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# Bioethical perspective of convalescent plasma therapy for COVID-19: A systematic review



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#### ABSTRACT

Convalescent plasma therapy (CP) has long been used to prevent and treat various infectious diseases before COVID-19 such as SARS, MERS, and H1N1. Because the viral and clinical characteristics of COVID-19 share the similarities between SARS and MERS, CP treatment could be a promising treatment option to save COVID-19. With only low quality medical evidence, but massive media support and a very significant public demand for the use of convalescent plasma for COVID-19, we are now faced with an ethical dilemma. Therefore, this paper uses a structured analysis that focuses on the preferred reporting items for a systematic review of ethical issues regarding the use of Convalescent Plasma Therapy for COVID-19. The use of convalescent plasma must meet the ethical principles of autonomy; such as voluntary, informed consent, and confidentiality. Consideration of the risk-benefit ratio for potential donor recipients also needs to be considered in order to meet the beneficence and non-maleficence principles. The principle of justice also needs to be applied both to donors, donor recipients and health workers, such as determining the priority of donor recipients, due to the increasing demand for convalescent plasma amid the limited circumstances of patients who have recovered from Covid-19 who voluntarily donate.

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#### 1. Introduction

After the 11 March 2020 pandemic declaration, Coronavirus Disease 2019 (COVID-19) patients continued to increase [1]. More than 30 million people worldwide have suffered from COVID-19 by the end of september 2020 [2–4]. To date, there are no options for SARS – CoV-2 exposure prophylaxis [5].

The World Health Organization (WHO) and other clinical institutions have not established a definite treatment for this disease, because specific treatments are still under study [6,7]. Antiviruses, such as favipiravir, oseltamivir, are used, but patient responses to receiving these drugs are mixed. Even though the death rate from COVID-19 is around 3–4%, because the number of cases is very high, this is a big problem [2,8]. Convalescent plasma therapy (CP), has long been used to prevent and treat many infectious diseases before COVID-19 [9]. In the last two decades, this CP therapy has been used successfully in treating the SARS, MERS, and H1N1 epidemics with patient efficiency and safety [10]. Because the viral and clinical characteristics of COVID-19 have similarities between SARS and MERS [11], CP treatment could be a promising treatment option to save COVID-19 [6,12].

With only low quality medical evidence, but massive media support and a very significant public demand for the use of convalescent plasma for COVID-19, we are now faced with an ethical dilemma. The huge public demand for the use of CP is causing immense and inexorable pressure on physicians who treat patients and administrators have complied with this demand and are committed to only compassionately using convalescent plasma [12,13].

This document specifically analyzes the bioethical issues surrounding the potential use and study of convalescent plasma therapy in COVID-19.

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#### 2. Methods

Several search strategies were used to identify relevant studies. Search for data and information using electronic sites as data sources. In the search results, articles that are not relevant to the criteria for identification, screening, eligibility, and finally downloading of the relevant articles are carried out.

Document selection using the keywords "Convalescent Plasma Therapy in COVID-19" and "Ethics for Convalescent Plasma Use" in the journal Scopus, Springer, Database Scienceirect/Elsevier, NCBI, NEJM, Nature, Wiley, Oxford academy. Researchers found 1,246 documents based on full text access to free or paid documents and English-based documents. Then re-selection of journals based on titles and abstracts into 250 documents, then found 30 documents that meet the research criteria and 1 national health regulation in Indonesia, then these documents are analyzed.

The document inclusion criteria that we consider appropriate for conducting a systematic review are research journals, reported in English, relevant and reliable discussing the Ethics of Conventional Plasma Use. Studies are excluded if they are inaccessible, lack reliable references, and are expensive.

#### 3. Result and discussion

Convalescent plasma (CP) therapy is suggested to be used as an adjunctive treatment for COVID-19 [14]. This approach was used in Ebola, Middle East respiratory syndrome (MERS) and severe acute respiratory coronavirus (SARS-CoV) infection, and several studies showed promising results. Convalescent plasma therapy works to decrease the viral load, cytokine response, and mortality rate. In addition, CP therapy also works by transferring antibody of a certain infectious agent from survivors to patients who are infected with the same agent of disease. This form of passive immunity helps the patient to fight the disease from getting worse immediately [5]. CP has been used in a small population of clinically severe COVID-19 patients [15], and promising results are seen in this population [16].

First of all, it is important to understand the types of resources we are talking about, why they are needed at a vital level, and what it means to be a donor. Blood is a fluid network that is essential for life and can cure very serious diseases, such as in this case COVID-19, but it can also be the cause. It is important to imitate blood collection and management, not forgetting that the goal is not to be lucrative, but to curative [17].

COVID-19 recovery plasma can be experimentally available through local production, provided that ethical and safety standards are met for preparation and use. Blood management systems that provide COVID-19 recovery plasma must ensure that blood companies have adequate capabilities to collect, process and store this particular product in a manner that is quality assured according to the World Health Organization and other internationally recognized standards for plasma transfusion [18].

The limited clinical data available suggests that healing plasma (CP) may have therapeutic benefits in COVID-19 [19]. There is no known effective therapy and considering local production potential, CP of COVID-19 is becoming a global priority for investigative use. This has a devastating effect on the blood supply and blood components in many countries through the reduction of blood donations and disruption of routine practices in blood companies. Blood services around the world must move quickly in response to a pandemic to maintain adequate blood for the critical needs of patients, ideally through developing, implementing and activating emergency response plans in collaboration with hospitals [18]. High-income countries with established national infrastructures and effective regulatory oversight can produce quality and safe plasma for transfusion that complies with international stan-

dards and have initiated controlled clinical studies of COVID-19 CP [20].

Unfortunately, in low and middle income countries (LMICs) safe blood collection and transfusion is a challenge due to the absence of a nationally organized and regulated blood collection system and the limitations of essential resources and labor. Nonetheless, the provision of CP for COVID-19 at LMICs must meet the same principles of product safety and ethics regarding collection and use as at HIC, and guidelines are required [5].

There are interim guidelines provided by WHO on "Maintaining a safe and adequate blood supply during the Coronavirus (COVID-19) pandemic on March 20, 2020. Recently, on July 10, 2020, WHO published updated interim guidelines entitled "Guidance on Keeping a Safe and enough blood supply during the 2019 coronavirus disease (COVID-19) pandemic and collection of COVID-19 convalescent plasma". These updated interim guidelines by WHO provide greater detail on the management of blood supply and expanded recommendations on the collection of plasma recovered from COVID-19 compared to previous versions [18], these guidance can be seen in (Table 1).

The use of convalescent plasma must fulfill the ethical principles of autonomy, nonmaleficence, beneficence, justice and respect for people.

#### 3.1. Donor-related issues

#### 3.1.1. Autonomy

3.1.1.1. Voluntariness. All blood and plasma donors must be voluntary and unpaid [21]. This highly voluntary approach to blood donation is consistent with emphasizing the importance of altruistic donation of donors and the principle of human dignity insofar as it does not use the human body or its parts as a source of financial gain [22]. Identifying donors in health facilities, willing to volunteer to donate plasma once they have fully recovered, should be done in a way that does not apply undue pressure.

3.1.1.2. Obtaining informed consent. Potential donors should be well informed about the reasons for donating their blood or plasma, the potential benefits and risks associated with this procedure to them so that they can make an informed decision. If possible, potential donors should also be notified that they can be contacted again for further donations informed that potential donors may not be suitable after certain tests or screening may be needed to confirm the usefulness of donor plasma [23].

3.1.1.3. Avoiding coercion and exploitation. Respecting donor autonomy also means that potential donors should not be coerced or exploited. In the context of donating convalescent plasma, coercion refers to the act of threatening people who have recovered from COVID-19 regardless of their health status. Whereas exploitation refers to any practice that leads to an unfair distribution of burdens and benefits from donations. An example of exploitation is receiving recurring donations from a single person who has recovered from COVID-19 regardless of their health status [23].

#### 3.1.2. Fair selections of donor

Donation of convalescent plasma from patients who have recovered from COVID-19 can only be accepted if the donation is deemed safe for donors and mechanisms to guard against exploitation of potential donors are strictly assessed by competent health workers [23].

3.1.2.1. Children. Because children are at high risk for vasovagal reactions and adolescents have a higher need for iron, children who have recovered from COVID-19 should in principle be excluded from donations (in accordance with WHO guidelines for donor

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#### Table 1

Guidance on healthy and adequate blood supply during 2019 coronavirus disease (COVID-19) and COVID-19 plasma convalescent collection [12].
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Goals	Ethical procedure
Mitigating the potential risk of transmission through the transfusion of blood and blood components	<ul> <li>Potential blood donors should be told that they need to postpone on the basis of risk factors for COVID-19 or feel dissatisfied</li> <li>In areas where the SRAS-CoV-2 population is common, blood donors should be advised to alert the blood center if respiratory diseases grow within 14 days of donation</li> <li>People with potential direct exposure to SARS-CoV2 should not give blood for a period of time when they have been near in contact with infected patients and move from areas with population transmission</li> <li>People who tested SARS-CoV-2 positively but never had symptoms should delay 14 days after the last positive test</li> <li>Persons that have recovered from COVID-19 should be deferred from normal blood donation for 14 days after total symptom resolution and cessation of disease therapy</li> <li>Donor postponement can take the form of a self-delay or postponement by a blood collection facility</li> <li>Due to the lack of a future illness identified to donors, a quarantine of delayed release components is possible during transition to the population</li> <li>A mechanism should be in place for donors to disclose a COVID-19 compatible post-donation disease or interaction with a reported post-donation case</li> <li>Blood supply checks are too early if there are no cases of transfusion or if there are SARS-CoV-2 blood infections obtained from asymptomatic patients, including people with earlier symptoms</li> <li>Pathogen reduction technologies (PRTs) have demonstrated their effectiveness in both SARS-CoV and MERS-CoV plasma and thrombosis</li> <li>Current plasma derivatives development processes can disable and eradicate enveloped viruses such as SARS-CoV-2. There is therefore no alleged risk of transmission through this product</li> <li>The hemovigilance system relies on the capacity of an individual to use these components. Hemovigilance is invaluable because it helps to consider the toxicity of blood and its components and the potency of the whole</li> </ul>
Mitigating the risk of staff and donor exposure to SARS-CoV-2 Mitigating the impact of reduced availability of blood donors	blood [17] Minimize interaction between donors and workers, decontaminate the area on a regular basis. Measurement of temperature at arrival, facial masks, hand sanitization and physical isolation of incoming donors [18] Workers should be trained and aware about COVID-19 if they feel diseased or are exposed to it [18] Because mobile donation activities have been reduced as a result of the closure of workplaces, schools and community organizations, strategies that could be used include rapid movements to places to draw blood, donor transportation, increased effort to schedule donation rates or adjustment of operating times Governments should recognise blood donation as an important service and provide frameworks to ensure that donors are not penalised for donating Systems need to be in place to allow contaminated donors to re-enter after recovery Importing blood and components from a non-affected nation or country region (where approved by regulatory bodies) is a possible solution if insufficient local stocks
Managing the demand for blood and blood products	Blood services must regularly monitor their blood supply so that the size of collection operations can be expected unpredictable. Blood transfusions are also required in emergencies including trauma, postpartum hemorrhage, serious infant anemia, blood dyscrasia, or urgent blood surgeries. Increased stock may also be required to support COVID-19 patients with serious sepsis or to support oxygenation of an extracorporeal membrane Blood services should collaborate and clearly coordinate with the health professionals responsible for transfusion operations in order to ensure that blood and components are only used where they are clinically suitable [19]
Ensure undisrupted supplies of critical material and equipment	The global supply network of vital materials and equipment used in the collection of blood, components and laboratory tests (including immunohematologic reagents and infectious disease tests) which be reduced by transportation and trade constraints, quarantine requirements, border control and development disturbances. Blood services must take action to ensure supply stability
Communication	Governments and blood services can clearly communicate to ensure national emergency response teams, donors and beneficiaries and the public are adequately advised and recognize the action planned, including acknowledgement of the activities of blood collection as an indispensable service [20]
Collection of COVID-19 convalescent plasma	Qualification based on normal blood or plasma donation requirements Diagnostic confirmation of previous SARS-CoV-2 infection Total symptom resolution and discontinuation of COVID-19 therapy at least 14 days before donation The minimum neutralizing antibody titer required for plasma to be used as convalescent plasma Measurement of the titration of the neutralizing antibody in the plasma convalescent device

selection due to a lower benefit-risk ratio [24]. The minimum age of donation should be in accordance with international guidance on blood donation and national legislation on consent. The minimum age for donors to include children under 16 years of age may be ethically permissible if: (1) a minor meet the standard physical and hematological criteria required for blood donation and (2) minors and their parents are given the appropriate consent Minors must be able to fully understand, be properly informed and agree to blood and/or plasma donations, and their parents or guardians must not override their decision regarding donations [23].

3.1.2.2. Other persons with diminished autonomy. Potential donors with disabilities, such as individuals with moderate or recurring mental health problems, must consider the following: (1) an assessment of their ability to give consent for the donation process,

including blood tests for heirs [24], and (2) there are sufficiently strong mechanisms to ensure that potential donors, with reduced autonomy, are not forced to donate or submit to exploitative practices. If the above criteria are met, individuals with low autonomy and family members or legal representatives must give the appropriate consent [25].

#### 3.1.3. Confidentiality

In Indonesian, if we look at it from a legal point of view, then medical secrets can be revealed in a number of circumstances. According to PMK Number 36 of 2012 concerning Medical Secrets, there are several conditions that allow doctors or health workers to disclose medical secrets, namely for the benefit of the patient's health, in the context of law enforcement, at the request of the patient himself and for the public interest, one of which is when there is a threat of an outbreak [26]. However, in conditions of blood donation, the identities of people who have recovered from COVID-19 must be carefully protected from wider disclosure to protect the freedom of individuals to refrain from donations. Likewise, transfusions must be anonymous, which means that the identities of donors and recipients must be kept confidential. To do this, sites should consider storing donated blood and plasma rather than conducting a one-to-one transfusion service by donating blood or plasma directly to a specific person such as a family member or friend. To further protect donor confidentiality, care centers should store blood and plasma units using only ID numbers instead of identifiable information and ensure adequate disposal of unused units. Access to areas where confidential records of donors, patients or staff are kept should be limited to authorized staff [27].

#### 3.1.4. Reimburstment for donation

Giving blood is considered a voluntary act of great human value and social significance and, therefore, the service should be provided by the majority of people.

Donations are considered an act of solidarity, compassion and altruism, and there is international agreement that individuals may not accept payments to donate blood or plasma. However, reimbursing donors for any costs directly related to donations, such as travel expenses, is reasonable [28].

#### 3.2. Recipient-related Issues

#### 3.2.1. Autonomy

3.2.1.1. Voluntariness. Giving convalescent plasma to COVID-19 patients is an additional therapy and should not interfere with the standard of supportive therapy given during treatment. Therefore, sufferers of COVID-19 must be given the option to refuse treatment with healing products at any time. For minors, the consent of the parent or guardian and the consent of the minors who are older must be obtained. However, when investigative therapy promises therapeutic benefits and there are no alternative therapies, the parent or guardian can override the child's objection to participating [29]. When a child is nearly able to refuse independent informed consent, the researcher must seek specific approval from the scientific and ethical review committee before administering investigative therapy. Situations of disagreement between parents or guardians and doctors regarding transfusions should be anticipated and mechanisms put in place to ensure that the welfare of the child is protected [23].

*3.2.1.2. Informed consent.* Informed consent is mandatory for the patient before the patient is given action, in this case the convalescent plasma administration. Patients should receive explanations, including if there is any up-to-date information on convalescent plasma, as this may affect the subject's willingness to receive whole blood or healing plasma [30].

- patients are admitted to the isolation ward, and a limited number of health workers are allowed in the treatment area;
- HCWs can spend only a limited amount of time in the treatment area and in personal protective equipment, which limits the opportunities for normal communication;
- the patient's family or closest relatives are not allowed into the treatment area.

Service providers must ensure that patients are conscious and healthy, in the sense that they are able to understand the riskbenefit ratio of this therapy and obtain prior ethical approval to seek consent from their closest relatives. Information and possible consent should be considered of the seriously ill patient, as soon as he or she is well enough to discuss treatment. A situation in which a person with COVID-19 is unable to give consent to participate in research and that person's representative is not present should be anticipated, and prior ethical approval should be sought, especially when whole blood or healing plasma is planned to be administered [30].

3.2.1.3. Maintaining a positive risk-benefit ratio for recipients. Ethically, the risk of being exposed to people with COVID-19 should be minimized as much as possible. Given the uncertain effectiveness of using recovery plasma in treating patients with COVID-19 and given the prevalence of transfusion-transmissible infections in communities where the COVID-19 pandemic is occurring, no shortcuts should be taken in screening donor blood for other infections and residual marks. Sars-CoV-2 infectivity (e.g., RT-PCR not infectivity). Adhering to safety standards avoids adding risk to unknown benefit interventions and thus maintains a positive benefit - a balance of risks. Therefore, implementation of strict protocols to ensure compatibility between donor and recipient and safety regarding transmissible infections is mandatory. Developing a warning system to monitor, investigate, manage and record any adverse transfusion events is also highly recommended [23].

#### 3.2.2. Fair selection of people with COVID-19

The priority of patients receiving healing plasma therapy should be consulted, as the need for recovery plasma exceeds the available supply. On the other hand, consideration of equality suggests that those who are sicker or those who are more vulnerable, such as pregnant women, children with mental disabilities and those with low autonomy, should not be excluded from this intervention.

In determining priority recipients, the community and stakeholders must be involved. Priority setting must prioritize the principle of justice, where all beings are equal [31]. However, in this process it must be seen from the patient's clinical condition, and the main priority is the COVID-19 patients who are most likely to benefit from the intervention, or those who are most likely to benefit from this treatment, in accordance with the principle of triage in disaster conditions [32]. The process used to develop priority setting criteria should be fully transparent and involve the governments of affected countries or their representatives, panels of experts in infectious diseases, treatment and transfusion ethics and communities in a participatory and inclusive manner to avoid creating perceptions of unfair allocations, frustration or community mistrust towards the health system and health actors, national and/or international.

# 3.3. Issues related to health workers and research and ancillary staff

Staff working at donation and care sites need to be provided with adequate safety standards, including appropriate personal protective equipment, as any action related to blood, of course, carries several types of risks. Health care workers also need to be specially trained in standard international procedures to prevent transmission of Sars-CoV-2 and to treat patients with COVID-19 with whole blood and recovered plasma.

HCWs, researchers and ancilliary personnel also need to be adequately informed about the risks of their possible procedures and agree to implement these interventions, whether they are part of the study or part of the monitored emergency use of unregistered and experimental interventions. However, the risks associated with this procedure need to be minimized to the greatest extent possible.

#### 4. Conclusion

The use and preparation of convalescent plasma for COVID-19 must be supervised by the Ministry of Health and must be coordinated with the National Blood Service and must comply with legal principles and human research ethics that apply to COVID-19. The use of convalescent plasma must meet the ethical principles of autonomy; such as voluntary, informed consent, and confidentiality. Consideration of the risk-benefit ratio for potential donor recipients also needs to be considered in order to meet the beneficence and non-maleficence principles. The principle of justice also needs to be applied both to donors, donor recipients and health workers, such as determining the priority of donor recipients.

#### **Disclosure of interest**

The authors declare that they have no competing interest.

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