April 8, 2020

STANDARD OPERATING PROCEDURE (SOP) Interim Guidance for Acute Medical Management of COVID-19 Patients

PURPOSE AND AUTHORITY

The purpose of this document is to outline standard guidance for the acute medical management of suspected or confirmed COVID-19 cases. It replaces the earlier Interim Guidance issued on March 21, 2020. *This is a living document that will be continually updated – for the most current version, staff are directed to check the website* https://www.va.gov/covidtraining/.

Facility preparedness and increasing acute care infrastructure and capacity are of prime importance but are not addressed here - consult VHA guidance¹ and the Society of Critical Care Medicine (SCCM) ICU Preparedness Checklist.² This document also does not address the implementation of Tele-ICU capabilities, which will provide direct access to specialist expertise that will be a valuable supplement to this guidance.

The separate document, *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in VHA* contains on pages 27-40 VHA's approved procedures for establishing local Scare Resource Allocation teams.

BACKGROUND

Although most people with COVID-19 have uncomplicated or mild illness (81%), some will develop severe illness requiring oxygen therapy (14%) and approximately 5% will require intensive care unit treatment. Of those critically ill, most will require mechanical ventilation.

The bulk of the guidance below is derived from interim guidance from the World Health Organization (WHO)³ the Society for Critical Care Medicine⁴, the Centers for Disease Control (CDC)⁵, and other authoritative sources. Clinicians are urged to consult the reference links in this document for the most recent updates.

PROCEDURES

1. Clinical Presentation

¹ <u>https://dvagov.sharepoint.com/sites/VACOVHAPublicHealth/HCI/SitePages/Home.aspx</u>

² <u>https://sccm.org/getattachment/Disaster/ICU-Preparedness-Checklist-Coronavirus.pdf?lang=en-US</u>

³ <u>https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected</u>

⁴https://journals.lww.com/ccmjournal/Abstract/onlinefirst/Surviving_Sepsis_Campaign__Guidelines_on_th e.95707.aspx

⁵ https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html

COVID-19 cannot be distinguished from other viral syndromes by its presenting symptoms. Regardless of chief complaint, every acutely ill patient presenting to the hospital should be screened for possible COVID-19 using the most current national (VHA or CDC) guidance followed by a comprehensive initial assessment and extended COVID Review of Systems (below). While most patients present with fever and symptoms of acute respiratory illness (cough, dyspnea), atypical presentations can occur including GI symptoms, anosmia, ageusia or confusion.

2. Initial Assessment:

- <u>A.</u> Vital signs: Initial severity should be rapidly assessed: temperature, heart rate (HR), respiratory rate (RR), blood pressure (BP), peripheral oxygen saturation (SpO2) by pulse oximetry, Glasgow Coma Scale, and an early warning severity score⁶ calculated by using NEWS, NEWS2, or qSOFA⁷.
- B. COVID Extended Review of Systems: Assessment for dyspnea; new or escalating O2 requirement; cough; change in sputum production; rhinorrhea; myalgias; fatigue; diarrhea; changes in taste or smell; nausea/vomiting; contacts with sick individuals in the past 3 weeks.
- C. Risk factors: Older patients (> 65) and those with comorbidities, such as diabetes mellitus and heart disease, have increased risk of severe disease and mortality even if presenting with mild COVID-19 illness. Their higher risk for deterioration warrants a lower threshold for close monitoring, either with the appropriate tele-health modality or hospitalization. However, younger patients without comorbidities can also develop severe disease.
- D. Diagnostic studies:
 - 1. For all patients with respiratory illness or suspicion of COVID: COVID testing, rapid influenza PCR (check updated CDC or VHA guidance as test availability evolves). Identification of other viral illnesses do not rule out COVID, as co-infection is possible.
 - 2. For patients with moderate or severe illness: CBC w/differential, comprehensive metabolic panel (electrolytes, liver function tests), Magnesium, troponin, BNP, PT/PTT/INR, pro-calcitonin when available, CRP, LDH, ferritin, D-dimer. Severe lymphopenia and elevated D-dimer have been associated with mortality. Procalcitonin is more likely to be elevated in patients needing ICU care.
 - 3. Chest X-ray
 - 4. Obtaining early Chest CT as a substitute for COVID testing is strongly discouraged⁸
 - <u>5.</u> EKG
 - <u>6.</u> For patients with severe illness: arterial blood gas with lactate and endotracheal aspiration for cultures and repeat COVID test. Lab collection should not delay notification of the ICU team.

3. Assessing Severity:

A. Mild disease:

⁶ Early warning scores are an adjunct, not a replacement, for clinical judgment. Concern about a patient's clinical condition should prompt urgent investigation regardless of the score

⁷ <u>https://qsofa.org/calc.php</u>

⁸ <u>https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Recommendations-for-Chest-Radiography-and-CT-for-Suspected-COVID19-Infection</u>

Patients with uncomplicated disease may present with "flu-like-Illness" (FLI) consisting of nonspecific symptoms such as fever, fatigue, cough (with or without sputum production), anorexia, malaise, muscle pain, sore throat, dyspnea, nasal congestion, or headache.

The elderly and immunosuppressed may present with atypical symptoms.

Exacerbation of chronic conditions such as heart failure, diabetes or COPD, and pregnancy or adverse pregnancy events may also overlap with COVID-19 symptoms. Those conditions should be considered in the differential diagnosis but not used to rule-out COVID-19.

B. Pneumonia:

Adult with pneumonia on CXR, but none of the signs of severe pneumonia listed below.

C. Severe Pneumonia:

Fever or suspected respiratory infection, plus one of the following: elevated respiratory rate; severe respiratory distress; or desaturation despite the use of nasal cannula oxygen.

- D. Acute respiratory distress syndrome (ARDS):
 - 1. Onset: within 1 week of a known clinical insult or new or worsening respiratory symptoms.
 - 2. Chest imaging (radiograph or CT scan): bilateral opacities, not fully explained by volume overload, lobar or lung collapse, or nodules.
 - 3. Origin of pulmonary infiltrates: respiratory failure not fully explained by cardiac failure or fluid overload.
 - 4. Oxygenation impairment in adults
 - a. <u>Mild ARDS</u>: 200 mmHg < PaO2/FiO2a \leq 300 (with PEEP or CPAP \geq 5 cmH2O, or non-ventilated)
 - b. <u>Moderate ARDS:</u> 100 mmHg < PaO2/FiO2 ≤ 200 (with PEEP ≥ 5 cmH2O, or non-ventilated)
 - c. <u>Severe ARDS</u>: $PaO2/FiO2 \le 100 \text{ mmHg}$ (with PEEP $\ge 5 \text{ cmH2O}$, or non-ventilated)
 - d. When PaO2 is not available, SpO2/FiO2 ≤ 315 suggests ARDS (including in non-ventilated patients).
 - 5. Co-infection has been reported in COVID-19 patients. Consider testing for other respiratory infections as clinically indicated.

4. Management of mild COVID-19

- A. Patients with mild disease and no medical comorbidities may not require hospital admission, but strict home isolation is necessary. Provide symptomatic treatment such as antipyretics for fever. Counsel patients with mild COVID-19 about signs and symptoms of complicated disease and to seek care urgently if their condition worsens.
- B. Patients discharged to home with mild disease often return with more severe illness as the infection progresses. Older patients with comorbidities may have higher risk of deterioration, warranting close monitoring with the appropriate tele-health modality (e.g., home pulse oximeters).

5. Management of Pneumonia (uncomplicated)

Give supplemental O2 therapy, treat empirically for community-acquired pneumonia according to IDSA/ATS Practice Guidelines⁹, and monitor closely for clinical deterioration. When possible, patients should be isolated in negative-pressure rooms or negative-pressure wards.

6. Management of severe COVID-19

Give supplemental oxygen therapy to patients with respiratory distress, hypoxemia or shock and target an oxygenation goal of PaO2 55-80 mmHg or SpO2 88-95%.

Patients with emergency signs (obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma, or convulsions) should receive airway management and oxygen therapy during resuscitation to target SpO2 \geq 94%. Initiate oxygen therapy and titrate flow rates to reach target SpO2 \geq 93% during resuscitation if patient in critical condition. Once patient is stable, the target is > 90% SpO2 in non-pregnant and \geq 92–95% in pregnant patients.

Closely monitor patients with COVID-19 for signs of progressive hypoxemia and clinical deterioration, such as rapidly progressive respiratory failure and sepsis and respond immediately with supportive care interventions.

7. Hypoxemia requiring 6 liters per minute of oxygen or rapid increase in needs should trigger a discussion about goals of care and intubation versus high-flow nasal oxygen (HFNO) or non-invasive ventilation (NIV).

Routine lab and other testing should be done. Patients in an ICU should have a Sequential Organ Failure Assessment (SOFA) score performed initially and every 48 hours to help monitor for organ failure and categorize severity as outlined in VHA Pandemic ethical guidance¹⁰.

All patients with respiratory failure, regardless of whether they meet the formal definition of ARDS, should have their hypoxemia managed according to the principles of lung-protective ventilation and conservative fluid management as laid out in ARDS-Net recommendations¹¹. Aggressive fluid resuscitation may worsen oxygenation, especially in settings where there is limited availability of mechanical ventilation.

Although a patient may be suspected of having COVID-19, some patients with COVID-19 infection will present with secondary bacterial lower respiratory infection, and appropriate empirical antimicrobials for community-acquired pneumonia should still be administered according to clinical practice guidelines.⁹ Treat all likely pathogens based on the clinical diagnosis, e.g., community acquired pneumonia or influenza, with de-escalation as soon as safe.

8. Management of critical COVID-19: acute respiratory distress syndrome (ARDS)

 ⁹ <u>https://www.idsociety.org/practice-guideline/community-acquired-pneumonia-cap-in-adults/</u>
¹⁰ <u>https://www.ethics.va.gov/docs/policy/meeting_the_challenge_of_pan_flu_ethical_guidance_vha_2010_web_posting_2013.pdf</u>

¹¹ <u>http://www.ardsnet.org/tools.shtml</u>

Recognize severe hypoxemic respiratory failure when a patient with respiratory distress is failing to respond to standard oxygen therapy and prepare to rapidly provide advanced oxygen/ventilatory support. In general, patients deteriorating with multi-organ failure, or at risk for hypoventilation (e.g. due to deteriorating mental status) should be closely monitored and considered for intubation.

There is limited direct evidence to guide use of High-flow nasal oxygen (HFNO) or Non-invasive ventilation (NIV) in COVID-19 patients with acute hypoxemic respiratory failure despite conventional oxygen therapy. HFNO may reduce need for intubation in selected patients (thereby preserving scarce ventilatory resources) but does not appear to reduce mortality or ICU length of stay. Both HFNO and NIV are aerosol-generating procedures. In the previous SARS epidemic, NIV but not HFNO was associated with increased risk of transmission to healthcare workers. *If HFNO or NIV are used, close monitoring for delayed deterioration requiring subsequent intubations is essential, and Airborne Infection Isolation Rooms (AIIRs) should be used.* Most NIV equipment does not permit adequate filtration of the exhaled gas mixture. Helmet NIV's, under the supervision of experiences providers with strict monitoring for rebreathing, may reduce risk for aerosolization but its safety and efficacy in COVID-19 is unclear. Currently, SCCM suggests using HFNO over NIV, but theirs is a weak recommendation based on low-quality evidence.

Recent clinical experience from centers caring for critically ill patients with deteriorating oxygenation suggests that placing the patient in the prone position without intubation may improve oxygenation, possibly avoiding or delaying endo tracheal intubation.

Endotracheal intubation should be performed in accordance with your pandemic response plan using established protective precautions. Rapid Learning materials based on strong practices that have been reviewed by VA subject matter experts are available at: https://www.va.gov/covidtraining/

Perform endotracheal intubation in a negative pressure room by the most experienced provider using airborne precautions. Remember that this process will take longer than a standard intubation. Pre-oxygenate with 15L/min NRB as soon as the decision to intubate is made, as bag-mask ventilation should not be used during rapid sequence induction. If bag mask ventilation is necessary, a viral filter should be in place.

- A. During laryngoscopy and intubation:
 - 1. Double gloves will enable one to shed the outer gloves after intubation and minimize subsequent environmental contamination.
 - Awake fiberoptic intubation should be avoided unless specifically indicated. Droplets containing viral pathogens may become aerosolized during this procedure. Aerosolization generates smaller liquid particles that may become suspended in air currents, traverse filtration barriers, and inspired.
 - 3. Use of a viral/HEPA filter is strongly recommended.
 - 4. Rapid sequence induction (RSI) (with video laryngoscopes if available) is strongly recommended in order to avoid manual ventilation of patient's lungs and potential aerosolization. If manual ventilation is required, apply small tidal volumes.

- 5. Use established doffing instructions after intubation or other procedures likely to generate aerosolization.
- 6. Bundling the intubation with other procedures (central access, arterial line, feeding tube, endotracheal aspirate, and possibly CXR and EKG as well) is strongly recommended as it reduces subsequent room entries and repeated donning and doffing.

If available, use a closed suction system during airway suctioning. Closed suctioning systems may only be available in the critical care setting.

Avoid unnecessary disconnection of the patient from the ventilator. Use in-line catheters for airway suctioning and clamp endotracheal tube when disconnection is required (for example, transfer to a transport ventilator).

Minimize bronchoscopy and other aerosolizing procedures, which should be done only in negative pressure rooms.

Implement mechanical ventilation using lung protective strategy of lower tidal volumes with initial tidal volume of 6 mL/kg *ideal* body weight calculated by measured height and goal plateau pressures less than 30. Refer to ARDS-Net Ventilator Protocol Card.¹²

In patients with moderate or severe ARDS, higher PEEP instead of lower PEEP is suggested, with close monitoring for signs of pneumothorax.

In adult patients with severe ARDS, prone ventilation for 12–16 hours per day is recommended. To minimize risk to patients and staff from a disconnected ventilator circuit, facilities should have sufficient experience and established protocols to perform this safely. Facilities that do not routinely perform prone positioning should not institute this practice without careful training and simulation before implementing (training videos will be available through SimLearn). Other rescue therapies, such as recruitment maneuvers or pulmonary vasodilators, have not been reported to as beneficial, but may be considered according to SCCM COVID practice guidelines.¹³

In the setting of refractory hypoxemia due to progressive ARDS, extracorporeal membrane oxygenation (ECMO) may be considered if prone ventilation fails. This should only be attempted in centers with access to expertise in ECMO, and with recognition that ECMO may not be feasible because it requires intensive staff resources, poses infection control challenges, and requires frequent blood transfusions at a time when blood supplies may be severely limited.

In patients with moderate-severe ARDS (PaO2/FiO2 < 150), neuromuscular blockade (NMB) should not be routinely used except for ventilator dyssynchrony despite sedation, or to facilitate lung protective ventilation for refractory hypoxemia or hypercapnia. If NMB is used, intermittent is recommended rather than continuous infusion. Continuous infusion NMB should not be delivered for greater than 48 hours.

9. Management of Critical illness and COVID-19: septic shock and cardiac and renal insufficiency

¹² <u>http://www.ardsnet.org/files/ventilator_protocol_2008-07.pdf</u>

Recently revised guidelines for management of septic shock in COVID-19 are available from the Surviving Sepsis Campaign¹³. Consider cardiac insufficiency as an additional contribution to shock. Aggressive fluid administration may worsen oxygenation. If resuscitation is deemed necessary, use 500ml boluses with dynamic assessments (passive leg raise, pulse pressure variation) to guide fluid therapy.

Published and anecdotal reports indicate cases of acute onset heart failure, myocardial infarction, myocarditis, cardiac arrhythmias, and cardiac arrest; as with any acute illness, higher cardiometabolic demand can precipitate cardiac complications.

Many centers have experienced an increased incidence of acute renal injury that can be rapidly progressive. Nephrology consultation, discussion of goals of care, and consideration of renal replacement therapy should be pursued once deterioration in renal function is detected. A hypercoagulable state may complicate renal replacement therapy.

10. Special populations: Pregnancy:

To date, there are limited data on COVID-19 and pregnancy or the puerperium. There is no evidence that pregnant women present with different signs or symptoms, have a higher risk of severe illness, or demonstrate mother-to-child transmission when infection manifests in the third trimester. Current evidence of neonatal outcomes is limited to infection in the third trimester.

VA facilities generally do not have personnel or equipment needed to manage pregnant and post-partum patients and their infants. While managing pregnant patients, every effort should be made to consult with obstetric specialists to manage their care, with the goal to stabilize them for transfer to a facility that can provide obstetrical care. Facilities should ensure that processes (including local policies and agreements) are in place.

11. Adjunctive or investigational treatments for COVID-19:

There is no current evidence to recommend any specific anti-COVID-19 treatment for patients with confirmed COVID-19. Consultation with infectious disease, pharmacy, or tele-critical care for current recommendations should be considered. Additional guidance on off-label drug use is available through VA Pharmacy Benefits Management Services (PBM).¹⁴

The FDA recently granted emergency use authorization for chloroquine and hydroxychloroquine to treat COVID-19.¹⁵ Clinical evaluation of contraindications (retinopathy,

¹³<u>https://www.sccm.org/disaster?utm_source=COVID19_SSC%20GUIDELINES_032020&utm_medium=</u> Email&utm_campaign=COVID19&_zs=9HWqe1&_zl=2wbc6

https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Clinical%20Recommendations/VHA %20PBM%20Information%20on%20Investigational%20and%20offlabel%20Treatment%20Options%20COVID-19%20Mar%2017%202020.docx

¹⁵ Emergency Use Authorization is not the same as FDA Approval. It only facilitates availability of these agents for patients for whom clinical trial enrollment is not feasible.

prolonged QT), risks (arrhythmias), and benefits (unclear) including thorough medication review for QT-prolonging agents is advised.

The VA Office of Research & Development is in daily contact with other federal and industry organizations regarding potential clinical trial opportunities and is working to provide Veterans with access to these studies. These studies are registered on https://clinicaltrials.gov, and a list of specific VA clinical trial opportunities has been sent to VA facility Research Offices. For more information, please contact ORDCOVID19@va.gov.

ETHICS & COMMUNICATION CONSIDERATIONS

Maintain family communications and compassionate engagement when hospitals are closed to visitors. Facilities should make accommodations for communications between patients and loved ones using telephonic or video connections (tablets are one suggested means), as well as for family conferences with the treatment team. These meetings should not be limited to end of life considerations but include routine family updates and severity assessments (SOFA) at least every 48 hours.

1. Ethics Guidance for CPR on a COVID-19 patient/suspected patient

Health care providers have a duty to provide potentially life-saving treatments such as CPR to patients unless the patient or designated surrogate has indicated a wish to forego such treatment. Codes of ethics of all health care professionals include a duty to provide care for patients even at some risk to themselves. This is a primary ethical duty of the health care professional, but it is not absolute, and there are ethically justifiable exceptions. Those exceptions occur when there is disproportionate risk to the health care professionals providing the care. For a full analysis of this question, please see <u>FAQ: Ethical Challenges Preparing for and Managing COVID-19¹⁶</u>

Performing resuscitation or other procedures on a patient with COVID-19 poses unique challenges due to the risks of aerosolization. Staff may have limited experience and/or training in personal protective equipment (PPE) donning, usage, and doffing. To mitigate risk, staff responding to resuscitations must be properly trained in Basic Life Support (BLS) and or Advanced Cardiac Life Support (ACLS) and prepared in the use of PPE in accordance with CDC guidance.¹⁷ Re-certification can be accomplished rapidly through the through the Resuscitation Quality Improvement (RQI) program accessible by TMS which limits the training time required and meets AHA recommendations for social distancing and the ability to maintain a level of competency for quality care to our Veterans. For additional training resources on proper use of PPE, refer to https://myees.lrn.va.gov/SimLEARN/default.aspx.

Even in an emergency situation, such as a cardiopulmonary arrest, health care professionals and staff should never compromise safety protocols because doing so results in more overall harm than benefit given the high risk of infection without PPE. Staff should always don appropriate personal protective equipment (PPE) before performing a code for a patient with COVID-19, even if it means delaying the code. If a code occurs outside of a closed patient

¹⁶ <u>https://vaww.ethics.va.gov/activities/pandemic/FAQ_Ethics_and_COVID19.asp</u>

¹⁷ <u>https://www.cdc.gov/hai/pdfs/ppe/PPE-Sequence.pdf</u>

room within the hospital, every effort should be made to move the patient back into a closed room to avoid widespread aerosolization.

Finally, unilateral decisions to limit certain interventions like CPR to all patients with COVID-19 based solely on their diagnosis are ethically problematic. Evaluation of each individual patient is necessary to determine whether CPR is likely to achieve its intended goal of restoring circulatory function sufficient for meaningful survival and can be provided safely. *When CPR is initiated in a COVID-19 patient - as with all resuscitative efforts from cardiopulmonary arrest - the code leader has the authority and responsibility to rapidly assess the patient's condition and stop those efforts if benefit to the patient becomes unlikely (e.g., further attempts approach physiologic futility) and/or risk to staff is unacceptably high.*

2. Other Ethical Considerations: Addressing Scarcity

It is critical for the organization to support clinicians facing difficult decisions surrounding scarcity. The document *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in VHA*¹⁸ contains the ethical framework for pandemic response and includes a protocol for routine, standardized prognostication and triage of life-saving resources such as ventilators. *Refer to numbered pages 27-40 (may appear on Adobe toolbar as pp 39-52)* of the document for specific steps to establishment a Scarce Resource Allocation (SRA) team, a tertiary triage team, and a tertiary triage plan.

Ethics questions should be referred to local Integrated Ethics[®] programs, or the National Center for Ethics if Health Care at <u>vhaethics@va.gov</u>, if needed. Ethics information, including Frequently Asked Questions, are available at <u>https://vaww.ethics.va.gov/activities/pandemic/Ethics_Response.asp</u> or <u>https://www.ethics.va.gov/activities/Ethics_Response.asp</u>

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¹⁸ Available at

https://www.ethics.va.gov/docs/policy/meeting_the_challenge_of_pan_flu_ethical_guidance_vha_2010_w eb_posting_2013.pdf

NOTE: The signature remains valid until rescinded by an appropriate administrative action.

DISTRIBUTION: All VISNs, VAMCs, and VHA Integrated Clinical Communities