FAQ: What is the Role of Convalescent Plasma in COVID-19 and How Can My Hospital Obtain this Therapy?

DASON currently recommends traditional supportive care as the cornerstone of COVID-19 treatment. Several investigational therapies have been proposed, and we continue to support use of these therapies only in the setting of clinical trials that will help ascertain data regarding efficacy and safety. One such therapy is convalescent plasma.

Convalescent plasma has been studied for outbreaks of a variety of respiratory tract infections including Ebola, the 2009-2010 H1N1 influenza virus pandemic, the 2003 SARS-CoV-1 epidemic, and the 2012 MERS-CoV epidemic. There have been two published uncontrolled case series performed in China that evaluated convalescent plasma for treatment of COVID-19 in a total of 15 patients who were hospitalized with severe COVID-19 disease. Both case series noted clinical improvement in patients after administration of convalescent plasma; however, there were several limitations to these case series reports, including small sample sizes, lack of controls, and co-administration of other antiviral therapies and steroids. The larger of the two case series that included 10 of the 15 patients has not been peer reviewed. Based on this information, we cannot attribute patients’ clinical improvement or mortality outcomes in these case series to the administration of convalescent plasma.

The FDA and DASON consider convalescent plasma an investigational therapy and believe that it is necessary to determine the efficacy of this therapy prior to administering it routinely to patients with COVID-19. At this time, convalescent plasma is available through clinical trials, single patient emergency investigational new drug (IND) applications, and expanded access programs. The FDA website describes pathways for administering or studying convalescent plasma and considerations for eligibility of plasma donors. There is also a link to the National Expanded Access Treatment Protocol. This program is being coordinated through the Mayo Clinic, and the Mayo Clinic IRB will serve as the IRB of record. It is worth noting that hospitals who participate in the expanded access treatment protocol will need to supply their own convalescent plasma from local sources or a blood bank as outlined in the treatment protocol. Additional information and detailed protocols for current clinical trials and study protocols utilizing convalescent plasma are available at the National COVID-19 Convalescent Plasma Project website.

References:

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