







National Guidelines for Clinical Management and Treatment of COVID-19 18th February 2021

Version 5.1

Prepared and Reviewed by	National committee for Management of COVID-19 Cases
Approved by	Technical team for Pandemic Control









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Summary of Updates as of Version 5.1, 18th February 2021:

Mode of transmission added

Positive COVID19 case management in OPD or emergency department

Medication and treatment regimen updated

Updated VTE Thromboprophylaxis & Anticoagulants use

Pregnancy medication updates

Objectives

The objectives of this document are:

- To provide guidance on clinical management of the COVID-19 infection
- To provide a protocol on the practical steps to deal with COVID-19 infection in ambulatory and hospital settings.
- To detail the measures necessary to protect hospital staff, patients and visitors
- This guideline is **not intended to override the clinical decisions** that will be made by clinicians providing individualized patient care.
- This guideline will be updated as more information becomes available
- For quarantine of contacts or travellers. Please refer to Public health/Preventive medicine updates and recommendations.









Introduction to Coronaviruses (CoV) Mode of transmission:

- Corona virus is a large family of viruses that cause illness in humans and animals
- In people, Corona virus can cause illness ranging in severity from the common cold to Pneumonia and Severe Acute Respiratory Illness
- Corona virus is one of seven types of known human coronaviruses. SARS COV2 like the MERS and SARS coronaviruses, likely evolved from a virus previously found in animals
- The estimated incubation period is unknown and currently considered to be up to 14 days post exposure.

Mode of transmission:

Possible modes of transmission for SARS-CoV-2, include contact, droplet, airborne, fomite, fecal-oral, bloodborne and mother-to-child transmission. (62)

Contact and droplet transmission.

<u>The main mode of transmission</u> for SARS-CoV-2 transmission is through direct, indirect, or close contact with infected people through infected secretions such as saliva and <u>respiratory secretions or their respiratory droplets</u>, which are expelled when an infected person coughs, sneezes, talks or sings.

Respiratory droplet transmission can occur when a person is in close contact (within 1.5 meter) with an infected person who has respiratory symptoms (e.g. coughing or sneezing) or who is talking or singing; Indirect contact transmission involving contact of a susceptible host with a contaminated object or surface (fomite transmission) may also be possible

Airborne transmission

Airborne precautions should be used routinely when <u>performing aerosol-generating procedures</u> (see list below) on confirmed or suspected COVID-19 patients. Nebulizers use should be discouraged and alternative administration devices (e.g. spacers) should be used if possible.

Outside of medical facilities, some outbreak reports related to indoor crowded spaces have suggested the possibility of aerosol transmission, combined with droplet transmission, for example, during choir practice, in restaurants or in fitness classes, in specific indoor locations, such as crowded and inadequately ventilated spaces over a prolonged period of time with infected persons cannot be ruled out.

To date, transmission of SARS-CoV-2 by aerosol route outside healthcare facilities has not been demonstrated; much more research is needed given the possible implications of such route of transmission.









Fomite transmission

Respiratory secretions or droplets expelled by infected individuals can contaminate surfaces and objects, creating fomites (contaminated surfaces).

Viable SARS-CoV-2 virus and/or RNA detected by RT-PCR can be found on those surfaces for periods ranging from hours to days, depending on the ambient environment (including temperature and humidity) and the type of surface, in particular at high concentration in health care facilities where COVID-19 patients were being treated. Therefore, transmission may also occur indirectly through touching surfaces in the immediate environment or objects contaminated with virus from an infected person (e.g. stethoscope or thermometer), followed by touching the mouth, nose, or eyes.

Other modes of transmission

SARS-CoV-2 RNA has also been detected in other biological samples, including the urine and feces of some patients. To date, however, there have been no published reports of transmission of SARS-CoV-2 through feces or urine.

Some studies have reported detection of SARS-CoV-2 RNA, in either plasma or serum, and the virus can replicate in blood cells. However, the role of bloodborne transmission remains uncertain; and low viral titers in plasma and serum suggest that the risk of transmission through this route may be low. Currently, there is no evidence for intrauterine transmission of SARS-CoV-2 from infected pregnant women to their fetuses, although data remain limited. In breastfeeding, Studies have shown that there is no evidence of viable virus.

Case Definition:

Suspected COVID-19 case is defined as:

1. Please refer to the local health authority websites for updated information on local case definition. MOHAP, DoH, SEHA and DHA

Confirmed COVID-19 is defined as:

A person with confirmed positive COVID-19 test positive (SARS COV2 PCR) by an approved laboratory.

Probable COVID19 is defined as:

A person with clinical and radiological picture compatible with CVOID19 infection awaiting PCR result or repeatedly Negative PCR tests collected from different sites with no microbiological evidence of another Infectious etiology.









Clinical Findings and Complications

Some patients with initially mild symptoms may progress over the course of 5-10 days from symptom onset.

Clinical Symptoms: Signs and symptoms include:

- Fever or chills
- Cough
- Myalgia or muscle aches
- Fatigue
- · Shortness of breath
- Chest pain
- Sore throat
- Runny nose or congestion
- Diarrhoea and nausea
- Headache
- Pneumonia and ARDS
- Loss of sense of smell and/or taste
- Renal failure, pericarditis and Disseminated Intravascular Coagulation

Complications:

- Severe Pneumonia
- Acute Respiratory Failure and ARDS
- Acute Renal failure
- Disseminated intravascular coagulation
- Sepsis or septic shock

High-risk group

- Age above 60 years old
- Smoker
- Cardiovascular disease
- Diabetes
- Hypertension
- Obesity with BMI≥35
- Immune deficiency and or suppression (HIV/AIDS, long-term steroid therapy, post-transplant cases, chemotherapy, immune modulator therapy)
- Pre-existing pulmonary disease (uncontrolled Asthma, COPD, bronchiectasis)
- Other chronic disease such as chronic kidney disease, Chronic Respiratory disease, Sickle cell...etc.

Minimum baseline Investigations for a confirmed or probable COVID19

A set of minimum required baseline work up to be conducted for clinically stable patients when evaluating them in Isolation facilities, field hospitals, PHC Clinics or Emergency Departments to allow decision on required level of care and treatment Initiation:









- 1. Complete blood count
- 2. Renal function and Electrolytes
- 3. Random Glucose
- Liver function test including ALT/AST
- 5. CRP if available
- 6. Chest X ray
- 7. ECG if clinically indicated

Investigations for confirmed or probable COVID19 patients admitted to hospitals

Chemistry and Haematology:

- 1. Complete blood count and differential
- 2. Renal function and Electrolytes
- 3. Serum Glucose (HbA1C if diabetic)
- 4. Liver Function test including Liver enzymes
- 5. CRP
- 6. procalcitonin
- 7. LDH
- 8. Coagulation profile
- 9. Ferritin
- 10. D-dimer
- 11. fibrinogen
- 12. Troponin & creatinine kinase (CK)
- 13. Pro BNP
- 14. Pregnancy test in women of child-bearing age

Microbiology:

SARS COV2 PCR on following samples

- 1. Deep respiratory samples (sputum or deep tracheal aspirate) if intubated
- 2. Nasopharyngeal Aspirate/Swab and oropharyngeal swab (should use non-cotton flocked swab) if upper respiratory tract infection

Staff should be trained on Sample collection.

Health care workers collecting NP and OP swab specimens from suspected or confirmed COVID-19 patients should wear a clean, non-sterile, long-sleeve gown, a medical mask, eye protection (i.e., googles or face shield), and gloves. Procedure should be conducted in a separate/isolation room, and during NP specimen collection health care workers should request the patients to cover their mouth with a medical mask or tissue.³⁵

- 3. For intubated patients, obtain deep tracheal aspirate for:
- a) SARS-CoV2 PCR
- b) Atypical PCR panel if available (Mycoplasma, chlamydia, legionella)
- c) Respiratory viral panel









- d) Other investigations to consider if the aetiology of the severe pneumonia is not identified:
 - i. Legionella urinary antigen
 - ii. Mycoplasma titres
 - iii. AFB stain/culture Tuberculosis culture and PCR
 - iv. Opportunistic pathogens in immunocompromised patients

All specimens should be regarded as potentially infectious, and HCWs who collect, or transport clinical specimens should adhere rigorously to standard precautions to minimize the possibility of exposure to pathogens.

Radiology

Ensure infection control measure are takes if patient is transferred to radiology or any other department outside the isolation room

- 1. CXR
- 2. Chest CT scan (HRCT or non-contrasted CT scan) is preferred for all high-risk group patients admitted to hospitals and for patients with rapidly progressing illness. Consider CT scan chest while waiting CVOID19 PCR report as a diagnostic modality to guide early treatment and in patients with clinical features of pneumonia and normal chest X ray.

(When mobilising patient ensure infection control measures are followed during and after transport)

Cardiac investigations:

- 3. ECG
- 4. Transthoracic Echocardiogram, pro-BNP, Troponin T and CK-MB if clinically indicated

Other tests If and when clinically indicated as per clinical condition and judgment of managing physician.

Requesting COVID19 PCR test:

Fill notification form and patient under investigation (PUI) form

Governmental & Private Facilities:

Send the samples to their dedicated approved virology laboratory.

Transport of Respiratory Secretions Samples

Transport of the respiratory secretions sample to the laboratory, using double packing system at 2-8°C temperature.

Trained personnel following safe handling practices should transport specimen









Medical Care for Patients with confirmed COVID-19 infection

- All suspected or confirmed cases should have the appropriate forms for public health filled and submitted to concerned Public Health Authority
- All confirmed cases should be screened for eligibility for treatment, as per UAE Health Authorities' recommendation.
- All positive cases to be assessed, if fitting criteria for home isolation or institutional isolation, can be
 isolated at designated isolation building, with full instructions and to inform PH/PHC/OPD for follow
 up

If patient's condition deteriorates, they will be transferred to the nearest healthcare facility for further assessment and management.

- Asymptomatic and mild cases can be isolated at home if meet the criteria as per the public health guidelines.
- If patient's condition deteriorates, upgrade level of care, with immediate arrangement for transfer to hospital, if elsewhere, with proper communication with receiving facility
- Admit all severe and critically ill patients to hospitals and once their condition stabilizes, they can be transferred to lower levels of care areas or discharge for home isolation.
- Admit all patients with COVID19 infection to single rooms with good ventilation and separate toilet, unless aerosol generating procedures is anticipated then in a room with Negative Pressure Ventilation.
- If hospital capacity is full, positive COVID 19 cases can be cohorted in the same room, provided there is 6 feet distance between the patients.
- Implement standard, contact and droplet precautions whenever coming in contact with positive cases. (Appendix I). Unless aerosol generating procedure then, airborne precaution.
- Consider recommended active management plan for patients with moderate to severe illness.
- Avoid un-necessary use of Antibiotics in patients with COVID-19 infection and adhere to Antimicrobial Stewardship Principles.

Dealing with Patients attending Primary Health Care (PHC) or Accident and Emergency (AE)

*Suspected cases if admitted need to be in a single room with droplet precaution unless aerosol generating procedure then, airborne precaution.

Clinical Scenario	Decision		
No symptoms	1. COVID19 testing is not indicated		
Not meeting case definition	2. Reassure and discharge		
Meeting case definition	Collect sample for lab-based SARS CoV2 PCR on Respiratory		
	samples		
	Fill required notification forms		
	Respiratory Panel test if available		
	Baseline work up and chest X ray are indicated		









• If there is evidence of an alternate diagnosis and the patient			
	stable; less likely to be COVID19, and manage accordingly,		
	however, it does not rule out coinfection with COVID-19		

- Admission, discharge or transfer decision should be based on clinical stability and baseline work up results.
- If discharged, quarantine at home pending PCR results
- If first COVID19 test is Positive, follow Positive cases management pathway
- If first COVID19 test is Negative, and clinical presentation and investigation is suggestive of COVID-19, repeat SARS CoV2 PCR

Positive COVID19 case management in OPD or emergency department

- All patients with COVID19 positive result should be assessed at least once.
- Investigations to be requested as available, however, minimum to include CBC, Renal function tests, liver function tests, CRP, D-dimer, ferritin and CXR
- Azithromycin is not indicated.
- Even if clinically stable, if the patient is more than 60 years old or has one or more comorbidities to start treatment with Favipiravir (if no contraindications) 1600mg BID on day one and followed by 600mg BID for 7-10 days.
- Consider adding supplements: Vitamin C, Vitamin D and Zinc supplements.
- If baseline d-dimer is above 2, transfer the case to the hospital for prophylaxis/possible therapeutic anticoagulation.
- Any patient with comorbidities to be followed every 3 days either by teleconsultation or revisit to the facility.
- Patients with one or more comorbidities to ensure availability of pulse oximetry for monitoring daily progress at home, to be instructed if oxygen saturation drops below 94% to call an ambulance, attend COVID19 clinic assessment or emergency room.

SARS-CoV-2 illness severity index

(Based on National Institutes of Health (NIH) COVID-19 Treatment Guidelines)60

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) without shortness of breath, dyspnea, or abnormal chest imaging.

Moderate Illness: Individuals who have evidence of lower respiratory disease by clinical assessment or imaging, and a saturation of oxygen (SpO2) ≥94% on room air at sea level.









Severe Illness: Individuals who have respiratory frequency >30 breaths per minute, SpO2 <94% on room air (or, for patients with chronic hypoxemia, a decrease from baseline of >3%), ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, or lung infiltrates >50%.

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

* In pediatric patients, radiographic abnormalities are common and, for the most part, should not be used as the sole criteria to define COVID-19 illness category. Normal values for respiratory rate also vary with age in children, thus hypoxia should be the primary criterion to define severe illness, especially in younger children.

Severely immunocompromised." For the purposes of this guidance:

Some conditions, such as being on chemotherapy for cancer, being within one year out from receiving a hematopoietic stem cell or solid organ transplant, untreated HIV infection with CD4 T lymphocyte count < 200, combined primary immunodeficiency disorder, and receipt of prednisone >20mg/day for more than 14 days.

Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromised and not clearly affect decisions about duration of Transmission-Based Precautions.

*Ultimately, the degree of immunocompromised for the patient is determined by the treating provider.

Clinical Management and Treatment for confirmed COVID 19 cases

Disclaimer:

- 1. This document is a guideline and NOT a substitute for good clinical practice and judgment of clinician for individual cases
- 2. Literature is rapidly evolving & this document may not necessarily reflect all the updated day to day information's.
- **3.** Guidelines will be reviewed by National Committee can be modified/updated if National committee deems it necessary in case of significant update/changes in literature
- In view of the lack of specific antiCOVID-19 medication, consider treatment with currently available regimen.
- Treat all positive cases of COVID-19 when indicated as early as possible.
- Apply Standard Precautions, Contact Precautions, and Droplet Precautions with eye protection should always be used when caring for the patient
- If asymptomatic or mild symptoms can be cared for in single room with good ventilation and droplet precaution. Negative pressure rooms are not required unless aerosol generating procedures or anticipating these procedures.









- Clinical management includes prompt implementation of recommended infection prevention and control measures and supportive management of complications, including advanced organ support if indicated.
- There is no specific approved treatment for COVID19 infection to date. However, FDA has issued emergency use authorization for Remdesivir. FDA has also published recommendations for investigational COVID19 Convalescent Plasma. See table below
 - Give low flow oxygen therapy to mild pneumonia cases regardless of their saturations. For moderate and severe cases, oxygen to be given as per their clinical requirements.
 - o Consider awake proning for eligible patient regardless of level of care. (see appendix II)
 - Use conservative fluid management, whenever possible.
 - o Give empiric antimicrobials as indicated, preferably narrow spectrum, if clinically indicated.
 - Closely monitor patients for signs of clinical deterioration.
 - Use prophylaxis low molecular weight heparin when indicated
 - Address co-morbid condition(s).
 - Do not administer empirical antibiotic therapy to all patients upon admission unless clinically indicated for reasons other than pure COVID-19 pneumonia. Only patients with severe Pneumonia and unstable vital signs on admission will need empirical broad-spectrum antimicrobial therapy pending culture and lab reports. Antibiotics can be stopped or deescalated if there is no evidence of an active bacterial infection.

Pharmacological options: (based on limited available information's, expert's opinion & in view of regional and or international dynamics of practice)

- 1. National committee strongly encourage clinicians to maximize the efforts to start, participate in clinical trials to bring maximum patients in context of clinical trials.
- 2. Strict monitoring patient for drug induced potential harms and timely intervention in case of any early signals of possible treatment related potential harm
- If the patient is admitted to a private hospital and Active treatment is indicated, but not available, Public Health and Health Regulations in concerned Emirate/Health Authority to be contacted.

Laboratory and Radiological Monitoring

- Baseline tests should be done prior to treatment initiation for all patients.
- Repeat PCR test after 5 days of positive swab collection date.
- Thereafter, repeat blood tests every 72 hours and imaging every week, unless clinically indicated earlier, while on treatment.
- Repeat more frequently in critically ill patients if indicated









Recommended monitoring parameters for Drug Therapy management

oCBC, Renal Profile and extended electrolytes (Na+, K+, Mg++, Ca++, Phosphate), Uric Acid, Liver Function Tests, Serum Amylase, Serum Lipase, Coagulation profile, uric acid, ECG baseline

Prognostic Factors & Markers for Severe COVID-19 Disease

Epidemiological- Category 1	Vital signs- Category 2	Labs-Category 3
Age > 55	Respiratory rate>24 breaths/min	D-dimer>1000 ng/mL
Pre-existing pulmonary disease	Heart rate > 125 beats/min	CPK>twice upper limit of normal
Chronic kidney disease	SpO2 <90% on ambient air	CRP>100
Diabetes with A1c>7.6%		LDH>245 U/L
History of hypertension		Elevated troponin
History of Cardiovascular disease		Admission absolute lymphocyte count<0.8
Use of biologics		Ferritin>300 ug/L
Obesity with BMI ≥35		
History of transplant or other		
immunosuppression		
All patients with HIV (regardless of CD4 count)		

Treatment Options:

- The various treatment options including regimens are provided in table 1
- Any drug-induced side effect to be managed accordingly
- Rule out pregnancy before starting Favipiravir
- <u>Favipiravir</u>, absolutely contraindicated in first trimester of pregnancy
- Check details in Medication safety information section regarding Favipiravir before prescribing any of these drugs for women with childbearing age & and male patients who female partner is already pregnant or can be pregnant during & 7 days after end of treatment with Favipiravir, and during or up to 6 months after end of treatment with Ribavirin
- Get Informed consent from patient for treatment of COVID19, if patient can't provide consent then his family member /guardian









Table 1: Therapeutic Regimens for Adults

Based on updated available information from literature and in view of International practice and recommendations.

- Medications used are off label or experimental, based on limited data
- Baseline Monitoring parameters and early initiation of treatment is highly advisable
- For patients having renal or hepatic impairment, consult individual drug monograph for additional monitoring or dose adjustment.

Clinical	Suggested Medications		
Presentation			
Clinical	Dosing & frequency mentioned is for normal Renal & Hepatic Functions		
presentation 47	For Moderate to severe Hepatic Impairment & or severe Renal impairment, Drug interaction		
	etc.		
	(Consult individual drug monograph for additional monitoring or dose adjustment)		
Contact	No Post exposure Prophylaxis is indicated for the time being		
Probable case of COVID-19 URTI without pneumonia	Please follow the confirmed case management		
Probable case of	Please follow the confirmed case management		
COVID-19			
Pneumonia (see Probable case			
definition above)			
Confirmed	No treatment,		
COVID19	High risk		
Asymptomatic	Age ≥65 years or Age 55 years and with Cardiovascular disease, hypertension, Diabetics, Preexisting lung disease, Obesity with BMI≥35 or Immunocompromised / cancer patients.		
	If high risk:		
	Favipiravir 1600 mg PO BID X 2 doses then 600 mg PO BID (total 7 days) (49,50,51)		
	If radiological evidence of pneumonia, follow pneumonia recommendation		
Confirmed			
COVID19	Favipiravir 1600 mg PO BID X 2 doses then 600 mg PO BID (total 10 days)		
URTI without			
Pneumonia			
For 10 Days			









Confirmed COVID19

Pneumonia For (10-14 days)

[Inhaled Interferon therapy can be a possible add on option on case by case basis in patient with moderate to severe disease]

Patients without the need Supplemental oxygen and maintaining SpO2 > 94% on Room Air.

Favipiravir 1600 mg PO BID X 2 doses then 600 mg PO BID (total10-14 days) [49,50,51]

Patients with SpO2 ≤94% on room air and on supplemental oxygen but NOT on Mechanical ventilation or ECHMO

Remdesivir 200 mg intravenously (IV) for 1 day, followed by Remdesivir 100 mg IV for 4 days (total 5 days) + Dexamethasone 6 mg IV /PO daily for 7-10 days (if patient is on supplemental oxygen)[47,48]

OR

Favipiravir 1600 mg PO BID X 2 doses then 600 mg PO BID (total14 days) [8,13]

+ Dexamethasone 6 mg IV /PO daily for 7-10 days if patient is on supplemental oxygen

Confirmed COVID19

Severe Pneumonia /Critically ILL patients For 10 days

"In patients with severe Covid-19 not requiring mechanical ventilation, trial did not show a significant difference between a 5-day course and a 10-day course of Remedesivir."

(Goldman JD, et al. N Engl J Med. 2020 May 27)

*= Treatment duration of Remdesivir may be extended up to 10 days if there is no substantial clinical improvement by day 5(NIH Covid-19 guidelines) Patients who are on Oxygen therapy through high flow devices or Non-Invasive ventilation but Not Mechanically ventilated or not on ECHMO

Remdesivir 200 mg intravenously (IV) for 1 day, followed by Remdesivir 100 mg IV once daily + Dexamethasone 6 mg IV daily $^{[47,48]}$ or Methylprednisolone

OR

Dexamethasone 6 mg IV daily alone [47,48] or equivalent Corticosteroids

±nebulized Interferon Alpha or Interferon Beta through Nebulizer creating fine mist like ultrasonic nebulizers.

Patients who are critically ill and on Invasive Mechanical ventilation or ECHMO

Dexamethasone 6 mg IV daily alone [47]

Any equivalent corticosteroids, preferable methylprednisolone.

Can also consider higher doses corticosteroids if needed

Inhaled Interferons dosing options: (Can use one of Interferon from below two options) Interferon Alpha 2b, 5 million units /ampule (Bioferon): Dose is 10-million-unit BID (Dilute 2 ampules of 5 million units with 4 ml of normal saline, use nebulizer creating fine mist e.g. ultrasonic nebulizer Interferon beta 1b (Betaferon) Interferon beta 1b 8 million units (250 microgram)/vial:

Dose is 8 million units BID via Nebulization.

Mix reconstituted solution of 1 vial of Betaferon with 2 ml of normal saline and use through nebulizer creating fine mist e.g. ultrasonic nebulizers









Camostat 200 mg PO TID for 5 to 7 days (if available) cannot be used alone, however, can be added to Favipiravir course.

Tociluzimab⁶¹ should be considered in patients with severe COVID -19 Pneumonia requiring Oxygen therapy, preferably also in non-ventilated patients on high flow Oxygen or Non-Invasive ventilation. It can also be considered early in patient on mechanical ventilation.

It should be considered in above patients who has evidence of early cytokine release syndrome (cytokine storm) with increased IL6 level, or elevated CRP of 75 or more.

If decision is to initiate treatment, Tociluzimab should be given in combination with corticosteroids and not as single agent during acute phase of cytokine storm.

If used, the suggested dose is 4-8 mg/kg body weight (maximum dose 800 mg) once or twice

Administration: Dilute in 100 ml of 0.9 % saline, allow diluted solution to reach room temperature, infuse over more > 60 minutes using **dedicated line** (Do Not infuse if opaque particles or discoloration visible same)

Based on a cumulative evidence from systematic reviews conducted by Saudi, Qatar, Canada and US Mayo clinic shows that tocilizumab might reduce the risk of mechanical ventilation in hospitalized COVID-19 patients but not short-term mortality. This was based on 4 completed randomized controlled trials, three of them were double blinded [61]

Sarilumab: Is another IL6 that can be used in cytokine storm. If used, the suggested dose is 400mg IV infusion over 1 hour once

Monoclonal antibodies after ID/ internal medicine approval

Bamlanivimab: FDA has issued EUA (Emergency use authorization) for Bamlanivimab

This EUA is for the use of the unapproved product Bamlanivimab for the treatment of mild to moderate COVID-19 in adults and paediatric patients 12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥65 years of age?
- Are ≥55 years of age AND have o cardiovascular disease, OR
- Hypertension, OR
- Chronic obstructive pulmonary disease/other chronic respiratory disease.









Are 12 - 17 years of age AND have

- BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical charts.htm, 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.

LIMITATIONS OF AUTHORIZED USE

Bamlanivimab is not authorized for use in patients:

Who are hospitalized due to COVID-19,

OR

Who require oxygen therapy due to COVID-19,

OR

- Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with Bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as Bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Dosing regimen of Bamlanivimab Adult patients

Weight ≥40 kg: IV 700 mg as a single dose; administer as soon as possible after a positive SARS-CoV-2 test and within 10 days of symptom onset (FDA 2021).

Children ≥12 years and Adolescents weighing ≥40 kg: IV: 700 mg as a single dose; administer as soon as possible after a positive SARS-CoV-2 test and within 10 days of symptom onset.

Note: Bamlanivimab has not been studied in pediatric patients; emergency use authorization from the FDA is based on likelihood of similar exposures in patient's \geq 12 years of age weighing \geq 40 kg (FDA 2021).

For Administration/dilution, preparation, stability and monitoring: Consult /check product leaflet and Lexi comp drug information resource /FDA product authorization details

https://www.fda.gov/media/143603/download

Addition of Multivitamins/supplements [45,46]

Vitamin C1000 mg PO BID, Vitamin-D 50000 units weekly for 2 weeks, Zinc gluconate 10 mg BID or any other zinc supplement which is available as alternative e.g. Zinc acetate 25 to 50 mg once daily for 5 to 7 days based on treating physician choice (Currently being investigated in clinical trials), may have possible add on benefit









VTE Thromboprophylaxis & Anticoagulants use in COVID-19 patients:

All patients admitted with COVID 19 Infection should receive pharmacological VTE thromboprophylaxis irrespective of VTE risk, unless an absolute contraindication exists.

Institutional protocol/policy should be used for dosing Subcutaneous Heparin or Enoxaparin. A D-Dimer driven protocol can be considered, and higher doses of prophylactic-Not therapeutic doses- can be considered.

Full anticoagulation should be given only for patients with confirmed VTE disease in form of DVT or PE or if high clinical suspicion present.

There is currently no recommendation for empiric full anticoagulation outside clinical trials.

Intermittent pneumatic compression devices should be considered if there is a contra-indication to the use of prophylactic anticoagulation.

Upon discharge if clinically fit for discharge, however, d-dimer is high, patients to be discharged on anticoagulant for 2-4 weeks with reassessment after that to decide on further need.

Corticosteroids

Corticosteroids in early course of disease have been shown to have benefit in patients requiring oxygen or ventilation. However, no benefits in mild cases where oxygen is not required and it could be harmful.

Dexamethasone

As per the Recovery trial, 6mg (IV or Oral) once per day for 10 days for patients on oxygen or ventilated, to be given early in the disease, showed reduction in death by one third in ventilated patients and by one fifth in other patients receiving oxygen. (47)

Higher doses of Dexamethasone or equivalent corticosteroids mainly Methylprednisolone should be considered in Critically III patients.

Methylprednisolone:

Methylprednisolone has been used at a dose of 1-2mg/kg to treat COVID-19 cases with hypoxia and has resulted in improved outcome of intubation and mortality. (64)

Methylprednisolone pulse have also been tried, intravenous injection, 250 mg daily for 3 days. There are small trials to show its benefit. (65)









Favipiravir:

Dose may need adjustment based on clinical scenario, **Patient is elderly or any patient with other risk factors for CKD and develops** AKI i.e. 50% rise in serum creatinine from baseline during course of Favipiravir and the rise is persistent

Persistent rise in serum creatinine without any other possible obvious medical reason i.e

- No other nephrotoxic drugs,
- No hypotension or hypertensive emergency
- No sepsis,
- No dehydration
- No other medical cause of rise in serum creatinine (i.e. no recent exposure to contrast).

In these patients strict intake/output monitoring with daily serum urea & creatinine and correct any other reason i.e. dehydration, hypotension...etc. If rise is persistent despite all corrective actions then can modify dose and/or minimize duration or stop/hold to avoid permanent renal injury in high risk patients for renal toxicity i.e. elderly, diabetic, HTN, Heart diseases, other nephrotoxic medications.

For individual case it is advised to consult Nephrologist & clinical pharmacist for their input to advise based on risks vs benefits

Camostat Mesylate

Camostat Mesylate [14,] Is approved drug for medical use in Japan for more than 10 years in other indications like: Chronic Pancreatitis, Post surgery reflux esophagitis (Specific dosing regimen information for COVID-19 Not yet available the doses suggested in the guidelines are based on extrapolation from approved dosing regimens for above mentioned other indications.)

- According to research in Germany on SARS-2 Virus of COVID-19 attack on Lung cells in laboratory setting showed that Camostat Mesylate inhibited TMPRSS 2 partially & resulted in ~ 50 % blockage of attack through ACE2 receptors pathway. "Hoffmann et al., SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor", Cell (2020), https://doi.org/10.1016/j.cell.2020.02.052
- As per their recommendation the drug should be tried in clinical studies

Clinical Studies/Trials: [36]

To date 5 clinical trials registered with clinicaltrials.gov (2 in USA,1 in Denmark,1 in Germany,1 in Israel) to evaluate the efficacy of Camostat in RCT, so far, no published information's /findings, however expectations from the drug to show efficacy in early course of disease to prevent or minimize progression of disease into severe form.

Safety profile: Overall safe drug, rarely Hyperkalaemia, Eosinophilia with pneumonitis, urticaria etc.









Interferons:

Use being investigated in different clinical studies, Interferon beta 1 b used as 8 million units Sub-Q on alternative days for 3 doses in triple therapy in phase 2 trial in Hong Kong by Prof Ivan Fan Ngai Hung et al DOI

https://doi.org/10.1016/S0140-6736(20)31042-4

Interferon Alpha 2B and other interferon of Alpha group also being evaluated for COVID-19

Non-Pharmacological Options

<u>Convalescent plasma</u> (In context of clinical trial):

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has several therapies which are undergoing investigation, but the efficacy of these drugs is yet to be established, furthermore, the use of convalescent plasma was recommended as treatment during former viral infections, therefore, there is a hypothesis that convalescent plasma might be efficacious in the treatment of patients infected with COVID-19. However, there is limited evidence from a few, very small studies that its use is beneficial in these patients, and more recent studies demonstrated its potential benefit when administered to non-intubated patients. Therefore, CCP is recommended as follow:

Cases in the serious category with COVID pneumonia and oxygen requirements are the preferred candidates and we recommend to introduce COVID-19 convalescent plasma (CCP) treatment early in the admission process, patients should have their cardiac enzyme, ECG, renal function and Pro-BNP performed and patient should not demonstrate any cardiac or renal compromise prior to administration of CCP.

CCP is not recommended for the life-threatening intubated patients' category unless it's for compassionate use and in a case by case basis.

Two doses that are 48 hours apart is recommended, exception to the second dose are patients who either demonstrates a dramatic improvement or deterioration in their cardiac and/or renal status

FDA has approved the use of COVID-19 convalescent plasma as an investigational product under the EUA during the public health emergency. They state that convalescent plasma with high antibody titres may be more beneficial than low-titre plasma in no intubated patients, particularly when administered within 72 hours of COVID-19 diagnosis. Data are not sufficient to establish the efficacy or safety of convalescent plasma due to the lack of a randomized, untreated control group and potential confounding. ⁽⁶³⁾

However, WHO is cautious about endorsing the use of recovered COVID-19 patients' plasma to treat those who are ill, saying evidence it works remains "low quality"

Extra Corporeal Blood purification therapies in Cytokine Release syndrome in critically ill COVID-19 patients

(In context of clinical trial): COVID 19 patients can present with a cytokine release syndrome (CRS) and severe acute respiratory failure induced by high level of circulating cytokines levels. Currently there are limited options for patients who deteriorate requiring Intensive care. In view of the complexity of the immune response in response to COVID 19, and the resulting CRS, it is likely that a specific therapy directed against a single cytokine, may not be completely effective in modulating a very dysregulated inflammatory response.









Current therapeutic options in context of COVID 19 related CRS have been limited to experimental antibody-based therapies (e.g. tocilizumab, intravenous immunoglobulins (IV IgG) and convalescent plasma administration.

Extra Corporeal Blood purification (ECBP) has been proposed to remove cytokines in patients with sepsis and systematic inflammatory (1, 2, 3, 4). The rationale for use of these ECBP is that these extracorporeal adsorption membranes are used in cytokine removal, and potentially could improve immune homeostasis and perhaps might help prevent CRS-induced organ damage (2, 6). In addition, neither haemodialysis nor hemadsorption do not appear to remove molecules such as IgG and Tocilizumab as their size (e.g., 150 kDa for IgG, Tocilizumab 148 kDA) exceeds the upper size of molecules mainly being removed these therapies (around 60 kDa) (7). Hence these ECBP therapies will not preclude the use of the other experimental therapies on a compassionate use.

The U.S. Food and Drug Administration have recently provided an emergency use authorization of 4 Extra Corporeal Blood purification devices to treat acute respiratory failure in COVID 19 in context of clinical trials.

- 1. Oxiris Set device https://www.fda.gov/media/137267/download
- 2. Seraph 100 Microbind Affinity Blood Filter https://www.fda.gov/media/137101/download
- 3. Depuro D2000 Adsorption Cartridge https://www.fda.gov/media/136834/download
- 4. CytoSorb device https://www.fda.gov/media/136867/download

There are multiple clinical trials underway in assess effectiveness of this approach. ClinicalTrials.gov Identifier: NCT04358003, NCT04344080, NCT04385771, NCT04324528
These devices such as Cytosrob, HA330, Depuro D200 have theoretical value in the management of COVID-19 disease and some anecdotal evidence; however, actual clinical trial data that establish true efficacy are lacking even as the body of anecdotal evidence of benefits expands rapidly. For these reasons, among patients who have been admitted to Intensive Care Unit with COVID-19 related acute respiratory failure, the U.A.E COVID guideline writing panel recommends that "Extra Corporeal Blood purification therapies may be offered to patients with acute respiratory failure in the context of a clinical trial to improve patient access to these devices and to increase clinical knowledge"

Pregnant patients:

- In Pregnant Patients management of COVID-19 is on case by case basis with ID Consultation and obstetrician.
- Nebulized interferon alpha 2b, Interferon Beta 1b can be a possible option
- May consider antivirals as companionate use in the second and third trimester including:
 Favipiravir, Remdesivir, though there is no data of their use in pregnancy.

Pediatric Patients COVID-19 treatment options

- Treatment in Paediatric patients on case by case basis after consultation with ID Physician and concerned speciality as **there is lack of data in Paediatric population**
- Get Informed consent from patient for treatment of COVID19, if patient can't provide consent then his family member /guardian

Favipiravir dosing is in patient's ≥ 12 months of Age &body weight ≥10kg
(There is <u>no data</u> regarding use & dosing in COVID-19 in paediatrics, doses in below table derived & modified from Ebola study in 12 children)









Body weight	Favipiravir 200 mg Tablet			
10-15 kg	Loading Dose: One tablet PO BID for One day (maximum 400 mg/day)			
	Maintenance from Day2: Half tablet (100 mg) PO BID (maximum 200 mg/day)			
16-21 kg	Loading Dose: Two tablets PO BID One day (maximum 800 mg/day)			
	Maintenance fromDay2: One Tablet PO BID (maximum 400 mg/day)			
22-35 kg	Loading Dose: 3 Tablets PO BID for One day (maximum 1200 mg/day)			
	Maintenance from Day2: One tablet PO TID (maximum 600 mg/day)			
36-45 kg	Loading Dose: Four tablets PO BID for One day (maximum 1600mg/day)			
	Maintenance from Day2: Two tablets PO BID (maximum 800 mg/day)			
46-55 kg	Loading Dose: Five tablets PO BID for One day (maximum 2000 mg/day)			
	Maintenance from Day2: Two tablets qAM, thee Tablets qPM (maximum 1000 mg/day)			
For >55 kg	Can use adult dosing if age ≥16 years, if age <16years use dosing of 46-55 kg range			

Explanation for Calculation of "Favipiravir dosing" for COVID-19 in paediatrics

Use of Favipiravir [19,20] (Avigan) In Paediatrics' ≥ 12 months of Age &body weight ≥10kg. As such no dosing information data available from any ongoing or proposed trial or study in Paediatrics' in COVID-19.

Dosing regimens were derived dosing from the doses used in Ebola Trial [19]in 12 children \geq 12 months of Age &body weight \geq 10kg ^[19] (dosing regimen derived on almost similar scale used in adults from Ebola to COVID-19 regimen)

For Adult patients Favipiravir (Avigan) COVID-19 Dosing is less than Ebola dosing i.e. (COVID-19 Loading dose is 50% less, maintenance dose 25%-50% less compared to Ebola dosing) based on almost similar scale it is plausible to adopt the same strategy in children for dose reduction as well for the safety reasons and hence COVID-19 dosing was adopted for "Paediatrics"

In children of lower body weight range i.e. 10-15 & 16-21 kg range more conservative dosing approach adopted due to safety concerns.

Pediatric Multisystem Inflammatory Syndrome temporally associated with SARS-CoV-2

The Covid-19 pandemic has been temporally associated with the emergence of a pediatric presentation of severe inflammation and shock. This syndrome has some clinical similarities to Kawasaki shock and toxic shock. Patients have presented with mild to severe illness. In the majority of patients, coronavirus has not been detected by PCR on nasal swabs, however serological evidence of SARS- CoV-2 infection is present in some. The likeliest mechanism is a delayed antibody-mediated dysregulated host immune response.

 Pediatric Multisystem Inflammatory Syndrome associated with SARS-CoV-2 should be reported to the authorities as part of COVID 19 case reports.









Clinical features

May include one or more of the following:

- Persistent Fever > 39 C
- Neurocognitive symptoms: Lethargy, Headache and confusion
- Abdominal Pain, Diarrhoea and Vomiting
- Rash/Conjunctivitis/mucous membranes involvement
- Hypotension (Wide pulse pressure), tachycardia +/- Shock

Laboratory features

Raised CRP and ESR Raised Ferritin (>500) Raised Fibrinogen Raised D-Dimer Renal dysfunction

Raised LDH Raised Troponin and B-NP Lymphopenia / neutrophilia Platelets initially low or normal

Significant similarity in presentation with other pediatric conditions

Septic shock - may require higher volume fluid resuscitation and source control

Peritonitis -negative laparotomy reported in some cases: Needs surgical review with appropriate radiology

Initial management

Examination:

 Exclude potential septic foci and careful cardiac assessment (liver, JVP, cardiac / thoracic ratio on CXR)

Resuscitation:

- If signs of shock fluid resuscitation (10ml/kg NS) with re- evaluation after each bolus and discuss with PICU
- If no improvement with fluid, start inotropes: Dopamine@ 5 -10mcg/kg/min, until central access (consider Epinephrine)
- Ceftriaxone and Clindamycin as sepsis impossible to exclude. Add broader spectrum antibiotics (e.g. Vancomycin) if hospital acquired or concern of infections due to resistant pathogens, keep clindamycin to reverse toxins release
- Early IVIG 2g/kg (once over 10-12hours), Max 100 gram

Severe myocardial dysfunction common:

 If intubation required: cardio-stable induction (ketamine+ prepare emergency drugs)

Investigations

Core investigations

- · CBC/Diff, Renal function, LFT
- CRP, PCT, ESR
- Ferritin, Triglycerides, Trop-T, D-Dimers, CK, NT-pro BNP, LDH
- Serum IL-6level
- Coagulation profile (Including Fibrinogen)
- Blood / Urine culture
- Immunoglobulins levels
- Save serum & EDTA sample
- Chest X-ray
- Consider abdominal imaging to exclude abdominal pathology

Additional investigations (PICU admission)

- Vitamin D, amylase
- Type and screen (cross match if considering ECMO)
- · Blood smear
- Virology for SARS-CoV-2 PCR on Stool, NPA, blood serology for SARS-CoV-2
- Standard Respiratory Viral panel
- Viral serology blood PCR: EBV, CMV, Adeno, Enterovirus
- Pneumonia panel if intubated

PICU management

Patient to be managed as COVID+ (even if PCR negative for SARS- CoV-2) – full PPE and management in appropriate area

 Central access: awake femoral line preferable in self ventilating patients-most require Epinephrine

Cardiac Manifestations and Management

Pancarditis may include: bi-ventricular impairment, mitral/tricuspid valve regurgitation, diastolic dysfunction, pericardial effusion, coronary artery dilatation / aneurysm (may be better visualized on CT)

Clinical course unpredictable with









- Temperature control–regular paracetamol, active cooling if ventilated
- Ensure IVIG was administered otherwise give a dose as above, monitor for fluid overload during infusion.
- Methylprednisolone as per clinical severity table
- Proton pump inhibitors (esomeprazole 1 mg/kg/day, max 40mg/day)
- Aspirin/Anticoagulation as detailed in the third page.

Monitoring:

- Urgent Echo upon admission to PICU.
 Repeat as clinically indicated.
- 12 lead ECG at admission, repeat daily or if clinical concerns.
- · If oxygen requirement repeat CXR
- Regular blood gas measure lactate
- Repeat core investigations 12 hourly if rising inflammatory markers discuss with ID team.

Further immunomodulation poor response may include:

- Repeat IVIG dose
- Pulse Steroid
- Anakinra (IL-1 receptor antagonist)
- Infliximab (monoclonal antibody)
- Tocilizumab (IL-6 receptor antibody
- Details on second page

rapid deterioration observed in some.

- 12 lead ECG arrhythmias reported
- Urgent Echocardiogram
- Low threshold for Milrinone infusion
- Severe cases consider levosimendan
- VA ECMO for refractory shock Discuss with SKMC

Response to treatment

•Defined as the normalization of vital signs, CRP, and blood test, and the resolution of symptoms and signs

Therapy Complications

- Fluid overload risk with IVIG infusion consider diuretics
- Hypertension: high dose methyl prednisolone associated with severe hypertension and PRES. Treatment with Ca channel blockade or SNP if severe cardiac dysfunction.
- Hyperglycemia: may require insulin infusion.
- Gastritis: patients should all receive high dose
- Salicylate complications: AKI, Respiratory alkalosis

Antiviral therapies:

- Limited role as MIS-C is generally post infectious complication
- Consider Remdesivir only if positive PCR and evidence of active infection after discussing with Pediatric infectious disease.









Classification of Clinical Severity

- Mild: No vasoactive requirement, minimal/no respiratory support, minimal organ injury
- Moderate: Vasoactive-Inotropic Score* (VIS) ≤ 10, significant supplemental oxygen requirement, mild or isolated organ injury
- **Severe:** Vasoactive-Inotropic Score > 10, non-invasive or invasive ventilatory support, moderate or severe organ injury including moderate to severe ventricular dysfunction

Vasoactive-Inotropic Score (VIS)* below

Management by Clinical Severity			
Therapeutic Category	Mild	Moderate	Severe
Steroid Initial Dosing	Methylprednisolone	Methylprednisolone	Methylprednisolone
For 2 mg/kg/day dosing:	2 mg/kg/day	10 mg/kg X 1, then	30mg/kg/day (max 1000 mg/day)
max 60 mg/day		2 mg/kg/day	for 1-3 days,
For pulse dosing: max 1			then 2 mg/kg/day
g/day			
Other	Consider pulse	Consider 1-3 days	
Immunomodulation	Methylprednisolone	pulse	Consider Anakinra if refractory to
	or Anakinra if	Methylprednisolone,	steroids, consider other biologics
	refractory course	consider Anakinra if	if refractory to Anakinra
		refractory to	
		steroids	* Consult Rheumatology
	* Consult		
	Rheumatology	* Consult	
		Rheumatology	
GI prophylaxis with	Yes	Yes	Yes
proton pump inhibitor			
Broad-spectrum	Yes	Yes	Yes
antibiotics			
Steroid Taper	2-3 weeks	6-8 weeks	Steroid taper with subspecialty
			consultation

Adapted from Morgan Stanley children's Hospital



INTRAVENOUS IMMUNOGLOBULINS

All patients with MIS-C should receive IVIG 2g/kg up to 100g. A second dose of IVIG should be
considered in refractory cases. Obtain serum quantitative immunoglobulins and necessary serum
serologies before administration of IVIG.



Recommended doses for BIOLOGICS (following discussion with Paediatric rheumatology)









- Anakinra
 - Dose: 2-4 mg/kg/dose (max 100mg/dose) SQ twice daily (may increase to 3 times daily) for 3 days
 - doses up to 10 mg/kg/dose SQ q6hr have been utilized
- Tocilizumab (second line agent)
 - Dose: <30kg: 12mg/kg IV; >30kg 8mg/kg IV, max 800mg
 - * An additional dose may be given 12 hours after the first dose if clinical symptoms worsen or show no improvement.
 - * VIS = Dopamine dose (mcg/kg/minute) +

Dobutamine dose (mcg/kg/minute) +

100 X Epinephrine dose (mcg/kg/minute) +

100 X Norepinephrine dose (mcg/kg/minute) +

10 X Milrinone dose (mcg/kg/minute) +

10,000 X Vasopressin dose (U/kg/minute)

Aspirin/Anticoagulation Protocol

- All Patients regardless of coronary artery abnormalities
 - < 60 kg: enoxaparin 0.5 mg/kg/dose Q12hr, Max 30 mg/dose [Prophylaxis]</p>
 - > 60 kg: enoxaparin 30 mg Q12hr (Prophylaxis).
 - o Change Frequency to q24h If Cr Clearance < 30/min/1.73 m²
- Patients with coronary ectasia or dilation
 - Enoxaparin as above

AND

- Low-dose ASA (3-5 mg/kg/day, max 81 mg)
 - Exceptions to low-dose ASA: Platelets less than 100,000
- Consult cardiology to review anticoagulation/antiplatelet recommendations, on case-by-case basis
- Patients with moderate or severe systolic dysfunction (e.g., EF < 30%), rapidly expanding aneurysms, or giant aneurysms:
 - LMWH (<u>Therapeutic</u>) for all patients in consultation with cardiology
 - Usual dosing is 1 mg/kg/dose Q12h, with anti-Xa target of 0.5-1.0
 - o Cardiology will determine need for additional antiplatelet therapy with aspirin
- Duration of treatment with aspirin:
 - o In patients prescribed ASA as inpatients, low-dose ASA should be continued through at minimum the time of cardiology/rheumatology follow up with ultimate duration to be determined at the outpatient visit.









Duration of treatment with LMWH:

- LMWH should be discontinued when the patient no longer meets high-risk criteria for VTE prophylaxis, or at the time of hospital discharge.
- After LMWH is discontinued, patients should be transitioned to low-dose ASA, with duration as described above. Duration of LMWH for children with moderate or severe cardiac dysfunction should be discussed with cardiology team.

• Special Considerations for Aspirin:

- Avoid ibuprofen or other NSAID (antagonizes anti-platelet effect of aspirin)
- o Adverse effects (rare): GI bleed, tinnitus, Reye's syndrome
 - Reye's syndrome rare, but increased risk with aspirin and viral infection.
 - Consider inactivated influenza vaccine (avoid live vaccines (e.g. varicella) until off aspirin or discuss risk benefit when on low-dose aspirin).

COVID-19 Vaccination

The world is in the midst of a COVID-19 pandemic, scientists are racing to develop and deploy safe and effective vaccines.

There are currently more than 60 COVID-19 vaccine candidates in clinical trials.

In UAE, currently there are 2 vaccines that have received emergency use approval:

- 1. Sinopharm BeijingCOVOD-19 Vaccine (Vero cell), inactivated.
- 2. Pfizer-BioNTech COVID-19 vaccine

Medications Safety Information

For more details about the suggested medications, refer to Appendix VII-COVID -19 Treatment Options Index

Drug Use Management of COVID-19 Patients

Follow the basic principle of Medicine" First Do No Harm"

COVID -19 patients are often with underlying diseases receiving multiple types of drugs, at risk for adverse effects.

The following is expected from every healthcare giver to ensure safety of treatment options

- Strict compliance with monitoring parameters
- Side Effects Monitoring, prompt action accordingly
- Check for Drug interaction & if dose adjustment required when patient is on COVID-19 drugs **Nursing monitoring Parameters:**
- ♦ For any potential side effects and inform MD on Duty "
- ♦ Strict Monitoring of Glucose, Hypoglycaemia especially in diabetic or NPO, Insulin & Diabetic medications dose adjustment may be required case on cases basis
- Monitor sign of arrhythmia, immediately inform MD









Pregnancy Warning with "Avigan" (Favipiravir)

Avigan (Favipiravir) is contra-indicated in pregnancy

When administering AVIGAN® (Favipiravir) to women of child-bearing potential, rule out pregnancy Before starting the treatment. Explain fully the risks and instruct thoroughly to use most effective Contraceptive methods with her partner during and for 7 days after the end of the treatment. If pregnancy is suspected during the treatment, instruct to discontinue the treatment immediately and to consult a doctor.

Advice for Male patient

AVIGAN (Favipiravir) is distributed in sperm. When administering the drug to male patients, explain fully the risks and instruct thoroughly to use most effective contraceptive methods in sexual intercourse during and for 7 days after the end of the treatment (men must wear a condom). In addition, instruct not to have sexual intercourse with pregnant women during & for 7 days after the end of the treatment.

♦ **Favipiravir in Breastfeeding /Lactation**: When administering Favipiravir to lactating women, instruct to stop lactating (The major metabolite of Favipiravir, a hydroxylated form, was found to be distributed in breast milk.)

Rule out pregnancy before starting treatment whenever applicable

Discontinuation of isolation/transmission-based precautions for patients with SARS-CoV-2 infection 155/561

A test-based strategy or symptom-based strategy may be used (except as noted below). In the majority of cases, patients may continue to shed detectable SARS-CoV-2 RNA but are no longer infectious.

- For persons who never develop symptoms, isolation and other precautions can be discontinued 10 days after the date of their first positive RT-PCR test for SARS-CoV-2 RNA.
- For Persons who have mild to moderate symptoms discontinue isolation:
 - At least 3 days have passed since resolution of fever without the use of fever-reducing medications and
 - Other symptoms have improved and
 - At least 10 days have passed since symptom onset
 - Two consecutive negative SARS-COV-2 PT_PCR tests 24 hours apart from respiratory specimens
- For patients with severe illness:
 - At least 3 days have passed since resolution of fever without the use of fever-reducing medications and
 - Other symptoms have improved and
 - At least 20 days have passed since symptom onset









- Two consecutive negative SARS-COV-2 PT_PCR tests 24 hours apart from respiratory specimens
- Consider consultation with infection control experts.

Test-Based Strategy

*For all, except below, a symptom-based strategy can be used to discontinue isolation or other precautions

RT-PCR testing for detection of SARS-CoV-2 RNA is used for discontinuing isolation for persons who are **severely immunocompromised persons**:

- At least 3 days have passed since resolution of fever without the use of fever-reducing medications and
- Other symptoms have improved and
- at least two consecutive negative results for respiratory specimens collected ≥24 hours apart (total of two negative specimens), using RT-PCR for detection of SARS-CoV-2 RNA.

*Recovered persons can continue to shed detectable SARS-CoV-2 RNA in upper respiratory specimens for up to 3 months after illness onset, but at concentrations considerably lower than during illness, in ranges where replication-competent virus has not been reliably recovered and infectiousness is unlikely.

Discharge Criteria for COVID19 confirmed cases

Meeting criteria for discontinuation of Transmission-Based Precautions is not a prerequisite for discharge from a healthcare facility.

- Patients can be discharged from the healthcare facility whenever clinically indicated.
- If patients are discharged early based on clinical criteria, they be instructed to self-isolate at home until above criteria is met.
- Therefore, discharge should include considerations of the home's suitability for and patient's ability to adhere to home isolation recommendations.
- Discharged patients to be seen in the clinic in the hospital after 2 weeks, unless patient develops respiratory symptoms to attend earlier.
- If asymptomatic at 2 weeks, no more follow up
- Notify Public health/Preventive medicine at discharge especially if not completed isolation period.









Infection Control Measures for Suspected or Confirmed COVID19 Cases in Healthcare Facilities

Early Recognition

Enhance early recognition of suspected cases by:

- Visual triage at the entry point of the healthcare facility, for early identification of all patients with acute respiratory illness (ARI).
- Visual triage station should be placed at the entry point of the AE and any entry point
- Attended by a trained nurse or nurse assistant. Staff should be trained on appropriate questions to ask as well as actions based on findings and updated case definition
- Post visual alert signage to enhance self-reporting by symptomatic patients.
- Provide enough supply of surgical masks & hand hygiene sanitizers in the AE room.
- Prevention of overcrowding especially in the emergency department, keep stickers to maintain social distance
- Provision of dedicated waiting areas with clear signage of "Respiratory Waiting Area" for symptomatic patients
- Appropriate placement of hospitalized patients promoting adequate patient-to-staff ratio.
- Do not allow suspected COVID19 into common areas with other patients.
- Place suspected COVID19 in a dedicated waiting area with at least 3 feet and preferably 6 feet distance between them.
- Screen all patients walking into the ED for symptoms of acute respiratory illness (ARI) using the COVID-19 visual triage form below.
- Perform Infection Control Risk Assessment in triage.

Infection Control Practices in Healthcare Facilities:

Administrative measures

- Establishment of sustainable IPC infrastructures and activities is essential
- Facility level IPC programme with a dedicated and trained team or at least an IPC focal point should be in place and supported by facility senior management.
- Ensuring adherence to IPC policies and procedures in all aspects of health care.
- Ensure availability of essential supplies of PPE, Hand Hygiene
- Monitoring health workers' compliance with standard precautions / additional precaution and providing mechanisms for improvement as needed.









 Health-care facilities should consider using these tools to identify IPC gaps and to monitor progress in addressing them. WHO is developing a facility-readiness tool that will be available on the WHO technical guidance on COVID-19 website

Training

- All healthcare workers entering these rooms should be trained on proper use of PPE and fit tested in order to use N95. (Appendix I)
- Ensure that patients and visitors receive education about the precautions being used; the duration of precautions; the prevention of transmission of infection to others; and use of appropriate PPE.
- Ensure that front line staff as well as other staff at risks i.e. radiology, respiratory therapist; cleaning staff receive training on COVID19 preventative strategies.

General recommendations:

Implement Standard Precautions for all patients at all times focusing on

- Universal mask of all healthcare workers, patients and visitors
- Hand hygiene: adherence to WHO steps and moments
- Ensure availability and Proper use of PPE.
- Follow Respiratory Hygiene Practices:
- Offer a medical mask for suspected cases of COVID 19 for those who can tolerate it.
- Educate patient and relatives about cough and sneeze etiquette i.e. Cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others.
- Avoid touching your eyes, mouth or nose.
- o Post visual aid for cough etiquette, hand hygiene and symptoms to report early.
- Risk assessment is critical for all activities, i.e. assess each health care activity and determine the personal protective equipment (PPE) that is needed for adequate protection.
- Strict adherence by health care workers to infection control practices, hand hygiene between patients, new gloves between patients, wearing new set of personal protective equipment if the worn set become visibly soiled during the care of the patient, and cleaning and disinfection of medical care equipment that been shared after each use. if possible, use single use /dedicated item for COVID patients.
- All patients should be asked to wear surgical mask throughout their hospitalization period, they are required not to move in the rooms between beds and corridors
- Infection control practitioner should monitor staff adherence to infection control precaution









Practice droplet and contact Precaution when dealing with <u>Suspected Cases/ Confirmed Case of COVID in</u> addition to Standard Precautions, (Appendix I)

- All Patient suspected /confirmed cases should be isolated immediately.
- Place patient in a single room with good ventilation and with its own toilet, with the door closed.
 Airborne infection isolation room is only required if aerosol generating procedure is anticipated.
- If a negative pressure, room is needed for aerosol generation procedures but not available, put the patient in a single room, well ventilated, and place air disinfectant (Plasma air filter or Portable HEPA filter) in the room, next to patient's head.
- Place isolation precautions signs in the door and arrange the PPE supplies
- It is preferred and **strongly recommended not to cohort** suspected COVID-19 patients because it carries a risk of transmission of infection between patients if one of them will be confirmed
- Practise droplet and contact precautions for confirmed cases unless aerosol generating procedure,
 then Air borne precaution should be followed.
- HCP should wear respiratory protection equivalent to a fitted N95 filtering facepiece respirator or equivalent N95 respirator during aerosol-generating procedures.
- Unprotected HCP should not be allowed in a room where an aerosol-generating procedure has been conducted until sufficient time has elapsed to remove potentially infectious particles as per room air exchange per hour
- Conduct environmental surface cleaning following procedures (see section on environmental infection control).
- Avoid the presence of unnecessary individuals in the room.
- Note that high risk patients may present with mild symptoms but are at high risk of deterioration.

Airborne precaution for Aerosol- generating procedures

Below are most common Aerosol- generating procedures:

- Cardiopulmonary resuscitation
- Intubation
- Extubation
- High flow nasal oxygen
- Non-Invasive ventilation: BiPAP/CPAP
- Open suction
- Ambu Bagging









- Bronchoscopy
- Tracheostomy
- Upper GI endoscopy
- Dental Procedures
- Nebulizer therapy
- Sputum induction
- Perform procedures in negative pressure rooms with at least 12 air changes per hour (ACH) and controlled direction of air flow when using mechanical ventilation.
- Use a fit tested particulate respirator NOISH approved (N95 Mask) for all arousal generating procedure in addition to PPE required by Droplet and Contact precaution (Gown, Goggles or Face shield, long sleeve gloves
- Always perform the seal-check when putting on a disposable particulate respirator.
- HCW that all available types of respirators are not fit to him should be avoided from aerosol-generating procedures or use PAPR (Powered Air-Purifying Respirator).

Personal Protective Equipment (PPE) for confirmed cases of COVID 19

PPE should be available where and when it is indicated in the correct size and sufficient quantity

- HCP who enter the room of a patient with suspected or confirmed COVID cases should adhere to standard precautions and use a NIOSH-approved N95, equivalent or higher-level respirator, or facemask if a respirator is not available, in addition to gown, gloves, head cover and eye protection.
- Ensure that eye protection is compatible with the respirator so there is not interference with proper positioning of the eye protection or with the fit or seal of the respirator
- Double gloving and gowning are not recommended when providing care to patients with suspected or confirmed cases of COVID-19
- Designate staff who will be responsible for caring for suspected or known COVID-19 patients.
- All health care provider should wear and remove the PPE safely. (ensure presence of use checklist or poster)
- If there is concern and/or breach of PPE during patient care, leave the patient care area when safe to do so and properly remove and change the PPE and report it to <u>your direct line manager and</u> infection control Practitioner/unit
- Minimize the time spent and entry to the patient room by cohorting the task together
- All PPE should be used for certain task with certain patient and should be removed and discarded before leaving the patient room except N95 will be removed immediately outside patient's room
- In case of shortage of PPE, refer to WHO and CDC guidelines for extended use/reuse of PPE









Patient Care Equipment

- When possible use disposable devices or equipment.
- If disposables devices and equipment not an option, dedicate devices or equipment to a single patient
- If dedicated devices or equipment is not available, clean and disinfect the shared equipment before using it for other patients with approved disinfectant maintaining product contact time
- Approved disinfectant for COVID 19: quaternary ammonium compounds, sodium hypochlorite and 70% alcohol wipes

Patient Transport in the hospital

- Avoid the movement and transport of patients out of the isolation room or area unless medically necessary.
- The use of designated portable X-ray, ultrasound, echocardiogram and other important diagnostic machines is recommended when possible.
- If transport is unavoidable, the following should be observed:
- Patients should wear a surgical mask during movement to contain secretions.
- Use routes of transport that minimize exposures of staff, other patients, and visitors.
- Notify the receiving area of the patient's diagnosis and necessary precautions before the patient's arrival.
- Ensure that healthcare workers (HCWs) who are transporting patients wear appropriate PPE if they will participate in direct patient care and perform hand hygiene afterward.
- Transferred patient should not wait in the waiting or recovery room.
- Any area used by the patient/wheelchairto be cleaned appropriately after patient's transfer.

Patient Transport to another facility:

- Inform the other facility about referring a suspected/confirmed case
- Call ambulance and inform about the case being suspected/confirmed COVID 19, which will be transferred in designated ambulance
- Patient should wear facemask (if possible), the facemask reduces the ability of the patient to contaminate the immediate working environment of the ambulance staff.
- If ambulance personnel will come in contact with the patient, they should wear appropriate PPE, they should appropriately done and doff and dispose their PPE and perform hand hygiene after completing patient care, and prior to re-entering the isolated driver's section
- in situations where the ambulance/vehicle lacks an isolated driver's section, it is recommended that the driver use a respiratory/face mask during transport and other PPEs as above









- Once the patient has been handed over at the designated receiving health care facility, the ambulance should be aerated with several cycles of air changes by leaving its rear doors open. This will get rid of possibly infected particles.
- the ambulance must be cleaned and disinfected ensuring that all contaminated surfaces including stretcher, rails, control panels, floors, walls and work surfaces are thoroughly cleansed approved disinfectant using hospital approved disinfectant / hydrogen peroxide mist

Additional Measures

- As a measure to limit healthcare worker's exposure and conserve PPE, facilities could consider designating entire units within the facility, with dedicated HCP, to care for patients with suspected or confirmed SARS-CoV-2 infection
- Reduce number of staffs to the absolute minimum required for the patient's care and support
- Limit visitors entering the room to the minimum necessary.
- Keep log sheet of all persons coming in contact with the suspected/confirmed COVID 19 patients
- Exclude immunocompromised, pregnant, non-competent staff from the care of suspected/confirmed COVID 19 patients

Environmental cleaning in isolation rooms/areas

- Ensure that environmental cleaning and disinfection procedures are followed consistently and correctly
- Increase frequency of cleaning by housekeeping in patient care areas especially high touch surfaces (door handle, call bell, patient side rails ...etc.)
- Isolation areas should have their own cleaning supplies that are separate from clean patient care areas and are kept in or near isolation area
- Responsible housekeeping staff should be trained and educated with regard to cleaning method and technique, donning and doffing of PPE, spill management, dealing with occupational exposure ...etc.)
- Cleaners/housekeeping should wear appropriate PPE when cleaning an isolation room or area
- All waste from the isolation area is considered contaminated and should be disposed of following your facilities methods for contaminated waste.
- After patient is discharged, use terminal cleaning with fumigation with accelerated hydrogen peroxide 6% or use UVC, time and cycles adjusted per room size and shape.

Linen and laundry management, food service utensils and waste management, related to COVID19 case

Refer to the facility guideline/ protocol for waste management, to be dealt with as infectious material









Administrative measures to manage visitors

- Visiting is restricted
- identify alternatives for direct interaction between patients, family members, other visitors and clinical staff, including making remote communications available (e.g. telephone, internet connection);
- restrict entry to visitors who are essential such as the parents of paediatric patients and caregivers;

Managing Suspected / Confirmed case in Operation Theater

- Postpone elective operations immediately.
- Consider whether a non-surgical treatment can be used as an alternative to the surgical intervention.
- Only emergency or medically necessary surgery should be performed
- a careful risk assessment should be done to screen patients for COVID-19 symptoms, signs and exposure history to COVID-19 patients, COVID-19 test should be done 48hrs before the surgery
- Designate a specific operating theater for all COVID-19 cases. This room should be out of high-traffic areas and be completely emptied of all non-essential materials. When an anteroom is available, this should be used as an area for donning and doffing of personal protective equipment and exchange of equipment, medications and materials for the case.
- Use of personal protective equipment is recommended by the Centers for Disease Control for every operative procedure performed on a patient with confirmed COVID-19 infection or a patient where there is suspicion for infection.
- COVID-19 patients should wear a medical mask while being transported to the operating room, if tolerated
 - transporting staff should use contact and droplet precautions when transporting suspected or confirmed COVID-19 patients to the operating room.
 - N95 respirators or respirators that offer a higher level of protection should be used when performing, or present for, an aerosol-generating procedure (e.g. OR patient intubation) in COVID-19 or suspected infected patient.
- All traffic in and out of the operating theater should be minimized. A runner or support staff
 should be dedicated to the Operating theater to provide all materials needed throughout the
 case with exchanges performed using a material exchange cart placed immediately outside of
 the room or in the anteroom.
- Procedures should be performed by senior and experienced staff to minimize procedure time









Performing intubation and/or extubation in Operating Room (OR):

- Ideally intubate patients in an Airborne Infection Isolation Room (AII) room and then
 transfer them to the positive pressure OR (once intubated they are considered low risk
 because it is a closed system). Also consider transferring the patient to an AII room for
 extubation.
- If not possible, a portable high-efficiency particulate air (HEPA) filtration unit may be used by positioning the unit near the patient's breathing zone.
- Switching the portable unit off during the surgical procedure.
- Only essential personnel wearing respiratory protection, such as an N95 respirator or PAPR, should be in the OR when intubation and extubation occur
- A bacterial filter that filters particles 0.3 μm in size and has a filter efficiency of >95 percent should be placed on the patient's anesthesia breathing circuit at the endotracheal tube or expiratory side of the circuit. The entire circuit should be changed after the surgery is completed

After the procedure:

- the patient should be recovered in the operating theatre with dedicated staff until they can be transferred to an isolation room on the ward or in the intensive care unit.
- Adequate air exchanges should occur before environmental services enters the room for cleaning. With 15-20 air exchanges it will be around 30 minutes.

Managing bodies in the Mortuary

• Although no post-mortem transmission of COVID 19 has been documented, deceased bodies theoretically may pose a risk when handled by untrained personnel.

Preparing and packing the body for transfer from a patient room to mortuary

- ➤ The health worker attending to the dead body should follow standard precaution such as perform hand hygiene, ensure proper use of PPE (water resistant apron, goggles, N95 mask, gloves).
- ➤ All tubes, drains, and catheters on the dead body should be removed. Any puncture holes or wounds (resulting from removal of catheter, drains, tubes, or otherwise) should be contained with dressing.
- Keep both the movement and handling of the body to a minimum;
- > There is no need to disinfect the body before transfer to the mortuary area









- Ensure that any body fluids leaking from orifices are contained and cover the body in cloth
- Place patient in leak-proof plastic body bag (Cadaver bags) and those handling the body at this point should use PPE (surgical mask, clean gloves, and isolation gown).
- If the family of the patient wishes to view the body at the time of removal from the isolation room or area, they may be allowed to do so with the application of **Standard Precautions and should wash hands thoroughly with soap and water after the viewing.**
- ➤ Give the family clear instructions <u>not</u> to touch, kiss or hug the body, Adults >60 years and immunosuppressed persons should not directly interact with the body
- Morgue's staff should be informed about infectious status of the deceased, risk of infection and appropriate precautions required before transferring the patient to mortuary and should be well trained on standard precaution and infection control measure.
- Limit the number of Mortuary staff handling COVID dead body to limit the exposure
- No special transport equipment or vehicle is required. The trolley carrying the body must be disinfected after transmission with approved disinfectant (with 1% Hypochlorite solution, quarterly ammonium chloride ...etc.)
- > Dead bodies should be stored in cold chambers maintained at approximately 4°C
- The mortuary must be kept clean. Environmental surfaces, instruments and transport trolleys should be properly disinfected

Preparing and transferring the body from mortuary to Graveyard

- ➤ The body is prepared for burial in mortuary department of the healthcare facility as its forbidden to transport it to the home and it is only allowed to move it to public washing places with trained and competent people with appropriate equipment to deal with the dead bodies of infectious diseases.
- Limit the number of people washing the body
- All personal performing the body wash should be competent and should wear appropriate PPE (gloves, mask, gown and face shield) and should thoroughly wash their hands with soap and water when finished
- Instruct the family to avoid large gathering at the burial ground it should limited to close family contacts
- ➤ The belongings of the deceased person do not need to be burned or otherwise disposed of. However, they should be handled with gloves and cleaned with a detergent followed by disinfection with a solution of at least 70% ethanol or 0.1% (1000 ppm) bleach, Clothing and other fabric belonging to the deceased should be machine washed with warm water at 60–90°C (140–194°F) and laundry detergent









- After removing the body, the mortuary fridge, door, handles and floor should be cleaned with approved disinfectant such as 1% Hypochlorite solution
- The vehicle, after the transfer of the body must be decontaminated

Surveillance

- Develop a database containing information for all suspected/confirmed case who were/are assessed at your facility.
- Develop a database containing information for all healthcare workers and visitors that were in contact /caring for the confirmed cases of COVID 19

Surge capacity

■ Develop an emergency response plans to provide surge capacity, the plan should include human resources; staffed beds, ICU and non-ICU beds; critical equipment, supplies and other resources, including extra quantities of personal protective equipment, ventilators, ECMO machines, etc...).

Guidance for Extended Use, Limited Reuse and decontamination of N95 Respirators during Pandemic

Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability.

As supplies of N95 respirators can become depleted during a pandemic or wide-spread outbreak of other infectious respiratory illnesses. Combination of approaches to conserve supplies are recommended, while safeguarding health care workers in such circumstances. These existing guidelines recommend that health care institutions:

- Prioritize the use of N95 respirators for <u>aerosol generating procedure only</u> and
- Minimize the number of individuals who need to use respiratory protection through the
 preferential use of engineering and administrative controls (*limit number of personal dealing*with patient, cohorting the task of patient care Assigning designated teams of HCP...etc.)
- Prioritize the use of N95 respirators for those personnel at the highest risk of contracting or experiencing complications of infection.









- Use alternatives to N95 respirators (e.g., other classes of filtering facepiece respirators, elastomeric half-mask and full facepiece air purifying respirators, powered air purifying respirators) where feasible;
- N95 respirators must only be used by a single wearer, prevent inadvertent sharing of respirators.
- All staff should be trained in proper technique of extended use of the mask such as (removing, storing and re-wearing it)

1. Definitions

- **1.1 Extended use**: refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters. 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.
- <u>1.2 Reuse: -</u> refers to the practice of using the same N95 respirator for multiple encounters with patients but removing it ('doffing') after each encounter. The respirator is stored in between encounters to be put on again ('donned') prior to the next encounter with a patient.

2. Respirator Extended Use Recommendations

2.1 Discard N95 respirators

If contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients

- ➤ If used during aerosol generating procedures without face shield
- close contact with, or exit from, the care area of any patient co-infected with an infectious disease requiring contact precautions
- Obviously damaged or becomes hard to breathe through.
- 2.2 Consider use of a cleanable face shield (preferred) over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), Or surgical mask if face shield is not available, when feasible, to reduce surface contamination of the respirator
- **2.3** Minimize unnecessary contact with the respirator surface, strict adherence to hand hygiene practices, and proper PPE donning and doffing technique, including physical inspection and performing a user seal check.
- **2.4** Mask can be **re-use up to 5 times, no longer than 8 hours** and **decontaminated not more than** manufactural recommendation and sterilization method
- 2.5 Ensure that the mask maintains its fitness after decontamination.









- **2.6** All supplies of N95 respirators should be stored in locked or secured, designated areas (ex. Unit Manager) and will be issued to staff with an appropriately handled paper bag or container that allows breathability.
- **2.7** N95 respirators **must only** be used by a single wearer, prevent inadvertent sharing of respirators.

3. Instruction of reuse the N95 Mask

- **3.1** Keep used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.
- 3.2 Pack or store respirators between uses so that they do not become damaged or deformed.
- **3.3** Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene.
- **3.4** 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.
- **3.5** Strictly adhere to proper hand hygiene practices, and proper PPE donning and doffing technique.

4. Decontamination of N95 mask

4.1 In Department Procedures

- **4.1.1** Collect Plasma Sterilization pouch from CSSD.
- 4.1.2 Before use label the N95 respirator and paper storage bag with the <u>user's name, department</u>, <u>number of use and date</u> to prevent reuse by another individual. Write name on mask where straps are attachment or on elastic straps of N95 mask and on plasma CSSD pouch











- **4.1.3 Do not** decontaminate mask more than 2 times with STERRAD sterilizer or 10 times with Steris sterilizer or more frequent based on manufacture recommendation
- **4.1.4** You must wear full face shield over N95 mask to reduce risk of contamination especially if patient require Airborne and contact precaution such as COVID-19, varicella, etc.
- **4.1.5** Perform hand hygiene with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary, for comfort or to maintain fit).
- **4.1.6** Remove N95 mask carefully the front is potentially contaminated, so remove carefully by bending forward and using the elastic band.
- **4.1.7** After removing N-95, visually inspect for contamination, distortion in shape/form. If contaminated /wet, creased or bent, N95 should be discarded.
- **4.1.8** If the facemask is not visibly contaminated or distorted, carefully store in prepared CSSD pouch and seal with sterilization indicating tape to avoid destroying the shape of the mask place the pouch in designated CSSD container that with led cover in dirty utility room
- **4.1.9** Send it to CSSD decontamination Room.
- **4.1.10** Clean and disinfect the storage box.

5. In CSSD Department

- **5.1** Wear appropriate PPE (mask, gloves)
- **5.2** Receive N95 Mask boxes by the CSSD staff and keep in dedicated trolley.
- **5.3** inspect receiving mask of visible damage and soil/contamination (e.g. blood, dried sputum, soil, bodily fluids).
- **5.4** Any N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
- **5.5** Decontaminated the mask based on manufactural recommendation of your N95 mask.









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Appendix I: Proper Use of PPE











Donning Personal Protective Equipment (PPE)

The following PPE sequence is specific to the situation requiring Standard, Contact, and Airborne precautions.				
Step		Coaching Sequence	Observed	
1. Hand Hygiene	1.	Perform hand hygiene following WHO steps.		
2. Gown		Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back. Fasten gown by tying at the waist.		
3. Put the Head Cover	1.	1. Caps coverings must cover all hair, and jewellery must be removed or contained within the head.		
4. N95 Mask	3.	Cup the respirator in your hand with the nosepiece at fingertips, allowing the head straps to hang freely below hand. Position the respirator under your chin with the nosepiece up while holding the		
	4.	respirator in place, pull the top strap over your head. While continuing to hold the respirator firmly in place, pull the bottom strap over your head and position it below		
4	5.	your ears. Untwist the straps. Position the respirator low on your nose. Using both hands, mold the nosepiece to the shape of your nose by pushing inward while moving your fingertips		
Perform a user seal Check	6.	down both sides of the nosepiece. PERFORM A USER SEAL CHECK: Place both hands completely over the respirator, being careful not to disturb the position, and exhale sharply. If air leaks around your nose, adjust the nosepiece as described in step 5. If air leaks at respirator edges, adjust the straps back along the sides of your head.		









5. Face Shield	Place over face and eyes and adjust to fit.	
6.Wear Gloves	1. Wear the appropriate size. Extend to cover wrist of isolation gown.	









Doffing Personal Protective Equipment (PPE)

Standard, Contact, and Airborne precautions. Always assume that the outside of your gloves, mask, and face shield and the front and sleeves of your gown are contaminated. Use particular caution when maneuvering near your face. Remove all your PPE inside the patient room except N95 mask, it will be removed outside.

Step	Coaching Sequence	Observed		
1. Removing the Gloves	 Inspect the gloves for any torn, tears or holes. Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove. Hold removed glove in gloved hand. Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove. Discard gloves in a waste container. 			
2. Perform Hand Hygiene	Perform hand hygiene following WHO steps and adhere to proper timing (count for 5 for each step)			
3.Removing the Face Shield/googles	 Remove goggles or face shield from the back by lifting head band or ear pieces. Discard face shield in an infectious waste container. Decontaminate hands with alcohol-based hand sanitizer. 			
4. Perform Hand Hygiene	Perform hand hygiene following WHO steps and adhere to proper timing (count for 5 for each step			
5. Safely remove contaminated	1. Unfasten ties			
personal protective gowns	 Pull away from neck and shoulders, touching inside of gown only Turn gown inside out Fold or roll into a bundle and discard 			
6.Perform Hand Hygiene	Perform hand hygiene following WHO steps and adhere to proper timing (count for 5 for each step			









7. Removing N95 Mask	1.	If anti room is available remove your N95 mask in anteroom if not available then discard immediately outside patient room.	
	2.		
	3.	Lift off the top strap. Do not touch the respirator	
	4.	Discard the Mask in infectious Waste.	
8.Perform Hand Hygiene	1.	Perform hand hygiene following WHO steps and	
OR WA		adhere to proper timing (count for 5 for each	
		step).	
9. Remove the head cover	1.	Remove the head cover from behind the head to	
		front	_
10.Perform Hand Hygiene	1.	Perform hand hygiene following WHO steps and	
OR		adhere to proper timing (count for 5 for each step).	









Appendix II: Flow diagram decision tool for conscious proning process

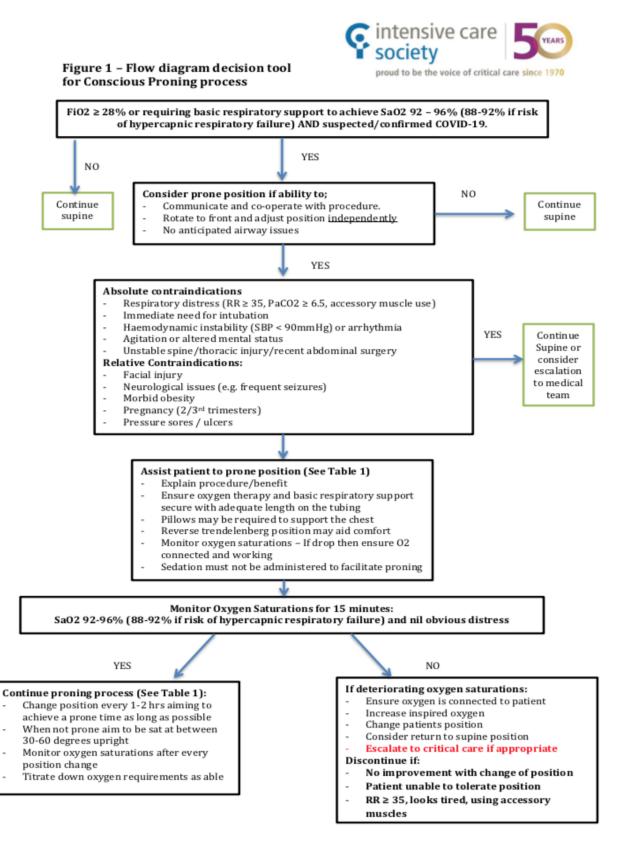






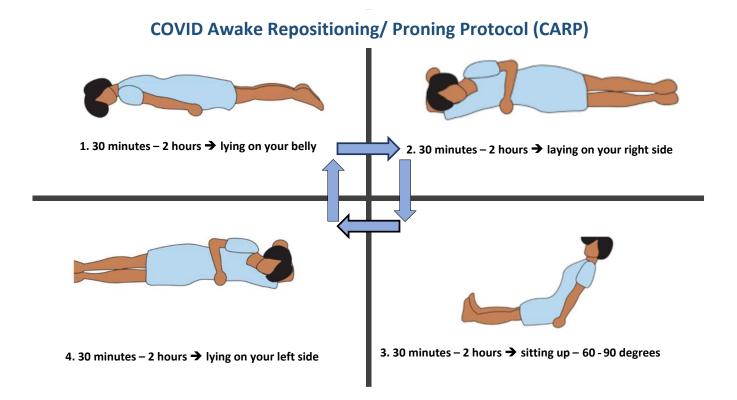




Table: Timed position changes for patients undergoing conscious proning process

If patient fulfils criteria for proning ask the patient to switch positions as follows. Monitor oxygen saturations 15 minutes after each position change to ensure oxygen saturation has not decreased. Continue to monitor oxygen saturations as per the National Early Warning Score (NEWS)

- 30 minutes to 2 hours lying fully prone (bed flat)
- 30 minutes to 2 hours lying on right side (bed flat)
- 30 minutes to 2 hours sitting up (30-60 degrees) by adjusting head of the bed
- 30 minutes to 2 hours lying on left side (bed flat)
- 30 minutes to 2 hours lying prone again
- Continue to repeat the cycle





Date/time:







Appendix III:

Informed consent to treatment with INVESTIGATIONAL medication









الموافقة المسبقة على العلاج بالأدوية التجريبية

هذا نموذج موافقة. الغرض منه هو إبلاغك بالمخاطر والفوائد عند استخدام دواء تحقيقي جديد في إدارة حالتك (كوفيد-19).

	بة التالية:	ج واحدًا أو أكثر من الأدوي	يمكن أن يشمل نظام العلاج
			مدة العلاج:
من إدارة الغذاء والدواء حتى الأن	أفهم أنه لا يوجد علاج معتمد		أناء
		<i>لي (حوفيد-19)</i> .	لعلاج مرضي المعدي الحا
، العلاج بالعقار/العقاقير التجريبية	والفعالة، أمنح موافقتي على		في ضوء النقص الحالي فا المذكورة أعلاه من قبل الفر
	قد تم شرحها لي.	الشائعة المتعلقة بالعقاقير	أقر بأن الأعراض الجانبية
			اسم المستشفى:
ع:	التوق	رقم الموظف:	اسم الطبيب:
بع:	التوق	رقم الموظف:	اسم الشاهد:
		اء) وتوقيعه:	اسم المريض (أقرب الأقرب
			التاريخ / الوقت:









Appendix: IV

Informed consent to treatment with OFF-LABEL medications

This is a consent form. Its purpose is to inform you about risks and benefits when using an OFF-LABEL drug in the management plan of your condition, covid-19 (SARS coV2 Infection)

0 0 1 7	,	,			
Any of the following treatment regimen:					
Interferon nebulization					
Favipiravir 1600 mg twice a day for 1 da	ay then 600 mg twice a day				
Interferon nebulization					
Other treatment as indicated					
Treatment duration:					
5-10 days					
I, understand medical indications with proven safety my acute infectious illness (2019 Novel	and efficacy, and they are not ap				
In view of the current lack of other safe with one or a combination of above dru	=	e my consent for being treated			
I acknowledge that possible drug-related side effects have been explained to me (drug allergy, skin rash, mild anaemia, loose motions)					
Hospital name:					
Physician name:	staff number	signature:			
Witness name:	staff number:	signature:			
Patient's name (next of kin):		signature:			
Date:	Time:				









الموافقة المسبقة على العلاج بالأدوية لغير استخدامها المعتمد

هذا نموذج موافقة. الغرض منه هو إبلاغك بالمخاطر والفوائد عند استخدام دواء لغير استخدامها المعتمد في خطة إدارة حالتك (كوفيد – 19).

	العلاج	-11:
٠	العلاج	تصام

600 ملغ يوميا	1. 11. 11. 4	l it Faut	:-::-1 COO
600 ملغ به منا	ليو ۾ الاول ٽم	Faviملغ في ا	iniravir1600

Interferon 1-Bعن طريق البخاخ

أي علاج آخر تستدعيه حالتي

مدة العلاج:

5-10يوم

i ,	. أن الأدرة الدكرة أولاء وت	دة من قول همئة الغذاء بالدياء أمكش الت	ىةأندە
ال المو وفعالية مثبتة، ولم تتم المو		دة من قِبل هيئة الغذاء والدواء لمؤشرات ي الحاد (كوفيد– 19) .	بیه احر;
		وافقتي على العلاج بواحد أو مجموعة مر	أدوية
		ساسية، طفح جلدي، فقر دم خفيف، اسم	
اسم المستشفى:			
اسم الطبيب:	رقم الموظف:	التوقيع:	
اسم الشاهد:	رقم الموظف:	التوقيع:	
اسم المريض (أقرب الأقرباء):		التوقيع:	
التاريخ:	اله قت-		









Appendix: V- Home Quarantine Consent

Undertaken to implement the home isolation/quarantine procedure

I the under-designed, declare that I was notified abou	it the health procedures and the medical advices
that I should follow, and that I am aware of the risks t	that could happen to the society in case I am not
committed to them, so for the sake of the public heal	th and to avoid the legal accountability I hereby
declare that I will not leave the house and I will consi	der not to get in contact with others as much as I
can until the required health measures end , and the	duration of the quarantine is 14 days starting from
(decided by health authority)	
This is my acknowledgment that I have been notified	of the above mentioned.
Name:	Passport / ID No.:
Mobile number:	Home address:
Number of friend/sponsor/next of kin:	Email address:
Signature:	Date:/
ات العزل أو الحجر الصحي	اقرار وتعهد بتنفيذ اجراءا
ى الصحة العامة وتجنب المسائلة القانونية اتعهد بعدم مغادرة اية الاجراءات الصحية المطلوبة وفترة الحجر الصحى لمدة 14	انا الموقع ادناه اتعهد بانه تم إبلاغي بالإجراءات الصحية والنص الممكن ان تلحق بالمجتمع في حال عدم التزامي، لذا حرصا على المنزل مع مراعاة تجنب مخالطة الاخرين قدر الامكان حتى نها يوما اعتبارا من تاريخ (تحدد
	وذلك اقرارا منى بانه تم إخطاري بما ذكر اعلاه
رقم الجواز/ الهوية الوطنية:	الاسم:
عنوان المنزل:	رقم الهاتف المتحرك:
البريد الالكتروني:	رقم أحد الأقارب أو الكفيل:
التاريخ:/	التوقيع:









Appendix:VI

Instructions for HOME Quarantine for (COVID-19)

Self- isolation for the next 14 days from the date of discharge from the hospital/clinic

- 1. Stay at home in a single room with separate washroom and separate yourself from other people in your home.
- 2. If you share any facility at home, please make sure you disinfect it thoroughly after every use with warm water and detergent then dry your items with a separate towel that only you would use
- 3. Don't go outside your room, unless its unavoidable and then wear a facemask
- 4. Cover your mouth and nose when you cough or sneeze with tissue then dispose of it immediately in a sealed plastic bag
- 5. Wash your hands frequently with soap and water for 20 seconds at least then dry them well and avoid touching your eyes, nose and mouth if you haven't washed your hands
- 6. Avoid sharing household items
- 7. Monitor your symptoms (Breathing difficulty, Fever, Sore throat, Cough, Runny nose, Headache) and check your temperature daily. (or the person you are caring for, as appropriate)
- 8. Do not have visitors in your home
- 9. If you have pets in the household, try to keep away from your pets. If this is unavoidable, wash your hands before and after contact.
- 10. Waste management: All waste that has been in contact with the individual, including used tissues, and masks if used, should be put in a plastic rubbish bag and tied when full. The plastic bag should then be placed in a second bin bag and tied.
- 11. If you need to visit your doctor, call ahead before visiting.

تعليمات الحجر الصحى المنزلي ل (كوفيد- 19)

العزلة الذاتية للأيام الـ 14 القادمة من تاريخ الخروج من المستشفى/ العيادة

- 1. ابق في المنزل في غرفة واحدة مع دورة مياه منفصلة وافصل نفسك عن الآخرين في منزلك
- إذا كنت تشارك أي مرفق في المنزل، يرجى التأكد من تطهيره جيدًا بعد كل استخدام بالماء الدافئ والمنظف، ثم جفف أغر اضك بمنشفة منفصلة تستخدمها انت فقط
 - 3. لا تخرج خارج غرفتك، إلا إذا كان ذلك لا مفر منه ثم ارتدِ كمامة
- 4. غطفمك وأنفك عند السعال أو العطس بالمنديل ثم تخلص منه فورًا في كيس بلاستيكي محكم الغلق
- 5. اغسل يديك بشكل متكرر بالماء والصابون لمدة 20 ثانية على الأقل ثم جففها جيدًا وتجنب لمس عينيك وأنفك وفمك إذا لم تخسل يديك
 - 6. تجنب مشاركة الأدوات المنزلية مع الآخرين
 7. راقب أعراضك (صعوبة التنفس، الحمى، التهاب الحلق، السعال، سيلان الأنف، الصداع) وافحص درجة حرارتك يومياً. (أو الشخص الذي تعتني به، حسب الاقتضاء)
 - 8. لا تستقبل الزوار في منزلك
 - 9. إذا كان لديك حيوانات أليفة في المنزل، حاول الابتعاد عن حيواناتك الأليفة. إذا كان ذلك لا مفر منه، اغسل يديك قبل وبعد الاتصال
- 10. إدارة النفايات: يجب وضع جميع النفايات التي كانت على اتصال مع الفرد، بما في ذلك المناديل الورقية المستخدمة والأقنعة في حالة استخدامها، فيكيس قمامة بلاستيكي وربطها عند امتلائها. يجب بعد ذلك وضع الكيس البلاستيكي في كيس آخر وربطه.
- 11. إذا كنت بحاجة إلى زيارة طبيبك، اتصل مسبقاً قبل الزيارة.

If you develop any active complaints (fever, body aches, headache, cough, throat pain or shortness of breath) during home quarantine period, please contact one of the following numbers for advice:

- o 8001717: The Operation Center, Department Of Health
- o 80011111: Ministry Of Health And Prevention
- o 800342: Dubai Health Authority









Appendix: VII drug information

For moderate to severe hepatic or renal impairment dosing, other drug interactions etc.

(Please consult the on-call pharmacist)

For further information on these medications please refer to the clinical pharmacist/pharmacist at your facility

Remdesivir:

It is an experimental broad-spectrum antiviral agent, which was synthesized and developed in 2017 as a treatment for Ebola virus infection.

In-vitro studies showed that Remdesivir can inhibit coronaviruses such as SARS-CoV and MERS-CoV replication, and against SARS-CoV-2.

Preclinical randomized, controlled, double blind trials are conducted to evaluate the efficacy and safety of Remdesivir in patients with moderate and severe COVID-19 respiratory disease.

Dosage Recommendations:

The dose which is used in these trials is 200 mg loading dose on day 1 followed by 100 mg once-daily for 9 days. Which is the same dose which was used before in Ebola Virus 2019 trial.

Administration:

IV infusion.

Monitoring:

- A baseline of:
- 1. CBC
- 2. Renal and liver functions

Common Side effects:

- Hypotension, anaphylactic shock, diarrhoea, constipation, nausea and vomiting.
- Elevated liver function tests (AST, ALT), phlebitis and headache.
- Remdesivir is co-formulated with sulfobutyl ether β-cyclodextrin (SBECD), so there is a theoretical risk of accumulation in renal failure promoting further renal injury, similar to intravenous voriconazole. Especially if creatinine clearance is < 50 ml/minute

Drug-Drug Interactions with other anti-covid-19:

No interaction documented so far.









Favipiravir

A novel pyrazine derivative, an inhibitor of influenza RNA dependent RNA polymerase that is active against influenza A, B, and C viruses, including oseltamivir-resistant variants.

A prospective study was conducted in 2019 to compare the clinical effectiveness of combined Favipiravir and oseltamivir therapy versus oseltamivir monotherapy in critically ill patients with influenza virus infection.

In this small study the results showed that the combination therapy can accelerate the recovery compared to oseltamivir alone.

In Vitro Favipiravir showed significant activity against a huge range of RNA viruses including rabies and influenza viruses.

A study of Ebolavirus-infected mice showed that Favipiravir treatment reduced viral loads and improved survival. A clinical trial in which all patients with Ebolavirus infection were given Favipiravir (6 g initially; then 2.4 g daily) showed a decrease in Ebolavirus RNA by 0.3 log10/day. (QT interval prolongation is a concern with this high dose), furthermore, the dose of 6 g loading requires 30 tablets which deems difficult to swallow.

Dosage Recommendations:

The dose regimens assessed in the combination trial were based on the approved Favipiravir regimen in Japan (two 1600 mg oral loading doses on day 1, followed by 600 mg twice daily (BID) on days 2–5) and on the higher one (1800 mg BID on day 1 followed by 800 mg BID thereafter) tested in randomized, placebo-controlled phase 3 treatment trials outside of Japan.

Clinical use of up to 3.6g on first day followed by 800mg twice daily can be considered safe according to the WHO guidelines for Ebola treatment.

The recommended dose by WHO for covid-19 is 1600 mg BID loading then 600 mg TID for 5-7 days.

Administration:

Orally.

Monitoring:

A baseline of:
 Liver functions. (Repeat after 1 week).

Common Side effects:

Transient elevation in serum alanine aminotransferase.

QT prolongation with high doses or if administered in combination with other QTc-prolonging agents such as chloroquine, hydroxychloroquine, azithromycin, metoclopramide, ondansetron, haloperidol, quetiapine ...etc)









Drug-Drug Interactions with other anti-covid-19:

Drug	Interaction			Recommendation
Paracetamol	Potential	increase	of	Observe liver function closely, if
	paracetamol I	evel by 14-16%		elevated reduce paracetamol dose.

Camostat

A serine protease inhibitor which was displayed antiviral activity in a pathogenic animal model for SARS-CoV1 infection.

It inhibits the enzymatic activity of cell-surface proteases involved in coronavirus activation. and the resultant production of inflammatory cytokines possibly through inhibition of transmembrane proteases activities.

Dosage Recommendations:

200 mg TID and adjust upon response

Administration:

Oral with meal.

Monitoring:

- A baseline of:
 - 1. CBC
 - 2. Liver enzymes.
 - 3. Electrolytes.
 - 4. Ferritin & CRP

Side effects:

Rarely GI disturbances & elevated liver enzymes

Drug-Drug Interactions with other anti-covid-19:

No interaction documented so far.

Zinc

Multiple meta-analyses and pooled analyses of randomized controlled trials (RCTs) have shown that oral zinc supplementation reduces the incidence rate of acute respiratory infections by 35%, shortens the duration of flu-like symptoms by approximately 2 days, and improves the rate of recovery.

The mechanisms by which zinc alters human susceptibility to acute lower respiratory infection likely include the regulation of pro-inflammatory cytokine secretion, lymphocyte proliferation, T lymphocyte function and protection of the integrity of respiratory epithelial cells in the setting of acute inflammatory lung injury.









Dosage Recommendations:

100 mg elemental zinc daily.

Administration:

Administer 1 hour after meal.

Side effects:

Rarely GI disturbances & elevated liver enzymes

Drug-Drug Interactions with other anti-covid-19:

No interaction documented so far.

Vitamin C (Ascorbic acid)

It acts as an antioxidant, limiting inflammation and tissue damage associated with immune response.

In six trials, orally administered vitamin C in doses of 1–3 g/day reduced the length of ICU stay by 8.6% and in three trials shortened the duration of mechanical ventilation by 18.2%.

Currently a trial using for high-dose IV vitamin C in COVID-19 patients in China is conducted and slated to be complete in the fall of 2020.

Dosage Recommendations:

Oral or IV 1-3 g daily. (For more details about IV preparation please call the pharmacist).

Administration:

Administer orally with food.

Common Side effects:

Hyperoxaluria (with high dose)

Drug-Drug Interactions with other anti-covid-19:

No interaction documented so far.