COVID-19 (Novel Coronavirus 2019)
Protocol
8/5/2021
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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.

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

As per WHO Situation Report of August 4th, 2021, globally there were 199,466,211 confirmed cases and 4,244,541 deaths. At least 223 countries, areas and territories in the world have COVID19 cases. August 3rd, 2021, per CDC USA had 35,286,935 cases and 612,386 deaths. As of July 30th, 2021, per FDOH Florida weekly report (July 23rd, 2021 - July 29th, 2021) had 2,590,699 cases and 39,079 deaths. In Miami Dade County as of July 29th, 2021, there were 542,481 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


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
Clinicians with help of local health department if needed, should determine whether a patient is a PUI for COVID-19. 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
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 Screening Tool for Identifying Persons Under Investigation for Coronavirus Disease 2019 (COVID-19) per Centers for Disease Control and Prevention (CDC)

May 11, 2020

Florida HEALTH

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

Please see the CDC’s Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination
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.

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, EliTtech 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.

**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 COVID-19.

PROCEDURAL STEPS FOR OBTAINING SPECIMEN

**PERFORM HAND HYGIENE AND DON APPROPRIATE PERSONAL EQUIPMENT**

- Hand Hygiene
- Isolation Gown (optional)
- Clean Gloves
- N95 Mask (and Surgical Mask for conservation of N-95 mask)
- Eye Protection (Goggles OR Face Shield)

**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.
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.

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

**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 bedside

To be completed at the bedside

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 into the processed specimen into sample well.

**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.

<table>
<thead>
<tr>
<th>Date/Time test performed</th>
<th>POC SARS-CoV-2 Antigen</th>
</tr>
</thead>
</table>

POC SARS-CoV-2 Antigen

- Positive
- Negative

Reference Range: negative
Negative test results are presumptive until results are confirmed by COVID19 RT PCR test
Notify Provider of results.

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
### COVID-19 SCREENING*

All patients entering a JHS facility should undergo triage by using the following questionnaire:

<table>
<thead>
<tr>
<th>Question</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you returned from International Travel (air or cruise or land) or USA areas of Defined or Widespread Community Transmission</td>
<td><a href="https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html">https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html</a></td>
</tr>
<tr>
<td>Or come in contact with suspected or confirmed COVID-19 case</td>
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</tr>
<tr>
<td>Do you have fever (temperature ≥ 100 or &gt; 37.8°C? (In Pediatric Patients &lt;22 year old fever is considered ≥ 38.3°C (100.9°F))</td>
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</tr>
<tr>
<td>Do you have any respiratory symptoms (shortness of breath or cough) within 14 days of possible exposure?</td>
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</table>

**If the answer to travel and fever OR travel and respiratory symptoms is yes:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>Place a surgical mask on the patient</td>
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</tr>
<tr>
<td>Use guidance on pages 12-21 for patient placement and PPE</td>
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</tr>
<tr>
<td>If an aerosol generating procedure is anticipated then use the guidance on pages 12-21 and 27-33 for patient placement and PPE.</td>
<td></td>
</tr>
<tr>
<td>Alert the clinician responsible for the patient and expedite the medical evaluation of the patient</td>
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</tr>
<tr>
<td>Contact the on-call Infection Preventionist at 786-266-0624</td>
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</tr>
</tbody>
</table>

*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


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  

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](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

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 one year 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
## COVID-19: Personal Protective Equipment Guidelines

<table>
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<tr>
<th>ANTICIPATED ACTIVITY</th>
<th>PPE REQUIRED</th>
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<tr>
<td>Required PPE for ALL JHS Employees</td>
<td>• Procedure Mask (N-95 respirator should be reserved for direct patient care providers)</td>
</tr>
</tbody>
</table>
| Standard PPE for Direct Contact with Patient Care (Hospital/Clinic Areas) | 1. Don the following:  
   • Procedure Mask  
   • 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  
   • N95 preferred, but face masks are an acceptable alternative**  
   • Procedure mask to be worn over the N95 respirator as an N95 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  
   • N95 Respirator  
   • Procedure Mask  
   **OR**  
   • Full Face Shield*** over N95 Respirator  
   • Shoe Covers (recommended)  
   **NOTE:**  
   - N95 must be covered.  
   - If not using face shield, must don eye protection.  
   - Place procedure mask over N95, if applicable. |

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*Base layer refers to clothing that will not have direct contact with the patient or their immediate environment.  
**According to the US CDC, May 2020.  
***N-95 Respirator required for aerosolizing procedures.  
****Eye Protection, Face Shield, Goggles, or hooded bunny suits are generally not required in Non-COVID-19 Locations.
# 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

<table>
<thead>
<tr>
<th>Required PPE for All JHS Employees</th>
<th>PPE Required</th>
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<tbody>
<tr>
<td>1. Procedure Mask (N-95 respirator should be reserved for Direct Patient Care Providers)</td>
<td></td>
</tr>
</tbody>
</table>

## Standard PPE for Direct Contact with Patient Care (Hospital/Clinic Areas)

<table>
<thead>
<tr>
<th>1. Procedure mask</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. *Eye protection</td>
</tr>
<tr>
<td>(Key: Observe Hand-Hygiene Protocol)</td>
</tr>
</tbody>
</table>

## Direct Patient Or Environmental Contact Within COVID 19 Patient Room Or Care Space

<table>
<thead>
<tr>
<th>1. Base layer (personal scrubs, hospital- laundered scrubs, disposable scrubs, or machine washable clothes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Isolation Gown</td>
</tr>
<tr>
<td>3. Gloves</td>
</tr>
<tr>
<td>4. N95 preferred but facemasks are an acceptable alternative (according to the US CDC May 2020)</td>
</tr>
<tr>
<td>5. Procedure mask to be worn over the N95 respirator as an N95 conservation strategy</td>
</tr>
<tr>
<td>6. *Eye protection</td>
</tr>
</tbody>
</table>

## Aerosolization

<table>
<thead>
<tr>
<th>Anticipated Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-risk Aerosolization:</td>
</tr>
<tr>
<td>• Airway suctioning</td>
</tr>
<tr>
<td>• Sputum induction</td>
</tr>
<tr>
<td>• Swallow studies</td>
</tr>
<tr>
<td>• Venti mask use</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PPE Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Isolation Gown</td>
</tr>
<tr>
<td>2. *Eye protection (Goggles and Face Shield)</td>
</tr>
<tr>
<td>3. N95 Respirator</td>
</tr>
<tr>
<td>4. Procedure mask (to be discarded after procedure)</td>
</tr>
<tr>
<td>5. Gloves</td>
</tr>
<tr>
<td>6. Hair cover (recommended)</td>
</tr>
<tr>
<td>7. Shoe covers (recommended)</td>
</tr>
</tbody>
</table>

*Eye Protection, Face Shield, Goggles, are generally not required in Non COVID-19 Locations.

JHS Clinical Learning & Development 3-25-2021 v4
# JHS PPE Guidelines

<table>
<thead>
<tr>
<th>Anticipated Activity</th>
<th>PPE Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Risk Aerosolization:</strong></td>
<td>1. Isolation Gown</td>
</tr>
<tr>
<td>• High-Flow Nasal Cannula</td>
<td>2. <em>Eye protection (Goggles and Face Shield)</em></td>
</tr>
<tr>
<td>• Nebulizer treatment</td>
<td>3. N95 Respirator</td>
</tr>
<tr>
<td>• Chest Physiotherapy</td>
<td>4. Procedure mask (to be discarded after procedure)</td>
</tr>
<tr>
<td>• Chest tube &amp; Thoracentesis</td>
<td>5. Two pairs of gloves</td>
</tr>
<tr>
<td>• Breaking the ventilator circuit:</td>
<td>6. Hair cover (recommended)</td>
</tr>
<tr>
<td>▪ Intentional: filter/equipment change</td>
<td>7. Shoe cover (recommended)</td>
</tr>
<tr>
<td>▪ Unintentional: unplanned disconnection/patient movement</td>
<td></td>
</tr>
<tr>
<td>• BIPAP/CPAP</td>
<td></td>
</tr>
<tr>
<td>• High Frequency Oscillatory Ventilation</td>
<td></td>
</tr>
<tr>
<td><em>Isolation Gown REQUIRED</em></td>
<td></td>
</tr>
<tr>
<td>• Endotracheal tube intubation</td>
<td></td>
</tr>
<tr>
<td>• Endotracheal tube extubation</td>
<td></td>
</tr>
<tr>
<td>• Bronchoscopy</td>
<td></td>
</tr>
<tr>
<td>• Laryngoscopy</td>
<td></td>
</tr>
<tr>
<td>• Endoscopy (upper and lower GI)</td>
<td></td>
</tr>
<tr>
<td>• Prone</td>
<td></td>
</tr>
<tr>
<td>• CPR</td>
<td></td>
</tr>
<tr>
<td>• Bag mask ventilation</td>
<td></td>
</tr>
<tr>
<td>• Mask ventilation in Operating Room</td>
<td></td>
</tr>
</tbody>
</table>

*Eye Protection, Face Shield, Goggles, are generally not required in Non COVID-19 Locations.*

JHS Clinical Learning & Development 3-25-2021 v4
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:**


*Eye Protection, Face Shield, Goggles, are generally not required in Non COVID-19 Locations.*

JHS Clinical Learning & Development 3-25-2021 v4
JHS PPE Guidelines

**Standard PPE for Direct Contact with Patient Care**
- Procedure Mask
- Eye Protection

**DIRECT PATIENT OR ENVIRONMENTAL CONTACT**
- Hand Hygiene
- Isolation Gown
- Gloves
- N95 Surgical Mask and Goggles
  - OR
- N95 and Face Shield

*Eye Protection, Face Shield, Goggles, are generally not required in Non COVID-19 Locations.*

JHS Clinical Learning & Development 3-25-2021 v4
COVID-19 PPE: DONNING AND DOFFING

**Donning Order**

- Hand Hygiene
- Gown
- Respirator
- Eye Protection
- Gloves

**Doffing Order**

- Hand Hygiene
- Gown
- Gloves
- Hand Hygiene
- Eye Protection
- Hand Hygiene
- N95
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

---

1. **Employee Completes the Voluntary Respirator Request Form and submits it to the Manager or Hospital Leader.**
   - **Does the employee want to pursue use of the approved respirator?**
     - **Yes:**
       - **Manager or Hospital Leader Reviews the Employee's Request and Approves it.**
     - **No:**
       - **Employee Continues to Use JHS Provided N95.**

---

2. **Manager or Hospital Leader Scans & Emails the Voluntary Reusable Respirator Request Form & Employee ID to EHS.**
   - EHS schedules an appointment for the 3M 6000 Series Respirator.
   - Employee contacts EHS to schedule an appointment to be fitted for the 3M 6000 Series Respirator.

---

3. **EHS Completes the fit test and authorizes the specific size for approved 3M 6000 Respirator.**
   - **Employee Purchases the 3M 6000 Reusable Elastomeric Half-Face Respirator at their own expense.**
   - **Employee Brings Copy of Final Approval Form and Purchased 3M 6000 Mask to EHS (Jackson Memorial Staff) or Hospital Leader (All Other Hospital Locations) for verification.**

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**Note:**
Employees who already have a 3M 6000 series respirator mask do not 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 mask 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

---

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


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

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 11-20.

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

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:
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

- 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
<table>
<thead>
<tr>
<th>Organism</th>
<th>Susceptibilities</th>
<th>Isolation Type</th>
<th>Isolation Duration</th>
<th>Patient Cohorting</th>
<th>Nursing Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterobacteriaceae family</td>
<td>CRE = intermediate or resistant to at least one carbapenem class drug</td>
<td>Standard Precautions</td>
<td>NA</td>
<td>Private room Cohort: matching organisms (genus and species, resistance pattern)</td>
<td>Routine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative</td>
<td></td>
</tr>
<tr>
<td>Pan resistant</td>
<td></td>
<td>Contact Precautions</td>
<td>1 year from last positive culture</td>
<td>Private room Cohort patients with matching organisms (genus and species, resistance pattern)</td>
<td>1:1 ICU Lowest ratio in acute care unit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbapenemase producer (CPE), incl NDM, IMP, OXA, VIM, KPC</td>
<td></td>
<td>Enhanced Contact Precautions</td>
<td>Indefinite until 2 consecutive cultures are neg beginning 90 days from last positive clin cx</td>
<td>Private room Cohort patients with matching organisms (genus and species, resistance pattern)</td>
<td></td>
</tr>
<tr>
<td>Extended spectrum beta lactamase producer (ESBL)</td>
<td></td>
<td>Standard Precautions</td>
<td>NA</td>
<td>Routine</td>
<td>Routine</td>
</tr>
<tr>
<td>Acinetobacter spp.</td>
<td>Pan resistant</td>
<td>Contact Precautions</td>
<td>1 year from last positive culture</td>
<td>Private room Cohort: matching organisms (genus and species, resistance pattern)</td>
<td>Routine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPO = carbapenemase producer, NDM, IMP, OXA, VIM</td>
<td></td>
<td>Enhanced Contact Precautions</td>
<td>Indefinite until 2 consecutive cultures are neg beginning 90 days from last positive clin cx</td>
<td>Private room Cohort patients with matching organisms (genus and species, resistance pattern)</td>
<td>1:1 ICU Lowest ratio in acute care unit</td>
</tr>
<tr>
<td>Candida auris</td>
<td>NA</td>
<td>Enhanced Contact Precautions</td>
<td>Indefinite, case by case decision</td>
<td>Private room Cohort: matching organisms (genus and species, resistance pattern)</td>
<td>1:1 or cohort staff and patients</td>
</tr>
<tr>
<td>Organism</td>
<td>Susceptibilities</td>
<td>Isolation Type</td>
<td>Isolation Duration</td>
<td>Patient Cohorting</td>
<td>Nursing Ratio</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------</td>
<td>----------------</td>
<td>--------------------</td>
<td>-------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Enterococcus spp.</td>
<td>Vancomycin resistant, surveillance or clinical cx; SICU, C7, WW14, WW15</td>
<td>Contact Precautions</td>
<td>Duration of hospitalization or unit transfer</td>
<td>Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative</td>
<td>Routine</td>
</tr>
<tr>
<td></td>
<td>Vancomycin resistant, uncontained draining wound, system-wide</td>
<td>Contact Precautions</td>
<td>Until wound is contained</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas spp.</td>
<td>Meropenem-resistant</td>
<td>Contact Precautions</td>
<td>1 year from last positive culture</td>
<td>Private room Cohort: matching organisms (genus and species, resistance pattern) Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative</td>
<td>Routine</td>
</tr>
<tr>
<td></td>
<td>Pan resistant</td>
<td>Contact Precautions</td>
<td>1 year from last positive culture</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CPO = carbapenemase producer, NDM, IMP, OXA, VIM</td>
<td>Enhanced Contact Precautions</td>
<td>Indefinite until 2 consecutive cultures are neg beginning 90 days from last positive clin cx</td>
<td>Private room Cohort patients with matching organisms (genus and species, resistance pattern)</td>
<td>1:1 ICU Lowest ratio in acute care unit</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Vancomycin intermediate or fully resistant</td>
<td>Enhanced Contact Precautions</td>
<td>Indefinite, case by case decision</td>
<td>Private room Cohort patients with matching organisms (genus and species, resistance pattern)</td>
<td>1:1 ICU Lowest ratio in acute care unit</td>
</tr>
<tr>
<td></td>
<td>Methicillin resistant, clinical cx at JMH trauma service line</td>
<td>Contact Precautions</td>
<td>1 year from last positive culture</td>
<td>Private room Cohort: matching organisms (genus and species, resistance pattern)</td>
<td>Routine</td>
</tr>
<tr>
<td></td>
<td>Methicillin resistant, surveillance cx at JMH trauma service line</td>
<td>Contact Precautions</td>
<td>1 year from last positive culture</td>
<td>Cohort with negative patients except patients are immunocompromised, burn, neutropenic, TP, or post-operative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methicillin resistant, uncontained draining wound, system-wide</td>
<td>Contact Precautions</td>
<td>Until wound is contained</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
De-escalation of COVID Isolation Precautions

In an effort to reduce the impact of COVID-positive patients on resources and throughput and to more accurately quantify our inpatient COVID burden, we will begin a formal isolation de-escalation process for patients who remain hospitalized after the period of COVID infectivity has ended.

The process is described in the table below:

<table>
<thead>
<tr>
<th>Immunocompetent, non-ICU/IMCU patient</th>
<th>Immunocompetent, ICU/IMCU patient</th>
<th>Severely immunocompromised (transplant, receiving chemotherapy for cancer diagnosis) patient*</th>
</tr>
</thead>
<tbody>
<tr>
<td>On or following <strong>day #12</strong>, patient will be evaluated for reduced symptoms, including being afebrile for 24 hours without antipyretic medication</td>
<td>On or following <strong>day #22</strong>, patient will be evaluated for reduced symptoms, including being afebrile for 24 hours without antipyretic medication</td>
<td>On or following <strong>day #28</strong>, patient will be evaluated for reduced symptoms, including being afebrile for 24 hours without antipyretic medication</td>
</tr>
<tr>
<td>If criteria above met, IP will resolve COVID problem, document rationale for resolution in the record</td>
<td>If criteria above met, IP will resolve COVID problem, document rationale for resolution in the record</td>
<td>If criteria above are met, IP will collaborate with ID team to make decision about need for isolation precautions</td>
</tr>
<tr>
<td>Once COVID problem has been resolved, the banner bar will indicate “history of COVID” and “COVID” tag will disappear</td>
<td>Once COVID problem has been resolved, the banner bar will indicate “history of COVID” and “COVID” tag will disappear</td>
<td>Additional laboratory testing or other diagnostics may be employed to inform decision-making</td>
</tr>
<tr>
<td>Patient will no longer require COVID isolation, can be moved to non-COVID (convalescent) unit; all patient contacts will require face mask and protective eyewear (as is our practice with all patients)</td>
<td>Patient will no longer require COVID isolation, can be moved to non-COVID (convalescent) unit; all patient contacts will require face mask and protective eyewear (as is our practice with all patients)</td>
<td>If the decision is to de-escalate isolation precautions, that process will mirror other patient populations with transfer to convalescent unit (decision about patient placement to be collaboratively determined)</td>
</tr>
</tbody>
</table>

*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.

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 COVID-19 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 COVID-19 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 COVID-19 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.

Ultraviolet Light Germicidal Irradiation (UVGI)

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:
  o First initial and last name
  o Department or unit location
  o 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
2. Coronavirus Disease 2019 (COVID-19) Strategies for Optimizing the Supply of Facemasks
3. Checklist for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response (46)
5. Strategies for Optimizing the Supply of Isolation Gowns
6. Strategies for Optimizing the Supply of N95 Respirators
7. Personal Protective Equipment (PPE) Burn Rate Calculator
8. Strategies to Allocate Ventilators from Stockpiles to Facilities
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 O2 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.
  o 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.
  o 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.
  o 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.
  o 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.
  o Sit down on a clean chair and use disinfectant wipes to clean all external surfaces of your shoes. Disinfect your gloves.
  o 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)
o RT o Primary nurse ☐ Outside of room (ready to come in an assist): o Intubation assistant 
(2\textsuperscript{nd} 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. 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, 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 patient has comorbid asthma or COPD. If nebulized treatment is deemed necessary for bronchospasm, the patient must be in a negative pressure room 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 single, negative pressure room with the doors closed.
  - 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 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:
  o Patient in a negative pressure room
  o Patients cannot be transported on high flow nasal cannula
  o 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 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 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.

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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):**

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**

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)

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


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”

Interim Guidelines for COVID-19 Antibody Testing

**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
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
Intra-Hospital Transportation of COVID-19+ Patients & Patients under Investigation (PUI) SOP

**General Principles:**
- Patients should only be transported across the hospital after careful consideration and only if urgent test or procedure required.
- If travel in an elevator is required, only the patient, transport staff, and essential clinicians (e.g., respiratory therapist for patient on a ventilator) are allowed in the elevator during the transport. The elevator override function will be used when necessary during transport to ensure patients are transported without potential disruptions.
- **COVID –designated elevators are C061 (Central Building), SW 361 (South Wing), and WW 388 (West Wing).**
- Transportation routes for dedicated COVID-19 units are as follows:

<table>
<thead>
<tr>
<th>TRAVEL FROM</th>
<th>TRAVEL TO</th>
<th>ROUTE</th>
<th>ELEVATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER/Trauma</td>
<td>SW 8</td>
<td>Take SW elevator direct to SW 8th floor</td>
<td>SW 361</td>
</tr>
<tr>
<td>ER/Trauma</td>
<td>All other SW Floors</td>
<td>Take Central elevator direct to floor; cross into SW</td>
<td>C061</td>
</tr>
<tr>
<td>ER/Trauma</td>
<td>MIC A&amp;B/CCU</td>
<td>Take Central to 4th floor and transport direct to unit</td>
<td>C061</td>
</tr>
<tr>
<td>ER/Trauma</td>
<td>C6</td>
<td>Take Central to 6th floor and transport direct to unit</td>
<td>C061</td>
</tr>
<tr>
<td>ER/Trauma</td>
<td>SIC B</td>
<td>Take Central to 3rd floor and transport direct to unit</td>
<td>C061</td>
</tr>
<tr>
<td>ER/Trauma</td>
<td>WW</td>
<td>Take West Wing elevator direct to floor via NW corridor</td>
<td>WW388</td>
</tr>
<tr>
<td>ER/Trauma</td>
<td>OR/Rad</td>
<td>Take Central or WW elevator and transport to procedural area</td>
<td>C061 WW388</td>
</tr>
<tr>
<td>ER</td>
<td>Trauma Bldg</td>
<td>Take back route through NW outdoor overhang near ground helipad and continue through Trauma Bldg/OR</td>
<td>N/A</td>
</tr>
<tr>
<td>SW 8</td>
<td>All other SW and Central Floors</td>
<td>Take SW elevator direct to floor; For SW 5, take SW elevator to 6th floor → cross into Central and take Central elevator to 5th floor and transport direct to unit</td>
<td>SW 361→C061</td>
</tr>
<tr>
<td>SW 8</td>
<td>OR/Rad</td>
<td>Take SW elevator to 4th Floor → cross into Central; Take Central to 2nd or 3rd floor and transport to procedural area</td>
<td>SW 361→C061</td>
</tr>
<tr>
<td>All SW/Central Covid-19 Units (except SW 8)</td>
<td>OR/Rad</td>
<td>Take Central elevator to 2nd or 3rd floor and transport to procedural area</td>
<td>C061</td>
</tr>
<tr>
<td>WW</td>
<td>OR/Rad</td>
<td>Take West Wing elevator to 2nd or 3rd floor and transport to procedural area</td>
<td>WW388</td>
</tr>
<tr>
<td>SIC B</td>
<td>Rad</td>
<td>Take Central elevator to 2nd floor</td>
<td>C061</td>
</tr>
<tr>
<td>MIC A&amp;B/CCU</td>
<td>OR/Rad</td>
<td>Take Central elevator to 3rd floor</td>
<td>C061</td>
</tr>
</tbody>
</table>

**NOTE:** In the event of a surge to other units, elevator routes may be adjusted to meet need.

For reverse routes or locations not listed, please take closest COVID-designated elevator
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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Low Risk Care Episode</th>
<th>High Risk Care Episode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Short duration</td>
<td>≥1 hour duration, close patient contact,</td>
</tr>
<tr>
<td></td>
<td>Aerosol-generating procedure NOT</td>
<td>Aerosol-generating anticipated or planned</td>
</tr>
<tr>
<td></td>
<td>anticipated</td>
<td>Collection of nasopharyngeal swab</td>
</tr>
<tr>
<td>Mouth/Nose Protection</td>
<td>Surgical/procedure mask</td>
<td>N95 respirator</td>
</tr>
<tr>
<td>Eye Protection</td>
<td>Goggles or face shield</td>
<td>Goggles or face shield</td>
</tr>
</tbody>
</table>
COVID19 Personal Protective Equipment Minimum* Standards

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

*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 6 feet 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),
  o 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,
  o 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.
  o 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.
  o BVMs, and other ventilatory equipment, should be equipped with HEPA filtration to filter expired air.
  o 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.
  o Close the door/window between these compartments before bringing the patient on board.
  o 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.
  o 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.
  o 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.
  o 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.
  o The time to complete transfer of the patient to the receiving facility and complete all documentation should provide sufficient air changes.
  o 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.
  o 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.
  o 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/143892/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

The New England Journal of Medicine

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). Inclusive terms: 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.

DELIBERACY 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. High risk deliveries –
• All team members will enter the room. Team consists of MD, RT, NNP, RN
  o RN & NNP wearing standard PPE and
  o 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.

DISPOSITION OF THE BABY

1. Healthy baby (PUI)
• If the mother is COVID-19 positive, 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).
  • For a healthy PUI mother, 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. The same precautions will be followed by Covid-19 positive mothers who select rooming-in.
  • 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;
  o If a repeat COVID-19 swab on day 14 is negative, the baby may enter general NICU population.
  o 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 floor 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.
    - 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 in 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
DISCHARGE PROTOCOL

(Please see Appendix 7 for CDC 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 O₂ 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:
• 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. 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-assessment-hcp.html](https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html)

Please use the “Travel, Symptoms or exposure employee screening tool” under COVID-19 part of the Jackson Badge Buddy App. To Download 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 also see appendix 4 for CDC’s, Interim Guidance document “Criteria for Return to Work for Healthcare Personnel with Confirmed or who are Suspected of COVID-19”, but was not tested.

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 Download 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.


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 August 4th, 2021 Jackson Health System updated guidance on Masks and Visitation Policy”.

Jackson Health System Mask and Visitation Guidelines 8/4/2021
### COVID Designated and NON-COVID Designated Units

**Updated List 5/19/2021**

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<thead>
<tr>
<th>Unit</th>
<th>IMCU/ICU</th>
<th>Med/surg beds</th>
<th>Total beds</th>
<th>MD Staff Coverage</th>
<th>Admission requests</th>
<th>Admit to team</th>
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<td>Central 6</td>
<td>23 (mixed unit)</td>
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### Contact Numbers

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<td><strong>DOH</strong></td>
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<tr>
<td>Miami Dade County Department of Health</td>
<td>305 470-5660</td>
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<td><strong>JACKSON HEALTH SYSTEM</strong></td>
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<tr>
<td><strong>24 HR Phone list</strong></td>
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<tr>
<td>Jackson Memorial Hospital Main Campus</td>
<td>305 585-1111</td>
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<td>Jackson South Medical Center</td>
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<tr>
<td>Jackson North Medical Center</td>
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<tr>
<td>Case Management (Main)</td>
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<td>Case Management (North)</td>
<td>305-654-5018</td>
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<tr>
<td>Case Management (South)</td>
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<td>Risk Management</td>
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<td>Environmental Services</td>
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<td>Anti-microbial Stewardship</td>
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<td>Microbiology Lab at JMH</td>
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<td>Procurement /Supply chain</td>
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<td>AIC JSMC</td>
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<td><strong>SECURITY COMMAND CENTERS</strong></td>
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<td>JSMC</td>
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<tr>
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</tr>
<tr>
<td>Manager</td>
<td>305-494-2899 Raymonde Jouissance</td>
</tr>
<tr>
<td>Manager</td>
<td>305-319-2210 Lanetra Garvin</td>
</tr>
<tr>
<td>Director</td>
<td>305-975-1657 William Tanelus Holtz</td>
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<tr>
<td>Lead pager #</td>
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<tr>
<td>Chief Therapist</td>
<td>954-243-6613 Micheline Plantada</td>
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<tr>
<td><strong>North</strong></td>
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<td>Office</td>
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<tr>
<td>Lead Ascom</td>
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<tr>
<td>Chief Therapist</td>
<td>305-469-9552 Ana Sanchez-Valdez</td>
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<tr>
<td><strong>South</strong></td>
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<td>Office</td>
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<tr>
<td>Lead Ascom</td>
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<tr>
<td>Chief Therapist</td>
<td>305-772-8499 Juan Castell</td>
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</tbody>
</table>
Please see previous Reference list at this link (99.102). New References below

Guidance for Fully Vaccinated People

Vaccination to Prevent COVID-19 Outbreaks with Current and Emergent Variants — United States, 2021
https://emergency.cdc.gov/han/2021/han0447.asp

Guidance for Implementing COVID-19 Prevention Strategies in the Context of Varying Community Transmission Levels and Vaccination Coverage
https://www.cdc.gov/mmwr/volumes/70/wr/mm7030e2.htm

Efficacy of Pfizer/BioNTech COVID Vaccine Slips to 84% after six months, Data show

Universal Use of N95 Respirators in Healthcare Settings When Community Coronavirus Disease 2019 Rates Are High
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab539/6296401

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021
https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_x

ACOG and SMFM Recommend COVID-19 Vaccination for Pregnant Individuals


COVID-19 Science Update released: July 30, 2021 Edition 100
https://www.cdc.gov/library/covid19/07302021_covidupdate.html

About 99.999% of fully vaccinated Americans have not had a deadly Covid-19 breakthrough case, CDC data shows

COVID-19 Vaccine Breakthrough Case Investigation and Reporting
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine breakthrough infections: a multi-center cohort study
https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1.full.pdf

Viral infection and transmission in a large well-traced outbreak caused by the Delta SARS-CoV-2 variant
https://doi.org/10.1101/2021.07.07.21260122 or https://www.medrxiv.org/content/10.1101/2021.07.07.21260122v2

Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant

A prospective study of long-term outcomes among hospitalized COVID-19 patients with and without neurological complications
https://doi.org/10.1016/j.jns.2021.117486

Persistent neuropsychiatric symptoms after COVID-19: a systematic review and meta-analysis.
https://doi.org/10.1016/j.jns.2021.117486

https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm?s_cid=mm7031e1_x
### Clinical Pearls for Treatment Options

1. **Remdesivir**
   - Veklury (Remdesivir) received FDA approval for treatment of COVID-19 for hospitalized patients ≥ 12 years old and weighing > 40 kg; see JHS criteria below
   - 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
     - eGFR > 30 ml/min (if eGFR < 30 ml/min or patient on renal replacement therapy, determine if benefit outweighs risk)
     - ALTs < 10x ULN
     - No known hypersensitivity to remdesivir
     - No known drug interactions
   - 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.

2. **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)

3. **Convalescent Plasma**
   - For ARDS steroid dosing please refer to page 5
   - For ARDS steroid dosing please refer to page 5
   - Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset

### Table 1: Adult JHS (confirmed or highly suspected) Treatment Guide (6.8.2021)

<table>
<thead>
<tr>
<th>Criteria (confirmed COVID-19 only)</th>
<th>Treatment Options</th>
<th>Clinical Pearls for Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mild +/- risk factors:</strong> any of the following</td>
<td>Refer to JHS REGEN-COV Criteria (Appendix 5)</td>
<td></td>
</tr>
<tr>
<td>• Fever, malaise, cough, headache, sore throat, myalgia, nasal congestion, diarrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk factors:</strong> Age ≥ 65, coronary artery disease, diabetes, obesity, hypertension, transplant, or immunosuppressed</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moderate:</strong> All must be met in a non-intubated patient:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• SpO2 &lt; 93% on room air or requiring supplemental oxygen above baseline</td>
<td></td>
<td></td>
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<tr>
<td>• Any symptom of mild disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or bilateral consolidations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No additional signs or symptoms of severe COVID-19 (see below)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tocilizumab:</strong> Appendix 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Moderate criteria plus all of the following must be met):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• PaO2/FiO2 &lt; 300mmHg or at least 4L NC if ABG not available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Clinical deterioration (i.e. elevated respiratory rate, persistent fever, increasing O2 requirement, etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Two or more of the following: IL-6 &gt; 40 pg/mL, CRP &gt; 10 mg/dL, D-dimer &gt; 1 mcg/mL FEU, Ferritin &gt; 100 ng/mL, or LDH &gt; 500 units</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*For ARDS steroid dosing please refer to page 5

For any suspected cases at JHS, please contact JHS Infection Prevention (IP) at: 786-266-0624. If treatment is warranted at JHS, contact ID COVID Team C 786-674-2884
**Jackson Health System**  
**COVID-19 Treatment Information**  
**June 8, 2021**

### Severe: ≥ 2 of the following
- Intubated
- Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or consolidations
- ARDS with PaO₂/FiO₂ 151-300 mmHg
- Lymphopenia (ALC < 0.6 x 10³/μL)

### 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 PaO₂/FiO₂ ≤ 150mmHg
- *Septic Shock (with >1 vasopressor)*
- Altered Consciousness
- *Multi-organ failure*

### Tocilizumab: Appendix 3

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recent intubation due to COVID (within 24h)</td>
<td>Tocilizumab may be considered if intubated within 24h</td>
</tr>
<tr>
<td>Two or more of the following: IL-6 &gt; 40 pg/mL, CRP &gt; 10 mg/dL, D-dimer &gt; 1 mcg/mL FEU, Ferritin &gt; 1,000 ng/mL, or LDH &gt; 500 units/L</td>
<td>Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset</td>
</tr>
</tbody>
</table>

### Dexamethasone

- 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)
  - For ARDS steroid dosing please refer to page 5

### Remdesivir

- 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 by primary team if patient meets criteria

### Tocilizumab

- IL-6 or CRP levels may be used to guide Tocilizumab therapy; current thresholds for treatment are based on clinical practice experience
- All patients receiving Tocilizumab should be ruled out for latent TB per package insert
- Tocilizumab should be used with caution in patients with history of GI perforation/diverticulitis or active infection
- Do not use in patients with LFTS ≥ 10x ULN

### 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 not approved for Strongyloides prophylaxis in non-transplant patients while receiving corticosteroids.

---

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](https://www.covid19-druginteractions.org/checker).
3. Recommend obtaining an IL-6 level at time of suspicion (if available) since there may be a delay in turnaround time. Other markers can be trended daily or as needed.
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 x 1, 30-50kg 8mg/kg/dose x 1, 51-62 kg 400mg IV x 1; 63-86kg 600mg IV x 1; ≥ 87kg 800mg x 1
5. 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. 24.5% 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](https://doi.org/10.1101/2020.06.22.20137273)).
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 (confirmed or highly suspected COVID-19)

<table>
<thead>
<tr>
<th>Mild +/- risk factors: any of the following</th>
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<tr>
<td>Fever, malaise, cough, headache, sore throat, myalgia, nasal congestion, diarrhea</td>
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</tr>
<tr>
<td>No additional signs or symptoms of severe COVID-19 (see below)</td>
</tr>
</tbody>
</table>

### Moderate: All must be met in a non-intubated patient:

- Oxygen requirement 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)

### 4Tocilizumab Criteria: all of the following are met

- A minimum of 4L NC
- Clinical deterioration (i.e. elevated respiratory rate, persistent fever, increasing O₂ requirement, etc.)
- Two or more of the following: 2IL-6 > 40 pg/mL, CRP > 10 mg/dL, D-dimer > 1 mcg/mL FEU, Ferritin >1,000 ng/mL, or LDH >500 units/L

### Off-label Treatment Options¹

1. Refer to JHS REGEN-COV Criteria (Appendix 5)

2. **Remdesivir**

   - 5mg/kg/dose IV LD (max 200mg per dose) (day 1), then 2.5mg/kg/dose IV daily (max 100mg per dose) x 4 days
   - No longer restricted to ID/ASP; may be ordered be primary team if patient meets criteria

   **Additional therapies to consider:**

   3. **Tocilizumab:** requires multidisciplinary discussion between ASP, ID, and critical care

   4. **Dexamethasone 0.15mg/kg PO (max 6mg) q24h up to 10 days**

   5. 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

   **Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset**

### Clinical Pearls for Treatment Options

2. **Remdesivir**

   - Veklury (Remdesivir) received FDA approval for treatment of COVID-19 for hospitalized patients ≥ 12 years old and weighing ≥ 40 kg. However may be used in younger children if clinically indicated (see JHS criteria below)

   - 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
     - eGFR >30 ml/min (if eGFR <30ml/min or patient on renal replacement therapy, determine if benefit outweighs risk)
     - ALTs < 10x ULN
     - No known hypersensitivity to remdesivir
     - No known drug interactions (https://www.covid19-druginteractions.org/checker)

   - **Duration:** 5 days

   - Eight institutions across the country were polled and we feel assured in our decision to not expand Remdesivir to all hospitalized SARS-CoV-2 positive patients without an ID/ASP multidisciplinary discussion. If a provider strongly believes that a patient not meeting JHS criteria would benefit from Remdesivir, please contact ASP.
## Severe: ≥ 2 of the following
- Intubated
- Radiographic imaging (chest x-ray or lung ultrasound) with bilateral ground glass opacities or consolidations
- ARDS with Oxygen Index > 4 to 10
- Lymphopenia (ALC < 0.6 x 10³/mCL)

### Tocilizumab Criteria
All of the following must be met:
- Recent intubation (within 24h)
- Two or more of the following:
  - IL-6 > 40 pg/mL, CRP > 10 mg/dL, D-dimer > 1 mcg/mL FEU, Ferritin > 1,000 ng/mL, or LDH > 500 units/L

### 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 Oxygen Index > 10
- Septic Shock (> 1 vasopressor)
- Altered Consciousness
- Multi-organ failure

---

2. **Remdesivir** (may consider if intubated within 24h)
   - 5mg/kg/dose IV LD (max 200mg per dose) (day 1), then 2.5mg/kg/dose IV daily (max 100mg per dose) x 4 days
   - No longer restricted to ID/ASP; may be ordered by primary team if patient meets criteria
   - Additional therapies to consider:
     - Tocilizumab; requires multidisciplinary discussion between ASP, ID, and critical care
     - Dexamethasone 0.15mg/kg PO (max 6mg) q24h up to 10 days
   - Consider shorter duration based on patient improvement (methylprednisolone 1mg/kg IV q24 or divided q12h or prednisone/prednisolone 1mg/kg/dose PO q24 (max 30mg daily) may be used if dexamethasone is not available
   - Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset

3. **Remdesivir** (may consider if intubated within 24h)
   - 5mg/kg/dose IV LD (max 200mg per dose) (day 1), then 2.5mg/kg/dose IV daily (max 100mg per dose) x 4 days
   - No longer restricted to ID/ASP; may be ordered by primary team if patient meets criteria
   - Additional therapies to consider:
     - Tocilizumab; requires multidisciplinary discussion between ASP, ID, and critical care
   - Dexamethasone 0.15mg/kg PO (max 6mg) q24h up to 10 days
   - Consider shorter duration based on patient improvement (methylprednisolone 1mg/kg IV q24 or divided q12h or prednisone/prednisolone 1mg/kg/dose PO q24 (max 30mg daily) may be used if dexamethasone is not available
   - Consider high-titer (IgG 1:1000) convalescent plasma if within 72h of symptom onset

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**REGEN-COV**
- Effective March 01, 2021 we will transition to recommending REGEN-COV monoclonal antibody cocktail instead of Bamlanivimab for non-hospitalized COVID-19 patients > 12 years old and weighing > 40 kg (for more information see appendix 5)

### Tocilizumab
- IL-6 or CRP levels may be used to guide Tocilizumab therapy, current thresholds for treatment are based on clinical practice experience
- All patients receiving Tocilizumab should be ruled out for latent TB per package insert
- Tocilizumab should be used with caution in patients with history of GI perforation/diverticulitis or active infection
- Do not use in patients with LFTS ≥ 10x ULN

**Pregnant Patients:**
- Safety of Remdesivir in pregnancy is unknown
- Tocilizumab should not be administered to pregnant patients due to risks to the fetus
- Hydroxychloroquine/chloroquine cross the placenta; has been detected in ocular tissues in animal studies; evidence exists that use is safe in pregnant women with lupus

**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 not approved for Strongyloides prophylaxis in non-transplant patients while receiving corticosteroids.

---

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 patients with an eGFR < 30 mL/min unless the potential benefits outweigh the risks. It should not be initiated in patients if baseline ALT ≥ 10x the upper limit of normal or should be discontinued if this occurs while on therapy. Evaluate for drug interactions at [https://www.covid19druginteractions.org/checker](https://www.covid19druginteractions.org/checker).
3. Recommend obtaining an IL-6 level at time of suspicion (if available) since there may be a delay in turnaround time. Other markers can be trended daily.
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 x 1; 63-86kg 600mg IV x 1; ≥87kg 800mg x 1
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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

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

1. 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.\(^1\)

2. Ivermectin
   - At this time, the FDA has not approved ivermectin to prevent or treat COVID-19.
   - At JHS, ivermectin is not approved for Strongyloides prophylaxis in non-transplant 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.\(^1\)

3. 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.\(^1\)

4. 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

For all patients:

1. **On Admission:**
   a. Obtain: D-dimer, PT, PTT, fibrinogen

2. **Monitoring:**
   a. Trend D-dimer daily

3. **Management:**
   a. All patients should receive standard prophylactic anticoagulation (preferred agent is UFH 5000 either BID or TID and or enoxaparin 40 mg QD)
   b. Non-ICU patients who are on a direct oral anticoagulant or warfarin as an outpatient should remain on same therapeutic therapy inpatient unless contraindicated
   c. ICU patients who are on a direct oral anticoagulant or warfarin as an outpatient should be switched to therapeutic dose of heparin
   d. Is unclear if COVID-19 patients have an increased risk of VTE compared to other critical processes, therefore we suggest limiting therapeutic anticoagulation to the following patients:
      1. Documented acute DVT/PE
      2. If high clinical suspicion for DVT/PE on admission
      3. Acute worsening hypoxia, worsening hypotension or/and tachycardia with imaging findings not consistent with worsening.
      4. If echocardiogram with evidence of acute, otherwise unexplained right heart strain, or intra-cardiac thrombus
   e. If the patient is on CRRT and there is an issue with the filter clotting, please refer to the CRRT anticoagulation therapy SOP
Appendix 3: Tocilizumab

May be considered on a case by case basis in patients with the following criteria:

1. 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
2. SpO2 ≤ 93% or PaO2/FiO2 < 300 mmHg or within 24h of mechanical ventilation
3. Requires multidisciplinary discussion with ASP, ID and critical care
4. All patients should be ruled out for latent TB, strongyloides, hepatitis B
5. Do not use in patients with LFTS ≥ 10x ULN
6. Should be used along with corticosteroids (i.e. dexamethasone) and other standard of care
Appendix 4: Management of Special Populations

8A. Solid organ transplant recipients

Table 1: Suggested treatment/use of investigational agents

<table>
<thead>
<tr>
<th>Severity of disease</th>
<th>Suggested Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>• Supportive Care</td>
</tr>
<tr>
<td></td>
<td>• Every 4 hours Oxygen monitoring</td>
</tr>
<tr>
<td></td>
<td>• Every other day inflammatory markers</td>
</tr>
<tr>
<td></td>
<td>• Decrease Immunosuppression as in Table 2</td>
</tr>
<tr>
<td>Moderate</td>
<td>• Consider one or a combination of these if indicated</td>
</tr>
<tr>
<td></td>
<td>o Remdesivir 200 mg IV LD x 1, then 100 mg IV daily x 5 days</td>
</tr>
<tr>
<td></td>
<td>o Convalescent Plasma</td>
</tr>
<tr>
<td></td>
<td>o Tocilizumab (If criteria in Appendix 5 met and approved by multidisciplinary team)</td>
</tr>
<tr>
<td></td>
<td>o Total plasma exchange</td>
</tr>
<tr>
<td></td>
<td>And</td>
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</tr>
<tr>
<td></td>
<td>• Decrease Immunosuppression as in Table 2</td>
</tr>
<tr>
<td>Severe</td>
<td>• First: Remdesivir 200 mg IV LD x 1, then 100 mg IV daily x 9 days, if available and criteria met (must be mechanically intubated to receive 10 days of therapy)</td>
</tr>
<tr>
<td></td>
<td>• If Remdesivir unavailable, consider one or a combination of these if indicated</td>
</tr>
<tr>
<td></td>
<td>o Convalescent Plasma</td>
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<td></td>
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<tr>
<td></td>
<td>o Total plasma exchange</td>
</tr>
<tr>
<td></td>
<td>o Methylprednisolone per protocol</td>
</tr>
<tr>
<td></td>
<td>o Mesenchymal stem cells as part of clinical trial</td>
</tr>
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<td></td>
<td>And</td>
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<td></td>
<td>• Daily inflammatory markers</td>
</tr>
<tr>
<td></td>
<td>• Decrease Immunosuppression as in Table 2</td>
</tr>
<tr>
<td>Critical ARDS + MOD</td>
<td>• ARDS Management</td>
</tr>
<tr>
<td></td>
<td>• Consider one or a combination of these if indicated</td>
</tr>
<tr>
<td></td>
<td>o Methylprednisolone per protocol</td>
</tr>
</tbody>
</table>
Jackson Health System
COVID-19 Treatment Information
June 8, 2021

- 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

<table>
<thead>
<tr>
<th>Liver/ Multi-visceral transplant</th>
<th>Mild disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● Decrease Mycophenolate mofetil dose by 50%</td>
</tr>
<tr>
<td></td>
<td>● Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions.</td>
</tr>
<tr>
<td>Moderate disease</td>
<td>● Hold Mycophenolate mofetil</td>
</tr>
<tr>
<td></td>
<td>● Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions.</td>
</tr>
<tr>
<td>Severe disease</td>
<td>● Hold Mycophenolate mofetil</td>
</tr>
<tr>
<td></td>
<td>● Decrease Tacrolimus/Everolimus dose by 50%. Closely monitor drug interactions.</td>
</tr>
<tr>
<td></td>
<td>● Consider Methyprednisolone as part of ARDS management if indicated by critical care team.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kidney/Pancreas transplant</th>
<th>Mild disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● Decrease Mycophenolate mofetil dose by 50%</td>
</tr>
<tr>
<td></td>
<td>● Continue Tacrolimus/Everolimus with same target trough concentrations. Closely monitor drug interactions.</td>
</tr>
<tr>
<td></td>
<td>● 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.</td>
</tr>
<tr>
<td></td>
<td>● Continue Prednisone</td>
</tr>
<tr>
<td>Moderate disease</td>
<td>● Hold Mycophenolate mofetil</td>
</tr>
<tr>
<td></td>
<td>● Decrease Tacrolimus/Everolimus dose by 50%. Closely monitor drug interactions.</td>
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</tr>
<tr>
<td></td>
<td>● Continue Prednisone</td>
</tr>
<tr>
<td>Severe disease</td>
<td>● Hold Mycophenolate mofetil</td>
</tr>
<tr>
<td></td>
<td>● Decrease Tacrolimus dose by 50%. Closely monitor drug interactions.</td>
</tr>
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<td></td>
<td>● Consider Methyprednisolone as part of ARDS management if indicated by critical care team.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heart transplant</th>
<th>Mild disease</th>
</tr>
</thead>
</table>

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## Jackson Health System
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<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Disease Severity</th>
<th>Therapy Recommendations</th>
</tr>
</thead>
</table>
| Lung transplant    | Mild disease     | - Decrease Mycophenolate mofetil 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. |
|                    | 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:**

5. COVID-19 Treatment Algorithm Yale School of Medicine (https://medicine.yale.edu/news-article/23611/)
Appendix 5: REGEN-COV

1. A recent phase 2 portion of a randomized phase 2/3 clinical trial (BLAZE-1) demonstrated that Bamlanivimab monotherapy was not associated with a statistically significant reduction in SARS-CoV-2 viral load compared to placebo in 577 patients. (JAMA. 2021;325(7):632-644. doi:10.1001/jama.2021.0202)

2. The combination of bamlanivimab and etesevimab did significantly reduce SARS-CoV-2 log viral load at day 11 for patients with mild to moderate COVID-19.

3. REGEN-COV is another monoclonal neutralizing antibody cocktail consisting of imdevimab and casirivimab. This antibody cocktail was found to significantly reduce SARS-CoV-2 viral load (day 1 to 7: - 0.56 log (95% CI, -1.02 to -0.11) in outpatients with negative antibodies at baseline, compared to placebo.

4. In addition, early (non-peer reviewed data) suggests that while bamlanivimab has been found to be ineffective against the B.1.351 (South Africa) variant, REGEN-COV has been found to be effective against both the B.1.351 and the B.1.1.7 (U.K.) variant. Data is pending regarding the 1.1.248 (Brazil) variant. (https://www.biorxiv.org/content/10.1101/2021.01.25.428137v2.full.pdf)

5. There is no comparative data at this time between bamlanivimab monotherapy or bamlanivimab and etesevimab combination therapy and REGEN-COV2 for non-hospitalized patients with COVID-19.

6. In light of this evidence, we are recommending use of REGEN-COV2 instead of bamlanivimab for the time being. Updates may change as information is rapidly evolving.

7. Please see next page for REGEN-COV2 criteria.
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This version supersedes all previous versions

JHS Monoclonal Antibody “REGEN-COV” (casirivimab with imdevimab) Criteria

Due to limited supply, REGEN-COV is restricted to the Antimicrobial Stewardship Program (ASP).

*If treatment is warranted, please call ASP.

*In patients who have received monoclonal antibodies, vaccination should be deferred for at least 90 days to avoid interference of treatment with vaccine-induced immune responses. For those who have received first dose of COVID-19 vaccine, please contact ASP for guidance*

All criteria must be met in order for REGEN-COV to be considered:

- Not hospitalized (i.e. patients in the emergency department not admitted, outpatient encounters)
- Positive SARS-CoV-2 viral test (Positive Rapid Antigen or PCR) OR recent positive SARS-CoV-2 test within the last 10 days
- Mild to moderate COVID-19 with symptoms

For pediatric patients 12 – 17 years of age and weighing at least 40 kg, may consider REGEN-COV if they have any of the following:

- BMI ≥85th percentile for their age and gender based on CDC growth charts, sickle cell disease, congenital/ acquired heart disease, neurodevelopmental disorders, for example, cerebral palsy, a medical-related technological dependence (i.e. tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19), asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

For adult patients, REGEN-COV may be considered for those at high risk for progression to severe COVID-19/hospitalization that meet at least one the following criteria:

- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or receiving immunosuppressive therapy
- ≥65 years of age
- BMI ≥30
- Pregnancy (limited data, only if benefit outweighs risk)
- ≥18 years of age with at least one of the following: cardiovascular disease, hypertension, chronic obstructive pulmonary disease, 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)
- Other risk factors such as race and ethnicity might have an increased risk of progression and cases will be analyzed on an individual basis as needed
Exclusion Criteria:
- Hospitalized due to COVID-19
- Requiring oxygen therapy due to COVID-19
- Requiring an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity

Treatment:
REGEN-COV 1,200 mg IV x 1 dose (60 mL; infuse over 20 minutes)

Administration:
- Use a dedicated line with a 0.2 micron filter
- Flush infusion line with approximately 25-50 mL of 0.9% sodium chloride to ensure delivery of the total dose

Monitoring/Side Effects:
*Patients should be monitored for at least 1 hour after the infusion is complete.*

Monitor for the following reactions:
- Hypersensitivity reactions/anaphylaxis; if the reactions occur, stop the infusion immediately and administer appropriate medications/supportive care
- Infusion related reactions (e.g. fever, bronchospasm, angioedema, etc.); if an infusion related reaction occurs, consider slowing/stopping infusion and administer appropriate medications/supportive care
- Other common side effects include nausea/vomiting, abdominal pain, pruritus, urticarial, chills, flushing

ED Physicians must complete the following:
- Provide a copy of the “Fact Sheet for Patients, Parents and Caregivers” to the patient
- Inform the patient to alternatives to receiving authorized REGEN-COV
- Inform the patient that REGEN-COV is an unapproved drug that is authorized for use under the FDA’s Emergency Use Authorization
- Obtain verbal consent from the patient or their caregiver and document in the patient’s chart
- **JMH: Please call ASP (786-586-0607) from 7am-11pm. From 11pm-7am: please call Central Pharmacy (305-585-5389)**
- **Holtz: Please call ASP (786-586-0607) from 7am-11pm. From 11pm-7am: please call Pediatric Pharmacy (305-585-5697)**
- **Jackson North and South: please see numbers above**
Regeneron Order process

Patient does not meet criteria as detected by system (eg. Age or Encounter Type)

If you would like to further discuss your case, call the ASP team

ASP phone numbers
- Jackson Memorial Hospital & Holtz: 786-586-0607 (7am-11pm)
- Jackson Memorial Hospital After Hours: 305-585-5389 (11:01pm-6:59am)
- Holtz Children’s Hospital After Hours: 305-585-5697 (11:01-6:59am)
- Jackson North Medical Center: 305-654-5022; option 1; internal: 2
- Jackson South Medical Center: 305-256-5180

If patient passes automated screen, the user is presented with initial screening questions.

Regen-Cov is indicated if patient meets criteria, Check all that apply from the listed below

- Age ≥ 18 years, or Age 12 - 18 years and weight ≥ 40kg
- NOT Hospitalized
- Confirmed active SARS-CoV-2 infection (positive Antigen or PCR)
- Mild-moderate COVID-19 symptoms
- NOT requiring oxygen supplementation/ saturating > 94% on room air, at rest and on ambulation
If user attempts to continue without selecting all options. This window informs them that they cannot continue.

Patient does not meet criteria for Regeneron administration
If you would like to further discuss your case, call the ASP team

ASP phone numbers
- Jackson Memorial Hospital & Holtz: 766-586-0607 (7am-11pm)
- Jackson Memorial Hospital After Hours: 305-585-5389 (11:01pm-6:59am)
- Holtz Children's Hospital After Hours: 305-585-5697 (11:01-6:59am)
- Jackson North Medical Center: 305-654-5022; option 1; internal: 2
- Jackson South Medical Center: 305-256-5180

Selecting all the options from the first screen, shows an “Additional Criteria” window for data entry.

Regen-Cov is indicated if patient meets criteria, Check all that apply from the listed below
- Age ≥ 18 years, or Age 12 - 18 years and weight ≥ 40kg
- NOT Hospitalized
- Confirmed active SARS-CoV-2 infection (positive Antigen or PCR)
- Mild-moderate COVID-19 symptoms
- NOT requiring oxygen supplementation/ saturating > 94% on room air, at rest and on ambulation
At least one value should be selected from the “Additional Criteria” screen. If not, this message informs the user that they cannot continue.
You are being given a medicine called REGEN-COV (casirivimab with imdevimab) for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV, which you may receive.

Receiving REGEN-COV may benefit certain people with COVID-19.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?
COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can occur and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

WHAT ARE THE SYMPTOMS OF COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (casirivimab with imdevimab)?
REGEN-COV is an investigational medicine used to treat mild to moderate symptoms of COVID-19 in non-hospitalized adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)), and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the “What is an Emergency Use Authorization (EUA)?” section at the end of this Fact Sheet.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?
Tell your healthcare provider about all of your medical conditions, including if you:
- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
• Have any serious illnesses
• Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab with imdevimab)?
• REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together as a single intravenous infusion (through a vein) for at least 1 hour.
• You will receive one dose of REGEN-COV by intravenous infusion.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab with imdevimab)?
Possible side effects of REGEN-COV are:
• Allergic reactions. Allergic reactions can happen during and after infusion with REGEN-COV. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness and sweating. These reactions may be severe or life threatening.
• Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?
Like REGEN-COV (casirivimab with imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on other medicines used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.
WHAT IF I AM PREGNANT OR BREASTFEEDING?
There is limited experience treating pregnant women or breastfeeding mothers with
REGEN-COV (casirivimab with imdevimab). For a mother and unborn baby, the benefit of
receiving REGEN-COV may be greater than the risk from the treatment. If you are pregnant or
breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab with
imdevimab)?
Tell your healthcare provider right away if you have any side effect that bothers you or does not
go away.

Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088 or
call 1-844-734-6643.

HOW CAN I LEARN MORE?
• Ask your health care provider.
• Visit www.REGENCOV.com
• Visit https://www.covid19treatmentguidelines.nih.gov/
• Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made REGEN-COV (casirivimab with imdevimab) available under
an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health
and Human Service (HHS) declaration that circumstances exist to justify the emergency use of
drugs and biological products during the COVID-19 pandemic.

REGEN-COV has not undergone the same type of review as an FDA-approved or cleared
product. The FDA may issue an EUA when certain criteria are met, which includes that there are
no adequate, approved, available alternatives. In addition, the FDA decision is based on the
totality of scientific evidence available showing that it is reasonable to believe that the product
meets certain criteria for safety, performance, and labeling and may be effective in treatment of
patients during the COVID-19 pandemic. All of these criteria must be met to allow for the
product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying
emergency use of these products, unless terminated or revoked (after which the products may no
longer be used).

REGENERON
Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

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Revised: 02/2021
Se le está administrando un medicamento llamado REGEN-COV (casirivimab con imdevimab) para tratar la enfermedad por coronavirus 2019 (COVID-19). Este Folleto contiene información que lo ayudará a comprender los posibles riesgos y beneficios de la administración de REGEN-COV que usted podría recibir.

La administración de REGEN-COV puede tener beneficios en ciertas personas con COVID-19.

Lea este Folleto para obtener información sobre REGEN-COV. Ante cualquier inquietud, comuníquese con su proveedor de atención médica. Recibir REGEN-COV o suspender su administración en un momento dado es su elección.

¿QUÉ ES EL COVID-19?
El COVID-19 es una enfermedad causada por un virus llamado coronavirus. Se puede contraer COVID-19 mediante el contacto con otra persona que esté infectada con el virus.

Los casos de COVID-19 abarcan desde aquellos que son muy leves (incluidos algunos cuadros asintomáticos) hasta los más graves, que incluyen casos letales. Si bien la información con la que se cuenta hasta el momento indica que la mayoría de los casos de COVID-19 son leves, se pueden presentar cuadros graves, que pueden provocar un agravamiento de otras afecciones médicas preexistentes. Las personas de todas las edades que padecen afecciones médicas graves y de larga duración (crónicas), como enfermedades cardíacas o pulmonares, o diabetes, tienen mayor riesgo de ser hospitalizadas por COVID-19.

¿CUÁLES SON LOS SÍNTOMAS DEL COVID-19?
Los síntomas del COVID-19 incluyen fiebre, tos y dificultad para respirar, los cuales pueden presentarse entre dos y catorce días posteriores a la exposición al virus. Pueden desarrollarse cuadros graves, que incluyen problemas respiratorios, lo que puede provocar el agravamiento de otras afecciones médicas preexistentes.

¿QUÉ ES REGEN-COV (casirivimab con imdevimab)?
REGEN-COV es un medicamento en investigación utilizado para tratar síntomas leves a moderados de COVID-19 en adultos y adolescentes que no estén hospitalizados (a partir de los 12 años y que pesen más de 88 libras (40 kg)) y que tengan alto riesgo de desarrollar síntomas graves de COVID-19 o de ser hospitalizados. Se utiliza el término "en investigación" porque REGEN-COV aún se encuentra en fase de estudio. No existe abundante información sobre el uso seguro y la eficacia de REGEN-COV en el tratamiento de personas con COVID-19.

La FDA ha autorizado el uso de emergencia de REGEN-COV para tratar el COVID-19 conforme a una Autorización de Uso de Emergencia (EUA, por sus siglas en inglés). Para más información sobre las EUA, vea el apartado “¿Qué es una Autorización de Uso de Emergencia (EUA)?” al final de este Folleto.
¿QUÉ DEBO INFORMARLE A MI PROVEEDOR DE ATENCIÓN MÉDICA ANTES DE RECIBIR REGEN-COV?
Infórmele a su proveedor de atención médica sobre su estado de salud, e incluya lo siguiente:
- si tiene alergias;
- si está embarazada o tiene planes de quedar embarazada;
- si está amamantando o tiene planes de amamantar;
- si padece enfermedades graves;
- si está tomando medicamentos (medicamentos de venta con receta y de venta libre, vitaminas y productos herbales).

¿CÓMO SE ME VA A ADMINISTRAR REGEN-COV (casirivimab con imdevimab)?
- REGEN-COV está compuesto por dos medicamentos en investigación, casirivimab e imdevimab, que se administran como una única inyección lenta intravenosa (a través de una vena) durante 1 hora, como mínimo.
- Se le administrará una dosis de REGEN-COV por vía intravenosa.

¿CUÁLES SON LOS POSIBLES EFECTOS SECUNDARIOS IMPORTANTES DE REGEN-COV (casirivimab con imdevimab)?
Los posibles efectos secundarios de REGEN-COV son los siguientes:
- Reacciones alérgicas. Pueden producirse reacciones alérgicas durante la administración de REGEN-COV y después de ella. Infórmelo a su proveedor de atención médica de inmediato si observa alguno de los siguientes signos o síntomas de reacción alérgica: fiebre, escalofríos, náuseas, cefalea, dificultad para respirar, presión arterial baja o alta, frecuencia cardíaca rápida o lenta, molestia o dolor de pecho, debilidad, confusión, cansancio, sibilancias, hinchazón de labios, rostro o garganta, sarpullido, urticaria, prurito, dolor muscular, mareos y sudoración. Estas reacciones pueden ser graves o potencialmente mortales.
- Agravamiento de los síntomas luego del tratamiento: puede padecer un agravamiento de los síntomas o pueden aparecer nuevos tras la administración, como fiebre, dificultad para respirar, frecuencia cardíaca rápida o lenta, cansancio, debilidad o confusión. Si esto ocurre, contacte a su proveedor de atención médica o procure asistencia médica de inmediato, dado que algunos de esos eventos pueden requerir hospitalización. Se desconoce si estos eventos están relacionados con el tratamiento o se deben a la evolución del COVID-19.

Los efectos secundarios de recibir un medicamento por vía intravenosa pueden incluir dolor pasajero, sangrado, moretones en la piel, inflamación, hinchazón y posible infección en el lugar de la inyección.

Estos no son todos los posibles efectos secundarios de REGEN-COV. No se ha administrado REGEN-COV a muchas personas. Pueden presentarse efectos secundarios graves e inesperados. REGEN-COV todavía está en fase de estudio, por lo que es posible que aún no se conozcan todos los riesgos.

Es posible que REGEN-COV interfiera con su capacidad de combatir una futura infección por SARS-CoV-2. Asimismo, REGEN-COV puede reducir su respuesta inmunológica frente a una
vacuna contra el SARS-CoV-2. No se han realizado estudios específicos para analizar estos posibles riesgos. Ante cualquier inquietud, comuníquese con su proveedor de atención médica.

¿QUÉ OTRAS OPCIONES DE TRATAMIENTO EXISTEN?
Como ha sucedido con REGEN-COV (casirivimab con imdevimab), la FDA puede autorizar el uso de emergencia de otros medicamentos para tratar personas con COVID-19. Para obtener más información sobre otros medicamentos utilizados para tratar personas con COVID-19, visite covid19treatmentguidelines.nih.gov/https://www.. Puede que su proveedor de salud le hable de ensayos clínicos en los que usted podría participar.

Ser tratado o no con REGEN-COV es su elección. Si opta por no recibir REGEN-COV, o por suspender su administración en un momento dado, ello no modificará el cuidado médico habitual que usted recibe.

¿QUÉ SUCEDERÁ SI ESTOY EMBARAZADA O AMAMANTANDO?
No existen muchos antecedentes en los que se haya tratado a mujeres embarazadas o a madres lactantes con REGEN-COV (casirivimab con imdevimab). En las madres y sus fetos, el beneficio de recibir REGEN-COV puede ser mayor que el riesgo derivado del tratamiento. Si está embarazada o amamantando, consulte sus opciones y su situación particular con su proveedor de atención médica.

¿CÓMO INFORMO EFECTOS SECUNDARIOS DE REGEN-COV (casirivimab con imdevimab)?
Informe de inmediato a su proveedor de atención médica si presenta algún efecto secundario que le genere molestias o que no desaparezca.

Puede informar la existencia de efectos secundarios a la FDA MedWatch ingresando a www.fda.gov/medwatch o llamando al 1-800-FDA-1088 o al 1-844-734-6643.

¿CÓMO PUEDO OBTENER MÁS INFORMACIÓN?
- Consulte a su proveedor de atención médica.
- Visite www.REGENCOV.com
- Visite https://www.covid19treatmentguidelines.nih.gov/
- Contacte al departamento de salud pública local o de su estado.

¿QUÉ ES UNA AUTORIZACIÓN DE USO DE EMERGENCIA (EUA)?
La Administración de Alimentos y Medicamentos de los Estados Unidos (FDA, por sus siglas en inglés) ha puesto REGEN-COV (casirivimab con imdevimab) a disposición conforme a un mecanismo de acceso de emergencia denominado EUA, el cual se encuentra respaldado por una declaración del Departamento de Salud y Servicios Humanos (HHS, por sus siglas en inglés), que considera que existen circunstancias que justifican el uso de emergencia de los medicamentos y productos biológicos durante la pandemia de COVID-19.

REGEN-COV no ha atravesado el mismo proceso de revisión que el de un producto aprobado o autorizado por la FDA. La FDA puede emitir una EUA siempre que se cumplan ciertos criterios, entre los cuales se encuentra la falta de alternativas adecuadas, aprobadas y disponibles. Asimismo, la decisión de la FDA se basa en la totalidad de la evidencia científica disponible que
demuestra que es razonable pensar que el producto cumple con ciertos criterios de seguridad, rendimiento y etiquetado, y que puede resultar eficaz en el tratamiento de los pacientes durante la pandemia de COVID-19. Todos estos criterios deben cumplirse para permitir que se utilice el producto en el tratamiento de pacientes durante la pandemia de COVID-19.

La EUA para REGEN-COV regirá durante el plazo correspondiente a la declaración de la emergencia sanitaria provocada por el COVID-19 que justifique el uso de emergencia de estos productos, salvo que se cancele o se revoque (luego de lo cual, los productos no se podrán seguir utilizando).

**REGENERON**

Fabricado por:
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Appendix 1c

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

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.

Pfizer-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](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. The Moderna schedule is separated by 28 days and is currently approved for patients 18 years of age and older.

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.

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.


### COVID-19 Vaccines with Emergency Use Authorization\(^2,3,5\)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Type</th>
<th>Age</th>
<th>Administration</th>
<th>Efficacy</th>
<th>Absolute Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>mRNA</td>
<td>≥ 16 years</td>
<td>Two doses IM 30 ug, 0.3 mL each; 3 weeks (21 days) apart</td>
<td>95.0% at 14 days post second dose</td>
<td>Known history of a severe allergic reaction (i.e. anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine (ex: PEG/laxatives)</td>
</tr>
<tr>
<td>Moderna</td>
<td>mRNA</td>
<td>≥ 18 years</td>
<td>Two doses IM 100 ug, 0.5 mL each; 1 month (28 days) apart</td>
<td>94.1% at 14 days post second dose</td>
<td>Known history of a severe allergic reaction (i.e. anaphylaxis) to any component of the Moderna COVID-19 vaccine (ex: PEG/laxatives)</td>
</tr>
<tr>
<td>Janssen</td>
<td>Adenovirus vector</td>
<td>≥ 18 years</td>
<td>Single dose IM 0.5 mL</td>
<td>76.7% and 85.4% effective against severe/critical disease at least 14 and 28 days after vaccine, respectively. 0 hospitalizations after 28 days and 0 COVID-19 related deaths during the 8 weeks of study.</td>
<td>Known history of severe allergic reaction (i.e. anaphylaxis) to any component of the Janssen COVID-19 vaccine</td>
</tr>
</tbody>
</table>
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
  - 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

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

### Description

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech COVID-19 vaccine</th>
<th>Moderna COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
</tr>
<tr>
<td>Lipids</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
</tr>
<tr>
<td></td>
<td>(N4-hydroxybutyl)(2-naphthalenyl)bis(2-hydroxyethyl)</td>
<td>SM-102: (N4-hydroxybutyl)(2-naphthalenyl)bis(2-hydroxyethyl)</td>
</tr>
<tr>
<td>Salts, sugars, buffers</td>
<td>Potassium chloride</td>
<td>Tromethamine</td>
</tr>
<tr>
<td></td>
<td>Monosodium phosphate</td>
<td>Tromethamine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>Sucrose</td>
</tr>
</tbody>
</table>

* Neither vaccine contain eggs, gelatin, latex, or preservatives
The CDC currently recommends individuals receive the mRNA COVID-19 vaccine alone with a minimum of 14 days before or after administration with any other vaccine. However, when deemed clinically necessary and the benefits of vaccine co-administration outweigh potential risks, it is recommended to provide patients with all necessary vaccinations regardless of timeframe in relation to mRNA COVID-19 vaccine (i.e. tetanus toxoid-containing vaccination in setting of wound management). In situations where mRNA COVID-19 vaccines are provided within a 14-day timeframe of another vaccine, there is no need to repeat either vaccine.6

It is currently not recommended to interchange the vaccines (i.e. receive one dose of Pfizer and one dose of Moderna) since there is no data on the efficacy or safety of this practice.

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 recommended6.

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 time6.

Receipt of the mRNA COVID-19 vaccine should not affect treatment decisions (including the use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments should a patient develop acute COVID-19 illness6.

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 Pfizer-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). 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.

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.
Patients with coagulopathies or on anticoagulants
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.

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).

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).

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.

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.

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.
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.

**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](https://vaers.hhs.gov) or by calling 1-800-822-7967.


**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.

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

**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.

**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.

**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.

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.

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).

Pregnant patients should be supported regardless of their decision to receive or decline COVID-19 vaccination.

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.

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.

Janssen Vaccine
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. 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**

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.

**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.

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.

**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.

**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.
Quarantine Guidance
All vaccinated persons should be advised to continue to follow all guidance to protect themselves and others 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:

- Are fully vaccinated (i.e., ≥2 weeks following receipt of the second dose in a 2-dose vaccine 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.

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.

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. 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. 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 infection16.

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 infection16.

Current Miami-Dade County Testing Sites can be found at:
https://www.floridadisaster.org/covid19/testing-sites/?fbclid=IwAR0jiqxcUC6buG6UWA8PuSiNNyZSb9i6JM4uZPDAPqYG9SaZEUWtVl354&gclid=CjwKCAjwkdL6BRAREiwA-kiyczD4kdx2er-LRjsNAgDKwgsjPLXw9twO0a55kHN7h1TnSJn96RoC6kQAVD_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-1917. 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.
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\textsuperscript{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
   - Hemothysis
   - 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 (\geq 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\textsuperscript{19}.

Based on the current evidence, the CDC has identified people \geq 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 2 94
      - If resting 2 96 2 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)\(^1\)
   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\(^1\)
      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\(^1\):
         "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:**
   1. Vomiting and/or diarrhea: “How often? Are you able to drink without vomiting?”
   2. Fluid intake. Decreased food intake is normal in illness and would focus the patient on keeping hydrated rather than eating.
   3. 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
   4. Mentation: Important to know the patient's baseline. Can ask family and/or roommates to describe any changes or increased confusion or lethargy.
   5. 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)
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:

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\textsuperscript{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\textsuperscript{20}.

c. **Qualifying Criteria:**
   - Individuals aged $\geq 12$ years and weigh $\geq 40$ kg who have one of the following conditions:
     - $\geq 35$
     - Chronic kidney disease
     - Diabetes mellitus
     - Immunosuppressive disease
     - Currently receiving immunosuppressive treatment
   - $\geq 65$
   - $\geq 55$ 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:
     - $85^{th}$ 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\textsuperscript{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 Imdevimab 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 Jackson Memorial Hospital, please visit [https://jhsiami.org/stewardship/](https://jhsiami.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](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\textsuperscript{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\textsuperscript{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
(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
Per current CDC guidelines, average risk patients with COVID-19 infection do not require a negative test result to be cleared from isolation.

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 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.

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. 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. 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. 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.

   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.

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:

### 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.
   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.
      - Use a separate bathroom, if possible.
      - Avoid sharing utensils, dishware, and towels with other members of the household.

28. ..
29. ..
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](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](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**

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

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.
**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.*

△ 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.
References


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

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
Negative test

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

Discontinue isolation
Discuss repeat testing with Ped ID

Is patient improving and alternative diagnosis likely?

Yes
No

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

Appendix 2
COVID-19 Testing Guidelines for Admitted Symptomatic Pediatric Patients

Algorithm based on Clinical Guidance and CDC Recommendations

Updated 4.6.2020
### COVID-19 Testing Algorithm for Pediatric Patients (Emergency Department)

Patient presents with symptoms concerning for COVID-19 as stated in the guidelines by the Florida Department of Health and Jackson Memorial Hospital

If available, place patient in a negative pressure room.

If a negative pressure room is unavailable, then place patient in a single room with the door closed. Place sign on door for respiratory evaluation.

*If the patient requires aerosol generating procedures, place in a negative pressure room.

**Aerosol generating procedures:**
1. Intubation
2. Non-invasive ventilation
3. High-flow nasal cannula
4. Nebulizer treatments
5. Tracheostomy suctioning

Evaluate for other causes of symptoms and perform clinical assessment per Emergency Department standard of care.

Does patient require admission?

**Yes,** meets criteria for COVID-19 testing per Florida Department of Health and Jackson Memorial Hospital Guidelines

Attending to perform test for SARS-CoV-2 and RVP at the same time if clinically indicated.

**Yes,** but does NOT meet criteria for COVID-19 testing per Florida Department of Health and Jackson Memorial Hospital Guidelines

Consider COVID-19 testing in patients being admitted with the following symptoms:

1. Pharyngeal erythema
2. Vomiting and/or Diarrhea
3. Loss of smell or taste

Discharge patient with education for self-quarantine x 14 days. Instruct to return if symptoms worsen.
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

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Available Community Laboratory Testing for COVID Diagnosis and Screening

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

**Key Features**

**SARS-CoV-2 nucleic acid amplification (PCR)**

- **Most reliable test for diagnosis of acute COVID-19.**
- Detects Viral RNA

**SARS-CoV-2 Antigen (Ag)**

- Alternate rapid testing.
- Targets 1 or more portions of the virus (env, N, S, RdRp, ORF1)

**Serologic assays for SARS-CoV-2**

- COVID Specific Total IgM and IgG
  - Supports assessment of high-risk populations and diagnosis of post-infectious syndromes (including MIS-C)

<table>
<thead>
<tr>
<th>Feature</th>
<th>SARS-CoV-2 nucleic acid amplification (PCR)</th>
<th>SARS-CoV-2 Antigen (Ag)</th>
<th>Serologic assays for SARS-CoV-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity/Specificity</td>
<td>95-100%/71-98%</td>
<td>84-97%/100%</td>
<td>95%</td>
</tr>
<tr>
<td>Positive</td>
<td>No Confirmatory Testing Needed</td>
<td>No Confirmatory Testing Needed</td>
<td>No Confirmatory Testing Needed</td>
</tr>
<tr>
<td>Negative</td>
<td>Only repeat if high clinical suspicion</td>
<td>SARS-CoV2 PCR test to Confirm</td>
<td>Consider SARS-CoV2 PCR if early illness</td>
</tr>
<tr>
<td>Timing</td>
<td>Day 1 to 21 after symptom onset</td>
<td>Days 1 to 6 After symptom onset</td>
<td>Day 4 to Week 7 After symptom onset</td>
</tr>
<tr>
<td>Result Availability</td>
<td>Lab Dependent: 1 - 72hrs</td>
<td>15 minutes</td>
<td>15 minutes – 48 hours</td>
</tr>
<tr>
<td>Sample</td>
<td>Nasopharyngeal swab</td>
<td>Nasal swab</td>
<td>Serum sample</td>
</tr>
<tr>
<td></td>
<td>Throat swab</td>
<td>Saliva sample</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Saliva sample</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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


**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.


### Return to School

**Get help planning for return to school or virtual learning**


### 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


### 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

Patient Group Specific Recommendations
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.

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.

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.

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]

**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**
  - No symptoms

- **Mild Disease**
  - **Respiratory Score for Clinical Assessment of Respiratory Distress**
    - See Table below
  - Risk stratification for Severe Disease
    - Low Risk
    - High Risk

- **Moderate Disease**
  - Fever
  - Nasal congestion
  - Cough
  - Diarrhea
  - Vomiting
  - Myalgia
  - Sore throat

- **Severe/Critical Disease**
  - Fever
  - Nasal congestion
  - Cough
  - Diarrhea
  - Vomiting
  - Myalgia
  - Sore throat
  - Tachypnea
  - Retractions
  - Respiratory distress
  - SpO2 <94%
  - Signs/symptoms of dehydration

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

- Follow up febrile patients in 24-48hrs with a telemedicine visit
- Follow up in 12 – 24 hours via telemedicine visit

**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

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

**Respiratory Clinical Score**

**Assessment of Severity of Dehydration**

**Table from the Harriet Lane Handbook, 21st edition**

Current Monoclonal Antibody Therapy available for children with Covid-19

Regeneron Antibody Cocktail (Casirivimab and Imdevimab)

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

Bamlanivimab

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:
- 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.

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://www.regeneron.com/covid19

Guidance Regarding Isolation & Quarantine Duration

- 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.

Updated from CDC guidelines Dec 3, 2020
Clinical Criteria for Diagnosis of Multi-System Inflammatory Syndrome Associated with COVID-19

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

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

Clinical Criteria

- Fever
- Minimum 24-hours of T ≥38.0 C
- Severe illness necessitating hospitalization
- ≥2 Organ Systems Affected
- ± Kawasaki like Symptoms
  - Mucocutaneous inflammation, conjunctivitis, rash, lymphadenitis, stomatitis, extremity swelling
- Myocarditis, ↑ Troponin, ↑ pro-BNP, coronary aneurysms, hypotension, hypoperfusion, tachycardia
- Thrombocytopenia, neutrophilia, lymphopenia
- Nausea, Vomiting, Abdominal pain, Diarrhea, ↑ AST/ALT
- Headache, Meningismus, Lethargy
- Hypoxemia, Pulmonary infiltrates, chest pain
- Hyponatremia, Renal failure

Laboratory Evidence of Inflammation

≥ 1 of the following

- Decreased
  - Albumin
  - Lymphocytes

- Increased
  - ESR, CRP, IL-6
  - Neutrophils
  - Ferritin
  - D-Dimer
  - Fibrinogen
  - Procalcitonin
  - Lactate Dehydrogenase

No alternative diagnosis

Age <21 years

Laboratory or Epidemiologic Evidence of SARS-CoV-2

Stage I (Early Infection)

Nasopharyngeal colonization +/- Mild infection

Stage II (Pulmonary Phase)

No Pulmonary Infection

Unusual in children due to lack of ACE2 receptors & other factors

Stage III (Hyperinflammation Phase)

Occurs due to Hyperimmune Response to infection with Excess Macrophage Activation & Cytokine Release
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.

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 Considerations for COVID-19 Infection and MIS-C

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.\textsuperscript{15,16} Patients who take NSAIDS chronically should be advised to continue therapy as prescribed.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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

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

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.
<table>
<thead>
<tr>
<th>Drug Name &amp; Class</th>
<th>Indications &amp; Recommendations for Inpatient Use</th>
<th>Consequences Requiring Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remdesivir</td>
<td>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</td>
<td>No long-term side effects anticipated from short course of therapy.</td>
</tr>
<tr>
<td>Steroids</td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td>IVIG</td>
<td>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</td>
<td>Live Vaccines should be delayed for 11 months after administration. Vaccine titers and repeat dosing of some vaccines may be needed after IVIG use.</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Low dose aspirin recommended in MIS-C pediatric patients unless contraindicated.⁹ Duration to be determined by Cardiology Team</td>
<td>Monitor for GI upset and bleeding or easy bruising with use.</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>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.</td>
<td>Monitor for excessive bleeding or easy bruising. If therapy continued post discharge, duration to be determined by a specialist.</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>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&gt;24 hours post steroids/IVIG.⁶</td>
<td>Monitor for infections including TB, especially if concurrently taken with immunosuppression. Avoid live vaccines for 3 months</td>
</tr>
<tr>
<td>Anakinra</td>
<td>Considered for cytokine storm syndrome in children.¹¹</td>
<td>Monitor for infections including TB. Avoid live vaccines for 3 months</td>
</tr>
<tr>
<td>Lopinavir</td>
<td>Not recommended in children. For adults, only recommended under clinical trial.⁸</td>
<td>Monitor for Hyperglycemia which may persist after discontinuation. No long-term consequences from short term use expected. Frequent use may lead to GI upset from gastritis and Acute Kidney Injury.</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>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</td>
<td>No long-term consequences from short term use expected. Myelosuppression seen with high doses and long-term use.</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
<td>Safety of hydroxychloroquine in children is still controversial. Monotherapy with hydroxychloroquine in adults is currently only recommended under clinical trial.⁵,⁶,⁸</td>
<td>No long-term consequences from short term use expected.</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>Routine use of azithromycin is not recommended except for suspected superimposed bacterial pneumonia.⁶</td>
<td>No long-term consequences from short term use expected.</td>
</tr>
<tr>
<td>Convalescent plasma</td>
<td>Current research is controversial since evidence is under significant risk of confounding bias.⁶</td>
<td>No long-term consequences from short term use expected.</td>
</tr>
</tbody>
</table>


Back to School Guideline for the COVID-19 Pandemic


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.

Return to Sports Recommendations for Athletes Affected by COVID-19

Mild COVID symptoms, exposure, or asymptomatic:
- 14-day rest period &
- >14 days without symptoms

Moderate COVID symptoms:
- 14-day rest period &
- If prolonged fever or cardiac symptoms obtain EKG &
- PCP* +/- subspecialty clearance

Severe COVID symptoms (MIS-C, hypotension, arrhythmia, organ failure):
- 3 to 6-month rest period &
- PCP* and subspecialty clearance &
- Normal cardiac function

Gradual return to sports
- Small group size
- Frequent disinfection
- Social distance, good ventilation, mask if exercise is non-vigorous
- General testing not recommended unless confirmed exposure or symptoms

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

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

Miami Dade: [http://reopening.dadeschools.net/](http://reopening.dadeschools.net/)
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

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®

Children's Hospital of Philadelphia

 Centers for Disease Control
Phone: +1 (800) 232-4636

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

Community Resources

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

Miami-Dade County Temporary Housing Program:
Call 305-614-1716 from 8 am and 5 pm daily

Government based organizations for assistance with food & housing insecurity
References


Acknowledgements

We would like to thank the additional individuals who assisted with the development of this guideline. This was a collaboration between members of the Pediatric and Internal Medicine Departments of the University of Miami/Jackson Health Group. The following people were vital to the development of this document.

We thank them for their time and invaluable input.

Dr. Lillian Abbo
Dr. Michael Borchetta
Dr. Brandon Chatani
Dr. Hector Chavez
Dr. Barry Gelman
Dr. Bhavarth Shukla
Appendix 3

**Charge RN (Desk)**
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 will be needed after case. (Clorox 360; UV)

**OR/GI Runner (RN preferred)**
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

**RN Circulator**
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 of OR
5. Ensure COVID supply cart is outside of OR

**Anesthesia Team**
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

**Surgical/GI Technician**
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

**Pre Procedure**
*Prior to arrival of pt into room*

**Intra Procedure**
1. Be available for support/additional needs. (blood)
2. Traffic control in corridor as needed

**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)

**Facilitate Transfer of Patient**
1. Delegate staff member to wipe down and restock COVID cart, anesthesia cart etc.

**Doff PPE**
1. Wipe down and restock COVID supply cart

**Exit Room**

**Follow-Up**
1. Delegate staff member to wipe down and restock COVID cart, anesthesia cart etc.

**Don PPE**

**PPE SAFETY PAUSE AS A TEAM**
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

**Enter Room – Once in Room must stay for entirety of procedure**
Use OR Runner as needed

**Perform Procedure**
Do not enter and exit OR Suite unless coordinated with Charge RN/Desk

**Facilitate Transfer of Patient**
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

**DE-BRIEF POST PATIENT TRANSPORT**

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**POSITIVE 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

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**Appendix 3**

**OR/GI Runner**
## Registration/PAT

1. Day of surgery, patient arrives to DTC Registration (DT/OR/IR)
   - Security check at all entry points: masks on persons entering Hospital. VUMI Guest Services Staff provides mask (SURGICAL Mask) for patient/acompanying adults & notifies patient access of patient arrival. *All patients treated as PUI*
   1. Is patient on REGISTRATION BYPASS LIST?
     - YES → Activate surgical encounter, ID COVID19 Protocol Document
     - NO → Register patient, isolate pt

## Preop Area: DTC

- **(All PEDS & confirmed negative COVID19 patients)**
- **SW3** (All confirmed positive COVID19 patients)
- *SW 3: Spot 12 is negative pressure, can be used for intubation as needed*
- **All NEGATIVE PEDS and GI patients will be prepped in SW3**
- 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.

## Preop Area: SW3

- **(All confirmed positive COVID19 patients)**
- *SW 3: Spot 12 is negative pressure, may be used if needed.*

## Preop Area: SW 3: Spot 12

- **(confirmed positive COVID+ patients)**
- **(Procedural Staff/Anesthesia should transport pt to procedure area directly after pt assessment/ interview; do not doff until after procedure completed.)**
- **(Transport back to preop area for D/C) contact responsible adult for transport home (To designated pick up area)**

## 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

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

## NO VISITORS ALLOWED IN ADULT PREOP OR POSTOP AREAS

- **Case by case:**
  - Peds/mother baby patients

## 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.

## 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.

## Registration/PAT

1. Day of surgery, patient arrives to DTC Registration (DT/OR/IR)
   - Security check at all entry points: masks on persons entering Hospital. VUMI Guest Services Staff provides mask (SURGICAL Mask) for patient/acompanying adults & notifies patient access of patient arrival. *All patients treated as PUI*

## Preop 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

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### Preop Nurse


### Anesthesia & Procedural Team


### PACU RN

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

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### 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 prep for D/C home once D/C criteria met

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### Recovery (DTC PACU-All confirmed negative pts)

All COVID+ pts will be recovered in Procedure suites; TOP: Trauma Recovery spot 1 is negative pressure, may be used if needed.
Return to Work Criteria for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance)

Updated June 2, 2021

CDC guidance for SARS-CoV-2 infection may be adapted by state and local health departments to respond to rapidly changing local circumstances.

This guidance provides information for making decisions about return to work for healthcare personnel (HCP) with SARS-CoV-2 infection using a symptom-based strategy. See history of updates.

Summary of Recent Changes

Updates as of June 2, 2021

As of June 2, 2021

- Clarified that a laboratory-based NAAT is recommended if using the test-based strategy.
- Updated the list of immunocompromising conditions to include hematologic malignancies and other examples of immunosuppressive medications.
- Included recommendation to consult occupational health if using the test-based strategy to determine when HCP can return to work.

Key Points

- The symptom-based strategy (described below) depends on: the time period since symptoms first appeared and whether symptoms are improving; whether HCP are immunocompromised; the severity of their illness
- A test-based strategy is not recommended (except as noted below)

Introduction

This guidance is for occupational health programs and public health officials making decisions about return to work for HCP with confirmed SARS-CoV-2 infection, or who have suspected SARS-CoV-2 infection (e.g., developed symptoms of COVID-19) but were never tested for SARS-CoV-2.
HCP with symptoms of COVID-19 should be prioritized for viral testing with approved nucleic acid or antigen detection assays. When a clinician decides that testing a person for SARS-CoV-2 is indicated, negative results from at least one FDA Emergency Use Authorized COVID-19 laboratory-based NAAT for detection of SARS-CoV-2 RNA indicates that the person most likely does not have an active SARS-CoV-2 infection at the time the sample was collected. A second test for SARS-CoV-2 RNA may be performed at the discretion of the evaluating healthcare provider, particularly when a higher level of clinical suspicion for SARS-CoV-2 infection exists. If the second test is positive, consultation with an infectious diseases expert should be considered to resolve the discrepant results.

For HCP who were suspected of having COVID-19 and had it ruled out, return to work decisions should be based on their other suspected or confirmed diagnoses.

Decisions about return to work for HCP with SARS-CoV-2 infection should be made in the context of local circumstances. In general, a symptom-based strategy should be used as described below. The time period used depends on the HCP’s severity of illness and if they are severely immunocompromised.

A test-based strategy is not recommended (except as noted below) because, in the majority of cases, it results in excluding from work HCP who continue to shed detectable SARS-CoV-2 RNA but are no longer infectious.

Asymptomatic HCP with potential exposure: For guidance about assessment of risk and application of work restrictions for asymptomatic HCP with potential exposure to patients, visitors, or other HCP with confirmed COVID-19, refer to the Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19.

Symptom-based strategy for return to work.

HCP with mild to moderate illness who are not 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

HCP who were asymptomatic throughout their infection and are not severely immunocompromised:

- At least 10 days have passed since the date of their first positive viral diagnostic test.

HCP 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
- 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
- Consider consultation with infection control experts

HCP who are 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. Consultation with infectious diseases specialists is recommended. Use of a test-based strategy, in consultation with occupational health, for determining when these HCP may return to work could be considered.
As described in the Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19, an estimated 95% of severely or critically ill patients, including some with severe immunocompromise, no longer had replication-competent virus 15 days after onset of symptoms; no patient had replication-competent virus more than 20 days after onset of symptoms. Recovery of replication-competent virus has been reported in severely immunocompromised patients beyond 20 days, and as long as 143 days, after a positive SARS-CoV-2 test result.

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 example, HCP with characteristics of severe illness may be most appropriately managed by staying home for at least 15 days before return to work. Use of a test-based strategy, in consultation with infectious disease specialists and occupational health, for determining when HCP who are severely immunocompromised may return to work could be considered.

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 when HCP with SARS-CoV-2 infection may return to work, 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 HCP at any point in their clinical course should be used when determining when they may return to work.

**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.

Severely immunocompromised definition

The studies used to inform this guidance did not clearly define “severely immunocompromised”. For the purposes of this guidance, CDC used the following definition:

- Some conditions, such as being on chemotherapy for cancer, hematologic malignancies, being within one year out from receiving a hematopoietic stem cell or solid organ transplant, untreated HIV infection with CD4 T lymphocyte count < 200, combined primary immunodeficiency disorder, and taking immunosuppressive medications (e.g., drugs to suppress rejection of transplanted organs or to treat rheumatologic conditions such as mycophenolate and rituximab, receipt of prednisone >20mg/day for more than 14 days), may cause a higher degree of immunocompromise and require actions such as lengthening the duration of HCP work restrictions.

- Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect occupational health actions to prevent disease transmission.

- Ultimately, the degree of immunocompromise for HCP is determined by the treating provider, and preventive actions are tailored to each individual and situation.
When to use a test-based strategy

In some instances, a test-based strategy, in consultation with occupational health, could be considered to allow HCP to return to work earlier than if the symptom-based strategy were used. However, as described in the Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19, many individuals will have prolonged viral shedding, limiting the utility of this approach. A test-based strategy could also be considered for some HCP (e.g., those who are severely immunocompromised) in consultation with local infectious diseases experts if concerns exist for the HCP being infectious for more than 20 days.

The criteria for the test-based strategy are:

**HCP who are symptomatic:**

- 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 ≥24 hours apart (total of two negative specimens) tested using an FDA-authorized laboratory-based NAAT to detect SARS-CoV-2 RNA. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).

**HCP who are not symptomatic:**

- Results are negative from at least two consecutive respiratory specimens collected ≥24 hours apart (total of two negative specimens) tested using an FDA-authorized laboratory-based NAAT to detect SARS-CoV-2 RNA. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).

Return to Work Practices and Work Restrictions

- After returning to work, HCP should self-monitor for symptoms, and seek re-evaluation from occupational health if symptoms recur or worsen.

Mitigating HCP staffing shortages

Maintaining appropriate staffing in healthcare facilities is essential to providing a safe work environment for HCP and safe patient care. As the COVID-19 pandemic progresses, staffing shortages will likely occur due to HCP exposures, illness, or need to care for family members at home. Healthcare facilities must be prepared for potential staffing shortages and have plans and processes in place to mitigate them, including considerations for permitting HCP to return to work without meeting all return to work criteria above. Refer to the Strategies to Mitigate Healthcare Personnel Staffing Shortages document for information.

History of Updates

As of February 16, 2021

Changes to more closely align guidance with updates to the Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19:

HCP who are severely immunocompromised could remain infectious more than 20 days after symptom onset. Consultation with infectious diseases specialists is recommended; use of a test-based strategy for determining when these HCP may return to work could be considered.
As of August 10, 2020

Changes to more closely align guidance with Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19:

- For HCP with severe to critical illness or who are severely immunocompromised, the recommended duration for work exclusion was changed to at least 10 days and up to 20 days after symptom onset.
- Recommendation to consider consultation with infection control experts.
- Added example applying disease severity in determining duration before return to work.
- Added hematopoietic stem cell or solid organ transplant to severely immunocompromised conditions.
Summary of Recent Changes

As of March 10, 2021

The interim guidance was updated to:

- 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.

Purpose

This interim guidance is intended to assist with assessment of risk and application of work restrictions for asymptomatic healthcare personnel (HCP) with potential exposure to patients, visitors, or other HCP with confirmed SARS-CoV-2 infection. Separate guidance is available for travel- and community-related exposures. CDC has created frequently asked questions that can be used to inform risk assessment for patients and visitors exposed to SARS-CoV-2 in a healthcare setting. CDC has also released guidance about return to work criteria for HCP with COVID-19 and strategies for mitigating HCP staffing shortages.

Because of their often extensive and close contact with vulnerable individuals in healthcare settings, a conservative approach to HCP monitoring and applying work restrictions is recommended to prevent transmission from potentially contagious HCP to patients, other HCP, and visitors. Occupational health programs should have a low threshold for evaluating symptoms and testing HCP.

The feasibility and utility of performing contact tracing of exposed HCP and application of work restrictions depends upon the degree of community transmission of SARS-CoV-2 and the resources available for contact tracing. For areas with:
Minimal to no community transmission of SARS-CoV-2, sufficient resources for contact tracing, and no staffing shortages, risk assessment of exposed HCP and application of work restrictions may be feasible and effective.

- Moderate to substantial community transmission of SARS-CoV-2, insufficient resources for contact tracing, or staffing shortages, risk assessment of exposed HCP and application of work restrictions may not be possible.

This guidance is based on currently available data about SARS-CoV-2. Recommendations regarding which HCP are restricted from work might not anticipate every potential scenario and will change if indicated by new information. Occupational health programs should use clinical judgement as well as the principles outlined in this guidance to assign risk and determine the need for work restrictions. This approach might be updated as more information becomes available and as response needs change in the United States.

Evolution of Currently Recommended HCP Assessment Guidance

CDC’s recommendations for the assessment of and response to HCP exposures to SARS-CoV-2-infected patients have evolved as the incidence of COVID-19 in the United States has changed. Before recognized widespread transmission in the United States, CDC recommended an aggressive approach to identifying exposed HCP and included recommendations for restricting some HCP from work who had higher risk exposures. As community spread of COVID-19 became apparent in many areas and as transmission from asymptomatic individuals was recognized, this approach became impractical and diverted resources away from other critical infection prevention and control functions. In response, CDC advised facilities to consider forgoing formal contact tracing and work restrictions for HCP with exposures in favor of universally applied symptom screening and source control strategies.

This updated guidance describes a process for resumption of contact tracing and application of work restrictions that can be considered in areas where spread in the community has decreased and when capacity exists to perform these activities without compromising other critical infection prevention and control functions. It has been simplified to focus on exposures that are believed to result in higher risk for HCP (e.g., prolonged exposure to patients with SARS-CoV-2 infection when HCP’s eyes, nose, or mouth are not covered). Other exposures not included 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. The specific factors associated with these exposures should be evaluated on a case by case basis; interventions, including restriction from work, can be applied if the risk for transmission is deemed substantial.

The operational definition of “prolonged” refers to a cumulative time period of 15 or more minutes during a 24-hour period, which aligns with the time period used in the guidance for community exposures and contact tracing. Although this definition can be used to guide decisions about work restriction, appropriate follow-up, and contact tracing, 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 the purposes of this guidance, any duration should be considered prolonged if the exposure occurs during performance of an aerosol generating procedure.

Footnote 1

Data are insufficient to precisely define the duration of time that constitutes a prolonged exposure. Until more is known about transmission risks, it is reasonable to consider a cumulative exposure of 15 minutes or more during a 24-hour period as 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, any duration should be considered prolonged if the exposure occurred during performance of an aerosol generating procedure.
Guidance for Asymptomatic HCP Who Were Exposed to Individuals with Confirmed SARS-CoV-2 Infection

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 (See row 1 of the table).

Following a higher-risk exposure, work restriction of asymptomatic HCP who have recovered from SARS-CoV-2 infection in the prior 3 months and asymptomatic HCP who are fully vaccinated HCP is not necessary. Additional information about these scenarios, including possible exceptions, is available here and here.

HCP who have traveled should continue to follow CDC travel recommendations and requirements, including restriction from work, when recommended for any traveler. HCP with community exposures should be restricted from work if they have a community exposure for which quarantine is recommended.

This guidance applies to HCP with potential exposure in a healthcare setting to patients, visitors, or other HCP with suspected SARS-CoV-2 infection. Exposures can also occur after prolonged close contact with someone with suspected SARS-CoV-2 infection when testing has not yet occurred or if results are pending. Work restrictions described in this guidance might be applied to HCP exposed to such an individual if test results for the individual are not expected to return within 48 to 72 hours. Therefore, a record of HCP exposed to individuals with suspected SARS-CoV-2 infection should be maintained. If test results will be delayed more than 72 hours or the patient is positive for SARS-CoV-2 infection, then the work restrictions described in this document should be applied.

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Personal Protective Equipment Used</th>
<th>Work Restrictions</th>
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| HCP who had prolonged close contact with a patient, visitor, or HCP with confirmed SARS-CoV-2 infection | • HCP not wearing a respirator or facemask  
• HCP not wearing eye protection if the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask  
• HCP not wearing all recommended PPE (i.e., gown, gloves, eye protection, respirator) while performing an aerosol-generating procedure | • Exclude from work for 14 days after last exposure  
• Advise HCP to monitor themselves for fever or symptoms consistent with COVID-19  
• 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. |

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<thead>
<tr>
<th>Exposure</th>
<th>Personal Protective Equipment Used</th>
<th>Work Restrictions</th>
</tr>
</thead>
</table>
| HCP other than those with exposure risk described above | • N/A | • No work restrictions  
• Follow all recommended infection prevention and control practices, including wearing a facemask for source control while at work, monitoring themselves for fever or symptoms consistent with COVID-19 and not reporting to work when ill, and undergoing active screening for fever or symptoms consistent with COVID-19 at the beginning of their shift.  
• 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. |

HCP with travel or community exposures should inform their occupational health program for guidance on need for work restrictions. HCP who have traveled should continue to follow CDC travel recommendations and requirements, including restriction from work, when recommended for any traveler. HCP with community exposures should be restricted from work if they have a community exposure for which quarantine is recommended.

HCP=healthcare personnel

1. Data are insufficient to precisely define the duration of time that constitutes a prolonged exposure. Until more is known about transmission risks, it is reasonable to consider an exposure of 15 minutes or more as prolonged. However, any duration should be considered prolonged if the exposure occurred during performance of an aerosol generating procedure.

2. Data are limited for the definition of close contact. 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.

3. Determining the time period when the patient, visitor, or HCP with confirmed SARS-CoV-2 infection could have been infectious:
   1. 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.
   2. 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.
      1. In general, individuals with SARS-CoV-2 infection should be considered potentially infectious beginning 2 days after their exposure until they meet criteria for discontinuing Transmission-Based Precautions.
      2. 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. Cloth face coverings are not considered PPE because their capability to protect HCP is unknown.

5. Work restriction of asymptomatic HCP who have recovered from SARS-CoV-2 infection in the prior 3 months and asymptomatic HCP who are fully vaccinated HCP is not necessary. Additional information about these scenarios, including possible exceptions, is available here and here.

6. If staffing shortages occur, it might not be possible to exclude exposed HCP from work. For additional information and considerations refer to Strategies to Mitigating HCP Staffing Shortages.

7. Guidance addressing testing HCP, including asymptomatic HCP with known or suspected exposure to SARS-CoV-2, is available in the Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2

8. 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]).

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, 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.

More Information

Public Health Recommendations after Travel-Associated COVID-19 Exposure

Public Health Recommendations for Community-Related Exposure

Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 (Interim Guidance)

Strategies to Mitigate Healthcare Personnel Staffing Shortages

Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease (COVID-19) in a Healthcare Setting.

Summary of Changes

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 Mar. 11, 2021
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases
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

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 (i.e., 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:

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 (https://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

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:
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

**COVID Testing for Adult ED Admissions, Transfers, & Direct Admits**

**Is patient asymptomatic?**
- Yes: Order Tier 1 PCR
  - Test Result Positive?:
    - Yes: Admit to Isolation
    - No: Order BD Veritor Antigen Test
  - Test Result Negative: No isolation; Assign to standard bed
- No/Unknown: Order BD Veritor Antigen Test
  - Test Result Positive?:
    - Yes: Admit to Isolation
    - No: Assign Pt to bed & Order Tier 1 PCR
  - Test Result Negative: No isolation; Assign to standard bed

*Proof of full vaccination must come from Florida Shots, AND be documented in EMR*
Inpatient Consult

Check record for proof of FULL vaccination AND/OR prior COVID result within 14 days

Yes

Is case an Emergency?

No

Day prior to procedure check record for proof of FULL vaccination AND/OR prior COVID result within 14 days

Yes

COVID19 Negative OR Fully Vaccinated?

No

COVID19 Negative OR Fully Vaccinated?

Yes

Is patient asymptomatic?

No/Uknown

Perform procedure with standard PPE

Perform procedure with COVID+ PPE & Contact Infection Control re: Isolation

Yes

Schedule & Perform procedure with standard PPE

No/Uknown

Discharge Pt and follow Procedural Area Outpatient COVID19 Workflow*

Perform procedure with COVID+ PPE & Contact Infection Control re: Isolation

*Proof of full vaccination must come from Florida Shots, AND be documented in EMR

Version: 05/28/2021
OP Procedure

Check EMR:
Does Pt have COVID-19 Test < 48 hrs?

COVID-19 Test Negative?

1. Inform Provider
2. Follow OP COVID-19+ Test Process*

COVID-19 Test Negative?

1. Inform Provider
2. Follow OP COVID-19+ Test Process*

Book Case

*Proof of full vaccination must come from Florida Shots. AND be documented in EMR

---

Day Prior to Procedure

Check Medical Record for COVID-19 Results or vaccination history

Are Results Available for COVID or vaccination?

Yes

COVID-19 Test Negative or Proof of Vaccination?

Yes

Screen Pt via phone for COVID19 Symptoms

Yes

1. Inform Provider to order PCR test or cancel case
2. Follow OP COVID19+ Test Process*

Telephone Screen Negative?

Yes

Confirm Pt for Procedure

No

1. Call Lab to F/U on Test Results or request proof of vaccination from pt
2. If Results unavailable and no proof of vaccination, consider re-test
3. If Results found or proof of vaccination provided, continue with processing

No

1. Place COVID19 PCR Test Order
2. Send Excel to PAT to designate time for COVID Testing
3. Call Pt to inform of appointment and instructions

No

Yes

No

No

Yes

No

No

Yes

No

No

Yes

No

No

Yes

No

No

Yes

1. Inform Provider
2. Provider to decide to:
   A) Postpone procedure
   B) Follow COVID19+ Test Process*

Procedure Performed

---

3 Days Prior to Procedure

OP Procedure

Patient fully vaccinated
OR has history of COVID+ diagnosis >10 days AND <90 days

Yes

Is patient asymptomatic?

Yes

Book Case

No

Check EMR:
Does Pt have COVID-19 Test < 48 hrs?

No

COVID-19 Test Negative?

1. Inform Provider
2. Follow OP COVID-19+ Test Process*
CDC guidance for SARS-CoV-2 infection may be adapted by state and local health departments to respond to rapidly changing local circumstances.

This guidance provides information on using a symptom-based strategy to determine when Transmission-Based Precautions can be discontinued for a patient with confirmed SARS-CoV-2 infection.

Interim Guidance

Summary of Recent Changes

Updates as of June 2, 2021

- Clarified that a laboratory-based NAAT is recommended if using the test-based strategy
- Updated the list of immunocompromising conditions to include hematologic malignancies and other examples of immunosuppressive medications.

Key Points

- Meeting criteria for discontinuation of Transmission-Based Precautions is not a prerequisite for discharge from a healthcare facility.
- The symptom-based strategy (described below) depends on the time period since symptoms first appeared and whether symptoms are improving; whether the patients is immunocompromised; the severity of their illness
- A test-based strategy is not recommended (except as noted below)
Introduction

This guidance is for infection control personnel making decisions about when to discontinue Transmission-Based Precautions for patients with confirmed SARS-CoV-2 infection.

Decisions about discontinuing Transmission-Based Precautions for patients with SARS-CoV-2 infection should be made in the context of local circumstances. In general, a symptom-based strategy should be used as described below. The time period used depends on the patient’s severity of illness and if they are severely immunocompromised.

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

A test-based strategy is not recommended (except as noted below) because, in the majority of cases, it results in prolonged isolation of patients who continue to shed detectable SARS-CoV-2 RNA but are no longer infectious.

Symptom-Based Strategy for Discontinuing Transmission-Based Precautions

Patients with mild to moderate illness who are not 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 severely immunocompromised:

- At least 10 days have passed since the date of their first positive viral diagnostic test.

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
- 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
- Consider consultation with infection control experts

Patients who are 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. Consultation with infectious diseases specialists is recommended. Use of a test-based strategy for determining when Transmission-Based Precautions may be discontinued could be considered.

As described in the Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19, an estimated 95% of severely or critically ill patients, including some with severe immunocompromise, no longer had replication-competent virus 15 days after onset of symptoms; no patients had replication-competent virus more than 20 days after onset of symptoms. Recovery of replication-competent virus has been reported in severely immunocompromised patients beyond 20 days, and as long as 143 days after a positive SARS-CoV-2 test result.

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 in determining the appropriate duration for specific patient populations. For example, patients with characteristics of severe illness may be
most appropriately managed with at least 15 days of isolation under Transmission-Based Precautions. Use of a test-based strategy, in consultation with infectious disease specialists, for determining when to discontinue Transmission-Based Precautions for patients who are severely immunocompromised could be considered.

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.

Severely immunocompromised definition

The studies used to inform this guidance did not clearly define “severely immunocompromised.” For the purposes of this guidance, CDC used the following definition:

- Some conditions, such as being on chemotherapy for cancer, hematologic malignancies, being within one year out from receiving a hematopoietic stem cell or solid organ transplant, untreated HIV infection with CD4 T lymphocyte count < 200, combined primary immunodeficiency disorder, and taking immunosuppressive medications (e.g., drugs to suppress rejection of transplanted organs or to treat rheumatologic conditions such as mycophenolate and rituximab, receipt of prednisone >20mg/day for more than 14 days), may cause a higher degree of immunocompromise and inform decisions regarding the duration of Transmission-Based Precautions.
- Other factors, such as advanced age, diabetes mellitus, or end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about duration of Transmission-Based Precautions.
- Ultimately, the degree of immunocompromise for the patient is determined by the treating provider, and preventive actions are tailored to each individual and situation.

When to use a test-based strategy

In some instances, a test-based strategy could be considered for discontinuing Transmission-based Precautions earlier than if the symptom-based strategy were used. However, as described in the Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19, many individuals will have prolonged viral shedding, limiting the utility of this
approach. A test-based strategy could also be considered for some patients (e.g., those who are severely immunocompromised) in consultation with local infectious diseases experts if concerns exist for the patient being infectious for more than 20 days.

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 ≥24 hours apart (total of two negative specimens) tested using an FDA-authorized laboratory-based NAAT to detect SARS-CoV-2 RNA. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).

**Patients who are not symptomatic:**

- Results are negative from at least two consecutive respiratory specimens collected ≥24 hours apart (total of two negative specimens) tested using an FDA-authorized laboratory-based NAAT to detect SARS-CoV-2 RNA. See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for 2019 Novel Coronavirus (2019-nCoV).

Discontinuation of empiric Transmission-Based Precautions for Patients Suspected of Having 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 suspected SARS-CoV-2 infection can be made based upon having negative results from at least one respiratory specimen tested using an FDA-authorized laboratory-based NAAT to detect SARS-CoV-2 RNA.

- If a higher level of clinical suspicion for SARS-CoV-2 infection exists, consider maintaining Transmission-Based Precautions and performing a second test for SARS-CoV-2 RNA.
- If a patient suspected of having SARS-CoV-2 infection is never tested, the decision to discontinue Transmission-Based Precautions can be made using the symptom-based strategy described above.

Ultimately, clinical judgement and suspicion of SARS-CoV-2 infection determine whether to continue or discontinue empiric Transmission-Based Precautions.

Disposition of Patients with SARS-CoV-2 Infection

Patients can be discharged from the healthcare facility whenever clinically indicated.

**If discharged to home:**

- The decision to send the patient home should be made in consultation with the patient's clinical care team and local or state public health departments. It should include considerations of the home's suitability for and patient's ability to adhere to home isolation recommendations. Guidance on implementing home care of persons who do not require hospitalization and the discontinuation of home isolation for persons with COVID-19 is available.

**If discharged to a nursing home or other long-term care facility (e.g., assisted living facility), AND**

If Transmission-Based Precautions are still required, the patient should go to a facility with an ability to adhere to infection prevention and control recommendations for the care of residents with SARS-CoV-2 infection. Preferably, the patient would be placed in a location designated to care for residents with SARS-CoV-2 infection.

- If Transmission-Based Precautions have been discontinued, the patient does not require further restrictions, based upon their history of SARS-CoV-2 infection.

Previous Updates

Updates from Previous Content

As of February 16, 2021

Changes to more closely align guidance with updates to the Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19:

- Patients who are severely immunocompromised could remain infectious more than 20 days after symptom onset. Consultation with infectious diseases specialists is recommended; use of a test-based strategy for determining when to discontinue Transmission-Based Precautions could be considered.

As of August 10, 2020

Changes to more closely align guidance with Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19:

- For patients with severe to critical illness or who are severely immunocompromised', the recommended duration for Transmission-Based Precautions was changed to at least 10 days and up to 20 days after symptom onset.
- Recommendation to consider consultation with infection control experts.
- Added example applying disease severity in determining duration of isolation using Transmission-Based Precautions.
- Added hematopoietic stem cell or solid organ transplant to severely immunocompromised conditions.
Low Risk Diagnostic Radiology Workflow
COVID19 Workflow

1. Pt to reschedule via Conifer
2. Instruct pt f/u with PCP/ Referring Team
3. Appointment Coordinator to f/u with Referring Team re postponing exam

Repeat Low Risk Diagnostic Rad Workflow for R/S Appointments

Can test wait 7-14 days?

Yes

No

Is telephone screening negative?

Yes

Confirm Appointment and follow standard PPE Protocol
Pt Dons Mask during visit

No

1. Proceed with Moderate Risk PPE and proceed with Low Risk Diagnostic Procedure
2. Have pt f/u with PCP following exam

Pt screened at time of appointment by Rad department 48 hrs in advance

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

<table>
<thead>
<tr>
<th></th>
<th>High Risk</th>
<th>Moderate Risk</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Procedures/studies that require airway access/maintenance, endotracheal intubation, lower GI tract involvement</td>
<td>Invasive procedures/studies without anticipation of contact/ manipulation of the respiratory or lower GI tract</td>
<td>Non-invasive procedures/studies or those that require peripheral intravenous access</td>
</tr>
<tr>
<td><strong>Pre-Testing Required</strong></td>
<td>Yes. Results required for elective procedures/studies; immediate pre-procedure test required in emergent situation</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>PPE Recommendation</strong></td>
<td>• Base layer* &lt;br&gt; • Isolation gown &lt;br&gt; • N95 respirator* with procedure mask as a protective cover &lt;br&gt; • Shoe covers* &lt;br&gt; • Hair cover* &lt;br&gt; • Eye protection (goggles and faceshield)* for intubation &lt;br&gt; • Two pairs of non-sterile gloves</td>
<td>• Isolation gown &lt;br&gt; • Non-sterile gloves &lt;br&gt; • N95 respirator* with procedure mask as a protective cover &lt;br&gt; • Eye protection*</td>
<td>• PPE per standard precautions AND &lt;br&gt; • Procedure mask* &lt;br&gt; • Eye protection*</td>
</tr>
<tr>
<td><strong>Environmental Cleaning and Disinfection</strong></td>
<td>• Clean and disinfect all surfaces following procedure/study using sporidal disinfectant &lt;br&gt; • If aerosol-generating procedure performed, allow 30 – 60 minutes between patients to ensure adequate air exchanges have occurred &lt;br&gt; • Terminal cleaning at end of day</td>
<td>• Clean and disinfect all surfaces following procedure/study using sporidal disinfectant &lt;br&gt; • Terminal cleaning at end of day</td>
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</tr>
</tbody>
</table>

*PPE elements with this symbol may be re-used for subsequent patients and cases unless contaminated.*
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, 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 COVID-19 exposure within the 4 weeks prior to the onset of symptoms

1Fever >38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours
2Including, 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

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.
For Parents: Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19
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*:

<table>
<thead>
<tr>
<th>TOTAL MIS-C PATIENTS MEETING CASE DEFINITION*</th>
<th>TOTAL MIS-C DEATHS MEETING CASE DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>4018</td>
<td>36</td>
</tr>
</tbody>
</table>

*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*
*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)**

![Graph showing MIS-C and COVID-19 cases](https://www.cdc.gov/mis-c/cases/index.htm)

The graph shows the number of daily MIS-C cases and COVID-19 cases reported to CDC. The data is represented on a 7-day moving average scale.

Number of included COVID-19 patients and MIS-C patients with date of onset between February 10, 2020 and May 25, 2021.

The grayed-out area on the right side of the graph represents data for which reporting of MIS-C patients is still incomplete. The actual number of MIS-C patients during this period is likely larger. The numbers are expected to increase as additional case reports are incorporated. The scale for the Y-axes on the left and the Y-axis of the figure. The left Y-axis marks the number of daily 7-day average MIS-C patients in units of 5 with a scale of 0 to 35; the right Y-axis marks the number of daily 7-day average COVID-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.

https://www.cdc.gov/mis-c/cases/index.html

6/7/2021
MIS-C Patients by Race & Ethnicity

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Percentage of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic/Latino</td>
<td>30%</td>
</tr>
<tr>
<td>Black, Non Hispanic</td>
<td>25%</td>
</tr>
<tr>
<td>White, Non Hispanic</td>
<td>15%</td>
</tr>
<tr>
<td>Other</td>
<td>10%</td>
</tr>
<tr>
<td>Multiple</td>
<td>5%</td>
</tr>
<tr>
<td>Asian</td>
<td>2%</td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander</td>
<td>1%</td>
</tr>
<tr>
<td>*American Indian/Alaska Native</td>
<td>1%</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Sex</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>40.0%</td>
</tr>
<tr>
<td>Male</td>
<td>60.0%</td>
</tr>
</tbody>
</table>

Sex was not reported for 45 of 4,018 patients.

https://www.cdc.gov/mis-c/cases/index.html

6/7/2021
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.
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

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 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
- Fillable Multisystem Inflammatory Syndrome Associated with COVID-19 Case Report Form
References


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
- 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)
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

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.
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 (7). 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.

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.

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 vasoplastic 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).
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, (7) 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.1 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.1 MIS-C has also been reported disproportionately in these communities (7). 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.

Acknowledgments


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1CDC COVID-19 Response Team; 2Epidemic Intelligence Service, CDC; 3University of Miami Miller School of Medicine and Jackson Health System, Florida; 4New York City Department of Health and Mental Hygiene; 5Massachusetts General Hospital, Boston, Massachusetts; 6Broad Institute of MIT and Harvard, Cambridge, Massachusetts; 7Maine Center for Disease Control and Prevention; 8University of Southern Maine, Portland, Maine; 9Maine Medical Center/Maine Medical Partners, Portland, Maine; 10Minnesota Department of Health; 11Louisiana State University Health Sciences Center, New Orleans, Louisiana; 12Southeast Louisiana Veterans Healthcare System, New Orleans, Louisiana; 13Louisiana Department of Health; 14Section of Infectious Diseases, Atlanta VA Medical Center, Decatur, Georgia; 15Division of Infectious Diseases, Emory University School of Medicine, Atlanta, Georgia; 16Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee.

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† 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.


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References


<table>
<thead>
<tr>
<th>Age (yrs), sex, race/ethnicity, location</th>
<th>Underlying medical conditions</th>
<th>Clinical signs and symptoms</th>
<th>Previous respiratory illness/SARS-CoV-2 testing</th>
<th>SARS-CoV-2 testing at time of MIS-A admission</th>
<th>Laboratory studies (peak)*</th>
<th>Imaging/Other diagnostic studies</th>
</tr>
</thead>
</table>

TABLE 1. Demographics, clinical features, treatments, and outcomes of nine adults reported to CDC: inflammatory syndrome (MIS) associated with SARS-CoV-2 infection — United States, March–Aug
<table>
<thead>
<tr>
<th>Age (yrs), sex, race/ethnicity, location</th>
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<th>Previous respiratory illness/SARS-CoV-2 testing</th>
<th>SARS-CoV-2 testing at time of MIS-A admission</th>
<th>Laboratory studies (peak)*</th>
<th>Imaging/Other diagnostic studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient 1:</strong> 27, female, African American, Maine</td>
<td>None</td>
<td>Rigors, profuse diarrhea, diffuse rash x 5 days. Admitted with mixed shock (hypovolemic, vasoplegic, cardiogenic) and acute renal failure.</td>
<td>No/Testing unknown</td>
<td>PCR (-), Ab (+)</td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Patient 2:</strong> 50, male, African American, Florida</td>
<td>None</td>
<td>Poor oral intake, chest pressure, palpitations, diaphoresis x 3 days. Hemodynamically unstable on admission.</td>
<td>No/Testing unknown</td>
<td>PCR (+), Ab (+)</td>
<td>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</td>
<td>EKG: atrial fibrillation/flutter with rapid ventricular response, ST segment changes. TTE: ejection fraction 25%–30% with global hypokinesis. CXR: small pleural effusions.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs and symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>Laboratory studies (peak)*</td>
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<tr>
<td>Patient 3: 46, male, African American, Florida</td>
<td>Obesity, chronic right lower extremity pain</td>
<td>Malaise, bilateral tinnitus, chest pain, and vomiting x 4 days. Hypotensive and mildly hypoxemic on admission.</td>
<td>Yes/Testing unknown</td>
<td>PCR (-), Ab (+)</td>
<td>CRP 217 mg/L; D-dimer 3790 ng/mL; ferritin &gt;100,000 ng/mL; troponin I 2.5 ng/mL; IL-6 1412 pg/mL; ALT &gt;10,000 IU/L; ALC nadir 400 cells/μL</td>
<td>EKG: ST-T segment changes. CT chest: dependent ground glass opacities. CT abdomen: hepatic steatosis.</td>
</tr>
<tr>
<td>Patient 4: 21, male, African American, Louisiana</td>
<td>Obesity</td>
<td>Fever, cough, nausea, vomiting, lymphadenopathy x 6 days.</td>
<td>No/Testing unknown</td>
<td>PCR (-), Ab (+)</td>
<td>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</td>
<td>TTE: severely decreased ejection fraction, mild mitral regurgitation, right ventricular dysfunction, coronary artery dilatation. CT chest: ground glass opacities and atelectasis.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs and symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>Laboratory studies (peak)*</td>
<td>Imaging/Other diagnostic studies</td>
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</tr>
<tr>
<td>Patient 5: 33, male, African American, Georgia</td>
<td>Obesity, HTN, depression</td>
<td>Fever, chest pain, abdominal pain, diarrhea, dark urine x 4 days.</td>
<td>Yes/PCR (+) 41 days earlier</td>
<td>PCR (+), Ab (+)</td>
<td>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</td>
<td>CT chest: atelectasis. CT abdomen/pelvis: normal. TTE: mitral and tricuspid regurgitation.</td>
</tr>
<tr>
<td>Patient 6: 22, female, African American, New York</td>
<td>None</td>
<td>Fever, chills, throat pain, odynophagia x 2 days.</td>
<td>No/Testing unknown</td>
<td>PCR (+), Ab (+)</td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs and symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>Laboratory studies (peak)*</td>
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<tr>
<td>Patient 7: 21, female, African American, New York</td>
<td>Obesity</td>
<td>Fever, fatigue, throat and neck pain, nausea, vomiting x 1 day.</td>
<td>Yes/PCR (+) 25 days earlier</td>
<td>PCR (+), Ab (+)</td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td>Patient 8: 47, female, African American, New York</td>
<td>None</td>
<td>Weakness, sore throat, shortness of breath, decreased exercise tolerance x 3 days.</td>
<td>Yes/Testing unknown</td>
<td>PCR (+), Ab testing not performed</td>
<td>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</td>
<td>EKG: first degree AV block and nonspecific T-wave abnormalities. TTE: borderline left ventricular ejection fraction (55%).</td>
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<tr>
<td>Patient 9: 42, male, Asian, New York</td>
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<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Obesity</td>
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</tr>
<tr>
<td>Underlying medical conditions</td>
<td>Fever, shortness of breath, cough, diarrhea, poor appetite, dysuria x 5 days.</td>
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<tr>
<td>Clinical signs and symptoms</td>
<td>Yes/PCR (+) 37 days earlier</td>
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</tr>
<tr>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>CRP (-), Ab testing not performed</td>
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<tr>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>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.</td>
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<tr>
<td>Laboratory studies (peak)*</td>
<td>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</td>
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<tr>
<td>Imaging/Other diagnostic studies</td>
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</tbody>
</table>

**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.
<table>
<thead>
<tr>
<th>Age (yrs), sex, race/ethnicity, location</th>
<th>Underlying medical conditions</th>
<th>Clinical signs/symptoms</th>
<th>Previous respiratory illness/SARS-CoV-2 testing</th>
<th>SARS-CoV-2 testing at time of MIS-A admission</th>
<th>Laboratory studies (peak)*</th>
<th>Imaging/Other diagnostic studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 10: 36, female, Hispanic, New York</td>
<td>None</td>
<td>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.</td>
<td>No/Not tested</td>
<td>PCR (+), Ab (+)</td>
<td>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</td>
<td>TTE: moderate tricuspid regurgitation, pericardial effusion. CT chest: right pleural effusion. Ultrasound gallbladder wall edema.</td>
</tr>
<tr>
<td>Patient 11: 45, male, Hispanic, New York</td>
<td>None</td>
<td>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.</td>
<td>No/Not tested</td>
<td>PCR (+), Ab testing not performed</td>
<td>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</td>
<td>EKG: ST elevations in anterolateral leads. TTE: ejection fraction 40% with global hypokinesis. CT head/neck: pre-septal edema. Slit lamp: uveitis.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs/symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
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<tr>
<td>Patient 12*: 44, female, Hispanic, Massachusetts</td>
<td>GERD, mild obstructive sleep apnea, depression</td>
<td>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.</td>
<td>Yes/Not tested</td>
<td>PCR (+), Ab testing not performed</td>
<td>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</td>
<td>EKG: submillimeter S segment elevation in leads I/aVL, low QRS voltage. TTE: severely depressed left ventricular function, trace pericardial effusion. CT chest: mild group glass opacities bilateral lung fields. CT abdomen/pelvis: small amount of ascites, periportal edema.</td>
</tr>
<tr>
<td>Patient 13**: 21, male, African origin, United Kingdom</td>
<td>None</td>
<td>Fever, headache, and abdominal pain x 6 days; transient palmar rash. Hypotensive on admission with nonexudative conjunctivitis, mucositis, cervical lymphadenopathy.</td>
<td>No/Not tested</td>
<td>PCR (-), Ab (+)</td>
<td>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</td>
<td>CT abdomen/pelvis: mesenteric adenopathy and ilei EKG: sinus tachycardia. CT chest: normal. TTE: normal. CT coronary angiogram: normal.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs/symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>Laboratory studies (peak)*</td>
<td>Imaging/Other diagnostic studies</td>
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<tr>
<td>Patient 14*: 31, female, African American, Louisiana</td>
<td>Obesity, HTN, diabetes mellitus type 2</td>
<td>Fever x 1 day, throbbing neck pain, nausea, vomiting.</td>
<td>Yes/PCR (+) 14 days before admission</td>
<td>PCR (-), Ab testing not performed</td>
<td>CRP 580 mg/L; D-dimer 453 ng/mL; ferritin 793 ng/mL; ALT 52 IU/L; ALC nadir 2120 cells/μL</td>
<td>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-glass opacities with cervical and anterior mediastinal lymphadenopathy.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs/symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>Laboratory studies (peak)*</td>
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<td>Patient 15th: 25, female, Hispanic, Georgia</td>
<td>None</td>
<td>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.</td>
<td>No/Not tested</td>
<td>PCR (+), Ab (+)</td>
<td>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</td>
<td>TTE: moderate to severely reduced right-sided ventricular dysfunction, flattened 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, nonspecific bilateral perinephric fat stranding.</td>
</tr>
<tr>
<td>Age (yrs), sex, race/ethnicity, location</td>
<td>Underlying medical conditions</td>
<td>Clinical signs/symptoms</td>
<td>Previous respiratory illness/SARS-CoV-2 testing</td>
<td>SARS-CoV-2 testing at time of MIS-A admission</td>
<td>Laboratory studies (peak)*</td>
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<tr>
<td>Patient 16&lt;sup&gt;¶¶&lt;/sup&gt;</td>
<td>None</td>
<td>Fever, occipital headache, conjunctival injection, odynophagia, mucositis, glossitis, shortness of breath, vomiting, polyarthritis, and rash x 5 days.</td>
<td>Yes/PCR (+) 28 days earlier</td>
<td>PCR (+), Ab (+)</td>
<td>CRP 217 mg/L; D-dimer 1250 ng/mL; ferritin 196 ng/mL; troponin I &lt;0.03 ng/mL; ALT 126 IU/L; ALC nadir 120 cells/μL</td>
<td>TTE: trace pericardial effusion, elevated pulmonary artery pressure (46–51 mm Hg), normal left ventricular ejection fraction, no coronary artery abnormalities. CT chest/abdomen/pelvis: no pulmonary embolus; right upper lobe perihilar ground-glass opacities, septal and bronchial wall thickening, bilateral small-to-moderate pleural effusions.</td>
</tr>
</tbody>
</table>

**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.

7 https://www.cdc.gov/mmwr/volumes/69/wr/mm6940e1.htm
## COVID-19 TESTING CRITERIA:
FOR HEALTHCARE WORKERS AND PATIENTS

<table>
<thead>
<tr>
<th>Group</th>
<th>Category</th>
<th>Definition</th>
<th>COVID-19 Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Workers (HCW)</td>
<td>Exposure</td>
<td>Exposure[^1] to a known COVID-19 positive individual</td>
<td>Contact employee health and you will be directed for your testing date and time</td>
</tr>
<tr>
<td></td>
<td>Symptomatic</td>
<td>Symptomatic defined as new fever &gt;100°F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology</td>
<td>One (1) test upon decision to admit; if negative, may consider testing via serology method and repeat PCR test &gt;24 hours If no plan for admission, discharge patient with COVID-19 education information on accessing results</td>
</tr>
<tr>
<td></td>
<td>Asymptomatic</td>
<td>No known exposure to a known COVID-19 positive individual or symptoms</td>
<td>Visit PCP or local testing center[^2]</td>
</tr>
<tr>
<td>Emergency Department/ Trauma Resus</td>
<td>Symptomatic</td>
<td>Symptomatic defined as new fever &gt;100°F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology. <em>Apply clinical judgment for alternative symptomatology.</em></td>
<td>One (1) test immediately upon high suspicion for admission</td>
</tr>
<tr>
<td></td>
<td>Asymptomatic / Unknown</td>
<td>Patients without symptoms of COVID-19 or unable to provide history (e.g. nonverbal ED or trauma)</td>
<td>One (1) test upon decision to admit</td>
</tr>
<tr>
<td>Behavioral Health</td>
<td>Symptomatic/Asymptomatic</td>
<td>Symptomatic defined as new fever &gt;100°F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology. <em>Apply clinical judgment for alternative symptomatology.</em> Patients without symptoms of COVID-19 or unable to provide history</td>
<td>One (1) test upon decision to admit For patients who require medical clearance, behavioral unit must swab prior to transfer to ED</td>
</tr>
<tr>
<td>Inpatients</td>
<td>Exposure</td>
<td>New exposure[^1] to a known COVID-19 positive individual during admission</td>
<td>One (1) test based on clinical suspicion</td>
</tr>
<tr>
<td></td>
<td>Symptomatic</td>
<td>Symptomatic defined as new fever &gt;100°F AND/OR new onset of respiratory symptoms unless fever can be attributed to an alternative etiology. <em>Apply clinical judgment for alternative symptomatology.</em></td>
<td>One (1) test based on clinical suspicion; if negative, may consider testing via serology method and repeat PCR test &gt;24 hours if no other etiology has been identified</td>
</tr>
<tr>
<td></td>
<td>Asymptomatic</td>
<td>Internal JHS transfers</td>
<td>Confirm COVID-19 test results prior to transfer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Direct admissions from other healthcare institutions</td>
<td>Transferring institution must provide proof of testing no more than 72 hours prior to admission &amp; must be documented in the EMR</td>
</tr>
<tr>
<td></td>
<td>Nursing Home Discharges</td>
<td>Individuals who are prepared to be discharged to a nursing home</td>
<td>Two (2) negative tests 24 – 48 hours apart prior to discharge If one (1) test is positive, next test &gt;72 hours after last positive result</td>
</tr>
</tbody>
</table>

[^1]: Direct = less than 6 feet; prolonged = more than 10 mins; unprotected = no PPE or Direct Contact to secretions

[^2]: Visit [https://floridahealthcovid19.gov/](https://floridahealthcovid19.gov/) for your local county health department testing locations
<table>
<thead>
<tr>
<th>Pre-surgical</th>
<th>ALL patients</th>
<th><strong>Outpatient</strong>: One (1) test for COVID-19 within 72 hours of case/procedure</th>
<th>← See left</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient</strong>: One (1) test upon admission only</td>
<td>ONLY if patient develops symptoms of COVID-19 during hospitalization, you may retest prior to procedure</td>
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</tr>
<tr>
<td><strong>Outpatient Procedures (Diagnostic or Interventional)</strong></td>
<td>High-risk procedures(^4)</td>
<td>Patients at high-risk(^1) for COVID-19 transmission to HCW (e.g. aerosol-generating procedures or proximal to the respiratory tract)</td>
<td>One (1) test within 72 hours of the procedure</td>
</tr>
<tr>
<td>Low-risk</td>
<td>Low-risk outpatient procedures do not require COVID-19 testing unless patients are symptomatic (see above for Inpatient Symptomatic)</td>
<td>No testing required</td>
<td></td>
</tr>
<tr>
<td><strong>Outpatient Clinic</strong></td>
<td>Symptomatic</td>
<td>All patients (seen in person or by telemedicine) who are showing COVID-19 symptoms</td>
<td>Refer to PCP and reschedule appointment if telemedicine visit</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>If patient presents to hospital for outpatient appointment with symptoms refer for testing</td>
</tr>
</tbody>
</table>

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
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

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

Questions? Call Micro Lab 305-585-6508
### COVID-19 TESTING CRITERIA:
FOR SPECIAL POPULATIONS, TRANSPLANT AND ONCOLOGY PATIENTS

<table>
<thead>
<tr>
<th>Group</th>
<th>Category</th>
<th>Definition</th>
<th>COVID-19 Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-surgical Transplant</strong> (Deceased or Living Donors)</td>
<td>ALL asymptomatic transplant recipients</td>
<td>Screening questionnaire for symptoms</td>
<td><strong>Outpatient:</strong> One (1) test for COVID-19 within 72 hours of case/procedure for living donation</td>
</tr>
<tr>
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<td>These are emergency cases that will be hospitalized at the time of organ offer</td>
<td><strong>Inpatient:</strong> One (1) test upon admission only</td>
</tr>
<tr>
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<td>ONLY if patient develops symptoms of COVID-19 during hospitalization, you may retest prior to procedure</td>
</tr>
<tr>
<td><strong>Pre-Solid Organ Transplant</strong> (Adult and Pediatric)</td>
<td>Previously infected or tested positive and convalescent from COVID-19</td>
<td>Patient with a known history or confirmed exposure to COVID-19 referred to MTI for evaluation or previously listed awaiting organ transplant</td>
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<td>Should be at least 10 days asymptomatic prior to scheduling in person appointment in MTI laboratory or clinic</td>
<td><strong>Outpatient:</strong> One (1) negative PCR test for COVID-19</td>
</tr>
<tr>
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<td></td>
<td>Test should be done &gt; 14 days from the onset of COVID-19 illness</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Exceptions:</strong> Patient listed and on hold due to recent COVID-19 infection with decompensation and urgent need for transplant, repeat PCR sooner than 14 days and consult ID</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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 COVID-19 illness</td>
</tr>
<tr>
<td>Exposure</td>
<td>Exposure to a known COVID-19 positive individual</td>
<td>Follow by PCP in the community</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>One (1) NP swab PCR test and monitor symptoms, self-quarantine for 14 days and report to MTI clinic coordinator any changes</td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td>Symptomatic defined as new fever &gt;100°F AND/OR new onset of respiratory symptoms, GI, anosmia or dysgeusia</td>
<td><strong>Clinically stable/ outpatient:</strong> 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 &gt;24 hours unless symptoms can be attributed to an alternative etiology</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Clinically unstable/ send to ED:</strong> 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 &gt;24 hours unless symptoms can be attributed to an alternative etiology</td>
<td></td>
</tr>
</tbody>
</table>

---

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*
<table>
<thead>
<tr>
<th>Asymptomatic Presenting in ED for other reasons non COVID-19 related</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal JHS transfers</td>
<td>Confirm COVID-19 test results prior to transfer</td>
</tr>
<tr>
<td>Direct admissions from other healthcare institutions</td>
<td>Transferring institution must provide proof of testing no more than 72 hours prior to admission &amp; must be documented in the EMR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post- Solid Organ Transplant (Adult and Pediatric)</th>
<th>Exposure</th>
<th>Exposure to a known COVID-19 positive individual</th>
<th>One (1) NP swab PCR test and monitor symptoms, self-quarantine for 14 days and report to MTI clinic coordinator any changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>Symptomatic defined as new fever &gt;100-F AND/OR new onset of respiratory symptoms, GI, anosmia or dysgeusia</td>
<td>Clinically stable/ outpatient: One (1) NP swab PCR test if negative, may consider testing via serology method and repeat PCR test &gt;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.</td>
<td></td>
</tr>
<tr>
<td>Asymptomatic / Unknown</td>
<td>Patients without symptoms of COVID-19 or unable to provide history (e.g. nonverbal ED or trauma)</td>
<td>One (1) test immediately upon high suspicion for admission</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Convalescent Patients with COVID19 Solid Organ Transplant</th>
<th>Asymptomatic Previously infected or tested positive</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>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</td>
</tr>
</tbody>
</table>

---

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Category</th>
<th>Definition</th>
<th>COVID-19 Testing</th>
</tr>
</thead>
</table>
| **Convalescent Patients with COVID-19 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** |
| **Oncology Outpatient (Pre-Chemotherapy)** | 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* to a known COVID-19 positive individual during admission                                                                                                                                  | One (1) test based on clinical suspicion |
| **Oncology Inpatients**        | 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** |
| **Oncology Inpatients**        | Asymptomatic                   | Hospitalized for work up or chemotherapy                                                                                                                                                               | One (1) test **upon decision to admit to the hospital** |
| **Oncology Inpatients**        |                                | **Internal JHS transfers**                                                                                                                                                                              | **Confirm COVID-19 test results prior to transfer** |
| **Oncology Inpatients**        |                                | **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 |

*Note: *Exposure refers to a known COVID-19 positive individual during admission.**
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
**Hospital to Post-Acute Care Facility Transfer – COVID-19 Assessment**

**INSTRUCTIONS:** In accordance with Agency for Health Care Administration (AHCA) Emergency Rule 59AER20-11, issued November 3, 2020, hospitals are required to test all patients, using a nucleic acid amplification (PCR) test that has been given Emergency Use Authorization from the Food & Drug Administration (FDA) for detection of COVID-19, within 48 hours prior to discharging/transferring patient to a long term care facility. Hospitals are prohibited from discharging any patient who has tested positive for COVID-19 or is exhibiting symptoms consistent with COVID-19 to any long-term care facility until the patient has been cleared for discharge, unless the receiving facility has a dedicated wing, unit, or building with dedicated staff to accept the COVID-19 positive individual as a resident. AHCA stresses Centers for Disease Control and Prevention (CDC) guidance regarding “symptom-based strategy” for clearance for discharge and advises that long-term care facilities should not expect a “test-based” clearance to be performed prior to transfers for previously positive individuals.

This assessment format facilitates documentation of the patient’s status as it relates to COVID-19 AHCA requirements and CDC guidance.


---

**Patient Name:** ____________________  **DOB:** ___________  **Accepting Facility:** ____________________

**Transferring Hospital:** ____________________  **Hospital Contact Name/Phone:** ____________________

---

**Check the appropriate TRANSFER STATUS box to indicate this patient’s transfer eligibility:**

<table>
<thead>
<tr>
<th>COVID-19 Test Status</th>
<th>Additional Clinical Information</th>
<th>TRANSFER STATUS (Check the appropriate BOX)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NEGATIVE</strong></td>
<td>This patient has tested COVID-19 negative during this admission and is not suspected of having COVID-19 infection. Date of Test: __________________</td>
<td>☐ MAY BE TRANSFERRED</td>
</tr>
</tbody>
</table>
| **POSITIVE**         | This patient has tested COVID-19 positive and currently meets ALL of the CDC defined SYMPTOM-BASED strategy requirements following “mild to moderate” illness in patients who are not-immunocompromised:  
  • At least 24 hours since resolution of fever without the use of fever-reducing medications.  
  • Improvement in respiratory symptoms.  
  • At least 10 days since symptoms first appeared. | ☐ MAY BE TRANSFERRED  
  ☐ ISOLATION FOR COVID-19 IS NO LONGER INDICATED |
| **POSITIVE**         | This patient has tested COVID-19 positive and currently meets ALL of the CDC defined SYMPTOM-BASED strategy requirements following “severe to critical” illness in patients OR for patients who are severely immunocompromised:  
  • At least 24 hours since resolution of fever without the use of fever-reducing medications.  
  • Improvement in respiratory symptoms.  
  • At least 10 days and up to 20 days since symptoms first appeared. | ☐ MAY BE TRANSFERRED  
  ☐ ISOLATION FOR COVID-19 IS NO LONGER INDICATED |
| **POSITIVE**         | This patient has been asymptomatic for COVID-19 throughout their infection.  
  • Not severely immunocompromised – At least 10 days have passed since the date of the first positive viral diagnostic test.  
  • Severely immunocompromised – At least 10 days and up to 20 days have passed since the first positive viral diagnostic test. | ☐ MAY BE TRANSFERRED |
| **POSITIVE**         | This patient has tested COVID-19 positive and currently meets ALL of the TEST-BASED strategy requirements for discharge:  
  • Resolution of fever without the use of fever-reducing medications.  
  • Improvement in respiratory symptoms.  
  • Two consecutive negative COVID-19 test results, separated by 24 hours.  
    » The first test by an FDA Emergency Use Authorized (EUA) COVID-19 molecular assay RT-PCR test.  
    » The second test by either an FDA EUA COVID-19 molecular assay RT-PCR test or an FDA EUA COVID-19 antigen test. | ☐ MAY BE TRANSFERRED  
  ☐ ISOLATION FOR COVID-19 IS NO LONGER INDICATED |
| **POSITIVE**         | This patient has tested COVID-19 positive and continues to require transmission-based isolation, per CDC guidance. | ☐ MAY BE TRANSFERRED TO A COVID-19 POSITIVE FACILITY |
| **PENDING**          | This patient’s COVID-19 test result is pending. The patient is NOT suspected of having COVID-19 infection. Requires transmission-based isolation, per CDC guidance.  
  Date test submitted: __________________  
  Testing Lab: __________________ | ☐ MAY BE TRANSFERRED |
59AER20-11 Hospital Screening Requirements for Long-Term Care Facility Residents.

(1) Applicability. The requirements of this emergency rule apply to all hospitals licensed under Chapter 395, F.S.

(2) Definitions.

(a) “Long-term care facility” is defined, for purposes of this rule, as any of the following facilities:

1. Nursing Homes, as provided under Chapter 400, F.S.;
2. Group Home Facilities, as provided under Chapter 393, F.S.;
3. Intermediate Care Facilities for the Developmentally Disabled, as provided under Chapter 400, F.S.; and
4. Assisted Living Facilities, as provided under Chapter 429, F.S.;

(b) “Long-term care facility resident” is defined, for the purposes of this rule, as any individual in Florida that is considered to be a resident, client, or patient of a long-term care facility or who will imminently become a resident, client, or patient of a long-term care facility upon discharge from a hospital licensed under chapter 395.

(3) Every hospital must test any long-term care facility resident whose COVID-19 status is unknown using a nucleic acid amplification laboratory test that has been given Emergency Use Authorization from the Food and Drug Administration (“FDA”) for the detection of SARS-CoV-2 (COVID-19) no more than 48 hours prior to discharging the individual to any long-term care facility. Hospitals may discharge a long-term care facility resident who is awaiting test results for COVID-19 if the long-term care facility resident has never tested positive for nor been suspected of having COVID-19, as long as the hospital confirms that the long-term care facility is able to isolate the resident while the hospital’s test results are pending and the hospital confirms that the long-term care facility is able to follow Centers for Disease Control and Prevention (“CDC”) infection prevention and control precautions for a person with unknown COVID-19 status.

(4) A long-term care facility resident that has tested positive for COVID-19 or is symptomatic must be isolated by the hospital pursuant to the hospital’s isolation protocols. A hospital is prohibited from discharging any long-term care facility resident that has tested positive for COVID-19 or is exhibiting symptoms consistent with COVID-19 to any long-term care facility until the long-term care facility resident has been cleared for discharge, unless the receiving facility has a dedicated wing, unit, or building with dedicated staff to accept the COVID-19 positive resident. The long-term care facility resident must meet the following criteria for symptom-based strategy prior to discharge:

(a) At least 24 hours have passed since resolution of fever without the use of fever-reducing medications; and
(b) Improvement in respiratory symptoms; and
(c) The minimum number of days set forth below have passed since symptoms first appeared:

1. At least 10 days have passed since symptoms first appeared, unless the patient has severe or critical illness or is severely immunocompromised, or

2. At least 20 days have passed since symptoms first appeared in patients with severe or critical illness or who are severely immunocompromised.

(d) For persons who never developed symptoms, the date of first positive FDA Emergency Use Authorized COVID-19 diagnostic laboratory test should be used in place of the date of symptom onset.

(5) Test-based strategy: a test-based strategy is only required to discontinue isolation and discharge earlier than would occur with a symptom-based strategy. Hospitals are not required to use the test-based strategy if the symptom-based strategy has been met. Under the test-based strategy, the long-term care facility resident must have:

(a) Resolution of fever without the use of fever-reducing medications;

(b) Improvement in respiratory symptoms; and

(c) Two consecutive negative test results separated by 24 hours. The first by an FDA Emergency Use Authorized COVID-19 nucleic acid amplification laboratory test, and the second by either an FDA Emergency Use Authorized COVID-19 nucleic acid amplification laboratory test or an FDA Emergency Use Authorized COVID-19 antigen test.

(6) This rule supersedes emergency rule 59AER20-8.

Rulemaking authority 408.819, 408.821(4), FS Law Implemented 408.819, 408.821(4) FS

EFFECTIVE DATE: November 3, 2020
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):

<table>
<thead>
<tr>
<th>DATE</th>
<th>BADGE #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMAIL</th>
<th>PHONE #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Department</th>
<th>Supervisor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CHECK REASON FOR THIS REQUEST:

- [ ] Individual Health
- [ ] Surgical Case over 4 hours
- [ ] Other

CHECK REUSABLE RESPIRATOR YOU ARE REQUESTING:

- [ ] 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
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):

<table>
<thead>
<tr>
<th>Anticipated Activity</th>
<th>Facemask requirements</th>
</tr>
</thead>
</table>
| 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:

1. End user will complete mandatory respirator use training via Webinar prior to obtaining initial respirator.
2. End user will report to Employee Health for mandatory medical evaluation and fit testing. (OHSA 1910.134) → JMM Main: No appointment necessary, Monday thru Friday 07:30am-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. (Name and date on the filter using shape)

RESPIRATOR INSPECTION & USE

Inspect each filter 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

4. If not being used immediately, end users will store their respirator in a separate, dustproof container. (Name and date on the filter using shape)
## Half-Face Reusable Respirator Request & Use Process

### 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)

### 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 fail/form upon pick up. (Write name and date on their filter using 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 Facepiece Respirator for Healthcare Facilities (4/20)

### 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).

### JHS Employees

- **Medical Staff (MDs/Allied Health/Residents)**

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.**

### JHS Employee Health Office

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.)

### JHS Central Sterile Services (CSS)

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.


**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)**

**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 Coronavirus. (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):

<table>
<thead>
<tr>
<th>DATE</th>
<th>BADGE #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>EMAIL</th>
<th>PHONE #</th>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Department</th>
<th>Supervisor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CHECK REASON FOR THIS REQUEST:
- [ ] Individual Health
- [ ] Surgical Case over 4 hours
- [ ] Other

CHECK REUSABLE RESPIRATOR YOU ARE REQUESTING:
- [ ] 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?

What is the health related or “other” reason for this request?

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.

- [ ] APPROVED
- [ ] DENIED

**REASON:** ________________________________________________________________

____________________________________________  DATE: _________________________

Medical Director or Designee Signature
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):

<table>
<thead>
<tr>
<th>Anticipated Activity</th>
<th>Facemask requirements</th>
</tr>
</thead>
</table>
| 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: | 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.                                                                                                                                                                                                                           |
| 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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 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
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 ao@jhf.org, Gwendolyn Mike GMike@jhsmiami.org and Frances Jara FJara@jhsmiami.org.

IV. Reference

Responsible Party: Director of Patient Care Services
Holtz/WHJ

Reviewing Committee(s): Holtz/WHJ Policy & Procedure Committee

Authorization: Department Head
Appendix 14

FACTORS THAT INCREASE COMMUNITY SPREAD AND INDIVIDUAL RISK

RISK FOR HOSPITALIZATION IF YOU HAVE ANY OF THESE CONDITIONS AND GET COVID-19 COMPARED TO THOSE PEOPLE WITHOUT THE CONDITION(S).

- Asthma: 1.5x
- Hypertension: 3x
- Obesity (BMI ≥ 30): 3x
- Diabetes: 3x
- Chronic Kidney Disease: 4x
- Severe Obesity (BMI ≥ 40): 4.5x
- 2 Conditions*: 4.5x
- 3 or More Conditions*: 5x

*Conditions include asthma, obesity, diabetes, chronic kidney disease, severe obesity, coronary artery disease, history of stroke and COPD.

Data has shown that racial and ethnic minority groups with the referenced conditions are at even higher risk for severe COVID-19 illness. Race and ethnicity are risk markers for other underlying conditions that impact health — including socioeconomic status, access to health care, and increased exposure to the virus due to occupation (e.g., frontline, essential, and critical infrastructure workers).

ALSO ANONYMIZING ACTIONS TO REDUCE RISK OF COVID-19

WEARING A MASK

SOCIAL DISTANCING (6 FT GOAL)

HAND HYGIENE

CLEANING AND DISINFECTION

ALTHOUGH RISK GENERALLY INCREASES WITH AGE, ALL INDIVIDUALS SHOULD ROUTINELY TAKE ACTIONS TO REDUCE RISK OF INFECTION AND AVOID ACTIVITIES THAT INCREASE COMMUNITY SPREAD.

Source: Ko JY, Danielson ML, Town M et al. 2020.
## COVID-19 Cases, Hospitalization, and Death by Race/Ethnicity

### Factors that Increase Community Spread and Individual Risk

<table>
<thead>
<tr>
<th>Rate ratios compared to White, Non-Hispanic Persons</th>
<th>American Indian or Alaska Native, Non-Hispanic persons</th>
<th>Asian, Non-Hispanic persons</th>
<th>Black or African American, Non-Hispanic persons</th>
<th>Hispanic or Latino persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASES¹</td>
<td>2.8x higher</td>
<td>1.1x higher</td>
<td>2.6x higher</td>
<td>2.8x higher</td>
</tr>
<tr>
<td>HOSPITALIZATION²</td>
<td>5.3x higher</td>
<td>1.3x higher</td>
<td>4.7x higher</td>
<td>4.6x higher</td>
</tr>
<tr>
<td>DEATH³</td>
<td>1.4x higher</td>
<td>No Increase</td>
<td>2.1x higher</td>
<td>1.1x higher</td>
</tr>
</tbody>
</table>

Race and ethnicity are risk markers for other underlying conditions that impact health — including socioeconomic status, access to health care, and increased exposure to the virus due to occupation (e.g., frontline, essential, and critical infrastructure workers).

### Actions to Reduce Risk of COVID-19

- **Wearing a Mask**
- **Social Distancing** (6 ft goal)
- **Hand Hygiene**
- **Cleaning and Disinfection**

---

¹ Data source: COVID-19 case-level data reported by state and territorial jurisdictions. Case-level data include about 80% of total reported cases. Numbers are unadjusted rate ratios.


## COVID-19 HOSPITALIZATION AND DEATH BY AGE

### FACTORS THAT INCREASE COMMUNITY SPREAD AND INDIVIDUAL RISK

<table>
<thead>
<tr>
<th>CROWDED SITUATIONS</th>
<th>CLOSE / PHYSICAL CONTACT</th>
<th>ENCLOSED SPACE</th>
<th>DURATION OF EXPOSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate ratios compared to 18-29 year olds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HOSPITALIZATION¹</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-4 years</td>
<td>5-17 years</td>
<td>18-29 years</td>
<td>30-39 years</td>
</tr>
<tr>
<td>4x lower</td>
<td>9x lower</td>
<td><strong>Comparison Group</strong></td>
<td>2x higher</td>
</tr>
<tr>
<td><strong>DEATH²</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-4 years</td>
<td>5-17 years</td>
<td>18-29 years</td>
<td>30-39 years</td>
</tr>
<tr>
<td>9x lower</td>
<td>16x lower</td>
<td><strong>Comparison Group</strong></td>
<td>4x higher</td>
</tr>
</tbody>
</table>

### ACTIONS TO REDUCE RISK OF COVID-19

- WEARING A MASK
- SOCIAL DISTANCING (6 FT GOAL)
- HAND HYGIENE
- CLEANING AND DISINFECTION

---


Appendix 15

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.
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
Discontinuation of Isolation Precautions, COVID Re-Testing, and Procedural Area Recommendations**
for JHS and UHealth: COVID-19

Isolation & Testing for Patients Recovering from COVID-19 Infection

<table>
<thead>
<tr>
<th></th>
<th>Immunocompetent/Non-critical Care</th>
<th>Immunocompromised/Critically Ill</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>JHS and UHealth Process</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td>At least 10 days after symptom onset PLUS resolution of fever X 24 hours (without anti-pyretic med) and improvement in other symptoms</td>
<td>At least 20 days after symptom onset PLUS resolution of fever X 24 hours (without anti-pyretic med) and improvement in other symptoms</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>10 days after first positive RT-PCR test for SARS-CoV-2-RNA</td>
<td>20 days after first positive RT-PCR test for SARS-CoV-2-RNA</td>
</tr>
<tr>
<td><strong>Role of Testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not recommended for discontinuation of isolation precautions</td>
<td>May be considered, in consultation with ID</td>
</tr>
<tr>
<td></td>
<td>Not recommended for discontinuation of isolation precautions</td>
<td>May be considered, in consultation with ID</td>
</tr>
<tr>
<td><strong>PPE/Placement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard Precautions/Non COVID unit</td>
<td>Standard Precautions/Non COVID unit OR based on re-test results if performed</td>
</tr>
<tr>
<td></td>
<td>Standard Precautions/Non COVID unit</td>
<td>Standard Precautions/Non COVID unit OR based on re-test results if performed</td>
</tr>
</tbody>
</table>

Readmission of IMMUNOCOMPETENT Previously COVID-19 Positive Patients (10 days after original COVID diagnosis)

<table>
<thead>
<tr>
<th></th>
<th>Readmission WITHIN 90 days of original COVID diagnosis</th>
<th>Readmission BEYOND 90 days of original COVID diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no alternative etiology exists, consider ID consult and testing and place patient based on clinical presentation and test results</td>
<td>No testing required Routine patient placement No COVID-related isolation precautions</td>
<td>Perform COVID testing and place patient based on clinical presentation and test results</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Testing methodology: PCR and antibody tests</strong></td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Appendix 16
## Readmission of IMMUNOCOMPROMISED Previously COVID-19 Positive Patients (20 days after original COVID diagnosis)

<table>
<thead>
<tr>
<th>Readmission WITHIN 90 days of original COVID diagnosis</th>
<th>Readmission BEYOND 90 days of original COVID diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptomatic</strong></td>
<td><strong>Asymptomatic</strong></td>
</tr>
<tr>
<td>Placement and isolation precautions per COVID testing results</td>
<td>No testing required</td>
</tr>
<tr>
<td></td>
<td>Routine patient placement</td>
</tr>
<tr>
<td></td>
<td>No COVID-related isolation precautions</td>
</tr>
<tr>
<td><strong>Symptomatic</strong></td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>Placement and isolation precautions per COVID testing results</td>
<td>Place and isolation precautions per COVID testing results</td>
</tr>
<tr>
<td><strong>Testing methodology: PCR and antibody tests</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Placement and isolation precautions per COVID testing results**

- No testing required
- Routine patient placement
- No COVID-related isolation precautions

**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.)

<table>
<thead>
<tr>
<th>Timeframe from known symptom onset or positive test result</th>
<th>Early</th>
<th>Interim</th>
<th>&gt;90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMUNOCOMPETENT</td>
<td>&lt;10 Days</td>
<td>11-90 Days</td>
<td>Retest based on clinical judgement and exposure history</td>
</tr>
<tr>
<td></td>
<td>Retest not needed. Treat as COVID-positive. Use full PPE and isolation</td>
<td>Re-test not needed. For aerosol generating procedure use PPE during the procedure. Routine bed placement</td>
<td><strong>Negative</strong> ➔ Routine PPE and procedure room</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Positive</strong> ➔ full PPE and COVID designated procedure room</td>
</tr>
</tbody>
</table>

**IMMUNOCOMPROMISED or Critically Ill**

| <20 Days | 21-90 Days | Retest as appropriate using clinical judgement. PPE and room placement based on test results |
| Retest not needed. Treat as COVID-positive. Use full PPE and isolation | Retesting as appropriate using clinical judgment |

* Per CDC guidance, reinfection highly unlikely within 90 days of original COVID diagnosis

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.

<table>
<thead>
<tr>
<th>Timeframe from known symptom onset or positive test result</th>
<th>Early</th>
<th>Interim</th>
<th>&gt;90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PREGNANCY IMMUNOCOMPETENT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10 Days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treat as COVID positive; labor in negative pressure room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>full PPE in OR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no family in OR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mother and any family exposed to the mother may not visit NICU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If baby goes to the NICU, will be admitted to the COVID cohort nursery in NICU D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>11-90 Days</strong></td>
<td></td>
<td></td>
<td>Retest based on clinical judgement and exposure history</td>
</tr>
<tr>
<td>Treat as COVID negative labor in regular room; N95 + eye protection in OR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>family allowed in OR &amp; mother &amp; family allowed in NICU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>&gt;90 Days</strong></td>
<td></td>
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</tr>
</tbody>
</table>

| **PREGNANCY IMMUNOCOMPROMISED or Critically Ill**           |       |         |          |
| <20 Days                                                   |       |         | Retest as appropriate using clinical judgment          |
| 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 |       |         |          |

*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.)

<table>
<thead>
<tr>
<th>Timeframe from known symptom onset or positive test result</th>
<th>Early</th>
<th>Interim</th>
<th>&gt;90 Days</th>
</tr>
</thead>
</table>
| **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 | 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
**PAPR TYPES**

- 3M Breathe Easy & Versaflow (TR800) PAPR systems: used for first responder, 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.

**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 BIOBASED.
4. Designate individual responsible for daily cleaning, battery charging oversight and minimum monthly maintenance per manufacturer guidance.

**Key Roles:**

- **PAPR Administrator**
  - 1. Each PAPR Administrator will ensure appropriate storage environment is designated per manufacturer instructions for use.
  - 2. Manufacturer instructions for use (IFU) must be consulted for SOP development.
  - 3. End user will report to designated location to obtain the PAPR.
  - 4. End user will complete mandatory PAPR respirator donning, doffing, cleaning and use training per manufacturer instructions via WeLearn prior to using any PAPR system.
  - 5. End user will present to Employee Health for mandatory medical evaluation prior to using PAPR.
  - 6. Training on daily cleaning, decontamination and use training per manufacturer instructions.

- **PAPR END USER**
  - 1. Will wipe down device with hospital approved wipes per manufacturer instructions before and after use.
  - 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 after each use. (Follow proper hand hygiene)

**Recommended Cleaning & Decontamination**

1. 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 care areas.
   - 4. Notify PAPR Administrator immediately with any concerns.

- **Other methods of cleaning, disinfection or sterilization have not been tested for compatibility with the PAPR and may damage the PAPR system and therefore must not be used. (3M Breathe Easy PAPR for First Responders Presentation)**

**General PAPR Assembly & Use**

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. Manufacturer instructions for use (IFU) must be consulted for SOP development.
   - a. 3M Breathe Easy PAPR Assembly Guidance
   - b. 3M Versaflow (TR800) PAPR Assembly Guidance
   - c. Ford Limited Use Public Emergency PAPR Guidance
   - d. Stryker Modified Flyte Helmet (Journal of Arthroplasty, 4/13/20)
3. End user will report to designated location to obtain the PAPR.
4. End user will present to Employee Health for mandatory medical evaluation prior to using PAPR.
5. End user will complete mandatory PAPR respirator donning, doffing, cleaning and use training per manufacturer instructions via WeLearn prior to using any PAPR system.
6. End user will present to Employee Health for mandatory medical evaluation prior to using PAPR.
7. Training on daily cleaning, decontamination and use training per manufacturer instructions.
8. 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 headgear.
   - c. If a replacement unit, hood, parts are needed.
   - d. If a replacement unit, hood, parts are needed.

**Storage & Maintenance:**

- **PAPR parts, batteries, and chargers**
  - 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 Versaflow (TR800) PAPR Assembly Guidance
  - c. Stryker Modified Flyte Helmet (Journal of Arthroplasty, 4/13/20)
  - d. Ford Limited Use Public Emergency PAPR Guidance
  - e. 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.

1. 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 care areas.
   - 4. Notify PAPR Administrator immediately with any concerns.

2. Do not clean with organic solvents.
3. Do not soak the blower unit or battery in cleaning solutions.
4. Other methods of cleaning, disinfection or sterilization have not been tested for compatibility with the PAPR and may damage the PAPR system and therefore must not be used. (3M Breathe Easy PAPR for First Responders Presentation)

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.
4. Other methods of cleaning, disinfection or sterilization have not been tested for compatibility with the PAPR and may damage the PAPR system and therefore must not be used. (3M Breathe Easy PAPR for First Responders Presentation)
Appendix 18

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

<table>
<thead>
<tr>
<th>Test/Method</th>
<th>TAT</th>
<th>Facility</th>
<th>Tier</th>
<th>Population</th>
<th>Testing Option</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cepheid/Biofire RP2</td>
<td>2 hr</td>
<td>JHS*</td>
<td>1</td>
<td>Unscheduled Labor and Delivery (OB Triage)</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Trauma Resus</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Asymptomatic Transplant - (Adult &amp; Peds)</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Symptomatic Transplant - (Adult &amp; Peds) Immunocompromised</td>
<td>Respiratory Panel (RP2)</td>
<td>For Recipients</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Respiratory Panel (RP2)</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Symptomatic Admitted ED patients</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Asymptomatic Admitted ED patients</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Same day Surgery or Procedure (eg: cath lab)</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>Admitted Behavioral Health Patients</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td>Elitech</td>
<td>6-8 hr</td>
<td>JMH</td>
<td>2</td>
<td>LTC Symptomatic</td>
<td>FluA/FluB, RSV, COVID (4-Plex)</td>
<td>Test via POC antigen. Reflex to PCR for negative antigen results ONLY. No additional testing required for positive antigen results.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>Symptomatic Healthcare Workers (HCW) for COVID-19</td>
<td>FluA/FluB, RSV, COVID (4-Plex)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>Symptomatic MTI Clinic Patients</td>
<td>FluA/FluB, RSV, COVID (4-Plex)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>Asymptomatic MTI Clinic Patients</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td>Qiagen</td>
<td>24 Hr</td>
<td>JMH</td>
<td>3</td>
<td>Long Term Care (LTC) Residents</td>
<td>COVID ONLY</td>
<td>POC antigen test</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Scheduled L&amp;D Patients</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Inpatients</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Pre-Op, Pre-procedure Via PAT</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Scheduled Surgery or Procedure (eg: cath lab)</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Symptomatic CHS Inmates</td>
<td>FluA/FluB, RSV, COVID (4-Plex)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Asymptomatic Healthcare Workers (HCW)</td>
<td>COVID ONLY</td>
<td>Test via POC antigen and reflex to PCR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Partners of Unscheduled L&amp;D Emergent Cases</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Direct admissions from other facilities (Documentation of Test Required) if needed</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>JHS Patients Discharged from ED</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Newborns of Covid Positive Mothers</td>
<td>COVID ONLY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>LTC New Placement (Discharge from JHS Facility)</td>
<td>COVID ONLY</td>
<td></td>
</tr>
</tbody>
</table>

*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 03/03/21
COVID-19

Interim Recommendations for Emergency Medical Services (EMS) Systems and 911 Public Safety Answering Points/Emergency Communication Centers (PSAP/ECCs) in the United States During the Coronavirus Disease (COVID-19) Pandemic

Updated July 15, 2020

This guidance applies to all medical first responders, including fire services, emergency medical services, and emergency management officials, who anticipate close contact with persons with suspected or confirmed Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection in the course of their work.

Summary of Recent Changes

As of July 15, 2020

- Reorganized recommendations into 2 sections:
  - Recommended infection prevention and control (IPC) practices for routine activities during the pandemic.
  - Recommended IPC practices when caring for a patient with suspected or confirmed SARS-CoV-2 infection.
- Added recommendations that were included in healthcare IPC FAQs addressing:
  - Universal use of PPE for healthcare personnel working in communities with moderate to sustained transmission of SARS-CoV-2, the virus that causes COVID-19
  - Creating a process for responding to SARS-CoV-2 exposures among healthcare personnel and others.

Background
This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. EMS practices should be based on the most up-to-date clinical recommendations and information from appropriate public health authorities and EMS medical direction about SARS-CoV-2 infection. Most recommendations in this updated guidance are not new (except as noted in the summary of changes above); they have been reorganized into the following sections:

- Recommended infection prevention and control (IPC) practices for routine healthcare delivery during the pandemic.
- Recommended IPC practices when caring for a patient with suspected or confirmed SARS-CoV-2 infection.

EMS play a vital role in responding to requests for assistance, triaging patients, and providing emergency medical treatment and transport for ill or injured persons. However, unlike patient care in the controlled environment of a healthcare facility, care and transports by EMS present unique challenges because of the nature of the setting, enclosed space during transport, frequent need for rapid medical decision-making, interventions with limited information, and a varying range of patient acuity and jurisdictional healthcare resources.

When preparing for and responding to patients with suspected or confirmed SARS-CoV-2 infection, close coordination and effective communications are important among 911 Public Safety Answering Points/Emergence Communication Centers (PSAP/ECCs)—commonly known as 911 call centers, the EMS system, healthcare facilities, and the public health system. Each PSAP/ECC and EMS system should seek the involvement of an EMS medical director to provide appropriate medical oversight. When SARS-CoV-2 infection is suspected in a patient needing emergency transport, prehospital care providers and healthcare facilities should be notified in advance that they may be caring for, transporting, or receiving a patient who might have SARS-CoV-2 infection.

This interim guidance applies to all EMS personnel (i.e., prehospital EMS and medical first responders involved in 911 responses or interfacility transfers) across multiple EMS models including, but not limited to, free standing, third-service, fire-based, hospital-based, and related EMS providers. Note that fire services are also included as they respond to emergency medical calls and may do so with or without an ambulance.

**Additional Key Resources:**

- Strategies to Optimize the Supply of PPE and Equipment
- Criteria for Return to Work for Healthcare Personnel with Suspected or Confirmed COVID-19 (Interim Guidance)
- Strategies to Mitigate Healthcare Personnel Staffing Shortages
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance)

### 1. Recommended infection prevention and control (IPC) practices for routine healthcare delivery during the pandemic

CDC recommends using additional infection prevention and control practices during the COVID-19 pandemic, along with standard practices recommended as a part of routine healthcare delivery to all patients. These practices are intended to apply to all patients, not just those with suspected or confirmed SARS-CoV-2 infection (See Section 2 for additional practices that should be used when caring for patients with suspected or confirmed SARS-CoV-2 infection).

**Recommendations for 911 PSAP/ECCs**

Municipalities and local EMS authorities should coordinate with state and local public health, PSAP/ECCs, and other emergency call centers to address the need for modified caller queries about SARS-CoV-2 infection, outlined below.

These modified caller queries should be developed in collaboration with an EMS medical director and informed by local, state, territorial,
tribal and federal public health authorities, including the city or county health department(s), state health department(s), and CDC.

**Modified Caller Queries**

911 Public Safety Answering Points/Emergency Communication Centers (PSAP/ECCs) should question callers and determine whether the call concerns a person who might have SARS-CoV-2 infection (e.g., ask about signs and symptoms of COVID-19 or recent close contact with someone with SARS-CoV-2 infection). The query process should never supersede the provision of pre-arrival instructions to the caller when immediate lifesaving interventions (e.g., CPR or the Heimlich maneuver) are indicated.

Information about a patient who might have SARS-CoV-2 infection should be communicated immediately to EMS personnel before arrival on scene in order to limit the number of EMS personnel exposed to the patient and to allow use of appropriate PPE. As part of pre-arrival instructions, PSAP/ECCs should encourage the universal use of cloth face coverings for all persons who are safely able to wear them at the scene prior to EMS arrival. PSAP/ECCs should utilize medical dispatch protocols that are approved by their EMS medical director in consultation with the local or state public health department. These protocols should be updated, as needed, to accommodate changes in EMS availability, and/or the redirection of low acuity calls to alternate disposition (e.g., nurse triage line, telemedicine triage line).

PSAP/ECCs and EMS units that respond to calls for ill travelers at US international airports or other ports of entry to the United States (maritime ports or border crossings) should be in contact with the CDC quarantine station of jurisdiction for the port of entry (see: CDC Quarantine Station Contact List) for planning guidance. They should notify the quarantine station when responding to that location if a communicable disease is suspected in a traveler. CDC has provided job aids for this purpose to EMS units operating routinely at US ports of entry. The PSAP/ECCs or EMS unit can also call CDC’s Emergency Operations Center at (770) 488-7100 to be connected with the appropriate CDC quarantine station.

**Recommendations for EMS Personnel**

**EMS Employer Responsibilities**

The responsibilities described in this section are for the care and transport of all patients, and not only for the care and transport of patients with suspected or confirmed SARS-CoV-2 infection. The Ryan White HIV/AIDS Treatment Extension Act of 2009 addresses notification procedures and requirements for medical facilities and state public health officers and their designated officers regarding exposure of emergency response employees (EREs), which includes EMS and other first responders, to potentially life-threatening infectious diseases. In March 2020, CDC/NIOSH updated the list of potentially life-threatening infectious diseases to which EREs might be exposed that are covered by the Act to include the addition of COVID-19, the disease caused by the virus SARS-CoV-2. A medical facility must respond to appropriate requests by making determinations about whether EREs have been exposed to infectious diseases included on the list. Infectious Diseases and Circumstances Relevant to Notification of Emergency Response Employees [1.52 MB, 10 Pages] for more information.

In addition, employers are required to:

- Develop IPC policies and procedures for EMS units that include a recommended sequence for safely donning and doffing PPE.
- Provide all EMS personnel with job- or task-specific education and training on preventing transmission of infectious agents, including refresher training.
- Ensure that EMS personnel are educated, trained, and have practiced the appropriate use of PPE prior to caring for a patient, including attention to correct use of PPE and preventing self-contamination and contamination of environmental surfaces during the process of removing such equipment.
- As part of the Occupational Safety and Health Administration (OSHA) respiratory protection program, ensure EMS personnel are medically cleared, trained, and fit tested for respiratory protection device use (e.g., N95 filtering facepiece respirator), or medically cleared and trained in the use of an alternative respiratory protection device (e.g.,

loose fitting powered air-purifying respirator, PAPR) whenever respirators are required. OSHA has a number of 
respiratory training videos.

- EMS units should be provided adequate supplies (e.g., hand sanitizer, cleaning supplies, EPA-registered hospital
disinfectants, PPE) so EMS personnel can adhere to recommended IPC practices.
- Ensure that EMS personnel and professional cleaners contracted by the EMS employer tasked to clean and disinfect transport vehicles 
and equipment are educated, trained, and have practiced the process according to EPA-registered label instructions, equipment 
manufacturer’s instructions, and the EMS agency’s standard operating procedures.

**Screen all EMS Personnel for Signs or Symptoms of SARS-CoV-2 Infection at the Start of Each Shift**

Although screening for symptoms will not identify asymptomatic or pre-symptomatic individuals with SARS-CoV-2 infection, symptom 
screening remains an important strategy to identify those who could have COVID-19 and require prompt assessment and response.

- Screen all EMS personnel and visitors (i.e., anyone entering the facility) for symptoms consistent with COVID-19 and 
exposure to others with SARS-CoV-2 infection. Screen EMS personnel at the start of each shift. Screen visitors prior to 
entry to the facility (e.g., firehouse or EMS station).
  - Actively take their temperature and confirm absence of symptoms consistent with COVID-19. Fever is either measured 
temperature ≥100.0°F or subjective fever.
  - Ask them if they have been advised to self-quarantine because of exposure to someone with SARS-CoV-2 
infection.
- Promptly manage anyone with symptoms of COVID-19 or who has been advised to self-quarantine:
  - EMS personnel should don a facemask if not already wearing one, return home, and notify occupational health 
services to arrange for further evaluation.
  - Visitors should be restricted from entering the facility.

**Assess All Patients for SARS-CoV-2 Infection**

- If PSAP/ECC telecommunicators advise that the patient is suspected of having SARS-CoV-2 infection, based on 
symptoms or close contact with an individual with SARS-CoV-2 infection, EMS personnel should put on appropriate 
PPE (as described in Section 2) before entering the scene. EMS personnel should be aware of the signs and symptoms 
of COVID-19.
- If information about potential for SARS-CoV-2 infection has not been provided by the PSAP/ECC, EMS personnel should exercise 
caution when responding to any patient. Initial assessment should begin from a distance of at least 6 feet from the patient, if possible. If 
the patient’s condition allows, the patient may be directed to meet the EMS crew at an appropriate location outside or in a more 
ventilated area.
- All patients (if tolerated), regardless of COVID-19 symptoms, should be instructed to practice source control. Patient 
contact should be minimized to the extent possible until a cloth face covering or facemask is on the patient.
- If possible, EMS personnel should ask the patient about signs and symptoms of COVID-19 or if the patient has had 
recent close contact with someone with SARS-CoV-2 infection.
- If SARS-CoV-2 infection is suspected, PPE as described in Section 2 should be used. If SARS-CoV-2 infection is not 
suspected, EMS personnel should follow standard procedures and use appropriate PPE for evaluating and providing 
care to the patient. Consideration for universal PPE (as described below) should be given depending on the level of 
community transmission.

**Implement Universal Source Control Measures**
Source control refers to use of cloth face coverings or facemasks to cover a person's mouth and nose to prevent the release of respiratory secretions when they are talking, sneezing, or coughing. Because of the potential for asymptomatic and pre-symptomatic transmission, source control measures are recommended for everyone, even if they do not have symptoms of COVID-19.

- Patients and family members should be wearing their own cloth face covering (if tolerated) prior to the arrival of EMS personnel and throughout the duration of the encounter, including during transport. If they do not have a face covering, they should be offered a facemask or cloth face covering, as supplies allow.
  - Facemasks and cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
  - If a nasal cannula is used, a facemask should (ideally) be worn over the 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.
- EMS personnel should wear a facemask at all times while they are in service, including in breakrooms or other spaces where they might encounter co-workers.
  - When available, facemasks are preferred over cloth face coverings for EMS personnel as facemasks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.
    - Cloth face coverings should NOT be worn instead of a respirator or facemask if more than source control is needed.
  - To reduce the number of times EMS personnel must touch their face and potential risk for self-contamination, EMS personnel should consider continuing to wear the same respirator or facemask (extended use) throughout their entire work shift, instead of intermittently switching back to their cloth face covering.
    - Respirators with an exhalation valve are not recommended for source control, as they allow unfiltered exhaled breath to escape.
    - EMS personnel should remove their respirator or facemask, perform hand hygiene, and put on their cloth face covering when leaving at the end of their shift.
- Educate EMS personnel about the importance of performing hand hygiene immediately before and after any contact with their respirator or facemask.

**Encourage Physical Distancing**

Healthcare delivery requires close physical contact between patients and EMS personnel. However, when possible, physical distancing (maintaining at least 6 feet between people) is an important strategy to prevent SARS-CoV-2 transmission.

- During transport, limit the number of EMS personnel in the patient compartment to essential personnel.
- Limit others riding in the ambulance while the patient is transported to the healthcare facility to only those essential for the patient’s physical or emotional well-being or care (e.g., care partner, parent, etc.)
  - They should wear a cloth face covering if possible, and, ideally, be screened for symptoms of COVID-19 or close contact with an individual with COVID-19 prior to transport including taking their temperature before entering the ambulance.
  - Those with symptoms or a history of close contact in the prior 14 days should not be permitted in the ambulance.

For EMS personnel, the potential for exposure to SARS-CoV-2 is not limited to direct patient care interactions. Transmission can also occur through unprotected exposures to asymptomatic or pre-symptomatic co-workers in breakrooms, co-workers or visitors in other common areas, or other exposures in the community. Examples of how physical distancing can be implemented for EMS personnel include:
Reminding EMS personnel that the potential for exposure to SARS-CoV-2 is not limited to direct patient care interactions.

- Emphasizing the importance of source control and physical distancing when engaged in non-patient care activities.
- Designating areas for EMS personnel to take breaks, eat, and drink that allow them to remain at least 6 feet apart from each other, especially when they must be unmasked.

**Implement Universal Use of Personal Protective Equipment**

- **EMS personnel working in areas with moderate to substantial community transmission** are more likely to encounter asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection. If SARS-CoV-2 infection is not suspected in a patient (based on symptom and exposure history), EMS personnel should follow Standard Precautions (and Transmission-Based Precautions if required based on the suspected diagnosis). They should also:
  - Wear eye protection in addition to their facemask to ensure the eyes, nose, and mouth are all protected from splashes and sprays of infectious material from others.
  - Wear an N95 or equivalent or higher-level respirator, instead of a facemask, for:
    - Aerosol generating procedures (refer to [Which procedures are considered aerosol generating procedures in healthcare settings FAQ](https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html))
  - Respirators with exhalation valves are not recommended for source control.

- **For EMS personnel working in areas with minimal to no community transmission**, the universal eye protection and respirator recommendations described for areas with moderate to substantial community transmission are optional. However, EMS personnel should continue to adhere to Standard and Transmission-Based Precautions, including use of eye protection and/or an N95 or equivalent or higher-level respirator based on anticipated exposures and suspected or confirmed diagnoses. Universal use of a facemask for source control is recommended for EMS personnel.

**Create a Process to Address to SARS-CoV-2 Exposures Among EMS Personnel and Others**

EMS should have a process for notifying the health department about suspected or confirmed cases of SARS-CoV-2 infection, and should establish a plan, in consultation with local public health authorities, for how exposures in EMS personnel will be investigated and managed and how contact tracing will be performed. The plan should address the following:

- Who is responsible for identifying contacts (e.g., EMS personnel, patients, family members) and notifying potentially exposed individuals?
- How will such notifications occur?
- What actions and follow-up are recommended for those who were exposed?

Contact tracing should be carried out in a way that protects the confidentiality of affected individuals and is consistent with applicable laws and regulations. EMS personnel and patients who were transported to a healthcare facility should be prioritized for notification. These groups, if infected, have the potential to expose many individuals at higher risk for severe disease, or in the situation of admitted patients, are at higher risk for severe illness themselves.

Information about risk assessment and work restrictions for healthcare personnel (HCP) including EMS personnel exposed to SARS-CoV-2 is available in the **Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to Coronavirus Disease 2019 (COVID-19)**.

Information about when HCP including EMS personnel with suspected or confirmed SARS-CoV-2 infection may return to work is available in the **Interim Guidance on Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19**.
The EMS system must be prepared for potential staffing shortages and have plans and processes in place to mitigate these, including providing resources to assist EMS personnel with anxiety and stress. Strategies to mitigate staffing shortages are available.

2. Recommended IPC practices when caring for a patient with suspected or confirmed SARS-CoV-2 infection

Personal Protective Equipment (PPE)

EMS personnel who will directly care for a patient with suspected or confirmed SARS-CoV-2 infection or who will be in the compartment with the patient should adhere to Standard Precautions and use a NIOSH-approved N95 or equivalent or higher-level respirator (or facemask if a respirator is not available), gown, gloves, and eye protection.

When available, respirators (instead of facemasks) are preferred; they should be prioritized for situations where respiratory protection is most important, including the care of patients with pathogens requiring Airborne Precautions (e.g., tuberculosis, measles, varicella). Additional information about infection control practices and Transmission-Based Precautions is available in the Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19).

- **Hand Hygiene**
  - EMS personnel should perform hand hygiene before and after all patient contact, contact with potentially infectious material, and before putting on and after removing PPE, including gloves. Hand hygiene after removing PPE is particularly important to remove any pathogens that might have been transferred to bare hands during the removal process.
  - EMS personnel should perform hand hygiene by using alcohol-based hand sanitizer (ABHS) with 60-95% alcohol or washing hands with soap and water for at least 20 seconds. If hands are visibly soiled, use soap and water before returning to ABHS.
  - EMS personnel should ensure that hand hygiene supplies are readily available to all personnel on the transport vehicle.

- **Personal Protective Equipment Training**
  EMS should select appropriate PPE and provide it to EMS personnel in accordance with OSHA PPE standards (29 CFR 1910 Subpart I). EMS personnel must receive training on and demonstrate an understanding of:
    - when to use PPE
    - what PPE is necessary
    - how to properly don, use, and doff PPE in a manner to prevent self-contamination
    - how to properly dispose of or disinfect and maintain PPE
    - the limitations of PPE.

Any reusable PPE must be properly cleaned, decontaminated, and maintained after and between uses. Facilities should have policies and procedures describing a recommended sequence for safely donning and doffing PPE.

The PPE recommended when caring for a patient with suspected or confirmed SARS-CoV-2 infection includes the following:

- **Respirator or Facemask** (*Cloth face coverings are NOT PPE and should not be worn for the care of patients with suspected or confirmed SARS-CoV-2 infection or other situations where use of a respirator or facemask is recommended.*)
  - Put on an N95 respirator (or equivalent or higher-level respirator) or facemask (if a respirator is not available) before performing patient care, if not already wearing one as part of extended use strategies to optimize PPE.
Other respirators include other disposable filtering facepiece respirators, powered air purifying respirators (PAPRs), or elastomeric respirators.

- N95 respirators or respirators that offer an equivalent or higher level of protection should be used instead of a facemask when performing or present for an aerosol generating procedure. See appendix for respirator definition and more information about respiratory protection.

- Disposable respirators and facemasks should be removed and discarded after exiting the patient’s care area unless implementing extended use or reuse. Perform hand hygiene after removing the respirator or facemask.
  - If reusable respirators (e.g., PAPRs or elastomeric respirators) are used, they should also be removed after exiting the patient’s care area. They must be cleaned and disinfected according to manufacturer’s reprocessing instructions prior to reuse.

- When the supply chain is restored, EMS personnel using facemasks instead of respirators should return to use of respirators for patients with suspected or confirmed SARS-CoV-2 infection.

**Eye Protection**

- Put on eye protection (i.e., goggles or a face shield that covers the front and sides of the face) before performing patient care, if not already wearing as part of extended use strategies to optimize PPE supply.
  - Protective eyewear (e.g., safety glasses, trauma glasses) with gaps between glasses and the face likely do not protect eyes from all splashes and sprays.
  - Personal eyeglasses and contact lenses are NOT considered adequate eye protection.

- Ensure that eye protection is compatible with the respirator so there is not interference with proper positioning of the eye protection or with the fit or seal of the respirator.

- Remove eye protection after performing patient care, unless implementing extended use.

- Reusable eye protection (e.g., goggles) must be cleaned and disinfected according to manufacturer’s reprocessing instructions prior to re-use. Disposable eye protection should be discarded after use unless following protocols for extended use or reuse.

**Gloves**

- Put on clean, non-sterile gloves before performing patient care.
  - Change gloves if they become torn or heavily contaminated.

- Remove and discard gloves after providing patient care, and immediately perform hand hygiene.

**Gowns**

- Put on a clean isolation gown before performing patient care. Change the gown if it becomes soiled. Remove and discard the gown in a dedicated container for waste or linen after providing patient care. Disposable gowns should be discarded after use. Cloth gowns should be laundered after each use.

- If coveralls are used as an alternative to gowns, put on a clean coverall before performing patient care. A new coverall is required for each patient. Change the coverall if it becomes soiled. Remove and discard the coverall in a dedicated container for waste after providing patient care. Disposable coveralls should not be reused.

EMS systems should work with their health department, healthcare coalition, or emergency management agency to address shortages of PPE.

**Aerosol-Generating Procedures**

- If possible, consult with medical control before performing aerosol-generating procedures for specific guidance. EMS personnel should exercise caution if an aerosol-generating procedure (AGP) is necessary.
  - An N95 or equivalent or higher-level respirator such as disposable filtering facepiece respirators, PAPR, or elastomeric respirator instead of a facemask, should be used in addition to the other PPE described above, by EMS personnel present for or performing aerosol-generating procedures.

- 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 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.

EMS Transport of a Patient with Suspected or Confirmed SARS-CoV-2 Infection to a Healthcare Facility (including interfacility transport)

If a patient with suspected or confirmed SARS-CoV-2 infection requires transport to a healthcare facility for further evaluation and management (subject to EMS medical direction), the following actions should occur during transport:

- EMS personnel should notify the receiving healthcare facility that the patient has suspected or confirmed SARS-CoV-2 infection so that appropriate infection control precautions may be taken prior to patient arrival.
- 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 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 [1.52 MB, 10 Pages].
- 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 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 respirator (or facemask if a respirator was not available).
- Follow routine procedures for a transfer of the patient to the receiving healthcare facility (e.g., wheel the patient directly into an examination room, wheel to dedicated receiving area). At a minimum, EMS personnel should continue to wear their respirator (or facemask) and eye protection while transferring the patient from the ambulance into the facility. Depending on the level of direct patient contact and care being provided during transfer (e.g., CPR), it may be appropriate for EMS personnel to also continue wearing their gown and gloves when entering the facility. In such circumstances, transfer should be coordinated with receiving facility and care must be taken to avoid contaminating surfaces in the healthcare facility.

Documentation of Patient Care

- EMS documentation should include a listing of EMS personnel 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 and level of PPE worn). This documentation may need to be shared with local public health authorities if contact tracing becomes necessary.
Cleaning EMS Transport Vehicles after Transporting a Patient with Suspected or Confirmed SARS-CoV-2 Infection

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

- 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 personnel should wear a disposable gown and gloves, as well as their respirator or facemask. A face shield or 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 SARS-CoV-2 in healthcare settings, including those patient-care areas in which aerosol-generating procedures are performed.
  - 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 used linens.

Additional Resources

The EMS Infectious Disease Playbook, published by the Office of the Assistant Secretary for Preparedness and Response’s Technical Resources, Assistance Center, Information Exchange (TRACIE) is a resource available to planners.

Appendix: Additional Information about Respirators and Facemasks

Information about Respirators:

- 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 the CDC/NIOSH, including those intended for use in healthcare.
- Respirator use must be in the context of a complete respiratory protection program in accordance with OSHA Respiratory Protection standard (29 CFR 1910.134). EMS personnel should be medically cleared and fit tested if using respirators with tight-fitting facepieces (e.g., a NIOSH-approved N95 respirator) and trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use.
- NIOSH information about respirators
- OSHA Respiratory Protection eTool
- Strategies for Optimizing the Supply of N95 Respirators
Filtering Facepiece Respirators (FFR) including N95 Respirators

- A commonly used respirator in healthcare settings is a filtering facepiece respirator (commonly referred to as an N95). FFRs are disposable half facepiece respirators that filter out particles.
- To work properly, FFRs must be worn throughout the period of exposure and be specially fitted for each person who wears one. This is called “fit testing” and is usually done in a workplace where respirators are used.
- **Three key factors for an N95 respirator to be effective**
- FFR users should also perform a user seal check to ensure proper fit each time an FFR is used.
- Learn more about how to perform a user seal check.

NIOSH-approved N95 respirators list.

- PAPRs have a battery-powered blower that pulls air through attached filters, canisters, or cartridges. They provide protection against gases, vapors, or particles, when equipped with the appropriate cartridge, canister, or filter.
- Loose-fitting PAPRs do not require fit testing and can be used with facial hair.
- A list of NIOSH-approved PAPRs is located on the NIOSH Certified Equipment List.

Information about Facemasks:

- If worn properly, a facemask helps block respiratory secretions produced by the wearer from contaminating other persons and surfaces (often called source control).
- Surgical facemasks are cleared by the U.S. Food and Drug Administration (FDA) for use as medical devices. Facemasks should be used once and then thrown away in the trash.

Definitions:

**Source Control**: Use of cloth face coverings or facemasks to cover a person’s mouth and nose to prevent spread of respiratory secretions when they are talking, sneezing, or coughing. Facemasks and cloth face coverings should not be placed on children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.

**Cloth face covering**: Textile (cloth) covers that are intended for source control. They are not personal protective equipment (PPE) and it is uncertain whether cloth face coverings protect the wearer. Guidance on design, use, and maintenance of cloth face coverings is available.

**Facemask**: Facemasks are PPE and are often referred to as surgical masks or procedure masks. Use facemasks 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. Facemasks that are not regulated by FDA, 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 the CDC/NIOSH, including those intended for use in healthcare. Refer to the Appendix for a summary of different types of respirators.

**Substantial community transmission**: Large scale community transmission, including communal settings (e.g., schools, workplaces)

**Minimal to moderate community transmission**: Sustained transmission with high likelihood or confirmed exposure within communal settings and potential for rapid increase in cases
**No to minimal community transmission:** Evidence of isolated cases or limited community transmission, case investigations underway; no evidence of exposure in large communal setting

Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases
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.
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
# JACKSON HEALTH SYSTEM MASKS AND VISITATION GUIDELINES

**August 4, 2021**

<table>
<thead>
<tr>
<th>RISK LEVEL</th>
<th>CRITICAL</th>
<th>HIGH</th>
<th>MEDIUM</th>
<th>LOW</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COVID-positive cases per day over 3-day period at Jackson</strong></td>
<td>&gt;250 cases</td>
<td>151-250 cases</td>
<td>51-150 cases</td>
<td>&lt;50 cases</td>
</tr>
<tr>
<td>Cafeteria Seating</td>
<td>Restricted/avoided</td>
<td>Limited seating, wear mask when not eating/drinking</td>
<td>Limited seating, wear mask when not eating/drinking</td>
<td>Normal operations</td>
</tr>
<tr>
<td>Masking Requirements in Clinical Areas</td>
<td>Always required for everyone</td>
<td>Always required for everyone</td>
<td>Required for everyone indoors</td>
<td>Required for all unvaccinated individuals in all locations AND all employees, patients, and visitors in units caring for immunocompromised patients: **</td>
</tr>
</tbody>
</table>

**Clinical areas are: buildings where clinical services are provided to patients, including hospitals, urgent care centers, and clinics.**

<table>
<thead>
<tr>
<th>Masking Requirements in Non-Clinical Areas</th>
<th>Optional, but preferred, for fully vaccinated employees AND always required for unvaccinated employees.</th>
<th>Optional for fully vaccinated employees AND</th>
<th>Optional for fully vaccinated employees AND</th>
<th>Always required for unvaccinated employees**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-clinical areas are: Jackson Medical Towers, Park Plaza West, and the warehouse on the Jackson Memorial campus.</td>
<td>Always required for everyone</td>
<td>Always required for everyone</td>
<td>Always required for unvaccinated employees**</td>
<td>Always required for unvaccinated employees**</td>
</tr>
<tr>
<td>Visitors</td>
<td>Mask always required in all areas</td>
<td>Mask always required in all areas</td>
<td>Mask always required in all areas</td>
<td>Mask required in patient care areas</td>
</tr>
<tr>
<td>Visitor Allowance</td>
<td>None except rehab, pediatrics, OB, NICU, end-of-life (non-COVID), and administrative exceptions</td>
<td>None except rehab, pediatrics, OB, NICU, end-of-life (non-COVID), and administrative exceptions</td>
<td>Limited hours</td>
<td>Normal operations</td>
</tr>
<tr>
<td>In-Person Meetings</td>
<td>Not allowed, Live clinical learning will continue at reduced room capacity with masks required.</td>
<td>Limited (up to 50% of room capacity), masks always required for everyone Essential hands-on training recommended in person; Zoom encouraged for all other meetings</td>
<td>Limited (up to 50% of room capacity)</td>
<td>Normal operations</td>
</tr>
<tr>
<td>Entry Screening</td>
<td>Symptom screening for all; Daily CARE Check-In for employees</td>
<td>Symptom screening for all; Daily CARE Check-In for employees</td>
<td>Symptom screening for patients/visitors; Daily CARE Check-In for employees</td>
<td>Symptom screening for patients/visitors; Daily CARE Check-In for employees</td>
</tr>
<tr>
<td>Volunteers</td>
<td>Not allowed</td>
<td>Not allowed</td>
<td>Restricted (vaccinated only)</td>
<td>Normal operations</td>
</tr>
</tbody>
</table>

**Individuals who are significantly immunocompromised should discuss appropriate PPE use, including masks, with their medical provider and may be advised to continue to wear a mask despite being fully vaccinated at all risk levels. Fully vaccinated, not immunosuppressed individuals may remove mask if alone in an enclosed room in an administrative area of a building.**
TO: All Jackson Health System

From: Michael E Goldberg MD, Medical Director Perioperative Services, Jackson Health System

RE: Procedures and COVID 19

In light of the recent increase in COVID 19 infections, the increase in prevalence in the community and out of an abundance of caution, we are requiring that all individuals in all procedure areas don appropriate PPE including an N95 mask. (Even if vaccinated and even if you have contracted a previous COVID infection)

Thank you for your continued care and cooperation.