COVID-19 Convalescent Plasma Resources

-last updated APRIL 4, 2020

QUICK LINKS
COVID-19 Convalescent Plasma Collection: Donor Eligibility, Processing, Labeling, and Distribution (last updated 04 04 20) THIS PROTOCOL IS EXPECTED TO CHANGE AS FDA RELEASES NEW INFORMATION IN RESPONSE TO THE EVOLVING PANDEMIC. CHECK FREQUENTLY FOR UPDATES.

FDA has posted:
- April 04, 2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs
- March 26, 2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs Frequently Asked Questions

Overview
AABB joins the National Academies of Science, the National Academy of Engineering, and the National Academy of Medicine in calling for research into the use of convalescent plasma, a well-established technique that is showing promise in early studies with COVID-19 patients.

Although the indications are very preliminary at this stage, it appears that COVID-19 convalescent plasma (CCP) may be safe and may have the potential to reduce the duration and severity of COVID-19. Convalescent plasma treatment works because plasma collected from individuals who have already recovered from COVID-19, contains antibodies that could provide passive immunity, which may help patients fight the infection. Further investigation is still necessary to determine if convalescent plasma will shorten the duration of illness, reduce morbidity, or prevent death associated with COVID-19. If this treatment is effective, a hyperimmune globulin pharmaceutical product will be the preferred delivery device for these antibodies. However, it could take several months to manufacture and produce this product. CCP will provide the bridge to future treatment with hyperimmune globulin - In the interim, blood centers and hospitals are partnering to collect convalescent plasma from patients who have recovered from COVID-19 to make this treatment widely available as quickly as possible.

FDA has posted these documents:
Investigational COVID-19 Convalescent Plasma - Emergency INDs
Investigational COVID-19 Convalescent Plasma - Emergency INDs Frequently Asked Questions

Key Points to Consider

- COVID-19 convalescent plasma (CCP) is currently being studied as a therapy for COVID patients; preliminary data from China suggest this is a promising bridge to the availability of a hyper immune globulin product.
- During this interim period, convalescent plasma from COVID-19 patients will be collected under a well-coordinated master protocol approved by FDA, to support administration of CCP under patient-specific emergency Investigational New Drug application (eIND) protocols, or under traditional FDA-approved INDs.
Points to consider in the preparation and transfusion of COVID-19 convalescent plasma (Jay Epstein & Thierry Burnouf, on behalf of the ISBT Working Party on Global Blood Safety)

**ICCBBA Codes for COVID-19 Convalescent Plasma**

**Frequently Asked Questions**

**What is COVID-19 Convalescent Plasma (CCP)?**

CCP provides passive immune antibody therapy, with a track record of use dating back to the Spanish Influenza outbreak: [https://annals.org/aim/fullarticle/729754/meta-analysis-convalescent-blood-products-spanish-influenza-pneumonia-future-h5n1](https://annals.org/aim/fullarticle/729754/meta-analysis-convalescent-blood-products-spanish-influenza-pneumonia-future-h5n1)

The use of CP was evaluated as a possible tool during outbreaks of other influenza and respiratory illnesses (HSN1, H1N1, MERS-COV, SARS).

**Will it help the treatment of COVID patients?**

It appears that way – further investigation is still necessary. While we are a few months away from a possible pharmaceutical plasma product, blood centers and hospitals are partnering to produce CCP that could be used for COVID-19 patients under an FDA approved treatment protocol.

The use of convalescent plasma in the treatment of coronaviruses may be safe and effective. [https://academic.oup.com/jid/article/211/1/80/799341](https://academic.oup.com/jid/article/211/1/80/799341). Furthermore, early studies from China (https://www.medrxiv.org/content/10.1101/2020.03.16.20036145v1) suggest this may be [https://www.thelancet.com/journals/lancet/article/PIIS1473-3099(20)30141-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS1473-3099(20)30141-9/fulltext) a promising option for management of COVID-19 patients, with the potential to reduce the severity and duration of illness in some patients.


**How Will Convalescent Plasma Be Collected?**

With support from FDA, AABB has a project underway to create a master collection protocol under which blood centers would be able to quickly implement uniform practices to expedite the availability of CCP. This master collection protocol will be different from the pathway described by FDA earlier this week because it will not be a patient-specific collection; rather, blood centers will collect and store plasma from convalesced individuals for use by hospitals under an FDA approved IND.

We expect the work on the master protocol to continue for a short time as we coordinate efforts to expedite FDA approval.
Again – We remind you to check back often for updates on rapidly changing events and information.