Australian Red Cross Lifeblood

COVID-19 Convalescent Plasma and COVID-19 Immunoglobulin – Recruitment Information for External Providers

While there are limited treatment options available for COVID-19, whole blood or plasma collected from patients in the convalescent phase of infection has been used as an empirical treatment in treatment of other infectious diseases.

The concept that this treatment could be efficacious is biologically plausible, as convalescent plasma has been used successfully for the treatment of a variety of infectious agents including SARS. In the 2003 SARS outbreak convalescent plasma was used with a confirmed reduction in mortality, although this finding was limited by the generally poor quality of studies.[1] On 24 March 2020, the FDA approved convalescent plasma as an emergency investigational new drug for patients with severe or life-threatening disease.[2] In addition, there has been a small pilot study. Ten patients with severe illness were given 200 mL convalescent plasma with COVID-19 neutralising antibodies. There was clinical improvement, including progression to undetectable viral load, in the seven patients who were viraemic pre-transfusion, with no severe adverse events.[3] An additional three small case series have also demonstrated similar results. However, these are limited by their small sample sizes, lack of randomisation and other confounding factors including multiple other treatments. While there is limited knowledge of the efficacy and safety of convalescent plasma for COVID-19, given the severity of COVID-19, Lifeblood has developed the capacity to produce COVID-19 convalescent plasma as an experimental treatment option that will be used for approved clinical trials. Further information on these clinical trials can be obtained from a Lifeblood Transfusion Medicine Specialist. Given the current lack of evidence for clinical benefit and to ensure equitable access, Lifeblood will not be issuing convalescent plasma outside of approved clinical trials for compassionate use. If the evidence or lack thereof of a treatment benefit emerges internationally, we will adjust our protocols accordingly.

Additionally, CSL Behring is manufacturing COVID-19 Immunoglobulin for future treatment of patients with COVID-19. Lifeblood will predominantly supply convalescent plasma from female donors for the production of COVID-19 Immunoglobulin, consistent with the existing TRALI risk reduction strategy to use only male donors for clinical plasma.

Lifeblood has developed acceptance criteria for potential COVID-19 convalescent plasma donors. Donors are considered eligible when they:

- had a laboratory-confirmed COVID-19 infection
- are recovered from COVID-19 and non-infectious as evidenced by being symptom free for four weeks, and
- otherwise meet our eligibility requirements.

In the future, SARS-CoV-2 antibody testing will be performed on all eligible donors. However, this process has not been finalised, so currently we are collecting but not releasing convalescent plasma. We expect to commence testing in the near future.

Given the limited number of people who have recovered from COVID-19, Lifeblood requires your assistance to identify potential donors. Lifeblood asks that you provide your patient/confirmed case with our attached information sheet for them. They can then contact Lifeblood to further discuss and/or to make an appointment.

If you would like to discuss this further please call Prof Iain Gosbell on 02 9234 2313 or Dr Veronica Hoad on 08 9219 1612.

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[1] Mair-Jenkins J, Saavedra-Campos M, Baillie JK et al. The effectiveness of convalescent plasma and hyperimmune immunoglobulin for the treatment of severe acute respiratory infections of viral etiology: a systematic review and exploratory meta-analysis. J Infect Dis. 2015;211(1):80-90.

[2] https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds

[3] Duan K, Bende L Ceshang L et al. Effectiveness of convalescent plasma therapy in severe COVID-19 patients. *PNAS* April 2020 DOI: 10.1073/pnas.2004168117