VoxSanguinis
The International Journal of Transfusion Medicine
ISBT International Society of Blood Transfusion
Vox Sanguinis (2021) **116**, 136–137

DOI: 10.1111/vox.12940
Vox Sanguinis

LETTER TO THE EDITOR

Operational protocol for donation of anti-COVID-19 convalescent plasma in Italy

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Coronavirus disease-19 (COVID-19) represents a public health threat worldwide, and Italy at the present time is considered the epicentre of this severe infection in the Western world [1,2]. Unfortunately, no standardized therapy does exist for COVID-19 and a number of investigational drugs for use in patients with life-threatening COVID-19 infections have been tried [3]. One investigational treatment being explored for COVID-19 involves the use of convalescent plasma collected from recovered COVID-19 patients [4]. Convalescent plasma, containing antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, the virus that causes COVID-19), might be effective against the infection. This treatment has been studied in particular during previous outbreaks of other respiratory infections, including the 2009–2010 H1N1 influenza virus pandemic, the 2003 SARS-CoV-1 epidemic and the 2012 Middle East respiratory syndrome (MERS)-CoV epidemic [4].

Based on the dramatic situation in Italy, but aware the convalescent plasma therapy is to be considered 'empirical' and not supported by robust scientific evidence and solid haemovigilance data on its safety [5], the Italian National Blood Center has decided to derogate from the current blood donor selection criteria in order to permit to individuals recovered from COVID-19 to donate convalescent plasma. Mandatory conditions that have to be met for donor eligibility are the following:

(1) Patient–donor, with virologically documented diagnosis of COVID-19, completely recovered by at least 14 days according to the clinical and laboratory criteria defined by the Superior Health Council on 28 February 2020 ('The recovered patient is the one who resolves the symptoms of COVID-19 infection and who is negative in two consecutive tests, carried out 24 h apart, for the search for SARS-CoV-2');
(2) Male patient–donor or a nulliparous female donor with a negative history of blood component transfusion;
(3) Careful clinical evaluation of the patient–donor with particular reference to the criteria provided for the current rules to protect the health of the apheresis donor;
(4) As at the moment no definitive scientific evidence supports the adoption of a defined titre of neutralizing antibodies in this specific setting, the presence of adequate levels of anti-SARS-CoV-2 neutralizing antibodies is recommended [a titre of at least 1:320 is recommended only for patients affected by primary or acquired (including patients treated with B-cell depleting monoclonal antibodies) immunodeficiencies];
(5) Negative results of the biological qualification tests provided for by the current rules;
(6) Negative results of the following additional tests performed at each donation, that is RNA testing for hepatitis A and E viruses and DNA testing for parvovirus B19.

In addition, each unit of plasma apheresis collected from convalescent patient–donors must be the following:

(1) Processed with a pathogen reduction method of recognized efficacy;
(2) Clearly labelled as 'Plasma unit collected from a convalescent patient–donor with a virologically documented diagnosis of COVID-19';
(3) Kept separately from other units for clinical use or industrial fractionation.

Finally, it is recommended to suitably adapt the donors' and recipients' informed consents, to strengthen haemovigilance (on patient–donors and recipients), and to keep the Italian National Blood Center and the Regional Blood Coordinating Centers informed on the start of the apheresis procedures and on the quantity of plasma units collected and available for transfusion to COVID-19-infected patients.

References

1 Peeri NC, Shrestha N, Rahman MS, *et al.*: MERS and novel coronavirus (COVID-19) epidemics, the newest and biggest global health threats: what lessons have we learned? *Int J Epidemiol* 2020. pii: dyaa033. doi: 10.1093/ije/dyaa033 [Epub ahead of print]

2 World Health Organization: Coronavirus disease (COVID-19) outbreak. https://www.who.int/emergencies/diseases/novel-coronavirus-2019 [Last accessed 20-3-2020]

3 Zhang L, Liu Y: Potential interventions for novel coronavirus in China: a systematic review. *J Med Virol* 2020; **92**:479–490

4 Chen L, Xiong J, Bao L, *et al.*: Convalescent plasma as a potential therapy for COVID-19. *Lancet Infect Dis* 2020; **20**:398–400. [Epub ahead of print]

5 Chang L, Yan Y, Wang L: Coronavirus Disease 2019: Coronaviruses and blood Safety. *Transfus Med Rev* 2020. https://doi.org/10.1016/j.tmrv.2020.02.003 [Epub ahead of print]

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