

Guidance on maintaining a safe and adequate blood supply during the coronavirus disease 2019 (COVID-19) pandemic and on the collection of COVID-19 convalescent plasma

Interim guidance

10 July 2020



Background

This document provides interim guidance on the management of the blood supply in response to the pandemic outbreak of coronavirus disease (COVID-19) including recommendations on collection of COVID-19 convalescent plasma. It is intended for blood services, national health authorities, and others responsible for the provision of blood and blood components and integration of the blood system within the public health system. WHO will continue to update this guidance as new information becomes available.

This guidance is adapted from the WHO Guidance for National Blood Services on Protecting the Blood Supply during Infectious Disease Outbreaks¹ and risk assessment publications on COVID-19 from WHO and regional networks/institutions.²⁻⁴

The present document provides an update to the previous Interim Guidance recommendations on donor deferral, post-donation illness reporting, and collection of COVID-19 convalescent plasma, published under the title “Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19): interim guidance”. It also provides additional detail in response to issues raised by stakeholders and requests from WHO regions for clarifications and additional information.

General considerations

The COVID-19 pandemic has reduced the supply of blood and blood components and adversely affected blood system activities in many countries. Blood services should therefore take steps to assess, plan, and respond appropriately and proportionately.

In the absence of reported cases, the risk of transmission of SARS-CoV-2 through transfusion of blood and components is currently only theoretical and likely minimal. But the current pandemic outbreak already has had a significant impact on blood supplies through reduced blood donation and appropriate collection facilities.⁵⁻¹¹

Effective and accurate data-driven risk assessment is necessary to determine the most appropriate and proportionate action, taking into consideration: a) the extent of COVID-19 spread in the country or geographical area; b) level of community circulation (isolated cases or clusters of cases vs

community transmission); c) local epidemiology; d) risk of transfusion transmission in context of overall burden of disease; e) quality of health care system; f) public health response; g) blood supply sufficiency; h) operational impacts; and i) cost effectiveness of blood safety interventions in reducing disease morbidity in relation to the overall situation in the country.

Blood services must be prepared to move quickly in response to changes in the pandemic situation. A national rather than sub-national or local approach should be adopted for coherence and coordination and to ensure public confidence in blood safety and supply. Coordination and support should be fostered between all stakeholders in the blood system to help maintain blood and blood component availability. Blood services should be included in the national outbreak response, through experts linked to the national emergency response team. Blood services should develop, implement and activate their emergency response plans.

1. Mitigating the potential risk of transmission through the transfusion of blood and blood components

SARS-CoV-2 has not been reported to be transmitted through blood or blood components, and in a small study, blood components collected from donors in the pre-symptomatic phase of COVID-19 did not transmit the infection.¹² Therefore, any risk of transmission by transfusion of blood collected from asymptomatic individuals is theoretical, and any actions taken to mitigate risk are precautionary. Options include:

- a. Potential blood donors should be educated about the need to self-defer based on risk factors for COVID-19 or feeling unwell. Current pre-donation criteria for donor suitability that exclude symptomatic individuals who are unwell or with signs and symptoms of fever and respiratory disease (such as cough or breathlessness) must be strictly complied with. Those whose symptoms meet standardized definitions for COVID-19 should be referred for testing and isolation in line with national control policies.
- b. In areas with widespread community transmission of SARS-CoV-2, persons who donate blood should be advised to inform the blood centre immediately if

they develop a respiratory illness within 14 days following the donation.

- c. Persons with possible direct exposure to SARS-CoV-2 from close contact with a confirmed case or care of an infected patient, and those who have travelled from areas with community transmission should refrain from blood donation for a defined period. A minimum deferral period of 14 days (one incubation period) is generally considered adequate to assure absence of contagion with SARS-CoV-2.
- d. Persons who had a positive test for SARS-CoV-2 but never had symptoms should be deferred for 14 days after the last positive test.
- e. Persons who have recovered from diagnosed COVID-19 should be deferred from routine blood donation for 14 days after full resolution of symptoms and cessation of therapies for their illness.
- f. Donor deferral may take the form of self-deferral or deferral by the blood collection establishment. In the event of community transmission, donor restrictions may need to be modified to fit the local situations so as not to affect availability of blood for critical transfusion therapy.
- g. Quarantine of components with delayed release based on absence of a reported subsequent illness in the donor is an option during community transmission. This is difficult to implement, disrupts existing processes and delays release of blood into available inventory. Quarantine of platelets is particularly problematic given their short shelf-life.
- h. As part of haemovigilance, a system must be in place for donors to report post-donation illness consistent with COVID-19 or contact with a case that is confirmed post-donation. Blood and components collected within 14 days prior to disease onset in the donor or collected within 14 days subsequent to contact exposure may be recalled as a precautionary measure. Notification of the clinician of confirmed infection in the donor may also be considered if the blood or components have been transfused.
- i. Testing of the blood supply is premature in the absence of cases of transfusion transmission or demonstrated infectivity of SARS-CoV-2 in blood collected from asymptomatic persons including persons who are pre-symptomatic.
- j. Pathogen reduction technologies (PRTs) have been demonstrated to be effective against SARS-CoV and MERS-CoV in plasma and platelets, but requires significant logistical and financial investment. Introduction of PRT for SARS-CoV-2 in the absence of evidence for transfusion-transmission would not be cost effective or proportionate and is not recommended in settings where it is not already in practice.
- k. Current manufacturing processes for plasma derivatives can inactivate and remove enveloped viruses such as SARS-CoV-2. There is thus no presumed risk for transmission through these products.
- l. A haemovigilance system should be in place to capture any possible cases of transmission through blood and components. Haemovigilance is invaluable in helping to understand the risk from blood and components and the overall effectiveness of the measures taken by the blood service.¹³

The decision as to whether to implement precautionary measures with their resulting impact on blood sufficiency and operational resources must be carefully considered. Measures introduced during one phase of the outbreak may also become impractical or unsustainable at another phase.

2. Mitigating the risk of staff and donor exposure to SARS-CoV-2

Any transmission from a donor is far more likely to occur through the respiratory route than through parenteral routes (including phlebotomy during blood donation). Strategies taken to mitigate this risk should follow the public health measures taken in the country. As blood donor centres and manufacturing premises are not patient care settings, public health measures appropriate to community environments with frequent public contact should be applied rather than those specific to medical clinics and hospitals. Measures include screening for COVID-19 related symptoms, social distancing, hand hygiene and use of personal protective equipment, e.g. masks and gloves for staff.^{14,15} Providing information to donors and the public about the measures taken will contribute towards gaining their confidence to continue donating blood.^{8,10}

The safety of the donation process should be ensured by appropriate protective measures while assuring proper flow of work. Potential donors should be informed of the importance of self-deferral if they are feeling unwell or have COVID-19 related symptoms, and of reporting immediately to the blood service any COVID-19 related illness within 14 days after donation. Individuals who should not donate blood should be excluded at the earliest opportunity through relevant information on websites or pre-selection procedures to identify potentially infected donors before entry into the donation area.^{6,8} If COVID-19 is suspected or confirmed in a potential blood donor or staff, the management of the donor, staff and contacts should follow national public health guidelines.

To avoid crowding at the collection centre, efforts should be made to schedule blood donations by appointment and to avoid crowding of staff members (e.g. by reducing overlapping shifts and lessening movement of staff members between sections of the facility). Minimizing contacts between donors and staff, regular environmental decontamination, temperature measurement at the entrance, providing entering donors with face masks and hand sanitization, and physical distancing should also be considered.^{6,8-10,14,16,17}

Standard laboratory biosafety practices, based on national or international guidelines, should be followed in all circumstances.¹⁸ If blood service laboratories provide any pre-transfusion investigations, samples from patients suspected or confirmed with COVID-19 should be handled in accordance with COVID-19 guidance.¹⁹

Staff should be educated about COVID-19 and advised not to come to work if they feel ill or may have been exposed. Infection prevention and control measures should be reinforced. During community transmission, staff may be reduced through illness and measures considered to mitigate the impact on essential activities.^{11,14,20}

3. Mitigating the impact of reduced availability of blood donors

Reduction of donor numbers before, during and after a COVID-19 outbreak is a major risk and should be considered early to enable preparedness and response. As this is often dynamic throughout the course of the pandemic, blood donation numbers should be closely monitored so that measures can be taken quickly to pre-empt any decline.^{9,11} This is particularly critical for components with short shelf life, such as platelets, where a constant supply is needed for patients dependent on platelet transfusions. Cooperation among hospitals and blood collection centers to monitor inventories and to redistribute blood components to prevent wastage may help to balance local supplies and demands.

A significant decline in blood donor attendance occurs when individuals are unwilling to donate through fear of being infected during blood donation.⁸ A clear, proactive and consistent communication strategy is key to addressing and overcoming donor anxiety and fears which often stem from lack of awareness or misinformation. These are most effective when they are part of national emergency response messaging. Effective public awareness campaigns on the importance of maintaining an adequate national blood supply, need for blood donors, and safety of the donation process should be disseminated continuously, using different communication platforms to reach all segments of the population.^{8-11,17}

Containment strategies may limit the ability of donors to attend donation sessions and prevent blood collection teams from visiting areas where public health restrictions are in place. Mobile blood donation drives and group donations may be reduced due to closure of workplaces, schools and community organisations. Strategies to overcome this include rapid switching of sites for blood collections, providing donor transportation, intensifying efforts to schedule appointments for donations, or adjusting operating hours. Blood collection activities may be organized on a more targeted basis through focused (including blood group specific) retention and recall of healthy repeat donors.^{7-9,16} Governmental authorities need to identify blood collection as an essential service and provide mechanisms to assure that blood donors do not get penalized for coming out to donate.

Routine practices for donor management and infectious disease testing should not be changed. However, in the event of extreme blood shortages, changes in certain criteria may be considered., e.g. reduction of whole blood donation intervals for donors with robust haemoglobin levels who are able to tolerate more frequent donations.

Systems should be in place to enable re-entry of infected donors after recovery. A minimum deferral period of 14 days is advisable to maintain donor health and to allay fears of contagion in the blood collection centre. A standard deferral period also supports the collection of convalescent plasma at the blood donor centre (see Section 7: Collection of convalescent plasma).

Importation of blood and components from unaffected areas of the country or an unaffected country (if permitted by regulatory authorities) is a potential solution if there are insufficient local stocks. There are also logistical issues with safely transporting blood and components.

4. Managing the demand for blood and blood products

Blood services should continually assess their blood stocks carefully in anticipation of uncertainty in the scale of collection activities. During community transmission, demand for blood and components may decrease as the health care system shifts toward treating increasing numbers of COVID-19 patients and elective surgeries and non-urgent clinical interventions are deferred. Blood transfusions will still be necessary for emergency situations such as trauma, post-partum haemorrhage, severe infant anaemia, blood dyscrasias, and urgent surgeries requiring availability of blood. Increased stocks may also be needed to support COVID-19 patients with severe sepsis or requiring extracorporeal membrane oxygenation support.

Good patient blood management will help safeguard blood stocks. The blood service must clearly communicate and coordinate with health care professionals responsible for transfusion activities to ensure that blood and components are only used when clinically appropriate.^{9,11}

5. Ensure undisrupted supplies of critical material and equipment

Transport and trade restrictions, quarantine requirements, border control measures and production disruptions may decrease the global supply chain of critical materials and equipment used in blood and component collection, laboratory testing (including immuno-haematology reagents and infectious disease screening assays). The blood service must take steps to ensure continuity of supplies.

6. Communication

Public and stakeholder confidence in the blood system is important to maintaining an adequate blood supply. Governmental authorities and the blood service must communicate clearly to ensure that the national emergency response team, donors and recipients, and the public are properly informed and understand planned actions including recognition of blood collection activities as essential services. Messaging and actions should be consistent with overall national emergency response messaging.^{9,21,22}

Within the blood service, all staff should understand the infectious threat and actions taken to ensure safety and reliability of the blood supply and the safety of staff and donors.

7. Collection of COVID-19 convalescent plasma

WHO recognizes COVID-19 convalescent plasma as an experimental therapy that is appropriate for evaluation in clinical studies or as a starting material for the manufacture of experimental hyper-immune immunoglobulins. This position is based on an assessment that the potential benefit of providing antibodies that may neutralize infectivity of SARS-CoV-2 outweighs the risks of administration of these plasma products. Reports of a randomized controlled trial (RCT) and several uncontrolled case series of use of COVID-19

convalescent plasma have suggested favorable patient outcomes^{23,24} In comparison, treatment of 5,000 patients with COVID-19 convalescent plasma was associated with a low rate of serious adverse reactions similar to those seen with non-immune plasma infusions.²⁵ There was also no evidence of antibody-dependent enhancement, a well-recognized effect in other viral illnesses.^{26,27} Positive historic experience with use of convalescent plasma to treat SARS and pandemic influenza further supports the plausibility of a clinical benefit in COVID-19.^{28,29}

This document provides guidance on collection and preparation of COVID-19 convalescent plasma. Further clinical evidence is needed before guidance can be provided on its clinical use. WHO recommends strongly that COVID-19 convalescent plasma should be used in RCTs as the most effective and efficient strategy to determine the efficacy and safety of this experimental therapy. In settings where randomization of patients is infeasible, structured observational studies linked to RCTs can be considered, in which standardized protocols consistent with the active arm of an established RCT are used to generate data on the properties of the administered COVID-19 convalescent plasma, the characteristics of treated patients and pre-defined patient outcomes. Where structured clinical studies are also not possible, efforts nevertheless should be made to document patient outcomes and to obtain and archive blood samples from donors and recipients for future scientific study. Data on product preparation and use collected through close cooperation between treating physicians and blood establishments and reported to a central national authority can provide information that complements the findings of RCTs.

COVID-19 convalescent plasma can be made available on an experimental basis through local production provided that medical, legal and ethical safeguards are in place both for the donors of COVID-19 convalescent plasma and the patients who receive it. Detailed risk assessment must always be conducted to ensure that the blood service has sufficient capability to safely collect, process and store these specific blood components in a quality-assured manner in compliance with established standards and requirements for plasma for transfusion. WHO has previously released interim guidance for the use of convalescent plasma collected from patients recovered from Ebola Virus Disease.³⁰ Additionally, the WHO Blood Regulators Network published a position paper that provides helpful considerations on use of convalescent plasma in an epidemic of an emerging virus.³¹ Regulatory agencies should enable progress by establishing appropriate conditions for the collection of convalescent plasma, the ethical conduct of clinical studies, and the monitoring and reporting of assessable patient outcomes.

WHO is committed to liaise with its international partners to obtain and share information on policies and protocols for studies of COVID-19 convalescent plasma that emerge in different countries and regions. A Cochrane rapid systematic review on the use of COVID-19 convalescent plasma and hyperimmune immunoglobulin provides information on case series and on studies that have been registered in clinical trial websites, and also reinforces the importance of using COVID-19 convalescent plasma in randomized controlled trials (RCTs).³² Additional information relevant to studies of COVID-19 convalescent plasma can be found at an open access website of the International Society of Blood

Transfusion. However, WHO does not specifically endorse any of the statements or protocols listed at that website.

While no universal protocol exists for collection of COVID-19 convalescent plasma, common criteria for acceptance of donors of COVID-19 convalescent plasma include:

- a. Qualification based on standard criteria for blood or plasma donation
- b. Diagnostic evidence of prior infection with SARS-CoV-2
- c. Complete resolution of symptoms and cessation of treatments for COVID-19 for at least 14 days prior to the donation
- d. Establishment of the minimum neutralizing antibody titre required for plasma to be suitable for use as convalescent plasma
- e. Measurement of the neutralizing antibody titre in the unit of convalescent plasma.

In settings where donor selection based on the titre of neutralizing antibodies is infeasible, retention of a blood sample from the convalescent donor for subsequent characterization of antibodies to the virus is strongly recommended. Potential donors may also be tested for presence of antibodies to SARS-CoV-2 in antigen binding assays (e.g. ELISA) although correlation with antibody neutralization titres is uncertain.

Ideally, donations of convalescent plasma should be obtained by plasmapheresis to avoid unnecessary red blood cell loss in the donor and to optimize the volume of plasma that can be collected. Infection control precautions should follow WHO interim guidance on rational use of personal protective equipment, taking into consideration that the donor has fully recovered from COVID-19.³³ Red blood cell concentrates that are prepared as a byproduct of preparation of COVID-19 convalescent plasma can be released for transfusion if the donor was asymptomatic for at least 14 days after full recovery from symptoms.

Data elements for reporting of outcomes in patients treated with COVID-19 convalescent plasma should include: a) patient characteristics (e.g. sex, age, co-morbidities); b) timing of therapy in relation to disease onset; c) therapies administered including number, volume and antibody titre of transfused units of COVID-19 convalescent plasma; d) clinical and laboratory indicators of disease severity at baseline and at defined subsequent time points; e) adverse reactions linked to transfusions; and f) time to hospital discharge or fatality. In settings where donor selection based on the titre of neutralizing antibodies is infeasible, COVID-19 antibodies can be measured and characterized in retained samples of the convalescent plasma units. In post-trial analyses, outcomes from the treatment can be stratified by the dose (volumes and titres) of the units administered to determine the effect of the titre of the convalescent plasma on the clinical outcomes.

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WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.