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COMMENTARY

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Use of COVID-19 convalescent plasma in low- and middle-income countries: a call for ethical principles and the assurance of quality and safety

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The limited clinical data available suggest that convalescent plasma (CP) may have a therapeutic benefit in COVID-19 [1]. Absent any known effective therapy and considering the potential for local production, COVID-19 CP is becoming a global priority for investigational use. High-income countries with established national infrastructures and effective regulatory oversight can produce quality and safe plasma for transfusion that complies with international standards [2] and have initiated controlled clinical studies of COVID-19 CP [3,4].

Unfortunately, in low- and middle-income countries (LMIC) safe blood collection and transfusion are the challenges in the absence of a well-organized and nationally regulated blood collection system and limitations of critical resources and manpower. Nevertheless, provision of COVID-19 CP in LMIC needs to comply with the same principles of product safety and ethics regarding collection and use as in HIC, and guidance is needed [5,6].

The preparation of COVID-19 CP in LMIC should be organized as national initiatives supervised by the Ministries of Health and coordinated by the National Blood Services (or in its absence, cooperating blood establishments demonstrably meeting quality standards) to assure that legal and ethical guidelines for human research are applied to COVID-19. COVID-19 CP should be obtained only from volunteer, non-remunerated donors with reliable clinical, virologic or serologic evidence of prior infection with SARS-CoV-2. CP can be collected without additional testing for SARS-CoV-2 at >14 days after full recovery from symptoms. However, as an additional precaution against contagion in the donor room, prior demonstration of resolution of infection by a non-reactive Nucleic Acid Test (NAT) for SARS-CoV-2 performed on a nasopharyngeal swab sample can be considered for collections of CP between 14 and 28 days after full recovery from symptoms [7]. Collecting blood or plasma only from male donors or from female donors who have never been pregnant (including miscarriages and abortions) is advised for prevention of Transfusion Related Acute Lung Injury (TRALI). Selection criteria for blood donation and blood testing procedures should meet the established local requirements and standards. Where plasmapheresis is unavailable, CP should be prepared through component separation from whole blood (WB) while selecting donors carefully to avoid causing undue red cell loss and a low haemoglobin level. Transfusing convalescent WB should be considered only if WB transfusion is clinically indicated. ABO and RhD testing are needed to ensure blood group compatibility of CP and red blood cells.

The COVID-19 epidemic is one additional wake-up call that capacity building of a sustainable national blood system integrated within the public health system is crucial to ensure adequate, accessible and safe life-saving blood products in all countries, including in emergency situations [8].

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Disclaimer

Jay Epstein's contributions to this article reflect his own views and should not be construed to represent FDA's views or policies.

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