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REVIEW ARTICLE

Blood Products Management and Safety During COVID-19: a Public Health Challenge

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SUMMARY

Background: **Blood products are essential therapeutics that are pivotal in saving and improving millions of lives worldwide. A sufficient and safe blood supply is necessary for efficient healthcare services to provide effective patient care in various acute and chronic conditions. Blood donations are the main source of blood products in almost all nations of the world. The coronavirus 2019 (COVID-19) pandemic negatively impacted blood product management worldwide and has added stress to the already stressed healthcare system. Most of the earlier months of 2020 witnessed a decrease in blood donations as donors were highly apprehensive about their safety, and the isolation practices implemented to contain the virus spread discouraged donor participation. Because of the spread of the virus, blood collection centers and regulatory bodies have undertaken numerous strategic steps to prevent any viral transmission at the blood collection centers while aiming to increase donor participation. Maintaining extra sterilization in all the processes involved in blood product management and the modified criteria for participating donors changed the entire paradigm of blood product management. This review discusses various challenges and modifications adopted by different roles of participants involved in blood product availability to maintain an adequate and safe blood supply during the emerging COVID-19 pandemic.**

Methods: **An extensive online search was done to obtain the necessary information regarding various scenarios concerning blood product crises, advisories, and availability.**

Results: **A change in how the blood supply chain works that has overcome and prevented a crisis in blood demand and supply during the COVID-19 pandemic world over was observed.**

Conclusions: **Blood products are critical for medical and surgical procedures. The COVID-19 pandemic has led to a crisis in the availability of blood products with decreased participation of donors. It has become the prime responsibility of the blood collection centers and government agencies to change strategies, so that blood stocks do not become exhausted and create another crisis.**

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KEY WORDS

blood products, availability, safety, COVID-19

LIST OF ABBREVIATIONS

WHO - World Health Organization
RBC - red blood cell
COVID-19 - coronavirus disease - 2019
SARS-CoV-2 - severe acute respiratory syndrome coronavirus 2
PPE-personal protective equipment

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INTRODUCTION

Blood products are essential therapeutic constituents of numerous treatment regimens that are derived from human blood. These products include whole blood, blood components, and plasma derivatives [1]. Whole blood has been previously used to improve oxygen-carrying capacity, volume expansion, and replacement of clotting factors and treat massive blood loss; however, component therapy, which is equally effective and is a more efficient use of donated blood, is preferred nowadays [2]. Ensuring a safe and effective uninterrupted blood supply remains crucial in any therapeutic setting to prevent loss of life due to the unavailability of blood products. The use of blood products causes a decrease in mortality but has associated contraindications, such as infectious and noninfectious complications [3]. As blood donations are still the main source of blood for therapeutic use, it is crucial to maintain a safe and adequate supply of blood products. It requires cautious donor recruitment and selection, combined with careful infection screening, serological testing, and blood component production to obtain safe blood products [4]. The debate in the medical literature concerning the appropriate use of blood and blood products is ongoing. The World Health Organization (WHO) and various government agencies and professional bodies enact wide ranging measures to ensure safety during blood transfusion and use of blood products. Numerous regulations and safety measures are employed in the collection, storage, distribution, and usage of blood products to produce adequate and safe blood products [5].

An inadequate and unsafe blood supply is most likely to have a negative impact on the overall healthcare facilities and management of various acute and chronic diseases. Therefore, it becomes imperative to have an interrupted and safe supply of adequate blood products in a healthcare setting at all times. This process, however, has been disrupted by the outbreak of the coronavirus 2019 (COVID-19) pandemic that started in December 2019. While the need for blood products has remained high during the pandemic and is required even in many COVID-19 patients, a shortage of donors has been observed worldwide [6]. In addition, the high rate of transmittance of the COVID-19 virus (severe acute respiratory syndrome coronavirus 2 [SARS COV-2]) causing severe respiratory distress has led to strict isolation and distancing protocols associated with the prevention of the disease; however, these policies have led to a decrease in the number of donors globally. As a result, updated instructions for blood donors to maintain blood product supply with the best precautions and safety concerns for the donors and the recipients have been established.

Despite the efforts of healthcare organizations to maintain the required blood supply, a significant decrease in the availability of blood products has been reported [7]. This decrease has caused a worsening of treatment outcomes associated with various cancers, leukemias and hematological disorders, and in women with post-partum complications. Furthermore, healthcare professionals associated with blood product availability have been observing uncertain demand patterns with a mismatch between demand and supply during the pandemic [8]. With a limited shelf life of the blood products and various health concerns of the donors, an overall limited supply of blood products is now being observed, which can have detrimental effects, especially in low-income health care settings. This review aimed to discuss various challenges and modulations in blood product availability and safety during the COVID-19 pandemic from the perspective of various stakeholders in the blood supply chain.

The donor

With the advent of natural disasters and other crises globally, an increase in the need for blood products has arisen and is generally met with great public enthusiasm to prevent the loss of life [9]. However, pandemics usually lead to a reduction in blood donation. In Singapore, a 60% decline in blood donors during the SARS epidemic in 2003, and an overall 10% - 30% decrease in blood donations occurred worldwide during the influenza pandemic in 2009 [10]. The same pattern was observed with the COVID-19 pandemic that has engulfed the world starting in late December 2019. Initially, during the pandemic, the supply and demand of the blood and blood products were volatile factors that were dictated by donor availability. Although the need for the blood products has remained constant during the COVID-19 pandemic, downtrends in blood collection and blood usage were observed during early 2020 because of less outpatient services and cancellations of routine surgeries [11]. The main source of blood is donors, and a decreased supply resulted as nonremunerated blood donors refrained from donating owing to numerous consternations and regulations [12]. A Saudi Arabian study reported a 39.5% drop in donor attendance in the first five months of 2020 [13]. A study from the Eastern Mediterranean Region reported a 26% - 50% decrease in the blood supply with public fear being the chief contributor to this decrease in 14 of the 15 participating countries [7]. A Brazilian study indicated a 17% decrease in attendance of blood donors from March to June 2020 [14]. The drop in blood supply has been balanced by the reduced demand as most elective surgeries, and other outpatient services were canceled [13]. From a donor's perspective, the fear of visiting high-risk areas, such as hospitals and blood collection centers and the risk while traveling to these settings, has contributed to the reluctance to donate blood [15]. Wang et al. also reported a fear of acquiring SARS-COV-2 during blood donation as a major concern (The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China) [16]. Lockdowns implemented in most parts of the world were an additional barrier to willing donors. The concept of social distancing also played a role in preventing any prospective donors from

donating blood [12]. The donor guidelines and deferrals (Table 1) issued during the pandemic and the hemovigilance system initiated to mitigate the donor risks also hindered donor participation [17]. In numerous regions, a one-month deferral of donors with a history of overseas travel is required along with post-donation information given to blood collecting units [18]. The European Centre for Disease Prevention and Control suggested a 21-day precautionary deferral from blood donation after any possible exposure to SARS-CoV-2 [19]. Generally, eligible donors who have been in contact with a COVID-19 patient are also required to defer their donation for fourteen days. Persons with a positive SARS-CoV-2 test but no symptoms and persons who have recovered from SARS-CoV-2 infection are also required to defer their donations for fourteen days [20]. Although healthy volunteers are encouraged to keep donating and utmost care is being taken to ensure donor safety, the reluctance of a donor may be overcome by enabling the donors to perceive the increased need for blood and lower risk of infection as indicated by a Chinese study [21]. By the last quarter of 2020, the demand for convalescent plasma was exceptionally high; unfortunately, a sharp decrease in blood availability leading to dangerously low levels was noted because the pandemic caused a further decrease in participation during the holidays [22]. Since most people are getting vaccinated globally, donors are advised to wait seven full days from the date of vaccination before donating on the eighth day and are supposed to wait 28 days post-recovery if they had side effects from the vaccine, such as headache, temperature, aches, and/or chills. Donors are also advised to wear a fabric face-covering unless medically exempt and are encouraged to attend donation sites alone to help minimize social contact (coronavirus update). The donor should share the vaccine manufacturer's name and, if the name is not known, should wait for two weeks out of precaution before donating after vaccination. Although certain parts of the world have seen an overall recovery in blood donor participation during the second quarter of 2020, it has become imperative to make the donor feel safe even when eligibility criteria have become more stringent [21].

Blood collection centers

The blood collecting units also raise concerns for the donors, and these concerns need to be addressed with certain extra measures to maintain staff and recipient safety. The asymptomatic nature of the donor or pre-symptomatic infection in donors and false history of exposure are causes of concern for the collecting centers. Since many individuals are asymptomatic, this characteristic has become a huge challenge in the recruitment of blood donors [17]. The donors need to be informed about the importance of being non-infectious and recognize any feature that makes them ineligible for blood donation (Table 1). Suppose a situation exists in which a potential donor has undergone high COVID-19 risk activity, such as long-distance travel, and requires quarantining as per the country regulations. In that case, the collection center should ensure that the quarantine period has been observed before a donation can be made. If a donor receives a vaccine that has received Emergency Use Authorization or has been approved for the public and is feeling well, no deferral is required. Generally no deferral is recommended for the non-live vaccines or toxoids blood donations, while a deferral period of 14-28 days is recommended for live attenuated vaccine. Various countries however follow different deferral guidelines [23]. The vaccines from the approved manufacturers include AstraZeneca, Moderna, Johnson & Johnson, Novavax, and Pfizer (webmd.com). In the case of live-attenuated virus vaccines, a 4-week waiting period ensures patient safety. The blood from a recently vaccinated donor may contain an infective agent, which, although harmless to the donor, may pose a risk to immunosuppressed or immunocompromised patients. Donors, if infectious, are more likely to cause infection via respiratory routes rather than parenteral routes. Since these centers are not patient care settings, procedures applicable to medical centers are not applicable; rather, community measures to minimize transmission such as screening for COVID-19 related symptoms, practicing social distancing, maintaining stringent hand hygiene, and using personal protective equipment (PPE) are used and highly recommended in blood collection centers [24].

The blood donation process itself does not predispose the donor to any increased risk. However, increased measures to reduce any possible transmission risk to the donor must also be implemented. Blood donation was already a highly sanitized procedure, but the sanitization standards have increased during the coronavirus pandemic. The donors will not be allowed to enter the donation area without a temperature check that is measured just before donating [20]. Cleanliness of the donor area is highly maintained, the equipment used is mostly single-use or highly sanitized after each use, all high touch areas are wiped often and after every collection, and continuous sanitization of the area is performed [17]. The phlebotomist must wear appropriate PPE and use only disposable tourniquets. An appointment is recommended for a donation time to prevent any crowding at the donation center. The donors are placed at an increased distance during the donation process (about 6 feet or more) [23].

It has become highly critical to have post-donation information from the donor to determine whether blood and platelet transfusions from pre-symptomatic donors can carry a risk of transmission. However, no COVID transmission from the use of blood products has been reported to date [19]. A close follow-up of the donor and maintenance of registers until the expiration date of the blood products is maintained to prevent the use of the blood with suspected SARS-CoV-2 infection. Blood donors are also encouraged to contact the donation centers post-donation if they develop any symptoms within fourteen days after donating in certain settings [17].

Table 1. Ineligibility and deferral criteria for blood donation in view of COVID-19.

Ineligible	**Donor based**	**Individuals testing positive for COVID-19**
		Individuals who developed a fever and cough after close contact with someone who has tested positive
		Individuals who had symptoms or suspected COVID-19 infection in the last four weeks and have not subsequently had a negative COVID-19 test result
		Individuals who have lived with or been in close contact with individuals diagnosed with or suspected of having COVID-19 infection in the last two weeks
		Healthcare workers who have been caring for patients diagnosed with or suspected of having COVID-19 in the last two weeks and may not have used recommended personal protective equipment continuously
		Individuals having a pending COVID-19 test
	Vaccine based	**Individuals who received a COVID-19 vaccine are not eligible to donate convalescent plasma**
		Regardless of the type of vaccine an individual receives, the donor must have no symptoms of COVID-19 and should be feeling well at the time of donation
Deferral	**Donor based**	**Recovered COVID-19 patients should defer from blood donation for 14 days after all symptoms have resolved and therapies are stopped**
		Asymptomatic persons who had positive test for SARS-CoV-2 should be deferred for 14 days after the last positive test
	Vaccine based	**Eligible blood donors must wait two weeks before giving blood if they are vaccinated with a replication defective virus COVID-19 vaccine manufactured by AstraZeneca or Janssen/J&J**
		Eligible blood donors who do not know what type of COVID-19 vaccine they received must wait four weeks before giving blood
		Individuals experiencing any symptoms after receiving the COVID-19 vaccine should postpone their donation until they feel better

The criteria for ineligibility and deferrals as instructed by various international and national bodies.

This process may contribute to lessening an apprehensive situation for the donor and a burden for the collecting center.

The staff of the blood donation centers also need to be constantly checked to identify any potential infections. The staff is discouraged from reporting to work if they have any symptoms of COVID-19 or have been in contact with any infected person. The staff members need to use personal protection gear to their best abilities and wear face masks at all times. Staff may be reduced to prevent community transmission and reduce the impact of the outbreak [24]. In a move to encourage voluntary blood donation with no trips to blood donation banks or hospitals, the Saudi Arabian government has launched an initiative called “Donate at your Home” that aims to ensure adequate blood supply and health for all citizens (Media Center/New).

Blood processing

The processing of the blood from noninfectious donors is not too strenuous but requires handling by competent personnel who were previously trained in technical and safety procedures and must maintain proper safety procedures needed during the pandemic. Donor information is stored electronically. The blood is centrifuged to separate it into transfusable components: (1) red blood cells (RBC), (2) platelets, and (3) plasma and concurrently tested for blood type and transfusion-transmitted diseases. The tests are carried out by computer-controlled automated machines which can test many samples quickly and easily. Numerous blood donation organizations worldwide have started to test all blood, platelet, and plasma donations for COVID-19 antibodies, providing donors insight into whether they have been exposed to this coronavirus without testing donors to diagnose COVID-19 [20,17]. A positive antibody test result can lead to the blood being processed into a convalescent plasma product to help treat the COVID-19 patients. A positive result may also invite a donor to participate in research to study individuals who have positive results. However, certain bodies have advised against collecting convalescent plasma donations since no overall benefit for people in hospital with coronavirus during trials has been demonstrated, and the decision was made not to proceed with a third trial addressing plasma use early in the disease. This process, however, has significance for finding an approach to treat viral diseases in general [25].

While processing blood from COVID-19 patients, a high level of precautions is required, and the containment measures are determined mainly by the individual countries and facilities. In certain areas seriously affected by the virus, the collected blood may be temporarily isolated for 14 days after collection, and the release for clinical use may also be delayed [17]. Therefore, the specimen collection should be regarded as potentially infectious, and the personnel transporting specimens should be trained in safe handling practices and spill decontamination procedures. However, the blood samples have rarely been found to be positive (three among thousands of samples) with a very low viral load (COVID-19 screening guidelines). Therefore, the processing should be performed in well-equipped laboratories by highly trained and competent personnel. The personnel must follow national guidelines concerning laboratory biosafety under all circumstances. WHO recommends that all diagnostic laboratory work on clinical specimens from COVID-19 suspected or confirmed individuals of being infected with the novel coronavirus be conducted according to practices and procedures described for basic laboratory protocols (Biosafety Level 2 as detailed in the WHO Laboratory biosafety manual, 3rd edition [26]). Several organizations handle blood from COVID-19 patients in Biosafety Level-2 laboratories that contain Class II biological safety cabinets.

All cabinets are equipped daily with internal waste collection vesicles (containing 0.5% bleach) to discard any contaminated biological material [27]. The use of auto analyzers without opening the cap of sample containers is preferred for testing whenever possible. After running suspected/confirmed COVID-19 samples in the analyzers, two tubes of 1% sodium hypochlorite solution are run to decontaminate the machine. Finally, after the process is completed, the sample tubes and PPE are autoclaved and incinerated. The work surfaces are decontaminated continuously with an appropriate disinfectant, such as hypochlorite, hydrogen peroxide, alcohol, phenolic compounds, and quaternary ammonium compounds [28].

If required, the Centers for Disease Control and Prevention (CDC) recommends packing and shipping both the suspected and confirmed SARS-CoV-2 patient specimens as UN 3373 Biological Substance, Category B, according to the current editions of the transportation regulations [29].

Storage of blood components

To prevent any potential or real shortage, a modification in the storage of the blood components to extend their shelf life should be a prime goal during the pandemic. With blood supplies being pushed to the brink as reported by various organizations, it is highly required to minimize any waste and develop newer methods to increase blood and blood products [30,31]. The shelf life of RBCs varies in various nations ranging between 35 and 49 days for most [32]. RBCs are mostly stored under refrigeration in a solution containing a preservative, such as saline-adenine-glucose-mannitol, which enables RBC storage for up to 42 days following collection. Methods for extended storage of RBCs up to 50% have been developed by numerous scientific and commercial establishments but have not been approved worldwide [33]. While some nations are proposing an extension of the red cell shelf life as an emergency response to depleted blood availability, anaerobic storage of RBCs and the use of modified additive solutions are encouraging methods that may extend the shelf life of RBCs [34]. These methods may be considered to prevent shortages during low availability by individual providers in accordance with their local regulations [35]. RBC concentrates are obtained as a byproduct with a surge in blood collection from recovered COVID-19 patients for convalescent plasma. They could be released for transfusion if the donor was asymptomatic for at least 14 days after full recovery from symptoms. This can be helpful to overcome a deficit. Platelets are stored at room temperature (20 - 24ºC) with gentle agitation and have a shelf life of 5 to 7 days. This shelf life can be extended to 7 - 14 days by cold storage of platelets at 2 to 6°C without the need for agitation [36]. Certain institutions have made a transition from room temperature to cold storage for platelets after they reached their 5-day shelf life as a response to COVID-19 related blood shortages and platelet outdating, and no transfusion-related complications have been observed [37]. Storage of the frozen plasma components is less likely as they already have a long shelf life of several years; hence, the availability can be maintained for longer durations. Liquid plasma typically has a maximum shelf life of 26 days and is stored refrigerated at 1 to 6ºC. With the increase in the use of convalescent plasma as a potential treatment for COVID-19, liquid plasma may be stored between 1 and 6°C for up to 40 days or frozen at -18°C or colder within 24 hours blood collection and stored for up to 12 months [8]. Convalescent plasma, however, should be labelled as a special product for the treatment of COVID-19.

Distribution

The most critical feature of the blood supply chain is to have a failsafe blood product distribution system. A real-world blood product distribution network should aim to have a low average distribution cost with minimal shortage. The blood products should be systematically distributed to hospital blood banks that have a higher probability of product requirement [38]. The traditional model of blood collection in most high high-income countries occurs via blood centers that recruit their own voluntary, non-remunerated blood donors thus allowing an equitable distribution based on need. The COVID-19 model distributes the units to institutions (such as hospitals), rather than to individual patients, for transfusion to patients under emergency conditions. However, it raises the question of whether the blood centers can allocate units equitably [39]. During the ongoing pandemic, monitoring supply and demand

by hospital-based or separate blood transfusion services is essential to modulate distribution to maintain sufficient blood stocks. A highly efficient information technology infrastructure can be pivotal in the easy retrieval of program data from the individual hospitals and help in need-based distribution [40]. The establishment of a blood management information system as seen in China can be highly beneficial to balance excesses and deficits in the blood supply across the country's various regions (17).

For the distribution of convalescent plasma for COVID-19 patients, some regulatory bodies have released guidelines, stating that convalescent plasma should be distributed by blood establishments per request of a hospital only when the specific patient has laboratory-confirmed COVID-19 and has been hospitalized and signed informed consent to undergo transfusion with COVID-19 convalescent plasma is obtained from the patient or legal representative [41].

An efficient transport system is primary to the distribution of blood products worldwide/restrictions in transport and trade coupled with quarantine requirements, border control measures, and hampered production can cause a lower global supply chain of critical materials and equipment used in blood product supply and consequently impact efficient distribution. In such a scenario, blood service can ensure continuity of supplies by making necessary arrangements with local administrative bodies [42].

Communication of stake holders

Clear, consistent communication is the key to overcoming all anxieties of and misinformation given to ineligible donors and the general public and can lead to maintaining an adequate blood product stock. With knowledge of COVID-19 increasing over time, misconceptions and fear among donors may increase. In nations, such as Albania, problems in communication with potential donors were observed during the COVID-19 pandemic, and these problems need to be addressed to increase donor participation. Social and mass media can act as excellent routes for communicating with the public and potential donors to increase confidence in the process of blood donation [43]. Government agencies must maintain an efficient communication strategy with the general public about blood stocks, requirements, and planned actions. The public and the staff should be made aware of the threat of infection and any safety measures taken to prevent any infections to maintain the reliability of the blood supply [44]. Encouraging communication is necessary to motivate voluntary blood donors to donate. Communication that aims to inform the public about the importance, requirements, and real-time situation in blood product availability can play the role of a game-changer in these times of an evolving pandemic.

Minimizing blood product shortage

An important approach during the pandemic is to minimize blood product shortages by decreasing blood product usage. Pharmacological agents should be used wherever possible instead of transfusing blood. For the treatment of mild hemophilia, desmopressin is recommended instead of blood transfusion, and aprotinin, a vasoconstrictor agent, is recommended to reduce blood loss at the operative site. During the pandemic, fluid replacement volume expanders, such as crystalloids or colloids, are good alternatives to blood transfusion. Besides, the use of hematinic is a good alternative for anemic patients [45]. Another approach may be to use one unit of blood instead of two if it can suffice, and use minimally invasive surgical procedures to reduce blood product requirement. However, this approach has many limitations and needs caution for implementation [46].

CONCLUSION

Blood products are an indispensable part of blood management systems that contribute to saving lives, improving life expectancy, and improving the quality of life of patients suffering from life-threatening conditions. These products are also critical for those undergoing complex medical and surgical procedures. Voluntary donations are the main source of blood products in most nations, and donating one unit of blood may save the lives of up to three people, thus providing a vital service to the community. However, situations, the ongoing COVID-19 pandemic has led to a crisis in the availability of blood products with decreased participation of donors. The necessary processing, testing, and distribution procedures have also changed with the pandemic owing to its infectious nature and led to an overall change in the blood product supply network. It has become the prime responsibility of the blood collection centers and government agencies to change strategies and increase means and modes of communications so that blood stocks do not become exhausted and create another crisis.

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