

## Analysis of immediate transfusion incidents reported in a regional blood bank

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**Background:** Blood transfusion is imperative when treating certain patients; however, it is not risk free. In addition to the possible transmission of contagious infectious diseases, incidents can occur immediately after transfusion and at a later time.

**Aims:** This study aimed to examine the immediate transfusion incidents reported in a regional blood bank in the state of Minas Gerais between December 2006 and December 2009. A retrospective quantitative epidemiological study was conducted. Data were obtained from 202 transfusion incident reports of 42 health institutions served by the blood bank. Data processing and analysis were carried out using the Statistical Package for the Social Sciences (SPSS) software.

**Results:** The rate of immediate transfusion incidents reported in the period was 0.24%; febrile non-hemolytic reactions were the most common type of incident (56.4%). The most frequent clinical manifestations listed in transfusion incident reports were chills (26.9%) and fever (21.6%). There was a statistically significant association ( $p$ -value < 0.05) between the infusion of platelet concentrates and febrile non-hemolytic reactions and between fresh frozen plasma and febrile non-hemolytic reaction. The majority (73.3%) of transfused patients who suffered immediate transfusion incidents had already been transfused and 36.5% of the cases had previous transfusion incident reports.

**Conclusions:** Data from the present study corroborate the implementation of new professional training programs aimed at blood transfusion surveillance. These measures should emphasize prevention, identification and reporting of immediate transfusion incidents aiming to increase blood transfusion quality and safety.

**Keywords:** Blood safety; Blood transfusion; Immunologic surveillance

### Introduction

In general, blood component transfusions are an efficient means of temporarily correcting a deficiency of red blood cells, platelets or coagulation factors.<sup>(1)</sup> In certain clinical situations, transfusions can be the only way to save a life or to quickly recover from a serious disease. However, even in contexts of accurate prescription and correct administration, the transfusion process involves health risks with the potential occurrence of immediate or delayed transfusion incidents. These incidents vary from mild to severe and even involve risk of death.<sup>(2)</sup>

Immediate transfusion incidents occur during transfusion or within 24 hours after and include: acute hemolytic transfusion reactions (AHTR), febrile non-hemolytic reactions, allergic reactions (mild, moderate, severe), transfusion associated circulatory overload (TACO), reaction to bacterial contamination of blood bag, transfusion-related acute lung injury (TRALI), hypotensive reaction and non-immune hemolysis.<sup>(3)</sup>

There are difficulties in prescribing blood components and identifying and dealing with transfusion incidents. In addition, statistics expressing the reality of these incidents are not widely available in Brazil.<sup>(4)</sup>

The blood surveillance system appeared in the 1990s with particularities in different countries, but with the single objective of improving the quality of blood transfusions and increasing safety.<sup>(5)</sup>

In Brazil, the blood surveillance system was created in 2001 by the Brazilian National Health Surveillance Agency (ANVISA) which adopted the Transfusion Incident Report structure as an essential instrument to enable the identification of risk related to transfusions and the establishment of measures aimed at minimizing these risks.<sup>(6)</sup>

The aim of this study was to analyze immediate transfusion incidents reported in a regional blood bank between December 2006 and December 2009.

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## Methods

A retrospective epidemiological study was conducted with a quantitative approach. Data were obtained from 202 transfusion incident reports between December 2006 and December 2009 of 42 health institutions in a regional blood bank network in the state of Minas Gerais.

Reports on 202 immediate transfusion incidents that were sent to the regional blood bank's Transfusion Committee were analyzed. This center is responsible for the distribution of blood components to these institutions. The Transfusion Committee subsequently sent these reports to the Technical-Scientific Management Committee of the Fundação de Hematologia e Hemoterapia de Minas Gerais (Hemominas). Finally, copies of the transfusion incident reports were sent to the State Blood Transfusion Technical Committee.

An instrument developed from data recorded in transfusion incident reports was used for data collection. This instrument included information about socio-demographic data and clinical aspects of transfused patients and data on transfusions.

Data were input into a Windows XP Excel spreadsheet, validated using double data entry and exported to the Statistical Package for the Social Sciences software (SPSS) for processing and analysis.

Descriptive analysis was performed to identify the types of immediate transfusion incidents, blood component type, clinical manifestations and previous history of blood transfusions.

The Fisher's exact test was used to verify whether there was an association between each type of blood component and the immediate transfusion incidents.

Transfusion incident reports not sent to the Technical-Scientific Management Committee were excluded from this study as they were not fully completed by the Transfusion Committees of the institution where the immediate transfusion incident occurred.

This study was approved by the Research Ethics Committee of the Fundação Hemominas (Number 259).

## Results

Between December 2006 and December 2009, this blood bank provided 83,951 blood component units to 42 institutions and to the in-house transfusion outpatient clinic. During this period, 202 immediate transfusion incidents were reported. Of these, 38 (18.8%) were reported in 2007, 90 (44.6%) in 2008 and 74 (36.6%) in 2009.

Packed red blood cells were the most commonly supplied blood components (64.6%).

The rate of immediate transfusion incident reports sent to the blood bank was 0.24% in the study period.

With regard to sociodemographic variables of the patients who suffered reactions, 102 (50.5%) were men, 99

(49.0%) were women and one (0.5%) transfusion incident report did not identify the patient's gender.

In terms of the medical diagnosis used to prescribe blood transfusions, 79 (39.1%) patients had a diagnosis of neoplasias, 47 (23.3%) anemia of chronic disease, 34 (16.8%) acute post-hemorrhagic anemia, 29 (14.4%) aplastic anemias; six (3.0%) clotting disorders and five (2.5%) patients had hemolytic anemias. Two transfusion incident reports (1%) did not inform the patient's diagnosis.

With regard to blood component types, packed red blood cells were the most frequent with 107 (53%) transfusion incident reports (Table 1).

As regards the types of immediate transfusion incidents reported, the majority (114 – 56.4%) were febrile non-hemolytic reactions (Table 2).

Table 1 - Type of blood components identified in the transfusion incident reports

Blood component type	n	%
Packed red blood cells	107	53.0
Platelet concentrate	78	38.5
Fresh frozen plasma	8	4.0
Packed red blood cells and fresh frozen plasma	5	2.5
Packed red blood cells and platelet concentrate	4	2.0
Total	202	100.0

Table 2 - Immediate transfusion incidents reported

Type of immediate transfusion incident	n	Incidence
Febrile non-hemolytic reactions	114	1.35
Mild allergic reactions	49	0.58
Non-identified incidents	11	0.13
Moderate allergic reactions	7	0.08
Bacterial contamination	5	0.06
Mild allergic reaction and febrile non-hemolytic reactions	5	0.06
Severe allergic reactions	3	0.03
Transfusion associated circulatory overload	3	0.03
Acute hemolytic transfusion reactions	3	0.03
Febrile non-hemolytic reactions and bacterial contamination	2	0.02

The most frequent clinical manifestations reported in transfusion incident reports were chills (26.9%) and fever (21.6%).

Of the 202 transfusion incident reports observed, there were significant statistical associations between platelet concentrates and febrile non-hemolytic reactions (p-value = 0.009) and between fresh frozen plasma and febrile non-hemolytic reactions (p-value = 0.015).

The majority of transfused patients (73.3%) who

suffered immediate transfusion incidents had previously been transfused and there were records of previous transfusion incidents in 36.5% of all transfusion incident reports.

## Discussion

Professionals involved in the prescription and administration of blood components must be qualified to identify the signs and symptoms, to deal with transfusion incidents and to establish measures to prevent future incidents.<sup>(7)</sup>

Thus, collaboration of all parties involved in blood transfusion medicine, including the blood surveillance systems is key to guarantee the safety of blood supplies.<sup>(8)</sup>

In the present study, the majority of blood components provided were packed red blood cells thus corroborating a study on blood component supply conducted in a university hospital in Southern Brazil.<sup>(9)</sup>

The numbers of men and women in this study were similar, agreeing with the results of another study carried out using a comparable methodology.<sup>(1)</sup>

The high number of transfused patients with clinical diagnoses of neoplasias is in accordance with other studies in which there were more reports on cancer patients.<sup>(9,10)</sup> Blood transfusions in cancer patients are very common due to bone marrow depression with decreases in blood cell production resulting from the specific treatment of this disease.<sup>(11)</sup> Consequently, these patients are more likely to have reactions to blood transfusions.

Packed red blood cells were the blood components most frequently involved in immediate transfusion incidents compared to other components. This is probably due to the high consumption of packed red blood cells, especially by hospitals that care for patients with multiple injuries and acute hemorrhages and those requiring surgical procedures.

This result diverges from those found in other studies with a similar methodology, in which platelet concentrates were more frequently identified in reports.<sup>(1,9,12-17)</sup>

Of all types of transfusion incidents reported, the majority involved febrile non-hemolytic reactions.

Similar results were observed in studies conducted with this methodology, in which the occurrence of febrile non-hemolytic reactions was higher than other types of incidents reported.<sup>(1,12,13,16,18)</sup> However, divergent results were found in some studies, again using a similar methodology, which described allergic reactions as being the most common reported incidents, followed by febrile non-hemolytic reactions.<sup>(19-22)</sup>

Febrile non-hemolytic reactions are a diagnosis of exclusion as non-specific signs and symptoms have many causes. Fever, one of the characteristic signs of this type of reaction, can be caused by other types of reactions or underlying diseases. Other findings, such as previous history of transfusion, transplant, pregnancy and drug therapy are

important for diagnostic accuracy.<sup>(23)</sup> Thus, the diagnosis of these reactions is often complex.

There were three cases of AHTR, corroborating a study with a similar methodology conducted in Switzerland, in which six cases of AHTR occurred as a result of ABO-incompatible blood transfusions.<sup>(13)</sup>

It should be emphasized that due attention must be paid to AHTR as this is a serious incident that can be avoided. The four main causes of preventable laboratory errors are as follows: inadequate sample identification, inadequate patient identification, incorrect antibody identification and incorrect cross-reaction procedures. With regard to medical and nursing team errors, inadequate patient identification is the main cause of death from transfusions.<sup>(23)</sup>

In a study conducted in the United Kingdom, there were 97 AHTR cases over two years, in which four patients died and 29 suffered immediate morbidity.<sup>(24)</sup>

The great difference in the number of AHTR reported in Brazil and the United Kingdom could suggest underreporting of immediate transfusion incidents in this country. The United Kingdom has a consolidated blood surveillance system, known as Serious Hazards of Transfusion (SHOT), which prepares reports on the most frequent events through report analysis, with guidance and standardization for all British health services and professionals aiming at minimizing transfusion errors.<sup>(6)</sup>

In contrast, Brazilian health services and professionals seem to be afraid that reports will spoil the positive image of blood transfusion services and hospitals.<sup>(6)</sup>

There were no reports of TRALI in the period studied, which suggests underreporting even though this type of reaction is rarely diagnosed.

TRALI is easily mistaken for other situations of acute respiratory insufficiency, such as acute respiratory distress syndrome (ARDS), fluid overload and congestive heart failure. It is believed that this type of incident must occur more frequently than is reported.<sup>(25)</sup>

Another finding in this study was the simultaneous occurrence of febrile non-hemolytic reactions and bacterial contamination in two reports. However, there were no reports of sample collection for blood cultures of transfused patients and blood components in these two cases.

Researchers have questioned the veracity of the occurrence of the two types of incidents. Questions may arise in some cases, given the complexity of the patient's condition and the lack of complementary tests for an effective diagnosis.

In view of the low incidence of reports in this study and the classification of two types of immediate transfusion incidents which may include diagnostic bias, it is believed that there may be errors in transfusion incident identification and classification.

This process is probably associated with the health team's lack of preparation for and guidance on possible adverse events resulting from transfusion.

Knowledge about the variables that can lead to undesirable transfusion effects and their control enable risk management, thus reducing and preventing adverse events.<sup>(6)</sup>

In certain European countries such as France, England, Denmark and Sweden, blood surveillance systems have been consolidated and are currently active, whereas surveillance systems are still being planned and constructed in other countries.<sup>(26)</sup>

The clear reality in countries that decide to determinedly deal with adverse events in transfusion, whether through an active search for cases of immediate transfusion incidents as in France or as a volunteer basis as in England, shows that a basal rate of events is always present and that it can be reduced by analyzing undesirable effects and by developing and implementing measures that can prevent incidences.<sup>(6)</sup>

Thus, it is essential to recognize blood surveillance limitations and the existence of risks that can be reduced, aiming to raise knowledge about the transfusion process, increase transfusion safety and gather more data that reveal the reality of adverse events in Brazil.

Chills and fever were the most frequently found clinical manifestations in patients, corroborating findings from another study.<sup>(13)</sup> Despite these manifestations being characteristic of febrile non-hemolytic reactions, they are common in other incidents such as reactions to bacterial contamination and TRALI.<sup>(7)</sup>

It is important to remember that the identification of clinical manifestations was by clinical assessment of transfused patients taking into consideration the signs and symptoms; there are no records of complementary tests that could confirm the diagnosis and/or contribute to differential diagnoses.

The statistically significant association between fresh frozen plasma and febrile non-hemolytic reactions observed in this study diverged from the result obtained in a study in which fresh frozen plasma had a statistically significant association with allergic reactions.<sup>(13)</sup>

This is justified in the present study by the fact that an observation of the association between transfusion incidents and blood components was made in a group of reports, instead of a comparison between groups that had transfusion incidents or not, according to the blood components used in the transfusions. This points to a need for further studies.

The majority of transfused patients had previously received transfusions, corroborating studies conducted with a similar methodology, in which the incidence of transfusion reactions is also higher in patients who had received multiple transfusions.<sup>(10,16)</sup>

Transfusion therapy can lead to many complications; however, the majority of these occur in patients requiring multiple transfusions.<sup>(27)</sup>

It is important to know the history of transfusions in patients and the occurrence of previous incidents as this can

contribute to the prevention of new incidents using strategies such as premedication and the use of blood components that have undergone a reduction in factors that cause reactions.

The results of the present study point to the need for greater blood surveillance and the creation of transfusion committees, because the number of reports is still low. This suggests that there is underreporting and a lack of knowledge about transfusion incident identification, management and prevention.

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