

CASE REPORT FORM(CRF) of COVID-19 Convalescent Plasma Recipient
SECTION A : PATIENT DETAILS

| | | |
|--|---|--|
| 1. Name of Patient: | 2. Age: | 3. Gender: M <input type="checkbox"/> F <input type="checkbox"/> TG <input type="checkbox"/> |
| 4. Blood Group: | 5. Address: | 6. Phone No: |
| 7. (a) Hospital Name: (b) Ward : | 8. IPD No.: | 9. Date of Hospital Admission: 10. Date of Hospital Discharge: |
| 11. Tested positive for COVID-19 by RT PCR : Yes <input type="checkbox"/> No <input type="checkbox"/> | | |
| 12. Recipient of Pooled Immunoglobulin in last 30 days : Yes <input type="checkbox"/> No <input type="checkbox"/> | | |
| 13. Any Allergies to food/drugs: Yes <input type="checkbox"/> No <input type="checkbox"/> (if Yes , then specify) : | | |
| 14. Known hyper sensitivity to blood products : Yes <input type="checkbox"/> No <input type="checkbox"/> (if Yes , then specify) : | | |
| 15. Transfusion history: Yes <input type="checkbox"/> No <input type="checkbox"/> (if yes please specify below) | | |
| a) Type of Blood/Component received : <input type="checkbox"/> PRBC <input type="checkbox"/> Platelet <input type="checkbox"/> FFP <input type="checkbox"/> Cryoprecipitate <input type="checkbox"/> CCP | | |
| b) Date of last Transfusion : c) Number of transfusion : | | |
| 16. Medications and treatment detail of the present admission (dose, dosage, duration) : | | |
| a. Hydroxychloroquine : | b. Heparin: | |
| c. Remdesivir : | d. Azithromycin : | |
| e. Lopinavir/Ritonavir: | f. Antibiotics (Name): | |
| g. Methylprednisolone: | h. IVIG: | |
| i. Tocilizumab: | j. Heparin: | |
| 17. Known case of (tick if Yes or No) | HIV : Yes <input type="checkbox"/> No <input type="checkbox"/> | |
| | HBsAg : Yes <input type="checkbox"/> No <input type="checkbox"/> | |
| | HCV : Yes <input type="checkbox"/> No <input type="checkbox"/> | |
| | Other (please specify) : | |
| 18. (a) Height (in cm) : | (b) Weight (in Kg) : | |
| 19. Number and Volume of CCP transfusions given (off label): | | |

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| 20. a. Date of CCP transfusion : b. CCP Unit ID : | 21. Consent obtained: Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 22. Any known Immunosuppressive Condition | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 23 . History of Smoking | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 24. Known Coexisting Chronic Condition (Please tick) | <input type="checkbox"/> COPD <input type="checkbox"/> Diabetes Mellitus <input type="checkbox"/> Hypertension, <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Cerebrovascular Disease <input type="checkbox"/> Cancer <input type="checkbox"/> Liver Cirrhosis <input type="checkbox"/> Tuberculosis <input type="checkbox"/> Chronic Kidney Disease <input type="checkbox"/> Obesity BMI> 30 <input type="checkbox"/> Others |
| 25. Any other medical co-morbidity, specify | |
| 26. Interval Between Symptom onset and Admission |days |
| 27. Interval Between Symptom onset and CCP transfusion | days |
| 28. Vasopressor support for at least 6 hours to maintain MAP>65 during hospital stay | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 29. Duration of Vasopressor Support | days |
| 30. Cause of Shock | <input type="checkbox"/> Hypovolemic Shock <input type="checkbox"/> Septic Shock <input type="checkbox"/> Cardiogenic Shock <input type="checkbox"/> Other |
| 31. Already in ICU during transfusion | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 32. ICU transfer after transfusion | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 33. Interval Between Admission and ICU transfer |days |
| 34. Reason for ICU transfer | <input type="checkbox"/> Respiratory Failure <input type="checkbox"/> Shock <input type="checkbox"/> Altered Mental Status <input type="checkbox"/> Acute Kidney Injury <input type="checkbox"/> Other |
| 35. Duration of ICU stay | days |
| 36. Duration of respiratory support | days |
| 37. Modality of Respiratory support | <input type="checkbox"/> Nasal Cannula <input type="checkbox"/> Face Mask <input type="checkbox"/> BiPAP <input type="checkbox"/> High Flow <input type="checkbox"/> Invasive Ventilation |

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|---|---|
| 38. Duration of invasive mechanical ventilation |days |
| 39. Cause of respiratory failure | <input type="checkbox"/> COVID induced <input type="checkbox"/> Non COVID |
| 40. Required renal replacement therapy during hospitalisation | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 41. Organ failure during hospitalisation | <input type="checkbox"/> Yes <input type="checkbox"/> No (tick below if yes) Heart failure <input type="checkbox"/> Respiratory failure <input type="checkbox"/> Acute kidney injury <input type="checkbox"/> Acute Hepatitis <input type="checkbox"/> Altered mental status <input type="checkbox"/> |
| 42. Hospital acquired infection | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 43. If yes, Name of the organism | |
| 44. Duration of hospital stay |days |
| 45. Outcome of hospital stay | <input type="checkbox"/> Discharged to home <input type="checkbox"/> Death in ward <input type="checkbox"/> Death in ICU <input type="checkbox"/> Death in ward after step down from ICU |
| 46. Cause of death (NA if alive) | |

SECTION B : CLINICAL EXAMINATION

| <u>Parameters</u> | Day 0 - Before transfusion | 1st Day post transfusion (24hrs after transfusion) | 3rd Days post transfusion | 7th Days post transfusion |
|---|---|--|---|---|
| 01. Presence of shortness of breath (<i>Yes / No</i>) | | | | |
| 02. Fever (<i>Yes / No</i>) (<i>temperature >100.4^o F</i>) | | | | |
| 03. Cough (<i>Yes / No</i>) | | | | |
| 04. Fatigue (<i>Yes / No</i>) | | | | |
| 06. Maximum respiratory rate/min in 24 hours | | | | |
| 07. Maximum heart rate/min in 24 hours | | | | |
| 08. GCS(noon) (final number; not in EVM) | | | | |

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| 09. SaO ₂ (%) on room Air If on Vent (NA) or if not possible to put on | | | | |
| 10. FiO ₂ req. to maintain SaO ₂ >92% (Add 3 to 21% for each liter of O ₂ , if on nasal cannula) | | | | |
| 11. Invasive mechanical ventilation(<i>Yes / No</i>) | | | | |
| 12. Arterial pH | | | | |
| 13. Lactate (mm/L) | | | | |
| 14. HCO ₃ (mEq/L) | | | | |
| 15. SaO ₂ /FiO ₂ | | | | |
| 16. PaO ₂ /FiO ₂ | | | | |
| 17. PEEP (Number) (NA if not on Vent) | | | | |

SECTION C : INVESTIGATIONS

| Parameter | Day 0 before transfusion | 1st Day post transfusion (24hrs after transfusion) | 3rd Day post transfusion | 7 Day post transfusion |
|-----------------------------|---|--|--|-----------------------------------|
| 18. Haemoglobin (g/dl) | | | | |
| 19. WBC count (Cell / cumm) | | | | |
| 20. Neutrophil count (%) | | | | |
| 21. Lymphocyte count (%) | | | | |
| 22. Platelets(Lakhs/cumm) | | | | |
| 23. Serum Sodium(mEq/L) | | | | |
| 24. Serum Potassium(mEq/L) | | | | |
| 25. Creatinine(mg/dL) | | | | |
| 26. Total Bilirubin(mg/dL) | | | | |
| 27. AST/SGOT (u/L) | | | | |

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|--|--|--|--|--|
| 28. ALT/SGPT (u/L) | | | | |
| 29. PT/INR | | | | |
| 30. aPTT (seconds) | | | | |
| 31. Fibrinogen (mg/dL) | | | | |
| 32 Ferritin (ng/mL) | | | | |
| 33. LDH (IU/L) | | | | |
| 34. CRP (mg/L) | | | | |
| 35. D-dimer (mg/L) | | | | |
| 36. IL 6 (pg/ml) | | | | |
| 37. Viral Load (Ct Value: E gene; RdRp and N gene) | | | | |
| 38. Chest X ray | | | | |

Signature of Doctor: _____ Name: _____ Date _____

SECTION D . ADVERSE EVENT RECORDING FORM FOR RECIPIENT OF CCP
(To be monitored for 6 hours after transfusion & fill below Yes or No)

| | | | |
|---------------------------------------|--|-----------------------------------|--|
| 1. Pain (Chest/Abdomen/Flank) | | 2. Fever (Temp >100.4F) | |
| 3. Reddish Urine | | 4. Chills/Rigors | |
| 5. Dyspnoea/Wheezing/Stridor | | 6. Urticaria/ Pruritus | |
| 7. Vertigo | | 8. Nausea/Vomiting | |
| 9. Perioral paraesthesia | | 10. Hypothermia (Temp <96.5F) | |
| 11. Tachycardia (Pulse > 100/min) | | 12. Bradycardia (Pulse 60/min) | |
| 13. Change in Hemodynamic status (BP) | | 14. Change in respiratory status | |

Signature of Doctor: _____ Name _____ Date _____

Filled by (Signature and Name) _____ Date _____

Note:

This Case Report Form (MGH/BB/CCP/CRF/Pt/211) should be filled by doctor /residents/MO at appropriate days after CCP transfusion. A scanned copy of this CRF should be sent to Blood Center, Mahatma Gandhi Medical College and Hospital, Jaipur along with the Transfusion Reporting Form(MGH/BB/CCP/TRF/207) by mail on covidplasmamgh@gmail.com .

Coexisting Chronic Condition

1. COPD – Has known history of COPD or clinical diagnosis during current admission.
2. Diabetes Mellitus - Has known history of Diabetes Mellitus or clinical diagnosis during current admission.
3. Hypertension - Has known history of Hypertension or clinical diagnosis during current admission.
4. Coronary Artery Disease - Has known history of coronary artery disease or clinical diagnosis during current admission.
5. Cerebrovascular Disease – Has known history of cerebrovascular disease or clinical diagnosis during current admission.
6. Liver Cirrhosis – Has known history of liver cirrhosis or clinical diagnosis during current admission.
7. Tuberculosis – Has known history of Tuberculosis or clinical diagnosis during current admission.
8. Cancer – Has known history of malignancy or clinical diagnosis during current admission.
9. Chronic Kidney Disease – Has known history of chronic kidney disease or clinical diagnosis during current admission.
10. Obesity BMI> 30 – Has known history of Obesity or clinical diagnosis during current admission.

Definitions

1. Hypovolemic Shock : Reduction in effective circulating blood volume which leads to MAP <65. Clinically : Cool extremities, pale moist skin, feeble pulse, oliguria.
2. Septic Shock : Patient with a septic source with MAP <65mmHg or requiring vasopressor to maintain MAP >65 despite adequate volume resuscitation. Clinically : fever, extremities warm, full bounding pulse, flushed skin.
3. Cardiogenic Shock – MAP <65 mm Hg after fluid resuscitation. Clinically :Cold extremities, oliguria, thready pulse, crackles tachypnea.
4. Respiratory Failure - SaO₂<92% on room air
5. Altered Mental Status – Glasgow Coma Scale <14
6. Acute Kidney Injury – Urine output less than 0.5ml/kg/h for 6 hours or rise in serum creatinine 1.5 times the baseline within 72 hours.

Number of organ failure during hospitalization

- a. Heart failure – EF <35%
- b. Respiratory failure – SaO₂ <92% on room Air.
- c. Acute kidney injury – Urine output less than 0.5ml/kg/h for 6 hours or rise in serum creatinine 1.5 times the baseline within 72 hours.
- d. Acute Hepatitis – Transaminitis – 5 times the upper limit of normal or 3 times the upper limit of normal along with symptoms.
- e. Altered Mental Status - Glasgow Coma Scale <14