

# Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19)

Interim guidance

May 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 and experimental clinical use 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 document is adapted from the WHO Guidance for National Blood Services on Protecting the Blood Supply During Infectious Disease Outbreaks<sup>1</sup> and risk assessment publications on COVID-19 from regional networks/institutions.<sup>2-4</sup>

## Changes from the Interim Guidance dated 20 March 2020

The present document updates the previous Interim Guidance to provide flexibility in defining a 14 to 28-day standard period of deferral from blood donation after travel to a defined area of ongoing community transmission of SARS-CoV-2, direct exposure to COVID-19 from a confirmed case, or recovery from the illness.

This document also adds details to the previous sections on Mitigating the risk of staff and donor exposure to COVID-19 virus, Mitigating the impact of reduced availability of blood donors, Communication, and Collection of Convalescent Plasma.

These updates are provided to address issues raised by stakeholders and requests from multiple WHO regions for clarifications and additional information.

## General considerations

The COVID-19 virus outbreak is primarily transmitted by the respiratory route and theoretically by transfusions. The epidemic has the potential to reduce the supply of blood and blood components and adversely affect blood system activities. Blood services should therefore take steps to assess, plan, and respond appropriately and proportionately.

The risk of transmission of COVID-19 through transfusion of blood and components is now only theoretical and likely minimal. But experience with outbreaks of other

coronaviruses as well as the current pandemic outbreak suggests that there will be significant impact on blood supplies through reduced blood donation.<sup>5-11</sup>

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 (limited and contained vs widespread and sustained); 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, during which blood sufficiency is most likely to be affected. 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. Blood services should be included in the national outbreak response, through experts linked to the national emergency response team. Blood services should activate their emergency response plans. Networks of cooperating blood services across regions can help maintain the availability of blood and blood components.

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

Respiratory viruses have never been reported to be transmitted through blood or blood components; therefore, any potential risk of transmission by transfusion of blood collected from asymptomatic individuals is theoretical. Any actions taken to mitigate risk are therefore precautionary. Options include donor education, self-deferral or deferral of at-risk donors, quarantine of blood components, retrieval of in-date products based on a report of post-donation illness in the donor, screening of donations using laboratory tests, and pathogen reduction:

- a. Potential donors should be educated about the need to self-defer based on risk factors for COVID-19 or feeling unwell. Current donor screening measures excluding 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. Persons who donate should inform the blood centre immediately if they develop a respiratory illness within 28 days of donation.

- b. Persons who have fully recovered from confirmed COVID-19, those with possible direct exposure to COVID-19 from a confirmed case, and those who have travelled from defined areas with ongoing community transmission should refrain from blood donation for a defined period. In settings where the blood supply is not in shortage, a precautionary approach with a deferral period of 28 days (two incubation periods) has been recommended in some jurisdictions. A deferral period of 14 days (one maximal incubation period) is generally considered adequate to assure absence of an acquired active infection by SARS-CoV-2. This approach would be appropriate in settings with significant reduction of the available blood supply.
- c. This may take the form of self deferral or mandatory deferral. In the event of widespread transmission, donor restrictions based on definitions of exposure risk and duration of deferral may need to be reduced to fit the local situations so as not to affect availability of blood for critical transfusion therapy.
- d. Quarantine of components with delayed release based on absence of a reported subsequent illness in the donor is an option in the event of widespread and sustained transmission. But this is difficult to implement and disrupts existing processes and workflows, leading to greater potential for errors. Release of blood into available inventory is delayed, and quarantine of platelets is particularly problematic given their short shelf-life.
- e. 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 to 28 days of disease onset in the donor or after contact exposure may be recalled as a precautionary measure. Although risk of transfusion transmission is theoretical, notification of the clinician of confirmed infection in the donor may also be considered if the blood or components have been transfused.
- f. Testing of the blood supply is premature in the absence of cases of transfusion transmission or demonstrated infectivity of the COVID-19 virus in blood collected from asymptomatic persons.
- g. Pathogen reduction technologies (PRTs) have been demonstrated to be effective against SARS-CoV and MERS-CoV in plasma and platelets. However, PRT requires significant logistical and financial investment. PRT for whole blood is less widely available and studies of inactivation of coronaviruses in whole blood are lacking. Introduction of PRT for the COVID-19 virus would not be cost effective or proportionate and is not recommended.
- h. Current manufacturing processes for plasma derivatives can inactivate and remove viruses related to the COVID-19 virus. As an enveloped virus, the COVID-19 virus is susceptible to many of the steps involved in preparation of therapeutic agents from fractionated plasma; thus, there is no

presumed risk for transmission through these products.

- i. 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.<sup>12</sup>

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. For example, a country with no locally acquired cases may opt as a precaution to defer donors recently returned from affected areas. This is possible if the numbers of deferred potential donors are low and can easily be managed without affecting supply. However, once more countries are affected and particularly when locally acquired cases start to appear, the risk becomes more general and it is harder to identify individual at-risk donors. In such situations, deferral becomes impractical and unsustainable.

## 2. Mitigating the risk of staff and donor exposure to COVID-19 virus

Any transmission from a donor is far more likely to occur through the respiratory route than through parenteral routes (including phlebotomy during blood donation). It is possible that an infected donor who is asymptomatic, pre-symptomatic, or has very mild symptoms may infect other donors and staff. Strategies taken to mitigate this risk should be proportionate and evidence-based and should follow the public health measures taken in the country. Blood donor centres and manufacturing premises are not acute care medical facilities, and so public health measures appropriate to the general public rather than clinics and hospitals should be applied. Providing information to donors and the public about the measures taken will contribute towards gaining their confidence to continue donating blood.<sup>8,10</sup>

Efforts should be made to schedule blood donations by appointment to avoid crowding at the collection centre.<sup>8,10</sup> Donors and potential donors should be informed of the importance of self-deferral if they are feeling unwell, and of reporting immediately to the blood service any COVID-19 related illness within 28 days after donation. Individuals who should not donate blood should be screened off at the earliest opportunity, by providing relevant information on websites and posters or setting up triage stations.<sup>6,8</sup> If COVID-19 is confirmed in a blood donor or staff, the management of contacts should follow national public health guidelines.

The safety of the donation process should be ensured through the use of appropriate protective measures by staff.<sup>13</sup> In addition to regular environmental decontamination, organization of donation procedures to minimise contagion between donors, including temperature screening at the entrance, providing entering donors with face masks and hand sanitization, and physical distancing, may be considered while assuring proper flow of work.<sup>8-10,14,15</sup> It is not necessary for precautions taken in health care settings with sick patients

to be applied to donor centres unless the donor centre is sited within hospital premises or there is evidence of their effectiveness in community settings.

Standard laboratory biosafety practices, based on national or international guidelines, should be followed in all circumstances.<sup>16</sup> 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.<sup>17</sup>

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.<sup>18</sup> During widespread community transmission, staff may be reduced through illness; blood centres should consider measures to mitigate the impact on essential activities.<sup>11</sup>

### 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 for blood services. Blood services should consider the sufficiency risk early to enable preparedness and response. The exact factors affecting blood donations vary in extent depending on local situation, and is dynamic throughout the course of the pandemic.<sup>9,11</sup> Blood donation numbers should be closely monitored so that measures can be taken quickly to pre-empt any decline in donor attendance or to consider importation of blood and components. 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.

A significant decline in blood donor attendance occurs when individuals are unwilling to donate through fear of being infected during blood donation.<sup>8</sup> 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 also be disseminated continuously. Different communication platforms and tools should be used, including social media, in order to reach all segments of the population.<sup>8-11,15</sup>

Containment strategies may limit the ability of donors to attend donation sessions and prevent blood collection teams from visiting areas associated with infection clusters or where public health restrictions are in place. Reduction in routine blood collection practices, such as mobile blood donation drives and group donations, may occur due to closure of workplaces, businesses, schools and community-based institutions. Strategies to overcome this include rapid switching of sites for blood collections where feasible, providing donor transportation, intensifying efforts to schedule appointments for donations, or adjusting operating hours. Blood collection activities may need to be organized on a more targeted basis through focused retention and recall of healthy repeat donors. Innovative use of social media and

communication tools may help in fostering donor networks and organising virtual donor-related events.<sup>7-9,14</sup>

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 such as 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. Most can donate again 28 days after full recovery. Shortening the duration of deferral to less than 28 days for routine donation can be considered in settings of significant risk of blood shortages. However, a minimum deferral period of 14 days after full recovery from symptoms additionally is advocated as a precautionary measure for maintaining health of the donor and to allay fears that the donor might be a source of contagion in the blood collection centre. A standard deferral period after full recovery may also support the collection of convalescent plasma for treatment of COVID-19 patients (see Section 7: Collection of convalescent plasma).

Importation of blood and components from unaffected areas of the country or another unaffected country (if permitted by regulatory authorities) is a potential solution if there are insufficient local stocks, although if widespread transmission is occurring, this may be difficult. 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 widespread 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. But 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.<sup>9,11</sup>

### 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 immunohaematology 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. 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 proportionate, evidence-based and consistent with overall national emergency response messaging.<sup>9,19,20</sup>

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 and clinical use of convalescent plasma

WHO recognizes convalescent plasma as an experimental therapy that may be useful in treatment of COVID-19 in the context of clinical studies to establish the feasibility, safety and medical effectiveness for its collection and use. This position is based on promising early reports of empirical use of COVID-19 convalescent plasma and encouraging historic experience with use of convalescent plasma to treat SARS and pandemic influenza.<sup>21,22,23,24</sup>

WHO recommends strongly that COVID-19 Convalescent Plasma should be used in prospectively conducted and controlled Randomized Clinical Trials (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 defined patient outcomes. Data on product preparation and use collected in this way and reported to a central national authority can provide information that supports the findings of prospectively controlled RCTs.

COVID-19 Convalescent Plasma can be made available on an experimental basis through local production provided that ethical and safety criteria are met for its preparation and use. 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.<sup>25</sup> Additionally, the WHO Blood Regulators Network Position Paper on Use of Convalescent Plasma, Serum or Immune Globulin Concentrates as an Element in Response to an Emerging Virus (2017) provides

helpful considerations.<sup>26</sup> Consistent with prior guidance, medical, legal and ethical safeguards should be in place both for the donors of COVID-19 Convalescent Plasma and the patients who receive it. Regulatory agencies should enable progress in this area 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. Examples of such documents are provided in the Appendix to this document. WHO does not endorse any of these statements or protocols. The information is provided exclusively to assist stakeholders with identifying links to the various statements, guidelines and protocols. 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 at <http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/>. A Cochrane rapid systematic review on the use of COVID-19 Convalescent Plasma also provides information on case series and on studies that have been registered in clinical trial websites.<sup>27</sup>

While no universal protocol exists for collection and use of COVID-19 Convalescent Plasma, common criteria for acceptance of donors of COVID-19 Convalescent Plasma include diagnostic evidence of prior infection with SARS-CoV-2, deferral for a standard period after full recovery (or a negative virologic test for earlier collections), and retention of a blood sample for characterization of antibodies to the virus. Data elements for reporting of patient outcomes commonly include patient characteristics (e.g. gender, age, co-morbidities), timing of therapy in relation to disease onset, therapies administered including number, volume and antibody titre of transfused units of COVID-19 Convalescent Plasma, clinical and laboratory indicators of disease severity at baseline and at defined subsequent time points, adverse reactions linked to transfusions, and time to hospital discharge or fatality. In settings where donor selection based on the titre of neutralizing antibodies is infeasible, outcomes from the treatment can be stratified in post-trial analyses to determine the effect of the titre of the convalescent plasma administered.

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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.

## Appendix

Position statements and/or study protocols for evaluation of COVID-19 Convalescent Plasma have been issued by several Member States and regional organizations. Examples available at the time of this writing are provided in the following table.

INITIATOR	TITLE OF DOCUMENT	LINK TO THE DOCUMENT
Saudi Arabia, King Abdulaziz University Jeddah.	Use of Convalescence Plasma in The Treatment of Patients Infected with Covid-19 Virus Infection Protocol Version V 1.2	<a href="http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/">http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/</a>
SIMTI (Societa Italiana di Medicina Transfusionale e Imunoematologia) SIdEM (Societa Italiana di Emaferesi e Manipolazione Cellulare)	Convalescent Plasma “Position paper” on the preparation of immune plasma to be used in the treatment of patients with COVID-19.	<a href="http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/">http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/</a>
US Food and Drug Administration	Recommendations for Investigational COVID-19 Convalescent Plasma  National Expanded Access Treatment Protocol	<a href="https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma">https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma</a>  <a href="https://www.uscovidplasma.org/">https://www.uscovidplasma.org/</a>
COVID-19 Convalescent Plasma Project (CCPP19) Leadership Group	US National COVID-19 Convalescent Plasma Project	<a href="https://ccpp19.org/">https://ccpp19.org/</a>
UP-Philippine General Hospital Technical Working Group on Convalescent Plasma Therapy	Guide on The Compassionate Use of Convalescent Plasma Therapy for Covid-19	<a href="http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/">http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/</a>
European Commission Directorate-General for Health and Food Safety Directorate B - Health systems, medical products and innovation	An EU programme of COVID-19 convalescent plasma collection and transfusion Guidance on collection, testing, processing, storage, distribution and monitored use.	<a href="https://ec.europa.eu/health/blood_tissues_organs/covid-19_en">https://ec.europa.eu/health/blood_tissues_organs/covid-19_en</a>
ISBT Working Party on Global Blood Safety	Points to consider in the preparation and transfusion of COVID-19 convalescent plasma  Points to consider in the preparation and transfusion of COVID-19 convalescent plasma in low- and middle- income countries	<a href="http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/">http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/</a>
Pan American Health Organization (PAHO)	Regulatory considerations on authorization of the use of convalescent plasma (PC) to address the COVID-19 emergency	<a href="https://iris.paho.org/handle/10665.2/52036">https://iris.paho.org/handle/10665.2/52036</a>

WHO reference number: WHO/2019-nCoV/BloodSupply/2020.1