



# COVID-19 convalescent plasma experience in the US

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**Abstract:** Convalescent whole blood, plasma, and serum have been used as passive immune therapy of infectious diseases since the late 1800s. Following favorable reports of safety and clinical improvement after limited use of convalescent plasma (CP) to treat SARS-CoV-2 disease (COVID-19), the United States Food and Drug Administration (FDA) invited investigational use of this product. Single-patient emergency Investigational New Drug Applications (eINDs) were soon followed by an expanded access program (EAP). Data from the EAP led to FDA's emergency use authorization of COVID-19 CP (CCP). The elements of a CCP program are donor recruitment, prevention of disease transmission at the collection site, donor screening at the collection site, plasma collection, testing plasma for potency, and the use of postdonation information from the donor. These elements are based on practices already used for allogeneic donation generally. Data supporting current CCP potency criteria, which are related to the titer of antibody against SARS-CoV-2, are limited. A report of rates of adverse donor outcomes and product loss exceeding those for non-CCP donations needs further study. Initially high demand for CCP appears to have declined. Regulatory restrictions on eligible recipients may further decrease demand. The effects of vaccination on donor and recipient availability are to be determined.

**Keywords:** COVID-19 convalescent plasma (CCP); plasma collection; plasma manufacture; United States

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## Background on convalescent plasma (CP)

In a rapidly evolving pandemic, therapeutic options such as a vaccine or specific therapy are usually not available for emerging viruses. One approach has been passive immune therapy with convalescent whole blood, CP or convalescent serum. The transfusion of convalescent blood products is not a new clinical tool in emerging infectious disease outbreaks. Use of blood products from recovered patients dates back to the late 1800s (1). The pandemic of 1918–1920 (Spanish influenza) was the first viral infection for which convalescent blood products were used. A meta-analysis suggested reduced mortality in patients who received convalescent blood products (2).

CP was used for prevention and/or treatment during the West African Ebola outbreak because there was no

specific treatment or vaccine (3). CP has been used to treat infections by other viruses such as MERS-CoV, SARS-CoV-1, and influenza A (H1N1) 2009 (4,5). Despite a long history of use of CP, its clinical efficacy has not been established. Its effectiveness appears to vary depending on the pathogen and treatment protocols (e.g., timing, volume, and dosing). Early in the pandemic of SARS-CoV-2 disease (COVID-19), it was suggested that use of CP transfusions could be of great value, given the lack of specific therapeutic options (6). Some COVID-19 patients who received COVID-19 CP (CCP) showed clinical improvement (7). An uncontrolled trial of CCP in 10 severely ill COVID-19 patients reported that administration was safe and was associated with improvement in symptoms, oxygenation, and radiographic findings and resolution of viremia (8).

## Early history of CCP in the United States

On Mar 24, 2020, the United States Food and Drug Administration (FDA) encouraged investigators to submit requests for investigational use of CCP. Recognizing that not all COVID-19 patients may be able to participate in clinical trials, FDA facilitated access to CCP through single-patient emergency Investigational New Drug Applications (eINDs) (9). As FDA had neither approved any COVID-19 treatment at that time nor granted Emergency Use Authorization to any treatment, healthcare providers “flooded” FDA with eINDs (10,11). On Apr 1, FDA gave Mayo Clinic permission to start an expanded access program (EAP) under which it would collect data on CCP given to COVID-19 patients and the American Red Cross would help collect and distribute the plasma (12,13). The EAP found plasma to be safe, with a low risk of serious adverse events (14). This program, which led to the transfusion of over 94,000 units (15), was the first large-scale CCP collection activity in the United States.

## Elements of a CCP program

A CCP program is not simple. There are scientific, operational and logistical considerations when obtaining plasma from recovered patients and converting it to a therapy (4). The essential elements of a CCP program are:

- (I) Recruitment of donors who have recovered from the disease and meet eligibility criteria to donate CCP;
- (II) Prevention of disease transmission at the collection site;
- (III) Screening of donors at the collection site;
- (IV) Plasma collection;
- (V) Testing plasma for potency;
- (VI) Use of postdonation information.

## Recruitment of eligible donors

CCP donors must meet requirements for allogeneic plasma donation in general as well as criteria specific for CCP donation. The latter include evidence of COVID-19 documented by specified laboratory testing and complete resolution of symptoms at least 14 days before the donation (16). A donor who received a COVID-19 vaccine is acceptable if vaccination occurred after diagnosis of COVID-19 and donation occurs within 6 months after complete resolution of COVID-19 symptoms (16); the

intent of this requirement is that collected plasma should contain sufficient antibodies in response to COVID-19 infection rather than to vaccination (17). A donor who received a live-attenuated viral COVID-19 vaccine should not donate for a short waiting period (e.g., 14 days) after vaccination (18). A donor who was treated with COVID-19 monoclonal antibodies is deferred for 3 months (16,19). These criteria are publicized to encourage plasma donation by eligible individuals.

Early in the pandemic, hospitals were a significant source of donors, as much COVID-19 testing was done in that setting (20). As antibody testing became more widely available, screening of current donors and recruitment of convalescent patients by blood centers became dominant (21). Many individuals and organizations have publicly encouraged donation. These include AABB (formerly the American Association of Blood Banks), blood centers (22,23), FDA (24), and the US Surgeon General (25). “The Fight Is in Us”, a national donor recruitment campaign, is supported by academic medical institutions, plasma companies, national blood organizations, technology supporters, and others (26).

## Prevention of disease transmission at the collection site

Plasma collection sites pose a risk of transmitting the very disease that CCP is intended to treat. To mitigate this risk and to assure donors of their safety, several measures are taken. Social distancing is enforced. Infection control protocols to support practices such as cleaning of surfaces and temperature checks are in place (23,27). To control the number of people at the site and thus maintain social distancing, donation appointments are encouraged. Donors are required to wear face coverings (28). A person at risk for spreading COVID-19—such as one with COVID-19 symptoms or recent exposure to someone with COVID-19, or one who had COVID-19 and had symptom resolution less than 14 days earlier—is advised not to donate (18,27). Staff performing plasma collection, as well as other blood center staff, have a high priority for COVID-19 vaccination (29).

## Screening of donors at the collection site

Eligibility of plasma donors, like eligibility of other blood donors, is determined using a health history questionnaire, physical examination, and hemoglobin determination. In addition, the aforementioned detailed criteria specific to

CCP donation are reviewed with the donor to ensure that they are met.

### Plasma collection

Whole blood collection has the advantages of relative speed and simplicity of collection but the disadvantage of resulting in only one plasma unit every eight weeks. On the other hand, a collection of plasma by apheresis can be performed much more often and results in up to 4 transfusable products rather than just the one obtained from a whole blood unit (30,31). In one blood center, CCP donors undergoing plasmapheresis were found to be more likely to be first-time and female than whole-blood or standard plasma/platelet apheresis donors. CCP donations had a higher rate of donor adverse reactions, deferrals, and product loss than standard apheresis donations, as expected due to the predominance of first-time donors (32).

### Testing of plasma for potency

The results of an assay for treatment potency should relate to clinical effectiveness. Data from the Mayo EAP showed that administration of plasma with a titer over 250 in the Broad Institute (Cambridge, MA, USA) viral neutralization assay was associated with decreased 7- and 28-day mortality of nonintubated hospitalized COVID-19 patients compared to transfusion of plasma with a lower titer, although there was no control group of untreated patients (11). Based on these data, FDA granted Emergency Use Authorization (EUA) for CCP, under which each plasma unit was required to be labeled as high titer or low titer depending on whether the anti-SARS-CoV-2 antibody titer by an accepted assay was at least a specified value or less than that value. On Aug 23, 2020, FDA set this discriminatory titer to be a signal-to-cutoff ratio of 12 by the Ortho VITROS SARS-CoV-2 IgG test (33). The value of 12 corresponded to a titer of 250 in the Broad Institute assay (34). On Nov 16, FDA announced that it would exercise enforcement discretion to allow distribution of investigational plasma without titer determination through Feb 28, 2021 (35). On Nov 30, 2020, FDA accepted a second assay, the Mount Sinai COVID-19 ELISA IgG Antibody Test, with a discriminatory titer of 1:2,880 (36). On Jan 8, 2021, blood centers asked for an extension of the enforcement discretion period to allow approval of alternate COVID-19 antibody assays that would give the centers “more flexibility and resiliency” (37). On Jan 15, FDA extended the enforcement discretion period

through May 31, 2021 (17). On Feb 4, after a study from Argentina showed that the incidence of severe respiratory disease following CCP treatment of mild COVID-19 symptoms was inversely related to the CCP's titer of IgG against the SARS-CoV-2 spike protein (38), FDA withdrew authorization of low titer plasma but accepted 7 more assays for qualifying plasma as high titer (39), using in part the correlations of these assays' values to the Broad Institute assay values (40). The Ortho assay's minimum qualifying titer was lowered from 12 to 9.5 (39); data supporting this change were not given, but an analysis of 30-day mortality in the Mayo EAP was consistent with a minimum qualifying titer between 4.62 and 18.45 (41).

The ultimate availability of high titer plasma is unknown. Assay instability has been observed and caused significant fluctuations in the proportion of plasma units that were high titer. It is estimated that EUA implementation will result in 50–60% of collections from convalescent donors being high titer; but this could be affected by, for example, changes in donor criteria (42).

### Use of postdonation information

Although respiratory viruses are not known to be transmitted by blood transfusion, if a donor reports a COVID-19 diagnosis or COVID-19 symptoms shortly after donation, FDA suggested that retrieval and quarantine of their blood and blood components be considered (43). As of Feb 19, 2021, this suggestion is no longer on the agency's website.

### Challenges of future collections

The report of higher rates of adverse outcomes and product loss for CCP donors compared to other donors requires further study. Whether these findings are replicated by other blood centers remains to be seen.

CCP supply and demand trends are complex. From Sep 28 through Dec 27, 2020, US plasma distribution exceeded collections (44). From November through December 2020, the percentage of AABB member hospitals reporting delays in obtaining CCP rose (45). US blood collection organizations distributed more than 100,000 units of CCP to healthcare providers in December (46), but in January 2021 the demand approached over 30,000 units per week (25). On the other hand, from Nov 30, 2020, to Jan 4, 2021, progressively more AABB member hospitals reported declining CCP

transfusion rates (45). And the limitation of the EUA to hospitalized patients early in the disease course or with impaired humoral immunity—effective Feb 4, 2021 (39)—will decrease demand. The effect of vaccination is uncertain as the resultant reduction in COVID-19 disease will decrease the demand for CCP but also the supply of convalescing donors. Future clinical studies are also expected to affect demand as the indications for CCP become better defined.

The data supporting current serologic criteria for plasma potency are limited. More results should be forthcoming as randomized clinical trials are completed.

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