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Current News

Antiviral Remdesivir Receives U.S. Food and Drug Administration Emergency Use Authorization for the Treatment of COVID-19


Authorization Enables Broader Use of Remdesivir to Treat Hospitalized Patients with Severe COVID-19 Disease in the United States. Based on Patients' Severity of Disease, Authorization Allows 5-day and 10-day Treatment Durations.

Gilead Sciences, Inc. (Biopharmaceutical Firm) today announced that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the investigational antiviral Remdesivir to treat COVID-19. The EUA will facilitate broader use of Remdesivir to treat hospitalized patients with severe COVID-19 disease, enabling access to Remdesivir at additional hospitals across the country.

Remdesivir is authorized for the treatment of hospitalized patients with severe COVID-19 disease. The optimal duration of treatment is still being studied in ongoing clinical trials. Under the EUA, both 5-day and 10-day treatment durations are suggested, based on the severity of disease. Remdesivir remains an investigational drug and has not been approved by FDA.

Remdesivir must be administered intravenously. The optimal dosing and duration of Remdesivir for the treatment of COVID-19 is still unknown. Under this EUA, the 10-day dosing duration is suggested for patients requiring invasive mechanical ventilation and/or Extra-Corporeal Membrane Oxygenation (ECMO), and the 5-day dosing duration is suggested for patients not requiring invasive mechanical ventilation and/or ECMO.

Reference: <https://www.gilead.com/news-and-press/press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19>



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Introduction

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Message of the Chairman & Editor in Chief *Infectio*[®]

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After successful launch, of the special edition on IMNCI guidelines in collaboration with UNICEF & WHO, now we would like to convey the virtual edition on this current pandemic state for health care practitioners which will definitely help them to manage their patients and families during COVID-19.

Currently worldwide outbreak of COVID-19 has left many people with concerns about the spread of this new disease. This spread of the novel coronavirus, SARS-CoV-2, was officially defined as a pandemic by the World Health Organization (WHO), due to its sudden emergence and expansion around the world.

In this issue, we will explore the introduction of COVID-19 and learn how to save ourselves from this contagious virus. Follow Social Distancing which is an effective preventive strategy in current scenario, I am thankful to Dr. Naseem Salahuddin who explained precisely about that pandemic situation around the globe as 'A world in Shock' and also grateful to Brig (R) Prof. Waheed uz Zaman who described about the burden on humanity and importance of our priorities which needs to analyze initially in 'Changing Scenario'. Moreover we incorporated the COVID Treatment Guideline & Management algorithm provided by NIH Protocol and Government of Pakistan respectively.

We further appreciate SAMI Pharmaceuticals for their support to medical community & also would like to acknowledge the determination of the editorial board especially Prof. Col. Nasarullah Malik and other contributors of this virtual issue of Infectio magazine.

Prof. Dr. Ejaz Ahmed Vohra
Chairman Editorial Board
Dean Post graduate (Clinical)
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It is a matter of great pleasure for me to know that the next/current issue of INFECTIO is going to be devoted to COVID-19. Considering the current scenario of COVID pandemic, this is very welcome and timely decision by the editorial board

Pakistan is also going through tough time because of COVID-19, especially our health care personnel, Doctors and paramedics need to be complimented for taking up front line position in the fight against COVID-19. At the same time health care personnel need to be fully equipped with up-to-date scientific knowledge of COVID

Current issue of INFECTIO is going to be a great support to the practicing physicians of Pakistan in their fight against COVID-19 for providing scientific treatment to patients and also for protecting themselves and their families

My very best compliments to the editorial board and the publishing team of INFECTIO for their commendable job

Prof. Abdul Gaffar Billoo (Sitara-e-Imtiaz)
Editor-in-Chief
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What you need to know about coronavirus disease 2019?

Summarized by:
Prof. Ejaz Ahmed Vohra
Dr. Ziauddin University - Karachi

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What is coronavirus disease 2019 (COVID-19)?

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. The virus that causes COVID-19 is a novel coronavirus that was first identified during an investigation into an outbreak in Wuhan, China.

Can people around the world get COVID-19?

Yes. COVID-19 is spreading from person to person in different parts of the world. Risk of infection with COVID-19 is higher for people who are close contacts of someone known to have COVID-19, for example healthcare workers, or household members. Other people at higher risk for infection are those who live in or have recently been in an area with ongoing spread of COVID-19.

How does COVID-19 spread?

The virus that causes COVID-19 probably emerged from an animal source, but is now spreading from person to person. The virus is thought to spread mainly between people who are in close contact with one another (within about 6 feet) through respiratory droplets produced when an infected person coughs or sneezes. It also may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes, but this is not thought to be the main way the virus spreads.

What are the symptoms of COVID-19?

Patients with COVID-19 have had mild to severe respiratory illness with symptoms of

- **fever**
- **cough**
- **shortness of breath**

Categories of COVID-19?

- **Asymptomatic or Pre-symptomatic Infection:** Individuals who test positive for SARS-CoV-2 but have no symptoms.
- **Mild Illness:** Individuals who have any of various signs and symptoms (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal imaging
- **Moderate Illness:** Individuals who have evidence of lower respiratory disease by clinical assessment or imaging and a saturation of oxygen (SaO₂) >93% on room air at sea level.
- **Severe Illness:** Individuals who have respiratory frequency >30 breaths per minute, SaO₂ ≤93% on room air at sea level,

ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO₂/FiO₂) <300, or lung infiltrates >50%

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

What should I do if I recently traveled from an area with ongoing spread of COVID-19?

If you have traveled from an affected area, there may be restrictions on your movements for up to 2 weeks. If you develop symptoms during that period (fever, cough, and trouble breathing), seek medical advice. Call the office of your health care provider before you go, and tell them about your travel and your symptoms. They will give you instructions on how to get care without exposing other people to your illness. While sick, avoid contact with people, don't go out and delay any travel to reduce the possibility of spreading illness to others.

Is there a treatment?

There is no specific antiviral treatment for COVID-19. People with COVID-19 can seek medical care to help relieve symptoms.

Prophylaxis:

Pre-Exposure Prophylaxis

At present, no agent given before an exposure (i.e., as PrEP) is known to be effective in preventing SARS-CoV-2 infection. Clinical trials using hydroxychloroquine, chloroquine, or HIV protease inhibitors as PrEP are in development or underway.

Post-Exposure Prophylaxis

At present, no agent is known to be effective for preventing SARS-CoV-2 infection after an exposure (i.e., as PEP). Potential options for PEP currently under investigation in clinical trials include hydroxychloroquine, chloroquine, or lopinavir/ritonavir.

Diagnosis of SARS-CoV-2:

CDC recommends that nasopharynx samples be used to detect SARS-CoV-2. Nasal swabs or oropharyngeal swabs may be acceptable alternatives. Lower respiratory tract samples have a higher yield than upper tract samples, but often they are not obtained because of concerns about aerosolization of virus during sample collection procedures.

A World in Shock

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IT feels as though the earth has stopped turning. There is a pervasive sense of gloom over our disrupted lives as we wake each morning wishing for pre-pandemic times. Alas, each day is like the other, with worsening news erupting by the hour from across the globe. The graph of Covid-19 fatalities in Europe and North America climbs relentlessly, raising waves of panic. In Pakistan, three sets of counterproductive reactions are evident: blissful complacency, outright denial and stubborn defiance, while unscientific claptrap messages provoke frenzied emotions and hysteria. Here I present rational and scientific explanations to frequently asked questions.

The Influenza (flu) virus, as well as several other respiratory viruses, belong to distinct groups, although most produce similar or overlapping symptoms of fever, cough and body ache, and are diagnosed accurately only by specific and targeted laboratory tests. The novel SARS Cov-2 virus belongs to the coronavirus family and has been named Covid-19. All respiratory viruses are transmitted from one to the other through nasal secretions or sputum, but this novel coronavirus is by far the most easily transmissible and is highly virulent.

Covid-19 remains mysterious to scientists. As yet, only its general effects on the body are known, and since its structure has been identified, diagnostic tests have been developed. It will take perhaps a year or more to understand its seasonality, i.e. how it will fare in extreme climates. More confounding is whether it will make a comeback in areas where its presence has been reduced or even eliminated and, most intriguingly, whether a single attack will confer permanent immunity.

How a patient responds to any infection, be it viral or bacterial, depends upon the quantity and the potency of the microorganisms that invade the body, and the response of the defense or immunity cells of the host individual. Thus, there is an ongoing battle between the invader and the victim. Antibiotics selectively kill bacteria but not

viruses. There are proven antivirals against the AIDS virus, but none known to work definitely against Covid-19.

At present, the only way to battle the virus is to avoid it

While the epidemic raged in China and South Korea, medical literature emanating from there demonstrated that over 80 percent of patients suffered mild symptoms and recovered with no specific treatment and 14 percent were sick enough to be hospitalized; they were given empirical combinations of antimalarial, antiviral, anti-cytokine and plasma therapy. Few recovered, but it is unclear which treatment could be given credit for the cure. 5 percent were critically ill with severe pneumonia and were admitted into ICUs to receive breathing assistance on a ventilator, and nearly half of them died.



Surprisingly, European countries are reporting much higher attack and death ratios, for which various theories are being considered. When the tempest subsides we will analyze the outcome disparities, if any, between Caucasian and Asian races.

Scientists in Western countries reeling from the Covid-19 pandemic are feverishly attempting to produce a vaccine. The process of developing an effective and safe vaccine is complex, and involves several phases of trials on volunteers; after receiving the trial vaccine, the antibody levels in their blood will be assayed over several months while they are observed for side effects. If all goes well, the trial will proceed to the next phase and more people will be tested. Barring unacceptable complications in volunteers, production will speed up. However, making enough doses for 7.3 billion people around the globe is a daunting challenge, hence the most vulnerable population will be prioritized. Assuming all hurdles are crossed, it is only realistic to expect that the vaccine will not be deployed before late 2021. By then, Covid-19 may have vanished, or we may have developed mass immunity

As treatment and vaccine are still distant visions, the only way to escape the virus is to avoid it by physically distancing oneself from obviously infected persons and even symptomless carriers. Like Russian roulette, only chance picks the next victim. Practicing strict personal and environmental hygiene is always good for preventing all infectious disease. In the time of Covid-19, you cannot be overcautious.

Compounding the issue are idle people who while away time making outlandish predictions and spouting baseless remedies that, with a click of the finger, spread around the world faster than the coronavirus itself, preying upon vulnerable minds.

Eight Do's and Don'ts During the COVID-19 Pandemic

		Keep a distance of at least 1.5 m between yourself and others.			Don't shake hands. Greet others with a wave, a nod or a bow.
		Cover your mouth and nose with a tissue or your elbow when you cough or sneeze.			Wash your hands frequently with soap and water for at least 20 seconds.
		Avoid unnecessary social contact. Stay at home.			Don't buy more than you need. Offer your help to others.
		If you develop flu-like symptoms, get in touch with your doctor by phone before going to his or her office.			When staying at home, try to keep calm. Be supportive and kind.

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Reference: meta.m.wikimedia.org/wikipedia/commons/14/hegasy_COVID19

COVID-19: Social Distancing



Social distancing actions are taken to restrict when and where people can gather to stop or slow the spread of coronavirus disease (COVID-19) or other infectious diseases in communities. Social distancing actions include limiting large groups of people coming together, closing buildings or canceling events.

Protect yourself and your community

Wash your hands often with soap and water for at least 20 seconds, especially after going to the bathroom, before eating, and after blowing your nose, coughing or sneezing. If you don't have soap or water, use an alcohol-based hand sanitizer with at least 60 percent alcohol. Avoid close contact with people who are sick and stay home when you're sick.



Change your daily habits

Avoid shopping at peak hours and take advantage of delivery or pick-up services with retailers.



Work with your employer

Cooperate with leadership to change company practices, set up flexible shift plans, have employees telecommute, and cancel large meetings or conferences.



Universities and colleges

Consider suspending on campus classes, implementing web-based learning and canceling large campus meetings and gatherings.



Keep at least six feet between you and others.

Avoid shaking hands as a social greeting.



Public transit

Avoid public transit if possible and don't travel to areas with active outbreaks.

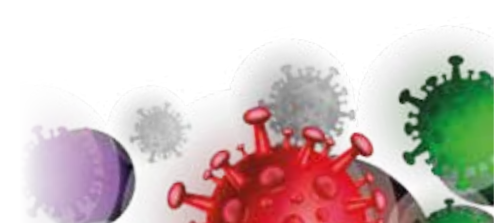


Crowded places

Avoid crowded places. Events with 1,000 or more people have been canceled. Community events with 250 or more recommended be canceled or postponed. Major sports events are canceled.



Reference:
www.dph.illinois.gov



COVID-19: Changing Scenario



Brig (R) Professor Waheed uz Zaman Tariq
Departmental Head, Infectious Diseases
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The Novel Coronavirus-19 is now named SARS CoV-2 and is now everywhere in the world. If any corner is free from it, is not clearly known to anybody. It has played havoc in many countries and west European countries and North American nations are going through one of the worst test of time, despite their affluence, scientific knowledge, and technological advancement. The economies are crumbling and airlines are at standstill. The current pandemic has led to the confessional debates about the serious matters pertaining to the Virology, Medical Sciences, Public Health, Economy, Social Development, Communications, Budgets, and Defense. Furthermore, it had reshaped the Foreign Policies, Trade and Strategic Outlook of many regions. The poor nations have to choose between hunger and disease. The poverty struck nations cannot maintain a social order with no activity.

Whatever we have achieved in Pakistan was due to concerted efforts of the functionaries of the government; whether in civilian dress or in uniform. All worked hard and planned after a lot of brain-storming. The progress of the disease was slowed down and we received lesser corona cases so far than many other nations in that scale of time. A lot of resources were consumed and we did much at the expense of other projects.

All other diseases, elective surgeries, OPDs, and clinics were neglected and people talked of Coronavirus only. Our young enthusiastic medical and paramedical staff was vulnerable and many of them acquired the disease, with occasional deaths. The test kits were procured but the hard reality was the lack of existing infrastructure for virologic diagnosis and interpretation. The Personal Protective Kits were procured but late and, in less quantity, and there was a problem of the release of stock. We did not have enough ventilators and specialized units. Even then all worked and the wheel was rolling despite a lot many difficulties.

So far so good but the situation is fast changing. At times fatigue is visible in the system and the infected medical and paramedical staff is

becoming unavailable for their duties. The systems are overloaded. The disease itself is a taboo and all infected people might not be brought to the hospitals and many of them dying outside the specialized units. There is a fear that we may be seeing the tip of iceberg and the situation may be more serious than what we perceive. Indeed, the percentage of positive test results is increasing and it looks as if the problem is becoming more serious and may be in next few days it may really be a test of our nerves.

It is happening when the public attitude is showing complacency and social distancing is not respected anymore. With more cases and exhaustion of available personnel and monetary resources, we may be heading towards a disaster.

The policy makers are confused, the external and internal debts are becoming unmanageable and the agencies involved in law and order are under pressure of work. They are doing their job day and night. Physical factors of their workers are to be kept in mind. The system is overstretched. Obviously, under such situation political rigmarole changes and excuses start converting into blame games. After eighteenth amendments the federal units have much leverage and they may change the language the way it suits to them.

The workers and expatriates are stranded. They need repatriation and we lay much emphasis on quarantine and their potential threat to bring in the virus. The quarantine worked when our country was free from the virus and visitors from highly affected countries were kept at bay for two weeks. Now we have the indigenous foci of disease and locally acquired cases. There is a question asked to the philosophy of quarantine and its benefit. Home quarantine works very little in poor quarters of the country and affluent people do socialize despite the honest advice of authorities.

Treatment Guidelines for patients with COVID-19

Labs Indicating Severe Disease

- D-dimer >1000
- CPK > 2x ULN
- CPR > 100
- LDH > 245
- Troponin elevated/up-trending
- Abs lymphocyte count < 0.8
- Ferritin > 300

Diagnostics

Daily Labs

- CBC with diff (trend lymphocyte count)
- CPK
- Abs lymphocyte count < 0.8
- Ferritin > 300

Risk Start Q2-3 Day PRN

- D-dimer
- Ferritin/CRP/ESR
- LDH
- EKG
- NO ROUTINE DAILY CXR

Hemodynamics

- Norepinephrine first choice pressor
- If WORSENING:
- Consider myocarditis/ Cardiogenic shock
- Obtain echo, EKG, troponin

Therapeutic Options for COVID-19

At present, no drug has been proven to be safe and effective for treating COVID-19. Recommended clinical management of patients with COVID-19 includes infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated. As in the management of any disease, treatment decisions ultimately reside with the patient and their health care provider.

Antivirals:

- There are insufficient clinical data to recommend either for or against using chloroquine or hydroxy chloroquine for the treatment of COVID-19 (AIII).
- If chloroquine or hydroxychloroquine is used, clinician should monitor the patient for adverse effects, especially prolonged QTc interval (AIII).
- There are insufficient clinical data to recommend either for or against using the investigational antiviral drug remdesivir for the treatment of COVID-19 (AIII).
- **Remdesivir** as a treatment for COVID-19 is currently being investigated in clinical trials and is also available through expanded access and compassionate use mechanisms for certain patient populations.
- **Favipiravir (Avigan)** used in Japan & under trial in Pakistan **PROTECT study** (UHS, Lahore)
- The combination of hydroxychloroquine plus azithromycin (AIII) because of the potential for toxicities.

Host Modifiers/Immune-Based Therapy:

- There are insufficient clinical data to recommend either for or against the use of convalescent plasma or hyperimmune immunoglobulin for the treatment of COVID-19 (AIII)

Care of Critically Ill Patients with COVID-19

Infection Control:

- For health care workers who are performing aerosol generating procedures on patients with COVID-19, the COVID-19 Treatment Guidelines Panel (the Panel) recommends using fit-tested respirators (N-95 respirators) or powered air-purifying respirators rather than surgical masks, in addition to other personal protective equipment (i.e., gloves, gown, and eye protection such as a face shield or safety goggles) (AIII).
- The Panel recommends that endotracheal intubation for patients with COVID-19 be done by health care providers with extensive airway management experience, if possible (AIII).

Ventilatory Support:

- For adults with COVID-19 and acute hypoxemic respiratory failure despite conventional oxygen therapy, the Panel recommends high-flow nasal cannula (HFNC) oxygen over noninvasive positive pressure ventilation (NIPPV) (BI).
- In the absence of an indication for endotracheal intubation, the Panel recommends a closely monitored trial of NIPPV for adults with COVID-19 and acute hypoxemic respiratory failure for whom HFNC is not available (BIII).
- For adults with COVID-19 who are receiving supplemental oxygen, the Panel recommends close monitoring for worsening of respiratory status and recommends early intubation by an experienced practitioner in a controlled setting (AII).
- For mechanically ventilated adults with COVID-19 and acute respiratory distress syndrome (ARDS), the Panel recommends using low tidal volume (Vt) ventilation (Vt 4-8 mL/kg of predicted body weight) over higher tidal volumes (Vt > 8 mL/kg) (AI).
- For mechanically ventilated adults with COVID-19 and refractory hypoxemia despite optimized ventilation, the Panel recommends prone ventilation for 12 to 16 hours per day over no prone ventilation (BII).
- For mechanically ventilated adults with COVID-19, severe ARDS, and hypoxemia despite optimized ventilation and other rescue strategies, the Panel recommends a trial of inhaled pulmonary vasodilator as a rescue therapy; if no rapid improvement in oxygenation is observed, the patient should be tapered off treatment (CIII).

Drug Therapy:

- There are insufficient data for the Panel to recommend either for or against any antiviral or immunomodulatory therapy in patients with severe COVID-19 disease (AIII).
- In patients with COVID-19 and severe or critical illness, there are insufficient data to recommend empiric broad-spectrum antimicrobial therapy in the absence of another indication (BIII).
- The Panel recommends against the routine use of systemic corticosteroids for the treatment of mechanically ventilated patients with COVID-19 without ARDS (BIII).
- In mechanically ventilated adults with COVID-19 and ARDS, there are insufficient data to recommend either for or against corticosteroid therapy in the absence of another indication (CI).

Reference:

1. COVID-19 Management Guidelines 2020/Pakistan Chest Society
2. NIH. Gov/COVID-19

Safe Ramadan practices in the context of the COVID-19



Summarized by:
Prof. Ejaz Ahmed Vohra
Dr. Ziauddin University - Karachi

Background

The holy month of Ramadan is marked by social and religious gatherings where Muslim families and friends unite to break their fast together, after sunset during iftar or before dawn during suhour. Many Muslims increase their attendance at mosques during the month and congregate for longer prayers for taraweeh and qiyam. Some Muslims also spend consecutive days and nights at mosques during the last 10 days of Ramadan (i'tikaf) for prayers. These traditional and religious practices are regularly observed throughout the month. This year Ramadan falls between late April and late May as the COVID-19 pandemic continues.

The transmission of COVID-19 is facilitated by close contact between people, as the virus is spread through respiratory droplets and contact with contaminated surfaces. To mitigate the public health impact, several countries have implemented physical distancing measures aimed at interrupting transmission by reducing interaction between people. These measures are fundamental control mechanisms to control the spread of infectious diseases, particularly respiratory infections, associated with large gatherings of people. Physical distancing measures, including the closing of mosques, monitoring of public gatherings and other restrictions on movement, will have direct implications for the social and religious gatherings central to Ramadan.

Informed decision making for conducting religious and social gatherings

Cancelling social and religious gatherings should be seriously considered. WHO, therefore, recommends that any decision to restrict, modify, postpone, cancel, or proceed with holding a mass gathering should be based on a standardized risk assessment exercise. These decisions should be part of a comprehensive approach taken by national authorities to respond to the outbreak. If cancelling social and religious gatherings, where possible, virtual alternatives using platforms such as television, radio, digital, and social media can be used instead. If Ramadan gatherings are

allowed to proceed, measures to mitigate the risk of COVID-19 transmission should be implemented.

Advice on physical distancing

- Practice physical distancing by strictly maintaining a distance of at least 1 metre (3 feet) between people at all times.
- Use culturally and religiously sanctioned greetings that avoid physical contact, such as waving, nodding, or placing the hand over the heart.
- Stop large numbers of people gathering in places associated with Ramadan activities, such as entertainment venues, markets, and shops.

Advice to high-risk groups

- Urge people who are feeling unwell or have any symptoms of COVID-19 to avoid attending events and follow the national guidance on follow-up and management of symptomatic cases.
- Urge older people and anyone with pre-existing medical conditions (such as cardiovascular disease, diabetes, chronic respiratory disease, and cancer) not to attend gatherings, as they are considered vulnerable to severe disease and death from COVID-19.

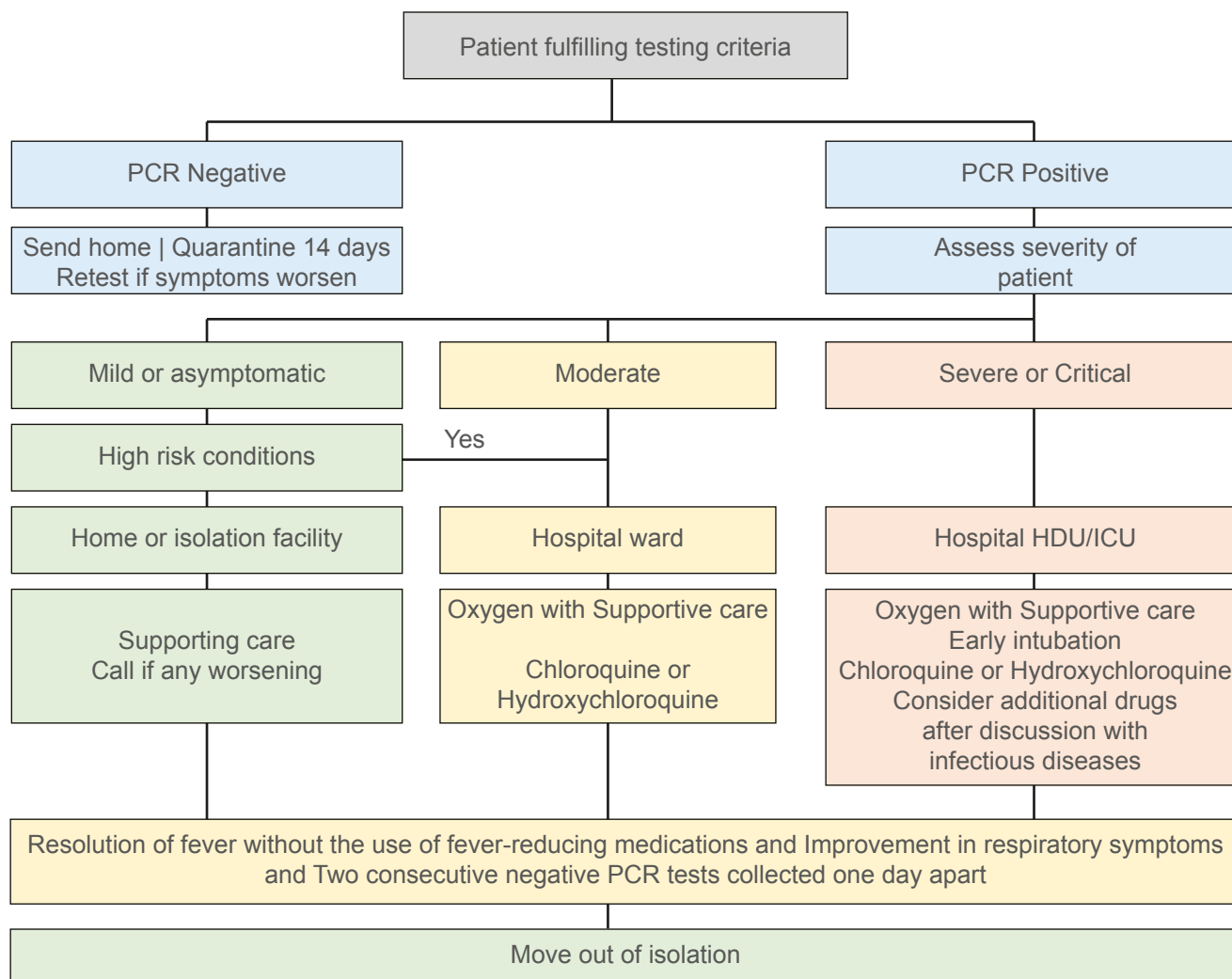
Mitigation measures for physical gatherings

- The following measures should be applied to any gathering occurring during Ramadan, such as prayers, pilgrimages, and communal meals or banquets.

Venue

- Consider holding the event outdoors if possible otherwise, ensure that the indoor venue has adequate ventilation and air flow
- Shorten the length of the event as much as possible to limit potential exposure
- Give preference to holding smaller services with fewer attendees more often, rather than hosting large gatherings
- Adhere to physical distancing among attendees, both when seated and through

Summary Algorithm of COVID-19 Management




Reference:



Quiz (Choose the correct answer)

Choose the best possible statement regarding COVID-19

- a) It can easily spread by speaking
- b) Frequently touched objects are the main source
- c) Mask is required, while walking in streets, roads
- d) Disinfection tunnels are useful in prevention
- e) Meditation/prayers should be discouraged in this pandemic

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