Punjab Blood Transfusion Authority

OFFICE OF THE SECRETARY
PUNJAB BLOOD TRANSFUSION AUTHORITY
Inside Institute of Mental Health, Jail Road, Lahore
pbtapunjab@gmail.com, 04299201073, 03082818125

NO----- 228 **Dated----- 05-06-2020**

Government of the Punjab
Health Department

CIRCULAR

POINTS TO CONSIDER IN THE PREPARATION AND TRANSFUSION OF COVID-19 CONVALESCENT PLASMA

Keeping in view the increasing influx of serious COVID-19 patients at both public and private sector hospitals following instructions are being issued:

1. All the blood banks Licensed by Punjab Blood transfusion Authority under Category A are allowed to collect and store Plasma to be used as Convalescent Plasma Therapy. Complete list of these blood banks is available at **pbta.punjab.gov.pk** (Downloads).

2. Complete traceability record of both donor and recipient must be maintained and shared with PBTA.

3. Salient points of consideration in preparation, storage and transfusion of CP are given below to be strictly followed:

A. CONVALESCENT PLASMA DONOR SELECTION AND ASSESMENT.

a. Document a medical diagnosis of COVID-19 by signs and symptoms of the illness and, where feasible, a positive Nucleic Acid Test (NAT) (PCR) for SARS-CoV-2.

b. An interval of at least 28 days after full recovery.

c. Standard selection criteria for blood donation according to local requirements and standards (age, weight, collection frequency, vital signs, freedom from deferral criteria)

d. ABO and RhD testing to ensure blood group compatibility with a possible recipient

e. Haemoglobin measurement or validated haemoglobin estimation

f. Non-reactivity of blood samples for transfusion transmitted infections including HIV, HBV, HCV, syphilis and malaria.(By WHO recommended methods only)

g. Blood collection should be done from male donors or from female donors who have never been pregnant including miscarriages and abortions, or taking into consideration current local practices in the transfusion of plasma. This measure lowers the possibility of presence in the plasma of the antibodies to HLA or granulocyte antigens that cause Transfusion Related Acute Lung Injury (TRALI). Testing for these antibodies in female donors and in male donors with history of transfusion is desirable as an added precaution where feasible.

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B. PRE-SCREENING AND PRE-DONATION TESTING OF CONVALESCENT COVID-19 DONORS

Recovery from COVID-19 infection should be confirmed through:

1. Physical examination of the donor to establish good health including absence of fever and respiratory symptoms.
2. The approximate date of COVID-19 infection, history of symptoms, treatments received and date of resolution of all symptoms documented and traceable.
3. When blood or plasma needs to be collected prior to 28 days after full recovery from illness, the collection should not take place prior to 14 days after full recovery and additional confirmation of the resolution of the infection should be obtained through demonstration of a non-reactive Nucleic Acid Test (NAT) for SARS-CoV-2 performed on a nasopharyngeal swab sample.
4. **Whenever feasible**, the donor's plasma should be tested for neutralizing titers of anti-SARS-CoV-2 antibodies. Current data suggest that donations with a minimal titre by end-point dilution of 1:80 or preferably 1:160 should be selected. However, further studies are needed to define the minimal titer recommended. Absent a test for neutralizing antibodies, and where feasible, donations also can be selected based on high reactivity in a serologic assay for anti-SARS-CoV-2 antibodies.

C. CRITERIA FOR COLLECTION OF COVID-19 BLOOD OR PLASMA

a Managed by legally approved best quality blood or plasma collection devices and equipment

b Supervision of the collection process by trained and qualified staff.

c Volume of whole blood to be collected: 200-450 mL (plus the anticoagulant/preservative) based on the procedure and regulatory limits; in the case of apheresis plasma: 600 mL (plus the anticoagulant)

d Blood should be separated into the plasma component using standard operating procedures. For small amounts of blood specific blood bags must be only used.

e Blood or plasma units intended for use as convalescent products should be clearly labeled.

f (By Aphaeresis only, the first blood or plasma donation can be followed by further donations at a frequency compliant with local regulations and taking into full account the health status of the donor including a normal plasma protein level if plasma is collected more than once in 28 days.)

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D. POST-DONATION TREATMENT OF BLOOD OR PLASMA:

a *Where feasible*, pathogen inactivation of plasma using a licensed technology in place in the blood establishment, is desirable to control residual risks of transfusion transmitted infectious diseases and to allay concern about possible superinfections with SARS-CoV-2.

b Whole blood should be stored between 2°C and 6°C for a duration depending upon the anticoagulant and preservative used.

c Liquid plasma may be stored between 1°C and 6°C for up to 40 days.

d Plasma frozen at -18°C or colder within 24 hours after blood collection can be stored for up to 12 months.

e. Convalescent plasma collected from donors who do not fulfill post-COVID-19 suitability criteria for routine blood donation should be stored separately from other blood products in inventory.

f. Convalescent plasma should bear special labeling as an investigational product for treatment of COVID-19.

g. Donor blood/serum/plasma samples obtained at the time of donation should be saved frozen at -20°C or colder for retrospective testing of the total and neutralizing titers of anti-SARS-CoV-2 antibodies and further scientific investigations.

E. RECOMMENDATIONS FOR PLASMA TRANSFUSION:

Proper consent of recipient/ attendants must be obtained after proper explanation of the benefits and risks.

a. Follow standard hospital procedures and recommendations for thawing and transfusion of plasma.

b. It is crucial to ensure ABO compatibility of plasma between the donor and the recipient and avoidance of RhD sensitization in cases where whole blood is transfused.

c. Transfusion of plasma from at least two donors may be therapeutically beneficial to achieve more effective immune protection from delivery of diverse antibodies.

d. In the absence of published peer-reviewed reports of transfusion of convalescent COVID-19 plasma, patients could receive an initial dose of 200 mL, followed by one or two additional doses of 200 mL according to disease severity and tolerance of the infusions.

e. Blood/serum/plasma samples of the recipient prior to and after transfusion should be taken for future potential scientific investigations.

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It is further stressed that

- Athough early reports have been promising , the safety and efficacy of COVID-19 convalescent plasma as a treatment for COVID-19 are unproven at this time. However, in the absence of any known effective therapy, the theoretical benefit and feasibility of local production of COVID-19 convalescent plasma have generated global priority for its investigational use.

  Proper awareness and guidance must be provided to both donor and recipient.

SECRETARY
PUNJAB BLOOD TRANSFUSION AUTHORITY
LAHORE

No. and Date even.
Copy is forwarded for information to: -

1. Minister for Health Punjab.
2. Secretary Specialized Healthcare & ME Department, Lahore.
3. Secretary, P&Sec healthcare Department, Punjab, Lahore.
4. Chairman Corona Experts Advisory Group, Punjab.
5. Additional Secretary, Technical Specialized Healthcare & ME Department, Lahore.
6. Additional Secretary, Technical P& Sec Healthcare Department, Lahore.
7. Director Operations Punjab Health Care Commission.
8. Master File