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Improving donor and patient safety. Portuguese haemovigilance system — donor adverse reactions, errors and near miss events — reports

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Abstract

Understanding the critical points in the blood transfusion chain through reporting, monitoring and analysis of donor and transfusion adverse reactions, transfusion errors, near miss events and their (potential) consequences is essential for defining of appropriate prevention and corrective measures and is therefore crucial for improvement of donor and patient safety.

The system of reporting transfusion-related adverse reactions was implemented in Portugal in 2008 however the process of notification of donor adverse reactions, blood establishment and hospital blood bank errors and near miss events was in use since 2009. As regards frequency and severity, the data concerning donor adverse reactions are consistent with data reported in medical literature and underline the safety of blood donation in Portugal.

The most critical area for hospital blood bank near miss events and errors is the clinical area. In most of the cases these events are associated with patient misidentification. Correct patient identification must be considered the core clinical skill as errors due to misidentification have major impact in every field of medicine, particularly in transfusion where such errors may even be fatal. However, with effective education, training and competency assessment most of such errors and events are preventable and can be eliminated.

Key words: blood safety, risk assessment, medical errors, patient safety

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Introduction

Blood supply depends entirely on the daily commitment of donors who are exposed to potential risk of discomfort and complications related to the procedure of blood collection.

Blood and apheresis donations are generally considered to be safe with a low incidence rate of adverse reactions. However, in order to further enhance blood donation safety it is essential to monitor and analyze adverse reactions.

Although many international standards recommend that donors should be informed of donation risks, pre donation informing is primarily focused on risk activities relevant to the safety of the recipient.

In order to improve the safety of the patient, it is essential to understand the critical areas in the blood transfusion chain. This aim can be achieved through focusing attention on reporting, monitoring and analysis of transfusion adverse reactions, as well as transfusion errors, near miss events and their potential consequences.

In Portugal the Instituto Portugues do Sangue e da Transplantação (Portuguese Blood and Transplantation Institute) is the institution responsible at national level for regulation of activities related to transfusion medicine, transplantation and en-

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surance of the safety of blood collection, testing, processing, storage and distribution of human blood, blood components, organs, tissues and cells of human origin. The scope of the responsibilities of this institution includes also the promotion of communication with hospital blood banks and functioning of the Portuguese Hemovigilance System (PHS).

The PHS was implemented in 2008 following the transposition into the national law of the relevant European directives: the European Union Blood Safety Directive (2002/98/EC) which applies to all European countries since February 2005 and ensures health protection by setting standards of quality and safety for the collection, testing, processing, storage and distribution of blood as well as Directive 2005/61/EC which implements Directive 2002/98/EC as regards traceability and notification of serious adverse reactions and events requirements [1, 2]. PHS is managed by a steering committee which includes representatives of the Portuguese Blood and Transplantation Institute in cooperation with the competent authority as regards the reactions and adverse events related to the quality and safety products, blood and blood components.

The notification system currently covers the entire transfusion chain, from donor to recipient as well as collection of data on the activities of blood establishments, hospital blood banks and facilities. The database is accessible through a web site and supplies surveillance and monitoring information which are used for data analysis and risk calculation, benchmarking as well as education and training.

The notification system includes not only serious adverse reactions and events but also donor adverse reactions, all the recipient adverse reactions as well as all the events (errors and near miss events) which occur in the blood transfusion chain. Available are also notifications of exclusion when institutions have no events or reactions to report as well as reports on the activity of blood establishments and hospital blood banks. The system of reporting transfusion-related adverse reactions was implemented in Portugal in 2008 however the process of notification of donor adverse reactions, blood establishment and hospital blood bank errors and near miss events was in use since 2009. Reporting on the activities of blood establishments and hospital blood banks on web site was implemented in 2012. All serious adverse reactions and serious adverse events, errors and near miss events are reported to the European Commission.

At the end of 2012 [3] there were 294 notifiers as part of the Portuguese Haemovigilance System that belonged to 188 public and private institutions: 1 blood establishment, 33 institutions which simultaneously combine the functions of blood establishments and hospital blood bank, 74 hospital blood banks and 80 facilities. Up to date the information on errors and near misses in blood establishments are scarce and the implementation of a sentinel event notification process is necessary. Therefore the aim of this report was to analyze the frequency and severity of donor adverse reactions and hospital blood bank errors and near miss events in order to define appropriate prevention and corrective measures to improve the safety of blood donations and patients.

Material and methods

A retrospective analysis of donor adverse reactions and hospital blood bank errors and near miss events reported to the PHS in 2012 has been performed.

Data concerning donor adverse reactions was recorded following local procedures and classified using the ISBT/IHN standard for surveillance of donation complications [4]. Only the reactions that required any kind of clinical intervention were reported, as defined by the Portuguese haemovigilance steering committee. The data referring to hospital blood bank errors and near miss events were classified according to error type and stage of occurrence in the transfusion chain with special focus on the clinical stage i.e. from request for blood component to its transfusion.

To make the analysis of the results easier the clinical stage of the transfusion chain was divided into three parts: the clinical area before the order for blood component is issued to the blood bank; the area of hospital blood bank; the clinical area after the blood component is delivered.

According to the European Union blood safety Directives *blood establishment* [1] is defined as any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. The definition does not include hospital blood banks.

Hospital blood bank [1] shall mean a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities.

Facilities [1, 6]. means hospitals, clinics, manufacturers, and biomedical research institutions to which blood or blood components may be delivered.

According to ISBT/IHN [4] a *donor adverse reaction* is an undesirable response or effect in a donor temporally associated with the collection of blood or blood component.

Severity [4] of donor adverse reactions is graded in two main levels, severe and non-severe, based on requirements for treatment and on outcome, in a way which corresponds to other systems in use internationally (i.e. ISBT for grading of adverse reactions to blood transfusion, European Commission for grading of transfusion reactions, FDA for grading of drug adverse events).

Conditions which define a donor adverse reaction as severe are [4]: hospitalization if it was attributable to the complication; intervention to preclude permanent damage or impairment of a body function; to prevent death (life-threatening); symptoms causing significant disability or incapacity following a complication of blood donation and persisting for more than a year after the donation (long term morbidity); death if it follows a complication of blood donation and is possibly, probably or definitely related to the donation. The non-severe complications are complications which do not satisfy any of the requirements for being severe.

The grading of imputability [4] of donor adverse reactions was defined as the strength of relationship between donation and the complication and can be:

— **Definite (certain)**: when there is conclusive evidence beyond reasonable doubt for the relation.
— **Probable (likely)**: when the evidence is clearly in favor of a relation
— **Possible**: when the evidence is indeterminate for attributing the adverse reaction to the donation or alternate cause.
— **Unlikely or doubtful**: when the evidence is clearly in favor of attributing the complication to other causes.
— **Excluded**: when there is conclusive evidence beyond reasonable doubt that the complication is not related to donation.

An *adverse event* [5] is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or not result in a reaction in a recipient. Adverse events shall mean all the errors and near miss events.

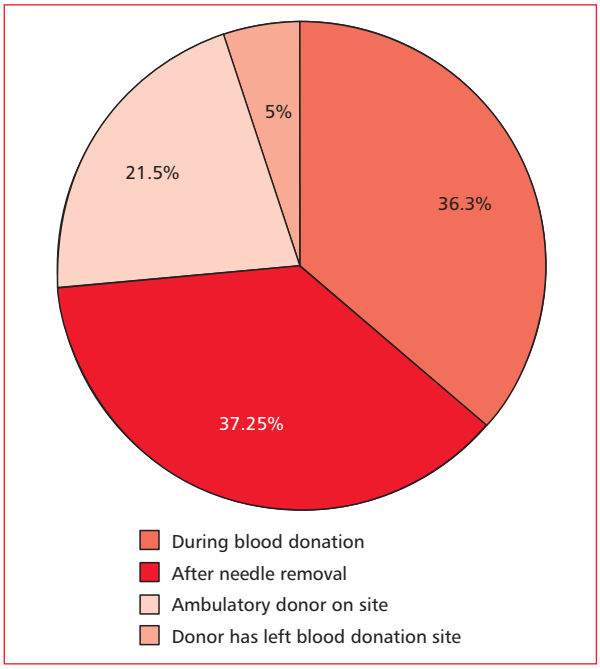

Figure 1. Donor adverse reactions at different stages that refer to blood donation

An *error* is defined as a deviation from the standard procedures or policies which had not been detected before the transfusion was administered and which may result in the transfusion of an inappropriate blood component or adverse reaction.

A near miss event [5, 6] is defined as an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient.

Results and discussion

Donor adverse reactions

A total of 1455 donor adverse reactions (DAR) were reported to the Portuguese Haemovigilance System during 2012, with a rate of 3.7/1000 donations and 5.88/1000 donors (similar data were reported for the years 2010, 2011).

These adverse reactions occurred at different stages of the donation process: 36.3% were reported during blood donation (from needle insertion to needle removal); 58.75% after the donation (37.25% after needle removal and 21,5% after the donor stands up from blood donation bed and before he leaves the blood donation site) and approximately 5% (4.95%) were donor delayed adverse reactions after the donor left the blood donation site (Figure 1).

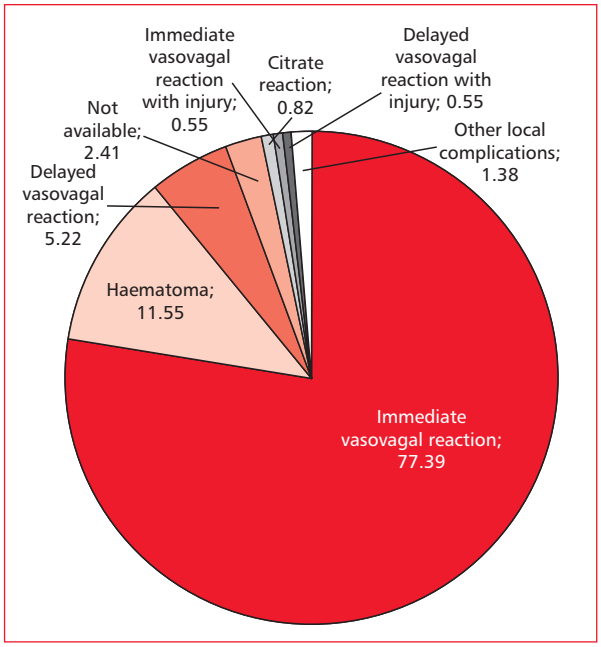

Figure 2. Donor adverse reactions following whole blood and apheresis donations (% of all donations)

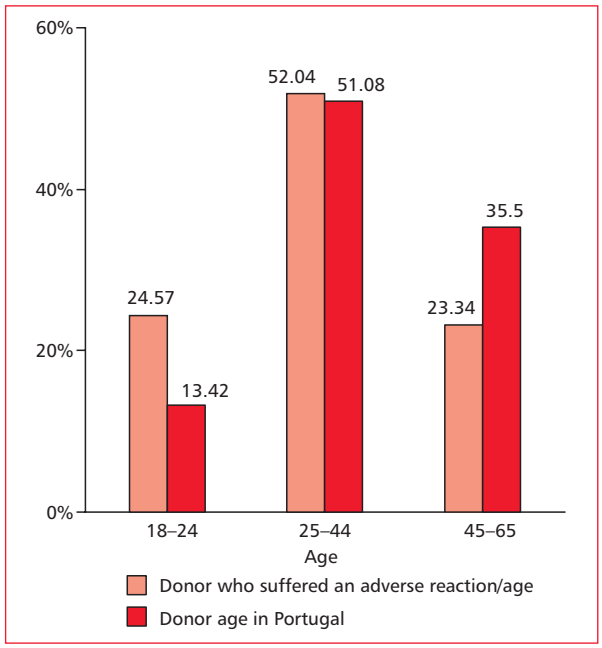

Figure 3. Age distribution in donors who suffered adverse reactions against donor age in Portugal

Of the reported DAR 95.95% were non severe while 4.05% were severe and required medical care (hospital admission or urgent medical intervention). Injuries, falls with injury or wounds, occurred in 1,09% of the reactions. Severe reactions represent 15/100 000 donations.

As concerns imputability levels: 76.36% of the reactions were probable, likely related to the event, 18.63% were definite, certain and 4.88% were possible. Further analysis of the data revealed that the most common complication were immediate vasovagal reactions which were observed in 77.4% of all reactions and that corresponds to 0.3% of the overall number of donations. Of the overall number of reactions 12.9% were reactions with local symptoms: haematoma, arterial puncture, delayed bleeding, nerve irritation/injury, tendon injury and pain at venipuncture site. Haematoma reactions were 11.5% of the overall number of reactions (0.04% of the overall number of donations) (Figure 2).

In 2012 in Portugal a total of 4769 apheresis procedures were performed and 56 reactions were reported (3.8% of the overall number of reactions were related to apheresis donation). These reactions were complications such as haematoma (the most frequent) and citrate reactions.

In 2012 in Portugal 51.6% of the donors were males, and DAR were more frequently reported for males than for females (52.78% of the overall reactions). Of the adverse reactions approximately 39.9% occurred in first-time donors and 32.2% in donors with 1 to 4 previous donations. The remaining 30% is attributed to donors who had donated blood 5 to 31 times.

As regards age distribution of donors who experienced adverse reactions such complications were observed more frequently in young donors (18–24 years who represented 13.4% of the whole donor population. In this age group 24.57% of all the adverse reactions were reported (Figure 3).

Reports on errors and near miss events

A total of 166 near miss events and 28 errors were reported to the Portuguese Haemovigilance System with a rate of 4.9 near miss and 0.82 errors/10 000 red blood cell (RBC) units transfused. We observed a maximum of three different types of near miss events or errors per report (transfusion event) and a minimum of one.

The reported near miss events occurred mostly in clinical areas (81.92%) before issue of the order to the blood bank (2.41% in the clinical decision process, 10.84% in filling the request form and 68.67% during sample collection). In hospital blood banks there occurred 13.25% of near miss events while 1.2% in the clinical areas during the transfusion process (Figure 4).

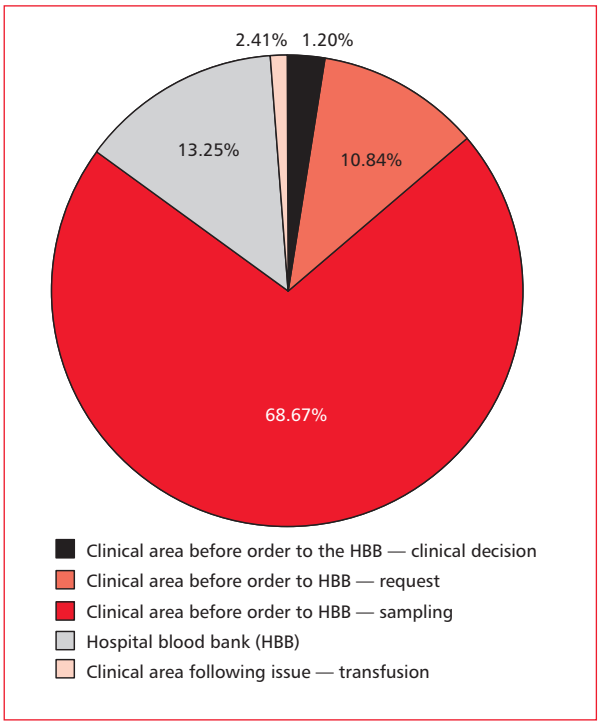

Figure 4. Areas of the blood transfusion chain where the reported near miss events occurred

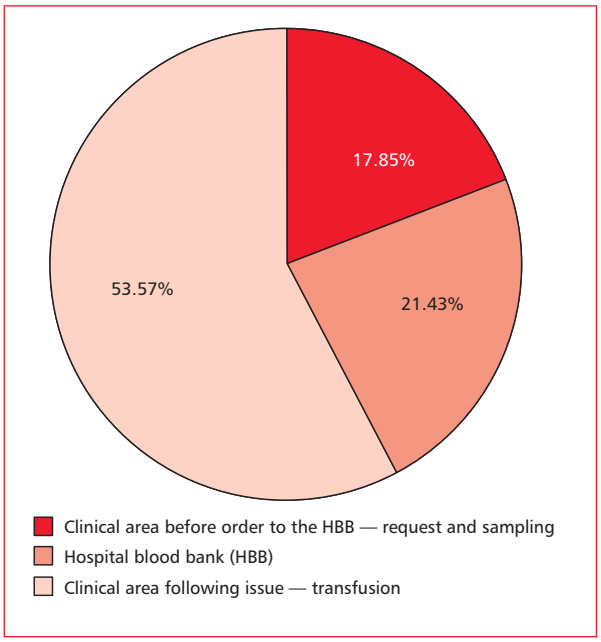

Figure 5. Areas of the blood transfusion chain where the reported errors occured

The reported errors were distributed as follows: in 17.85% of the cases the errors occurred in the clinical area before the order to the blood bank, in 21.43% in hospital blood banks and in 53.57%. in the clinical areas during transfusion process (Figure 5).

The most prevalent errors occurring in clinical areas were the transfusions of the wrong unit to the wrong patient, administration of the wrong ABO group with or without ABO compatibility and incorrect sample collection.

The most prevalent near miss events were associated with wrong name on the tube, sample collection from the wrong patient and labeled with the intended patient's identification data or sample collection from the intended patient but labeled with other patient's identification data.

Most of these near miss events were associated with patient misidentification. Analysis of 2012 data indicates that for every wrong blood in tube error (4 cases) there were about 30 near miss sample mistakes (120 cases) (Figure 6).

Errors and near miss events which occurred in blood banks were associated with improper labeling and transcription errors as well as with the issue of inappropriate blood component. As regards location for errors and near miss events, we observed that 92.7% of near miss events were detected in hospital blood banks while 57.14% of the errors in the clinical areas.

In 18 cases of reported errors (64%) consequences to the patient were found. When we compare this data with the data for the year 2011 we observe a decrease in the number of reported errors but their severity level is higher. In 2011 only 12% of the reported errors were found to have consequences to the patient.

In 2012, a total of 12 ABO incompatible adverse transfusion reactions were reported to the Portuguese Haemovigilance System. Seven (7) of these reactions (58%) were severe, 2 were life threatening (16.6%) and 2 were fatal (16.6%). In what concerns imputability levels, 50% of these reactions were certain 16.6% probable and 25% possible.

In 2012 other adverse transfusion reactions were also reported: 46.8% were febrile non hemolytic reactions, 22.6% allergic reactions, 7.8% delayed serologic reactions, 5.8% transfusion associated dyspnea, 4.6% transfusion associated circulatory overload, 2.4% hipotensive transfusion reactions, 0.36% anaphylactic reaction, 0.18% (one) TRALI and 7.3% were classified as other reactions.

In 2012 ABO Incompatible Adverse Transfusion Reactions represented 2.2% of the overall number of reports of adverse transfusion reactions,

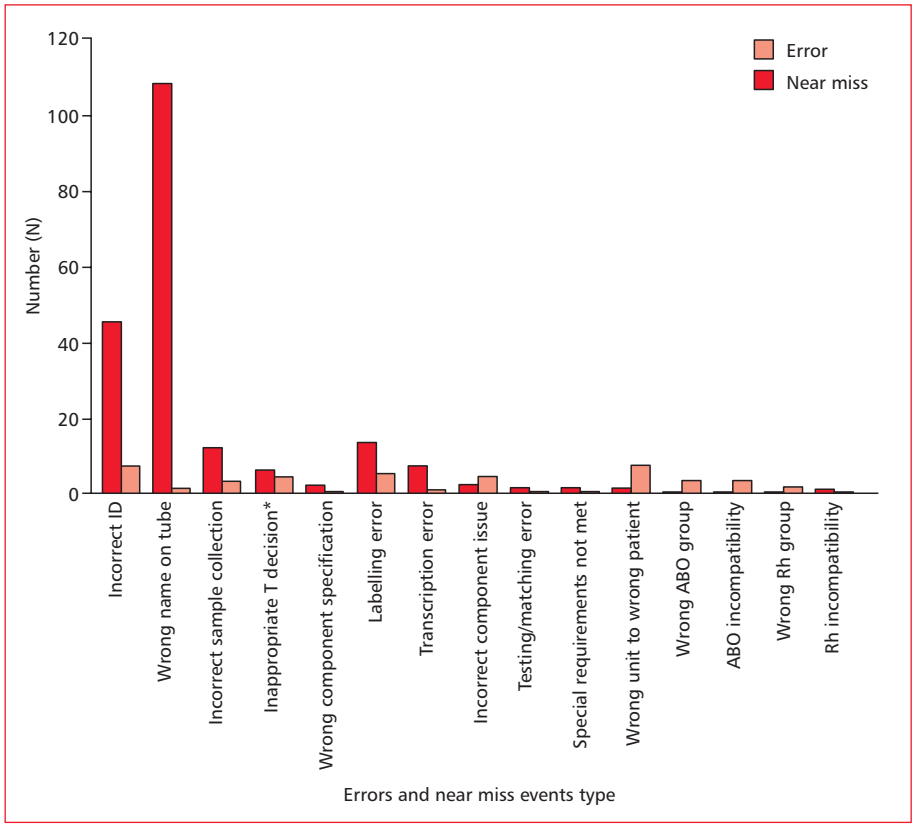

Figure 6. Types of near miss events and errors
*Innapropriate T decision means that there was no need for transfusion order. The evaluation is performed by the hospital/institution reporting body and validated by the Portuguese Haemovigilance Steering Committee

Table 1. Number and severity of hemolytic reactions due to ABO incompatibility in the period 2008–2012

	Non severe	Severe	Life threatening	Death	Total
2008	5	5	0	0	10
2009	4	8	0	0	12
2010	1	6	2	0	9
2011	1	2	2	2	7
2012	1	7	2	2	12
Total	12	28	6	4	50

with a rate of 3.1/100 000 red blood cells units transfused.

As compared to the previous years the frequency of ABO incompatible reactions decreased (3.6/100 000 RBC in 2008 and 2009; 3.8/100 000 RBC in 2010; 2.4/100 000 RBC in 2011) while the level of severity increased (Table 1).

Conclusions

The data referring to the frequency and severity of donor adverse reactions is consistent with literature reports and points to the safety of blood donation. The rate for severe adverse reactions was low; only 4.05% of the reactions were severe and required the donor to seek medical care and that corresponds to 15/100 000 donations.

Most critical for both near miss events and errors is the clinical area rather than the hospital blood bank laboratory. Near miss events occur more frequently during the request and sampling process while the errors mostly occur during the procedure of transfusing blood components.

Employees of hospital blood banks are more prone to detect non-conformities than those who work in clinical areas. Of the near miss events 92.7% were detected in hospital blood banks where screening of all the requests/orders is performed and the comparison with patient's transfusion

history takes place. Specialists in transfusion medicine can largely contribute to the analysis of causes for error and near miss events.

Correct patient identification must be considered the crucial clinical skill because identification errors have significant impact in every area of medicine, particularly in transfusion. Awareness of the importance of correct identification and its impact on the safety of the patient who is scheduled for transfusion is fundamental as any such error may be fatal.

The majority of events which threaten donor and patient safety are preventable and can be avoided with careful and systematic education, training and competency assessment of all staff involved in the transfusion chain.

As for other preventive measures which could be used to eliminate or reduce the number of donor adverse reactions and that go beyond the requirements for staff education and training we can mention careful donor vigilance and strategies to reduce vasovagal reactions. Donors could be supplied with better educational materials to instruct them how to avoid such reactions and report any medical problems that may occur within days or weeks of donation.

What seems equally important is to support the patient identification procedure with new identification techniques, to organize more regular audits and promote a closer liaison and cooperation between a well-trained, enthusiastic, active Hospital Transfusion Committee and the staffs of the hospital blood bank and clinical areas.

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