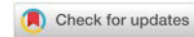


# KEY FACTORS FOR SAFE AND RATIONAL SECURITY OF BLOOD AND BLOOD COMPONENTS

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**Abstract:** The use of human blood for therapeutic purposes requires the continuous construction of safety and quality systems, in order to minimize potential risks during the process of collection, processing, circulation and final use. Safety, security, rationality, and reliability are important prerequisites for the continuous provision of blood products, regardless of their purpose. Health institutions for blood and blood products should have an organized quality system that will be compatible with strategic goals, while at the same time emphasizing the self-sufficiency of a particular community. In this context, it is necessary to establish a stable and applicable mechanism for issuing permits and accreditation by certified institutions, from this field, which would ensure their operation in accordance with current regulations. Modern blood transfusion practice must provide guarantees to voluntary blood donors regarding the security and confidentiality of all data related to the health of each individual. The key factors, on which safe and rational provision of blood and blood products are based, are visible through continuous activities associated with the promotion of voluntary and unpaid blood donation, thus contributing, in a specific way, to raising and maintaining high standards. Medical and other personnel involved in the process of collection, examination, processing, storage and circulation of human blood and blood components should be qualified and should undergo continuous education. The future development of transfusiology will be based on teamwork and interdisciplinary cooperation, as well as continuous monitoring and application of regulations from this field. The implementation of the Type and Screen method, i.e., blood group typing and antibody screening, should become a standard in the rationalization of the need for blood, which ensures a greater number of available blood units, increases self-sufficiency and directly contributes to the preservation of the health of donors and recipients of blood and blood components.

**Keywords:** transfusion, blood, blood groups, compatibility  
Field: Medical Sciences and Health

## 1. INTRODUCTION

The first successful transfusion of blood from man to man was carried out in 1818 by the English doctor James Blundell. A turning point in transfusionology was the discovery of the ABO blood group system by the Austrian physician Karl Landsteiner. (Nikolić et al., 2022)

People belonging to the AB+ blood group are universal recipients, i.e., their relaxed position is based on the fact that they can receive all blood groups, while those with O- have the least choice as recipients considering that in case of a transfusion they are limited only to O- donors.

The aim of this paper is to point out the practical importance of ensuring safe, secure and comfortable blood donation, as well as the harmonization of national statutory regulations with international recommendations, guidelines and directives.

Stefanović et al. (2021) indicate that there is a need to rationalize testing and consumption of blood during transfusions. In this sense, the introduction of the Type and Screen method (T&S), which includes the determination of the blood group in the ABO and Rh system and screening for clinically significant antibodies, is generally sufficient for patients being admitted for hospital treatment. The Type and Screen list became the standard for blood product requirements at the Đorđe Joanović General Hospital in Zrenjanin (Serbia). During the period from October 1, 2010 to July 31, 2011, and following the parameters of the crossmatch/transfusion ratio (C/T), the probability of transfusion (%T) and the transfusion index (TI) for surgical departments that need blood, it was established that the number of units of blood that are routinely reserved for certain operations was rationalized: the use of reserved blood increased, i.e., the number of patients for whom blood was taken off a reservation decreased. (Tešić et al., 2013)




























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## 2. COMPATIBILITY OF BLOOD GROUPS

On the surface of erythrocytes there are hereditary chemical structures - antigens, which can cause the immune system to react by producing antibodies against them. Emphasizing the importance of matching blood groups, i.e., that the recipient receives compatible blood during the transfusion, the American Society of Hematology (<https://www.hematology.org/>) states that people have 35 major groups, as well as other smaller groups, but two are considered, ABO and RhD groups. Blood type in humans is determined by the presence of antigens within these groups: type A, type B, type AB (the presence of both A and B antigens) and type O (having neither A nor B antigens), followed by the presence or absence of the Rh antigen. The presence of antigens within these groups determines a person's blood group. Blood types are called type A, type B, type AB (with both A and B antigens), and type O (with neither A nor B antigens), followed by the presence or absence of the Rh antigen. The most important Rh antigen is RhD: most people have the RhD present on the surface of their red blood cells and are RhD positive, while those who do not have the RhD are RhD negative. Individuals belonging to the O group are called universal red blood cell donors, while universal plasma donors are individuals belonging to the AB blood group. (<https://www.redcrossblood.org>)

Table 1. Blood type compatibility chart

		DONOR							
		O-	O+	B-	B+	A-	A+	AB-	AB+
RECIPIENT	AB+								
	AB-								
	A+								
	A-								
	B+								
	B-								
	O+								
	O-								

Source: Authors

Universal donors of plasma and platelets are AB negative donors, because these blood components can be given to any patient through transfusion. When a donor is AB positive, he is considered a universal plasma donor, given that this blood component can be given to all patients, regardless of their blood group. And positive erythrocytes and platelets can receive A positive and AB positive, while A negative blood group can be transfused only to patients with A positive and AB positive and AB negative blood groups. B negative erythrocytes can be given to patients who have B positive, B negative, AB positive and AB negative blood types. If the donor has B positive erythrocytes, blood can be given to patients who also have B positive as well as AB positive blood group. The zero positive blood group (0+) is the most useful in practical application, because it can be given to all patients with a positive Rh group, while the zero negative blood group (0-) is compatible with all other blood groups. (<https://www.rch.org.au/>)

### 2.1. Complications and risks of donating blood

Complications associated with donating blood are rare, with the most common being fainting. However, this complication can be minimized if the donor is suggested not to stand up immediately after donating blood, but also to be given enough fluids to drink or eat. In addition, there are sometimes bruises on the flesh of the needle. Sometimes, bruising occurs at the needle injection site.

Erythrocyte hemolysis may occur if ABO-incompatible erythrocytes are transfused. Reactions resulting from blood group incompatibility can lead to shock, renal failure, and death. (<https://www.rch.org.au/>)

If the recipient develops antibodies against minor antigens on the transfused red blood cells, delayed hemolytic reactions may occur. These reactions are, for the most part, mild: rash, itching, fever, low TA, etc. However, when a patient receives massive blood transfusions, complications may develop on the lungs accompanied by inflammatory reactions.

The greatest attention is paid to infections, especially those caused by agents known to be blood-borne.

Medical indications permitting, a patient can have blood taken for a transfusion in advance, prior to

the planned surgical procedure. This method, although not without risks, is the safest form of transfusion for a recipient, as it eliminates the potential risks of blood-borne infections such as HIV, hepatitis B or hepatitis C.

Pre-transfusion testing includes blood analysis for infectious agents (Milošević Manojlović et al., 2005):

- Hepatitis B surface antigen (HbsAg). This test detects the outer envelope of the hepatitis B virus;
- Hepatitis C;
- Human immunodeficiency virus (HIV). EIA tests, fluorescence microscopy techniques and PCR can be used for proof;
- *Treponema pallidum* - Syphilis.

Antigens of the ABO blood system genes are determined by genes located at three independent loci. Weakening or loss of ABO antigen expression is often associated with hematological malignancies, as well as solid tumors in the body. A change in the expression of ABO antigens leads to problems when determining the blood group and represents a risk of incompatible transfusions. (Grujić et al., 2022)

Authorized institutions for transfusion medicine are required to establish a unified system for reported adverse and unexpected events and reactions related to the collection and testing of blood, as well as the production, storage and distribution of blood derivatives, that is their application in case of doubt about effectiveness, quality and harmlessness. (Law on Blood and Blood Products, 2011)

### 3. PROMOTION OF VOLUNTARY BLOOD DONATION

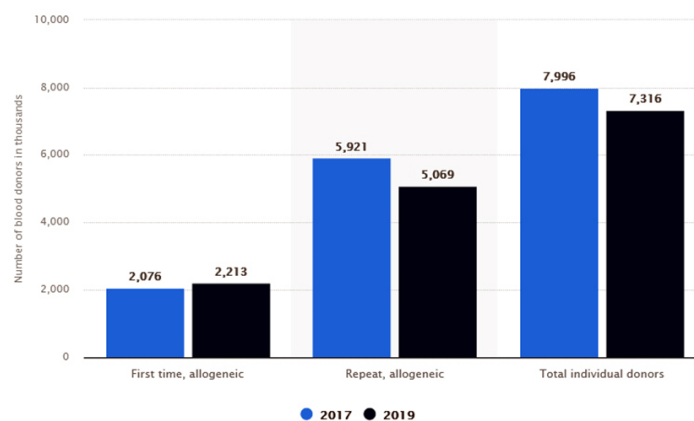
The donor can be any healthy adult weighing more than 50 kg, with a body temperature of less than 37° C, a pulse between 50 and 100/min, blood pressure not lower than 110/50 and not higher than 180/90 kPa, hemoglobin must be above 135 g/l for men, i.e., 125 g/l for women, hematocrit greater than 0.40 for men and 0.38 for women, while the interval between donating blood is three months for men and four months for women. (<https://itm.org.mk>)

In general, the age limit for voluntary blood donors of 18 to 65 years of age can be deviated from in case of autologous transfusion of blood and blood components, in that case a minor donor can give blood only with the written consent of a parent or guardian. The exception also applies when the recipient is unconscious, or for other reasons is unable to give consent, with the opinion of the competent doctor who provides an emergency measure (Law on Transfusion Medicine, 2017)

During one calendar year in the Republic of Serbia, it is necessary to provide 240,000 units of blood. Although 64% of the population can donate blood, out of 100 inhabitants aged 18 to 65, on average, only three are voluntary blood donors. The average age of a blood donor in Serbia is 38 years of age. The majority of voluntary donors are men (73.5%), while women are less represented (26.5%). (<https://itks.rs/>)

The total number of blood donors in the USA in 2019 was 7.3 million blood donors. However, almost 5.1 million were multiple donors. Given that the O blood group can be given as a substitute for any other, and considering the fact that it is the most common blood group in the American population (45%), this blood group is also the most sought after. The most common reason for postponing blood donation is low hemoglobin/hematocrit of donors (Statista, 2022a).

Figure 1. Number of first donations and multiple blood donors in the USA in 2017 and 2019 (In 000)



Source: Statista, 2022b

Countries with larger populations have a large number of blood donations, in absolute terms these are: Italy is the first with three million donors and a population of 59.6 million, France has 67 million inhabitants and 2.8 million donors while Germany has 82.2 million inhabitants and 2.4 million donors. However, when viewed per capita, Greece comes out on top with 0.053 blood donations per capita, while the United Kingdom ranks fourth in absolute terms with 1.7 million, but ranks 24th out of 26 countries per capita with 0.026, which means one donation for every 38 people.

The Ipsos survey of more than 23,000 adults from 28 countries, assessed international sentiments on a range of health topics such as quality of care, access to medical professionals and waiting times. The respondents were also asked if they agree with the statement, "I often give blood to help others". 58% of Saudis said that they agree with the statement and often donate blood, this share was 52% in India and 36% in Serbia. The following are the countries with significantly lower agreeable responses: USA and France 23%, United Kingdom 18%, Germany 17%, Russia and Canada 16% and Japan 11% (Ipsos, 2018).

Countries of the European Union were required to harmonize their national regulations by August 31, 2006 in order to ensure the continuous implementation and maintenance of the quality system, which implies the validation of all procedures, premises and equipment, sufficiently educated personnel with clear tasks and responsibilities, unambiguous procedures for identification, interviewing and assessment of donors, whereby the risk of microbial contamination must be minimized, as well as labeling, dispensing, storage and distribution of blood and blood components. (Commission Directive 2005/61/EC, 2005

#### 4. STATUTORY FRAMEWORK

The field of collection, storage, and circulation, as well as complex technical requirements, is regulated by the European Union with directives, on the basis of which the national legislation of 27 member states has been harmonized:

- Directive 2002/98/EC of the European Parliament and Council of January 27, 2003 establishing quality and safety standards for the collection, testing, processing, storage and circulation of human blood and blood components and amending Directive 2001/83/EC (SL L 033, 8. 2. 2003),
- Directive 2004/33/EC of March 22, 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council in relation to certain technical requirements for blood and blood components (OJ L 091, 30. 3. 2004),
- Commission Directive 2005/61/EC of September 30, 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council with regard to requirements for traceability and notification of serious adverse reactions and events (OJ L 256, 1. 10. 2005),
- Directive 2005/62/EC of September 30, 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council regarding standards and specifications of the Community in relation to the quality system of authorized institutions for blood and blood products (OJ L 256, 1. 10. 2005).

European Union countries must ensure that blood and blood product establishments adhere to safety and quality standards, and ensure that good practice guidelines are available and used by all blood banks. In addition, the Directive constitutes an obligation to control the quality of blood and blood components from non-EU countries before they are imported into the EU. (Commission Directive 2005/61/EC, 2005)

The manner, procedure, conditions, organization, and activity of transfusion medicine in the Republic of Serbia is regulated by the Law on Transfusion Medicine (2017), which includes the promotion, planning, collection, testing, processing, storage and distribution of blood and blood components. The provisions of this Law refer to the collection and testing of blood and blood components, but not to the supply of medicines obtained from human blood or plasma, nor to stem cells that create blood cells. The promotion of voluntary, unpaid and anonymous donation of blood and blood components within the territory of the Republic of Serbia is carried out by transfusion institutions and the Red Cross, and they must be continuous and aligned with the need for sufficient amounts of safe blood and blood components throughout the year. In this context, it was decided that the Institute for Blood Transfusion of Serbia will adopt an annual plan for the needs of blood and components, no later than November 15 of the current year for the following year.

Similar solutions and wording can be found in the Law on Blood and Blood Components of the Federation of Bosnia and Herzegovina (2017), as well as in the Law on Transfusion Activity of the Republic of Srpska (2015). Within the territory of the Federation of Bosnia and Herzegovina, transfusion centers and transfusion departments have approval for the performance of transfusion activities, which is

issued for a period of five years. The Federal Ministry of Health maintains a register of authorized health institutions. In order to provide expert assistance to the Ministry of Health and Social Protection, the Government of the Republic of Srpska establishes a ten-member Council for Transfusion Activity with the aim of defining a general policy in the field of transfusion activity, as well as for giving an opinion on the proposal of an annual plan for blood and blood components.

Blood collection and testing, as well as the production of blood derivatives in the Republic of Croatia, can only be performed by an authorized health institution that has a permit for the performance of transfusion activities, which is issued for a period of five years. Authorized healthcare institutions must establish a quality assurance system aligned with the requirements of internationally recognized standards for transfusion medicine and scientific and technological development. (Law on Blood and Blood Products, 2011)

The Law on Safe Collection of Blood in Macedonia (2007) created formal and legal prerequisites for ensuring self-sufficiency and meeting the national needs for blood and blood groups. Predictable needs for blood are determined by an annual plan, which is adopted by the Minister of Health at the suggestion of the transfusion institution. In addition, the minister determines areas for blood collection based on professional, medical, economic, and other criteria, and the Institute for Transfusion Medicine and the Red Cross are responsible for implementation. Donating blood is based on the principles of voluntariness and anonymity and does not involve monetary or any other compensation. The institution for transfusion medicine is required to keep the documentation obtained, or created, during the performance of its activities for a period of at least 30 years, while ensuring the confidentiality and secrecy of data in the manner regulated by regulations on the protection of personal data and the protection of patients' rights.

## 5. CONCLUSION

Improvements to voluntary blood donation should be resolved by systemic measures that involve the organization of a significantly larger number of transfusion centers, in order to enable donors to give blood in a fast, safe, and comfortable manner. In addition, more efficient planning, implementation, and valorization of public health campaigns has been suggested. Health education and stressing the irreplaceability of blood donation, due to its relevance, should be highly positioned in curricula starting from primary school. This paper affirms voluntary, anonymous, and unpaid blood donation and points to the necessity of establishing measures and instruments for the stronger public recognition of donors. Certified health facilities should adopt blood supply management plans, as well as change their approach to attracting, recruiting, selecting, and retaining health personnel, as the most important resource they have. This paper emphasizes the positive reflections of the introduction of the Type and Screen method, i.e., determination of the blood group in the ABO and Rh system and screening for clinically significant antibodies, which has been confirmed as a reliable and rational standard for the use of blood products. However, this standard must be periodically revised in order to comply with the latest global standards.

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