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Review Article International Blood Transfusion Regulations: Considerations, Safety Precautions Discussion, and Preliminary Testing Precedents Before Transfusion: Minireview Amal Ismail Joudeh

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ABSTRACT:

Blood transfusions form a network of integral medical processes for trauma, surgical interventions, and management of chronic diseases all over the world. Nonetheless, different infrastructures in different countries tailor recruitment of donors and policy execution, guaranteeing a safe, sufficient, and equitable blood supply, continue to be challenged. This study examined international blood transfusion policies: donor systems, clinical procedures, safety standards, and pre-transfusion testing guidelines, backed by such key health organizations as AABB and the World Health Organization. Important areas of concern include the incidence of transfusion-transmissible infections (TTIs), the encouragement of voluntary non-remunerated blood donation (VNRBD), the imposition of stringent transfusion practices, and the imposition of laboratory testing before transfusion. Evidence-based suggestions will be put forward towards improving global standards for blood safety and availability using data from PubMed and other reliable sources.

Keywords: Blood transfusions, Discussion, study, Preliminary Testing Precedents

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INTRODUCTION:

A blood transfusion is an essential part of modern medicine in the treatment of various diseases. Although 118 million donations are made around the world every year, inequities continue to exist in access to safe blood owing to structural issues concerning the infrastructure, regulation, and culture of donation [1]. The WHO has underlined the need for blood systems nationally coordinated to guarantee safety and sufficiency, to which AABB and other international standards provide complementary guidance [2,6]. This overview of blood transfusion regulations worldwide will particularly address the safety protocols, donor recruitment strategies, clinical guidelines, pre-transfusion testing requirements, and ongoing challenges. The aim is to collate up-to-date information and propose strategies for the improvement of transfusion practices on a global scale [7].

Literature Review

Blood Safety Standards

Blood safety, which covers rigorous donor screening, TTI (transfusion-transmitted infection) testing for HIV, Hepatitis B, Hepatitis C, and syphilis, blood grouping, compatibility testing, and quality assurance programs, is a public health concern [5]. To this end, WHO mandates that all donated blood be screened for major TTIs [2]. In areas where applicable, further testing for localized diseases such as malaria is also needed. Despite these recommendations, TTI prevalence is highly variable, with higher incidences in low-income countries due to inadequate screening and greater background rates of infection [3,8]. The WHO and International Federation of Red Cross and Red Crescent Societies consider 100% VNRBD as the safest source of blood, reducing the risk of TTIs, as opposed to paid or replacement donations [2,4]. Even though VNRBD has been part of global health policy since the 1975 World Health Assembly resolution, only 64 percent of countries have established national blood safety laws, with minimal application in low- and middle-income countries [6]. Most places experience cultural obstacles and gaps in knowledge and infrastructure.

Transfusion Techniques and Clinical Use

Blood must be used wisely to minimize unnecessary transfusions and risks associated with them [9].Most often, a restrictive transfusion strategy should be followed for hemodynamically stable patients, according to the 2023 guidelines of the AABB [1]. It must be remembered that for both adults and critically ill children, this hemoglobin threshold is now set at 7 g/dL, with modifications made for certain conditions such as congenital heart disease (for instance, for single-ventricle palliation, the threshold was raised to 9 g/dL) [1,10]. Fundamental trials have supported these restrictive approaches in different patient populations [11,12,13]. These decrease the volume of blood transfused while still ensuring safety for patients, which the WHO recommends for risk mitigation and resource optimizations [2,14].

Pre-Transfusion Testing

The blood of both the donor and the recipient must be compatible to avoid dangerous reactions that could potentially be fatal [15]. Pre-transfusion testing involves ABO and RhD typing, antibody screening, and crossmatching to detect possible incompatibilities and unexpected antibodies (2). These tests are necessary to prevent kidney damage from acute hemolytic reactions due to alloantibody interaction or even ABO mismatches, which can be life-threatening if not treated. Safety regulations of blood worldwide are based on such extensive testing types [5].

MATERIALS AND METHODS:

Using the peer-reviewed literature available on PubMed, the WHO information sheets, and international recommendations published between 2010 and 2025, this review has employed the narrative synthesis method to look into some international blood transfusion policies. Important issues include pretransfusion testing, clinical transfusion practices, donor systems, TTI prevalence, blood safety, and policy frameworks. Following analysis of the data to compare practices in high-, middle-, and low-income countries while giving special attention to WHO and AABB guidelines, quantitative data on TTI prevalence, transfusion rates, and testing procedures were extracted to highlight global disparities.

Highlights and Analysis

Global prevalence of TTIs and blood safety

There are steep differences between income categories worldwide with regard to blood safety. While TTI prevalence drops to less than 1% in many areas of high-income countries through means like modern screening technologies, nucleic acid testing (NAT), it is more than that in many low- and middle-income countries (LMICs) due to lack of resources and inefficient testing methods [2,8].In the view of WHO, these discrepancies mirror other larger health

system problems of infrastructure and donor selection [2].

Problems with donor systems and supplies

Despite the widespread endorsement of VNRBD, certain countries continue to permit paid or family donations, thereby increasing the risk of TTI (4). Additional comprehensive blood safety legislations exist in about 79% of high-income countries, in contrast to 39% of low-income countries [2]. The WHO reports that low rates of donation, low levels of awareness in public, and logistical challenges are some of the causes of continuous blood shortages in LMICs [7].

Transfusion Rates and Clinical Practices

Lower mortality and transfusion-related problems for bleeding at certain hemoglobin thresholds (e.g., 7 g/dL in stable patients) resulted in the ever-increasing acceptance of restrictive transfusion techniques all around the world [1,14]. The implementation, however, is different. Some areas have neither hospital transfusion committees nor national guidelines to back reasonable use. The disparity of transfusion rates within the European Union member states demonstrates that custom and policy implementation vary in the clinical setting [16]. The trial with trauma patients also suggested that in some cases, there should be certain component ratios when transfusing blood [17].

Prerequisites for Pre-Transfusion Testing

Pre-transfusion testing is an important prerequisite to ensure compatibility and prevent adverse reaction events. ABO type and Rh type, as well as antibody screening and cross-matching, are required tests to find the right blood units for transfusion, according to the World Health Organization [2]. These procedures are essential to detect incompatibilities that might give rise to very severe hemolytic reactions [5,15].

Global Transfusion Metrics, Safety, and Pretransfusion Testing Tables

Such quantitative measures are necessary to show the differences in transfusion practices, blood safety, and pre-transfusion testing, and the setting of transfusion requirements across the globe. The following tables provide a comprehensive overview of such issues related to well-known international sources. EU-wide distribution of components transfused in 2021 is presented in Table 1 below, as well as each component's share of overall transfusion volume, detailed incidence of serious adverse events and fatalities as documented in the EU's annual summary of transfusion-related incidents [16]. Table 2 gives an overview of some TTIs - transfusion-transmissible infections - such as HIV, hepatitis B and C, and syphilis within national income groups, as per data from the World Health Organization [15]. In Table 3, the essential laboratory investigations needed for transfusion are described and are stated to be mandatory, according to WHO and AABB, and the additional literature to draw from includes systematic reviews and clinical guidelines [1,2,5]. In brief, all these tables illustrate the different safety levels and practices in transfusions worldwide, as well as emphasize the need for evidence-based policies that will lead to improved blood transfusion outcomes globally.

Blood Component	Units Transfused (2021, EU Data)	Percentage of Total Transfusions	SAR (Serious Adverse Reactions, Levels 2-3)	Fatalities (Levels 2-3)
Red Blood Cells (RBCs)	13,375,434	55%	697	19
Platelets	2,158,095	29%	356	4
Plasma	2,272,341	13%	149	0
Whole Blood	2,999	0%	2	0
Multiple Components	45	3%	2	0
Source: EU 2022 Annual Reporting on Serious Adverse Reactions				

Table 1: Transfusion Metrics by Blood Component

Table 2: TTI Prevalence in Blood Donations by Income Group

Income Group	HIV Prevalence in Donations (Median, IQR)	Hepatitis B Prevalence (Median, IQR)	Hepatitis C Prevalence (Median, IQR)	Syphilis Prevalence (Median, IQR)
High-Income Countries	0.001% (0.000-0.003%)	0.02% (0.01-0.05%)	0.02% (0.01-0.04%)	0.02% (0.01-0.05%)
Middle-Income Countries	0.03% (0.01-0.08%)	0.5% (0.2-1.0%)	0.3% (0.1-0.6%)	0.2% (0.1-0.4%)
Low-Income Countries	0.2% (0.1-0.5%)	2.0% (1.0-3.5%)	1.5% (0.8-2.5%)	0.8% (0.4-1.5%)
Source: WHO Fact Sheet on Blood Safety and Availability				

Table 3: Essential Pre-Transfusion Tests

Test Name	Purpose	Mandatory Status (WHO/AABB)	Notes on Application
ABO Typing	Determine blood group (A, B, AB, O)	Mandatory	Includes forward and reverse grouping for accuracy
RhD Typing	Determine Rh factor (positive/negative)	Mandatory	Essential for compatibility matching
Antibody Screen	Detect unexpected antibodies in recipient's plasma	Mandatory	Identifies non-ABO antibodies that may cause reactions
Crossmatch	Confirm compatibility between donor and recipient	Mandatory for RBCs	Serological or electronic; not always needed for plasma/platelets
TTI Screening (HIV, HBV, HCV, Syphilis)	Detect transfusion- transmissible infections	Mandatory	Includes NAT in some regions for higher sensitivity
Source: Compiled from WHO, AABB guidelines, and PubMed literature			

DISCUSSION:

As one can see, now that institutionalized blood transfusion safety TTI screening and VNRBD systems have come into existence, their effects can be seen globally. However, the disproportionality in blood transfusion safety still exists [2,7]. While LMICs limit their availability for voluntary donation because of a shortage of funds, high-income countries

enjoy low TTI rates and a reliable blood supply due to advanced technology or effective law [8]. Although the AABB and WHO support restrictive transfusion techniques as a balanced approach to risk reduction, their implementation is variable since most countries do not have national guidelines [14]. Although the practice of pre-transfusion testing, such as ABO/Rh type and cross-matching, varies according to availability, it remains an important precaution against hemolytic responses [15]. The serious adverse reactions (SARs), which are mostly related to red blood cell transfusions, shed more light on the need for improved hemovigilance systems in the world [16].It was the incorporation of systematic TTI (transfusion-transmitted infection) screening and the growth of voluntary non-remunerated blood donation (VNRBD) systems that consolidated blood transfusion safety into a system, showing clear progress worldwide. Nonetheless, the enormous gaps between both the regions and income groups that blood transfusion safety leaves negatively affect this progress [18].

Enduring Inequities

Low-and Middle-Income Countries (LMICs):

They are often limited in voluntary blood donation because of insufficient funding, infrastructure gaps, and persistent cultural barriers. It is found that there is a higher prevalence of TTIs in blood donations, due to the less comprehensive screening technologies and reliance on family or paid donors [3,8]. Blood shortages and supply fluctuations are common due to logistical and educational challenges [4].

High-Income Countries:

They have all the advantages of advanced laboratory technologies, good regulatory frameworks, and efficient blood national programs. They experience low prevalence of TTIs and enjoy a steady blood supply; thus, they have a "safe" active blood donation popularization through the modernized adopted measures of VNRBD and strict legal control [2,7]. Restrictive Transfusion Techniques Implementation

The AABB and WHO recommend restrictive transfusion policies to limit unnecessary transfusions and reduce risk. However, the implementation of these policies remains variable. Because many countries do not have national guidelines or hospital-based transfusion committees, clinical practice and patient outcomes are highly inconsistent [14].

Pre-Transfusion Testing and Hemovigilance

Pre-Transfusion Testing: Some of the checks performed before transfusion include blood group typing, such as ABO and Rh typing, antibody screening, and crossmatching. These checks play important roles in the prevention of hemolytic transfusion reactions. The extent to which tests are performed, as well as their quality, is dependent on resource availability. Most LMICs cannot conduct comprehensive testing because their laboratory capacity is limited [15,18]. Serious Adverse Reactions (SARs): Most SARs are associated with red blood cell transfusions, emphasizing that hemovigilance systems should be strengthened. High-income countries would have monitoring and reporting systems in place. Meanwhile, most LMICS will not have such systems, and hence, underreporting of adverse events occurs, denying opportunities for quality improvement [16].

Recommendations

- Strengthen National Blood Systems: Create efficient, nationally coordinated blood transfusion programs with laws and well-defined procedures in order to provide prompt availability of safe blood according to WHO standards [4,6].
- Encourage Voluntary Non-Remunerated Donation: past and present initiatives at national and international levels aimed at increasing VNRBD have included efforts to eliminate cultural myths surrounding blood donation and to build public confidence in blood donation programs [2].
- Improve Screening and Testing: require effective testing for Exposure to Transfusion-Transmitted Infections (HIV, Hepatitis B and C, and syphilis) on each blood donor, and use the highly affordable technologies like NAT whenever applicable, especially within lowand middle-income countries [2,3].
- Adopt Restrictive Transfusion Practices: Establish AABB recommended thresholds with transfusion committees to minimize needless transfusion and the hazards that accrue from it in hospitals (e.g. 7 g/dL for stable patients) (1).
- Standardize Pre-Transfusion Testing: All personnel providing health care will have training on ABO/Rh typing, antibody screening, and immunohematology crossmatching protocols that require universal adherence and are intended to prevent incompatibility responses [15].
- Enhance Hemovigilance and Quality Systems: Institutionalize tracking systems for adverse responses, guarantee quality in transfusion processes from patient follow-up to donor recruiting [5.16].

In conclusion, transfusion regulations should confirm the existence of blood in sufficient quantity and quality, yet many hurdles remain to be taken due donor systems' system differences, to the infrastructure, and enforcement of the law [7]. VNRBD and advanced screening measures work well in high-income countries, but TTI prevalence is higher and resources are scarce in lower-middlecountries[2,8].Safeguarding income access of everyone to safe blood shall be ensured by national blood system strengthening, pre-transfusion testing standardization, and stricter transfusion policy implementation [1]. Collaborative synergies fostering

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best practice implementation, aligning with WHO and AABB frameworks for improved health outcomes, are critical for governments, health organizations, and communities to close these gaps.

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