Ortho Clinical Diagnostics

When you’re pulled in a thousand different directions, we’ll help you move forward.

Ortho’s transfusion medicine solutions are designed to help you overcome your lab’s challenges, so you can continue delivering safe transfusions—no matter what. Because every test is a life.
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The COVID-19 pandemic has led members of the blood and biotherapies community to utilize social media apps more than before.
A year ago, we were in the early stages of a pandemic caused by a novel pathogen with no vaccine and limited therapeutic options. Treatments for COVID-19 were not supported by research; in fact, research on the efficacy of COVID-19 convalescent plasma (CCP) was being conducted even as CCP was being administered to patients as a bridge therapy under the Expanded Access Protocol.

A year later, we now have wide access to vaccines that are effective at preventing severe disease among those infected with the virus, as well as a better array of treatments. At this juncture, AABB News decided to take a look back at the pandemic and at how the blood and biotherapies community has responded to the crisis.

Rising to the Challenge

Beginning last March, blood centers were forced to find new ways to collect blood during the shutdown, while being simultaneously called upon to develop procedures and begin collecting CCP at breakneck speed, and they responded to that call. The first feature article in this issue, which starts on page 10, discusses how blood centers responded when they were faced with the sudden shutdown of schools and offices, which necessitated finding new ways to collect blood in a changed world of masks and social distancing. The second feature, beginning on page 15, examines how CCP became a treatment for COVID-19 even as it was being studied as a therapy, collected by blood centers that had to come up with a new set of policies, protocols and procedures, and administered as a form of compassionate care to patients with few treatment options.

Social media has become a lifeline for some during the COVID-19 pandemic. The third feature, starting on page 20, looks at the ways members of the blood and biotherapies community have turned to social media platforms as a means of seeking and sharing information and connecting with their colleagues.

As I reflect on what members of our community — as well as people throughout the world — have dealt with during this challenging time, I do so with a sense of pride. The blood and biotherapies community has faced unprecedented challenges and been forced to quickly adapt to new realities. But, as always, this community continues to adjust and respond accordingly — and continues to ensure that a safe and adequate blood supply is available for patients in need. ✍️

David Green, MSA
AABB President
A world with fewer, better transfusions.

That’s our vision
Addressing Remaining Questions About the Use of CCP

By Claudia S. Cohn, MD, PhD
Chief Medical Officer

COVID-19 convalescent plasma (CCP) has been widely used since April 2020, when the virus began to spread rapidly throughout the United States and the world. Its positive safety profile and the lack of other proven therapies made CCP a popular option for the treatment of patients with COVID-19. In the U.S., approximately 530,000 units had been distributed to hospitals at press time; however, we still do not fully understand the best ways to use CCP in regard to timing, dosage and patient population.

By early 2021, the supply of CCP was outstripped by demand as COVID-19 cases surged. The need for evidence-based guidelines led AABB to assemble a group of experts from the transfusion community, with representatives from critical care, anesthesiology, microbiology, hematology and Cochrane, as well as a patient representative. Based on the available evidence, this group developed interim recommendations for CCP use. These interim recommendations will be updated as more peer-reviewed clinical trial data are published.

The recommendations (see Table 1) addressed the four most important questions surrounding CCP use:

- **Safety:** The first interim recommendation notes that CCP and conventional plasma carry the same level of risk. This is based on strong evidence from multiple randomized controlled trials (RCT), studies and case reports. In a paper from the Mayo Expanded Access Protocol, a 0.39% rate of adverse events was reported after 20,000 units of CCP were transfused. No deaths were ascribed to transfusion of CCP. No evidence was found that CCP caused other adverse events such as thromboembolism or antibody mediated enhancement.

- **Timing of CCP transfusion:** The second interim recommendation stated that CCP should be given as early as possible after symptom onset and emphasized that CCP should not be given late in the disease course or if a patient is on mechanical ventilation. Since the SARS-CoV-2 virus is generally cleared from a patient’s system 9 days after infection, it seems likely that CCP will only be effective during the early viremic stage of the disease. Nearly all trials to date have given CCP to inpatients who have moderate to severe COVID-19 and often are aviremic; these trials have found that CCP confers no benefit when compared to controls. One trial, however, tested CCP in the outpatient setting and found that recipients of CCP were significantly less likely to progress to severe respiratory disease when compared to other outpatients given placebo. But another trial (C3PO) also tested CCP in the outpatient setting and closed due to futility. The details of why C3PO ended early have not yet been released. Until more data are available, the best evidence suggests that the earlier CCP is given, the more likely it is to confer some benefit.

- **Titer:** The interim recommendations

### Table 1: Interim Recommendations for COVID-19 convalescent plasma use

<table>
<thead>
<tr>
<th>Interim Recommendation 1</th>
<th>When making risk benefit decisions, one should consider the risk of CCP as comparable to standard (SARS-CoV-2 non-immune) plasma.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Recommendation 2</td>
<td>CCP is optimally effective when transfused as close to symptom onset as possible. CCP is unlikely to provide benefit for patients with late-stage disease or on mechanical ventilation.</td>
</tr>
<tr>
<td>Interim Recommendation 3</td>
<td>The effectiveness of CCP is related to the antibody quantity within a unit; high-titer CCP is superior to low-titer CCP. A single high-titer unit should be sufficient for most patients.</td>
</tr>
<tr>
<td>Interim Recommendation 4</td>
<td>If group B or group AB CCP is unavailable, transfusion of group A or group O CCP with low anti-A/B titer may be acceptable for group B and group AB patients.</td>
</tr>
</tbody>
</table>
support the use of high titer, rather than low titer, CCP. CCP titers indicate the level of neutralizing antibodies that can bind and inhibit the SARS-CoV-2 virus. The higher the titer, the greater the number of neutralizing antibodies and the greater the therapeutic potential. Nearly all trials strive to use high titer units, and a dosage effect was seen in one trial in which patients receiving the highest titer units did significantly better than patients receiving lower titer units. FDA now requires all CCP units released under the emergency use authorization (EUA) to be high titer.

ABO compatibility: The fourth interim recommendation states that in the absence of group B or group AB CCP, the transfusion of group A or group O CCP with low anti-A/B titer may be acceptable for group B and group AB patients. Usually, transfused plasma is ABO-identical or ABO-compatible with the recipient in order to prevent passive hemolysis of the recipient’s red cells. For patients with lower prevalence ABO groups, such as blood groups B and AB, ABO-identical or -compatible CCP may not be available. Evidence and clinical experience have shown that incompatible plasma, such as group A with low-titer anti-B, is safe in situations when compatible plasma is not available.

The interim recommendations were based on the best available evidence at the time of writing. They were designed as a guide to maximize the potential benefit of CCP for COVID-19 patients. Additional data from ongoing RCTs will lead to more robust clinical practice guidelines in the future.

Citations
Paul Molfese, BB(ASCP), is a compliance officer with UCLA Blood and Platelet Center at UCLA Health.

**TMSCC: How did you come into your role?**

Through a bit of a journey coupled with some serendipity. I started my career at the Children’s Hospital of Buffalo in 1968 as a lab trainee working in the Transfusion Service. For the next 35 years, I gained experience and took on increasing responsibility, eventually becoming supervisor of the transfusion service, core laboratory supervisor and then serving as an interim lab manager. While all of this was going on, I earned a Bachelor of Science degree in biology and a Master of Science in health services administration.

Prior to my serving as interim lab manager, four Buffalo hospitals merged into one entity, Kaleida Health. This was a full merger with one administration, one human resources department and one department of pathology. Eventually, Kaleida hired a team of consultants who made a series of observations and suggestions, one of which was that the laboratory — which had six managers at the time — really only needed five.

During my time as interim lab manager, I was approached by a recruiter who was looking for a compliance officer for HemaCare, located in Los Angeles. At this time, HemaCare managed blood drives for client hospitals and ran their own fixed site for collection of apheresis platelets. I accepted the position at HemaCare as a compliance officer, with Lieta Maffei as the director of quality. After Lieta accepted a similar position at the San Diego Blood Bank, I received a call from Maryanne Anthony, who was a blood bank supervisor at what is now the Ronald Reagan UCLA Hospital. Maryanne said that UCLA needed a compliance officer for their donor center and strongly suggested that I apply. I was hired and have been a compliance officer assigned to the Division of Transfusion Medicine for the past 15 years. My primary area of responsibility is the UCLA Blood & Platelet Center, though for the past year I have also served as compliance officer for the Transfusion Service.

**TMSCC: Was there someone who mentored you along the way?**

Yes, John Fitzpatrick, MD, who was my medical director at Children’s. John and I had long discussions concerning blood banking and lab operations. He gave me encouragement and, when needed, a swift kick. Together we worked to improve operations at the Transfusion Service. One of our accomplishments was to move from tube testing to Ortho’s gel technology.

**TMSCC: What is one thing every leader should know and apply daily?**

A leader is only as good as the support staff working with them. If you encourage and mentor your staff, the department will shine and some of that shine will rub off on you.

**TMSCC: What are the top challenges you face in your segment of the industry?**

Like everyone else, adjusting to and recovering from COVID-19. The pandemic presented us with multiple significant challenges. As the pandemic appears to be winding down, the challenge is to rebuild our donor base and to collect enough apheresis platelets and whole blood to support the needs of the hospital while upgrading equipment and computer systems to improve collections and maintain compliance with regulatory needs. Equally, and maybe more importantly, maintaining the confidence and enthusiasm of our staff.