

Director

Tel. 91-11-23736851
Fax 91-11-23731746
E-mail nbtc mohfw@gmail.com



सत्यमेव जयते

राष्ट्रीय रक्त संवर्ण परिषद
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार

National Blood Transfusion Council
Ministry of Health and Family Welfare
Government of India

O.M. S-12016/99/2019-NACO(NBTC)

Dated:- 25/06/2020

Dear *sir/Madam,*

As you are all aware, National Blood Transfusion Council had already issued a detailed first interim "National guidance to blood transfusion services in India in light of COVID-19 pandemic" on 25th march 2020 for preventive measures to be undertaken by the health care professionals and various stakeholders for Blood Transfusion Services to prevent the possible spread of COVID-19 in Blood Centers and blood donors.

In the continuation of first Interim National Guidance, the second interim "National guidance to blood transfusion services in India in light of COVID-19 pandemic" subsequently is being issued in light of newer evidences generated for COVID-19. This guidance has been developed with Multi-Stakeholder consultation. **"National guidance to blood transfusion services in India in light of COVID-19 pandemic" dated 25th June 2020 is in supersession of first guidance issued by NBTC dated 25th March 2020.**

The guidance developed in the context of blood transfusion services is enclosed for your reference. I request all State AIDS Control Societies and State Blood Transfusion Councils to adopt the guidelines to their specific needs and accordingly direct the professionals engaged in blood transfusion services to facilitate maintenance of adequate stocks of safe blood to meet requirements.

It is also re-iterated that updated MoHFW guidelines with respect to various protocols for COVID-19 available on <http://www.mohfw.gov.in> should also be fully complied with.

You may please feel free to contact us for any further information and/or necessary directions in this regard.



Dr. Sunil Gupta,
Additional Director General,
Blood Transfusion Services, NACO

Enclosure: Second Interim "National guidance to blood transfusion services in India in light of COVID-19 pandemic".

To
Project Directors,
State AIDS Control Societies (All States/UTs)

The Directors,
State Blood Transfusion Councils (All States/UTs)

Copy to:

- PPS to SS&DG (NACO&NTEP)
- PS to JS, NACO
- Director General of Health Services
- Director General, ICMR
- DCG(I), CDSCO
- Director, NCDC
- Blood Cell, NHM
- All Governing Body members
- All Standing Committee members
- All TRG of Blood Transfusion Services members
- Members of Expert Working Group for VBD
- All HoDs, NACO

Second Interim
NATIONAL GUIDANCE
TO
BLOOD TRANSFUSION
SERVICES IN INDIA
IN LIGHT OF
COVID-19 PANDEMIC

25th June 2020

**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

BACKGROUND

National Blood Transfusion Council (NBTC) in this document provides second interim Guidance to Blood Transfusion Services in the country in view of COVID-19 pandemic. The first interim guidance "National Guidance to Blood Transfusion Services in India in light of Covid-19 pandemic" was released by NBTC on 25th of March 2020.

This second interim guidance is being issued in light of latest evidences generated for COVID-19 and including inputs from WHO interim guidance for maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19). **Second interim guidance dated 1st June 2020 is in supersession of first guidance issued by NBTC dated 25th March 2020.**

While revising the existing National Guidance for BTS in view of COVID-19 pandemic, NBTC has thrown light upon following points while updating the guidelines

- a) Exclusion criteria for donors to maintain blood safety, infection control measures etc.
- b) Criteria for post donation care
- c) Recommendation on testing of blood and blood components for COVID-19, pathogen reduction technologies etc.
- d) Incorporation of the guidance issued by NBTC to State Blood Transfusion councils for promotion of voluntary blood donation to mitigate the impact of COVID-19 pandemic on blood collection.
- e) Incorporation of communications from Ministry of Home Affairs for promotion of voluntary blood donation.
- f) Guidance to maintain the bloodstock at blood centres in accordance to the blood requirement of the region.
- g) Managing the supply chain system for commodities required in blood transfusion services
- h) Collection of convalescent plasma.
- i) Information on MoHFW helpline and toll-free number for COVID-19.

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Novel Coronavirus (nCoV) is a new strain of Coronavirus (CoV) family that has not been previously identified in humans. COVID-19 is the infectious disease caused by the most recently discovered coronavirus (SARS-CoV-2)(1).

The "incubation period" means the time between catching the virus infection and beginning of the symptoms of the disease. Most estimates of the incubation period for COVID-19 range from 1-14 days, average duration of around five days (1).

**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

The most common symptoms of COVID-19 are fever, tiredness, and dry cough, nasal congestion, runny nose, sore throat and in some cases may have diarrhoea. These symptoms are usually mild and begin gradually. Most people (about 80%) recover from the disease without needing special treatment. Around one out of six people develop more serious disease and experience difficulty in breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. (1)

People can catch COVID-19 from case of COVID-19 disease or from a fomite, which is a possible carrier of coronavirus(SARS-CoV-2). The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. This is why, it is important to stay more than 1 meter (3 feet) away from a person who is sick and maintain a similar social distance. (1)

Approximately 15% of clinically ill patients in one study had RNA in plasma or serum, but the presence or absence of infectious virus has not been reported and there remains no precedent for the occurrence of transfusion-transmitted respiratory viruses (2). A recent study from the Korean Red Cross Blood Services did not identify transfusion transmission in recipients of blood components from donors diagnosed with SARS-CoV-2 RNA infection following blood donation. However, the initial samples of these donors were negative (3). In a retrospective study from China, virus was detected in 4 out of 5000 blood donors. This implies more safety measures for blood donor staff and further research to identify infectious virions in asymptomatic blood donors (4).

No cases of transfusion-transmission were ever reported for the other two coronaviruses that emerged during the past two decades (SARS and MERS-CoV). Virus detection in blood has only been detected in symptomatic patients with COVID-19 to date. American Association of Blood Banks (AABB), US-FDA and CDC are not recommending any additional action by blood collection establishments at this time because there are no data or precedent suggesting risk of transfusion transmission for COVID-19 (2). Individuals are not at risk of contracting COVID-19 through the blood donation process or via a blood transfusion, since respiratory viruses are generally not known to be transmitted by donation or transfusion (5). According to the U.S. Food and Drug Administration (FDA), there have been no reported or suspected cases of transfusion-transmitted COVID-19 (6).



IMPLICATIONS ON BLOOD TRANSFUSION SERVICES

Blood Centres, world over are dependent on voluntary blood donation from healthy individuals to meet their blood supplies. In light of the COVID-19, there are several national and global reports of apprehensions among potential blood donors and donor organizations with respect to risks of contracting the infection through blood donation camps and visiting the blood centre to donate blood. The social distancing being advocated for preventing an individual from contracting COVID-19 is also being interpreted to not congregate for blood donation opportunities. If people do not turn up to donate at blood centres or camp locations, there is a likelihood of shortfall in blood supplies, which may be detrimental to those who are in urgent need of blood and blood components, like thalasseemics, persons with severe anaemia, instances of severe blood loss, road traffic accidents, ante partum and post-partum haemorrhage, patients needing urgent surgeries etc.

The WHO has released its interim guidance on the issue of maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19).

RECOMMENDATIONS:

The following recommendations should be followed in the context of blood transfusion services to maintain a safe and adequate blood supply during this period. It may be noted that while the Ministry continues to monitor the situation actively, these recommendations may be considered interim till revised in light of upcoming evidence for COVID-19 and revision in global guidance for the same. .

1) Exclusion of at-risk donors to maintain safety:-

Based on the history of the exposure of blood donor to the Coronavirus (SARS-CoV-2), following are the deferral criteria that should be applied while selecting the donor for blood donation.

- a) **Confirmed case:** -A confirmed case is a person with laboratory confirmation of SARS-COV-2 infection by RT-PCR test, irrespective of clinical signs and symptoms.

All Very mild / mild / pre symptomatic / moderate / severe cases must be deferred for 28 days after the discharge from the treating facility or 28 days after the end of home isolation (7).

The definition of "end/discontinuation of home isolation" should be as per the home isolation guidelines issued by MoHFW from time to time. For defining the severity of illness, the guidelines issued by MoHFW may be referred to.

- b) **Contact history:** -Individuals should be deferred from donating blood for 28 days with the last possible close contact exposure to a person who is confirmed/suspected case of COVID-19 including those under quarantine.

**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

- c) **Travel history:** -Individuals should be deferred from donating blood for 28 days after the date of departure from a country with COVID-19 transmission in the community and areas as notified by Ministry of Health and Family Welfare time to time.

2) Management of blood collection to ensure adequacy: -

As per the advisory issued by Ministry of Health and Family Welfare, Government of India, it is advised that mass gatherings may be avoided or possibly be postponed until the disease spread is contained. It is however also mentioned that for such gatherings, States may take necessary action to guide the organizers on precautions to be taken as per the existing guidelines. (9).

Therefore, keeping in view the essentiality of maintaining safe blood supplies, it is recommended that in-house blood donation as well as outdoor blood donation activities may be continued, while ensuring compliance with extant social distancing norms, mass gathering rules, infection control guidelines and biomedical waste disposal rules. This is to be ensured not only by the staff of the blood centres, but also by organizers, potential blood donors and all other stakeholders.

- a) **Social Distancing measures** which are advised from time to time by the concerned authorities should be followed in the blood donation site like physical distancing of one meter between the individuals, restriction of social norms of hand shaking and hugging, measures to reduce the overcrowding, managing the blood donation couches such that one meter distance is maintained between the two couches of blood donation, calling the donors in a staggered manner to donate blood such that overcrowding is prevented etc.
- b) **Infection control measures** should be consistent with national and state communicable disease control guidelines for COVID-19 for communities. Blood collection centres are not medical care facilities so general public guidelines rather than hospital guidelines can be followed.
Following general measures for infection prevention and control should be undertaken by the health care workers as well as the blood donors. All blood centres and camp organizers should educate the staff and donors for the same and provide facilities like running water, soap, hand sanitizers, personal protective equipment, colour coded dustbins etc.
- a) **Hand hygiene:** This is appropriate for all modes of transmission including airborne, droplet and contact. Hand washing with soap and water is preferred when hands are visibly dirty or soiled with blood or other body fluids or after using the toilet. Hand rubbing with an alcohol-based preparation is the preferred method for routine hygienic antisepsis if hands are not visibly soiled and running water is not available.
- b) **Cough etiquette:** appropriate for all modes of transmission.

**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

- c) **Avoid close contact with confirmed or suspected case of coronavirus disease.** Stay at home or self-defer if **staff/donor** are unwell or have contact with someone confirmed for COVID-19. Due to the ongoing transmission of coronavirus, the availability of staff may be reduced because of illness or redeployment as per COVID-19 priorities; and hence blood centres should consider measures to mitigate the impact on essential activities. Small groups of blood donation teams may be formed with the available staff at the blood centre and utilized accordingly for voluntary blood donation for minimizing the exposure and maximizing the output.
- d) **Safe disposal** of used gloves, masks, caps and other soiled material should be ensured
- e) **Protocols for proper cleanliness** of the equipment used during the blood donation should be maintained. Follow procedures for cleaning and disinfecting and increase frequency of these activities. This includes: The donor bed and other surfaces in the collection area after each donor, the donor screening and refreshment areas, restrooms, doorknobs and other surfaces, donor screening tools such as clipboards, tablets, pens and styluses, empty waste bins more frequently, protect supplies in the refreshment area by limiting donor access to the supply of snacks and drinks. Serving each donor individually wrapped snacks and drinks

The National Guidelines for infection prevention and control for healthcare facilities as issued by Ministry of Health and family welfare, Government of India may be referred for better understanding and implementation of the measures for infection prevention and control in the healthcare settings (10). The safety of the donation process should be ensured with appropriate protective measures by staff. Enhanced infection control would not normally be required unless on specific advice of public health and/or infection control personnel. ***Use of facemask by healthcare provider in blood centre, blood mobile van or an outdoor blood donation camp shall be mandatory to prevent transmission of virus.***

Additional personal protective equipment such as N95 masks, additional gloves and gowns for collection of blood is not currently considered necessary. Standard laboratory biosafety practices, based on national or international guidelines, should be followed in all circumstances. Enhanced environmental cleaning would not normally be required but may be recommended to decrease the risk of exposure or in the situation, that a suspected case was present at a blood centre. This will include ensuring that all the frequently touched surfaces are sanitized and all biomedical waste is disposed off correctly.



**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

- c) **Blood collection** through recruitment of healthy individuals as blood donors should be ensured so as to have a continuity in sufficient supply of blood to the blood banks. Wherever possible, regular repeat voluntary blood donors should be encouraged to come for blood donation at sites convenient to them. In-house and outreach voluntary blood donation camps may be organized as usual with appropriate precautionary measures. The blood donors during the blood donation sessions may be called for blood donations in a staggered manner such that crowding and mass gathering is avoided and social distancing is maintained. Similarly, blood centres for blood collection may deploy smaller blood donation teams. The specific norms for mass gatherings and social distancing as issued by Central Government or respective State Governments must be adhered to with respect to numbers that define such gatherings.

In some circumstances, an outbreak may be geographically restricted to a small identified area like a village, block etc., and such areas may be declared as containment zones by the administrative authorities. In such cases blood collection from voluntary blood donors of these areas may be temporarily ceased.

Depending on the circumstances, needs and capacity in the system, the loss of donations from a specific area may need to be supplemented by increasing recruitment for blood donors and collections in non-affected areas. IEC Campaigns should be organized to increase awareness and encourage donation in these areas.

The several steps that may be undertaken to facilitate the activities of voluntary blood donation as follows.

- a. Issuance of **Donor Appointment Letter** by the licensed Blood centres as identified by State Blood Transfusion Councils.
 - b. **Coordinating in getting the permission for movement of blood mobile vans and blood transportation vans** for conducting the outdoor blood donation.
 - c. **Engage Voluntary Blood Donor Organization** for conducting the above-mentioned activities and creation of awareness among healthy individuals.
 - d. Leverage the means of **IEC and social media activity** to raise the awareness about the need for blood donation, recruit and retain the healthy voluntary blood donors in the public at large.
- d) **Donor Education and Communication** is of paramount importance during any outbreak situation. Donors should be apprised to any changes in either the donor selection process or in the screening of donations or overall flow in the blood centres or outdoor camps. Donors are more likely to understand the situation and therefore be able to either self-defer or answer the donor selection



**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

questions more easily, accurately and honestly if they fully understand the situation, the actions being taken by the blood centre and why those actions are being taken. Blood centres may review the SOP for their blood collection and donor screening flow to accommodate for these changes. Donor educational materials in the form of leaflets, handouts or the posters, instructing individuals to self-defer and refrain from donation if they have any history of travel or contact or are confirmed case for COVID-19 may be displayed prominently at the blood donation site. Communicate to donors about new safety measures implemented in response to the outbreak. The counsellor and the medical officer posted in the blood centre or the blood donation camp should strictly follow the routine as well as additional measures.

Helpline number(+91-11-23978046) and toll-free number 1075 of Ministry of Health and Family Welfare, Government of India, may be contacted if any donor wants any information related to COVID-19.

- e) **Role of Voluntary Blood Donor Organizations** can be critical in ensuring that there is a sufficient blood supply. Countries that have efficient voluntary blood donor organizations are able to sustain a constant inflow of donors. The VBDOs should maintain close contact with local blood centres to ascertain the need for donors. They should work closely with health authorities to disseminate the necessary guidelines for blood donation during the infectious disease outbreak like COVID-19. Written or e-Communication in a jargon-free language can be used to inform and educate the voluntary blood donor organizations about the expected roles and responsibilities of Voluntary Blood Donation Organizations in blood transfusion services during the outbreak of the infectious disease like COVID-19. These roles and responsibilities should be in synchronization with the extant rules and regulations for mass gatherings and social distancing measures to be undertaken and as communicated by the concerned authorities during the epidemic period while conducting the voluntary blood donation camp (9).
- f) **Post donation care** is to be ensured for every donor donating blood at the blood centre or in outdoor locations as per standard of care.

In the present context following are the recommendation to be followed for ensuring the blood safety.

- a. **Blood donor related:** -The blood donor should be encouraged to report back to the blood centre or the camp organizer within twenty eight days of donating blood if the donor is experiencing the following(8)
- i. Post donation illness suspicious of COVID -19 in self
 - ii. Been confirmed positive for COVID-19
 - iii. A close contact having been confirmed positive for COVID-19

It is to be ensured by the Blood Centre Medical officer that if clinical intervention is required for the donor, he should be appropriately referred for

**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

further management as per extant guidelines. The SBTC should ensure that the details with respect to facilities where such services for diagnosis and treatment of Coronavirus disease are made available with all licensed blood centres in their State.

- b. **Blood and blood component related:** -Although risk of transfusion transmission is theoretical the unutilized whole blood or blood components collected within 28 days of onset of illness or after contact exposure from such individuals as under and above should be recalled and discarded (8). If such blood has been transfused to the recipient prior to such disclosure by the donor, then the treating clinician and other concerned hospital administrators must be informed.
- c. **Testing of the blood supply** for COVID-19 is not recommended in light of the risk of transfusion transmission being theoretical or lack of demonstrated infectivity of the COVID-19 virus in blood collected from asymptomatic persons. Routine practices of infectious disease testing for transfusion transmissible infections should not be changed (8).
- d. **Pathogen Reduction Technologies (PRT):**-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 (8).
- g) **Sharing and transfer of screened blood and blood components** is enabled in the Drugs and Cosmetics Rules and NBTC guidelines. This approach is also a potential solution when the effect of the disease outbreak leads to insufficiency of blood supply as donors and blood collection activities may be restricted, but demand for blood and components continues at a normal level as usual. .

If operations of any blood centre or a blood storage centre is temporarily suspended during the COVID-19 outbreak, the available blood and blood components should be transferred to other nearby blood centres where they can be utilized within shelf life after taking necessary precautions for surface decontamination of the blood bags. These provisions may be exercised by licensed blood centres and facilitated by SBTC to obviate the instances of scarcity of blood in the affected part of the country (13). However, the blood bank receiving the blood bags needs to check the TTI reporting and blood grouping from the donor blood bank and also check the blood bag for haemolysis etc.

- h) **Guidelines on appropriate clinical use of blood and blood components**, though are a matter of routine, should be built into all clinical training and practice. In situations where the normal sufficiency or safety of the blood supply may be compromised, only giving blood and components when absolutely necessary will



**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

help to both safeguard supplies and protect recipients from unnecessary exposure to a potentially infectious clinical product.

The Hospital Transfusion Committee of the hospitals should be regularly apprised of the developments of the outbreak in the region. The committee should be empowered to take the appropriate decision and provide the necessary guidelines to the treating physician and the surgeons of the hospital for the appropriate clinical use of blood and blood product during the period of outbreak of COVID-19.

- i) **Haemovigilance** has an important role to play. Since a National Haemovigilance Program is in place in National Institute of Biologicals, it should continue to capture and analyse any adverse events, which are associated with blood and blood component transfusion, including post donation instances of COVID-19. All possible cases post donation and post transfusion infections should be reported to HvPI of NIB with copies to respective SBTC and State FDA and properly investigated.
- j) **Maintenance of blood stock and management of supply chain of commodities during COVID-19:-**
- During widespread transmission, demand for blood and blood 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. However, blood transfusions will still be necessary for emergencies such as trauma, ante partum and post-partum haemorrhage, severe anaemia, blood dyscrasias, and urgent surgeries requiring availability of blood. Blood services should continually assess their bloodstocks and the blood requirement carefully in anticipation of uncertainty in the scale of collection activities. Daily reporting to the State Blood Transfusion Council and other agencies should be complied with.
 - Strategy has to be in place to timely address the increased demand of blood and blood components once the blood requirement for routine medical and surgical management of cases returns back to normalcy into the healthcare system. Blood centres should be in the position to anticipate such changes in the situation early such that necessary timely corrective actions in terms of escalating the intensity of the activities related to blood collection can be initiated and thus ensuring the adequate availability of safe blood.
 - 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 (blood bags, testing kits, immunohematology reagents etc.). The blood service must take steps to ensure continuity of supplies (8).
- k) **Collection of convalescent plasma:** - Systems should be in place to enable re-entry of cured COVID-19 patients as donors for convalescent plasma for



**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

treatment of COVID-19 patient. The treatment of COVID-19 patients using the convalescent plasma is under clinical trial and currently no evidence of the efficacy of the convalescent plasma as a treatment modality for SARS-COV-2 is established.

For collection of convalescent plasma under clinical trail from the cured COVID-19 patients, the donor selection criteria specifically for this purpose should be as per the protocol approved by DCG(I), CDSCO.

The use of convalescent plasma for routine treatment of COVID-19 patients is not recommended at present. The necessary guidelines for collection of convalescent plasma from the recovered COVID-19 patients for the treatment of such cases will be issued as and when the efficacy of this form of treatment is established and approved by the competent bodies.



**National Blood Transfusion Council
Ministry of Health & Family Welfare
Government of India**

REFERENCES

- 1) <https://www.who.int/news-room/q-a-detail/q-a-coronaviruses>
- 2) Update: Impact of 2019 Novel Coronavirus and blood safety, Feb 25 2020, by AABB's Transfusion Transmitted Disease Committee.
- 3) Kwon SY, Kim EJ, Jung YS, Jang JS, Cho NS. Post-donation COVID-19 identification of blood donors. Vox Sang 2020.
- 4) Chang L, Zhao L, Gong H, Wang Lunan, Wang L. Severe acute respiratory syndrome coronavirus 2 RNA detected in blood donations. Emerg Infect Dis 2020 Jul; 26(7)
- 5) The AABB Interorganizational Task Force Statement on Coronavirus and Blood Donation; <http://www.aabb.org/advocacy/regulatorygovernment/Pages/Statement-on-Coronavirus-and-Blood-Donation.aspx>
- 6) <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19-frequently-asked-questions>
- 7) Discharge Policy of nCoV Case, Ministry of Health and Family Welfare, Government of India
<https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>, and Revised guidelines for Home Isolation of very mild/pre-symptomatic COVID-19 cases
<https://www.mohfw.gov.in/pdf/RevisedguidelinesforHomeIsolationofverymildpresymptomaticCOVID19cases10May2020.pdf>
- 8) WHO interim guidance for maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19), 20 March 2020.
- 9) Advisory for the mass gatherings issues by MoHFW through an Office Memorandum dated 5th March 2020.
- 10) National Guidelines for Infection Prevention and Control in Healthcare Facilities as issued by MoHFW, GOI.
- 11) AABB's Optional Resources for FDA's Communication to Blood Establishments Regarding the COVID-19 Outbreak February 2020
- 12) Voluntary Blood Donation Program: An operational guideline by NBTC
- 13) Guidelines on bulk transfer of blood and the blood components by NBTC