CORONAVIRUS CONVALSCENT PLASMA PROGRAM:
HOW YOU CAN HELP

Background:

There are currently no proven treatment options for COVID-19. COVID convalescent plasma (CCP) is collected from patients who have recovered from COVID-19. This plasma may contain antibodies to COVID-19 which can be administered to patients with severe COVID-19 infections. The anticipated mechanism of action by which passive antibody therapy via CCP would mediate protection is viral neutralization. Though limited studies are available, the information suggests that CCP administration reduces COVID viral load and is safe. Further investigation is needed to determine if CCP can reduce duration of illness, morbidity, or mortality.

Theoretical benefit:

Use of convalescent plasma has been studied in other respiratory infections, such as the 2003 SARS-CoV-1, 2009 H1N1, and 2012 MERS-CoV epidemics. It was also used in 2013 African Ebola epidemic.

- Shen C, Wang Z, Zhao F, et al. Treatment of 5 Critically Ill Patients With COVID-19 With Convalescent Plasma. *JAMA.* 2020;323(16):1582–1589. doi: 10.1001/jama.2020.4783
- Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clin Infect Dis. 2020 doi: 10.1093/cid/ciaa344
- Bloch E, Shoham S, et al. Deployment of convalescent plasma for the prevention and treatment of COVID-19. Journal of Clinical Investigation. 2020 doi: 10.1172/JCI138745.

Patient eligibility: WHO CAN HELP

- Laboratory confirmed COVID19 infection (e.g. nasopharyngeal swab or other respiratory sample)
- Severe or life-threatening disease. Clinical trial on going to evaluate for prophylactic use at this point.

Patient access may be obtained through

- Single Patient Emergency IND – Immediate use. Rapid approval by FDA over telephone or email within 4 to 6 hours. Form is short and quick to fill out. Prior IRB not needed. Must be done for each patient.
- National Expanded Access Treatment Protocol IND: Protocol offered by Mayo Clinic. Must register hospital and at least one physician from treating hospital. Registered hospitals may transfuse CCP for any patient with, or at risk of, severe or life-threatening COVID-19 disease. Documentation: Must enroll patient on website. Fill out 4-hours and 7-day post transfusion form. Though local IRB not required, UTHSC IRB has been obtained. NO charge for CCP obtained through this protocol if provided by ARC, funded by BARDA.

Donor eligibility:

- Laboratory confirmed COVID19 infection (e.g. nasopharyngeal swab or other respiratory sample) OR a positive serological test for SARS-CoV-2 antibodies after recovery
- (1) Asymptomatic for at least 28 days OR (2) asymptomatic for 14 days with negative SARS-CoV-2 molecular test
- Meet usual blood donation eligibility criteria (e.g. If previously pregnant, negative for HLA antibodies)
- Ideally have SARS-CoV-2 neutralizing antibody titers, although this is not a readily available assay or required. Donor centers are going to keep tubes of blood to test these later.

Conceptual Risks (actual unknown):

- Transfusion-transmitted SARS-CoV-2 (There is no evidence that coronaviruses are transmitted by receiving blood transfusion. SARS-CoV-2 rare in blood. Recipients are already infected).
- Antibody-mediated enhancement of infection (theoretical concern that antibodies to one type of coronavirus could enhance infection to another viral strain) is unknown, and not described in other respiratory viruses
- Blunting of development of natural immune response (humoral and/or cellular)
- Risk associated with transfusion of any blood product (transfusion transmitted infections and adverse transfusion reactions)

Risk to donors:

- Same as risk associated with routine plasma donation. Plasma donation is safe and generally well tolerated by most patients. Some side effects include IV site bruising, allergic reactions, or rarely, symptoms of citrate toxicity. Plasma donation centers are well equipped with personal protective equipment to protect everyone at the center.

Further information/Reference:
https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma#Patient%20Eligibility
https://covidplasma.org/

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