Convalescent Plasma Updates

Authorization of Emergency Use and Discontinuation of Expanded Access Program

Timeline:

1) **Expanded Access Program (EAP) sponsored by Mayo Clinic (April 2020- August 2020)-**
    a. UHS was providing COVID-19 convalescent plasma to COVID-19 patients through the under the Mayo Clinic EAP.
    b. Convalescent plasma was considered an investigational product and had specific inclusion and exclusion criteria that required IRB approval with informed consent, including a Mayo Clinic EAP specific IRB approved consent form. Transfusion medicine was responsible for consenting patient and IRB paperwork submission.
2) **Transition Period (August 2020- November 30, 2020)-**
    a. UHS was providing COVID-19 convalescent plasma to COVID-19 patients through a FDA approved pathway that allowed the administration of investigational products that do not meet the conditions of the Emergency Use Authorization (EUA) product during a 90-day transition period.
    b. Convalescent plasma was considered an investigational product and required consent with the statement that this was investigational drug and did not meet the EUA product specifications.
    c. A consult to Transfusion Medicine prior to ordering convalescent plasma to enroll and consent patients is no longer necessary.
    d. The treating physicians were responsible for consenting patient and ordering convalescent plasma product.
3) **Emergency Use Authorization Period- (December 1, 2020 to present)**
    a. We now have convalescent plasma that is labeled and meets the specifications of the Emergency Use Authorization from the FDA.
    b. Convalescent plasma is considered part of the practice of medicine in a temporary emergency situation and requires informed consent per institutional policy without the approval of IRB.
    c. A consult to Transfusion Medicine prior to ordering convalescent plasma to enroll and consent patients is not necessary.
    d. **Providers can obtain consent for convalescent plasma using the Convalescent Plasma Transfusion Blood Consent form available in EPIC.**
    e. **Additionally per FDA requirements, a "Fact Sheet for Patients and Parents/Caregivers" must be provided to the patient or designated healthcare proxy during consent.**

The Transfusion Medicine service will continue to review and prioritize requests depending on supply and demand of product. Adverse events must be reported and thoroughly investigated after transfusion of convalescent plasma. If any adverse events are noted, please initiate a suspected transfusion reaction evaluation.

Key Points

- UHS has officially transitioned to the EUA convalescent plasma product.

- COVID-19 convalescent plasma provided under the EUA must meet certain conditions labeling of high titer or low titer anti-SARS-CoV-2 antibodies based on testing accepted by FDA under the EUA.
- FDA requirements for consent:
    - Must communicate the following:
        - FDA has authorized emergency use of COVID-19 convalescent plasma, which is not an FDA-approved biological product.
        - The patient or caregiver has the option to accept or refuse administration of COVID-19 convalescent plasma.
        - The significant known and potential risk and benefits of COVID-19 convalescent plasma and the extent of such risk and benefits are unknown.
        - Information on available alternative treatments and the risk and benefits of those alternatives
    - Must also provide recipients with the Fact Sheet for Patients and Parents/Caregivers
- Providers should use the Convalescent Plasma Transfusion Blood Consent form.
    - Consent form should be solely for the purpose of administering convalescent plasma
        - If the patient is consented for convalescent plasma in addition to other blood products, there should be two separate blood consent forms.
    - Transfusion medicine will continue to review and prioritize requests depending on supply and demand.

Please review the updated protocol to obtain convalescent plasma for COVID-19 patients.

UHS Updated Guide to Convalescent Plasma for the Treatment of Patients with COVID-19

1) Is my patient eligible for convalescent plasma? - UPDATED

a) There is no specific inclusion/exclusion criteria under the EUA

b) COVID-19 Infectious Diseases Service consult for treatment with convalescent plasma is required (Pager: 210-203-4139)

2) How do I get convalescent plasma for my patient at UHS? - UPDATED

a) Consult to the Transfusion Medicine service is no longer necessary

b) Consent the patient or healthcare proxy

i) Include information as per FDA requirements above

ii) Provide recipients with the Fact Sheet for Patients and Parents/Caregivers

c) Use the UHS Convalescent Plasma Transfusion Blood Consent form

i) Signed consent form should be solely for the purpose of administering convalescent plasma

d) Required pre-transfusion testing

i) A current blood type and a confirmatory blood type (ABO recheck) performed at UHS will be required prior to issue

(1) A type and screen is not required

e) Order the product

i) Order plasma within EPIC

ii) Choose 1 unit for quantity

(1) Orders beyond 1 unit for patient will be reviewed by the Transfusion Medicine service based on patient status and supply and demand

iii) Enter justification for transfusion as “Convalescent plasma for COVID-19 critically ill patient”

f) All orders will be reviewed and prioritized by the Transfusion Medicine Team based on supply and demand

3) Administration – No changes

a) Follow UHS transfusion protocols
   i) Nursing guidelines 3.100
   ii) Corporate 9.02.01
b) What is the volume transfused?
   i) A single unit (200-400 mL) of ABO compatible plasma
c) What is the recommended rate of transfusion?
   i) 100 to 250 mL/hour (will take approximately 1-2 hours)
d) Is premedication recommended?
   i) No, however, patients may be pre-medicated with acetaminophen and diphenhydramine per routine practice.
   ii) Blood bank will request the blood product from local blood supplier
      (1) Turnaround time of obtaining product will depend on the availability of ABO compatible plasma

4) Reporting adverse events – No changes

a) Initiate a suspected transfusion reaction for significant changes in vital signs or signs/symptoms from pre-infusion values
   i) Refer to nursing guideline 3.100 and corporate policy 9.02.01
   ii) Call the blood bank (210-743-4466) and initiate a suspected transfusion reaction evaluation

Contact information:

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University Hospital Blood Bank
210-743-4466
Request to speak to Pathology/Transfusion Medicine Faculty

Resources

Fact sheet for patients and parents/caregivers - https://www.fda.gov/media/141479/download

Fact sheet for health care providers - https://www.fda.gov/media/141478/download

Comparing EAP vs EUA: What you need to know - https://www.uscovidplasma.org/pdf/EAP%20vs%20EUA.pdf

Expanded Access Program for Convalescent Plasma discontinues enrollment as FDA authorizes its emergency use - https://newsnetwork.mayoclinic.org/discussion/expanded-access-program-for-convalescent-plasma-discontinues-enrollment-as-fda-authorizes-its-emergency-use/?_ga=2.152707449.1343930340.1598359160-2027740757.1593615238

Process for Obtaining Convalescent Plasma for Critically Ill COVID-19 patients