Clinical Guidance for Evaluation, Testing and Treatment of Patients with Respiratory symptoms and Suspicion for COVID19

– Version 5. Updated 8/31/2020-

**Testing criteria**

* Adult patients
1. Asymptomatic, if contact with COVID patient – consider testing starting day 5-7 after exposure if testing available, prioritizing persons with high public health risk or at high personal risk(e.g. healthcare personnel, teachers). Reassure, quarantine of contact as per CDC guidelines
2. Symptoms of acute respiratory tract infection (new cough, fever, new shortness of breath, myalgias, GI symptoms etc ) and no significant co-morbid conditions, outpatient or ER not requiring admission – Test if sufficient testing ability\*, home with instructions per CDC guidelines while awaiting results.

\*For Prompt Care or patients seen in the ED not requiring admission – start with antigen testing (SOFIA2 or equivalent). If positive no further testing is required, patient is diagnosed with COVID 19. If negative and there is a high pretest probability (sick contacts, suggestive symptoms)- send NP swab for PCR

1. Symptoms of acute respiratory tract infection (new cough, fever, new shortness of breath, myalgias etc ) and significant co-morbid conditions (immunocompromised from cancer, chemotherapy, immunomodulators, primary or acquired immunodeficiency etc, DM, asthma/COPD, cardiac disease, HTN) regardless of hospitalization requirements– testing is recommended
2. Symptomatic or exposed asymptomatic healthcare workers
* Pediatric patients
* test for COVID 19 only if admitted with respiratory illness (rarely applying to our institution -UH)
* Consider testing for COVID if outpatient or ER that does not require admission if known sick contacts.

**COVID-19 retesting criteria**

* if **previously positive** for COVID 19 by any testing method within 90 days – retesting is NOT recommended unless specifically required for transfer to another facility (no further recommended per CDC guidelines)
* if **previously negative** for COVID 19 AND
	+ there is significant clinical suspicion without alternate diagnoses
	+ suspicion of inadequate sample collection (e.g. self-collection of specimen or collection by untrained personnel )
	+ patient has been discharged from our facility since the previously negative test and readmitted with symptoms

consider retesting

**Clinical, radiologic and lab criteria to suspect COVID 19 in hospitalized patients:**

* Respiratory symptoms as described above
* Hypoxia without alternate explanation
* Fever
* GI symptoms
* Bilateral CXR infiltrates or CT scan with patchy bilateral lung infiltrates, ground glass opacities, mostly peripheral/subpleural and round in appearance
* Negative influenza/RSV PCR
* Negative or low Procalcitonin (note that later in the disease procalcitonin may become elevated without evidence of overimposed bacterial infection)
* Lymphopenia
* Elevated inflammatory markers (sedimentation rate, CRP, ferritin)

**Workflow for suspected patients:**

* Decide if COVID testing is appropriate
* Place in negative airflow room, airborne/contact precautions\*
* Asses labs and CXR available
* Test for flu/RSV by PCR if appropriate
* Test procalcitonin
* Test urine antigens for legionella and strep pneumo if indicated (more focal infiltrate versus bilateral infiltrates, high procalcitonin)
* Collect COVID test - testing is done with an NP swab and viral transport media or saline

\*preoperative testing does not require placement in negative airflow room

**Treatment:**

The following options are based on available information at the time of writing of this document.

1. **Remdesivir**
* FDA has issued an Emergency Use Authorization (EUA) permitting use of the unapproved product remdesivir for treatment of laboratory confirmed or suspected COVID-19 in adults and children who are hospitalized.
* NIH guidelines recommend prioritizing use in hospitalized patients who require supplemental oxygen but who are NOT on high flow oxygen, NIPPV, mechanical ventilation or ECMO. Because there is uncertainty regarding whether starting remdesivir confers clinical benefit in these groups of patients, the NIH Panel cannot make a recommendation either for or against starting remdesivir. There are insufficient data on the optimal duration of **remdesivir** therapy for patients with COVID-19 who have not shown clinical improvement after 5 days of therapy. Some experts extend the total remdesivir treatment duration to up to 10 days (expert opinion recommendation)
* Severe disease is defined by O2 saturation <94% on room air, or requiring supplemental oxygen, mechanical ventilation or ECMO.
* This medication is restricted to infectious diseases and critical care services
* Dosing:
* Loading dose of 200 mg IV day 1 followed by
* Maintenance dose of 100 mg IV q24h for 9 more days in vented/ECMO patients, 4 more days in non- ventilated patient
* Of note, the duration of treatment for non-ventilated patient is of 5 days OR until hospital discharge, whichever comes first
* Restarting remdesivir after 5 days in patients without clinical improvement or clinical worsening is not encouraged
* Lab monitoring:
* baseline GFR
* daily CBC, CMP to monitor for toxicity
* Do not use or discontinue if:
* GFR<30
* ALT>5 times normal
* Evidence of liver dysfunction by other parameters
* Adverse events judged to be due to Remdesivir
* Prior to starting the treatment fact sheet needs to be provided to the patient or family and alternatives discussed. <https://www.fda.gov/media/137565/download>
* Document in the progress note acceptance or denial of this treatment, discussion of alternatives and the fact they were informed it is an unapproved treatment and only authorized under EUA
* Immediately report any adverse events or administration errors to pharmacy
1. **Hydroxychloroquine** is not recommended based on the available data.
* If the individual physician decides to use it, please consider monitoring for toxicity
* baseline (pre-treatment EKG) and daily EKG for the duration of treatment. Keep patient on telemetry for the duration of treatment
* If baseline QTc is >475 ms – not recommended
* Discontinuation: if QTc >500ms or >550ms if paced
* Monitor potassium and magnesium levels daily and keep normal
* Addition of azithromycin is discouraged as it is not demonstrated to be beneficial and it showed potential harm
1. **Dexamethasone or methylprednisolone** in patients meeting a majority of the following criteria AND with a positive COVID-19 test:
* Increasing O2 requirements or >2 L O2 on NC
* Significant bilateral infiltrates on CXR or other pulmonary imaging studies
* Significant dyspnea and/or tachypnea
* Elevated or increasing inflammatory markers: ESR, CRP, Ferritin. Consider checking these at baseline and q48h if clinically warranted or elevated
* Suggested dose: Methylprednisolone 40 mg IV q8h or Dexamethasone 6 mg IV or PO daily for up to 10 days
* Corticosteroids generally should not be used in early or mild disease (not requiring O2 supplementation) since the drugs can inhibit immune response, reduce pathogen clearance, and increase viral shedding
1. COVID-19 **convalescent plasma infusion** – please see special section below describing criteria and process
2. Other therapies (such as Tocilizumab, Sarilumab etc) are under investigation and available at our institution on a case by case basis with ID consultation for ventilated patients
3. In general **use of antibiotics is discouraged** (available data supports very low incidence of over-imposed bacterial infections) – if ordered prefer PO over IV and ID consult
4. Other therapies such as zinc, vitamin C have no proven benefits - no recommendations
5. NSAIDS not recommended at this time
6. DVT prophylaxis – Lovenox/Heparin if no contraindication

**Criteria for ID consult:**

* Concern for bacterial superimposed infection
* Need for Remdesivir and/or Convalescent plasma, Tocilizumab
* Negative COVID-19 test with persistent clinical concern for COVID-19
* Other ID issues that need to be addressed
* General oversight considered necessary per primary team

COVID-19 convalescent plasma protocol

1. Description

The open label expanded access program is no longer in place.

Matched convalescent plasma is now available for the treatment of patients in acute care facilities infected with SARS-CoV-2 who have severe or life threatening COVID-19, or who are judged by a healthcare provider to be at high risk for progression to severe or life-threatening disease under EUA.

1. Volume of plasma to be transfused - a full unit of COVID-19 convalescent plasma or at least 200 mls – single dose
2. Inclusion criteria
* Age of at least 18 years
* Laboratory confirmed diagnosis of infection with SARS-CoV-2
* Admitted to an acute care facility for the treatment of COVID-19 complications
* Severe or life-threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease
* Informed consent provided by patient or healthcare proxy is no longer required – please provide fact sheet that can be found at <https://www.fda.gov/media/141478/download>
* Severe COVID-19 disease is defined by one or more of the following:
* Dyspnea
* Respiratory frequency >30/min
* Blood oxygen situation <93%
* Partial pressure of arterial oxygen to fraction of inspired oxygen ration <300
* Lung infiltrates >50% within 24-48h
* Life-threatening COVID-109 is defined as one or more of the following:
* Respiratory failure
* Septic shock
* Multiple organ dysfunction or failure
1. Strategy for recruitment:
* patients eligible for convalescent plasma will be identified by the treating physician or provider
* consent is no longer necessary. Instead, please provide fact sheet from FDA-<https://www.fda.gov/media/141478/download>
* treating physician to contact **ID Physician on call** for University Hospital for evaluation

**Discontinuation of precautions criteria for confirmed COVID 19 cases**

1. symptomatic patients: 10 days after symptom onset and 1 days without fever and antipyretics and improvement of symptoms. For severe and critical cases at least 10 and up to 20 days

2. asymptomatic patients: 10 days after positive test. If they become symptomatic during this 10 days period follow #1