


COMMENTARY

The impact of the SARS-CoV-2 outbreak on the safety and availability of blood transfusions in Italy

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Coronaviruses are enveloped single-stranded RNA viruses belonging to the family of *Coronaviridae*. While initial research focused on their ability to cause enzootic infections, infections that have emerged in the past two decades demonstrate their ability to cross the species barrier and infect humans [1,2]. The ensuing epidemics have included severe acute respiratory syndrome (SARS) in 2002 and the more recent Middle East respiratory syndrome (MERS) in 2012 and have resulted in severe disease burden, mortality and economic disruption [3]. A novel flu-like coronavirus, emerging towards the end of 2019 and subsequently named SARS-CoV-2, has been associated with an epidemic initially focused in Wuhan, China. SARS-CoV-2 belongs to the same group (β -coronavirus) of coronaviruses responsible of SARS and MERS [2]. Over December 2019 and February, SARS-CoV-2 spread rapidly throughout China, infecting many thousands of people and causing more than 3000 deaths [4,5]. As a consequence, on 30 January the World Health Organization (WHO) announced that the outbreak of SARS-CoV-2 in China was a Public Health Emergency of International Concern (PHEIC) [6]. The influence of globalization, particularly on travel, rapidly caused the infection to spread to countries outside China, initially to neighbouring Asian countries and then to more than 120 countries around the world. As of the time of writing this Commentary, more than 200 000 individuals have contracted SARS-CoV-2 (data updated on 20 March 2020) [7]. On 11 March, the WHO declared the rapidly spreading coronavirus outbreak to be a pandemic [6]. Currently, Italy is the country with the highest number of cases of SARS-CoV-2 infection after China, a situation which has precipitated a health and social emergency.

Focusing on our role within the Italian Blood System, we note that there has been no scientifically documented

evidence of the transmission of coronavirus infection through the transfusion of blood components during previous epidemics. The current SARS-CoV-2 outbreak has stimulated further discussion on this issue, particularly on the safety of blood donations in endemic countries [8]. In Italy, the transfusion network is overseen, through Regional Blood Coordinating Centres (RBCCs), by the Italian National Blood Centre (CNS), which is the Health Ministry's technical and scientific advisory body on matters related to blood and blood products. The CNS acts also as the National Competent Authority, as established by the European Commission, on blood and related issues on behalf of the same Ministry. To guarantee high standards of blood safety and sufficiency, blood donation is sourced both from public hospital-based blood establishments (BEs) and licensed and accredited blood donor associations and federations' blood collection sites in a 2:1 split and is restricted to voluntary unpaid donors. The first SARS-CoV-2 local transmitted cases in Italy were observed on 18 February 2020 and were initially clustered in a few cities in northern Italy. The Italian government, starting on 23 February and up to the date of writing this manuscript, has released eight decrees aimed at limiting the spread of SARS-CoV-2. The CNS has already released since 22 January 2020 a recommendation outlining preventative measures for the transmission of SARS-CoV-2 by transfusion of labile blood components related to travels from the People's Republic of China. On 24 February 2020, a new document was released with reference also to Italian territories. This document included the following recommendations:

- strengthen surveillance measures on possible imported cases by questioning blood donors for travel to the People's Republic of China;
- strengthen surveillance measures on possible cases with contacts with documented SARS-CoV-2 infection;
- defer from donating for 28 days:

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- (a) donors who have been in the People's Republic of China;
 - (b) donors who have possibly been exposed to the risk of infection by contact with subjects with SARS-CoV-2 documented infection;
 - (c) donors at risk because they have transited and stopped since 1 February 2020 in the municipalities of Lombardy and Veneto regions [designated as the Zona Rossa (red zone)] identified as the initial foci of the infection in Italy;
 - (d) donors with a history of SARS-CoV-2 infection (documented infection or onset of symptoms compatible with SARS-CoV-2 infection) who are convalescent;
- require donors to inform their BEs in the case of symptoms compatible with SARS-CoV-2 infection or in the case of diagnosis of SARS-CoV-2 infection within 14 days after donation (post-donation information);
 - promote the implementation, at BEs and associated collection sites, of simple triage processes during the reception of donors, in order to avoid the possible spread of the virus in the waiting rooms. These included the measurement of body temperature outside the collection area. A body temperature value of

37.5°C was defined as a criterion for the temporary deferral of the donor;

- request all the personnel working at BEs and collection sites to comply scrupulously with behavioural protocols designed to prevent the spread of respiratory infections, including SARS-CoV-2 infection.

In addition, the CNS advised the associations and federations of voluntary blood donors to inform adequately all their staff and donors about the epidemiology, symptoms and preventative measures of SARS-CoV-2 infection. The CNS recommended that the RBCCs further implement regional patient blood management programmes, in order to conserve the blood supply, and enhance and monitor closely strategic regional blood component stocks (using information systems), in order to ensure balance and adjustment, thus minimizing any intra- or inter-regional blood component shortages.

Several updates of this document were released by the CNS as the epidemiology of SARS-CoV-2 infection rapidly evolved. On 2 March 2020, following the recommendations of the European Centre for Disease Prevention and Control (ECDC) [9] and reflecting the decrees of the Italian government, the CNS updated the prevention measures, reducing the period of temporary deferral of donors from the previous 28 to 14 days. Along with appeals to

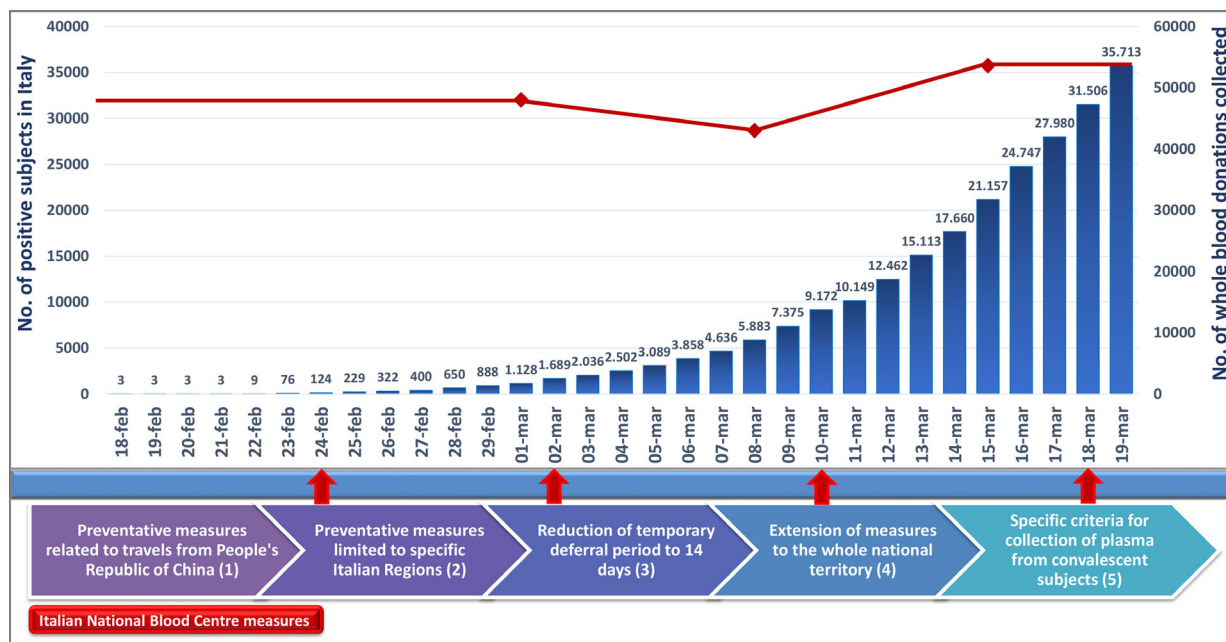


Fig. 1 Trends of SARS-CoV-2 cases in Italy. Notes: 1: On 22 January 2020, the Italian National Blood Centre (CNS) released preventative measures related to travels from the People's Republic of China. 2: On 24 February 2020, the CNS's recommendation with SARS-CoV-2 preventative measures limited to specific Italian regions was released: 28 days of deferral. 3: On 2 March 2020, the CNS updated the prevention measures, reducing the period of temporary deferral of donors from the previous 28 to 14 days. 4: On 10 March 2020, the CNS extended these measures to the whole national territory of Italy. 5: On 18 March 2020, the CNS authorized collection of convalescent plasma. The red line reports the nationwide trend of blood donations. [Colour figure can be viewed at wileyonlinelibrary.com]

donate in order to avoid shortages in the blood supply, the same document also included additional recommendations for the associations and federations of voluntary blood donors. These included the maintenance of safe inter-individual distance (a minimum of 1 m) in waiting rooms, a careful planning of the schedule for calling up donors in order to regulate the volume of human traffic within centres, a meticulous disinfection of hands of the BE and collection sites' personnel, and similarly rigorous protocols for the sanitation and disinfection of the collection rooms. The use of masks for both BE personnel and donors was not required following the recommendations of the WHO and National Health Authorities. These measures were progressively extended to most of the cities of northern Italy (9 March 2020). Following the declaration of the government of the widespread dissemination of the SARS-CoV-2 infection in Italy, the last update of the CNS on 10 March 2020 extended these measures to the whole national territory of Italy. On 18 March, the CNS defined specific criteria for collection of plasma from convalescent subjects.

The CNS continues to reinforce its appeal to donate blood components in both public hospital BEs and associated collection sites. Given the limitations on movement imposed by the government, the CNS has been pivotal in communicating and managing the necessary deviations from these measures of donors and the healthcare personnel involved in blood donation, in order to maintain the smooth collection of blood.

In the first week of March, a reduction of 10% whole blood donations per week was experienced by the Italian Blood System (from 48 000 – as a standard number of

blood donations per week in this period – to 43 000 nationwide), but the inventory was maintained by a contemporary reduction of elective surgery using medium-high amounts of blood. The strategic reserve of blood kept for emergencies was not accessed. During the second week of March, after the campaign of the CNS and Italian government encouraging blood donation, we observed a 12% increase in the collection of whole blood (from 48 000 to 53 600 nationwide).

In Fig. 1, the trend of positive cases for SARS-CoV-2 infection in Italy, updated on 20 March 2020, is reported with a concise chronology of the main documents released and the trend of blood donations in the same period.

These measures have been able to guarantee blood safety and supply in Italy. We hope that our ongoing experience, as briefly reported in this *Commentary*, will help transfusion medicine specialists from other countries, who are facing the effect of this epidemic on the blood supply. We propose that it is possible to manage a transfusion system during this critical period, using pragmatic, prudent and evidence-based measures. In our country, so far, blood donation, after an initial fall (–10%), has been maintained during SARS-CoV-2 emergency, having been recognized by the government as a priority in order to maintain basic healthcare services. With the SARS-CoV-2 outbreak spreading in all European Countries, we recommend defining common European guidelines that establish screening criteria for blood donors. Such criteria need to take into account the different epidemiological situations in different countries, while establishing common principles ensuring blood safety throughout Europe.

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