V 11.2

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الحملة الوطنية
لمكافحة
فيروس كورونا
(COVID-19)

مَمْلَكَةُ البَحْرَيْن
KINGDOM OF BAHRAIN

Bahrain COVID-19 National Protocols

Disclaimer:

- This protocol was prepared and approved by The National Taskforce for Combating the Coronavirus COVID-19 – NTCC19
- These recommendations will be changed frequently based on available evidence about the best practices in caring for novel Coronavirus 2019 (COVID-19) disease

Table of Content

	Protocol	Page Number
1	COVID-19 Case Definitions	3 to 4
2	Visual Triage checklist for healthcare facilities	5 to 6
3	COVID-19 Risk Assessment and Stratification	7 to 9
4	COVID-19 Testing Protocol	10 to 21
5	Testing strategy for COVID-19 in High-Density Workplace	22 to 29
6	Vaccination status categorization	30 to 31
7	Travelers Protocol	32 to 35
8	Admissions of COVID-19 Patients	36 to 37
9	COVID-19 Patient Allocation	38 to 39
10	Readmission guidelines for post-COVID19 cases	40 to 41
11	Home isolation Protocol	42 to 45
12	Discharge Protocol and follow up guidelines	46 to 49
13	Outpatient and follow up guidelines	50 to 52
14	Return to Work	53 to 55
15	Reporting COVID-19 Death	56 to 62
16	Guidance for management of Neonates born to Mothers with Suspected or Confirmed COVID-19 Infection	63 to 65
17	Treatment Guidelines and Pathways	66 to 88
18	COVID-19 Multisystem Inflammatory Disease in Children	89 to 95
	Appendix	96 to 115

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COVID-19 Case Definitions

COVID-19 Case Definitions

Suspected Cases

A **suspected case** is a person that fulfill **any** of the following

1. **Any Symptoms of Fever, Cough , Shortness of Breath, loss of smell or taste, or Gastrointestinal symptoms**
2. **Acute respiratory illness with or without fever**
3. **Any patient with community acquired pneumonia requiring admission**
4. **Any admitted inpatient with unexplained severe acute respiratory infection (SARI)**
5. **Contact with a positive case with *SARS-CoV2*, with or without symptoms**
6. **History of Travel, with or without symptoms**
7. **Any case fitting definition of Multisystem inflammatory syndrome in children** (page 78)

Note :
- False Negative results can be seen early during the infection. Peak of viral shedding appears 3 to 5 days after the onset of disease.
- If the nucleic acid test is negative at the beginning, and case is suspected, to test on subsequent days.

Contact Cases

A **contact** is a person that belongs to either of the two defined groups

There are two types of contact cases

1 - Close Contact (High Risk Exposure), any of the following

1. A person living in the same household as a COVID-19 case
2. Had direct physical contact with a COVID-19 case (e.g shaking hands, infectious secretions of a COVID-19 case)
3. Had face-to-face contact with a COVID-19 case within 2 metres and > 15 minutes or cumulative total of 15 minutes or more over a 24-hour period starting from **2 days** before illness onset or positive test)
4. Was in a closed environment (e.g. classroom, meeting room, hospital waiting room, etc.) with a COVID-19 case for 15 minutes or more and at a distance of less than 2 metres
5. A healthcare worker (HCW) or other person providing direct care for a COVID-19 case, or laboratory workers handling specimens from a COVID-19 case without recommended PPE or with a possible breach of PPE;
6. A contact in an aircraft sitting within two seats (in any direction) of the COVID-19 case, travel companions or persons providing care, and crew members serving in the section of the aircraft where the index case was seated (if severity of symptoms or movement of the case indicate more extensive exposure, passengers seated in the entire section or all passengers on the aircraft may be considered close contacts).

2 - Casual Contacts (Low Risk Exposure)

Casual contact defined as any of contacts not listed in the close contacts, examples such as:
- Had casual contact with an ambulant COVID-19 case
- Had casual contact with presumptive (not confirmed) COVID-19 case
- Had stayed in an area presumed to have ongoing, community transmission

https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/

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Visual Triage checklist for healthcare facilities

For early detection and isolation of suspected cases in any outpatient healthcare facility

Visual triage checklist

- Visual triage is to be used at Health Centres, A/E, Private Clinics and any Outpatient healthcare setting.
- Visual triaging is to be done on entry of patients, in order to early identify suspected cases and to isolate early if necessary

Risks	Score
A. Exposure risk	
Contact with a confirmed case of COVID19 in the last 14days prior to symptoms onset OR Lived or worked in a facility known to be experiencing an outbreak of COVID-19 in the last 14days prior to onset of symptoms	3
B. Clinical Signs and Symptoms	
Fever or recent history of fever	4
Cough (new or wrosening)	4
Shortness of breath (new or wrosening)	4
Headache, sore throat or rhinorrhea	1
Nausea, vomiting and/or diarrhea	1
Chronic renal failure, Chronic heart disease, immunocompromisded patient	1
Total Risk Score (A +B)	

If score of ≥4, isolate patient, ask to wear a mask, inform physician for assessment and call 444

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فيروس كورونا
(COVID-19)

COVID-19 Risk Assessment and Stratification

444 phone risk assessment for symptomatic suspected COVID-19 cases

Sign and Symptoms	Routine Care (test within 72hrs)	Intermediate Care (test within 24hrs)	Urgent Care (Act Immediately)
Sore thorat and flu like symptoms	✓	Patient wth the the following risk factors regardless the presence of symptoms (excluding "Urgent care*" symptoms) Risk factors include **ANY** of the following • Diabetes • Hypertension • Heart disease • Lung disease • Malignancy • Age>60 years	-
Loss of Smell or Taste	✓		-
Myalgia	✓		-
Fatigue	✓		-
Fever*	Less than 38°C		**≥38°C**
Shortness of Breath*	-		✓
Chest Pain*	-		✓
Respiratiry Rate >30*	-		✓
Change in Mental Status*	-		✓
Oxygen Saturation*	Normal		**≤93% on Room Air**

COVID-19 Risk Assessment for confirmed or suspected COVID-19 Cases

Sign and Symptoms	Mild: Home isolation *(refer to home isolation protocol)* or Isolation facility admission	Moderate to Severe: Transfer to Treatment facility
Sore thorat and flu like symptoms Loss of Smell or Taste Myalgia and Fatigue GI Symptoms	✓	-
Fever	Less than 38°C	**≥38°C with either one of the below**
Shortness of Breath	X	✓
Chest Pain	X	✓
Change in Mental Status	X	✓
Respiratiry Rate >30	X	✓
Saturation	Normal	**Saturation ≤93% on Room Air**
Chest Xray changes	Normal	**Changes suggetsive of pneumonia**

If patient revisit a clinic more than once with symptoms suspecting COVID-19, regardless of swab result, patient should be referred to A/E for evaluation, assessment and testing

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COVID-19 Testing Protocol

COVID-19 Molecular, Serology and Antigen Tests

Testing categories for SARS-CoV2

- Three types of tests are available : Molecular (PCR), Serology (Antibody test) and Antigen tests

1. Molecular (PCR) tests the presence of Viral nucleic acid, it indicates the presence of the virus
2. Serology tests the presence of antibodies against the virus, and it indicates previous infection
3. Rapid Antigen detection test (RADT), detects the presence of viral proteins

Acceptable Specimens

Molecular and RADT nasopharyngeal swab, mid-turbinate swab, anterior nasal swab, saliva

Serology : blood

Molecular testing is the main national testing strategy in the Kingdom of Bahrain to diagnose COVID19

Testing categories for SARS-CoV2

1. Molecular testing (ie Viral testing by PCR)

- Two methods are available : RT-PCR and Xpert Xpress SARS-CoV 2

- When to test using Molecular assays ?
  1. Acute Care Hospitals/ Emergency Departments or COVID19 centers
     1. All symptomatic suspected cases presenting to a healthcare facility
     2. Patients who are seeking hospitalization for non-COVID related symptoms, in the following high risk group
        - Immunosuppressed or undergoing chemotherapy
        - Elderly with comorbidities
     3. Patients undergoing aerosol-generating surgical or non-surgical interventions
        - Surgical procedures like neurosurgery, ENT surgery, dental procedures; Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis
  2. Public health department directed testing
     1. Contact Tracing – Close Contacts
     2. Regular screening of healthcare workers in COVID19 facilities and other certain workplace settings
     3. Random testing for targeted subpopulations

Testing for CLOSE CONTACTS of COVID-19 cases

Close Contacts that are Green shield carrier

حاصل على التطعيم
COVID-19 Vaccinated

حاصل على التطعيم
COVID-19 Vaccinated

غير حاصل على التطعيم
Not Vaccinated

- Quarantine required for 7 days
- NP RT-PCR Test on Day 1 followed by an exit swab on day 7

Close Contacts that are Green shield carrier

متعافي
Recovered

حاصل على التطعيم
COVID-19 Vaccinated

- No quarantine required
- NP RT-PCR Test on Day 1 followed by an exit swab on day 7

Testing for suspected COVID-19 cases in governmental and private hospitals and clinics

Inpatient Suspected Case

As per COVID-19 case definition

1. **Immediate isolation**
2. **Collect Nasopharyngeal swab**
3. **PCR testing of NP swab**
4. **If positive, inform 444 and arrange transfer to COVID-19 facilities**
5. **If negative, continue usual inpatient care**

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6. **History of Travel, with or without symptoms**
7. **Any case fitting definition of Multisystem inflammatory syndrome in children (page 78)**

Note :

- False Negative results can be seen early during the infection. Peak of viral shedding appears 3 to 5 days after the onset of disease.
- If the nucleic acid test is negative at the beginning, and case is suspected, to test on subsequent days.

BACK

Healthcare providers (HCP) and Laboratory personnel COVID-19 testing protocol

The following procedures apply to all HCP and lab personnel exposed to positive/suspected COVID19 cases

High Risk

Defined as prolonged (15min) close contact without recommended PPE
Exposure during the performance of an aerosolizing procedure without recommended PPE

1. Isolate and test for COVID-19 and wait for result
2. HCP working in COVID-19 facilities can undergo testing in their facility. Otherwise, can be tested in testing center
3. If positive, admit in isolation facility/Home isolation
4. If negative*, home isolation 10 days
5. Retest at the end of the isolation period before going back to work

If the PCR test is negative, and case is suspected, to test on subsequent days*.

If the exposed HCW is a recovered case, follow close contact testing in page 13

Low Risk

Defined as exposure other than high risk, without recommended PPE

1. Isolate and test for COVID-19 and wait for result
2. HCP working in COVID-19 facilities can undergo testing in their facility. Otherwise, can be tested in testing center
3. If positive, admit in isolation facility/Home isolation
4. If negative* and asymptomatic, can return to work with extra safety precautions (face mask and daily symptoms assessment for 10 days).
5. If negative* and symptomatic, home isolate until symptoms resolve for 24hrs and retest, if negative can return to work with daily RADT for 10 days from last exposure.

*If the PCR test is negative, and case is suspected, to test on subsequent days.

If the exposed HCW is a recovered case, follow close contact testing in page 13

- * IN CASE OF THE INABILITY TO PROVIDE SAFE PATIENT CARE DUE STAFF SHORTAGE, any HCP with history of exposure and is asymptomatic can managed as the low-risk pathway. Daily RADT checking and recording of symptoms for 10 days from last exposure . In case of any symptoms appear, immediately isolate and retest. If negative, HCP can return to work when asymptomatic for at least 24hrs **REFERENCE**
- All HCP should report any symptoms or unprotected exposure to confirmed cases of COVID19, to their designated department and 444

All healthcare providers caring for COVID19 positive cases should undergo molecular test for COVID-19 by NP swab or RADT **every 7 days in their facilities, EXCEPT for Recovered HCW, who should undergo monthly serological testing during the first 3 months from their initial confirmed COVID19 diagnosis. After 3 months period or if negative antibody, HCPs should go back for weekly PCR testing** or RADT testing**.** Results are to be traced by the facility supervisor

Testing for Prison Personnel and Inmates

General Recommendations

- Encourage good hygiene by education and posters
- Increase the frequency of cleaning lavatories
- Distribution of hand sanitizers and tissues in the building
- Strict procedure to prevent animals entering the prison site

Prison

Symptomatic Inmates/Staff

- Isolate immediately
- Take nasopharyngeal swab and send to lab for PCR testing
- Inform 444/War room
- If positive, to arrange transfer to isolation facility

Prison Guard & Staff

- Daily checking of temperature and symptoms
- Encourage self reporting of close contact to COVID-19 cases
- Test any staff who fits the criteria for testing, based on case definitions
- Encourage use of rapid antigen detection test as screening tool (Page 23)

Testing categories for SARS-CoV2

2. Serology

- National Taskforce for combating COVID -19 does not currently recommend using antibody testing as the sole basis for diagnosis of acute infection
  - Antibody tests are not authorized by FDA for diagnostic purposes until this date
- Antibodies start developing within 1 to 3 weeks after infection
  - IgM and IgG antibodies arise nearly simultaneously and its uncommon to detect IgM alone
- Positive antibody test indicates a person has been infected with *SARS-CoV-2* in the past.
  - It does not necessarily mean they are currently infected (based on current available evidence)
  - False positive result can be expected in a population with low prevalence of COVID-19 (<5% of the population affected)
  - Serologic tests may NOT be used routinely at this time to determine if an individual is immune, until more evidence becomes available
  - It is currently not clear whether a positive serologic test indicates immunity against *SARS-CoV-2*
- Serologic assays may be used to support clinical assessment of a person who present late in their illness, in conjunction with viral molecular tests

Serology Surveillance Testing Strategy

COVID19 serology survillance startegy invloves two pouplations

Recovered COVID-19 Patients	NO previous COVID-19 diagnosis
• Any patient who <u>was</u> infected with SARS-CoV2 Diagnosis made since 10 days or **<u>longer</u>**	• Never tested for COVID19 or tested negative for COVID-19

1. Collect venous blood sample in designated centres
2. Enter serology request with patient required information
3. Send Sample to BDFRMS lab; where it will be recieved and processed
4. Result available in BDF-RMS External Portal accesible to all healtcare facilities

Antibody result <u>reactive</u> → Reassure, consider for **plasma donation**

Antibody result non-reactive → Reassure , no action needed & repeat after 2 weeks from last non-reactive result

Antibody result <u>reactive</u> → Perform NP swab for PCR test, **only if <u>Symptomatic</u>**

- ✓ if PCR negative: Indicates Past exposure ; or need further clinical assessment for his current symptoms
- ✓ If PCR Positive: Active infection, proceed as per protocol

Antibody result non-reactive → Reassure

Testing categories for SARS-CoV2

3. Antigen Test

- Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection.
- Antigen tests are currently authorized to be performed on nasopharyngeal or nasal swab specimens
- The currently NHRA authorized devices return results in approximately 15-20 minutes
- Antigen tests for SARS-CoV-2 are generally less sensitive than molecular tests
- The clinical performance of rapid antigen diagnostic tests largely depends on the circumstances in which they are used
- Rapid antigen tests perform best when
  1. The person is tested in the early stages of infection with SARS-CoV-2 usually within 7 days of symptom onset
  2. The person has a known exposure to a confirmed case of COVID-19
  3. Can be used for screening testing in high-risk congregate_settings in which repeat testing could quickly identify infectious individuals with SARS-CoV-2

Testing categories for SARS-CoV2

3. Antigen Test

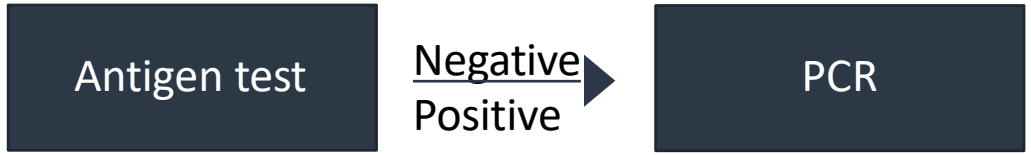
Interpretation of results

- Positive antigen results should be confirmed by PCR

- Negative results do not rule out SARS-CoV-2 infection
  - Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
  - They should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
  - In the presence of a high pretest likelihood, a negative test should warrant a repeat PCR test , especially if the patient is symptomatic or has a known exposure to a person confirmed to have COVID-19

Rapid Antigen Detection Tests Interpretation

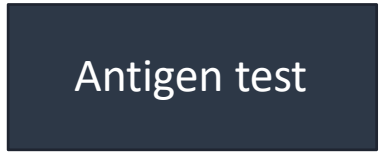
- **For Symptomatic* individuals:**



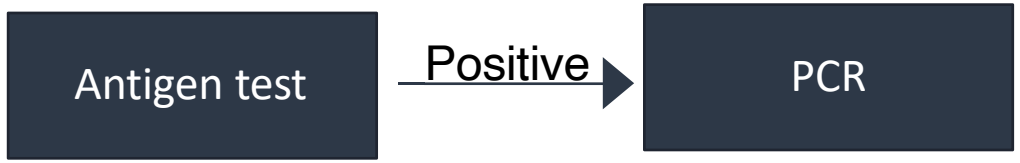
- All Symptomatic individuals should be isolated
- If PCR positive, case is confirmed
- if PCR negative, repeat PCR test after 24hr continue self isolation and follow result

***High pre-test probability for SARS CoV2 infection: known contact, very symptomatic, high community transmission) should do Rt PCR and advised to be assessed by physician.**

- **For Asymptomatic individuals/ No known history of contact:**



Negative, Stop



- If PCR positive, case is confirmed
- If PCR negative, repeat PCR test after 24hr continue self isolation and follow result

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(COVID-19)

Testing strategy for COVID-19 in High-Density Workplace

High-Density Workplaces Outbreak Control Measures

With the introduction Of Rapid Antigen Detection Tests (RADT)

1. Positive cases were moved to isolation centers
2. All close contacts were quarantined in quarantine facilities
3. Other workers living in the camp could work under supervision given RADT were done daily for 10 days from the last exposure to the positive case

- Buildings were not locked down.
- This have allowed continuity of work while ensuring adequate testing and safety.

High-Density Workplaces ***Surveillance*** Measures

High density locations like ***prisons, labourers accomodations and camps*** are breeding grounds for the spread of the virus, as such decisive preventative action needs to be taken.

Rapid antigen tests have proven their efficiency both in cost and early detection, thus we recommend that rapid antigen testing should conduct in such locations at least 3 times a week. As these locations pose a great risk for outbreaks.

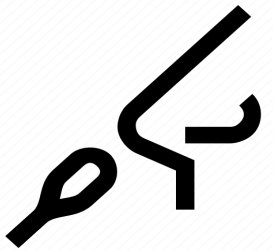
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Rapid Antigen Test		Rapid Antigen Test		Rapid Antigen Test		

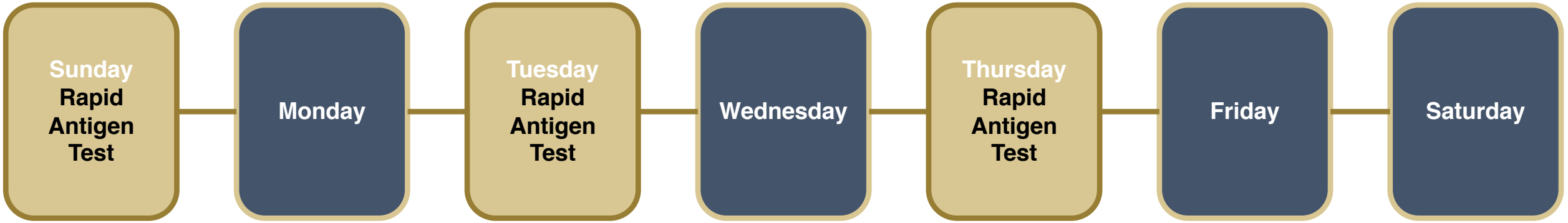
Alternatively, PCR or Antibody testing in such locations can be used as surveillance tool

School **Surveillance** Measures

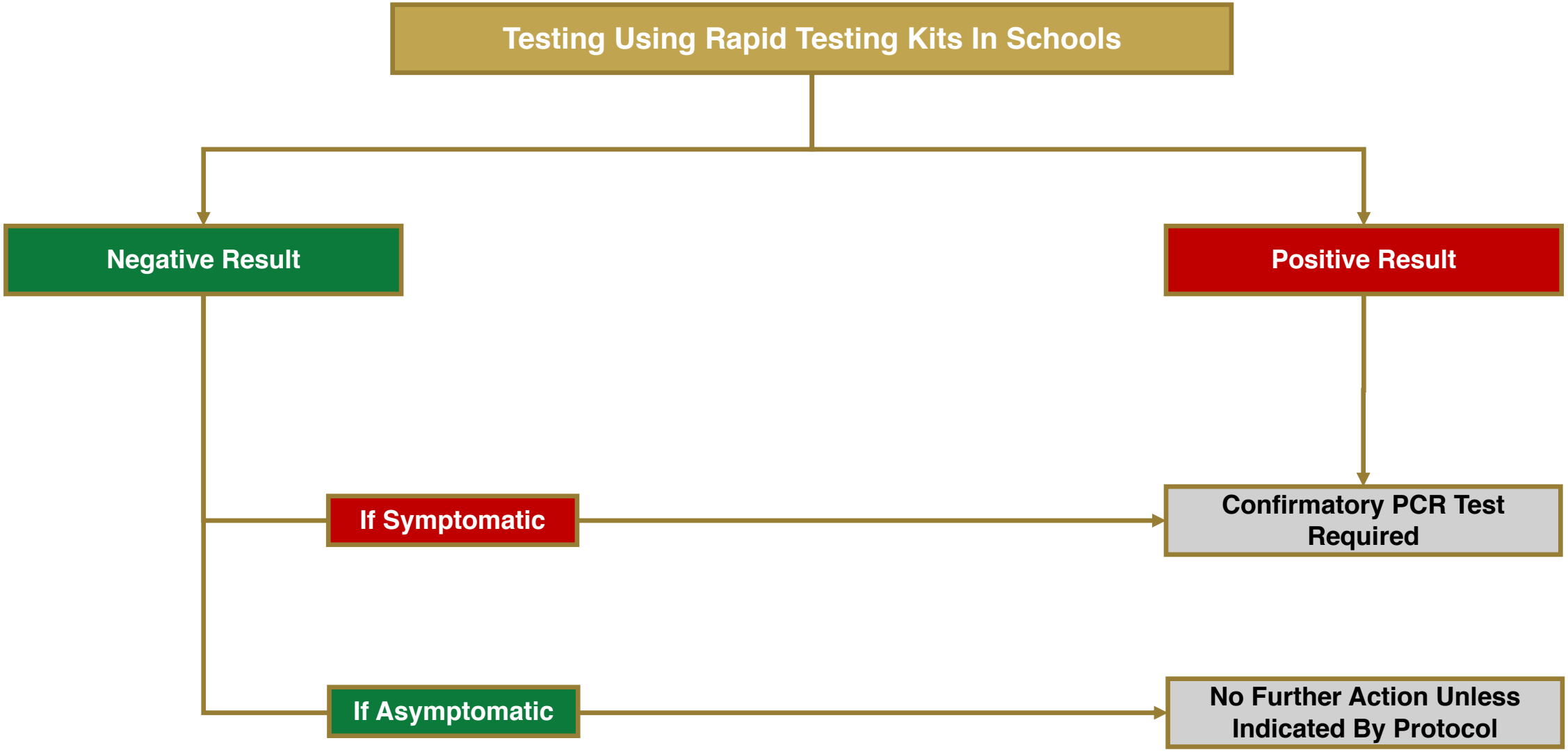
Following the good outcomes in the trial, the RADT was used in all schools and the test was done by the school staff:

- **The RADT can be deployed in all schools for attending students and staff**
- **The RADT is preferably done on Sunday Tuesday and Thursday**
- **This allows early detection of cases and keeping schools safe**
- **This also provides reassurance to families and teachers**





Schools Protocol



Bahrain Sports Model

Bubble group training

Three times weekly antigen surveillance test for all players and staff

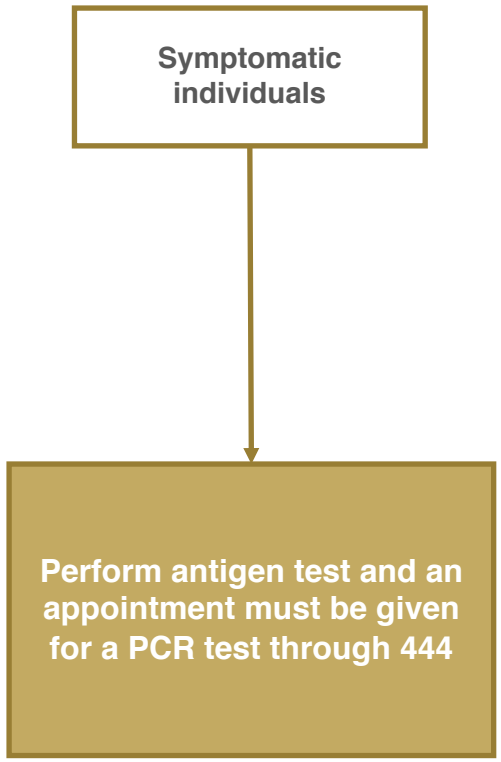
Close contacts (with negative PCR) are tested on daily basis for 10 days (antigen test) and must remain isolated except for games and training

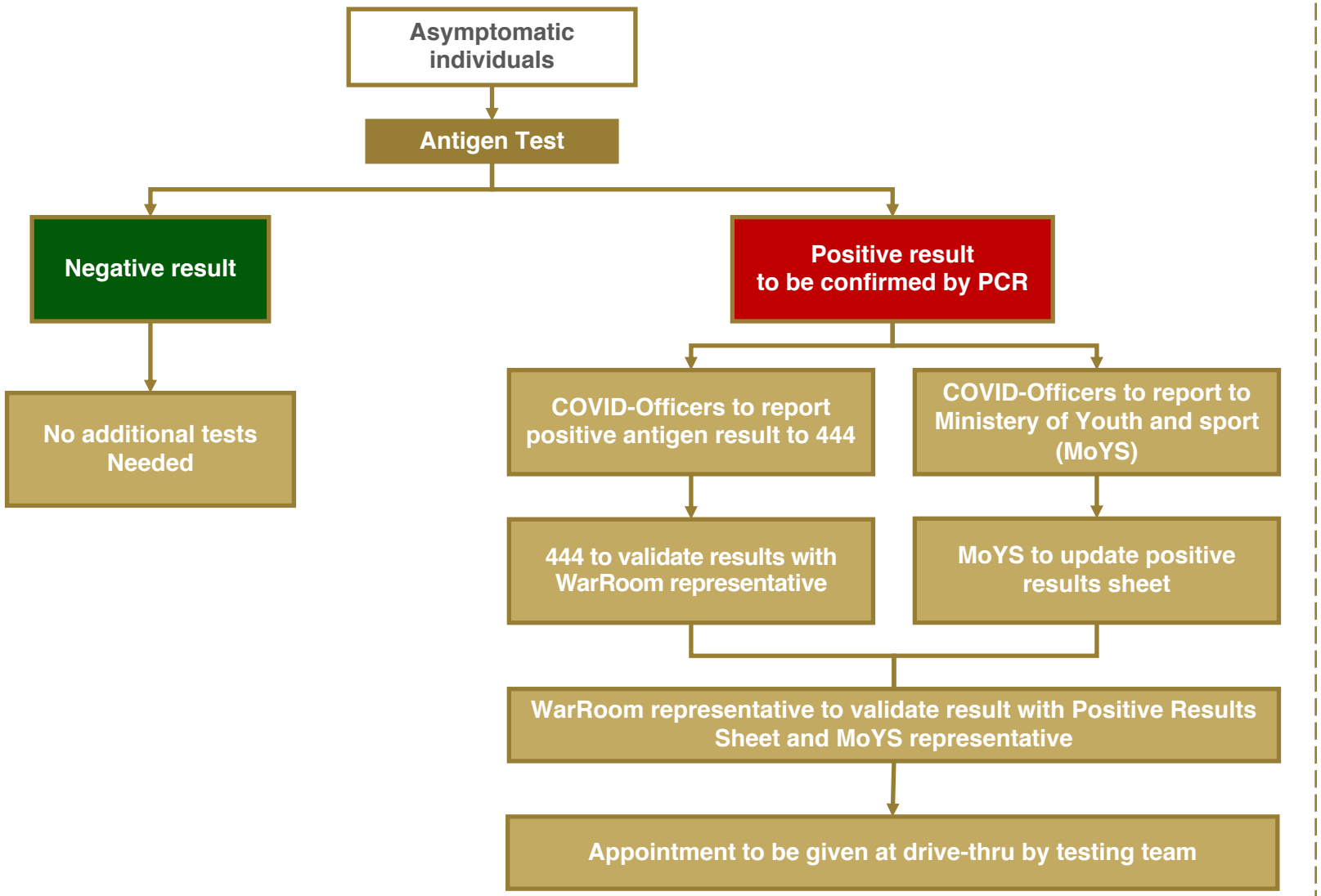
Prior to matches, antigen test for all involved players and staff

Continue all public health measures, including restricted community engagement

In case of cluster or crisis inside one or multiple teams escalate it to national taskforce medical team

Sports Protocol of Outbreak Control Measures



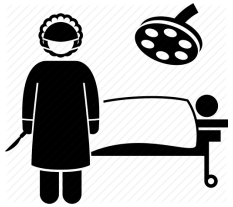


The Use of Rapid Antigen Detection Tests (RADT) in Hospitals

1

Admissions*

2



Surgical Procedures*

3

Delivery

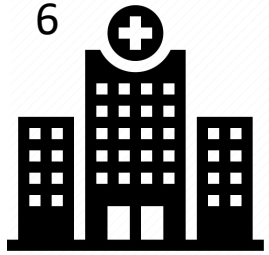
4

Health Care Workers Weekly Screening

5

Inpatients Overnight Visitors

6



(Stable symptomatic patients in Emergency Room and health centers)

- ❑ The antigen test can be used to screen admitting patients with **low COVID-19 disease probability.**
- ❑ Any positive antigen test must be confirmed by RT-PCR.
- ❑ **All admitted or patients undergoing surgical procedures can be tested using RADT except the followings:**
  - All clinically **suspected COVID-19** (including pneumonia or any COVID19 like presentation)
  - **High Risk Admission Groups**
    - Immunosuppressed or undergoing chemotherapy
      - Transplant within last 6 months and actively on immunosuppressed medications
  - Patients undergoing **aerosol-generating surgical or non-surgical procedures**
    - Surgical procedures like ENT surgery, dental procedures;
    - Non-surgical interventions like bronchoscopy, upper GI endoscopy
    - Any procedure requiring intubation

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Vaccination status categorization

Vaccination status categorization pathway

Vaccination status

Booster Dose
Completed primary vaccination

- Did not get infected with COVID-19
  - Take one booster shot according to the protocol **6 months** after second dose
  - 国药致君 SINOPHARM ZHIJUN, AstraZeneca, Pfizer, Sputnik V
- infected with COVID-19 and **Recovered** (2020 +2021)
  - Take one booster shot according to the protocol **12 months** after last documented infection
  - 国药致君 SINOPHARM ZHIJUN, AstraZeneca, Pfizer, Sputnik V

Got infected after first dose
- Complete the second dose after the completion of isolation period

Not Vaccinated with COVID-19 vaccine

- Did not get infected with COVID-19
  - **2 doses Vaccine** recommended according to age and risk status
  - 国药致君 SINOPHARM ZHIJUN, AstraZeneca, Pfizer, Sputnik V
- infected with COVID-19 and **Recovered**
  - **2 doses Vaccine** according to age and risk status *after* 3 months from date of positive PCR
  - 国药致君 SINOPHARM ZHIJUN, AstraZeneca, Pfizer, Sputnik V

HIGH RISK CATEGORY

Age ≥ 50 years.
- **Morbid obesity (BMI ≥ 35))**
- **Immunocompromised individuals.**
- **Frontliners (i.e., health care workers)**

Report any adverse events related to vaccination by following this link:
https://healthalert.gov.bh/category/reporting-vaccines

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Travelers Protocols

Travelers

Passengers

V27

01/09/2021

All arriving passengers above the age of 6 years will be subject to the following procedures

⚠ Any passenger presenting any medical emergency unrelated to the coronavirus will be immediately transferred to the relevant medical facility. However, medical staff must treat the passenger as potentially contagious until such time as a nasopharyngeal swab test can be safely conducted

Countries	Asymptomatic (*No Symptoms*)		Symptomatic (*Fever/Cough/Breathing difficulties*)	
1. **Vaccinated passengers from the GCC** 2. **Countries with mutual vaccination recognition agreement** 3. **Countries eligible for on-arrival visa**	1. **Vaccination proof** 2. **Swab upon arrival** 3. **Activate BeAware app** 4. **Swab at day 5** 5. **Swab at day 10**	1. Passenger must present completed and signed health declaration form 2. **Passenger is required to present a valid vaccination proof through an official mobile app or an approved vaccination certificate** 3. Passenger is required to undergo three PCR tests (costing BHD 36): upon arrival, on the 5th day and on the 10th day after arrival 4. The cost of the PCR test can be paid through the "BeAware Bahrain" mobile application in addition to the platforms at the airport which permit to pay in cash or electronically by credit cards 5. Passenger must also activate the 'BeAware Bahrain' application and sign an agreement to self-isolate, which requires them to quarantine at their place of residence until their arrival test results are available 6. Passenger must also be advised to call 444 should symptoms develop and follow instructions provided 7. Neither presenting a PCR test before boarding the plane nor quarantining upon arrival is required **If results are positive:** the passenger will be contacted by health authorities	1. **Transfer to Exhibition** 2. **Swab** 3. **Wait** 4. **Home Isolate**	1. Transfer to Exhibition immediately 2. Passenger is tested at Exhibition 3. Passenger remains at Exhibition until results are reported 4. **If results are negative:** Public Health tracks passenger's health status during a period of 10 days **If results are positive:** the passenger will be guided by health authorities

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V27
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⚠ Any passenger presenting any medical emergency unrelated to the coronavirus will be immediately transferred to the relevant medical facility. However, medical staff must treat the passenger as potentially contagious until such time as a nasopharyngeal swab test can be safely conducted

Countries	Asymptomatic (*No Symptoms*)		Symptomatic (*Fever/Cough/Breathing difficulties*)	
Non-vaccinated passengers and those without a recognized vaccine certificate	1. **PCR test certificate** 2. **Swab upon arrival** 3. **Activate BeAware app** 4. **Swab at day 5** 5. **Swab at day 10** 6. **Quarantine**	1. Passenger must present an approved PCR test certificate with a QR Code before boarding the plane, administered within 72 hours of departure 2. Passenger is required to undergo three PCR tests (costing BHD 36): upon arrival, on the 5th day and on the 10th day after arrival 3. The cost of the PCR test can be paid through the "BeAware Bahrain" mobile application in addition to the platforms at the airport which permit to pay in cash or electronically by credit cards 4. Passenger must also activate the 'BeAware Bahrain' application and sign an agreement to self-isolate, which requires them to quarantine at their place of residence 5. Passenger must quarantine for a period of 10 days at their residence or at a quarantine center licensed by the National Health Regulatory Authority. Passengers who are under the age of 12, are to quarantine for 5 days 6. Passenger must also be advised to call 444 should symptoms develop and follow instructions provided 7. Passenger must provide a proof of a pre-paid booking in their name at a quarantine facility before their departure to Bahrain 8. Passengers who choose to spend their quarantine periods in their homes must provide proof of residence, whether owned or rented in their name or the name of an immediate relative, before boarding **If results are positive:** the passenger will be contacted by health authorities	1. **Transfer to Exhibition** 2. **Swab** 3. **Wait** 4. **Home Isolate**	1. Transfer to Exhibition immediately 2. Passenger is tested at Exhibition 3. Passenger remains at Exhibition until results are reported 4. **If results are negative:** Public Health tracks passenger's health status during a period of 10 days **If results are positive:** the passenger will be guided by health authorities

Travelers

Passengers

V27
01/09/2021

All arriving passengers above the age of 6 years will be subject to the following procedures

⚠ Any passenger presenting any medical emergency unrelated to the coronavirus will be immediately transferred to the relevant medical facility. However, medical staff must treat the passenger as potentially contagious until such time as a nasopharyngeal swab test can be safely conducted

Countries	Asymptomatic (*No Symptoms*)		Symptomatic (*Fever/Cough/Breathing difficulties*)	
Vaccinated and Unvaccinated arrivals from red list countries who are allowed to enter Bahrain	1. **PCR test certificate** 2. **Swab upon arrival** 3. **Activate BeAware app** 4. **Swab at day 5** 5. **Swab at day 10** 6. **Quarantine**	1. Passenger must present an approved PCR certificate with a QR code before boarding the plane, administrated within 48 hours of departure 2. Passenger must conduct a PCR test upon arrival 3. Passenger must also activate the 'BeAware Bahrain' application and sign an agreement to self-isolate, which requires them to quarantine at their place of residence 4. Passenger must Quarantine for a period of 10 days at their residence or at a quarantine center licensed by the National Health Regulatory Authority (NHRA) 5. Passenger must also be advised to call 444 should symptoms develop and follow instructions provided 6. Passenger must conduct a PCR test on the 5th day after arrival 7. Passenger must conduct a PCR test on the 10th day after arrival **If results are positive:** the passenger will be contacted by health authorities	1. **Transfer to Exhibition** 2. **Swab** 3. **Wait** 4. **Home Isolate**	1. Transfer to Exhibition immediately 2. Passenger is tested at Exhibition 3. Passenger remains at Exhibition until results are reported 4. **If results are negative:** Public Health tracks passenger's health status during a period of 10 days **If results are positive:** the passenger will be guided by health authorities

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(COVID-19)

Admissions of COVID19 patients

Admissions of COVID19

Sources of admission:

- Triage clinic : for newly diagnosed cases
- BIH COVID Clinic : for home isolation cases who develop symptoms
- Emergency room: cases with severe or life-threatening symptoms
- In-hospital transfer: Cases diagnosed as COVID19 while being hospitalized in a non-COVID facility
- Direct admission from home with no clinical assessment is prohibited

Admission of patient should be based on the primary admitting diagnosis and the level of care required, regardless of COVID-19 result:

- If type of care can be provided in COVID facility without jeopardizing level of care, then patient can be admitted in COVID facility and followed by concerned specialty
- If optimum patient care cannot be provided in COVID facility , then patient should be admitted under concerned specialty in the appropriate level of care, while taking full infectious control precaution
  - This also concerns any kind of intervention required
- Clinical Judgment should be prioritized over SARS-CoV2 swab result. Infectious disease consultation for follow up, assessment and interpretation is also required
- For non-COVID presentation and SARS-CoV2 PCR CT Value ≥ 30
  - Patient unlikely to be infectious, however precautionary measures should be taken and can be admitted in non-COVID facility
  - Perform Serology tests
  - Repeat swab in 24hours
  - Consult Infectious disease and Infection control for interpretation and assessment

Contingency plan

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فيروس كورونا
(COVID-19)

COVID-19 Patient Allocation

Patient Allocations

Clinical assessment with the possible need for laboratory and/or radiological evaluation of cases is needed to allow allocation to the most appropriate treatment facility and promote optimal resource utilization

COVID-19 patients will be allocated to the following categories based on clinical symptoms and admission criteria's

- Home isolation : Subject to specific criteria (refer to Home isolation protocol)
- Isolation facilities : Asymptomatic cases who don't fit home isolation
  - Hidd/Shamel Isolation, Sitra Camp, and other NHRA approved private facilities: for cases lacking proper home isolation setup.
- Treatment Facilities: Mild to Moderate Disease and those who require in-hospital medical care
  - **JMH:** Mild-moderate COVID cases, adults only both male and female
  - **BIH:** Mild pneumonia, and Mild cases with comorbidities that need hospital management
  - **EKK:** Moderate pneumonia, and Mild cases with comorbidities that need hospital management
  - **SMC 6th floor:** Moderate pneumonia, and Mild cases with comorbidities that need hospital management or requiring other subspecialty care, Paediatric, and uncomplicated Obstetric cases.
  - **SMC Helipad:** Moderate pneumonia, and Mild cases with comorbidities that need hospital management or requiring other subspecialty care.
- ICU Facilities : Severe Diseases or cases who require advanced therapies
  - HBDC, BDF FICU, Sitra FICU
- Ward 17 BDF Hospital: VIP Cases - subject to prior approval

This slid will be updated as the COVID situation changes

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فيروس كورونا
(COVID-19)

Recovered COVID-19 Cases : Readmission guidelines

Readmission guideline

Definition of Recovered Case: Recovered COVID-19 cases are patients who were diagnosed with COVID19 and fulfilled all the isolation and discharge criteria

Definition of COVID-19 Pathway refers to all the processes encountered in a confirmed COVID-19 case from the diagnosis until satisfying discharge criteria and end of isolation

Within 14 days from COVID-19 Pathway Discharge

1. Any Recovered COVID-19 who presented with COVID-19 related symptoms AND positive swab, can be readmitted to COVID-19 facilities if clinically indicated.
    - If Recovered cases develops respiratory symptoms, consider investigating for post COVID-19 complications (such as bacterial pneumonia, VTE) and other infections.
    - If negative swab, consult Infectious disease for assessment and justification for readmission into COVID facility
2. If Recovered COVID-19 patients presents with non COVID related illness and requires admission to a non COVID-19 facility relating to his presenting illness, patient can be admitted to the appropriate medical are facility with infection control precaution

If within 14 to 44 days from COVID-19 Pathway Discharge:

- Consult Infectious disease for assessment and justification for readmission into COVID facility

If within 45 to 89 days from COVID-19 Pathway Discharge:

- Tested positive with CT value of less than 33 or suspected new variant (missing S gene on RT-PCR)
- **Or** Symptomatic second episode and no obvious alternate etiology **Or** close contact with confirmed COVID-19 case

If beyond 90 days:

- Patient follow normal care pathway if COVID19 positive, to be considered as a new case

Scientific Justification *Reference: Alberta Health Services Scientific Advisory Group COVID-19 Recommendations*

- The possibility of reinfection with SARS-CoV-2 is not impossible: there have been some well documented cases of reinfection especially with the new variants
- Current evidence suggest that viable virus declines relatively quickly in initial infection, but RT- PCR positivity can be prolonged
- Rising antibody titers over the second and third week of illness are likely protective or partially protective. However, The duration of likely immunity is unclear as yet, but reinfection is unlikely in the short term.

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(COVID-19)

Home isolation Protocol

Home Isolation

All newly diagnosed cases need to be evaluated by the COVID19 triage team to assess fitness for home isolation

- Criteria that **must be met** to qualify patients for Home Isolation:
  1. Appropriate home setting for a self isolation
  2. Able to stay in contact with the medical team electronically
  3. Activation of “Be Aware Bahrain” App
- Clinical Criteria (either)
  - Mild symptoms without risk factors, or
  - Asymptomatic regardless of risk factors

Risk factors include Obesity, Cardiac diseases, Chronic lung diseases, Clotting risk factors, SCD in crisis

Household contacts shall be continued to be managed as close contacts through public health

COVID-19 Home isolation Risk Assessment

Sign and Symptoms	Mild: Home isolation	Moderate to Severe: Transfer to Treatment facility
Sore thorat and flu like symptoms Loss of Smell or Taste ; Myalgia and Fatigue ; GI Symptoms	✓	-
Fever	Less than 38°C	**≥38°C and if clinically indicated**
Shortness of Breath	X	✓
Chest Pain	X	✓
Change in Mental Status	X	✓
Respiratiry Rate >30	X	✓
Saturation	Normal	**Saturation ≤93% on Room Air**
Chest Xray changes	Normal	**Changes suggestive of pneumonia**
Major Risk factors for Severe COVID19	X	Any one of the mentioned risk factors
• Obesity	X	✓
• Cardiac disease: Heart Failure, Coronary artery disease, Cardiomyopathy	X	✓
• Chronic Lung Disease: Fibrosis, Sever Asthma/ COPD	X	✓
• Clotting Predispoising condition	X	✓
• SCD in crisis	X	✓

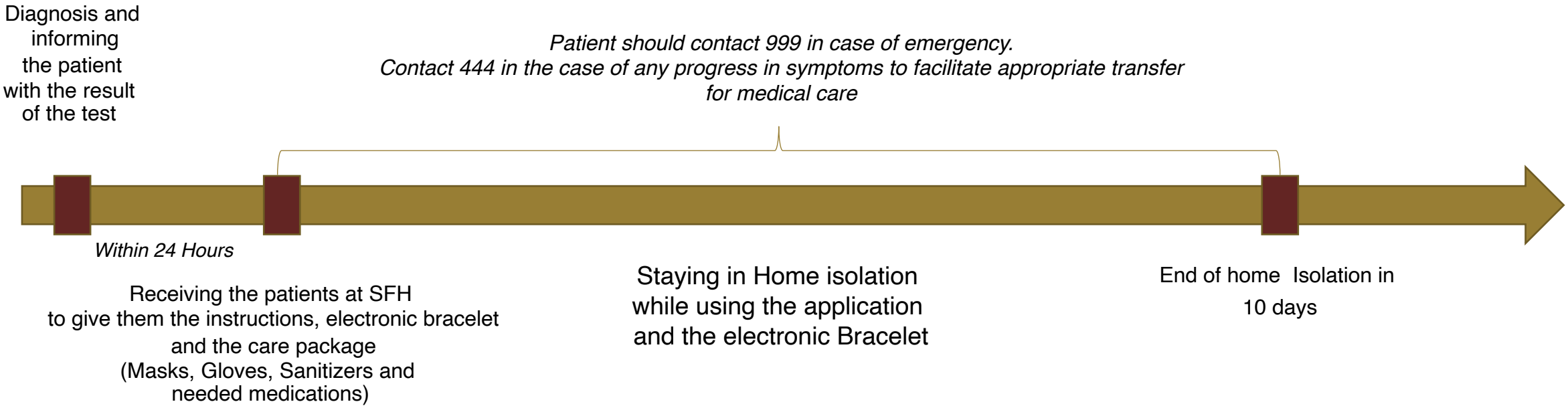
Home Isolation Protocol

- Primary Healthcare workers will follow up patients with phone calls on day 3 and 6.
- Instruction sheet to be given to all individuals
- Patient will continue to fill the daily follow-up form on the BeAware application
- In case of deterioration, severe cases are referred to closest A/E and mild-moderate cases are referred to COVID19 clinics at BIH

Discharge from home isolation

- After completion of 10days in home isolation while being asymptomatic atleast 72hrs prior to discharge ; patient can be discharged without a PCR test
- 10 days of home isolation is counted from onset of symptoms if patient is symptomatic ; otherwise will be counted from diagnosis

Timeline



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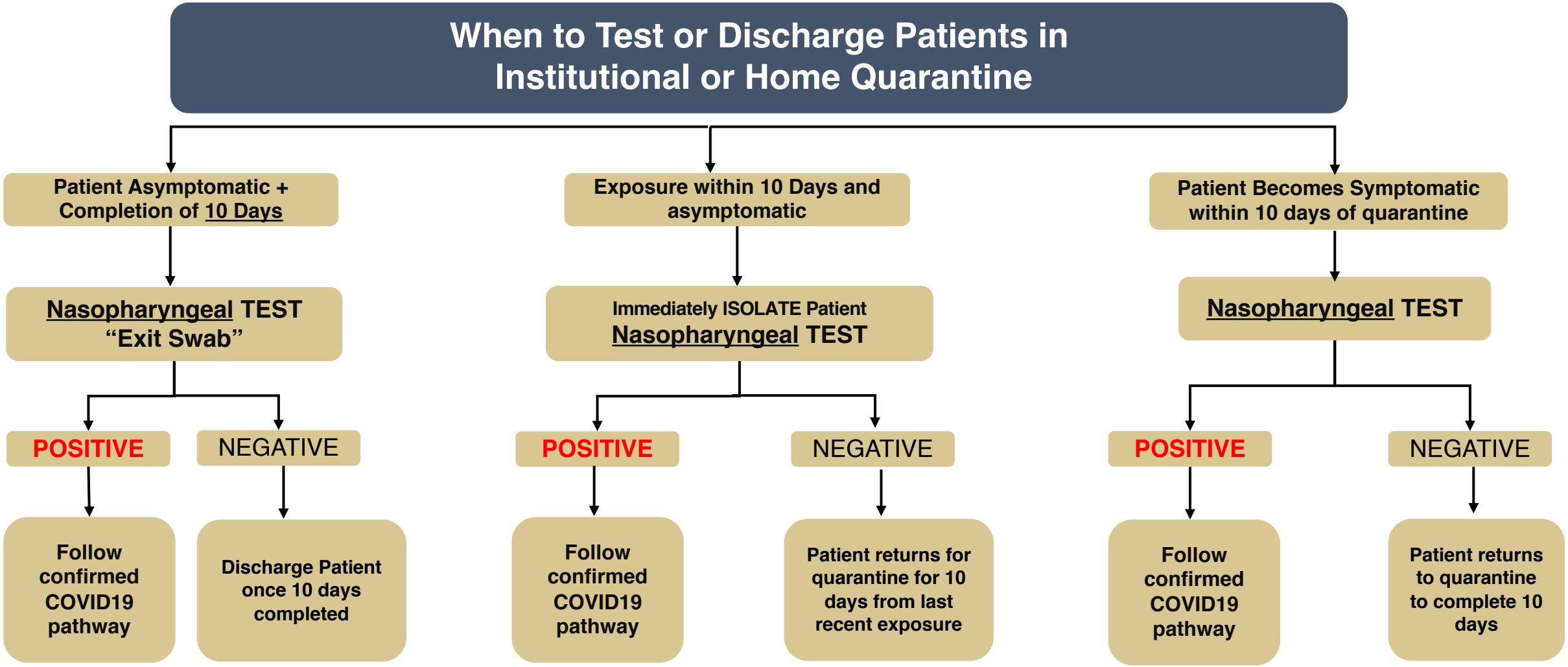
(COVID-19)

Discharge Protocol and Repeat testing guidelines

for Quarantine and Isolation/Treatment facilities

Testing and Discharge Protocol for Patients in Institutional or Home Quarantine (Close contacts with Negative PCR)



EXPROSURE: Patient was exposed to a confirmed case for at least 15 minutes at a distance of less than 1 meter without proper PPE

COVID19 Discharge protocol from all treatment facilities : ASYMPTOMATIC OR MILD SYMPTOMS

The Following Procedures Govern Discharge of Patients who are Mildly symptomatic or Asymptomatic at Treatment Facilities

Mild Symptoms
- Absence of Pneumonia
- Symptoms limited to upper respiratory tract

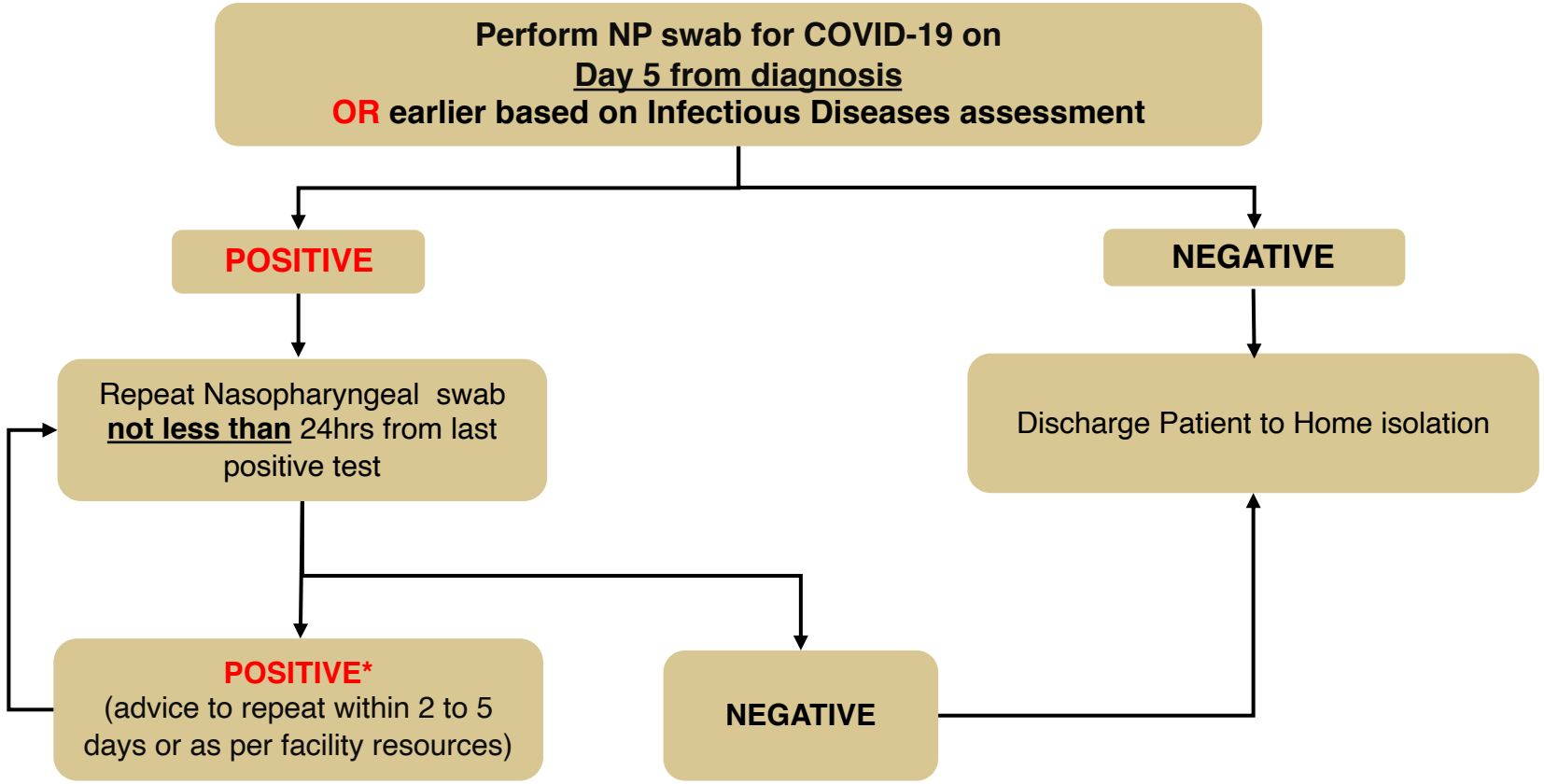
Discharge criteria

(1) Resolution of symptoms for **atleast 24hrs** prior to discharge

Isolation instruction
- Need to complete a total of 10 days of self isolation since onset of symptoms (or since date of their first positive COVID-19 test if Asymptomatic)
- Follow home isolation instruction with the use of BeAware App
- Sick leave to be issued from the discharging treatment facility

Return to work

Refer to the Return to work protocol



- ***If patient has persistent positive PCR + atleast 24hrs have passed since resolution of symptoms – Discharge Patient with total 10 days in home isolation**
- If patient was admitted for observation for few days only and fit for discharge, then can be discharged to home isolation (follow home isolation protocol i.e. total 10 days self-isolation) without need to do swab

COVID19 Discharge protocol from all treatment facilities : MODERATE TO SEVERE DISEASE

Moderate to Severe Disease

- Chest Xray suggestive of pneumonia
- Or Shortness of Breath
- Or Signs of respiratory distress (tachypnea >20breath/min) or Hypoxia (Sat <94%) on Room Air

Discharge criteria

1) Resolution of symptoms for atleast **24hrs** prior to discharge (or earlier based on infectious disease assessment)

OR

2) Two consecutive negative Nasopharyngeal swabs that are 24hrs apart or more
   - If fails to have two negative swabs : can be discharged as per symptom-based policy

Isolation instruction

- Need to complete a total of 14 days of self isolation since onset of symptoms
- Sick leave to be issued from the discharging treatment facility Follow home isolation instruction with the use of BeAware App

Return to work

Refer to the Return to work protocol

The Following Procedures Govern Discharge of Patients at any Treatment Facilities for Moderate and Severe disease

At least 24 hours have passed since resolution of symptoms or earlier based on Infectious Diseases assessment
If not, asses regularly until fitting above criteria

Retest (Nasopharyngeal swab)

POSITIVE

Repeat Nasopharyngeal swab **after 24 hours** from last positive test

POSITIVE (Refer to symptoms-based policy)

NEGATIVE

NEGATIVE

Repeat Nasopharyngeal swab **not less than** 24hrs after last test

POSITIVE (Repeat within 24 hours)

NEGATIVE

Discharge Patient (need to complete a total of 14 days in isolation since onset of symptoms)

Symptoms-based policy: If patient fails to have two negative swabs and 24hrs have passed since resolution of symptoms – Discharge Patient with additional home isolation to complete 20 days of isolation since swab result

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(COVID-19)

Outpatient and follow up guidelines

Discharge Instruction and follow up

- Discharge instruction leaflet to be provided in different languages
  1. Continuation of the specified isolation period
  2. Patient should be instructed to visit closest A/E should they develop severe symptoms (chest pain, SOB)
  3. Patient discharged before 10 days should visit COVID clinic in case symptoms recur

- **After hospital discharge, VTE prophylaxis is not recommended for patients with COVID-19**

- **Any decision to use post-discharge VTE prophylaxis for patients with COVID-19 should consider the individual patient's risk factors for VTE, including reduced mobility, bleeding risks, and feasibility**

Outpatient follow up post discharge

1. Categorization of patients to be followed up
   1. Age >60 yrs regardless of comorbidities
   2. Patients with the following risk factors: CVD, lung disease, Obesity, or at risk for thrombosis

2. The above categorized patients must be followed up within 10 days from discharge, either by phone or scheduled appointment

3. Follow up to be done according to patient entitlement
   1. BDF personnel to follow at BDF clinics
   2. MOI personnel to follow at MOI clinics
   3. Public population (non BDF nor MOI) to follow up at MOH sites (SMC, LHC)

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لمكافحة
فيروس كورونا
(COVID-19)

Return to Work

Return to Work Criteria

- Recovered COVID-19 patients (Non-Health Care Workers) can return to work whenever:
  1. Have completed the isolation period specified by the discharge protocol
  2. AND are Asymptomatic for atleast 24 hours (without the use of fever reducing medications) or Symptoms (e.g., cough, shortness of breath) have improved

- **Healthcare workers** can return to work based on **one** of the following criteria:
  1. 24 hours have passed from resolutions of symptoms (without the use of fever reducing medications) **AND** has 2 negative NP swabs within 10 days from onset of symptoms

     (or)
  2. Patient is asymptomatic for at least 24hours (without the use of fever reducing medications) **AND** 10 days have passed from diagnosis

Cases with persistent positive PCR or fluctuating PCR result within 90 days from the initial COVID19 diagnosis can return to work after physician assessment, given

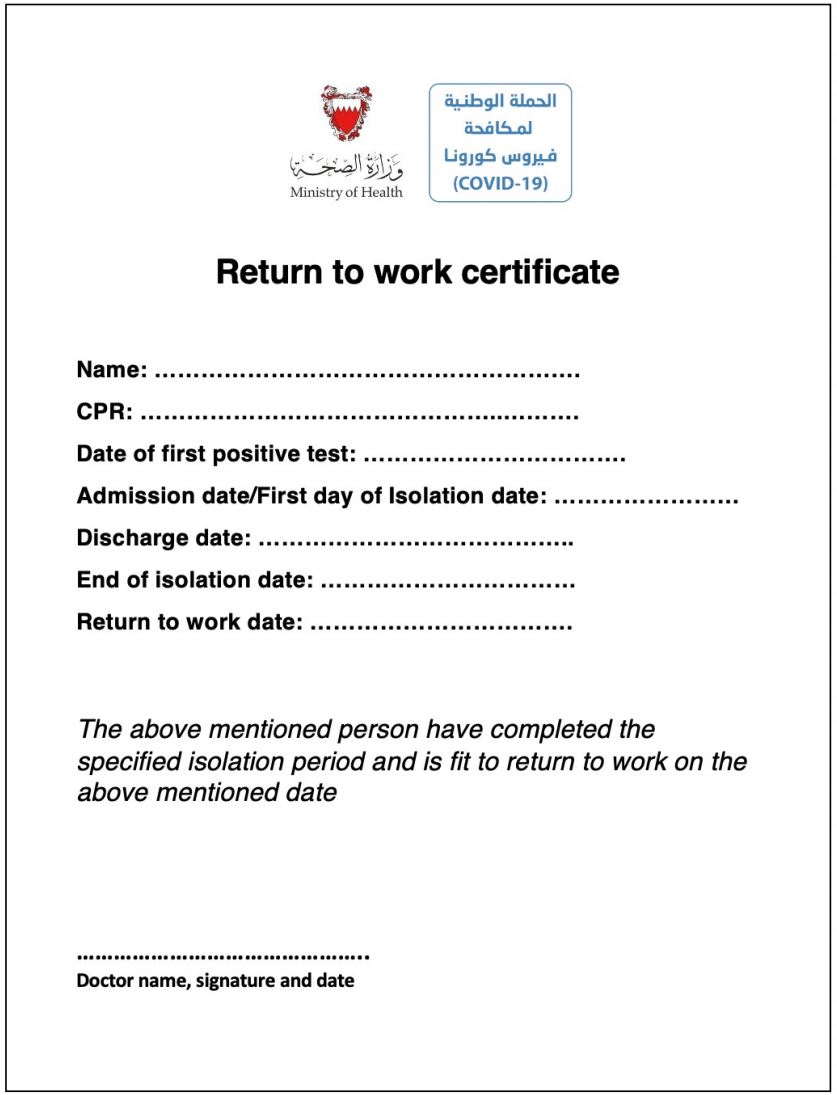
- They are asymptomatic for at least 24 hours (without the use of fever reducing medications)
- Completed the isolation period specified by the discharge protocol
- The latest positive PCR has a Ct value > 30

Please note that cases who were asymptomatic during their initial diagnosis , should be retested and isolated if symptoms occur
In case of the inability to provide safe patient care due staff shortage – refer to page 15 for feasible recommendation

Return to Work Criteria

- Return to work certificate is to be issued from the admitting facility once the specified criteria were completed (page 49-51)

- Primary care physicians will issue the certificate for home isolated patients, once the specified criteria were completed (page 49-51)



وزارة الصحة
Ministry of Health

الحملة الوطنية لمكافحة فيروس كورونا (COVID-19)

Return to work certificate

Name: .....

CPR: .....

Date of first positive test: .....

Admission date/First day of Isolation date: .....

Discharge date: .....

End of isolation date: .....

Return to work date: .....

The above mentioned person have completed the specified isolation period and is fit to return to work on the above mentioned date

.....

Doctor name, signature and date

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لمكافحة
فيروس كورونا
(COVID-19)

Reporting of COVID-19 death

COVID-19 related death

Following WHO guidance REF

Definition of COVID-19 related death:

- A death due to COVID-19 is defined for surveillance purposes as a death resulting from a clinically compatible illness, in a probable or confirmed COVID-19 case, unless there is a clear alternative cause of death that cannot be related to COVID disease (e.g. trauma). There should be no period of complete recovery from COVID-19 between illness and death.

- A death due to COVID-19 may not be attributed to another disease (e.g. cancer) and should be counted independently of pre-existing conditions that are suspected of triggering a severe course of COVID-19.

Guidelines for certifying COVID-19 as a cause of death

Recording COVID-19 on the medical certificate as cause of death:
for all decedents if the disease caused, or is assumed to have caused, or contributed to death

Terminology:
The use of official terminology, COVID-19, should be used for all certification of death

Chain of events:
Specification of the causal sequence leading to death in part of the certificate is important, Example on slide 59

Comorbidities:
There is increasing evidence that people with existing chronic conditions or compromised immune systems due to disability are at higher risk of death due to COVID-19. Chronic conditions may be non-communicable diseases such as coronary artery disease, chronic obstructive pulmonary disease (COPD), and diabetes or disabilities. If the decedent had existing chronic conditions, such as these, they should be reported in Part 2 of the medical certificate of cause of death. Example on slide 59

Examples of COVID-19 deaths

Chain of events example

Here, on the International Form of Medical Certificate of Cause of Death, is an example of how to certify this chain of events for deaths due to **COVID-19** in Part 1:

***Frame A*: Medical data: Part 1 and 2**

1 Report disease or condition directly leading to death on line a Report chain of events in due to order (if applicable) State the underlying cause on the lowest used line		Cause of death	Time interval from onset to death
	a	Acute respiratory distress syndrome	2 days
	b	Due to: Pneumonia	10 days
	c	Due to: COVID-19 (test positive)	14 days
	d	Due to:	

Underlying cause of death

2 Other significant conditions contributing to death (time intervals can be included in brackets after the condition)	

Manner of death:

▬ Disease	▬ Assault	▬ Could not be determined
▬ Accident	▬ Legal intervention	▬ Pending investigation
▬ Intentional self harm	▬ War	▬ Unknown

Note: This is a typical course with a certificate that has been filled in correctly. Please remember to indicate whether the virus causing COVID-19 had been identified in the defunct.

Comorbidities example

Here, on the International Form of Medical Certificate of Cause of Death, are examples of how to certify this chain of events for deaths due to **COVID-19** in Part 1, with comorbidities reported in Part 2:

***Frame A*: Medical data: Part 1 and 2**

1 Report disease or condition directly leading to death on line a Report chain of events in due to order (if applicable) State the underlying cause on the lowest used line		Cause of death	Time interval from onset to death
	a	Acute respiratory distress syndrome	2 days
	b	Due to: Pneumonia	10 days
	c	Due to: Suspected COVID-19	12 days
	d	Due to:	

Underlying cause of death

2 Other significant conditions contributing to death (time intervals can be included in brackets after the condition)	**Coronary artery disease [5 years], Type 2 diabetes [14 Years], Chronic obstructive pulmonary disease [8 years]**

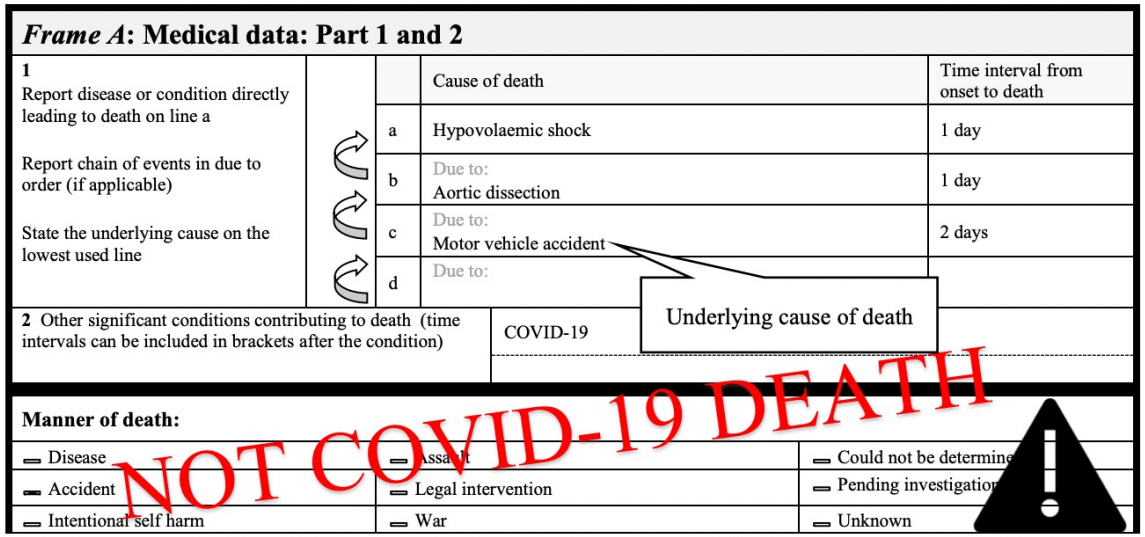
Manner of death:

▬ Disease	▬ Assault	▬ Could not be determined
▬ Accident	▬ Legal intervention	▬ Pending investigation
▬ Intentional self harm	▬ War	▬ Unknown

Note: This is a typical course with a certificate that is filled in correctly. COVID-19 cases may have comorbidity. **The comorbidity is recorded in Part 2.**

Examples of non-COVID-19 deaths

The examples below show recording of cases where death may have been influenced by COVID-19, but death was caused by another disease or an accident.



***Frame A*: Medical data: Part 1 and 2**

1 Report disease or condition directly leading to death on line a Report chain of events in due to order (if applicable) State the underlying cause on the lowest used line		Cause of death	Time interval from onset to death
	a	Hypovolaemic shock	1 day
	b	Due to: Aortic dissection	1 day
	c	Due to: Motor vehicle accident	2 days
	d	Due to:	

Underlying cause of death

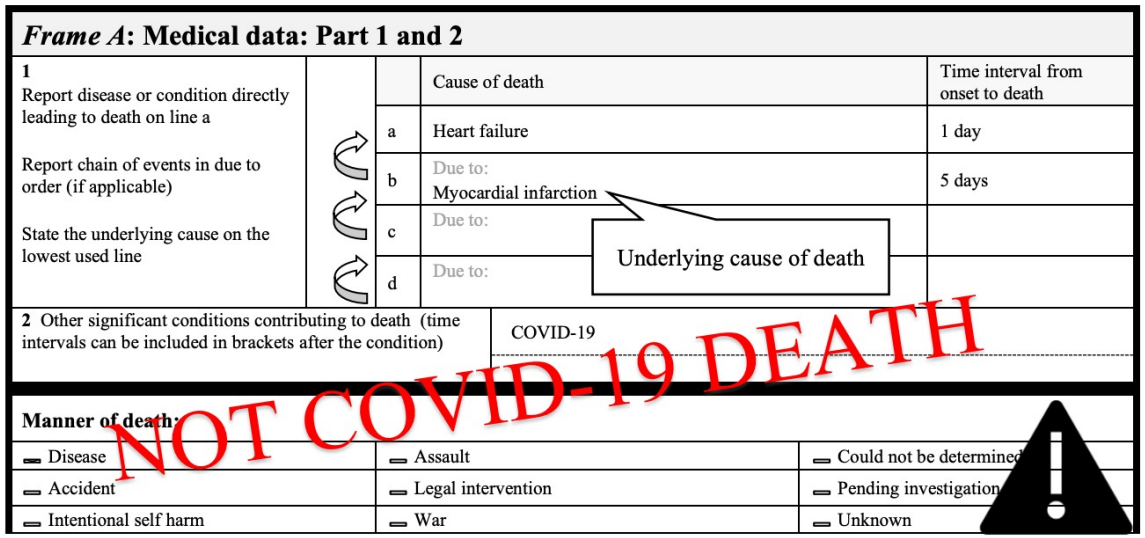
2 Other significant conditions contributing to death (time intervals can be included in brackets after the condition)	COVID-19

Manner of death:

▬ Disease	▬ Assault	▬ Could not be determine
▬ Accident	▬ Legal intervention	▬ Pending investigation
▬ Intentional self harm	▬ War	▬ Unknown

NOT COVID-19 DEATH

Note: Persons with COVID-19 may die of other diseases or accidents, such cases are not deaths due to COVID-19 and should not be certified as such. In case you think that COVID-19 aggravated the consequences of the accident, you may report COVID-19 in Part 2. Please remember to indicate the manner of death and record in part 1 the exact kind of an incident or other external cause.



***Frame A*: Medical data: Part 1 and 2**

1 Report disease or condition directly leading to death on line a Report chain of events in due to order (if applicable) State the underlying cause on the lowest used line		Cause of death	Time interval from onset to death
	a	Heart failure	1 day
	b	Due to: Myocardial infarction	5 days
	c	Due to:	
	d	Due to:	

Underlying cause of death

2 Other significant conditions contributing to death (time intervals can be included in brackets after the condition)	COVID-19

Manner of death:

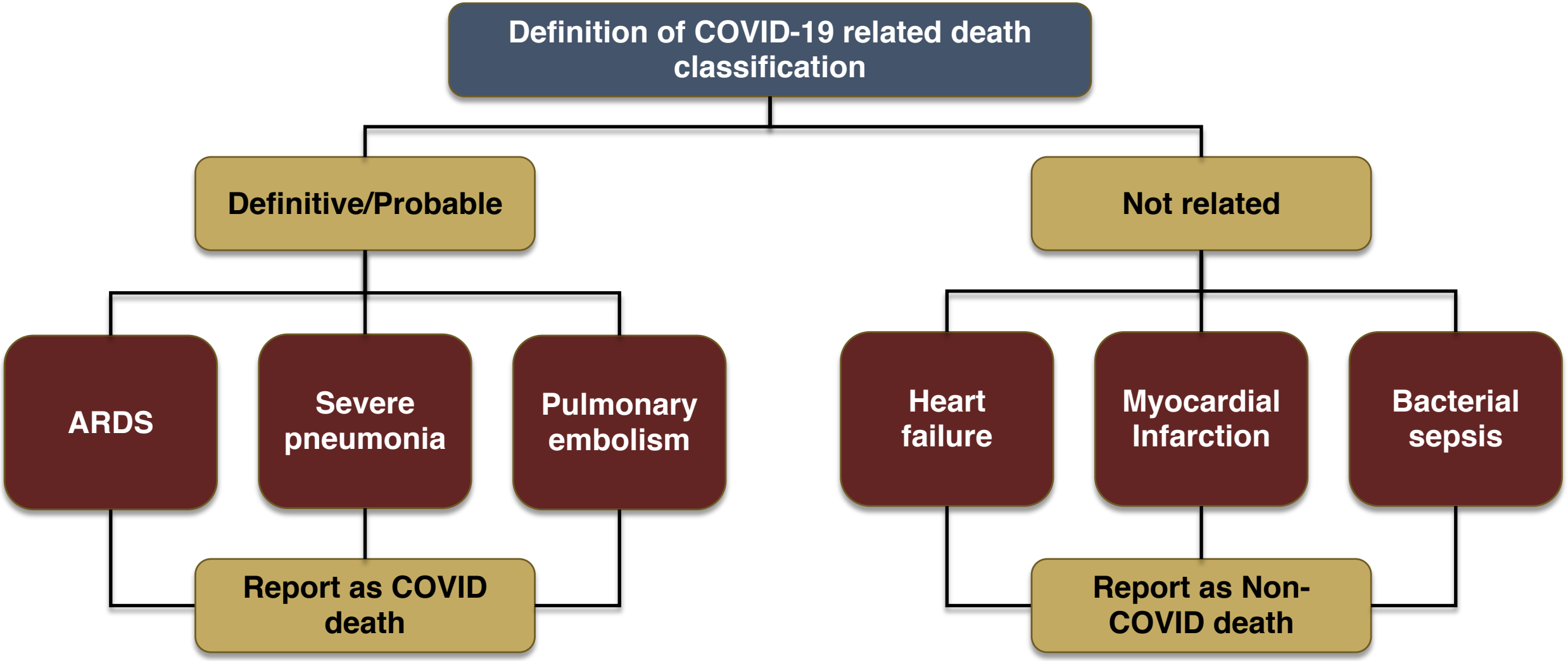
▬ Disease	▬ Assault	▬ Could not be determined
▬ Accident	▬ Legal intervention	▬ Pending investigation
▬ Intentional self harm	▬ War	▬ Unknown

NOT COVID-19 DEATH

Note: Persons with COVID-19 may die due to other conditions such as myocardial infarction. Such cases are not deaths due to COVID-19 and should not be certified as such.

Difference between definitive and probable COVID-19 related death

All these causes of deaths are examples, as other scenarios can occur; what is important is the chain of events having direct corelation to COVID-19 death:



Reporting COVID-19 unexpected death

Due to the current pandemic and the prevalence of the virus in the community, it is challenging to differentiate between cases who died WITH the virus or those who died because OF the virus

- There is no consensus in the literature nor a recommendation on reporting sudden death in COVID-19

The National task force provides the following recommendations for reporting cases of sudden death outside the COVID-19 pathway (ie at home)

1. If swab is taken before death and turns to be positive:
   - Patient will be counted as a case of COVID19; however, mortality will not be reported due to COVID19, if no clinical evidence is present

2. If swab is taken after death of the individual and is positive
   - The case will NOT be counted neither as a case of COVID19 nor as a case of COVID-19 Death

Guidance for management of Neonates born to Mothers with Suspected or Confirmed COVID-19 Infection

Management of Neonate born to Mothers with Suspected or Confirmed COVID-19 Infection : **Healthy and Asymptomatic Neonate**

Newborns should be separated at birth from their mother and bathed as soon as possible
Neonate to be kept in isolation from other infants
NP swab for mother – use Gene Xpert or RADT for more rapid results

Mother tetsed Positive

If mother tetsed Negative and neonate is asymptomatic and stable, discharge from COVID pathway

Tests newborn for COVID-19 at 24hours of age and if negative, repeat at 48hours of age

- If testing is limited and baby is stable and asymptomatic and are expected to be discharged before 48 hours a single test can be done at 24-48 hours

If both PCR tests negative and neonate is asymptmatic and stable, can be discharged and to follow the advised guidelines (page 47)

If newborn tested positive, follow COVID-19 Pathway

1. Newborns can remain with their mothers
2. Observe for the development of any symptoms
3. Discharge once two consecutive negative NP test
4. Plan for frequent follow-up through 14 days after birth

If neonate is symptomatic or unstable, provide appropriate care in an isolation room and perform COVID19 swabs as indicated if mother tested positive

Source: American Academy of Pediatrics and KSA guidelines

Newborns and Infected Mothers

The following guideline are recommended regarding Neonate born to Mothers with Confirmed COVID-19 Infection

- Temporary separation between the mother and the newborn minimizes the risk of transmission and is advised
  - If parents refuse separation and willing to room in together, then precautions should be taken to minimize risk of viral transmission:
    1. Staying 2 meters away from the mother,
    2. practice safe hand hygiene
    3. wear a mask
- Breastfeeding: mothers may express breast milk after appropriate breast and hand hygiene. Caregivers who are not infected may feed the breast milk to the infant
  - Mother who request direct breastfeeding, should understand the increased risk of transmission and comply with strict preventive precautions that include use of a mask and meticulous breast and hand hygiene.

Source: American Academy of Pediatrics

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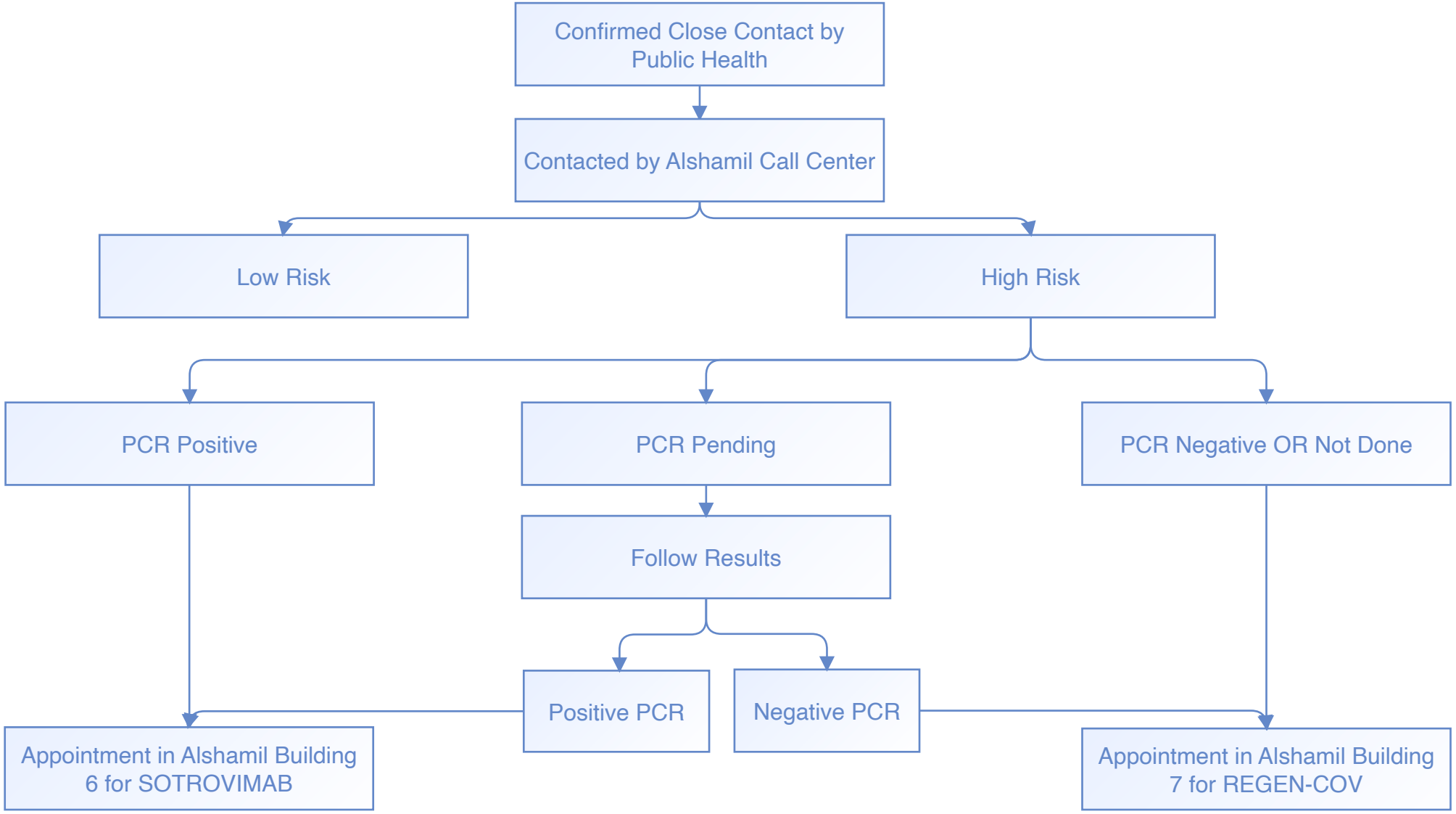
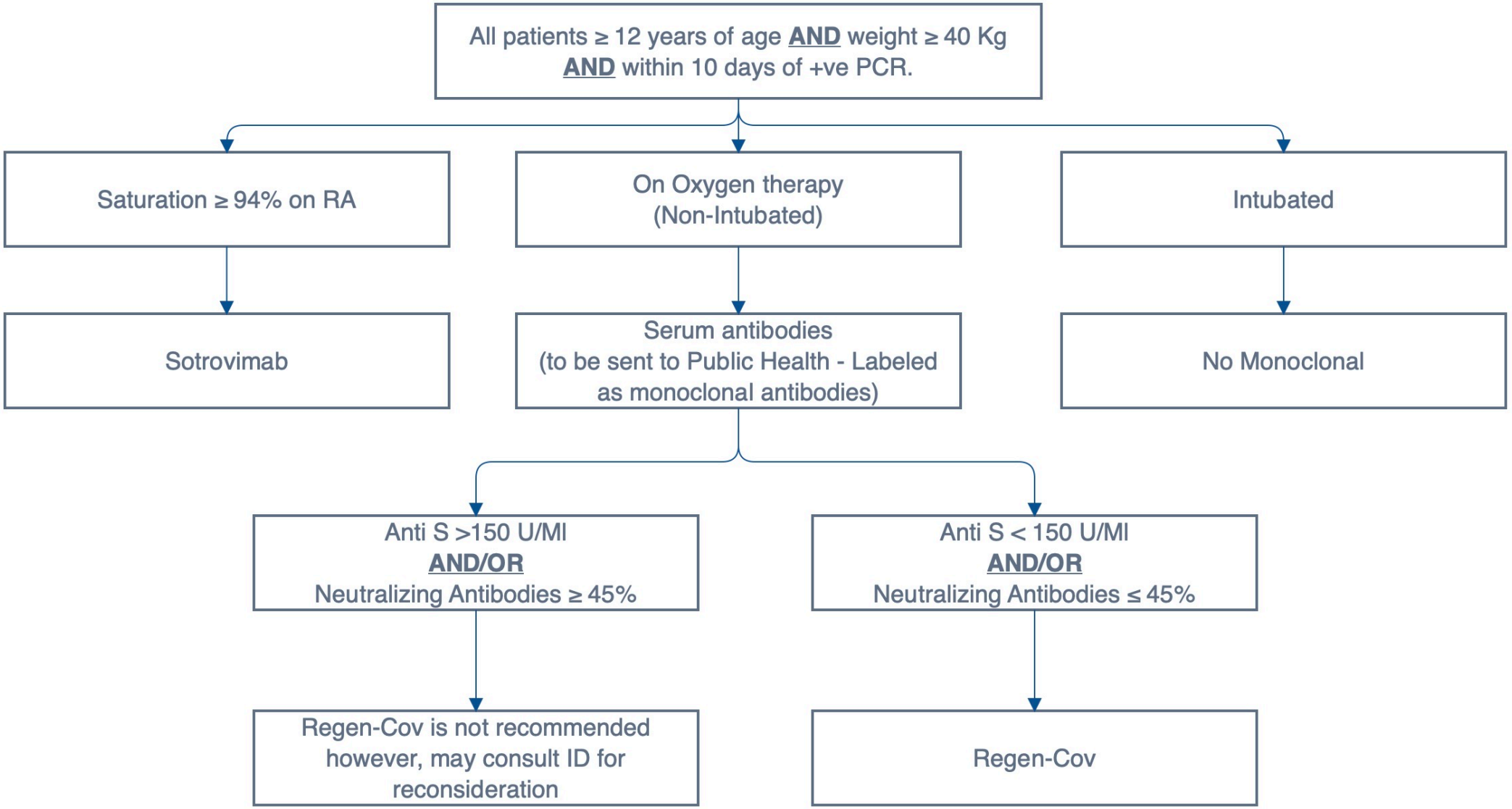
Treatment Guidelines and Pathways

Monoclonal Antibodies Treatment Pathway



Responsible team: Prof. Manaf Alqahtani, Dr. Aamal Husain, Dr. Alwaleed Behzad

Monoclonal Selection Criteria Inpatient Setting



Bamlanivimab

•Bamlanivimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.

FDA issued an Emergency Use Authorization (EUA) for bamlanivimab to be available to treat non hospitalized patients with mild to moderate COVID-19 who are at high risk for progressing to severe disease and/or hospitalization.
However, as it has been retracted due to the fact it is less effective towards certain variants.

•Bamlanivimab is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are ≥12 years of age and weighing ≥40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization (This includes those who are ≥65 years of age, or who have certain chronic medical conditions.

•While the safety and effectiveness of this investigational therapy continues to be evaluated, bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo.

•Bamlanivimab is **NOT** authorized for use in the following patient populations:

- Adults or pediatric patients who require oxygen therapy due to COVID-19.
- Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19- related comorbidity

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.

Bamlanivimab Patient Requirements

•Lab confirmed COVID-19 PCR.
•Weighs ≥40 kg
•Age ≥ 18 years old
•Does not require oxygen or an increase in oxygen flow rate due to COVID-19 for those on oxygen due to underlying comorbidity.

•Have at least 1 risk factor from boxes below:

Meets at least one of the following:

•Have a BMI ≥35
•Have chronic kidney disease
•Have diabetes
•Have immunosuppressive disease
•Are currently receiving immunosuppressant treatment
•Are ≥65 years of age

OR

Is ≥55 years of age AND has one of the following:

•Cardiovascular disease **OR**
•Hypertension **OR**
•COPD/other chronic respiratory disease

Bamlanivimab Treatment Protocol

Category	Details
Dose	• Its available as solution and must be diluted prior to administration • 700mg in 200mL 0.9% NaCl IVPB over at least 60 minutes (PVC infusion set with 0.20/0.22-micron filter)
Monitoring	• Monitor during infusion (no specified interval) and for 1 hour after post infusion
Adverse effects	• Hypersensitivity reactions • Nausea and dizziness • Diarrhea and vomiting • Headache • Pruritis
Contraindication	None confirmed yet however monitor for hypersensitivity and anaphylaxis signs

Sortovimab

Sotrovimab

- Within 10 days of Lab Confirmed COVID 19 PCR.
- Weight ≥ 40 Kg.
- Do Not require Oxygen

Has at least one of the following:

1. Age ≥50 years.

OR

2. Age ≥ 18 years + Non vaccinated
   - Not Vaccinated = Yellow/Red/Grey shield carrier in Beaware application **OR** 6 Months post 2nd dose of any type of vaccine (for those who received their vaccination outside Bahrain)

OR

3. Age ≥ 12 + has at least one of the following
   - BMI ≥ 35 (BMI ≥85th percentile in <18 years age group).
   - Pregnancy.
   - Chronic Kidney Disease.
   - Diabetes.
   - Immunosupressive disease or on Immunosupressive Treatment.
   - Cardiovascular Diseases (including Congenital heart disease) or hypertension.
   - Chronic Lung Disease.
   - Having a medical-related technological dependence.
   - Sickle Cells disease.
   - Neurodevelopmental disorders.

Sortovimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells. It is FDA Emergency use authorization (EUA) approved for Treatment of mild to moderate COVID-19 in adult and pediatric patients who are ≥12 years of age and weighing at least 40 Kg with positive result of direct SARS-CoV-2 viral testing.

- Sotrovimab use should be considered for persons with mild to moderate COVID-19 who are hospitalized for a reason other than COVID-19 and who otherwise meet the EUA criteria.

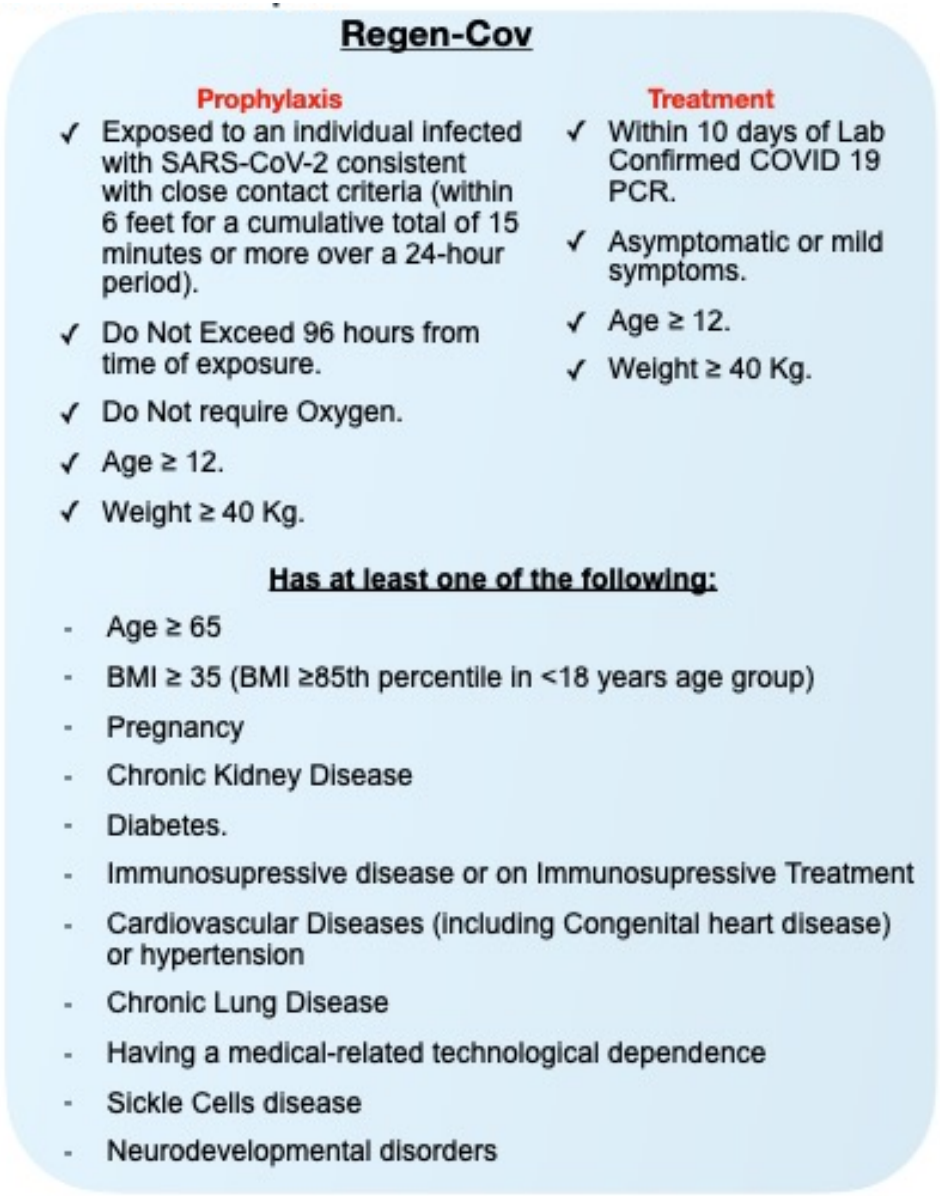
Sotrovimab Treatment Protocol

Category	Details
Dose	• The dosage of sotrovimab is 500 mg of Sotrovimab. (One vial of sotrovimab (500 mg/8mL) - single dose. • Sotrovimab should be given as soon as possible aier positive results of direct SARS- CoV-2 viral testing and within 10 days of symptom onset. Sotrovimab must be diluted in 50 OR 100ml Normal Saline and administered as a single intravenous infusion of 500 mg over 30 minutes. • Dosage Adjustment in Specific Populations: • No dosage adjustment is recommended based on renal impairment, during pregnancy or while lactating. • No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg and are 12 years of age and older.

Monitoring	• Full sets of vital signs should be measured as follows:
	  • Pre-infusion.
	  • 15 minutes after start of infusion.
	  • End of infusion.
	• Patient should stay 60 minutes post completion of dose for observation and final sets of vitals will be taken before discharge.

Adverse effects	• Hypersensitivity reactions • Infusion related reactions
Contraindication	• Severe Covid • Passing of more than ten days since onset of symptom

Regen-Cov



FDA Emergency use authorization (EUA) of the approved product Regen-Cov (casirivimab and imdevimab) for Treatment of mild to moderate COVID-19 or as a post-exposure prophylaxis in adult and pediatric patients who are ≥12 years of age and weighting at least 40 Kg with positive result of direct SARS-CoV-2 viral testing. Target patient who are at high risk of progression to severe COVID-19. With the Aim to Reduce COVID-19 Related Hospitalization and death.

For Positive Cases: Within 10 days of Lab Confirmed COVID-19 PCR.

For Post Exposure Prophylaxis:

- Exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria (within 6 feet of someone for a cumulative total of 15 minutes or more over a 24-hour period)
- Do Not Exceed 96 hours from time of exposure.

Regen-Cov Treatment Protocol

Category	Details
Dose	• 600 mg of casirivimab and 600 mg of imdevimab administered together as a single intravenous infusion over a minimum of 20 minutes. • For COVID-19 Positive PCR: Regen-Cov should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset. • For Post Exposure Prophylaxis: Regen-Cov should be given as soon as possible after exposure to an individual infected with SARS-CoV-2 and within 96 hours from time of exposure. • No dosage adjustment is recommended in pregnant or lactating women • No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg and are older than 12 years of age. • No dosage adjustment is recommended in patients with renal impairment

Monitoring	• Full sets of vital signs should be measured as follows:
	  • Pre-infusion.
	  • 15 minutes after start of infusion.
	  • End of infusion.
	• Patient should stay 60 minutes post completion of dose for observation and final sets of vitals will be taken before discharge.

Adverse effects	• Hypersensitivity Reaction, including anaphylaxis. • Infusion Related Reaction, occurring during the infusion and up to 24 hours after the infusion.
Contraindication	• Severe Covid • individuals with previous severe hypersensitivity reactions, including anaphylaxis, to REGEN-COV

Treatment Guidelines : General approach

- Daily clinical assessment of patients is required
- It have been reported that deterioration is more common within the 8 to 10 days from symptoms onset
- Strict Isolation and adherence to infection control measures
- Baseline investigations for all patients:
  - ECG, Chest Xray/ Ultrasound chest
  - Echocardiography
  - CBC, Urea/Electrolytes, Creatinine, LFT
  - CRP, LDH, ESR, D-Dimer, Ferritin, PCT
- Risk stratification and prognostic markers
  - D-dimer, Fibrinogen, PT/PTT, Mg
  - Ferritin, CRP, ESR, PCT
  - LDH, Troponin, BNP
  - VWF, IL6
- All Patients should have the baseline investigations done, with the addition of Blood Grouping and Vitamin D level
- Medication Order Sheet
- Figure 1: Pharmacological management of patients with COVID-19 based on disease severity.
- Disclaimer
  - At present, no drug has been proven to be safe and effective for treating COVID-19. There are insufficient data to recommend either for or against the use of any antiviral or immunomodulatory therapy in patients with COVID-19 who have mild, moderate, severe, or critical illness
  - Guidelines are created based on best available evidence. Physicians should use this as a guide and depend on clinical and scientific judgment and individualizing of care
  - Physician should use this as a guide and depend on clinical and scientific judgment and individualizing of care
  - This guideline is subject to change based on more evidence and will be updated regularly whenever needed

BACK

Uncomplicated Infection (Upper Respiratory Tract Infection)

Definition:
- non-specific symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache, muscle pain.
- These patients do not have any signs of dehydration, sepsis or shortness of breath.
- Absence of signs of pneumonia

***Risk Factors**: any ONE of :
- Age ≥65 years
- Residence in a nursing home or long-term care facility
- Immunocompromising condition
- Chronic lung disease or moderate to severe asthma
- Cardiovascular disease (including hypertension)
- Severe obesity (body mass index [BMI] ≥40 kg/m2)
- Diabetes mellitus
- Chronic kidney disease (undergoing dialysis)
- Cerebrovascular disease
- Chronic liver disease
- Tobacco use disorder

Immediately implement strict infection control measures

Supportive care:
- IVF
- Antipyretics (Avoid NSAID)
- Symptomatic care

Consider the use of Zinc, Vitamin C and Vitamin D
Consider Thromboprophylaxis with **low molecular weight heparin (LMWH)** if not contraindicated (page 68)
Regular laboratory investigations for individuals with risk factors*

Baseline investigations :
- ECG, Chest Xray/ Ultrasound chest
- CBC, Urea/Electrolytes, Creatinine, LFT
- Blood Group and Vitamin D
- CRP, LDH, ESR, D-Dimer, Ferritin, PCT (and Respiratory panel PCR if available)

Investigations:

Risk stratification and prognostic markers (Daily for individuals with risk factors)
- D-dimer, Fibrinogen, PT/PTT, Mg
- Ferritin, CRP, ESR, PCT
- LDH, Troponin, BNP
- VWF, IL6

Guidelines are created based on best available evidence.
Physicians should use this as a guide and depend on clinical and scientific judgment and individualizing of care

BACK

Pneumonia

Definition

Pneumonia:

Patient with pneumonia and no signs of severe pneumonia.
Child with non-severe pneumonia has cough or difficulty breathing + tachypnea

Severe Pneumonia:

Adolescent or adult:
fever or suspected respiratory infection, **plus** one of

- Respiratory rate >30 breaths/min
- Severe respiratory distress
- SpO2 <93% on room air
- Lung infiltrates >50% of the lung field within 24- 48 hours
- Ferritin >500 ug/L; Ddimer >1mg/L ; CRP>100mg/L ; LDH>245 U/L ; Elevated Troponin

Child with cough or difficulty in breathing, **plus** at least one of the following:

- Central cyanosis
- SpO2 <93%;
- Severe respiratory distress (e.g. grunting, very severe chest indrawing);
- Signs of pneumonia with a general danger sign:
- Inability to breastfeed or drink,
- lethargy or unconsciousness, or convulsions.
- Other signs of pneumonia may be present: chest indrawing and tachypnea.

Immediately implement strict infection control measures (refer to Figure 1)

Pneumonia

- ICU Consultation and ICU care if necessary
- **Supportive care:**
  - IVF
  - Antipyretics (Avoid NSAIDS) and Symptomatic care
  - Oxygen (keep saturation >94%, start with 5L)
- Consider the use of Zinc, Vitamin C and Vitamin D
- **Remdesivir** (refer to page 73)
- **Tocilizimab** (refer to page 73 , 76)
- **Dexamethasone or Methylprednisolone** (if evidence of hypoxia)
- Consider the use of **Convalescent Plasma Therapy** (Based on Antibody titer for both the donor and the recipient)
- **LMWH/UFH** if not contraindicated (refer to page 68)
- Rule out other causes of pneumonia and PE

Severe Pneumonia

- ICU Consultation and ICU care
- **Supportive care:**
  - IVF, Antipyretics (Avoid NSAIDS) and Symptomatic care
  - Oxygen (keep saturation >94%, start with 5L)
  - Ventilatory support if needed
- **Remdesivir** (refer to page 73)
- **Tocilizimab** (refer to page 73 , 76)
- **Dexamethasone or Methylprednisolone** (if evidence of hypoxia)
- Consider the use of **Convalescent Plasma Therapy** (Based on Antibody titer for both the donor and the recipient)
- Consider the use of **Tocilizumab** (if fitting criteria)
- **LMWH/UFH** if not contraindicated (refer to page 68)
- Rule out other causes for pneumonia and PE

Baseline investigations :

- ECG, Chest Xray/Ultrasound chest
- CBC, Urea/Electrolytes, Creatinine, LFT
- CRP, LDH, ESR, D-Dimer, Ferritin, PCT
- Blood group and Vitamin D
- and Respiratory panel PCR (if available)

Investigations:

Risk stratification and prognostic markers (q12hr)

- D-dimer, Fbrinogen, PT/PTT, Mg
- Ferritin, CRP, ESR,PCT
- LDH, Troponin, BNP
- VWF, IL6

Daily: CBC, Biochemistry, ECG

Guidelines are created based on best available evidence.
Physicians should use this as a guide and depend on clinical and scientific judgment and individualizing of care

Acute Respiratory Distress Syndrome (ARDS)

Definition

Onset: new or worsening respiratory symptoms within one week of known clinical insult.

Chest imaging (radiograph, CT scan, or lung ultrasound): bilateral opacities, not fully explained by effusions, lobar or lung collapse, or nodules.

Origin of edema: respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic cause of edema if no risk factor present.

Oxygenation (adults):

- Mild ARDS: 200 mmHg < PaO2/FiO2 ≤ 300 mmHg (with PEEP or CPAP ≥5 cmH2O,
- Moderate ARDS: 100 mmHg < PaO2/FiO2 ≤200 mmHg with PEEP ≥5 cmH2O
- Severe ARDS: PaO2/FiO2 ≤ 100 mmHg with PEEP ≥5 cmH2O,
- When PaO2 is not available, SpO2/FiO2 ≤315 suggests ARDS (including in non-ventilated patients)

Oxygenation (children):

- Bilevel NIV or CPAP ≥5 cmH2O via full face mask: PaO2/FiO2 ≤ 300 mmHg or SpO2/FiO2 ≤264
- Mild ARDS (invasively ventilated): 4 ≤ OI < 8 or 5 ≤ OSI < 7.5
- Moderate ARDS (invasively ventilated): 8 ≤ OI < 16 or 7.5 ≤ OSI < 12.3
- Severe ARDS (invasively ventilated): OI ≥ 16 or OSI ≥ 12.3

OI= Oxygenation Index and OSI = Oxygenation Index using SpO2

Immediately implement strict infection control measures

- ICU Consultation and ICU care
- **Supportive care:**
  - IVF, Antipyretics (Avoid NSAIDS) and Symptomatic care
  - Oxygen (keep saturation >94%, start with 5L)
  - Ventilatory support if needed
- **Remdesivir**
- **Dexamethasone or Methylprednisolone** (if evidence of hypoxia)
- Consider the use of **Convalescent Plasma Therapy** (Based on Antibody titer for both the donor and the recipient)
- Consider the use of **Tocilizumab** (if fitting criteria)
- **LMWH/UFH** if not contraindicated (refer to page 68)
- Rule out other causes for pneumonia and treat accordingly
- Rule out the possibility of PE incase of worsening hypoxia

Baseline investigations :

- ECG, Chest Xray/ Ultrasound chest
- CBC, Urea/Electrolytes, Creatinine, LFT
- CRP, LDH, ESR, D-Dimer, Ferritin, PCT
- Blood Group and Vitamin D
- and Respiratory panel PCR (if available)

Investigations

Risk stratification and prognostic markers (q12hr)

- D-dimer, Fbrinogen, PT/PTT, Mg
- Ferritin, CRP, ESR,PCT
- LDH, Troponin, BNP
- VWF, IL6

Daily: CBC, Biochemistry, ECG

Consider ruling out PE (by echo or CTPA)

Guidelines are created based on best available evidence.
Physicians should use this as a guide and depend on clinical and scientific judgment and individualizing of care

Thromboprophylaxis dosing schedule

D-Dimer level (mcg/ml)	Weight (kg)	LMWH dose
<1	<100kg	Enoxaparin 40mg SC once daily
	100 – 150kg	Enoxaparin 40mg SC twice daily
	>150kg	Enoxaparin 60mg SC twice daily
>1	<100kg	Enoxaparin 40mg SC twice daily
	100 – 150kg	Enoxaparin 80mg SC twice daily
	>150kg	Enoxaparin 120mg SC twice daily

Empiric therapeutic anticoagulation in critical ill patient may be linked with increase complications. However, it is likely to be beneficial for moderate to severe cases. The choice and dose of Heparin should be adjusted based on creatine clearance, refer to your hospital protocol.

Clinician should weigh the potential benefit and harms based on the most up to date available evidence REFERENCE

Oxygenation and Ventilation

- For adults with COVID-19 and acute hypoxemic respiratory failure despite conventional oxygen therapy, high-flow nasal cannula (HFNC) oxygen is recommended over noninvasive positive pressure ventilation (NIPPV)
- Consider awake prone positioning to improve ventilation, if possible
- Incentive Spirometry if patient can perform
- Indirect evidence from other critical illnesses suggests the optimal oxygen target is an SpO2 between 92% and 96%
- Close monitoring for worsening respiratory status and intubation if necessary, in a controlled setting and by an experienced practitioner

Oxygenation and Ventilation

- For mechanically ventilated adults with COVID-19 and ARDS:
  - Use low tidal volume (Vt) ventilation (Vt 4–8 mL/kg of predicted body weight)
  - Target plateau pressures of <30 cm H2O
  - Use conservative fluid strategy over a liberal fluid strategy

- For mechanically ventilated adults with COVID-19 and moderate-to-severe ARDS:
  - Use a higher positive end-expiratory pressure (PEEP) strategy over a lower PEEP strategy

- For mechanically ventilated adults with COVID-19 and refractory hypoxemia despite optimizing ventilation, use prone ventilation for 12 to 16 hours per day

Antithrombotics in patients with COVID19

Hospitalized Patients	Patients for Home isolation
Laboratory Testing	
Measure coagulation markers (e.g.,CBC, D-dimers, prothrombin time, platelet count, fibrinogen) in Hospitalized patients.	There are currently no data to support the measurement of coagulation markers in non-hospitalized COVID-19 confirmed cases.
Venous Thromboembolism Prophylaxis and Screening:	
Hospitalized patient should be screened and VTE prophylaxis be initiated. Reference doses in page 68	Anticoagulants and antiplatelet therapy should not be initiated for prevention of venous thromboembolism (VTE) or arterial thrombosis unless there are other indications
Chronic Anticoagulant and Antiplatelet Therapy:	
Anticoagulant or antiplatelet therapies for underlying conditions should be continued unless there is need for switching to heparin	Patients who are receiving anticoagulant or antiplatelet therapies for underlying conditions should continue these medications if they receive a diagnosis of COVID-19
Special Considerations During Pregnancy	
Management of anticoagulation therapy in pregnant patients with COVID-19 is same as other conditions that require anticoagulation in pregnancy (40mg once daily) (Lexicomp, 2021).	If antithrombotic therapy is prescribed during pregnancy for another indication, this therapy should be continued if the patient receives a diagnosis of COVID-19 and is not admitted in hospital.
The D-dimer level may not be a reliable predictor of VTE in pregnancy, because there is a physiologic increase of D-dimer levels throughout gestation.	
Venous Thromboembolism Prophylaxis in children with COVID-19	
Pediatric patients admitted for COVID-19 who are moderately or severely ill be given VTE risk prophylaxis in accordance with existing institutional guidelines.	

Thromboprophylaxis post COVID 19 infection

- Extended thromboprophylaxis on discharge can be considered if the patient is at high risk of VTE and if risk of thrombosis outweight risk of bleeding

- The nature and duration of thromboprophylaxis in patients recovering from COVID-19 pneumonia is not clear but a standard prophylactic dose of LMWH or DOAC for **4 weeks** may be a reasonable approach.
  - Duration also depend on disease severity, bleeding risk, possibility of VTE and patient condition

- **Possible medications to be considered:**
  - Apixaban 2.5 mg BD
  - Rivaroxaban 15 mg OD
  - Clexane 40 mg SC OD

- **Risk factors for high risk of VTE**
  - Past history VTE
  - Known case of malignancy
  - Significantly reduced mobility
  - Critical care admission
  - Disease severity (e.g. need for MV, NIV, or high oxygen requirements (e.g. PaO2/FiO2 ≤40 kPA (300 mmHg)) during admission
  - D-dimer >1 mcg/ml

- **Important Considerations**
  - Bleeding risk to be evaluated, the risk of VTE should be outweigh the risk of bleeding.
  - Renal function should be checked before starting patient on DOAC.
  - Drug interaction needs to be reviewed.
  - Coagulation profile and platelet count need to be reviewed before starting patient on thromboprophylaxis

Reference: BTS Guidance on Venous Thromboembolic Disease in patients with COVID-19 Updated 4 May 2020

COVID19 Medications and Dosage

Drugs	Dose
Zinc	50mg Oral Once daily
Vitamin C	1g Oral once daily
Vitamin D (dependig of patients Vitamin D levels)	2000 to 4000 iU daily or 50,000 iU weekly (With Ca+2 monitoring twice a week) or Can also consider dosing related to Vitamin D Level • Serum 25(OH)D 20 to 30 ng/mL: 2000- 4000 iU once daily • Serum 25(OH)D<20 ng/ml: 50,000 iU per day for 7 days with Rechecking level at Day 7. Adjust the dose based on Vit D level **Reference**
Remdisivir	Adult dose: • Day 1: 200mg IV Once Daily • Days 2 to 5: 100mg IV Once Daily *may extend for up to 5 additional days in patients who do not demonstrate clinical improvement.*
Dexamethasone	6mg IV OD for 5-10 days For pregnant: consider prednisolone 40mg OD or 20mg BID Reference Equivalent to Dexamethasone: Prednisolone 40mg or Methylprednisolone 32mg or Hydrocortisone 160mg
Tocilizumab (refer to page 76)	The initial dose is 4-8mg/kg (recommended dose of 400mg diluted with 0.9% normal saline to 100ml). If the initial medication is not effective, one extra administration can be given after 12 hours (same dose as before). No more than two administrations should be given, with the maximum single dose no more than 800mg. The infusion time should be more than 1 hour. Contraindicated for people with active infections such as tuberculosis. Avoid using with interferon

Remdesivir Treatment Protocol

Category	Details
Dose	Adult dose: • Day 1: 200mg IV Once Daily • Days 2 to 5: 100mg IV Once Daily Pediatric dose: *weight-based dosing 3.5 ≥40* • Day 1: 5 mg/kg IV Once Daily • Days 2 to 5: 2.5 mg/kg IV Once Daily General comments: For patients **not requiring** invasive mechanical ventilation and/or ECMO, recommended total treatment duration is **5 days**; if patients do not demonstrate clinical improvement, treatment may be extended for up to **5 additional days** (i.e., up to a total treatment duration of 10 days). For those **requiring** invasive mechanical ventilation and/or ECMO, recommended total treatment duration is **10 days**.
Contraindications	• Hypersensitivity to Remdesivir or any component of the formulation. • Patients with ALT ≥5 times the ULN (upper limit of normal) at baseline. • Renal impairment. (eGFR <30)
Monitoring	• Serum Creatinine, • Biochemical profile • Liver Function tests: ALT, AST, ALP, Bilirubin
Adverse Reactions	• Increased serum glucose • Fever • Infusion reactions

Dexamethasone Treatment Protocol

Category	Details
Dose	Adult dose: 6mg IV OD for 5 -10 days or until discharge
Monitoring	• Serum K, Glucose, sugars • Blood pressure, hemoglobin • Occult blood loss • WBC and Neutrophil count
Adverse effects	• Hypertension • Hyperglycemia • Gastric perforation
Precautions:	**Cardiovascular disease:** Use with caution in patients with heart failure and/or hypertension/ following acute myocardial infarction **Diabetes:** More frequent monitoring and dose titration of Anti-diabetic medications **Gastrointestinal disease:** Use with caution in patients with GI diseases (diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, ulcerative colitis, abscess or other pyogenic infection) due to perforation risk. **Myasthenia gravis:** exacerbation of symptoms has occurred especially during initial treatment with corticosteroids. **Seizure disorders:** Seizures have been reported with adrenal crisis.
Contraindication	Hypersensitivity to dexamethasone or any component of the product Systemic fungal infection Concomitant use of more than a single dose of dexamethason with rilpivirine

Tocilizumab

- Tocilizumab can be given in COVID19 in the presence of severe cytokine storm
- Criteria of Severe Cytokine Syndrome:

1. **It should be used with Dexamethasone (NHS, ASHP)**
2. AND Laboratory parameters supportive of cytokine storm including:
   - Serum IL-6 at least 3 X ULN; OR
   - Ferritin >300 ug/L (or surrogate) with doubling within 24 hours; OR
   - Ferritin > 600 ug/L at presentation with LDH >250 U/L; OR
   - Elevated D-dimer (> 1 mg/L).
   - CRP ≥75 mg/L or >50 but doubled in past 48 hours
3. AND Rapidly worsening gas exchange within 24hrs requiring >6 L/min or HFNC, or O2 sats <93% (NHS, NIH ASHP)

Avoid use

- Avoid use in patients with platelets <50,000 and those with ANC <1,000
- Known hypersensitivity to tocilizumab or any component of the formulation
- Active infections, interrupt the treatment in case of developing severe infection.
- Patient with decompensated cirrhosis
- A baseline alanine aminotransferase (ALT) or aspartate aminotransferase (AST) more than 5 times the upper limit of normal.
- A pre-existing condition or treatment resulting in ongoing immunosuppression. (NHS, NIH)

(Recovery and REMAP –CAP)

References and Further Reading

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

الحملة الوطنية
لمكافحة
فيروس كورونا
(COVID-19)

COVID-19 Multisystem Inflammatory Disease in Children

Background

- Children compromise a small percentage of symptomatic SARS-COV-2 cases, even with symptoms children are usually reported to have mild to moderate symptoms.
- Recent reports have shown rare cases of systemic inflammation associated temporarily with SARS-COV-2.
- Children with this condition present with fever and hyper-inflammation, and may also have features of Kawasaki disease (KD), features of Toxic Shock Syndrome (TSS), or with acute gastrointestinal symptoms mimicking appendicitis.
- This can further develop into life threatening shock with single or multi-system dysfunction and require admission into critical care.
- A temporal association is clear, and the onset of PIMS/MIS-C typically follows 3 to 6 weeks after the peak of a COVID-19 outbreak in the local population.
- Studies have shown that most children test negative for SARS-COV-2 by PCR from nasopharyngeal swabs, however 80-100% tested positive to SARS-COV-2 antibodies.

Case Definition

- Case definition varies between institutes and its important to be aware of all

Category	RCPCH	CDC	WHO	CPSP
Age	Child	<21years	0 to 19 years	<18 years
Length of fever	Not specified	≥ 24hr	≥3days	≥3days
Evidence of inflammation	Yes	Yes	Yes	Yes
Multisystem	Single organ or multisystem	≥ 2 systems involved	≥ 2 systems involved	Implied, but not specified
Exclude other causes	Yes	Yes	Yes	Yes
SARS-CoV2 PCR or Antibody or exposure	Not necessary	Necessary	Necessary	Necessary

RCPCH: Royal College of Pediatrics and Child Health
CPSP: Canadian Pediatric Surveillance Program

Presentation

	Classic pre-pandemic KD	PIMS/MIS-C
Average age at presentation (years)	<5	7 to 9
Ethnicity	East Asian +	African, Afro-Caribbean +
Gastrointestinal symptoms	+	+++
Cardiac dysfunction	+	+++
Coagulopathy	+	++
Shock	+	++
Macrophage activation syndrome	+	++
Markedly elevated CRP	++	++++
Elevated ferritin	+	++
Elevated D-dimers	+	++
Elevated cardiac biomarkers (NT-proBNP, troponin)	+	++
Thrombocytopenia	rare	++
Coronary artery abnormalities	++	+

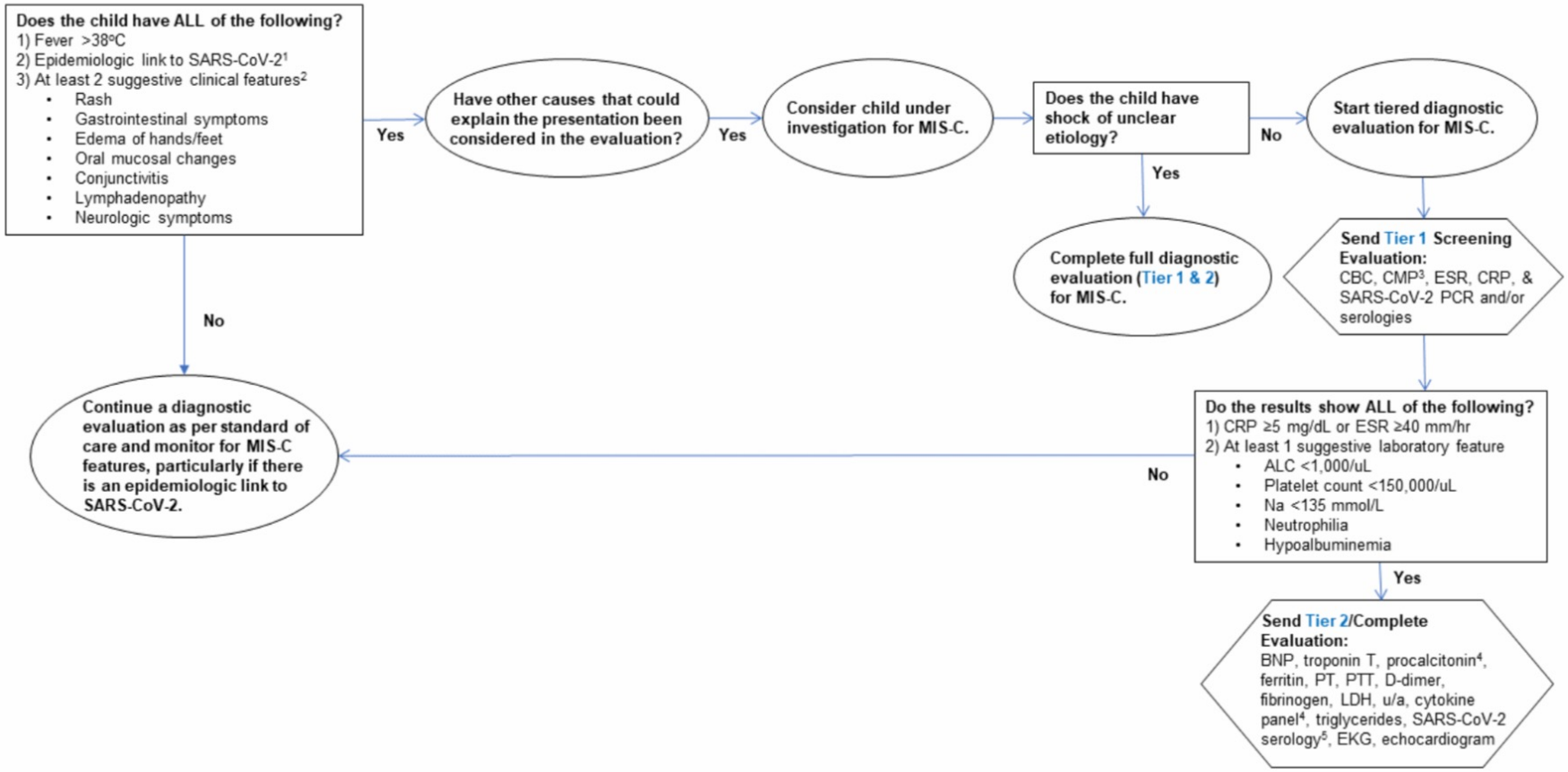
Presentation

- The hallmark of PIMS/MIS-C is fever >3 days that is unexplained by other causes, evidence of systemic inflammation, and a temporal association with COVID-19.
- The clinical presentation is fever with hyper-inflammation with features of Kawasaki Disease or features of Toxic Shock Syndrome with signs of shock or shock-like state with hypotension or poor perfusion and myocardial dysfunction, or GI distress, or neurological symptoms (like neck stiffness, lethargy, and altered mental status)
  - see appendix Table A and Table B for features of KD and TSS

- PIMS/MIS-C shares many symptoms with KD. A few major differentiating features are
  - PIMS/MIS-C has GI symptoms (rare in classic KD) and more severe myocarditis and cardiac dysfunction.
  - GI symptoms at presentation have been prominent in all case series reported to date and included features of an acute abdomen, with vomiting, diarrhea, and severe pain, but have rarely prompted surgical intervention.
  - While the major cardiac morbidity associated with KD is the development of coronary artery aneurysms, children with PIMS/MIS-C have presented with severe myocarditis and cardiogenic shock.

Evaluation

- Early diagnosis is essential to provide the required care



1An epidemiologic link to SARS-CoV-2 infection is defined as a child with ANY of the following criteria: positive SARS-CoV-2 polymerase chain reaction (PCR), positive SARS-CoV-2 serologies, preceding illness resembling COVD-19, or close contact with confirmed or suspected COVID-19 cases in the past 4 weeks.
2Rash, (polymorphic, maculopapular, or petechial, but not vesicular); GI symptoms, (diarrhea, abdominal pain, or vomiting); oral mucosal changes, (red and/or cracked lips, strawberry tongue, or erythema of the oropharyngeal mucosa); conjunctivitis, (bilateral conjunctival injection without exudate); neurologic symptoms, (altered metal status, encephalopathy, focal neurologic deficits, meningismus, or papilledema).
3Complete metabolic panel: Na, K, CO2, Cl, BUN, Cr, glucose, Ca, albumin, total protein, AST, ALT, ALP, Bilirubin. 4Send procalcitonin and cytokine panel, if available.
5If not sent in tier 1 evaluation. If possible, send SARS-CoV-2 IgG, IgM, IgA.

Management of MIS-C involves:

- Immunomodulatory treatment in MIS-C
- Antiplatelet and anticoagulation therapy in MIS-C
- Cardiac management of MIS-C
- Immunomodulatory treatment in children with acute symptoms of COVID-19 (respiratory symptoms of SARS-CoV2)

- Details on management provided in appendix

- **Further management:** https://www.rheumatology.org/Portals/0/Files/ACR-COVID-19-Clinical-Guidance-Summary-MIS-C-Hyperinflammation.pdf

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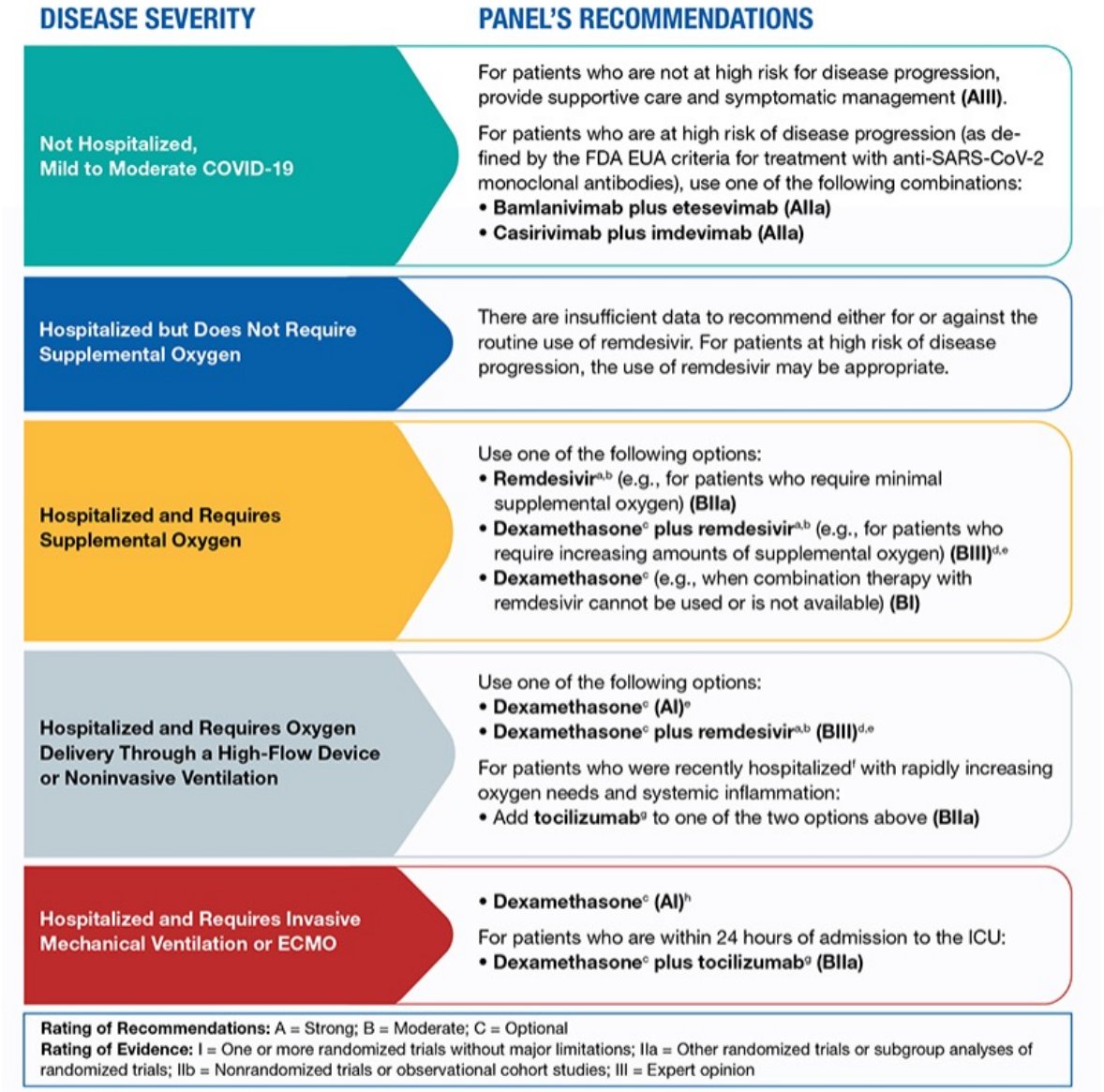
Appendix

Pharmacological Management of Patients With COVID-19 Based on Disease Severity

Figure (1)



DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Not Hospitalized, Mild to Moderate COVID-19	For patients who are not at high risk for disease progression, provide supportive care and symptomatic management **(AIII)**. For patients who are at high risk of disease progression (as defined by the FDA EUA criteria for treatment with anti-SARS-CoV-2 monoclonal antibodies), use one of the following combinations: • **Bamlanivimab plus etesevimab (AIIa)** • **Casirivimab plus imdevimab (AIIa)**
Hospitalized but Does Not Require Supplemental Oxygen	There are insufficient data to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, the use of remdesivir may be appropriate.
Hospitalized and Requires Supplemental Oxygen	Use one of the following options: • **Remdesivir**[a,b] (e.g., for patients who require minimal supplemental oxygen) **(BIIa)** • **Dexamethasone**[c] **plus remdesivir**[a,b] (e.g., for patients who require increasing amounts of supplemental oxygen) **(BIII)**[d,e] • **Dexamethasone**[c] (e.g., when combination therapy with remdesivir cannot be used or is not available) **(BI)**
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	Use one of the following options: • **Dexamethasone**[c] **(AI)**[e] • **Dexamethasone**[c] **plus remdesivir**[a,b] **(BIII)**[d,e] For patients who were recently hospitalized[f] with rapidly increasing oxygen needs and systemic inflammation: • Add **tocilizumab**[g] to one of the two options above **(BIIa)**
Hospitalized and Requires Invasive Mechanical Ventilation or ECMO	• **Dexamethasone**[c] **(AI)**[h] For patients who are within 24 hours of admission to the ICU: • **Dexamethasone**[c] **plus tocilizumab**[g] **(BIIa)**

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion

https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/

Management of MIS-C

Immunomodulatory treatment in MIS-C

- A stepwise progression of immunomodulatory therapies should be used to treat MIS-C with IVIG and/or glucocorticoids considered as first tier treatments (M/H).
- High dose IVIG (typically 1-2 gm/kg) may be considered for treatment of MIS-C. Cardiac function and fluid status should be assessed in MIS-C patients with shock before IVIG treatment is provided, and IVIG should be administered when cardiac function is restored. (M/H).
- Low-moderate dose glucocorticoids may be considered for treatment of MIS-C. High dose, IV pulse glucocorticoids may be considered to treat patients with life-threatening complications, such as shock, and specifically, if a patient requires high dose or multiple inotropes and/or vasopressors (M/H).
- Anakinra (IV or SQ) may be considered for treatment of MIS-C refractory to IVIG and glucocorticoids or in patients with contraindications to these treatments (M/H).
- Serial laboratory testing and cardiac assessment should guide immunomodulatory treatment response and tapering. Patients will often require a 2-3-week taper of immunomodulatory medications (H).

Antiplatelet and anticoagulation therapy in MIS-C

- Low dose aspirin (3-5 mg/kg/day; max 81 mg/day) should be used in patients with MIS-C and KD-like features and/or thrombocytosis (platelet count ≥450,000/μL) and continued until normalization of platelet count and confirmed normal coronary arteries at ≥4 weeks after diagnosis. Treatment with aspirin should be avoided in patients with a platelet count ≤80,000/μL (M).
- MIS-C patients with CAAs and a maximal z-score of 2.5-10.0 should be treated with low dose aspirin. Patients with a z-score ≥10.0 should be treated with low dose aspirin and therapeutic anticoagulation with enoxaparin (factor Xa level 0.5-1.0) or warfarin (M/H).
- Patients with MIS-C and documented thrombosis or an ejection fraction (EF) <35% should receive therapeutic anticoagulation with enoxaparin until at least 2 weeks after discharge from the hospital (H).
- Indications for longer outpatient therapeutic enoxaparin dosing include: CAA with z-score >10.0 (indefinite treatment), documented thrombosis (treatment for ≥3 months pending thrombus resolution), or ongoing moderate to severe LV dysfunction (H).
- For MIS-C patients who do not meet the above criteria, the approach to antiplatelet and anticoagulation management should be tailored to the patient's risk for thrombosis (H).

Cardiac management of MIS-C:

- Patients with MIS-C and abnormal BNP and/or troponin T at diagnosis should have these laboratory parameters trended over time until they normalize (H).
- EKGs should be performed at a minimum of every 48 hours in MIS-C patients who are hospitalized and during follow-up visits. If conduction abnormalities are present, patients should be placed on continuous telemetry while in the hospital, and Holter monitors should be considered during follow-up (M/H).
- Echocardiograms conducted at diagnosis and during clinical follow-up should include evaluation of ventricular/valvar function, pericardial effusion, and coronary artery dimensions with measurements indexed to body surface area using z-scores (H).
- Echocardiograms should be repeated at a minimum of 7-14 days and 4-6 weeks after presentation. For those patients with cardiac abnormalities occurring in the acute phase of their illness, an echocardiogram 1 year after MIS-C diagnosis could be considered. Patients with left ventricular (LV) dysfunction and/or CAA will require more frequent echocardiograms (M/H).
- Cardiac MRI may be indicated 2-6 months after MIS-C diagnosis in patients who presented with significant transient LV dysfunction in the acute phase of illness (LV ejection fraction <50%) or persistent LV dysfunction. Cardiac MRI should focus on myocardial characterization including functional assessment, T1/T2 weighted imaging, T1 mapping and extracellular volume (ECV) quantification, and late gadolinium enhancement (H).
- Cardiac CT should be performed in patients with suspicion of distal CAAs that are not well seen on echocardiogram (M).

Immunomodulatory treatment in children with COVID-19 (Current acute symptoms of SARS-COV2):

- Children with severe respiratory symptoms due to COVID-19 with any of the following should be considered for immunomodulatory therapy: acute respiratory distress syndrome (ARDS), shock/cardiac dysfunction, substantially elevated lactate dehydrogenase (LDH), D-dimer, IL-6, IL-2R, CRP, and/or ferritin, and depressed lymphocyte count, albumin, and/or platelet count (M/H).
- Glucocorticoids may be considered for use as immunomodulatory therapy in patients with COVID-19 and hyperinflammation (as outlined in point above) (M).
- Anakinra appears safe in severe infections and in children with hyperinflammatory syndromes. In children with COVID-19 and hyperinflammation, anakinra (>4mg/kg/day IV or SQ) should be considered for immunomodulatory therapy. Initiation of anakinra before invasive mechanical ventilation may be beneficial (H).
- Children with COVID-19 treated with anakinra should be monitored for liver function test (LFT) abnormalities (M).
- Compared to standard care, tocilizumab may be effective in reducing mortality and ICU admission in patients with severe COVID-19 pneumonia and signs of hyperinflammation; however, patients treated with tocilizumab may be at higher risk for bacterial and fungal infections (M).
- When tocilizumab is used to treat children with COVID-19, weight-based dosing should be employed (<30kg: 12mg/kg IV; ≥30kg: 8mg/kg IV, max 800mg). Children treated with tocilizumab should be monitored for LFT abnormalities and elevated triglycerides (M/H).
- In the absence of randomized controlled trails or comparative effectiveness studies, if immunomodulation is to be used at all, the balance of risks and benefits suggests anakinra as first-line immunomodulatory treatment of children with COVID-19 and hyperinflammation. There is insufficient evidence to support the use of other immunomodulatory agents unless glucocorticoids

References

- Canadian Pediatric Society
- Royal College of Pediatrics and Child Health
- American College of Rheumatology

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(COVID-19)

COVID-19 Medication Order Sheet

Medication Order sheet for Adult COVID-19

Indicate choice by checking the box:

□ **Pregnancy test** for Hydroxychloroquine, Lopinavir/ritonavir, Ribavirin, or Favipiravir

□ **ECG monitoring 12-lead or telemetry**: (check all that apply per guideline): □ Baseline. □ 2 hours after Hydroxychloroquine dose. □ Daily. □ Every 48 hours

□ **Baseline tests**: CBC with differential, Blood Group and Vitamin D level, urea, creatinine, electrolytes serum glucose level, LFT, CRP, PCT, ESR, D-dimer, PT&PTT, Fibrinogen (repeat 24 - 48 hrs as indicated)

□ **Tests to assess complicated infection**: serum ferritin, LDH, triglycerides, serum lactate, Troponin-I, BNP, CK-MP, VWF and IL-6 *(repeat 24 - 48 hours as indicated)*

Medication	Dose	Contraindication	Monitoring
Vitamins			
□ **Zinc**	□ 50 mg daily	Hypersensitivity	• Serum copper • serum zinc • Alkaline phosphatase • Mental depression • taste acuity
□ **Vitamin C**	□ 1g daily	Non specific	• Renal function • Hb and CBC (in patients with G6PD)
□ **Vitamin D**	□ 50,000 unit's PO/NGT weekly or 2000/4000 PO/NGT Daily	No specific contraindications	Vitamin D level
Antipyretics			
□ **Paracetamol**	□ 325 - 650 mg q4-6 hr Or 1 g q 6hr Not Exceed 4 g/day	Hypersensitivity Severe hepatic impairment	Relief of fever

Medication Order sheet for Adult COVID-19

Medication	Dose	Contraindication	Monitoring
Antivirals			
□ **Remdesivir**	□200 mg iv day 1 then 100 mg daily for 9 days	Hypersensitivity	• Baseline and daily (ALT, AST, Bilirubin, ALP) • serum creatinine and CrCl
Anticoagulants			
□ **Enoxaparin**	□ 40 mg once daily Consider higher dose if D Dimer >1000 ng/ml	• Hypersensitivity • Active major bleeding	▪ Bleeding parameter ▪ Serum creatinine
□ **Heparin**	□ 5000 IUq 8-12 hr	• Hypersensitivity • Active major bleeding • HIT in the past 100 days	▪ Bleeding parameter
□ **Fondaparinux**	□ 2.5mg SC Daily	• Hypersensitivity • Active major bleeding	▪ Bleeding parameter

Medication Order sheet for Adult COVID-19

Medication	Dose	Contraindication	Monitoring
Steroids			
□ **Dexamethasone (For patients who require non- invasive or invasive ventilation):**	Adult dosing: **6 mg once daily** oral (liquid or tablet or IV for 5-10 days	■ **In pregnant or breastfeeding women**, prednisolone or IV Hydrocortisone 80 mg twice daily **should be us instead of Dexamethasone** ■ **Take precautions** when used with: Cardiovascular, diabetes, Gastrointestinal, Myasthenia graves and seizure patients	
□ **Methylprednisolone**	1 mg/kg/day (based on actual body weight divided in 2 doses) mg □ IV or □ PO/NGT BID for 3 days	■ (If severe hypoxia persists with continued supplemental oxygen requirement on day 3, extend to a total duration of 5 - 7 days)	
Statin			
□ **Atorvastatin**	□ 40 mg PO daily	If patient receiving Lopinavir/Ritonavir, then Atorvastatin 20 mg PO daily	
□ **Rosuvastatin**	□ 20 mg PO daily	If patient receiving Lopinavir/Ritonavir, then Rosuvastatin 10 mg PO daily	
Disease modifying interleukin 6 receptor antagonist			
□ **Tocilizumab**	□ 4-8 mg/kg/dose. Maximum 2 doses □ 50-59 kg: 400 mg IV X 1 dose □ 60-85 kg: 600 mg IV X 1 dose □ >85 kg: 800 mg IV X 1 dose	Laboratory criteria for patient at high risk of developing cytokine storm: • Ferritin >500 mcg/l • Elevated D-Dimer > 1 mg • CRP>75-100 mg/dl • LDH >250 U/L • Lymphocyte count <0.8	

Medication Order sheet for Adult COVID-19

Medication	Dose	Contraindication	Monitoring
Antibiotics ONLY for Community or Hospital Acquired Pneumonia :			
□ **Vancomycin**	15 mg/kg .....mg IV every.....hours	Vancomycin trough 30-minute pre 4th dose or 24 hours if renal impaired (target trough 15 - 20 mg/dl)	
□ **Azithromycin**	500 mg IV or PO Daily		
□ **Ceftriaxone**	1 or 2g IV Daily		
□ **Cefepime**	2 g IV q 8 hours:		
□ **Piperacillin/tazobactam**	___g IV q___hours		
□ **Meropenem**	___mg IV q___hours		
□ **Doxycycline**	100 mg □ IV or OPO ql2 hours		

Medication Order sheet for Adult COVID-19

Medication	Dose	Contraindication	Monitoring
Monoclonal antibodies			
Bamlanivimab	• Bamlanivimab 700mg in 200ml Normal Saline via IV infusion over at least 60 minutes /1 dose. • Administer via pump using a polyvinylchloride (PVC) of polyethersulfone (PES) set containing a 0.22 micron in–line filter. • Flush line with normal saline after infusion complete to insure delivery of the total dose.	Hypersensitivity And Anaphylaxis	• Vital Signs pre–infusion, 15 minutes after start of infusion, then every 30 minutes during, andone hour after completion of dose • A nurse to be in attendance during the first 15 minutes of infusion, and then close observationfor the remainder of infusion. • If patient develops flushing of face, chest tightness, chills, fever, dizziness, nausea, diaphoresis, or hypotension, stop infusion and restart normal saline. Take vital signs andnotify physician and pharmacist. Monitor until condition resolves. • Have immediately available, T B syringe, 12ml syringe, 22 gauge needles x2, Epinephrine1:1000 x1 amp, sterile water x2, Benadryl 50mg inject x1 amp, and 3ml syringe.

Medication Order sheet for Adult COVID-19

Medication	Dose	Contraindication	Monitoring
Monoclonal antibodies			

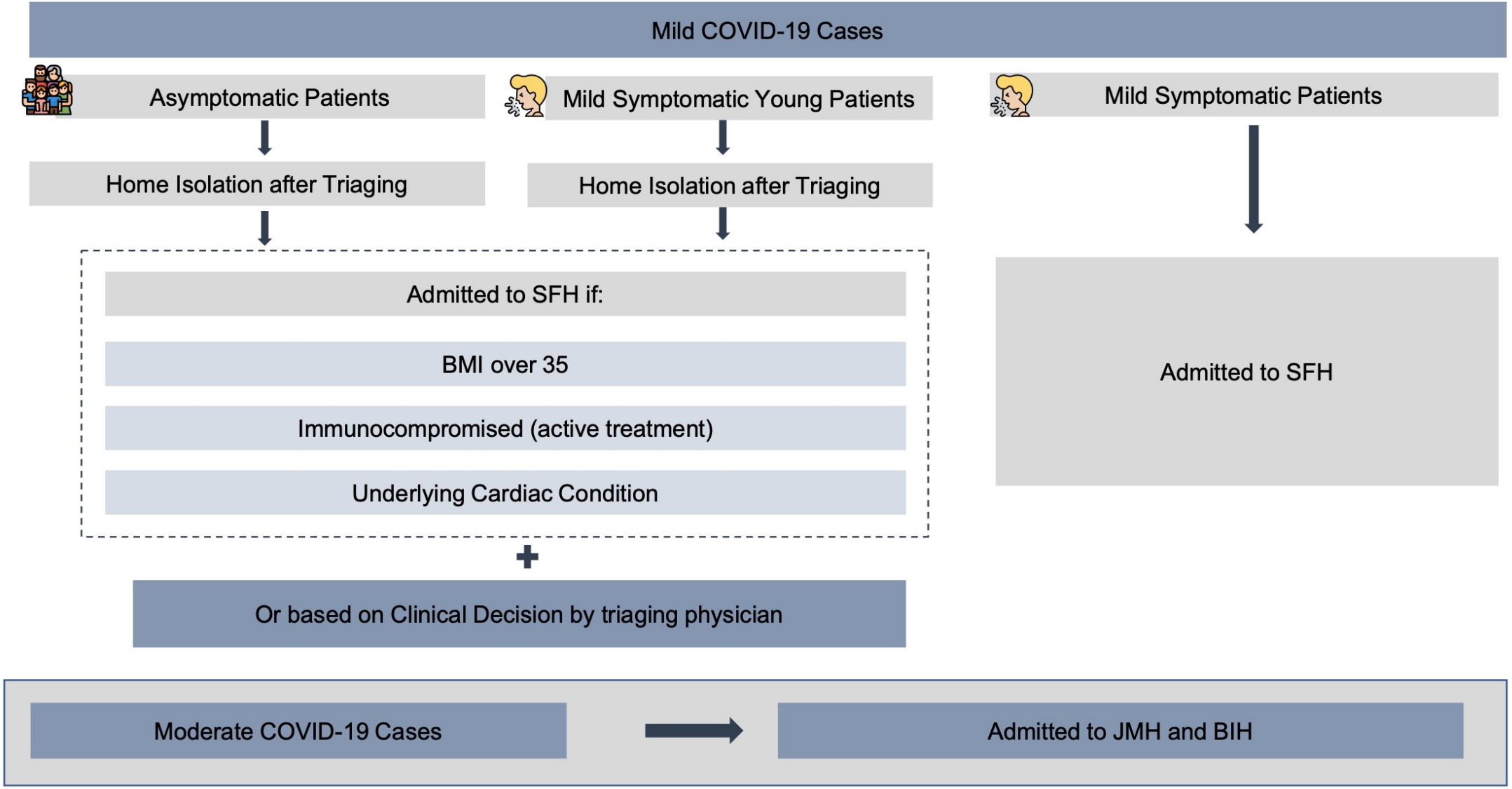
Sortovimab	• The dosage of sotrovimab is 500 mg of Sotrovimab. (One vial of sotrovimab (500 mg/8mL) - single dose.
	• Sotrovimab should be given as soon as possible aier positive results of direct SARS- CoV-2 viral testing and within 10 days of symptom onset. Sotrovimab must be diluted in 50 OR 100ml Normal Saline and administered as a single intravenous infusion of 500 mg over 30 minutes.
	• Dosage Adjustment in Specific Populations:
	• No dosage adjustment is recommended based on renal impairment, during pregnancy or while lactating.
	• No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg and are 12 years of age and older.
		• Severe Covid
		• Passing of more than ten days since onset of symptom
			• Full sets of vital signs should be measured as follows:
			  • Pre-infusion.
			  • 15 minutes after start of infusion.
			  • End of infusion.
			• Patient should stay 60 minutes post completion of dose for observation and final sets of vitals will be taken before discharge.

Medication Order sheet for Adult COVID-19

Medication	Dose	Contraindication	Monitoring
Monoclonal antibodies			

Regen-Cov	• 600 mg of casirivimab and 600 mg of imdevimab administered together as a single intravenous infusion over a minimum of 20 minutes.
	• For COVID-19 Positive PCR: Regen-Cov should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.
	• For Post Exposure Prophylaxis: Regen-Cov should be given as soon as possible after exposure to an individual infected with SARS-CoV-2 and within 96 hours from time of exposure.
	• No dosage adjustment is recommended in pregnant or lactating women
	• No dosage adjustment is recommended in pediatric patients who weigh at least 40 kg and are older than 12 years of age.
	• No dosage adjustment is recommended in patients with renal impairment
		• Severe Covid
		• individuals with previous severe hypersensitivity reactions, including anaphylaxis, to Regen-COV
			• Full sets of vital signs should be measured as follows:
			  • Pre-infusion.
			  • 15 minutes after start of infusion.
			  • End of infusion.
			• Patient should stay 60 minutes post completion of dose for observation and final sets of vitals will be taken before discharge.

Contingency plan



Contingency plan

Triaging

Admission based on clinical decision (in SFH)*

Primary Care Physicians + Five STRPs

+

Four Team Leaders from Secondary Care (Decision Makers)

Ambulance

Coordination between the ER Departments

Setting up a waiting area for COVID cases

Visual/tele-triaging system

Contingency plan

Modified Admission Criteria

Category	Criteria	Destination
High Risk Asymptomatic Very mild Symptoms	High clinical score	Home Isolation (Close F/U Primary Care)
Mild	•Mild symptoms •O2 Sat RA ⩾95% •Minimal CXR changes •Other non acute indications	Home Isolation (Close F/U Primary Care) Unless clinically not fit Very selected cases to be admitted to RAF, BIH, JMH
Moderate	•Moderate symptoms • O2 saturation of <94 % on room air or decrease in saturation to < 90% with ambulation • Respiratory rate of >30/min • Lung infiltrates >50 %	Sitra FICU SMC level 5/6 EKK Helipad MKCC KIMS Sehati BIH JMH
Severe	•Severe Symptoms or altered mental status •Pneumonia +Other system/organ failure •Requiring ≥6L to maintaining O2 Sat ≥96%	HBDC SMC level 6 Sitra FICU Sehati
Critical	•Unstable hemodynamic status •Requiring >15L Oxygen. •HFNC, Intubation or NIV •Impending Respiratory Failure on ABG	HBDC SMC 61,66 Sitra FICU BDF FICU Sehati

Contingency plan

General Rules for GP/ED physicians

CONSIDER ADMISSION	CONSIDER HOME ISOLATION
Medical Criteria for Admission:	
Advanced Comorbid condition with new/worsening shortness of breath	**None of admission criteria**
New oxygen requirement (compared to baseline for those on home oxygen or those with known baseline hypoxia)	**Reliable phone number where the patient could be reached for post-discharge follow-up**
Chest x-ray showing significant opacities (Viral pneumonia)* if performed	**Ability to understand and follow self-isolation recommendations**
Abnormal respiratory rate >30	**Satisfactory Home isolation setup**
Temperature >38.9 C only if associated with abnormal RR, chest x-ray changes or new oxygen requirement	
Confusion or altered mental status	
Other indications that requires admission. (e.g. CRF on HD, etc..)	