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

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Sir/ Madam

As you may be aware, Government of India had already issued a detailed advisory on preventive measures to be taken to contain the spread of Novel Coronavirus (COVID-19). Requests have however been received from several stakeholders engaged with managing blood centres and blood transfusion services regarding concerns with maintaining safety and adequacy of blood during this period of restrained gatherings and social distancing.

Blood Centers, world over, are dependent on voluntary blood donation from healthy individuals to meet their blood supplies. Since there continues to be a demand for blood and blood components, especially for those patients depending on blood transfusions as a life saving measure, like Thalassemics, or to mitigate blood loss in accident victims, pregnant women, critically sick patients etc, it is essential that supplies of safe blood continue to be maintained at licensed blood centres in the country. Activities for blood collection and voluntary blood donation therefore are required to be continued judiciously during this period to meet the blood requirements.

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 adapt or adopt the guidance 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.

While the Ministry of Health and Family Welfare continues to monitor the situation actively, these recommendations may be considered interim till revised. It is also re-iterated that updated MoHFW guidelines with respect to protocols for COVID-19 available on http://www.mohfw.gov.in and other national guidelines 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. Shobini Rajan)

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



BACKGROUND

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 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).

The most common symptoms of COVID-19 are fever, tiredness, and dry cough, nasal congestion, runny nose and sore throat. These symptoms are usually mild and begin gradually. Most people (about 80%) recover from the disease without needing special treatment. 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. 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 sickand also 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).

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 (3). According to the U.S. Food and Drug Administration (FDA), there have been no reported or suspected cases of transfusion-transmitted COVID-19 (4).

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 thalassemics, persons with severe anaemia, instances of severe blood loss, road traffic accidents, post partum haemorrhage etc.

Alongside, there are also queries from various blood centres with respect to temporary deferral criteria for blood donors in light of the pandemic. The WHO guidance on the issue is yet to be released. Nevertheless, it is imperative to define such criteria to maintain the safety of donated blood, donor and patient safety.

RECOMMENDATIONS:

The following interim recommendations may 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 WHO guidance and upcoming evidence.

- 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) **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 (4).
 - 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-19including those under quarantine.
 (4).
 - c) **Confirmed case:** Individuals should be deferred from donating blood for 28 days till there is complete recovery from the disease including radiological and virological clearance(5).
- 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 till 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. (6).

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, 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 should be followed in the blood donation site which are advised from time to time by the concerned authorities like physical distancing of one meter between the individuals, restriction of social norms of hand shaking and hugging, handwashing protocols, protocols for maintaining the proper cleanliness of the equipment used during the blood donation, measures to reduce the overcrowding, managing the blood donation couches such that one meter distance is maintained between the two couches of blood donation 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 under taken 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.
 - c) Avoid close contact with confirmed or suspected case of coronavirus disease
 - d) Stay at home or self defer if staff/donor are unwell or have contact with someone confirmed for COVID-19.
 - e) Safe disposal of used gloves, masks, caps and other soiled material.



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 to be taken for infection prevention and control in the healthcare settings (7).

Enhanced infection control would not normally be required unless on specific advice of public health and/or infection control personnel. Additional personal protective equipment such as P2/N95 masks, additional gloves and gowns for collection of blood is not currently considered necessary as blood is collected from people who are healthy. 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 centres. This will include ensuring that all the frequently touched surfaces are sanitized and all biomedical waste is disposed off correctly.

- c) Blood collectionthrough recruitment of healthy individuals as blood donors should be ensured so as tohave 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. The specific norms for mass gatherings and social distancing as issued by respective State Governmentsmay be adhered to with respect to numbers that define such gatherings. Similarly, smaller blood donation teams may be deployed by blood centres for blood collection.
 - a) In some circumstances an outbreak may be geographically restricted to a small identified area like a village, block etc, in which case blood collection from such areas may be temporarily ceased.
 - b) 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 increase awareness and encourage donation in these areas.



- d) Donor Education and Communication is of paramount importance during any outbreak situation. Donorsshould be appraised to any changes in eitherthe 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 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. 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.
- 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 communication in a jargon-free languagecan 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 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:
 - a. Blood donor related:-In case a donor reports back to the blood centre or camp organizer within fourteen days of donating blood experiencing
 - 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 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 aremade available with all licensed blood centres in their State.

- b. Blood and blood component related:- The unutilized whole blood or blood components collected from such individuals as under and above should be recalled and discarded.
- g) Sharing and transfer of screened or otherwise low risk blood and blood components 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 have to be reduced, but demand for blood and components continues at a normal level as usual than can be supplied at the current level of blood collection. 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 (10).
- 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 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 epidemic 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) Haemovigilancehas an important role to play. Since a National HaemovigilanceProgram 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.

REFERENCES

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- 2) Update: Impact of 2019 Novel Coronavirus and blood safety, Feb 25 2020, by AABB's Transfusion Transmitted Disease Committee.
- 3) 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
- 4) https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19-frequently-asked-questions
- 5) Discharge Policy of nCoV Case, Ministry of Health and Family Welfare, Government of India.
- 6) Advisory for the mass gatherings issues by MoHFW through an Office Memorandum dated 5th March 2020.
- 7) National Guidelines for Infection Prevention and Control in Healthcare Facilities as issued by MoHFW, GOI.
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- 9) Voluntary Blood Donation Program: An operational guideline by NBTC
- 10) Guidelines on bulk transfer of blood and the blood components by NBTC

