arrives.</li> <li>Notify First Responders (to include Fire and Law Enforcement) that the patient meets pre- arrival screening criteria for COVID-19. Advise donning of appropriate PPE prior to patient contact.</li> <li>Follow local agency policies to limit multi-unit responses.</li> <li>Transport Agencies will contact the receiving facility as soon as possible, preferably prior to transport (See EMS TRANSPORT OF PERSONS UNDER INVESTIGATION OR PATIENTS WITH CONFIRMED COVID-19).</li> </ul>		

Table adapted from the Southwest Texas Regional Advisory Council (STRAC); EMS Pre-Arrival Screening for Coronavirus 2019-nCoV - V1.2, issued 02/28/2020.

### EMS Non-Transport/Treat on Scene

- Purpose: Identify patients that do not require EMS transport to a hospital or alternate facility during the COVID-19 pandemic, in order to accomplish the following: 1) Minimize disease transmission to the community and health care system; 2) Protect first responders and health care providers and; 3) Preserve the health care system functionality by not overwhelming emergency resources.
- Transport decision and final destination versus non-transport with self-care should be considered by EMS Medical Directors, partnering with MTF leadership, to develop local policies. The following are provided as recommendations:
  - Careful consideration for EMS Non-Transport should be given for pediatric patients, pregnant females, or patients who are immunocompromised. Discussion with Online Medical Control is advised.
  - The below assessment tool is to inform the necessity to transport an adult patient when the patient reports symptoms related to COVID-19.
  - If a patient is not transported, he/she should be directed to contact 911 if he/she develops significant shortness of breath, or chest pain. Recommendations for non-emergent care follow up per local resources should be provided. Inability to schedule follow-up with an appropriate health care provider/facility is not a 911 call unless emergent symptoms above are present instead a non-emergent resource line should be provided.
  - The patient must be in agreement with non-transport and the time taken to explain other resources that are more appropriate to get patients buy-in and understanding.



Table 13. Emergency Management System Patient Considerations for Non-Transport in COVID-19

PATIENT CONSIDERATION FOR NON-TRANSPORT:	
INITIAL ASSESSMENT WITH VITAL SIGNS	
(initial encounter should ideally be by a single provider in appropriate PPE from a distance of 6 feet, if feasible)	
<ul style="list-style-type: none"> <li>• SBP 100-180 mm Hg</li> <li>• Respiratory Rate 8-20</li> <li>• EtCO<sub>2</sub>/EtCO<sub>2</sub> &gt; 25 (if available)</li> <li>• HR &lt; 110 bpm</li> </ul>	<ul style="list-style-type: none"> <li>• GCS 15, Alert &amp; Oriented</li> <li>• SpO<sub>2</sub> &gt; 90% (with basic ADLs)</li> <li>• Well appearing, speaks in full sentences, ambulatory</li> <li>• Viral sx: cough, sore throat, body aches, congestion</li> </ul>
PATIENT MEDICAL HISTORY & PRESENTATION	
<ul style="list-style-type: none"> <li>• Age &lt; 65 years</li> <li>• Non-Immunocompromised</li> <li>• No known respiratory disease</li> </ul>	<ul style="list-style-type: none"> <li>• Non-diabetic</li> <li>• No known cardiac disease</li> <li>• No end-stage renal disease or dialysis</li> </ul>
LIVING ARRANGEMENTS	
<ul style="list-style-type: none"> <li>• Has appropriate support system at home</li> </ul>	<ul style="list-style-type: none"> <li>• Patient has means for follow-up</li> </ul>
IF THE PATIENT IS IN A PUBLIC LOCATION	
<ul style="list-style-type: none"> <li>• Place a surgical mask on the patient</li> <li>• Instruct the patient to directly transport themselves home while minimizing exposure to others/the community</li> </ul>	<ul style="list-style-type: none"> <li>• Discourage the use of public transportation</li> </ul>

Pre-hospital personnel should continue to reference current CDC guidance regarding PPE and Transport of PUIs or Patients with Confirmed COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html>

### EMS Transport in Resource-Limited Environments

1. During the pandemic, MTFs and civilian EMS services may become inundated with critically ill patients, exceeding MTF treatment and transport capabilities. It is strongly recommended that EMS Medical Directors partner with MTF leadership to discuss disaster response contingency plans relating to inter-facility transports. Nationally Registered Paramedics (NRPs), with approval and guidance from local EMS Medical Directors, are authorized to transport critically ill patients via ambulance. The following are ambulance staffing recommendations to be utilized according to staffing capabilities and patient acuity:

GOOD	
If the patient:	Crew (in addition to the EMT/NRP driver):
Is not ventilated and has no more than two intravenous (IV) or intraosseous (IO) pump infused medications	Paramedic
Is not ventilated and has ≥3 IV/IO pump infused meds	Paramedic <b>AND</b> Critical Care Registered Nurse (CCRN) <b>OR</b> Certified Emergency Nurse (CEN)
Is ventilated and has ≤2 IV/IO pump infused meds	Paramedic x 2 <b>OR</b> Paramedic <b>AND</b> Respiratory Therapist (RT)
Is ventilated and has ≥3 IV/IO pump infused meds	Paramedic x 2 <b>AND</b> CCRN <b>OR</b> CEN <b>OR</b> Paramedic, RT, <b>AND</b> CCRN <b>OR</b> CEN
Is ventilated and has three or more IV/IO pump infused medications	If NRPs are unavailable, consider utilizing MTF CCAT Teams <b>OR</b> hybrid transport teams consisting of a CCRN, Critical Care Technician and a RT. All patient transports should have 2 EMTs on board to assist with ambulance operations.

BETTER		
If the patient:	Crew (in addition to the EMT/NRP driver):	References:

Is ventilated with IV/IO infusion medication, but no central lines or arterial lines	NRP trained in ventilator management  ABG should be obtained within 30 minutes of transport. If time allows, patient should be placed on transport ventilator for at least 15 minutes prior to transport.	ALS standards Commission on Accreditation of Medical Transport Systems (CAMTS) 11th Ed. <a href="https://www.camts.org/standards/">https://www.camts.org/standards/</a>  <a href="https://its.amedd.army.mil/assets/docs/cpgs/Prehospital_En_Route_CPGs/Standard_Medical_Operating_Guidelines_(SMOG)_for_Critical_Care_Flight_Paramedics_2020.pdf">https://its.amedd.army.mil/assets/docs/cpgs/Prehospital_En_Route_CPGs/Standard_Medical_Operating_Guidelines_(SMOG)_for_Critical_Care_Flight_Paramedics_2020.pdf</a> Procedure A-XII
Is ventilated with central line, or arterial line, or chest tube	At least 2 providers trained at the NRP level or above (physician (MD/DO), physician's assistant (PA), nurse practitioner (NP), or registered nurse (RN))  Primary care provider requirement: > 3 years ED, ICU, or critical care experience.	Emergency Critical Care standards CAMTS 11 <sup>th</sup> Edition <a href="https://www.camts.org/standards/">https://www.camts.org/standards/</a>
Above criteria <b>AND</b> complex ventilator settings <b>OR</b> > 4 IV/IO infusions	Above requirements <b>AND</b> 1 crew member must be an RN with Certified Flight RN, Critical Care RN, or Certified Transport Registered Nurse within 2 years of hire, or equivalent national certification.  At least 1 critical care transport provider shall be licensed as a MD/DO, PA, APRN, or RN with documented competency and experience in the provision of critical care in a tertiary critical care unit, commensurate with the type and acuity of patient requiring transport.	Intensive Care Standards CAMTS 11 <sup>th</sup> Edition <a href="https://www.camts.org/standards/">https://www.camts.org/standards/</a>  Para 1.2.3 Critical Care Transport Team Association of Critical Care Transport-Critical Care Transport Standards-Version 1.0 ©2016 (AACT is a professional organization recommendation but not a certifying organization.)

<b>BEST</b>	
If the patient: requires critical care	<b>Crew (in addition to the driver):</b>
	<b>Military or civilian trained and equipped critical care transport crew (Ground, Rotary, or Fixed Wing)</b>

2. Additional considerations for interfacility transport include:
  - a. **On-line Medical Control.** On-line Medical Control must be available to transport critically ill patients.
  - b. **Training.** Personnel involved in interfacility transports should be trained on ambulances, facility transport ventilators, infusion pumps and all required equipment. Additionally, NRPs with critical care training: Critical Care Paramedic Program (CCEMT-P), Certified Critical Care Paramedics (C-CCPs), Certified Flight Paramedics (FP-Cs), or individuals with previous critical care experience should be tasked as primary transport personnel given their increased education/experience.
  - c. **Ventilators.** NRPs and RNs should be deemed proficient in ventilator operation and management by the local EMS Medical Director prior to performing patient transport. Ventilated patients should be transported with physician documented orders which detail ventilator settings. All patients will be monitored with wave-form capnography. If a BVM is utilized for transport, or if use of the BVM becomes necessary during transport, a positive-end expiratory pressure (PEEP) valve must be applied and dialed to the ventilator PEEP setting. Ventilators and BVMs should be equipped with HEPA filters.
  - d. **IV/IO Infusions.** Many pre-hospital NRP infusions are currently delivered without the use of an infusion pump (epinephrine, norepinephrine, dopamine, amiodarone, and magnesium sulfate), however any infusion for an interfacility transfer should be on an infusion pump. Medications not detailed in the formulary outlined by EMS protocols are authorized with a written physician order. Orders should specify the name of the medication, the drug concentration, and the infusion rate. Infusions must be initiated by the sending facility. Infusions will be maintained at the physician-prescribed dosing regimen. Alterations to dosing regimens require authorization from a physician, preferably, On-line Medical Control. Rapid deterioration in patient clinical status negates the requirement for physician

- authorization (e.g. vasopressor titration).
- e. Prior to placing a transport request, MTF in-patient units should communicate with local EMS Medical Directors or attending Emergency Department physicians to determine transport capabilities. If possible, patient documentation (to include compact discs containing images) should be prepared prior to transport crew arrival.
- 3. If trained healthcare personnel are severely limited, local Medical Directors should partner with MTF and Logistics leadership to discuss the use of licensed drivers/ government owned vehicles to transport of low acuity patients.

### **EMS Operations**

1. Prior to the provision of patient care, EMS personnel should be provided job- or task-specific education and training on preventing transmission of infectious agents. Training should include the appropriate use of PPE.
2. As part of the Occupational Safety and Health Administration respiratory protection program, EMS providers must be fit tested for respiratory protection devices. To reduce the number of times EMS personnel must touch their face and potentially risk self-contamination, they should consider wearing the same respirator or facemask throughout their shift. Respirators with an exhalation valve are not recommended given that they allow unfiltered air to escape.
3. Individuals providing pre-hospital care should notify their direct supervisor immediately if they are feeling ill, have fever (> 100.4), frequent cough, diffuse muscle aches or otherwise have concern they are suffering from COVID-19. Said individuals should be promptly tested for COVID-19, treated and quarantined as deemed necessary by local MTF clinic, urgent care or emergency department if deemed necessary by licensed provider.
4. During transport, the number of personnel in the patient compartment should be limited to only essential personnel to minimize exposure.

### **EMS Personnel Precautions for Procedures**

1. See CDC guidance for AGPs: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html>.
2. If patient presentation allows, EMS personnel providing care to a patient suspected of having COVID-19 should contact Medical Control and/or follow local protocols before initiating an AGP.
3. Nebulized medications for known or suspected COVID-19 patients should be limited given the risk of virus transmission. It is recommended that local Medical Directors work with MTF leadership to obtain single-use albuterol metered-dose inhalers with spacers for prehospital use. If an AGP is required/recommended, the doors to the patient compartment of the ambulance should remain open to allow ventilation of the area during these procedures. If the ambulance is equipped with an HVAC system it should remain on during patient transport.
4. If used, BVMs, SGAs, and ET tubes should have a HEPA/viral filter attached. If the EMS agency has access to ventilators, units should contact the specific ventilator manufacturer for additional guidelines and to obtain part numbers for compatible HEPA/viral filters.

### **Mechanical CPR**

1. The American College of Cardiology recommends use of mechanical CPR devices on PUIs or patients with confirmed COVID-19 who arrest (<https://www.acc.org/latest-in-cardiology/articles/2020/03/19/13/14/cvd-in-the-setting-of-COVID-19-coronavirus-considerations-to-prepare-patients-providers-health-systems>). See updated Cardiac Arrest Algorithms for best practice for COVID-19 patients (**Appendix O**). (<https://professional.heart.org>)
2. Local Medical Directors & EMS/Fire Leadership are responsible for ensuring personnel education of device indications/contraindications, application, and cleaning of mechanical CPR devices. Initial and continuing education should be documented in training records.
3. Devices should be cleaned according to CDC recommendations for known or suspected COVID-19 patients.
4. Contact the device manufacturer for additional recommendations.

**Cleaning EMS Transport Vehicles After Transporting a PUI or Patient with Confirmed COVID-19: See current CDC guidelines:** <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html>

**Follow-up for EMS Personnel after Caring for a PUI or Patient with Confirmed COVID-19**

1. Local public health and infectious disease authorities should be notified regarding PUIs or confirmed COVID-19 patients so that appropriate follow-up monitoring can occur.
2. EMS personnel who have been exposed to a patient with suspected or confirmed COVID-19 should notify their chain of command to ensure appropriate follow-up.
3. EMS agencies should develop local policies for assessing exposure risk and the management of EMS personnel potentially exposed to COVID-19. Decisions for monitoring and quarantine should be made in consultation with public health and infectious disease authorities.
4. EMS personnel should be alert for fever or respiratory symptoms (e.g. cough, shortness of breath, sore throat). If symptoms develop, it is recommended that they self-isolate and notify their primary care provider and/or public health authority to arrange for evaluation.

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**EN ROUTE CRITICAL CARE CONSIDERATIONS FOR PERSONS WITH COVID-19**

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1. The DoD has issued a COVID-19 specific Force Health Protection Guidance Supplement 5 – Department of Defense Guidance for Movement and Medical Treatment of COVID-19 Patients, Symptomatic Persons Under Investigation or Potentially Exposed COVID-19 Persons (FHP; Sup 5) to DoDI 6000.11 “Patient Movement.” Attachment 1 of this supplement provides guidance for the air movement of COVID-19 patients and COVID-19 exposed persons. “Treatment in Place” remains the primary guidance with transport of patients with COVID-19 requiring an Exception to Policy (ETP). The document ([https://www.whs.mil/Portals/75/Coronavirus/FHP%20Guidance%20\(Supplement%205\)%20-%20DoD%20Guidance%20for%20Mvmt.%20and%20Med.%20Treatment.pdf?ver=2020-04-08-142257-760](https://www.whs.mil/Portals/75/Coronavirus/FHP%20Guidance%20(Supplement%205)%20-%20DoD%20Guidance%20for%20Mvmt.%20and%20Med.%20Treatment.pdf?ver=2020-04-08-142257-760)) discusses procedures for obtaining an exception to policy, preferred means of transport, airframe selection, biocontainment, cabin airflow, patient placement, and infection control. It also discusses specific safety precaution considerations regarding mechanical ventilators, clinical specimen management, waste disposal, aircraft cleaning, logistical planning, and in-flight emergencies. Repeating the document is not an intent of this guidance. Medical planners and clinicians are strongly encouraged to review FHP 5 when considering transport for patients with COVID-19.
2. There have been important updates since publication of FHP;(sup5). Additional military biocontainment transport capability has come on line, making DoD contagious patient movement more feasible and frequently utilized during the COVID-19 pandemic due to the intense competition for civil aviation contagious patient movement (PM) resources. Additionally, ETP authority has been delegated to the TRANSCOM Deputy Commander for inter-theater PM and to any general or flag officer within the GCC for intra-theater PM .
3. **Biocontainment:** For USAF CCAT or aeromedical evacuation (AE) teams tasked to transport patients on USAF aircraft, the best practice is to use a biocontainment care module. The DoD’s Transport Isolation System (TIS) has been replaced by the Negative Pressure Connex (NPC) and Negatively Pressurized Connex – Lite (NPC-L). Transport in open aircraft should be considered as a last resort. AMC has issued AMC COVID-19 PMP, which discusses best practices for transport in open aircraft and offers guidance on appropriate PPE measures. FHP Supplement 5 discusses these measures as well.
4. **Initial assessment:** The pre-evacuation assessment requires additional time due to the complexity of these patients. Consider continuing to treat in place those not requiring mechanical ventilation or depleting local resources in austere locations. In environments with fewer resource constraints, consider allowing patients to declare themselves on the ground to require mechanical ventilation before transport. Teleconsultation over time may assist in the management of non-ventilated patients and help determine the need for mechanical ventilation before transport.
5. **Neurologic:** Sedation can be challenging in the controlled environment of the ICU and even more

complicated in flight. Adjust management to conserve common medications in short supply. Reports indicate a ceiling dose of propofol (30 mcg/kg/min), with little effect of increasing infusions. Consider combinations of acetaminophen (IV/PO), opiates (gtts/IVP/PO), propofol (gtts), atypical antipsychotics (IV/IM/PO), and sub-dissociative ketamine (IV) for a multi-modal approach to patient analgesia/sedation. Use caution with dexmedetomidine due to reports of significant bradycardia. Utilize low dose benzodiazepines (IVP) as a last resort due to their association with delirium and prolonged mechanical ventilation. Continue the same or a more aggressive analgesia/sedation strategy for flight if a patient is receiving neuromuscular blockade.

6. **Pulmonary:** Practices of reflexive “early intubation” or, alternatively, “permissive hypoxemia” are not evidence based. However, there may be certain patients with stable mild hypoxemia without signs or symptoms of end-organ damage who are appropriately being managed without intubation prior to evidence based. Clinical decisions to intubate prior to flight should be based not only on evidence-based guidelines and evolving knowledge regarding COVID-19 but also clinician gestalt regarding the likelihood of in-flight deterioration. CCAAT team leads must consider the difficulty in predicting when COVID-19 patients will deteriorate, and if not choosing to intubate pre-flight, anticipate a need for in-flight intubation. Plan patient placement and airflow characteristics on the aircraft to minimize aircraft/crew exposure in case of in-flight intubation. Signs of persistent respiratory distress, complaints of dyspnea, persistent hypoxia with  $SpO_2 < 92\%$ , or a pH of  $< 7.2$  despite preflight proning and conventional supplemental oxygen likely indicate a need for intubation. Careful observation during flight and avoiding intubation may be appropriate for patients whose symptoms improve with awake proning and supplemental oxygen. Consider using the ARDSNet low PEEP/ $FiO_2$  titration table for intubated patients with a low driving pressure (Pplat – PEEP) and 6–8 ml/kg IBW tidal volume. Conversely, for patients with moderate to severe ARDS and less compliant lungs with a higher driving pressure, consider using the high PEEP table. Lastly, it is important to note that High Flow Nasal Cannula (HFNC) is not generally feasible for use on CCAAT missions due to oxygen requirements.

**Cabin Altitude Restriction (CAR):** Consider a CAR when transporting non-intubated patients requiring supplemental oxygen or intubated patients on high PEEP or high  $FiO_2$  in anticipation of potential in-flight patient decompression. During pre-mission planning, the CCAAT lead should discuss a CAR with the TPRMC validating flight surgeon. A lower CAR is associated with a longer duration of the flight. A sea-level CAR can provide an increased safety buffer if the aircraft is capable.

**Prone Positioning:** Strongly consider lung team consultation before transporting intubated patients in the prone position or patients requiring PEEP  $> 14$ ,  $FiO_2 > 60\%$ . For intubated patients that are to be transported in the prone position, initiate prone positioning preflight with adequate time (i.e.,  $> 4$  hours or physician discretion) to verify patient stability and adequate ABG. After proning, wean  $FiO_2$  to maintain  $SpO_2 > 92\%$ . Ideally, design a patient load strategy allowing access for bilateral chest tubes placement, particularly when utilizing high PEEP. Prone positioning complicates the treatment of cardiac arrhythmias, cardiac arrest, pneumothorax, and shock. Before proning, consider placing cardioversion pads for dysrhythmia treatment. Leave the patient on the ventilator to avoid additional aerosolized particles during cardiac arrest. Consider CPR in the prone position during cardiac arrest (see AHA 2010 guidelines). Avoid rotation (proning/reversal) of intubated patients during flight. Refer to **Appendix G** for further discussion of prone positioning. It highlights the need for thorough patient handoff preflight. Be aware prone positioning requires frequent repositioning and padding to prevent pressure wounds. Prone-positioned patients may have intermittent scheduled times in a supine position. Cautiously consider patient movement during the supine period, as  $FiO_2$  requirements usually increase upon supination and may continue to increase throughout the supine period.



**HEPA/viral filters** should be placed on exhalation limb of transport ventilator circuit and on suction exhaust. In-line suction should be utilized and care should be taken to avoid breaking ventilator circuit in flight. Refer to **Appendix J** for a demonstration of the transport ventilator setup. **Table 14** shows the required  $\text{FiO}_2$  to maintain a constant  $\text{PaO}_2$  at different altitudes. It may be useful when assessing stability for flight and the need for cabin altitude restriction.

Table 14. Altitude Physiology Table (10)

Altitude (Ft)	Atmospheric Pressure (mmHg)	Oxygen 21% (mmHg)	Oxygen Requirements to Maintain Sea Level Equivalency**																		
10000	522	110		32	38	45	53	60	68	75	83	90	98								
9000	543	114		30	36	43	50	58	65	72	79	86	93								
8000	565	119		29	34	41	48	55	62	69	76	83	89	96							
7000	587	123		28	33	40	46	53	59	66	73	79	86	92	99						
6000	609	128		27	32	38	44	51	57	63	70	76	82	89	95	101					
5000	633	133		26	30	37	43	49	55	61	67	73	79	85	91	97					
4000	656	138		25	29	35	41	47	53	59	64	70	76	82	88	94	100				
3000	681	143		24	28	34	39	45	51	56	62	67	73	79	84	90	96				
2000	707	148		23	27	32	38	43	49	54	59	65	70	76	81	86	92	97			
1000	733	154	22	26	31	36	42	47	52	57	62	68	73	78	83	88	94	99			
0	760	160	PiO <sub>2</sub>	150	178	214	250	285	321	357	392	428	463	499	535	570	606	642	677	713	
			FiO <sub>2</sub>	0.21	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	1.00	
O <sub>2</sub> Source			RA	Nasal Cannula (1-6 L/min)					Non-Rebreathing Mask (7-15 L/min)												
				Simple Mask (5-10 L/min)					Partial Rebreathing Mask with Bag (7-15 L/min)												
			**Pertinent Formula:																		
			$\text{PiO}_2 = \text{FiO}_2 \times (\text{P}_{\text{sea level}} - \text{P}_{\text{H}_2\text{O}})$ $\text{Required FiO}_2 = [\text{FiO}_2 \times (\text{P}_{\text{sea level}} - 47 \text{ mmHg})] / (\text{P}_{\text{altitude}} - 47 \text{ mmHg})$																		

$\text{FiO}_2$ , fraction of inspired oxygen.

- Cardiovascular:** Optimize electrolytes (e.g., Ca, Mg, and K) preflight due to the incidence of tachydysrhythmias. Consider requesting electrolyte supplementation preflight due to the allowance standard limitations. Review the EKG. Consider holding QTc prolonging medications (e.g., chloroquine derivatives, antipsychotics, etc.) if the QTc >500 ms. Due to the incidence of cardiomyopathy, obtain an echo, if readily available, preflight to inform treatment if in-flight shock develops. For intubated patients, place a CVC preflight, in case a vasopressor requirement develops during the flight.
- Renal:** AKI is common in COVID-19 patients. Renally adjust medication dosage and convert renally metabolized medications as appropriate (e.g., morphine  $\rightarrow$  hydromorphone (Dilaudid), or enoxaparin (Lovenox)  $\rightarrow$  heparin).
- Gastrointestinal:** Continue stress ulcer prophylaxis. Continue post-pyloric enteric feeds, as suggested in **Appendix M**. OGT should be placed preflight and on intermittent suction.
- Fluids:** Euvolemia is the goal. If hypovolemia is suspected, consider low volume (250–500ml) boluses of balanced crystalloid solutions. Anticipate K and Mg replacement need if patient diuresis is ongoing. Recall potassium is not in the CCATT allowance standard.
- Hematologic:** Ensure administration of DVT prophylaxis. Patients who are critically ill or intubated may merit doses of anticoagulation that are higher than those given for conventional DVT prophylaxis. For dosing guidance, please refer to the Hematology Section under Critical Care Prevention of Complications. Recommend discussion with sending/receiving critical care specialists to determine the appropriate dose of prophylactic anticoagulation.
- Non-COVID-19 patient transports may continue within the PM system. Utilize standard transmission-based precautions in accordance with AFI 48-307. Movements should be requested when it is essential to provide appropriate care while minimizing opportunities for transmission of pathogens within and between theaters and countries.

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## PUBLIC HEALTH CONSIDERATIONS AND RESPONSE

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### 1. Public Health Emergency Management (PHEM)

- a. Primary reference: DoD Instruction (DoDI) 6200.03 (Public Health Emergency Management (PHEM) within the DoD); March 28, 2019.
  - b. **The Public Health Emergency Officer (PHEO):** PHEOs provide military commanders with guidance and recommendations on preparing for, declaring, responding to, mitigating, and recovering from public health emergencies. PHEO responsibilities fall into 10 major categories, including: advising the military commander regarding the declaration of a public health emergency and the implementation of emergency health powers, assisting in public affairs risk communications, including dissemination of health protection measures detailed in the Health Protection Condition (HPCON) framework in coordination with the Public Affairs Officer, coordinating with other DoD Components, civilian state, legal, tribal, and territories (SLTT), other federal agencies, and others.
  - c. **Declaring a Public Health Emergency (PHE):** Commanders must be prepared to make timely decisions in order to protect lives, property, and infrastructure and enable DoD installations and/or military commands to sustain mission-critical operations and essential services. Declaration of a PHE allows the installation commander access to the emergency health powers described in DoDI 6200.03, including restriction of movement (ROM), directing examinations and testing, and controlling or restricting the distribution of commodities, and others. The process by which the Commander makes decision to declare a PHE is summarized in the DoDI. Definitions of types of ROM (quarantine, isolation) and their applicability are discussed at: <https://www.public.navy.mil/bupers-npc/reference/messages/Documents/NAVADMIN/NAV2020/NAV20083.txt>
  - d. **Health Protection Condition (HPCON) levels** are used by installation commanders during a health emergency to communicate what health protection measures are required to protect the community from a health threat. The decision to adjust HPCON posture is not based on strictly objective criteria - rather, it is based on a constellation of factors. These factors are similar to deciding whether to declare a Public Health Emergency. The decision to adjust HPCON levels is heavily influenced by the installation commander's risk tolerance, but should be informed by public health statistics, regional and local jurisdictional issues, mitigation strategies, mission impact, and the degree of compliance with Public Health recommendations. Specific mitigation action for each HPCON level may also communicate necessary actions during difficult situations. For example:
    - i. Emphasis on simple personal actions (hand washing)
    - ii. Need for % of population to telework
    - iii. Requirement to listen to message from unrecognized telephone numbers as they may be about contact tracing
    - iv. Reminding the base community that social distancing and mask wearing saves lives and reduces disease transmission and the burden on the medical community
  - e. Further information on HPCONs can be found in the DoDI and the Army Public Health Center (APHC), <https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/HPCON.aspx>, FHP Supplement 2 at: <https://media.defense.gov/2020/Feb/26/2002255006/-1/-1/1/FORCE-HEALTH-PROTECTION-SUPPLEMENT-2.PDF>, and in Secretary of Defense Guidance at: <https://www.whs.mil/Portals/75/Coronavirus/Guidance%20for%20Commanders%20on%20Risk-Based%20Changing%20of%20HPCON%20During%20COVID-19%20OSD004891-20%20RES%20Final.pdf?ver=2020-05-20-161100-313>
  - f. Public Health Emergency Management (PHEM) training (which is required by DoDI 6200.03) and POCs can be found at: <https://www.health.mil/Training-Center/Defense-Medical-Readiness-Training-Institute/Public-Health-Emergency-Management-Course>
2. **Non-pharmaceutical interventions (NPIs)** are critical when no vaccine or therapeutic is available to mitigate a public health threat. NPIs directed towards control of COVID-19, for example, were largely based on the CDC's "Community Mitigation Guidelines to Prevent Pandemic Influenza—United States, 2017," at:

<https://www.cdc.gov/mmwr/volumes/66/rr/rr6601a1.htm>. These include:

- a. **Personal Protective Measures (PPMs) for everyday use:**
  - i. Voluntary home isolation (i.e., staying home when ill or self-isolation)
  - ii. Respiratory etiquette
  - iii. In health care settings, screening for respiratory symptoms immediately upon entry
  - iv. Hand hygiene
- b. **Personal Protective Measures (PPMs) reserved for pandemics:** During a pandemic, the PPMs described above should be strengthened and augmented with additional measures:
  - i. Active, rapid identification of persons having symptoms consistent with COVID-19, followed by referral for testing and home isolation.
  - ii. Identification and home quarantine of non-ill household members or other close contacts of persons with COVID-19. See “contact tracing” section below.
  - iii. Use of face masks or cloth face coverings by well persons: [IMPORTANT NOTE: respirators (e.g. N95, PAPR) are medical supplies and are reserved for use by at-risk medical providers. See information differentiating masks and respirators at the APHC website: <https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/healthcare.aspx> ]
  - iv. Preemptive or reactive school and work closures/dismissals.
  - v. Elimination or reduction of other mass gatherings.
  - vi. Social/physical distancing measures to no less than 6 feet separation.
  - vii. Environmental surface cleaning measures in all settings.
3. **Contact tracing** (contact investigation): When a person gets sick, they are interviewed by public health personnel to make a contact list of other individuals who they might have exposed. See: <https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing/index.html> See: <https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing/index.html>. Steps include:
  - a. **Contact identification:** Each case of COVID-19 is interviewed to identify contacts (people) and activities starting 2 days before symptoms started.
  - b. **Contact notification:** All contacts are notified that they may have been exposed to COVID-19.
  - c. **Quarantine and public health guidance for contacts** (<https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html>).
  - d. **Contact Testing:** Testing is recommended for **all close contacts** of confirmed or probable COVID-19 patients for active case finding. Contacts who test positive are managed and reported as a confirmed COVID-19 case. In general contacts should continue to quarantine for 14 days as stated above. However, CDC has released options to eliminate quarantine for vaccinated individuals that wear a mask or for others to 10 or 7 days if testing is negative and the patient remains asymptomatic: (<https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html>). FHP Supplement 15 (<https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html>) gives the DoD flexibility to use these options based on risk assessment.
  - e. **Contact follow-up:** Regular follow-up may be needed with all contacts to monitor for symptoms and provide additional information about COVID-19.
  - f. PLEASE NOTE! Contact tracing is very time consuming and requires large amount of man power! Therefore, force multiplying protocols were developed to train nonmedical individuals to assist in the process. Additional information on contact tracing, including a toolkit for contact tracing, can be found at service-specific public health guidance, such as the APHC website: <https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/healthcare.aspx>
  - g. **NOTE:** For patients with a new (+) COVID test within 72 hours of patient transport by AF Aeromedical Evacuation (AE/CCATT) or civilian air ambulance, in addition to usual contact tracing procedures, please notify the regional TRANSCOM Patient Movement Requirements Center (TPMRC) that services that MTF (TPMRC-A DSN (312) 779-4200, TPMRC-E DSN (314) 480-8040, TPMRC-W DSN (315) 448-1609).
4. **Risk assessment for potential COVID-19 exposures:**

- a. (<https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-risk.html#after-you-travel>) Travel exposures (<https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-risk.html#after-you-travel>):
  - i. Travelers engaging in any domestic or international travel should be vigilant about following recommended precautions to prevent exposures to others. See FHP Guidance Supplement 14 at: <https://www.whs.mil/Portals/75/Coronavirus/20201229%20FHP%2014%20-%20DoD%20Guidance%20for%20Personnel%20Traveling%20during%20the%20Coronavirus%20Dis-ease%202019%20Pandemic.pdf?ver=ViENRxtcYUJQKe5xuldUXw%3d%3d>.
  - ii. Situations with potentially higher risk of exposure include: Travel from another country, a US state, or a county (according to state data) where COVID-19 transmission is high or increasing, attendance at large social or mass gatherings, or travel on a cruise ship or river boat.
    1. Travelers should take the following precautions in addition to the ones listed above:
      - If traveling to a foreign country, follow host nation and Geographic Combatant Command guidance for testing and quarantine. If not specified, DoD requires restriction of movement (quarantine) for 14 days after international travel. However, DoD components may, after risk assessment, consider reducing quarantine to 10 days without testing or to 7 days if a negative test is obtained within the preceding 48 hours.
      - If arriving from a foreign country: As of 26 January 2021, CDC requires a negative pre-departure COVID test or documented recovery from COVID. See: <https://www.cdc.gov/quarantine/fr-proof-negative-test.html>. See: <https://www.cdc.gov/quarantine/fr-proof-negative-test.html>. DoD also requires the same 14 day quarantine requirement listed above for all travelers arriving from locations designated by CDC as travel health notice (THN) levels 4, 3, or 2. As with travel to a foreign country, reductions to 10 or 7 days described above are also possible based on risk assessment. Those arriving from CDC THN level 1 locations are only required to self-monitor for symptoms for 14 days.
      - For travel within the US: travelers must consult the latest installation guidance from DoD at <https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/> and comply with all DoD, state, and local travel restrictions. They further must comply with CDC, Military Department, and DoD Component-specific guidance and/or procedures for screening, restriction of movement, and testing.
- b. **Community-based exposures** (<https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html>):
  - i. Applies to: Household members, intimate partners, individuals providing care in a household without using recommended infection control precautions, and Individuals who have had close contact (< 6 feet) for a prolonged period of time
  - ii. **Exposure to:** Person with symptomatic COVID-19 during period from 48 hours before symptoms onset until meets criteria for discontinuing home isolation (can be a laboratory-confirmed disease or a clinically compatible illness in a state or territory with widespread community transmission)
  - iii. **Public health actions:** same as under “travel exposures” above
- c. Health care personnel (HCP) exposures (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>).
  - i. **HCP exposures in areas with moderate to substantial transmission:** CDC suggests that facilities may consider foregoing formal contact tracing and work restriction for HCP in favor of universally applied screening and source control strategies. From a work restriction perspective, this is consistent with DoD guidance for mission-essential activities in FHP Supplement 8 ([https://www.whs.mil/Portals/75/Coronavirus/Force%20Health%20Protection%20\(Supplement%208\)%20DOD%20Guidance%20for%20Protecting%20Personnel%20in%20Workplaces%20during%20the%20Response%2](https://www.whs.mil/Portals/75/Coronavirus/Force%20Health%20Protection%20(Supplement%208)%20DOD%20Guidance%20for%20Protecting%20Personnel%20in%20Workplaces%20during%20the%20Response%2)

[Oto%20the%20Coronavirus%20Disease%202019%20Pandemic.pdf?ver=2020-04-13-112859-193](#)). Proper adherence to currently recommended infection control practices, including all recommended PPE, should protect HCP having prolonged close contact with patients infected with COVID-19. However, to account for any inconsistencies in use or adherence that could result in unrecognized exposures, HCP should still perform self-monitoring with delegated supervision. Additionally, many DoD installations have continued to perform contact tracing in these areas.

- ii. **HCP in areas with minimal to no community transmission** may have the ability to apply risk assessment and work restrictions:
  - 1. HCP who have had prolonged ( $\geq 15$  minutes) close ( $< 6$  feet) contact with patients with COVID-19 (beginning 48 hours before onset of symptoms) and the HCP was: 1) not wearing a respirator or facemask (n.b. not a face covering), 2) not wearing eye protection, or 3) not wearing all recommended PPE (i.e. gown, gloves, eye protection, and respirator) while performing an AGP) should be excluded from work for 14 days and self-monitor for symptoms.
  - 2. HCP with exposures other than those listed above have no work restrictions.
- iii. **HCP with travel or community exposures** should consult occupational health.

5. **Guidance for when to discontinue isolation.**

- a. **Non-health care settings** (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>):
    - i. **Test-based strategy:** No longer used.
    - ii. **Non-test-based strategy:** Exclude from work until:
      - 1. At least 1 day (24 hours) have passed since recovery defined as resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (e.g., cough, shortness of breath); and
      - 2. At least 10 days have passed since symptoms first appeared
  - b. **Return to work criteria for HCP** ([https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhealthcare-facilities%2Fhcp-return-work.html](https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhealthcare-facilities%2Fhcp-return-work.html)):
    - i. **Symptom-based strategy:**
      - 1. For mild to moderate illness is the same as non-health care settings;
      - 2. For severe illness the duration since symptom onset should be at least 10 days (some institutions may require 20 days).
      - 3. For asymptomatic HCP, at least 10 days must have passed since the first positive viral diagnostic test (20 days may be required if severely immunocompromised).
    - ii. **Test-based strategy:** in some cases may allow HCP to return to work sooner than above strategy.
      - 1. Symptomatic HCP must have: 1) resolution of fever without fever-reducing medications, 2) improvement of symptoms, and 3) Results are negative from at least two consecutive respiratory specimens collected  $\geq 24$  hours apart (total of two negative specimens) tested using an FDA-authorized molecular viral assay.
      - 2. Asymptomatic HCP must only fulfill the third criterion above (the two negative specimens).
    - iii. HCP without symptoms may use the test-based strategy or a time-based strategy, in which HCP are excluded from work until 10 days have passed since the date of their first positive COVID-19 diagnostic test. If they develop symptoms, then the symptom-based or test-based strategy should be used.
6. **Reporting and Surveillance:** All confirmed and probable cases of COVID-19 must be reported to inform, and evaluate control and prevention efforts. Cases are reported by DoD public health personnel to BOTH: 1) military and 2) civilian public health authorities. Military service members and other beneficiaries must be reported through DoD public health authorities via the Disease Reporting System internet (DRSi) in coordination with the Service-specific public health chain of command. All cases must also be reported to the supporting local or state health department according to state requirements. All DoD medical reporting entities should report cases of COVID-19 to the DRSi using the "COVID-19" and answer all event-related



questions in the report. Cases must be classified according to the most recent DoD COVID-19 case definition.

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## VACCINATIONS TO PREVENT COVID-19

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CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States are available at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

See **Appendix U** for a summary.

1. **Background:** COVID-19 vaccination is recommended for everyone aged 5 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19) and efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic. The Omicron variant (B.1.1.529) (currently the predominant SARS-CoV-2 variant in the United States) and the Delta variant (B.1.617.2) are associated with increased transmissibility.(61) Available evidence suggests vaccines offer protection against known variants, particularly against severe disease, hospitalization, and death. There are currently three COVID-19 vaccines authorized for use in the United States either approved under a Biologics License Application (BLA) or Emergency Use Authorization (EUA). The age groups approved under BLA or authorized under EUA to receive vaccination vary by vaccine product. Summaries of the available vaccines and dosing recommendations are in **Table 15** and **Table 16**.(329)
  - a. **Pfizer-BioNTech COVID-19 vaccine** (COMIRNATY) is a mRNA COVID-19 vaccine and has been FDA-approved for use as a 2-dose primary series in persons  $\geq 16$  years of age. It is also authorized under EUA to be administered as:(330-332)
    - i. A 2-dose primary series in persons aged 5-15 years of age
    - ii. A third dose (i.e., additional dose) to persons aged  $\geq 5$  years with certain kinds of immunocompromising conditions at least 28 days following the second dose of a mRNA vaccine
    - iii. A single booster dose for those 12 and older at least 5 months after completing the 2-dose primary series
    - iv. A single booster dose in persons  $\geq 18$  years of age who completed a COVID-19 primary vaccination series with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.
  - b. **Moderna COVID-19 vaccine** is an mRNA vaccine and has been authorized under EUA for persons  $\geq 18$  years of age to be administered as:(333)
    - i. A 2-dose primary series
    - ii. A third dose (i.e., additional dose)  $\geq 28$  days following the second dose in moderately to severely immunocompromised people who completed a 2-dose mRNA COVID-19 primary vaccination series
    - iii. A single booster dose  $\geq 5$  months after completion of a 2-dose mRNA COVID-19 primary vaccination series
    - iv. A single booster dose following completion of a COVID-19 primary vaccination series with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.
  - c. **Janssen (Johnson & Johnson) COVID-19 vaccine** is a viral vector vaccine and has been authorized under EUA for persons  $\geq 18$  years of age.(334) *NOTE: Based on updated vaccine effectiveness and safety data, Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination. The Janssen COVID-19 vaccine may be considered in some situations, including for persons with a contraindication to receipt of mRNA COVID-19 vaccines.*
2. **COVID-19 vaccine administration:** COVID-19 vaccines are administered intramuscularly as either a 2-dose (Pfizer-BioNTech, Moderna) or single dose (Janssen) primary series. In general, only a single primary vaccination series (i.e., either a 2-dose mRNA COVID-19 vaccine series or a single dose of Janssen COVID-19 vaccine) should be administered. People are not recommended to receive more than one complete COVID-19 primary vaccination series. Considerations for repeating a primary series in specific populations is covered in the “Immunocompromised Persons” section. A person is considered fully vaccinated against

COVID-19  $\geq 2$  weeks after receipt of the second dose in a 2-dose series (Pfizer-BioNTech and Moderna) or  $\geq 2$  weeks after receipt of the single dose of the Janssen vaccine. A person is considered “up to date” when they have received all recommended COVID-19 vaccines, including any additional primary or booster doses. Administration of an additional dose to people with moderate to severe immune compromise or a booster dose is not required to be considered fully vaccinated for public health purposes. People who have a contraindication to vaccination or who otherwise do not complete a vaccination series are not considered fully vaccinated. Upon eligibility for booster doses (5 months for Pfizer-BioNTech and Moderna; 2 months for Janssen) and receipt of the booster dose, individuals are again considered “fully vaccinated”.

- a. **Interval between mRNA COVID-19 primary vaccine series doses:** The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 21 days [Pfizer-BioNTech] or 28 days [Moderna]). However, individuals who receive the second dose up to 4 days before or at any time after the recommended date can be considered fully vaccinated.
  - i. **Vaccine administration errors and deviations:** Vaccine administration errors should be reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).<sup>(335)</sup> Guidance for specific scenarios can be found on the CDC Interim Clinical Considerations website.<sup>(329)</sup>
3. **Additional Doses:** There are two distinct potential uses for an additional dose of COVID-19 vaccine following a primary vaccine series (see **Tables 15 and 16**):
  - a. **Additional dose after an initial primary vaccine series:** administered when the immune response following a primary vaccine series is likely to be insufficient. For moderately to severely immunocompromised people  $\geq 5$  years of age, an additional mRNA COVID-19 vaccine dose is recommended  $\geq 28$  days after an initial 2-dose mRNA primary vaccine series.
  - b. **Booster dose:** administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. It is recommended that those  $\geq 12$  years of age receive a single Pfizer-BioNTech vaccine booster dose  $\geq 5$  months after completion of an mRNA COVID-19 vaccine primary series or  $\geq 2$  months after completion of a Janssen COVID-19 vaccine primary dose.
4. **Interchangeability of COVID-19 vaccine products:** Any currently FDA-approved or FDA-authorized COVID-19 vaccine can be used when indicated. In general, the same mRNA vaccine product (i.e., the same manufacturer) should be used for all doses in the primary series (including an additional primary dose) and any booster doses. The three currently FDA-approved or FDA-authorized COVID-19 vaccines (Pfizer, Moderna, and Janssen) are authorized under EUA for use as a heterologous (mix and match) booster dose.
  - a. **mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna):**
    - i. Data on the safety and efficacy of a mixed-product series are limited. For individuals  $\geq 18$  years of age, in exceptional situations in which the mRNA vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the primary series. In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the second dose to receive the same product than to receive a mixed series using a different product. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time. Such persons are considered fully vaccinated against COVID-19 2 weeks after receipt of the second dose of an mRNA vaccine and should be offered an additional primary dose or booster dose, if indicated.
    - ii. The FDA-approved COMIRNATY and the two EUA authorized formulations of Pfizer-BioNTech COVID-19 vaccine for people 12 years of age and older (purple cap and gray cap) can be used interchangeably for individuals  $\geq 12$  years of age. The Pfizer-BioNTech COVID-19 vaccine formulation with an orange cap vial should only be used for children 5–11 years of age.
  - b. **Janssen vaccine:** The safety and efficacy of Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established. However, for individuals  $\geq 18$  years of age, in limited situations where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to

contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. See the “Contraindications and Precautions” section for additional information on use of Janssen COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series—and are considered fully vaccinated against COVID-19 2 weeks after receipt of the single dose of the Janssen vaccine.

5. **Coadministration:** Studies to assess the safety and immunogenicity of coadministration of COVID-19 vaccines with other vaccines are underway or in development. As detailed in The ACIP General Best Practice Guidelines, extensive research on the simultaneous administration of the most widely used live and inactivated vaccines has demonstrated seroconversion rates and rates for adverse reactions similar to those observed when the vaccines are administered separately.(336) COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day. It is not known if the reactogenicity of COVID-19 vaccines is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines. When deciding whether to administer an(other) vaccine(s) with a COVID-19 vaccine, vaccination providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposure), and the reactogenicity profile of the vaccines. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection administered at different sites (separated by 1 inch or more) in the muscle. The one exception to simultaneous vaccine administration is with ACAM2000™ smallpox vaccine. Per DoD policy, ACAM2000™ vaccine must be separated from any mRNA COVID-19 vaccine by ≥28 days.(337)
6. **People vaccinated outside the United States:(338)**
  - a. Limited data are available on the safety or efficacy of receiving a COVID-19 vaccine currently approved or authorized in the United States after receipt of a non-FDA-approved or FDA-authorized COVID-19 vaccine. The minimum interval between the last dose of a non-FDA-approved or non-FDA-authorized vaccine, or a WHO-listed vaccine and an FDA-approved or FDA-authorized COVID-19 vaccine is 28 days. Only people who have completed a primary vaccine series of an FDA-approved, FDA-authorized, or WHO-listed COVID-19 vaccine are considered fully vaccinated for the purpose of public health guidance.
    - i. Received all of the recommended doses of a single dose or 2-dose primary COVID-19 vaccine series are considered fully vaccinated 2 weeks after completion of the series.
    - ii. Received the first dose of a 2-dose mRNA COVID-19 vaccine series do not need to restart the vaccine series in the United States. They should receive a single dose of Pfizer-BioNTech COVID-19 vaccine at least 28 days since receipt of their first dose, after which they are considered fully vaccinated.
    - iii. Were vaccinated in countries where only a single mRNA dose is recommended in certain populations (e.g., people with a history of SARS-CoV-2 infection, adolescents) are not considered fully vaccinated in the United States until after completion of the 2-dose series.
    - iv. After completion of a primary series, these individuals should follow guidance for an additional primary dose and/or booster dose as described in the “Additional Doses” section.
  - b. People who received all or some of the recommended doses of a non WHO-EUL COVID-19 vaccine primary series:
    - i. Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., 2-dose mRNA vaccine series or single Janssen vaccine dose), preferably with an mRNA COVID-19 vaccine, with a minimum interval of at least 28 days since after receipt of the last dose of a vaccine not listed for emergency use by WHO.
    - ii. After completion of the primary series of an FDA-approved or FDA-authorized COVID-19 vaccine, these individuals are considered fully vaccinated. Additional primary or booster doses are not

recommended for these individuals at this time.

7. **COVID-19 Clinical Trial Participants:** Individuals participating in clinical trials within or outside the United States who received a complete primary series of a WHO-EUL COVID-19 vaccine (i.e., not placebo) not FDA-approved or FDA-authorized or a non WHO-EUL vaccine for which efficacy has been independently confirmed (e.g., by a U.S. data/safety monitoring board or equivalent) are considered fully vaccinated. At this time, only the Moderna COVID-19 Vaccine in children aged 6–17 years and the Medicago COVID-19 Vaccine in people aged ≥18 years meet these criteria. *This recommendation does not imply that these vaccines have been approved or authorized by FDA or are recommended by CDC or ACIP.*
  - a. Moderately or severely immunocompromised clinical trial participants aged ≥12 years should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine as detailed in the “Immunocompromised Individuals” section, unless they have received or plan to receive an additional or booster dose through a clinical trial.
  - b. Clinical trial participants aged ≥12 years (including moderately or severely immunocompromised people who received an additional primary dose) should receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine, unless they have received or plan to receive a booster dose through a clinical trial.
  - c. Clinical trial participants who have questions about additional and/or booster doses outside of the clinical trial should consult their clinical trial point of contact and healthcare provider.
  - d. Clinical trial participants who did not receive all the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series
8. **COVID-19 vaccination and SARS-CoV-2 infection:** Data from multiple studies indicate that currently approved or authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. Current evidence suggests that the risk of SARS-CoV-2 reinfection is low after a previous infection but may increase with time due to waning immunity. Individual immune response after infection varies widely, while the immune response following vaccination is more reliable, consistent, and predictable. Numerous immunologic studies have shown that vaccination enhances the immune response and decreases the risk of subsequent infections in people with prior SARS-CoV-2 infection, including in the setting of increased circulation of more infectious variants.
9. **People with prior SARS-CoV-2 infection:** People ≥5 years of age should be offered COVID-19 vaccination (primary series, additional primary doses, and booster doses as applicable) regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection, to include those with prolonged post-COVID-19 symptoms.
10. **People with known current SARS-CoV-2 infection:**
  - a. Data on the optimal timing between SARS-CoV-2 infection and vaccination is limited. Defer vaccination until acute illness (if symptomatic) has resolved and criteria to discontinue isolation have been met. This recommendation applies to both those who have never received a COVID-19 vaccine, or who have only received the first dose of a 2-dose primary series.
  - b. Serologic testing to assess for acute SARS-CoV-2 infection or prior infection is not recommended for the purpose of vaccine decision-making. Present data are insufficient to determine a correlate of protection (antibody titer level), and there is no FDA-authorized or FDA-approved test or scientifically validated strategy to reliably determine if a person is protected from SARS-CoV-2 infection.
11. **People who received passive antibody products or antiviral therapies:**
  - a. There is limited data on the safety and effectiveness of COVID-19 vaccines in people who received passive antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment or post-exposure prophylaxis. As a precautionary measure until additional information becomes available, based on the estimated half-life of such products and the anticipated period of protection against infection or reinfection, COVID-19 vaccination should be temporarily deferred as specified below to avoid potential interference with vaccine-induced immune responses:
    - i. Passive antibody product used for post-exposure prophylaxis: Defer COVID-19 vaccination for 30 days

- ii. Passive antibody product used for COVID-19 treatment: Defer COVID-19 vaccination for 90 days. If a COVID-19 vaccine is inadvertently administered within these recommended deferral periods, the vaccine dose does not need to be repeated.
  - b. There is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM) and COVID-19 vaccination, as they are unlikely to substantially impair development of a vaccine-induced protective antibody response.(339) Similarly, receipt of an antiviral drug at any interval before or after vaccination with any of the currently FDA-approved or FDA-authorized COVID-19 vaccines (including the adenovirus vector Janssen COVID-19 vaccine) is unlikely to impair development of a protective antibody response.
12. **Vaccinated people who subsequently develop COVID-19:** COVID-19 treatment-specific clinical guidelines should be consulted when making treatment decisions (e.g., use of monoclonal antibodies, convalescent plasma, antivirals, or corticosteroids) for people who have previously received any COVID-19 vaccine and subsequently develop COVID-19. For purposes of surveillance, infections in fully vaccinated people (i.e., breakthrough infections) are defined as detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected  $\geq 14$  days after completion of all recommended doses of a currently FDA-approved or FDA-authorized COVID-19 vaccine. Infections in fully vaccinated people that result in hospitalization or death should be reported to VAERS.
13. **History of Multisystem Inflammatory Syndrome in children (MIS-C) or adults (MIS-A):**(340)
- a. MIS-C and MIS-A are rare but serious conditions. The exact cause and mechanisms of MIS-C and MIS-A are not well understood: they are thought to include a dysregulated immune response to SARS-CoV-2 infection, and the risk of recurrence (to include following COVID-19 vaccination) is unknown. Those with MIS-C have high SARS-CoV-2 antibody titers; however, it is unknown if this correlates with protection, or how long those levels persist.
  - b. Due to limited data on the safety of COVID-19 vaccines in people with a history of MIS-C or MIS-A, shared clinical decision-making (e.g., with parents/guardians, clinical team, specialist providers) should be utilized to determine if the use of COVID-19 vaccines is appropriate.
  - c. Given the widespread transmission of SARS-CoV-2, experts currently believe the benefits of COVID-19 vaccination outweigh the theoretical risks of MIS or myocarditis in persons with a history of MIS-C who:
    - i. Have achieved clinical recovery, to include a return to normal cardiac function;
    - ii. Whose diagnosis of MIS-C was  $\geq 90$  days ago AND prior to any COVID-19 vaccination; and
    - iii. Have an increased risk for SARS-CoV-2 exposure and transmission due to any reason (e.g., geographical location, occupation, etc.).
  - d. COVID-19 vaccination may also be considered for people who do not meet all the above criteria or for those with a history of MIS-A. Experts view clinical recovery, including return to normal cardiac function, as an important criterion. Additional factors to consider may include an increased risk of severe COVID-19 (e.g., due to age or underlying conditions), or the timing of immunomodulatory therapies.
  - e. **People diagnosed with MIS-C or MIS-A after COVID-19 vaccination:** In these rare instances, referral to a specialist in infectious diseases, rheumatology, or cardiology should be considered. Serologic testing for SARS-CoV-2 should be performed, as these are conditions known to occur with current or prior infection. Request for a consultation from the Clinical Immunization Safety Assessment (CISA) COVIDvax project should also be considered. All illnesses consistent with MIS-C or MIS-A after receipt of any COVID-19 vaccine should be reported to VAERS.
14. **Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks:** COVID-19 vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis to prevent SARS-CoV-2 infection in persons with a known exposure. Because the median incubation period of COVID-19 is 4–5 days, it is unlikely that a dose of COVID-19 vaccine would provide an adequate immune response within the incubation period: post-exposure prophylaxis with monoclonal antibodies is discussed elsewhere. People in the community or in outpatient settings who are unvaccinated or not up to date and have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to reduce the risk of transmission to others. This also avoids causing diagnostic confusion between possible adverse



effects of vaccination and symptoms of a new COVID-19 diagnosis. Asymptomatic residents or patients in congregate healthcare settings (e.g., long-term care facilities) or congregate non-healthcare settings (e.g., correctional and detention facilities, homeless shelters) with known COVID-19 exposure, undergoing screening, or awaiting SARS-CoV-2 testing results may be vaccinated. In these settings, exposure to and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, and healthcare personnel and other staff are already in close contact with residents. Vaccination providers should employ appropriate infection prevention and control procedures in these instances.

15. **Immunocompromised Individuals:** People with immunocompromising conditions or who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 illness. These conditions and treatments include but are not limited to:
  - i. Active treatment for solid tumor and hematologic malignancies
  - ii. Receipt of solid-organ transplant and taking immunosuppressive therapy
  - iii. Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
  - iv. Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
  - v. Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm<sup>3</sup>, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
  - vi. Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.
- b. **COVID-19 vaccine immune response and effectiveness in moderately and severely immunocompromised people:**(339) The currently FDA-approved or FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
  - i. Studies have found evidence of reduced immune response to a 2-dose mRNA COVID-19 primary vaccine series in some groups of immunocompromised people. In addition, reduced vaccine effectiveness has been observed in immunocompromised participants compared to participants who are not immunocompromised in a limited number of studies. The rate of SARS-CoV-2 infections in fully vaccinated immunocompromised people also may be higher than the rate in vaccinated members of the general population. Small studies have demonstrated that an additional mRNA COVID-19 vaccine dose in some immunocompromised people who received a mRNA COVID-19 primary vaccine series may enhance antibody response, increasing the proportion of people who respond. However, the exact correlation between antibody level and protection against severe COVID-19 outcomes as well as infectiousness remains unclear. The reactogenicity profile of the additional dose was similar to prior doses.
- c. **Use of an additional COVID-19 vaccine primary dose (i.e., a third dose) in moderately or severely immunocompromised people:**(339) Although the clinical benefit is still under investigation, the potential to increase immune response coupled with an acceptable safety profile supports use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose mRNA COVID-19 primary vaccine series in this population. Administration of a third dose of either Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine to moderately or severely immunocompromised people (e.g., who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise) who completed an mRNA primary series was authorized under EUA on 21 Aug 2021. The additional primary mRNA COVID-19 dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary series (Pfizer-BioNTech or Moderna). The additional dose should be provided ≥28 days after completion of the primary series as follows:
  - i. Pfizer-BioNTech, 5-11 years of age (orange cap): 0.2 mL, intramuscular administration
  - ii. Pfizer-BioNTech, ≥12 years of age (purple or gray cap); 0.3 mL, intramuscular administration

- iii. Moderna: aged  $\geq 18$  years; 0.5 mL, intramuscular administration
  - iv. Janssen COVID-19 vaccine is not authorized for use as an additional primary dose, and people who received a single-dose Janssen COVID-19 primary vaccine should not receive an additional primary dose. However, they should receive a booster dose.
  - d. **Use of a COVID-19 booster dose in moderately or severely immunocompromised people:** Moderately or severely immunocompromised people  $\geq 12$  years of age should receive a single COVID-19 booster dose (preferably with an mRNA COVID-19 vaccine)  $\geq 5$  months after completing their additional mRNA primary dose or  $\geq 2$  months after receiving a single dose Janssen COVID-19 vaccine primary series. For those 12–17 years of age, the booster dose can only be with the Pfizer BioNTech COVID-19 vaccine.
  - e. **Immunosuppressive therapy timing and COVID-19 revaccination:** COVID-19 vaccines should ideally be administered  $\geq 2$  weeks prior to initiation or resumption of immunosuppressive therapies, with the goal of optimization of both the patient's medical condition and response to vaccine. HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to or during treatment should repeat the primary vaccine series  $\geq 3$  months after transplant or therapy, preferably with an mRNA vaccine (regardless of vaccine issued for initial primary vaccination). These individuals should also receive an additional primary dose  $\geq 28$  days after the second dose. The patient's clinical team should determine the degree of immune compromise and appropriate timing of the primary series, additional primary dose, booster dose, and revaccination.
  - f. **Reinforcement of the need for prevention measures among immunocompromised people:** Vaccinated immunocompromised people (including people who receive an additional primary dose or a booster dose) should be educated about the potential for a reduced immune response to COVID-19 vaccines and the need to continue to follow current COVID-19 prevention measures (including wearing a mask, staying 6 feet apart from others they don't live with, and avoiding crowds and poorly ventilated indoor spaces), until advised otherwise by their healthcare professional. Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect these people.
16. **Considerations for vaccination of people with certain underlying medical conditions:** Any currently FDA-approved or FDA-authorized COVID-19 vaccine can be administered to people with underlying medical conditions who have no contraindications to vaccination; ACIP does not state a product preference. Clinical trials demonstrated similar safety and efficacy profiles in people with some underlying medical conditions, including those that place them at increased risk for severe COVID-19 symptoms, compared to people without comorbidities. Additional information for people with specific underlying medical conditions is included below. Healthcare professionals or health departments in the United States can request a consultation from the [Clinical Immunization Safety Assessment COVIDvax](#) project if they have complex COVID-19 vaccine safety questions not readily addressed by CDC guidance.
- a. **People with a history of myocarditis or pericarditis:**
    - i. Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart) have occurred rarely in some people following receipt of mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna). The mechanisms that cause myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine are not well understood. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12-29 years within a few days after receiving the second dose of vaccine. Most patients have been hospitalized for short periods, with the majority achieving resolution of acute symptoms. Follow-up is ongoing to identify and understand potential long-term outcomes among cases.
    - ii. There are limited data on the safety and efficacy of COVID-19 vaccines in people with a history of myocarditis or pericarditis. The interim considerations for the clinical scenarios detailed as follows may be updated as new information is obtained.
    - iii. **Myocarditis or pericarditis after receipt of a dose of an mRNA COVID-19 vaccine but before administration of a subsequent dose:**(150, 151, 341, 342) It is unclear if people who developed myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine may be at increased risk of

further adverse cardiac effects following a subsequent dose of the vaccine. **Until additional safety data are available, experts recommend that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine defer receiving a subsequent dose.** Administration of a subsequent dose of an mRNA COVID-19 vaccine can be considered in certain circumstances for people who develop myocarditis or pericarditis after receiving a dose of an mRNA COVID-19 vaccine. Considerations for vaccination may include:

- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
  - Level of COVID-19 community transmission and personal risk of infection
  - Additional data on the risk of myocarditis or pericarditis following an occurrence of either condition after a dose of an mRNA COVID-19 vaccine
  - Additional data on the long-term outcomes of myocarditis or pericarditis that occurred after receipt of an mRNA COVID-19 vaccine
  - Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information
- iv. People who choose to receive a subsequent dose of an mRNA COVID-19 vaccine should wait at least until their episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to assess cardiac recovery. Decisions about proceeding with a subsequent dose should include a conversation between the patient, their parent, guardian, or caregiver (when relevant), and their clinical team.
- v. Clinicians should consult current clinical guidance for information on the evaluation and management of myocarditis.
- vi. **History of myocarditis or pericarditis prior to COVID-19 vaccination:**(150, 151, 341, 342) People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved (minimum of 90 days). This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to assess cardiac recovery. CDC is continuing to investigate cases of myocarditis or pericarditis after mRNA COVID-19 vaccination; this guidance may be updated as new information is obtained. All cases of myocarditis or pericarditis following COVID-19 vaccination should be reported to VAERS
- b. **People with autoimmune conditions:** People with autoimmune conditions were enrolled in COVID-19 vaccine clinical trials. Safety and efficacy of vaccines in this population were similar to the general population. People with autoimmune conditions may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine. If people with these conditions are immunocompromised because of medications such as high-dose corticosteroids or biologic agents, they should follow the considerations for immunocompromised people.
- c. **People with a history of Guillain-Barré syndrome:**
- i. People with a history of GBS can receive any currently FDA-approved or FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 vaccine and an increased risk of GBS, a patient with a history of GBS and their clinical team should discuss the availability of mRNA COVID-19 vaccines to offer protection against COVID-19.
17. **Considerations for use of the Janssen COVID-19 vaccine in certain populations:**(334, 343)
- a. **Thrombosis with thrombocytopenia syndrome:** Thrombosis with thrombocytopenia syndrome (TTS) is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. In the United States, the majority of people with TTS that occurred after Janssen COVID-19 vaccination had clots located in cerebral venous sinuses; clots also occurred in other unusual locations, including in the portal vein and splenic vein, and included a

combination of venous and arterial thromboses. FDA updated the Janssen COVID-19 vaccine EUA Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) and Fact Sheet icon for Recipients and Caregivers to include information about rare clotting events that might occur after vaccination, primarily among women aged 18–49 years.

b. **People with a history of thrombosis or risk factors for thrombosis:**

- i. Although the etiology of TTS associated with the Janssen COVID-19 vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Until more information becomes available, experts advise that people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another currently FDA-approved or FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) if it has been ≤90 days since their TTS resolved. After 90 days, patients may be vaccinated with any currently FDA-approved or FDA-authorized COVID-19 vaccine.
- ii. Venous thromboembolism (VTE), defined as deep vein thrombosis, pulmonary embolism, or both, are common. The biologic mechanisms for VTE (as well as arterial thrombi) differ from the underlying immune-mediated mechanism for HIT. Based on current knowledge, experts believe that people with risk factors for VTE (e.g., inherited or acquired thrombophilia including Factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C, protein S or antithrombin deficiency), or a prior history of other types of thromboses (including cerebral venous sinus thrombosis [CVST]) not associated with thrombocytopenia are unlikely to be at increased risk for TTS. Likewise, although the risk of thrombosis is increased during pregnancy and the postpartum period, and with certain hormonal contraceptives (e.g., combined oral contraceptives, patch, and ring), experts believe that these factors do not make people more susceptible to TTS after receipt of the Janssen COVID-19 vaccine. People with risk factors for VTE can receive any currently FDA-approved or FDA-authorized vaccine, including the Janssen COVID-19 vaccine.

c. **Use of aspirin or anticoagulants:** It is not recommended that people take aspirin or an anticoagulant before vaccination with the Janssen COVID-19 vaccine or any other currently FDA-approved or FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) unless they take these medications as part of their routine medications.

d. **People with a history of Guillain-Barré syndrome:** Reports of adverse events following use of the Janssen COVID-19 Vaccine under EUA suggest an increased risk of GBS during the 42 days following vaccination. Investigations to assess whether there is a causal relationship between GBS and Janssen vaccine are ongoing. People with a history of GBS can receive any currently FDA-approved or FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 vaccine and an increased risk of GBS, a patient with a history of GBS and their clinical team should discuss the availability of mRNA COVID-19 vaccines to offer protection against COVID-19.

18. **Considerations involving pregnancy, lactation, and fertility:**(266) COVID-19 vaccination is recommended for all people aged 5 years and older, including people who are pregnant, recently pregnant, lactating, trying to get pregnant now, or might become pregnant in the future. Any of the currently FDA-approved or FDA-authorized COVID-19 vaccines can be administered to people in these groups; ACIP does not state a product preference. However, all women aged <50 years of age should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other currently FDA-approved or FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines) for which this risk has not been seen (see also “People with a history of thrombosis or risk factors for thrombosis”). There is no evidence that any of the COVID-19 vaccines affect current or future fertility. For purposes of decisions around administering both primary series vaccination and a booster dose, pregnant and recently pregnant people (for at least 42 days following end of pregnancy) should be considered in the same group as people with underlying medical conditions.

a. **Pregnancy:**

- i. Pregnant and recently pregnant people with COVID-19 are at increased risk for severe illness when compared with non-pregnant people. Severe illness includes illness that requires hospitalization, intensive care unit admission, mechanical ventilation, or extracorporeal membrane oxygenation or

illness that results in death, although the absolute risk for these outcomes is low. Additionally, pregnant people with COVID-19 are at increased risk for preterm birth and might be at increased risk for other adverse pregnancy complications and outcomes, such as preeclampsia, coagulopathy, and stillbirth.

- ii. **COVID-19 vaccination is recommended for all people aged 5 years and older, including people who are pregnant.** A conversation between the patient and their clinical team may assist with decisions about the use of a COVID-19 vaccine; however, approval by a healthcare professional is not required before vaccination. COVID-19 vaccines and other vaccines may be administered without regard to timing as detailed with other vaccines. If a person becomes pregnant following the first dose of a COVID-19 vaccine that requires two doses (i.e., Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine), the second dose should be administered as indicated for the person to be have maximum protection. Data on uptake of COVID-19 vaccination among pregnant people can be found on CDC's COVID Data Tracker. Pregnant people are encouraged to enroll in v-safe after COVID-19 vaccination.
  - iii. Side effects can occur after COVID-19 vaccination in pregnant people, similar to those among non-pregnant people. Acetaminophen can be offered as an option for pregnant people experiencing fever (fever has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.
  - b. **Lactation:** COVID-19 vaccination is recommended for all people aged 5 years and older, including lactating people. There are limited data on the safety of COVID-19 vaccines in lactating people or the effects of COVID-19 vaccines on the breastfed infant, milk production, and secretion. However, the currently FDA-approved or FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines and a non-replicating viral vector vaccine) cannot cause infection in either the lactating person or the infant. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination were present in breastmilk samples. More data are needed to determine if these antibodies convey protection against SARS-CoV-2 infection for neonates and infants.
  - c. **Fertility:** COVID-19 vaccination is recommended for all people aged 5 years and older, including people trying to get pregnant now or who might become pregnant in the future. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. Many women have become pregnant after receiving COVID-19 vaccine. However, results from ongoing long-term studies are not yet available.
19. **Vaccination of children and adolescents:**(329, 344) Individuals aged 5–17 years of age are eligible to receive the Pfizer-BioNTech COVID-19 vaccine and may be vaccinated as detailed above with appropriate consent and assent. Sites administering COVID-19 vaccines should follow current state/jurisdictional policies and practices for other routine immunizations in this age group. Children should receive the age-appropriate vaccine formulation regardless of their size or weight. Available safety, immunogenicity, and reactogenicity data are similar to those seen in young adults aged 18-25 years. Syncope (fainting) may occur in association with any injectable vaccines, especially among adolescents. Procedures should be in place to prevent falling injuries (e.g., patients should be seated or lying down during administration and observation) and to manage syncopal reactions. All people are recommended to be observed for at least 15 minutes after vaccination (including COVID-19 vaccination). Unless they are clinical trial participants, children younger than 5 years of age are not eligible to receive the Pfizer-BioNTech COVID-19 vaccine at this time, and children and adolescents younger than age 18 years are not eligible to receive the Moderna or Janssen COVID-19 vaccines at this time.
20. **Patient Counseling:** The vaccine-specific Fact Sheet for Recipients and Caregivers must be provided to all vaccine recipients, parents or guardians, or caregivers (as applicable) before vaccination with any currently FDA-approved or FDA-authorized COVID-19 vaccine.
- a. **mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna):**



- i. Based on results from manufacturers' clinical trials, data suggest high vaccine efficacy in preventing symptomatic laboratory-confirmed COVID-19 following receipt of two doses of mRNA COVID-19 vaccine: Pfizer-BioNTech: 91.1% (95% CI: 88.8%, 93.1%) for people aged  $\geq 16$  years with approximately 6 months of follow-up and 100% (95% CI: 75.3%, 100%) for adolescents aged 12–15 years with 2 months of follow-up; and Moderna: 94.1% (95% CI: 89.3%, 96.8%) for people aged  $\geq 18$  years with 2 months of follow-up. Patients should be counseled on the importance of completing the 2-dose series with the same vaccine product to optimize protection. Data on real-world vaccine effectiveness with the Omicron variant (B.1.1.529) as the predominant circulating variant continues to be updated, with early data supporting continued high effectiveness against hospitalization and death.(61)
  - ii. Before vaccination, vaccination providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms.
  - iii. Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–2 days of onset. Overall, symptoms are more frequent and severe following the second dose and among younger people compared with older people (i.e., aged  $>55$  or  $\geq 65$  years [for Pfizer-BioNTech or Moderna vaccines, respectively]). People with prior SARS-CoV-2 infection may be more likely to experience symptoms such as fever, chills, and myalgia after the first mRNA COVID-19 vaccine dose. Unless people have a contraindication to vaccination, they should be encouraged to complete the series to optimize protection against COVID-19 even if they experience local or systemic symptoms following the first dose.
- b. Myocarditis and pericarditis:**
- i. In view of reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after receipt of mRNA COVID-19 vaccines, the fact sheets for the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine include information about myocarditis and pericarditis.(330-333) For each mRNA vaccine, the Fact Sheet for Recipients and Caregivers notes that myocarditis or pericarditis have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of myocarditis or pericarditis occurring after receipt of an mRNA COVID-19 vaccine is very low and can occur in patients with SARS-CoV-2 infection at higher rates than in those who received mRNA vaccines. People should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
    - Chest pain
    - Shortness of breath
    - Feelings of having a fast-beating, fluttering, or pounding heart
  - ii. After reviewing benefit-risk assessments for myocarditis and pericarditis after vaccination with mRNA COVID-19 vaccines, ACIP determined that the benefits of using mRNA COVID-19 vaccines clearly outweigh the risks of myocarditis and pericarditis. People receiving mRNA COVID-19 vaccines, especially males aged 12-29 years, should be made aware of both the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the possibility of myocarditis or pericarditis following SARS-CoV-2 infection, and should be counseled about the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. Clinicians should consult current clinical guidance for information on the evaluation and management of myocarditis or pericarditis.(150, 151, 341, 342)
- c. Viral vector COVID-19 vaccine (Janssen):(334)**
- i. Preliminary data from the manufacturer's clinical trial suggest an overall efficacy of 66.3% (95% CI: 59.9%, 71.8%) against symptomatic, laboratory-confirmed COVID-19 from  $\geq 14$  days after vaccination with Janssen COVID-19 vaccine in people aged  $\geq 18$  years. Vaccine efficacy for the prevention of COVID-19-associated hospitalization was high; vaccine efficacy against hospitalization

≥14 days after vaccination was 93.1% (95% CI: 71.1%, 98.4%). No COVID-19–associated hospitalizations occurred ≥28 days after vaccination in the vaccine group, and 16 occurred in the placebo group (vaccine efficacy = 100%; 95% CI = 74.3%, 100.0%). Vaccine efficacy against all-cause death was 75.0% (95% CI: 33.4%, 90.6%). Data on real-world vaccine effectiveness with the Omicron variant (B.1.1.529) as the predominant variant continue to be updated.

- ii. Before vaccination, vaccination providers should counsel Janssen COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Fifty percent of vaccinated people experience at least one local symptom, with pain at the injection site most common, and approximately 55% experience at least one systemic symptom following vaccination. Most systemic post-vaccination symptoms are mild to moderate in severity and resolve within 1–2 days post-vaccination. Overall, symptoms were more frequent in people aged 18–59 years compared to people aged ≥60 years.

**d. Thrombosis with thrombocytopenia syndrome:(334)**

- i. In view of reports of TTS after receipt of the Janssen COVID-19 vaccine, FDA updated the EUA fact sheets. The Fact Sheet for Recipients and Caregivers notes that blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets have occurred in some people who received the Janssen COVID-19 vaccine and that these symptoms began approximately 1–2 weeks following vaccination. Most people who developed these blood clots were women aged 18–49 years. Although the chances of this occurrence are remote, people should seek medical attention right away if they have any of the following symptoms after receiving the Janssen COVID-19 vaccine:
  - Shortness of breath
  - Chest pain
  - Leg swelling
  - Persistent abdominal pain
  - Severe or persistent headaches or blurred vision
  - Easy bruising or tiny blood spots under the skin beyond the site of the injection.
- ii. ACIP reviewed a risk-benefit assessment of TTS events after vaccination with the Janssen COVID-19 vaccine. Based on this risk-benefit analysis, ACIP reaffirmed its interim recommendation for the use of the Janssen COVID-19 vaccine in all persons aged ≥18 years, while still acknowledging the increased risk for TTS in women aged <50 years. These women should be made aware of the increased risk for TTS and the availability of other currently FDA-approved or FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines). Clinicians should consult the Health Alert Network (HAN) notification and guidance from the American Society of Hematology for information on the diagnosis and treatment of suspected cases of TTS.(343)

**e. Guillain-Barré Syndrome:**

- i. Reports of adverse events following use of the Janssen COVID-19 Vaccine under EUA suggest an increased risk of GBS during the 42 days following vaccination. The Fact Sheet for Recipients and Caregivers includes information about GBS (a neurological disorder in which the body’s immune system damages nerve cells, causing muscle weakness and sometimes paralysis) and notes that in most people symptoms began within 42 days following receipt of Janssen COVID-19 vaccine.

**21. Contraindications and precautions:**

- a. Contraindications and precautions to COVID-19 vaccines are described below and summarized in **Appendix V**. For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.
- b. Healthcare professionals in DoD can request a consultation from the Defense Health Agency-Immunization Healthcare Division about an individual MHS beneficiary for a complex COVID-19 vaccine safety question not readily addressed by CDC or DoD guidance. DHA-IHD clinicians can be reached by

- calling 1-877-438-8222 (option 1).
- c. **Contraindications:** CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:
- i. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
  - ii. Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine
  - iii. For the Janssen COVID 19 vaccine: TTS following receipt of a previous Janssen COVID-19 vaccine (or other adenovirus vector-based COVID-19 vaccine)
  - iv. See **Appendix W** for a list of ingredients in COVID-19 vaccines. Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of any mRNA COVID-19 vaccine. However, people with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa, provided certain measures are taken (see “Precautions” below). Known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, it is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.
  - v. Healthcare professionals should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of common reactions, such as a vasovagal reaction or post-vaccination side effects (**Appendix X**). This will help determine which patients have a true contraindication to subsequent vaccination.
- d. **Precautions:**
- i. Most people deemed to have a precaution to a COVID-19 vaccine at the time of their vaccination appointment can and should be administered vaccine. CDC considers a history of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”]) as a precaution but not a contraindication to vaccination. People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.
  - ii. People with a contraindication to one type of the currently FDA-approved or FDA-authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consider consultation with an Allergist-immunologist should be considered to help determine if the patient can safely receive COVID-19 vaccination. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.
    - People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 vaccine. People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 vaccine.
    - People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy): consideration may be given to mRNA COVID-19 vaccination (see “Contraindications”).
- e. **Neither contraindications nor precautions to COVID-19 vaccination:**

- i. Allergic reactions (including severe allergic reactions) not related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), are not a contraindication or precaution to COVID-19 vaccination. The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and COVID-19 vaccines do not contain eggs or gelatin, therefore people with allergies to these substances do not have a contraindication or precaution to vaccination.
- ii. Delayed-onset local reactions have been reported after mRNA vaccination in some individuals beginning a few days through the second week after the first dose and are sometimes quite large. People with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose do not have a contraindication or precaution to the second dose. These individuals should receive the second dose using the same vaccine product as the first dose at the recommended interval, preferably in the opposite arm.

## 22. Reporting of vaccine adverse events: (335)

- a. Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:
  - Vaccine administration errors
  - Serious adverse events
  - Cases of Multisystem Inflammatory Syndrome
  - Cases of COVID-19 that result in hospitalization or death

**Table 15. FDA approved and EUA COVID-19 Vaccine Overview (329)**

Vaccine manufacturer	Recipient Age (years)	Vial Cap Color	Dose	Injection volume	Number of doses in primary series (interval between doses)	Additional primary dose in immunocompromised people (interval since 2 <sup>nd</sup> dose)
Pfizer-BioNTech	5–11	Orange	10 µg	0.2 ml	2 (21 days)	1 (≥28 days)
Pfizer-BioNTech	≥12	Purple or Gray	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)
Moderna	≥18	Not applicable	100 µg	0.5 ml	2 (28 days)	1 (≥28 days)
Janssen	≥18	Not applicable	5×10 <sup>10</sup> viral particles	0.5 ml	1 (Not applicable)	Not applicable

**Table 16. COVID-19 Vaccines: Booster Dose by Primary Series (329)**

Vaccine used for Primary series	Authorized Age for Booster (years)	Interval between last primary dose (including additional dose, when applicable) and booster dose	Number of doses	Injection Volume and Product that may be given as Booster Dose*c
Pfizer-BioNTech	≥12	≥ 5 months	1	0.3 mL Pfizer-BioNTech*, or 0.25 mL Moderna, or 0.5 mL Janssen†
Moderna	≥18	≥ 5 months	1	0.25 mL Moderna, or 0.3 mL Pfizer-BioNTech, or 0.5 mL Janssen†
Janssen	≥18	≥ 2 months	1	0.5 mL Janssen†, or 0.3 mL Pfizer-BioNTech, or 0.25 mL Moderna

\* Only Pfizer BioNTech can be used as a booster dose in persons 12–17 years of age.

† Use of an mRNA vaccine for a booster dose is preferred over Janssen vaccine.

## DOD COVID-19 VACCINE IMPLEMENTATION

1. **Overview:** The U.S. Department of Defense (DoD) remains committed to protecting its service members, civilian employees, and families around the globe; safeguarding its national security capabilities; and supporting the whole-of nation, while responding to the Coronavirus Disease 2019 (COVID-19) pandemic.

Since March 2020, the DoD has diligently worked closely with the Department of Health and Human Services (HHS), the State Department, and other public and private sector partners to develop a comprehensive plan for the rapid distribution of safe, effective vaccines and therapeutics against COVID-19. As a product of these efforts, the DoD has established a deliberate, data-driven, phased approach to distribute and administer the COVID-19 vaccine to individuals authorized to receive COVID-19 vaccines from the DoD. Specific deadlines for vaccination of Service Members, Federal Contractors, and Federal Employees is in **Table 17** below. **Table 18** provides a list of key vaccine resources. Following [CDC Coronavirus Guidance](#), DOD will continue to adjust health protection protocols to the local conditions of the communities in which we serve. The Department's priorities include:

- Protecting our Service members, DOD civilians, and families
  - Safeguarding our national security capabilities
  - Supporting the whole-of-nation response to the COVID-19 pandemic
2. **Background:** Beginning in May 2020, the Defense Health Agency (DHA) Immunization Healthcare Division (IHD) facilitated weekly meetings with clinical and logistical subject matter experts (SME) and other representatives across the DoD, Centers for Disease Control and Prevention (CDC), and the initial federal COVID-19 vaccination strategy, "Operation Warp Speed" (now "the federal response"), to begin planning DoD's COVID-19 vaccine implementation approach. In anticipation that the U.S. FDA would authorize the emergency use of at least one COVID-19 vaccine by the end of 2020, DoD's COVID-19 Vaccine Distribution (CVD) Operational Planning Team (OPT) was officially stood up in November 2020. The Director, Defense Health Agency (DHA) leads DoD's CVD OPT, tasked by the Secretary of Defense (SecDef) to synchronize acquisition, distribution, resource requirements, training, administration, reporting, internal/external communications, and other topics as required to manage DoD's COVID-19 vaccine allocation. The DoD COVID-19 Vaccine Task Force (CVTF) provides oversight to the OPT, ensuring that COVID-19-related plans, policies, and products align with DoD's guidance.
  3. **COVID-19 Vaccine Requirements for Uniformed Service Members:** On August 24, 2021, the Secretary of Defense signed a Memorandum requiring the mandatory vaccination of all service members with an FDA approved COVID-19 vaccine to protect the Force and defend the American people by mitigating the risk posed by COVID-19. Service members with previous COVID-19 infection are not considered to be fully vaccinated. Service members who voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated.
  4. **COVID-19 Vaccine Requirements for Federal Contractors:** On September 9, 2021, President Biden signed Executive Order (EO) 14042, entitled, Ensuring Adequate COVID Safety Protocols for Federal Contractors. The order directs executive departments and agencies to ensure that contracts and contract-like instruments covered by the order include a clause requiring the contractor—and their subcontractors at any tier—to, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Task Force. These workplace safety protocols will apply to all covered contractor employees, including employees in covered contractor workplaces who are not working on a Federal Government contract or contract-like instrument. Federal Acquisition Regulation (FAR) Council issued guidance for the implementation of EO 14042 on 30 September, 2021 and requires all covered contractor employees to be fully vaccinated for COVID-19 by December 8, 2021, except in limited circumstances where an employee is legally entitled to an accommodation.(345, 346)
  5. **COVID-19 Vaccine Requirements for Federal Employees:** On September 9, 2021, President Biden signed Executive Order (EO) 14043, entitled, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. The EO states, "[i]n order to promote the health and safety of the workforce and the efficiency of the civil service, it is necessary to require COVID-19 vaccination for Federal employees by November 22, 2021, subject only to such exceptions as required by law." Subsequent to the EO the Deputy Secretary of Defense issued guidance on the mandatory vaccination of Department of Defense (DoD) civilian employees requiring all DoD civilian employees to be fully vaccinated by November 22, 2021, subject to exemptions as required by law.(347)



6. **Exemptions from COVID-19 vaccination requirements:** There are two types of immunization exemptions: medical and administrative. All exemptions must be documented in the individual's electronic health record (EHR) and appropriate service-specific immunization tracking system (ITS).
  - a. *Medical exemption:* Determined by a health care provider based on the current health of the vaccine candidate and the COVID-19 vaccine being considered.
    - i. *Administrative exemption:* this includes exemptions for separation or retirement, religious, permanent change of station, emergency leave, missing or prisoner of war, deceased, and other categories. Requirements for granting administrative exemptions may be found in the [Joint Regulation](#), and are outside the scope of this document.
  - b. *Service-specific guidance:* Each service has specific guidance on the processing of immunization exemptions: please refer to your respective service guidance for details. Links to available service-specific guidance can be found at the [DHA COVID-19 Vaccine Resources Library](#).
7. **DoD's COVID-19 Vaccination Status:** All DoD immunization sites have access to FDA-authorized COVID-19 vaccines. As of 19 January 2022, more 1,614,069 service-members of the Active Duty, Reserve, and National Guard have been vaccinated. As of the end of Dec 2021, Over 98% of the active duty military is at least partially vaccinated against COVID-19.

**Table 17. Specific Deadlines for COVID-19 Vaccination by Service/Position**

Service/Position	Deadline to be Fully Vaccinated
Army Active Duty	15-Dec-21
Army Reserves/Army Reserves National Guard	30-Jun-22
Air Force Active Duty	2-Nov-21
Air Force Reserves/Air National Guard	2-Dec-21
Navy/Marine Corps Active Duty	28-Nov-21
Navy/Marine Corps Reserves	28-Dec-21
Federal Employees	22-Nov-21
Federal Contractors	8-Dec-21

Table 18. Key COVID-19 Vaccine Resources

Resource	Overview
<a href="#">DoD COVID-19 Vaccine Plan and Modifications</a>	CAC-enabled platform to access DoD's COVID-19 Vaccine Plan, outlining DoD's integrated global response to distribute and administer COVID-19 vaccinations, and subsequent modifications to the plan.
DHA Interim Procedures Memorandum (IPM 20-004), " <a href="#">Department of Defense (DoD) Coronavirus Disease 2019 (COVID-19) Vaccination Program Implementation</a> ," May 06, 2021	Establishes DHA's procedures and responsibilities for DoD's COVID-19 Vaccination Program, including guidance on the authorized use of COVID-19 vaccines, distribution and cold chain management, vaccine administration, adverse event reporting, and documentation.
<a href="#">DoD's COVID-19 Guidance</a>	Provides information and resources on a variety of coronavirus-related subjects for members of the DOD community and the general public.
<a href="#">DoD Vaccine Resource Center</a>	CAC-enabled platform that provides critical immunization policies, procedures, and guidance essential to information awareness, safety, and readiness of U.S. Forces as it pertains to the COVID-19 vaccine and to guide DoD facilities in daily clinical and immunization operations.
<a href="#">Military Health System COVID-19 Information Center</a>	Provides the most up-to-date information regarding the COVID-19 pandemic, including DoD and Health Affairs Resources, DHA Resources, and Training Resources for Providers.
<a href="#">Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States</a>	Provides CDC's clinical considerations for the COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines).
<a href="#">U.S. COVID-19 Vaccine Product Information</a>	Provides information and materials regarding the administration, storage and handling, safety, and reporting of COVID-19 vaccines.

## WHOLE OF GOVERNMENT RESPONSE IN COORDINATION OF RESOURCES

On 13 Mar 2020, President Trump declared a nationwide emergency under Sec. 501(b) of the Stafford Act, increasing support to HHS in this role as the lead federal agency for the federal government's response to the COVID-19 pandemic. Under this declaration, FEMA, in coordination with HHS, was empowered to assist state, local, tribal, territorial governments and other eligible entities to access resources made available through the Stafford Act.

HHS has many resources to leverage in the federal response to COVID-19, including the Strategic National Stockpile (SNS). The SNS has ventilators, medications, personal protective equipment and other important equipment and supplies that may be requested for COVID-19 response where state and local resources are overwhelmed or anticipated to be overwhelmed. SNS depots are located around the country by region. There is a Defense Coordinator at regional FEMA offices to coordinate requests to/from civilian and military hospitals and other entities for resources. MTFs can identify anticipated shortages and push a request through their local unit Crisis Action Team to the Regional FEMA Defense Coordinator for items in the SNS. It is recommended that facilities leverage available resources before running out of critical items such as PPE.

HHS link to Resources: <https://www.phe.gov/emergency/Tools/Pages/default.aspx>

HHS Regional Emergency Coordinators Contact List:

<https://www.phe.gov/Preparedness/responders/rec/Pages/default.aspx>

State FEMA Office contacts: <https://www.fema.gov/emergency-management-agencies>

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## ETHICAL CONSIDERATIONS DURING THE COVID-19 PANDEMIC

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Preparation and consideration of the myriad bioethics issues that surround the COVID-19 Pandemic is critical for all MHS health care professionals and medical facility leaders. Both the clinical outcomes of the MHS patients and the health/moral well-being of the MHS health care professionals are directly dependent upon the informed consideration and evaluation of these dilemmas. In response, the DoD Medical Ethics Center (DMEC) has created an array of resource materials addressing the various Bioethics contingencies involved in a pandemic. Those materials and other resources (consolidated on the DMEC Website below) offer guidance, but they are not directive, nor do they mandate a specific approach when faced with a particular issue. The guidance and recommendations contained therein need to be operationalized in concert with both the local medical facility leadership, and local legal advisor, in order to ensure overarching appropriateness in both domains. Finally, DMEC Personnel stand ready to help should MHS health care professionals require any direct assistance on specific case considerations.

DMEC Website: <https://www.usuhs.edu/dmec>

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## OTHER CONSIDERATIONS RELATED TO COVID-19

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### Facilities

Medical Heating, Ventilation and Air Conditioning (HVAC) Systems:

1. DHA Facilities Enterprise recommends maintaining building ventilation systems in balance and compliant. Attempts to adjust without professional mechanical engineering support may cause harm and rework later.
2. Medical facilities (hospitals/clinics) or administrative facilities are recommended not to alter the HVAC system operations or filtration in any way due to the outbreak of COVID-19.
3. Building maintenance personnel should not be exposed to COVID-19 unless they are physically in the same room as an infected person or come in contact with surfaces that have not been disinfected (such as air filters). No special COVID-19 PPE is required for maintenance personnel unless they are charged with disinfecting surfaces or working where infected persons may have deposited live virus. In those cases, the maintenance personnel should follow CDC guidelines.
4. Although it is not known exactly how long the virus can survive on a surface outside the human carrier, some reports suggest up to 4 days on some materials.
5. If a maintenance worker becomes infected with COVID-19, it is recommended to clean all surfaces the worker may have been in contact with for the past 7 days. A review of all work orders completed by the infected maintenance staff will aid in discovering where and when the employee contacted other surfaces.
6. DHA Facilities Enterprise does NOT recommend increasing filter media such as changing Minimum Efficiency Reporting Value (MERV) rated filters to High Efficiency Particulate Air (HEPA) if it is being done purely in hope of stopping the spread of COVID-19. MTFs should not add higher rated filters to existing HVAC systems without proper engineering management since the HVAC system may become imbalanced which could result in loss of isolation rooms. Care must be taken not to exceed the design performance of the HVAC as it will likely reduce equipment life with little or no positive impact.
7. The use of Ultraviolet (UV) lights in the HVAC system (e.g., AHU or ductwork) is not recommended for COVID mitigation.
8. The use of mobile or fixed air scrubber with integral HEPA or Ultra-Low Particulate Air (ULPA) filter may be used to increase the air changes in a room. Air scrubbers when used to create negative pressure rooms must be cautious in discharging exhaust air to the outside of the building or into the return air system. Coordination with Facilities Management, a professional mechanical engineer, Industrial Hygiene and Infection Control team to ensure virus exposures are minimized and tested prior to room use.
9. There are many new and evolving technologies coming out of industry today as a result of the COVID pandemic that claim to have outstanding results in mitigating COVID-19 viruses. Many of these systems are either experimental or have not been proven in the healthcare setting. DHA FE cannot advocate the use of these systems at this time. Should a MTF want to install a new technology, we recommend a multi-

discipline support team with engineers, infection control, and industrial hygiene practitioners to review and validate the product before purchasing to ensure it meets the building's requirements, is maintainable, and can produce the desired mitigation for the MTF.

10. When installing Plexiglas sneeze guards/barriers at reception desk or pharmacy window areas, the MTF should consider which ones should be permanently installed while other may be temporarily installed. Those reception areas with high volume should be more durable in construction while the low volume may be temporary. Also consider the choice of barrier material that is easily cleaned.
11. Due to dental procedures being high aerosolizing, it is recommend to use a room with a door and an air scrubber to create an Airborne Infection Isolation Room (AIIR) with negative pressure in relation to the corridor and 12+ air changes per hour when treating suspected or infected COVID-19 patients. The dwell time between COVID-19 patients is 35 minutes followed by terminal cleaning. The air scrubbers may be either ceiling mount or floor mount and connected to the existing return air system or exhausted to the building's exterior. If there is no door to the dental operatory, it is recommended to install a door or create a temporary door with a flame retardant plastic or magnetic door. Dental staff should work directly with their local Facilities Manager, Safety Office, Infection Control staff, host installation Fire Department, Industrial Hygiene/Bioengineering staff to ensure a negative pressure condition is created for the room before starting treatment and ensure all safety issues are resolved. Equipment maintenance and PPE requirements are at the ASHRAE website: <https://www.ashrae.org/technical-resources/healthcare>. For Dental Pilot information briefings and Pilot Dental Airborne Infectious Isolation Room Template Plans: <https://community.max.gov/display/DoDExternal/COVID+19+Data+Landing+Page>. For facilities question, contact the DHA FE Facilities Operations Emailbox at [dha.ncr.j-1-8.list.fe-facility-ops-br-owners@mail.mil](mailto:dha.ncr.j-1-8.list.fe-facility-ops-br-owners@mail.mil) for additional support.
12. MTFs should follow their Joint Commission required Water Management Plans for reopening their closed facilities to ensure opened facilities are safe to include eye wash stations, cooling towers, hot and cold domestic water systems and water heaters. The CDC has information on reopening closed facilities to include the stagnant water, mold and other issues, available at: [https://www.cdc.gov/coronavirus/2019-ncov/php/building-water-system.html?deliveryName=USCDC\\_248\\_DM25447](https://www.cdc.gov/coronavirus/2019-ncov/php/building-water-system.html?deliveryName=USCDC_248_DM25447).

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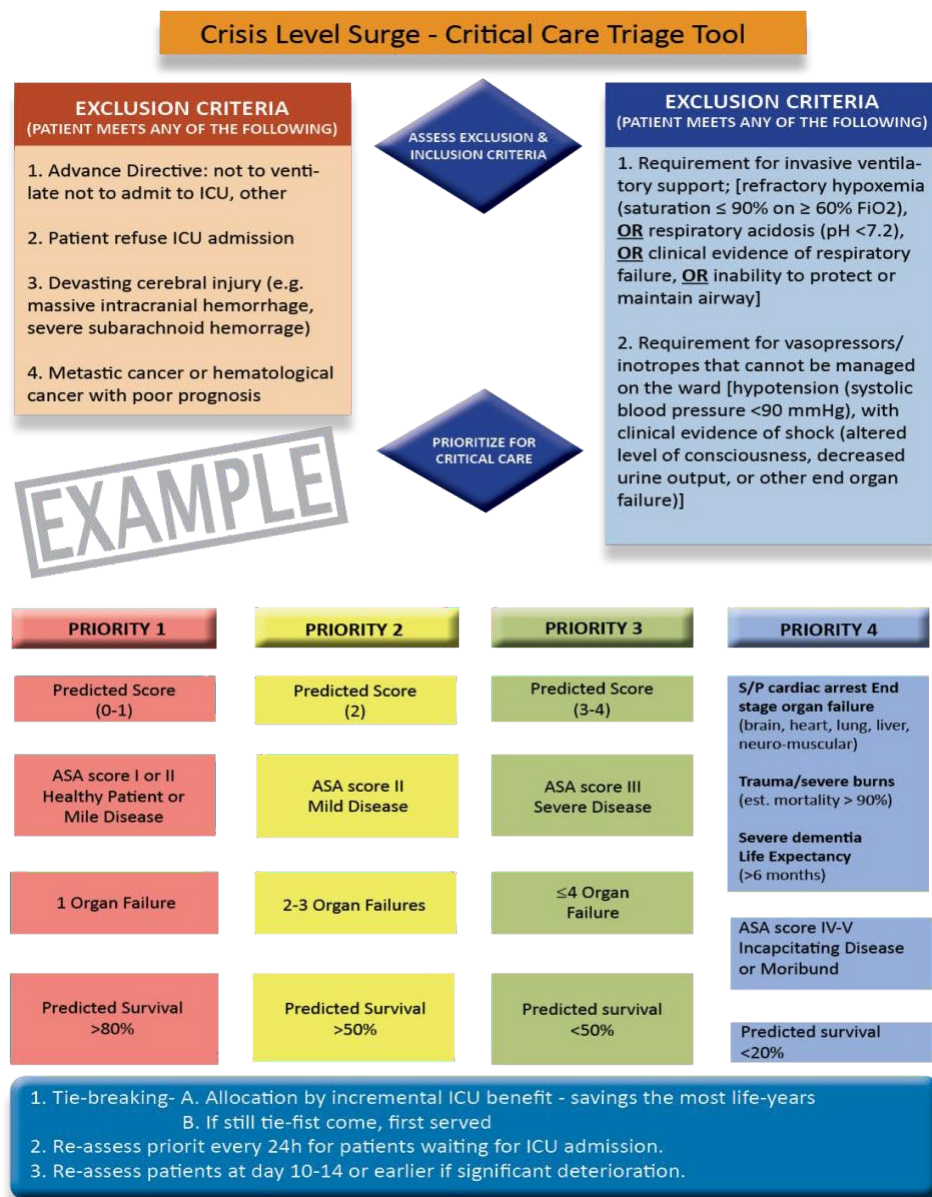


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## APPENDIX A: CRISIS LEVEL SURGE – CRITICAL CARE TRIAGE TOOL EXAMPLE

The MHS has among its duties to "create and maintain high morale in the uniformed services by providing an improved and uniform program of medical and dental care for members and certain former members of those services, and for their dependents." 10 U.S.C. 1071. DoDI 6025.27, 'Medical Ethics in the Military Health System' addresses the principles of medical ethics within the MHS. Of note, members of the MHS should regard responsibility to the patient as a primary responsibility, but recognize there may be extraordinary circumstances associated with the mission or military necessity that may require additional considerations and ethical consultation. DoD has been able to meet health care demands for its COVID-19 patients. We are aware, however, that this guide has been useful to providers outside the MHS and have received requests for our guidance in extraordinary circumstances. To that end, we offer the following critical care triage tool sample. Also, if an MTF implements this practice from Appendix A, please notify your higher headquarters.



**Figure A-1: Crisis Level Surge – Critical Care Triage Tool**

\*Performance status utilizes Eastern Cooperative Oncology Group Performance Score ECOG (0: Totally normal; 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work; 2: Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours; 3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours; 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair; 5: Dead). [<https://ecog-acrin.org/resources/ecog-performance-status>]

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**APPENDIX B: CRISIS LEVEL SURGE – COMPOSITION AND ROLES OF THE TRIAGE TEAM**


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TRIAGE PLANNING COMMITTEE	
<b><u>Members (Minimum)</u></b> 2 Senior Clinicians Senior Nursing Representative Ethics Representative Community Member Pastoral Care Palliative Care (as available)	<b><u>Roles</u></b> <ul style="list-style-type: none"> <li>- Planning for the greatest medical benefit to greatest number of people               <ul style="list-style-type: none"> <li>- Establish SOPs for conventional, contingency and crisis capacity</li> <li>- Provide oversight support of scarce resource allocation decisions</li> </ul> </li> <li>- Maintain available representative 24/7 to triage teams and command</li> <li>- Seek opportunities for regionalization of resources as permissible</li> </ul>
TRIAGE TEAM	
<b><u>Members</u></b> Triage Officer (Senior Clinician) Acute Care Nurse Administrative Staff Member Ethics Representative (as available) Community Member (as available)	<b><u>Roles</u></b> <ul style="list-style-type: none"> <li>- Liaison with command and planning committee on resources (ICU beds, staffing, equipment)               <ul style="list-style-type: none"> <li>- Initial contact with clinical teams for assessment of priority scoring</li> <li>- Collect only information relevant to priority scoring and maintain database</li> <li>- Make urgent allocation decisions within 90 minutes of clinical team request                   <ul style="list-style-type: none"> <li>- Meet twice daily to match resources to patient needs and</li> <li>- Reassess patients every 72 hours (Minimum)</li> </ul> </li> </ul> </li> <li>- Report conflicts or requests for appeal/oversight to Planning Committee representative</li> </ul>

**Figure B-1: Crisis Level Surge – Composition and Roles of the Triage Team**

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**APPENDIX C: INFECTION PREVENTION AND CONTROL RELEVANT RESOURCES AND DOCUMENTS**

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**Standard Precautions**

**FOR THE CARE OF ALL PATIENTS**

Includes Blood, Body Fluids, Secretions, Excretions, and Contaminated Items

Wash hands BEFORE and AFTER patient care regardless of whether gloves are worn. - Wash hands immediately after gloves are removed and between patient contacts.
Wear gloves when touching blood, body fluids, secretions, excretions, and contaminated items. - Put on clean gloves just before touching mucous membranes and non-intact skin.
Wear mask and eye protection or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures and patient care activities that are likely to generate splashes or sprays of blood/body fluids.
Wear gown to protect skin and prevent soiling of clothing during procedures and patient care activities that are likely to generate splashes or sprays of blood & body fluids. Remove soiled gown as promptly as possible and wash hands.
Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles.
Use mouthpieces, resuscitation bags, or other ventilation devices as an alternative to mouth-to-mouth resuscitation.
Cover your cough and sneeze with tissues or cough and sneeze into your sleeve.
Avoid touching your face (eyes, nose and mouth) with unclean hands.
Clean and disinfect shared patient equipment.
Use aseptic technique.



## POWERED AIR PURIFYING RESPIRATORS (PAPRs): April 2020

**NOTE:** This document was adapted from UNMC - Nebraska Medicine COVID-19 PPE Guidance for Extended Use and Limited Reuse of Disposable Facemasks, Respirators and Protective Eyewear.

**Introduction:** PAPRs are reusable respirators that are loose-fitting hoods or helmets. Caution should be applied with use of PAPRs in surgical settings due to concerns that the blower exhaust and exhaled air may contaminate the sterile field. The FDA issued an update Mar 2020 to address NIOSH-approved air purifying respirators for use in health care settings during the COVID-19 emergency available for review at the following link: <https://www.fda.gov/media/135763/download>. Facilities using elastomeric respirators and PAPRs are required to have up-to-date cleaning and disinfection procedures to facilitate protection against infectious agents.

**Recommendations:** This document provides an overview of current industry recommendations for consideration. Such recommendations are not all-inclusive, and decision-making must address the unique readiness challenges and concerns faced at each individual facility.

1. Staff are required to receive training on correct use of PAPRs.
  - a. Training ensures HCPs are knowledgeable and proficient in the donning and doffing of PAPR and other PPE prior to engaging in patient care. In addition, during practice, HCPs and their trainers will assess their proficiency and comfort with performing required duties while wearing PAPR and other PPE.
2. A trained observer is required.
  - a. The observer should be a dedicated and knowledgeable individual with the responsibility of ensuring adherence to the entire donning and doffing process, including disposal of used PPE. The sequence and actions involved in each donning and doffing step are critical, therefore a trained observer must read aloud to the HCP each step in the procedure checklist and visually confirm, document that the step has been completed correctly, and provide immediate corrective instruction if the HCP is not following the recommended steps.
3. The following supplies are gathered in preparation for PAPR use:
  - a. One pair of extended cuff gloves (two pairs if practicing double gloving technique)
  - b. One long-sleeve gown
  - c. One PAPR\*
  - d. One PAPR hood
  - e. One airflow indicator

\*Note: The PAPR must be inspected and a function check completed in accordance with the manufacturer's instructions for use. DO NOT USE and remove from service if airflow does not reach six cubic feet/minute (CFM). Change the filters and repeat the function test. If after changing filter the function test fails, take out of service.

4. PPE must remain in place and worn correctly for the duration of exposure to potentially contaminated areas. Avoid adjusting PPE during patient care. If PAPR malfunctions during patient care, the HCP must move immediately to the doffing area to assess the situation.

### **Donning PAPR Equipment**

1. Healthcare facilities that decide to add additional PPE or modify this PPE guidance, must consider the risk versus benefit of any modification, and train HCPs on modified donning and doffing procedures.
2. The practice of double-gloving provides an extra layer of safety during direct patient care and during the PPE removal process, however more than two pairs of gloves can make it more difficult to perform patient care duties.
3. PAPR and all other PPE must be donned correctly in proper order before entry into the patient care area. Donning activities must be directly observed by a trained observer. The following steps for donning must be followed:
  - a. Perform hand hygiene
  - b. Don PAPR

- i. Don PAPR belt with assistance
- ii. Position PAPR around waist
- iii. Fold/tuck extra belt webbing into belt
- iv. Test range of motion
- v. Power ON PAPR motor
- c. Don PAPR hood assembly
- d. Place hood on head. Ensure hood fits comfortably and is positioned properly
- e. Don surgical gown & secure gown over the hood shroud and hose (if possible), secure both neck & waist ties
- f. Don extended cuff gloves over gown wrist cuff (if desired, may use second pair of gloves)
- g. Check range of motion
- h. Donning partner will inspect member for defects in PPE. Pay close attention to gown/glove junction

### **Doffing PAPR Equipment**

1. Appropriate PAPR doffing procedures must be followed. All PPE must be removed slowly and deliberately in the correct sequence. Anytime a PAPR is used, a process checklist with a designated trained observer is required.
2. The following steps must be followed for doffing:
  - a. Doffing will begin in the patient's room. Doffing partner will be prepared to assist outside patient's room by performing hand hygiene and donning the surgical mask and gloves. Doffing partner will prepare the area outside the room, and gather the following supplies:
    - i. Intravenous (IV) Pole
    - ii. Disinfectant wipes
    - iii. Biohazard bags
    - iv. Plastic bag
  - b. HCP performs hand hygiene over gloves
  - c. Gown is removed by pulling away from the shoulders, taking care to avoid jerking motion; may remove gloves in conjunction with the gown (if using the double-gloving technique, remove outer pair of gloves prior to removing gown)
  - d. If gloves are still on, remove gloves using the "glove in glove" technique
  - e. Perform hand hygiene
  - f. HCP will leave the patient's room
  - g. Keeping the blower motor ON, HCP will disconnect belt, and hand it to the doffing partner
  - h. Doffing partner will hang belt on the IV pole
  - i. HCP completes hand hygiene
  - j. Doffing partner thoroughly disinfects PAPR hose and motor using approved disinfectant wipe
  - k. Doffing Partner will tell HCP that the hose will be disconnected from PAPR motor
  - l. Doffing partner will hold the hose and instruct HCP to lean forward and remove the hood
    - i. HCP will reach under the sides of the hood and carefully remove the hood over and off head
    - ii. Alternative method: HCP will pinch the crown of the hood and carefully pull the hood over and off head
  - m. Doffing partner will place the hood and hose into plastic bag. \*Note: the hood may be reused if supplies are low
  - n. HCP will complete hand hygiene and exit the area
  - o. Doffing partner will perform hand hygiene
3. Appropriate steps for doffing area cleanup must be performed as follows by doffing partner:
  - a. Dons new pair of gloves
  - b. Disinfects high-touch surfaces
  - c. Disinfects the IV pole
  - d. Place PAPR in biohazard bag and stores in designated area

- e. Remove regulated medical waste (RMW) bags from waste receptacles
  - i. Secure bags with tape
  - ii. Do not express any trapped air from the bag
  - iii. Place bags in the designated area/soiled utility room
  - iv. Perform hand hygiene
  - v. Replace red bag
  - vi. Perform hand hygiene
- 4. Steps for disinfection and storage of PAPR components including hood for re-use:
  - a. Perform hand hygiene
  - b. Don gloves and a procedure mask, and carry the PAPR to the PAPR processing area without allowing it to come in contact with clothing or skin
  - c. Visually inspect the PAPR hood for contamination; discard and do not re-use if visibly contaminated
    - i. If visible contamination is not observed and PAPR will be reused during the shift, do not disconnect any of the PAPR components
    - ii. Do not remove the PAPR filters from the motor unless flow test fails
  - d. Disinfect the PAPR motor, belt, hose and hood using Environmental Protection Agency (EPA) approved disinfectant wipes, while observing contact time
  - e. Disinfect in the following order (using a new wipe for each component):
    - i. PAPR motor and filters (avoid introducing liquid into the filter holes)
    - ii. Belt
    - iii. Tubing sleeve
    - iv. Hood (wipe the hood inside, then the outside)
  - f. Once completely dry, place the PAPR in a clean area
  - g. Ensure battery is charged or place on charger in accordance with the manufacturer instructions for use (IFU)
- 5. Steps for terminal disinfection and storage of used PAPR components:
  - a. Follow the above procedure for cleaning and disinfecting PAPR with the following additional steps:
    - i. Disconnect PAPR belt to disinfect separately and reattach to PAPR motor when dry
    - ii. Disconnect and dispose of PAPR hood
    - iii. Return PAPR motor with filters, belt, and tubing attached to unit storage area
    - iv. Plug in PAPR motor to recharge battery in accordance with manufacturer IFU

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## MTF/DTF *Legionella* & Other Waterborne Pathogen Risk Mitigation

### **Situation and Background**

Concerns have been raised regarding an increased risk for the bacterium *Legionella pneumophila* and other waterborne pathogens as a result of facility/unit closure throughout the SARS-CoV-2 pandemic. In persons at risk for infection (e.g., individuals who are over 50 years of age, are smokers, immunocompromised, or have underlying medical conditions), this bacterium can lead to a life-threatening pneumonia, called Legionnaires' disease. It is particularly important to note that *Legionella* infection can oftentimes mimic SARS-CoV-2 presentation. Outbreaks are linked to poorly maintained building water systems, especially those that are extensive or complex. Even in the setting of a long-term disinfection program, outbreaks of *Legionella* were noted. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and water fountains.

Throughout the SARS-CoV-2 pandemic, many facility units/areas were either closed or experienced reduced operations. In some instances, water was completely shut off (e.g., water fountains). Such closures and interruptions in normal operations have created an ecosystem that supports the growth of *Legionella* and other waterborne pathogens. It is therefore important to implement strategies to prevent healthcare-associated infections prior to reopening units, bringing employees back from telework, and/or turning on water fountains. In order to appropriately mitigate the risk for opportunistic infections, Military Medical Treatment Facilities (MTFs) must develop and adhere to policies and procedures that inhibit microbial growth and spread of *Legionella* and other waterborne pathogens in building water systems.<sup>1</sup>

Dental Treatment Facilities (DTFs) will continue to follow respective inspection/accreditation requirements, and/or national guidelines (The Joint Commission [TJC], CDC, Occupational Safety and Health Administration [OSHA], American Dental Association [ADA]) and DoD and service branch-specific regulations and policies for dental water lines.

### **Assessment**

TJC maintains standards requiring facilities to protect the health and safety of patients through establishment of a water management program that reduces the risk of growth and spread of *Legionella* and other opportunistic pathogens in facility water systems. TJC evaluates evidence of compliance with the following key elements:

- Completion of a facility risk assessment to identify where *Legionella* and other opportunistic waterborne pathogens could grow;
- Development and implementation of a water management program with corresponding testing protocols; and
- Establishment of testing protocols and acceptable ranges for control measures.<sup>2–3</sup>

Although TJC recommends establishment of testing protocols and acceptable ranges for control measures, more recent information is showing that interpretative results from *Legionella* cultures are variable. As a result, the Centers for Disease Control and Prevention (CDC) discourages the use of thresholds using colony forming units (CFU)/mL. Until more precise tests are available, any detectable level at a single site should be considered a hazard.

Facilities should follow the most current CDC Guidelines at the following link:

<https://www.cdc.gov/legionella/wmp/index.html>

### **Recommendation**

As considerations are made regarding reopening of facilities and units previously closed during the SARS-CoV-2 pandemic, leadership must ensure that a comprehensive water management program addressing safety concerns related to disruption in water flow are in place, and fully implemented.

As units begin to reopen, a multidisciplinary team to ensure proper implementation of the water management program is essential. At minimum, this team should include the following representatives: Preventive Medicine, Infection Prevention and Control, Facilities Management, Department of Medicine or Infectious Disease Physician (as applicable to in-patient facilities), Division of Nursing, Industrial Hygiene, Clinical Laboratory (Microbiology), and contracted subject matter experts. Primary responsibilities of this team must include, but are not limited to, the following:

1. Reviewing the facility's water management plan and implementing strategies to mitigate risks prior to turning on water systems where a disruption in flow occurred.  
This applies both to areas completely shut down, and those where a significant reduction in water use was noted.
2. Performing a risk assessment prior to opening areas or turning on water systems (e.g., water fountains).  
The risk assessment must take into account water temperatures, pH levels, and chlorine concentration following water disruptions.
3. Monitoring microbiological data as the systems are returned to normal operation.
4. Reporting cases of suspected and confirmed hospital-associated *Legionella* transmission (includes patients and staff).
5. Implementing water testing/treatment protocols as described in the facility's water management plan.

During the SARS-CoV-2 crisis, clinicians have maintained a high degree of suspicion for SARS-CoV-2 in patients presenting with respiratory illnesses. However, clinicians should also test patients with healthcare-associated pneumonia for Legionnaires' disease as described in the CDC toolkit. This is especially important in circumstances where Legionella growth risk factors are/may have been present (e.g., areas where water stagnation may have occurred). The preferred diagnostic tests for Legionnaires' disease include cultures of lower respiratory secretions on selective media and the Legionella urinary antigen test.

Facilities should utilize the CDC's comprehensive toolkit referenced in this document to ensure their water management program appropriately incorporates all industry recommended Legionella and other waterborne pathogen prevention strategies. Lastly, facilities must ensure their water management program is properly aligned with current TJC standards to effectively protect the safety and health of those in the facility, as well as to avoid adverse accreditation action.

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## **COVID–19 Recovery Plan: Guidance for IPC Programs**

### **Introduction**

As with any crisis situation, Military Medical and Dental Treatment Facilities (MTFs/DTFs) will need to take a strategic approach to optimize efficiency in recovery from the COVID–19 pandemic. Infection Prevention and Control (IPC) Programs at the MTF/DTF level face unique challenges, and the guidance provided within this document is intended to facilitate a coordinated approach to integration of best practices in alignment with current Centers for Disease Control and Prevention (CDC) and other evidence–based guidelines and standards.

### **Recommendations**

Infection Preventionists (IPs) must work closely with multidisciplinary team members, leadership, and logistics to optimize recovery efforts and ensure a comprehensive strategy remains in place. This document provides a high–level overview of recommendations for the following topics, as they relate to preparation for return of operations with pandemic resolution:

1. General IPC Program Preparation
2. Administrative Controls
3. Environment of Care
4. Water Plans
5. Personal Protective Equipment (PPE)
6. Additional IPC Considerations

Understanding that identified needs and existing resources are unique to each facility, the recommendations provided in this document are intended to serve as a guide, and are not an all–inclusive list of necessary actions.

### **General IPC Program Preparation**

1. A comprehensive IPC Risk Assessment for each facility must be performed based on review of national, state, and local COVID–19 specific epidemiology. As leaders make decisions to resume patient care services, it is important that IPC guidance is provided to prevent and/or mitigate potential harm to patients and health care employees.
2. In collaboration with the IPC committee and senior leadership, IPs should develop an IPC plan for de-escalation that addresses cleaning of patient care areas, equipment, and other environment of care requirements prior to re-opening clinical spaces. IPs should consider using a checklist similar to one that is used when reopening areas after a major renovation project. Additionally, the Patient Safety Checklist from the Defense Health Agency Memorandum “COVID-19 Guidance for Resuming Full Healthcare Operations” signed by RADM Riggs May 2020.
3. Basic IPC education should resume. Training on donning and doffing of PPE should become a routine requirement to prepare for a potential surge or other emerging disease. Additional information regarding PPE is available at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>
4. Facilities must continue to follow the most up to date guidance from the CDC regarding management of known or suspected cases of COVID–19.
5. Health care personnel must continue to assess potential risks of exposure during patient encounters, as well as ensure safe work practices, administrative, and engineering controls are in place in alignment with current guidelines and standards of practice.
6. IPC policies should be flexible, allowing for updates to be made based on new CDC and DHA guidance regarding universal source control.
7. If patient care items are reused between patients, health care workers must follow manufacturer’s instructions for use (IFUs) and adhere to guidelines for cleaning and disinfection.
8. As COVID-19 patient care units are no longer required, IPC plans must address optimal patient placement of known or suspected cases within a facility. If admitted, place a patient with known or suspected COVID-19 in a single-person room with the door closed. The patient should have a dedicated bathroom. Airborne Infection Isolation Rooms (AIIRs) should be reserved for patients who will be undergoing AGPs.

### **Administrative Controls**

1. Administrative controls are defined as changes in policy or procedures to reduce and/or minimize exposure to infectious diseases.
2. Facilities must maintain heightened awareness in triaging/assessing patients and staff for potential COVID-19 related symptoms. Leadership must also consider how to implement measures to mitigate risk of disease transmission while returning to normal operations.
3. Disease-specific clearance requirements for return to work must be established by occupational health and implemented based on CDC guidelines. Also, a process for documenting clearance results for both staff and patients must be in place.
4. Sick employees must be encouraged to remain home.
5. Leadership should consider establishing alternating days or extra shifts that reduce the total number of employees in a facility at a given time, allowing them to maintain distance from one another while maintaining a full work week during the ongoing COVID-19 pandemic.
6. All facilities should consider the implementation of a visitation policy that is in alignment with processes established for screening patients and staff.

### **Environment of Care**

#### *Facility Considerations*

IPs, in collaboration with Facilities Management and first-line leadership (e.g., C-suite) maintain responsibility for the following:

1. continue to screen IAW OSHA emergency temporary standard all patients for symptoms of COVID-19 (including temperature checks). As stated previously, all staff, patients, and visitors should continue to be routinely screened.
2. Considering areas for non-COVID care (i.e., separate building, designated rooms, or floor with a separate entrance and minimal crossover with COVID-19 areas). The use of segregated hallways/paths for transport of COVID-19 positive patients to minimize exposure to others should be also be considered. Based on facility risk.
3. Ensuring proper signage is in place to instruct patients on requirements for building entry (e.g., screening, source control (face coverings), and social distancing).
4. Ensuring facility, administrative, and engineering controls have been established to facilitate social distancing. Examples include, but are not limited to, minimizing time in waiting areas, spacing chairs at least 6 feet apart, installing stanchion barriers, and maintaining low patient volumes.
5. Considering installing physical barriers (e.g., plastic sneeze guards) in non-clinical areas such as pharmacy and medical records.
6. Ensuring all ventilation requirements are met. This includes evaluating all AIIR and rooms that have been, or may have been modified with air scrubbers/high-efficiency particulate air (HEPA) filtration.
7. Ensuring all sinks have hand washing supplies available, and are not expired. The establishment of cough etiquette stations throughout the MTF should be considered based on local resources and needs. Items for consideration to include at each cough etiquette station include signage, tissues, masks, and alcohol-based hand sanitizer. Additionally, facilities must ensure hand washing/hygiene signs are posted at hand washing stations as appropriate.

#### *Sanitation Protocols*

IPs, in collaboration with Facilities Management and first-line leadership (e.g., C-suite) maintain responsibility for the following:

1. Ensuring there is an established plan for thorough cleaning and disinfection prior to using spaces or units that may have been closed during the COVID-19 crisis.
  - a. Consideration may be required to modify housekeeping contracts to increase frequency of cleaning.

2. EVS personnel should wear a gown , mask, eye protection and gloves when performing terminal cleaning. Ensuring any equipment that was taken out of service is cleaned/disinfected in accordance with manufacturer's IFU prior to use.
3. Ensuring that equipment such as anesthesia machines used for COVID-19 positive patients, or any patient who has a disease that can potentially spread via the environment (e.g., Vancomycin-resistant enterococci) is thoroughly cleaned in accordance with CDC guidelines.
4. Ensuring staff understand the management of standard/office waste and regulated medical waste in accordance with local/state requirements.
5. Ensuring housekeeping rotates linen and privacy curtains in areas where COVID-19 patients were treated, and in areas that were closed during pandemic if contaminated.

#### ***Supplies and Linen***

IPs, in collaboration with Facilities Management and first-line leadership (e.g., C-suite) maintain responsibility for the following:

1. Assessing supply and linen rooms to ensure they meet IPC recommendations for storage and cleanliness.
2. Ensure section/unit personnel check expiration dates for all supplies.

#### ***Cleaning, Sterilization, and High-Level Disinfection***

All staff engaged in cleaning, sterilization, and high-level disinfection are responsible for the following:

1. Inspecting all sterile packages and instrument trays for integrity and expiration dates.
2. Ensuring all washer/decontaminators, sterilizers, automated endoscope reprocessors, ultrasonic machines, and other sensitive equipment have been tested (QC) to verify appropriate parameters are met.
3. Contact biomedical maintenance, if necessary.
4. Maintain documentation.
5. Assessing sterilant and disinfection solutions to confirm stability and date of expiration per manufacturer's IFU.
6. Reviewing endoscope reprocessing protocols if endoscopic procedures are performed. If there is a scheduled reprocessing interval (hang time), reprocess in accordance with local policy.
7. Reviewing competencies and IPC training for personnel who perform disinfection and sterilization practices, including personnel who handle instruments at the point of use. Consideration for retraining should be based on individual need and length of time passed since the activity was last performed.

#### **Water Plans**

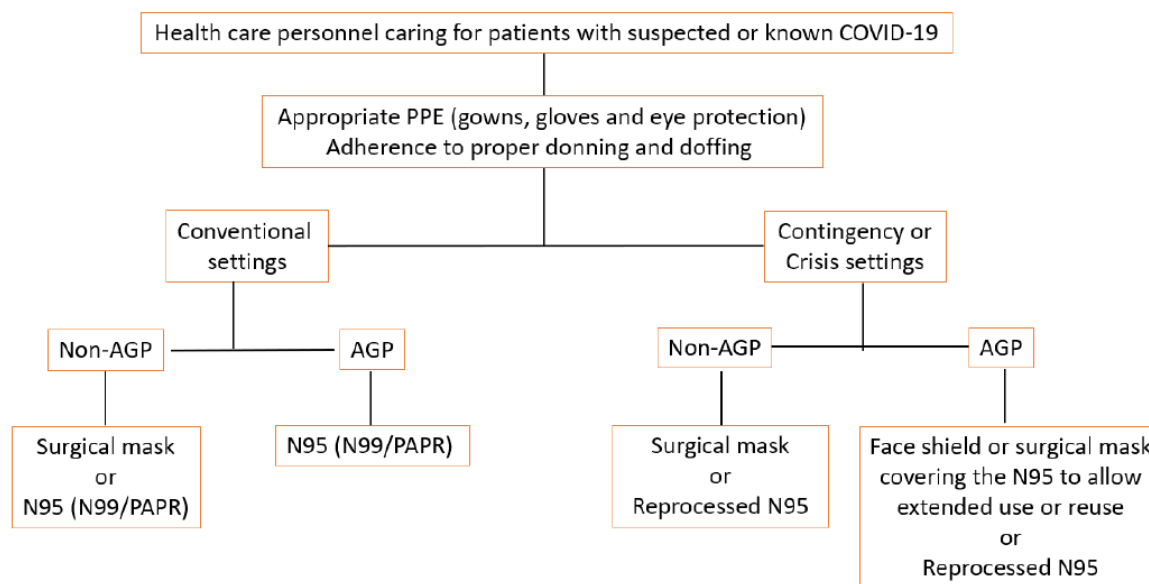
1. To prevent waterborne pathogen outbreaks, facilities will need to take water plans into consideration as units reopen and/or water is turned back on.
2. As part of the facility's water management plan, the following minimum requirements must be reviewed prior to opening:
  - a. Certify all sinks, showers, fountains, dental water lines, etc. are flushed in spaces that were closed or not used during the COVID-19 crisis.
  - b. Confirm ice machines have been maintained in accordance with manufacturer recommendations. In the absence of manufacturer recommendations, refer to CDC guidelines and recommendations.
3. Additional guidance includes policy on *Legionella* & other waterborne pathogen risk mitigation.

#### **Personal Protective Equipment**

1. As Health Protection Condition (HPCON) levels are reduced and operational status begins to normalize, MTF/DTF leadership must ensure staff are aware that all PPE extended and reuse strategies utilized during the pandemic must be discontinued since there is now sufficient levels of critical PPE.
2. MTF/DTF leadership should work in close collaboration with logistics to develop appropriate stockpile quantities for critical PPE and supplies, in preparation for future pandemic surges. In particular, the following should be considered for stockpile supply:

- a. Alcohol-based hand sanitizer (>60% alcohol content)
  - b. Liquid hand soap
  - c. Face masks (i.e. surgical masks)
  - d. Face shields
  - e. Eye protection
  - f. NIOSH approved surgical N95 respirators
  - g. Isolation gowns
  - h. Shoe and head covers
  - i. Gloves
  - j. Disinfecting surface wipes
  - k. Isolation signs
3. Facilities should develop and maintain a plan for decontaminating N95 respirators in the event of a critical shortage during a second-wave pandemic. Such a plan must demonstrate alignment with existing resources and needs.
  4. All staff must understand that industry guidelines continue to evolve, however, the following algorithm provided by the Infectious Diseases Society of America (IDSA) is a helpful resource in terms of caring for patients with suspected or known COVID-19 during either conventional or crisis situations.

**Figure 1.** IDSA Algorithm for Appropriate PPE in Conventional and Contingency or Crisis Settings



AGP: aerosol-generating procedures; PPE: personal protective equipment

#### **Additional IPC Considerations**

Discontinuation of transmission based precautions for patients with COVID-19 should be made using one of the following three strategies, based on current clinical evidence:

1. Test-based
2. Symptom-based
3. Time-based

The decision to discontinue empiric transmission-based precautions by excluding the diagnosis of COVID-19 for a suspected COVID-19 patient can be made based on obtaining negative results from at least one Food and Drug Administration Emergency Use Authorized COVID-19 molecular assay for detection of SARS-CoV-2 RNA. Still, clinical judgment and suspicion of SARS-CoV-2 infection must be applied to determine whether to continue or discontinue empiric transmission based precautions.

Additional information regarding discontinuation of isolation is available at the following link:  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html>

### **References**

1. Centers for Medicare & Medicaid Services (CMS) Recommendations Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I. <https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf>
2. U. S. Department of Labor, O. S. (2020, 03). Guidance on preparing workplaces for COVID-19. Retrieved from <https://www.osha.gov/Publications/OSHA3990.pdf>
3. Lynch, J., Davitkov, P., Anderson, D., Bhimraj, A., Chi-Chung Cheng, V., Guzman-Cottrill, J., Dhindsa, J., Duggal, A., Jain, M., Lee, G., Liang, S., McGeer, A., Lavergne, V., Murad, H., Mustafa, R., Morgan, R., Falck-Ytter, Y., & Sultan, S. (2020). Infectious Diseases Society of America Guidelines on Infection Prevention for Health Care Personnel Caring for Patients with Suspected or Known COVID-19. [www.idsociety.org/COVID19guidelines/ip](http://www.idsociety.org/COVID19guidelines/ip)
4. Defense Health Agency. (2020). Memorandum: COVID-19 Guidance for Resuming Full Healthcare Operations.



## Exam and Treatment Room Turnover Considerations

Despite awareness that COVID-19 is primarily spread by respiratory droplets, there remains an inability to produce clearly defined guidance and/or a comprehensive list of aerosol generating procedures (AGPs) due to limitations in available data. To increase the safety of staff members and patients at these facilities, an evaluation of patient exam and procedure room turnover and cleaning strategies for a variety of situations is warranted.

### Assessment

The U.S. Centers for Disease Control and Prevention (CDC) states that AGPs include commonly performed medical procedures that create uncontrolled respiratory secretions such as open suctioning of the airway, sputum induction, cardiopulmonary resuscitation, endotracheal intubation and extubation, non-invasive ventilation (e.g. BiPAP, CPAP), bronchoscopy, manual ventilation and the use of dental handpieces, air water syringes and ultrasonic scalers. It is uncertain whether aerosols generated from other procedures such as nebulizer administration and high flow oxygen delivery are also infectious. These AGPs potentially put healthcare personnel at an increased risk due to risk of exposure, and additional precautions should be observed.

The algorithm below (Figure C-2) was developed based on key recommendations from the references listed in this document. This should be used to determine the appropriate tier to follow for current guidelines from the CDC and Healthcare Infection Control Practices Advisory Committee (HIPAC), as well as the University of Nebraska (Table C-1).<sup>1-4</sup>

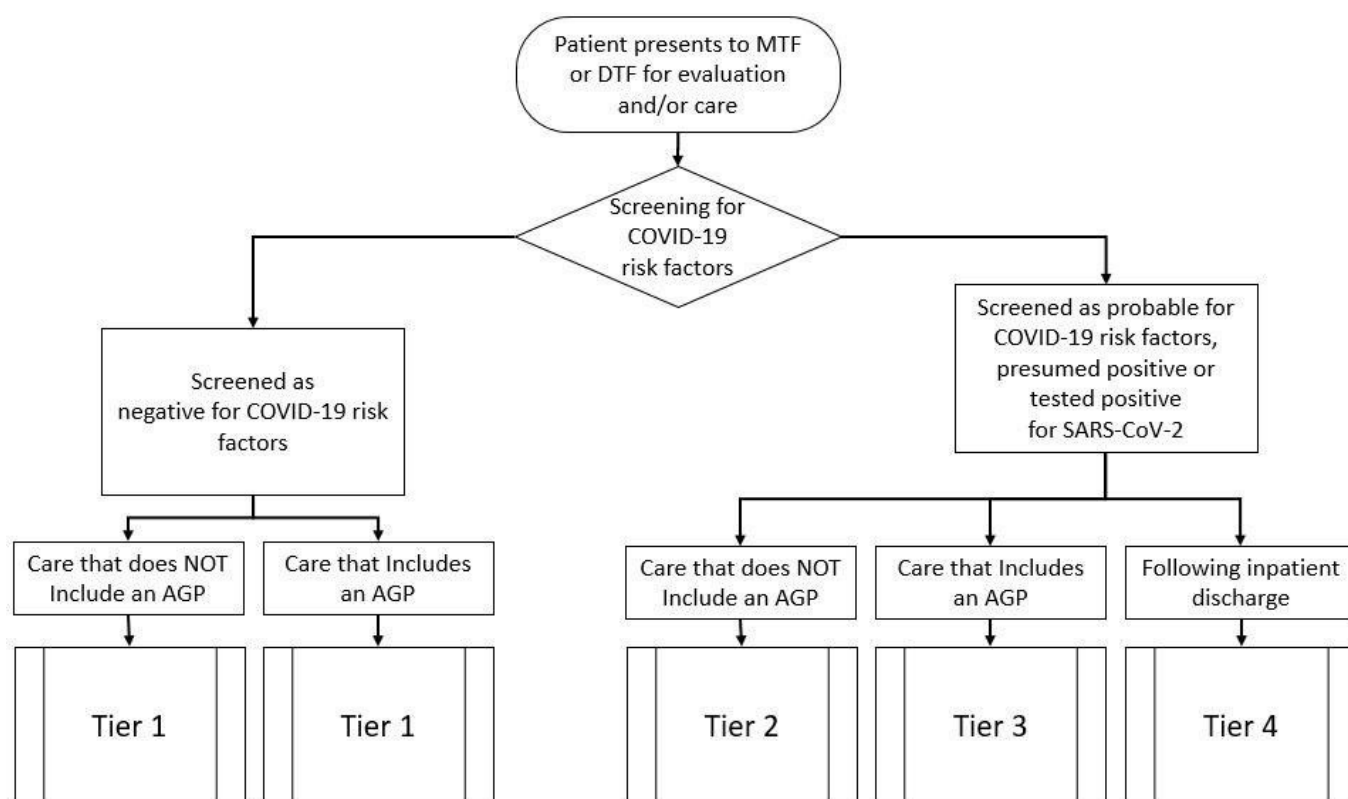


Figure C-2: COVID-19 Patient Algorithm<sup>1-5</sup>

### Recommendation

MTF and DTF leadership should circulate recommendations and make available to staff members as guidance for providing appropriate room turnover, cleaning, and disinfection in accordance with up-to-date CDC COVID-19 guidance, manufacturer IFUs, and EPA-standards. The information in this document serves as a guideline only and does not replace the need to assess the situation and need for cleaning and disinfection based on the environment of care and the procedure performed.

## DoD COVID-19 PMG: Clinical Management of COVID-19, v8

**Table C-1: Tiered Approach to Environmental Infection Control Guidelines During Room Turnover<sup>1-4</sup>**

	Hold or Wait Time	Personal Protective Equipment (PPE) for Staff Member Cleaning Environment	Room Turnover Time	Cleaning and Disinfection
<b>Tier 1</b>	No hold time required	Staff member cleaning room should adhere to standard precautions and transmission-based precautions, and, at a minimum, should wear: <ul style="list-style-type: none"> <li>Gloves</li> <li>Additional PPE in accordance with disinfectant instructions for use (IFU)</li> </ul>	Immediate turnover of room <ul style="list-style-type: none"> <li>Cleaning and disinfection process may begin directly following the patient's exit from the room</li> </ul>	<ul style="list-style-type: none"> <li>Consistently follow routine environmental cleaning and disinfection procedures</li> <li>Use an Environmental Protection Agency (EPA)-approved disinfectant: <a href="https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19">https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19</a></li> <li>Follow the manufacturer's instructions (including wet times) for disinfection to occur</li> <li>After cleaning and disinfection, the room is ready for the next patient</li> </ul>
<b>Tier 2</b>	No hold time required	Staff member cleaning room should wear: <ul style="list-style-type: none"> <li>Gloves</li> <li>N-95 preferred</li> <li>Additional PPE in accordance with disinfectant IFU</li> </ul>	Immediate turnover of room <ul style="list-style-type: none"> <li>Cleaning and disinfection process can begin directly following the patient's exit from the room</li> </ul>	<ul style="list-style-type: none"> <li>Consistently follow routine environmental cleaning and disinfection procedures</li> <li>Use an EPA-approved disinfectant: <a href="https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19">https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19</a></li> <li>Follow the manufacturer's instructions (including wet times) for disinfection to occur</li> <li>After cleaning and disinfection, the room is ready for the next patient</li> </ul>
<b>Tier 3</b>	Hold time starts when the AGP is completed  Isolation sign(s) should remain on the door until appropriate time has passed	Staff member cleaning room should wear: <ul style="list-style-type: none"> <li>Gloves</li> <li>N-95 preferred</li> <li>Additional PPE in accordance with disinfectant IFU</li> </ul>	Room will remain vacant based on air-exchanges per hour (ACH) as described in CDC Appendix A	<ul style="list-style-type: none"> <li>When recommended time has passed, healthcare personnel (HCP) will communicate with Environmental Services (EVS) or clinic personnel that the room is ready to be cleaned and disinfected and remove isolation sign</li> <li>Consistently follow routine environmental cleaning and disinfection procedures</li> <li>Use an EPA-approved disinfectant: <a href="https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19">https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19</a></li> <li>Follow the manufacturer's instructions (including wet times) for disinfection to occur</li> <li>After cleaning and disinfection, the room is ready for the next patient</li> </ul>
<b>Tier 4</b>	Hold time starts when the patient is discharged or vacates the room  Isolation sign(s) should remain on the door until appropriate time has passed	Staff member cleaning room should wear: <ul style="list-style-type: none"> <li>Gloves</li> <li>N-95 preferred</li> <li>Additional PPE in accordance with disinfectant IFU</li> </ul>	Room will remain vacant based on ACH as described in CDC Appendix A	<ul style="list-style-type: none"> <li>When recommended time has passed, HCP will communicate with EVS or clinic personnel that the room is ready to be cleaned and remove isolation sign</li> <li>Consistently follow routine environmental cleaning and disinfection procedures</li> <li>Use an EPA-approved disinfectant: <a href="https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19">https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19</a></li> <li>Follow the manufacturer's instructions (including wet times) for disinfection to occur</li> <li>After cleaning and disinfection, the room is ready for the next patient</li> </ul>

### References

1. CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) (2003, Updated July 2019). Guidelines for Environmental Infection Control in Health-Care Facilities. Appendix B. Airborne Contaminant Removal Retrieved from: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>

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## PPE CONSIDERATIONS FOR ROUTINE DENTAL CARE REOPENING

### **Situation and Background**

Concerns have been raised regarding the parameters for use of N95 filtering facemask respirators (FFRs) for patient encounters involving non-COVID-19 (the disease caused by the SARS-CoV-2 virus) patients. These concerns are based on the inability to screen out asymptomatic and presymptomatic individuals, the limits of testing, limited supplies, and the risks associated with aerosol generating procedures (AGPs) in the dental setting. They are also based on the risks associated with disease transmission from respiratory aerosols produced by the patient (e.g., during coughing, sneezing, talking, and breathing at close intervals where social distancing and source control is not possible). Dental providers are in direct, close contact with the anatomic region of the body where viral loads are the highest during an exam, or even while taking radiographs. The dental provider is directly exposed to the patient's respiratory aerosols/saliva, and the patient may sneeze or cough at any time.

Although personal protective equipment (PPE) recommendations for the management of patients with suspected or confirmed SARS-CoV-2 are clear, there remains a lack of consensus for routine dental care involving patients who are asymptomatic and properly screened. In the context of COVID-19, some infected individuals might not be identified based on clinical signs and symptoms. Surgical masks do not sufficiently protect providers from aerosols. The use of N95 FFRs and eye protection for all dental encounters could effectively serve to mitigate AGP-associated disease transmission risks, however the ability to meet supply demands may prove challenging. To address such logistical concerns, questions have been raised regarding the ability to decontaminate and reuse N95 FFRs. Given the lack of clear guidance, careful review and evaluation of PPE use strategies specific to the dental setting is warranted.

### **Assessment**

It is important to note that according to current CDC Interim Guidelines for Dental Settings, dental providers must assess the level of community spread and other patient risk factors when making decisions regarding appropriate PPE.<sup>1</sup> Even when community spread is low, the CDC urges a cautious approach due to challenges in identifying asymptomatic/presymptomatic individuals. The CDC states: "If your community is experiencing no transmission or minimal community transmission, dental care can be provided to patients without suspected or confirmed COVID-19 using strict adherence to standard precautions. However, given that patients may be able to spread the virus while pre-symptomatic or asymptomatic, it is recommended that dental healthcare personnel (DHCP) practice according to the below considerations whenever feasible. Because transmission patterns can change, DHCP should stay updated about local transmission trends."<sup>1</sup> The "below considerations" mentioned in the dental settings guidance refers to any and all protections that can be provided to staff to prevent transmission of COVID-19, including the use of N95 FFRs respirators.

### **Recommendation**

Facilities could consider using a tiered approach to universal PPE based on the level of transmission in the community. In areas where there is moderate to substantial community transmission, this includes consideration for DHCP for wearing an N95 FFR or higher-level respirator for patients undergoing procedures that might pose higher risk (e.g., those generating potentially infectious aerosols or involving anatomic regions where viral loads might be higher). The oral cavity is an anatomic region with high viral loads and an elevated risks for respiratory produced aerosols.<sup>22</sup>

Dental Treatment Facility (DTF) leadership and staff must work in close collaboration with local Military Medical Treatment Facility (MTF) leaders, as PPE supplies and decontamination availability will vary by location. N95 FFRs are normally single-use (under conventional standards) but extended use and limited reuse with decontamination is permitted under crisis standards as long as certain criteria are met. That said, extended use of PPE is not intended to encourage dental facilities to practice at a normal patient volume during a PPE shortage, but only to be implemented in the short term when other controls have been exhausted. Once the supply of PPE has

increased, facilities should return to standard (conventional) standards and procedures. For non-COVID patients, a good rule of thumb is when N95 FFR supplies are limited, consider extended use of N95 FFRs for non-AGP procedures (8-12 hrs.). To mitigate PPE supply shortage risks, the following recommendations apply:

- Coordinate with local logistician to ensure PPE needs are clearly articulated, including any anticipated situational changes (e.g., influx of soldiers mobilizing, influenza season).
- Monitor par levels and reorder points. Contact local logistician if supply levels are depleted past the facility's reorder point to determine way forward.
- Complete a Director's Critical Information Requirements (DCIR) if re-stock is not anticipated within 1-2 weeks.
- Once a DCIR has been submitted, request re-supply from the contingency stockpile.
- If contingency stockpile and cross-leveling are not available (supply chain constrained) institute the following contingency/crisis strategy measures:
  - Obtain suitable alternatives where feasible from non-DLA sources (local purchases).
  - Use respirators as identified by CDC as performing adequately for healthcare delivery beyond the manufacturer-designated shelf life.
  - Use respirators approved under standards used in other countries that are similar to NIOSH-approved N95 FFRs but may not necessarily be NIOSH-approved.
  - Extend use (if authorized).
  - Re-use (if authorized).

NOTE: All procurements, decontamination, or re-use protocols must adhere to current policy and procedures and meet the DoD, Defense Health Agency (DHA), military department, and CDC standards.

Based on currently known information, the following recommendations are also given:

Only use the CDC described "paper bag" or FDA-approved method for N95 decontamination <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas>

When using the breathable paper bag method, the N95 FFRs should "passively decontaminate" in a breathable paper bag for a minimum of 5 days before reuse.

Store in an environmentally controlled area with appropriate biohazard controls.

Respirators must be inspected to ensure they are not visibly contaminated or damaged before reusing.

- Use N95 FFRs (or equivalent) for AGP and non-AGP dental procedures whenever possible at Health Protection Condition (HPCON) A or higher.
- When N95 FFR supplies are limited, preserve them for the highest risk procedures (i.e., AGPs, and use a surgical mask/face shield combo for non-AGP (less risk) procedures).
- N95 FFRs worn for extended use and/or limited reuse with decontamination should be used only with non-AGP (lower risk) procedures.
- N95 FFRs are single use when used in an AGP.
- With extended use, if the N95 FFRs becomes visibly soiled, wet, and hard to breathe through or does not seal, or are otherwise damaged, then discard.
- DTFs should work in concert with supporting MTFs to coordinate supply ordering, use, and decontamination processes.



**Tiered Approach to N95 FFR/Surgical Mask Use in Dental Settings Based on Level of Community Transmission**

Community Spread	Patient Screening	Procedure Type <sup>1</sup>	PPE	Crisis Strategy (limited supplies of N95 FFRs available) <sup>3</sup>
Minimal-Low (HPCON A)	Non-COVID-19	Non-AGP	Surgical Mask with Full-face Shield	Surgical Mask may be worn for extended use if supplies limited as long as not visibly soiled, wet, or damaged Single-use
		AGP	N95 FFR	
Moderate (HPCON B)	Non-COVID-19	Non-AGP	N95 FFR, if available or Surgical Mask with Full-face Shield	Issue one per day per provider Decontaminate using Paper Bag or VHP Methods Single-Use
		AGP	N95 FFR	
Substantial (HPCON C/D)	Non-COVID-19	Non-AGP	N95 FFR	Issue one per day per provider Decontaminate using Paper Bag or VHP Methods Single-Use
		AGP	N95 FFR	

<sup>1</sup> Aerosol Generating Procedures (AGP) are much higher risk than non-AGP. When supplies are extremely limited, preserve N95 FFRs for AGPs.

<sup>2</sup> See CDC guidance for Paper Bag Decontamination Method. If using VHP decontamination method, consult the manufacturer for information on the effect decontamination might have on fit and function of the respirator. The manufacturer may also have information on the number of times their N95 FFRs may be decontaminated.

<sup>3</sup> When supplies are not limited and crisis/contingency standards no longer apply. PPE use should return to standard/conventional standards of single-use for N95 FFRs and surgical masks.

**References**

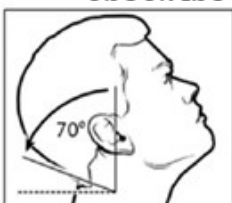
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- National Institute for Occupational Safety and Health. (2020). *Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings*. <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>
- ASD(HA) Memorandum, "Resuming Elective Surgical, Invasive, and Dental Procedures in Military Medical and Dental Treatment Facilities," May 19, 2020 <https://health.mil/Reference-Center/Publications/2020/05/19/ASDHA-Resumption-of-Elective-Surgery>
- DHA Memorandum, "COVID-19 Guidance for Resuming Full Healthcare Operations," May, 14, 2020 [pp. 75-78]
- DHA Memo (2020\_04\_08) - HPCON Guidance in a COVID-19 Environment (JointAccessMemo) available at: <https://info.health.mil/sites/DADMA/Shared%20Documents/JointAccessMemo8Apr.pdf>

## APPENDIX D: NASOPHARYNGEAL SPECIMEN COLLECTION PROTOCOL



### Collecting a Nasopharyngeal Specimen Swab Method

1. Don PPE as directed by your institutional policies and procedures and perform hand hygiene.
2. Introduce yourself to the patient.
3. Verify the correct patient using two identifiers – name and DOB.
4. Ensure the patient has completed a screening tool asking about history of nose bleeds, Ear, Nose or Throat (ENT) concerns, procedures i.e. nasal surgery, nasal polyps, and/or deviated septum.
5. Explain the procedure to the patient and ensure that he or she verbalizes understanding.
6. Instruct the patient to sit upright. If in vehicle, use headrest to stabilize head.
7. Have the swab and the sterile tube ready for use.
8. Offer the patient a facial tissue to blow his or her nose if needed.
9. Ask the patient to occlude each nostril and exhale.  
*Rationale: As the patient breathes through each open nostril, check for obstruction. For deviated septum or nasal polyps, contact provider.*
10. Position the patient with his or her head back and use a penlight to inspect the nasal passages for patency.



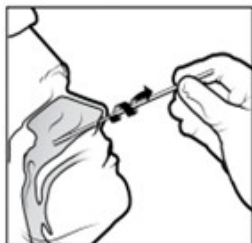
11. Tilt the patient's head back 70 degrees.
12. Insert minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions.

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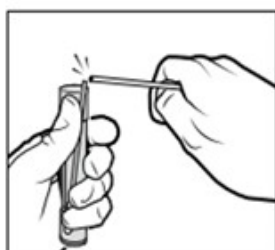
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## Collecting a Nasopharyngeal Specimen Swab Method



13. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. *Note: Hold the swab towards the end of the shaft.*

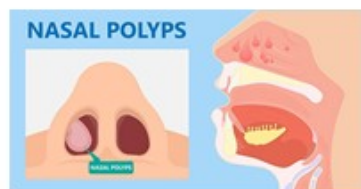


14. Remove the swab and insert into the sterile tube, push the tip into the liquid medium at the bottom of the tube, and snap the application stick. Place the top securely on the sterile tube.

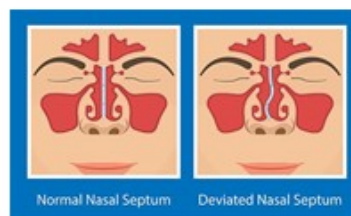
15. In the presence of the patient, label the specimen – date, time, and initials.
16. Place the labeled specimen in a biohazard bag for transport to the lab.
17. Doff PPE as directed by your institutional policies and procedures and perform hand hygiene.

Can you identify these anatomical anomalies?

### Nasal Polyps



### Deviated Septum



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## APPENDIX E: LIFESTYLE APPROACHES TO REDUCE COMORBIDITY FROM COVID-19

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Provided by the Air Force Lifestyle and Performance Medicine Working Group

The relationship between a healthy lifestyle and COVID-19 is not limited to primary prevention. This appendix provides a synopsis of personal health behaviors that should be discussed with anyone who tests positive for SARS-CoV-2. These low-risk strategies may help reduce complications and improve quality of life.

**Sleep.** Over 55% of active duty service members report getting less sleep than they need to perform well.<sup>1</sup> Short sleep duration of even a few days increases cortisol, insulin resistance, and pro-inflammatory cytokines.<sup>2,3</sup> It promotes loneliness,<sup>4</sup> encourages intake of non-nutritive food,<sup>5</sup> and escalates perceived severity of respiratory infections.<sup>6</sup> Sufficient sleep, on the other hand, improves cognitive function,<sup>7</sup> stress perception,<sup>8</sup> and all-cause mortality risk.<sup>9</sup> Given its sweeping impact on other health behaviors and on health outcomes, restorative sleep should undergird the treatment plan for anyone infected with SARS-CoV-2. Although exact sleep requirements vary between individuals and across one's lifespan, most adults need 7–9 hours of sleep per day<sup>10</sup>—a requirement that may increase while fighting an infection. Sleep quantity and quality can be improved by optimizing the bedroom environment, avoiding screens for 90 minutes before bed, and maintaining a regular bedtime routine.<sup>11</sup> Patients should be assessed for shift work disorder and sleep apnea. Shift workers may benefit from pharmacological and non-pharmacological interventions, as outlined by the American Academy of Sleep Medicine.<sup>12</sup> Patients at risk for obstructive sleep apnea, a highly prevalent but widely underdiagnosed condition that is associated with increased mortality from COVID-19, should be evaluated and treated by appropriate experts.<sup>13,14</sup>

**Stress Management and Social Connectedness.** Given the association between psychological stress and immunosusceptibility,<sup>15–17</sup> the negative impact of stress on oxygen consumption,<sup>18</sup> and the short- and long-term neuropsychiatric sequelae of SARS-CoV-2 infection,<sup>19,20</sup> providers should assess the psychosocial health of patients diagnosed with COVID-19. All patients should be screened for pre-existing mental health conditions and should be offered stress management techniques, regardless of their baseline psychological fitness. One technique is Mindfulness-Based Stress Reduction (MBSR), a standardized program that encourages self-awareness and attention control, such as through focused breathing. MBSR can ameliorate psychological distress and emotional exhaustion,<sup>21,22</sup> as well as reduce inflammation and loneliness in older adults.<sup>23</sup> Simpler evidence-based techniques include prayer, meditation, and physical activity.<sup>24</sup> Newly diagnosed SARS-CoV-2 patients will be asked to isolate physically from others; they should be encouraged, meanwhile, not to isolate socially, as social connectedness affects expression of many immune-response genes.<sup>25</sup> Patients at risk for suicidal ideation should be managed carefully and provided crisis resource information, such as the National Suicide Prevention Hotline (800-273-TALK) or Military Crisis Line (800-273-8255). For more information, see the “Behavioral Health and Wellness in COVID-19 Clinical Management” section in this PMG.

**Diet and Nutrition.** The notion of a “one-size-fits-all dietary prescription” is antiquated.<sup>26</sup> While acknowledging that the optimal diet, like the optimal sleep schedule, should be personalized, the following dietary advice is safe for all patients with COVID-19. First, stay hydrated with water and tea. Second, consume a whole-food, plant-predominant diet that minimizes pro-inflammatory foods—specifically added sugar, refined carbohydrates, processed meat, fried food, and partially-hydrogenated oils.<sup>27–30</sup> Third, ensure that immuno-protective nutrients, listed below with their major food sources, are part of the daily diet.

- Vitamin C: citrus fruits, kiwi, cantaloupe, bell peppers, tomatoes
- Vitamin D: cold-water oily fish, mushrooms, eggs
- Selenium: nuts (especially Brazil nuts), fish, eggs, brown rice, tofu, chicken
- Zinc: seafood, legumes, eggs, red meat, nuts, seeds, cocoa
- Monounsaturated fatty acids: nuts, seeds, avocado, olives



- Omega-3 polyunsaturated fatty acids: cold-water oily fish, nuts, seeds, olives
- Fiber: vegetables, fruits, legumes, nuts, seeds, whole grains (oatmeal, barley, quinoa)
- Antioxidants: herbs and spices, tea, coffee, berries, vegetables, nuts, seeds, cocoa<sup>31</sup>

Macronutrient and micronutrient requirements for severely ill patients is beyond the scope of this appendix. For more information, see the “Nutrition” subsection under the “Management of Critical Illness and COVID-19” section in this PMG.

**Physical Activity.** Routine physical activity has a profound impact on the immune system: It reduces systemic inflammation, mitigates immunosenescence, and decreases the risk of chronic diseases.<sup>32</sup> Even low-intensity activity, such as walking or housework, can spur production of anti-inflammatory cytokines and boost mental health.<sup>33,34</sup> More extreme exertion, however, can temporarily suppress the immune system and exacerbate respiratory symptoms. Physical activity recommendations after SARS-CoV-2 infection should be based on symptomatology and presence or absence of myocardial injury.

**Tobacco Use.** Current smoking is associated with COVID-19 severity, disease progression, mechanical ventilation requirements, and in-hospital mortality.<sup>35</sup> (The impact of e-cigarette use is not yet established.) Since health crises, such as a COVID-19 diagnosis, may provide the necessary prompt for smokers to initiate a quit attempt, every tobacco user should be advised to quit and supported as appropriate.<sup>36</sup> If the local military treatment facility cannot provide adequate support, patients should be encouraged to utilize their state quitline (800-QUIT-NOW) or the live chat feature at YouCanQuit2 (<https://www.ycq2.org/>).

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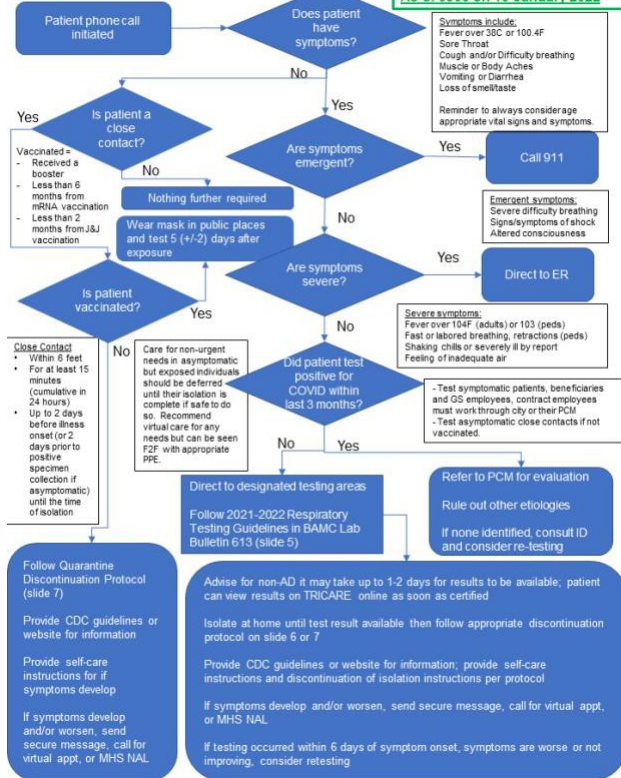


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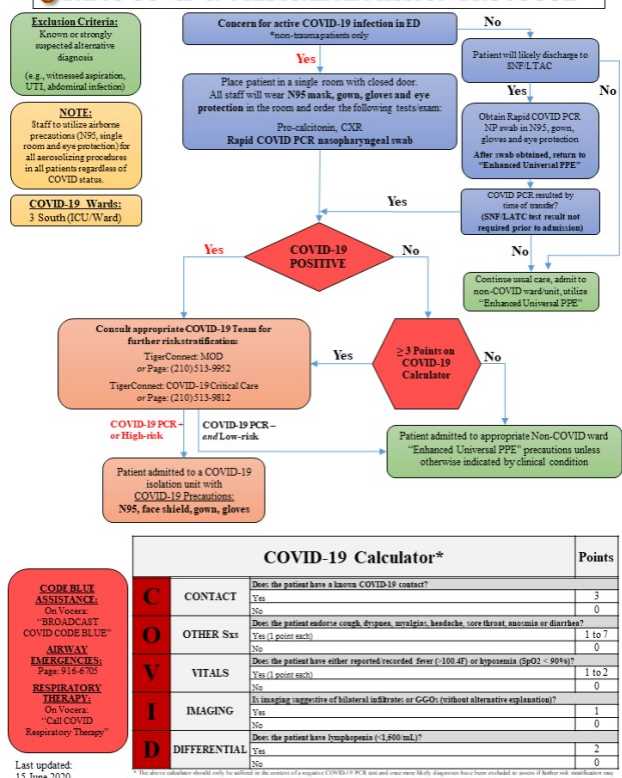
## APPENDIX F: EXAMPLE TRIAGE PROTOCOLS DURING COVID-19 PANDEMIC

## COVID-19 Telephone Triage Protocol

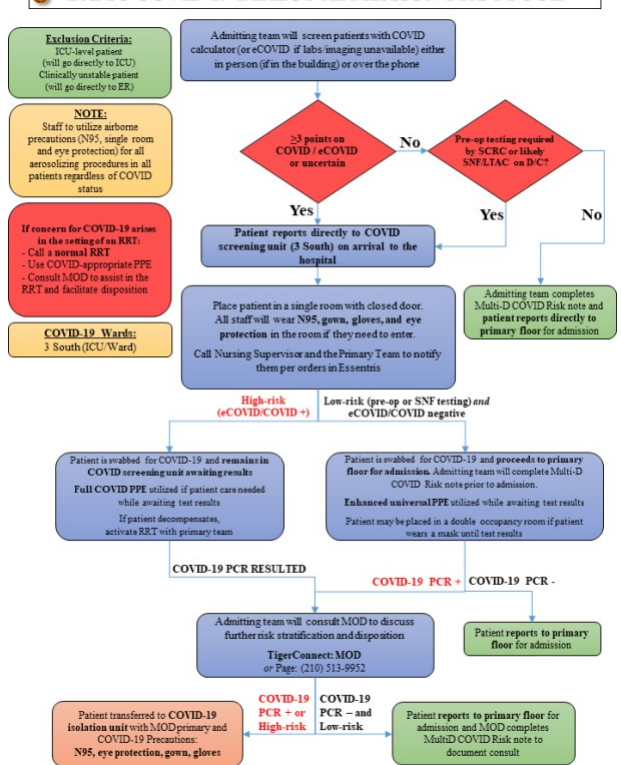
As of 0900 on 10 January 2022



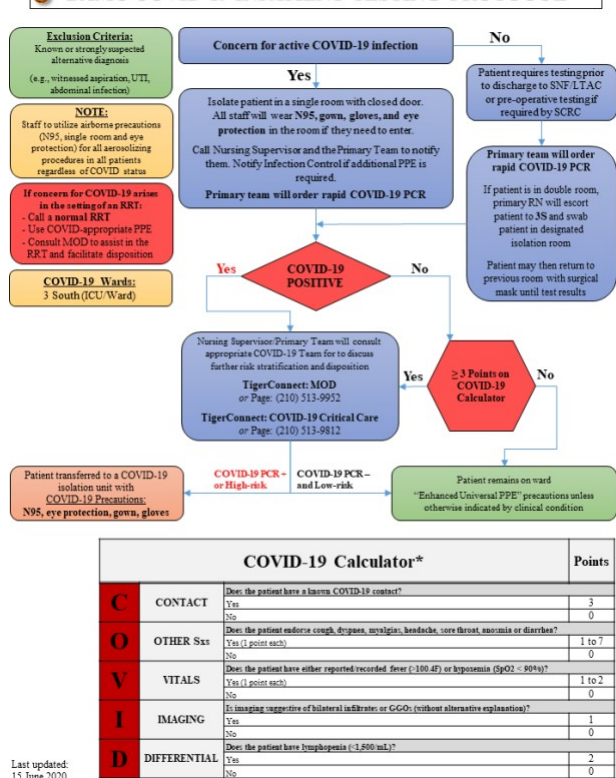
## BAMC COVID-19 MEDICAL ADMISSION PROTOCOL



## BAMC COVID-19 DIRECT ADMISSION PROTOCOL



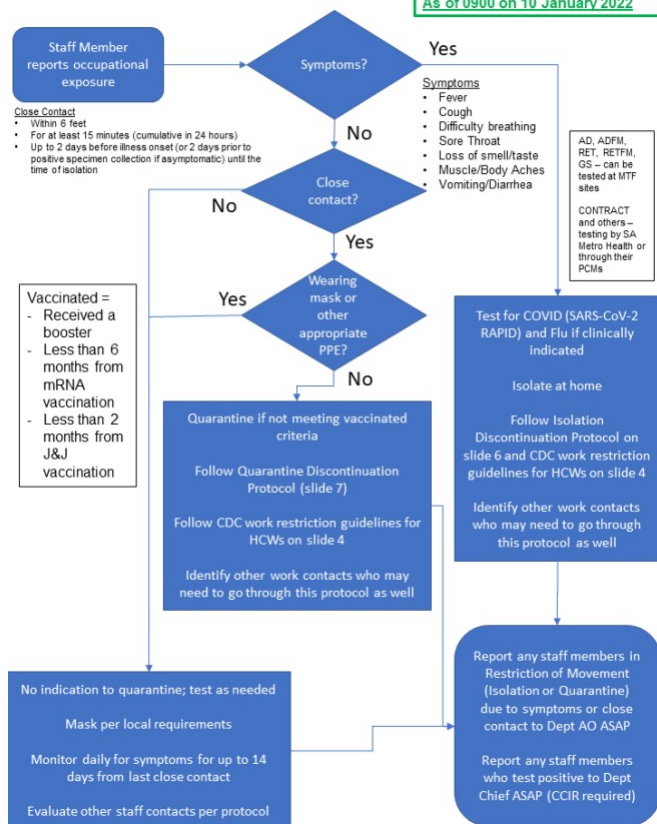
## BAMC COVID-19 INPATIENT TESTING PROTOCOL





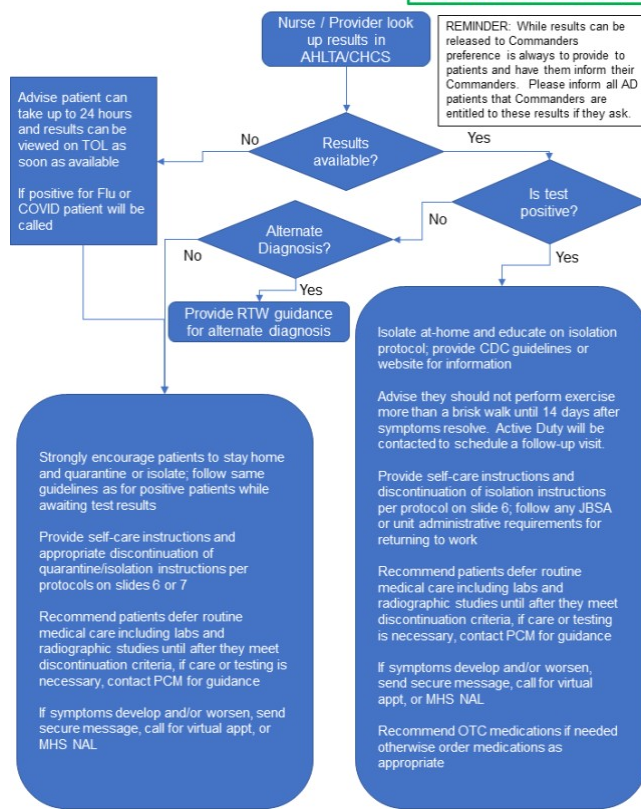
### COVID-19 Staff Member Exposure Screening Protocol

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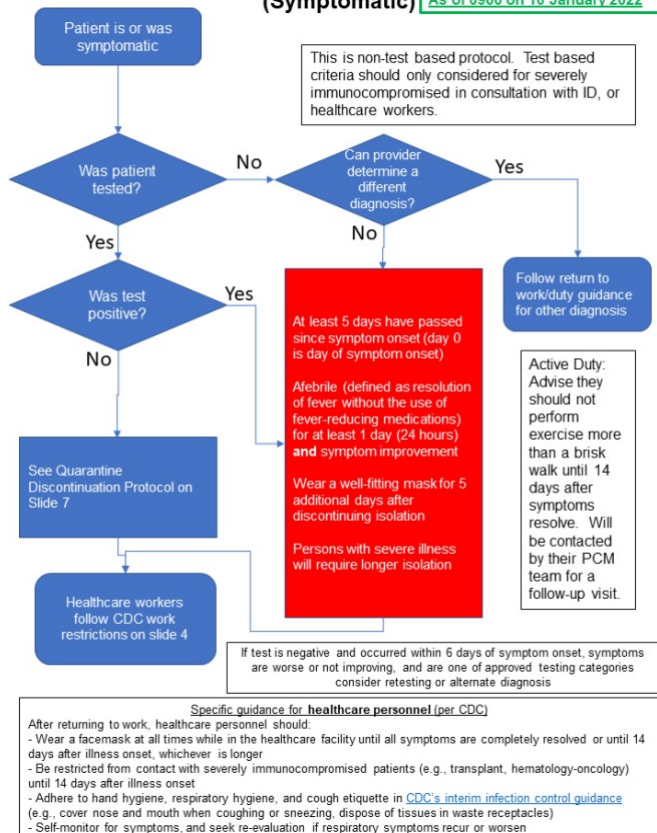
### COVID-19 Test Result Protocol

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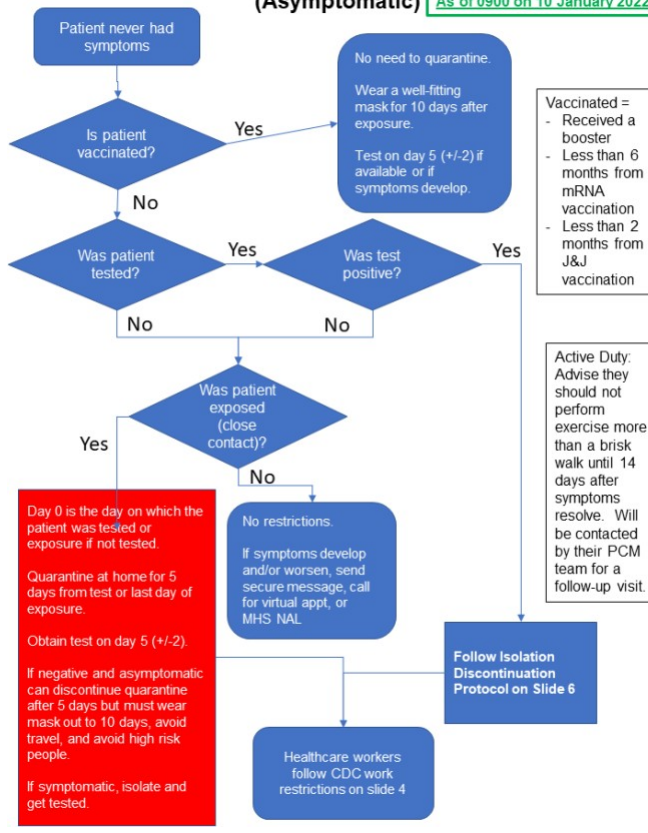
### COVID-19 Home Isolation Discontinuation Protocol (Symptomatic)

As of 0900 on 10 January 2022



### COVID-19 Home Quarantine Discontinuation Protocol (Asymptomatic)

As of 0900 on 10 January 2022



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## APPENDIX G: ADULT PRONE POSITIONING PROTOCOL EXAMPLE\*

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\*Adapted from University Medical Center (Las Vegas, NV)

Procedure for patient preparation prior to proning:

1. Obtain an order from the Fellow or Attending physician to place patient in the prone position. The order should include:
  - a. Proper sedation/pain medications and paralytic agents if necessary.
  - b. Length of time for each pronation cycle (patient should be in prone position a minimum of 16 hours, with a return to the supine position at least once a day).
  - c. Prone positioning should be performed within the first 24 hours of the diagnosis of severe hypoxemia.
2. Explain proning procedure and benefits to patient and family members when present.
3. Prior to proning patient, make sure the following criteria have been met and necessary equipment is made available:
  - a. Patient is mechanically ventilated via a secured endotracheal tube (ETT) with inline suction.
  - b. RT is at bedside to evaluate securement of ETT with commercial tape and to place bite block as needed. Twill may be used in addition to the tape if additional securement is needed. Do not secure ETT with a commercial securement device (i.e. Hollister).
  - c. Confirm patient intravenous access including central and arterial lines; verify lines are secure in place.
  - d. Remove ECG leads from anterior of torso; obtain new leads to place posteriorly once patient is prone. Electrocardiogram leads can be placed in the lateral limb position (left and right deltoid midaxillary line and left and right 12th intercostal space at the midaxillary line). The virtual lead (V1 or chest lead) can be placed on the dorsal surface.
  - e. Consider adhesive foam pads (i.e. Mepilex) to apply to bony prominences such as forehead, bilateral shoulders, chest, iliac crests and knees to prevent pressure ulcers.
  - f. Obtain positioning pillows, blanket rolls or foam prone positioning kit from materials management or supply room.
  - g. Continuous SpO<sub>2</sub> monitoring.
  - h. Foley catheter and oral gastric tube secured in place.
  - i. Use fecal management system if needed.
  - j. It is reasonable to provide enteral feedings while patient is in prone position. Elevation of head of bed in reverse Trendelenburg position helps reduce the risk of gastric aspiration. Gastric feeding tubes are preferred; however, post pyloric feeding tubes may be indicated in patients with high aspiration risk.
  - k. Lubricate patient's eyes prior to proning, then every six hours and as needed (Provider order needed).
  - l. Assess and document pain and provide adequate sedation and pain management throughout the procedure.
  - m. Patients may also require neuromuscular blocking agent during proning.
  - n. Remove head board and ensure bed brake is on.
  - o. RT will perform and document a complete vent check including auscultation of bilateral lung sounds, ventilator settings, ETT positioning/depth, patient tidal volumes and ETT cuff pressures pre and post turn.

Procedure of manual pronation:

1. Assemble a minimum of a 5-person team consisting of at least one RT and the patient's RN. RT is to manage airway protection at the head of the bed and the other team members are positioned on either side of the bed to manually prone the patient. A fellow or attending physician should be present for the first turn.
2. Correctly position all tubes, taking into account the direction of the turn.
3. Lines inserted in the upper torso are aligned with either shoulder, exception is chest tubes or large bore tubes.
4. Tubes in the lower torso are aligned with either leg and extended off the bed.

5. Always initially turn the patient in the direction of the ventilator.

Procedure for proper patient positioning (see diagram below):

1. Head and Neck positioning:

Place patient's head on a foam head positioner, which allows for the patient's head in a neutral position. Otherwise, support the patient's head in a rotated position paying attention to avoid pressure to the eyes and ears. Provide range of motion to the patient's head at least every hour, maintaining ETT tube alignment. Reposition head every two hours, head should be turned to the up arm while in swimmer's pose, to avoid traction on the brachial plexus. Coordinate with RT to be present to maintain the airway while repositioning the head every two hours. This may require positioning the ventilator at the head of the bed rather than on one side of the bed to allow for the head reposition. Raise the head enough to provide for proper spinal alignment: avoid hyperextension or flexion of the cervical spine. Ensure the eyes have no pressure on the orbits and ears are properly aligned, flat and not folded.

2. Arm positioning:

If using foam prone positioning kit, place patient's arms in foam positioners. While the patient is in a side lying position, gently position the arms in a swimmer's pose. The swimmer's pose entails the up arm is in a supported, flexed position at the level of the shoulder and the down arm is parallel to the body in a position of comfort. When the arm is in the up position, keep the shoulder in a neutral position, abducted to 90 degrees and the elbow flexed at 90 degrees. Utilize pillows or blanket rolls to prevent hyperextension of the shoulder and to ensure the weight of the arm is supported. Note: Head position should be turned to the up arm while in swimmer's pose, to avoid traction on the brachial plexus.

- a. Alternate the arm and head position every two hours with the patient in a side lying position and provide passive range of motion exercise to all joints of the upper and lower extremities.

3. Patient positioning:

- a. Manually reposition the patient a minimum of every 2 hours with a slight right lateral-pillow support position (20-30°) to prone (flat) to a slight left lateral-pillow supported position (20-30°) and back to prone position. The use of automatic bed rotation is not a replacement for manual repositioning.

Note: When placing the patient in the lateral-pillow support position, coordinate head and arm in the up position toward the tilted side (Do not use foam wedges for lateral turns).

- b. During lateral turns inspect the skin and positioning of the tubes, lines and catheters (tubing and penis) and reposition accordingly, i.e. Foley catheters, chest tubes, IV lines, etc.

4. Leg positioning:

While in prone and/or lateral prone position float the knees with a pillow (be careful not to cause hyperextension of the hip), and place a foam roller, pillow or blanket roll under the ankle area to elevate the toes and prevent tension on the tendons in the foot and ankle region.

5. Tilt the patient into reverse Trendelenburg:

Goal is 30 degrees, as patient tolerates.

6. Alternative position of the arms for comfort or if swimmer's position is contraindicated.

For example, the patient, family or PT/OT one-time evaluation report history of rotator cuff tear, stroke, nerve damage, osteoarthritis of shoulder complex, history of clavicle fracture, hyper flexible joints.

- a. Arms can be left in the side lying position aligned with the body and repositioned every two hours to a slightly abducted position.



**Patient monitoring and care:**

1. Time patient is prone/supine:
  - a. It is recommended in the literature that patient is placed in the prone position for a minimum of 16 hours. The timing for prone cycling requires a physician order and is always situational. Patients should be returned to supine position for up to four hours, once per day preferably early AM to allow the interdisciplinary team time to assess while in supine position. While in supine position, reassessment of oxygenation, skin assessment and other relevant exam elements should occur. If the patient does not tolerate being supine (i.e. requiring increased ventilator settings, decreasing  $\text{PaO}_2/\text{FiO}_2$  ratio, hemodynamically unstable or decreasing  $\text{SpO}_2/\text{PaO}_2$ ) return patient to the prone position.
  - b. Patients in prone position should receive the same standard of care as a patient that is supine (i.e. oral care, urinary catheter care, skin care, eye care, suctioning, etc.).
  - c. Discuss supine position tolerance and  $\text{PaO}_2/\text{FiO}_2$  ratio in bedside report and during interdisciplinary rounds.
  - d. Ongoing assessment of how the patient is tolerating prone therapy and repositioning; documentation of all vital signs, capnography, patient and family education, length of time prone, patient's response to turning supine, any adverse events that occur and changes in the patient's condition.
  - e. Primary RN will coordinate with RT to re-secure ETT when the patient is supine and assist with turns, checking cuff pressures and tube placement before and after repositioning the patient; coordinate with radiology for chest x-ray when supine.
  - f. Monitor all tubes, lines, drains and catheters throughout the repositioning process and continue airway management, suctioning oral and ETT secretions.
  - g. Continue to evaluate enteral nutrition tolerance and maintain reverse Trendelenburg to help prevent ventilator associated pneumonia (VAP).
  - h. RT to change ETT tape at least once a day or more frequently if necessary due to facial swelling.
  - i.  $\text{PaO}_2/\text{FiO}_2$  ratios should be calculated every day and when ventilator settings have been changed in order to identify candidates for returning to the supine position early.

**Consider discontinuation of the prone position if:**

2. The patient no longer shows a positive response to the position change or mechanical ventilation support has been optimized.
3. The patient's  $\text{PaO}_2/\text{FiO}_2$  ratio is  $>200$  on less than 50%  $\text{FiO}_2$  and  $\text{PEEP} \leq 10$  cm of water.

**Complications related to prone positioning:**

1. Unplanned extubation
  - a. Lines pulled
  - b. Tubes kinked
  - c. Hemodynamic instability
  - d. Facial edema
  - e. Pressure ulcers
  - f. Aspiration
  - g. Corneal abrasions

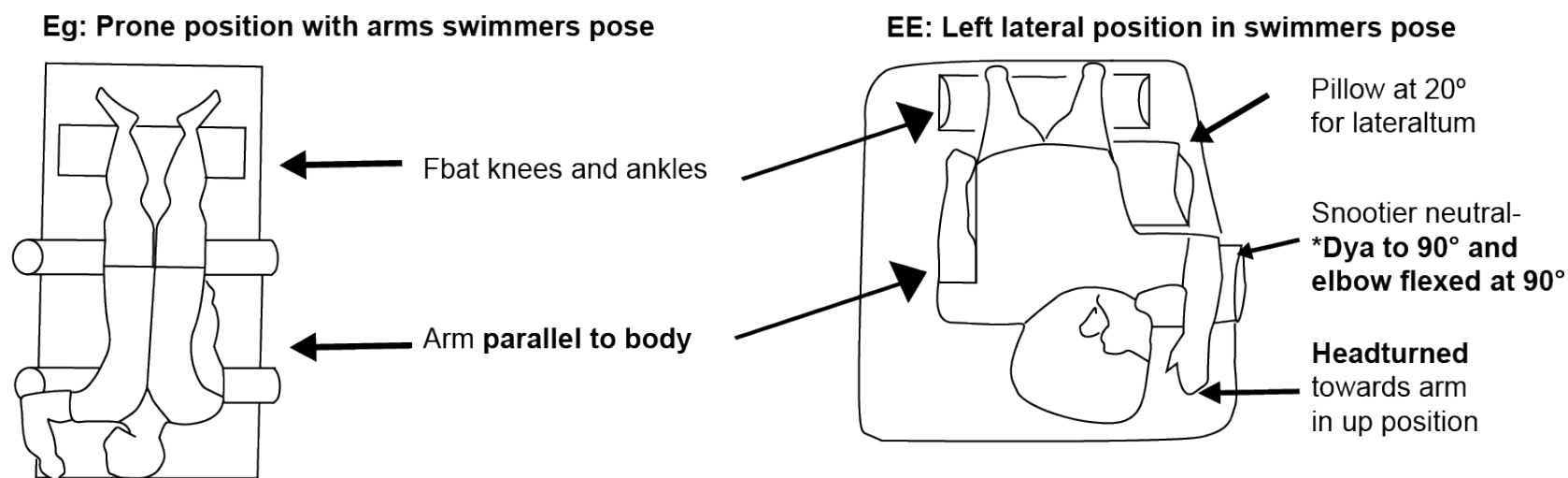
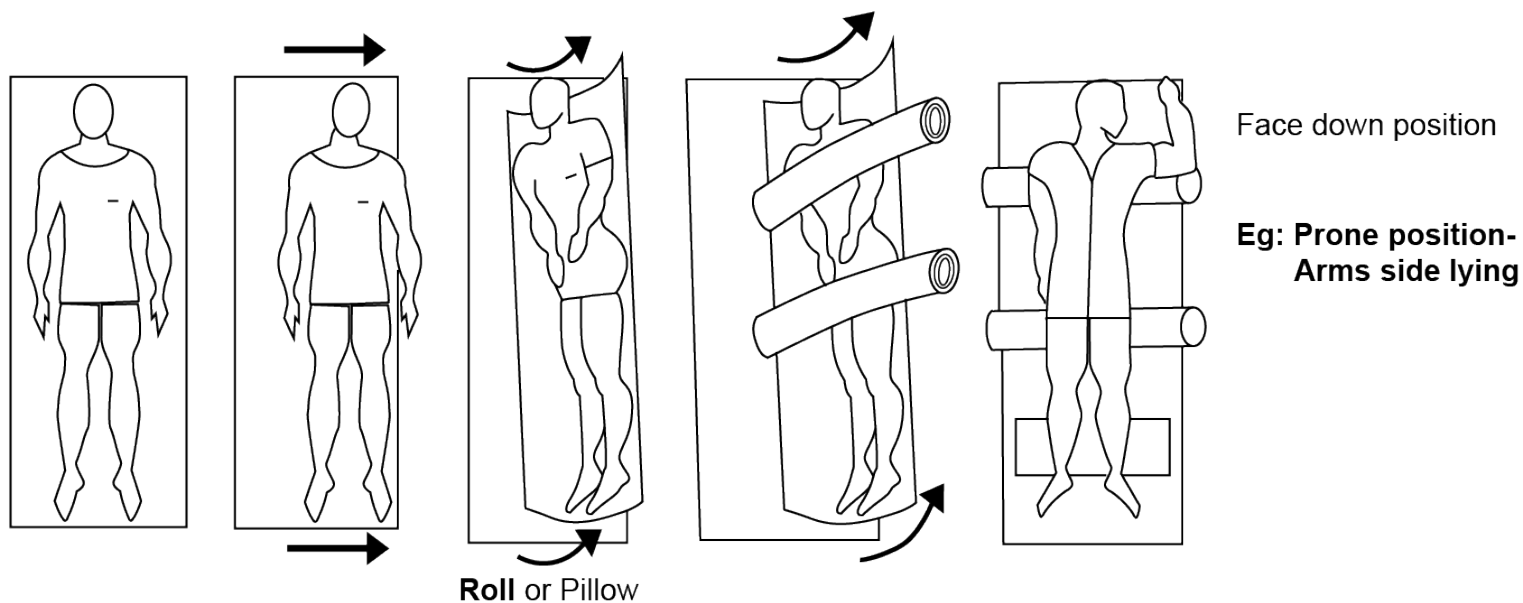


Figure G-1: proper patient positioning

### **COVID-19 INTUBATION PRE-ENTRY CHECKLIST\***

Ensure all members of the intubating team dons the appropriate PPE prior to entering the room, and verifies the patient's Code status.

#### **For Providers:**

##### **To bring inside room:**

Place a priority on rapid airway placement with video laryngoscopy (i.e., Glidescope) to create distance between operator and patient's airway, avoidance of BVM and NIV due to risk of aerosolization:

##### ☐ Airway Supplies:

- ETT (7, 7.5, 8 for adults, appropriate size for children) with syringe for cuff
- Glidescope or C-MAC (facilitate intubation from a distance)
- Appropriate stylet
- Bougie
- OG tube with syringe, lube and tape
- OP/NP airway
- Colorimetric end-tidal CO<sub>2</sub> detector
- Suction setup (Yankauer)

##### ☐ Disposable stethoscope

##### ☐ Sani-wipes (should be located inside room)

##### **Keep outside room (on standby):**

##### ☐ Back up Airway Supplies:

- Appropriate size laryngoscope blades (Mac 3 & 4 for adults) and handle (disposable preferred)
- Stylet
- BVM (avoid if possible due to risk of aerosolization of pathogen)

##### ☐ Airway cart (never bring in room)

##### ☐ EZ-IO

#### **For Nursing:**

##### ☐ RSI meds kit with free-flowing IV fluid set-up

##### ☐ Restraints

##### ☐ Foley

##### ☐ ABG syringe

##### ☐ Large-bore naso/orogastric tube (appropriate size for patient)

##### ☐ Post-intubation meds:

- propofol
- fentanyl
- phenylephrine
- norepinephrine drip

#### **For Respiratory Therapy:**

##### ☐ Ventilator with appropriate filters

##### ☐ ET securing device

##### ☐ Waveform capnography adapter

##### ☐ Viral filter for Ambu bag

\*Adapted from University of Washington (<https://COVID-19.uwmedicine.org/>)

## COVID-19 INTUBATION PROTOCOL

### Plan

- Evaluate airway to ensure normal airway anatomy
- Determine whether direct laryngoscope or video laryngoscope will be the fastest method (both should be available); Sufficient muscle relaxant should be used to abolish cough reflexes
- Determine intubation medications (Recommend: Ketamine 2mg/kg; Rocuronium\* 1 mg/kg)  
\*Succinylcholine 1 mg/kg may also be used provided no contraindications (e.g. hyperkalemia)

### Position

- Optimize patient position in the "sniffing" position
- Optimize bed height
- For obese patients, the "ramped" position should be used

### Pre-Oxygenate

- 100% FiO<sub>2</sub> for 5 minutes (avoid BiPAP or bagging if possible)
- If possible, use nasal cannula covered by filtered BiPAP mask without insufflating the BVM
- Alternative Pre-Ox: Jackson-Reese bag with viral filter; NRB over mask; NC.HFNC under mask; BVM with viral filter/PEEP valve
- Prepare BVM and airway with a high-efficiency particulate air (HEPA) filter placed between the mask and the breathing circuit or the respiratory bag, and one at the expiratory end of the breathing circuit

### Prepare

- IV/IO access patent
- Full cardiorespiratory monitors in place
- Pulse oximeter and BP cuff on opposite arms
- Equipment available and working (Suction, Airway and adjuncts, Back-up Plan - include cricothyroidotomy kit)
- Prepare for cardiovascular instability during intubation (availability of IVF bolus & pressors, e.g. Phenylephrine)

### Paralyze

- Push intubation meds AFTER physician to nurse order and nurse reply
- Avoid BVM, but if necessary, bag with low tidal volume/high frequency to maintain oxygenation & reduce exposure
- If difficult intubation is encountered, use external laryngeal manipulation or bougie to improve chance of success
- If tracheal intubation fails, place a 2nd generation laryngeal mask and attempt fiberoptic bronchoscope

### Post-Intubation

- Inflate cuff prior to first breath and then Secure tube
- Confirm proper tube position (direct visualization, continuous waveform capnography, CXR)
- Collect all airway devices in a double-sealed bag and implement proper disinfection during disposal
- Ongoing sedation
- VAP prevention: HOB elevated, oral swab, cuff pressures 20-30, NG/OG

# COVID-19 COGNITIVE AIDS FOR INTUBATION

## COVID-19 Emergency Intubation Checklist

### CHECK BEFORE ENTERING ROOM



SAFE AIRWAY SOCIETY

Team	Patient	Drugs	Equipment
<ul style="list-style-type: none"> <li>Anaesthesia contacted if difficulty anticipated</li> <li>Team introduced: <ul style="list-style-type: none"> <li>Airway Operator</li> <li>Airway Assistant</li> <li>Team Leader/Drugs</li> <li>In-room Runner: optional</li> <li>Door Runner</li> <li>Outside room Runner</li> </ul> </li> <li>Problems anticipated?</li> </ul>	<ul style="list-style-type: none"> <li>ECG, BP, Sats</li> <li>Pre-oxygenation <ul style="list-style-type: none"> <li>FIO2 100%</li> <li>Sitting position 45°</li> </ul> </li> <li>IV access x 2 <ul style="list-style-type: none"> <li>1L fluid on pump set</li> </ul> </li> <li>Haemodynamics optimised <ul style="list-style-type: none"> <li>Fluid bolus</li> <li>Pressor</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>RSI drugs drawn up, doses chosen</li> <li>Rescue drugs <ul style="list-style-type: none"> <li>Metaraminol</li> </ul> </li> <li>Post intubation sedation plan</li> <li>Drug C/I or allergies?</li> </ul>	<ul style="list-style-type: none"> <li>2 Laryngoscopes (tested)</li> <li>Tube chosen; cuff tested</li> <li>Bougie/stylet</li> <li>10ml syringe</li> <li>Tube tie</li> <li>Lubricant</li> <li>Supraglottic airway sized to pt</li> <li>Scalpel + bougie CICO kit</li> <li>Airway trolley/bronchoscope outside room</li> <li>ETCO2</li> <li>Viral filter</li> </ul>

### FINAL CHECK IN ROOM

- Patient position optimal
- Fluid runs easily
- Suction working
- Facemask with viral filter connected
- ETCO2 trace
- O2 running at 15L.min<sup>-1</sup>
- Oropharyngeal/nasal airways
- Airway plans:
  - Plan A: Videolaryngoscopy with bougie/stylet
  - Plan B: Supraglottic airway
  - Plan C: Vice grip, 2-person +/- Guedel/NPA
  - Plan D: Scalpel/bougie/tube

<https://www.safeairwaysociety.org/covid19/>

## COVID-19 AIRWAY MANAGEMENT

SAFE AIRWAY SOCIETY

- Intensive training
- Early intervention
- Meticulous planning
- Vigilant infection control
- Efficient airway management
- Clear communication

USE A 'BUDDY CHECK' FOR CORRECT PPE FITTING

### Planning

Intervene early - aim to avoid emergency intubation. Negative Pressure room or Normal pressure with strict door policy. Senior clinician involvement. Is Anaesthetist needed? Early airway assessment documented by senior clinician.

### Prepare

Assemble 5-6 person Airway Team (see reverse). Use COVID-19 Intubation Tray (see reverse). Ensure Viral Filter and ETCO2 in ventilation circuit. Share Airway Strategy. Use a dedicated COVID intubation checklist.

### PPE

Hand Hygiene (HH). Donning: HH > Gown > Mask > Eye-protection > Hat > HH > Gloves. Spotter to perform "Buddy Check" to ensure correct PPE fit. Airway operator to consider double gloves.

### Pre-Ox

45 degree head up position. Pre-oxygenate with Face Mask using 2 hands for full 5 minutes. Ensure a square ETCO2 waveform, to be confident of no leaks. Avoid Apnoeic Oxygenation techniques due to aerosolization risk.

### Perform

Use VL; use the screen (indirect view) to maximise operator distance from airway. Modified RSI technique (1.5mg/kg BW Roc OR 1.5mg/kg BW Sux). No ventilation prior to intubation unless for rescue oxygenation. Wait 60 seconds for paralysis to take effect - avoid triggering cough.

### Post-ETT

Inflate cuff BEFORE initiating ventilation and monitor cuff pressures to minimise leak. Remove outer gloves (if on), dispose of airway equipment in sealed bag. Doffing: Gloves > Gown > HH > Eye Protection > Mask > HH. Use a Spotter. Debrief and share lessons.

### Awake Intubation

Risk of aerosolization. Involve Senior Anaesthetist if this airway technique is indicated.

### Connection / Disconnection

Apply the viral filter directly to the ETT. Only disconnect the circuit on the ventilator side of the viral filter.

### CICO Rescue

Scalpel-bougie technique to avoid aerosolization.

Collaboration between Safe Airway Society + RNS ASCAR

@SafeAirway + @RnsAscAr

v1.2 March 2020

## COVID-19 AIRWAY MANAGEMENT

SAFE AIRWAY SOCIETY

### Team Members

### COVID Intubation Tray

<input type="checkbox"/> Macintosh VL blade <input type="checkbox"/> Hyperangulated VL blade (if available) <input type="checkbox"/> Macintosh direct laryngoscope <input type="checkbox"/> SGA (2nd generation) <input type="checkbox"/> ETT (appropriate size range)	<input type="checkbox"/> Bougie / Syer <input type="checkbox"/> 10 ml syringe <input type="checkbox"/> Tube tie <input type="checkbox"/> Lubricant sachet <input type="checkbox"/> Viral filter	<input type="checkbox"/> ETCO2 <input type="checkbox"/> NG tube (large bore) <input type="checkbox"/> OPA + NPA <input type="checkbox"/> Scalpel + bougie CICO kit <input type="checkbox"/> Inline suction
--	---	--

### Circuit Setup

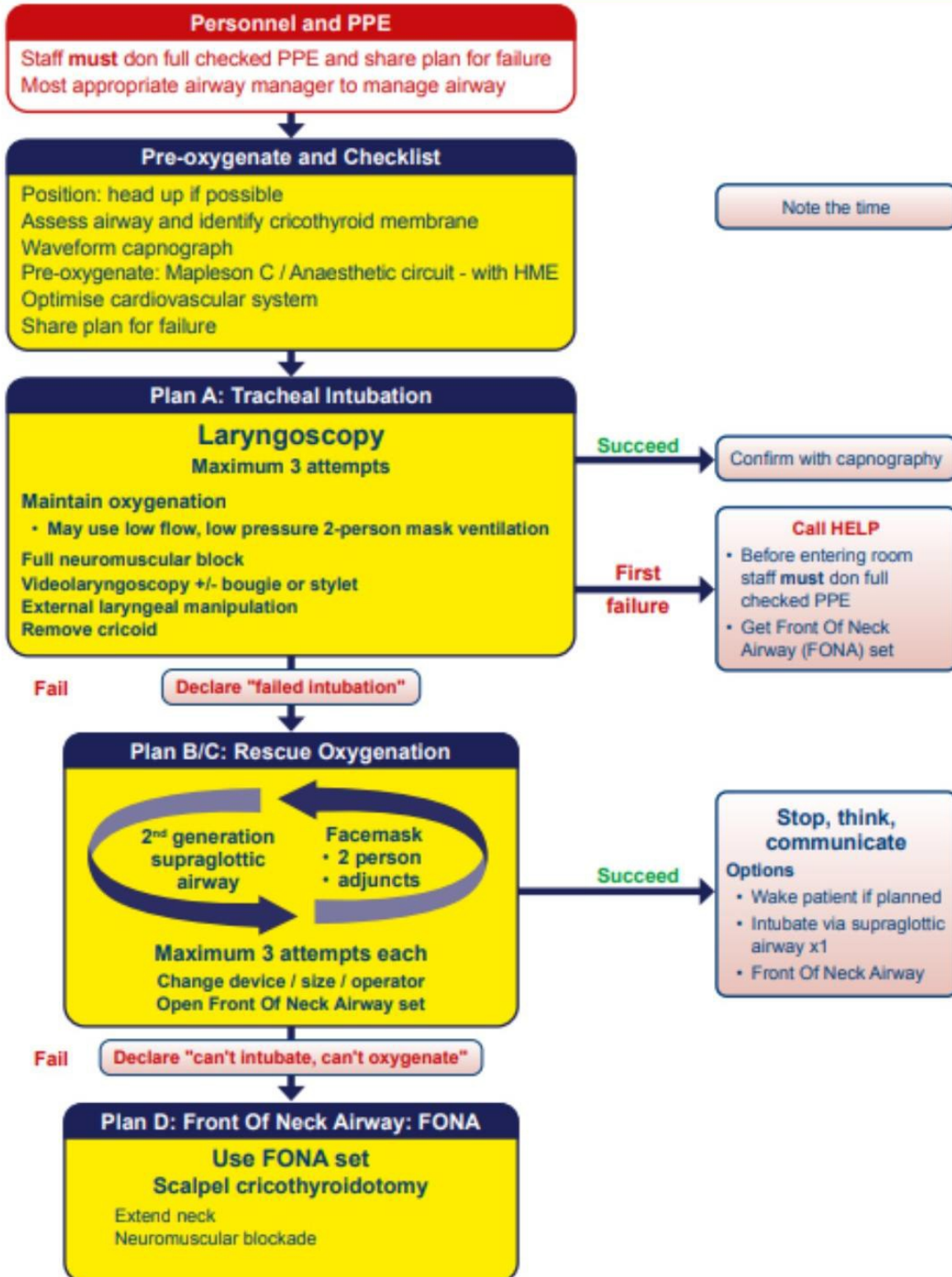
Collaboration between Safe Airway Society + RNS ASCAR

@SafeAirway + @RnsAscAr

v1.2 March 2020



# Adapted for COVID-19



This flowchart forms part of the 2020 COVID-19 Airway Guideline for tracheal intubation. Refer to the full document for further details.

# Can't Intubate, Can't Oxygenate (CICO) in critically ill adults Adapted for **COVID-19**

**CALL FOR HELP**



Declare "Can't Intubate, Can't Oxygenate"

## Plan D: Front Of Neck Airway: FONA

Extend neck

Ensure neuromuscular blockade

Exclude oxygen failure and blocked circuit

### Personnel and PPE

New staff **must** don full checked PPE

Most appropriate airway manager to perform FONA

## Scalpel cricothyroidotomy

**Equipment:** 1. Scalpel (wide blade e.g. number 10 or 20)

2. Bougie ( $\leq 14$  French gauge)

3. Tube (cuffed 5.0-6.0mm ID)

### Laryngeal handshake to identify cricothyroid membrane

#### Palpable cricothyroid membrane

Transverse stab incision through cricothyroid membrane

Turn blade through 90° (sharp edge towards the feet)

Slide Coudé tip of bougie along blade into trachea

Railroad lubricated cuffed tube into trachea

Inflate cuff, ventilate and confirm position with capnography

Secure tube

#### Impalpable cricothyroid membrane

Make a large midline vertical incision

Blunt dissection with fingers to separate tissues

Identify and stabilise the larynx

Proceed with technique for palpable cricothyroid membrane as above

### Post-FONA care and follow up

- Closed tracheal suction
- Recruitment manoeuvre (if haemodynamically stable)
- Chest X-ray
- Monitor for complications
- Surgical review of FONA site
- Agree airway plan with senior clinicians
- Document and complete airway alert

This flowchart forms part of the 2020 COVID-19 Airway Guideline for tracheal intubation. Refer to the full document for further details.

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## APPENDIX I: SAMPLE PROTOCOL FOR EXTUBATION OF COVID-19 PATIENTS\*

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\*Adapted from University Medical Center (Las Vegas, NV)

### Guidelines for Extubation of COVID-19 patients:

- Extubations require 2 HCP's one to hold the mask while the second extubates the patient.
- Whenever possible patient should be placed in negative pressure rooms, and use cube extubation device with plastic shield
- This is considered an aerosolized procedure so proper N-95 masks should be worn, along with goggles, gowns and gloves.
- Place patient at 30 degrees and place nasal cannula on patient at 5-L/M
- Suction ETT and mouth prior to deflating the cuff
- Loosen ETT holder and place anesthesia face mask with HEPA filter attached over the patients nose and mouth leaving space for ETT exiting under the face mask
- IF anesthesia bag is used, use a low oxygen flow, consider attempting to extubate at end of expiration
- Deflate ETT cuff and extubate while maintaining face-mask seal
- Maintain two-handed mask seal until any immediate post-extubation coughing has subsided.
- Remove anesthesia mask and place procedure mask over the patient while wearing nasal cannula oxygen.



Place 5L nasal cannula on patient



Anesthesia mask without anesthesia bag over face-allowing ETT to exit under face mask



Anesthesia mask with anesthesia bag over face-allowing ETT to exit under face mask



## APPENDIX J: TRANSPORT VENTILATOR SET UP GUIDE

### \*COVID-19\* Considerations – 7 April 2020

- A. A standard HME will not suffice for viral filtration. A HMEF (heat-moisture exchanger – filter) provides sufficient bacterial & viral filtration and can be used in place of an HME. If your patient does not already have an HMEF in place, place one prior to putting them on your transport ventilator. HMEFs are intended for extended use and filtration is not degraded over time. Any increase in resistance of gas flow is negligible. A HMEF that does not become visibly soiled can be used for 2-7 days.
- B. If you need to exchange the HMEF or anytime there is a circuit break without a HMEF in-line, you must clamp the ET tube.
- C. Whenever a circuit break is required all members in the area should be wearing full PPE with N95 mask or greater.

Based on availability, transport ventilators should be used with the following order of preference:

- Impact 731
  - Impact 754
  - Lung Transport Ventilator (LTV)
  - LP10 (not shown)
  - Hamilton T1 (only ground evac or *Rotary-wing* transport; Not flight approved for fixed or tilt-wing aircraft)
  - SAVE II
- D. Set up patient side with an HMEF for manual ventilation (below with and without accoutrements), as well as for a transport ventilator. The below three pictures are the “gold standard” for set up and NO additional filters are required.



Bag Valve device with PEEP valve. HMEF is connected between ETT and bag.



Bag Valve device with PEEP valve. In-line suction is on patient side of HMEF. EtCO<sub>2</sub> is between HMEF and bag.



Vent circuit. In-line suction is on patient side of HMEF. EtCO<sub>2</sub> is between HMEF and vent circuit.

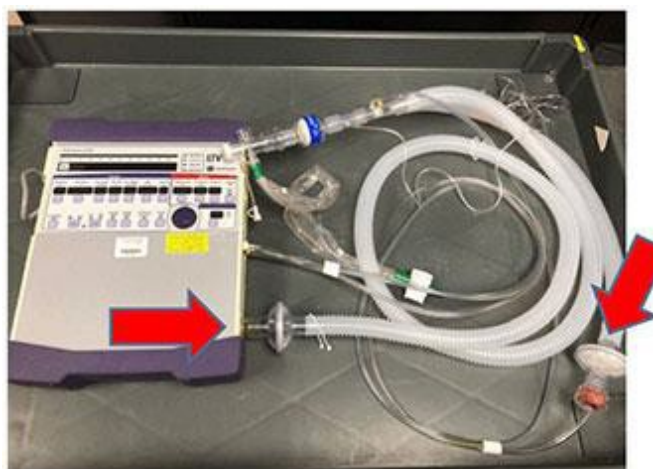
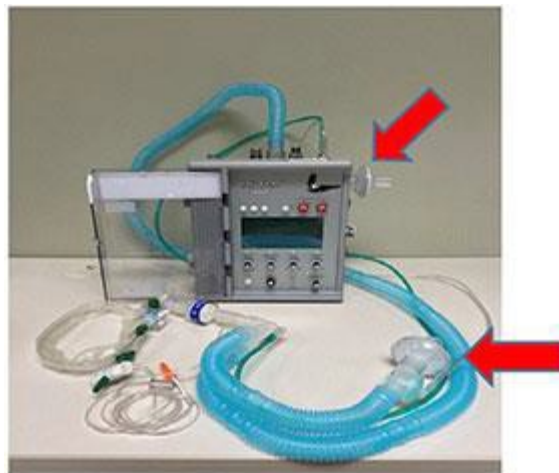
- E. **In the event that HMEFs are not available**, the standard bacterial/viral vent filters will be needed. At a minimum, a filter must be placed on the port that entrains room air and the exhalation valve of the circuit. When disconnecting a patient from the ventilator without a HMEF, a standard bacterial/viral filter must be placed between the BVM and ET tube.

Some examples below:



For the **Impact 731**, place filters on the gas intake and exhalation valve marked by red arrows. It is important to note, that placing a filter on the gas intake (top arrow) will bypass an anti-asphyxiation safety feature. If this filter becomes occluded, a “Fresh Gas Intake Failure” alarm is likely to occur. When this alarm occurs, the patient will no longer be ventilated and will need to be manually ventilated while the vent is reset.

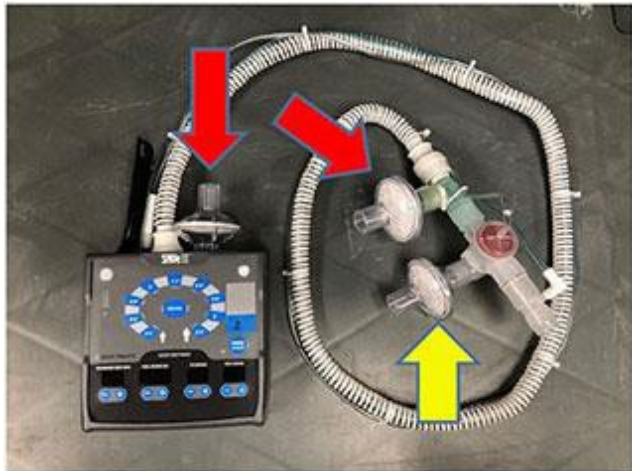
For the **Impact 754 ventilator**, place a filter on the gas intake (top arrow) and at the exhalation valve (bottom arrow). The setup for this ventilator will look identical to that of the Impact 731. The same caution must be taken when placing a filter on the gas intake due to the same risk of blocking gas flow to the ventilator resulting in vent failure.



For the **LTV ventilator**, there are some important considerations. Filters should be placed as marked by the red arrows. It is important to understand that a filter cannot be placed where the vent entrains room air, instead a filter is placed between the vent and the beginning of the circuit (left arrow). Also, to place a filter on the exhalation valve (right arrow), you must remove the exhalation valve and place a filter between the valve on the circuit tubing.

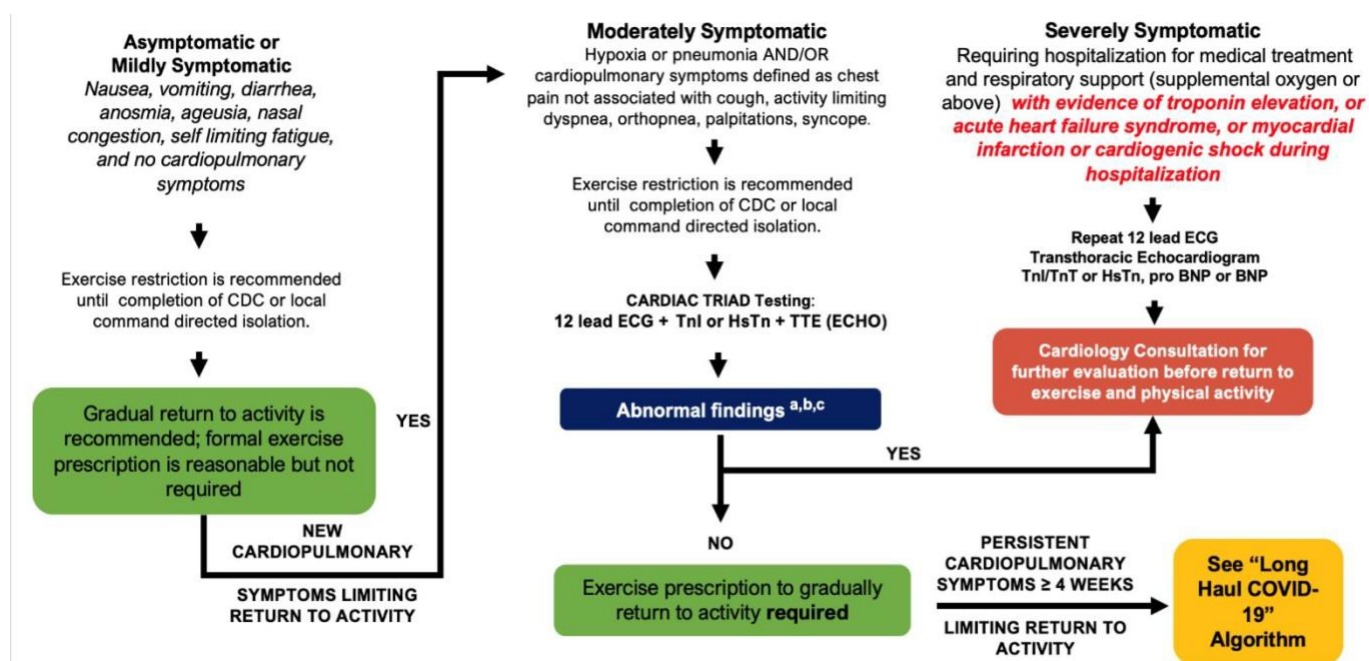


For the **Hamilton T1** ventilator, filters need to be placed on the inhalation and exhalation ports, conveniently located right next to each other. (Ground or Rotary-wing only)



For the **SAVE II** ventilator, 3 filters are necessary. The red arrows mark where room air is entrained into the circuit. The yellow arrow shows the exhalation valve. Not only does using this ventilator require more filters, it is also not ideal for managing mechanically ventilated patients requiring complex ventilator settings.

## APPENDIX K: POST-COVID-19 CARDIOPULMONARY RETURN TO EXERCISE RECOMMENDATIONS



**Figure K-1.** Return to Exercise and Physical Activity Recommendations following COVID-19 infection. Patients with no symptoms or mildly symptomatic infection do not require further evaluation and can return to physical activity without an exercise prescription. Moderate to severely symptomatic patients require further evaluation prior to returning to duty. (ECG, electrocardiogram; TnI, Troponin I; HsTn, high sensitivity troponin; TTE, transthoracic echocardiogram; BNP, B-type natriuretic peptide). See **Figure 14**.

**a: Abnormal ECG findings:** pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions, intraventricular conduction delays (BBB), AV nodal conduction delays (high grade AV block) that are outside of the normal parameters in athletes (<https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.01.015>)

**b: Abnormal Troponin:** >99<sup>th</sup> percent upper limit of normal levels for TnI/TnT or High Sensitivity Troponin I/T.

**c: Abnormal TTE (ECHO):** regional wall motion abnormalities, dilated ventricles, abnormal right or left ventricular systolic function with a reduced EF <45%, moderate pericardial effusion, severe valvular disease, or pulmonary hypertension.

A stepwise return to exercise and physical activity following COVID-19 infection is provided in Figure K-1 with a detailed return to exercise prescription as shown in Figure K-2.

### ASYMPTOMATIC COVID-19 infection

- a. Return to exercise and full physical activity after completion of isolation and meeting DOD Force Health Protection Guidelines Criteria for Redeployment:
  - 1) SM has no clinically significant abnormal findings (normal oxygen saturation on ambient air, stable vital signs, absence of fever).
  - 2) Absence of any symptoms.
  - 3) Confirmation of no exercise limitations or treatment needed.
- b. Repeat medical evaluation is only necessary if moderate cardiovascular symptoms develop following return of physical activity. Service Member (SM) has completed 10 day isolation with exercise limitations.

## Recommended Gradual Return to Exercise and Physical Activity Prescription

	Stage 1	Stage 2	Stage 3A	Stage 3B	Stage 4	Stage 5
<b>Activity Description</b>	Minimum Rest Period	Light Activity	Light Moderate	Moderate Activity	Prolonged Moderate Activity	Normal Training
<b>Exercise Allowed</b>	Walking and Activities of daily living	Walking, light jogging (15min/mile) for 0.5 -0.75 mile  Stationary bike (60 rpm, 0-25 Watts).  No resistance training.	Jogging (12-15min/mile) for 1 mile  Stationary bike (60 rpm, 25-50 Watts).  Low resistance training.	Slow run 10-15min/mile for 1.5 miles  Stationary bike (60 rpm 50-125 Watts)  Moderate resistance training	Run 10-12 min/mile for 1.5-2.5 miles  Stationary bike (60 rpm, 150+ Watts)  Moderate to High resistance training	Normal training exercise activities
<b>% Heart Rate MAX (220- age)</b>	N/A	<70%	<80%	<80%	<80%	Normal training
<b>Duration</b>	N/A	<15 min	<30min	<45min	<60min	Normal training duration
<b>Objective</b>	Allow time for recovery. Protect cardiorespiratory system	Gradual increase in HR	Increase load gradually. Manage post viral fatigue syndrome.	Exercise coordination and skills.	Restore confidence and assess functional skills	Resume standard fitness routine

	Stage 1 REST/ No activity	Stage 2 Light activity	Stage 3A Light Moderate Activity	Stage 3B Moderate Activity	Stage 4 Prolonged Moderate	Stage 5 Normal Training
<b>Mild Symptoms</b> <small>Nausea, vomiting, diarrhea, anosmia, ageusia, nasal congestion, self limiting fatigue, and no cardiovascular symptoms</small>	Activity restriction during isolation	1 day minimum	1 day minimum	1 day minimum	1 day minimum	Earliest Day 14
<b>Moderate Symptoms</b> <small>Hypoxia or pneumonia AND/OR cardiopulmonary symptoms defined as chest pain not associated with cough, activity limiting dyspnea, orthopnea, palpitations, syncope.</small>	Activity restriction during isolation	2 days minimum	2 days minimum	2 days minimum	2 days minimum	Earliest Day 18
<b>Severe symptoms</b> <small>Requiring hospitalization for medical treatment and respiratory support (supplemental oxygen or above) with evidence of troponin elevation, or acute heart failure syndrome, or myocardial infarction or cardiogenic shock during hospitalization</small>	Strict 3-6 months of activity restriction required if diagnosed with myocarditis/myopericarditis and must remain on stage 1 until cleared by cardiology to resume activity	5 days minimum	5 days minimum	5 days minimum	5 days minimum	Earliest Day 30

Adapted from Elliot N, et al. Br J Sports Med 2020

**New onset OR persistence of moderate symptoms lasting  $\geq 4$  weeks limiting return to exercise prescription require cessation of activity and further cardiac evaluation (see "Long Haul COVID 19" Algorithm)**

*Figure K-2. Return to exercise and physical activity prescription. Service members with mild symptoms can return to exercise and physical activity without an exercise prescription. Service members with moderate symptoms or severe symptoms should complete the minimum days of exercise prescription as above prior to returning to normal training.*

### MILDLY SYMPTOMATIC COVID-19 infection

- Defined as symptoms of nausea, vomiting, diarrhea, anosmia or ageusia, nasal congestion, or self-limiting fatigue with no cardiovascular symptoms.
- May consider gradual return with an exercise prescription but it is not required after completion of isolation and meeting DOD Force Health Protection Guideline Criteria for Redeployment:



- 1) SM has no clinically significant abnormal findings (normal oxygen saturation on ambient air, stable vital signs, absence of fever).
  - 2) Absence of any cardiopulmonary symptoms (chest pain not associated with cough, activity limiting dyspnea, orthopnea, palpitations, syncope or near syncope) at time of exam or reported during disease course.
  - 3) Confirmation of no exercise limitations or treatment needed.
- c. SM should cease physical activity and undergo a repeat evaluation with the development of moderate cardiovascular symptoms during return to physical activity. Defined as symptoms of nausea, vomiting, diarrhea, anosmia or ageusia, nasal congestion, or self-limiting fatigue.

#### **MODERATELY SYMPTOMATIC COVID-19 infection**

- a. Defined as symptoms of hypoxia or pneumonia, or cardiopulmonary symptoms (chest pain not associated with cough, activity-limiting dyspnea, orthopnea, palpitations, syncope) during or following COVID 19 infection.
- b. SM with should complete the following cardiac tests prior to return to duty
  - 1) 12 lead Electrocardiogram (ECG)
  - 2) Troponin I/ T or HsTn: Ensure cardiac enzyme tests are performed at least 24-48hrs after last exercise session. In the event of isolated abnormalities, confirm that the patient is adherent to this brief period of abstinence from exercise prior to repeating the test.
  - 3) Transthoracic Echocardiogram.
- c. If evaluation demonstrates evidence of any abnormal cardiac findings as listed below, SM needs further cardiology evaluation before return to exercise and physical activity.
  - 1) **Abnormal ECG findings:** pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions, intraventricular conduction delays (BBB), AV nodal conduction delays (high grade AV block) that are outside of the normal parameters in athletes (<https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.01.015>)
  - 2) **Abnormal Troponin:** >99th percent upper limit of normal levels for TnI/TnT or High Sensitivity Troponin I/T.
  - 3) **Abnormal TTE:** regional wall motion abnormalities, dilated ventricles, abnormal right or left ventricular systolic function with a reduced EF <45%, severe valvular disease, or pulmonary hypertension.
- d. Gradual return with an exercise prescription after completion of isolation, completion of cardiac tests, and meeting DOD Force Health Protection Guideline Criteria for Redeployment:
  - 1) SM has no clinically significant abnormal findings (normal oxygen saturation on ambient air, stable vital signs, absence of fever).
  - 2) Absence of abnormal cardiac test findings:
    - ECG without abnormalities
    - No evidence of myocardial injury by cardiac biomarkers
    - No abnormalities on TTE
  - 3) Confirmation of no further treatment needed SM has been cleared to return from isolation in accordance with local public health guidance.

#### **SEVERELY SYMPTOMATIC COVID-19 infection:**

- a. Defined as symptoms of hypoxia or pneumonia requiring hospitalization for medical treatment with respiratory support (supplemental oxygen or above) with evidence of troponin elevation (myocardial injury), or acute heart failure syndrome, or myocardial infarction, or cardiogenic shock during hospitalization.

- b. The following are required prior to return to duty after hospital discharge.
  - 1) 12 lead ECG
  - 2) Troponin I/T or HsTn
  - 3) Transthoracic Echocardiogram
- c. Cardiology Consultation for further evaluation to determine if further cardiac MRI or other evaluation is warranted or if myocarditis/myopericarditis criteria is met.
- d. Activity restriction for 3-6 months if diagnosis of myocarditis/myopericarditis is made by cardiologist.
  - 1) SM must complete the following evaluation before return to exercise and physical activity (by Cardiologist):
    - 2) 12 lead ECG
    - 3) Troponin I or High Sensitivity Troponin
    - 4) Natriuretic peptide (BNP or NT-pro BNP)
    - 5) Other supplemental studies to show resolution of COVID sequela and demonstrate normalization of end organ function (i.e. CXR, ESR, CRP)
    - 6) Transthoracic Echocardiogram (after completion of activity restriction)
    - 7) 2-week ambulatory cardiac event monitoring
    - 8) Cardiac MRI with T1, T2 mapping and late gadolinium enhancement (LGE). This should be performed by a DHA cardiac imaging center or center specializing in advanced cardiac imaging of high-level athletes.
    - 9) Graded Exercise stress test after completion of the tests above if no abnormalities, and asymptomatic.
  - 10) Cardiology evaluation to ensure safe return to exercise.
- e. SM should receive an exercise prescription to gradually re-acclimatize to activity based on severe symptoms categorization after being cleared to resume exercise by a cardiologist in the presence of low-risk findings. SM should undergo a repeat evaluation with recurrence of any symptoms.
- f. Severe Symptoms associated with a stroke, significant venous thromboembolism, respiratory failure, myocardial infarction, cardiac failure, renal failure, other end-organ failure: RTD based on expert consultation and case-by-case consideration for retention vs. referral to DES/MEB.



**Weight-Based Heparin Dosing for Venous Thromboembolism, anti-Xa goal 0.3-0.7****Initial Therapy**

Bolus <sup>a</sup>	80 units/kg
Infusion <sup>a</sup>	18 units/kg/hr

**Adjustments<sup>b</sup>**

Anti-Xa <0.2	Increase by 4 units/kg/hr
Anti-Xa 0.2-0.29	Increase by 2 units/kg/hr
Anti-Xa 0.3-0.7	No Change
Anti-Xa 0.71-0.8	Decrease by 1 unit/kg/hr
Anti-Xa 0.81-0.9	Hold for 0.5 hr; Decrease by 2 units/kg/hr
Anti-Xa >0.9	Hold for 1 hr; Decrease infusion by 3 units/kg/hr

(maximum 5,000 units), and typical initial infusion dose is 12 units/kg/hr (maximum 1,000 units/hr).

<sup>a</sup>Round all doses to nearest 100 units.

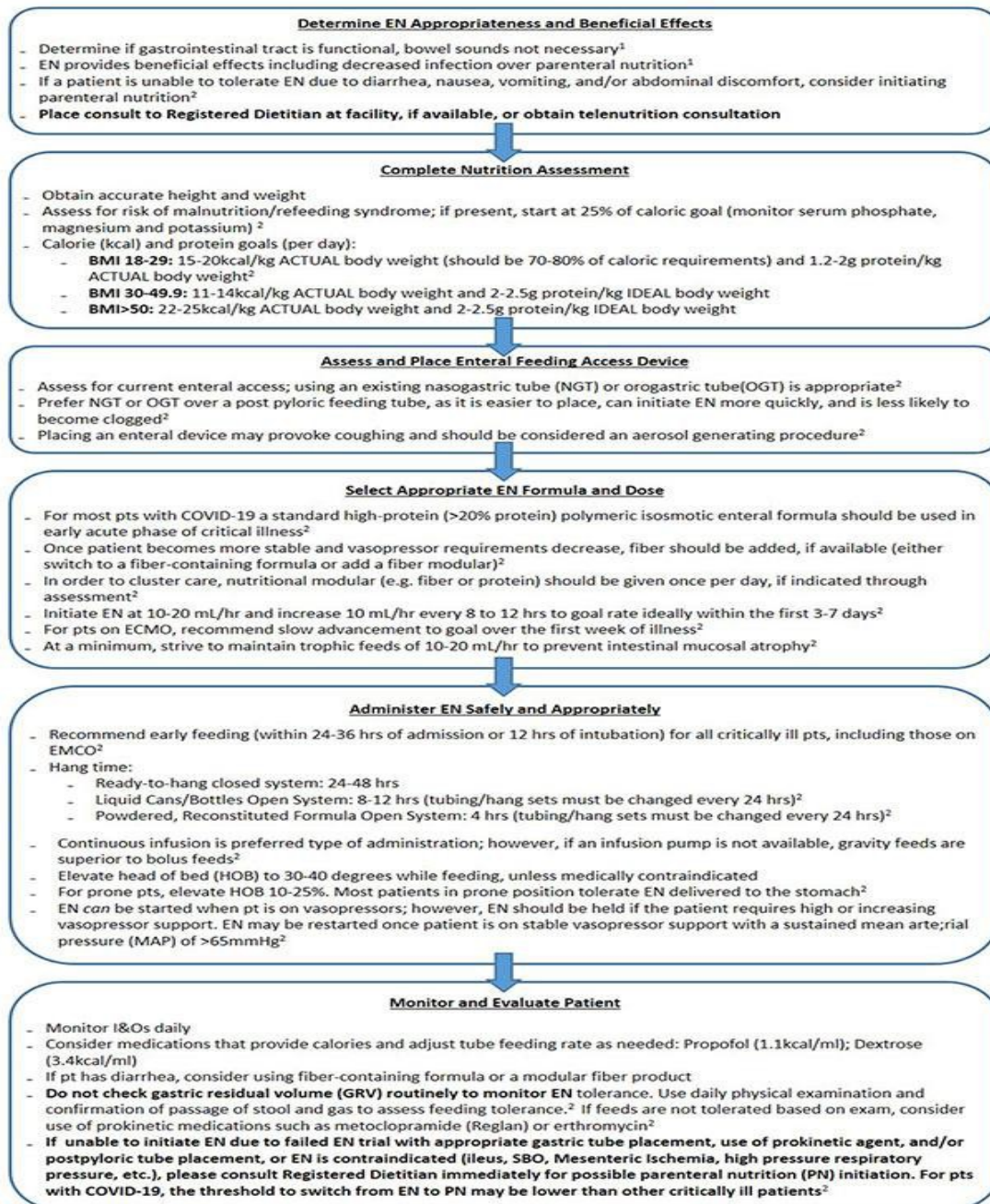
<sup>b</sup>Draw Anti-Xa 6 hours after STARTING therapy and 6 hours after any CHANGE in infusion rate.

Adapted from <https://journals.sagepub.com/doi/pdf/10.1345/aph.1Q161>

## APPENDIX M: ENTERAL NUTRITION CARE PATHWAY FOR PATIENTS WITH COVID-19

### Enteral Nutrition (tube feeding) Care Pathway for Critically-Ill Adult Patients Diagnosed with COVID-19

This pathway provides steps and resources for managing critically-ill adult patients (pts) requiring enteral nutrition (EN).

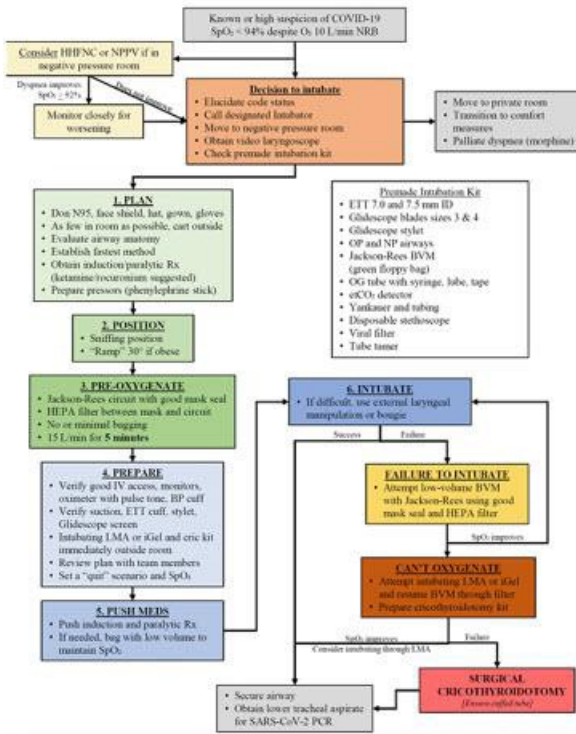


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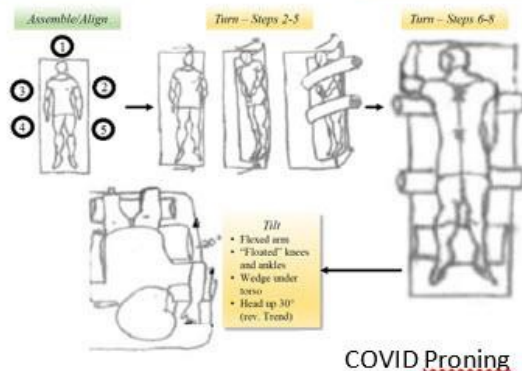
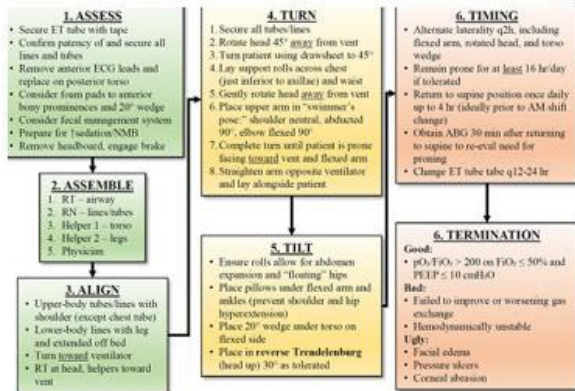
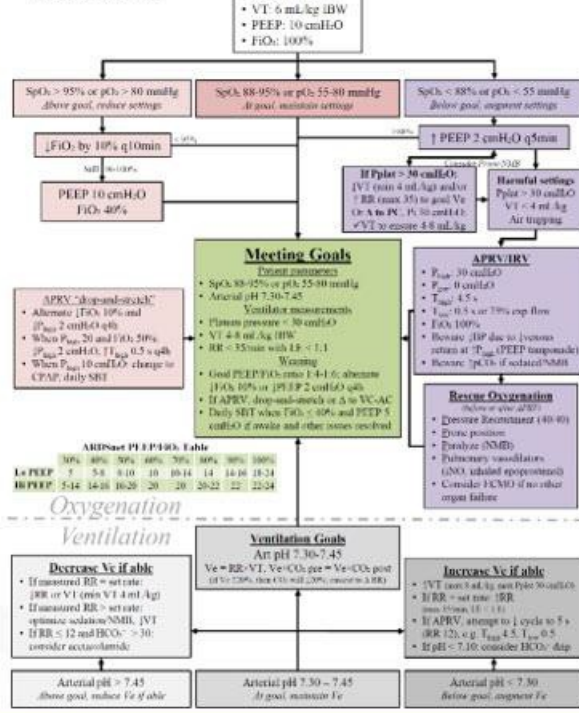
1. McClave, SA, Taylor BE, Martindale RD, et al; Society of Critical Care Medicine, American Society for Parenteral and Enteral Nutrition. Guidelines for the provision and assessment of nutrition support therapy in the adult critically ill patient: Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (ASPEN). *JPEN J Parenter Enteral Nutr.* 2016;40:159-211.
2. Martindale R, Patel JJ, Taylor B, Warren M. & McClave SA. Nutrition Therapy in the Patient with COVID-19 Disease Requiring ICU Care. Reviewed and approved by ASPEN and Society for Critical Care Medicine 26 May 2020. [https://www.nutritioncare.org/Guidelines\\_and\\_Critical\\_Resources/Resources\\_for\\_Clinicians\\_Caring\\_for\\_Patients\\_with\\_Coronavirus/](https://www.nutritioncare.org/Guidelines_and_Critical_Resources/Resources_for_Clinicians_Caring_for_Patients_with_Coronavirus/)
3. Abbott Laboratories. Guideline to Adult Tubefeeding. November 2018. [https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/182393-Adult-tube-feeding-home\\_tcm1226-57870.pdf](https://static.abbottnutrition.com/cms-prod/abbottnutrition-2016.com/img/182393-Adult-tube-feeding-home_tcm1226-57870.pdf)

## APPENDIX N: SAMPLE PROTOCOLS FOR VARIOUS ICU MANAGEMENT

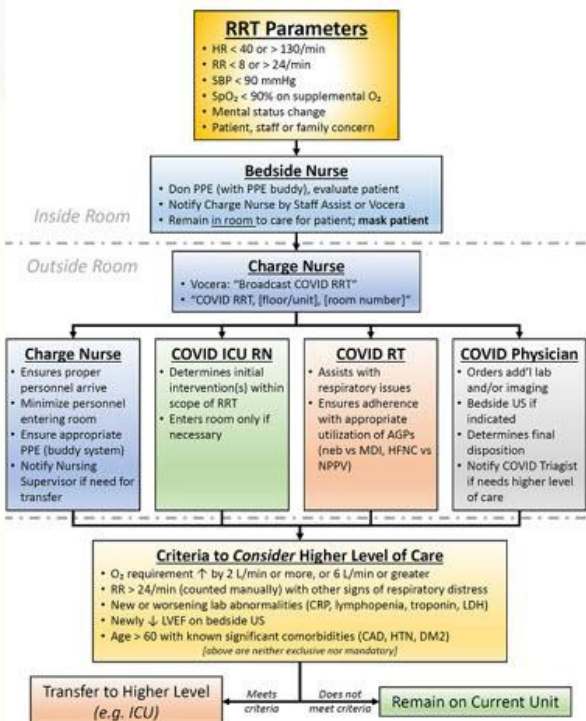
### Intubation



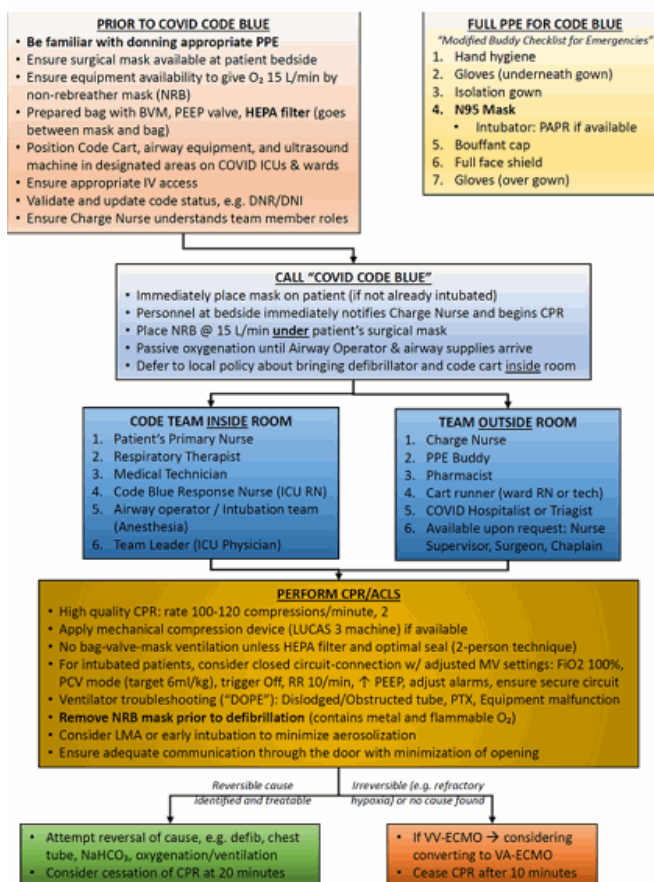
### Mechanical Ventilation



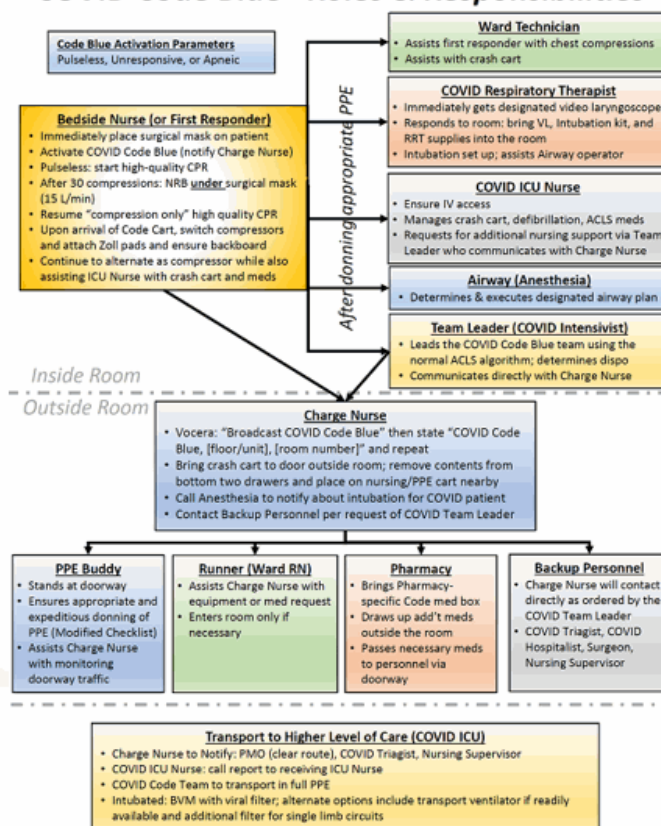
### COVID Rapid Response Team



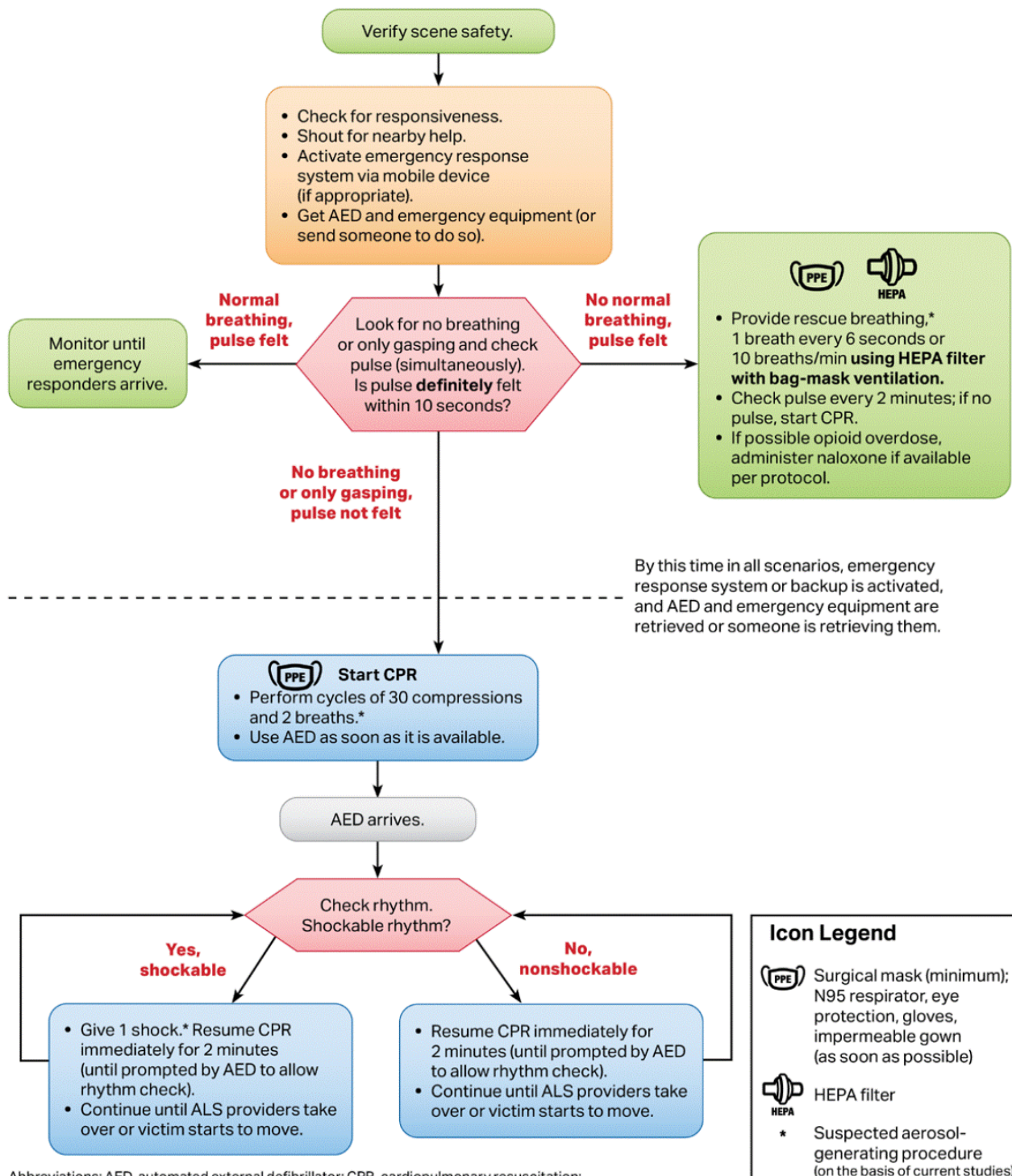




## COVID Code Blue - Roles & Responsibilities

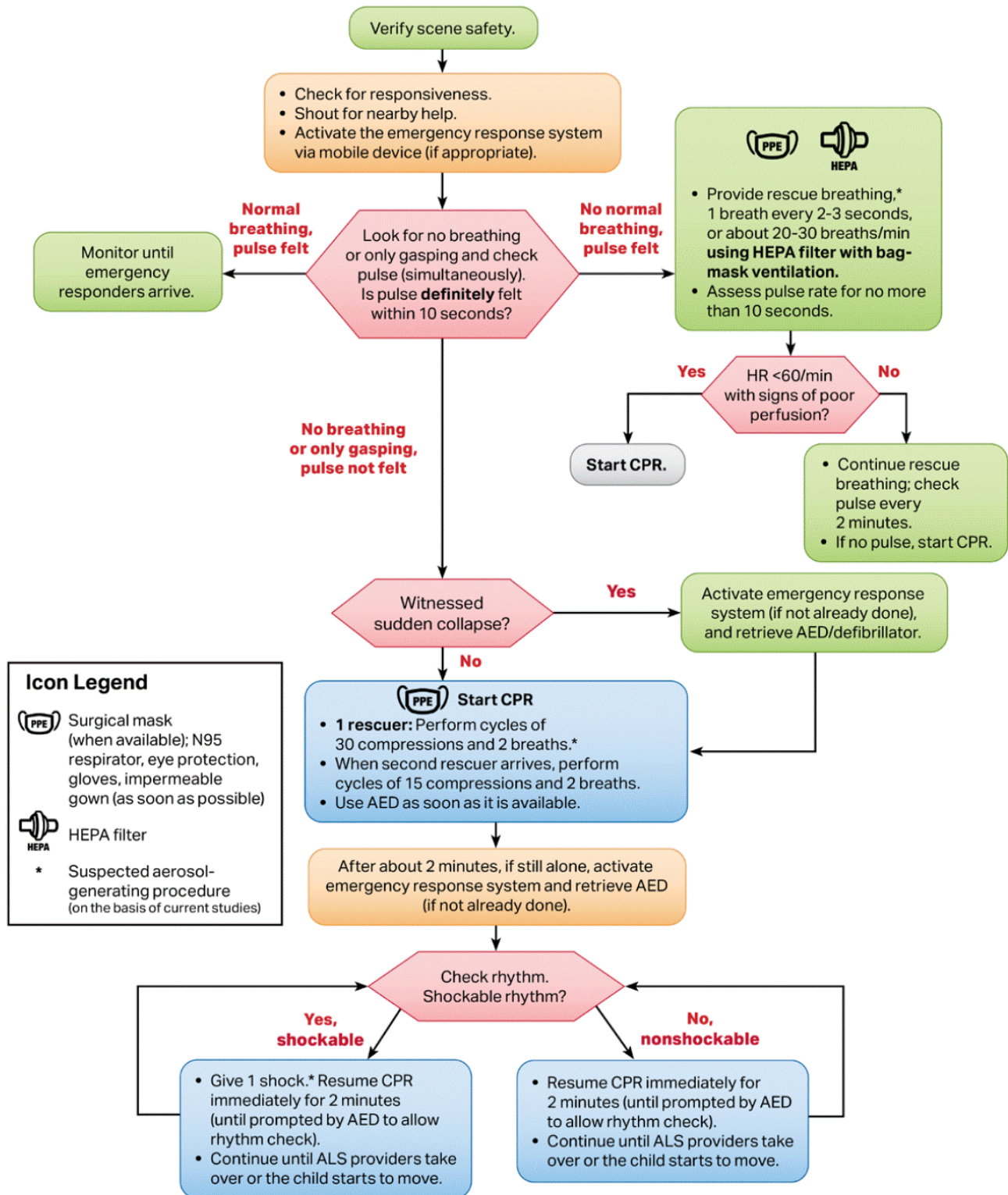


# Adult Basic Life Support Algorithm for Healthcare Providers for Suspected or Confirmed COVID-19





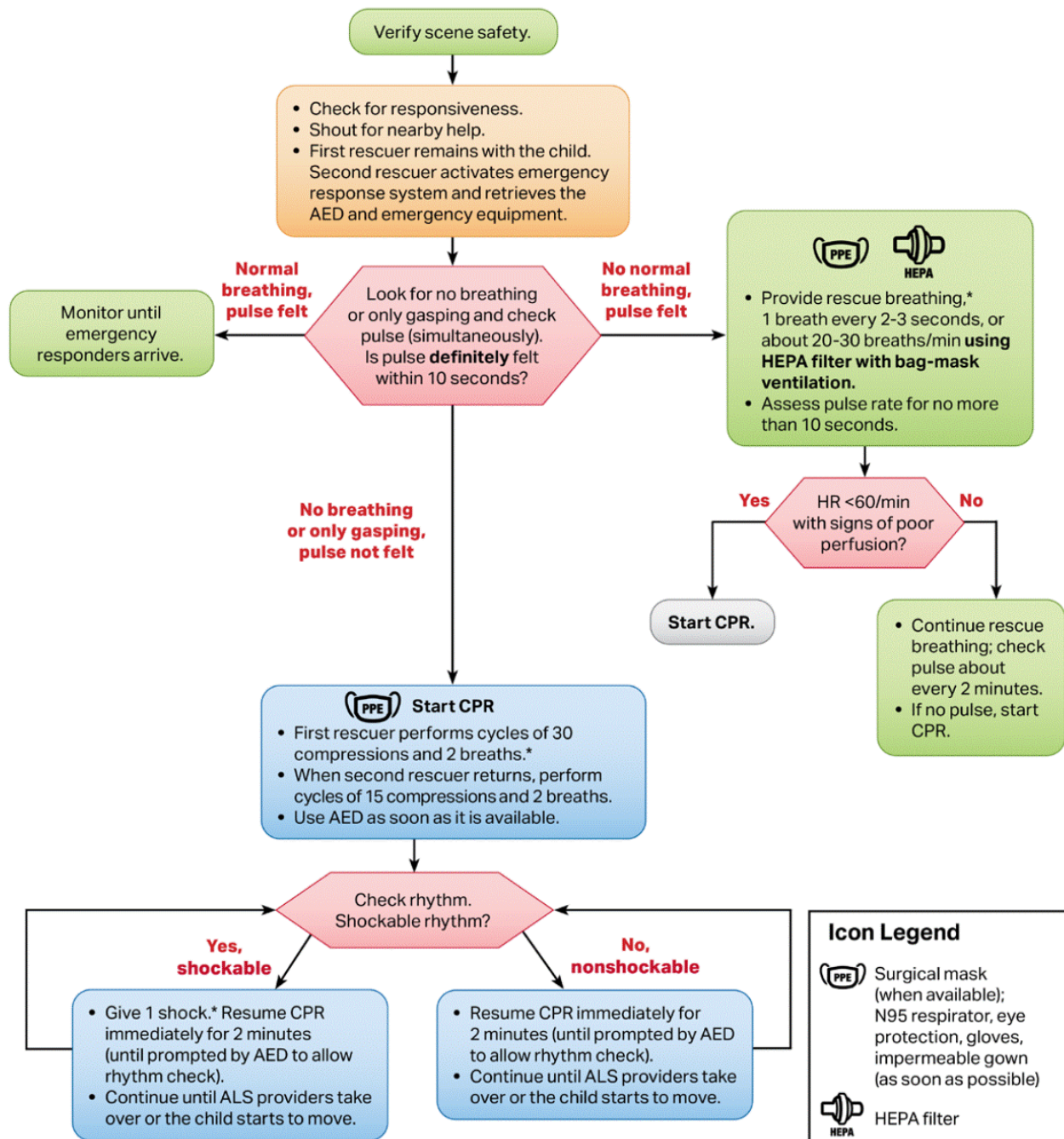
## Pediatric Basic Life Support Algorithm for Healthcare Provider—Single Rescuer for Suspected or Confirmed COVID-19



Abbreviations: AED, automated external defibrillator; ALS, advanced life support; CPR, cardiopulmonary resuscitation; HEPA, high-efficiency particulate air; HR, heart rate; PPE, personal protective equipment.

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## Pediatric Basic Life Support Algorithm for Healthcare Providers—2 or More Rescuers for Suspected or Confirmed COVID-19

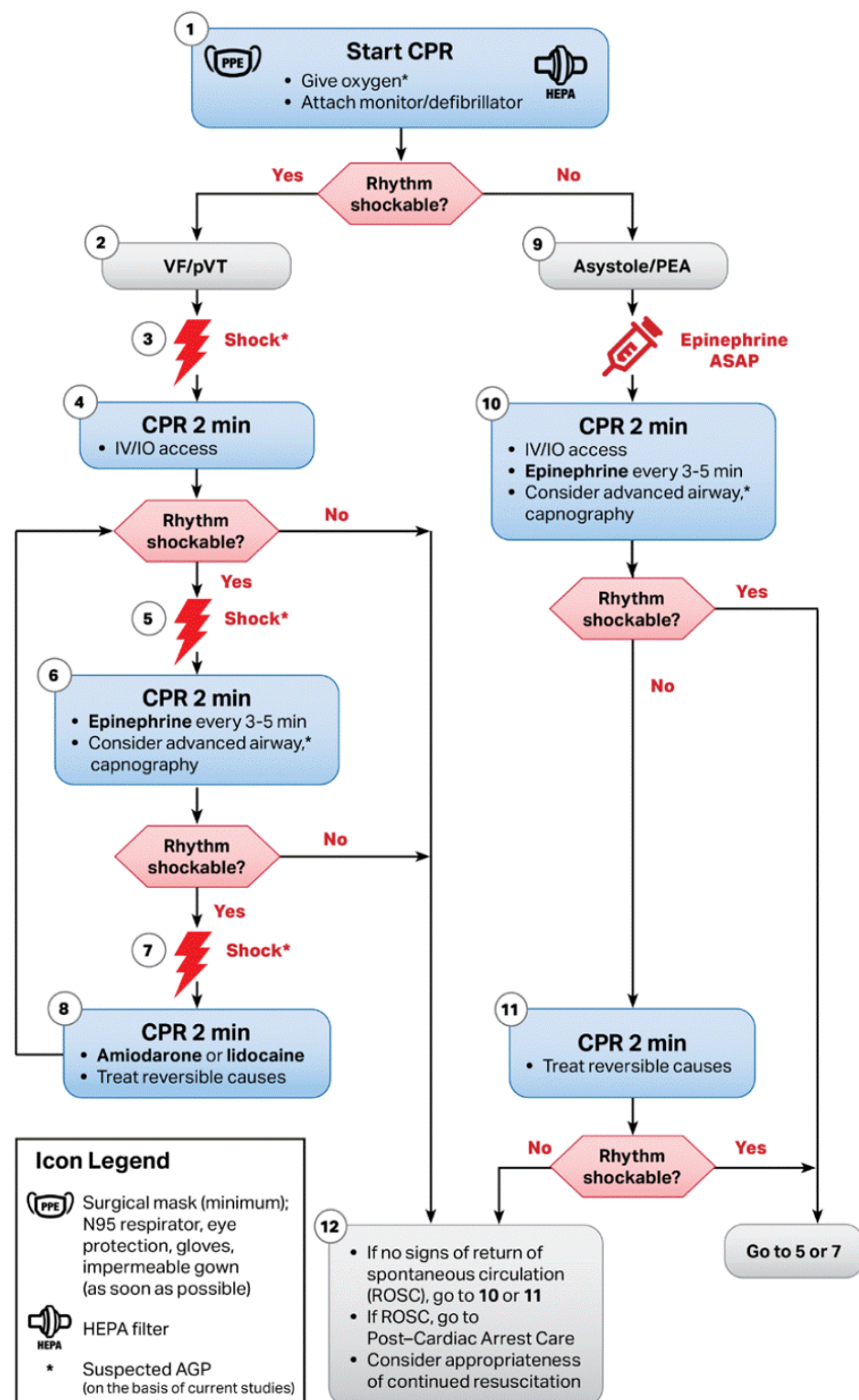


Abbreviations: AED, automated external defibrillation; ALS, advanced life support; CPR, cardiopulmonary resuscitation; HEPA, high-efficiency particulate air; HR, heart rate; PPE, personal protective equipment.

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# Adult Cardiac Arrest Algorithm for Patients With Suspected or Confirmed COVID-19 (VF/pVT/Asystole/PEA)



Abbreviations: AGP, aerosol-generating procedure; CPR, cardiopulmonary resuscitation; ET, endotracheal; HEPA, high-efficiency particulate air; IO, intraosseous; IV, intravenous; PEA, pulseless electrical activity; PPE, personal protective equipment; ROSC, return of spontaneous circulation; VF, ventricular fibrillation; pVT, pulseless ventricular tachycardia.

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## CPR Quality

- Push hard (at least 2 inches [5 cm]) and fast (100-120/min) and allow complete chest recoil.
- Minimize interruptions in compressions.
- Avoid excessive ventilation.
- Change compressor every 2 minutes, or sooner if fatigued.
- If no advanced airway, 30:2 compression-ventilation ratio.
- Quantitative waveform capnography
  - If PETCO<sub>2</sub> is low or decreasing, reassess CPR quality.

## Shock Energy for Defibrillation

- Biphasic:** Manufacturer recommendation (eg, initial dose of 120-200 J); if unknown, use maximum available. Second and subsequent doses should be equivalent, and higher doses may be considered.
- Monophasic:** 360 J

## Drug Therapy

- Epinephrine IV/IO dose:** 1 mg every 3-5 minutes
- Amiodarone IV/IO dose:** First dose: 300 mg bolus. Second dose: 150 mg.
- Lidocaine IV/IO dose:** First dose: 1-1.5 mg/kg. Second dose: 0.5-0.75 mg/kg.

## Advanced Airway

- Rapidly apply PPE before AGPs.**
- Provide endotracheal intubation or supraglottic advanced airway.
- For all ventilation, use a HEPA filter.**
- Perform waveform capnography or capnometry to confirm and monitor ET tube placement.
- Once advanced airway is in place, give 1 breath every 6 seconds (10 breaths/min) with continuous chest compressions.

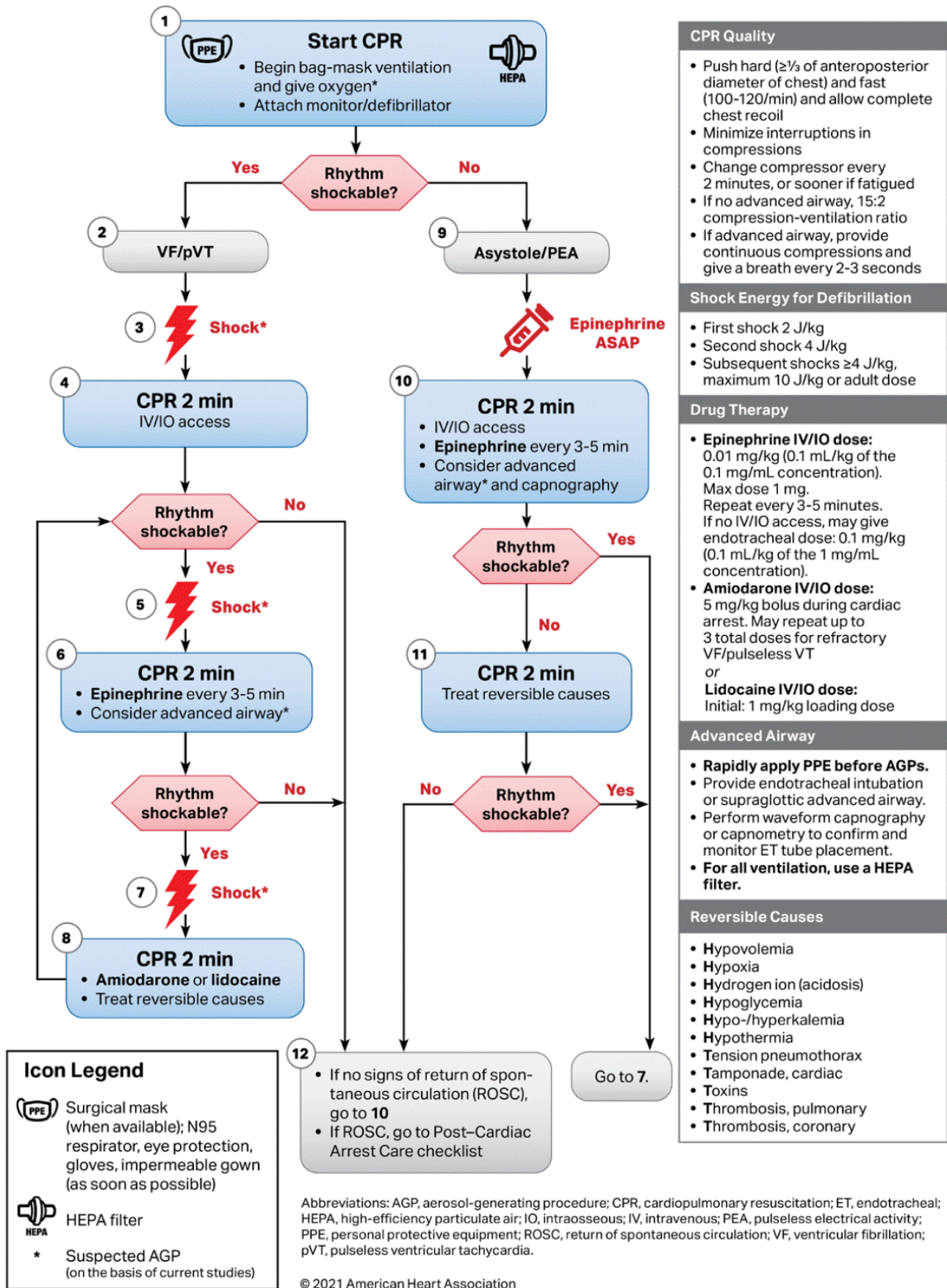
## Return of Spontaneous Circulation (ROSC)

- Pulse and blood pressure
- Abrupt sustained increase in PETCO<sub>2</sub> (typically ≥40 mm Hg)
- Spontaneous arterial pressure waves with intra-arterial monitoring

## Reversible Causes

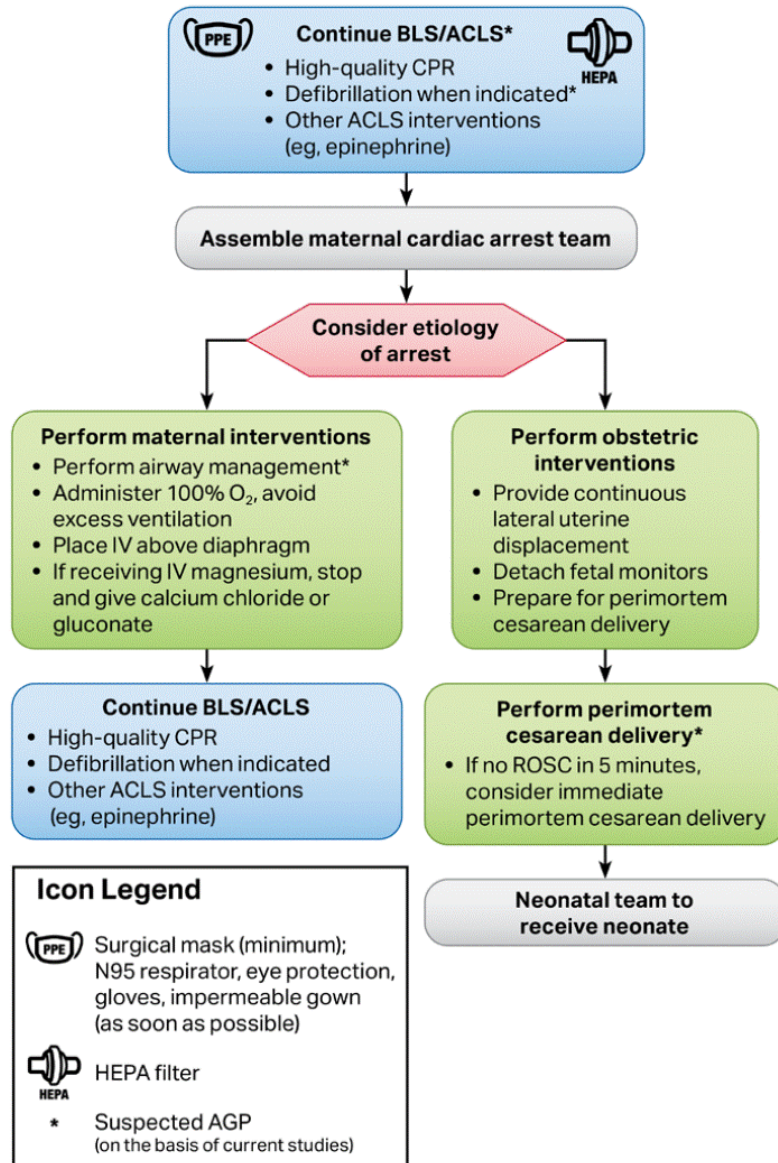
- Hypovolemia
- Hypoxia
- Hydrogen ion (acidosis)
- Hypo-/hyperkalemia
- Hypothermia
- Tension pneumothorax
- Tamponade, cardiac
- Toxins
- Thrombosis, pulmonary
- Thrombosis, coronary

# Pediatric Cardiac Arrest Algorithm for Patients With Suspected or Confirmed COVID-19





## Cardiac Arrest in Pregnancy In-Hospital ACLS Algorithm for Patients With Suspected or Confirmed COVID-19



Abbreviations: ACLS, advanced cardiovascular life support; AGP, aerosol-generating procedure; BLS, basic life support; CPR, cardiopulmonary resuscitation; ET, endotracheal; HEPA, high-efficiency particulate air; IV, intravenous; PPE, personal protective equipment; ROSC, return of spontaneous circulation.

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### Maternal Cardiac Arrest

- Team planning should be done in collaboration with the obstetric, neonatal, emergency, anesthesiology, intensive care, and cardiac arrest services.
- Priorities for pregnant women in cardiac arrest should include provision of high-quality CPR and relief of aortocaval compression with lateral uterine displacement.
- The goal of perimortem cesarean delivery is to improve maternal and fetal outcomes.
- Ideally, perform perimortem cesarean delivery\* in 5 minutes, depending on provider resources and skill sets.

### Advanced Airway

- **Rapidly apply PPE before AGPs.**
- In pregnancy, a difficult airway is common. Use the most experienced provider.
- Provide endotracheal intubation or supraglottic advanced airway.
- Perform waveform capnography or capnometry to confirm and monitor ET tube placement.
- **For all ventilation, use a HEPA filter.**
- Once advanced airway is in place, give 1 breath every 6 seconds (10 breaths/min) with continuous chest compressions.

### Potential Etiology of Maternal Cardiac Arrest

- A** Anesthetic complications
- B** Bleeding
- C** Cardiovascular
- D** Drugs
- E** Embolic
- F** Fever
- G** General nonobstetric causes of cardiac arrest (H's and T's)
- H** Hypertension



## APPENDIX P: IDSA COVID-19 TREATMENT GUIDELINES (v5.6.0 - November 18, 2021)

### Overview of IDSA COVID-19 Treatment Guidelines

Version 5.6.0 – November 18, 2021

		<i>Post-exposure prophylaxis: exposed and healthy</i>	<i>Ambulatory care: mild-to- moderate disease</i>	<i>Hospitalized: mild-to- moderate disease without need for suppl. oxygen</i>	<i>Hospitalized: severe but non-critical disease (SpO<sub>2</sub> ≤94% on room air)</i>	<i>Hospitalized: critical disease (e.g., in ICU needing MV, or septic shock, ECMO)</i>
1	Hydroxy- chloroquine*	NA	NA	Recommend against use ⊕⊕⊕○	Recommend against use ⊕⊕⊕○	Recommend against use ⊕⊕⊕○
2	Hydroxy- chloroquine* + azithromycin	NA	NA	Recommend against use ⊕⊕○○	Recommend against use ⊕⊕○○	Recommend against use ⊕⊕○○
3	Post-exposure hydroxy- chloroquine	Recommend against use ⊕⊕⊕○	NA	NA	NA	NA
4	Lopinavir + ritonavir	NA	NA	Recommend against use ⊕⊕⊕○	Recommend against use ⊕⊕⊕○	Recommend against use ⊕⊕⊕○
5-7	Corticosteroid s	NA	NA	Suggest against use ⊕○○○	Suggest use ⊕⊕⊕○  R: If dexamethasone is unavailable, equivalent total daily doses of alternative glucocorticoids may be used.**	Recommend use ⊕⊕⊕○  R: If dexamethasone is unavailable, equivalent total daily doses of alternative glucocorticoids may be used.**
8	Tocilizumab	NA	NA	NA	Suggest use ⊕⊕○○  R: Patients, particularly those who respond to steroids alone, who put a high value on avoiding possible adverse events of tocilizumab and a low value on the uncertain mortality reduction, would reasonably decline tocilizumab.  R: In the largest trial on the treatment of tocilizumab,	Suggest use ⊕⊕○○  R: Patients, particularly those who respond to steroids alone, who put a high value on avoiding possible adverse events of tocilizumab and a low value on the uncertain mortality reduction, would reasonably decline tocilizumab.  R: In the largest trial on the treatment of tocilizumab,
		<i>exposed and healthy</i>	<i>moderate disease</i>	<i>moderate disease without need for suppl. oxygen</i>	<i>non-critical disease (SpO<sub>2</sub> ≤94% on room air)</i>	<i>(e.g., in ICU needing MV, or septic shock, ECMO)</i>
					criterion for systemic inflammation was defined as CRP ≥75 mg/L	criterion for systemic inflammation was defined as CRP ≥75 mg/L
9	Sarilumab	NA	NA	NA	Suggest use ⊕○○○  R: Patients, particularly those who respond to steroids alone, who put a high value on avoiding possible adverse events of sarilumab and a low value on the uncertain mortality reduction, would reasonably decline sarilumab.	Suggest use ⊕○○○  R: Patients, particularly those who respond to steroids alone, who put a high value on avoiding possible adverse events of sarilumab and a low value on the uncertain mortality reduction, would reasonably decline sarilumab.
10- 11	Convalescent plasma	NA	Suggest against use outside context of a clinical trial ⊕⊕○○	Recommend against use ⊕⊕⊕○	Recommend against use ⊕⊕⊕○	Recommend against use ⊕⊕⊕○
12- 14	Remdesivir	NA	NA	Suggest against routine use ⊕○○○	Suggest use ⊕⊕⊕○  <i>5 days vs. 10 days, on supplemental oxygen but without mechanical ventilation or ECMO:</i>  Suggest use ⊕⊕○○	<i>Routine initiation of remdesivir:</i> Suggest against use ⊕○○○
15	Famotidine	NA	NA	Suggest against use outside context of a clinical trial ⊕○○○	Suggest against use outside context of a clinical trial ⊕○○○	Suggest against use outside context of a clinical trial ⊕○○○
16	Post-exposure casirivimab/ imdevimab	Suggest use*** ⊕⊕○○  R: Dosing for	NA	NA	NA	NA

		<b>Post-exposure prophylaxis:</b> <i>exposed and healthy</i>	<b>Ambulatory care:</b> <i>mild-to-moderate disease</i>	<b>Hospitalized:</b> <i>mild-to-moderate disease without need for suppl. oxygen</i>	<b>Hospitalized:</b> <i>severe but non-critical disease (SpO<sub>2</sub> ≤94% on room air)</i>	<b>Hospitalized:</b> <i>critical disease (e.g., in ICU needing MV, or septic shock, ECMO)</i>
		casirivimab 600 mg & imdevimab 600 mg IV or SC once.				
17	Bamlanivimab / etesevimab <i>OR</i> Casirivimab/imdevimab <i>OR</i> Sotrovimab	NA	<p><b>Suggest use****</b> ⊕⊕⊕○</p> <p><b>R:</b> Dosing for casirivimab/imdevimab is casirivimab 600 mg and imdevimab 600 mg IV. Subcutaneous injection is a reasonable alternative in patients for whom it cannot be given intravenously.</p> <p><b>R:</b> Dosing for sotrovimab is sotrovimab 500 IV once.</p> <p><b>R:</b> Dosing for bamlanivimab/etesevimab is bamlanivimab 700 mg and etesevimab 1400 mg IV or SC once.</p> <p><b>R:</b> Patients with mild to moderate COVID-19 who are at high risk of progression to severe disease admitted to the hospital for reasons other than COVID-19 may also receive bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab.</p> <p><b>R:</b> Local variant susceptibility should be considered in the choice of the most appropriate neutralizing antibody therapy. Local availability of different monoclonal antibody</p>	NA	NA	NA
		<i>exposed and healthy</i>	<i>moderate disease</i>	<i>moderate disease without need for suppl. oxygen</i>	<i>non-critical disease (SpO<sub>2</sub> ≤94% on room air)</i>	<i>(e.g., in ICU needing MV, or septic shock, ECMO)</i>
			<p>combinations may be affected by predominance of local variants.</p> <p><b>R:</b> There are limited data on efficacy of bamlanivimab/etesevimab, casirivimab/imdevimab, or sotrovimab in high-risk patients under 18 years of age.</p>			
18	Bamlanivimab monotherapy	NA	NA	NA	<p><b>Recommend against use</b> ⊕⊕⊕○</p>	NA
19	Baricitinib + remdesivir + corticosteroids	NA	NA	NA	<p><b>Suggest use</b> ⊕⊕⊕○</p> <p><b>R:</b> Baricitinib 4 mg per day (or appropriate renal dosing) up to 14 days or until discharge from hospital.</p> <p><b>R:</b> Baricitinib appears to demonstrate the most benefit in those with severe COVID-19 on high-flow oxygen/non-invasive ventilation at baseline.</p> <p><b>R:</b> Limited additional data suggest a mortality reduction even among patients requiring mechanical ventilation.</p> <p><b>R:</b> Patients who receive baricitinib for treatment of COVID-19 should not receive tocilizumab or other IL-6 inhibitors.</p>	NA
20	Baricitinib +	...	...	...	<b>Suggest use****</b>	...



		<b>Post-exposure prophylaxis:</b> exposed and healthy	<b>Ambulatory care:</b> mild-to-moderate disease	<b>Hospitalized:</b> mild-to-moderate disease without need for suppl. oxygen	<b>Hospitalized:</b> severe but non-critical disease (SpO <sub>2</sub> ≤94% on room air)	<b>Hospitalized:</b> critical disease (e.g., in ICU needing MV, or septic shock, ECMO)
					<b>R:</b> Baricitinib 4 mg daily dose for 14 days or until hospital discharge. The benefits of baricitinib plus remdesivir for persons on mechanical ventilation are uncertain.	
<b>21</b>	<b>Tofacitinib</b>	NA	NA	NA	<b>Suggest use</b> ⊕⊕○○ <b>R:</b> Tofacitinib appears to demonstrate the most benefit in those with severe COVID-19 on supplemental or high-flow oxygen. <b>R:</b> Patients treated with tofacitinib should be on at least prophylactic dose anticoagulant. <b>R:</b> Patients who receive tofacitinib should not receive tocilizumab or other IL-6 inhibitor for treatment of COVID-19. <b>R:</b> The STOP-COVID Trial did not include immunocompromised patients.	NA
<b>22-23</b>	<b>Ivermectin</b>	NA	<b>Suggest against use outside context of a clinical trial</b> ⊕○○○	<b>Suggest against use outside context of a clinical trial</b> ⊕○○○	<b>Suggest against use outside context of a clinical trial</b> ⊕○○○	<b>Suggest against use outside context of a clinical trial</b> ⊕○○○
<b>24</b>	<b>Fluvoxamine</b>	NA	Recommended only in the context of a clinical trial (knowledge gap)	NA	NA	NA

NA: not applicable/not reviewed; MV: mechanical ventilation; ECMO: extracorporeal membrane oxygenation; R: remark; AE: adverse events

\*Chloroquine is considered to be class equivalent to hydroxychloroquine.

\*\*Dexamethasone 6 mg IV or PO for 10 days (or until discharge) or equivalent glucocorticoid dose may be substituted if dexamethasone unavailable. Equivalent total daily doses of alternative glucocorticoids to dexamethasone 6 mg daily are methylprednisolone 32 mg and prednisone 40 mg.

\*\*\*Exposed but healthy patients at high risk for progression to severe disease

\*\*\*\*For patients with mild to moderate COVID-19 at high risk for progression to severe disease (see EUA at <https://www.fda.gov/media/143603/download>)

\*\*\*\*\*For hospitalized patients who cannot receive corticosteroids (which is standard of care) because of a contraindication

#### Strengths of recommendation:

**Recommend** (strong recommendation): Guideline panel is confident that the desirable effects of an intervention outweigh the undesirable effects. Most or all individuals will be best served by the recommended course of action.

**Suggest** (weak or conditional recommendation): Guideline panel after discussion concludes that the desirable effects probably outweigh undesirable effects, but appreciable uncertainty exists. Not all individuals will be best served by the recommended course of action and the caregiver needs to consider more carefully than usual the individual patient's circumstances, preferences, and values.

#### Certainty of evidence:

⊕⊕⊕⊕ high      ⊕⊕⊕○ moderate      ⊕⊕○○ low      ⊕○○○ very low

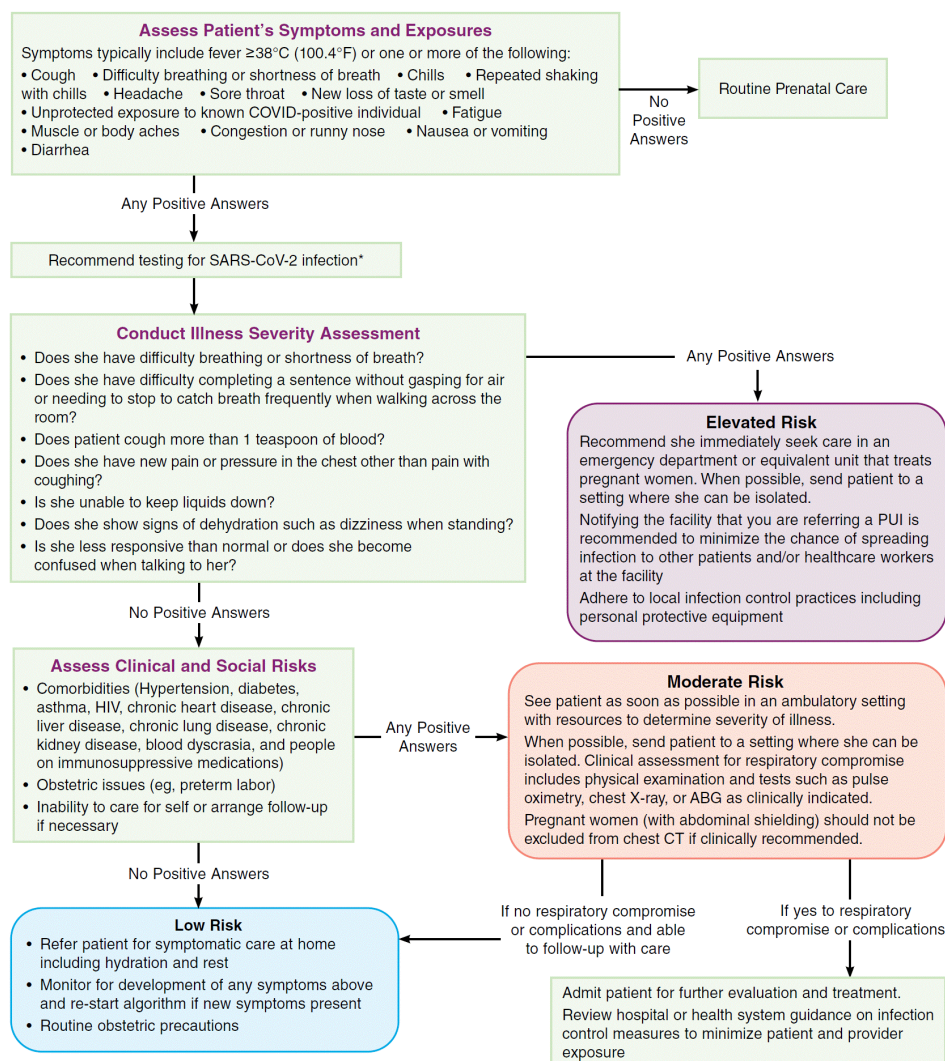
## APPENDIX Q: MANAGEMENT FOR PREGNANT WOMEN WITH SUSPECTED OR CONFIRMED COVID-19



### Outpatient Assessment and Management for Pregnant Women With Suspected or Confirmed Novel Coronavirus (COVID-19)

This algorithm is designed to aid practitioners in promptly evaluating and treating pregnant persons with known exposure and/or those with symptoms consistent with COVID-19 (persons under investigation [PUI]). If influenza viruses are circulating, influenza may be a cause of respiratory symptoms and practitioners are encouraged to use the [ACOG/SMFM influenza algorithm](#) to assess need for influenza treatment or prophylaxis.

**Please be advised that COVID-19 is a rapidly evolving situation and this guidance may become out-of-date as new information and data on COVID-19 in pregnant women becomes available. Please refer to the Centers for Disease Control and Prevention (CDC) <https://www.cdc.gov/coronavirus/2019-nCoV/index.html> and ACOG COVID-19 web pages: <https://www.acog.org/topics/covid-19> for comprehensive resources and guidance on COVID-19.**



Abbreviations: ABG, arterial blood gases; CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus.

\*Testing recommendations may vary based on facility and/or local guidance, community spread, and availability of testing

This information is designed as an educational resource to aid clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology. The American College of Obstetricians and Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on [www.acog.org](http://www.acog.org) or by calling the ACOG Resource Center.

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Available at:

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/03/novel-coronavirus-2019>



## Multisystem Inflammatory Syndrome in Children (MIS-C)

MHS Clinical Communities

### A COVID-19 Complication in Children and Young Adults: Information for Staff

The Centers for Disease Control and Prevention (CDC) and the MHS are tracking instances of a life-threatening pediatric condition that appears to be occurring in patients who were diagnosed with or exposed to COVID-19. Early detection and treatment of this condition, called multisystem inflammatory syndrome in children (MIS-C), is crucial.

Though MIS-C appears to be a rare complication, the MHS Clinical Communities want to raise awareness so that any MHS staff member can recognize a patient with symptoms of MIS-C and knows how to react. This could be staff conducting intake at urgent care clinics or emergency departments, and nursing and reception staff at family medicine clinics.



### What It Is and Who is Affected

The CDC has defined the syndrome and it is reported among patients with a variety of symptoms.

#### The CDC defines this syndrome as:

- An individual aged <21 years presenting with fever, laboratory evidence of inflammation, and evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic, or neurologic); **AND**
- NO alternative plausible diagnoses; **AND**
- Positive for current or recent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection by reverse transcription polymerase chain reaction (RT-PCR), serology, or antigen test; **OR** COVID-19 exposure within the 4 weeks prior to the onset of symptoms

**Note that emerging reports indicate that MIS-C may be affecting young adults over the age of 21.** The MHS Clinical Communities recommend not limiting your assessment of these conditions to only patients under the age of 21.

MIS-C shares symptoms with other pediatric inflammatory conditions including Kawasaki disease, toxic shock syndrome, and macrophage activation syndrome.

**It is critical for healthcare professionals to recognize syndrome symptoms early.** This includes primary care physicians, pediatricians, emergency room staff, urgent care staff, and all support staff.



### What to Look For

#### Child or young adult with:

- Fever of 100.4 °F for 4 or more days
- Abdominal pain, nausea, vomiting, diarrhea, or enteritis only on imaging
- Neck pain
- Rash
- Pink eye, bloodshot eyes
- Oral/mucosal changes
- Headache/irritability
- Cough, sore throat, pain swallowing
- Swelling in hands and/or feet
- Trouble breathing
- Low energy, tired



### What to Do

It is important for staff to be prepared to handle suspected cases of MIS-C.

#### Staff should prepare in advance by:

- Familiarizing themselves with the signs of MIS-C
- Collecting the contact information for local military or civilian pediatric specialists
- Utilizing existing DoD specialty telemedicine resources to reach out early to specialists for advice/consultation
- Understanding transportation options for transfer of MIS-C patients to specialty centers

#### Health care management should include:

- Familiarizing staff, especially providers and hospital and clinic intake staff, with the signs of MIS-C
- Ensuring all health care workers are wearing appropriate personal protective equipment (PPE) before examining patients
- Contacting the nearest hospital with pediatric inpatient capabilities, to including a pediatric intensive care unit (PICU) and pediatric cardiology at a minimum, plus pediatric infectious diseases, pediatric rheumatology, or immunology capabilities
- If the patient is clinically unstable, activating the emergency response system and following Pediatric Advanced Life Support algorithms
- If the patient is clinically stable and is in an emergency or tertiary care center, obtaining the 12-lead EKG and labs recommended in clinical guidance. MHS clinical guidance for MIS-C will be available in Version 4 of the *DoD COVID-19 Practice Management Guide*
- For facilities in a remote location without subspecialty care, contacting pediatric specialists via phone for guidance on management/stabilization until able to transfer patient to higher level of care

**Providers should report suspected cases to their local, state, or territorial health department.**



### Who to Contact

In addition to learning how to recognize MIS-C and preparing to manage cases, staff should know who to reach out to for additional guidance.

#### For questions about MIS-C and its management contact:

MHS Pediatric Tele-Critical Care: 833-238-7756, DSN 312-429-9089  
CDC's 24-hour Emergency Operations Center: 770-488-7100

For more information on MHS guidance, visit [health.mil/coronavirus](https://health.mil/coronavirus); for CDC information on MIS-C, visit <https://www.cdc.gov/mis-c/hcp>  
To read the May 14, 2020 CDC Health Advisory on MIS-C, visit <https://emergency.cdc.gov/han/2020/han00432.asp>.

June 1, 2020





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## APPENDIX S: RECOMMENDATIONS FOR SURGICAL TIMING IN COVID+ PATIENTS

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(Updated 3Jun21)

### For ELECTIVE surgery in patients with a positive COVID test:

Symptoms	Time Until Rescheduling Surgery	PPE required
Asymptomatic & Mild Symptoms not requiring hospitalization (ex: cough, SOB)	>49 days (>7 weeks) from onset of symptoms or positive test (whichever is later)	Standard enhanced precautions
Moderate Symptoms (required hospitalization without intensive care)	>56 days (8 weeks) from onset of symptoms	Standard enhanced precautions
Severe Symptoms (required intensive care with ventilator support/ECMO)	>84 days (12 weeks) from onset of symptoms	Standard enhanced precautions

*These recommendations are for patients who have recovered from COVID-19, stratified by their symptomatology, and who are now asymptomatic at the time of surgery.*

- **Asymptomatic through Mild Symptoms without hospitalization:** Wait >7 weeks from onset of symptoms or positive test (whichever is later). Patient may be de-isolated with standard enhanced precautions at 10 days post symptom onset.

- **Moderate Symptoms (required hospitalization without intensive care):** Wait >8 weeks from onset of symptoms and should be on a case-by-case basis after discussion between surgeon/anesthesiologist on risk/benefit of delaying surgery/anesthetic risk. Patient may be de-isolated with standard enhanced precautions at 20 days post symptom onset.

- **Severe Symptoms (required intensive care with ventilator support and/or ECMO):** Wait 12 weeks from onset of symptoms and should be on a case-by-case basis after discussion between surgeon/anesthesiologist on risk/benefit of delaying surgery/anesthetic risk. Patient may be de-isolated with standard enhanced precautions at 20 days post symptom onset.

Patients who have exceeded these times but remain symptomatic may benefit from further delay and a discussion regarding risk/benefit of surgical timing and increased morbidity/mortality should occur between surgeon/anesthesiologist on risk/benefit of delaying surgery/anesthetic risk prior to scheduling surgery.

**For URGENT surgery in patients with a positive COVID test:**

Symptoms	Time Until Rescheduling Surgery	PPE required
Asymptomatic	No mandatory wait **requires discussion between anesthesiologist/surgeon**	Enhanced COVID precautions if within 10 days of positive test
Mild Symptoms (without hospitalization)	No mandatory wait **requires discussion between anesthesiologist/surgeon**	Enhanced COVID precautions if within 10 days of symptom onset
Moderate/Severe Symptoms (hospitalization required)	No mandatory wait **requires discussion between anesthesiologist/surgeon**	Enhanced COVID precautions if within 20 days of symptom onset

- No mandatory wait time. Discussion regarding risk/benefit of surgical timing and increased morbidity/mortality should occur between surgeon/anesthesiologist on risk/benefit of delaying surgery/anesthetic risk
- If within 10 (asymptomatic – mildly symptomatic) to 20 (moderate – severely symptomatic) days of + test should proceed with enhanced precautions for all team members (isolation room, neutral pressure OR, N95/eye protection/gown for entire encounter, post-op either home or appropriate COVID-specific ward)

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\*These recommendations are based on DHA Memorandum Timing of Surgery After SARS-Cov-2 Infection 24MAR2021, Timing of surgery following SARS-CoV-2 infection: an international prospective cohort study doi: 10.1111/anae.15458, expert guidance from Infectious Disease and Infection Control as well as statements from the American Society of Anesthesiologists and Anesthesia Patient Safety Foundation.

\*In general, patients should not be re-tested within 90 days of a previously positive COVID test.

- Patients who develop additional symptoms during these 90 days should be discussed with Infectious Disease regarding testing utility
- Patients who previously test positive should be screened for concerning symptoms and additional exposures using the Pre-Op COVID screening tool

\*Patients should be screened prior to and on the morning of surgery. Patients scheduled for elective surgery who screen positive should be cancelled and referred for testing. Timing for rescheduling will be based on the above guidelines.

\*Patients who have completed their quarantine and met de-isolation guidelines (10 days for asymptomatic/mildly symptomatic, 20 days for moderate/severely symptomatic) may undergo their procedure at either an Ambulatory Surgery Center or a Medical Center with standard enhanced precautions as appropriate.

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## APPENDIX T: DHA QUICK REFERENCE GUIDE TO VIRTUAL HEALTH AND TELEPHONE ENCOUNTERS

Effective Date: 15 December 2020

# QUICK REFERENCE GUIDE

## Virtual Health Encounters V2.0



### Disclaimers:

1. The **MHS Specific Coding Guidelines** are the source for all DoD specific coding guidance. To ensure coding compliance and standardization across the DHA, all coding training, tools and/or coding manuals must be vetted through **DHA Medical Coding Program Branch** and **DHA Coding Work Group (CWG)** prior to implementation.
2. The codes listed in this document are for Type 1 or 2 **Privileged Providers**. Refer to the **MHS Specific Coding Guidelines** for codes related to all other provider types.
3. CMS eliminated the use of modifier GT for reporting Telehealth professional services effective 1 Oct 2018, however, the MHS will continue to use GT until further notice.
4. VH Functionals have ownership of this VH Coding Cheat Sheet and will update annual code changes in conjunction with the **MHS Coding Guidelines**.
5. VH and Telephone Encounters must meet coding and documentation requirements.

Method	Audio and Visual Patient Encounters (Privileged Provider to Patient)				Electronic Consultation (Privileged Provider to Provider)		Audio-Only Encounters (Privileged Provider to Patient) *for duration of pandemic			Electronic Encounters (Privileged Provider to Patient)
Interaction	Virtual Video Visit (V3) DISTANT SITE (where provider is located e.g. MTF)		Virtual Video Visit (V3) ORIGINATING SITE (where patient is located e.g. MTF)		Teleconsultation at distant site (where provider is located at e.g. MTF or on a ship) for professional interpretation REQUESTING Provider	Teleconsultation at distant site (where provider is located at e.g. different MTF or on ship) for diagnosis and treatment RESPONDING Provider	Clinical Telephone (audio only)	T-CON (patient initiated established only)		Secure Messaging
PHA										
Synchronous										
Asynchronous										
Type: Scheduled										
Type: Unscheduled										
Appointment	FTR	24HR, FTR, SPEC (provider discretion)	FTR	24HR, FTR, SPEC	SPEC, FTR		24HR, FTR, SPEC	24HR, FTR, SPEC	T-CON	N/A
Detail Code	PHA and TELMED	TELMED	PHA and TELMED	TELMED	N/A	N/A	HC		N/A	N/A
Code	Office Visit Code		99499	99499	99452 30 min requesting provider time in referral work	Verbal and Written Report: 99446 5-10 min 99447 11-20min 99448 21-30min 99449 +31 min 99451 ≥5 min consultant time including written report	Office Visit Code and *T2025 when encounter meets E/M or procedure criteria		99441 5-10min 99442 11-20min 99443 21-30min	99421 5-10min 99422 11-20min 99423 21+ min
Modifier	GT (patient is present at originating site e.g. clinic to clinic) or 95 (clinic to non-clinic patient location)		N/A	N/A	N/A	GP	N/A	N/A	N/A	GP
Code	96160	N/A	Q3014 (and any procedures performed at the originating site within presenter's scope of practice)		Procedures per documentation	N/A	96160 + G2012	*G2012 alone if E/M criteria not met	N/A	N/A
Modifier	N/A	N/A	N/A	TC (on procedure code if technical component of procedure/ test are completed and no interpretation and report are rendered)	N/A	26 (interpretation only; professional component)	N/A	N/A	N/A	N/A

CHCS  
E/M Code  
CPT/HCPCS



## APPENDIX U: CDC SUMMARY DOCUMENT FOR INTERIM CLINICAL CONSIDERATIONS FOR COVID-19 VACCINES CURRENTLY AUTHORIZED IN THE UNITED STATES

### Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States



	Pfizer-BioNTech	Moderna	Janssen
<b>Vaccine type</b>	mRNA	mRNA	Replication-incompetent adenovirus type 26 vector
<b>Age groups</b>	12 through 15 years of age (authorized) ≥ 16 years (approved COMIRNATY)	≥18 years	≥18 years
<b>Dose</b>	30 µg	100 µg	5x10 <sup>10</sup> viral particles
<b>Dose volume</b>	0.3 ml	0.5 ml	0.5 ml
<b>Number of doses in primary series</b>	2* (Booster dose recommended for certain people) <sup>†</sup>	2*	1
<b>Interval between doses</b>	3 weeks (21 days)	1 month (28 days)	N/A
<b>All currently authorized or approved COVID-19 vaccines</b>			
<b>Interchangeability of vaccines</b>	<ul style="list-style-type: none"> <li>Vaccines are not interchangeable. However, in exceptional situations, such as a contraindication to a second dose of mRNA vaccine or when a previous dose product cannot be determined or is not available, <u>interchangeability may be allowed</u> (<a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#">https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#</a>).</li> </ul>		
<b>Coadministration with other vaccines</b>	<ul style="list-style-type: none"> <li>COVID-19 vaccine and other vaccines may be administered on the same day, as well as any interval without respect to timing. When deciding whether to administer COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable diseases (e.g., during an outbreak), and the reactogenicity profile of the vaccines.</li> </ul>		
<b>Persons with prior or current COVID-19</b>	<ul style="list-style-type: none"> <li>COVID-19 vaccines can be given safely to people with prior SARS-CoV-2 infection.</li> <li>Defer vaccination until person has recovered from the acute illness and <u>criteria</u> have been met for them to discontinue isolation (<a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html</a>).</li> </ul>		
<b>Women aged &lt;50 years</b>	<ul style="list-style-type: none"> <li>Can receive any FDA-authorized or approved vaccine but should be informed of risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of Janssen (Johnson &amp; Johnson) COVID-19 Vaccine and the availability of other COVID-19 vaccine options.</li> </ul>		
<b>Persons who received monoclonal antibodies or convalescent plasma for COVID-19 treatment</b>	<ul style="list-style-type: none"> <li>Defer vaccination for at least 90 days.</li> </ul>		
<b>Persons with a known SARS-CoV-2 exposure</b>	<ul style="list-style-type: none"> <li>People in community or outpatient setting should defer vaccination until <u>quarantine period</u> has ended (<a href="https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html">https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html</a>).</li> <li>Residents or patients in congregate settings may be vaccinated if they do not have <u>symptoms consistent with COVID-19</u> (<a href="https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html">https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html</a>).</li> </ul>		
<b>History of heparin-induced thrombocytopenia (HIT)</b>	<ul style="list-style-type: none"> <li>If within 90 days of illness, offer an mRNA vaccine, after 90 days vaccinate with any FDA-authorized or approved COVID-19 vaccine.</li> </ul>		

### Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States



#### All currently authorized or approved COVID-19 vaccines

<b>Persons with underlying conditions</b>	<ul style="list-style-type: none"> <li>May receive COVID-19 vaccine</li> </ul>
<b>Persons with moderate to severe immune compromise</b>	<ul style="list-style-type: none"> <li>Can receive any FDA-authorized or approved COVID-19 vaccine                             <ul style="list-style-type: none"> <li>1 dose Janssen COVID-19 Vaccine; currently no recommendation for an additional dose, or</li> <li>2-doses of an mRNA COVID-19 vaccine; consider an additional dose at least 28 days after completion of the primary 2-dose series</li> </ul> </li> </ul>
<b>Persons with a history of myocarditis or pericarditis</b>	<ul style="list-style-type: none"> <li>If myocarditis or pericarditis occurred after a dose of an mRNA COVID-19 vaccine, should defer receiving a subsequent dose</li> <li>A subsequent dose can be considered in certain circumstances including personal risk of severe COVID-19 and level of community transmission.</li> <li>If a history of myocarditis or pericarditis unrelated to an mRNA COVID-19 vaccination, may receive COVID-19 vaccine after the episode has completely resolved.</li> </ul>
<b>Persons with a history of Guillain-Barré Syndrome</b>	<ul style="list-style-type: none"> <li>Can receive any FDA-authorized or approved COVID-19 vaccine, however, discuss the availability of mRNA vaccines to offer protection against COVID-19</li> </ul>
<b>Pregnant or breastfeeding people or people trying to get pregnant</b>	<ul style="list-style-type: none"> <li>Are recommended to receive a COVID-19 vaccine, inform of risk of TTS after receipt of Janssen (Johnson &amp; Johnson) COVID-19 Vaccine and the availability of other options</li> </ul>
<b>Adolescents</b>	<ul style="list-style-type: none"> <li>Adolescents aged 12-17 are <b>ONLY</b> eligible for Pfizer-BioNTech COVID-19 Vaccine</li> <li>Adolescents aged 18 years and older are eligible for all COVID-19 vaccines</li> </ul>
<b>Persons vaccinated outside the United States</b>	<ul style="list-style-type: none"> <li>Received all recommended doses of an FDA-authorized or approved COVID-19 vaccine, do not need additional doses</li> <li>Received a non FDA-authorized or approved vaccine                             <ul style="list-style-type: none"> <li>If vaccine is listed for emergency use by the World Health Organization (WHO) and received all recommended doses, do not need any additional doses with an FDA-authorized or approved vaccine</li> <li>If vaccine is listed for emergency use by WHO, but has not received all recommended doses, may be offered a complete FDA-authorized or approved series</li> <li>If vaccine is not listed for emergency use by WHO, may be offered a complete FDA-authorized or approved COVID-19 vaccine series</li> </ul> </li> </ul>
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine</li> <li>Immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine</li> </ul>
<b>Precaution</b>	<ul style="list-style-type: none"> <li>Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])</li> </ul>
<b>Post-vaccination observation periods</b>	<ul style="list-style-type: none"> <li><b>30 minutes:</b> persons with a precaution to vaccination (i.e., history of an immediate allergic reaction of any severity to a vaccine or injectable therapy) and persons with a history of anaphylaxis due to any cause</li> <li><b>15 minutes:</b> all other persons</li> </ul>
<b>SARS-CoV-2 antibody testing</b>	<ul style="list-style-type: none"> <li>Antibody testing not recommended for vaccine decision-making or to assess immunity following vaccination</li> </ul>

\*Consider an additional dose at least 28 days after the initial 2-dose primary series for people with moderate to severe immune compromise.

<sup>†</sup>Administer a Pfizer-BioNTech booster dose at least 6 months after the primary series to people aged 65 or older, residents aged 18 and older in long-term care settings, people aged 50-64 with underlying medical conditions (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>). Also a booster dose at least 6 months after primary series completion may be considered (based on individual benefits and risks) for people aged 18-49 years with underlying medical conditions or aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional settings.

<sup>‡</sup>Although CDC provides considerations for a mixed series in exceptional circumstances (<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#interchangeability>), this is still considered an administration error that requires VAERS reporting.



## APPENDIX V: TRIAGE OF PEOPLE WITH A HISTORY OF ALLERGIES OR ALLERGIC REACTIONS

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
<p><b>History of the following:</b></p> <ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine<sup>†</sup></li> <li>Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of a COVID-19 vaccine<sup>†</sup></li> </ul>	<p><b>Among people without a contraindication, a history of:</b></p> <ul style="list-style-type: none"> <li>Any immediate allergic reaction* to other vaccines or injectable therapies<sup>‡</sup></li> </ul> <p><b>Note:</b> people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.<sup>#</sup></p>	<p><b>Among people without a contraindication or precaution, a history of:</b></p> <ul style="list-style-type: none"> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul>
<p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>Do not vaccinate.</li> <li>Consider referral to allergist-immunologist.</li> <li>Consider other vaccine alternative.<sup>†#</sup></li> </ul>	<p><b>Actions:</b></p> <ul style="list-style-type: none"> <li><a href="#">Risk assessment</a></li> <li>Consider referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul>	<p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>30-minute observation period: people with history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: all other people</li> </ul>

<sup>†</sup> See Appendix W for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

\* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

<sup>‡</sup> People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

<sup>#</sup> Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

## APPENDIX W: INGREDIENTS INCLUDED IN COVID-19 VACCINES

Description	Pfizer BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
<b>Active ingredient</b>	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
<b>Inactive ingredients</b>	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl- $\beta$ -cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

\* None of the vaccines contain eggs, gelatin, latex, or preservatives. All COVID-19 vaccines are free from metals such as iron, nickel, cobalt, lithium, rare earth alloys or any manufactured products such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called “pegylation” to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. [CDC’s vaccine excipient summary](#) and the National Institutes of Health [DailyMed database](#) can also be used as a resource.

## APPENDIX X: POTENTIAL CHARACTERISTICS OF ALLERGIC REACTIONS, VASOVAGAL REACTIONS, AND VACCINE SIDE EFFECTS FOLLOWING COVID-19 VACCINATION

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day after vaccination)
<b>Signs and symptoms</b>			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, might have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; might have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia

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\*Denotes Section Editor