Clinical Brief #41 | COVID-19

Developed Thursday, August 27, 2020

INFORMATION FOR ALL CLINICIANS
Clinical leaders are providing frequent updates to all clinicians in an effort to keep you current about AdventHealth's response to COVID-19. The following topics are included in this brief:

- **FDA-Approved EUA for COVID-19 Convalescent Plasma**
- **Antimicrobial Hand Soap Shortage**
- **FDA Revokes Emergency Use Authorization for Passive Protective Barrier Enclosures Without Negative Pressure**
- **PPE Inventory and Distribution**

FDA-Approved EUA for COVID-19 Convalescent Plasma

The Multi-State Division has been enrolling patients in the Mayo Clinic Expanded Access Program (EAP) for COVID-19 convalescent plasma (CCP). On Sunday, August 23, 2020, the FDA granted an Emergency Use Authorization (EUA) for CCP. In anticipation of the FDA EUA, ***new patient enrollments in the Mayo EAP will be discontinued effective 11:59 p.m. ET on August 28, 2020***.

As part of the EUA, the FDA has required the qualification of COVID-19 antibody load as high and low-titer in each CCP unit. A significant reduction in mortality (relative reduction 37%, p=0.03) was shown when CCP of high-titer were administered within 72 hours of diagnosis to patients under age 80 who required supplemental oxygen compared to analogous patients treated with low-titer CCP in the Mayo Clinic EAP.

To facilitate EUA execution, modifications to the Convalescent Plasma Subphase PowerPlan (PP) are being made. Physicians and advanced allied health care providers (AHPs) will no longer be able to use the old CCP Subphase containing the Mayo EAP. If these were saved as favorites, the new CCP Subphase will need to be saved. This new CCP Subphase will no longer require a separate Mayo EAP consent. Only the AdventHealth Transfusion of Blood Products consent will be necessary, and no unique EIND/EAP identifier will be assigned to each patient. The AdventHealth Multi-State Convalescent Plasma Subphase PP will go live on Friday, August 28, 2020. Pregnant women and children are eligible to receive CCP under the EUA.

Availability of CCP is dependent upon collection and distribution of donated plasma from individuals who have recovered from COVID-19 and may not be readily available. CCP is ordered in a patient-specific fashion from the local blood supplier and no unassigned CCP inventory is maintained at AdventHealth.

Patients must meet the EUA criteria for use and the ordering physician must attest to the criteria via Cerner PowerPlan. An AdventHealth transfusion consent must be obtained from the patient/legally

authorized person (LAP) prior to CCP administration (following routine SOP). Nurse must give patient/LAP the CCP fact sheet prior to CCP administration.

Criteria for Use

1. Known COVID-19-positive
2. Currently requires supplemental oxygen (which includes patients supported with high-flow oxygen, mechanical ventilation and extracorporeal membrane oxygenation [ECMO])

Contraindications

1. Known history of severe transfusion reactions
2. Known allergies to blood or blood components
3. Religious objections (e.g., Jehovah's Witnesses who have not given authorization to transfuse blood products)

Treatment Timing

1. As soon as possible, ideally within three days of admission or new oxygen requirement

Administration

1. Treatment with CCP consists of either one unit of high-titer CCP or two units of low-titer CCP

*Rationale: Administration of multiple low-titer CCP units may approximate the minimum antibody load of one high-titer CCP unit. Low-titer CCP may be issued by your local blood supplier if high-titer CCP is not immediately available.**

   a. One unit of high-titer CCP: recommended transfusion rate is 200 mL/hr or as deemed clinically indicated.
   b. Two units of low-titer CCP: should be transfused sequentially at 200 mL/hr, or as deemed clinically indicated; total volume ≤ 600 mL; time ≤ 24 hours from start of first unit to completion of second unit to minimize risk for hypersensitivity reactions, including transfusion-related acute lung injury (TRALI) and/or volume overload.
2. If clinically indicated, premedicate with acetaminophen 650 mg PO and diphenhydramine 50 mg PO 30 minutes prior to start of CCP. May repeat one more time if >12 hours from premedication administration and CCP transfusion not yet complete.
3. When ordering the convalescent plasma, the ordering physician should discuss with the patient indications, risks and benefits of COVID-19 CCP and the patient must sign the AdventHealth Transfusion of Blood Products consent.

*Per verbal communication, the FDA has authorized a period of six weeks for blood suppliers to obtain antibody titers and appropriately label convalescent plasma. The FDA has indicated the EUA will proceed during this period of transition.

FDA CCP EUA Fact Sheet Links
Fact sheet for Health Care Providers: https://www.fda.gov/media/141478/download
Fact sheet for Patients and Caregivers: https://www.fda.gov/media/141479/download

Antimicrobial Hand Soap Shortage

Due to shortages in Ecolab Equi-Mild™ antimicrobial soap cartridges used in dispensers at various sinks, temporary auto substitution with Endure™ foam plain hand soap cartridges will occur. Per the CDC guidance on hand hygiene in health care settings, the use of plain soap is adequate for hand-washing with water for at least 20 seconds when hands are visibly soiled, before eating, after using

the restroom, after caring for a person with known or suspected infectious diarrhea, and after known or suspected exposure to spores.

FDA Revokes Emergency Use Authorization for Passive Protective Barrier Enclosures Without Negative Pressure

On August 20, the FDA revoked the EUA released on May 1 and issued a letter to health care providers (HCPs) due to preliminary evidence in simulation of potential adverse events or complications that could occur with protective barrier enclosures without negative pressure.

AdventHealth supports the FDA recommendations that HCPs:

- Should not use passive protective barrier enclosures without negative pressure as they may not be effective in decreasing HCP exposure to airborne particles. Two articles were referenced that concluded these devices may result in longer intubation times, result in a breach of PPE, and not only confer minimal or no benefit in reducing aerosols, but may actually increase airborne particle exposure.
- If electing to use for additional protection during aerosolizing procedures, use devices that incorporate negative pressure and authorized under an EUA.
- Never replace using PPE for protective barrier enclosures (with or without negative pressure).
- Remove any protective barrier enclosure if it impedes the HCP's ability to perform a medical procedure on a patient.

The FDA encourages HCPs to report any adverse events or suspected adverse events experienced with protective barrier enclosures.

PPE Inventory and Distribution

AdventHealth is currently in a strong position as it relates to personal protective equipment (PPE) inventory.

After partnering with the Amway Center in Orlando, Florida, to use the stadium as a distribution hub for the system earlier this year, our Supply Chain team has recently pivoted to a new warehouse dedicated to housing and storing PPE for the entire organization. At this warehouse, our teams actively monitor supplies using real-time dashboards for each of our markets. Those teams also proactively manage and order more supplies to ensure there is no disruption in PPE availability.

If you find that there is not adequate PPE at your facility, please reach out to your local Supply Chain leader to ensure the system is set up appropriately.

Because of our strong foundation of PPE inventory, **AdventHealth has stopped the reprocessing of small N95 respirators as of Monday, August 24**. This now means that no PPE is being reprocessed at this time. We will continue the reuse of respirators and extended use of **all** PPE (face masks, respirators, eye protection, gowns). **One respirator/mask will be issued per day** depending on your role, unless visibly soiled or difficult to breathe through.

- Extended use
    - Wear same face mask, respirator, eye protection and gown for repeated close contact with multiple patients without removing between patients
- Re-use
    - Wear same respirator for multiple patients, removing after each encounter

Due to the unknown future around COVID-19 spikes and limitations to receiving as much inventory as we would want, Supply Chain remains focused on procuring PPE inventory, especially respirators. They are committed to only requiring the reprocessing of respirators in the event that the supply needs move to crisis inventory levels. However, their teams will be collecting 3M N95 respirators at select facilities for offsite reprocessing in the event that we need to use as emergency backup inventory.

Please visit the amended PPE Standard Operating Procedure (SOP) Policy for more information.

We are in this together. The hard work and expertise of each team member contributes to the outstanding care that we provide to our communities each day. Thank you.

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We encourage you to take care of yourself, your families and each other as we move through this ongoing response to COVID-19.

GREATER AS A WHOLE | RESOURCES
Online
Novel Coronavirus Information Site
AdventHealth Coronavirus Website | Videos | Blog
Centers for Disease Control and Prevention (CDC)
Department of Health: Florida, Georgia, North Carolina, Kansas, Kentucky, Texas, Wisconsin
Worldwide Coronavirus Data: Johns Hopkins' global cases webpage
By Email:
coronavirusquestions@adventhealth.com
By Phone:
COVID-19 Hotline: 1-877-847-8747