The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Convalescent Plasma for the Treatment of COVID-19

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On August 23, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA)* for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19.[1,2] The COVID-19 Treatment Guidelines Panel (the Panel) reviewed the available evidence from published and unpublished data on convalescent plasma for the treatment for COVID-19, including the FDA analyses that supported the EUA.

There are currently no data from well-controlled, adequately powered randomized clinical trials that demonstrate the efficacy and safety of convalescent plasma for the treatment of COVID-19. The FDA analysis of data on a subset of hospitalized patients from the Mayo Clinic's Expanded Access Program (EAP) compared outcomes in patients who received convalescent plasma with high titers of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing antibodies to outcomes in patients who received plasma with low titers and found no difference in 7-day survival overall. Among patients who were not intubated, 11% of those who received convalescent plasma with high antibody titers died within 7 days of transfusion compared with 14% of those who received convalescent plasma with low antibody titers. Among those who were intubated, there was no difference in 7-day survival. Although these data suggest that convalescent plasma with high antibody titers may be beneficial in nonintubated patients, uncertainty remains about the efficacy and safety of convalescent plasma due to the lack of a randomized control group and possible confounding in the Mayo Clinic's EAP. Additionally, antibody levels in currently available COVID-19 convalescent plasma are highly variable, and assays to determine the effective antibody titers remain limited.[3]

Based on the available evidence, the Panel has determined the following:

- There are insufficient data to recommend either for or against the use of convalescent plasma for the treatment of COVID-19.
- Available data suggest that serious adverse reactions following the administration of COVID-19 convalescent plasma are infrequent and consistent with the risks associated with plasma infusions for other indications. The long-term risks of treatment with COVID-19 convalescent plasma and whether its use attenuates the immune response to SARS-CoV-2, making patients more susceptible to reinfection, have not been evaluated.
- Convalescent plasma should not be considered standard of care for the treatment of patients with COVID-19.
- Prospective, well-controlled, adequately powered randomized trials are needed to determine whether convalescent plasma is effective and safe for the treatment of COVID-19. Members of the public and health care providers are encouraged to participate in these prospective clinical trials.
- The Panel will continue to evaluate emerging clinical data on the use of convalescent plasma for the treatment of COVID-19 and will update the Convalescent Plasma section of the Guidelines in the near future.

* The criteria for issuance of an EUA are not the same as the standards for FDA approval.[4] There are currently no FDA-approved therapies for the treatment of COVID-19.

References

1. Food and Drug Administration. Coronavirus disease 2019 (COVID-19) EUA information. 2020. Available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas. Accessed August 31, 2020.
2. Food and Drug Administration. Convalescent plasma letter of authorization. 2020. Available at: https://www.fda.gov/media/141477/download. Accessed August 31, 2020.
3. Food and Drug Administration. EUA 26382: Emergency Use Authorization (EUA) Request. 2020. Available at: https://www.fda.gov/media/141480/download. Accessed August 31, 2020.
4. Food and Drug Administration. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders. January 2017; Available at: https://www.fda.gov/media/97321/download. Accessed August 31, 2020.