



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

28 April 2020

**DEPARTMENT MEMORANDUM**

No. 2020 - 0216

**TO :** ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, SERVICES AND CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO; EXECUTIVE DIRECTORS OF SPECIALTY HOSPITAL; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; REGIONAL BLOOD PROGRAM COORDINATORS, HEADS OF BLOOD SERVICE FACILITIES AND ALL OTHERS CONCERNED

**SUBJECT :** Collection of Convalescent Plasma (CP) and Networking for Therapeutic Strategy for COVID-19

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**I. BACKGROUND**

COVID-19 is a novel infectious disease caused by a new coronavirus named SARS-CoV-2. With the increasing number of cases worldwide, the World Health Organization (WHO) declared the outbreak of COVID-19 as Public Health Emergency of International Concern (PHEIC) on January 30, 2020 and as a pandemic on March 11, 2020.

As there is no approved drug or vaccine as of this time to treat the disease, an investigational treatment is being explored with the use of convalescent plasma which has been studied in outbreaks of other respiratory infections, including the 2003 SARS-CoV-1 epidemic, the 2009-2010 H1N1 influenza virus pandemic, and the 2012 MERS-CoV epidemic, with promising results.

Convalescent plasma is plasma taken from a person who has recovered from SARS-CoV-2 infection and contains neutralizing antibodies against the said infection. Giving convalescent plasma collected from individuals who have recovered from COVID-19 to infected patients is a form of passive antibody therapy, which could offer a possible therapeutic strategy.

In the interim, the following guidelines are issued for the immediate establishment and implementation of a COVID-19 CP Donation Program. This will be spearheaded by the Philippine Blood Center (PBC).

**II. GENERAL GUIDELINES**

1. The Blood Service Facility (BSF) shall notify the Department of Health - Health Facilities and Services Regulatory Bureau (DOH-HFSRB) through the National Voluntary Blood Service Program (NVBSP) of their intent to establish a CP donation program with the assurance of separate workflow for COVID-19. A letter of intent shall

be submitted to DOH-HFSRB for this purpose (*see Annex A for additional requirements*).

2. Only licensed BSF by DOH-HFSRB shall be allowed to establish and implement a COVID-19 Convalescent Plasma Donation Program.
3. The BSF shall designate a **supervising Clinical Pathologist** duly certified by the Philippine Board of Pathology of the Philippine Society of Pathologists (PSP) who shall oversee the CP donation program with the following members:
  - 3.1. **Medical Officer** trained to screen donors and manage donor reactions.
  - 3.2. Designated **apheresis physician or apheresis technician** and **blood donor recruitment officer** for CP under the direct supervision of the supervising clinical pathologist.
4. The voluntary donor for COVID-19 Convalescent Plasma must fulfill the following criteria to be eligible for CP donation:
  - 4.1. Passed the standard DOH-prescribed donor history questionnaires, where applicable with an age range of 18 to 65 years old
  - 4.2. Recovered from COVID-19 with the following order of preference for donors of CP:

1st Preference	<ul style="list-style-type: none"> <li>• <b>Previously diagnosed with COVID-19 by SARS CoV-2 RT-PCR</b></li> <li>• <b>Absence of any clinical evidence of COVID-19 for at least 14 days as determined by a licensed physician, preferably but not limited to an Infectious Disease Specialist (IDS) who will issue Medical clearance as part of documentary requirement.</b></li> <li>• <b>With at least 1 negative SARS-CoV-2 RT-PCR result done on recovery</b></li> </ul>
2nd Preference	<ul style="list-style-type: none"> <li>• <b>Previously diagnosed with COVID-19 by SARS-CoV-2 RT-PCR</b></li> <li>• <b>Absence of any clinical evidence of COVID-19 for at least 28 days as determined by a licensed physician, preferably but not limited to an IDS who will issue Medical Clearance.</b></li> <li>• <b>Even without a negative SARS-CoV-2 RT-PCR result done on recovery</b></li> </ul>
3rd Preference	<ul style="list-style-type: none"> <li>• <b>No SARS-CoV-2 RT-PCR test done to document disease</b></li> <li>• <b>Absence of any clinical evidence of COVID-19 for at least 28 days as determined by a licensed physician, preferably but not limited to an IDS who will issue Medical Clearance.</b></li> <li>• <b>Positive result for anti-SARS-CoV-2 IgG antibody-based test done on recovery</b></li> </ul>

- 4.3. Negative for **anti-HLA-antibodies**, for donors with prior transfusions and female donors' history of pregnancy
- 4.4. Meet additional laboratory parameters:

- 4.4.1. Hemoglobin greater than or equal to 12.5 g/dL for females or 13.5 g/dL for males
  - 4.4.2. Platelet count more than or equal to 150,000
  - 4.4.3. When the testing platform is available, donors shall be negative for SARS-CoV-2 IgM antibody and positive for SARS-CoV-2 IgG with a titer of at least 1:160.
- 4.5. Must have signed the informed consent for donation.
5. CP Voluntary Donor shall provide pertinent diagnostic results regarding the aforementioned requirements or clinical abstract signed by the attending physician preferably but not limited to Infectious Disease specialists.
6. Donor recruitment strategies shall abide by universally accepted principles of Voluntary Non-Remunerated Blood Donation (VNRBD) and donor safety shall always be the foremost priority of BSFs in recruiting CP voluntary donors (*see Annex B. CP Donor Recruitment*)
7. Donor screening shall follow the usual procedure with informed consent, risk assessment using the standard DOH Donor History Questionnaire and the donor exclusion based on the DOH-NVBSP Manual of Blood Donor Selection.
8. Plasma for COVID-19 patients may be harvested using whole blood collection or plasmapheresis (*see Annex C. Collection, Processing, Storage, Allocation and Transfusion Procedure*).
9. CP units are tested for TTIs and screened for rare blood group antibodies. The following are required testing results of CP blood units:
  - a. Non-reactive serologic testing to HBsAg, HCVAb, HIV, syphilis and malaria
  - b. Negative antibody screen (rare blood group antibodies)
  - c. NAT testing for HBsAg, HCV and HIV when available.

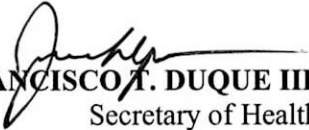
Alternatively, pre-donation testing for TTIs and rare blood group antibodies may be done on donors to minimize wastage of resources.
10. Harvested CP shall be processed, stored and transported in accordance to Blood Cold Chain protocol used in any plasma blood products.
11. To ensure sufficiency and equitable access to the supply of safe convalescent plasma, the distribution of **Convalescent Plasma** shall be encapsulated in the **CP Blood Services Network**. It shall be established by the NVBSP and spearheaded by the Philippine Blood Center (PBC) as the Lead CP Blood Service Facility and shall have the following functions:
  - a. Act as the Clearing House for the distribution of Convalescent Plasma
  - b. Maintain a nationwide CP Donor Registry
  - c. Conduct Public Education campaign
  - d. Facilitate in Donor Recruitment, Retention and Care
  - e. Collect Convalescent Plasma (CP)
  - f. Provide Pathogen Reduction Technology (PRT) and other tests necessary for the safety of convalescent plasma product
  - g. Submit Reports to the Public Health Services Team (PHST) and the Health Regulation Team (HRT)

- h. Conduct Convalescent Plasma Blood Services Network (CP BSN)
- i. Collect Payment meeting with satellite CP BSF

The PBC shall work with the Blood Service Facilities of COVID-19 Referral Hospitals or COVID Accepting Hospitals (COVAH) with the following functions:

- a. Submit daily inventory of CP to the Clearing house
  - b. Submit registry of CP Donors to the Philippine Blood Center
  - c. Participate in the planning and evaluation of the CP program.
  - d. Implement Donor Recruitment of CP in the hospital.
  - e. Screen donors, collect and process CP in the hospital
  - f. Refer CP to Philippine Blood Center for PRT
  - g. Submit the daily census of its CP stock position to the PBC
  - h. Attend the CP BSN meeting.
12. The Food and Drug Administration (FDA) is mandated to regulate biological products which include blood and blood products by virtue of the Administrative Order 2014-0016 "*Adoption of the World Health Organization Guidelines on the Evaluation of Similar Biotherapeutic Products for the Registration of Biosimilar Products*". However, as the regulatory framework for blood and blood products is still under development, health facilities that will utilize CP should report relevant information to the FDA for monitoring (*see Annex D. FDA Requirements*)

For dissemination and strict compliance.

  
**FRANCISCO T. DUQUE III, MD, MSc**  
Secretary of Health

## **Annex A. List of Other Requirements**

### **A.1. Physical Facilities/Workflow Environment**

There shall be a designated area for collection of CP with adequate space and separate from the regular/apheresis donation area. The area may be temporary but compliant with all the following requirements:

1. Reception/waiting area - 1.0 m<sup>2</sup> /person
2. Donor Counseling/Physical Exam area for donor - 5.02 m<sup>2</sup> with provision that ensure audio and visual privacy
3. Donor extraction — 6 m<sup>2</sup> per bed or couch
4. Access to a sink for hand washing
5. Area for Refrigerator/blood transport boxes and supplies (at least 1.2 m<sup>2</sup> per storage unit)
6. Work area with table and chairs — 1.0 m<sup>2</sup>
7. Post donation area with table and chair - 1.0 m<sup>2</sup>

### **A.2. Equipment/supplies in the donation area**

1. One set of apheresis machine with UPS and one donor couch with tilt adjustment for every 4 donors processed every 8-hour shift;
2. If whole blood collection is an option, supply of at least a triple blood bag and provide automated blood mixer;
3. Tube sealer preferably portable;
4. Surgical forceps, scissors, tube stripper, micropore tape, tourniquet;
5. Water dispenser or stock of bottled water;
6. Pathogen reduction treatment, if not available, Memorandum of Agreement with a facility that offers this blood product treatment. Alternatively, CP may be transfused without pathogen reduction treatment but this shall be stated in the consent.

### **A.3. Written Manual of Operations specific for CP donation program as incorporated to the Quality Manual of the BSF.**

It shall cover the following:

1. Recruitment of COVID-19 Donors
2. Collection, Processing and Storage of CP
3. Allocation and Release of CP

## **Annex B. Donor Recruitment Guide**

### **B.1. For Compassionate Use**

1. Donation of COVID-19 CP shall strictly comply with the Voluntary on Non Remunerated Blood Donation policy as mandated in AO 2010-0001 "Policies and Guidelines for the Philippine National Blood Services and the Blood Services Networks".
2. The donation shall remain unlinked. Directed donation is strongly discouraged. Voluntary Donors shall not be informed of the whereabouts of the patients who received their CP.
3. Donor rewards shall be consistent with the WHO definition of VNRBD:  
*"A person who donates blood (and plasma or cellular components) of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money."*
4. COVID-19 recovered patients shall be encouraged to become COVID-19 CP voluntary donors. They shall be free to decide which authorized Blood Service Facility will collect their CP.
5. A recovered COVID-19 patient who was first seen, diagnosed, admitted, or treated at a particular health facility/hospital cannot be forced to donate to that institution. However, donating in this hospital or health facility is highly advantageous since his/her medical record is readily available and verifiable.
6. Recovered COVID-19 patients who are eligible to donate CP to a health facility/hospital where they were first seen, diagnosed, admitted, or treated but is not authorized to collect COVID-19 CP shall be referred to an authorized CP Blood Service Facility. However, the COVID-19 CP collected from these voluntary donors cannot be tagged or exclusively allocated to the referring health facility/hospital who referred them. Allocation of COVID-19 CP shall be based on the distribution scheme stated in the section **Allocation of COVID-19 CP** - (see Annex B).
7. In referring COVID-19 recovered patients for CP donation, the basis for selecting the authorized CP Blood Service Facility shall be the proximity of the donor's residence or place of work to the collecting facility.
8. The authorized CP BSF is encouraged to provide conveyance to donors when public transport is not available. Donors may be reimbursed of their transport expenses consistent with the WHO definition of VNRBD.
9. The NVBSP shall maintain a registry of COVID-19 CP voluntary donors accessible by authorized personnel consistent with and in compliance to the data privacy law. All BSF collecting COVID-19 CP shall submit the list of donors on a daily basis to the NVBSP through the Philippine Blood Center.

### **B.2. For Research**

1. Recovered patients may be recruited for CP donation under research.
2. Recruiting COVID-19 CP donors already enrolled in a CP research is strongly discouraged.
3. Hospitals conducting research on COVID-19 with an approved protocol may refer their enrolled CP voluntary donors to a CP Blood Service Facility for collection of plasma provided there is a signed MOA between the CP BSF and the hospital if the facility conducting the research.



## **Annex C. Collection, Processing, Storage, Allocation and Transfusion Procedure**

### **C.1. Apheresis Donation**

1. For donors with prior whole blood donation or first-time donors who prefer apheresis procedure rather than whole blood donation.
2. Prophylactic calcium tablets may be given 10 to 30 minutes prior to the procedure.
3. Volume of plasma collected will be based on the height, weight, hematocrit and platelet count. About 300 to 600 mL of plasma will be collected by apheresis.
4. Plasmapheresis shall not take more than 120 minutes;
5. Covid-19 convalescent (apheresis) plasma may be frozen within 8 hours of collection and stored at least -18C
5. Alternatively, CP may not be frozen but transfused within 8 hours.
6. Pathogen reduction may be done when available or referred to a BSF with PRT.
7. Convalescent plasma will be labeled properly.

Donation ID using the prescribed NVBSP accession format.

Blood Type:

Date of Extraction:

Type of collection:

Results of TTI testing, Antibody screening and HLA Antibody when applicable:

Volume:

“CONVALESCENT PLASMA FROM A VOLUNTEER DONOR WHO  
RECOVERED FROM COVID-19.”

“This plasma product is for transfusion only to patients with COVID-19”

Store at: \_\_\_\_\_ °C

Transport at: \_\_\_\_\_ °C

8. Plasma may be collected as frequently as twice every month (every 2 weeks) and should not exceed a total of 12 liters in a 12-month period.
9. It is recommended to determine that serum/plasma protein is at normal level. This is repeated for donors undergoing plasmapheresis more often than once every 4 weeks, and once every four months for donors undergoing serial large volume plasmapheresis.

### **C.2. Whole Blood Collection**

1. For the first time donors or donors with unsuitable vein for plasmapheresis collection.
2. Collect blood in a triple bag and process into leukodepleted convalescent plasma about 200-250 mL.
3. Freeze within 8 hours.
4. Covid-19 whole blood derived convalescent plasma shall be stored at -18C or colder.
5. Packed red cells will be discarded and not used for transfusion.
6. Pathogen reduction may be done when available or referred to a BSF with PRT.
7. Convalescent plasma will be labelled properly.

Donation ID using the prescribed NVBSP accession format.

Blood Type:

Date of Extraction:

Type of collection:

Results of TTI testing, Antibody screening and HLA Antibody when applicable:  
Volume:

“CONVALESCENT PLASMA FROM A VOLUNTEER DONOR WHO  
RECOVERED FROM COVID-19.”

“This plasma product is for transfusion only to patients with COVID-19”

Store at : \_\_\_\_\_ °C

Transport at: \_\_\_\_\_ °C

8. Donors may donate again by whole blood donation after 12 weeks and by pheresis after 2 weeks thereafter.

### **C.3. Allocation of COVID-19 CP**

Allocation of CP shall be decided by the *Ad Hoc* committee for plasma collected by an authorized CP Blood Service Facility.

#### **CP collected by a Lead CP Blood Service Facility**

1. CP for compassionate use shall be available to all patients requiring it. The hospital shall institute an unbiased prioritization scheme by forming an Ad Hoc committee to decide allocation of convalescent plasma when the requests outnumber the supply of the hospital. There shall be established policy and criteria in allocating the CP. This may include but are not limited to availability of CP, severity and prognosis of intended recipient.
2. Authorized CP BSF shall provide CP plasma to all hospitals requesting this on a first-come first-served basis. CP shall not be released without the necessary documents: clinical abstract reviewed and approved by the ad hoc committee.
3. CP requests from a hospital for a particular patient cannot be transfused to another patient without the submission of necessary documents to the source BSF.
4. For CP collected by a Lead CP BSF for research shall only be released to the institution conducting the study.

### **C.4. Recommended Transfusion Procedure for COVID-19 CP**

1. Patient's ABO group must be determined by both forward (using anti-A and anti-B reagent) and reverse typing (using A1 and B red cells).
2. Type - specific compatible plasma may be used (refer to table below).

Recipient Blood Type	Plasma Blood Type
A	A, AB
B	B, AB
AB	AB
O	O, A, B, AB

3. Crossmatching is not required for plasma transfusion unless there is a significant red cell contamination of the plasma unit;



4. Thaw frozen plasma at 37 ° C;
5. Transfuse according to dose requirement;
6. Time at start and end of each infusion should be recorded;
7. Vital signs should be measured immediately prior to infusion, 10-20 minutes after start of infusion, at completion of infusion and 30-60 minutes after the end of infusion;
8. Pretreatment to minimize transfusion reactions (e.g., paracetamol, diphenhydramine) may be given per clinical care team discretion;
9. If an adverse event develops during infusion, the infusion may be slowed or stopped as per clinical care team's discretion. Transfusion of convalescent plasma should be halted if any of the following manifestations of anaphylaxis develop and will not be restarted.
  - a. Skin or mucous membrane manifestations: hives, pruritus, flushing, swollen lips, tongue or uvula
  - b. Respiratory compromise: dyspnea, wheezing, stridor, hypoxemia
  - c. Decrease in systolic blood pressure to <90 mmHg or >30% decrease from baseline or a diastolic drop of >30% from baseline
  - d. Tachycardia with an increase in resting heart rate to >130 bpm; or bradycardia <40 bpm that is associated with dizziness, nausea or feeling faint
  - e. Any other symptom which the good clinical judgment of the physician warrants halting the infusion (i.e., rapid onset of gastrointestinal symptoms, etc.)
10. Any adverse reaction (e.g. transfusion reaction) that occurred during or within 6 hours of completing the transfusion must be reported to the hospital blood bank and or blood collection facility/supplier for haemovigilance purposes.
11. Patients receiving convalescent plasma from recovered COVID-19 patients should be closely monitored using standard pathways to assess the effectiveness of the intervention.

## Annex D. FDA Requirements

The FDA requires the hospitals to submit the following to the Center for Drug Regulation and Research (CDRR):

- a. Health facility protocol for the use of convalescent plasma at [clinicalresearch@fda.gov.ph](mailto:clinicalresearch@fda.gov.ph)
- b. Information related to the use of CP at [pharmacovigilance@fda.gov.ph](mailto:pharmacovigilance@fda.gov.ph)
  1. Patient (Name, Age, Sex)
  2. Donor/s (Name, Age, Sex)
  3. Name of attending physician/s
  4. Name and address of the hospital where the patient is admitted
  5. Treatment outcome
  6. Drugs administered
  7. Suspected adverse events during the entire duration of therapy using MedDRA

The submission of the above-mentioned data must be consistent with the FDA Circular No. 2020-013 re: “*Guidance for the Monitoring of Drug Products Used for the Treatment of COVID-19*”. The Circular can be accessed through this link: <https://www.fda.gov.ph/?s=2020-013>. For any inquiries, please coordinate with CDRR through [cdrr@fda.gov.ph](mailto:cdrr@fda.gov.ph).