

## Covid-19 Insights: Analysis from Ethics, Human Rights and Law Perspectives

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**Open letter expressing concerns about convalescent plasma for COVID-19 / Yogesh Jain, Vivekanand Jha, Soumyadeep Bhaumik, Soumitra Pathare, Shahid Jameel, Priti Meena, Prathap Tharyan, Prashanth N Srinivas, Oommen John, Kamna Kakkar, Jyoti Tyagi, Gautam Menon, Gagandeep Kang, C.S. Pramesh, Sharita Saran, Aparna Ananthakrishnan, Anant Bhan, Amar Jesani,**

To  
The Principal Scientific Adviser,  
Government of India

**Subject: Open letter expressing concerns about convalescent plasma for COVID-19**

Dear Dr Vijay Raghavan,

We are writing to you as concerned clinicians, public health professionals and scientists from India about the irrational and non- scientific use of convalescent plasma for COVID-19 in the country. This has stemmed from guidelines issued by government agencies, and we request your urgent intervention to address the issue which can prevent harassment of COVID-19 patients, their families, their clinicians and COVID-19 survivors.

What treatments to offer, to which patients and at what stage of the disease are complex clinical decisions, but clinical guidelines provide recommendations to enable this process. You will also agree that clinical guidelines must necessarily be based on existing research evidence.

We therefore wish to bring to your attention the current evidence on plasma therapy in COVID-19 and how the ICMR guidelines are not based on the existing evidence:

- ICMR-PLACID Trial – The trial was the world’s first randomised controlled trial on convalescent plasma in 39 public and private hospitals across India which found “convalescent plasma was **not associated with a reduction in progression to severe covid-19 or all-cause mortality**. This trial has **high generalisability** and **approximates convalescent plasma use in real life settings with limited laboratory capacity.**”<sup>1</sup>
- Recovery Trial – The large trial of 11,588 patients **found no difference in death or proportion of patients discharged from hospital**. Even for those patients who were not on ventilation initially,

there was **no difference “in the proportion meeting the composite endpoint of progression to invasive mechanical ventilation or death.”**<sup>2</sup>

● **PlasmAr Trial** – the trial from Argentina concluded that there is **no significant difference in “clinical status or overall mortality between patients treated with convalescent plasma and those who received placebo.”**<sup>3</sup>

**Current research evidence unanimously indicates that there is no benefit offered by convalescent plasma for treatment of COVID-19.** However, it continues to be prescribed rampantly in hospitals across India. Families of patients run from pillar-to-post for getting plasma, which is in short supply and reports of black-marketing is common. You might already be aware of these issues which have been widely reported in the media, and experiences shared by ordinary Indians in social media. The desperation of patients and their families is understandable because they did like to try the best for their loved ones, when a doctor has prescribed this.

We would also like to point out some very early evidence<sup>4</sup> that indicates a possible association between emergence of variants with **“lower susceptibility to neutralizing antibodies in immunosuppressed”** people given plasma therapy. This raises the **possibility of more virulent strains developing due to irrational use of plasma therapy which can fuel the pandemic.**

The problematic scenario arises because of guidelines issued by ICMR/AIIMS which currently recommends plasma therapy (April 2021 version)<sup>5</sup> as **“off label” use. This is rather unusual as off-label use by its very definition implies “unapproved use”.** We would also like to point out that international guidelines such as those from National Institutes of Health (NIH), USA<sup>6</sup> and the IDSA guidelines<sup>7</sup> also recommend against general use of plasma therapy for COVID-19.

We request you to urgently **review the guidelines** and remove this unnecessary therapy which has no benefit but is only causing harassment of patients, their families and even COVID-19 survivors who are being pressured to donate plasma. This should also be **twinned with clear instructions to blood banks** across the country on the same.

We are also willing to assist, if required, to appraise the evidence critically, conduct evidence synthesis and develop recommendations based on GRADE (which are global standards and followed by WHO), which can enable better clinical decision making.

We hope you will look into this as a matter of urgency and get the ICMR and AIIMS guidelines rectified so they reflect the current research and scientific consensus on plasma therapy.

**Signatories** \* (in reverse alphabetical order)

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18. Amar Jesani, Editor, Indian Journal of Medical Ethics

\*Signed in individual capacity. Might not necessarily represent views of employer

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<sup>1</sup>Agarwal A et al. Convalescent plasma in the management of moderate covid-19 in adults in India: open label phase II multicentre randomised controlled trial (PLACID Trial) *BMJ* 2020; 371: m3939 doi:10.1136/bmj.m3939&lt

<sup>2</sup> The RECOVERY Collaborative Group. Convalescent plasma in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial. *medRxiv* 2021.03.09.21252736.

<sup>3</sup> PlasmAr Study Group. A Randomized Trial of Convalescent Plasma in Covid-19 Severe Pneumonia. *N Engl J Med.* 2021 Feb

18;384(7):619-629.4 Kemp SA. et al. SARS-CoV-2 evolution during treatment of chronic infection. *Nature* 592, 277–282 (2021).

<sup>4</sup> Kemp SA. et al. SARS-CoV-2 evolution during treatment of chronic infection. *Nature* 592, 277–282 (2021).

<sup>5</sup> AIIMS/ ICMR-COVID-19 National Task Force/Joint Monitoring Group (Dte.GHS) Ministry of Health & Family Welfare, Government of India. Clinical Guidance for Management of Adult Covid-19 Patients.

<sup>6</sup> USA-NIH COVID-19 Treatment Guidelines: Convalescent plasma. 2021 .Available online at (Accessed 6th May 2021)

<sup>7</sup> Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19. *Infectious Diseases Society of America* 2021; Version 4.2.0.

**Copy to:**

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