# DoD COVID-19 PRACTICE MANAGEMENT GUIDE

Clinical Management of COVID-19

This Practice Management Guide does not supersede DoD Policy.

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# DoD COVID-19 Practice Management Guide v7.0 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 & Clinical Course:** All sections updated, especially those including epidemiology, incubation period, reinfection, clinical course of pediatric cases. New information and sections added for SARS-CoV-2 variants, risk factors for severe disease, health and racial disparities, and vaccines.

**Planning & Preparation:** Revised/modified staffing ratios by: 1) providing a range of staffing ratios in step down and med-surg; 2) proportionally adjusting step down and med-surg patient pod size with a range from consistency with DoD ICU adjustment from SCCM (approximately 60% reduction) and original projections, and 3) separating licensed personnel (LVN/LPN) from non-licensed personnel to enhance flexibility.

Infection Prevention & Control: Updated date of access for CDC guidelines for PPE for patient visits During COVID19 Crisis Strategy, Clarified language regarding requirement for use of surgical masks for healthcare personnel engaged in direct patient care, Added note to Mask Guidance Crisis Capacity guidance that states, "Staff should follow manufacturer's instructions for use regarding extended use and reuse of N95 respirators. Data suggests that reuse of each device should be limited to no more than FIVE (5) uses." Revised Mask Decontamination SBAR to reflect most current guidance, including removal of all vendor-specific references and addition of link to FDA EUAs. Deleted Intubation Barriers SBAR in response to FDA removing umbrella EUA for such devices. Removed language in Dental PPE SBAR regarding N95 decontamination to align with content provided in Mask Decontamination SBAR.

**Laboratory Diagnosis**: Updated recommendations to avoid oropharyngeal swabs for specimen collection due to decreased sensitivity were included. Updated discussion on the good sensitivity of saliva as a specimen sample (particularly in the presence of cough). Decreased sensitivity of isothermal NAAT platforms were discussed with a recommendation to avoid if feasible. Lastly, included questions regarding durability of immune response and its effect on antibody testing as well as the role vaccination might play in affecting this type of testing. Added Appendix D related to DHA protocol for nasopharyngeal swab collection.

**Outpatient Management:** Added Appendix E related to lifestyle approaches to reducing comorbidities associated with COVID-19. Added section on use of monoclonal antibodies for treatment of mild-moderate outpatients at risk for progression to severe disease or hospitalization. Updated triage protocols.

**Diagnosis and Treatment of Co-Infections:** Discussed the unusually low incidence of influenza this season.

**Management of Critical COVID-19: Oxygen and ARDS:** Clarified recommendations regarding HFNC and noninvasive positive pressure ventilation. Removed the statement regarding intubation being performed by the most experienced provider, recognizing the important role of GME during the prolonged pandemic.

**Prevention of Complications**: Updated figure and Appendix K related to Cardiopulmonary Return to Exercise and Physical Activity Recommendations.

**Septic Shock & Cardiac Arrest**: Recent studies have confirmed the common prevalence of in-hospital cardiac arrest in critically ill patients with COVID-19, and is associated with poor survival, particularly among older patients. There are no new published guidelines regarding best practices for cardiopulmonary arrest in COVID-19 patients, and the main resuscitation goals center around risk reduction of viral transmission to participating healthcare personnel while optimizing resuscitation interventions. American Red Cross life support algorithms were added to Appendix O.

**Imaging of COVID-19:** Cardiac imaging updated to address that patients with minimal COVID-19 symptoms at presentation may have cardiac dysfunction on imaging several months after recovery on cardiac magnetic resonance (CMR) imaging. 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. Neuroimaging updates regarding prevalence of microvascular injury at post-mortem magnetic resonance microscopy and a retrospective review of brain imaging findings.

Therapeutic Management & Adjunctive Therapies: Changed the title of the section to reflect that medication management options for the pharmacologic management of COVID-19 have been identified and incorporated into the treatment guidelines. Added descriptions of illness severity and updated the NIH figure for recommended pharmacologic management of COVID-19 based on disease severity. Added Appendix P from the IDSA Treatment Guidelines. Updated the list of agents for which there is insufficient evidence to make recommendations for or against their use. Updated the list of agents for which use is not recommended. Updated anti-SARS-CoV-2 monoclonal antibodies sections to reflect current recommendations and evidence. Added a section for Janus kinase (JAK) inhibitors to include baricitinib. Added a section for antithrombotic therapy.

Special Populations: Added additional information on work restrictions for pregnant women and PPE for pregnant healthcare workers. Added an algorithm to guide ICU admission and treatment of refractory hypoxemia in pregnancy, as well as additional information on therapeutic options: neuromuscular blockade, pulmonary vasodilators, inhaled nitric oxide, inhaled prostacyclins, monoclonal antibodies, and ECMO in pregnancy. Provided information regarding vaccination in pregnant and lactating patients and for patients desiring to become pregnant. Patient shared decision-making aid on vaccination included in Appendix R. Added new figures, including Figures 13 (Algorithm for ICU Admission for OB Patients), 14 (Algorithm for Refractory Hypoxemia for Critically III Obstetrical Patients), and 15 (MIS-C Algorithm). Maternal infant dyads are no longer recommended to be separated after birth and circumcisions can now be performed on asymptomatic healthy infants even if they are a PUI. Updated information on Pediatric COVID-19, including information on studies related to school transmission (limited) and evaluation recommendations following COVID-19 infection for return to play or exercise. Considerations regarding testing for influenza, RSV and COVID-19 should be made during influenza season.

**Surgical & Invasive Procedures:** Minor changes compared to previous versions. Added considerations on resuming elective surgery after COVID-19 infection, including Appendix T to guide timing decisions. Removed section on "Opening Up America Again".

**Operational Considerations:** Updated unique challenges in austere environment to include resupply and updated strategies for treatment. Clarified close contact quarantine, ROM, and isolation guidelines, including the potential that SOPs may allow for a test out of close contact quarantine at 10 days.

**Behavioral Health:** Added the SCCM ABCDEF bundle as an additional consideration for medical management of delirium. Aside from new-onset psychiatric symptoms, COVID-19 is also associated with exacerbation of preexisting conditions. There is also increasing evidence that psychiatric symptoms persist past the acute infectious stage.

**Telemedicine Support during the COVID-19 Pandemic:** Updated Appendix T with the updated DHA guide.

**Emergency Medical Services:** Modified non-transport recommendations based upon current protocols. Added an EMS Operations section given new CDC recommendations.

**En Route Critical Care:** The Transport Isolation System (TIS) has been replaced by the Negative Pressure Connex (NPC) for aeromedical evacuation of positive or suspected positive COVID-19 patients in the DoD.

**Public Health:** Updated CDC guidance regarding reduced quarantine options for close contacts that remain asymptomatic and have a negative test. Added section for aeromedical transport to assist with contact tracing. Updated traveler quarantine guidance for foreign countries.

**DoD COVID-19 Vaccine Implementation:** This is a new section that highlights the components of the DoD vaccine strategy, including prioritization tiers and current vaccines approved under EUAs at time of publication.

# **DoD COVID-19 PRACTICE MANAGEMENT GUIDE**



# **Clinical Management of COVID-19**

To consolidate resources and optimize the management for patients requiring clinical care during the global COVID-19 pandemic.

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#### **BACKGROUND**

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 now a global pandemic with nearly 110 million cases and almost 2.4 million deaths worldwide. 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.(3, 4) 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.(5) Older age and certain comorbid conditions, including hypertension, diabetes, coronary artery disease, and chronic lung disease increase risk of death.(6-8) The virus is highly contagious and spread via respiratory droplets, direct contact, and if aerosolized, airborne routes. As of March 2021, three vaccines to prevent SARS-CoV-2 infection have been authorized for emergency use in the United States.

The intent of this publication is to provide clinicians and military medical treatment facilities (MTFs) with leading practices based on latest evidence to optimize DoD's response to the current COVID-19 pandemic. 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 reflects the most up-to-date material at the time of inclusion.

#### **EPIDEMIOLOGY, CLINICAL PRESENTATION & CLINICAL COURSE**

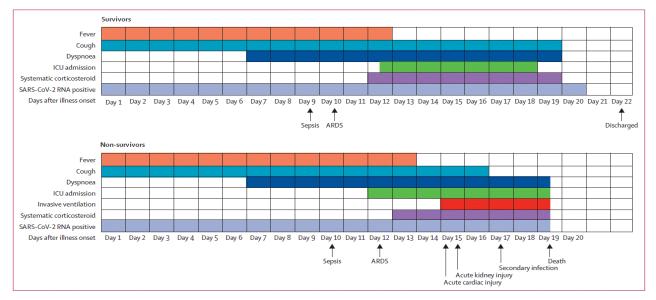
- Epidemiology: According to the US Centers for Disease Control and Prevention (CDC) as of February 17, 2021, data available for 20,704,750 reported cases and 349,630 deaths reflect a little over half (52.3%) infections occurred in women, though over half (54.2%) of the deaths occurred in men. Age distribution reflects approximately a third of cases (35%) are reported in persons ≥50 years, a third of cases (31%) in persons aged 30-49 years and a third of cases (34%) in persons under 30 years old (11.4% under 18 years). Persons aged 50 years and above comprised the overwhelming majority (95.5%) of deaths, with a majority (60%) aged 75 years and above. Race/ethnicity data is available for 10,702,189 (51%) of reported cases; 55.9% cases reported a race of White, 20.7% Hispanic/Latino, 12.2% Black, 3.6% Asian, 1.2% American Indian (AI)/ Alaska Native (AN) and 0.4% Native Hawaiian/ Other Pacific Islander persons.(9) The largest single report of cases in the United States was previously published in a Morbidity and Mortality Weekly Report (MMWR) by the CDC 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 ≥ 80 years (902.0) and lowest in children aged ≤ 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. (10) Details on pediatric cases and ethnicity/race are included in Section 13 below. All estimates underestimate the true prevalence and burden of disease since the above only reflect reported cases and not all positive/infected individuals who are not tested therefore would not be reported.
- 2. Incubation period: Approximately 4-5 days, although it appears to vary by statistical model used for estimation and by median age of the cohort.(11-13) 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 ≥ 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.(13-15) Additionally, the CDC reported that, of 616,541 infected persons for whom symptom status was reported, 22,007 (4%) were asymptomatic.(10)
- 3. **Transmission risk period**: Though the exact time period of infectiousness remains unconfirmed, studies strongly suggest transmission occurs even when infected persons do not manifest symptoms, either before they become symptomatic (when viral loads appear to be high) or as they remain asymptomatic. 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 / exposure after day 6 (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. Based on the current data, transmission beyond 7-10 days of infection is unlikely.(16, 17)
- 4. **Transmission risk by type**: Transmission risk does appear to depend on type, i.e., increases with close contact or in enclosed/ indoor spaces, and duration of exposure, i.e., increasing risk of transmission with increasing duration of exposure. Additionally, as noted in the Taiwan study described above and other contact and seroprevalence studies, household contacts, especially spouses, appear to be at higher transmission risk.(16, 18, 19)
- 5. **Mode of transmission**: Although other possible modes of transmission have been reported, person-to-person transmission remains the main way SARS-CoV-2 is spread. How long the virus can persist on surfaces/objects as well as how extensive a role fomites play in transmission remain unestablished. Accordingly, infection and prevention control measures including rigorous and frequent cleaning of surfaces and rooms that COVID-19 patients have occupied remain crucial to limiting/eliminating transmission. It also remains unclear what role animals play in transmission of SARS-CoV-2 to humans (minks appear to transmit to humans) and vice versa. Based on limited and mixed data on different animals, the CDC recommends that contact with pets be handled similar to humans, i.e., keep pets away from other animals / people outside of the household as well as away from those with suspected / confirmed infection.(20)
- 6. **Reinfection**: It is unclear if and how long primary infection with SARS-CoV-2 confers immunity, though data suggests protection may last at least several months. Though still infrequent, there have been case reports suggesting reinfection with SARS-CoV-2 is possible, including in a 33-year-old Hong Kong male with an isolated and sequenced, phylogenetically distinct strain from an episode of infection after resolution of an initial infection >4 months earlier.(21) Additionally, infection with a variant following infection with wild-type virus has been documented.(22, 23)
- 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. Three variants circulating in the US include those initially identified in the United Kingdom (B.1.1.7 or variant of concern (VOC) 202012/01 or 20I/501Y.V1), South Africa (B.1.351 or 20H/501Y.V2) and Brazil (P.1 or 20J/501Y.V3). According to the CDC, as of February 16, 2021, there have been reports of 1,277 cases of B.1.1.7 in 42 states, 19 cases of B.1.351 in 10 states and three cases of P.1 in two states.(24) Some unpublished data and preliminary trials involving vaccines have suggested that all three may be more efficiently transmitted. Additionally, the 20I/501Y.V1 strain appears to be associated with more severe disease. Ongoing trials and research are being conducted to elucidate more information on the efficacy of the different vaccines as well as what protection immunity from past infection may provide against the variant strains. Preliminarily, there are reports of neutralizing activity by antibodies produced after infection with wild-type virus and after vaccination, although there are also reported infections by variants after wild-type infection as well as reduced effectiveness of vaccines.(25, 26)
- 8. Symptoms: Frequently reported symptoms of patients admitted to the hospital: (6, 10, 27-33).
  - 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%)

Though 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.(12) In a study of 5,700 hospitalized COVID-19 patients in New York City, approximately 31% were febrile on presentation.(34) In older patients, atypical presentations such as reports of falls or decline in mental status or cognition have been reported.(35) Figure 1 illustrates a timeline of the clinical course of major symptoms. Less commonly reported symptoms: sore throat, rhinorrhea, conjunctivitis, headache, cough with sputum production and/or hemoptysis, and lower respiratory tract signs and symptoms.(6, 7, 12)

9. Dermatologic findings including maculopapular, urticarial and vesicular lesions ("COVID toes") and livedo reticularis have been reported in association with illness, although a clear association has not yet been established.(36, 37)



**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.

- 10. **Risk for severe disease**: Severe disease can occur in all persons, although older patients, pregnant patients, and those with chronic medical conditions appear to be at higher risk for severe illness.(6, 38) Factors associated with increased adverse outcomes include advanced age, certain comorbidities (e.g., cardiovascular disease, diabetes, hypertension, chronic lung and/or kidney disease, obesity), male gender, Black, Hispanic and South Asian descent, specific laboratory abnormalities such as those associated with thrombotic and inflammatory dysregulation.
- 11. 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). Males appear to be at higher risk for hospitalization and severe illness.(6, 10, 38, 39)
- 12. **Pregnant women**: Based on limited data, 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. Additionally, women who develop pneumonia appear to have increased risk of preterm labor. (40-45)
- 13. **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. In

the US, while earlier reports estimated children account for <2% of cases (median 11 years), current data reflect 11.4% of reported cases are in children under 18 years and account for <0.2% of deaths. In China, COVID-19 made up between 1.5-2% of acute respiratory admissions, with a median age of 7 years. One study in Korea reported that almost 25% of children were asymptomatic and that viral RNA was detected for a mean of 17.6 days in all cases vs 14.1 days in asymptomatic cases. 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%).(46) In the US, children account for <2% of cases, and the median age reported was 11 years. 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.(47) A recent MMWR published 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. (48)

- 14. **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 Al/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 Al/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% Al/AN; in those aged 5-17 years: 25.3% Hispanic, 16.3% Black, 2.4% Al/AN, 2.4% Asian, 0.6% NH/Other Pacific Islander) indicating that minority children are disproportionately affected by the pandemic.(9, 11, 47-56)
- 15. 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.(48) While most children experience mild disease, increasing reports of a syndrome similar to Kawasaki Disease or toxic shock, termed multisystem inflammatory syndrome in children (MIS-C), continue to evolve. These children may present with persistent fevers, GI symptoms, dermatologic manifestations or lesions or edematous extremities and rapidly progress to shock and multi-organ failure in the setting of known SARS-CoV-2 infection or exposure.
- 16. 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), 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. (49, 50, 57, 58)
- 17. Clinical presentation among cases of COVID-19 varies in severity from asymptomatic to fatal illness. Several

- reports suggest clinical deterioration can occur during the  $2^{nd}$  week of illness (range: 5 13 days).(6, 29)
- 18. 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.(59) Secondary infection developed in 10%, with a median time from symptom onset to of respiratory failure of 8 days.(6, 27, 28, 33)
- 19. 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%).(6, 28) 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.(60) 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) have also been supported with extracorporeal membrane oxygenation (ECMO).(27, 28, 38) Patients with severe disease appear to have an increased inflammatory response or "cytokine storm" with persistent fevers and elevated inflammatory markers. Additionally, Guillain-Barre syndrome has been described.(61)
- 20. 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. (62-66)
- 21. 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.(67) Viral inclusion bodies have been seen in endothelium of kidneys, small bowel, and heart suggesting that endotheliopathy could be contributing to thrombotic complications.(68) 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.(69)
- 22. Case fatality rates (CFR) appear to vary by location and to be related to demographics, e.g., median age, of the population. A CFR of 2.3% has been reported among confirmed cases of COVID-19 in China.(38) However, the majority of these cases were hospitalized patients, so this mortality estimate is likely biased upward. Among hospitalized patients with pneumonia, the case fatality proportion has been reported as 4–15%.(6, 27, 28) In a report from one Chinese hospital, 61.5% of critically ill patients with COVID-19 had died by day 28 of ICU admission. Among all critically ill COVID-19 patients in China, the reported case fatality proportion was 49%.(5) Of note, 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. 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.
- 23. As of 23 February 2021, (based on the latest data available from January 27, 2021), the Italian government COVID-19 surveillance group reported 93,074 deaths associated with COVID-19. Of the data available on 85,418 deaths on January 27, 2021, 86.2% ≥70 years, 9.4% 60-69 years, 3.5% 50-59 years, 3.3% 40-49 years, 0.8% 20-39 years, 0.02% <20 years. Of the 6,381 patients for whom data on pre-existing co-morbidities are available, approximately two-thirds (66.3%) had ≥3 pre-existing co-morbidities (e.g., hypertension, type 2 diabetes, ischemic heart disease, atrial fibrillation). The CFR for Italy has decreased since the early part of the pandemic when it was near 13% and is now estimated at 3.4%. https://www.epicentro.iss.it/en/coronavirus/
- 24. In the US, as of 24 February 2021, the CDC reports greater than 28 million cases and more than 500,000 COVID-19-related deaths. (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html)

- CFR increases with age (highest in ≥85 years, with risk of death 7900x that of persons aged 5-17 years).(70)
- 25. Racial disparities: Minorities appear to be at higher risk for more severe disease/ worse outcomes, i.e., hospitalizations and death. Compared to White persons, AI/AN risk of hospitalization is 3.7x, Hispanic/Latino is 3.2x, Black/African American is 2.9x and Asian is 1.1x. Compared with White persons, risk of death in AI/AN is 2.4x, in Hispanic/Latino is 2.3x, in Black/African American is 1.9x and Asian is 1.0x.(71) (https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html)
- 26. **Vaccines**: In December 2020, two mRNA vaccines were authorized to be administered in the US. The US began vaccinating persons on December 14, 2020. As of February 18, 2021, 57.7 million vaccine doses have been administered to 41.0 million people, which is 12.4% of the population. A third vaccine, a replication-incompetent human adenovirus vector vaccine, was approved for emergency use in late February 2021.

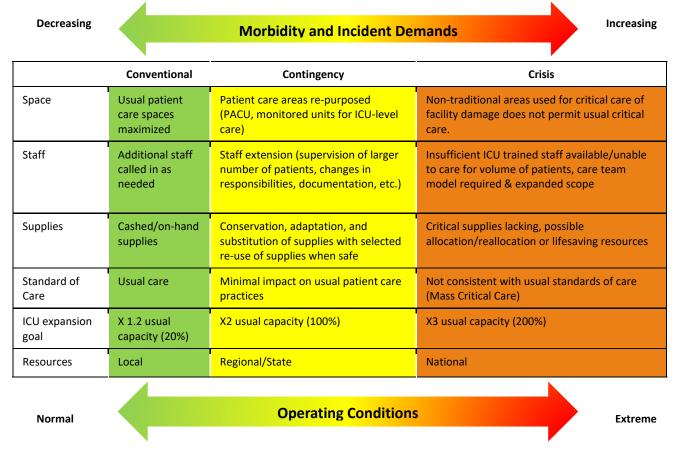
#### **PLANNING AND PREPARATION**

#### **Facility Incident Command and Systems**

- 1. A local emergency response command structure with clearly defined roles and lines of communication should be defined.(72, 73) 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** 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."(74) 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. In general Contingency when >120% typical capacity and Crisis when >200% capacity.
  - 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.(75-78)
  - e. Crisis Standards of Care, if invoked, triggers significantly altered staffing models as described below with incumbent increased relative risk of morbidity and mortality above conventional care.(75-78) 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) and should be individualized to a facility and consistent with the region. A list of 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).
    - 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.
- 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.
- 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. (79-81)
- 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, stuff 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 experience ICU RNs who typically work in an ICU environment) with "XX Crisis Critical Care Nursing augmentees" (i.e. augmentees (RN, LPN, etc., able to assist in crisis with minimal training but 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.(81)
- 6. Establish security, access points, and "clean" areas with access restricted:
  - a. Security should be included in the planning process given increased community stress and security risks during the COVID-19 pandemic.
  - b. Establish "satellite" units in alternative locations to care for patients unaffected by the pandemic to protect non-infected patients and high-risk staff (e.g., underlying medical conditions, age >60).(82)
  - c. Consider access to specialty or routine care that may be needed in these areas with screening as patients enter.
  - d. Establish single or controlled points of entry for every facility and initiate screening procedures for possibly infected patients at entrances.
- 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).(83)
  - 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.(84)
- b. Allocation of adequate space for safe, respectful care of the deceased.(85)
- 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. (82, 83)

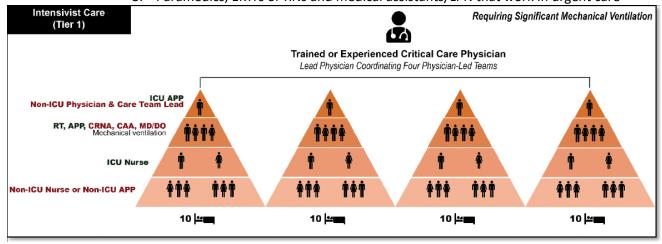


**Figure 2.** A framework outlining the conventional, contingency, and crisis surge responses. PACU: post-anesthesia care unit. [from Christian, et al.; Chest (2014)].(67) Note: Both morbidity and mortality relative risk increases as care needs progress through the levels.

#### **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.
- 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 with some estimates as high as 40-60% absenteeism.(82, 86)
    - 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 child care, cohort care teams, etc.) but planning should consider at least a 25-40% reduction in staff availability. Additional recommendations to augment staff availability include:(87)
  - 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.
     (88)
- 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. **Figure 3** provides a DHA-supported staffing model. At a minimum, the first four staff positions noted below should be ICU trained and experienced: (89)
  - 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.(89)
  - 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
    - CRNA, 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:(87)
      - 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. (82) In the setting of COVID-19, these are likely patients that would be hospitalized in fixed facilities not in ICUs.

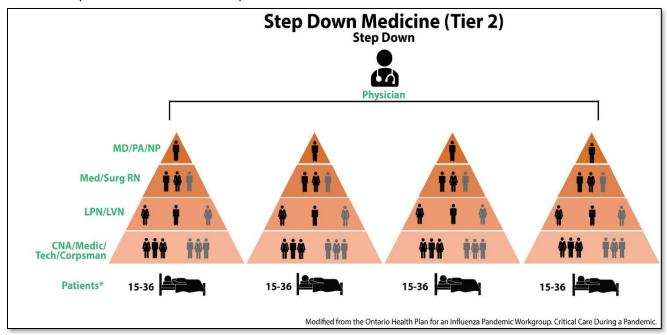


Figure 4. Tier 2 Staffing Strategy for Step-down Level Care during a Pandemic. \*Assumptions/Considerations for both Tiers 2 and 3: 1. Critical care/ICU staffed per DoD COVID Management Guideline; staff/patient ratio subject to local leadership judgment and may require modification for conditions based 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.(2)

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 "offsite" facilities with limited resources (e.g., tents, gyms, convention centers, etc.).

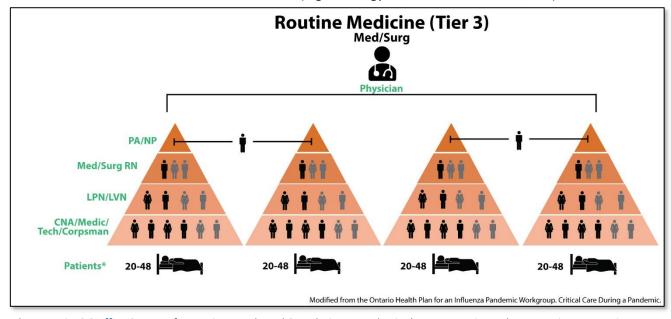


Figure 5. Tier 3 Staffing Strategy for Routine Ward Level Care during a Pandemic. \*For assumptions, please see Figure 4 caption.

#### 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.(90, 91) 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.(92) For MTFs with these capabilities, SCCM has released recommendations for caring for critically ill adults in Pediatric ICUs available at: <a href="https://journals.lww.com/pccmjournal/Fulltext/2020/07000/Caring">https://journals.lww.com/pccmjournal/Fulltext/2020/07000/Caring</a> for Critically Ill Adults With Coronavirus.1.aspx.
- 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).
- b. **Privileging options:** In accordance with national standards for accreditation, local leadership may cross-level providers to provide patient care, 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 <a href="https://www.sccm.org/covid19">https://www.sccm.org/covid19</a>, <a href="https://www.sccm.org/Guidelines-and-Resources/COVID-19/On-Demand-e-Learning">https://www.sccm.org/Guidelines-and-Resources/COVID-19/On-Demand-e-Learning</a>, <a href="https://www.sccm.org/Guidelines-and-Resources/COVID-19/Resource-Center">https://www.sccm.org/Guidelines-and-Resources/COVID-19/Resource-Center</a>, <a href="https://www.sccm.org/disaster">https://www.sccm.org/disaster</a>, and <a href="https://covid19toolbox.com">https://covid19toolbox.com</a>.
- 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. (<a href="https://info.health.mil/edu/Pages/COVID.aspx">https://info.health.mil/edu/Pages/COVID.aspx</a>)
- 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 (93)
- 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:
    <a href="https://www.chestnet.org/Guidelines-and-Resources/Resources/Essential-Institutional-Supply-Chain-Management-in-the-Setting-of-COVID-19-Pandemic (94)">https://www.chestnet.org/Guidelines-and-Resources/Resources/Essential-Institutional-Supply-Chain-Management-in-the-Setting-of-COVID-19-Pandemic (94)</a>

#### 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.

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

- 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.

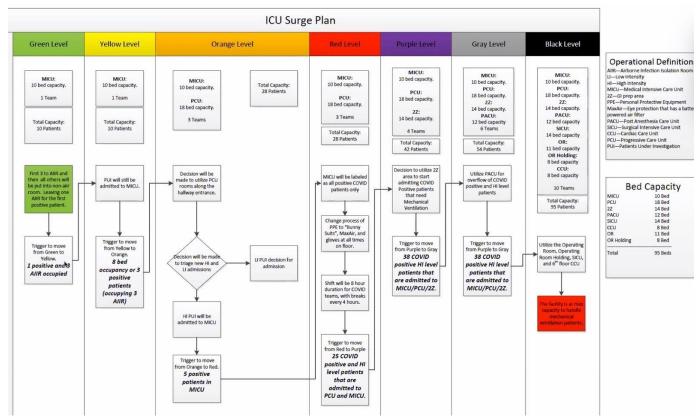
a. A potentially useful tool for initial categorization of clinical severity and aiding in triage is the National Early Warning Score (NEWS), **Figure 6**. This clinically derived score is easily measured in a triage area, clinic, emergency department or other initial assessment environment and consists of parameters listed below.

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				А			V, P, or U

Figure 6. National Early Warning Score (NEWS).(59)

- 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.(95)
- 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.(96)
- 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,(97) although this score has not been prospectively validated/evaluated.(98)
- 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%.(99-102)
- 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: (103)
  - 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/m²)
- 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).
- 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 7** 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**.(104)



**Figure 7.** 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 oversite 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.

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

- 1. See **Appendix C** for additional guidance related to mask use, PPE, and 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 provided in **Figure 8**, 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).
  - b. Implement restricted visitation policies for the facility (refer to example provided by Emory Healthcare: <a href="http://www.emoryhealthcare.org/covid/index.html">http://www.emoryhealthcare.org/covid/index.html</a>, no federal endorsement is intended or implied).
  - c. Practice social distancing.
  - d. Adhere to frequent hand hygiene and wear a surgical or cloth mask at all times (includes visitors).
  - e. Surgical masks are required for healthcare personnel engaged in direct patient care.
  - f. Limited re-use of N95 Respirators refers to practice of using same respirator by one HCP for multiple encounters with different patients but removing after each encounter. If no manufacturer guidance is available data suggest limiting the number of reuses to no more than five uses per device (23 November). https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html#crisis
- 3. **PPE visual for use during supply shortages:** The following visuals from the CDC are available as printable PDFs: <a href="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</a> and there is also a video at: <a href="https://www.nejm.org/doi/full/10.1056/NEJMvcm2014809?query=featured">https://www.nejm.org/doi/full/10.1056/NEJMvcm2014809?query=featured</a> home.
- 4. Questions related to IPC can be sent to: dha.ncr.clinic-support.list.ipc-group@mail.mil

CATEGORY	DEFINITION	REQUIRED ISOLATION/PPE
0	Patient not suspected of having	STAFF:  Surgical mask PPE according to task. See Standard Precautions.
	COVID-19	PATIENTS: Masking (e.g., cloth without valves, surgical mask)
1	Asymptomatic patient with known exposure or high-risk for	STAFF:  Surgical mask PPE according to task. See Standard Precautions.
	exposure to COVID-19 within the last 14 days	PATIENTS: MUST wear surgical mask if traveling outside room for medically essential purposes
	Patient under investigation (PUI) or positive COVID-19	<ul> <li>Contact Precautions (gown and gloves)</li> <li>Droplet Precautions (N95 Respirator preferred;</li> <li>Surgical mask if insufficient supply of N95 if no aerosol-generating procedures performed in room)</li> <li>Eye protection (face shield or goggles)</li> </ul>
		PATIENTS: MUST wear surgical mask if traveling outside room for medically essential purposes
aerosol- generating procedu (i.e., BiPAP, CPAP, endotracl intubation, high- flow nasal	Positive COVID-19 requiring aerosol- generating procedures (i.e., BiPAP, CPAP, endotracheal intubation, high- flow nasal cannula, nebulizers, tracheal	<ul> <li>Contact Precautions (gown and gloves)</li> <li>Consider head and foot covers</li> <li>Airborne Precautions (N95 Respirator or PAPR)</li> <li>Eye protection (face shield or goggles)</li> <li>Negative pressure room</li> </ul>
		PATIENTS: MUST wear surgical mask if traveling outside room for medically essential purposes

**Figure 8.** PPE Recommendations for the MHS (Adapted for the MHS using CDC guidelines accessed 28 December 2020: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html); PAPR, powered air-purifying respiratory; PPE, personal protective equipment; PUI, patient under investigation; High-risk Area - Areas with a Level 3 Travel Health Notice identified by the CDC

Visit www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html for current list.

Special Situations: ED staff and outpatient healthcare workers with any patient encounter with a PUI: Follow Category 2.

#### **LABORATORY DIAGNOSIS OF COVID-19**

1. Introduction: Testing capabilities, methodologies, and platforms for SARS-CoV-2 continue to rapidly evolve as the pandemic progresses, even well over a year into the pandemic. Experiences in countries around the world with testing development and success in widespread availability has varied. In the United States, challenges with rolling out large-scale testing and delays in turn-around times have improved since the first imported case was described on 15 January 2020.(105) 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.(106) The below is a summary of emerging lines of evidence regarding various testing modalities employed in the diagnosis of COVID-19. At this time, at home testing has become available (although not yet widely used), more Emergency Use Authorization PCR's and NAAT tests have become available, and questions regarding re-infection and testing have been raised. 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.(107)

- 2. Molecular testing [polymerase chain reaction (PCR) and other nucleic acid amplification tests (NAAT)]: Molecular testing by PCR for SARS-CoV-2 is the current gold standard for making the diagnosis of COVID-19. The initial CDC PCR assay received emergency use authorization (EUA) on March 3, 2020. The World Health Organization's (WHO) assay initially had difficulties with sensitivity due to reliance on the RNA-dependent RNA polymerase for detection rather than a combination of more sensitive Spike (S), Envelope (E) and Nucleocapsid (N) targets. (108) Since these earlier assays were developed numerous commercial laboratories and universities have developed assays with subsequent FDA EUA.(109) These assays are highly specific, but sensitivity may depend on the disease process (mild upper respiratory infection vs severe pulmonary disease), the specimen site, and quality of specimen collection. (110-113). Commercially available PCR based platforms (e.g., Cepheid, Biofire, Hologic, etc.) have largely supplanted the CDC assay and EUA waivered "inhouse" assays for daily use. (106, 109, 111, 112) 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), and some that have been granted EUA (specifically isothermal assays) by the FDA have had questions raised regarding their sensitivity and specificity (e.g., Abbott ID Now, sensitivity 70% based on one metaanalysis).(107) 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 COVID-19 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. (111) 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 nasopharygeal (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: 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. (114) 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. Early in the pandemic variation in sensitivity and specificity of various specimen sources generated additional research questions about the most appropriate source for collection. One study describing 1070 specimens from 205 patients with COVID-19 suggested that LRT samples were most likely to be positive for viral RNA. (115) In three studies including patients with specimens collected at multiple sites. URT samples in patients with SARS-CoV2 detection at one or more sample sites have a have an estimated sensitivity of 76%.(112) Several studies compared NP to salivary samples (saliva presents an attractive specimen source as it is less invasive to produce and has the potential to be used in pooled screening). (116-121) High concordance between NP and saliva samples were reported, with some studies reporting more frequent detection of SARS CoV-2 RNA in salivary vs NP swabs; however these findings were not consistent between studies, and collection method (spitting vs "coughing up" saliva) also varied. One group devised an elegant experimental model using reverse-engineered reporter viruses to show SARS-CoV-2 viral tropism was higher in the nasopharynx than oropharynx and lower respiratory tract tissues. (113) 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.(112) 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
- 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. The first antigen test received FDA authorization May 8, 2020.(122) 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. CDC updated their guidance on antigen testing on 16 August based on FDA regulatory guidance. 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 rapids identification and isolation are important. There are currently 13 antigen tests that have been granted EUAs by the FDA and we refer the reader to the FDA's website for test names and differences in characteristics in general these are most likely to be helpful in high pre-test probability clinical scenarios.
- 5. Serologic testing: Serologic testing continues to be developed, and as data are made available the potential role of serology in diagnosis has become clearer. (111) The majority of immunocompetent hosts will develop antibodies (IgG and/or IgM) 2-3 weeks after the onset of symptoms associated with COVID-19, although early sero-conversion has been described at 3-5 days.(111) The two major antigenic targets of SARS-CoV-2 virus against which antibodies are detected are spike glycoprotein (S) and nucleocapsid phosphoprotein (N), although other assays detect antibodies to different antigenic sites. (123) S antibodies are predicted to be better markers of seroconversion due to both initial evidence of their high specificity as well as their key role in viral attachment and cell entry. (106, 113, 124) 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). FDA provided EUA for the first antibody tests in April 2020. Unfortunately, early in the pandemic the market was rapidly flooded by over 70 assays, which were not evaluated or tested by the FDA. Many of these produced high rates of false-positive (likely secondary to cross-reactivity to other coronaviruses) and/or false-negative results. Previously the Infectious Diseases Society of America (IDSA) had advised against using serologic testing due to the aforementioned issues with sensitivity and specificity but as testing has improved, a recent update on 18 August outlined 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. (125) A recent meta-analysis of the available literature on serologic assays found that the majority of studies had risk for bias and the pooled sensitivity for Lateral Flow Assay (typically a point-of-care test) studies was low (65%). (124) A Cochrane review was published shortly after this which included 54 studies (more than half of them pre-prints). These authors argued that pooled sensitivity of IgM/IgG antibody testing in the first week after symptom onset was low (<30%) and that these tests were more likely to be useful later on in the disease course (pooled sensitivity IgM/IgG at 3 weeks after symptoms onset was reported to be 96%). Unfortunately the studies included had a high degree of heterogeneity in both method and results.(126) Ultimately, 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. Despite initial challenges, serologic testing is likely to play a role, particularly for patients who are considered "clinically positive" but have a negative NAAT, or those patients that are asymptomatic. It should be noted that the long term durability of antibody response in COVID-19 is still not well understood. (127, 128) To warn of this knowledge gap, the World Health Organization (WHO) issued a statement April 24, 2020 warning that prior infection with SARS-CoV-2 has not been proven to confer immunity to reinfection. (129) Animal model data examining serologic response to SARS-CoV-2 infection has recently argued that antibody production protects against re-infection in a re-challenge rhesus macaque model however this is still not well understood in humans.(130) With the increasing availability of SARs-CoV-2 vaccines questions regarding antibody positivity

and its significance for those vaccinated are likely to be raised. If an antibody assays is specifically targeting the S protein, then 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 COVID-19: Retesting persons with confirmed COVID-19 is not recommended as an infection prevention and control strategy, with the exception of profoundly immunocompromised hosts (e.g., transplant, hematologic maignancy). Initially, the CDC recommended using 2 negative tests (greater than 24 hours apart, obtained after clinical recovery) to document virus clearance. Published data has documented persons testing positive by molecular methods (using upper respiratory specimens) for up to 8 weeks. Other limited viral culture data, which continues to be replicated in larger studies, supports a much shorter course of shedding viable virus (7-9 days). Thus, repeat testing to "clear" patients may lead to prolonged enhanced isolation in the hospital, difficulty in placing clinically improved patients, and delay in return to work in otherwise healthy individuals. On July 17, 2020, CDC revised prior recommendations about symptom-based vs. test-based strategies for discontinuation of transmission-based precautions, and currently recommends symptom-based strategies in nearly all patients. In addition, there was a new recommendation to avoid retesting a patient with confirmed COVID-19 and subsequent clinical recovery in the 3 months after symptom onset.(131) Newer 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.(132)
- 7. **Personal Protective Equipment (PPE) during specimen acquisition:** Use appropriate PPE for specimen collection (droplet, contact, faceshield precautions for URT specimens; contact, faceshield, 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.(112)
- 9. **For pregnant and recently postpartum patients:** COVID-19 testing of symptomatic women may need to be prioritized due to need for inpatient care with delivery and ongoing outpatient visits, to enable access to specialized care, to allow appropriate maternal PPE, and appropriate care for the newborn.
- 10. **Co-infections and multiplex assays:** Co-infections with SARS-CoV-2 and other respiratory viruses are infrequent but well described. (133) Given that the clinical presentation of COVID-19 and influenza has 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 have been at a historic low, both between seasons and during the southern hemisphere's flu season. Data is still being collected for the northern hemisphere's flu season for 2020-2021, however it appears that the South's experience is likely to be duplicated in the North.(134)

#### MANAGEMENT OF COVID-19 BASED ON ILLNESS CATEGORY

Per National Institutes of Health (NIH) COVID-19 Treatment Guidelines, in general, patients with COVID-19 can be grouped into the following illness categories:(135)

- 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.

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

- 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.(68, 136, 137) Additional patient information from the Consortium for Military Health and Performance (CHAMP) can be found at: <a href="https://www.hprc-online.org/total-force-fitness/tff-strategies/personal-protective-nutrition-and-personal-protective-lifestyle">https://www.hprc-online.org/total-force-fitness/tff-strategies/personal-protective-nutrition-and-personal-protective-lifestyle</a>.
- 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).(38, 138, 139)
- 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.(3, 7, 27) 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 <a href="https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html">https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html</a>. 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 (<a href="https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/care-for-someone.html">https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/care-for-someone.html</a>)
  - c. Caring for Yourself at Home (<a href="https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html">https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html</a>)
- 5. **Targeted therapy:** There are currently no approved or recommended therapies for the treatment of COVID-19 in outpatients. While the majority of clinical trials are focused on hospitalized patients, there are a number of clinical trials targeting mild, outpatient cases and investigating the use of antiviral, immune-based, and adjunctive therapies. Further information and updates can be found at

https://www.clinicaltrials.gov. The NIH COVID-19 Treatment Guidelines

(<a href="https://covid19treatmentguidelines.nih.gov/introduction/">https://covid19treatmentguidelines.nih.gov/introduction/</a>) provides updated recommendations and supporting evidence for these therapies. Specifically, the NIH guidelines recommend against the routine use of corticosteroids in outpatients because of recent trials showing a trend towards mortality in more mild cases not requiring supplemental oxygen therapy.

6. Monoclonal antibodies (mAb): While there are no FDA-approved treatments for outpatients with COVID-19, three mAb preparations (bamlanivimab monotherapy, combination bamlanivimab/etesevimab, and cocktail of casirivimab/imdevimab) have been granted EUA for the treatment of outpatient adults and pediatric patients (≥ 12 years old, weighing ≥ 40 kg) with confirmed mild-to-moderate COVID-19 who are at high risk for progression to severe disease/hospitalization. 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 EUA Fact Sheets:

https://www.fda.gov/media/143603/download (bamlanivimab),

https://www.fda.gov/media/145802/download (bamlanivimab/etesevimab), and https://www.fda.gov/media/143892/download (casirivimab/imdevimab).

- a. The NIH COVID-19 Treatment Guidelines recommend combination bamlanivimab/etesevimab for the treatment of outpatients with mild-moderate COVID-19 at high risk for progression to severe disease, with infusion as soon as possible after a positive direct SARS-CoV-2 assay and within 10 days of symptom onset.(140, 141) However, neither the NIH COVID-19 Treatment Guidelines nor the IDSA Guidelines recommend the routine use of bamlanivimab monotherapy or casirivimab/imdevimab. Please see the "Therapeutic Management & Adjunctive Therapies" section of this Practice Management Guide for further discussion of the evidence behind these mAbs and the rationale behind these recommendations.
- b. The allocation of both mAb preparations is regulated by the US Department of Health and Human Services. The allocation of these preparations to the DOD and other jurisdictions can be found at <a href="https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/default.aspx">https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/default.aspx</a>.
- c. The implementation of mAb therapy into the outpatient setting presents significant challenges beyond the limited available efficacy and operational data to date. Challenges include:(142, 143)
  - 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.
- d. Each facility will need to balance these universal challenges within their unique context of physical and personnel infrastructure, resources, and patient population.
- 7. **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).(135)
- 8. **Discontinuation of home isolation:** 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.(139) 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 <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>.

#### **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.(144)
- 3. Multiple series have raised concern for *Aspergillus* pulmonary superinfections in critically-ill patients.(145, 146) 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.(147)
- 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.(148) As a starting point upon intubation, **Table 1** can be used until consultation is available.

 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 Pseudomonas aeruginosa*	<ul> <li>Ceftriaxone<sup>†</sup> 2 g once daily, <u>and</u></li> <li>Azithromycin<sup>†</sup> 500 mg once daily</li> </ul>
With comorbidities‡	Cefepime 2 g every 8 hours, <u>and</u> Azithromycin† 500 mg once daily OR  • Piperacillin-Tazobactam 4.5 g every 6 hours (or every 8 hours by extended infusion), <u>and</u> Azithromycin† 500 mg once daily

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.

- 5. Recommend obtaining blood cultures and tracheal aspirate prior to initiation of antibiotics if feasible.
- 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).(7, 149) 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**

A small favor 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.(150) 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:

- 1. 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.(151)
- 2. Depending on the severity of the influenza season for 2021 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.
- 3. 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.

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:

- 1. 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.(152)
- 2. 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.(153)
- 3. 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).
- 4. 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.
- 5. 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).(134)

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 9** offers a suggested algorithm for managing testing for COVID-19 during Influenza season.

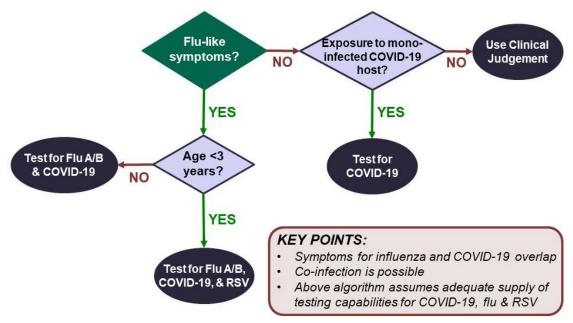


Figure 9. COVID-19 Testing during Influenza Season; RSV, respiratory syncytial virus

#### 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  $SpO_2$  92-96%.(154, 155) Hyperoxia ( $PaO_2 > 225$ mmHg) should be avoided and is associated with worse outcomes.(156)
- 2. Begin with low flow nasal cannula (1-6 L/min) followed by high flow nasal cannula (Figure 10).
- 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). (157) 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>.(158)
- 4. Non-invasive ventilation (NIV). While previously there were recommendations to avoid NIV out of fear of aerosolization, current guidance is that NIV, particularly CPAP with a good tight fitting seal, can be considered in order to treat the atelectasis component of COVID lung disease. CPAP is the preferred modality (with helmet if available). BiPAP can be considered in select cases, such as COPD. Viral filters should be utilized. Ideally, observe the patients response in the first few hours. Those with progressive hypoxia and/or increased work of breathing despite CPAP should be considered for intubation. (158, 159)
- 5. **Helmet ventilation.** The helmet can be connected to either a BiPAP circuit or a HFNC circuit (up to 60 L of flow) to increase the PEEP that the patient receives.(160, 161) The helmet has a tight seal around the neck and should decrease the amount of leak usually seen with mask interface NIV (such as BiPAP and CPAP). In one study comparing helmet to mask NIV with ARDS, there was a decreased rate of intubations.(161) There has been concern that CO<sub>2</sub> washout was inefficient using the helmet,(162) but a follow up study did not support that concern.(160) Helmet ventilation can prevent aerosolizing the virus.
- 6. **Awake proning** of non-intubated patients is currently being performed at some hospitals across the world.(163) A retrospective study of 15 non-intubated, hypoxemic patients placed in the prone position showed improvement of oxygenation. The effects were not sustained upon supine positioning.(164) See **Appendix G** for full protocol for prone positioning of non-intubated patients.

eterioration

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

#### Low flow nasal cannula

Typically set at 1-6 liters/minute.

# High flow nasal cannula

- Titrate FiO2 based on patient's saturation.
- Titrate flow rate to reduce work of breathing.
- Prone patient as much as possible.
- Choice based on tolerance and clinical response.
- Many patients respond well to nocturnal CPAP/BiPAP, with HFNC during the day (with awake proning).

# CPAP (or BiPAP with low driving pressure)

- Titrate CPAP up as tolerated (in more severe hypoxemia might target ~15 cm).
- CPAP or BiPAP may be especially useful at night, among patients who can't sleep in a prone position.

#### **Invasive mechanical ventilation**

- Target tidal volumes of ~6 cc/kg.
- · Permissive hypercapnia may be useful to allow for lung-protective settings.
- May use conventional lung-protective ventilation strategies or APRV.

#### **Prone positioning**

 Consider for severe hypoxemia (e.g. PaO2/FiO2 << 150) that doesn't respond to ~12-24 hours of invasive ventilation with high mean airway pressure (e.g. high PEEP or APRV).

#### VV-ECMO

- · Indications remain unclear.
- · Early discussion with ECMO center or team may be advisable if resources allow.

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.

Figure 10. 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).

- 7. **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).
- 8. **Avoid nebulizers**, as metered dose inhalers are recommended for staff protection/avoidance of aerosols.(114)
- 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.
- 10. Due to infection prevention needs, do not allow ICU visitors during a pandemic except under exigent circumstances.
- 11. Facilities should assess daily operational status via huddle of equipment including ventilators, medications (e.g. analgesics, sedatives, and paralytics), and staffing (including respiratory therapists, physicians and nursing) and initiate contingency or crisis standards of care as appropriate.

#### **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
- \* https://emcrit.org/pulmcrit/nlr/

#### **Endotracheal Intubation**

- 1. **Decision to intubate:** Recent non-peer reviewed references regarding COVID-19 respiratory support should be considered with caution. 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 80% for prolonged duration in order to avoid harms of intubation and mechanical ventilation) are evidence based. However, in the absence of significant clinical experience or high quality evidence with COVID-19 ventilation, it may be reasonable to not intubate select patients with stable mild hypoxemia on supplemental oxygen, but low PaCO<sub>2</sub> and without signs or symptoms of end-organ damage who demonstrate pulmonary shunt physiology for which intubation would not be expected to help.(165) 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 hypoxia and worsening chest infiltrates, hypercarbia or decreasing mental status, and progressive dyspnea.
- 3. Intubation (along with subsequent extubation) has the highest risk of aerosolization and exposure to COVID-19 of all procedures, and the person performing intubation is most at risk.(114) For this reason, the most experienced person should perform endotracheal intubation to reduce exposure to the healthcare team and all team members should be in appropriate PPE with PAPR during intubation. If PAPR is unavailable, an appropriate alternative may be the M50 CBRN gas mask. If these options are not available, N95, hair cover, gown, double gloves, face shields, goggles, and shoe covers should be used, along with a protective clear plastic cover over the patient to optimize protection for the providers. Consider intubation teams and limit the number of staff members during airway manipulation to reduce unnecessary exposure.

  (https://www.apsf.org/news-updates/perioperative-considerations-for-the-2019-novel-coronavirus-COVID-19/)
- 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.(166)
- 6. Some centers have advocated for further reducing exposure during pre-oxygenation and ventilation through preparing an additional COVID-19 Intubation Pack, in addition to intubation meds, a video laryngoscope (if used, or direct laryngoscopy), and a non-vented BiPAP mask. The following video demonstrates the set-up:

#### (https://youtu.be/C78VTEAHhWU).

- 7. **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.
- 8. **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.(167) 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.(155, 168)
  - a. Target an ARDSnet lung-protective strategy (4-8 mL/kg ideal body weight), and lower inspiratory pressures (plateau pressure <30 cm H₂O).(155, 168)
    - 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 may benefit from being placed in the prone position to improve oxygen saturation (PaO<sub>2</sub>), pulmonary mechanics, and arterial blood gases (ABGs).(169-173) Anecdotal reports from Italy and Singapore have found that patients with COVID-19 usually respond well to early pronation.(163)
  - 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.(174)
  - e. Pregnancy is not a contraindication for proning or neuromuscular blockade.(175)
  - 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 (PaO<sub>2</sub>/FiO<sub>2</sub><150), neuromuscular blockade by continuous infusion should <u>not</u> 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 COVD-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 for routine use of inhaled nitric oxide, prostacyclin or other selective pulmonary vasodilators in acute respiratory failure. However, during emerging infectious disease outbreaks when resources are exhausted, inhaled nitric oxide and prostacyclin may be considered as a temporizing measure when patients develop refractory hypoxemia despite prone ventilation, or in the presence of contraindications to proning or ECMO.
- 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. For more information: <a href="https://www.elso.org/COVID-19">https://www.elso.org/COVID-19</a>. For more information: <a href="https://www.elso.org/COVID-19">https://www.elso.org/COVID-19</a>.

#### 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 daily 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: (176-179)
  - 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.(176)
- 4. In accordance with professional society consensus statements, U.S. Public Health Service, and FDA guidance:(176, 177, 179)
  - 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.

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

#### Cardiovascular Disease (CVD)

Cardiovascular comorbidities and the presence of CVD are common in patients with COVID-19 infections. CVD and risk factors correlate with increasing age, and are associated with increased mortality. (33, 180, 181)

- 1. Troponins and Basic Natriuretic Peptide (BNP) evaluation: Elevated troponin is common (especially high sensitivity troponin), which is a strong predictor of mortality. Mild troponin elevation often does not represent a type-I (plaque rupture) myocardial infarction. The concentrations of BNP/NT-proBNP reflect the presence or extent of pre-existing cardiac disease or the acute hemodynamic stress. Troponin value, velocity of change in troponin level, elevated BNP/NT-proBNP and echocardiographic imaging should guide the management of the elevated biomarkers, although current opinion advises that troponin and BNP should only be measured if clinical evaluation suggests acute coronary syndrome or heart failure.(182)
- 2. **Electrocardiogram (ECG):** Recommend ECG in suspected or acute coronary syndrome. May consider of obtaining from cardiac tele-monitoring screen.(182)
- 3. **Echocardiogram:** An echocardiogram should only be ordered if it is likely to provide clinical benefit. Consider repeat echocardiograms only for clear change in clinical status. Point of Care Ultrasound (POCUS) exams may be used to screen/triage patients. Transesophageal echocardiogram (TEE) requests should only be considered when no other alternative imaging modalities are available as the procedure may be aerosol producing.(183)

#### 4. Acute Myocardial Injury:

- a. Definition: An algorithm for the interpretation of myocardial injury is provided for reference and is based on the 4th Universal Definition of Myocardial Infarction.(184)
- b. Incidence and Prognosis: Recent reports found that up to 19% of hospitalized patients with COVID-19, have a combination of elevated cardiac biomarkers, in addition to electrocardiographic and echocardiographic abnormalities.(6, 7, 27, 185) There are two patterns of myocardial injury, one pattern of a continued rise with inflammatory markers, and a second pattern similar to the pattern seen in patients with predominantly cardiac symptoms.(186) Myocardial injury appears to be a late manifestation (up to 14 days from illness onset) and has been found to be independently associated with an increased risk of mortality.(7, 182, 185)
- c. Evaluation: Cardiac Computed Tomography (CCTA): There may be a role for the use of CCTA as a non-invasive means to rule out significant coronary pathology as a cause of myocardial injury. Assessment for the appropriateness of testing and imaging protocols should be made in conjunction with a consulting Cardiologist and Radiologist as capabilities are site specific.(187)

#### 5. Myocarditis:

- a. Incidence: In a case series of 150 patients with COVID-19 patients, nearly 10% of deaths were attributed to myocarditis with circulatory failure, and in 33% of cases it was believed to have contributed as a mechanism for multisystem organ failure.(188)
- b. Diagnosis: There is currently no role for endocardial biopsy. POCUS at initial evaluation to help protocol TTE. Serial TTE/POCUS only if it will impact management.
- c. Management: Supportive care depending on hemodynamic status. There are case reports on different treatment strategies, but none are validated by clinical trials.(182)

#### 6. Acute Coronary Syndrome:

- a. Incidence: Based on available published data, there is a potential symptom overlap between acute coronary syndrome and COVID-19 infection.(5)
- b. Evaluation: Goal is to differentiate acute plaque rupture, demand related ischemia or myocarditis. Recommendation is for cardiology consultation when unable to determine etiology.
  - i. ST segment elevation on the 12 lead EKG has been reported in the absence of coronary thrombosis or spasms in COVID-19 patients.(180) The mechanism for these EKG changes is uncertain but is felt to be attributable to myocarditis vs possible endothelial dysfunction with micro thrombus formation.(180, 189) Confirmation of a wall motion abnormality, indicating regional myocardial

ischemia, can be made with POCUS prior to invasive angiography to aid selecting a revascularization strategy. Each MTF should consider individualizing its approach to the STEMI patients based on local expertise and patient characteristics.

- c. Management: Once the diagnosis of acute coronary syndrome is made, medical management should be coordinated with cardiology.
  - i. Cardiac Catheterization Laboratory Considerations: As most cardiac catheterization laboratories are either normal or positive pressure rooms, the benefits of invasive therapeutics must be weighed against the transmission risk to staff and patients. Deferral of invasive management can be considered based on these factors in favor of medical stabilization if necessary. Patients with borderline or deteriorating respiratory status should be considered for intubation prior to transport to the laboratory. Right heart catheterization, pericardiocentesis, and intra-aortic balloon pump placement can be done at bedside when appropriate. Fibrinolytic protocols should be reviewed at each institution with cardiology to discuss care plans if strained resources.(190)

# 7. Cardiac Dysrhythmias:

- a. Incidence: Common CV manifestation in COVID-19 patients. Current cases series report an occurrence of unspecified arrhythmias in 17% of hospitalized patients with COVID-19 (44% of ICU patients vs 7% non ICU patients).(7) The new onset of malignant tachydysrhythmias in combination with acute myocardial injury should raise suspicion for potential underlying myocarditis.(5)
- b. Management: Follow published COVID-19 specific life support protocols.(191) In patients with atrial fibrillation requiring cardioversion, CCTA may be preferred over TEE to rule out left atrial appendage or intra-cardiac thrombus.(187)

#### 8. Heart Failure and Cardiomyopathy:

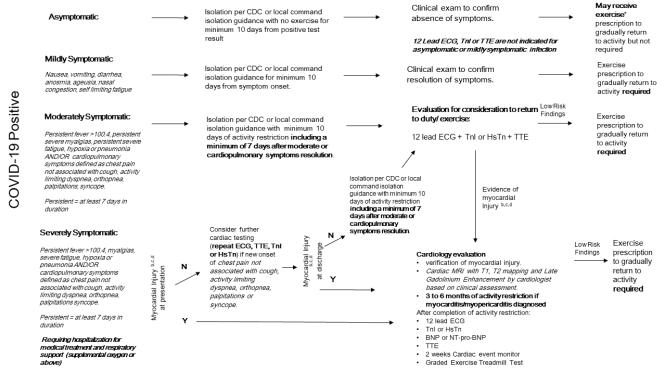
- a. Incidence: In a recent report it was observed that 23% of patients with COVID-19 had presentations consistent with heart failure. More frequently observed in patients who did not survive the hospitalization (51.9% vs 11.7%).(7) Fulminant cardiomyopathy can occur and is thought to be a late feature described in patients recovering from respiratory failure. Cardiogenic shock and cardiac arrest contributes to 7-33% of deaths.(182, 188)
- b. Mechanism: SARS-CoV-2 is thought to infect host cells through ACE2 to cause COVID-19, while also causing damage to the myocardium, although specific mechanisms are uncertain.(192)
- c. Management: In the absence of high grade AV block or unstable bradycardia, cardiogenic shock, or acute kidney injury (AKI), guideline directed medical therapies should be continued in patients with heart failure as it can impact mortality.(193) Assessment of continuation of these therapies should be determined on a frequent basis depending on the patient's clinical status. Assessment of continuation of these therapies should be determined on a frequent basis depending on the patient's clinical status. The American College of Cardiology, Heart failure Society of America, American Heart association, and European Society of Cardiology have published statements at the time of this writing that recommends continuation of ACE-I/ARB therapy in patients with COVID-19.(182)

#### 9. Cardiopulmonary return to exercise or physical activity recommendations:

a. The timing and safety for resuming exercise, intense training, or physical conditioning in those with COVID-19 infection are unknown. Given the potential risk surrounding cardiovascular complications in COVID-19, including cardiomyopathy, arrhythmias, coronary syndromes, and thromboembolic events, in addition to recent observational data, the following return to exercise and physical activity recommendations based on expert opinion are provided in **Figure 11** with detailed information in **Appendix K.** (194)

#### 10. Non-invasive cardiovascular imaging and testing during COVID-19 era:

a. Resumption of elective and time-sensitive non-invasive cardiovascular imaging will need to balance the risks of infection and the risk of delaying adequate management of cardiovascular conditions.(195) Practice patterns and policies may vary depending on the community prevalence of active COVID-19, and this section should serve as a framework for resuming non-invasive cardiac testing during the COVID -19 pandemic and recovery phase.



**Figure 11.** Cardiopulmonary Return to Exercise or Physical Activity Recommendations after COVID-19. (ECG, electrocardiogram; TnI, Troponin I; HsTn, high sensitivity troponin; TTE, transthoracic echocardiogram)

- a: Refer to Cardiovascular Disease Section under Management of Critical Illness and COVID-19 -Prevention of Complications.
- **b:** ECG findings that may indicate viral induced myocardial injury include pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions that are outside of the normal parameters based on the Internal Recommendations For Electrocardiographic interpretation in athletes.(2)
- c: Cardiac Biomarkers indicative of myocardial injury: >99th percent upper limit of normal levels for Troponin I or High Sensitivity Troponin I/T.
- d: Transthoracic echocardiogram findings of cardiac injury- regional wall motion abnormalities, dilated ventricles, abnormal systolic function with a reduced EF <45%. \*See Gradual Return to Exercise and Physical Activity Prescription in **Appendix K**.
  - b. Clinicians requesting non-invasive cardiovascular imaging tests should adhere to the following principles:
    - i. Avoid the layering of multiple tests by choosing the test that provides essential information to answer the clinical question.
    - ii. Balance the test's safety and accuracy to the required PPE for the procedure and potential exposure to healthcare providers.
    - iii. For cardiovascular clinicians performing these tests:
    - iv. Ensure workflows allow time in between studies for sanitation and slower throughputs due to COVID-19 precautions.
    - v. Adhere to local infection prevention and control guidance when performing any aerosol-generating (TEE) or potential aerosol-generating (Exercise stress testing) procedures.
    - vi. Perform aerosol-generating procedures (AGP) in negative pressure rooms with good air circulation if possible.
    - vii. Personal protective equipment (PPE) for patient encounters should follow recommendations for each patient category (0-3) outlined in this document (see Personal Protective Equipment For Patient Encounters During COVID-19 Pandemic).

# **Acute Kidney Injury (AKI)**

1. When defined by the Kidney Disease: Improving Global Outcomes Guidelines (KDIGO) criteria,(196) AKI occurs in 61-68% of critically ill patients with COVID-19.(197, 198) Among patients with AKI in the ICU

- setting, a significant proportion (31-55%) require renal replacement therapy.(197, 198)
- 2. The etiology of AKI in COVID-19 is predominantly acute tubular necrosis in the setting of multi-organ failure and shock.(198) 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.(199)
- 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.(196, 199)
- 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.(196) The subclavian vein should be avoided.
- 7. Patient 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 that are already familiar with the technique given the risks of hypocalcemia and citrate toxicity. Second line anticoagulation is heparin. This topic is reviewed extensively in section 5.3 of the Kidney Disease: Improving Global Outcomes Guidelines on AKI.(196) 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:(68, 200-203)
  - a. Endothelial cells abundantly express ACE2, the principal ligand for the SARS-CoV-2 Spike protein.
  - b. 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.
  - c. Damaged endothelium is incapable of maintaining an anticoagulant surface; microvascular and large vessel thrombosis is common in severe SARS-CoV-2 infection.
  - d. A recent study in ventilated ICU patients found thrombosis (PE or DVT) in 100% of patients receiving VTE prophylaxis (LMWH) and 56% of patients receiving full anticoagulation (anticoagulation treatment decisions made based on risk, not VTE diagnosis).
  - 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: (7, 67, 204, 205)
  - 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: (206)
  - 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:(207-212) (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, proned and persistently hypoxic; MOF; requiring CVVH), it is reasonable to consider therapeutic anticoagulation or 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). 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: <a href="https://www.covid19treatmentguidelines.nih.gov/whats-new/">https://www.covid19treatmentguidelines.nih.gov/whats-new/</a>. (213)
  - 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 prophylaxis for patients with moderate to severe COVID-19 not diagnosed with VTE (e.g., Apixaban 2.5 mg po q12 hrs for 30 days or Rivaroxaban 10mg PO q24 hours 30 days
  - 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; re-bolus tPA 50 mg if no/transient improvement in P/F) [salvage regimen in use at BIDMC, Harvard Medical School; courtesy of Dr. Chris Barrett].
- c. Transfusion considerations: (214-217)
  - i. Convalescent plasma transfusion may accelerate viral clearance and improve clinical outcomes through passive antibody transfer, though this has not been definitively established.
  - ii. In general, plasma transfusion is considered a relatively low risk intervention. In addition to antibody transfer, plasma may have positive effects on vascular endothelium and can restore coagulation homeostasis. However; the non-immune effects of plasma transfusion in COVID-19 have not been established.
  - iii. Consider convalescent plasma transfusion in COVID-19 patients early in the course of illness with moderate to severe disease. Obtain type and screen on admission to determine blood group.
  - iv. Refer to the Therapeutic Management and Adjunctive Therapies Section for additional information about convalescent plasma.
- d. 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. (218-227)
- 4. Ensure patients get adequate amount of Vitamin A and Vitamin C either in their diet or other route of

nutritional support.(228, 229)

- 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".(230)
- 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:

    <a href="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/</a>
  - 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/
- 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 3.** Prevention of Complications

Anticipated outcome	Interventions
Reduce days of invasive mechanical ventilation	<ul> <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> <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</li> </ul>

	damaged, but not routinely
	<ul> <li>Change heat moisture exchanger when it malfunctions, when soiled, or every 5–7 days</li> </ul>
Reduce incidence of venous thromboembolism	<ul> <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	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
Reduce incidence of pressure ulcers	Turn patient every 2 hours
Reduce incidence of	Give early enteral nutrition (within 24–48 hours of admission)
stress ulcers and gastrointestinal (GI) bleeding	<ul> <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, rena replacement therapy, liver disease, multiple comorbidities, and higher organ failure score</li> </ul>
Reduce incidence of ICU- related weakness	Actively mobilize the patient early in the course of illness when safe to do so

# 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.(154, 231)
- 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.(232, 233)

#### **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.(231)
- 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.(234)
- 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. (5) 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).(235) 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 <u>pregnant women</u>, (>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 (191)

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. (236, 237) 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. (236, 237) 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, which were developed and used at Brooke Army Medical Center (BAMC). Each institution should consider, based on local prevalence and perceived risk, whether all Code Blues and RRTs on patients who don't have a known recent highly-reliable negative PCR should be performed with full PPE and treated as a suspected COVID-19 patient.

- 1. 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. Current cardiopulmonary (CPR) recommendations were reviewed in the context of the COVID-19 pandemic. In this context, the delicate balance is to provide timely and high-quality resuscitation to patients while simultaneously protecting rescuers.(191)
- 2. The AHA Interim Guidance provides general principles, specific strategies, and rationales for algorithm changes. It should be used to develop local "Protected Code Blue" and "Protected Rapid Response Team (RRT)" Protocols for medical emergencies that involve the resuscitation or clinical deterioration of COVID-19 suspected or confirmed patients. These policies and protocols should be peer-reviewed and based on the best available data and evidence, and should also be updated based on performance improvement data and experience. In addition, the American Red Cross (ARC) published similar guidance in May 2020. Refer to Appendix O for cardiac arrest algorithms.
- 3. 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.

- 4. 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.
- 5. 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  $FiO_2$  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.
- I. 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.
- 6. 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**.
- 7. **Table 4** identifies best practices based on a "Minimum, Better, Best" model, as the COVID-19 outbreak could ultimately result in limited resources based on observational data from other countries. The goal is to achieve all elements of each category, as "Good" equates with the minimum standard-of-care while "Best" equates with the most ideal condition.

## **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.

**Table 4.** Minimum-Better-Best Paradigm for Limited Code Blue

	Minimum	Better	Best
Advance Directives (Code status, goals of care)	Discuss & document with every patient's medical power of attorney (MPOA) if patient unable to speak for self	Discuss & document with every patient; Involvement of Palliative Care for high risk	Develop a script for clinician that incorporates unique circumstances & ethical considerations if worsening pandemic.
Alert mechanism	Educate current Code Team members about who should respond to "Overhead Code	Early activation	Directed announcement ONLY to COVID-19 Code Team

Blue" to COVID-19 patients (used as backup or multiple codes at once) Airborne/Negative ISO; Droplet for room; Regular practice with "Tactical PPE / Precautions Infection Control Gatekeeper; PPE Donning" Checklist Minimize door opening Door remains closed Communication Personal communication Whiteboard for written Vocera; Speakerphone in room; (via PAPRs or individuals devices; instructions; Closed-loop Gatekeeper outside room) Dedicated audiovisual devices Rotate 2 individuals who don't Automated compressor device Rotate 2 individuals who don't leave room and accomplish CPR (e.g. LUCAS) to reduce risk to leave room additional tasks based on pre-**HCPs** established priorities Two standard functioning PIVs Early placement of central IV access Tibial IO (if needed) for all COVID-19 patients access prior to arrest Specialized cart/kit containing For high-risk patients: consider Dedicated Code Cart for COVIDappropriate meds, modular early placement of defib pads 19 ICU and wards; packs of equipment, and **ACLS Equipment** in room or on patient, or designated defibrillator; Accounting for Code Carts to prepositioning the Code Cart Dedicated COVID-19 ward: US, ensure appropriate backups outside patient room EKG machine, portable CXR Place NRB mask immediately BVM with viral filter and ETCO2 Strict adherence to COVID-19 on patient covered by a surgical (2-person technique to ensure **Intubation Protocol Airway** mask tight seal) Protocol to identify high risk (see "Intubation" protocol) Consider LMA (with viral filter) patients so that early by trained and experienced intubation occurs BEFORE personnel arrest

## **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 (<a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html</a>). 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.

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

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 are now deciding when and how to safely

resume 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.(238)

## **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: (239)
  - 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**

- 1. 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. (240)
  - b. Imaging should be reserved for cases where it will impact management or in order to evaluate for urgent/emergent alternative diagnoses. (241)
  - 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.(242)
- 2. The reported sensitivity of Chest CT for COVID-19 ranges from 80-90% and the reported specificity ranges from 60-70%. (243, 244)
  - 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. (245)
- 3. 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 recently published recommendations for imaging for pulmonary embolism or deep venous thrombosis (DVT) in COVID-19 patients. (246)
- ACR recommends minimizing magnetic resonance imaging (MRI) use except where absolutely necessary. (ACR guidance on COVID-19 and MR use, <a href="https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety/COVID-19-and-MR-Use">https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety/COVID-19-and-MR-Use</a>)
- 5. **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. (241)
  - 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
- 6. When performing image-guided procedures on patients who are positive or suspected positive for COVID-19, consider implementing the following infection control precautions: (247)
  - 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 airnegative 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%. (248)
- 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. (248)

## 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: (243, 249-252)
  - 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. (253, 254)
- 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. (255)
  - 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.(27) 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:(187) 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.(256-259)

# **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 (260). 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.(261)
- 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.(262) Later case series identified diffuse confluent symmetrical white matter T2/DWI hyperintensities with microhemorrhages reminiscent of delayed posthypoxic leukoencephalopathy (263) and cortical gray matter with subcortical white matter signal abnormalities suspicious for autoimmune encephalitis in COVID-19 patients with negative CSF RT-PCR.(264) 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.(265) 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%).(266)

# **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. (267)

# THERAPEUTIC MANAGEMENT AND ADJUNCTIVE THERAPIES FOR COVID-19

NIH COVID-19 Treatment Guidelines are available at: <a href="https://www.covid19treatmentguidelines.nih.gov/whats-new/">https://www.covid19treatmentguidelines.nih.gov/whats-new/</a> and Figure 12 contains the NIH Recommendations for Pharmacologic Management of Patients with COVID-19 Based on Disease Severity. (<a href="https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/">https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/</a>)
These evidence-based recommendations focused on medical therapies in this PMG are complementary to the NIH guidelines and are intended to be updated regularly in response to emerging evidence.

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 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 (SpO2) ≥94% while breathing ambient air at sea level.
- **Severe illness**: Individuals who have evidence of lower respiratory tract disease with SpO2 <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 12.

There are insufficient data to recommend for or against the routine use of convalescent plasma, anti-SARS-CoV-2 specific immunoglobulins, baricitinib, casirivimab plus imdevimab, bamlanivimab, ivermectin, interleukin (IL)-1 inhibitors (e.g., anakinra), and interferon beta for the treatment of early (i.e., <7 days from symptom onset) mild and moderate COVID-19.

We recommend against the use of:

- chloroquine or hydroxychloroquine with or without azithromycin for the treatment of COVID-19 in hospitalized patients (AI)
- chloroquine or hydroxychloroquine with or without azithromycin for the treatment of COVID-19 in non-hospitalized patients, except in a clinical trial (AI)
- high-dose chloroquine (600 mg twice daily for 10 days) in any setting (AI)
- lopinavir/ritonavir (AI) or other HIV protease inhibitors (AIII) to treat COVID-19, except in a clinical trial.
- ivermectin for the treatment of COVID-19, except in a clinical trial (AIII)
- Mesenchymal stem cells (AII)
- non-SARS-CoV-2-specific intravenous immunoglobulin (IVIG) (AIII)
- Interferons (alfa or beta) for the treatment of severely or critically ill patients with COVID-19 (AIII).
- Bruton's tyrosine kinase inhibitors (e.g., acalabrutinib, ibrutinib, zanubrutinib)

**Note:** With the exception of glucocorticoids and remdesivir, which have high-level RCT evidence and/or are FDA-approved, the majority of pharmacologic therapies for COVID-19 are investigational. No FDA-unapproved medications should be routinely recommended for use outside of a clinical trial. There is no evidence for use of the following medications for outpatients or mildly ill patients. The American Society of Health-System Pharmacists (ASHP) website has a number of regularly updated resources at: <a href="https://www.ashp.org/Pharmacy-Practice/Resource-Centers/Coronavirus">https://www.ashp.org/Pharmacy-Practice/Resource-Centers/Coronavirus</a>.

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 the 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." (268)

## **DISEASE SEVERITY**

# PANEL'S RECOMMENDATIONS

Not Hospitalized, Mild to Moderate COVID-19 There are insufficient data to recommend either for or against any specific antiviral or antibody therapy. SARS-CoV-2 neutralizing antibodies (bamlanivimab or casirivimab plus imdevimab) are available through EUAs for outpatients who are at high risk of disease progression.<sup>a</sup> These EUAs do not authorize use in hospitalized patients.

Dexamethasone should not be used (AIII).

Hospitalized<sup>a</sup> But Does Not Require Supplemental Oxygen Dexamethasone should not be used (Alla).

There are insufficient data to recommend either for or against the routine use of **remdesivir**. For patients at high risk of disease progression, the use of remdesivir may be appropriate.

# Hospitalized<sup>a</sup> and Requires Supplemental Oxygen

(But Does Not Require Oxygen Delivery Through a High-Flow Device, Noninvasive Ventilation, Invasive Mechanical Ventilation, or ECMO) Use one of the following options:

- Remdesivir<sup>b,c</sup> (e.g., for patients who require minimal supplemental oxygen) (Blla)
- Dexamethasone<sup>d</sup> plus remdesivir<sup>b,c</sup> (e.g., for patients who require increasing amounts of supplemental oxygen) (BIII)<sup>e,f</sup>
- Dexamethasone<sup>d</sup> (e.g., when combination therapy with remdesivir cannot be used or is not available) (BI)

Hospitalized<sup>a</sup> and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation Use one of the following options:

- Dexamethasone<sup>d,f</sup> (AI)
- Dexamethasoned plus remdesivirb,c (BIII)e,f

Hospitalized<sup>a</sup> and Requires Invasive Mechanical Ventilation or ECMO

Dexamethasoned (AI)9

Rating of Recommendations: A = Strong; B = Moderate; C = Optional

Rating of Evidence: 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

- <sup>a</sup> See the Panel's statements on the FDA EUAs for bamlanivimab and casirivimab plus imdevimab. These EUAs do not authorize use in hospitalized patients
- The remdesivir dose is 200 mg IV for one dose, followed by 100 mg IV once daily for 4 days or until hospital discharge (unless the patient is in a health care setting that can provide acute care that is similar to inpatient hospital care). Treatment duration may be extended to up to 10 days if there is no substantial clinical improvement by Day 5.
- ° For patients who are receiving remdesivir but progress to requiring oxygen through a high-flow device, noninvasive ventilation, invasive mechanical ventilation, or ECMO, remdesivir should be continued until the treatment course is completed.
- d The dexamethasone dose is 6 mg IV or PO once daily for 10 days or until hospital discharge. If dexamethasone is not available, equivalent doses of other corticosteroids, such as prednisone, methylprednisolone, or hydrocortisone, may be used. See the Corticosteroids section for more information.
- ° The combination of dexamethasone and remdesivir has not been studied in clinical trials.
- <sup>1</sup> In the rare circumstances where corticosteroids cannot be used, baricitinib plus remdesivir can be used (Blla). The FDA has issued an EUA for baricitinib use in combination with remdesivir. The dose for baricitinib is 4 mg PO once daily for 14 days or until hospital discharge.
- The combination of dexamethasone and remdesivir may be considered for patients who have recently been intubated (CIII). Remdesivir alone is not recommended.

**Key:** ECMO = extracorporeal membrane oxygenation; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; IV = intravenous; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2

Figure 12. Recommendations for Pharmacologic Management of Patients with COVID-19 Based on Disease Severity (3)

#### Remdesivir

- 1. Remdesivir (Veklury) is the first medication to receive FDA approval for the treatment of COVID-19 requiring hospitalization. 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 approved for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. 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.(269-272)
- 2. 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. (272-275) 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. (276)
- 3. 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.(277)
- 4. 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.(274)

## **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.(273, 275, 278, 279)
- 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).(135, 280)
- 3. Following the publication of the RECOVERY trial,(273) 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. (281)
- 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. 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. In this regard, although there are insufficient data from clinical trials to recommend either for or against the use of any specific therapy in this setting, preliminary data suggests that outpatients may 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. None of the monoclonal antibodies have shown benefit in the inpatient setting. (282, 283) The NIH and IDSA Guidelines explicitly recommend against the use of monoclonal antibodies in hospitalized patients outside of a clinical trial.
- 2. 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.
- 3. 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.(284, 285) 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.
- 4. 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 ≥12 years and weighing ≥40 kg who have a high risk for progressing to severe COVID-19 or hospitalization. High risks specified in the EUA are:
  - a. Individuals aged ≥12 years who have one of the following conditions:
    - i. BMI ≥35
    - ii. Chronic kidney disease
    - iii. Diabetes mellitus
    - iv. Immunosuppressive disease
    - v. Currently receiving immunosuppressive treatment
  - b. Individuals aged ≥65 years
  - c. Individuals aged ≥55 years who have:
    - i. Cardiovascular disease, or
    - ii. Hypertension, or
    - iii. Chronic obstructive pulmonary disease/other chronic respiratory disease
  - d. Individuals aged 12 to 17 years who have:
    - i. BMI ≥85th percentile for their age and gender based on the Centers for Disease Control and Prevention growth charts; or
    - ii. Sickle cell disease; or

- iii. Congenital or acquired heart disease; or
- iv. Neurodevelopmental disorders, for example, cerebral palsy; or
- v. A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19); or
- vi. Asthma or a reactive airway or other chronic respiratory disease that requires daily medication for control
- 5. 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.
- 6. 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) (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.(286, 287)
- 7. The FDA EUA allows for the use of casirivimab plus imdevimab for the treatment of COVID-19 in nonhospitalized adults and children aged ≥12 years and weighing ≥40 kg who are at high risk for progressing to severe COVID-19 and/or hospitalization. High-risk individuals specified in the EUA are those who meet at least one of the following criteria:
  - a. Body mass index (BMI) ≥35
  - b. Chronic kidney disease
  - c. Diabetes mellitus
  - d. Immunocompromising condition
  - e. Currently receiving immunosuppressive treatment
  - f. Aged ≥65 years
  - g. Aged ≥55 years and have:
    - i. Cardiovascular disease, or
    - ii. Hypertension, or
    - iii. Chronic obstructive pulmonary disease/other chronic respiratory disease
  - h. Aged 12 to 17 years and have:
    - i. BMI ≥85th percentile for their age and gender based on the Centers for Disease Control and Prevention growth charts; or
    - ii. Sickle cell disease; or
    - iii. Congenital or acquired heart disease; or
    - iv. Neurodevelopmental disorders, for example, cerebral palsy; or
    - v. A medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive

- pressure ventilation (not related to COVID-19); or
- vi. Asthma or a reactive airway or other chronic respiratory disease that requires daily medication for control
- i. Casirivimab and imdevimab are not authorized for use in patients:
  - Who are hospitalized due to COVID-19; or
  - ii. Who require oxygen therapy due to COVID-19; or
  - iii. Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to an underlying non-COVID-19 related-comorbidity.
- 8. To order either EUA product, sites must contact cpoc@dla.mil with site name, DoDAAC/UIC, site address, Amerisource Bergen account number, POC name, 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 is 10 vials with a maximum quanity of 30 vials per order. Orders should be placed in multiples of 5 vials. 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. 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. 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 ≥2 years with COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).(288)
- 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).(289)
- 4. The NIH guidelines currently recommend for the use of baracitinib only in combination with remdesivir, in hospitalized, non-intubated patients in those infrequent situations where glucocorticoids cannot be used. Baracitinib is not recommended to be used in combination with dexamethasone. The use of other Janus kinase (JAK) inhibitors, such as ruxolitinib and tofacitinib, is not recommended for the treatment of COVID-19 except in a clinical trial.(290)

## Chloroquine (CQ) and hydroxychloroquine (HCQ)

1. The FDA revoked the EUA for HCQ on 15 Jun 2020. Use of HCQ or CQ for the treatment of COVID-19 is not recommended outside of a clinical trial. (https://www.fda.gov/media/138945/download)

#### Lopinavir/ritonavir

- 1. 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.(291-293)
- 2. 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 receiving these drugs for the treatment of HIV infection should be continued on their therapy whenever possible, however.

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. The 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.
- 2. 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 tociluzimab to therapy for patients with severe or critical COVID-19.(294-297) 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.(298-300)
- 3. At the time of this writing, the NIH panel is pending an update of their recommendations regarding the use of IL-6 antagonists. Based on the platform trial results, however, the IDSA COVID-19 treatment guidelines were updated on 22 February 2021 to include of conditional recommendation for tocilizumab in hospitalized patients with hypoxemia, including mechanically ventilated patients, with evidence of systemic inflammation (defined as a C-reactive protein of 75 mg/L or greater), in combination with glucocorticoids.(301)

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

- 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.(302) 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.(303)</li>
- 2. 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.(304)
- 3. Multicenter trials of convalescent plasma in hospitalized patients with hypoxemia have generally shown no benefit; (305, 306) 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.
- 4. 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) are eligible for treatment with convalescent plasma. CONUS

and OCONUS (including deployed) providers should contact USAMMDA FHP at <u>usarmy.detrick.medcom-usammda.mbx.force-health-protection@mail.mil</u> or (301) 401-2768 to establish their facility as a treatment site. Plasma procurement will be coordinated by the Armed Services Blood Program.

# **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).5 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.(307-309)
- 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.(310) These results have not yet been submitted for publication and peer-review.
- 3. Patients who are receiving anticoagulant or antiplatelet therapies for underlying conditions should continue these medications if they receive a diagnosis of COVID-19.(311)
- 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.(311)
- 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.(311)
- 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.(311)
- 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.(311)
- 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.(311)
- 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.(311)
- 10. For hospitalized children with COVID-19, indications for VTE prophylaxis should be the same as those for children without COVID-19.(311)
- 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.(311)
- 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.(311)

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.

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

#### **Overview**

- Recent data from the Centers for Disease Control and Prevention COVID-19 surveillance suggest that in
  women with COVID-19, pregnant women appear to be at increased risk for certain manifestations of
  severe illness compared to non-pregnant women including ICU admission, mechanical ventilation,
  extracorporeal support, and death.
- Healthcare providers should be aware of the physiologic changes associated with pregnancy. Pregnant women have changes in their bodies that may increase their risk of some infections. Pregnant women have had a higher risk of severe illness when infected with viruses from the same family as COVID-19 and other viral respiratory infections, such as influenza.
- Healthcare providers treating pregnant women 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.
- 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 is no longer recommended for maternal COVID-19.
- 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.(1)
- 2. **Epidemiology:** Based on recent data from the CDC COVID-19 surveillance, pregnant women with COVID-19 appear to be at increased risk for more severe illness compared to non-pregnant women. This data also indicates an increased risk for ICU admission and mechanical ventilation, extracorporeal support, and death.(312) It is also important to emphasize that although this report suggests an increase in risk of severe outcomes in pregnant women with SARS-CoV-2 infection, the absolute risk for severe COVID-19 is low.(40-43) Similar to the general population, obesity and gestational diabetes were associated with hospitalization and worsening respiratory status, and Black and Hispanic pregnant women had disproportionate rates of SARS CoV-2 infection and death.(313) Clinical findings in reported cases were similar in cases of non-pregnant adults. Pregnant women experience immunologic and physiologic changes that make them more susceptible to viral respiratory infections.(41) Pregnant women are at greater risk for severe illness, morbidity, and mortality compared with the general population, as is observed with other related coronavirus infections.(42, 43) Pregnant women should receive the same care as those not pregnant in regards to screening, radiology studies, laboratory evaluations 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. (41, 42)
- 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) (<a href="https://priority.ucsf.edu/">https://priority.ucsf.edu/</a>).
- 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 HCO₃ 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 <a href="https://www.smfm.org/education/criticalcare">https://www.smfm.org/education/criticalcare</a>
- 7. **Screening guidelines:** ACOG and SMFM algorithm for outpatient assessment and management of pregnant women with suspected or confirmed COVID-19: <a href="https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/clinical-guidance/practice-advisory/COVID-19-algorithm.pdf?la=en&hash=2D9E7F62C97F8231561616FFDCA3B1A6">https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/clinical-guidance/practice-advisory/COVID-19-algorithm.pdf?la=en&hash=2D9E7F62C97F8231561616FFDCA3B1A6</a>
  - a. Pregnant women admitted with suspected COVID-19 or who develop symptoms consistent with COVID-19 during admission should be prioritized for testing. Testing of asymptomatic pregnant women 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. (314-316)
- 8. A system should be in place for pregnant women 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.(317) 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.(318)
- 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. (319)
- 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.(316)
    - 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.
      - 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 hematophagocytic 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).(1)
- 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.(320)
  - 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.(321) 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.(318)
  - 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 as in non-pregnant patients.
  - 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 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  $BMI \ge 35$ , 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.(1, 313) There is no absolute contraindication to their use in appropriate pregnant patients.

- 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.
- 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 (<a href="https://www.aium.org/officialStatements/57">https://www.aium.org/officialStatements/57</a>).
- 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 ≥ 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).(1)
- 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

Hospitalized obstetrical patient with COVID-19

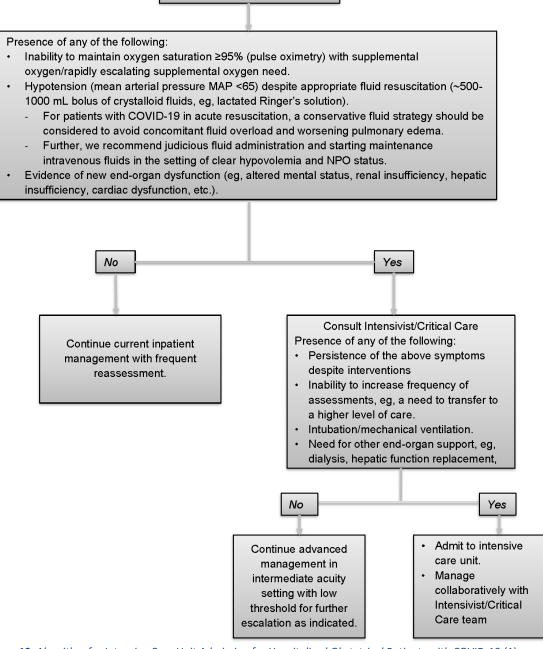


Figure 13. Algorithm for Intensive Care Unit Admission for Hospitalized Obstetrical Patients with COVID-19.(1)

- e. ICU admission criteria: The SMFM provides **Figure 13** 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<sub>2</sub> 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<sub>2</sub> and oxygenation targets while remaining mindful not to allow alveolar plateau pressures to exceed 35 cm H2O.
- 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.(1)
- I. 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.(1)
- 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 methemoglobn 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.(1)
- 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 PaO2 >70 mmHg with maximal FiO2 despite efforts to optimize ventilation, which differs from the threshold of 60 mmHg in non-pregnant patients. The SMFM provides the algorithm below (Figure 14) for management of refractory hypoxemia in pregnancy.(1)
- o. Goal BP should be < 160/110.

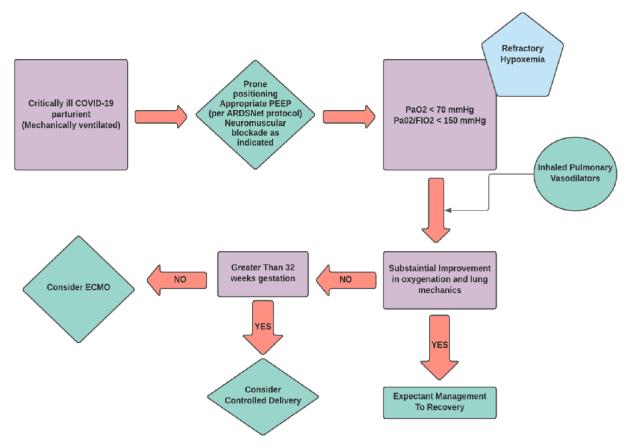


Figure 14. Algorithm for Refractory Hypoxemia for Critically III Obstetrical Patients with COVID-19.(1)

- 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.(322)
  - 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.(213)
  - 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.(1)
- 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.

## 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.(323, 324)
- 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.
  - 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.(325)
- 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 women 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 5. Use of Common Obstetric Medications

Gestational Age	< 32 weeks	6	32-34 weeks	Course	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).(326)

## 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.
- I. 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. (319)
  - 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 women 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.(319)
- 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.(327)
- 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 6.** Suggested PPE During Obstetric Care (319)

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

<sup>\*</sup> 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.(328)

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

- a. 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.
- b. No children < 16 years permitted.
- c. Additional visitors for end-of life situations or bereavement (e.g. IUFD) may be considered/evaluated on a case-by-case basis.
- d. 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.
- e. 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):

- a. Recommend early epidural to minimize need for general anesthesia in the event of an emergent cesarean.
- b. COVID-19 is not a contraindication to neuraxial anesthesia.
- c. 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).
- d. Recommend limiting exposure of trainees to COVID+/PUI, with experienced staff providing care.
- e. Suspend nitrous oxide programs on L&D due to possible aerosolization.(329)

#### 35. Postpartum care:

- a. 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.
- b. 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 women 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. (319) 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.(319) Pregnant women may continue to work until they give birth or go on social isolation (as above). ACOG recommends that:(313)
  - a. 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.
  - b. Employers follow current CDC guidance and direction from local and state health departments (CDC).
  - c. 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. (313)

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

- 1. A COVID-19 shred decision making information sheet is included as a reference in **Appendix R**.
- 2. The SMFM and the ACOG recommend that pregnant and lactating women have access to COVID-19 vaccines, and that they engage in a discussion about potential benefits and unknown risks with their

healthcare providers regarding receipt of the vaccine.(330) Counseling should balance available data on vaccine safety with the lack of data related to fetal risk, risk of the pregnant person for SARS-CoV-2 infection acquisition, and their individual risk of severe disease. The level of COVID-19 community transmission and personal risk of contracting COVID-19 should be considered in counseling for vaccination.(330)

- 3. 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.(330) Dosing recommendations for the vaccine(s) are the same as for non-pregnant individuals).
- 4. A pregnancy test prior to vaccination is not recommended, nor are there data to guide timing of conception following vaccination. If a person decides to receive the vaccine, there are no trimester specific considerations at this time.(330)
- 5. Pregnant women experiencing fever following vaccination should be counseled to take acetaminophen.
- 6. Vaccination is recommended for lactating persons. Counseling should balance the lack of data on vaccine safety and a person's individual risk for infection and severe disease. The theoretical risks regarding the safety of vaccinating lactating people do not outweigh the potential benefits of the vaccine.
- 7. Patients planning to become pregnant: Patients undergoing fertility treatment and pregnant patients should be encouraged to receive the vaccination based on eligibility criteria. Since the vaccine is not a live virus, there is no reason to delay pregnancy attempts because of vaccine administration or to defer treatment until the second dose has been administered.(331)
- 8. Because COVID-19 mRNA vaccines are not composed of live virus, they are not thought to 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.
- 9. 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.(331)

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

- Current evidence is inconclusive about in utero transmission of SARS-CoV-2 from mothers with COVID-19 to their newborns; however, date from the National Perinatal COVI-19 Registry, which includes over 4,300 maternal-infant dyads, suggests that symptomatic vertical transmission is rare.(332) Transmission of SARS-CoV-2 can occur after birth via contact with infectious respiratory secretions, and can lead to hospitalizations requiring respiratory support.(332) Data suggests that infants may be at higher risk for severe illness compared with older children. (333-335)
- 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.(336)

# Lactation: Breastfeeding, Pumping, or Expressed Breast Milk (337)

- 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.(335) Mothers with COVID-19 or PUI who are direct breastfeeding should perform hand hygiene and wear a mask.(332)
- 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 in 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.(338)

#### **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 2nd stage of labor and the potential need for AGPs (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.(334) 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.(336)
- 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.(339) If it is not easily available outpatient, ensure proper disinfection measures are used when cleaning equipment.

## **Neonatal Intensive Care Unit (332, 340)**

- 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.
- 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 14 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, at 7 days and 14 days after last maternal contact is recommended. This testing addresses the risk that the infant has acquired the virus by horizontal transmission.

## **Newborn Visitation (336)**

- 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. COVID-19 positive persons or their household contacts should not be allowed to visit 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 (332, 336)

- 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), <u>AND</u>
  - 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 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.
- 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.(341)

CDC Guidance: <a href="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</a>;

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

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

- 1. Children (0-18 years) currently make up 12.5% of all the laboratory-confirmed COVID-19 cases in the United States with nearly 2.3 million pediatric cases as of January 7, 2021. To put this into perspective, consider that children make up approximately 22% of the US population. There was a 17% increase in pediatric cases over the last two weeks in December, which is notable given holiday travel.(342)
- 2. Initial studies found approximately 90% of children with COVID-19 remain asymptomatic or have mildly symptomatic disease, with symptom duration from hours to a few days, and may go unrecognized. A more recent study in Korea found up to 22% of children were asymptomatic while 66.2% had unrecognized (often mild) symptoms prior to diagnosis.(343) Not enough testing of children, especially those asymptomatic, may underestimate the true prevalence of disease in pediatrics.
- 3. Both 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.
  - a. 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.(344) The relative impact of the various non-pharmacologic interventions is not well understood. Whether and if there is a point of community burden at which these interventions will fail is also not well understood.

- b. 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.
- c. For adults >65 years of age, living with children 0-11 years old was not associated with an increased risk of COVID. But living with children 12-18 years old had a slightly increased risk of COVID (Hazard Ratio 1.08, 95% CI 1.03-1.13) and no effects on mortality.(345)
- 4. While pediatric cases are rising, mortality remains low at <0.1% for acute COVID-19 in children <18 years old.(48)
  - a. 179 COVID-19 related-deaths have been reported in children 0-17 years old as of Jan 2021.
  - 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. (346)
- 5. 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.(347)
  - 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.(347)
  - 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%).(348)
- 6. 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%).(133)
- 7. 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.(349) 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
- 8. 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).
- 9. 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.(349)
- 10. 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. (144)
- 11. 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.
- 12. Those who require hospitalization should receive supportive care to include critical care interventions as required.

#### a. 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  $SpO_2 > 94\%$  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.

# b. 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.(234)
- 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.(234)
- c. Adjunctive Therapies for severe patients only (see 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. (350) i.
  - ii. Remdesivir is available at DoD sites, now FDA approved for use in children 12 years and older, 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. 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 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</li>
  - >40kg: 200mg IV loading dose on day 1; followed by 100mg IV Q24hr
- Recommended duration: up to 10 days with 5-day duration favored for fast responders
- One 5-week infant with COVID-19 induced severe ARDS improved after 5 days of remdesivir.(253)
- iii. **Convalescent Plasma** is available to patients, (regardless of age or beneficiary status), admitted to DoD facilities with confirmed COVID-19 and respiratory compromise (e.g., dyspnea, supplemental oxygen requirement). CONUS and OCONUS providers should contact USAMMDA FHP at <a href="mailto:usarmy.detrick.medcom-usammda.mbx.force-health-protection@mail.mil">usarmy.detrick.medcom-usammda.mbx.force-health-protection@mail.mil</a> or (301) 401-2768 to establish their facility as a treatment site. Plasma procurement will be coordinated by the Armed Services Blood Program as discussed above in the Adjunctive Therapies section.
- 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** has recently made the news as a potential therapy for COVID but has not been studied in a randomized control trial to determine efficacy. It has proven safety in children for treatment of helminths; ivermectin should be used prior to corticosteroids to prevent *Strongyloides* hyperinfection syndrome IF the patient has peripheral eosinophilia and a travel history to an endemic country.
- 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 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 possible also RSV, will be important during the traditional respiratory virus season, particularly if schools are 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: <a href="https://www.cdc.gov/coronavirus/2019-19">https://www.cdc.gov/coronavirus/2019-19</a>

## 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 interim guidance at: https://services.aap.org/en/pages/2019-novel-coronavirus-COVID-19-infections/clinical-guidance/COVID-19-infections/clinical-gu

https://services.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.(351)

# 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.(352) 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 S for DHA summary communication regarding MIS-C.
- 2. CDC case definition for MIS-C: (353-355)
  - 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-G, 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: (353-360)
  - 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. 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)(361), See Figure 15.
    - 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
    - ix. Ferritin
  - 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)(362)
    - 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. Procalcitonin
    - iv. Coagulation panel to include D-dimer and fibrinogen
    - v. Triglyceride, LDH
    - vi. Cytokine panel (typically a send out laboratory)
    - vii. CSF studies if signs/symptoms of meningitis
    - viii. Rickettsial serologies if exposure to endemic regions
    - ix. 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 ≥ 2, Phos ≥ 4
- ii. Empiric antibiotics early discontinuation if no evidence of bacterial infection

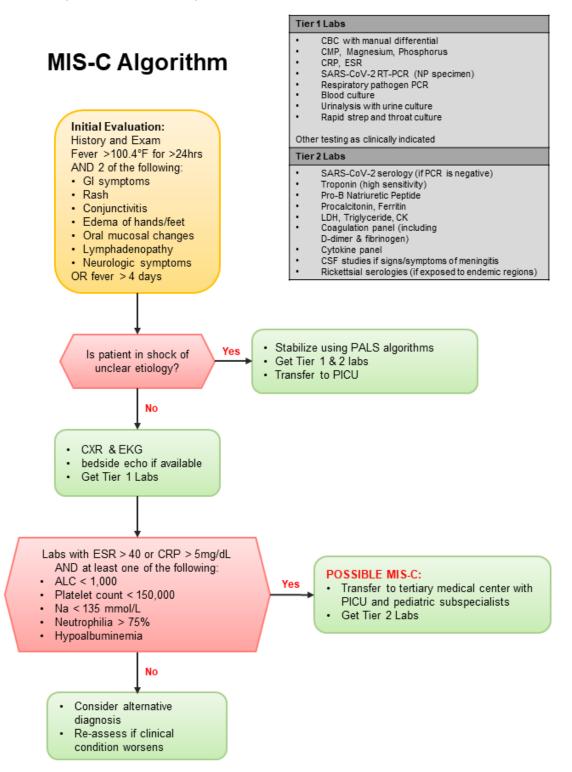


Figure 15. Multi-inflammatory Syndrome in Children (MIS-C) Algorithm

- 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.(363)
  - 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(364)
      - ii. IL-6R Antagonist (Tocilizumab)
      - iii. TNF-a Antagonist (Infliximab)
- iv. Anticoagulation
  - 1. Enoxaparin (Lovenox) with Peds Heme/Onc or Critical Care consultation
- v. Follow-up
  - 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

# **Sustaining Pediatric Preventive Medicine Services During the Pandemic**

The CDC and the American Academy of Pediatrics (AAP) both strongly support the sustainment 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. Local MTFs should plan for and be prepared to implement pediatric care in accordance with CDC and AAP recommendations, in the setting of DHA guidance based upon local Health Protection Condition (HPCON) levels (citation: Memorandum Resuming Full Operations\_ADHCA signed). These plans may include utilization of telehealth options, adjustments to patient flow, prioritization to continue to immunize the highest risk groups, and establishing database tracking mechanisms to proactively communicate with families to ensure that immunizations and overdue care is scheduled and provided for as soon as possible as local conditions and HPCON levels allow.

The AAP has also provided COVID-19 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 behavioral and 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.

#### References

CDC Information for Pediatric Healthcare Providers, May 2020 [Available from: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html</a>]

American Academy of Pediatrics Guidance on Providing Pediatric Well-Care During COVID-19, May 2020 [Available from: <a href="https://services.aap.org/en/pages/2019-novel-coronavirus-COVID-19-infections/guidance-on-providing-pediatric-well-care-during-covID-19/">https://services.aap.org/en/pages/2019-novel-coronavirus-COVID-19-infections/guidance-on-providing-pediatric-well-care-during-covID-19/</a>

Memorandum Resuming Full Operations\_ADHCA signed, May 2020 [Available from: <a href="https://www.milsuite.mil/book/docs/DOC-810764">https://www.milsuite.mil/book/docs/DOC-810764</a>]

## **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.(365)
- 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.(366)
- 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.

- 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).(367, 368)
- 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.(369)
- c. Delirium is prevalent in patients diagnosed with COVID-19, and is associated with increase in-hospital mortality.(370)
- d. Management of Delirium: (371, 372)

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.(373) 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. (374) 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.

## PALLIATIVE MEDICINE DURING THE COVID-19 PANDEMIC

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)

- 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 7** offers suggestions and examples to help guide your conversations.

Table 7. Difficult Conversations and Scripts for Communicating with Patients and Families

What the patient/family says	What you may say		
Admitting a Patient			
How bad is this?	<ul> <li>From the information I have now and from my exam, your situation is serious enough that you should be in the hospital. We will know more in the coming hours to days, 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> <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> <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> <li>The risk of spreading the virus is so high that I am sorry to say we cannot allow visitors.</li> <li>We can help you be in contact electronically. I wish I could let you visit, because I know it's important, but it is not possible now.</li> </ul>		
When things aren't going well, goals of	care discussion, code status discussions		
want everything possible. I want to  We are doing everything we can. This is a tough and scary situation for man we step back for a moment so I can learn more about you? What do I need about you to do a better job taking care of you?			
I don't think my grandfather would have wanted this.	<ul> <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> <li>Thank you, it is very important for me to know that. Can you say more about what you mean?</li> </ul>		
I am not sure what my grandfather wanted – we never spoke about it.	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. In a situation like that, I have recommended that we allow a natural death. That could be hard to hear. What do you think?		
When coping needs to be boosted, or en	motions are running high		
I'm scared.	<ul> <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> <li>Tell me about the things you are hoping for? I want to understand more.</li> </ul>		
You people are incompetent!	<ul> <li>I can see you are not happy with things. I am willing to do what is in my power to improve things for you. What could I do that would help?</li> </ul>		
I want to talk to your boss.	<ul> <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> <li>I'm hoping that's not the case and I worry time could indeed be short. What is most pressing on your mind?</li> </ul>		

# **Symptom Management Guidelines**

(Adapted from BC Centre for Palliative Care COVID-19 Resources and Information, 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. h:
      - 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 works 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 8**). Limit oropharyngeal suction. Reduce or stop saline infusions.
- ii. Medications may include:
  - 1. Glycopyrolate 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 8. Opioid Dosing to Relieve Dyspnea and Pain in Adults

<b>Dosing for Opioid Naïve Patient (</b>	patient not on opioid therapy) (For frail, elderly patients, begin at low end of any range)
Morphine	<ul> <li>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)</li> </ul>
Hydromorphone	<ul> <li>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)</li> <li>If more than 6 PRN doses of opioid in 24 hours:</li> <li>Consider a basal opioid such as MSContin 15 mg PO BID. If patient unable to make need known, consider SCHEDULED dosing of the immediate release opioid (q4H or 6H for frail elderly) AND continue PRN dose.</li> <li>TITRATE UP AS NEEDED for relief of dyspnea and/or pain</li> </ul>
Dosing for Patients ALREADY Tak	
Applies to any opioid	<ul> <li>Continue previous opioid, consider increasing dose by 25%</li> <li>To manage breakthrough symptoms: Start PRN opioid at 10% of total daily (24 hour) opioid dose.</li> <li>PRN q1H for PO and q30mins for SQ/IV</li> </ul>

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.

# **PCA Infusion Pump Strategy for Patient ALREADY Taking Opioids**

- 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 of treatment. 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** 0.5 mg 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:

- 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  $FiO_2$  to 40%, PEEP to 10, RR to 16. Recheck patient comfort and re-bolus opioids prn to achieve comfort. Reduce PEEP to 5,  $FiO_2$  to 0.21.
- 15. Once the ventilator is set at PS 5/5 and  $FiO_2$  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.

#### **IMPLICATIONS FOR SURGICAL AND INVASIVE PROCEDURES**

# **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.(375)
- 2. MTFs should establish a review process to triage and prioritize medically necessary and time-sensitive surgical care.(376) This process should include multidisciplinary representation and be led by a senior surgeon, preferably the Department/Service Chief.(377)
  - 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. (378)
  - 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.(379) 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 Health Protection 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. (380)
    - 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.(381)
  - 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.(382) **Appendix T** provides an example of Surgical Care Timing for COVID-19 positive patients from Brooke Army Medical Center.

## **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 wraparound 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 (383, 384)

- 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.(385)
- 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, pnuemoperitoneum, and through ultrafiltration of aerosolized particles in released CO<sub>2</sub>.(386)
  - 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.(387)
- 3. Endoscopes used in COVID-19 positive patients or PUIs may be reprocessed following standard guidelines for manual cleaning followed by high level disinfection.(388)
- 4. Consider standard PPE, engineering controls, and room turnover only when the following criteria are met:(388, 389)
  - 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 (390)

- 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.
  - . 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.

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- 4. JTS Management of COVID-19 in Austere Operational Environments v2.0 Clinical Practice Guideline 2020 [Available: <a href="https://jts.amedd.army.mil/index.cfm/PI\_CPGs/cpgs">https://jts.amedd.army.mil/index.cfm/PI\_CPGs/cpgs</a>].

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

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: lose 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. Aa 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 guarantined 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 guarantined individuals in the smallest possible groups; individual guarters 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 command 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) during AGPs. 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.

- 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.(168, 174) 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, remdesivir, and CCP have been used to treat hypoxemic COVID-19 patients requiring supplemental oxygen in the forward deployed setting. An investigational treatment protocol was used in austere environments like Operation Inherent Resolve (OIR) to administer both CCP and remdesivir under the investigational new drug application. There is ongoing research regarding the efficacy of remdesivir or CCP without clear mortality benefit.(272, 391, 392) 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.(272, 278, 393) This reduction in resource utilization alone is enormously beneficial in the deployed environment even in the absence of a mortality benefit. 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, 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.(394) 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.(395) 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.(67, 396)
- 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. Command staff 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.

# BEHAVIORAL HEALTH AND WELLNESS IN COVID-19 CLINICAL MANAGEMENT

#### **Delirium**

- 1. Delirium is a common complication in patients with COVID-19. 55% of critically ill COVID-19 patients will have delirium, for a median of 3 days.(397) Traditional methods of diagnosis and non-pharmacologic management may be difficult given isolation precautions.(398) 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.(399, 400) 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):(401)
  - a. Melatonin 10-15mg enteric at night for anti-inflammatory effects and regulation of sleep-wake cycle

- 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 (400)
- 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.

## **Psychopharmacology**

- 1. COVID-19 can invade the CNS and has been known to cause psychiatric illness. Full review of all medications as well as substance use history is necessary to delineate primary psychiatric symptoms versus medication side effects or symptoms directly attributable to COVID-19 infection. 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 these symptoms present without any other accompanying symptoms. Generally, patients are responsive to traditional treatment methods for their presenting symptoms though there is increasing evidence that psychiatric symptoms persist past the acute infectious stage.
- 2. 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, buproprion, tricyclic antidepressants (402)
- 3. 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). Specifics of medications:
  - a. Remdesivir: None noted
  - b. Favipiravir: No published information
  - c. Lopinavir/Ritonavir: Abnormal dreams, agitation, anxiety, confusion and emotional lability \*Ritonavir has been shown to lower concentration of some psychotropics due to presumed CYP induction (bupropion, methadone, lamotrigine, olanzapine)
  - d. Chloroquine and Hydroxychloroquine: psychosis, delirium, agitation, suicidality, personality changes, depression, sleep disturbance
  - e. Tocilizumab: Exacerbation of depression, anxiety, pain, and sleep disruption
  - f. Azithromycin: Psychotic depression, catatonia, delirium, aggression, anxiety, dizziness, headache, vertigo, somnolence
  - g. Corticosteroids: depression, mania, agitation, mood lability, anxiety, insomnia, catatonia, depersonalization, delirium, psychosis
  - h. Interferon-Alpha: boxed warning for "life threatening or fatal neuropsychiatric disorders" fatigue,

mood disorders, suicidality, anxiety disorders, irritability, lability, apathy, sleep disturbance, cognitive deficits (402)

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

# https://info.health.mil/army/bhsl/Covid19/Forms/AllItems.aspx (DoD CAC Enabled only)

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: <a href="https://www.cstsonline.org/COVID-19/supporting-healthcare-workers">https://www.cstsonline.org/COVID-19/supporting-healthcare-workers</a>

# **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. 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.
- 3. 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.
- 4. Healthcare systems should establish easily accessible pathways for BH referrals for family members of patients admitted for COVID-19.
- 5. 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.
- 6. Resources to help in caring for Patients and Families can be found at: <a href="https://www.cstsonline.org/COVID-19/caring-for-patients-and-families">https://www.cstsonline.org/COVID-19/caring-for-patients-and-families</a>

#### **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: <a href="https://www.cstsonline.org/COVID-19/healthcare-worker-self-care">https://www.cstsonline.org/COVID-19/healthcare-worker-self-care</a>

#### **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 staff, transport, food service, and others 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: <a href="https://www.cstsonline.org/COVID-19/mental-health-support">https://www.cstsonline.org/COVID-19/mental-health-support</a>.

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

https://www.cstsonline.org https://asprtracie.hhs.gov/COVID-19

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

# **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 and 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 <a href="https://www.milsuite.mil/book/groups/covID-19-clinical-operations-group">https://www.milsuite.mil/book/groups/acute-and-critical-care-physical-therapy</a>.

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

- 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)
    - . 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. <a href="https://c19check.com/start">https://c19check.com/start</a>. Site hosted by Emory University Medical Center, which provides likelihood of CoVID infection based on answering series of online questions.
      - 2. <a href="https://penn-chime.phl.io/">https://penn-chime.phl.io/</a> 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 Messaging 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):
  - 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 <a href="mailto:dod.advisor\_office@mail.mil">dod.advisor\_office@mail.mil</a> or scanning the QR code (shown to the right):
- e. Virtual Health to Patient Location (e.g. home)
  - 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
    - o 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.

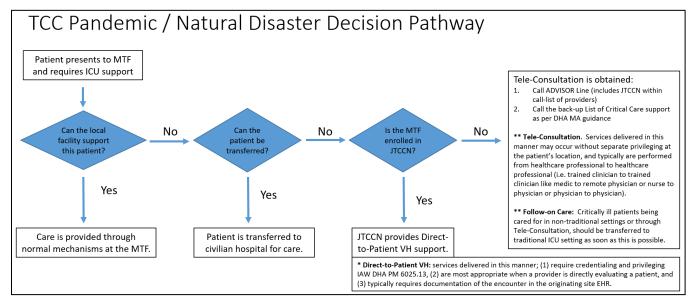


Figure 16. Telecritical Care Pandemic/Natural Disaster Decision Pathway

- 7. Documentation, Billing, and Coding (See Appendix U)
  - a. When direct-to-patient telemedicine is performed, encounters should be documented in the appropriate electronic medical record (AHTLA/Genesis for outpatients, Essentris/Genesis for inpatients).
  - b. 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
  - d. If the MTF is open, but is restricting access for patients who can be treated virtually, the processes are:
    - i. By telephone only:

- 1. 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.
- 2. Assign the diagnoses, as appropriate.
- 3. Assign G2012 in the procedure (Healthcare Common Procedure Coding System [HCPCS]) code section.
- 4. Assign E/M 99499 or leave blank.
- ii. By synchronous visual and audio telecommunications:
  - 1. 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.
  - 2. Assign the diagnoses, as appropriate.
  - 3. Assign any procedures performed and documented (e.g., psychotherapy, PHQ-9, etc.)
  - 4. Assign appropriate Evaluation and Management (E/M) service, if performed; otherwise assign 99499 or leave blank.
  - 5. Apply virtual encounter modifier to encounter (GT=MTF to MTF or 95=provider to patient location other than an MTF).

#### 8. Other Considerations:

- a. 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.
- b. 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

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

## 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.
- 2. 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)

- 1. Perform initial assessment from at least six feet away if possible. If the patient reports symptoms consistent with a respiratory illness, EMS personnel should don appropriate PPE. With widespread COVID-19, all patients should wear a surgical-type mask (best) [or alternatives as available, e.g., cloth (better)].
- 2. 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.
- 3. 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 9. Emergency Medical System/First Responder Pre-Arrival Screening for COVID-19

Does the patient have:						
Fever (or are they hot to the touch)     Cough     Shortness of Breathing or Difficulty Breathing     Other flu-like symptoms (sore throat, runny nose, body aches, chills, nausea, vomiting, diarrhea)	AND	Are they currently under investigation or isolation for COVID-19 by public health or other medical professionals?     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?				

#### If the patient meets at least one criteria item from Box 1 and Box 2, see below:

- Instruct the individual to isolate him/herself from close contact with others until EMS arrives.
- 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.
- Follow local agency policies to limit multi-unit responses.
- 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).

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**

- 1. 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.
- 2. 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:
  - a. 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.
  - b. The below assessment tool is to inform the necessity to transport an adult patient when the patient reports symptoms related to COVID-19.
  - c. 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. First use local nurse advice line or primary care telemedicine if there is the inability to tolerate oral intake even at very small amounts of 5-10 mL (1-2 tsp every 5 min). 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.
  - d. 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 10. 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)

- SBP 100-180 mm Hg
- Respiratory Rate 8-20
- EtCO<sub>2</sub> > 25 (if available)
- HR < 110 bpm

- GCS 15, Alert & Oriented
- $SpO_2 > 90\%$  (with basic ADLs)
- Well appearing, speaks in full sentences, ambulatory
- Viral sx: cough, sore throat, body aches, congestion

#### **PATIENT MEDICAL HISTORY & PRESENTATION**

- Age < 65 years</li>
- Non-Immunocompromised
- No known respiratory disease

- Non-diabetic
- No known cardiac disease
- No end-stage renal disease or dialysis

# LIVING ARRANGEMENTS

- Has appropriate support system at home
- Patient has means for follow-up

#### IF THE PATIENT IS IN A PUBLIC LOCATION

Place a surgical mask on the patient

- Discourage the use of public transportation
- Instruct the patient to directly transport themselves home while minimizing exposure to others/the community

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:

Chinical Management of COVID-13, V7					
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 OR Paramedic AND 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. https://www.camts.org/standards/ https://jts.amedd.army.mil/assets/docs/cpgs/Prehospital En Route CPGs/Standard Medical Operating Guidelines (SMOG) for Critical Care Flight Paramedics 2020.pdf 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 AND complex ventilator settings OR > 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 https://www.camts.org/standards/  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.)				

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

- 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 prehospital care should be screened for signs at symptoms of COVID-19 prior to the start of each shift. Screening serves as an important tool to identify those who may have COVID-19 and require prompt assessment and treatment. Screening includes: temperature monitoring and questioning regarding symptoms, exposures, and previous direction to quarantine due to a possible exposure.
- 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**

- The American College of Cardiology recommends use of mechanical CPR devices on PUIs or patients with confirmed COVID-19 who arrest (<a href="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">https://coronavirus-considerations-to-prepare-patients-providers-health-systems</a>). See updated Cardiac Arrest Algorithms for best practice for COVID-19 patients (Appendix O). (<a href="https://professional.heart.org">https://professional.heart.org</a>)
- 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: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html</a>

# 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.

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

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) 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 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 Conex 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 transport. 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. CCAT 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<sub>2</sub> <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<sub>2</sub> 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 CCATT 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<sub>2</sub> in anticipation of potential in-flight patient decompensation. During pre-mission planning, the CCAT 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<sub>2</sub> >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<sub>2</sub> to maintain SpO<sub>2</sub> >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<sub>2</sub> 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 11 shows the required  $FiO_2$  to maintain a constant  $PaO_2$  at different altitudes. It may be useful when assessing stability for flight and the need for cabin altitude restriction.

Table 11	L. Altitude	Physiolo	av Tahle

Altitude (ft)	Barometeric Pressure (mmHq)	FIO2 Required to Maintain Constant PaO12	PIO <sub>2</sub> While Breathing: 0.21 0.40 0.60 0.80 100					Gas Volume Expansion (% at Sea Level)
16000	412	0.41 0.59 0.78 0.98	76	146	219	292	365	184
14000	446	0.37 0.53 0.71 0.89	83	160	239	319	399	170
12000	483	0.34 0.49 0.65 0.81 0.98	91	174	262	349	436	157
10000	523	0.31 0.45 0.60 0.75 0.90	100	190	286	381	476	145
8000	564	0.29 0.41 0.55 0.69 0.83 0.96	108	207	310	414	517	135
6000	609	0.27 0.38 0.51 0.63 0.76 0.89	118	226	337	450	562	125
4000	656	0.24 0.35 0.47 0.58 0.70 0.82 0.94	127	244	365	487	609	116
2000	707	0.23 0.32 0.43 0.54 0.65 0.76 0.86 0.97	138	264	396	528	660	107
Sea Level	760	0.21 0.30 0.40 0.50 0.60 0.70 0.80 0.90 1.0	149	285	428	570	713	100

- 7. **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 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.
- 8. **Renal:** AKI is common in COVID-19 patients. Renally adjust medication dosage and convert renally metabolized medications as appropriate (e.g., morphine → hydromorphone (Dilaudid), or enoxaparin (Lovenox) → heparin).
- 9. **Gastrointestinal**: Continue stress ulcer prophylaxis. Continue post-pyloric enteric feeds, as suggested in **Appendix M**. OGT should be placed preflight and on intermittent suction.

- 10. **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.
- 11. **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.
- 12. 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.

# **PUBLIC HEALTH CONSIDERATIONS AND RESPONSE**

## 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: <a href="https://www.public.navy.mil/bupers-npc/reference/messages/Documents/NAVADMINS/NAV2020/NAV20083.txt">https://www.public.navy.mil/bupers-npc/reference/messages/Documents/NAVADMINS/NAV2020/NAV20083.txt</a>
- d. Health Protection Condition (HPCON) levels are used 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), <a href="https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/HPCON.aspx">https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/HPCON.aspx</a>, FHP Supplement 2 at: <a href="https://media.defense.gov/2020/Feb/26/2002255006/-1/-1/1/FORCE-HEALTH-PROTECTION-SUPPLEMENT-2.PDF">https://media.defense.gov/2020/Feb/26/2002255006/-1/-1/1/FORCE-HEALTH-PROTECTION-SUPPLEMENT-2.PDF</a>, and in Secretary of Defense Guidance at: <a href="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</a>
- f. Public Health Emergency Management (PHEM) training (which is required by DoDI 6200.03) and POCs can be found at: <a href="https://www.health.mil/Training-Center/Defense-Medical-Readiness-Training-Institute/Public-Health-Emergency-Management-Course">https://www.health.mil/Training-Center/Defense-Medical-Readiness-Training-Institute/Public-Health-Emergency-Management-Course</a>
- 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:
    - 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: <a href="https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing/index.html">https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing/index.html</a>. 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): Stay home until 14 days after last exposure and maintain social distance (at least 6 feet) from others at all times..
  - d. Contact Testing: Testing is recommended for <u>all close contacts</u> 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 reduce quarantine to 10 or 7 days if testing is negative and the patient remains asymptomatic (<a href="https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html">https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html</a>) 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: <a href="https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/healthcare.aspx">https://phc.amedd.army.mil/topics/campaigns/covid19/Pages/healthcare.aspx</a>
- 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. 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: <a href="https://www.whs.mil/Portals/75/Coronavirus/20201229%20FHP%2014%20-%20DoD%20Guidance%20for%20Personnel%20Traveling%20during%20the%20Coronavirus%20Disease%202019%20Pandemic.pdf?ver=ViENRxtcYUJQKe5xuIdUXw%3d%3d</a>
  - 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 predeparture COVID test or documented recovery from COVID. See:
         <a href="https://www.cdc.gov/quarantine/fr-proof-negative-test.html">https://www.cdc.gov/quarantine/fr-proof-negative-test.html</a>. 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 <a href="https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/">https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/</a> 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** (<a href="https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html">https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html</a>):
  - 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</li>
  - 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 (<a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html</a>).
  - 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)%20DO D%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:
    - HCP who have had prolonged (≥ 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** (<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>):
    - 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** (<a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html?CDC">https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html?CDC</a> 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.
      - 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 ≥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.

#### **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.
- 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. DoD's COVID-19 Vaccination Tiers: DoD has developed, and continues to update, its vaccination prioritization tiers in accordance with the latest guidance from the CDC/Advisory Committee on Immunization Practices (ACIP), while ensuring DoD's readiness and mission assurance. Table 12 provides an overview of DoD's COVID-19 Vaccination Prioritization Schema. Refer to the DHA Interim Procedures Memorandum (IPM) 20-004 "Department of Defense (DoD) Coronavirus Disease 2019 (COVID-19) Vaccination Program Implementation" for details on the population groups included in each phase.
- 4. **DoD's COVID-19 Vaccination Status:** DoD is currently administering the two COVID-19 vaccines that have received EUA from the FDA and are recommended to prevent COVID-19: Pfizer-BioNTech and Moderna. Table 2 provides an overview of Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines. As of 18 February 2021, more than 644K individuals have received at least their first dose of the COVID-19 vaccine at a DoD Immunization site; more than 284,000 individuals have received their second dose. COVID-19 vaccines are currently being administered at 550 DoD Vaccination Sites in the continental U.S. (CONUS) and outside the continental U.S (OCONUS). Vaccination Sites receive either the Pfizer-BioNTech and/or Moderna vaccine based on their storage and handling capabilities. Vaccines are ordered through the Vaccine Tracking System (VTrckS). The vaccine distribution process to DoD Vaccination Sites is managed by DHA Medical Logistics (MEDLOG), Defense Logistics Agency (DLA), and U.S. Army Medical Materiel Agency-Distribution Operations Center (USAMMA-DOC), in coordination with the Services. DoD's COVID-19 vaccination distribution and administration status are tracked and reported daily by ADVANA to DHA Senior Leadership.

Table 12. DoD COVID-19 Vaccination Prioritization Schema

DoD Tier Level (NOTE: The final tier is defined as the highest tier for which a person qualifies.)		Population Group <sup>2</sup>
Tier 1a All healthcare providers, healthcare support personnel, and emergency services and public safety personnel	Sub-tier 1*	Intensive Care Unit personnel, Emergency Room/Urgent Care Center personnel, First Responders (e.g., Emergency Medical Services personnel, police, and Search and Rescue personnel, and fire personnel (as identified by their DoD Component) and Armed Forces Retirement Home residents
Healthcare and support personnel at Military Medical Treatment Facility (MTF) outpatient clinics and ambulatory care facilities (including but not limited to dental clinics, medical homes, blood donation facilities, and counseling centerly	Sub-tier 2 *	Other inpatient healthcare and support personnel as identified by their DoD Component
"May include military, civilian, and contractor personnel, students, and other hospital non- clinical staff authorized to receive vaccinations from DoD and who support patient care and are at heightened risk of exposure to individuals who have contracted COVID-19.	Sub-tier 3*	Outpatient healthcare and support personnel. This includes Active Duty or National Guard and Reserve personnel supporting U.S. Government COVID-19 response efforts in a Title 10 or Title 32 duty status up to 90 days before deploying to provide such support (e.g., personnel providing patient care, administering vaccines, conducting testing, and assisting in vaccine distribution).
Tier 1b (all qualifying personnel have equal priority) Critical National Capabilities Personnel forward deployed to austere environments Personnel preparing to deploy to locations outside the United States		Strategic and nuclear deterrence forces, homeland defense forces, and national leadership (senior staff), as identified in writing by their DoD or OSD Component heads, U.S. Special Operations Command national mission force personnel, and U.S. Cyber Command National mission force personnel.
		Personnel forward deployed to austere environments (i.e., conditions where no non-DoD advanced medical providers are available); Forward Deployed Naval Forces (FDNF) in accordance with JP-3-32.
		Personnel preparing to deploy outside the U.S. within the next 90 days and individuals on dedicated stand-by for missions outside the US and its territories (e.g., IRF, PTDO). This includes military, civilian, and contractor personnel authorized to receive vaccines from DoD.
Authorized³ persons aged ≥ 75 years		Authorized² persons aged ≥ 75 years
Frontline essential workers		Front Line Essential Workers: Education sector personnel (e.g., teachers, support staff, and child and youth services staff), eligible defense manufacturing personnel (e.g., those operating in depots and shipyards'), DoD corrections staff, DoD postal service staff, DoD public transit workers, Military Service exchange workers <sup>2</sup> , and commissary and other installation food service or agricultural workers.
Tier 1c (all qualifying personnel have equal priority) Authorized <sup>2</sup>		Authorized² persons aged ≥ 65-74 years
		Authorized² persons aged ≥ 16-64 with increased risk for severe illness ¹ as defined by CDC
persons aged ≥ 65-74 years		Personnel deployed/TDY for over 30 days outside of the US This group does not include members on orders to locations that retain personnel on a permanent basis (PCS, etc.).
Authorized <sup>3</sup> persons aged ≥ 16-64 with increased risk for severe illness <sup>1</sup> as defined by CDC Personnel deployed/TDY for over 30 days outside of the U.S. Essential workers not previously included in Tier 1a or 1b		DoD and OSD Component personnel designated as Key, Essential (EE/NCE), or mission-essential <sup>2</sup> , as identified by their DoD or OSD Component in writing, not otherwise identified above.
		DoD prisoners
Tier 2  Persons aged ≥ 16 years not previously identified for vaccination  *As of February 24 2020, only the Pfizer-BioNTech COVID-19 vaccine is authorized for individuals ≥ 16  years and < 18 years of age		Healthy uniformed personnel (including authorized <sup>)</sup> new accessions and service academy cadets), and others authorized and those eligible to receive vaccines from DoD not otherwise mentioned above

Table 13. FDA EUA COVID-19 Vaccine Overview

Description	Pfizer BioNTech Vaccine	Moderna Vaccine	Janssen Vaccine
Type of Vaccine	mRNA		Replication-defective vector (Adenovirus type 26)
Number of Shots	2 shots, 21 days apart	2 shots, 28 days apart	1 shot
Who Should Get Vaccinated	Individuals ≥ 16 years of age	Individuals ≥ 18 years of age	Individuals ≥ 18 years of age
Who Should Not Get Vaccinated	<ul> <li>Individuals who have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction (i.e., within 4 hours of administration)—even if the immediate reaction was not severe—to any ingredient in the vaccine.</li> <li>Individuals who have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction (i.e., within 4 hours of administration)—even if the immediate reaction was not severe—after getting the first dose of the vaccine.</li> <li>Individuals who are allergic to polyethylene glycol (PEG) or polysorbate.</li> </ul>		Individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component in the vaccine
Common Side Effects	<ul> <li>At the injection site: Pain, Swelling, Redness</li> <li>Throughout the Body: Chills, Tiredness, Headache</li> </ul>		
Efficacy at Preventing Laboratory-Confirmed COVID-19 Illness (based on evidence from clinical trials)	95%	94.1%	<ul><li>72% in US</li><li>66% Overall</li><li>85% for severe disease</li></ul>

<sup>&</sup>lt;sup>1</sup>Please visit the following CDC link for the most recent list of conditions: <a href="https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html">https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html</a>
<sup>2</sup> Individuals authorized to be offered the COVID-19 vaccine in accordance with Deputy Secretary of Defense Memorandum, "Coronavirus Disease 2019 Vaccine Guidance," December 7, 2020 and "Supplemental Guidance for Providing DoD Coronavirus Disease 2019 Vaccines to DoD Contractor Employees and Select Foreign Nationals," December 31, 2020, or otherwise applicable law includes Service Members, DoD civilian employees, and DoD Contractor employees as set forth in applicable guidance.

3 As defined in 10 USC 1580, DoD Directive 1200.17, and DoD Instruction 3020.42.

Table 14. Key COVID-19 Vaccine Resources

Resource	Overview
DoD COVID-19 Vaccine Plan and Modifications	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-	Establishes DHA's procedures and responsibilities for DoD's
004), "Department of Defense (DoD) Coronavirus	COVID-19 Vaccination Program, including guidance on the
Disease 2019 (COVID-19) Vaccination Program	authorized use of COVID-19 vaccines, distribution and cold
Implementation," December 31, 2020	chain management, vaccine administration, adverse event
	reporting, and documentation.
DoD's COVID-19 Guidance	Provides information and resources on a variety of
	coronavirus-related subjects for members of the DOD
	community and the general public.
DoD Vaccine Resource Center	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.
Military Health System COVID-19 Information	Provides the most up-to-date information regarding the
<u>Center</u>	COVID-19 pandemic, including DoD and Health Affairs
	Resources, DHA Resources, and Training Resources for
	Providers.
Interim Clinical Considerations for Use of mRNA	Provides CDC's clinical considerations for the COVID-19
COVID-19 Vaccines Currently Authorized in the	vaccines currently authorized in the United States (i.e.,
<u>United States</u>	Pfizer-BioNTech and Moderna COVID-19 vaccines).
U.S. COVID-19 Vaccine Product Information	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

#### ETHICAL CONSIDERATIONS DURING THE COVID-19 PANDEMIC

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 an 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: <a href="https://www.usuhs.edu/dmec">https://www.usuhs.edu/dmec</a>

# OTHER CONSIDERATIONS RELATED TO COVID-19

#### **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 recommend 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 to 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 these systems at this time. Should a MTF wants 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: <a href="https://www.ashrae.org/technical-resources/healthcare">https://www.ashrae.org/technical-resources/healthcare</a>. For Dental Pilot information briefings and Pilot Dental Airborne Infectious Isolation Room Template Plans:

  <a href="https://community.max.gov/display/DoDExternal/COVID+19+Data+Landing+Page">https://community.max.gov/display/DoDExternal/COVID+19+Data+Landing+Page</a>. For facilities question, contact the DHA FE Facilities Operations Emailbox at <a href="mailto:dha.ncr.j-1-8.list.fe-facility-ops-br-owners@mail.mil">dha.ncr.j-1-8.list.fe-facility-ops-br-owners@mail.mil</a> 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: <a href="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</a>.

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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.

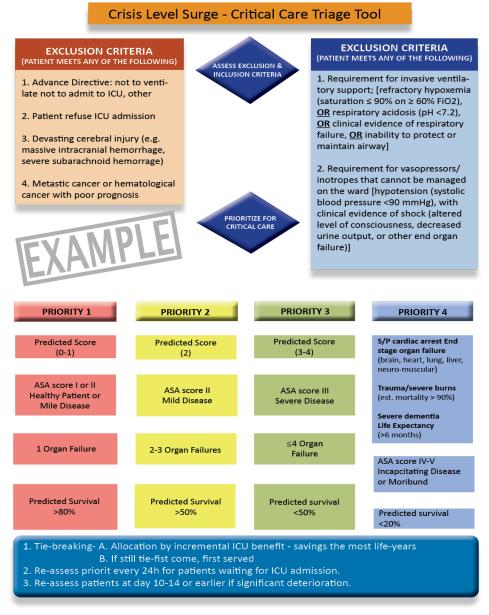


Figure A-1: Crisis Level Surge – Critical Care Triage Tool

<sup>\*</sup>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]

#### TRIAGE PLANNING COMMITTEE Members (Minimum) Planning for the greatest medical benefit to greatest number of people 2 Senior Clinicians Senior Nursing Representative Establish SOPs for conventional, contingency and crisis capacity **Ethics Representative** Provide oversight support of scarce resource allocation decisions Community Member Maintain available representative 24/7 to triage teams and command Pastoral Care Seek opportunities for regionalization of resources as permissible Palliative Care (as available) TRIAGE TEAM Roles Members Liaison with command and planning committee on resources (ICU beds, staffing, Triage Officer (Senior Clinician) equipment) Acute Care Nurse Initial contact with clinical teams for assessment of priority scoring Administrative Staff Member Collect only information relevant to priority scoring and maintain database Ethics Representative (as available) Make urgent allocation decisions within 90 minutes of clinical team request Community Member (as available) Meet twice daily to match resources to patient needs and Reassess patients every 72 hours (Minimum) Report conflicts or requests for appeal/oversight to Planning Committee representative

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

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

# **Mask Guidance Crisis Capacity**

# SURGICAL MASKS

#### DISCARD MASK IF:

- Contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Obviously damaged or hard to breathe through.
- At the conclusion of your shift.

#### **EXTENDED USE:**

- Wear mask for ENTIRE shift unless soiled, damaged, or hard to breathe through.
- Do not touch the mask. If you touch or adjust your mask, you must immediately perform proper hand hygiene.
- Leave the patient care area if you need to remove your mask.
- Consider use of a face shield over mask.

#### **REUSE:**

- Masks that fasten via ties that are unable to be undone and are torn need to be discarded.
- Masks should be carefully folded so the outer surface is held inward and against itself to reduce contact with the outer surface during storage.
- Keep used masks in a clean, breathable container such as a paper bag between uses.
   Do not store in a plastic bag. Keep in a clean space outside patient room, such as a wall locker next to patient room or top of the isolation cart. To prevent accidental use of another's mask, label the container with:
  - First initial and last name of owner
  - Strap of mask with first initial and last name of owner

#### Glossary

**Extended Use** — The practice of wearing the same mask/respirator for repeated close contact encounters with several patients, without removing the mask/respirator between patient encounters. **Reuse** — The practice of using the same mask/respirator for multiple encounters with several patients but removing it after each encounter.

# **N95 RESPIRATORS**

Extended and limited reuse of respirators were recommended for conserving respirators during previous respiratory pathogen outbreaks and pandemics.

Use face shield over N95 respirator to reduce surface contamination. This does not apply if use goggles. Perform hand hygiene with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting respirator.

#### **DISCARD N95 RESPIRATOR IF:**

- Used for aerosol-generating procedure.
- Contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Obviously damaged or hard to breathe through.

#### **EXTENDED USE\*:**

Extended use may be implemented when multiple patients are infected with the same respiratory pathogen and patients are placed together in dedicated waiting rooms or hospital wards.

REUSE\*:

- Keep used respirators in a clean, breathable container such as a paper bag between uses.
   Do not store in a plastic bag. Keep in a clean space outside patient room such as a wall locker near patient's room or top of the isolation cart. To prevent accidental use of another person's respirator, label the container with:
  - First initial and last name of owner
  - Strap of respirator with first initial and last name of owner
- Avoid touching the inside of the respirator. If inadvertent contact with the inside of the respirator, perform hand hygiene as above.

Use a pair of clean (non-sterile) gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.

\*Note: Staff should follow manufacturer's instructions regarding extended use and reuse of N95 respirators. Data suggests that reuse of each device should be limited to no more than FIVE uses.

# **Standard Precautions**

# FOR THE CARE OF ALL PATIENTS

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

- 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.

<u>Introduction:</u> 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: <a href="https://www.fda.gov/media/135763/download">https://www.fda.gov/media/135763/download</a>. Facilities using elastomeric respirators and PAPRs are required to have up-to-date cleaning and disinfection procedures to facilitate protection against infectious agents.

<u>Recommendations:</u> 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
    - 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
  - 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

#### References

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- 3. Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE 30 August 2018 https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html
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#### **DECONTAMINATION OF N95 RESPIRATORS**

#### **Situation and Background**

COVID-19 has caused significant disruption in the manufacturing of N95 filtering facemask respirators (FFRs), subsequently generating a need for strategies to decontaminate for reuse. To ensure existing resources are leveraged effectively, and Military Medical Treatment Facilities (MTFs) are equipped to optimally care for patients in a crisis situation, an evaluation of alternative strategies is warranted.

Disposable FFRs, are not approved for routine decontamination as conventional standards of care. Per the CDC guidance for crisis standards these FFRs should not be worn by healthcare providers when performing or present for an aerosol –generating procedures. Refer to table on Mask Guidance in this document.

#### **Assessment**

There are currently four strategies for decontamination of N95 FFRs. These include high—concentration hydrogen peroxide, hydrogen peroxide sterilization systems, heat and humidity, and ultraviolet (UV) decontamination. The implementation of each of these strategies carries with it unique benefits and challenges. Staff should refer to the FDA Emergency Authorization (EUA) for each individual method of decontamination:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-COVID-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas.

The use of UV–C disinfection is now gaining recognition in the literature as a potentially viable strategy for N95 FFR decontamination during this crisis<sup>1</sup>, and a number of reputable hospital systems have publicly supported the practice. ECRI has provided communications indicating this approach is acceptable as a last resort, and additional information regarding use of this method is available at the following link:

https://www.nebraskamed.com/sites/default/files/documents/COVID-19/n-95-decon-process.pdf. Currently some MTFs have developed protocols and may already be implementing this decontamination strategy. The advantages of using this process is that many masks could be decontaminated in fairly short period of time, but numerous disadvantages should be considered when implementing this strategy:

The UV–C light systems are not regulated as medical devices by FDA, and therefore must be validated for appropriate output.

UV—C light must shine directly on all surfaces, which is difficult to accomplish with curved masks (any shadows may leave masks still contaminated).

UV-C light must be delivered at proper dose. This should be verified by a UV-C-specific sensor.

UV light degrades mask components, and determining the number of decontamination cycles depends on the amount of UV light delivered per cycle.

It is likely that due to kinking, straps would not receive proper amount of UV–C light. Experts recommend that decontamination of straps is conducted manually.

The following considerations must be taken into account if using any decontamination strategy:

- 1. Decontaminated compatible N95 FFRs are not sterile, and in most cases must go back to the original wearer.
- 2. All hydrogen peroxide systems cannot decontaminate masks that contain cellulose-based materials.
- 3. Each of the systems has different requirements regarding the number of times they can be used.
- 4. If any of the N95 FFRs are visibly soiled (e.g., blood, dried sputum, makeup, body fluids) they must be disposed of.
- 5. If a good seal cannot be maintained, the mask must be discarded.
- 6. Any individual handling contaminated respirators must wear full personal protective equipment (PPE), including an N95 FFR and eye protection.

#### **Recommendation**

Leadership should utilize decontamination strategies aligned with the FDA's EUA (link provided above). If MTFs have concerns regarding an inability to maintain adequate supply of N95 respirators, a Director's Critical Information Request (DCIR) should be submitted.

#### References

- Card, K., Crozier, D., Dhawan, A., Dinh, M., Dolson, E., Farrokhian, N., Gopalakrishnan, V., Ho, E., King, E., Krishnan, N., Kuzmin, G., Maltas, J., Pelesko, J., Scarborough, J., Scott, J., Sedor, G., & Weaver, D. (2020). *UV Sterilization of Personal Protective Equipment with Idle Laboratory Biosafety Cabinets During the COVID-19 Pandemic*. <a href="https://doi.org/10.1101/2020.03.25.20043489">https://doi.org/10.1101/2020.03.25.20043489</a>
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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 pneumophilia 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.1

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.2–3
   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.

In 2016, the CDC and its partners developed a toolkit to facilitate implementation of the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) standards. This comprehensive toolkit provides environmental, clinical, and epidemiologic considerations for healthcare facilities, and can be accessed with the following link:<sup>4</sup> https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html.

#### **Risk Factors**

Several factors associated with building water systems can contribute to amplification of pathogenic bacteria, thereby leading to increased risk of exposure:

1. Water temperature fluctuations

Temperatures between 25° - 42° C (77° - 108° F) are ideal for Legionella growth.4 Legionella can continue to proliferate at temperatures outside the above range.

2. The absence of adequate free chlorine (chlorine residual) available in water to kill microorganisms. Click here for more information: https://www.cdc.gov/safewater/chlorine-residual-testing.html

Facilities should ensure that the free chlorine residual meets Safe Drinking Water Act requirements (0.2 parts per million) at a minimum.

3. pH level

The pH of potable water impacts the efficacy of chlorine disinfection. Such disinfectants are most effective within a narrow pH range of approximately 6.5-8.5.

4. Stagnation/flow

Low flow or stagnant water leads to increased water age, which depletes free chlorine. Stagnation encourages biofilm growth and promotes sediment accumulation, which uses up disinfectant and provides nutrients for bacteria colonization.

Changes in water pressure can dislodge biofilm, subsequently releasing Legionella into the water.

5. Aerosolization

Devices or processes that aerosolize water increase risk for inhalation and infection.

6. Immunocompromised patients are at higher risk of contracting Legionnaires' disease from inhalation of contaminated water.

#### **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.

#### References

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- 3. Centers for Disease Control and Prevention. (2017). *Toolkit: Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings*. <a href="https://www.cdc.gov/legionella/wmp/toolkit/index.html">https://www.cdc.gov/legionella/wmp/toolkit/index.html</a>
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## COVID-19 Recovery Plan: Guidance for IPC Programs - 21 May 2020

#### 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
- 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 deescalation 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. At a minimum, such training should address standard precautions and disease transmission based precautions. 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. Establishing non-COVID-19 care zones that screen 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.
- 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. Delaying entry into rooms where an AGP was performed until sufficient time has elapsed to allow for enough air changes to remove potentially infectious particles. Entry should also be avoided before terminal cleaning is completed.
- 8. 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.
- b. Environmental Service (EVS) personnel should refrain from entering vacated rooms until sufficient time has elapsed for enough air changes to remove potentially infectious particles.
- c. After the correct time has elapsed, EVS personnel may enter the room and should wear a gown and gloves when performing terminal cleaning. A mask and eye protection should be added if splashes or sprays during cleaning and disinfection activities are anticipated, or otherwise required based on the selected cleaning products.
- 2. 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.

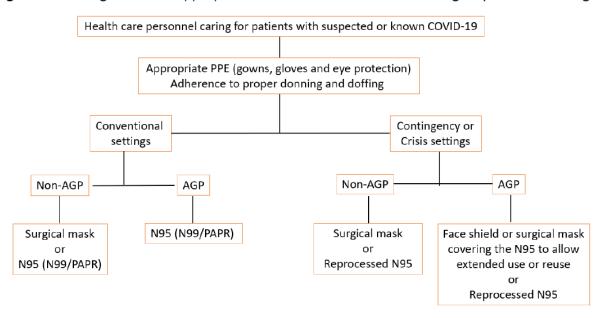
#### **Water Plans**

- 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**

- 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 when sufficient levels of critical PPE are achieved and able to be maintained.
- 2. MTF/DTF leadership should work in close collaboration with logistics to develop appropriate stockpile quantities for critical PPE and supplies, in preparation for a potential second pandemic surge. 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: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html</a>

#### References

- Centers for Medicare & Medicaid Services (CMS) Recommendations Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I. <a href="https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf">https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf</a>
- 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
- 4. Defense Health Agency. (2020). Memorandum: COVID-19 Guidance for Resuming Full Healthcare Operations.

#### **Exam and Treatment Room Turnover Considerations August 2020**

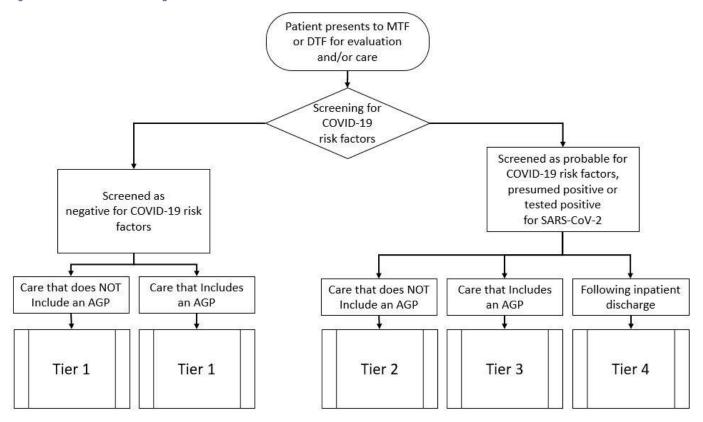
Despite awareness that COVID-19 is primarily spread by respiratory droplets, there remains an inability to produce clearly defined guidance and/or a comprehensive list of aerosol generating procedures (AGPs) due to limitations in available data. To increase the safety of staff members and patients at 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.

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
Tier 1	No hold time required	Staff member cleaning room should adhere to standard precautions and transmission-based precautions, and, at a minimum, should wear:  Gloves Additional PPE in accordance with disinfectant instructions for use (IFU)	Immediate turnover of room  • Cleaning and disinfection process may begin directly following the patient's exit from the room	Consistently follow routine environmental cleaning and disinfection procedures  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> Follow the manufacturer's instructions (including wet times) for disinfection to occur  After cleaning and disinfection, the room is ready for the next patient
Tier 2	No hold time required	Staff member cleaning room should wear:  • Gloves  • N-95 preferred  • Additional PPE in accordance with disinfectant IFU	Immediate turnover of room  • Cleaning and disinfection process can begin directly following the patient's exit from the room	<ul> <li>Consistently follow routine environmental cleaning and disinfection procedures</li> <li>Use an EPA-approved disinfectant:         https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19     </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>
Tier 3	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:  Gloves N-95 preferred Additional PPE in accordance with disinfectant IFU	Room will remain vacant based on air-exchanges per hour (ACH) as described in Appendix A	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  Consistently follow routine environmental cleaning and disinfection procedures  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> Follow the manufacturer's instructions (including wet times) for disinfection to occur  After cleaning and disinfection, the room is ready for the next patient
Tier 4	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:  Gloves  N-95 preferred Additional PPE in accordance with disinfectant IFU	Room will remain vacant based on ACH as described in Appendix A	<ul> <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: https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-COVID-19</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

- CDC (2020). Healthcare Infection Prevention and Control FAQs for COVID-19. Retrieved from: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html</a>.
- 2. 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/guidelines/environmental/index.html.
- 3. CDC (2020). Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. Retrieved from: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html</a>.
- 4. Nebraska Medicine (2020). COVID-19 Room Cleaning Protocol. Retrieved from: <a href="https://www.nebraskamed.com/sites/default/files/documents/COVID-19/room-cleaning-protocol-non-or.pdf">https://www.nebraskamed.com/sites/default/files/documents/COVID-19/room-cleaning-protocol-non-or.pdf</a>

#### 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.¹ 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."¹ 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>2</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 <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html</a>, <a href="https://www.fda.gov/medical-devices/coronavirus-disease-2019-COVID-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas">https://www.fda.gov/medical-devices/coronavirus-disease-2019-COVID-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas">https://www.fda.gov/medical-devices/coronavirus-disease-2019-COVID-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas</a>

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
		AGP	N95 FFR	Single-use
Moderate	Non-COVID-19	Non-AGP	N95 FFR, if available	Issue one per day per provider
(HPCON B)			or Surgical Mask with	Decontaminate using
			Full-face Shield	Paper Bag or VHP Methods
		AGP	N95 FFR	Single-Use
Substantial	Non-COVID-19	Non-AGP	N95 FFR	Issue one per day per provider
(HPCON C/D)				Decontaminate using Paper Bag or VHP Methods
		AGP	N95 FFR	Single-Use

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

#### References

- 1. Centers for Disease Control and Prevention. (17 June 2020). *Interim Infection Prevention and Control Guidance for Dental Settings During the COVID-19 Response*. https://www.cdc.gov/coronavirus/2019-ncov/hcp/dental-settings.html
- 2. Centers for Disease Control and Prevention. (2020). *Coronavirus Disease 2019 (COVID-19): Decontamination & Reuse of Filtering Facepiece Respirators*. <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html</a>
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- 5. DHA Memorandum, "COVID-19 Guidance for Resuming Full Healthcare Operations," May, 14, 2020 [pp. 75-78]
- 6. 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

<sup>&</sup>lt;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. <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html</a> <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.



# Collecting a Nasopharyngeal Specimen Swab Method

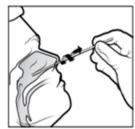
- Don PPE as directed by your institutional policies and procedures and perform hand hygiene.
- Introduce yourself to the patient.
- Verify the correct patient using two identifiers name and DOB.
- Ensure the patient has completed a screening tool asking about history of nose bleeds, Ear, Nose or Throat (ENT) concerns, procedures i.e. nasal surgery, nasal polyps, and/or deviated septum.
- Explain the procedure to the patient and ensure that he or she verbalizes understanding.
- 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.
- 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 have a penlight
  - 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.



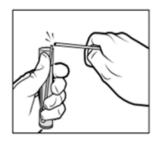
Your Partner in Trusted Care



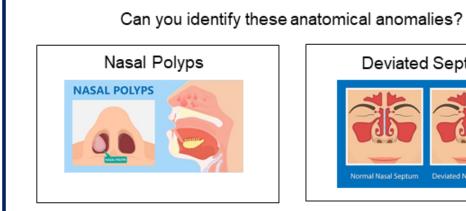
# Collecting a Nasopharyngeal Specimen Swab Method

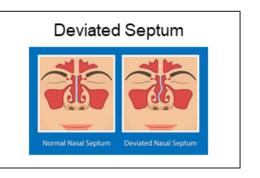


Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. Note: Hold the swab towards the end of the shaft.



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





2

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

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. Detailed information can be found in Appendix K, "Post-COVID-19 Cardiopulmonary Return to Exercise Recommendations."

**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 (<a href="https://www.ycq2.org/">https://www.ycq2.org/</a>).

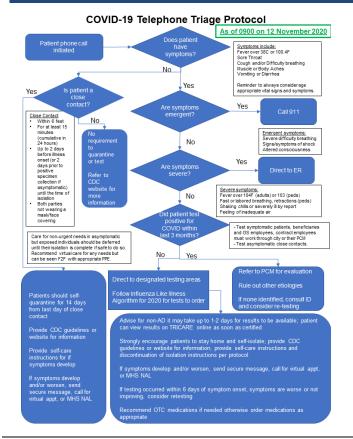
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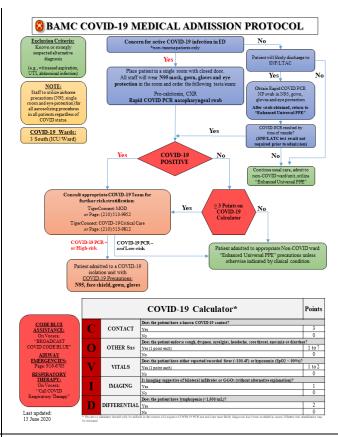
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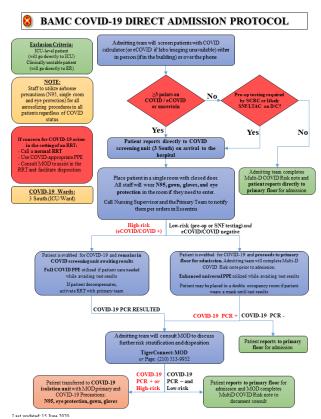
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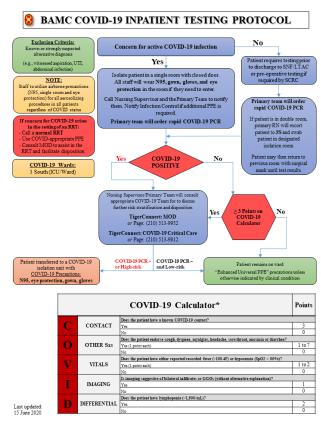
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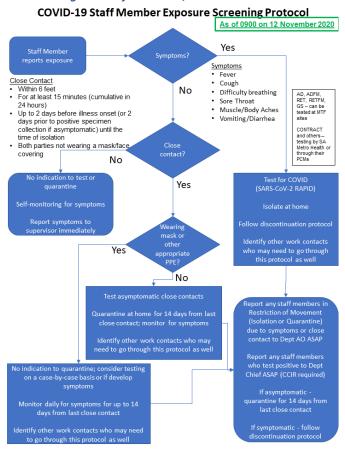
#### APPENDIX F: EXAMPLE TRIAGE PROTOCOLS DURING COVID-19 PANDEMIC



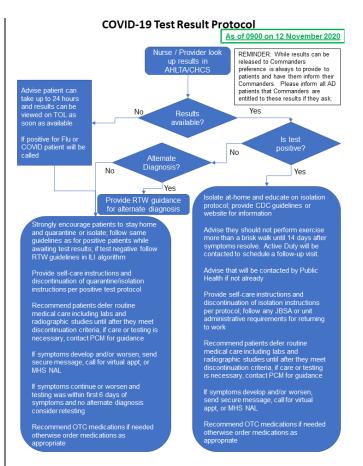


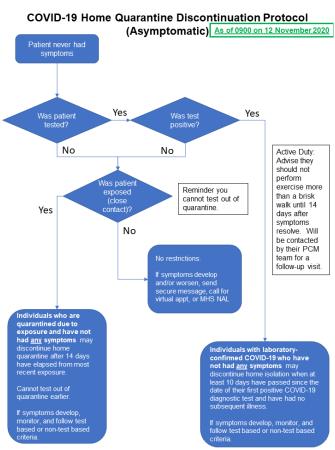






#### COVID-19 Home Isolation Discontinuation Protocol (Symptomatic) As of 0900 on 12 November 2020 Patient is or was symptomatic This is non-test based protocol. Test based criteria should only considered for severely immunocompromised in consultation with ID No Yes Was patient tested? determine a different No Yes Yes as passed since recovery lefined as resolution of ver without the use of Was test ever-reducing No 5 Active Duty: ast 1 day (24 hours) Advise they should not perform fever without the use of fever-reducing medications) and . exercise more than a brisk walk until 14 At least 10 days have passed since symptoms Improvement in respiratory symptoms (e.g., cough, shortness of breath) and days after symptoms resolve. Will first appeared be contacted by their PCM considered for up to 20 days of isolation after ID Healthcare workers should follow-up visit. immunocompromised patients and wear a mask If test is negative and occurred within 6 days of symptom onset, at all times until symptoms fully resolve or 14 days symptoms are worse or not improving, and are one of approved testing categories consider retesting or alternate diagnosis Specific guidance for healthcare personnel (per CDC) After returning to work, healthcare personnel should: - Wear a facemask at all times while in the healthcare facility until all symptoms are completely resolved or - vive a laterillass at an united with in the feature rate and a symptoms are completely resolve until 14 days after illness onset, whichever is longer - Be restricted from contact with severely immunocompromised patients (e.g., transplant, hematology-oncology) until 14 days after illness onset





 - Adhere to hand hygiene, respiratory hygiene, and cough etiquette in CDC's interim infection control guidance (e.g., cover nose and month when coughing or sneezing, dispose of tissues in waste receptacles)
 - Self-monitor for symptoms, and seek re-evaluation if respiratory symptoms recur or worsen

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

\*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 boney 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.
  - 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).
  - I. 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.
  - 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 on 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 are 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 simmers pose entails the up are 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 ever two hours to a slightly abducted positon.

#### Patient monitoring and care:

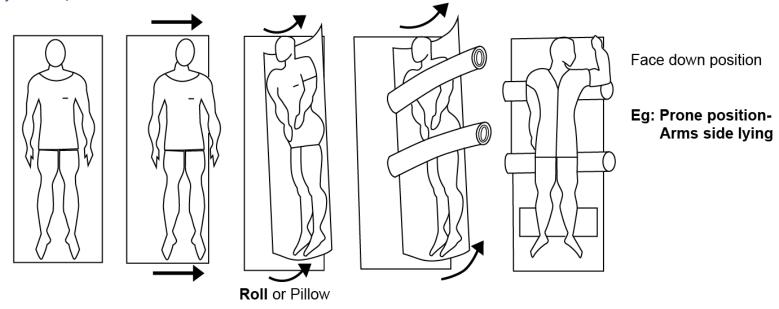
- 7. Time patient is prone/supine:
  - a. It is recommended in the literature that patient is placed in the prone position for a minimum of 16 hours. The timing for prone cycling requires a physician order and is always situational. Patients should be returned to supine position for up to four hours, 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 PaO<sub>2</sub>/FiO<sub>2</sub> ratio, hemodynamically unstable or decreasing SpO<sub>2</sub>/PaO<sub>2</sub>) 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 PaO<sub>2</sub>/FiO<sub>2</sub> 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. PaO<sub>2</sub>/FiO<sub>2</sub> 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:

- 1. The patient no longer shows a positive response to the position change or mechanical ventilation support has been optimized.
- 2. The patient's PaO<sub>2</sub>/FiO<sub>2</sub> ratio is >200 on less than 50% FiO<sub>2</sub> and PEEP ≤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



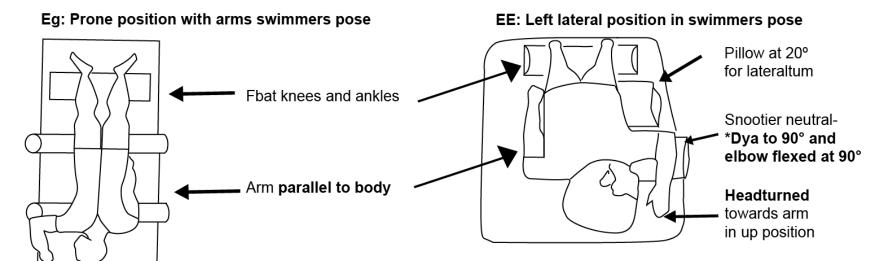


Figure G-1: proper patient positioning

# APPENDIX H: COVID-19 INTUBATION CHECKLISTS, PROTOCOLS, AND COGNITIVE AIDS

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

#### **For Providers:**

# To bring inside room:

To bring made room.
Place a priority on rapid airway placement with video laryngoscopy (i.e., Glidescope) to create distance operator and patient's airway, avoidance of BVM and NIV due to risk of aerosolization:
<ul> <li>□ Airway Supplies:         <ul> <li>ETT (7, 7.5, 8 for adults, appropriate size for children) with syringe for cuff</li> <li>Glidescope or C-MAC (facilitate intubation from a distance)</li> <li>Appropriate stylet</li> <li>Bougie</li> <li>OG tube with syringe, lube and tape</li> <li>OP/NP airway</li> <li>Colorimetric end-tidal CO₂ detector</li> <li>Suction setup</li> </ul> </li> </ul>
☐ Disposable stethoscope ☐ Sani-wipes (should be located inside room)
Keep outside room (on standby):
<ul> <li>□ Back up Airway Supplies:         <ul> <li>Appropriate size laryngoscope blades (Mac 3 &amp; 4 for adults) and handle (disposable preferred)</li> <li>Stylet</li> <li>BVM (avoid if possible due to risk of aerosolization of pathogen)</li> </ul> </li> <li>□ Airway cart (never bring in room)</li> <li>□ EZ-IO</li> </ul>
For Nursing:  RSI meds kit IV fluid  Restraints  Foley  ABG syringe  Post-intubation meds:  propofol  fentanyl  phenylephrine  norepinephrine drip
For Respiratory Therapy:  Ventilator with appropriate filters  ET securing device  Waveform capnography adapter  Viral filter for Ambubag

between

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

#### **COVID-19 INTUBATION PROTOCOL**

# Dlan

- 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
- $\bullet \ \ \text{Determine intubation medications (Recommend: Ketamine 2mg/kg; Rocuronium* 1 mg/kg)}\\$
- \*Succinylcholine 1 mg/kg may also be used provided no contraindications (e.g. hyperkalemia)

# Plan

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

Position

- 100% FiO2 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

# Pre Oxygenate

#### • 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)

# Prepare

- Push intubation meds AFTER physician to nurse order and nurse reply
- Avoid BVM, but if neccessary, 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

#### Paralyze

# 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

# SAFE AIRWAY SOCIETY

# **CHECK BEFORE ENTERING ROOM**

# Team

- Anaesthesia contacted if difficulty anticipated
- ☐ Team introduced:
- Airway Operator
- Airway Assistant
- Team Leader/Drugs
- In-room Runner: optional
- Door Runner
- Outside room Runner
- □ Problems anticipated?

#### **Patient**

- ☐ ECG, BP, Sats
- □ Pre-oxygenation •FIO2 100%
  - Sitting position 45°
- □ IV access x 2
  - 1L fluid on pump set
- □ Haemodynamics optimised
  - •Fluid bolus
  - Pressor

## Drugs

- RSI drugs drawn up, doses chosen
- Rescue drugs Metaraminol
- Post intubation sedation plan
- ☐ Drug C/l or allergies?

# **Equipment**

- □ 2 Laryngoscopes (tested)
- ☐ Tube chosen; cuff tested Bougie/stylet
- 10ml syringe
- ☐ Tube tie
- Lubricant
- Supraglottic airway sized to pt
- Scalpel + bougie CICO kit
- Airway trolley/bronchoscope outside room
- ☐ ETCO2
- Viral filter

# **FINAL CHECK IN ROOM**

- Patient position optimal
- □ Fluid runs easily
- Suction working
- ☐ Facemask with viral filter connected
- ☐ ETCO2 trace
- O2 running at 15L.min-1
- 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

#### USE A 'BUDDY CHECK' FOR CORRECT PPE FITTING

**Planning** 

ervene 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 wentilation 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 VI; use the screen (indirect view) to maximise operator distance from airway Modified RSI technique (1.5mg/kg IBW Roc OR 1.5mg/kg TBW Sux). No ventilation prior to intubation unless for rescue oxygenation.

Walt 60 seconds for paralysis to take effect - avoid triggering cough

**Post-ETT** 

Inflate culf BEFORE initiating ventilation and monitor culf pressures to minimise leak. Remove outer gloves (if an), dispose of airway equipment in sealed bag.

Daffing: Gloves > Gawn > HH > Hat > Eye Protection > Mask > HH. Use a Spatter. Debrief and share lessons.

Collaboration between Safe Airway Society + RNS ASCAR

v1.2 March 2020

# SAFE AIRWAY SOCIETY

# **COVID-19 AIRWAY** MANAGEMENT

#### **Team Members**



#### **COVID Intubation Tray**

	Macintosh VL blade	Bougle / Stylet
	Hyperangulated VL blade (if available)	10 mL syringe
	Macintosh airect laryngoscope	Tube tie
1	SGA (2nd generation)	Lubricant socher

10 mL syringe
Tube tie
Lubricant sochet

ETCO2
NG tube (large bore)
OPA i NPA
Scalpel + bougie CICO kit

Inline suction

#### Circuit Setup

Viral filter

Patient ETT / Filter ETCO2 Vent
---------------------------------

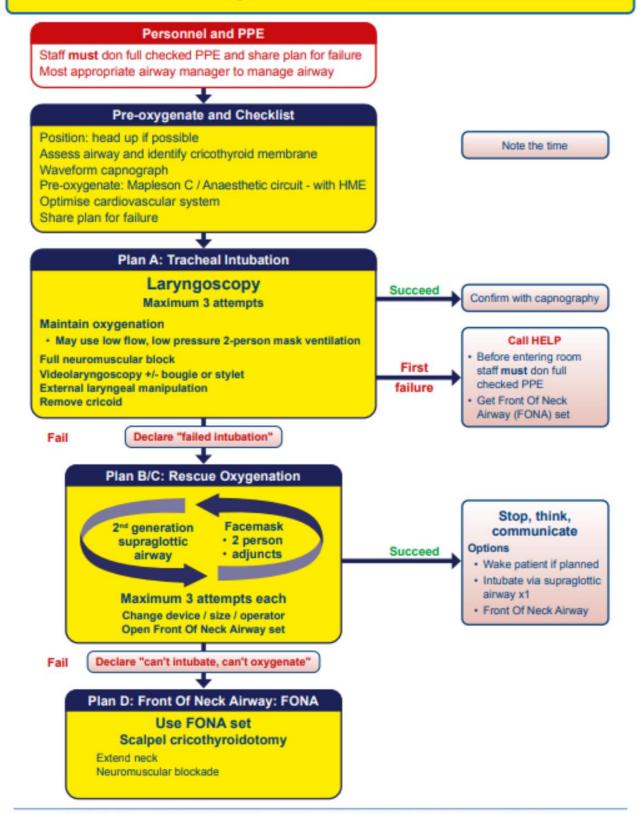
Collaboration between Safe Airway Society + RNS ASCAR

ETT (appropriate size range)

@SafeAirway + @RnsAscar 💟

v1.2 March 2020

# Tracheal intubation of critically ill adults 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)

- Bougie (≤ 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

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

\*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 exubate 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 faceallowing 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:

- 1. Impact 731
- 2. Impact 754
- 3. Lung Transport Ventilator (LTV)
- 4. LP10 (not shown)
- 5. Hamilton T1 (only ground evac or *Rotary-wing* transport; Not flight approved for fixed or tilt-wing aircraft)
- 6. 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.  ${\rm EtCO_2}$  is between HMEF and bag.



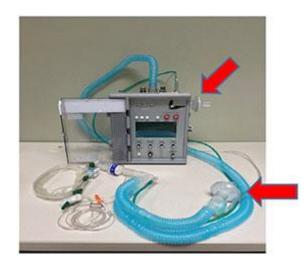
Vent circuit. In-line suction is on patient side of HMEF. EtCO<sub>2</sub> is between HMEF and vent circuit.

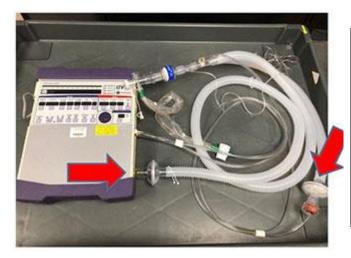
E. In the event that HMEFs are not available, the standard bacterial/viral vent filters will be needed. At a minimum, a filter must be placed on the port that entrains room air and the exhalation valve of the circuit. When disconnecting a patient from the ventilator without a HMEF, a standard bacterial/viral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



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 antiasphyxiation 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.

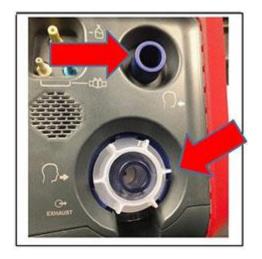
For the **Impact 754 ventilator**, place a filter on the gas intake (top arrow) and at the exhalation valve (bottom arrow). The setup for this ventilator will look identical to that of the Impact 731. The same caution must be taken when placing a filter on the gas intake due to the same risk of blocking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



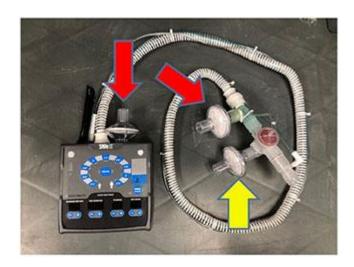


For the LTV ventilator, there are some important considerations. Filters should be placed as marked by the red arrows. It is important to understand that a filter cannot be placed where the vent entrains room air, instead a filter is placed between the vent and the beginning of the circuit (left arrow). 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)

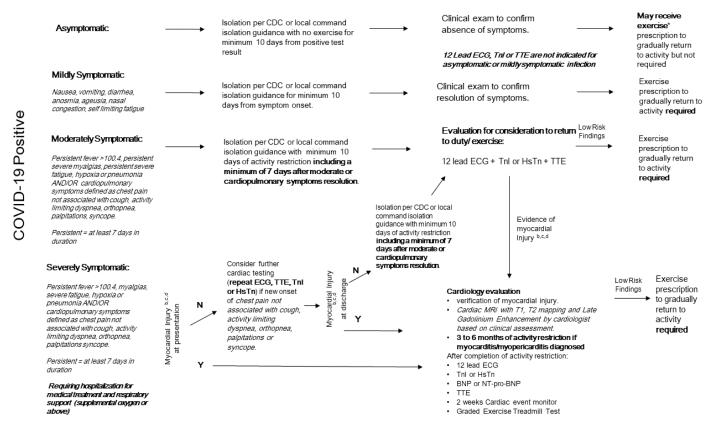






For the **SAVE II** ventilator, 3 filters are necessary. The red arrows mark where room air is entrained into the circuit. The yellow arrow shows the exhalation valve. Not only does using this ventilator require more filters, it is also not ideal for managing mechanically ventilated patients requiring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

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



**Figure K-1.** Cardiopulmonary Return to Exercise or Physical Activity Recommendations after COVID-19. (ECG, electrocardiogram; TnI, Troponin I; HsTn, high sensitivity troponin; TTE, transthoracic echocardiogram)

a: Refer to Cardiovascular Disease Section under Management of Critical Illness and COVID-19 - Prevention of Complications.

**b:** ECG findings that may indicate viral induced myocardial injury include pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions that are outside of the normal parameters based on the Internal Recommendations For Electrocardiographic interpretation in athletes.(2)

c: Cardiac Biomarkers indicative of myocardial injury: >99th percent upper limit of normal levels for Troponin I or High Sensitivity Troponin I/T.
d: Transthoracic echocardiogram findings of cardiac injury- regional wall motion abnormalities, dilated ventricles, abnormal systolic function with a reduced EF <45%. \*See Gradual Return to Exercise and Physical Activity Prescription below.

#### **ASYMPTOMATIC COVID-19 infection**

- a. Service Member (SM) has completed 10 day isolation with exercise limitations.
- b. Exercise limitations (no more than brisk walking) is recommended for a minimum of 10 days with a gradual increase in exercise, permitting resumption of intense exercise no earlier than day 10.
- c. May return to exercise and full physical activity at earliest 10 days after diagnosis AND upon meeting DoD Force Health Protection Guidelines Criteria for Redeployment.<sup>1</sup>
- d. Physician or Healthcare professional has determined SM is low risk based on:
  - 1) Focused clinical exam without 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
- e. Electrocardiogram (ECG), Troponin I or High Sensitivity Troponin (HsTn), and Transthoracic echocardiogram (TTE) are not required for asymptomatic infection.
- f. SM may receive an exercise prescription (below) to gradually re-acclimatize to activity if deemed necessary.
- g. Repeat medical evaluation is only necessary if moderate or cardiovascular symptoms develop.

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## **MILDLY SYMPTOMATIC COVID-19 infection**

- a. Defined as symptoms of nausea, vomiting, diarrhea, anosmia or ageusia, nasal congestion, or self-limiting fatigue.
- b. SM has been cleared to return from isolation in accordance with local public health guidance.
- c. SM has completed a minimum of 10 days of activity restriction including a minimum of 7 days after mild symptom resolution.
- d. Physician or Healthcare Professional has determined SM is low risk based on:
  - 1) Clinical exam without 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.
- e. ECG, Troponin I or HsTn, and TTE are not required for mildly symptomatic infection.
- f. SM should receive an exercise prescription (see below) to gradually re-acclimatize to activity and should cease physical activity and undergo a repeat evaluation with the development of cardiovascular symptoms.

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

- a. Defined as symptoms of persistent fever (at least 100.4), persistent myalgias, persistent fatigue (persistent defined as at least 7 days in duration), hypoxia or pneumonia, and /or cardiopulmonary symptoms (chest pain not associated with cough, activity limiting dyspnea, orthopnea, palpitations, syncope).
- b. SM has been cleared to return from isolation in accordance with local public health guidance.
- c. SM has completed a minimum of 10 days of activity restriction including a minimum of 7 days after moderate or cardiac symptoms resolution.
- d. In the presence of moderate or cardiac symptoms, the following are required prior to return to duty:
  - 1) 12 lead ECG
  - 2) Troponin I or HsTn
    - i. Ensure cardiac enzyme tests are performed at least 24-48 hours after exercise and should be repeated after a small similar period of rest following an isolated abnormality.
  - 3) TTE
- e. Physician or Healthcare Professional has determined SM is low-risk based on:
  - 1) Clinical exam without clinically significant abnormal findings (normal oxygen saturation on ambient air, stable vital signs, absence of fever)
  - 2) Absence or resolution of moderate or cardiopulmonary symptoms, AND:
    - i. ECG without abnormalities i
    - ii. No evidence of myocardial injury by cardiac biomarkers ii
    - iii. No abnormalities on TTE iii
  - 3) Confirmation of no further treatment needed
- f. SM should receive an exercise prescription (see below) to gradually re-acclimatize to activity and should cease physical activity and undergo a repeat evaluation with the recurrence or development of cardiovascular symptoms.
- g. If evaluation demonstrates evidence of myocardial injury <sup>i,ii</sup> and/or abnormal cardiac study, <sup>iii</sup> follow recommendations for symptomatic COVID-19 infection with myocardial injury.

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

- a. Defined as symptoms of persistent fever (at least 100.4), persistent myalgias, persistent fatigue (persistent defined as at least 7 days in duration), hypoxia or pneumonia, and /or cardiopulmonary symptoms (chest pain not associated with cough, activity limiting dyspnea, orthopnea, palpitations, syncope) requiring hospitalization for medical treatment and respiratory support (supplemental oxygen or above).
- b. SM has been cleared to return from isolation in accordance with local public health guidance.
- c. SM has completed a minimum of 10 days of activity restriction including a minimum of 7 days after moderate or cardiac symptoms resolution.
- d. In the presence of severe or cardiac symptoms, the following are required prior to return to duty:
  - 1) 12 lead ECG
  - 2) Troponin I or HsTn
    - i. Ensure cardiac enzyme tests are performed at least 24-48 hours after exercise and should be repeated after a small similar period of rest following an isolated abnormality.
  - 3) TTE
- e. Physician or Healthcare Professional has determined SM is low-risk based on:
  - 1) Clinical exam without clinically significant abnormal findings (normal oxygen saturation on ambient air, stable vital signs, absence of fever)
  - 2) Absence or resolution of severe or cardiopulmonary symptoms, AND:
    - ECG without abnormalities in the control of the control
    - ii. No evidence of myocardial injury by cardiac biomarkers ii
    - iii. No abnormalities on TTE iii
  - 3) Confirmation of no further treatment needed
- f. SM should receive an exercise prescription (see below) to gradually re-acclimatize to activity and should cease physical activity and undergo a repeat evaluation with the recurrence or development of any cardiovascular symptoms.
- g. If evaluation demonstrates evidence of myocardial injury <sup>i,ii,iii</sup> follow recommendations for symptomatic COVID-19 infection with myocardial injury.

## MODERATE OR SEVERELY SYMPTOMATIC COVID-19 infection WITH MYOCARDIAL INJURY

- a. Defined as a clinical course with cardiopulmonary findings suggestive of myocardial injury (presence of chest pain not associated with cough, activity limiting dyspnea, orthopnea, palpitations, syncope, or signs of heart failure in the presence of abnormal ECG, abnormal cardiac biomarkers, abnormal TTE)
- b. SM has been cleared to return from isolation in accordance with local public health guidance.
- c. Cardiology Consultation for further evaluation to confirm diagnosis, determine if further cardiac MRI or other evaluation is warranted, and if myocarditis/myopericarditis criteria is met.
- d. Activity restriction for 3-6 months if diagnosis of myocarditis/myopericarditis is made by Cardiologist.
- e. Must complete the following evaluation before resuming exercise and physical activity (by Cardiologist):
  - 1) 12 lead ECG
  - 2) Troponin I or High Sensitivity Troponin
    - i. Ensure cardiac enzyme tests are performed at least 24-48hrs after exercise and should be repeated after a small similar period of rest following an isolated abnormality.
  - 3) Natriuretic peptide (BNP or NT-pro BNP)
  - 4) Other supplemental studies to show resolution of COVID-19 sequela and demonstrate normalization of end organ function (i.e., CXR, ESR, CRP)
  - 5) Transthoracic Echocardiogram (after completion of activity restriction)
  - 6) 2-week ambulatory cardiac event monitoring
  - 7) Cardiac MRI with T1, T2 mapping and late gadolinium enhancement (LGE)

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- 8) Graded Exercise stress test after completion of the tests above if no abnormalities, and asymptomatic.
- 9) Cardiology evaluation to ensure safe return to exercise.
- f. SM should receive an exercise prescription to gradually re-acclimatize to activity based on high severity 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.

# SYMPTOMATIC COVID-19 infection complicated by stroke, deep venous thromboembolism, respiratory failure, myocardial infarction, cardiac failure, renal failure, other end-organ failure

a. RTD based on expert consultation and case-by-case consideration for retention vs. referral to DES/MEB.

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<sup>&</sup>lt;sup>i</sup> ECG findings that may indicate viral induced myocardial injury include: pathological Q waves, ST segment depressions, (new) diffuse ST segment elevation, and T wave inversions that are outside of the normal parameters based on the Internal Recommendations For Electrocardiographic interpretation in athletes. <sup>ii</sup> Cardiac Biomarkers indicative of myocardial injury: >99<sup>th</sup>% upper limit of normal levels for Troponin I or High Sensitivity Troponin I / T.

Transthoracic echocardiogram findings of cardiac injury- regional wall motion abnormalities, dilated ventricles, abnormal systolic function with a reduced EF <45%

## **Gradual Return to Physical Activity and Exercise Prescription and Duration of Recovery Stages**

	Stage 1	Stage 2	Stage 3A	Stage 3B	Stage 4	Stage 5		
Activity Description	Minimum Rest Period	Light Activity	Light Moderate	Moderate Activity	Prolonged Moderate Activity	Normal Training		
Exercise Allowed	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		
% Heart Rate MAX (220- age)	N/A	<70%	<80%	<80%	<80%	Normal training		
Duration	N/A	<15 min	<30min	<45min	<60min	Normal training duration		
Objective	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		
Monitoring	Persistence of symptoms.	New onset or recurrence of moderate or cardiopulmonary symptoms during return						

Gradual Return to Exercise and Physical Activity Prescription: Recommended exercise prescription following COVID 19 resolution of symptoms. Stages indicate the objectives within each. The duration of each recovery stage is determined by the severity of experienced symptoms and listed as a separate table

## **Duration of Recovery Stages According to Symptoms**

**Table K1.** Gradual Return to Exercise and Physical Activity Prescription: Recommended exercise prescription following COVID-19 resolution of symptoms. Stages indicate the progression and duration of activity and objectives within each. The duration of each recovery stage is determined by the severity of experienced symptoms.<sup>3</sup>

	Stage 1	Stage 2	Stage 3A	Stage 3B	Stage 4	Stage 5
Asymptomatic	10 days from (+) test exercise prescription may be considered but it is not required	1 day minimum	1 day minimum	1 day minimum	N/A	Earliest Day 13
Mild Severity Symptoms nausea vomiting, diarrhea, anosmia or ageusia, nasal congestion, self-limiting fatigue	10 days minimum of activity restriction including a minimum of 7 days <b>after</b> symptom resolution.	1 day minimum	1 day minimum	1 day minimum	1 day minimum	Earliest Day 14
Moderate Severity Symptoms  Persistent fever >100.4, persistent myslajas, severe fatigue, hypoxia or pneumonia, Andlor chest pain not associated with cough, activity limiting dyspnea, orthopnea, polpitations, symcopo  Persistent is defined as at least 7 days of symptoms duration	10 days minimum of activity restriction including a minimum of 7 days after moderate or cardiac symptoms resolution.  Symptomatic patients with myocardial injury require strict 3-6 months of any activity restriction and must remain on stage 1	2 days minimum	2 days minimum	2 days minimum	2 days minimum	Earliest Day 18
High Severity Symptoms  Requiring hospitalization for medical treatment and respiratory support (supplemental oxygen or above)  Persistent fever >100.4, Andior Andior and analysis of the support of the	10 days minimum of activity restriction including a minimum of 7 days after severe or cardiac symptoms resolution.  Symptomatic patients with myocardial injury require strict 3-6 months of any activity restriction and must remain on stage 1	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.

Presence of new onset or recurrence of moderate or cardiopulmonary symptoms during return to exercise prescription require cessation of activity and further cardiac evaluation (ECG + Troponin I or HsTn + TTE if not previously performed) or cardiology evaluation if ECG, Troponin I or HsTn and TTE were previously performed)

## APPENDIX L: WEIGHT-BASED HEPARIN DOSING ALGORITHM FOR VENOUS THROMBOEMBOLISM

## 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).

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

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

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

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

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

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

#### Determine EN Appropriateness and Beneficial Effects

- Determine if gastrointestinal tract is functional, bowel sounds not necessary<sup>1</sup>
- EN provides beneficial effects including decreased infection over parenteral nutrition<sup>1</sup>
- If a patient is unable to tolerate EN due to diarrhea, nausea, vomiting, and/or abdominal discomfort, consider initiating parenteral nutrition
  - Place consult to Registered Dietitian at facility, if available, or obtain telenutrition consultation

## Complete Nutrition Assessment

- Obtain accurate height and weight
- Assess for risk of malnutrition/refeeding syndrome; if present, start at 25% of caloric goal (monitor serum phosphate, magnesium and potassium) 2
- Calorie (kcal) and protein goals (per day):
  - BMI 18-29: 15-20kcal/kg ACTUAL body weight (should be 70-80% of caloric requirements) and 1.2-2g protein/kg
  - BMI 30-49.9: 11-14kcal/kg ACTUAL body weight and 2-2.5g protein/kg IDEAL body weight BMI>50: 22-25kcal/kg ACTUAL body weight and 2-2.5g protein/kg IDEAL body weight

### Assess and Place Enteral Feeding Access Device

- Assess for current enteral access; using an existing nasogastric tube (NGT) or orogastric tube(OGT) is appropriate Prefer NGT or OGT over a post pyloric feeding tube, as it is easier to place, can initiate EN more quickly, and is less likely to
- become clogged<sup>2</sup> Placing an enteral device may provoke coughing and should be considered an aerosol generating procedure<sup>2</sup>

## Select Appropriate EN Formula and Dose

- For most pts with COVID-19 a standard high-protein (>20% protein) polymeric isosmotic enteral formula should be used in early acute phase of critical illness?
- Once patient becomes more stable and vasopressor requirements decrease, fiber should be added, if available (either switch to a fiber-containing formula or add a fiber modular)2
- In order to cluster care, nutritional modular (e.g. fiber or protein) should be given once per day, if indicated through assessment<sup>2</sup>
- Initiate EN at 10-20 mL/hr and increase 10 mL/hr every 8 to 12 hrs to goal rate ideally within the first 3-7 days<sup>2</sup>
- For pts on ECMO, recommend slow advancement to goal over the first week of illness<sup>2</sup>
  At a minimum, strive to maintain trophic feeds of 10-20 mL/hr to prevent intestinal mucosal atrophy<sup>3</sup>

## Administer EN Safely and Appropriately

- Recommend early feeding (within 24-36 hrs of admission or 12 hrs of intubation) for all critically ill pts, including those on EMCO<sup>2</sup>
- Hang time
  - Ready-to-hang closed system: 24-48 hrs
  - Liquid Cans/Bottles Open System: 8-12 hrs (tubing/hang sets must be changed every 24 hrs)<sup>2</sup>
  - Powdered, Reconstituted Formula Open System: 4 hrs (tubing/hang sets must be changed every 24 hrs)2
- Continuous infusion is preferred type of administration; however, if an infusion pump is not available, gravity feeds are
- Elevate head of bed (HOB) to 30-40 degrees while feeding, unless medically contraindicated
- For prone pts, elevate HOB 10-25%. Most patients in prone position tolerate EN delivered to the stomach
- EN can be started when pt is on vasopressors; however, EN should be held if the patient requires high or increasing vasopressor support. EN may be restarted once patient is on stable vasopressor support with a sustained mean arte; rial pressure (MAP) of >65mmHg<sup>2</sup>

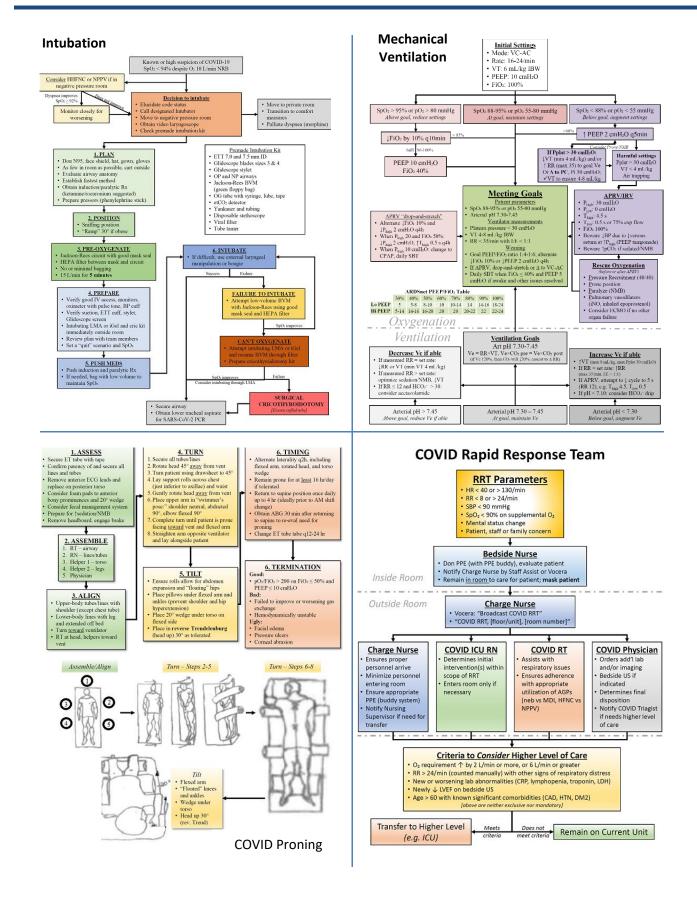
## Monitor and Evaluate Patient

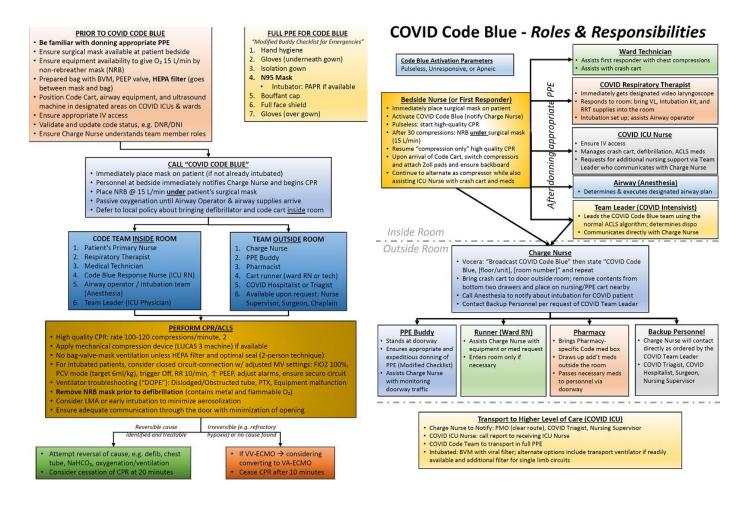
- Monitor I&Os daily
- Consider medications that provide calories and adjust tube feeding rate as needed: Propofol (1.1kcal/ml); Dextrose (3.4kcal/ml)
- If pt has diarrhea, consider using fiber-containing formula or a modular fiber product
- Do not check gastric residual volume (GRV) routinely to monitor EN tolerance. Use daily physical examination and confirmation of passage of stool and gas to assess feeding tolerance.<sup>2</sup> If feeds are not tolerated based on exam, consider use of prokinetic medications such as metoclopramide (Reglan) or erthromycin<sup>2</sup>
- If unable to initiate EN due to failed EN trial with appropriate gastric tube placement, use of prokinetic agent, and/or postpyloric tube placement, or EN is contraindicated (ileus, SBO, Mesenteric Ischemia, high pressure respiratory rre, etc.), please consult Registered Dietitian immediately for possible parenteral nutrition (PN) initiation. For pts with COVID-19, the threshold to switch from EN to PN may be lower than other critically ill patients

## **References:**

- 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/
- 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

## APPENDIX N: SAMPLE PROTOCOLS FOR VARIOUS ICU MANAGEMENT



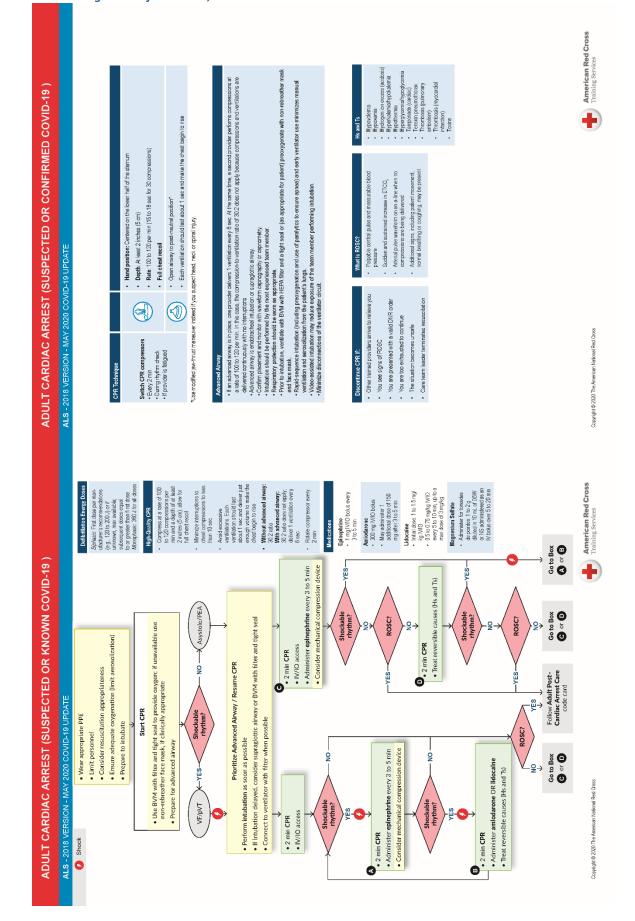


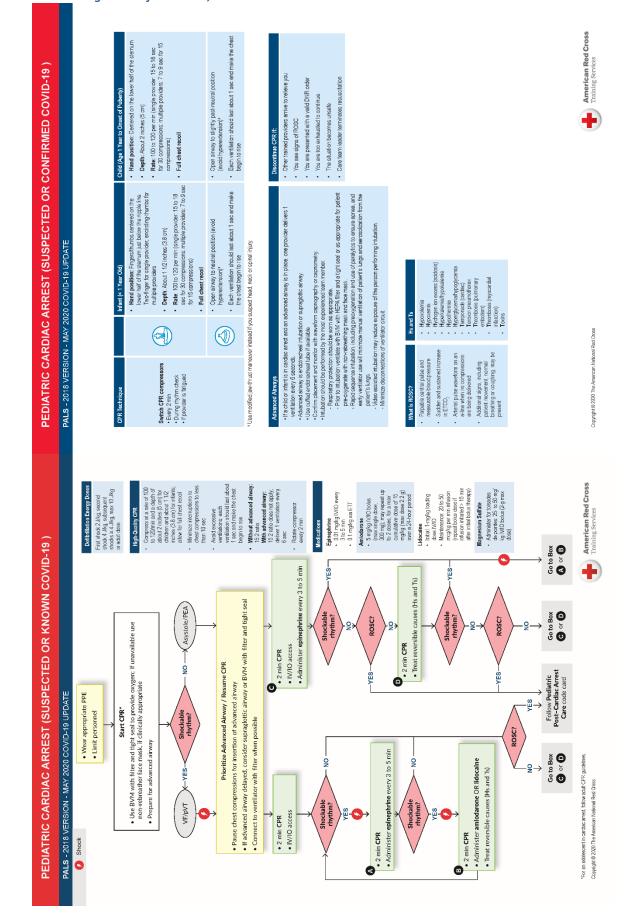
## APPENDIX O: CARDIAC ARREST ALGORITHMS FOR COVID-19 PATIENTS

#### **ACLS Cardiac Arrest Algorithm** Push hard (at least 2 inches [5 cm]) For Suspected or Confirmed COVID-19 Patients and fast (100-120/min) and allow complete chest recoil. **Updated April 2020** · Minimize interruptions in compressions. **Don PPE** Avoid excessive ventilation. Limit personnel · Change compressor every 2 minutes, Consider resuscitation appropriateness or sooner if fatigued. • If no advanced airway, 30:2 compression-ventilation ratio Start CPR · Quantitative wave form capnography If PETCO<sub>2</sub> <10mm Hg, attempt to improve CPR quality. Give oxygen (limit aerosolization) Attach monitor/defibrillator · Intra-arterial pressure Prepare to intubate - If relaxation phase (diastolic) pressure <20mm Hg. Attempt to improve CPR Yes Rhythm shockable? Shock Energy for Defibrillation Asystole/PEA VF/pVT Biphasic: Manufacturer recommendation (eg. Initial dose of 120-200 J): If unknown, use maximum 3 Shock available. Second and subsequent doses should В be equivalent, and higher doses may be considered. Prioritize Intubation / Resume CPR Monophasic: 360 J Pause chest compressions for intubation Advanced Airway If intubation delayed, consider supraglottic airway or bag-mask device with filter and tight seal Connect to ventilator with filter when possible Minimize closed-circuit disconnection 10 · Use intubator with highest likelihood CPR 2 min of first pass success CPR 2 min Consider video laryngoscopy IV/IO access IV/IO access · Endotracheal intubation or supraglottic • Epinephrine every 3-5 min advanced airway **Consider mechanical** · Waveform capnography or capnometry to confirm and monitor ET tube compression device placement No Yes · Once advanced airway in place, give 1 Rhythm Rhythm breath every 6 seconds (10 shockable? shockable? breaths/min) with continuous chest compressions Shock Drug Therapy No • Epinephrine IV/IO dose: 11 1 mg every 3-5 minutes 6 · Amiodarone IV/IO dose: First dose: CPR 2 min 300 mg bolus. Second dose: 150 mg. CPR 2 min Treat reversible causes • Epinephrine every 3-5 min Lidocaine IV/IO dose: · Consider mechanical First dose: 1-1.5 mg/kg. Second dose: compression device 0.5-0.75 mg/kg. Return of Spontaneous No Circulation (ROSC) No Yes Rhythm Rhythm • Pulse and blood pressure shockable? shockable? · Abrupt sustained increase in PETCO2 Yes (typically ≥40 mm Hg) Shock Spontaneous arterial pressure waves with intra-arterial monitoring 8 Reversible Causes CPR 2 min Hypovolemia Amiodarone or lidocaine Hypoxia Treat reversible causes · Hydrogen ion (acidosis) • Hypo-/hyperkalemia • If no signs of return of spontaneous • Hypothermia Go to 5 or 7 circulation (ROSC), go to 10 or 11 • Tension pneumothorax • If ROSC, go to Post-Cardiac Arrest Care Tamponade, cardiac • Toxins @ 2020 American Heart Association · Thrombosis, pulmonary · Thrombosis, coronary

#### **Pediatric Cardiac Arrest Algorithm** CPR Quality Push hard (≥ 1/3 of anteroposterior For Suspected or Confirmed COVID-19 Patients diameter of chest) and fast (100-120/min) and allow complete **Updated April 2020** chest recoil **Don PPE** · Minimize interruptions in Limit personnel compressions. · Avoid excessive ventilation. 1 · Change compressor every Start CPR 2 minutes, or sooner if fatigued. • If no advanced airway, · Ventilate with oxygen using bag-mask device with filter 15:2 compression-ventilation ratio. and tight seal, if unavailable use nonbreathing face mask Attach monitor/defibrillator Shock Energy for Defibrillation Prepare to intubate • First shock 2 J/kg, second shock 4 J/kg, subsequent shocks >4 J/kg. maximum 10 J/kg or adult dose No Yes Rhythm Advanced Airway shockable? • Minimize closed-circuit Asystole/PEA VF/pVT disconnection · Use intubator with highest likelihood of first pass success 3 Shock Consider video laryngoscopy · Prefer cuffed endotracheal tube В if available **Prioritize Intubation / Resume CPR** · Endotracheal intubation or supraglottic advanced airway Pause chest compressions for intubation Waveform capnography or If intubation delayed, consider supraglottic airway or bag-mask device with filter and tight seal capnometry to confirm and Connect to ventilator with filter when possible monitor ET tube placement Once advanced airway in place. 10 4 give 1 breath every 6 seconds (10 breaths/min) with continuous CPR 2 min CPR 2 min chest compressions IV/IO access IV/IO access Drug Therapy Epinephrine every 3-5 min • Epinephrine IV/IO dose: 0.01 mg/kg (0.1 mL/kg of the No Yes 0.1 mg/mL concentration). Repeat Rhythm Rhythm every 3-5 minutes. shockable? shockable? Amiodarone IV/IO dose: 5 mg/kg bolus during cardiac arrest. May repeat up to 2 times for refract-Shock tory VF/pulseless VT. No Lidocaine IV/IO dose: 11 6 Initial: 1mg/kg loading dose. Maintenance: 20-50 mcg/kg per CPR 2 min CPR 2 min minute infusion (repeat bolus dose • Epinephrine every 3-5 min Treat reversible causes if infusion initiated > 15 minutes after initial bolus therapy). Return of Spontaneous Circulation (ROSC) No No Yes • Pulse and blood pressure Rhythm Rhythm · Spontaneous arterial pressure shockable? shockable? waves with intra-arterial monitoring Reversible Causes Shock Hypovolemia 8 Hypoxia Hydrogen ion (acidosis) CPR 2 min • Hypo-/hyperkalemia Amiodarone or lidocaine Hypothermia · Treat reversible causes • Tension pneumothorax • Tamponade, cardiac Toxins • If no signs of return of spontaneous · Thrombosis, pulmonary circulation (ROSC), go to 10 or 11 Go to 5 or 7 · Thrombosis, coronary • If ROSC, go to Post-Cardiac Arrest Care

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## APPENDIX P: IDSA COVID-19 TREATMENT GUIDELINES (v4.0)

		Ambulatory care: mild-to- moderate disease	Hospitalized: mild-to-moderate disease without need for suppl. oxygen	verity of illness  Hospitalized: severe but non- critical disease (spO <sub>2</sub> <94% on room air)	Hospitalized: critical disease (e.g., in ICU needing MV, or septic shock, ECMO)
1	Hydroxy- chloroquine (HCQ)*	NA	Recommend against use	Recommend against use	Recommend against use
2	HCQ*+ azithromycin	NA	Recommend against use  ⊕⊕○○	Recommend against use	Recommend against use
3	Lopinavir + ritonavir	NA	Recommend against use  ⊕⊕⊕○	Recommend against use	Recommend against use
4-6	Corticosteroids	NA	Suggest against use	Suggest use  ①①①①① R: If dexamethasone is unavailable, equivalent total daily doses of alternative glucocorticoids may be used.**	Recommend use  ①①①①① R: If dexamethasone is unavailable, equivalent tota daily doses of alternative glucocorticoids may be used
7	Tocilizumab	NA	NA	suggest use  ———————————————————————————————————	Suggest use
8	Convalescent plasma	NA	Recommended only in the context of a clinical trial (knowledge gap)	Recommended only in the context of a clinical trial (knowledge gap)	Recommended only in the context of a clinical trial (knowledge gap)
9- 11	Remdesivir	NA	Suggest against routine use	Suggest use  ⊕⊕○○ R: In patients on mechanical ventilation or ECMO, the duration of treatment is 10 days.	Suggest use  \(\begin{array}{cccccccccccccccccccccccccccccccccccc
12	Famotidine	NA NA	Suggests against use except in a clinical trial	Suggests against use except in a clinical trial	Suggests against use except a clinical trial
13- 14	BamlanIvimab	Suggest against routine use  ⊕○○ R: In ambulatory patients with COVID-19 or in patients with mild-moderate COVID admitted to the hospital for management of conditions other than COVID-19 who are at increased rist,*** bamlanivimab is a reasonable treatment option if, after informed decision-making, the patient puts a high value on the uncertain benefits and a low value on uncertain adverse events.	NA	Recommend against use	NA
15	Casirivimab/ imdevimab	Suggest against routine use  ⊕○○  R: in ambulatory patients with COVID-19 or in patients with mild-to-moderate COVID-19 admitted to the hospital for management of conditions other than COVID-19 who are at increased risk,***are at increased risk,***are at increased risk,***are at resonable treatment option if, after informed decision- making, the patient puts a light value on the uncertain benefits and a low value on uncertain adverse events.	NA	NA NA	NA
16	Baricitinib + Remdesivir	NA	NA	Suggest use****  ⊕⊕○○ R: For hospitalized patients who cannot receive corticosteroids because of a contraindication. Banichinib 4 mg dally dose for 14 days (or until hospital discharge). The benefits of banichinib plus remdesivir for persons on mechanical ventilation are uncertain.	
17	Baricitinib + remdesivir + corticosteroids	Recommended only in the context of a clinical trial (knowledge gap)	NA	NA	NA
18	Ivermectin	Suggests against use except in a clinical trial	NA	Suggests against use except in a clinical trial	NA

NA: not applicable/not reviewed; MV: mechanical ventilation; ECMO: \*Chloroquine is considered to be class equivalent to hydroxychloroquine.

## 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:
-----------	----	-----------

⊕⊕⊕○ moderate ⊕○○○ very low

<sup>\*\*</sup>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.

\*\*\*Patients at increased risk, see EUA at https://www.fda.gov/media/143603/download

<sup>\*\*\*\*</sup>For hospitalized patients who cannot receive corticosteroids because of a contraindication

## APPENDIX Q: MANAGEMENT FOR PREGNANT WOMEN WITH SUSPECTED OR CONFIRMED COVID-19

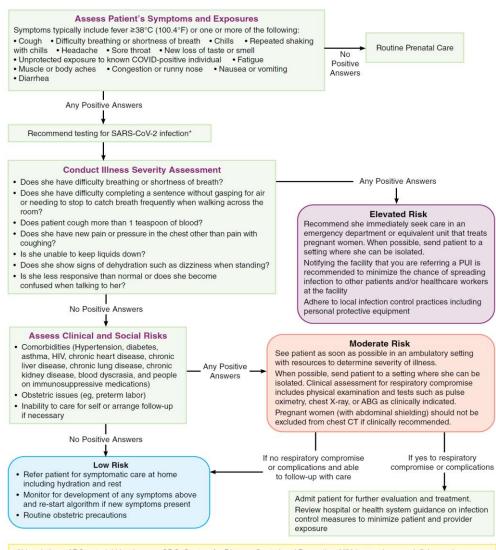




# Outpatient Assessment and Management for Pregnant Women With Suspected or Confirmed Novel Coronavirus (COVID-19)

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 respiratory.

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 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

## APPENDIX R: COVID-19 VACCINE SHARED DECISION-MAKING AID FOR PREGNANT WOMEN



# I'm pregnant. Should I get a COVID\* vaccine?

\*The information here is about the Pfizer and Moderna COVID-19 vaccines. These are also called "mRNA" vaccines.

> For most people, getting the COVID vaccine as soon as possible is the safest choice.

However, these vaccines have not been tested in pregnant and breastfeeding people yet.

The information below will help you make an informed choice about whether to get an mRNA COVID vaccine while you are pregnant or trying to get pregnant.

## Your options:



Get a COVID vaccine as soon as it is available



Wait for more information about the vaccines in pregnancy

## What are the benefits of getting an mRNA COVID Vaccine?

- 1. COVID is dangerous. It is more dangerous for pregnant people.
  - COVID patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than COVID patients who are not pregnant.
  - · Preterm birth may be more common for pregnant people with severe COVID.
  - Pregnant people are more likely to die of COVID than non-pregnant people with COVID who are the same age.34
- 2. The mRNA COVID vaccines prevent about 95% of COVID infections.
  - As COVID infections go up in our communities, your risk of getting COVID goes up too.
  - Getting a vaccine will prevent you from getting COVID and may help keep you from giving COVID to people around you, like your family.

## 3. The mRNA COVID vaccines cannot give you COVID.

- These vaccines have no live virus.
- These vaccines do NOT contain ingredients that are known to be hamful to pregnant people or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how these vaccines work can be found on page 5.

## What are the risks of getting an mRNA COVID vaccine?

- 1. These COVID vaccines have not yet been tested in pregnant people.
  - These vaccines were tested in over 40,000 people, and there were no serious side effects related to the vaccine.
  - We do not know if the vaccines work as well in pregnant people as they did in non-pregnant people.
  - We do not know whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.
    - The Moderna vaccine was tested in female rats to look at its effects on pregnancy. No significant negative effects were found on female fertility or fetal development.
  - Some women became pregnant during the vaccine studies. Eighteen of these women were in the vaccine group, and two months later none had miscarried. There were seventeen women in the placebo group who became pregnant, and two months later two of them had had miscarriages. (In general, 10-20% of pregnancies end in miscarriage).
  - Because these studies are still ongoing, we don't know how the rest of the pregnancy went for these women.
- 2. People getting the vaccine will probably have some side effects.
  - · Many people had symptoms caused by their immune system's normal response to the vaccine. The most common side effects were:
    - injection site reactions like sore
- muscle pain (~38%)
  - arm (~84%)
- chills (~32%)
- fatigue (~62%)
- joint pain (~24%) fever (~14%)
- headache (~55%)
- Of 100 people who get the vaccine, 1 will get a high fever (over 102°F). A persistent high fever during the first trimester might increase the risk of fetal abnormalities or miscarriage. The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever. Another option is to delay your COVID vaccine until after the first trimester.

# are no clea COVID is dangerous and easily spread, the CDC says that the mRNA

This is standard for a new drug and is not yet,

The American College of Obstetricians and Gynecologists recommends that the They recommend that each person The **Society for Maternal-Fetal Medicine <u>strongly recommends</u> that pregnan**t from pregnant individuals.9 talk to their doctor or midwife about their own personal choice.8 individuals have access to COVID vaccines. not be withheld COVID vaccine should

What else should I think about to help me decide?

and about the vaccine. Ask a trusted source, like your midwife Make sure you understand as much as you can about COVID or doctor. Page 5 has more information about the vaccine

below and think about your risk of getting COVID (left). Look at the columns Think about your stay safe (right)?

If you are not at higher risk for COVID Think about your safety - are you able and... The risks of getting sick from COVID

are always able to wear a mask and the people you live with socially distance from others our community does NOT have pregnancy our whole can

> You have other medical problems like diabetes, high blood pressure

You have contact with people

are higher if...

You are 35 years old or older

You are overweight

think the vaccine itself will make vorried about the unknown risks nigh or increasing COVID cases ou very nervous (you are more than about getting COVID) on

you to wait ou have had a severe allergic for more information

COVID, it probably makes sense to get you are at a higher risk of getting You are a healthcare worker10 of COVID infections

or your community has a high rate

You are a racial or You are a smoker

What do the experts recommend?

for COVID-19 are recommended

vaccines

for pregnant people.

due to any particular

195

## What about breastfeeding?

The Society for Maternal-Fetal Medicine and the Academy of Breastfeeding Medicine report that there is no reason to believe that the vaccine affects the safety of breastmilk.8,11 The vaccine does not contain the virus, so there is no risk of infecting your baby. Because mRNA is fragile, it is very unlikely that any part of the vaccine gets into breastmilk.

When we have an infection or get a vaccine, our bodies make antibodies to fight the infection. Antibodies can pass into the breastmilk and then to the baby - and may help prevent infections.

## Summary

- 1. COVID seems to cause more harm in pregnant people than in people of the same age who are not pregnant.
- 2. The risks of getting an mRNA COVID vaccine during pregnancy are thought to be small but are not totally known.
- 3. You should consider your own personal risk of getting COVID. If your personal risk is high, or there are many cases of COVID in your community, it probably makes sense for you to get a vaccine while
- 4. Whether to get a COVID vaccine during pregnancy is your choice.

## What do pregnant doctors think?

We know COVID can be terrible in pregnancy, and we know the vaccine doesn't contain live virus. I'm approaching my third trimester and I work on the front lines of this disease, so for me the choice is clear, I intend to be first in line as soon as they will let me have one. (Pregnant Emergency Department Doctor)

I am a little nervous about getting something that hasn't been tested in pregnant patients. Early pregnancy is a nerve-wracking time, even without the unknown of a new vaccine. So, I went over the risks and benefits of getting or not getting it as a front-line worker - with myself, my partner, and my doctors. We ended up deciding I should get the vaccine. (Pregnant Emergency Department Doctor)

I'm 34 weeks and I'm going to try to get vaccinated after delivery, but during pregnancy I'm holding out. Pregnant people were excluded from the studies and, in the meantime, I don't see COVID patients at work so I feel like my exposure will be low during this second wave. (Pregnant physician)

I am still breastfeeding my baby, and I think the risk of exposing my infant and other children and partner to COVID is far greater than any theoretical risk this novel vaccine may have. I've decided to get vaccinated whenever it becomes available. (Breastfeeding OB/GYN Doctor)

Do you have more questions? Call your doctor or midwife to talk about your own personal decision.

## Thoughts about this tool?

Was this decision aid helpful? Please take a moment to give us feedback about this decision aid at https://is.qd/COVIDVac or by scanning the QR code below. We need your help!



## Tell the CDC about your experience with the vaccine

If you decide to get the vaccine, you will get a "V-safe information sheet" with instructions about the V-safe website and app. Consider registering so we can better counsel people in the future.

## More information about mRNA COVID Vaccines

How do mRNA COVID vaccines work?

- The Pfizer and Moderna COVID vaccines are mRNA vaccines (messenger RNA)
- mRNA is not new our bodies are full of it. mRNA vaccines have been studied for the past two decades.
- mRNA vaccines mimic how viruses work. The mRNA is like a recipe card that goes into your body and makes one recipe for a brief time. The recipe is for a small part of the virus (the spike protein).
- When this spike protein is released from cells, the body recognizes it as foreign and the immune system responds. This immune response causes the side effect symptoms (like aches and fever) but leads to improved immunity.
- mRNA breaks down quickly, so it only lasts a brief time.
- This is also how the other viruses like a cold virus work viruses use our body and cells to make their proteins. Then our immune system attacks those proteins to keep us healthy.

Severe cases of COVID were also reduced in both mRNA vaccine groups.

There were no serious safety concerns.

ntended Use: This decision aid is intended for use by pregnant people (and people planning on Fetal Medicine, Shared Decision-Making and risk communication, Emergency Medicine, and School – Baystate. This group consists of experts in the fields of OB/GYN, Matemal-Making: COVID Vaccination in Pregnancy working group at the University of Massachusetts nealthcare providers, and their friends and family. It was created by the Shared Decision-@bhs.org. Feedback regarding the utility of this decision aid can be becoming pregnant) who are considering getting the COVID-19 vaccine, as well as their Elizabeth Schoenfeld, current COVID-19 research. Questions should be directed to Dr. Medical

Massachusetts
MASS. Medical School University of Health

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Baystate the survey (see link on page 5).

of Pregnancy Women with SARSwith and without severe acute respiratory syndrome coro DeBolt CA, et al. Pregnant women with severe or critical COVID-19 have increased conceptions and the Country of the Country of

Obstet Gynecol. 2020 Sept.

Centers for Disease Control

 COVID-19 and mRNA Vaccines—First Large Test for a New Approach. JAMA. 2020;324(12):1125-1127. Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status doi:10.1001/jama.2020.16866

United States, January 22-October 3, 2020.

etr. html (Accessed Dec14, 2020) c.gov/vaccines it on COVID v

VID-19 (Accessed December 14, 2020)

risk of severe COVID-19: p nald EB,

Available at: https://foamcast.org/covidvacpregnancy/

(including those who got placebo) and showed that the vaccine lowers a person's getting COVID and severe COVID. In each study, over 15,000 people

Pfizer and Moderna mRNA vaccine trials each had over 30,000 people

There is no way for the vaccine to give people COVID.

What did the research show?

After one dose, the vaccine appears to be 50% effective. After 2 doses,

got the vaccine and over 15,000 people got a saline injection (placebo).

chance of

In other words, for every 100 people who got COVID in the placebo

both vaccines are about 95% effective.

group, only 5 people got COVID in the mRNA vaccine groups.

## APPENDIX S: DHA SUMMARY ON MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C)

# 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 neurological); 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.



## 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
- 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; 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





## APPENDIX T: RECOMMENDATIONS FOR SURGICAL TIMING IN COVID+ PATIENTS

## For ELECTIVE surgery in patients with a positive COVID test:

Symptoms	Time Until Rescheduling Surgery	PPE required
Asymptomatic	ASA 1 &2:14 days from positive test  ASA ≥ 3: 28 days from positive test	Standard enhanced precautions (if at least 10 days have passed since symptom onset)
Mild, Non-Respiratory Symptoms (ex: fever, chills, myalgias, GI symptoms, loss of taste/smell)	28 days from onset of symptoms	Standard enhanced precautions (if at least 10 days have passed since symptom onset)
Mild Respiratory Symptoms without hospitalization (ex: cough, SOB)	42 days (6 weeks) from onset of symptoms	Standard enhanced precautions (if at least 10 days have passed since symptom onset)
Moderate Symptoms (required hospitalization without intensive care)	56 days (8 weeks) from onset of symptoms	Standard enhanced precautions (if at least 20 days have passed since symptom onset)
Severe Symptoms (required intensive care with ventilator support/ECMO)	84 days (12 weeks) from onset of symptoms	Standard enhanced precautions (if at least 20 days have passed since symptom onset)

- **Asymptomatic**: Wait 14 days prior to surgery to watch for symptom development. For ASA 1 & 2 patients, as long as symptoms do not occur, proceed with standard enhanced precautions after 14 days. For ASA 3 and above, wait for 28 days as even an asymptomatic (or paucisymptomatic) case increases their risk of morbidity and mortality with a significant decrease at 28 days. After 28 days, proceed with standard enhanced precautions.
- Mild, Non-Respiratory Symptoms (without hospitalization): Wait 28 days from onset of symptoms. Patient may be de-isolated with standard enhanced precautions at 10 days post symptom onset.
- Mild, Respiratory Symptoms (cough, shortness of breath without hospitalization): Wait 6 weeks from onset of symptoms. 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. 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.

## 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 14 days of positive test
Mild Symptoms (without hospitalization)	No mandatory wait  **requires discussion between anesthesiologist/surgeon**	Enhanced COVID precautions if within 14 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 14 (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)

\*\*\*\*\*\*\*\*\*\*\*\*\*\*

- 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

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

<sup>\*</sup>These recommendations are based on expert guidance from Infectious Disease and Infection Control as well as statements from the American Society of Anesthesiologists and Anesthesia Patient Safety Foundation.

<sup>\*</sup>In general, patients should not be re-tested within 90 days of a previously positive COVID test.

<sup>\*</sup>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.

<sup>\*</sup>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.

## APPENDIX U: 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.
- $2. \ The codes listed in this document are for Type 1 or 2 \underline{Privileged Providers}. Refer to the \textbf{MHS Specific Coding Guidelines} for codes related to \underline{all other provider types}.$
- 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)			rs	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 V DISTANT SITE provider is loc			SITE (where	Teleconsultation at distant site (where provider islocated ate.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			Ø							
	Synchronous	(	>	•				0	•	•	
	Asynchronous					•	•				•
	Type: Scheduled		>	•							
	Type:Unscheduled					<b>Ø</b>	<b>Ø</b>			<b>Ø</b>	<b>Ø</b>
CHCS	Appointment	FTR	24HR, FTR,SPEC (provider discretion)	FTR	24HR, FTR, SPEC	SPEC, FTR		24HR, FTR, SPEC	24HR, FTR, SPEC	T-CON	N/A
Ĺ	Detail Code	PHA and TELMED	TELMED	PHA and TELMED	TELMED	N/A	N/A	HC		N/A	N/A
E/M Code	Code	Office Visit C	ode	99499	99499	20452 30 min requesting provider time in referral work	Verbal and Written Report:  99445 5-10min  99447 11-20min  99449 3-30min  99449 +31min  99451≥5 min consultant time including written report	Office Vis and *T20 encounte E/M or pr criteria	25 when r meets	994415-10min 9944211-20min 9944321-30min	99421 5-10min 99422 11-20min 99423 21+ min
E/	Modifier	(patient is presoriginating site clinic) or 95 (clinic to non-dication)	e.g. dinic to	N/A	N/A	N/A	GO	N/A	N/A	N/A	<u>eq</u>
	Code	96160	N/A		cedures the originating esenter's scope	Procedures per documentation	N/A	96160 + G2012	*G2012 alone if E/M criteria not met	N/A	N/A
CPT/HCPCS	Modifier	N/A	N/A	N/A	(on procedure code if technical component of procedure/ test are completed and no interpretation and report are rendered)	N∕A	(interpretation only: professional component)	N/A	N/A	N/A	N/A

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