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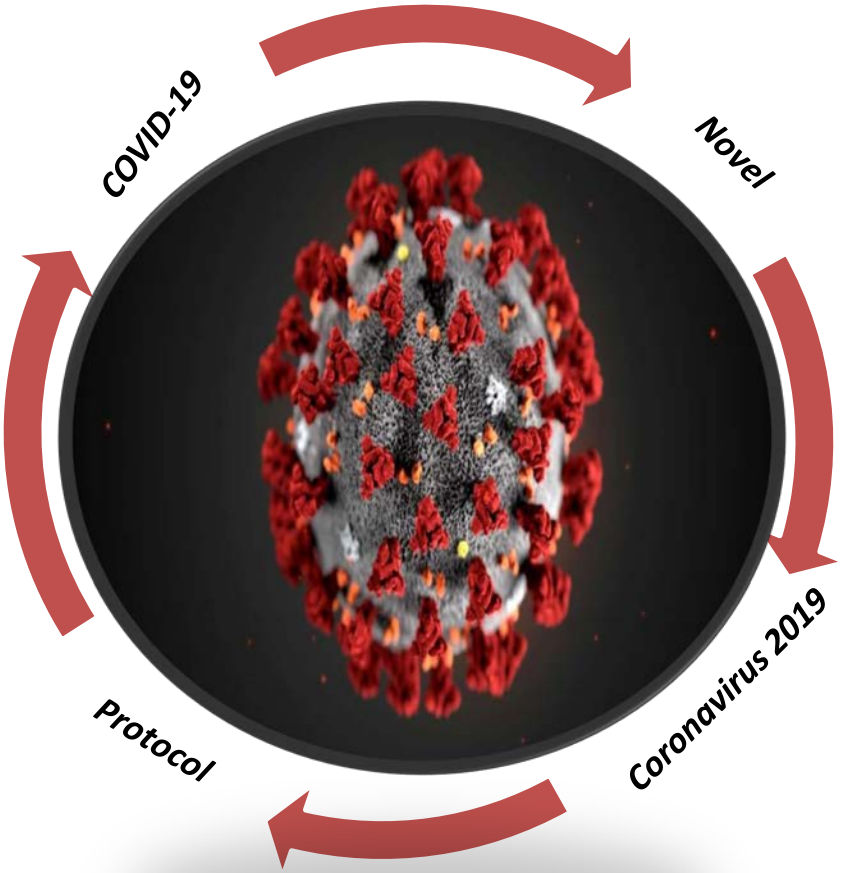
www.JacksonHealth.org
305 585-1111

COVID-19 (Novel Coronavirus 2019) Protocol

4/27/2023



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SCOPE:
All Jackson Healthcare System facilities

PURPOSE:
This document provides guidance for clinicians, health care workers, and other staff who provide care for patients with suspected or confirmed infection with novel coronavirus 2019 (COVID-19). It also describes guidelines for the screening and management of employees who may be exposed to or ill with this viral infection. This protocol is designed to be an overall protocol for JHS facilities and can serve as a template that can be adapted to individual needs or concerns at each JHS facility. Jackson Health System also has each facility's OPS Plans for COVID-19, which can be accessed by your facilities executive leadership. This protocol will be revised and updated as additional information related to the epidemiology, prevention and management of COVID-19 becomes available. The reader is encouraged to visit the main websites of the Centers for Disease Control and Prevention at https://www.cdc.gov/coronavirus/index.html and the Florida Department of Health at www.floridahealth.gov. Since the guidance change periodically, hence please check on CDC website (and other websites in the links) for latest up-to-date information.

COVID-19 is a viral respiratory illness caused by a novel coronavirus.

As per WHO Situation Report of April 26th, 2023, globally there were 764,474,387 confirmed cases and 6,915,286 deaths. At least 223 countries, areas and territories in the world have COVID19 cases. As of April 26th, 2023, per CDC USA had 104,445,294 cases and 1,129,573 deaths. As of April 14th, 2023, per FDOH Florida weekly report (April 7th – 13th) Florida had 7,537,137 cases and 87,799 deaths. In Miami Dade County as of April 26th, 2023, there were a total of 1,538,371 cases.

FDOH weekly cases and vaccination data is available at this link
(http://ww11.doh.state.fl.us/comm/_partners/covid19_report_archive/covid19-data/covid19_data_latest.pdf**)**

As far as COVID Vaccination data, please see the following links

World COVID19 Vaccination Data Tracker: https://ourworldindata.org/covid-vaccinations
CDC COVID19 cases and Vaccine Data Tracker: https://covid.cdc.gov/covid-data-tracker/#datatracker-home
FDOH COVID19 Vaccine Data: http://ww11.doh.state.fl.us/comm/_partners/covid19_report_archive/covid19-data/covid19_data_latest.pdf

Please also look at the daily updates sent to JHS Employees by our communications department and see COVID-19 part of Jackson Badge Buddy App. **To Down Load Jackson Badge Buddy App:**
iPhone: Enter "JacksonBadgeBuddy.org" into the browser (Safari, Google Chrome, etc.) to reach the site. Scroll to bottom of screen to  **icon, select the add to home screen icon**  **and save.**

CRITERIA TO GUIDE EVALUATION OF PUI FOR COVID-19 AND CLINICAL GUIDANCE FOR COVIDE-19
Clinicians with help of local health department if needed, should determine whether a patient is a PUI for COVID-2019. The CDC clinical criteria for COVID-19 PUIs have been developed based on available information about this novel virus, as well as what is known about Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). These criteria are subject to change as additional information becomes available

Clinical Care Quick Reference for COVID-19 (99.197)
Using Therapeutics to Prevent and Treat COVID-19 (99.198)
Hospitalized Adults: Therapeutic Management | COVID-19 Treatment Guidelines (99.199)

COVID Testing Update
July 23, 2021

Out of an abundance of caution and as we experience a rise in COVID cases throughout the county, city, and local hospitals, Jackson Health System will implement the below change to the COVID testing protocol for all admissions to our hospitals **effective immediately regardless of vaccination status**.

ED Admissions:

- *Vaccinated AND Asymptomatic*– Perform rapid antigen POC test.
  - If positive, reflex to PCR to confirm positive results.
  - If negative, proceed to admission.

NO change to all other areas, including:

- *Vaccinated AND symptomatic OR Unvaccinated* (regardless of symptoms) – Perform rapid antigen POC test.
  - If negative, test will automatically reflex to PCR (**no new order required**).
  - If positive, admit to COVID-designated area.
- Transplant patients require PCR testing for admission or surgical procedures regardless of vaccination status.
- Always test with PCR regardless of vaccination status:
  - Behavioral Health
  - Labor and Delivery
  - Corrections
- **Hospital transfers** (within health system and external) regardless of immunization status or previous infection will require a PCR test within the last 72 hours, especially if immunocompromised. If the patient is critically ill with a life-threatening condition that requires immediate transfer and a test cannot be obtained prior to transfer, that patient will require isolation and immediate testing upon arrival to JHS.

Finally, **effective Monday, July 26th – Friday, July 30th**, all procedural areas will resume testing all vaccinated AND asymptomatic patients up to 72 hours prior to anticipated date of surgery in order to determine the percentage of positive cases within this population. The data will allow us to make an educated decision on the need for testing all patients regardless of vaccination status going forward. As is standard, the surgeon will be informed of the results and allowed to decide whether or not to proceed with surgery under the current COVID provisions.

Pre-Procedures Testing for COVID: To all providers: The Jackson Health System will be reinstating the policy of pre-procedure testing for COVID beginning this Friday for all patients (vaccinated or not). The testing must be obtained 72 hours or less prior to the procedure. The Blue garage at Jackson main will serve as a testing site, accessible from 7 AM until 12 Noon. The process previously in place at Jackson North and South will be followed. Jackson West will complete testing at the UHealth/Jackson Doral UCC. Once again, the need to proceed with surgery on a COVID positive patient must be weighed against the increased risk for a bad outcome. As with all care of patients, adherence to PPE policy is expected. Thank you for your continued care and cooperation. Michael E Goldberg MD Clinical Care Information for COVID-19

Date: Friday, Jul 30, 2021, 9:17 AM **Subject:** COVID Testing for Procedures
This message is being sent on behalf of Michael E. Goldberg, MD, Medical Director of Perioperative Services, Diagnostic Treatment Center, Jackson Health System: For the upcoming week, the Jackson Health System will return to the process of allowing procedures to proceed in fully vaccinated, asymptomatic individuals that can demonstrate proof of vaccination. No COVID test is necessary. If any changes to this policy occur, we will reach out. Continued vigilance and adherence to PPE policy is expected. (All those in contact during procedures must wear N95 masks). Thank you for your continuing cooperation and care for our patients.

Clinical Care Quick Reference for COVID-19
https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care-quick-reference.html

Clinical Screening Tool for Identifying Persons Under Investigation for Coronavirus Disease 2019 (COVID-19) per Centers for Disease Control and Prevention (CDC)

Take steps to ensure rapid safe triage and isolation of patients with symptoms of suspected COVID-19 or other respiratory infection (e.g., fever, cough). If an examination room is not readily available ensure the patient is not allowed to wait among other patients seeking care. Health care personnel should adhere to Standard and Transmission-Based Precautions Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

May 11, 2020

PRIORITIES FOR COVID-19 TESTING

(Nucleic Acid or Antigen)

HIGH PRIORITY

- Hospitalized patients with symptoms
- Health care facility workers, workers in congregate living settings, and first responders with symptoms
- Residents in long-term care facilities or other congregate living settings, including correctional and detention facilities and shelters, with symptoms

PRIORITY

- Persons with symptoms of potential COVID-19 infection, including fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat
- Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans

TESTING

Collection of diagnostic respiratory specimens (e.g., nasopharyngeal swab) should be performed in a normal examination room with the door closed.

- The health care provider is responsible for specimen collection, handling and shipping. Please follow CDC guidance.
- High priority specimens should be processed within your health care facility, if available; a commercial laboratory (e.g., LabCorp and Quest), or the Florida Bureau of Public Health Laboratory (BPHL).
  - Before sending specimens to BPHL, contact your local county health department (CHD) at (305) 470-5660.
- Priority specimens can be processed within your health care facility, if available; or a commercial laboratory (e.g., LabCorp and Quest).
- Health care providers may consult a local CHD for additional guidance as needed.

ADDITIONAL GUIDANCE

Providers are encouraged to frequently monitor Florida Department of Health and CDC websites for updated guidance on COVID-19.

- www.flhealth.gov
- https://www.cdc.gov/coronavirus/2019-nCoV/index.html

Please see the CDC's Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

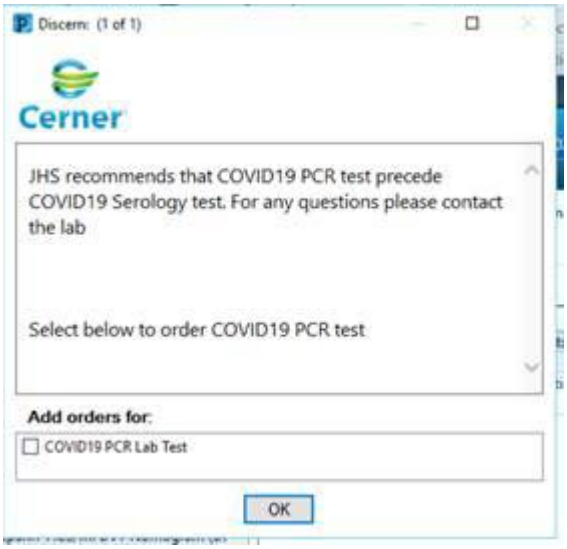
Restrictions and stewardship of testing are in place to maintain the judicious use of tests and be able to provide care to all our patients, providers and employees across JHS. Reagents are limited so we need to use resources effectively.

COVID19 PCR will also now be available for inpatients who have screened negative on admission and have been in the hospital for 14 days and now require surgery or an invasive procedure.
Symptomatic patients will continue to be tested without restrictions regardless of procedures.

"Covid19 Antibody Total (IgM, IgG and IgA)"
Is now available in Cerner for general use, including inpatient, observation, emergency, urgent care and outpatient settings.
"Covid19 Antibody Total with IgG (Transplant Only)" is available in the catalog for MTI/Transplant patients only.

Antibody testing is not recommended for the diagnosis of acute symptomatic infection as a stand alone test. It is also not recommended for asymptomatic patients trying to rule out acute infection.

Judicious use of Ab test is strongly encouraged and please consult with our virology laboratory and infectious diseases experts if you have any questions regarding test indications and interpretation prior to ordering the test.



This information might change in the near future. Appraisal

The microbiology laboratory is offering 3 different testing modalities for the diagnosis of SARS-CoV-2 infections. Each platform has unique characteristics. Therefore, it is important to understand the purpose and utility of each test.

Please refer to appendices 2, 2a, 6, 8 and 10 for more information about testing guidelines and testing workflow.

Since Wednesday August 5th, 2020 JHS has started offering **COVID-19 ANTIGEN** (BD Veritor SARS-CoV-2 Antigen test kit) point of care testing for **SYMPTOMATIC** patients who present within the first 5 days of the onset of illness to our Emergency Departments (adult and pediatric).

- The Turn around (TAT) time is estimated to be under 20 minutes
- Uses a nasal swab provided as a kit component
- Positive tests are confirmatory of acute infection and do not require additional testing
- All negative tests must be confirmed by nasopharyngeal swab PCR. Please note this is a different test and patients will require a separate NP swab that must be directed to the laboratory
- The Antigen test should NOT be used in asymptomatic patients, pre-operative or pre-procedural
- Will only be available in our EDs. In the near future, we may deploy antigen testing in other clinical areas

PCR Molecular tests

Jackson Health system has 3 testing platforms (Cepheid, EllTtech and Qiagen) with specific algorithms and TAT based on our current workflows. The sensitivity and specificity of these tests is high, yet there are multiple variables in interpreting results including: sample collection, timing of infection, clinical picture if there has been migration of the virus from the upper to the lower respiratory tract.

Molecular tests are performed in NP swabs or BAL/ tracheal aspirates.

The CDC has issued updated guidelines (July 17th, 2020) based on recent studies that have shown that so far in most patients the infectivity period is 10 days and in immunocompromised or critically ill could be up to 20 days. Please follow our protocols for return to work and isolation precautions based on Symptoms. If you have any questions, please contact infection control and/or employee health.

Antibody Testing

Total antibody (Ab) testing (IgG, IgM and IgA combined) is available on blood samples collected at all of our hospitals and UCCs.

This test is valuable in **asymptomatic patients** with high risk of previous exposure OR evaluation of patients who have recovered from COVID-19 infection.

Ab testing is also being recommended in the diagnosis of adults and children that present acutely ill and symptomatic but have a negative PCR result. See diagnostic algorithm attached. The Emergency Department is currently testing symptomatic patients with PCR and antibody testing when clinically indicated.

At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative: FDA Safety Communication
https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication?utm_medium=email&utm_source=govdelivery

Please also see Quest Diagnostic COVID-19 Specimen Collection Guidelines at this link (98)

POC COVID-19 ANTIGEN TESTING

The BD Veritor System for Rapid Detection of SARS-CoV-2 is a rapid (approximately 15 minutes) chromatographic digital immunoassay for the direct detection of the presence or absence SARS-CoV-2 antigens in respiratory specimens taken from patients with signs and symptoms who are suspected of COVD-19.

PROCEDURAL STEPS FOR OBTAINING SPECIMEN

PERFORM HAND HYGIENE AND DON APPROPRIATE PERSONAL EQUIPMENT

STEP: 1

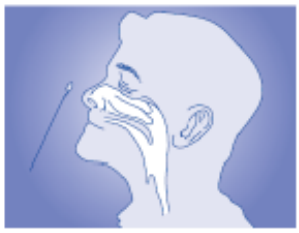
- Gather swab and extraction reagent tube provided in the kit and bring to the patient's bedside.
- Insert the swab* into one nostril of the patient.
- The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril.
- Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.

*Use only swabs provided with the kit.

STEP: 2

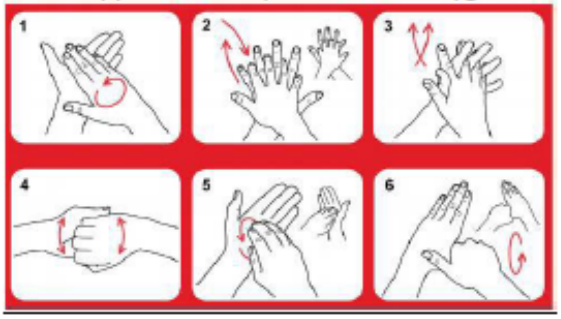
- Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

STEP: 3



- Withdraw the swab from the nasal cavity.
- The sample is now ready for processing using the BD Veritor System SARS-CoV-2 kit.
- **Please see next page for detailed instructions**
- **Note: Test only one patient at a time. Avoid collecting specimen for multiple patients since only one test can be analyzed at a time.**

- Once test is completed and resulted, dispose of PPE as applicable and perform Hand Hygiene.



CL &D 8-3-20

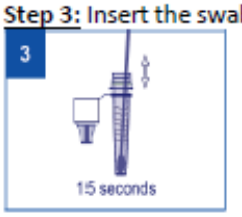
POC COVID-19 ANTIGEN TESTING
PROCEDURAL STEPS FOR PROCESSING SPECIMEN

Freshly Collected Specimens Should Be Processed Within 1 Hour.

STEP 1 &2:

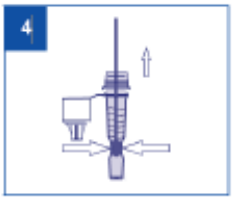
- Place the extraction reagent tube(s) in a rack, if available, in the designated area of the workspace.
- Remove and discard the cap from the extraction reagent tube. Label the tube.

Step 3: Insert the swab into the tube and plunge the swab up and down in the fluid **for a minimum of 15 seconds,** taking care not to splash contents.



To be completed at the beside

Step 4: Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



To be completed at the beside

Step 5: Press the attached tip firmly onto the extraction reagent tube containing the processed sample. Mix thoroughly by Swirling or flicking bottom of the tube.

To be completed at the beside
Testing should be done within 30 minutes after sample insertion in the extraction reagent tube.

Using the BD Veritor Plus Analyzer in "Walk Away" mode: with no barcode scanning module installed

To use Walk Away mode - Connect the AC power adapter to the Analyzer and a power source

Step 6B: Starting Walk Away Mode

1. Turn the BD Veritor Plus Analyzer on by pressing the blue power button once.

2. Label cassette, when the display window reads: "INSERT TEST DEVICE OR DOUBLE-CLICK FOR WALK AWAY MODE, Double-click blue power button.
3. The display window reads "ADD SPECIMEN TO TEST DEVICE AND INSERT IMMEDIATELY"

You will have 3 minutes to insert the test device

Step 7B: Adding the specimen to the test device

1. Invert the tube, holding it vertically (approximately one inch above the BD Veritor System test device sample well).
2. Gently squeeze the ridged body of the tube, dispensing three (3) drops the processed specimen into sample well.

- **NOTE:** Squeezing the tube too close to the tip may cause leakage.
- **CAUTION:** A countdown timer displays the time remaining for test insertion. Walk Away mode must be activated again when this timer expires. Confirm timer is visible and Walk Away mode is activated before inserting test device.

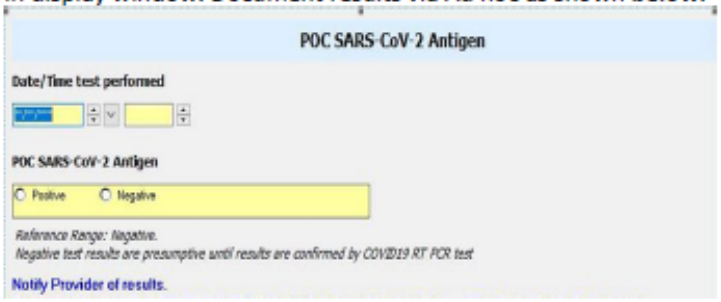
Step 8B: Starting the development and reading sequence

1. Insert the test device into the slot on the right side of the BD Veritor Plus Analyzer.

The test device must remain horizontal to prevent spilling the specimen out of the sample well
2. "DO NOT DISTURB TEST IN PROGRESS" appears in the display window. Automatic timing of the assay development, image processing and result analysis begins.
3. The display window shows the remaining analysis time.

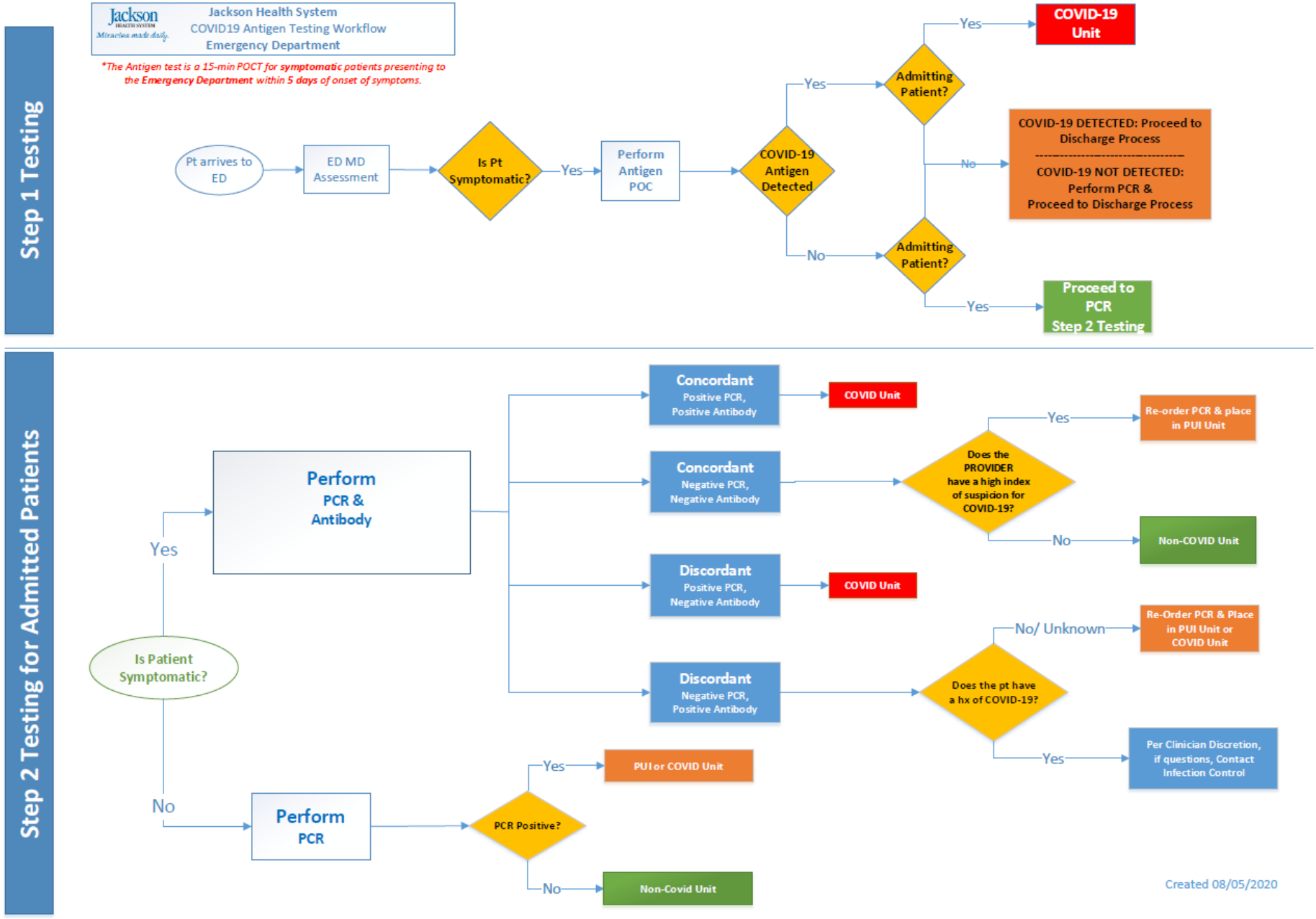
Do not touch the BD Veritor Plus Analyzer or remove the test device during this process. Doing so will abort the assay analysis.

Step 9B: Record the Result. Once analysis completed, see result in display window. Document results via Ad hoc as shown **below.**



ATTENTION: *TEST Results are NOT maintained in the display window when the device is removed or if the Analyzer is left unattended for more than 15 minutes. Historical data will not be able to be retrieved from the device*

CL &D 8-3-20


Step 1 Testing
Jackson Health System
COVID19 Antigen Testing Workflow
Emergency Department
*The Antigen test is a 15-min POCT for symptomatic patients presenting to the Emergency Department within 5 days of onset of symptoms.
Pt arrives to ED
ED MD Assessment
Is Pt Symptomatic?
Yes
Perform Antigen POC
COVID-19 Antigen Detected
Yes
Admitting Patient?
Yes
COVID-19 Unit
No
COVID-19 DETECTED: Proceed to Discharge Process
COVID-19 NOT DETECTED: Perform PCR & Proceed to Discharge Process
No
Admitting Patient?
Yes
Proceed to PCR Step 2 Testing
Step 2 Testing for Admitted Patients
Is Patient Symptomatic?
Yes
Perform PCR & Antibody
Concordant Positive PCR, Positive Antibody
COVID Unit
Concordant Negative PCR, Negative Antibody
Does the PROVIDER have a high index of suspicion for COVID-19?
Yes
Re-order PCR & place in PUI Unit
No
Non-COVID Unit
Discordant Positive PCR, Negative Antibody
COVID Unit
Discordant Negative PCR, Positive Antibody
Does the pt have a hx of COVID-19?
No/ Unknown
Re-Order PCR & Place in PUI Unit or COVID Unit
Yes
Per Clinician Discretion, if questions, Contact Infection Control
No
Perform PCR
PCR Positive?
Yes
PUI or COVID Unit
No
Non-Covid Unit
Created 08/05/2020

COVID-19 SCREENING*
All patients entering a JHS facility should undergo triage by using the following questionnaire:
Have you returned from International Travel (air or cruise or land) or USA areas of Defined or Widespread Community Transmission https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html • Or come in contact with suspected or confirmed COVID-19 case • Do you have fever (temperature ≥ 100 or > 37.8C? (In Pediatric Patients <22 year old fever is considered ≥ 38.3°C (100.9°F) • Do you have any respiratory symptoms (shortness of breath or cough) within 14 days of possible exposure?
If the answer to travel and fever OR travel and respiratory symptoms is yes:
• Place a surgical mask on the patient • Use guidance on pages 12-21 for patient placement and PPE • If an aerosol generating procedure is anticipated then use the guidance on pages 12-21 and 27-33 for patient placement and PPE. • Alert the clinician responsible for the patient and expedite the medical evaluation of the patient • Contact the on-call Infection Preventionist at **786-266-0624**

*Person may also have chills, repeated shaking with chills, muscle pain, headache, sore throat, new loss of taste or smell, Diarrhea, nausea, vomiting and abdominal pain

See also all COVID-19 Travel Health Notices. (https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html)

The criteria are intended to serve as guidance for evaluation. If needed consultation with public health departments, can be obtained on a case-by-case basis to determine the need for testing. Testing may be considered for deceased persons who would otherwise meet the PUI criteria.

INFECTION PREVENTION AND CONTROL MEASURES

Please see the pages 13-20 for JHS PPE Guidelines and COVID-19 PPE Donning and Doffing Pictorial

Also, see pages 29-35 for Strategy to manage Respiratory Failure, intubation and other aerosol generating procedures

COVID19: Personal Protective Equipment Guidelines
http://jhsmiami.org/LeadingForward/COVID19PPEProtocolAugust2021.pdf

Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021 https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm

1- Double masking with a surgical mask is not being recommended at this time for HCW for routine activities
2- We continue our protocols with N95 in high-risk areas or procedures and surgical mask in other areas and surgical mask over N-95 when appropriate as per our protocol.
3- Surgical masks should be tightly fitted and we can add the article reference
4- For patients and visitors or any other employee we advise against cloth masks at work. Please ensure the masks are fitted and appropriately worn at all times

On July 27th, 2021, the CDC updated COVID-19 mask use guidance for fully vaccinated individuals (2 weeks post the second dose of Pfizer or Moderna and the single dose for J&J) in **non-healthcare settings**.

Please see CDC July 27th , 2021 guidance for fully vaccinated people at the link below
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

These rules are not to be extrapolated to our hospitals, including rounds in conference rooms or at bedside in non-COVID-19 units. The information might evolve with time but there are still many patients and caregivers that are not vaccinated within our health system so we need to err on the side of caution.

In Miami, it is very concerning the rapid rise in symptomatic patients with variant strains (B.1.617.2 Delta variant has exponentially spread in our community). Other variants of concern also continue to emerge. These are more contagious and potentially virulent.

- Vaccination continues to be a fundamental primary prevention strategy
- Jackson Health System will continue to monitor and reinforce compliance with guidance from regulatory bodies related to COVID-19 infection and prevention of transmission of the virus.

As we commemorate about 2 years since the WHO declared the pandemic, we are very grateful for your continuous teamwork through our most difficult times.

Please continue to lead by example in our hospitals and the community. Our COVID PPE protocol has been key to our very successful prevention program and will remain in place until further notice.

Please also see July 19, 2021, JHS Mask and visitation guidelines

COVID19: **Personal Protective Equipment Guidelines**

ANTICIPATED ACTIVITY	PPE REQUIRED
Required PPE for ALL JHS Employees	Procedure Mask or N-95
Standard PPE for Direct Contact with Patient Care *(Hospital/Clinic Areas)*	1. Don the following: N-95 Eye Protection **KEY:** Observe hand-hygiene protocol.
Direct Patient or Environmental Contact within COVID-19 Patient Room or Care Space	1. Base Layer* (personal scrubs, hospital laundered scrubs, disposable scrubs, or machine washable clothes) 2. Don the following: Isolation Gown Gloves N-95 Procedure mask to be worn over the N-95 respirator as an N-95 conservation strategy Eye Protection
PPE Donning for Aerosolizing Procedures**	1. Hand hygiene 2. Inspect PPE to ensure it is serviceable 3. Don the following: Isolation Gown Bouffant (recommended) Gloves Eye Protection N-95 Respirator Procedure Mask **OR** Full Face Shield over N-95 Respirator **NOTE:** N-95 must be covered. - If not using face shield, must don eye protection. - Place procedure mask over N-95, if applicable.

**Base layer refers to clothing that will not have direct contact with the patient or their immediate environment.*
***N-95 Respirator required for aerosolizing procedures.*

According to the US CDC, August 2021.

Jackson HEALTH SYSTEM

JHS PPE Guidelines

What you need to know: COVID-19 Mode of Transmission
Large diameter respiratory droplets containing COVID-19 virus enter the body via mucous membranes of eyes, nose, and mouth. Droplets are expelled from the respiratory tract of a COVID-19 infected individual, and may be transmitted even when the infected individual is asymptomatic or mildly symptomatic. In addition, contamination of environmental surfaces may contribute to transmission when an individual touches that surface, contaminating their hands or fingers with droplets, and then touches the mucous membranes of eyes, nose, or mouth without performing hand hygiene.

Anticipated Activity	PPE Required
Required PPE for All JHS Employees	1. Procedure Mask or N95 respirator 2. Eye protection required in all clinical areas
Standard PPE for Direct Contact with Patient Care *(Hospital/ Clinic Areas)*	1. N95 2. Eye protection **(Key: Observe Hand-Hygiene Protocol)**
Direct Patient Or Environmental Contact Within COVID 19 Patient Room Or Care Space	1. Base layer (personal scrubs, hospital- laundered scrubs, disposable scrubs, or machine washable clothes) 2. Isolation Gown 3. Gloves 4. N95 5. Procedure mask to be worn over the N95 respirator as an N95 conservation strategy 6. Eye protection
Aerosolization	
Anticipated Activity	**PPE Required**
Low-risk Aerosolization: • **Airway suctioning** • **Sputum induction** • **Swallow studies** • **Venti mask use**	1. Isolation Gown 2. Eye protection (Goggles and Face Shield) 3. N95 Respirator 4. Procedure mask (to be discarded after procedure) 5. Gloves 6. Hair cover (recommended)

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JHS PPE Guidelines

Anticipated Activity	PPE Required

High Risk Aerosolization:
• High-Flow Nasal Cannula
• Nebulizer treatment
• Chest Physiotherapy
• Chest tube & Thoracentesis
• Breaking the ventilator circuit:
  ○ Intentional: filter/equipment change
  ○ Unintentional: unplanned disconnection/patient movement
• BIPAP/CPAP
• High Frequency Oscillatory Ventilation
*Isolation Gown **REQUIRED**
	1. Isolation Gown
	2. Eye protection (Goggles and Face Shield)
	3. N95 Respirator
	4. Procedure mask (to be discarded after procedure)
	5. Gloves
	6. Hair cover (recommended)

• Endotracheal tube intubation • Endotracheal tube extubation • Bronchoscopy • Laryngoscopy • Endoscopy (upper and lower GI) • Proning • CPR • Bag mask ventilation • Mask ventilation in Operating Room	

JHS PPE Guidelines

Donning and Doffing Recommendations for Inpatient Areas *(Excludes procedural areas)*

Donning:

1. Perform hand hygiene
2. Don isolation gown
3. Don hair covering
4. Don gloves
5. Don N95 respirator and procedure mask over N95 (to conserve N95 respirator place procedure mask over N95)
6. Don eye protection (Goggles or Face Shield)
7. Enter room

Doffing*:

1. Perform hand hygiene over gloves
2. Remove isolation gown, turning inside out while still in patient room/care space
3. Remove gloves, utilizing "glove in glove" technique and perform hand hygiene in patient room/care space
4. Perform hand hygiene
5. Exit patient room or care space and close door if applicable
6. Perform hand hygiene
7. Don gloves
8. Remove eye protection and disinfect with EPA approved disinfectant
9. Remove gloves, utilizing "glove in glove" technique and perform hand hygiene in patient room/care space
10. Remove procedure mask
11. Perform hand hygiene
12. Don new procedure mask and re-don eye protection

*Due to the unknown contamination of any single piece of PPE, great care should be taken during the doffing process. Consider the exterior of all devices to be contaminated and perform hand hygiene accordingly and avoid self-contamination while removing PPE.

NOTE: Non-sterile gloves should not be worn unless contact with the patient or immediate patient care environment (room or care space) is anticipated

References:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html
https://www.who.int/news-room/q-a-detail/q-a-on-infection-prevention-and-control-for-health-care-workers-caring-for-patients-with-suspected-or-confirmed-2019-ncov

Jackson HEALTH SYSTEM
Miracles made daily.

JHS PPE Guidelines

Standard PPE for Direct Contact with Patient Care

N95 Surgical Mask and Goggles

OR

N95 and Face Shield

DIRECT PATIENT OR ENVIRONMENTAL CONTACT

Hand Hygiene

Isolation Gown

Gloves

N95 Surgical Mask and Goggles

OR

N95 and Face Shield

JHS Clinical Learning & Development 8.11-2021 v5

Jackson
HEALTH SYSTEM

COVID-19 PPE: DONNING AND DOFFING

Items Required
Gown - standard isolation
N95 Respirator
Eye protection - Face shield or goggles
Gloves

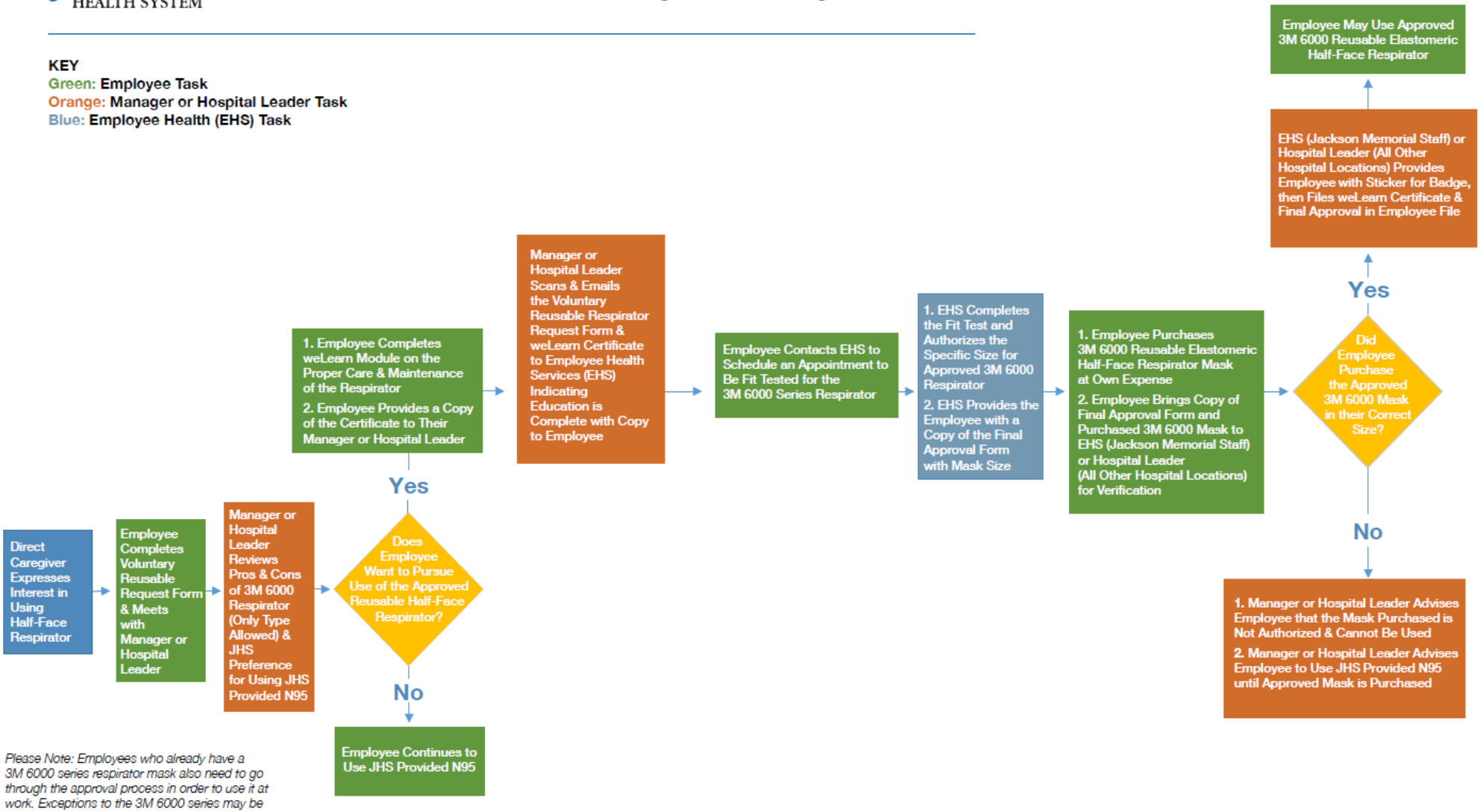
Donning Order

Doffing Order

Jackson HEALTH SYSTEM

Jackson 3M 6000 Reusable Elastomeric Half-Face Respiratory Request & Approval Process for Direct Caregivers Expressing Interest

KEY
Green: **Employee Task**
Orange: **Manager or Hospital Leader Task**
Blue: **Employee Health (EHS) Task**



Please Note: Employees who already have a 3M 6000 series respirator mask also need to go through the approval process in order to use it at work. Exceptions to the 3M 6000 series may be considered for any employee who previously purchased a different make/model. Employees should specify this information in the request form.

Using Personal Protective Equipment During Procedures

Standards for personal protective equipment (PPE) should be followed with every patient, and according to the descriptive protocol circulated earlier this week in our COVID-19 updates. Providers directly involved in procedures should don the following equipment:

- **For procedures being performed that are aerosol generating in a known or suspected COVID-19 case:** An N95 respirator, goggles AND face shield, two pairs of nonsterile gloves (unless in the sterile field), hooded isolation suit, and shoe covers.
- **For aerosol-producing procedures being performed on a low-risk patient (such as a tracheostomy or airway surgery where the trachea is to be opened and ventilation may be occurring):** An N95 respirator, goggles OR face shield, and non-sterile gloves.
- **N95 for all intubations regardless of the risk as well as goggles, face shields and non-sterile gloves**

Dr. Michael Goldberg
Medical Director
Perioperative Services
Jackson Health System

Dr. Keith Candiotti
Chief
Anesthesiology
Jackson Memorial Hospital

Jackson HEALTH SYSTEM
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Addendum from Abdul Memon 8/31/2020" Please also see Appendix 3 (Positive COVID-19 care of Patients Perioperative Protocol) and Appendix 14 (Perioperative Services Half Face Elastomeric Respirator Issuance, use and Decontamination protocol)

The difference between respirators and surgical masks: 5min 37 seconds (OSHA)
https://www.youtube.com/watch?v=ovSLAuY8ib8

Personal Protective Equipment for COVID-19 (https://www.nebraskamed.com/for-providers/covid19)

Please see NETEC poster for Donning and Doffing PPE at this link (https://icap.nebraskamed.com/wp-content/uploads/sites/2/2020/02/1-Page-COVID-19-PPE-00000002.pdf)

Doffing (removal) of PPE must be performed in a manner that minimizes risk of self-contamination during the process. Treat used/contaminated PPE as medical waste.

Please see link below to IDSA guidelines for on Infection Prevention for Healthcare Personnel
https://www.idsociety.org/COVID19guidelines/ip

PPE Skin effects https://www.medscape.com/viewarticle/929590_print

INTERIM INFECTION PREVENTION AND CONTROL RECOMMENDATIONS FOR PATIENTS HOSPITALIZED WITH COVID-19

As the transmission dynamics of this virus become clearer, CDC recommends a cautious approach to patients under investigation for COVID 19. Patients should be directed to wear a surgical mask as soon as they are identified and immediately segregated. Patient with low risk care episode should be evaluated in a private room with the door shut (if an aerosol-generating procedure is anticipated, they should be placed in an airborne infection isolation room or AIIR). Healthcare personnel entering the room should wear PPE appropriate for the anticipated level of care. See more information pages 12-28.

PUI IN AN AMBULATORY CARE SITE

If a PUI is identified in an ambulatory care site, including ACC, PCC< or UCC, PUI should immediately don a mask and placed in a private room with door closed and arrangement should be made for PUI evaluation in an Emergency Department after notifying Emergency Department and Ambulance EMS if such Transport is needed. Healthcare workers should don appropriate PPE during evaluation and care see table on page. See pages 41-47 for emergency transport of a PUI by Ambulance protocol.
Outpatient and Ambulatory Care Settings: Responding to Community Transmission of COVID-19 in the United States Please also see the link below for Risk Stratification guide for severity assessment and triage of suspected or confirmed COVID-19 patients (Adults) urgent care

For Risk Stratification guide for severity assessment and triage of suspected or confirmed COVID-19 patients (adults) in urgent care at this link (96)

HAND HYGIENE

Hands must be decontaminated after patient and/or environmental contact.

- If hands are visibly soiled or have had unprotected contact with visible blood, body fluids (respiratory and nasal secretions, excretions, wound drainage, or skin visibly contaminated with blood or body fluids), soap and water must be used for performance of hand hygiene
- If hands are not visibly soiled, an alcohol-based hand rub can be used to decontaminate hands

After performing hand hygiene, avoid touching the patient and surfaces or items in the immediate vicinity of the patient.

COUGHING AND SNEEZING/RESPIRATORY HYGIENE

Employees and patients should be instructed to cover their nose and mouth with a tissue when coughing or sneezing and the tissue should be discarded in a trash container after use. Unit and area managers should ensure that an adequate supply of respiratory hygiene supplies is available.

Environmental Services

- Routine cleaning and disinfection: A hospital approved hospital environmental disinfectant should be used for daily disinfection of surfaces within the patients room
- Terminal cleaning: A hospital approved, hospital environmental disinfectant should be used for terminal cleaning and disinfection of the patient room upon transfer or discharge; where available, ultraviolet disinfection should be implemented as the last step in the terminal cleaning/disinfection process

Linen

Soiled/contaminated linen will be managed as per the JHS standard procedure (no special instructions related to linen)

Postmortem Care for Patients with Suspect/Confirmed COVID-19 Illness

HCW involved in preparing body for transport should don PPE, including isolation gown, non-sterile gloves, N95 respirator, and eye protection. The body should be handled per routine and placed in a fluid-impermeable zippered bag. The exterior of the bag should be wiped with hospital disinfectant. At this point, the body bag can be safely handled using nitrile gloves as PPE, there is no requirement for the HCW to wear additional PPE for transporting the body to the morgue. Please contact the Infection Preventionist on call at 786-266-0624 to inform the team of the patient's death for Medical Examiner reporting.
If an autopsy is planned, additional precautions must be taken, and those can be found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html

UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM | UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE
Pathology & Laboratory Medicine

Updated Policy on Autopsy

July 30, 2020

Considering the current situation of COVID 19 outbreak, we are keeping a close eye on the daily developments and staying updated on the guidelines issued by the CDC.
https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html Many training programs are not performing autopsies on confirmed or suspected COVID 19 cases. First and foremost, the health and safety of our residents, staff and faculty is our priority.

Chapter 406.11 of the Florida Statutes requires certain deaths be brought to the attention of the Medical Examiner (ME). These include cases of PUBLIC HEALTH INTEREST in which the death may be a threat to public health. This generally refers to cases not yet confirmed. Please also see Appendix 15

The Autopsy Service, physically located at Jackson Memorial Hospital and providing services to the Jackson Health System, Uhealth and Outreach Services in the Department of Pathology & Laboratory Medicine will adopt the following policy:

Please see Appendix 15 related to COVID-19 death reporting to Medical Examiners

If a medically necessary autopsy on a COVID-19 positive patient is required, where the cause of death is not believed to be due to COVID-19 or its complications, the attending physician who took care of the patient should communicate with the Autopsy Pathology Attending to discuss. In cases where laboratory data, radiology examination or other testing modality lead to a diagnosis, autopsy will be discouraged.

In cases where results of COVID 19 testing are pending, the autopsy will be delayed until such time the results are known. If negative, we will perform an autopsy as usual.

AUTOPSY ON CONFIRMED COVID 19 CASE
Please see Appendix 15 related to COVID-19 death reporting to Medical Examiners

- ***The autopsy on COVID 19 cases will be performed in the JMH Morgue.***
- ***The morgue attendants will use the proper Personal Protective Equipment as outlined in the Autopsy Pathology Manual.***
- ***The Morgue Attendant will discuss the case with the Attending Pathologist.***
- ***The Morgue Attendant will photograph the outside of the body, remove all organs and place them in formalin for 48 hours, as outlined for surgical pathology cases.***
- ***The Attending Pathologist and Resident will review the organs.***
- ***Examination of brain and spinal cord currently cannot be performed.***
- ***In cases of questions by a surgeon, they will discuss the case with the Attending Pathologist, and they will come up with a plan for directly examining the body.***

For outreach cases, we will not accept any cases of confirmed or suspected COVID 19 infection. If referrals are made for another reason, we will carefully screen the case as to the clinical circumstances.

Any questions, please reach out to us,

Clara Milikowski, MD, FACP
Director of Adult Autopsy Services, JMH and UM
Ali Saad, MD
Director of Pediatric Autopsy Services
Sakir H. Gultekin, MD
Director of Residency Program, Department of Pathology

Please see the COVID-19 Testing and workflow for OR and Procedural area for inpatients, OR and Procedural area for Outpatient, ED-Trauma and Non Elective Direct Admit and COVID19 Stroke Alert Workflow in Appendix 6

Jackson Health System
Isolation Precautions for Multdrug Resistant Organisms and Cdiff. Revision as a Component of PPE Conservation Plan (Adult)
Version 2: September 25, 2020

Organism	Susceptibilities	Isolation Type	Isolation Duration	Patient Cohorting	Nursing Ratio
Enterobacteriaceae family	CRE = intermediate or resistant to at least one carbapenem class drug	Standard Precautions	NA	Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative	Routine
	Pan resistant	Contact Precautions	1 year from last positive culture		
	Carbapenemase producer (CPE), incl NDM, IMP, OXA, VIM, KPC	Enhanced Contact Precautions	Indefinite until 2 consecutive cultures are neg beginning 90 days from last positive clin cx	Private room Cohort patients with matching organisms (genus and species, resistance pattern)	1:1 ICU Lowest ratio in acute care unit
	Extended spectrum beta lactamase producer (ESBL)	Standard Precautions	NA	Routine	Routine
Acinetobacter spp.	Pan resistant	Contact Precautions	1 year from last positive culture	Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative	Routine
	CPO = carbapenemase producer, NDM, IMP, OXA, VIM	Enhanced Contact Precautions	Indefinite until 2 consecutive cultures are neg beginning 90 days from last positive clin cx	Private room Cohort patients with matching organisms (genus and species, resistance pattern)	1:1 ICU Lowest ratio in acute care unit
Candida auris	NA	Enhanced Contact Precautions	Indefinite, case by case decision	Private room Cohort: matching organisms (genus and species, resistance pattern)	1:1 or cohort staff and patients

Jackson Health System
Isolation Precautions for Multidrug Resistant Organisms and Cdiff. Revision as a Component of PPE Conservation Plan (Adult)
Version 2: September 25, 2020

Organism	Susceptibilities	Isolation Type	Isolation Duration	Patient Cohorting	Nursing Ratio
Enterococcus spp.	Vancomycin resistant, surveillance or clinical cx; SICU, C7, WW14, WW15	Contact Precautions	Duration of hospitalization or unit transfer	Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative	Routine
	Vancomycin resistant, uncontained draining wound, system-wide	Contact Precautions	Until wound is contained		
Pseudomonas spp.	Meropenem-resistant	Contact Precautions	1 year from last positive culture	Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative	Routine
	Pan resistant	Contact Precautions	1 year from last positive culture		
	CPO = carbapenemase producer, NDM, IMP, OXA, VIM	Enhanced Contact Precautions	Indefinite until 2 consecutive cultures are neg beginning 90 days from last positive clin cx	Private room Cohort patients with matching organisms (genus and species, resistance pattern)	1:1 ICU Lowest ratio in acute care unit
Staphylococcus aureus	Vancomycin intermediate or fully resistant	Enhanced Contact Precautions	Indefinite, case by case decision	Private room Cohort patients with matching organisms (genus and species, resistance pattern))	1:1 ICU Lowest ratio in acute care unit
	Methicillin resistant, clinical cx at JMH trauma service line	Contact Precautions	1 year from last positive culture	Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative	Routine
	Methicillin resistant, surveillance cx at JMH trauma service line	Contact Precautions	1 year from last positive culture		
	Methicillin resistant, uncontained draining wound, system-wide	Contact Precautions	Until wound is contained		

COVID-19 Infection Prevention and Control Measures

Patient Placement for Inpatient Units

- When available, place a patient with suspected or confirmed SARS-CoV-2 infection in a single-person room. The door should be kept closed (if safe to do so). Ideally, the patient should have a dedicated bathroom.
- When housing patients in semi-private rooms, every effort will be made to cohort patient with the same respiratory pathogen.
- Patients determined to be non-contagious (based on time since onset of symptoms/test [see Table – Deescalation of COVID-19 Isolation Precautions], or based on individual case review) can be housed with non-infected patients.
- Whenever needed, asymptomatic healthcare personnel, using appropriate PPE and other infection prevention measures, can be assigned to the care of patients independent of their COVID-19 testing status.
- The need for designating an entire unit for care of patients with COVID-19 will be done jointly by administrative, nursing and Infection Prevention leadership based on an assessment of indicators of facility and community levels of transmission.
- Limit transport and movement of the patient outside of the room to medically essential purposes.
- Communicate information about patients with suspected or confirmed SARS-CoV-2 infection to appropriate personnel before transferring them to other departments in the facility (e.g., radiology) and to other healthcare facilities.

DE-ESCALATION OF COVID-19 ISOLATION PRECAUTIONS

IMMUNOCOMPETENT, NON-ICU/IMCU PATIENT	**IMMUNOCOMPETENT, ICU/IMCU PATIENT**	**SEVERELY IMMUNOCOMPROMISED (TRANSPLANT, RECEIVING CHEMOTHERAPY FOR CANCER DIAGNOSIS) PATIENT***
On or following **day #10,** patient will be evaluated for reduced symptoms, including being afebrile for 24 hours without antipyretic medication. If a patient has a positive SARS-CoV-2 test but is asymptomatic, then additional clinical, epidemiological and laboratory testing may be employed to inform decision to de-escalate prior to day 10.	On or following **day #22**, patient will be evaluated for reduced symptoms, including being afebrile for 24 hours without antipyretic medication. If a patient has a positive SARS-CoV-2 test but is asymptomatic, then additional clinical, epidemiological and laboratory testing may be	On or following **day #28,** patient will be evaluated for reduced symptoms, including being afebrile for 24 hours without antipyretic medication. If a patient has a positive SARS-CoV-2 test but is asymptomatic, then additional clinical, epidemiological and laboratory testing may be employed to inform decision regarding need to de-escalate prior to day 28, or to extend isolation beyond day 28.

	employed to inform decision to de-escalate prior to day 22.	
If criteria above met, IP will resolve COVID problem, document rationale for resolution in the record	If criteria above met, IP will resolve COVID problem, document rationale for resolution in the record	If criteria above are met, IP will collaborate with ID team to make decision about need for isolation precautions. Additional laboratory testing or other diagnostics may be employed to inform decision-making.
Once COVID problem has been resolved, the banner bar will indicate "history of COVID" and "COVID" tag will disappear	Once COVID problem has been resolved, the banner bar will indicate "history of COVID" and "COVID" tag will disappear	Once COVID problem has been resolved, the banner bar will indicate "history of COVID" and "COVID" tag will disappear
Patient will no longer require COVID isolation, and can be moved to any unit, either single-patient or semi-private room.	Patient will no longer require COVID isolation, and can be moved to any unit, either single-patient or semi-private room.	Patient will no longer require COVID isolation. Decision about patient placement will be determined collaboratively with ID Team.

*There is some evidence that severely immunocompromised patients may continue to shed viable virus for months after a COVID diagnosis, making the de-escalation process for this population very complex. At no time, will an immunocompromised patient have COVID isolation precautions discontinued without extremely careful consideration.

Source: Choi B, Choudhary MC, Cernadas M, & Li JZ. 2020. Persistence and evolution of SARS-Co-V-2 in an immunocompromised host. N Engl J Med, 383(23), pp. 2291-3.

COVID-19 PANDEMIC N95 RESPIRATOR USE

As you are aware, the N95 respirator is a key component of personal protective equipment used during aerosol-generating procedures performed on a patient with suspect or confirmed COVID19 infection. A respirator acts as a barrier between large respiratory droplets and filters small diameter droplets to prevent inhalation of those. For routine care of the patient with suspect or confirmed COVID19 infection, an isolation mask provides protection from contact with large respiratory droplets with mucous membranes of the mouth and nose. However, during aerosol-generating procedures, it is possible for those large droplets to be broken into smaller droplets and become airborne; in this case, the use of an N95 respirator is recommended.

It is anticipated that the COVID19 pandemic will extend for a significant amount of time and supplies of respirators may become limited. To ensure that respirators will be available throughout the pandemic, JHS has implemented a multi-prong respirator conservation program.

Extended Use and Reuse of N95 Respirators

Extended use refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters. Extended use may be implemented when multiple patients are infected with the same respiratory pathogen and patients are placed together in dedicated waiting rooms or hospital units. Extended use has been recommended as an option for conserving respirators during previous respiratory pathogen outbreaks and pandemics.

Reuse refers to the practice of using the same N95 respirator for multiple encounters but removing it ("doffing") after each encounter. The respirator is stored between encounters to be put on again ("donned") prior to the next encounter with a patient.

Reuse Protocol:

- For the first use, the respirator is considered clean and may be donned with non-gloved hands
- After use, the respirator should be removed with hands covered with clean gloves
- The used respirator may be stored in a paper bag or a plastic bag (not closed) between uses
    - Handle the used respirator with gloved hands and perform hand hygiene immediately after handling and removal of gloves
- The exterior of the respirator should be considered to be potentially contaminated, so care must be taken when handling it during subsequent uses
    - Remove respirator from bag with gloved hands and apply, taking care to avoid contact between eyes, nose, or mouth with exterior of respirator and gloves
    - Once the respirator is in place, remove gloves and perform hand hygiene
- Wearing a surgical mask over the respirator or a clear shield that covers the eyes, mouth and nose of the wearer provides protection from respirator contamination
- The respirator may be reused until it fails the self-check (user seal check) process, described below

What is a User Seal Check?

- A user seal check is a procedure conducted by the respirator wearer to determine if the respirator is being properly worn. The user seal check can either be a positive pressure or negative pressure check.
- During a **positive pressure user seal check**, the respirator user **exhales** gently while blocking the paths for air to exit the facepiece. A successful check is when the facepiece is slightly pressurized before increased pressure causes outward leakage.
- During a **negative pressure user seal check**, the respirator user **inhales** sharply while blocking the paths for air to enter the facepiece. A successful check is when the facepiece collapses slightly under the negative pressure that is created with this procedure.
- A user seal check is sometimes referred to as a fit check. A user seal check should be completed each time the respirator is donned (put on). It is only applicable when a respirator has already been successfully fit tested on the individual.

<u>Ultraviolet Light Germicidal Irradiation (UVGI)</u>

UVGI decontamination of N95 respirators involves delivery of ultraviolet irradiation to used respirators to render them safe for a second and third use.

UVGI Protocol:

- HCW obtains new N95 respirator and uses permanent marker to write the following information of the respirator:
    - First initial and last name
    - Department or unit location
    - Date of first use
- HCW uses the respirator per current recommendations related to reuse and extended use

- When ready to sanitize, the HCW doffs the respirator and places it in a brown paper bag, labeling the bag with the HCW full name and unit/department (perform hand hygiene after placing respirator into bag
- Place bag into respirator return container
- Reprocessing will occur at a central location throughout the day
- The respirator can be retrieved from the central location (it will be in a white bag which also contains a brown bag for the next return process)

Each respirator will be reprocessed twice and may be used until it fails the self-check process (user seal check)

N95 Mask Sanitizing Process at this link (97)

PPE Conservation Strategies

Please see pages 13-21 (JHS PPE Guidelines) for PPE conservation strategy

1. Coronavirus Disease 2019 (COVID-19) Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html
2. Coronavirus Disease 2019 (COVID-19) Strategies for Optimizing the Supply of Facemasks https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html
3. Checklist for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response (46)
4. Strategies for Optimizing the Supply of Eye Protection https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html
5. Strategies for Optimizing the Supply of Isolation Gowns https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/isolation-gowns.html
6. Strategies for Optimizing the Supply of N95 Respirators https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html
7. Personal Protective Equipment (PPE) Burn Rate Calculator https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html
8. Strategies to Allocate Ventilators from Stockpiles to Facilities https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/ventilators.html

Please have your unit call **305-585-5668 (24/7)** if you do not have PPE and need additional PPE (except for N95 mask and for N95 Masks. Please call AIC at your facility.

- **AIC JMH 786-299-7517**
- **AIC JNMC 305-654-5095 ext #1**
- **AIC JSMC 305 256-5331**

COVID-19 JHS STRATEGY FOR MANAGEMENT OF RESPIRATORY FAILURE, INCLUDING INTUBATION AND RESPIRATORY THERAPY GUIDELINES FOR AEROSOL GENERATING PROCEDURES IN CASES OF SUSPECTED OR PROVEN COVID 19

Strategy for Management of Respiratory Failure

- BiPAP may be considered. Conduct intubation or procedure in an Airborne Infection Isolation Room (AIIR) when possible. Such rooms are designed to reduce the concentration of infectious

aerosols and prevent their escape into adjacent areas using controlled air exchanges and directional airflow. If none are available, a regular room with a closed-door may suffice.

- Some procedures may be more likely to generate higher concentrations of infectious respiratory aerosols than coughing, sneezing, talking, or breathing. These procedures potentially put Healthcare Provider (HCP) and others at an increased risk for exposure. Although not quantified, procedures that might pose such a risk include cough-generating procedures, bronchoscopy, sputum induction, intubation and extubation, cardiopulmonary resuscitation, and open suctioning of airways.

If Plan to Intubate:

EQUIPMENT

- All assembled outside room (avoid enter/re-enter room)
- Need HEPA filter in line with 02 mask, LMA, and vent
- If equipment reusable, should sequester for handling as per infection control
- Ventilator in room with settings preset pre-intubation
- If you wear prescription eyeglasses, make sure they are secure on your face before placing personal protective equipment (PPE).
- Do not bring bags or any objects into the patient care area that are not disposable or able to be properly disinfected. Technique
- Most experienced person does intubation (Anesthesia, ICU or ED attending). RSI (avoid ambu-bag if at all possible; use LMA if needed)
- Glidescope / C-MAC (as back-up in room or as primary device – concern about DL and close exposure)
- If clinically indicated, it may be beneficial to use an induction agent, and neuromuscular blocking agent to facilitate intubation as well as minimize coughing, bucking, and aerosol creation.
- It may be difficult in the presence of PPE to effectively and safely use a stethoscope. Placement of the endotracheal tube should be confirmed by ETCO2, chest rise, etc. Auscultation can be performed if the placement is uncertain or at a later time, once the risk of self-contamination is reduced. Medical equipment used on an infected patient should remain with that patient or be cleaned according to hospital policy before leaving the patient area
- **Procedure for putting on PPE:** o Put on the first pair of gloves, place boot or shoe covers, then gown/coveralls; then N95 respirator; pull up the hood on the coveralls or put on a headcover; then goggles or face shield; then a final pair of gloves (making sure they cover the sleeves over the gown or coveralls).
  - o Before leaving the patient use a disinfectant wipe to disinfect any visible contamination on the PPE.

- **Procedure for removal of PPE.** o Disinfect your gloves with an alcohol-based hand rub and allow the gloves to dry. Sit down on a chair and remove your shoe covers. Grasp the heel of one cover and slowly pull it off your leg and foot. Avoid touching your scrubs and shoes. Dispose of the boot covering in the biohazardous waste container. Repeat with the other boot covering. Use an alcohol-based hand rub on the outer gloves. o Remove the outer glove by grasping the glove on the one hand with the other hand. Grasping the exterior of the glove at the wrist, pull the glove off of your hand, with the contaminated exterior folded inside. Hold the removed glove in the double-gloved hand. Slide a single-gloved finger under the

wristband of the remaining outer glove. Gently pull off the glove so that it is now inside-out, forming a bag for the other glove, and discard. Disinfect the inner pair of gloves.

- Remove the face shield. It is particularly important to avoid contamination of the eyes and mucous membranes when removing facial PPE. Tilt your head forward and lift the shield by the strap. Lift it above and away from your head without touching the shield itself and discard it in the biohazardous waste container. Disinfect your gloves.
- Remove your gown by first undoing the fastening at the waist. (Another individual may assist you if they are wearing appropriate PPE) Grasp the shoulder area and peel the gown away from your body, turning the gown inside-out and wrapping it into a bundle. Only the interior of the gown should remain visible. Discard the gown, and then disinfect your gloves.
- Remove the inner pair of gloves as described for the outer pair, taking precaution to avoid contaminating your bare hands. Use an alcohol-based hand rub for disinfection after taking off the gloves. Put on a new pair of gloves once your hands have dried.
- Remove the N95 respirator. To minimize the possibility of contamination, avoid contact with the respirator itself, touching only the straps. Tilt your head forward, grab the strap that is around your neck, and lift it over your head, allowing it to hang freely. Then bring the top strap over your head and use it to remove the respirator from your face. Discard the respirator, then disinfect your gloves. The respirator should be removed after leaving the room.
- Sit down on a clean chair and use disinfectant wipes to clean all external surfaces of your shoes. Disinfect your gloves.
- Remove the last set of gloves, as described previously. Disinfect your hands with an alcohol-based hand rub.

- The proper removal and disposal of contaminated PPE is the most difficult challenge in preventing inadvertent exposure to pathogens; careful attention is required, and persons who wear prescription eyeglasses should make sure their glasses are not contaminated when they remove PPE.
- All in PPE (donning and doffing for RN, RT, XRAY tech and intubator
- In-room: o Intubator (more experienced person)
    - RT o Primary nurse Outside of room (ready to come in an assist): o Intubation assistant (2nd intubator) if not in room o RN

PROCEDURE

- Team huddle before entering room so all know plans, assure have equipment needed, and people know roles (in and out of room)

Aerosol Generating Procedures (AGP):

Procedures that could generate infectious aerosol and droplets as a source of respiratory pathogens. Such procedures should be performed cautiously and avoided if possible. These procedures should be conducted in a negative air flow room when possible, or in single-person room with closed door.

JHS PPE guidelines for low-risk and high-risk AGP must be followed when performing the following procedures.

- Bag mask ventilation **(High-Risk)****
- Manual ventilation **(High-Risk)****
- Endotracheal tube intubation **(High-Risk)****

- Endotracheal tube extubation **(High-Risk)****
- Airway suctioning **(Low-Risk)**
- Nebulizer treatment **(High-Risk)***
- Bronchoscopy **(High-Risk)****
- Laryngoscopy **(High-Risk)****
- Endoscopy (upper and lower GI) **(High-Risk)****
- Cardio-pulmonary resuscitation (CPR) **(High-Risk)****
- BiPAP/CPAP **(High-Risk)***
- High-Flow Nasal Cannula **(High-Risk)***
- High Frequency Oscillatory Ventilation **(High-Risk)***
- Chest physiotherapy **(High-Risk)***
- Sputum induction **(Low-Risk)**
- Breaking the ventilator circuit o Intentional: filter/equipment change **(High-Risk)***
    - o Unintentional: unplanned disconnection/patient movement

**Isolation gown REQUIRED*
***Hooded Bunny Suit REQUIRED*

Bag Mask/ Manual Ventilation (High-Risk):

- Contra-indicated in adults; may be used in children in a negative airflow room or in an airway emergency, or single person room with closed door, with proper PPE for providers
- When necessary, the expiratory port must have a HEPA or Bacterial/Viral filter.
- A HEPA or Bacterial/Viral filter may be used at the patient connection port between the device and the mask or artificial airway device as an alternative.
- The used HEPA or Bacterial/Viral filter must be properly disposed of following manual ventilation.

Endotracheal tube intubation and Endotracheal tube extubation (High-Risk):

- Please refer to the JMH COVID-19 intubation guidelines
- For extubations, prior to disconnecting the ventilator circuit from the ETT, consider placing the vent on standby or any other mode that will suspend positive airflow to help prevent expulsion of aerosol and droplets.

Airway suctioning (Low-Risk):

- Prior to intubation, airway suctioning will be avoided unless needed to clear the patient's airway during endotracheal tube intubation. While on the ventilator, only a closed suction catheter will be used.
- Suction will be done as necessary, not routinely.

Nebulizer treatment (High-Risk):

- There is no role for inhaled bronchodilators in patients with COVID-19 unless the patent has
- comorbid asthma or COPD.If nebulized treatment is deemed necessary for bronchospasm, the patient should be in a negative pressure room when possible, or single person room with closed door, and a hybrid nebulizer with filter must be used to administer the medication. Staff must follow guidelines and don proper PPE for administration.
- Pre-treatment assessment must be completed prior to starting the nebulizer.

- While the nebulizer is on, staff are to step as far away as possible but must maintain a visual of the patient to monitor for any adverse reactions.
- Precautions must be continued for at least 30 minutes post nebulizer treatment.
- Inline nebs may be used on ventilated patients with a closed circuit system. Ultrasonic nebulizers are preferred

Note: If an MDI is ordered, the goal is for the patient to self-administer the MDI treatment. Assistance from the RN or RT may be needed if the patient has difficulty with administration.
When using a hybrid nebulizer, a mouthpiece set up is recommended. A non-vented mask set up may be used for those unable to use a mouthpiece. A tight seal must be maintained when using the non-vented mask.

Bronchoscopy (High-Risk):

- Disposable bronchoscopes are to be used, subject to availability.
- Certain pediatric bronchoscopes (not disposable) may be used in a negative airflow room with proper PPE for the providers, and must be cleaned per protocol for Covid-19.

Laryngoscopy (High-Risk):

- PPE guidelines for intubation must be followed.
- The amount of team members involved during the procedure should be limited

Endoscopy (upper/lower GI) (High-Risk):

- PPE guidelines for intubation must be followed.
- The amount of team members involved during the procedure should be limited

CPR (High-Risk):

- PPE guidelines for intubation must be followed whenever possible during CPR

BiPAP/CPAP (High-Risk):

- BiPAP/CPAP can be used safely under the following conditions:
    - Patients must be in negative pressure room when possible, or single person room with closed door.
    - Ensure masks/devices fit well and there is minimal air leak.
    - Transportation on BiPAP/CPAP not allowed..
- In children, NIV may be used in negative airflow rooms or single person room with closed door, with proper PPE for providers.
  Note: There is the theoretical concern that BiPAP/CPAP will result in aerosolization of infected droplets. However, with the above precautions in place, risk to clinicians should be low. The use of BiPAP/CPAP in COVID patients is supported by the American Association of Respiratory Care and the Society of Critical Care Medicine.

High-Flow Nasal Cannula (High-Risk):

- High flow nasal cannula can be used safely under the following conditions:
    - Patient in a negative pressure room, or single person room with closed door
    - Patients cannot be transported on high flow nasal cannula

- Patient wears surgical mask over high flow device

Note: There is the theoretical concern that high flow nasal cannula will result in aerosolization of infected droplets. However, with the above precautions in place, risk to clinicians should be low. The use of high flow nasal cannula in COVID patients is supported by the American Association of Respiratory Care and the Society of Critical Care Medicine.

No limits are placed on the flow rates to be used for these patients. However, use of rates >30L/min should prompt consideration of intubation in patients who are not do-not-intubate (DNI) status

- In the pediatric population (except NICU), HFNC may be used in negative airflow rooms, or single person room with closed door, with proper PPE for providers

- For NICU, HFNC will be avoided. Use of low flow O2 of 2 Liters or less, use of CPAP or Intubation will be considered

Note: In children, the decision to intubate early must be balanced against the particular risks of maintaining the ETT, e.g. heavy sedation, dislodgement of ETT, need for frequent re-taping or suctioning of small diameter tubes.

High Frequency Oscillatory Ventilation (High-Risk):

- The adult population will not be considered for HFOV
- In children, HFOV may be used in negative airflow rooms or single person room with closed door, with proper PPE.

Chest Physiotherapy (High-Risk):

- The adult population will not be considered
- For children, CPT is discouraged but may be used in a negative airflow room with proper PPE for the provider.

Mechanical Ventilation (High-Risk):

- While on mechanical ventilation, patients are to remain on a closed, dry (HME) circuit with HEPA or Bacterial/Viral filters on both inspiratory and expiratory ends proximal to the ventilator.
- An HME/HEPA filter combo may be considered.
- Consider a heated wire circuit for patients with mucus plugging, thick copious secretions or hemoptysis.
- Heated wire circuits must be used with the administration of inhaled Epoprostenol.

Breaking the ventilator circuit (High-Risk):

- To change any inline equipment, volume flow from the ventilator should be suspended prior to patient disconnection to help prevent expulsion of aerosols and droplets generated by positive pressure from the ventilator.

  Jackson Main –Ventilators will be placed on standby for no longer than 10 seconds for inline changes. Ventilation will be resumed immediately after reconnection.

  Holtz – Avea and PB 840 Vents will be placed on suction mode which will suspend flow when disconnected. Ventilation resumes when patient is reconnected.

Jackson South – 840 Vents will be placed on suction mode which will suspend flow when disconnected. Ventilation resumes when patient is reconnected.

Jackson North – Servo Vents will be placed on suction mode which will suspend flow when disconnected. Ventilation resumes when patient is reconnected.

Equipment change schedule:

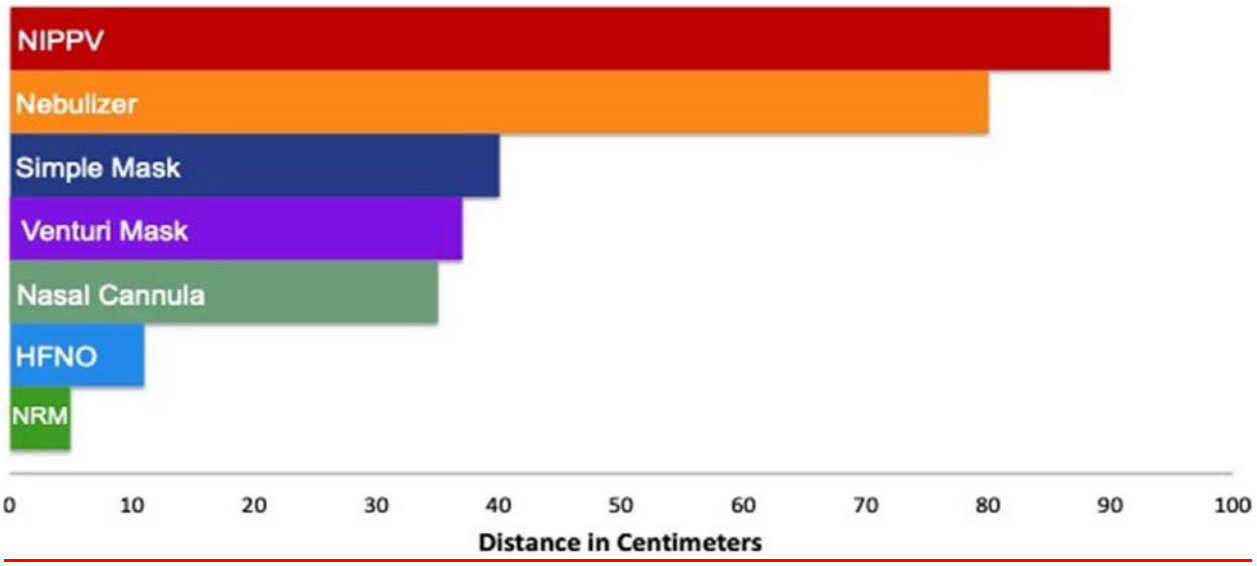
- Circuit: PRN
- HEPA or Bacterial/Viral filters: PRN
- HME: PRN
- Ballard: PRN

Note: All components of the closed system must be assembled prior to disconnection. The Goal is to minimize the number of breaking points made and duration of the change.

Supplemental Oxygen Therapy:

- When ordered, application of supplemental oxygen must follow Lippincott Procedures guidelines.
- Improper usage, liter flow and equipment augmentation may lead to a rapid decline towards emergency intubation
- N95 masks must be worn while treating patients on supplemental oxygen

Aerosol Dispersion distances (cm) for various oxygen supplementation modalities:



Distance depicted is the average dispersal for that modality over the range of flow rates typically used for that modality:

- NC ranges 3-40 cm,
- SM at all flows ≈ 30 cm,
- VM range 33-40 cm,
- NRM at all flows < 10 cm,
- HFNO ranges 4.8-17 cm,
- NiPPV ranges 85-95 cm, Nebulizers < 80 cm

Note that normal tidal breathing was not measured, but the distance measured at a flow rate of 1L/min via nasal cannula was 30 cm.

This current guideline is subject to revision. It is expected that this document will be updated and rereleased as additional experience is accumulated.

RECOMMENDATIONS AND GUIDELINES FOR PREVENTING TRANSMISSION OF CORONAVIRUS DUE TO VIRAL ENTRY THROUGH EYES (CONJUNCTIVA). *(By **Eduardo C. Alfonso MD,** Director Bascom Palmer Eye Institute, Chairman of Ophthalmology University of Miami Miller School of Medicine, Medical Director Ophthalmology UHealth, Co-Medical Director University of Miami Hospital and Clinics and Chief of Ophthalmology Service, Jackson Health System)*

American Academy of Ophthalmology Recommendations (Abridged):

https://www.aao.org/headline/alert-important-coronavirus-context
The Academy and federal officials recommend protection for the **mouth**, **nose** and **eyes** when caring for patients potentially infected with SARS-CoV-2.

It is possible that SARS-CoV-2 is transmitted to the conjunctiva by aerosol or through hand to eye contact. There is also evidence for SARS-CoV-2 RNA in tears of COVID-19 patients with conjunctivitis, although infectious virus has not yet been cultured from the conjunctiva of any COVID-19 patient.

BPEI Recommendations:
Face shields, goggles or safety glasses (with side shields, if available) are recommended. Avoid wearing contact lenses. If you have prescription glasses, it may be safer to wear them instead of contact lenses.

CDC Strategies for Optimizing the Supply of Eye Protection (abridged):
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html
Contingency and crisis strategies:

1. Facilities understand their eye protection inventory and supply chain
2. Facilities understand their eye protection utilization rate

Conventional Capacity Strategies:
Use eye protection according to product labeling and local, state, and federal requirements.
Contingency Capacity Strategies
Shift eye protection supplies from disposable to re-usable devices (i.e., goggles and reusable face shields).
Consider preferential use of powered air purifying respirators (PAPRs) or full-face elastomeric respirators which have built-in eye protection.

- Ensure appropriate cleaning and disinfection between users if goggles or reusable face shields are used.

Implement extended use of eye protection.

Extended use of eye protection is the practice of wearing the same eye protection for repeated close contact encounters with several different patients, without removing eye protection between patient encounters. Extended use of eye protection can be applied to disposable and reusable devices.

- Eye protection should be removed and reprocessed if it becomes visibly soiled or difficult to see through.
    - If a disposable face shield is reprocessed, it should be dedicated to one HCP and reprocessed whenever it is visibly soiled or removed (e.g., when leaving the isolation area) prior to putting it back on. See protocol for removing and reprocessing eye protection below.
- Eye protection should be discarded if damaged (e.g., face shield can no longer fasten securely to the provider, if visibility is obscured and reprocessing does not restore visibility).
- HCP should take care not to touch their eye protection. If they touch or adjust their eye protection, they must immediately perform hand hygiene.
- HCP should leave patient care area if they need to remove their eye protection. See protocol for removing and reprocessing eye protection below.

Crisis Capacity Strategies:
Use eye protection devices beyond the manufacturer-designated shelf life during patient care activities. If there is no date available on the eye protection device label or packaging, facilities should contact the manufacturer. The user should visually inspect the product prior to use and, if there are concerns (such as degraded materials), discard the product.
Prioritize eye protection for selected activities such as:

- During care activities where splashes and sprays are anticipated, which typically includes aerosol generating procedures.
- During activities where prolonged face-to-face or close contact with a potentially infectious patient is unavoidable.

Consider using safety glasses (e.g., trauma glasses) that have extensions to cover the side of the eyes.

Selected Options for Reprocessing Eye Protection
Adhere to recommended manufacturer instructions for cleaning and disinfection.
When manufacturer instructions for cleaning and disinfection are unavailable, such as for single use disposable face shields, consider:

1. While wearing gloves, carefully wipe the *inside, followed by the outside* of the face shield or goggles using a clean cloth saturated with neutral detergent solution or cleaner wipe.
2. Carefully wipe the *outside* of the face shield or goggles using a wipe or clean cloth saturated with EPA-registered hospital disinfectant solution.
3. Wipe the outside of face shield or goggles with clean water or alcohol to remove residue.
4. Fully dry (air dry or use clean absorbent towels).
5. Remove gloves and perform hand hygiene.

LABORATORY SPECIMEN COLLECTION RECOMMENDATIONS
For guidance on specimen collection and laboratory testing, please contact Infection Prevention at 786-266-0624 and review **"Interim Guidance for Collecting, Handling and testing clinical specimens from persons under Investigation (PUIs) for Corona Virus Disease 2019 (COVID 2019) 3/24/2020" at link below** https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html?deliveryName=USCDC_2067-DM26911

Please also see Quest Diagnostic COVID-19 Specimen Collection Guidelines at this link (98)

Please see FDOH May 11th, 2020, Clinical Screening Tool for Identifying PUI for COVID 19 on page 6 and CDC Priorities for Testing on Page 6 The provider will be responsible for completing required forms for determination of eligibility for testing and submission of specimens and this form can be found at https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf
https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.doc : The laboratory department will be responsible for sending collected specimens to the appropriate designated laboratory (currently, DOH Miami Lab and Private lab (Viracor)). Please see the FDOH 5/11/2020 Algorithm for "Who should be tested" guidance on page 5.

Information about Miracle ordering for COVID-19 was sent out to Medical Staff

24/7 phone number for Miami-Dade County Health Department is **305-470-5660**
JMH Microbiology Lab Number is **305-585-6508**

All specimens collected from a PUI should be considered to be potentially infectious and handled appropriately. Specimens should be hand delivered to the laboratory and not sent via the pneumatic tube system. Please use appropriate PPE for Specimen Collection (described in the pictograph on Page 12)

Please see the link below to CDC March 10th, 2021 document "COVID-19 Testing and Reporting by Laboratories Q and A
https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html

Interim Guidelines for COVID-19 Antibody Testing
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Standardized process of ordering PCR Lab tests and COVID-19 work flow
In an effort to continuously improve the safety of our patients and healthcare workers at Jackson Health System, all patients admitted to any of our hospitals and prior to any scheduled or emergency procedure will be tested with an NP swab for COVID-19.
The process and workflows are attached for your reference as we are streamlining and prioritizing testing platforms based on risk.
We are currently using highly sensitive and specific platforms for PCR testing. In order to use our finite resources wisely please follow our testing guidelines and recommendations:

- Pre-procedural areas including surgery, labor and delivery and IR a single PCR test is needed for symptomatic or asymptomatic patients
- Asymptomatic admissions (low probability of COVID-19) recommend a single PCR NP swab
- Symptomatic patients (high probability for COVID-19) single PCR unless the results are negative and IF the patient's clinical presentation is consistent with COVID-19 a repeat PCR might be indicated and we encourage consultation with the virology laboratory and infectious diseases.

- Discharges to nursing homes require test based strategy (2 consecutive negative PCRs 24 hours apart) or symptom based strategy

For "direct" admissions and hospital transfers, the orders will have to be entered by the provider. Please see instructions in the attached word document.

Regardless of testing results, our current infection prevention practices must continue with universal use of surgical masks and eye protection in all clinical areas.
Hand hygiene and environmental cleaning are the foundation to prevent further spread. Always wear the appropriate PPE based on the level of care and risk of aerosol generating procedures in COVID-19 infected patients.

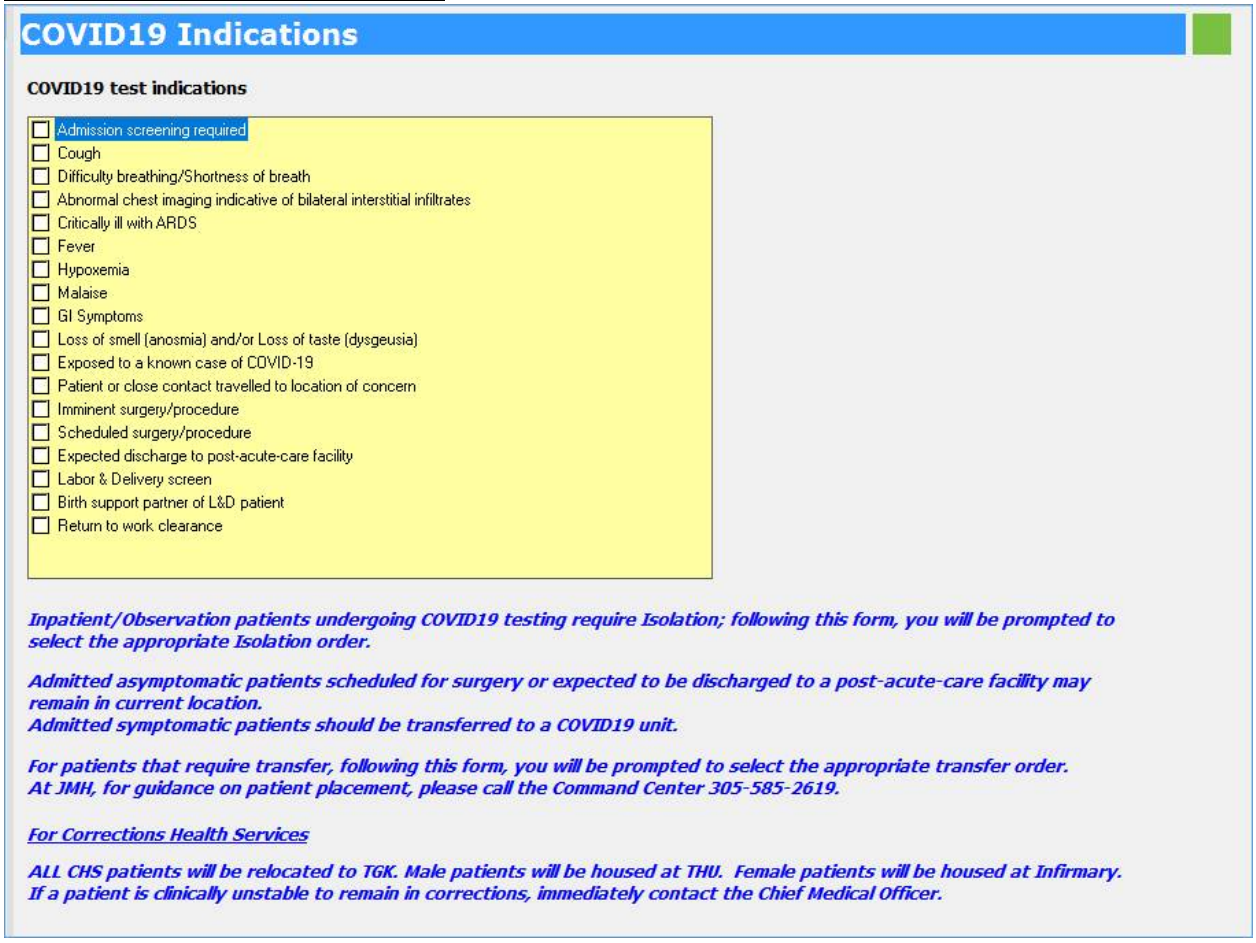
Starting now the process for ordering the COVID19 PCR lab test order will be standardized to require an indication for ordering the test.

Regardless of the type of patient or encounter that the order is being placed, ED, inpatient, observation, UCC, surgical invasive, all physicians will be prompted to enter a reason for ordering the test.

The prompt for isolation and transfer to a COVID unit will remain for all inpatient and observation admitted cases.

Please also see Appendix 10 for COVID-19 TESTING CRITERIA FOR SPECIAL POPULATIONS, TRANSPLANT AND ONCOLOGY PATIENTS

COVID-19 SCREENING FORM



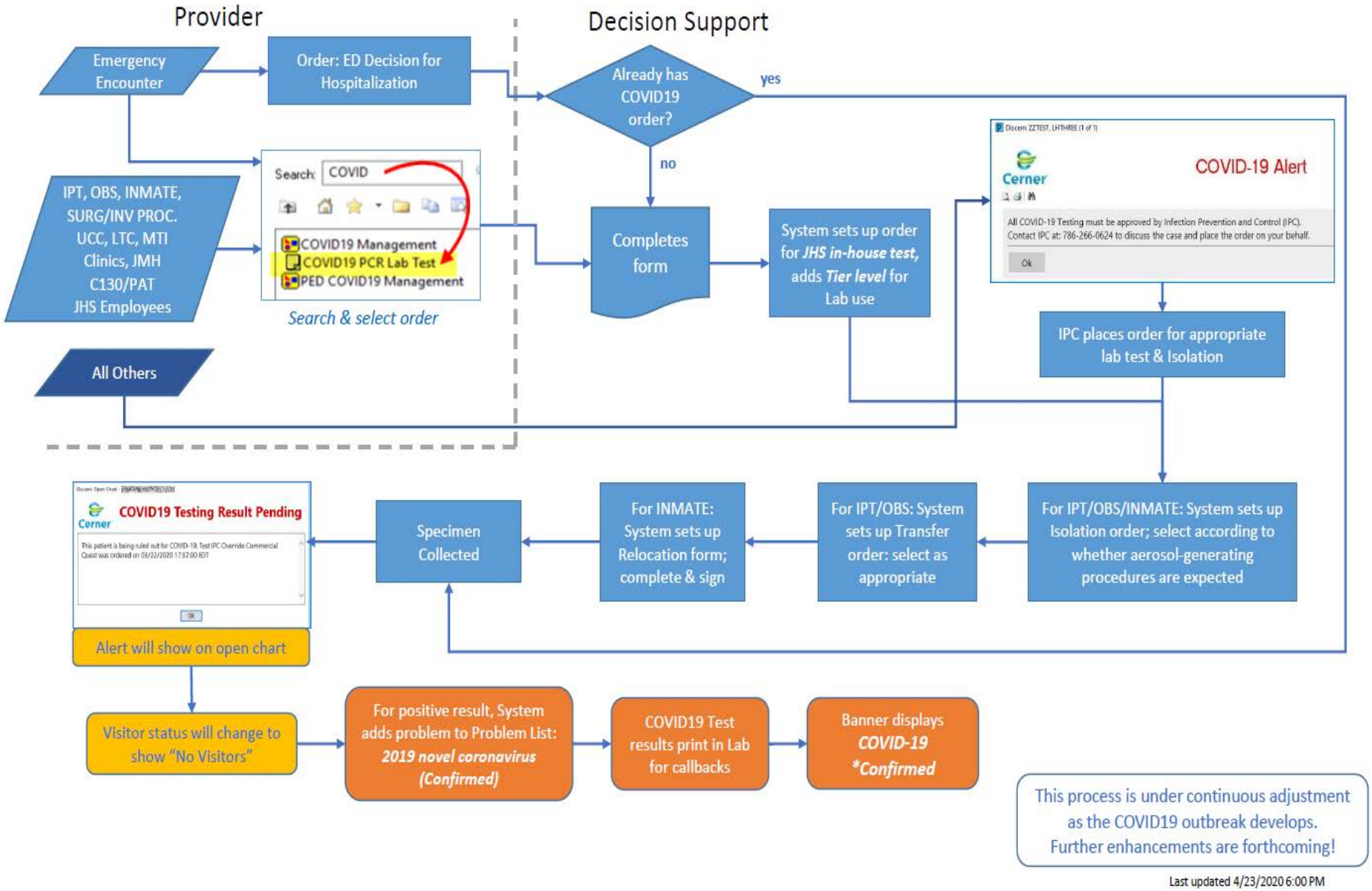
Additional reasons have been added to the form that was initially used for inpatient and observation cases only to support universal screening across JHS.

For scheduled outpatient surgery, use the pre-surgery surgical invasive encounter to enter the COVID19 PCR lab test order as today, now, and select from the list "**scheduled surgery/procedure**".

For universal screening of patient admitted for non-COVID related reasons, select "**admission screening required**". As part of the ED process, the ED physician will be prompted at the time of entering the "ED decision for hospitalization" order to also enter the COVID19 PCR lab test order if one has not been entered prior.

For direct admissions, the provider entering admission orders will be responsible of entering the COVID19 PCR lab test order for all patients admitted directly to the unit.
You will not be able to enter the order from an "outpatient encounter", please reach out to your clinic administration for additional guidance on how to test. The only exception are the employee clinics set up in ACC.

Please also see Appendix 10 for JHS COVID-19 Testing Criteria for Healthcare workers and patients, High Risk procedure list and SARSCoV2 Diagnostic Stewardship of Testing


Provider
Decision Support
Emergency Encounter
Order: ED Decision for Hospitalization
Already has COVID19 order?
yes
no
IPT, OBS, INMATE, SURG/INV PROC. UCC, LTC, MTI Clinics, JMH C130/PAT JHS Employees
Search: COVID
COVID19 Management
COVID19 PCR Lab Test
PED COVID19 Management
Search & select order
All Others
Completes form
System sets up order for JHS in-house test, adds Tier level for Lab use
Cerner
COVID-19 Alert
All COVID-19 Testing must be approved by Infection Prevention and Control (IPC). Contact IPC at: 786-266-0624 to discuss the case and place the order on your behalf.
Ok
IPC places order for appropriate lab test & Isolation
For IPT/OBS/INMATE: System sets up Isolation order; select according to whether aerosol-generating procedures are expected
For IPT/OBS: System sets up Transfer order: select as appropriate
For INMATE: System sets up Relocation form; complete & sign
Specimen Collected
Cerner
COVID19 Testing Result Pending
This patient is being ruled out for COVID-19. Test:IPC Override Commercial Quest was ordered on 03/22/2020 17:37:00 EDT
OK
Alert will show on open chart
Visitor status will change to show "No Visitors"
For positive result, System adds problem to Problem List: 2019 novel coronavirus (Confirmed)
COVID19 Test results print in Lab for callbacks
Banner displays COVID-19 *Confirmed
This process is under continuous adjustment as the COVID19 outbreak develops. Further enhancements are forthcoming!
Last updated 4/23/2020 6:00 PM

Process Steps for Safe Transport:

1. Nurse (and/or unit staff) alerts all parties (transport staff, receiving nurse, and/or respiratory therapy) about the transport. This should be done at the time report to the receiving nurse is given.
2. Nurse dresses the patient in appropriate PPE (see below).
3. When transport staff arrives, nurse wheels patient out of isolation area.
4. Transport staff (in appropriate PPE, see below) meets patient outside "isolation" area.
5. Patient is transported to receiving location following JMH transportation routes as detailed above.
6. Transport staff hands-off patient to receiving nurse (in appropriate PPE) outside of "isolation" area. Receiving nurse and/or additional unit staff transports patient into "isolation" area & room.
7. Transport staff doffs PPE and discards in appropriate bin.

Personal Protection Equipment (PPE) for Transport Staff:

Transport staff will wear appropriate PPE based on patient status and per JHS protocol (pages 9-14 of Novel Coronavirus 2019 (COVID-19) Protocol. Donning & Doffing PPE will be assisted by an observer to ensure use of proper procedure.

PPE by patient status:

- Being transferred to/from a **designated COVID-19** unit (e.g. SW 5, SW 8, MICU B):
  - N95 Respirator
  - Face Shield
  - Disposable Gown
- Being transferred to/from a **non-COVID-19** unit:
  - Surgical Face Mask
  - Face Shield
  - Disposable Gown
  - Gloves

During evaluation of the PUI and if admission is ordered, the following precautions should be followed per JHS COVID-19 protocol, pages 9-14:

COVID19 Personal Protective Equipment *Minimum Standards**

Component	Low Risk Care Episode	High Risk Care Episode
Definition	Short duration Aerosol-generating procedure NOT anticipated	≥1 hour duration, close patient contact, Aerosol-generating anticipated or planned Collection of nasopharyngeal swab
Mouth/Nose Protection	Surgical/procedure mask	N95 respirator
Eye Protection	Goggles or face shield	Goggles or face shield

COVID19 Personal Protective Equipment *Minimum Standards**

Component	Low Risk Care Episode	High Risk Care Episode
Clothing/Exposed Skin Protection	Isolation gown	Isolation gown
Hand Protection	Non-sterile gloves	Non-sterile gloves
Shoe Protection	None	None
Patient Placement	Private room with door closed	AIIR or private room with door closed only if AIIR is not available

**All healthcare workers must don PPE per minimum standards above; it is acceptable practice to don a higher level of PPE (e.g. N95 respirator for a Low Risk Care Episode) based on the healthcare worker's assessment of risk.*

Personal Protection Equipment (PPE) placed on the Patient:

- All patients should be wrapped in a blanket to prevent incidental contact with staff and environment during transport.
- If the patient is not intubated, a surgical mask should be placed over the patient's nose and mouth.

Disinfecting After the Transport:

- Transport equipment (wheelchair, stretcher or bed) will be disinfected per protocol after use.
- All elevators used during transport will be disinfected per JHS protocol by EVS department a regular basis and whenever visible soiling or contamination has occurred. In the event of a surge, this practice may be modified in consultation with Infection Prevention team.

Special Circumstances:

- Intubated patients
    - Respiratory therapist should accompany transport team throughout
    - Portable ventilators should be used (preferable to manual ventilation)
    - HEPA filters should be connected to the exhalation tubing
- High-flow nasal cannula or non-invasive positive pressure ventilation (e.g., CPAP/BIPAP)
    - Patient *cannot* be transported using these modalities

Transport by Ambulance:

- For transport by EMS, teams will follow the following:

Ambulance Transport of Suspected or confirmed COVID-19 Patients

- Before picking up any patient with fever and respiratory symptoms (cough, shortness of breath) the Ambulance crew should ask the requesting entity about any suspicion of COVID-19 or other emerging Infection
- Initial Assessment should begin from a distance of at least 6feet from patient if possible
- Patient contact should be minimized to the extent possible until a face mask is on the patient
- If COVID-19 is suspected, put appropriate PPE as described in CDC document at the link below.
- Take precautions for aerosol generating procedures as described in CDC document at the link below

- Clean EMS Transport Vehicle after transporting a patient suspected/confirmed COVID-19
- Further details derived from CDC document are outlined below

THIS INFORMATION IS FROM CDC FOR EMS TRANSPORT OF COVID-19 PATIENTS

Recommendations for EMS Clinicians and Medical First Responders

EMS clinician practices should be based on the most up-to-date COVID-19 clinical recommendations and information from appropriate public health authorities and EMS medical direction.

State and local EMS authorities may direct EMS clinicians to modify their practices as described below.

Patient assessment

If PSAP call takers advise that the patient is suspected of having COVID-19, EMS clinicians should put on appropriate PPE before entering the scene. EMS clinicians should consider the signs, symptoms, and risk factors of COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html).

If information about potential for COVID-19 has not been provided by the PSAP, EMS clinicians should exercise appropriate precautions when responding to any patient with signs or symptoms of a respiratory infection. Initial assessment should begin from a distance of at least 6 feet from the patient, if possible. Patient contact should be minimized to the extent possible until a facemask is on the patient. If COVID-19 is suspected, all PPE as described below should be used. If COVID-19 is not suspected, EMS clinicians should follow standard procedures and use appropriate PPE for evaluating a patient with a potential respiratory infection.

A facemask should be worn by the patient for source control. If a nasal cannula is in place, a facemask should be worn over the nasal cannula. Alternatively, an oxygen mask can be used if clinically indicated. If the patient requires intubation, see below for additional precautions for aerosol-generating procedures.

During transport, limit the number of providers in the patient compartment to essential personnel to minimize possible exposures.

Recommended Personal Protective Equipment (PPE)

EMS clinicians who will directly care for a patient with possible COVID-19 infection or who will be in the compartment with the patient should follow Standard, Precautions and use the PPE as described below. Recommended PPE includes:

- N-95 or higher-level respirator or facemask (if a respirator is not available),
    - N95 respirators or respirators that offer a higher level of protection should be used instead of a facemask when performing or present for an aerosol-generating procedure
- Eye protection (i.e., goggles or disposable face shield that fully covers the front and sides of the face). Personal eyeglasses and contact lenses are NOT considered adequate eye protection.
- A single pair of disposable patient examination gloves. Change gloves if they become torn or heavily contaminated, and isolation gown.,
    - If there are shortages of gowns, they should be prioritized for aerosol-generating procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of EMS clinicians (e.g., moving patient onto a stretcher).

- When the supply chain is restored, fit-tested EMS clinicians should return to use of respirators for patients with known or suspected COVID-19.
- Drivers, if they provide direct patient care (e.g., moving patients onto stretchers), should wear all recommended PPE.
- After completing patient care and before entering an isolated driver's compartment, the driver should remove and dispose of PPE and perform hand hygiene to avoid soiling the compartment.
    - If the transport vehicle does not have an isolated driver's compartment, the driver should remove the face shield or goggles, gown and gloves and perform hand hygiene. A respirator or facemask should continue to be used during transport.
- All personnel should avoid touching their face while working.
- On arrival, after the patient is released to the facility, EMS clinicians should remove and discard PPE and perform hand hygiene. Used PPE should be discarded in accordance with routine procedures.
- Other required aspects of Standard Precautions (e.g., injection safety, hand hygiene) are not emphasized in this document but can be found in the guideline titled Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

Precautions for Aerosol-Generating Procedures

- If possible, consult with medical control before performing aerosol-generating procedures for specific guidance.
- An N-95 or higher-level respirator, instead of a facemask, should be worn in addition to the other PPE described above, for EMS clinicians present for or performing aerosol-generating procedures.,
- EMS clinicians should exercise caution if an aerosol-generating procedure (e.g., bag valve mask (BVM) ventilation, oropharyngeal suctioning, endotracheal intubation, nebulizer treatment, continuous positive airway pressure (CPAP), biphasic positive airway pressure (biPAP), or resuscitation involving emergency intubation or cardiopulmonary resuscitation (CPR)) is necessary.
    - BVMs, and other ventilatory equipment, should be equipped with HEPA filtration to filter expired air.
    - EMS organizations should consult their ventilator equipment manufacturer to confirm appropriate filtration capability and the effect of filtration on positive-pressure ventilation.
- If possible, the rear doors of the transport vehicle should be opened and the HVAC system should be activated during aerosol-generating procedures. This should be done away from pedestrian traffic.

EMS Transport of a PUI or Patient with Confirmed COVID-19 to a Healthcare Facility (including inter facility transport)

If a patient with an exposure history and signs and symptoms suggestive of COVID-19 requires transport to a healthcare facility for further evaluation and management (subject to EMS medical direction), the following actions should occur during transport:

- EMS clinicians should notify the receiving healthcare facility that the patient has an exposure history and signs and symptoms suggestive of COVID-19 so that appropriate infection control precautions may be taken prior to patient arrival.
- Keep the patient separated from other people as much as possible.
- Family members and other contacts of patients with possible COVID-19 should not ride in the transport vehicle, if possible. If riding in the transport vehicle, they should wear a facemask.

- Isolate the ambulance driver from the patient compartment and keep pass-through doors and windows tightly shut.
- When possible, use vehicles that have isolated driver and patient compartments that can provide separate ventilation to each area.
    - Close the door/window between these compartments before bringing the patient on board.
    - During transport, vehicle ventilation in both compartments should be on non-recirculated mode to maximize air changes that reduce potentially infectious particles in the vehicle.
    - If the vehicle has a rear exhaust fan, use it to draw air away from the cab, toward the patient-care area, and out the back end of the vehicle.
    - Some vehicles are equipped with a supplemental recirculating ventilation unit that passes air through HEPA filters before returning it to the vehicle. Such a unit can be used to increase the number of air changes per hour (ACH) (https://www.cdc.gov/niosh/hhe/reports/pdfs/1995-0031-2601.pdf).
- If a vehicle without an isolated driver compartment and ventilation must be used, open the outside air vents in the driver area and turn on the rear exhaust ventilation fans to the highest setting. This will create a negative pressure gradient in the patient area.
- Follow routine procedures for a transfer of the patient to the receiving healthcare facility (e.g., wheel the patient directly into an examination room).

Documentation of patient care

- Documentation of patient care should be done after EMS clinicians have completed transport, removed their PPE, and performed hand hygiene.
    - Any written documentation should match the verbal communication given to the emergency department providers at the time patient care was transferred.
- EMS documentation should include a listing of EMS clinicians and public safety providers involved in the response and level of contact with the patient (for example, no contact with patient, provided direct patient care). This documentation may need to be shared with local public health authorities.

Cleaning EMS Transport Vehicles after Transporting a PUI or Patient with Confirmed COVID-19

The following are general guidelines for cleaning or maintaining EMS transport vehicles and equipment after transporting a PUI:

- After transporting the patient, leave the rear doors of the transport vehicle open to allow for sufficient air changes to remove potentially infectious particles.
    - The time to complete transfer of the patient to the receiving facility and complete all documentation should provide sufficient air changes.
    - When cleaning the vehicle, EMS clinicians should wear a disposable gown and gloves. A face shield or facemask and goggles should also be worn if splashes or sprays during cleaning are anticipated.
    - Ensure that environmental cleaning and disinfection procedures are followed consistently and correctly, to include the provision of adequate ventilation when chemicals are in use. Doors should remain open when cleaning the vehicle.
    - Routine cleaning and disinfection procedures (e.g., using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's

label) are appropriate for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in healthcare settings, including those patient-care areas in which aerosol-generating procedures are performed.

- Products with EPA-approved emerging viral pathogens claims are recommended for use against SARS-CoV-2. Refer to List N on the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-CoV-2.
- Clean and disinfect the vehicle in accordance with standard operating procedures. All surfaces that may have come in contact with the patient or materials contaminated during patient care (e.g., stretcher, rails, control panels, floors, walls, work surfaces) should be thoroughly cleaned and disinfected using an EPA-registered hospital grade disinfectant in accordance with the product label.
- Clean and disinfect reusable patient-care equipment before use on another patient, according to manufacturer's instructions.
- Follow standard operating procedures for the containment and disposal of used PPE and regulated medical waste.
- Follow standard operating procedures for containing and laundering used linen. Avoid shaking the linen.

Follow-up and/or Reporting Measures by EMS Clinicians After Caring for a PUI or Patient with Confirmed COVID-19

EMS clinicians should be aware of the follow-up and/or reporting measures they should take after caring for a PUI or patient with confirmed COVID-19:

- State or local public health authorities should be notified about the patient so appropriate follow-up monitoring can occur.
- EMS agencies should develop policies for assessing exposure risk and management of EMS personnel potentially exposed to SARS-CoV-2 in coordination with state or local public health authorities. Decisions for monitoring, excluding from work, or other public health actions for HCP with potential exposure to SARS-CoV-2 should be made in consultation with state or local public health authorities. Refer to the Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19) for additional information.
- EMS agencies should develop sick-leave policies for EMS personnel that are nonpunitive, flexible, and consistent with public health guidance. Ensure all EMS personnel, including staff who are not directly employed by the healthcare facility but provide essential daily services, are aware of the sick-leave policies.
- EMS personnel who have been exposed to a patient with suspected or confirmed COVID-19 should notify their chain of command to ensure appropriate follow-up.
    - Any unprotected exposure (e.g., not wearing recommended PPE) should be reported to occupational health services, a supervisor, or a designated infection control officer for evaluation.
    - EMS clinicians should be alert for fever or symptoms consistent with COVID-19. If symptoms develop, they should self-isolate and notify occupational health services and/or their public health authority to arrange for appropriate evaluation.

Please also see Appendix 20: CDC July 15, 2020 recommendations for EMS

TREATMENT OPTIONS

Although there is no specific treatment for COVID-19, early supportive care is of utmost importance. Appendix 1 lists treatment options under Investigation at this time (See details in Appendix 1, which also has literature review for "treatment" of COVID-19)

The Antimicrobial Stewardship teams at Jackson Health System and University of Miami Health Towers continue to review and assess the appropriate utilization of resources and therapeutics for the management of patients infected with SARS-CoV2. Please be aware of these important updates in clinical practice.

Dexamethasone use:

- Dexamethasone, 6 mg once daily for 10 days is recommended, in conjunction with Remdesivir, for patients on oxygen support.
- Data from the RECOVERY trial, a RCT published in the NEJM, indicated survival benefit for patients with severe or critical COVID-19; however, the RCT did not show benefit (and possibly harm) in patients not requiring oxygen support.

Ivermectin use:

- The use of ivermectin is not approved in the treatment of COVID-19; ivermectin is restricted to the transplant population only for the indication of Strongyloides prophylaxis or treatment per the Infectious Diseases team.
- At this time, the ASP team at Jackson Health System and U Health Tower, and ID division faculty do not support the use of ivermectin in COVID-19 for the treatment or prophylaxis due to a lack of substantial and convincing data. The team is aware of, and has reviewed, the publications from other countries regarding this topic and we will continue to review as information becomes available. This also not supported by the Infectious Diseases Society of America nor the NIH Guidelines.

- **Casirivimab/Imdevimab (Regeneron) Monoclonal Antibody Cocktail EUA:** https://www.fda.gov/media/145611/download

- **Bamlanivimab/Etesevimab (Lilly) Monoclonal Antibody Cocktail EUA:** https://www.fda.gov/media/145802/download
-
- **Sotrovimab (Glaxo Smith Kline) Monoclonal Antibody EUA**: https://www.fda.gov/media/149534/download

Please see previous reference list at this link (99.102)

Aspirin Use Is Associated With Decreased Mechanical Ventilation, Intensive Care Unit Admission, and In-Hospital Mortality in Hospitalized Patients With Coronavirus Disease 2019 (99.147)

Thrombotic Thrombocytopenia NEJM (99.152)

Convalescent plasma in patients admitted to hospital with COVID-19 (RECOVERY): a randomised controlled, open-label, platform trial (99.157)

As of April 12, 2021, approximately 6.85 million doses of the Johnson & Johnson COVID-19 vaccine have been administered in the US.

A total of 6 reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia have occurred following the Johnson & Johnson COVID-19 vaccine. All patients were White women with a median age of 33 years of age (range 18-48 years) and median time to symptom onset of 8 days (range 6-13 days).

We encourage providers to be aware of patients that may present with serious thrombotic events/thrombocytopenia in patients who have recently received the J&J COVID vaccine.

Please see CDC recommendations below for patients who have received the J&J COVID-19 vaccine:

Symptoms

- Severe headache, backache, new neurologic symptoms, severe abdominal pain shortness of breath, leg swelling, petechiae, new/easy bruising

Labs/Consults

- Platelet count/screen for evidence of immune thrombotic thrombocytopenia
- PF4 test as would be performed for autoimmune HIT
- Consultation with a hematologist is strongly recommended

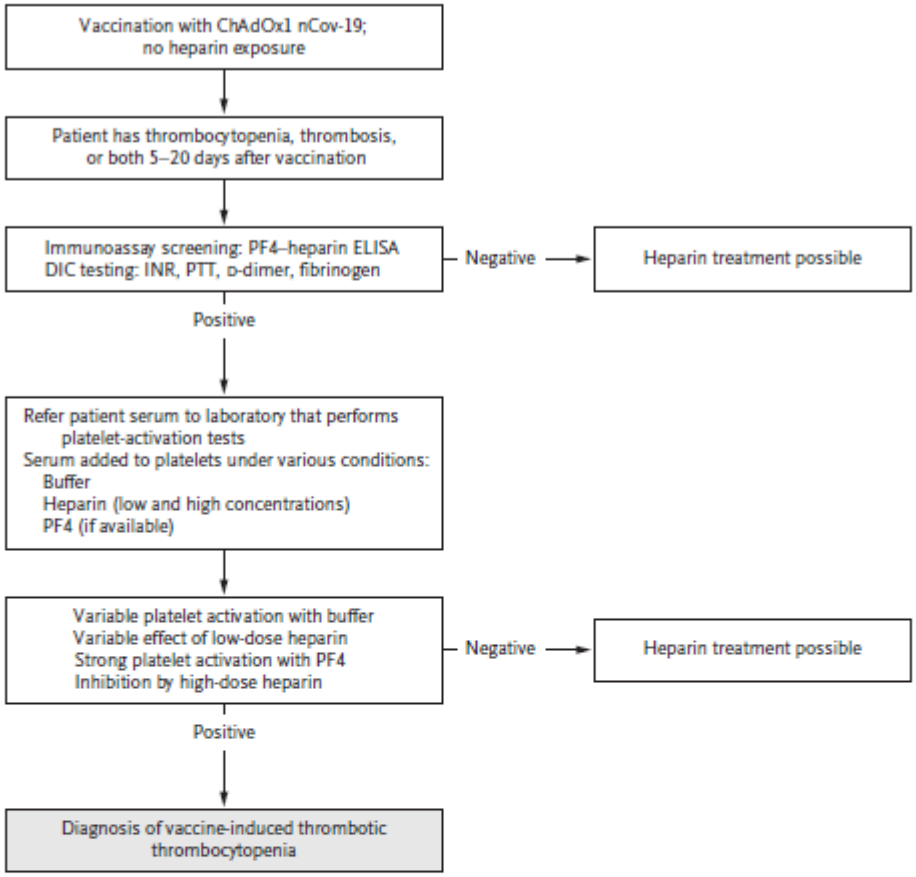
Treatment

- **Do not treat thrombotic events and thrombocytopenia with heparin, unless HIT testing is negative**
- If HIT testing is positive/unable to be performed, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered

All serious vaccine-related adverse effects should be reported to VAERS (vaers.hhs.gov.) Following receipt of COVID-19 vaccines.

For patients who are being ruled out for potential vaccine induced CVST, the NEJM article (See the link on page 48) provides an algorithm for the diagnosis and management patients with vaccine induced immune thrombotic thrombocytopenia:

Vaccine-induced Immune Thrombotic Thrombocytopenia



Treatment Options	Comment
High-dose intravenous immune globulin (1 g per kg for 2 days)	Raises platelet count and decreases hypercoagulability (by analogy with autoimmune HIT); inhibits platelet activation by platelet-activating anti-PF4 antibodies (platelet Fcγ receptors)
Anticoagulants often used to treat heparin-induced thrombocytopenia	Direct oral Xa inhibitors (apixaban, rivaroxaban) Direct thrombin inhibitors (argatroban, bivalirudin) Indirect (antithrombin-dependent) Xa inhibitors: danaparoid (not available in U.S.), fondaparinux
Platelet transfusions	Avoid unless presence of bleeding (theoretical prothrombotic risk)
Vitamin K antagonist	Contraindicated during acute thrombocytopenia and disseminated intravascular coagulation (microthrombosis associated with protein C depletion)

Figure 2. Potential Diagnostic and Therapeutic Strategies for Management of Suspected Vaccine-Induced Immune Thrombotic Thrombocytopenia.

Shown is a decision tree for the evaluation and treatment of patients who have symptoms of thrombocytopenia or thrombosis within 20 days after receiving the ChAdOx1 nCov-19 vaccine and who have had no heparin exposure. The diagnostic and therapeutic strategies in such patients differ from those in patients with autoimmune heparin-induced thrombocytopenia (HIT).[13] DIC denotes disseminated intravascular coagulation, INR international normalized ratio, PF4 platelet factor 4, and PTT partial thromboplastin time.

COVID Guidelines for the Newborn Service
Holtz Children's Hospital

(Please also see the Policy 430, Management of Infant Born to Known or suspected COVID Positive Mothers, as Appendix 16

Delivery room, baby placement and care
Transport from OR/LRD to NIN3
Perinatal consults
Daily rounds
Visitor policy
Hospital discharge
Transport team guidelines
Breast milk policy
Trauma universal precautions

NEWBORN SERVICE
HOLTZ CHILDREN'S HOSPITAL
UM-JACKSON HEALTH SYSTEM, MIAMI, FLORIDA

Universal screening of mothers is being conducted by the OB service and results are usually reported by the time of delivery. The OB service will have discussed consequences of a positive test and expected care of the newborn with the mother prior to delivery.

DELIVERY ATTENDANCE:

1. **Normal vaginal delivery/uncomplicated scheduled caesarean section in asymptomatic COVID.+ mother whose baby will be going to NICU D –**

   For a baby rooming-in, OB charge nurse will inform NICU charge nurse of the baby for staffing purposes, in the event of the baby needing subsequent NICU care.

   - For all other babies, OB Charge Nurse will call the Charge Nurse in NICU A and communicate that a baby is coming over to NICU D. They will decide whether an L&D nurse or a NICU nurse will pick up & transport the baby to NIN3.
   - OB nursing should make sure that the baby is not exposed to the mother or her partner.
   - The OB nurse will catch the baby and prepare baby for transport ensuring baby is banded prior to transport.
   - The NICU nurse, if transporting, will **not enter** the OR/LDR room, & while wearing **standard PPE** wait outside the room to receive the baby in the transporter from OB nursing.
   - The identification and handoff of the baby will occur from OB nurse to NICU nurse at this handoff point.
   - The nurse will transport the baby to NIN3 and do the appropriate handoff to NIN3 nurse receiving baby.

2. **Low-risk deliveries –**
   - NICU fellow and NNP should enter in **standard PPE**.
   - Baby should be banded prior to transport and handoff report given to NICU NNP in delivery.
   - Once baby is ready for transport, NICU team will bring baby in transporter to NIN3 where handoff to receiving nurse will occur.
   - Exit from the delivery suite should occur as outlined in the *Process for transporting babies from delivery room to NIN3* for those babies meeting criteria.

3. **<u>High risk deliveries –</u>**
   - All team members will enter the room. Team consists of MD, RT, NNP, RN
     - **RN & NNP wearing standard PPE** and
     - **MD & RT in full protective PPE for aerosol procedure (in case intubation is required).**
   - After stabilization of the baby, baby is banded, and Identification/Handoff with L&D nurse occurs.
   - Exit from the delivery suite should occur as outlined in the *Process for transporting babies from delivery room to NIN3* for those babies meeting criteria.

<u>DISPOSITION OF THE BABY</u>

1. **Healthy baby (PUI)**
   - <u>If the mother is COVID-19 positive</u>, the discussion about where the baby (now PUI) will be cared for will be had by OB when mother's results are communicated to her. If she refuses to allow the baby to be cared for separately, and both mother and baby are asymptomatic, the baby will stay with mother following CDC precautions. If the baby is to be cared for separately, the following will occur:
   - Transfer the baby to the PUI Observation Nursey (NICU D – NIN3).
   - The baby will receive a bath as soon as possible, will be cared for in an air-mode incubator and will have a NP swab for Covid-19 PCR obtained by RN at 24 h of age.
   - Care will be provided with contact precautions until the baby is ready for discharge to a pre-screened healthy family member or to the mother, if cleared to care for baby (following to the most recent CDC guidelines).
   - With the Universal Screening Protocol, there should be relatively few PUI mothers, however, all mothers with recent exposure to a Covid-19 positive individual will be considered PUI (follow above guidelines for baby).
   - <u>For a healthy PUI mother</u>, the baby will be in rooming-in; she can do so provided she uses approved PPE, practices good hand hygiene and keeps the baby (now also PUI) at a 6 ft distance, in an air-mode incubator, unless providing care. <u>The same precautions will be followed by Covid-19 positive mothers who select rooming-in.</u>
   - The baby should receive a bath as soon as possible & a NP swab for Covid-19 PCR obtained by RN at 24 h.
   - The baby is ideally cared for by a healthy family member who is not a PUI or suspected to be the source of the mother's infection.
   - A PUI baby may be discharged with a PUI mother, assuming appropriate follow up.

2. **Sick baby (PUI)**
   - Admit to NICU D-NIN3 & provide care appropriate to acuity level with contact precautions.
   - Keep infant cohorted for 14 days if the condition of the baby requires a prolonged hospitalization;
     - If a repeat COVID-19 swab on day 14 is negative, the baby may enter general NICU population.
     - If COVID-19 positive on admission or thereafter, the baby will shift to a negative pressure room in PICU/overflow unit.
   - Any intubations done in the NICU will have follow intubation protocol and wear full PPE.

BREAST FEEDING FOR COVID-19 positive or PUI mothers

- Education of breastfeeding will be initiated with mother by OB L&D team and lactation team and documented in the mother's medical record.
- Mothers will be encouraged to use masks, good hand hygiene and pumping of breast milk. o Please see COVID Breast Pumping protocol
- Although there is no data to suggest the virus is transferred through breast milk, we recommend that provision of breast milk from positive mothers or PUIs adhere to strict guidelines on collection, administration and storage of breast milk.
- Latest CDC guidelines will be followed at discharge.

VISITORS FOR EXPOSED INFANTS:

- While the PUI infants are in NICU – NIN3 isolation area, babies will be allowed only 1 visitor for brief visits, pre-screened and not in contact directly with the mother (as per COVID visitation policy).
- A visitor cannot be a PUI or the person suspected of having infected the mother.

HEALTH CARE PROVIDERS and Response Teams:

- **For OB OR/Labor floo**r **in babies needing resuscitation**– Low-Risk & High-Risk Teams
- **Healthy Baby PUI in NICU D**– NICU D doctors & staff
- **Healthy Baby PUI rooming-in with mother** – Pediatric hospitalists and Mother-Baby staff **Sick infant PUI, irrespective of location** – NICU A & B doctors & staff
- **Standard PPE in OR/LDR - Droplet & Contact Precautions**: Hats, N95 masks, face shields, yellow disposable gowns, 2 sets of non-sterile gloves. Outside OR/LDR, standard surgical masks indicated.
- **Full PPE – Aerosol, Droplet and Contact Precautions (for intubation)**: Hats, N95 masks, goggles, face shield, full protective hooded waterproof suit, bootees, 2 sets of gloves.

PROCESS FOR TRANSPORTING BABIES FROM NEGATIVE PRESSURE DELIVERY ROOM/OR 43 TO NIN3, AND CLEANING PLAN FOR TRANSPORTER WHICH MOVES BETWEEN AREAS

1. **Healthy baby planned for rooming in:**
   - If the baby is assessed to be well by usual measures, care as per COVID guidelines will commence.
2. **Healthy baby with Covid-19 positive mother, being cared for separately**
   - If the baby is assessed to be well by usual measures, transport to NIN3 and care as per COVID guidelines will commence.
3. **Potentially mildly affected infant anticipated to Covid-19 positive mother:**
   - If it is anticipated that the baby will be minimally compromised, members of the LowRisk team should be summoned, with notification that this is a Covid positive mother. In this case a fellow will step in for the intern. The fellow and NNP should enter in appropriate PPE to assist & assess the baby. When ready, the baby should be transferred to the transporter. Again, the baby should not come within 6 feet of mother. OB staff should push the transporter out through the doorway WHILE REMAINING INSIDE ROOM. They should then doff protective PPE, exiting as per protocol.
   - Once the transporter is pushed out of the room, the waiting team will receive it. The RN will wipe the transporter down with bleach wipes & the RT will monitor the baby.
   - Upon exit by team members, clean standard PPE will be donned and the team will escort the baby to NIN3 for hand-off to the accepting MD & RN. All linens and disposables will be stripped from the transporter, disposed off in NIN3, and the outside of the transporter will be wiped down again

with bleach wipes in the room before return for terminal cleaning, to a designated cleaning spot in LDRP by an individual designated by the NM.

4. **Sick baby anticipated to Covid-19 positive mother:**
   - If the baby is intubated or being bagged non-invasively, two members of the High-Risk team (RT & RN) should doff PPE/exit room as per protocol and put on fresh standard PPE in the waiting area. Once ready, they should knock a signal of readiness on door. MD and NNP, who have remained inside with the baby providing PPV will push the transporter through the doorway WHILE STILL INSIDE the negative pressure room, then doff full protective PPE & exit as per protocol. Once outside they will don clean, standard PPE.
   - As soon as the transporter is pushed out of the room, the waiting RT will assume bagging. The waiting RN will wipe down the transporter with bleach wipes. MD and NNP, having donned fresh standard PPE outside the delivery room will assume bagging, and the team will transport the baby to NIN3 for hand-off to the accepting MD, RT & RN. All linens and disposables will be stripped from the transporter, disposed off in NIN3, and the outside of the transporter will be wiped down again with bleach wipes in the room before return for terminal cleaning, to a designated spot in LDRP by an individual designated by the NM.

PERINATAL CONSULTS:

1. **OUTPATIENT:** During this period of shelter-at-home, we ask that Perinatal consults only be made as strictly necessary, after approval by MFM. As the Neonatology office staff are currently mostly working from home, calls should be made to the NICU FELLOW (NICU: 305-585-5140) and information given should include the name of patient, MR #, working contact telephone number and the reason for the consult. An H & P on the patient should be in the chart or sent to the fellow in the case of UM prenatal care.
   - The fellow will call the mother, provide the consultation via phone, discuss with his/her attending and document the exchange in the Cerner chart. If no Cerner chart is available, a consult note will be sent to UM attending.
   -

2. **INPATIENT:**
   - For inpatients on the **antepartum floor**, the same process will apply. Perinatal consults only to be made as strictly necessary, after approval by MFM. A call should be made to the NICU FELLOW (NICU: 305-585-5140) and consult information should include the name of patient, MR #, room #, working contact telephone number and the reason for the consult. An H & P on the patient should be in the chart. The fellow will call the mother, provide the consultation via phone, discuss with his/her attending and document the exchange in the Cerner record.
   - For patients on the Labor floor, fellows will continue to receive information as above, but will provide face-to-face consultation and document as usual. For PUI or COVID+ patients, full PPE will be provided to the fellow by L & D for use prior to entering patient room. If patient is able to use a phone, following the phone consult protocol is preferred.

NEWBORN SERVICE:
MODIFICATION OF ROUNDS & DAYTIME COVERAGE DURING COVID-19 PERIOD

Neo A:

To reduce exposure, only one person (preferably the fellow or attending) will examine babies before rounds, and discussions will be done outside of patient care areas. Nurses & RTs can be invited to participate from a distance, when a particular baby is being discussed. After rounds, resident and fellow

can update staff. In some cases, as for a particularly complex baby, it may be necessary to round at the bedside.

Sign out rounds will be done by phone every afternoon between attendings and fellows, including the on-call fellow & the attending and fellow remotely participating.

Neo B:

After examining the babies, attendings will work from their offices to minimize time in NICU, being available to staff and parents. There will be a fellow assigned to B. The fellow will follow regular duty hours. At 4 pm, sign-out should be given to the NNP/on-call, as usual. Every effort should be made to take care of daytime issues before leaving.

Transfers:

It is highly encouraged that transfer decisions consider not only the census in the transferring and receiving units, but also the anticipated length of stay. If a baby is anticipated to leave in 1-2 days, every effort should be made to discharge from the unit the baby is in, as transfer invariably adds extra hospital days.

Neo D:

Attendings should see their patients and then work from their offices. As with B attendings, availability to staff and parents should continue. At 4 pm, sign-out should be given to the NNP on-call. Every effort should be made to take care of daytime issues before leaving.

JNorth:

Attending and fellow will come in daily on weekdays. At 4 pm, in-person handing over will occur to the on-call person. Weekend arrangements will not change.

JSouth: No change from present arrangements.

MODIFIED VISITING POLICY FOR NEONATAL INTENSIVE CARE UNIT (NICU) at HOLTZ CHILDREN'S HOSPITAL IN RESPONSE TO THE COVID-19 PANDEMIC

In response to the COVID-19 Pandemic, the **Visitation Policy for the Neonatal Intensive Care Unit (NICU)** has been modified in our best efforts to prevent the current risk of community transmission of COVID-19 to our high-risk patients, families & healthcare workers. This difficult decision was made to keep our babies safe and to protect the healthcare workers who are on the front line of this pandemic.

We recognize these limitations can add to the worry of having a newborn baby in the NICU, so we apologize for this added burden.

Per our healthcare systems current response to COVID-19 pandemic, only pre-screened **healthy** visitors are allowed entry into the Holtz Children's Hospital. This is limited to 1 adult visitor in the building at a time, preferably the parent or legal guardian.

If you have recently traveled anywhere, have had a recent cough, cold, runny nose, headache, diarrhea, general malaise, flu like symptoms or a temperature ≥ 100.4 or 38°C, we must **restrict entry**. We recommend staying home to take care of yourself, rest and recover. You can call for updates on your baby/babies' condition.

Visitation Changes Implemented for the NICU during the pandemic:

1. Each baby is allowed **two** preidentified adult visitors, **not at the same time** (social distancing protects, both, your baby & healthcare providers). Each preidentified adult visitor will be issued a visitor **wristband** which must be shown at the desk prior to admission into the NICU.
2. Visiting hours are allowed during the following times daily:
    - ❖ A mother who has tested Covid-19 negative may visit for short periods of time around the clock while still an in-patient.

      For all other visiting, the following times apply:
    - ❖ 9 AM - 12 noon
    - ❖ 3 PM – 6 PM

- ❖ 9 PM – 12 MN

3. The preidentified visitor is expected to be the mother & father/or alternate, as designated by the mother.
4. Each parent or alternate may visit singly (not at the same time), to comply with the Jackson Healthcare System's visitation policy.
5. A visitor may enter the NICU and stay at the baby's bedside throughout the visit, but there can be no in-and-out traffic during the visit.
6. Use of cellphone covers and cellphone etiquette, including photography & FaceTime will need strict adherence to hand hygiene guidelines.
7. Visitors are discouraged from touching their faces during the visit and encouraged to repeat hand hygiene if they do so.
8. Mothers are encouraged to carry in pumped breast milk from home for their baby when they visit. The pump room is closed as a safety measure; mothers are asked to pump at home.

The Family Room in NICU is closed, again as a safety measure.

Exception:

- *For a baby born to a mom who is Covid-19 positive and separated to NIN3, only 1 designated visitor, in accordance with guidelines, will be approved to visit.*
- *Test-positive or PUI parents will not be allowed to visit the baby until medically cleared.*
- *The visitor must be someone who has had **no contact with the mother or anyone who has come in contact with the mother in the previous 14 days.***
- *This designated visitor may stay no more than 10 mins during a visiting period in NIN3 and must wear appropriate protective gear.*

The rare exceptions to this policy will **only be made** by the Medical Director, Director of Nursing or the Nurse Manager under grave circumstances, such as end-of-life.

NEWBORN HOSPITAL DISCHARGE FOR BABIES OF COVID+ MOTHERS:

Since this is a novel infection, with several impediments to standard discharge planning and practices, Medical Social Worker will be involved in every discharge from the NICU and will help the clinical team to ensure a safe discharge in every instance.

Well newborns should be discharged as per normal criteria:

- Infants who have tested negative for SARS-CoV-2 by molecular testing and are otherwise well should optimally be discharged to a designated (healthy) caregiver.
- If the mother is in the same household, she should continue distancing to greater than 6 feet from the baby.
    - If mother chooses to be close to baby, it is recommended by CDC guidelines that a mask be worn and good hand hygiene be performed to provide newborn care in the home. o For the **mild to moderately symptomatic mother or partner**, this should **continue** until the parent **has been afebrile for at least 24 hours *and* at least 10 days have passed since symptoms first appeared. For severely symptomatic or immunocompromised mother or partner, the precautions should be extended to 20 days, & ID consulted. For the asymptomatic mother or partner, they should wait at least 10 days from the positive test** before discontinuing precautions.

    - Other caregivers in the home who remain under observation for development of Covid19 should use standard procedural masks and hand hygiene when within 6 feet of the baby until their status is resolved.
- Infants who have tested positive for SARS-CoV-2 by molecular testing and are otherwise well should be discharged home on a case-by-case basis with appropriate precautions and plans for frequent outpatient contact (either by phone or telemedicine) through 14 days after birth.
- Specific guidance about use of standard procedural masks, gloves and hand hygiene should be provided to all caregivers and documented in infants chart prior to discharge.
- Uninfected individuals > 60 years of age and those with comorbid conditions should not provide care if possible.

Sick newborns who have recovered and are ready for discharge:

- Infants who have tested negative for SARS-CoV-2 by molecular testing and are now well should optimally be discharged to a designated (healthy) caregiver.
- If the mother is in the same household, she should continue distancing to greater than 6 feet from the baby, and whenever closer use a mask and good hand hygiene for home newborn care.
    - This should continue until she meets CDC guidelines for discontinuation of precautions (same criteria apply before mother can visit sick newborn in NICU).
    - Other caregivers in the home who remain under observation for development of Covid19 should use standard procedural masks and hand hygiene when within 6 feet of the baby until their status is resolved.
    - Training for discharge should be done over the phone and videoconferencing if there is no family member of negative status to come in and be trained.
- Infants who have tested positive for SARS-CoV-2 by molecular testing and are recovered from all signs of illness and deemed stable should be discharged home on a case-by-case basis with appropriate precautions and plans for frequent outpatient contact (either by phone or telemedicine) through 14 days after birth.
- Specific guidance about use of standard procedural masks, gloves and hand hygiene should be provided to all caregivers.
- Uninfected individuals > 60 years of age and those with comorbid conditions should not provide care if possible.
- Training for discharge should be done over the phone and video-conferencing if there is no family member of negative status to come and be trained.

COVID Household Baby Telehealth Clinic:

- Referral of babies within the 14-day PUI window may be made to Dr. Audrey Ofir for telehealth follow-up through the ACC Pediatric Comprehensive Care Clinic.
- NICU discharge staff are familiar with the mechanism for referral, which requires an email to Dr. Ofir's two coordinators, Ms. Frances Jara (fjara@jhsmiami.org) and Ms. Iliana Meyer (imeyer@jhsmiami.org), and *cc* to Dr. Ofir (aofir@miami.edu).
- Some families may choose follow-up elsewhere, but this is an excellent resource for post-discharge follow-up for this at-risk population.

NICU TRANSPORT FOR PUI OR COVID-19 POSITIVE BABY:

- Consent for transport will be Faxed to referring hospital and obtained by the referring MD prior to team departure from Holtz

- Transport Team (3 members: MD, RN & RT, for ventilated baby or 2 members: MD/RN or NNP/RN for stable, non- ventilated baby) – may go by ground ambulance or fixedwing aircraft. For an otherwise healthy baby being transported solely for cohorting and observation, a single nurse and paramedic will suffice for ground transport locally.
- No family member may travel back with the team
- Full protective PPE will be carried by team and donned prior to entry into baby's room.
- The transport ventilator, Ambu bag and t-piece will be fitted with HEPA filters.
- The transporter and the hard-plastic COVID Transport bag, containing transport equipment, medications, and respiratory equipment will stay outside the room.
- One team member will stay outside and hand required equipment or medication through doorway to a second team member, inside the room.
- Once the baby has been stabilized, the transporter will be brought in and the baby transferred to it. All team members will doff gown and gloves and sanitize. Fresh gown and gloves will be worn. Eye shields and N-95 masks remain. The RN will double glove and wipe down the transporter with a bleach wipe. Gloves will be discarded.
- The hard-plastic bag will also be wiped down with a bleach wipe prior to departure.
- Team will prepare to leave after communicating with family by phone.
- Upon exiting, team will take the route and elevator indicated by the referring hospital, to the waiting ambulance for return.
- If doing an air transport, the team will follow guidelines of the air ambulance team members.
- During transport, no ambulance EMTs will be allowed in the back of the truck.
- Communication between team & crew will only be by phone.
- Team will call Charge Nurse in NICU to notify the Estimated Time team will be arriving at JMH. (Please allow 15 minutes so internal teams can assemble).
- If there is any opening of the transporter in travel, team member entering the transporter will have to remove contaminated gloves and gown, sanitize and wear a fresh gown and gloves prior to entering hospital. Contaminated PPE will be bagged & left in ambulance for disposal at the time of its terminal cleaning. The transporter will be wiped down again with a bleach wipe prior to hospital entry.
- Ambulance is to park in ambulance bay, crew will open the doors of the cab and remove stretcher from back of truck.
- § Ambulance drivers can bring the stretcher to the ER entrance but are not allowed entry into the hospital for PUI/ Covid + patients.
- Transport within Jackson will follow active JHS policy. Team will push transport stretcher and equipment to the designated unit (NICU or PICU)
- Baby will go to NIN3 if PUI, and to a PICU negative pressure room if symptomatic or COVID+.
- After transfer of care, PPE will be appropriately doffed and team members will sanitize before re-entry to NICU.
- Transporter and hard-plastic bag will be sanitized prior to leaving the room, and the transporter and transport ventilator will be terminally cleaned prior to storage.

BREAST MILK FROM PUI or COVID+ MOTHERS:

- For mothers who wish to breast feed, provisions will be made for safe collection and storage of breast milk. Detailed instructions will be provided by OB nursing and lactation consultants.
- It is recommended that breast milk be pumped with precautions and be fed to the baby by a healthy attendant. However, if rooming-in and the mother prefers putting the baby to the breast, it is

acceptable by current CDC guidelines. The mother must perform good hand hygiene, wear a mask, and breastfeed the infant with precautions. Babies should normally be kept at least 6 feet from the mother.

- For mothers pumping milk for babies, a dedicated pump will stay in the room. Containers and labels will be provided by the lactation consultants. Prior to each pumping, the mother will put on a mask, perform hand hygiene and pump under direct observation of a staff member. Milk will be placed on a clean surface previously prepared, and handled by the staff member after sanitizing and gloving, The milk will be transferred into a container, labeled, and bagged in the room, wiped down with a bleach wipe and taken to NICU by the staff member.
- The NICU charge nurse will accept the milk and place it in the designated freezer in NICU D.
- Milk intended for a baby will be taken from the freezer and thawed in the refrigerator in NIN3.

COVID-19 TRAUMA / BIRTHS OUTSIDE OF L&D RESPONSE TEAM - UNIVERSAL PRECAUTIONS:

- OB team will respond as usual for births outside L&D floor, & the response will include taking an infant transporter with t-piece resuscitator to Trauma.
- NICU High Risk team will respond as usual for births outside L&D floor, bringing 'run bag' with necessary supplies, including HEPA filters for the ambu bag & t-piece resuscitator.
- Trauma will supply both teams with PPE (team members should carry their own N-95 masks, especially if they are of non-standard sizes).
- Although the Trauma team will send Covid testing on arrival, this will not be immediately available. Hence, all mothers will be considered PUI and therefore both teams will use PPE while in the same room as the mother.
- OB will initially enter the mother's room to assess the mother and fetus, and to make a decision about whether observation or an immediate delivery is required.
- All team members will be dressed, at a minimum, in droplet & contact precautions, wearing hats, bootees, N-95 face masks, face shields, protective gown, and gloves before room entry.
- Team members who will be directly exposed to aerosolized material (anesthesia team, surgical team, including surgeon, first assistant and scrub nurse, and intubation team, comprising of fellow & respiratory therapist) will be dressed in aerosol, droplet and contact precautions - full protective PPE, including hats, bootees, N-95 face masks, goggles, face shields, hooded waterproof gown and double sets of gloves.
- If a delivery occurs in Trauma, the steps for exiting the OR and subsequent entry into Holtz will follow the same precautions as listed in *Transport from OR/LDR to NIN3* and
    - *Transport Team Guidelines* of the document *COVID Guidelines of the Newborn Service,*
    - *Holtz's Children's Hospital, 4/10/2020*
- Upon admission to NIN3, care of the baby will follow standard Covid care measures.

Contact page:

For clarification or comment, please contact Shahnaz Duara, MD sduara@miami.edu

Please See Appendix 9 "CDC HAN Health Advisory 432 "Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Corona Virus Disease 2019 (COVID-19)

Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19) CDC COCA Call Slides. **(73)**

Evaluation and Management Considerations for Neonates At Risk for COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-newborns.html

DISCHARGE PROTOCOL

(Please see Appendix 7 for CDC guidance on "guidance on " Duration of Isolation and precautions for adults with COVID-19

Discharge Protocol for COVID-19 Positive Patients or Patients Under Investigation (PUI) at time of discharge. *Prior to discharge, all patients or caregivers need to have received appropriate education of discharge plans and be made aware of any signs or symptoms that he/she should return back to the hospital*

Special considerations when discharging patients with COVID-19 include the following:

- COVID-19 illness can be prolonged and patients can worsen clinically over one week into their illness
- Hospital staff are at risk of infection from the patient during the discharge process
- Those transporting the patient home are at risk of exposure to COVID-19
- Household contacts—or staff and other patients at facilities—are at risk of exposure to COVID-19

Discharge to a Private Residence:

Medical Readiness for Discharge:

- Patient has reached stability such that they are not expected to need in-person follow up, ambulatory medical care, or urgent care within 14 days after discharge
  - ➢ Improvement of initial symptoms (e.g cough, SOB, diarrhea)
  - ➢ Resolution of fever for 24 hours
  - ➢ Downtrending inflammatory markers (e.g. CRP)
  - ➢ Return to baseline oxygen requirements or a maximum of 2L while doing ADLs without SOB (or O_2 sat >92%)
  - ➢ Return to baseline mentation
  - ➢ Please also see Appendix 8

Discharge Location:

- Verify private residence
- Verify and document contact number for patient, as well as name and contact number for primary support person
- Verify if the patient lives alone. If other persons live in the same house, ensure that the patient has their own room with a dedicated bathroom while isolated.
- If patients lives with someone who is immunocompromised or >65, we suggest of appropriate accommodations to be made, by case management and the county, for patient and appointed person to not live together for at least next 7 days.
- Also see Appendix 8 Duration of Isolation and precaution for Adults with COVID-19

Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) considerations:

- Confirm that patient is able to manage ADL/IADLs for at least 14 days alone or with the degree of available home support
- Confirm patient has resources/social support to receive 1-2 weeks of food and supplies Discharge Medications:

- Ensure patient has a 30-day supply of all necessary maintenance medications. Discharge prescriptions should be electronically prescribed to either Jackson Memorial Pharmacy for meds to beds delivery or patient's preferred pharmacy to minimize exposure.
- If patient is to be discharged on hydroxychloroquine or azithromycin, must have obtained an EKG while inpatient

Transportation:

- Verify ride home with a private vehicle
- If no private vehicle, arrange for medical transport home
- Ensure patient wears surgical mask in vehicle

Follow up:

- ICU/hospitalist team to designate a healthcare worker to follow up with patient at 24 hours, 48 hours and 1 week after discharge by phone call. These encounters should be documented in Cerner as a telephone encounter.

Discharge to a Long Term Care Facility (nursing home, assisted living facilities, intermediate care facilities for the developmentally disabled and group home facilities):

Please see Appendix 11 for AHCA Emergency Rule for discharging patients from Hospitals for Long Term Care and Residential Facilities.

Discharge Location:

- Verify and document contact number for patient, as well as name and contact number for primary support person and facility

Transportation:

- Arrange for medical transport to facility
- Ensure patient wears surgical mask in vehicle

Follow up:

- ICU/hospitalist team to designate a healthcare worker to follow up with patient at 24 hours, 48 hours and 1 week after discharge by phone call. These encounters should be documented in Cerner as a telephone encounter.

Discharge for Patients Receiving Hemodialysis:

CDC has interim guidance for dialysis centers which can be found here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

- Dialysis center must be contacted and alerted to patient's COVID-19 status and confirm that they can accommodate dialysis for this patient.
- Check nasopharyngeal swab PCR twice at least 24 hours apart when patient nearing ready for discharge o Discharge does not depend on the results of these tests, but if both are negative, the dialysis center should be aware that the patient has low likelihood of infectivity
- Contact dialysis center with results of the PCR tests.

Hospital Post Acute Care Facility Transfer COVID-19 Assessment Form can be found in Appendix 11

EMPLOYEE HEALTH ISSUES

Healthcare workers who provide direct patient care who have been exposed to a confirmed case of COVID-19 while not wearing recommended PPE are required to contact their immediate supervisor and the Employee Health Clinic to report the potential exposure. If the Employee Health Clinic is closed, the

employee Health should report to the nearest Emergency Department for evaluation. A mask should be worn by the employee https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

COVID-19 Guidelines For Returning to Work
https://jhsmiami.org/LeadingForward/COVID19GuidelinesReturningtoWorkJune2022.pdf

Jackson Health System has changed its return-to-work policy for employees who have tested positive for COVID-19. The process has also been streamlined by using a tool on **JacksonBadgeBuddy.org** to make it faster and easier to be cleared to return to work.

Employees, regardless of vaccination status, can return to work after 5 days – not 10 – if they meet ALL of the following criteria:

- Asymptomatic, including no fever for at least 24 hours without fever-reducing medicine.
- Wearing an N95 mask for an additional five days at all times while in Jackson facilities. Employees who are unvaccinated and working under a medical or religious exemption should wear an N95 mask at all times while at work, regardless of their COVID status.

Employees should use the process above once they are feeling better between days 5 and 9. Employees who are symptomatic or immunocompromised will be required to wait 10 days, in addition to following the other criteria listed above.

All employees, regardless of vaccination or symptom status, are required to log into the tool on **JacksonBadgeBuddy.org** and complete the attestation.

Employees should reference **JacksonCOVID19.org** for information on Jackson employee testing locations and hours of operation.

Employee screening to prevent and control infection from entering facility from all entrances
As per CDC recommendations, Jackson Health System requires that everyone (Patients, Healthcare Personnel and Visitors) entering a healthcare facility be screened for signs and symptoms of COVID19.

- The in-person screening for Patients and Visitors is performed at all entrances of each facility by our Public Safety Staff.
- For Healthcare Staff Employees, screening by using the COVID-19 Daily Check-In Report to Work application tool is recommended. Specifics on the use of the tool is being provided by our Human Resources Department. For staff that are unable to use the app, in person screening will be required.
- Medical staff members with privileges at another hospital may present a daily check in screening from the outside facility as evidence of compliance.
- Visiting vendor representatives are using Reptrax Kiosks to complete attestation for symptoms and exposure as it relates to COVID19.

Employee Travel and Return to Work
If you have travelled outside of the United States within the last 14 days then you must immediately contact Jackson Employee Health Services by calling 305 585-2676

Employees traveling outside of United States must notify Employee Health Services prior to returning to work to receive clearance. This notification can be done via email at JHS-returnwork@jhsmiami.org or by calling 305 585-2676. Employees will receive a response with direction within 24 hours.
Please use the "Travel, Symptoms or exposure employee screening tool" under COVID-19 part of the Jackson Badge Buddy App. . **To Down Load Jackson Badge Buddy App: iPhone: Enter "JacksonBadgeBuddy.org" into the browser (Safari, Google Chrome, etc.) to reach the site. Scroll to bottom of screen to**  **icon, select the add to home screen icon**  **and save.**

Please see Appendix 4 "CDC Criteria for return to work for Healthcare personnel with confirmed or suspected COVID-19 Interim Guidance"

All business Travel is suspended effective immediately. Exceptions may be granted at the executive vice president level.

If you have traveled and are presenting with symptoms, please go to your nearest emergency department or urgent care center immediately for Triaging and medical attention.

Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19)
https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

VISITORS:
Please check Jackson Health System daily COVID-19 information emails communication and www.SafeAtJackson.org and **JacksonBadgeBuddy.org** for updated information. To Down Load Jackson Badge Buddy App:

- **iPhone**: Enter **"JacksonBadgeBuddy.org"** into the browser (Safari, Google Chrome, etc.) to reach the site. Scroll to bottom of screen to  icon, select the add to home screen icon  and save.

Jackson Health System Announces Updates to its COVID-19 Visitation Policy
"Please see Appendix 22 for Jackson Health System updated guidance on Masks and Visitation Policy".
Jackson Health System Mask and Visitation Guidelines
https://jhsmiami.org/LeadingForward/JacksonVisitationGuidelines2022.pdf

UPDATE: Jackson COVID-19 Risk Level

COVID risk-level increase; required masking resumes

- **Due to a decrease in COVID-19 cases throughout our hospitals and community, and consistent with our existing standards, we have moved our systemwide COVID risk level down to "low."**
    - **Surgical masks are required in all clinical and public areas at all times.** Surgical masks are **preferred, but optional, for vaccinated personnel in non-clinical facilities and office suites.** Employees not vaccinated against COVID must wear N95 masks at all times. As a reminder, N95 masks are also required in areas where COVID patients are being treated and aerosol-generating procedures are being performed, including intubation and extubation.
    - **Visitors** are required to wear surgical masks in all areas at all times.

- **Strict enforcement will resume that public lobbies and lounges are for patients and visitors only.** Employees are welcome to enjoy their meals and breaks in cafeterias, staff lounges, and break rooms, as well as our outdoor spaces.

- It is critically important that employees and providers **monitor any potential COVID symptoms, and report them with the online tool before arriving to work at any Jackson facility.** The tool can be found in the COVID-19 section on **Jackson Badge Buddy**.

Main things you need to know:

- **All patients, including those who are COVID-positive, may have visitors of any age.** Visitors must wear masks at all times, including in the patient's room. Visitors for COVID-positive patients must wear N95 masks at all times, including in the patient's room.
- **Unless otherwise detailed, visiting hours are 8 a.m. to 8 p.m.** Emergency Department patients may have up to two companions at any time. Maternity patients may have one visitor stay overnight. Pediatric patients, including newborns, may have two visitors stay overnight. Administration may approve one overnight visitor for other patients.
- **Most patients may have two visitors at a time.** Behavioral health inpatients may have one visitor at a time. Adult ICU patients may have one visitor at a time.
- Every patient may designate one "essential caregiver," who must be allowed to visit two hours in addition to the hours in this policy.
- **Click here to review the full policy** for other details.
- For additional COVID resources, visit **JacksonCOVID19.org**

CONTINUING THIS WEEK: COVID-19 Booster Vaccines

We are offering the **Pfizer COVID-19 booster vaccine to eligible employees and providers now until this Friday, October 8.**

The booster vaccines are available at all hospital campuses. Click **here** to view the **vaccine schedule** for each facility and **here** for **frequently asked questions.**

Please remind your employees to check their booster vaccine eligibility prior to visiting a vaccine location with the COVID-19 booster eligibility checker on **JacksonCOVID19.org** or **Jackson Badge Buddy**.

As the pandemic continues to evolve with the rapid spread of the highly contagious omicron variant we all continue to adapt.

Our priority remains patient and employee safety while at the same time continuing to provide the highest level of excellence and patient centric care.

In the last two weeks we are seeing a decrease of hospitalizations yet more than 13% of Miami Dade county is still testing positive for COVID. The UK and Denmark have seen now a second omicron wave with the BA2 variant. We need to remain cautious and vigilant.

Our ask is that for all elective surgical cases the attending surgeon or team appropriately document

- Patients symptoms
- Day of COVID test if positive or negative
- Number of days the patient completed isolation

As you all know our infection prevention protocols recommend that in PCR positive cases:

Emergency surgeries: proceed with COVID precautions including post op care
Non emergent/elective cases

- Immunocompetent: reschedule in 10 days and document appropriately
- Immunocompromised, including transplant, oncology on active chemotherapy and solid tumors, when possible postpone for 20 days due to prolonged viral shedding in this high risk population

New update:
In cases where an immunocompromised patient requires surgery before 20 days including solid tumors we recommend that a repeat PCR is done at JHS 24 hours prior to the procedure. The infection prevention team will evaluate based on symptoms and Ct PCR value if is safe to proceed or to discontinue isolation and coordinate placement pre and post op.

We ask for your cooperation and communication as the procedures may be safely done with COVID precautions without delays. We also need to plan patient disposition in pre-procedure holding, PACU and recovery areas, to ensure the safety of all our patients and healthcare workers

As always, we are always available for consultation for clarity and the need to proceed or delay.

COVID Designated and NON-COVID Designated Units
Updated List 5/19/2021

Unit	IMCU/ICU	Med/surg beds	Total beds	MD Staff Coverage	Admission requests	Admit to team
Central 6	23 (mixed unit)		23	Pulmonary critical care	C6APP	Medicine-IMCU6
MICUB	8		8	Pulmonary critical care	MICU triage	Team MICU
CCU	11(non covid)		11	Pulmonary critical care	MICU triage	Team MICU
SICUB (1-12)	12 (mixed unit)		12	ECMO/Covid/Heart and lung transplant	SICU pgr2238/ CSICU pgr 2802	CVICU Team
SW5	(non covid)	30	30	JMH Hospitalist/ FLACS/Team 2	ED case manager assigns	ED case manager assigns
SW6	closed	30	30		Currently closed	Currently closed
SW7	All covid	28	28	JMH Hospitalist/ FLACS/Team 2	ED case manager assigns	ED case manager assigns
SW8	IMCU 21 beds		21	Hospitalist/ Pulmonary critical care	Assigned team/ hospitalist	JMH hospitalist/ FLACS
TICU	2		2	Trauma/surgery	TICU fellow 851168	Surgical team
DTC 5	ICU (2 beds may hold covid)		27	Neurosurgery/Neurology		
DTC 6	ICU (2 beds may hold covid)		27	SICU Team Transplant (except heart and lung) General Surgery		
TOTAL	58	126	180			

Contact Numbers

DOH		
Miami Dade County Department of Health	**305 470-5660**	
JACKSON HEALTH SYSTEM		
24 HR Phone list		
Jackson Memorial Hospital Main Campus	305 585-1111	
Jackson South Medical Center		
Jackson North Medical Center	305 651-1100	
Case Management (Main)	786-382-3453	
Case Management (North)	305-654-5018	
Case Management (South)	305-256-2127	
Risk Management	305 986-8921	
Environmental Services	305-585-7270	
Anti-microbial Stewardship	786-586-0607	
Microbiology Lab at JMH	305 585-6508	
Procurement /Supply chain	305 585-5668	
Infection Control/Prevention	305-585-6820	
Operating Room		
Patient Transport	305 585-6613	
AIC's		
AIC JMH	786-299-7517	
AIC JNMC	305-654-5095 ext #1	
AIC JSMC	305 256-5331	
SECURITY COMMAND CENTERS		
JMH	305-585-6111	
JNMC	305 651-1100 x2770	
JSMC	305 256-5222	
RESPIRATORY THERAPY 24 HR Phone list		
Office	305-585-7060	
Lead pager #	1842	
Manager	305-494-2899	Raymonde Jouissance
Manager	305-319-2210	Lanetra Garvin
Director	305-975-1657	William Tanelus
Holtz		
Lead pager #	2571	
Chief Therapist	954-243-6613	Micheline Plantada
North		
Office	305-654-5042	
Lead Ascom	291123	
Chief Therapist	305-469-9552	Ana Sanchez-Valdez
South		
Office	305-265-5032	
Lead Ascom	761795	
Chief Therapist	305-772-8499	Juan Castell

Please see previous Reference list at this link (99.102). New References below

CDC simplifies COVID-19 vaccine recommendations, allows older adults and immunocompromised adults to get second dose of the updated vaccine
https://www.cdc.gov/media/releases/2023/s0419-covid-vaccines.html

Suspected Suicide Attempts by Self-Poisoning Among Persons Aged 10–19 Years During the COVID-19 Pandemic — United States, 2020–2022
https://www.cdc.gov/mmwr/volumes/72/wr/mm7216a3.htm?s_cid=mm7216a3_x

Stroke Mortality Among Black and White Adults Aged ≥35 Years Before and During the COVID-19 Pandemic — United States, 2015–2021
https://www.cdc.gov/mmwr/volumes/72/wr/mm7216a4.htm?s_cid=mm7216a4_x

The Association of Reported Experiences of Racial and Ethnic Discrimination in Health Care with COVID-19 Vaccination Status and Intent — United States, April 22, 2021–November 26, 2022
https://www.cdc.gov/mmwr/volumes/72/wr/mm7216a5.htm?s_cid=mm7216a5_x

Jackson HEALTH SYSTEM
Miracles made daily.

Jackson Health System
COVID-19 Treatment Information
February 3, 2023

This version supersedes all previous versions

ASP Phone numbers for Therapy Approval
Jackson Memorial: 786-586-0607
Holtz: 305-750-0716 (Pediatric ID)
Jackson North Medical Center: 305-654-5022; option 1; internal: 20-4022
Jackson South Medical Center: 305-256-5180

Table 1: Adult JHS Confirmed COVID-19 Treatment Guide (2.3.2023)

For any suspected cases at JHS, please contact JHS Infection Prevention (IP) at: 786-266-0624. **For ID consult at JHS, contact ID COVID Team C 786-674-2884**

Supportive care is the mainstay of therapy for COVID-19. This includes fluid resuscitation, oxygen supplementation, and antipyretics (acetaminophen preferred). **Prior to initiating SARS-CoV-2 targeted therapy, consider baseline functional status, goals of care, and DNR status.** Below are possible treatment options based on ongoing investigational trials, case reports, and *in vitro* data. **At this time, ASP does not recommend the routine use of empiric broad-spectrum antibiotics for pneumonia in patients diagnosed with COVID-19 (appendix 1).** Information is rapidly evolving, and this protocol will be updated as more data becomes available.

Criteria	Treatment Options[1] (Drug interactions: http://www.covid19-druginteractions.org/)	Clinical Pearls for Treatment Options

Mild: any of the following without hypoxia
• Fever, malaise, cough, headache, sore throat, myalgia, nasal congestion, diarrhea
	[3]Monoclonal Antibody Treatment (outpatient encounters only)
	Regeneron, sotrovimab bamlanivimab-etesevimab, and bebtelovimab (as of 11/30/2022) are no longer approved by the FDA under EUA (Appendix 1).
	
	[2]Remdesivir
	200 mg IV LD x 1, then 100 mg IV daily x **2 days (3 days total)** is an option for symptomatic COVID-19 patients, whom **are not** hypoxic (SpO2 ≤ 94% on room air), meet high risk criteria (clinical pearls). Must have positive test within 5 days. These patients do not require dexamethasone.
	
	Paxlovid (nirmatrelvir/ritonavir)
	300 mg nirmatrelvir / 100 mg ritonavir PO twice daily x 5 days is recommended for mild-moderate symptomatic COVID-19 patients whom are **not** hypoxic (SpO2 ≤ 94% on room air). It has important drug-drug interactions and dose is renally adjusted (Appendix 6).
	
	[3]**Pre-exposure** prophylaxis: Evusheld is **no** longer approved by the FDA; no agent for pre-exposure prophylaxis is currently approved by the FDA (Appendix 1).
		[2]Remdesivir
		• Veklury (Remdesivir) is FDA approved for treatment of COVID-19 for hospitalized patients
		• JHS criteria for use:
		  ◦ Confirmed, active COVID-19 infection
		  ◦ **SpO2 ≤ 94% on RA or PaO2/FiO2 < 300**
		  ◦ If mechanically ventilated, may consider remdesivir **only within 24h of intubation**
		  ◦ **ALTs < 10x ULN**
		  ◦ No known hypersensitivity
		
		[4]Tocilizumab
		• **Due to national shortage and difficulty in procuring tocilizumab, baricitinib is preferred when tocilizumab is unavailable.**
		• CRP levels may be used to guide Tocilizumab therapy (trend inflammatory markers daily)
		• All patients receiving Tocilizumab should be ruled out for latent TB per package insert, and screened for hepatitis B and strongyloides serologies.
		• Use with caution in patients with history of GI perforation/diverticulitis or active infection
		• Do not use in patients with ALT ≥ 5x ULN, ANC <500 cells/µL and/or platelet count <50,000 cells/µL
		
		[5]Baricitinib
		• CRP levels may be used to guide Baricitinib therapy, current thresholds for treatment are based on clinical practice experience
		• VTE prophylaxis should be utilized while on Baricitinib
		• If patient experiences a thromboembolic event or is placed on therapeutic anticoagulation due to concern for a embolus, **baricitinib should be discontinued**
		• Baricitinib should be avoided in cases of active TB

Moderate: **All** must be met in a non-intubated patient: • SpO2 < 93% on room air or requiring supplemental oxygen above baseline • Any symptom of mild disease • Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or bilateral consolidations • No additional signs or symptoms of severe COVID-19 (see below)	[2]Remdesivir 200mg IV LD x 1, then 100mg IV daily x 4 days No longer restricted to ID/ASP; may be ordered be primary team if patient meets criteria [6]Dexamethasone 6mg IV/PO once daily up to 10 days* *Consider shorter duration based on patient improvement (methylprednisolone 40mg daily/prednisone 40mg daily equivalents may be used) Additional therapies to consider if patient rapidly decompensating: [4,5]Tocilizumab or Baricitinib; requires multidisciplinary discussion between ASP, ID, and critical care; see below, severe/critical *Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset if patient is unvaccinated, vaccinated > 5 months ago with an mRNA vaccine, > 2 months ago with J&J, or immunocompromised (regardless of vaccination date)*	

Severe: ≥ 2 of the following • Intubated • Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or consolidations • ARDS with PaO_2/FiO_2 151-300 mmHg • Lymphopenia (ALC < 0.6 x 10^3/mcL) OR **Critical** : ≥ 2 of the following in intubated patients: • Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or consolidations • ARDS with PaO_2/FiO_2 ≤ 150mmHg • *Septic Shock (with >1 vasopressor) • Altered Consciousness • Multi-organ failure	[2]Remdesivir (may consider if intubated within 24h) 200mg IV LD x 1, then 100mg IV daily x 4 days No longer restricted to ID/ASP; may be ordered be primary team if patient meets criteria [6]Dexamethasone 6mg IV/PO once daily up to 10 days* *Consider shorter duration based on patient improvement (methylprednisolone 40mg daily/prednisone 40mg daily equivalents may be used) **[5]Baricitinib: Appendix 4** (Severe/Critical criteria, plus all of the following): • On high-flow nasal cannula or non-invasive mechanical ventilation or recently intubated within 24 hours • Two or more of the following :CRP > 10 mg/dL, D-dimer > 1 mcg/mL FEU, Ferritin >1,000 ng/mL, or LDH >500 units/L • Receiving or received remdesivir and/or corticosteroid • Oral, orogastric, or nasogastric route is available • **Cannot receive or have received tocilizumab for COVID-19** **OR** **[4]Tocilizumab: Appendix 3** (Severe/Critical criteria plus all of the following must be met): • Recent intubation due to COVID (within 24h) • Two or more of the following :CRP > 10 mg/dL, D-dimer > 1 mcg/mL FEU, Ferritin >1,000 ng/mL, or LDH >500 units/L • **Cannot receive or have received baricitinib for COVID-19** *Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset if patient is unvaccinated vaccinated > 5 months ago with an mRNA vaccine, > 2 months ago with J&J, or immunocompromised (regardless of vaccination date)*	• Baricitinib requires dose adjustment for eGFR <60 and should be avoided in patients with eGFR ≤15 • Baricitinib should be used with caution in patients with a history of GI perforation/diverticulitis or active infection • Avoid or interrupt use in patients with ALT ≥10x ULN, ANC < 500 cells/µL or ALC < 200 cells/µL [6]Dexamethasone • Dexamethasone 6 mg IV or PO once daily for 10 days is recommended, in conjunction with Remdesivir, for **patients experiencing hypoxemia.** • Data from the RECOVERY trial, an RCT published in the NEJM, indicated survival benefit for patients with severe or critical COVID-19; however, the RCT did not show benefit (and possibly harm) in patients **not** requiring oxygen supplementation. Pregnant Patients: • Safety of Remdesivir in pregnancy is unknown • Tocilizumab should be used only if the potential benefit justifies the potential risk for the mother and the fetus; limited data available in pregnancy • Baricitinib has not been evaluated in pregnancy or breastfeeding Hydroxychloroquine(HCQ)/Chloroquine • Has been removed from this protocol. The current body of literature does not support the routine use of HCQ. • Patients may not be discharged on HCQ for COVID-19 Ivermectin • At this time, the FDA has not approved ivermectin to prevent or treat COVID-19. At JHS, ivermectin is approved for Strongyloides prophylaxis in immunocompromised patients while receiving corticosteroids living in endemic areas such as Florida

[1]Some of these agents are being used off label and are not approved by the FDA for COVID-19.
[2]Remdesivir is not recommended in adults with an eGFR < 30 mL/min unless the potential benefits outweigh the risks. It should not be initiated in patients if baseline ALT ≥ 10 times the upper limit of normal or discontinued if this occurs while on therapy. For drug interactions, check the most up to date drug interactions at https://www.covid19-druginteractions.org/checker; Remdesivir 3-days study (PINE-TREE trial: https://www.nejm.org/doi/full/10.1056/NEJMoa2116846)
[3]Bebtelovimab and older COVID-19 monoclonal antibody products are no longer FDA approved under EUA, this includes Evusheld for pre-exposure prophylaxis
[4]Tocilizumab is under investigation as supportive therapy for potential cytokine storming in COVID-19 patients. **Current data is not definitive.** Dosing (1h infusion) < 30kg: 12mg/kg x1, 30-50kg 8mg/kg/dose x 1, 51-62 kg 400mg IV x1; 63-86kg 600mg IV x1; ≥87kg 800mg x1
[5]The standard dose of baricitinib in adults with eGFR ≥60 ml/min/1.73m^2 is 4mg by mouth daily for a duration of 14 days or until hospital discharge, whichever is first. Dosing adjustments are available for renal dysfunction and drug-drug interactions with strong OAT3 inhibitors (i.e. probenecid)
[6,7]Corticosteroids: The role of corticosteroids in coronavirus infections is controversial. There is suggested benefit as salvage therapy in patients with ARDS. However, steroids may also be associated with increased viral replication due to immunosuppression as well as several side effects, including increased risk of nosocomial infections. The newly published Surviving Sepsis COVID-19 guidelines, recommend using corticosteroids in ventilated adults with COVID-19 and ARDS, and in refractory shock. Dexamethasone 6mg PO once daily for up to 10 days showed a mortality benefit (21.6% vs. 24.6% p<0.001) when compared to usual care at day 28. Dexamethasone decreased mortality by 25% in patients requiring supplemental oxygen and decreased mortality by 35% in mechanically ventilated patients. (RECOVERY Trial DOI: https://doi.org/10.1101/2020.06.22.20137273).

Jackson HEALTH SYSTEM
Miracles made daily.

Jackson Health System
COVID-19 Treatment Information
February 3, 2023

ASP Phone numbers for Therapy Approval
Jackson Memorial: 786-586-0607
Holtz: 305-750-0716 (Pediatric ID)
Jackson North Medical Center: 305-654-5022; option 1; internal: 20-4022
Jackson South Medical Center: 305-256-5180

Table 2 Pediatric (confirmed or highly suspected) Treatment Guide (2.3.2023)

For any suspected cases at JHS, please contact JHS Infection Prevention (IP) at: 786-266-0624. **If treatment is warranted at Holtz, contact Pediatric ID 305-750-0716**

Children exposed to SARS-CoV-2 or with current COVID-19 may present with Multisystem Inflammatory Syndrome in Children associated with COVID-19 (MIS-C). Presentation commonly includes persistent fever and high inflammatory markers, and ranges from abdominal pain to a Kawasaki type picture to shock. If suspected, contact Pediatric ID.

Supportive care is the mainstay of therapy for COVID-19. This includes fluid resuscitation, oxygen supplementation, and antipyretics (acetaminophen preferred). **Prior to initiating SARS-CoV-2 targeted therapy, consider baseline functional status, goals of care, and DNR status.** Below are possible treatment options based on ongoing investigational trials, case reports, and *in vitro* data. **At this time, ASP does not recommend the routine use of empiric broad-spectrum antibiotics in patients diagnosed with COVID-19 (appendix 1).** Information is rapidly evolving and this protocol will be updated as more data becomes available**.**

Criteria	Off-label Treatment Options[1] (Drug interactions: http://www.covid19-druginteractions.org/)	Clinical Pearls for Treatment Options

Mild: any of the following without hypoxia
• Fever, malaise, cough, headache, sore throat, myalgia, nasal congestion, diarrhea
	[3]Monoclonal Antibody Treatment (outpatient encounters only)
	Regeneron, sotrovimab bamlanivimab-etesevimab, and bebtelovimab (as of 11/30/2022) are no longer approved by the FDA under EUA (Appendix 1).
	
	[2]Remdesivir
	5mg/kg/dose IV LD (max 200mg/dose) (day 1), then 2.5mg/kg/dose IV daily (max 100mg/dose) **x 2 days (3 days total)** is an option for symptomatic COVID-19 patients, whom **are not** hypoxic (SpO2 ≤ 94% on room air), meet high risk criteria (clinical pearls). Must have positive test within 5 days. These patients do not require dexamethasone
	
	Paxlovid (nirmatrelvir/ritonavir) – (outpatient encounters only)
	300 mg nirmatrelvir / 100 mg ritonavir PO twice daily x 5 days is recommended for mild-moderate symptomatic COVID-19 patients age ≥ 12 years and ≥ 40 kg whom are **not** hypoxic (SpO2 ≤ 94% on room air). It has important drug-drug interactions and dose is renally adjusted (Appendix 6).
	
	[3]**Pre-exposure** prophylaxis: Evusheld is **no** longer approved by the FDA; no agent for pre-exposure prophylaxis is currently approved by the FDA (Appendix 1).
		[2]Remdesivir
		• Veklury (Remdesivir) is FDA approved for treatment of COVID-19 for hospitalized patients
		• JHS criteria for use:
		  • Confirmed, active COVID-19 infection
		  • **SpO2 ≤ 94% on RA or PaO2/FiO2 < 300**
		  • If mechanically ventilated, may consider remdesivir **only within 24h of intubation**
		  • **ALTs < 10x ULN**
		  • No known hypersensitivity
		
		[4]Tocilizumab
		• Due to national shortage and difficulty in procuring tocilizumab, baricitinib is preferred when tocilizumab is unavailable.
		• CRP levels may be used to guide Tocilizumab therapy, (trend inflammatory markers daily)
		• All patients receiving Tocilizumab should be ruled out for latent TB per package insert, and screened for Hepatitis and Strongyloides
		• Use with caution in patients with history of GI perforation/diverticulitis or active infection
		• Do not use in patients with ALT ≥ 5x ULN, ANC <500 cells/µL and/or platelet count <50,000 cells/µL
		
		[5]Baricitinib
		• CRP levels may be used to guide Baricitinib therapy, current thresholds for treatment are based on clinical practice experience
		• VTE prophylaxis should be utilized while on Baricitinib
		• If patient experiences a thromboembolic event or is placed on therapeutic anticoagulation due to concern for a embolus, **baricitinib should be discontinued**
		• Baricitinib should be avoided in cases of active TB
		• Baricitinib requires dose adjustment for eGFR <60 and should be avoided in patients with eGFR ≤30

Moderate: **All** must be met in a non-intubated patient: • SpO2 < 93% on room air or requiring supplemental oxygen above baseline • Any symptom of mild disease • Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or bilateral consolidations • No additional signs or symptoms of severe COVID-19 (see below)	[2]Remdesivir 5mg/kg/dose IV LD (max 200mg/dose) (day 1), then 2.5mg/kg/dose IV daily (max 100mg/dose) x 4 days No longer restricted to ID/ASP; may be ordered be primary team [6]Dexamethasone 0.15mg/kg PO (max 6mg) q24h x 10 days [7]Consider shorter duration based on patient improvement (methylprednisolone 1mg/kg IV q24 or divided q12h or prednisone/prednisolone 1mg/kg/dose PO q24h (max 30mg daily) may be used if dexamethasone is not available *Per discussion with ASP and ID, consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset if patient is unvaccinated, vaccinated > 5 months ago with an mRNA vaccine, > 2 months ago with J&J, or immunocompromised (regardless of vaccination date)* Additional therapies to consider if patient rapidly decompensating: [4,5]Tocilizumab or Baricitinib; requires multidisciplinary discussion between ASP, ID, and critical care; see below, severe/critical	

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[3]Bebtelovimab and older COVID-19 monoclonal antibody products are no longer FDA approved under EUA, this includes Evusheld for pre-exposure prophylaxis

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[5]Baricitinib is an alternative in patients unable to receive tocilizumab, however tocilizumab remains the preferred option. The standard dose of baricitinib in pediatrics with eGFR ≥60 ml/min/1.73m^2 aged 2 to <9 years is 2mg by mouth daily for a duration of 14 days or until hospital discharge, whichever is first. Pediatric patients ≥9 years of age receive standard adult dosing of 4mg daily. Dosing adjustments are available for renal function and drug-drug interactions with strong OAT3 inhibitors (i.e. probenecid)

[6,7] Corticosteroids: The role of corticosteroids in coronavirus infections is controversial. There is suggested benefit as salvage therapy in patients with ARDS. However, steroids may also be associated with increased viral replication due to immunosuppression as well as several side effects, including increased risk of nosocomial infections. The newly published Surviving Sepsis COVID-19 guidelines, recommend using corticosteroids in ventilated adults with COVID-19 and ARDS, and in refractory shock. Dexamethasone 6mg PO once daily for up to 10 days showed a mortality benefit (21.6% vs. 24.6% p<0.001) when compared to usual care at day 28. Dexamethasone decreased mortality by 25% in patients requiring supplemental oxygen and decreased mortality by 35% in mechanically ventilated patients. (RECOVERY Trial DOI: https://doi.org/10.1101/2020.06.22.20137273).

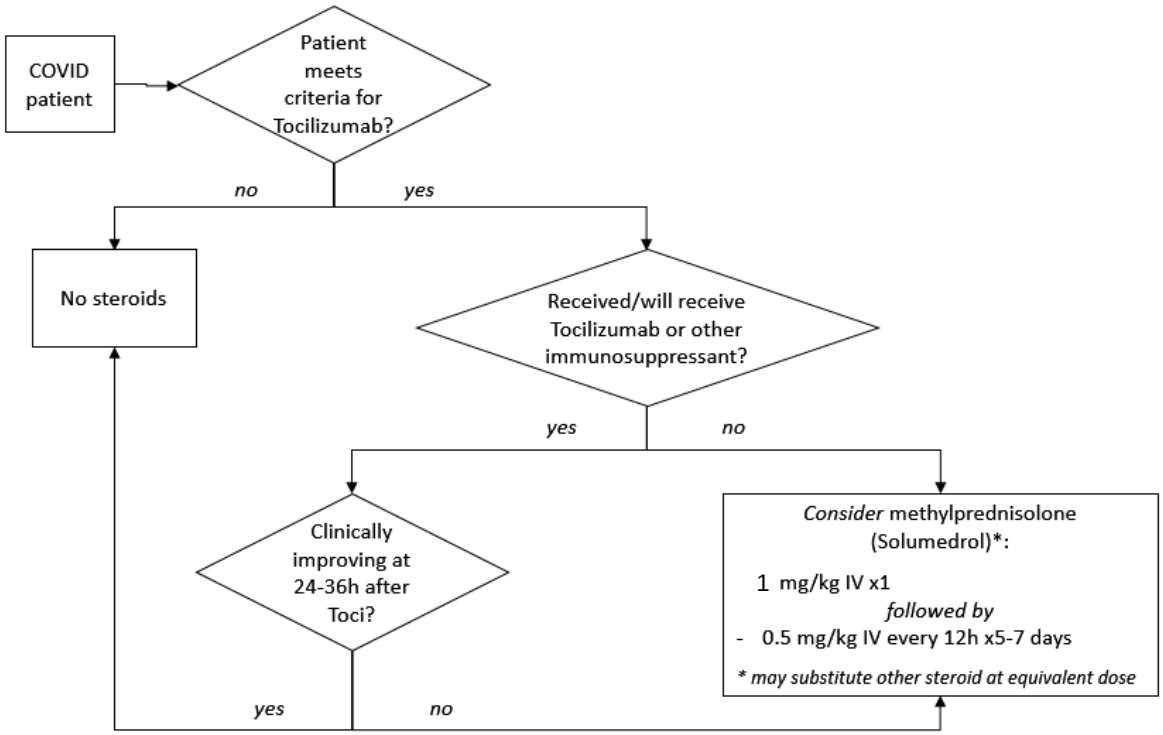
SOP for Use of Steroids in COVID-associated ARDS/Shock

Data do not support use of steroids for non-COVID ARDS and small studies of non-COVID viral illnesses (SARS, MERS, influenza) treated with steroids show mixed results – improvements in inflammatory markers, but delayed viral clearance, complications (e.g., psychosis, diabetes, femoral head avascular necrosis), and (in influenza) higher mortality. The degree of inflammation seen with COVID is substantial and it is plausible that steroids may be beneficial; however, no data exists to support this assertion.

The following general principles should be adhered to which weigh the risks and potential benefits of steroid use in COVID:

- Steroids should not be withheld from anyone on steroids chronically or in whom steroids are appropriate for another acute indication (e.g., COPD exacerbation)
- If steroids are to be used for COVID "cytokine storm" and ARDS, lower doses should be used
- The decision to initiate and/or discontinue steroids will be made by the primary team (e.g., ICU team for critically ill patients) after discussion with consultants

Algorithm for Use of Steroids for COVID "cytokine storm"



*Note: Patient may already be receiving dexamethasone per RECOVERY trial, therefore, additional steroids may be considered duplication of therapy. Please discuss with ICU teams.

Appendix 1: Treatments no longer recommended for COVID-19[1]

For more information please visit: [1]https://www.covid19treatmentguidelines.nih.gov/

1. **Casirivimab-imdevimab (Regeneron), Bamlanivimab-Etesevimab, Sotrovimab, and Bebtelovimab**
   - Currently, the prevalent COVID-19 variant across the United States is omicron, with 36.5% variant BA2.12.1 and 61.9% BA.2 (https://covid.cdc.gov/covid-data-tracker/#variant-proportions); this distribution holds true in the southeast US, including Florida. As of 12/1/22 – subvariants BQ.1 and BQ.1.1 comprise 57% of all subvariant populations nationally.
   - Sotrovimab is active against the Omicron BA.1 and BA.1.1 subvariants, **but it has substantially decreased in vitro activity against the Omicron BA.2**
   - The FDA has rescinded its authorization for three monoclonal treatments – Regeneron. Sotrovimab, and Eli Lilly's bamlanivimab-etesevimab – because they have been found "highly unlikely" to work against the current variants. As such, Jackson has immediately and completely halted the used of these treatments.
   - The FDA has also indicated it could quickly re-approve the withdrawn monoclonal treatments if they prove effective against future variants.
   - https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/
   - As of November 30th, 2022 the FDA announced bebtelovimab is no longer authorized under EUA in the US, as it is no longer expected to neutralize Omicron subvariants BQ.1 and BQ.1.1. Subvariant prevalence has surpassed 50% in all individual US regions but one, with trends towards increased prevalence. (https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-bebtelovimab-not-currently-authorized-any-us-region)

2. **Tixagevimab-cilgavimab (Evusheld)**
   - The prevalence of SARS-CoV-2 Omicron subvariants that are not susceptible to tixagevimab plus cilgavimab (Evusheld) has reached > 97% in the USA
     i. These subvariants are BA.2.75.2, BA.4.6, BA.5.2.6, BF.7, BF.11, BQ.1, BQ.1.1, XBB, and XBB.1.5.
   - Due to Evusheld's inactivity against these isolates, the FDA has rescinded its authorization for Evusheld in the United States as of January 26, 2023.
   - Currently, there is no authorized or approved agent for use as pre-exposure prophylaxis of COVID-19.
   - Please see the following guidance on the revised statement from the NIH: Revised Statement on Evusheld | COVID-19 Treatment Guidelines (nih.gov)

3. **Hydroxychloroquine with or without azithromycin**
   - Hydroxychloroquine (HCQ) recommendation has been removed from this protocol and use is discouraged due to the body of available literature suggesting a lack of benefit.
   - Patients may not be discharged on HCQ for COVID-19.
   - The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel recommends against the use of chloroquine or hydroxychloroquine with or without azithromycin for the treatment of COVID-19 in hospitalized patients (AI).[1]
   - Data from several randomized controlled trials demonstrate no benefit and both drugs have several adverse effects (i.e. QTc prolongation) and drug-drug interactions.[1]

4. **Ivermectin**
   - At this time, the FDA has not approved ivermectin to prevent or treat COVID-19.
   - At JHS, ivermectin is only approved for Strongyloides prophylaxis in immunocompromised patients while receiving corticosteroids.
   - Ivermectin has been shown to inhibit the replication of SARS-CoV-2 in cell cultures. However, pharmacokinetic and pharmacodynamic studies suggest that achieving the plasma concentrations necessary for the antiviral efficacy detected in vitro would require administration of doses up to 100-fold higher than those approved for use in humans.[1]
   - Current studies have had incomplete information and significant methodological limitations, which make it difficult to exclude bias.[1]

5. **Lopinavir/ritonavir and Other HIV Protease Inhibitors**
   - The COVID-19 Treatment Guidelines Panel recommends against the use of lopinavir/ritonavir and other HIV protease inhibitors for the treatment of COVID-19 in hospitalized patients (AI).[1]

- The pharmacodynamics of lopinavir/ritonavir raise concerns about whether it is possible to achieve drug concentrations that can inhibit the SARS-CoV-2 proteases.[1]
- In addition, lopinavir/ritonavir did not show efficacy in two large randomized controlled trials in hospitalized patients with COVID-19.[1]

6. **Community-acquired bacterial pneumonia (CABP) antibiotics**
   - In a recent study assessing the prevalence of co-infection at hospital admission amongst COVID-19 patients, only 1.2% (12/1016) has proven or probable CABP. Despite this, 69% of patients received CABP antibiotics. (https://doi:10.1093/ofid/ofaa578)
   - Another retrospective study looking at microbiologically proven CABP in COVID-19 patients found a bacterial co-infection rate of 2.2%. Despite this, 69% of patients received antibiotics. (https://doi.org/10.1093/cid/ciaa902)
   - At this time, we do not recommend CABP antibiotics for COVID-19 patients unless patient meets clinical and microbiologic criteria (urinary antigens, positive culture), or if otherwise recommended by ID. For sepsis or septic shock, empiric antimicrobials are still indicated.

Appendix 2: Anti-coagulation and COVID-19

Background

COVID-19 has been associated with inflammation and a prothrombotic state accompanied by increases in fibrinogen and D-dimer.[1,2] In some studies, elevations in these markers have been associated with worse clinical outcomes.[3,4] Hospitalized patients with COVID-19 are at high risk for venous thromboembolism (VTE).[5] **At a minimum, hospitalized COVID-19 patients should receive prophylactic doses of anticoagulants, such as low molecular weight heparin (LMWH) or unfractionated heparin, for the duration of their hospitalization.**

Recommendations

For Hospitalized, Nonpregnant Adults Who Require Low-Flow Oxygen and Are Not Receiving Intensive Care Unit Level of Care

• The Panel recommends using **therapeutic-dose heparin** for patients who have a D-dimer above the upper limit of normal (ULN), require low-flow oxygen, and have no increased bleeding risk **(CIIa)**. LMWH is preferred over unfractionated heparin.

• Based on clinical trial exclusion criteria, contraindications for therapeutic anticoagulation for COVID-19 due to an increased bleeding risk are as follows: platelet count <50 x 10^9/L, hemoglobin <8 g/dL, need for dual antiplatelet therapy, known bleeding within the last 30 days requiring an emergency room visit or hospitalization, known history of a bleeding disorder, or an inherited or active acquired bleeding disorder.

- In patients without a VTE who are started on therapeutic-dose heparin, treatment should continue for 14 days or until hospital discharge, whichever comes first.
- The Panel recommends using **prophylactic-dose heparin** (LMWH or unfractionated heparin) for patients who are not administered therapeutic heparin unless a contraindication exists **(AIIb)**.
- The Panel **recommends against** the use of **therapeutic-dose oral anticoagulants** for VTE prophylaxis or prevention of COVID-19 progression in hospitalized patients, except in a clinical trial **(AIIa)**.

For Hospitalized, Nonpregnant Adults Who Are Receiving Intensive Care Unit Level of Care (Including Patients Who Are Receiving High-Flow Oxygen)

- The Panel recommends using **prophylactic-dose heparin** as VTE prophylaxis unless a contraindication exists **(AI)**.
- The Panel **recommends against** the use of **intermediate-dose** (e.g., enoxaparin 1 mg/kg daily) and **therapeutic-dose anticoagulation** for VTE prophylaxis, except in a clinical trial **(BI)**.
- For patients who start on therapeutic-dose heparin while on low-flow oxygen due to COVID-19 and then transfer to the intensive care unit (ICU), the Panel recommends switching from therapeutic to **prophylactic-dose heparin** unless a VTE is confirmed **(BIII)**.

For Hospitalized Pregnant Adults

- The Panel recommends using **prophylactic-dose anticoagulation** for pregnant patients hospitalized for manifestations of COVID-19 unless otherwise contraindicated (see below) **(BIII)**.
- Because pregnant patients have not been included in most clinical trials evaluating therapeutic anticoagulation in the setting of COVID-19, there is currently insufficient evidence to recommend either for or against therapeutic anticoagulation for pregnant patients with COVID-19 in the absence of a known VTE.[2]

Appendix 3: Tocilizumab

1. May be considered on a case-by-case basis in patients with the following criteria. Due to national shortage and difficulty in procuring tocilizumab, baricitinib is preferred until tocilizumab becomes available. There are currently no head-to-head trials.
2. Hospitalized with COVID-19 pneumonia confirmed per WHO criteria (including a positive PCR of any specimen; e.g., respiratory, blood, urine, stool, other bodily fluid) and evidenced by chest X-ray or CT scan
3. PaO2/FiO2 < 300 mmHg or at least requiring 4L NC if ABG is not available or within 24h of mechanical ventilation
4. Requires multidisciplinary discussion with ASP, ID and critical care
5. All patients should be ruled out for latent TB, strongyloides, hepatitis B
6. Tocilizumab should be used with caution in patients with history of GI perforation/diverticulitis or active infection
7. Do not use in patients with ALT ≥ 5x ULN
8. Avoid use in patients with absolute neutrophil count <500 cells/µL; platelet count <50,000 cells/µL
9. Should be used alongside corticosteroids (i.e. dexamethasone) and other standard of care (i.e. Remdesivir)
10. FDA Fact Sheet must be provided to patient and/or caregiver, however, if providing this information will delay the administration of tocilizumab to a degree that would endanger the life of a patient, the information must be provided to the patient and/or caregiver when feasible post-infusion.
    - https://www.gene.com/download/pdf/actemra_eua_patient_fact_sheet.pdf (English version)
    - https://www.gene.com/download/pdf/actemra_eua_patient_fact_sheet_es.pdf pdf (Spanish version)

Appendix 4: Baricitinib

May be considered on a case-by-case basis in patients with the following criteria. Due to national shortage and difficulty in procuring tocilizumab, baricitinib is preferred until tocilizumab becomes available. There are currently no head-to-head trials.

1. Criteria for use:
   - A. Hospitalized (≥2 years old) with COVID-19 pneumonia confirmed per WHO criteria (including a positive PCR of any specimen; e.g., respiratory, blood, urine, stool, other bodily fluid) and evidenced by chest X-ray or CT scan
   - B. Not eligible to receive Tocilizumab or Tocilizumab is unavailable for use (i.e. drug shortage)
   - C. Clinical deterioration with at least 2 elevated inflammatory markers: CRP > 10 mg/dL, D-dimer > 1 mcg/mL FEU, Ferritin >1,000 ng/mL, LDH >500 units/L
   - D. Requiring high-flow nasal cannula or non-invasive mechanical ventilation or recently intubated within 24 hours
   - E. Should be used alongside corticosteroids (i.e. dexamethasone) and other standard of care (i.e. Remdesivir)
   - **F.** If patient experiences a thromboembolic event or is placed on therapeutic anticoagulation due to concern for a embolus, **baricitinib should be discontinued**
2. Requires multidisciplinary discussion with ASP, ID and the primary team
3. Dosing/Duration and Administration
   - A. Dosing

	Adult (Age ≥9 years)	Pediatric (2 to <9 years)
Standard dose	4 mg once daily	2 mg once daily
Renal impairment: eGFR 30 to <60 eGFR 15 to <30 eGFR <15	 2 mg once daily 1 mg once daily Not recommended	 1 mg once daily Not recommended Not recommended
Strong OAT3 inhibitor (ie. probenecid)	Reduce dose by 50% If initial recommended dose is 1mg discontinue probenecid	
Hepatic impairment	Interrupt until diagnosis of drug-induced liver injury is excluded If ALT >10x ULN, discontinue	
ANC <500 or ALC <200	Interrupt until ANC ≥500 and ALC ≥200	

     - Duration of treatment is 14 days or until hospital discharge, whichever is first
   - B. Administration
     - Oral, orogastric or nasogastric access is required for use
     - Baricitinib tablets may be crushed and dispersed in water for patients who are unable to swallow
4. Additional considerations:
   - A. Do not administer concurrently with tocilizumab or in patients who received tocilizumab recently
   - B. All patients should be ruled out for latent TB, strongyloides, hepatitis B
   - C. All patients should be on appropriate VTE prophylaxis if not contraindicated
   - D. Use caution in patients with history of GI perforation, history of diverticulitis, or active infection
   - E. Please inform ASP if any of the following criteria are present:
     - Active VTE or Recent VTE within the past 3 months or recurrent VTEs (>1 episode)
     - Active malignancy
     - ALT ≥ 10x ULN
     - Absolute neutrophil count (ANC) <500 cells/µL or Absolute lymphocyte count (ALC) <200 cells/µL
     - eGFR <15 mL/min/1.73m^2 or dialysis
   - F. FDA Fact Sheet must be provided and patient or caregiver must be in agreement with treatment and provided with informed consent
     - http://pi.lilly.com/eua/baricitinib-eua-factsheet-patient.pdf (English version)
     - http://pi.lilly.com/eua/span/baricitinib-eua-factsheet-patient-span.pdf (Spanish version)

Appendix 5: Management of Special Populations; Solid Organ Transplant Recipients

Table 1: Suggested treatment/use of investigational agents

Severity of disease	Suggested Management
Mild	• Supportive Care • Every 4 hours Oxygen monitoring • Every other day inflammatory markers • Decrease Immunosuppression as in Table 2 • Remdesivir 200 mg IV LD x 1, then 100 mg IV daily x 3 days

Moderate	• Consider one or a combination of these if indicated
	  ○ Remdesivir 200 mg IV LD x 1, then 100 mg IV daily x 5 days plus dexamethasone 6 mg IV/PO daily x 10 days
	  ○ Convalescent Plasma
	  ○ Tocilizumab x 1 or Baricitinib x 14 days (If criteria in Appendix 3-4 met and approved by multidisciplinary team)
	  ○ Total plasma exchange
	And
	• Every 4 hours Oxygen monitoring
	• Every other day inflammatory markers
	• Decrease Immunosuppression as in Table 2

Severe	• First: Remdesivir 200 mg IV LD x 1, then 100 mg IV daily x 5 days plus dexamethasone 6 mg IV/PO daily x 10 days
	• Consider one or a combination of these if indicated
	  ○ Convalescent Plasma
	  ○ Tocilizumab x 1 or Baricitinib x 14 days (If criteria in Appendix 3-4 met and approved by multidisciplinary team)
	  ○ Total plasma exchange
	  ○ Methylprednisolone per protocol (page 5)
	  ○ Mesenchymal stem cells as part of clinical trial
	And
	• Daily inflammatory markers
	• Decrease Immunosuppression as in Table 2

Critical
ARDS + MOD
	• ARDS Management
	• Consider one or a combination of these if indicated
	  ○ Methylprednisolone per protocol (page 5)
	  ○ Total Plasma exchange
	  ○ Mesenchymal stem cells as part of clinical trial

	• Treat coinfections if any • Daily inflammatory markers • Decrease Immunosuppression as in Table 2

Table 2: Management of Immunosuppression

The strategy of decreasing immunosuppression during active viral infection has been suggested by expert opinion and limited published data.
This will be guided by the transplant, infectious disease and critical care team. The extent of immunosuppression reduction should be based on disease severity and risk of graft rejection.

Management of immunosuppression in confirm COVID-19 positive patient	
Liver/ Multi-visceral transplant	Mild disease
	• Decrease Mycophenolate mofetil dose by 50% • Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions.
	Moderate disease
	• Hold Mycophenolate mofetil • Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions.
	Severe disease
	• Hold Mycophenolate mofetil • Decrease Tacrolimus/Everolimus dose by 50%. Closely monitor drug interactions. • Consider Methyprednisolone as part of ARDS management if indicated by critical care team.
Kidney/Pancreas transplant	Mild disease
	• Decrease Mycophenolate mofetil dose by 50% • Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions. • If a patient is on Belatacept at the time of diagnosis, hold subsequent dose. Will be assessed on a case by case basis in discussion with transplant nephrologist. • Continue Prednisone
	Moderate disease
	• Hold Mycophenolate mofetil • Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions. • If a patient is on Belatacept at the time of diagnosis, hold subsequent dose. Will be assessed on a case by case basis in discussion with transplant nephrologist. • Continue Prednisone
	Severe disease
	• Hold Mycophenolate mofetil • Decrease Tacrolimus dose by 50%. Closely monitor drug interactions. • Consider Methyprednisolone as part of ARDS management if indicated by critical care team.
Heart transplant	Mild disease
	• Decrease Mycophenolate mofetil dose by 50% • Continue Tacrolimus with same target trough concentrations. Closely monitor drug interactions.

	• Continue Prednisone
	Moderate Disease
	• Hold Mycophenolate mofetil • Continue Tacrolimus with same target trough concentrations. Closely monitor drug interactions. • Continue Prednisone
	Severe disease
	• Hold Mycophenolate mofetil • Continue Tacrolimus with same target trough concentrations. Closely monitor drug interactions. • Consider Methyprednisolone as part of ARDS management if indicated by critical care team.
Lung transplant	Mild disease
	• Decrease Mycophenolate mofetil by 50% • Continue Tacrolimus/Sirolimus with same target trough concentrations. Closely monitor drug interactions. • Continue Prednisone
	Moderate Disease
	• Hold Mycophenolate mofetil • Continue Tacrolimus/Sirolimus with same target trough concentrations. Closely monitor drug interactions. • Continue Prednisone
	Severe disease
	• Hold Mycophenolate mofetil • Continue Tacrolimus with same target trough concentrations. Closely monitor drug interactions. • Consider Methyprednisolone as part of ARDS management if indicated by critical care team.

Note:

- Continue prophylaxis (Valcyte, Bactrim/Atovaquone, Ivermectin) per protocol
- Monitor for drug-drug interactions closely

References:

1. **National Institute of Health (NIH) COVID 19 Treatment Guidelines** (https://www.covid19treatmentguidelines.nih.gov/introduction/)
2. **Infectious Diseases Society of America Guidelines on the treatment and management of patients with COVID-19** (https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/
3. **Society of Critical Care Medicine (SCCM): Surviving Sepsis Campaign: Guidelines on the management of critically ill adults with COVID-19** (https://link.springer.com/article/10.1007/s00134-020-06022-5)
4. **Massachusetts General Hospital COVID 19 Treatment Guidelines** (https://www.massgeneral.org/assets/MGH/pdf/news/coronavirus/mass-general-COVID-19-treatment-guidance.pdf)
5. **COVID-19 Treatment Algorithm Yale School of Medicine** (https://medicine.yale.edu/news-article/23611/)
6. **University of Michigan, inpatient Guidance for treatment of COVID-19** (http://www.med.umich.edu/asp/pdf/adult_guidelines/COVID-19-treatment.pdf)

Appendix 6: Paxlovid™ (nirmatrelvir/ritonavir)

Created by: JHS Antimicrobial Stewardship Team
Last revised: 12/22/2022

Paxlovid™ (nirmatrelvir-ritonavir)

- Recommended for the treatment of mild-moderate COVID-19 in patients ≥ 12 years of age and ≥ 40 kg; restricted to ASP/ID at JMH and Pediatric ID at Holtz
- At JHS, Paxlovid is **NOT** recommended for:
  - Asymptomatic patients
  - Hypoxic patients (requiring oxygen or maintaining oxygen saturation < 94% on room air)
  - Solid organ transplant recipients
  - Pre-exposure or post-exposure prophylaxis for COVID-19
  - If contraindications exist (see below)
- **Alternative regimen for patients who cannot receive Paxlovid: Intravenous Remdesivir x 3 days**
- Dosing:

	Dose	Frequency	Duration
	Renal function		
eGFR ≥ 60	300mg nirmatrelvir (2 tablets) + 100mg ritonavir (1 tablet)	BID	5 days
eGFR ≥ 30 to <60	150mg nirmatrelvir (1 tablet) + 100mg ritonavir (1 tablet)	BID	5 days
eGFR <30	Not recommended	N/A	N/A
	Liver function		
Severe hepatic impairment (Child Pugh Class C)	Not recommended	N/A	N/A

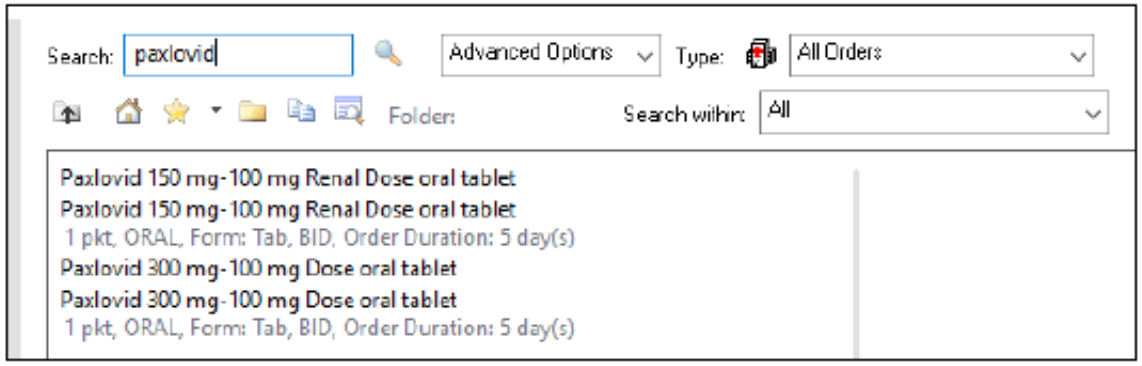
❖ Monitoring & Contraindications:

Drug Class	Example Agents	Management
Anti-arrhythmics	Amiodarone	**Contraindicated.**
Anti-cancer agents	various	Refer to individual product label for anti-cancer drug
Anti-coagulants	Warfarin	**Avoid use.**
	Rivaroxaban	**Contraindicated.**
Anti-convulsants	Carbamazepine, Phenytoin	**Contraindicated.**
Antifungals	Voriconazole	**Contraindicated.**
HIV-Protease Inhibitors	Darunavir, Ritonavir	Refer to individual protease inhibitor labeling; patients on ritonavir- or cobicistat-containing regimens should continue treatment as indicated
Antimycobacterials	Rifampin	**Contraindicated**. Consider rifabutin
Cardiac glycoside	Digoxin	**Avoid use.**
Hepatitis C antivirals	various	Refer to individual product label; Mavyret is **contraindicated**
Statins	Lovastatin, Simvastatin	**Contraindicated**
	Atorvastatin, Rosuvastatin	Consider temporary discontinuation
Transplant Immunosuppressants	Tacrolimus, Sirolimus	**Avoid use.**

For a comprehensive list of drug-drug interactions by agent, please refer to section 7 under the EUA Fact Sheet for Healthcare Providers at https://www.fda.gov/media/155050/download

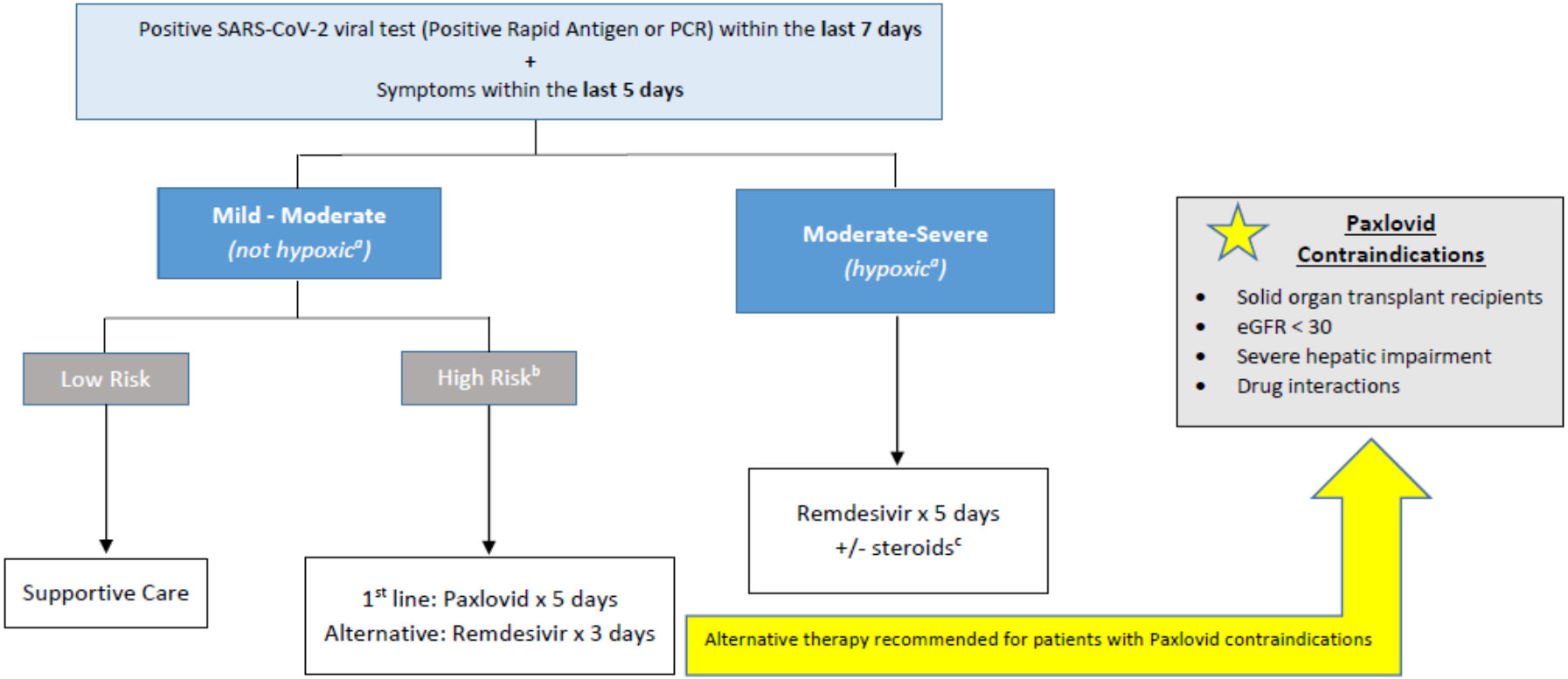
Ordering Process:

❖ Providers are able to place orders for Paxlovid in Cerner via CPOE



Created by: JHS Antimicrobial Stewardship Team
Last revised: 12/22/2022

Treatment of Acute COVID Infection



[a]Hypoxic = satting < 94% oxygenation on room air or requiring oxygen supplementation
[b]**High risk if any of the following are present:** BMI ≥ 30 (adults) or ≥ 85th percentile for age & gender based on CDC growth charts (pediatrics, 12-17 years old), pregnancy, immunosuppressive disease or receiving immunosuppressive therapy, chronic kidney disease, diabetes, underlying chronic respiratory disease (e.g., COPD, asthma), sickle cell disease, congenital/ acquired heart disease, neurodevelopmental disorders (i.e. cerebral palsy), a medical-related technological dependence (i.e. tracheostomy not related to COVID-19), ≥ 55 years of age: hypertension, cardiovascular disease, or any of the risk factors above for ≥ 12 years of age
[c]Dexamethasone 6 mg PO or IV daily x 10 days is indicated for patients requiring supplemental oxygen (e.g., nasal cannula, BIPAP, intubation) based on the RECOVERY Trial

Jackson HEALTH SYSTEM

PHARMACY FLASH

JHS PHARMACY & THERAPEUTICS COMMITTEE

March 8th, 2022

Paxlovid™ (nirmatrelvir-ritonavir) for Treatment of COVID-19

- Paxlovid has recently received FDA emergency use authorization for treatment of patients ≥12 years of age and ≥40kg with COVID-19
  - **JHS Recommendation: Alternative to monoclonal antibody treatment in patients without severe renal/liver impairment or significant drug-drug interactions**
  - **Currently available only at JMH retail pharmacy**

- Paxlovid is **NOT** authorized for:
  - Initiation of treatment in patients requiring hospitalization for COVID-19
  - Use as pre-exposure or post-exposure prophylaxis for COVID-19
  - Use for longer than **5 consecutive days**

- Product information, dosing, duration and administration:
  - Packaging: Each product contains 5 blister cards containing a morning and an evening dose
  - May be taken with or without food

Dosing	
Standard dose	300mg nirmatrelvir + 100mg ritonavir PO twice daily
Renal impairment eGFR 30 to <60 eGFR <30	150mg nirmatrelvir + 100mg ritonavir PO twice daily **Not recommended**
Severe hepatic impairment (Child Pugh Class C)	**Not recommended**

- Drug-drug interactions:

Drug Class	**Example Agents**	**Management**
Anti-arrhythmics	Amiodarone	**Contraindicated**
Anti-cancer agents	various	Refer to individual product label for anti-cancer drug
Anti-coagulants	Warfarin	Monitor INR closely
	Rivaroxaban	**Contraindicated**
Anti-convulsants	Carbamazepine, Phenytoin	**Contraindicated**
Anti-fungals	Voriconazole	**Contraindicated**
HIV-Protease Inhibitors	Darunavir, Ritonavir	Refer to individual protease inhibitor labeling; patients on ritonavir- or cobicistat-containing regimens should continue treatment as indicated
Antimycobacterial	Rifampin	**Contraindicated**. Consider rifabutin
Cardiac glycoside	Digoxin	Monitor serum digoxin levels closely
Hepatitis C antivirals	various	Refer to individual product label; Mavyret is **contraindicated**
Statins	Lovastatin, Simvastatin	**Contraindicated**
	Atorvastatin, Rosuvastatin	Consider temporary discontinuation
Transplant Immunosuppressants	Tacrolimus	For management of Paxlovid with transplant immunosuppressants, please refer to the JHS Antimicrobial Stewardship App > COVID-19 Management > JHS Paxlovid Resources

For a comprehensive list of drug-drug interactions by agent, please refer to section 7 under the EUA Fact Sheet for Healthcare Providers at https://www.fda.gov/media/155050/download

For more information please refer to: JHS Antimicrobial Stewardship App > COVID-19 Management > JHS Paxlovid Resources

UM/JMH OUTPATIENT COVID-19 PROTOCOL

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Introduction

Current evidence estimates that approximately 80% of persons infected with SARS-CoV-2 (the virus responsible for COVID-19 illness) will have mild to moderate symptoms (defined as absence of hypoxia and no or mild pneumonia symptoms) that do not require hospitalization, while 20% of patients will go on to develop severe symptoms that require a higher level of care. This provides an opportunity to create a comprehensive outpatient program that works to prevent COVID-19 illness with vaccination efforts as well as safely monitor and treat acute infections at home. This effort can help to offload the burden to our emergency rooms and hospitals, while also promptly identifying patients who are decompensating. We aim to provide a framework for outpatient providers to effectively triage, support and advise non-hospitalized COVID-19 patients as they manage their illness at home as well as prevent COVID-19 illness by providing current information about COVID-19 vaccines.

Vaccination Guidance

Please see updated vaccination guidance at this link
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Introduction

To date, there are three COVID-19 vaccines that have received emergency use authorization in the United States to prevent SARS-CoV-2 infection that causes COVID-19 illness: Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines. As of February 28, 2021, two additional COVID-19 vaccines were being studied in phase 3 clinical trials: AstraZeneca and Novavax COVID-19 vaccines[1].

Pzifer-BioNTech and Moderna COVID-19 vaccines

Both vaccines are messenger RNA (mRNA) vaccines. To learn more about how mRNA vaccines work, please see: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html. Both vaccines are a 2-dose series of intramuscular injection. The Pfizer-BioNTech schedule is separated by 21 days and is currently approved for patients 16 years of age and older[2]. The Moderna schedule is separated by 28 days and is currently approved for patients 18 years of age and older[3].

Janssen COVID-19 Vaccine by Johnson and Johnson

On February 27, 2021, the U.S. Food and Drug Administration issued emergency use authorization for the Janssen COVID-19 vaccine by Johnson and Johnson. As of February 28, 2021, the CDC had yet to update their guidance in regards to COVID-19 vaccinations to include information about the Janssen COVID-19 vaccine[4].

There are currently no guidelines indicating that specific populations should get a specific vaccine. We recommend that all patients should get the vaccine that is offered and available to them, with no preference towards one vaccine over the other.

For more information and frequently asked questions regarding COVID-19 Vaccines visit: https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines-information--faq/.

To learn about the University of Miami's COVID-19 Vaccine Plans and Frequently Asked Questions visit: https://umiamihealth.org/coronavirus/covid-19-vaccine.

To learn about Jackson Health System's COVID-19 Vaccine Appointments visit: https://jacksonhealth.org/keeping-you-safe/ and Frequently Asked Questions visit: https://storage.googleapis.com/jackson-library/notices/COVID-19-Vaccine-FAQ.pdf.

To learn about Florida's COVID-19 Vaccine Plans visit: https://floridahealthcovid19.gov/covid-19-vaccines-in-florida/.

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Pfizer and Moderna Vaccines

The following information relates to the two mRNA COVID-19 vaccines as provided by the Centers for Disease Control and Prevention (CDC)[6].

Clinical Considerations

Anticipatory Guidance

Patients should be counseled on the importance of completing the two-dose vaccination series if getting the Pfizer or Moderna vaccines, as there is currently limited data available about the efficacy of a single dose.

Patients should be informed about post-vaccination symptoms. Approximately 80-89% of vaccinated persons develop at least one local symptom and 55-83% develop at least one systemic symptom. These include:

- Local
    - Pain
    - Swelling
    - Erythema at the injection site
    - Localized axillary lymphadenopathy on the same side as the vaccinated arm
- Systemic
    - Fever
    - Fatigue
    - Headache
    - Chills
    - Chills
    - Myalgia
    - Arthralgia

Patients should be advised that post-vaccination symptoms not listed above, including respiratory symptoms, are not common. Clinicians should consider other causes of these uncommon symptoms including COVID-19 illness in the post-vaccination period. Most post-vaccination symptoms occur within the first three days of vaccination, are mild to moderate in severity, resolve within 1-3 days of onset, and are more frequent and severe following the second dose and among younger persons compared to older persons. Unless a patient develops a contraindication to vaccination (see below), patients should be advised to complete the series even if they experience local or systemic symptoms following the first dose[6].

The Centers for Disease Control and Prevention (CDC) **does not recommend** the routine use of antipyretic or analgesic medications (i.e. acetaminophen, non-steroidal anti-inflammatory drugs) for the purpose of preventing post-vaccination symptoms due to a lack of information on the impact on mRNA COVID-19 vaccine-induced antibody response. However, if medically appropriate, antipyretic or analgesic medications may be taken for the treatment of post-vaccination symptoms[6].

Administration

	CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
ALLERGIES	History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines*: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)# • Immediate allergic reaction of any severity to polysorbate^#	Among persons without a contraindication, a history of: • Any immediate allergic reaction‡ to other vaccines or injectable therapies*	Among persons without a contraindication or precaution, a history of: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
ACTIONS	• Do not vaccinate# • Consider referral to allergist-immunologist	• Risk assessment • 30-minute observation period if vaccinated • Consider deferral of vaccination for further risk assessment and possible referral to allergist-immunologist	• 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) • 15-minute observation period: All other persons

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

* Neither vaccine contain eggs, gelatin, latex, or preservatives

For latest (Jan 7th, 2022) Interim Recommendations for COVID vaccines, please see the information at the link below
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Patients with current or prior history of COVID-19 illness
Patients with a history of prior asymptomatic SARS-CoV-2 infection or symptomatic COVID-19 illness can safely receive COVID-19 vaccines. Testing for acute SARS-CoV-2 infection or prior infection with SARS-CoV-2 antibodies prior to COVID-19 vaccination is **NOT** recommended[6].

Patients with symptomatic COVID-19 illness should not receive vaccination until they have recovered from the acute illness and have met CDC criteria to safely discontinue isolation (see isolation section of guide). This recommendation is for *all patients regardless of vaccination status* (i.e. for patients who have received the first COVID-19 vaccine and patients who have yet to receive the COVID-19 vaccine)[6].

Latest data suggests the risk of SARS-CoV-2 reinfection is low in the months following initial infection. Patients with recent documented SARS-CoV-2 infection may delay vaccination if desired with the understanding that risk of reinfection increases and the immunity provided by primary infection decreases with time[6].

Receipt of the mRNA COVID-19 vaccine should not affect treatment decisions (including the use monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments should a patient develop acute COVID-19 illness[6].

Patients who received passive antibody therapy for COVID-19 illness
There is no data regarding the safety and efficacy of mRNA COVID-19 vaccines in patients who received monoclonal antibodies or convalescent plasma as part of the treatment for COVID-19 illness. It is currently recommended that vaccination be deferred for *at least 90 days* in patients that have received passive antibody therapy for COVID-19 illness to avoid potential interference of antibody therapy with vaccine-induced immune responses. This recommendation applies to all patients regardless of vaccination status (i.e. patients who have received the first COVID-19 vaccine and patients who have yet to receive the COVID-19 vaccine)[6].

Vaccine Reactions and Adverse Events

An immediate allergic reaction to vaccination is defined by the CDC as any hypersensitivity-related signs or symptoms such as urticarial, angioedema, respiratory distress (i.e. wheezing or stridor), or anaphylaxis that occur within four hours following administration.

Post-vaccination anaphylaxis was not observed in the Pfizer-BioNTech and Moderna COVID-19 vaccine clinical trials. However, rare anaphylactic reactions following vaccination have been reported following receipt of these mRNA COVID-19 vaccines outside of clinical trials. In a study of over 50,000 healthcare employees who received either the Pfzier-BioNTech or Moderna mRNA vaccines, less than 2% of all vaccinated people had an acute allergic reaction. The rate of anaphylaxis which usually occurs within 17 minutes post vaccination was less than 0.0005% (2.47 per 10,000 vaccinations)[7]. **Thus far, the mRNA COVID-19 vaccines continue to be safe with very low rates of allergic reactions.**

The CDC considers the following to be a contraindication to receiving either the Pfizer-BioNTech or Moderna COVID-19 vaccines:

- Severe allergic reaction (i.e. anaphylaxis) after a prior dose of an mRNA COVID-19 vaccine or any of its components (see table above for a list of components)
- Immediate allergic reaction of any severity to a prior dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

*These patients should not receive Pfizer-BioNTech or Moderna vaccines unless they have been evaluated by an allergist-immunologist and it is determined that they can safely receive the mRNA COVID-19 vaccines.

A history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e. intramuscular, intravenous, or subcutaneous vaccines or other therapies not related to components of the mRNA COVID-19 vaccines) is a precaution but not a contraindication to Pfizer-BioNTech or Moderna vaccination. Per the CDC, these patients should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

Allergic reactions (including severe allergic reactions) not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates, such as food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications) are **NOT** a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. There is **NO** contraindication or precaution to vaccination for patients with allergies to latex, eggs, gelatin, or other food products[6].

The University of Miami and Jackson Memorial Hospital are partnering with the National Institute of Health to conduct a trial for allergic patients. For any questions related to vaccination and history of allergies, Dr. Gary Kleiner is available for questions or seeing patients in the University of Miami and Jackson Memorial Hospital clinics.

<u>Patients with coagulopathies or on anticoagulants</u>

A patient with a coagulopathy or on anticoagulation can receive the COVID-19 vaccine but may need to take extra precautions, as with any intramuscular (IM) injection. If they have been able

to tolerate IM injections without incident in the past, no further guidance is necessary. If they have had serious intramuscular bleeding from a prior vaccine, the risks and benefits of vaccine administration should be reviewed. The Advisory Committee on Immunization Practices (ACIP) recommends using a fine-gauge needle (23 gauge or smaller caliber), followed by firm pressure on the site, without rubbing, for at least two minutes in order to minimize risk[8].

In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Patients with a history of Guillain-Barré syndrome

To date, no participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials developed Guillain-Barré syndrome (GBS) following vaccination. Patients with a history of GBS may receive the mRNA COVID-19 vaccine unless they have a contraindication to vaccination. If GBS occurs following mRNA COVID-19 vaccination, a report should be filed with the Vaccine Adverse Event Reporting System (VAERS) (see below)[6].

Patients with a history of Bell's palsy

In both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials, cases of Bell's palsy were reported post-vaccination. However, the U.S. Food and Drug Administration does not consider these cases to be above the frequency expected in the general population and has not concluded that the cases were related to vaccination. Patients with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any post-vaccination cases of Bell's palsy should be reported to the VAERS (see below)[6].

Dermal Fillers

Patients who receive dermal fillers should be advised that swelling at or near the site of filler injection (usually face or lips) has infrequently occurred following administration of an mRNA COVID-19 vaccine. This reaction appears to be temporary and can resolve with medical treatment including corticosteroid therapy. Patients should be advised to contact their healthcare provider if they develop post-vaccination swelling at or near the site of dermal filler. Receiving dermal fillers is not a contraindication to COVID-19 vaccination[6].

Observation following vaccination

Patients with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy or a history of anaphylaxis from any case should be observed for 30 minutes following vaccination. All other patients should be observed for 15 minutes[9].

Anaphylaxis after COVID-19 vaccination

Per CDC guidelines, each COVID-19 vaccination location should have at least 3 doses of epinephrine on hand at any given time to manage post-vaccination anaphylaxis. Additionally, vaccination locations should have antihistamines, a blood pressure cuff, stethoscope, and a timing device to assess pulse[9].

Patients who experience post-vaccination anaphylaxis should be advised not to receive additional doses. These patients should be referred to an allergist-immunologist for work-up and additional counseling[9].

Reporting post-vaccination adverse events

Any adverse event following COVID-19 vaccination, including anaphylaxis, should be reported to the Vaccine Adverse Event Reporting System (VAERS). Information on how to submit a report to VAERS is available at: https://vaers.hhs.gov or by calling 1-800-822-7967.

The CDC has developed v-safe, a voluntary, smartphone-based tool that provides patients with health check-ins after COVID-19 vaccination. Information on v-safe is available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

Special Populations

Patients with immunocompromising conditions

Patients with immunocompromising conditions or who take immunosuppressive medications or therapies should be offered the mRNA COVID-19 vaccines as long as they have no absolute contraindications to vaccination. These patients should be counseled about the limited data regarding mRNA COVID-19 vaccine safety and efficacy in immunocompromised populations and the possible reduced immune responses. Patients who are awaiting or have received a bone marrow transplant should discuss the benefits and risks of the COVID-19 vaccine with their hematologist or oncologist prior to vaccination. All patients should be instructed to continue following the CDC's current guidance to protect against COVID-19 illness[6].

It is not currently recommended to re-vaccinate patients who regain immune competence who previously received mRNA COVID-19 vaccines[6].

Patients receiving non-COVID-19 antibody therapies

The receipt of an antibody-containing product for non-COVID-19 treatment (i.e. intravenous immunoglobulin, RhoGAM, etc.) is unlikely to substantially impact mRNA COVID-19 vaccine induced immune responses. The CDC does not recommend any minimum interval between antibody therapies not specific to COVID-19 treatment and mRNA COVID-19 vaccination[6].

Patients with autoimmune conditions

Patients with autoimmune conditions who have no absolute contraindications to vaccination may receive the mRNA COVID-19 vaccines. These patients should be advised that there is currently limited data about the safety and efficacy of mRNA COVID-19 vaccines in patients with autoimmune conditions[6].

Pregnancy

Observation data has shown pregnant patients with SARS-CoV-2 infection causing COVID-19 illness are at increased risk of severe COVID-19 illness including intensive care admission,

mechanical ventilation, or death as well as increased risk of adverse pregnancy outcomes such as preterm birth[6].

Both the CDC and the American College of Obstetricians and Gynecologists (ACOG) support the decision of pregnant women to receive the COVID-19 vaccines. Pregnant patients considering COVID-19 vaccination should be provided available information to make an informed decision about vaccination. The mRNA COVID-19 vaccines are not live virus vaccines. They do not enter the nucleus and do not alter human DNA to cause genetic changes. Presently experts believe the mRNA COVID-19 vaccines are unlikely to be harmful to the pregnant patient or fetus. The potential risks of mRNA COVID-19 vaccines have not been studied in pregnant patients to date. However, studies in pregnant patients are planned for the future and vaccine manufacturers are currently following outcomes in patients in clinical trials who became pregnant. The risks and benefits of receiving the COVID-19 vaccine can be discussed with each patient but pregnant patients are not required to have a conversation with a healthcare provider prior to vaccination[6,10].

Pregnant patients should be counseled like all patients about the expected side effects of COVID-19 vaccination. Side effects are similar to those expected among non-pregnant patients (see vaccine reaction section above)[6,10].

Pregnant patients should be supported regardless of their decision to receive or decline COVID-19 vaccination[6,10].

Pregnancy testing prior to COVID-19 vaccination is not recommended. There is no evidence to suggest patients who receive the mRNA COVID-19 vaccines need to avoid pregnancy after vaccination[6,10].

Breastfeeding patients

The CDC and ACOG recommend COVID-19 vaccines be offered to lactating patients. These patients should be advised that there is currently no data on the safety of mRNA COVID-19 vaccines or their effects on the breastfed infant or milk production/excretion[6,10].

Janssen Vaccine

In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for primary and booster vaccination.
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

The Janssen vaccine is a single dose, intramuscular injection that uses a recombinant, replication-incompetent adenovirus vector that expresses the SARS-CoV-2 spike antigen. It has been studied and received emergency use authorization (EUA) by the FDA for individuals 18 years and older. The clinical trial showed excellent protection against severe/critical COVID-19 disease, which was 76.7% and 85.4% effective at 14 days and 28 days post-vaccination, respectively. It was about 66% effective of preventing moderate to severe/critical illness. It is

notable that among all COVID-19 positive cases with onset 14 days post vaccination, there were only 2 COVID-related hospitalizations and none at 28 days. There were also no COVID-related deaths reported in the vaccine recipient group[5]. The efficacy of the vaccine varied across world regions, but remained high. This suggests that the Janssen vaccine may provide protection against severe illness from variant strains, but further research is needed.
This slide deck from the ACIP provides a summary of evidence for the efficacy and adverse events of the Janssen vaccine: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/04-COVID-Oliver.pdf

Vaccine Reactions and Adverse Events
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

As per the EUA, the most common side effects were local injection site pain, headache, fatigue, myalgias, nausea, and fever. Overall, side effects were more prevalent in younger populations (18-59 years old) than older (60 years or older). There were a few numerical imbalances of adverse events, where there were more events in the vaccine group than the placebo group; however, a causal relationship with the vaccine cannot be determined. These events include thromboembolic events (DVT, PE and transverse sinus thrombosis), seizures and tinnitus[5].

Special Populations
As with the mRNA vaccines, this vaccine was not studied in children, pregnant or lactating patients. As of now, children under 18 years old are not included in the EUA and are no permitted to get the vaccine. The EUA does allow pregnant and lactating patients to get the vaccine if they wish. We recommend using the same risk vs benefit discussion as outlined for the Pfizer/Moderna vaccines[5].

The CDC and ACIP has not yet released their full guidance on this vaccine at the time of writing. Please refer to their websites periodically to see if further guidance or updates have been published regarding the Janssen vaccine. We will update this guide as soon as more information is released.
Please check this link for any updated guidance by the CDC:
https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm

Post-vaccination Guidance

Antibody testing post vaccination
The CDC does **not recommend** using antibody testing to assess for immunity to COVID-19 following mRNA COVID-19 vaccination[6].

SARS-CoV-2 testing post vaccination
SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests) will not be affected by the receipt of mRNA COVID-19 vaccines[6].

Immunity

Data is currently being collected about the lasting impact of COVID-19 vaccine-induced immunity. At this time, the study of how long vaccine induced immunity lasts and the need for boosters is uncertain but being actively studied[6].

Quarantine Guidance

All vaccinated persons should be advised to continue to follow all guidance to protect themselves and other including wearing a mask, staying at least 6 feet away from others, avoiding crowds, washing hands often, and following any applicable workplace or school guidance, including guidance related to personal protective equipment use or SARS-CoV-2 testing. **However, vaccinated persons who are exposed to someone suspected or confirmed to have COVID-19 do not need to quarantine if they meet all of the following criteria**[6]:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine)
- Are within 3 months following receipt of the last dose in the series
- Have remained asymptomatic since the current COVID-19 exposure

SARS-CoV-2 Virus Variants

The CDC is working with other public health agencies to monitor the spread, emergence, and surveillance of SARS-CoV-2 virus variants that cause COVID-19 illness. Multiple variants of the virus that causes COVID-19 illness have been documented in the United States[11].

There are many known variants but the following are a few commonly discussed:

- United Kingdom (UK) or B.1.1.7 variant
  - Spreads more easily and quicker than other variants of SARS-CoV-2 virus
  - First detected in the U.S.: end of December 2020
- South Africa or B.1.351 variant
  - First detected in the U.S.: end of January 2021
- Brazil or P.1 variant
  - Contains mutations that may affect its ability to be recognized by antibodies
  - First detected in the U.S.: end of January 2021

These variants appear to spread more easily and quicker than other variants. Antibodies induced by COVID-19 vaccination appear to recognize these variants and provide some protection. More studies are underway to further understand the protection current COVID-19 vaccines provide against known variants.

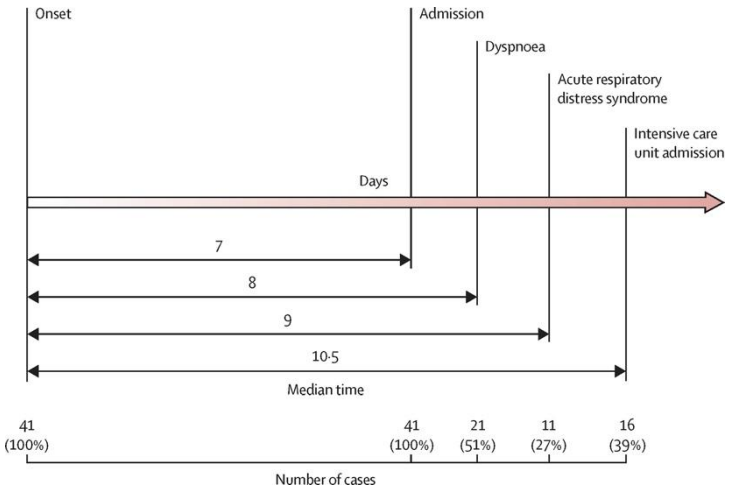
Public health mitigation strategies are vital to limit the emergence and spread of more SARS-CoV-2 variants[11].

For updated information about SARS-CoV-2 Virus variants visit: https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html.

Acute COVID-19 Infection

Clinical Course

The clinical course of COVID-19 illness (caused by SARS-CoV-2 infection) is typically 14 days: 4-5 days from exposure to symptom onset and approximately 10 days or more of symptoms. However, a recent study found that only 39% of symptomatic inpatients and 64% of symptomatic outpatients reported they had returned to their baseline level of health at 14-21 days[12]. COVID-19 is a late-peaking disease, and patients may clinically deteriorate in the second week of illness. For example, dyspnea typically develops 5-8 days after symptom onset with ARDS following approximately 2.5 days after (day 8-10 of illness). Similarly, one study found that the median time to hospitalization was 7 days from symptom onset[13]. This data suggests that peak illness can occur as late as 10-14 days after a known exposure. It is therefore important to continue to follow patients closely after an exposure and throughout their illness, even if initial symptoms are absent or mild. Scheduling a follow-up telemedicine appointment in the second week of illness provides an opportunity to reassess symptoms and either reassure patients who may feel sicker but do not require hospitalization or to intervene early in cases where patients are critically deteriorating. Educating patients about the long clinical course as well as the potential late onset of clinical decline can help set expectations and alleviate anxiety as patients try to navigate their symptoms at home.



Clinical Presentation

The most common symptoms of COVID-19 are:

- Fever or chills
- Cough (most commonly non-productive)

- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Data on the prevalence of each symptom exist but seem to vary widely, and patients can have any mix of these symptoms throughout their course. Many of these symptoms can be seen in other common viral syndromes, although the loss of taste or smell seems to be relatively specific to COVID-19. Regardless, COVID-19 cannot be diagnosed or ruled out based on clinical history alone and should be confirmed with testing.

Estimates from studies in China and the US showed that approximately 80% of patients have mild symptoms, defined as absence of hypoxia and no or mild pneumonia symptoms. About 14% of patients have severe symptoms (hypoxia, dyspnea, abnormal lung imaging) requiring hospitalization, including 2-5% that need ICU level care. Case fatality rate for all patients with COVID-19 illness was 2-5%[14,15].

COVID-19 Testing

Currently, Jackson Health System and the University of Miami do not perform any outpatient testing on symptomatic patients. There are specific protocols for testing on asymptomatic patients prior to a procedure or starting high-risk treatments that are arranged by the department performing the procedure or starting the high-risk treatment. At this time, for patients receiving care through the University of Miami health system we recommend sending patients to community testing centers for testing when indicated.

Indications for PCR Testing:
All patients with symptoms of COVID-19 illness should be tested for SARS-CoV-2 infection[16].

Antibody Testing
The FDA has not authorized the use of antibody tests to diagnose SARS-CoV-2 infection and the CDC does not recommend using antibody testing for the purpose of diagnosing acute infection[16].

Current Miami-Dade County Testing Sites can be found at:
https://www.floridadisaster.org/covid19/testing-sites/?fbclid=IwAR0jiqxcUC6buG6UWA8PuSiNNyZSb9i6JMa4uZPDApAqYg9SaZEUWtVl354&gclid=CjwKCAjwkdL6BRAREiwA-kiczD4kdx2er-LRjsNAgDKwgsjpLXwsr2tqsOr0a55kHN7h1TnSJnQh6RoCL6kQAvD_BwE#miamidade

CVS is also supporting testing via self-administered swabs:
https://cvshealth.com/covid-19/testing-information-locations#self-swab-locations

Starting Nov 2, 2020, UHealth Walgreens clinics will be offering testing. Please see their website for the most updated information: https://umiamihealth.org/en/patient-,-a-,-visitors/walgreens-clinics.

Indications for Antibody Testing:
COVID-19 Antibody testing can be recommended to patients who believe they have had and recovered from COVID-19 illness in order to confirm prior infection. Patients should be advised that it might take at least three weeks after infection for antibodies to be produced. Additionally, patients should be educated about the possibility of a positive test result indicating past infection with other strands of coronavirus not SARS-CoV-2 or COVID-19[17]. Jackson Health System and the University of Miami have partnered to provide COVID-19 antibody testing at multiple urgent care sites.

More information about COVID-19 Antibody Testing can be found at:
https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html

Locations can be found at:
https://jacksonurgentcare.com/lab-testing/covid-19-antibody-testing/

Telemedicine Evaluation

Jackson Health System and the University of Miami recommend telemedicine consultation for outpatient COVID-19 management. Telehealth evaluations minimize risk of exposure to staff and vulnerable patients while still providing substantial access to our health care team. Below is a framework of how to perform a clinical assessment during a telephone or video consultation. As the outpatient treatment of COVID-19 is supportive care, the objective of the consultation is to assess the severity of symptoms, determine the appropriate level of care, and provide anticipatory guidance to the patient. By following a stepwise procedure, we aim to support those with milder symptoms to avoid unnecessary escalation of care and to intervene early for those at risk for clinical decompensation.

Stepwise Assessment of Risk [Figure 1]:

1. **Patient Self-Assessment Tools**: These web-based tools can help patients determine their need for testing and medical care based on their exposure risk and symptoms according to the latest CDC guidance. Links can be distributed to high-risk patients, patients who had an exposure and are monitoring symptoms, patients who are at the start of their disease, and any patient coming to routine appointments as part of general counseling and anticipatory guidance regarding COVID-19. Patients will fill out their exposure risk, risk factors and symptoms and receive guidance on whether to get tested (if not already), call their physician or go straight to the ER.

a. CDC Symptom Checker: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/coronavirus-self-checker.html
b. University of Miami Symptom Checker

2. **Initial Telephone Triage** – performed by trained nursing staff, mid-level provider or physician to identify symptoms that require immediate referral to ER[18]:
    - New or worsening confusion
    - Difficulty breathing at rest
    - Pain or pressure in the chest
    - Cold, clammy or pale and mottled skin
    - Lethargy, confusion
    - Blue lips or face
    - Poor urine output
    - Hemoptysis
    - Hypotension (<90/60)
    - Oxygen saturation (SpO2) < 90% at rest

3. **Risk Stratification**: Quickly review the patient's past medical history to identify risk factors for poor outcome (see risk stratification below). Older age (≥ 65 years old) and underlying medical conditions pose increased risk of hospitalization, severe complications, and death. One study found that hospitalizations and deaths were 6 and 12 times higher respectively among those with underlying conditions compared to those with none. The most common conditions listed in this study were diabetes, heart disease and chronic lung disease[19].

    Based on the current evidence, the CDC has identified people ≥ 65 years old or of any age with the following conditions **are at increased risk** of severe illness from COVID-19:

    - Cancer
    - Chronic kidney disease
    - COPD (chronic obstructive pulmonary disease)
    - Immunocompromised state from solid organ transplant
    - Obesity (body mass index [BMI] of 30 or higher)
    - Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
    - Sickle cell disease
    - Type 2 diabetes mellitus

    People with the following conditions **might be at an increased risk** for severe illness from COVID-19:

    - Asthma (moderate-to-severe)
    - Cerebrovascular disease
    - Cystic fibrosis
    - Hypertension or high blood pressure

- Immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immunosuppressants
- Neurologic conditions, such as dementia
- Liver disease
- Pregnancy
- Pulmonary fibrosis
- Smoking
- Thalassemia
- Type 1 diabetes mellitus

4. **Vital signs (if available):**
    a. **Oxygen Saturation (SpO2)**
        - Mild illness: SpO2 > 95% at rest
        - Moderate illness:
            - Low risk patients: oxygen saturation 90-95% at rest
            - High risk patients:
                - If resting SpO2 ≤94%, consider sending to ER
                - If resting SpO2 ≤96%, ambulate and if SpO2 ≤92% consider transferring to ER
        - **Red Flag**: oxygen saturation < 90%. Advise patient to report to the ER

    b. **Blood Pressure:**
        - Assess for hypotension (<90/60). If present, send to the ER.
        - If BP cuff unavailable, assess for other signs of hypotension: presyncope, syncope, postural light-headedness, weakness, or change in mentation. If present, send to the ER.

5. **Clinical Assessment:** While this may feel difficult to do via telephone or video, targeted questions and observations can help identify those who need immediate evaluation. Below are examples of targeted questions developed from expert opinion (note, these are published recommendations but the effectiveness has not been adequately studied)[18].
    a. **Remote assessment of breathlessness:** There are no validated tests for the remote assessment of breathlessness in an acute primary care setting. However, a rapid survey of 50 clinicians found consensus among respondents around the following advice[18]:
        i. Ask open ended questions and listen to whether the patient can complete their sentences comfortably
        ii. Assess clinical change. Clinical deterioration is a warning sign that a patient needs continued monitoring, even if current symptoms are mild.
        iii. If video connection available, assess respiratory rate and look for signs of respiratory distress (tracheal tugging, tripoding, subcostal retractions)
        iv. Examples of questions from expert advice[19]:
            - "How is your breathing today?"
            - "Are you so breathless that you are unable to speak more than a few words?"

- "Are you breathing harder or faster than usual when doing nothing at all?"
- "Are you so ill that you've stopped doing all of your usual daily activities?"
- "Is your breathing faster, slower, or the same as normal?"
- "What could you do yesterday that you can't do today?"
- "What makes you breathless now that didn't make you breathless yesterday?"

b. **Assessment of other clinical symptoms:**
   i. Vomiting and/or diarrhea: "How often? Are you able to drink without vomiting?"
   ii. Fluid intake. Decreased food intake is normal in illness and would focus the patient on keeping hydrated rather than eating.
   iii. Urine Output
      1. 3 times per day indicates moderate illness
      2. Less than 3 times per day indicates severe illness and the patient should be advised to go to the ER
   iv. Mentation: Important to know the patient's baseline. Can ask family and/or roommates to describe any changes or increased confusion or lethargy.
   v. Function and ability to perform ADLs (compared to baseline): "Are you still able to walk to the bathroom, put on your clothes, walk around your house without getting short of breath, light headed or dizzy?"
      1. Patient has mildly decreased ability to perform ADLs: moderate
      2. Patient requires significant assistance when performing ADLs: severe

6. **Establishing the Timeline of Illness**: The majority of people are unaware of their exposure, so day of illness is most commonly counted from symptom onset. Setting a timeline of symptoms, particularly dyspnea, can help determine the likelihood of further decline and the frequency of follow-up. Clinical peak can be as late as day 10 of illness, and follow-up in the second week of illness can provide either early intervention or reassurance to patients who continue to have symptoms [see section on clinical course].

7. **Assessment of illness trajectory:** After you assess their timeline, it is important to assess where they are in their illness trajectory by simply asking: "Are you better, worse, or the same as yesterday?" If they are close to day 8-10 and are worsening, it is reasonable to expect them to continue to deteriorate and may need further evaluation.

8. **Assessment of home setting and social support:** Some patients may need a higher level of care if their access to support or ability to self-monitor symptoms is limited. These patients may need closer follow-up (perhaps via nursing staff) or could be referred for admission if needed. Questions to help assess your patient's home setting:
   - "Is anyone at home to help monitor your symptoms?"
   - "Do you have adequate access to food and water while quarantining?"
   - "Do you live with anyone at increased risk for severe disease (see risk factors above)?"

- "Does your home have a separate bedroom where you can stay and recover without sharing immediate space with others?"

Determination of Appropriate Level of Care [Figures 2 & 3]

All patients should have current symptoms, time course, and progression of illness assessed by the clinician in order to determine appropriate level of care. Symptoms can be classified as mild, moderate, or severe. Time course can be further classified as symptoms that began less than or equal to 10 days ago or symptoms that began greater than 10 days ago. Illness trajectory can be classified as worsening or improving symptoms. It should be noted that the below recommendations are designed to supplement clinical judgement in order to determine the appropriate level of care for each patient.

1. Mild symptoms include:
    a. No shortness of breath
    b. Cough
    c. Temperature less than 100.4F or no subjective fever
    d. Mild vomiting and/or diarrhea
    e. Patient able to tolerate fluid intake
    f. No changes in urine output
    g. No changes to baseline mental status
    h. No changes to baseline function (i.e. activities of daily living)

2. Moderate symptoms include:
    a. Mild shortness of breath
    b. Patient able to complete sentences without stopping to catch their breath
    c. Patient able to climb a flight of stairs (if dyspnea climbing stairs at baseline then worsening of dyspnea with climbing stairs)
    d. Temperature between 100.4-103F or subjective fever but able to be controlled with antipyretic medications
    e. Moderate vomiting and/or diarrhea
    f. Patient tolerating less than 50% of normal daily fluid intake
    g. Patient urinating at least three times per day
    h. No changes to baseline mental status
    i. Mildly reduced baseline function (i.e. activities of daily living mildly impacted by COVID-19 illness)

3. Severe symptoms include:
    a. Severe shortness of breath
    b. Inability to speak in full sentences due to shortness of breath
    c. Dyspnea with stairs (if dyspnea climbing stairs at baseline than significant worsening of dyspnea with climbing stairs)
    d. Severe vomiting and/or diarrhea
    e. Patient urinating less than three times per day
    f. Oxygen saturation <90% (if pulse oximetry available)

g. Temperature greater than 103F OR greater than 100.4F and unchanged with antipyretic medications or subjective fever unchanged with antipyretic medications
h. Presyncope or syncope
i. Altered mental status
j. Severely reduced baseline function (i.e. activities of daily living are severely impacted by COVID-19 illness)

4. **Low Risk [Figure 2]**
    a. Mild symptoms:
        i. Symptoms that began less than or equal to 10 days ago: Consider referral to the UM URI clinic for further assessment or Bamlanivumab infusion (see outpatient therapy) or follow up in 3-5 days
        ii. Symptoms that began more than 10 days ago: follow up as needed
    b. Moderate symptoms:
        i. Symptoms that began less than or equal to 10 days ago:
            1. Stable or early disease: Consider referring to URI clinic for further evaluation or Bamlanivumab infusion or follow up in 24-48 hours
            2. Worsening symptoms: refer to the Emergency Department
            3. Improving symptoms: follow up within 24-48 hours or as needed
        ii. Symptoms that began more than 10 days ago:
            1. Worsening symptoms: refer to the Emergency Department or consider follow up within 24 hours
            2. Improving symptoms: follow up in 48-72 hours or as needed
    c. Severe symptoms: refer to the Emergency Department

5. **High Risk [Figure 3]**
    a. Mild symptoms:
        i. Symptoms that began less than or equal to 10 days ago: follow up within 24-28 hours, refer to the UM URI clinic for further evaluation, or Bamlanivumab infusion (see outpatient treatment)
        ii. Symptoms that began more than 10 days ago: follow up as needed
    b. Moderate symptoms:
        i. Symptoms that began less than or equal to 10 days ago:
            1. Stable/early disease: follow up within 24-28 hours or refer to the UM URI clinic or giving Bamlanivumab infusion (see outpatient treatment)
            2. Worsening symptoms: refer to the Emergency Department
            3. Improving symptoms: follow up within 24-48 hours or refer the University of Miami's URI clinic
        ii. Symptoms that began more than 10 days ago:
            1. Worsening symptoms: refer to the Emergency Department
            2. Improving symptoms: follow up in 24-48 hours or as needed
    c. Severe symptoms: refer to the Emergency Department

6. **General Anticipatory Guidance:** Patients should be advised to seek acute care if they develop the following:
    - Severe dyspnea (dyspnea at rest that interferes with the patient's ability to speak in full sentences)
    - Oxygen saturation on room air of ≤90 percent, regardless of severity of dyspnea
    - Altered mentation (i.e. confusion, change in behavior, inability to awake or stay awake)
    - Signs or symptoms of hypoperfusion: falls, hypotension, cyanosis (bluish lips or face), anuria, oliguria, chest pain suggestive of acute coronary syndrome

7. **University of Miami URI Clinic**: UM has started a specific clinic for symptomatic patients to be seen in-person for further evaluation and management. Patients must first be evaluated via telehealth prior to referral to the clinic. This clinic may be used for patients who may need vitals and a physical exam to help with appropriate decision-making or for patients who are unable to be adequately assessed through telemedicine. Patients must have a PCP in the University of Miami Health System. The clinic is located on Center for Family Studies 1425 NW 10th Ave 1st floor Miami, FL 33136. For referrals, please call 305-243-4900.

Outpatient Treatment

To date there are no known medicines that can prevent or treat COVID-19, and recommended management for most patients with COVID-19 illness is supportive care only. Below is the current evidence on investigational therapeutics and other common medications often used or asked for in the outpatient setting:

Please see updated information on Monoclonal Antibody and other Treatments in Appendix 1

1. **Monoclonal Antibodies:** Two investigational infusions have received FDA Emergency Use Authorization (EUA) for outpatient treatment of COVID-19 illness and can be considered for high-risk patients. At this time, both UM and JHS have access to these medication for qualifying individuals. EUA does not indicate FDA approval of the drug and **should not be considered** the standard of care for outpatient treatment. There is currently not enough evidence to support one therapeutic over the other, and the decision for which therapy will mostly be based on available supply. We recommend shared decision making with high-risk patients when deciding whether or not to pursue infusion with monoclonal antibodies. We recommend patients receive infusions as early as possible in the course of their COVID-19 illness, ideally within three days of symptoms but up to ten days of symptoms.

    a. **Bamlanivimab** is a monoclonal antibody produced by Eli Lilly that targets the receptor-binding domain of the spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes COVID-19 illness. Bamlanivumab is currently being evaluated for the outpatient treatment of mild to moderate COVID-19 illness in high-risk individuals. Per the National Institute of Health, at this time, there are insufficient data to recommend either for or against the use of Bamlanivimab for the outpatient treatment of COVID-19 illness (17). In the Blocking Viral Attachment and Cell Entry with SARS-

CoV-2 Neutralizing Antibodies (BLAZE-1) trial, an interim analysis suggested a potential clinical benefit of Bamlanivimab for outpatients with mild to moderate COVID-19 illness. In this randomized, double blind, placebo-controlled, Phase 2 trial, participants received a single intravenous infusion of Bamlanivimab within 3 days of having a positive SARS-CoV-2 test result[21,22].

b. Casirivumab and Imedevimab are a recombinant of two human monoclonal antibodies designed to block viral attachment and viral entry by non-competitive binding to Spike protein receptor binding domain. See Regeneron Antibody cocktail algorithm below for more details. Developed by Regeneron pharmaceutical company[20].

c. Qualifying Criteria:

- Individuals aged ≥12 years and weigh ≥40 kg who have one of the following conditions:
  - BMI ≥ 35
  - Chronic kidney disease
  - Diabetes mellitus
  - Immunosuppressive disease
  - Currently receiving immunosuppressive treatment
- Individuals aged ≥65 years
- Individuals aged ≥55 years that have one of the following:
  - Cardiovascular disease
  - Hypertension
  - Chronic obstructive pulmonary disease/other chronic respiratory disease
- Individuals aged 12 to 17 years old who have one of the following:
  - BMI ≥85th percentile for their age and gender based on the Center for Disease Control and Prevention growth charts
  - Sickle cell disease
  - Congenital or acquired heart disease
  - Neurodevelopmental disorders, for example, cerebral palsy
  - A medical-related technological dependent, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19 illness)
  - Asthma or a reactive airway or other chronic respiratory disease that requires daily medication for control

*The definitions of high risk for use of monoclonal antibodies differ from the high risk criteria previously defined in this outpatient guide

d. Limitations of Authorized Use[20,21]:

- Monoclonal antibody treatment is NOT authorized for use in patients:
  - Who are hospitalized due to COVID-19 illness, or
  - Who require oxygen therapy due to COVID-19 illness, or
  - Who require an increase in baseline oxygen flow rate due to COVID-19 illness in those on chronic oxygen therapy due to

underlying non-COVID-19 related comorbidity

- The benefit of treatment has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen ventilation.

e. **Safety concerns**[20,21]: Due to the limited clinical data available regarding side effects for these therapies serious and unexpected adverse events may occur that have not been previously reported with use. For more detailed information, please refer to the EUA of the therapeutic.
   - Among the 850 participants who have participated or are enrolled in ongoing trials with bamlanivimab, one anaphylaxis reaction and one serious infusion-related reaction have been reported to date.
   - Among the 799 participants in the Casirivumab and Imedevimab trial, one anaphylaxis and two infusion-related reactions were also noted. Other serious adverse effects were noted (pneumonia, hyperglycemia, intestinal obstruction, etc.), but none were attributed to the drug.

f. **How to Order:**
   - For information on how to order infusions for your patients at the University of Miami please refer to the workflow sheet at: https://uchart.it.miami.edu/_assets/pdf/uchart-learning-resources/uchart/new-covid-therapeutic-workflow/provider-nurse-and-pharmacist---new-covid-therapeutic-workflow.pdf
   - For information on how to order infusions for your patients at Jackson Memorial Hospital, please visit https://jhsmiami.org/stewardship/ and contact the Antibiotic Stewardship Program for approval and instructions.

2. Other Investigational Therapeutics: Patients may qualify for clinical trials for both investigational treatments as well as prophylaxis for those who have been exposed to COVID-19. Please consider referring patients to participate in research. Active trials can be found on https://umiamihealthresearch.org under COVID-19 studies.

3. NSAIDS: Acetaminophen is the preferred medication choice for antipyretic and analgesic therapy due to limited data suggesting possible negative effects of NSAID use in COVID-19. That being said, evidence to support worse outcomes with NSAID use is limited and both the World Health Organization and the United States National Institutes of Health (NIH) recommend NSAIDs be used when clinically indicated[20]. Patients who take NSAIDS chronically should be advised to continue therapy as prescribed[23]. Patients who do not have adequate relief with acetaminophen alone can use NSAIDs at the lowest dose effective to control symptoms.

4. Antibiotics: There is no role for empiric antibiotics as treatment for COVID-19 illness. COVID-19 illness may present clinically similar to community-acquired pneumonia. In situations where the diagnosis is unclear it may be reasonable to prescribe a course of antibiotics for community acquired pneumonia.

5. Vitamins and Supplements: Currently, there is insufficient evidence to support the use of vitamin C, vitamin D, or zinc for the treatment of COVID-19[20].

6. Corticosteroids: Steroids are not recommended for outpatient treatment of COVID-19 infection. Per the results of the Randomized Evaluation of COVID-19 Therapy (RECOVERY) trial, steroid medication is useful in patients with COVID-19 illness who require supplemental oxygen and who are mechanically ventilated. The NIH recommends dexamethasone 6 mg daily for up to 10 days only in patients who require supplemental oxygen and recommends **against** using steroids to treat patients who do not require supplemental oxygen. Steroids being used to treat underlying medical conditions prior to COVID-19 illness should not be discontinued during COVID-19 illness[20].

7. Bronchodilators: To date there is no evidence to recommend the use of albuterol or other bronchodilators for treating COVID-19 illness in patients without any other indication to be using bronchodilators. Patients who use bronchodilators chronically for asthma, COPD, or other lung disease should be advised to continue using their bronchodilators as prescribed.

8. Hydroxychloroquine: Hydroxychloroquine or chloroquine should not be used to treat COVID-19. Per the National Health Institute, the use of hydroxychloroquine or chloroquine in the outpatient setting is only recommended in the setting of a clinical trial. The use of hydroxychloroquine plus azithromycin is only recommended in the setting of a clinical trial[20].

Adjustment of Common Medications: For mild to moderate symptoms being monitored at home, chronic medications can likely be continued as normal. However, some examples of medications that may be temporarily decreased or discontinued are:

1. Type 2 Diabetes Mellitus: Consider holding oral hypoglycemics and/or pre-prandial insulin for those who are not eating at baseline and are at high risk of hypoglycemia. Basal insulin can likely be continued as dosed, but can be decreased by 50-80% if fasting glucose is dropping or <100 mg/dl.
2. Hypertension: Antihypertensives should be continued as usual. There is no evidence to hold ace-inhibitors. If there is concern for risk of dehydration, temporarily discontinuing diuretics may be considered. Would recommend keeping a home blood pressure log if feasible.
3. Immunosuppressants: Some are held during the acute illness phase. We recommend discussing with their specialist about the risks vs benefits of continued treatment while symptomatic.

Follow Up Telemedicine Visit:

Consider a follow up telemedicine visit for most patients during week two of symptom onset (day 7-10 of symptoms).

1. For patients living alone:
    - Consider follow up telemedicine visit within 24-48 hours in addition to week two of symptom onset follow up visit.

- Consider using trained clinic staff (MA, LPN, RN, APRN) that can be trained to do brief check-ins and triage patients that may benefit from frequent follow-up.

2. For patients at high risk of clinical deterioration, we recommend follow up telemedicine appointment. These patients include:
    - Patients ≥65 years who have one or more additional risk factors for severe disease (see risk stratification section)
    - Any patient with moderate dyspnea during initial evaluation
    - Patients who would be possible candidates for inpatient care but are being managed at home due to personal preference
    - Patients who may not reliably report deterioration in symptoms

Advance Care Planning

We recommend beginning discussions with patients about end-of-life care in the case they become critically ill. These conversations would ideally occur prior to patients becoming ill, when patients are able to have time to reflect and discuss their wishes with family and friends.

1. Ask permission first: "Would it be okay if we talk about what would happen if you were to get very sick from COVID-19?"
2. Discuss their code status, which includes their wish to be intubated in the case of respiratory failure and resuscitated in the event of cardiac arrest.
3. Identify a health care surrogate and document in the patient's chart. Ask "who would you like to make medical decisions on your behalf if you are otherwise unable?" It is important to discuss that they should choose someone who has a good understanding of what they would want done in this situation.

Discontinuation of Isolation **(please see updated "De-escalation of COVID-19 Isolation Precautions on Page 27)**

Per current CDC guidelines, average risk patients with COVID-19 infection do not require a negative test result to be cleared from isolation[23,24].

1. For **asymptomatic patients**, isolation can be discontinued 10 days after their first positive COVID test.
2. For patients with **mild to moderate illness who are not severely immunocompromised:**
    - ≥ 10 days have passed since symptom onset
    - AND no fever (without antipyretic use) for ≥ 24 hours
    - AND clinical improvement of other symptoms. Loss of taste and smell may continue for weeks to months after recovery and should not delay clearance from isolation
    - For asymptomatic patients, clearance from isolation is 10 days after the date of the first positive COVID-19 PCR test
3. For patients with **severe to critical illness or who are severely immunocompromised:**
    - At least 10 days and up to 20 days have passed since symptoms first appeared
    - AND no fever (without antipyretic use) for ≥ 24 hours
    - AND clinical improvement of symptoms (e.g., cough, shortness of breath)
    - A test-based strategy could also be considered for some patients in consultation with local infectious diseases experts if concerns exist for the patient being infectious for more than 20 days

- Immunocompromising conditions include:
    - HIV
    - Patients taking immunosuppressants or daily prednisone for ≥ 1 month duration
    - Hematologic malignancies or other severe immunodeficiency syndromes
    - Any other patient who is considered immunocompromised but does not fall into any category above and are at risk for prolonged viral shedding by their health care provider

Prognosis and Recovery

We are still in the process of learning about the duration of symptoms and long-term complications of COVID-19 illness.

1. **How long to expect symptoms:** Based on data from China, the recovery time is around two weeks for mild COVID-19 illness and three to six weeks for severe disease requiring hospitalization[25].
2. **Long Term Sequelae:**
    a. Mild Symptoms Not Requiring Hospitalization: In one survey of 350 patients with mild COVID-19 illness (defined as not requiring hospitalization), 39 percent of patients had not returned to baseline health 2-3 weeks after diagnosis. In this group of patients treated in the outpatient setting, 42 percent reported cough, 35 percent reported fatigue, and 29 percent reported dyspnea during follow up 14-28 days after diagnosis. Even in younger patients aged 18-34 years old with no underlying medical conditions, one in five reported yet to return to their usual state of health[12]. The loss of taste and smell may continue for weeks to months after COVID-19 illness and should not alone delay clearance from isolation.

    b. Moderate to Severe Symptoms Requiring Hospitalization: In a study of hospitalized patients with COVID-19 in Italy, only 13 percent were symptom free after a mean of 60 days following symptom onset. Common symptoms reported were fatigue (53 percent), dyspnea (43 percent), joint pain (27 percent), and anosmia (13 percent). It should be noted no fever was reported[26]. Another study surveyed 161 patients with severe COVID-19 illness (defined as requiring at least 6 liters of oxygen supplementation during admission) thirty to forty days after hospital discharge and found 12.6 percent were symptom free, 43 percent had continued dyspnea, 13.5 percent required new home oxygen supplementation, 43.8 percent reported worse physical health, and 47 percent reported worse mental health as a result of COVID-19 illness[19]. Patients requiring ICU level care have been shown to report more sequelae when compared to patients requiring regular ward level care. A survey of 100 hospitalized patients compared symptoms four to eight weeks after discharge. In the group of patients that required ward level care 12 percent reported cough, 60 percent reported fatigue, 43 percent reported dyspnea, and 16 percent reported memory loss. In the group of patients requiring ICU level care, 25 percent reported cough, 72 percent reported fatigue, 66 percent reported dyspnea, and 18 percent reported memory loss[27].

c. Multisystem Inflammatory Syndrome in Adults (MIS-A)**:** Similar to the new multisystem inflammatory syndrome described in children (MIS-C) due to COVID-19, a similar syndrome is being seen in adults. This syndrome is a hyperinflammatory syndrome that causes multi-organ failure, particularly causing acute heart failure and cardiogenic shock. The interval between COVID-19 acute infection and presentation of symptoms is still unknown but estimated to be about 2-5 weeks. Unlike acute COVID-19 infection, this syndrome tends to spare the respiratory tract. All reported patients presented with a fever for several days, and most have negative COVID PCR testing but antibody positive. It is therefore recommended that suspected patients undergo both PCR and antibody testing to help with diagnosis. While rare, it is important to recognize potential signs early to ensure prompt hospitalization and treatment[28].

d. "Long COVID Syndrome:" This is an active area of investigation with the NIH just recently dedicating research money to study this syndrome. Symptoms, such as persistent brain fog, fatigue, malaise, and shortness of breath, can be described in patients six months or more after their acute infection, even if the initial infection was not severe. Some of these symptoms can be considered debilitating, with many patients stating they are unable to keep a full-time job.

   At this time, there are *no specific treatments* recommended, and treatment plans should be individualized for each patient's particular complaints. The following article may be helpful for patients:
   - Tips for patients from a survivor: https://www.washingtonpost.com/health/long-haul-covid-patients/2020/10/23/ab7c5324-0712-11eb-9be6-cf25fb429f1a_story.html

General Tips for Self-Care at Home

1. **How to self isolate at home:** It is important to note that asymptomatic patients who test positive for COVID-19 need to perform self isolation for 10 days following a positive test result per current CDC guidelines[29].
   a. For patients that live alone with adequate access to food and water:
      - Stay home except to get medical care until otherwise notified (see recovery section below)
      - Educate about warning signs (see "General Anticipatory Guidance" above)
   b. For patients that live in a multiple person household:
      - Use a mask when around other members of the household
      - Stay in a separate bedroom/space and avoid using shared spaces.
        - If not possible, consider staying alternative housing options
        - Miami-Dade County Temporary Housing Program: Call a 305-614-1716 from 8 am and 5 pm daily
        - https://www.miamidade.gov/releases/2020-07-18-mayor-COVID-hotels.asp
      - Use a separate bathroom, if possible.

- Avoid sharing utensils, dishware, and towels with other members of the household.
- Wash hands with soap and water often, about 6-10 times per day.
- Wear a mask around other household members
- Avoid touching your face and eyes
- Avoid interacting with household pets
- Maintain 6 feet distance from other members of the household

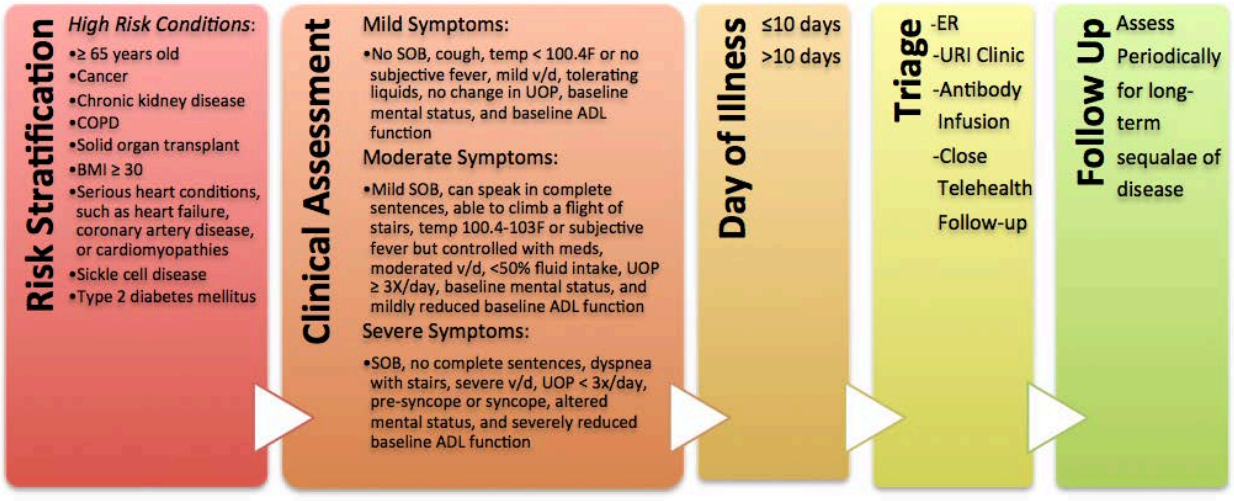
2. **Clean "high touch" shared spaces daily.** Information regarding cleaning techniques are provided by the CDC at: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/disinfecting-your-home.html

Common Myths and Misconceptions

Many patients have had difficulty distinguishing truth and disinformation regarding the pandemic. The information above can help guide providers in these discussions and will be updated regularly with any new information and responses to common myths. For more information about common COVID-19 myths please see World Health Organization COVID-19 Mythbusters Advice For The Public: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters

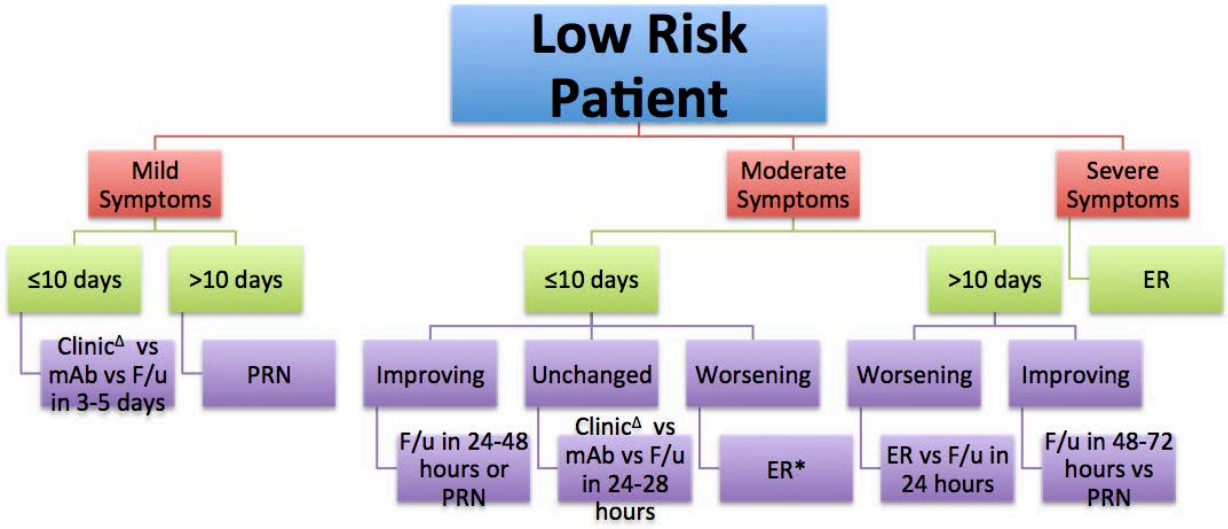
Telemedicine COVID-19/PUI Evaluation

Figure 1: Stepwise Assessment of Risk[30]



Adapted from: https://www.bumc.bu.edu/gimcovid/files/2020/05/Confirmed-COVID-or-Highly-Suspected-Symptom-Assessment-and-Triage.pdf

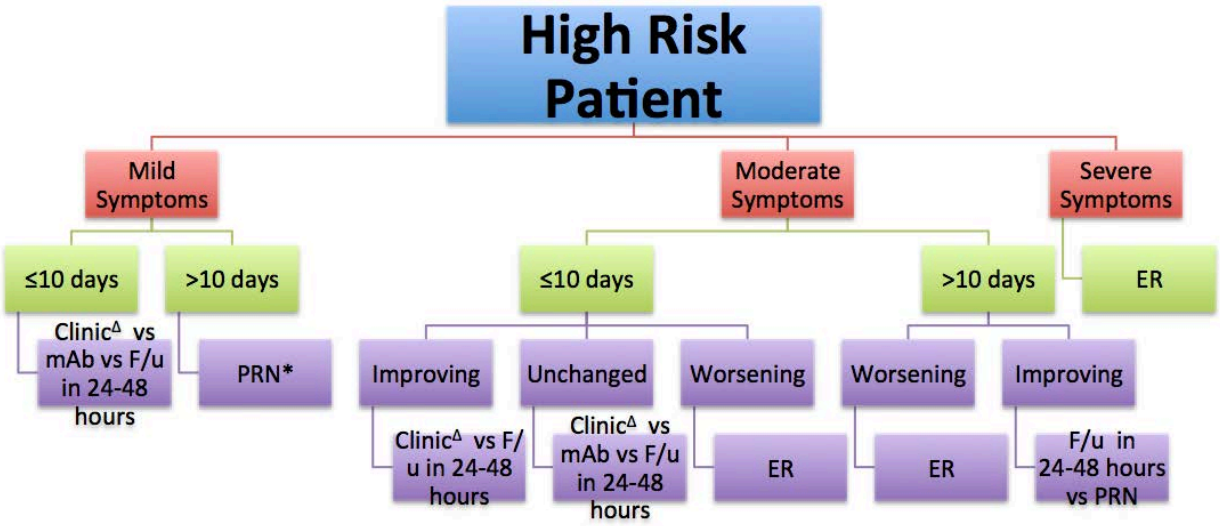
Figure 2: Telemedicine Triage for Low Risk COVID Patients



*For low risk patients with moderate symptoms and worsening disease course we recommend using clinical judgment when determining appropriate level of care.

ΔUniversity of Miami URI Clinic: For in person clinic visits, consider referral to the URI clinic. The clinic is located at the Center for Family Studies 1425 NW 10th Ave 1st floor Miami, FL 33136. Patients must first have a Telehealth visit or a telephone conversation with the referring provider.

Figure 3: Telemedicine Triage for High Risk COVID Patients



*For patients at high risk with >10 days illness and mild symptoms, we recommend the use of clinical judgment and shared decision making when determining appropriate follow up. If the patient has improving symptoms then as needed follow up could be recommended. Alternatively, if patient symptoms are stable or worsening we recommend follow up within 48-72 hours if not sooner.

Δ University of Miami URI Clinic: For in person clinic visits, consider referral to the URI clinic. The clinic is located at the Center for Family Studies 1425 NW 10th Ave 1st floor Miami, FL 33136. Patients must first have a Telehealth visit or a telephone conversation with the referring provider, and their PCP must be a UM provider.

§ Please see “Outpatient Treatment” section for more information regarding qualifying high risk individuals and ordering information.

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Appendix 2

COVID-19 Testing Guidelines for Admitted Symptomatic Pediatric Patients

Consider COVID-19 testing (after ruling out other etiologies) in patients with any two of the following symptoms:

1. Fever ≥ 38.3°C
2. Cough
3. Shortness of breath
4. Pharyngeal erythema/pain
5. Vomiting and/or diarrhea
6. Loss of smell or taste

↓

Select Covid19 PCR Lab Test from the order catalog

↓

The EMR will ask you to confirm the patient's symptoms. For Holtz, symptomatic patients are transferred to negative airflow rooms.

↓

Determine the level of care needed based on the patient's condition.
Enter the appropriate transfer order:
Med/Surg COVID or ICU COVID including other required information: team, attending

↓

Select the type of isolation needed which will be Airborne Precautions with Eye protection.

↓

SARS-CoV-2 test will be ordered

Swabs can be collected in a private room with droplet precautions and eye protection.

For patients over 14 years of age a swab nurse will be dispatched. For

↓

For critically ill patients consider activation of PED COVID19 Management orders: EKG, CXR, RVP, IL-6, CRP, D-dimer, Ferritin, Magnesium even while awaiting test results.

↓

Positive test

↓

Consult Pediatric Infectious Disease (305-750-0716) for treatment recommendations

↓

Criteria for lifting isolation and safely discharging COVID positive patients: Available through JHS Badge Buddy

Negative test

↓

Is patient improving and alternative diagnosis likely?

Yes

↓

Discontinue isolation

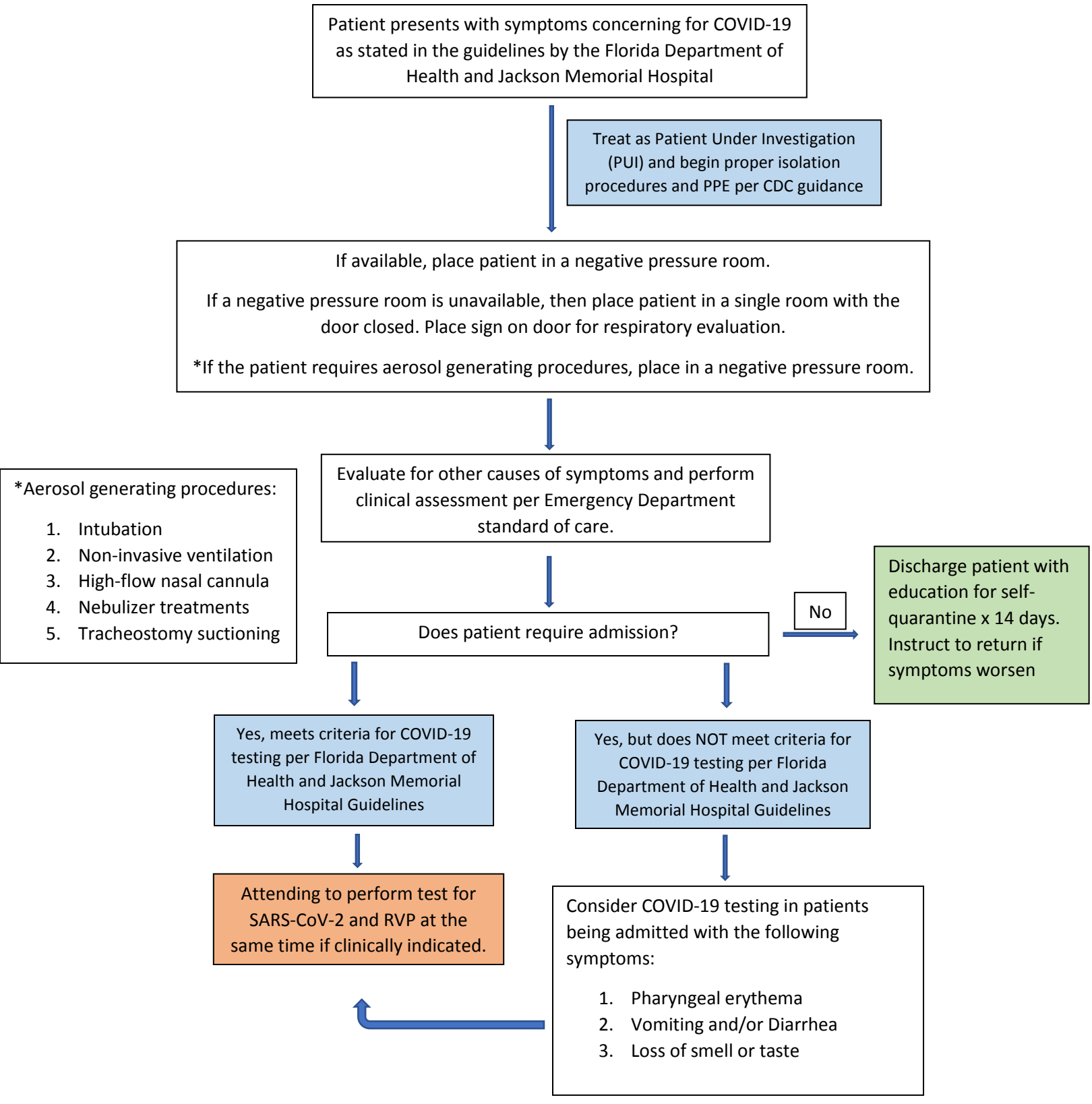
No

↓

Discuss repeat testing with Ped ID

Updated 4.6.2020
Algorithm based on Clinical Guidance and CDC Recommendations
https://www.cdc.gov/coronavirus/2019-ncov/index.html

COVID-19 Testing Algorithm for Pediatric Patients (Emergency Department)



Updated 4.7.2020
Algorithm based on Clinical Guidance and CDC Recommendations
https://www.cdc.gov/coronavirus/2019-ncov/index.html

Appendix 2a

COVID Outpatient Clinician Guide

UM Health/Jackson Memorial Hospital

A Compilation of Recommendations and Resources for Comprehensive Care of Pediatric Patients at Risk for COVID-19 Infection

Version 1

December 9, 2020

Authors: Cecilia Banda, Nina Hein, Audrey Ofir, Anjali Saxena, Kathryn Swaby

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Introduction

There are distinct groups of pediatric patients whom we believe require unique follow up care which is what we aim here to outline in a protocol for the purpose of both optimal patient care and early identification of the full spectrum of impact of COVID-19 on this vulnerable population.

The American Academy of Pediatrics Guidelines and the Center for Disease Control were the main sources in formulating these guidelines.

Document Outline

Follow the Trends in COVID Cases

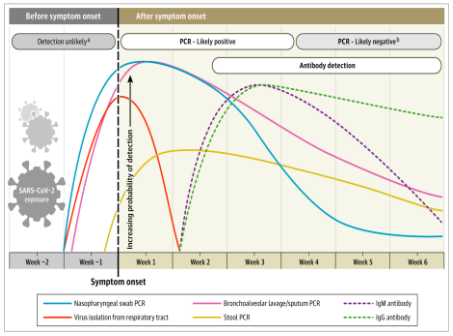
Resources for tracking the epidemiology in the Pediatric Population

CDC Tracking
https://covidtracking.com/data

John Hopkins Coronavirus Resource Center:
https://coronavirus.jhu.edu/data/new-cases-50-states/florida

Available Community Laboratory Testing for COVID Diagnosis and Screening

JAMA 2020 Graphical Representation of timing for Interpreting Diagnostic Tests for SARS-CoV-2



https://jamanetwork.com/journals/jama/fullarticle/2765837

CDC guidelines state health care workers can return to work, if "at least **1 day** (24 hours) has passed since recovery defined as resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (e.g., cough, shortness of breath); and, at least 10 days have passed since symptoms first appeared."

	SARS-CoV-2 nucleic acid amplification (PCR)	SARS-CoV-2 Antigen (Ag)	Serologic assays for SARS-CoV-2
Key Features	**Most reliable test for diagnosis of acute COVID-19**. Detects Viral RNA	**Alternate rapid testing.** Targets 1 or more portions of the virus (*env*, *N*, *S*, *RdRp*, *ORF1)*	**COVID Specific Total IgM and IgG** Supports assessment of high-risk populations and diagnosis of post-infectious syndromes (including MIS-C)
Sample	Nasopharyngeal swab Throat swab. Saliva sample	Nasal swab Saliva sample	Serum sample
Timing	Day 1 to 21 after symptom onset May remain positive for months	Days 1 to 6 After symptom onset	Day 4 to Week 7 After symptom onset
Result Availability	Lab Dependent: 1 - 72hrs	15 minutes	15 minutes – 48 hours
Sensitivity **Specificity**	95-100% 71-98%	84-97% 100%	95%
Positive	No Confirmatory Testing Needed	No Confirmatory Testing Needed	No Confirmatory Testing Needed
Negative	Only repeat if high clinical suspicion	SARS-CoV2 PCR test to Confirm	Consider SARS-CoV2 PCR if early illness

Testing sites: https://www.miamidade.gov/global/initiatives/coronavirus/testing-locations.page
UM mobile van: 305-243-2059 (0-20 years old) Appointments encouraged
Mailman Center for Child Development: Through UM Primary Care Providers

General COVID-19 Infectious Precautions

Daily Precautions

- Know how it spreads
- Wash your hands often
- Avoid Close Contact
- Cover Your Mouth & Nose with A Mask around others
- Cover your Coughs and Sneezes
- Clean and disinfect
- Monitor your health daily

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

Return to School

Get help planning for return to school or virtual learning

In Person Classes
Check for signs of illness each day.
Talk to your child about precautions.
Develop a routine before & after school.

Virtual Classes
Find a space free of distraction and noise.
Create a schedule and commit to it.
Take frequent breaks
Identify opportunities for your child to connect with peers and be social.

https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/schools-childcare/back-to-school-decision-checklist.pdf

Travel

Before you travel, consider:

Destination Details
Is your travel a priority?
Is COVID-19 spreading at your destination?
Are there requirements or restrictions?

Individual Factors
Do you live with an individual at increased risk for severe illness from COVID?
Are you at increased risk for severe illness from COVID?

If you travel:
Take steps to protect yourself & others
Consider lower risk forms of travel

https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html

Coping and Support

Take care of yourself and your community by prioritizing:

- Physical health
- Mental Health
- Emotional health
- Connecting with others

Get immediate help in a crisis

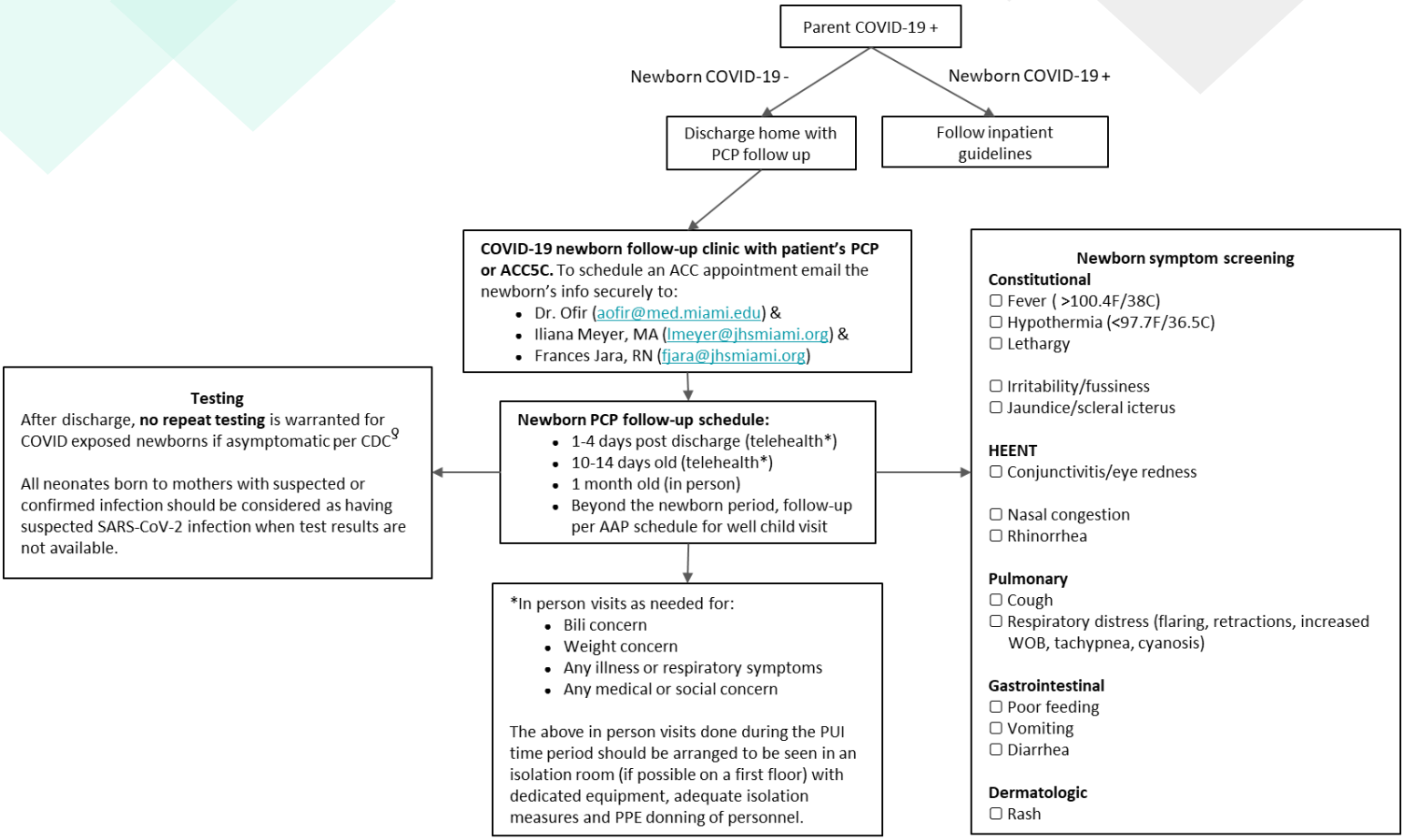
Find a health care provider or treatment for substance use disorder and mental health

https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/stress-coping/index.html

Patient Group Specific Recommendations

(Please also see updated Treatment Information in Appendix 1)

Outpatient follow up for newborns (0-28 days old) with peri- or postnatal COVID-19 exposure



[9] **CDC: Evaluation and Management Considerations for Neonates At Risk for COVID-19** https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-newborns.html

Newborn COVID-19 Key Points and Anticipatory Guidance

Modified from the CDC: Evaluation and Management Considerations for Neonates at Risk for COVID-19
https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-newborns.html

Statistics

Current evidence suggests that SARS-CoV-2 infections in neonates are uncommon.
To date, **none of the 100+ newborns** born to COVID-19 + moms at our institutions have been COVID-19 PCR+ at time of discharge. Long-term effects from perinatal exposure to SARS-CoV-2 have not yet been determined.

If neonates do become infected, the majority are either asymptomatic or have mild disease (do not require respiratory support) and recover. Severe illness in neonates, including illness requiring mechanical ventilation, has been reported but appears to be rare. Neonates with medical conditions and preterm infants (<37 weeks GA) may be at higher risk of severe illness

Breast feeding

The limited data available suggests breast milk is not likely to be a source of COVID-19 transmission. Breast milk is beneficial for babies and protects them from many infections including by passing along antibodies to many infections, promotes wellness of the mother, and is readily available.

Pumped breastmilk with the appropriate infectious precautions (wearing mask, handwashing, cleaning pump after each use) can also be given by a healthy caretaker. Whether to continue or start breastfeeding should be a family decision in coordination with healthcare providers.

Transmission

Neonatal transmission of SARS-CoV-2 is thought to occur primarily through **respiratory droplets** during the postnatal period when neonates are exposed to mothers/caregivers with SARS-CoV-2 infection

Rates of SARS-CoV-2 infection in neonates do not appear to be affected by mode of delivery, method of infant feeding, or contact with a mother with suspected or confirmed SARS-CoV-2 infection.

Early and close contact between the mother and neonate has many well-established benefits. Current evidence suggests the risk of a neonate acquiring SARS-CoV-2 from their mother is low and there is no difference in risk of infection whether a neonate is cared for in a separate room or remains in the mother's room.

COVID Positive Caretakers

Anticipatory guidance
- Wear a mask during feeding and when within 6 feet of newborn
- Wash hands before holding baby
- Breast milk encouraged but wash mother's nipples prior to feeding
- Clean breast pump after use
- Assign restroom for COVID19+ household members (potential fecal transmission)
- When possible defer childcare to COVID-19 negative or asymptomatic caretaker

Continue precautions per CDC guidelines for:
- At least **10 days*** from onset of symptoms *and*
- **24hrs afebrile** without antipyretics *and*
- **Improvement** in symptoms

*Isolation of caretaker prolonged to 20 days if had a "severe illness" or immunosuppressed.

Outpatient Evaluation of Children Suspected to have Acute COVID Infection (PUI)

Source: Modified from CDC guidelines Covid-19 acute infection, Seattle children's hospital guideline for acute covid-19 infection, CHOP guideline for covid-19 acute infection.

Suspected Covid-19 infection / Positive PCR

Clinical Assessment

Asymptomatic

Recommend social isolation at home
Provide resources for community testing
Review need for services over duration of illness

Mild Disease

- ✓ Fever
- ✓ Nasal congestion
- ✓ Cough
- ✓ Diarrhea
- ✓ Vomiting
- ✓ Myalgias
- ✓ Sore throat

Moderate Disease

- ✓ Tachypnea
- ✓ Retractions
- ✓ Respiratory distress
- ✓ SpO2 <94%
- ✓ Signs/symptoms of dehydration

Use Respiratory Clinical Score *
Use Assessment of Severity of Dehydration**

Severe/Critical Disease

- ✓ Suspected sepsis
- ✓ Suspected SARS
- ✓ Suspected multi-organ failure

Risk Factors for Severe Disease:

- Obesity
- Congenital/acquired immunodeficiency
- High dose or long-term steroid use
- Transplant recipient on Immunosuppressive agents
- Recent administration of myelosuppressive chemotherapy
- Underlying respiratory disease
- Underlying cardiac disease
- End Stage Renal Disease
- Liver failure
- Sickle Cell Disease

Risk stratification for Severe Disease

Immediate referral to the Emergency Room for Tiered Testing and Further Workup

Low Risk

Follow up febrile patients in 24-48hrs with a telemedicine visit

High Risk

- ✓ Obesity
- ✓ Underlying respiratory disease (including asthma) or cardiac disease
- ✓ ESRD
- ✓ Liver disease
- ✓ SCD
- ✓ Long-term steroid therapy

If currently on immunosuppressant therapy

Consider Monoclonal Antibodies (See Pages 6 & 7 for details)

Follow up in 12 – 24 hours via telemedicine visit
Reassess case-by-case

If PUI/Confirmed Covid-19 by PCR patient is seen in-person, consider the following:

1. Isolate patient in a room with closed doors
2. Alert charge nurse, treating physician and any health team member involved in care
3. Flag room door with strict isolation precautions
4. Discharge patient/ transfer patient and caretaker masked, minimizing exposure to other individuals

Routine vaccination is still recommended for well patients with COVID infection. Decision to vaccinate as a procedure in the acute phase of infection is institution/case dependent.

*Respiratory Score for Clinical Assessment of Respiratory Distress

Variable	0 points	1 point	2 points	3 points
Respiratory Rate				
<2 mo.		< 60	61-69	>70
2-12 mo.		< 50	51-59	>60
1-2 y		< 40	41-44	>45
2-3 y		< 34	35-39	>40
4-5 y		< 30	31-35	>36
6-12 y		< 26	27-30	>31
>12 y		< 23	24-27	>28
Retractions	None	Intercostal	Intercostal and substernal	Intercostal, substernal and supraclavicular
Dyspnea				
0-2 y	Normal Feeding, vocalizations, activity	1 of the following: Difficulty feeding, decreased vocalization or agitated	2 of the following: difficulty feeding, decreased vocalization, or agitated	Stops feeding, no vocalization, drowsy or confused.
2-4 y	Normal feeding, vocalizations, and play	1 of the following: decreased appetite, increased coughing after play, hyperactivity	2 of the following: decreased appetite, increased coughing after play, hyperactivity	Stops eating or drinking, stops playing, drowsy or confused.
> 5 y	Counts to >10 in 1 breath	Counts to 7-9 in 1 breath	Counts to 4-6 in 1 breath	Counts to <3 in 1 breath
Wheeze	Normal Breathing; no wheezing present	End Expiratory wheeze only	Expiratory wheeze only (greater than end-expiratory wheeze)	Inspiratory and expiratory wheeze or diminished breath sounds or both

Interpretation
Based on the total score obtained there can be 3 categories of respiratory distress: **Mild (<3), Moderate (4-7), Severe (8-12)**

Source: Liu LL, Gallaher MM, Davis RL, Rutter CM, Lewis TC, Marcuse EK. Use of a respiratory clinical score among different providers. Pediatric Pulmonology 2004 Mar;37(3):243-8. DOI: 10.1002/ppul.10425. PMID: 14966818.

**Assessment of Severity of Dehydration

	Percentage Dehydration in an Older Child		
	3% (30mL/kg)	6% (60mL/kg)	9% (90mL/kg)
	Percentage Dehydration in an Infant		
	5% (50mL/kg)	10% (100mL/kg)	15% (150mL/kg)
Examination			
Dehydration	Mild	Moderate	Severe
Skin Turgor	Normal	Tenting	None
Skin (Touch)	Normal	Dry	Clammy
Buccal Mucosa/lips	Dry	Dry	Parched/Cracked
Eyes	Normal	Deep Set	Sunken
Tears	Present	Reduced	None
Fontanelle	Flat	Soft	Sunken
Mental Status	Alert		Lethargic/Obtunded
Pulse Rate	Normal	Slightly Increased	Increased
Pulse Quality	Normal	Weak	Feeble/Impalpable
Capillary Refill	Normal	= 2-3 seconds	> 3 Seconds
Urine Output	Normal/mild oliguria	Mild Oliguria	Severe Oliguria

Note: Serum Sodium concentration affects the clinical manifestations of dehydration such as skin turgor and mucous membranes. For example, hyponatremia exaggerates instability, and hypernatremia maintains intravascular volume at the expense of intracellular volume

Source: Table from the Harriet Lane Handbook, 21st edition, John Hopkins Hospital, HK Hughes, LK Kahl, 2018. Data from Kleigman RM, Behrman RE, Jenson HB, et al: Nelson textbook of pediatrics, 18th ed. Philadelphia, WB Saunders, 2007 and Oski FA: Principles and practice of pediatrics, 4th Ed. Philadelphia, JB Lippincott, 2007.

Current Monoclonal Antibody Therapy available for children with Covid-19

Link to FDA **Emergency Use Authorization Statement** regarding use of Monoclonal Antibodies in COVID-19
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19#:~:text=Today%2C%20the%20U.S.%20Food%20and,88%20pounds%5D)%20with%20positive

Currently Available Monoclonal Antibody Therapies for COVID-19 at the U Health/Jackson System include:

Regeneron Antibody Cocktail (Casirivimab and Imdevimab)

In January 2022 FDA amended the EUA to exclude its use in geographic regions where infection or exposure is likely due to a variant that is not susceptible to the treatment. Therefore Regeneron Antibody Cocktail is not currently authorized for use in any US States, Territories or Jurisdictions

Special considerations:
- Casirivimab and Imdevimab must be administered together by intravenous infusion.
- Authorized dose is 1,200 mg of Casirivimab and 1,200 mg of Imdevimab. Start infusion as soon as possible after positive result and up to 10 days after the onset of symptoms.
- Infuse above dose over at least 60 min via pump or gravity. Max infusion rate is 250ml/hr.
- Should only be administered at a facility prepared to treat severe infusion reactions and to activate Emergency services, as necessary.
- Monitor patient for at least 1 hour after infusion is completed.
- Patients would still need to self-isolate and use infection control measures according to CDC guidelines.
- No dosage adjustment is recommended in pregnant/lactating woman/renal impairment.
- There is currently a Regeneron UM trial ongoing for prophylaxis in the pediatric population, see details at umiamihealthresearch.org or call 305-243-5684

Side effects:
- Anaphylaxis
- Infusion related reactions: Pyrexia, chills, urticaria, pruritus, abdominal pain, flushing
- Serious adverse events reported in clinical trial were not considered to be related to the study drug. Included pneumonia, hyperglycemia, nausea, vomiting, intestinal obstruction and dyspnea.

https://www.regeneron.com/covid19

Bamlanivimab

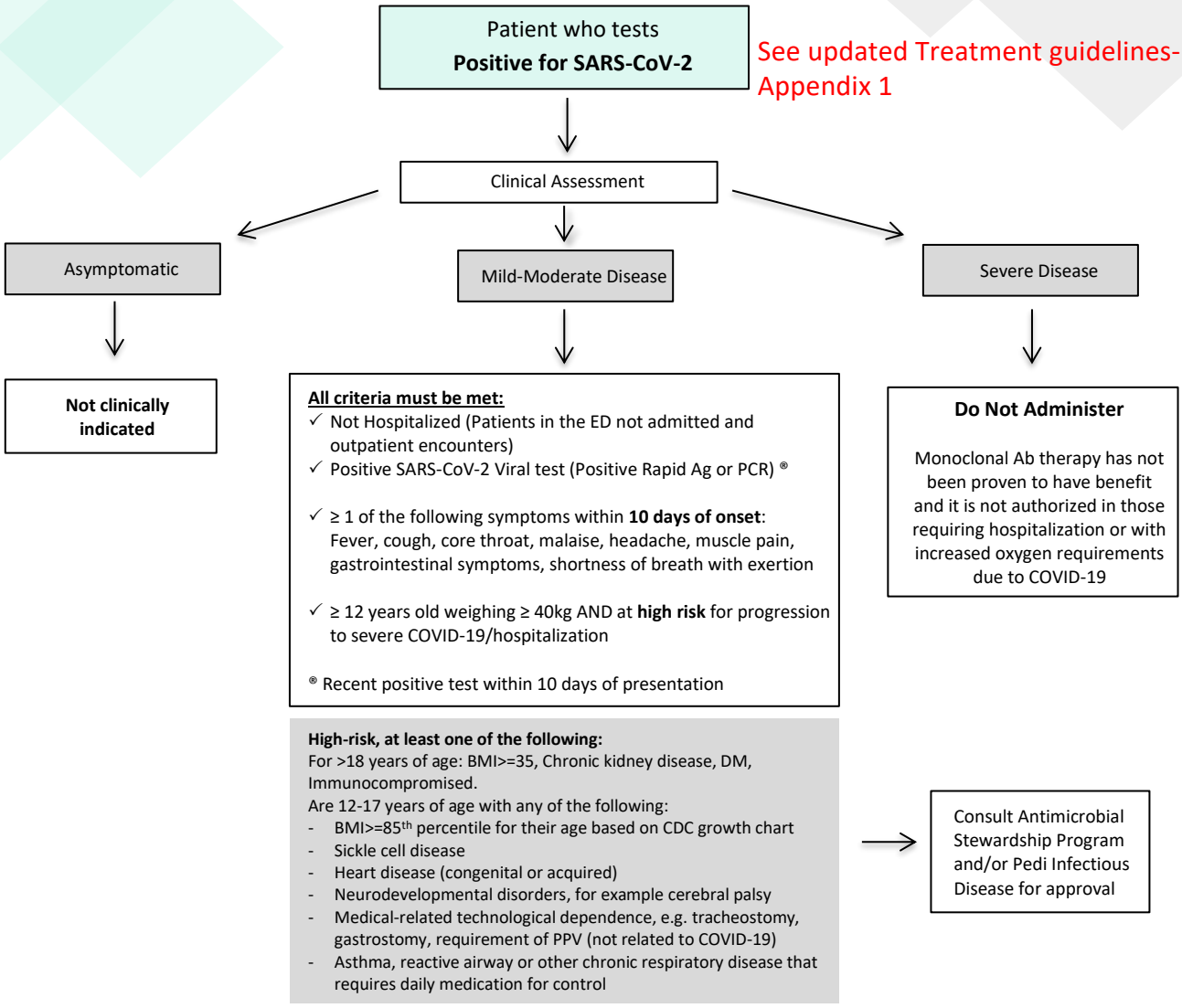
This is not currently authorized to treat any diseases or conditions including COVID 19 in any USA region

Special considerations:
- Authorize dosage of Bamlanivimab is a single intravenous infusion of 700 mg, administered over at least 60 minutes. Flush line after infusion with 25 mL of 0.9% sodium chloride to ensure delivery of total dose. Max infusion rate 200ml/hr.
- Use a dedicated line with a 0.2-micron filter.
- Administer as soon as possible after positive result and within 10 days of symptom onset.
- Monitor patient for at least 1 hour after infusion is complete.
- No dosage adjustment is recommended based on age, sex, race, body weight, renal or mild hepatic impairment, during pregnancy or while lactating.

Side effects:
- There are limited clinical data available for Bamlanivimab.
- Anaphylaxis
- Infusion related reactions: Pyrexia, chills, headache, bronchospasm, urticaria, angioedema, pruritus, flushing, myalgia, dizziness, throat irritation.
- Other side effects: Nausea, vomiting, diarrhea.

https://jhsmiami.org/stewardship/UploadData/834_docs/Bamlanivimab%20JHS%20Criteria%2011.19.20.pdf

JMH Protocol for Administration of Monoclonal Antibodies for children with Covid-19



Special considerations:
- The decision to use Regeneron versus Bamlanivimab is dependent on availability as well as physician preference
- There is currently ongoing research to determine the utility of Monoclonal Antibodies as Prophylaxis in individuals who are SARS-CoV2 Negative. Updates regarding criteria for administration will be added when they become available.

Guidance Regarding Isolation & Quarantine Duration

Updated from CDC guidelines Dec 3, 2020
https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html

- **For individuals who test positive for COVID-19**, a test-based strategy is no longer recommended to determine when to discontinue home isolation, except in certain circumstances (i.e. immunocompromised).
- **For asymptomatic patients,** isolation and other precautions can be discontinued 10 days after the date of their first positive Covid-19 test.
- **For symptomatic patients**, isolation and other precautions can be discontinued 10 days after symptom onset and resolution of fever for at least 24 hours without the use of antipyretics and with improvement of other symptoms.
- **For patients with severe illness**, duration of isolation for up to 20 days after symptom onset may be warranted. Consider Pedi Infectious disease consult.
- **Options to reduce quarantine for close contact of COVID Exposure**: On day 10 without testing or on day 7 after a negative test result (test must occur on day 5 or later). After stopping quarantine watch for symptoms until 14 days after exposure, if symptoms immediately self-isolate, continue following infection prevention recommendations.

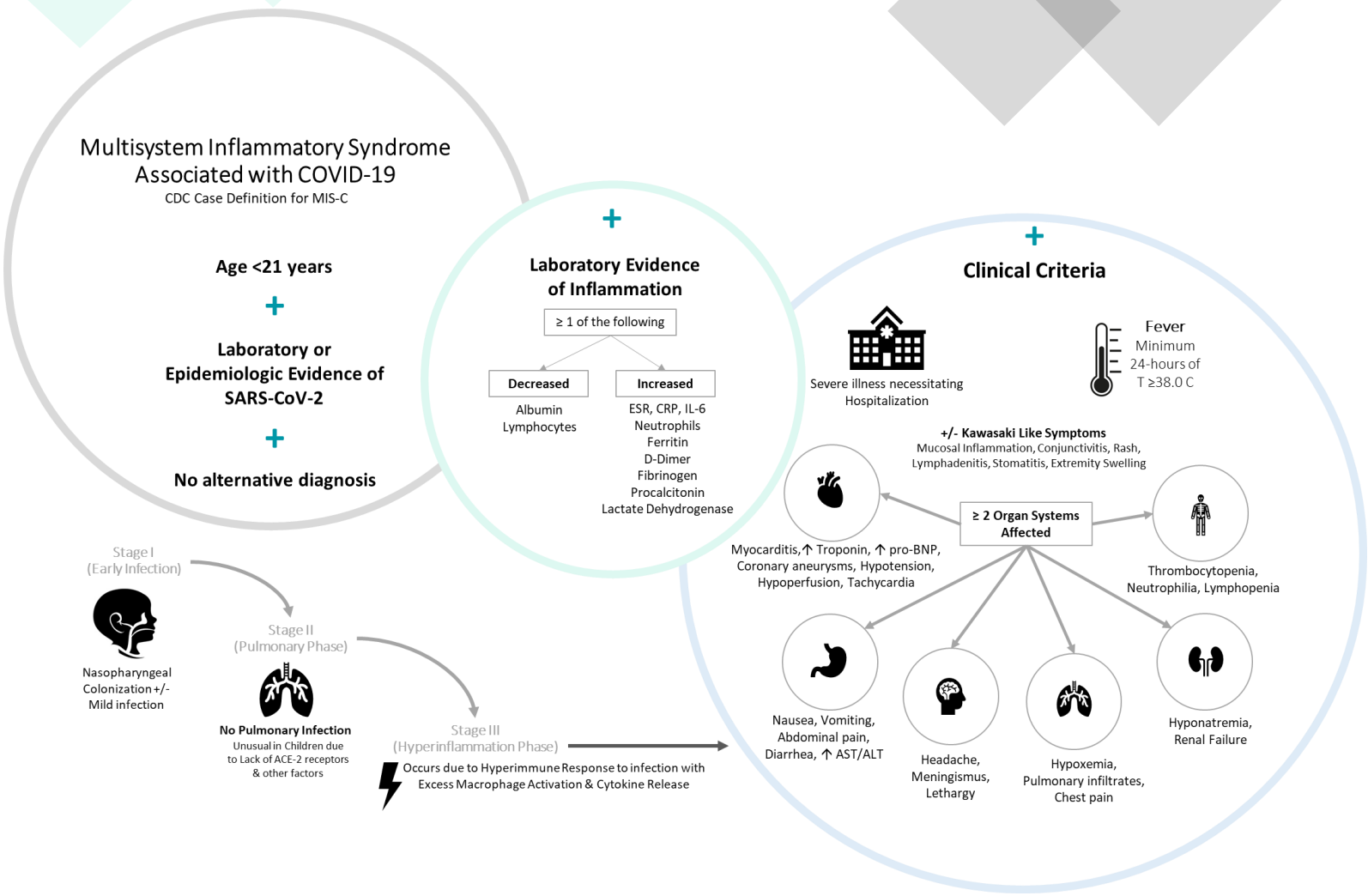


Diagram depicting the CDC Criteria for Diagnosis of Multi-System Inflammatory Syndrome Associated with COVID-19 infection and the Presumed Stages of Infection.

Adapted from: Infographic showing CDC criteria for the diagnosis of MIS-C. Published online 2020 Jul DOI: 10.3390/children7070069[3], Pathogenesis of MIS-C. Published online 2020 Jul 1. DOI: 10.3390/children7070069[3]

Outpatient Evaluation of Patients Suspected to have MIS-C

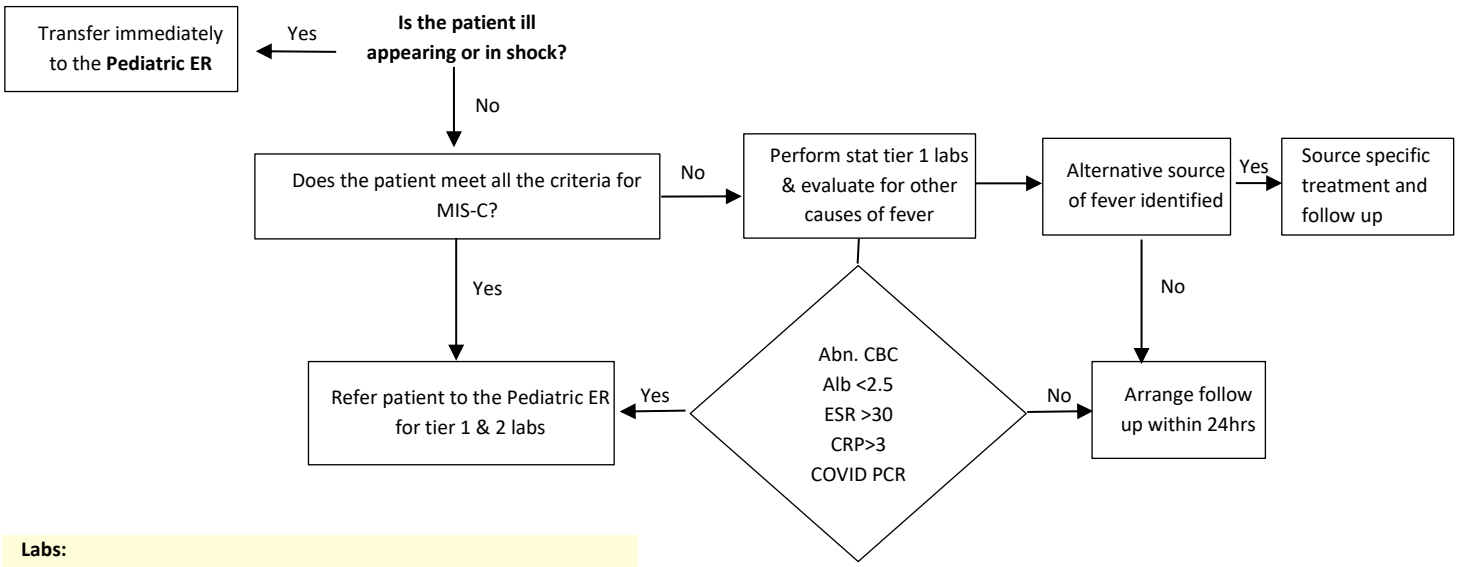
Modified based on the inpatient Holtz Children's Hospital cardiology protocol
Jackson Memorial Hospital

If an outpatient facility has the ability to perform rapid labs and is comfortable doing so, the following sequence of investigations can be done to stratify the risk for MIS-C in a patient with COVID-19. If this is not available, investigations can be performed in an urgent care or emergency room setting.

Consider MIS-C if:

- ✓ **Fever** >24 hours, usually **>3 days' duration increases concern for MIS-C**
- ✓ **Ill appearing**
- ✓ Any of the following: **GI symptoms**, Kawasaki-like symptoms, **Cardiovascular symptoms** (shock, palpitations, PE, tachycardia), **respiratory symptoms** (respiratory distress, hypoxia, chest pain, cough)
- ✓ Documented or suspected **prior exposure** to Covid-19 or acute illness

Kawasaki Disease Criteria
Complete 4-5/Incomplete 2-3
Fever >3 days
Bilateral conjunctival injection
Oral mucosal changes
Peripheral extremity changes
Rash (polymorphic)
Cervical adenopathy >1.5cm



Labs:
Tier 1: CBC, CRP, ESR, CMP, UA w/ reflex to culture, Blood culture SARS-CoV-2 PCR, COVID-19 Ab

Tier 2: D-dimer, Fibrinogen, LDH, Troponin, ProBNP, Ferritin, EKG, CXR

Special Considerations for Patients Diagnosed with MIS-C

Prognosis:
The Exact incidence of MIS-C following an asymptomatic or mildly symptomatic infection with SARS-CoV2 is not known[3]

Follow up:
Primary Care Physician: Within 24-72h after discharge
Pediatric Infectious Disease: Within 1 week with repeated labs (CBC, CRP, BNP, D-dimer, Ferritin)
Cardiology: Within two weeks from the initial echocardiogram. If Kawasaki disease, repeat echocardiogram at six weeks, if the patient has myocarditis or a large aneurysm, may need more frequent monitoring.

Vaccines:
If IVIG is given as therapy for Kawasaki disease (1600-2000 mg/kg), postpone live vaccines for 11 months. If IVIG must be given within 14 days after administration of measles- or varicella-containing vaccines, these vaccines should be administered again at 11 months.

Outpatient Treatment

To date there are no known medications that can prevent or treat COVID-19. Recommended management of COVID-19 illness is supportive care only. Below is the current evidence on medications often used or asked for in the outpatient setting:

1. **NSAIDS**: Acetaminophen is the preferred medication of choice for antipyretic and analgesic therapy due to limited data suggesting possible negative effects of NSAID use in COVID-19. Evidence to support worse outcomes with NSAID use is limited and bother the World Health Organization and the United States National Institutes of health (NIH) recommend NSAIDS be used when clinically indicated.[15, 16] Patients who take NSAIDS chronically should be advised to continue therapy as prescribed.[15] Patients who do not have adequate relief with acetaminophen alone can use NSAIDs at the lowest dose effective to control symptoms.
2. **Antibiotics**: There is no role for empiric antibiotics as treatment for COVID-19 illness. COVID-19 illness may present clinically similar to community acquired pneumonia. In situations where the diagnosis is unclear it may be reasonable to prescribe a course of antibiotics for community acquired pneumonia.
3. **Vitamins and Supplements**: Currently, there is insufficient evidence to support the use of vitamin C, vitamin D, or zinc for the treatment of COVID-19. [16]
4. **Corticosteroids**: Per the results of the Randomized Evaluation of COVID-19 Therapy (RECOVERY) trial, steroid medication is useful in patients with COVID-19 illness who require supplemental oxygen and who are mechanically ventilated. The NIH recommends dexamethasone 6 mg daily for up to 10 days only in patients who require supplemental oxygen and recommends against using steroids to treat patients who do not require supplemental oxygen. Steroids being used to treat underlying medical conditions prior to COVID-19 illness should not be discontinued during COVID-19 illness. [15]
5. **Bronchodilators**: To date there is no evidence to recommend the use of albuterol or other bronchodilators for treating COVID-19 illness in patients without any other indication to be using bronchodilators. Patients who use bronchodilators chronically for asthma, COPD, or other lung disease should be advised to continue using their bronchodilators as prescribed.
6. **Hydroxychloroquine**: Hydroxychloroquine or chloroquine should not be used to treat COVID-19. Per the National Health Institute, the use of hydroxychloroquine or chloroquine in the outpatient setting is only recommended in the setting of a clinical trial. The use of hydroxychloroquine plus azithromycin is only recommended in the setting of a clinical trial. [15]
7. **Regeneron (Casirivimab & Imdevimab):** Recombinant of 2 human monoclonal antibodies designed to block viral attachment and viral entry by non-competitive binding to Spike protein receptor binding domain. See Regeneron Antibody cocktail algorithm below for more details. Developed by Regeneron pharmaceutical company. For more information visit clinicaltrials.gov (Currently not authorized to be used in USA. See Appendix 1 for update).
8. **Bamlanivimab:** Recombinant neutralizing monoclonal antibody (IgG1 variant) directed against the spike protein of SARS-CoV-2 blocking attachment and entry into human cells through ACE2 receptor. Has shown to reduce Covid-19 related hospitalizations or ER visits in patient at high risk for disease progression within 28 days after treatment compared to placebo. See Bamlanivimab algorithm below for more details. Developed by Eli Lilly pharmaceutical company. For more information visit clinicaltrials.gov (Currently not authorized to be used in USA. See Appendix 1 for update).

Adjustment of Common Medications: For mild to moderate symptoms being monitored at home, chronic medications can likely be continued as normal. However, some examples of medications that may be temporarily decreased or discontinued are:

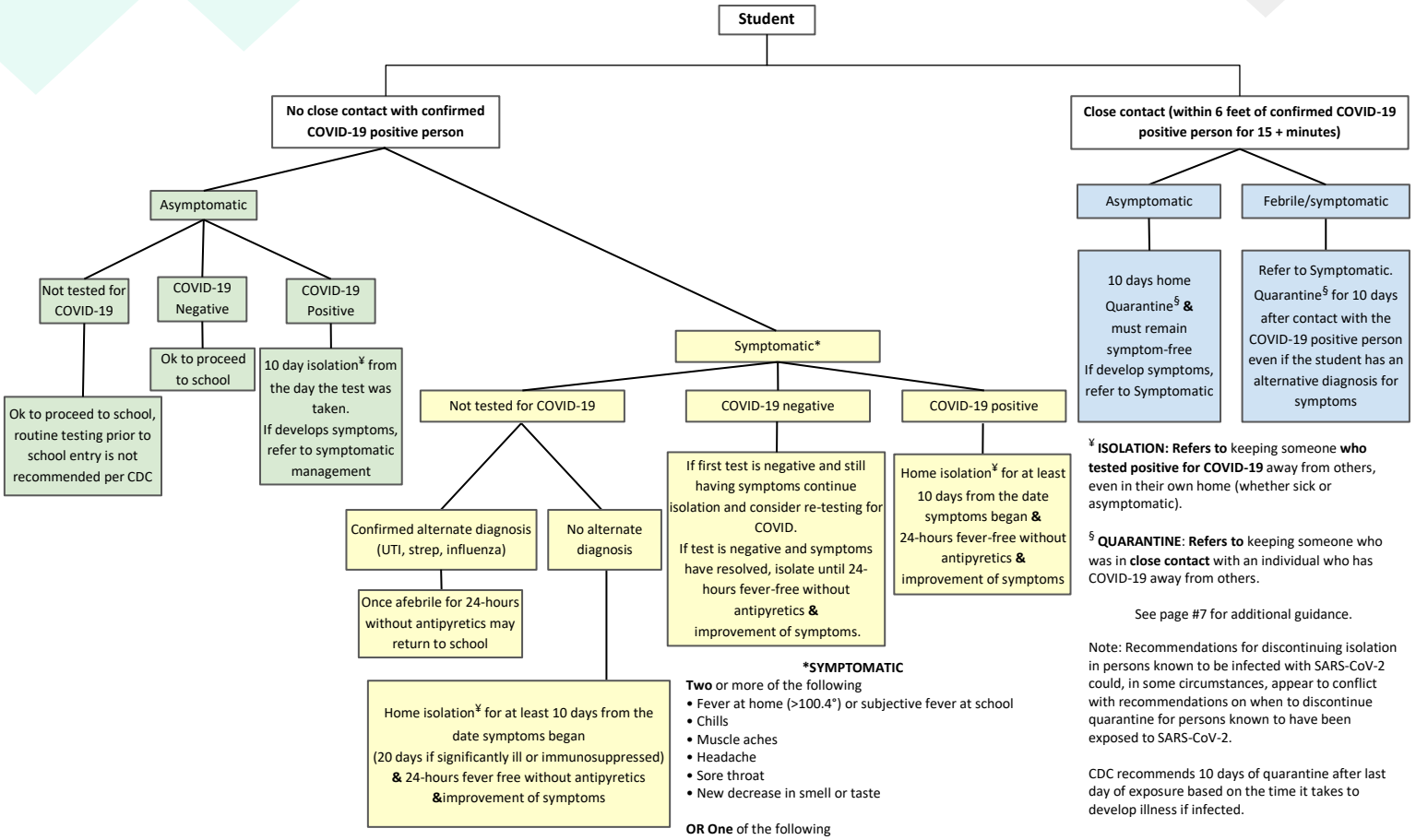
1. **Type 1 & 2 Diabetes Mellitus**: Modifications to insulin doses should be discussed with the patient's primary endocrinologist. Consider holding oral hypoglycemic agents and/or pre-prandial insulin for those who are not eating at baseline and are at high risk of hypoglycemia. Basal insulin can likely be continued as dosed but can be decreased by 50-80% if fasting glucose is dropping or <100.
2. **Hypertension**: Changes to the patient's medications should be discussed with the managing renal or cardiology team. At baseline, most antihypertensive agents should be continued as usual. There is no evidence to hold ace-inhibitors.
3. **Immunosuppressant medication**: Some are held during the acute illness phase. We recommend discussing with their specialist about the risks vs benefits of continued treatment while symptomatic.

Information Regarding Treatment Options for MIS-C in the Inpatient Setting

Drug Name & Class	Indications & Recommendations for Inpatient Use	Consequences Requiring Follow up
Remdesivir	Recommended for patients with severe Covid-19 over no antiviral treatment. Most benefits shown for patients on supplemental oxygen rather than patients on mechanical ventilation. A 5-day course is recommended to avoid side effects. Evidence indicates reduction of mortality at 14 days.[6]	No long-term side effects anticipated from short course of therapy.
Steroids	Indicated for patients with Severe Covid-19. Dexamethasone has shown to decrease the number of ventilator days and to reduce mortality when used for a 10-day course. There was no benefit shown in patients that did not require ventilator support. [5,6]	This short course does not require a steroid taper. Side effects such as weight gain, hypertension and elevated glucose are unlikely in the long-term setting.
IVIG	More studies are needed to determine efficacy of IVIG in Covid-19 but as the community develops antibodies, the possibilities of protective antibodies being present in the pooled product increases. No studies in children available at this time.[2]	Live Vaccines should be delayed for 11 months after administration. Vaccine titers and repeat dosing of some vaccines may be needed after IVIG use.
Aspirin	Low dose aspirin recommended in MIS-C pediatric patients unless contraindicated.[9] Duration to be determined by Cardiology Team	Monitor for GI upset and bleeding or easy bruising with use.
Enoxaparin Low Molecular Weight Heparin	Prophylaxis is recommended in critically ill pediatric patients with confirmed COVID-19 infection unless contraindicated.[10] Decision to continue therapy is dependent on the presence of thrombotic complications and should be guided by a hematologist.	Monitor for excessive bleeding or easy bruising. If therapy continued post discharge, duration to be determined by a specialist.
Tocilizumab IL-6 inhibitor	Recommended only in the setting of a clinical trial in the adult population. Considered in children for cytokine storm syndrome and MIS-C if fevers>24 hours post steroids/IVIG.[6]	Monitor for infections including TB, especially if concurrently taken with immunosuppression. Avoid live vaccines for 3 months
Anakinra IL-1 Inhibitor	Considered for cytokine storm syndrome in children.[11]	Monitor for infections including TB. Avoid live vaccines for 3 months
Lopinavir	Not recommended in children. For adults, only recommended under clinical trial.[6]	Monitor for Hyperglycemia which may persist after discontinuation.
NSAIDs	Initial data proposed that NSAIDs may worsen COVID-19. There is currently no data that correlates worst clinical outcomes in COVID-19 patients using NSAIDs.[12,13]	No long-term consequences from short term use expected. Frequent use may lead to GI upset from gastritis and Acute Kidney Injury.
Hydroxychloroquine	Safety of hydroxychloroquine in children is still controversial. Monotherapy with hydroxychloroquine in adults is currently only recommended under clinical trial.[5,6,8]	No long-term consequences from short term use expected. Myelosuppression seen with high doses and long-term use.
Azithromycin	Routine use of azithromycin is not recommended except for suspected superimposed bacterial pneumonia.[6]	No long-term consequences from short term use expected.
Convalescent plasma	Current research is controversial since evidence is under significant risk of confounding bias.[6]	No long-term consequences from short term use expected.

Back to School Guideline for the COVID-19 Pandemic

Adapted from the CDC; Back to School Planning: Checklists to Guide Parents, Guardians, and Caregivers https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/parent-checklist.html
The FCAAP: Recommendations Regarding School Reopening https://custom.cvent.com/EDE603C5145F48C8BBC5477DB676A0EB/files/444951ea982e446db7a77961aba82d66.pdf
The CDC: Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
The CDC: Public Health Guidance for Community-Related Exposure. https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html
CHOP Policy Lab, Policy Review: Evidence and Considerations for School Reopening. https://policylab.chop.edu/reports-and-tools/policy-review-evidence-and-considerations-school-reopenings



***SYMPTOMATIC**
Two or more of the following
- Fever at home (>100.4°) or subjective fever at school
- Chills
- Muscle aches
- Headache
- Sore throat
- New decrease in smell or taste

OR One of the following
- Cough
- Shortness of breath
- Difficulty breathing

¥ **ISOLATION: Refers to** keeping someone **who tested positive for COVID-19** away from others, even in their own home (whether sick or asymptomatic).

§ **QUARANTINE**: **Refers to** keeping someone who was in **close contact** with an individual who has COVID-19 away from others.

See page #7 for additional guidance.

Note: Recommendations for discontinuing isolation in persons known to be infected with SARS-CoV-2 could, in some circumstances, appear to conflict with recommendations on when to discontinue quarantine for persons known to have been exposed to SARS-CoV-2.

CDC recommends 10 days of quarantine after last day of exposure based on the time it takes to develop illness if infected.

Thus, it is possible that a person known to be infected could leave isolation earlier than a person who is quarantined

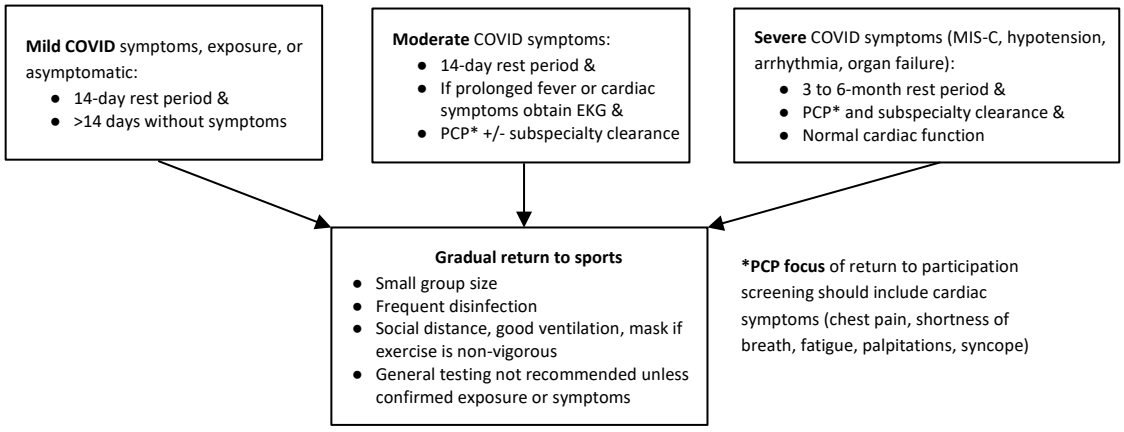
Please see local guidelines for your specific school district as instructions may differ between regions

Miami Dade: http://reopening.dadeschools.net/

Return to Sports Recommendations for Athletes Affected by COVID-19

Modified from the AAP: COVID-19 Interim Guidance: Return to Sports
https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-interim-guidance-return-to-sports/

Below is a graphical representation of the AAP guidance for return to sports intended to mitigate risk and specifically meant to help prevent the spread of COVID-19. Little is known about the long-term effects of COVID-19 infection on the physical health of the pediatric population and the recommendations below are based on current best practice for patients affected by myocardial disease.



***PCP focus** of return to participation screening should include cardiac symptoms (chest pain, shortness of breath, fatigue, palpitations, syncope)

Additional Resources

Red Book® 2018

Committee on Infectious Diseases; American Academy of Pediatrics; David W. Kimberlin, MD, FAAP; Michael T. Brady, MD, FAAP; Mary Anne Jackson, MD, FAAP; Sarah S. Long, MD, FAAP

https://redbook.solutions.aap.org/selfserve/sspage.aspx?selfservecontentid=rbo_outbreaks_page_3

Florida HEALTH Miami-Dade County

COVID-19 Call Center Available 24/7
Phone: +1 (866) 779-6121
Email: COVID-19@flhealth.gov

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Breastfeeding: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Breastfeeding/Pages/default.aspx
COVID-19: https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/

Ambulatory Care Center West 5C
1611 NW 12th Ave, Miami, FL, 33136
Phone: + 1 (305) 585-7456

Children's Hospital of Philadelphia®

Outpatient: https://www.chop.edu/clinical-pathway/2019-novel-coronavirus-ambulatory-clinical-pathway
Inpatient: https://www.chop.edu/clinical-pathway/2019-novel-coronavirus-emergency-clinical-pathway

CDC Centers for Disease Control and Prevention

Centers for Disease Control
Phone: + 1 (800) 232-4636
https://www.cdc.gov/coronavirus/2019-ncov/index.html

CHILDREN'S HOSPITAL OF THE KING'S DAUGHTERS

https://www.chkd.org/uploadedFiles/Documents/COVID-19/CHKD%20COVID%2019%20treatment%20guideline.pdf
https://www.chkd.org/uploadedFiles/Documents/COVID-19/CHKD%20MIS-C%20Guideline%20D2.pdf

World Health Organization

https://www.who.int/emergencies/diseases/novel-coronavirus-2019

Community Resources

Government based organizations for assistance with food & housing insecurity

Food Distribution Events
https://www.miamidade.gov/global/initiatives/coronavirus/assistance/food.page

The Emergency Food Assistance Program
https://www.fdacs.gov/Food-Nutrition/Nutrition-Programs/The-Emergency-Food-Assistance-Program-TEFAP

WIC Support Services
http://miamidade.floridahealth.gov/programs-and-services/wic/_documents/wic-program-locations-covid19-100120.pdf

Miami-Dade County Temporary Housing Program:
Call 305-614- 1716 from 8 am and 5 pm daily
https://www.miamidade.gov/releases/2020-07-18-mayor-COVID-hotels.asp

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POSITVE COVID-19: Care of the Patient Perioperative Protocol

All confirmed COVID pts intubated in negative pressure room PRIOR to entering OR Suite: Minimum 1 hr notice from sending unit prior to direct transport to OR

	Charge RN (Desk)	OR/GI Runner (RN preferred)	RN Circulator	Anesthesia Team	Surgical/GI Technician
Pre Procedure *Prior to arrival of pt into room*	1. Activate Team, use only dedicated OR suite 2. Minimize staff assigned to OR suite 3. Ensure COVID supply cart is available for team 4. Notify EVS Supervisor that Terminal cleaning wll be needed after case. (Clorox 360;UV)	1. Place isolation sign on OR suite door 2. Anticipate all equipment and supplies needed using preference card 3. Ensure COVID supply cart stocked using inventory list 4. Ensure PPE available for all staff entering OR suite 5. Traffic control in corridor as needed	1. Wipe down all horizontal and high touch items in OR suite 2. Perform PPE safety pause as team prior to pt arrival(PPE Kit) 3. Anticipate equipment/ supplies needed using preference card 4. Ensure instrument case cart is outside OR 5. Ensure COVID supply cart is outside of OR	1. Verify anesthesia cart is stocked and is outside OR suite (Anes Tech/ PUA) 2. Perform PPE safety pause as team prior to pt arrival(PPE Kit) 3.All meds needed for case will be prepared and brought into OR.	1. Perform PPE safety pause as team prior to pt arrival(PPE Kit) 2. Ensure instrument case cart and all supplies needed are in OR suite 3. Communicate any needs to OR Runner & RN Circulator
	Don PPE				
	PPE SAFETY PAUSE AS A TEAM				
	Enter Room – Once in Room must stay for entirety of procedure-Use OR Runner as needed				
Intra Procedure	1. Be available for support/additional needs. (blood)	1. Assist with additional supply/lab needs i.e. blood 2. Traffic control in corridor as needed	1. Unused consumables/meds MUST be discarded in OR Suite prior to patient leaving 2. Specimens to be double bagged 3. Specimens to be sent direct to Lab, transporter to don non sterile gloves		
			Perform Procedure ***Do not enter and exit OR Suite unless coordinated with Charge RN/Desk***		
Post Procedure	1. Activate EVS for terminal cleaning of OR Suite	1. Facilitate transfer of patient/assist Circulator as needed (i.e. transfer from OR table to transport bed) 2. Monitor doffing of any staff exiting OR Suite (Trained staff can monitor each other for doffing if needed)	1. Inform Charge RN/OR Desk of any needs outside of procedure room 2. Notify receiving team timely to ensure proper coordination for transportation **3. Transport patient back to unit:** A. Doff all PPE except N95, If not visibly soiled, same N95 may be used for transport. B. Don new PPE per intra-hospital transport protocol as needed		**1. Break down OR/GI setup, Pretreat/spray instruments/GI scope per policy double** **2 .Double bag used GI scopes with biohazard bags.** **3. Send GI Scope/dirty case cart via dumb waiter only** **4. Remove used PPE per doffing protocol** ***N95 & hair cover should remain on**
	Facilitate Transfer of Patient				
	Doff PPE				
	Exit Room				
Follow-Up	1. Delegate staff member to wipe down and restock COVID cart, anesthesia cart etc.	1. Wipe down and restock COVID supply cart	DE-BRIEF POST PATIENT TRASPORT		

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OUTPATIENT & SAME DAY SURGERY COVID-19: Perianesthesia Protocol

NO COVID+ outpatients will be scheduled unless deemed urgent/emergent. Outpatient COVID Testing Workflow Appendix 13 of JHS COVID19 Protocol Document MUST BE FOLLOWED PRIOR TO OUTPATIENT PROCEDURES.

	Registration/PAT	Perianesthesia Runner/Preop Charge Nurse	Preop Nurse	Anesthesia& Procedural Team	PACU RN
Prior to arrival to Preop Areas	1. Day of surgery, patient arrives to DTC Registration (DTC OR/IR) Security check at all entry points: masks on persons entering Hospital. VUMI Guest Services Staff provides mask (SURGICAL Mask) for patient/accompanying adults & notifies patient access of patient arrival *All patients treated as PUI **1. Is patient on REGISTRATION BYPASS LIST?** **YES→** Activate surgical encounter, ID pt and place arm band & notify OR Front Desk/Preop **NO→** Register patient, isolate pt 2. When Preop area calls for patient, patient is transported to Preop area. *3. Accompanying adult to designated waiting area*	1. Preop RN will verify COVID testing results prior to entering Preop Areas. **CONFIRMED NEGATIVE COVID RESULT:** DTC Preop RN will proceed with preparing patient for procedure UNKNOWN COVID STATUS / NO COVID TEST PREOP: Patient to be transported to Preanesthesia testing (PAT rm C130) PAT RN to administer the rapid testing Patient to wait in DTC waiting area, ensuring social distancing and mask in place *(May change procedure time as needed by admin)* If negative COVID confirmed: Patient to be transported to DTC Preop Area If positive COVID confirmed: Escalate to Perioperative Medical Direct or designee --If determined to postpone surgery- Patient to be sent home with return to clinic instructions re-testing per Attending Surgeon. **--If determined to proceed with surgery, patient will be taken to designated positive Preop Area**			

All patients transported to Preop & OR Areas per APPENDIX 5-Intra-Hospital Transportation of COVID-19 Patients & Patients under Investigation (PUI) SOP of JHS COVID19 Protocol document. Intra-Hospital Transportation # 85-6180 to be called for all COVID positive patient transports
All transports will be coordinated with Public Safety (to clear and secure area) and Environmental Services (EVS) (to disinfect the hallways and elevators immediately after the patient has been transported). The direct phone line for Public Safety is 85-6111 and EVS is 85-7270.

Preop Area: DTC (All PEDS & confirmed negative COVID19 patients)	**PAT**(pre-anesthesia testing): TO ENSURE ALL ELEMENTS OF PREOP CHECKLIST ARE COMPLETED PRIOR TO DAY OF SURGERY. *If a consent is outstanding on day of procedure for COVID+ patients, an oral/verbal consent can be executed. Provider must ensure risk and benefits discussion is documented, preferably within H&P/23 hr note.*		1. Perform normal preoperative patient preparation duties.	1. Perform normal preoperative patient preparation duties.	
Preop Area: SW3 (All confirmed positive COVID19 patients) *SW 3: Spot 12 is negative pressure, can be used for intubation as needed*		**Don PPE** Anesthesia to wear gown for intubation and only remove gown after intubation, perform hand hygiene. All other PPE remains on (N95, Face shield stay on). **PPE SAFETY PAUSE**			
All NEGATIVE PEDS and GI patients will be prepped in SW3		1. Ensure COVID supply cart is stocked and available 2. Assist with additional supply/ lab needs i.e. blood 3. Monitor donning/doffing of any staff 4. Traffic control as needed 5. Facilitate transfer from Preop to Procedure Area with Public Safety	1. Wipe down all horizontal & high touch items in Preop bay area before and after pt goes to OR; Call EVS once pt transferred out of preop area. Coordinate for Decontamination of bay used. 2. All equip/ supplies are outside of pt bay; where possible use disposable/dedicated items 3. Perform normal preop pt preparation duties.	1. Perform normal preoperative patient preparation duties. 2. Consider safety measures needed to protect staff, and patients in the area. PPE PRESERVATION: **Procedural Staff/Anesthesia should transport pt to procedure area directly after pt assessment/ interview;do not doff until after procedure completed.*	
PEDS confirmed COVID+ pts: Pre-op in BMT ET7. Will be scheduled as last case of the day in OR 90. Will be recovered in OR, D/C home from BMT unit.					
RECOVERY (DTC PACU-All confirmed negative pts)	**NO VISITORS ALLOWED IN ADULT PREOP OR POSTOP AREAS** ****Case by case:** **Peds/mother baby patients**	1. Communicate w/ PACU RN recovering in Procedure Area Suites-assist as needed for recovery *MEDS & supplies packs 2. Coordinate D/C needs with Recovery RN & OR front Desk (transport back to preop area for D/C) contact responsible adult for transport home (To designated pick up area)		1. Anesthesia to extubate pt and wait for 28 minutes minimum for air exchanges before leaving OR & provide handoff to Recovery RN *(PACU RN to recover pt in procedure area after extubation and air exchanges)* 2. Procedure Area RN to act as 2nd recovery RN for phases I & II	A. Recover pt per ASPAN standards B. Procedure Area RN to be 2nd RN C. Discharge pt (D/C instructions, obtain wheelchair & transport to home) C. Only D/C to home after Anes sign off in EMR D. Transport pt to area where they were prepped for D/C home once D/C criteria met
All COVID+ pts will be recovered in Procedure suites; TOR: **Trauma Recovery spot 1 is negative pressure, may be used if needed.**				**Doff PPE ONLY AFTER Exiting Procedure Area-perform hand hygiene** Procedure Area/front desk to coordinate terminal cleaning of room	

COVID-19 GUIDELINES

For Returning to Work

Jackson Health System has changed its return-to-work policy for employees who have tested positive for COVID-19. The process has also been streamlined by using a tool on JacksonBadgeBuddy.org to make it faster and easier to be cleared to return to work.

Employees, regardless of vaccination status, can return to work after 5 days – not 10 – if they meet ALL of the following criteria:

- Asymptomatic, including no fever for at least 24 hours without fever-reducing medicine.
- Wearing an N95 mask for an additional five days at all times while in Jackson facilities. Employees who are unvaccinated and working under a medical or religious exemption should wear an N95 mask at all times while at work, regardless of their COVID status.

Employees should use the process above once they are feeling better between days 5 and 9. Employees who are symptomatic or immunocompromised will be required to wait 10 days, in addition to following the other criteria listed above.

All employees, regardless of vaccination or symptom status, are required to log into the tool on JacksonBadgeBuddy.org and complete the attestation.

Employees should reference JacksonCOVID19.org for information on Jackson employee testing locations and hours of operation.

Jackson HEALTH SYSTEM

Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2

Updated Sept. 23, 2022

Summary of Recent Changes

Updates as of September 23, 2022

- In most circumstances, asymptomatic HCP with higher-risk exposures **do not** require work restriction.
- Updated recommendations for testing frequency to detect potential for variants with shorter incubation periods and to address the risk for false negative antigen tests in people without symptoms.

Previous updates

Key Points

- In general, asymptomatic HCP who have had a higher-risk exposure do not require work restriction, regardless of vaccination status, if they do not develop symptoms or test positive for SARS-CoV-2.

Background

This interim guidance is intended to assist with the following:

1. Determining the duration of restriction from the workplace for HCP with SARS-CoV-2 infection.
2. Assessment of risk and application of workplace restrictions for asymptomatic HCP with exposure to SARS-CoV-2.

Guidance addressing recommended infection prevention and control practices including use of source control by HCP is available in Infection Control: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Employers should be aware that other local, territorial, tribal, state, and federal requirements may apply, including those promulgated by the Occupational Safety and Health Administration (OSHA).

Evaluating Healthcare Personnel with Symptoms of SARS-CoV-2 Infection

HCP with even mild symptoms of COVID-19 should be prioritized for viral testing with nucleic acid or antigen detection assays.

When testing a person with symptoms of COVID-19, negative results from at least one viral test indicate that the person most likely does not have an active SARS-CoV-2 infection at the time the sample was collected.

- If using NAAT (molecular), a single negative test is sufficient in most circumstances. If a higher level of clinical suspicion for SARS-CoV-2 infection exists, consider maintaining work restrictions and confirming with a second negative NAAT.
- If using an antigen test, a negative result should be confirmed by either a negative NAAT (molecular) or second negative antigen test taken 48 hours after the first negative test.

For HCP who were initially suspected of having COVID-19 but, following evaluation, another diagnosis is suspected or confirmed, return-to-work decisions should be based on their other suspected or confirmed diagnoses.

Return to Work Criteria for HCP with SARS-CoV-2 Infection

The following are criteria to determine when HCP with SARS-CoV-2 infection could return to work and are influenced by severity of symptoms and presence of immunocompromising conditions. After returning to work, HCP should self-monitor for symptoms and seek re-evaluation from occupational health if symptoms recur or worsen. If symptoms recur (e.g., rebound) these HCP should be restricted from work and follow recommended practices to prevent transmission to others (e.g., use of well-fitting source control) until they again meet the healthcare criteria below to return to work unless an alternative diagnosis is identified.

HCP with mild to moderate illness who are *not* moderately to severely immunocompromised could return to work after the following criteria have been met:

- At least 7 days have passed *since symptoms first appeared* if a negative viral test* is obtained within 48 hours prior to returning to work (or 10 days if testing is not performed or if a positive test at day 5-7), **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications, **and**
- Symptoms (e.g., cough, shortness of breath) have improved.

*Either a NAAT (molecular) or antigen test may be used. If using an antigen test, HCP should have a negative test obtained on day 5 and again 48 hours later

HCP who were asymptomatic throughout their infection and are *not* moderately to severely immunocompromised could return to work after the following criteria have been met:

- At least 7 days have passed since the date of their first positive viral test if a negative viral test* is obtained within 48 hours prior to returning to work (or 10 days if testing is not performed or if a positive test at day 5-7).

*Either a NAAT (molecular) or antigen test may be used. If using an antigen test, HCP should have a negative test obtained on day 5 and again 48 hours later

HCP with severe to critical illness who are *not* moderately to severely immunocompromised could return to work after the following criteria have been met:

- At least 10 days and up to 20 days have passed *since symptoms first appeared,* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications, **and**
- Symptoms (e.g., cough, shortness of breath) have improved.
- The test-based strategy as described below for moderately to severely immunocompromised HCP can be used to inform the duration of work restriction.

The exact criteria that determine which HCP will shed replication-competent virus for longer periods are not known. Disease severity factors and the presence of immunocompromising conditions should be considered when determining the appropriate duration for specific HCP. For a summary of the literature, refer to Ending Isolation and Precautions for People with COVID-19: Interim Guidance (cdc.gov)

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HCP who are moderately to severely immunocompromised may produce replication-competent virus beyond 20 days after symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test

symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test.

- Use of a test-based strategy (as described below) and consultation with an infectious disease specialist or other expert and an occupational health specialist is recommended to determine when these HCP may return to work.

Test-based strategy

HCP who are symptomatic could return to work after the following criteria are met:

- Resolution of fever without the use of fever-reducing medications, **and**
- Improvement in symptoms (e.g., cough, shortness of breath), **and**
- Results are negative from at least two consecutive respiratory specimens collected 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT.

HCP who are not symptomatic could return to work after the following criteria are met:

- Results are negative from at least two consecutive respiratory specimens collected 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT.

Return to Work Criteria for HCP Who Were Exposed to Individuals with Confirmed SARS-CoV-2 Infection

Exposures that might require testing and/or restriction from work can occur both while at work and in the community. Higher-risk exposures generally involve exposure of HCP's eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if these HCP were present in the room for an aerosol-generating procedure.

Other exposures not classified as higher-risk, including having body contact with the patient (e.g., rolling the patient) without gown or gloves, may impart some risk for transmission, particularly if hand hygiene is not performed and HCP then touch their eyes, nose, or mouth. When classifying potential exposures, specific factors associated with these exposures (e.g., quality of ventilation, use of PPE and source control) should be evaluated on a case-by-case basis. These factors might raise or lower the level of risk; interventions, including restriction from work, can be adjusted based on the estimated risk for transmission.

For the purposes of this guidance, higher-risk exposures are classified as HCP who had prolonged[1] close contact[2] with a patient, visitor, or HCP with confirmed SARS-CoV-2 infection[3] and:

- HCP was not wearing a respirator (or if wearing a facemask, the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask)[4]
- HCP was not wearing eye protection if the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask
- HCP was not wearing all recommended PPE (i.e., gown, gloves, eye protection, respirator) while present in the room for an aerosol-generating procedure

Following a higher-risk exposure, HCP should:

- Have a series of three viral tests for SARS-CoV-2 infection.
  - Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.
  - Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who have recovered in the prior 31-90 days; however, an antigen test instead of NAAT is recommended. This is because some people may remain NAAT positive but not be infectious during this period.
- Follow all recommended infection prevention and control practices, including wearing well-fitting source control, monitoring themselves for fever or symptoms consistent with COVID-19, and not reporting to work when ill or if testing positive for SARS-CoV-2 infection.

- Any HCP who develop fever or symptoms consistent with COVID-19 should immediately self-isolate and contact their established point of contact (e.g., occupational health program) to arrange for medical evaluation and testing.

Work restriction is not necessary for most asymptomatic HCP following a higher-risk exposure, regardless of vaccination status. Examples of when work restriction may be considered include:

- HCP is unable to be tested or wear source control as recommended for the 10 days following their exposure;
- HCP is moderately to severely immunocompromised;
- HCP cares for or works on a unit with patients who are moderately to severely immunocompromised;
- HCP works on a unit experiencing ongoing SARS-CoV-2 transmission that is not controlled with initial interventions;

If work restriction is recommended, HCP could return to work after either of the following time periods:

- HCP can return to work after day 7 following the exposure (day 0) if they do not develop symptoms and all viral testing as described for asymptomatic HCP following a higher-risk exposure is negative.
- If viral testing is not performed, HCP can return to work after day 10 following the exposure (day 0) if they do not develop symptoms.

In addition to above:

- HCP should follow all recommended infection prevention and control practices, including wearing well-fitting source control, monitoring themselves for fever or symptoms consistent with COVID-19, and not reporting to work when ill or if testing positive for SARS-CoV-2 infection.
- Any HCP who develop fever or symptoms consistent with COVID-19 should immediately contact their established point of contact (e.g., occupational health program) to arrange for medical evaluation and testing.

HCP with travel or community exposures should consult their occupational health program for guidance on need for work restrictions. In general, HCP who have had prolonged close contact with someone with SARS-CoV-2 in the community (e.g., household contacts) should be managed as described for higher-risk occupational exposures above.

Footnotes:

1. For this guidance an exposure of 15 minutes or more is considered prolonged. This could refer to a single 15-minute exposure to one infected individual or several briefer exposures to one or more infected individuals adding up to at least 15 minutes during a 24-hour period. However, the presence of extenuating factors (e.g., exposure in a confined space, performance of aerosol-generating procedure) could warrant more aggressive actions even if the cumulative duration is less than 15 minutes. For example, **any duration** should be considered prolonged if the exposure occurred during performance of an aerosol generating procedure.
2. For this guidance it is defined as: a) being within 6 feet of a person with confirmed SARS-CoV-2 infection or b) having unprotected direct contact with infectious secretions or excretions of the person with confirmed SARS-CoV-2 infection. Distances of more than 6 feet might also be of concern, particularly when exposures occur over long periods of time in indoor areas with poor ventilation.
3. Determining the time period when the patient, visitor, or HCP with confirmed SARS-CoV-2 infection could have been infectious:
    a. For individuals with confirmed COVID-19 who developed symptoms, consider the exposure window to be 2 days before symptom onset through the time period when the individual meets criteria for discontinuation of Transmission-Based Precautions
    b. For individuals with confirmed SARS-CoV-2 infection who never developed symptoms, determining the infectious period can be challenging. In these situations, collecting information about when the asymptomatic individual with SARS-CoV-2 infection may have been exposed could help inform the period when they were infectious.
        i. If the date of exposure cannot be determined, although the infectious period could be longer, it is reasonable to use a starting point of 2 days prior to the positive test through the time period when the individual meets criteria for discontinuation of Transmission-Based Precautions for contact tracing.
4. While respirators confer a higher level of protection than facemasks and are recommended when caring for patients with SARS-CoV-2 infection, facemasks still confer some level of protection to HCP, which was factored into this risk

assessment if the patient was also wearing a cloth mask or facemask

Definitions:

Healthcare Personnel (HCP): HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, home healthcare personnel, physicians, technicians, therapists, phlebotomists, pharmacists, dental healthcare personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel). For this guidance, HCP does not include clinical laboratory personnel.

Immunocompromised: For the purposes of this guidance, moderate to severely immunocompromising conditions include, but might not be limited to, those defined in the Interim Clinical Considerations for Use of COVID-19 Vaccines.

- Other factors, such as end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about need for work restriction if the HCP had close contact with someone with SARS-CoV-2 infection. However, people in this category should still consider continuing to practice physical distancing and use of source control while in a healthcare facility, even if they have received all COVID-19 vaccine doses, including booster dose, as recommended by CDC.
- Ultimately, the degree of immunocompromise for the HCP is determined by the treating provider, and preventive actions are tailored to each individual and situation.

SARS-CoV-2 Illness Severity Criteria (adapted from the NIH COVID-19 Treatment Guidelines)

The studies used to inform this guidance did not clearly define “severe” or “critical” illness. This guidance has taken a conservative approach to define these categories. Although not developed to inform decisions about duration of Transmission-Based Precautions, the definitions in the National Institutes of Health (NIH) COVID-19 Treatment Guidelines are one option for defining severity of illness categories. The highest level of illness severity experienced by the patient at any point in their clinical course should be used when determining the duration of Transmission-Based Precautions.

Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal chest imaging.

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

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

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

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

Fever: For the purpose of this guidance, fever is defined as subjective fever (feeling feverish) or a measured temperature of 100.0°F (37.8°C) or higher. Note that fever may be intermittent or may not be present in some people, such as those who are elderly, immunocompromised, or taking certain fever-reducing medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDS]).

Facemask: OSHA defines facemasks as "a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as 'medical procedure masks'." Facemasks should be used according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Other facemasks, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

Respirator: A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators are certified by CDC/NIOSH, including those intended for use in healthcare.

Cloth mask: Textile (cloth) covers that are intended primarily for source control in the community. **They are not personal protective equipment (PPE) appropriate for use by healthcare personnel.** Guidance on design, use, and maintenance of cloth masks is available.

More Information

Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Strategies to Mitigate Healthcare Personnel Staffing Shortages

Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022 | MMWR (cdc.gov)

Summary of Changes

As of December 23, 2021

Due to concerns about increased transmissibility of the SARS-CoV-2 Omicron variant, this guidance is being updated to enhance protection for healthcare personnel (HCP), patients, and visitors, and to address concerns about potential impacts on the healthcare system given a surge of SARS-CoV-2 infections. These updates will be refined as additional information becomes available to inform recommended actions.

- Ensure that SARS-CoV-2 testing is performed with a test that is capable of detecting SARS-CoV-2, even with currently circulating variants in the United States.
- Updated recommendations regarding when HCP with SARS-CoV-2 infection could return to work
- The definition of higher-risk exposure was updated to include use of a facemask (instead of a respirator) by HCP if the infected patient is not also wearing a facemask or cloth mask.
- Added options that would allow asymptomatic HCP with a higher-risk exposure who have not received all COVID-19 vaccine doses, including booster dose, as recommended by CDC to return to work prior to the previously recommended 14-day post-exposure period of work restriction, assuming they do not develop symptoms or test positive for SARS-CoV-2.

As of September 10, 2021

The interim guidance was updated to:

- Combine information from previously posted CDC guidance addressing when healthcare personnel (HCP) with SARS-CoV-2 infection could return to work and risk assessment and work restriction for HCP with higher-risk exposure to SARS-CoV-2
- Clarify the recommended intervals for testing asymptomatic HCP with a higher-risk exposure.

As of March 10, 2021

- Clarified that asymptomatic HCP who are fully vaccinated and have a higher-risk exposure as described in this guidance do not need to be restricted from work; possible exceptions and additional information is available here.

As of February 16, 2021:

- Clarified that work restriction of asymptomatic HCP with a higher-risk exposure who have recovered from SARS-CoV-2 infection in the prior 3 months might not be necessary. Additional information about this scenario is available here.
- Clarified that work restriction of fully vaccinated HCP with a higher-risk exposure continues to be recommended. Additional information is available here.

Updates as of Dec 14, 2020:

- Include a link to the Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2, which provides guidance on testing potentially exposed healthcare personnel.
- Clarify that, in general, healthcare personnel with travel or community-associated exposures where quarantine is recommended should be excluded from work for 14 days after their last exposure.

Last Updated Sept. 23, 2022

Appendix 5

ACEP COVID-19 Field Guide

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Behavioral Health Patients

Special Populations

Joint Statement for Care of Patients with Behavioral Health Emergencies and Suspected or Confirmed COVID-19

Joint Statement by the American Association for Emergency Psychiatry, American College of Emergency Physicians, American Psychiatric Association, Coalition on Psychiatric Emergencies, Crisis Residential Association, and Emergency Nurses Association

As with environmental disasters and other crises, pandemics can exceed people's usual coping skills and capacity, which, in turn, can lead to problems with anxiety, depression, and increased use of substances as well as exacerbation of underlying psychiatric disorders. Factors including, but not limited to, social and physical isolation, uncertainty, fear, evolving facts, changes in how individuals access outpatient care, and public health recommendations can contribute to this stress. People with and without pre-existing psychiatric illnesses can be impacted, which then contributes to a number of challenges for our already taxed emergency and crisis health care systems.

The most severely ill people with psychiatric illnesses have high rates of baseline medical comorbidity, have reduced access to primary care medical resources, and may lack resources to participate in telehealth services. As a result, this group may be more vulnerable to COVID-19 and have limitations in accessing services other than in emergency and crisis settings.[1]

For care of behavioral health patients with suspected or confirmed COVID-19:

1. Encourage preparedness by supporting education and training on the treatment of psychiatric disorders and best practices for the care of behavioral health patients. Consult educational resources, including:
   a. ACEP's resources on "Mental Health and Substance Use Disorders (/by-medical-focus/mental-health-and-substanc-use-disorders/)";
   b. Emergency Medicine Foundation's "CPE Resources (https://www.emfoundation.org/em-resources/coalition-on-psychiatric-emergencies/cpe-resources/)"; and
   c. Psych Hub's "COVID-19 Mental Health Resource Hub (https://psychhub.com/covid-19/)."
2. Provide staff with appropriate and adequate PPE.

3. Encourage the use of existing, available behavioral health crisis services to mitigate unnecessary visits to the emergency department for psychiatric emergencies or for diverting people from psychiatric hospitals whenever possible.
4. Support medical screenings via telehealth or telephone as well as clinical preadmission screenings and assessments by qualified, licensed professionals. In addition, use expanded telehealth, including prescribing controlled substances for opioid use disorder via telemedicine and for patient and provider safety in line with infectious disease recommendations (ie, social distancing). Encourage novel use of telehealth in high-risk environments for diversion and mitigation of unnecessary emergency department visits. For more information, consult resources such as:
    a. Substance Abuse and Mental Health Services Administration's "FAQs: Provision of methadone and buprenorphine for the treatment of opioid use disorder in the COVID-19 emergency (https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf)"
5. Recognize that patients who present with psychiatric complaints may also have co-occurring medical disorders that warrant a proper medical evaluation. Use pre-existing, evidence-based recommendations and screening algorithms to perform appropriate and directed medical evaluations. Encourage providers to identify alternate methods and modalities to make those assessments in the current COVID environment.
6. Understand that people will present with an acute psychiatric crisis who are at risk of, have symptoms consistent with, or have tested positive for COVID-19, who will not meet medical admission criteria but will meet criteria for further psychiatric care. Mental health and substance use care, based on the needs of the individual, must remain available.
7. Discourage the use of restraints while keeping people in the least restrictive setting possible that corresponds to their condition or presenting symptoms.
8. Ensure that medical personnel are evaluating for signs of domestic violence in children, partners and spouses, the elderly, those with intellectual and developmental disabilities, and other vulnerable populations, as implementation of social distancing and home-based self-quarantine can increase this risk.
9. Encourage staff to formulate aftercare services that are based on existing resources and partnerships in the community.
10. Provide individuals at risk of suicide with local and national resources of people to talk to when they are feeling suicidal, such as the:
    a. Local crisis call center number;
    b. ICAR2E (/patient-care/iCar2e/) app developed by ACEP;
    c. National Suicide Prevention Lifeline (https://suicidepreventionlifeline.org/);
    d. Trans LifeLine (https://www.translifeline.org/);
    e. Trevor Project (https://www.thetrevorproject.org/); or
    f. Crisis Text Line (https://www.crisistextline.org/).
11. Encourage the creation and use of psychiatric advance directives by patients, wherever local jurisdictions permit, that will help provide treatment guidance for providers by patients before their symptoms worsens to the point of impairment in psychiatric medical decision making. For more information, see the:
    a. Substance Abuse and Mental Health Services Administration's resource manual *A Practical Guide to Psychiatric Advance Directives* (https://www.samhsa.gov/sites/default/files/a_practical_guide_to_psychiatric_advance_directives

12. Encourage and promote self-care among those providing care to patients and their families. Acknowledge that health care workers are committed to assisting all shortages and vacancies during this time of crisis and that it is just as important to maintain one's individual health and wellness for the overall stability of patients and the care delivery system. In addition to using one's own internal coping skills and resources, ensure staff are aware of all other local, state, and regional options for care, including:
    a. ACEP's "Wellness and Assistance Program (/life-as-a-physician/ACEP-Wellness-and-Assistance-Program/)."
13. Ensure adequate funding — governmental, nongovernmental, and private funding — to support all activities noted and ensure all insurance agencies, both public and private, provide appropriate and reasonable reimbursement for the care and treatment of patients with behavioral emergencies.
14. Identify patients with behavioral emergencies in your community by working with local agencies (ie, hospitals, outpatient centers, shelters, and public agencies).
15. As much as possible, try to ensure all behavioral health patients have phone access and that their numbers are recorded, but be cognizant of CFR-42 regulations if this information is shared across organizations.
16. Create a process to contact all identified patients on a regular basis for "check-ins" during the pandemic, ideally at least weekly and, if resources allow, several times per week. Consider using "furloughed" staff to help with this task. Consider a process to identify at-risk behaviors and concerns during these check-ins, and establish standard processes to address concerns once identified.
17. Create a standard approach to the organizational and community messaging that occurs during these check-ins, which can be particularly helpful in mitigating anxiety associated with the pandemic.
18. Make a list of community online resources, particularly any local online Alcoholics Anonymous and Narcotics Anonymous meetings, even if some patients will not have access to these electronic tools, because these programs can make a significant difference when they are accessible.

Reference

Osborn DP. The poor physical health of people with mental illness. *West J Med*. 2001;175(5):329-332. doi:10.1136/ewjm.175.5.329

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Previous
Psychiatric Patients

Next
Patients With Substance Use Disorders
(/corona/covid-19-field-guide/special-populations/patients-with-substance-use-disorders/)

Special Populations
Immigrants
Authors: Caroline Schulman, MD; and Aisha T. Terry, MD, MPH, FACEP Despite worldwide efforts to cont...

Special Populations
Incarcerated Population
Authors: Nicholas J. Dreyer, MD; and Aisha T. Terry, MD, MPH, FACEP Overview With nearly 2.2 million...

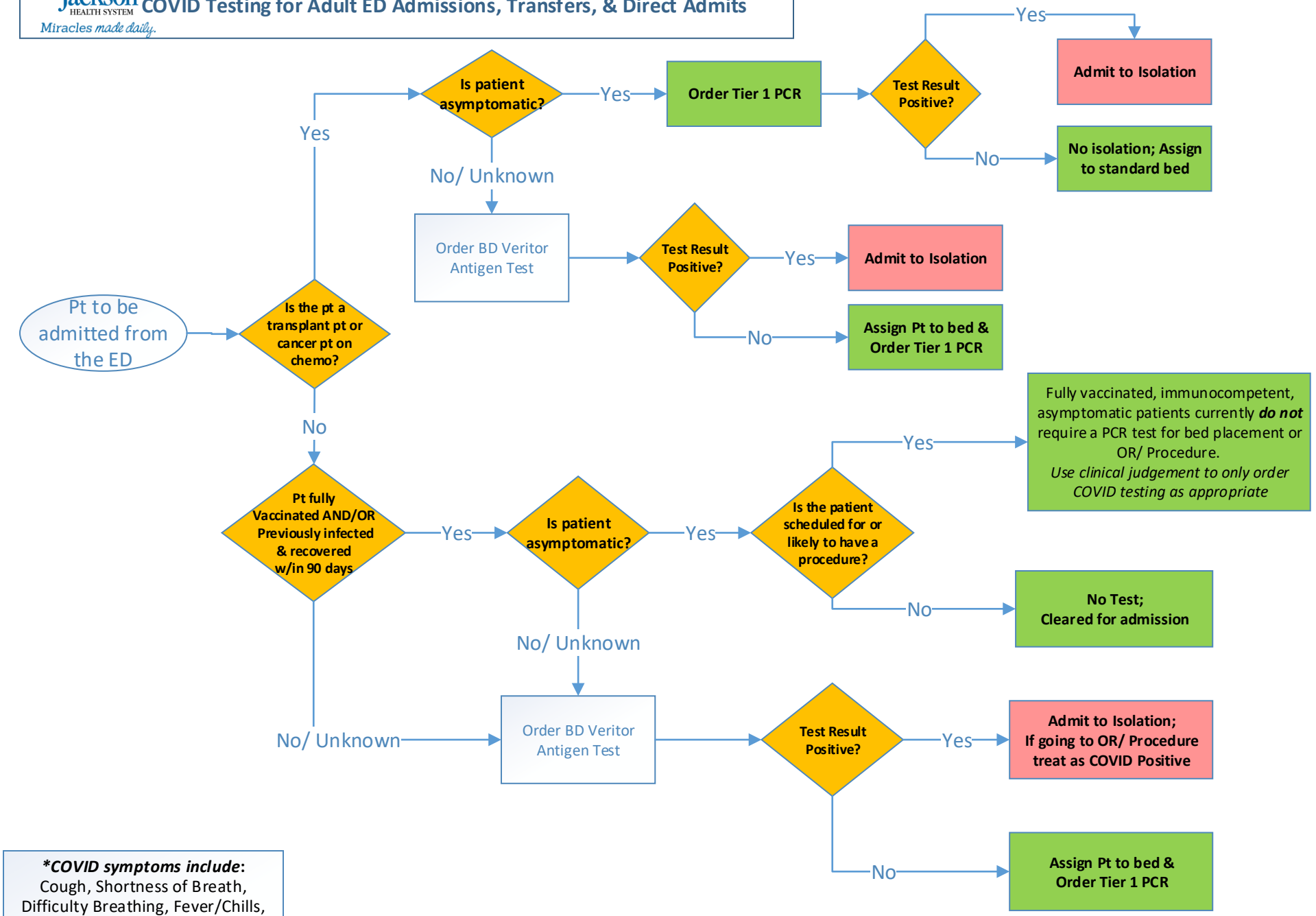
Financial Guidance and Information
Financial Resources
Refer to ACEP's "COVID-19 Financial Survival Guide: What You Need to Know." ACEP has also summarize...

(/corona/covid-19-field-guide/special-populations/immigrants/)
(/corona/covid-19-field-guide/special-populations/incarcerated-population/)
(/corona/covid-19-field-guide/business/financial-resources/)

American College of Emergency Physicians®

Please also see Appendix 21a & 21b for updates

Jackson HEALTH SYSTEM Miracles made daily. COVID Testing for Adult ED Admissions, Transfers, & Direct Admits



COVID symptoms include:
Cough, Shortness of Breath, Difficulty Breathing, Fever/Chills, Muscle or body aches, Vomiting or diarrhea, New loss of taste or smell
https://www.cdc.gov/coronavirus/2019-ncov/downloads/COVID19-symptoms.pdf

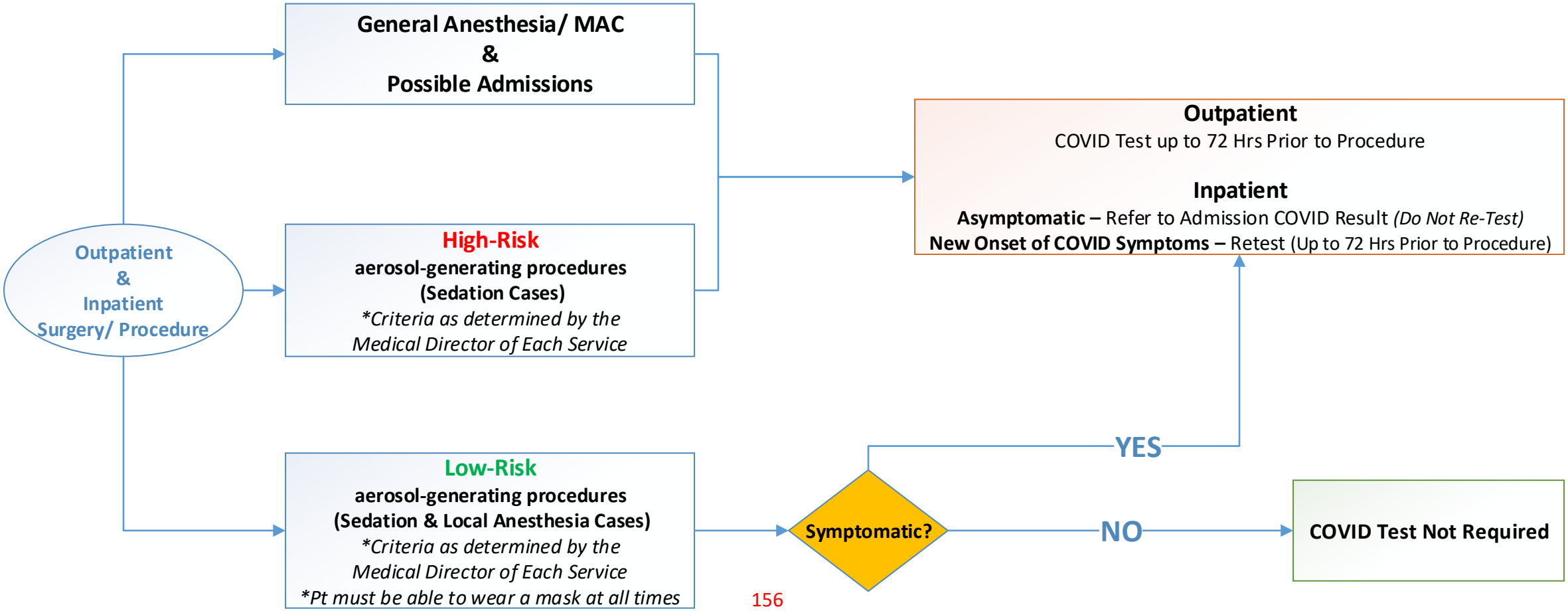
*Proof of full vaccination must come from Florida Shots, AND be documented in EMR

Jackson HEALTH SYSTEM
Miracles made daily.

OR & Procedural Area

Outpatient & Inpatient COVID Testing Guidelines

Updated Feb 25, 2022



Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic

Updated Sept. 23, 2022

For healthcare personnel, see Isolation and work restriction guidance. For strategies to mitigate healthcare personnel staffing shortages, see Contingency and crisis management. For healthcare professionals advising people in non-healthcare settings about isolation for laboratory-confirmed COVID-19, see Ending Isolation and Precautions for People with COVID-19.

Summary of Recent Changes

Updates as of September 23, 2022

- Updated to note that vaccination status is no longer used to inform source control, screening testing, or post-exposure recommendations
- Updated circumstances when use of source control is recommended
- Updated circumstances when universal use of personal protective equipment should be considered
- Updated recommendations for testing frequency to detect potential for variants with shorter incubation periods and to address the risk for false negative antigen tests in people without symptoms.
- Clarified that screening testing of asymptomatic healthcare personnel, including those in nursing homes, is at the discretion of the healthcare facility
- Updated to note that, in general, asymptomatic patients no longer require empiric use of Transmission-Based Precautions following close contact with someone with SARS-CoV-2 infection.
- Archived the Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes and special considerations for nursing homes not otherwise covered in Sections 1 and 2 were added to Section 3: Setting-specific considerations
  - Updated screening testing recommendations for nursing home admissions
- Clarified the types of long-term care settings for whom the healthcare infection prevention and control recommendations apply

Key Points

- This guidance applies to all U.S. settings where healthcare is delivered, including nursing homes and home health.

Introduction

This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of community transmission).

This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health). **This guidance is not intended for non-healthcare settings (e.g., restaurants) and not for persons outside of healthcare settings.** CDC's main landing page for COVID-19 content will help readers navigate to information regarding modes of transmission, clinical management, laboratory settings, COVID-19 vaccines and CDC guidance on other COVID-19-related topics.

Employers should be aware that other local, territorial, tribal, state, and federal requirements may apply, including those promulgated by the Occupational Safety and Health Administration (OSHA).

Defining Community Transmission of SARS-CoV-2

Select IPC measures (e.g., use of source control, screening testing of nursing home admissions) are influenced by levels of SARS-CoV-2 transmission in the community. Community Transmission is the metric currently recommended to guide select practices in healthcare settings to allow for earlier intervention, before there is strain on the healthcare system and to better protect the individuals seeking care in these settings. The Community Transmission metric is different from the COVID-19 Community Level metric used for non-healthcare settings. Community Transmission refers to measures of the presence and spread of SARS-CoV-2. COVID-19 Community Levels place an emphasis on measures of the impact of COVID-19 in terms of hospitalizations and healthcare system strain, while accounting for transmission in the community.

1. Recommended routine infection prevention and control (IPC) practices during the COVID-19 pandemic

Encourage everyone to remain up to date with all recommended COVID-19 vaccine doses.

- HCP, patients, and visitors should be offered resources and counseled about the importance of receiving the COVID-19 vaccine.

Establish a Process to Identify and Manage Individuals with Suspected or Confirmed SARS-CoV-2 Infection

- Ensure everyone is aware of recommended IPC practices in the facility.
  - Post visual alerts (e.g., signs, posters) at the entrance and in strategic places (e.g., waiting areas, elevators, cafeterias) These alerts should include instructions about current IPC recommendations (e.g., when to use source control and perform hand hygiene). Dating these alerts can let help ensure people know that they reflect current recommendations.
- Establish a process to make everyone entering the facility aware of recommended actions to prevent transmission to others if they have any of the following three criteria:
  - 1) a positive viral test for SARS-CoV-2
  - 2) symptoms of COVID-19, or
  - 3) close contact with someone with SARS-CoV-2 infection (for patients and visitors) or a higher-risk exposure (for healthcare personnel (HCP)).
    - For example:
      - Instruct HCP to report any of the 3 above criteria to occupational health or another point of contact designated by the facility so these HCP can be properly managed.
        - The definition of higher-risk exposure and recommendations for evaluation and work restriction of these HCP are in the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2.

- Provide guidance (e.g., posted signs at entrances, instructions when scheduling appointments) about recommended actions for patients and visitors who have any of the above three criteria.
  - Patients should be managed as described in Section 2.
  - Visitors with confirmed SARS-CoV-2 infection or compatible symptoms should defer non-urgent in-person visitation until they have met the healthcare criteria to end isolation (see Section 2); this time period is longer than what is recommended in the community. For visitors who have had close contact with someone with SARS-CoV-2 infection or were in another situation that put them at higher risk for transmission, it is safest to defer non-urgent in-person visitation until 10 days after their close contact if they meet any of the criteria described in Section 2 (e.g., cannot wear source control).
    - Additional information about visitation from the Centers for Medicare & Medicaid Services (CMS) is available at Policy & Memos to States and Regions | CMS .

Implement Source Control Measures

Source control refers to use of respirators or well-fitting facemasks or cloth masks to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. Further information about types of masks and respirators, including those that meet standards and the degree of protection offered to the wearer, is available at: Masks and Respirators (cdc.gov). People, particularly those at high risk for severe illness, should wear the most protective form of source control they can that fits well and that they will wear consistently.

Healthcare facilities may choose to offer well-fitting facemasks as a source control option for visitors but should allow the use of a mask or respirator with higher-level protection that is not visibly soiled by people who chose that option based on their individual preference. Additional information is available in the FAQ: What should visitors use for source control (masks or respirators) when visiting healthcare facilities?

Source control options for HCP include:

- A NIOSH-approved particulate respirator with N95 filters or higher;
- A respirator approved under standards used in other countries that are similar to NIOSH-approved N95 filtering facepiece respirators (Note: These should not be used instead of a NIOSH-approved respirator when respiratory protection is indicated);
- A barrier face covering that meets ASTM F3502-21 requirements including Workplace Performance and Workplace Performance Plus masks; OR
- A well-fitting facemask.

When used solely for source control, any of the options listed above could be used for an entire shift unless they become soiled, damaged, or hard to breathe through. If they are used during the care of patient for which a NIOSH-approved respirator or facemask is indicated for personal protective equipment (PPE) (e.g., NIOSH-approved particulate respirators with N95 filters or higher during the care of a patient with SARS-CoV-2 infection, facemask during a surgical procedure or during care of a patient on Droplet Precautions), they should be removed and discarded after the patient care encounter and a new one should be donned. Additional information is available in the FAQ: Can employees choose to wear respirators when not required by their employer?

When SARS-CoV-2 Community Transmission levels are high, source control is recommended for everyone in a healthcare setting when they are in areas of the healthcare facility where they could encounter patients.

- HCP could choose not to wear source control when they are in well-defined areas that are restricted from patient access (e.g., staff meeting rooms) if they do not otherwise meet the criteria described below and Community Levels are not also high. When Community Levels are high, source control is recommended for everyone.

When SARS-CoV-2 Community Transmission levels are **not** high, healthcare facilities could choose not to require universal source control. However, even if source control is not universally required, it remains recommended for individuals in healthcare settings who:

- Have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or
- Had close contact (patients and visitors) or a higher-risk exposure (HCP) with someone with SARS-CoV-2 infection, for 10 days after their exposure; or
- Reside or work on a unit or area of the facility experiencing a SARS-CoV-2 outbreak; universal use of source control could be discontinued as a mitigation measure once no new cases have been identified for 14 days; or
- Have otherwise had source control recommended by public health authorities

Individuals might also choose to continue using source control based on personal preference, informed by their perceived level of risk for infection based on their recent activities (e.g., attending crowded indoor gatherings with poor ventilation) and their potential for developing severe disease. For example, if an individual or someone in their household is at increased risk for severe disease, they should consider wearing masks or respirators that provide more protection because of better filtration and fit to reduce exposure and infection risk, even if source control is not otherwise required by the facility. HCP and healthcare facilities might also consider using or recommending source control when caring for patients who are moderately to severely immunocompromised.

Implement Universal Use of Personal Protective Equipment for HCP

If SARS-CoV-2 infection is not suspected in a patient presenting for care (based on symptom and exposure history), HCP should follow Standard Precautions (and Transmission-Based Precautions if required based on the suspected diagnosis).

As community transmission levels increase, the potential for encountering asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection also likely increases. In these circumstances, healthcare facilities should consider implementing broader use of respirators and eye protection by HCP during patient care encounters. For example, facilities located in counties where Community Transmission is high should also consider having HCP use PPE as described below:

- NIOSH-approved particulate respirators with N95 filters or higher used for:
  - All aerosol-generating procedures (refer to Which procedures are considered aerosol generating procedures in healthcare settings?).
  - All surgical procedures that might pose higher risk for transmission if the patient has SARS-CoV-2 infection (e.g., that generate potentially infectious aerosols or involving anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, respiratory tract).
  - NIOSH-approved particulate respirators with N95 filters or higher can also be used by HCP working in other situations where additional risk factors for transmission are present, such as the patient is unable to use source control and the area is poorly ventilated. They may also be considered if healthcare-associated SARS-CoV-2 transmission is identified and universal respirator use by HCP working in affected areas is not already in place.
  - To simplify implementation, facilities in counties with high transmission may consider implementing universal use of NIOSH-approved particulate respirators with N95 filters or higher for HCP during all patient care encounters or in specific units or areas of the facility at higher risk for SARS-CoV-2 transmission.
- Eye protection (i.e., goggles or a face shield that covers the front and sides of the face) worn during all patient care encounters.

Optimize the Use of Engineering Controls and Indoor Air Quality

- Optimize the use of engineering controls to reduce or eliminate exposures by shielding HCP and other patients from infected individuals (e.g., physical barriers at reception / triage locations and dedicated pathways to guide symptomatic patients through waiting rooms and triage areas).
- Take measures to limit crowding in communal spaces, such as scheduling appointments to limit the number of patients in waiting rooms or treatment areas.
- Explore options, in consultation with facility engineers, to improve ventilation delivery and indoor air quality in patient rooms and all shared spaces.
  - Guidance on ensuring that ventilation systems are operating properly, and other options for improving indoor air quality, are available in the following resources:
    - Guidelines for Environmental Infection Control in Health-Care Facilities

- American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) resources for healthcare facilities , which also provides COVID-19 technical resources for healthcare facilities
- Ventilation in Buildings, which includes options for non-clinical spaces in healthcare facilities

Perform SARS-CoV-2 Viral Testing

- Anyone with even mild symptoms of COVID-19, **regardless of vaccination status**, should receive a vi al test for SARS-CoV-2 as soon as possible.
- Asymptomatic patients with close contact with someone with SARS-CoV-2 infection should have a series of three viral tests for SARS-CoV-2 infection. Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.
  - Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who have recovered in the prior 31-90 days; however, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period.
  - Guidance for work restrictions, including recommended testing for HCP with higher-risk exposures, are in the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2.
  - Guidance for use of empiric Transmission-Based Precautions for patients with close contact with someone with SARS-CoV-2 infection are described in Section 2.
- Testing considerations for healthcare facilities with an outbreak of SARS-CoV-2 are described below.
- The yield of screening testing for identifying asymptomatic infection is likely lower when performed on those in counties with lower levels of SARS-CoV-2 community transmission. However, these results might continue to be useful in some situations (e.g., when performing higher-risk procedures or for HCP caring for patients who are moderately to severely immunocompromised) to inform the type of infection control precautions used (e.g., room assignment/cohorting, or PPE used) and prevent unprotected exposures. If implementing a screening testing program, testing decisions should not be based on the vaccination status of the individual being screened. To provide the greatest assurance that someone does not have SARS-CoV-2 infection, if using an antigen test instead of a NAAT, facilities should use 3 tests, spaced 48 hours apart, in line with FDA recommendations .
  - In general, performance of pre-procedure or pre-admission testing is at the discretion of the facility. However, for residents admitted to nursing homes, admission testing is recommended as described in Section 3.
  - Performance of expanded screening testing of asymptomatic HCP without known exposures is at the discretion of the facility.

Create a Process to Respond to SARS-CoV-2 Exposures Among HCP and Others

Healthcare facilities should have a plan for how SARS-CoV-2 exposures in a healthcare facility will be investigated and managed and how contact tracing will be performed.

If healthcare-associated transmission is suspected or identified, facilities might consider expanded testing of HCP and patients as determined by the distribution and number of cases throughout the facility and ability to identify close contacts. For example, in an outpatient dialysis facility with an open treatment area, testing should ideally include all patients and HCP. Depending on testing resources available or the likelihood of healthcare-associated transmission, facilities may elect to initially expand testing only to HCP and patients on the affected units or departments, or a particular treatment schedule or shift, as opposed to the entire facility. If an expanded testing approach is taken and testing identifies additional infections, testing should be expanded more broadly. If possible, testing should be repeated every 3-7 days until no new cases are identified for at least 14 days.

Guidance for outbreak response in nursing homes is described in setting-specific considerations below.

Healthcare facilities responding to SARS-CoV-2 transmission within the facility should always notify and follow the recommendations of public health authorities.

2. Recommended infection prevention and control (IPC) practices when caring for a patient with suspected or confirmed SARS-CoV-2 infection

The IPC recommendations described below (e.g., patient placement, recommended PPE) also apply to patients with symptoms of COVID-19 (even before results of diagnostic testing) and asymptomatic patients who have met the criteria for empiric Transmission-Based Precautions based on close contact with someone with SARS-CoV-2 infection. However, these patients should NOT be cohorted with patients with confirmed SARS-CoV-2 infection unless they are confirmed to have SARS-CoV-2 infection through testing.

Duration of Empiric Transmission-Based Precautions for Symptomatic Patients being Evaluated for SARS-CoV-2 infection

The decision to discontinue empiric Transmission-Based Precautions by excluding the diagnosis of current SARS-CoV-2 infection for a patient with symptoms of COVID-19 can be made based upon having negative results from at least one viral test.

- If using NAAT (molecular), a single negative test is sufficient in most circumstances. If a higher level of clinical suspicion for SARS-CoV-2 infection exists, consider maintaining Transmission-Based Precautions and confirming with a second negative NAAT.
- If using an antigen test, a negative result should be confirmed by either a negative NAAT (molecular) or second negative antigen test taken 48 hours after the first negative test.

If a patient suspected of having SARS-CoV-2 infection is never tested, the decision to discontinue Transmission-Based Precautions can be made based on time from symptom onset as described in the Isolation section below. Ultimately, clinical judgement and suspicion of SARS-CoV-2 infection determine whether to continue or discontinue empiric Transmission-Based Precautions.

Duration of Empiric Transmission-Based Precautions for Asymptomatic Patients following Close Contact with Someone with SARS-CoV-2 Infection

In general, asymptomatic patients do not require empiric use of Transmission-Based Precautions while being evaluated for SARS-CoV-2 following close contact with someone with SARS-CoV-2 infection. These patients should still wear source control and those who have not recovered from SARS-CoV-2 infection in the prior 30 days should be tested as described in the testing section.

Examples of when empiric Transmission-Based Precautions following close contact may be considered include:

- Patient is unable to be tested or wear source control as recommended for the 10 days following their exposure
- Patient is moderately to severely immunocompromised
- Patient is residing on a unit with others who are moderately to severely immunocompromised
- Patient is residing on a unit experiencing ongoing SARS-CoV-2 transmission that is not controlled with initial interventions

Patients placed in empiric Transmission-Based Precautions based on close contact with someone with SARS-CoV-2 infection should be maintained in Transmission-Based Precautions for the following time periods.

- Patients can be removed from Transmission-Based Precautions after day 7 following the exposure (count the day of exposure as day 0) if they do not develop symptoms and all viral testing as described for asymptomatic individuals following close contact is negative.
- If viral testing is not performed, patients can be removed from Transmission-Based Precautions after day 10 following the exposure (count the day of exposure as day 0) if they do not develop symptoms.

Patient Placement

- Place a patient with suspected or confirmed SARS-CoV-2 infection in a single-person room. The door should be kept closed (if safe to do so). Ideally, the patient should have a dedicated bathroom.
  - If cohorting, only patients with the same respiratory pathogen should be housed in the same room. MDRO colonization status and/or presence of other communicable disease should also be taken into consideration during the cohorting process.
- Facilities could consider designating entire units within the facility, with dedicated HCP, to care for patients with SARS-CoV-2 infection when the number of patients with SARS-CoV-2 infection is high. Dedicated means that HCP are assigned to care only for these patients during their shifts. Dedicated units and/or HCP might not be feasible due to staffing crises or a small number of patients with SARS-CoV-2 infection.
- Limit transport and movement of the patient outside of the room to medically essential purposes.
- Communicate information about patients with suspected or confirmed SARS-CoV-2 infection to appropriate personnel before transferring them to other departments in the facility (e.g., radiology) and to other healthcare facilities.

Personal Protective Equipment

- HCP who enter the room of a patient with suspected or confirmed SARS-CoV-2 infection should adhere to Standard Precautions and use a NIOSH-approved particulate respirator with N95 filters or higher , gown, gloves, and eye protection (i.e., goggles or a face shield that covers the front and sides of the face).
- Respirators should be used in the context of a comprehensive respiratory protection program, which includes medical evaluations, fit testing and training in accordance with the Occupational Safety and Health Administration's (OSHA) Respiratory Protection standard (29 CFR 1910.134)
- Additional information about using PPE is available in Protecting Healthcare Personnel | HAI | CDC

Aerosol-Generating Procedures (AGPs)

- Procedures that could generate infectious aerosols should be performed cautiously and avoided if appropriate alternatives exist.
- AGPs should take place in an airborne infection isolation room (AIIR), if possible.
- The number of HCP present during the procedure should be limited to only those essential for patient care and procedure support. Visitors should not be present for the procedure.

Visitation

- For the safety of the visitor, in general, patients should be encouraged to limit in-person visitation while they are infectious. However, facilities should adhere to local, territorial, tribal, state, and federal regulations related to visitation. Additional information about visitation from the Centers for Medicare & Medicaid Services (CMS) is available at Policy & Memos to States and Regions | CMS .
  - Counsel patients and their visitor(s) about the risks of an in-person visit.
  - Encourage use of alternative mechanisms for patient and visitor interactions such as video-call applications on cell phones or tablets, when appropriate.
- Facilities should provide instruction, before visitors enter the patient's room, on hand hygiene, limiting surfaces touched, and use of PPE according to current facility policy.
- Visitors should be instructed to only visit the patient room. They should minimize their time spent in other locations in the facility.

Duration of Transmission-Based Precautions for Patients with SARS-CoV-2 Infection

The following are criteria to determine when Transmission-Based Precautions could be discontinued for patients with SARS-CoV-2 infection and are influenced by severity of symptoms and presence of immunocompromising conditions. Patients should self-monitor and seek re-evaluation if symptoms recur or worsen. If symptoms recur (e.g., rebound), these patients should be placed back into isolation until they again meet the healthcare criteria below to discontinue Transmission-Based Precautions for SARS-CoV-2 infection unless an alternative diagnosis is identified.

In general, patients who are hospitalized for SARS-CoV-2 infection should be maintained in Transmission-Based Precautions for the time period described for patients with severe to critical illness.

In general, patients should continue to wear source control until symptoms resolve or, for those who never developed symptoms, until they meet the criteria to end isolation below. Then they should revert to usual facility source control policies for patients.

Patients with mild to moderate illness who are *not* moderately to severely immunocompromised:

- At least 10 days have passed *since symptoms first appeared* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved

Patients who were asymptomatic throughout their infection and are *not* moderately to severely immunocompromised:

- At least 10 days have passed since the date of their first positive viral test.

Patients with severe to critical illness and who are *not* moderately to severely immunocompromised:

- At least 10 days and up to 20 days have passed *since symptoms first appeared* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved
- The test-based strategy as described for moderately to severely immunocompromised patients below can be used to inform the duration of isolation.

The exact criteria that determine which patients will shed replication-competent virus for longer periods are not known. Disease severity factors and the presence of immunocompromising conditions should be considered when determining the appropriate duration for specific patients. For a summary of the literature, refer to Ending Isolation and Precautions for People with COVID-19: Interim Guidance (cdc.gov)

Patients who are moderately to severely immunocompromised may produce replication-competent virus beyond 20 days after symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test.

- Use of a test-based strategy and (if available) consultation with an infectious disease specialist is recommended to determine when Transmission-Based Precautions could be discontinued for these patients.

The criteria for the test-based strategy are:

Patients who are symptomatic:

- Resolution of fever without the use of fever-reducing medications **and**
- Symptoms (e.g., cough, shortness of breath) have improved, **and**
- Results are negative from at least two consecutive respiratory specimens collected 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT

Patients who are not symptomatic:

- Results are negative from at least two consecutive respiratory specimens collected 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT

Environmental Infection Control

- Dedicated medical equipment should be used when caring for a patient with suspected or confirmed SARS-CoV-2 infection.
  - All non-dedicated, non-disposable medical equipment used for that patient should be cleaned and disinfected according to manufacturer's instructions and facility policies before use on another patient.

- Routine cleaning and disinfection procedures (e.g., using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's label) are appropriate for SARS-CoV-2 in healthcare settings, including those patient-care areas in which AGPs are performed.
  - Refer to List N on the EPA website for EPA-registered disinfectants that kill SARS-CoV-2; the disinfectant selected should also be appropriate for other pathogens of concern at the facility (e.g., a *difficile* sporicidal agent is recommended to disinfect the rooms of patients with *C. difficile* infection).
- Management of laundry, food service utensils, and medical waste should be performed in accordance with routine procedures.
- Once the patient has been discharged or transferred, HCP, including environmental services personnel, should refrain from entering the vacated room without all recommended PPE until sufficient time has elapsed for enough air changes to remove potentially infectious particles [more information (to include important footnotes on its application) on clearance rates under differing ventilation conditions is available]. After this time has elapsed, the room should undergo appropriate cleaning and surface disinfection before it is returned to routine use.

3. Setting-specific considerations

In addition to the recommendations described in the guidance above, here are additional considerations for the settings listed below.

Dialysis Facilities

Considerations for Patient Placement

- Patients on dialysis with suspected or confirmed SARS-CoV-2 infection or who have reported close contact should be dialyzed in a separate room with the door closed.
  - Hepatitis B isolation rooms can be used if: 1) the patient is hepatitis B surface antigen-positive or 2) the facility has no patients on the census with hepatitis B infection who would require treatment in the isolation room.
- If a separate room is not available, patients with confirmed SARS-CoV-2 infection should be cohorted to a specific well-ventilated unit or shift (e.g., consider the last shift of the day). Only patients with confirmed SARS-CoV-2 infection should be cohorted together:
  - In the context of an outbreak or an increase in the number of confirmed SARS-CoV-2 infections at the facility, if a separate shift or unit is not initially available, efforts should be made to create specific shifts or units for patients with confirmed SARS-CoV-2 infection to separate them from patients without SARS-CoV-2 infection.

Additional Guidance for Use of Isolation Gowns

- When caring for patients with suspected or confirmed SARS-CoV-2 infection, gowns should be worn over or instead of the cover gown (e.g., laboratory coat, gown, or apron with incorporate sleeves) that is normally worn by hemodialysis personnel.

Cleaning and Disinfecting Dialysis Stations

- Current procedures for routine cleaning and disinfection of dialysis stations are appropriate for patients with SARS-CoV-2 infection.
- Internal disinfection of dialysis machines is not required immediately after use unless otherwise indicated (e.g., post-blood leak). It should be done according to the dialysis machine manufacturer's instructions (e.g., at the end of the day).

Emergency Medical Services

Considerations for vehicle configuration when transporting a patient with suspected or confirmed SARS-CoV-2 infection

- Isolate the ambulance driver from the patient compartment and keep pass-through doors and windows tightly shut.
- When possible, use vehicles that have isolated driver and patient compartments that can provide separate ventilation to each area.

  - Before entering the isolated driver's compartment, the driver (if they were involved in direct patient care) should remove and dispose of PPE and perform hand hygiene to avoid soiling the compartment.
  - Close the door/window between these compartments before bringing the patient on board.
  - During transport, vehicle ventilation in both compartments should be on non-recirculated mode to maximize air changes that reduce potentially infectious particles in the vehicle.
  - If the vehicle has a rear exhaust fan, use it to draw air away from the cab, toward the patient-care area, and out the back end of the vehicle.
  - Some vehicles are equipped with a supplemental recirculating ventilation unit that passes air through high-efficiency particulate air (HEPA) filters before returning it to the vehicle. Such a unit can be used to increase the number of air changes per hour (ACH) Health Hazard Evaluation Report 95–0031–2601 pdf .
  - After patient unloading, allowing a few minutes with ambulance module doors open will rapidly dilute airborne viral particles.
- If a vehicle without an isolated driver compartment must be used, open the outside air vents in the driver area and turn on the rear exhaust ventilation fans to the highest setting to create a pressure gradient toward the patient area.
  - Before entering the driver's compartment, the driver (if they were involved in direct patient care) should remove their gown, gloves and eye protection and perform hand hygiene to avoid soiling the compartment. They should continue to wear their NIOSH-approved particulate respirator with N95 filters or higher.

Additional considerations when performing AGPs on patients with suspected or confirms SARS-CoV-2 infection:

- If possible, consult with medical control before performing AGPs for specific guidance.
- Bag valve masks (BVMs) and other ventilatory equipment should be equipped with HEPA filtration to filter expired air.
- EMS systems should consult their ventilator equipment manufacturer to confirm appropriate filtration capability and the effect of filtration on positive-pressure ventilation.
- If possible, the rear doors of the stationary transport vehicle should be opened and the HVAC system should be activated during AGPs. This should be done away from pedestrian traffic.
- If possible, discontinue AGPs prior to entering the destination facility or communicate with receiving personnel that AGPs are being implemented.

Dental Facilities

- Dental healthcare personnel (DHCP) should regularly consult their state dental boards and state or local health departments for current information and recommendations and requirements specific to their jurisdictions, which might change based on SARS-CoV-2 transmission levels in the county where their healthcare facility is located.
- Patients with suspected or confirmed SARS-CoV-2 infection should postpone all non-urgent dental treatment until they meet criteria to discontinue Transmission-Based Precautions. Because dental patients cannot wear a mask, in general, those who have had close contact with someone with SARS-CoV-2 infection should also postpone all non-urgent dental treatment until they meet the healthcare criteria to end quarantine.
  - Dental care for these patients should only be provided if medically necessary. Follow all recommendations for care and placement for patients with suspected or confirmed SARS-CoV-2 infection. Extra attention may be required to ensure HVAC ventilation to the dental treatment area does not reduce or deactivate during occupancy based on temperature demands.
  - If a patient has a fever strongly associated with a dental diagnosis (e.g., pulpal and periapical dental pain and intraoral swelling are present) but no other symptoms consistent with COVID-19 are present, dental care can be provided following the practices recommended for routine health care during the pandemic.
- When performing aerosol-generating procedures on patients who are not suspected or confirmed to have SARS-CoV-2 infection, ensure that DHCP correctly wear the recommended PPE (including consideration of a NIOSH-approved particulate respirator with N95 filters or higher in counties with high levels of transmission) and use mitigation methods such as four-handed dentistry, high evacuation suction, and dental dams to minimize droplet spatter and aerosols.
  - Commonly used dental equipment known to create aerosols and airborne contamination include ultrasonic scaler, high-speed dental handpiece, air/water syringe, air polishing, and air abrasion.
- Dental treatment should be provided in individual patient rooms whenever possible with the HVAC in constant ventilation mode.

For dental facilities with open floor plans, strategies to prevent the spread of pathogens include:

For dental facilities with open floor plans, strategies to prevent the spread of pathogens include:

- At least 6 feet of space between patient chairs.
- Adjunct use of portable HEPA air filtration systems to enhance air cleaning
- Physical barriers between patient chairs. Easy-to-clean floor-to-ceiling barriers will enhance effectiveness of portable HEPA air filtration systems (check to make sure that extending barriers to the ceiling will not interfere with fire sprinkler systems).
- Operatories oriented parallel to the direction of airflow when possible.
- Where feasible, consider patient orientation carefully, placing the patient's head near the return air vents, away from pedestrian corridors, and toward the rear wall when using vestibule-type office layouts.
- Ensure to account for the time required to clean and disinfect operatories between patients when calculating your daily patient volume.

Nursing Homes

- Assign one or more individuals with training in IPC to provide on-site management of the IPC program
  - This should be a full-time role for at least one person in facilities that have more than 100 residents or that provide on-site ventilator or hemodialysis services. Smaller facilities should consider staffing the IPC program based on the resident population and facility service needs identified in the IPC risk assessment.
- Stay connected with the healthcare-associated infection program in your state health department, as well as your local health department, and their notification requirements. Report SARS-CoV-2 infection data to National Healthcare Safety Network (NHSN) Long-term Care Facility (LTCF) COVID-19 Module. See Centers for Medicare & Medicaid Services (CMS) COVID-19 reporting requirements .
- Managing admissions and residents who leave the facility:
  - In general, admissions in counties where Community Transmission levels are high should be tested upon admission; admission testing at lower levels of Community Transmission is at the discretion of the facility.
    - Testing is recommended at admission and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test.

    They should also be advised to wear source control for the 10 days following their admission. Residents who leave the facility for 24 hours or longer should generally be managed as an admission.

- Empiric use of Transmission-Based Precautions is generally not necessary for admissions or for residents who leave the facility for less than 24 hours (e.g., for medical appointments, community outings) and do not meet criteria described in section 2.
- Placement of residents with suspected or confirmed SARS-CoV-2 infection
  - Ideally, residents should be placed in a single-person room as described in Section 2.
  - If limited single rooms are available, or if numerous residents are simultaneously identified to have known SARS-CoV-2 exposures or symptoms concerning for COVID-19, residents should remain in their current location.
- Responding to a newly identified SARS-CoV-2-infected HCP or resident
  - When performing an outbreak response to a known case, facilities should always defer to the recommendations of the jurisdiction's public health authority.
  - A single new case of SARS-CoV-2 infection in any HCP or resident should be evaluated to determine if others in the facility could have been exposed.
  - The approach to an outbreak investigation could involve either contact tracing or a broad-based approach; however, a broad-based (e.g., unit, floor, or other specific area(s) of the facility) approach is preferred if all potential contacts cannot be identified or managed with contact tracing or if contact tracing fails to halt transmission.
  - Perform testing for all residents and HCP identified as close contacts or on the affected unit(s) if using a broad-based approach, regardless of vaccination status.
    - Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.
    - Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who have recovered in the prior 31-90 days; however, an antigen test instead of a nucleic acid amplification

test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period.

- Empiric use of Transmission-Based Precautions for residents and work restriction for HCP are not generally necessary unless residents meet the criteria described in Section 2 or HCP meet criteria in the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, respectively. However, source control should be worn by all individuals being tested.
  - In the event of ongoing transmission within a facility that is not controlled with initial interventions, strong consideration should be given to use of Empiric use of Transmission-Based Precautions for residents and work restriction of HCP with higher-risk exposures. In addition, there might be other circumstances for which the jurisdiction's public authority recommends these and additional precautions.
  - If no additional cases are identified during contact tracing or the broad-based testing, no further testing is indicated. Empiric use of Transmission-Based Precautions for residents and work restriction for HCP who met criteria can be discontinued as described in Section 2 and the Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, respectively.
  - If additional cases are identified, strong consideration should be given to shifting to the broad-based approach if not already being performed and implementing quarantine for residents in affected areas of the facility. As part of the broad-based approach, testing should continue on affected unit(s) or facility-wide every 3-7 days until there are no new cases for 14 days.
    - If antigen testing is used, more frequent testing (every 3 days), should be considered.
- **Indoor visitation during an outbreak response:**
  - Facilities should follow guidance from CMS about visitation.
  - Visitors should be counseled about their potential to be exposed to SARS-CoV-2 in the facility.
  - If indoor visitation is occurring in areas of the facility experiencing transmission, it should ideally occur in the resident's room. The resident and their visitors should wear well-fitting source control (if tolerated) and physically distance (if possible) during the visit.

Assisted Living, Group Homes and Other Residential Care Settings (excluding nursing homes)

In general, long-term care settings (excluding nursing homes) whose staff provide non-skilled personal care* similar to that provided by family members in the home (e.g., many assisted livings, group homes), should follow community prevention strategies based on COVID-19 Community Levels, similar to independent living, retirement communities or other non-healthcare congregate settings. Residents should also be counseled about strategies to protect themselves and others, including recommendations for source control if they are immunocompromised or at high risk for severe disease. CDC has information and resources for older adults and for people with disabilities.

Visiting or shared healthcare personnel who enter the setting to provide healthcare to one or more residents (e.g., physical therapy, wound care, intravenous injections, or catheter care provided by home health agency nurses) should follow the healthcare IPC recommendations in this guidance. In addition, if staff in a residential care setting are providing in-person services for a resident with SARS-CoV-2 infection, they should be familiar with recommended IPC practices to protect themselves and others from potential exposures including the hand hygiene, personal protective equipment and cleaning and disinfection practices outlined in this guidance.

*Non-skilled personal care consists of any non-medical care that can reasonably and safely be provided by non-licensed caregivers, such as help with daily activities like bathing and dressing; it may also include the kind of health-related care that most people do themselves, like taking oral medications. In some cases where care is received at home or a residential setting, care can also include help with household duties such as cooking and laundry.

Definitions:

Healthcare Personnel (HCP): HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, home healthcare personnel, physicians, technicians, therapists, phlebotomists, pharmacists, dental healthcare personnel, students

and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

Healthcare settings refers to places where healthcare is delivered and includes, but is not limited to, acute care facilities, long-term acute-care facilities, nursing homes, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, dental offices, and others.

Source control: Use of respirators, well-fitting facemasks, or well-fitting cloth masks to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. Source control devices should not be placed on children under age 2, anyone who cannot wear one safely, such as someone who has a disability or an underlying medical condition that precludes wearing one safely, or anyone who is unconscious, incapacitated, or otherwise unable to remove their source control device without assistance. Face shields alone are not recommended for source control. At a minimum, source control devices should be changed if they become visibly soiled, damaged, or hard to breathe through. Further information about source control options is available at: Masks and Respirators (cdc.gov)

Cloth mask: Textile (cloth) covers that are intended primarily for source control in the community. **They are not personal protective equipment (PPE) appropriate for use by healthcare personnel.** Guidance on design, use, and maintenance of cloth masks is available.

Facemask: OSHA defines facemasks as "a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as 'medical procedure masks'." Facemasks should be used according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Other facemasks, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

Respirator: A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators are certified by CDC/NIOSH, including those intended for use in healthcare.

Airborne Infection Isolation Rooms (AIIRs):

- AIIRs are single-patient rooms at negative pressure relative to the surrounding areas, and with a minimum of 12 ACH (6 ACH are allowed for AIIRs last renovated or constructed prior to 1997).
- Air from these rooms should be exhausted directly to the outside or be filtered through a HEPA filter directly before recirculation.
- Room doors should be kept closed except when entering or leaving the room, and entry and exit should be minimized.
- Facilities should monitor and document the proper negative-pressure function of these rooms.

Immunocompromised: For the purposes of this guidance, moderate to severely immunocompromising conditions include, but might not be limited to, those defined in the Interim Clinical Considerations for Use of COVID-19 Vaccines

- Other factors, such as end-stage renal disease, may pose a lower degree of immunocompromise. However, people in this category should still consider continuing to use of source control while in a healthcare facility.
- Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.

Close contact: Being within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period with someone with SARS-CoV-2 infection.

SARS-CoV-2 Illness Severity Criteria (adapted from the NIH COVID-19 Treatment Guidelines)

The studies used to inform this guidance did not clearly define "severe" or "critical" illness. This guidance has taken a conservative approach to define these categories. Although not developed to inform decisions about duration of Transmission-Based Precautions, the definitions in the National Institutes of Health (NIH) COVID-19 Treatment Guideline

s are one option for defining severity of illness categories. The highest level of illness severity experienced by the patient at any point in their clinical course should be used when determining the duration of Transmission-Based Precautions. Clinical judgement regarding the contribution of SARS-CoV-2 to clinical severity might also be necessary when applying these criteria to inform infection control decisions.

Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal chest imaging.

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

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

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

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

More Information

- Interim Clinical Considerations for Use of COVID-19 Vaccines
- Management of Patients with Confirmed 2019-nCoV
- Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- Clinical Questions about COVID-19: Questions and Answers
- Management of Patients with Confirmed 2019-nCoV

Previous Updates

Updates as of February 2, 2022

Due to concerns about increased transmissibility of the SARS-CoV-2 Omicron variant, this guidance is being updated to enhance protection for healthcare personnel, patients, and visitors and to address concerns about potential impacts on the healthcare system given a surge in SARS-CoV-2 infections. These updates will be refined as additional information becomes available to inform recommended actions.

- Empiric use of Transmission-Based Precautions (quarantine) is recommended for patients who have had close contact with someone with SARS-CoV-2 infection if they are not up to date with all recommended COVID-19 vaccine doses.
  - In general, quarantine is not needed for asymptomatic patients who are up to date with all recommended COVID-19 vaccine doses or who have recovered from SARS-CoV-2 infection in the prior 90 days; potential exceptions are described in the guidance. However, some of these patients should still be tested as described in the testing section of the guidance.
- A test-based strategy and (if available) consultation with infectious disease experts is now recommended for determining the duration of Transmission-Based Precautions for patients with SARS-CoV-2 infection who are

moderately to severely immunocompromised.

- Included additional examples when universal respirator use could be considered
- Additional updates that will have implications for healthcare facilities were made in the following guidance documents:
  - Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2
  - Strategies to Mitigate Healthcare Personnel Staffing Shortages
  - Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes

Updates as of September 10, 2021

- Updated source control recommendations to address limited situations for healthcare facilities in counties with low to moderate community transmission where select fully vaccinated individuals could choose not to wear source control. However, in general, the safest practice is for everyone in a healthcare setting to wear source control.
- Updated quarantine recommendations for fully vaccinated patients who have had close contact with someone with SARS-CoV-2 infection to more closely align with recommendations for the community.
- Clarified the recommended intervals for testing asymptomatic HCP with a higher-risk exposure and patients with close contact with someone with SARS-CoV-2 infection.
- Added content from previously posted CDC guidance addressing:
  - Recommendations for fully vaccinated HCP, patients, and visitors
  - SARS-CoV-2 testing
  - Duration of Transmission-Based Precautions for patients with SARS-CoV-2 infection
  - Specialized healthcare settings (e.g., dental, dialysis, EMS)

As of February 10, 2021

- Updated the Implement Universal Use of Personal Protective Equipment section to expand options for source control and patient care activities in areas of moderate to substantial transmission and describe strategies for improving fit of facemasks. Definitions of source control are included at the end of this document.
- Included a reference to Optimizing Personal Protective Equipment (PPE) Supplies that include a hierarchy of strategies to implement when PPE are in short supply or unavailable.

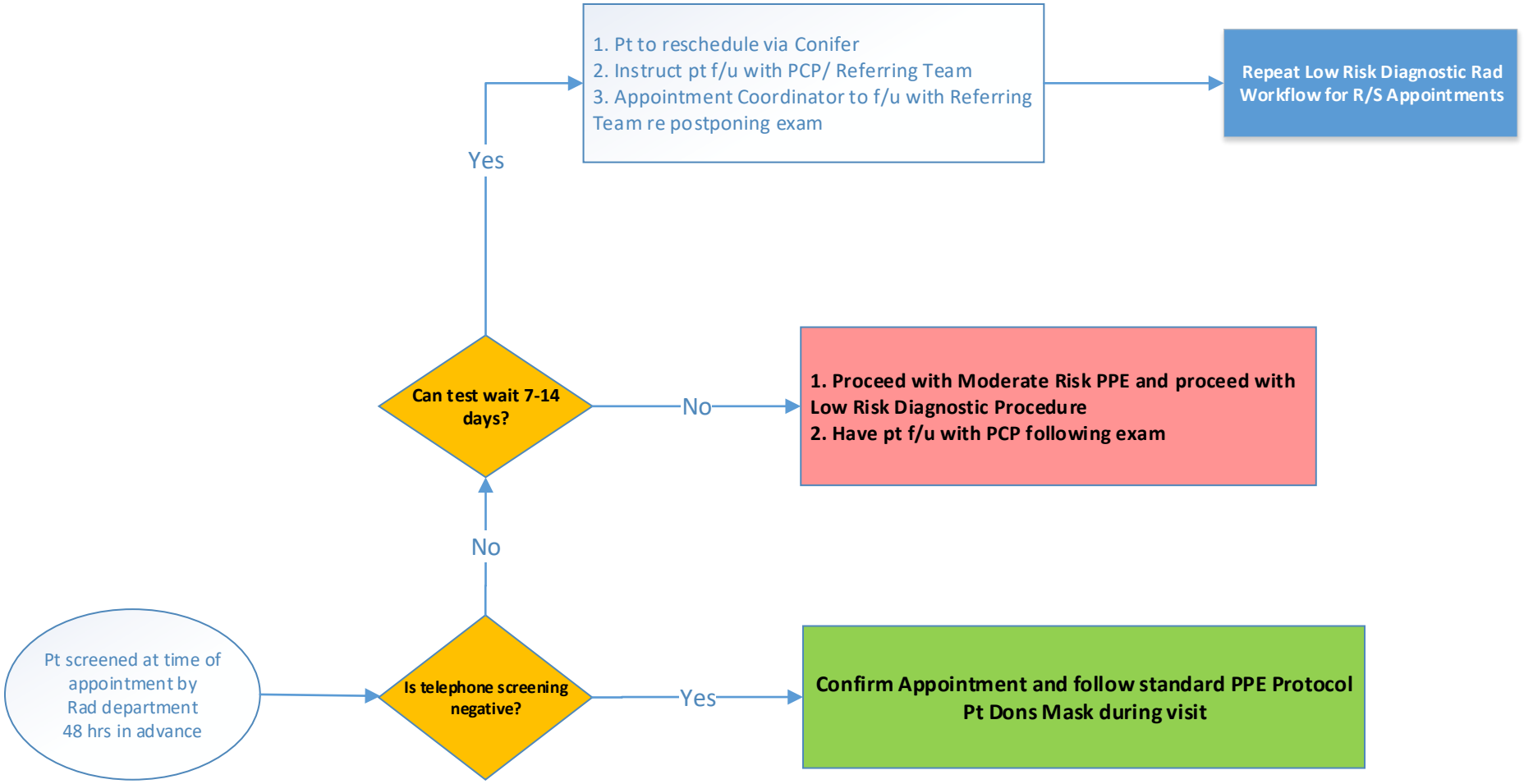
As of December 14, 2020

- Added links to Frequently Asked Questions addressing Environmental Cleaning and Disinfection and assessing risks to patients and others exposed to healthcare personnel who worked while infected with SARS-CoV-2
- Described recommended IPC practices when caring for patients who have met **criteria for a 14-day quarantine based on prolonged close contact with someone with SARS-CoV-2 infection**.
- **Added reminders that:**
  - Double gloving is not recommended when providing care to patients with suspected or confirmed SARS-CoV-2 infection
  - In general, HCP caring for patients with suspected or confirmed SARS-CoV-2 infection should not wear more than one isolation gown at a time.

As of November 4, 2020

- Provided different options for screening individuals (healthcare personnel, patients, visitors) prior to their entry into a healthcare facility
- Provided information on factors that could impact thermometer readings
- Provided resources for evaluating and managing ventilation systems in healthcare facilities
- Added link to Frequently Asked Questions about use of Personal Protective Equipment

Low Risk Diagnostic Radiology Workflow
COVID19 Workflow



Low Risk Diagnostic Radiology Procedures
DO NOT Require COVID-19 Testing

Moderate and High Risk Diagnostic Radiology Procedures follow Pre-Procedure COVID-19 Testing Guidance

Pre-Procedure COVID-19 Testing Guidance

	High Risk	Moderate Risk	Low Risk
Definition	Procedures/studies that require airway access/maintenance, endotracheal intubation, lower GI tract involvement	Invasive procedures/studies without anticipation of contact/ manipulation of the respiratory or lower GI tract	Non-invasive procedures/studies or those that require peripheral intravenous access
Pre-Testing Required	**Yes**. Results required for elective procedures/studies; immediate pre-procedure test required in emergent situation	**No**	**No**
PPE Recommendation	• Base layer* • Isolation gown • N95 respirator* with procedure mask as a protective cover • Shoe covers* • Hair cover* • Eye protection (goggles and faceshield)* for intubation • Two pairs of non-sterile gloves	• Isolation gown • Non-sterile gloves • N95 respirator* with procedure mask as a protective cover • Eye protection*	• PPE per standard precautions **AND** • Procedure mask* • Eye protection*
Environmental Cleaning and Disinfection	• Clean and disinfect all surfaces following procedure/study using sporicidal disinfectant • If aerosol-generating procedure performed, allow 30 – 60 minutes between patients to ensure adequate air exchanges have occurred • Terminal cleaning at end of day	• Clean and disinfect all surfaces following procedure/study using sporicidal disinfectant • Terminal cleaning at end of day	• Clean and disinfect all surfaces following procedure/study using sporicidal disinfectant • Terminal cleaning at end of day

** PPE elements with this symbol may be re-used for subsequent patients and cases unless contaminated.*

Appendix 9

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
May 14, 2020, 4:45 PM ET
CDCHAN-00432

Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)

Summary
The Centers for Disease Control and Prevention (CDC) is providing 1) background information on several cases of a recently reported multisystem inflammatory syndrome in children (MIS-C) associated with coronavirus disease 2019 (COVID-19); and 2) a case definition for this syndrome. CDC recommends healthcare providers report any patient who meets the case definition to local, state, and territorial health departments to enhance knowledge of risk factors, pathogenesis, clinical course, and treatment of this syndrome.

Background
On April 26, 2020, clinicians in the United Kingdom (UK) recognized increased reports of previously healthy children presenting with a severe inflammatory syndrome with Kawasaki disease-like features.[1] The cases occurred in children testing positive for current or recent infection by SARS-CoV-2, the novel coronavirus that causes COVID-19, based on reverse-transcriptase polymerase chain reaction (RT-PCR) or serologic assay, or who had an epidemiologic link to a COVID-19 case. Patients presented with a persistent fever and a constellation of symptoms including hypotension, multiorgan (e.g., cardiac, gastrointestinal, renal, hematologic, dermatologic and neurologic) involvement, and elevated inflammatory markers.[2] Respiratory symptoms were not present in all cases.

Eight cases, including one death, from the UK were described in a recent publication.[3] In the limited sample of 8 children, it was reported that 75% of the patients were of Afro-Caribbean descent and 62.5% were male. The report also indicated that all 8 patients tested positive for SARS-CoV-2 through antibody testing, including the patient that died.[3]

During March and April, cases of COVID-19 rapidly increased in New York City and New York State. In early May 2020, the New York City Department of Health and Mental Hygiene received reports of children with multisystem inflammatory syndrome. From April 16 through May 4, 2020, 15 patients aged 2-15 years were hospitalized, many requiring admission to the intensive care unit. As of May 12, 2020, the New York State Department of Health identified 102 patients (including patients from New York City) with similar presentations, many of whom tested positive for SARS-CoV-2 infection by RT-PCR or serologic assay. New York State and New York City continue to receive additional reports of suspected cases.

Additional reports of children presenting with severe inflammatory syndrome with a laboratory-confirmed case of COVID-19 or an epidemiological link to a COVID-19 case have been reported by authorities in other countries.[4]

It is currently unknown if multisystem inflammatory syndrome is specific to children or if it also occurs in adults.

There is limited information currently available about risk factors, pathogenesis, clinical course, and treatment for MIS-C. CDC is requesting healthcare providers report suspected cases to public health authorities to better characterize this newly recognized condition in the pediatric population.

Recommendations
Healthcare providers who have cared or are caring for patients younger than 21 years of age meeting MIS-C criteria should report suspected cases to their local, state, or territorial health department.

For additional information, please contact CDC's 24-hour Emergency Operations Center at 770-488-7100. After hour phone numbers for health departments are available at the Council of State and Territorial Epidemiologist website (https://resources.cste.org/epiafterhours).

Case Definition for Multisystem Inflammatory Syndrome in Children (MIS-C)

- An individual aged <21 years presenting with fever[i], laboratory evidence of inflammation[ii], and evidence of clinically severe illness requiring hospitalization, with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); **AND**
- No alternative plausible diagnoses; **AND**
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or COVID-19 exposure within the 4 weeks prior to the onset of symptoms

[i]Fever ≥38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours
[ii]Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin

Additional comments
- Some individuals may fulfill full or partial criteria for Kawasaki disease but should be reported if they meet the case definition for MIS-C
- Consider MIS-C in any pediatric death with evidence of SARS-CoV-2 infection

References
[1] https://www.cdc.gov/kawasaki/index.html
[2]Royal College of Paediatrics and Child Health Guidance: Paediatric multisystem inflammatory syndrome temporally associated with COVID-19, https://www.rcpch.ac.uk/sites/default/files/2020-05/COVID-19-Paediatric-multisystem-%20inflammatory%20syndrome-20200501.pdf.
[3]Riphagen S, Gomez X, Gonzales-Martinez C, Wilkinson N, Theocharis P. Hyperinflammatory shock in children during COVID-19 pandemic. Lancet. 2020. Advance online publication, doi: 10.1016/S0140-6736(20)31094 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31094-1/fulltext
[4]Verdoni L, Mazza A, Gervasoni A, Martelli L, Ruggeri M, Ciuffreda M, Bonanomi E, D'Anitga L. An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study. Lancet. 2020. Advance online publication, doi: 10.1016/ S0140-6736(20)31129-6 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31103-X/fulltext

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##

For Parents: Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19
https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/mis-c.html

Centers for Disease Control and Prevention
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Multisystem Inflammatory Syndrome (MIS-C)

Health Department-Reported Cases of Multisystem Inflammatory Syndrome in Children (MIS-C) in the United States

Since mid-May 2020, CDC has been tracking case reports of multisystem inflammatory syndrome in children (MIS-C), a rare but serious condition associated with COVID-19. CDC is working to learn more about why some children and adolescents develop MIS-C after having COVID-19 or contact with someone with COVID-19, while others do not.

As of October 1, 2020, the number of patients meeting the case definition for MIS-C in the United States surpassed 1,000. In 2021, this number surpassed 2,000 as of February 1, 3,000 as of April 1, and 4,000 as of June 2.

Last updated with cases reported to CDC on or before June 2, 2021*:

TOTAL MIS-C PATIENTS MEETING CASE DEFINITION*	TOTAL MIS-C DEATHS MEETING CASE DEFINITION
4018	36

*Additional patients are under investigation. After review of additional clinical data, patients may be excluded if there are alternative diagnoses that explained their illness.

Summary

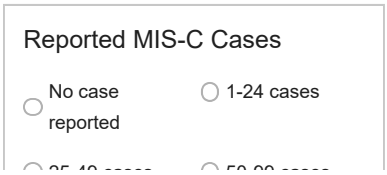
- The median age of patients with MIS-C was 9 years. Half of children with MIS-C were between the ages of 5 and 13 years.
- 62% of the reported patients with race/ethnicity information available occurred in children who are Hispanic or Latino (1,208 cases) or Black, Non-Hispanic (1,128 cases).
- 99% of patients had a positive test result for SARS CoV-2, the virus that causes COVID-19. The remaining 1% of patients had contact with someone with COVID-19.
- 60% of reported patients were male.

MIS-C Cases by Jurisdiction

Since reporting began in 2020, 51 U.S. jurisdictions (including 48 states, New York City, Puerto Rico, and Washington, DC) have reported at least one MIS-C patients to CDC. Because of the small number of patients reported in some jurisdictions, this report includes case ranges instead of exact case counts from individual jurisdictions to protect the privacy of patients and their families.

Reported MIS-C Case Ranges by Jurisdiction, on or before June 2, 2021*

Reported MIS-C Case Ranges by Jurisdiction, on or before June 2, 2021*

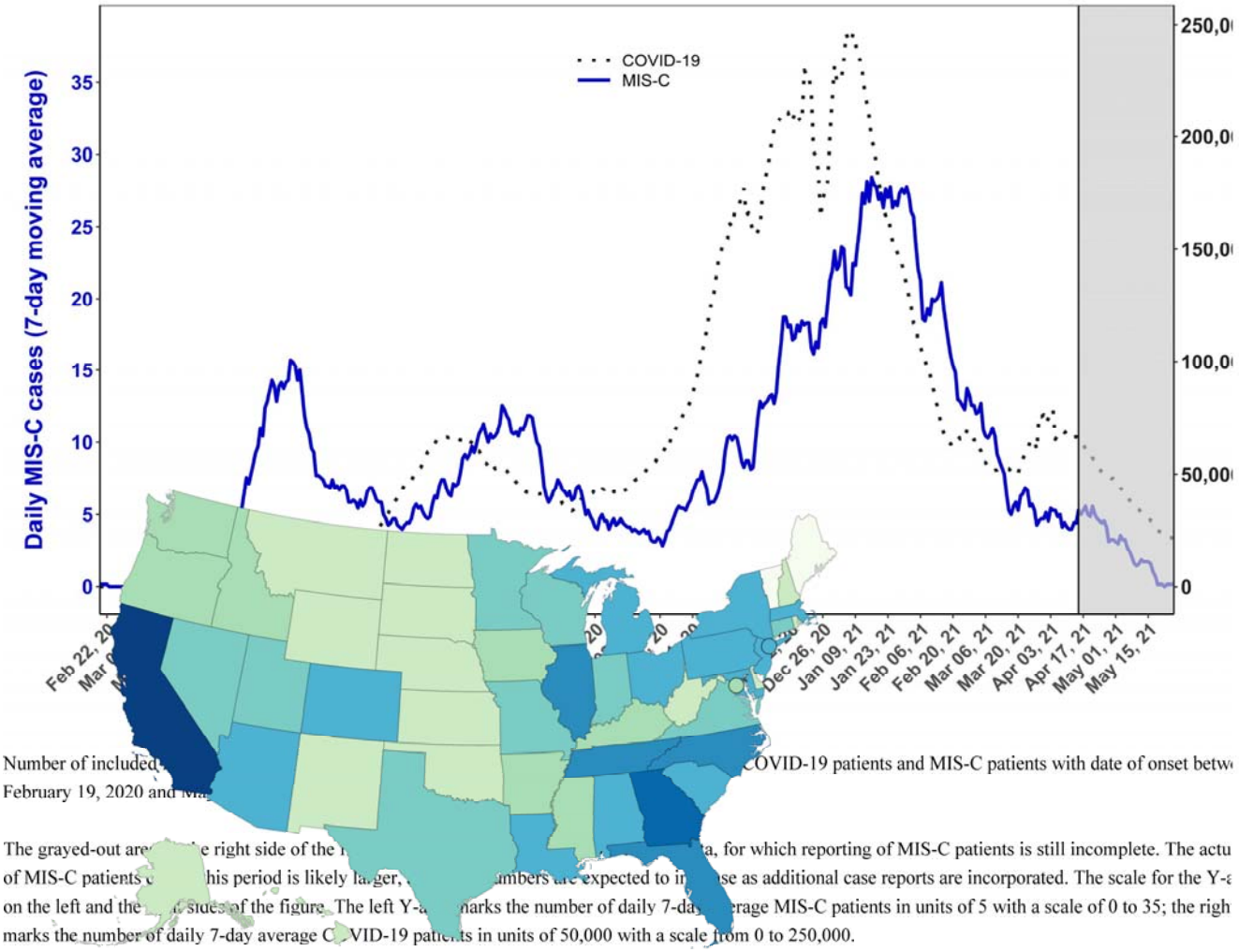


Page 2 and 3 were blank and was deleted

Download Data (CSV)

*CDC defers to jurisdictions to release additional information on patients.

Daily MIS-C Cases and COVID-19 Cases Reported to CDC (7-Day Moving Average)



Number of included COVID-19 patients and MIS-C patients with date of onset betw
February 19, 2020 and Ma

The grayed-out are right side of the a, for which reporting of MIS-C patients is still incomplete. The actu
of MIS-C patients his period is likely la ger, umbers are expected to i se as additional case reports are incorporated. The scale for the Y-a
on the left and the sides of the figure. The left Y-a narks the number of daily 7-da erage MIS-C patients in units of 5 with a scale of 0 to 35; the righ
marks the number of daily 7-day average C VID-19 patients in units of 50,000 with a scale from 0 to 250,000.

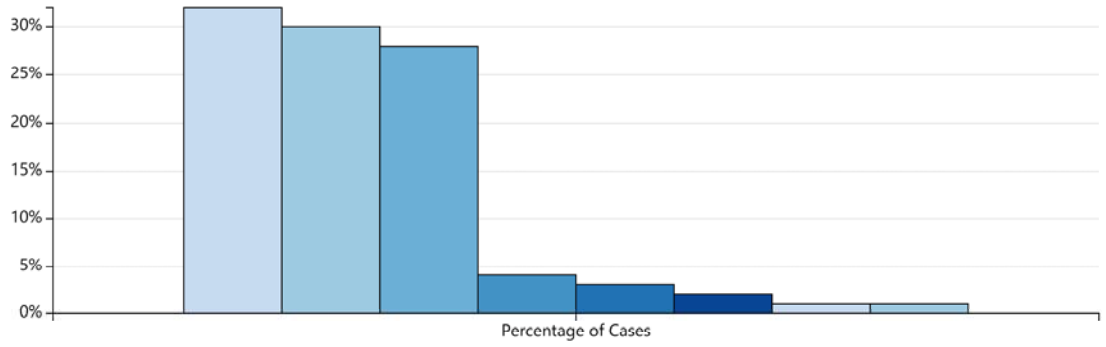
Date of onset was missing for 5 of the 4,018 patients.

Characteristics of Reported MIS-C Patients

CDC is closely monitoring characteristics of MIS-C patients by race and ethnicity, sex, and age.

To date, the majority of MIS-C patients have been of Hispanic/Latino or Non-Hispanic Black race/ethnicity. Hispanic/Latino and Non-Hispanic Black populations are also disproportionately affected by COVID-19 overall. Additional studies of MIS-C are needed to learn why certain racial or ethnic groups may be disproportionately affected and to understand the risk factors for this disease.

MIS-C Patients by Race & Ethnicity



☐ Hispanic/Latino ☐ Black, Non Hispanic ☐ White, Non Hispanic ☐ Other ☐ Multiple ☐ Asian ☐ *American Indian/Alaska Native ☐ *Native Hawaiian/ Other Pacific Islander

Reset

Data Table +

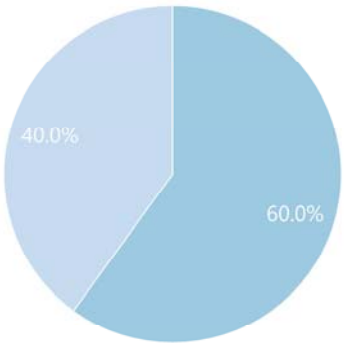
Download Table Data (csv)

*Values are less than 1%

Race/ethnicity data were not reported for 276 of the 4,018 cases. Column percents may add up to more than 100% due to children who fit within more than one race category.

MIS-C Patients by Sex

☐ Female ☐ Male Reset



Data +

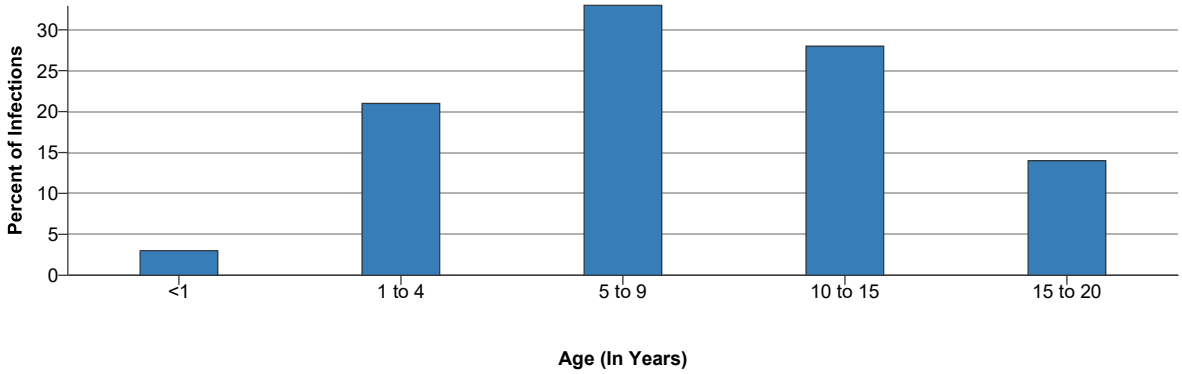
Download Table Data (csv)

Sex was not reported for 45 of 4,018 patients.

MIS-C Patients by Age Group

179

MIS-C Patients by Age Group



Data Table

Download Data (CSV)

Age group was not reported for 53 of the 4,018 cases.

Next steps

MIS-C can occur weeks after COVID-19 and even if the child or family did not know the child had COVID-19. CDC and state partners will be monitoring for additional cases and will adapt MIS-C recommendations as needed. Learn more about children and COVID-19 here.

CDC investigators are assessing reported cases of MIS-C and associated health outcomes to try to learn more about specific risk factors for MIS-C, progression of the illness in children and adolescents, and how to better identify MIS-C and distinguish it from similar illnesses.

About the data

This page is updated on the first Friday of each month.

Reported by Jurisdiction's Health Department

Data on this page are reported voluntarily to CDC by each jurisdiction's health department. CDC encourages all jurisdictions to report the most complete and accurate information that best represents the data available in their jurisdiction.

Timing of reporting

Case reporting may be delayed due to limited capacity at local/state health departments and as CDC assesses data to ensure cases meet the MIS-C case definition.

Page last reviewed: June 4, 2021
Content source: National Center for Immunization and Respiratory Diseases (NCIRD)

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Multisystem Inflammatory Syndrome (MIS-C)

Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C)

Partner Updates

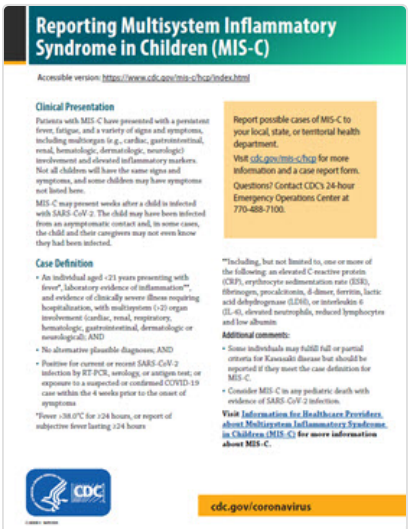
The American Academy of Pediatrics has published interim guidance on multisystem inflammatory syndrome in children (MIS-C).

Case Definition for MIS-C

As described in the CDC Health Advisory, "Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)," the case definition for MIS-C is:

- An individual aged <21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms.

*Fever ≥38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours
**Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin


Reporting Multisystem Inflammatory Syndrome in Children (MIS-C)

Accessible version: https://www.cdc.gov/mis-c/hcp/index.html

Clinical Presentation

Patients with MIS-C have presented with a persistent fever, fatigue, and a variety of signs and symptoms, including multiorgan (e.g., cardiac, gastrointestinal, renal, hematologic, dermatologic, neurologic) involvement and elevated inflammatory markers. Not all children will have the same signs and symptoms, and some children may have symptoms not listed here.

MIS-C may present weeks after a child is infected with SARS-CoV-2. The child may have been infected from an asymptomatic contact and, in some cases, the child and their caregivers may not even know they had been infected.

Report possible cases of MIS-C to your local, state, or territorial health department.

Visit cdc.gov/mis-c/hcp for more information and a case report form.

Questions? Contact CDC's 24-hour Emergency Operations Center at 770-488-7100.

Case Definition

- An individual aged <21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms

*Fever ≥38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours

**Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin

Additional comments:

- Some individuals may fulfill full or partial criteria for Kawasaki disease but should be reported if they meet the case definition for MIS-C.
- Consider MIS-C in any pediatric death with evidence of SARS-CoV-2 infection.

Visit Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C) for more information about MIS-C.

CDC

cdc.gov/coronavirus

Download the fact sheet

Clinical Presentation

Patients with MIS-C usually present with persistent fever, abdominal pain, vomiting, diarrhea, skin rash, mucocutaneous lesions and, in severe cases, with hypotension and shock. They have elevated laboratory markers of inflammation (e.g., CRP, ferritin), and in a majority of patients laboratory markers of damage to the heart (e.g., troponin; B-type natriuretic peptide (BNP) or proBNP). Some patients develop myocarditis, cardiac dysfunction, and acute kidney injury. Not all children will have the same signs and symptoms, and some children may have symptoms not listed here. MIS-C may begin weeks after a child is infected with SARS-CoV-2. The child may have been infected from an asymptomatic contact and, in some cases, the child and their caregivers may not even know they had been infected.

For more information on the clinical presentation of MIS-C, listen to the Clinician Outreach and Communication Activity (COCA) Call, hosted by CDC on May 19, 2020. During this call, clinicians discussed clinical characteristics, how cases have been diagnosed and treated, and how to respond to recently reported cases associated with COVID-19.

Evaluation

Laboratory Testing

- Testing aimed at identifying laboratory evidence of inflammation as listed in the Case Definition section is warranted.
- Similarly, SARS-CoV-2 detection by RT-PCR or antigen test is indicated.
- Where feasible, SARS-CoV-2 serologic testing is suggested, even in the presence of positive results from RT-PCR or antigen testing. Any serologic testing should be performed prior to administering intravenous immunoglobulin (IVIG) or any other exogenous antibody treatments.

Other Evaluations

Given the frequent association of MIS-C with cardiac involvement, many centers are performing[1-3] cardiac testing including, but not limited to:

- echocardiogram;
- electrocardiogram;
- cardiac enzyme or troponin testing (per the center's testing standards); and
- B-type natriuretic peptide (BNP) or NT-proBNP.

Other testing to evaluate multisystem involvement should be directed by patient signs or symptoms. Additionally, testing to evaluate for other potential diagnoses should be directed by patient signs or symptoms.

Treatment

At this time, there have been no studies comparing clinical efficacy of various treatment options. Treatments have consisted primarily of supportive care and directed care against the underlying inflammatory process. Supportive measures have included:

- fluid resuscitation;
- inotropic support;
- respiratory support; and
- in rare cases, extracorporeal membranous oxygenation (ECMO).

Anti-inflammatory measures have included the frequent use of IVIG and steroids. The use of other anti-inflammatory medications and the use of anti-coagulation treatments have been variable. Aspirin has commonly been used due to concerns for coronary artery involvement, and antibiotics are routinely used to treat potential sepsis while awaiting bacterial cultures. Thrombotic prophylaxis is often used given the hypercoagulable state typically associated with MIS-C.

The American College of Rheumatology has developed clinical guidance for pediatric patients diagnosed with MIS-C associated with SARS-CoV-2.

Coding

New ICD-10-CM Diagnosis Code for MIS: M35.81

- Applicable to:
  - MIS-A
  - MIS-C
  - Multisystem inflammatory syndrome in adults
  - Multisystem inflammatory syndrome in children
  - Pediatric inflammatory multisystem syndrome
  - PIMS
- Use additional code, if applicable, for:
  - Sequelae of COVID-19 (B94.8)
  - Personal history of COVID-19 (Z86.16)
  - Exposure to COVID-19 or SARS-CoV-2 infection (Z20.822)
- Code first, if applicable, COVID-19 (U07.1)
- Code also any associated complications

Follow up

Patients with a diagnosis of MIS-C should have close outpatient follow-up, including pediatric cardiology follow-up starting 2 to 3 weeks after discharge.

For more information, see AAP Interim Guidance on Multisystem Inflammatory Syndrome in Children (MIS-C) .

Reporting

Healthcare providers should report suspected cases among patients younger than 21 years of age meeting MIS-C criteria described in the case definition above to their local, state, or territorial health department. Clinicians can report by submitting either completed case report forms or medical records for review to their state, local, or territorial health department. After-hours phone numbers for health departments are available at the Council of State and Territorial Epidemiologists website . For additional reporting questions, please contact CDC's 24-hour Emergency Operations Center at 770-488-7100.

Case Report Form

- Instructions for Multisystem Inflammatory Syndrome Associated with COVID-19 Case Report Form [164 KB, 5 pages]

  Fillable Multisystem Inflammatory Syndrome Associated with COVID-19 Case Report Form [464 KB, 1 Page]

References

1. Belhadjer Z, Meot M, Bajolle F, et al. Acute heart failure in multisystem inflammatory syndrome in children (MIS-C) in the context of global SARS-CoV-2 pandemic . Circulation 2020.
2. Riphagen S, Gomez X, Gonzalez-Martinez C, Wilkinson N, Theocharis P. Hyperinflammatory shock in children during COVID-19 pandemic . Lancet 2020.
3. Verdoni L, Mazza A, Gervasoni A, et al. An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study . Lancet 2020.

Additional Resources

- New ICD-10-CM code for the 2019 Novel Coronavirus (COVID-19)
- American Academy of Pediatrics: Multisystem Inflammatory Syndrome in Children (MIS-C) Interim Guidance
- American College of Rheumatology: Clinical Guidance for Pediatric Patients with Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with SARS-CoV-2 and Hyperinflammation in COVID-19
- Clinical Outreach and Communication Activity (COCA) Webinar, May 19, 2020: Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)
- CDC Health Advisory (5/14/20): Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)
- COVID-19 Information for Pediatric Healthcare Providers
- Clinical Questions about COVID-19: Questions and Answers
- Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)
- Kawasaki Disease
- Multisystem Inflammatory Syndrome in Children: Survey of Early Hospital Evaluation and Management
- For Parents: Multisystem Inflammatory Syndrome in Children (MIS-C)

Page last reviewed: May 20, 2021
Content source: National Center for Immunization and Respiratory Diseases (NCIRD)

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Morbidity and Mortality Weekly Report (*MMWR*)

Case Series of Multisystem Inflammatory Syndrome in Adults Associated with SARS-CoV-2 Infection — United Kingdom and United States, March–August 2020

Weekly / October 9, 2020 / 69(40);1450–1456

On October 2, 2020, this report was posted online as an MMWR *Early Release.*

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View suggested citation

Summary

What is already known about this topic?

Multisystem inflammatory syndrome in children (MIS-C) is a rare but severe complication of SARS-CoV-2 infection in children and adolescents. Since June 2020, several case reports and series have been published reporting a similar multisystem inflammatory syndrome in adults (MIS-A).

What is added by this report?

Cases reported to CDC and published case reports and series identify MIS-A in adults, who usually require intensive care and can have fatal outcomes. Antibody testing was required to identify SARS-CoV-2 infection in approximately one third of 27 cases.

What are the implications for public health practice?

Clinical suspicion and indicated SARS-CoV-2 testing, including antibody testing, might be needed to recognize and treat adults with MIS-A. Further research is needed to understand the pathogenesis and long-term effects of this condition. Ultimately, the recognition of MIS-A reinforces the need for prevention efforts to limit spread of SARS-CoV-2.

Table 2

References

Related Materials

PDF [400K]

During the course of the coronavirus disease 2019 (COVID-19) pandemic, reports of a new multisystem inflammatory syndrome in children (MIS-C) have been increasing in Europe and the United States (*1*–*3*). Clinical features in children have varied but predominantly include shock, cardiac dysfunction, abdominal pain, and elevated inflammatory markers, including C-reactive protein (CRP), ferritin, D-dimer, and interleukin-6 (*1*). Since June 2020, several case reports have described a similar syndrome in adults; this review describes in detail nine patients reported to CDC, seven from published case reports, and summarizes the findings in 11 patients described in three case series in peer-reviewed journals (*4*–*6*). These 27 patients had cardiovascular, gastrointestinal, dermatologic, and neurologic symptoms without severe respiratory illness and concurrently received positive test results for SARS-CoV-2, the virus that causes COVID-19, by polymerase chain reaction (PCR) or antibody assays indicating recent infection. Reports of these patients highlight the recognition of an illness referred to here as multisystem inflammatory syndrome in adults (MIS-A), the heterogeneity of clinical signs and symptoms, and the role for antibody testing in identifying similar cases among adults. Clinicians and health departments should consider MIS-A in adults with compatible signs and symptoms. These patients might not have positive SARS-CoV-2 PCR or antigen test results, and antibody testing might be needed to confirm previous SARS-CoV-2 infection. Because of the temporal association between MIS-A and SARS-CoV-2 infections, interventions that prevent COVID-19 might prevent MIS-A. Further research is needed to understand the pathogenesis and long-term effects of this newly described condition.

Potential MIS-A patients were identified from several sources: reports from clinicians and health departments, published case reports, and published case series. Clinicians and health departments in the United States voluntarily reported adult patients with suspected MIS-A to CDC using the case report form* developed for MIS-C after a Health Advisory was published on May 14, 2020, calling for reporting of MIS-C cases. The case report form included information on patient demographics, underlying medical conditions, clinical findings, complications, laboratory test results including those from SARS-CoV-2 testing, imaging findings, treatments, and outcomes. Two clinician reviewers selected patients who fulfilled the working MIS-A case definition used in this report, which included the following five criteria: 1) a severe illness requiring hospitalization in a person aged ≥21 years; 2) a positive test result for current or previous SARS-CoV-2 infection (nucleic acid, antigen, or antibody) during admission or in the previous 12 weeks; 3) severe dysfunction of one or more extrapulmonary organ systems (e.g., hypotension or shock, cardiac dysfunction, arterial or venous thrombosis or thromboembolism, or acute liver injury); 4) laboratory evidence of severe inflammation (e.g., elevated CRP, ferritin, D-dimer, or interleukin-6); and 5) absence of severe respiratory illness (to exclude patients in which inflammation and organ dysfunction might be attributable simply to tissue hypoxia). Patients with mild respiratory symptoms who met these criteria were included. Patients were excluded if alternative diagnoses such as bacterial sepsis were identified.

To identify potential published cases, a literature search was performed on August 20, 2020, and 355 publications were identified.† Abstracts were screened by one reviewer to determine whether cases met the working MIS-A case definition; when no abstract was available, the full paper was examined. The references were reviewed to identify additional relevant articles. Data were obtained from published reports; authors were contacted to confirm published data and, when necessary, to provide data not included in the original articles.

Top

Case Reports

Demographic characteristics and underlying conditions. Cases in nine patients reported to CDC (Table 1) and seven published case reports (Table 2), originating from seven U.S. jurisdictions and the United Kingdom, met the working case definition. The 16 patients ranged in age from 21 to 50 years and included seven men and nine women. Five were reported as Hispanic, nine as African American, one as Asian, and one as a United Kingdom–born man of African ethnicity. Nine patients had no reported underlying medical conditions; six were obese, one had poorly controlled diabetes mellitus type 2 (hemoglobin A1C >9.0%), two had hypertension, and one had obstructive sleep apnea. Eight patients had documented respiratory illness before developing symptoms of MIS-A, and eight did not.

Initial signs and symptoms. Twelve of 16 patients had fever (≥100.4°F [38.0°C] for ≥24 hours or report of subjective fever lasting ≥24 hours) at the time of presentation. Six patients were initially evaluated for possible cardiac symptoms such as chest pain or palpitations; all 16 had evidence of cardiac effects, including electrocardiogram abnormalities such as arrhythmias, elevated troponin levels, or echocardiographic evidence of left or right ventricular dysfunction. Thirteen patients had gastrointestinal symptoms on admission; five had dermatologic manifestations on admission, including three with mucositis. Despite minimal respiratory symptoms, 10 patients had pulmonary ground glass opacities, and six had pleural effusions identified on chest imaging.

Inflammatory markers. All patients had markedly elevated laboratory markers of inflammation, including CRP (range of peak values = 84–580 mg/L; upper limit of normal [ULN] = 10 mg/L) and ferritin (196 to >100,000 ng/mL; ULN = 150 ng/mL for women, 300 ng/mL for men), as well as markers of coagulopathy including D-dimer (275–8691 ng/mL; ULN = 500 ng/mL). Ten patients had absolute lymphocyte counts lower than normal range (range of nadir values 120–2120 cells/μL; lower limit of normal = 1000 cells/μL).

SARS-CoV-2 test results. Ten patients received positive SARS-CoV-2 PCR test results at the time of initial assessment for MIS-A, seven of whom also had serologic evidence of infection (positive antibody test results) at that time. Six patients received negative SARS-CoV-2 PCR test results; of those, four had positive anti-SARS-CoV-2 antibody test results when first evaluated. Two patients had positive SARS-CoV-2 PCR test results 14 and 37 days before admission, negative PCR results at the time of admission, and no known antibody testing. Three additional patients had positive SARS-CoV-2 PCR test results 25–41 days before admission and continued positive PCR test results at the time of admission.

Treatment. Seven patients were treated with intravenous immunoglobulin, 10 with corticosteroids, and two with the interleukin-6 inhibitor, tocilizumab. Ten patients required intensive care; seven required inotropes or vasopressors, and one required mechanical circulatory support (extracorporeal membrane oxygenation followed by temporary left and right ventricular assist devices). Three patients required endotracheal intubation and mechanical ventilation, and two patients died.

Top

Published Case Series

Three published case series were identified describing adult patients with manifestations consistent with MIS-A (*4*–*6*). One series describes seven previously healthy, young adult men aged 20–42 years who experienced mixed cardiogenic and vasoplegic shock and hyperinflammation along with high SARS-CoV-2 immunoglobulin G antibody titers indicating active or previous infection (*4*). Two of the patients identified as African American, two as Hispanic, two as Middle Eastern, and one as White. Four of the seven patients had negative PCR test results for SARS-CoV-2 at the time of admission, all had markedly elevated inflammatory markers and required inotropes or vasopressors, and three required intraaortic balloon pumps. All were treated with corticosteroids and therapeutic anticoagulation. All seven patients recovered and were discharged home after 7 to 18 days of hospitalization with improved cardiovascular function.

A second case series describes two patients aged 21 and 50 years who came to medical attention because of large-vessel strokes associated with positive SARS-CoV-2 tests (*5*). Information on race/ethnicity of these patients was not reported. These patients had elevated inflammatory markers and minimal respiratory symptoms, consistent with MIS-A. The authors proposed endothelial dysfunction and coagulopathy related to SARS-CoV-2 infection as potential etiologies. Incidence of large-vessel stroke among young adults during this same time the previous year was statistically significantly lower (*5*).

A third case series describes the pathologic findings of endothelialitis and complement deposition in the vessels of two patients with illness resembling MIS-A (cardiac dysfunction, abdominal signs and symptoms, and rash) associated with positive SARS-CoV-2 test results (*6*). Information on race/ethnicity of these patients was not reported. One of these two patients had no underlying medical conditions and recovered; the other had multiple underlying conditions at higher risk for severe COVID-19 and died hours after seeking care. Pathologic findings in this case series were similar to autopsy findings for those of patient 14 (Table 2).

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Discussion

Findings indicate that adult patients of all ages with current or previous SARS-CoV-2 infection can develop a hyperinflammatory syndrome resembling MIS-C. Although hyperinflammation and extrapulmonary organ dysfunction have been described in hospitalized adults with severe COVID-19, these conditions are generally accompanied by respiratory failure (*7*). In contrast, the patients described here had minimal respiratory symptoms, hypoxemia, or radiographic abnormalities in accordance with the working case definition, which was meant to distinguish MIS-A from severe COVID-19; only eight of 16 patients had any documented respiratory symptoms before onset of MIS-A.

The pathophysiology of MIS in both children and adults is currently unknown. Eight of 27 (30%) adults described in this report and 45% of 440 children with MIS-C reported to CDC through July 29, 2020, (*1*) had negative PCR and positive SARS-CoV-2 antibody test results, suggesting MIS-A and MIS-C might represent postinfectious processes. However, in some patients, persistent infection outside the upper respiratory tract is possible; SARS-CoV-2 has been identified in multiple organs including the heart, liver, brain, kidneys, and gastrointestinal tract (*7*). Additional proposed mechanisms for extrapulmonary dysfunction in COVID-19 include endothelial damage and thromboinflammation, dysregulated immune responses, and dysregulation of the renin-angiotensin-aldosterone system (*7*).

The interval between infection and development of MIS-A is unclear, adding to uncertainty regarding whether MIS-A represents a manifestation of acute infection or an entirely postacute phenomenon. In patients with COVID-19, dyspnea is typically experienced a median of 5–8 days and critical illness 10–12 days after onset of symptoms.[§] In patients who reported typical COVID-19 symptoms before MIS-A onset, MIS-A was experienced approximately 2–5 weeks later. However, eight MIS-A patients reported no preceding respiratory symptoms, making it difficult to estimate when initial infection occurred.

Given the high proportion of MIS-C patients with negative PCR testing, clinical guidelines recommend the use of both antibody and viral testing to assist with diagnosis (*8–10*). In patients with atypical or late manifestations of SARS-CoV-2 infection, including MIS-A, positive antibody results might be crucial to augment clinical recognition of this condition and guide treatment. In addition, the use of a panel of laboratory tests for inflammation, hypercoagulability, and organ damage (e.g., CRP, ferritin, D-dimer, cardiac enzymes, liver enzymes, and creatinine) might assist in the early identification and management of this COVID-19–associated condition.

All but one of the patients with MIS-A described in this report belonged to racial or ethnic minority groups. Long-standing health and social inequities have resulted in increased risk for infection and severe outcomes from COVID-19 in communities of color.[¶] MIS-C has also been reported disproportionately in these communities (*1*). Because patients described in this review represent a convenience sample from a small number of jurisdictions, conclusions cannot be made regarding the true burden or determinants of MIS-A in different groups; further research is needed.

The majority (24 of 27) of patients with MIS-A survived, similar to those with MIS-C, associated with receiving care in acute, often intensive, health care settings. Because of the potential therapies that might benefit these patients as described in these case reports, clinicians should consider MIS-A within a broader differential diagnosis when caring for adult patients with clinical and laboratory findings consistent with the working MIS-A case definition.

The findings in this report are subject to at least three limitations. First, cases described here were voluntarily reported or published and therefore are not representative of the true clinical spectrum or racial/ethnic distribution of this emerging syndrome. Additional cases might not have been reported or published; others might have remained unrecognized because of absence of COVID-like symptoms, lack of antibody testing, or negative test results. Second, the working case definition excludes patients with severe respiratory dysfunction to distinguish MIS-A from severe COVID-19; however, the two conditions might overlap in some cases. Finally, the working case definition for this syndrome is potentially nonspecific, and some patients with other disease processes might have been misclassified as having MIS-A.

Clinicians and health departments should consider MIS-A in adults with signs and symptoms compatible with the current working MIS-A case definition. Antibody testing for SARS-CoV-2 might be needed to confirm previous COVID-19 infection in patients who do not have positive SARS-CoV-2 PCR or antigen test results. Findings in this convenience sample emphasize the importance of collecting race/ethnicity data on case reports at the jurisdictional level. As with children, it is important that multidisciplinary care be considered to ensure optimal treatment. In the process of learning more from MIS-A cases, the working case definition might need to be revised in order to systematically conduct a call for cases. Further research is needed to understand the pathogenesis and long-term effects of this newly described condition. Ultimately, the recognition of MIS-A reinforces the need for prevention efforts to limit spread of SARS-CoV-2.

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* Multisystem Inflammatory Syndrome Associated with COVID-19 Case Report Form. https://www.cdc.gov/mis-c/pdfs/hcp/mis-c-form-fillable.pdf .

† Medline (OVID), Embase (OVID), CINAHL (EBSCOHost) and Cochrane Library were searched as primary sources, which were supplemented with searches in the following databases: Global Health, CAB abstracts, PsycInfo, Scopus, PubMed Central, Global Index Medicus, and several preprint databases. Each database was searched using the following terms: novel coronavirus/COVID-19 (multiple iterations) and severe inflammation/multisystem, cardiogenic shock/Kawasaki disease, and adult.

§ https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html.

¶ https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.

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TABLE 1. Demographics, clinical features, treatments, and outcomes of nine adults reported to CDC with multisystem inflammatory syndrome (MIS) associated with SARS-CoV-2 infection — United States, March–Aug

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs and symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs and symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 1: 27, female, African American, Maine	None	Rigors, profuse diarrhea, diffuse rash x 5 days. Admitted with mixed shock (hypovolemic, vasoplegic, cardiogenic) and acute renal failure.	No/Testing unknown	PCR (-), Ab (+)	CRP 344 mg/L; D-dimer 2818 ng/mL; ferritin 1082 ng/mL; troponin I 0.43 ng/mL; ALT 37 IU/L; ALC nadir 420 cells/μL	TTE: mild to moderate global hypokinesis, left ventricular ejection fraction 45%, mildly dilated right ventricle, mild tricuspid regurgitation, pericardial effusion. CT chest: bilateral patchy ground-glass opacities, pleural effusion. CT abdomen/pelvis: abdominal free fluid.
Patient 2: 50, male, African American, Florida	None	Poor oral intake, chest pressure, palpitations, diaphoresis x 3 days. Hemodynamically unstable on admission.	No/Testing unknown	PCR (+), Ab (+)	CRP 84 mg/L; D-dimer 2310 ng/mL; ferritin 1919 ng/mL; troponin I 0.48 ng/mL; ALT 440 IU/L; ALC nadir 2500 cells/μL	EKG: atrial fibrillation/flutter with rapid ventricular response, ST segment changes. TTE: ejection fraction 25%–30% with global hypokinesis. CXR: small pleural effusions.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs and symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 3: 46, male, African American, Florida	Obesity, chronic right lower extremity pain	Malaise, bilateral tinnitus, chest pain, and vomiting x 4 days. Hypotensive and mildly hypoxemic on admission.	Yes/Testing unknown	PCR (-), Ab (+)	CRP 217 mg/L; D-dimer 3790 ng/mL; ferritin >100,000 ng/mL; troponin I 2.5 ng/mL; IL-6 1412 pg/mL; ALT >10,000 IU/L; ALC nadir 400 cells/μL	EKG: ST-T segment changes. CT chest: dependent ground glass opacities. CT abdomen: hepatic steatosis.
Patient 4: 21, male, African American, Louisiana	Obesity	Fever, cough, nausea, vomiting, lymphadenopathy x 6 days.	No/Testing unknown	PCR (-), Ab (+)	CRP 318 mg/L; D-dimer 1760 ng/mL; ferritin 4400 ng/mL; troponin T 0.65 ng/mL; IL-6 7 pg/mL; ATL 279 IU/L; ALC nadir 700 cells/μL	TTE: severely decreased ejection fraction, mild mitral regurgitation, right ventricular dysfunction, coronary artery dilatation. CT chest: ground glass opacities and atelectasis.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs and symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 5: 33, male, African American, Georgia	Obesity, HTN, depression	Fever, chest pain, abdominal pain, diarrhea, dark urine x 4 days.	Yes/PCR (+) 41 days earlier	PCR (+), Ab (+)	CRP 182 mg/L; D-dimer 275 ng/mL; ferritin 375 ng/mL; troponin I 1.8 ng/mL; IL-6 74.3 pg/mL; ALT 30 IU/L; ALC nadir 2070 cells/μL	CT chest: atelectasis. CT abdomen/pelvis: normal. TTE: mitral and tricuspid regurgitation.
Patient 6: 22, female, African American, New York	None	Fever, chills, throat pain, odynophagia x 2 days.	No/Testing unknown	PCR (+), Ab (+)	CRP 355 mg/L; D-dimer 1882 ng/mL; ferritin 378 ng/mL; troponin T 0.06 ng/mL; IL-6 34.8 pg/mL; ALT 119 U/L; ALC nadir 360 cells/μL	CT neck: retropharyngeal and parapharyngeal edema. EKG: intermittent complete heart block with narrow junctional escape without hemodynamic compromise. TTE: ejection fraction 50%. CXR: dense bilateral lower lobe air-space disease.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs and symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 7: 21, female, African American, New York	Obesity	Fever, fatigue, throat and neck pain, nausea, vomiting x 1 day.	Yes/PCR (+) 25 days earlier	PCR (+), Ab (+)	CRP 319 mg/L; D-dimer 713 ng/mL; ferritin 351 ng/mL; troponin T 0.04 ng/mL; IL-6 56.2 pg/mL; ALT 160 IU/L; ALC nadir 260 cells/μL	CT neck: bilateral supraclavicular and cervical lymphadenopathy with no discrete abscess or collection. CT chest: bilateral patchy ground-glass opacities, pleural effusion. TTE: mild to moderate diffuse left ventricular hypokinesis. Mild to moderate decreased left ventricular ejection fraction (40%). Small posterior pericardial effusion. Mild tricuspid and mitral valve regurgitation.
Patient 8: 47, female, African American, New York	None	Weakness, sore throat, shortness of breath, decreased exercise tolerance x 3 days.	Yes/Testing unknown	PCR (+), Ab testing not performed	CRP 485 mg/L; D-dimer 1365 ng/mL; ferritin 948 ng/mL; troponin T 0.24 ng/mL; ALT 45 U/L; ALC nadir 1980 cells/μL	EKG: first degree AV block and nonspecific T-wave abnormalities. TTE: borderline left ventricular ejection fraction (55%).

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs and symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 9: 42, male, Asian, New York	Obesity	Fever, shortness of breath, cough, diarrhea, poor appetite, dysuria x 5 days.	Yes/PCR (+) 37 days earlier	PCR (-), Ab testing not performed	CRP 387 mg/L; D-dimer 3519 ng/mL; ferritin 7529 ng/mL; troponin T 0.60 ng/mL; ALT 66 U/L; ALC nadir 1740 cells/μL	TEE: mildly dilated left ventricle, moderately dilated right ventricle, moderate biventricular hypokinesis, moderately decreased left ventricular ejection fraction (35%). CXR: bilateral lower lobe opacities/airspace disease.

Abbreviations: Ab = antibody; ALC = absolute lymphocyte count; ALT = alanine aminotransferase; ASA = aspirin; CRP = C-reactive protein; CT = computed tomography; CXR = chest radiograph; EKG = electrocardiogram; HTN = hypertension; IL-6 = interleukin-6; IVIG = intravenous immunoglobulin; PCR = polymerase chain reaction; TEE = transesophageal echocardiogram; TTE = transthoracic echocardiogram.

* Normal ranges for laboratory studies: ALC 1000–4000 cells/μL; ALT 5–30 IU/L; CRP 0–10 mg/L; D-dimer <500 ng/mL; ferritin 12–300 ng/mL (men), 12–150 ng/mL (women); IL-6 ≤1.8 pg/mL; troponin I <0.03 ng/mL; troponin T < 0.1 ng/mL.

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TABLE 2. Demographics, clinical features, treatments, and outcomes of seven adults reported in pub multisystem inflammatory syndrome (MIS) associated with SARS-CoV-2 infection — United Kingd –August 2020

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs/symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs/symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 10†: 36, female, Hispanic, New York	None	Fever, abdominal pain, vomiting, and diarrhea x 7 days; arthralgias and diffuse rash x 2 days. On admission, nonexudative conjunctivitis, mucositis, edema of bilateral hands and feet, palmar erythema, diffuse maculopapular rash, and cervical lymphadenopathy.	No/Not tested	PCR (+), Ab (+)	CRP 300 mg/L; D-dimer 652 ng/mL; ferritin 684 ng/mL; troponin I 0.07 ng/mL; ALT 116 IU/L; ALC nadir 900 cells/μL	TTE: moderate tricuspid regurgitation, pericardial effusion. CT chest: right pleur effusion. Ultrasounc gallbladder wall edema.
Patient 11§: 45, male, Hispanic, New York	None	Fever, sore throat, diarrhea, lower extremity pain, and diffuse rash x 6 days. On admission, hypotensive and tachycardic with nonexudative conjunctivitis, periorbital edema, mucositis, unilateral cervical lymphadenopathy, and diffuse exanthem.	No/Not tested	PCR (+), Ab testing not performed	CRP 547 mg/L; D-dimer 2977 ng/mL; ferritin 21,196 ng/mL; troponin 8.1 ng/mL; IL-6 117 pg/mL; ALT 133 IU/L; ALC nadir 700 cells/μL	EKG: ST elevations i anterolateral leads. TTE: ejection fractio 40% with global hypokinesis. CT head/neck: pre-septal edema. Slit lamp: uveitis.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs/symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 12¶: 44, female, Hispanic, Massachusetts	GERD, mild obstructive sleep apnea, depression	Chills, sore throat, cough, myalgias x 2 days (8 days before admission); followed by diarrhea and back pain x 3 days; followed by pleuritic chest pain and dyspnea. Admitted with profound cardiogenic shock.	Yes/Not tested	PCR (+), Ab testing not performed	CRP 141 mg/L; D-dimer 8691 ng/mL; ferritin 2564 ng/mL; hs-Trop T 1810 ng/L; IL-6 53.3 pg/mL; ALT 242 IU/L; ALC nadir 670 cells/μL	EKG: submillimeter segment elevation i leads I/aVL, low QRS voltage. TTE: severely depressed left ventricular function, trace pericardial effusion. CT chest: mild grour glass opacities bilateral lung fields. CT abdomen/pelvis: small amount of ascites, periportal edema.
Patient 13**: 21, male, African origin, United Kingdom	None	Fever, headache, and abdominal pain x 6 days; transient palmar rash. Hypotensive on admission with nonexudative conjunctivitis, mucositis, cervical lymphadenopathy.	No/Not tested	PCR (-), Ab (+)	CRP 338 mg/L; D-dimer 4260 ng/mL; ferritin 1249 ng/mL; troponin T 3.3 ng/mL; ALT 330 IU/L; ALC nadir 390 cells/μL	CT abdomen/pelvis: mesenteric adenopathy and ilei EKG: sinus tachycardia. CT chest: normal. TTE: normal. CT coronary angiogram: normal.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs/symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 14††: 31, female, African American, Louisiana	Obesity, HTN, diabetes mellitus type 2	Fever x 1 day, throbbing neck pain, nausea, vomiting.	Yes/PCR (+) 14 days before admission	PCR (-), Ab testing not performed	CRP 580 mg/L; D-dimer 453 ng/mL; ferritin 793 ng/mL; ALT 52 IU/L; ALC nadir 2120 cells/μL	Pathology: small-vessel cardiac vasculitis; new pulmonary thrombi a background of otherwise reparative changes in the lungs CT head/neck: bilateral enlarged parotid glands. CT chest: interval improvement of bibasilar ground-gla opacities with cervic and anterior mediastinal lymphadenopathy.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs/symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 15[§§]: 25, female, Hispanic, Georgia	None	Fever, weakness, and shortness of breath x 7 days; followed by sore throat, mild cough, vomiting, and diarrhea. Hypotensive on admission with conjunctivitis, mucositis, cervical lymphadenopathy.	No/Not tested	PCR (+), Ab (+)	CRP 90 mg/L; D-dimer 1918 ng/mL; ferritin 798 ng/mL; troponin I 0.06 ng/mL; ALT 25 IU/L, ALC nadir 1150 cells/μL	TTE: moderate to severely reduced right-sided ventricul dysfunction, flattene interventricular septum in systole consistent with right ventricular pressure overload. EKG: right axis deviation. CT chest: scattered patchy ground glass opacities and peripheral consolidation, small bilateral pleural effusions with adjacent atelectasis; mild enlargement of the main pulmonary artery without pulmonary embolus CT abdomen/ pelvis mild peripancreatic stranding, nonspeci bilateral perinephric fat stranding.

Age (yrs), sex, race/ethnicity, location	Underlying medical conditions	Clinical signs/symptoms	Previous respiratory illness/SARS-CoV-2 testing	SARS-CoV-2 testing at time of MIS-A admission	Laboratory studies (peak)*	Imaging/Other diagnostic studies
Patient 16¶¶: 38, female, Hispanic, Texas	None	Fever, occipital headache, conjunctival injection, odynophagia, mucositis, glossitis shortness of breath, vomiting, polyarthralgia, and rash x 5 days.	Yes/PCR (+) 28 days earlier	PCR (+), Ab (+)	CRP 217 mg/L; D-dimer 1250 ng/mL; ferritin 196 ng/mL; troponin I <0.03 ng/mL; ALT 126 IU/L; ALC nadir 120 cells/μL	TTE: trace pericardial effusion, elevated pulmonary artery press (46–51 mm Hg), norn left ventricular ejection fraction, no coronary artery abnormalities. CT chest/abdomen/pel no pulmonary embo right upper lobe perihilar ground-gla opacities, septal and bronchial wall thickening, bilateral small-to-moderate pleural effusions.

Abbreviations: Ab = antibody; ALC = absolute lymphocyte count; ALT = alanine aminotransferase; ASA = aspirin; CPR = cardiopulmonary resuscitation; CRP = C-reactive protein; CT = computed tomography; ECMO = extracorporeal membrane oxygenation; EKG = electrocardiogram; GERD = gastroesophageal reflux disease; hs-Trop T = high sensitivity troponin T; HTN = hypertension; IL-6 = interleukin-6; IVIG = intravenous immunoglobulin; LVAD = left ventricular assist device; PCR = polymerase chain reaction; RVAD = right ventricular assist device; TTE = transthoracic echocardiogram.

* Normal ranges for laboratory studies: ALC 1000–4000 cells/μL; ALT 5–30 IU/L; CRP 0–10 mg/L; D-dimer <500 ng/mL; Ferritin 12–300 ng/mL (men), 12–150 ng/mL (women); hs-Trop T 0–9 ng/L IL-6 ≤1.8 pg/mL; troponin I <0.03 ng/mL; troponin T < 0.1 ng/mL.

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Multisystem Inflammatory Syndrome (MIS)

Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C)

Partner Updates

The American Academy of Pediatrics has published interim guidance on multisystem inflammatory syndrome in children (MIS-C).

Case Definition for MIS-C

y Operations Center at 770-488-7100. Download and print the Reporting MIS-C fact sheet [76 KB, 1 page] to learn more.

As described in the CDC Health Advisory, "Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)," the case definition for MIS-C is:

- An individual aged <21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms.

*Fever ≥38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours
**Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin

Additional comments:

- Some individuals may fulfill full or partial criteria for Kawasaki disease but should be reported if they meet the case definition for MIS-C.
- Consider MIS-C in any pediatric death with evidence of SARS-CoV-2 infection.

Clinical Presentation

Patients with MIS-C usually present with persistent fever, abdominal pain, vomiting, diarrhea, skin rash, mucocutaneous lesions and, in severe cases, with hypotension and shock. They have elevated laboratory markers of inflammation (e.g., CRP, ferritin), and in a majority of patients laboratory markers of damage to the heart (e.g., troponin; B-type natriuretic peptide (BNP) or proBNP). Some patients develop myocarditis, cardiac dysfunction, and acute kidney injury. Not all children will have the same signs and symptoms, and some children may have symptoms not listed here. MIS-C may begin weeks after a child is infected with SARS-CoV-2. The child may have been infected from an asymptomatic contact and, in some cases, the child and their caregivers may not even know they had been infected.

For more information on the clinical presentation of MIS-C, listen to the Clinician Outreach and Communication Activity (COCA) Call, hosted by CDC on May 19, 2020. During this call, clinicians discussed clinical characteristics, how cases have been diagnosed and treated, and how to respond to recently reported cases associated with COVID-19.

Evaluation

Laboratory Testing

- Testing aimed at identifying laboratory evidence of inflammation as listed in the Case Definition section is warranted.
- Similarly, SARS-CoV-2 detection by RT-PCR or antigen test is indicated.
- Where feasible, SARS-CoV-2 serologic testing is suggested, even in the presence of positive results from RT-PCR or antigen testing. Any serologic testing should be performed prior to administering intravenous immunoglobulin (IVIG) or any other exogenous antibody treatments.

Other Evaluations

Given the frequent association of MIS-C with cardiac involvement, many centers are performing[1-3] cardiac testing including, but not limited to:

- echocardiogram;
- electrocardiogram;
- cardiac enzyme or troponin testing (per the center's testing standards); and
- B-type natriuretic peptide (BNP) or NT-proBNP.

Other testing to evaluate multisystem involvement should be directed by patient signs or symptoms. Additionally, testing to evaluate for other potential diagnoses should be directed by patient signs or symptoms.

Treatment

At this time, there have been no studies comparing clinical efficacy of various treatment options. Treatments have consisted primarily of supportive care and directed care against the underlying inflammatory process. Supportive measures have included:

- fluid resuscitation;
- inotropic support;
- respiratory support; and
- in rare cases, extracorporeal membranous oxygenation (ECMO).

Anti-inflammatory measures have included the frequent use of IVIG and steroids. The use of other anti-inflammatory medications and the use of anti-coagulation treatments have been variable. Aspirin has commonly been used due to concerns for coronary artery involvement, and antibiotics are routinely used to treat potential sepsis while awaiting bacterial cultures. Thrombotic prophylaxis is often used given the hypercoagulable state typically associated with MIS-C.

The American College of Rheumatology has developed clinical guidance for pediatric patients diagnosed with MIS-C associated with SARS-CoV-2.

Coding

New ICD-10-CM Diagnosis Code for MIS: M35.81

- Applicable to:
  - MIS-A
  - MIS-C
  - Multisystem inflammatory syndrome in adults
  - Multisystem inflammatory syndrome in children
  - Pediatric inflammatory multisystem syndrome
  - PIMS
- Use additional code, if applicable, for:
  - Sequelae of COVID-19 (B94.8)
  - Personal history of COVID-19 (Z86.16)
  - Exposure to COVID-19 or SARS-CoV-2 infection (Z20.822)
- Code first, if applicable, COVID-19 (U07.1)
- Code also any associated complications

Follow up

Patients with a diagnosis of MIS-C should have close outpatient follow-up, including pediatric cardiology follow-up starting 2 to 3 weeks after discharge.

For more information, see AAP Interim Guidance on Multisystem Inflammatory Syndrome in Children (MIS-C) .

Reporting

Healthcare providers should report suspected cases among patients younger than 21 years of age meeting MIS-C criteria described in the case definition above to their local, state, or territorial health department. Clinicians can report by submitting either completed case report forms or medical records for review to their state, local, or territorial health department. After-hours phone numbers for health departments are available at the Council of State and Territorial Epidemiologists website . For additional reporting questions, please contact CDC's 24-hour Emergency Operations Center at 770-488-7100.

Case Report Form

- Instructions for Multisystem Inflammatory Syndrome Associated with COVID-19 Case Report Form [164 KB, 5 pages]

  Fillable Multisystem Inflammatory Syndrome Associated with COVID-19 Case Report Form [464 KB, 4 pages]

References

1. Belhadjer Z, Meot M, Bajolle F, et al. Acute heart failure in multisystem inflammatory syndrome in children (MIS-C) in the context of global SARS-CoV-2 pandemic . Circulation 2020.
2. Riphagen S, Gomez X, Gonzalez-Martinez C, Wilkinson N, Theocharis P. Hyperinflammatory shock in children during COVID-19 pandemic . Lancet 2020.
3. Verdoni L, Mazza A, Gervasoni A, et al. An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study . Lancet 2020.

Additional Resources

- New ICD-10-CM code for the 2019 Novel Coronavirus (COVID-19)
- American Academy of Pediatrics: Multisystem Inflammatory Syndrome in Children (MIS-C) Interim Guidance
- American College of Rheumatology: Clinical Guidance for Pediatric Patients with Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with SARS-CoV-2 and Hyperinflammation in COVID-19
- Clinical Outreach and Communication Activity (COCA) Webinar, May 19, 2020: Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)
- CDC Health Advisory (5/14/20): Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)
- COVID-19 Information for Pediatric Healthcare Providers
- Clinical Questions about COVID-19: Questions and Answers
- Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)
- Kawasaki Disease
- Multisystem Inflammatory Syndrome in Children: Survey of Early Hospital Evaluation and Management
- For Parents: Multisystem Inflammatory Syndrome in Children (MIS-C)
- Interim Clinical Considerations for Use of COVID-19 Vaccines

Page last reviewed: May 20, 2021
Content source: National Center for Immunization and Respiratory Diseases

Appendix 10

COVID-19 TESTING CRITERIA:

FOR HEALTHCARE WORKERS AND PATIENTS

Please also see updated information on pages 65 -66
and also see Appenix 21a & 21b for updates

Group	Category	Definition	COVID-19 Testing
Healthcare Workers (HCW)	Exposure	Exposure[1] to a known COVID-19 positive individual	Contact employee health and you will be directed for your testing date and time
	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms, unless fever can be attributed to an alternative etiology	
	Asymptomatic	No known exposure to a known COVID-19 positive individual or symptoms	Visit PCP or local testing center[2]
Emergency Department/ Trauma Resus	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology. *Apply clinical judgment for alternative symptomatology.*	One (1) test *upon decision to admit*; if negative, may consider testing via serology method *and repeat PCR test* >24 hours If *no plan for admission*, discharge patient with COVID -19 education information on accessing results
	Asymptomatic / Unknown	Patients without symptoms of COVID-19 or unable to provide history (e.g. nonverbal ED or trauma)	One (1) test immediately upon high suspicion for admission
Behavioral Health	Symptomatic/ Asymptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology. *Apply clinical judgment for alternative symptomatology.* Patients without symptoms of COVID-19 or unable to provide history	One (1) test *upon decision to admit* For patients who require medical clearance, behavioral unit must swab prior to transfer to ED
Inpatients	Exposure	New exposure[1] to a known COVID-19 positive individual during admission	One (1) test based on clinical suspicion
	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology. *Apply clinical judgment for alternative symptomatology.*	One (1) test based on clinical suspicion; if negative, may consider testing via serology method *and repeat PCR test* >24 hours if no other etiology has been identified
	Asymptomatic	Internal JHS transfers	Confirm COVID-19 test results prior to transfer
		Direct admissions from other healthcare institutions	Transferring institution must provide proof of testing no more than 72 hours prior to admission & must be documented in the EMR
	Nursing Home Discharges	Individuals who are prepared to be discharged to a nursing home	Two (2) negative tests 24 – 48 hours apart prior to discharge If one (1) test is positive, next test >72 hours after last positive result

[1] *Direct = less than 6 feet; prolonged = more than 10 mins; unprotected = no PPE or Direct Contact to secretions*

[2] *Visit https://floridahealthcovid19.gov/ for your local county health department testing locations*

Pre-surgical	ALL patients	Outpatient: One (1) test for COVID-19 within 72 hours of case/procedure	← See left
		Inpatient: One (1) test upon admission[3] only ONLY if patient develops symptoms of COVID-19 during hospitalization, you may retest prior to procedure	
Outpatient Procedures (Diagnostic or Interventional)	High-risk procedures[4]	Patients at high-risk[1] for COVID-19 transmission to HCW (e.g. aerosol-generating procedures or proximal to the respiratory tract)	One (1) test within 72 hours of the procedure
	Low-risk	Low-risk outpatient procedures do not require COVID-19 testing unless patients are symptomatic (see above for Inpatient Symptomatic)	No testing required
Outpatient Clinic	Symptomatic	All patients (seen in person or by telemedicine) who are showing COVID-19 symptoms	Refer to PCP and reschedule appointment if telemedicine visit If patient presents to hospital for outpatient appointment with symptoms refer for testing

For infection control-related questions, please contact JHS Infection Prevention at 786-266-0624.

For laboratory or testing-related questions, please contact your local JHS Laboratory Department at 305-585-6508 (JMH), 305-654-5020 (JNMC), or 305-256-5060 (JSMC).

[3] *Testing upon admission should NOT be done if a) test was collected at any JHS facility within the last 72 hours OR b) there is a documented positive COVID-19 test in the past 7 days*

[4] *Please refer to High-Risk procedure list*

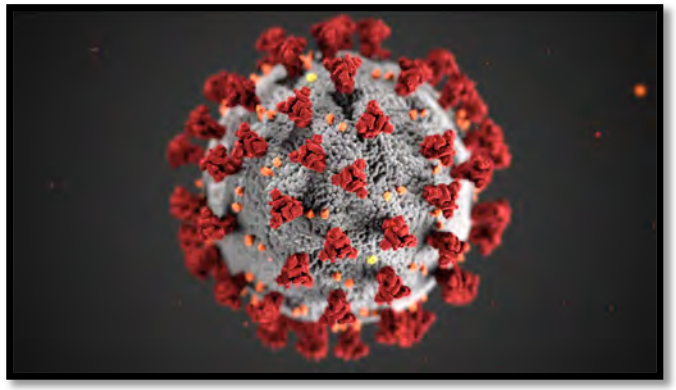
High-Risk Procedure List

High-risk procedures are procedures that could generate infectious aerosol (AGP) and droplets as a source of respiratory pathogens. Such procedures should be performed cautiously and avoided if possible. Jackson Health System PPE guidelines for AGP must be followed when performing the following high-risk procedures.

- Bag mask ventilation
- Manual ventilation
- Endotracheal tube intubation
- Endotracheal tube extubation
- Airway suctioning
- Nebulizer treatment
- Bronchoscopy
- Laryngoscopy
- Endoscopy (upper and lower GI)
- Cardio-pulmonary resuscitation (CPR)
- BiPAP/CPAP
- High-Flow Nasal Cannula
- High Frequency Oscillatory Ventilation
- Chest physiotherapy
- Sputum induction
- Breaking the ventilator circuit
    - Intentional: filter/equipment change
    - Unintentional: unplanned disconnection/patient movement

SARS CoV2
Diagnostic Stewardship of Testing
Jackson Health System

5.20.2020



JHS SARS CoV2 Testing

- Studies published in China earlier in the pandemic reported up to 40% false negative results for SARS-CoV2 → poorly sequenced virus; different testing platforms

- JHS has 3 testing platforms for PCR tests and all have been internally and externally validated with high reliability.

- Test can be ordered in Nasopharyngeal swab or tracheal aspirate/ lower respiratory tract

- To date we have tested **over 14,000 patients** across the health system
-
- April 24, 2020 we went live with universal testing of all pre-op and admissions to our hospitals

- We analyzed the performance of the test since the implementation of testing in our patient population by looking at aggregated data to further guide the appropriate use and frequency of tests between 4/24 and 5/20/2020

Asymptomatic* Admissions to JHS Hospitals (N= 2051) tested → Positive for SARS-CoV2 by Nasopharyngeal swab PCR → 3% of all JMH asymptomatic patients
2% at Holtz, JSMC and BH
9% at JNMC

Asymptomatic Pre-Operative/ IR and Procedures (N= 1452) → 96% negative on first test
Only 1 patient tested repeat positive within 72 hours (<0.2%)
all others were repeat negative
4% positive on first NP swab PCR → **Our data suggests that repeat testing for asymptomatic patients (admissions or pre op) is NOT needed**

Pre op/ Diagnostic convalescent confirmed COVID-19 infection in present hospitalization →
Urgent procedure → airborne isolation precautions no not delay the case
Non urgent → postpone until negative PCR if possible
PPE/ isolation precautions while hospitalized until PCR negative
If PCR positive do not retest sooner than 7 days

Some patients have persistent post-infection detectable RNA (> 45 days) Infectivity period is not yet determined and studies suggest that in viral cultures is around 10 days (more data needed)

Symptomatic patients (adult or pediatric) →
If PCR positive do not retest sooner than 7 days

→
PCR negative and high pre test probability
Our data suggests false negative (symptomatic cases) is around 4%
- Perform serum antibodies
- Repeat the NP PCR or lower airway (aspirate) if intubated around **24-72 hours if symptoms progress**

*Asymptomatic definition extracted from Cerner powerchart COVID-19 order form upon order entry

5.21.2020

Questions? Call Micro Lab 305-585-6508

COVID-19 TESTING CRITERIA:
FOR SPECIAL POPULATIONS, TRANSPLANT AND ONCOLOGY PATIENTS

Group	Category	Definition	COVID-19 Testing
Pre-surgical Transplant (Deceased or Living Donors)	ALL asymptomatic transplant recipients	Screening questionnaire for symptoms These are emergency cases that will be hospitalized at the time of organ offer	Outpatient: One (1) test for COVID-19 within 72 hours of case/procedure for living donation Inpatient: One (1) test upon admission[1] only ONLY if patient develops symptoms of COVID-19 during hospitalization, you may retest prior to procedure
Pre- Solid Organ Transplant (Adult and Pediatric)	Previously infected or tested positive and convalescent from COVID-19	Patient with a known history or confirmed exposure to COVID19 referred to MTI for evaluation or previously listed awaiting organ transplant Should be at least 10 days asymptomatic prior to scheduling in person appointment in MTI laboratory or clinic	Outpatient: One (1) negative PCR test for COVID-19 Test should be done > 14 days from the onset of COVID-19 illness Exceptions: Patient listed and on hold due to recent COVID-19 infection with decompensation and urgent need for transplant, repeat PCR sooner than 14days and consult ID Patient NOT listed or listed but NO clinical decompensation requiring emergent transplant, NP PCR to be repeated at least 28 days from the onset of COVID19 illness
	Exposure	Exposure[2] to a known COVID-19 positive individual	Follow by PCP in the community One (1) NP swab PCR test and monitor symptoms, self-quarantine for 14 days and report to MTI clinic coordinator any changes
	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms, GI, anosmia or dysgeusia	*Clinically stable/ outpatient*: One (1) NP swab PCR test if negative, if symptoms progress and high suspicion for COVID-19 may consider testing via serology method *and repeat PCR test* >24 hours unless symptoms can be attributed to an alternative etiology *Clinically unstable/ send to ED:* One (1) NP swab PCR test *upon decision to admit* if negative, symptoms progress or high index of suspicion may consider testing via serology method *and repeat PCR test* >24 hours unless symptoms can be attributed to an alternative etiology

[1] *Testing upon admission should NOT be done if a) test was collected at any JHS facility within the last 72 hours OR b) there is a documented positive COVID-19 test in the past 7 days*

[2] *Direct = less than 6 feet; prolonged = more than 10 mins; unprotected = no PPE or Direct Contact to secretions*

Jackson HEALTH SYSTEM

	Asymptomatic	Presenting in ED for other reasons non COVID-19 related	Follow JHS protocol One (1) test immediately upon high suspicion for admission If *no plan for admission*, and no symptoms or exposure to COVID no need to test
		Internal JHS transfers	Confirm COVID-19 test results prior to transfer
		Direct admissions from other healthcare institutions	Transferring institution must provide proof of testing no more than 72 hours prior to admission & must be documented in the EMR
Post- Solid Organ Transplant (Adult and Pediatric)	Exposure	Exposure[3] to a known COVID-19 positive individual	One (1) NP swab PCR test and monitor symptoms, self-quarantine for 14 days and report to MTI clinic coordinator any changes
	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms, GI, anosmia or dysgeusia	*Clinically stable/ outpatient*: One (1) NP swab PCR test if negative, may consider testing via serology method *and repeat PCR test* >24 hours No need to repeat testing unless symptoms progress and cannot be attributed to an alternative etiology etiology. *Apply clinical judgment for alternative symptomatology.* *Clinically unstable/ send to ED:* One (1) NP swab PCR test *upon decision to admit* if negative, may consider testing via serology method *and repeat PCR test* >24 hours
	Asymptomatic / Unknown	Patients without symptoms of COVID-19 or unable to provide history (e.g. nonverbal ED or trauma)	One (1) test immediately upon high suspicion for admission
Convalescent Patients with COVID19 Solid Organ Transplant	Asymptomatic Previously infected or tested positive	Patient with a known history or confirmed exposure to COVID19 referred to MTI for evaluation, previously listed awaiting organ transplant or transplant recipient discharged from the hospital Should be at least 10 days asymptomatic prior to scheduling in person appointment in MTI laboratory or clinic	Outpatient: One (1) negative PCR test for COVID-19 prior to listing or scheduling clinic Test should be done 28 days from the onset of illness If repeat test is positive should be repeated no sooner than 7 days *Transplant should be postponed until resolution of COVID infection*

[3] *Direct = less than 6 feet; prolonged = more than 10 mins; unprotected = no PPE or Direct Contact to secretions*

COVID-19 TESTING CRITERIA:
FOR SPECIAL POPULATIONS, TRANSPLANT AND ONCOLOGY PATIENTS

Group	Category	Definition	COVID-19 Testing
Convalescent Patients with COVID19 Oncology	Asymptomatic Previously infected or tested positive	Patient with a known diagnosis of Cancer and confirmed exposure or infection with COVID19 Should be at least 10 days asymptomatic and from the day of initial testing	Outpatient: One (1) negative PCR test for COVID-19 prior to start chemotherapy Test should be done > 14 days from the onset of illness prior to rescheduling chemotherapy unless urgent and could be retested sooner If repeat test is positive should be repeated no sooner than 14 days *Chemotherapy and non-emergency invasive procedures should be postponed until resolution of COVID infection*
Oncology Outpatient (Pre- Chemotherapy)	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms, GI, anosmia or dysgeusia	Refer patient to ED for evaluation and testing. Symptomatic patients should not enter/ expose others in ACC One (1) test based on clinical suspicion; if negative, may consider testing via serology method *and repeat PCR test* >24 hours if no other etiology has been identified
	Asymptomatic	Patients without symptoms of COVID-19 or unable to provide history who need to start chemotherapy	One (1) test upon decision to start chemotherapy (to be scheduled and collected in ACC clinic at least 72 hours prior to starting chemotherapy and no longer than 7 days prior)
Oncology Inpatients	Exposure	New exposure[1] to a known COVID-19 positive individual during admission	One (1) test based on clinical suspicion
	Symptomatic	Symptomatic defined as new fever >100◦F AND/OR new onset of respiratory symptoms, GI, anosmia or dysgeusia	One (1) test based on clinical suspicion; if negative, may consider testing via serology method *and repeat PCR test* >24 hours if no other etiology has been identified
	Asymptomatic	Hospitalized for work up or chemotherapy	One (1) test *upon decision to admit to the hospital*
		Internal JHS transfers	Confirm COVID-19 test results prior to transfer
		Direct admissions from other healthcare institutions	Transferring institution must provide proof of testing no more than 72 hours prior to admission & must be documented in the EMR

HIGH-RISK PROCEDURE LIST

High-risk procedures are procedures that could generate infectious aerosol (AGP) and droplets as a source of respiratory pathogens. Such procedures should be performed cautiously and avoided if possible. Jackson Health System PPE guidelines for AGP must be followed when performing the following high-risk procedures.

- Bag mask ventilation
- Manual ventilation
- Endotracheal tube intubation
- Endotracheal tube extubation
- Airway suctioning
- Nebulizer treatment
- Bronchoscopy
- Laryngoscopy
- Endoscopy (upper and lower GI)
- Cardio-pulmonary resuscitation (CPR)
- BiPAP/CPAP
- High-Flow Nasal Cannula
- High Frequency Oscillatory Ventilation
- Chest physiotherapy
- Sputum induction
- Breaking the ventilator circuit
    - Intentional: filter/equipment change
    - Unintentional: unplanned disconnection/patient movement

Table of Contents

I. Purpose

To provide guidelines per manufacturer recommendations and training for collection, handling, reprocessing, and appropriate handling of contaminated non-disposable 3M Respirator from Perioperative Services end users. Central Support Services (CSS) will staff the reprocessing room only on Wednesdays.

II. Process for Issuing Personal Respirator:

1. **Refer to attachment B, Half Face Reusable Respirator Request & Use Process Map**

KEYPOINT: All respirator end users will have completed mandatory WeLearn respirator manufacturer use training and fit testing prior to obtaining their respirator from PPE supply room C351 or Trauma OR Charge.

Filters must be removed and discarded by end user prior to taking for cleaning to CSS.

KEYPOINT: End user must present respirator fit testing completion form to supply room staff or Trauma OR Charge upon prior to obtaining respirator.

KEY POINT: Upon respirator issuance, staff in the PPE supply room C351 or Trauma OR Charge will mark filter with the Organization's recommended 2 week expiration date using a sharpie.

The end user must:

1. Take their respirator for cleaning and filter replacement on or prior to date marked on filter
2. If upon inspection of face piece it is noted to be damaged, end user must wipe respirator, place in brown bag & annotate "Damaged" outside of the bag
3. If the respirator was used in a confirmed/suspected COVID positive patient:
    a. Filters must be discarded
    b. Respirator wiped down, placed in brown bag and placed in designated dirty bin to be sent to decontamination area

III. Trauma Universal Use Process:

1. Only previously approved end users will be granted a respirator
2. Clean/reprocessed respirators will be kept separate from dirty respirators
    i. Only clean/reprocessed respirators to be on hook placed inside white bag (No filters on)
    ii. End user must request their own personal filter & storage bag from OR Charge
        1. End user will write their name and next 2 week filter replacement date on filters using sharpie
        2. End user stores their personal filter in a clean, dry location until next use

3. If a known or suspected exposure occurred during use of respirator:
    a. Discard filters
    b. Place dirty respirator in brown bag in designated bin
    c. Obtain new filter and respirator for next needed use from OR Charge
3. End user will wipe down respirator using hospital approved wipes after each use and place in brown bag in designated dirty bin
4. CSS will retrieve dirty bins from Trauma once a week for reprocessing of respirators

IV. Cleaning Procedure

1. CSS Staff member must perform hand hygiene and don proper PPE before starting decontamination process:
    a. Hair covering
    b. Eye protection
    c. N95 mask
    d. Gown
    e. Shoe covers
    f. Gloves

2. Contaminated 3M respirators will be returned to Room 15B via a brown paper bag. CSS staff must open the bag, remove the respirator and log it into the log with the end user's name as it appears on the mask.

3. The mask will be inspected for cracks, tears, dirt and distortion before proceeding with cleaning, If damaged then end user's name will be on logged onto the discard form and a copy of that form is given to the COVID supply room (C351) personnel at the end of the shift for replacement respirator when the end user returns to pick up clean processed respirator.

4. Decontamination-Soaking/Washing Preparation: CSS staff will prepare sink for cleaning by measuring 2.5 ounces of detergent into 5 gallons of water not to exceed 120 degree F for soaking/cleaning of the 3M respirators masks.

5. Using a soft bristle brush or soft cloth wash the respirator under the water until all debris (if any) is removed. Water must be changed after each respirator is cleaned.

6. Rinse the respirator under running water temperature not to exceed 120 degrees F until detergent residue is removed.

7. Using a clean blue towel pat dry the respirator and the straps before passing respirator through the pass thru window for next step to High Level Disinfecting (HLD).

8. The CSS staff member will receive the clean 3M respirator and will stage the respirator for the immersion into the 70% Isopropanol (Alcohol) when solution is ready.

9. Place the clean respirator into the HLD solution for 1 minute completely immersed. Alcohol must be discarded and refilled after each use. After 1 minute then rinse in warm water temperature not to exceed 120 deg F and begin pat dry, place on counter onto clean blue towels to begin the air drying process. Air drying could take up to 2 hours.

10. At the end of the drying process the CSS tech will label a clean white paper bag with that respirator's owner name on bag and insert the 3M respirator into bag.

11. At end of shift the bin of clean 3M respirators are to be taken to the COVID Supply room across the hall to C351 along with a copy of the discarded form of respirators that had been damaged and discarded and new ones to be issued to those end users.

12. Sinks, Respirator Decontamination room, Respirator Clean room must be kept neat and clean at all times. At the end of each shift all trash must be removed.

13. Decontamination room will be terminally cleaned at the end of the day after use.

KEYNOTE: Per the latest CDC/FDA recommendations and direction from Perioperative Medical Director, all employees performing reprocessing of PPE will be routinely COVID tested.

V. References

3M 6000 Series Half Face piece Respirator Instructions for Use
3M 6000 Series Half piece Respirator with 7093 Filter Reprocessing Respirator training
CDC Guidelines 6/2020

Attachment A: Voluntary Reusable Respirator Request Form

Attachment B: Respirator Request & Use Process Map

Responsible Party: Associate Director Central Support Services

Reviewing Committee(s): OR Executive Committee

Authorization: Department Head

ATTACHMENT A:

VOLUNTARY
REUSABLE RESPIRATOR REQUEST FORM

This request and approval process in the current state of emergency addresses the use of the half-face mask relative to regulatory agencies. Please complete this request and return to your facility Chief Medical Officer or Designee for consideration of alternative respiratory protection when an N95 mask may not personally be considered optimal for a particular case (comfort, duration) or individual (health reasons):

DATE		BADGE #	
First Name		Last Name	
EMAIL		PHONE #	

Department		Superviser	

CHECK REASON FOR THIS REQUEST:

- ☐ Individual Health
- ☐ Surgical Case over 4 hours
- ☐ Other

CHECK REUSABLE RESPIRATOR YOU ARE REQUESTNG:

- ☐ 6000 Series Respirator

KEYNOTE: Do not use Series 6000 Respirator with beards, facial hair or anything that prevents direct contact between the face

What is the health related or "other" reason for this request?

☐ APPROVED

If approved:

1. *It is the responsibility of the employee/Medical Staff member to follow up with Employee Health for fit testing*
2. *Must complete training module as well as follow manufacturer guidelines for use.*

☐ DENIED REASON: _____

☐ DATE: _____

Medical Director or Designee Signature

Section: Perioperative Services

Subject: 3M Respirator Model 6000 Series Issuance, Use & Decontamination PROTOCOL

Many Health Systems are faced with the dilemma of providing maximum protection to personnel and patients while conserving resources and operating within the mandate for adequate PPE and social distancing. A need for enhanced respiratory protection has been identified that includes half-face masks as well as Powered Air Purified Respirators (PAPR's). The approval process in the current state of emergency addresses the use of the half-face mask relative to regulatory agencies. PAPR's are approved for use in procedural areas that require a higher level of protection. With the current understanding that there is a need for widespread use of N95 masks across the health system and that the N95 disposable mask is uncomfortable and not tolerated in certain circumstances, we propose the following guidelines for the use of alternative respiratory protection when an N95 mask is not optimal for a particular case (comfort, duration) or individual (health reasons):

Anticipated Activity	Facemask requirements
Surgical care of known COVID-19 positive patient or PUI	1. N95 mask with surgical mask covering in all cases/ all individuals 2. Where the case is anticipated to last greater than 4 hours and the operator/assistants in direct contact with the patient, have a physiologic issue wearing the N95 mask for that duration of time, either an approved half face mask or PAPR device may be used.
Surgical care of COVID-19 negative patient for certain surgical procedures: ***Procedures involving the mucosa of the upper aero-digestive tract, lower respiratory tract, middle ear and mastoid, gastrointestinal lining, aerosol generating procedures including endoscopy, laparoscopy and or power instrumentation and lasers***	1. N95 mask with surgical mask covering for operator and all in the surgical field 2. Where the case is anticipated to last greater than 4 hours and the operator/assistants in direct contact with the patient, have a physiologic issue wearing the N95 mask for that duration of time, either an approved half face mask or PAPR device may be used.
Intubation	1. N95 mask with surgical mask covering for operator and all in direct contact with the patient or field. 2. In situations where operator/ assistants in direct contact with intubation field have a physiologic issue wearing the N95 mask, either an approved half face mask or PAPR device.
KEYNOTE: Do not use Series 6000 Respirator with beards, facial hair or anything that prevents direct contact between the face	

ATTACHMENT B:

Half-Face Reusable Respirator Request & use Process	JHS Employees	Medical Staff (MDs/ Allied Health/Residents)	JHS Employee Health Office	JHS Central Sterile Services (CSS)
VOLUNTARY USE REQUEST PROCESS	1. Prior to obtaining a newly appointed reusable respirator JHS Employee/Medical staff (End User) must, obtain, complete and submit "Reusable Respirator Request Form" for approval to facility Medical Director or Designee (Respirator Program Administrator). 2. Once approved, Respirator Program Administrator will provide information for end user to self-register for mandatory training via WeLearn. *KEYNOTE: Do not use with beards, facial hair or anything that prevents direct contact between the face and the respirator faceseal. (IFU pg 1)*		1. Respirator Program Administrator will notify Employee Health via email of all approvals. 2. Employee Health will store 2 respirators of each size (small, medium & large) to use for fit testing. (The respirators will be wiped down with hospital approved sani-wipes after each fit test.)	
	**Occupational use of respirators must be in compliance with applicable health and safety standards. By law U.S. employers must establish a written respiratory protection program meeting the requirements of the OSHA Respiratory Protection Standard 29 CFR 1910.134 and any applicable OSHA substance specific standards.(IFU pg 2)**			
FIT TESTING & TRAINING	1.End user will complete mandatory respirator use training via WeLearn prior to obtaining initial respirator. 2. End user will report to Employee Health for mandatory medical evaluation and fit testing. OSHA 1910.134(f) → JMH Main: No appointment necessary. Monday thru Friday 07:00am-2:00pm (excludes Holidays) 3. End user will then report to CSS or designated location to obtain their respirator. Must present pass/fail form upon pick up. (Write name and date on their filter using sharpie)		1. Mandatory Respirator Medical Evaluation Questionnaire (1910.134: OSHA) must be completed prior to fit testing. 2. Employee Health will provide a copy of the pass/fail form to end user so they may obtain their initial respirator from CSS or designated location. *Dept. Managers to support/facilitate Employee fit testing & training.*	1. End user to report to CSS or designated location to obtain their initial respirator. → Must present pass/fail form upon pick up. →Must write their name on face piece using sharpie. 2. Upon receipt of the pass/fail form from end user, CSS or designated location staff will provide the initial respirator. → Filters will be marked with 2 week expiration date for replacement using a sharpie.
RESPIRATOR INSPECTION & USE	**End user must inspect their respirator and parts before each use and at the time of cleaning.** 1. Check for cracks, tears and dirt. 2. Examine inhalation valves for signs of distortion. 3. Make sure straps are intact/elastic. 4. Remove exhalation valve cover and examine for signs of dirt, distortion, cracking or tearing 5. If any damage or defective parts are identified, end user must take the damaged respirator to CSS or designated location and obtain replacement respirator. *Per 3M Training: 6000 Series Half Face piece Reusable Respirator for Healthcare Facilities (4/20)*			*1. CSS staff must follow 3M Training: 6000 Series Half Face piece Reusable Respirator for Healthcare Facilities.* **Respirator Disinfection: Face piece Inspection & Submersion (4/20)**
	Inspect each filter case for any visible damage. Replace filter(s) if any damaged is observed. DO NOT WEAR if parts are damaged, defective or missing. (Source: IFU)			
CLEANING & STORAGE	Per mandatory WePerform training: 1. Wipe down the respirator between uses during the work shift using hospital approved wipes. 2. Every 2 weeks (minimum) end user must take their respirator to CSS or designated location for disinfection, cleaning, and replacement filters. 3. Upon inspection, if respirator is VISIBLY SOILED OR DAMAGED— end user must take their respirator to CSS or designated location for disinfection, cleaning, and/ or replacement as applicable. 4. If not being used immediately, end user will store their respirator in a separate, breathable container (i.e. brown paper bag).			*1. CSS staff must follow 3M Training: 6000 Series Half Face piece Reusable Respirator for Healthcare Facilities:* **Respirator Disinfection: Face piece Inspection & Submersion (4/20)** 2. CSS staff will follow JHS developed protocol for step by step process for cleaning, disinfection of respirators and filter replacement. 3. CSS will ensure laminated signage is posted in the respirator reprocessing and supply storage areas for the following: → JHS developed protocol for step by step process for cleaning, disinfection of respirators and filter replacement → 3M Technical Bulletin Cleaning & Disinfecting 3M Reusable Elastomeric Half & Full Facepiece Respirators following Potential Exposure to Coronaviruses. (4/20; Rev4)

Jackson HEALTH SYSTEM
Miracles made daily.

Half-Face Reusable Respirator Request & use Process

	JHS Employees	Medical Staff (MDs/ Allied Health/Residents)	JHS Employee Health Office	JHS Central Sterile Services (CSS)
VOLUNTARY USE REQUEST PROCESS	1. Prior to obtaining a newly appointed reusable respirator JHS Employee/Medical staff (End User) must, obtain, complete and submit "Reusable Respirator Request Form" for approval to facility Medical Director or Designee (Respirator Program Administrator). 2. Once approved, Respirator Program Administrator will provide information for end user to self-register for mandatory training via WeLearn. *KEYNOTE:* ***Do not use with beards, facial hair or anything that prevents direct contact between the face and the respirator faceseal.*** *(IFU pg 1)*		1. Respirator Program Administrator will notify Employee Health via email of all approvals. 2. Employee Health will store 2 respirators of each size (small, medium & large) to use for fit testing. (The respirators will be wiped down with hospital approved sani-wipes after each fit test.)	
 Reusable Respirator	Occupational use of respirators must be in compliance with applicable health and safety standards. By law U.S. employers must establish a written respiratory protection program meeting the requirements of the OSHA Respiratory Protection Standard 29 CFR 1910.134 and any applicable OSHA substance specific standards.(IFU pg 2)			
FIT TESTING & TRAINING	1.End user will complete mandatory respirator use training via WeLearn prior to obtaining initial respirator. 2. End user will report to Employee Health for mandatory medical evaluation and fit testing. OSHA 1910.134(f) **→ JMH Main: No appointment necessary. Monday thru Friday 07:00am-2:00pm (excludes Holidays)** 3. End user will then report to CSS or designated location to obtain their respirator. Must present pass/fail form upon pick up. (Write name and date on their filter using sharpie)		1. Mandatory Respirator Medical Evaluation Questionnaire (1910.134: OSHA) must be completed prior to fit testing. 2. Employee Health will provide a copy of the pass/fail form to end user so they may obtain their initial respirator from CSS or designated location. ***Dept. Managers to support/facilitate*** *Employee fit testing & training.*	1. End user will report to CSS or designated location to obtain their initial respirator. → Must present pass/fail form upon pick up. →Must write their name on face piece using sharpie. 2. Upon receipt of the pass/fail form from end user, CSS or designated location staff will provide the initial respirator. → Filters will be marked with 2 week expiration date for replacement using a sharpie.
RESPIRATOR INSPECTION & USE	**End user must inspect their respirator and parts before each use and at the time of cleaning.** 1. Check for cracks, tears and dirt. 2. Examine inhalation valves for signs of distortion. 3. Make sure straps are intact/elastic. 4. Remove exhalation valve cover and examine for signs of dirt, distortion, cracking or tearing 5. If any damage or defective parts are identified, end user must take the damaged respirator to CSS or designated location and obtain replacement respirator. *Per 3M Training: 6000 Series Half Face piece Reusable Respirator for Healthcare Facilities (4/20)*			*1. CSS staff must follow 3M Training: 6000 Series Half Face piece Reusable Respirator for Healthcare Facilities.* **Respirator Disinfection: Face piece Inspection & Submersion (4/20)**
	Inspect each filter case for any visible damage. Replace filter(s) if any damaged is observed. **DO NOT WEAR if parts are damaged, defective or missing.** (Source: IFU)			
CLEANING & STORAGE	**Per mandatory WePerform training:** 1. Wipe down the respirator between uses during the work shift using hospital approved wipes. 2. Every 2 weeks (minimum) end user must take their respirator to CSS or designated location for disinfection, cleaning, and replacement filters. 3. Upon inspection, if respirator is VISIBLY SOILED OR DAMAGED— end user must take their respirator to CSS or designated location for disinfection, cleaning, and/ or replacement as applicable. 4. If not being used immediately, end user will store their respirator in a separate, breathable container (i.e. brown paper bag).			*1. CSS staff must follow 3M Training: 6000 Series Half Face piece Reusable Respirator for Healthcare Facilities.* **Respirator Disinfection: Face piece Inspection & Submersion (4/20)** 2. CSS staff will follow JHS developed protocol for step by step process for cleaning, disinfection of respirators and filter replacement. 3. CSS will ensure laminated signage is posted in the respirator reprocessing and supply storage areas for the following: → JHS developed protocol for step by step process for cleaning, disinfection of respirators and filter replacement → 3M Technical Bulletin Cleaning & Disinfecting 3M Reusable Elastomeric Half & Full Facepiece Respirators following Potential Exposure to Coronaviruses. (4/20; Rev4)

VOLUNTARY
REUSABLE RESPIRATOR REQUEST FORM

This request and approval process in the current state of emergency addresses the use of the half-face mask relative to regulatory agencies. Please complete this request and return to your facility Chief Medical Officer or Designee for consideration of alternative respiratory protection when an N95 mask may not personally be considered optimal for a particular case (comfort, duration) or individual (health reasons):

DATE		BADGE #	
First Name		Last Name	
EMAIL		PHONE #	
Department		Superviser	

CHECK REASON FOR THIS REQUEST:

- ☐ Individual Health
- ☐ Surgical Case over 4 hours
- ☐ Other

CHECK REUSABLE RESPIRATOR YOU ARE REQUESTNG:

- ☐ 6000 Series Respirator

KEYNOTE: Do not use Series 6000 Respirator with beards, facial hair or anything that prevents direct contact between the face

What is the health related or "other" reason for this request?

☐ APPROVED

If approved:

1. *It is the responsibility of the employee/Medical Staff member to follow up with Employee Health for fit testing*
2. *Must complete training module as well as follow manufacturer guidelines for use.*

☐ DENIED REASON: _____

_____ DATE: _____

Medical Director or Designee Signature

Jackson HEALTH SYSTEM | PUBLIC HEALTH TRUST

VOLUNTARY
REUSABLE RESPIRATOR REQUEST FORM

Many Health Systems are faced with the dilemma of providing maximum protection to personnel and patients while conserving resources and operating within the mandate for adequate PPE and social distancing. A need for enhanced respiratory protection has been identified that includes half-face masks as well as Powered Air Purified Respirators (PAPR's). The approval process in the current state of emergency addresses the use of the half-face mask relative to regulatory agencies. PAPR's are approved for use in procedural areas that require a higher level of protection. **With the current understanding that there is a need for widespread use of N95 masks across the health system and that the N95 disposable mask is uncomfortable and not tolerated in certain circumstances, we propose the following guidelines for the use of alternative respiratory protection when an N95 mask is not optimal for a particular case (comfort, duration) or individual (health reasons):**

Anticipated Activity	Facemask requirements
Surgical care of known COVID-19 positive patient or PUI	1. N95 mask with surgical mask covering in all cases/ all individuals 2. Where the case is anticipated to last greater than 4 hours and the operator/assistants in direct contact with the patient, have a physiologic issue wearing the N95 mask for that duration of time, either an approved half face mask or PAPR device may be used.
Surgical care of COVID-19 negative patient for certain surgical procedures: ***Procedures involving the mucosa of the upper aero-digestive tract, lower respiratory tract, middle ear and mastoid, gastrointestinal lining, aerosol generating procedures including endoscopy, laparoscopy and or power instrumentation and lasers***	1. N95 mask with surgical mask covering for operator and all in the surgical field 2. Where the case is anticipated to last greater than 4 hours and the operator/assistants in direct contact with the patient, have a physiologic issue wearing the N95 mask for that duration of time, either an approved half face mask or PAPR device may be used.
Intubation	1. N95 mask with surgical mask covering for operator and all in direct contact with the patient or field. 2. In situations where operator/ assistants in direct contact with intubation field have a physiologic issue wearing the N95 mask, either an approved half face mask or PAPR device.

KEYNOTE: *Do not use Series 6000 Respirator with beards, facial hair or anything that prevents direct contact between the face*

Jackson HEALTH SYSTEM Miracles made daily.

Section: Care of the Patient

Subject: Management of Infants Born to Known or Suspected Covid Positive Mothers

Table of Contents

I. Purpose

As per the American Academy of Pediatrics guidelines, COVID-19 positive mothers are advised to maintain separation from their infants. The expectant mother's provider will discuss with her testing requirements, and recommendations should the mother test positive or be suspected of having CoVID-19 based on symptoms or exposure. Using shared decision making the outcome of the discussion will be documented in the medical record. As breastfeeding requires close contact, it is not recommended; however, pumping and provision of breastmilk is encouraged.

II. Definitions

PPE for Aerosolizing Procedures in Known or Suspected COVID-19 Infection:

1. Low Risk: Standard PPE plus hair and shoe cover
   Airway suctioning
   Sputum Induction
   CPR
   Bag mask ventilation
   Manual ventilation
   Swallow studies

2. High Risk: All of the above plus a second pair of gloves
   High Flow nasal cannula
   Nebulizer therapy
   Chest physiotherapy
   BiPAP/CPAP
   High Frequency ventilation
   Ventilator circuit disconnect

3. Highest Risk: All of the above plus a hooded bunny suit under isolation gown
   Endotracheal intubation
   Endotracheal extubation
   Prone Position

Bronchoscopy
Laryngoscopy
Endoscopy (upper and lower)

PUI Infant: An infant born to a mother who meets one of the following definitions:

1. Covid-19 Positive mother
2. Suspected Covid19 mother: For the purpose of obstetric care, a suspected COVID-19 case is someone who has symptoms of COVID-19, a mother who has had a recent high risk contact (such as a family member at home with confirmed COVID-19) and does not have a negative test result because the test is still pending).

   Key point: Regardless of pending test results, individuals who are asymptomatic at the time of admission/visit and have no history of high risk contact should not be considered to be suspected cases.

Standard PPE for Known or Suspected COVID-19 Infection room/Space

Hand hygiene
Gloves
Isolation gown
N 95 preferred (surgical masks over N95 as conservation strategy)
Eye protection

III. Procedure

A. Antepartum
   1. In the antepartum period, the need for Covid19 testing prior to delivery, the possible outcomes of the test and the implications of a positive test on the care of the newborn will be discussed with the patient by their provider.
   2. All patients for scheduled C sections or planned induction have COVID-19 testing performed prior to delivery. Pregnant women who present to OB triage without testing within 72 hours will be tested as soon as a decision to admit is made.

B. Intrapartum
   1. All patients are surveyed for symptoms and contact risks at the time of admission.
   2. Universal masking is required at Jackson Health System (JHS) including during childbirth.
   3. If necessary, Perinatal consults will be conducted using Telemedicine. Call the NICU Fellow at 305 585 5140.
   4. During labor/prior to delivery, the High-Risk Team will be notified of COVID-19 positive mothers or suspected COVID-19 mothers with a positive screen (symptoms and/or known exposures) and pending test results.

C. Delivery
   1. The Pediatric Team present at Delivery is dependent on the clinical status of the newborn
      a. Normal Delivery: no attendant, call NICU charge nurse when infant is ready for transfer.
      b. Any resuscitation of Covid-19 or PUI patient page High Risk Team.
      c. Low risk delivery: Only NICU Fellow and Neonatal Nurse Practitioner will enter the room in standard PPE.
      d. High risk delivery: All team members will enter the room. The MD and RT will wear PPE as above for possible aerosolizing procedures.

Key point: In Ryder Trauma Center, the NICU High Risk team will take necessary neonatal equipment including HEPA filters. The OB team will determine if the Neonatal Team is needed inside the room. The same processes as described above will apply.

D. Transfer/Transport of PUI Infants
   1. Once the infant is ready for transport, any team members inside of the delivery room/OR will push the isolette/transporter out of the room and then remove their PPE before exiting the room. The receiving team will monitor the patient until the team inside the room has had a chance to doff the PPE worn inside and don new PPE outside the room if indicated.
   2. Healthy Infant: The infant will not be exposed to COVID-19 positive individuals (no skin-to-skin) and will be placed in air-mode incubator. The NIN3 RN will be called if the plan is to transfer infant.
   3. Sick infant: The infant will not be exposed to COVID-19 positive individuals and will be placed in transporter. Team members will exit separately in such a way as to doff PPE inside the room, don PPE outside the room while monitoring the baby. For example, for the ventilated infant in a High-Risk Delivery, the RT and RN will exit first, knock on the door, and receive the transporter. The RN will wipe the transported down with bleach while the RT will monitor the baby as the physician exits.
   4. On arrival in NIN3 on transfer of the baby, the linens and disposables will be disposed of in NIN3 and the transporter wiped down with bleach before terminal cleaning.

E. Care of the PUI Infant as Defined Above

   Care of the PUI infant of a COVID-19 positive mother or mother with a positive screen awaiting testing:
   1. Bathe the infant.
   2. Test the infant for Covid19 by NP swab at 24 hours of age.
   3. Continue droplet, contact precautions with eye protection until infant is discharged or tested and negative after 14 days.
   4. If the healthy infant tests positive, return infant to the mother.
   5. If mother tests negative, return healthy infant to the mother.
   6. If infant still requires hospitalization at 14 days, retest infant for COVID-19.
      a. If test is negative, return baby to general NICU population.
      b. If test is positive, infant will be moved to a negative air flow room.
   7. Breastfeeding
      a. Expressed milk is recommended for all PUI infants. If possible, expressed breast milk should be fed to the infant by a healthy caregiver, who is not at high-risk for severe illness from COVID-19.
      b. Mothers should be educated about recommendations on how to properly clean and sanitize breast pumps. Prior to each pumping, the mother will put on a mask, perform hand hygiene and pump under direct supervision of a staff member.
         i. Milk will be placed on a cleaned surface. A staff member, after performing hand hygiene and gloving will transfer the milk to container, labeled, and bagged in the room. The bag will be wiped with a bleach wipe and delivered to the NICU charge nurse.
         ii. Milk will be stored in the designated freezer in NICU D and thawed in the refrigerator in NIN3.
      c. Whether and how to start or continue breastfeeding should be determined by the mother in coordination with her family and healthcare providers.

i. A mother with suspected, probable, or confirmed COVID-19 should be counseled to take all possible precautions to avoid spreading the virus to her infant. She should be instructed to wash her hands using soap and water before touching the infant. If soap and water are not available, she should use a hand sanitizer with at least 60% alcohol.
ii. Additionally, mothers should wear a cloth face covering while feeding at the breast.

F. Visiting Policy
1. The symptomatic COVID-19 positive mother or partner cannot visit until the following criteria have been met.
   a. At least 3 days (72 hours) have passed since recovery defined as resolution of fever without the use of fever-reducing medications and improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**,
   b. At least 10 days have passed since symptoms first appeared.
2. The asymptomatic COVID-19 positive mother or partner cannot visit until 10 days have passed since their positive COVID-19 test, assuming they have remained asymptomatic and with no new contact history since testing.
3. Visiting in NIN3 is limited to an asymptomatic, family member designated by the mother who has not had contact with the mother or partner in the previous 14 days.
4. Visiting is limited to 10 minutes during one of the visiting hours (AM or PM).

G. Discharge Considerations
1. All infants born to COVID-19 positive mothers can be discharged when medically ready.
2. Social work should be consulted for all discharges of PUI infants.
3. Given the potential challenges related to breastfeeding in the context of COVID-19, the need for weight checks and visual or laboratory assessment for jaundice, and the stressors of social distancing, every effort should be made to conduct in person newborn follow-up visits soon after discharge.
4. To arrange telemedicine follow up in the Pediatric Comprehensive Care Clinic, please email Dr. Audrey Ofir aofir@miami.edu, Gwendolyn Mike GMike@jhsmiami.org and Frances Jara FJara@jhsmiami.org.

IV. Reference

https://www.cdc.gov/coronavirus/2019-ncov/hcp/inpatient-obstetric-healthcare-guidance.html#f1, updated April 6, 2020
https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-newborns.html, updated May 20, 2020
https://www.cdc.gov/coronavirus/2019-ncov/hcp/care-for-breastfeeding-women.html, updated May 5, 2020
https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/faqs-management-of-infants-born-to-covid-19-mothers/, updated May 21, 2020

Responsible Party: Director of Patient Care Services
Holtz/WHJ

Reviewing Committee(s): Holtz/WHJ Policy & Procedure Committee

Authorization: Department Head

Appendix 13

CDC Centers for Disease Control and Prevention

COVID-19

Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity

Updated Dec. 28, 2022

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases[1]	1.5x	0.8x	1.1x	1.5x
Hospitalization[2]	2.5x	0.7x	2.1x	1.9x
Death[3, 4]	2.1x	0.8x	1.6x	1.7x

Race and ethnicity are risk markers for other underlying conditions that affect health, including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

Note: Adjusting by age is important because risk of infection, hospitalization, and death is different by age, and age distribution differs by racial and ethnic group. If the effect of age is not accounted for, racial and ethnic disparities can be underestimated or overestimated.

Footnotes

[1]Data Source: Case level surveillance data from state, local and territorial public health jurisdictions (data through December 7, 2022). Numbers are ratios of age-adjusted rates standardized to the 2019 U.S. intercensal population estimate. Calculations use only the 65% of case reports that have race and ethnicity; this can result in inaccurate estimates of the relative risk among groups.

[2] Data source: COVID-NET (March 1, 2020 through December 3, 2022). Numbers are ratios of age-adjusted rates standardized to the 2020 US standard COVID-NET catchment population.

[3] Data Source: National Center for Health Statistics Provisional Death Counts (data through December 3, 2022). Numbers are ratios of age-adjusted rates standardized to the 2019 U.S. intercensal population estimate.

Last Updated Dec. 28, 2022

MOTION

Commissioner Barbara Wolf, M.D., made a motion that Florida medical examiners need not accept jurisdiction of COVID-19 related deaths unless the provisions of Rule 11G-2.001(3), F.A.C., apply. Rule 11G-2.001(3), F.A.C., provides the following:

> If a medical examiner becomes aware of a death, apparently from disease, he or she shall investigate it as a death from a disease constituting a threat to the public health, if:
>
> > The investigation is requested by an official of the Department of Health pursuant to Section 381.0011 or 381.0012, F.S., or
> >
> > The medical examiner determines that additional information concerning the cause and mechanism of death, beyond that available in the decedent's medical history, is needed to protect the public health.

Commissioner Carol Whitmore, seconded the motion, and the motion passed 7-1, with Commissioner Ken Jones opposing only because he would have preferred the motion to be vetted with outside entities prior to the vote.

In support of the motion, the Commission cited the knowledge gained of the disease during the past five months, delay in obtaining medical records, and the overwhelming number of cases that have resulted in insurmountable and growing backlogs for many districts throughout the State (i.e. 650 cases in Miami-Dade County, 510 cases in Palm Beach County, 100 cases in Broward County, and 100 cases in the 6 counties in the panhandle around Bay County). The Florida Emergency Mortuary Operations Response System (FEMORS) was activated and there were not enough forensic pathologists and medicolegal investigators to support the statewide caseload. FEMORS was created to support short-term events such as natural disasters or other short-term emergency events. The volume of COVID-19 cases pending with medical examiner offices has created significant delays in the issuance of death certificates and cremation authorizations. It has proven to be unsustainable for the State's medical examiner system, and is diverting resources from unnatural deaths that the medical examiners must investigate and certify.

Medical examiners will not automatically assume jurisdiction of COVID-19 cases and treating physicians may certify COVID-19 deaths. It was noted that any cases accepted by medical examiners that are pending would still be certified by the medical examiner.

MIAMI-DADE COUNTY

miamidade.gov

Medical Examiner Department
Number One on Bob Hope Road
(1851 NW 10th Avenue)
Miami, Florida 33136-1133
(305) 545-2425

August 15, 2020

Dear Hospital Administration/Risk Management:

RE: COVID-19 Cases

The Florida Medical Examiner Commission has determined that "Medical Examiners will not automatically assume jurisdiction of COVID-19 cases and treating physicians may certify COVID-19 deaths." Please refer to the accompanying document.

This policy is **effective immediately**. Therefore, a COVID-19-related death may be certified by the attending/treating physician provided there is no condition or circumstance that would make it a non-natural death or a Medical Examiner case.

A case that is positive for COVID-19 does NOT need to be reported to the Medical Examiner unless there is a condition or circumstance that would make it a Medical Examiner case, such as trauma, suspected overdose, etc. If such a condition or circumstance exists, or if you are uncertain, please refer the case to the Medical Examiner.

We are hopeful that this change in policy will simplify procedures, increase efficiency for your staff and expedite the release of bodies to funeral homes. Please notify the funeral home if a body is COVID-19 positive so that they know to bring the appropriate equipment.

Thank you for your exceptional cooperation with the Medical Examiner, especially since March 2020. Best wishes to you and your staff as we continue to work through this COVID-19 pandemic.

Yours sincerely,

Emma O. Lew, M.D.
Director and Chief Medical Examiner

EOL:lac
Enclosure

Appendix 15

"Please see updated De-escalation of COVID19 isolation precautions on pages 28 & 29

Discontinuation of Isolation Precautions, COVID Re-Testing, and Procedural Area Recommendations** for JHS and UHealth: COVID-19

Version 9.14.2020

Isolation & Testing for Patients Recovering from COVID-19 Infection

	Immunocompetent/Non-critical Care		Immunocompromised/Critically Ill	
	Symptomatic	**Asymptomatic**	**Symptomatic**	**Asymptomatic (rare)**
JHS and UHealth Process	At least 10 days after symptom onset PLUS resolution of fever X 24 hours (without anti-pyretic med) and improvement in other symptoms	10 days after first positive RT-PCR test for SARS-CoV-2-RNA	At least 20 days after symptom onset PLUS resolution of fever X 24 hours (without anti-pyretic med) and improvement in other symptoms	20 days after first positive RT-PCR test for SARS-CoV-2-RNA
Role of Testing	Not recommended for discontinuation of isolation precautions	Not recommended for discontinuation of isolation precautions	May be considered, in consultation with ID	May be considered, in consultation with ID
PPE/Placement	Standard Precautions/Non COVID unit	Standard Precautions/Non COVID unit	Standard Precautions/Non COVID unit OR based on re-test results if performed	Standard Precautions/Non COVID unit OR based on re-test results if performed

Readmission of IMMUNOCOMPETENT Previously COVID-19 Positive Patients (10 days after original COVID diagnosis)

Readmission WITHIN 90 days of original COVID diagnosis		Readmission BEYOND 90 days of original COVID diagnosis	
Symptomatic	Asymptomatic	Symptomatic	Asymptomatic
If no alternative etiology exists, consider ID consult and testing and place patient based on clinical presentation and test results	No testing required Routine patient placement No COVID-related isolation precautions	Perform COVID testing and place patient based on clinical presentation and test results	*Use clinical judgement order COVID testing as appropriate* Contact infection prevention for questions regarding bed placement
Testing methodology: PCR and antibody tests	N/A	Testing methodology: PCR and antibody tests	N/A

Readmission of IMMUNOCOMPROMISED Previously COVID-19 Positive Patients (20 days after original COVID diagnosis)

Readmission WITHIN 90 days of original COVID diagnosis		Readmission BEYOND 90 days of original COVID diagnosis	
Symptomatic	Asymptomatic	Symptomatic	Asymptomatic
Placement and isolation precautions per COVID testing results	No testing required Routine patient placement No COVID-related isolation precautions	Placement and isolation precautions per COVID testing results	
Testing methodology: PCR and antibody tests	N/A	Testing methodology: PCR test	

Outpatient or Inpatient Preoperative Testing in Asymptomatic or Recovered Previously COVID-19 Positive Patients

(For symptomatic patients who have not recovered, follow testing and isolation recommendations above. A previously negative test within 72 hours prior to scheduled procedure (96 hours for holiday weekend) is acceptable.

Timeframe from known symptom onset or positive test result	Early	Interim	>90 Days
IMMUNOCOMPETENT	<10 Days Retest not needed. Treat as COVID-positive. Use full PPE and isolation	11-90 Days Re-test not needed. For aerosol generating procedure use PPE during the procedure. Routine bed placement	Retest based on clinical judgement and exposure history • **Negative** →Routine PPE and procedure room • **Positive** → full PPE and COVID designated procedure room
IMMUNOCOMPROMISED or Critically Ill	<20 Days Retest not needed. Treat as COVID-positive. Use full PPE and isolation	21-90 Days Retesting as appropriate using clinical judgement. PPE and room placement based on test results	**Retest** as appropriate using clinical judgment

* Per CDC guidance, reinfection highly unlikely within 90 days of original COVID diagnosis

** https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Jackson L&D/OB OUTPATIENT Testing in Asymptomatic or Recovered > 72 h from prior COVID-19 Positive results

(For symptomatic patients who have not recovered, follow testing and isolation recommendations above. A previously negative test within 72 hours prior to scheduled procedure is acceptable.

Timeframe from known symptom onset or positive test result	**Early**	**Interim**	**>90 Days**
PREGNANCY IMMUNOCOMPETENT	**<10 Days** Treat as COVID positive; labor in negative pressure room full PPE in OR no family in OR mother and any family exposed to the mother may not visit NICU If baby goes to the NICU, will be admitted to the COVID cohort nursery in NICU D	**11-90 Days** Treat as COVID negative labor in regular room; N95 + eye protection in OR family allowed in OR & mother & family allowed in NICU	Retest based on clinical judgement and exposure history • **Negative** →Routine PPE and procedure room • **Positive** → full PPE and COVID designated procedure room
PREGNANCY *IMMUNOCOMPROMISED* or Critically Ill	**<20 Days** Treat as COVID positive; labor in negative pressure room full PPE in OR no family in OR mother and any family exposed to the mother may not visit NICU. If baby goes to NICU, will be admitted to the COVID cohort nursery in NICU D	**21-90 Days** Treat as COVID negative labor in regular room; N95 + eye protection in OR; family allowed in OR & mother & family allowed in NICU	**Retest** as appropriate using clinical judgment

Immunocompromised in Pregnancy will be identified as:
- Receiving chemotherapy
- stem cell or solid organ transplant recipient on active immunosuppression
- Untreated HIV with CD4 < 200
- Chronic steroid use or Clinical judgement - any patient the provider deems should be considered this way
- Critically ill: pregnant patient who required hospitalization for the treatment of COVID-19

Jackson L&D/OB INPATIENT Testing in Asymptomatic or Recovered Previously COVID-19 Positive Patients

(For symptomatic patients who have not recovered, follow testing and isolation recommendations above. A previously negative test within 72 hours prior to scheduled procedure is acceptable.

Timeframe from known symptom onset or positive test result	**Early**	**Interim**	**>90 Days**
PREGNANCY IMMUNOCOMPETENT	**<10 Days** Treat as COVID positive labor in negative pressure room; full PPE in OR no family in OB OR mother and any family exposed to the mother may not visit NICU If baby goes to NICU, will be admitted to the COVID cohort nursery in NICU D	**11-90 Days** Treat as COVID negative labor in regular room N95 + eye protection in OR Family allowed in OR & NICU	Retest based on clinical judgement and exposure history • **Negative** →Routine PPE and procedure room • **Positive** → full PPE and COVID designated procedure room
PREGNANCY *IMMUNOCOMPROMISED* or Critically Ill	**<20 Days** Treat as COVID positive labor in negative pressure room full PPE in OR no family in OB OR mother and any family exposed to the mother may not visit NICU If baby goes to NICU, will be admitted to the COVID cohort nursery in NICU D	**21-90 Days** Retesting as appropriate using clinical judgement and PPE/room placement based on test results. NICU visitation will depend on results of testing.	**Retest** as appropriate using clinical judgment

Immunocompromised in Pregnancy will be identified as:
- Receiving chemotherapy
- stem cell or solid organ transplant recipient on active immunosuppression
- Untreated HIV with CD4 < 200
- Chronic steroid use or Clinical judgement - any patient the provider deems should be considered this way
- Critically ill: pregnant patient who required hospitalization for the treatment of COVID-19

Jackson HEALTH SYSTEM
Miracles made daily.

Powered Air Purifying Respirator (PAPRs) Process

PAPR TYPES

3M Breathe Easy & Versaflo (TR800) PAPR systems: used for first receiver, patient decontamination programs are approved to the chemical, biological, radiological, and nuclear (CBRN) loose-fitting PAPR standard developed by the National Institute for Occupational Safety and Health (NIOSH) for gases and vapors. The high efficiency filters in a CBRN cartridge filter out 99.97% of particulates. No N95 required under hood for either.

Stryker Modified Flyte Helmet as PAPR: This helmet system covers the entire head and neck. The system is designed to pull air in through the top of the hood through a white section of AAMI class 3 material. The air then passes through the blue AAMI class 4 material on the sides of the hood. A fan mounted in the top of the helmet drives this flow. While class 4 material provides the highest level of protection against pathogens [5], the class 3 material may allow some pathogens to pass through. N95 respirators should be used under any of the Stryker togas or hoods.

Ford Limited Use Public Emergency PAPR: With support from 3M, Ford developed a unique powered-air purifying respirator (PAPR) for use in reducing exposure to airborne particles. This PAPR is designed to provide constant filtered airflow to healthcare workers during the COVID-19 pandemic.

KEY ROLES:	PAPR Administrator	PAPR END USER	Recommended Cleaning & Decontamination
Obtaining PAPR Device & End User Training	1. Ensure availability of needed inventory in a designated location. 2. Assures mandatory medical evaluation and training is completed by end user prior to use. 3. Ensures process maintenance for repairing or replacing components of PAPRs. (In conjunction with BIOMED) 4. Designate individual responsible for daily cleaning, battery charging oversight and minimum monthly maintenance per manufacturer guidance.	1. End user will complete mandatory PAPR respirator donning, doffing, cleaning and use training per manufacturer instructions via WeLearn prior to using any PAPR system. 2. End user will present to Employee Health for mandatory medical evaluation prior to using PAPR. 3. End user will report to designated location to obtain the PAPR. a. Will wipe down device with hospital approved wipes per training before and after use. b. Will ensure batteries are cleaned and placed on charger in designated areas after use.	1. Each PAPR Administrator will develop specific standard operating procedure (SOP) to fit their area workflow needs. 2. Manufacturer instructions for use (IFU) must be consulted for SOP development: a. 3M Breathe Easy PAPR Assembly Guidance b. 3M Versaflo (TR800) PAPR Assembly Guidance c. Stryker Modified Flyte Helmet (Journal of Arthroplasty,4/13/20) d. Ford Limited Use Public Emergency PAPR Guidance
General PAPR Assembly & Use		****Manufacturer instructions for use (IFU) must be consulted**** ****End user must inspect PAPR and parts before each use and at the time of cleaning**** 1. PAPR must be inspected before each use to ensure good operating condition. Detach the belt, battery pack, breathing tube, headgear, filter cover, filter, and prefilter or spark arrestor/prefilter (if used) from the motor/blower.(Report issues immediately to PAPR Administrator) 2. Disinfect hood with hospital approved germicidal wipes before and after each use. (Follow proper hand hygiene) 3. Store in a clean dry place, ensure batteries are wiped down and placed in designated recharging area; do not store in patient rooms. 4. Notify PAPR Administrator immediately with any concerns: a. If a replacement unit, hood, parts are needed. b. If the PAPR malfunctions, there are cracks in the airflow tube or hood etc.	1. For general cleaning wipe the outside surfaces of the PAPR system with hospital approved germicidal wipes. 2. Do not clean with organic solvents. 3. Do not soak the blower unit or battery in cleaning solutions. **Other methods of cleaning, disinfection or sterilization have not been tested for compatibility with the PAPR and may damage the PAPR system and therefor must not be used. (3M Breath Easy PAPR for First Responders Presentation)
Storage & Maintenance: PAPR parts, batteries, and chargers	1. Each PAPR Administrator will ensure appropriate storage environment is designated per manufacturer instructions for use (IFU) must be consulted for SOP development: a. 3M Breathe Easy PAPR Assembly Guidance b. 3M Versaflo (TR800) PAPR Assembly Guidance c. Stryker Modified Flyte Helmet (Journal of Arthroplasty,4/13/20) d. Ford Limited Use Public Emergency PAPR Guidance 2. **Batteries must be stored at room temp-See IFU for specifics.**	1. Store components in a cool dry area that is free from contaminants and direct sunlight. 2. Store in such a way as to protect the PAPR from physical damage a. For the hood, tuck the shroud up into the head area to help preserve the shape of the lens. 3. Respirator assigned to an individual should be marked as such and stored in specific location (3M Breath Easy PAPR for First Responders Presentation)	

JHS Lab Testing Algorithm

NO TESTING REQUIRED

COVID-19+ within 90 days (via PCR or antigen ONLY)
Received COVID-19 Convalescent Plasma (CCP) or monoclonal antibody treatment within 90 days
Day of transplant for ***living*** donors (serology testing can be continued)
Discharged patients (with the exception of SNF, BH, NH)

REDUCED TESTING

Inpatient requiring PFT or bronch testing (minimum 72 before procedures)
Post-transplant (within 24 hours for lung recipient) and minimum 14 days for BAL specimens

Test/Method	TAT	Facility	Tier	Population	Testing Option	Comments
Cepheid/Biofire RP2	2 hr	JHS*	1	Unscheduled Labor and Delivery (OB Triage)	COVID ONLY	
			1	Trauma Resus	COVID ONLY	
			1	Asymptomatic Transplant - (Adult & Peds)	COVID ONLY	For Recipients
			1	Symptomatic Transplant - (Adult & Peds) Immunocompromised (Adult & Peds) (eg: chemotherapy)	Respiratory Panel (RP2)	For Recipients
			1	Symptomatic Admitted ED patients	COVID Antigen w/in 5 days of symptoms. Neg Antigen results reflex to 4-Plex PCR test	Test via POC antigen. Reflex to PCR for negative antigen results ONLY. No additional testing required for positive antigen results.
			1	Aymptomatic Admitted ED patients	COVID ONLY	No Point of Care antigen testing
			1	Same day Surgery or Procedure (eg: cath lab)	COVID ONLY	
			1	Admitted Behavioral Health Patients		
Elitech	6-8 hr	JMH	2	LTC Symptomatic	FluA/FluB,RSV, COVID (4-Plex)	
			2	Symptomatic Healthcare Workers (HCW) for COVID-19	FluA/FluB,RSV, COVID (4-Plex)	Test via POC antigen. Reflex to PCR for negative antigen results ONLY. No additional testing required for positive antigen results.
			2	Symptomatic MTI Clinic Patients	FluA/FluB,RSV, COVID (4-Plex)	
			2	Asymptomatic MTI Clinic Patients	COVID ONLY	
Qiagen	24 Hr	JMH	3	Long Term Care (LTC) Residents	COVID ONLY	POC antigen test
			3	Scheduled L&D Patients	COVID ONLY	
			3	Inpatients	COVID ONLY	
			3	Pre-Op, Pre-procedure Via PAT	COVID ONLY	
			3	Scheduled Surgery or Procedure (eg: cath lab)	COVID ONLY	
			3	Symptomatic CHS Inmates	FluA/FluB,RSV, COVID (4-Plex)	
			3	Asymptomatic Healthcare Workers (HCW)	COVID ONLY	Test via POC antigen and reflex to PCR
			3	Partners of Unscheduled L&D Emergent Cases	COVID ONLY	
			3	Direct admissions from other facilities (Documentation of Test Required) if needed	COVID ONLY	
			3	JHS Patients Discharged from ED	COVID ONLY	
			3	Newborns of Covid Positive Mothers	COVID ONLY	
			3	LTC New Placement (Discharge from JHS Facility)	COVID ONLY	

***Testing methods (Cepheid 4-Plex and Biofire RP2) available at all JHS sites.**
Testing will automatically default to the next Tier based on availability of test kits.
All requests for Flu A/ Flu B, RSV and COVID will be performed on Cepheid 4-Plex
Biofire RP2 = Respiratory Pathogen Panel, which includes SARS-CoV-2
EMR rules to disallow COVID order in combination with RP2 or 4-Plex testing
Provider will be called and comment added to EMR report if Flu A/B or RSV positive incidental result discovered when testing on Cepheid 4-Plex

Revised 03/01/21

Appendix 18

Interim Guidance for Emergency Medical Services (EMS) Systems and 9-1-1 Emergency Communications Centers/Public Safety Answering Points (ECC/PSAPs) for Management of Patients Under Investigation (PUIs) for Ebola Virus Disease (EVD) in the United States

Who this is for: EMS clinicians (including emergency medical responders (EMR), emergency medical technicians (EMTs), advanced EMTs (AEMTs), paramedics, and other medical first responders who could be providing patient care in the field, such as law enforcement and fire service personnel), managers of 9-1-1 ECC/PSAPS, EMS agencies, EMS systems, and agencies with medical first responders.

What this is for: Guidance to assure EMS and first responders are safe and patients are appropriately managed while handling inquiries and responding to PUIs for EVD. The information contained in this document is intended to complement existing guidance for healthcare personnel.

How to use: Employers and supervisors should use this information to understand and explain to staff how to respond and stay safe. Supervisors can use this information to prepare, educate, and train EMS personnel. Individuals can use this information to stay safe when responding to PUIs.

- The likelihood of contracting Ebola virus disease (EVD) in the United States is extremely low unless a person has direct contact with the blood or body fluids (like urine, saliva, sweat, feces, vomit, breast milk, amniotic fluid, and semen) of a person with EVD who has symptoms or the blood or body fluids of a person who has died of EVD.
- It is important for ECC/PSAPs to question callers about:
  - Having traveled internationally to a country with ongoing EVD transmission or having had contact with a person with suspected or confirmed EVD within the previous 21 days; AND
  - Signs and symptoms of EVD (such as fever, severe headache, muscle pain, weakness, fatigue, diarrhea, vomiting, abdominal pain, and unexplained hemorrhage).
- Managers of 9-1-1 ECC/PSAPs, EMS agencies, EMS systems, and agencies with medical first responders such as fire and law enforcement should collaborate with local public health authorities to develop coordinated plans for responding to a PUI in a given jurisdiction, including the possibility of designating certain teams for this response.
- All personnel should be educated and trained regarding Ebola response protocols. Those who may respond to a PUI also should be educated and trained in the use of the appropriate PPE consistent with their response role.
- If ECC/PSAP call takers have information alerting them to a PUI, they should make sure first responders and EMS clinicians are made aware of the potential for a patient with possible exposure/signs and symptoms of EVD before responders arrive on scene. This will enable EMS clinicians to select and correctly put on PPE following the principles described in CDC's Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients Under Investigation (PUIs) for Ebola Virus Disease (EVD) and Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE. The fundamental principle of standard and transmission-based precautions is to prevent contact with blood or potentially infectious body fluid.
- Before treating and/or transporting a patient or PUI, personnel should have been educated, trained, and demonstrated competency in all Ebola-related infection control practices and procedures, specifically in donning and doffing proper PPE.
- When EMS clinicians arrive at the scene, they should immediately check for symptoms and risk factors for EVD and don PPE appropriate to the situation. When transporting a PUI, EMS clinicians should notify the receiving healthcare facility in

advance, so that proper infection control precautions are ready to be implemented at the healthcare facility before arrival. EMS medical directors and EMS agencies should collaborate with healthcare and public health agencies to define local or regional protocols for transporting a PUI to an appropriate facility for EVD triage and care.

- Local protocols should be developed for cleaning and disinfecting of the ambulance and equipment as well as disposing of medical waste consistent with this guidance.

Background

Ebola virus spreads through direct contact (such as through broken skin or mucous membranes in the eyes, nose, or mouth) with blood or body fluids (urine, saliva, sweat, feces, vomit, breast milk, amniotic fluid, and semen) of a person who is sick with or has died from Ebola Virus Disease (EVD) or direct contact with objects (such as needles and syringes) contaminated with body fluids from a person sick with EVD or the body of a person who died from EVD. Signs and symptoms of EVD include fever, severe headache, muscle pain, weakness, fatigue, diarrhea, vomiting, abdominal (stomach) pain, and unexplained hemorrhage (e.g., bleeding from gums, blood in urine, or bruising). Symptoms may appear anywhere from 2 to 21 days after contact with the virus, with an average of 8 to 10 days.[1]

EVD can cause illness similar to other travel-related infectious diseases. Attention is needed when coming into direct contact with a recent traveler from a country with ongoing Ebola virus transmission and who also has signs and symptoms of EVD. The initial signs and symptoms of EVD are often nonspecific and similar to other infectious diseases, such as malaria and typhoid. EVD should be considered in anyone with a fever who has traveled to, or lived in, an area where EVD is present.[2]

Most patients with fever and other non-specific signs and symptoms in the United States will not have EVD. Nevertheless, because early EVD symptoms are similar to those seen with other febrile illnesses, providers should consider and assess patients for the possibility of EVD. Transport by emergency medical services (EMS) presents unique challenges because of the uncontrolled nature of the work, the potential for resuscitation procedures being needed, enclosed space during transport, and a varying range of patient acuity.

Key safe work practices include avoiding

- Unprotected exposure to blood or body fluids of patients with EVD through contact with skin, mucous membranes of the eyes, nose, or mouth.
- Injuries with contaminated needles or other sharp objects.
- Aerosol-generating procedures when possible.

Coordination among 9-1-1 ECC/PSAPs, the EMS system, healthcare facilities, and the public health system is important. Educating, training, and exercising with all stakeholders is critical when preparing to respond to PUIs. Each 9-1-1 and EMS system should include an EMS medical director to provide appropriate medical oversight.

Case Definition for EVD

CDC's most current case definition for Ebola may be accessed at: Case Definition for Ebola Virus Disease (EVD)

Recommendations for 9-1-1 ECC/PSAPs

If a community is considered at higher risk for having patients with EVD, state and local EMS authorities should coordinate with state and local public health, ECC/PSAPs, and other emergency call centers to use modified caller queries about EVD, outlined below. This should be decided from information provided by local, state, and federal public health authorities, including the city or county health department(s), state health department(s), and CDC.

Modified Caller Queries

It will be important for ECC/PSAPs to question callers and determine the possibility of anyone having signs or symptoms and risk factors for EVD. This information should be communicated immediately to EMS clinicians before arrival in order to assign the appropriate EMS resources. Local or state public health officials should also be notified. ECC/PSAPs should utilize medical

dispatch procedures that are coordinated with their EMS medical director and with the local public health department.

- Use modified caller queries that ask for risk factors for EVD.
- If ECC/PSAP call takers have information alerting them to a PUI, they should make sure any first responders and EMS clinicians are made aware of the potential for a patient with possible exposure/signs and symptoms of EVD before the responders arrive on scene.
- If responding to a report of an ill traveler at an airport or other port of entry to the United States, the ECC/PSAP or EMS unit should notify the CDC Quarantine Station for the port of entry. For contact information check the CDC Quarantine Station Contact List. The ECC/PSAP or EMS unit also may call CDC's Emergency Operations Center at (770) 488-7100 to be connected with the appropriate quarantine station.

Recommendations for EMS and Medical First Responders

For the purposes of this section, "EMS clinician" means prehospital EMS and medical first responders. These EMS clinician practices should be based on the most up-to-date EVD clinical recommendations and information from appropriate public health authorities and EMS medical direction.

When state and local EMS authorities determine there is an increased risk, they may direct EMS clinicians to modify their practices as described below.

Patient assessment

- If ECC/PSAP call takers advise the patient is suspected of having EVD, EMS clinicians should put on appropriate PPE before entering the scene. PPE options are described in detail below.
- Initial assessment in circumstances of increased risk should include wearing all appropriate PPE if approaching within 6 feet. Only one EMS clinician should approach the patient and perform the initial screening. Based on the initial screening, if the EMS clinician suspects possible EVD, then all other personnel should wear appropriate PPE for all subsequent interactions. Keep other emergency responders further away, while assuring they are still able to support the EMS clinician with primary assessment duties.
- During patient assessment and management, EMS clinicians should consider the signs, symptoms, and risk factors of EVD. A relevant exposure history should be taken including:
  - Residence in, or travel to, a country or area with ongoing Ebola virus transmission or cases in urban settings with uncertain control measures.
  - Contact with blood or body fluids of a PUI or patient with confirmed EVD.
- Patients with any of the above exposures should be questioned regarding the presence of signs or symptoms of EVD.

Safety and PPE

Based on the clinical presentation of the patient, there are two PPE options.

- If the patient is not exhibiting obvious bleeding, vomiting, or diarrhea and does not appear to be acutely ill, EMS personnel should follow the PPE guidance for clinically stable PUIs.
- If the patient is exhibiting obvious bleeding, vomiting, or diarrhea or is clinically unstable then EMS personnel should wear PPE described in Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE. This PPE should also be worn if the patient requires invasive or aerosol-generating procedures (such as intubation, suctioning, cardiopulmonary resuscitation). Extreme care should be followed in these instances.
- PPE should be put on before entering a scene with a PUI and continued to be worn until clinicians no longer are in contact with the patient. PPE should be carefully put on and removed under the supervision of a trained observer as described in Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE.

- If blood, body fluids, secretions, or excretions from a PUI come into direct contact with the EMS clinicians' unprotected skin or mucous membranes, then the EMS clinician should immediately **STOP** working. They should wash the affected skin surfaces with a cleansing or antiseptic solution, and mucous membranes (e.g., conjunctiva) should be irrigated with a large amount of water or eyewash solution, as per usual protocols. All waste should be placed in a biohazard bag. EMS clinicians should immediately report exposure to an occupational health provider, supervisor, or designated infection control officer for immediate care.

Patient management and Infection Control

EMS clinicians can safely manage a PUI by following the recommendations for appropriate PPE and following these recommendations:

- Use caution when approaching a PUI. On rare occasions, illness can cause delirium, with erratic behavior, such as flailing or staggering. This type of behavior can place EMS clinicians at additional risk of exposure.
- Keep the patient separated from others as much as possible.
- Limit the number of personnel who care for a PUI. All personnel within the range of coughs and splashes (i.e., 6 feet) of a PUI must wear PPE.
- Limit activities, especially during transport, that can increase the risk of exposure to infectious material.
- Invasive procedures should be limited to those essential for patient management.
- Limit the use of needles and other sharps as much as possible. Needles and sharps should be handled with extreme care and disposed in puncture-proof, sealed containers specific to the care of this patient, in accordance with OSHA's Bloodborne Pathogens Standard , 29 CFR 1910.1030 . Do not dispose of used needles and sharps in containers that have sharps from other patients in them.
- Consider giving the patient oral me icine to reduce nausea, per medical director protocols and consistent with scope of practice.
- If patient is vomiting, give them a large red biohazard bag to contain any emesis.
- If patient has profuse diarrhea, c nsider wrapping the patient in an impermeable sheet to reduce contamination of other surfaces.
- Prehospital resuscitation procedures such as endotracheal intubation, open suctioning of airways, and cardiopulmonary resuscitation frequently result in a large amount of body fluids, such as saliva and vomit. Performing these procedures in a less controlled environment (for example, a moving vehicle) increases risk of exposure to infectious pathogens for EMS clinicians. Perform these procedures according to protocol under safer circumstances (e.g., when the vehicle has stopped, upon arrival at the hospital destination) and wear the PPE recommended for use during aerosol-generating procedures.
- Donning and doffing of PPE must be supervised by a trained observer to ensure proper completion of established PPE protocols. In collaboration with the receiving hospital, EMS agencies should consider how best to facilitate a supervised doffing process.

Prehospital care considerations

EMS systems should design their procedures to accommodate their local operational challenges while still following the principles of CDC PPE guidance.

- It may be as simple as having one clinician put on PPE and manage the patient while the other provider does not engage in patient care but serves in the role of trained observer.
- There may be situations where a patient must be carried and multiple personnel are required to put on PPE. In those instances, EMS clinicians having had contact with the patient must remain in the back of the ambulance and should not join or serve as the driver.
- EMS agencies may consider sending additional resources to eliminate the need for putting on PPE by additional clinicians. For example, a dedicated driver for the ambulance may not need to wear PPE if they remain > 6 feet from the patient and other EMS clinicians, and do not provide patient care.
- Doffing of PPE must be performed with meticulous care to prevent self-contamination. See guidance on PPE doffing and ensure education and training emphasizes adherence to a standardized protocol.

- Prepare and use safe procedures to treat and transport the patient to the hospital.
- The person driving the ambulance should contact the receiving hospital and follow local or regional protocols to transport the patient to the receiving hospital.
- Remove and keep nonessential equipment away from the patient on the scene and in the ambulance. This will eliminate or minimize contamination.
- Avoid contamination of reusable porous surfaces not designated for single use. Cover the stretcher with an impermeable material.
- Conduct appropriate patient assessment according to established protocols, using minimal equipment.

EMS Transport of Patient to a Healthcare Facility

People who may have an exposure history and signs and symptoms suggestive of EVD should be transported to a healthcare facility prepared to further evaluate and manage the patient as instructed by EMS medical direction and local/regional protocols. These should be consistent with the predefined transportation/destination plan developed by public health officials, hospital, medical, and EMS personnel.

- Isolate the driver from the patient compartment.
- During transport, ensure that an appropriate disinfectant (EPA-approved hospital grade disinfectant with a nonenveloped virus claim) is available in spray bottles or as commercially prepared wipes.

Interfacility transport

EMS personnel involved in the interfacility transfer of PUIs or patients with confirmed EVD should follow donning and doffing procedures as recommended in CDC guidance. Provide patient care as needed to minimize contact with the patient and follow infection control guidelines noted below.

Documentation of patient care

- Documentation of patient care should be done after EMS clinicians have completed their personal cleaning and decontamination of equipment and the vehicle. Any written documentation should match the verbal communication given to the emergency department providers at time of patient handover.
- EMS documentation should include a listing of public safety providers involved in the response and level of contact with the patient (e.g., no contact with patient, provided direct patient care). This documentation may need to be shared with local public health authorities.

Cleaning EMS Transport Vehicles after Transporting a PUI for EVD

The following are general guidelines for cleaning or maintaining EMS transport vehicles (i.e., ambulances) and equipment after transporting a PUI:

- Personnel performing cleaning and disinfection where body fluids from a PUI are present should wear PPE as recommended by CDC. If no body fluids from a patient with EVD are present, follow PPE guidance for PUIs who are Clinically Stable and Do Not Have Bleeding, Vomiting, or Diarrhea.
- Use an EPA-registered hospital disinfectant with a label claim for a nonenveloped virus (for example, norovirus, rotavirus, adenovirus, poliovirus)[3, 4] to disinfect environmental surfaces in the transporting vehicle and rooms of PUIs or patients with confirmed EVD. Cleaning and decontaminating surfaces or objects soiled with blood or body fluids are addressed below. There should be the same careful attention to the safety of EMS personnel during cleaning and disinfection of transport vehicles as during care of the patient.
- Patient-care surfaces (including stretchers and wheels, railings, door handles, medical equipment control panels, adjacent flooring, walls, and work surfaces), as well as stretcher wheels, brackets, and other areas are likely to become contaminated and should be cleaned and disinfected thoroughly after each transport.

- A blood spill or spill of other body fluids or substances should be managed by personnel wearing correct PPE. This includes removing bulk spill matter, cleaning the soiled site, and then disinfecting the site. Follow the chemical disinfectant product's labeled instructions and dispose of the potentially contaminated materials used during the cleaning and disinfecting process as recommended in CDC guidance.
- Contaminated reusable patient care equipment (such as glucometer, blood pressure cuff) should be placed in biohazard bags and labeled for cleaning and disinfection or disposal according to agency policies and manufacturer recommendations. Reusable equipment should be cleaned and disinfected according to manufacturer's instructions by trained personnel wearing correct PPE. Avoid contamination of reusable porous surfaces not designated as single use.
- Use only a mattress and pillow with intact plastic or other covering that fluids cannot penetrate.
- To reduce exposure among staff to potentially contaminated textiles (cloth products) while laundering, discard used linens and nonfluid-impermeable pillows or mattresses as appropriate at the receiving facility.

Ebola is a Category A infectious substance regulated by the U.S. Department of Transportation's Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Any item transported for disposal that is contaminated or suspected of being contaminated with a Category A infectious substance must be packaged and transported in accordance with the HMR.[5, 6] This includes: disposable medical equipment; sharps; linens; and used healthcare products such as soiled absorbent pads or dressings, emesis pans, portable toilets; used PPE such as, gowns or coveralls, masks, gloves, goggles, face shields, respirators, and booties; and contaminated waste from cleaning. EMS systems should work with designated receiving hospitals to dispose of waste from PUIs.

Follow-up and/or Reporting Measures by EMS Clinicians After Caring for a PUI for EVD

- EMS clinicians should be aware of the follow-up and/or reporting measures they should take after caring for a PUI.
- EMS agencies should develop policies for monitoring and management of EMS personnel potentially exposed to Ebola virus.
- EMS agencies should develop sick-leave policies for EMS personnel that are nonpunitive, flexible, and consistent with public health guidance.
- Ensure all EMS personnel, including staff who are not directly employed by the healthcare facility but provide essential daily services, are aware of the sick-leave policies.
- EMS personnel with exposure to blood, urine, saliva, sweat, feces, vomit, breast milk, amniotic fluid, semen, or diarrhea should immediately
  - **STOP** working and wash the affected skin surfaces with a cleansing or antiseptic solution, and mucous membranes (such as conjunctiva of the eye) should be irrigated with a large amount of water or eyewash solution, as per usual protocols. All wipes and solution should be placed in a biohazard bag.
  - Contact occupational health/supervisor/designated infection control officer for immediate assessment and access to post-exposure management services.
  - Receive medical evaluation and follow-up care, based upon EMS agency policy and consultation with local, state, and federal public health authorities. Additional monitoring and movement restrictions may be imposed by public health authorities for personnel with unprotected exposure to a patient with EVD.
- All mission personnel should be advised to self-monitor for a period of 21 days after the last known contact with the patient with EVD. They should immediately report elevated body temperature or subjective fever or any other signs or symptoms consistent with EVD to their occupational health/supervisor/designated infection control officer.

Additional Resources:

- Q&A's about the Transport of Pediatric Patients (< 18 years of age) Under Investigation or with Confirmed Ebola | Emergency Services | Clinicians | Ebola (Ebola Virus Disease) | CDC
- Guidance for Developing a Plan for Interfacility Transport of Persons Under Investigation or Confirmed Patients with Ebola Virus Disease in the United States | Emergency Services | Clinicians | Ebola (Ebola Virus Disease) | CDC
- EMS Infectious Disease Playbook | Technical Resources | ASPR TRACIE (hhs.gov)

References

[1] Ebola virus disease Information for Clinicians in U.S. Healthcare Settings | For Clinicians | Ebola (Ebola Virus Disease) | Ebola Hemorrhagic Fever | CDC

[2] Outbreaks | Ebola (Ebola Virus Disease) | CDC

[3] List G: EPA's Registered Antimicrobial Products Effective Against Norovirus | Pesticide Registration | US EPA

[4] List L: Disinfectants for Use Against the Ebola Virus | Pesticide Registration | US EPA

[5] Packaging of Ebola Contaminated Waste | PHMSA (dot.gov)

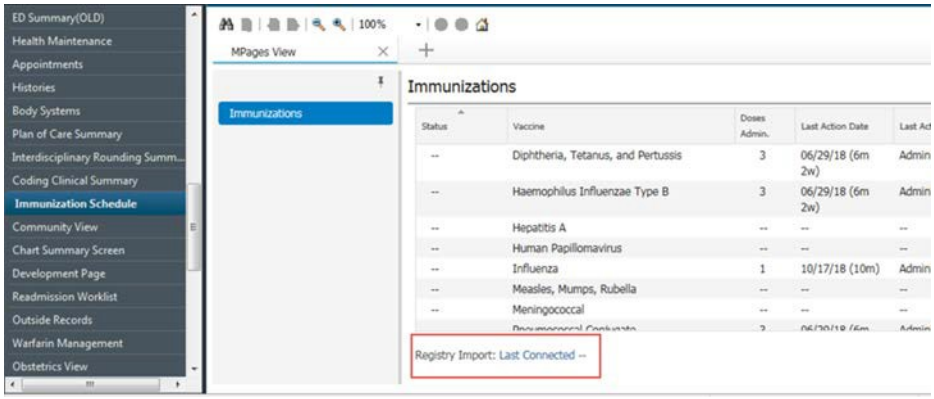
[6] Managing Solid Waste Contaminated with a Category A Infectious Substance (dot.gov) [PDF – 2.62 MB]

Page last reviewed: September 2, 2021

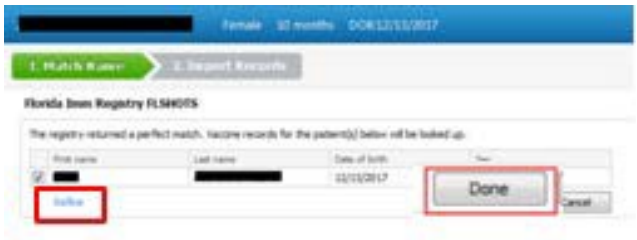
MIRACLE Quick Tip
How to Import Vaccines from Florida Shots

MIRACLE has a direct interface with Florida Shots.
You are now able to view all immunization records, download to the patient's chart and print the immunization record, directly from MIRACLE.

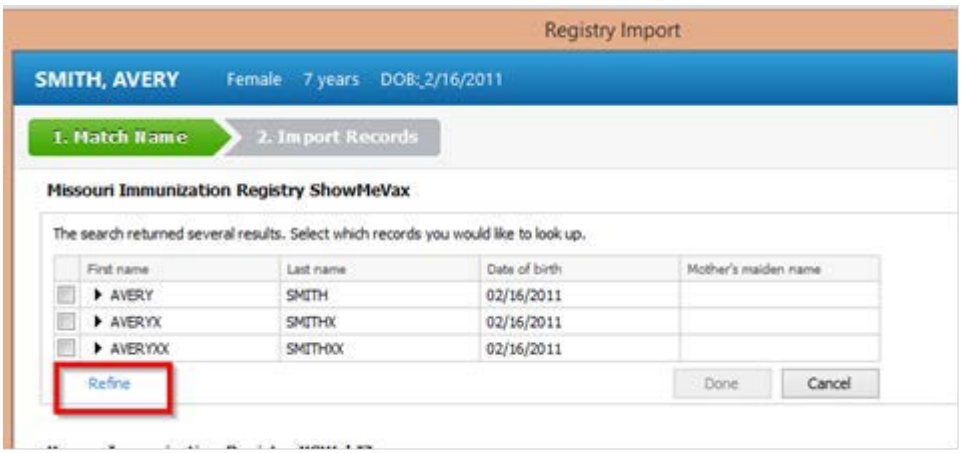
1. From the **Immunization Schedule**, click on **Registry Import: Last Connected--**



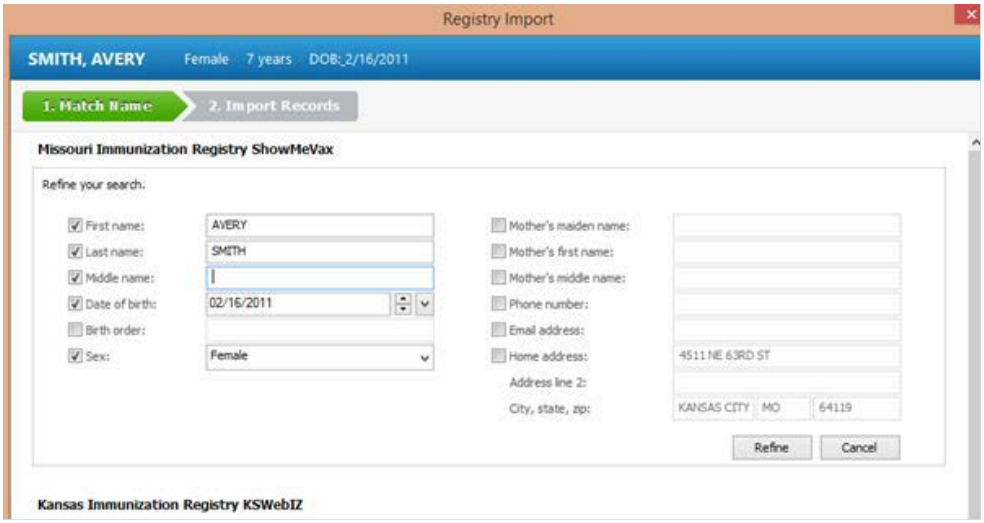
2. Once the system searches and returns a match, click on **Done or Refine** if more information is needed.



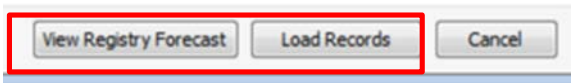
3. If no exact match is found, the system will return a list of possible matches. Click on **Refine** to add additional information.



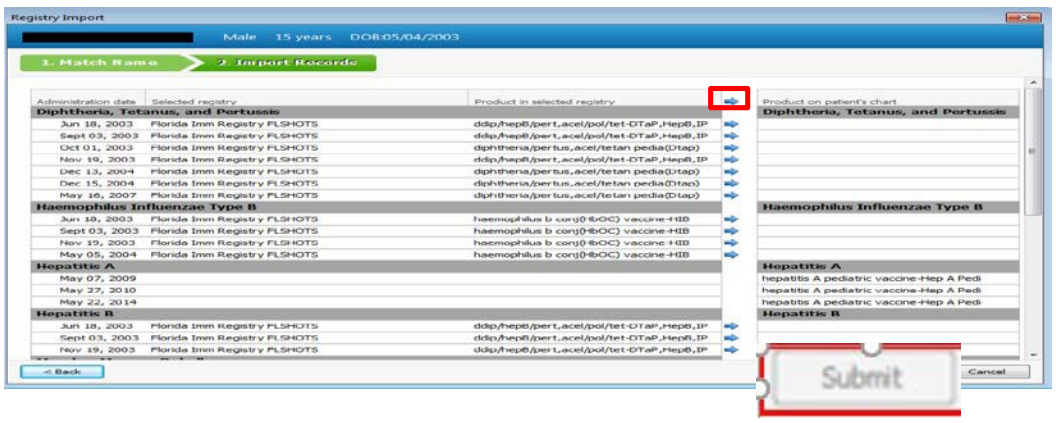
4. Enter additional details and click refine. Once an exact match is made, click on Done.



5. Select either **View Registry Forecast or Load Records.**



6. Once the records are loaded, click on **Blue arrow** next to vaccines to import and click **Submit**



The information is now part of the MIRACLE chart. Please note that if the patient requires an official vaccine record, the user must still access Florida Shots.

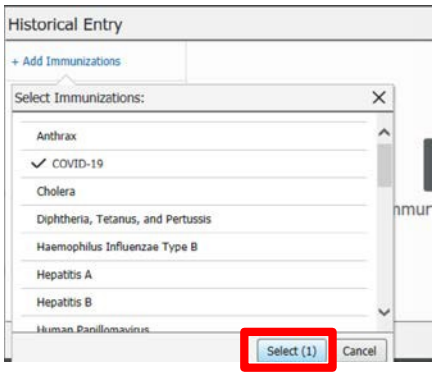
MIRACLE Quick Tip

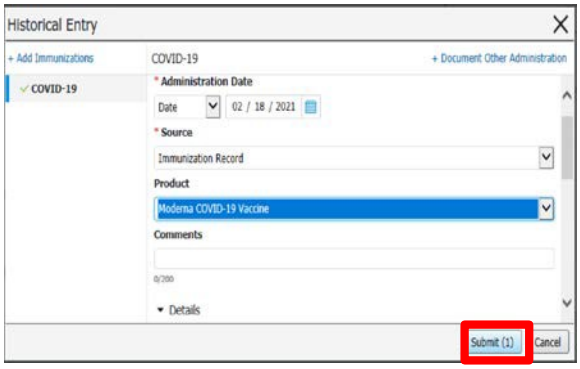
How to Import Vaccines from Florida Shots

Keypoint: For vaccines given out of state; document as historical vaccine.

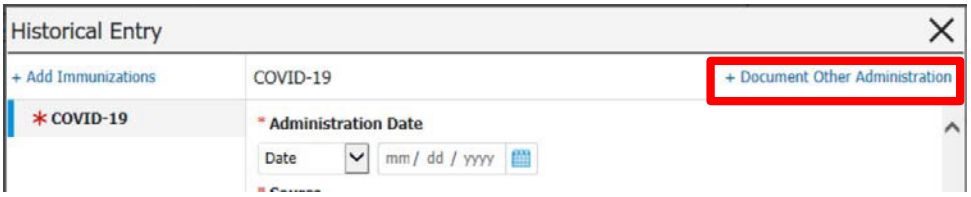
7. Click the Arrow next to **Immunizations** and Select **Document History**

8. Select the desired **Immunizations** and choose **Select,** enter details and **Submit**



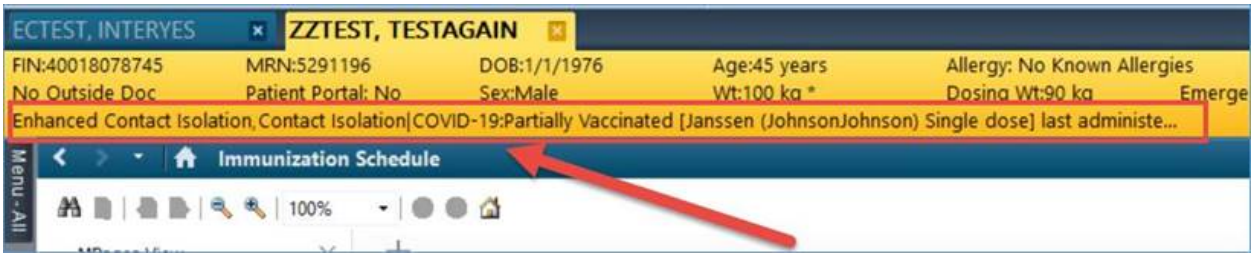


9.. Use the **Document Other Administration** button to document multiple doses of the same vaccine.



Changes in MIRACLE/Cerner patient Banner Bar-COVID 19 vaccination status

In order to facilitate clinical decision making, COVID 19 vaccination status for each of our patients will display in the Banner Bar.



The COVID 19 vaccination status in the Banner Bar pulls directly from Cerner/MIRACLE Immunization tab and is highly dependent on the accuracy and maintenance of this documentation.

Make sure that for every patient seen at JHS

- The immunization information is **being updated** by **querying Florida Shots and uploading** into Cerner/MIRACLE all the missing shots that the patient might have received outside JHS
- If vaccines were received **outside of Florida**(no information available in Florida Shots), and patient has documentation of the vaccination, this information has to be **manually entered under Immunization in Cerner/MIRACLE**

The System will look at this information in real time and depending on the number of doses and timing will display on the Banner Bar the following:

- Moderna/Pfizer COVID 19 vaccines
  - 2 doses separated by at least 1 day (to filter out errors) up to 60 days and last dose > 14 days ago = **fully vaccinated**
  - 2 doses, last dose < 14 days ago = **partially vaccinated**
  - 1 dose = **partially vaccinated**
- Janssen COVID 19 vaccine
  - 1 dose given >= 14 days ago = **fully vaccinated**
  - 1 dose < 14 days ago = **partially vaccinated**
- Anything Else: **unknown**

Appendix 21a

JACKSON HEALTH SYSTEM VISITATION POLICY

DEPARTMENT	NUMBER OF VISITORS ALLOWED	VISITATION HOURS	OVERNIGHT VISITORS
Emergency Departments			
Adult	One companion	At all times	
Pediatric	Two companions	At all times	
Intensive Care Unit and Intermediate Care Unit (ICU and IMCU) Inpatients			
Adult	One visitor at a time	8 a.m. to 8 p.m. daily	Administration may approve one overnight visitor
Pediatric	Two visitors at a time	8 a.m. to 8 p.m. daily	One overnight visitor
Newborn ICU	One visitor at a time	At all times	
Inpatients (Non-ICU/IMCU and Lynn Rehab)			
Adult	Two visitors at a time	8 a.m. to 8 p.m. daily	Administration may approve one overnight visitor
Pediatric	Two visitors at a time	8 a.m. to 8 p.m. daily	One overnight visitor
Maternity	Two visitors at a time	8 a.m. to 8 p.m. daily	One overnight visitor
Behavioral Health Inpatients			
Jackson South Medical Center	One visitor at a time	6 to 7 p.m. daily	
Jackson Behavioral Health Hospital	One visitor at a time	5 to 6 p.m. daily for patients whose last name begins with A-M 6 to 7 p.m. daily for patients whose last name begins with N-Z	
Urgent Care, Primary Care, Ambulatory Care, Community Mental Health, and Physician Offices			
Adult and Pediatric	One companion	At all times	
Outpatient Hospital Procedures (Radiology, Diagnostic Tests, and Same-Day Procedures)			
Adult	One companion		
Pediatric	Two companions		

COVID-19-positive adult inpatients may have one visitor in extreme cases, such as end-of-life care, with administration's approval. **COVID-positive pediatric and maternity inpatients** may have one visitor at a time.

*Visitation is allowed at Jackson long-term care facilities, as directed by state and AHCA requirements.

Florida law allows every patient to choose one 'essential caregiver,' who may visit an additional two hours beyond the times in this policy. The patient's nurse or other care team member can assist with designating an essential caregiver and scheduling additional time together.

Jackson HEALTH SYSTEM
Miracles made daily.

Appendix 21b we are currently at "Low" Risk Level

JACKSON HEALTH SYSTEM MASKS AND VISITATION GUIDELINES

	RISK LEVEL			
	CRITICAL	**HIGH**	**MEDIUM**	**LOW**
COVID-Positive Cases Per Day Over Three-Day Period at Jackson	>250	151-250	76-150	<75
Patient COVID testing	Pre-encounter testing for all scheduled encounters; on-site testing for emergency cases.	Pre-encounter testing for all scheduled inpatient encounters; on-site testing for emergency cases upon admission order.	Testing for symptomatic patients	Testing for symptomatic patients
	Always COVID test patients being admitted for transplant, labor and delivery, or behavioral health, as well as oncology patients being admitted for chemotherapy. Always COVID test patients from Corrections Health Services or nursing homes.			
Cafeteria Requirements	Limited seating. Wear mask when not eating/ drinking.	Limited seating. Wear mask when not eating/ drinking.	Limited seating.	Normal operations
	Unvaccinated employees and providers are not allowed to eat or drink in Jackson facilities. All meals and snacks must be consumed outside.			
Employee, Provider, and Vendor Masking	Surgical masks required for everyone at all times, including non-clinical areas.	Surgical masks required in all clinical areas at all times and during all in-person meetings. Surgical masks are preferred but optional for vaccinated personnel in non-clinical facilities and office suites.	Surgical masks required in all clinical areas at all times. Surgical masks are preferred but optional for vaccinated personnel in non-clinical facilities and office suites.	Surgical masks required during clinical interactions (see below) and at all times in areas identified by signage as high-risk areas.
	N95 masks required in areas where COVID patients are being treated and aerosol-generating procedures are being performed, including intubation and extubation. *Clinical interactions include providing clinical care, as well as activities such as patient transport, office consults, diagnostic encounters, and any interaction in a patient's room.* ***Employees not vaccinated against COVID must wear N95 masks at all times. From October through March, employees who have not received the current flu vaccine must wear surgical or N95 masks at all times.*** *Masks will always be available for any employee or provider who prefers to wear a mask, even when not required.*			
Visitor Masking	Surgical masks always required in all areas.	Surgical masks always required in all areas.	Surgical masks always required in all areas.	Surgical masks required in hospital rooms with more than one patient, and at all times in areas identified by signage as high-risk areas.
Visitor Allowance	Restricted consistent with state and federal law.	Normal operations	Normal operations	Normal operations
In-Person Meetings	Not allowed	Limited (up to 50 percent of room capacity), masks always required for everyone. Essential hands-on training recommended in person; Zoom encouraged for all other meetings.	Normal operations, consistent with mask requirements.	Normal operations, consistent with mask requirements.
Entry Screening	Daily CARE Check-In for employees. Symptom screening for all others.	Daily CARE Check-In for employees. Symptom screening for all others.	Daily CARE Check-In for symptomatic employees only. Staff may deny entry to visitors with visible symptoms.	Daily CARE Check-In for symptomatic employees only. Staff may deny entry to visitors with visible symptoms.
Volunteers	Not allowed	Must be vaccinated against COVID	Must be vaccinated against COVID	Must be vaccinated against COVID

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REVIEW

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Omicro variant of SARS-CoV-2: Genomics, transm ssibilit and resp nses to curren es

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Abstract

Currently, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread worldwide as an Omicron variant. This variant is a heavily mutated virus and designated as a variant of concern by the World Health Organization (WHO). WHO cautioned that the Omicron variant of SARS-CoV-2 held a very high risk of infection, reigniting anxieties about the economy's recovery from the 2-year pandemic. The extensively mutated Omicron variant is likely to spread internationally, posing a high risk of infection surges with serious repercussions in some areas. According to preliminary data, the Omicron variant of SARS-CoV-2 has a higher risk of reinfection. On the other hand, whether the current COVID-19 vaccines could effectively resist the new strain is still under investigation. However, there is very limited information on the current situation of the Omicron variant, such as genomics, transmissibility, efficacy of vaccines, treatment, and management. This review focused on the genomics, transmission, and effectiveness of vaccines against the Omicron variant, which will be helpful for further investigation of a new variant of SARS-CoV-2.

KEYWORDS

coronavirus, disease control, immune responses, SARS coronavirus, vaccines/vaccine strains, virus classification

Yusha Araf and Fariya Akter contributed equally to this study

1 | INTRODUCTION

Different variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been identified since the first coronavirus disease 2019 (COVID-19) infection appeared in December 2019. Until November 2021, the Delta variant was designated as variant of concern (VOC) because of different characteristics.[1] According to the Centers for Disease Control and Prevention (CDC), the variant responsible for increased transmissibility, severe disease course, reduced effectiveness of treatments, and many other alarming factors is designated as the VOC.[2] Omicron variant is a new heavily mutated SARS-CoV-2 variant known as B.1.1.529, and it is now designated as a VOC by the World Health Organization on November 26, 2021.[1–3] Many cases have already been identified after the first confirmed Omicron variant infection from a sample collected on November 9, 2021, in South Africa and reported to WHO on November 24, 2021.[4] However, later it was found out that the Netherlands had the first Omicron variant positive patient diagnosed with the variant a week before the announcement from Africa, and surprisingly, the first Omicron variant positive patients of Africa were international travelers.[5] The Omicron variant is the most heavily mutated variant among all the VOC so far, which paves the way for enhanced transmissibility and partial resistance to immunity induced by COVID-19 vaccines.[4,6] Following the D614G, Beta/Gamma, and Delta VOCs, the SARS-CoV-2 Omicron variant could be the catalyst for the fourth wave of the COVID-19 outbreak to sweep the globe.[7] Unfortunately, this variant has already been spotted in 80 countries worldwide until December 15, 2021. The death of one confirmed patient infected with the Omicron variant of SARS-CoV-2 in the UK was reported on December 13, 2021.[6,8] Therefore, it is important to pay attention and take the required steps to strengthen surveillance and undertake public health measures. As a response, the goal is to raise awareness while avoiding overreaction.[9] New COVID-19 variants, such as Omicron, remind us that the epidemic is far from ended. People must acquire the vaccination as soon as it becomes available and continue to follow existing guidelines for limiting the transmission of the virus, including physical separation, wearing masks, handwashing regularly, and keeping indoor spaces ventilated. Vaccines and other public health measures must be readily available worldwide.[10] This review discussed the genomics of the SARS-CoV-2 Omicron variant with its transmissibility and efficacy of current COVID-19 vaccines. In addition, the treatment and management were discussed along with several recommendations to keep safe from the SARS-CoV-2 Omicron variant.

2 | GENOMICS OF OMICRON VARIANT

The Omicron variant of the SARS-CoV-2 genome constitutes 18 261 mutations from which more than 97% mutations are present in the coding region, and the remaining 558 are detected in the extragenic region.[11] Mutations in the coding region are 2965 indels and non-synonymous, and synonymous single-nucleotide polymorphisms (SNPs) mutations are 11 995 and 2743, respectively.[11] Thirty mutations have been found within the spike proteins mostly located at the receptor-binding domain (RBD) of the spike protein of the Omicron variant (Figure 1).[12] For more than 270 million reported SARS-CoV-2 infections worldwide, the virus has evolved into over 1500 distinct Pango lineages.[13] Additionally, three other deletions and one insertion mutation are present outside the spike protein. Preliminary data analyzed from the Global Initiative on Sharing All Influenza 101 Data (GISAID) showed that NTD contains 11 mutations, including six deletions and one insertion, with mutations N211 and ins214EPE being unique.[14]

Interestingly, some of the mutations were already found in the previous VOC that helps in neutralizing antibodies.[15,16] Five different variants of SARS-CoV-2 have been considered VOC at different times.[17] Investigations performed by epidemiologists in South Africa identified the mutational data that manifests some of the concerning mutations (N501Y, D614G, K417N, and T478K) along with new mutations present in the Omicron variant, which increased the overall risk of reinfection, partial resistance to existing vaccines [17] (Figure 1). The Delta variant shares two out of three RBD mutations with Omicron. The first, a lysine to asparagine substitution at position 417, has been linked to S protein structural alterations that may enhance immune evasion. The second mutation, a threonine to lysine substitution at position 478, is likely to boost the residue's electrostatic potential and steric interference, perhaps increasing RBD binding affinity and allowing immunological escape. A leucine to arginine substitution at position 452, which is present in Delta but not in the Omicron variant, is known to boost affinity for ACE2 receptors found on the surface of various human cells, including the lungs.[18] Even though Wuhan-Hu-1 has 1273 amino acids, the Delta variation has 1271, and the Omicron variant has 1270, both contain fewer residues than the wild-type due to sequence loss.[19] Genome analysis by Kandeel et al. reported that the Omicron variant of SARS-CoV-2 forms a new monophyletic clade.[20] On the other hand, Wang et al. showed that the Omicron variant of SARS-CoV-2 evolved from the 20B clade and formed two subclades.[21]

3 | TRANSMISSIBILITY OF OMICRON VARIANT

There is still a scarcity of sufficient essential data regarding the infection rate to analyze the transmissibility of the new heavily mutated Omicron variant. However, analysis from the early data of South Africa manifested that the Omicron variant can spread way more easily from person to person, though experts could not draw any conclusion within this short period.[22] The concern of Omicron variant transmissibility increases as it spreads worldwide within a few days, and cases have been increasing dramatically.[23] According to the report of CDC, a 2.5% increasing capacity of Omicron variant has been observed in the US within 2 weeks. However, in New York/New

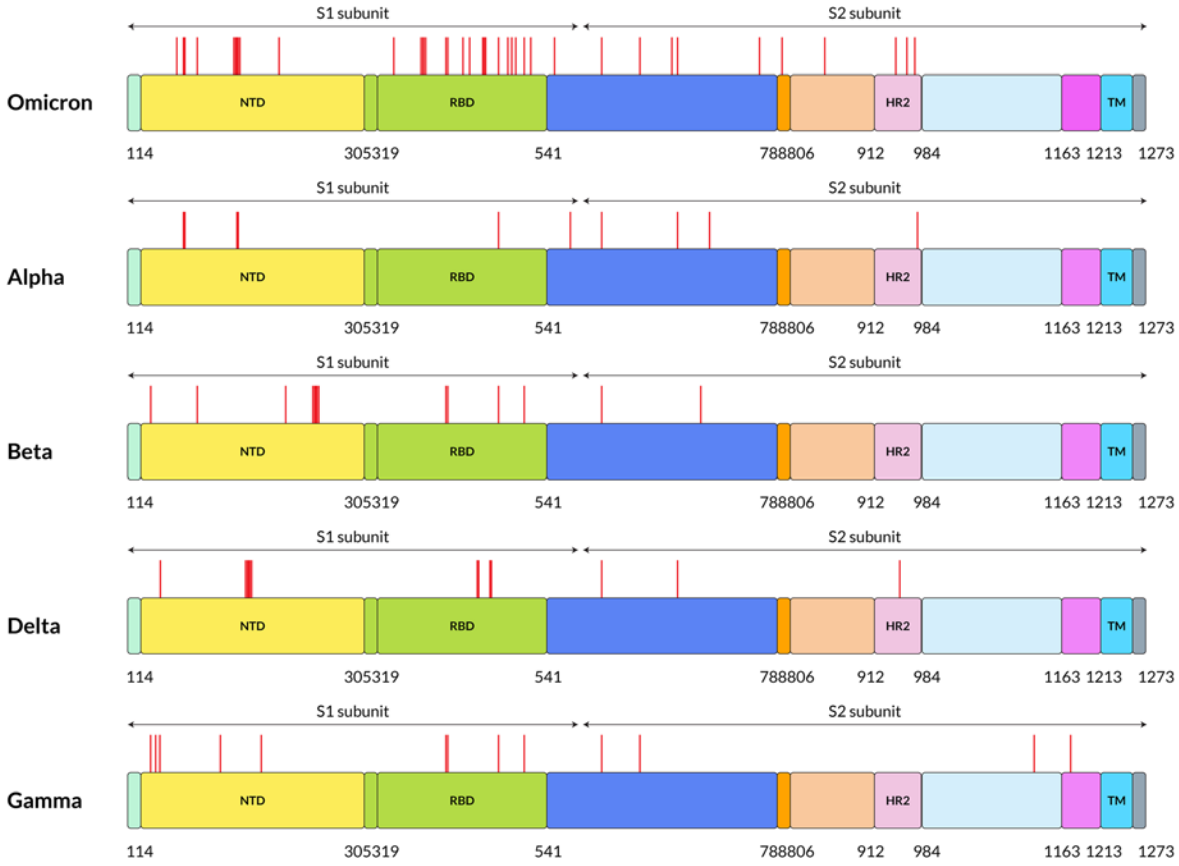

FIGURE 1 Five SARS-CoV-2 variants have different amino acid mutation locations on their S proteins. On this figure, red lines indicate the mutation locations on the S protein of SARS-CoV-2 at the specified positions. FP stands for fusion peptide, and pink color specifies HR2: heptapeptide repeat sequence 2, TM: transmembrane domain, which showed in sky shade, NTD: N-terminal domain shown in yellow and green color denotes RBD: receptor-binding domain

Jersey area, the infection rate is around 13%. On the other hand, in Britain, Omicron variant cases doubled every 2–3 days.[22] The infection rate of the Omicron variant in South Africa is increasing faster than any other country's three previous waves. On November 30, the number of cases was 10.3%, shifting to 16.5% within two days. Surprisingly, on December 2 and 3, cases were 22.4% and 24.3%, respectively.[24] When the linear regressions of each pseudovirus were compared to the wild type over the entire range, it was discovered that while the Gamma variant had similar infection rates to the wild type, the Beta variant had less infection, and Delta was nearly two-fold more efficient at infecting target cells. Infection rates were four times higher in the Omicron variant than in the wild type and twice as high in the Delta variant. These findings indicate that spike sequence influences infectivity, with the Omicron variant displaying more effective ACE2-mediated infection than the wild type or other variant strains.[13]

Numerous factors can influence the high transmissibility of the Omicron variant. Genome sequenced data of the Omicron variant demonstrated more than 30 mutations in the spike protein by which the SARS-CoV-2 protein recognizes host cells.[25] Analysis of these mutations data indicates the chance of increased transmission by evading the immune response.[26] The N501Y mutation increases the binding affinity with the ACE2 receptor, which is a major influencer of increased transmission, and in combination with Q498R, the binding affinity gets stronger, and the Omicron variant gets easy access into the host.[26] Moreover, the risk of reinfection of previously COVID-19 infected patients with the Omicron variant is very evident, indicating higher transmissibility.[15] Omicron variant mutations H655Y and N679K are present near the furin cleavage site (FCS) and can increase spike cleavage, making the virus more contagious.[27,28] On the other hand, P681H can multiply transmissibility by increasing the spike protein cleavage.[29]

Furthermore, the new variant Omicron gives a false negative result in polymerase chain reaction tests because of the "S gene target failure," which paves the way of spreading the infection at a higher speed worldwide.[4] A previous study suggested a likely relationship between the positive electrostatic potential and affinity in the Delta VOC.[30] The increased electrostatic potential is revealed in the case of Delta and Delta-plus variants of SARS-COV-2, including the Omicron variant at the RBD interface with ACE2.[31] The titer of several pseudotyped SARS-CoV-2 S/HIV-1 viruses was determined using HEK293T cells stably expressing the ACE2 receptor. Without ACE2, Omicron variant S/HIV-1 pseudotyped viruses cannot enter the HEK293T. The RBD and

ACE2 maintain a nanomolar level of binding affinity, which is similar in Beta, Delta, and Omicron. Because ACE2 is required for RBD, it appears that all variants have already reached the nanomolar scale, making it difficult for the virus to progress further.[7] Another computational study predicted that the Omicron variant had increased affinity to the ACE2 compared to the other SARS-CoV-2 variant such as Delta. Many mutations in the receptor-binding domain of spike protein of Omicron variants, such as Q493R, N501Y, S371L, S373P, S375F, Q498R, and T478K are responsible for this higher affinity to the ACE2.[21,32] Therefore, it suggests that omicron VOC is highly transmissible than other variants.[31]

Moreover, once within the cells, the Omicron variant was less effective than Delta at causing cell fusion, linked to the poor cell-to-cell transmission. Fused cells are frequently found in respiratory tissues collected after a serious illness. Indeed, in a spreading infection experiment utilizing lung cells, a live Omicron variant virus was compared to Delta variant and found that the Omicron variant was considerably worse at replication, corroborating the findings of the decreased entrance.[33]

4 | OMICRON VARIANT AND CURRENT COVID-19 VACCINES

The Omicron variant of SARS-CoV-2 was identified from the COVID-19 vaccinated patients, suggesting the new variant's immune invasion and demanded updated vaccines.[34] Saxena et al. analyzed the mutations reported in the RBD of the spike of Omicron variant of SARS-CoV-2 and hypothesized that currently, available entry inhibitors might not be effective for emerging variants.[35] The heavy mutation in the spike protein of the Omicron variant is related to increased infectivity and antibody evasion.[36] In SARS-CoV-2 convalescent or vaccinated people, the amount of neutralizing epitopes targeted by polyclonal antibodies is a significant predictor of the genetic barrier to viral escape. Single monoclonal antibodies are susceptible to escape mutations, but combinations targeting non-overlapping epitopes are more resistant.[37] Surprisingly, Omicron variant neutralization was undetectable in the majority of vaccines.[14] The computational approach also demonstrated that antigenic properties of the Omicron variant are ominous and correlated with its mutations.[38] Although various investigations have been performed to create effective vaccines, the emergence of new VOCs has raised concern over the efficacy of neutralizing antibodies induced by COVID-19 vaccines as the Omicron variant has already infected vaccinated individuals in South Africa, Hong Kong, and many other countries.[36,39,40] The potential impact of the COVID-19 vaccine is still being analyzed against this new variant. Two BNT vaccinations, which can provide more than 90% protection against serious disease when infected with the Delta variant, maybe significantly less effective against the Omicron type of SARS-CoV-2.[14] However, the effect of COVID-19 vaccines against the previous VOC, such as Delta, manifested the vaccine's potential in reducing severe disease and death.[41] Moreover, multiple Delta transmissions from and between completely vaccinated persons were confirmed using genomic and epidemiological data.[42] As vaccine-induced immunity is targeted through the spike proteins of the virus, heavily mutated Omicron variant spike protein is capable of reducing the neutralization activity of sera of vaccinated individuals that indicated less protection from Omicron variant.[26] Only 20% and 24% of BNT162b2 recipients had detectable neutralizing antibodies against the Omicron variants HKU691 and HKU344-R346K, respectively, but none of the Coronavac recipients did. The geometric mean neutralization antibody titers (GMT) of the Omicron variant isolates were 35.7–39.9-fold lower than the ancestral virus for BNT162b2 recipients, and the GMT of both Omicron isolates were significantly lower than the Beta and Delta variants. Between HKU691 and HKU344-R346K, there was no discernible difference in GMT.[43] Pfizer/BioNTech and Moderna's mRNA vaccines have been essential in launching mass vaccination campaigns in the United States and worldwide. Both vaccines produce high-titer anti-SARS-CoV-2 Spike (S) protein-specific antibodies that can neutralize the original circulating SARS-CoV-2 strains and subsequent variations developed after the vaccine design phase. In animal models and humans, neutralizing antibodies generated by mRNA vaccinations appear to be the primary correlate of COVID-19 protection.[44] Laboratory investigations on Pfizer-BioNTech vaccines show a high level of protection from the Omicron variant with three doses.[45] Only the booster dose can increase the neutralizing antibody titers by 25-fold compared with the other two doses. Anti-spike antibody levels can predict the neutralization of SARS-CoV-2 variants. CD4 + T cell responses are strong in SARS-CoV-2 mRNA vaccines. TFH cell responses are critical in the formation of long-term immunity by this successful human vaccination, according to recent findings.[44] Individuals given mRNA vaccinations had robust neutralization of the Omicron variant that was only 4–6 times lower than the wild type, implying increased cross-reactivity of neutralizing antibody responses.[14] Therefore, it is hypothesized that current COVID-19 vaccines will protect in reducing disease severity to the vaccinated individuals as a majority of the epitopes targeted by vaccine-induced T cells are not mutated in the Omicron variant. However, the various institutions have already started the development of Omicron variant-specific COVID-19 vaccines and are confident enough to supply the vaccine within March 2022 in the market.[45] Because of worries about diminishing immunity and the likelihood of a new wave of illnesses throughout the winter, booster doses of the COVID-19 vaccine have been rolled out in many nations since summer.[46] On the other hand, 75% of Omicron variant-positive patients in a South African hospital (NetCare's Hospital) are unvaccinated and have critical outcomes compared to the vaccinated individuals, which indicates the possible protection of the existing vaccines from the variant Omicron.[47] Omicron variant, a novel and potentially more transmissible strain of the SARS-CoV-2, is suspected of having emerged in a location where vaccination rates are low, with only 7.5% of people in South Africa vaccinated. Scientists have discovered that the virus is more likely to mutate in low vaccination rates and high transmission rates.[48]

5 | CURRENT SITUATIONS AND REACT ON TO OMICRON VARIANT WORLDWIDE

The Omicron variant of SARS-CoV-2 did not stop after being detected in South Africa and Botswana and now has been detected in more than 80 different regions of the world till December 15, 2021. Along with South Africa, Botswana spreads rapidly in Britain, Denmark, and Norway. Thirty-six (36) states of the United States have already been affected by the Omicron variant, and cases are increasing at a higher rate.[8] Among all the countries, the Omicron variant has been locally transmitted in Canada, USA, Britain, France, Spain, Zambia, Botswana, Namibia, South Africa, Iceland, Norway, Ireland, India, South Korea, Singapore, Hong Kong, Australia, and Mozambique till December 15, 2021. Though the other countries such as Brazil, Argentina, Thailand, Russia, China, Mexico, and many more countries have Omicron variant patients, it was detected in visitors who had traveled from the infected countries (Figure 2). It is hypothesized that the new heavily mutated variant will not be transmitted locally.[8] The patients infected with the Omicron variant are still not showing any severe disease outcome. Thus, it is considered that the variant is a mild one compared with the other VOCs. However, more data are needed to conclude the disease severity due to the Omicron variant of SARS-CoV-2.[49] Due to the scarcity of data, the infectivity and pathogenicity of the Omicron variant cannot be determined. Reports of a newly identified coronavirus variety in South Africa sent many of those doors crashing shut again, just as several countries around the world were beginning to relax their border restrictions.

On November 26, the World Health Organization (WHO) identified the novel B.1.1.529 variant of SARS-CoV-2 named Omicron. Therefore, various tactics have been taken throughout the world to restrict the spread of this new variant.[50] WHO has taken several approaches in South Africa to help with monitoring, contact tracing, infection prevention, and treatment. Oxygen production and delivery have increased in Botswana, vital for treating critically ill patients.[51] To protect the United States from Omicron, the American government announced multiple plans on December 2, 2021. It includes reaching individuals eligible for booster dose, making at home COVID-19 tests free, travel restrictions, paid time off for getting booster dose, and to help other countries beat Omicron variant, USA is planning to send 200 million more doses of vaccine.[52] Exemptions apply to all sorts of hospitality establishments. They also take the initiative to keep places adequately ventilated and emphasize wearing masks. The vaccine program and the test, as well as tracing and isolating the system remain the most effective ways of reducing transmission.[53] All private-sector workers in New York City will be required to be vaccinated.[54] Similarly, the UK government has announced different measures, such as mandatory masking in all public places, isolation for ten days if contact with an Omicron variant infected individual, and compulsory self-isolation for travelers.[4]

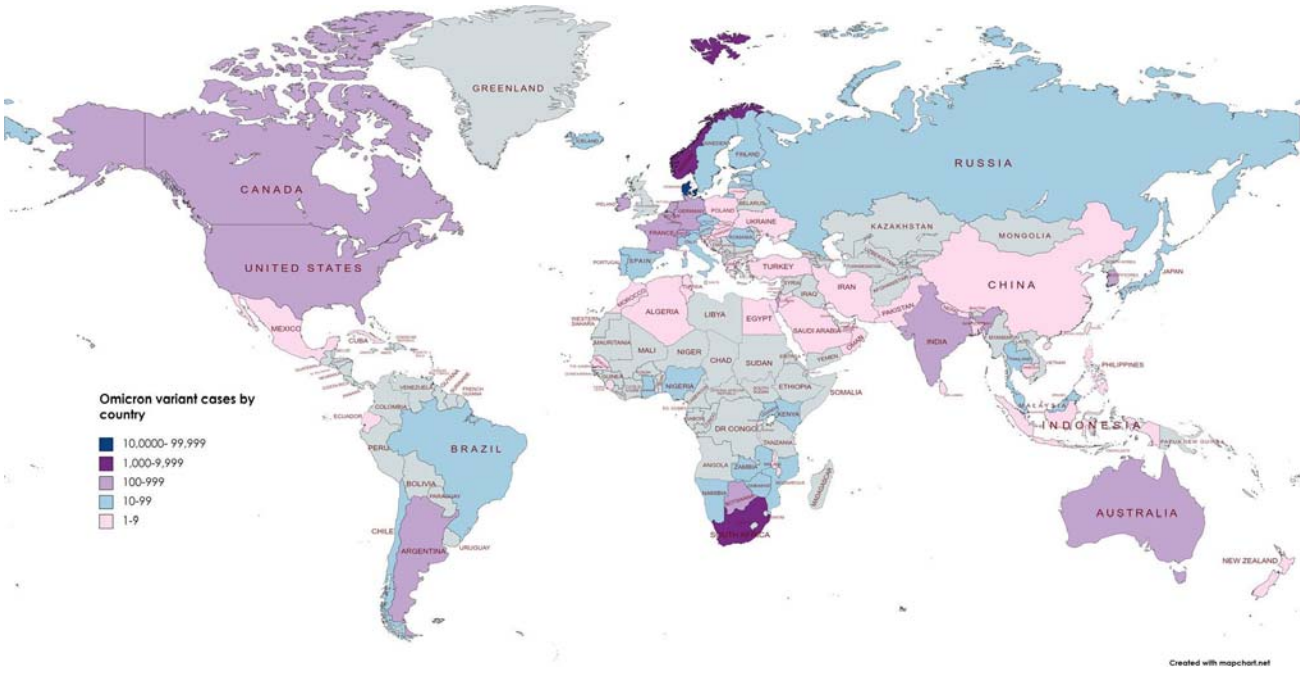

FIGURE 2 The total number of confirmed Omicron variant cases per country and the probability of identifying a case. The figure shows that South Africa sequences many more samples than any other African country, but slower than most Western countries. Additionally, returning a viral sequence might take up to 2 weeks in countries with technical competence. Thus reliable statistics on verified instances lag behind the actual situation. Cases detected using their variant qPCR test, which is rather fast and tests numerous genes, are considered sufficient for counting as an Omicron variant by Norway and Denmark, even before full sequencing. So, it can be said that the sequencing rate influences the probability of discovering a case

One of the most densely populated countries, India, has taken five steps to combat the new COVID-19 spread. The mandatory risk profile of each individual, institution-wide quarantine, genome sequencing of samples, intensive contact tracing of suspects, and strict adherence to COVID-19 appropriate behavior are among them.[55] Bangladesh, a low-income country, has announced a plan to tackle the Omicron strain, though it is yet to be discovered in Bangladesh. The plan includes travelers from South Africa, Namibia, Zimbabwe, Botswana, Eswatini, Lesotho, and other new variant-infected countries listed by the WHO that should be exposed to increased medical testing and screening. Whether social, political, religious, or otherwise, any type of public gathering must be avoided. Facemasks must be worn when leaving the house, and all other basic health needs.[56] The introduction of the Omicron variant is causing concern in countries worldwide, emphasizing the significance of pandemic preparedness.[51] However, there is growing hope that the Omicron variety of SARS-CoV-2, becoming more prevalent, will cause less severe disease than prior strains. Researchers in England, Scotland, and South Africa discovered that the Omicron variation has a 15%–80% reduced risk of hospitalization than the delta variant. Despite far greater case counts, surveillance data shows that the latest omicron-driven wave of illnesses has significantly fewer hospital admissions and deaths than past waves.[57]

6 | TREATMENT AND MANAGEMENT STRATEGIES

Omicron variant-positive patients in South Africa showed very mild symptoms, and no oxygen support was required until now.[58] However, the UK is facing a different scenario in the case of Omicron variant-positive patients. In an interview with Global Health Crisis Coordination Center, vaccine expert Shabir Madhi said that "In the South African much of the immunity that currently exists is large because of the prior infection that has taken place during the first three waves." Thus, being ready with all the existing treatment and management procedures for any unfortunate situation is a must.[59] A recovered Omicron variant positive patient from India shared his recovery journey and informed that he did not experience any concerning symptoms and tiredness while in hospital in contrast to the period he had been in hospital with Delta. Based on the severity of the infection, he had been given vitamin C and antibiotics.[60] Dr. Angelique Coetzee, one of the first doctors in South Africa treating Omicron variant positive patients, informed that the symptoms of the disease are just a sore throat, fatigue that stays for a day; thus, meeting with a health professional and getting tested is compulsory to have efficient treatment as per need.[61] According to health experts Kumar and Wu, antiviral pills from Pfizer and Merck can efficiently treat mild to moderate COVID-related illnesses.[62] Different laboratory findings have manifested the usefulness of sotrovimab, a monoclonal antibody found in the blood of recovered SARS patients, as it has the potential of blocking SARS and SARS-CoV-2.[63] According to recent data, corticosteroids and IL6 receptor blockers are still effective in treating people with severe COVID-19 cases.[41]

To manage the upcoming surge, WHO recommends that countries improve surveillance and sequencing of cases, share genome sequences on publicly available databases like GISAID, report initial cases or clusters to WHO, and conduct field investigations and laboratory assessments to understand better if Omicron variant has different transmission or disease characteristics, or has an impact on vaccine effectiveness.[41] WHO issues travel advisory due to the Omicron variant. People aged 60 and above and those with particular health concerns are advised to limit the trip plans for the time being. Experts recommended vaccines and maintained up to date on all injections until further information is available since they may still protect people from all variants of the SARS-CoV-2.[64] Individuals infected with the new variant must be isolated.[65]

7 | CONCLUSIONS AND RECOMMENDATIONS

Mutation in the SARS-CoV-2 is a continuous process leading to multiple variant introductions. The VOC is the reason behind the waves of heavy infection, which might continue with the new variant Omicron. Though the latest variant's infectivity, prevalence, and severity are still unknown, investigations are ongoing to get every detail about the SARS-CoV-2 Omicron variant to recommend efficient ways to prevent the upcoming surge. Meanwhile, the previous recommendations to tackle the COVID-19 pandemic need to be maintained worldwide along with the newly improvised directions, such as genome sequencing of all the samples, maintaining social distance, continuing vaccination for everyone, and isolating the Omicron variant positive patients in a different place. WHO recommended countries strengthen surveillance and adopt necessary actions since the Omicron variant has been classified as a VOC.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Yusha Araf and Md. Golzar Hossain designed the manuscript. Md. Golzar Hossain and Chenfu Zheng supervised the study. Yan-dong Tang, Fariya Akter, Yusha Araf, and Rabeya Fatemi wrote the preliminary draft manuscript. Yusha Araf illustrated the figures. Md. Golzar Hossain and Chenfu Zheng reviewed the preliminary draft manuscript. Yusha Araf, Md. Sorwer Alam Parvez, Md. Golzar Hossain, and Chenfu Zheng edited, revised, and finalized the manuscript. All the authors read and approved the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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JHS Omicron BA2 Variant and Testing updates

Colleagues and residents in training,

As we adapt to new information arising from the spread of the BA2 Omicron variant it seems possible that people infected with the BA1 strain might be reinfected with BA2.

So far, what we know:
The BA2 variant spreads rapidly and is more contagious
In South Africa it has taken over the BA1 variant in a period of 4 weeks.
Some of the monoclonal therapies could be ineffective. We are monitoring this closely to adapt our protocols as needed
As of now, about 2% of our genome sequencing has shown BA2 variants and the majority remain BA1 (Omicron)
Well fitted masks continue to work (especially N95)

In an abundance of caution, we will modify the JHS protocols to allow retesting at 60 days from a previous infection as opposed to our current process of 90 days.

As of this week, Ct values are being reported for most of our JHS SARS-COv2 PCR platforms.

We urge clinicians to contact infection prevention prior to making any isolation or de-isolation decisions based on Ct values. We are cautious in the interpretation of these values in the context of history, symptoms, contact tracing and lab results.

We urge you to remain cautious and in compliance with PPE protocols. This is not over, yet we are optimistic about the future and we will continue to adapt.

Thank you and please reach out if you have any questions,

Regards,

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Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

COVID-19 vaccine products currently approved or authorized in the United States

Pfizer-BioNTech

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
					Dose	Injection volume	Dose	Injection volume
6 months–4 years	Monovalent (Use for 1st and 2nd Dose)*	Maroon	Maroon	Yes	Doses 1 and 2: 3 μg/0.2 m		A booster dose is not authorized for children who received a 3-dose primary series regardless which vaccine (monovalent or bivalent) was administered for Dose 3.	
6 months–4 years	Bivalent (Use for 3rd Dose)	Maroon	Maroon	Yes	Dose 3: 3 μg/0.2 mL			
5–11 years	Monovalent	Orange	Orange	Yes	10 μg	0.2 mL	NA	NA
5–11 years	Bivalent	Orange	Orange	Yes	NA	NA	10 μg	0.2 mL
12 years and older	Monovalent	Gray	Gray	No	30 μg	0.3 mL	NA	NA
12 years and older	Bivalent	Gray	Gray	No	NA	NA	30 μg	0.3 mL

Moderna

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
					Dose	Injection volume	Dose	Injection volume
6 months–5 years	Monovalent	Dark blue	Magenta	No	25 μg	0.25 mL	NA	NA
6 months–5 years	Bivalent*	Dark pink	Yellow	No	NA	NA	10 μg	0.2 mL
6-11 years	Monovalent	Dark blue	Purple	No	50 μg	0.5 mL	NA	NA
6-11 years	Bivalent	Dark blue	Gray	No	NA	NA	25 μg	0.25 mL
12 years and older	Monovalent	Red	Light blue	No	100 μg	0.5 mL	NA	NA
12 years and older	Bivalent	Dark blue	Gray	No	NA	NA	50 μg	0.5 mL

* A monovalent Pfizer-BioNTech vaccine is used for the first and second primary doses; a bivalent Pfizer-BioNTech vaccine is used for the third primary dose.

Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

COVID-19 vaccine products currently approved or authorized in the United States Continued

Janssen

Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older in certain limited situations due to safety considerations. For guidance on retrospective record review, scheduling and administration of Janssen vaccine see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
					Dose	Injection volume	Dose	Injection volume
18 years and older	Monovalent	Blue	No Color	No	5×10^{10} viral particles	0.5 mL	5×10^{10} viral particles	0.5 mL

Novavax

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses†	
					Dose	Injection volume	Dose	Injection volume
12 years and older	Monovalent	Royal blue	No Color	No	5 *µg* rS and 50 *µg* of Matrix-M™ adjuvant	0.5 mL	5 *µg* rS and 50 *µg* of Matrix-M™ adjuvant	0.5 mL

† Booster doses are only indicated for recipients 18 years and age and older in limited situations, see: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

All currently authorized or approved COVID-19 vaccines

COVID-19 vaccination schedule	■ See the Interim COVID-19 Immunization Schedule for Ages 6 Months or Older
Pre-vaccination counseling	Prior to vaccination: ■ Provide the vaccine-specific Fact Sheet for Recipients and Caregivers ■ Screen for contraindications and precautions. CDC's Prevaccination Screening Form and Guidance document can be found at, U.S. COVID-19 Vaccine Product Information | CDC. ■ Inform vaccine recipients mRNA or Novavax COVID-19 vaccines are recommended over Janssen COVID-19 Vaccine. ■ Counsel vaccine recipients, parents, or guardians about expected reactions post-vaccination (e.g., pain and swelling at the injection site, fever, fatigue, headache). ■ Inform mRNA and Novavax vaccine recipients, especially males ages 12-39 years, of the rare risk of myocarditis and pericarditis following receipt of these COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19.‡ Counseling should also include the need to seek care if symptoms of myocarditis or pericarditis occur after vaccination, particularly in the week following vaccination. For more information see: COVID-19 vaccination and myocarditis and pericarditis. ■ Inform vaccine recipients interested in or receiving Janssen COVID-19 Vaccine of the risk and symptoms of thrombosis with thrombocytopenia syndrome (TTS), as well as the need to seek immediate medical care should symptoms develop after receiving Janssen vaccine. For more information see: Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A. Guidance for use of Janssen COVID-19 Vaccine.

‡ See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States for detailed guidance.

Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

All currently authorized or approved COVID-19 vaccines	
Interchangeability of vaccines	■ In general, the same COVID-19 monovalent vaccine product (Pfizer-BioNTech, Moderna, Novavax) should be used for all doses in the primary series. In exceptional situations when the previous product cannot be determined/not available or if a person is unable to complete a series with the same COVID-19 vaccine due to a contraindication any age-appropriate mRNA COVID-19 vaccine may be used (administer at a minimum interval of 28 days). ■ For booster vaccination, any homologous or heterologous age-appropriate mRNA vaccine can be used. Recommendations vary based on age and primary series product. See, Timing, spacing, age transitions, and coadministration of COVID-19 vaccines | CDC.§
Coadministration with other vaccines	■ COVID-19 vaccines may be administered on the same day as other vaccines. ■ Persons, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus (monkeypox) vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNtech COVID-19 vaccine. ■ Administer each injection in a different injection site.
Contraindications	History of: ■ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine ■ A known diagnosed allergy to a component of the COVID-19 vaccine ■ For the Janssen COVID-19 Vaccine, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized or approved in the United States that are based on adenovirus vectors, e.g., AstraZeneca)¶
Precautions	■ History of anaphylaxis after any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) ■ History of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) ■ History of an immediate (within 4 hours of exposure) non-severe allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine ■ Allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the other types of COVID-19 vaccines.** ■ Moderate or severe acute illness, with or without fever ■ History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine ■ For Janssen COVID-19 Vaccine, a history of Guillain-Barré syndrome††

§ For booster vaccination, homologous or heterologous mRNA booster is recommended.

¶ Additionally, people with a history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. These people should receive an mRNA or Novavax COVID-19 vaccine booster dose.

** People with a known allergy to polysorbate have a contraindication to both Novavax ad Janssen COVID-19 vaccines.

†† People who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen COVID-19 Vaccine. These people should receive a booster dose of an mRNA COVID-19 vaccine for subsequent doses.

Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

Considerations for all FDA-authorized or -approved COVID-19 vaccines	
Persons receiving HCT and CAR-T-cell therapy	■ If received doses of COVID-19 vaccine prior to or during HCT or CAR-T cell therapy, should be revaccinated for any monovalent primary series and bivalent booster doses received before or during treatment at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. There is no revaccination for monovalent booster doses.
Persons who are moderately or severely immunocompromised	■ See the Interim COVID-19 Immunization Schedule for Ages 6 Months or Older
Persons receiving immunosuppressive therapies	■ Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies.
SARS-CoV-2 infection ■ Current infection ■ History of previous infection ■ Exposed to an infected person	COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. ■ Defer vaccination until person has recovered from acute illness and criteria have been met for them to discontinue isolation. ■ People who recently had SARS-CoV-2 infection may consider delaying their next COVID-19 dose by 3 months from symptom onset or positive test (if infection was asymptomatic). ■ Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making. ■ Additional information at: Interim Clinical Considerations for Use of COVID-19 Vaccines: COVID-19 vaccination and SARS-CoV-2 infection | CDC ■ COVID-19 vaccination is not recommended for post-exposure prophylaxis.
Persons with history of multisystem inflammatory syndrome (MIS-C and MIS-A) from SARS-CoV-2 infection	■ Wait until clinical recovery and at least 90 days after an MIS-C or MIS-A diagnosis to administer COVID-19 vaccine. ■ For persons who developed MIS-C or MIS-A after COVID-19 vaccination, a conversation between the vaccine recipient, guardian, and clinical team or specialist to discuss benefits and risks of receiving a COVID-19 vaccine is encouraged. ■ Additional information at: Interim Clinical Considerations for Use of COVID-19 Vaccines COVID-19 vaccination and MIS-C and MIS-A | CDC
Persons who received passive antibody therapy (convalescent plasma/ monoclonal antibodies)	■ COVID-19 vaccination can be given at any interval following receipt of passive antibody therapy. ■ Persons should wait 2 weeks after COVID-19 vaccination before receiving tixagevimab/cilgavimab (EVUSHELD) for pre-exposure prophylaxis.
Persons who are pregnant, breastfeeding, trying to get pregnant, or might become pregnant in the future	■ Are recommended to be vaccinated according to the recommended schedule.

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for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

Considerations for mRNA vaccines and Novavax	
Persons with a history of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine. ■ If after a risk assessment the decision is made to administer a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. ■ For information on potential use of Janssen COVID-19 Vaccine in this situation, see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A | CDC ■ Persons who have a history of myocarditis or pericarditis unrelated to mRNA or Novavax COVID-19 vaccination may receive any age-appropriate COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved. ■ For more information, see Interim Clinical Considerations for Use of COVID-19 Vaccines: COVID-19 vaccination and myocarditis and pericarditis | CDC

Considerations for Janssen COVID-19 Vaccine	
Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older in certain limited situations due to safety considerations. For more information, see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A | CDC	
Persons with a history of Guillain-Barré syndrome (GBS)	■ A history of GBS is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA or Novavax vaccine is recommended.. ■ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine (monovalent or bilvalent vaccine as indicated) for subsequent doses.
Persons with a history of thrombosis with thrombocytopenia syndrome (TTS)	■ It is contraindicated to administer Janssen COVID-19 Vaccine to persons with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca's COVID-19 Vaccine). ■ These persons should receive a dose of an mRNA COVID-19 vaccine as a booster dose at least 2 months (8 weeks) following their dose of the Janssen COVID-19 Vaccine and after their clinical condition has stabilized.
Persons with a history of heparin-induced thrombocytopenia (HIT)	■ Persons with a history of an episode of an immune-mediated syndrome characterized by TTS, such as a spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. ■ These persons should receive an mRNA or Novavax COVID-19 vaccine.

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General COVID-19 Vaccination Information	
Persons vaccinated outside the United States	■ The recommendations for people vaccinated outside the United States depend on the number and type of vaccine(s) received for the primary series and booster doses. Current guidance can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix B | CDC
Post-vaccination observation periods	**15 minutes**: Vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination because of the risk of syncope. **30 minutes**: Vaccination providers should consider observing persons with the following medical histories for 30 minutes after vaccination to monitor for allergic reactions: ■ An allergy-related contraindication to a different type of COVID-19 vaccine ■ Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine ■ Anaphylaxis after non-COVID-19 vaccines or injectable therapies
SARS-CoV-2 antibody testing	■ Antibody testing is not recommended for vaccine decision-making or to assess immunity following vaccination.
Reporting requirements	Adverse events that occur following COVID-19 vaccination should be reported to VAERS. COVID-19 providers are required to report: ■ Vaccine administration errors ■ Serious adverse events ■ Myocarditis or pericardiitis after mRNA or Novavax COVID-19 Vaccine ■ Cases of Multisystem Inflammatory Syndrome ■ Cases of COVID-19 that result in hospitalization or death

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