Rapid Implementation of a COVID-19 Convalescent Plasma Program

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OBJECTIVES

The objective was to create a program to collect and distribute CCP to meet the anticipated patient needs. Specifically, it should be:

- Rapidly implemented
- Readily expandable and contractible to meet changing needs
- Address local and national needs
- Focused on donor and patient safety

RESULTS

- As planned, we implemented the program in phases. Important aspects of each phase are shown in Figure 1.
- Collection began the week of March 22 and rapidly increased through April, and plateaued at ~4000 units/week through mid-May (Figure 2). By the end of May, we had distributed over 16,000 units of CCP.
- As shown in Figure 3, collections began decreasing in late May as whole blood collections began to increase. The large increase in distribution of CCP units in June corresponds to the increase in cases in various areas of the US and represents shipment to those regions for use in their hospitalized patients. Through the end of August, we had distributed over 45,000 units.
- The evolution of testing, use of collection technology, and distribution in our program, as well as the evolution of passive immune products, is shown in Figure 4.

MATERIALS AND METHODS

We took a phased approach to CCP collection.

In phase I, which began in early March 2020, our partnered hospitals assumed a major role in recruitment, including identification and testing of recovered COVID-19 patients. Eligibility included a prior diagnosis of COVID-19 by laboratory test, resolution of symptoms for 214 days, and a negative follow-up COVID-19 molecular test. A system of direct referral from hospitals was established, and CCP units collected from donors were returned to the referring hospital for use under IND.

In phase II, NYBCe directly recruited donors to create a general pool of CCP for equitable distribution. To facilitate recruitment, our website was updated with information for donors, healthcare providers, and a web-based form for donors to provide information and documentation of COVID-19 testing results. We received lists of potential donors from communities and public health agencies and increased the number of staff available to contact and schedule potential donors.

Redeployment and training were used to increase staff for these CCP-related activities. Based upon data from various sources and after consultation with the FDA, we also dropped the requirement for a negative test after symptom resolution.

CCP LANDING PAGE

The COVID-19 pandemic is caused by SARS-CoV-2. By early May 2020, ~1.2 million cases and over 70,000 deaths occurred in the US alone. New York State, an early epicenter in the US, had over 325,000 cases and 25,000 deaths, over half (56%) of which were in New York City, where New York Blood Center Enterprises (NYBCE) is headquartered. Given the potential of using convalescent plasma to prevent and treat COVID-19, we adopted a phased approach to developing a COVID-19 convalescent plasma (CCP) program in partnership with our hospitals. As the pandemic progressed, the program was expanded to support the changing needs across the country.

CONCLUSIONS

- Rapid implementation and scale up of a CCP donation program was realized.
- We have met the needs of hospitals in our regions including support of various clinical trials, as well as contributed to the national distribution of CCP.
- As focus changes, CCP can employed to the production of hyperimmune globulin.

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