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

A. Study Design:

This study provides access to investigational convalescent plasma for patients in acute care facilities infected with SARS-CoV-2 who have severe or life-threatening COVID-19, or who are judged by a healthcare provider to be at high risk of progression to severe or life-threatening disease.

University Hospital is participating under Mayo clinic’s IRB and is registered at this time.

Following provision of informed consent, patients will be transfused with one unit of ABO compatible convalescent plasma obtained from an individual who has recovered from documented infection with SARS-CoV-2.

Safety information collected will include serious adverse events judged to be related to the administration of convalescent plasma. Other information to be collected retrospectively will include patient demographics, acute care facility resource utilization (total length of stay, days in ICU, days intubated, and survival to discharge from an acute care facility.

B. Is my patient eligible (inclusion criteria)?

1) Age at least 18 years
   a. if less than 18 years call Transfusion Medicine Director for initiation of Investigational Drug Protocol
2) Laboratory confirmed diagnosis of infection with SARS-CoV-2
3) Admitted to an acute care facility for the treatment of COVID-19 complications
4) Severe or life threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease
5) Informed consent provided by the patient or healthcare proxy

Severe COVID-19 is defined by one or more of the following:
- dyspnea
- respiratory frequency ≥ 30/min
- blood oxygen saturation ≤ 93%
- partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300
- lung infiltrates > 50% within 24 to 48 hours

Life-threatening COVID-19 is defined as one or more of the following:
- respiratory failure
- septic shock
- multiple organ dysfunction or failure
C. How do I get convalescent plasma for my patient at UHS?

1) COVID-19 Infectious Diseases Service approval for treatment with convalescent plasma required (pager: 210-203-4139)

2) Notify Transfusion Medicine Faculty
   i. Call Transfusion services medical faculty
      1. Spok on call
         a. Pathology → Transfusion Medicine Faculty
            i. Leslie Greebon, John Daniels or Rahaf Alkhateb
      2. Alternatively call Blood bank (210-743-4466) and ask for the Transfusion Medicine Faculty on Call.

3) Consent the patient or healthcare proxy
   i. Transfusion Medicine Medical Staff will consent with Mayo consent and UHS blood transfusion consent (treating/requesting physician may be asked to be a witness)
      1. Virtual/distance vs. in person consent

4) 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

5) Order the product:
   i. Order plasma within Sunrise
   ii. Choose 1 unit for quantity
   iii. Enter Justification for transfusion as “Convalescent plasma for COVID-19 critically ill patient”

UHS TEST. ZOWIE

Allergies: METHYL SALICYLATE TOPICAL, PENICILLIN, EGGS, SHRIMP

Intolerances: 12 Hour

Order: Fresh-Frozen Plasma Transfusion

Requested By: Greebon, Leslie J

Messages:

Transfusion Date: Apr 08, 2020

UHS Guidelines for Transfusion

UHS guidelines recommend the use of FFP according to the following INR values: INR > 1.6 in a patient who is patient scheduled for an invasive procedure. the FFP should be infused within 4 hours of scheduled procedure to your patient and provide justification for transfusion in the field below if the INR value does not meet UHS guidelines. FFP Concentrate for transfusion is recommended for patients who are bleeding or who are actively bleeding.

Hematocrit = 30 (Jan 24-2019 15:07:02) Platelet Count = 271 (Jan 24-2019 15:07:02)

If there is no INR above, consider ordering an INR level test

Justification for Transfusion

Convalescent plasma for COVID-19 critically ill patient

Amount in UNITS

1

Dose Calculation Instructions

The dose of FFP should be 15 mL/kg of patient weight. The average unit of FFP contains 250 mL.

Transfusion Duration (Hours)

2

Diagnosis
D. Administration
   a. Follow UHS transfusion protocols
      i. Nursing guideline 3.100
      ii. Corporate policy 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. Are premedications recommended?
      i. No, however, patients may be pre-medicated with acetaminophen and
diphenhydramine per routine practice.
   e. Blood bank will request the blood product from local blood supplier
      i. Turnaround time of obtaining product will depend on the availability of ABO
compatible plasma.
   f. Blood bank staff will instruct nursing staff if the transfusion can be documented in Soft IDTX
transfusion administration module vs. down time documentation will be required.

E. Reporting adverse events:
   1) Initiate a suspected transfusion reaction for significant changes in vital signs or signs/symptoms
from pre-infusion values
      a. Refer to nursing guideline 3.100 and corporate policy 9.02.01.
      b. Call the blood bank (210-743-4466) and initiate a suspected transfusion reaction
evaluation
      c. Severe Adverse Events will be reported to the Sponsor from transfusion medicine/pathology department.

Contact information:

Leslie J. Greebon, MD
Transfusion Services Medical Director (Section Chief)
Cell: 830-237-0943
Greebon@uthscsa.edu

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

Resources and Forms:

Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19-Mayo-
https://www.uscovidplasma.org/

Study Protocol Document- https://www.uscovidplasma.org/pdf/20-003312%20COVID-
19%20Plasma%20EAP%20Version%202.0.pdf

FDA Webpage, Recommendations for Investigational COVID-19 Convalescent Plasma:
https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-
process-cber/recommendations-investigational-covid-19-convalescent-plasma
Process for Obtaining Convalescent Plasma for Critically Ill COVID-19 Patients

Identify a critically ill patient who has tested positive for COVID-19
COVID-19 Infectious Diseases Service approval for treatment with convalescent plasma required (pager: 210-203-4139)

Is the patient 18 years old and meets inclusion criteria?

No
Notify Blood Bank (21-743-4466) or Transfusion Medicine Medical Director (Pathology on call) for possible initiation of Emergency Investigational Drug Use Protocol

Yes
Contact Blood Bank (21-743-4466) or Transfusion Medicine Faculty (Pathology) on call

Transfusion Medicine to consent the patient or proxy with Mayo consent and UHS Blood consent
- Treating/ requesting physician may be asked to be witness

Order plasma:
- 1 unit
- Justification: “Convalescent plasma for COVID-19 critically ill patient

Transfusion Medicine Faculty to consent patient or healthcare proxy with UHS Blood consent (the Treating/ requesting physician may be asked to be witness).

Complete FDA Form 3926 and e-mail to greebon@uthscsa.edu for submission to the FDA (https://www.fda.gov/media/98616/download)

Administration and reporting of transfusion related adverse events per UHS transfusion guidelines
Corporate policy 9.02.01
Nursing guideline 3.100