Carter BloodCare
SPECIALTY SERVICES

Blood Matters

April 2020

News for Blood Bank Medical Directors, Physicians and the Lab

Blood Matters is a quarterly news *outlet with important medical information for you, our customers and colleagues, from Carter BloodCare. We hope you will share it with others interested in the work we do together.*

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COVID-19: SPECIAL EDITION

COVID-19 and Adequacy of the Blood Supply – an Ongoing Story

Laurie J. Sutor, MD, MBA

Carter BloodCare normally needs to see 1000 donors a day to collect the red cell units needed daily for the facilities we serve in our 54 North, East and Central Texas counties. We collect roughly half those donors on mobile blood drives, and the other half in our neighborhood donor centers.

With the onset of the SARS-CoV-2 epidemic, however, and the mandate for individuals to stay at home, the vast majority of our mobile blood drives were cancelled. Schools, churches, and businesses were not having the gatherings of people they normally had to host blood drives. Even our neighborhood center donor numbers fell as people were uncertain of whether they were allowed to leave their homes to donate blood. For a period of time in mid-March, our blood supply got perilously low. This situation was mirrored across the country, so there was no blood to share from other blood centers.

Our blood banking organizations worked diligently to spread the word to health authorities, the media, governmental leaders, and our communities that blood was still going to be needed. The cancellation of elective surgeries in our community and the efforts by hospitals and physicians to conserve in other ways dropped the use of blood by about 25%, but the need of blood for cancer treatment, trauma, obstetrics, burns, GI bleeds and other uses continues.

By the third week of March we started to get public support from figures such as the Surgeon General and others who urged individuals to go donate. We put most of our efforts into the neighborhood donor centers, expanding hours with our mobile collection staff, and a few mobile drives in large open spaces that would make people comfortable. We emphasized extra cleaning for the collection sites and social spacing for waiting areas.

The efforts worked and the blood supply has rebounded for the moment. We are grateful to the community for stepping up and coming to donate in this time of uncertainty. We got about 25% new donors during the last three weeks. We are currently scheduling donors at donor centers for future weeks to months, anticipating that schools and churches will be out for a while yet, and hoping that the “stay at home” initiative keeps many of our donors healthy and willing to donate.

For near future help, the FDA on April 2 released three new guidance documents which update and relax donor eligibility rules regarding variant Creutzfeldt Jakob disease, high risk blood exposure activities (including men who have sex with men), and malaria travel rules. Carter BloodCare will get these new eligibility guidelines implemented as soon as new staff procedures and training can be put in place.

References:

FDA Guidance on vCJD risk www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-reduce-possible-risk-transmission-creutzfeldt-jakob-disease-and-variant-creutzfeldt

FDA Guidance on HIV Risk Factors www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-reducing-risk-human-immunodeficiency-virus-transmission-blood-and-blood

FDA Guidance on Malaria Travel www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-reduce-risk-transfusion-transmitted-malaria

COVID-19: SPECIAL EDITION Continued

SARS-CoV-2 Infection and the Risk of Transmission by Blood

Laurie J. Sutor, MD, MBA

When the new coronavirus infection showed up on the radar of blood collecting agencies worldwide in late December 2019 and early January of 2020, the focus was on whether the virus could be transmitted by blood transfusion from one person to another. Initial safety measures to protect the blood supply in those early times included making sure individuals with illness were not allowed to donate, and taking the body temperature of each donor. Some blood centers implemented travel deferrals for donors coming from China, but as the virus spread, travel restrictions quickly became unwieldy.

The good news is that previous coronaviruses, and respiratory viruses in general, have not been shown to be transfusion-transmitted, and this coronavirus seems to be following the same pattern. Although some viral RNA has been detected in blood donors (and patients, of course), early studies from China and Korea looking at blood donors who became sick soon after donating with COVID-19 have shown no evidence of SARS-CoV-2 illness in their transfusion recipients.

The Food and Drug Administration has not made any recommendations for special measures to protect the blood supply from COVID-19 infection beyond what we already do routinely. There is no FDA approved assay for testing blood donors for SARS-CoV-2 for either viral RNA nor antibody.

References:

Wolfel R, Corman VM et al. Virological assessment of hospitalized patients with COVID-2019. Nature online early publication 1 April 2020. www.nature.com/articles/s41586-020-2196-x (Patients were not found to have infectious virus in the blood)

Kwon S-Y, Kim E-J et al. Post-donation COVID-19 identification in blood donors. Vox Sanguinis, early review, accepted for publication. doi:10.1111/vox.12925 (Lookback study of 7 donors – no illness in any recipients 19 to 29 days later)

Updated information for Blood Establishments regarding the novel coronavirus outbreak. March 11, 2020. Food and Drug Administration communication www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-blood-establishments-regarding-novel-coronavirus-outbreak

Convalescent Plasma

Laurie J. Sutor, MD, MBA

On March 27, 2020, Carter BloodCare collected the first unit of apheresis convalescent plasma for a COVID-19 patient in our community. In the two days prior to that, we had been bombarded with requests from numerous hospitals wanting to try this unproven therapy for seriously ill patients who were not responding to other treatments.

Convalescent plasma is plasma taken from persons who have recovered from an illness. The theory is that antibodies formed by these recovered patients will help fight the disease in seriously ill persons currently afflicted. This therapy has been previously used in other infections, including the Ebola outbreak in 2014. It has not yet been proven to work for COVID-19, but studies are underway. The early use of the product for many patients in our community has been done with application to the Food and Drug Administration (FDA) for an emergency IND for individual patients under 21 CFR 312.310. This allows rapid approval for gravely ill patients when a formal clinical trial is not available. The transfusing facility should also be involving their own institutional review board for protection of patients' rights. Updated information on obtaining FDA approval for using convalescent plasma can be found at: www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/revised-information-investigational-covid-19-convalescent-plasma

COVID-19: SPECIAL EDITION Continued

Convalescent Plasma (Continued)

Laurie J. Sutor, MD, MBA

Another route for hospitals to gain use of convalescent plasma is to use the FDA-approved Expanded Access program. In this program, facilities can use the IRB of Mayo Clinic for use of convalescent plasma. Physicians, facilities and individual patients must still be registered prior to use. Information on this program can be found at: www.uscovidplasma.org

The current best guess at dosing for convalescent plasma is to give one unit (200-250 ml) per patient. This has seemed to be effective in anecdotal reports, in as soon as 2 to 3 days.

Carter BloodCare has been collecting plasma from donors recruited and qualified by the hospitals. These donors must have tested positive for SARS-CoV-2 infection in the past, have had at least 14 days elapsed since their last symptoms, and have tested negative now for SARS-CoV-2 on subsequent testing. The hospital is also responsible for doing the SARS-CoV-2 antibody titers on the prospective donor. Once qualified, the donor is referred to Carter BloodCare for collection, where they must pass all allogeneic donor criteria to donate, including TRALI† safety criteria (male donor or female never pregnant or tested negative for HLA antibodies). These donor eligibility criteria were set out by FDA in their communication of April 3, 2020 which can be read here: www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds Donors who are recovered from proven COVID-19 infection and are more than 28 days out from all symptoms will soon start to be collected as well through a direct program at Carter BloodCare. These donors will not need a negative COVID-19 test prior to donating plasma, per FDA rules.

The donor collection is occurring on a mobile apheresis machine on a donor coach at a location separate from normal blood donor collection. The product collected ranges from 650 to 825 ml of plasma, depending on donor weight, sex and hemoglobin. Current procedures only allow for a donor to give once every 28 days to protect their own health and immunoglobulin levels. The product is generally broken into 3 or 4 individual units for ease of thawing and administration, and stored frozen until routine donor infectious disease testing is received and the product can be shipped to the hospital. If all goes well, the product is usually available 24 to 28 hours after collection.

† = Transfusion-related acute lung injury

References:

Duan K, Liu B, Li C et al. Effectiveness of convalescent plasma therapy in severe COVID-19 patients. PNAS 2020 www.pnas.org/cgi/doi/10.1073/pnas.2004168117